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Responses to Public Comments on Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation Rulemaking

Office of Water (4607M)
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List of Acronyms

Acronym	Definition
AACE	American Association of Cost Engineering (AACE)
ACIL	American Council of Independent Laboratories
AIS	American Iron and Steel
AIX	Anion Exchange
ALT	Alanine Aminotransferase
AMWA	Association of Metropolitan Water Agencies
ANPRM	Advanced Notice of Proposed Rulemaking
ANSI	American National Standards Institute
APA	Administrative Procedure Act
ARAR	Applicable or Relevant and Appropriate Requirement
ASCVD	Atherosclerotic Cardiovascular Disease
ASDWA	Association of State Drinking Water Administrators
ATP	Alternate Test Procedure
ATSDR	Agency for Toxic Substances and Disease Registry
AWWA	American Water Works Association
B&V	Black & Veatch
BABA	Build America Buy America
BAT	Best Available Technologies
BIL	Bipartisan Infrastructure Law
BMD	Bone Mineral Density
BMDL	Benchmark Dose Level
BMR	Benchmark Reduction
BP	Blood Pressure
BTGA	Best Technologies Generally Available
BV	Bed Volume
CA	Cooperative Agreement
CAAC	Chemical Assessment Advisory Committee
CAS	Chemical Abstract Service
CASAC	Clean Air Scientific Advisory Committee
CASRN	Chemical Abstract Service Registry Number
CBX	Cost Benefit Model
CCL	Contaminant Candidate List
CCR	Consumer Confidence Report
CCT	Corrosion Control Treatment
CDC	Centers for Disease Control and Prevention
CERCLA	Comprehensive Environmental Response Compensation and Liability Act
CFR	Code of Federal Regulations
CGE	Computational general equilibrium
CI	Confidence Interval
CMDP	Compliance Monitoring Data Portal

Acronym	Definition
COI	Cost of Illness
CSF	Cancer Slope Factor
CVD	Cardiovascular Disease
CWA	Clean Water Act
CWS	Community Water System
CWSRF	Clean Water State Revolving Fund
CWSS	Community Water System Survey
DALY	Disability-Adjusted life year
DBP	Disinfection Byproducts
DoD	Department of Defense
DOH	Department of Health
DWI-BW	Drinking Water Intake Bodyweight-Adjusted
DW-SFTIES	Drinking Water State-Federal-Tribal Information Exchange System
DWSRF	Drinking Water State Revolving Fund
EA	Economic Analysis
EAC	Economic Analysis Committee
EBCT	Empty Bed Contact Time
EC-SDC	Emerging Contaminants in Small or Disadvantaged Communities
EGLE	Department of Environment, Great Lakes, and Energy
EJ	Environmental Justice
EO	Executive Order
EoX	Electrochemical Oxidation
EPA	Environmental Protection Agency
EPTDS	Entry Point to the Distribution System
ETT	Enforcement Targeting Tool
ETV	Environmental Technology Verification
FCA	Financial Capability Assessment
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FR	Federal Register
FRB	Field Reagent Blank
FRFA	Final Regulatory Flexibility Analysis
FRN	Federal Register Notice
FSIS	Food Safety and Inspection Service
FY	Fiscal Year
GAC	Granular Activated Carbon
GAO	Government Accountability Office
GDP	Gross Domestic Product
GE	General Equilibrium
GHG	Greenhouse gas
GRA	Groundwater Resources Association of California

Acronym	Definition
GRR	Galvanized Requiring Replacement
GWUDI	Ground Water Under the Direct Influence
HA	Health Advisory
HBWC	Health Based Water Concentration
HDLC	High-Density Lipoprotein Cholesterol
HESD	Health Effects Support Documents
HFPO-DA	Hexafluoropropylene Oxide Dimer Acid
HI	Hazard Index
HISA	Highly Influential Scientific Assessment
HPT	Hypothalamic-Pituitary-Thyroid
HQ	Hazard Quotient
HRL	Health Reference Level
HRRCA	Health Risk Reduction and Cost Analysis
IARC	International Agency for Research on Cancer
ICR	Information Collection Request
IDC	Initial Demonstration of Capability
IHS	Indian Health Services
IIJA	Infrastructure Investment and Jobs Act
IPC	Interagency Policy Committee
IPM	Integrated Planning Model
IRFA	Initial Regulatory Flexibility Analysis
IRIS	Integrated Risk Information System
ISI	Influential Scientific Information
IX	Ion Exchange
LAM	Laboratory Approval Manual
LAP	Laboratory Approval Program
LBW	Low Birth Weight
LC/MS/MS	Liquid Chromatography/Tandem Mass Spectrometry
LCMRL	Lowest Concentration Minimum Reporting Level
LCR	Lead and Copper Revisions
LCRI	Lead and Copper Rule Improvements
LCRR	Lead and Copper Rule Revisions
LDLC	Low-density Lipoprotein Cholesterol
LFB	Laboratory Fortified Blank
LIMS	Laboratory Information Management System
LOD	Limit of Detection
LQI	Lowest Quintile Income
LRAA	Locational Running Annual Average
LRB	Laboratory Reagent Blank
LSL	Lead Service Line
LT2	Long Term 2 Enhanced Surface Water Treatment Rule
MCBC	Multi-Contaminant Benefit Cost

Acronym	Definition
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
MCMC	Markov Chain Monte Carlo
MDL	Method Detection Limit
MGD	Million Gallons Per Day
MHI	Median Household Income
MRL	Minimum Reporting Level
NAMs	New Approach Methods
NAS	National Academy of Science
NASA	National Aeronautics and Space Administration
NASEM	National Academies of Science, Engineering and Medicine
NCHS	National Center for Health Statistics
NDWAC	National Drinking Water Advisory Council
NECI	National Enforcement and Compliance Initiative
NF	Nanofiltration
NHANES	National Health and Nutrition Examination Study
NJDEP	New Jersey Department of Environmental Protection
NJPDES	New Jersey Pollution Discharge Elimination System
NPDES	National Pollutant Discharge Elimination System
NPDWR	National Primary Drinking Water Regulation
NRDC	National Resources Defense Council
NSF	National Sanitation Foundation
NSF/ANSI	National Sanitization Foundation/American National Standards Institute
NTNCWS	Non Transient Non Community Water Systems
NTP	National Toxicology Program
O&M	Operation & Maintenance
OCSPP	Office of Chemical Safety and Pollution Prevention
OECA	Office of Enforcement and Compliance Assurance
OECD	Organization of Economic Co-operation and Development
OFR	Office of the Federal Register
OIRA	Office of Information and Regulatory Affairs
OLEM	Office of Land and Emergency Management
OMB	Office of Management and Budget
ORD	Office of Research and Development
OST	Office of Science and Technology
OW	Office of Water
OWASA	Orange Water and Sewer Authority
PAC	Powdered Activated Carbon
PAF	Population Attributable Fraction
PBPK	Physiologically-Based Pharmacokinetic
PCB	Polychlorinated Biphenyls
PCoSTs	Cost of State Transactions Study (ASDWA 2023 report)

Acronym	Definition
PE	Performance Evaluation
PFAS	Per- and Polyfluoroalkyl Substances
PFBA	Perfluorobutanoic Acid
PFBS	Perfluorobutane Sulfonic Acid
PFDA	perfluorodecanoic acid
PFHpA	Perfluoroheptanoic Acid
PFHxA	Perfluorohexanoic Acid
PFHxS	Perfluorohexane Sulfonic Acid
PFNA	Perfluorononanoic Acid
PFOA	Perfluorooctanoic Acid
PFOS	Perfluorooctane Sulfonic Acid
PFPeA	Perfluoropentanoic Acid
PITT	PFAS Innovative Treatment Team
PK	Pharmacokinetic
PN	Public Notification
PNG	Policy Navigation Group
POD	Point-of-Departure
POE	Point of Entry
POTW	Publicly Owned Treatment Works
POU	Point of Use
PQL	Practical Quantitation Level
PRA	Paperwork Reduction Act
PT	Proficiency Testing
PWS	Public Water System
QA	Quality Assurance
QC	Quality Control
R&C	Reliably and Consistently
RAA	Running Annual Average
RCC	Renal Cell Carcinoma
RCRA	Resource Conservation and Recovery Act
RDX	Royal Demolition Explosive
RFA	Regulatory Flexibility Act
RfD	Reference Dose
RML	Removal Management Levels
RO	Reverse Osmosis
RO/NF	Reverse Osmosis/Nanofiltration Membrane
RPF	Relative Potency Factor
RRSCTs	Rapid Small-scale Column Tests
RSC	Relative Source Contribution
RSL	Regional Screening Levels
RTCR	Revised Total Coliform Rule
SAB	Science Advisory Board

Acronym	Definition
SAB-EEAC	Science Advisory Board Environmental Economics Advisory Committee
SARA	Superfund Amendments and Reauthorization Act
SBA	Small Business Association
SBAR	Small Business Advocacy Review
SBIR	Small Business Innovation Research
SBREFA	Small Business Regulatory Enforcement Fairness Act
SDVB	Styrene Divinylbenzene
SDWA	Safe Drinking Water Act
SDWARS	Safe Drinking Water Accession and Review System
SDWIS	Safe Drinking Water Information System
SDWIS/Fed	Safe Drinking Water Information System Fed Data Warehouse
SER	Small Entity Representative
SGA	small gestational age
SISNOSE	Significant Economic Impact on a Substantial Number of Small Entities
SL	Service Line
SMF	Standardized Monitoring Framework
SOPs	Standard Operating Procedures
SPD	Statistical Policy Directive
SPE	Solid Phase Extraction
SRF	State Revolving Fund
SSCT	Small System Compliance Technologies
SSCTs	Small System Compliance Technologies
SUDC	Small, Underserved, and Disadvantaged Communities
SYR	Six Year Review
TC	Total Cholesterol
THM	Trihalomethanes
TMDL	Total Maximum Daily Load
TMF	Technical, Managerial and Financial
TNCWS	Transient Non-Community Water System
TNI	The NELAC Institute
TNI LAMS	The NELAC Institutes' National Environmental Laboratory Accreditation Management System
TOC	Total Organic Carbon
TOSHI	Target-Specific Hazard Index
TSCA	Toxic Substances Control Act
TSH	Thyroid Stimulating Hormone
TSS	Total Suspended Solids
UCMR	Unregulated Contaminant Monitoring Rule
UF	Uncertainty Factor
UFA	Uncertainty Factor for Interspecies Differences
UFD	Uncertainty Factor for Database Limitations
UFH	Uncertainty Factor for Lifestage-Specific Susceptibility

Acronym	Definition
UIC	Underground Injection Control
UMRA	Unfunded Mandates Reform Act
USDA	United States Department of Agriculture
USDW	Underground Sources of Drinking Water
USEPA	U.S. Environmental Protection Agency
VLBW	Very Low Birth Weight
VOC	Volatile Organic Compounds
VSL	Value of Statistical Life
WaterTA	Water Technical Assistance
WBS	Work Breakdown Structure
WDEQ	Wyoming Department of Environmental Quality
WHO	World Health Organization
WIFIA	Water Infrastructure Finance and Innovation Act
WQA	Water Quality Association
WSSC	Washington Suburban Sanitary Commission
WTP	Willingness-to-Pay

Introduction and Overview

Background

The EPA is promulgating data-driven drinking water standards that are based on the best available, peer-reviewed science and meet the requirements of the Safe Drinking Water Act (SDWA). Under the *Administrative Procedure Act* notice-and-comment process for rulemakings, the EPA considers all relevant and timely-submitted comments and responds to all significant comments received during the public comment period. The EPA's final PFAS National Primary Drinking Water Regulation is based on the administrative record, including the EPA's consideration of these comments.

The U.S. Environmental Protection Agency (the EPA or "the agency") has the authority under SDWA to set enforceable National Primary Drinking Water Regulations (NPDWRs) for drinking water contaminants and require monitoring of public water supplies. The EPA is finalizing a NPDWR for per-and polyfluoroalkyl substances (PFAS) (EPA-HQ-OW-2022-0114). The agency initiated the process for developing a NPDWR for PFAS compounds in March 2021, when the EPA published the fourth regulatory determination for contaminants on the fourth Contaminant Candidate List (CCL), which included a final determination to regulate perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) in drinking water. Additionally, in the EPA's final regulatory determination for PFOA and PFOS, as well as its PFAS Strategic Roadmap, the agency committed to evaluating additional PFAS beyond PFOA and PFOS and considering actions to address groups of PFAS (86 FR 12272; USEPA, 2021a). In March of 2023, the EPA made a preliminary regulatory determination for four additional PFAS and their mixtures: perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salt (also known as GenX chemicals), perfluorohexanesulfonic acid (PFHxS), and perfluorobutanesulfonic acid (PFBS). Additionally, the EPA proposed a NPDWR and health-based Maximum Contaminant Level Goals (MCLG) for PFOA, PFOS and these four PFAS and their mixtures (88 FR 18638). The final NPDWR is one of several actions consistent with the agency's commitment to address these long-lasting "forever chemicals" that occur in drinking water supplies and impact communities across the U.S.

The EPA requested public comment on the proposed regulation. The public comment period ended on May 30, 2023. The EPA's proposed rule received over 120,000 public comments. The public docket can be accessed at www.regulations.gov under Docket ID: EPA-HQ-OW-2022-0114. The EPA also held an informational general overview webinar of the proposed PFAS NPDWR on March 16, 2023, and another informational webinar about the proposed PFAS NPDWR specifically for water utilities and the drinking water professional community on March 29, 2023. On May 4, 2023, the EPA held a public hearing on the proposed PFAS NPDWR. All original public submissions and supporting documents for the PFAS proposal and final NPDWR can be found at www.regulations.gov, under Docket ID EPA-HQ-OW-2022-0114.

EPA's Categorization of Public Comments and Document Organization

In March 2023, the Environmental Protection Agency (EPA) proposed and requested comment on the National Primary Drinking Water Regulation (NPDWR) and health-based Maximum Contaminant Level Goals (MCLGs) for six per- and polyfluoroalkyl substances (PFAS) including perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorohexane sulfonic acid (PFHxS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO-DA, commonly known as GenX Chemicals), and perfluorobutane sulfonic acid (PFBS) (88 FR 18638; USEPA, 2023).

The data and information requested by the EPA include peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices, and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the review justifies use of the data).

The EPA specifically requested comment on all aspects of the rule and sought specific feedback on the following topics within each section of the proposed rule preamble.

Section III—Regulatory Determinations for Additional PFAS

- The EPA requests comment on its preliminary regulatory determination for PFHxS and its evaluation of the statutory criteria that supports the finding. The EPA also requests comment on if there are additional data or studies the EPA should consider that support or do not support the agency's preliminary regulatory determination for PFHxS, including additional health information and occurrence data.
- The EPA requests comment on its preliminary regulatory determination for HFPO–DA and its evaluation of the statutory criteria that supports the finding. The EPA also requests comment on if there are additional data or studies the EPA should consider that support or do not support the agency's preliminary regulatory determination for HFPO–DA, including additional health information and occurrence data.
- The EPA requests comment on its preliminary regulatory determination for PFNA and its evaluation of the statutory criteria that supports the finding. The EPA also requests comment on if there are additional data or studies the EPA should consider that support or do not support the agency's preliminary regulatory determination for PFNA, including additional health information and occurrence data.
- The EPA requests comment on its preliminary regulatory determination for PFBS and its evaluation of the statutory criteria that supports the finding. The EPA also requests comment on if there are additional data or studies the EPA should consider that support or do not support the agency's preliminary regulatory determination for PFBS, including additional health information and occurrence data.
- The EPA requests comment on whether there are other peer-reviewed health or toxicity assessments for other PFAS the agency should consider as a part of this action.

- The EPA requests comment on its evaluation that regulation of PFHxS, HFPO–DA, PFNA, PFBS, and their mixtures, in addition to PFOA and PFOS, will provide protection from PFAS that will not be regulated under this proposed rule.

Section V—Maximum Contaminant Level Goal

- The EPA requests comment on the derivation of the proposed MCLG for PFOA and its determination that PFOA is Likely to be Carcinogenic to Humans and whether the proposed MCLG is set at the level at which there are no adverse effects to the health of persons and which provides an adequate margin of safety. The EPA is also seeking comment on its assessment of the noncancer effects associated with exposure to PFOA and the toxicity values described in the support document on the proposed MCLG for PFOA.
- The EPA requests comment on the derivation of the proposed MCLG for PFOS, its determination that PFOS is Likely to be Carcinogenic to Humans and whether the proposed MCLG is set at the level at which there are no adverse effects to the health of persons and which provides an adequate margin of safety. The EPA is also seeking comment on its assessment of the noncancer effects associated with exposure to PFOS and the toxicity values described in the support document on the proposed MCLG for PFOS.
- The EPA requests comment on the general Hazard Index approach for the mixture of four PFAS.
- The EPA requests comment on the merits and drawbacks of the target- specific Hazard Index or RPF approach.
- The EPA requests comment on significant figure use when calculating both the Hazard Index MCLG and the MCL. The EPA has set the Hazard Index MCLG and MCL using two significant figures (i.e., 1.0). The EPA requests comment on the proposed use of two significant figures for the MCLG when considering underlying health information and for the MCL when considering the precision of the analytical methods.
- The EPA requests comment on the derivation of the HBWCs for each of the four PFAS considered as part of the Hazard Index.
- The EPA requests comment on whether the HBWCs should instead be proposed as stand-alone MCLGs in addition to or in lieu of the mixture MCLGs.

Section VI—Maximum Contaminant Level

- The EPA requests comment on its proposed determination to set MCLs at 4.0 ppt for PFOA and PFOS and whether 4.0 ppt is the lowest PQL that can be achieved by laboratories nationwide.
- The EPA seeks comment on its PFOA and PFOS evaluation of feasibility for the proposal, including analytical measurement and treatment capability, as well as reasonable costs, as defined by SDWA.
- The EPA seeks comment on its evaluation of feasibility for the proposed Hazard Index MCL finding, including analytical measurement and treatment capability, as well as reasonable costs, as defined by SDWA.

- The EPA requests comment on implementation challenges and considerations for setting the MCL at the PQLs for PFOA and PFOS, including on the costs and benefits related to this approach.
- The EPA requests comment on the underlying assumptions that sufficient laboratory capacity will be available with the proposed MCLs; that demand will be sufficiently distributed during rule implementation to allow for laboratory capacity; and on the cost estimates related to these assumptions.
- The EPA requests comment on its proposal of using an Hazard Index approach for PFHxS, HFPO–DA, PFNA, and PFBS, including whether it can be clearly implemented and achieves the goal of protecting against dose additive noncancer health effects.
- The EPA requests comment on its proposed decision to establish stand- alone MCLs for PFOA and PFOS in lieu of including them in the Hazard Index approach.
- The EPA requests comment on whether establishing a traditional MCLG and MCL for PFHxS, HFPO–DA, PFNA, and PFBS instead of, or in addition to, the Hazard Index approach would change public health protection, improve clarity of the rule, or change costs.

Section VII—Occurrence

- The EPA requests comment on the number of systems estimated to solely exceed the Hazard Index (but not the PFOA or PFOS MCLs) according to the approach outlined in USEPA (2023).

Section IX—Monitoring and Compliance Requirements

- The EPA requests comment on the proposed monitoring flexibility for groundwater systems serving 10,000 or fewer to only collect two samples at each EPTDS to satisfy initial monitoring requirements.
- The EPA requests comment on monitoring-related flexibilities that should be considered to further reduce burden while also maintaining public health protection including a rule trigger level at different values than the currently proposed values of 1.3 ppt for PFOA and PFOS and 0.33 for the Hazard Index PFAS (PFHxS, HFPO–DA, PFNA, and PFBS), specifically alternative values of 2.0 ppt for PFOA and PFOS and 0.50 for the Hazard Index PFAS. The EPA also requests comment other monitoring flexibilities identified by commenters.
- The EPA requests comment on the proposed allowance of a water system to potentially have each EPTDS on a different compliance monitoring schedule based on specific entry point sampling results (i.e., some EPTDS being sampled quarterly and other EPTDS sampled only once or twice during each three-year compliance period), or if compliance monitoring frequency should be consistent across all of the system's sampling points.
- The EPA requests comments on whether water systems should be permitted to apply to the primacy agency for monitoring waivers. Specifically, the EPA is requesting comment on the allowance of monitoring waivers of up to nine years if after at least one year of sampling results are below the proposed rule trigger level. Similarly, the EPA also requests comment on whether allowance of monitoring waivers of up to nine years should be permitted based on previously acquired monitoring data results that are below

the proposed rule trigger level. Additionally, the EPA is also requesting comment on the identification of possible alternatives to traditional vulnerability assessments that should be considered to identify systems as low risk and potentially eligible for monitoring waivers.

- The EPA requests comment on if all water systems, regardless of system size, be allowed to collect and analyze one sample per three-year compliance period if the system does not detect regulated PFAS in their system at or above the rule trigger level.
- The EPA requests comment on its proposal to allow the use of previously acquired monitoring data to satisfy initial monitoring requirements including the data collection timeframe requirements and if other QA requirements should be considered.
- The EPA requests comment on whether the EPA should consider an alternative approach to what is currently proposed when calculating compliance with proposed MCLs. Specifically, in the case where a regulated PFAS is detected but below its proposed PQL, rather than using zero for the measurement value of the specific PFAS in the running annual average compliance calculation, that the proposed rule trigger levels (1.3 ppt for PFOA and PFOS and 0.33 of each of the Hazard Index PFAS PQLs (i.e., PFHxS=1.0, HFPO– DA=1.7, PFNA=1.3, and PFBS=1.0)) be used as the values in calculating the running annual average for compliance purposes.
- The EPA requests comment on other monitoring related considerations including laboratory capacity and QA/ QC of drinking water sampling.
- The EPA seeks comment on the agency's proposed initial monitoring timeframe, particularly for NTNCWS or all systems serving 3,300 or fewer.

Section X—Safe Drinking Water Right to Know

- The EPA requests comment on its proposal to designate violations of the proposed MCLs as Tier 2.
- The EPA requests comment on what may be needed for water systems to effectively communicate information about the PFAS NPDWR to the public.

Section XI—Treatment Technologies

- The EPA requests comment on whether PWSs can feasibly treat to 4.0 ppt or below.
- The EPA requests additional information on PFAS removal treatment technologies not identified in the proposed rule that have been shown to reduce levels of PFAS to the proposed regulatory standard.
- The EPA requests comment on the co- removal of the Hazard Index chemicals (PFHxS, PFBS, PFNA, and HFPO–DA) when GAC, IX, or RO are used in the treatment of PFOA and/or PFOS.
- The EPA requests comment on whether there are additional technologies which are viable for PFAS removal to the proposed MCLs as well as any additional costs which may be associated with non-treatment options such as water rights procurement.
- The EPA estimates GAC treatment will be sufficiently available to support cost- effective compliance with this proposed regulation, and requests comment on whether additional guidance on applicable circumstances for GAC treatment is needed.

- The EPA is seeking comment on the benefits from using treatment technologies (such as reverse osmosis and GAC) that have been demonstrated to co-remove other types of contaminants found in drinking water and whether employing these treatment technologies are sound strategies to address PFAS and other regulated or unregulated contaminants that may co- occur in drinking water.
- The EPA requests comment on the estimates for disposing of drinking water treatment residuals or regenerating drinking water treatment media including assumptions related to the transport distance to disposal sites and other costs that arise out of disposal of PFAS contaminated drinking water treatment residuals.
- The EPA requests comment on the availability of facilities to dispose of or regenerate drinking water treatment media that contains PFAS. The EPA requests comment on whether there will be sufficient capacity to address the increased demand for disposal of drinking water treatment residuals or to regenerate media for reuse by drinking water treatment facilities.
- The EPA requests comment on the impacts that the disposal of PFAS contaminated treatment residuals may have in communities adjacent to the disposal facilities.
- The EPA requests comment on the type of assistance that would help small public water systems identify laboratories that can perform the required monitoring, evaluate treatment technologies and determine the most appropriate way to dispose of PFAS contaminated residuals and waste the systems may generate when implementing the rule.

Section XII—Rule Implementation and Enforcement

- The EPA is seeking comment as to whether there are specific conditions that should be mandated for systems to be eligible for exemptions under 1416 to ensure that they are only used in rare circumstances where there are no other viable alternatives and what those conditions would be.

Section XIII—HRRCA

- The EPA requests comment on all components of the HRRCA for the proposed NPDWR.
- In the Economic Analysis, the EPA presented estimated costs and benefits of regulatory alternatives for PFOA and PFOS if setting MCLs at 5.0 ppt and 10.0 ppt. The EPA is requesting comment on its evaluation of these alternatives within the Economic Analysis.
- The EPA requests comment on the methodology used to estimate national costs for the proposed rule and regulatory alternatives. The EPA's cost analysis can be found in Chapter 5 of the Economic Analysis.
- The EPA is requesting comment on the WBS models, including the range of component levels assumed in the input to the models, and the range of cost estimates for GAC, IX, and centralized RO.
- The EPA requests comment on Table 26 which provides the initial treatment technology compliance forecast, presented in percentages of systems adopting GAC, PFAS-selective IX, centralized RO, system interconnection, and use new wells across system design flows and TOC levels. This information is used in the EPA's cost and benefit modeling. Please also comment on the potential for point-of-use devices, including those using RO or activated carbon as a compliance option.

- The EPA requests comment on the cost of treatment when additional co- occurring but not targeted PFAS chemicals are found in source water.
- The EPA requests comment generally on its estimation of sampling costs. The agency is also specifically requesting comment on the ability of systems to demonstrate they are reliably and consistently below 1.3 ppt for PFOA and PFOS and 0.33 ppt for PFAS regulated by the Hazard Index in order to qualify for reduced monitoring.
- The EPA requests comment on the underlying assumptions that, under UCMR 5, individual water systems would be able to request the full release of data from the labs for use in determining their compliance monitoring frequency and that PWSs may be able to use these lab analyses to demonstrate a ''below trigger level'' concentration using the UCMR 5 analyses by following up with the lab for a more detailed results report.
- The EPA requests comment on the costs associated with the storage, transportation and underground injection of the brine concentrate residuals from the RO/NF process.
- The EPA requests comment on the small system affordability analysis, including both the national affordability determination using the EPA's existing 2.5% of median household income (MHI) methodology and the supplemental analyses using use of alternative metrics (i.e., expenditure margins at 1% of MHI and 2.5% of lowest quintile income). The EPA's national small system affordability determination can be found in Section 9.12.1 of the Economic Analysis. The EPA's supplementary affordability analyses can be found in Section 9.12.2 of the Economic Analysis.
- The EPA requests comment on the discussion of estimated PN costs provided in the proposed rule.
- The EPA requests comment on the assumption that exceedances of Hazard Index PFAS not included in the national cost analyses (HFPO–DA, PFBS, and PFNA) will not significantly impact overall compliance costs and national costs estimates are, therefore, unlikely to be substantially underestimated.
- The EPA requests comments on the approaches we used to estimate each of the health impacts of exposure to the PFAS chemicals covered in this proposed rule, including the transparency of the assumptions we made and the impact of these assumptions on the magnitude of the risks avoided by the proposed regulatory action.
- The EPA requests comment on whether factors such as anticipated Federal funding, the structure of PWSs relative to private enterprises, or the nature of the public health benefits should be further explored in the final rule analysis, including as it relates to the estimated range of impacts under the applied discount rates.

Section XV—Statutory and Executive Order Reviews

- The EPA requests comment on all aspects of its EJ analysis, particularly its choice of comparison groups to determine potential demographic disparities in anticipated PFAS exposure and its use of thresholds against which to examine anticipated exposures. For more information, please see section XV.J of this preamble.

The comments and responses presented in this document are organized first by the EPA Topic Code. Readers can first find the Topic Code of interest, and then find a brief summary of the public comments and the EPA's responses to the comments for each Topic Code. Individual comments (identified by unique identifiers, i.e., SBC codes) can be found within each Topic

Code along with the EPA's response. The commenter name, organization, Document ID, and commenter page numbers are also given for each comment. Any comment can be read as it appears within the commenter's original letter, e-mail, or posting by searching on the associated Document ID at www.regulations.gov (see explanation of Document IDs in the next section "Who Submitted Comments"). The Document ID can also be used to find additional information, such as tables or figures, which may be included within the context of comments or attachments in the commenter's original submission at www.regulations.gov.

Who Submitted Comments

The EPA received approximately 122,200 total comments (including in writing to the docket and orally during the public hearing) were received on the Proposed PFAS National Primary Drinking Water Regulation Rulemaking. Of those comments, approximately 120,500 were mass mailers from Clean Water Action, Slingshot, Green America, Environmental Working Group (EWG), National Wildlife Federation (NWF), Environment America Research and Policy Center, US Public Interest Research Group (PIRG) Education Fund, North Carolina (NC) Conservation Network, Great Lakes PFAS Action Network, National Caucus of Environmental Legislators, and Alliance for Risk Assessment. There were approximately 1,700 unique public comments. The vast majority of the comments were generally supportive of the EPA's efforts to regulate PFAS in drinking water and requested that the EPA expeditiously finalize the PFAS NPDWR.

References

USEPA. 2021. Announcement of Final Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List. *Federal Register*. 86 FR 12272. March 3, 2021.

USEPA. 2023. PFAS National Primary Drinking Water Regulation Rulemaking. *Federal Register*. 88 FR 18638. March 29, 2023.

1 General Information

1.1 SDWA Rulemaking Process

Summary of Major Public Comments and EPA Responses

The United States Environmental Protection Agency (EPA) received comments of both agreement and disagreement with the Safe Drinking Water Act (SDWA) process and the EPA's approach in establishing this final per- and polyfluoroalkyl substances (PFAS) National Primary Drinking Water Regulation (NPDWR). Some commenters described their interpretation of the established rulemaking process and provided arguments that they believe demonstrate whether the EPA did or did not follow that process. Some comments noted how Maximum Contaminant Levels (MCLs) are required by SDWA and argued that the EPA has produced a factual and scientific record to support the MCLs, and that the proposed NPDWRs are protective, feasible, and cost-justified. Commenters highlight that NPDWRs should be based on science, and that they be considered as both feasible and justifiable. Some commenters contend that the EPA has not done as such. Other opposing commenters disagreed with the EPA's decision to make a preliminary regulatory determination and propose an NPDWR at the same time.

In promulgating this PFAS NPDWR, the EPA has met all requirements under SDWA. The EPA disagrees with comments that state or argue otherwise. The EPA disagrees with commenters that state that the final MCLs are not set at a feasible level. The EPA's final rule represents data-driven drinking water standards that are based on a thorough analysis of feasibility consistent with requirements under SDWA, as discussed in section V of the Federal Register Notice (FRN) and section 5 of the EPA response in this *Response to Comments* document. The EPA also disagrees with comments that oppose the EPA's decision to make a preliminary regulatory determination and propose an NPDWR at the same time. A preliminary regulatory determination allows the public to comment on the EPA's view about whether certain unregulated contaminants meet the three statutory criteria. The EPA can then issue a final regulatory determination after consideration of public comment. Section 1412(b)(1)(E) requires that the EPA propose an NPDWR no later than 24 months after a final determination to regulate. The statute also authorizes the EPA to issue a proposed rule concurrent with a preliminary determination to regulate. The EPA must then promulgate a final regulation within 18 months of the proposal (which may be extended by 9 additional months). For additional discussion on the regulatory determinations, please see section III of the final rule preamble and section 3 of the EPA response in this *Response to Comments* document.

For the EPA's responses to general and specific comments discussing SDWA requirements related to the NPDWR rulemaking process and the EPA's findings for the PFAS NPDWR consistent with those requirements, please see the following non-exhaustive list of key FRN and *Response to Comments* document sections. Some responses to comments in section 1.1 of this *Response to Comments* document may also be addressed in other topical sections in this

Response to Comments document. For relevant cross-references, please see the EPA's responses to individual comments.

- Section I of the FRN and section 1 of this *Response to Comments* document for the EPA's description of the PFAS final rule requirements for regulating six PFAS of concern in drinking water, along with a description for whom the requirements apply.
- Section II of the FRN and section 2.3 of this *Response to Comments* document for the EPA's statutory authority and statutory framework, including topics such as the Contaminant Candidate List (CCL), the Unregulated Contaminant Monitoring Rule (UCMR), and previous regulatory determinations for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS).
- Section III of the FRN and section 3 of this *Response to Comments* document for discussion of the EPA's updated regulatory determinations and evaluations of the three statutory criteria for the four additional PFAS following public comment, as well as the agency's authority to concurrently determine to preliminarily regulate a contaminant and propose that regulation.
- Section IV of the FRN and section 4 of this *Response to Comments* document for the EPA's finalization of the Maximum Contaminant Level Goals (MCLGs) and health determinations for PFOA, PFOS, and the four additional PFAS.
- Section V of the FRN and section 5 of this *Response to Comments* document for the EPA's feasibility analysis and finalization of the MCLs and the Hazard Index for mixtures of PFAS in drinking water.
- Section VI of the FRN and section 6 of this *Response to Comments* document for the EPA's sufficiently robust occurrence analyses that serve as the best available public health information in making a regulatory determination.
- Section VII of the FRN and section 7 of this *Response to Comments* document for the EPA's discussion of the analytical methods and the practical quantitation levels (PQLs) for the regulated PFAS.
- Section VIII of the FRN and section 8 of this *Response to Comments* document for the EPA's monitoring and reporting requirements for PWSs to comply with the NPDWR.
- Section IX of the FRN and section 9 of this *Response to Comments* document for the EPA's requirements for the Consumer Confidence Reports (CCRs) and Public Notification (PN) as it relates to this NPDWR.
- Section X of the FRN and section 10 of this *Response to Comments* document for the EPA's list of feasible technologies for public water systems that can be used to comply with the MCLs.
- Section XI of the FRN and sections 11 and 12 of this *Response to Comments* document for the EPA's rule implementation and enforcement requirements, including for primacy, record keeping, reporting, and exemptions and extensions.
- Section XII of the FRN and section 13 of this *Response to Comments* document for the EPA's evaluation of the quantifiable and nonquantifiable health risk reduction benefits and costs associated with the final NPDWR, as part of the *Health Risk Reduction and Cost Analysis* (HRRCA). These sections also affirm the EPA Administrator's determination, consistent with the determination made for the proposal, that the quantified and nonquantifiable benefits of the PFAS NPDWR justify the costs.

- Section XIII of the FRN and section 14 of this *Response to Comments* document for the EPA's actions under statutory and executive order reviews, which includes the various acts and executive orders, as well as consultations.

Individual Public Comments

San Antonio Water System (SAWS) (Doc. #1570, SBC-042469)

• EPA's established rulemaking process is well-documented but has not been followed in the case of this proposed regulation. SAWS urges EPA to follow its established rulemaking procedures.

Below are SAWS' specific concerns regarding the ad hoc approach being used by EPA.

o The EPA's established rulemaking process has generally followed the sequence below:

*A Contaminants Candidate List (CCL) is created and finalized;

*UCMR sampling is planned, implemented, and evaluated;

*Preliminary regulatory determinations or proposed rules are then created if warranted by UCMR data; and

*If more data is required, the contaminants are placed back on the CCL and another UCMR is scheduled.

EPA Response: The commenter mischaracterizes that a contaminant must be on the CCL prior to the agency making a regulatory determination; or that UCMR data must be collected prior to making a determination to regulate if the agency has sufficiently available information through other sources. The EPA has met all statutory requirements for establishing a PFAS NPDWR. Please see section 1.1 of the EPA response in this *Response to Comments* document that directs the commentor to the various *Response to Comments* document sections with the EPA's full response. Regarding whether the EPA must list a contaminant on the CCL prior to making a regulatory determination, SDWA 1412(b)(1)(B)(i)(III) specifically states that "The Administrator may make a determination to regulate a contaminant that does not appear" on the CCL. Regarding the sole use of UCMR data, please see sections 3.1.2 and 6.8 of the EPA response in this *Response to Comments* document.

Wyoming Department of Environmental Quality (WDEQ) (Doc. #1716, SBC-044766)

Order of Regulatory Actions

EPA should approach regulation of PFAS under the SDWA strategically and incrementally to ensure successful implementation. For PFOA and PFOS, EPA waited two years between issuing its final determination to regulate and issuing a draft NPDW rule. For PFHxS, GenX, PFNA, and PFBS, EPA has both proposed to regulate and is finalizing regulation at the same time. In June 2022, EPA released final health advisories for GenX and PFBS and interim health advisories for

PFOA and PFOS. EPA has yet to propose interim or final health advisories for PFNA and PFHxS. Although WDEQ recognizes the challenges in establishing federal PFAS regulations as well as the urgency in addressing PFAS to best protect public health, we urge EPA to consider the following recommendations to make the proposed regulations more effective.

EPA Response: Please see section 1.1 of the EPA response in this *Response to Comments* document that directs the commentor to the various *Response to Comments* document sections with the EPA's full response. Health Advisories are not a pre-requisite for an NPDWR under SDWA and there is nothing in the statute or the EPA's historical regulatory practice that suggests that the agency must or should delay regulation of a contaminant to develop a health advisory (HA) first. Regarding the determination to regulate perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO-DA) (Gen-x Chemicals), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS) concurrently with the proposed NPDWR, please see section 3.3 of the EPA response in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-045658)

II. LEGAL FRAMEWORK

The SDWA regulates public water systems by limiting the allowable level of substances in drinking water. [FN5: City of Portland, Oregon v. EPA, 507 F.3d 706 (2007).] Prior to promulgating an MCLG or MCL, EPA must (1) identify substances for listing on the Contaminant Candidate List ("CCL"), and (2) determine which of those substances it will regulate under the SDWA. [FN6: Id. [sec] 300g-1(b)(1)(B).] At each step, EPA must follow specific procedures, consider information prescribed by the SDWA, and offer opportunities for public engagement.

When considering which substances from the CCL to regulate, the SDWA requires EPA to consider:

(1) Whether the substance may have an adverse effect on the health of persons;

(2) Whether the substance is known to occur, or there is a substantial likelihood that the substance will occur, in public water systems with a frequency and at levels of public health concern; and

(3) Whether the regulation of such substance presents a meaningful opportunity for health risk reduction for persons served by public water systems. [FN7: 42 U.S.C.A. [sec] 300g-1(b)(1)(A).]

The decision to regulate "is the beginning of the Agency's regulatory development process, not the end." [FN8: 85 Fed. Reg. 14098, 14100 (Mar. 10, 2020).] As EPA continues the analyses required by the SDWA, it may determine that a chemical does not meet the statutory criteria for finalizing a NPDWR. [FN9: Id.] If EPA determines the three statutory criteria are met, it may make a final determination that an NPDWR is needed. That determination to regulate triggers a

24-month statutory period to publish a proposed MCLG and NPDWR, and 18 months after that to promulgate a final standard. [FN10: Id. [sec] 300g-1(b)(1)(E)I.] Importantly, EPA may only promulgate an NPDWR for a substance that it has determined to regulate through the public notice and comment process. [FN11: See 85 Fed. Reg. at 14100 ("The development of the CCL, regulatory determinations, and any subsequent rulemaking should be viewed as a progression where each process builds upon the previous process, including the collection of data and analyses conducted.").]

After determining to regulate a substance, EPA must set an MCLG for each identified substance at a level at which no known adverse health consequences will occur. [FN12: 42 U.S.C.A. [sec] 300g–1(b)(4)(A).] EPA must then set an MCL for each substance as close to the MCLG as is feasible. [FN13: Id. [sec] 300g–1(b)(4)(B).] Under the statute, "feasible" means "feasible with the use of the best technology, treatment techniques and other means which the Administrator finds ... are available (taking cost into consideration)." [FN14: Id. [sec] 300g–1(b)(4)(D).]

The SDWA requires that, when undertaking this process, EPA base its decisions on the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices, and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data). [FN15: Id. at [sec] 300g-1(b)(3)(A)] The legislative history of the 1996 SDWA Amendments makes clear that Congress intended to ensure that drinking water standards regulations promulgated under the SDWA are meaningful and science-based:

Our intent was simple. Drinking water standards should not be set just because they are technologically feasible as they are under current law; they must also be justifiable. If we are going to demand that our states, counties and towns spend billions of dollars to comply with new chlorine standards, for example, at the very least, we owe them the assurance that these are dollars well spent. [FN16: Congressional Record Vol. 141, No. 189, Nov. 29, 1995; S177723; Statement of Sen. Kempthorne. See also Congressional Record Vol. 140, No. 62, May 18, 1994, S55929; Statement of Sen. Breaux ("…only contaminants which present a significant threat to public health will be regulated. EPA will also have to base its analysis on sound science and risk assessment when determining whether or not a contaminant poses a significant enough threat to merit regulation.").]

III. FACTUAL BACKGROUND

a. EPA Has a Clearly Established Process to Set a NPDWR

The process for setting an MCL begins with a determination of which chemicals should be considered for regulation. As discussed above, under the SDWA, EPA is required to publish a list of chemicals (the CCL) that are currently not subject to any proposed or promulgated NDPWRs but are known or anticipated to occur in public water systems. SDWA [sec]1412(b)(1)(B)(i). EPA must publish this list every five years. The list is used to identify priority chemicals for regulatory decision making and information collection.

During the regulatory determination process, EPA selects a minimum of five chemicals from the CCL to evaluate for regulation. [FN17: SDWA [sec] 1412(b)(1)(B)(ii)] Based on the criteria in [sec] 1412(b)(1)(A)(i)-(iii), EPA must make a regulatory determination for whether the chemical ought to be regulated under the SDWA. Once EPA makes a determination to regulate the chemical, EPA must then propose an MCLG and MCL or treatment technique.

The MCLG is the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on human health would occur, allowing an adequate margin of safety. [FN18: Id. [sec] 1412(b)(4)(A).] MCLGs are not enforceable but they are meant to guide public health goals. MCLGs do not take into consideration the limits of detection and treatment technology effectiveness; therefore, they are sometimes set at levels that water systems cannot meet. The way EPA determines MCLGs depends on the type of contaminant targeted for regulation. All microbial contaminants have an MCLG of zero because even one microbial contaminant can cause adverse health effects. The MCLG is also set at zero for chemicals where there is no dose at which the chemical is considered safe, including some chemicals that may cause cancer. Finally, for chemicals that are non-carcinogens but can cause adverse non-cancer health effects, the MCLG is based on a reference dose. [FN19: See https://www.epa.gov/sdwa/how-epa-regulates-drinking-water-contaminants.]

A reference dose (RfD) is defined as an estimate of human daily exposure that is likely to be without an appreciable risk of adverse effects during a lifetime. [FN20: See https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system] RfDs are derived using a point of departure (POD). The POD is a dose that represents the low or no effect level derived from dose-response relationships in experimental or observational studies. [FN21: See EPA's IRIS Program Glossary: https://sor.epa.gov/sor_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists/search.do?details=&glossaryName=IRIS%20Glossary] The most common PODs used to derive RfDs are the no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or statistical benchmark dose (BMD). The BMD, currently EPA's preferred POD, is the dose or concentration that produces a predetermined change in the response rate of an adverse effect. [FN22: See https://www.epa.gov/sites/default/files/2015-01/documents/benchmark_dose_guidance.pdf at 6.] In other words, the BMD is the minimum dose expected to produce a low-level health impact. EPA takes the POD (typically the BMD) and divides that number by uncertainty factors, which are used to account for potential differences between the experimental data and real life (such as the existence of sensitive populations or lack of information). The RfD is then multiplied by body weight and divided by expected daily water consumption to provide a Drinking Water Equivalent Level (DWEL). The DWEL is then multiplied by the relative source contribution (also called the RSC), which is the portion of the total exposure that comes from the ingestion of water. The value at the end of those calculations is the MCLG.

EPA often uses several types of modeling to extrapolate from known data to support risk analyses. Physiologically Based Pharmacokinetic (PBPK) models are mathematical models that

can be used to predict absorption, distribution, metabolism, and excretion (ADME) of substances in humans or animal species. Models are built using compartments that correspond to different tissues in the body and describe the relationship between the external exposure dose and the internal plasma or tissue concentration of a compound over a period of time.

Once the MCLG is calculated, EPA then crafts an enforceable standard. Typically, and at issue here, that standard is the MCL. The MCL is the maximum amount of a chemical allowed in water delivered to any user of a public water system. MCLs are set as close to the MCLG as feasible. Feasible here means taking into consideration cost and the technical limitations of available treatments.

EPA must submit its draft MCLG and MCL for technical peer review to EPA's Science Advisory Board before they are proposed as regulations. [FN23: See SDWA [sec]1412(e)]

EPA Response: The commenter submitted background information in support of this comment. The EPA is not responding to background information in section 1.1 of the *Response to Comments* document. Instead, the EPA is addressing comments directly in other sections of the *Response to Comments* document organized by topic. Please see the applicable sections of the *Response to Comments* document responding to each detailed comment topic. For an overview of how the EPA has met the requirements under the SDWA to promulgate this PFAS NPDWR, please see section 1.1 of the EPA response in this *Response to Comments* document. Regarding the regulatory determination process, please see section 3 of the EPA response in this *Response to Comments* document, including section 3.3 pertaining to the EPA's concurrent preliminary regulatory determination and proposed NPDWR. Regarding the establishment of reference doses and modelling used for this regulation, please see section IV of the FRN, as well as sections 4.2.2, 4.3.1, and 4.3.3 of the EPA response in this *Response to Comments* document. Additionally, the EPA consulted with the Science Advisory Board (SAB) prior to its NPDWR proposal, fulfilling its statutory obligations under SDWA (see section XIII.K.1. of the final rule preamble and sections 4.3.2 and 14.11.1 of the EPA response in this *Response to Comments* document).

Bailey Smith (Doc. #1787, SBC-045809)

I. EPA's Proposed Rule Comports With SDWA: How Water Systems Can Convey This Information to the Public and Possible Future Challenges

This section briefly lays out SDWA's requirements and demonstrates that EPA has complied with it. This section will then address EPA's request for how water systems can effectively communicate information about the PFAS NPDWR to the public. Lastly, this section will provide two past cases in which the EPA successfully defended against challenges to drinking water standards it promulgated under SDWA, to exemplify that EPA's proposed rule is analogous to past action it has taken that survived legal challenges.

A. SDWA's Requirements and What EPA Has Found

SDWA Section 300g-1(b)(3)(A) states as follows:

• "In carrying out this section, and, to the degree that an Agency action is based on science, the Administrator shall use-- o (i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and

o (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data)." (italics added). [FN6: 42 U.S.C. § 300g-1(b)(3)(A)(i).]

EPA's "PFAS National Primary Drinking Water Regulation Rulemaking" is based on science. Thus, EPA is required to use the best available, peer-reviewed science in promulgating its regulations. [FN7: 42 U.S.C. § 300g-1(b)(3)(A)(i).] This comment argues that the EPA has achieved this statutory requirement.

The EPA has found that PFAS "can result in harmful health effects."[FN8: Proposed Rule, supra note 3 at 18638.] More specifically, EPA has found that PFAS can lead to "negative impacts on fetal growth after exposure during pregnancy, on other aspects of development, reproduction, liver, thyroid, immune function, and/or the nervous system; and increased risk of cardiovascular and/or certain types of cancers."[FN9: Id.] Equally devastating, EPA has found that PFOA and PFOS (two common PFAS),[FN10: Priscilla (Polly) E. Hampton et al., EPA Proposes Stringent National Drinking Water Standards for Six PFAS, PERKINSCOIE.COM (Mar. 16, 2023), https://www.perkinscoie.com/en/news-insights/epa-proposes-stringent-national-drinking-water-standards-for-six-pfas.html#a11.] are likely to cause cancer, and there is no ingestion level at which either chemical is safe. [FN11: Proposed Rule, supra note 3 at 18639.]

To support that EPA relied on the best available science in coming to these conclusions, EPA explains that it has consulted with the Science Advisory Board ("SAB") as well as the National Drinking Water Advisory Council ("NDWAC") in developing the proposed rule. [Fn12: Id. at 18640.] In addition to consulting with advisory boards, EPA continues to evaluate available scientific literature to ensure its proposed rule reflects the best available science. [Fn13: Id. at 18654.]

Furthermore, SAB provided input to the EPA which, in EPA's words, made its proposed rulemaking "more scientifically sound and [ensured] it reflected the best available science."[Fn14: Id. at 18652.] To prove that SAB was not beholden to EPA, it did more than simply agree with EPA's findings; it also identified areas where EPA could provide additional clarification and transparency. [Fn15: Id. at 18736.] As such, it seems clear that EPA took the requirements under SDWA seriously, and relied on the best available, peer-reviewed science.

EPA Response: The commenter submitted background information in support of this comment. The EPA is not responding to background information in section 1.1 of the *Response to Comments* document. Instead, the EPA is addressing comments directly in other sections of the *Response to Comments* document organized by topic. Please see the applicable sections of the *Response to Comments* document responding to each detailed comment topic. For an

overview of how the EPA has met the requirements under the SDWA to promulgate the PFAS NPDWR, please see section 1.1 of the EPA response in this *Response to Comments* document. Regarding the EPA's consultations with the SAB and National Drinking Water Advisory Council (NDWAC), please see sections XIII.K.1. and XIII.K.2. of the final rule preamble.

Bailey Smith (Doc. #1787, SBC-045806)

May 16, 2023

U.S. Environmental Protection Agency

EPA Docket Center, Office of Ground Water and Drinking Water Docket

Docket ID No. EPA–HQ– OW–2022–0114,

Mail Code 28221T

1200 Pennsylvania Avenue, NW

Washington, DC 20460

Re: Comments on "PFAS National Primary Drinking Water Regulation Rulemaking" at Docket ID No. EPA–HQ–OW–2022–0114

To Whom it May Concern,

I appreciate the opportunity to comment on the Environmental Protection Agency's ("EPA") recently released, proposed rulemaking titled, "PFAS National Primary Drinking Water Regulation Rulemaking."

I agree with EPA's proposed rulemaking for two primary reasons. First, the Safe Drinking Water Act ("SDWA") requires the EPA to use the best available science,[FN1: 42 U.S.C. § 300g-1(b)(3)(A)(i).] which (in my view), the EPA has done.

EPA Response: The EPA acknowledges and agrees with the commenter. Please see section 1.1 of the EPA response in this *Response to Comments* document.

Bailey Smith (Doc. #1787, SBC-045811)

C. EPA Can Cogently Defend Against Potential Challenges to its Proposed Rule

According to "biglaw" firms who have written about EPA's proposed rule, industry and other stakeholders are expected to challenge the "PFAS National Primary Drinking Water Regulation Rulemaking" due to the costs they will incur in having to protect the public from toxic PFAS. [FN21: See Hampton et al., supra note 10; Paul D. Tanaka et al., PFAS Update: EPA Proposes National Standard to Regulate PFAS in Drinking Water, KIRKLAND.COM (Mar. 20, 2023), https://www.kirkland.com/publications/kirkland-alert/2023/03/epa-proposes-national-standard-to-regulate-pfas-in-drinking-water#fn21.] One common challenge to EPA rulemaking under

SDWA is that EPA did not use the best available science. [FN22: See e.g., City of Waukesha v. E.P.A., 320 F.3d 228, 247 (D.C. Cir. 2003); City of Portland, Oregon v. E.P.A., 507 F.3d 706, 708 (D.C. Cir. 2007).]

Therefore, this comment provides two brief summaries of cases in which EPA action under SDWA was challenged under the "best available science" standard. The EPA prevailed in both cases, and this comment believes the EPA action here aligns with its conduct in the two cases outlined here. Therefore, this comment argues that any challenges to EPA's science in its currently proposed rule would likely fail.

In City of Waukesha v. E.P.A., 320 F.3d 228 (D.C. Cir. 2003)., EPA issued regulations establishing standards governing radionuclide levels in public water systems. [FN23: City of Waukesha, 320 F.3d at 231.] Plaintiffs argued EPA did not use the best available science in setting the maximum contaminant level goal ("MCLG") and maximum contaminant level ("MCL") for radium-226 and radium-228. [Fn24: Id. at 247, 231.] Plaintiffs argued that EPA should have relied on particular data from dial painters' ingestion of luminescent paint brushes from the early 20th century. [Fn25: Id. at 247.] In rejecting this argument, the Court pointed out that the EPA had in fact relied on the "dial painter data" in part," and explained that to the extent the EPA did not rely on it, they explained their reasons for not using it. [Fn26: Id. at 247-48.] Thus, EPA considered and rejected Ps arguments and cited support for doing so, which is all the APA requires. [Fn27: Id. at 258.] Accordingly, the EPA did not fail to use the best available science. [FN28: See id.]

Regarding EPA's current proposed PFAS rule, if EPA declines to use particular datasets, so long as it provides legitimate reasons for declining to use them, challengers will likely not be able to dispute the EPA's decision.

The second case involving a similar challenge was City of Portland, Oregon v. E.P.A., 507 F.3d 706 (D.C. Cir. 2007). In City of Portland, EPA promulgated a rule regulating the microbial contaminant, Cryptosporidium, in drinking water. [FN29: City of Portland, Oregon v. E.P.A., 507 F.3d 706, 708 (D.C. Cir. 2007).] The proposed rule required the following three items:

"(1) it required all water systems to monitor their source water for Cryptosporidium;

(2) it required systems that do not filter their water, such as New York and Portland, to treat their source water for Cryptosporidium; and

(3) it imposed new requirements on existing uncovered reservoirs, giving cities with such reservoirs three options: covering their reservoirs, treating the water in them for viruses (but not Cryptosporidium), or implementing a state-approved risk mitigation plan."[Fn30: Id. at 709.]

The final rule was identical to the proposed rule, except that it eliminated the risk mitigation option, and required treatment for Cryptosporidium (as opposed to only viruses). [Fn31: Id. at 710.] In other words, the rule required Portland and New York to take steps to eliminate Cryptosporidium (a parasite that could lead to sickness or even death) from their drinking water. [FN32: See id. at 709.]

To prevent Cryptosporidium outbreaks, most cities run their source water through high-tech filters, however, Portland and New York did not. [Fn33: Id. at 708.] Instead, they tried to control the sources from which their water originated. [FN34: See id. at 709.] They argued that this was sufficient to meet EPA's requirements under its new rule, but the EPA disagreed, stating that Portland and New York (hereinafter "Cities") still needed to treat their water for Cryptosporidium. [FN35: City of Portland, 507 F.3d at 709.]

The Cities challenged the rule on many grounds, including that the EPA "failed to use the best available science."[Fn36: Id. at 710.] The Cities put forward multiple arguments, most pertinently, that the EPA ignored one of its comments that questioned EPA's rejection of an infectivity estimate developed by one of its scientists in a 2001 study. [Fn37: Id. at 714.]

The District Court rejected this argument. [FN38: Id.] First, the District Court reasoned that although the Cities cogently attacked the merits of the EPA's responses to their comments, "the Agency clearly thought about the cities' objections and provided reasoned replies—all the APA requires."[FN39: Id.] Ultimately, the Court held that "EPA used the best available science and provided ample evidence to support the rule, clear notice to the public about what it was considering, and adequate responses to comments."[Fn40: Id. at 716]

Regarding EPA's "PFAS National Primary Drinking Water Regulation Rulemaking," EPA has provided ample scientific evidence to support its proposed rule (indeed, the proposed rule is 117 pages). It has also provided clear notice to the public about the information EPA considered [FN41: See Proposed Rule, supra note 3 at 18645.] and has solicited the public's feedback as to various parts of the rule. [FN42: See id. at 18729.] Therefore, assuming that the EPA provides adequate responses to comments it receives about its proposed PFAS rule, it should survive a "best available science" challenge should one arise.

EPA Response: The commenter submitted background information in support of this comment. The EPA is not responding to background information in section 1.1 of the *Response to Comments* document. Instead, the EPA is addressing comments directly in other sections of the *Response to Comments* document organized by topic. Please see the applicable sections of the *Response to Comments* document responding to each detailed comment topic. For an overview of how the EPA has met the requirements under the SDWA to promulgate the PFAS NPDWR, please see section 1.1 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046100)

II. The Proposed MCLs are Required by the SDWA and Supported by an Extensive Factual and Scientific Record

A. Statutory and Regulatory Background

"The Safe Drinking Water Act … was enacted to ensure that public water supply systems meet minimum national standards for the protection of public health." [FN36: Nat'l Wildlife Fed'n v. EPA, 980 F.2d 765, 768 (D.C. Cir. 1992).] To prevent drinking water contamination, the SDWA

requires EPA to establish National Primary Drinking Water Regulations ("NPDWRs") that specify the "maximum levels for contaminants that may have an adverse effect on the health of consumers." [FN37: Id. (citing 42 U.S.C. § 300g-1).]

EPA's obligation to issue NPDWRs is triggered by the Administrator's determination that: (1) a contaminant "may have an adverse effect on the health of persons," (2) "the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern," and (3) "regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems." [FN38: 42 U.S.C. § 300g-1(b)(1)(A).] EPA's regulatory determinations, and other science- based decisions under the SDWA, "shall use . . . the best available, peer-reviewed science and supporting studies." [FN39: Id. § 300g-1(b)(3)(A)(i).] Here, EPA made regulatory determinations for PFOA and PFOS in March 2021, and it made a preliminary regulatory determination for the HI PFAS in the Proposed Rule. [FN40: Proposed Rule, 88 Fed. Reg. at 18,638; see also 42 U.S.C. § 300g-1(b)(1)(E) (authorizing EPA to publish a proposed NPDWR "concurrent with the determination to regulate").]

An NPDWR must contain either a "maximum contaminant level" or a "treatment technique." [FN41: 42 U.S.C. § 300f(1)(C).] A maximum contaminant level, or "MCL," is "the maximum permissible level of a contaminant in water which is delivered to any user of a public water system." [FN42: Id. § 300f(3).] An MCL must be set at a level that is "as close . . . as is feasible" to the "level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety," also known as the Maximum Control Level Goal or "MCLG." [FN43: Id. § 300g–1(a)(4). The SDWA authorizes, but does not require, EPA to set an MCL above the most health-protective, feasible level if EPA determines that the "benefits of [the] maximum contaminant level … would not justify the costs of complying with the level." Id. § 300g– 1(b)(6)(A). EPA did not make such a finding in its proposed rule, and, as described in greater detail below, EPA's analysis of the rule's costs and benefits precludes such a finding. See pp. 18- 20 infra.] The analysis of feasibility "tak[es] costs into consideration," [FN44: 42 U.S.C. § 300g-1(a)(4)(D).] but it does not prioritize those considerations over public health protection or require EPA to find that the economic benefits of an MCL outweigh the costs. [FN45: See S. Rep. No. 104-169, at 33 (Nov. 7, 1995) ("The Administrator is not precluded from … set[ting] a maximum contaminant level as close to the maximum contaminant level goal as feasible, even if the Administrator determines that the benefits of the MCL at this level do not justify the costs."); see also 42 U.S.C. § 300g-1(b)(3)(C)(i) (requiring EPA to consider "nonquantifiable health risk reduction benefits" when establishing MCLs); City of Portland, Oregon v. EPA, 507 F.3d 706, 712 (D.C. Cir. 2007).]

EPA has broad authority under the SDWA to set MCLs for groups of related contaminants. The SDWA broadly defines "contaminant" as "any physical, chemical, biological, or radiological substance or matter in water," encompassing both individual chemicals and chemical mixtures that are found in the same water supplies. [FN46: 42 U.S.C. § 300f(6) (emphasis added).] EPA set, and the D.C. Circuit Court of Appeals upheld, a single MCL for combined levels of radium-

226 and radium-228 based on those substances' co-occurrence in drinking water and common carcinogenic effects. [FN47: See Final Rule, National Primary Drinking Water Regulations; Radionuclides, 65 Fed. Reg. 76,708, 76,718, 76,720 (Dec. 7, 2000); City of Waukesha v. E.P.A., 320 F.3d 228 (D.C. Cir. 2003).] Similarly, EPA's NPDWR for disinfectants and disinfection byproducts set combined MCLs for four different trihalomethanes ("THMs") and five different haloacetic acids ("HAA5"). [FN48: Final Rule, National Primary Drinking Water Regulations: Disinfectants and Disinfection Byproducts, 63 Fed. Reg. 69390 (Dec. 16, 1998).] In setting its original drinking water standards for THMs, EPA rejected calls to establish chemical- specific MCLs for individual THMs, such as chloroform, explaining that "as a family of compounds, the THMs are similar in chemical composition and nature" and are commonly found together in drinking water. [FN49: Final Rule, National Interim Primary Drinking Water Regulations; Control of Trihalomethanes in Drinking Water, 44 Fed. Reg. 68,624, 68,627 (Nov. 29, 1979).] As explained above, EPA's NPDWR for PCBs established a single MCL for "complex mixtures" of up to 209 possible PCB isomers. [FN50: 56 Fed. Reg. at 3,546.] In each of those rules, the use of a class-based MCL protects communities that are exposed to mixtures of related contaminants and furthers the SDWA's purpose of "prevent[ing] the harmful contamination of public water systems." [FN51: Int'l Fabricare Inst. v. EPA, 972 F.2d 384, 387 (D.C. Cir. 1992).]

EPA Response: The commenter submitted background information in support of this comment. The EPA is not responding to background information in section 1.1 of the *Response to Comments* document. Instead, the EPA is addressing comments directly in other sections of the *Response to Comments* document organized by topic. Please see the applicable sections of the *Response to Comments* document responding to each detailed comment topic. For an overview of how the EPA has met the requirements under the SDWA to promulgate the PFAS NPDWR, please see section 1.1 of the EPA response in this *Response to Comments* document.

Regarding the part of the comment on the EPA's authority under SDWA "to set an MCL above the most health-protective, feasible level if EPA determines that the 'benefits of [the] maximum contaminant level … would not justify the costs of complying with the level,'" the EPA notes that it did make a finding during the PFAS NPDWR proposal, as expressed through the Administrator's determination, that the benefits of the rule justify the costs. In the final NPDWR, considering both quantifiable and nonquantifiable costs and benefits of the rule, the EPA is reaffirming the Administrator's determination at the time of proposal, that the quantifiable and nonquantifiable benefits of the final rule justify the quantifiable and nonquantifiable costs. For additional cost considerations regarding the evaluation of the benefits and costs of regulatory alternatives associated with the final NPDWR, please see section 5.1.3 of the EPA response in this *Response to Comments* document. For additional discussion on the feasibility analysis and considerations for treatment capability of the best available technologies (BATs) to reach a PQL that is the closest to a feasible level, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding the Administrator's determination that the benefits of the rule justify the costs, please see section 13.8 of the EPA response in this *Response to Comments* document. Please see section 5 of the EPA response in this *Response to Comments* document for additional discussion regarding feasibility of the set MCLs, including the EPA

response to comment Doc. #1808, SBC-046103 in section 5.1.4 in this *Response to Comments* document.

Midwest Environmental Advocates +more (Doc. #1846, SBC-045829)

II. EPA's Proposed NPDWRs for PFOS, PFOA, PFBS, GenX, PFNA, and PFHxS are Protective, Feasible, and Cost-Justified.

Commenters commend EPA for adhering to the standard-development process established by the SDWA to propose NPDWRs for the substances subject to this rulemaking. Section 1412 of the SDWA specifies the requirements EPA must follow to promulgate NPDWRs. Section 1412(b)(4)(A) requires that each Maximum Contaminant Level Goal (MCLG) "shall be set at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety. [FN17: 42 U.S.C. § 300g-1(b)(4)(A).] Section 1412(b)(4)(B) mandates that, except in limited circumstances, each NPDWR for a contaminant with an MCLG "shall specify a maximum contaminant level [(MCL)] for such contaminant which is as close to the [MCLG] as is feasible."[FN18: 42 U.S.C. § 300g-1(b)(4)(B).] Here, EPA followed the meticulous statutory process to derive MCLGs and MCLs for each of the PFAS subject to the rulemaking.

EPA Response: Please see section 1.1 of the EPA response in this *Response to Comments* document.

1.2 Communications

Summary of Major Public Comments and EPA Responses

In the proposed rule, the EPA requested comment on what may be needed for water systems to effectively communicate information about the PFAS NPDWR to the public, among other topics. The EPA requested input on the types of guidance, training, and implementation support documents that may be beneficial in supporting utilities and communities in implementing the rule. In this section of this *Response to Comments* document, the EPA is responding to comments received in response to this specific request for comment. Most of the recommendations for communications materials that the EPA received are about materials that are not required by this final NPDWR, but could help states, Tribes, and utilities implement the rule and help the public understand the rule and its public health protections against some PFAS in drinking waters. Where there are NPDWR requirements related to communications materials, they are noted accordingly. For required rule communications materials, such as the CCR and the PN requirements, please see sections 9.1 and 9.2, respectively, of the EPA response in this *Response to Comments* document. The EPA received a large range of comments from various states, organizations, and industries with examples of the types of guidance they hope to see following final promulgation. The EPA acknowledges the requests for various communications, guidance, and training materials to be produced after finalization of this regulation.

Examples of some of the many recommended and requested guidance and training materials include (but are not limited to): staff education for understanding the NPDWR itself, risk communication guidance and trainings, PN templates and tools to communicate to the public, materials around other PFAS-related statutes, such as the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and the Resource Conservation and Recovery Act (RCRA), sampling and data management tools, funding information, low income and/or small community and/or environmental justice (EJ)-specific materials and guidance, treatment technology and waste disposal guidance, NPDWR-specific guidance for the public, NPDWR-specific terminology explanatory materials for systems and primacy agencies such as for the Hazard Index and MCLs/MCLGs, targeted technical assistance, and general "safety of water" documents.

Although some communication materials requests are out of scope for this rulemaking, the EPA notes that the agency currently has resources available on its website regarding various PFAS and NPDWR topics that address some of the provided comments. The EPA has a website (https://www.epa.gov/pfas) dedicated to PFAS, including basic fact sheets about PFAS and its public health effects, actions the agency is taking to address PFAS, as well as resources and tools available to learn more about and take action against some PFAS. The website includes a four-page "PFAS Explained" document with basic information around PFAS and human health; see https://www.epa.gov/system/files/documents/2023-10/final-virtual-pfas-explainer-508.pdf. The EPA website (https://www.epa.gov/sdwa/sdwa-evaluation-and-rulemaking-process) also has a link to an EPA webpage that describes the SDWA rulemaking process and how the EPA regulates water to protect public health. For more information, please visit: https://www.epa.gov/pfas. Some commenters suggested that the EPA develop various communication, education, and outreach materials for the public, water utilities, and primacy agencies. The agency intends to produce implementation materials, including some recommended materials provided by commenters, during the implementation stage of this final PFAS NPDWR. The EPA notes that the scope of this NPDWR is to only account for PFAS exposure from drinking water contaminants in public water systems, and the implementation materials will be tailored to this rule. Communication materials to support a whole-of-government approach to PFAS reductions more broadly are outside the scope of this final rulemaking. However, as noted at the start of this paragraph, the EPA has already produced some communications materials that address PFAS contamination and remediation more broadly. The EPA may consider developing additional implementation communication materials and guidance that address communications challenges associated with different or multiple types of PFAS exposures beyond drinking water, as needed, as requested by many commentors.

Once the NPDWR is promulgated, the EPA anticipates developing a suite of implementation products, such as guidance documents, risk communication materials, and trainings, like those conducted for previous regulations, to assist primacy agencies and public water systems with implementing the PFAS NPDWR. The Small System Compliance Guide is one example of a document required upon rule effective date, per the Regulatory Flexibility Act (for more information, please see FRN section XIII.C or see https://advocacy.sba.gov/resources/the-

regulatory-flexibility-act/rfa-in-a-nutshell-a-condensed-guide-to-the-regulatory-flexibility-act/). Other common EPA documents that have followed new NPDWRs include Quick Reference Guides, Frequently Asked Questions support documents, and a State Implementation Guidance document. The Hazard Index Calculator is an example of a specific PFAS-focused tool that, once finalized, will support systems in calculating their individual Hazard Index. The Calculator is an informational technical assistance tool developed to assist drinking water systems and primacy agencies in calculating the Hazard Index. The calculator allows for entry of individual samples (based on the Health-Based Water Criteria for PFAS under the Hazard Index), along with a graphical layout to further clarify the Hazard Index outcome.

Some commenters oppose the rule because they believe the NPDWR is confusing, and they believe it will be difficult for the EPA to communicate and explain the rule. A few commentors believe the new NPDWR will cause the public to question drinking water safety and the agency will be unable to communicate otherwise. Therefore, these commenters oppose the NPDWR because they believe these negative communication tradeoffs, among other concerns, will together outweigh any public health benefits of the rule. The agency disagrees with commenters who believe that the agency should not promulgate this NPDWR to improve drinking water health risks from PFAS because some communication challenges may result. The EPA acknowledges there may be some communication challenges in implementing the PFAS NPDWR. However, the EPA disagrees with these commentors because the agency has found this NPDWR will result in public health benefits to reduce PFAS in drinking water. Further, the EPA believes that some communications challenges can be avoided or mitigated through targeted actions, such as the production of effective communication and outreach materials that will help support more effective implementation. As stated above, the agency plans to evaluate the development of materials explaining the rule and supporting implementation, among other things.

Commentors spoke to the importance of risk communication and the need for the EPA to take the lead in communicating about this new rule to the public and others. The EPA agrees with commenters that risk communication is important because providing meaningful, understandable, and actionable information to many audiences is a fundamental aspect of the work that the EPA does to meet the agency's mission to protect human health and the environment. As reiterated in IX.A.3 of the FRN, the EPA acknowledges the need to protect public health with clear and concise language that outlines the risks associated with exposures exceeding the MCLs and Hazard Index. Therefore, the agency plans to evaluate ways to support the production of targeted risk communication materials related to the rule. As discussed in the EPA PFAS Action Plan, the agency will also continue to take concrete steps, in cooperation with our federal, state, and Tribal partners, to communicate how the efforts of the EPA and other partners help to protect public health and the environment. For more information on federal agency efforts outlined in the EPA's PFAS Strategic Roadmap, please see section 15 of the EPA response in this *Response to Comments* document.

Additionally, the EPA received many comments on the required PN health effects language. The EPA agrees that additional explanation of the Hazard Index framework and health effects of PFAS exposure will more effectively communicate risk to consumers when they receive PN from their water system. The EPA has considered this input and has revised health effects language for the final rule to clarify the health effects associated with PFAS exposure, including language related to the Hazard Index. For discussion around these specific required communications through the CCR or PN requirements, please see section 9 of the EPA response in this *Response to Comments* document.

Regarding comments about targeted and/or enhanced PFAS-related technical assistance, commenters suggested that the EPA develop new programs for PFAS or enhance existing ones. The EPA agrees with this comment to support effective implementation of this NPDWR. One example of an existing technical assistance program that could be expanded to encompass PFAS is the EPA's free Water Technical Assistance (WaterTA), which supports communities to identify water challenges, develop plans, build technical, managerial, and financial capacity, and develop application materials to access water infrastructure funding. The EPA collaborates with states, Tribes, territories, community partners, and other key stakeholders to implement WaterTA efforts. The EPA has a history of providing WaterTA to support communities to build their capacity and address compliance challenges—and is expanding its technical assistance efforts to help more communities, including in response to new sources of federal funding. Notably, the Bipartisan Infrastructure Law (BIL) appropriated $50 billion in new funding, the largest federal investment in water in U.S. history. The EPA anticipates that new and existing EPA WaterTA programs will be utilized to support effective implementation of the BIL. The EPA anticipates some of these efforts will focus on identifying and addressing emerging contaminants, including for PFAS NPDWR implementation. For more information regarding BIL and other funding, particularly for small, underserved, or disadvantaged communities, please see section 2.4 of the EPA response in this *Response to Comments* document.

Individual Public Comments

Water Environment Federation (WEF) (Doc. #1529, SBC-043315)

Communication: Stakeholder communication throughout the process is critical to both proactively address concerns and correct misinformation.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Brooke Young (Doc. #1554, SBC-043971)

[Some actions the EPA can do to address these challenges as part of the proposed PFAS drinking water regulation include:]

• Require state and local authorities to more effectively communicate to the public the risks associated with exposure to PFAS compounds, identify which communities are more impacted than others by PFAS in drinking water, what is being done to limit exposure to those communities, and how maximum contaminant levels (MCLs) will be enforced.

EPA Response: Regarding the part of the comment about more effective communication to the public on the risks associated with exposure to PFAS compounds, please see section 1.2 of the EPA response in this *Response to Comments* document. This section reiterates that the EPA aims to consider these recommendations, among others, in developing optional guidance and other materials to support implementation of this NPDWR. Regarding the part of the comment about mandated utility communication about PFAS in drinking water, the EPA finds that the communication-related requirements in this final NPDWR are reasonable and sufficient for water systems to effectively communicate to the public. For more information on those requirements, please see sections 9.1 and 9.2 of the EPA response in this *Response to Comments* document. For specific information regarding the MCLs, please see section V of the FRN and section 5 of the EPA response in this *Response to Comments* document. For details regarding rule implementation and enforcement challenges, please see section XI of the FRN and section 11 of the EPA response in this *Response to Comments* document.

As for specific targeted communications materials for communities most impacted by PFAS, the agency intends to consider producing recommended materials during the implementation stage of this final PFAS NPDWR. The EPA disagrees with the commenter that the PFAS NPDWR should require state and local authorities to "identify which communities are more impacted than others" and "what is being done to limit exposures to those communities." None of these recommendations are included as requirements for the final NPDWR. However, the EPA notes that as part of its EJ analysis for this regulatory action, the agency evaluated the distribution of anticipated baseline PFAS exposure in drinking water across demographic groups. While the EPA's analysis does not identify impacts to specific localized communities, this national analysis provides information on which race/ethnicity and income groups are anticipated to be most impacted by PFAS exposure in drinking water. This analysis is consistent with the agency's *Technical Guidance for Assessing Environmental Justice in Regulatory Analysis* (USEPA, 2016e) and Executive Order 14096 by identifying and analyzing disproportionate and adverse human health or environmental effects of agency actions on communities with EJ concerns. For additional discussion on this topic, please see the EPA's EJ analysis in Chapter 8 of the Economic Analysis (USEPA, 2024a) and section 14.10 of the EPA response in this *Response to Comments* document.

Maine Water Utilities Association (MWUA) (Doc. #1567, SBC-042741)

It is imperative that EPA immediately develop an appropriate communication strategy so that water suppliers are not left on their own to individually figure out how to handle risk communication. Thus far, there have been many questions raised by residents at public forums in the communities grappling with PFAS contamination, especially about potential impacts to

health, with very few direct answers available from primacy and health agencies. EPA must be better prepared to answer questions and address mounting fears of residents, and to assist PWS which are often the first responders for questions from their customers. We also believe that there needs to be more communication by EPA to consumers regarding the other routes of exposure; it does a disservice to the public if the EPA and the states focus on drinking water to the exclusion of other, perhaps more significant PFAS contributions to one's body burden (e.g. consumer products, food). EPA must consult with risk communication professionals to develop the messaging as the materials EPA has made available thus far are not particularly helpful.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. The commenter's statements about environmental contributions of PFAS other than from drinking water are outside the scope of this NPDWR.

National Special Districts Coalition (NSDC) (Doc. #1571, SBC-043001)

This issue could be best met with technical assistance and training opportunities for agencies in need.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. For a thorough response regarding the mentioned "issue" and "opportunities," please see the EPA response to comment Doc. #1571, SBC-043000 in section 2.4 in this *Response to Comments* document.

COMM Water Department (Doc. #1577, SBC-042437)

EPA and primacy states must ensure that PWS have training on proper sampling protocols and provide the appropriate technical assistance and outreach to PWS once the rule is implemented.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

COMM Water Department (Doc. #1577, SBC-042444)

EPA needs to ensure that any required educational statements have clear and appropriate messaging. EPA needs to revisit its proposed required Standard Health Language for Public Notice as it is not well written, nor easily understood by the lay person. EPA also needs to inform consumers about the other routes of exposure; it does a disservice to the public if the EPA and the states focus on drinking water to the exclusion of other, perhaps more significant PFAS contributions to one's body burden (e.g., consumer products, food). EPA must consult with risk communication professionals to develop the messaging, as the materials EPA has made available thus far are not particularly helpful.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. Regarding mandated utility communication about PFAS in drinking water,

please see sections 9.1 and 9.2 of the EPA response in this *Response to Comments* document. The commenter's statements about environmental contributions of PFAS other than from drinking water are outside the scope of this NPDWR.

Association of State and Territorial Solid Waste Management Officials (ASTSWMO) (Doc. #1583, SBC-042406)

Finally, ASTSWMO recommends the development of guidance documents and training following the promulgation of the PFAS NPDWR, and to the extent possible, requests that some of the training modules provide a cross-walk between the SDWA rule and CERCLA and RCRA programs managed by our membership.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Association of State and Territorial Solid Waste Management Officials (ASTSWMO) (Doc. #1583, SBC-042400)

Risk Communication: The proposed MCLGs are higher than EPA's 2022 Lifetime Health Advisories for the same PFAS contaminants. The proposed MCLGs are also considerably lower than the previous 2016 Health Advisory (still currently used as an action level by the Department of Defense), the May 2023 Regional Screening Levels (RSLs) used in the CERCLA program, and most of the drinking water standards promulgated by States. As such, we are extremely concerned about how to approach health risk communication with the public and stakeholders. ASTSWMO members face continual risk communication challenges, as they attempt to explain the myriad of different risk-based standards employed in different contexts to constituents who are justifiably concerned about PFAS concentrations in their drinking water. ASTSWMO requests a greater degree of consistency between the values issued by different offices of the EPA and more straightforward risk communication guidance. While this proposed drinking water rulemaking is extremely important to further the goal of regulating PFAS at a federal level, ASTSWMO recognizes that other regulatory programs (e.g., CERCLA, RCRA), and their respective decisions, rely on the science used to derive drinking water standards. ASTSWMO strongly urges more coordination across all EPA programs, particularly when developing other health-based standards in the future (e.g., soil, air).

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. The commenter is mistaken regarding their comment on the proposed MCLGs related to the 2022 Lifetime Health Advisories. The proposed and final MCLGs for PFOA and PFOS are zero, meaning that they are lower than the interim health advisories, which are based on noncancer health effects, as well as the Health Advisories published in 2016. For discussion on the final MCLGs, please see section 4 of the EPA response in this *Response to Comments* document. For additional discussion regarding the relationship between the interim Health Advisories for PFOA and PFOS and this rulemaking, please see the EPA response to

comment Doc. #1761, SBC-053404 in section 4.2.6 in this *Response to Comments* document. Please see section V of the FRN and section 5 of the EPA response in this *Response to Comments* document for the EPA's requirements under SDWA to set MCLs as close as feasible to the MCLGs.

As described in section 1.2 of the EPA response in this *Response to Comments* document, the agency will consider producing implementation materials, including some recommended materials provided by commenters, during the implementation stage of this final PFAS NPDWR. The EPA acknowledges the need to protect public health with clear and concise language that outlines the risks associated with exposures exceeding the MCLs and Hazard Index. The EPA agrees that additional explanation of the Hazard Index framework and health effects of PFAS exposure will more effectively communicate risk to consumers, especially when they receive PN from their water system. The EPA has considered commentor input and has revised health effects language for the final rule to clarify the health effects associated with PFAS exposure, including language related to the Hazard Index. The updated health effects language for the rule is outlined in section IX.A.3 of the preamble for this action. Further, the EPA remains coordinated across programs in efforts to implement the actions discussed under the PFAS Strategic Roadmap.

Although CERCLA and RCRA programs are outside the scope of this rule, the EPA notes that the agency continues to closely coordinate between its regulatory programs. See section 15 of this *Response to Comments* document for discussion on the agency's PFAS strategic roadmap and the whole of agency approach the EPA is taking to reduce PFAS exposure. The EPA's Office of Water coordinates closely with the EPA's Office of Land and Emergency Management (OLEM) on both its CERCLA and RCRA programs through the EPA Council on PFAS, among other ways. Please see section 10.4.2 of the EPA response in this *Response to Comments* document regarding disposal of drinking water materials in the context of future regulatory actions, such as those within OLEM.

American Public Works Association (APWA) (Doc. #1584, SBC-042395)

All of these requests have a common theme and at this time, we urge the EPA to proceed carefully so as to ensure personnel are appropriately educated with the adoption of new well-developed standards in an efficient manner that minimizes costly mistakes such as the acquisition of unnecessary or insufficient equipment or usage of improper procedures. We believe IIJA is a historic and comprehensive law that warrants thoughtful implementation in order to avoid disruptive and unintended consequences. APWA wants to ensure updates in standards not only strengthen public health protections and environmental safety but are enforced appropriately. We urge that the new rules harmonize with other related requirements and allow for a thorough plan for phased implementation.

It is imperative that actions taken by the government provide clarity and relief, and not contribute to uncertainty that threatens to stall necessary improvements to our communities. APWA places

a high priority on respecting and enhancing local control for infrastructure projects. This is especially pertinent at a time when the water sector is still overcoming the compounding difficulties caused by workforce shortages, lingering supply chain issues, and inflation. Public works professionals balance public health and environmental concerns with doing what is best in the communities where they live and serve.

APWA members pride themselves on being committed to public service by profession and being a trusted resource is another way we work to protect our communities. If APWA may be of further assistance, please contact Ryan McManus, APWA Government Affairs Manager, at rmcmanus@apwa.net or 202-218-6727.

Thank you for your time and consideration of these comments.

Sincerely,

Scott D. Grayson, CAE B. Keith Pugh, PE, PWLF

Chief Executive Officer APWA President

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. Regarding implementation timeline of the rule, please see section 12.1 of the EPA response in this *Response to Comments* document.

American Public Works Association (APWA) (Doc. #1584, SBC-042393)

We urge the EPA, should it move forward with the levels as proposed, to communicate with states to work with water systems and support with resources along with time to adjust. While we understand that once a rule is finalized, water systems would have three years to be in compliance with the MCLs, there is variation in state assistance and enforcement. We also believe that it will be crucial for EPA to provide sufficient staffing for this process. Communities across the country will need technical assistance and will often need to rely upon the EPA to ensure the investments they are making will achieve compliance for the significantly foreseeable future and they are able to prove so.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. In addition to the three-year period for compliance, which the commenter noted, the EPA is exercising its authority under SDWA § 1412(b)(10) to implement a nationwide capital improvement extension to comply with the MCL. These additional two years can provide states and public water systems with more time to implement the applicable NPDWR requirements and seek potential opportunities for technical assistance, as needed. All systems must comply with other requirements of the NPDWR, including initial monitoring, three years following the promulgation date. For specific information regarding this extension, please see section XI.D.3 of the preamble and section 12 of the EPA response in this *Response to Comments* document.

Washington Suburban Sanitary Commission (WSSC Water) (Doc. #1585, SBC-042776)

Risk assessment:

PFAS are almost universally present in drinking water samples due to their widespread environmental presence. In many water systems, detected levels are only slightly below the MCL of 4 ppt, which leaves little margin for safety in maintaining compliance. This makes it challenging to make capital improvement decisions, as the risks primarily depend on future vulnerability, including changes in the regulatory landscape as new PFAS compounds are identified and regulated, and potential changes in certain PFAS levels as new variants are continuously produced and released into the environment without regulatory control. As such, we encourage the EPA to create risk assessment guidelines tailored specifically to PFAS, similar to EPA's PFAS Analytic Tools, and to make the necessary resources available to assist water systems in quantifying their PFAS risk levels and to inform future treatment and non-treatment mitigation measures.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Public Health, Seattle & King County (PHSKC) (Doc. #1594, SBC-042355)

And, more importantly, that funding and processes for remediation are clearly laid out so that local jurisdictions and the public can easily navigate the actions needed to rapidly address contaminated drinking water sources.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. For discussion regarding federal funding available for PFAS, please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA is setting enforceable MCLs for six PFAS compounds, so that water systems nationwide can monitor and determine compliance to ensure they are ultimately delivering water that does not exceed the maximum permissible levels of the six PFAS to any user of their public water system. If any of the MCLs are violated, then the water system will need to take actions to reduce levels of the regulated PFAS to at or below the MCLs. Actions may include installation of treatment as a remediation measure for PFAS in drinking water. For more details on the MCLs, please see section V of the FRN.

Michigan Department of Environment, Great Lakes, and Energy (EGLE) Drinking Water and Environmental Health Division (DWEHD) (Doc. #1597, SBC-042994)

I. General Comments

Expanding regulatory implementation requirements is challenging for agencies and regulated entities. EPA should provide robust data management tools and guidance before the rules take

effect. Successful and consistent implementation of the rules will require a functional data management system and final data entry instructions prior to implementation.

Significant resource investment will be necessary for successful implementation of these regulations. EPA must commit to providing additional resources to regulating agencies in the form of federal funding for human resources, extensive guidance materials and training, and data management upgrades.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. For discussion regarding federal funding available for PFAS, please see section 2.4 of the EPA response in this *Response to Comments* document. For specific details regarding resources and affordability, please visit Section 9.13.2.2 of the EA document (USEPA, 2024a).

Michigan Department of Environment, Great Lakes, and Energy (EGLE) Drinking Water and Environmental Health Division (DWEHD) (Doc. #1597, SBC-042988)

In our experience, the need for PWS to effectively communicate information related to PFAS monitoring and compliance requirements is of utmost importance. EGLE DWEHD requests that in coordination with any final version of the proposed NPDWR, EPA provides clear and concise language for supplies to use in developing their communications, as well as for guiding PWS in the requirements around collection, interpretation, and submission of PFAS samples and sample results.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

National Tribal Water Council-Tribal PFAS Working Group (NTWCTPWG) (Doc. #1598, SBC-042341)

Standardized easily adapted reference materials for educating individuals and communities with accurate contemporary information about PFAS chemicals are needed. It is unrealistic to expect that each potentially impacted tribal community will have the resources necessary to create germane educational and informational materials. A case in point is that notification of the presence of PFAS in customers‘ drinking water needs to be accompanied by educational materials on what the number(s) mean, what actions the water utility will take, or is required to take, and when, and what community members, at their option, can do in the interim and going forward. For example, if there are ways to reduce PFAS to safe levels through point-of-use or home-based units, that information should be provided.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. For required rule communications materials, such as the CCR and the PN requirements, please see sections 9.1 and 9.2, respectively, of the EPA response in this *Response to Comments* document.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043644)

C. Public communication of PFAS-related information while maintaining customer confidence will be significant challenges considering the nuanced technical /scientific detail relevant to the rule.

Educating the community on PFAS requires a tremendous amount of public communication effort, as PFAS awareness is very limited outside of the water industry. The regulation of PFAS compounds using a composite Hazard Index complicates the ability to communicate safe drinking water information to customers.

In addition, there are public notification requirements in the proposed rule for systems with certain violations, but public notification costs were not included in cost estimates. Nor was public education on rule compliance considered. While communication/outreach costs might not be a significant additional burden (relative to installation and operation of treatment, for instance), it could suggest that utilities will need additional support and resources to adequately perform these activities. It is recommended that USEPA provide additional guidance and perhaps develop community outreach tools and resources for utilities to be able to use, as needed.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. For water system cost concerns, including administrative costs to water systems (such as PN costs), please see section 13.4.5 of the EPA response in this *Response to Comments* document.

Marlene Ladderbush (Doc. #1612, SBC-042920)

EPA also needs to inform consumers about the other routes of exposure; it does a disservice to the public if the EPA and the states focus on drinking water to the exclusion of other, perhaps more significant PFAS contributions to one's body burden (e.g., consumer products, food). EPA must consult with risk communication professionals to develop the messaging, as the materials EPA has made available thus far are not particularly helpful.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. The commenter's statements about environmental contributions of PFAS other than from drinking water are outside the scope of this NPDWR.

Marlene Ladderbush (Doc. #1612, SBC-042913)

EPA and primacy states must ensure that PWS have training on proper sampling protocols and provide the appropriate technical assistance and outreach to PWS once the rule is implemented.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Town of Lincoln Water Department (Doc. #1613, SBC-043025)

EPA and primacy states must ensure that PWS have training on proper sampling protocols and provide the appropriate technical assistance and outreach to PWS once the rule is implemented.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Oklahoma Department of Environmental Quality (DEQ) (Doc. #1616, SBC-043038)

DEQ recommends that in the development of risk communication materials, EPA should focus on providing further information as to what the Hazard Index is and how it relates to the MCLs.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Oklahoma Department of Environmental Quality (DEQ) (Doc. #1616, SBC-043052)

Guidance and Training Needed

DEQ recommends EPA prioritize the development of guidance, training, and implementation tools ahead of the promulgation of the final rule.

Guidance and training should include the following:

• Detailed information for water systems on the available PFAS mitigation strategies, including considerations for using an alternative water source, and best available technology (BAT) installation

• Updated guidance on simultaneous compliance, especially in consideration of chemical contaminants, lead, corrosion control, and disinfection byproducts

• Best practices for pilot testing the available treatment technologies, including examples of successful pilot test results

• Detailed information for state primacy agencies to aid in the review of PFAS treatment or alternative sources, including best practices for ensuring the long-term operation and maintenance of each strategy.

• Alternatives for testing the raw and finished water in water treatment plants that are treating for PFAS, to maintain and ensure process control

• Funding roadmap targeted at small and disadvantaged communities, outlining options across state and federal programs to ensure systems are funded in the most effective way possible

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044057)

35. General comment for consideration. It is important to relay to the public that PFAS are ubiquitous from the everyday products they use, and primarily enter the water systems through the use and disposal of consumer products. Diminishing PFAS levels in drinking water is typically only a small pathway of PFAS exposure that you are reducing your risk from. We do not want to give a false sense of security to the public that they are safe from PFAS because it is non-detect (or low detect) in their drinking water. Other more pertinent sources of PFAS (including bottled water) need to be relayed to the public as well.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. The commenter's statements about other contributions of PFAS other than from drinking water are outside the scope of this NPDWR. However, for discussion on relative source contributions, please see section 4.2.5 of the EPA response in this *Response to Comments* document for PFOA and PFOS, and section 4.3 of the EPA response in this *Response to Comments* document for the MCLG derivation for a PFAS mixture (Hazard Index) for one or more PFAS. For concerns regarding bottled water, please see section 1.4 of the EPA response in this *Response to Comments* document.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044044)

25. EPA requests comment on what may be needed for water systems to effectively communicate information about the PFAS NPDWR to the public.

a. Communications points and health language should be established by EPA, just like with every other regulated parameter. Also language to include in the CCR is needed by early 2024.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. Please see section 9.1 of the EPA response in this *Response to Comments* document for discussion about the CCR.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043089)

Beyond the technical challenges of this aspect of the monitoring requirements, there are challenges with the risk communication of these results. As proposed, the EPA would require that PFAS monitoring levels be estimated in two different ways. This will create further risk communication challenges for water systems with data below the PQL, as they will have a reporting value based on the RAA for MCL compliance and a separate value for reduced monitoring eligibility. It is unclear if EPA has considered how this data would be reported and communicated to the public in a meaningful manner.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. Please see section 9.1 of the EPA response in this *Response to Comments* document for discussion about the CCR. For the concerns regarding monitoring communication,

specifically related to the Running Annual Average (RAA) and PQL, please see section 8 of the EPA response in this *Response to Comments* document, particularly the EPA response to comment Doc. #1623, SBC-043082 in section 8.2 in this *Response to Comments* document.

WaterPIO (Doc. #1624, SBC-043466)

7. As the EPA's proposed regulations wreak havoc on the nation's public water systems, they will have to conduct public communication efforts they've never implemented before because they don't have the staff or resources to carry them out. As a result, public communication mistakes, like those made by CFPUA, will occur in hundreds of cities and towns, resulting in plummeting public confidence.

EPA Response: While some public water systems will have to make capital improvements to control for PFAS, the EPA has determined that this NPDWR is feasible for water systems and will result in public health benefits consistent with the SDWA, as described in detail throughout section V and XII.E-I of the FRN. Please see section 1.2 of the EPA response in this *Response to Comments* document regarding communication materials and the EPA's plan to support the development of risk communication materials related to this NPDWR.

WaterPIO (Doc. #1624, SBC-043468)

A strong case can even be made that the EPA wants the end of the public's confident use of its tap water, based on the clear, cumulative effect of:

• these proposed MCLs and Hazard Index;

EPA Response: The EPA disagrees with the commenter's statement. As described throughout the executive summary for this final rule, as well as sections I.A, I.E, V, and XII, the EPA has found that this regulatory action will improve drinking water quality and public health protection. Please see section 1.2 of the EPA response in this *Response to Comments* document. For information specifically on the final MCLs, please see section 5 of the EPA response in this *Response to Comments* document.

WaterPIO (Doc. #1624, SBC-043478)

Finally, we'll close with a "look ahead" into the world the EPA apparently wants to create, as evidenced by the proposed CCR Rule, the health advisories, the proposed MCLs, and the Hazard Index. A world where the people of the United States, en masse, will feel that they no longer trust their tap water AND will accuse the good, hard- working people who deliver it to their homes and businesses every day of poisoning them.

Once the proposed MCLs/HI are finalized, there will be an expectation set that current PFAS levels in drinking water are poisoning the public, even when water providers will have just over three to five years to comply with the new standards. Then, when the effective date kicks in, we

will see hundreds – if not thousands – of water systems receive Notices of Violation. This will undoubtedly impact how the nation views the safety of its drinking water.

As we stated at the start of this comment, it appears the EPA wants this collapse in public confidence to occur. However, one must ask why the EPA – which is so attuned to making sure EVERY American can afford clean drinking water – is instituting regulations, without settled science, that will devastate the affordability of drinking water.

These regulations will put even more pressure on people living in disadvantaged communities to move away from tap water to bottled water will be exponentially more expensive. (And when it is technically no safer, according to the EPA's PFAS health advisories.)

Heck, one can envision a world in the next few years where the public won't even want to use tap water for non-consumption uses because they'll be afraid of any exposure to it, let alone the risks they'll take if they consume it.

WaterPIO has heard people say, "Polluters will pay!" for years, even after PFAS discoveries where they haven't paid a dime to the water provider or their customers. And now activists will add, "These MCLs and the Hazard Index will guarantee polluters will be punished!" No, they won't. That's simply not true.

This is why we believe the EPA is seeking to punish public water systems. Wrecking the public's confidence in its drinking water is necessary for the EPA to get to where it wants to be, a place where people are so scared of their taps that the EPA will finally be able to attack corporations who have contaminated our source waters.

The problem is, eviscerating the public's confidence in its drinking water will have a destructive ripple effect on the country, and that is what a proper rulemaking process is designed to prevent. There's supposed to be a recognition that regulations will both properly protect public health and avoid establishing unattainable burdens on the entities being regulated, in this case, public water systems.

That is what makes the proposed MCLs and a new Hazard Index so frustrating for those of us who work closely with the good people in public water who work 24/7/365 to serve their communities every day. They haven't created ONE DROP of PFAS that has found its way into the nation's drinking water sources.

But that doesn't matter to the EPA. The thousands of public water systems will be harmed by these proposed MCLs and HI when they didn't have any role in causing this problem. Because of the past failures of the EPA and a variety of other state regulators, water providers are left to clean up a problem they didn't create. And now, they'll have to do so when they don't have the financial resources or personnel to pull it off, and all while they will be accused of poisoning their customers.

That's a position to fail.

That's what the EPA is putting public water systems in with its proposed MCLs and Hazard Index.

EPA Response: As discussed throughout the preamble of this regulatory action and this *Response to Comments* document, the EPA is finalizing MCLs that are feasible to implement, and which will substantially improve public health protection. Please see section 1.1 of this *Response to Comments* document for the EPA's responses to many topics across the rule that are raised in this comment, including (but not limited to) the feasibility of the MCLs, the use of the Hazard Index, the regulation's protection of public health, and the discussion of the impacts of the rule on disadvantaged communities.

The EPA disagrees with the commenter's statements regarding public health concerns about exposure to PFAS in drinking water and how the EPA, primacy agencies, and water systems will be required to communicate that risk in the final rule. The EPA disagrees with these statements because the EPA has met the requirements of SDWA to determine that the quantifiable and nonquantifiable benefits of the final rule justify the quantifiable and nonquantifiable costs, and once fully implemented, the EPA estimates that the rule will prevent thousands of deaths and reduce tens of thousands of serious PFAS-attributable illnesses (as highlighted in the executive summary of the preamble for this rule). As further described in section III of the FRN, individual regulation of PFHxS, PFNA, and HFPO-DA, and regulation of mixtures of these three PFAS and PFBS, presents a meaningful opportunity for health risk reduction for persons served by public water systems (PWSs). Regarding the communication of this public health risk, the implementation of this NPDWR includes public education and notification requirements, such as through the CCR or through PN, that will protect the public and communicate those risks to communities to mitigate PFAS exposure through drinking water. Please see section IX of the FRN and section 9 of the EPA response in this *Response to Comments* document for more information on these notification requirements. Please see section 1.2 of the EPA response in this *Response to Comments* document for further discussion on communications materials for this NPDWR.

For concerns regarding the sufficiency of the monitoring compliance dates, please see section 8.1 of the EPA response in this *Response to Comments* document.

While beyond the scope of this rulemaking, the EPA is also taking action in addition to this NPDWR to address PFAS, and these actions can be found in the EPA's Strategic Roadmap outlined in section II, part F of the FRN and section 15 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenter's statements that the PFAS NPDWR will make drinking water unaffordable, particularly for people in "disadvantaged communities." Under SDWA, affordability to smaller water systems is addressed through SDWA section 1412(b)(4)(E). If the EPA makes a finding that an MCL is not affordable for certain categories of water systems, the EPA can enable variances for those systems. For the PFAS NPDWR, the EPA has determined that there are several affordable treatment technologies for small systems in accordance with SDWA section 1412(b)(4)(E); therefore, variances are not triggered for this rule. For more information, see Chapter 9.13 of the EA. For the EPA's response

to comments on the EPA's affordability analysis for this rule, please see section 13.10 of the EPA response in this *Response to Comments* document. Additionally, in its EJ analysis for the final rule, the EPA has determined that cost differences across race/ethnicity and income groups are typically small, with no clear unidirectional trend in cost differences based on demographic group. The agency also found that communities of color are anticipated to experience the greatest quantified benefits associated with the final rule. For more information, see Chapter 8.4 of the EA. For the EPA's response to comments on the agency's EJ analysis for this rule, please see section 14.10 of the EPA response in this *Response to Comments* document. The EPA provides information and discussion regarding funding in relation to this rule in section II.E of the FRN and section 2.4 of the EPA response in this *Response to Comments* document, as well as across the cost and benefit analysis, found in section XII of the FRN and section 13 of the EPA response in this *Response to Comments* document. For water system cost concerns, including administrative costs to water systems, please see section 13.3.3-13.3.6 in this *Response to Comments* document.

Lastly, the EPA disagrees with the commenter's statements that the EPA is not using "settled science," and that the agency is not regulating to properly protect public health and avoid establishing unattainable burdens on the entities being regulated. The EPA's final rule represents data-driven drinking water standards that are based on a thorough analysis of feasibility consistent with requirements under SDWA, as discussed in section V of the FRN and section 5 of the EPA response in this *Response to Comments* document. Please see section IV of the FRN, as well as section 4 of the EPA response in this *Response to Comments* document, for further information and discussion regarding the MCLGs and the appropriate health information for the MCLG derivations. Specifically in section 4.2 of this *Response to Comments* document, please see the EPA response to comment Doc. #1761, SBC-053404 in section 4.2.6 in this *Response to Comments document* regarding the 2022 interim health advisories. Again, the EPA estimates that once fully implemented, the rule will prevent thousands of deaths and reduce tens of thousands of serious PFAS-attributable illnesses. Please see section 1.1 of the EPA response in this *Response to Comments* document for information about the SDWA requirements for a NPDWR and the EPA's findings for the PFAS NPDWR that met those requirements, and section 5.1.6 in this *Response to Comments* document on the use of pending and evolving science. For additional discussion on the MCLGs, please see section 4 of the EPA response in this *Response to Comments* document.

WaterPIO (Doc. #1624, SBC-047684)

[A strong case can even be made that the EPA wants the end of the public's confident use of its tap water, based on the clear, cumulative effect of:]

• and the PFAS health advisories, which were set in June 2022 at literally immeasurable parts-per-quadrillion levels. They enabled, by EPA's own admission, every public water system in the country to be accused of having unsafe PFAS levels in its drinking water. The EPA's website even states, "Based on current methods, the 2022 interim health advisory levels for PFOA and

PFOS are below the level of both detection (determining whether or not a substance is present) and quantitation (the ability to reliably determine how much of a substance is present). This means that it is possible for PFOA or PFOS to be present in drinking water at levels that exceed health advisories even if testing indicates no level of these chemicals."

EPA Response: Please see the EPA response to comment Doc. #1624, SBC-043478 in section 1.2 in this *Response to Comments* document regarding the EPA's response to the PFAS health advisories. While Health Advisories are beyond the scope of this regulatory action, the EPA disagrees with the commenter's statements about the PFAS health advisories. The EPA is not sure about the "admission" to which the commenter refers because no citation is provided. Hence, the EPA is unable to address that part of the comment. The EPA notes that this regulation does not require systems to detect to the 2022 EPA PFOA or PFOS HA levels; rather, this regulation requires systems use the EPA methods 533 or 537.1 for their monitoring. For additional discussion on laboratory considerations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For more discussion of communications for this PFAS NPDWR, please see section 1.2 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044063)

3. ASDWA recommends that EPA work directly with ASDWA and its members on risk communication materials for the PFAS NPDWR before the rule's final publication. Materials from non-governmental organizations (NGOs) do not absolve EPA of its responsibility for developing robust risk communication resources. Resources from the Agency hold greater weight for the public and primacy agencies than from NGOs. Using EPA's materials ensures that everyone is communicating the same essential messages.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044061)

1. ASDWA recommends that EPA prioritize the development of robust guidance, training, and implementation tools ahead of promulgating the final rule. Timely and comprehensive guidance on rule implementation and simultaneous compliance, public notice templates, data management, and information on PFAS mitigation strategies and compliance timelines is necessary to ensure that primacy agencies and water systems can effectively implement the rule. ASDWA recommends that the Agency share these documents with primacy agencies in advance of the public release to allow for preparation for engagement with their water systems, the public, and the media.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044075)

Guidance and Training Needed

ASDWA recommends that EPA prioritize the development of robust guidance, training, and implementation tools as part of promulgating the final rule.

As the first newly regulated drinking water contaminant in over twenty years, primacy agencies and water systems must have timely, clear, and concise guidance from EPA on rule implementation. Guidance, training, and implementation tools should be developed with primacy agencies' input and released when the rule is finalized so that primacy agencies and water systems are prepared to effectively implement the rule upon the compliance date. ASDWA recommends that the Agency share these documents with primacy agencies in advance of the public release to allow them time to prepare to engage with their water systems, the public, and the media. Primacy agencies must be partners with EPA in developing guidance, training, and tools.

Guidance and training should include the following:

• Regulatory implementation guidance to ensure consistency across primacy agencies and EPA regions, including details on the waiver process, compliance determinations, data management and reporting requirements, the trigger level for reduced monitoring, and using previously collected data for monitoring determinations.

• Templates for public notice, including minimum required elements.

• Detailed information for water systems on the available PFAS mitigation strategies that consider scalability, including considerations for using an alternative water source, point-of-use (POU) and point-of-entry (POE) devices, and best available technology (BAT) installation.

• Updated guidance regarding residual waste handling and disposal, including

Resource Conservation and Recovery Act (RCRA) requirements and POU devices that have reached the end of their useful life.

• Detailed information for primacy agencies to aid in reviewing PFAS mitigation strategies (i.e., installation of BAT, use of POU/POE devices, or switching to an alternative source), including best practices for ensuring the long-term maintenance of each strategy. This information should include recommended sampling plans for each option to ensure efficacy.

• Best practices for pilot testing the available BATs, including examples of successful pilot test results. To the extent practical, baseline water quality should be considered to guide pilot testing and effective treatment.

• Protocols for testing the raw and finished water in water systems that are performing operational (process control) testing in-house to ensure their treatment is operating correctly. This guidance will help to maintain and ensure process control.

• Updated guidance on simultaneous compliance, especially considering chemical contaminants, lead, corrosion control, and disinfection byproducts.

• Information on the expected compliance timelines for mitigating a maximum contaminant level (MCL) exceedance.

• Funding roadmap targeted at small and disadvantaged communities, outlining options across state and federal programs to ensure systems are funded most effectively.

This list of needed guidance and training from EPA is extensive, and meeting these needs is essential and critical to support primacy agencies and water systems in meeting the rule requirements.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044107)

Primacy agencies have noted that the start-up of granular activated carbon (GAC) treatment may release arsenic at levels that may exceed the arsenic MCL. Regardless if the released arsenic exceeds the MCL, primacy agencies want to ensure that treatment for one contaminant does not pose exposure risks for other regulated contaminants. ASDWA recommends that EPA develop additional guidance on GAC start-up and conditions that may be utilized to ensure the safe start-up of GAC. Additionally, GAC is not optimal for the removal of every PFAS. EPA should continually release the most up-to-date guidance and research to primacy agencies that show what treatment media is most effective depending on what PFAS analytes are being addressed on an individual water system basis.

EPA Response: The EPA acknowledges the specific requests for granular activated carbon (GAC) and treatment guidance. For concerns around GAC itself, please see section X of the FRN. For additional discussion on treatment, particularly relating to concerns around arsenic, please see sections 10 and 10.1, respectively, of the EPA response in this *Response to Comments* document. For general communications concerns, please see section 1.2 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044109)

ASDWA recommends that EPA develop guidance for water systems considering their options to address the PFAS MCL, both treatment and non-treatment. EPA should include some of the above considerations in that guidance material to ensure systems fully evaluate their options and understand the challenges associated with the various options. EPA should include considerations for regionalization/consolidation and utilize the opportunity to encourage systems that are currently not viable to connect to viable water systems. Primacy agencies have noted that there are also corrosion control concerns when consolidating systems and changing sources.

Additionally, ASDWA recommends that EPA develop updated, in-depth simultaneous compliance guidance for primacy agencies. Simultaneous compliance guidance will help to ensure that compliance with one contaminant is not being traded for another, similar to the past water quality problems in Washington, DC, in which elevated lead levels were caused due to a change in disinfectant to address disinfection by-product concerns. Drinking water chemistry is very complex, and primacy agencies want to ensure treatment protects consumers from all NPDWR contaminants.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. For the comment regarding corrosion control concerns, Sections 3.5.1 and 4.5.1 of the *Best Available Technologies and Small System Compliance for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water* document (USEPA, 2024b) contain corrosion control and other process integration information for anion exchange resin (AIX) and nanofiltration/reverse osmosis (NF/RO) respectively. Regarding the commentor's request for "considerations for regionalization/consolidation" for systems, the EPA notes that creating water system partnerships may be a viable option for water systems seeking to address PFAS contamination in their drinking water and ensuring compliance with NPDWRs. For some general information about water system partnerships and building capacity of drinking water systems, please visit the EPA website at https://www.epa.gov/dwcapacity/learn-about-water-system-partnerships. The EPA also continues to host workshops regarding water system partnerships. For their most recent workshop, which includes a list of resources for systems, please visit the EPA website at https://www.epa.gov/dwcapacity/water-system-partnerships-workshop. Regarding the commenter's request for simultaneous compliance guidance, please see section 1.2 of the EPA response in this *Response to Comments* document. The agency will consider producing implementation materials, including the request for simultaneous compliance guidance, during the implementation stage of this final PFAS NPDWR.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044105)

Treatment Efficacy

ASDWA recommends that EPA develop guidance and in-depth training for primacy agencies and water systems on PFAS treatment technologies, including guidance that addresses simultaneous compliance concerns. ASDWA strongly recommends that EPA invest funding into evaluations of the PFAS treatment technologies (especially for small systems) to support primacy agencies.

As outlined in the rule proposal, each of the BAT, in most cases, has the technical capability of removing the target PFAS to below the detection limit for PFAS; however, some primacy agencies have limited experience with some of the BAT, and other agencies have not approved the use of some of the BAT for PFAS or other contaminants. In-depth training will help ensure primacy agencies are comfortable approving these technologies for the removal of PFAS at their water systems. Additionally, because each of the available treatment technologies may require a

pilot test to ensure treatment efficacy, ASDWA recommends that EPA develop specific guidance on what should be required and the ideal timeline for a pilot for each of the technologies at differently sized systems. This guidance should also include BAT design criteria recommendations and best practices (e.g., redundant treatment vessels, intermediate sample taps, etc.).

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. For additional discussion on treatment, please see section 10 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044081)

Public Communication

Risk Communication

ASDWA recommends that EPA work directly with ASDWA and its members on the risk communication materials for the PFAS NPDWR. ASDWA recommends that EPA work with the primacy agencies ahead of the final rule publication to identify communication gaps that need to be addressed before the rule is final.

A substantial number of helpful risk communication resources, such as the Water Research Foundation's toolkit, have been developed and released over the past few years. These materials should not be seen as absolving EPA of its responsibility for developing its own risk communication resources for broad use across the water sector. The media and public's interest in PFAS has increased substantially over the past few years, with the term "forever chemicals" becoming commonplace in the press. The widespread use of this term creates risk communication challenges for the water sector. Resources with the gravitas of the Agency behind them hold greater weight to both the public and the primacy agencies in delivering the challenging risk communication messages surrounding PFAS. Using EPA's materials ensures that everyone is communicating the same essential messages.

ASDWA appreciates EPA's willingness to work with the primacy agencies on risk communication after the Agency's health advisories were released in 2022. ASDWA recommends that EPA continue to ask the primacy agencies for feedback on the materials released by the Agency to identify areas that require clarification or improvement. These opportunities allow ASDWA to engage with primacy agency staff with expertise in public communication and "bridge the gap" for public information sharing to substantially improve these materials. ASDWA recommends that EPA work directly with ASDWA and its members again on the risk communication materials for the PFAS NPDWR. ASDWA recommends that EPA work with the primacy agencies ahead of the publication of the final rule to identify communication gaps that need to be addressed before the rule is final. ASDWA recognizes that some materials will not be able to be publicly distributed ahead of time, but state staff can provide valuable insights into EPA's work.

To assist with the development of the risk communication materials, ASDWA's members have identified multiple focus areas for EPA's materials:

• Explain the differences, in plain language, between the health advisories, maximum contaminant level goal (MCLG), and Maximum Contaminant Level (MCL) and what they mean from the perspectives of human health and feasibility.

• Characterize the impact of drinking water versus all other exposure routes.

• Explain the differences between PQL, method detection limit (MDL), minimum reporting level (MRL), etc., and ensure this is consistent throughout EPA's materials, the rule language, and the preamble.

• Provide language for water systems to use when the results of PFAS testing are above detection and the health advisory but below the PQL.

• Further explain the logic behind the levels EPA has chosen for determining reduced monitoring. These levels are above the health advisories and will be a public communication challenge.

• Provide further information on the Hazard Index and how it relates to the MCLs.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Texas Commission on Environmental Quality (TCEQ) (Doc. #1632, SBC-044125)

TCEQ urges EPA to strengthen and develop additional risk communication materials prior to the final rule being promulgated. The public's awareness and concern over PFAS continues to grow so it is critical that primacy agencies, in coordination with EPA, communicate consistent messaging to the public. TCEQ recommends strengthening and developing additional risk communication materials for the following areas of concern:

• Characterize the impact of PFAS in drinking water versus all other exposure routes;

• Differentiate between health advisories, MCLGs, and MCLs;

• Differentiate between a practical quantitation limit (PQL), a detection limit, and the method reporting limit, and ensure consistency throughout the communication materials, rule language, and preamble;

• Provide template language for public water systems to use when the results of PFAS testing are above detection and the health advisory but below the PQL;

• Clarification and logic for determining reduced monitoring frequency, as these levels are above the health advisories and will be difficult to communicate to the public;

• Provide plain language for the public to understand what the HI is and how it relates to the MCLs; and

• How running annual and quarterly averages will be used to identify compliance and violations.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Rural Community Assistance Partnership Incorporated (RCAP) (Doc. #1633, SBC-044141)

We urge EPA to provide additional guidance regarding testing and compliance options both to public water systems and Primacy agencies' staff, and to double down on the essential work that EPA is already doing to invest in the water workforce of the future. RCAP stands ready to partner with EPA on this and other matters as the Agency moves forward to implement and enforce these standards.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Town of Tewksbury, Massachusetts (Doc. #1637, SBC-043243)

EPA and primacy states must ensure that PWS have training on proper sampling protocols and provide the appropriate technical assistance and outreach to PWS once the rule is implemented.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

New England Interstate Water Pollution Control Commission (NEIWPCC) (Doc. #1650, SBC-043153)

Our member state's reservations pertaining to the Hazard Index approach center on communication of the concept and the need to educate systems about how to interpret their analytical results. We are concerned that this burden will fall to local and state officials, leading to inconsistent interpretation regarding compliance. We, therefore, urge EPA to provide appropriate outreach materials to state and local officials and water suppliers.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

New England Interstate Water Pollution Control Commission (NEIWPCC) (Doc. #1650, SBC-043147)

Communication

Effective communication and education will be vital to the success of the rule. This is true for both those water system professionals who will be responsible for implementing the rule, as well

as the public. Some of our member states will need to transition away from summing approaches under the rule. Our members states have concerns about how the public will perceive the change. For instance, our member states expect some members of the public to have concerns pertaining to past exposures that are currently allowed under state MCLs. Addressing these concerns will require thoughtful communication strategies. Our member states request EPA's assistance in communicating the health impact of such exposures.

Similarly, large portions of the northeast region currently rely on private wells for drinking water. In many cases, states and local boards of health will be asked to provide guidance and recommendations to private well owners and their tenants. While we do not expect EPA to devise solutions for private well owners under the rule, we urge EPA to consider private well users in devising EPA's communication strategies.

Likewise, our member states have various requirements for transient, non-community (TNC) systems, such as motels, churches, recreational facilities, food service establishments, and shelters. Many of those TNC systems are operated by small businesses or non-profit organizations and some may serve marginalized populations. We encourage EPA to consider including TNC systems in its communication strategies to further EPA's goal of prioritizing the protection of disadvantaged communities, a core principle under EPA's PFAS Strategic Roadmap. [FN6: https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024]

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. For discussion around private well owners and transient non-community water systems (TNCWS) systems, please see section 1.4 of the EPA response in this *Response to Comments* document.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044171)

B. Guidance and Training Needed

1. NCDEQ requests that EPA develop robust guidance, training, and implementation tools as soon as practicable upon the promulgation of the final rule.

As EPA takes action on the first newly regulated drinking water contaminant in over twenty years, North Carolina will need clear guidance from EPA on rule implementation. Guidance, training, and implementation tools should be released expeditiously so that NCDEQ is well positioned to effectively implement the rule. NCDEQ recommends that the Agency share these documents with states in advance of the public release to allow us time to prepare to engage with our water systems, the public, and the media. We want to be partners with EPA in developing guidance, training, and tools.

Factors to be considered in guidance and training include the following:

• Regulatory implementation guidance to ensure consistency across state agencies and EPA regions, including details on the waiver process, compliance determinations, the trigger level for reduced monitoring, and using previously collected data for monitoring schedule determinations.

• Templates for public notice, including minimum required elements.

• Detailed information for water systems on the available PFAS mitigation strategies that consider scalability, including considerations for using an alternative water source, point-of-use (POU) and point-of-entry (POE) devices, and best available technology (BAT) installation.

• Updated guidance regarding residual waste handling and disposal, including for POU devices.

• Detailed information for state agencies to aid in reviewing PFAS mitigation strategies (i.e., installation of BAT, use of POU/POE devices, or switching to an alternative source), including best practices for ensuring the long-term maintenance of each strategy. This information should include recommended sampling plans for each option to ensure efficacy.

• Best practices for pilot testing the available BATs, including examples of successful pilot test results. To the extent practical, baseline water quality should be considered to guide pilot testing and effective treatment.

• Protocols for testing the raw and finished water in water systems that are performing operational (process control) testing in-house to ensure their treatment is operating correctly.

• Updated guidance on simultaneous compliance, especially considering chemical contaminants, lead, corrosion control, and disinfection byproducts.

• Information on the expected compliance timelines for mitigating a MCL exceedance.

• Funding roadmap targeted at small and disadvantaged communities, outlining federal programs to ensure systems are funded in the most effective way possible.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044175)

E. Public Communication

1. NCDEQ recommends that EPA work directly with state agencies to develop risk communication materials for the PFAS NPDWR and identify communication gaps that need to be addressed before the rule is finalized.

A substantial number of helpful risk communication resources, such as the Water Research Foundation's toolkit, have been developed and released over the past few years. These materials should be supplemented with PFAS specific risk communication resources for broad use across the water sector. The media and public's interest in PFAS has increased substantially over the past few years, with the term "forever chemicals" becoming commonplace in the press. The

widespread use of this term creates risk communication challenges for the water sector. Using EPA's materials ensures that everyone is communicating the same essential messages.

NCDEQ appreciates EPA's willingness to work with state agencies on risk communication after the Agency's health advisories were released in 2022. NCDEQ recommends that EPA continue to seek feedback on the materials released by the Agency to identify areas that require clarification or improvement. We are available to work with EPA to identify any communication gaps that need to be addressed before the rule is final. NCDEQ recognizes that some materials will not be able to be publicly distributed ahead of me, but state staff can provide valuable insights into EPA's communication approaches.

To assist with the development of the risk communication materials, the following focus areas for EPA's materials should be considered:

• Explain the differences between the health advisories, MCLG, and MCL, and what they mean from the perspectives of human health and feasibility.

• Characterize the impact of drinking water versus all other exposure routes.

• Explain the differences between PQL, detection limit, minimum reporting level (MRL), etc., and ensure this is consistent throughout EPA's materials, the rule language, and the preamble.

• Provide language for water systems to use when the results of PFAS testing are above detection and the health advisory but below the PQL.

• Further explain the logic behind the levels EPA has chosen for determining reduced monitoring. These levels are above the health advisories and will prove to be a public communication challenge.

• Provide further Information as to what the Hazard Index is and how it relates to the MCLs.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. For discussion on the reduced monitoring, please see section 8.1.2 of the EPA response in this *Response to Comments* document, as well as section 8.8 of the EPA response in this *Response to Comments* document for the trigger level values.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044191)

NCDEQ staff and systems will also need in-depth guidance and training on PFAS mitigation techniques ahead of the compliance date for the final rule.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Blue Ridge Environmental Defense League (BREDL) (Doc. #1663, SBC-044384)

• EPA should direct federally funded state agencies to take all steps necessary to inform the public about PFAS in their drinking water.

• EPA should post federally funded state agencies' comments on these proposed regulations on an easily accessible web page so that impacted communities can determine if their state agency is protecting their health.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. All public comments on this regulatory action, including those from state regulatory agencies, are available at https://www.regulations.gov/docket/EPA-HQ-OW-2022-0114.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044390)

In the absence of adopted National Primary Drinking Water Standards for PFAS, DOH developed State Action Levels (SALs) for PFAS in drinking water. The Washington State Board of Health adopted SALs for 5 PFAS analytes on January 1, 2022 [FN1: PFAS in Drinking Water—Monitoring and Analysis | Washington State Department of Health (link: https://doh.wa.gov/community-and-environment/drinking-water/contaminants/pfas-drinking-water)]. DOH also developed informational materials, publications, fact sheets, and a PFAS dashboard to educate and communicate key information to drinking water consumers, local health departments, and public water systems.

We also needed to develop informational resources including PFAS exposure routes, clinician resources, home treatment devices and filter options, and accredited laboratories to perform drinking water sample analysis. Informational materials to address general questions and concerns about potential health effects of exposure to PFAS from the drinking water pathway were developed and posted on our website [FN2: PFAS in Drinking Water—Monitoring and Analysis | Washington State Department of Health (Link: https://doh.wa.gov/community-and-environment/drinking-water/contaminants/pfas-drinking-water)].

Under Washington State's rule, Group A Community, Non-Transient Non-Community and some Transient Non-Community water systems are required to monitor for PFAS beginning in January 2023 through December 2025. Systems must collect samples at the entry point to the distribution system and have them analyzed by EPA method 531.7 or 533 by a laboratory accredited for these analytes in Washington State. DOH sponsored a PFAS sampling project starting in early 2022 to allow public water systems to have their PFAS samples analyzed at no cost, and results satisfied state requirements that began in 2023. A total of 698 systems so far have actively participated in the PFAS monitoring project and approximately 1,136 system sources were sampled for PFAS.

A critical component to successful implementation of the proposed PFAS drinking water standards depends upon EPA providing additional clarification, guidance, and direction in

several areas that could represent significant implementation challenges. It is essential these resources are developed and made available prior to adoption of the rule.

The attached document contains comments grouped into two sections: (1) general comments, and (2) specific comments to questions posed in the proposed regulation.

Sincerely,

Lauren Jenks

Assistant Secretary, Environmental Public Health Washington State Department of Health

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. The commenter submitted background information from Washington State's experiences regulating PFAS in support of this comment. The EPA is not responding to background information nor the attached documents with "general comments" and "specific comments to questions posed in the proposed regulation" in the attached documents referenced in section 1.2 of the EPA response in this *Response to Comments* document. There is one exception to this, the EPA response to comment Doc. #1665, SBC-044427 in section 1.2 in this *Response to Comments* document, as that comment is the subject of section 1.2. Instead, the EPA is addressing those "general" and "specific" comments directly in other sections of the *Response to Comments* document organized by topic. Please see the applicable sections of the *Response to Comments* document responding to each detailed comment topic.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044427)

EPA requests comment on what may be needed for water systems to effectively communicate information about the PFAS NPDWR to the public.

• Please provide guidance for electronic delivery for public notice (PN), and include different methods of communication in consideration of cost reductions for regular PN. Alternating methods of communication in addition to providing language translation allows for a broader reach to diverse audiences. Electronic delivery is allowed for CCRs, for which EPA has provided guidelines, but not for tier 2 PN.

Be transparent in communication related to what is known and understood. This allows public water systems to communicate to their consumers with facts and resources when a PN is issued. DOH developed a historical PFAS timeline highlighting milestones from when PFAS substances were invented in 1938-present. [FN9: 334-488 PFAS Timeline (wa.gov) (Link: https://doh.wa.gov/sites/default/files/2023-03/334-488.pdf)] Informational materials to address general questions and concerns about potential health effects of exposure to PFAS via the drinking water pathway were developed and made available on our website. [FN10: Local Health Jurisdiction PFAS Resources | Washington State Department of Health (Link: https://doh.wa.gov/public-health-healthcare-providers/public-health-system-resources-and-services/local-health-resources-and-tools/pfas-resources)]

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. For additional discussion on CCR and PN, please see sections 9.1 and 9.2, respectively, of the EPA response in this *Response to Comments* document.

Aurora Water, City of Aurora, Colorado (Doc. #1669, SBC-043730)

Aurora Water recommends EPA informs consumers that drinking water is just a fraction of PFAS exposure in their lives.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. The EPA provides this information in the Hazard Index MCLG document and the PFOA and PFOS Toxicity Assessments when deriving the Relative Source Contributions (RSCs) for these chemicals.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-047691)

EPA is seeking comment on what may be needed for water systems to effectively communicate information about the PFAS NPDWR to the public. We are aware that EPA's PFAS Action Plan includes an action to work "collaboratively to develop a risk communication toolbox that includes multi-media materials and messaging for federal, state, tribal, and local partners to...help ensure clear and consistent messages to the public..." Cleveland Water would like to emphasize critical need for these tools to be developed as soon as possible.

EPA should also be at the forefront of explaining the relative risk from drinking water compared to all PFAS exposure pathways. The public should be informed of the other sources of PFAS and how drinking water, if it contains PFAS, is only a small portion of the overall potential exposure pathways. This type of information helps the public make decisions that can limit their PFAS exposure from more than just drinking water, further protecting public health and not unduly placing the entirety of burdens and blame on PWSs. Water systems are just removing contaminants from drinking water that others put in source water. It is important for EPA and water systems to work together on messaging to inform the public, who is responsible for the contamination, what can be done to stop the contamination and what choices they can make as consumers to limit their exposure.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-044900)

EPA and other agencies must work to reduce direct human exposures, and better communicate the risks associated with PFAS. Drinking water should only be one part of a larger, holistic approach to addressing the public's exposure to PFAS.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Arizona Corporation Commission (Doc. #1680, SBC-044217)

Comments

1. EPA should develop implementation guidance that includes a uniform approach to public notifications and communications to regulators.

It would be valuable to state regulators if the EPA published detailed implementation guidance before, or contemporaneous with, the final rule. Guidance from the EPA setting a uniform notification and customer communication standards would be particularly helpful to the ACC. The EPA should set the expectation for customers, companies, and enforcement agencies on how information is to be disseminated to the public regarding PFAS. This includes not only customer notifications when levels exceed the new MCLs, but also information regarding health risks and compliance timetables. Guidance should also be provided regarding information sharing between enforcement agencies and utility state reporting requirements.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

New Hampshire Department of Environmental Services (NHDES) (Doc. #1690, SBC-044356)

c. Improved Risk Communication support. Currently, there is insufficient risk communication information for the EPA's proposed MCLs for PFOA, PFOS and the Hazard Index of 4 PFAS. Most of the information released has focused on the technical definitions of terminology, regulations and implications for water system operators and regulators, with minimal focus on clear and concise information for the general public about what these thresholds mean for risk to health. The EPA is obviously in a complicated position in proposing these thresholds and rules; however, given the widespread occurrence of PFAS and the potential for a significant number of communities to be notified about PFOA or PFOS presence, EPA should provide clear risk communication documents and guidance for states, local health districts and public water system operators. The current documents defer the responsibility to entities other than the EPA, even though EPA is the one repeatedly stating the urgent health risks of PFOA and PFOS as a part of this rulemaking process.

Deferring the interpretation and development of risk communication materials to local partners, without EPA providing adequate support to its partners, will lead to mixed and possibly conflicting messaging about public health risks. This has been an ongoing challenge for several years as different states have established MCLs in the absence of EPA's current leadership on this problem. Areas where risk communication could be improved include the following, with special attention given to a target audience of the general public and not water system operators or EPA's own technical/regulatory/legal staff:

i. Clarification if MCLs and health advisories are considered acute (i.e., do not drink immediately) or chronic guidance (i.e., personal risk management) for all or specific segments of the population. This has been unclear since the EPA issued the interim health advisories for PFOA and PFOS, with official documents conflicting (e.g., exposure reduction where possible) with public statements or presentations of EPA officials stating, "no safe level" and referencing sensitive populations such as infants. The nuances of risk assessment and regulatory jargon are poorly understood by the general public and EPA should approach this with its own guidance for Risk Communication or that of ATSDR.

ii. Clarification as to what are the specific risks to health at the detection levels for PFOA and PFOS that residents and their clinicians should be aware of, and what guidance is provided to healthcare providers or local public health agencies? This should be a part of the "whole of government approach" that is embodied in the PFAS Action Plan and the PFAS Strategic Roadmap, but the current supporting information is lopsided towards only addressing PFAS in water without consideration of how communities will respond.

iii. Development of risk communication materials that provide improved context of PFAS exposure and are adaptable for states that have led on the evaluation of PFAS in drinking water and other environmental media at the local level. As pointed out by several commenters, peer-reviewed scientific studies, investigations by multiple states, and EPA's own programs, PFAS exposure is complex and comes from multiple sources. While the currently proposed rule is specific to drinking water, the notion that managing drinking water alone is an adequate intervention to reduce PFAS exposure is an oversimplification that is not supported by the science and a source of contention that alienates certain groups that are a part of EPA's target audience for risk communication.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. Regarding the commentor's first point of clarification, please see section 9.2 of the EPA response in this *Response to Comments* document and section IX of the FRN for discussion on PN requirements and its associated tiering.

Clean Water Action/Clean Water Fund (Doc. #1697, SBC-045005)

EPA should ensure that all guidance documents are comprehensive and clear and take innovative approaches to providing technical assistance, training and other support to water systems and to complement state agency implementation activities.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045110)

Discussion/information pertaining to "Safety" of the water – consistent and clear messaging are needed. PFOA and PFOS are identified in the proposed regulation as having a cancer endpoint, however PFAS is the only contaminant whereby the messaging around the MCL and health advisory is discussed as being "safe" or "not safe" or "no risk". MCLs for chronic contaminants are often set based on risk of 1 in some number of the population (such as 1 in 100,000 or 1 in 1,000,000), however, all the messaging and discussion to date regarding PFAS is "lowest point at which there are no health risks". This has created a difficult task for States to discuss and apply the MCLs. It is to the point where no one wants PFAS in their water due to any risk. While this sentiment is justified, it is not how the regulatory program has functioned historically.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. For further discussion of the MCLs for PFOA and PFOS, please see section V of the FRN and section 5.1 of the EPA response in this *Response to Comments* document. For further information regarding required messaging to consumers, please see section IX of the FRN and section 9 of the EPA response in this *Response to Comments* document.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045112)

2) Assistance to help small systems ID labs, evaluate treatment, and determine best ways to dispose of residuals.

As identified above, small systems need detailed information about where, when and why to sample and what those results mean when compared with the MCL. No information is provided and the 3- year sampling that will ensue following treatment installation is not sufficient.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Citizens Campaign for the Environment (CCE) (Doc. #1710, SBC-045137)

Recommendations for next steps:

• EPA should be prepared with accurate educational information and language to assist local water suppliers and health departments when local water supplies are exceeding MCLs. In New York State, which has adopted MCL's for PFAS, we have seen that many water suppliers, particularly from smaller, low-income communities, don't have the capacity, resources, or know-how to effectively communicate health risks associated with MCL violations to the public. In fact, if communities are left to their own devices, they may misinform the public, unnecessarily putting their health at risk.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Wyoming Department of Environmental Quality (WDEQ) (Doc. #1716, SBC-044747)

General Comments

1. EPA Should Publish Accessible Guidance on How the Proposed PFAS NPDW Rule Was Developed

EPA should develop guidance on how the NPDW rule for PFAS was developed to provide clarity and regulatory certainty on the approach for deriving MCLs and MCLGs, including the six PFAS contemplated under the proposal as well as those that may be regulated in the future. WDEQ understands that EPA relied on existing EPA guidance and policy to derive the proposed MCLs and MCLGs, that the Scientific Advisory Board was generally supportive of EPA's approach, and that EPA provided justification for the approach and rationale in the preamble. However, given the volume of PFAS compounds (some estimates at more than 12,000) that may need to be regulated, the variability in health effects of these compounds, the rapidity with which scientific data and information are becoming available, and the novelty of using a HI for a NPDW rule, it is important that EPA provide clarity on the approach for deriving MCLs and MCLGs for PFAS under the proposed NPDW rule through written guidance.

WDEQ recommends that EPA provide guidance to describe: (1) the use of human versus animal endpoints in derivation of health endpoints; (2) replication requirements for studies to derive human health effects endpoints; (3) how to combine the results of studies to derive an MCLG; (4) consideration of cancer versus noncancer human health effects; (5) circumstances under which PFAS compounds would be combined in a HI; (6) circumstances where compounds would not be combined in a HI; (7) how to address instances where the health advisory or Health Based Water Concentrations are below reporting limits; (8) approaches for deriving relative source contribution; and (9) how to derive MCLs from MCLGs.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. For information on the use of human versus animal endpoints to derive health endpoints (1), please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document. For information on replication requirements for studies to derive human health endpoints (2), how to combine results of studies to derive an MCLG (3), the consideration of cancer versus noncancer human health effects (4), and the approaches for deriving relative source contributions (8), please see the Toxicity Assessments (USEPA, 2024c; USEPA, 2024d) and the PFOA/PFOS and Hazard Index MCLG supporting documents (USEPA, 2024e; USEPA, 2024f). For additional discussion on circumstances under which PFAS compounds would be and would not be combined in a Hazard Index (5, 6), please see section 4.3.5 of the EPA response in this *Response to Comments* document, as well as the Mixtures Framework supporting document. For additional discussion on instances where the Health Based Water Concentrations are below

reporting limits (7) or how to derive MCLs from MCLGs (9), please see section V of the FRN and section 5 of the EPA response in this *Response to Comments* document.

Wyoming Department of Environmental Quality (WDEQ) (Doc. #1716, SBC-044764)

13. EPA Should Provide Training and Guidance on the Health Risk Reduction and Cost Analysis Regarding Establishing PFAS MCLs and MCLGs

EPA has specifically requested comment on the Health Risk Reduction and Cost Analysis for the proposed MCLs and MCLGs, including the quantifiable and nonquantifiable health risk reduction benefits, the incremental costs and benefits of alternative MCL concentrations, and other factors such as data quality and uncertainty. Where states do not have the technical staff ability or capacity to provide a comprehensive review and provide comments, EPA should provide accessible guidance and training to assist states with providing the requested information, particularly for states without staff positions dedicated to addressing PFAS and other emerging contaminants.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. For additional discussion on the HRRCA, please see section 13 of the EPA response in this *Response to Comments* document.

Wyoming Department of Environmental Quality (WDEQ) (Doc. #1716, SBC-044777)

In addition, EPA should provide clarity, through the development of guidance, on the use of the HI approach for PFAS, including how His might be modified should additional data and information become available.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. For discussion on incorporating additional PFAS into the Hazard Index in the future, please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045144)

2. Guidance and Training Needed

MassDEP recommends EPA prioritize the development of robust guidance, training, and implementation tools as part of the promulgation of the final rule.

PFAS will be the first new nationally regulated drinking water contaminant in over twenty years. State agencies and water systems should have clear guidance from EPA on rule implementation. Guidance, training, and implementation tools should be released when the rule is finalized, or as soon thereafter as feasible, so that all stakeholders are able to effectively implement the rule ahead of the compliance date. EPA should partner with the states in the development of guidance, training, and tools, which should include the following:

• Regulatory implementation guidance to ensure consistency across primacy agencies and EPA regions, including details on initial monitoring, compliance determinations, the trigger level for reduced monitoring, and using previously collected data for monitoring determinations.

• Templates for public notice, including minimum required elements.

• Detailed information for water systems on the available PFAS mitigation strategies that consider scalability, including considerations for using an alternative water source, POU and POE devices, and BAT installation.

• Updated guidance regarding residual waste handling and disposal, ideally including for POU devices.

• Detailed information for primacy agencies to aid in the review of PFAS mitigation strategies (i.e., installation of BAT, use of POU/POE devices, or switching to an alternative source), including best practices for ensuring the long-term maintenance of each strategy. This information should include recommended sampling plans for each option to ensure efficacy.

• Best practices for pilot testing BATs, including examples of successful pilot test results. To the extent practical, baseline water quality should be considered to guide pilot testing and effective treatment.

• Updated guidance on simultaneous compliance, especially in consideration of chemical contaminants, lead, corrosion control, and disinfection byproducts.

• Information on the expected compliance timelines for mitigating an MCL violation.

• Funding roadmap targeted at small and disadvantaged communities, outlining options across state and federal programs to ensure systems are funded in the most effective way possible.

• Guidance for water systems considering their treatment and non-treatment options to address the PFAS MCLs. EPA should include considerations such as the necessary operator skill level, the fraction of water wasted, waste disposal, maintenance and O&M costs in that guidance to ensure systems fully evaluate their options and understand the challenges associated with the various options.

• Updated in-depth simultaneous compliance guidance to help ensure that compliance with one contaminant is not being traded for another. Drinking water chemistry is very complex and we want to ensure treatment is protecting consumers from all NPDWR contaminants.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045147)

5. Public Communication

Risk communication

MassDEP recommends that EPA work directly with the Association of State Drinking Water Administrators (ASDWA) and its members as well as other stakeholders on developing risk communication materials for the PFAS NPDWR before the rule is final, including identifying and addressing gaps in currently available materials.

A substantial number of helpful risk communication resources, such as the Water Research Foundation's toolkit, as well as state-specific fact sheets and web pages, have been developed and released over the past few years. While these materials are helpful, EPA should provide additional risk communication resources for broad use across the water sector.

MassDEP appreciates EPA's willingness to work with the primacy agencies on risk communication after the Agency's health advisories were released in 2022. MassDEP recommends that EPA continue to ask the primacy agencies for feedback on the materials released by the Agency to identify areas that require clarification or improvement. These opportunities allow for engagement with primacy agency staff with expertise in public communication to substantially improve these materials. MassDEP recommends that EPA work directly with ASDWA and its members as well as other stakeholders on the risk communication materials for the PFAS NPDWR. Further, MassDEP recommends that EPA work with the primacy agencies prior to publication of the final rule to identify and address communication gaps. MassDEP recognizes that some materials will not be able to be publicly distributed ahead of time, but state staff can provide valuable insights to help improve EPA's communications materials.

To assist with the development of the risk communication materials, we've identified the following focus areas for EPA's materials:

• Explain the differences between the 2022 health advisories, the Maximum Contaminant Level Goal (MCLG), and the MCL, and what they mean from the perspectives of human health and feasibility.

• Explain the differences between Practical Quantitation Limit (PQL), Method Detection Limit (MDL), MRL, etc., and ensure that this explanation is consistently applied throughout EPA's materials, the rule language, and the preamble.

• Provide language for water systems to use when the results of PFAS testing are above detection and the health advisory but below the PQL.

• Further explain the rationale behind the trigger levels EPA has chosen for determining reduced monitoring. These levels are above the health advisories and therefore might require a more detailed explanation to the public.

• Provide further information as to what the Hazard Index (HI) is and how it relates to the MCLs.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Thurston Public Utility District (PUD), WA (Doc. #1729, SBC-043580)

I want to urge the EPA to proceed carefully so as to ensure personnel are appropriately educated with the adoption of new well-developed standards in an efficient manner that minimizes costly mistakes such as the acquisition of unnecessary or insufficient equipment or usage of improper procedures. We want to ensure updates in standards not only strengthen public health protections and environmental safety but are enforced appropriately. We advise that new rules harmonize with other related requirements and allow for a thorough plan for phased implementation.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. With regard to additional time for meeting MCLs (and therefore providing regulated PWSs more time to acquire necessary equipment and develop effective procedures), please see section 12.1 of the EPA response in this *Response to Comments* document.

U.S Conference of Mayors, National League of Cities and National Association of Counties (Doc. #1733, SBC-043894)

This discrepancy also makes it difficult for local leaders to effectively communicate the risk associated with PFAS to the public and will likely lead to confusion among residents as they seek to determine if their water is safe to drink. EPA should work with local governments and water utilities to collaboratively develop a risk communication toolkit that explains the relative public health risks and clarifies why additional measures are necessary despite higher current state and international standards. Importantly, this language and toolkit should be voluntary for local governments to use, rather than mandatory.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Michigan Section American Water Works Association (MI-AWWA) (Doc. #1734, SBC-044479)

Communication

The proposed rule would introduce yet another hazard index, further complicating an already difficult communication issue. To the lay person, any exceedance, whether regulatory or advisory, is deemed "unsafe." Communicating clearly and effectively the nuance associated with MCLs and how they relate to MRLs that perhaps change over time would be difficult for communication professionals. There are many water systems in Michigan that do not have communication professionals on staff and so their challenge would be even greater. Poor communication would at best confuse the public and erode their trust. At the worst, it could incite panic. Customers will be less inclined to use and pay for water, which exacerbates the financial burden of treating for PFAS.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. As mentioned in the EPA's response, the EPA will be releasing the Hazard

Index Calculator, which will support systems in calculating their individual Hazard Index. The Calculator is an informational technical assistance tool developed to assist drinking water systems and primacy agencies in calculating the Hazard Index, which should also help with communicating results of the calculation. For concerns regarding rule implementation and enforcement by primacy agencies, particularly related to record keeping, reporting, and enforcement, please see section XI in the FRN and section 11 of the EPA response in this *Response to Comments* document. For additional discussing the MRLs, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Arizona Corporation Commission (ACC) (Doc. #1735, SBC-045184)

Finally, the ACC believes the EPA should provide guidance on how small water utilities with insufficient operating revenues to service loans for FCRT can fund the addition of FCRT once federal funding at the state level is depleted.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. The EPA notes there may be opportunities for many communities to utilize external funding streams to address such challenges. The BIL, the Low-Income Water Household Assistance Program through the American Rescue Plan, and other funding sources may be able to provide financial assistance for addressing emerging contaminants. In particular, the BIL funding has specific allocations for disadvantaged and/or small communities to address emerging contaminants, including PFAS. For example, the *Emerging Contaminants in Small or Disadvantaged Communities grant program* will provide states and territories with $5 billion to provide grants to public water systems in small or disadvantaged communities to address emerging contaminants, including PFAS. Grants will be awarded non-competitively to states and territories. For more on this, please see section XIII.J of the FRN. For additional discussion around federal funding, please see section 2.4 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045975)

Section 6.2: Communication

EPA is seeking comments on what may be needed for water systems to effectively communicate information about the PFAS NPDWR to the public. AMWA is aware that EPA's PFAS Action Plan includes an action to work "collaboratively to develop a risk communication toolbox that includes multi-media materials and messaging for federal, state, tribal, and local partners to...help ensure clear and consistent messages to the public." The association would like to emphasize the critical need for these tools to be developed as soon as possible and asks EPA to include AMWA in the collaboration to work with the agency to develop useful and timely communication material that will help water systems explain EPA's decisions to the public.

EPA should also be at the forefront of explaining the relative risk from drinking water compared to all PFAS exposure pathways. The public should be informed of the other sources of PFAS and

how drinking water is only a portion of that. This helps the public make decisions that can limit their PFAS exposure from more than just drinking water, which further protects public health, and does not place the entirety of blame on PWSs. Water systems are removing contaminants from drinking water that other parties put in, so EPA and water systems need to work together on messaging to inform the public about who is responsible for contamination, what can be done to lessen or stop it, and what choices consumers can make to limit their exposure.

An important message that has been made difficult to communicate to the public is letting customers know that their water is safe to drink, even when PFAS concentrations are below detection limits. EPA's announcements of health advisories that are in the parts per quadrillion realm made it difficult to say that the water was safe to drink because water systems cannot detect the presence of contaminants at those levels – and therefore cannot tell customers whether their water meets EPA's health advisory. Additionally, EPA had proposed using drinking water health advisory levels for HBWCs in this NPDWR rulemaking. Questions will arise on why the health advisories are used for some PFAS but not others, and the public will lose trust in drinking water if these inconsistencies are not effectively communicated. EPA made these decisions based on its analysis, and, therefore, should be the leader in these communication efforts.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. The commenter incorrectly stated that the EPA has proposed using drinking water health advisories as health-based water concentrations (HBWCs) under this rulemaking. The EPA's previous issuance of the PFAS health advisories is outside the scope of this action. Drinking water health advisories are distinct from MCLs and MCLGs, including the HBWCs that were derived as part of the Hazard Index MCLG, as each serves a different purpose. Health advisories provide technical information on chemical and microbial contaminants that can cause human health effects and are known or anticipated to occur in drinking water. Health advisories primarily serve to provide information to drinking water systems and officials responsible for protecting public health when emergency spills or other contamination events occur. The health advisories help Tribes, states, and local governments inform the public and determine whether local actions are needed to address public health impacts in affected communities. The EPA's HA documents describe information about health effects, analytical methodologies, and treatment technologies. HAs are not legally enforceable federal standards and are subject to change as new information becomes available.

As mandated by SDWA, MCLGs are proposed and finalized when promulgating NPDWRs. The EPA proposed and is now finalizing the Hazard Index MCLG as part of this rulemaking. The agency documented the derivation of the HBWCs for each of the four PFAS considered in the Hazard Index MCLG in the document titled "Maximum Contaminant Level Goals (MCLGs) for Three Individual Per- and Polyfluoroalkyl Substances (PFAS) and a Mixture of Four PFAS" (USEPA, 2024e). This derivation was independent of the publication of the health advisories for HFPO-DA and PFBS in 2022, though the HBWCs cite to the same toxicity assessments for these two chemicals (USEPA, 2021a; USEPA, 2021b) as the previously published health advisories.

Please see section 4.3 of the EPA response in this *Response to Comments* document for how the EPA set the Hazard Index MCLG.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045976)

This communication would be helpful for utilities to use in their CCRs. AMWA would like to stress that not all communication techniques work for every utility, so it is important any EPA language be guidance, not required CCR language, for water systems. AMWA welcomes the opportunity to partner on PFAS communication efforts but believes EPA should be the leader in developing and disseminating communication on PFAS health advisories, MCLs, and all information related to the PFAS NPDWR to the public.

EPA Response: Please see the EPA's response regarding "this communication" in the EPA response to comment Doc. #1738, SBC-045975 in section 1.2 in this *Response to Comments* document. For additional communications and guidance concerns, please see section 1.2 of the EPA response in this *Response to Comments* document. For discussion regarding required communications, such as CCRs and PN, please see section 9 of the EPA response in this *Response to Comments* document, particularly the EPA response to comments Doc. #1738, SBC-045971 and Doc. #1738, SBC-045974 in sections 9.1 and 9.2, respectively, in this *Response to Comments* document. Health advisories are outside the scope of this rulemaking. For discussion on the individual MCLs, including risk communication and feasibility concerns, please see section 5.3.1 of the EPA response in this *Response to Comments* document.

Del-Co Water Company, Inc. (Doc. #1744, SBC-043618)

Many questions have been raised in communities dealing with PFAS contamination, especially about potential impacts to health, with very few direct answers available from primacy and health agencies. EPA must be better prepared to answer questions and address mounting concerns of residents, and to assist PWS which are often the first responders for questions from their customers. We also believe that there needs to be more communication by EPA to consumers regarding the other routes of exposure; it does a disservice to the public if the EPA and the states focus on drinking water to the exclusion of other, perhaps more significant PFAS contributions to one's body burden (e.g. consumer products, food). EPA must consult with risk communication professionals to develop more meaningful messaging.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045204)

5. CT DPH recommends EPA provide public communication materials. Consistent messaging regarding PFAS risks from an authoritative federal source can help alleviate confusion, foster trust, facilitate awareness and promote compliance. Adaptable and customizable public notice

templates for public water systems to notify their customers of various monitoring and occurrence outcomes could help ensure consistent and timely communications.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045238)

2. EPA requests comment on what may be needed for water systems to effectively communicate information about the PFAS NPDWR to the public.

It is essential that risk communication resources and materials come directly from EPA. States and water systems need tools to communicate the health and environmental risks from PFAS to their residents and customers. While PFAS risk communication resources are available from various sources (states, agencies, organizations, etc), EPA needs to set the standard for the states and the water utility sector. This is an opportunity for EPA to define the overall risk communication messaging and language, define the national context, and establish consistency across the nation. Consistent messaging regarding PFAS risks coming from an authoritative federal source can help alleviate confusion, foster trust, facilitate awareness and promote compliance. Adaptable and customizable public notice templates for public water systems to notify their customers of various monitoring and occurrence outcomes could help ensure consistent and timely communications.

Resources developed and disseminated by EPA need to clearly explain the key concepts of the NPDWR in plain, consistent language the general population can understand. Specifically, Health Advisories, Maximum Contaminant Level Goals, and Maximum Contaminant Level need to be explicitly described and their differences clarified. Furthermore, these concepts need to be examined from a human health feasibility perspective and their implications need to be expounded upon.

Since drinking water is only one means of exposure for PFAS, other exposure routes need to be mentioned without confusing or negating the importance of this rule. These routes need to be considered, placed in context, and characterized with respect to PFAS sources in drinking water.

While the concept of the Hazard Index may be familiar to some, it is probably a new concept for the general public that needs to be clearly spelled out. How the Hazard Index works, why it is useful, how it relates to the Maximum Contaminant Levels, and the assumptions of the "PFAS Mixtures Framework" need to be addressed. Furthermore, the utility of dealing with PFAS as a class or group of chemicals using the Hazard Index also needs to be pointed out.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045215)

EPA requests comment on what may be needed for water systems to effectively communicate information about the PFAS NPDWR to the public.

Because the HI approach is new to drinking water regulation, EPA should define "Hazard Index" or "HI" in all publications or communications by providing the HI formula to avoid misinterpretation that the number "1.0" represents a water concentration. EPA should also develop risk communication messages to help water systems interpret HI for the reasons mentioned in Comment 3.

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EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045239)

Under the Safe Drinking Water Act "Right to Know" community water systems would be required to report detected PFAS in their annual Consumer Confidence Reports. This would require the reporting detections of PFAS in the NPDWR; specifically, individual concentrations for PFOA and PFOS, and concentrations and Hazard Index for mixtures of PFHxS, HFPO–DA (GenX), PFNA, and PFBS. While many of the larger public water systems in Connecticut that voluntarily tested for PFAS are already reporting PFAS results in their Consumer Confidence Reports, smaller systems may require technical assistance and could benefit from EPA guidance. Therefore, we urge EPA to set the standard, provide clear and understandable messaging, and provide effective resources all public water systems can use.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. For additional discussion on SDWA Right to Know, please see section 9 of the EPA response in this *Response to Comments* document.

West Virginia Rivers Coalition et al. (Doc. #1746, SBC-045253)

Lastly, more specific implementation guidance is needed for non-transient non-community water systems that will be subject to the rule, such as schools and hospitals.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. For additional information on which entities the rule applies to, please see section 1.4 of the EPA response in this *Response to Comments* document.

Harris County Attorney's Office (HCA) (Doc. #1751, SBC-045263)

EPA should provide robust guidance and assistance to water systems, especially those in EJ and low-resource areas, on pathways to avoid shifting the cost of PFAS cleanup onto overburdened communities.

HCA requests EPA develop guidance on 1) applying for and navigating grant funding, 2) other potential funding sources 3) recommended technologies, 4) best practices to ensure sufficient notice is given to residents on PFAS should be provided to water systems, with a particularized guidance to aiding small, rural, and EJ communities. This guidance should be easily accessible to water systems and should be made available online or through request. EPA should make efforts to communicate the availability of this guidance to all regualted entities and the public.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. The EPA acknowledges the potential for implementation challenges for overburdened communities; however, to help address the challenge of funding availability particularly in low-resource areas, there may be opportunities for many communities to utilize external funding streams to address such challenges. The BIL, the Low-Income Water Household Assistance Program through the American Rescue Plan, and other funding sources

may be able to provide financial assistance for addressing emerging contaminants. In particular, the BIL funding has specific allocations for disadvantaged and/or small communities to address emerging contaminants, including PFAS. For example, the *Emerging Contaminants in Small or Disadvantaged Communities grant program* will provide states and territories with $5 billion to provide grants to public water systems in small or disadvantaged communities to address emerging contaminants, including PFAS. Grants will be awarded non-competitively to states and territories. For more information, please see section XIII.J in the FRN. For additional discussion federal funding programs, please see section 2.4 of the EPA response in this *Response to Comments* document.

Environmental Council of the States (ECOS) (Doc. #1752, SBC-044502)

Risk Communication

ECOS appreciates EPA's work to coordinate with states on risk communication activities around PFAS and encourages EPA to continue to work with states to develop risk communication materials related to the NPDWR before rule finalization. As public awareness and concern over PFAS has grown, the ability for states in coordination with EPA to communicate consistent messages to the public using EPA risk communication materials has only become more critical. Some areas that would benefit from additional risk communication materials include information on the differences between health advisories, Maximum Contaminant Levels (MCL), and Maximum Contaminant Levels Goals (MCLG); the meaning of a hazard index approach to capture risk from four PFAS chemicals together; the difference between chronic and sub-chronic exposure and clarity around developmental endpoints; and how running annual and quarterly averages will be used to identify compliance and violations. Strong centralized messaging and risk communication materials will help states better communicate with the public and facilitate the successful implementation of the PFAS rule.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

El Paso Water (Doc. #1757, SBC-044520)

EPA role to identify sources of PFAS exposure

It is to the benefit of the EPA and all water suppliers that the public be made aware that PWSs are not the primary or only source of PFAS exposure. The revision's requirements for testing put much of the responsibility for PFAS detection and removal on PWSs, which could create the perception among consumers that their drinking water suppliers are the main source of PFAS exposure. However, with PFAS exposure stemming from contact with many everyday items such as household cleaners, personal care products, fire extinguishing foam and fire retardants as well as food and food packaging, it is important for EPA to increase understanding of the harmful effects of a customer's exposure from these items. This information will help influence consumer behavior and put more of a burden on manufacturers to find PFAS-free alternatives.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

El Paso Water (Doc. #1757, SBC-044531)

And we must examine the requirements for additional public notification when there is no need and when the public at large has little context on the complicated issue of PF AS.

Thank you for taking these considerations under advisement as you deliberate the NPDWR revisions.

Sincerely,

Gilbert Trejo, P.E.

Vice President – Operations & Technical Services

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. For additional discussion on PN, please see section 9.2 of the EPA response in this *Response to Comments* document.

Arizona Water Company (Doc. #1758, SBC-044532)

May 30, 2023

United States Environmental Protection Agency Office of Groundwater and Drinking Water
1200 Pennsylvania Ave NW

Washington, DC 20460

Re: EPA PFAS Rule

To Whom It May Concern:

Introduction and Background

Arizona Water Company ("Company") is a privately owned water utility that serves over 29 communities throughout the state of Arizona. Like many other water utilities, the Company is impacted by the proposed new per- and polyfluoroalkyl substances ("PFAS") rule issued by the Environmental Protection Agency ("EPA"). The Company compiled comments on the proposed PFAS rule, stated below.

PFAS Removal Costs and Funding

PFAS removal facilities are completely new to operators and management and will require training and demonstration facilities. While the EPA's three currently known treatment technologies of granular activated carbon (GAC), ion exchange (IX), and reverse osmosis and nanofiltration (RO/NF) are similar to existing treatment technologies, the Company does not

operate any current treatment facilities to remove PFAS in its water systems. It will be helpful for operators and management to gain experience and training with treatment facilities using these technologies in a demonstration setting. The Company recommends the EPA fund training and demonstration facilities as they will be helpful for numerous private and public water utilities. The Company participated in two arsenic treatment facilities demonstrations and would like to participate in similar demonstrations for PFAS treatment facilities.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. For additional discussion around treatment, please see section 10.1 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045628)

Beyond the technical challenges of this aspect of the proposed monitoring requirements, there are challenges with the risk communication of associated results it would produce. As proposed, EPA would require that PFAS monitoring levels be described in two different ways. Risk communication will be especially challenging for water systems with observed values below the PQL, as they will have a reporting PFAS values based on the RAA for MCL compliance and a separate value for reduced monitoring eligibility. It is unclear if EPA has considered how these data would be reported and communicated to the public in a meaningful manner.

Analytical results below the PQL should not be used, rather the rule requirements should use 0 ppt for all analytical results below the PQL. Consistent with previous AWWA comments, AWWA recommends that one-half the MCL be used to determine if PFAS levels at an entry point are reliably below the MCL.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. For additional discussion around the PQL, as well as monitoring and reporting, please see sections 5.1.2 and 8.2 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-047694)

EPA's proposed use of the general hazard index combining risks across multiple health outcomes prevents water systems from having a effective risk communication strategy. If EPA moves forward with any rule using the hazard index, risk communication should be considered more carefully.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Connecticut Section of the AWWA (CTAWWA) and Connecticut Water Works Association (CWWA) (Doc. #1763, SBC-044238)

• Communication

As utilities and water industry professionals, we have communicated directly with customers and stakeholders since 2013 when the UCMR3 monitoring period commenced. Although the PFAS topic is challenging and complex to understand, communication materials from regulators have been limited. Consequently, we have consistently observed misunderstanding amongst customers and inconsistency in messaging amongst utilities. Further compounding this issue are the existing regulatory differences between states, many of whom have varying enforceable MCLs, and the EPA. We encourage EPA to share communication materials and guidance immediately upon finalizing the PFAS Rule. Delays in these materials impact both the primacy agency and CTAWWA and CWWA members, who are compelled to individually and inefficiently develop their own materials to address customer concerns.

Thank you for carefully considering our comments on the proposed PFAS Rule. We would be pleased to discuss these comments and any resulting questions with you and your team, as well as collaborate with your agency to address the concerns we have pointed out.

Sincerely,

Daniel Lawrence, P.E.

President, CWWA

Alexander M. Cosentino , P.E., BCEE, CCM

Chair, CTAWWA

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

New Mexico Environment Department (NMED) (Doc. #1766, SBC-044250)

Guidance and Training

EPA must develop a robust guidance, training, and implementation plan that includes tools for assisting public water systems and state primacy agencies for achieving and maintaining compliance with these proposed regulations, including solids generated during the treatment process. NMED also believes that these guidance, training, and implementation materials must be developed in a manner that allows small and underserved community water systems to easily understand and effectively implement the proposed regulations. The development of these materials should be completed prior to the promulgation of the final rule. This is the first newly regulated drinking water contaminant in over twenty years. States and water systems need clear guidance from EPA on implementing the new rule.

Risk Communication

As a result of several highly publicized drinking water contamination events across the country, the general public appears to be increasingly skeptical about the safety of community drinking water supplies. NMED believes that EPA has a responsibility to work with state primacy agencies ahead of final rule publication to develop and disseminate risk communication materials to the public and water systems and their customers. NMED recommends that EPA work with state primacy agencies, state departments of health, and organizations such as ASDWA to develop robust risk communication materials to ensure that public water systems and their customers fully understand the health impacts of PFAS and other drinking water contaminants in their drinking water supply. This should include easily understood public notice templates that public water systems and state primacy agencies can use to communicate information to public water system consumers.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

New Mexico Environment Department (NMED) (Doc. #1766, SBC-044256)

Other Concerns

NMED strongly encourages EPA to directly engage with states and organizations to develop guidance on treatment technologies and invest funding into evaluations of these treatment technologies to support state programs.

NMED recommends that EPA develop guidance for water systems considering their options to address the PFAS MCL, both treatment and non-treatment. EPA should include some of the above considerations in that guidance material to ensure systems fully evaluate their options and understand the challenges associated with the various options. EPA should include considerations for regionalization/consolidation and utilize the opportunity to encourage systems that are currently not viable to connect to viable water systems.

EPA should prioritize research on waste disposal methods and move to address PFAS waste disposal utilizing a regulatory mechanism as soon as possible to ensure that PFAS contamination isn't being moved from one media type to another. ASDWA recommends that EPA finalize the Agency's Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances ahead of the final rule.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. For additional discussion on treatment and waste disposal, please see section 10 of the EPA response in this *Response to Comments* document, particularly sections 10.1 and 10.4. For the remainder of concerns brought up in this comment, please see the EPA response to comment Doc. #1628, SBC-044109 in section 1.2 in this *Response to Comments* document.

New Mexico Environment Department (NMED) (Doc. #1766, SBC-044248)

EPA, like states, must continue to move quickly to protect communities from these toxic chemicals. This rulemaking and the many other actions underway by EPA are necessary to ensure federal, state, tribal and local governments have the regulatory framework, tools, and resources needed to protect human health and the environment. Throughout development and implementation of the final rule, EPA must lead the way for states, tribes, and local governments with strong risk communication resources and tools. Federal support for effective risk communication about PFAS contamination and cleanup must address the needs of minority and disadvantaged communities and support environmental justice and equity across all communities impacted by PFAS.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Council of State and Territorial Epidemiologists (CSTE) (Doc. #1770, SBC-044261)

2. Epidemiological Assessments: The proposed new testing standards are expected to necessitate additional epidemiologic assessments to evaluate a variety of health effects. While these epidemiological assessments will result in a better understanding of population exposure levels and serum concentrations and the results would help inform prioritization of high-risk groups and outreach efforts it is anticipated that epidemiological programs will require additional resources to assess potential health impacts of PFAS at the proposed levels, and especially for several PFAS which have not yet been researched thoroughly for their impact on health. As discussed in the rule, epidemiological studies on the impact of the proposed MCLs on varying ethnic groups and disadvantaged communities will also be necessary. Public health agencies will need dedicated resources to support analytic requests and CSTE recommends support for responding to underserved or resourced areas. CSTE supports development of guidelines, similar to the development of the cancer cluster guidelines to respond to the increase in requests for a wide range of epidemiologic assessments to assess health effects.

3. Risk Communication Needs: Given the magnitude and scope of proposed changes it is anticipated risk communication materials will be needed to inform various audiences such as the general public, clinicians, business, community groups, water operators, and private well owners. Risk Communication materials are needed for the general public on the Hazardous Index. Consistent public messaging for when PFAS levels are slightly above the MCL, communication to health care providers to promote awareness, communication for health care providers on how to counsel their patients, communication packages that can assist water companies, as well as communication materials for private well owners are anticipated. Further, public health agencies are expected to need to consult on what actions will need to be taken by consumers, especially as testing results will likely change over time. It is anticipated private companies may offer testing and having clear recommendations on the effectiveness of testing practices as well as effective

remediation actions and the length of time necessary for improvements will be part of what public health agencies will be asked to consult on.

EPA Response: Regarding risk communication, please see section 1.2 of the EPA response in this *Response to Comments* document. While beyond the scope of this rulemaking, the EPA acknowledges the commenter's statements on the importance of additional epidemiological programs and research to evaluate a variety of health effects from PFAS. In response to the commenter's mention of "epidemiological studies on the impact of the proposed MCLs on varying ethnic groups and disadvantaged communities", the agency notes as part of its EJ analysis for the final rule, the EPA conducted a literature review that includes discussion of available literature that identify demographic disparities in adverse health outcomes. For more information, including the findings and limitations of these studies, please see Section 8.2 of the EA.

Council of State and Territorial Epidemiologists (CSTE) (Doc. #1770, SBC-044258)

Public Health Agencies (PHAs) across the U.S. face many challenges in their efforts to collect and provide complete, timely and accurate information for decision- making, and in communicating the risks and response to communities related to PFAS, PFOA and PFOS. The availability of feasible, effective guidelines to regulate PFAS levels in drinking water is crucial to assisting PHAs with reducing PFAS pollution, protecting public health, and delivering safe drinking water.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Bailey Smith (Doc. #1787, SBC-045810)

B. How Water Systems Can Communicate EPA's Science to the Public

EPA seeks comment on how water systems can effectively communication information about the EPA's proposed rule to the public. [FN16: Proposed Rule, supra note 3 at 18731.]

A study from the PEW Research Center indicates that eight in ten Americans receive their news from digital devices. [FN17: Elisa Shearer, More than eight-in-ten Americans get news from digital devices, PEWRESEARCH.ORG (Jan. 12, 2021), https://www.pewresearch.org/short-reads/2021/01/12/more-than-eight-in-ten-americans-get-news-from-digital-devices/.] More specifically, most Americans get their news from news websites or apps. [FN18: Id.] The second most common method of news consumption is through search engines, and the third most common is by social media. [FN19: Id.] As such, one option that public water systems ("PWS") can explore in communicating information about EPA's proposed rule (and its subsequent impacts on the PWS) to the public is to engage with local news outlets who publish their news on smartphone applications. Because this is the most common method of news consumption among American adults,[FN20:Id.] this may be the best way to reach a widespread audience.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Fairfax Water (Doc. #1789, SBC-045297)

Utilities rely on EPA to be able to effectively communicate the rationale and health implications of drinking water rules since EPA is the entity that undertakes the scientific analysis. This information should be easy for the public to understand and address the risk of PFAS in drinking water relative to other exposure routes such as food and consumer products. EPA should provide water utilities with communication materials, including factsheets and text for use on websites, Consumer Confidence Reports, and Frequently Asked Questions that explain the health risks from PFAS in drinking water relative to other exposure routes.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Fairfax Water (Doc. #1789, SBC-045317)

7. Utilities need a comprehensive understanding of EPA's proposed regulatory framework for PFAS from drinking water sources of supply to water treatment plant residuals in order to make cost effective decisions and reduce rate impacts to our customers.

Fairfax Water appreciates the opportunity to comment on EPA's proposed PFAS National Primary Drinking Water Regulations. Please let me know ifwe can provide any additional information or share our utility operating expertise to inform improvements to the proposed rule with the goal of ensuring its successful implementation.

Sincerely,

Jamie Bain Hedges,

P.E. General Manager

Attachment: Illustrative Schedule to Implement PFAS Treatment

cc: Senator Mark Warner Senator Tim Kaine

Representative Gerry Connolly

Representative Don Beyer

Representative Jennifer Wexton

[Attachment 1: see docket ID EPA-HQ-OW-2022-0114-1789]

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Safe Drinking Water Branch, Hawaii Department of Hawaii (Doc. #1801, SBC-043756)

Other PFAS Contaminants and the Health Language

As more than 14,000 PFAS contaminants have been found in the environment and 29 PFASs are under study in UCMR5, can EPA provide more thoroughly health language? It will provide the state agency, and water purveyors a valid and authoritative source to address the detection of PFASs in press release and CCR. Furthermore, it will avoid the confusion among the public.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. Please see section 9.1 of the EPA response in this *Response to Comments* document for discussion of the CCR.

Millie Garcia-Serrano (Doc. #1803, SBC-044288)

4. Risk Communication: The proposed MCLGs are higher than EPA's 2022 Lifetime Health Advisories for the same PFAS contaminants. The proposed MCLGs are also considerably lower than the previous 2016 Health Advisory (still currently used as an action level by the Department of Defense), the May 2023 Regional Screening Levels (RSLs) used in the CERCLA program, and most of the drinking water standards promulgated by States. As such, we are extremely concerned about how to approach health risk communication with the public and stakeholders. ASTSWMO members face continual risk communication challenges, as they attempt to explain the myriad of different risk-based standards employed in different contexts to constituents who are justifiably concerned about PFAS concentrations in their drinking water. ASTSWMO requests a greater degree of consistency between the values issued by different offices of the EPA and more straightforward risk communication guidance. While this proposed drinking water rulemaking is extremely important to further the goal of regulating PFAS at a federal level, ASTSWMO recognizes that other regulatory programs (e.g., CERCLA, RCRA), and their respective decisions, rely on the science used to derive drinking water standards. ASTSWMO strongly urges more coordination across all EPA programs, particularly when developing other health-based standards in the future (e.g., soil, air).

EPA Response: Please see the EPA response to comment Doc. #1583, SBC-042400 in section 1.2 in this *Response to Comments* document.

Millie Garcia-Serrano (Doc. #1803, SBC-044294)

Finally, ASTSWMO recommends the development of guidance documents and training following the promulgation of the PFAS NPDWR, and to the extent possible, requests that some of the training modules provide a crosswalk between the SDWA rule and CERCLA and RCRA programs managed by our membership.

ASTSWMO appreciates EPA's efforts to address PFAS contamination through this rulemaking and looks forward to participating in the continuing development of an effective national

regulatory framework for PFAS contaminants in the environment. If you have any questions about these comments, please contact me at millie.garcia-serrano@mass.gov or (508) 946-2727.

Sincerely,

Millie Garcia-Serrano (MA)

ASTSWMO President

cc: Dania Rodriguez, ASTSWMO

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. Although out of scope of this rulemaking, for additional discussion on possible future regulatory actions through CERCLA and RCRA, please see section 10.4.2 of the EPA response in this *Response to Comments* document.

National Ground Water Association (NGWA) (Doc. #1804, SBC-045457)

EPA should support an education and outreach effort to assure proper sampling techniques are followed. Consideration of strategic partnerships with approved water-related groups such as NGWA, will help facilitate the timeline and efficacy of the education.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

National Ground Water Association (NGWA) (Doc. #1804, SBC-045463)

Communication - Technical and risk communication to water supply customers will be critical. Since PFAS is widely reported in the media, clear, specific information that tells the public how to respond is important, rather than to report that it is found and is a potential problem. Clearly communicating when a problem is more likely is more useful.

In cases of small water systems and private well owners, the best relationships may be between water contractors and their customers rather than regulatory agencies and small and private system consumers. EPA should focus on what information water contractors could usefully communicate to their customers regarding PFAS and meeting health protective requirements. A significant education and outreach program to reach water consumers in meaningful ways should be implemented.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Florida Rural Water Association (FRWA) (Doc. #1806, SBC-044699)

Messaging to customers needs to be careful not to scare the public and lose confidence in drinking water and driving them to alternatives to public supply that are much more costly and often not as regulated.

Another concern with the promulgation of this proposed PFAS regulation is that it is not accompanied by guidance regarding public messaging.

For these reasons, on behalf of Florida's drinking water systems, we urge you to carefully consider the economic and social impacts of federal PFAS regulation. Thank you for considering these comments.

EPA Response: Regarding risk communication and guidance, please see section 1.2 of the EPA response in this *Response to Comments* document. Please see section 13 of the EPA response in this *Response to Comments* document for discussion of economic impacts. Regarding the social impacts of the NPDWR, the EPA anticipates that once implemented, the regulation will improve drinking water quality and ultimately improve public confidence in the safety of their drinking water.

Wisconsin Department of Health Services (Doc. #1823, SBC-044282)

Transparent, prompt communication about contaminant levels can build confidence in drinking water and reduce risk to human health. There is significant community and media interest in PFAS, and there is widespread contamination at low levels throughout the environment: 34% of public water systems that participated in a recent voluntary sampling project in Wisconsin had detectable levels of any of the six PFAS with proposed MCLs. Prompt, responsive, and thoughtful risk communication can provide people with the information they need to make decisions while avoiding the risk of creating undue concern by leading people to think information has been hidden from them.

We look forward to continued dialogue and engagement between EPA and the states about these important steps to protect public health from unsafe exposures to PFAS in drinking water. We are encouraged by action taken to date and expect that a continued emphasis on protecting those at greatest risk will be valuable. If you have questions or would like to discuss these comments further, please contact me at mark.werner@dhs.wisconsin.gov or 608-264-9880.

Sincerely,

Mark A. Werner, PhD

Director, Bureau of Environmental and Occupational Health

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

New England Water Works Association (Doc. #1836, SBC-045393)

It is imperative that EPA immediately develop an appropriate communication strategy so that water suppliers are not left on their own to individually figure out how to handle risk communication. Thus far, there have been many questions raised by residents at public forums in the communities grappling with PFAS contamination, especially about potential impacts to health, with very few direct answers available from primacy and health agencies. EPA must be better prepared to answer questions and address mounting fears of residents, and to assist PWS which are often the first responders to questions from their customers. We also believe that there needs to be more communication by EPA to consumers regarding the other routes of exposure; it does a disservice to the public if the EPA and the states focus on drinking water to the exclusion of other, perhaps more significant PFAS contributions to one's body burden (e.g., consumer products, food). EPA must consult with risk communication professionals to develop the messaging as the materials EPA has made available thus far are not particularly helpful.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Citizens Energy Group (Doc. #1838, SBC-044869)

Section X – Safe Drinking Water Right to Know

EPA requests comment on what may be needed for water systems to effectively communicate information about the PFAS NPDWR to the public.

Community water systems are not the experts in the health effects of PFAS compounds, nor in the toxicity of individual compounds or the mixtures seen in the environment, or on the potential sources of PFAS in the environment. Ensuring that water systems and the state and tribal agencies have communication messages and tools from the EPA will help ensure consistent communication across the U.S.

EPA Response: Regarding communication and tools, please see section 1.2 of the EPA response in this *Response to Comments* document.

Alexa Sofia Mendoza (Doc. #1966, SBC-046307)

We as the people have a right to know about the things that are put in our water. Water is important for all forms of life. Having these things reported and known to the public will make people reduce the hazardous amounts of these PFAS in our drinking water. *especially HFPO-DA (commonly referred to as GenX Chemicals* That can even have hazardous levels for us to drink. This would limit the number of deaths and can also reduce many of these water borne illnesses! As a young person I would like to be notified of the things in my water, and I want the population to know when these levels get out of hand and to force the govenemernment and

other compaines to make a change if the population knows about these awful levels of chemicals in our water, FORCE THEM TO CHANGE THESE LEVELS BY TELLING US THE TRUTH!

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Tor Olsson (Doc. #3041, SBC-047329)

We must also focus on education and publicity as well. People should know what they are being exposed to, and the potential acute or chronic effects that can come from these chemicals. If people understood the full scale of the consequences of PFAS exposure, it could potentially lead to them becoming more involved in the policy process if they knew how it could affect them. We can no longer let profits get in the way of our lives. The time for regulation is now.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Kimley Horn & Associates (Doc. #3072-23, SBC-046352)

Hi, this is Tanya Miro, and I work actually as a consultant with municipalities in the water and wastewater industry. And as this, I think it's great that we're finally looking at these chemicals in our water. However, as I'm working with municipalities, there is strong and great concern in regard to how they are going to manage public outreach, and the perception that they are the ones who have contaminated their water. How do we put programs in place to mitigate their industrial users is also a strong concern. As they're coming to us, we are collaborating with our water boards and TCEQ just to get feedback in regard to how we're going to manage the efforts of these new regulations and policies and be able to manage things with the lack of resources within all of the organizations. So, recognizing that this is going to overload our labs, and also put a strong restraint on our municipal operations teams, really we are looking to see what kind of programs are going to be provided from EPA to help enhance those elements, and educate both the public and operations for water operations how they need to mitigate and manage this element. Really, I'm glad that we've finally started looking at these chemicals, but it is going to really call for a holistic view between water and wastewater, as well as all of the lab services and other industrial users. So really, coming at this with a holistic approach, and feel like EPA needs to help with putting some guidelines in place that will really help to bring that kind of circular concept in place, so that PFAS can be addressed in all areas, not just one.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Gina Hara (Doc. #3072-69, SBC-046383)

Hello, my name is Gina Hara. I'm from Oahu, Hawaii. My background is that for the past eight years I have been going to every single meeting regarding the Red Hill oil spill. Actually, there's

so many oil spills, but it's 27,000 initial gallons in 2014 and a total of, by the time 2021, maybe 180,000 gallons. More than ever though, we are more afraid now of the PFAS that we found out is in the water aquifer and the water that we drink here is with your new standard. Actually, it makes ours dangerous and we didn't know. We didn't know we had been drinking that and it was only in 2021 that we were notified. So, what I want to suggest is that one, you need to stop the flow of PFAS, so we need to stop the PFAS from even being produced. I think that the EPA needs to clarify your verbiage to the state departments because they are testing for PFAS, but then they say it doesn't match your MCL description, so then they are unable to tell us that it's safe or not. So there needs to be coordination on all these forever chemicals. And secondly, I would like to suggest that the remediation we also encouraged in terms of bioremediation, that is multifaceted. That means using indigenous microbes that have been attenuated with the PFAS eating microbes. This is based on Korean natural farming practices where with indigenous microbes you can make friends with those that eat either oil or those that eat PFAS. This would rapidly help solve everybody's problems as every single military base seems to have been contaminated, at least their aquifer has. Thank you for your time and allowing me to speak.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. In response to the commentor's request to "stop the flow of PFAS," please see section 15 of the EPA response in this *Response to Comments* document, which discusses the EPA's efforts under the PFAS Strategic Roadmap to address PFAS with a whole-of-agency approach. Please see this same section for topics outside the scope of the final NPDWR, including non-drinking water sources of PFAS and bioremediation. The EPA acknowledges the commenter's suggestion on bioremediation. The EPA notes that the agency and others are researching the potential of different destruction technologies for PFAS, including bioremediation.

Citizens Campaign for the Environment (Doc. #3072-64, SBC-047394)

Also, we recommend EPA be prepared with accurate educational information to assist communities and water suppliers that are exceeding MCLs. We've seen here in New York State that many water suppliers don't have the knowledge or capacity to effectively communicate these risks to the public.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document.

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-042892)

We want to caution EPA that any required educational statements must have clear and appropriate messaging. MWWA believes EPA must revisit its proposed required Standard Health Language for Public Notice, as it is not well written, nor easily understood by the lay person. While by no means perfect, MassDEP's language is more easily understood than EPAs: "Some people who drink water containing these PFAS in excess of the MCL may experience

certain adverse effects. These could include effects on the liver, blood, immune system, thyroid, and fetal development. These PFAS may also elevate the risk of certain cancers."

In Massachusetts, the notices MassDEP requires suggest that consumers in sensitive populations use alternative sources of water, yet there is very little guidance given as to what alternatives are guaranteed to be "PFAS-free." The guidance on MassDEP's own website regarding Point of Use filters states "Treatment systems and devices are not specifically designed to meet Massachusetts' drinking water standard for PFAS6. There are systems that have been designed to reduce the sum of PFOS and PFOA to below EPA's former Health Advisory of 70 ng/L. Any treatment device you use should be certified to meet the National Sanitation Foundation (NSF) standards to remove PFOS and PFOA compounds so that the sum of their concentrations is below 70 ng/L. Please be aware that 70 ng/L is significantly greater than the MassDEP's drinking water standard of 20 ng/L for the PFAS6 compounds. Many of these treatment devices certified to meet NSF standards will likely be able to reduce PFAS6 levels to well below 70 ng/L, but there are no federal or state testing requirements for these treatment devices. If you choose to install a treatment device, you should check to see if the manufacturer has independently verifiable PFAS6 monitoring results demonstrating that the device can reduce PFAS below 20 ng/L." It is very confusing for the public to be instructed to seek alternative supplies, yet not be provided with definitive information on what those alternatives are. EPA should concurrently encourage NSF to begin a process to certify Point of Use filters for PFAS removal to the levels of the proposed MCL if EPA is going to suggest this approach as an alternative. The public deserves to have the information necessary to make informed decisions and not be at the mercy of the water filter dealers. Since EPA issued interim Health Advisories for PFOA and PFOS stating that there are health effects at levels thousands of times lower than current lab detection limits, suggesting alternative compounds the problem. No water source (PWS, private well, bottled water) or treatment technology can claim to achieve full protection from health impacts of PFOA and PFOS since laboratories cannot come close to detecting these contaminants anywhere near the purported Health Advisory level.

It is imperative that EPA immediately develop an appropriate communication strategy so that water suppliers are not left to individually figure out how to handle risk communication. Thus far, there have been many questions raised by residents at public forums in the communities in Massachusetts that are grappling with PFAS contamination, especially about potential impacts to health, with very few direct answers from MassDEP and the Massachusetts Department of Public Health available. EPA must be better prepared to answer questions and address mounting fears of residents, and to assist PWS which are often the first responders to questions from their customers. As stated before, MWWA believes that there needs to be more communication by EPA to consumers regarding the other routes of exposure. It is a disservice to the public if the EPA and the states focus on drinking water to the exclusion of other, perhaps more significant PFAS contributions to one's body burden (e.g., consumer products, food). EPA must consult with risk communication professionals to develop the messaging, as the materials EPA has made available thus far are not particularly helpful.

EPA Response: Please see section 1.2 of the EPA response in this *Response to Comments* document. For more information on laboratory considerations, including capacity and capability, as well as practical quantitation limits in setting the MCL, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For information about required education statements and communication, such as the CCR and PN, please see sections 9.1 and 9.2 of the EPA response in this *Response to Comments* document. For discussion on small system compliance technologies, such as point of use (POU) filters, please see section X.D of the FRN and section 10.5 of the EPA response in this *Response to Comments* document. Certification of filters is outside the scope of this rulemaking.

1.3 Other General Information

Summary of Major Public Comments and EPA Responses

This *Response to Comments* document section contains comments which generally support, oppose, or suggest modifications to the EPA's PFAS NPDWR. Comments in support of the NPDWR stress the need for health-protective standards for the nation's drinking water. Many commenters share their stories of PFAS contamination in their houses and communities, describing the experiences of family members, friends, and loved ones and the impact that PFAS contamination has had on their lives. The EPA appreciates this information and agrees with many of the comments that summarize the characteristics of PFAS, their persistence in the environment, their impacts on human health, and the importance of the EPA's role in protecting human health and the environment. As many commenters highlight, the NPDWR will save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. Many commenters support the agency's decision to set the MCLGs at zero and to regulate six PFAS via individual MCLs and/or the Hazard Index for mixtures and view the NPDWR as feasible and justified. Many commenters discuss the amounts of PFAS exposure in drinking water compared to other sources; some highlight that the NPDWR, while only providing protection from one source of exposure, is an important step in improving public health protection.

As described in the EPA's PFAS Strategic Roadmap, the agency is committed to addressing PFAS contamination, including through the development of this final PFAS NPDWR. The science is clear that long-term exposure to certain PFAS, including those proposed for regulation in this action, is linked to significant health risks, and when drinking water is contaminated it can form a significant portion of a person's total PFAS exposure. As the lead federal agency responsible for ensuring safe drinking water for Americans, the EPA is following the process outlined in the SDWA and is regulating PFAS in drinking water as a significant step toward protecting the health of hundreds of millions of people. Again, the EPA anticipates that over many years, this action will save thousands of lives and prevent tens of thousands of serious illnesses that would otherwise result from long-term exposure to PFAS in drinking water. The agency denied requests for extending the comment period to move as swiftly as reasonable to finalize this rule to protect the American people. For additional discussion regarding the timeline

for the comment period, please see sections 2.3 and 17 of the EPA response in this *Response to Comments* document.

Many comments explicitly ask the EPA to keep PFAS and other harmful chemicals out of the drinking water supply. Finalizing this PFAS NPDWR addresses these requests and is a crucial step in ensuring safe drinking water for all Americans. The EPA is doing this by using the best available science for setting health-based standards. Many commenters also stress the need for the EPA to protect the environment, and to protect all waters and communities. The EPA believes this rule will protect the American people directly from potential PFAS exposures that might otherwise occur from PFAS-contaminated drinking water.

Many commenters, while expressing support for the new NPDWR, note that this rule is long overdue and that this rule should just one of numerous actions the agency should take to protect Americans from PFAS. This final PFAS NPDWR achieves one of many key goals for protecting Americans from PFAS. While non-SDWA actions are beyond the scope of this rulemaking, it is important to note that the EPA is initiating other important actions under other statutes to address PFAS in the environment, such as through the RCRA, Toxic Substances Control Act (TSCA), Clean Water Act (CWA), SDWA and CERCLA. For example, under the CWA, the EPA is using the National Pollutant Discharge Elimination System (NPDES) program to protect against PFAS through point source discharges; under TSCA, data on PFAS manufactured and used in the United States must be reported to the EPA to better understand the PFAS lifecycle; and under CERCLA, in 2022 the EPA issued a proposal to designate two of the most widely used PFAS as hazardous substances. Tackling and reducing PFAS contamination continues to be a significant priority for the EPA. The EPA continues to work with its federal, state, and Tribal regulatory partners to protect human health and the environment by ensuring that the regulated community complies with environmental laws and regulations. To learn more about these important actions, please see the summary of the EPA's PFAS Strategic Roadmap in section II.F of the preamble for this regulation, as well as section 15 of the EPA response in this *Response to Comments* document for further discussion on out-of-scope topics.

Some commenters ask the EPA to address additional PFAS in this NPDWR or following promulgation. For discussion as to why the EPA is only regulating six specific PFAS through this final NPDWR, please see section 2.2 of the EPA response in this *Response to Comments* document. For additional discussion on potential future regulation of additional PFAS, please see sections 2.2, 3.1, 4.3.5, and 10.3 of the EPA response in this *Response to Comments* document. Many commenters stress the need to stop PFAS upstream, such as by banning its use in manufacturing processes or addressing discharges and other exposure pathways. Some commenters argue that a "preventive approach" would be more effective and less costly than treating drinking water downstream. While this NPDWR was developed pursuant to the SDWA, which does not generally regulate the use of chemicals in consumer and industrial products or regulate the remediation of contaminated sites, the EPA is taking action under other statutory authorities to reduce PFAS exposure and risk. Please see the previous paragraph discussing the EPA's PFAS Strategic Roadmap for further information.

Some commenters requested that the EPA not only address PFAS contamination, but also reduce contamination from other drinking water contaminants. A few commenters urge EPA to act under the CWA. These topics are outside the scope of the PFAS NPDWR; please see section 15 of the EPA response in this *Response to Comments* document for further discussion. For specific discussion about fluoride as a chemical in drinking water, please see section 10.3 of the EPA response in this *Response to Comments* document. For general concerns about treatment discharges and waste residuals, as well as concerns about water recovery or water reuse applications, please see section 10.4 of the EPA response in this *Response to Comments* document. For discussions of the impacts of climate change and water scarcity as it relates to treatment options, please see the EPA response to comment Doc. #1929, SBC-047449 in section 1.3 in this *Response to Comments* document.

Some commenters stated that while they agreed with establishing the drinking water regulation, they view the rule as insufficient and think more stringent or broader requirements should be established. The EPA disagrees with the view that the rule is insufficient. The EPA has set the MCLGs, MCLs, and other rule requirements consistent with the statutory standards established in the SDWA using best available science. The PFAS NPDWR is an implementable regulation that will significantly improve public health protection.

Some commenters supported the general premise of the rule but provided significant comments for consideration prior to rule finalization. Others opposed the NPDWR in its entirety. Some commenters who opposed the rule argued that EPA failed to comply with legal and procedural requirements to justify the rule, and that the process that the EPA followed is arbitrary, capricious, an abuse of discretion or otherwise not in accordance with the law. Commenters in opposition also asserted that the evidence provided by the EPA cannot be validated and lack merit, and that existing health and occurrence data does not support the preliminary determination to regulate PFNA, PFHxS, PFBS and HFPO-DA both individually and as part of mixture combinations. Some argued that the EPA improperly proposes MCLGs and MCLs for these substances together with the preliminary determination to regulate, that the studies provided show abnormal or inconsistent data, and/or that the occurrence data are not nationally representative. Commenters suggested that the EPA did not comply with the SDWA or agency guidance, including those for good data and statistical analysis practice, consistency for methods and models, and ability to replicate analytical results. Like the comments provided under section 1.1 of this *Response to Comments* document, some comments critical of the EPA's approach argued that the rule is inappropriate, not based on the best available, peer-reviewed, or sound science, is unreasonable and unachievable, is too extreme, reactionary, or may cause unintended harm. Some commenters suggest this NPDWR has excessive negative impacts on small businesses and low income and environmental justice communities.

The EPA disagrees with these comments. As described in section I of the preamble as well as section 1.1 of the EPA response in this *Response to Comments* document, the agency has followed all statutory requirements under the SDWA to promulgate the PFAS NPDWR. The SDWA states that the EPA must evaluate the best available information when making a

regulatory determination and developing an NPDWR. The EPA disagrees with the comments stating that existing health and occurrence data does not support the proposed determination to individually regulate PFHxS, PFNA, HFPO-DA and to regulate mixtures of these three PFAS and PFBS. The agency used a health-based approach with the best available science and conducted a robust analysis of PFAS health and occurrence information for the six PFAS included in the regulation, as required under the SDWA. This information provides support for the final determination to individually regulate PFHxS, PFNA, HFPO-DA and to regulate mixtures of these three PFAS and PFBS, as well as the individual NPDWRs for PFHxS, PFNA, HFPO-DA, PFOS and PFOA, and the NPDWR for mixtures of PFHxS, PFNA, HFPO-DA, and PFBS. Please see section III.B and IV of the final rule preamble and sections 3.1.1, 3.2.1, and 4 of the EPA response in this *Response to Comments* document for discussion and documentation of the EPA's evaluation of existing health information. Taking public comment into consideration, the EPA updated sampling information to evaluate PFAS occurrence in drinking water and has included updated information in its occurrence analyses. Please see sections III.C and VI of the FRN, sections 3.1.2, 3.2.2, and 6 of the EPA response in this *Response to Comments* document, as well as the *Occurrence Technical Support Document* (USEPA, 2024g), for thorough discussion of the occurrence evaluations to support this rulemaking. The EPA disagrees that the agency did not use appropriate data and statistical analyses to support the development of this NPDWR. As discussed throughout this *Response to Comments* document and multiple technical support documents, the agency provided robust quality assurance (QA) of data, used commonly accepted statistical methods, and used robust and comprehensive datasets. For example, see discussion on the use of state occurrence data in sections 3.1.2, 3.2.2, and 6.2 of the EPA response in this *Response to Comments* document, discussion of the national statistical occurrence model in section 6.5 of the EPA response in this *Response to Comments* document, or the physiologically-based pharmacokinetic (PBPK) model in section 4.2.4 of the EPA response in this *Response to Comments* document. Please see the EPA responses to the following comments in this section for additional defense of the methods used for setting an MCLG and MCL, health effects evidence for setting the MCLGs, evidence of toxicity for these six PFAS, all in support of the MCLGs and MCLs outlined in this NPDWR: Doc. #2324, SBC-046269; Doc. #2589, SBC-047310; Doc. #2946, SBC-046559; Doc. #1873, SBC-046592. For additional responses regarding the use of UCMR 5 for the occurrence model, as well as other questions about the Hazard Index and health assessments, please see the EPA response to comment Doc. #1714, SBC-045945 in section 1.3 in this *Response to Comments* document.

Some commenters highlight components of the rule that they believe are confusing and will make the rule difficult to implement. Most comments opposed to the rule request that the EPA withdraw the NPDWR or not regulate these six PFAS at this time. For discussion about how EPA is communicating about this rule to help clarify and facilitate implementation, please see section 1.2 of the EPA response in this *Response to Comments* document. The EPA disagrees that the rule will be difficult to implement, as it has clear MCL values (see section V of the preamble), clear monitoring requirements (see section VIII of the preamble), and a clear path forward to compliance like other NPDWRs. Furthermore, the EPA disagrees with the request to

withdraw this NPDWR. This is because, among other things, as discussed in sections III, IV, and XIII of the preamble, PFAS are harmful and have a significant public health impact; moreover, PFOA and PFOS have already been determined to meet the statutory criteria for regulation and the EPA is making a determination in this action that PFHxS, PFNA, HFPO-DA, and PFBS (and their mixtures) also meet that same statutory criteria (as described in section III of the FRN). Given they meet the statutory requirements, it is the EPA's obligation to move forward with developing an NPDWR. As discussed in section V of the preamble, the EPA has identified a feasible MCL that can significantly reduce the public health risk, and as discussed in section XIII of the preamble, the Administrator has reaffirmed his determination from the proposed PFAS NPDWR that the costs of the rule are justified by the benefits.

Some commenters ask the EPA to comprehensively evaluate the implementation challenges of this rule, and a few suggested the agency needs more time to do so. The EPA disagrees with delaying the official promulgation of the NPDWR for the reasons noted earlier in this *Response to Comment* and because it has already undertaken a robust process to consider implementation challenges. Through the regulatory development process, the EPA has considered all factors and comments in establishing the final NPDWRs consistent with the SDWA, including implementation concerns. The EPA plans to develop and disseminate materials that will support the needs of water systems and primacy agencies associated with rule implementation, as well as public education. To aid in planning and developing materials to support implementation of the final rule, the EPA has consolidated suggestions for topics and considerations to include in guidance, training, and tools, including suggestions communicated in public comments, in relevant *Response to Comments* document section. For discussion of considerations related to Consumer Confidence Reports and public notifications regarding detections of PFAS, see section 9 of the EPA response in this *Response to Comments* document. As noted there and in section 1.2 of the EPA response in this *Response to Comments* document, the agency intends to produce communications materials related to risks related to PFAS in drinking water that can be used by utilities and others as they deem appropriate. For discussion of potential implementation concerns with laboratory and sampling methods, monitoring, and compliance, please see section 8 of the EPA response in this *Response to Comments* document. For a discussion of laboratory availability and capability, see section 5.1.2 of the EPA response in this *Response to Comments* document. For discussion of potential implementation concerns related to treatment technologies and waste disposal, please see section 10 of the EPA response in this *Response to Comments* document. For further discussion of rule implementation considerations (primarily for primacy agencies) and enforcement, please see section 11 of the EPA response in this *Response to Comments* document; for example, section 11.2 of the EPA response in this *Response to Comments* document addresses potential data management considerations. Finally, in addition to developing and disseminating materials referenced above, the EPA is offering an unprecedented amount of funding and WaterTA, in close collaboration with states, to support communities, small systems, and others, including to address PFAS and other emerging contaminants, identify water challenges and solutions, build capacity, and develop application materials to access water infrastructure funding. The EPA's WaterTA efforts are focused on disadvantaged and

underserved communities, communities that have never accessed State Revolving Fund (SRF) funding before, and communities that are not currently receiving an equivalent kind of technical assistance. Please see further discussion in section II.E of the preamble to the final rule and section 2.4 of the EPA response in this *Response to Comments* document.

A few opposing commenters say the rule puts too much burden onto the water industry, with what they describe as both aggressive MCLs and harsh timelines. Some noted that public utilities are already working to characterize and reduce PFAS levels in finished drinking water, wastewater, and stormwater, including rebalancing water sources to reduce PFAS levels, working with upstream dischargers to reduce their loadings, and evaluating available technologies should PFAS barrier technology become necessary. The EPA acknowledges and appreciates existing efforts utilities are making to reduce PFAS levels in drinking water, wastewater, and stormwater. These efforts do not obviate the EPA's statutory obligations to regulate PFAS. Moreover, the EPA disagrees that the MCLs are aggressive, as the EPA has followed the process and requirements outlined in the SDWA and found them to be feasible, taking cost into consideration. Regarding the implementation timelines, based on public comment, the EPA extended the compliance timeline by two years to allow for capital improvements (see discussion below and in section XI.D of the FRN and section 12 of this *Response to Comments* document). The EPA also disagrees that this rule puts too much burden on the water industry. First, the EPA has conducted a robust national level cost analysis using the best available data and considering all public comments received on the proposed rule. For more information, see sections 13.3 of the EPA response in this *Response to Comments* document and Chapter 5 of the Economic Analysis (USEPA, 2024a) for a detailed description of the EPA's cost analysis. Additionally, the EPA determined that there are several affordable treatment technologies for small systems; for more information on this determination, see Chapter 9.13 of the Economic Analysis (USEPA, 2024a). Second, while this regulatory action is important for protecting public health from PFAS contaminated drinking water, as previously described, this NPDWR is just one key goal within the EPA's PFAS Strategic Roadmap for addressing PFAS from all sources. Other actions will reduce PFAS in the environment, which over time, may reduce PFAS in source water (thereby reducing treatment needs in the long-term). This NPDWR will directly protect the American people every day from PFAS exposures that might otherwise occur from PFAS-contaminated drinking water in the short to medium term. While all actions not included in this final NPDWR are beyond the scope of this regulatory action, the finalization of the NPDWR action complements many other actions in the PFAS Strategic Roadmap to protect public health and the environment from PFAS.

Some comments suggest that the EPA must consider the cost impacts, sampling detection, and disposal challenges prior to finalization. The EPA has considered these factors. As discussed in section 13 of the EPA response in this *Response to Comments* document, the EPA has considered cost impacts. As discussed in sections 5.1.2 and 7 of the EPA response in this *Response to Comments* document, the EPA has considered analytical detection and quantitation issues, among other topics related to analytical methods and monitoring. As discussed in sections 10 and

13 of the EPA response in this *Response to Comments* document, the EPA has considered media disposal as part of this regulation.

Many comments opposing the NPDWR express concerns about the general cost burden of the NPDWR. These commenters are concerned that it imposes high costs on utilities and that the rule is not economically feasible or achievable. Some commenters also express concerns that the rule will have the most significant cost impacts on already overburdened communities and on what commenters consider higher-risk water systems. Some commenters ask who will pay for the implementation and clean-up of the PFAS, suggesting that PFAS manufacturers and those discharging into our waters should pay for removing PFAS. Some commenters state they are concerned that all costs will fall on water utilities and/or rate paying customers, especially those in low-income or overburdened communities. The EPA acknowledges that the final NPDWR will have costs associated with implementation, and after consideration of all public comments on the proposal, the EPA is reaffirming the Administrator's determination at proposal that the quantified and nonquantifiable benefits of the PFAS NPDWR justify the quantified and nonquantifiable costs. As discussed in sections 13 and 14.10 of the EPA response in this *Response to Comments* document, the EPA has thoroughly evaluated the costs, benefits, and affordability of the rule, as well as its impacts on disadvantaged communities. These analyses demonstrate that while the rule will increase costs for impacted communities, there are several affordable treatment technologies that will allow small systems to comply with the rule. In addition, disadvantaged communities will also realize significant benefits of reduced illness and deaths. Please see section 13 of the EPA response in this *Response to Comments* document for further discussion of the EPA's benefit and cost analysis, section 10.4 for more information on handling PFAS laden treatment residuals, and section 10.4.2 for more information on the potential future regulatory actions involving RCRA. For more information on the HRRCA itself, please see section XII of the FRN and the Economic Analysis (USEPA, 2024a) supporting document. For a specific response regarding concerns to small businesses, low-income or environmental justice communities, please see the EPA response to comment Doc. #1644, SBC-043423 in this section of this *Response to Comments* document.

To help communities on the frontlines of PFAS contamination, federal funding is available to support water utilities via the Infrastructure Investment and Jobs Act (IIJA), also referred to as BIL. BIL invests over $11.7 billion in the Drinking Water State Revolving Fund (DWSRF) General Supplemental; $4 billion to the Drinking Water SRF for Emerging Contaminants; and $5 billion in grants to the Emerging Contaminants in Small or Disadvantaged Communities. These funds will assist many disadvantaged communities, small systems, and others with the costs of treatment installation when it might otherwise be cost-challenging. Discussion about this can be found in section 2.4 of the EPA response in this *Response to Comments* document.

Some commenters explicitly outline challenges of what they describe as the very low MCLs. As discussed in section 5 of the EPA response in this *Response to Comments* document, the EPA has found the MCLs to be feasible, consistent with the SDWA. Some commenters state the proposed MCLs are not based on reliable data, and for this reason ask the EPA to consider

further analyses prior to finalization. The EPA disagrees that the MCLs are not based on reliable data. The EPA's final rule represents data-driven drinking water standards that are based on the best available science and meet the requirements of the SDWA. The agency has provided adequate data and evidence of PFAS toxicity and public health risks in the Toxicity Assessments supporting documents (USEPA, 2024c; USEPA, 2024d), as well as the PFOA, PFOS, and Hazard Index MCLG supporting documents (USEPA, 2024e; USEPA, 2024f). The EPA has also outlined its methodology for setting the MCLs, consistent with the SDWA, in section V of the FRN. Additional discussion on determining the MCLs is included in section 5 of the EPA response in this *Response to Comments* document. As discussed in sections III, IV, V, VI, X, and XIII of this preamble, the EPA has a high degree of confidence in its health, occurrence, cost, benefit, and engineering analyses, among other analyses. All these analyses included significant Quality Assurance of data when collecting and analyzing datasets. See sections 3.1.2, 3.2.2, 4.1.2, 6.2, 13.1, and 13.3.3 of the EPA response in this *Response to Comments* document for further discussion. Please see the EPA response to comments Doc. #1713, SBC-045926 and Doc. #1714, SBC-045945 in section 1.3 in this *Response to Comments* document for the EPA's response to the following critiques of the NPDWR as a whole: allegations that steps were skipped during the SDWA NPDWR development process, the EPA lacks evidence to warrant regulatory determinations of four PFAS in mixtures (PFHxS, PFNA, HFPO-DA, and PFBS) and three PFAS individually (PFHxS, PFNA, and HFPO-DA), that the EPA should abandon the Hazard Index, the EPA should wait until UCMR 5 is complete, that the PFOA and PFOS MCLs of 4.0 ppt are not justified, analytical detection reliability and reduced monitoring rule trigger levels are flawed, the rule's cost and benefits analysis is flawed, that the NPDWR should be postponed until the EPA updates and releases its *Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances*, and that the EPA must finalize its toxicity assessments, health advisories, and reference doses prior to promulgation of the MCLs for three PFAS (PFHxS, PFNA, and HFPO-DA).

Some commenters expressed concern over the compliance timeline of this NPDWR and contended that limited time would impede implementation. Based on public comments, the EPA is exercising its authority under SDWA 1412(b)(10) to implement a two-year nationwide capital improvement extension to comply with the MCL. For additional discussion on the extensions and exemptions, please see section XII of the FRN and section 12 of the EPA response in this *Response to Comments* document.

Lastly, some commenters questioned the EPA's authority or ability to regulate any contaminants, or expressed distrust in the agency generally, Congress, or the current administrative branch of government. These comments are out of scope. Please see section 15 of the EPA response in this *Response to Comments* document for responses to these out of scope comments.

Brian Hackman (Doc. #1539, SBC-042898)

USEPA has not done the level, or quality, of studies required to eliminate the potential that the PFAS compounds proposed for regulation could initiate a synergistic hormesis effect that could be a benefit to people. Given the recent development of the testing methods to measure at 4 ppt concentrations, USEPA is assuming all PFAS is bad without true epidemiological data, using the National Institutes of Health gold standard methods to verify the reported dated in USEPA's initial determination.

EPA Response: The EPA disagrees with the commenter: the agency has conducted extensive analyses demonstrating that the rule will produce significant human health benefits. See section XII of the preamble of this action for discussion of benefits. The EPA is not aware of any data that support the commenter's hypothesis that PFAS can initiate a synergistic hormesis effect which would benefit people, and the commenter does not provide any scientific studies to support this claim. In fact, the EPA has demonstrated that PFOA and PFOS are dose additive (Conley et al., 2022; USEPA, 2024h) and the SAB PFAS review panel supported the assumption of dose additivity for PFAS (USEPA, 2022). Additionally, the EPA is regulating six PFAS at this time; not all PFAS. This NPDWR covers six PFAS that all have assessments showing and quantifying adverse effects resulting from exposure. For PFOA and PFOS, many of those quantified adverse effects are from epidemiological data (USEPA, 2024c; USEPA, 2024d). See section IV of the preamble of this action for why the EPA set the PFOA and PFOS MCLs at 4.0 ppt. The EPA did not set the MCLs for the other four regulated PFAS (or all PFAS) at 4.0 ppt. No citations are provided on what is the National Institutes of Health gold standard method. For additional information on the MCLGs, please see section IV of the FRN and section 4 of the *Response to Comments* document.

Sophia Milone (Doc. #1487, SBC-042703)

This proposed rule would take steps in the right direction by establishing the National Primary Drinking Water Regulation and Maximum Contaminant Level Goals. Because there is no safe exposure to PFAS or other similar chemicals, it is appropriate that the safe levels are set to zero so that ensure that drinking water, bottled water, and groundwater are safe for human and animal consumption.

EPA Response: The EPA acknowledges and appreciates this comment in support of the proposed NPDWR and the MCLG. Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA does not have the authority to directly regulate bottled water: bottled water is regulated by the Food and Drug Administration. Please see section 1.4 of the EPA response in the *Response to Comments* document for more information concerning bottled water.

Anonymous (Doc. #1506, SBC-042574)

PFAS are perfluoroalkyl/polyfluoroalkyl substances used for manufacturing purposes in consumer products (EPA). They exist for a long duration of time due to their inability to decompose in the environment (EPA). Meaning, these chemicals build up in our bodies and ecosystems over time (EPA). More specifically, they weaken immune systems, increase risk of cancers, cause liver damage, and elevate cholesterol levels (EPA). This is especially true for pregnant women, babies, and poor individuals who may not be able to afford clean water. PFAS are ingested through drinking water, making the sanitation and filtration of water highly important (CDC, 2022). With EPA's new proposed rule alone, we would see improvements in many different health sectors (EPA). However, we would argue that these drinking regulations are still not enough.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. The EPA agrees with the commenter that PFAS have adverse health effects. The EPA disagrees with the commenter that the "rules are not enough". The EPA has set the MCLGs, MCLs, and other rule requirements consistent with the statutory standards established in the SDWA. Please see section 1.3 of the EPA response in this *Response to Comments* document for further discussion.

Liliana Salcido (Doc. #1509, SBC-042583)

The regulation the EPA is proposing will help further research. For now, focusing on these six specific PFAS (PFOA, PFOS, GenX, PFBS, PFNA and PFHxS) is a good approach for two reasons: 1) they are the most researched PFAS and we know their danger to the human population, and 2) this regulation will also lead to the regulation of over 29 different PFAS in water (Amarelo, 2023).

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Liliana Salcido (Doc. #1509, SBC-042581)

"Forever Chemicals" Water Regulation

To whom it may concern,

The EPA's new rule on regulating six specific PFAS would significantly improve the well-being of every single human on Earth. This regulation will be historic and it will pave a path for future regulation and further research on other "forever chemicals" in the U.S and other countries that have subsequently been affected.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kaden Heldt (Doc. #1510, SBC-042591)

The general public obviously has a stake in the outcome of this decision as public health is at harm, but also, chemical companies and manufacturers of anything with PFASs in them certainly have a stake in this outcome as well because it will affect the chemicals they can produce and put in products, potentially decreasing profits. There is also a chance that some of these companies are held responsible for damages. Options for acting are few, however, advocacy and using PFAS free products are the best options to help the overall cause. These new regulations are helpful. Undoubtedly. However, they are extremely lacking in scope. Not everything is known about PFASs, sure, however we do know that some of them are harmful and that an educated guess can be made on many others, not just the six being regulated. The government and those creating these regulations must take into account the greater good of public health and the potential dangers of harmful chemicals.

A challenge that I had while working through these steps was finding solid information because not very much is known about these chemicals other than the simple fact that they are dangerous. These steps were very insightful for my thought and research process overall however, and it was a very useful experience. My decision was different from what I thought it would be going into the assignment. I thought that the EPA had made a good and final decision, but I was incorrect in that assumption. The EPA could use some updates to their decisions in order to properly protect citizens from the dangers of PFASs. Recommendations could possibly be implemented with care and attention to the concerns of all stakeholders, however, there is a chance that some stakeholders could be to blame. Chemical companies and companies who manufacture products with PFASs could potentially be at fault for harming and endangering citizens. If that is the case, then I don't think their wants should entirely be taken into consideration.

Citations

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Press, The Associated. "EPA Warns That Even Tiny Amounts of Chemicals Found in Drinking Water Pose Risks." NPR, NPR, 15 June 2022, https://www.npr.org/2022/06/15/1105222327/epa-drinking-water-chemicals-pfas-pfoa-pfos.

Underferth, Danielle. "Understanding the EPA's Proposed Regulations of 'Forever Chemicals' in Water Systems." The Hub, 21 Mar. 2023, https://hub.jhu.edu/2023/03/21/epa-regulationsforever-chemicals/.

Agency for Toxic Substances and Disease Registry. "Potential Health Effects of Pfas Chemicals." Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 1 Nov. 2022, https://www.atsdr.cdc.gov/pfas/health-effects/index.html.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kaden Heldt (Doc. #1510, SBC-042588)

I believe this ruling is a good idea, however, more needs to be done. There are still many questions and concerns surrounding PFASs, many of which cannot yet be answered, but to only ban six of these chemicals is not enough to adequately address the situation. I believe this opinion would be popular among those who are well educated on this topic on concerned for the common goal of protecting public health.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. The EPA disagrees with the commenter that the "rules are not enough". The EPA has set the MCLGs, MCLs, and other rule requirements consistent with the statutory standards established in the SDWA. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jon Raclin (Doc. #1511, SBC-042594)

The groups that have an important stake in the outcome are the citizens of the U.S.. Not only are the common lower middle class working citizens exposed, but also the very high up positions in the government. This is a widespread issue for all people in the country and will presumably turn into a global issue since the science of these forever chemicals is used, as similar products are made and traded across the globe.

The damage to health is the primary concern, and from my perspective understanding this issue, it is also and enviromental conflict as the forever chemicals don't break down, under mother earth's natural causes and climates.

The health and life preservation is the most important, because without a definitive human health, nothing about our loves matter. If we make ourselves subject to diseases left and right without care we will erase our species. Understanding that this is a health issue is the first concern.

The tradeoffs involved in the EPAs new regulations are that the changes would cause the cost of living to increase, per person, however it would result in a smaller chance of developing a disease or illness in older age in the U.S. The investment in our future life is more valuable than anything we could say. The bare bones of this issue is that the health regulations of the EPA need to protect the three hundred million U.S. citizens that rely on the products being sold and given.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Southern Methodist University Dedman School of Law (Doc. #1512, SBC-042601)

3. Conclusion

In conclusion, I would like to express may gratitude to the EPA for its commitment to ensuring safe drinking water standards and reducing PFAS exposure. I believe that the proposed NPDWR rules are a crucial part of this effort, and will have a significant impact on the health and safety of our communities. I look forward to seeing additional rules proposed under the EPA's PFAS Strategic Roadmap in the months and years to come.

With Best Regards,

Whitney Bosch

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Southern Methodist University Dedman School of Law (Doc. #1512, SBC-042596)

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Submitted Electronically

April 21, 2023

Dr. Jennifer McLain

Director, Office of Ground Water and Drinking Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue NW

Washington DC 20460

RE: Docket No. EPA-HQ-OW-2022-0114: PFAS National Primary Drinking Water Regulation Rulemaking

Dear Dr. McLain:

Thank you for the opportunity to provide comment on the proposed National Primary Drinking Water Regulation (NPDWR) rulemaking regarding per- and polyfluoroalkyl substances (PFAS). I am a second year law student at the SMU Dedman School of Law with an interest in environmental law. To start, I would like to express my appreciation to the EPA for taking action on the PFAS issue. These chemicals are an underrated threat to public health, and it is time to address the threats posed by their presence in our Nation's drinking water.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Christian Garcia (Doc. #1513, SBC-042602)

April 21, 2023

Dr. Jennifer L. McLain

Director

Office of Ground Water and Drinking Water

U.S. Environmental Protection Agency

1200 Pennsylvania Ave NW

Washington, DC 20460

Re: Docket ID No. EPA-HQ-OW-2022-0114, Comments on the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

Dear Dr. McLain,

Thank you for the opportunity to provide comment on proposed per- and polyfluoroalkyl substances (PFAS) National Primary Drinking Water Regulations (NPDWR). I am a third-year law student at Southern Methodist University. As a law student, I have studied various aspects of environmental law and the EPA's role in proposing and enforcing regulations. In my environmental law class, we had the unique privilege of visiting with the EPA's legal team at their Region 6 office, which has encouraged me to take an active rule in the EPA's rulemaking process. I appreciate the EPA's efforts to engage with stakeholders and consider the perspectives and concerns of all stakeholders when developing regulations. As such, I am writing to express my strong support for the proposed NPDWR for six PFAS, including perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO-DA, commonly known as GenX Chemicals), perfluorohexane sulfonic acid (PFHxS), and perfluorobutane sulfonic acid (PFBS).

The EPA is taking a critical step to protect public health by proposing to establish legally enforceable levels for PFAS found in drinking water.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Christian Garcia (Doc. #1513, SBC-042604)

Accordingly, the EPA is taking a monumental step towards developing a strong regulatory framework to protect public health and ensure that everyone has access to clean drinking water. Specifically, the EPA is proposing to regulate PFOA and PFOS at a level they can be reliably measured, which is 4 parts per trillion (4.0 nanograms/Liter). [FN11: U.S. ENVIRONMENTAL PROTECTION AGENCY, EPA's Proposal to Limit PFAS in Drinking Water (March 2023), https://www.epa.gov/system/files/documents/2023-04/Fact%20Sheet_PFAS_NPWDR_Final_4.4.23.pdf (last visited Apr. 21, 2023).] It would place limits on any mixture containing one or more of PFNA, PFHxS, PFBS, and/or GenX Chemicals by using a hazard index, which is employed to determine if the combined levels of these PFAS pose a potential risk. [FN12: Id.] Using the hazard index would protect communities from the additive effects of multiple PFAS when they occur together. [FN13: Id.] Part of this regulation would include regular testing and establishing monitoring systems to ensure compliance. [FN14: Id.] Further, public water systems would be required to notify the public if monitoring detects these PFAS at levels that exceed the proposed regulatory standards. Such notifications would make people aware of the risks they are assuming when they drink water. Finally, for public water systems that have PFAS levels that exceed regulatory standards, including removing the chemicals through various types of treatment or switching to an alternative water supply that meet the standard. [FN15: Id.]

Indeed, the proposed NPDWR for regulating PFAS in drinking water is a significant step towards protecting public health. However, it is essential to recognize that this is only the beginning, and much more must be done to ensure the safety of our drinking water.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Christian Garcia (Doc. #1513, SBC-042606)

Finally, I commend the EPA for its efforts to address the issue of PFAS in drinking water and engaging stakeholders throughout the rulemaking process. Collaborating with environmental groups and affected communities provide valuable insights into the impacts of contamination on public health. By engaging with all stakeholders, the EPA can continue developing regulations that are informed by diverse perspectives and are more likely to be effective in protecting public health and ensuring access to safe drinking water for all Americans. I fully support the proposed National Primary Drinking Water Regulation for PFAS and am grateful for the opportunity to participate in the rulemaking process.

Sincerely,

Christian Garcia

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Cayro Bustos (Doc. #1517, SBC-042717)

April 21, 2023

Mr. Michael S. Regan

Environmental Protection Agency

Mail Code 1101A

1200 Pennsylvania Avenue, N.W.

Washington, DC 20460

Dear Mr. Regan,

My name is Cayro Bustos, and I am a current third-year student at the SMU Dedman School of law. I am writing to express my strong support for the proposed PFAS National Primary Drinking Water Regulation. This represents what I believe is a right of every citizen of this country: to have access to healthy drinking water. As a concerned citizen, I believe that it is crucial for our government to take action to protect public health from the potential harms of PFAS exposure.

PFAS, or per- and polyfluoroalkyl substances, are a group of chemicals that have been widely used in a variety of consumer and industrial products for decades. ASTHO Statement on U.S. EPA's Proposed PFAS National Primary Drinking Water Regulation, Association of State and Territorial Health Officials (March 22, 2023) https://www.astho.org/communications/newsroom/2023/astho-statement-on-epas-proposed-pfas-national-primary-drinking-water-regulation/. These chemicals are highly persistent in the environment and can accumulate in the bodies of humans and animals, leading to potential health effects such as cancer, thyroid disease, and developmental effects in fetuses and infants. What are the health effects of PFAS?, Agency for Toxic Substances and Disease Registry (last visited April 14, 2023) https://www.atsdr.cdc.gov/pfas/health-effects/index.html.

While PFOS are no longer manufactured in the United States, they continue to persist in the environment and have been detected in soil, surface water, groundwater and public water supplies in numerous locations. Still, there are currently no federal regulations in place to limit PFAS levels in drinking water. This is in spite of the European Union (EU) regulating these chemicals since many years ago and despite the many calls for federal action to limit and

regulate these "forever chemicals," which are now detected in the blood of nearly all Americans because they don't break down in the body. Karen Feldscher, Why more stringent regulation is needed for 'forever chemicals', Harvard (Jan. 4, 2022), https://www.hsph.harvard.edu/news/features/why-more-stringent-regulation-is-needed-for-forever-chemicals/.

The proposed PFAS National Primary Drinking Water Regulation would establish a maximum contaminant level (MCL) for two of the most common PFAS chemicals, PFOA and PFOS, at 10 parts per trillion (ppt) each. While this level is not as strict as some experts recommend, it would still represent a major step forward in protecting public health and ensuring access to safe, clean drinking water. The EU, for example, regulates four of the most common PFAS chemicals, and the U.S. proposed PFAS limits are more than 30 times higher than the European limit. Id.

It is well past due that the U.S. catches up with our peers, and this is a step in the right direction. I urge the Environmental Protection Agency to move forward with the proposed regulation without delay. This legislation is far less strict with PFAS than it ought to be; the current regulations only target drinking water and only target two PFAS. Nevertheless, as with global warming and many other issues, small actions can accumulate to big impacts. As such, I also urge the EPA to consider even stricter limits on PFAS levels in the future and ban PFAS entirely—not just the two most common kinds of PFAS. This agency has long recognized the importance of access to clean drinking water, and we need to limit and rid the health risks associated with PFAS exposure. Factsheet Clean Water Rule, EPA (last visited April 15, 2023), https://www.epa.gov/sites/default/files/2016-02/documents/cleanwaterrulefactsheet.pdf. The dangers of PFAS as discussed are too great to ignore, and we must take action to protect the most vulnerable members of our communities, including the impoverished, the elderly, children, and pregnant women.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Cayro Bustos (Doc. #1517, SBC-042719)

Given all of the above, there is no legitimate argument for not adopting this regulation for limiting PFAS in our drinking water. Not only does the EPA need to adopt this regulation expeditiously, but it is also imperative that it is implemented effectively. This means providing adequate resources and support to local water systems to comply with the new standards, and monitoring and enforcing compliance to ensure that all Americans have access to safe drinking water. We must ensure that this regulation is properly in effect as soon as possible.

In addition, the EPA should take a comprehensive approach to addressing PFAS contamination, including efforts to reduce and eliminate the use of these chemicals in consumer and industrial products, as well as remediation of contaminated sites. It is essential that we take a holistic

approach to addressing the PFAS crisis, rather than simply treating the symptoms of a much larger problem.

Finally, I urge the EPA to prioritize transparency and public engagement throughout the rulemaking process. The public has a right to know about the potential health risks associated with PFAS exposure, as well as the steps being taken to address these risks. The EPA should provide regular updates and opportunities for public comment and input and should make all relevant information and data available to the public.

In conclusion, I strongly support the proposed PFAS National Primary Drinking Water Regulation and urge the EPA to take swift action to implement this important public health protection. With millions of Americans at risk of exposure to these harmful chemicals, we cannot afford to wait any longer. It is time to prioritize the health and well-being of our communities and take decisive action to address the PFAS crisis.

Thank you for your consideration.

Sincerely,

Cayro Bustos

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. For discussion of implementation and enforcement, please see section 11 of this document. For additional discussion on other ways the EPA can address PFAS contamination, please see section 15 for topics that are out of scope for this rulemaking.

Daniel Varon (Doc. #1518, SBC-042720)

21 April 2023

Michael S. Regan

Environmental Protection Agency EPA H.Q.

1200 Pennsylvania Avenue NW Washington, DC 20004

Dear Director Regan,

I am pleased to have the opportunity to provide comment on the EPA's Proposed Per- and Polyfluoroalkyl Substance (PFAS) National Primary Drinking Water Regulation. I am a 2L in law school, and my environmental law class has sparked my interest in becoming more active in proposed EPA legislation. As a concerned citizen, while I agree that maintaining clean water is an important priority, I believe the government should do so in the most cost-effective matter.

As is stands, there are many unknowns surrounding PFAS and their health consequences. The studies the EPA has conducted show abnormal circumstances. Further, these studies are not applicable to the majority of the Country. For this reason, I call for the EPA to investigate PFAS

solutions further. I believe that we can be more efficient with how we allocate resources meant to better citizen's and environmental health. Whether it be adjusting the MCL level, exploring alternative PFAS sources or solutions, or putting this money towards entirely different environmental projects, I think we can do better.

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the method in which the agency is implementing this final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

The Garden Club of America (GCA) (Doc. #1519, SBC-042608)

April 24, 2023

Michael S. Regan

Administrator, U.S. Environmental Protection Agency

1200 Pennsylvania Avenue NW Washington, DC 20460

Docket ID No. EPA-HQ-OW-2022-0114

Dear Administrator Regan,

The Garden Club of America (GCA) is a national organization founded in 1913, comprising 199 member clubs and representing approximately 18,000 citizens across the United States. The GCA actively seeks to restore, improve, and protect the quality of the environment through programs and action in the fields of conservation, civic improvements and education. We appreciate the opportunity to comment on the regulation of PFAS chemicals.

On behalf of the Conservation Committee and the National Affairs and Legislation Committee of the Garden Club of America, we write to commend your proposed National Drinking Water Standards for six PFAS chemicals. These include legally enforceable Maximum Contaminant Levels for the legacy chemicals PFOA and PFOS as individual contaminants. Also included are the regulation of the Genx chemicals PFHxS, PFNA, PFB, and HFBO-DA as a PFAS mixture with health based, non-enforceable Maximum Contaminant Level Goals.

The GCA is concerned about PFAS chemicals because they have a chain of linked carbon and fluorine atoms. Because the carbon-fluorine bond is one of the strongest molecular bonds found, these chemicals do not degrade in the environment. Outside of industry, contaminated food and water is the way most people are exposed to these chemicals, and since PFAS chemicals don't break down, blood levels of PFAS will increase over time. Indeed, the Center for Disease Control has found that 97 percent of Americans have PFAS in their blood.

PFAS chemicals have been shown in scientific studies to increase the incidence of a wide array of health problems, including liver toxicity, endocrine, immunologic, and neurologic abnormalities. They have been shown to increase the incidence of kidney cancer, and testicular cancer.

The GCA encourages all efforts to improve water quality and protect the health of Americans. Plants and animals (which play critical roles in the food web) will also be protected from exposure to these persistent chemicals with these proposed measures. EPA regulations are crucial because it is impossible for individual consumers to protect themselves from these chemicals through personal actions. To meet the standards you are proposing, the water utilities will be correctly held responsible for testing and removal of these toxic chemicals and industries will have to stop discharging these chemicals into waterways.

The GCA has supported the Clean Water Act and the Safe Drinking Water Act (SDWA) since their inception. The SDWA gives the EPA the ability and obligation to update standards to address new contaminants. Regulating these six PFAS chemicals meets those obligations.

Sincerely,

Karen Gilhuly

Chair

National Affairs and Legislation Committee

The Garden Club of America

Cayce McAlister

Chair

Conservation Committee

The Garden Club of America

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Ruoyu Zhang (Doc. #1520, SBC-042746)

Public Comment

To Whom It May Concern:

I am a student in Mount Holyoke College. I really apricate EPA putting resources and labors into making our drinking water safer. Ensuring the safety of drinking water is a crucial measure in safeguarding public health.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

City of Alexandria, Virginia (Doc. #1523, SBC-042611)

Please see the pdf file here, as submitted by Mayor Justin M. Wilson, Mayor of City of Alexandria, Va.

Thank you,

Mark McHugh

(Aide to Mayor of Alexandria, Va., mark.mchugh@alexandriava.gov)

April 24, 2023

U.S. Environmental Protection Agency

EPA Docket Center

Docket ID: EPA-HQ-OW-2022-Ol 14

Mail Code 28221 T

1200 Pennsylvania Avenue, NW

Washington, DC 20460-6629

To Whom It May Concern:

I write on behalf of the Alexandria City Council and the residents that we are privileged to serve. The

City of Alexandria is pleased to endorse the proposed PFAS National Primary Drinking Water Regulation [FN1: https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas] (Docket ID: EPA-HQ-OW-2022-0114) that has been promulgated by the Environmental Protection Agency, as published in the Federal Register on March 29, 2023.

As detailed in the proposed regulation, PFAS, the so-called "forever chemicals" have been proven to have negative impacts of the health of those who receive long-term exposure, including:

• Negative impacts on pregnant women and in their developing babies

• Weakening immune response

• An increased risk of cancers and liver damage

• Elevated cholesterol levels and the concomitant risk for heart attack or stroke

The regulations will propose new Maximum Contaminant Level Goals (MCLG) and enforceable

Maximum Contaminant Levels (MCL) for these chemicals in our drinking water. As detailed by the EPA's analysis, full implementation of these new standards will prevent tens of thousands of illnesses and deaths.

Alexandria is a community of 160,000 residents in 15.5 square miles in Northern Virginia. The City of Alexandria's 75,000 households receive drinking water from the Virginia-American Water Company, a waterworks owned by the publicly-traded American Water Works Company, Inc. Alexandria's waterworks is one of the thousands of systems nationally that currently exceed the MCL that the EPA has proposed.

According to the 2022 Water Quality Report provided by Virginia-American Water Company [FN2: https://www.amwater.com/ccr/alexandria.pdf], our drinking water contains levels of several PFAS that would be actionable under the proposed regulations, including:

• Perfluorooctanoic Acid (PFOA): Range Detected 2.8 — 4.5/ppt

• Perfluorooctanesulfonic Acid (PFOS): Range Detected 3.2 — 4.0/ppt

• Perfluorohexanesulfonate (PhHxS): Range Detected 0.0 — 2.3/ppt

• Perfluorobutanesulfonic Acid (PFBS): Range Detected 0.0 — 4.7/ppt

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Orange Water and Sewer Authority (OWASA) (Doc. #1524, SBC-042613)

See attached file from Orange Water and Sewer Authority in Carrboro, NC. Thank you.

OWASA

Orange Water and Sewer Authority (OWASA) provides water, wastewater and reclaimed water services to the Chapel Hill and Carrboro communities in Orange County North Carolina. OWASA’s vision is to be our community’s trusted partner for clean water and environmental protection and our mission is that our dedicated team delivers valuable water and sewer services that are essential to our community’s health, environment, and economy through the stewardship of infrastructure and natural resources.

OWASA began proactive quarterly testing of raw water samples and treated drinking water samples for PFAS in 2018. Once we understood that PFAS could be a potential concern for us we began a more robust monitoring program and had engaged consultant assistance prior to the MCLs being released. OWASA supports the rule with regards to highlighting the importance of protecting our customers health.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Isabelle Dominguez (Doc. #1525, SBC-042628)

Opponents lay out several arguments against the proposed regulation. For one, PFAS come from other sources that would not be regulated by this rule, such as cookware and food packaging. However, there are some rules limiting the use of PFAS in other contexts. For example, the FDA has established limits on PFAS levels in such products, demonstrating concern of exposure. [FN18: Per- and Polyfluoroalkyl Substances (PFAS), FDA (Jul. 6, 2022), https://www.fda.gov/food/environmental-contaminants-food/and-polyfluoroalkyl-substances-pfas.] Like the FDA regulation, the proposed rule does not seek to eliminate all PFAS exposure; instead, it sets standards to limit exposure and mitigate the cumulative effects of PFAS exposure. This proposed rule would completest the existing FDA regulation.

Another counterargument is that PFAS regulation should be left to the state. It is true that as of the end of 2022, nine states have enacted laws setting similar limits to PFAS levels in drinking water. [FN19: Per- and Polyfluoroalkyl Substances (PFAS): State Legislation and Federal Action, NAT'L CONF. OF STATE LEGS., https://www.ncsl.org/environment-and-naturalresources/per-and-polyfluoroalkyl-substances (updated Mar. 23, 2023).] However, some states may not prioritize safe drinking water and will fail to pass legislation setting limits of PFAS levels. In some instances, these states are the states that have the most vulnerable populations that require protection. Moreover, as stated above, many communities cannot afford to upgrade their water systems to limit PFAS exposure. The funds granted by the Bipartisan Infrastructure Law and other federal aid monies would support these underdeveloped communities by allocating to them funds specifically for upgrading water systems to conform with the proposed rule.

There is no denying that this rule will require costly and labor-intensive upgrades and maintenance to new water systems. However, the human benefit for the rule greatly outweighs any economic cost. With so many environmental issues affecting our society, the EPA's bold new rule addresses one that affects all individuals in the United States. We all have a right to safe drinking water, [FN20: G.A. Res. 64/292 (Jul. 28, 2010).] and the EPA's rule is one step forward to ensuring that right is protected.

Thank you for your consideration,

Isabelle Dominguez

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Isabelle Dominguez (Doc. #1525, SBC-042624)

April 18, 2023

Michael S. Regan, Administrator

Environmental Protection Agency 1200 Pennsylvania Ave., N.W.

Washington, D.C. 20460

Re: Docket ID No. EPA-HQ-OW-2022-0114, Comment in Support of the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

Dear Administrator Regan,

My name is Isabelle Dominguez, and I am a third-year law student located in Dallas, TX. I write in my capacity as private citizen to express support for the EPA's proposed rule regulating the amount of PFAS in our drinking water. The scientific evidence is clear that it is highly probable that PFAS exposure through drinking water (and other means) can have devastating impacts on human health. Moreover, other studies demonstrate that some of our most vulnerable populations are at the highest risk of PFAS exposure. These considerations warrant the EPA stepping in to work with local water providers to preserve our water and protect our communities.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Samantha Deem (Doc. #1526, SBC-045707)

Civic Engagement - Sam Deem

Within the last century, a category of manufactured chemicals called PFAS have caused a lot of damage to not only the environment but also the general population. Recently in the last month, the Environmental Protection Agency (EPA), has proposed the PFAS National Primary Drinking Water Regulation in order to regulate the usage, disposal and information released to the public about these toxic chemicals in water sources. This ruling would force city and state water systems to monitor, notify and reduce the PFAS in the water sources. After doing research about the effects of PFAS and what is known about their long term effects on humans, I have come to the conclusion that these regulations are not enough. There are too many loopholes that many large corporations can exploit in order to save money that are harmful to many populations and the environment.

PFAS are a replacement for their predecessor, the PFOAs, since most companies like DuPont stop producing those in 2013. Companies claim that these PFASs are more easily biodegradable and can be used safely unlike the PFOAs. That being said, with the secrecy and the fact that many of the PFASs are not regulated by EPA as seen in the case of DuPont, I don't trust that

only regulating 6, as proposed in this new rule, is enough to keep us and the environment safe. The EPA has determined that the safety regulations for the amount of PFAS consumed is 4 parts per trillion and for short term exposure it's 0.4 parts per billion. With this level confirmed by the EPA, we as a community now have a way to hold these companies accountable but, even then I'm not sure it's enough.

After reading Rob Bilott's story about his fight against DuPont and their lack of care for the environment and the general population, I believe more is needed in this fight against PFASs. DuPont used their own scientists and corporate funded studies to "prove and support" anything they needed in order to continue to process and use the PFOAs and PFASs. They also had multiple studies that showed that these chemicals were toxic and caused health concerns for workers and their families but withheld this information so they could blame these concerns elsewhere and remain using what was convenient for them. If the EPA has delegated 9 and 12 billion to helping make water safer through water systems, I believe we also need to fund jobs of auditors paid by EPA to ensure that these rules are actually being followed and that there are smoke screens of lies hiding the truths that companies are not. In the Tennant's case, they were lucky that a family friend lawyer was willing to take their case because in the poorer/underserved communities, there's no one to fight these battles if we leave it up to the companies to "ensure the safety of the people and their environment.

Overall, I know that fixing this problem is going to require a lot of funding as there are many studies that need to be conducted about the effects of the PFASs past the 6 on the proposed rule, to help eliminate the already circulating chemicals and the monitor the future chemicals. However, I believe that if the public knew about the negative health effects of these chemicals and understood that their taxes would help go towards making themselves and the environment, I believe we could increases taxing to help fund these needs.

References

Mussabek, D., Söderman, A., Imura, T., Persson, K. M., Nakagawa, K., Ahrens, L., & Berndtsson, R. (2023). PFAS in the Drinking Water Source: Analysis of the Contamination Levels, Origin and Emission Rates. Water (20734441), 15(1), 137. https://doi-org.dml.regis.edu/10.3390/w15010137

Proposed PFAS National Primary Drinking Water Regulation, Presentation of the EPA Office of Water, March 2023. https://www.epa.gov/system/files/documents/2023-03/PFAS%20NPDWR%20Public%20Presentation_Overview_3.16.23_508.pdf

Read Rich, N. (2016). The Lawyer Who Became DuPont's Worst Nightmare. The New York Times Magazine. https://www.nytimes.com/2016/01/10/magazine/the-lawyer-whobecame-duponts-worst-nightmare.html

Wylie, B., & Malits, J. (2022). Beware of "forever chemicals": Counsel pregnant and breastfeeding patients about dangers from exposure to PFAS. Contemporary OB/GYN, 67(7), 20–24.

Reflection – Sam Deem

After reading the article about the DuPont incident and the other sources alongside the new proposed rule, I was shocked. I did not think the rule was anywhere close to being enough to make an effective change. The DuPont article talked about how most of the PFASs haven't even really been researched enough to make the EPA cautious and that scared me a lot. It also scares me that these companies can hire a scientist and fund a study to the point where the results say their chemicals aren't harmful when they know that they are but choose to lie to the public. That's why I strongly suggest that many jobs are funded to make sure that companies can't do this and that water sources are actually being regulated like how this rule declares it needs to be. Maybe by fining the companies for not following the rules and using that money for funding initially might help alongside taxing but either way, I think the public needs to be made fully aware of everything that goes on with PFASs and their harmful effects. I would feel comfortable knowing that my taxes are going into something beneficial towards my health and the health of the environment.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for protecting human and environmental health against PFAS. Please see section 1.3 of the EPA response in this *Response to Comments* document. Please see section 15 of the *Response to Comments* document for topics that are out of scope of this rule, such as PFAS manufacturing.

Samantha Matterson (Doc. #1527, SBC-042629)

Proposed Action for the PFAS NPDWR Review

After reviewing the Proposed Action for the PFAS NPDWR, I would like to share my opinion. I believe that the proposed action is a good start, with the expectation that there will be further legislation in the future. I agree that reducing the amount of PFAS chemicals in drinking water is of upmost importance, especially given that drinking water is where most people are exposed to these chemicals, however I do feel that this action has limitations that must be addressed, and this action cannot be a fix-all solution especially given that over 180 countries globally have moved to ban the PFOA chemical from production (Hogue, 2019). I appreciate that this action moves the safe limit of pfas from 70ppt to 4ppt, and that the public must be notified of the levels of PFAS in their drinking water.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Water Environment Federation (WEF) (Doc. #1529, SBC-043303)

Please find attached comments from the Water Environment Federation.

April 28, 2023

Michael S. Regan

Administrator

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue NW Mail Code: 4607M

Washington, DC 20460

Re: Docket ID No. EPA-HQ-OW-2022-0114, Comments on the Development of the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

Dear Administrator Regan,

The Water Environment Federation (WEF) thanks the US EPA for the opportunity to provide comments on the proposed per- and polyfluoroalkyl substances (PFAS) National Drinking Water Regulations (NPDWR). WEF is a nonprofit association that provides technical education and training for tens of thousands of water quality professionals who clean water and return it safely to the environment. WEF members have proudly protected public health, served their local communities, and supported clean water worldwide since 1928.

WEF stands with EPA in its goal to utilize the best available science to stop PFAS pollution, protect human health, and harmonize policies that strengthen public health protections with infrastructure funding to help communities, especially disadvantaged communities, deliver safe drinking water. WEF understands the critical need in providing clean drinking water and the importance of this proposed rule. We also see the unintentional impacts the proposed regulation will have on the water resource recovery facilities (WRRFs) that modern society has come to rely upon since the promulgation of the Clean Water Act of 1972. Some of these impacts are described below and include the eventual discharge to WRRFs of residuals from water treatment operations.

EPA Response: The EPA acknowledges this comment. Please section 1.3 of the EPA response in this *Response to Comments* document. For additional discussion regarding residuals and discharges, please see section 10.4 of the *Response to Comments* document.

Robert Adamski (Doc. #1530, SBC-043337)

Worldwide," According to the UN, approximately 5 billion people worldwide [Link: https://www.unwater.org/publications/world-water-development-report-2018] will be impacted by increasingly limited access to clean water by 2050, making it a core focus of sustainable development and a fundamental underpinning for all SDGs [Link: https://sdgs.un.org/goals]. Although the UN has long recognized clean water and sanitation as a human right [Link: https://www.un.org/waterforlifedecade/human_right_to_water.shtml], the UN Secretary-General has acknowledged [Link: https://www.un.org/development/desa/en/news/sustainable/sdg6-global-acceleration-framework.html] that we are alarmingly off track on water-related SDGs.

Without access to clean, healthy, and abundant water, the global community will not make tangible progress on climate change, poverty, hunger, equality, peace, or any of the other laudable goals."

Given the lack of sufficient evidence of health effects, the lack of capacity to implement the rule and the need for expenditures in more urgent areas like lead service lines, I urge the rule not be implemented and instead additional monitoring and research be carried out

Sincerely,

Robert E. Adamski

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

HNOJ Laudato Si' Circle (Doc. #1532, SBC-042635)

We suggest the proposed National Primary Drinking Water Regulation (NPDWR) for six PFAS be implemented as a starting point. This action alone could prevent thousands of deaths and reduce tens of thousands of serious PFAS-attributable illnesses, especially in under-resourced communities.

EPA act now. Make states responsible for keeping their constituents as healthy as possible, using policies based on credible scientific research. Perhaps science can bring us to: "Single use" means "made from 100% biodegradable components." Now that truly is healthy!

• HNOJ Laudato Si' Circle is part of a Catholic international and national network LAUDATO SI' CIRCLES - Laudato Si' Movement (laudatosimovement.org). We hail from many different communities, but we all want the best for ourselves and for future generations, as we live on our common home, Earth.

Sincerely, Monica K, (author), Jeffrey E (editor), Barbara Q (editor), Patrick I, Pat K, Paul K ("our family in Wilmington NC have been especially impacted."), Stephen K and Patty O from NC. Julia SM from NH. Marilyn W. from OH. Brigid B from OR.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Linda Shosie (Doc. #1533, SBC-043956)

Administrator Michael S. Regan

U.S. Environmental Protection Agency

EPA Docket Center, OW Docket

Mail Code 28221T

1200 Pennsylvania Avenue NW

Washington, DC 20460

May 1, 2023

Re: Per and-polyfluoroalkyl Substances (PFAS) Proposed National Drinking Water Regulations (Docket ID: EPA-HQ-OW-2022-0114)

Dear Administrator Regan, Assistant Administrator for Water Fox, and Office of Ground & Drinking Water Director McCain,

My name is Linda Shosie (aka Linda Robles), I am the owner and founder of the Environmental Justice Task Force- a grassroots community-based organization (CBO) supported by a committee of concerned citizens advocating for environmental justice (EJ) and health equity (HE) for all in Tucson, Arizona. I am writing to express my strong support for the establishment of the new Maximum Contaminant Levels (MCLs) for per-and polyfluoroalkyl substances (PFAS) in drinking water. There is growing scientific evidence describing the toxic effects of PFAS, in people, that even at the lowest levels of exposure to PFAS can cause very large and varying sets of serious health effects, including on the growth and development of children, dangers for pregnant woman and threaten the developing fetus, and damages of the liver, immune system disfunction and increases the risk for cancer. The establishment of new MCLs will help protect our communities from the harmful effects of these chemicals.

The EJTF is dedicated to protecting its members and others in the Tucson community from the harms caused by toxic chemicals, including Per-and polyfluoroalkyl Substances ("PFAS") such as perfluorooctanoic acid ("PFOA") and perfluorooctanesulfonic acid ("PFOS"). To inform the public and educate policy makers about our knowledge of, and awareness efforts on, PFAS and its health effects, to help impacted individuals reduce the negative health risks that they face, the EJTF relies on EPAs proposed MCL's for PFOA and PFOS.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Linda Shosie (Doc. #1533, SBC-043963)

Environmental Justice Task Force

Administrator Michael S. Regan

U.S. Environmental Protection Agency

EPA Docket Center, OW Docket

Mail Code 28221T

1200 Pennsylvania Avenue NW

Washington, DC 20460

April 25, 2023

Re: Per and-polyfluoroalkyl Substances (PFAS) Proposed National Drinking Water Regulations (Docket ID: EPA-HQ-OW-2022-0114)

Dear Administrator Regan, Assistant Administrator for Water Fox, and Office of Ground & Drinking Water Director McCain,

The Environmental Justice Task Force- a grassroots community-based organization, advocating for citizens of Tucson, affected by PFAS contamination from multiple sources and we strongly believe that everyone deserves clean, safe, healthy and sustainable drinking water supplies. We are writing to express our strong support for the establishment of new Maximum Contaminant Levels (MCLs) for per-and polyfluoroalkyl substances (PFAS) in drinking water. As you are aware, PFAS are toxic, harmful to human health, and extremely persistent in the environment. We have experienced these effects firsthand and know the cost, not just physically, but financially and emotionally as well. The establishment of new MCLs will help protect our communities from the harmful effects of these chemicals.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Linda Shosie (Doc. #1533, SBC-043961)

The National standards to limit the contamination of PFAS in drinking water are long overdue.

For years, impacted communities like mine lacked reliable guidance from EPA about the hazards posed by PFOA and PFOS in drinking water, because there were no federal National Drinking Water Standards for PFAS set by EPA. By regulating six dangerous PFAS in drinking water, EPA proposal helps us reduce overall PFAS exposure, and improve drinking water safety in thousands of communities like mine, and across the country.

But Enough is Enough! All people deserve to have the human right to clean, safe, healthy and sustainable drinking water supplies.

For the last six years, I have strongly persuaded EPA to set strong federal drinking water standards for PFAS, to avoid putting people like my daughter at risk, and to prevent environmental disasters like this from happening again.

Today, we are so overwhelmed with joy at the EPAs federal Drinking Water Standards for PFAS, but it comes to many residents whose health has already been disproportionately impacted by all these toxins.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

The Democratic Party of Hawai'i (Doc. #1536, SBC-042642)

MELODIE ADUJA, Co-chair

P.O. Box 775, Kaneohe, HI 96744

Email: LegislativePriorities@gmail.com

May 4, 2023

Comments for the Proposed PFAS National Primary Drinking Water Regulation

POSITION: STRONG SUPPORT

PFAS are known to cause kidney cancers, liver damage, heart attacks, strokes, and developmental (birth weight) effects. PFAS have been detected in Kunia, Waipio, Honolulu and Kahului airports, and eight Hawaii military sites, including the Navy's Pearl Harbor drinking water. This liquid cancer is ingested through drinking water, breathing, and eating fish, animal, and agricultural products. It is absorbed through cosmetics, personal items, clothing, carpets, linen, and bedding.

Given the gravity of the adverse health effects from long-term PFAS exposure, the 7500-member DPH Environmental Caucus strongly supports the proposed Rules. The NPDWR establishes MCLs at 4 ppt for PFOA and PFOS, and 1.0 ppt Hazard Index for combined GenX chemicals.

With these Rules come uniformity, nationally, and statewide. Hawaii is a highly militarized state where the PFAS EALs do not follow the EPA's Science Advisory Board but rather follow military requests for increased EALs upon releases of the contaminants to relieve it of notice requirements and remediation duties.

In Hawaii, on Dec. 2022, PFOA EAL was at 6 ppt; last month it was increased to 12 ppt. PFOS EAL was at 4 ppt, then increased to 7.7 ppt last month. Combined GenX Chemicals EALs were at 652 ppt, then increased to 1801 ppt.

The Hawaii Dept. of Health, rather than reducing the PFAS EALs, increased them to greater unsafe levels. Adopting the NPDWR would create national uniformity, bringing Hawaii closer to a safe measurable drinking water standard.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce (Doc. #1537, SBC-042644)

Our coalition supports a national drinking water standard for PFOA and PFOS based on the best science and risk -- as opposed to the current patchwork of state requirements.

EPA Response: The EPA has used best available science in developing the final PFAS NPDWR. The EPA has also made appropriate risk management decisions, considering health effects, treatment technologies, costs, benefits, feasibility, and other factors discussed throughout the administrative record for this action. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kevin Korro (Doc. #1538, SBC-042657)

In conclusion, I support the national primary drinking water regulation that has been suggested for PFAS, and I strongly encourage the Environmental Protection Agency (EPA) to enforce rigorous MCLGs to safeguard the general public's health. I am thankful for your careful examination of the points I made in my notes.

Sincerely,

Kevin

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kevin Korro (Doc. #1538, SBC-042653)

Water Regulation

Greetings, EPA!

This is to express support for the proposed national primary drinking water rule for per- and polyfluoroalkyl chemicals, most often referred to as PFAS. Per- and polyfluoroalkyl compounds are what are referred to as PFAS. As a concerned citizen, I believe guaranteeing the safety of our drinking water is of the utmost importance and that the regulation of these potentially harmful compounds is an essential step in the process of reaching that objective. In addition, I believe regulating these potentially hazardous substances is a vital step in the process of attaining that objective.

PFAS have been associated with a wide range of adverse consequences for human health, some of which include impaired function of the immune system, cancer, and difficulties in both development and reproduction. A proposed regulation to regulate perfluorohexanesulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO-DA), and its ammonium salt; perfluoro nonanoic acid (PFNA); and perfluorobutanesulfonic acid (PFBS); and mixtures of these PFAS is

a necessary step to protect the public's health in accordance with the Safe Drinking Water Act (SDWA).

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Brian Hackman (Doc. #1539, SBC-042882)

See attached file statement. My statement is in objection to the current PFAS proposed MCLs and HIs being discussed as part of the USEPA (United States Environmental Protection Agency) Docket EPA-HQ-OW-2022-0114.

This statement is in objection to the current PFAS proposed MCLs and HIs being discussed as part of the USEPA (United States Environmental Protection Agency) Docket EPA-HQ-OW-2022-0114.

The presence of organics in water does not necessarily require regulation in drinking water.

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. For discussion of the MCLs and the Hazard Index, please see section V of the FRN and section 5 of the *Response to Comments* document.

Brian Hackman (Doc. #1539, SBC-042909)

In summary, the PFAS MCL and HI proposal for the six PFAS components is myopically being shoved onto the American people based on an emotional response without reasonable logic or basis in regards to the scientific method demonstrated through third party independent verification, financial boundaries and budgets and demonstrated return on investment, and sense of reasonableness to the risk vs. benefit approach of living life when so much of the exposure routes are not protected and may exist beyond the Agency’s control.

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. The EPA disagrees with the commenter on the methods the agency has used to develop this PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Hufsa Ahmed (Doc. #1540, SBC-042658)

Comment submitted by Hufsa Ahmed

Posted by EPA on May 9, 2023

To Whom It May Concern,

I am writing in regards to the proposed rule for Per- and Polyfluoroalkyl Substances (PFAS) to be included into the National Primary Drinking Water Regulations. As stated on your website, "EPA expects that if fully implemented, the rule will prevent thousands of deaths and reduce tens of thousands of serious PFAS-attributable illnesses." I agree with this statement wholeheartedly because PFAS are quite literally killing individuals in my community of Saint Paul, Minnesota. Just this week, I read an article (attached) about a push in the Minnesota legislature to regulate PFAS after a 20 year old student died in April from a rare for of cancer this year. The suspected source of this cancer: a 3M PFAS plant miles from this student's high school that releases toxic waste into the community. High rates of cancer in this suburb of Saint Paul is no coincidence: PFAS takes lives. It is unacceptable and abhorrent that corporations can continue to engage in actions that cost people their lives. Regulations are necessary to prevent further harm, damage, and deaths.

[Attachment 1: see docket ID EPA-HQ-OW-2022-0114-1540].

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Alliance of Nurses for Healthy Environments (Doc. #1544, SBC-042665)

Per- and Polyfluoroalkyl Substances (PFAS): Proposed National Primary Drinking Water Regulations

The Alliance of Nurses for Healthy Environments (ANHE) is the only national nursing organization focused solely on the intersection of health and the environment. One of our roles as nurses is to create healthy environments in which individuals, families, groups and communities cannot just survive but thrive. [FN1: American Nurses Association (2020). Nursing: Scope and standards of practice, (4th ed.). ANA: Silver Spring, MD.] Nurses have been ranked the most trusted profession for 20 consecutive years [FN2: Yale School of Nursing. (2022, February 7). Gallup: Nurses are Most Trusted Profession for 20th Straight Year.https://nursing.yale.edu/news/gallup-nurses-are-most-trusted-profession-20th-straight-year] and we are led by our professional obligations [FN3: American Nurses Association. (2020). Nursing: Scope and Standards of Practice (4th ed.). Standard 18: Environmental Health. ANA: Silver Spring, MD.] which make addressing health, environment and safety a professional focus of ours. The Alliance of Nurses for Healthy Environments supports EPA's proposed regulation of per- and polyfluoroalkyl substances (PFAS) in drinking water under the federal Safe Drinking Water Act.

EPA's proposed rule to set strong, scientifically supported drinking water standards for six PFAS is an important step toward fulfilling the Biden Administration's commitment to tackle these toxic forever chemicals. We thank EPA for the opportunity to comment and applaud EPA's recognition that both individual PFAS and chemical mixtures of PFAS can threaten human health. EPA's proposed rule would provide safer drinking water for communities from coast to

coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Alliance of Nurses for Healthy Environments (Doc. #1544, SBC-042667)

National standards to limit the concentration of PFAS in drinking water are long overdue. For decades, PFAS have been used in thousands of applications, and a peer-reviewed study estimates that PFAS may be present in the drinking water of more than 200 million Americans. EPA's proposal for six PFAS would set the national standard for PFOA and PFOS at the lowest detection level approved by the agency, and would establish limits on GenX, PFBS, PFNA, and PFHxS using a hazard index. EPA estimates that 94 million Americans currently receive drinking water contaminated by one or more these PFAS chemicals at levels above the limits proposed by EPA. The regulation of PFAS will improve drinking water safety for millions of Americans.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lawrence and Penelope Higgins (Doc. #1545, SBC-042862)

Dear Administration Regan, Assistant Administrator for Water Fox and Office of Ground & Drinking Water Director McClain,

My name is Lawrence Higgins and I live in Fairfield Maine with my wife Penny, and I am one of the leaders of the community group Fairfield Water Concerned Citizens. I'm writing in support of a strong national drinking water standard for PFAS. National drinking water standards for PFAS have been long overdue and essential for ensuring safe and clean water for all Americans.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lawrence and Penelope Higgins (Doc. #1545, SBC-042864)

The EPA's proposed rule reflects what communities across the country already know to be true: There is no safe level of PFAS in our water. For too many Americans, especially those of us who live every day in the shadow of environmental pollution, enough is enough.

We have lived here going on 29 years where we raised our kids and grandchildren. We built a barn for our alpacas, mini horse, mini mule, and mini donkey. We have always had chickens to supply our whole family and neighbors with eggs which now we were told are full of PFAS from the water and soil, which is why we support strong national drinking water standards to protect our communities from toxic forever chemicals.

October of 2020, we found out that our well water was contaminated from the sludge that had been spread in the fields across the road from our house. DEP came out and took samples of our water. Three weeks later we got a phone call from the DEP saying to stop drinking, cooking, bathing, or giving your water to your animals. This phone call knocked the wind right out of us and made us sick to our stomach. We have worked our whole lives raising our family, providing for them and trying our best to protect them in every way possible. We have invested over $200,000.00 over the past ten years building our new retirement house and a new barn for all our animals so that we could enjoy our golden retirement years. Now we find out that all of us including our animals have been poisoned with the PFAS chemicals in our water, soil, and chicken eggs from the sludge that the State of Maine allowed to be spread. We never even thought that one water test would change our lives forever. We still have a mortgage on our new house so if we wanted to sell our home right now, we could not even give it away. We are living in limbo and just waiting to see which one of our organs are going to shut down from this PFAS through no fault of our own. Nobody can even imagine what it is like sitting here knowing that these forever chemicals will one day kills us.

We have (8) alpacas, a mini-horse, a mini-Mule, a mini-Donkey, chickens, ducks, 2 dogs and 2 cats. Our local Vet does not know how much this PFAS has or will affect our animals. Now we have found out that the deer in Fairfield are contaminated with PFAS. I am sure that all the wild life in this area is also. So, you tell me what all of this has done to the value of our properties. What do you think it is doing to our physical and mental well-being? Our water is testing at around 5,690 ppt. Both mine and my Wife's PFAS levels in our blood is over 350. This is why we support strong national drinking water standards to protect our communities from toxic forever chemicals.

A strong national standard is necessary to protect public health and ensure consistent regulation across the country. It would also provide certainty and clarity for water utilities, industries, and consumers to keep our water sources free of PFAS. It encourages research to develop safer alternatives to PFAS and improve methods for detecting and removing them from our water systems.

I urge the EPA to finalize this rule as soon as possible and to continue working on developing standards for regulating PFAS together as a class of chemicals.

Thank You,

Lawrence and Penelope Higgins

4 Currier Road

Fairfield, Me. 04937

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Dylan Pilger (Doc. #1546, SBC-042679)

In summary, I STRONGLY SUPPORT [with amendments] the development of federal regulations of PFAS in public water systems by the EPA. PFAS is a real and pressing danger in my community and nationwide which requires immediate action. To enhance this regulation, particularly with regards to the health of Indigenous communities, I put forth the following three recommendations: 1) The EPA must consider possible synergistic effects of PFAS and adjust monitoring guidelines accordingly. 2) The EPA must comply with OMB Statistical Directive 15 and disaggregate Asian and Pacific Islander data. 3) The National Drinking Water Advisory Council must include Indigenous representation.

With the addition of these recommendations we can protect the safety of our communities.

Thank you kindly for your time and consideration.

Sincerely,

Dylan Pilger

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[Attachment 2 – Attachment 20: see docket ID EPA-HW-OW-2022-0114-1546:

Attachment 2 - Forever Chemicals Have Been Found in Hawaii's Environment

Attachment 3 - Combined effects and toxilogical interactions of PFAS human liver cells

Attachment 4 - Assessing the human health risks of per and polyfluoroalkyl substances

Attachment 5 - Population Asian

Attachment 6 - A new direction for water management Indigenous nation building

Attachment 7- hemming2019

Attachment 8 - High content analysis synergistic effects PFOS PFOA human breast

epithelial cell carcinogenesis

Attachment 9 - Indigenous water management

Attachment 10- jackson2019

Attachment 11 - Mapping Indigenous land management for threatened species

conservation

Attachment 12 - moggridge2019

Attachment 13 - Sprout 95MarqLRev127

Attachment 14 - Synergist effects of perfluoroalkyl acids mixtures

Attachment 15 - Water Worries: Quick Review of PFAS Contamination as a Health Threat

Attachment 16 - williams2019

Attachment 17 - mooney2019

Attachment 18 - PFAS Contamination from US Military Facilities in Mainland

Attachment 19 - poelina2019

Attachment 20 - Population Native Hawaiian and Other Pacific Islander]

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. In response to the synergistic effects of PFAS, specific discussion on dose additivity and aggregate health effects is included in section IV of the FRN. For a response on the disaggregation of Asian and Pacific Islander data, please see the EPA response to comment Doc. #1546, SBC-042677 in section 14.10 in this *Response to Comments* document. For a response to indigenous representation within the NDWAC, please see the EPA response to comment Doc. #1546, SBC-042678 in section 14.11.2 in this *Response to Comments* document.

Dylan Pilger (Doc. #1546, SBC-042675)

Mr. Michael S. Regan

Environmental Protection Agency

Mail Code 1101A

1200 Pennsylvania Avenue, N.W.

Washington, DC 20460

Dear Director Regan,

My name is Dylan Pilger. I was born and raised on the island of Oʻahu, Hawaiʻi, and am a 5th generation descendant of Chinese and Okinawan laborers who migrated to Hawaiʻi to work on plantations in Hawaiʻi. I currently reside in Honolulu, Hawaiʻi with my wife and four-year-old son. I possess a Bachelor of Science in Biochemistry, and am currently pursuing a Master of Public Health specializing in Native Hawaiian and Indigenous Health. I have a strong interest in this regulation due to its relevance to the health and well-being of not only my own family, but also the broader community here in Hawaiʻi and future generations to come. This issue was brought to my attention through learning about the disastrous impacts PFAS has had on the water systems in Okinawa (Mitchell, 2020) and recent discoveries of PFAS in the local environment in Hawaiʻi (Jedra, 2022).

I STRONGLY SUPPORT [with the following amendments] the development of federal regulations of PFAS in public water systems and believe it is in line with the Environmental Protection Agency's (EPA) mission to ensure that "Americans have clean air, land and water" and "contaminated lands and toxic sites are cleaned up by potentially responsible parties and revitalized." Per- and polyfluoroalkyl substances (PFAS) pose a real and pressing danger to the health of our communities as evidenced by a number of recent studies (Langenbach & Wilson, 2021; Ojo et al., 2021; Zuzelo, 2020). Action must be taken to protect the health of waterways and the people which rely on them.

This regulation may have additional benefits to Indigenous communities, which should be strengthened. Water is important to many Indigenous cultures. Water is of special importance in Hawaiian culture and in ancient Hawai'i complex systems of water management were created to manage this precious resource (Ho'okano, 2020; Sproat, 2020). Wai or water was not only important for daily survival, but also the embodiment of the god Kāne. Therefore, water was sacred and continues to be sacred for Native Hawaiians today. This further reinforces the need for strong regulations for protecting water.

Although this rule is a good first step, the following three amendments must be made in order for the rulemaking to reach its full potential, especially for Indigneous communities. The first recommendation is that the EPA further investigate the synergistic effects of different PFAS compounds and their impacts on human health and adjust monitoring guidelines accordingly. The second recommendation is that the EPA comply with OMB Statistical Directive 15 and disaggregate Asian and Pacific Islander data for conducting their environmental justice analysis. The third recommendation is that the National Drinking Water Advisory Council include representation from Indigenous communities.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. In response to the synergistic effects of PFAS, specific discussion on dose additivity and aggregate health effects is included in section IV of the FRN. For a response on the disaggregation of Asian and Pacific Islander data, please see the EPA response to comment Doc. #1546, SBC-042677 in section 14.10 in this *Response to Comments* document. For a response to indigenous representation within the NDWAC, please see the EPA response to comment Doc. #1546, SBC-042678 in section 14.11.2 in this *Response to Comments* document.

Gabriella Thoppil (Doc. #1551, SBC-042698)

To: Administrator Michael S. Regan

From: Dr. Gabriella Davies, MD, MPH

US Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington, DC 20460

Re: Expressing Support and Requesting Reform for Increased Regulation of Per- and Polyfluoroalkyl Substances (Docket ID No. EPA-HQ-OW-2022-0114 [Link: https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0027])

Administrator Regan,

Background Summary

The presence of per- and poly-fluoroalkyl substances (PFAS) in drinking water is a serious threat to human health, as empirical evidence has proven the multitude of adverse effects PFAS can have on the human body. [REF1: Panieri E, Baralic K, Djukic-Cosic D, Djordjevic AB, Saso L. PFAS Molecules: A Major Concern for the Human Health and the Environment. Toxics 2022, Vol 10, Page 44. 2022;10(2):44. doi:10.3390/TOXICS10020044; REF2: Fenton SE, Ducatman A, Boobis A, et al. Per- and Polyfluoroalkyl Substance Toxicity and Human Health Review: Current State of Knowledge and Strategies for Informing Future Research. Environ Toxicol Chem. 2021;40(3):606-630. doi:10.1002/ETC.4890] This new proposal of the EPA to regulate four more types of PFAS under the Safe Drinking Water Act (SDWA) with a new National Primary Drinking Water Regulation (NPDWR), and to enforce lower Maximum Contaminant Level Goals (MCLG) of PFAS in public drinking water, is an inspiring effort to ensure that our public drinking water is becoming safer. I strongly support the approval of the proposal and respectfully propose a reform toward the ideal goal of someday eliminating all PFAS from our public drinking water.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Brooke Young (Doc. #1554, SBC-043968)

May 12, 2023

Alexis Lan

Office of Ground Water and Drinking Water

Standards and Risk Management Division (Mail Code 4607M)

Environmental Protection Agency

1200 Pennsylvania Avenue NW

Washington, DC 20460

RE: EPA's Proposed PFAS National Primary Drinking Water Regulation Rulemaking Docket ID No. EPA-HQ-OW-2022-0114

Dear Ms. Lan,

PFAS compounds have been utilized for many years and pose several risks to public health across our nation. Therefore, more must be done to prevent public exposure to the contamination of PFAS compounds in our drinking water. Consequently, I support the EPA's proposed PFAS National Primary Drinking Water Regulation rulemaking (docket ID number EPA-HQ-OW-2022-0114).

As a resident of Colorado, my community has challenges related to PFAS in our drinking water. The more I learned about the exposure risks from PFAS compounds, the more I was compelled to understand the common sources in my community and know what is being done at a federal, state, and local level to prevent harmful exposure to the public. The origins and levels of contamination vary throughout the state. However, some common sources of PFAS contamination in Colorado water sources include firefighting foams, mining and extraction activities, industrial discharges, agricultural runoff, and landfill leachate.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Shelley V.L. (Doc. #1555, SBC-042559)

Federal, state, and local governments need to work together to address the risk from PFAS. The dangers are known, and perhaps when more research is conducted, the findings will be more severe than current scientific research suggests. This issue is no longer an innocent case of not understanding the dangers of the contaminants. The EPA has authority through the Safe Drinking Water Act (SDWA) to act on this issue. The SDWA provides the EPA with the authority to set national drinking water at the federal and state level standards, specifically over the maximum level of contaminant (MCLs), annual contaminant reporting requirements, as well as maximum contaminant level goals (MCLGs) for water utilities. The EPA is well within its authority to establish this regulation on behalf of the safety and health of the nation.

I support the EPA's proposal and I urge legislation to take the necessary steps to protect our drinking water from the harmful effects of these chemicals.

Thank you,

Shelley VL.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Virginia Health Catalyst (Doc. #1556, SBC-042865)

May 30, 2023

The Honorable Michael S. Regan

United States Environmental Protection Agency

1200 Pennsylvania Avenue, N.W.

Washington, DC 20460

Submitted via www.regulations.gov

Re: EPA-HQ-OW-2022-0114, PFAS National Primary Drinking Water Regulation Rulemaking.

Administrator Regan:

I am pleased to provide a comment on behalf of Virginia Health Catalyst in response to the Environmental Protection Agency's (EPA's) proposed rule: PFAS National Primary Drinking Water Regulation Rulemaking.

Virginia Health Catalyst (Catalyst) is a public health nonprofit organization that ensures all Virginians have equitable access to comprehensive health care, including oral health. Catalyst meets this mission through advocacy and programmatic initiatives anchored by our four pillars: policy, public awareness, community and clinical care, and public health.

Founded in 2010, Catalyst's roots are in oral health advocacy and education. Catalyst has also long worked to ensure Virginia's public drinking water is properly fluoridated so everyone can access this affordable and effective intervention. Since 2019, we have broadened our efforts to ensure equitable access to safe, affordable, and fluoridated drinking water that is trusted and preferred by all Virginians.

We applaud EPA's proposal to reduce per- and polyfluoroalkyl substances (PFAS) in the nation's water supply. This historic rule – if finalized – will protect the environment and strengthen the nation's public health.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Great Lakes Water Authority (GLWA) (Doc. #1558, SBC-042545)

May 12, 2023

The Honorable Michael Regan

Administrator

U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, N. W.

Washington, D.C. 20460

Re: DOCKET ID NO: EPA-HQ-OW-2022-0114

Proposed Per- and polyfluoroalkyl substances (PFAS): Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) National Primary Drinking Water Regulation Rulemaking

Dear Administrator Regan:

The Great Lakes Water Authority ("GLWA") appreciates the opportunity to submit comments on the U.S. Environmental Protection Agency's ("EPA") Proposed Per- and polyfluoroalkyl substances (PFAS): Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) National Primary Drinking Water Regulation Rulemaking. GLWA is encouraged that EPA is working to address per- and polyfluoroalkyl (PFAS) substances and shares the concerns regarding the presence of these chemicals in the environment and our collective source waters.

GLWA provides water and wastewater services to 112 member communities in southeast Michigan. This represents 3.8 million Michigan residents, including large numbers of people with difficulty affording their current water and sewerage charges. GLWA's main areas of concern with the proposed regulations include:

• Financial implications of long-term waste stream disposal options if treatment is required;

• Sampling clarifications for consecutive systems; and

• Reduction/Elimination of PFAS.

Following this discussion, GLWA addresses some specific questions posed by EPA.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. For additional discussion around waste stream disposal options, please see section 10.4 of the *Response to Comments* document. For additional discussion around consecutive systems, please see section 1.4 of the EPA response in this *Response to Comments* document.

Kristina Winter (Doc. #1559, SBC-042541)

From: kristinawinterdesigns@everyactioncustom.com on behalf of Kristina Winter kristinawinterdesigns@everyactioncustom.com

Sent: Tuesday, April 11, 2023 11:46 PM

To: OW-Docket

Subject: Docket ID No. EPA-HQ-OW-2022-0114

Dear whom it may concern,

I strongly support adoption of EPA's proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation. The proposed regulation is a critically important step to protect drinking water and public health from dangerous PFAS chemicals.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lecsy Gonzalez (Doc. #1561, SBC-042867)

May 18, 2023

U.S. Environmental Protection Agency,

EPA Docket Center,

Office of Ground Water and Drinking Water Docket,

Mail Code 2822IT,

1200 Pennsylvania Avenue NW,

Washington, DC 20460.

From: Lecsy Gonzalez, Master of Public Health Candidate from Cornell University

Re: Docket ID No. EPA-HQ-OW-2022-0114, Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

I am pleased to have the opportunity to comment on the health equity aspect of the per- and polyfluoroalkyl substances (PFAS) national primary drinking water regulation, mainly as it concerns indigenous populations. PFAS contamination is a serious health concern that has been linked to several birth complications and thyroid issues, [REF1: Stoiber, T., Evans, S., Temkin, A.M., Andrews, D.Q. and Naidenko, O.V., 2020. PFAS in drinking water: an emergent water quality threat. Water Solutions, 1(40), p.e49.; REF2: Kazwini, T., Yadav, S., Ibrar, I., Al-Juboori, R.A., Singh, L., Ganbat, N., Karbassiyazdi, E., Samal, A.K., Subbiah, S. and Altaee, A., 2022. Updated review on emerging technologies for PFAS contaminated water treatment. Chemical Engineering Research and Design.] and it is, therefore, essential to regulate its pollution in drinking water sources.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Michigan Farm Bureau (MFB) (Doc. #1562, SBC-043363)

Conclusion

Michigan Farm Bureau's grass roots member-developed policy supports funding for research and collaboration between agencies, universities, and the public and private sector to evaluate health risks and mitigation/destruction technologies for emerging contaminants like PFAS, and using sound science to determine the level of impact of emerging contaminants and determining financial impact to the regulated community before regulations are established. [FN24: Michigan Farm Bureau. 2023. Michigan Farm Bureau 2023 Policy Book, Adopted by the Delegates to the 103rd Annual Meeting. Retrieved from: https://www.michfb.com/sites/default/files/2023-01/michigan-farm-bureau-policy-book.pdf.] The American Farm Bureau Federation, of which Michigan Farm Bureau is a member, additionally calls for using the best available science and appropriate risk assessment for establishing health goals and regulatory standards that are feasible to achieve. [FN25: American Farm Bureau Federation. 2023. Farm Bureau National Policies 2023: Resolutions on National Issues Adopted by the Voting Delegates of the Member State Farm Bureaus to the 104th Annual Meeting of the American Farm Bureau Federation. Retrieved from: https://www.michfb.com/sites/default/files/2023-01/afbf-policy-book.pdf.] Farmers not only have the potential to be exposed to PFAS through drinking water, surface and groundwaters, air, and soil amendments, but have the additional responsibility to produce a safe, abundant, and affordable food supply for our nation and people around the world.

We support that EPA is strategically working to reduce the risks of exposure to PFAS. However, we urge EPA to:

1) Consider and include research, quality assurance, consistency, and transparency in its review and selection of research on health impacts of PFAS chemicals to ensure it is appropriately assigning risk based on real world results.

2) Consider the work of other agencies and organizations also collecting data and performing research on impacts and harmful concentrations of PFAS exposure to ensure there is alignment in determining health impacts based on the best quality research.

3) Proactively seek accurate cost information and acknowledge impacts and challenges of implementation for the regulated community, to not only perform the best possible economic cost-benefit analysis, but also to inform funding and technical assistance needs of regulated facilities and suppliers.

4) Work closely within its departments and with other agencies to ensure studies, research, regulatory standards, and water quality values are of the highest quality, most transparent analysis and development, and most rigorously analyzed as the information collected to develop MCLs will inform and influence subsequent regulations including those under the Clean Water Act, which will also have profound impacts on the regulated community.

We appreciate the opportunity to provide comments and look forward to working with EPA to ensure that final PFAS MCLs reflect the best research and data, have support for implementation and compliance, and meet the need of communities of all sizes – especially small, rural, and impoverished communities who will endure the most disproportionate impacts from the requirements for meeting these regulatory standards. These MCLs will set the precedent for

regulation of other PFAS as well as other emerging contaminants. It is therefore crucial for EPA to conduct this regulatory process in a way that will provide a good example for future regulations as well.

Thank you for your attention. Please feel free to contact me with any questions.

Sincerely,

Laura A. Campbell

Senior Conservation and Regulatory Relations Specialist

Michigan Farm Bureau

Office: 517-679-5332; Cell: 517-420-7936

lcampbe@michfb.com

www.michiganfarmbureau.com

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for a PFAS NPDWR, with additional considerations. Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA has considered and included the best available research on health impacts. Additional discussion on the scientific evidence for health effects is described in section 4 of the *Response to Comments* document. Specifically for discussion on how the agency followed the 2005 Guidelines for Carcinogen Risk Assessment and the scientific evidence supporting the cancer classifications, please see section 4.1.

The EPA has incorporated all available data and used the best available data whether it originated inside or outside of the agency. The EPA used data from other entities for occurrence and concentration levels, as well as for the health information, which are outlined in section IV and VI of the FRN. For additional discussion on the data sources that the EPA used for PFAS occurrence, please see section 6 of the *Response to Comments* document.

The EPA has provided clarity in the final rule based on public comments surrounding implementation and monitoring. For additional discussion on implementation guidance and monitoring requirements, please see sections 1.2 and 8.

The EPA conducted a thorough economic analysis that considered implementation, technical assistance, and funding for systems, described in the HRRCA in section XII of the FRN, as well as the Economic Analysis (USEPA, 2024a). The EPA used the most accurate cost information available at the time of the rule proposal and finalization. Please see section 13.3 of the *Response to Comments* document for additional discussion of EPA's methods on estimating costs.

The EPA's final rule represents data-driven drinking water standards that are based on the best available science, meet the requirements of SDWA, and that regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our

nation's drinking water. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation. For additional discussion on how the agency considers analytic feasibility when establishing the MCL, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Missouri Department of Natural Resources (Doc. #1563, SBC-042506)

May 19, 2023

Honorable Radhika Fox

Assistant Administrator Radhika Fox

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue NW

Washington, DC 20460

RE: Proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulations Docket ID No. EPA-HQ-OW-2022-0114

Dear Assistant Administrator Fox:

The Missouri Department of Natural Resources recognizes the considerable effort the United States Environmental Protection Agency (EPA) has taken to develop the proposed rule, Proposed PFAS National Primary Drinking Water Regulations. The proposal is a substantial undertaking and it will have a significant impact on public water systems, state primacy agencies, and public health. We recognize the importance of our shared responsibility to protect public health, and appreciate the opportunity to provide comments on the proposal.

In general, the Department agrees with most of the comments submitted by the Association of State Drinking Water Administrators (ASDWA) pertaining to this proposed rule. However, there are areas where the Department has a different opinion, which we detail in this letter. Please find the Department's comments and recommendations for improvement of the proposed rule outlined below.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Provencher Engineering, LLC (Doc. #1564, SBC-042505)

While the 4 ng/L MCL will require more PFAS treatment, it is important to understand the importance of the chemical industry's lobby and manipulation against these PFAS MCLs. They claim there is no evidence about the cancers, sicknesses, and harm caused by PFAS. But their

opinions can not be believed because they are biased by their drive for profits! The chemical inductry has lied all laong, even since 1950's. It's time for the chemical inductry to prove the converse, that PFAS is safe for human consumption! It really is all as simple and strainght-forward as I describe above. Time for public health and protection of American citizens to take priority over the chemical industry's lies and deception it has propagated since the 1950's.

Based on the above, I am fully on board and in favor, with my personal opinion being that the new PFAS MCLs proposed by the EPA must be adopted as proposed.

[Attachment 1: See Docket ID: EPA-HQ-OW-2022-0114-1564]

[Attachment 2: See Docket ID: EPA-HQ-OW-2022-0114-1564]

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Provencher Engineering, LLC (Doc. #1564, SBC-042503)

I am Donald A. Provencher, P.E., professional civil engineer and business owner of Provencher Engineering, LLC in Merrimack, NH. I am also chair of the Merrimack Village District (MVD), which is a non-profit comminuty public water supply water district funded entirely by its rate payers to provide drinking water to over 20,000 people throughout most of the town of Merrimack, NH. MVD's peak day demand is as high as 5 million gallons per day. In 2019, MVD customers voted 92% in favor to spend $14.5 million to construct two PFAS treatment plants, in addition to one other PFAS plant that was partially funded by a PFAS polluter in Merrimack. MVD represented to its customers that the treatment goal was to have no detecteable PFAS of any kind in their drinking water. With that vote, MVD customers believe that there is no level of safe PFAS in drinking water! This belief was essentially confirmed in June 2022 by EPA's PFAS health advisories which included PFOA at 0.004 ng/L. That health advisory is already 1,000 times lower as compared to EPA's proposed MCL of 4 ng/L for PFOA.

I also own and operate my own engineering company, Provencher Engineering, LLC, and provide drinking water engineering servicies to small public water systems in NH & MA, including PFAS treatment design. Most of my clients also do not want any PFAS in their drinking water. This is because the public has become aware that no level of PFAS can be considered safe based on the track record of certain PFAS, which since the 1950's has been known to cause certain sicknesses in tests conducted by PFAS manufacturers.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Minnesota Pollution Control Agency (MPCA) (Doc. #1569, SBC-042488)

May 25, 2023

Sent Via Regulations.gov

U.S. Environmental Protection Agency

Mail Code: 28221T

1200 Pennsylvania Ave. NW

Washington, D.C. 20460

RE: Docket ID No. EPA-HQ-OW-2022-0114

PFAS National Primary Drinking Water Regulation Rulemaking

Dear Administrator Regan:

The Minnesota Pollution Control Agency (MPCA) commends the U. S. Environmental Protection Agency (EPA) for taking substantive action and proposing Maximum Contaminant Levels (MCLs) for PFOS and PFOA as well as incorporating a hazard index (HI)-based PFAS MCL for PFHxS, HFPO-DA, PFNA, PFBS (HI-based PFAS MCL). These are the first regulatory values proposed by EPA to address PFAS in drinking water and will provide Safe Drinking Water Act (SDWA) administrators with critically needed regulations to ensure drinking water is protected for these PFAS chemicals. The proposed MCLs are greatly needed to begin systematically evaluating and treating the nation's drinking water, given that exposure to PFAS in drinking water has been shown to substantially increase human body burdens of PFAS even at low levels. The increased body burden can persist for many years after exposure ends (Post GB et al. 2017). The establishment of federal MCLs means that SDWA-regulated facilities in all states will be required to test, inform, and treat for PFAS in supplied drinking water – a critical outcome of this federal regulatory action.

Though the MPCA does not administer the SDWA (that responsibility is held by the Minnesota Department of Health or MDH), the MCLs are cited in Minnesota rules as Class 1 water quality standards (WQS), which protect source waters with the domestic consumption use (i.e. drinking water, food processing and similar uses) pursuant to the federal Clean Water Act. Federally established MCLs also are utilized by the MPCA as applicable standards in situations where a more restrictive state standard has not been promulgated for contaminated sites managed under the Minnesota Environmental Response and Liability Act (MERLA), the federal Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), and the Petroleum Tank Cleanup Act.

For the reasons stated above, MPCA supports EPA's development and adoption of MCLs for PFOS, PFOA and the HI-based PFAS MCL. Moreover, research taking place around the world continues to generate evidence of new impacts to people's health that are associated with PFAS

exposure. The need for promulgation of the proposed MCLs, as well as the urgent need to prevent further contamination of people and the environment by PFAS, is very clear.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Minnesota Pollution Control Agency (MPCA) (Doc. #1569, SBC-042498)

In conclusion, MPCA supports EPA's proposed action to promulgate MCLs for PFOS, PFOA and the HI-based PFAS MCL. Promulgation of the proposed MCLs will provide a measure of fairness and equity across states regarding exposure to these specific PFAS chemicals in drinking water. Promulgation will also assist MPCA in advancing other initiatives as outlined in MPCA's PFAS Blueprint, including establishing WQS for source water protection and addressing sites contaminated with PFAS.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sammamish Plateau Water and Sewer District (Doc. #1573, SBC-042459)

VIA (PDF) FEDERAL ERULEMAKING PORTAL REGULATIONS.GOV

May 24, 2023

United States Environmental Protection Agency (USEPA)

Re: Comments on Proposed Rule: Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation [Federal Register Docket ID EPA-HQ-OW-2022-0114-0027]

On behalf of the Sammamish Plateau Water and Sewer District, please accept the following comments regarding the proposed rules related to regulating Per- and Polyfluoroalkyl Substances (PFAS) under the National Primary Drinking Water Regulations. The proposed rules would require public water systems to:

• Monitor for PFAS;

• Provide public notification of the levels of PFAS in drinking water; and

• Reduce the levels of PFAS in drinking water if they exceed the proposed Maximum Contaminant Levels (MCLs).

The Sammamish Plateau Water and Sewer District (District) first detected PFAS in three of its potable groundwater wells as an outcome of UCMR3 testing in 2016. PFAS was detected in three additional wells in 2021. As a result, the District has been conducting extensive testing and monitoring for PFAS. Since PFAS is an unregulated contaminant, the District has been eagerly

awaiting USEPA or the Washington State Department of Health to establish formal drink water limits/MCLs so that the District can mitigate PFAS in its potable groundwater based upon an official regulatory standard. As such we commend and support USEPA's effort to implement formal MCLs.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Endocrine Society (Doc. #1579, SBC-042424)

Submission by the Endocrine Society to the U.S. Environmental Protection Agency regarding proposed rule "Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation" to regulations.gov docket EPA-HQ-OW-2022-0114-0027.

May 25, 2023

See attached file(s)

The Endocrine Society appreciates the opportunity to comment on the proposed National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances (PFAS). Founded in 1916, the Endocrine Society is the world's oldest, largest, and most active organization of scientists and healthcare professionals dedicated to research on hormones and the clinical treatment of patients with endocrine diseases. Our membership includes 18,000 clinicians and scientists from over 120 countries, including many researchers engaged in the study of the adverse effects of per- and polyfluoroalkyl substances (PFAS) on endocrine systems.

In general, we are encouraged by the strong standards for the six PFAS established by this new regulation. We welcome and support the proposed maximum contaminant level goal (MCLG) of zero, as well as the enforceable maximum contaminant level (MCL) standards of 4.0 ng/L for PFOA and PFOS. We also support the approach for the other PFAS covered by the regulation based on the limits proposed. We commend EPA for recognizing the effects of these persistent and bioaccumulative chemicals on endocrine systems at biologically relevant levels of exposure, with adverse effects on thyroid hormone levels, metabolic systems, reproduction, development, and others. We also appreciate the agency's recognition of the effects of mixtures of these chemicals.The proposed regulation represents an important step towards more comprehensive protections addressing PFAS, which as described in the supporting documentation for the regulation are an increasingly large class of chemicals with preliminary data indicating similar hazards across many members of this class.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Association of State and Territorial Solid Waste Management Officials (ASTSWMO) (Doc. #1583, SBC-042407)

ASTSWMO appreciates EPA's efforts to address PFAS contamination through this rulemaking and looks forward to participating in the continuing development of an effective national regulatory framework for PFAS contaminants in the environment. If you have any questions about these comments, please contact me at millie.garcia-serrano@mass.gov or (508) 9462727.

Sincerely,

Millie Garcia-Serrano (MA)

ASTSWMO President

cc: Dania Rodriguez, ASTSWMO

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Washington Suburban Sanitary Commission (WSSC Water) (Doc. #1585, SBC-042766)

May 25, 2023

Michael S. Regan

Administrator

Environmental Protection Agency 1200 Pennsylvania Avenue, N.W.

Washington, DC 20460

Re: Docket ID: EPA-HQ-OW-2022-0114, PFAS National Primary Drinking Water Regulation Rulemaking

Dear Administrator Regan,

Washington Suburban Sanitary Commission (or WSSC Water) appreciates the opportunity to provide comments on EPA's PFAS National Primary Drinking Water Regulation Rulemaking. WSSC Water is a public water system (PWS ID: MDOI 50005) serving 1.9 million customers in Montgomery County and Prince George's County in Maryland. In 105 years of service, WSSC Water has never had a Safe Drinking Water Act violation. This is a track record we are working diligently to continue to safeguard the health of our customers.

WSSC Water commends EPA's dedication to safeguarding public health against PFAS contamination through its PFAS Action Plan. Considering the relatively brief history of PFAS as an emerging contaminant, the advancements made in science, regulatory initiatives, and public awareness have been remarkable. WSSC Water is equally concerned about this issue, and our

efforts to address PFAS in our drinking water surpass the requirements of regulatory measures. We have been voluntarily monitoring PFAS at our Potomac and Patuxent Water Filtration Plants since January 2020, using the latest EPA-approved analytical methods. In 2020, we conducted an initial source water risk assessment on PFAS, and more recently, we are collaborating with other water systems in the National Capital Region to conduct source water assessments and developing plans to update our risk assessment to inform future mitigation measures.

While we appreciate EPA's efforts to establish regulatory measures to combat PFAS contamination in drinking water, wastewater, and biosolids, we are concerned that regulating PFAS under the SDWA and CWA framework, as well as designating PFOA and PFOS in municipal treatment works discharges as hazardous substances under CERCLA, ultimately places the cost burden on the public, despite the limited availability of supporting funds. Within this framework, the public is responsible for demonstrating the harm to public health after PFAS has been discharged and is also responsible for remediation. Therefore, we strongly urge EPA to consider altering its regulatory approach to regulate PFAS at the source, placing the burden of proof that the products are safe for consumers and the environment on those who manufacture and utilize PFAS products before they are manufactured. This preventive approach aligns with environmental justice and equity from a broader perspective, shifting the cost burden from the public, especially disadvantaged communities, to the polluters. We recognize EPA's proposed Significant New Use Rule on several products containing PFAS and encourage the agency to continue expanding and strengthening these efforts to eventually eliminate all PFAS chemicals from our everyday products.

WSSC Water believes that the regulation of PFAS in drinking water can be achieved through the SDWA's multi-step rulemaking process, which includes contaminant identification and occurrence via CCL and UCMR processes, risk assessment, preliminary and final regulatory determinations, proposed and final MCLs, and a six-year review process. We observe that the proposed MCLs for PFOA and PFOS, as well as the preliminary regulatory determinations for four PFAS compounds released concurrently with their proposed MCLs, do not adequately meet the statutory criteria for proving adverse health effects, occurrence, and meaningful opportunities for public health protection. We urge EPA to adhere to these mandates and ensure that future regulatory actions are based on sound science, conclusive evidence, and accurate analysis of cost and health risk reduction.

We offer our comments based on decades of successful compliance with Safe Drinking Water Act regulations, and many other voluntary steps that we have taken to protect the safety of our customers. We hope that our comments help EPA develop a final rule that is practical, implementable, and yet still provides meaningful opportunities for public health protection. We thank you in advance for your consideration.

If you have any questions regarding our comments, please contact me or Jin Shin at jin.shin@wsscwater.com.

Sincerely,

Kishia L. Powell,

General Manager / CEO

Washington Suburban Sanitary Commission

(301) 206-8500 kishia.powell@wsscwater.com

Attachment (1)

Cc: Radhika Fox, Assistant Administrator for the Office of Water, U.S. EPA

Aklile Tesfaye, Deputy General Manager of Operations, WSSC Water

James "J.C." Langley, Director of Production, WSSC Water

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. Regarding the commenter's suggestion that the PFAS be regulated "at the source," please see the discussion of the statutory framework found in section 2.3 of the *Response to Comments* document. Regarding the statutory criteria, the EPA disagrees that the statutory criteria were not adequately met for the six PFAS. Please see sections 1.1 and 1.3 of the EPA response in this *Response to Comments* document.

Center for American Progress (CAP) (Doc. #1586, SBC-042384)

May 26, 2023

The Honorable Michael S. Regan

Administrator

U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, N.W.

Washington, D.C. 20460

Re: Docket ID No. EPA-HQ-OW-2022-0114, Public Health Considerations for the Development of the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

Dear Mr. Regan,

The Center for American Progress (CAP) is an independent, nonpartisan policy institute dedicated to improving the lives of all Americans, and committed to advancing policies and practices that strengthen health and tackle environmental injustice. We are submitting these comments in response to the proposed rule to create a new National Primary Drinking Water Regulation (NPDWR) for six types of per- and polyfluoroalkyl substances (PFAS): perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO-DA, commonly known as GenX

Chemicals), perfluorohexane sulfonic acid (PFHxS), and perfluorobutane sulfonic acid (PFBS).

We applaud the Environmental Protection Agency's (EPA) efforts to limit exposure to PFAS, otherwise known as forever chemicals, after years of inaction at the federal level. Combined with the funding made available by the Infrastructure Investment and Jobs Act to help local drinking water systems monitor and remove forever chemicals and other emerging contaminants from the drinking water supply, this rule will protect Americans from these dangerous chemicals and invest in and improve their drinking water systems.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Center for American Progress (CAP) (Doc. #1586, SBC-042386)

Since the passage of the 1996 Safe Drinking Water Act (SDWA), the EPA has issued regulations on over 90 contaminants to protect the public from the danger of water contaminants to human health—including disease-causing pathogens, heavy metals, and radioactive particles— but up until now, has not acted on forever chemicals. In proposing a strict new NPDWR for forever chemicals, the EPA is taking an important step to protect public health against PFAS. The rule would set legally enforceable Maximum Contaminant Levels (MCLs) at four parts per trillion for both PFOA and PFOS, while HFPO-DA, PFBS, PFHxS, and PFNA would be regulated together as a mixture using a "Hazard Index" method. At those levels, the NPDWR would be the strictest PFAS standard ever imposed in the United States, including at the state level. These standards would further protect individuals in states with existing standards as well as individuals in states that have not taken action against PFAS. All Americans, but particularly communities overburdened by exposure to dangerous chemicals, stand to benefit. Thousands of public drinking-water systems across the United States are not being tested regularly for PFAS, and no nationwide system dedicated to tracking the proliferation of forever chemicals or their impact on communities exists. Numerous studies, however, have documented the inequitable distribution of PFAS concentration and exposure; across the United States, low-income communities and communities of color are far more likely to live near PFAS-contaminated areas [FN5: Anita Desikan and others, "Abandoned Science, Broken Promises: How the Trump Administration's Neglect of Science Is Leaving Marginalized Communities Further Behind" (Cambridge, MA: Center for Science and Democracy at the Union of Concerned Scientists, 2019) available at https://www.ucsusa.org/sites/default/files/2019-10/abandoned-science-broken-promises-web-final.pdf; Susan Lee and others, "Dirty Water: Toxic 'Forever' PFAS Chemicals are Prevalent in the Drinking Water of Environmental Justice Communities" (New York, NY: Natural Resources Defense Council, 2021) available at https://www.nrdc.org/sites/default/files/dirty-water-pfas-ej-communities-report.pdf].

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Cape Fear Public Utility Authority (CFPUA) (Doc. #1588, SBC-042379)

An important step toward regulatory guidance for PFAS

CFPUA and our community made the journey from the discovery of PFAS contamination in our source water to implementation of effective treatment in finished drinking water in the absence of federal or state drinking water regulations for PFAS. This critical gap poses significant challenges to setting contaminant-level treatment goals and communicating the new filters' treatment efficacy to customers. CFPUA believes the PFAS National Primary Drinking Water Regulation (NPDWR) proposed by the U.S. Environmental Protection Agency (EPA) includes important steps to begin eliminating this gap.

CFPUA supports adoption of the Maximum Contaminant Levels (MCLs) as proposed for PFOA and PFOS in drinking water. The MCLs are both needed to protect human health and achievable by currently available treatment technologies. We are proud to say that PFOA and PFOS are consistently not detected in the finished drinking water treated by CFPUA's new GAC filters.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Suffolk County Water Authority (SCWA) (Doc. #1589, SBC-043364)

VIA: regulations.gov

May 26, 2023

Jennifer McLain, Director

Office of Ground Water and Drinking Water

United States Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Mail Code 4601M

Washington, DC 20460

Re: Docket ID: EPA-HQ-OW-2022-0114

Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

Dear Director McLain:

Please accept these comments from the Suffolk County Water Authority (SCWA) regarding the establishment of a National Primary Drinking Water Regulation for six per- and polyfluoroalkyl substances (PFAS). The SCWA commends the Environmental Protection Agency (EPA) for proposing a National Primary Drinking Water Regulation for these PFAS because it will improve the health of public water supply customers across the nation. The SCWA has substantial experience implementing new PFAS drinking water regulations of the State of New York, and it offers these comments to enhance the feasibility and effectiveness of EPA's proposed PFAS regulation.

1. Background and Experience

The SCWA is an independent public benefit corporation operating pursuant to New York Public Authorities Law Article 5, Title 4 (Section 1074, et seq.), with its principal place of business located at 4060 Sunrise Highway, Oakdale, New York. As a public benefit corporation, SCWA does not make a profit. All revenues received by the SCWA must be used for operating expenses, construction costs, and paying outstanding debts related to the operation of its public water supply system. The SCWA and the carrying out of its powers, purposes and duties are in all respects for the benefit of the people of the County of Suffolk and State of New York, for the improvement of their health, welfare and prosperity. Pursuant to its statute, the SCWA's purposes are public purposes, and it performs an essential governmental function.

The SCWA is one of the largest groundwater suppliers in the nation and the largest in New York State serving approximately 1.2 million Suffolk County residents. The SCWA has 242 pump stations with approximately 600 wells in its distribution system located throughout Suffolk County. The SCWA currently has approximately 169 granular activated carbon (GAC) treatment systems, 29 iron removal systems, four resin treatment systems, two packed tower aeration treatment systems, one reverse osmosis treatment system, and 17 advanced oxidation process (AOP) treatment systems. The SCWA distribution system includes approximately 6,053 miles of water main, 36,193 fire hydrants, 48 booster stations, and 69 water storage facilities with the capacity to store nearly 73.6 million gallons of potable drinking water. To meet the demands of its customers, the SCWA pumped 71.9 billion gallons of water in the calendar year 2022.

The SCWA also has its own state-of-the-art drinking water testing laboratory that analyzes more than 91,000 samples per year to produce over 190,000 tests and more than 1.7 million test results for more than 400 different chemical constituents. The SCWA's laboratory is approved for testing constituents identified under the federal Unregulated Contaminants Monitoring Rules (UCMR) 1, 2, 3, 4 and 5, and it is approved to monitor for the subject PFAS using EPA Method 533.

In August 2020, New York State adopted contaminant specific maximum contaminant levels (MCLs) for PFOA and PFOA of 10 parts per trillion (ppt), respectively. The SCWA installed GAC filters to provide treatment for wells where PFOA and PFOS have been detected above the New York MCLs, and it can reliably treat these PFAS to non-detectable levels. For over two years, the SCWA has had a full-scale pilot of an ion exchange resin for PFAS removal to

determine the efficacy of this treatment technology as compared to GAC filter media. So far, the SCWA installed more than 25 GAC filtration systems in order to meet the New York MCLs over a four to five year period, and additional systems are being purchased as fast as they can be manufactured. Thus, SCWA has substantial experience with the implementation of new PFAS drinking water regulations.

In light of this background and experience, the SCWA offers the following comments in an effort to enhance the feasibility and effectiveness of EPA's proposed PFAS regulations.

EPA Response: The EPA appreciates this information about the commenters' experience in addressing PFAS in drinking water regulations.

New York Section American Water Works Association (NYSAWWA) (Doc. #1591, SBC-042377)

We appreciate your attention to these important matters and the opportunity to provide our input. As a water supplier dedicated to the well-being of our community, we strongly believe that the final regulations should strike a balance between protecting public health and considering the practical challenges faced by water suppliers.

Thank you for your time and consideration. We look forward to continued collaboration and the opportunity to contribute to the development of effective and scientifically sound PFAS regulations.

Sincerely,

David A. Rowley, PE

NYSAWWA Regulatory Review Chair

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Pennsylvania Chamber of Business and Industry (Doc. #1592, SBC-042799)

For These Reasons, We Request EPA Withdraw This Rulemaking for Future Consideration

As we noted in joint comment letter co-signed by 21 other state chambers of commerce and business groups, a durable, workable national framework on this issue can avoid a costly and complicated patchwork of state-level regulatory approaches. However, the rules as proposed will impose substantial costs and challenges to the regulated community, and we urge a withdrawal of this rule for further consideration on these issues.

On behalf of the Pennsylvania Chamber of Business and Industry, thank you for the opportunity to comment on this matter.

Sincerely,

Kevin Sunday

Director, Government Affairs

EPA Response: The EPA disagrees with this commenter's request for withdrawal of the final PFAS NPDWR due to what they believe to be substantial costs and challenges to the regulated community. The EPA acknowledges the commenter's support for a workable national framework on this issue. Please see section 1.3 of the EPA response in this *Response to Comments* document. For additional discussion on costs, please see section XII of the FRN, as well as additional discussion in section 13.3 of the *Response to Comments* document. For additional responses made to the U.S. Chamber of Commerce's comment letter, especially relating to the costs and challenges of the rule, please see the EPA response to comments Doc. #1713, SBC-045874 and Doc. #1713, SBC-045926 in section 1.3 in this *Response to Comments* document.

Public Health, Seattle & King County (PHSKC) (Doc. #1594, SBC-042352)

Administrator Regan

Attention: Alexis Lan

Office of Ground Water and Drinking Water,

Standards and Risk Management Division (Mail Code 4607M),

Environmental Protection Agency,

1200 Pennsylvania Avenue NW,

Washington, DC 20460; Telephone: 202-564-0841

email: PFASNPDWR@epa.gov

Re: Proposed PFAS National Primary Drinking Water Regulation; Docket ID: EPA-HQ-OW-2022-0114 May 26, 2023

Dear Administrator Regan:

Public Health – Seattle & King County (PHSKC) is grateful for the opportunity to comment on the proposed PFAS National Primary Drinking Water Regulation; Docket ID: EPA-HQ-OW-2022-0114.

King County is the 13th largest county in the United States, and our local health department serves over 2.2 million residents. A number of Cities in King County have PFAS contaminated drinking water identified through EPA's Unregulated Contaminant Monitoring Rule 3 (UCMR 3) or through testing for Washington State's PFAS drinking water standards, or State Action Levels (SALs). PHSKC has concerns about PFAS in drinking water sources in King County, and

expect the number of utilities identified with PFAS contaminated drinking water to increase when testing and regulation are required. King County thanks EPA for their actions in issuing a final regulatory determination for PFOS and PFOA, and for developing Maximum Contaminant Levels (MCLs) and Maximum Contaminant Level Goals (MCLGs) for PFOS, PFOA, GenX, PFBS, PFNA, and PFHxS. PHSKC feels the approach and levels set by EPA are strong and will better protect the health and lives of residents in our county.

PHSKC appreciates EPA's approach, which includes identifying specific MCLs and MCLGs for chemicals that are well characterized for their significant health impacts, like PFOS and PFOA.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Public Health, Seattle & King County (PHSKC) (Doc. #1594, SBC-042364)

Again, PHSKC thanks EPA for the opportunity to comment and for the proposed actions to ensure drinking water in the US is healthy and safe from PFAS contamination. Please do not hesitate to reach out to PHSKC's senior toxicologist, Dr. Shirlee Tan (shirlee.tan@kingcounty.gov) with any follow-up questions.

Respectfully,

Faisal Khan, MBBS, MPH

Director, Public Health – Seattle and King County401 5th Ave, 13th Floor, Seattle, WA 98104
Tel: (206) 848-0331

E-mail: fakhan@kingcounty.gov

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR.

Alameda County Water District (ACWD) (Doc. #1595, SBC-042345)

The Alameda County Water District (ACWD) appreciates the opportunity to submit comments on Environmental Protection Agency's (EPA) proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulations (NPDWR). The EPA is proposing the NPDWR to strengthen public health protection. As a public water utility that serves water to approximately 350,000 people in the cities of Fremont, Newark, and Union City in the San Francisco Bay Area, ACWD has a strong commitment to the protection of public health through the development of more stringent drinking water regulations.

On March 29, 2023, EPA announced in the Federal Registry the availability for public comment of the proposed PFAS NPDWR.

ACWD supports the development of EPA's PFAS NPDWR to protect public health, and requests consideration of the comments that are noted in the letter uploaded to this portal.

Thank you for your consideration.

May 26, 2023

Mr. Michael Regan

Administrator

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue. NW

Washington, DC 20460

Dear Mr. Regan,

Subject: Comments on Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking

Water Regulations, Docket ID No. EPA-HQ-OW-2022-0114

The Alameda County Water District (ACWD) appreciates the opportunity to submit comments on Environmental Protection Agency's (EPA) proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulations (NPDWR). The EPA is proposing the NPDWR to strengthen public health protection. As a public water utility that serves water to approximately 350,000 people in the cities of Fremont, Newark, and Union City in the San Francisco Bay Area, ACWD has a strong commitment to the protection of public health through the development of more stringent drinking water regulations.

On March 29, 2023, EPA announced in the Federal Registry the availability for public comment of the proposed PFAS NPDWR.

ACWD supports the development of EPA's PFAS NPDWR to protect public health, and requests consideration of the following comments:

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR.

Michigan Department of Environment, Great Lakes, and Energy (EGLE) Drinking Water and Environmental Health Division (DWEHD) (Doc. #1597, SBC-042970)

To: Office of Ground Water and Drinking Water U.S. Environmental Protection Agency

From: Drinking Water and Environmental Health Division

Michigan Department of Environment, Great Lakes, and Energy

Date: May 26, 2023

Subject: Comments on Proposed PFAS National Primary Drinking Water Regulation; Docket No. EPA-HQ-OW-2022-0114

The Michigan Department of Environment, Great Lakes, and Energy (EGLE) Drinking Water and Environmental Health Division (DWEHD) appreciates the opportunity to review and provide comment on the Environmental Protection Agency PFAS National Primary Drinking Water Regulation Rulemaking, as published in the Federal Register on March 29, 2023 (Vol. 88, No. 60, Wednesday, March 29, 2023).

EGLE DWEHD stands in support of the effort to establish a National Primary Drinking Water Regulation (NPDWR) for per- and polyfluoroalkyl substances (PFAS) based on the best available peer-reviewed scientific study, as outlined in the aforementioned publication. EGLE DWEHD respectfully provides the following comments for EPA's consideration.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Michigan Department of Environment, Great Lakes, and Energy (EGLE) Drinking Water and Environmental Health Division (DWEHD) (Doc. #1597, SBC-042974)

B. Maximum Contaminant Level Goals/Maximum Contaminant Levels for 6 PFAS

Having reviewed Sections V and VI of the proposed NPDWR, EGLE DWEHD generally agrees with EPA's proposed maximum contaminant level goals (MCLGs) and maximum contaminant levels (MCLs) for four of the six PFAS compounds, (PFOA, PFOS, HFPO-DA, PFHxS) based on the best available peer-reviewed scientific study.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

National Tribal Water Council-Tribal PFAS Working Group (NTWCTPWG) (Doc. #1598, SBC-042344)

Conclusion

PFAS are known as "forever chemicals" that persist in the environment, bioaccumulate in plants and throughout the food chain into animals (e.g., Stahl et al., 2023; Zhang et al., 2022; Andvik et al., 2022) and that are important to tribal subsistence, cultural, and ceremonial practices. It cannot be overstated that tribal people have no alternatives when it comes to their environmental exposures to PFAS. The NTWC-TPWG supports the adoption of primary drinking water regulations for PFAS chemicals.

On behalf of the NTWC-TPWG, we thank you for the opportunity to comment on the proposed National Primary Drinking Water Regulation (NPDWR) for six PFAS chemicals.. Should you or

your staff have questions or comments regarding our letter, please contact Page Hingst, TSC at (402) 8573347 or Dianne Barton, NTTC Chair, at (503) 887-5370. You may also contact Elaine Wilson, NTWC Project Manager, at Elaine.Wilson@nau.edu for any questions regarding the NTWC-TPWG.

Sincerely,

Ken Norton, Chair Page Hingst, Vice Chair

National Tribal Water Council Tribal Science Council

Dianne Barton, Chair Mark Junker, Chair

National Tribal Toxics Council Tribal Waste & Response Steering Committee

Cc: Karen Gude, US EPA Office of Water

References

Aker, A., et al., Associations between dietary profiles and perfluoroalkyl acids in Inuit youth and adults, Science of the Total Environment, 857 (2023a) 159557.

Aker, A., et al., Plasma concentrations of perfluoroalkyl acids and their determinants in youth and adults from Nunavik, Canada, Chemosphere 310 (2023b) 136797.

Andvik, C., et al., Emerging and legacy contaminants in common minke whale from the Barents sea, Environmental Pollution 319 (2023) 121001.

Butt, C.M., et al., Biotransformation pathways of fluorotelomer-based polyfluoroalkyl substances: A review, Environmental Toxicology and Chemistry, Vol. 33, No. 2, pp 243-267, 2014.

Stahl, L.L., et al., Contaminants in fish from U.S. rivers: Probability-based national assessments, Science of the Total Environment 861 (2023) 160557.

Zhang, W., et al., Uptake of per- and polyfluoroalkyl substances (PFAS) by soybean across two generations, Journal of Hazardous Materials Advances 8 (2022) 100170.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

First Focus on Children (Doc. #1599, SBC-042333)

Submitted via www.regulations.gov

May 22, 2023

Dr. Jennifer L. McLain

Director, Office of Ground Water and Drinking Water U.S. Environmental Protection Agency

1201 Constitution Ave NW Washington, DC 20004

Re: Docket No. EPA-HQ-OW-2022-0114, "Per- and polyfluoroalkyl substances (PFAS):

Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) National Primary Drinking Water Regulation Rulemaking

On behalf of First Focus on Children, thank you for the opportunity to comment on the proposed rule concerning Per- and polyfluoroalkyl substances (PFAS): Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) National Primary Drinking Water Regulation Rulemaking. First Focus on Children is a bipartisan children's advocacy organization dedicated to ensuring children and families are a priority in federal policy and budget decisions. We commend the U.S. Environmental Protection Agency (EPA) for putting children's health and well-being at the forefront of their policy making. Under the proposed rule, EPA thoughtfully advances its commitment to ensuring children have access to clean, safe drinking water as they develop. We further applaud EPA for implementing enforceable limits on PFAS levels in our drinking water.

EPA's proposal takes much needed steps to reduce our children's exposure to PFAS. This rule creates a National Primary Drinking Water Regulation (NPDWR) that would establish Maximum Contaminant Levels (MCLs) for six types PFAS in drinking water, as well as Maximum Contaminant Level Goals MCLGs). These MCLs are legally enforceable and will apply to perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) as individual chemicals and perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO-DA, or GenX Chemicals), perfluorohexane sulfonic acid PFHxS), and perfluorobutane sulfonic acid (PFBS) as a combined mixture. Additionally the MCLGs, while not legally enforceable, require that municipalities alert the public if PFAS levels are above the required threshold.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lehigh County Authority (LCA) (Doc. #1600, SBC-042806)

May 26, 2023

Michael Regan

Administrator

Environmental Protection Agency 1200 Pennsylvania Avenue, N.W.

Mail Code: 1309

Washington, DC 20004

SUBMITTED ELECTRONICALLY

RE: Per- and polyfluoroalkyl substances (PFAS): Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) National Primary Drinking Water Regulation Rulemaking, Docket No. (Docket ID: EPA-HW-OW-2022-0114)

Dear Administrator Regan,

Lehigh County Authority (LCA) is a medium sized water utility serving approximately 200,000 people in the City of Allentown and surrounding communities in eastern Pennsylvania. We appreciate the opportunity to comment on the Environmental Protection Agency's proposed rule, PFAS National Primary Drinking Water Regulation Rulemaking – EPA-HQ-OW-2022-0114.

Per- and Polyfluoroalkyl Substances (PFAS) have gained public attention over the past several years; however, the chemical class has been in production since the 1940s. LCA supports EPA's efforts to ensure safe drinking water for all citizens by establishing national primary drinking water regulations for perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS).

Due to the importance of this rulemaking, LCA has reviewed the proposed rule and offers the following comments for your consideration.

EPA Response: The EPA appreciates this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lehigh County Authority (LCA) (Doc. #1600, SBC-042812)

PFOA and PFOS are the most common PFAS compounds found in the nation's drinking water. Based on the effectiveness of treatment methods available for PFOA and PFOS, which will also be effective in removing other per- and polyfluoroalkyl substances, we believe the establishment of regulatory standards for PFOA and PFOS will provide significant public health protections from PFAS compounds.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lehigh County Authority (LCA) (Doc. #1600, SBC-042826)

Summary

LCA's mission is to protect public health and the environment by providing high-quality, safe and reliable water services to the communities that we serve. We support the establishment of national primary drinking water standards for PFAS, and applaud EPA's efforts to address this important public health issue. However, it is important for EPA to consider the burden on utilities, which translates to a rate impact to our customers. The comments provided in this submission are intended to offer reasonable refinements to the approaches EPA has developed, to ensure utilities can achieve compliance while navigating the many challenges we face.

Thank you for the opportunity to comment on this important regulatory change. Please contact me at lieselgross@lehighcountyauthority.org or 610-398-2503 if you wish to discuss the comments and concerns expressed in this submission.

Sincerely,

Liesel M. Gross

Chief Executive Officer

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-042876)

MWWA's comments to EPA draw on our actual experiences in complying with PFAS drinking water standards, as Massachusetts set drinking water and groundwater cleanup standards prior to the release of EPA's proposed PFAS standards. In October 2020, the Massachusetts Department of Environmental Protection (MassDEP) promulgated a Massachusetts Maximum Contaminant Level (MMCL) of 20 ppt for any one, or the sum, of six PFAS compounds: perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS), perfluorononanoic acid (PFNA), perfluorohexanesulfonic acid (PFHxS), perfluoroheptanoic acid (PFHpA), and perfluorodecanoic acid (PFDA), hereafter referred to as PFAS6.

EPA needs to carefully consider the implementation challenges for PWS caused by regulatory efforts related to PFAS which we will outline below. MWWA is not sure that EPA has put enough time into this effort before moving forward with the proposed drinking water regulations. Without adequate consideration regarding these implementation challenges, public confidence in drinking water could be further jeopardized. EPA must address these challenges before finalizing the rule. We hope that EPA will fully consider the information we are providing on behalf of Massachusetts PWS and will craft a final rule that is reasonable in its expectations of implementation and schedule.

EPA Response: The EPA acknowledges and appreciates this comment expressing concerns about the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. For responses to concerns about implementation, please see section 11 of the *Response to Comments* document. Also note that the EPA has provided clarity on monitoring requirements in the final rule based on public comments and is summarized in section VIII of the FRN. For concerns about public confidence in drinking water, please see section 1.2 of the EPA response in this *Response to Comments* document.

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-042872)

May 26, 2023

Mr. Michael S. Regan, Administrator

U.S. Environmental Protection Agency

EPA Docket Center, OLEM Docket, Mail Code 28221T

1200 Pennsylvania Avenue, NW

Washington, DC 20460

RE: Docket ID No. EPA-HQ-OW-2022-0114 – National Primary Drinking

Water Regulation Rulemaking for per- and polyfluoroalkyl substances (PFAS)

Dear Administrator Regan:

The Massachusetts Water Works Association (MWWA) is a non-profit organization representing more than 1,400 water supply professionals across Massachusetts. Let us state unequivocally for the record that public health protection is the primary mission and goal of all Public Water Systems (PWS). This role is taken very seriously and PWS work diligently to ensure that the water provided to our residents and businesses meets all Safe Drinking Water Act (SDWA) standards. In Massachusetts, we take great pride in the fact that according to the Environmental Protection Agency's (EPA) own statistics for Quarter 1 of 2023, 96% of community water systems met all applicable health-based standards and 91% of the population served by community water systems received drinking water which met all applicable health-based drinking water standards.

We are providing the following comments on EPA's proposed National Primary Drinking Water Regulation Rulemaking for per- and polyfluoroalkyl substances (PFAS). We note that EPA has engaged in rulemaking on several major rules impacting the water sector concurrently. With public comments all due within the past month, it is challenging to give each rule the thorough review it requires. This regulation is complicated, with new concepts not well understood by the drinking water profession. We are discouraged that EPA denied our request to extend the public comment period to give more time for thoughtful review on a regulation that will have substantial impact on our industry, management of our water resources, and the customers we serve. We fully support efforts to expand verified public health protections, but EPA needs to consider the challenges associated with implementation of the proposed PFAS rule before finalizing these standards.

General Comments:

MWWA and its members are very comfortable offering our expertise and opinions as they relate to the very real impact that the proposed drinking water standards will have on our operations and related services. However, our ability to offer comments and opinions on more nuanced toxicological principles is well beyond our area of expertise. We are not toxicologists, nor epidemiologists, so we will leave it to other experts to comment on the appropriateness of the standards from a public health protection standpoint. We do know that while EPA is moving

forward with drinking water standards, health studies and exposure assessments are still ongoing [FN1: https://www.atsdr.cdc.gov/pfas/activities/studies.html] by the Centers for Disease Control and the Agency for Toxic Substances and Disease Registry to "provide a better scientific understanding about the relationships between PFAS exposure and certain health outcomes and help people understand their risk for health effects." [FN2: https://www.atsdr.cdc.gov/pfas/activities/pease.html#anchor_45429]

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for public health protections, while offering concerns for the PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. For responses to concerns about the lack of extension of the comment period, please see section 2.3 and 17 of the *Response to Comments* document; this is also addressed in section 1.3 of the EPA response in this *Response to Comments* document. While some health studies and exposure assessments may be ongoing for other PFAS, the EPA has used the best available peer reviewed science to set the MCLs and Hazard Index approach. For more information, please see sections 3.1.1 and 3.2.1 of the *Response to Comments* document. Sections III.B and IV of the FRN, as well as sections 4.1, 4.2, and 4.3.3 of the *Response to Comments* document, describe the EPA's health-based approach using the best available science for the toxicity assessments of the six PFAS, providing sufficient evidence of the health effects of these six PFAS.

Arlington County Virginia (Doc. #1603, SBC-043021)

Conclusion

For the reasons described herein, we are not supportive of the proposed regulations at the levels being set. We understand both the public interest in, and justification for, regulating these chemicals. However, we believe that focusing the regulatory burden predominantly upon the water industry is misguided. Further, we believe that the remarkably aggressive stance – in terms of MCL levels and timeline – is unwarranted and misleading for consumers. PFAS will continue to exist in the products which our customers purchase and in the environments they inhabit at levels hundreds and thousands of times higher than the levels which are being established for drinking water. In fact, absent complex producer regulations, of which we are unaware, PFAS presence in products and the environment will likely continue to increase even while drinking water levels are driven to the limits of measurable technology.

We would recommend a more measured approach where resources are directed to the pathways which do exhibit exceptionally high levels of PFAS. This should include restrictions on introduction of additional harmful chemicals to the consumer product stream, as well as a more measured approach to regulation in the drinking water industry. Such a regulatory framework in the drinking water industry should focus the limited resources available upon drinking water systems with excessive levels of PFAS, and MCL levels should be increased to focus investments in these communities while studies proceed to better understand the relative impact of PFAS ingestion in humans amongst the many pathways that have been identified. It is also

recommended that we continue the UCMR5 monitoring requirements for PFAS elements to gather data from water systems which will provide better insight into the characteristics of PFAS in our water infrastructure.

Such a graduated approach would allow for more intelligent and effective utilization of limited resources in research, engineering, construction, equipment, manufacturing, regulatory capacity, and public and private funding.

Sincerely,

Greg Emanuel, P.E.

Director, Department of Environmental Services

Arlington County

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. For a response to the suggested approach of restricting harmful chemicals instead of regulations for drinking water, please see section 2.3 of the *Response to Comments* document. The EPA believes there are sufficient studies to understand the relative impact of PFAS ingestion in humans based on the SDWA requirements. Please see section 3.1.1 and 3.2.1 of the EPA response in this *Response to Comments* document for more information. The EPA does not agree that MCL levels should be increased. Please see sections 5.1.1, 5.2 and 5.3 of the EPA response in this *Response to Comments* document. The EPA does not believe that the MCL levels and timeline are misleading to consumers. Please see section 1.2 of the EPA response in this *Response to Comments* document for comments regarding communication of the NPDWR. Lastly, the EPA does not believe that UCMR 5 is necessary to gather data from water systems to provide better insight into PFAS characteristics for this rule action. The EPA is not obligated to use UCMR prior to finalization of the rule, but did include preliminary data for discussion. For further discussion of UCMR 5 data, please see section 6.8 of the *Response to Comments* document, as well as the EPA response to comment Doc. #1714, SBC-045945 in section 1.3 in this *Response to Comments* document.

Arlington County Virginia (Doc. #1603, SBC-043004)

While we understand the value in regulating these chemicals, the proposed regulations do not target the polluters where investment would most likely be effective for the public and drive the right behaviors to reduce PFAS which have become ubiquitous in most environments in many forms. Instead, they target all water consumers where the inevitable significant resulting rate increases will disproportionately affect low-income citizens. The proposed limits are set far too low without a sufficient basis in logic, and we believe the costs and impacts are significantly understated. Finally, the implementation schedule is unrealistic and will lead to poor decisions that affect all rate payers. These concerns are laid out in greater detail in the attached letter. We

do appreciate the opportunity to comment on EPA's proposed PFAS National Primary Drinking Water Regulations, and strongly urge the EPA to reconsider its approach.

May 26, 2023

Ms. Radhika Fox

Assistant Administrator

Office of Water - U.S. Environmental Protection Agency

EPA Docket Center

Office of Ground and Drinking Water Docket

Mail Code 2822IT

1200 Pennsylvania Avenue

Washington, D.C. 20460

Re: Docket ID No. EPA-HQ-OW-2022-0114

PFAS National Primary Drinking Water Regulation Rulemaking

Dear Assistant Administrator Fox:

Arlington County operates a public water and sewer utility that serves daily 230,000 residents, 160,000 workers, tens of thousands of visitors, and some of the Federal Government's most critical facilities to include the National Foreign Affairs Training Center, Joint Base Myer Henderson Hall, and Arlington National Cemetery. We purchase our drinking water from the Washington Aqueduct Division (WAD)of the Army Corps of Engineers. Along with our partners, DC Water and Fairfax Water, we serve on the wholesale Customer Board which is responsible for providing and allocating all operational and capital costs at the WAD. In addition to the important customers described previously, the WAD is the sole or primary provider for the White House, Pentagon, Reagan National Airport, US Capitol grounds, Central Intelligence Agency, and every other Federal installation in Washington DC, Arlington, and much of Fairfax County.

Arlington County understands and fundamentally supports the EPA's interest in regulating this family of chemical compounds. However, we believe that there are numerous challenges with the proposed NPDWR regulations which will not further our shared goals of protecting public welfare.

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. For a response to the concern that the regulations do not target polluters, please see section 2.3 of the *Response to Comments* document. For a response to the concern that there will be significant rate increases and that the regulations will disproportionally

impact low-income residents, please see section 14.10 of the *Response to Comments* document. For a response to the concern that the regulation imposes limits that are too low without justification, please see section 5.1.1, 5.2 and 5.3 of the *Response to Comments* document. The EPA disagrees that the costs are understated. Please see sections XII.A.2.b, XII.A.3.b and XII.A.4.b of the FRN for this rule for responses to comments about the analyzed costs.

Mass Comment Campaign sponsored by National Caucus of Environmental Legislators (NCEL) (Doc. #1605, SBC-042332)

May 25, 2023

Administrator Michael S. Regan

U.S. Environmental Protection Agency

EPA Docket Center, OW Docket

Mail Code 28221T

1200 Pennsylvania Avenue NW Washington, DC 20460

Dear Administrator Regan,

Re: Per- and Polyfluoroalkyl Substances (PFAS): Proposed National Primary Drinking Water Regulations (Docket ID: EPA-HQ-OW-2022-0114)

The undersigned 278 state legislators strongly support the regulation of per- and polyfluoroalkyl substances (PFAS) in drinking water under the authority of the federal Safe Drinking Water Act, as proposed by the Environmental Protection Agency (EPA) and published in the Federal Register on March 29, 2023. EPA's proposal to set strong, scientifically supported drinking water standards for six PFAS is an important step toward fulfilling the Biden Administration's commitment to tackle these toxic forever chemicals. We commend EPA's recognition that both individual PFAS and chemical mixtures of PFAS can threaten human health. We urge you to finalize the standards as quickly as possible.

National standards to limit the concentration of PFAS in drinking water are long overdue. For decades, PFAS have been used in thousands of applications, and a peer-reviewed study estimates that PFAS may be present in the drinking water of more than 200 million people across the country. EPA's proposal for six PFAS would set the national standard for PFOA and PFOS at a level of four parts per trillion and would establish limits on GenX, PFBS, PFNA, and PFHxS using a hazard index. EPA estimates that 94 million people currently receive drinking water contaminated by one or more of these PFAS chemicals at levels above the limits proposed by EPA. The regulation of PFAS will improve drinking water safety for millions of residents we serve.

Due to drinking water being a significant pathway of PFAS exposure, addressing contamination before it reaches our taps is key to reducing associated health problems. The Safe Drinking

Water Act requires that national drinking water standards present a meaningful opportunity to reduce health risks. EPA's proposal would significantly reduce exposure to PFAS in drinking water and as a result, lower risks of related health impacts.

The PFAS addressed by EPA's proposal are among a class of thousands of forever chemicals. EPA's proposal to use a hazard index to address multiple co-occurring PFAS recognizes the risks associated with harmful chemical mixtures. Like many members of the PFAS class, PFBS, PFNA, GenX, and PFHxS have similar chemical structures and cause similar health effects. Many of the communities we represent are exposed and harmed by mixtures of those PFAS in their drinking water. EPA's approach provides a framework for addressing additional PFAS and mixtures of chemicals in the future, which would allow the Agency to move more rapidly to protect public health.

Under EPA's proposal, drinking water utilities will be required to test water for PFOA, PFOS, GenX, PFBS, PFNA, and PFHxS and install treatment technologies to reduce the concentrations of these chemicals to the level of EPA's proposed "maximum contaminant levels" or lower. Fortunately, proven technology is available that will not only reduce the presence of the six PFAS in EPA's proposal, but will also improve protection against other PFAS compounds and common contaminants.

While some water utilities have already installed water treatment technology capable of reducing PFAS, many are not yet equipped to do so. To help communities, Congress passed the Bipartisan Infrastructure Law which provides $9 billion in funding for drinking water treatment upgrades, and an additional $11.7 billion for other necessary drinking water infrastructure needs. This funding will aid utilities in meeting EPA's proposed drinking water standards and improve drinking water safety.

As state legislators, we are well aware of the prevalent nature of PFAS contamination and the need to curb all pathways of PFAS exposure and sources of pollution. National standards for PFAS in drinking water is an important step for urgently needed action to address PFAS contamination and exposure.

Thank you for your consideration.

[Table 1 - List of signatories: See Docket ID EPA-HQ-OW-2022-0114-1605]

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

American Water Works Company Inc. (Doc. #1608, SBC-043980)

In conclusion, providing safe, reliable, and affordable water is American Water's business, and we look forward to working cooperatively and collaboratively with the U.S. EPA, Congress,

regulators, and policymakers so that the implementation of these proposed water standards protects customers, communities, and the general public.

Please direct any questions regarding these comments to my attention at 856-676-5799 or Lynda.DiMenna@amwater.com.

Sincerely,

Lynda DiMenna

VP Chief Environmental and Safety Officer

Detailed American Water Comments on

Proposed PFAS National Primary Drinking Water Regulation

Docket ID No. EPA-HQ-OW-2022-0114

May 24, 2023

American Water Works Company, Inc. (American Water) appreciates the opportunity to provide comment to the U.S. Environmental Protection Agency (U.S. EPA) regarding your preliminary regulatory determinations and proposed national primary drinking water regulation for certain per- and polyfluoroalkyl substances (PFAS) as described in the March 29, 2023, Federal Register (88 FR 18638). American Water provides drinking water and wastewater service to an estimated 14 million people in 24 states, including more than 300 public water drinking water systems. In addition to our regulated operations, we also provide water and wastewater services to various military installations across the country through our regulated-like business, Military Services Group. We currently operate 50-year contracts at 18 military installations across the nation as part of the U.S. Government's Utilities Privatization Program. Our comments are based on our extensive experience in designing and installing treatment for groundwater and surface water, including treatment for PFAS that allows us to meet state standards, and implementing drinking water regulations across our footprint.

EPA Response: The EPA appreciates this comment.

American Water Works Company Inc. (Doc. #1608, SBC-043974)

American Water Works Company, Inc. (American Water) appreciates the opportunity to provide comment to the U.S. Environmental Protection Agency (U.S. EPA) regarding your preliminary regulatory determinations and proposed national primary drinking water regulation for certain per- and polyfluoroalkyl substances (PFAS) as described in the March 29, 2023, Federal Register (88 FR 18638). American Water provides drinking water and wastewater service to an estimated 14 million people in 24 states, including more than 300 public water drinking water systems. In addition to our regulated operations, we also provide water and wastewater services to various military installations across the country through our regulated-like business, Military Services Group. We currently operate 50-year contracts at 18 military installations across the nation as

part of the U.S. Government's Utilities Privatization Program. Our comments are based on our extensive experience in designing and installing treatment for groundwater and surface water, including treatment for PFAS that allows us to meet state standards, and implementing drinking water regulations across our footprint.

May 24, 2023

Water Docket

Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington, DC 20460

RE: Docket ID No. EPA-HQ-OW-2022-0114

Comment Clerk:

American Water Works Company, Inc. (American Water) appreciates the opportunity to provide comment to the U.S. Environmental Protection Agency (U.S. EPA) regarding your preliminary regulatory determinations and proposed national primary drinking water regulation for certain per- and polyfluoroalkyl substances (PFAS) as described in the March 29, 2023, Federal Register (88 FR 18638). American Water provides drinking water and wastewater service to an estimated 14 million people in 24 states, including more than 300 public water drinking water systems. In addition to our regulated operations, we also provide water and wastewater services to various military installations across the country through our regulated-like business, Military Services Group. We currently operate 50-year contracts at 18 military installations across the nation as part of the U.S. Government's Utilities Privatization Program. Our comments are based on our extensive experience in designing and installing treatment for groundwater and surface water, including treatment for PFAS that allows us to meet state standards, and implementing drinking water regulations across our footprint.

American Water supports the U.S. EPA's efforts to protect public health by proposing national drinking water standards for PFAS. These contaminants are among the multiple challenges the water industry faces regarding water quality, quantity, and reliability. That is why American Water remains committed to being a leader in the U.S. water and wastewater industry and a provider of solutions to these challenges.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR.

Prince William County Service Authority (Doc. #1609, SBC-042829)

May 25, 2023

Ms. Radhika Fox

Assistant Administrator

Office of Water

U.S. Environmental Protection Agency

EPA Docket Center

Office of Ground and Drinking Water Docket

Mail Code 2822IT

1200 Pennsylvania Avenue

Washington, D.C. 20460

Re: Docket ID No. EPA-HQ-OW-2022-0114

PFAS National Primary Drinking Water Regulation Rulemaking

Dear Assistant Administrator Fox:

The Prince William County Service Authority (Service Authority) is a not-for-profit utility that proudly provides high quality drinking water to over 380,000 residents in Prince William County, Virginia. We purchase water from two purveyors; Fairfax Water and the City of Manassas.

The Service Authority supports the development of primary drinking water standards for PFAS compounds based on the best available science and understanding of risk. A national standard which provides clarity for both water utilities and the public we serve is preferable to the current patchwork of differing state standards that exist. However, we have significant concerns with EPA's proposed regulations.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR, as well as the expression of concerns.

Prince William County Service Authority (Doc. #1609, SBC-042841)

In closing:

1. The Service Authority supports the development of primary drinking water standards for PFAS compounds based on the best available science and understanding of risk.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR.

Wisconsin Conservation Voters (Doc. #1611, SBC-042861)

PFAS are already presenting well-known health risks in Wisconsin communities like Campbell, Eau Claire, La Crosse, Madison, Marinette, Peshtigo, Rhinelander, Stella, and Wausau. Other Wisconsin communities are just beginning to learn about the potential impact of these chemicals. Since testing Wisconsin drinking water systems began in 2022, PFAS have been detected in over 70 communities, impacting the drinking water of more than 2.2 million Wisconsinites – more than one third of our state.

We need help from the federal government. Our current standards for PFOA and PFOS are not protective of public health, and local leaders are looking for guidance on how to protect their constituents. By finalizing the NPDWR and MCLG, we can finally deliver clear guidance to our communities and begin protecting Wisconsin families from these dangerous forever chemicals. We urge you to finalize the proposed NPDWR and MCLG as expeditiously as possible.

Thank you for your time,

Peter Burress

Government Affairs Manager

Wisconsin Conservation Voters

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For more information, contact Peter Burress at peter@conservationvoters.org or 920-421-3601.

Visit Wisconsin Conservation Voters at www.conservationvoters.org.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Wisconsin Conservation Voters (Doc. #1611, SBC-042858)

May 25, 2023

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue NW

Washington, DC 20004

Support for PFAS National Primary Drinking Water Regulation [Docket No. EPA-HQ-OW-2022-0114]

Dear Administrator Regan,

We are writing today to show our strong support for the proposed National Primary Drinking Water Regulations (NPDWR) and health-based Maximum Contaminant Level Goals (MCLG) for PFOA, PFOS, PFHxS, PFNA, PFBS, and GenX chemicals. This is a critical step in addressing contamination associated with all dangerous chemicals in the PFAS family.

Wisconsin Conservation Voters is a nonpartisan, nonprofit organization dedicated to engaging Wisconsinites to protect our environment. We have offices in Green Bay, Madison, and Milwaukee. We build relationships with impacted community members, local elected officials, coalitions partners, and our network of over 40,000 members and supporters to fight for a future where every Wisconsin community has equitable access to clean drinking water.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Marlene Ladderbush (Doc. #1612, SBC-042911)

May 26, 2023

Mr. Michael S. Regan, Administrator

U.S. Environmental Protection Agency

EPA Docket Center, OLEM Docket, Mail Code 28221T

1200 Pennsylvania Avenue, NW

Washington, DC 20460

RE: Docket ID No. EPA-HQ-OW-2022-0114 - National Primary Drinking Water Regulation Rulemaking for per- and polyfluoroalkyl substances (PFAS)

Dear Administrator Regan:

I am writing to provide comments on the Environmental Protection Agency's (EPA) proposed National Primary Drinking Water Regulation Rulemaking for per- and polyfluoroalkyl substances (PFAS). The drinking water sector fully supports efforts to expand verified public health protections, but EPA needs to consider the challenges associated with its proposed rulemaking and address the water sectors' implementation concerns before finalizing any standards.

I work for Georgetown Water Department; we provide drinking water to 8500 residents. I am a member of the Massachusetts Water Works Association; I am aware that they, and other water works organizations, are submitting more comprehensive comments. I would urge EPA to pay close attention to the points raised by these associations as they are comprised of individuals and companies with expertise in designing and operating Public Water Systems (PWS) and they have

the best understanding of the challenges which will be associated with implementing any final rule EPA adopts. My major concerns are as follows:

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the protection of public health from PFAS.

Marlene Ladderbush (Doc. #1612, SBC-042923)

Thank you for the opportunity to provide these comments. As a water professional, I work hard to always follow the laws and regulations put forth by our regulatory agencies. I am sounding the alarm that I do not think this rule is reasonable, nor easily achievable. EPA has an obligation to address the water sector's implementation concerns and craft a final rule that is more realistic in its expectations of implementation and schedule and comes with the requisite funding to ensure PWS can comply.

Sincerely,

Marlene Ladderbush

Utility Director

Georgetown Water Department

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Town of Lincoln Water Department (Doc. #1613, SBC-043035)

Thank you for the opportunity to provide these comments. As a water professional, I work hard to always follow the laws and regulations put forth by our regulatory agencies. I am sounding the alarm that I do not think this rule is reasonable, nor easily achievable. EPA has an obligation to address the water sector's implementation concerns and craft a final rule that is more realistic in its expectations of implementation and schedule and comes with the requisite funding to ensure PWS can comply.

Sincerely,

Darin LaFalam

Water Superintendent

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Oakland County Water Resources Commissioner (WRC) (Doc. #1615, SBC-042925)

May 25, 2023

The Honorable Michael Regan, Administrator U.S. Environmental Protection Agency 1200 Pennsylvania Ave., N.W.

Washington, D.C. 20460

Re: Docket ID No.: EPA-HQ-OW-2022-0114

Proposed Per- and polyfluoroalkyl substances (PFAS): Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) National Primary Drinking Water Regulation Rulemaking

Dear Administrator Regan:

My office operates and maintains 22 local water systems that service over 175,000 people and protects public health and safety through the delivery of safe, clean, and affordable drinking water. I appreciate the actions of the Environmental Protection Agency (EPA) to further protect public health by proposing a National Primary Drinking Water Regulation to establish legally enforceable Maximum Contaminant Levels for six PFAS known to occur in drinking water but submit comments to highlight two significant concerns with the proposed regulations.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR, while suggesting some changes can be made. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Oklahoma Department of Environmental Quality (DEQ) (Doc. #1616, SBC-043036)

May 26, 2023

Michael S. Regan, Administrator

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue NW

Mail Code: 4607M

Washington, DC 20460

Re: Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation, Docket ID No. EPA-HQ-OW-2022-0114

Administrator Regan:

The Oklahoma Department of Environmental Quality (DEQ) appreciates the opportunity to comment on the proposed "Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation" (PFAS NPDWR). DEQ has primacy in the State of Oklahoma for

administering the drinking water program and other provisions of the Safe Drinking Water Act (SDWA). DEQ staff are active members of the Association of State Drinking Water Administrators (ASDWA), the Association of Clean Water Administrators (ACWA), and the Environmental Council of the States (ECOS).

DEQ asks that the following comments be taken into consideration relative to the proposed Personal and Polyfluoroalkyl Substances National Primary Drinking Water Regulation.

EPA Response: The EPA acknowledges this comment.

Aquarion Water Company (Doc. #1617, SBC-043371)

U.S. Environmental Protection Agency

May 26, 2023

EPA Docket Center

Office of Ground Water and Drinking Water Docket Mail Code 2822IT

1200 Pennsylvania Avenue NW Washington, DC 20460

RE: Docket ID No. EPA-HQ-OW-2022-0114

PFAS National Primary Drinking Water Regulation Rulemaking

Aquarion Water Company respectfully provides the following comments on EPA's proposed PFAS National Primary Drinking Water Regulation (NPDWR), as described in the Federal Register / Vol. 88, No. 60 / Wednesday, March 29, 2023 / Proposed Rules.

Aquarion Water Company is an investor-owned water utility that serves a population of more than 700,000 people in 72 cities and towns in Connecticut, Massachusetts, and New Hampshire. Across its operations, the company has 10 reservoir systems and more than 300 wells.

It should first be stated that we recognize and respect the significant effort that has been put forth by EPA and other contributors to develop the proposed PFAS regulation. We appreciate the opportunity to offer comments on the regulation. Our goal is to provide meaningful input to the regulatory process to assist in making the final regulation effective for protecting public health.

Aquarion shares EPA's desire to keep harmful levels of PFAS out of the nation's drinking water. Providing safe, high quality drinking water to our customers is Aquarion's top priority, which is why since 2019 we have undertaken a voluntary program to test for and manage PFAS in our water systems. Aquarion has shared all point-of-entry PFAS testing results on our website at aquarionwater.com/pfas and shares PFAS results in its annual Consumer Confidence Reports (CCRs) available at aquarionwater.com/wqr.

EPA Response: The EPA appreciates the information provided to inform the final PFAS NPDWR.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044016)

May 29, 2023

Docket Id No. EPA-HQ-OW-2022-0114

Environmental Protection Agency EPA Docket Center

Mail code: 28221T

1200 Pennsylvania Avenue NW Washington, DC 20460

Via Federal eRulemaking Portal: https://www.regulations.gov/

RE: National Primary Drinking Water Regulations: PFAS Rule (EPA-HQ-OW-2022-0114).

The purpose of the Colorado Water Utility Council is to initiate, evaluate, respond, and comment, within the policy framework of RMSAWWA, on legislative, regulatory, and other matters which directly affect water utilities in Colorado, and to encourage provision of better water service to the consuming public.

Thank you for the opportunity to provide comments on the proposed PFAS MCL determinations. PFAS are a great health concern and as water professionals we care deeply about this subject. Please keep in mind that these regulations must include a balanced and appropriate approach that requires reduction of the chemicals at their source. Water and wastewater treatment facilities are not creating these chemicals and cannot bear the full burden of removing them from the environment. Further, the astronomical costs to remove PFAS in water and wastewater are borne by rate-paying customers, and these regulations (along with a multitude of others) may eventually cause water and sewer rates to become unreasonable, particularly for low-income residents. The comments below are select responses at EPA's request, followed by general comments for consideration.

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. For responses to comments about reduction of chemicals at the source, please see sections 2.3 and 15 of the *Response to Comments* document. For a response to the concerns about costs for low-income residents, please see section 14.10 of the *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043092)

Summary of Key Recommendations

Aqua appreciates the Agency's interest in preparing a thoughtful, thoroughly crafted proposal to establish national primary drinking water regulations for PFOA, PFOS, and additional PFAS. As EPA demonstrates in its health risk reduction analysis, the potential health benefits of a drinking water standard for PFAS could be significant. Advancing public health is a shared goal between

drinking water systems and EPA. Aqua believes addressing PFAS in drinking water will require multiple stages and continuous efforts as additional information on PFAS toxicity and innovative technologies for PFAS treatment are developed. Thus, Aqua advocates that the regulation EPA promulgates focus on achieving the best initial step in reducing PFAS risks (verses addressing all PFAS risks before adequate data is available).

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the method in which the agency is addressing PFAS via an NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA believes that current information on PFAS toxicity and innovative technologies is sufficient to implement this rule based on SDWA requirements. For a response about toxicity information, including the toxicity assessments, please see sections 3.1.1, 3.2.1, 4.3.1, and 4.3.3 of the *Response to Comments* document. For a response about treatment technologies, please see sections 5.1.4 and 10.1 of the *Response to Comments* document, as well as section X.A of the FRN.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043102)

In summary, EPA is strongly encouraged to consider the impacts of this rule carefully and to ensure that, if finalized, the regulations are feasible. While the Agency has a strong interest in expeditious action, it is important to move actions forward meaningfully and in a way that avoids consequences that could be avoidable. The recommended approach would ensure that high- risk water systems are prioritized while also providing EPA with additional time to get better data and improve the science.

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the method in which the agency is addressing PFAS via an NPDWR. The EPA disagrees that better data are needed to support the regulation. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043055)

Christopher S. Crockett, Ph.D., P.E.

Essential Utilities, Inc.

762 W. Lancaster Avenue

Bryn Mawr, PA 19010

May 30, 2023

Michael Regan Administrator

Office of Ground Water and Drinking Water

U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, NW Washington, DC 20460

TRANSMITTED ELECTRONICALLY

RE: Per- and polyfluoroalkyl substances (PFAS): Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) National Primary Drinking Water Regulation Rulemaking, Docket No. EPA–HQ–OW-2022-0114 [Link: https://www.regulations.gov/docket/EPA-HQ-OW-2022-0114]

Dear Administrator Regan,

Aqua, an Essential Utilities Company, appreciates the U.S. Environmental Protection Agency's (EPA) efforts to propose national primary drinking water regulations for per- and polyfluoroalkyl substances (PFAS), including perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS). Aqua operates approximately 1,500 water systems covering eight states and three million people. Aqua believes in efforts to strengthen regulations and improve drinking water quality. The proposed regulation includes standards for both PFOA and PFOS as well as regulatory determinations and a standard for four other PFAS

Aqua supports the development of standards for PFOA and PFOS and the Agency's interest in proposing regulatory determinations for additional PFAS. Aqua was the first private utility to establish its own companywide standard for PFOA, PFOS, and PFNA of 13 parts per trillion individually across its eight states in 2020. A standard that is both equally protective and consistently enforced for all affected drinking water customers across the United States is especially important.

Aqua believes that EPA has put forward a rule framework that begins to address several concerns. The proposal serves as a good starting point for finalizing a rule that address PFAS compounds in drinking water. Attached are detailed comments on the proposed rule preamble, supporting documentation, and draft regulatory text. We hope that these comments will help EPA finalize the rule effectively leveraging the science and the authorities of the Safe Drinking Water Act. Within these comments there are several high priority recommendations for the final rule.

Aqua appreciates the opportunity to provide comments regarding the proposed changes to the Proposed PFAS NPDWR Rulemaking.

Sincerely,

Christopher S. Crockett, Ph.D., P.E.

Vice President - Chief Environmental, Safety and Sustainability Officer

EPA Response: The EPA acknowledges and appreciates this comment in general support for the agency's approach in this rulemaking, as well as the recommendations provided. Please see section 1.3 of the EPA response in this *Response to Comments* document.

WaterPIO (Doc. #1624, SBC-043459)

By Electronic Submission: Docket EPA-HQ-OW-2022-0114

U.S. Environmental Protection Agency EPA Docket Center

PFAS: PFOA and PFOS National Primary Drinking Water Regulation Rulemaking Mail Code 28221T

1200 Pennsylvania Avenue, NW Washington, DC 20460

To Whom It May Concern:

WaterPIO greatly appreciates the opportunity to submit our comments about USEPA's proposed National Primary Drinking Water Regulation (NPDWR), which includes Maximum Contaminant Levels (MCLs), a "Hazard Index" ("HI"), and Maximum Contaminant Level Goals (MCLGs) for six PFAS compounds.

EPA Response: The EPA acknowledges this comment.

Environmental Monitoring Coalition (EMC) (Doc. #1625, SBC-043104)

Comments on PFAS National Primary Drinking Water Regulation Rulemaking

May 26, 2023

The Environmental Monitoring Coalition (EMC) was created in 2020 to address a void created by the dissolution of EPA's Environmental Laboratory Advisory Board. The following EMC organizations represent private and government laboratories from state and local governments and drinking and wastewater utilities:

• American Council of Independent Laboratories,

• American Water Works Association,

• Association of Public Health Laboratories,

• The NELAC Institute, and

• Water Environment Federation.

The EMC was established in response to the need for the environmental monitoring community to have a mechanism to develop consensus opinions on issues affecting environmental monitoring.

The EMC supports EPA's efforts to provide clear and uniform requirements for monitoring of the specific PFAS in drinking water nationally, especially since many states are developing their own programs and standards.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Water One - Water District No. 1 of Johnson County, Kansas (Doc. #1627, SBC-042323)

May 19, 2023

Mr. Michael S. Regan,

Administrator Office of Ground Water and Drinking Water, Standards and Risk Management Division, U.S. Environmental Protection Agency

1200 Pennsylvania Avenue Northwest,

Mail Code: 4670M, Washington, D.C. 20460

RE: Docket ID No. EPA-HQ-OW-2022-0114

Dear Administrator Regan:

Water District No. 1 of Johnson County, Kansas (WaterOne) appreciates the opportunity to submit comments regarding the proposed "Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation (NPDWR)". WaterOne is an independent, quasi-municipal public water utility serving 475,000 people across 17 cities throughout Johnson County, Kansas. WaterOne is dedicated to providing safe and clean drinking water that keeps pace with the cutting edge of science and technology. We commend the U.S. Environmental Protection Agency (EPA) for their efforts to address public health and advocate for safe and clean drinking water across the county. WaterOne acknowledges that the proposed PFAS regulation is a positive effort in protecting water quality through science-based regulations. However, water utilities across the U.S. are being disproportionately targeted as polluters by this proposed regulation and direct polluters of consumer and industry products containing PFAS are not being held responsible. Moreover, the proposed regulation is not based upon a deliberate and thorough analysis of data that is normally applied to the regulatory process. WaterOne would like to highlight several concerns for the EPA to consider including the premature regulatory process, implications to water utility operations, laboratory science and technology challenges, residuals disposal, permitting implications, cost and logistical consequences, and supply chain difficulties.

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. The EPA disagrees that the regulation is not based upon a deliberate and thorough analysis of data and that the regulatory process is premature. Please see section 1.3 of the EPA response in this *Response to Comments* document. For responses to comments about reduction of chemicals at the source, please see sections 2.3 and 15 of the *Response to Comments* document. For concerns about the regulatory process, please see sections 1.1 and 3 of the EPA response in this *Response to Comments* document, as well as section III of the FRN. For challenges with laboratories, please see sections 5.1.2 (specifically, the EPA

response to comment Doc. #1627, SBC-042326 in section 5.1.2 in this *Response to Comments* document) and section 8.7 of the EPA response in this *Response to Comments* document. For residuals disposal discussion, please see section 10.4 of the *Response to Comments* document, specifically, the EPA response to comment Doc. #1627, SBC-042331 in section 10.4.2 in this *Response to Comments* document. For potential permitting implications, please see section 5.1.2 and 10.4.1 of the *Response to Comments* document. For comments on costs and logistical consequences, including supply chain difficulties, please see sections 10.6 (specifically, the EPA response to comment Doc. #1627, SBC-042329 in section 10.6 in this *Response to Comments* document) and section 13.3 of the *Response to Comments* document (specifically, the EPA response to comment Doc. #1627, SBC-042328 in section 13.3.3 in this *Response to Comments* document).

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044068)

Addressing these recommendations and our detailed comments will optimize implementation of this regulation and improve public health protection by reducing PFAS levels in drinking water. Addressing ASDWA's recommendations will help states effectively implement this rule and ensure that water systems have achievable paths to compliance. ASDWA recommends that EPA continue to engage the primacy agencies as the Agency works to finalize this rule. A coordinated effort will help ensure that public communication is effective and that primacy agencies are prepared to engage with their water systems as soon as the final rule is published. As partners with EPA, ASDWA is ready to coordinate meetings between the primacy agencies and EPA as needed to ensure the successful implementation of the NPDWR.

EPA Response: The EPA acknowledges these comments. As partners in the implementation of the SDWA, the EPA will coordinate with primacy agencies to ensure successful rule implementation. For additional responses on communications, please see section 1.2 of the EPA response in this *Response to Comments* document, including the EPA response to comment Doc. #1628, SBC-044063; SBC-044061; SBC-044075; SBC-044107; SBC-044109; SBC-044105; and SBC-044081 in section 1.2 in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044071)

Comments by the Association of State Drinking Water Administrators (ASDWA) for the Proposed PFAS National Primary Drinking Water Regulations Docket ID No. EPA-HQ-OW-2022-0114

Introduction

The Association of State Drinking Water Administrators (ASDWA) appreciates the opportunity to provide comments on the Environmental Protection Agency's (EPA) proposed PFAS National Primary Drinking Water Regulation (NPWDR). ASDWA is the professional association that serves the individuals (and their staff) who lead and implement the 57 state, territorial, and tribal drinking water programs (hereinafter "primacy agencies"). Formed in 1984 to address a growing

need for drinking water administrators to have national representation, ASDWA is a respected voice for primacy agencies with Congress, EPA, and other professional organizations.

ASDWA supports EPA's proposed regulation which provides national leadership and consistency for assessing and addressing PFAS in drinking water. These comments focused on topics significantly impacting primacy agencies and where ASDWA's members could provide the most robust feedback. As co-regulators, these comments offer a unique perspective given ASDWA's members' collective experience implementing the Safe Drinking Water Act. The input provided in this letter will help ensure that the final rule is feasible and effectively implemented and, therefore, results in increased public health protection. It should be noted, however, that these comments do not necessarily represent the specific comments and concerns of individual primacy agencies. ASDWA's comments also do not represent a consensus from all members. We encourage EPA to consider all individual primacy agency comments, in addition to ASDWA's, to gain further perspective.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR and has considered all comments submitted in the finalization of this rule. For responses on issues concerning feasibility and implementation, please see section 1.3 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044060)

May 30, 2023

Honorable Radhika Fox

Assistant Administrator Radhika Fox

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue NW

Washington, DC 20460

Re: Proposed PFAS National Primary Drinking Water Regulation Rulemaking (EPA-HQ-OW2022-0114)

Dear Assistant Administrator Fox,

The Association of State Drinking Water Administrators (ASDWA) appreciates the opportunity to comment on EPA's proposed PFAS National Primary Drinking Water Regulation. ASDWA is the professional association that serves the individuals (and their staff) who lead and implement the 57 state, territorial, and tribal drinking water programs (hereinafter "primacy agencies").

ASDWA would like to thank the Office of Ground Water and Drinking Water (OGWDW) for its continued engagement on this critical rulemaking. ASDWA supports EPA's proposed regulation as it provides national leadership and consistency for addressing PFAS in drinking water. In the

absence of a National Primary Drinking Water Regulation (NPDWR), some primacy agencies have been struggling to appropriately use EPA's health advisory levels for perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salt (also known as GenX chemicals), and perfluorobutane sulfonic acid (PFBS) or have moved ahead to set their own state-level standards.

As co-regulators with EPA, ASDWA has a unique role with the Agency on rule development and implementation. ASDWA collaborated with primacy agency staff across the country to develop these comments on PFAS treatment, monitoring, laboratory analysis, and communication. However, these comments do not necessarily represent the specific comments of individual primacy agencies, and ASDWA's comments also do not represent a consensus, as perspectives can diverge on specific issues. ASDWA encourages EPA to consider all individual primacy agency comments in addition to these comments.

The attached detailed comments address specific components of the proposed rule and highlight several critical feasibility issues that warrant a thoughtful response. ASDWA supports the proposed rule, with the caveat that the seven critical recommendations below warrant the Agency's consideration for inclusion in the final rule:

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. For general responses on feasibility, please see section 1.3 of the EPA response in this *Response to Comments* document. For responses to the specific feasibility issues raised, please see the applicable sections of this *Response to Comments* document that address each of the issues, which are located in section 1.3 of this *Response to Comments* document. For concerns about communication, please see section 1.2 of the EPA response in this *Response to Comments* document, including the EPA response to comment Doc. #1628, SBC-044063; SBC-044061; SBC-044075; SBC-044107; SBC-044109; SBC-044105; and SBC-044081. For concerns around monitoring and laboratory analysis, please see the EPA response to comment Doc. #1628, SBC-044088 in section 5.1.2, as well as the EPA response to comment Doc. #1628, SBC-044098; SBC-044089; SBC-044096; SBC-044093; SBC-044099; SBC-044065; SBC-044097; SBC-044095; SBC-044094; SBC-044066; and SBC-044102 found across topics in section 8 of the *Response to Comments* document. For concerns around treatment, please see the EPA response to comment Doc. #1628, SBC-044118; SBC-044108; SBC-044111; SBC-044110; and SBC-044112 found across topics in section 10 of the *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044119)

Conclusion

Primacy agencies and water systems will face significant feasibility challenges implementing the proposed PFAS NPDWR. This rule will require significant additional resources from primacy agencies beyond the additional resources for SDWIS modernization, lead service line inventories, cybersecurity, and BIL funding. EPA must address the numerous feasibility

concerns in these comments to ensure this public health measure is achievable and effective. However, ASDWA's members remain dedicated to partnering with EPA and their water systems to reduce PFAS levels and improve public health protection by complying with this rule. ASDWA recommends that EPA continue its engagement with primacy agencies as the Agency finalizes this rule. A coordinated effort will help ensure that public communication is effective and that primacy agencies are prepared to engage with their water systems and the public with the promulgation of the final rule. ASDWA is prepared to help coordinate meetings between its members and EPA as needed to ensure the successful implementation of the final rule over the next decade.

EPA Response: As partners in the implementation of the SDWA, the EPA will coordinate with primacy agencies to ensure successful rule implementation. For responses on issues concerning feasibility, implementation, and primacy agencies, please see section 1.3 of the EPA response in this *Response to Comments* document, as well as the EPA response to comment Doc. #1628, SBC-044078; SBC-044100; and SBC-044079 in section 11 in this *Response to Comments* document. For responses on issues concerning communication, please see section 1.2 of the EPA response in this *Response to Comments* document.

Illinois Farm Bureau (IFB) (Doc. #1630, SBC-043133)

May 30, 2023

Submitted via www.regulations.gov

Ms. Radhika Fox

Assistant Administrator

Office of Water

Environmental Protection Agency 1200 Pennsylvania Avenue, N. W.

Washington, DC 20460

Re: Comments regarding Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation, Docket ID No. EPA-HQ-OW-2022-0114

Dear Ms. Fox:

The Illinois Farm Bureau® ("IFB") appreciates to opportunity to submit comments to the U.S. Environmental Protection Agency ("EPA") in response to the proposed rule to set National Primary Drinking Water Regulations (NPDWR) for six PFAS chemicals, including perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS). IFB is a member of the American Farm Bureau Federation® ("AFBF"), a national organization of farmers and ranchers. Founded in 1916, IFB is a non-profit, membership organization directed by farmers who join through their county Farm Bureau ("CFBs"). IFB has a voting membership of more than 74,000.

Our organization represents Illinois farm families working together to build a sustainable future of safe and abundant food, fiber and renewable fuel for our nation and the world. We support EPA's underlying goal of addressing widespread contamination of the environment caused by historic use of PFOA and PFOS. Unfortunately, EPA's proposed Maximum Contaminant Level (MCLs) of 4 ppt for PFOA and PFOS and the designation of a hazard index for perfluorononanoic acid (PFNA), PF perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid and its ammonium salt (also known as Gen X chemicals), and perfluorobutane sulfonic acid (PFBS) overlooks the many challenges that will be placed on farm families in Illinois and around the country.

Illinois farmers share concerns regarding the health impacts of PFAS exposure; however, research to prove causation is still under development. We encourage this work to continue as there are many factors that must be considered when developing regulatory limits.

EPA Response: The EPA acknowledges these concerns regarding the proposed rule. Please see section 1.3 of the EPA response in this *Response to Comments* document. For additional discussion on the set MCL levels for the final PFAS NPDWR, please see section 5 of the *Response to Comments* document.

Superfund Settlements Project (SSP) and RCRA Corrective Action Project (RCAP) (Doc. #1631, SBC-043431)

SSP and RCAP support the development of PFAS drinking water regulations developed in compliance with the SDWA, protective of human health, based in sound science and fiscally responsible. The Proposal, however, falls short.

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. Please see the EPA response to comment Doc. #1631, SBC-043427 in section 1.3 in this *Response to Comments* document.

Superfund Settlements Project (SSP) and RCRA Corrective Action Project (RCAP) (Doc. #1631, SBC-043427)

May 30, 2023

BY ELECTRONIC FILING

HTTPS://WWW.REGULATIONS.GOV

DOCKET ID NO. EPA-HQ-OW-2022-0114

Radhika Fox

Assistant Administrator

Office of Water

US Environmental Protection Agency

1200 Pennsylvania Avenue NW

Washington, DC 20460

Alexis Lan

Office of Ground Water and Drinking Water

Standards and Risk Management Division

US Environmental Protection Agency

1200 Pennsylvania Avenue NW

Washington, DC 20460

Re: Comments on Proposed PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18638 (Mar. 29, 2023)

Dear Administrator Fox and Ms. Lan:

On behalf of the Superfund Settlements Project ("SSP") and RCRA Corrective Action Project ("RCAP") [FN1: SSP and RCAP are associations of major companies from many different sectors of American industry. SSP was organized in 1986 to help improve the effectiveness of the Superfund program by encouraging settlements and processes that would result in the Superfund program operating efficiently and rationally, achieving site closures with a minimum of expense and delay. RCAP was established in 1988 in the wake of EPA's earliest draft corrective action regulatory proposals with a goal to encourage cleanup standards and procedures that achieve environmental benefits in a risk-based and cost-effective manner. Since their formation, SSP and RCAP have provided constructive input to EPA, other regulatory agencies and Congress on critical policy issues affecting the cleanup of contaminated sites.], I submit these comments on the United States Environmental Protection Agency's ("EPA's") proposed PFAS National Primary Drinking Water Regulation Rulemaking, (the "Proposed Rule" or "the Proposal") [FN2: 88 Fed. Reg. 18638 (Mar. 29, 2023)] under the Safe Drinking Water Act ("SDWA"). [FN3: 42 U.S.C. §§ 300f et seq]. The Proposed Rule proposes maximum contaminant level goals ("MCLGs") and national primary drinking water regulations ("NPDWRs") in the form of maximum contaminant levels ("MCLs") for perfluorooctanoic acid ("PFOA") and perfluorooctane sulfonic acid ("PFOS"). EPA also published its preliminary determination to regulate four other per- and polyfluoroalkyl substances ("PFAS") — perfluorononanoic acid ("PFNA"), perfluorohexanesulfonic acid ("PFHxS"), perfluorobutane sulfonic acid ("PFBS"), and hexafluoropropylene oxide dimer acid and its ammonium salt ("GenX") — and simultaneously proposes MCLGs and MCLs for those substances as a mixture through the novel use of a Hazard Index ("HI") calculation.

The Proposal suffers from several defects that, should it be finalized, would result in the final rule being arbitrary, capricious, an abuse of discretion or otherwise not in accordance with the law. Existing health and occurrence data do not support the proposed determination to regulate PFNA, PFHxS, PFBS and GenX, and EPA improperly proposes MCLGs and MCLs for these substances together with the proposal to regulate.

EPA Response: The EPA does not agree that the rule is arbitrary, capricious, an abuse of discretion or otherwise not in accordance with the law. Please see section 1.3 of the EPA response in this *Response to Comments* document.

The EPA believes that health and occurrence data support the regulation of PFNA, PFHxS, PFBS and HFPO-DA based on SDWA requirements. Please see sections 3.2.1 and 3.2.2 of the EPA response in this *Response to Comments* document, specifically the EPA response to comment Doc. #1631, SBC-043435; SBC-043436; SBC-043437; SBC-043441; and SBC-043432 in section 3 in this *Response to Comments* document. See sections 4.3.2 and 5.2.1 (specifically, the EPA response to comment Doc. #1631, SBC-052848 in section 5.2.1 in this *Response to Comments* document) of the EPA response in this *Response to Comments* document for responses to concerns that MCLGs and MCLs were improperly imposed. The EPA disagrees that its preliminary determination to regulate PFHxS, HFPO-DA, PFNA, and PFBS does not follow SDWA criteria, and also disagrees that the EPA's proposal of a preliminary determination for PFHxS, HFPO-DA, PFNA, and PFBS simultaneously with its proposed MCL and MCLG is inconsistent with SDWA. The EPA has thoroughly responded to these concerns in section 3 of the EPA response in this *Response to Comments* document, particularly the EPA response to comment Doc. #1713, SBC-045875; SBC-045894; and SBC-045897.

Rural Community Assistance Partnership Incorporated (RCAP) (Doc. #1633, SBC-044138)

May 30, 2023

U.S. Environmental Protection Agency

1200 Pennsylvania Ave NW

Washington, D.C. 20460

RE: Docket ID No. EPA-HQ-OW-2022-0114 – Per- and polyfluoroalkyl substances (PFAS):

Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) National Primary Drinking Water Regulation Rulemaking

Since 1973, the Rural Community Assistance Partnership Incorporated (RCAP) has helped build capacity for and facilitated access to the most basic necessities in rural communities: clean, safe, and affordable drinking water and wastewater services. RCAP uses a locally driven approach in every state and territory to address various needs in rural and tribal communities, driven by a network of regional non-profit partners, who provide hands-on technical assistance under the

Safe Drinking Water Act (SDWA) and conduct in-person training on a variety of technical and regulatory topics as it relates to safe drinking water and sanitary wastewater disposal.

RCAP appreciates the opportunity to provide comment to the Environmental Protection Agency (EPA) on the Per- and polyfluoroalkyl substances (PFAS) National Primary Drinking Water Rulemaking (NPDWR) announced on March 29, 2023.

RCAP commends EPA for proposing NPDWRs for these 6 PFAS contaminants. RCAP stands ready to help small, rural, and tribal communities finally remove these harmful carcinogens from drinking water in their communities.

RCAP believes that the proposed MCLs of 4.0 parts per trillion (ppt) also expressed as nanograms per liter (ng/L) for PFOA and PFOS as individual contaminants, and PFHxS, PFNA, PFBS, and HFPO-DA (commonly referred to as GenX Chemicals) as a PFAS mixture regulated using a Hazard Index formula are protective of public health. RCAP agrees with EPA that--when fully implemented--the PFAS Rule will prevent tens of thousands of PFAS-related illnesses or deaths. Additionally, while other PFAS compounds that are not targeted through the Proposed Action may still have negative impacts on health, treatment for these six compounds will also reduce the potential amount of other PFAS compounds in the drinking water, which often appear as several compounds together, and lower human exposure to this class of chemicals in general.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Orange County Water District (OCWD), California (Doc. #1634, SBC-043228)

May 30, 2023

Michael Regan

Administrator

Environmental Protection Agency 1200 Pennsylvania Avenue, N.W.

Mail Code: 1309

Washington, DC 20004

TRANSMITTED ELECTRONICALLY

Subject: Per- and polyfluoroalkyl substances (PFAS): Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) National Primary Drinking Water Regulation Rulemaking, Docket No. EPA-HQ-OW-2022-0114

Dear Administrator Reagan,

The Orange County Water District (OCWD) appreciates the opportunity to comment on the United States Environmental Protection Agency's (EPA) proposed national primary drinking water regulations for per- and polyfluoroalkyl substances (PFAS) under the Safe Drinking Water Act (SDWA). The current above-referenced proposal includes standards for both perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS), as well as regulatory determinations and a combined standard for four other PFAS. OCWD shares EPA's goal of protecting public health via the provision of clean, safe, and affordable drinking water and supports the development of national standards for PFOA and PFOS, while also sharing EPA's interest in proposing regulatory determinations for additional PEAS.

OCWD is a groundwater management agency located in southern California, serving a population of 2.5 million. We work closely with 19 large public water systems that obtain 85% of their water supply from the OCWD-managed groundwater basin and collectively own and operate more than 200 large system drinking water production wells across our 350 square mile service area. These 19 public water systems (Groundwater Producers) include, for example, the cities of Anaheim, Santa Ana, Fullerton, and Orange, as well as independent special water districts such as the Irvine Ranch Water District and Yorba Linda Water District.

EPA Response: The EPA acknowledges and appreciates this comment and its general agreement with the final PFAS NPDWR.

Orange County Water District (OCWD), California (Doc. #1634, SBC-043240)

Conclusion

OCWD believes that EPA has put forward a PFAS rule framework that begins to address several stakeholder concerns. The proposal serves as a good starting point for finalizing a rule that addresses PFAS compounds in drinking water. We hope that our comments will help EPA finalize the rule, effectively leveraging the underlying science and the authorities of the SDWA.

Sincerely,

Michael R. Markus, P.E., D.WRE, BCEE, F.ASCE

General Manager

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Association of Environmental Authorities (AEA) (Doc. #1635, SBC-042960)

May 30, 2023

Michael S. Regan, Administrator

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue NW

Mail Code: 4607M

Washington, DC 20460

Re: Docket ID No. EPA-HQ-OW-2022-0114, Comments on the Development of the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

Dear Administrator Regan:

The Association of Environmental Authorities (AEA) appreciates the opportunity to comment on the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation (NPDWR). AEA represents New Jersey government providers of drinking water, wastewater, and solid waste services. Our municipal, regional, county, and state agency members, mainly authorities, provide one or more of these services to most of New Jersey's population. In some cases, AEA government utility members manage water reuse/recycling; some partner with municipal partners to manage storm water. AEA is a member of the National Association of Clean Water Agencies (NACWA).

AEA fully supports the EPA goal to eliminate PFAS pollution to protect public health and the environment. Our 50-year-old association has consistently supported water quality regulations at the state and federal levels that rely on science. AEA member water utilities already subject to New Jersey's PFAS chemical regulations are sampling and reporting PFAS in drinking water. Wastewater utilities are voluntarily sampling wastewater and biosolids. AEA members are working with the New Jersey Department of Environmental Protection to profile PFAS chemicals in New Jersey wastewater.

EPA Response: The EPA acknowledges and appreciates this comment and its general support for the goal of the final PFAS NPDWR.

American Association for Justice (AAJ) (Doc. #1636, SBC-042967)

May 30, 2023

Administrator Michael Regan

Environmental Protection Agency

1200 Pennsylvania Ave. N.W.

Washington, D.C. 20004

Re: [Docket No. EPA-HQ-OW-2022-0114] Comments Regarding PFAS National Primary Drinking Water Regulation Rulemaking

Dear Administrator Regan:

The American Association for Justice (AAJ), formerly known as the Association of Trial Lawyers of America (ATLA), hereby submits comments in response to the Environmental Protection Agency's (EPA) proposed rules to create a Maximum Contaminant Level Goal (MCLG) and Maximum Contaminant Level (MCL) for Per- and Polyfluorinated Substances (PFAS) in drinking water. Specifically, AAJ strongly supports EPA's proposal to create an MCLG and MCL for PFAS in drinking water. This is a necessary and critical step in protecting human health and the environment from these dangerous chemicals. The significant body of research and scientific findings on these chemicals demonstrate that they pose a clear and present danger to human health even at extremely low levels.

AAJ, the world's largest plaintiffs trial bar with members in the U.S., Canada, and abroad, was established to safeguard victims' rights, strengthen the civil justice system, promote injury prevention, and foster transparency. And as representatives for those injured, and those who may be injured, we submit these comments. This proposed rule will help protect individuals from the devastating consequences of PFAS exposure.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Town of Tewksbury, Massachusetts (Doc. #1637, SBC-043252)

Thank you for the opportunity to provide these comments. As a water professional, I work hard to always follow the laws and regulations put forth by our regulatory agencies. I am sounding the alarm that I do not think this rule is reasonable, nor easily achievable. EPA has an obligation to address the water sector's implementation concerns and craft a final rule that is more realistic in its expectations of implementation and schedule and comes with the requisite funding to ensure PWS can comply.

Sincerely,

Kevin Hardiman, P. E. Director of Public Works

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Citizens Against Ruining the Environment (CARE) (Doc. #1638, SBC-043445)

With that background in mind, CARE makes the following public comments:

CARE Comment 1- There Is A Legally and Factually Well-Established Basis for EPA's Proposed Maximum Contaminant Levels for PFOA and PFOS and EPA's Proposed Maximum Contaminant Level for the Mixture of PFNA, GenX Chemicals, PFHxS, and PFBS Under a Hazard Index

EPA's proposed regulation to the six highly toxic PFAS chemicals is a critical step towards protecting our communities. EPA's move in regulating four PFAS as a class in its proposed hazardous index is a welcome change. The myriad of harmful health effects, including cancer, immune suppression, and developmental harms, linked to extremely low levels of exposure warrants these novel and aggressive PFAS MCLs. CARE fully supports the MCLs proposed by EPA and believes the strong standards will help ensure safe drinking water across the country.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Citizens Against Ruining the Environment (CARE) (Doc. #1638, SBC-043442)

Please be advised that I represent Citizens Against Ruining the Environment, a Will County Illinois-based environmental advocacy organization whose members are directly affected by endangering levels of PFAS in drinking water supplies. CARE's comments on U.S. EPA's proposed regulations are in the attached document.

May 30, 2023

United States Environmental Protection Agency

Via: regulations.gov

Re: Docket ID: EPA-HQ-OW-2022-0114-0027, Per- and Polyfluoroalkyl National Primary Drinking Water Regulations for PFOA, PFOS PFNA, GenX Chemicals, PFHxS, and PFBS

To Whom It May Concern:

Please be advised that I represent Citizens Against Ruining the Environment ("CARE"). CARE is a not-for-profit environmental education organization based in Will County, Illinois. CARE members live in several Will County communities including Lockport, Joliet, Crest Hill, Rockdale, and others. These communities depend on groundwater resources for their drinking water. Residents either receive their drinking water from municipal water suppliers or, in many cases, private wells. Will County communities have faced years of environmental injustice. For example, 11 of the 12 EJScreen environmental justice indices for Rockdale (where there is extensive, documented PFAS-contaminated drinking water) are in the top quartile when compared to the U.S. as a whole.

For more than 30 years, CARE's mission has been to educate Will County residents about the cumulative environmental and public health issues they face. PFAS contamination is now CARE's highest priority due to the widespread presence of PFAS across all environmental media, including extensive Will County drinking water contamination, and an increasing awareness of the harmful health effects of PFAS.

Will County's drinking water contains concentrations of PFOA that are up to 3,750 times higher than what the best available science indicates is safe for human consumption. Concentrations of PFOS in Will County drinking water are up to 365 times higher than what is safe. Four other PFAS were also detected. In total, 20 different Will County community water supplies contain PFAS, with some public water supplies containing six different PFAS at the same time. [FN1: Illinois EPA, PFAS Sampling Network, available at https://www.arcgis.com/apps/dashboards/bd611162a7f74cfe88b6928c926416c3.] Though private wells were not part of Illinois's PFAS sampling initiative (samples were not taken from private wells in the U.S. EPA's Third Unregulated Contaminant Monitoring Rule PFAS sampling effort either), given the widespread contamination found in public water supplies sourced from groundwater, CARE believes it is highly probable that private wells are contaminated.

EPA Response: The EPA appreciates this information. This rule was developed using the authorities of the SDWA, which does not authorize regulation of the use of chemicals in consumer and industrial products, the remediation of contaminated sites or private wells. Please see section 15 of the EPA response in this *Response to Comments* document that discusses topics that are out of scope for this rulemaking. For specifics on private wells, please see section 1.4 of the EPA response in this *Response to Comments* document.

California Municipal Utilities Association (CMUA) (Doc. #1639, SBC-043258)

All these unintended consequences would add costs and concern for public water agencies and should be thoroughly addressed prior to EPA's adoption of the Regulation. CMUA urges the EPA to take the necessary time to work through the issues iterated in this letter prior to making a final determination on the proposed PFAS MCLs.

Thank you for the opportunity to provide these comments. Should you have any questions about the contents of this letter, please contact Andrea Abergel at aabergel@cmua.org.

Sincerely,

Andrea Abergel Manager of Water Policy

California Municipal Utilities Association

EPA Response: The EPA acknowledges the commenter's general disagreement with the final PFAS NPDWR. The EPA has addressed each specific individual detailed comment raised by the commenter individually where raised. For more information on financial assistance, please see section 2.4 (specifically, the EPA response to comment Doc. #1639, SBC-043254) of the *Response to Comments* document. For more discussion on timeline for MCL compliance, please see section 12.1 (specifically, the EPA response to comment Doc. #1639, SBC-043255) of the *Response to Comments* document. For more information on treatment considerations, please see section 8.9 (specifically, the EPA response to comment Doc. #1639, SBC-043256) of the *Response to Comments* document. For additional discussion on hazardous substances disposal,

please see section 10.4.2 (specifically, the EPA response to comment Doc. #1639, SBC-043257) of the *Response to Comments* document.

American Farm Bureau Federation et al. (Doc. #1642, SBC-043488)

There are a number of other issues associated with the proposed MCLs that deserve in-depth discussion, including the benefits identified by the agency, the health end points, and the possible conflict between other Administration policies. We hope that the EPA will consider all of these factors before finalizing this rule.

EPA Response: The EPA's final rule represents data-driven drinking water standards that use the best available science and meet the requirements of SDWA. The PFAS regulation is vital to protecting public health. For additional discussion around the MCLs, please see section 5 of the EPA response in this *Response to Comments* document. The EPA reviewed the best available science on health effects associated with exposure to the PFAS considered in the rulemaking. The EPA's quantification of health benefits resulting from reduced PFAS exposure in drinking water was driven by the availability of PFAS related occurrence estimates, pharmacokinetic (PK) models, information on exposure-response relationships, and economic data to monetize the impacts. For information on the benefits of the PFAS NPDWR, please see section 13.5 of the *Response to Comments* document.

For the health endpoints from PFAS exposure, the EPA used a systematic literature review approach to determine the strength of evidence. Additional discussion of the PFOA and PFOS literature review can be found in section 4.1.1 of the *Response to Comments* document and in section IV of the FRN.

The PFAS NPDWR has gone through an interagency review process to reduce conflict between administration policies. For concerns with the Administration and its policies, please see section 15 of the *Response to Comments* document for topics out of scope of this NPDWR.

Raptor Pharm & Tox, Ltd (Doc. #1644, SBC-043423)

Conclusion

Raptor has concluded that the US EPA's safe drinking water standards for these PFAS chemicals to be inappropriate. The proposed standards are not based on sound science, they will impact small businesses, they will impact the poor, and they will have negative and unstudied impacts on environmental justice.

EPA Response: The EPA disagrees that the standards are not based on sound science. The EPA's final rule represents data-driven drinking water standards that are based on the best available science and meet the requirements of SDWA. Please see sections 1.1 and 1.3 of the EPA response in this *Response to Comments* document, as well as section I of the FRN concerning the EPA's assessment of best available science to support the rulemaking.

The EPA disagrees that the standards will have negative and unstudied impacts on low income and environmental justice communities. Contrary to the commenter's assertion, the EPA has evaluated the rule's impacts on environmental justice communities. For discussion of how EPA considered environmental justice communities, please see section 14.10 of the EPA response in this *Response to Comments* document, as well as section XIII.J of the FRN that supports the EPA's assessments of impacts on low-income populations and environmental justice communities.

The EPA disagrees with the commenter's assertion that the rule will negatively impact the small business community. The EPA has met all the requirements of the Regulatory Flexibility Act (RFA), including seeking the input of small entities through a Small Business Advocacy Review (SBAR) Panel. In the final rule, the EPA has included a number of burden-reducing flexibilities to decrease significant impacts to small entities while also ensuring adequate public health protection. For more information, please see section XIII.C of the FRN and section 14.3 of this document.

Massachusetts Water Resources Authority (Doc. #1645, SBC-043281)

May 30, 2023

VIA Federal eRulemaking Portal: https://www.regulations.gov

U.S. Environmental Protection Agency EPA Docket Center

Office of Ground Water and Drinking Water Docket Mail Code 2822IT

1200 Pennsylvania Avenue NW Washington, DC 20460

Re: PFAS National Primary Drinking Water Regulation Rulemaking, Docket ID No. EPA–HQ–OW-2022-0114

To Whom It May Concern:

On March 29, 2023, the U.S. Environmental Protection Agency (EPA) published a preliminary regulatory determination and proposed rule regarding per- and polyfluoroalkyl substances (PFAS) under the Safe Drinking Water Act (SDWA). 88 Fed. Reg. 18638 (March 29, 2023). EPA's current actions are twofold and follow a March 2021 final regulatory determination to regulate perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) as contaminants under the SDWA. First, EPA is issuing a preliminary regulatory determination to regulate perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO–DA) and its ammonium salt (also known as a GenX chemicals), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS), and mixtures of these PFAS as contaminants under SDWA. Second, EPA is proposing a National Primary Drinking Water Regulation (NPDWR) and health- based Maximum Contaminant Level Goals (MCLG) for these four PFAS and their mixtures, as well as for PFOA and PFOS.

In particular, EPA is proposing to set the MCLG for PFOA and PFOS at zero and individual maximum contaminant levels (MCLs) of 4.0 nanograms per liter (ng/L) or parts per trillion (ppt) for PFOA and PFOS. Further, with respect to PFHxS, HFPO–DA and its ammonium salt, PFNA, and PFBS, EPA is proposing to: (1) use a Hazard Index (HI) approach; (2) use a HI of 1.0 as the MCLGs for these four PFAS and any mixture containing one or more of them; and (3) set the MCLs for these four PFAS and for a mixture containing one or more of PFHxS, HFPO–DA and its ammonium salt, PFNA, PFBS as a unitless HI of 1.0. The Massachusetts Water Resources Authority (MWRA) respectfully submits these comments regarding EPA's actions, including the proposed rule.

1. MWRA Overview

MWRA provides wholesale water and wastewater services to 3.1 million people and more than 5,500 businesses in 61 communities in eastern and central Massachusetts. On a daily basis, MWRA provides 200 million gallons of water to 2.5 million people in 53 communities across the greater Boston area.

MWRA's source water originates from two highly protected reservoirs, the Quabbin and Wachusett reservoirs. Eighty-five percent of the watersheds of these reservoirs are comprised of forested landscapes and wetlands. The high quality of MWRA's source water equates to limited treatment requirements. MWRA's John J. Carroll Treatment Plant has the capacity to treat up to 405 million gallons per day. Treatment at the facility includes ozone and ultraviolet disinfection and chemical additions to buffer the finished water and ensure adequate residual disinfection in the drinking water as it travels through MWRA's transmission system to our customers.

EPA Response: The EPA acknowledges this comment.

Association of Public Health Laboratories (APHL) (Doc. #1646, SBC-043297)

May 30, 2023

US Environmental Protection Agency

Re: APHL's comments on EPA-HQ-OW-2022-0114

PFAS National Primary Drinking Water Regulation

The Association of Public Health Laboratories (APHL) appreciates the opportunity to comment on the proposed PFAS National Primary Drinking Water Regulation. APHL works to strengthen laboratory systems serving the public's health in the United States and globally. The organization represents state and local public health, environmental, and agricultural laboratories in the United States. Our members [Link: https://www.aphl.org/membership/Pages/memberlabs.aspx] monitor, detect and respond to health threats.

We agree with the United States Environmental Protection Agency (US EPA) that per- and polyfluoroalkyl substances (PFAS) are nearly ubiquitous anthropogenic compounds that have

been shown to be harmful to public health. We support EPA actions to establish health advisory levels (HALs), maximum contaminant levels (MCLs), and maximum contaminant level goals (MCLGs) for two PFAS Compounds (PFOA, PFOS) and a hazard index (HI) for four additional (GenX, PFBS, PFNA, and PFHxS). Establishing consistent national standards will aid states and businesses in developing long-term strategies that further protect public health and the environment, aiming to improve health equity and environmental justice outcomes.

APHL provided technical comments to the proposed rule through our participation in the Environmental Monitoring Coalition [Link: https://envmoncoalition.org/](EMC). This group represents environmental laboratory perspectives of APHL members, as well as the American Council of Independent Laboratories, American Water Works Association, The NELAC Institute, and Water Environment Federation.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR and appreciates the technical comments provided. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Association of Public Health Laboratories (APHL) (Doc. #1646, SBC-043301)

Comments on PFAS National Primary Drinking Water Regulation Rulemaking

May 26, 2023

The Environmental Monitoring Coalition (EMC) was created in 2020 to address a void created by the dissolution of EPA's Environmental Laboratory Advisory Board. The following EMC organizations represent private and government laboratories from state and local governments and drinking and wastewater utilities:

• American Council of Independent Laboratories,

• American Water Works Association,

• Association of Public Health Laboratories,

• The NELAC Institute, and

• Water Environment Federation.

The EMC was established in response to the need for the environmental monitoring community to have a mechanism to develop consensus opinions on issues affecting environmental monitoring.

The EMC supports EPA's efforts to provide clear and uniform requirements for monitoring of the specific PFAS in drinking water nationally, especially since many states are developing their own programs and standards.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR.

New England Interstate Water Pollution Control Commission (NEIWPCC) (Doc. #1650, SBC-043136)

May 30, 2023 Michael S. Regan

Administrator

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue NW

Mail Code: 4607M

Washington, DC 20460

Re: Docket ID No. EPA-HQ-OW-2022-0114, NEIWPCC Comments in response to the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

Dear Administrator Regan:

The New England Interstate Water Pollution Control Commission (NEIWPCC) appreciates the opportunity to comment on behalf of our member States' Health Commissioners [FN1: 35 commissioners—five from each member state—oversee NEIWPCC. Each commissioner is appointed by their state governor. A state's delegation typically consists of the heads of its environmental and health agencies, who generally designate representatives to attend NEIWPCC meetings on their behalf, supplemented by three highly experienced individuals from outside state government. The Health Commissioner meetings are a subset of the Commissioners which consists of the heads of our member states' health agencies or their representatives] on the U.S. Environmental Protection Agency's (EPA) proposal to regulate six per- and polyfluoroalkyl substances (PFAS) under the Safe Drinking Water Act through issuance of a proposed National Primary Drinking Water Regulation (NPDWR). NEIWPCC is providing higher-level perspectives below. NEIWPCC urges EPA to consider the comments of our member states that, especially for this proposed rule, have concerns uniquely applicable to their states.

NEIWPCC was established by an act of the United States Congress which ratified the New England Interstate Water Pollution Control Compact in 1947. NEIWPCC is a regional commission that helps Northeast states preserve and advance water quality. [FN2: NEIWPCC member states include the six New England states and the State of New York.] We engage and convene water quality professionals and other interested parties from New England and New York to collaborate on drinking water, wastewater, and environmental science challenges across shared regions and ecosystems.

NEIWPCC commends the EPA's effort to establish Maximum Contaminant Levels for six per- and polyfluoroalkyl substances. Our member states are fundamentally supportive of the intent and spirit of the proposed rule. Our members have targeted PFAS substances with a variety of approaches. In recent years, our members have enacted laws restricting PFAS in firefighting foam; regulating the presence of PFAS in drinking water, food packaging and consumer

products; and allocating funds for cleanup and remediation; among other measures. All our member states have addressed PFAS through agency rulemaking, including adopting standards for PFAS levels in drinking water supplies. NEIWPCC offers the following high-level comments on their behalf for EPA's consideration in developing a final rule.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

NCASI (Doc. #1651, SBC-043159)

TO: Ms. Alexis Lan

Office of Ground Water and Drinking Water

Standards and Risk Management Division U.S. Environmental Protection Agency 1200 N. Pennsylvania Avenue, N.W.

Washington, D.C. 20460

Docket: EPA-HQ-OW-2022-0114

Submitted through the Federal eRulemaking Portal

May 30, 2023

RE: "Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation Rulemaking"

NCASI conducts research and technical studies on behalf of forest products companies across the US, and its members represent more than 80% of pulp and paper and two-thirds of wood panels produced nationwide. NCASI has been an active participant at the state and federal levels in technical and scientific aspects of risk assessment, water quality criteria development for many years and, more recently, has collaborated with other researchers to consider approaches to the systematic review of toxicological and epidemiological information when estimating toxicity factors for environmental contaminants.

NCASI appreciates the opportunity to provide technical comments regarding the "Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation". Our technical analysis of the proposed rulemaking has identified a number of scientific issues, including:

• A classification of PFOS as a likely carcinogen without a scientifically defensible evidence base.

• Potential implementation challenges due to laboratory limitations for an MCL of 4 ppt and an action level of 1.3 ppt for PFOA and PFOS.

• The inappropriate application of the Hazard Index approach for additionally listed PFAS under The MCL framework.

EPA Response: The EPA acknowledges these comments of concern in the proposed rule. Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA disagrees that the classification of PFOS as a likely carcinogen lacks a scientific basis. Please see section 4.1.4 of the EPA response in this *Response to Comments* document. Please see section 5.1.2 of the EPA response in this *Response to Comments* document (specifically, the EPA response to comment Doc. #1651, SBC-043226) for concerns about laboratory limitations related to the MCL. The EPA does not agree that the Hazard Index approach was inappropriately applied. Please see sections 4.3.2 and 5.2.1 of the EPA response in this *Response to Comments* document.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044168)

May 30, 2023

Honorable Radhika Fox

Assistant Administrator Radhika Fox

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue NW

Washington, DC 20460

Re: Proposed PFAS National Primary Drinking Water Regulation Rulemaking (EPA-HQ-OW-2022-0114)

Dear Assistant Administrator Fox,

The North Carolina Division of Water Resources (DWR), within the Department of Environmental Quality (DEQ), appreciates the opportunity to provide comments on the U.S. Environmental Protection Agency's (EPA), proposed PFAS National Primary Drinking Water Regulation published in the Federal Register on March 29, 2023 (FR Vol. 88, No. 60).

Please find our detailed comments attached. We appreciate your consideration of these comments. If we can be of assistance regarding these comments, please contact Dr. Rebecca Sadosky, Chief of the Public Water Supply Section at 919-707-9096 or at Rebecca.Sadosky@deq.nc.gov.

Sincerely,

Richard E. Rogers, Jr., Director

Division of Water Resources,

Department of Environmental Quality

Enclosure

Comments by North Carolina Department of Environmental Quality (NCDEQ) for the Proposed PFAS National Primary Drinking Water Regulations Docket ID No. EPA-HQ-OW-2022-0114

Introduction

NC Department of Environmental Quality (NCDEQ) appreciates the opportunity to provide comments on the Environmental Protection Agency's (EPA or Agency) proposed per- and polyfluoroalkyl substances (PFAS) National Primary Drinking Water Regulation (NPDWR). NCDEQ applauds EPA for taking this important step towards developing enforceable limits under the Safe Drinking Water Act. We support EPA's efforts to provide national leadership and consistency for assessing and addressing PFAS in drinking water.

NCDEQ's comments below focus on topics related to North Carolina's role in the implementation of the regulation where we could provide the most robust feedback in support of expeditious and increased public health protection for our residents. Our comments are grouped into the following topics:

A. General Comments

B. Guidance and Training Needed

C. State Agency Staff and Resource Needs

D. Data Management

E. Public Communication

F. Laboratory Readiness

G. Monitoring Requirements

H. PFAS Treatment

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044200)

Conclusion

In conclusion, NCDEQ commends EPA for taking an important step to propose first-ever science based drinking water standards for PFAS. NCDEQ is committed to working in partnership with EPA and other federal agencies to prevent PFAS pollution and protect our drinking water supplies from toxic chemicals. We recognize that there are numerous technical, feasibility, and resource challenges in implementing this rule. We request that EPA address the recommendations described above to the extent possible as it finalizes the rule and continue

needed investments to respond to the remaining comments going forward. As co-regulators, state agencies must work closely with EPA throughout all stages of rule development and implementation. A coordinated effort will help ensure that public communication is effective and that state agencies are prepared to engage with their water systems and the public with the promulgation of the final rule. North Carolina looks forward to continued collaboration with EPA to protect our communities and the environment from PFAS.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

National Association of Manufacturers (NAM) (Doc. #1655, SBC-043197)

Conclusion

The NAM's members want to ensure they continue to be excellent environmental stewards but also want to make sure that any regulations are achievable. When regulations are set near zero, that is not something manufacturers or water systems can economically achieve. Regulations that are not economically achievable will lead to critical substances being manufactured outside of the U.S. where environmental protections are often less stringent. EPA should set the cleanup standards at a level that provides appropriate health and safety benefits while making cleanup for affected communities economically feasible.

Sincerely, Brandon Farris

VP, Energy and Resources Policy

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA believes that it is feasible to achieve the MCLs established in this regulation. Please see sections 5.1.3 and 5.1.4 of the EPA response in this *Response to Comments* document for feasibility and cost considerations, as well as section 13.3 (specifically, the EPA response to comment Doc. #1655, SBC-043195) regarding cost estimates for the rule. The manufacturing of substances is out of scope for this NPWDR. Please see section 15.1 of the EPA response in this *Response to Comments* document for topics that are out of scope.

National Association of Manufacturers (NAM) (Doc. #1655, SBC-043194)

The NAM supports commonsense regulations on PFAS that ensure that manufacturers continue to be excellent environmental stewards while recognizing that in many cases we will need to continue to use these chemicals for the foreseeable future. However, the EPA's proposed regulations under the Safe Drinking Water Act (SDWA) on six per- and polyfluoroalkyl substances fail to meet the commonsense test as they are set at cleanup levels that are near zero.

Furthermore, EPA failed to go through the required legal and procedural requirements to justify the proposed rule for the mixture of four of the six PFAS.

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. The EPA notes that it is not directly setting clean up levels with this action; rather, the agency is directly setting national primary drinking water regulations through this action. The EPA has conducted all necessary scientific, economic, and other required analyses. The EPA disagrees that it failed to go through the required legal and procedural requirements for this NPDWR. Please see sections 1.1 and 1.3 of the EPA response in this *Response to Comments* document. Please see SDWA 1412(b)(3)(C)(iii) for the requirements that the EPA must only consider the impacts and costs directly imposed by this NPDWR. Specifically, that section of SDWA requires that the EPA include quantifiable and non-quantifiable costs that are likely to occur solely because of compliance with the rule including monitoring, treatment and other costs and excluding costs resulting from compliance with other proposed or promulgated regulations.

Consumer Reports (Doc. #1656, SBC-043179)

May 30, 2023

Docket Clerk

U.S. Environmental Protection Agency

EPA Docket Center

Office of Ground Water and Drinking Water Docket, Mail Code 2822IT

1200 Pennsylvania Avenue NW

Washington, DC 20460

Re: Docket No. EPA-HQ-OW-2022-0114; PFAS National Primary Drinking Water Regulation Rulemaking

To Whom it May Concern:

Thank you for the opportunity to submit comments on the Environmental Protection Agency's (EPA's) determinations to regulate six per- and poly-fluoroalkyl substances (PFAS) as contaminants under the Safe Drinking Water Act (SDWA) and set regulatory limits for these PFAS in drinking water.

Founded in 1936, Consumer Reports (CR) is an independent, nonprofit and nonpartisan organization that works with consumers to create a fair and just marketplace. Known for its rigorous testing and ratings of products, CR advocates for laws and company practices that put consumers first. CR is dedicated to amplifying the voices of consumers to promote safety, digital rights, financial fairness, and sustainability. The organization surveys millions of Americans

every year, reports extensively on the challenges and opportunities for today's consumers, and provides ad-free content and tools to 6 million members across the U.S.

In March 2021, EPA made a final regulatory determination to regulate perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) under the SDWA. With this notice, EPA is issuing a preliminary regulatory determination to regulate perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salts (aka GenX chemicals), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS) and mixtures of these PFAS as contaminants under SDWA.

We agree with EPA's preliminary determination to regulate these 4 PFAS and their mixtures as contaminants under SDWA. We also agree with EPA's proposed National Primary Drinking Water Regulation (NPDWR) and health-based maximum contaminant level goals (MCLGs) for these 4 PFAS and their mixtures as well as PFOA and PFOS. In addition, we support MCLGs of zero for PFOA and PFOS and enforceable maximum contaminant levels (MCLs) for PFOA and PFOS in drinking water at 4.0 parts per trillion (ppt). We agree with EPA's proposal to use a Hazard Index (HI) approach to protecting public health from mixtures of PFHxS, HFPO-DA, PFNA and PFBS. We also support EPA's proposal to set a Hazard Index (HI) of 1.0 as the MCLGs and for the enforceable MCLs for these 4 PFAS and any mixture containing one or more of them.

More detailed comments are below.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Virginia Municipal Drinking Water Association (VMDWA) (Doc. #1657, SBC-043174)

Eighth, we are concerned that the proposed regulation will lead to a loss of public confidence in the safety of public water, when implementation activities unavoidably extend past regulatory deadlines due to the types of real world conditions and challenges discussed in this comment letter.

For all of the above reasons, EPA should provide for a health-based phased approach, as discussed in the next section.

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. For concerns with public confidence, please see section 1.2 of the EPA response in this *Response to Comments* document.

Virginia Municipal Drinking Water Association (VMDWA) (Doc. #1657, SBC-043160)

May 30, 2023

By Electronic Submission: Docket EPA–HQ–OW–2022–0114

U.S. Environmental Protection Agency

EPA Docket Center

PFAS: PFOA and PFOS National Primary

Drinking Water Regulation Rulemaking,

Mail Code 28221T

1200 Pennsylvania Avenue NW

Washington, DC 20460

Dear Sir/Madam:

The Virginia Municipal Drinking Water Association, Inc. (VMDWA) appreciates the opportunity to comment on U.S. EPA's PFAS National Primary Drinking Water Regulation Rulemaking, including the proposed Maximum Contaminant Levels and implementation procedures for PFOA, for PFOS, and for PFHxS, HFPO–DA and its ammonium salt, PFNA, and PFBS and their mixtures.

Below we present our comments organized in six parts:

Part 1 Support for Safe and Affordable Water Generally

Part 2 Whether Proposed MCLs Are Set at Appropriate Levels

Part 3 Actual Compliance Costs Are Likely to Be Much Higher Than EPA Estimates

Part 4 The Unrealistically Short Schedule For Compliance Will Cause Harm to the Nation and Local Communities and Should Be Replaced With a Health-Based Phased Approach

Part 5 Recommendation

Part 6 Conclusion

1. SUPPORT FOR SAFE AND AFFORDABLE WATER GENERALLY

VMDWA is a non-profit membership association comprised of 42 local governments and local water authorities that provide the essential public service of supplying the vast majority of Virginians with safe drinking water. VMDWA's purpose is to advocate for science-based, sensible, and sustainable laws and policies to help ensure safe and affordable water for Virginians. VMDWA supports safe water as well as overall vibrant and healthy communities. This includes making prudent investments and operational enhancements in public water systems to continue delivering safe water to the public based on the current scientific research. VMDWA Members do this and do this well.

As public water utilities, VMDWA Members do not manufacture or use PFAS chemicals in their water (or wastewater) treatment processes. Rather, when PFAS chemicals are found in their systems, it is due to the manufacture and use of PFAS chemicals by various other actors in society. The proposed regulations target public water systems, however, with a massive new regulatory burden and tremendous compliance costs that will necessarily be passed on to families and businesses in the form of higher water rates and charges.

Based on VMDWA's experience, EPA's proposed regulations appear to have the potential to impose the greatest compliance costs in the history of the Safe Drinking Water Act considering capital and ongoing operation and maintenance costs discussed below. In addition, EPA's rulemaking will impose a major opportunity cost on local communities and families, insofar as the resources required for compliance with this regulation will simply be unavailable to spend on other personal/business (ratepayer) or utility/governmental (water system owner) objectives in the future.

Again, as mentioned above, VMDWA supports safe water and vibrant, healthy communities. It is out of deep commitment to the public interest that VMDWA brings the following issues, concerns, and recommendations to EPA's attention for further consideration as EPA works to adopt a final regulation.

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns of the rule. Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA has addressed the cost concerns described here, all of which can be found within the responses and throughout sections 5.1, 5.3, 13.3 and 13.3.3 of the *Response to Comments* document. Responses to the costs for PFAS removal can be found in section 10.4.1 of the EPA response in this *Response to Comments* document (specifically, the EPA response to comment Doc. #1657, SBC-043166).

Virginia Municipal Drinking Water Association (VMDWA) (Doc. #1657, SBC-043178)

6. CONCLUSION

VMDWA supports safe water and certainly does not oppose necessary and appropriate public health-related requirements. To better serve the public health, local communities, and the Nation as a whole, VMDWA respectfully submits that certain material aspects of the proposed regulation and its real world implementation infeasibility should be considered further and restructured to better serve the public interest as described above.

Sincerely,

VMDWA BOARD OF DIRECTORS

Copy to:

VMDWA Members

Christopher D. Pomeroy, Esq., AquaLaw

Justin W. Curtis, Esq., AquaLaw

EPA Response: The EPA has determined that this final PFAS NPDWR is both implementable and feasible. The EPA has identified feasible MCLs, taking costs into consideration, that can significantly reduce public health risks related to PFAS, as outlined in section 5 of the EPA response in this *Response to Comments* document and section V of the FRN. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Maryland Association of Municipal Wastewater Agencies (MAMWA) (Doc. #1658, SBC-043409)

Eighth, we are concerned that the proposed regulation will lead to a loss of public confidence in the safety of public water, when implementation activities unavoidably extend past regulatory deadlines due to the types of real world conditions and challenges discussed in this comment letter.

For all of the above reasons, EPA should provide for a health-based phased approach, as discussed in the next section.

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. This PFAS NPDWR follows a health-based approach, as outlined in section 1.3 of the EPA response in this *Response to Comments* document. For concerns with public confidence, please see section 1.2 of the EPA response in this *Response to Comments* document.

Maryland Association of Municipal Wastewater Agencies (MAMWA) (Doc. #1658, SBC-043413)

CONCLUSION

MAMWA supports safe water and certainly does not oppose necessary and appropriate public health-related requirements. To better serve the public health, local communities, and the Nation as a whole, MAMWA respectfully submits that certain material aspects of the proposed regulation and its real world implementation infeasibility should be considered further and restructured to better serve the public interest as described above.

Sincerely,

MAMWA BOARD OF DIRECTORS

Copy to:

MAMWA Members

Christopher D. Pomeroy, Esq., AquaLaw

Lisa M. Ochsenhirt, Esq., AquaLaw

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR as it is. Please see section 1.3 of the EPA response in this *Response to Comments* document, as well as the EPA response to comment Doc. #1657, SBC-043178 in section 1.3 in this *Response to Comment* document regarding implementation and feasibility of this rule.

Maryland Association of Municipal Wastewater Agencies (MAMWA) (Doc. #1658, SBC-043395)

Maryland Association of Municipal Wastewater Agencies, Inc.

Washington Suburban Sanitary Commission

14501 Sweitzer Lane, 7th Floor

Laurel, MD 20707

Tel: 301-206-7008

May 30, 2023

By Electronic Submission: Docket EPA–HQ–OW–2022–0114

U.S. Environmental Protection Agency

EPA Docket Center

PFAS: PFOA and PFOS National Primary

Drinking Water Regulation Rulemaking,

Mail Code 28221T

1200 Pennsylvania Avenue NW

Washington, DC 20460

Dear Sir/Madam:

The Maryland Association of Municipal Wastewater Agencies, Inc. (MAMWA) appreciates the opportunity to comment on U.S. EPA's PFAS National Primary Drinking Water Regulation Rulemaking, including the proposed Maximum Contaminant Levels and implementation procedures for PFOA, for PFOS, and for PFHxS, HFPO–DA and its ammonium salt, PFNA, and PFBS and their mixtures. The Association has been supporting clean water, vibrant communities, and a strong state economy for nearly 20 years by seeking to align clean water goals, smart management practices, and affordable technology and infrastructure. In promoting abundant clean water in this manner, MAMWA helps support a strong economy and a high quality of life in local communities.

Below we present our comments organized in six parts:

[Table 1: See Docket ID EPA-HQ-OW-2022-0114-1658]

1. SUPPORT FOR SAFE AND AFFORDABLE WATER GENERALLY

MAMWA is a non-profit membership association comprised of 22 local governments and local water and wastewater authorities, most of which provide the essential public service of supplying Marylanders with safe drinking water in addition to treating their wastewater to high standards. MAMWA advocates for science-based, sensible, and sustainable laws and policies to help ensure clean, safe, and affordable water for Marylanders. MAMWA supports clean and safe water as well as overall vibrant and healthy communities. MAMWA appreciates that clean and safe water sometimes requires making prudent investments and operational enhancements in public infrastructure based on the current scientific research. When necessary, MAMWA Members do this and do this well.

Of course, MAMWA Members do not manufacture or use PFAS chemicals in their water or wastewater treatment processes. Rather, when PFAS chemicals are found in their systems, it is due to the manufacture and use of PFAS chemicals by various other actors in society. The proposed regulations target public water systems, however, with a massive new regulatory burden and tremendous compliance costs that will necessarily be passed on to families and businesses in the form of higher water rates and charges.

EPA's proposed regulations appear to have the potential to impose the greatest compliance costs in the history of the Safe Drinking Water Act considering capital and ongoing operation and maintenance costs discussed below. In addition, EPA's rulemaking will impose a major opportunity cost on local communities and families, insofar as the rule's compliance costs will require resources that will simply be unavailable to spend on other personal/business (ratepayer) or utility/governmental (water system owner) objectives in the future. Therefore, it is important to protect public health in a cost-effective manner in finalizing and implementing this regulation.

Again, as mentioned above, MAMWA supports clean and safe water and vibrant, healthy communities. It is out of deep commitment to the public interest that MAMWA brings the following issues, concerns, and recommendations to EPA's attention for further consideration as EPA works to adopt a final regulation.

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document, as well as the EPA response to comment Doc. #1657, SBC-043160 in this *Response to Comments* document. For more discussion on costs, please see section XII of the FRN for this rule.

National Association of Clean Water Agencies (NACWA) (Doc. #1659, SBC-043131)

NACWA's comments, outlined in more detail below, include concerns over EPA's severe underestimation of cost impacts to public water systems (PWSs), EPA's shortsightedness in not fully considering laboratory capacity and the guaranteed backlog that will occur when tens of thousands of PWSs and clean water utilities are trying to monitor and comply simultaneously, the likelihood of treatment equipment and carbon supply shortages, and, lastly, the potential impacts on greenhouse gas emissions due to energy consumption at PWSs and clean water utilities.

EPA Response: The EPA disagrees that the topics listed were not fully considered. Please see section 1.3 of the EPA response in this *Response to Comments* document. Please see the EPA response in this *Response to Comments* document for responses to the following: section 5.1.2 (specifically, the EPA response to comment Doc. #1659, SBC-043155) for laboratory capacity, availability, and capability; and section 10.6 (specifically, the EPA response to comment Doc. #1659, SBC-043156) and section 5.1.4 for treatment technology availability and capacity. For responses to comments on the analyses for greenhouse gas emissions, please see section XIII.A.2 in the FRN.

Maine Organic Farmers and Gardeners Association (MOFGA) (Doc. #1660, SBC-043379)

SUBMITTED VIA REGULATIONS.GOV PORTAL

May 30, 2023

Michael S. Regan

Administrator

Environmental Protection Agency 1200 Pennsylvania Avenue, N. W.

Mail Code: 4607M

Washington, DC 20460

RE: Comments submitted by the Maine Organic Farmers and Gardeners Association on EPA's Proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation, Docket ID: EPA-HQ-OW-2022-0114.

Dear Administrator Regan,

The Maine Organic Farmers and Gardeners Association (MOFGA) appreciates the opportunity to submit these comments in strong support of the proposed rule. We oppose any delay in completing this rulemaking, which is long overdue.

MOFGA'S interest in the rulemaking. MOFGA has a strong interest in this rulemaking, which will improve the lives and health of Maine's farming families and communities. A broad-based

community, MOFGA is creating a food system that is healthy and fair for all of us. Through education, training and advocacy, we are helping farmers thrive, making more local, organic food available and building sustainable communities. MOFGA certifies 535 organic farms and processing operations representing roughly $90 million in sales, and we are working hard to create opportunities for Maine's next generation of farmers. Each of these farmers is a Maine businessperson for whom economic health and environmental health are interdependent.

Unfortunately, adhering to organic practices provides no guarantee that the scourge of PFAS contamination won't impact an organic farm business. Whether organic or conventional, farms can produce contaminated crops and animal products, and farm families are vulnerable to health problems, if using drinking and irrigation water contaminated with PFAS, or growing crops on soils once spread with PFAS-contaminated sludge.

Since 2016, when PFAS was first found to have contaminated water, milk and soils at a Maine dairy farm, the state has been on the front lines developing its own health standards in the absence of enforceable federal drinking water standards. At least 56 Maine farms, both conventional and organic, are now known to have been contaminated with PFAS, and more than 300 drinking water wells have been polluted. These investigations are still underway; PFAS contamination at more farms and wells is likely to be discovered as the Maine Department of Environmental Protection (MDEP) completes this 3-year investigation. [FN1: Maine DEP PFAS Investigation, https://maine.maps.arcgis.com/apps/webappviewer/index.html?id=468a9f7ddcd54309bc1ae8ba173965c7]

Maine taxpayers have invested more than $100 million to test soil, water and food for PFAS, install filtration systems, conduct research, fund farmer assistance, and initiate testing and health monitoring for people exposed to high levels of PFAS in drinking water. This doesn't include additional sludge disposal costs now the State has – correctly -- banned land-spreading.

Removing and destroying contaminated soils and restoring healthy agricultural soils currently isn't feasible either technologically or economically. MOFGA has been on the front lines helping farmers dealing with the devastating consequences of PFAS contamination, including by fundraising and administering with the Maine Farmland Trust an emergency relief fund as a bridge to the State's efforts to stand up publicly funded assistance. [FN2: https://www.mofga.org/pfas/pfas-emergency-relief-fund/]

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. For topics out of scope of this rulemaking, please see section 15 of the *Response to Comments* document.

Maine Organic Farmers and Gardeners Association (MOFGA) (Doc. #1660, SBC-043381)

Federal regulation and funding is necessary. Is Maine's PFAS experience an outlier? We very much doubt it. Even today, PFAS-contaminated sludge is being spread on farm fields across the country. It's just that Maine is the only state methodically investigating every site where sludge-spreading may have occurred in the past 40 years. Other states must do the same to protect the health of their residents and the safety of the Nation's food system.

EPA's proposed drinking water testing, monitoring and health standard for six PFAS is an important first step towards this needed national response. Without this standard, states like Maine have had to establish their own health and safety criteria for water and food, with only EPA's outdated and unenforceable 70ppt advisory as federal guidance. Some other states are doing nothing and likely allowing meat, milk and produce onto the market without regulation, and PFAS-contaminated drinking water in their schools, nursing home facilities, residences and workplaces.

We support EPA setting an MCLG at zero for PFOA and PFOS. As testing technologies become more sensitive and reliable, the rule should require the 4 parts per trillion MCL to ratchet down.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

J.R. Simplot Company (Doc. #1661, SBC-044154)

Conclusion

Proper regulation for PFAS substances in water is important but must be done in a lawful and science-based process. Thus, for an appropriate and science-based regulation of PFAS chemicals, EPA must ensure that its regulations are based on robust scientific evaluations and meet statutory criteria. The proposed rule does not meet this benchmark. Several examples are provided in this comment letter as the deficiencies in this rulemaking. EPA should withdraw the proposed rule.

Please reach out to Rachel Roskelley, Sr. Environmental Programs Manager, at rachel.roskelley@simplot.com or 208-780-7426 or myself at 208-780-7365 if you have any questions about these comments.

Sincerely,

Alan L. Prouty

Vice President, Environmental & Regulatory Affairs

C:

Ed Thomas

The Fertilizer Institute

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

J.R. Simplot Company (Doc. #1661, SBC-044147)

May 30, 2023

SUBMITTED VIA: www.regulations.gov

Docket #: EPA-HQ-OW-2022-0114

Mr. Alex Lan

Office of Ground Water and Drinking Water Environmental Protection Agency 1200 Pennsylvania Ave, N.W.

Washington, D.C. 20460-0001

RE: The J.R. Simplot Company Comments for Proposed EPA PFAS National Primary Drinking Water Regulation, 40 CFR Parts 141 and 142

(Docket# EPA-HQ-OW-2022-0114)

Dear Mr. Lan:

The J.R. Simplot Company (Simplot) submits these comments in response to U.S. Environmental Protection Agency's (EPA's) proposed PFAS National Primary Drinking Water Regulation (PFAS NPDWR) published in the Federal Register on March 29, 2023 (88 FR 18638) and effective 3 years after the date of publication of the final rule in the Federal Register.

EPA has proposed Maximum Contaminant Levels (MCLs) and Maximum Contaminant Level Goals (MCLGs) in drinking water for per- and polyfluoroalkyl substances (PFAS) substances, as follows:

• Proposed MCLs for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) are 4 parts per trillion (individually)

• Proposed MCL and MCLG as a mixture containing perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonia salt (also known as GenX Chemicals), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS) with a Hazard Index (HI) of 1.0

• Proposed MCLGs for PFOA and PFOS are zero

The proposed rule would also require public water systems to implement a monitoring program for PFAS substances, provide public notification of MCL exceedances to the public, and reduce the levels, including installing best available technology (BAT) if proposed MCLs are exceeded.

The J.R. Simplot Company (Simplot) is a privately held agribusiness corporation based in Boise, Idaho. The corporation is engaged in a number of businesses including food processing, farming, fertilizer manufacturing, mining, ranching and other enterprises related to agriculture. Simplot has operations throughout the United States. Simplot's facilities operate non-transient, non-community water systems (NTNCWSs) or obtain water from community water systems (CWS). Thus, this PFAS NPDWR rulemaking is of direct interest to the company, and we offer the following comments.

EPA Response: The EPA acknowledges this comment.

Water Supply District of Acton (Doc. #1662, SBC-043668)

Thank you for the opportunity to provide these comments. As a public utility, our staff and elected officials work hard to always follow the laws and regulations put forth by our regulatory agencies. I am sounding the alarm that I do not think this rule is reasonable, nor easily achievable. EPA has an obligation to address the water sector's implementation concerns and craft a final rule that is more realistic in its expectations of implementation and schedule and comes with a guarantee of the requisite funding to ensure PWS can comply.

Sincerely,

Matthew L. Mostoller

District Manager

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Water Supply District of Acton (Doc. #1662, SBC-043659)

May 30, 2023

Mr. Michael S. Regan, Administrator

U.S. Environmental Protection Agency

EPA Docket Center, OLEM Docket, Mail Code 28221 T 1200 Pennsylvania Avenue, NW

Washington, DC 20460

RE: Docket ID No. EPA-HQ-OW-2022-0114 - National Primary Drinking Water Regulation Rulemaking for per- and polyfluoroalkyl substances (PFAS)

Dear Administrator Regan

I am writing on behalf of the Water Supply District of Acton (District) to provide comments on the Environmental Protection Agency's (EPA) proposed National Primary Drinking Water Regulation Rulemaking for per- and polyfluoroalkyl substances (PFAS). Our utility fully supports efforts to expand verified public health protections, but EPA needs to consider the challenges associated with its proposed rulemaking and address the concerns regarding implementation before finalizing any standards. The District has a long track record of dealing with emerging contaminants dating back to the discovery of Volatile Organic Compounds (VOCs) in our water supply during the 1970s and 1980s. We believe our experience is extremely valuable and should be considered as the EPA intends to act relating to the newest class of emerging contaminants, PFAS.

The District provides drinking water and fire protection to approximately 95% of homes and businesses in Acton, MA, a suburb of Boston with almost 24,000 residents. All our supply is sourced from a network of groundwater wells located within the community. Through extensive sampling, we have identified PFAS at varying concentrations in every well we operate. A definitive source, or more likely sources, has yet to be identified. Our utility is aware that EPA will receive comments from other utilities and water works organizations that are submitting more comprehensive comments. I would urge EPA to pay close attention to the points raised by these associations as they are comprised of individuals and companies with expertise in designing and operating Public Water Systems (PWS) and they have additional understanding of the challenges which will be associated with implementing any final rule EPA adopts. The District's major concerns about the proposed rulemaking are as follows:

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Blue Ridge Environmental Defense League (BREDL) (Doc. #1663, SBC-044388)

Millions of people in this country are unknowingly drinking, cooking, making Kool Aid, and baby formula with water contaminated by PFAS. The Environmental Protection Agency must use its authority to confirm that state and local agencies are taking adequate steps to inform the public about PFAS in their drinking water. EPA should take additional steps to improve their own guidance regarding notification and to regulate PFAS as a class.

Respectfully Submitted,

Therese Vick

North Carolina Healthy, sustainable Communities Campaign Coordinator

[Attachment 2: see docket ID EPA-HQ-OW-2022-0114-1663]

[Attachment 3: see docket ID EPA-HQ-OW-2022-0114-1663]

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. For additional discussion around communications, please see section 1.2 of the *Response to Comments* document.

Santa Clara Valley Water District (Valley Water) (Doc. #1664, SBC-043129)

Valley Water appreciates the extensive work by the EPA to date to address PFAS and the significant public health and environmental challenge they pose. While we strongly support EPA's effort to develop drinking water standards based on sound science, we respectfully ask that you consider our comments prior to finalizing the regulation.

Again, thank you for the opportunity to provide comments. If you have any questions or would like follow-up information, please contact me at (408) 630-2135 or abaker@valleywater.org.

Sincerely,

Aaron Baker, P.E. Chief Operating Officer Water Utility Enterprise

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR as well as its comments. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Santa Clara Valley Water District (Valley Water) (Doc. #1664, SBC-043124)

The Honorable Michael Regan

Administrator

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue NW

Washington, D.C. 20460

Jennifer McLain

Director

Office of Ground Water and Drinking Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue NW

Washington, D.C. 20460

Subject: PFAS National Primary Drinking Water Regulation Rulemaking; EPA–HQ– OW–2022–0114; FRL 8543–01– OW

Dear Administrator Regan and Director McLain:

The Santa Clara Valley Water District (Valley Water) appreciates the opportunity to comment on the per- and polyfluoroalkyl substances (PFAS) National Primary Drinking Water Regulation (NPDWR) proposed by the Environmental Protection Agency (EPA) as part of Docket No. EPA-HQ-OW-2022-0114.

Valley Water provides safe, clean water to nearly two million people who live in Santa Clara County, the heart of Silicon Valley. Valley Water operates three water treatment plants that clean and disinfect imported water and water from our local reservoirs, producing as much as 220 million gallons of drinking water per day. Valley Water also operates the Silicon Valley Advanced Water Purification Center which can produce up to eight million gallons of highly purified water each day and is used to improve non-potable recycled water quality; ultimately Valley Water has plans to use water purification for potable reuse. Valley Water also operates seven managed aquifer recharge systems throughout the county. As the water wholesaler and groundwater management agency for the region, Valley Water collaborates with 13 local retailers to deliver drinking water to homes and businesses throughout the county.

Valley Water strongly supports the EPA's effort to limit PFAS and provide a nationwide health-protective drinking water standard based on sound science. We have been proactive in evaluating PFAS risks to local water supplies through voluntary testing and monitoring as well as collaboration with retailers and regulatory agencies.

PFAS presents unique challenges for drinking water and recycled water providers, water and wastewater treatment plants, and water purification facilities nationwide, with many agencies facing similar issues. Valley Water therefore supports the comments submitted by the Association of California Water Agencies (ACWA), the California Municipal Utilities Association, and the Western Urban Water Coalition along with the joint comments submitted by the Association of Metropolitan Water Agencies, National Association of Clean Water Agencies, National Rural Water Association, and League of Cities. We also respectfully offer the following Valley Water comments regarding the proposed NPDWR.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044389)

May 30, 2023

The Honorable Michael S. Regan

Administrator

U.S. Environmental Protection Agency

EPA Docket Center

Mail Code 2822IT

1200 Pennsylvania Avenue, NW

Washington, DC 20460

Subject: PFAS National Primary Drinking Water Regulation Rulemaking Comments - Docket ID No. EPA-HQ-OW-2022-0114

Dear Mr. Regan,

Thank you for the opportunity to review this proposed rulemaking for regulating per- and polyfluoroalkyl substances (PFAS). The Washington State Department of Health (DOH) has reviewed the proposed PFAS National Primary Drinking Water Regulation in Federal Register Volume 88, No. 60, dated March 29, 2023. This letter represents DOH's general and detailed comments on the proposed PFAS drinking water standards.

DOH strongly supports the proposed PFAS drinking water standards. This represents an important step in reducing exposure to PFAS to consumers of drinking water supplied by public water systems. Based upon our implementation experience of state PFAS rules, we recommend clarification, additional information, and guidance as discussed in the attached general and detailed comments document and include the following important areas of the rule:

1. Hazard Index methodology

2. Data challenges for compliance

3. Implementation challenges

4. Laboratory capability and capacity

5. Monitoring waivers

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Inland Empire Utilities Agency (IEUA), California (Doc. #1666, SBC-043387)

May 30, 2023

Electronically submitted to EPA via the Federal eRulemaking Portal:

https://www.regulations.gov Docket ID No. EPA–HQ–OW–2022–0114

Federal eRulemaking Portal

U.S. Environmental Protection Agency (EPA) EPA Docket Center

Office of Ground Water and Drinking Water Docket Mail Code 2822IT

1200 Pennsylvania Avenue NW Washington, DC 20460

Re: PFAS National Primary Drinking Water Regulation Rulemaking - Docket ID No. EPA–HQ–OW– 2022–0114; FRL 8543–01–OW

To Whom It May Concern,

On behalf of the Inland Empire Utilities Agency (IEUA), we greatly appreciate the opportunity to provide comments in response to the U.S. Environmental Protection Agency's (EPA) request for public comments on the proposed PFAS National Primary Drinking Water Regulation (NPDWR), published in the Federal Register on March 29, 2023.

IEUA is a regional public water and wastewater treatment agency servicing a population of approximately 935,000 in western San Bernardino County, California (known as the Inland Empire). The communities within IEUA's 242 square miles service area depend upon a diverse portfolio of water resources and demand management strategies to responsibly support an increasing population and a growing economy.

Over the past 70 years, IEUA's services have expanded well-beyond its original mission of providing imported water supplies to nine retail water agencies. It now includes recharging local groundwater basins with captured stormwater and recycled water, and several other innovative programs that conserve water within the basin area. IEUA also uses recycled water for non-potable uses such as landscape irrigation through a separate distribution system. To manage salinity and in anticipation of increasingly stringent regulatory requirements, IEUA's wastewater treatment processes are evolving to include advanced water treatment.

PFAS contamination presents challenges for many drinking water and wastewater treatment providers throughout our nation. While IEUA strongly supports EPA's approach to addressing PFAS to safeguard public health, protect the environment, and hold polluters accountable, we do have significant concerns with the proposed rule as drafted.

EPA Response: The EPA appreciates this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Inland Empire Utilities Agency (IEUA), California (Doc. #1666, SBC-043393)

Conclusion

IEUA supports EPA's efforts to address PFAS contamination through investments in research, development, and innovation, through a comprehensive approach that prevents PFAS from entering air, land, and water through source control, and ultimately to broaden and accelerate the cleanup of PFAS contamination to protect human health and ecological systems.

IEUA recommends additional monitoring efforts to better understand the extent of PFAS in drinking water and the environment; this data will ensure science-based decision-making in support of EPA's Health Risk Reduction and Cost Analysis for the determination of the MCLs.

Most importantly, IEUA seeks assurances that all public sanitation agencies will be allowed a minimum of five years to comply with the new regulations, by extension or otherwise. Anything less is insufficient lead time to install the necessary capital improvement projects. Finally, it is imperative that significant federal funding be made available to minimize affordability impacts on the public.

We appreciate your consideration of these comments and the opportunity to collaborate with EPA staff on the proposed rulemaking. If you have any questions, please contact Mr. Pietro Cambiaso at pcambiaso@ieua.org or (909) 993-1639.

Sincerely,

INLAND EMPIRE UTILITIES AGENCY

Shivaji Deshmukh, P.E. General Manager

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. In response to the compliance deadline concern, the EPA has exercised its authority under SDWA to implement a nationwide capital improvement extension to comply with the MCL. For more information on this, please see section 13.1 of the *Response to Comments* document as well as section XI.D of the FRN. In response to the recommendation about monitoring, please see section 8 of the *Response to Comments* document.

City of Allentown and Lehigh County Authority (LCA), Pennsylvania (Doc. #1667, SBC-043686)

In summary the City and LCA have a joint mission to protect public health and the environment by providing high-quality, safe, and reliable water services to the communities that we serve. We support the establishment of national primary drinking water standards for PFAS and applaud EPA's efforts to address this important public health issue. However, it is equally important for EPA to consider the impact on communities, which translates to a financial burden to our citizens. Please consider these comments as reasonable refinements to the approaches EPA has developed so that communities can achieve compliance while navigating the many challenges we face. Thank you for the opportunity to comment on this important regulatory change

Sincerely,

Mark Shahda

Director of Public Works

CC: Office of Compliance, City of Allentown

Liesel Gross, Lehigh County Authority

[Attachment: See Docket ID EPA-HQ-OW-2022-0114-1600]

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR, and acknowledge the commenters' concern about the financial burden on this rulemaking. Please see sections 1.3 and 13.3 of the EPA response in this *Response to Comments* document.

Aurora Water, City of Aurora, Colorado (Doc. #1669, SBC-043735)

Conclusion

In conclusion, Aurora Water appreciates the opportunity to provide feedback on the proposed National Primary Drinking Water Regulation of PFOA, PFOS, PFBS, GenX, PFNA, and PFHxS. We support EPA's continued efforts to ensure the safety of our nation's drinking water and look forward to working with the EPA to ensure the safety and reliability of our drinking water supply. However, we urge the EPA to review our comments and consider our recommendations to ensure the proposed regulation is practical and cost-effective for water systems to comply with. In addition, Aurora Water strongly encourages the EPA to include measures for removing PFOA, PFOS, PFBS, GenX, PFNA and PFHxS from manufacturing processes to prevent their introduction into water supplies and avoid the burden from being placed only on water providers and wastewater treaters.

If you have any questions or would like to meet to discuss our comments in more detail, please reach out to Sherry Scaggiari by email at sscaggia@auroragov.org or by phone at 303.739.7390.

Thank you,

Sherry Scaggiari

Environmental Services Manager Aurora Water

cc: Marshall Brown

Todd Brewer Bethany Green

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. In response to the commenter's urging that the EPA ensure the proposed regulation is practical and cost-effective for water systems to comply with, please see section 13.3 of the EPA response in this *Response to Comments* document. In response to the comment regarding removing PFOA, PFOS, PFBS, HFPO-DA, PFNA and PFHxS from manufacturing processes, please see section 15.1 of the EPA response in this *Response to Comments* document.

Aurora Water, City of Aurora, Colorado (Doc. #1669, SBC-043706)

May 30, 2023

Docket Id No. EPA-HQ-OW-2022-0114

Environmental Protection Agency EPA Docket Center

Mail code: 28221T

1200 Pennsylvania Avenue NW Washington, DC 20460

Via Federal eRulemaking Portal: https://www.regulations.gov/

RE: National Primary Drinking Water Regulations: PFAS Rule (EPA-HQ-OW-2022-0114).

Aurora Water welcomes the opportunity to provide comments on the proposed National Primary Drinking Water Regulation of PFOA, PFOS, PFBS, GenX, PFNA, and PFHxS. We are supportive of the determination to regulate certain PFAS chemicals using MCLs based on sound science while balancing feasibility and the most up-to-date information available to the agency. We do not believe the cost analysis is reflective of the cost of treating to the proposed MCL level. Aurora proposes an MCL of 10 ppt for PFOA and PFOS and a trigger level of 4 ppt. In addition, Aurora Water urges EPA to work with anyone who is manufacturing PFAS chemicals to remove the compounds from use. Until the source of the contaminants are controlled, the public's health will be at risk and the burden should not be solely placed on water providers and wastewater treaters to fix the issue. Our comments below expand on several areas of the proposed regulation where Aurora Water believes changes could be made to improve the effectiveness, practicality, and cost-effectiveness of the regulation.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the regulation of PFAS, although with different MCL levels. Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA has determined that 4.0 ppt is feasible for treatment and costs. Please see additional discussion in section 5.1 of the *Response to Comments* document. Please see section 13.3 of the EPA response in this *Response to Comments* document addressing costs of this rule.

National Association of Water Companies (NAWC) (Doc. #1670, SBC-044155)

U.S. Environmental Protection Agency

EPA Docket Center

Docket EPA-HQ-OW-2022-0114

Mail Code 28221T

1200 Pennsylvania Avenue

Washington, D.C. 20460

Re: Comments by the National Association of Water Companies (NAWC) on EPA PFAS National Primary Drinking Water Regulation Rulemaking, Docket No. EPA-HQ-OW-2022-0114.

Dear Administrator Regan,

The National Association of Water Companies (NAWC) and its members are pleased to offer this comment letter regarding the agency's PFAS National Primary Drinking Water Regulation Rulemaking published in the Federal Register on March 29, 2023. NAWC agrees that EPA should take action to address the health risk posed by the presence of PFAS chemicals in drinking water supplies. We support a national drinking water standard for PFOA and PFOS based on the best available science and an appropriate balancing of potential risks and the costs to implement the rulemaking.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

National Association of Water Companies (NAWC) (Doc. #1670, SBC-044167)

Conclusion

NAWC and its members appreciate EPA's efforts to protect public health and the environment from the harmful PFAS chemicals that pose a risk to many. We support EPA's efforts to better understand PFAS sources, take measured and practical approaches in gathering data and assessing the risks of PFAS to public health and the environment and urge EPA to consider NAWC's comments to ensure that the agency produces a rule that is protective, feasible and affordable.

Please feel free to contact me at (267) 291-7765.

Sincerely,

Robert Powelson

cc: Radhika Fox

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

National Association of Water Companies (NAWC) (Doc. #1670, SBC-044157)

About NAWC

NAWC represents regulated water and wastewater companies, as well as those engaging in partnerships with municipal utilities. NAWC members provide 73 million Americans with safe and reliable water service and have an exceptional record of compliance with federal and state health and environmental regulations. Ensuring this high standard of quality requires extraordinary amounts of capital investment. NAWC estimates that its 10 largest members alone are collectively investing $3.9 billion each year in their water and wastewater systems.

Providing affordable, safe, clean water to the customer is a high priority for NAWC's members. Toward that end, a 2018 study published in the Proceedings of the National Academy of Sciences confirmed that investor-owned water companies have a more consistent record of delivering high-quality water that meets or surpasses federal standards than their municipal counterparts. [FN1: See article, February 12, 2018 (https://www.pnas.org/doi/10.1073/pnas.1719805115)] NAWC is proud of that record and its members will continue to lead in delivering the highest attainable compliance results. NAWC works with its members to adopt a public commitment beyond compliance to proactively protecting the public health of its members' customers.

EPA Response: The EPA acknowledges this comment.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-044898)

Docket ID: EPA-HQ-OW-2002-0114

Per- and Polyfluoroalkyl Substances

Proposed PFAS National Primary Drinking Water Regulation

Cleveland Water Comments

Section 1: Overarching comments

Cleveland Water supports regulation based on sound science that is protective of human health. Due to the significant risks of severe health effects and their persistent nature, we agree with EPA's 2021 final determination to regulate PFOA and PFOS in drinking water. Public water systems (PWSs) and EPA share the same goal of ensuring the delivery of clean, safe drinking water to the public, and welcome continued dialogue on the best ways to accomplish this goal.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

North Jersey District Water Supply Commission (NJDWSC) (Doc. #1673, SBC-044201)

May 30, 2023

The North Jersey District Water Supply Commission (NJDWSC) was established in 1916 by the State of New Jersey to provide safe and reliable drinking water to a large portion of Northern New Jersey. NJDWSC owns and operates the Wanaque Water Treatment Plant located in Wanaque, New Jersey. The facility is a conventional surface water plant with an average daily demand of 100 MGD and max daily demand of 140 MGD and provides drinking water to over 3 million people in 14 member municipalities and many consecutive systems.

EPA Response: The EPA acknowledges this comment.

A. O. Smith Corporation (Doc. #1674, SBC-043690)

Mr. Lan, please see the attached file of the comments submitted by the A. O. Smith Corporation. A. O. Smith appreciates the opportunity to submit these comments to the U.S. Environmental Protection Agency regarding its request for comment on its PFAS National Primary Drinking Water Regulation Rulemaking No. EPA-HQ-OW-2022-0114/ RIN 2040-AG18 and looks forward to continuing the dialogue with the Agency moving forward.

May 30, 2023

Alexis Lan

Office of Ground Water and Drinking Water, Standards and Risk Management Division

(Mail Code 4607M)

Environmental Protection Agency

1200 Pennsylvania Avenue, NW Washington, DC 20460

E-Mail: PFASNPDWR@epa.gov

Re: A. O. Smith Comments on Docket ID No. EPA-HQ-OW-2022-0114/ RIN 2040-AG18 - PFAS National Primary Drinking Water Regulation Rulemaking

Dear Mr. Lan

A. O. Smith Corporation ("A. O. Smith" or "Company"), with global headquarters in Milwaukee, Wisconsin since 1874, is a global leader in applying technology and energy-efficient solutions to products manufactured and marketed worldwide. Listed on the New York Stock Exchange (NYSE: AOS), the company is one of the world's largest manufacturers of residential and commercial water heating equipment and boilers, as well as a leading global manufacturer of water treatment and air purification products.

A. O. Smith appreciates the opportunity to submit these comments to the U.S. Environmental Protection Agency ("EPA") regarding its request for comment on its PFAS National Primary Drinking Water Regulation Rulemaking ("PFAS NPDWR"). The Company has long standing working relationship with the EPA as a participant in the ENERGY STAR® program having received multiple Partner of the Year awards for its high-efficiency water heating equipment.

The Company's North American Water Treatment division is a vertically integrated business unit that manufacturers point-of-use and point-of-entry drinking water treatment and filtration solutions for residential and commercial applications with distribution through channels such as Lowe's® as well as through its nation-wide network of professional water quality dealers and installers. It is this experience helping consumers daily to improve their drinking water quality at the point of consumption that informs the Company's comments.

Overview

A. O. Smith applauds the EPA for proposing a national primary drinking water standard for six covered PFAS chemicals, including establishing maximum contaminant level goals ("MCLG") as well as a maximum contaminant level ("MCL") for perfluorooctanoic acid ("PFOA") and perfluorooctane sulfonic acid ("PFOS"). As the EPA has laid out in the PFAS NPDWR, and as independent research and toxicological data demonstrates, exposure to elevated levels of PFAS or so-called "forever chemicals" are harmful to human health and accordingly the Company agrees that an NPDWS will help mitigate one of the pathways through which people are exposed to PFAS – their drinking water. The Company also supports and is encouraged by EPA's recognition that third-party certified point-of-use ("POU") and point-of-entry ("POE") water treatment systems are a cost-effective solution to address PFAS chemicals at the point of consumption of drinking water and may be a more cost-effective solution for small community water systems to utilize to demonstrate compliance with the proposed PFAS NPDWS.

Finally, the Company does have some concerns relating to the 4 ppt MCL regulatory determination for PFOA and PFOS; the workability of the Hazard Index ("HI") related to GenX chemicals; certified laboratory capacity to timely, and cost-effectively, test drinking water samples from thousands of public water systems that are covered under the proposed PFAS NPDWS; as well as potential supply chain impacts on certain activated carbon and other treatment media that are primarily sourced outside of the United States. What follows are the Company's comments to some of the EPA's specific requests for comment as outlined in Section XIV of the proposed PFAS NPDWS. [FN1: 88 FR 18729.]

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Association of California Water Agencies (ACWA) (Doc. #1675, SBC-044926)

May 30, 2023

The Honorable Michael Regan

Administrator

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue NW

Washington, D.C. 20460

Re: PFAS National Primary Drinking Water Regulation Rulemaking; EPA–HQ–OW–2022–0114; FRL 8543–01– OW

Dear Administrator Regan:

The Association of California Water Agencies (ACWA) appreciates the opportunity to provide comments on the Environmental Protection Agency's (EPA) proposed PFAS National Primary Drinking Water Regulation (NPDWR). ACWA's more than 460 public water agency members supply over 90 percent of the water delivered in California for residential, agricultural, and business uses. ACWA strongly supports drinking water standards for PFAS that are based on sound science and robust analysis.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Association of California Water Agencies (ACWA) (Doc. #1675, SBC-044929)

II. Comments

The Safe Drinking Water Act (SDWA) was established to protect the quality of drinking water. SDWA authorizes EPA to set national health-based standards for drinking water to protect against both naturally occurring and man-made contaminants that may be found in drinking water [FN1: EPA, Overview of the Safe Drinking Water Act (last updated Feb. 14, 2023), click here [Link: https://www.epa.gov/sdwa/overview-safe-drinking-water-act]]. Under SDWA a significant responsibility is placed on EPA "to realistically assess the capabilities of and resources available to those who could be affected by any future drinking water rulemaking." [FN2: EPA, SDWA Economic Analysis (last updated Feb. 14, 2023), click here.[link: https://www.epa.gov/sdwa/sdwa-economic-analysis]].

ACWA recognizes that SDWA is a vital tool in EPA's mission to safeguard public drinking water. We strongly support setting drinking water standards for PFAS that are based on sound science and robust analysis. EPA's proposed PFAS NPDWR, however, raises several concerns for our members. Following are ACWA's comments on EPA's proposed rule.

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Association of California Water Agencies (ACWA) (Doc. #1675, SBC-044939)

III. Conclusion

ACWA strongly supports EPA's efforts to address PFAS contamination and protect public health through setting drinking water standards that are based on sound science and robust analysis. We

have concerns with this proposal in its current form and ask EPA to take our comments under consideration before finalizing the regulation.

Thank you for the opportunity to provide comments on this proposed rule. If you have any questions or would like any follow-up information, please contact Madeline Voitier, ACWA's Federal Relations Representative at madelinev@acwa.com.

Sincerely,

Madeline Voitier, Federal Relations Representative

CC:

The Honorable Radhika Fox, Assistant Administrator, Office of Water, U.S. Environmental Protection Agency

Jennifer McLain, Director, Office of Ground Water and Drinking Water, U.S. Environmental Protection Agency

Alexis Lan, Ground Water and Drinking Water, Standards and Risk Management Division, U.S. Environmental Protection Agency

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document.

California Association of Mutual Water Companies (Doc. #1676, SBC-043773)

May 30, 2023

Jennifer McLain, Director

Office of Ground Water and Drinking Water

U.S. Environmental Protection Agency

1201 Constitution Avenue, NW

Washington, DC 20004

Subject: Comment Letter- Proposal to Limit PFAS in Drinking Water- Docket ID Number: EPA-HQ-OW-2022-0114

Dr. McLain,

I am writing on behalf of the California Association of Mutual Water Companies (CalMutuals). Our organization represents almost 500 small water systems throughout the state that collectively serve 1.3 million Californians. We appreciate the Environmental Protection Agency's (EPA) commitment to protecting public health and note that the action of setting a federal standard is an extraordinary and atypical response to addressing contaminants that impact our water supply.

While CalMutuals recognizes the challenge of developing a nation-wide proposal that would apply to systems of all sizes and types, CalMutuals does not believe the needs and concerns of very small water systems (i.e., those having 15 to 3000 service connections) are adequately addressed. This letter sets forth several areas of concern with respect to application of the proposed PFAS standard to small water systems.

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA disagrees that small water systems were not considered or have their needs adequately addressed in this rule. Please see the following sections of the EPA response in this *Response to Comments* document for evidence of the EPA's considerations for small water systems: section 10.5 for small system compliance technologies identification and evaluations, section 13.10 for discussion on affordability, as well as section 14.10 for federal actions to address EJ in minority and low-income populations.

Arizona Corporation Commission (Doc. #1680, SBC-044216)

May 30, 2023

By Electronic Submission to http://www.regulations.gov/

Michael S. Regan, Administrator

U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, N.W.

Mail Code: 1101A Washington, DC 20460

Re: Per- and polyfluoroalkyl substances (PFAS): Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) National Primary Drinking Water Regulation Rulemaking (EPA- HQ-OW-2022-0114).

Dear Administrator Regan,

My name is Commissioner Anna Tovar and I am writing as the sole Democrat member of the Arizona Corporation Commission ("ACC").1 [FN1: A majority of Commissioners signed public comments filed on behalf of the Arizona Corporation Commission in this docket. While I join in those sentiments, I am providing these comments to highlight two additional areas of concern not addressed in the comments from the ACC.] I appreciate the opportunity to submit comments to the Environmental Protection Agency's ("EPA" or "Agency") PFAS National Primary Drinking Water Regulation Rulemaking. I agree that EPA should take action to address the health risk posed by the presence of PFAS chemicals in drinking water supplies.

About the ACC

The ACC is the state regulatory body responsible for the regulation of Arizona's public service corporations, including 266 water utilities providing service to the residents of Arizona. The ACC has broad authority over private utilities under Article XV of the Arizona Constitution and

Arizona Revised Statutes, Title 40, and sets the rates and provides for the health and safety of the public these companies serve.

In Arizona, smaller utilities are classified as Class D and E and serve populations ranging from five to 10,000 customers. These utilities typically have wells with flow rates between 50 GPM and 200 GPM (0.07-0.288 MGD). Class D utilities have operating revenues between $50,000 and $249,000, while Class E utilities have operating revenues of less than $50,000. In Arizona, Class D and E utilities comprise 228 of the approximately 266 regulated water utilities. The vast majority of these water systems are rural and draw upon a finite supply of water that is dwindling as the Arizona desert continues to grow.

EPA Response: The EPA acknowledges this comment.

Arizona Corporation Commission (Doc. #1680, SBC-044219)

In conclusion, I applaud the EPA for taking this important step to protect the public health and appreciate the opportunity to provide comments.

Sincerely,

Anna Tovar Commissioner

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mass Comment Campaign sponsored by Slingshot. (email) (Doc. #1681, SBC-045708)

From: Derek Campfield <derek@slingshot.org>

Sent: Sunday, May 28, 2023 5:01 PM

To: OW-Docket <OW-Docket@epa.gov>

Subject: Bundled/collected comments re: Docket ID EPA-HQ-OW-2022-0114

Hello,

Attached, please find bundled [47] public comments our organization has collected from our supporters for the EPA-HQ-OW-2022-0114 docket. Each page of the PDF corresponds to a different comment. I've also attached a spreadsheet of collected comments.

If there is a different format needed to ensure these comments are submitted before the deadline, please let me know.

Thank you!

--

Derek Campfield (he/him)

Communications & Grants Coordinator

Slingshot

phone: (714) 614-2400

derek@slingshot.org

slingshot.org

Join our mailing list!

Comment:

Dear Administrator Regan,

I'm writing in support of a strong national drinking water standard for PFAS. National drinking water standards for PFAS have been long overdue and essential for ensuring safe and clean water for all Americans.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mass Comment Campaign sponsored by Slingshot. (email) (Doc. #1681, SBC-045710)

A strong national standard is necessary to protect public health and ensure consistent regulation across the country. It would also provide certainty and clarity for water utilities, industries and consumers to keep our water sources free of PFAS, while encouraging innovation and research on developing safer alternatives to PFAS and improving methods for detecting and removing them from water systems.

I urge the EPA to finalize this rule as soon as possible and to continue working on developing standards for regulating PFAS together as a class of chemicals.

Thank you,

[Excel 1: see docket ID EPA-HQ-OQ-2022-0114-1681].

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mass Comment Campaign sponsored by Slingshot. (email) (Doc. #1682, SBC-045717)

Comment:

Dear Administrator Regan,

I'm writing in support of a strong national drinking water standard for PFAS. Please use your power and authority to ensure safe drinking water for all Americans. National drinking water standards for PFAS have been long overdue and essential for ensuring safe and clean water for all Americans.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mass Comment Campaign sponsored by Slingshot. (email) (Doc. #1682, SBC-045711)

From: Derek Campfield <derek@slingshot.org>

Sent: Tuesday, May 30, 2023 7:05 PM

To: OW-Docket <OW-Docket@epa.gov>

Subject: Bundled Comments on EPA-HQ-OW-2022-0114-0027

Hi,

Attached, please find additional bundled public comments our organization has collected from our supporters for the EPA-HQ-OW-2022-0114 docket. Each page of the attached PDF corresponds to a different comment. I've also attached a spreadsheet of collected comments.

If there is a different format needed to ensure these comments are submitted before the deadline, please let me know.

Thank you!

Derek Campfield (he/him)

Communications & Grants Coordinator

Slingshot

phone: (714) 614-2400

derek@slingshot.org

slingshot.org

Comment:

Dear Administrator Regan,

I'm writing in support of a strong national drinking water standard for PFAS. National drinking water standards for PFAS have been long overdue and essential for ensuring safe and clean water

for all Americans. Our farmers and other residents are living the nightmare of water, soil, livestock, crops, wildlife and human bodies contaminated with astounding levels of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mass Comment Campaign sponsored by Slingshot. (email) (Doc. #1682, SBC-045714)

Comment:

Dear Administrator Regan,

I'm writing in support of a strong national drinking water standard for PFAS. National drinking water standards for PFAS have been long overdue and essential for ensuring safe and clean water for all Americans! Many of us have families and children and are worried about their health.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please section 1.3 of the EPA response in this *Response to Comments* document.

Mass Comment Campaign sponsored by Slingshot. (email) (Doc. #1682, SBC-045716)

What we need is a strong national standard. A strong national standard is necessary to protect public health and ensure consistent regulation across the country. It would also provide certainty and clarity for water utilities, industries and consumers to keep our water sources free of PFAS, while encouraging innovation and research on developing safer alternatives to PFAS and improving methods for detecting and removing them from water systems.

I urge the EPA to finalize this rule as soon as possible and to continue working on developing standards for regulating PFAS together as a class of chemicals.

Thank you,

First Name: Lola

Last Name: Olateju

City: Trumansburg

State: NY

Postal Code: 14886

Country: US

Timestamp: 2023-05-30 08:50:04 EST

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mass Comment Campaign sponsored by Slingshot. (email) (Doc. #1682, SBC-045713)

A strong national standard is necessary to protect public health and ensure consistent regulation across the country. It would also provide certainty and clarity for water utilities, industries and consumers to keep our water sources free of PFAS, while encouraging innovation and research on developing safer alternatives to PFAS and improving methods for detecting and removing them from water systems. The costs of delay are already staggering and will only escalate. Inaction is NOT an option that can be supported morally or ethically.

I urge the EPA to finalize this rule as soon as possible and to continue working on developing standards for regulating PFAS together as a class of chemicals. PFAS must be considered as well within a cumulative and synergistic framework. Without this approach, any response will continue the environmental injustice suffered by low-income, Indigenous, and communities of Color.

Thank you,

First Name: Jackie

Last Name: Elliott

City: Waterboro

State: ME

Postal Code: 00877

Country: US

Timestamp: 2023-05-30 08:20:21 EST

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mass Comment Campaign sponsored by Slingshot. (email) (Doc. #1682, SBC-045719)

A strong national standard is necessary to protect public health and ensure consistent regulation across the country. It would also provide certainty and clarity for water utilities, industries and consumers to keep our water sources free of PFAS, while encouraging innovation and research on developing safer alternatives to PFAS and improving methods for detecting and removing them from water systems.

I urge the EPA to finalize this rule as soon as possible and to continue working on developing standards for regulating PFAS together as a class of chemicals.

Thank you,

First Name: Martha

Last Name: Merson

City: Jamaica Plain

State: MA

Postal Code: 02130

Country: US

Timestamp: 2023-05-30 14:19:21 EST

[Attachment "Spreadsheet of Collected Comments": see docket ID EPA-HQ-OQ-2022-0114-1682]

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Public Employees for Environmental Responsibility (PEER) (Doc. #1683, SBC-044967)

May 30, 2023

U.S. Environmental Protection Agency

EPA Docket Center

Office of Ground Water and Drinking Water Docket

Mail Code 2822IT

1200 Pennsylvania Avenue NW Washington, DC 20460.

RE: Docket ID No. EPA-HQ-OW-2022-0114

Sent via www.regulations.gov

To Whom It May Concern:

Public Employees for Environmental Responsibility (PEER) is providing comments on the U.S. Environmental Protection Agency's (EPA) proposed "Per-and Polyfluoroalkyl Substances National Drinking Water Regulation" for six PFAS published on March 29, 2023. Specifically, EPA proposes to:

• regulate perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) as contaminants under the Safe Drinking Water Act (SDWA), with health-based Maximum Contaminant Level Goals (MCLG) of zero, and individual Maximum Contaminant Levels (MCLs) of 4.0 nanograms per liter (ng/L) or parts per trillion (ppt); and

• regulate perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salt (also known as a GenX chemicals), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS), and their mixtures as contaminants under SDWA, using a unitless Hazard Index (HI) of 1.0.

While PEER is pleased that EPA is finally setting MCLs for some PFAS in drinking water, we believe much more needs to be done. Our specific comments are set forth below.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

City of Vancouver Water Utility, Vancouver, WA (Doc. #1684, SBC-044317)

Conclusion:

Vancouver is in support of PFAS rulemaking utilizing a science-based approach in which the data is clear and complete.

The majority of public water systems make the provision of clean, safe water to their customers their number one priority. This rulemaking process and uncertainty regarding the data and results can only create mistrust across the nation. Please ensure that an adequate benefit/cost analysis is completed and levels are set accordingly to the outcome of that analysis and not based on an interpretation of data.

Thank you for your consideration of these comments. Sincerely,

Tyler Clary, P.E., W.D.M 4

Water Engineering Program Manager City of Vancouver

cc: Lon Pluckhahn Brian Wilson Tim Buck Patrick Craney

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. An adequate benefit and cost analysis was completed by the agency, and can be reviewed in section XII of the FRN.

Wisconsin Department of Justice et al. (Doc. #1687, SBC-044451)

Conclusion

The States appreciate this opportunity to submit these comments supporting EPA's proposed drinking water standards for PFOA, PFOS, PFHxS, GenX, PFNA, and PFBS. We urge EPA to promptly finalize the rule and proceed apace to consider regulating additional PFAS that pose demonstrable risks to human health.

Sincerely,

FOR THE STATE OF CALIFORNIA

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Attorney General of California

By: /s/ Nick Campins

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Deputy Attorney General

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EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Wisconsin Department of Justice et al. (Doc. #1687, SBC-044440)

Attorneys General of the States of Arizona, California, Colorado, Connecticut, Delaware, Illinois, Maine, Maryland, Massachusetts, Michigan, New Jersey, New York, North Carolina, Oregon, Pennsylvania, Wisconsin, and the District of Columbia

May 30, 2023

Via Regulations.gov Water Docket

EPA Docket Center

U.S. Environmental Protection Agency

Mail Code: 28221T

1200 Pennsylvania Ave. NW

Washington, D.C. 20460

Re: Comments on Preliminary Regulatory Determination and Proposed Rule; PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18638 (Mar. 29, 2023)

Docket ID No. EPA-HQ-OW-2022-0114

Dear Administrator Regan:

The Attorneys General of the States of Arizona, California, Colorado, Connecticut, Delaware, Illinois, Maine, Maryland, Massachusetts, Michigan, New Jersey, New York, North Carolina,

Oregon, Pennsylvania, Wisconsin, and the District of Columbia (collectively, the States) offer these comments in support of the U.S. Environmental Protection Agency's (EPA) preliminary regulatory determination and proposed rule to set enforceable drinking water standards for certain per- and polyfluoroalkyl substances (PFAS) (PFAS Rule). [FN1:Preliminary Regulatory Determination and Proposed Rule; PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18638 (March 29, 2023).] The PFAS Rule would set Maximum Contaminant Levels (MCL) and Maximum Contaminant Level Goals (MCLG) for six PFAS as follows:

• Perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS): EPA proposes an MCL of four parts per trillion (ppt) and an MCLG of zero for each contaminant. [FN2: In March 2021, EPA issued a final regulatory determination to regulate PFOA and PFOS as contaminants under the federal Safe Drinking Water Act, 42 U.S.C. § 300f, et seq. (SDWA).]

• Perfluorohexane sulfonic acid (PFHxS); hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salt (known collectively as GenX); perfluorononanoic acid (PFNA); and perfluorobutane sulfonic acid (PFBS): EPA makes a preliminary regulatory determination to regulate these four PFAS, and mixtures of these PFAS, as contaminants under the Safe Drinking Water Act (SDWA). EPA also proposes a Hazard Index approach to set a limit on these four PFAS and any mixture containing one or more of these four PFAS. EPA proposes a Hazard Index of 1.0 as the MCL and MCLG for these four PFAS and any mixture containing two or more of them. [FN3: The Hazard Index is a tool used by EPA to evaluate the potential health risks from exposure to chemical mixtures. The PFAS Rule proposes a ratio for each of the four PFAS to be used to calculate a compliance value based on detected levels of these PFAS—a combination of these four ratios equaling or exceeding 1.0 will trigger the need to reduce their levels in drinking water; see EPA Fact Sheet: Understanding the PFAS National Primary Drinking Water Proposal Hazard Index, https://www.epa.gov/system/files/documents/2023-03/How%20do%20I%20calculate%20the%20Hazard%20Index._3.14.23.pdf.]

The States have a significant interest in ensuring that their residents have access to safe drinking water, and many have taken action to set their own drinking water standards for various PFAS. [FN4: See infra at 13-14; see also Envt'l Council of the States, Processes & Considerations for Setting State PFAS Standards 7 (Feb. 2020; updated Mar. 2023), https://www.ecos.org/wpcontent/uploads/2023/03/2023-ECOS-PFAS-Standards-Paper-Update.pdf.] We strongly support EPA's proposed action to set national standards to protect the public from the harmful health impacts of PFAS in drinking water and offer the following comments for the agency's consideration as it proceeds in this important effort. We also emphasize the need for significant resources for state and local governments to remove PFAS from drinking water supplies and to help with the cost of rule implementation and regulatory enforcement. The comments proceed as follows:

• First, we explain EPA's authority to set enforceable drinking water standards for these PFAS because they: (a) have known adverse health effects, (b) are likely to occur in public water systems, and (c) present a meaningful opportunity for health risk reduction, if regulated.

• Second, we explain that EPA has authority to issue a preliminary determination and simultaneously propose MCLs and MCLGs for PFAS in drinking water.

• Third, we offer support for the proposed Hazard Index approach to regulate PFHxS, HFPO-DA, PFNA, and PFBS and explain why the Hazard Index approach is both appropriate and justified to address the health effects of PFAS mixtures.

• Fourth, we urge EPA to make technical and engineering resources available to public water systems so that the financial burden of removing PFAS does not unfairly fall on ratepayers and customers.

• Fifth, we urge EPA to issue the final rule as quickly as possible because these contaminants are so toxic, while at the same time giving States the opportunity to revise their programs.

• Sixth, after finalizing this PFAS Rule, we suggest that EPA should similarly consider setting drinking water standards for other PFAS both alone and in combination.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR, and appreciates the subsequent comments provided. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Three Rivers Waterkeeper (3RWK) (Doc. #1689, SBC-044971)

U.S. Environmental Protection Agency

EPA Docket Center

Office of Ground Water and Drinking Water Docket

Mail Code 2822IT

1200 Pennsylvania Avenue

NW, Washington, DC 20460

(filed online via eComment)

Comment on Docket Number EPA-HQ-OW-2022-0114. Re: EPA's proposed national drinking water standard for six per- and polyfluoroalkyl substances (PFAS).

To Whom it May Concern:

Three Rivers Waterkeeper (3RWK) thanks you for the opportunity to comment in support of the Environmental Protection Agency's (EPA) proposed national drinking water standard for six per- and polyfluoroalkyl substances (PFAS), Docket ID Number: EPA-HQ-OW-2022-0114. 3RWK was founded in 2009 and aims to improve and protect the water quality of the Allegheny, Monongahela, and Ohio Rivers. These waterways are critical to the health, vitality, and economic prosperity of our region and communities. We are both a scientific and legal advocate for the community, working to ensure that our three rivers are protected and that our waters are

safe to drink, fish, swim, and enjoy. We are one of the 300 organizations that make up the global Waterkeeper Alliance and work together to connect local communities to global environmental and advocacy resources. For these reasons and due to our significant experience and knowledge as stewards and advocates for the Three Rivers, we believe that we can provide the EPA with valuable insight on the proposed rulemaking.

PFAS, commonly known as "forever chemicals," do not degrade and are bioaccumulative, polluting waterways and sickening people and wildlife. They are associated with a wide range of health risks including cancers, birth defects, and weakened immune systems. While 3RWK supports further legislation and regulation, including up to a total phase-out of PFAS as a class of chemicals, this proposed rule is an important step toward reducing the deaths and illnesses caused by PFAS.

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Three Rivers Waterkeeper (3RWK) (Doc. #1689, SBC-044973)

II. The inconsistency of State regulation and the transboundary nature of PFAS pollution make federal regulation necessary to effectively address the issue.

3RWK's work at the confluence of the Allegheny, Monongahela, and Ohio rivers has profoundly demonstrated to us the importance of halting pollution at its source. The Ohio River provides drinking water to over 5 million people. It sends more water into the Mississippi than any other tributary, along with any contaminants it picks up along its 981-mile stretch through the Rust Belt. [FN13: Susan Cosier, The Ohio River Defines the Borders of Five States–But Its Pollution Doesn't Stop at State Lines, National Resources Defense Council, Aug. 21, 2019, https://www.nrdc.org/stories/ohio-river-defines-borders-five-states-its-pollution-doesnt-stop-state-lines#:~:text=Five%20million%20people%20rely%20on,most%20polluted%20in%20the%20country.] With the United States' current patchwork of regulation, downstream States are at the mercy of their upstream neighbors to regulate PFAS and prevent the contamination of the watershed. The Pennsylvania Department of Environmental Protection (DEP) published its final PFAS drinking water regulation only in January 2023, setting Maximum Contaminant Levels (MCLs) for PFOS and PFOA at 18 ppt and 14 ppt respectively. [FN14: 25 Pa. Code §109.202 (Jan. 14, 2023).] Other States at the time had stricter PFAS standards, including California, Colorado, Connecticut, Massachusetts, Michigan, Minnesota, New Hampshire, New Jersey, New York, North Carolina and Vermont, leaving Pennsylvania residents more at risk for PFAS exposure than residents of those States.

The regulatory framework has already changed substantially in recent months, with Minnesota recently agreeing to pass new PFAS protections, including blanket prohibitions on certain consumer goods containing PFAS of any kind. [FN15: Min. 3 HF 2310-4 § 21 (May 25, 2023) https://www.revisor.mn.gov/bills/text.php?number=HF2310&type=bill&version=4&session=ls9

3&session_year=2023&session_number=0.] PFAS regulations are inconsistent across the country, leaving some States with stronger protections than others, even as PFAS originating in one state can flow through waterways into neighboring areas. We need strong federal PFAS protections that account for the known danger of PFOS and PFOA, as well as the cumulative effects of those and other PFAS.

Although PFAS are dangerous and widespread, there is currently no federal regulatory safeguard protecting us from PFAS in our drinking water. This puts the U.S. behind the EU, which currently regulates PFOS and PFOA under the Persistent Organic Pollutants (POPs) Regulation, and which is currently considering universal PFAS restriction. [FN16: Per- and Polyfluoroalkyl Substances (PFAS), European Chemicals Agency, https://echa.europa.eu/hot-topics/perfluoroalkyl-chemicals-pfas (Last Accessed May 30, 2023).] While the U.S. has been slow to adopt stringent federal PFAS regulations, this proposed drinking water standard is a crucial step in the right direction.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Three Rivers Waterkeeper (3RWK) (Doc. #1689, SBC-044978)

In conclusion, while 3RWK believes that this rule would be a major improvement to the nation's overall PFAS regulatory scheme, it should not be the end if the EPA is to satisfy the goals of the Clean Water Act and the Safe Drinking Water Act. We know that the EPA and other agencies are continuously researching PFAS and working on new regulations to better protect the public. [FN20: PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024, United States Environmental Protection Agency, 10-21, Oct. 18, 2021, https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf.] The danger posed by PFAS and the rapidly-evolving scientific understanding of these chemicals necessitate a regulatory approach that is both strong and able to withstand new information. While the given PFOS and PFOA MCLs provide more protection than the MCLs in 3RWK's home state of Pennsylvania, the science is always developing. It will be necessary to adjust these rules in the future as the situation evolves, but in the meantime we cannot ignore the tens of thousands of illnesses and deaths that the EPA expects this rule to prevent. Thank you for your time and consideration,

Sincerely,

Heather Hulton VanTassel, PhD

Executive Director, Three Rivers Waterkeeper

PO Box 97062

Pittsburgh, PA 15229

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Massachusetts Coalition for Water Resources Stewardship (MCWRS) (Doc. #1691, SBC-044318)

May 30, 2023

Mr. Michael S. Regan, Administrator

U.S. Environmental Protection Agency

EPA Docket Center, OLEM Docket, Mail Code 28221T 1200 Pennsylvania Avenue, NW

Washington, DC 20460

RE: Docket ID No. EPA-HQ-OW-2022-0114

National Primary Drinking Water Regulation Rulemaking PFAS MCL

Dear Administrator Regan,

The Massachusetts Coalition for Water Resources Stewardship (MCWRS) is a non-profit organization representing the interests of municipalities, districts and commissions in the world of wastewater, stormwater and drinking water. Members include municipal, district and commission wastewater, stormwater and drinking water utilities, engineering consultants, legal firms and stormwater coalitions. MCWRS offers the following comments on EPA's draft Maximum Contaminant Levels (MCLs) for various polyfluoroalkyl substances (PFAS) in drinking water.

MCWRS understands there is tremendous pressure on EPA from advocacy groups, the media and politicians to set a very low MCL for certain PFAS compounds. While it is agreed that PFOA and PFOS need to be regulated in drinking water through an MCL, the proposed limits are far too extreme, not supported by science, too costly, reactionary and fraught with unintended consequences that may lead to greater threats to drinking water quality and public health than are posed by the contaminants being regulated.

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. The EPA disagrees with the comments stating that the rule is too extreme, not supported by science, too costly, reactionary, and fraught with unintended consequences. Please see the preamble and sections 1.1 and 1.3 of the EPA response in this *Response to Comments* document.

Massachusetts Coalition for Water Resources Stewardship (MCWRS) (Doc. #1691, SBC-044320)

PFOA and PFOS in drinking water is not an emergency. It is a 70-year old problem that was only recently brought to light as a result of improved laboratory detection levels. Our ability to detect contaminants far exceeds our ability to understand what minute levels of these contaminants in drinking water may mean. We cannot afford, both financially and from a societal perspective, to regulate drinking water based on irrational fears, irresponsible media and the hyper-political world where we currently find ourselves.

EPA Response: The EPA disagrees with this comment objecting to the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA has conducted health assessments to determine what small levels of these contaminants may mean in drinking water, and these assessments can be found in the Toxicity Assessments and the PFOA/PFOS MCLG support documents. See also sections 3.1.1 and 3.2.1 of the *Response to Comments* document for more information on health impacts of PFOA and PFAS. For concerns around affordability, the agency conducted a cost and benefit analysis that can be found in section XII of the FRN, the Economic Analysis support document (USEPA, 2024a), with response to comments regarding costs throughout section 13.3 of the *Response to Comments* document.

American Council of Independent Laboratories (ACIL) (Doc. #1692, SBC-044735)

May 30, 2023

U. S. Environmental Protection Agency

Water Docket (Mail code: 4203M)

1200 Pennsylvania Ave. NW.,

Washington, DC 20460.

Attention Docket ID number EPA–HQ–OW–2022-0114

Re: ENVIRONMENTAL PROTECTION AGENCY

40 C.F.R. Part 141 Safe Drinking Water Act National Primary Drinking Water Regulation Rulemaking on Per- and polyfluoroalkyl substances (PFAS): Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS)

The American Council of Independent Laboratories (ACIL) is broadly supportive of the EPA's efforts to regulate PFAS in the nation's drinking water and to provide clear guidance on the monitoring of the specific compounds listed. The laboratory community is well placed to respond to the additional monitoring demands arising from this MCL determination and look

forward to supporting drinking water utilities in their efforts to monitor PFAS, and to deal with any analytical issues they encounter.

The American Council of Independent Laboratories (ACIL) serves as the trade association representing independent, commercial scientific and testing laboratories. Its members are professional services firms engaged in testing, product certification, consulting, and research and development. Affiliated members include testing instrument manufacturers, consultants, laboratory assessment and accreditation organizations, consultants, and other suppliers to the industry. The association was founded in 1937. ACIL member environmental testing laboratories are independent scientific services firms engaged in environmental sampling and testing. They are not affiliated with any institution, company, or trade group that might affect their ability to conduct investigations, render reports, or give professional, objective, and unbiased counsel. As a result, the industry has a long history of serving government agencies (including the Environmental Protection Agency (EPA), the Department of Defense (DOD), and the Department of Energy (DOE)) with environmental sampling and analysis services in support of agency regulatory rulemaking, site assessment, site cleanup efficacy evaluations, and enforcement data gathering.

The measurement and research conducted by ACIL members yield data about chemical and biological pollutants and their effects on the environment and citizen health and, over the years, have formed the basis of much of EPA's regulatory and enforcement actions.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Ontario International Airport Authority (OIAA), California (Doc. #1693, SBC-043504)

May 30, 2023

Michael S. Regan, Administrator Environmental Protection Agency 1200 Pennsylvania Ave, NW Mail Code: 4670M

Washington, D.C. 20460

Re: Docket ID No. EPA-HQ-OW-2022-0114 – Comments on PFAS, PFOA, and PFOS National Primary Drinking Water Regulation Rulemaking

Dear Mr. Regan:

This firm represents the Ontario International Airport Authority, located in southern California. We have reviewed the proposed rulemaking that would establish National Primary Drinking Water standards and regulations for certain species of per- and polyfluoralkyl stances (PFAS), including perfluorooctanoic acid (PFOA), and perfluorooctane sulfonic acid (PFOS), under the federal Safe Drinking Water Act. As we understand it, EPA is proposing a maximum

contaminant level (MCL) of 4.0 nanograms per liter (ng/L) or parts per trillion (ppt) for PFOA and PFOS.

EPA Response: EPA acknowledges this comment.

Water Quality Association (WQA) (Doc. #1694, SBC-044979)

May 30, 2023

Alexis Lan

Office of Ground Water and Drinking Water, Standards and Risk Management Division

(Mail Code 4607M)

Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington, DC 20460

Re: WQA's Comments on Docket ID No. EPA-HQ-OW-2022-0114

Dear Alexis Lan,

On behalf of the Water Quality Association (WQA), a not-for-profit trade association representing 2500 member companies in the residential, commercial, and industrial water treatment industry, we are submitting comments in reference to the EPA's proposed National Primary Drinking Water Regulation (NPDWR) Rulemaking for six PFAS chemicals. We applaud the agency's actions in researching and taking action to improve water quality across the country and hope you will utilize us as a resource in responding to PFAS contamination.

About WQA

Since its creation in 1974, WQA and its member companies have worked tirelessly to improve water quality through sustainable technologies and services. As a leader in the point-of-use (POU) and point-of-entry (POE) drinking water treatment system industry, the association operates an American National Standards Institute National Accreditation Board (ANAB) accredited testing and certification program that evaluates and certifies water filtration products to nationally accepted industry standards for contaminant removal. The association also operates a Professional Certification Program with a rigorous continued education component that qualifies a level of knowledge to enhance the application of the certified products. WQA also offers a variety of technical skills and educational resources, many of which can serve as vital tools as the EPA aims to reduce PFAS in drinking water.

WQA's Comments to the proposed-NPDWR

Navigating drinking water challenges and regulating contaminants is a complex and difficult task. Setting Maximum Contaminant Levels (MCLs) and monitoring the nation's water supply

are the first steps, but as areas of contamination are identified, residents will be looking for assurance of safe water supplies. While our association will not be providing recommendations on appropriate MCLs for PFAS chemicals, we can inform you of the current feasibility of mitigation and treatment techniques in relation to the proposed NPDWR. Most of our comments will focus on the industry's current capabilities, including information on performance standards, lab capabilities, and available treatment technologies. However, it's important to highlight a few other considerations in direct response to the proposed MCLs.

Outlined below are WQA's comments on the preliminary regulatory determination and the proposed rule. Supporting information for WQA's comments can be found in the attached analysis.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

City of Lancaster, Pennsylvania (Doc. #1695, SBC-044991)

May 26th, 2023

U.S. Environmental Protection Agency

Re: Safe Drinking Water PFAS MCL Rule

Ladies and Gentlemen:

The City of Lancaster is in favor of protecting the citizens of the United States and instituting a PFAS/PFOA mean contaminant level (MCL) based upon thoroughly collected data analysis of all scientific, journaled and peer reviewed studies on PFAs contamination. UCMR5 has still not been completed and it is designed to specifically include analysis of the PFAS contaminants. The proposed limits are confusing and problematic.

Setting a regulatory limit that is near the baseline detection limit that excludes key research data is a troubling and problematic practice on multiple levels for both the taxpayer and the regulatory body. The proposed low limit of 4 ppt can barely be differentiated from the background noise of detection systems, and creates a narrow and challenging window to operate in. Constructing new treatment systems will result in significant economic impacts on water systems and their rate payers. However, this proposed regulation does nothing to stop the polluters and sources of contamination and sends a questionable message. Please consider the following comments on the Environmental Protection Agency's new MCL limit for PFAS chemicals.

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA disagrees that the limit of 4.0 ppt is too low. Please see section 5.1 and section 7 of the *Response to Comments* document discussing chosen limits and analytical methods. The available UCMR 3 and state occurrence data are sufficiently robust

to support the final rule and the EPA is not obligated to use/collect the entire UCMR 5 dataset prior to finalizing the rule. UCMR 5 data are relevant for reduction of initial monitoring costs and for informing regulatory decisions for 23 PFAS not included in this rule action. For more discussion on the UCMR 5 data set, please section 6.8 of the EPA response in this *Response to Comments* document. For concerns around affordability, the agency conducted a cost and benefit analysis that can be found in section XII of the FRN, the Economic Analysis support document, with response to comments regarding costs throughout section 13.3 of the *Response to Comments* document.

Clean Water Action/Clean Water Fund (Doc. #1697, SBC-045001)

Finalizing Health-Protective NPDWR is essential given on-going PFAS water pollution

Despite widespread concern about PFAS chemicals in water, including drinking water sources, progress in regulatory and non-regulatory approaches for keeping PFAS chemicals out of water is disturbingly slow in comparison to the increased discovery of these chemicals in drinking water at very low levels and the growing knowledge base on their health effects, including at low levels. Despite the pollution prevention values that have guided United States environmental policy conceptually, the reality is that often pollution is not handled at its source and it falls on communities and water systems and their customers to handle contaminants that put public health at risk. This is certainly the case with PFAS chemicals. While it is ultimately more efficient and equitable to address PFAS water pollution at its source, the public health risks posed by PFAS in drinking water must be addressed now despite the fact that the contamination should be controlled upstream. EPA's own summary in the proposed rule of ongoing manufacture and use of PFOA and PFOS illustrates the problem.

Domestic production and import of PFOA has been phased out in the United States by the companies participating in the 2010/2015 PFOA Stewardship Program. Small quantities of PFOA may be produced, imported, and used by companies not participating in the PFOA Stewardship Program and some uses of PFOS are ongoing (see 40 Code of Federal Regulations (CFR) § 721.9582). EPA is also aware of ongoing use of the chemicals available from existing stocks or newly introduced via imports. Additionally, the environmental persistence of these chemicals and formation as degradation products from other compounds may still contribute to their release in the environment. [FN4: PFAS National Primary Drinking Water Regulation Rulemaking, Federal Register / Vol. 88, No. 60 / Wednesday, March 29, p. 18642]

Despite widespread perception that PFOA and PFOS are "behind us," EPA notes that their manufacture and use continue and that they are highly persistent and can form as degradation products of other compounds. Monitoring and setting drinking water limits for PFOA and PFOS is needed to protect public health.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045009)

May 30, 2023

U.S. Environmental Protection Agency

Submitted Via Regulations.gov EPA Docket Center

Office of Ground Water and Drinking Water Docket Mail Code 2822IT

1200 Pennsylvania Avenue NW Washington, DC 20460

Re: Proposed PFAS National Primary Drinking Water Regulation Rulemaking (Docket ID No. EPA-HQ-OW-2022-0114)

Dear Assistant Administrator Fox,

The New Jersey Department of Environmental Protection (NJDEP) is pleased to provide comments on the U.S. Environmental Protection Agency's (EPA) proposed "PFAS National Primary Drinking Water Regulation Rulemaking."

We applaud EPA for moving forward with the establishment of primary drinking water standards for PFAS.

As a result of our unique experience in implementing MCLs for PFOA, PFOS, and PFNA, NJDEP is particularly well-suited to provide feedback on EPA's proposal. In 2018, New Jersey became the first state to establish a Maximum Contaminant Level (MCL) for any PFAS chemical, setting a limit of 13 parts per trillion (ppt) for PFNA based on recommendations from the New Jersey Drinking Water Quality Institute. This was followed by the adoption of MCLs for PFOA (14 ppt) and PFOS (13 ppt) in 2020. Community and non-transient non-community water systems in New Jersey have been monitoring for PFNA since 2019 and PFOA and PFOS since 2021. Many of these systems have completed or are in the process of taking remedial actions to reduce the levels of PFAS in drinking water.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045012)

NJDEP offers detailed comments attached in response to EPA's request. These comments are informed by NJDEP's experience in adopting and implementing primary drinking water standards for PFOA, PFOS, and PFNA. The NJDEP would like to highlight the following topic areas for the EPA's consideration:

1) Health-based science supports the development of drinking water standards

2) Implementation of MCLs from a primacy agency perspective

3) Evaluation of existing treatment technology

4) Cost analysis

My NJDEP colleagues and I look forward to collaborating with our partners at EPA as this proposal advances.

Sincerely,

Shawn M. LaTourette, Commissioner

New Jersey Department of Environmental Protection

New Jersey Department of Environmental Protection (NJDEP)

Comments on USEPA's Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

Docket EPA-HQ-OW-2022-0114

Introduction

To address the public health risk from PFAS contamination, in 2014, NJDEP called upon the expertise of the New Jersey Drinking Water Quality Institute (DWQI), to recommend enforceable drinking water standards for perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS) , and perfluorononanoic acid (PFNA). The DWQI is an advisory body, established by the New Jersey Safe Drinking Water Act, made up of scientists and technical experts that is charged with providing NJDEP with recommendations regarding its drinking water program, including the development of New Jersey- specific drinking water standards. Based on recommendations from the DWQI, in 2018, New Jersey became the first state to establish a Maximum Contaminant Level (MCL) for any PFAS chemical, setting a limit of 13 part per trillion (ppt) for PFNA. This was followed by the adoption of MCLs for PFOA (14 ppt) and PFOS (13 ppt) in 2020. Community and non-transient non-community water systems in New Jersey have been monitoring for PFNA since 2019 and PFOA and PFOS since 2021. Many of these systems have taken action to reduce the levels of PFAS in their drinking water or are in the process of doing so.

NJDEP is familiar with the unique challenges of implementing drinking water standards for PFAS and has years of data which can be utilized to benefit EPA in this endeavor. This places New Jersey in a unique position to comment on EPA's proposed rulemaking. NJDEP applauds EPA for moving forward with establishing National Primary Drinking Water Regulations (NPDWR) for PFAS and urges EPA to consider the detailed comments provided below.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

National Wildlife Federation et al. (Doc. #1702, SBC-043513)

The PFAS crisis is widespread in our nation's drinking water, with an estimated 200 million Americans drinking water in which PFAS chemicals are detected. National drinking water standards to reduce PFAS are long overdue and EPA's current proposal marks the first ever federal limits on PFAS in drinking water. Currently, we have a woefully inadequate regulatory regime across the country that leaves our drinking water, communities, and wildlife at risk from further PFAS contamination. While some states like Michigan have advanced PFAS standards, the current patchwork of regulations does not adequately protect people and wildlife.

This proposal will significantly reduce the exposure to PFAS in our nation's drinking water by setting strong science-based drinking water standards for six types of PFAS, which will provide more protection and certainty that doesn't depend on where you live. The proposal would set the national standard for PFOA and PFOS at the lowest detection level approved by the EPA, 4 parts per trillion each. It would also establish limits on GenX, PFBS, PFNA, and PFHxS using a hazard index, recognizing that chemical mixtures of PFAS as well as individual PFAS can threaten human health. The proposal allows the EPA to establish legally enforceable levels, called Maximum Contaminant Levels (MCLs), requiring public water systems to monitor for, notify the public about, and reduce the levels of the six PFAS chemicals in our drinking water. The EPA estimates that between 70-94 million people receive drinking water contaminated by one or more of these PFAS chemicals above the proposed limits, so this move will help reduce the threat of PFAS exposure through drinking water for millions of Americans.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

California Farm Bureau Federation (Doc. #1704, SBC-045064)

May 30, 2023

Submitted via www.regulations.gov

Alexis Lan

Office of Ground Water and Drinking Water Environmental Protection Agency

1200 Pennsylvania Avenue, N.W. Washington, DC 20460

Re: Docket ID No. EPA-HQ-OW-2022-0114, Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

The California Farm Bureau is a non-governmental, non-profit, voluntary membership California corporation whose purpose is to protect and promote agricultural interests throughout the state of California and to find solutions to the problems of the farm, the farm home, and the rural community. California Farm Bureau is California's largest farm organization, comprised of 53

county Farm Bureaus currently representing approximately 29,000 agricultural, associate, and collegiate members in 56 counties. California Farm Bureau strives to improve the ability of farmers and ranchers engaged in production agriculture to provide a reliable food and fiber supply through responsible stewardship of California's resources.

On behalf of California family farmers and ranchers, California Farm Bureau appreciates the opportunity to submit these comments to the U.S. Environmental Protection Agency ("EPA") in response to its proposed rule to set National Primary Drinking Water Regulations (NPDWR) for six PFAS chemicals,[FN1: "Perfluoroalkyl or polyfluoroalkyl substance" (PFAS) means a non-polymeric perfluoroalkyl or polyfluoroalkyl substance that contains at least 2 sequential fully fluorinated carbon atoms, excluding gases and volatile liquids, that is a hazardous substance (as defined in section 101 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9601)).] including perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS). While California Farm Bureau supports EPA's underlying goal of addressing widespread contamination of the environment caused by historic use of PFOA and PFOS, the proposed Maximum Contaminant Level (MCLs) of 4 ppt for PFOA and PFOS and the designation of a hazard index for PFNA, PFHxS, Gen X, and PFBS overlooks the many challenges that will be placed on farm families located in rural communities.

California Farm Bureau shares the concerns regarding the health impacts of PFAS exposure. The research to prove causation is still under development and we encourage this work to continue. In addition, many additional factors must also be considered when developing regulatory limits. For this reason, we offer the following comments which outline the challenges we foresee with setting the drinking water MCL for PFOA and PFOS at the very low level of 4ppt. We are additionally concerned that the costs to rural farming communities will be disproportionally burdensome and ask that this review be taken into consideration.

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA disagrees that more research is needed to prove causation. Please see sections 3.1.1 and 3.2.1 of the EPA response in this *Response to Comments* document for more information, as well as the EPA response to comment Doc. #1704, SBC-045066 in section 3.1.2 in this *Response to Comments* document. Please see section 5.1 of the EPA response in this *Response to Comments* document for responses to concerns about the level of the MCL. The EPA conducted a cost and benefit analysis that took into consideration the costs for small and/or low-income communities. Please see sections 13.10 and 14.10 of the EPA response in this *Response to Comments* document.

Minnesota Center for Environmental Advocacy et al. (Doc. #1707, SBC-045720)

INTRODUCTION

The Environmental Protection Agency's ("EPA" or the "Agency") Proposed PFAS National Primary Drinking Water Regulation Rulemaking (the "Proposed Rule") is an exhaustive

scientific and economic digest that soundly supports the need to stringently regulate six per- and polyfluoroalkyl substances ("PFAS") in American's public water systems. Minnesota Center for Environmental Advocacy, [FN1: Minnesota Center for Environmental Advocacy ("MCEA") is a Minnesota non-profit organization whose mission is to use the law, science, and research to preserve and protect Minnesota's natural resources, its wildlife, and the health of its people. For over forty years, MCEA has worked with citizens and government decision-makers to protect and improve the quality of Minnesota's environment.] Clean Water Action Minnesota, [FN2: Clean Water Action has been in Minnesota since 1982, focusing on finding solutions to health, consumer, environmental and community problems, developing strong, community-based environmental leadership, and working for policies that improve lives and protect water.] and the collection of concerned clean water, public health, and environmental conservation organizations identified on the endorsement page (collectively, "Commenters"), applaud EPA's proposed regulatory approach, and write in support of the Agency's 1) carcinogenic determinations for PFOA and PFOS; 2) use of a hazard index to regulate PFHxS, GenX Chemicals, PFNA, and PFBS; and 3) conclusion that the benefits of the proposed rule outweigh the costs of implementation. The tome of supporting scientific data is clear: PFAS are a national threat to public health, and only near-zero levels of PFAS in our nation's public water systems are tolerable.

But the Commenters also write for a different, more personal reason. As EPA and others sift through the scientific literature that more than adequately justifies the proposed Maximum Contaminant Levels ("MCLs"), it's easy forget that behind the numbers and figures are individuals and communities ravaged by these synthetic chemicals. People like Amara Strande and the other Tartan High School students whose lives are marked by hospital visits and diagnoses of mysterious afflictions attributed to chemicals in the water. It's people like JD and Ben Rule, who were both stricken with rare and aggressive cancers before graduating high school, that offer evidence EPA must consider as it weighs just how costly weakened or watered-down enforcement will be.

The pathway to EPA's proposed MCLs is littered with corporate deception, a patchwork of rapidly stringent and expanding state regulation, and clear scientific proof that national, aggressive action is needed to protect our nation's public water systems from PFAS. EPA's Proposed Rule meets the moment, and the Commenters urge the Agency to swiftly enact the MCLs into law.

I. Minnesota's Fight Against PFAS Offers Stark Evidence To Support EPA's Proposed Rule

Minnesota, home to 3M and one of the country's largest groundwater PFAS plumes, offers compelling lessons for EPA to cite in support of adopting the proposed MCLs. The alarming rate of rare cancers among students at one east Minneapolis / St. Paul Metropolitan Area (the "East Metro") school and similar stories of trauma caused by contaminated drinking water lend credit to EPA's determination that the human health benefits of the proposed MCLs eclipse the costs of compliance. Moreover, the repeated and dramatic changes in Minnesota's PFAS drinking water

regulations cements the need for swift and strict action to protect America's public water supplies from these insidious chemicals.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Minnesota Center for Environmental Advocacy et al. (Doc. #1707, SBC-045722)

B. Minnesota's History Regulating PFAS Supports EPA's Proposed Rule

EPA would be wise to heed the lessons learned from Minnesota and its regulators in the push to respond to PFAS contamination aggressively and meaningfully. These lessons include the rapidly evolving scientific understandings that spark significant regulatory changes, and the need to protect citizens from the PFAS pollution that is already released into the environment.

1. The Minnesota Department of Health's Rapid and Radical Regulatory History of PFAS

As the stories above illuminate, Minnesota has been facing some of the country's worst PFAS contamination for years. Minnesota was also on the vanguard of PFAS regulation, which began in the early 2000s. In the following decades, as the scientific literature grew and the connections to PFAS and adverse health outcomes continued to get clearer at lower and lower concentrations, Minnesota revised its regulations repeatedly to try and protect public health. The frequency and severity of these regulatory changes highlight the need for EPA to take a firm and committed stance now.

In 2002, the Minnesota Department of Health ("MDH") established a Health Based Value ("HBV") [FN19: Health Based Values are "the concentration of a chemical (or a mixture of chemicals) that is likely to pose little or no risk to human health. Health-Based Values and Risk Assessment Advice for Water, Minn. Dep't of Health, https://www.health.state.mn.us/communities/environment/risk/guidance/hbvraawater.html (last visited May 22, 2023).] for PFOS in drinking water at 1,000 parts-per-trillion ("ppt"). [FN20: Toxicological Summary for Perflourooctane Sulfonate, Minn. Dep't of Health (Aug. 2020), https://www.health.state.mn.us/communities/environment/risk/docs/guidance/gw/pfos.pdf.] That same year, MDH set the HBV for PFOA in drinking water at 7,000 ppt. [FN21: Toxicological Summary for Perfluorooctanoate, Minn. Dep't of Health (Mar. 2022), https://www.health.state.mn.us/communities/environment/risk/docs/guidance/gw/pfoa2022.pdf.] MDH developed these standards after reviewing the available peer-reviewed data about the toxicity and adverse health effects from consuming these chemicals. At that time, scant data was available to MDH to guide and justify its regulatory approach, and testing limitations further hampered the ability of labs to accurately identify and quantify the type of PFAS in water. As the scientific literature expanded and testing capabilities became more robust, MDH revised its guidance values for PFOA and PFOS, and the agency started regulating other PFAS, including PFBS and PFHxS.

In 2007, MDH revised its HBVs for PFOS and PFOA to 300 ppt. [FN22: Toxicological Summary for Perflourooctane Sulfonate, supra note 11; Toxicological Summary for Perfluorooctanoate, supra note 12.] These figures remained unchanged until 2017, when MDH revised its guidance values again, this time to 27 ppt for PFOS and 35 ppt for PFOA. [FN23: Id.] The following year, MDH lowered the HBV for PFOS to 15 ppt. [FN24: Toxicological Summary for Perflourooctane Sulfonate, supra note 11.] MDH explained that these changes were due, in part, to "additional toxicological information." [FN25: Id.] Dr. Philippe Grandjean, a preeminent PFAS researcher who has repeatedly published highly cited papers centered around PFAS, noted in 2020 that,

[b]ecause independent PFAS research began only in the last decade or so, our understanding of PFAS toxicity has developed substantially in the past few years and will likely continue to do so. By now, risks to human health have been identified at exposure levels that in the past were considered safe. Thus, as the literature on PFAS toxicity has continued to expand, previous guidelines turned out to be outdated as we discovered the levels to be unsafe. [FN26: Memorandum from Philippe Grandjean to Minn. Ctr. for Envt'l Advocacy (Dec. 7, 2020) at 2 [hereinafter "Grandjean Mem.") (Attachment 5)]

A now-retired senior researcher at MDH charged with developing the agency's guidance values echoed the sentiment of Dr. Grandjean, stating that in his career he had never seen such repeated and significant changes to toxicity levels for contaminants in drinking water.

Minnesota's stunning regulatory changes in only two decades teaches that strong enforcement is needed to stave off the worst public health effects associated with PFAS. It also shows that as the threats these chemicals pose are studied further, that research will likely identify more dangerous links to chronic and debilitating illnesses at lower and lower concentrations. These lessons must be heeded by EPA, who, under the Safe Drinking Water Act ("SDWA"), are obligated to review each national primary drinking water regulation at least once every six years. As the regulatory history of PFAS in Minnesota shows, six years is an eternity, and comes with the risk of many years of public exposure to PFAS at levels which science may later show to be toxic. EPA must pass the Proposed Rule without laxing the MCLs to ensure our nation's public water supplies are protected now and are better insulated from subsequent changes that toxicity research may later reveal.

2. The Minnesota Legislature Starts Turning Off the Tap

One of the troublesome aspects of PFAS is its persistence in the environment. Unlike other contaminants, PFAS do not biodegrade or otherwise decay over reasonable periods of time. Instead, PFAS like PFOA and PFOS are incredibly durable and loom as hazards to drinking water years after being released into the environment. This is one reason why remediating contaminated PFAS areas is so difficult and expensive. While improvements to in-situ treatment are on the horizon, the scientific and regulatory consensus is that upstream source-reduction measures are a vital tool in the fight against PFAS.

Recognizing this, the Minnesota Legislature has responded strongly. In June 2021, Governor Tim Walz signed legislation that, effective January 1, 2024, prohibits PFAS in food packaging. [FN27: Minn. Stat. § 325F.075.] This session, Governor Walz signed a "transformative" environmental bill that effectively bans PFAS in a range of consumer product categories, and phases in a complete ban on intentionally added PFAS unless the product is "essential for health, safety, of the functioning of society and for which alternatives are not reasonably available." [FN28: 2023 Minn. Laws page no. 195, available at https://www.revisor.mn.gov/bills/text.php?number=HF2310&type=bill&version=4&session=ls93&session_year=2023&session_number=0] This law, which is one of the strictest PFAS bans in the country, is named "Amara's Law," after Amara Strande who died from cancer in April. [FN29: Deena Winter, Lawmakers to Name Chemical Ban 'Amara's Law' to Honor 20-Year-Old Cancer Victim, MINN. REFORMER, May 9, 2023, https://minnesotareformer.com/2023/05/09/lawmakers-to-name-chemical-banamaras-law-to-honor-20-year-old-cancer-victim/ (last visited May 30, 2023); Deena Winter, Outspoken PFAS Critic Amara Strande Dies from Cancer, MINN. REFORMER, May 3, 2023, https://minnesotareformer.com/2023/05/03/amara-kind-of-was-someone-wholooked-out-for-the-underdog/ (last visited May 30, 2023).] She was 20 years old. Amara's Law will undoubtedly help prevent further PFAS from infecting Minnesota's drinking water supplies. But it does nothing to respond to the plumes of PFAS contamination that are already in the groundwater below large population centers across Minnesota. EPA's Proposed Rule is a mighty arrow in the quiver of regulations needed to protect public health. The Commenters urge the Agency to work swiftly to protect our nation's drinking water from these toxic contaminants.

II. The Commenters Support EPA's Proposed Rule

The Commenters agree with EPA that the Safe Drinking Water Act ("SDWA") compels the Agency to take swift responsive action to regulate PFAS in our nation's drinking water supplies. Without a robust nationwide standard, Americans will be reliant upon a patchwork of state regulations that vary dramatically across the country, exposing millions of households to contaminated drinking water that undeniably leads to adverse health outcomes. Part of EPA's mandate is to ensure that Americans have clean water. [FN30: Our Mission and What We Do, EPA, https://www.epa.gov/aboutepa/our-mission-andwhat-we-do (last visited May 30, 2023).] The Proposed Rule does just that. The Commenters offer support for the Proposed Rule in sum, and write to specifically support the Agency's carcinogenic determinations, the use of a hazard index, and the Health Risk Reduction and Cost Analysis ("HRRCA").

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. The EPA acknowledges the shared experiences and state perspective on this regulation. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Minnesota Center for Environmental Advocacy et al. (Doc. #1707, SBC-045728)

CONCLUSION

EPA has spilled a lot of ink explaining why swift and decisive action is needed to ensure the integrity of our nation's public water supplies are not compromised by synthetic PFAS. But between the lines of technical text explaining the causal links between PFAS and adverse health outcomes are real people who can tell you directly just how toxic these chemicals are. EPA is obligated to ensure that every American has access to clean, safe drinking water. The Proposed Rule honors that mandate. Commenters implore the Agency to act quickly to compel water suppliers to monitor and eradicate dangerous levels of PFAS from the drinking water they serve to tens of millions of Americans every day.

Respectfully submitted,

/s/Jay E. Eidsness

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Clean Water Action and Clean Water Fund

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The following organizations endorse these comments:

Conservation Minnesota

Environmental Working Group

Hastings Environmental Protectors

Friends of the Mississippi River

Friends of Minnesota Scientific and Natural Areas

League of Women Voters of Minnesota

Minnesota Environmental Partnership

Minnesota Interfaith Power & Light

Prairie Horizons Farm LLC Starbuck, Minnesota

Save Lake Superior Association

Save Our Sky Blue Waters

Sierra Club North Star Chapter

WaterLegacy

[Attachment 1 – Attachment 4: see docket ID EPA-HQ-OW-2022-0114-1707:

Attachment 1 to Comments by MCEA et al. on EPA's Proposed PFAS National Primary Drinking Water Regulation Rulemaking

Attachment 2 to Comments by MCEA et al. on EPA's Proposed PFAS National Primary Drinking Water Regulation Rulemaking

Attachment 3 to Comments by MCEA et al. on EPA's Proposed PFAS National Primary Drinking Water Regulation Rulemaking

Attachment 4 to Comments by MCEA et al. on EPA's Proposed PFAS National Primary Drinking Water Regulation Rulemaking]

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045086)

The State of Vermont Agency of Natural Resources and Department of Health is hereby submitting these comments to docket EPA-HQ-OW-2022-0114; Per- and polyfluoroalkyl substances (PFAS): Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) National Primary Drinking Water Regulation Rulemaking.

The State of Vermont is supportive of the EPA taking the lead and enacting federal nation-wide minimum standards for PFAS in drinking water; however, we have some specific concerns as

identified below, based on our experience implementing our state specific MCL since 2019. We also have information to answer questions posed in the preamble of the proposed regulation which we provide below.

Based on our experience implementing a state PFAS regulation since 2019, Vermont is providing a broad range of comments, with specific recommendations on the following:

• Vermont requests that additional financial support and resources be provided to address impacts to water systems with a focus on small water systems.

• EPA should establish a dedicated funding source for O&M expenses for small water systems who are disproportionately impacted by PFAS contamination.

• Vermont is identifying laboratory capacity concerns, specifically for EPA to ensure that there is sufficient, reliable laboratory capacity nation-wide to support the proposed PQL of 4 parts per trillion (ppt).

• Vermont requests EPA accept existing data on-file by states with state programs if that data meets the current EPA Method 537.1 or 533.

• EPA must establish an equitable and health-protective sampling framework, accommodating the subtleties of PFAS regulation, and a post-treatment sampling framework due to the shortcomings of the use of the existing Synthetic Organic Chemical (SOC) sampling framework that is proposed to be applied.

• Vermont requests clarification of health effects as it relates to treatment design, treatment Operation & Maintenance, and messaging to system users.

EPA Response: The EPA acknowledges and appreciates this comment in general agreement of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. For laboratory capacity and availability concerns, please see section 5.1.2 and 8.7 of this *Response to Comments* document. For cost-related concerns, please see section 13.3.1 of this *Response to Comments* document, particularly the EPA response to comment Doc. #1708, SBC-045091. For discussion on the use of existing data that meets the current EPA Method 537.1 or 533, please see section 8.3 of this *Response to Comments* document, particularly the EPA response to comment Doc. #1708, SBC-045105. For a response to the sampling framework, please see the EPA response to comment Doc. #1708, SBC-045093 in section 8.1.2 in this *Response to Comments* document. The EPA recognizes the importance of communication during the implementation phases of this NPDWR, and the EPA is taking these requests under consideration. Please see section 1.2 of the EPA response in this *Response to Comments* document for additional discussion around communications.

Philadelphia Water Department (PWD) (Doc. #1709, SBC-045755)

PWD requests that the EPA consider the following actions:

• EPA should reevaluate the proposed MCL values for PFOA and PFOS and must consider more factors in evaluating technical and economic feasibility.

• EPA must utilize a holistic regulatory approach to rulemaking that includes considerations for PFAS generators, an extension to the implementation timeline of up to two years to accommodate capital improvements associated with proposed Best Available Technology (BATs) and competing regulatory requirements when determining implementation of MCLs for PFOA and PFOS.

• EPA should pursue a separate rulemaking determination from PFOA and PFOS for the constituents considered in the Hazard Index (HI) and should provide more data supporting its analyses.

• EPA should provide additional clarification and support around compliance and communication and allow more time for implementation.

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document, as well as arguments outlined in the EPA response to comment Doc. #1709, SBC-045729. For additional information about the rationale for the selected MCL levels of PFOA and PFOS, please see section 5 of this *Response to Comments* document. Please see section 12 of the EPA response in this *Response to Comments* document for information about the two-year extension for capital improvements. The EPA disagrees that the agency should pursue a separate regulatory determination for PFOA and PFAS compared to the Hazard Index contaminants. The EPA conducted a concurrent preliminary regulatory determination, and the EPA has statutory authority to do so, as discussed in section III of the FRN and section 3 of this *Response to Comments* document. The EPA agrees that communications materials are important for implementation of this rule, as discussed in section 1.2 of this *Response to Comments* document.

Philadelphia Water Department (PWD) (Doc. #1709, SBC-045729)

May 30, 2023

U.S. Environmental Protection Agency

Office of Ground Water and Drinking Water

1200 Pennsylvania Avenue NW

Washington, DC 20460

Re: Docket ID No. EPA-HQ-OW-2022-0114

Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation

To Whom It May Concern:

The Philadelphia Water Department (PWD) appreciates the opportunity to provide comment on the Environmental Protection Agency's (EPA's) landmark proposed rulemaking for enforceable limits on the presence of per- and polyfluoroalkyl substances (PFAS) in drinking water. Given that the presence of PFAS in drinking water may pose a risk to human health over a lifetime of exposure, PWD fully supports regulating these compounds.

PWD is the largest public utility in the Commonwealth of Pennsylvania, providing 1.6 million residents with clean drinking water and more than 2.2 million people with reliable wastewater and stormwater collection and treatment services. PFAS have been used in a multitude of industries since the 1940s, but it has only been recently that the general scientific community has developed a better understanding that they accumulate and cycle throughout the environment, entering air, water, soil, and biota. As a combined utility providing water, wastewater, stormwater, and biosolids treatment services, PWD is particularly concerned with PFAS as these harmful and persistent chemicals can exist throughout our collection and treatment systems.

PWD operates three drinking Water Treatment Plants (WTPs) with a combined maximum rated capacity of over 500 million gallons per day (MGD). Like many regions across the country, Philadelphia is subject to pollution from the producers, manufacturers, users, and disposers of PFAS and, like many other water suppliers across the nation, PFAS exists throughout Philadelphia's source waters, impacting the greater water supply area and the Delaware River Watershed.

PWD has the following overarching comments related to the draft National Primary Drinking Water Rule (NPDWR):

• EPA should reevaluate the proposed MCL values for PFOA and PFOS and must consider more factors in evaluating technical and economic feasibility.

• EPA must utilize a holistic regulatory approach to rulemaking that includes considerations for PFAS generators, an extension to the implementation timeline of up to two years to accommodate capital improvements associated with proposed Best Available Technology (BATs) and competing regulatory requirements when determining implementation of MCLs for PFOA and PFOS.

• EPA should pursue a separate rulemaking determination from PFOA and PFOS for the constituents considered in the Hazard Index (HI) and should provide more data supporting its analyses.

• EPA should provide additional clarification and support around compliance and implementation.

PWD appreciates the opportunity to provide comments and has taken this opportunity to provide detailed comments to support these positions below. PWD greatly appreciates EPA's steadfast commitment to implementing the holistic management approach in the PFAS Strategic Roadmap and its continued efforts to address one of the most significant environmental challenges facing the nation.

Sincerely,

Randy E. Hayman

Commissioner and Chief Executive Officer

Philadelphia Water Department

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR, with some additional modifications. Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA has considered the MCL values for PFOA and PFOS to be appropriate and meet technical and economic feasibility, as discussed further in section 5.1 of this *Response to Comments* document. Discussion on PFAS generators is considered out of scope and a response can be found in section 15 of this *Response to Comments* document. Based on public comment and interest, a national two-year capital extension has been granted, and details can be found in section 12 of this *Response to Comments* document. The EPA has the authority to pursue a rulemaking determination for the four additional PFAS with the final NPDWR. In 2021, the EPA made a determination to regulate two PFAS—PFOA and PFOS—in drinking water under SDWA. The EPA describes its regulatory determination findings of the three additional PFAS and the mixtures of four PFAS in section III of the FRN and section 3 of this *Response to Comments* document. The EPA recognizes the importance of communication for systems to comply with this NPDWR and will take these recommendations into consideration during the implementation phase of this rulemaking. For additional discussion on communications, please see section 1.2 of this *Response to Comments* document.

<u>Citizens Campaign for the Environment (CCE) (Doc. #1710, SBC-045126)</u>

Comments to the United States Environmental Protection Agency (EPA)

By Citizens Campaign for the Environment

RE: U.S. EPA's proposed National Primary Drinking Water Regulation (NPDWR) for six PFAS

Docket ID: EPA-HQ-OW-2022-0114

May 30, 2023

On behalf of Citizens Campaign for the Environment (CCE), thank you for the opportunity to provides comments on the U.S. EPA's proposed National Primary Drinking Water Regulation (NPDWR) for six PFAS, including perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO-DA, commonly known as GenX Chemicals), perfluorohexane sulfonic acid (PFHxS), and perfluorobutane sulfonic acid (PFBS).

CCE is a 120,000-member, non-profit, non-partisan organization that empowers communities and advocates solutions to protect public health and the natural environment in New York State

and Connecticut. Since our inception in 1985, protecting clean drinking water for the public has been a top priority for CCE. CCE is grateful that EPA has taken this action and we are very supportive of adopting the proposed regulations with recommendations to further strengthen them thereby providing additional public health protection.

New York State is a national leader on clean water and an early adopter of MCLs for PFOA and PFOS, however EPA's proposed regulations follow the latest science and further enhance public health protections for New Yorkers and all Americans. We support the EPA's stronger proposed federal standard which will increases public health and drinking water protections for New Yorkers and other states across the nation.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045874)

In addition, costs of the proposed rule, as presented in EPA's own analysis, could exceed $1,000 per household annually. As a result, EPA's proposed rule raises the following concerns:

• EPA substantially underestimates the potential costs that this proposed rule will impose on public water systems and overstates the benefits of the rule.

• EPA's preliminary determination to regulate PFHxS, HFPO-DA, PFNA, and PFBS is inconsistent with statutory criteria under SDWA because the available health data and occurrence data do not support a decision to regulate, and the data does not demonstrate that this rulemaking is a "meaningful opportunity" for health risk reduction.

• EPA skirted its own required procedures by proposing a preliminary determination for PFHxS, HFPO-DA, PFNA, and PFBS simultaneously with its proposed MCL and maximum contaminant level goal (MCLG), contrary to SDWA requirements, and deprived the public of sufficient time and opportunity to comment on the proposal.

• EPA has also failed to satisfy its obligations under SDWA when it did not consult with the Science Advisory Board (SAB) prior to proposing a National Primary Drinking Water Regulation (NPDWR) and MCLG for PFHxS, HFPO-DA, PFNA, and PFBS.

• EPA also fails to use the best available science in proposing the MCLs and MCLGs for all six PFAS.

• The Hazard Index approach proposed by EPA as the MCL and MCLG for PFHxS, HFPO-DA, PFNA, and PFBS violates SDWA because it does not reflect the use of the best available science and is not actually a proposed level for the contaminants.

• The Hazard Index approach is not a proposed level for a contaminant, but a mixture of contaminants. SDWA requires MCLs and MCLGs for individual contaminants rather than mixtures.

• EPA's re-interpretation of PFOS as a "likely carcinogen" is not supported by the science.

Consistent with the comments presented, significant scientific uncertainties and legal inadequacies must be addressed. EPA has not demonstrated that PFNA, PFHxS, PFBS, and HFPO-DA warrant regulation under SDWA, and EPA should withdraw the proposed MCL and MCLG for these four PFAS.

While the science is better developed for PFOA and PFOS, the documents EPA presented to the SAB were not sufficiently robust to allow the SAB to make actionable recommendations, and EPA did not adequately apply the SAB input to refine the documents prior to proposing the rule. Consequential uncertainties remain regarding the cancer classification for PFOS, and EPA is still awaiting robust and representative occurrence data from the Unregulated Contaminants Monitoring Rule (UCMR) 5 sampling for both PFOA and PFOS. EPA's cost and benefits analyses for these PFAS is flawed, both qualitatively and quantitatively, with notable underestimates of the costs and overestimates of the benefits. An MCL of 4 ppt is simply not justified, and the MCL must be adjusted upward to make this proposal feasible.

[Table of Contents: see docket ID EPA-HQ-OQ-2022-0114-1713].

I. Introduction

The U.S. Chamber of Commerce (the Chamber) and its coalition of companies, trade associations, and other stakeholders appreciate this opportunity to comment on EPA's proposed rule, [FN1: 88 Fed. Reg. 18638 (Mar. 29, 2023).] which (1) issues a preliminary regulatory determination for PFNA, PFHxS, PFBS, and HFPO-DA, and (2) proposes MCLs [FN2: In these comments, we use the term "MCL" interchangeably with the term national primary drinking water regulation or "NPDWR." The NPDWR refers to EPA's regulation which specifies contaminants and a MCL or a treatment technique (if it is not economically or technologically feasible to ascertain the level of the contaminant). The MCL is the level set under the NPDWR—the maximum permissible level of a contaminant in water delivered to a user of a public water system. In this proposed rule, EPA proposes MCLs and MCLGs (not treatment techniques), which is why the term is used interchangeably.] and MCLGs for these four PFAS as well as PFOA and PFOS [FN3: Throughout these comments references to specific PFAS also refer to all salts, isomers and derivatives, including derivatives other than the anionic form. This is consistent with EPA's approach in the proposed rule. However, we note that the inclusion of isomers for each PFAS is not justified as EPA presented virtually no scientific information on these various isomers and their environmental and human health effects. This expanded listing is problematic for multiple reasons.]. We represent member companies, trade associations, and state and local chambers that span key U.S. supply chains using PFAS chemistries and whose products and technologies are essential to America's economic growth, water infrastructure, and national security. Many of these companies operate public water systems, including Non-

Transient Non-Community Water Systems (NTNCWS) that would be regulated. The Chamber and its coalition are committed to managing PFAS safely and protecting human health and the environment. The Chamber and the coalition support national drinking water standards for select PFAS based on the best science and risk, rather than the current patchwork of state approaches. Customers, employees, and the communities where Chamber and coalition members operate depend on clean, safe drinking water for a better quality of life and economic growth. But any regulation of PFAS must be informed by the best available science and comply with the rigorous mandates of SDWA [FN4: SDWA also requires the use of best available science, stating "In carrying out this section, and, to the degree that an Agency action is based on science, the Administrator shall use— (i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data)." 42 U.S.C. [sec] 300g-1(a)(3)(A).]. The proposed rule falls short of those requirements, would impose significant and underestimated costs, and will lead to considerable challenges for the water utilities and many other industries.

EPA Response: The EPA disagrees with the critiques of the final PFAS NPDWR in the comment. The EPA used the best available and peer-reviewed science to promulgate this PFAS NPDWR as required by the SDWA. Please see the FRN and section 1.3 of the EPA response in this *Response to Comments* document, as well as the EPA response to comments Doc. #1713, SBC-045926 and Doc. #1714, SBC-045945 in section 1.3 in this *Response to Comments* document.

For specific analysis on the costs and benefits of this rule, please see section 13.3 of the EPA response in this *Response to Comments* document, particularly the EPA response to comment Doc. #1713, SBC-045911; SBC-045906; SBC-045918; SBC-045914; and SBC-045916.

In response to concerns raised about occurrence data, as documented in the FRN the available UCMR 3 and state occurrence data are sufficiently robust to support the final rule. The EPA is not obligated to use/collect the entire UCMR 5 dataset prior to finalizing the rule. For additional discussion of the UCMR 3 and UCMR 5 occurrence data, please see sections 6.1 and 6.8 of the EPA response in this *Response to Comments* document.

The EPA disagrees that its preliminary determination to regulate PFHxS, HFPO-DA, PFNA, and PFBS does not follow SDWA criteria, or that proposing a preliminary determination for PFHxS, HFPO-DA, PFNA, and PFBS simultaneously with a proposed MCL and MCLG violates the SDWA. The EPA has thoroughly addressed the rationale for its determination in the FRN as well as responding to these concerns throughout section 3 of this *Response to Comments* document, particularly in the EPA response to comment Doc. #1713, SBC-045875; SBC-045894; and SBC-045897.

The EPA notes that it satisfied its obligations to consult with the SAB prior to proposing a NPDWR and MCLG for PFHxS, HFPO-DA, PFNA, and PFBS. Please see section 14.11 of the

EPA response in this *Response to Comments* document, particularly the EPA response to comment Doc. #1713, SBC-045896 in section 14.11.1 in this *Response to Comments* document.

The EPA disagrees with the comments stating that the EPA failed to use the best available science for determining the MCLs, as well as the claims that the hazard index violates SDWA. Please see section 5 of the EPA response in this *Response to Comments* document, particularly the EPA response to comments Doc. #1713, SBC-053343 and Doc. #1713, SBC-045898 in section 5.2.1 in this *Response to Comments* document.

Please see section 4.1.4 of the EPA response in this *Response to Comments* document for a response regarding PFOS deemed a "likely carcinogen".

Regarding the inclusion of isomers for the six PFAS in this NPDWR, please see additional discussion in section 2.1 of this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045926)

VIII. Conclusion

SDWA sets a high bar by requiring best available science because drinking water regulations are vital to protect human health. At the same time, SDWA can impose significant costs on many public water systems throughout the country. Accordingly, regulation for PFAS substances in water is important but must be done in a lawful and science-based process. This proposal falls short in both respects. Significant scientific uncertainties and legal inadequacies remain. EPA has not yet demonstrated that PFNA, PFHxS, PFBS, and HFPO-DA warrant regulation under SDWA. As such, it is premature to set MCL or an MCLGs. Because EPA skipped important steps in the statutory process, including by forgoing the advice of the SAB on these four PFAS, EPA's proposals for these four should be withdrawn.

While the science is more developed for PFOA and PFOS, the documents EPA presented to the SAB were not sufficiently robust to allow the SAB to make actionable recommendations. Where SAB made valuable and important recommendations, EPA appears to have failed to revise the proposals in a meaningful and cohesive manner. Consequential uncertainties remain regarding the cancer classification for PFOS, and EPA is still awaiting robust and representative occurrence data from the UCMR 5 sampling for both PFOA and PFOS. EPA's cost and benefits analyses for PFOA and PFOS is flawed (as it is for the other PFAS as well), both qualitatively and quantitatively, with notable underestimates of the costs and overestimates of the benefits. An MCL of 4 ppt is simply not justified, and the MCL must be adjusted upward to meet SDWA's feasibility requirements. Finally, if EPA moves forward with setting the proposed MCLs at near-zero levels based on the level of information available for the six PFAS and without adequate weight placed on cost and feasibility, it would set a precedent that is inconsistent with prior MCLs and one that would be difficult to meet when applied going forward.

The Chamber and coalition members welcome any questions and further discussion from EPA on this important, precedent-setting rulemaking. Please contact Chuck Chaitovitz, Vice President

of Environmental Affairs and Sustainability at the U.S. Chamber of Commerce (cchaitovitz@uschamber.com), with any questions.

Sincerely,

American Council of Engineering Companies American

Forest & Paper Association

American Fuel and Petrochemical Manufacturers American

Petroleum Institute

Council of Industrial Boiler Owners

The Fertilizer Institute

Fluid Sealing Association

National Association of Chemical Distributors National

Association for Surface Finishing

National Association of Printing Ink Manufacturers

National Council of Textile Organizations

National Oilseed Processors Association

National Mining Association

PRINTING United Alliance

RCRA Corrective Action Project

The Superfund Settlements Project

TRSA - The Linen, Uniform and Facility Services Association

U.S. Chamber of Commerce

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. Please see the EPA response to comment Doc. #1713, SBC-045874 in section 1.3 in this *Response to Comments* document. The EPA disagrees that it did not follow a lawful and science-based process for promulgating this NPDWR. Please see sections 1.1 and 1.3 of the EPA response in this *Response to Comments* document for the EPA's discussion of its adherence to the SDWA process.

The EPA disagrees that it has not shown that PFNA, PFHxS, PFBS, and HFPO-DA warrant regulation under SDWA. The EPA provides ample information to support individual regulation of PFHxS, PFNA, and HFPO-DA, as well as mixtures of these three PFAS and PFBS, based on the three statutory criteria, as well as its authority to regulate. This is described in both section

III.2 of the FRN, as well as sections 3.1 and 3.2 of this *Response to Comments* document, particularly the EPA response to comment Doc. #1713, SBC-045875 in section 3.1 in this *Response to Comments* document. Additionally, the EPA has outlined its process for considering feasibility (as defined by SDWA) for establishing MCLGs and MCLs for mixtures of PFHxS, PFNA, HFPO-DA, and PFBS. Please see section V.B.2 of the EPA response in this *Response to Comments* document for discussion on the use of an Hazard Index approach and the regulation of additional PFAS. For additional discussion on evidence used to establish Hazard Index MCLGs or the occurrence in relation to the Hazard Index PFAS compounds, please see sections 4.3 and 6.3 of this *Response to Comments* document.

The EPA also disagrees that important steps were skipped in the SDWA process, including forgoing the advice from the SAB on the four PFAS. The EPA disagrees that the documents presented to the SAB were not sufficiently robust to allow the SAB to make actionable recommendations, and that the EPA failed to revise proposals in a meaningful and cohesive manner. The EPA sent four documents to the SAB, including the *Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS)*. The SAB responded with input summarized in a report. It explicitly applauded the agency's efforts to develop new approaches for assessing the risk of PFAS mixtures and recognized the benefits arising from reducing exposure to these chemicals as adopted by the EPA in the Hazard Index approach in this proposed rule. The SAB also provided recommendations that the EPA took under consideration, and the agency made many adjustments based on SAB input, as described in section XIII.K.1 of the FRN. The commenter does not provide any details or support for its claims that the EPA did not respond to or meaningfully address the SAB's advice. For more discussion of the SAB's advice and the EPA's consideration of their input, please see section 14.11.1 of the EPA response in this *Response to Comments* document, specifically in the EPA response to comment Doc. #1713, SBC-045896. See also the EPA response to comment Doc. #1713, SBC-045901 in section 14.11.1 in this *Response to Comments* document.

Regarding the UCMR 5 dataset, the EPA has determined that it is not appropriate to wait to finalize the rule until it receives occurrence data from the UCMR 5 sampling for both PFOA and PFOS. The EPA is not required under the statute to wait for another round of UCMR data to be collected before proposing or finalizing a regulation; in this case, the completion of UCMR 5 data reporting is expected at the end of 2025, with the final dataset not being available until 2026. Rather, SDWA Section 1412(b)(1)(B)(ii)(II) expressly provides that the EPA must use the "best available public health information" in making a regulatory determination (emphasis added). The EPA has sufficiently robust occurrence information to make regulatory determinations and promulgate a regulation for the six PFAS in this regulation. In addition to serving as a significant way for helping many utilities reduce initial monitoring costs, the final full UCMR 5 dataset will also be valuable for informing future regulatory decisions for the 23 PFAS included in UCMR 5 that are not directly addressed by this proposed rulemaking. The agency believes that the best currently available occurrence data demonstrates sufficient occurrence or substantial likelihood of occurrence for the contaminants included in the proposed

rule. While the EPA is under no legal obligation to consider the preliminary, partial UCMR 5 dataset prior to rule promulgation, based on public comment and interest, the agency considered UCMR 5 data released as of July 2023 (USEPA, 2024i). The partial data results are included in section VI of the FRN. Please see section 6 of the EPA response in this *Response to Comments* document for further discussion regarding UCMR and the best available science for the occurrence analysis, particularly the EPA response to comment Doc. #1713, SBC-045902 in section 6.8 in this *Response to Comments* document.

The EPA disagrees with the commenter's arguments on the benefits and costs of the rule, as well as the MCL of 4.0 ppt not being justified. Please see the FRN and sections 1.3 and 13.8 of the EPA response in this *Response to Comments* document for further discussion of these issues.

Protecting Our Water, Environment, and Ratepayers (POWER) (Doc. #1714, SBC-045945)

II. CONCLUSION

POWER! Believes it is important for EPA to address the risks of PFAS, including PFOA and PFOS, in the environment. However, POWER! Believes that EPA's proposed rule is premature because it precedes completion of processes under the Safe Drinking Water Act that are intended to help EPA understand the full impacts of the MCLs, and precedes technologies or standards for cleanup, handling, or destruction and/or disposal of the proposed chains.

To arrive at a proposal that considers and comports with precedent and sound science, EPA should:

• Finalize technological standards for the disposal and destruction of treatment byproducts prior to finalizing the MCLs.

• Adequately consider the reasonably foreseeable costs of the proposed rule.

• Use the data received from UCMR 5 through 2025 to assess the prevalence of the six PFAS substances and inform the costs and benefits of any MCLs for these compounds.

• Provide a longer implementation period to allow sufficient time to bring new treatment facilities online and expand lab capacity for the monitoring the proposed rule requires.

• Abandon a Hazard Index approach that is unsupported by precedent or science.

• Finalize Toxicity Assessments, Health Advisories, and Reference Doses before determining and finalizing MCLs for PFHxS, HFPO-DA (GenX), PFNA, or PFBS.

• Follow EPA precedent and sound science in setting trigger levels, PQLs, and MCLs that can be detected reliably using Method 533 and Method 537.1.

Thank you for the opportunity to provide comments on this proposed rule. If you have any questions or would like any additional information, please contact Ana Schwab at Ana.Schwab@BBKLaw.com.

Sincerely,

POWER!

Protecting Our Water, Environment, and Ratepayers!

CC: The Honorable Radhika Fox, Assistant Administrator, Office of Water, U.S. Environmental Protection Agency

Alexis Lan, Ground Water and Drinking Water, Standards and Risk Management Division, U.S. Environmental Protection Agency

EPA Response: Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA disagrees that it has not completed processes required under the SDWA prior to promulgation of this rulemaking. For full details regarding the preliminary regulatory determinations of four PFAS, please see section 3 of the EPA response in this *Response to Comments* document.

The EPA currently has the *2020 Interim PFAS Destruction and Disposal Guidance* (USEPA, 2020) that discusses disposal options for systems. The National Defense Authorization Act for Fiscal Year 2020, Public Law No: 116-92 Section 7361 directs the EPA to revise the *PFAS Destruction and Disposal Guidance* triennially; the new destruction and disposal guidance is anticipated to be released approximately concurrently with this rule and further revisions may be expected before the effective dates for this rule. Therefore, the EPA disagrees that the projected significant and direct public health protections for drinking water consumers in this rule should be delayed for the revision of guidance on management of PFAS waste streams. Please see section 10.4 of the EPA response in this *Response to Comments* document, particularly the EPA response to comment Doc. #1714, SBC-045930 in section 10.4.1 in this *Response to Comments* document.

The costs of this rule have been adequately considered and are described in section XII of the FRN, as well as the Economic Analysis. Additional discussion on the costs of the rule is included in section 13.3 of this *Response to Comments* document, particularly in the EPA response to comment Doc. #1714, SBC-045931.

The EPA has determined that it is not appropriate to wait to finalize the rule until it receives another round of UCMR 5 data. The EPA is not required under the statute to wait for another round of UCMR data to be collected before proposing or finalizing a regulation; in this case, the completion of UCMR 5 data reporting is expected at the end of 2025, with the final dataset not being available until 2026. Rather, SDWA Section 1412(b)(1)(B)(ii)(II) expressly provides that the EPA must use the "best available public health information" in making a regulatory determination (emphasis added). The EPA has sufficiently robust occurrence information to make regulatory determinations and promulgate a regulation for the six PFAS in this regulation. In addition to serving as a significant way for helping many utilities reduce initial monitoring costs, the final full UCMR 5 dataset will also be valuable for informing future regulatory decisions for the 23 PFAS included in UCMR 5 that are not directly addressed by this proposed

rulemaking. The agency believes that the best currently available occurrence data demonstrate sufficient occurrence or substantial likelihood of occurrence for the contaminants included in the proposed rule. While the EPA is under no legal obligation to consider the preliminary, partial UCMR 5 dataset prior to rule promulgation, based on public comment and interest, the agency considered UCMR 5 data released as of July 2023 (USEPA, 2024i). The partial data results are included in section VI of the FRN. Please see section 6 of the EPA response in this *Response to Comments* document for further discussion, particularly in the EPA response to comment Doc. #1714, SBC-045936 in section 6.8 in this *Response to Comments* document.

Based on public comment and further considerations, the EPA is exercising its authority under SDWA § 1412(b)(10) to implement a two-year nationwide capital improvement extension to comply with the MCL. All systems must comply with the MCLs by five years after the rule is promulgated. All systems must comply with all other requirements of the NPDWR, including initial monitoring, by three years after the rule is promulgated. For additional discussion on extensions and exemptions, please see section XI of the FRN.

The EPA disagrees with and denies the request for abandoning the Hazard Index approach. The EPA has provided ample science and health-based evidence for using the Hazard Index. The Hazard Index approach is outlined in section IV.B of the FRN, as well as section 4.3 of this *Response to Comments* document. Additionally, please see section VI.D for the occurrence data relative to the Hazard Index.

The EPA disagrees that finalizations of the Toxicity Assessments, Health Advisories, and Reference Doses are required prior to promulgating MCLs for the three additional PFAS (PFHxS, HFPO-DA [GenX], PFNA). Please see sections 4.3.3 and 3.1.1 f the EPA response in this *Response to Comments* document for a more thorough response to the request to finalize the EPA toxicity assessments for PFHxS and PFNA rather than relying on the Agency for Toxic Substances and Disease Registry (ATSDR) assessments. For the request on health advisories, Health Advisories are not a pre-requisite for an NPDWR under the SDWA and there is nothing in the statute or the EPA's historical regulatory practice that suggests that the agency should delay regulation of a contaminant in order to develop a Health Advisory first. The EPA does have final toxicity assessments and reference doses (RfDs) for HFPO-DA and PFBS. The EPA maintains that the final published peer-reviewed human health toxicity assessment that derives the RfD for HFPO-DA is appropriate and sound, reflects the best available peer-reviewed science, and is consistent with agency guidance, guidelines, and best practices for human health risk assessment. Notably, the EPA sought external peer review of the toxicity assessment *twice* (USEPA, 2018; USEPA, 2021c), released the draft toxicity assessment for public comment and provided responses to public comment (USEPA, 2021d), and engaged a seven-member pathology working group at the National Institutes of Health—an entirely separate and independent organization—to re-analyze pathology slides from two critical studies (USEPA, 2021b, Appendix D), all of which supported the EPA's conclusions in the toxicity assessment, including the RfD derivation. Lastly, regarding the PFBS assessments, the Feng et al. (2017) study, the critical effect of thyroid hormone disruption in offspring, dose-response assessment,

and corresponding RfD were subjected to extensive internal EPA, interagency, and public/external peer review and should be treated as best-available science.

Lastly, the EPA agrees that it is important to use precedent and sound science in setting trigger levels, PQLs, and MCLs that can be detected reliably using Method 533 and Method 537.1, and the EPA believes it has done so. For further response, please see the EPA response to comment Doc. #1714, SBC-045943 in section 7.2 in this *Response to Comments* document.

Monterey One Water (Doc. #1715, SBC-043826)

May 30, 2023

Dear Administrator Regan:

Monterey One Water appreciates the opportunity to submit comments regarding the U.S. Environmental Protection Agency's (EPA) preliminary regulatory determination and proposed rule to establish Maximum Contaminant Levels (MCLs) for certain per- and polyfluoroalkyl substances (PFAS). Monterey One Water is a public utility providing wastewater and water recycling services for diverse communities throughout northern Monterey County in California. We recognize the importance of addressing threats from chemicals to public health and the environment, and we are an organization dedicated to providing safe and reliable clean water services to the public. However, we are concerned about tangential impacts created by the preliminary determination and proposed rule, as described in our complete comment letter attached. Key concerns relate to the compliance timeline, economic impact, and PFAS disposal guidelines.

We thank EPA for the continued engagement with the water stakeholder community. Monterey One Water recognizes the need to address PFOA and PFOS in our environment but urges EPA to evaluate and consider unrealistic implementation goals. This includes identifying or establishing additional financial avenues that follow the polluter pays principle to fund required changes.

Regards,

Rachel Gaudoin, Federal Advocacy Lead

May 30, 2023

The Honorable Michael S. Regan Administrator

U.S. Environmental Protection Agency William Jefferson Clinton Building 1201 Pennsylvania Avenue, N.W. Washington, D.C. 20460

Submitted Electronically: https://www.regulations.gov

Re: Docket ID No. EPA–HQ–OW–2022–0114

Dear Administrator Regan:

Monterey One Water appreciates the opportunity to submit comments regarding the U.S. Environmental Protection Agency's (EPA) preliminary regulatory determination and proposed rule to establish Maximum Contaminant Levels (MCLs) for certain per- and polyfluoroalkyl substances (PFAS). Monterey One Water is a public utility providing wastewater and water recycling services for diverse communities throughout northern Monterey County in California. Every day we collect and treat approximately 17 million gallons of used water before safely reintroducing it into the environment, including through potable reuse via groundwater replenishment of a critical drinking water aquifer.

Monterey One water recognizes the importance of addressing threats from chemicals to public health and the environment, and is an organization dedicated to providing safe and reliable clean water services to the public. However, we are concerned about tangential impacts created by the preliminary determination and proposed rule as described below.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR with some additional considerations. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Wyoming Department of Environmental Quality (WDEQ) (Doc. #1716, SBC-044746)

May 30, 2023

U.S. Environmental Protection Agency

EPA Docket Center, Office of Ground Water and Drinking Water Docket Mail Code 2822IT

1200 Pennsylvania Avenue NW Washington, DC 20460

Via: https://www.regulalion .gov /

RE: Docket ID No. EPA-HQ-OW-2022-0114; FRL 8543-01-OW

PFAS National Primary Drinking Water Regulation Rulemaking, A Proposed Rule by the Environmental Protection Agency on March 29, 2023

Preliminary Regulatory Determination and Proposed Rule; Request for Public Comment; Notice of Public Hearing

To Whom It May Concern:

As part of its mission to protect, conserve, and enhance the quality of Wyoming's environment for the benefit of current and future generations, the Wyoming Department of Environmental Quality (WDEQ) implements programs that help ensure the public has access to safe drinking water. Under the Wyoming Environmental Quality Act, the WDEQ issues permits for the construction of public water systems in accordance with regulations. The WDEQ also implements several Safe Drinking Water Act (SDWA) programs, including Operator Certification, Capacity Development, and, in coordination with partner agencies, the Drinking

Water State Revolving Fund. EPA Region 8 directly implements the SDWA Public Water System Supervision (PWSS) Program in Wyoming, and WDEQ routinely communicates and coordinates with EPA Region 8 on drinking water protection activities.

Therefore, the WDEQ takes considerable interest in the proposed rulemaking, as National Primary Drinking Water (NPDW) standards and new regulations for drinking water systems will impact Wyoming's communities and their infrastructure, including publicly owned treatment works (POTW) and Public Water Systems (PWSs). In addition, NPDW standards and drinking water regulations will impact activities in other WDEQ programs, including establishing surface water quality standards, point source discharge permitting under the Wyoming Pollutant Discharge Elimination System (WYPDES), and any implications for assessment and remediation of sites that are regulated by the Solid and Hazardous Waste Division (SHWD).

WDEQ appreciates the opportunity to review (1) the proposed NPDW rule to set Maximum Contaminant Levels (MCLs) for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) and (2) the preliminary determination to regulate perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salt (also known as GenX), perfluorononanoic acid (PFNA), perfluorobutane sulfonic acid (PFBS), and mixtures of these PFAS using a Hazard Index (HI).

WDEQ shares EPA's interest in protecting human health and the environment from PFAS. However, WDEQ recommends the following comments be addressed before EPA finalizes the proposed rule.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR with additional considerations. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Monte Vista Water District (MVWD) (Doc. #1718, SBC-043533)

May 30, 2023

Federal eRulemaking Portal

U.S. Environmental Protection Agency (EPA)

EPA Docket Center

Office of Ground Water and Drinking Water Docket

Mail Code 2822IT

1200 Pennsylvania Avenue NW

Washington, DC 20460

Re: PFAS National Primary Drinking Water Regulation Rulemaking – Docket ID No. EPA-HQ-OW-2022-0114; FRL 8543-01-OW

To Whom it May Concern,

On behalf of the Monte Vista Water District (MVWD), we appreciate the opportunity to provide comments in response to the U.S. Environmental Protection Agency's (EPA) request for public comments on the proposed PFAS National Primary Drinking Water Regulation (NPDWR), published in the Federal Register on March 29, 2023.

MVWD provides retail and wholesale water supply services to over 130,000 individuals residing within the communities of Montclair, Chino, and Chino Hills in San Bernardino County, California. Our service area includes disadvantaged, low-income communities with a high Social Vulnerability Index according to the Center for Disease Control.

Over the past several decades, MVWD has expanded its water resources portfolio and demand management strategies to build a resilient water supply for its customers. MVWD is committed to delivering high quality drinking water that meets or exceeds drinking water standards. We have implemented costly new treatment technologies to meet increasingly more stringent drinking water standards, and the proposed NPDWR could drive treatment costs even higher and force consumers to bear the expense.

PFAS contamination presents many challenges for drinking water providers, and MVWD supports EPA's efforts in addressing PFAS to protect public health and the environment. That said, MVWD has significant concerns with the proposed regulation, including the costs, timeline, and methodology for setting the proposed Maximum Contaminant Levels (MCLs).

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for EPA's PFAS efforts with significant additional considerations. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Monte Vista Water District (MVWD) (Doc. #1718, SBC-043527)

Monte Vista Water District (MVWD) provides retail and wholesale water supply services to over 130,000 individuals residing within the communities of Montclair, Chino, and Chino Hills in San Bernardino County, CA. Our service area includes disadvantaged, low-income communities with a high Social Vulnerability Index according to the Center for Disease Control.

Over the past several decades, MVWD has expanded its water resources portfolio and demand management strategies to build a resilient water supply for its customers. MVWD is committed to delivering high quality drinking water that meets or exceeds drinking water standards. We have implemented costly new treatment technologies to meet increasingly more stringent drinking water standards, and the proposed NPDWR could drive treatment costs even higher and force consumers to bear the expense.

PFAS contamination presents many challenges for drinking water providers, and MVWD supports EPA's efforts in addressing PFAS to protect public health and the environment. That

said, MVWD has significant concerns with the proposed regulation, including the costs, timeline, and methodology for setting the proposed MCLs.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the EPA's PFAS efforts with significant additional considerations. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Louisville Water Company (Doc. #1720, SBC-043550)

Louisville Water appreciates the opportunity to provide input to the U.S. Environmental Protection Agency (EPA) as the agency considers finalizing a National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances. We also welcome continued dialogue with how best to approach the regulation of PFAS. In that regard, we are providing the attached comments on key issues that we think require consideration.

May 30, 2023

Dr. Jennifer McLain, Director

Office of Ground Water and Drinking Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington, DC 20460

Submitted electronically

RE: Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation ((88 FR 18638, EPA-HQ-OW-2022-0114-0027)

Dear Dr. McLain:

Louisville Water is proud to provide safe, high-quality drinking water to a diverse community of approximately one million people in the Louisville Metro region. Our retail service area includes Louisville Metro and parts of Bullitt and Oldham counties in Kentucky. Louisville Water provides wholesale service to nine regional water utility partners. We serve the urban core of Louisville with historic areas dating back to the early 1800s, suburban communities, rural areas, and some of the region's largest employers such as Ford Motor Company, UPS, and nearly two dozen bourbon distilleries. Public health, equitable infrastructure investment, and the economic well-being of the communities we serve are amongst Louisville Water's highest priorities.

Louisville Water continues to support regulations based on sound science and that are protective of human health. Due to the significant risks of health effects and the persistent nature of PFAS, Louisville Water appreciates EPA's 2021 final decision to regulate PFOA and PFOS in drinking water. Louisville Water and EPA share the goal of ensuring the delivery of clean, safe drinking water to our customers.

Louisville Water appreciates the opportunity to provide input to the U.S. Environmental Protection Agency (EPA) as the agency considers finalizing a National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances. We also welcome continued dialogue with how best to approach the regulation of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Environmental Working Group (EWG) (Doc. #1721, SBC-045402)

May 30, 2023

Submitted via www.regulations.gov

Assistant Administrator Radhika Fox

Office of Water

U.S. Environmental Protection Agency

1200 Pennsylvania Ave. NW

Washington, DC 20460–0001

Re: Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation, EPA-HQ-OW-2022-0114-0027

Dear Assistant Administrator Fox:

The Environmental Working Group offers these comments in strong support of the EPA's proposal to set maximum contaminant levels, or MCLs, for PFOA, PFOS, PFNA, PFHxS, PFBS, and GenX.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Environmental Working Group (EWG) (Doc. #1721, SBC-045405)

The EPA estimates that twenty percent of exposure to the PFAS covered by the proposed rule comes from drinking water. [FN9: PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18638, 18654, 18664-65, 18670 (March 29, 2023).] The MCLs proposed by the Environmental Protection Agency will dramatically reduce that exposure and improve health outcomes for Americans across the country.

The Environmental Working Group offers the following comments:

• The EPA should finalize the proposed drinking water standard as quickly as possible.

• The proposed regulatory determination for GenX, PFBS, PFNA, and PFHxS is appropriate and necessary.

• The hazard index is a critical tool to address cumulative risks from mixtures of PFAS.

• The benefits of the proposed rule are underestimated and outweigh the costs.

• The proposed MCLs are feasible with current technology.

• The costs of the proposed rule are affordable.

• The EPA should lower the health-based water concentrations.

• After finalizing the rule, the EPA should promulgate national primary drinking water standards for additional PFAS.

• The EPA should update the final rule as new science emerges and as detection methods improve.

• The EPA should take additional steps to address source reduction and regulate PFAS under additional statutes.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. For a response on the comment that the benefits have been underestimated, please see section XII.A.1.b of the FRN. For a response to the comment that the EPA should lower the health-based water concentrations, please see section 4.3.3 of the *Response to Comments* document, including the EPA response to comment Doc. #1721, SBC-045417. While beyond the scope of the PFAS NPDWR, this rule complements many other actions in the PFAS Strategic Roadmap to protect public health and the environment from PFAS. For more discussion on the PFAS Strategic Roadmap, please see section 15 of the *Response to Comments* document.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045140)

May 30, 2023

U.S. Environmental Protection Agency

Office of Water

Health and Ecological Criteria Division

Washington, DC

RE: MassDEP Comments on PFAS National Primary Drinking Water Regulation Rulemaking Docket ID No. EPA-HQ-OW-2022-0114

Dear EPA Reviewers:

The Massachusetts Department of Environmental Protection (MassDEP) commends the U.S. Environmental Protection Agency (EPA) for working to develop a National Primary Drinking Water Regulation (NPDWR) for Per- and Polyfluoroalkyl Substances (PFAS) and is pleased to submit comments on EPA's PFAS National Primary Drinking Water Regulation Rulemaking, published March 29, 2023 (88 Fed. Reg. 18638).

The Commonwealth of Massachusetts has a strong record of addressing emerging contaminants in drinking water and is committed to continuing to protect public health through ensuring safe drinking water from public water systems (PWS). Specifically, MassDEP has been at the forefront of regulating PFAS in drinking water. In October 2020, Massachusetts established one of the most protective, enforceable drinking water standards in the nation of 20 nanograms per liter (ng/L) (or parts per trillion (ppt)) for the sum of six PFAS and required all PWS to test for PFAS in their drinking water. In addition to these requirements, between July 2020 and June 2022, MassDEP implemented a PFAS Free Analyses Program for PWS and select private well owners to provide the opportunity for one round of free PFAS drinking water analysis and technical assistance. 1,171 public water systems and 1,668 private wells were sampled as part of this initiative. To date, all PWS in Massachusetts have completed at least one round of sampling of their finished water sources for PFAS and MassDEP continues to work with systems to reduce levels.

In addition to regulatory and technical assistance activities, Massachusetts has already provided PWS in the state with financial assistance to address PFAS. MassDEP and the Massachusetts Clean Water Trust have provided 0% interest rate loans totaling more than $149 million to remove PFAS contamination from drinking water in communities across the Commonwealth.

Massachusetts is committed to continuing its strong track record of addressing emerging contaminants in drinking water. MassDEP is preparing Massachusetts PWS for the adoption of EPA's PFAS NPDWR and is pleased to offer these comments.

EPA Response: The EPA acknowledges and appreciates this comment.

North Carolina Conservation Network (Doc. #1728, SBC-043559)

May 30, 2023

Administrator Michael S. Regan

U.S. Environmental Protection Agency

EPA Docket Center, OW Docket

Mail Code 28221T

1200 Pennsylvania Avenue NW

Washington, DC 20460

Re: Per- and Polyfluoroalkyl Substances (PFAS): Proposed National Primary Drinking Water Regulations (Docket ID: EPAHQ-OW-2022-0114)

Dear Administrator Regan,

We submit this comment to express support for the U.S. Environmental Protection Agency's (EPA) proposal to establish a national primary drinking water regulation for a set of per- and polyfluoroalkyl substances (PFAS). The NC Conservation Network advocates in coordination with dozens of partners organizations and on behalf of tens of thousands of North Carolinians. Too many of our activists and supporters have experienced years of exposure to high levels of PFAS in the Cape Fear River, including both PFAS that are covered by the proposed standard: PFOS, PFOA, GenX - as well as PFAS that are not: PFMOAA, Nafion byproducts 1 & 2.

We have joined technical comments by Earthjustice and the Natural Resources Defense Council (NRDC) that spell out in detail the reasons why EPA should adopt both the proposed maximum contaminant levels (MCLs) for PFOS and PFOA, and the index approach for four other PFAS (PFHxS, PFNA, PFBS, and GenX). In this short letter, we also write separately to highlight a challenge that your proposed rule will face in North Carolina, and to recommend a solution that we think could significantly increase the benefits of your rule here and in similarly situated states across the nation.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Chattahoochee Riverkeeper (CRK) (Doc. #1730, SBC-043562)

We need national drinking water standards for PFAS. We applaud EPA for the proposed National Primary Drinking Water Regulation (NPDWR) that includes six known, harmful PFAS chemicals—perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO-DA, commonly known as GenX Chemicals), perfluorohexane sulfonic acid (PFHxS), and perfluorobutane sulfonic acid (PFBS). We urge EPA to maintain the stringent proposed maximum contaminant levels (MCLs) included in the proposal.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Clean Air Council, et al. (Doc. #1731, SBC-043887)

Conclusion

Commenters strongly support the proposed NPDWR. Commenters thank EPA for the sound research and effort that generated the proposed NPDWR and for the opportunity to comment. The MCLs and HI/HBWC are reasonable and adequate to protect public health based on current data, and are feasible for both testing and treatment. To maintain the efficacy of the proposed rule in protecting public health as scientific knowledge and technical methods improve, EPA should regularly update the rule by modifying MCLs/HBWC and adding more chemicals to the regulations. Furthermore, EPA needs to address the safe disposal of the PFAS waste produced during treatment to avoid re-introduction of the contaminants into groundwater and soil, or of their fluorinated incomplete combustion products into air.

In summary, the current rule is a crucial step in protecting human health from significant harm caused by PFAS contamination.

Sincerely,

Joseph Otis Minott, Esq.

Executive Director & Chief Counsel Clean Air Council

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apwc.nepa@gmail.com
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6425 Living Place Suite 200
Pittsburgh, PA 15206 215-732-5897
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Pittsburgh, PA 15219 412-514-5008

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Ginny Marcille-Kerslake

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gmarcillekerslake@fwwatch.org

Edward C. Ketyer, M.D., F.A.A.P., President

Physicians for Social Responsibility

Pennsylvania (724) 255-7440

ned@psrpa.org

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Clean Air Council, et al. (Doc. #1731, SBC-043839)

May 30, 2023

U.S. Environmental Protection Agency

EPA Docket Center

Docket ID No. EPA-HQ-OW-2022-0114

Via Federal eRulemaking Portal:

https://www.regulations.gov/commenton/EPA-HQ-OW-2022-0114-0027

Re: Docket ID No. EPA-HQ-OW-2022-0114, Comments on Proposed Per- and

Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation

To Whom It May Concern:

Clean Air Council (the "Council"); Environmental Integrity Project; PennFuture; Mountain Watershed Association; Aquashicola Pohopoco Watershed Conservancy; PennEnvironment; Breathe Project; Food and Water Watch; and Physicians for Social Responsibility Pennsylvania (collectively, "Commenters") appreciate the opportunity to submit the following comments in response to the Environmental Protection Agency's ("EPA's") proposed Per- and

Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation [FN1: Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation, 88 Fed. Reg. 18638 (proposed March 29, 2023) (to be codified at 40 C.F.R. pts. 141, 142), available at https://www.govinfo.gov/content/pkg/FR-2023-03-29/pdf/2023-05471.pdf.]. As is detailed herein, Commenters strongly support this rulemaking as a vital step in protecting public health from a subset of harmful PFAS. Commenters urge EPA to provide for the regulation to be updated to regulate additional chemicals and set more stringent standards as scientific knowledge and technical feasibility increase.

About the Commenters

Clean Air Council is a nonprofit environmental health organization headquartered in Philadelphia, Pennsylvania with additional offices in Pittsburgh, Pennsylvania. The Council has been working to protect everyone's right to a clean and healthy environment for over 50 years. It has members throughout Pennsylvania and the Mid-Atlantic region who support its mission. It works closely with frontline communities who trust the Council to advocate for their right to a healthy environment and environmental justice.

The Environmental Integrity Project ("EIP") is a national nonprofit organization with staff in Pittsburgh and Philadelphia. EIP is dedicated to advocating for effective enforcement and implementation of environmental laws, including the Safe Drinking Water Act and the Clean Water Act. EIP has three goals: (1) to provide objective analyses of how the failure to enforce or implement environmental laws increases pollution and affects public health; (2) to hold federal and state agencies, as well as individual corporations, accountable for failing to enforce or comply with environmental laws; and (3) to help local communities obtain the protection of environmental laws. Comprised of former EPA enforcement attorneys, public interest lawyers, analysts, investigators, and community organizers, EIP has worked in partnership with communities and organizations affected by water pollution for many years.

PennFuture is a Pennsylvania-statewide environmental organization dedicated to leading the transition to a clean energy economy in Pennsylvania and beyond. PennFuture strives to protect our air, water and land, and to empower citizens to build sustainable communities for future generations. A main focus of PennFuture's work is to improve and protect air quality across Pennsylvania through public outreach and education, advocacy, and litigation.

Mountain Watershed Association (MWA) is the home of the Youghiogheny Riverkeeper. MWA is a nonprofit, citizen-led, environmental organization that works to protect, preserve and restore the Indian Creek and greater Youghiogheny River watersheds. MWA represents over 1,900 members, many of whom are impacted by the poor air quality-linked extractive industries such as mining and fracking, which are prevalent throughout the watershed.

The Aquashicola Pohopoco Watershed Conservation was organized in 2002. Volunteers monitor several different sites for water quality in the Aquashicola Pohopoco watershed and participate in stream clean-ups, roadside clean-ups, and share their knowledge and experience with others. APWC plans educational and community events to be held throughout the year, reports on water

quality and monitors for threats of pollution, engages in improvement plans such as planting riparian barriers to protect runoff into the streams, and engages members who appreciate and value our watershed.

PennEnvironment Research & Policy Center is dedicated to protecting our air, water and open spaces. We work to protect the places we love, advance the environmental values we share, and win real results for our environment. For more information, visit www.pennenvironment.org/center.

The Breathe Project is a coalition of citizens, environmental advocates, public health professionals and academics working to improve air quality, eliminate climate pollution and make Southwestern Pennsylvania a healthy and prosperous place to live through science-based work and a community outreach platform.

Food and Water Watch, with more than 2 million supporters, fights for safe food, clean water, and a livable climate for all of us. We protect people from the corporations and other destructive economic interests that put profit ahead of everything else.

Physicians for Social Responsibility Pennsylvania (PSR PA) promotes socially and environmentally responsible practices, policies, and programs to safeguard and improve public health. We accomplish this through education, training, direct service, and advocacy.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Rio Grande Waterkeeper and WildEarth Guardians (Doc. #1732, SBC-045423)

In the Rio Grande Basin, concern about PFAS contamination of our water sources is heightened by the arid environment and lack of alternative drinking water sources in the case of contamination. Climate change is only magnifying this problem. As temperatures warm and winter precipitation becomes less reliable, drought is becoming more of the norm in the Rio Grande Basin, adding stress to an already over-appropriated river. [FN15: Sara E. Pratt, Rio Grande Runs Dry, Then Wet, NASA EARTH OBSERVATORY, https://earthobservatory.nasa.gov/images/150244/rio-grande-runs-dry-then-wet (last visited May 23, 2023).] Rising temperatures will likely cause available water in the river to decrease, due to increased evapotranspiration, while crop irrigation requirements will increase. [FN16: Home – About, Rio Grande Water, http://riograndewater.org/about/ (last visited May 23, 2023).] Meanwhile, population centers relying on the Rio Grande for drinking water continue to grow. Given the limited - and shrinking - water available in the Rio Grande Basin, protection of these scarce water sources is of the utmost importance.

We believe the EPA's proposed national drinking water standard for six PFAS substances represents an important first step in securing the safety of our drinking water and the wellbeing of our communities. EPA should follow through by finalizing this rule to prevent PFAS-

attributable illness and death in our communities. However, there is much more work to be done in protecting the environment and safeguarding the public health from these harmful "forever chemicals".

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Rio Grande Waterkeeper and WildEarth Guardians (Doc. #1732, SBC-045421)

May 30, 2023

Michael S. Regan Administrator

U.S. Environmental Protection Agency 1200 Pennsylvania Avenue NW

Mail Code: 4607M Washington, DC 20460

Re: Comments for EPA's proposed national drinking water standard for six per- and polyfluoroalkyl substances (PFAS) (Docket ID: EPA-HQ-OW-2022-0114)

Dear Administrator Reagan,

On behalf of Rio Grande Waterkeeper and WildEarth Guardians, I write to express support for the Environmental Protection Agency's (EPA) proposed national drinking water standard for six per- and polyfluoroalkyl substances (PFAS). These chemicals are detrimental to the public health and the environment, taking thousands of years to break down. PFAS contamination in the Rio Grande and its tributaries is a threat to the ecological integrity of the Rio Grande ecosystem, people recreating on the River, and the numerous communities in Colorado, New Mexico, and Texas which rely on the Rio Grande and its tributaries for their drinking water.

As a member of the Waterkeeper Alliance, Rio Grande Waterkeeper protects and restores flows in the Rio Grande to ensure that life is sustained throughout the Rio Grande Basin for generations. WildEarth Guardians advocates for the protection of wild rivers, wildlife, wild places, and public health throughout the American West. This includes advocacy for clean water, healthy flows, and resilient communities in the Rio Grande Basin.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Rio Grande Waterkeeper and WildEarth Guardians (Doc. #1732, SBC-045426)

IV. Conclusion

Thank you for taking this first step to address the widespread public health threat posed by PFAS in drinking water. We are hopeful that you will uphold EPA's mandate to protect people and the

environment by expeditiously finalizing your plan to limit PFAS contamination in drinking water; however, we also urge that you consider more comprehensive regulation of PFAS chemicals, including adopting drinking water standards addressing a much broader swathe of PFAS contaminants, as well regulating these chemicals at the source of discharge under the Clean Water Act. Thank you for your consideration of our comments.

Sincerely,

Daniel Timmons

Rio Grande Waterkeeper

Wild Rivers Program Director, WildEarth Guardians

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Michigan Section American Water Works Association (MI-AWWA) (Doc. #1734, SBC-044474)

May 30, 2023

Mr. Michael Regan Administrator

Environmental Protection Agency

1200 Pennsylvania Ave, NW

Washington, DC 20460

Re: Observation on Implementation of Proposed PFAS rule Dear Administrator Regan:

We write to you regarding EPA's Memorandum to State Drinking Water Administrators on Implementability of Proposed PFAS rule.

The Michigan Section of the American Water Works Association represents water professionals in Michigan. Collectively, we are dedicated to protecting public health and the environment by providing safe drinking water to Michigan communities. What follows are highlights of input from our members. We ask that you reconsider implementation of the new rule on the grounds of cost of treatment, feasibility of reliable treatment at the method reporting level (MRL) for PFOA and PFAS, and communication challenges.

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. For responses on cost of treatment, please see section XII.A.2.b of the FRN, as well as section 13.3.3 in this *Response to Comments* document (particularly, the EPA response to comment Doc. #1734, SBC-044475). For responses on feasibility of treatment, please see section 5.1.4 of the *Response to Comments* document

(particularly, the EPA response to comment Doc. #1734, SBC-044476 in section 5.1.2 in this *Response to Comments* document). For communication challenges, please see section 1.2 of the *Response to Comments* document (particularly, the EPA response to comment Doc. #1734, SBC-044479).

Michigan Section American Water Works Association (MI-AWWA) (Doc. #1734, SBC-044480)

We hope you will consider the feedback of Michigan water professionals highlighted here and implore you to consider gathering more data before proceeding. Use the full time available to set realistic and meaningful MCLs that will provide more reliable and meaningful action levels while also enabling water systems to continue to build and maintain a productive relationship with their customers.

Sincerely,

Bonnifer Ballard

Executive Director

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Arizona Corporation Commission (ACC) (Doc. #1735, SBC-045191)

CONCLUSION

In conclusion, while the ACC is a strong proponent for safe, clean drinking water, it believes that adopting the MCLs as proposed for PFAS before further consideration of the cost impacts, sampling detection challenges, and disposal issues identified in this Comment will have a far-reaching negative impact on some of Arizona's most vulnerable citizens. The ACC therefore urges the EPA to address the aforementioned issues before finalizing the rule.

RESPECTFULLY submitted this 30th day of May, 2023.

/s/ Kathryn M. Ust

Kathryn M. Ust, Staff Attorney

Legal Division

Arizona Corporation Commission

1200 West Washington Street

Phoenix, Arizona 85007

kust@azcc.gov

(602) 542-3402

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA has considered the cost impacts, sampling detection challenges and disposal issues for this NPDWR. For responses concerning cost impacts, see sections XII.A.2.b and XII.A.3.b, as well as section 13.3.3 of the *Response to Comments* document. Please see section 1.2, particularly, the EPA response to comment Doc. #1735, SBC-045184, for discussion on guidance and other communications materials related to costs. For responses concerning sampling detection, see section 8 of the *Response to Comments* document (particularly, the EPA response to comment Doc. #1735, SBC-045188 in section 8.8 in this *Response to Comments* document). For responses concerning disposal issues, please see section 10.4.2 of the *Response to Comments* document (particularly, the EPA response to comment Doc. #1735, SBC-045186).

Pennsylvania Farm Bureau (PFB) (Doc. #1736, SBC-043565)

We appreciate the opportunity to provide comments and look forward to working with EPA to ensure that final PFAS MCLs reflect the best research and data, have support for implementation and compliance, and meet the needs of communities of all sizes.

Thank you for the opportunity to provide comments.

Sincerely,

Grant R. Gulibon

Regulatory Affairs

Specialist

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Washington County Department of Public Health and Environment (Doc. #1739, SBC-043566)

May 30, 2023

Radhika Fox, Assistant Administrator

Office of Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue NW

Mail Code: 410M

Washington, DC 20460-0001

RE: PFAS National Primary Drinking Water Regulation Rulemaking (Docket EPA-HQ-OW-2022-0114)

Dear Assistant Administrator Fox:

Washington County Department of Public Health and Environment appreciates the opportunity to provide comment on the PFAS National Primary Drinking Water Regulation Rulemaking proposal. We commend the EPA for taking action and proposing Maximum Contaminant Levels (MCLs) for PFOS and PFOA, and a hazard index for additional PFAS contaminants. Our county is located in the Minneapolis-St Paul metropolitan area of Minnesota. Communities in the southern half of our county are greatly impacted by PFAS groundwater contamination. Our state agencies, Minnesota Department of Health (MDH) and Minnesota Pollution Control Agency (MPCA), have worked closely with the county, affected communities and private well owners for many years, to mitigate impacts of PFAS. The comments reflected within this letter echo those from our state partners.

Please contact me with any questions at 651-430-6662 or David.brummel@co.washington.mn.us.

Sincerely,

David Brummel, Director Washington County

Department of Public Health and Environment 14949 62nd St N

Stillwater, MN 55082

CC: Washington County Board of Commissioners, Washington County Administrator Kevin Corbid

EPA Response: The EPA acknowledges this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Brewers for Clean Water et al. (Doc. #1740, SBC-043593)

Allagash Brewing

Alter Brewing Company

Alulu Brewpub

Aslan Brewing Co.

Backslope Brewing

Bang Brewing

Banging Gavel Brews

Bent Paddle Brewing Co.

Bent River Brewing Co.

Big Grove Brewery

Brewery Techne

BrickStone Brewery

Bull City Burger and Brewery

Cahaba Brewing Company

Checkerspot Brewing

Elmhurst Brewing Company

Engrained Brewing Company

Fibonacci Brewing Company

Fiddlin' Fish Brewing Company

Forward Brewing

Georgetown Brewing Company

Greenstar Organic Brewery

Hailstorm Brewing Company

Half Acre Beer Company

Illuminated Brew Works

Imperial Oak Brewing

Kinslahger Brewing

Knack Brewing

Lake Effect Brewing Company

Lakefront Brewery

Mad Swede Brewing Company

Maui Brewing Co.

Miskatonic Brewing Company

MotoSonora Brewing Company

New Belgium Brewing

Niteglow

Odell Brewing

Old Bust Head Brewing Company

One Allegiance Brewing

One World Brewing

Open Outcry Brewing Company

Orono Brewing Company

Pig Minds Brewing Co.

Pilot Project Brewing Company

Pivot Brewing Company

Prairie Street Brewing Company

Pure Project

Revolution Brewing

Roaring Table Brewing

Sedona Beer Company

Sketchbook Brewing Co.

Soundgrowler Brewing Company

Stockholm's Restaurant & Brewery

Temperance Beer Co.

The Alchemist

The People's Pint

Tighthead Brewing Co.

Twisted Hippo

Warfield Distillery & Brewery

Wren House Brewing Co.

Zed's Beer

May 30, 2023

Michael Regan, Administrator

U.S. Environmental Protection Agency

Office of Ground Water and Drinking Water Docket 1200 Pennsylvania Ave NW

Washington, DC 20460

Submitted online via regulations.gov

RE: Docket ID Number EPA-HQ-OW-2022-0114, PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18,638 (Mar. 29, 2023)

Dear Administrator Regan:

We support the EPA's proposal to establish the first-ever nationwide limits on per- and polyfluoroalkyl substances (PFAS) in drinking water. Craft brewers understand the importance of clean and safe drinking water not only for our businesses but also for the health and well-being of our communities. We urge you to finalize the proposed standards as quickly as possible.

PFAS chemicals are present in the drinking water of millions of people across the country. They have been linked to numerous health problems, including cancer, immune system dysfunction, and developmental issues. The fact that these chemicals do not easily break down in the environment and can accumulate in the human body is particularly concerning. It is essential that we take action to limit people's exposure to them.

Beer is mostly water, and we depend on reliable access to clean water to produce a high- quality finished product. It is thanks in part to this critical resource that the craft brewing industry contributed about $76.3 billion to the U.S. economy in 2021, along with more than 490,000 jobs.1 [FN1: Brewers Association statistics from 2021. https://www.brewersassociation.org/statistics-and- data/economic-impact-data/]. If our water supplies were contaminated with PFAS, it could affect the integrity of the brewing process and harm the reputation and profitability of our businesses, putting our bottom lines and the health of our customers at risk.

The proposed PFAS limits are an important and scientifically supported step toward protecting public health and the environment. They would significantly reduce exposure to some of these harmful chemicals. We are counting on you to adopt, implement, and enforce them swiftly. Protecting safe water is central to our long-term success. Moreover, it is vital to the health and the economy of the communities where we live and work.

Thank you for considering our views on this important matter. Sincerely,

Rob Tod Owner Portland, ME

Dave Yob CEO Downers Grove, IL

Jason James Head Brewer Chicago, IL

Layne Carter Operations Manager Bellingham, WA

Christopher Mueller Lead Brewer Columbia Falls, MT

Sandy & Jay Boss Febbo Owners/Brewers St. Paul, MN

Beckie OConnor Partner/Managing Director Tinley Park, IL

Laura S.F. Mullen Co-Founder Duluth, MN

Nick Bowes President Moline/Rock Island, IL

David Moore COO/Owner Iowa City, IA

Peggy Zwerver Owner Philadelphia, PA

Stamatina Vasilakis Manager Bourbonnais, IL

Seth Gross Owner Durham, NC

Walter Meyer COO Birmingham, AL

Judy Neff Owner & Brewer Baltimore, MD

Cam Horn Head Brewer Elmhurst, IL

Brent Schwoerer Owner/Founder Springfield, IL

Betty Bollas President Cincinnati, OH

Stuart Barnhart President Winston-Salem, NC

Claire Bowdren Co-Owner Annapolis, MD

Caitlin Singer Quality & Sustainability Mgr. Seattle, WA

Michael & Helen Cameron Co-Owners Chicago, IL

Christopher Schiller Owner Tinley Park, IL

Matt Gallagher Engineer Chicago, IL

Brian Buckman Owner/Head Brewer Chicago, IL

Grant Hamilton Owner Willow Springs, IL

Keith Huizinga Owner Oak Park, IL

Emily Strysik Co-Owner/Manager Kankakee, IL

Clint Bautz Owner Chicago, IL

Russ Klisch President Milwaukee, WI

Susan Larson Owner Boise, ID

Garrett W. Marrero CEO/Co-Founder Kihei, HI

Josh Mowry Owner Darien, IL

Jeremy DeConcini Co-Founder Tucson, AZ

Steve Fechheimer Chief Executive Officer Fort Collins, CO

Jonathan Ifergan Co-Founder/Lead Brewer Chicago, IL

Matt Bailey Plant Manager Fort Collins, CO

Julie Broaddus Owner Warrenton, VA

Zack Judickas Founder Chicago Ridge, IL

Jason D. Schutz Owner, Brewer Asheville, NC

Eric Padilla Head Brewer Chicago, IL

Abe Furth Co-Founder Orono, ME

Brian Endl President Machesney Park, IL

Damian Padilla Brewery Manager Chicago, IL

Kevin Compton President Lexington, KY

Reed Sjostrom Chief Brand & Products Officer Rockford, IL

Mat Robar Owner San Diego, CA

Josh Deth Chairman of the Party Chicago, IL

Elizabeth May Owner Lake Zurich, IL

Mac Crawford Owner Sedona, AZ

Cesar Marron Owner/Head Brewer Skokie, IL

Arturo Lamas Owner Tinley Park, IL

Michael Olesen Owner Geneva, IL

Josh Gilbert Owner/Founder Evanston, IL

Hallie Picard HR Manager Stowe, VT

Alden Booth Owner Greenfield, MA

Bruce Dir Owner Mundelein, IL

Karl Rutherford Brewery Director Chicago, IL

Alexander R. Buck Founder Ketchum, ID

Drew Pool Co-Founder Phoenix, AZ

Geoff Bado Founder Marlton, NJ

EPA Response: The EPA acknowledges this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Defend Our Health (Doc. #1741, SBC-045192)

Assistant Administrator Radhika Fox

Office of Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, N.W.

Washington, DC 20460

May 30, 2023

Via Regulations.gov

Re: PFAS National Primary Drinking Water Regulation Rulemaking, Docket No. EPA–HQ–OW–2022–0114

Dear Assistant Administrator Fox:

Defend Our Health submits these comments in support of the EPA's proposed drinking water standards for six per- and polyfluoroalkyl substances ("PFAS"). Our non-profit is headquartered in Maine and has played a pivotal role in identifying the impacts of PFAS contaminated sludge spreading to farmland and farmland-adjacent water supplies including surface water and groundwater wells. Defend Our Health believes that all people deserve clean drinking water, clean air and a healthy life free from toxic chemicals, and we advocate to protect the health of people whose water supplies have been contaminated with PFAS and other chemicals.

We support the speedy implementation of a national drinking water standard for PFAS. While some states have adopted regulations that move towards health protective drinking water standards, the current regulatory patchwork leaves people unfairly at risk of exposure to these chemicals depending on where they live. Defend Our Health applauds the EPA's move towards a

national drinking water standard based on the most current understanding of the toxicity and risks of these chemicals.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

LSP Association (LSPA) (Doc. #1742, SBC-043599)

Slide 5: Concurrent with these preliminary regulatory determinations, EPA is proposing an NPDWR for these four PFAS as well as for PFOA and PFOS

• A model was used to estimate blood PFAS levels associated with a certain toxicity value. This was part of the calculation for deriving the MCLs and it includes numerous safety/uncertainty factors. The actual background levels of PFAS in blood have decreased over time since the prohibition of PFOS and PFOA in commercial products (cf. PFAS in the US population | ATSDR (cdc.gov)) [Link: https://www.atsdr.cdc.gov/pfas/health-effects/us-population.html]. Was this actual decrease in background blood PFAS level taken into account with the proposed MCLs?

• The decrease in PFAS blood concentrations observed by the CDC indicates that prohibition of PFAS in commercial products has significantly decreased potential PFAS exposures. While the LSPA absolutely believes that public health should be protected by safe drinking water supplies, promulgating extremely low MCLs, at concentrations that are barely detectable by a laboratory, without significantly limiting their use in commercial products is a fruitless effort because there will continue to be more PFAS introduced into the environment.

• There are significant hurdles for all stakeholders if USEPA proceeds with the proposed NPDWR. The LSPA concurs with and wishes to amplify the implementation challenges identified by the Massachusetts Water Works Association (MWWA of Acton, MA) in their May 26, 2023 comment letter to USEPA regarding the proposed rule. Of particular note are the sections related to Occurrence; Source Water and Analytical Variability; Analytical Methodology; Treatment Considerations; Liability Concerns; Supply Chain/Procurement; and Cost.

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. The EPA disagrees with the first bulleted statement on estimated blood PFAS levels, as the statement is inaccurate. The MCLs are not calculated as the commenter described. The MCLs represent "the maximum permissible level of a contaminant in water which is delivered to any user of a public water system," Section 1401(3). In setting the MCL level, the EPA also identifies the level at which it is technologically feasible to measure the contaminant in the public water system. To identify this level, the EPA considers (1) the availability of analytical methods to reliably quantify levels of the contaminants in drinking water and (2) the lowest levels at which contaminants can be reliably quantified within specific

limits of precision and accuracy during routine laboratory operating conditions using the approved methods (known as the PQLs). The PFOA and PFOS MCLGs are zero based on the cancer classifications and did not incorporate quantitative toxicokinetic models, toxicity values, or uncertainty factors. Carcinogens have no safe exposure level regardless of whether the serum concentrations are declining. Lastly, the unique physical and chemical properties that make some PFAS, including PFOA and PFOS, highly stable and resistant to degradation in the environment and human body, resulting in their colloquial name of "forever chemicals," indicates that exposure to these chemicals will continue.

For bullet two, the EPA disagrees that the PFAS levels are barely detectable by a laboratory. Discussion on laboratory detections can be found in sections 5.1.2 and 7 of the *Response to Comments* document. The EPA has described other actions that are occurring simultaneously with this NPDWR in sections 1.3 and 15 of the EPA response in this *Response to Comments* document.

For bullet three on implementation challenges, please see sections 1.3 and 11 of the EPA response in this *Response to Comments* document.

San Gabriel Basin Water Quality Authority (WQA) (Doc. #1743, SBC-043611)

Sent Via Federal eRulemaking Portal: https://www.regulations.gov/

May 26, 2023

U.S. Environmental Protection Agency EPA Docket Center

Office of Ground Water and Drinking Water Docket, Mail Code 2822IT

1200 Pennsylvania Avenue NW, Washington, DC 20460

Subject: Docket ID: EPA-HQ-OW-2022-0114

Proposed National Primary Drinking Water Regulation (NPDWR) for six PFAS including perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO-DA, commonly known as GenX Chemicals), perfluorohexane sulfonic acid (PFHxS), and perfluorobutane sulfonic acid (PFBS).

Thank you for the opportunity to comment on U.S. Environmental Protection Agency's (EPA's) proposed National Primary Drinking Water Regulation for six PFAS compounds (Docket ID #EPA-GQ-OW-2022-0114).

The San Gabriel Basin Water Quality Authority (WQA) was created by the California State Legislature to oversee the groundwater cleanup of the San Gabriel Groundwater Basin (Basin) which is one of the largest Superfund sites in the country. The Basin provides drinking water to over 1.4 million residents and is served by dozens of water purveyors that include cities, water districts and private water companies.

We respectfully submit the following comments:

1. WQA appreciates EPA's goal of protecting the public health and urges EPA to follow good science-based approaches when establishing drinking water standards for PFAS and other emerging contaminants to assure the public's confidence in any adopted regulation.

EPA Response: The EPA has followed a strong science-based approach in establishing the drinking water standards in this regulation. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Del-Co Water Company, Inc. (Doc. #1744, SBC-043614)

May 29, 2023

United Sates Environmental Protection Agency

Docket ID No. EPA-HQ-OW-2022-0114

PFAS National Primary Drinking Water Regulation

Rulemaking Office of Ground Water and Drinking Water

1200 Pennsylvania Avenue NW Washington, DC 20460

To Whom it May Concern,

Del-Co Water Company, Inc. appreciates the opportunity to comment on the U.S. Environmental Protection Agency's proposed PFAS National Primary Drinking Water Regulation. Del-Co Water is a private, non-profit, member-owned PWS that owns and operates three surface water plants and one groundwater plant. Del-Co Water is the 7th largest PWS in the State of Ohio, covering 800 square miles, and currently serving over 52,000 customers in eight Central Ohio counties. Our mission is to enhance the quality of life to our growing region by providing exceptional water services in an affordable and environmentally responsible manner. We strive to partner with peer water utilities, consultants, manufacturers, vendors, regulators, academia, and other interested parties to network, educate, and advocate for safe drinking water.

Our objective and goal is to provide public health protection to all customers. We take this role very seriously and work hard to ensure that the water provided to residents meets all Safe Drinking Water Act standards.

Del-Co Water fully supports the efforts to strengthen verified, scientifically-proven public health protections, but EPA must consider the challenges and complexities associated with implementation of the proposed PFAS rules before finalizing these regulations.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR with additional considerations. Please see section 1.3 of the EPA response in this *Response to Comments* document.

West Virginia Rivers Coalition et al. (Doc. #1746, SBC-045244)

May 30th, 2023

Submitted via www.regulations.gov

Radhika Fox

Assistant Administrator, Office of Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, N.W.

Washington, DC 20460–0001

Re: Comments on Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation [Docket ID: EPA-HQ-OW-2022-0114]

Dear Assistant Administrator Fox,

Thank you for the opportunity to comment on EPA's proposed National Primary

Drinking Water Regulation for six per- and polyfluoroalkyl substances (PFAS). West Virginia Rivers Coalition (WV Rivers) is the statewide organization focused on promoting the overall health of West Virginia's waters, and the associated environmental and public health benefits. We submit these comments on behalf of our members and the undersigned organizations.

We strongly support EPA's proposal to set science-based drinking water standards for six PFAS and commend EPA's recognition that both individual PFAS and chemical mixtures of PFAS threaten human health. PFAS-contaminated water has harmed the health of West Virginians for decades, and people in our communities have lost parents, children, and other loved ones to cancer. This is a critical and long overdue step to protect our public health. We applaud this step and provide the following comments for EPA's consideration.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Liberty (Doc. #1747, SBC-043622)

May 30, 2023

The Honorable Radhika Fox

Assistant Administrator

Office of Water

Environmental Protection Agency

Washington, DC 20020

RE: Docket No.: EPA-HQ-OW-2022-0114 PFAS: PFOA and PFOS NPDWR

Dear Assistant Administrator Fox,

Liberty Utilities (Liberty) provides potable water service to nearly 70 communities in seven states [FN1: Liberty provides water and/or wastewater services to customers in Arizona, Arkansas, California, Illinois, Missouri, New York, and Texas.] through more than 250,000 customer service connections. We are heavily invested in the welfare of our customers and the communities in which we serve. The protection of public health and the environment is at the forefront of all we do, and our mission is sustaining energy and water for life.

Given this mission, Liberty does not oppose the Environmental Protection Agency's (EPAs) proposed MCL for PFOA and PFOS; or the assigned Hazard Index for the four additional PFAS species.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

City of Thornton, Colorado (Doc. #1748, SBC-044790)

Thornton supports a MCL of 4 ppt for both PFOA and PFOS and the approach of using a Hazard Index MCL of 1 for PFHxS, PFBS, PFNA, and Gen-X.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

City of Thornton, Colorado (Doc. #1748, SBC-044780)

May 30, 2023

Michael S. Regan, Administrator Environmental Protection Agency 1200 Pennsylvania Avenue, N. W. Washington, DC 20460

*Comments submitted through the Federal Register Portal

RE: Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation (Docket ID EPA-HQ-OW-2022-0114)

Administrator Regan,

The City of Thornton, Colorado (Thornton) appreciates the opportunity to partner with the EPA on the development of a National Primary Drinking Water Regulation for six PFAS compounds. Thornton applauds the EPA’s efforts to protect public and environmental health from the risks of

PFAS. Thornton operates two drinking water treatment plants producing approximately 8.3 billion gallons of treated drinking water annually to more than 160,000 customers. Following the issuance of the revised HAL in 2022, Thornton begun plans to implement treatment processes to remove PFAS from our waters in anticipation of the forthcoming NPDWR. We appreciate the opportunity to provide the following comments to the EPA to ensure that the proposed rule is properly informed and effective.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR with additional considerations. Please see section 1.3 of the EPA response in this *Response to Comments* document.

National Center for Health Research (NCHR) (Doc. #1749, SBC-044495)

The National Center for Health Research (NCHR) appreciates the opportunity to provide public comment on the Environmental Protection Agency (EPA) Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation.

NCHR is a nonprofit think tank that conducts, analyzes, and scrutinizes research on a range of health issues, with particular focus on which environmental exposures are most dangerous for consumers. We do not accept funding from companies that make products that are the subject of our work, so we have no conflicts of interest.

We agree that this proposed rule will improve public health, reducing cancer, heart disease, stroke, low birth weight, and other harms to adults and children. It will save lives. However, we have several concerns and here are our recommendations to improve the proposed rule.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR with some additional considerations. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Harris County Attorney's Office (HCA) (Doc. #1751, SBC-045266)

In conclusion, the Harris County Attorney's Office supports the EPA's current proposed rule regarding an MCL for perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salt (also known as a GenX chemicals), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS), and mixtures of these per- and polyfluoroalkyl substances (PFAS) under the Safe Water Drinking Act (SDWA); however, HCA has concerns about fiscal and timeline hurdles that stand in the way of effective compliance.

HCA appreciates the work EPA has done to minimize PFAS exposure and the opportunity to comment. If you have any questions, please reach out to Annie.Hutson@harriscountytx.gov or elizabeth.hidalgo@harriscountytx.gov.

Sincerely,

CHRISTIAN D. MENEFEE

Harris County Attorney

JONATHAN G. C. FOMBONNE

First Assistant County Attorney

TIFFANY S. BINGHAM

Managing Counsel, Affirmative

Litigation, Environmental & Compliance

SARAH J. UTLEY

Division Director, Environmental

Elizabeth Hidalgo

Elizabeth Hidalgo

Assistant County Attorney Environmental Division

Annie Hutson

Annie Hutson

Assistant County Attorney

Environmental Division

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR with additional considerations. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Environmental Council of the States (ECOS) (Doc. #1752, SBC-044500)

May 30, 2023

Honorable Radhika Fox

U.S. Environmental Protection Agency 1200 Pennsylvania Avenue NW Washington, DC 20460

Re: Proposed PFAS National Primary Drinking Water Regulation Rulemaking (EPA-HQ-OW-2022-0114)

Dear Assistant Administrator Fox,

The Environmental Council of the States (ECOS) appreciates the opportunity to provide comments on EPA's proposed per- and polyfluoroalkyl substances (PFAS) National Primary Drinking Water Regulation (NPDWR). State and territorial environmental agencies are the primary regulators for water, land, and air in almost all the states and have called on U.S. EPA to

advance science-based standards to protect our precious drinking water supplies from toxic chemicals. EPA has taken an important step forward under the Safe Drinking Water Act proposing first-ever enforceable limits for PFAS.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Environmental Council of the States (ECOS) (Doc. #1752, SBC-044508)

States are committed to working in partnership with EPA and other federal agencies to prevent pollution and achieve enforceable standards. ECOS understands that there are numerous technical and feasibility challenges in implementing this rule. We request that EPA address these concerns to the extent possible as it finalizes the rule and continue needed investments to respond to them going forward. ECOS recommends your consideration of individual state comments and those of other state associations. ECOS appreciates your review of these comments and continued collaboration with states to work to protect communities and the environment from PFAS. Please reach out to me at 803-898-4132 with any questions.

Sincerely,

Myra Reece ECOS President

Director, South Carolina Department of Health and Environmental Control

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR with additional considerations. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Las Cruces Utilities (LCU) (Doc. #1753, SBC-043925)

In the short time allocated for reviewing the proposed rulemaking documents, LCU concludes that EPA's determinations necessitate more open discussion for input from the water service providers and extended research prior to finalizing the regulations.

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Aclarity (Doc. #1755, SBC-044509)

May 26, 2023

SUBMITTED ELECTRONICALLY

U.S. Environmental Protection Agency EPA Docket Center Attn: EPA-HQ-OW-2022-0114

1200 Pennsylvania Avenue NW Washington, D.C. 20460

SUBJECT: Proposed PFAS National Primary Drinking Water Regulation

Docket ID No. EPA-HQ-OW-2022-0114

Introduction

We urge the federal government to support PFAS drinking water legislation. While there is known toxicity of PFAS, there are no meaningful federal regulatory standards preventing their release into our waters. This has led to PFAS being found in our drinking water and ecosystems throughout the United States. Virtually all Americans have detectable levels of PFAS in their bodies. We are extremely concerned that these toxic chemicals remain unregulated despite the fact that they have been used in manufacturing and sold in commerce for more than a half century. A dangerous amount of PFAS have already been released into our waterways, and because of their persistence in the environment, they never truly go away. Instead, these dangerous chemicals continue to bioaccumulate in people and in the ecosystems we all rely upon to survive. For these reasons, we must immediately address the discharge of PFAS with strong legislation. This legislation should require EPA to review sources of contamination, set protective limits, establish water quality criteria, set enforceable deadlines, and, most critically, appropriate funding to support this necessary work.

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document. New Congressional legislation is outside the scope of this rulemaking.

Los Angeles County Sanitation Districts (Doc. #1756, SBC-044517)

The Sanitation Districts appreciate the opportunity to comment on the EPA's proposed NPDWR for PFAS. The Sanitation Districts support EPA's effort to protect public health by regulating PFAS. However, we are concerned about the potential impacts of the proposed rule on wastewater treatment, water recycling and solid waste management facilities, and we urge the EPA to comprehensively consider these impacts when assessing costs and feasibility of the proposed rule and finalizing the MCLs. Thank you for your consideration of these comments. If you have any questions, please do not hesitate to contact Sharon Green, Legislative & Regulatory Programs Manager at sgreen@lacsd.org or (562) 908-4288, ext. 2503.

Very truly yours,

Ajay M. Malik, Head Technical Services Department

AMM:KCM:SNG:djm

EPA Response: The EPA acknowledges concerns raised about the potential impacts of the PFAS rule. Please see sections 1.3 and 13 of the EPA response in this *Response to Comments* document.

El Paso Water (Doc. #1757, SBC-044528)

El Paso Water is proud to provide safe and reliable drinking water for our community, and we support regulations based on sound science that is protective of human health. Our staff is dedicated to protecting our water supplies from harmful contaminants that could render them unsafe and cause our customers to lose faith in our product. This is a charge we do not take lightly, and we will continue to find new ways to improve our detection and treatment methods.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for ensuring drinking water is safe. Please see section 1.3 of the EPA response in this *Response to Comments* document.

El Paso Water (Doc. #1757, SBC-044518)

May 30, 2023

Dr. Jennifer Mclain Director

Office of Ground Water and Drinking Water

U.S. Environmental Protection Agency

Submitted electronically

Re: Docket ID: EP•HQ-OW•2022·0114, PFAS NPDWR

Dear Dr. McLain:

As the municipally owned water utility for the City of El Paso, Texas, El Paso Water provides water to a community of nearly 700,000 residents. With a broad range of consumers residing in both incorporated and unincorporated areas, we welcome the opportunity to provide public comment on the Environmental Protection Agency's proposed PFAS National Primary Drinking Water Regulations (NPDWR).

Both the City and County of El Paso are home to large populations of Hispanic residents as well as economically distressed populations. These groups often experience disproportionate negative impacts from contaminants and from lack of affordable safe drinking water. As the public water system (PWS) serving these populations, we appreciate the intent of the EPA to improve conditions for these groups.

However, as proposed, the PFAS NPDWR revisions raise several concerns among PWSs that the EPA is overlooking:

• Honoring the "polluter pays" principle

• Better identification of the source of PFAS introduction

• Addressing other sources of PFAS exposure

• Cost increases for heightened testing and treatment

• lowering the MCL is costly and not based on reliable data

EPA Response: The EPA acknowledges this input to the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045643)

In summary, EPA is strongly encouraged to consider the impacts of this rule carefully and to ensure that, if finalized, the regulations are feasible, based on the best available public health information, based on accurate cost assessments, and legally defensible. While the agency has a strong interest in expeditious action, it is important to move actions forward meaningfully and in a way that avoids negative consequences that are avoidable. AWWA's recommendations are intended to assist EPA ensure that high-risk water systems are prioritized while also providing EPA with additional time to get better data and make additional sound, defensible risk management decisions. AWWA's recommendations also reflect EPA placing the onus of PFAS risk reduction on polluters rather than communities through the source water protection actions framed in the agency's Strategic Roadmap for PFAS.

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EPA Response: The EPA's final rule represents data-driven drinking water standards that are based on the best available science and meet the requirements of SDWA. Regulation of

the PFAS covered by the NPDWR is vital for protecting public health by removing these contaminants from our nation's drinking water. The EPA believes that the regulations are feasible, based on the best available public health information, based on accurate cost assessments, and legally defensible. Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA has addressed the many comments by the American Water Works Association (AWWA) regarding costs and the cost-benefit analysis, which can be found throughout section 13.3 of the *Response to Comments* document. For concerns around high-risk systems, please see section 14 of the *Response to Comments* document, particularly the EPA response to comment Doc. #1759, SBC-045632 in section 14.10 in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045548)

Michael Regan

Administrator

Environmental Protection Agency

1200 Pennsylvania Avenue, N.W.

Mail Code: 1309

Washington, DC 20004

SUBMITTED ELECTRONICALLY

RE: Per- and polyfluoroalkyl substances (PFAS): Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) National Primary Drinking Water Regulation Rulemaking, Docket No. EPA–HQ–OW-2022-0114 [Link: https://www.regulations.gov/docket/EPA-HQ-OW-2022-0114]

Dear Administrator Regan,

The American Water Works Association appreciates the U.S. Environmental Protection Agency's (EPA) efforts to propose national primary drinking water regulations for per- and polyfluoroalkyl substances (PFAS), including perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS). The proposal includes several major actions for PFAS in drinking water, including:

- Proposal for drinking water standards for PFOA and PFOS, individually,

- Preliminary determinations for perfluorohexanesulfonic acid (PFHxS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO-DA), perfluorobutanesulfonic acid (PFBS), and the mixture of these four PFAS, and

- Proposal for drinking water standard for PFHxS, PFNA, HFPO-DA, and PFBS as a mixture using a hazard index.

AWWA supports the development of primary drinking water standards for PFOA and PFOS and supports the agency's interest in proposing regulatory determinations for additional PFAS. AWWA recommended the development of standards for PFOA and PFOS in comments to the EPA in 2021 and provided a shortlist of PFAS compounds for the agency's consideration for additional action as appropriate. In these comments, AWWA provided additional recommendations relating to the use of occurrence data, an approach to monitoring requirements, and available cost data for drinking water treatment facilities.

AWWA believes that EPA has put forward a rule framework that begins to address a number of stakeholder concerns. The proposal serves as a good starting point for finalizing a rule that will address PFAS compounds in drinking water. Attached are detailed comments on the proposed rule.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR with heavy considerations. Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA has addressed the many comments by AWWA regarding the following topics. For responses concerning occurrence data, please see sections 3.1.2 and 3.2.2 of the *Response to Comments* document. For responses concerning monitoring requirements, see sections 8.1.1 and 8.1.2 of the *Response to Comments* document. For responses concerning cost data, please see section XII.A.2.b of the FRN for this rule.

California State Water Resources Control Board (Doc. #1760, SBC-044221)

State Water Resources Control Board

May 30, 2023

Honorable Radhika Fox

Assistant Administrator Radhika Fox

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue NW

Washington, DC 20460

COMMENTS ON PROPOSED PFAS NATIONAL PRIMARY DRINKING WATER REGULATION RULEMAKING: EPA-HQ-OW-2022-0114

Dear Assistant Administrator Fox,

The California State Water Resources Control Board (State Water Board) appreciates the opportunity to comment on the U.S. Environmental Protection Agency's (EPA) proposed PFAS National Primary Drinking Water Regulation. The State Water Board is the Safe Drinking Water Act Primacy Agency for California and implements the Safe Drinking Water Act in California.

Extensive PFAS contamination has been found in California's groundwater that supplies many of the state's public drinking water systems. Over 600 contaminated wells have been identified so far and more are expected as testing continues to expand to new wells. California has not yet adopted a primary maximum contaminant level (MCL) for any of the identified PFAS compounds but has issued notification and response level values, essentially California health advisory numbers, for perfluorooctanoic acid (PFOA), perfluorooctance sulfonic acid (PFOS), perfluorobutane sulfonic acid (PFBS), and perfluorohexane sulfonic acid (PFHxS). California statutes were also amended by the Legislature to require water systems to provide public notice if a source water containing a PFAS compound exceeds a notification and response level set by the State Water Board. As a result, many water systems have proceeded to or are planning to install treatment in order to serve water to the public that is below notification and response levels and thus will not require public notification.

Based on our experience so far in dealing with PFAS contamination of drinking water supplies, the State Water Board overall supports EPA's proposed PFAS rule, including the inclusion of a hazard index. Attempting to establish MCLs for every PFAS shown to have detrimental health impacts would be impossible to accomplish given the large number of compounds and the ability for industry to quickly switch to new compounds with similar properties but different formulations. The State Water Board has utilized a similar approach as the health index when permitting highly impaired source waters containing contaminants that do not have an MCL with success.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

PFAS Regulatory Coalition (Doc. #1761, SBC-046092)

I. Conclusion

In these comments, the PFAS Regulatory Coalition has raised a series of substantial concerns with the EPA Proposal, which need to be addressed before EPA moves forward with any rulemaking setting drinking water standards for PFAS. The Coalition looks forward to continuing to engage with EPA on these issues. Please feel free to call or email if you have any questions, or if you would like any additional information concerning the issues raised in these comments.

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Coordinators

Attachments

• ATSDR, “PFAS in the U.S. Population,” December 22, 2022

• Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures,” EPA Risk Assessment Forum Technical Panel, August 2000

• Draft Principles for Cumulative Risk Assessment, EPA Document # EPA-740-P-23001, Feb. 2023, United States Office of Chemical Safety and Environmental Protection Agency, Pollution Prevention.

• Processes & Considerations for Setting State PFAS Standards, ECOS, Feb. 2020, updated March 2023

• FACT SHEET: Biden-Harris Administration, Combatting PFAS Pollution to Safeguard Clean Drinking Water for All Americans, June 15, 2022

• Environmental Standards Laboratory Survey, May 2023

Survey Summary of Commercial Drinking Water Analytical Laboratories to Support the Proposed National Primary Drinking Water Maximum Contamination Levels (MCLs) for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonoic Acid (PFOS) and Proposed Hazard Index For Perfluorohexane Sulfonic Acid (PFHxS), Hexafluoropropylene Oxide Dimer Acid (HFPO-DA), Perfluorononanoic Acid (PFNA), and Perfluorobutane Sulfonic Acid (PFBS)

May 26, 2023

Prepared for:

AMERICAN PETROLEUM INSTITUTE

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Table of Contents

1.0 Introduction

The US EPA issued a PFAS National Primary Drinking Water Regulation Rulemaking notice in the Federal Register Volume 88 Number 60 on March 29, 2023. Within the notice, the US EPA indicated that the US EPA is issuing a preliminary regulatory determination to regulate perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO–DA) and its ammonium salt (also known as a GenX chemicals), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS), and mixtures of these per- and polyfluoroalkyl substances (PFAS) as contaminants under Safe Drinking Water Act (SDWA). Through this action, US EPA is also proposing a National Primary Drinking Water Regulation (NPDWR) and health-based maximum contaminant level goals (MCLGs) for these four PFAS and their mixtures as well as for PFOA and PFOS. US EPA is proposing to set the health-based value, the MCLG, for PFOA and PFOS at zero. Considering feasibility, including currently available analytical methods to measure and treat these chemicals in drinking water, US EPA is proposing individual maximum contaminant levels (MCLs) of 4.0 nanograms per liter (ng/L) or parts per trillion (ppt) for PFOA and PFOS.

US EPA is proposing to use a Hazard Index (HI) approach to protecting public health from mixtures of PFHxS, HFPO–DA and its ammonium salt, PFNA, and PFBS because of their known and additive toxic effects and occurrence and likely co-occurrence in drinking water. US EPA is using Health-Based Water Concentrations (HBWCs) as follows: 9.0 ppt for PFHxS, 10.0 ppt for HFPO–DA; 10.0 ppt for PFNA; and 2000 ppt for PFBS. US EPA is proposing an HI of 1.0 as the MCLGs for these four PFAS and any mixture containing one or more of them because it represents a level at which no known or anticipated adverse effects on the health of persons is expected to occur and which allows for an adequate margin of safety. US EPA has determined it is also feasible to set the MCLs for these four per- and polyfluoroalkyl substances (PFAS) and for a mixture containing one or more of PFHxS, HFPO–DA and its ammonium salt, PFNA, PFBS as an HI MCLG of 1.0 (unitless). In addition, the US EPA has proposed a trigger level of 1/3 of the MCL for PFOS and PFOA (i.e., 1.3 ppt).

EPA Response: The EPA acknowledges this comment. The EPA has addressed the concerns of the commenter throughout this *Response to Comments* document. Please see section 1.3 of the EPA response in this *Response to Comments* document.

PFAS Regulatory Coalition (Doc. #1761, SBC-046066)

May 30, 2023

Ms. Alexis Lan

Office of Ground Water and Drinking Water

Standards and Risk Management Division (Mail Code 4607M) U.S.

Environmental Protection Agency 1200 N. Pennsylvania Avenue,

N.W.

Washington, D.C. 20460

Re: Comments on EPA's Proposed PFAS National Primary Drinking

Water Regulation Rulemaking

Docket ID No. EPA-HQ-OW-2022-0114

Dear Ms. Lan:

The PFAS Regulatory Coalition (the Coalition) submits the following comments on EPA's Proposed PFAS National Primary Drinking Water Regulation Rulemaking, ("the EPA Proposal") (88 Fed. Reg. 18638, Mar. 29, 2023).

The Coalition is a group of industrial companies, municipal entities, agricultural parties, aviation representatives and trade associations, each of which has facilities or members that are directly affected by the development of policies and regulations related to per- and poly-fluoroalkyl substances (PFAS). Coalition membership includes entities in the automobile, airport, coke and coal chemicals, iron and steel, municipal, paper, petroleum, and other sectors. None of the Coalition members manufacture PFAS compounds. Coalition members, for purposes of these comments, include: Airports Council International – North America; American Coke and Coal Chemicals Institute; American Forest and Paper Association; American Fuel and Petrochemical Manufacturers; American Iron and Steel Institute; American Petroleum Institute; Barr Engineering; Brown & Caldwell; City of Pueblo, CO; Gary Sanitary District (IN); HDR; Illinois Association of Wastewater Agencies; National Oilseed Processors Association; Portland Cement Association; Trihydro; and Western States Petroleum Association.

PFAS Regulatory Coalition member entities or their members own and operate facilities located throughout the country. Many of those facilities would incur substantial costs to comply with the new drinking water standards being proposed by EPA. In addition, these standards would affect

other regulatory requirements that are regularly imposed on Coalition members and their operations, including remediation mandates. The Coalition, therefore, has a direct interest in the EPA Proposal.

The Coalition had requested an extension of the comment period on the EPA Proposal, in a letter dated April 17, 2023. On May 5, 2023, EPA denied all requests for extension. The Coalition has prepared these comments in the limited timeframe allowed by EPA. Other issues may have been included if additional time for review and comment had been allowed by the Agency.

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document. For a response to the concern about the lack of extension of the comment period, please see sections 2.3 and 17.1 of the *Response to Comments* document.

Center for Environmental Health et al. (Doc. #1764, SBC-044242)

The proposal is a significant step in the right direction, both in terms of setting health protective drinking water standards for PFOA and PFOS, and also in taking the first approach to addressing PFAS as a class, including GenX chemicals. We believe the MCLs for PFOA and PFOS are as close as feasible to the maximum contaminant level goal (MCLG) of zero for these stressors, in accordance with the mandate of the Safe Drinking Water Act. We also believe the proposal adequately reflects the MCLs for PFBS, PFHxS, PFNA, HFPO-DA and its ammonium salts. We urge the agency to quickly finalize these MCLs, and further refine its calculations of MCLs for PFBS, PFHxS, PFNA, HFPO-DA using additional data sources, such as the epidemiological data called for in our petition.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

U.S. Poultry & Egg Association et al. (Doc. #1765, SBC-044543)

May 30, 2023

RE: Docket ID No. EPA–HQ–OW–2022–0114

To whom it may concern:

The following comments are submitted in response to the US Environmental Protection Agency's (EPA) March 29, 2023, proposed drinking water regulation that includes six Per- and Polyfluorinated Substances (PFAS). EPA's proposal would establish Maximum Contaminate Level Goals (MCLGs) and a National Primary Drinking Water Regulation (NPDWR) for the six PFAS in public drinking water supplies. Specifically, the March 29, 2023, proposal would establish MCGLs of zero (0) for PFOA and PFOs and an enforceable Maximum Contaminate Level (MCL) for PFOA and PFOS in drinking water at 4.0 ppt.

EPA is also requesting comment on a preliminary determination to regulate additional PFAS to include PFHxS, HFPO–DA1 (also known as and referred to as ‘‘GenX Chemicals’’), PFNA, and PFBS. Concurrent with this preliminary determination, EPA is proposing a “Hazzard Index” (HI) of 1.0 as the MCLG and enforceable MCL to address individual and mixtures of these four contaminants where they occur in drinking water.

The U.S. Poultry & Egg Association (USPOULTRY), the National Turkey Federation (NTF) and numerous state poultry associations (collectively, the U. S. Poultry and Egg Industry) appreciate the opportunity to submit these comments. These comments align with a more comprehensive set of comments submitted by the U.S. Chamber of Commerce

USPOULTRY is the world’s largest and most active poultry organization with membership comprised of producers and processors of broilers, turkeys, ducks, eggs, and breeding stock, and alliances that include farmers and growers ranging from large agricultural operations to mom-and-pop shops. NTF serves as the national advocate for America’s turkey farmers and producers, raising awareness for its members’ products while strengthening their ability to profitably and safely deliver wholesome, high-quality, and nutritious food to consumers worldwide.

Many of our members live and operate in small rural communities that will certainly be affected by the proposed NPDWR. Additionally, some of our processor members operate their facilities using groundwater. As such, these facilities are classified as Non-Transient Non-Community Water System (NTNCWS).

The following comment topics are of relevance to the U. S. Poultry and Egg Industry, and other food and agricultural stakeholders:

Key Comments

1. Limited technical expertise to execute, interpret, and manage compliance with the proposed MCLs

2. Lack of adequate laboratory capabilities, especially in the southeastern U.S. region

3. Challenges associated with inconsistent and dynamic regulations across EPA and state-led drinking water programs:

a. Fragmented US federal approach and lack of coordination with relevant federal agencies with additional oversight of the U.S. food and agriculture industry (e.g., FDA, USDA)

b. Inconsistent messaging across federal agencies and international community regarding the human health risks associated with low levels of PFAS

c. Unintended consequences of EPA’s proposed regulation on other environmental and public health sectors including WWTPs, biosolids, and food safety

4. The use of a Hazard Index to regulate “levels” of PFAS Mixtures

5. Flaws in the Economic Analysis

EPA Response: The EPA acknowledges and appreciates this comment that expresses concerns with the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. The concerns and considerations about laboratory capability and availability, including technical expertise, are discussed in section 5.1 (particularly, the EPA response to comments Doc. #1765, SBC-044544 and Doc. #1765, SBC-044546 in section 5.1.2 in this *Response to Comments* document) and section 8.7 of the *Response to Comments* document. After the NPDWR takes effect, SDWA requires primacy agencies to have a standard that is no less stringent than the NPDWR, which should reduce confusion on inconsistent regulations. Additional discussion on state drinking water standards can be found in section 5.1.5 of the *Response to Comments* document. The EPA disagrees that there is fragmented coordination across the federal government. The EPA coordinated with all applicable federal agencies as required. For responses to comments concerning this coordination, please see section 14 of the *Response to Comments* document. For discussion on communications materials, including for implementation by water systems and for health risks, please see section 1.2 of the EPA response in this *Response to Comments* document. For the unintended consequences of the regulation, please see section 15 for out-of-scope topics. The EPA believes the Hazard Index is an appropriate approach for regulating levels of PFAS mixtures, and additional discussion can be found in section 4.3 of the EPA response in this *Response to Comments* document. Please see section 13.3 (particularly, the EPA response to comment Doc. #1765, SBC-044549) of the EPA response in this *Response to Comments* document for a discussion about the EPA's cost estimate methods.

New Mexico Environment Department (NMED) (Doc. #1766, SBC-044246)

May 30, 2023

EPA Docket Center

Office of Ground Water and Drinking Water Docket

Mail Code 2822IT

1200 Pennsylvania Avenue NW, Washington, DC 20460

Submitted electronically to: https://www.regulations.gov/

RE: Preliminary Regulatory Determination and proposed rule for PFAS National Primary Drinking Water Regulation Rulemaking Docket ID No. EPA–HQ–OW–2022–0114

Dear Administrator Regan,

The New Mexico Environment Department (NMED) appreciates the opportunity to submit comments to the U.S. Environmental Protection Agency (EPA) on the Preliminary Regulatory Determination and proposed rule for PFAS National Primary Drinking Water Regulation Rulemaking under the authority of the Safe Drinking Water Act (SDWA). EPA published the

preliminary determination in the Federal Register on March 19, 2023, Docket ID No. EPA–HQ–OW–2022–0114.

NMED serves as a coregulator with EPA for the National Primary Drinking Water Regulations (NPDWRs) and is responsible for overseeing their implementation across 1,076 active public water systems in New Mexico. Protecting New Mexico's drinking water quality for present and future generations is fundamental to NMED's mission.

NMED supports EPA's positive regulatory determination for perfluorooctanoic acid (PFOA), perfluorooctanesulfonic acid (PFOS), Perfluorononanoic acid (PFNA), Perfluorohexane sulfonate (PFHxS), Perfluorobutane sulfonic acid (PFBS), and hexafluoropropylene oxide dimer acid (HFPO-DA, commonly known as GenX). The absence of an NPDWR for these compounds has resulted in varying or nonexistent regulatory actions among states, despite their occurrence in public drinking water systems across the country.

While NMED supports EPA's positive regulatory determination for these PFAS chemicals, NMED also believes that it is important for EPA to consider a number of factors that may impact effective implementation of this rule by local public water systems and state primacy agencies like NMED.

As a member of the Association of State Drinking Water Administrators (ASDWA), NMED also supports ASDWA's comments regarding EPA's Preliminary Regulatory Determination and proposed rule for PFAS National Primary Drinking Water Regulation Rulemaking. Similarly, NMED supports the Environmental Council of the States' (ECOS) comments on the proposed rule. The ASDWA and ECOS letters are attached to this letter.

NMED appreciates this opportunity to comment on this regulatory determination. NMED encourages EPA to work hand in glove with states like New Mexico to ensure effective implementation of drinking water regulations and ensure a safe and sustainable drinking water supply for our communities.

Sincerely,

James C. Kenney

Cabinet Secretary

Attachment (3)

Cc: Courtney Kerster, Senior Advisor, Office of Governor Michelle Lujan Grisham

Sydney Lienemann, Deputy Cabinet Secretary of Administration, NMED Bruce Baizel, General Counsel, NMED

John Rhoderick, Director, Water Protection Division, NMED

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR with additional considerations. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Western Urban Water Coalition (WUWC) (Doc. #1768, SBC-043936)

May 30, 2023

U.S. Environmental Protection Agency

EPA Docket Center

Office of Ground Water and Drinking Water Docket

Mail Code 2822IT

1200 Pennsylvania Avenue, N.W.

Washington, DC 20460

RE: PFAS National Primary Drinking Water Regulation Rulemaking; Docket ID No. EPA-HQ-OW-2022-0114

Dear Administrator Regan:

The Western Urban Water Coalition (WUWC) appreciates the opportunity to comment on the Environmental Protection Agency's (EPA) proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation Rulemaking (the "Proposed Rule"). [FN1: 88 Fed. Reg. 18638 (Mar. 29, 2023)] WUWC is a coalition of 19 of the largest western water utilities [FN2: WUWC was established in 1992 to address the West's unique water supply and water quality challenges, and consists of the following members: Arizona (Central Arizona Project, City of Phoenix and Salt River Project); California (Eastern Municipal Water District, City of Los Angeles Department of Water and Power, The Metropolitan Water District of Southern California, San Diego County Water Authority, Santa Clara Valley Water District, and City and County of San Francisco Public Utilities Commission); Colorado (Aurora Water, Colorado Springs Utilities, and Denver Water); Nevada (Las Vegas Valley Water District, Southern Nevada Water Authority, and Truckee Meadows Water Authority); New Mexico (Albuquerque Bernalillo County Water Utility Authority); Utah (Salt Lake City Public Utilities and Washington County Water Conservancy District); and Washington (Seattle Public Utilities).] formed more than 30 years ago to address the unique water issues facing the western United States. Its members serve over 40 million water consumers in major metropolitan areas in seven western states, including through operation of water treatment facilities that will become subject to the Proposed Rule.

WUWC appreciates that regulation of PFAS under the Safe Drinking Water Act (SDWA) is an appropriate and necessary step to address public safety concerns with the potential for service of PFAS-contaminated drinking water. WUWC also understands that the Proposed Rule represents

just one piece of a broader federal regulatory priority that EPA is addressing through several ongoing rulemaking proceedings and concurrent policy setting. WUWC shares the fundamental goal to ensure that its western water agencies and their customers are assured a public water supply that is reliable, affordable, and safe.

The proposal to adopt national primary drinking water standards for perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorohexane sulfonate (PFHxS), hexafluoropropylene oxide dimer acid (HFPO–DA), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS) is a historic milestone in the regulation of PFAS as emerging contaminants. EPA has not issued a primary drinking water standard for a new contaminant on its own volition for the past twenty-six years. The drinking water standards adopted through this rulemaking have the potential to set a new precedent for further regulation of additional PFAS.

Given the significance of this moment, WUWC urges EPA to adopt a rule only after assuring that the standards it selects are based on best available peer-reviewed science and are feasible, as required by the SDWA. WUWC offers the following comments to EPA that animate WUWC's concern that EPA has not yet fully analyzed the legal, practical, or economic feasibility of the Proposed Rule.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR with additional considerations. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Council of State and Territorial Epidemiologists (CSTE) (Doc. #1770, SBC-044259)

CSTE applauds and supports the Proposed Primary Drinking Water Regulation and recognizes the many factors and considerations that informed the proposed rule. CSTE applauds the recognition that a determination of public health concern involves consideration of a number of factors, some of which include the level at which the contaminant is found in drinking water, the frequency at which the contaminant is found and at which it co-occurs with other contaminants, whether there is an sustained upward trend that these contaminant will occur at a frequency and at levels of public health concern, the geographic distribution (national, regional, or local occurrence), the impacted population, health effect(s), the potency of the contaminant, other possible sources of exposure, and potential impacts on sensitive populations or life stages. Given the many possible combinations of factors, a simple threshold is not viable and is a highly contaminant-specific decision that takes into consideration multiple factors.

Additionally, CSTE recognizes due to the environmental persistence of these chemicals, there is potential for toxicity at environmentally relevant concentrations as studies show it can take years for many PFAS to leave the human body. Given this, a multifaceted approach is needed to support implementation of the regulation.

In accordance with EPA's request for comments on the proposed rule, CSTE reviewed the proposed rule and solicited input from its members to inform the following comments.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR with additional considerations. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Council of State and Territorial Epidemiologists (CSTE) (Doc. #1770, SBC-044257)

The Council of State and Territorial Epidemiologists (CSTE) is a member organization representing all U.S. states and territories and over 3,000 applied public health epidemiologists. CSTE's mission is to promote effective use of epidemiologic data to guide public health practice and improve health, and advocate for epidemiologic capacity, resources, and scientifically based policy. Public health action by CSTE member states has led to improvements in clinical practice, medical procedures, surveillance, detection and control of public health threats, and the ongoing development of evidence-based environmental contaminant, occupational health, and disease control policies. Additional disease and condition prevention successes include multiple position statements to standardize national surveillance efforts.

We greatly appreciate the opportunity to comment on the proposed rule and applaud the tremendous amount of thought, time and energy EPA has invested in proposing meaningful changes to PFAS, PFOA, and PFOS Maximum Contaminant Levels (MCL), which has critical importance to public health practice in the United States.

Public Health Agencies (PHAs) across the U.S. face many challenges in their efforts to collect and provide complete, timely and accurate information for decision-making, and in communicating the risks and response to communities related to PFAS, PFOA and PFOS. The availability of feasible, effective guidelines to regulate PFAS levels in drinking water is crucial to assisting PHAs with reducing PFAS pollution, protecting public health, and delivering safe drinking water. In accordance with EPA's request for comments on the proposed rule, CSTE reviewed the proposed rule and solicited input from its members to inform the attached detailed comments for critical review and consideration by the EPA.

May 30, 2023

Dr. Jennifer L. McLain

Director, Office of Ground Water and Drinking Water

U.S. Environmental Protection Agency

1201 Constitution Ave NW Washington, DC 20004

Re: Docket ID No. EPA-HQ-OW-2022-0114, Per- and polyfluoroalkyl substances (PFAS): Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) National Primary Drinking Water Regulation Rulemaking

Dear Dr. McLain,

Please find enclosed comments from the Council of State and Territorial Epidemiologists (CSTE) on the proposed rule, EPA-HQ-OW-2022-0114, Per- and polyfluoroalkyl substances (PFAS): Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) National Primary Drinking Water Regulation Rulemaking.

CSTE is a member organization representing all U.S. states and territories and over 3,000 applied public health epidemiologists. CSTE's mission is to promote effective use of epidemiologic data to guide public health practice and improve health, and advocate for epidemiologic capacity, resources, and scientifically based policy. Public health action by CSTE member states has led to improvements in clinical practice, medical procedures, surveillance, detection and control of public health threats, and the ongoing development of evidence-based environmental contaminant, occupational health, and disease control policies.

Additional disease and condition prevention successes include multiple position statements to standardize national surveillance efforts.

We greatly appreciate the opportunity to comment on the proposed rule and applaud the tremendous amount of thought, time and energy EPA has invested in proposing meaningful changes to PFAS, PFOA, and PFOS Maximum Contaminant Levels (MCL), which has critical importance to public health practice in the United States.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR with additional considerations. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sierra Club of Hawai'i (Doc. #1771, SBC-044733)

PFAS in Hawai‘i

In Hawai‘i, fresh water is a public trust resource and is a critical part of Native Hawaiian traditional and customary practices. Much of Hawai‘i's drinking water is sourced from finite groundwater aquifers. It takes nearly 30 years for rainfall to percolate down to replenish our aquifers, making our drinking water aquifers irreplaceable. Hawai‘i's water security is already fragile, and becomes increasingly threatened by impacts like climate change, growing populations, and pollution. Safeguarding our ‘aina and people is incredibly important to our cultural integrity and resilience. Setting enforceable limits on PFAS is an extremely important mechanism in enacting this protection. Facilitating this protection is a key pillar for building resilience in our communities based on foundations of Indigenous science, values, and practices.

Cultural Importance of Water

The Sierra Club urges the EPA to adopt PFAS regulations because PFAS disrupt the sacred relationship Native Hawaiians have with wai or water. The proposed limits and regulations of PFAS work toward restoring the quality of water that Native Hawaiians have stewarded for

generations, wai is not a commodity; it is an entity with which Native Hawaiians have held a deeply sacred relationship since time immemorial. Wai is spiritually significant in its purest form because it is one of the forms of akua or gods. Because of this spiritual and timeless form, wai represents a pillar of life for Native Hawaiians across ancestral and future generations. Native Hawaiians' intergenerational dependency on clean water is not replaceable; and it is not contaminable. Nevertheless, our wai has been contaminated by PFAS. Future generations depend on present-day stewards to ensure water is free from contamination. Currently the non-naturally occurring placement of PFAS significantly disrupts this relationship. An entity, sacred to the Hawaiian people, has the opportunity to be addressed. Mandated limits by the EPA have been successful in decreasing the detectable amount of PFOS in water. With the EPA's adoption of limits on persistent PFAS, kupuna, or elders, may once again have the assurance that the water inherited by future generations will be clean.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sierra Club of Hawai'i (Doc. #1771, SBC-044729)

To: Michael S. Regan Administrator

Environmental Protection Agency 1200 Pennsylvania Avenue, N.W. Mail Code: 4607M

Washington, DC 20460 Via Regulations.gov

Date: May 29, 2023

Re: Comments on Docket No. EPA-HQ-OW-2022-0114

Administrator Regan,

On behalf of our over 20,000 members and supporters, the Sierra Club of Hawai‘i strongly supports docket number EPA-HQ-OW-2022-0114, the proposed regulations on Per- and Polyfluoroalkyl Substances in drinking water. These proposed regulations confirm the urgency and severity of the threat that PFAS and other forever chemicals pose to our water, our ‘aina, and our current and future generations.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Environmental Protection Network (EPN) (Doc. #1773, SBC-043838)

EPN Comments on EPA's Proposed Per- and Polyfluoroalkyl Substances

National Primary Drinking Water regulation

Docket No.: EPA-HQ-OW-2022-0114

May 30, 2023

Founded in 2017, the Environmental Protection Network [Link: https://www.environmentalprotectionnetwork.org/] (EPN) harnesses the expertise of more than 550 former Environmental Protection Agency (EPA) career staff and confirmation-level appointees from Democratic and Republican administrations to provide the unique perspective of former regulators and scientists with decades of historical knowledge and subject matter expertise.

EPN commends EPA for making a preliminary determination to regulate PFHxS, HFPO-DA, PFNA, and PFBS and for proposing health protective MCLs for PFOA and PFOS. We provide comments on the preliminary determination, the MCLGs and MCLs for PFOA and PFOS, the Hazard Index MCLG and MCL for PFAS mixtures, monitoring requirements, public notification requirements, compliance requirements, and the benefit/cost analyses.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR with additional considerations. Please see section 1.3 of the EPA response in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-045699)

XI. CONCLUSION

As detailed in the above comments and the attached appendices, EPA's Proposed Rule does not comply with either the SDWA or the APA. The Proposed Rule is not based on best available, peer-reviewed science, as required by the SDWA, nor does it comport with EPA's own guidance on how to conduct the analyses underlying the Proposed Rule. These numerous failures are identified in detail in 3M's comments.

3M appreciates the opportunity to comment on the Proposed Rule.

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EPA Response: The EPA disagrees with the commenter's statements that the agency did not comply with SDWA or the Administrative Procedures Act. As described in the FRN, the EPA has finalized the PFAS NPDWR based on the requirements of the SDWA, using the best

available science, state-of-the-art scientific approaches, and high-quality information sources. The agency has provided reasonable explanations for its decisions in the rule. Please see section 1.3 of the *Response to Comments* document, including the EPA response to comment Doc. #1774, SBC-045706 in section 1.3 in this *Response to Comments* document, and the subsequent sections of this *Response to Comments* document for responses to specific comments elsewhere in this letter.

3M Company (Doc. #1774, SBC-045706)

Conclusion

The methods and procedures used by EPA to support the Proposed NPDWR did not follow EPA's own established procedures and guidance, including those for good data practice, good statistical analysis practice, consistency of methods and models, and the ability to replicate analytical results. Therefore, the analytical findings by EPA and outside sources cannot be validated, and EPA's proposed standard lacks scientific and statistical merit. EPA's reliance on non-national data bases, work by external authors, inability to quality control the data, models, and outputs is shown to be a major criticism of the underlying statistical approaches EPA has used to support the MCLG and MCL.

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Education:

1990 Ph.D., Environmental Statistics, Duke University

1979 M.S., Environmental Toxicology and Statistics, University of Texas School of Public Health

1976 B.S., Magna cum laude, Biology with Honors, University of Houston

Professional Associations:

American Statistical Association

Society of Environmental Toxicology and Chemistry

Positions:

EcoStat, Inc., Mebane, NC

2004 – ongoing Chief Executive Officer. EcoStat Inc. is a small women-owned business specializing in the quantitative environmental and human health sciences. Areas of expertise include environmental risk assessment in air, water and terrestrial environments; statistics and data analysis in both human health and environmental sciences; data base development and management; computer programming; water and air quality permitting; quantitative toxicity test evaluation; terrestrial and water quality modeling and model validation; and chemical exposure modeling and model validation.

Example Clients: 3M, Dow Chemical, Syngenta Crop Science, private clients through attorneys, British Petroleum, US EPA Clean Air Markets Division, US EPA Office of Water, US EPA Office of Groundwater and Drinking Water, Bayer Crop Science, Department of Energy, Water Environment Research Foundation (WERF), Florida Power and Light, California Wind Energy Association (CalWEA), and NextEra Energy.

Social and Scientific Systems, Durham, NC

2015 – 2016 Director of Biostatistics. Provide senior leadership in the statistical sciences and related quantitative disciplines applicable to public health research. These areas include (1) public and private clinical trials of new and existing pharmaceutical products, (2) analysis of epidemiological data including –omics studies, (3) statistical analysis of laboratory derived assay data, and (4) oversight of data operations and data management for clinical studies. Manage a group of approximately 40 individuals, in the areas of statistics, modeling, statistical programming, data base management, and analytics.

Clients: National Institute of Health, Center for Disease Control, Coast Guard, National Institute of Environmental Health Sciences, private biotech firms, and private pharmaceutical companies.

Cardno ENTRIX., Raleigh, NC

2011 – 2015 Principal/Vice President/Technical Director/Biostatistics Practice Leader. Responsible for Cardno-wide intellectual leadership and business development in the quantitative sciences. Lead statistician for BP Gulf Oil Spill (Clean Water Act litigation, National Resource Damage Assessment litigation). Incrementally managed over 25 statisticians and scientists in the role of biostatistics practice leader.

Other clients: US Fish and Wildlife Service, Upper Neuse River Basin Association, Mosaic Fertilizer, Inpex Oil (Australia), Sidley Austin (Washington), Arnold and Porter (New York), and Duke Energy.

The Cadmus Group, Chapel Hill, NC

2003 - 2004 Vice President for Strategic Science Initiatives: Member of the Cadmus executive committee that provides overall business oversight and direction for the company; responsible for business management and development in human health and environmental sciences, strategic company planning, market forecasting, and intellectual leadership at the corporate level. Technical areas of responsibility include human health and environmental risk assessment, modeling and statistics in the air quality sciences, and exposure and effects assessment in both human and ecological risk sciences.

Example clients:

Government: EPA Office of Research and Development, EPA Office of Water, EPA Office of Air and Radiation, EPA Clean Air Markets Division, EPA Office of Ground Water and Drinking Water, Department of Energy, Corps of Engineers.

Industry:

3M, Syngenta Crop Science, Bayer Crop Science, Aventis Crop Science, City of Cary, NC, Weyerhaeuser Pulp and Paper, American Chemistry Council, CEFIC, Water Environment Research Foundation (WERF), American Metropolitan and Sewage Association (AMSA), Utility Water Act Group.

1997 - 2003 Vice President and Group Manager: Responsible for business development, business management, and personnel management in the ecological risk sciences, statistics, and engineering; manager of the Cadmus North Carolina office; responsible for offices in Ottawa, Ontario, Canada, Oak Ridge, TN, Laramie, WY, Springfield, MA, and Cincinnati, OH; Managed over 60 scientists, statisticians, and engineers; developed both a government and private client practice; responsible for group-level contracts, budgets, legal issues, and personnel issues. Responsible for over 100 projects in the human and environmental risk sciences, and air quality.

1991 - 1997 Principal Scientist: responsible for business development and personnel management in the ecological risk sciences, statistics, and engineering; manager of the Cadmus North Carolina office and four other offices in the US and Canada.

Kilkelly Environmental Associates, Raleigh, NC

1988 - 1991 Senior Scientist: responsible for data analysis and statistical assessments of environmental exposure and effects data; worked with EPA's Corvallis Laboratory to develop EPA's first risk assessment documents including the development of assessment and measurement endpoint concepts; published well received papers on toxicity test variability; worked with EPA's Acid Rain Division to develop the Acid Rain rules for utility emissions of SO2, NOx CO2, and particulates.

Carolina Power and Light Company, Raleigh, NC

1982 - 1988 Senior Statistician: supported over 60 biologists in the assessment of impacts to biota at CP&L's nuclear and coal-fired power plants; generated survey designs, performed statistical analyses, participated in on-site sample collection activities, and generated reports to State and Federal agencies; developed thousands of lines of code in SAS and Fortran for the statistical assessment of environmental data.

TRW Environmental, RTP, NC

1980 - 1982 Engineer: supported EPA's Office of Air Quality Policy and Standards (OAQPS) in running air quality models, setting of NAAQS values, and PSD permit development.

Duke University Center for Demographic Studies

1977 - 1985 Programmer and Statistician: developed maximum likelihood statistical models of longitudinal cancer trends over various demographic groups and geographical areas of the US; developed program code in Fortran, IBM assembly language, and Basic.

Professional Highlights

• Over 35 years of experience supporting industry, government programs, academic institutions, and research initiatives in water, air, and terrestrial environments. Areas include development of statistical analysis of water, air, biota, and groundwater data; NRDA studies; exposure and effects data analysis, risk assessment methods and procedures development in both human health and environmental sciences, evaluation of toxicity data for both terrestrial and aquatic species, criteria development, development and implementation of regulations, overall support of programmatic goals and objectives, formal research activities, analysis of avian survey measurements, development collision risk assessment methods and models for the wind industry.

• Manager of over 400 projects for industry and government resulting in numerous reports, conference proceedings, and peer-reviewed publications in the areas of NRD litigation, wind power, water quality, air quality, environmental statistics, epidemiology studies, human health

risk assessment, probabilistic risk analysis, watershed assessment, bioassessment, and Bayesian decision and inference.

• Initiated and developed four individual businesses within existing firms: (1) air quality division The Cadmus Group, (2) risk assessment division The Cadmus Group, (3) statistics group Cardno ENTRIX, (4) Biostatistics Center within Social and Scientific Systems.

• Originated, managed, and maintained EcoStat, Inc., a small business working with both industry and government.

• Science Advisory Board: Restoration of the Missouri River (ongoing).

• EPA Science Advisory Board: Ecological Risk Assessment of PCB Impacts, Kalamazoo River, Michigan.

• Statistician: Evaluation of airborne risk from radioactive nuclides. Hunters Point, CA Superfund Site.

• Statistical support to Dow Chemical: Tittabawassee River Risk Assessment. Evaluation of risk to avian species.

• Fish and Wildlife Service Science Advisory Board: Evaluation of PCB toxicity on the Hudson River, NY: Evaluation of Laboratory Toxicity Tests.

• Fish and Wildlife Service Science Advisory Board: Evaluation of PCB toxicity on the Hudson River, NY: Evaluation of PCB Effects on Mink.

• Fish and Wildlife Service, State of Michigan, EPA- Science Advisory Board: Evaluation of PCB toxicity to avian species on the Hudson River, NY.

• Invited panel member of the National Wind Coordination Committee (NWCC), Risk Assessment Workgroup.

• Invited speaker and associated lead chapter author of six SETAC Pellston Conferences including Sediment Risk Assessment, Multiple Stressors (steering committee member), Probabilistic Risk Assessment of Pesticides, Whole Effluent Toxicity Testing, Uncertainty Analysis In Ecological Risk Assessment (chair, lead editor, lead conference organizer, and creator), and Pesticide Risk Assessment for Pollinators.

• Instructor and creator of a continuing education course sponsored by the Duke University School of the Environment entitled New Advances in Quantitative Ecological Risk Assessment. Invited speaker in the School of the Environment at Duke University in the areas of risk assessment, data analysis, probability, and ecological modeling.

• Invited panel member and reviewer of the EPA Framework Document For Ecological Risk Assessment, The Superfund Risk Assessment Guidance Document, and the Canadian Risk Assessment Guidance Document for New Substances.

• Lead consulting statistician supporting the majority of the EPA Acid Rain Division's (now the Clean Air Markets Division) regulatory development activities under the 1990 Clean Air Act Amendments.

• Project manager for major research initiatives including: ecological risk assessment methods and software (WERF), assessments of whole effluent toxicity test variability (WERF), site-specific nutrient criteria, development of risk assessment methods for DOE sites (DOE EM-6), state-of-the-science in ecological risk assessment uncertainty methods (American Chemical Society), and case studies in ecological risk assessment (CEFIC Long-term Research Initiatives).

• Lead statistician for British Petroleum on the Deepwater Horizon Oil Spill in the Gulf of Mexico.

• Developer of Using Monte Carlo Analysis In The Probabilistic Risk Assessment of Pesticides, a course in uncertainty analysis methods that was given multiple times to EPA's Office of Pesticide Programs (OPP), individual chemical companies, and industry coalitions. Created courses in statistics and probability for Environment Canada's Priority Substances Assessment Program. Developer of courses at Duke University and SETAC in decision sciences, statistics, and probabilistic risk assessment.

• Lead statistician to the Federal Insecticide, Fungicide and Rodenticide Act Environmental Model Validation Task Force (FEMVTF) Statistics Committee in conducting an uncertainty analysis of the PRZM3.12 model.

• Lead statistician supporting 316(b) studies for the assessment of fish entrainment at the Brunswick nuclear power plant, Duke Energy.

• Over 50 platform and poster presentations at NWCC, SETAC, and SOT annual meetings. Frequent invited session chair and speaker at conferences, symposium, and ASTM meetings.

CLASSES TAUGHT

Decision-Making Under Uncertainty – Bayesian Inference. 2016. Seminar Series. Law Seminars International.

New Advances in Ecological Risk Assessment: July 2008. Duke University, School of the Environment, Durham, NC.

Statistical Methods for Water Quality Data Analysis. March 2008. U.S. EPA Region 5. Chicago, Ill.

Bayesian Statistics for Dummies. With Tom Aldenberg. November 2004. Portland, Oregon.

Statistics MTH 112. Fall Semester. 2004. Elon University, Elon, NC.

New Advances in Ecological Risk Assessment: June 2004. Duke University, School of the Environment, Durham, NC.

Methods (Old and New) in Probabilistic Ecological Risk Assessment. April 2004. SETAC Europe Annual Meeting Short Course, Prague, Czech Republic.

Methods (Old and New) in Probabilistic Ecological Risk Assessment. November 2003. SETAC Annual Meeting Short Course, Austin, TX.

Technical Approaches to Setting Site-specific Nutrient Criteria. September 2002. Water Environment Federation, Chicago, IL.

Using Monte Carlo Analysis in the Probabilistic Risk Assessment of Pesticides. June 2002. Syngenta, Jealott's Hill Research Station, Jealott's Hill, England.

Uncertainty Analysis. Duke University School of Engineering. Spring Semester 2001. Durham, NC.

Using Monte Carlo Analysis in the Probabilistic Risk Assessment of Pesticides. November 2001. Syngenta, Greensboro, NC.

Using Monte Carlo Analysis in the Probabilistic Risk Assessment of Pesticides. July 2001. American Crop Protection Association, Baltimore, MD.

Using Monte Carlo Analysis in the Probabilistic Risk Assessment of Pesticides. January 2001. EPA Office of Pesticide Programs, Washington, DC.

Using Monte Carlo Analysis in the Probabilistic Risk Assessment of Pesticides. March 2000. EPA Office of Pesticide Programs, Washington, D.C.

New Advances in Ecological Risk Assessment: April 2002. Duke University, School of the Environment, Durham, NC.

Advanced Topics in Ecological Risk Assessment: March 1999. Duke University, School of the Environment, Durham, NC.

Uncertainty Analysis in Ecological Risk Assessment. 1998. SETAC Annual Meeting, Charlotte, NC

Advanced Topics in Ecological Risk Assessment: March 1998. Duke University, School of the Environment, Durham, NC.

Statistics Course. April,1997. Priority Substances Assessment Program. Environment Canada. Hull, Ontario, Canada.

Advanced Topics in Ecological Risk Assessment: March 1997. Duke University, School of the Environment, Durham, NC.

Uncertainty Analysis in Ecological Risk Assessment. 1996. SETAC Annual Meeting, Washington, DC.

Aquatic Ecological Risk Assessment: Methods for Screening-Level and Probabilistic Risk Assessments. November 1996. Sponsored by the Water Environment Federation. Washington, DC.

Advanced Topics in Ecological Risk Assessment: February 1996. Duke University, School of the Environment, Durham, NC.

Invited Lectures: Overview of Ecological Risk Assessment. Spring 1995. Course title: Environmental Risk Assessment and Decision Making. Duke University, School of the Environment, Durham, NC.

Aquatic Ecological Risk Assessment: April 1995. Duke University, School of the Environment, Durham, NC.

Invited Lectures: Risk Assessment Methods in Water Quality. Spring 1993. Course title: Environmental Risk Assessment and Decision Making. Duke University, School of the Environment, Durham, NC.

Invited Lectures: Risk Assessment Methods in Water Quality. Spring 1992. Course title: Environmental Risk Assessment and Decision Making. Duke University, School of the Environment, Durham, NC.

Invited Lectures: Risk Assessment Methods in Water Quality. Spring 1992. Short course: Environmental Risk Assessment. Duke University Continuing Education Series, Duke University, Durham, NC.

Invited Lecture: Variability of Biological Endpoints and Effects on Standard Setting. Fall 1991. Course title: Environmental Toxicology. Duke University, School of the Environment, Durham, NC.

Regression Analysis, With Laboratory. Spring Semesters 1986-1988. Duke University, School of Environmental Sciences, Durham, NC.

Graduate Student Committee Assignments

Eric Thirolle, M.S.: Thesis title: Guidance for the selection and use of exposure models in ecological risk assessment. Duke University School of the Environment. 1996.

Tom Stockton, Ph.D. Thesis title: Using Bayesian MARS methods for assessing acid deposition. Duke University School of the Environment. 1998.

Molly Haviland. M.S. Thesis title: Soil carbon and dryland spring wheat yield response to a onetime compost application. Montana State University. Ongoing.

PRESENTATIONS

Warren-Hicks, W. J. Role of Statistics in Litigation. 2019. Law Seminars Institute. Albuquerque, New Mexico.

Warren-Hicks, W. J., Bohrmann, T., Robbins, K., 2013. Geospatial Modeling: Don't Take Your GIS Statistics Software for Granted. SETAC National Conference. Nashville, TN.

Warren-Hicks, W. J. and S. Bartell. 2009. Models Versus Data. Invited Presentation. SETAC Debate Series. SETAC National Conference. New Orleans, LA.

Kravits, M., Eskew, D., Warren-Hicks, W. J. 2008 Application of the Stressor Identification (SI) Methodology to a Contaminated Floodplain and Adjacent Irrigated Meadows – Upper Arkansas River, Colorado Case Study. SETAC Annual Meeting, Tampa, Fl.

Zillioux, E. J., Newman, J. R., Warren-Hicks, W. J. 2008. Ranking Wildlife Risks from Multiple Anthropogenic Stressors. SETAC Annual Meeting, Tampa, Fl.

Giddings, J., and Warren-Hicks, W. J. 2008. Developing a plant-based chronic water quality standard for acetochlor. SETAC Annual Meeting, Tampa, Fl.

Warren-Hicks, W. J. 2006. Chair: The Future of Environmental Statistics and Ecological Modeling. SETAC Annual Meeting, Montreal, Canada.

Arnold, R.W, and Warren-Hicks, W. J. Site-specific, Regional, or National Metals Criteria? – A Case Study With Cu In San Francisco Bay. 2005. SETAC Annual Meeting, Baltimore, MD.

Warren-Hicks, W. J., Parkhurst, B. R. 2003. Whole Effluent Toxicity Tests: Using Bayesian Methods To Calculate Model-Based Endpoint Variability. SETAC Annual Meeting, Austin, TX.

Parkhurst, B. R., Warren-Hicks, W. J. 2003. Alternatives to EPA's Methods for Calculating Reasonable Potential for WET: Case Studies. SETAC Annual Meeting, Austin, TX.

Giddings, J. M., Gonzalez-Valero, J. F., Warren-Hicks, W. J. 2003. Exposure Duration and Effects of Atrazine on Aquatic Plant Communities in Mesocosms. SETAC Annual Meeting, Austin, TX.

Giddings, J. M., Gonzalez-Valero, J. F., Warren-Hicks, W. J. 2003. Integrating Dose-Response With Species Sensitivity Distributions. SETAC Annual Meeting, Austin, TX.

Warren-Hicks, W. J. 2003. Statistical Methods and Approaches in Risk Assessment: Lessons Learned. Invited Address. SETAC European Congress, Hamburg, Germany.

Warren-Hicks, W. J., Parkhurst, B.P., Beach, S., Butenhoff, J., Giesy, J. 2002. Understanding the Global Distribution and Environmental Effects of PFOS. Society of Toxicology Annual Meeting. Salt Lake City, Utah.

Warren-Hicks, W. J., Qian, S., Dobbs, M. 2002. Species Sensitivity Distributions in Non-Target Plant Risk Assessments. Society of Toxicology Annual Meeting. Salt Lake City, Utah.

Dobbs, M. G., Ramanarayanan, T. S., Warren-Hicks, W. J., Qian, S., Giddings, J. M., Kelly, I.D., Allen, R., Fischer, R.W. 2002. Assessing the risk to non-target crops through irrigation water. Society of Toxicology Annual Meeting. Salt Lake City, Utah.

Parkhurst, B. P., Warren-Hicks, W. J., Bartell, S., Smart, M. 2002. Site-Specific Nutrient Criteria: An Alternative To US EPA Nutrient Criteria. Society of Toxicology Annual Meeting. Salt Lake City, Utah.

Parkhurst, B. P., Warren-Hicks, W. J., Bartell, S., Smart, M. 2002. Site-Specific Nutrient Criteria: An Alternative To US EPA Nutrient Criteria. Water Environment Federation Annual Meeting. Chicago, IL.

Warren-Hicks, W. J., Santoro, M., Bacon, D., Parkhurst, B. P., Moore, D. J. 2001. Ecological Risk Assessment of PFOS. Invited Address. Society of Toxicology and Chemistry World Congress. Baltimore, Maryland.

Warren-Hicks, W. J., Carbone, J.P., Havens, P. 2001. Using Monte Carlo Techniques to Judge Model Prediction Accuracy: Validation of PRZM 3.1. Society of Toxicology and Chemistry World Congress. Baltimore, MD.

Carbone, J. P., Havens, P., Warren-Hicks, W. J. 2001. Validation of a Complex Fate and Transport Model. Model Accuracy and Regulatory Criteria. Society of Toxicology and Chemistry World Congress. Baltimore.

Salvito, D. T., Allen H. E., Parkhurst, B. R., Warren-Hicks, W. J. 2001. Comparison of Trace Metals in the Intake of Discharge Water of Power Plants Using "Clean" Techniques. Water Environment Research. Vol 73, No. 1, 24-29.

Dobbs, M., R, Ramanarayanan, T., Warren-Hicks, W. J. 2001. The Risk of Balance To NonTarget Plants. Society of Toxicology and Chemistry World Congress. Baltimore, Maryland.

Warren-Hicks, W. J., Santoro, M., Bacon, D. Parkhurst, B.P., Moore. D.J. 2000. Understanding the Global Distribution and Environmental Effects of PFOS. SETAC Annual Meeting. Nashville, TN.

Warren-Hicks, W. J., Wolpert, R. L. 2000. Estimating national distributions of Giardia and Cryptosporidium in the U.S. with Hierarchical Bayesian models. Third SETAC World Congress. Brighton, United Kingdom.

Warren-Hicks, W. J. 2000. Propagating Uncertainty In Non-Hierarchal Models. SETAC Annual Meeting. Nashville, TN.

Warren-Hicks, W. J., Moore, D. 2000. Uncertainty Analysis In Ecological Risk Assessment: American Chemistry Council and CEFIC Long-Range Research Initiatives. SETAC Annual Meeting. Nashville, TN.

Warren-Hicks, W. J., Biddinger, G. 1999. Debates In Ecological Risk Assessment. Chair. Society of Toxicology and Chemistry World Congress. Philadelphia, PA.

Warren-Hicks, W. J., Moore, D. 1999. Beyond Monte Carlo. Invited Address. Society of Toxicology and Chemistry World Congress. Philadelphia, PA.

Warren-Hicks, W. J., Parkhurst, B. R., Moore. D. R. J. 1999. Whole Effluent Toxicity Test Variability: A Variance Components Analysis. Water Environment Federation Annual Meeting.

Moore, D. R. J., R. S. Teed, W. J. Warren-Hicks, B. R. Parkhurst, R. B. Berger, J. J. Pletl, D. L. Denton, R. B. Baird. 1999. Intra- and Inter-treatment variance in reference toxicant tests. 20th Annual Society of Environmental Toxicology and Chemistry Conference.

Warren-Hicks, W. J., Parkhurst, B. R., Moore, D., Berger, B., Pletl, J., Denton, D., Baird, R. 1999. Whole Effluent Toxicity Test Variability: A Variance Components Analysis. Society of Toxicology and Chemistry World Congress. Philadelphia, PA.

Parkhurst, B. R., Warren-Hicks, W. J., Moore, D., Berger, B., Pletl, J., Denton, D., Baird, R.1999. WET Test Variability: Demonstration of Effects on Compliance with WET.

Warren-Hicks, W. J., Moore, D. 1999. Uncertainty Analysis: With Examples From the Chemical Industry. Society of Toxicology and Chemistry World Congress. Philadelphia, PA.

Carbone, J. P., Havens, P., Warren-Hicks, W. J. 1999. A Critical Evaluation of PRZM3.12

Estimated Environmental Concentrations Accounting For The Uncertainty Associated With Measured Environmental Fate Data and Model Inputs. Society of Toxicology and Chemistry World Congress. Philadelphia, PA.

Teed, R. S., Qian, S. Warren-Hicks, W. J. 1999. Examination Of The Spatial Relationship and Interaction of Selected Environmental Parameters To Mercury Concentration In Fish Tissue in the Northeastern United States. Society of Toxicology and Chemistry World Congress. Philadelphia, PA.

Warren-Hicks, W. J., Biddinger, G. 1998. Debates In Ecological Risk Assessment. Chair. Society of Toxicology and Chemistry World Congress. Charlotte, NC.

Warren-Hicks, W. J., Solomon, K. R. R., Gentile J. H., Butcher, J., Ratner, B.A. 1998. Linking Stressors and Ecological Responses. Society of Toxicology and Chemistry Annual Meeting. Charlotte, NC.

Warren-Hicks, W. J., B. Parkhurst. 1995. Review of EPA's Framework for Ecological Risk Assessment. Invited Address. Colloquium on Developing an EPA Ecological Assessment Guidelines.

Warren-Hicks, W. J., B. Parkhurst. 1995. The Role of Laboratory Selection in Passing Toxicity Tests and Conducting Toxicity Reduction Evaluations. Presented at the Water Environment Federation's Conference: Toxic Substances in Water Environments. Cincinnati, Ohio. May 14 B 17.

Warren-Hicks, W. J., 1995. Uncertainty in Ecological Risk Assessment: A Review of the 1995 Pellston Conference. Second Society of Toxicology and Chemistry World Congress. Vancouver, British Columbia, Canada. November 6B10.

Warren-Hicks, W. J., 1995. Variability of Chronic Toxicity Tests. Invited Address. Presented at the 75th N.C. American Waste Water Association Conference. Greensboro, North Carolina. November 13.

Parkhurst, B. P., Warren-Hicks, W. J., 1994. The Role of Laboratory Selection in Passing Toxicity Tests and Conducting Toxicity Reduction Evaluations. Presented at Water Environment Federation 1994. Chicago, Illinois. October 15B19.

Warren-Hicks, W. 1994. The Role of Laboratory Selection in Passing Toxicity Tests and Conducting Toxicity Reduction Evaluations. Presented at the SETAC Ecological Risk: Science, Policy, Law, and Perception Conference. Denver, Colorado. October 30BNovember 3.

Warren-Hicks, W. J. 1992. The Use of Bayesian Inference in Environmental Assessments and Decision-Making: Explanation of Theory and Case Study Examples. Invited Presentation. Atmospheric Environmental Research Laboratory, Research Triangle Park, NC.

Parkhurst, B. R., W. J. Warren-Hicks. 1988. What is the Role of Environmental Toxicology In Assessing the Ecological Impacts of Superfund Sites? Presented at the Ninth Annual Meeting of the Society of Environmental Toxicology and Chemistry. Arlington, VA. November13 B 17.

SELECTED PUBLICATIONS

Kishi T, Warren-Hicks W, Bayat N, Targoff IN, Huber AM, Ward MM, Rider LG; with the Childhood Myositis Heterogeneity Study Group. Corticosteroid discontinuation, complete clinical response and remission in juvenile dermatomyositis. Rheumatology (Oxford). 2021 May 14;60(5):2134-2145. doi: 10.1093/rheumatology/keaa371. PMID: 33067611; PMCID: PMC8121446.

Kishi T, Bayat N, Ward MM, Huber AM, Wu L, Mamyrova G, Targoff IN, Warren-Hicks W.J., Miller FW, Rider LG, for the Childhood Myositis Heterogeneity Study Group. (2018). Medications Received by Patients with Juvenile Dermatomyositis. Seminars Arthritis and Rheumatism. Mar 28. pii: S0049-0172(17)30753-9. doi: 10.1016/j.semarthrit.2018.03.016. [Epub ahead of print]. PMID: 29773230, PMCID PMC6162169.

Kishi T, Warren-Hicks W.J., Ward M, Bayat N, Wu L, Mamyrova G, N. Targoff I, Miller F, Rider LG. (2017). Predictors of Corticosteroid Discontinuation, Complete Clinical Response and Remission in Patients with Juvenile Dermatomyositis]. Arthritis Rheumatol. 2017; 69 (suppl 4). http://acrabstracts.org/abstract/predictors-of-corticosteroid-discontinuation-complete-clinicalresponse-and-remission-in-patients-with-juvenile-dermatomyositis/.

Kishi T, Wilkerson J, Smith M, Bayat N, Henrickson M, Lang B, Passo M, Miller FW, Ward M, Rider LG. Early Treatment with Intravenous Pulse Methylprednisolone or Methotrexate Is Associated with Decreased Medication Requirements at 12 and 24 Months in Patients with Juvenile Dermatomyositis: A Propensity Score Analysis [abstract]. Arthritis Rheumatol. 2018; 70 (suppl 9). https://acrabstracts.org/abstract/early-treatment-with-intravenous-

pulsemethylprednisolone-or-methotrexate-is-associated-with-decreased-medication-requirements-at12-and-24-months-in-patients-with-juvenile-dermatomyositis-a-propensi/.

Kishi T, Warren-Hicks W, Ward M, Bayat N, Wu L, Mamyrova G, N. Targoff I, Miller F, Rider LG. Predictors of Corticosteroid Discontinuation, Complete Clinical Response and Remission in Patients with Juvenile Dermatomyositis [abstract]. Arthritis Rheumatol. 2018; 70 (suppl 9). https://acrabstracts.org/abstract/predictors-of-corticosteroid-discontinuation-complete-clinicalresponse-and-remission-in-patients-with-juvenile-dermatomyositis/.

Schwede, D., Bowker, G., Warren-Hicks, W. J. 2011. Quality Assurance Decisions with Air Models: A Case Study of Imputation of Missing Input Data Using EPA's Multi-Layer Model. Water, Air, and Soil Pollution. Vol. 222, pps. 391-402.

Warren-Hicks, W. J., and Hart, A. eds., 2010. Application of Uncertainty Analysis to Ecological Risks of Pesticides. Taylor & Francis, New York, New York.

Warren-Hicks, W. J., S. Qian, J. Toll, D. L. Fischer, E. Fite, W. G. Landis, M. Hamer, and E. P. Smith. Monte Carlo, Bayesian Monte Carlo, and First-Order Error Analysis. 2010. In Application of Uncertainty Analysis to Ecological Risks of Pesticides. Eds. W. J. Warren-Hicks and A. Hart. Taylor & Francis, New York, New York.

D. R. J. Moore, W. J. Warren-Hicks, S. Qian, A. Fairbrother, T. Aldenberg, T. Barry, R. Luttik, and H. T. Ratte. Uncertainty Analysis Using Classical and Bayesian Hierarchical Models. 2010. In Application of Uncertainty Analysis to Ecological Risks of Pesticides. Eds. W. J. WarrenHicks and A. Hart. Taylor & Francis, New York, New York.

Giddings, J. M., Barber, I., Warren-Hicks, W. J. 2008. Comparative aquatic toxicity of the pyrethroid insecticide lambda-cyhalothrin and its resolved isomer gamma-cyhalothrin. Ecotoxicology. Published online at: http://www.springerlink.com/content/e85343g234802606.

Arnold, R. W., Warren-Hicks, W. J. 2007. Assessment of Aquatic Ecological Risk and SiteSpecific Criteria of Copper in San Francisco Bay, California, USA. Integrated Environmental Assessment and Management. Vol 3, No. 1, pp. 32 - 48.

Arnold, R. W., Warren-Hicks, W. J. 2007. Probability-Based Estimates of Site-Specific Copper Water Quality Criteria for the Chesapeake Bay, USA. Integrated Environmental Assessment and Management. Vol 3, No. 1, pp. 101 - 117.

Warren-Hicks, W. J., Efroymson, R. A., Newman, J., Strickland, D. 2006. Ecological Risk Assessment: A Framework for Wildlife Assessments At Wind Energy Facilities. National Wind Coordinating Committee, Washington, D. C.

Warren-Hicks, W., B. J. Parkhurst, Butcher, J. B. 2002. Methodology for Aquatic Ecological Risk Assessment. In: Species Sensitivity Distributions in Ecotoxicology. Leo Posthuma, Glenn Suter, Theo Trass. eds. Lewis Publishers, New York. 206p.

Warren-Hicks, W. J., Carbone, J. P., Havens, P. L. 2002. Using Monte Carlo Techniques To Judge Model Prediction Accuracy: Validation Of The Pesticide Root Zone Model 3.12. Environmental Toxicology and Chemistry. Vol. 21, No. 8, pp. 1570 - 1577.

Carbone, J. P., Havens, P. L., Warren-Hicks, W. J., 2002. Uncertainty Analysis in Model Validation. Environmental Toxicology and Chemistry. Vol. 21, No. 8., pp. 1532 - 1548.

Qian, S., Warren-Hicks, W. J., Keating, J. 2001. A Predictive Model of Mercury Fish Tissue Concentrations for the Southeastern United States. Environmental Science & Technology. Vol. 35, No. 5, 941-947.

Warren-Hicks, W. J., B. Parkhurst, D. Moore. 2000. Whole Effluent Toxicity Test Variability: Partitioning Sources of Variability. Environmental Toxicology and Chemistry. Vol. 19, No. 1, pp. 94-104.

D. Moore, Warren-Hicks, W. J., Parkhurst, B. J. 2000. Intra- and Inter-Treatment Variance. Environmental Toxicology and Chemistry. Vol. 19, No. 1, pp. 94-104.

Gentile, J. H., Soloman, K. R., Butcher, J. B., Harrass, M., Landis, W. G., Power, M., Rattner, B. A, Warren-Hicks, W. J., Wenger, R. 1999. Linking Stressors and Ecological Responses. In:

Multiple Stressors In Ecological Risk and Impact Assessment. Eds.: Foran, J. A., Ferenc, S.A. SETAC Press, Florida.

Warren-Hicks, W. J. 1999. Formal Methods for Risk-Based Decision-Making. HERA 5(2):225229.

Warren-Hicks, W. J., D. Moore. eds. 1998. Uncertainty Analysis in Ecological Risk Assessment: Pellston '95. SETAC Press, Florida.

Warren-Hicks, W. J., J. Tao, P. Kellar, G. Sun, P. Tsirigotis. 1998. The NOx-Load Relationship. Proceedings of the Acid Rain and Electric Utilities Conference. Air and Waste Management Association. Scottsdale AZ.

Warren-Hicks, W. J., J. Tao, P. Kellar, G. Sun, P. Tsirigotis. 1997. Using Long-Term Hourly CEM Data to Assess Performance Capabilities of Low NOx Burners. Proceedings of the Acid Rain and Electric Utilities Conference. Air and Waste Management Association. Scottsdale AZ.

Warren-Hicks, W. J. 1997. Special Issues of Uncertainty in Sediment Risk Assessment. In: Ecological Risk Assessments of Contaminated Sediments. Proceedings of the 22nd Pellston Workshop. SETAC Press, Florida.

Warren-Hicks, W. J, J. B. Butcher. 1997. Issues of Uncertainty in Ecological Risk Assessments. In: Ecological Risk Assessments of Contaminated Sediments. Proceedings of the 22nd Pellston Workshop. SETAC Press, Florida.

Warren-Hicks, W. J., B. Parkhurst. 1996. Issues in Whole Effluent Toxicity Test Uncertainty Analyses. In: Whole-Effluent Toxicity Testing: An Evaluation of Methods and Predictability of

Receiving System Responses. (eds.) D. R. Grothe, K. L. Dickson, D. K. Reed. SETAC Press, Florida.

Warren-Hicks, W. J., J. B. Butcher. 1996. Monte Carlo Analysis: Classical and Bayesian Applications. Human and Ecological Risk Assessment. Vol. 2, No. 4, pp. 643-650.

Peacock, C. H., M. M. Smart, W J. Warren-Hicks. 1996. Best Management Practices and Integrated Pest Management Strategies. Proceedings of Watershed '96: Moving Ahead Together Conference, Water Environment Research Foundation, June.

Warren-Hicks, W. J., 1996. Comparability of Human and Ecological Risk Assessment. Human and Ecological Risk Assessment. Vol. 2, No. 1, pp. 2-5.

Warren-Hicks, W. J., M.M. Smart, C. H. Peacock. 1996. Evaluation and Use of Transport and Fate Models of Fertilizers and Pesticides at Golf Courses. Proceedings of Watershed '96: Moving Ahead Together Conference, Water Environment Research Foundation, June, 1996.

Parkhurst, B. R., W. J. Warren-Hicks, C. S. Creager. 1996. Methods for Assessing WatershedScale Aquatic Risks for Multiple Stressors. In: Environmental Toxicology and Risk Assessment: Modeling and Risk Assessment (Sixth Volume) STP 1317. American Society for Testing and Materials.

Warren-Hicks, W. J. 1996. The Role of Uncertainty in Ecological Risk Assessment: Invited Plenary Address. Proceedings of the ASTM Committee E-37 Conference on Probabilistic Methods in Ecological Risk Assessment. Orlando, FL. April.

Lieberman, E., W. J. Warren-Hicks. 1995. EPA's CEM Certification Review (C_REV) System. Proceedings of the Air and Waste Management Association International Specialty Conference, Acid Rain & Electric Utilities: Permits, Allowances, Monitoring & Meteorology. Tempe, Arizona. January.

Warren-Hicks, W. J., E. Lieberman. 1995. Innovative Role of Statistics in Acid Rain Performance Testing. Proceedings of the Air and Waste Management Association International Specialty Conference, Acid Rain & Electric Utilities: Permits, Allowances, Monitoring & Meteorology. Tempe, Arizona. January.

Lieberman, E., W. J. Warren-Hicks. 1995. Precision of CEMS: Results of Field Studies Conducted by EPA. Proceedings of the Air and Waste Management Association International Specialty Conference, Acid Rain & Electric Utilities: Permits, Allowances, Monitoring & Meteorology. Tempe, Arizona. January.

J. B. Parkhurst, Warren-Hicks, W. J., R. Cardwell, J. Volosin, T. Etchison, J. Butcher, S. Covington. 1995. Risk Managing Methods: Aquatic and Ecological Risk Assessment Aids Decision-Making. Water Environment & Technology. November.

Baker, J.P., W. J. Warren-Hicks, S.J. Christensen. 1993. Fish Population Losses From Adirondack Lakes: The Role of Surface Water Acidity and Acidification. Water Resources Research 29:861-874.

Warren-Hicks, W. J., R. L. Wolpert. 1993. Predictive Models of Fish Response to Acidification: Using Bayesian Inference to Combine Laboratory and Field Measurements. In Environmental Statistics, Assessment and Forecasting. C.R. Cothern ed. Lewis, Chelsea, Michigan.

Wolpert, R. L., W. J. Warren-Hicks. 1992. Bayesian Hierarchical Logistic Models for Combining Field and Lab Data. In: Bayesian Statistics 4. eds.: J. M. Bernado, J. O. Berger, J. P. Dawid, and A.F.M. Smith. Oxford Press, Oxford England.

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Warren-Hicks, W. J., B. R. Parkhurst. 1991. Ecological Risk Assessment Methods In Water Quality Standards and Regulations: A Case Study. Proceedings of the Water Pollution Control Federation. Toronto, Canada.

Parkhurst, B .R., W. J. Warren-Hicks. 1991. Urban Runoff and Receiving Systems: An Interdisciplinary Analysis of Impact, Monitoring, and Management. Proceedings of the Risk Assessment Forum Conference on Uncertainty and Risk: Receiving System Issues.

Warren-Hicks, W. J. 1990. Empirical Bayes Models. In: Baker, J.P. et al., Biological Effects of Changes in Surface Water Acid-Base Chemistry. State-of-Science/Technology Report 13. National Acid Precipitation Assessment Program, Washington, DC.

Warren-Hicks, W. J., B. R. Parkhurst. 1990. Impact of Variability in EPA's Effluent Toxicity Tests on Regulatory Standard Setting. Proceedings of the Water Pollution Control Federation. Washington, D.C.

Warren-Hicks, W. J., B. R. Parkhurst. 1990. Variability of EPA’s Effluent Toxicity Tests. Proceedings of the Society of Environmental Toxicology and Chemistry (SETAC), Seattle, WA.

Warren-Hicks, W. J. 1989. Bayesian Models Predicting Fish Response to Acidification. Proceedings of the Society of Environmental Toxicology and Chemistry Annual Meeting, Toronto, Canada.

Warren-Hicks, W. J., J. Crutchfield. 1985. Comparison of population estimates on a known largemouth bass population. Proceedings of the Annual Conference of the Southeastern Association of Fish and Wildlife Agencies. Lexington, KY. October.

Warren-Hicks, W. J., W. Mallin. 1985. Food habits of larval Lepomis spp. and gizzard shad in a Piedmont reservoir. Proceedings of the Annual Conference of the Southeastern Association of Fish and Wildlife Agencies. Lexington, KY. October.

Warren-Hicks, W. J., G. Siple. 1984. Time-series model for predicting ambient TSP concentrations from coal-fired power plants. Proceedings of the 77th Annual Air Pollution Control Association Meeting. San Francisco, CA.

Warren-Hicks, W. J., G. Schroder. 1979. Marking fleas with Fe59: uptake and retention of a tag acquired from a natural host. Journal of Medical Entomology 16(5):432- 436.

Contact Information

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DONALD G. CATANZARO, PHD

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Dr. Catanzaro is a Project Scientist and Project Manager that has over 20 years of experience working in statistics, human and ecological health, internet technologies, and Geographic Information Systems (GIS). I have devoted my career to turning large data systems into information and eventually into knowledge. I have developed skills over the long-term using several different GIS, remote sensing, CAD, and GPS software and hardware systems. Dr. Catanzaro's previous employment has been with County Planning Agencies, Federal Agencies, and private firms where his clients have included Federal, State, Tribal, Local, Non-Government organizations as well as private companies. I have a broad Biogeographical and Computer Science background and am well grounded in data analysis including survival, uni/multi-variate, nonparametric, and spatial statistics. My career has been multidisciplinary in approach, wide in scope, and international in scale.

I have the ability to move seamlessly between large relational databases (multi- million rows) and several computer languages and have analyzed large datasets such as forest inventory data for bioenergy assessments; risk analysis of invasive species to the Great Lakes based on shipping data and habitat niche models; analysis of NO2 and SO2 National Ambient Air Quality Standards (NAAQS) for the EPA; analysis of long term monitoring of air quality monitors within California; creating interactive graphical libraries to explore the scientific literature, and conceptual models of nitrogen and phosphorus flows through ecosystems; analyzing pollution attenuation through ground water with spatial statistics; genetic determinates of Extensively Drug-Resistant Tuberculosis (XDR-TB); and; creating population models using multiple US Census Bureau products. I am also currently investigating the effects of air pollution on TB patients (California and Viet Nam), long-term mortality trends in Moldova TB patients, and the use of Artificial Intelligence (Google's TensorFlow) to detect tuberculosis in chest x-rays.

Education

PhD, Biology, University of Arkansas, 1998

BA, Geography, University of California – Los Angeles, 1991

Additional Training

Human Subjects Training (CITI and NIH)

McGill Infectious Diseases and Global Health (2016)

Course I: Tuberculosis Research Methods

Course II: Advanced TB Diagnostics Research

Good Clinical Practice (GCP)

Curry International Tuberculosis Center (2015)

Course I: Focus on LTBI

Course II: Tuberculosis Clinical Intensive

Specialized Computer Applications

Statistics

Microsoft Office

R, MatLab/Octave, SAS , SAS JMP, SPLUS

Excel (expert), Word, PowerPoint, Access

Programming

Business Intelligence

SQL, Python, Visual Basic for Applications,

PowerBI

Java, JavaScript, HTML, XML, Flash / Flex,

Relational Databases

UNIX

MS SQL Server/Azure, MySQL, PostgresSQL,

GIS/Remote Sensing

Oracle, Informix

ESRI ArcPro/GIS/View/Info, CAD, GRASS 6.4,

ERMapper, GeniePro, PCI, ERDAS

Other Technical Skills

Univariate, Multivariate Parametric and Non-Parametric Statistics, Artificial Intelligence/Machine Learning, Regression, Geostatistics, Time Series, Survival Analysis

Database Theory and Management

Integration of data collection hardware and software - mobile computers, depth sounder, GPS

Remote Sensing Application and Theory (aerial photography and digital systems)

Professional Experience

University of Arkansas, Fayetteville, Department of Biological Sciences

Dates Employed: 2014 - Present

Research Assistant Professor: I am the lead Data Analyst & Statistician for a large group researching various aspects tuberculosis diagnostics and treatment. My core responsibilities includes installing & managing REDCap (a browser-based clinical data system), developing and implementing data capture/entry systems (paper, computer, mobile), and creating web-enabled databases which drive project related analysis. As leader of the Data Core, I develop SQL code (and other languages) to support project management by displaying analytics of disparate datasets and creating unique data visualizations. I have used Artificial Intelligence (Google's TensorFlow) to detect tuberculosis in chest x-rays; combined Python & SQL to ingest data from REDCap to MS SQL Server and display information in MS PowerBI, implemented a bioinformatics pipeline to process whole genome sequencing data; developed SQL code which ingests and processes XML data created by a tuberculosis diagnostic device; performed statistical analysis (e.g. trend, regression) for several scientific papers; served as SQL developer to use the common cellphone to provide a simple/easy way to monitor adherence to anti-tuberculosis therapy; performed spatial analysis combining coccidioidomycosis natural history, epidemiology, and global climate change data to predict areas where coccidioidomycosis may increase over time; and used SQL and R to analyze Arkansas All Payer's Claim Database (APCD) investigating age/gender relationships and nontuberculous mycobacterial infection.

Sustainment & Restoration Services (SRS) / Oneida Total Integrated Enterprises (OTIE)

Dates Employed: Jan 2006 - Present

Landscape Ecologist: I have been both a Project Manager (PM) and Project Scientist (PS) for OTIE for the last 16 years. On work assignments where I was PM, I was responsible for developing work plans and budgets, ensuring the overall quality of project work, supervising work performed by other PS and staff members, writing monthly reports and summaries, and preparing final project report(s). On work assignments where I was a PS, I was responsible for

assembling data sources, analyzing spatial and temporal patterns, running statistical analysis, reviewing and writing reports.

Projects I have been involved in over the last 16 years include: providing technical support to the EPA National Center for Environmental Assessment (NCEA) and National Exposure Research Laboratory (NERL) who provide guidance to regions, states and tribes on how tools and science to support implementation of the Clear Water Act & Clean Air Act. Both offices in particular are working to develop metrics that define a relationship between specific ecosystem service and one (or more) aspects of community health.

I have worked with Census 2010, 2000, and 1990 as well as American Community Survey (ACS) data and recreational user data (e.g. USFWS National Survey of Fishing, Hunting, and Wildlife-Associated Recreation).

Selected Project Experience

• Lyme Disease - Over three Work Assignments served as the statistical analyst and GIS support for determining the generalized applicability of a model to predict Lyme disease incidence across Maryland and Pennsylvania from landscape variables such as population and forest cover. An online interactive viewer was developed tying ArcGIS for Server Javascript API to logistic regression predictive equations and assisted users as they explore models by the usage of interactive sliders to vary disease rate thresholds and risk probabilities and examine the consequences

• CADStat – Served as QA/QC Manager for two EPA Work Assignments to develop CADStat, a menu-drive statistical package of several data visualization and statistical methods. CADStat is currently deployed on EPA's server (http://www.epa.gov/caddis) and is a Java Graphical User Interface to R (R is an open source statistical software). Methods in CADStat include: scatter plots, box plots, correlation analysis, linear regression, quantile regression, conditional probability analysis, and tools for predicting environmental conditions from biological observations

• CCAT – I developed an HTML5/Javascript application for the EPA called the Community Cumulative Assessment Tool (CCAT) which combines EPA's Environmental Justice, Risk Assessment, and Community Involvement concepts to address multiple stressors within the EPA's cumulative risk assessment framework.

• C/T-FERST – Performed data development, integration and deployment of the EPA's Community/Tribally-Focused Exposure and Risk Screening Tool (C/T-FERST) which supports EPA's integration with other decision-support tools for communities and tribes. C/T-FERST is intended to assist community partners with the challenge of identifying and prioritizing community environmental health risk issues.

EcoStat, Inc

Dates Employed: Feb 2010 - Present

Statistician Provided data quality, processing and statistical analysis for multiple projects including in the development of Data Quality Objectives (DQOs) for the EPA's NO2 and SO2 National Ambient Air Quality Standards (NAAQS). NAAQS are designed to provide requisite protection of public health as appropriate under section 109 of the Clean Air Act (CAA). The interacting effects of precision, bias, and completeness were investigated using hourly measurements at over 300 monitoring stations across the country. Other projects include developing an interactive data exploration tool (using MS Excel) for pesticide risk assessment, data processing and analysis of MTBE contamination of private wells, spatial and time series analysis of pollutant inputs into Puget Sound ,exploratory data analysis and model development between Carbon Dioxide emissions and measurements of other power plant variables.

San Diego State University, Bioinformatics & Medical Informatics Department

Dates Employed: May 2012-May 2013

Adjunct Faculty: Data Core leader, lead statistician, and member of the Leadership Team for a NIH sponsored project to test new genetic-based diagnostics tools to detect XDR-TB (U01-AI082229). The project enrolled over 1,110 subjects in three international sites to investigate common mutations which confer drug-resistance. I provided technical oversight of data collection systems (both web and laptop/netbook based), quality assurance, as well as liaison support between the Health Information Technology Group and the clinical staff.

The complexity of project components required several staff members input into how to most efficiently store, manage, query, analyze, and visualize the large quantity of data collected. I played a major role in many of these activities, using expert knowledge to maintain a high level of data collections efficiency and quality. I provided statistical analysis, geographic analysis, and data visualizations to other project staff working with epidemiological and genetic data.

BioEnergy Systems LLC

1726 N Charlee Fayetteville, Arkansas

72703 Dates Engaged: 2007-2012

As a consultant to BioEnergy Systems, I worked on natural resource evaluations, project site assessments (desk studies), renewable energy systems, and data visualizations of complex issues for clients. I compiled the data to support an assessment of agricultural and forest biomass resources in the mid portion of the Mississippi River Alluvial Valley, an area that included 98 counties in Arkansas, Kentucky, Mississippi, Missouri and Tennessee)

Co-developed a high-resolution user-interactive tool for analyzing biomass feedstock supplies (BioFeedStAT® see http://www.biomass2.com/fsa/fsa.html). The tool is used to determine quantities vs. distances (in 0.5-mile increments -- actual road miles, not air miles) and transport costs of any combination of target feedstocks. Source data for BioFeedStAT® is a combination

of large databases housing data from the US Forest Service Forest Inventory Data, USDA Cropland Data Layer, and USDA Census of Agriculture.

US Census Bureau / Census Coverage Measurement, Kansas City Regional Census Center

Dates Employed: May 2009- July 2011

Regional Technician (Grade GG-0301-12): As a Regional Technician for 2010 Census, provided technical assistance to the Kansas City Regional Census Center (KC-RCC) for all five Census Coverage Measurement (CCM) operations. CCM operations have three primary objectives: (1) to inform the public about the quality of the census counts; (2) to help identify sources of error to improve census taking, and (3) to provide alternative counts based on information from the coverage measurement program.

As a Regional Technician, I worked under specific direction from the regional office to provide technical and administrative support for all recruitment, personnel, payroll, field data collection, group quarters, office and evaluation operations, automation activities, postal liaison activities, map/geography problems.

Served as a Master Trainer and trained Field Operation Supervisors, Crew Leaders, and Enumerators in all CCM operations in Arkansas, Oklahoma, Missouri, and Minnesota. I trained over 350 employees in small group settings (classes of 10-20). I served as trouble shooter in all five CCM operations and backfilled Field Operation Supervisors, Crew Leaders, and/or Enumerators when field staff quit or not available to work.

Enercon Services, Inc

Dates Employed: Mar 2006 – May 2007

Project Scientist: Provided training to subordinate employees on how to conduct a Severe Accident Mitigation Alternatives (SAMA) for the Nuclear Regulatory Commission (NRC). Oversaw work of subordinate employees, and performed quality checks to ensure high quality work was submitted.

Provided project work, Quality Assurance, and Technical Review for several different nuclear license renewal applications from Entergy Corporation to the NRC. Project works included using GIS to collect, analyze, and support the writing of reports to support the construction of a SAMA for submittal to the NRC. Used US Census Bureau Summary File (SF) 1 and SF3 (for general and environmental justice populations) and Agricultural Census, and local sources of data (e.g. tourism, tax assessment, population growth) to investigate how a severe accident at a nuclear power plant may affect the surrounding communities.

Quality reviews included ensuring all calculations and methodologies follow NRC guidance, performing independent checks on data, reviewing all written materials and sources to ensure accuracy and veracity.

FTN Associates, LTD

Dates Employed: Oct 2002 – Dec 2005

Landscape Ecologist: Provided GIS, biological and statistical expertise for industrial, governmental, and nongovernmental clients for a water resources environmental consulting company. Wrote proposals (technical and cost), analyzed data, wrote monthly and final report(s) and recruited and supervised subordinate employees (as necessary).

Created socio-economic and agricultural datasets (data sources were Census 2000 SF1 and SF3 and Census of Agriculture 1997 and 2002) to support Severe Accident Mitigation Alternatives (SAMA) and NEPA analyses for nuclear power industry; providing global climate change research on coral reefs of American Samoa; used GIS to model a new framework for sustainable water resources management; remote sensing and wildlife assessment for Columbian Sharp-Tailed Grouse; organizing and facilitating a 30 person workshop to address multiple stressors to aquatic ecosystems; synthesizing and reviewing the results of the EPA STAR Ecosystem Indicator Program; conducting literature review and analysis on nitrogen phosphorus-algae dynamics; and used GIS to model pollution attenuation through groundwater.

National Park Service, Virgin Islands / South Florida Cluster – Long Term Ecological Monitoring

Dates Employed: Oct 1999 - Oct 2002

Inventory & Monitoring Coordinator (Grade GS-0401-12): Number of Employees: 3

Budget: $350,000Supervised employees, responsible for purchasing major/minor equipment, develop and tracked budgets for a brand new Inventory & Monitoring Program. Responsible for developing and implementing a statistically defensible program to inventory and monitor six marine natural resources found in the 98,000 acres of natural resources at three National Park Service (NPS) units: Virgin Islands National Park, Buck Island Reef National Monument, and Dry Tortugas National Park. These six resources were: water quality, coral reefs, seagrass, seabirds, fish, and sea turtles. Infused several technological improvements in the monitoring program which reduced field time and data transcription such as: obtaining remote sensing datasets (multispectral and hyperspectral), creating several park-wide fully functional GIS, using SONAR technology to locate monitoring sites for coral reefs and seagrass beds, standardizing underwater digital photography and videography, use of digital field data recorders, and storage of field data in relational databases. During my tenure, I was able to infuse several technological improvements in the monitoring program which reduced field time and data transcription by at least 30%. Developed and maintain a comprehensive GIS and Relational Database Management System (RDMS) for spatial and biological data to link coral reef, seagrass, fish population, seabird, water quality and sea turtle datasets together into one cohesive unit. Created interactive programs to ensure correct data entry into computerized systems, served as primary statistical consultant for data analysis, and presented results of data analysis to NPS management.

National Park Service

Virgin Islands / S Florida Cluster – Long Term Ecological Monitoring

Dates Employed: Apr 1999 – Oct 1999

Ecologist/Data Manager (Grade GS-0401-11): Primary duties were to develop and maintain a comprehensive Relational Database Management System for spatial and biological data associated with the Virgin Islands-LTEM program. I was responsible for the upkeep of computer systems and linking previously collected datasets together into one cohesive unit. As the lead individual for the VI-LTEM program, I provided oversight for the construction of statistically defensible I & M protocols that are consistent with current policies and guidelines. Hired new employees, tracked budgets and projected budgetary needs into the future. I increased the visibility of the Virgin Islands-LTEM program by increasing communication and information flow to the national NPS I&M Program, higher level management in each park, and division managers within each park.

National Park Service

Prairie Cluster-Long Term Ecological Monitoring Program

Wilson's Creek National Battlefield

Dates Employed: Sep 98 – Apr 99

Ecologist/Data Manager (Grade GS-0401-11 (Term Position)): Primary duties were to develop and maintain a comprehensive Relational Database Management System for spatial and biological data associated with the Prairie Cluster LTEM program. As Data Manager, I met with Principal Investigators which were writing monitoring protocols and worked to standardize data collection procedures while ensuring contracted work fulfilled NPS I&M goals. I constructed digital databases using geographically registered data, analyzed and derived new data themes to interpret long-term monitoring data, ensured that documentation of these datasets was maintained and that long-term archiving, integration, and retrieval of data sets produced by the Prairie Cluster LTEM program and supporting cooperators occurred. I was program liaison with GIS providers to ensure appropriate development of spatial layers and integration of Prairie Cluster LTEM datasets into GIS themes. I provided technical support with respect to accuracy, precision and completeness of all resultant datasets of Prairie Cluster LTEM work. Other duties included interpreting aerial photographs, satellite and other types of data using knowledge of geography, physical and biological resources and wrote a scope of work for an adjacent land use study using historic aerial photographs dating to 1936. I installed and integrated GIS and data management software programs and provided training on new software applications.

EPA Response: The EPA disagrees with the commenter's statements; the EPA followed its procedures and guidance, including those for good data and statistical practices, good statistical analysis practices, consistency of methods and models, and the ability to replicate analytical results. The EPA disagrees with the commenter that the EPA's proposed standard lacks scientific and statistical merit. As discussed throughout the *Response to Comments* document, the EPA has used best available, peer-reviewed science to inform its decision making. See section 1.3 of the *Response to Comments* document, and section I and III.A-D of the FRN

and section 3 of the *Response to Comments* document for summaries of best available science used for preliminary regulatory determinations of four PFAS. Please see section IV of the FRN, as well section 4.1.2 of the EPA response in this *Response to Comments* document, particularly the EPA response to comment Doc. #1774, SBC-045680, for discussion of the EPA's health-based approach, which relies on the EPA's guidance and procedures and the best available science for the toxicity assessments for the six PFAS.

In response to the commenter's critique that the agency considered research produced by external authors, the EPA notes that excluding this research would ignore the best available science, given that the vast majority of peer-reviewed science is produced by scientists not employed by the EPA. The EPA has addressed other specific comments raised by the commenter in subsequent sections of the *Response to Comments* document.

California-Nevada Section American Water Works Association (CA-NV AWWA) (Doc. #1775, SBC-045267)

May 30, 2023

Jennifer McLain

Director

Office of Ground Water and Drinking Water

U.S. Environmental Protection Agency

1201 Constitution Avenue, NW

Washington, DC 20004

Re: Docket EPA-HQ-OW-2022-0114 FRL 8543-01-OW – Proposed National Primary Drinking Water Regulation for Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS)

Dear Dr. McLain:

The California-Nevada Section of the American Water Works Association (CA-NV AWWA) is pleased to have the opportunity to submit comments on the proposed National Primary Drinking Water Regulation (NPDWR) for the PFAS compounds, PFOA and PFOS. CA-NV AWWA comprises the members of the American Water Works Association in California and Nevada: over 5,000 water professionals and over 500 water utilities of all sizes and types, collectively providing the drinking water for over 90 percent of the population of the two states, or about 40 million people. Many of our member utilities also provide wastewater collection and treatment service to their communities.

Per- and polyfluoroalkyl substances (PFAS) burst into public awareness as a drinking water and wastewater contaminant, triggering massive efforts to understand the full impacts of this broad category of thousands of chemical compounds. The water sector is on a steep learning curve

along with government regulators about the geographic occurrence, the health effects, the effective methods for treatment and disposal or destruction of the substances, and the cost and economic feasibility of dealing with this new scourge. CA-NV AWWA strongly supports the regulatory system developed under the statutory framework of the Safe Drinking Water Act (SDWA), which rests on application of the best scientific knowledge of human health effects, expert understanding of technical feasibility, and careful analysis of the economic feasibility of a proposed regulation. AWWA has been a leader in pursuing the goal of safe and affordable water and successful, well managed utilities since its formation in 1881 – and in the case of the California-Nevada Section, since 1920. We support following these same objectives and established SDWA regulatory processes as EPA and drinking water providers strive to protect public health and balance competing, sometimes incompatible factors.

CA-NV AWWA supports the extensive comments submitted by the American Water Works Association and wishes to highlight some of the main concerns our members have raised. First, we have concerns with several technical aspects of the proposed regulation: misapplication of the Practical Quantitation Limits (PQLs); inclusion of nonviable "trigger levels"; effects of the novel Hazard Index (HI) as proposed; and constraints on both laboratory capacity and capabilities. Second, we find the economic feasibility analysis to be inadequate by relying on incomplete PFAS occurrence data, underestimating the cost of compliance for water systems and communities nationwide, and being unresponsive to serious concerns about the impact on household affordability, contrary to environmental justice concerns expressed to the Agency. Third, CA-NV AWWA has several concerns about the regulatory process underway. We make several recommendations on steps and timeframes EPA should adopt to strengthen this rulemaking process and implementation of the regulation when it is promulgated.

EPA Response: Please see section 1.3 of the EPA response in this *Response to Comments* document. For additional discussion on PQLs, trigger levels, and laboratory capacity please see sections 5.1, 8.8, and 7 of the *Response to Comments* document. For additional discussion on the MCLG derivation for a PFAS mixture (Hazard Index), please see section 4.3 of the *Response to Comments* document. Please see section 13.3 of the *Response to Comments* document for a discussion on costs and affordability.

California-Nevada Section American Water Works Association (CA-NV AWWA) (Doc. #1775, SBC-045282)

Until practical and achievable PFAS regulations are developed, CA-NV AWWA supports the use of existing health protective measures already implemented by states and EPA to protect public health.

EPA Response: Please see section 1.3 of the EPA response in this *Response to Comments* document.

American Fluoridation Society, Inc. (Doc. #1776, SBC-043830)

May 30, 2023

U.S. Environmental Protection Agency

Office of Ground Water and Drinking Water

Mail Code 2822IT

1200 Pennsylvania Avenue NW

Washington, DC 20460

Re: Docket ID No. EPA-HQ-OW-2022-0114—PFAS National Primary Drinking Water Regulation

To Whom it May Concern,

On behalf of, and as President of, the American Fluoridation Society, Inc., we would like to comment on the Environmental Protection Agency's proposal to reduce exposure to several per- and polyfluoroalkyl (PFAS) substances in drinking water. These comments are in response to your Federal Register notice of March 29, 2023 (88 FR 18638).

The American Fluoridation Society, Inc. is a 501c4 not for profit that works to assure that all residents of the U.S. served by community water systems continue to have community water fluoridation (fluoridation, water fluoridation). We are a group of healthcare professionals that do not receive any income or remuneration for our efforts to defend, protect, and to expand water fluoridation.

Water fluoridation is the only public oral health measure that provides health equity among everyone in our country. We must continue to provide fluoridation uninterrupted to our families as it is the only cost-effective means to provide the right amount of fluoride to everyone on community water systems. Fluoridation does not take a change in behavior or cognitive effort for people to realize its benefits. Water fluoridation reduces cavities by at least 25% for adults and children regardless of age, race, ethnicity, socioeconomic status, level of education, or access to dental care. As of 2018, the U.S. Centers for Disease Control and Prevention lists the number of U.S. residents served by fluoridation to be in excess of 207 million people.

Water fluoridation improves the general health of our nation's families through improving good oral health. You cannot have good general health without good oral health. For many families, fluoridation is the only dental preventive care that they will ever receive.

The American Fluoridation Society applauds the EPA for its diligence to protect our residents from the health effects of PFAS "forever" manmade chemicals. We all want to improve the lives of our residents in all ways that we possibly can without removing positive measures that protect them from preventable diseases. Dental cavities are the number one chronic disease of adults and

children, multiple times more common than asthma, diabetes, and obesity. Cavities are an infectious and transmissible disease that is reduced by at least 25% by water fluoridation.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Metropolitan Water District of Southern California (Doc. #1777, SBC-045427)

May 30, 2023

U.S. Environmental Protection Agency

EPA Docket Center

Office of Ground Water and Drinking Water Docket, Mail Code 2822IT 1200

Pennsylvania Avenue NW

Washington, DC 20460

Subject: Docket ID No. EPA–HQ– OW–2022–0114 -- PFAS National Primary Drinking Water Regulation Rulemaking

Dear Sir/Madam:

The Metropolitan Water District of Southern California (Metropolitan) appreciates the opportunity to comment on the United States Environmental Protection Agency's (EPA's) proposed PFAS National Primary Drinking Water Regulation (NPDWR) Rulemaking. As a regional water wholesaler, Metropolitan delivers water to 26 member agencies (including 14 cities, 11 municipal water districts, and one county water authority), which in turn, directly or through their customers, provide water to approximately 19 million people in southern California. Metropolitan's mission is to provide its service area with adequate and reliable supplies of high-quality water to meet present and future needs in an environmentally and economically responsible way.

The issue of per- and polyfluoroalkyl substances (PFAS) in drinking water supplies is of growing concern in southern California, including for many of Metropolitan's member agencies and other retail water and groundwater management agencies within our region. Perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) have been detected in groundwater in monitoring wells, private drinking water wells, and public drinking water systems across the country. [FN1: See 87 Fed. Reg. 54415, at 54417 (Sept. 6, 2022).] PFOA and PFOS have been detected in over 400 groundwater wells in southern California alone. [FN2: GeoTracker PFAS Map (ca.gov)] Water agencies have taken numerous groundwater wells out of service due to PFAS detections and are seeking alternative supplies or investing in costly treatment to ensure a safe and reliable water supply for their communities.

Metropolitan supports EPA's effort to regulate PFOA and PFOS in drinking water and recognizes EPA is uniquely qualified to address the complex issues surrounding PFAS in the environment. In this letter, Metropolitan highlights the operational feasibility and financial impacts of the proposed NPDWR Rulemaking which water agencies may face and provides recommendations to strengthen the regulation. Specifically, Metropolitan has the following comments and recommendations:

1. EPA's proposed Maximum Contaminant Levels (MCLs) and Maximum Contaminant Level Goals (MCLGs) for PFHxS, GenX chemicals, PFNA, and PFBS are premature and should follow EPA's established regulatory process.

2. EPA should consider data from UCMR 5 and updated treated drinking water occurrence data from states for PFHxS, GenX chemicals, PFNA, and PFBS.

3. Current analytical methods cannot reliably quantify PFOA and PFOS at the proposed trigger level of 1.3 parts per trillion (ppt).

4. EPA should consider the consequences and impacts of using the proposed Hazard Index approach.

5. EPA should fully consider the economic impacts and feasibility of the proposed regulations.

These comments are supported by a more detailed explanation below.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. For additional information on MCLs and MCLGs, please see sections 4 and 5 of the *Response to Comments* document, respectively. For additional discussion of UCMR 5 data, please see section 6.8 of the *Response to Comments* document. For additional discussion of analytical methods, please see section 7 of the *Response to Comments* document. For additional discussion on the Hazard Index approach, please see section 4.3.2 of the *Response to Comments* document. For additional discussion on economic impacts and feasibility, please see section 13 of the *Response to Comments* document.

Metropolitan Water District of Southern California (Doc. #1777, SBC-045438)

Conclusion

Metropolitan supports EPA's efforts to address the issue of PFAS in drinking water supplies. However, absent sufficient occurrence data, adequate analytical methods and lab capacity, feasible procedures for treating and disposing of residuals, and a thorough economic analysis, Metropolitan is concerned that this regulatory action may have far-reaching implications and could unintentionally harm water agencies, as well as their ratepayers. Metropolitan urges EPA to ensure that regulatory decisions are made after appropriate consideration of the likely consequences and all available data, the proposed NPDWR Rulemaking's benefits justify the costs, and accountability and transparency are promoted as described in this letter.

Metropolitan appreciates the attention that EPA is placing on this important issue that impacts drinking water systems across the country. If you have any questions regarding these comments, please contact me at prochelle@mwdh2o.com or (909) 392-5155.

Sincerely,

Paul A. Rochelle, Ph.D.

Water Quality Section Manager Water System Operations

[Attachment 1: see docket ID EPA-HQ-OW-2022-0114-1777]

EPA Response: The EPA acknowledges this comment. As discussed in the FRN and sections 1.1, 1.3, and 13 of the *Response to Comments* document, the EPA is taking this action after full consideration of the likely consequences and available data, costs and benefits, and ensuring accountability and transparency. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Uttara Jhaveri (Doc. #1778, SBC-045452)

Conclusion

Ultimately, the regulation's purpose is to protect and promote human health and safety. The permissible limit should be more achievable considering the current technology and economic feasibility. The scope of the regulation should be extended to other PFAS, which are part of the UCMR, and cost-benefit analysis should highlight the public health benefit and 'Polluter Pays Principle' to push the rulemaking with stakeholders.

I appreciate the opportunity to comment on the "PFAS National Primary Drinking Water Regulation Rulemaking," and I hope that the regulations create a safer environment and drinking water standards for our community and children. The regulation is historic and a much-anticipated step towards providing clean and safe drinking water for Americans.

Sincerely,

Uttara Jhaveri

Healthcare Attorney

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see generally section 1.3 of the EPA response in this *Response to Comments* document, and please see section 4.3.5 in response to the request to incorporate additional PFAS into the scope of the final rule.

San Diego County Water Authority, CA (Doc. #1779, SBC-045285)

May 30, 2023

The Honorable Michael S. Regan

Administrator

U.S. Environmental Protection Agency

William Jefferson Clinton Building

1201 Pennsylvania Avenue, N.W.

Washington, D.C. 20460

RE: PFAS National Primary Drinking Water Regulation – Docket ID No. EPA-HW-OW-2022-0114

Dear Administrator Regan:

The San Diego County Water authority (Water Authority) appreciates the opportunity to provide comments on the U.S. Environmental Protection Agency's (EPA) proposed PFAS National Primary Drinking Water Regulation. The Water Authority is a regional wholesale water supply agency whose mission is to provide a safe and reliable water supply to 24 retail member agencies in San Diego County. We provide approximately 80% of the water used in San Diego County, sustaining a $240 billion economy and quality of life for 3.3 million residents. The Water Authority supports EPA establishing drinking water standards for FPAS to protect health, and offer the following additional comments:

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR with additional considerations. Please see section 1.3 of the EPA response in this *Response to Comments* document.

San Diego County Water Authority, CA (Doc. #1779, SBC-045292)

In closing, we support EPA taking steps to protect public health, and encourage EPA to prioritize protecting source water quality and investing in research to reduce the impacts of costs to end users. If you have any questions, please contact Lesley Dobalian at LDobalian@sdcwa.org.

Sincerely,

Kelley Gage

Director of Water Resources

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR with additional considerations. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Coralie Pryde (Doc. #1781, SBC-043813)

Comment on Docket ID: EPA-HQ-OW-2022-0114.

From: Coralie Pryde, Wilmington, DE

Date: May30, 2023

I strongly support the EPA's proposed action to establish a National Primary Drinking Water Regulation that would create enforceable limits for the concentrations of PFOA and PFOS in our drinking water.

I believe regulations would be particularly important in Delaware. We have had several situations in which drinking water levels near military airports and sites used for testing PFOAS on fires were extremely high. In the city of New Castle, PFOS levels as high as 4500 ppt were measured in city wells. [FN1: https://apnews.com/ar1cle/business-health-environment-and-nature-956fa8e2d60f3e5b2f92B520ea2ac53]

Tests near Dover Air Force Base showed levels of POA and PFOS of about 290.000 ppt a decade after a fire from a plane crash necessitated the use of massive amounts of fire-fighting foam. [FN2: https://www.delawareonline.com/story/opinion/2022/12/10/contaminated-delaware-bases-threaten-vulnerable-communi1es/69715281007/] This contamination was found to have spread to nearby wells serving Environmental Justice communities.

Water from these extremely contaminated wells has bens treated by filtration. State officials say that PFAS contamination in such sites is now "acceptable", but it is not clear what standard is being used.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Northwest Biosolids Association et al. (Doc. #1783, SBC-043791)

Thank you for the opportunity to comment on the National Drinking Water Regulations for Per- and polyfluoroalkyl substances (PFAS) proposed by the Environmental Protection Agency (EPA) on March 31, 2023. Our collective biosolids associates represent Publicly Owned Treatment Plants (POTWs), Farmers, Foresters, Scientists and Regulators from across the U.S. We applaud EPA's efforts to protect public health by minimizing exposure to PFAS from drinking water sources. There is more work to be done and we offer the following attached comments to further efforts on protection.

May 30, 2023

SUBMITTED ELECTRONICALLY: HTTPS://WWW.REGULATIONS.GOV

Subject:

Docket ID #EPA-HQ-OW-2022-0114 Per- and polyfluoroalkyl substances (PFAS): Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) National Primary Drinking Water Regulation Rulemaking

To Whom It May Concern:

On behalf of NW Biosolids Association, Mid-Atlantic Biosolids Association, Northeast Biosolids and Residuals Association, Midwest Biosolids Association, Virginia Biosolids Council, and Southeast Biosolids Association, thank you for the opportunity to comment on the National Drinking Water Regulations for Per- and polyfluoroalkyl substances (PFAS) proposed by the Environmental Protection Agency (EPA) on March 31, 2023. Our collective biosolids associates represent Publicly Owned Treatment Plants (POTWs), Farmers, Foresters, Scientists and Regulators from all four corners of the U.S. We applaud EPA's efforts to protect public health by minimizing exposure to PFAS from drinking water sources. National Drinking Water Regulations have implications for other regulated programs. Therefore, we offer the following comments for the agency to consider before establishing drinking water regulations for these substances.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR with additional considerations. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Silent Spring Institute (Doc. #1784, SBC-045798)

We commend the EPA for proposing drinking water MCLs for PFOA, PFOS, PFHxS, HFPO-DA, PFNA, and PFBS. Below is a summary of our main points:

1. There is strong evidence of harm from low-dose exposures to PFOA and PFOS, including for sensitive subpopulations such as pregnant women, children, and nursing individuals.

2. Setting standards for PFHxS, HFPO-DA, PFNA, and PFBS, in addition to PFOA and PFOS, is appropriate given strong evidence for adverse health effects and their prevalence in public water supplies.

3. Regulating PFHxS, HFPO-DA, PFNA, and PFBS cumulatively under a hazard index is appropriate. It is a practical decision for addressing noncancer effects, and has been previously applied in numerous regulatory settings such as Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). We recognize the proposed rule as a step in the right direction toward a class-based approach.

4. The Health Risk Reduction and Cost Analysis (HRRCA) likely omits or underestimates significant health and environmental benefits to PFAS limits in drinking water.

5. EPA should target support towards communities and water systems that bear the brunt of PFAS contamination, including, but not limited to, small water systems, rural or isolated

systems, overburdened systems, communities of color, low-income communities, and communities in proximity to PFAS-manufacturing and media-disposal facilities.

In addition to our comments on the current proposed standards, we have included supplemental comments for EPA's consideration after these current standards are finalized. Beyond the six compounds included in the current draft standards, other PFAS are also prevalent in U.S. public water supplies and are linked with adverse health outcomes.

The proposed standards will go a long way toward addressing this class of pervasive, highly persistent, and toxic compounds that are well documented to be associated with many health concerns and should be finalized as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. For additional discussion on the HRRCA, please see section 13 of the *Response to Comments* document. For additional discussion about other PFAS, please see section 4.3.5 of the *Response to Comments* document. For additional discussion about environmental justice, please see section14.10 of the *Response to Comments* document.

Bailey Smith (Doc. #1787, SBC-045808)

Thus, this public comment seeks to elaborate on the reasons for which I support EPA's proposed rule as well as address the following requests for comments from the EPA:

• "what may be needed for water systems to effectively communicate information about the PFAS [National Primary Drinking Water Regulations] NPDWR to the public,"[FN3: PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18638, 18731 (proposed Mar. 29, 2023) (to be codified at 40 C.F.R. pts. 141 and 142) [hereinafter "Proposed Rule"].]

• "the impacts that the disposal of PFAS contaminated treatment residuals may have in communities adjacent to the disposal facilities,"[FN4: Proposed Rule, supra note 3 at 18731.] and

• "proposed determination to set [maximum contaminant levels] MCLs at 4.0 ppt for PFOA and PFOS."[FN5: Id. at 18730.]

Ultimately, I believe that EPA's proposed rule will benefit the public health and this comment aims to express support for it as well as provide recommendations to strengthen it.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR with additional considerations. For the requests for comment from the EPA on the listed topics, please see the below EPA responses in this *Response to Comments* document. Regarding communications between water systems and the public, please see section 1.2 in this *Response to Comments* document, including the EPA response to comment Doc. #1787, SBC-045810. For further discussion regarding disposal of PFAS contaminated treatment residuals, please see section 10.4.3, particularly the EPA response

to comment Doc. #1787, SBC-045813. For comments regarding the set MCLs for PFOA and PFOS, please see section 5.1.1, particularly the EPA response to comment Doc. #1787, SBC-045814.

Bailey Smith (Doc. #1787, SBC-045816)

Ultimately, I believe it is in the public's best interest for the EPA to move forward with its "PFAS National Primary Drinking Water Regulation Rulemaking." The proposed rule comports with SDWA's "best available science" standard [FN50: 42 U.S.C. § 300g-1(b)(3)(A)(i).] and protects vulnerable communities.

Thank you for your time and consideration.

Sincerely,

Bailey Smith, J.D., LL.M.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mindi Messmer (Doc. #1788, SBC-044704)

From: Mindi Messmer <mmessmer@me.com>

Sent: Tuesday, May 30, 2023 6:14 PM

To: OW-Docket

Subject: Support for regulating PFAS chemicals in drinking water (EPA DOCKET ID NO: EPA-HQOW-

2022-0114)

Attachments: PFAS MCLs_53023.pdf

Please find the attached comments on EPA DOCKET ID NO: EPA-HQ-OW-2022-0114).

Thank you.

Mindi Messmer, MS, PG, CG

May 30, 2023

Mr. Michael Regan, Administrator

U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, N. W. Washington, D.C. 20460

Re: Support for regulating PFAS chemicals in drinking water (EPA DOCKET ID NO: EPA-HQ-OW-2022-0114)

Dear Administrator Regan,

I, like many others, were pleased to see the revised health advisories (HAs) for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) and issued new HAs for four additional PFAS (US Environmental Protection Agency, 2022). The new HAs for PFOA and PFOS HAs are 17,500 times lower than the prior HAs and are below the current capabilities of laboratories to detect PFOA and PFOS. This supports what many of us have been saying for years: there is no safe level of exposure to PFOA and PFOS and prior HAs greatly underestimated health risks from PFOA and PFOS (Grandjean & Clapp, 2015).

Without federal action to curb public exposure, between 2016 and 2022, legislators like me in New Hampshire in several other states including New Jersey, New York, Vermont, and Massachusetts, etc. took action to regulate PFOA and PFOS, and other PFAS chemicals in drinking water in response to concerns raised by exposed communities like mine. The states enacted MCLs that were approximately 1/10th of the 2016 EPA HAs.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Fairfax Water (Doc. #1789, SBC-045311)

In closing we offer the following summary of our comments:

1. Fairfax Water supports the development of primary drinking water standards for PFAS compounds based on the best available science and understanding of risk as part of a national, comprehensive regulatory regime to remove these substances from the environment.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Fairfax Water (Doc. #1789, SBC-045293)

From: Jamie Bain Hedges <jhedges@fairfaxwater.org>

Sent: Thursday, May 25, 2023 1:59 PM

To: OW-Docket

Subject: Docket ID No. EPA-HQ-OW-2022-0114

Attachments: Fairfax Water Comments on PFAS Rule_5_25_23.pdf

The attached comments are provided in reference to Docket ID No. EPA-HQ-OW-2022-0114, PFAS National Primary Drinking Water Regulation Rulemaking.

Thank you,

Jamie Bain Hedges, P.E.

General Manager

Fairfax Water

703-289-6011

May 25, 2023

Ms. Radhika Fox Assistant

Administrator Office of Water

U.S. Environmental Protection Agency

EPA Docket Center

Office of Ground and Drinking Water Docket

Mail Code 2822IT

1200 Pennsylvania Avenue

Washington, D.C. 20460

Re: Docket ID No. EPA-HQ-OW-2022-0114

PFAS National Primary Drinking Water Regulation Rulemaking

Dear Assistant Administrator Fox:

Fairfax Water is a not-for-profit utility that proudly provides high quality drinking water to over two million residents of Northern Virginia. One in four Virginians receives water produced by Fairfax Water. We operate two water treatment plants sourced by the Occoquan Reservoir and Potomac River respectively, with a combined production capacity of 345 million gallons per day.

Fairfax Water supports the development of primary drinking water standards for PFAS compounds based on the best available science and understanding of risk. A national standard is preferable to the current patchwork of differing state standards and will provide clarity for both water utilities and the public we serve. However, we do have significant concerns with aspects of the proposed regulation and its successful implementation.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR as well as additional considerations. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Metropolitan Washington Council of Governments (COG) (Doc. #1791, SBC-043770)

From: Lisa Ragain <lragain@mwcog.org>

Sent: Tuesday, May 30, 2023 6:16 PM

To: OW-Docket

Subject: EPA-HQ-OW-2022-0114

Attachments: CBPC Comment Letter- EPA PFAS NPDWR.pdf

To: U.S. Environmental Protec□on Agency

EPA Docket Center

EPA-HQ-OW-2022-0114

Mail Code 28221T

1200 Pennsylvania Avenue, NW

Washington, DC 20460

From: Lisa Ragain

Principal Water Resources Planner

Metropolitan Council of Governments

202-962-3357 (o)

503-927-3322 (c)

May 30, 2023

The Honorable Michael S. Regan Administrator

U.S. Environmental Protection Agency

Office of the Administrator, Mail Stop 1101A 1200 Pennsylvania Avenue, NW Washington, DC 20004

Re: Docket ID No. EPA-HQ-OW-2022-0114, Development of the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

Dear Administrator Regan,

I am writing on behalf of the Metropolitan Washington Council of Governments (COG) Chesapeake Bay and Water Resources Policy Committee (CBPC) to provide our committee's comments on the proposed per- and polyfluoroalkyl substances (PFAS) National Primary Drinking Water Regulations (NPDWR). COG is a nonprofit association, with a membership of

300 elected officials from 24 local governments, the Maryland and Virginia state legislatures, and U.S. Congress. Every month, more than 1,500 officials and experts connect through COG to develop solutions to the region's major challenges and plan for the future. Established in 1998, the CBPC is comprised of local elected officials and representatives from COG's member governments and water and wastewater utilities in the metropolitan Washington region. The CBPC recommends water resources policies to the COG Board of Directors, addressing issues related to water and wastewater treatment, local water quality, stormwater management, flooding, and more.

COG and our member jurisdictions have a long history of partnership with the federal government, including strong support for environmental regulations based on sound science and equity. We share the same goal as EPA of ensuring the delivery of clean, safe drinking water to the public. Considering the persistent nature of PFAS and their potential human health risks, COG supports EPA's decision to regulate PFOS and PFOA in drinking water.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Ohio Environmental Council (Doc. #1794, SBC-045319)

From: Melanie Houston <mhouston@theoec.org>

Sent: Saturday, May 27, 2023 10:31 PM

To: OW-Docket

Cc: Chris Tavenor; ekelly@theoec.org; Nathan Johnson

Subject: Comments regarding Proposed PFAS National Primary Drinking Water Regulation (Docket ID: EPA- HQ-OW-2022-0114)

Attachments: Ohio Environmental Council Comments to US EPA on Drinking Water Standards for PFAS.May 30, 2023.pdf

Hello:

Please see attached comments from the Ohio Environmental Council regarding Proposed PFAS National Primary Drinking Water Regulation (Docket ID: EPA-HQ-OW-2022-0114).

Thank you,

Melanie

May 27, 2023

Ms. Radhika Fox Assistant

Administrator Office of Water

U.S. Environmental Protection Agency

1200 Pennsylvania Ave. NW

Mail code: 4101M

Washington, DC 20460–0001

RE: Comments regarding Proposed PFAS National Primary Drinking Water Regulation (Docket ID: EPA-HQ-OW-2022-0114)

Dear Assistant Administrator Fox:

The Ohio Environmental Council appreciates the opportunity to provide comments on EPA's proposed National Primary Drinking Water Regulation (NPDWR) for six PFAS including perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO-DA, commonly known as GenX Chemicals), perfluorohexane sulfonic acid (PFHxS), and perfluorobutane sulfonic acid (PFBS). In 2018, the Ohio Environmental Council submitted a petition for rulemaking to the EPA pertaining PFAS, outlining the need for comprehensive regulation under the Safe Drinking Water Act and Clean Water Act. Since submission, the science surrounding PFAS has provided even more evidence demonstrating its risks. And while it has taken nearly five years for the agency to take substantive action under either law, we're excited by these first steps, and look forward to additional PFAS regulation over the coming years.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Peggy Kurtz (Doc. #1799, SBC-046043)

I urge you to approve these regulations as written. And then to begin the work to halt the approval of all new PFAS.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Massachusetts Municipal Association (MMA) (Doc. #1800, SBC-043759)

May 30, 2023

Michael S. Regan, Administrator

U.S. Environmental Protection Agency

EPA Docket Center, OLEM Docket, Mail Code 28221T

1200 Pennsylvania Avenue, NW

Washington, DC 20460

Submitted via Regulations.gov

Re: Docket ID No. EPA-HQ-OW-2022-0114 - National Primary Drinking Water Regulation Rulemaking for per- and polyfluoroalkyl substances (PFAS)

Dear Administrator Regan,

On behalf of the 351 cities and towns of the Commonwealth, the Massachusetts Municipal Association (MMA) is writing to provide comments on the proposed National Primary Drinking Water Regulation (NPDWR) for per- and polyfluoroalkyl substances (PFAS).

We deeply appreciate the Environmental Protection Agency's (EPA) focus to address emerging contaminants in drinking water, including PFAS. The MMA greatly appreciates the intent of the proposed regulations by the EPA to protect public and environmental health. Massachusetts municipalities and their public water systems (PWS) take their role as stewards of clean, safe drinking water seriously. Their continued protection of this important natural resource to the residents, businesses, and communities they serve reflects an ongoing commitment to the well-being of the environment, our economy, and our daily lives.

As one of several states with experience regulating PFAS through a state-specific drinking water standard, we would like to provide further context on how the EPA's proposed National Primary Drinking Water Regulation for PFAS could impact the cities and towns of Massachusetts in the future, and identify areas of concern.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR with additional considerations. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Millie Garcia-Serrano (Doc. #1803, SBC-044283)

May 30, 2023

U.S. Environmental Protection Agency

EPA Docket Center

Mail Code 2822IT

1200 Pennsylvania Avenue, NW

Washington, DC 20460

RE: ASTSWMO Comments on U.S. EPA's Proposed PFAS National Priority Drinking Water Regulation; Docket ID No. EPA-HQ-OW-2022-0114

Dear Sir or Madam:

The Association of State and Territorial Solid Waste Management Officials (ASTSWMO) appreciates the opportunity to provide comments regarding the U.S. Environmental Protection Agency's (EPA) proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation (NPDWR) Rulemaking. ASTSWMO is an association representing the waste management and remediation programs of the 50 States, five Territories, and the District of Columbia (States). Our membership includes State program experts from all States who manage State-run programs under both the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and the Resource Conservation and Recovery Act (RCRA).

ASTSWMO commends the EPA for taking this important step to regulate perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO–DA) and its ammonium salt (also known as GenX chemicals), perfluorononanoic acid (PFNA), perfluorobutane sulfonic acid (PFBS), and mixtures of these PFAS under the Safe Drinking Water Act (SDWA) and is pleased to offer comments on this proposed regulation.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046122)

Conclusion

For the millions of people with PFAS in their tap water, strong federal drinking water standards are essential and long overdue. We appreciate EPA's leadership in developing this proposed rule, and we urge EPA to resist efforts to weaken its proposal. We further urge EPA to revise its proposed HBWCs and to incorporate the changes outlined above. Finally, EPA should move quickly to finalize this rule and to pursue s for the PFAS that are not addressed in the proposed rule.

If you have any questions about these comments, please contact Jon Kalmuss-Katz (jkalmusskatz@earthjustice.org) or Katherine O'Brien (kobrien@earthjustice.org) at Earthjustice or Erik Olson (eolson@nrdc.org), Anna Reade (areade@nrdc.org) or Katherine Pelch (kpelch@nrdc.org) at the Natural Resources Defense Council.

Respectfully submitted,

Alaska Community Action on Toxics

Alliance for the Great Lakes

Buckeye Environmental Network

Center for Biological Diversity

Clean Cape Fear

Clean Water Action

Delaware Riverkeeper Network

Earthjustice

Elevate Energy

Environmental Advocates NY

Environmental Defense Fund

Environmental Justice Task Force -Tucson

Environmental Working Group

Fight for Zero

Green Science Policy Institute

Holy Spirit Missionary Sisters, USA-JPIC

Lawyers for Good Government

Merrimack Citizens for Clean Water

Mountain Watershed Association

National PFAS Contamination Coalition

Natural Resources Defense Council

North Carolina Conservation Network

Ohio Environmental Council

Ohio River Foundation

Passaic River Coalition

People Over Petro Coalition

PfoaProject NY

Religious Coalition for the Great Lakes

Save The River, Upper St. Lawrence Riverkeeper

Save Our Sky Blue Waters

Sierra Club

Toxic Free NC

Union of Concerned Scientists

Vermont Natural Resources Council

Waterkeeper Alliance

Zero Waste Washington

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR with additional considerations. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046094)

May 30, 2023

Via Regulations.gov

Assistant Administrator Radhika Fox Office of Water

U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, N.W. Washington, DC 20460

Re: PFAS National Primary Drinking Water Regulation Rulemaking, Docket No. EPA– HQ–OW–2022–0114

Dear Assistant Administrator Fox:

The undersigned 36 organizations submit these comments on EPA's proposed National Primary Drinking Water Regulation for six per- and polyfluoroalkyl substances ("PFAS") (the "Proposed Rule"). [FN1: Preliminary Regulatory Determination and Proposed Rule, PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18,638 (Mar. 29, 2023). The six PFAS covered by the Proposed Rule are perfluorooctanoic acid ("PFOA"), perfluorooctane sulfonic acid ("PFOS"), perfluorohexane sulfonic acid ("PFHxS"), hexafluoropropylene oxide dimer acid and its ammonium salt ("GenX"), perfluorononanoic acid ("PFNA"), and perfluorobutane sulfonic acid ("PFBS") (collectively, the "Six PFAS").] Our organizations include communities with PFAS-contaminated drinking water, scientists who study the harms associated with PFAS, and longtime advocates for health- protective PFAS drinking water standards.

We strongly support EPA's issuance of PFAS drinking water standards, which are a critical and long overdue step to address a public health crisis that threatens the health and lives of hundreds of millions of people in the United States. For decades, communities across the country have been drinking tap water contaminated with PFAS, a large class of long-lasting and dangerous

chemicals. People in those communities have lost parents, children, and other loved ones to cancer, liver and heart disease, and other diseases associated with PFAS. The longer that EPA waits to establish federal drinking water standards, the more people will be exposed, in violation of the Safe Drinking Water Act ("SDWA") mandate to reduce the harmful effects from drinking water contaminants as much as feasible.

The Proposed Rule is an important step forward. EPA correctly found that there is no safe exposure level for many PFAS, including PFOA and PFOS, and it proposed maximum contaminant levels ("MCLs") for PFOA and PFOS that are readily achievable using existing treatment technologies. EPA also recognized the serious health risks associated with exposures to mixtures of GenX, PFNA, PFBS, and PFHxS—PFAS that are frequently found in the same drinking water supplies—and it proposed an MCL that is designed to protect people who are exposed to those contaminants individually or in combination. EPA's proposed Maximum Contaminant Level Goals ("MCLGs") and MCLs are supported by an extensive factual record and are required by the SDWA. EPA must resist efforts to weaken those levels and diminish the rule's protections.

At the same time, EPA must revise aspects of its Proposed Rule that would limit the rule's reach and undermine its effectiveness. First, EPA should update its Health Based Water Concentrations ("HBWCs")—the toxicity values that EPA uses to calculate the drinking water limits—for PFBS, GenX, PFNA, and PFHxS to address the dangers those chemicals pose to infants, children, and other higher-risk populations. Second, while EPA conducted an extensive economic analysis and found that the Proposed Rule's benefits outweigh its costs, that analysis understates the benefits of reduced PFAS exposures and should be expanded to better account for health benefits that EPA has acknowledged but has not yet quantified or monetized. Third, when determining compliance with the new drinking water standards, EPA should consider all monitoring results with detectable PFAS rather than treating samples with lower but still harmful levels of PFAS as though they were PFAS-free. Fourth, EPA should maintain the minimum requirement of quarterly PFAS monitoring for all water systems with prior PFAS detections and should not permit such systems to evade further detections and necessary treatment by monitoring just once or twice every three years. Finally, EPA should mandate public notification of MCL violations within 24 hours, as is required for all violations that may cause serious, short-term health effects.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. For additional discussion on toxicity values for HFPO-DA, PFNA, PFHxS, and PFBS, please see section 4.3 in the *Response to Comments* document. For more discussion on the benefits from this final PFAS NPDWR, please see section 13.4 of the *Response to Comments* document. For discussion of the comparison of costs and benefits for this action, please see section 13.8 of the *Response to Comments* document. For more discussion on compliance monitoring, please see section 8.1.2 in the *Response to Comments* document. For

additional discussion on public notification, please see section 9.2 of the *Response to Comments* document.

Green America (Doc. #1809, SBC-045339)

May 30, 2023

Docket (EPA-HQ-OW-2022-0114)

Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

Green America, a nonprofit organization founded in 1982, submits the following comment to the Environmental Protection Agency on behalf of 11,877 individuals.

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is an important first step to protecting our families and communities.

PFAS chemicals are now found in the drinking water of many communities nationwide. These toxic chemicals are linked to cancer, immune suppression, developmental harm, and many other adverse health impacts.

The EPA's proposed rule would provide safer drinking water for millions of people, save thousands of lives, and prevent tens of thousands of serious PFAS-related illnesses each year.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

National Wildlife Federation Action Fund (Doc. #1811, SBC-045341)

May 30, 2023

Michael S. Regan, Administrator

U.S. Environmental Protection Agency

Dear Administrator Regan,

Attached are a total of 15,851 comments submitted by advocates and supporters of the National Wildlife Federation Action Fund in support of the Environmental Protection Agency's proposed drinking water standards to provide long overdue federal protections against six types of highly toxic PFAS.

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Clean Water Action (Doc. #1812, SBC-045817)

US Environmental Protection Agency

EPA docket center office of groundwater and drinking water docket

mail code 2822 IT

1200 Pennsylvania Ave. NW

Washington DC 20460

Dear Administrator Reagan,

Attached are 6 handwritten comments in favor of the proposed enforceable Safe Drinking Water Act limits on the two oldest PFAS chemicals - PFOA and PFOS. These comments were collected by the Clean Water Action Philadelphia Field Canvass from individuals who live in Southeastern PA, an area with PFAS contaminated groundwater well above the proposed limits.

Thank you for reading these comments and considering the major impact PFAS contamination has already had in Southeastern PA communities.

April 25th, 2023

Dear Administrator Reagan,

As a mother of 3 small children, living in an area adjacent to the Willow Grove Air Force Base in PA, and having worked in Willow Grove for five years, I am so grateful that the ban on PFAS is nearly complete. We work so hard to do what we can to protect our families and rely on agencies such as yours to protect us as well through protections and legislation that limits the harmful impact of these dangerous chemicals.

Sincerely,

Carmen Lewis

Oreland, PA

Dear Representative Nelson

Thank you for your leadership on Environmental Justice in the State House! Please continue by co-sponsoring Rep. Bullock's “Environmental Justice - Permit Applications” bill. This will make a major impact on communities all across PA!

Name

Address & Zip Code

US Environmental Protection Agency

EPA Docket Center

Office of Ground Water and Drinking Water Docket

Mail Code 2822T

1200 Pennsylvania Ave. NW

Washington, DC 20460

Dear Administrator Reagan,

Thank you for proposing health protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects. The EPA should finalize these safe drinking Water Act regulations as quickly as possible, including the hazard index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures and water around the country. EPA should address the whole class of PFAS chemicals whenever possible.

All parts of EPA and the federal government need to take equally bold action to stop pfos pollution, hold polluters accountable, and curtail users of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Clean water should be a priority for every living being.

Sincerely

Judith A. Krouse

2337 Tague Ave

Glenside, PA 19038

Dear Administrator Reagan,

EPA should finalize the Safe Drinking Water Act regulations ASAP, and should address the whole class of PFAS chemicals wherever possible.

Sincerely,

Jenna Hoffman

517 Filbert Rd.

Oreland PA 19075

US Environmental Protection Agency

EPA docket center

office of groundwater drinking water docket

mail code 28221T

1200 Pennsylvania Ave. NW

Washington DC 20460

Dear Administrator Reagan,

Attached are 113 handwritten comments in favor of the proposed enforceable Safe Drinking Water Act limits on the two oldest PFAS chemicals- PFOA and PFOS. These comments were collected by the Clean Water Action Philadelphia Field Canvas from individuals who live in Southeastern PA, an area with PFAS contaminated groundwater well above the proposed limits.

Thank you for reading these comments and considering the major impact PFAS contamination has already had southeastern PA communities.

US Environmental Protection Agency

EPA docket center office of groundwater and drinking water docket

mail code 2822 IT

1200 Pennsylvania Ave. NW

Washington DC 20460

Dear Administrator Reagan,

Attached are 100 handwritten comments in favor of the proposed enforceable safe drinking Water Act limits on the two oldest PFAS chemicals- PFOA and PFOS. These comments were collected by the Clean Water Action Philadelphia Field Canvass from individuals who live in Southeastern PA, an area with PFAS contaminated groundwater well above the proposed limits.

Thank you for reading these comments and considering the major impact PFAS contamination has already had in southeastern PA communities.

Thank you for proposing limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible!

Dear Admin Regan,

Adopt the EPA regulations is the least you can do. PFAS is a huge class, and this is a small step toward solving the problem.

Dawn [Illegible]

Wynnewood, PA 19096

U.S. Environmental Protection Agency

EPA Docket Center

Office of Ground Water and Drinking Water Docket

Mail Code 2822IT

1200 Pennsylvania Avenue NW

Washington DC 20460

Dear Administrator Regan,

Thank you for proposing health-protection limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects. EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal gov. need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

[Illegible] 340 [Illegible] Meadow Lane

[Illegible]

To EPA/Administrator Regan-

Think you for your work. I'm writing to add any encouragement to the push for the EPA to address all PFAS chemicals. The EPA & the federal government need to work together to ban all PFAS chemicals and hold polluters accountable! We want Safe Water for all kids, families, pregnant women, single people living their best life and teenagers, too. Everyone! Keep up your good work and push for more- ban PFAS!

Thank you for protecting us.

-Lindsay, Owen & Eliot

U.S. Environmental Protection Agency

EPA Docket Center

Office of Ground Water and Drinking Water Docket

Mail Code 2822IT

1200 Pennsylvania Avenue NW

Washington DC 20460

Dear Administrator Regan,

Thank you for proposing health-protection limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects. EPA should finalize these Safe Drinking Water Act regulations as soon & quickly as possible, including the Hazard Index approach for four PFAS chemicals. Placing [Illegible]…

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Environment America Research & Policy Center (Doc. #1814, SBC-045499)

Dear EPA Administrator Regan,

Attached please find 14,949 individual comments in support of the proposed PFAS drinking water standard from collected by Environment America Research and Policy Center.

RE: Docket ID: EPA-HQ-OW-2022-0114

Dear EPA Administrator Regan:

PFAS are known as "forever chemicals" and can be found everywhere, including clothes, food packaging and even Norwegian Arctic ice. And now these toxic substances are getting into our drinking water, threatening the health of millions of Americans.

I am writing in support of the proposed National Primary Drinking Water Regulation to set low, health-based limits on 6 PFAS chemicals in our drinking water. I also urge the EPA to prevent future PFAS water contamination by phasing out the use of these dangerous substances to begin with.

Sincerely,

[Table 1: Signatures See Docket ID EPA-HQ-OW-2022-0114-1814]

[Attachment 2: Signatures see docket ID EPA-HQ-OW-2022-0114-1814]

[Attachment 3: Signatures see docket ID EPA-HQ-OW-2022-0114-1814]

[Attachment 4: Signatures see docket ID EPA-HQ-OW-2022-0114-1814]

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

US PIRG Education Fund (Doc. #1815, SBC-045347)

Dear EPA Administrator,

Attached please find 6776 individual comments in support of EPA's proposed limits on PFAS in drinking water collected by U.S. PIRG Education Fund.

RE: Docket ID: EPA-HQ-OW-2022-0114

Dear EPA Administrator Regan,

I am writing in support of the proposed National Primary Drinking Water Regulation to set low, health-based limits on six PFAS chemicals in our drinking water. And I also urge the EPA to prevent future PFAS contamination by phasing out the use of these dangerous substances in manufacturing.

By the EPA's own estimation, this new rule if fully implemented will prevent thousands of deaths and reduce tens of thousands of serious PFAS-attributable illnesses. And it comes not a moment too soon -- the Centers for Disease Control and Prevention (CDC) has found these chemicals in the bodies of nearly every American it has tested.

Sincerely,

[Table 1 of 840 signatures: see docket ID EPA-HQ-OQ-2022-0114-1815]

[Attachment 2 “Mass Mail WA (890)”: see docket ID EPA-HQ-OQ-2022-0114-1815]

[Attachment 3 “Mass Mail WA (914)”: see docket ID EPA-HQ-OQ-2022-0114-1815]

[Attachment 4 “Mass Mail WA (907)”: see docket ID EPA-HQ-OQ-2022-0114-1815]

[Attachment 5 “Mass Mail WA (885)”: see docket ID EPA-HQ-OQ-2022-0114-1815]

[Attachment 6 “Mass Mail WA (878)”: see docket ID EPA-HQ-OQ-2022-0114-1815]

[Attachment 7 “Mass Mail WA (599)”: see docket ID EPA-HQ-OQ-2022-0114-1815]

[Attachment 8 “Mass Mail WA (863)”: see docket ID EPA-HQ-OQ-2022-0114-1815]

EPA Response: The EPA acknowledges and appreciates this comment expressing general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

West Virginia Municipal Water Quality Association (Doc. #1816, SBC-044663)

May 30, 2023

By Electronic Submission

U.S. Environmental Protection Agency EPA Docket Center

PFAS: PFOA and PFOS National Primary Drinking Water Regulation Rulemaking, Mail Code 28221T

1200 Pennsylvania Avenue NW Washington, DC 20460

Re: Docket EPA–HQ–OW–2022–0114

Dear Sir/Madam:

The West Virginia Municipal Water Quality Association (WVMWQA) appreciates the opportunity to comment on USEPA's proposed National Primary Drinking Water Regulation (NPDWR) and health-based Maximum Contaminant Level Goals (MCLG) for PFOA and PFOS, as well as PFHxS, HFPO–DA and its ammonium salt, PFNA, and PFBS and their mixtures.

The WVMWQA comprises public utilities statewide in the drinking water, wastewater, and stormwater fields. As public utilities that do not manufacture or use PFAS chemicals in our water or wastewater treatment processes, we are innocent receivers of these chemicals. Our members are dedicated to protecting both public health and the environment. However, as public utilities we must provide these essential services in an affordable and cost-effective manner. We never seek to avoid necessary and appropriate requirements. Instead, we embrace such requirements and simply work to prioritize them and obtain the funding necessary to comply from the public that we serve.

With that perspective, we are compelled to submit these comments because EPA's proposed MCLs for PFAS have the potential to impose the greatest compliance costs in the history of the Safe Drinking Water Act both from a capital as well as ongoing operation and maintenance cost perspective. Such massive and far-reaching regulatory impacts are particularly unprecedented given that thousands of water plants will be impacted and will have to plan, design, and construct still embryonic PFAS barrier technologies at an unprecedented speed. This costly effort will be borne by the customers of public utilities all while PFAS levels in Americans have been dropping dramatically and are poised to plummet even farther due to the legislative, regulatory, and litigation pressure around these chemicals.

Below we explain why we believe EPA's draft MCLs are based upon significant errors which must be addressed and then EPA must republish different MCLs, ideally using a tiered or phased approach that will allow us to prioritize water plant upgrades over a 15- 20-year period. We also explain our significant concern that EPA has chosen to extrapolate public health impacts from literature and animal studies rather than using the extensive human health PFAS-related data both from the Federal Drug Administration and its own information from PFAS hotspots around the country.

We also explain why we believe EPA's cost estimate understates compliance costs by upwards of an order of magnitude while simultaneously overstating public health benefits because EPA has relied on extrapolation and associated uncertainty factors rather than using available public health PFAS-related data.

Finally, it bears noting that our members – and public utilities nationwide – have been aggressively working to characterize and reduce PFAS levels in our finished drinking water, wastewater, and stormwater. On the drinking water side, we have evaluated rebalancing water sources to reduce PFAS levels, working with upstream dischargers to reduce their loadings, and evaluating available technologies should PFAS barrier technology become necessary. We believe enormous PFAS reductions have occurred through these efforts. Thus, we are not waiting

for EPA to adopt MCLs to further minimize PFAS chemicals in public utility drinking water, wastewater, and stormwater. We will continue to make significant further progress while EPA reevaluates its proposed MCLs.

We appreciate the Agency's consideration of our comments and are available to discuss our concerns.

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document. For additional discussion on the set MCLs for the final PFAS NPDWR, please see section 5 of the *Response to Comments* document. For additional discussion on the cost estimates for the rule, please see section 13.3 of the *Response to Comments* document.

Association of Missouri Cleanwater Agencies (Doc. #1817, SBC-044641)

May 30, 2023

By Electronic Submission: Docket EPA–HQ–OW–2022–0114

U.S. Environmental Protection Agency EPA Docket Center

PFAS: PFOA and PFOS National Primary Drinking Water Regulation Rulemaking, Mail Code 28221T

1200 Pennsylvania Avenue NW Washington, DC 20460

Dear Sir/Madam:

The Association of Missouri Cleanwater Agencies (AMCA) appreciates the opportunity to comment on USEPA's proposed National Primary Drinking Water Regulation (NPDWR) and health-based Maximum Contaminant Level Goals (MCLG) for PFOA and PFOS, as well as PFHxS, HFPO–DA and its ammonium salt, PFNA, and PFBS and their mixtures.

AMCA comprises public utilities statewide in the drinking water, wastewater, and stormwater fields. As public utilities that do not manufacture or use PFAS chemicals in our water or wastewater treatment processes, we are innocent receivers of these chemicals. Our members are dedicated to protecting both public health and the environment. However, as public utilities we must provide these essential services in an affordable and cost-effective manner. We never seek to avoid necessary and appropriate requirements. Instead, we embrace such requirements and simply work to prioritize them and obtain the funding necessary to comply from the public that we serve.

With that perspective, we are compelled to submit these comments because EPA's proposed MCLs for PFAS have the potential to impose the greatest compliance costs in the history of the Safe Drinking Water Act both from a capital as well as ongoing operation and maintenance cost perspective. Such massive and far-reaching regulatory impacts are particularly unprecedented given that thousands of water plants will be impacted and will have to plan, design, and construct

still embryonic PFAS barrier technologies at an unprecedented speed. This costly effort will be borne by the customers of public utilities all while PFAS levels in Americans have been dropping dramatically and are poised to plummet even farther due to the legislative, regulatory, and litigation pressure around these chemicals.

Below we explain why we believe EPA's draft MCLs are based upon significant errors which must be addressed and then EPA must republish different MCLs, ideally using a tiered or phased approach that will allow us to prioritize water plant upgrades over a 15-20-year period. We also explain our significant concern that EPA has chosen to extrapolate public health impacts from literature and animal studies rather than using the extensive human health PFAS-related data both from the Federal Drug Administration and its own information from PFAS hotspots around the country.

We also explain why we believe EPA's cost estimate understates compliance costs by upwards of an order of magnitude while simultaneously overstating public health benefits because EPA has relied on extrapolation and associated uncertainty factors rather than using available public health PFAS-related data.

Finally, it bears noting that our members – and public utilities nationwide – have been aggressively working to characterize and reduce PFAS levels in our finished drinking water, wastewater, and stormwater. On the drinking water side, we have evaluated rebalancing water sources to reduce PFAS levels, working with upstream dischargers to reduce their loadings, and evaluating available technologies should PFAS barrier technology become necessary. We believe enormous PFAS reductions have occurred through these efforts. Thus, we are not waiting for EPA to adopt MCLs to further minimize PFAS chemicals in public utility drinking water, wastewater, and stormwater. We will continue to make significant further progress while EPA reevaluates its proposed MCLs.

We appreciate the Agency's consideration of our comments and are available to discuss our concerns.

EPA Response: The EPA refers the commenter to the summary of major public comments for this section. For additional discussion on the set MCL levels for the final PFAS NPDWR, please see section 5 of the EPA response in this *Response to Comments* document. For additional discussion on the cost estimates for the rule, please see section 13.3 of the EPA response in this *Response to Comments* document.

NORTH CAROLINA WATER QUALITY ASSOCIATION (Doc. #1818, SBC-044619)

NORTH CAROLINA WATER QUALITY ASSOCIATION

May 30, 2023

U.S. Environmental Protection Agency EPA Docket Center

PFAS: PFOA and PFOS National Primary Drinking Water Regulation Rulemaking, Mail Code 28221T

1200 Pennsylvania Avenue NW Washington, DC 20460

Re: By Electronic Submission: Docket EPA–HQ–OW–2022–0114

Dear Sir/Madam:

The North Carolina Water Quality Association (NCWQA) appreciates the opportunity to comment on USEPA's proposed National Primary Drinking Water Regulation (NPDWR) and health-based Maximum Contaminant Level Goals (MCLG) for PFOA and PFOS, as well as PFHxS, HFPO–DA and its ammonium salt, PFNA, and PFBS and their mixtures.

The NCWQA comprises public utilities statewide in the drinking water, wastewater, and stormwater fields. As public utilities that do not manufacture or use PFAS chemicals in our water or wastewater treatment processes, we are innocent receivers of these chemicals. Our members are dedicated to protecting both public health and the environment. However, as public utilities we must provide these essential services in an affordable and cost-effective manner. We never seek to avoid necessary and appropriate requirements. Instead, we embrace such requirements and simply work to prioritize them and obtain the funding necessary to comply from the public that we serve.

With that perspective, we are compelled to submit these comments because EPA's proposed MCLs for PFAS have the potential to impose the greatest compliance costs in the history of the Safe Drinking Water Act both from a capital as well as ongoing operation and maintenance cost perspective. Such massive and far-reaching regulatory impacts are particularly unprecedented given that thousands of water plants will be impacted and will have to plan, design, and construct still embryonic PFAS barrier technologies at an unprecedented speed. This costly effort will be borne by the customers of public utilities all while PFAS levels in Americans have been dropping dramatically and are poised to plummet even farther due to the legislative, regulatory, and litigation pressure around these chemicals.

Below we explain why we believe EPA's draft MCLs are based upon significant errors which must be addressed and then EPA must republish different MCLs, ideally using a tiered or phased approach that will allow us to prioritize water plant upgrades over a 15- 20-year period. We also explain our significant concern that EPA has chosen to extrapolate public health impacts from literature and animal studies rather than using the extensive human health PFAS-related data both from the Federal Drug Administration and its own information from PFAS hotspots around the country.

We also explain why we believe EPA's cost estimate understates compliance costs by upwards of an order of magnitude while simultaneously overstating public health benefits because EPA has relied on extrapolation and associated uncertainty factors rather than using available public health PFAS-related data.

Finally, it bears noting that our members – and public utilities nationwide – have been aggressively working to characterize and reduce PFAS levels in our finished drinking water, wastewater, and stormwater. On the drinking water side, we have evaluated rebalancing water sources to reduce PFAS levels, working with upstream dischargers to reduce their loadings, and evaluating available technologies should PFAS barrier technology become necessary. We believe enormous PFAS reductions have occurred through these efforts. Thus, we are not waiting for EPA to adopt MCLs to further minimize PFAS chemicals in public utility drinking water, wastewater, and stormwater. We will continue to make significant further progress while EPA reevaluates its proposed MCLs.

We appreciate the Agency's consideration of our comments and are available to discuss our concerns.

EPA Response: The EPA refers the commenter to the summary of major public comments for this section. For additional discussion on the set MCL levels for the final PFAS NPDWR, please see section 5 of the EPA response in this *Response to Comments* document. For additional discussion on the cost estimates for the rule, please see section 13.3 of the EPA response in this *Response to Comments* document.

South Carolina Water Quality Association (Doc. #1819, SBC-044597)

May 30, 2023

U.S. Environmental Protection Agency EPA Docket Center

PFAS: PFOA and PFOS National Primary Drinking Water Regulation Rulemaking, Mail Code 28221T

1200 Pennsylvania Avenue NW Washington, DC 20460

By Electronic Submission: Docket EPA–HQ–OW–2022–0114

Dear Sir/Madam:

The South Carolina Water Quality Association (SCWQA) appreciates the opportunity to comment on USEPA's proposed National Primary Drinking Water Regulation (NPDWR) and health-based Maximum Contaminant Level Goals (MCLG) for PFOA and PFOS, as well as PFHxS, HFPO–DA and its ammonium salt, PFNA, and PFBS and their mixtures.

The SCWQA comprises public utilities statewide in the drinking water, wastewater, and stormwater fields. As public utilities that do not manufacture or use PFAS chemicals in our water or wastewater treatment processes, we are innocent receivers of these chemicals. Our members are dedicated to protecting both public health and the environment. However, as public utilities we must provide these essential services in an affordable and cost-effective manner. We never seek to avoid necessary and appropriate requirements. Instead, we embrace such requirements

and simply work to prioritize them and obtain the funding necessary to comply from the public that we serve.

With that perspective, we are compelled to submit these comments because EPA's proposed MCLs for PFAS have the potential to impose the greatest compliance costs in the history of the Safe Drinking Water Act both from a capital as well as ongoing operation and maintenance cost perspective. Such massive and far-reaching regulatory impacts are particularly unprecedented given that thousands of water plants will be impacted and will have to plan, design, and construct still embryonic PFAS barrier technologies at an unprecedented speed. This costly effort will be borne by the customers of public utilities all while PFAS levels in Americans have been dropping dramatically and are poised to plummet even farther due to the legislative, regulatory, and litigation pressure around these chemicals.

Below we explain why we believe EPA's draft MCLs are based upon significant errors which must be addressed and then EPA must republish different MCLs, ideally using a tiered or phased approach that will allow us to prioritize water plant upgrades over a 15-20-year period. We also explain our significant concern that EPA has chosen to extrapolate public health impacts from literature and animal studies rather than using the extensive human health PFAS-related data both from the Federal Drug Administration and its own information from PFAS hotspots around the country.

We also explain why we believe EPA's cost estimate understates compliance costs by upwards of an order of magnitude while simultaneously overstating public health benefits because EPA has relied on extrapolation and associated uncertainty factors rather than using available public health PFAS-related data.

Finally, it bears noting that our members – and public utilities nationwide – have been aggressively working to characterize and reduce PFAS levels in our finished drinking water, wastewater, and stormwater. On the drinking water side, we have evaluated rebalancing water sources to reduce PFAS levels, working with upstream dischargers to reduce their loadings, and evaluating available technologies should PFAS barrier technology become necessary. We believe enormous PFAS reductions have occurred through these efforts. Thus, we are not waiting for EPA to adopt MCLs to further minimize PFAS chemicals in public utility drinking water, wastewater, and stormwater. We will continue to make significant further progress while EPA reevaluates its proposed MCLs.

We appreciate the Agency's consideration of our comments and are available to discuss our concerns.

EPA Response: The EPA refers the commenter to the summary of major public comments for this section. For additional discussion on the set MCL levels for the final PFAS NPDWR, please see section 5 of the EPA response in this *Response to Comments* document. For additional discussion on the cost estimates for the rule, please see section13.3 of the EPA response in this *Response to Comments* document.

Wet Weather Partnership (Doc. #1820, SBC-044575)

May 30, 2023

By Electronic Submission: Docket EPA–HQ–OW–2022–0114

U.S. Environmental Protection Agency EPA Docket Center

PFAS: PFOA and PFOS National Primary Drinking Water Regulation Rulemaking, Mail Code 28221T

1200 Pennsylvania Avenue NW Washington, DC 20460

Dear Sir/Madam:

The Wet Weather Partnership (WWP) appreciates the opportunity to comment on USEPA's proposed National Primary Drinking Water Regulation (NPDWR) and health-based Maximum Contaminant Level Goals (MCLG) for PFOA and PFOS, as well as PFHxS, HFPO–DA and its ammonium salt, PFNA, and PFBS and their mixtures.

The Wet Weather Partnership comprises public utilities statewide in the drinking water, wastewater, and stormwater fields. As public utilities that do not manufacture or use PFAS chemicals in our water or wastewater treatment processes, we are innocent receivers of these chemicals. Our members are dedicated to protecting both public health and the environment. However, as public utilities we must provide these essential services in an affordable and cost-effective manner. We never seek to avoid necessary and appropriate requirements. Instead, we embrace such requirements and simply work to prioritize them and obtain the funding necessary to comply from the public that we serve.

With that perspective, we are compelled to submit these comments because EPA's proposed MCLs for PFAS have the potential to impose the greatest compliance costs in the history of the Safe Drinking Water Act both from a capital as well as ongoing operation and maintenance cost perspective. Such massive and far-reaching regulatory impacts are particularly unprecedented given that thousands of water plants will be impacted and will have to plan, design, and construct still embryonic PFAS barrier technologies at an unprecedented speed. This costly effort will be borne by the customers of public utilities all while PFAS levels in Americans have been dropping dramatically and are poised to plummet even farther due to the legislative, regulatory, and litigation pressure around these chemicals.

Below we explain why we believe EPA's draft MCLs are based upon significant errors which must be addressed and then EPA must republish different MCLs, ideally using a tiered or phased approach that will allow us to prioritize water plant upgrades over a 15-20-year period. We also explain our significant concern that EPA has chosen to extrapolate public health impacts from literature and animal studies rather than using the extensive human health PFAS-related data both from the Federal Drug Administration and its own information from PFAS hotspots around the country.

We also explain why we believe EPA's cost estimate understates compliance costs by upwards of an order of magnitude while simultaneously overstating public health benefits because EPA has relied on extrapolation and associated uncertainty factors rather than using available public health PFAS-related data.

Finally, it bears noting that our members – and public utilities nationwide – have been aggressively working to characterize and reduce PFAS levels in our finished drinking water, wastewater, and stormwater. On the drinking water side, we have evaluated rebalancing water sources to reduce PFAS levels, working with upstream dischargers to reduce their loadings, and evaluating available technologies should PFAS barrier technology become necessary. We believe enormous PFAS reductions have occurred through these efforts. Thus, we are not waiting for EPA to adopt MCLs to further minimize PFAS chemicals in public utility drinking water, wastewater, and stormwater. We will continue to make significant further progress while EPA reevaluates its proposed MCLs.

We appreciate the Agency's consideration of our comments and are available to discuss our concerns.

EPA Response: The EPA refers the commenter to the summary of major public comments for this section. For additional discussion on the set MCL levels for the final PFAS NPDWR, please see section 5 of the EPA response in this *Response to Comments* document. For additional discussion on the cost estimates for the rule, please see section 13.3 of the EPA response in this *Response to Comments* document.

Neuse Regional Water and Sewer Authority (Doc. #1822, SBC-044565)

May 26, 2023

Filed via regulations.gov

The Honorable Michael Regan Administrator

Environmental Protection Agency Mail Code: 1101A

1200 Pennsylvania Avenue, N.W. Washington, DC 20460

RE: Comments on Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

Docket ID No. EPA-HQ-OW-2022-0114

Dear Administrator Regan:

The Neuse Regional Water and Sewer Authority ("NRWASA") is a public body established pursuant to Chapter 162A of the North Carolina General Statutes. NRWASA appreciates the opportunity to comment on the Environmental Protection Agency's ("EPA") proposed PFAS National Primary Drinking Water Regulation Rulemaking ("Proposed Rulemaking"). NRWASA

agrees with EPA's overall goal of limiting the public's exposure to PFAS, and we believe our comments will help EPA improve its approach to its regulation of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Neuse Regional Water and Sewer Authority (Doc. #1822, SBC-044567)

,COMMENTS

The Proposed Rulemaking is a welcomed step to protect public health from the harmful effects of PFAS. However, it is important to note that the regulation will have a significant cost for water utilities. It should be implemented only after careful consideration of various factors that impact cost and ability to comply.

Specifically, NRWASA's comments focus on four recommendations. EPA's Proposed Rulemaking should:

1. Address how wholesale water systems with multiple system customers should comply with the new regulations.

2. Temporarily exempt from compliance water systems not responsible for causing the PFAS pollution problem; instead, shift compliance costs to those responsible for creating PFAS pollution, including PFAS manufacturers.

3. Delay the official promulgation of a PFAS National Primary Drinking Water Standard until EPA completes its identification of all PFAS substances and the levels at which it deems such substances harmful so that water systems can treat all regulated PFAS substances effectively through a single capital upgrade to a comprehensive purification system.

4. Provide guidance and support to NRWASA and similarly-situated entities in need of significant, unfunded capital investments to comply with treatment standards under any legally enforceable level.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA addressed the responsibilities of wholesale systems in section I of the FRN and additional discussion on the applicability of this action is in section 1.4 of the EPA response in this *Response to Comments* document. For finished water that is provided through a system interconnection, the wholesale systems will be responsible for conducting the monitoring requirements at the entry point to the distribution system (EPTDS). The final regulation does not require that any monitoring be conducted at a system interconnection point. Where a violation does occur, the wholesale system must notify any consecutive systems of this violation and it is the responsibility of the consecutive system to provide PN to their customers pursuant to § 141.201(c)(1). In addition, wholesale systems must also provide information in Subpart O to

consecutive systems for developing CCRs (§ 141.201(c)(1)). Consecutive systems are responsible for providing their customers with the reports (§ 141.153(a)).

For the exemption requirements, please see section 12.1 of the EPA response in this *Response to Comments* document. For recommendation 3, the EPA disagrees with delaying the official promulgation of the NPDWR. The EPA completed its assessment with the best available science and has determined it has sufficient information to promulgate under SDWA, as discussed in section 1.3 of the EPA response in this *Response to Comments* document. As to the concern for capital upgrades, treatment is available to effectively remove all regulated PFAS substances; please see section XII in the FRN and section 13.3 of the EPA response in this *Response to Comments* document. For information on funding and capital investments, please see section 2.4 of the EPA response in this *Response to Comments* document.

Oneida Nation (Doc. #1825, SBC-044271)

Submitted electronically: Federal eRulemaking Portal: https://www.regulations.gov/

Office of Management and Budget (OMB) 725 17th St., NW

Washington, DC 20503

May 30, 2023

RE: Per- and Polyfluoroalkyl Substances (PFAS) Proposed PFAS National Primary Drinking Water Regulation

Docket ID No. EPA-HQ-OW-2022-0114

To Whom It May Concern:

On behalf of the Oneida Nation, I am submitting comments on the proposed National Primary Drinking Water Regulation (NPDWR) for six PFAS, including perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO-DA, commonly known as GenX Chemicals), perfluorohexane sulfonic acid (PFHxS), and perfluorobutane sulfonic acid (PFBS).

Water Quality Monitoring on the Oneida Reservation

The primary objective of water quality monitoring is to gather environmental information on the water quality of the Reservation. This information is used to detect trends in water quality, measures success and effectiveness of water resource management practices, and to detect water quality/quantity problems on the Reservation. We use the best available science for decision-making related to freshwater ecosystems and communicate this science as necessary to inform the Oneida community and decision makers.

Introduction

On March 14, 2023, EPA announced the proposed National Primary Drinking Water Regulation (NPDWR) for six PFAS compounds including PFOA, PFOS, PFNA, PFHxS, PFBS, and GenX chemicals.

• PFOA and PFOS: EPA is proposing to regulate PFOA and PFOS at a level they can be reliably measured at 4 ppt.

• PFNA, PFHxS, PFBS, and GenX Chemicals: EPA is also proposing a regulation to limit any mixture containing one or more of PFNA, PFHxS, PFBS, and/or GenX Chemicals. For these PFAS, water systems would use an established approach called a hazard index calculation, defined in the proposed rule, to determine if the combined levels of these PFAS pose a potential risk.

The proposed PFAS NPDWR does not require any actions until it is finalized. EPA anticipates finalizing the regulation by the end of 2023. The Agency expects that if fully implemented, the rule will prevent thousands of deaths and reduce tens of thousands of serious PFAS-attributable illnesses. EPA is re-questing public comment on the proposed regulation.

Oneida Environmental, Health and Safety Area supports this action as a first step to having regulatory oversight of these contaminants in drinking water. We believe it is in the best interest of the Oneida Community and the Nation.

More technical version of above description of their action if preferred:

Through this action, EPA is also proposing a National Primary Drinking Water Regulation (NPDWR) and health-based Maximum Contaminant Level Goals (MCLG) for these four PFAS and their mixtures as well as for PFOA and PFOS. EPA is proposing to set the health-based value, the MCLG, for PFOA and PFOS at zero. Considering feasibility, including currently available analytical methods to measure and treat these chemicals in drinking water, EPA is proposing individual MCLs of 4.0 nanograms per liter (ng/L) or parts per trillion (ppt) for PFOA and PFOS. EPA is proposing to use a Hazard Index (HI) approach to protecting public health from mixtures of PFHxS, HFPO-DA and its ammonium salt, PFNA, and PFBS because of their known and additive toxic effects and occurrence and likely co-occurrence in drinking water. EPA is proposing an HI of 1.0 as the MCLGs for these four PFAS and any mixture containing one or more of them because it represents a level at which no known or anticipated adverse effects on the health of persons is expected to occur and which allows for an adequate margin of safety. EPA has determined it is also feasible to set the MCLs for these four PFAS and for a mixture containing one or more of PFHxS, HFPO-DA and its ammonium salt, PFNA, PFBS as an HI of unitless 1.0.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Plymouth Village Water & Sewer District (Doc. #1827, SBC-044554)

May 30, 2023

U.S. Environmental Protection Agency EPA Docket Center

Docket ID: EPA-HQ-OW-2022-0114;

Mail Code 28221T

1200 Pennsylvania Ave., NW Washington, DC 20460

Subject: Docket ID: EPA-HQ-OW-2022-0114; Proposed PFAS Drinking Water Standards

Dear EPA Office of Water:

The Plymouth Village Water & Sewer District's (PVWSD) mission is to provide the highest quality water and wastewater services possible. The Commissioners and staff members' primary responsibility is to the ratepayers. In meeting the needs of the District, we strive to provide clean, safe, and affordable public water and wastewater services, using sound science to define practical policy that protects human health and the environment. As a leader in the discovery, definition, regulation, treatment, and funding to reduce threats caused by per- and polyfluorinated substances (PFAS) chemicals, we are providing important input to EPA's proposed MCLs for six PFAS compounds; PFOA (4 ppt), PFOS (4 ppt), PFNA (Hazard Index 10 ppt), HFPO-DA (Hazard Index 10 ppt), PFHxS (Hazard Index 9 ppt), PFBS (Hazard Index 2000 ppt).

PVWSD and New Hampshire have been at the forefront of this issue in the past decade, having experienced significant contamination issues with firefighting foam (AFFF) at a former airbase on the Seacoast and with a manufacturing facility in Merrimack. PFAS compound prevalence is far and wide, reaching even the most remote parts of our state, including native soils, air, and water. The PVWSD and the state have taken a pro-active approach with sampling, outreach, community engagement, and regulatory action. We have not only sampled PFAS in our drinking water, but also have completed a significant amount of testing of wastewater Biosolids (residuals from wastewater treatment).

Since 2016 our primacy agency, the New Hampshire (NH) Department of Environmental Services (NHDES), and hundreds of public water and wastewater systems and their communities, have spent substantial time and money collecting and analyzing water and sludge samples to identify PFAS occurrence. NHDES requires regulated public water and wastewater systems to continue monitoring for PFAS, with sampling frequencies based on initial occurrence analysis. See where PFAS chemicals are found across the state and review USGS Soil and Sludge Leaching Study data.

In order to develop science-based MCL's/AGQS for each compound protective of the most sensitive population at all life stages, NH legislators adopted Chapter Law 368 directing NHDES to consider: 1) the extent to which the contaminants are found in NH; 2) the ability to detect the

compound; 3) the ability to treat the contaminant; 4) benefits associated with adopting an MCL; and 5) the costs associated with adopting an MCL. NHDES provided a summary technical report on the MCL development that included a health risk assessment for each compound and information on occurrence, and ability to detect and treat these chemicals, along with an estimate of costs and benefits for impacted cities and towns. Although, the report states… "as with any risk assessment, this process was subject to uncertainty and limitations… A major uncertainty was quantifying the exact risks of disease incidence for each compound, which is also a significant challenge for quantifying, or monetizing, the benefits of the proposed MCL's."

EPA Response: The EPA acknowledges the commenters' significant experience in addressing PFAS contamination. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Wisconsin Department of Natural Resources (Doc. #1828, SBC-044800)

May 30, 2023

Jennifer McLain, Director

Office of Ground Water and Drinking Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington, DC 20460

Subject: National Primary Drinking Water Regulations: PFAS Rules Promulgation (88 FR 18638, EPA-HQ-OW-2022-0114)

Dear Dr. McLain,

Wisconsin Department of Natural Resources (WDNR) maintains primacy for implementation of the Safe Drinking Water Act (SDWA) in the state of Wisconsin. WDNR is generally in agreement with the comments provided by the Association of State Drinking Water Administrators (ASDWA) as characterized below, and is hereby submitting these comments on the proposed PFAS standards during the public comment period between 3/29/2023 – 5/30/2023.

EPA Response: The EPA acknowledges WDNR's comments.

National PFAS Contamination Coalition (Doc. #1830, SBC-044550)

Via www.regulations.gov

U.S. Environmental Protection Agency EPA Docket Center

EPA-HQ-OW-2022-0114

Mail Code 28221T

1200 Pennsylvania Avenue, NW Washington, DC 20460

May 30th, 2023

Public Comment in Support of EPA-HQ-OW-2022-0114

Dear Administrator Regan, Assistant Administrator Fox, and Director McClain,

The National PFAS Contamination Coalition is pleased to submit comments in support of the proposed EPA drinking water standard for six PFAS. A strong enforceable national drinking water standard has been long overdue and are essential for ensuring safe, clean water for all.

The National PFAS Contamination Coalition is composed of more than 30 community groups from across the country who are directly impacted by PFAS from a variety of contamination sources. We envision a PFAS-free world where people are not exposed to any PFAS, where the environment and public health are protected, where there is justice for the victims of PFAS exposure, and where laws and regulations prevent contamination disasters like this from happening again. We strongly believe that everyone deserves clean, safe, sustainable, and affordable drinking water supplies.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

National PFAS Contamination Coalition (Doc. #1830, SBC-044552)

We have experienced the impacts of PFAS contamination first hand. We have known the true cost of this crisis, not just physically, but financially and emotionally as well. We know that the establishment of a strong Maximum Contaminant Levels is critical to protect communities from the harmful effects of these chemicals, and to ensure that our drinking water is safe for all.

We support the EPA's proposal to regulate PFOA and PFOS as individual contaminants at 4 parts per trillion (ppt), and PFHXS, PFNA, PFBS, and HFPO-DA (commonly referred to as GenX Chemicals) together at a Hazardous Index of 1.0 (unitless), as well as the requirement for public water systems to monitor for these PFAS, notify the public to the levels of these PFAS, as well as reduce the levels of these PFAS in drinking water if they exceed the proposed standards.

These new regulations will provide a clear standard for water utilities and other organizations to follow, and will ensure that they are taking appropriate steps to remove PFAS from our water supply. We applaud the acknowledgment that individual PFAS and PFAS mixtures can have an impact on our health. We believe using mixtures as a regulatory tool is an incredibly useful framework for regulating additional groups of PFAS. We hope to see implementation of this as soon as possible as we know that all of these chemicals have a cumulative impact on our bodies.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Groundwater Resources Association of California (Doc. #1831, SBC-045359)

GRA believes that by incorporating all available statewide PFAS data, considering equity and resource availability for smaller water systems, evaluating groundwater considerations in the cost-benefit-risk analyses, ensuring clarity in sampling and monitoring requirements, and adding clarity and flexibility to the sampling/monitoring requirements, the proposed ruling could be further improved, which in turn increases the acceptance among industries and practitioners. We hope that EPA finds our comments useful in finalizing the proposed MCLs. If you have any questions or require clarifications regarding GRA's comments, please do not hesitate to contact the GRA Technical Committee Chair, Dr. Abhishek Singh (asingh@intera.com).

GRA appreciates the opportunity to provide comments on the proposed PFAS regulations. We also wish to acknowledge and thank all members of the GRA Technical Committees and participants from other affiliate organizations who participated and contributed to the review and comment process.

Sincerely,

Abhishek Singh, PhD, PE GRA Director

GRA Technical Committee Chair

Roohi Toosi, PE

GRA Director

GRA Technical Committee Member

Michael Schaefer

GRA Technical Committee Member

cc: GRA Board of Directors, Technical Committee Members

EPA Response: The EPA used the best available public health information including data from UCMR 3 and state occurrence data for the PFAS NPDWR. For additional information on the occurrence data used in the PFAS NPDWR, please see section VI of the FRN and section 6 of the EPA response in this *Response to Comments* document. Please see section 1.3 of the EPA response in this *Response to Comments* document for discussion on small system considerations. The EPA includes small system flexibilities in the PFAS NPDWR and additional information can be found in section 10.5 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenter that further evaluation of groundwater considerations in the benefit cost analysis is necessary. Benefit cost estimates are informed by

data on occurrence, exposure, and treatment in both ground and surface water systems. For additional information on the EPA's methodology to assess impacts to PWSs including ground water systems, see the economic analysis for the final NPDWR (USEPA, 2024a). For the EPA responses to comments raised on the cost-benefit model, please see section 13.2 of the EPA response in this *Response to Comment*s. The EPA has provided clarity on sampling and monitoring in the final rule based on public comments. For more discussion on compliance monitoring, please see section 8 of the EPA response in this *Response to Comments* document.

Corix Infrastructure Inc. (Doc. #1834, SBC-045360)

May 30, 2023

U.S. Environmental Protection Agency

EPA Docket Center

Docket EPA-HQ-OW-2022-0114

Mail Code 28221T

1200 Pennsylvania Avenue

Washington, D.C. 20460

Dear Administrator Regan:

RE: Comments by the Corix on EPA PFAS National Primary Drinking Water Regulation Rulemaking, Docket No. EPA-HQ-OW-2022-0114.

Corix Infrastructure Inc., on behalf of itself and its operating subsidiaries, respectfully submits this comment letter regarding the U.S. Environmental Protection Agency's PFAS National Primary Drinking Water Regulation Rulemaking published in the Federal Register on March 29, 2023.

Through its operating subsidiaries, Corix provides drinking water to approximately 800,000 people in 18 states and two Canadian provinces. Corix is a member of the National Association of Water Companies (NAWC) and agrees with the NAWC in its support for the EPA taking action to address the health risk posed by the presence of PFAS chemicals in drinking water supplies. We support a national drinking water standard for PFOA and PFOS based on the best available science and an appropriate balancing of potential risks and the costs to implement the rulemaking.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document..

Little Hocking Water Association (Doc. #1835, SBC-045506)

After confronting years of informational obstacles and getting no assistance from the state of Ohio, LHWA was finally forced to file a Resource Conservation and Recovery Act (RCRA) citizen suit and damage claims in federal court. The suit led to the first judicial finding of DuPont's liability for PFOA contamination. Little Hocking Water Ass'n v. E.I. du Pont de Nemours & Co., 91 F. Supp. 3d 940 (S.D. Ohio 2015). The parties resolved the case through settlement, the terms of which are confidential.

At Little Hocking, a granular activated carbon (GAC) plant treats the PFOA contamination before it enters the LHWA water supply pipes. To date the GAC plant's dual set of carbon beds filters out HFPO-DA down to the detection limits. If bi-weekly testing shows exceedance of the 15 ppt trigger between both carbon beds, a new set of carbon beds is added.

Even though this arrangement reduces the prospective additive drinking water risk for LHWA water users, it does not eliminate the risk of "drinking DuPont's surfactant" during the decades of secrecy. This cost carries forward and so does the cost of regulatory delay. LHWA had a front row seat to the promises of regulation. After starting to learn of the severity of the PFOA contamination in its wellfield in 2002, LHWA spent many days in Washington DC as a member of the Enforceable Consent Agreement (ECA) process under the Toxic Substances Control (TSCA) review process. LHWA spent considerable resources to serve throughout this process and was the only representative of a public water system to serve as a member throughout the process. At the end of the ECA process, LHWA was told that there would be an MCL for PFOA in 2005.

While LHWA fully supports most of today's 2023 proposed MCLs, Little Hocking is keenly aware of the staggering health and social cost incurred over the 18 years it took to reach this proposed action. Those health and social costs of the period of regulatory delay will continue to be incurred by the community served by LHWA even after the MCLs are adopted. This speaks to prompt, albeit overdue, adoption of robust MCLs that are protective of human health.

PFAS is a pressing public health crisis created by entities which greatly profited while they created the crisis. Those entities should promptly pay for measures to abate threats.

Little Hocking's story illustrates that the pervasive contamination of PFOA and other PFAS in the environment, including public water supplies, and the potential threats to public health have been known to the few companies that invented and/or manufactured PFAS for decades. It shows the gross excesses of self-regulation. The contamination and threat were intentionally hidden for decades, creating a public health crisis. This makes EPA's current proposed rulemaking under the Safe Drinking Water Act (SDWA), and other environmental laws, urgently needed.

EPA Response: The EPA acknowledges the commenters' efforts in addressing PFAS contamination and its general support for the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document..

WASHINGTON STATE BOARD OF HEALTH (Doc. #1837, SBC-044264)

STATE OF WASHINGTON

WASHINGTON STATE BOARD OF HEALTH

PO Box 47990 • Olympia, Washington 98504-7990

May 30, 2023

Michael S. Regan, Administrator

U.S. Environmental Protection Agency

EPA Docket Center

Office of Ground Water and Drinking Water Docket

Mail Code 2822IT

1200 Pennsylvania Avenue, NW

Washington, DC 20460

Subject: Public Comment on PFAS National Primary Drinking Water Regulation, Docket ID No. EPA-HQ-OW-2022-0114

Dear Mr. Regan,

Thank you for the opportunity to comment on the proposed National Primary Drinking Water Regulation for per- and polyfluoroalkyl substances (PFAS). The Washington State Board of Health (Board) is submitting the following comments in strong support of this proposed action.

In Washington State, the Board serves as the rulemaking authority and the Washington Department of Health serves as the regulatory agency administering the rules for Group A public drinking water systems under chapter 246-290 WAC, Group A Public Water Supplies.

In the absence of national primary drinking water standards for PFAS, the Board adopted State Action Levels (SALs) for five PFAS analytes that took effect January 1, 2022. Implementation of the rule's monitoring requirements coupled with past voluntary monitoring for PFAS is providing valuable insights and detections of PFAS drinking water contamination in many water supplies across the state.

National maximum contaminant levels (MCLs) are essential for protecting public health and creating greater regulatory certainty for drinking water systems, local communities, and other parties. Adoption of national primary drinking water standards for PFAS will help set a level playing field for this national drinking water problem that involves significant financial, emotional, and public health effects on communities served by public water systems. Sadly,

these same effects extend to people and businesses served by small drinking water systems and private wells in impacted areas.

EPA Response: The EPA acknowledges the commenters' efforts in addressing PFAS contamination and its comment in general agreement with the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document..

Gujarat Fluorochemicals Limited (Doc. #1840, SBC-044852)

Fluoropolymers are indispensable for critical applications in many existing and emerging technologies like electric vehicles, hydrogen fuel cells and semiconductors but the use of PFAS processing aids is not necessary for manufacturing of majority of such fluoropolymers. As a result, GFL supports EPA's efforts to protect human health and environment by setting MCLs and MCGLs to address the presence of PFAS of concern in drinking water, and looks forward to working with the Agency to foster the shift to alternatives to GenX and other PFAS of Concern. Such targeted regulation encourages the shift towards the use of non-PFAS processing aids in fluoropolymer manufacturing.

GFL would be pleased to answer any questions and to provide additional technical assistance as the EPA refines this proposed NPDWR.

[Attachment 1: see docket ID EPA-HQ-OQ-2022-0114-1840].

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please section 1.3 of the EPA response in this *Response to Comments* document..

American Chemistry Council (ACC) (Doc. #1841, SBC-044814)

ACC urges the Agency to withdraw its preliminary regulatory determination and proposed standard for the four PFAS until its has collected additional information on the national occurrence of these substances. ACC further urges EPA to reconsider the proposed standards for PFOA and PFOS in light of the inability to determine that the benefits of the current proposal justify its costs, per Section 1412(b)(4)(C) of the SDWA.

Sincerely,

Stephen P. Risotto

Senior Director

Enclosure

EPA Response: The EPA disagrees with the need to collect additional information on national occurrence to promulgate this PFAS NPDWR. The available UCMR 3 and state occurrence data are sufficiently robust to support the final rule. Please see sections 3.1.2, 3.2.2,

6.2 and 6.5 of the EPA response in this *Response to Comment*s document. In addition, please see the EPA response to comment Doc. #1841, SBC-044810, SBC-044819 and SBC-044840 in section 6.5 of this *Response to Comments* document for detailed responses to specific concerns about national occurrence provided to the commenter.

The EPA Administrator reaffirms the finding made at proposal under Section 1412(b)(4)(C) of SDWA that the quantified and nonquantifiable benefits of the MCLs justify the costs. See section XII of the preamble for this final rule and section 13.8 of this *Response to Comments* document for an explanation of this finding.

American Chemistry Council (ACC) (Doc. #1841, SBC-044824)

As a result of the numerous and significant shortcomings of its analysis, the Agency cannot determine that the benefits of the proposed standards for PFOA and PFOS justify the costs per Section 1412(b)(4)(C) of the Act. [FN4: 42 U.S.C. Section 300g-1(b)(4)(C)] Nor can the Administrator conclude that there is a meaningful opportunity for public health risk reduction by reducing levels of PFBS, HFPO-DA, PFHxS, or PFNA per Section 1412(b)(1)(A). EPA must revise its economic analysis to better assess the costs and benefits of reducing PFOA and PFOS levels in drinking water systems and must delay any attempt to regulate PFBS, HFPO-DA, PFHxS, or PFNA until it has collected sufficient and appropriate data to make a regulatory determination regarding these substances.

EPA Response: The EPA disagrees that it cannot determine that the benefits for PFOA and PFOS justify the rule costs or that the Administrator cannot conclude there is a meaningful opportunity for regulation of PFBS, HFPO-DA, PFHxS, and PFNA. Please see section 1.3 of the EPA response in this *Response to Comments* document.. For an explanation of why the Administrator confirms the finding made at proposal under section 1412(b)(4)(C) of SDWA that the quantified and nonquantifiable benefits of the MCLs justify the costs, see section XII of the PFAS NPDWR preamble and section 13.8 of the EPA response in this *Response to Comments* document. For discussion on the Administrator's meaningful opportunity determinations, please see sections 3.1.3 and 3.2.3 of the EPA response in this *Response to Comments* document.. For additional general information on the health risk reduction from the PFAS NPDWR, please see section 13 of the EPA response in this *Response to Comments* document.

Washington Association of Sewer and Water Districts (Doc. #1842, SBC-044768)

VIA (PDF) FEDERAL ERULEMAKING PORTAL REGULATIONS.GOV

May 30, 2023

United States Environmental Protection Agency (USEPA)

Re: Comments on Proposed Rule: Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation [Federal Register Docket ID EPA-HQ-OW-2022-0114-0027]

The Washington Association of Sewer and Water Districts (WASWD) appreciates the opportunity to comment on the proposed rules setting limits for PFAS compounds in drinking water. WASWD represents more than 180 public water and sewer districts in the state, serving nearly 25% of our state's population. These districts provide cost-effective water and sewer services—ranging from the state's largest population centers, to the smallest rural communities. The potential for contamination is always a concern. Beyond our wellheads and collection points, we have no control over what is sprayed, injected, discharged, or built proximal to our facilities. The situation with PFAS is especially disturbing due to the longevity of the compounds, their toxicity, and their ability to travel long distances in water and soil.

We all must move forward with efforts to eliminate the use of PFAS compounds and clean up contaminated drinking water. For this reason, we commend EPA for moving forward to propose national standards for some of these compounds. As our members are the "boots on the ground" people dealing day to day to provide safe drinking water to our state's residents, our comments on the proposed rule focus on the significant challenges for implementation.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Metropolitan Washington Council of Governments (Doc. #1843, SBC-044751)

May 30, 2023

The Honorable Michael S. Regan Administrator

U.S. Environmental Protection Agency

Office of the Administrator, Mail Stop 1101A 1200 Pennsylvania Avenue, NW Washington, DC 20004

Re: Docket ID No. EPA-HQ-OW-2022-0114, Development of the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

Dear Administrator Regan,

I am writing on behalf of the Metropolitan Washington Council of Governments (COG) Chesapeake Bay and Water Resources Policy Committee (CBPC) to provide our committee's comments on the proposed per- and polyfluoroalkyl substances (PFAS) National Primary Drinking Water Regulations (NPDWR).

COG is a nonprofit association, with a membership of 300 elected officials from 24 local governments, the Maryland and Virginia state legislatures, and U.S. Congress. Every month, more than 1,500 officials and experts connect through COG to develop solutions to the region's major challenges and plan for the future. Established in 1998, the CBPC is comprised of local elected officials and representatives from COG's member governments and water and wastewater

utilities in the metropolitan Washington region. The CBPC recommends water resources policies to the COG Board of Directors, addressing issues related to water and wastewater treatment, local water quality, stormwater management, flooding, and more.

COG and our member jurisdictions have a long history of partnership with the federal government, including strong support for environmental regulations based on sound science and equity. We share the same goal as EPA of ensuring the delivery of clean, safe drinking water to the public. Considering the persistent nature of PFAS and their potential human health risks, COG supports EPA's decision to regulate PFOS and PFOA in drinking water.

EPA Response: The EPA acknowledges and appreciates this comment supporting the EPA's decision to regulate PFOS and PFOA in drinking water. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Amigos Bravos (Doc. #1844, SBC-045399)

Regulation for PFAS is Growing

The State of New Mexico is taking its concern over PFAS and turning it into action via monitoring, sampling, and increased regulation. Regulatory action has been taken by the New Mexico Environment Department (NMED), conjointly with the NM Office of the Attorney General, against the DoD. Additionally, NMED, in partnership with the US Geological Survey, and the NM Department of Health, engage in PFAS testing across the state, and the State of New Mexico follows EPA guidelines on PFAS regulation. New Mexico is also taking action by engaging with affected communities, working with industry for PFAS mitigation and remediation, partnering with academia to research and create advancements in capture and eradication solutions, and most of all- taking action to hold polluters accountable. Amigos Bravos partners with the New Mexico Department of Environment to help bring community concern on PFAS to the fore, and work on evidence and science based solutions that support science and policy when mitigating and regulating PFAS.

The EPA is required to make amendments to drinking water standards every five years. This process includes developing a contaminant candidate list of unregulated chemicals that are known to and can occur in public water systems, as well as specifically including the MCL's of these chemicals. Several States are taking initiative and developing more stringent PFAS MCL standards as more information on impacts to health and the environment comes available and New Mexico is working to do the same.

Amigos Bravos supports the proposed NPDWR rule and urge the EPA to finalize it quickly, and move to take additional action on PFAS including taking steps to make sure PFAS doesn't enter our environment by: limiting new PFAS production, cleaning up PFAS contaminated sites, sunset the most toxic and environmentally mobile forms of PFAS as it has with PFOA, PFOS, PFHxS, and ensure that federal and state issued Clean Water Act permits can adequately regulate

PFAS discharges by setting effluent limits and regulating PFAS under the Resource Conservation and Recovery Act.

EPA Response: The EPA acknowledges the commenters' efforts in addressing PFAS contamination and its comment in general agreement with the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

The Chemours Company FC, LLC (Doc. #1845, SBC-046049)

May 30, 2023

Submitted via the Federal eRulemaking Portal: https://www.regulations.gov/

U.S. Environmental Protection Agency

EPA Docket Center, Office of Ground Water and Drinking Water Docket

1200 Pennsylvania Avenue NW

Washington, DC 20460

Re: Comments of The Chemours Company FC, LLC

EPA PFAS National Primary Drinking Water Regulation Rulemaking

Docket ID No. EPA–HQ–OW–2022–0114

Dear Sir or Madam:

We are submitting these comments on behalf of The Chemours Company FC, LLC ("Chemours" or "the Company") on EPA's proposed PFAS National Primary Drinking Water Regulation Rulemaking ("Proposed Rulemaking") under the Safe Drinking Water Act ("SDWA"), including specific comments with respect to EPA's proposed regulation of hexafluoropropylene oxide dimer acid and its ammonium salt. These compounds are sometimes referred to collectively by the trade name "GenX" or "GenX technology" and will be collectively referred to here as "HFPO-DA."[FN1: Chemours is a domestic manufacturer that uses HFPO-DA as a polymerization aid in the manufacture of fluoropolymers. Fluoropolymers—extremely stable molecules composed of multiple carbon-fluorine bonds—are essential to a variety of key industries. To provide just a few examples, fluoropolymers are used in every car, airplane, and cellphone. They are critical to maintaining the integrity and quality of most prescription drugs; to producing medical equipment; and to manufacturing computer chips. Fluoropolymers are also necessary for green technology, including hydrogen fuel cells.]

In the Proposed Rulemaking, EPA has proposed to set both the Maximum Contaminant Level Goal ("MCLG") and the enforceable Maximum Contaminant Level ("MCL") as a Hazard Index ("HI") of 1.0 for mixtures containing one or more of the following four PFAS compounds: perfluorohexane sulfonic acid ("PFHxS"), HFPO-DA, perfluorononanoic acid ("PFNA"), and perfluorobutane sulfonic acid ("PFBS"). In calculating the HI value, EPA has proposed to use

Health Based Water Concentrations ("HBWCs") of 9 parts per trillion ("ppt") for PFHxS, 10 ppt for HFPO-DA, 10 ppt for PFNA, and 2000 ppt for PFBS. In sum, with respect to HFPO-DA under EPA's proposal, if water delivered to any user of a public water system ("PWS") were to contain greater than 10 ppt of HFPO-DA, then the HI of 1.0 (and hence, the MCLG and MCL) would be exceeded. If such water were to contain less than 10 ppt of HFPO-DA but detectable amounts of PFHxS, PFNA, or PFBS, then the HI of 1.0 (and the MCLG and MCL) could also be exceeded, depending on the specific amount of each compound detected as compared to its HBWC. If any of the levels of PFHxS, PFNA, or PFBS exceeded their respective HBWC, any detectable level of HFPO-DA could be considered an exceedance of the MCL.

Chemours supports EPA's efforts to protect public drinking water using established statutory and regulatory processes and the best available science. However, EPA's proposed regulation of HFPO-DA under the SDWA, as part of the Proposed Rulemaking, falls far short of these standards. As discussed below, as well as in the materials attached hereto and in the materials incorporated herein by reference, EPA's proposed regulation of HFPO-DA does not comply with the legal requirements of the SDWA and is based on substantial scientific flaws at every step of its development, including flaws that Chemours previously identified and requested EPA to correct. EPA's cost-benefit analysis for the proposed regulation is also flawed. Accordingly, Chemours requests that EPA withdraw the proposed regulation.

EPA Response: The EPA disagrees that the proposed regulation of HFPO-DA does not comply with the legal requirements of SDWA, that it is not based on the best available science, and that the EPA's cost-benefit analysis is flawed. Please see sections 1.3, as well as sections 3.1, 3.2, 4, 6, and 13 of the EPA response in this *Response to Comments* document for discussion on the regulatory determinations, health and occurrence data, and cost-benefit analysis. For information on the appropriateness of using the Hazard Index approach for MCLGs, please see section 4.3.2 of the EPA response in this *Response to Comments* document. For information on the appropriateness of using the Hazard Index approach for MCLs, please see section 5.2 of the EPA response in this *Response to Comments* document.

Regarding the commenter's statement on water delivered to systems with HFPO-DA and the use of the Hazard Index, the EPA would like to clarify that HFPO-DA is just one component of the Hazard Index. In the instance that there is a concentration of HFPO-DA below its HBWC, it's not that the detectable level of HFPO-DA below its HBWC is individually considered an MCL exceedance, but it is that when combined with any of the other three PFAS in the Hazard Index that the combination of concentrations exceeding the overall Hazard Index is considered an exceedance of the Hazard Index MCL. Moreover, as part of the Hazard Index, the four PFAS are not considered in isolation.

The EPA disagrees with the request to withdraw this NPDWR, as the EPA has completed its assessment with the best available science and has determined there is sufficient information to promulgate under SDWA. Please see section 1.3 of the EPA response in this *Response to Comments* document for more information.

For the specific concerns regarding legal requirements and scientific flaws referenced in this comment, please see the applicable sections of the EPA response in this *Response to Comments* document responding to the detailed comments. The EPA responses are in section 3, specifically the EPA responses to comment Doc. #1845, SBC-046050; SBC-046051; SBC-046052; and SBC-046057.

The EPA disagrees that the cost-benefit analysis is flawed. For additional information on the appropriateness of the cost-benefit analysis, please see section 13.3.2, specifically the EPA response to comment Doc. #1845, SBC-046055, in this *Response to Comments* document.

Midwest Environmental Advocates +more (Doc. #1846, SBC-045822)

Finally, we commend the Agency's decision to regulate these PFAS in public water systems and provide great risk reduction benefits nationwide. In Wisconsin, the roughly four million people relying on public water systems for drinking water will benefit from adequate monitoring of their water supplies and the subset of people already impacted by PFAS contamination will greatly benefit from protective action under the proposed NPDWRs.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Midwest Environmental Advocates +more (Doc. #1846, SBC-045818)

May 30, 2023

Assistant Administrator Radhika Fox

Office of Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, N.W.

Washington, DC 20460

Submitted via Regulations.gov

Re: Comments on Proposed National Primary Drinking Water Regulations for Certain Per- and Polyfluoroalkyl Substances under the Safe Drinking Water Act

(Docket ID: EPA-HQ-OW-2022-0114)

Dear Assistant Administrator Fox,

Please accept these comments on behalf of the undersigned Wisconsin-based organizations (collectively, Commenters) in strong support of the U.S. Environmental Protection Agency's (EPA's or the Agency's) proposed National Primary Drinking Water Regulations (NPDWRs) for

Perfluorooctanoic Acid (PFOA), Perfluorooctane Sulfonic Acid (PFOS), Perfluorobutane Sulfonic Acid (PFBS), Perfluorononanoic Acid (PFNA), Hexafluoropropylene Oxide Dimer Acid (GenX), and Perfluorohexane Sulfonic Acid (PFHxS) pursuant to the Safe Drinking Water Act (SDWA). [FN1: PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18,638 (proposed March 29, 2023).]

We strongly support EPA's commitment to "using and advancing the best available science to tackle per- and polyfluoroalkyl substances (PFAS) pollution, protect public health, and harmonize policies that strengthen public health protections with infrastructure funding to help communities, especially disadvantaged communities, deliver safe drinking water." [FN2: Id. at 18,638.] The establishment of standards under the SDWA for certain PFAS is an important step towards the fulfillment of the Agency's commitment.

Commenters support the proposed NPDWRs as a meaningful action to mitigate the health risks associated with oral exposure to the PFAS subject to this rulemaking. Following the years- long, meticulous process established by the SDWA, EPA seeks to establish protective and feasible national standards to regulate contaminants of health concern in public water systems based on the best available science. This proposed regulation will improve drinking water safety for millions of Americans. In Wisconsin, thousands of people who rely on drinking water via community water systems will receive meaningful risk-reduction benefits from this proposed rule. Accordingly, for the reasons detailed below, we urge EPA to finalize the proposed NPDWRs.

I. EPA is Required to Promulgate NPDWRs for PFOS, PFOA, PFBS, GenX, PFNA, and PFHxS Based on the Best Available Science and Information.

Commenters support EPA's determinations triggering EPA's obligation to promulgate standards for PFOS, PFOA, PFBS, GenX, PFNA, and PFHxS. Because the Agency determined that these substances meet the criteria for health risk regulation, EPA is obliged to promulgate NPDWRs under the SDWA.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mary Anderson (Doc. #1863, SBC-045842)

Dear whom it may concern,

I strongly support adoption of EPA's proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation. The proposed regulation is a critically important step to protect drinking water and public health from dangerous PFAS chemicals.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Laura Spilotros (Doc. #1864, SBC-045846)

Dear whom it may concern,

I strongly support adoption of EPA's proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation. The proposed regulation is a critically important step to protect drinking water and public health from dangerous PFAS chemicals.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document..

Jeanne Forster (Doc. #1865, SBC-045850)

Dear whom it may concern,

I strongly support adoption of EPA's proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation. The proposed regulation is a critically important step to protect drinking water and public health from dangerous PFAS chemicals.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

K Murphy (Doc. #1866, SBC-045854)

Dear whom it may concern,

I strongly support adoption of EPA's proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation. The proposed regulation is a critically important step to protect drinking water and public health from dangerous PFAS chemicals.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Paula Okin (Doc. #1867, SBC-045858)

Dear whom it may concern,

I strongly support adoption of EPA's proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation. The proposed regulation is a critically important step to protect drinking water and public health from dangerous PFAS chemicals.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document..

Katrina Rudmin (Doc. #1868, SBC-045862)

Dear whom it may concern,

I strongly support adoption of EPA's proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation. The proposed regulation is a critically important step to protect drinking water and public health from dangerous PFAS chemicals.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

North Carolina Conservation Network (Doc. #1869, SBC-045868)

Environmental Protection Agency,

Thank you for the strong proposal to regulate PFAS in drinking water.

Many North Carolina residents have been over-exposed to PFAS chemicals in their drinking water for decades. The public first learned about the widespread contamination in the Cape Fear River basin in 2017. In the years since, we've learned how pervasive PFAS chemicals are and that the chemicals are extremely toxic at levels far lower than previously understood.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

North Carolina Conservation Network (Doc. #1869, SBC-045866)

May 25, 2023

Environmental Protection Agency 1200 Pennsylvania Avenue NW Washington, DC 20460

Re: Docket ID No. EPA-HQ-OW-2022-0114

Dear Environmental Protection Agency,

Please see the petitions signed by over 1,230 North Carolina residents who strongly support the proposed drinking water standards for PFOS and PFOA, as well as the use of the hazard index

for additional PFAS chemicals, and urge Environmental Protection Agency to swiftly finalize the proposal.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Great Lakes PFAS Action Network (Doc. #1870, SBC-045871)

Comment letter submitted by the Great Lakes PFAS Action Network and signed by 213 individuals, Re: Per- and Polyfluoroalkyl Substances (PFAS): Proposed National Primary Drinking Water Regulations (Docket ID: EPA-HQ-OW-2022-0114)

Great Lakes PFAS Action Network

340 Beakes St., Suite 110, Ann Arbor, MI 48104

734-222-9650

connect@glpan.org

Dear Administrator Regan,

Re: Per- and Polyfluoroalkyl Substances (PFAS): Proposed National Primary Drinking Water Regulations (Docket ID: EPA-HQ-OW-2022-0114)

We commend the Environmental Protection Agency (EPA) for proposing to regulate six per- and polyfluoroalkyl substances (PFAS) in drinking water. We urge you to finalize these standards as quickly as possible. While this is an important first step, in order to fully protect the health of people, communities and the environment we urge the EPA to move toward regulating PFAS as an entire class of chemicals instead of one-by-one.

EPA's proposed rule would provide safer drinking water for communities by establishing strong limits on six widely detected PFAS. While PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. The proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

The Great Lakes PFAS Action Network (GLPAN) represents PFAS-impacted communities across the Great Lakes region who are unified in their efforts to prevent and clean-up PFAS contamination. We are encouraged that the EPA is proposing to use a hazard index on GenX, PFBS, PFNA, and PFHxS to inform risks of chemical mixtures. GLPAN's impacted community members have been exposed to both individual PFAS and chemical mixtures of PFAS. These exposures are linked to serious health issues including increased rates of cancer, developmental and reproductive harm, and other diseases. Many community members in GLPAN have personally experienced health problems or live in health-affected communities. We have waited long enough for the EPA to take action.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #1872, SBC-046574)

Docket ID No. EPA-HQ-OW-2022-0114

RE: EPA Proposed Rule – Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

March 30, 2023

I live in Madison, Wisconsin. On Feb. 23, 2022, the State of Wisconsin Natural Resources Board met to discuss the proposed WDNR standard of 20 parts per trillion (ppt) for two of the most studied PFAS compounds - PFOA and PFOS. The Natural Resources Board amended the proposed Drinking Water rule, changing the maximum contaminate level (MCL) for PFOA and PFOS to 70 ppt to match the U.S. Environmental Protection Agency's Health Advisory level for the same compounds.

The science is clear: PFAS persists in the environment – air, water, and soil – for long periods of time and has deleterious health effects on humans. Human exposure to PFOA and PFOS, members of the PFAS chemical group, disrupts hormone production, immune responses, and cell growth leading to problems with reproductive health, developmental issues in children, and increases the risk of developing cancer.

Please consider taking immediate action.

-Elimination in the production of unnecessary PFAS compounds.

-Establish a safe federal PFAS drinking water standard.

-Establish safe federal PFAS surface & groundwater standards.

-Provide federal recourse for states that do not comply with established PFAS regulations.

Thank you for your consideration.

Respectfully,

A Concerned Citizen

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

M Love (Doc. #1873, SBC-046592)

Since studies of PFAS/PFOA are extremely limited, and conclusions used by the EPA are inconclusive at best, 4 PPT seems particularly random. The MCL for cyanide is 0.2 PPM (200,000 PPT) and you are effectively saying that PFAS/PFOA is roughly 50,000 times more toxic than cyanide, an extremely toxic chemical with known effects. This makes the EPA seem untrustworthy, much like the CDC with Covid-19, especially since the correlation between PFAS/PFOA is inconclusive at best.

In addition to seeming fishy as to where the numbers come from, along with all the assumptions, it also sounds like someone within this regulatory community has something to gain from the proposed regulatory amount. Confidence in the government to put the health and safety of US citizens ahead of their own political and economic gains is at an all-time low.

Perhaps it's time to literally go back to the lab again and conduct more scientific research before coming out with the proposed MCLs. Also, federal agencies should wait for the "Advisory Committee for International Collaboration on the PFOA/PFAS Safe Dose" report due later this year before rushing to make random MCL levels law.

The EPA's own analysis considers that 20% of total PFAS exposure comes from drinking water sources, with 80% from food and other sources. Proposing such a low drinking water number will do little to reduce human exposure to PFAS.

Again, this legislation is appealing to people's emotional response to the issue, much like Covid, in order to over-regulate something where there is little data to support the effort. My guess, and the guess of many, is that persons within the government at several levels have something to gain at the detriment to the taxpayers and everyday citizens.

EPA Response: Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenter that the conclusions from heath studies are inconclusive and that the 4 ppt was randomly decided. The EPA has provided ample science and health-based evidence for the health effects of PFOA and PFOS, outlined in section IV of the FRN. For discussion on why 4 ppt was used for the PFOA and PFOS MCLs, please see section 5 of the EPA response in this *Response to Comments* document. The EPA disagrees with the statement that the agency is not putting the health and safety of US citizens at the forefront of this work. On the contrary, the EPA believes that this NPDWR is putting Americans first in protecting them from potential PFAS contamination from drinking waters. Further, the commenter has provided no evidence for the lack of information or data around these contaminants. The EPA has provided ample evidence on the health effects of the six PFAS and have been transparent on the use of best available science, the systematic review process, what evidence was used to determine hazard characterizations, the data used to derive all components of the health assessments, as well as the rationale behind the final conclusions for the MCLGs of the six PFAS. This information is outlined in section IV of the FRN, the Toxicity Assessments support documents, the PFOA/PFOS and Hazard Index MCLG documents (USEPA, 2024c;

USEPA, 2024d; USEPA,2024e; USEPA, 2024f), and is further discussed in section 4 of the EPA response in this *Response to Comments* document.

Regarding commenter's allegations that "persons within the government at several levels have something to gain", EPA employees, like all executive office government officials, may not use public office for private gain. All EPA government employees must follow stringent ethics guidelines which prevents the actual or perception of personal financial gain or conflict of interest. The public entrusts EPA employees to implement its regulatory programs in a fair and impartial manner, and each EPA employee is responsible for performing their duties in accordance with federal ethical requirements. To help ensure that EPA decision makers meet and exceed federal ethical requirements, they regularly review their financial interests (including for spouses and minor children) and outside activities and affiliations. They are expected to adhere to any recusal requirements and do not participate in agency matters that create an actual or perceived conflict of interest or a loss of impartiality.

Darlene Price (Doc. #1874, SBC-047326)

I am entering this letter in support of the EPA proposed rule on "Forever Chemicals" (www.regulations.gov, Docket ID: EPA-HQ-OW-2022-0114.)

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

James Sorrells (Doc. #1875, SBC-046623)

Dear Administrator Regan,

We continue to pump toxins into the environment we rely on to survive. We are poisoning the people we claim to love and setting up our children and their children for a tragic future. It is time to take a stand against those that contribute to the destruction of our natural environment.

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

D Salerno (Doc. #1876, SBC-046682)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water.

I encourage the EPA to finalize Safe Drinking Water Act regs soon, including the Hazard Index approach for 4 PFAS chemicals, based on the latest scientific information on health effects. Please consider addressing the whole class of PFAS chemicals when possible.

Let's stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. It isn't right to place more burdens on our communities, drinking water, and our health. Be well.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #1877, SBC-047308)

I am in full support of this proposed rule. Our health including sensitive populations, children, wildlife, pets, natural resources are the most important factor here. Public water utility companies will do the best they can to adapt to the changes within the confines of their resources and be fully transparent with the community with the help of EPA backing as it is of no fault to them. There are water filters--POET, R/O, bottled water other available in Lowes, Home Depot, private companies etc. should individuals want to take further control inside one's home/business.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Louise Nolta (Doc. #1878, SBC-046624)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects. Water is so essential to life and health for all. Please do all to keep dangerous PFAS chemicals in drinking water. Please do what you can to keep our water safe.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Gloria Shen (Doc. #1879, SBC-046625)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Without hefty fines or other deterrents in place for polluters, the problem will only get worse.

I look to your leadership today and hope that you will make the decision that serves the best interest of families, communities and wildlife.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Michael Bange (Doc. #1880, SBC-046626)

Dear Administrator Regan,

Please don't delay in implementing the proposed protections for our drinking water. No consideration about this proposal can supersede that of the safety of our water and, thus, the survival of humans and other life on the planet.

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Suzanne Chapelle (Doc. #1882, SBC-046627)

Dear Administrator Regan,

This is important to me personally as well as to Americans everywhere! We need totally safe drinking water. It is unforgivable that some people in thei wealthy nation do not have regular access to safe drinking water.

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Enviro Show (Doc. #1883, SBC-046678)

Administrator Regan,

The EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Margaret Karen Rist (Doc. #1884, SBC-046628)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible. Wouldn't you agree that something so vital to our health, the water we drink, needs the strongest protections possible?

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge. I shouldn't have to filter my water, at great expense to me as a retired senior, because of this harmful pollution from industry.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Cynthia Morton (Doc. #1885, SBC-046629)

Dear Administrator Regan,

In order that our grandchildren may live long, healthy lives, we are anxious to see that PFAS contamination of our water supplies is strictly regulated and existing pollution is cleaned up. This cannot wait, as the harm is being done today.

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

Cynthia Morton

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Eleuthera Paulina Dupont Passigli (Doc. #1886, SBC-046630)

Dear Administrator Regan,

Thank you for proposing these limits on the toxins in drinking water.I am lucky to have a well of my own, but many people are forced to drink water from iffy sources or go to the expense of buying bottled water. And there are all sorts of worries about the safety of bottled water as well. I hope that your scientists are fierce in grading the safety of water that our children will drink. Thank you

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Ralph Heimlich (Doc. #1887, SBC-046631)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

In particular, it would be helpful for EPA to reach out to industries that use PFAS chemicals in their production processes and encourage them to explore substitutes that do not pollute forever.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Tina Back (Doc. #1888, SBC-046632)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals.

Variations thereofs are just as hazardous. Stop this.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Gloria McClintock (Doc. #1889, SBC-046633)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

Since PFAS are forever chemicals and remain in our environment forever, they undoubtedly also remain in our human bodies forever and are a detriment to our health.

Even nursing infants have been found to be ingesting these chemicals in their mother's breast milk. This is not the legacy that we want to give our children.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals.

Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Bernadette Tourtual (Doc. #1890, SBC-046634)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

I add my personal comments to this letter indicating that it is a national health issue that I am concerned about that PFAS are allowed in our drinking water. We have had many areas in our country where communities have been exposed and have suffered. Please make an effort to remove these chemicals.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Dale King (Doc. #1891, SBC-046635)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects. Here in Maine we have seen first hand the effects of PFAs in both water and soil. Though Maine is working diligently to test people's wells and soil, this issue with PFA contamination is happening all over the United States; it is the responsibility of the federal government to create regulations to assure the American public that the water people are drinking is not contaminated with PFAs that are a hazard to their health.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Andy Bauer (Doc. #1892, SBC-046490)

Dear Administrator Regan,

Way to go on your recent proposal limit PFAS chemicals in our drinking water! Thank You! It is indeed refreshing to have an agency that embraces, rather than runs from, making rules based on actual science.

Please fast track this. Gently inform industry opposition that safequarding public health really needs to take precedence over profits, and maybe this will spur them to develop safer alternatives. Especially if the whole class of PFAS chemicals is affected (as it rightly should be!).

Sincerely,

Andy Bauer

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Dorothy Jordan (Doc. #1893, SBC-046636)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

These chemicals have been spreading in our environment for years. Now that we know the toxic effects which can be caused by these chemicals, we need to take immediate action.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lori Stetson (Doc. #1894, SBC-046637)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals.

Taking the burden off our communities, our drinking water, and our health is the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Dayle Severns (Doc. #1895, SBC-046638)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects. We need to do all we can to protect and clean our water -get the chemicals, pipeline seepage, train derailment spills, big corporations dumping who knows what into our waterways, and runoff from farms out of our precious drinking water.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Diane Krassenstein (Doc. #1896, SBC-046639)

Dear Administrator Regan,

The toxins in these chemicals are absorbed by people. They contribute to various health issues and deaths from diseases such as cancer. As a nation we need to protect everyone.

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Derek Benedict (Doc. #1897, SBC-046640)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects. And I strongly hope that you continue to lead the fight to get all varieties of man-made toxic poisons out of our air, soil, and water. C'mon man, you can do this!

And the EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sandy Bell (Doc. #1898, SBC-046641)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge. The only way for individuals to obtain clean water is with a reverse osmosis water system. Not only are many families unable to afford this, but it wastes water to clean it. We need our government to provide clean water for everyone.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Julieann Putt (Doc. #1899, SBC-046409)

Dear Administrator Regan,

Clean water = Life. Thank you for regulating PFAS

Sincerely,

Julieann Putt

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joan Ramos (Doc. #1902, SBC-046680)

Dear Administrator Regan,

I strongly support your proposal for health-protective limits for PFAS chemicals in drinking water, based the latest scientific information on their health effects.

EPA must see that these Safe Drinking Water Act regulations as soon as possible, including the Hazard Index approach for four PFAS chemicals. EPA should address the whole class of PFAS chemicals wherever possible. There are thousands of PFAS chemicals in use and found in water around the country.

EPA and the federal government must take bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the problem of PFAS.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Todd Snyder (Doc. #1903, SBC-046676)

As a stakeholder, I urge the EPA to finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lori Baranoff (Doc. #1904, SBC-046642)

Dear Administrator Regan:

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

All departments and agencies in the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

The EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. The EPA should address the whole class of PFAS chemicals wherever possible.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #1905, SBC-047315)

Water is a basic human right. We should have the right to clean air, clean water, and clean food. These are essential for life, health, and happiness which are/should be universal rights as we co-exist on this planet. There are alternatives to use of these products and while cost is a factor, the associated costs for increased healthcare in an already over-stressed system, is far greater. Our water utility made us aware that this was happening and they have also stated that they already meet the proposed requirements so nothing will change with our water. Any amount of these substances is too much as our bodies do not recognize it. We all know too well what cigarettes, wildfire smoke, smoke from wood-burning, coal, and other contaminates do in our bodies. Must we wait for "more research" to know that PFAs and other contaminants do? We know what they do already. We don't need proof. They likely cause cancer, maybe metabolic issues, possibly hormonal issues. We must do more than the proposed reduction by requiring industries to eliminate the use of these products. We must use BEHAVIORAL principles such as PREVENTION and REACTIVE strategies. Prevention: Do not make the contaminant. Reactive: clean up and filter the already-present contaminants. Let's use the law of parsimony here and use the simplest method. We can deduct that these cause harm, so let's fix it before it gets worse and the population continues to rise. I'd like to put my feet in clear creek water and enjoy what time I have left and leave it better than I left it for the next generations. Our policies are not making that so.

EPA Response: The EPA acknowledges this comment in agreement with safe, clean drinking water. The EPA believes this NPDWR does just that. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Ellen E Barfield (Doc. #1906, SBC-046643)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA MUST finalize these Safe Drinking Water Act regulations SOON, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge. Pass and ENFORCE real regulations which protect our water NOW!!!

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lisa Trimboli (Doc. #1907, SBC-046644)

Dear Administrator Regan,

I heard on the news the other day that 1 in 6 humans around the world experience infertility, but they don't know why. Maybe it's in the water.

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Monte Rogers (Doc. #1908, SBC-046195)

Think of our kids & grankids. Something impactful must be done now,

EPA Response: The EPA acknowledges this comment and believes this NPDWR is an impactful action to reducing PFAS exposure and health effects. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kari Pohl (Doc. #1910, SBC-046645)

Dear Administrator Regan,

I live in a community that routinely has brown drinking water due to the legacy of industrial pollution (namely, from a steel mill that for decades dumped slag into a river that runs directly above the wells that service our municipal water authority). As such, I would like to thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

Protecting our nation's drinking water is critical. That's why the EPA should finalize these Safe Drinking Water Act regulations as quickly as possible--including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. Residents in affected communities need the EPA to address the whole class of PFAS chemicals wherever possible.

Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge--rather, that's just one more way to privatize profit (allowing transnational corporations to subsidize their wealth with our health) and socialize the expense (forcing taxpayers to cover the costs of corporate criminality). Therefore, it is imperative that all parts of EPA and the federal government take bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Shellee Davis (Doc. #1911, SBC-046646)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

Usually, tthe industry itself recommends limits on toxic substances instead of banning them. I believe these "forever chemicals" warrant being banned. There is no safe amount that we can all imbibe along with the hundreds of other toxic chemicals that are already in all of our bodies. They all create havoc by disregulating our systems. The result is chronic disease, or new and rare diseases that are no longer rare, causing American's bodies and pocket books to take the brunt of the problem instead of preventing the problem in the first place.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible. Please use the most stringent, enforceable guidelines for safety.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Guy Marsters (Doc. #1912, SBC-046684)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

What the Hell is wrong with corporate America putting this crap in ANYTHING? What valid reason is there to even produce such compounds? Are people really still living too long with all the other crap you've put into the environment? Is it so profitable that it justifies contaminating the environment for hundreds of thousands of years? Who ever is doing this must have an escape

plan to get off this planet once it becomes just too toxic to sustain life or else the producers of these molecules are dumber than trump supporters! . Stop this nonsense before its too late. Please. What is the motivation to even produce these? And knowing what they are, how can you conscientiously introduce them into products consumers are in direct contact withi, or consume? Do you have such contempt for humanity?

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Guy Marsters

Claremont, CA 91711

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Cassandra Reid (Doc. #1915, SBC-046426)

Dear Michael Regan,

I think it's incredibly important to set limits on allowable amount of PFA's in drinking water. I strongly support drinking water regulations regarding these chemicals. Thank you.

Sincerely,

Cassandra Reid

Albuquerque, NM 87105

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Laura Ziegler (Doc. #1916, SBC-046647)

Dear Administrator Regan,

I grew up in Nassau County on Long Island, where the underground aquifer drinking water water source is especially vulnerable to PFA contamination. So I'm writing to thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Arthur Moss (Doc. #1917, SBC-046685)

Dear Michael Regan,

"Thank you for taking the first step to regulate PFAS in drinking water." EARTH JUSTICE

It's simple. Your family, my family, my friends' families, any and all families DO NOT want to drink contaminated water of any kind. Ban what shouldn't be in our water. Fine those who ignore the rules.

Aloha.

Sincerely,

Arthur Moss

Portland, OR 97239

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Fred Davis (Doc. #1918, SBC-046686)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS has contaminated drinking water for millions across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide essential and long overdue protections against six of these toxic chemicals. We strongly support the proposed measures and urge EPA to finalize them as quickly as possible.

PFAS is a significant, long-lasting, and hazardous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the atmosphere. PFAS has contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies exposed in utero. Yet despite the severe health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing solid limits on six widely detected PFAS, the proposal would save thousands of lives and prevent thousands of PFAS-related severe illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities that are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to finalize these standards quickly and to implement a most health-protective rule, resisting the industry's efforts to weaken them.

Respectfully I remain

FRED R DAVIS, ("MORTAL" - As Are We All)

Sincerely,

FRED DAVIS

Tampa, FL 33613

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Torger Johnson (Doc. #1919, SBC-046687)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. PFAS have contaminated drinking water supplies for millions of people. The EPA's proposed drinking water standards would provide important protections against six of these toxic chemicals. I strongly support the proposed standards, and urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Torger Johnson

Oakland, CA 94605

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Elaine Mayer (Doc. #1920, SBC-046688)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water to provide safer drinking water for communities from coast to coast. It will save thousands of lives and prevent serious PFAS-related illnesses each year. By issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. Quickly finalize these standards, and implement a rule to resist any effort to weaken them.

Sincerely,

Elaine Mayer

Minneapolis, MN 55447

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Holly McDonald (Doc. #1921, SBC-046575)

I write today as a deeply concerned American to urge the EPA to swiftly implement drinking water protections against unhealthy PFAS contamination.

Our country must have strong national standards for PFAS. Expanding protections to six PFAS, as well as the combination of different PFAS, will protect our drinking water from this toxic contamination and keep countless Americans safe from enduring the health risks associated with these dangerous chemicals.

PFAS, which are used to manufacture a range of goods, break down very slowly over long periods of time and, instead, accumulate in people, wildlife, aquatic life, plants, and the environment. This contamination poses a direct threat to our health and our ecosystems. Also known as "forever chemicals," PFAS are pervasive contaminants that are linked to serious health conditions such as cancer, liver and kidney disease, reproductive issues, immunodeficiencies, and hormonal disruptions.

PFAS' ubiquity is why action must be taken quickly and decisively. Finalizing these regulations will protect drinking water for countless communities. Therefore, I strongly urge your support for these badly needed regulations to protect people and our rivers, oceans, lakes, and communities from unacceptable PFAS contamination.

Thank you for your consideration of my message and for your vital action in this critically important matter to safeguard public health and the environment.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #1922, SBC-046267)

EPA should strongly regulate perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salt (also known as a GenX chemicals), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS), and mixtures of these PFAS. These substances pose a major risk to public health and must be rapidly addressed.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Margaret Karen Rist (Doc. #1925, SBC-046572)

On behalf of myself and every other human who drinks water to urge EPA to swiftly implement drinking water protections against PFAS contamination. Most of us can't afford to filter our way to safer water.

We need national standards for PFAS. Expanding protections to six PFAS, as well as the combination of different PFAS, will protect our drinking water from this toxic contamination and keep countless Americans safe from enduring the health risks associated with these dangerous chemicals.

PFAS, which are used to manufacture a range of goods, break down very slowly over long periods of time and instead accumulate in people, wildlife, aquatic life, plants, and the environment. This contamination poses a direct threat to our health and our ecosystems. Also known as "forever chemicals," PFAS are pervasive contaminants that are linked to serious health conditions such as cancer, liver and kidney disease, reproductive issues, immunodeficiencies, and hormonal disruptions.

PFAS' ubiquity is why we need to act quickly and decisively. Finalizing these regulations now would protect drinking water for countless communities across our country.

I urge your support for these badly needed regulations to better protect people and our rivers, oceans, lakes, and communities from PFAS contamination. this is the kind of protection the EPA is mandated to deliver.

Thank you,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jacqueline Barnes (Doc. #1926, SBC-046418)

Dear Michael Regan,

Please get these toxic chemicals out of our drinking water. Please we are exposed to too much of them as it is in our environment.

Sincerely,

Jacqueline Barnes

Florence, AL 35633

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Diane and Jerry Balin (Doc. #1928, SBC-046581)

We are writing today to urge EPA to swiftly implement drinking water protections against PFAS contamination.

Diane worked for the Metropolitan Water Reclamation District of Greater Chicago in the 1970 when EPA was created to address the degraded state of our waterways. Industry was polluting our wastewater with many deadly chemicals, including heavy metals, arsenic, etc. We created standards to address this problem.

Now we need national standards for PFAS. Expanding protections to six PFAS, as well as the combination of different PFAS, will protect our drinking water from this toxic contamination and keep countless Americans safe from enduring the health risks associated with these dangerous chemicals.

PFAS, which are used to manufacture a range of goods, break down very slowly over long periods of time and instead accumulate in people, wildlife, aquatic life, plants, and the environment. This contamination poses a direct threat to our health and our ecosystems. Also known as "forever chemicals," PFAS are pervasive contaminants that are linked to serious health conditions such as cancer, liver and kidney disease, reproductive issues, immunodeficiencies, and hormonal disruptions.

PFAS' ubiquity is why we need to act fast and decisively. Finalizing these regulations would protect drinking water for countless communities.

We urge your support for these badly needed regulations to better protect people and our rivers, oceans, lakes, and communities from PFAS contamination.

Thank you,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Amelia Davis (Doc. #1929, SBC-047449)

Another issue that arises with your third step of this plan is just how the filtering and reduction of PFAs would happen. Laurel Shadier, a senior scientist at Silent Spring Institute, describes ways to reduce these PFAs an describes that some may just close contacted wells and depend on other sources for water, that has the acceptable amount of PFAs. This would be an easier way to bypass the cost that comes with filtering the water mentioned above, but this solution also has serious implications. With climate change being a serious issue, we are already seeing droughts

throughout the world and just cutting off access to water because it's contaminated and using up other water can advance this climate change issue. While safe water is better than contaminated water, it won't make a difference if we run out of safe water because we are unable to use the wells of PFA water. In order, to not advance climate change, it becomes important to focus on the contaminated water and to fix that issue instead of looking for the easy way out. The focus should be on cleaning up the water that we already have easy access to, even though it will cost more financially.

The proposed plan looks good on paper but once you look at the details it is clear that there are some holes, and in order to use these new standards to the best of their ability those holes need to be covered.

EPA Response: The EPA acknowledges and appreciates this comment in support of the PFAS NPDWR, with some concerns that need addressed. Please see section 1.3 of the EPA response in this *Response to Comments* document. The final NPDWR does not require a specific technology and does not dictate specific actions that water systems must take (such as installing a treatment to remove PFAS or use a non-treatment option like drilling a new well). The rule requires that water systems achieve compliance at or below the MCLs by the compliance date but is not prescriptive in how this must be met. There are important considerations in choosing treatment and non-treatment options that need to be considered on a site-by-site basis. Water systems should consider the impacts of new source water wells on existing PFAS contamination plumes before selecting options. PFAS treatment option selection should consider conditions for a given utility including water quality, available space, disposal options, local rules, and currently installed unit operations. These compliance decisions will be made at a system level, and additional considerations that utilities and communities will weigh include relative costs of the various treatment and non-treatment options, viability of alternative water sources or interconnection options, feasibility, existing treatment processes and potentially other co-occurring contaminants, etc. Not every BAT represents the best treatment option for an individual system and site-specific considerations can limit BAT selection. For instance, residuals management considerations can limit the choice of RO/NF, particularly in states with limited water resources. The EPA anticipates that a small subset of water systems will elect for a non-treatment option, based to the decision tree included in section 5 of the Economic Analysis. Additional discussion around treatment technologies and compliance options, please see section X of the FRN and section 10 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #1930, SBC-047318)

The ability of companies to disregard the rulings for PFAS due to the sheer amount of leniency and loopholes within this proposed action is absurd. By being under the minimum needed to be reported or cleaned, companies can continuously pollute drinking water with PFAS, known as forever chemicals due to their inability to be broken down and how hard it is to remove from the environment. Once these forever chemicals pollute our drinking water, even a meager amount can have a multitude of adverse health risks such as hampering the immune system, interfering

with hormones, and reducing the effectiveness of vaccines" while in larger doses, PFAS can cause even more dangerous health anomalies such as kidney cancer, testicular cancer, liver damage, and thyroid disease. The toxicity of PFAS has been known by Depont which is the U.S.s leading manufacturer of these forever chemicals for years after they conducted clinical trials on rats. Yet, Dupont willfully chose not to release this information to the public or even to switch to the biodegradable and safer alternative that was at their disposal. How as citizens, are we expected to put our trust in our local public water systems to detect PFAS and help regulate these companies when they failed to even test the harmful effects of these forever chemicals in the past, and what is stopping manufacturers from creating new PFAS that don't fall under the proposed regulation? Additionally, it has been shown by journalistic sites such as Pewtrusts that the American Chemistry Council even finds that the regulation is also inappropriately broad in the way it categorizes what is a forever chemical, leading to many other unintended substances that carry a low safety risk to fall under this regulation despite not being PFAS leading to unnecessary complications with uninvolved private sectors. For the above reasons, I believe the proposed regulation is both too lax and far too broad for it to be reliable in protecting public health, what is needed is not a wide regulation on substances similar to PFAS but rather for the government to hold the private sector more accountable as to what it is allowed to dump into our waterways.

EPA Response: The EPA acknowledges this comment. Please section 1.3 of the EPA response in this *Response to Comments* document. The EPA disagrees that this rule is too relaxed and too broad for reliably protecting public health. The EPA provides ample evidence for public health effects of these six PFAS and the occurrence of these PFAS in drinking waters that indicate that this NPDWR will provide public health protection for many years. Discussion of the health effects information and the occurrence data can be found in section IV and VI of the FRN. For discussion on why the EPA is regulating these six PFAS, please see section 2.1 of the EPA response in this *Response to Comments* document, as well as section 15 of the EPA response in this *Response to Comments* document for remaining topics that are out of scope of this NPDWR.

Mary C. (Doc. #1931, SBC-046605)

As I've learned from the presentation, the EPA is proposing a "National Primary Drinking Water Regulation" (NPDWR) to establish legally enforceable levels (Maximum Contaminant Levels, or MCL's) for six PFAS in our drinking water. After reading the slideshow and the article, PFAS are a category of manufactured chemicals that have been used in industry and consumer products for many years. Because of their widespread use and their persistence in the environment, PFAS tend to break down very slowly and can build up in people, animals, and the environment over time. Scientific studies have shown that the exposure to some PFAS are known to cause an increased risk of cancer, increased cholesterol, decreased vaccine response in children, lead to negative health effects towards pregnant people and in developing babies, and weaken the immune system. They are the same chemicals that exist within our pots and pans, raincoats, and

in our fire extinguisher foam. And, lucky for us, these chemicals are often found in our drinking water.

As we've learned from the article and presentation, these chemicals have a serious and harmful impact on people and animals that they come in contact with. Additionally, we know this because I learned from the Bilott and DuPont case that Wilbur Tennant, a farmer in West Virginia, said that his cattle were dying left and right, and were acting deranged and had been suffering from strange effects. Some had blood running from their noses and mouths, chemical blue eyes, blackened teeth, and much worse. This was a huge problem for Tennant. He needed help- so he contacted Rob Bilott. Bilott, after a lot of research over several years, eventually cracked the case wide open and exposed DuPont (the chemical company responsible for the deaths of Tennant's cattle) and that they had known the damage they were doing for years. This kind of behavior is a huge threat towards our world. It's a threat because not only is it completely morally wrong, and these chemicals can cause serious issues towards people and animals, but DuPont is surely not the only company doing this. I wonder how many other companies are getting away with this to this day.

Although I like the idea of regulating the amount of chemicals in our drinking water, and think it's a good step towards improvement, I still don't think that it's enough. I think it's good that they're finally taking action on this serious issue, and wanting to notify the public of the levels of the PFAS in the drinking water. However, why are we permitting harmful chemicals in our water in the first place? If healthcare authorities are aware that these chemicals are harmful to the public, why are we okay with "minimal levels" of these in our water? We shouldn't have any PFAS in our water at all. Although it's hard to completely avoid these chemicals, they need to take more action against allowing any of these harmful chemicals in our water. These big chemical companies need to be more cautious of what they are releasing into our environment and where they are dumping them.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR, with a request for further action. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Diego Carrasco (Doc. #1932, SBC-047313)

The Environmental Protection Agency (EPA) is requesting the public's input on the proposed rule about rules regulating six PFAS also known as chemicals that have been found to be harmful for humans since the 1940s. I think that the proposed rule for requiring the state and city public water system to monitor these PFAS and notify the public when the levels of the drinking water exceed the proposed standard is an excellent proposal that should have been created a long time ago. Giving the public access to the PFAS analytic tool will be very beneficial because it gives individuals information to make their own decisions. Governmental agencies should use this situation with the PFAS as a template on what should be done every time a chemical compound

such as PFAS is created. This would allow them to have more control over the regulations, and have updated data readily available for the citizens of this country.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Patricia Guarrera (Doc. #1933, SBC-046689)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. Yet despite the serious health risks, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Patricia Guarrera

Pearce, AZ 85625

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Seth Roseman (Doc. #1934, SBC-046539)

PFAS chemicals have been associated with a number of adverse health effects, including cancer, thyroid disease, and developmental issues in fetuses and infants. Studies have found that exposure to PFAS can lead to increased cholesterol levels, decreased fertility, and immune system dysfunction. Even low levels of exposure to PFAS over an extended period can be harmful to human health. Over ninety percent of Americans are estimated to have PFAS chemicals in their blood stream as well.

Drinking water is a major source of PFAS exposure for humans. PFAS can leach into groundwater and surface water from industrial sites, landfills, and wastewater treatment plants.

These chemicals are difficult to remove from water, and traditional water treatment methods are not always effective in removing them. Therefore, it is essential to limit the levels of PFAS in drinking water to protect public health, lower healthcare spending, and stop PFAS-related disease from burdening our healthcare system..

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Patrick Coles (Doc. #1936, SBC-046648)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Most importantly, we need to remove PFAs from the water supply in water treatment plants - please direct funding to these plants to remove PFAs from the water supply! Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

Patrick Coles

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mason LaRusso (Doc. #1937, SBC-046323)

Reading through the EPA's proposed rule regarding the Drinking Water Regulation of PFASs, I would say it doesn't go anywhere near "too far," as it's a very serious matter that affects life in many aspects. If anything, it doesn't go far enough. Because PFASs are a group of man-made chemicals, they are primarily used for consumer products and/or industrial applications and are not meant to be mixed with the environment or human bodies. PFASs are used in making things like nonstick cookware, water-repellent clothing, carpets, firefighting foams, and other products that resist grease, water, and oil. According to pbs.org on PFASs, "This stuff is toxic at incredibly low levels and it's persistent – it stays there for hundreds of years in the groundwater,

thousands of years." These chemicals do not break down, so they will remain in the environment, exposing more people to them. It is also mentioned that evidence suggests that exposure to PFASs could potentially lead to increased cholesterol levels, decreased vaccine responses in children, higher risk of preeclampsia in pregnant people, and increased risk of kidney and testicular cancer. The fact that such a harsh chemical is being put into our drinking water is absurd, and should be regulated much more closely - we have no idea where it could hit us from. From the article on atsdr.cdc.gov, it talks about how exposure to PFASs could occur from a) drinking contaminated water, b) food grown or raised near places that use or make PFAS, c) eating fish caught from water contaminated by PFAS (PFOS more specifically), d) accidentally swallowing contaminated soil or dust, e) eating food packaged in material that contains PFAS, or f) using consumer products like the ones I'd listed above - nonstick cookware, water-repellent clothing, etc. etc. Though the EPA's proposed rule to regulate PFASs more closely is a decently significant step towards addressing the public's concerns and protecting our health as humans, it could still be pushed further. Mainly, it focuses on the issue of public drinking water and food products, preventing the PFASs from contaminating those things in particular. Personally, now knowing that PFASs are used in so many products, I think the EPA could take it a step further and strengthen the limits of these chemicals being used in products. The rule definitely has the right idea and does cover quite a bit, they still might not be strong enough to truly and effectively reduce the risk of PFAS exposure in things like food packaging or drinking water containers. By more strongly enforcing these limits within the area of consumer products, it would further reduce the chance for PFASs to be ingested by the public. Another thing the EPA could do to take it a bit further, is expand the list of PFASs that are to be regulated. The rule currently only covers a limited number of them, but according to the EPA's master list of PFAS substances, there are thousands of other PFASs that have been used in various industries and could have similar effects on the environment and human health (12,034 to be exact.). By expanding the list of regulated PFASs, the EPA could ensure that all of the relevant chemicals would be covered and regulated by the rule, therefore reducing the use of them overall. The new rule is definitely a step in the right direction for this country, and it should be pushed as far as it can be by anyone that is concerned about the negative health and environmental impacts these chemicals could have.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Matilda Phillips (Doc. #1938, SBC-046503)

Please urge EPA to swiftly implement drinking water protections against PFAS contamination.

We need national standards for PFAS. Expanding protections to six PFAS, as well as the combination of different PFAS, will protect our drinking water from this toxic contamination and keep countless Americans safe from enduring the health risks associated with these dangerous chemicals.

We need to act fast and decisively. Finalizing these regulations would protect drinking water for countless communities.

Please support these badly needed regulations to better protect people and our rivers, oceans, lakes, and communities from PFAS contamination.

Thank you,

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Terri Arnold (Doc. #1939, SBC-046222)

Its time the Federal Government start doing their jobs to protect the US citizens! Stop adding cancer to our drinking water and foods! This is horrendous! DO YOUR JOBS!!

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR, as the EPA feels this rule does protect US citizens from PFAS in our drinking water. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Alyssa Simms (Doc. #1941, SBC-046211)

I am in support of this new drinking water regulation. I don't want any PFAS in my drinking water, and this is a step in the right direction.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Stephen Ocallaghan (Doc. #1942, SBC-046563)

Re: Docket ID No. EPA-HQ-OW-2022-0114

Administrator Regan:

Thank you for taking a historic step to regulate PFAS in public drinking water. I urge EPA to finalize the proposed standards as quickly as possible.

I am 77 years old and have enjoyed a pretty healthy life. I have several grandchildren. I very much doubt that my grandchildren will live to my age, certainly not in good health. Why? Because our environment can be bought by wealthy people and corporations. It's time that the rights of the citizens of this country be recognized and protected by our government. The citizens have the right to a healthy life , liberty and a pursuit of

happiness. These rights surpass the rights of large corporations who can buy politicians to do their bidding and make it more profitable to do business that pollutes our environment.

In Wisconsin, two-thirds of the population relies on municipal drinking water. To date, over 70 Wisconsin communities have confirmed detections of PFAS in their water systems. Despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water. EPA's proposed rule would provide safer drinking water, reduce health risks and save thousands of lives.

These standards need to be finalized IMMEDIATELY!

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Janet Anderson (Doc. #1943, SBC-046585)

These are my comments regarding Docket ID No. EPA-HQ-OW-2022-0114.

Thank you for taking this step to regulate PFAS in public drinking water.

I strongly support the proposed standards and I urge the EPA to finalize them as quickly as possible. For decades, PFAS have contaminated drinking water supplies for millions of people across the country .... resulting in increased rates of cancer, developmental and reproductive harm, and other serious impacts. PFAS have been found in the blood of nearly every individual in the United States, including newborn babies who are exposed in utero.

In WI, 2/3 of the population relies on municipal drinking water. PFAS pollution is affecting an increasing number of communities throughout our state. Many of these contaminated systems have been contaminated for many years already; many of our WI citizens STILL have to purchase water for washing, cooking, bathing, etc because they do not have clean, safe water in their homes. This is absurd that this issue continues to be a hazard to our citizens.

To date, over 70 Wisconsin communities have confirmed detections of PFAS in their water systems. This number is expected to increase as statewide testing continues. Despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water. EPA's proposed rule would provide safer drinking water, reduce health risks and save thousands of lives.

We urge the agency to finalize these proposed standards as soon as possible to protect public health in communities in Wisconsin and across the country. Sincerely, janet anderson

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mary Buchholz (Doc. #1945, SBC-046690)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water.

I am personally terrified. I am 26 years old and I have spent the last 5 years learning about how much your generation has poised mine. You have borrowed from and stolen and poisoned my future and our planet to the point I fear we wont be abke to fix it. Please. Do the RIGHT thing. Now that we KNOW about these MANY issiues, including PFAS, help us change.

For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Mary Buchholz

Memphis, TN 38122

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Chris BarsyEckman (Doc. #1946, SBC-046231)

This is water we are talking about. You know water we drink and wash in and cook with. We need strong stringent safety standards and protections to guarantee our water is safe for all.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR, as the EPA believes this regulation is a strong protection from PFAS in our waters. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Devyn Crane (Doc. #1947, SBC-046203)

The updates guidelines are better but we must strive to be as restrictive with pollution as possible.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #1948, SBC-046226)

We need strong drinking water standards to protect us from toxic pfas contamination. Please prioritize public health and enact the proposed standards. We deserve clean water.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Annabelle Ott (Doc. #1949, SBC-047324)

I believe regulating the PFASs (a chemical compound composed of carbon and fluorine) by the Environmental Protection Agency would be good. However, in my opinion, this new regulation would only limit it to 6 PFASs; otherwise known as an unidentifiable amount, although it is known to have adverse effects on humans and animals alike. However, I am aware of the cost this would take on large-scale businesses and those like licensed state professionals, attorneys, and remediation companies, as they could face fines of up to $250,000 with a starting point of $25,000, according to John P. Gardella of Bloomberg Law. Although it is my firm belief that the adverse effects of the chemicals outweigh the cost for companies and those involved in the business of this chemical composition.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR, with a few concerns. Please see section 1.3 of the EPA response in this *Response to Comments* document.

J. Cicini (Doc. #1951, SBC-046608)

The recent US Environmental Protection Agency (EPA) rule regulating six per- and polyfluoroalkyl substances (PFASs), also known as forever chemicals, is a step in the right direction towards protecting human health and the environment. I think the EPA finally batting an eye at PFAs is great and well overdue. However, the new rules are not enough to address the significant harm that these chemicals pose to human health and the environment. The EPA's rule only focuses on six specific PFASs, including perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS), which have been widely used in products such as non-stick cookware, stain-resistant fabrics, and firefighting foam. There are over 5,000 PFASs in use, and many of them have not been studied for their potential harm to human health and the environment according to a Harvard University article done by Professor Karen Feldscher. Furthermore, the EPA's rule only requires companies to report any new uses of these six PFASs and provide information about their use in products. This falls short of what is necessary to protect human health and the environment from the harm caused by these chemicals since it leaves out lots of vital information as to what we are consuming. The harm caused by PFASs is significant. These chemicals do not break down easily and can be present in the environment for decades, accumulating in soil, water, and air. The contamination of these chemicals have devastating effects on wildlife, including fish and other aquatic animals which was seen in the "Dark Waters" film. In addition, PFASs are known to cause a range of health problems, including cancer, liver damage, and developmental issues in fetuses and infants. A 2007 study showed that over 98% of Americans had detectable levels of PFAS in their blood, regardless of demographics(Statnews.com) This alone demonstrates that it is crucial that the EPA take a more serious approach to regulating PFASs. The EPA needs to establish strict limits on the amount of PFASs allowed in products and the environment to prevent further contamination so no places end up like Parkersburg. The EPA should also require companies to disclose information about all PFASs used in their products. Another idea the EPA could implement is to prioritize the protection of vulnerable populations; such as children, pregnant women, and communities living near PFASs manufacturing facilities. These populations are often harmed the most by these chemicals, and it is crucial that they are protected from exposure to PFASs. In addition to stricter regulations, more research is needed to fully understand the impact of PFASs on human health and the environment. This research should be funded by the government and conducted independently of the chemical industry to ensure unbiased results. While regulating PFAs is fantastic and a great start, the guidelines presented and the small number of chemicals . The EPA needs a tighter approach to regulating PFAS. The examples provided would be excellent additions to the rule and create lots of change quicker. I understand why companies use these PFAs and it might be difficult to replace these chemicals in certain products but the amount that is rampant is worrisome.

https://www.statnews.com/2022/12/21/forever-chemicals-pfas-epa-drinking-water/

https://www.hsph.harvard.edu/news/features/why-more-stringent-regulation-is-needed-for-forever-chemicals/

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joan Wolf (Doc. #1952, SBC-046206)

I strongly support federal limits on PFAFs in our water. This " forever chemical " is indeed forever. Tgank you.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #1953, SBC-047431)

Greetings, Mrs. Greene.

I support EPA's Proposed PFAS National Primary Drinking Water Regulations (NPDWR). These efforts to regulate PFAS "forever chemicals" address nuisances to the environment and public health because of its persistent nature. Since the substance does not degrade, it accumulates in sediments and waterbodies. The chemical has especially been a topic of urgency that demands environmental regulation due to PFAS contamination in water supply and agriculture. Potential life threats can occur when people and wildlife indirectly consume PFAS, which are absorbed and can accumulate over long periods of time. High exposure to PFAS can lead to immune suppression, changes in liver function, thyroid cancer, and much more (Minnesota Department of Health 2022). Thus, it is critical that the federal government initiates limitation of exposure to these compounds.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Vojin Mastilovic (Doc. #1954, SBC-046252)

I believe that this proposal should be implemented as soon as possible because water should be something we don't have to worry about being clean or bad for us. This rule would be useful to take precautions to take out dangerous chemicals from our water such as PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #1955, SBC-047447)

The 'Forever Chemical' called PFAS surrounds billions of people every second of every day making it almost impossible to avoid. PFAS are found in nonstick cookware, clothing (i.e yoga pants and raincoats) and the public water system. Without even knowing you or the person next to you might be wearing clothes that contain PFAS or cooked eggs using a teflon pan. Millions of people have been exposed to PFAS over many decades from the 1940s. The use of PFAS must be stopped or at least contained to limit the amount of exposure that everyone has experienced or will experience in the near future.

As of January 2023 the EPA proposed a rule that would prohibit anyone from starting or continuing the use of PFAS without complete EPA review, risk determination and manufacture. These new regulations provide a safer environment for all. According to the CDC, exposure to PFAS over a period of time can cause damage to the liver, immune system, increase cholesterol levels, hormone disruption and thyroid disease.

Now water is accessible to everyone and without sufficient amounts of water it would lead to dehydration and potentially death. Clean water should be accessible to everyone because without clean water, there is no saying what the chemicals could do to our body. As of now, some states have passed laws regulating certain PFAS but there is no federal mandate. Without a federal mandate that means not all public water systems have to test for PFAS or filter before others consume it (Isaacs-Thomas). The new proposed rule would require state and city public water systems to monitor for PFAS, notify the public of the PFAS levels, and reduce the levels of these PFAS in drinking water if they exceed the proposed standards is a good start towards having a safer drinking environment for future generations. The EPA is proposing the National Primary Drinking Water Regulation (NPDWR) to have a standard for public water which could legally enforce levels called Maximum Contaminant Level (MCL).

Not only is PFAS found in water systems, they are also found in nonstick cookware such as pans. The PFAS in the nonstick cookware have polluted the water system causing it to be forever contaminated ("Undisclosed PFAS Coatings Common on Cookware, Research Shows"). When the teflon comes in contact with metal or high amounts of heat, PFAS is released into the air which cannot be easily broken down into a simpler compound. The reason why PFAS is considered to be the "˜forever chemical' because it cannot be easily broken down but it is man made ("Frequently Asked Questions about PFAS Chemicals | ATSDR").

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Iresli Jurado (Doc. #1960, SBC-047446)

The fact is that there are proposed rules by the EPA to regulate these six harmful chemicals in drinking water, and it has the potential to protect public health and the environment. It may have negative impacts on businesses and public water systems, however, it should be possible to regulate the rules as long as the aim is to make the water systems better. Trying and failing is

better than not trying at all. Additional evidence is needed to fully analyze the issue, including data on PFAS prevalence and health effects, economic analysis, and examination of alternative approaches. To address this issue, an option for action is to study the benefits and eventual negatives coming with the rule. Ultimately, finding a solution is the number one priority, thereafter one can work on balance and competing concerns.

The ultimate goal will be to protect public health and the environment while maintaining good economic standards. Considering the economy of the public, and more specifically stakeholders in the company, my ethical opinion is that if you invest in something bad, you do not deserve better. However, I want the best for the highest number possible, and it would be great if the government could help out. Reducing private costs for employers and shareholders to keep their jobs would be huge. What justifies this, is that the potential costs for a new monitored water system would possibly be lower than the costs of fixing health issues and other costs coming with bad water systems down the line. We completely agree with the proposed rules and think the focus on knowing how well the rules are regulating the water have to be just as much focused on as implementing them.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Gary Overby (Doc. #1961, SBC-046430)

We in the Madison, Wisconsin area are struggling with the legacy effects of PFAS as a result of years of use as fire fighting foam for military planes.

Please help us to rectify this problem with the strongest possible standards, and remediation, Thank you

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jerry M. Littlefield D.O. (Doc. #1963, SBC-046583)

I live in Rome GA. Our city water was drawn from the Oostanaula river, now from the Etowah river. They come together in downtown Rome to form the Coosa I live in Rome Georgia. We formerly drew our water supply from the Oostanaula River, now from the Etowah. These join in downtown Rome to form the Coosa River which flows west into Alabama and eventually to the Gulf of Mexico. This change in source was forced by pollution by PFASs dumped into thOostanaula watershed by carpet mills and other industries upstream in the vicinity of Dalton GA, which prides itself as the "carpet capital of the world."

This will require the construction of a reverse osmosis water treatment plant to use water from the Oostanaula, which has a better flow-costing millions.

We now know that some PFAS compounds are endocrine disrupters and possible carcinogens. Others have as yet unknown effects. As a physician and a parent I am very concerned about increasing exposure to the "forever" chemicals.

While many of these dangerous compounds may make for convenience, most uses are not vital for life or saftey. Most have replacements with known safety records.

I urge you to require monitoring for these compounds by municipalities, and testing to demonstrate saftey by manufacturers and users. Convenience and more profits are not good reasons for poisioning our children!

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR, as the rule will require monitoring of six PFAS. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Anya Mulvaney (Doc. #1965, SBC-047320)

I believe the best approach, for the common good, what is just, and what is ethical is to pass this policy. But furthermore, for the local governments to instate regulations on chemical companies so that they are being held accountable. It is not fair for citizens to pay taxes to address problems they aren't making. So I would argue this policy doesn't take it far enough. We need to work towards the regulation of the industry, not just place the burden on local government and even make these chemicals illegal to pump in water. This would have economic costs but the health benefits and safety outways the costs. I would guess that the majority of individuals would mostly agree that it is the fairest and just outcome. The one argument that could appear is from a rights approach. Citizens have a right to safe water, but the question is do companies have a right to pump their waste into sources of water and expect governments to ensure it's safe? Some may argue yes; some may argue no. I would argue that these companies do not have this right. They must take responsibility for their actions and the consequences that come with them. If they wish not to have these consequences, then they should work towards finding an alternative to dumping harmful chemicals into drinking water sources.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Marcia Garceau (Doc. #1967, SBC-046691)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in

increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Marcia Garceau

San Diego, CA 92129

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Patricia Massa (Doc. #1968, SBC-046445)

Dear Michael Regan,

I am extremely concerned about the harmful effects of PFAS in our drinking water on our health and well being and absolutely approve of the EPA's proposed standards. I am asking you to put them into place as soon as possible to save lives.

Sincerely,

Patricia Massa

Saint John, IN 46373

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Carlo Provanzano (Doc. #1969, SBC-046692)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

With so very many toxic chemicals in our air, food, and water, and with the health of millions of Americans suffering for it, it's about time the whole nefarious operation was stopped and our air food, and water cleaned up for the sake of not only the present generation suffering the direct results of toxins and pollutants, but for those yet unborn.

DO SOMETHING! Stop the slow genocide!

Sincerely,

CARLO PROVANZANO

Palos Verdes Peninsula, CA 90274

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Barbara Fuoco (Doc. #1970, SBC-046693)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Barbara Fuoco

Portland, OR 97202

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Elmo Patrick (Doc. #1971, SBC-046694)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against 6 of these toxic chemicals. We urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment and drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on 6 widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water.

Sincerely,

Elmo Patrick

Wrightstown, NJ 08562

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mona Perrotti (Doc. #1972, SBC-046695)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. I very strongly support the proposed standards, and urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals.PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to very quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Mona Perrotti

Clinton, NY 13323

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Paul Tippery (Doc. #1973, SBC-046696)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Paul Tippery

Decatur, NE 68020

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Daniel Hosking (Doc. #1974, SBC-046432)

Dear Michael Regan,

Please quickly finalize EPA's proposed standards for regulating PFAS in drinking water and implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Thank you!

Sincerely,

Daniel Hosking

Payson, AZ 85541

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kay Schaser (Doc. #1975, SBC-046697)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Kay Schaser

Eureka, CA 95503

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Karen Burtness Prak (Doc. #1976, SBC-046698)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water!

As you know, PFAS have contaminated drinking water supplies for millions of people across the country for decades, a situation which has caused (among other problems) increased rates of cancer, developmental and reproductive harm, as well as other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of

these toxic chemicals. I strongly support the proposed standards, and urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm for decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and have entered the blood of nearly every individual in the United States, including that of newborn babies (who are exposed in utero). Yet, despite the serious health risks known to be associated with PFAS, there remain no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely-detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS.

By issuing this proposal, EPA is taken one important step toward fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and -- resisting industry's efforts to weaken them -- to implement a rule that is extremely protective of individuals' health.

Sincerely,

Karen Burtness Prak

Menlo Park, CA 94025

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kathleen Corr (Doc. #1977, SBC-046699)

Dear Michael Regan,

Pure and clean water for a human 70% water means health humans are swimming in internal water all of our lives. If that water has poisons in it the poisons seep into our organs then more toxicity builds up and more diseases occur and deaths. it is your job to prevent this and keep our water clean for all.

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue

protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Kathleen Corr

Springdale, UT 84767

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Susan Green (Doc. #1978, SBC-046700)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite

the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Susan Green

San Francisco, CA 94114

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Susan DuBois (Doc. #1979, SBC-046701)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a problem in the region of New York State where I live.

Sincerely,

Susan DuBois

Albany, NY 12209

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Vivian Ehresman (Doc. #1980, SBC-046702)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

How these drinking water standards can even be a question/issue to ponder is crazy. These chemicals should have been banned years ago. Science has proven this time and time again and everyone including you and the US government know it. So, at the very lease, please enforce these limits immediately at the very least. We and all the generations to come are depending on it.

Sincerely,

Vivian Ehresman

Chatsworth, CA 91311

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Carolynn Kohout (Doc. #1981, SBC-046703)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water.

For decades, PFAS have

- contaminated drinking water supplies

- for millions of people across the country,

-resulting in

- increased rates of cancer,

- developmental and reproductive harm, and

- other serious diseases.

EPA's proposed drinking water standards would - provide important and long overdue protections

- against six of these toxic chemicals.

We strongly support the proposed standards. We urge EPA to finalize them as quickly as possible.

PFAS are

1. a large, long-lasting, and highly dangerous class of chemicals

- called "forever chemicals,"

2. persist in the environment,

3. build up in our blood and organs, and 4. continue to cause harm decades

- AFTER released into the environment.

4. have contaminated drinking water supplies

- for approximately 200 million people and

- the blood of nearly every individual in the United States,

- including newborn babies who are exposed in utero.

There are currently NO federal limits on PFAS levels in drinking water.

EPA's proposed rule would

1- provide safer drinking water for communities from coast to coast.

2- establishing strong limits on six widely detected PFAS,

3- save thousands of lives and

4- prevent tens of thousands of serious PFAS-related illnesses each year.

The EPA acknowledges and addresses the cumulative impacts on communities

- who are exposed to multiple PFAS,.

By issuing this proposal,

EPA is one step closer to fulfilling its commitment

- under the 2021 PFAS Strategic Roadmap

to begin regulating PFAS in drinking water.

We urge you to

1) quickly finalize these standards,

2) implement a rule that is the most health-protective,

3) resist industry's efforts to weaken them.

Sincerely,

Carolynn Kohout

Hillsboro, OR 97124

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mary-Ellen Maynard (Doc. #1982, SBC-047488)

"PFAS are synthetic, fluorinated hydrocarbons, where fluorine takes the place of most of the hydrogen, according to a recent article in Cosmos. Like most everything that's now the product of organic chemistry, the creation of PFAS built upon those first substances derived from coal."

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Mary-Ellen Maynard

Canon City, CO 81212

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Elena Engel (Doc. #1983, SBC-046441)

Dear Michael Regan,

Please make sure we get these toxic chemicals out of our drinking water, out of the ocean, out of everything. Who thought this was a good idea to unknowingly take this stuff into our bodies? Not us! Please ban PFAS

Sincerely,

Elena Engel

San Francisco, CA 94110

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Tanya Cobb (Doc. #1984, SBC-046704)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, they have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. Your proposed drinking water standards will provide important and long overdue protections against six of these toxic chemicals. I strongly support the proposed standards and ask you to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," they persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. They have contaminated drinking water supplies for about 200 million people and the blood of nearly every individual in the United States, including newborn babies. Despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule will provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal will save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. You acknowledge and address the cumulative impacts on communities who are exposed to multiple PFAS,. By issuing this proposal, you are one step closer to fulfilling your commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water.

I ask you to quickly finalize these standards and to implement a rule that is the most health-protective.

Sincerely,

Tanya Cobb

Alexandria, VA 22311

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Ruth Fruland (Doc. #1985, SBC-046534)

Dear Michael Regan,

Please take the continuing decline in male sperm counts and the relentless increase in autism seriously.

We lack perfect knowledge but not the wisdom to clean up our environment.

EPA's proposed drinking water standards would provide important and long overdue protections against six PFAS toxic chemicals.

We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment.

PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual.

If you are not determined enough to withstand industry's efforts to weaken the standards, what makes you think that you and your children will escape the tragic consequences?

Sincerely,

Ruth Fruland

Seattle, WA 98115

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Yvette Kuhns (Doc. #1986, SBC-046705)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

It is unfortunate and preventable cancer plaguing my family, friends and neighbors since the use of PFAS. Our family medical history did not show cancer and other illnesses now linked to PFAS. I never smoked, drank alcohol or took drugs yet I was diagnosed with colon cancer at age 50. My cousin died of colon cancer before age 40 and she worked in the medical field. Many more family members got different forms of cancer and we all live in an area where the water is unsafe for drinking, washing or cleaning. My cat doesn't even want to drink the water!

It is clear that since we use plastic instead of glass bottles, we are being polluted, poisoned and killed by toxic chemicals. Our ancestors were lucky not to have them in their environment and we are trying to reduce the use of plastic and recycle rather than fill the landfills with plastic. But

we have no control over anyone else... but you do! Please do not allow manufacturer's to use unsafe products and packaging.

Please test the water in rural areas as well as urban areas. Be sure the environment is safe for water, air, plants, animals and humans. We have a well pump that brings water into our home. We buy bottled water and we wash dishes, clothes and ourselves with the well water. I don't feel safe drinking well water or bottled water but we have no choice. It is unfair that we are forced to consume poisoned water. Please enact and enforce stricter rules to protect the environment and those who live in it.

Sincerely,

Yvette Kuhns

Orefield, PA 18069

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Nancy Ullrich (Doc. #1987, SBC-046474)

Dear Michael Regan,

Clean our water!

PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States.

However, despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

Establish strong limits on six widely detected PFAS now!!

Sincerely,

Nancy Ullrich

Long Beach, CA 90808

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Rosanne Couston (Doc. #1988, SBC-046706)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

Sincerely,

Rosanne Couston

Tucson, AZ 85745

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Amy Merritt (Doc. #1989, SBC-046707)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

Companies like dupont need to be heavily fined. Any company that builds near a water source needs to be added to the watchdog list, because this is not something new that companies/corporations do. Waterways are an easy way for the bad actors to dispose of their waste. These companies/corporations are happy with their profits at the expense of people/animal/fish/communities. Don't you think this needs to end now?? COMMON SENSE.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to

multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them. COMMON SENSE.

Sincerely,

AMY MERRITT

Belle Vernon, PA 15012

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Michael Wherley (Doc. #1990, SBC-046708)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Michael Wherley

Eugene, OR 97402

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Edward Simpson (Doc. #1991, SBC-046477)

Dear Michael Regan,

We are pleased you for taking the first step to regulate PFAS in drinking water. Our drinking water has had these chemicals for a long time. Maybe some of the more frequent cases of human disabilities and disease are from these PFAS.

New standards are OVERDUE and NECESSARY. We hope we will be reading that finally someone cares. Please finalize them now.

Thank you.

Sincerely,

Edward Simpson

South Pasadena, CA 91030

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Deborah Hanson (Doc. #1992, SBC-046709)

Dear Michael Regan,

Our drinking water is taken from the Yellowstone River here in Montana. We are downriver from many cities and towns plus agricultural operations. We thank you for taking the first step to regulate PFAS in drinking water. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast by establishing strong limits on six widely detected PFAS, and begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them. With every glass of water I drink, I urge you to take action.

Sincerely,

Deborah Hanson

Miles City, MT 59301

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

John Vanellis (Doc. #1993, SBC-046710)

Dear Michael Regan,

As a former high school biology teacher I understand the importance of science in policy and decision making in our government. I'm afraid too often scientific evidence is ignored. It's time to side with science, not polluters. Please prevent the destruction of our environment and its inhabitants by using standards based on good scientific evidence not big business interests.

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

John Vanellis

Trenton, NJ 08618

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Malin Moench (Doc. #1994, SBC-046538)

Dear Michael Regan,

I strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible. Despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA

acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Malin Moench

Falls Church, VA 22041

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

James Sorrells (Doc. #1995, SBC-046711)

Dear Michael Regan,

We are poisoning our environment on an astronomical scale. It is completely unacceptable. Toxins are entering into every aspect of our lives from the incessant pollution that is saturating air, land, and waters. In turn wildlife and humans in general are unknowingly ingesting these chemicals daily. As humankind continues to grow and expand, we must begin to change for our children to have a chance.

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment

under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

James Sorrells

Clermont, FL 34715

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Deirdre Scott (Doc. #1996, SBC-046712)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Deirdre Scott

Buhl, ID 83316

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Judy Althaus (Doc. #1997, SBC-046713)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water.

Now, please complete the task. It's time to stop companies from poisoning me, you, our children, and future generations.

Sincerely,

Judy Althaus

Louisville, CO 80027

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Nancy Anne Earl (Doc. #1998, SBC-046714)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water.

We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Nancy Anne Earl

San Francisco, CA 94131

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Judi Beardsley (Doc. #1999, SBC-046715)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

I suffer immensely from a condition called Multiple Chemical Sensitivities along with MAST Cell/serious allergies and am literally poisoned by all the every day products most use daily in our world today. I deeply understand the importance of getting toxic chemicals out of drinking water. I have pretty much been a prisoner in my home for nearly 2 decades due to serious and severe reactions to the toxic chemicals in our world. I was always chemically sensitive but after multiple toxic black mold exposures and working in a "tight" building full of toxins for decades, I now suffer greatly. We all deserve and need safe and clean drinking water as it is essential for life. Please do the right thing and get these toxic chemicals out of our drinking water. These chemicals lead to many illnesses including many Cancers.

Sincerely,

Judi Beardsley

Arnold, MO 63010

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Carol Wong (Doc. #2000, SBC-046716)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks

associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Carol Wong

Los Angeles, CA 90045

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joan Gussow (Doc. #2001, SBC-046717)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. PFAS are a large, long-lasting, and highly dangerous class of chemicals. that have for decades, contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases.

Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. and bring, EPA one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Joan Gussow

Piermont, NY 10968

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Peter Scheirer (Doc. #2002, SBC-046718)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

Sincerely,

peter scheirer

Lafayette, CA 94549

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

M'lou Christ (Doc. #2003, SBC-046556)

Dear Michael Regan,

It's decades late, but at last you have begun to address the horrors of PFAS that have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases.

I urge the EPA to finalize and adopt asap the proposed drinking water standards for protections against six of these toxic chemicals.

PFAS, e a large, long-lasting, and highly dangerous class of chemicals have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. I urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

m'lou christ

Seattle, WA 98103

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

MarieJo Binet (Doc. #2004, SBC-046719)

Dear Michael Regan,

I am a constituent. I suppose you agree with me and most people in their right mind: should not having access to safe clean drinking water, like breathing clean air be basic Human and Animal Rights?

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious

diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them. Thank you thank you for doing what it takes make our drinking water safe.

Sincerely,

MarieJo Binet

Frederick, MD 21702

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joanna Vintilla (Doc. #2005, SBC-046522)

Dear Michael Regan,

Thank you for starting the process to regulate PFAS in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Joanna Vintilla

Seattle, WA 98133

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sandra Lilligren (Doc. #2006, SBC-046720)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water.

Water is Life, and we must take every measure to keep it healthy. It is the lifeblood of the planet, and we cannot afford to make any further mistakes in its care.

I urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Ethical behavior before power or profit is imperative.

Sincerely,

Sandra Lilligren

Clarkston, WA 99403

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Randall Potts (Doc. #2007, SBC-046721)

Dear Michael Regan,

We desperately need to get PFAS out of our water and keep them out of our bodies. Access to clean water is a fundimental human right. We must act now because the problem is destructive to human health at all levels. I live in Bellingham WA, where our water supply is heavily contaminated and our reservor is rated as an "impaired" water source. The cancer rate here is very very high. Local and state officials will not address the problem for political reasons; we need the EPA to protect our bodies and the water we drink.

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases.

EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

randall potts

Bellingham, WA 98226

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Cheryl Mitchell (Doc. #2008, SBC-046899)

Dear Michael Regan,

I am an attorney in Washington State and I am writing to express my thanks for taking the first steps to regulate PFAS in drinking water. I am alarmed by the fact that for decades, PFAS have contaminated drinking water supplies for millions of people across the country. This contamination has resulted in increased rates of cancer, developmental and reproductive harm, and other serious diseases. For many years the EPA has done nothing to protect the public from PFAS contamination.

Finally, the EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. I, along with many others, strongly support the proposed standards, and I hope that I can count on the EPA to finalize these standards as quickly as possible.

I know from doing research that PFAS are a large, long-lasting, and highly dangerous class of chemicals. PFAS are often called "forever chemicals." These chemicals persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every person in the United States, including newborn babies who are exposed in utero. But despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water. Clearly, the interests of chemical companies are much more important than the health of the American people.

Finally, the EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, the EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water.

I can't even begin to state how important it is for the EPA to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them. Let's end the "Greed is good" rule which has been applied for far too long.

Sincerely,

Cheryl Mitchell

Spokane, WA 99205

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Janice Gintzler (Doc. #2009, SBC-046722)

Dear Michael Regan,

After I saw the film "Dark Waters" that was about PFAS in water that killed animals and farmers who lived down river from Dupont, in West Virginia, I became an activist against PFAS in our lives.

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Janice Gintzler

Crestwood, IL 60418

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

David Williams (Doc. #2010, SBC-046436)

Dear Michael Regan,

Clean water is vital to the general welfare of the American people, one of the first things listed in the Constitution. Any failure to enforce adequate clean water protections is a crime against all Americans.

Sincerely,

David Williams

Elkmont, AL 35620

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jason Brogan (Doc. #2011, SBC-046723)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Jason Brogan

Long Island City, NY 11101

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Dwight Johnson (Doc. #2012, SBC-046724)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water.

I urge you to quickly finalize these standards, and to implement a rule that is the most health-protective. Please resist industry's efforts to weaken them.

Sincerely,

Dwight Johnson

Orinda, CA 94563

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Perry Kendall (Doc. #2013, SBC-046891)

Dear Michael Regan,

Making the first move to regulate PFAS in our drinking water is extremely important. They have contaminated our essential drinking water supplies nationwide for decade. Tragically we have increased rates of cancer, developmental, reproductive harm, and other serious diseases to demonstrate that. EPA's proposed drinking water standards necessarily provide crucial long overdue protections against six of these toxic chemicals. Your continued support for the proposed standards is urgent l. We need EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

The proposed rule ensures safer drinking water we all require. Establishing strong limits, on six widely detected PFAS, will save thousands of lives preventing tens of thousands of serious PFAS-related illnesses annually. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Perry Kendall

Glenside, PA 19038

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Rhona Schwartz (Doc. #2014, SBC-046725)

Dear Michael Regan,

My family and I thank you for taking the first step to regulate PFAS in drinking water.

So much more needs to be done and quickly!

Please keep working hard to finalize the standards and put into place iron-clad rules that hold all companies accountable.

Sincerely,

Rhona Schwartz

Seattle, WA 98119

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

James Boone (Doc. #2015, SBC-046886)

Dear Michael Regan,

Thank you, thank you, thank you !!! For taking the first step to regulate PFAS in drinking water. Every day, millions of people across the country drink water contaminated with toxic chemicals known as PFAS. This exposure poses serious health hazards, as PFAS can damage the immune system and cause cancer and other health problems.

EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Thank you for considering my comments.

Sincerely, James Boone

Sincerely,

James Boone

Portland, OR 97229

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Nancy Garret (Doc. #2016, SBC-046481)

Dear Michael Regan,

EPA's proposed drinking water standards would provide important and long overdue protections against six toxic PFAS -- a large, long-lasting, and highly dangerous class of chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

Also, please implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Thank you.

Sincerely,

Nancy Garret

Redwood City, CA 94062

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jacquelyn Brown (Doc. #2017, SBC-046726)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite

the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

I will no longer take baths at my sister's house which is Town of Campbell, mailing address is La Crosse, Wisconsin due to PFAS in the water on the island. She no longer drinks from her well because it may be unsafe. This is ridiculous! At some point our health needs to be taken into account before profits of corporations. I am so saddened and disappointed that our health is not considered. It is a sad day for us.

Sincerely,

Jacquelyn Brown

Saint Paul, MN 55119

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Brian Levo (Doc. #2018, SBC-046549)

Dear Michael Regan,

Greetings. Thank you for taking the effort to regulate PFAS in our drinking water. I understand PFAS are persistant in the environment, build up in our blood and organs, and continue to cause harm decades after being released into our environment. Yet, despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

I understand that the EPA's proposed rule would provide safer drinking water for communities, establish limits on six widely detected PFAS, and would save lives and prevent PFAS-related illnesses. I have heard the EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. I would urge you to please quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them. Thank you for your consideration in this matter.

Sincerely,

Brian Levo

Falls Church, VA 22044

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lena Nilsson (Doc. #2019, SBC-046485)

Dear Michael Regan,

For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. I strongly support the proposed standards, and I urge EPA to finalize them as quickly as possible.

Sincerely,

Lena Nilsson

Laguna Beach, CA 92651

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Betsy Webster (Doc. #2020, SBC-046727)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people.

EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives.

The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Forever chemicals have no place in our water!

Sincerely,

Betsy Webster

Mount Ulla, NC 28125

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lea Thomas (Doc. #2021, SBC-046484)

Dear Michael Regan,

Thank you for taking action to regulate PFAS in drinking water. But more must be done. It is a health and economic hardship for communities across the country, including my town in NH.

Please quickly finalize the EPS's proposed standards, and do not accommodate industry's attempt to weaken them.

They are only the minimum needed to begin addressing the serious threat these chemicals pose to our health and the future of our society.

Sincerely,

Lea Thomas

Bedford, NH 03110

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jeremy Ehrlich (Doc. #2022, SBC-046453)

Dear Michael Regan,

I strongly support the proposed regulation of PFAS chemicals and hope to see it finalized as soon as possible.

I support EPA's taking the strongest possible protections for our health and our climate. Thank you for these regulations and please let's get them official!

Sincerely,

Jeremy Ehrlich

Seattle, WA 98109

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Vasu Murti (Doc. #2023, SBC-047489)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Rebecca Walding (Doc. #2024, SBC-046728)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water.

EPA's proposed drinking water standards would provide important and long overdue protections against six toxic chemicals.

We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Rebecca Walding

Cerrillos, NM 87010

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Catherine Carter (Doc. #2025, SBC-046729)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible, because despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Catherine Carter

Cullowhee, NC 28723

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Peter Macfarlane (Doc. #2026, SBC-046730)

Dear Michael Regan,

I congratulate and thank you for taking the first step to regulate PFAS in drinking water. And I urge you strongly to finalise the EPA's proposed drinking water regulations for the six most abundant PFAS.

For decades, PFAS have contaminated drinking water for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water. The EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals.

I fully support these proposed standards, and I strongly urge EPA to finalize them as quickly as possible, and to resist any and all efforts to weaken them.

Thank you for your consideration.

Sincerely,

Peter Macfarlane

Vergennes, VT 05491

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Bonnie Bledsoe (Doc. #2027, SBC-046731)

Dear Michael Regan,

I have a water filter that purifies many of the toxins in my city water; many people don't have this option.

It seems extremely urgent to me that all of us have pure drinking water.

Please move to regulate PFAS in drinking water. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Bonnie Bledsoe

Seattle, WA 98125

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Leslie Mink (Doc. #2028, SBC-046452)

Dear Michael Regan,

Thank you for regulating PFAS in drinking water. Max PFAS levels will start to at least limit exposure to these toxins. Its long overdue. Please finalize the regulations as quickly as possible.

Then start working to protect our life support ecosystem from PFAS as well.

Sincerely,

Leslie Mink

Quincy, CA 95971

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Michael Margulis (Doc. #2029, SBC-046732)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. We urge you to quickly finalize these new standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Michael Margulis

Valencia, CA 91354

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Thelma S Garbutt (Doc. #2030, SBC-046733)

Dear Michael Regan,

As a resident of Pittsboro, NC and as an American, I would like to thank you for taking the first step to regulate PFAS in drinking water. I have friends with family members who exhibit immune deficiencies and other health problems consistent with their documented high PFAS levels in their blood. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. I strongly support the proposed standards, and urge EPA to finalize them as quickly as possible.

However, I would like to emphasize that while limiting these six forms of PFAS is an important step, it will not solve the problem of PFAS contamination across our nation. Manufacturers will simply substitute new forms of PFAS for the six PFAS that will be regulated. WHAT IS NEEDED IS REGULATION OF ALL FORMS OF PFAS AS A CLASS OF CHEMICALS. Only then will we be able to begin to limit the prevalence of these chemicals in our environment and in ourselves.

Sincerely,

Thelma S Garbutt

Pittsboro, NC 27312

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mary Hirose (Doc. #2031, SBC-046734)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water.

We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Mary Hirose

Hoffman Estates, IL 60192

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lynne Harkins (Doc. #2032, SBC-046735)

Dear Michael Regan,

In my view, we simply must not betray today's children and future generations by failing to clean up our drinking water. Therefore, I most enthusiastically thank you for taking the first step to regulate PFAS in drinking water. For decades, as we now know, PFAS have contaminated drinking water supplies for millions of people across the country; resulting in increased rates of cancer, developmental and reproductive harm and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. Along with many others, I most strongly support the proposed standards, and most strongly urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule, it's heartening to see, would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal

would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water.

Summarily, with hopes for a better future for our life-sustaining waters, I join all others in urging and supporting you to quickly finalize these standards and to implement a rule that is the most health-protective;

Thank you for your work!

Sincerely,

Lynne Harkins

Cambria, CA 93428

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Dan Rosenberg (Doc. #2033, SBC-046736)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Dan Rosenberg

San Antonio, TX 78201

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

s h (Doc. #2034, SBC-046737)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible--although I would prefer they were stronger--there seems to be no recognition by Congress or EPA that it's quite likely that few people are exposed to just one "forever chemical" or one of known very long term toxicity. Rather most people in the US are exposed to many of them, PCBs, TCDD/other dioxins, BPA, BPS, PFAS and other of that chemical family. Very little to no research has been done on synergistic effects. It's up to a majority of Congress to provide that funding and to do it NOW. Supposedly all the anti-choice people care so very much about life, let them show it by making sure babies aren't being exposed to toxics in the womb, and later in breast milk (as so many are).

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

s h

Newport, OR 97365

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Emily Wilkins (Doc. #2036, SBC-046738)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. "Clean water" ought to mean safe for human consumption in any quantity without additional filtration. Clean drinking water is essential and the federal government is responsible for overseeing and helping fund water treatment systems nationwide so NO community need experience the disasters of Flint Michigan or Jackson Mississippi.

Endocrine-disrupting chemicals are ubiquitous and having a negative impact on our health. From making it harder to conceive to influencing people's gender identity, the cancer-causing chemicals allowed in a wide range of products must be restricted NOW.

For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases.

EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge

you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Emily Wilkins

Durham, NC 27704

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Bonnie Vendig (Doc. #2037, SBC-046739)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. EPA's PROPOSED DRINKING WATER STANDARDS would provide important and long overdue protections against six of these toxic chemicals. We strongly SUPPORT the proposed standards, and we urge EPA to finalize them as quickly as possible.

Despite the serious health risks associated with PFAS,THERE ARE CURRENTLY NO LAWS AGAINST THEM IN DRINKING WATER.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly FINALIZE these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Bonnie Vendig

Silver City, NM 88061

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Russell Freeland (Doc. #2038, SBC-046740)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. chemicals. I strongly support the proposed standards, and urge EPA to finalize them as quickly as possible.

Sincerely,

Russell Freeland

Vancouver, WA 98665

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mandy Senechal (Doc. #2039, SBC-046741)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. I strongly support the proposed standards, and urge EPA to finalize them as quickly as possible.

Please implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Mandy Senechal

Marine On Saint Croix, MN 55047

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Rima Goldman (Doc. #2041, SBC-046742)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated

drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Although now retired, I worked in healthcare and saw and diagnosed many cancer diagnoses. I strongly believe our environment is contaminated with too many toxic pollutants. Water, being so vital to life is essential and needs to be as pure as possible. Out water sources are becoming limited therefore it is crucial to protect those resources now for our future life on earth.

Sincerely,

R.Goldman MD

Sincerely,

Rima Goldman

Oakland, CA 94610

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Marbry Walker (Doc. #2042, SBC-046743)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Marbry Walker

Portland, OR 97203

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Todd Cochran (Doc. #2043, SBC-046744)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

Sincerely,

Todd Cochran

Missoula, MT 59801

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Gary Andrews (Doc. #2044, SBC-046896)

Dear Michael Regan,

Thank you for enacting the first tactics in a strategy to regulate PFA Substances in drinking water.

For decades, companies have profited selling PFAS that contaminated drinking water supplies for millions of people across America, causing the effect of increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would supply strategic and long overdue protections against six of these toxic chemical Substances. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible, and commence enforcement.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to

cause harmful effects decades after companies profit releasing them into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Despite serious health threats associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would supply safer drinking water for Citizens from coast to coast. By establishing strong limits on the profiteering of six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFA Substance-related illnesses each year. The EPA acknowledges and addresses the cumulative effects on Citizens who are exposed to multiple PFA Substances, and by issuing this proposal, EPA is one step closer to fulfilling its tactical commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFA Sibstamces in Citizens' drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's lobbying efforts to weaken them.

Sincerely,

Gary Andrews

Portsmouth, OH 45662

EPA Response: The EPA acknowledges and appreciates this comment in support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2045, SBC-046314)

Next you will be pushing that plastic and PVC is a contaminant that causes cancer and thyroid issues and must be eliminated from contact with drinking water. No one believes the so called best available science you are pushing. This is all Politics and trying to run up the federal debt using the not bypartisan infrastructure waste of tax payers money law funds on shovel ready BS. The people urge you to Drop this regulation and let the states decide. There is no link to cancer, thyroid kidney or any other health issue in people drinking PFAS at below 75 PPT over a 10 year period that can be proven to be from drinking water, no case studies no proof or science whatsoever, just manipulated extrapolations. Forever chemicals is another false statement. There is no repeatable tested science behind this. No links to cancer in humans. As a person sows so they will reap ion all things. It is an immutable law of nature created by Nature's God.

EPA Response: EPA disagrees with this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2046, SBC-046254)

Environmental justice rules where the unelected government decides what is justice and what is not is socialism/communism. America is a representative form of Government. It is a republic and not a democracy and not a bureaucratic nation state. Stop the PFAS regulations.

EPA Response: The comment is out of scope of this NPDWR, please see section 15 of the EPA response in this *Response to Comments* document.

Eri Higashi Durnell (Doc. #2048, SBC-047628)

I live on land polluted by the local Air Force before I moved here, and they have been held to filtering and maintaining the water quality of wells in the area since the groundwater has been so badly damaged by their pollution. However its clear with more recent scientific research that the 4 ppt PFAS limits on our water reports are still too high for our physical health and well-being. The base has shared they are waiting to see what the EPA does before doing anything differently, so I urge you to move forward with stronger measures to ensure lower limits of PFAS are achieved for a healthier populace.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. For additional information on the MCLs under the PFAS NPDWR, please see section 5.3 of the EPA response in this *Response to Comments* document.

Judith Moriarty (Doc. #2049, SBC-047636)

Clean, chemical-free water is vital for human, animal, and even some plant life. I personally know some Wisconsin citizens who have had to purchase bottled water for the past few years because their city water is contaminated with PFAS. A fellow university student was in near tears as he described this type of situation in his middle-of-Wisconsin rural community which has no access to clean, potable water because of the reckless use of "forever" chemicals by corporate concerns. This HAS to STOP!

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Dorie Reisenweber (Doc. #2050, SBC-047351)

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Chris Rauber (Doc. #2051, SBC-047606)

PFAS chemicals last forever. That's not a good thing, when we're talking about unnatural chemicals that are dangerous to humans and animals, and have unknown long-term effects on living creatures and the natural environment. I strongly urge the EPA to put the strictest limits possible on these chemicals. And by strict, I mean they shouldn't be allowed. They should be banned as quickly as possible. If an absolute ban isn't possible right away, the strictest of limitations should be imposed. Thanks for listening.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Edward Hyman (Doc. #2052, SBC-047658)

As a healthcare professional, former university administrator and assistant medical school program head I understand the scientific basis of concern for this chemical, which does not belong in water being consumed by human beings, or other mammals.

I strongly support the proposed drinking water limits for six PFAS chemicals currently endorsed by the EPA. During prolonged administrative proceedings, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These new EPA rules will speed the

implementation of life-saving water treatment for U.S. communities. Therefore, I strongly urge the Agency to finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Cinda Flynn (Doc. #2053, SBC-047650)

I do not understand why clean drinking water is even an issue. Especially when it comes to cancer causing, endocrine disrupting chemicals, and theres even more. Lets get strong protections from PFAS so we can have a healthy population, healthy kids, healthy environment. All those chemicals ultimately go into the environment, the river and oceans, where wildlife and fish drink them, concentrate them and then people are exposed yet again at even higher levels. Lets get this done!! Thank you!

Oh! You know what would be a good Idea How about we test all the chemicals BEFORE we turn them loose on the environment and people Think how many lives wilder been saved, could be saved by doing that. But seems we only care about a few people making money while the rest of us pay the the price. Do better please!

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Anthony Gatenby (Doc. #2054, SBC-047665)

The presence of emerging pollutants, including per- and polyfluorinated alkyl substances (PFAS) are of particular concern as they have been implicated in diseases using animal models. These animal studies indicate PFAS may affect reproduction, thyroid function, the immune system, and injure the liver, and are described in more detail by the Centers for Disease Control and Prevention (https://www.cdc.gov/biomonitoring/PFAS_FactSheet.html) and the Agency for Toxic Substances and Disease Registry (https://www.atsdr.cdc.gov/pfas/). Diseases caused by PFAS exposure are likely to be concentration dependent. The Working Environmental Group considers that any public water sample that has more than 1 part per trillion may be harmful to the human body (https://www.ewg.org/research/ewg-proposes-pfas-standards-fully-protect-childrens-health) while the Environmental Protection Agency sets the health advisory levels for humans as 70 parts per trillion for drinking water (https://www.epa.gov/sites/default/files/2016-06/documents/drinkingwaterhealthadvisories_pfoa_pfos_updated_5.31.16.pdf).

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lorene A (Doc. #2055, SBC-047592)

I'm honestly dumbfounded that we even have to have this conversation. It's ridiculous to think that these "chemical companies" are OK with poisoning Americans. Despicable behavior, we should have higher, MUCH HIGHER standards!!! As with all toxins nowadays, if you as a company produce this toxin, then you should have a plan to safely get rid of it too. This should apply to all you jerks who are poisoning our water, land and air just to make a buck. You make me sick!

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Andrea Thompson (Doc. #2056, SBC-047573)

As a consumer and constituent I demand that theEPA be given great big teeth to insure our water is clean and pure its not to much to ask and if the wealthy paid their fair share it wouldnt be an issue. Of course they can afford whole house filters but that wont remove the PFAS for anyone we need to stop plastics from being produced in the first place we are smart enough to find a plant based alternative! I dont want to be poisoned, do you!

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Paul Fishman and Mike Kurokawa (Doc. #2057, SBC-047537)

Our future is our children, and they are being continuously exposed to these low level toxins whose deleterious effects are not felt for decades. We should not make our children into lab rats in a giant experiment on the health effects of toxins. We need to act now on the toxins we already know are harmful to the kids.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

George Banziger (Doc. #2058, SBC-046427)

Protections Against PFAS Chemicals

In Appalachian Ohio and in the Ohio River Valley, where I live, PFAS chemicals are frequent inhabitants which endanger our water and have long-term health consequences. Please strengthen regulations against PFAS chemicals.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joy Schroeder (Doc. #2059, SBC-047571)

In my lifetime, thousands of chemicals have been added to our food, products we use and leak into our groundwater. I know we can live a cleaner, more safe for our health life when industries are held accountable for polluting. At one time, our country acted and were leading on environmental protection. Allow the EPA to follow the science which can help humans, plants, other creatures and all living things stay more healthy.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-

saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Larry Menkes (Doc. #2060, SBC-047539)

AFFF in our Warminster tap water has given my entire family cancer which was fatal to my wife and father-in-law and nearly bankrupted me. I also have serious cancer and may soon lose my life. What was unethical was that there was so much known and hidden from the general public which caused thousands of needless deaths.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Grason Weinstein (Doc. #2061, SBC-047652)

I'm 18 and everyday I open my computer, look at the news, and I see something bad. Sometimes, I think that things are fake because they sound so preposterous. There's no way us humans would let the world get that bad, right What do you mean there's microplastics in the rainwater, how could that be possible What do you mean that our cheese is filled with cellulose How could 'forever chemicals' exist I thought everything in the world cycled anew As much as I try to eat healthy, drink only water and no soda, I am held back by things literally out of my control. A lot of things are only in the control of the profit-makers. A lot of things are in control of the working class, but not enough. Then, there's policy makers and voters. If those making the profit don't care, then we have to. Think about it long-term.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Alice Svendson (Doc. #2062, SBC-047612)

As someone who is very concerned about the health of our growing children, our families and citizens of this powerful country, I want our government leaders to be world leaders in the clean water movement globally. Clean drinking water is vital for human health and well-being. It is vital to a healthy planet. Therefore, the EPA must stand responsible and exert a conscientious effort to protect all our communities from toxic elements in our drinking water. It is a battle that must be won, putting people's health and not profits first.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Faith Moeller (Doc. #2063, SBC-047610)

We have known about the dangers of PFA's for years. Chemical companies have long known of the dangers of these PFAS (Perfluoroalkyl and Polyfluoroalkyl substances) chemicals that never break down in the environment. They are linked to health problems including kidney and testicular cancer, damaged immune systems, and harm to the liver, thyroid, and pancreatic function. We should never have these type of chemicals put in anything that will impact human, animal, or plant health. Please finalize these rules quickly!

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges with this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joey Lindsey (Doc. #2064, SBC-047545)

Dirty water is number one killer of mankind. You elected officials were given your jobs on the promise to protect the citizens. You need to be tried in the Hague for crimes against humanity if you fail to do the right thing. Trump when he took office set about to destroy the EPA. Looks like all of you think it's fine to betray your fellow humans.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Andrew Kaufman (Doc. #2065, SBC-047656)

capitalism and cupidity will be the demise of us all. Once we care about each other, we will make progress. Until then the almighty dollar will rule. We are composed of 60-70% water. The most vital resource on earth for our survival, yet we are constantly abusing it. We all need to just slow down. We are the only creatures on this planet that take resources and modify them to our benefit. We don't live in harmony with mother earth, we take and take and expect it to never run out.

Mother Nature is fickle, and we never know what to expect and we are not very good at figuring it out yet. We are in a conundrum between the resources we now need to live our lives accustomed to what we have evolved to expect. Every person must start to conserve every day. Be conscious of water usage. We all need safe water. We are all just one big chemical reaction and water plays a big role in the correct functioning of our anatomy.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please section 1.3 of the EPA response in this *Response to Comments* document.

Brad Findlay (Doc. #2066, SBC-047594)

Keeping our drinking water, groundwater, as well as the rivers, creeks and lakes we recreate in clear from harmful chemicals is of utmost importance for our communities, our families, our ecosystems and our future. We must do everything possible to prevent and minimize future contamination of water sources by removing these forever chemicals wherever they are used and also set an example for other countries who may use the chemicals and not have any protections in place.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jefferson Hall (Doc. #2067, SBC-047583)

I am greatly concerned with the quality of my drinking water, it comes out of a river that allows surfboard boats to pull surfers on. These boats blast water down 16 feet and kick up silt, copious amounts of silt to be exact. Are used to change my water filters once a year, now its four times a year, that cant be good to the water quality. A lot of states and bodies of water are banning these boats. How can I go about getting them banned from my water way

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. A portion of this comment is out of scope of this NPDWR, please see section 15 of the EPA response in this *Response to Comments* document.

Frederick Ellsworth (Doc. #2068, SBC-047517)

Military is greatest polluter. Regulate, downsize, and convert to clean renewables.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please section 1.3 of the EPA response in this *Response to Comments* document.

Tonda Bian (Doc. #2069, SBC-047549)

It is on you to protect our Earth...We need to reduce emissions and pollutants. Now.. Otherwise, the earth will not be habitable in the near future...I have a Grandson, Miles, who won't be 1 until June, 2023. What will his future be like in a toxic world We owe it to his generation to stop thinking about only money and start thinking about people. Tonda

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges with this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jenny Walker (Doc. #2070, SBC-047563)

As a physician and public health advocate, I am very aware of the myriad of problems PFASs can create or worsen. As water becomes more scarce due to climate change, it is even more imperative that we clean up what we have contaminated and prevent further contamination.

Due to the slow pace of regulatory agencies understanding and actions, many Americans have been drinking harmful amounts of PFAS chemicals for decades. This has negatively impacted health and economics locally and nationally.

Therefore, I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. These rules will speed the implementation of life-saving water treatment for communities across the U.S.

Given the harms caused by PFASs, the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Elsa Obuchowski (Doc. #2071, SBC-047531)

EPA needs to do more to stop the chemical companies and manufacturers of household goods from producing PFAS and selling products that contain PFAS. If I understand correctly, PFAS can still be imported and sold in the USA. Needs to stop.

I am glad to see the proposed drinking water limits EPA has proposed for six PFAS chemicals, but I am concerned that there aren't enough labs that can do the testing, especially at the very low

levels EPA is proposing. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. Stronger EPA rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please section 1.3 of the EPA response in this *Response to Comments* document.

Marti Sowka (Doc. #2072, SBC-046446)

Hello - I am writing in support of the EPA proposal of new limits on PFAS pollution. For too long, Americans have been at the mercy of the chemical industry when it comes to PFAS. It is time to issue limits and also to limit the use of these chemicals in the manufacture of consumer products. Thanks you.

Marti Sowka

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Samantha Corte (Doc. #2073, SBC-047547)

We all need water every day--we can't avoid our drinking water. So it's especially important to keep it safe. This affects everyone. And we know that without regulation, there isn't much incentive for companies to be as careful as they should be with our water. We need to measure what's in our water and take steps to keep documented hazards out of it.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Thomas Driscoll (Doc. #2074, SBC-047434)

I believe the EPA's current proposed federal drinking water standards are a step in the right direction and will safeguard the health and safety of Americans for generations to come.

Thank you for your time and please do not hesitate to contact me at thd2tj@virginia.edu if you have any further questions.

Sincerely,

Thomas Driscoll

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Dawna Hammers (Doc. #2075, SBC-047525)

Water is sacred and needs to be pure and free of all toxic chemicals now and forever. When we pray for and appreciate water and pray for each other , the water and the planet we purify ourselves and the water. We are all connected! PLEASE STOP polluting our water!!!

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Charles Adelman (Doc. #2076, SBC-047575)

I live in the city of Los Angeles where our municipal water agency is spending $100 millions to build filtration plants to remove chemical contamination from our ground water that has forced us to abandon most of the water wells in the San Fernando valley that used to provide nearly 1/3 of our potable water supply. The more of these chemicals that get into our ground water, th more money we will have to spend to make the water potable again!

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

N L (Doc. #2077, SBC-047644)

The constant nonchalant exposure and ingestion of PFAS which our modern society deems totally acceptable without realizing the definite harm imposed to our lives, health and longevity +some yet unknown; has been longstanding concern in our family; and to know there are virtually no governmental standards in place for safety and real regulation- yet, with all dangers evident- is alarming and should be so for everyone /any with concern for life sustenance.

To us, this concern is for all living matter; but one would think all people would have concern for their own/family's health and safety from dangerous PFAS.

Please do much more.. and at least support the EPA's new limits regarding PFAS everywhere and especially drinking water.

Thank you for your care-

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Katherine Weaver (Doc. #2078, SBC-047523)

I think we need to be change course and start protecting the environment in ways we never have before. Business and the economy will never put long term preservation as a priority and that is why we need regulations to step in and force it.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Patricia Guthrie (Doc. #2079, SBC-047614)

Since "PROTECTION" is part of the name of your agency, it would seem to me that taking STRONG action against PFAS pollution SHOULD be a priority in PROTECTING our drinking water. I'm happy you FINALLY are taking your responsibility for protecting our drinking water seriously. This matters to me because, although I'm in my mid-70s, I have grandchildren and a great-grandson, all of whom could be negatively impacted by these "forever chemicals" in our drinking water. THEY ARE THE FUTURE AND SHOULD NOT HAVE TO WORRY ABOUT POISONS IN THEIR WATER!

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges with this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Linda Schneider (Doc. #2081, SBC-047555)

I like very much the idea that I can turn on my faucet and have reasonably safe drinking water. The chemicals discussed below have had their useful properties, which is why they were developed and used so many years, but now that we know the hazards they can pose in drinking water or emissions, we need to act to control and limit them! As discussed below, I support your proposed rule.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sue Keller (Doc. #2082, SBC-047259)

From firefighting foams to non-stick frying pans to food wrappers, the presence of toxic "forever chemicals" have become ubiquitous.

I strongly support the drinking water limits EPA has proposed for six PFAS chemicals. Many Americans have been drinking harmful amounts of PFAS chemicals for decades. These new

rules will speed the implementation of life-saving water treatment for communities across the U.S. I recommend the Agency finalize these rules as quickly as possible.

The hazards posed by PFOS, PFOA, HPFO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach.

EPA also should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Edith Couchman (Doc. #2083, SBC-047349)

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. The Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Carl Zimmerman (Doc. #2084, SBC-047535)

Chemical companies have long known of the dangers of these PFAS (Perfluoroalkyl and Polyfluoroalkyl substances) chemicals that never break down in the environment. They are linked to health problems including kidney and testicular cancer, damaged immune systems, and harm to the liver, thyroid, and pancreatic function.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joseph Gibbs (Doc. #2085, SBC-047577)

While we humans are smart enough to create these chemicals

compounds we certainly are smart to keep them out of our water aquifers and other surface water supplies. Why can't these compounds be created with a limited life cycle These compounds are remind of the PCB compound issue in the 70's and 80's. We are stewards of this earth and should leave it as we found it. Strengthen the requirements controlling PFAS pollution in our drinking water.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Erin Kilpatrick (Doc. #2086, SBC-047559)

We have a lot of work to do here and it needs to start now! Not only do we need drinking water limits for six PFAS chemicals, but we also need the corporations responsible for inventing these chemicals (Dupont/Dow) and profiting off them for decades to pay for remediation/water treatment and clean up. But we have to start now! Come on US government, let protect our citizens, not corporations.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Linda Zahrt (Doc. #2087, SBC-047533)

As a public health nurse I am delighted to see that the EPA is acting on this long-term water issue for its citizens. Hold the chemical companies accountable to pay for this serious pollution. The US Military must immediately take care of the water supply for those and their families who protect the rest of us.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Alan Birmingham (Doc. #2088, SBC-047620)

Poly- and perfluoroalkene chemicals, otherwise known as PSAFs and "forever chemicals" present a serious problem for the environment at large. The chemicals do not break down, which makes them unique. They are also poisonous at extremely small levels. These are being used by the increasingly large hydraulic frackturing industry by the gallon to pump underground where they are almost certain to seep into the earth and water supplies. This is likely to cause disasterous health consequences for anyone affected. The scope of this problem should not be overlooked.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Louise Usechak (Doc. #2089, SBC-047604)

Not only is PFAS an urgent problem, but the chemicals the industry is using to replace PFAS may be even worse and along the same chemical chain.with tweaks and variations about which we know nothing. We need to stop using PFAS or chemicals in this family in the items we come into contact with daily.. It is shockingly scary how much microplastic we now have in our blood and how much PFAS we have in our bodies. We must remove it from our drinking water which we rely on to maintain health and cook our food.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Debra Johnson (Doc. #2090, SBC-047626)

"Although there is evidence that makers of PFAS were aware of their adverse health effects as far back as the 1950s, the general public was largely uninformed. The companies kept health research from employees and the public for decades, as EWG chronicles in this timeline. We know much more about the health impacts of PFAS today....Bottled water constitutes another emerging PFAS risk. A 2021 study led by Johns Hopkins researchers found 39 out of 100 bottled waters tested contained PFAS...." (https://www.ehn.org/what-are-pfas-2656619391.htmlgclid=EAIaIQobChMIscGe9-HO_gIVoRJlCh3yIAJtEAAYASAAEgLwC_D_BwE)

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Amy Mueller (Doc. #2091, SBC-047551)

PFAS is a huge issue where I live in Wisconsin, and we need these federal protections as we have been held hostage by state governments tightly aligned with businesses that dont want to be held accountable or change their polluting practices because it will cost them too much!

As citizens - we have paid too much and will continue to pay until we figure this out!

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Karen Uhlenhuth (Doc. #2092, SBC-046479)

I do not want PFAS in my drinking water. The notion that we're taking in toxic chemicals from firefighting foam and the coating of non-stick pans is abhorrent. Please proceed quickly to adopt standards you have proposed to reduce allowable PFAS in our water. We are counting on you to base your decisions on the science, which solidly supports the need for lower PFAS limits. Thank you very much.

Please adopt stricter limits on PFAS in drinking water.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Bill Johnson (Doc. #2093, SBC-047541)

Drinking water is more critical to survival than food. You can live a lot longer without food than you can without water. Do the right thing. Protect everyone and everything that needs water to survive. Your grandkids will thank you for it. The only ones opposed to this are the companies getting rich off poisoning our future.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Peter Beves (Doc. #2094, SBC-047350)

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Barbara Lambdin (Doc. #2095, SBC-047553)

I live on Cape Cod MA. Here we have a single source aquafer so anything on the ground sinks into IT. It seems to me stronger regulations would be helpful, but more important would be for Chemical companies to be required to undergo the same scrutiny new drugs go through BEFORE they're allowed on the market. If the FDA can monitor before approval the EPA be able to do the same.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Israfel Mark Pafford (Doc. #2096, SBC-047642)

I am an avid supporter of protecting our natural resources and find every opportunity to spend time outside in nature. And I see on occasion, the impact of garbage and runoff both industrial and agricultural on our natural watercourses. Where the least regulated and least monitored states and communities have had to post signs and warnings about limited or no consumption of fish or no swimming is allowed due to the toxic water quality. The residents of these regions are greatly diminished when access to these areas become restricted or outright banned. I hope for a future soon where my neighbors and family can once again feel confident and safe about the quality of drinking water, and waterways for continued recreation and renewal.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Shellee Davis (Doc. #2097, SBC-047598)

PFAS chemicals are deadly and permanent, so they should be banned. Establishing limits is usually a boon to the industry that provide them in any form, leaving the toxic burden to destroy people and all life our environment. I implore you to establish the strongest, enforceable rules to stop this deadly pollution and to find solutions to make products and out environment clean and

safe again. This should be a priority, or we sacrifice all life to those who profit from making and spreading PFAS.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Robert Sander (Doc. #2098, SBC-046745)

Dear Michael Regan,

As a family physician concerned about the health of all Americans, I wanted to thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. I strongly support the proposed standards, and I urge EPA to finalize them as quickly as possible.

Sincerely,

Robert Sander

Custer, WI 54423

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Perry Cogburn (Doc. #2099, SBC-047608)

Growing up in Maine and living along the Androscoggin River, one of the most polluted rivers in the country due to paper mill discharges, no one ever thought that the river was recoverable. However due to environmental activists and strong water pollution laws, the river has become habitable again. We need the same sort of actions now to deal with PFAS. If not now, when How much more pollution do we have to subject people to before action is warranted We need to turn the corner on this problem and now is the time.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful

amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Judith Allen-Leventhal (Doc. #2100, SBC-047557)

The harm done by PFAS is not yet known. When I first became aware of the seriousness of the harm that PFAS pollution has been causing without public awareness, I was flabbergasted. This situation must be brought to light and broadly publicized so that the US can protect its citizens and citizens can protect themselves. Enacting the drinking water limits will be a helpful first step.

I strongly support instituting drinking water limits as EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These new rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency should finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Donna Thomas (Doc. #2101, SBC-047352)

strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. We need to reduce the toxic in our water. And maintain out water plants up standards. Its up to the EPA to unforced stronger rules. I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Laurie Peek (Doc. #2102, SBC-046242)

I completely support the proposed drinking water limits EPA has proposed for six PFAS chemicals, and I urge the Agency to increase its restrictions on and ideally, eliminate manufacture of these forever chemicals!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Marcia Jacobs (Doc. #2103, SBC-046746)

Dear Michael Regan,

As a mom of a child who died at age 4 of cancer our family had no history of, brainstem cancer, aka DIPG, and whose second child was born with a brain malformation we have no family history of, Chiari, I know there are too many dangerous chemicals getting into our bodies and causing diseases. We must clean up our water, air & soils.

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Marcia Jacobs

Sumner, WA 98390

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Patrick Sharp (Doc. #2104, SBC-047567)

I strongly support stricter standards for limiting PFAS content in our drinking water. These chemicals have the potential to drastically decrease the average quality of life of every human being on earth. I feel horrible when I think about what it would be like to raise a generation of people prone to debilitating and potentially life-threatening health problems due to the use of certain classes of chemicals.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Rian Raby (Doc. #2105, SBC-047569)

America wants clean, safe drinking water. My question is why would anyone with the knowledge that our water is being poisoned allow that to persist Why would anyone protect polluters and allow them to continue to poison our water with harmful substances that cause serious health complications and even death It should be an absolute no brainer to enact measures to ensure America has clean, safe drinking water for all.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges with this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Roland Hofman (Doc. #2106, SBC-047581)

Too many people are being exposed to harmful levels of PFAS chemicals in their drinking water. There have been a number of instances where citizens have had to drink bottled water because of these increased levels. Now we need to also address the emissions of these chemicals into our air. Clean air and clean water should be a right not a privilege. Let us all work toward to reducing our PFAS levels to everyone can have better air and water quality.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Susan Gottfried (Doc. #2107, SBC-046747)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. I strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water.

I urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Susan Gottfried

State College, PA 16803

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Tina Masterson (Doc. #2109, SBC-047602)

It is of great concern to me and thousands of other people that actions are taken now to support the EPA's proposed limits for PFAS chemicals in drinking water! Prevention is always the best course of action and it's already very late in the game. I urge everyone to do everything in their power to stop these toxic chemicals from invading our water supply in any way. We only have one Earth and we must preserve her to ensure life for us as humans as well as the animals fauna and Flora that we share it with.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

kate siegel (Doc. #2111, SBC-046748)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. I strongly support EPA's proposed drinking water standards which would provide important and long overdue protections against six of these toxic chemicals, and urge you to finalize them as quickly as possible.

PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. By issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic

Roadmap to begin regulating PFAS in drinking water. I urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

kate siegel

Atlanta, GA 30317

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Susan Adams (Doc. #2112, SBC-047527)

I have asthma and COPD and certainly don't need any more problems that PFAS would cause. I have grandchildren and I'm worried about the future of the world if we don't stop poisoning ourselves. Thank you for what you do to protect us from the chemicals that we continue making.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lara Levison (Doc. #2113, SBC-047638)

When people fear that their tap water is not safe to drink, they instead buy bottled water, which is not a good solution. As you know, bottled water isn't necessarily safer, but it is a LOT more expensive than tap water, putting an additional strain on the budgets of low-income people. Further, the empty water bottles create tremendous amounts of plastic pollution. Some go into landfills, some are burned for fuel-to-energy (releasing toxic air pollution), and some escape into the environment. I pulled dozens of plastic water bottles out of a stream on Earth Day, and I was one person out of hundreds and thousands of volunteers trying to clean up trash on Earth Day. Tap water needs to be safe and affordable for everyone.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-

saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Susan Allmart (Doc. #2114, SBC-046749)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible. My husband and I are now elderly, with our bodies reflecting a lifetime of exposures we now know were dangerous (lead mining in the neighborhood; second-hand smoke; fertilizers; PFAS; DDT; Agent Orange, etc.) For the sake of the old like us, but especially for the sake of everyone's grandchildren, and for wildlife, please DO give as much support as possible to the effort to eliminate PFAS from our food, water,...everywhere.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Susan Allmart

Mexico, MO 65265

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Aileen Curfman (Doc. #2115, SBC-047624)

I live in Berkeley County, WV, where several local public water supplies are contaminated with PFAS. One huge spill was the result of misuse of a PFAS-containing fire retardant during a National Guard training exercise. The city of Martiinsburg, WV had to find an alternate source of water when the city's normal source, a spring, showed contamination.

The harmful effects of these chemicals are well-known. The health needs of the public must take precedence over the convenience of the chemical industry, and even over the perceived benefits from using these toxic chemicals that never go away.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document

Doris Cellarius (Doc. #2116, SBC-047519)

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals.

Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sue Phelps (Doc. #2117, SBC-046533)

Dear Michael Regan,

Thank you for taking the first step to regulate per- and polyfluoroalkyl substances (PFAS) that have contaminated drinking water supplies for millions of people across the country. EPA's proposed drinking water standards would provide important and long overdue protections against

six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

Despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water. By establishing strong limits on six widely detected PFAS, the EPA's proposed rule would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

We urge you to quickly finalize these drinking water PFAS standards that were committed to under the 2021 PFAS Strategic Roadmap.

Sincerely,

Sue Phelps

Albuquerque, NM 87111

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mary Bautista (Doc. #2118, SBC-047515)

It is terrifying to think about the state of public health in this country without strong protections against PFAS.

We need to adopt the proposed drinking water limits that the EPA has proposed for six PFAS chemicals.

It is truly shocking to me that Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Nancy Blanton (Doc. #2120, SBC-046218)

I strongly support all efforts to reduce the per- and Polyfluoroalkyl substances in our drinking water!!!!!!! These substances are a health risk to everyone.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Monica Mull (Doc. #2121, SBC-046535)

I urge EPA to implement drinking water protections against PFAS contamination. This matter is a local issue for me as we have emergency situation's near Appleton, Wisconsin with PFF's in the drinking water.

We need national standards for PFAS. Expanding protections to six PFAS will protect our drinking water from this toxic contamination and shield Americans from enduring the health risks associated with these dangerous chemicals.

PFAS accumulate in people, wildlife, aquatic life, plants, and the environment. This contamination poses a direct threat to our health and our ecosystems. PFAS are pervasive contaminants that are linked to serious health conditions such as cancer, liver and kidney disease, reproductive issues, immunodeficiencies, and hormonal disruptions.

I urge your support for these badly needed regulations to better protect people and our rivers, oceans, lakes, and communities from PFAS contamination.

Thank you,

Monica Mull

Wisconsin resident

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kathleen Peterson (Doc. #2122, SBC-046750)

Dear EPA Environmental Protection Agency,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Ms Kathleen Peterson

711 Clifford Ave Akron, OH 44306-2281

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Caleb Merendino (Doc. #2123, SBC-046596)

Dear Honorable Administrator Regan,

Thank you for taking this historic step to keep our drinking water safe from PFAS contamination. For decades, PFAS chemicals have contaminated both public and private drinking water supplies across the country. PFAS contamination exposes communities to serious health risks, including cancers, impacts to the immune and reproductive systems, and other harms. The EPA's proposed drinking water standards would provide long overdue federal protections against six types of highly toxic PFAS. I strongly support this proposed rule and urge EPA to move swiftly to finalize health-protective standards to reduce PFAS in our drinking water.

The PFAS crisis is widespread, contaminating the blood of humans, fish, and wildlife worldwide. Communities of color and low-income communities are particularly impacted by PFAS exposure, where health impacts are often compounded because these communities tend to face cumulative effects from multiple environmental injustices and public health hazards.

EPA's proposal would significantly reduce exposure to PFAS in our drinking water for millions of people by setting strong, science-based drinking water standards for six types of PFAS. While this proposal is an important first step towards addressing PFAS exposure, it is critical that EPA also expedite efforts to prevent these chemicals from entering our waters and environment in the first place, before it even reaches our taps. This includes regulating industrial discharges of PFAS into surface waters, addressing PFAS in permits consistent with EPA's 2022 Clean Water Act guidance, cleaning up PFAS contaminated sites under the Comprehensive Environmental

Response, Compensation, and Liability Act, and preventing current and future use of PFAS chemicals.

I urge you to quickly finalize and implement the proposed PFAS drinking water standards rule to begin federally regulating PFAS in drinking water.

Respectfully,

Caleb Merendino

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. For more information on EPA's PFAS Strategic Road Map, please see section 15 of the EPA response in this *Response to Comments* document.

Donna Brown (Doc. #2124, SBC-047596)

I rely heavily on the drinking water supply as water is my primary drink and I love it! I am also a cancer survivor, as are many others, and my immune system is especially vulnerable to all the pollutants in our water. Naturally, I also have grave concerns for children who drink water indiscriminately as well as the rest of the living population of the world to include plants and animals. The great tragedies that have resulted from the abuse of our natural water system hurt my soul!

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

M. Christina Amundson (Doc. #2125, SBC-046936)

Dear Administrator Regan:

As a member of The Summit Garden Club, a constituent club of the Garden Club of America, and a resident of New Jersey, I am writing to express my concern about PFAS. The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the danger of PFAS.

PFAS are extremely persistent and widespread, and already have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS, including most of densely populated New Jersey. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Karen Rice (Doc. #2126, SBC-046937)

Dear Administrator Regan:

Because clean water world wide is becoming scarce and will become even more so in the near future , it is a particular concern of mine that we do everything we can to protect our drinking water.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Thank you for reading this,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Cathleen Davis (Doc. #2127, SBC-046938)

Dear Administrator Regan:

How ya gonna live without CLEAN water? Drink oil? Gas? Gold? Or, perhaps just continue promoting cancer, a by product of toxins released in our drinking water so DuPont and other corporations can make shareholders happy?

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jean Beyer (Doc. #2128, SBC-046939)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm. The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Ann Rauch (Doc. #2129, SBC-046940)

Dear Administrator Regan:

Public awareness of the dangers of PFAS continues to grow. It is long past time to regulate the use of PFAS and it's presence in our water. The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Brad Snyder (Doc. #2130, SBC-046941)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS!!

As a Science Teacher/Environmental Educator, Mechanical Engineering (Emphasis: Environmental Science/Engineering), and an extremely concerned citizen, I wholeheartedly insist the EPA develop the strongest rules possible to protect humans and the environment from PFAS chemicals!!

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm!!

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS!! This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year!!

I strongly urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing ALL other types of PFAS!! Thanks!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jean Nandfi (Doc. #2131, SBC-046942)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS. But note that across the U.S. there is very little pure drinking water that is now safe from serious pollution due to fracking and bursting oil pipelines that go under major rivers and other causes. The EPA needs increased enforcement capabilities to keep after these constantly increasing causes of pollution, or soon none of us will be safe.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Cristina Arnold (Doc. #2133, SBC-046943)

Dear Administrator Regan:

Enough with allowing people to unknowingly harm themselves, their families and environment with RoundUp. It isn't safe and the EPA needs to protect Americans already.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Vera Buk-Bjerre (Doc. #2134, SBC-046944)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a good first step to protecting our families and communities from the scourge of PFAS. Please do the right thing

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Laura Cotts (Doc. #2135, SBC-046435)

Dear Administrator Regan:

As a grandmother I am extremely concerned about the damage to young bodies caused by the PFAS chemicals. I am happy with your six proposals but urge you to tighten restrictions on these and other related chemicals as soon as possible. Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Teresa Ladd (Doc. #2136, SBC-046945)

Dear Administrator Regan:

Our family lives in Pittsboro, North Carolina where some of the highest levels PFAS/PFOS in our DRINKING water have been recorded. Anyone in the community who can afford to drink

bottled water does so. That, of course, leaves economically vulnerable families to drink contaminated, carcinogenic water! This is unconscionable and must change now! We don't need more studies. We need clean, chemical free drinking water and protection from upstream polluters who continue to dump toxic chemicals into our waterways. This is an outrage that must change now! Thank you for your service.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Linda Yow (Doc. #2137, SBC-046946)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

Please quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

Please quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kevin Bessett (Doc. #2138, SBC-046947)

Dear Administrator Regan:

The damage humans have caused upon Earth is catching up with us. Pollution is everywhere and is killing us in many different ways. Water is the key to life, and it must be cleaned up.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Roberta Waddle (Doc. #2139, SBC-046751)

Dear Michael Regan,

I live less than 10 miles from Dupont/Chemours plant where many of these chemicals are manuafactured and my well water is contaminated to the extent that Chemours will install a 'whole' house filtering system for our well. That will help with our drinking/cooking/bathing water. What it will not do is clean our soil so we can eat vegetables from our garden; it will not give us clean water for our birds and other pets and creatures on our small farm; it will not clean the pond water so we can eat the catfish in it. It does not make up for the pollution in our drinking water over the past 30 years we have lived here before we knew about the pollution. My husband and I cannot prove but suspect some health problems may be linked to our consuming contaminated well water for over 30 years. We believe Chemours owes us clean municipal water.

Chemours incinerated these chemicals and their by-products which put them in the air. They were then deposited on our surface water and our soils contaminating them, also. Drinking water is important, but it is not the whole story. Our soil is contaminated. Some research indicates that plants take these chemicals up and give us another source of contamination.

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Roberta Waddle

Fayetteville, NC 28306

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jo Rodgers (Doc. #2140, SBC-046884)

Dear Michael Regan,

Regulating PFAs in our drinking water is critical so that the damage done to health can be stymied. How many people have gotten sick with cancer and other illnesses due to this contaminant in their water? Too many.

EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Jo Rodgers

Eugene, OR 97405

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Allan Weiss (Doc. #2141, SBC-046948)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

If you people at EPA continue to do nothing to correct our polluted water supply, I deem you to be charged with aiding and abetting in the knowingly continuation of polluting our drinkable water supply. This cannot be tolerated any longer. More and more people are being compromised by this practice.

From a concerned 84 year old retired citizen without prejudice. "THE PROOF IS IN THE PUDDING."

Allan Weiss

CC: Wew Jjw Dy

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Stephanie Wright (Doc. #2142, SBC-046752)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. I STRONGLY support the proposed standards, and urge the EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals that persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. And yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Stephanie Wright

Douglasville, GA 30135

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

D. Meier (Doc. #2143, SBC-046949)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Andrew Michaelson (Doc. #2144, SBC-046950)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Marguerite Williams (Doc. #2145, SBC-046951)

Dear Administrator Regan:

I live in rural Maine and I know the issue of PFA's is an important one for all of us. We have many farms in our area, everyone has well water, we have coastal fisheries, ponds, and rivers that are all impacted by PFA's in the environment. PLEASE adopt the proposed regulations on PFAs!!

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mia DiFelice (Doc. #2146, SBC-046753)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases.

EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

But EPA must go further to regulate all PFAS, not just these six. Already, news has emerged that replacements for legacy PFAS have similar ill health effects. If EPA does not approve a rule that

covers PFAS as a class of chemicals, the Agency will be playing whack-a-mole with thousands of chemicals that are poisoning us. Chemical corporations' quick buck isn't worth a single cancer diagnosis; yet their pursuit of profit has been linked to thousands and probably untold more.

I strongly support the proposed standards, and urge EPA to finalize them as quickly as possible. I also urge the Agency to implement the most stringent, health-protective rules as quickly as possible, resisting industry efforts to weaken them.

Sincerely,

Mia DiFelice

Pittsburgh, PA 15232

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. As for regulating additional PFAS, the EPA will pursue additional PFAS as sufficient occurrence and health effects data are available based on SDWA requirements. For discussion on incorporating additional PFAS in the future, please see section 4.3.5 of the EPA response in this *Response to Comments* document. For additional information, please see section 15 for the EPA's PFAS Strategic Roadmap and section 6.3 of the EPA response in this *Response to Comments* document for PFAS Co-occurrence. The EPA's PFAS Strategic Roadmap is also discussed in section II.F of the FRN.

Isabella Molina (Doc. #2147, SBC-046504)

Dear Administrator Regan:

The EPA's proposed regulations on six highly toxic PFAS chemicals found in our drinking water are extremely necessary. Finalizing these regulations is the bare minimum.

PFAS are incredibly dangerous. They have severe effects not only on our environment but on our own health.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS.

I urge you to do the right thing. Not only do you have the responsibility to approve these regulations, you have to push for more regulations that will improve our water's quality and save lives.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

George Ball (Doc. #2148, SBC-046952)

Dear Administrator Regan:

America's chemical manufacturers must be tightly regulated. Too many deadly chemicals have been destroying our biodiversity for years. We live in an organic world and we must keep it that way. Modern science often does more harm than good. Products must be carefully vetted.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

David Dow (Doc. #2149, SBC-046754)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

I participated in last week's EPA PFAS MCL hearing where a number of ENGOs recommended the following improvements: Polluter pays component for BIPOC communities impacted by PFAS pollution of their drinking water; Precautionary Principle approach for PFAS chemical replacements; addressing PFAS residuals from PFAS treatment technologies; including Environmental Justice concerns in the dialog; addressing PFAS chemicals as a class of over 15,000 isomers.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

David Dow

East Falmouth, MA 02536

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. For discussion on incorporating additional PFAS in the future, please see section 4.3.5 of the EPA response in this *Response to Comments* document. For more information on disposal concerns for EJ communities and federal actions to address EJ, please see sections 10.4.3 and 14.10 of the EPA response in this *Response to Comments document*, respectively.

Jill Dahlman (Doc. #2150, SBC-046953)

Dear Administrator Regan:

I am a voting US citizen, born and raised in the US. When I was a child, my father, who was also born and raised in the US and served in the US Navy as a commander, told me the story of a river in Ohio that caught fire due to its unhealthy status. The Cuyahoga River. At the time, Dad told me that it is our duty (with the government's help) to maintain our waterways so that we citizens could have safe drinking water. The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS and supports what my Dad envisioned for all citizens (with help from the government) to protect that which is essential for survival: water.

I hold a doctoral degree. While it is not in science, I am smart enough to read articles about these PFAS, which are infamous for their extreme persistence and widespread pollution and have been

linked to a long list of health effects, including cancer, immune suppression, and developmental harm. As a victim of cancer (twice...), I do all I can to ensure that nothing bad gets put into my system so that the cancer does not return. Not everyone in the US has this privilege.

What I noted about the EPA's proposed rule is that it would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This is especially important for those poverty-stricken people who, unlike me, cannot self-educate and cannot afford to purchase expensive systems to filter their water. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. I applaud this.

Please finalize the regulations of these six PFAS chemicals quickly, implement a rule that is health protective for all people, and then begin addressing all other types of PFAS. We humans have caused these problems, so we need to fix them.

Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Judi Beardsley (Doc. #2151, SBC-046954)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

I personally understand the dangers of chemicals because I suffer from a horrific condition called Multiple Chemical Sensitivities/MCS along with severe Mast Cell and SIBO - which also cause the same issues. I am genetically predisposed to MCS and also had the misfortune to suffer from 4 toxic black mold exposures in which the last one turned something on in my body which quickly left me intolerant to almost everything in the world. I already suffered from very severe allergies including many medications and environmental factors. I have literally been a prisoner

in my home for nearly 20 years now. I have such severe reactions to most things that I have to pay thousands of times more for pretty much everything my family needs in order to find something I can safely tolerate. I can't even tolerate hardly any foods. These toxic chemicals build up in our system and we are unable to eliminate them like normal people. We all deal with so many Cancers in our world mainly due to toxic chemicals. It is vital that our water be safe and free of toxic chemicals for the health and well-being of all living beings. I wouldn't wish my life on anyone. Once you have MCS, it is a life sentence and the only effective treatment is 100% avoidance of all chemicals. It robs you of any semblence of a normal life and you are forced to such severe isolation that no one could ever fathom it ... or the horrible reactions that are a constant. The reactions affect every system in the body and can be life-threatening.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Melody Hamilton (Doc. #2152, SBC-046955)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS.

I ask you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and begin addressing all other types of PFAS.

Thank You,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Ralph D'Alessandro (Doc. #2153, SBC-046956)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS. Water is the most important and under appreciated resource we have in the US, with many taking clean and abundant water for granted. Expeditious implementation of regulations will help make more water safer for all of America.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Margaret Samu (Doc. #2154, SBC-046957)

Dear Administrator Regan:

Thank you for your role in the EPA's proposed national drinking water regulations to limit six PFAS chemicals. This is a very welcome first step to protecting our families and communities.

I am concerned about PFAS because of their extreme persistence and widespread pollution. As you know, they have been linked to a long list of health problems, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I am writing to urge you to quickly finalize the regulations of these six PFAS chemicals. Now is the time to implement a rule that is protects our health, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Adam Hersko-RonaTas (Doc. #2155, SBC-046958)

Dear Administrator Regan,

There's no time to waste. You have an opportunity to make history! The EPA's proposed national drinking water regulations for six PFAS chemicals is a VITAL step to protecting our families and communities from toxins.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Thanks for leading the charge on doing the right thing.

Sincerely,

Adam

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Pamela Smith (Doc. #2156, SBC-046959)

Dear Administrator Regan:

THESE REGULATIONS MAKE SENSE! WE SHOULD DO ALL WE CAN TO KEEP "FOREVER" CHEMICALS OUT OF OUR LIVES. LET'S GET STARTED NOW... FUTURE GENERATIONS WILL BE "FOREVER" GRATEFUL!

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Hazel Cope (Doc. #2157, SBC-046960)

Dear Administrator Regan:

Please read the following letter very carefully and consider one thing: How would you feel if your family's water supply was contaminated? Then decide what action you would wish your government to take. The read the message below.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Trish Pool (Doc. #2158, SBC-046961)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kate Cunningham (Doc. #2160, SBC-046962)

Dear Administrator Regan:

I live in a cancer belt, namely the Ohio River Valley. Our local water company wins awards for pure drinking water that meets EPA standards. Unfortunately, current EPA standards are not enough to protect us from PFAS. The water company would not even test for PFAS until EPA set some standards, and current standards, we now know, are not sufficient to protect public health. This is important:

Please implement the strongest possible PFAS standards asap, to protect me and everyone else who drinks water in the US.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Dorothy Frisch (Doc. #2161, SBC-046462)

Dear Administrator Regan:

We have a severe problem with PFAS contamination here in Michigan, and I'd like to see the strongest possible regulations to protect the health of Michiganders! Please act quickly to finalize the regulations of the proposed six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Janet Beazlie (Doc. #2162, SBC-046963)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

My mother developed lymphoma in her 80s from her 30-plus years of exposure to Monsantos' RoundUp. She based her use on her belief that her government would never allow businesses to approve and sell dangerous

chemicals.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Marya Tyler (Doc. #2163, SBC-046964)

Dear Administrator Regan:

For real! The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting us from PFAS.

Get it done!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Cameron Fischer (Doc. #2164, SBC-046464)

Dear EPA:

I will be glad once you institute regulation of the additional PFAS chemicals, and I hope that you do more. Unlike many environmental crises we're facing which, while critical, can theoretically be reversed, the introduction of PFAS chemicals into our environment cannot be undone. Which is why stronger enforcement cannot come soon enough.

-Cameron Fischer

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Fran Teresi (Doc. #2165, SBC-046965)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals to preserve residents' health, to reduce health care costs and to secure the health of America's children, implement a rule that is health protective, and then begin addressing all other types of PFAS.

I believe Europe is was ahead of America on this type of action. Catch up!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Janet Smarr (Doc. #2166, SBC-046542)

Dear Administrator Regan:

I support the EPA's proposed national drinking water regulations for six PFAS chemicals to protect our families and communities from the harms of PFAS.

PFAS are dangerous both for their extreme persistence and for their widespread pollution. They have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm. Sadly, they are found pervasively and are impossible to avoid; but we can help by at least getting them out of our drinking water.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals and implement a rule that protects our health.

After that, please begin addressing all other types of PFAS.

Thank you for your attention and concern.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Darcy Duda (Doc. #2167, SBC-046888)

Dear Michael Regan,

EPA's proposed drinking water standards would provide important and long overdue protections against six toxic PFAS chemicals. I strongly support the proposed standards. Please finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. And that's only for humans. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water. The time is long since passed to limit these l—and many other—substances.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. Your

people and the earth urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Darcy Duda

Gardiner, ME 04345

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sean Ross (Doc. #2168, SBC-046966)

Dear Administrator Regan:

First off...the EPA is supposed to PROTECT the citizens of the United States, meaning to do something BEFORE it happens NOT afterwards!! I'm tired of being exposed to chemicals that the EPA should never have approved to begin with. The EPA is a FARCE!!!

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Elaine Hasbrook (Doc. #2169, SBC-046967)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mark van Rossen (Doc. #2170, SBC-046495)

Dear Administrator Regan:

It is of primary importance that the EPA protect the people it meant to serve.

The EPA cannot sit on its hands in regard to reigning in the spread of PFAs in our environment. PFAs are known to cause serious detrimental health effects, therefore they should be banned from any usage that would present them into the waters of this land.

The corporate control of our governments must be addressed and no amount of campaign cash should influence the policies of the EPA. The American people deserve environmental protections under the law.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lana Huber (Doc. #2171, SBC-047491)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jonathan Lee (Doc. #2172, SBC-046968)

Dear Administrator Regan:

Thank you for serving our great nation.

It's unnerving to think that we are releasing forever chemicals into the environment before understanding their long term consequences or how to break them down. Until we have a better handle on the situation, we should avoid making the problem worse.

-- NRDC message below --

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lauren Luis (Doc. #2173, SBC-046969)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

we need the EPA to do more to protect against PFAS.

Exposure to PFAS – known as "forever" chemicals because they are extremely resistant to breaking down in the environment – has been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

But every day, millions of people across the country drink water contaminated with PFAS. Unfortunately, PFAS are almost impossible to avoid. They are found in our homes, our offices, our supermarkets – practically everywhere. What's worse, manufacturers don't have to disclose to consumers that they're using them. It needs to stop!!!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

John Evenson (Doc. #2174, SBC-046970)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Personally, I am one of hundreds of people who fish the Madison, WI chain of lakes, which is heavily polluted with PFAS. I no longer eat the fish that I catch, but many people still do at great risk. Please help!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jane Twitmyer (Doc. #2175, SBC-046755)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. EPA's proposed drinking water standards would provide important and long overdue protections against six toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water.

We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Jane Twitmyer

Nellysford, VA 22958

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Cheryl Nelson (Doc. #2176, SBC-046223)

Safe drinking water is the lowest bar for government. If we can't trust our water, the US government has failed. Whatever is needed to make our water safe should be done.

EPA Response: The EPA believes this final NPDWR is what is needed to protect our waters from PFAS. Therefore, the EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mark Freitag (Doc. #2177, SBC-046971)

Dear Administrator Regan:

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Linda V Maloney-Tarvers (Doc. #2178, SBC-046972)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I live in Hawaii on Oahu and we have a huge problem with PFAS in our main acquifer on this island.....AND the Navy admits responsibility after covering up and finally being discovered.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kathleen Port (Doc. #2179, SBC-046973)

Dear Administrator Regan:

I am a health care professional, and I urge you to take science-backed protective measures to protect American families and communities. Please advocate for protecting the people based on what we know about the 6 dangerous PFAS. The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Noah Goodman (Doc. #2180, SBC-046578)

Dear Administrator Regan:

The Environmental Protection Agency's (EPA) proposition to instigate national drinking water standards for six PFAS chemicals is a significant stride in the right direction. As a parent of three beautiful children, I see this as a vital measure towards shielding my family, and indeed all families, from the harmful effects of PFAS.

PFAS are notorious for their resilience and widespread contamination. Their association with numerous health issues, including cancer, immune system impairment, and developmental harm, is deeply worrying.

The EPA's proposed rule holds the promise of cleaner, safer drinking water for millions of individuals across our nation. This includes communities where the purity of drinking water has been marred by PFAS contamination. The potential impact of this proposition is not to be underestimated - it could save countless lives and ward off tens of thousands of severe PFAS-related illnesses each year.

As a concerned parent, I implore you to expedite the approval of these regulations concerning the six PFAS chemicals. A health-protective rule needs to be implemented promptly, after which we should turn our attention to addressing the remaining types of PFAS. This appeal is driven by a simple yet profound motivation - to ensure the safety and well-being of my three children, and indeed, all children. They are our most precious treasures and their health should be of utmost priority.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Chris OMeara Dietrich (Doc. #2181, SBC-046570)

Dear Michael Regan,

PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Despite the known serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

I am happy that the EPA is finally taking the first step to regulate PFAS in drinking water.

I live in an area that draws some of its drinking water from wells, which were discovered to be contaminated by PFAS after years of using the water for our community.

EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals, and I strongly support the proposed standards, and urge EPA to finalize them as quickly as possible.

The EPA acknowledgement and address of the cumulative impacts on communities who are exposed to multiple PFAS will bring change, and by this proposal, the EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap.

I strongly urge the EPA to quickly finalize these standards and to implement a rule that is the most health-protective, and most importantly, resist industry's efforts to weaken them.

Sincerely,

Chris OMeara Dietrich

San Jose, CA 95148

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Paul Grove (Doc. #2182, SBC-046433)

To Administrator Regan:

We need the strongest possible protections from PFAS chemicals and we need them NOW.

Please finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Reihn Bailey (Doc. #2183, SBC-046756)

Dear EPA Environmental Protection Agency,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment

under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Ms Reihn Bailey

576 Keller St Barberton, OH 44203-1808

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Berthe Ladd (Doc. #2184, SBC-046974)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sarah Stretton (Doc. #2185, SBC-046282)

I want to let the EPA and the US Federal Government know that I fully support any and all efforts to limit toxic chemicals, especially the class of chemicals commonly known as "forever chemicals", in our nation's drinking water. Research has shown that these forever chemicals are linked to a plethora of health problems, including serious and deadly conditions like cancer. Please go forward with limiting the presence of these chemicals in our drinking water supply.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Drew Beck (Doc. #2186, SBC-046271)

Please (please please please!) put these rules into effect. PFAS are the leaded gasoline/lead paint of this generation, they are slowly poisoning us. Drastic action is needed. This rule is a good start. Please test all drinking water for PFAS and take immediate action to ensure safe levels. There is no room for leniency on this issue, PFAS must be eliminated now.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Anne Baldwin (Doc. #2187, SBC-046975)

Dear Administrator Regan:

Contamination of our drinking water is not an option, it is a health risk creating issues that are eventually paid for by our economy with job loss and burdens on social welfare.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Stanley J. Solomon (Doc. #2188, SBC-046976)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

I would add that because of the laws of thermodynamics, global warming will cause all human reactions to proceed at a faster rate. Consequently human reaction to a foreign substance that is a minor problem today will be a much stronger reaction in the future. the only way out is to lower the forein sustance's concentration.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Teresa Piccolo (Doc. #2189, SBC-046977)

Dear Administrator Regan:

I am totally supportive of EPA's proposed national drinking water regulations for six PFAS. We must trust that the government will do its duty and insure that our right to have safe drinking water is adhered to. It is now well known that PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS.

Please finalize the regulations of these six PFAS chemicals, and monitor our water system to outlaw other harmful chemicals in our water system. Thank you for passing legislation which has top priority to protecting our health.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Megan Williamson (Doc. #2190, SBC-046450)

Dear Administrator Regan:

First steps are excellent! So glad the EPA is proposing national drinking water regulations for PFA chemicals!

It is well know what harm these things to to our health - on so many levels! Let's get this regulation through and start addressing other harmful things in our drinking water.

Thank you!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Laurel Nakanishi (Doc. #2192, SBC-046262)

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Please finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lynn Pique (Doc. #2193, SBC-046978)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme resistance to breaking down in the environment and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

The sooner the regulations of these six PFAS chemicals are finalized, the better. I urge you to quickly implement a rule that is health-protective and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Elizabeth Tatus (Doc. #2194, SBC-046979)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

I believe that by restricting these harmful chemicals you will cut the hydra of health issues, which are a burden emotionally to families and financially to the nation. It is your responsibility to do so, to protect those who do not have the power or financial means to protect themselves. Only you can stand up to corporate greed to do what is in the best interest of humanity. Thank you.

Elizabeth Tatus

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Barbara Pikus (Doc. #2195, SBC-046980)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

THIS so-called first step should have happened years ago. So many people seem perplexed that the population, especially children, are afflicted with serious diseases, autism, cancers, behavioral problems, hormonal problems. Yet, we keep poisoning the water we drink, the food we eat, the produce and the animals we grow, and it goes on and on. Such mysteries! Walk down

an aisle in any major supermarket and you have potential answers, BUT there's too much corporate money and power to change anything.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Meredith Stone (Doc. #2196, SBC-046444)

Dear Administrator Regan:

Please quickly finalize EPA's proposed national drinking water regulations for six PFAS chemicals, as a first step to protecting our families and communities from these toxic forever chemicals. I also hope that EPA will also begin addressing all other types of PFAS.

Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Henry Pinkerton (Doc. #2197, SBC-046981)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal

would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS. I would also like information about combating air pollution. Polluters pollute because they believe and act "because we can!" We need to believe and act " because we can"!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Hugo Steensma (Doc. #2198, SBC-046982)

Dear Administrator Regan:

It is IMPERATIVE that you act NOW, to protect th Public Health on this nation, our domestic animals & our wildlife from All toxic chemicals that may contaminate our drinking water -- especially the "forever chemicals" like PFAS's.

The EPA's proposed national drinking water regulations for six PFAS chemicals is an URGENTLY NEEDED first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

My husband & I, & our family, MUST DEMAND that you act to protect our health, & VERY quickly finalize the regulations of these six most prevalent PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

THANKS YOU

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Raphael Rivera (Doc. #2199, SBC-046983)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

The government is supposed to care about its citizens and their health. By continuing to allow all of these different chemicals in our water, it shows us that our own government is against its citizens.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Dawn Barry-Griffin (Doc. #2200, SBC-046984)

Dear Administrator Regan:

Last month, the citizens of Vancouver,WA where I live were informed that 3 of 6 water wells had higher than acceptable levels of PFA's and PFOA's. This created HUGE concern in my household and our general community.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lynnette Saunders (Doc. #2201, SBC-046518)

Dear Administrator Regan:

I am relieved that the EPA is proposing national drinking water regulations for some of the PFAS chemicals. As you no doubt know, PFAS chemicals are known for their extreme persistence and wide spread and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Paula Myles (Doc. #2202, SBC-046985)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

For 60 years on Cape Cod, I swam in clear natural ponds that are now testing positive for PFA's , no longer safe for people or animals.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sarah McUmber-House (Doc. #2204, SBC-046986)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

We live in this environment! We deserve to be protected from these poisons, not see profiteers protected, while we pay the price of losing our health, safety, and even lives.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Andrea Zuckerman (Doc. #2205, SBC-046987)

Dear Administrator Regan:

I am pleased that the EPA has proposed national drinking water regulations for six PFAS chemicals which have been proven to effect the health of millions of people in this country.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Suellen Rowlison (Doc. #2206, SBC-046988)

Dear Administrator Regan:

AS A RETIRED PUBLIC HEALTH NURSE, I URGE YOU TO TAKE ACTION TO PROTECT OUR CHILDREN AND ALL OF US. THANK YOU.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mary Shumay (Doc. #2207, SBC-046989)

I don't even understand how this is up for debate with your completely co-opted agency.

You should be ashamed to not consider this a true crisis, at the very least for the sake of the children. DO THE RIGHT THING AND SHAME ON YOU for bending to the likes of Gates and other disgusting Corporations poisoning Earth and everything on it for profit! Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Howard Higgins (Doc. #2208, SBC-046990)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

The reclassification that lower amounts of PFOA/PFOS cause higher harm means that action must be taken immediately to filter these forever chemicals from our biosphere. The health of our entire world community is at stake!

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Laurie O'Rourke (Doc. #2209, SBC-046991)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

Additionally, these standards must be applied to all drinking water, and not just larger community supply sources. The ubiquitous dispersion or PFAs around the globe is alarming. It's imperative that standards apply to all bottled water and eventually all wells.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Evan Lloyd (Doc. #2210, SBC-046412)

Dear Administrator Regan:

I urge you to quickly finalize the regulations of PFAS chemicals and implement a rule that is health protective of all types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

John Vanellis (Doc. #2211, SBC-046992)

Dear Administrator Regan:

As a former high school biology teacher I understand the importance of science in policy and decision making in our government. I'm afraid too often scientific evidence is ignored. It's time to side with science, not big business.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Carl Martin (Doc. #2212, SBC-046993)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals are a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

I will add that this egregious instance of corporate malfeasance (a damaging invasion of every ecosystem) shows how capitalist profit always involves the offloading and obfuscation of the real costs of production.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Margaret Bartenhagen (Doc. #2213, SBC-046994)

Dear Administrator Regan:

PFAS, or 'forever chemicals" are turning up in the soil and water everywhere in this country. These discoveries have damaged the health and livelihood of farmers and others where these chemicals have been found. We must stop using these and similar chemicals, and also aggressively work to address existing and further contamination.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I STRONGLY urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Cheryl Najor (Doc. #2214, SBC-046995)

Dear Administrator Regan:

No one should live in a world where PFAS and its accompanying 9,000 counterpart poison should be found in our drinking water and bodies. According to the NIH website, to date, the research conducted reveals possible links between human exposures to PFAS and adverse health outcomes. These health effects include altered metabolism, fertility, reduced fetal growth and increased risk of being overweight or obese, increased risk of some cancers, and reduced ability of the immune system to fight infections.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Glenn Rawson (Doc. #2215, SBC-046516)

Dear Administrator Regan:

PFAS are pervasively dangerous, and I welcome the EPA's proposed national drinking water regulations for six PFAS chemicals as a first step in protecting our communities from this terrible problem.

PFAS are an extremely persistent, widespread pollution that's linked to cancer, immune suppression, developmental harm and more.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to finalize these regulations quickly, implement a rule that protects our health, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joanne Edmundson (Doc. #2216, SBC-046996)

Dear Administrator Regan:

PFAS are a serious threat to Americans. These widespread, dangerous persistent chemicals are nefarious widespread pollutants linked to cancer, immune suppression, and developmental harm.

Our government must be more proactive in protecting the health of our people. The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities.

A strong and healthy country depends on the health and safety of its people and the communities where they live and work. The EPA's proposed rule would provide safer drinking water for millions of people in communities across the nation where their drinking water is contaminated by PFAS. Not to take steps to save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year is morally and economically indefensible.

For the sake of my neighbors, grandchildren and fellow Americans across our great country I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Respectfully,

Joanne A. Edmundson

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kayan Sherrer (Doc. #2217, SBC-046997)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals are a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to finalize the regulations of these six PFAS chemicals quickly, implement a health-protective rule, and then begin addressing all other types of PFAS.

WATER is life and should NOT be TOXIC!!!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Gary Lee (Doc. #2218, SBC-046998)

Dear Administrator Regan:

The EPA's proposed drinking water regulations for PFAS chemicals are a start for protecting our families and communities from the scourge of PFAS.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jan Wright (Doc. #2219, SBC-046999)

Dear Administrator Regan:

Though the EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities, it is not enough!

I am careful to filter my water, but who knows what PFAS get through, and what about people who can't afford to filter their water? PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

David Shpak (Doc. #2220, SBC-047000)

Dear Administrator Regan:

The EPA's proposed national drinking water regulation for six PFAS chemicals is a welcome first step to protecting people from PFAS exposure.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS.

Please finalize the regulations of these six PFAS chemicals, implement a rule that is health-protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kate Considine (Doc. #2221, SBC-047001)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a very welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been scientifically linked to a long list of negative health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in all our communities, but especially our low-income and communities of color across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of our lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I strongly urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Thank you for caring about us.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Donna Luna (Doc. #2222, SBC-047002)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

It is imperative that you take action to assure that the American people have safe drinking water without these harmful PFA's. We are aware of the damage caused to the human body by these chemicals, and it makes no sense to continue to allow them.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see the section 1.3 of the EPA response in this *Response to Comments* document.

Michelle Eul (Doc. #2223, SBC-046478)

Dear Administrator Regan:

I am an engineer from Wisconsin and a mother of two young children.

Thank you for the EPA's proposed drinking water regulations for six PFAS chemicals! This proposal would provide safer drinking water for the millions of people.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Thank you,

Michelle

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Don Hittle (Doc. #2224, SBC-047003)

Dear Administrator Regan:

I know this is a form letter of sorts, but it does express my own personal views in a way that is direct and reasonable, so I wholeheartedly endorse it. Please continue to do whatever you can to protect or resources and our health. Thank you!

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal

would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Paula Posas (Doc. #2225, SBC-047004)

Dear Administrator Regan:

It is not common knowledge for people to know about PFAS and drinking water concerns. Federal action is needed to help people.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Thank you for starting the task and please make haste to completing it!

Best,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

John Twentyfive (Doc. #2226, SBC-047005)

Dear Administrator Regan:

The fact that we have to ask for these things to be done is on it's own, troubling. That said, please enforce the strictest rules possible in banning these harmful chemicals from our water. Future generations are counting on you.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sheli Tabachnik (Doc. #2227, SBC-047006)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

I'd like to see my children and grandchildren survive cancer and any of horrendous illnesses caused by these chemicals. Wouldn't you????

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Elspeth Kerr (Doc. #2228, SBC-047007)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals ARE a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

In Hawaii we are particularly concerned with the safety of our water supply, especially following the difficulties we have had with the Navy & the possibility of oil leaking into our aquifer from "accidental" spillage.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Rebekah Creshkoff (Doc. #2229, SBC-046227)

Hats off to the EPA for proposing national drinking water regulations for six PFAS chemicals. Now please go forth and do likewise with all 9,000-15,000 other PFAS. Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jean Pullen (Doc. #2230, SBC-046434)

Dear Administrator Regan,

Please protect our nation's health and drinking supply by finalizing the new regulations for these six PFAS chemicals. Move on, then, to regulate other types of PFAS.

Thank you for helping to save thousands of lives.

Sincerely,

Jean Pullen

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Elizabeth Makiewicz (Doc. #2231, SBC-046491)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is long overdue. We need protection for our families and communities from this scourge.

PFAS cause widespread pollution. They have been linked to a long list of detrimental health issues.

The EPA's proposed rule would provide safer uncontaminated drinking water for the millions of people in communities in the USA. Please quickly finalize the regulations of these six PFAS chemicals. The EPA may then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Barbara Vogel (Doc. #2232, SBC-047008)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

If a substance, ANY substance, has been shown to be harmful, it should not be in our air, water, food or medicine. We have such lax regulations compared to the EU. Why?

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Christine Miller (Doc. #2233, SBC-046493)

Dear Administrator Regan:

I am encouraged by the EPA's proposal for national regulations on Per- and Polyfluoroalkyl chemicals in drinking water. This proposal has the potential to prevent many thousands of serious PFAS-related health issues each year - included issues of such seriousness that they result in death.

Please finalize this proposal to help save lives as well as greatly improve the lives of the many people whose health and quality of life is seriously affected by ingesting drinking water contaminated by these chemicals.

Sincerely,

C Miller

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jenna Poulin (Doc. #2234, SBC-047009)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

I have been studying the forever chemicals trying to get the PUR water project here in Tampa fl stopped. There is plenty of evidence and studies proving how harmful forever chemicals are to not just humans animals as well who drink the water. The government will save over time

on.health care issues banning these chemicals vs treating people for them. I am begging you to plz say no! Thank you for your time and consideration!

With love,

Jenna Jewel Poulin

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Linda Holt (Doc. #2235, SBC-047010)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

It would so wonderful if we could clean up all of our "city" water, but our streams, rivers, lakes and oceans are in dreadful shape too, and need our attention also.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Dee Grimsrud (Doc. #2236, SBC-046577)

Dear Administrator Regan:

I live in Madison, Wisconsin, whose water is considered to be safe, according to all past and current standards. But we stopped drinking and cooking with tap water decades ago because of old lead water pipes (now replaced), and continue to do so because of the other toxic chemicals, such as PFAS, that are only now being recognized as causing a long list of health effects, including cancer, immune suppression, and developmental harm.

As far as I'm concerned, the EPA should allow ZERO of such chemicals, so that our water is actually safe to drink out of the tap without users themselves having to regularly buy purified water or purchase and maintain expensive filter systems at home. If that means utilizing high cost infrastructure, then utility companies should receive subsidies from state and federal governments.

Yes, the EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

So I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective. But this should be just the first step in a series of new regulations that address all other types of toxic chemicals.

Safe water should be considered a human right, not a luxury.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Melissa McSwigan (Doc. #2237, SBC-046469)

Dear Administrator Regan:

Thanks for the EPA's proposed national drinking water regulations for six PFAS chemicals. I'm concerned about the junk in my drinking/bathing water.

PFAS stick around for way too long and can be linked to diseases.

Please finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS. Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Bonnie Benjamin (Doc. #2238, SBC-047011)

Dear Administrator Regan:

There are enough things out there that can kill an older woman like me. We can do something about this one. Let's do it.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Nancy Linder (Doc. #2239, SBC-047012)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

Children are being born with more disabilities. More rare cancers are being diagnosed in adults and children. PFAS chemicals are being found in human blood. We must stop this cycle.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mary Herman (Doc. #2240, SBC-047013)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

It would seem to me to be a "no brainer" to implement tighter controls on what is going into our water supply and the fact that these chemicals cause so many health issues. It would save lives as well as money since there would be less health problems, many of which will have to be paid for via Medicare\Medicade. Please pass laws to protect the environment and the lives of the people you are serving.

Thank you,

Mary Herman

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Judy Schultz (Doc. #2241, SBC-046526)

Dear Administrator Regan:

As a nurse, I appreciate the EPA's proposed national drinking water regulations for six PFAS chemicals as a first step to protecting our families and communities from toxic PFAS.

As you know, PFAS are extremely persistent, widespread, and are associated with many adverse health effects, including cancer, immune suppression, and developmental harm.

The proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS and save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

We simply cannot continue to tolerate these chemicals in our environment, so I implore you to quickly finalize these regulations, implement a rule that is health protective, and address all other types of PFAS.

Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Robert Pantel (Doc. #2242, SBC-047014)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Please protect the health of my grandchildren. We now know enough to tightly restrict and regulate these chemicals. The time to act is now.

Thank you,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Amanda Treat (Doc. #2243, SBC-047015)

Dear Administrator Regan:

As the wife of someone who has suffered from PFA poisoning from his drinking water (he grew up in Parkersburg, WV), I have witnessed the immense physical suffering these chemicals caused my husband, his brother and his mother.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

It is too late to protect my husband, but we can save future generations from these terrible chemicals.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Robert Aronson (Doc. #2244, SBC-047016)

Dear Administrator Regan:

Please implement national drinking water regulations for six PFAS chemicals as soon as possible.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

John Duggan (Doc. #2245, SBC-047017)

Dear Administrator Regan:

Growing up in the 1950's I kept reading about the wonders of modern agriculture. Fast forward seven decades and those wonders have proved to be less than wonderful. As we've learned that the law of unintended consequences was ignored as we rushed into chemical agriculture,, we must try to heal the damage and stop it from occurring. That's your job and the public expects you to do it well.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kathy Kahn (Doc. #2246, SBC-047018)

Dear Administrator Regan:

Clean drinking water is necessary for the health of all people. This should be one of the priorities of our government. Water is being affected by plastic pollutants more every day. Is this what we want to leave our children?

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Julie Breskin (Doc. #2247, SBC-047019)

Dear Administrator Regan:

Just today, JAMA published a study, linking toxic industrial solvents in drinking water on a military base to Parkinson's disease in Camp Lejeune veterans. The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS. Our veterans deserve it, our children deserve it, and we all deserve healthier, drinking water!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Colonel Williams (Doc. #2248, SBC-046463)

Dear Administrator Regan:

Forever chemicals are creepy. We can't know when they are present. Producers and manufacturers insert these ingredients for their purposes We are unaware and being hurt.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lois Rodenhuis (Doc. #2249, SBC-046568)

Docket !# EPA-HQ-OW-2022-0114

The proposed regulation is critically important both for the health of the American people, and also as a statement that we as a nation and a culture trust the scientific process and we will regulate both private and public activities to first protect the health of our populace. I understand that businesses and agencies that will need to spend considerable funds to implement the proposed regulation have made understandable proposals to moderate or negate the regulations - for the purpose of saving money. The science says that the life of people, and especially the vulnerable, developing children, are at known risk from the PRAS chemicals. The global climate crisis also began from business and public agencies moving forward with new ideas and inventions and not understanding the underlying complexities of their actions. Now we know and are having to work at enormous scales to try and save the planet for our children and grandchildren. The PFAS chemicals have leeched into our systems for decades, but can be

stopped now. The sources are known and confined. Some businesses may not survive, but the people who work there will reinvent, revise, and go forward. The distribution of these chemicals through public water systems can be halted - expensively, but halted.

It must be done, now.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Frances Lamberts (Doc. #2250, SBC-047429)

To the Environmental Protection Agency: on Docket ID No. EPA-HQ-OW-2022-0114

I wish to thank the Environmental Protection Agency for initiating rulemaking on the "forever" PFAS chemicals, and for soliciting public input on it.

We had an incident in our Town, many years ago when, for quite a long stretch within a low-lying wetland area, a tributary to the Little Limestone creek was found to be covered with a thick foam layer, this having resulted from an earlier fire-department drill in the park through which the tributary creek flows, near its bank. By the time the local field office of the Tennessee Department of Environment and Conservation was able to inspect and test the water, the foam was gone and, fortunately, no harm appeared to have resulted to the creek.

From several reports in Science in recent years I gather, however, considerable toxicity of these chemicals in the environment and long-lasting damaging effects from them, and a study at the Harvard School of Public Health, reported last year, reveals their many, serious problems for human health.

Therefore, let me again state strong support for your rulemaking on some of the PFAS chemicals which now go into our drinking-water sources, and I thank the Administration for it.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Daniel Duda (Doc. #2251, SBC-047020)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

Please finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Janet Smarr (Doc. #2252, SBC-047021)

Dear Administrator Regan:

I applaud and support the EPA's proposed national drinking water regulations for six PFAS chemicals to protect our families and communities from the dangers of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, and implement a rule that truly protects our health. Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Ellen Lane (Doc. #2253, SBC-047022)

Dear Administrator Regan:

I can't believe that nothing has been done to protect American citizens from PFAS all this time and that we all are being poisoned by them w/o our even knowing what they are or where they're found. Why are their manufacture legal in the first place. Please outlaw them now, if not yesterday!!!

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Laura Livesay (Doc. #2254, SBC-046552)

Dear Administrator Regan:

Clean water is the most basic human necessity, and we need stronger regulations and better enforcement to protect it. I am pleased to see the EPA is finally taking action on the serious threat posed by PFAs in our drinking water. Please pass the proposed drinking water regulations for six PFAS chemicals as soon as possible. Because these chemicals persist so long, and cause such a wide and serious range of health threats including cancer, immune suppression, and developmental damage, we simply cannot afford any further delay to prevent further contamination of our water supplies and further exposure of our citizens to these dangerous and persistent chemicals.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Dorothy Hinman (Doc. #2255, SBC-047023)

Several towns in Iowa already have high levels and are needing to dig deeper wells, after exposing their communities for years.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS. Thousands of children already have high levels in their bodies; the time is now for action!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Han Schoening (Doc. #2256, SBC-047024)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

At 24, I should not have friends younger than me who have died as a result of PFAS contamination. Please make sure no one else has to ensure this pain.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Asra Baig (Doc. #2257, SBC-047025)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal

would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals so that 0% of them are allowed in our water.

Regards,

Asra Baig

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Regina Reilly (Doc. #2258, SBC-047026)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

To not take this action is to forsake your responsibility to all of us who need you to get this done, so we can all survive.

Regina

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Julie Bernstein (Doc. #2259, SBC-047027)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

Unfortunately, without EPA standards and funding for monitoring and enforcement, even municipalities and states who seek to mitigate the danger of PFAS in our drinking water will not be able to do so.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Thank you,

Julie Bernstein

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Susan Quinn (Doc. #2260, SBC-046290)

Please strengthen our national guidelines for PFAS and other "forever chemicals". I filter the water in my home, not because my local water is in violation of EPA guidelines but because I don't think the guidelines go nearly far enough to provide long-term safety. There are just too many pollutants we've been actively pumping into the environment for far too long, and forever chemicals in particular are very concerning. And while I can filter my water, many people don't have the knowledge or ability to do so – and everyone should be protected.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

S Laverne Coleman (Doc. #2261, SBC-047028)

Dear Administrator Regan:

It has been a long time since I have been willing to drink tap water in this country. I strongly urge you to begin doing whatever it takes to return the US water supply to a safe option. Europe is way ahead of the US in terms of choosing citizen health and safety over corporate interests. PLEASE DO THE SAME.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Melissa Tomlinson (Doc. #2262, SBC-047632)

So tired of all the things poisoning us on the daily from the folks in government allowing it. No amount is safe. How do people in government look around and feel like a job has been well done, like how. How is their any semblance of pride for what is going on in the world today as a result of western ideology. Western as in genocidal, western as in racist, western as in profit over everything, western as anti-abortion but pro-gun. You all can and will never make it make sense because it doesnt. Keep the poisons out of our water and foods. Seriously that its taken over two decades for regulationsdo better.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Susan Harris (Doc. #2263, SBC-047029)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS. Since these are "forever" chemicals, the need to stop them from being in our food and water is immediate and great.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lauren Dvonch (Doc. #2264, SBC-047030)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The health contained in a glass of water we are used to taking for granted. A glass of water is perhaps a symbol of what can be right with our environment, our health, and our life. Water is extremely important. How could ever have lost sight of that?

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Katherine Silsbee (Doc. #2265, SBC-047031)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

I don't think that the public is fully aware of the extent of the problem of PFAS in our nation's drinking water, and it is something we really need to focus on abating for all of our sakes.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kristina Pappas (Doc. #2266, SBC-046437)

Dear Administrator Regan:

Thank you for proposing national drinking water regulations for six PFAS chemicals.

Please quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sharon Bills (Doc. #2267, SBC-047032)

Dear Administrator Regan:

Thank you for your proposal that will take a lifesaving first step toward protecting people across the country from some of the PFA's in our drinking water. I look forward to seeing the next step that will protect us from all of the PFAs in the near future.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Rosemary Churnside (Doc. #2268, SBC-047033)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Give pause, and consider these important words:

"The earth does not belong to man, man belongs to the earth. All things are connected like the blood that unites us all. Man did not weave the web of life, he is merely a strand in it. Whatever he does to the web, he does to himself."

~ Chief Seattle ~

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Alan Benforfd (Doc. #2269, SBC-047034)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

Clean fresh water is a human right, or at least should be. As a basic necessity for life, water should be protected from damaging contaminants, and action taken to remove any such contaminants.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Timothy Dungan-Levant (Doc. #2270, SBC-046443)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step.

Please finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Anju S. (Doc. #2271, SBC-047035)

Dear Administrator Regan:

PFAS pollution is an issue that I and many others find extremely concerning; the lack of research and regulation thus far, relative to the persistent and widespread harms imposed on all life forms by this class of chemicals, has been perplexing and frustrating. As you are aware, PFAS have been linked to a very long list of health effects, including cancer, immune suppression, and developmental harm.

Industry profit at what cost?

The EPA's proposed national drinking water regulations for six PFAS chemicals is a much appreciated first step to protecting our families and communities from the scourge of PFAS. The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of the six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS with urgency.

Please, do everything in your power to comprehensively address this for ourselves, our planet, and innocent future generations who deserve better.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mary Ann Graffagnino (Doc. #2273, SBC-047036)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

My husband and I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

FOR THE HEALTH AND WELL-BEING OF ALL CURRENT AND FUTURE GENERATIONS, WILDLIFE AND THE ENVIRONMENT, no more toxic "forever" chemicals in our water! THIS IS THE HEALTHY, RIGHT, FAIR, JUST, HUMANE ACTION TO TAKE!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Linda Sue Barnes (Doc. #2274, SBC-047037)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The rule should be made as stringent as possible. There also needs to be a solution for taking responsibility for damage they have already done. In our area people's homes, which are typically the major part of their holdings, are now worthless because they can't sell them knowing that the water as contaminated the land and they can't even have gardens. Of course they have been using bottled water since this whole mess was discovered. It is shameful.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Krisanne Baker (Doc. #2275, SBC-047038)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS. The US has such a lax record compared to Europe when it comes to limiting chemicals in our food, water, and air, so I'm really glad to hear about this!

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Nicole Riggs (Doc. #2276, SBC-047039)

Dear Administrator Regan:

I support the EPA's proposed national drinking water regulations for six PFAS chemicals. This is a much needed first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression.

I want the safer drinking water that this proposed rule would protect for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Marcia Barber (Doc. #2277, SBC-047040)

Dear Administrator Regan:

We live in the foothills of Boulder Colorado.

Our Volunteer Fire Dept used Fire fighting foam for training purposes and thought it was on toxic.

It has polluted the groundwater and some of the private wells in our area.

The state and the EPA are not helping those of us with private wells but we did not polite our own wells. The manufacturers of the foam did by selling toxic products.

All PFOAS need to be eliminated right now! The companies that made them need to be held accountable and they need to pay for clean up.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Maura Kelsea (Doc. #2278, SBC-047041)

Dear Administrator Regan:

This long overdue regulation is very important for health of people and planet. I urge you to implement it as soon as possible.

Maura Kelsea

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joanne Bernstein (Doc. #2279, SBC-047042)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

Waiting and watching for more cancer diagnoses is not an option. The burden of proof for safety should fall on industry or those profiting, not the American people.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Henry Morgen (Doc. #2280, SBC-047043)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

I hope that the EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal should save thousands of lives and prevent tens of thousands of serious PFAS-related

illnesses each year. Do what you can to make the allowable level as low as practical to minimize the cumulative effect of ingestion over a lifetime.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Connor Godek (Doc. #2281, SBC-047044)

To Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

It is crucial to finalize the regulations on PFAS. In the year 2023, Americans should not have to worry about contaminated drinking water.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Leslie Bennett (Doc. #2282, SBC-047529)

It's critical that we have clean water for our children. This is the next generation and we don't want them to come down with cancers that could have been prevented. Also it impacts our wildlife. And costs will soar for medical care if we don't stop putting contaminates in our water.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sharon Smith (Doc. #2283, SBC-047045)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I am ready to see the EPA take action on these pollutants and getting them out of our water system.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Chris Eaton (Doc. #2284, SBC-047046)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

Our environment grows more toxic every year as chemical producers continue to formulate new chemicals and fail to test for so many unanticipated reactions because they are determined to make profits and don't want to look for reasons to stop.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Katie Walsh (Doc. #2285, SBC-047047)

Dear Administrator Regan:

My husband & I were thrilled to read about the proposed changes to protect people from forever chemicals. It's a serious problem that needs to be acted on as soon as possible. The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Thank you very much. Kathleen Walsh

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sarah Gagne (Doc. #2286, SBC-047048)

Dear Administrator Regan:

We have to have clean water to drink, so we need the strongest of regulations concerning PFAS. I completely agree with the statement below.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lillian Barrett (Doc. #2287, SBC-047049)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

As a mother, I thank you for taking this the risks of PFAS seriously.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Elizabeth Becker (Doc. #2288, SBC-047588)

As an Environmental Science professor at the College of Southern Nevada, I am in strong support of these new standards. This week my Environmental Pollution students are taking their

final exam and many of them indicated that persistent, bioaccumulative, and toxic materials are their number 1 concern. All Americans, regardless of their knowledge and background, should be protected from PFAS chemicals when cooking meals for their families and drinking tap water.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Evelyn Epstein (Doc. #2289, SBC-047050)

Dear Administrator Regan:

PFAS are infamous for their persistence and widespread pollution, and have been linked to many adverse health effects, including cancer, immunity suppression, and developmental harm.

The EPA's proposed national drinking water regulations for six PFAS chemicals would provide safer drinking water for millions of people in communities across the nation and could thereby save many lives and prevent many serious PFAS-related illnesses each year.

Please finalize the regulations of these six PFAS chemicals, implement a rule will protect our health, and then begin addressing other types of PFAS.

Thank you for your consideration.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

John Donlin (Doc. #2290, SBC-047051)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals are a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities nationwide where PFAS contaminates the drinking water. This proposal would save thousands of lives and prevent tens of thousands of PFAS-related severe illnesses each year.

I urge you to finalize the regulations of these six PFAS chemicals quickly, implement a health-protective rule, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

James Hubbard (Doc. #2291, SBC-047052)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a necessary first step to protecting our families and communities from the scourge of PFAS, infamous for their extreme persistence and widespread pollution, linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS and would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

Please quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Thank you!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Carolyn Heath (Doc. #2292, SBC-047053)

Dear Administrator Regan:

As a professor of Biology I have long followed the development of knowledge about the insidious threats caused by even the smallest amounts of certain chemicals in our food and water. The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Rosemary Ross (Doc. #2293, SBC-047054)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is first step to protecting our families from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

Please quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Linda Deschaine (Doc. #2294, SBC-047055)

Dear Administrator Regan:

PLEASE, PLEASE, PLEASE do what is necessary to remove PFAS from our drinking water. The thought of injesting these dangerous chemicals is appaling.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joseph Hodkin (Doc. #2296, SBC-046236)

We all want safe water. Today's focus must be to prevent future problems by removing harmful chemicals immediately. Now, not in later years after allowing critical safety issues to be ignored. Thank you.

EPA Response: The EPA acknowledges this comment. The EPA believes this final PFAS NPDWR will lead to safer waters and can prevent potential PFAS-related illnesses from drinking water now and in the future. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Stephen Wyzykiewicz (Doc. #2297, SBC-047056)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

In the 1950's, the slogan was: "make the world better through chemistry!" There was no thought as to the consequences. Now we know the consequences. Don't subject living things to the folly of the 1950's. Protect the planet, and the health of all living things. Regulate PFAS now.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Linda Dietrichson (Doc. #2298, SBC-047057)

Dear Administrator Regan:

PFAS chemicals are an alarming world-wide problem that has been covered up for too long. The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Thank you for leading the long-overdue effort to rid us from this forever threat to the health of all people throughout the world.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Betsy Berger (Doc. #2299, SBC-046506)

Dear Administrator Regan:

Like most Americans, I count on the EPA to ensure that my family and I are using safe products. It is distressing to learn that this is not always the case. However, it is a relief to learn of the WPA 's proposed national drinking water regulations for PFAS chemicals in our drinking water.

PFAS have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm, and I do not want my family to be exposed to such dangerous chemicals.

Please finalize the regulations to deal with the six most toxic PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Beth Jones - expat (Doc. #2300, SBC-047058)

Dear Administrator Regan:

Our Environmental Protection Agency's proposed national drinking water regulations for six PFAS chemicals is a verywelcome first step toward finally protecting our families and communities from the pernicious toxins of PFAS.

As you well know, PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

So why in the hell were they ever permitted in the first place?!?

PFAS should have never been permitted and should have been banned long ago!

The EPA's proposed rule would provide SOMEWHAT safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS, potentially saving thousands of lives and preventing tens of thousands of serious PFAS-related illnesses each year.

This means our EPA should finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS as soon as humanly possible.

Thank you for your efforts -- please KNOW that the vast majority of Americans support environmental protection and thus always support your work on our behalf.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Amy St. Peter (Doc. #2301, SBC-047059)

Dear Administrator Regan:

You will most likely receive quite a few of these letters. I am in no way a public speaker or someone who would even matter to the general public. I am just a hard working woman concerned with the health and safety of our country. We are making a mess and a laughing stock of most of what we do lately. While we used to be the tough kid on the block, we are now the

one who cries out "don't bully me." By showing we can take a stand on things without others, we can once again be that leader, the one people listen to for making the tough but right decisions, like the one below.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Loreen Hackett (Doc. #2302, SBC-047060)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Considering I'm from Hoosick Falls, NY, having been dealing with this issue for almost 9 years, as well as finding out recently from test results of our multi-site study that I dreadfully have, in fact, even more of these chemicals in my body and the bodies of my family and community, it's long past time to act. We are, quite literally, sick of it. Industry and/or corporations should not continue to be allowed to buy the health of our communities and families and distort science to pad their profits via lobbyists and lies. Follow the science, listen to and give more credence to

the contaminated communities living this nightmare, and enforce a more sustainable future for our children.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Pamela Johnson (Doc. #2303, SBC-047061)

Dear Administrator Regan:

A friend who lives near Chemours Company's PPA plant in NC lost five animals from cancer in close succession. Of course, proving Chemours Company's PPA is responsible is not possible at this time. The dangerous effects of forever chemicals are real.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lucy Hitchcock (Doc. #2304, SBC-047062)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. PFAs are hidden from our view. A silent killer.This proposal would save thousands of lives.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Marilyn Lohr (Doc. #2305, SBC-047063)

Dear Administrator Regan

I am writing because the harmful effects of PFAs are truly potentially life threatening and they are so ubiquiious in our environment. A huge source for PFAs is the continuous use of plastic and the resultant litter that ends up

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Marilyn Lohr (Doc. #2306, SBC-047064)

Dear Administrator Regan

I am writing to express my concern over the health effects of PFAs which can be life threatening. One of the main sources of PFA pollution is the over production and use of plastic products that frequently end up as litter finding their way into our waterways. This is a serious widespread issue that needs immediate attention. Everyday when I look at plastic trash I think of my health as well as the fish, birds, and other wildlife affected by this pollution.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

US Army (Doc. #2307, SBC-046550)

TO: Administrator Regan:

As a retired Army officer I greatly appreciate the EPA's proposed national drinking water regulations but these protections are not enough. As you know

PFAS are persistent and widespread. They have caused serious and devastating health problems and deaths in this country and around the world.

Please strengthen the EPA's proposed rule and implement them ASAP to provide safe drinking water for the people in communities across the nation where the drinking water is contaminated by PFAS. I lived near the Badger Army Ammunition Plant in Wisconsin and know personally of the community concerns there about PFAS. Citizens for Safe Water Around Badger (CSWAB) is a community organization that has been fighting the U.S. Army for years to have have clean drinking water. I'm sure you are aware that you have the ability with this proposal to save thousands of lives and prevent PFAS-related health conditions that arise in our communities.

I hope you will finalize the regulations of these six PFAS ASAP. There's more work with other PFAS for the Agency to address. I will follow your work with great interest. Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Megan LeCluyse (Doc. #2308, SBC-047065)

Dear Administrator Regan:

In the United States, we should be able to trust that our tap water is safe and healthy, not harmful. I am privileged to have had the opportunity to travel around the world, including to

places where people can't just get water from their sink or fridge to drink. Our water here at home should help our bodies, not potentially harm them in the process.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Julia Wolny (Doc. #2313, SBC-047452)

Hello,

My name is Julia Wolny and I am currently a student at Loyola University Chicago studying environmental policy. I am also one out of millions of other people in the United States that relies on public drinking water. I, like many others, count on my drinking water to be safe and not a contributor to health issues. Yet as the EPA has stated, PFAS poses various health threats to human health and drinking water remains one way that people may be exposed to PFAS. At this time, there is still no federal regulations on PFAS, and I would like to applaud the EPA for taking action to implement such regulations. However, I would also like to provide further comments and concerns that I have for the proposed Per- and Polyfluoroalkyl substances (PFAS) National Primary Drinking Water Regulation (NPDWR).

To begin, I would like to emphasize the urgent need for the regulation of PFAS on a federal level. While some states have developed their own regulations for PFAS, such action is inconsistent and entirely nonexistent in other states. Various states and local governments may not have the means to address this issue or may not view the regulation of PFAS as a priority. Co-founder of Merrimack Citizens for Clean Water, Laurene Allen, stated that "state by state is just absolutely ridiculous" and stressed that "the progress you have shouldn't be determined by your ZIP code" (Brown, 2022). By implementing federal regulations for PFAS in drinking water, there will be significantly greater chances of seeing a reduction in PFAS in humans. Yet without a (NPDWR), it is unlikely that there would be a significant decrease in PFAS in humans due to the high quantities often found in public drinking water. It is evident that the regulation of PFAS

in drinking water on a national scale is absolutely necessary and I fully support the EPA's initiative to pass such a regulation.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Catherine Swanson (Doc. #2316, SBC-046500)

I strongly support the proposed MCLs for PFAS. PFAS does not belong in our drinking water. The science is clear on the health effects. The EPA is bound by its charter to protect even the most vulnerable of us - not to pander to corporate interests.

The costs for treatment are reasonable, and only a fraction of the taxes that are dumped into the war machine. As humans, we made a mess, now we must pay to clean up. Compared to the costs of healthcare, there is a clear mandate to enforce PFAS treatment.

I thank the EPA for stepping up to the challenge, I and support the proposed MCLs and Hazard Index.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2318, SBC-047303)

As an individual who is currently a sophomore in high school, I am worried about the environmental changes we are experiencing. The proposition of docket EPA-HQ-OW-2022-0114 is influential to me because it provides a way for a cleaner environment. The proposition will also contribute to getting rid of a harmful water supply, which is a concern for numerous individuals. Decreasing perfluorobutane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO-DA), its ammonium salt (also known as a GenX chemical), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS) is highly crucial since these chemicals can cause many side effects, so, for these reasons, I do think it is important to regulate the number of chemicals that are contaminating the environment. I also believe that these are not the only chemicals that are worth reviewing. Chemicals like lead, chlorine, mercury, pesticides, and many others, should also be taken into account because of the long-term effects that they have on people and the environment as well, (e.g., a decrease in biodiversity, decreased growth and reproductive rates in plants and animals, slow growth development in little children, damage to the lungs, and more) so again I do think it is crucial, of course, to look at PFAS. This proposition should include a few changes, but I still find what EPA is doing admirable.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kathryn Burns (Doc. #2319, SBC-046649)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

I know a lot of people on the right (as in "right-wing") side will fuss and cry. Let them. Water is a necessity, not a luxury, and when we learn that a certain substance in it can be harmful, we need to insist it be removed.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2323, SBC-046312)

It seems like some of the supposed illnesses attributed to PFAS in drinking water exposure are side effects of receiving the Covid19 shot. This seems strange and maybe data should be collected on how many of those in the control group for health damage from PFAS received a Covid shot. Statistically or otherwise it is impossible to declare statistically or any other way that these cancers or other illnesses are a result of exposer to PFAS in drinking water at levels below 70 ppt. This is why in the past the EPA had a health advisory at 70 PPT. This EPA seems to be effected by politics and not science. This rule should be canceled. PFAS are "forever chemicals" and are therefore inert and quite stable. Thus it is difficult to see that at level in PPT range they could definitively be causing health problems in any age group. Obviously the credibility of the EPA and the current administration is suspect.

EPA Response: The EPA disagrees with the statements made in this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA has provided adequate and science-based health effects evidence for PFAS exposures that are outlined in section IV of the FRN and section 4 of the EPA response in this *Response to Comments* document. The commenter provided no evidence to back up their claims that low levels of PFAS cannot be causing health problems in any age group. The remainder of statements, such as the effects of the COVID-19 vaccine, the influence of politics, and questions on the agency's credibility and the current administration, are all out of scope of this rulemaking and can be addressed in section 15 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2324, SBC-046269)

There is no factual information or evidence in a controlled test that isolates other factors that PFAS accumulates in the blood or can be directly linked to any illness or disease. There is no evidence of the health cost savings from removing PFAS to below 70 PPT. EPA is not credible and has turned into a political organization. Drop this rule and MCL

EPA Response: The EPA disagrees with this comment. The comment did not provide evidence in support of its claims. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Current scientific research and available evidence have shown the potential for harmful human health effects after being exposed to some PFAS. The EPA acknowledges that drinking water is just one of several ways people can be exposed to PFAS. The EPA's examination of drinking water data shows that different PFAS can often be found together and in varying combinations as mixtures. Additionally, decades of research demonstrates that exposure to mixtures of different chemicals can elicit dose-additive health effects: even if the individual chemicals are each present at levels considered "safe," the mixture may cause significant adverse health effects. The high potential for different PFAS to co-occur in drinking water; their potential to cause additive health concerns when present in mixtures; the diversity and sheer number of PFAS; and their general persistence in the environment and the human body are the cause of the environmental and public health challenges the American public faces with PFAS. Please see section IV of the FRN for more information on the health effects of PFAS.

As for the costs, as part of its HRRCA, the EPA evaluated quantifiable and nonquantifiable health risk reduction benefits and costs associated with the final NPDWR. Considering both quantifiable and nonquantifiable costs and benefits of the rule, the EPA is reaffirming the Administrator's determination at the time of proposal, that the quantifiable and nonquantifiable benefits of the final rule justify the quantifiable and nonquantifiable costs. Please see section XII of the FRN for further information about the HRRCA.

Ruth Moore (Doc. #2325, SBC-046650)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. The EPA should address the whole class of PFAS chemicals wherever possible. Many of the thousands of these chemicals in use have been detected in water around the country.

The EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge. I hope that you continue to take action to reduce the spread of PFAS chemicals in our water.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Rae Ma (Doc. #2326, SBC-046757)

Dear Michael Regan,

Firstly, I would like to thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country. I would like to have the comfort of knowing that my family and friends are drinking clean water that won't result in health problems for them. The EPA's proposed drinking water standards would provide important and long overdue protections against six toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Thank you for your time and consideration.

Sincerely,

Rae Ma

Portland, OR 97229

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Karl Weber (Doc. #2327, SBC-046264)

I think this is one of the best things the epa has ever done and is a critical step in improving the health of Americans and reducing their exposure to cancer linked chemicals. I hope the epa goes further to reduce the production of them in the first place and studies the amount people are exposed to through food and other forms.

EPA Response: The EPA acknowledges this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Terrell Yelverton (Doc. #2328, SBC-046191)

Please ensure these chemicals are kept out of the water supply

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2329, SBC-046536)

Removal of PFAS to 4 PPT is very costly and infrastructure plan money or borrowing is not a sound answer for financing these costs. The EPA has lost credibility and the savings in health care cost are not provable or believable. Cost benefit has to be taken into account , this is why states like New York have not regulated PFAS down to 4 PPT. With over 90% of water not used for ingestion this rule is a waste of resources. PFAS at less than 70 PPT is not responsible for any cancer or ill health effects. There is no proof it accumulates in the blood and like lead drinking water is not the greatest avenue of exposure in humans. Drop this expensive and wasteful resolution, it is not cost effective. The testing for it quarterly alone is a waste of money when people struggle to pay their water bills in Indiana, Michigan and Ohio now.

People can use carbon filters at their house at their own expense to remove PFAS down to 20 Ppt if it is their water system

EPA Response: The EPA disagrees with this commenter. The EPA believes that this NPDWR is vital to protecting public health by removing these contaminants from our nation's drinking water. The commenter did not include references to back up their arguments that the savings are not provable or believable, that 90 percent of water is not ingested once in a home,

and that PFAS at levels less than 70 ppt is not responsible for health effects. Please see section 1.3 of the EPA response in this *Response to Comments* document. For additional evidence on the health effects of PFAS, please see section IV of the FRN, the PFOA/PFOS MCLG document, as well as the Toxicity Assessments (USEPA, 2024c; USEPA, 2024d; USEPA,2024e; USEPA, 2024f).

Vivian Sclafani (Doc. #2330, SBC-046263)

Well I hope you truly do have our health concerns in mind and to protect us from these horrible chemicals in our water public trust has already gone down the drain. And while you're at it why don't you investigate the chem trails that are seeping into our lungs and water supply as well as our farm lands thank you for listening

EPA Response: The EPA acknowledges this comment. This NPDWR has the health of Americans in mind and will protect them from PFAS in their waters. Please see section 1.3 of the EPA response in this *Response to Comments* document.

G. Paul Richter (Doc. #2332, SBC-047561)

As a former resident of WV for 55 years and a chemist whose professional interest and expertise is the non-metals (especially P, N, F, and Cl), I know quite a bit about PFAs , including their ubiquitousness and persistence in the environment and their production. The relevant industries have been too slow in acknowledging the problems with PFAs and taking appropriate, remedial action on PFAs.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Cris Corley (Doc. #2333, SBC-047521)

I strongly support lowering PFAS chemicals in our drinking water. Representing the Tennessee Chapter of the Sierra Club as Chair, our club wants to lower the limits of these dangerous chemicals.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-

saving water treatment for communities across the U.S. Therefore the agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lori Olinger (Doc. #2334, SBC-047543)

PFAS are hazardous and harming our health and the environment. Thank you for setting drinking water limits for PFOS, PFOA and 4 other PFAS chemicals. We must do more to limit PFAS in our water. This is a good start. Please move as aggressively as possible to protect our water from PFAS chemicals. I support the proposed drinking water limits.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Stephen Brown (Doc. #2335, SBC-047640)

Chronic exposures to PFAS chemicals found in drinking water can cause severe health problems, especially in young children. I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. My community's drinking water was contaminated for decades by PFOS, (6:2)-FTS, and other PFAS compounds by a permitted chrome metal plating plant upstream. This was not discovered until the UCMR(3) results were available, and taxpayers here in Ann Arbor spent $1.5M to remediate it. Please regulate PFAS as a chemical class, like PCBs, etc. and demand Total Organic Fluorine measurements as a PFAS Hazard index, until validated health data on individual chemicals determines an acceptable health risk to the public.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

David Dow (Doc. #2336, SBC-047648)

The Fire Training Area-1 plume from Joint Base Cape Cod underlies the Yearling Meadows development where I live in East Falmouth, Ma. PFAS6 groundwater pollution from Massa. Army National Guard Training threatens Well #2 on the Upper Cape Water Supply nReserve which provides public drinking water to Falmouth and Sandwich. Public Drinking Water Wells in Falmouth and Mashpee have been fitted with Granular Activated Carbon and Ion Exchange Filters to remove the PFAS6 and 1,4-dioxane. Freshwater fish in Johns Pond have high PFAS6 levels which pose health threats to sensitive populations. Seabirds on the Stellwagen Bank have PFAS contamination from airborne transport. Thus EPA and Ma. DEP face serious toxic chemical threats on land and in water bodies via various exposure routes.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joseph Alvarado (Doc. #2337, SBC-047493)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to

multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Margaret Barrett (Doc. #2339, SBC-046901)

Dear Michael Regan,

I want to express my thanks to you for taking the first step to regulate PFAS in drinking water. I'm a cancer survivor and know personally how dangerous these chemicals can be. Your agency cannot act too soon to reduce the risks of cancer, developmental and reproductive harm, and other serious diseases which PFAS can cause.

EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. I strongly support the proposed standards, and I urge EPA to finalize them as quickly as possible.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. And by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. I urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Margaret Barrett

Malvern, PA 19355

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jan Ellen Burton (Doc. #2340, SBC-046758)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country. EPA's proposed drinking water standards would provide important and long overdue protections against six of

these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Jan Ellen Burton

Salt Lake City, UT 84105

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Walt Garvin (Doc. #2341, SBC-046192)

Please keep these dangerous chemicals out of our environment.

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Patricia Heithaus (Doc. #2342, SBC-046892)

Dear Michael Regan,

I am encouraged that the EPA is finally taking steps to regulate PFAS in drinking water. I have family members that live in areas where PFAS have contaminated drinking water resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. I strongly support the proposed standards, and urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every

individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Patricia Heithaus

Gambier, OH 43022

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Alan Montemayor (Doc. #2343, SBC-046759)

Dear Michael Regan,

I am very concerned with PFAS in our drinking water, particularly as I live in San Antonio, TX and there are three known PFAS contaminated sites in our city. These were the result of firefighting foam application at three air force bases. Our local water utility, San Antonio Water System, does not report PFAS content in our water. Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Alan Montemayor

San Antonio, TX 78213

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Matthew Brown (Doc. #2344, SBC-046498)

Dear Michael Regan,

For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals.

Despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

If you would finalize the EPA's standards, I would be very grateful.

Sincerely,

Matthew Brown

Easton, PA 18042

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Thomas Seaman (Doc. #2345, SBC-046760)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water... EPA's proposed drinking water standards would provide important, long overdue, and not strong enough protections against six of these toxic chemicals. I support the proposed standards as a start towards more stringent ones, and urge EPA to finalize them as quickly as possible.

PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States. There are very serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. I urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Thomas Seaman

Moscow, ID 83843

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sue Chartock (Doc. #2346, SBC-046761)

Dear Michael Regan,

Clean drinking water is imperative and necessary for the health of all living things. People and animals need it for survival. However the hidden dangers of these forever chemicals in the water can be downright dangerous and unhealthy to consume. Most water filters do not remove all substances from tap water either. Therefore steps to eliminate there presence in the water if at all possible is a big deal and a high priority.

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated

drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Sue Chartock

Flushing, NY 11358

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Diane Wallace (Doc. #2347, SBC-047494)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA

acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Catherine Penna (Doc. #2348, SBC-046762)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

Despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water. This must stop!

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

CATHERINE PENNA

Oakdale, NY 11769

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Erin D'Alessandro (Doc. #2349, SBC-046763)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Erin D'Alessandro

Lyons, CO 80540

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Christopher Buecheler (Doc. #2350, SBC-046764)

Dear Michael Regan,

A brief, personalized message before the form letter: I appreciate the EPA's renewed dedication under the Biden administration to focus on the "Protection" part of its name. In keeping with that mission, I urge you to swiftly finalize the proposed drinking water standards and help to ensure access to clean, safe drinking water for all Americans.

Thank you for your time. Form letter follows.

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Christopher Buecheler

Providence, RI 02906

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jennifer Hartman (Doc. #2351, SBC-046765)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. We have the data to show the ongoing harm that PFAS does to human and ecological health. As both a mother and a woman in my mid-forties who is already a two time cancer survivor despite no prior family history, I feel strongly that government must protect its citizens when a substance has been shown to be harmful. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. I strongly support the proposed standards, and urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every

individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. Again, as a cancer survivor and mother, I urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Jennifer Hartman

Lexington, MA 02420

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2352, SBC-046302)

This morning, a local TV news station had a segment on this proposed rule. I read through enough material, until I found this comment section. Of course, the website information about this proposed rule includes a plethora of bureaucracy and mind-numbing details that are amazing! I know how to read and sort it all out, even if it takes time. I hope that our monthly water bill does not increase. It's high enough already. We should have had a water well drilled, during the construction phase of our house. I hope that every government official, who is involved, uses enough educated common sense, to do right by we the people. You serve us, after all. Serve us properly, please!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

James T. Field (Doc. #2353, SBC-046766)

Dear Michael Regan,

" PFAS", a class of more than 12,000 chemicals found in everyday products like waterproof jackets, nonstick pans, food wrappers, and personal care products, can persist in the environment for up to hundreds of years, readily spread in the air, soil and water, and can remain in our bodies

for decades. This is why they are known as "forever chemicals." PFAS are linked to serious medical problems, including cancer, infertility, impaired fetal development, and immune system suppression that decreases vaccine effectiveness.

For decades, companies have been allowed to manufacture and use PFAS and release these toxic chemicals into the environment with impunity, contaminating drinking water supplies for approximately 200 million Americans. EPA's proposed drinking water standards are a critical step toward addressing the PFAS drinking water crisis, and helping communities across the country remove these dangerous chemicals from their water.

I strongly urge the EPA to act quickly to finalize its proposed national drinking water regulations. Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. I strongly support the proposed standards, and urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. I urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

james t field

El Paso, TX 79912

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Heidi Blanck (Doc. #2354, SBC-046767)

Dear Michael Regan,

Hello. On the heals of Earth Day I thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

I am surprised that despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water.

I urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Heidi Blanck

Decatur, GA 30033

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Steve Liska (Doc. #2355, SBC-047496)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to

cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Nan Corliss (Doc. #2356, SBC-046768)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Why are other countries way ahead of this country in banning these chemicals? We should be a leader, not a follower when it comes to protecting our health and that of the planet. It is time to act responsibly and do what needs to be done to protect and preserve our environment, our health and our future.

Sincerely,

Nan Corliss

Minneapolis, MN 55437

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Andrea Amico (Doc. #3072-5, SBC-046342)

Good Afternoon, my name is Andrea Amico, and I'm from Portsmouth, New Hampshire, which is home to the Former Pease Air Force Base. The old base was redeveloped into a successful Pease Tradeport and Business Park that it is today. I will start by saying I wholeheartedly support the proposed EPA MCLs for PFAS in drinking water. These MCLs are long overdue and will save lives. PFAS are toxic and incredibly low levels cause cancer, and never go away. These regulations are very much needed to protect human health. I moved to Portsmouth, New Hampshire in 2007 when my husband started working for a business at the Pease Tradeport. In 2011, we welcomed our first child, a daughter, and in 2013, we had a son. On the Pease Tradeport and right next door to my husband's work was a brand new, beautiful daycare center. As a mom, it was really hard for me to have to send my kids to daycare. I was not in a financial position to stay home with them, and we did not have family around to help us. We toured so many daycare centers in our area and we asked so many questions about their curriculum, their staffing ratios, were they CPR certified, but I never once questioned the quality of the water. It was just not on my radar. In May of 2014, my life changed forever when I read a newspaper article that said high levels of PFAS were discovered in the water at the Pease Tradeport. My husband worked there, and my two children were attending daycare there. The contamination was so bad that one large drinking water well was shut down immediately. At the time, I had no idea what PFAS were or how harmful they were, but my heart sank because my husband and children were drinking the water every day. I spent countless hours and sleepless nights researching PFAS, and the more I learned, the more scared I became. I often asked myself "How could these chemicals be so toxic, and yet there are no regulations in place to protect people?", and "how could they have been allowed into our products in the first place? Why are they still allowed today, after we know what we know?" This doesn't make sense. I've had nine years of more questions than answers. Nine years of stress, anxiety, and guilt. I worry about the health of my family every day, particularly my children, who drank high levels of PFAS as babies and toddlers, and at critical stages of their growth and development. They were contaminated without consent, poisoned without permission, guinea pigs in an experiment I did not sign up for. I would not wish this pain and devastation on anyone. These MCLs will save lives. Thank you to EPA for proposing standards that protect human health. My hope is that these MCLs become law quickly, and that EPA does not stop there. Please continue to take swift and aggressive action on PFAS; I'd like to see PFAS regulated as a class, because no amount of PFAS are safe for humans, and please hold the polluters accountable. They polluted the planet, the human race, and

have had minimal to no repercussions. That is deplorable and unacceptable. Thank you very much.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Connie Kennedy (Doc. #2358, SBC-046769)

Dear Michael Regan,

THANK YOU for taking the first step to regulate PFAS in drinking water.

EPA's proposed drinking water standards will provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Connie Kennedy

Menifee, CA 92586

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Via Reznor (Doc. #2359, SBC-046770)

Dear Michael Regan,

You probably don't read these seemingly standardized messages, but I urge you to read just one. I know that I do not need to explain to you the dangers of these toxic chemicals. Please, please do everything in your power to make our water safe for consumption!

Thank you for taking the first step to regulate PFAS in drinking water.

The EPA's proposed rule would provide safer drinking water for communities from coast to coast.

Sincerely,

Via Reznor

Volant, PA 16156

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lois Hughes (Doc. #2360, SBC-046771)

Dear Michael Regan,

The water available for everyone on this planet, in every consumable form, affects every person on the planet. Drinking water is not the only form of water that we consume. The effects on the human body of contaminates we've put in that water do not exclude people on the basis of wealth, political or religious beliefs, age, gender or nationality. Everyone involved in making this decision is responsible for choosing to allow these contaminants to harm themselves and their families. This is a personal choice! Ask yourselves if you want to be the ones responsible for allowing these devastating effects to continue to happen or will you step up and say no for yourselves and your families. Corporations are run by people who are not exempt from the harm to their families from these contaminates and must be helped to see that their bottom line must not come before their responsibility to humanity.

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to

cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Lois Hughes

Iowa City, IA 52240

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Gina Hardin (Doc. #2361, SBC-046540)

Dear Michael Regan,

I am relieved to hear that the EPA is taking the first step to regulate PFAS in drinking water.

However, I am wondering why you're proposing placing the burden on municipalities and their water treatment systems (hence taxpayers), to undertake the expensive process of removal of FASs but continue to allow their manufacture and use - for private profit? If companies continue to produce and use and place these in our ecosystems, taxpayers will be engaged in an endless and useless chase of PFAS. I do not understand....

For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

Sincerely,

Gina Hardin

Lyons, CO 80540

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Laurie Lohrer (Doc. #2362, SBC-046772)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. EPA's proposed drinking water standards will provide important protections against six of these toxic chemicals. I strongly support the proposed standards, and urge EPA to finalize them asap.

PFAS are long lasting and persist in the environment, our bodies, and cause harm decades after they are released into the environment. There are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for US communities. I urge you to quickly finalize these standards, and to implement a rule that resists industry's efforts to weaken.

Sincerely,

Laurie Lohrer

Lewistown, MT 59457

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joanne Dunlap (Doc. #2363, SBC-046773)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite

the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

This is a good begining. I seem to always have to remind you folks that your mission is to protect the life forms (particularly human but all of them) and not the corporations. Removing PFAS from the usable chemicals for manufacturing will not destroy our world but keeping ti surely will.

Sincerely,

Joanne Dunlap

Rangeley, ME 04970

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Maryann Roby (Doc. #2364, SBC-046774)

Dear Michael Regan,

PFAS and other forever chemicals are deadly contaminants in our water. Thank you for taking the first step to regulate PFAS in drinking water. Contaminated waiter poisons all life forms undermining our sources of subsistence. The EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. Please put the proposed standards in place as urgent and quick action is needed.

PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

Protect us from severe health consequences from exposure to PFAS despite industry's efforts to weaken them.

Sincerely,

Maryann Roby

Nunda, NY 14517

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Julie Pearson (Doc. #2365, SBC-046488)

Dear Michael Regan,

Thank you for taking this long overdue first step in regulating PFAS in drinking water. Even though of us who weren't scientists couldn't help but wonder what all these products from paint to shampoo and toothpaste were doing to the water, to our health and the health of the plants and animals and insects that share this world with us. Please finalize these rules asap and do not allow the chemical and oil and gas industries to delay or sabotage or weaken these measures.

Sincerely,

Julie Pearson

Tulsa, OK 74112

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kara Masters (Doc. #2366, SBC-046775)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. EPA's proposed drinking water standards would provide important protections against six of these toxic chemicals that, for decades, have contaminated drinking water for millions of people, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. Please finalize the proposed standards as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in blood and organs, and continue to cause harm decades after they are released. PFAS have contaminated drinking water for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies exposed in utero. Yet, despite the serious health risks associated with PFAS, there are currently no federal limits on their levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens

of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to its commitment under the 2021 PFAS Strategic Roadmap to regulate PFAS in drinking water. Please finalize these standards and implement a health-protective rule, resisting industry's efforts to weaken them. Thank you.

Sincerely,

Kara Masters

Topanga, CA 90290

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jerald Wray (Doc. #2367, SBC-046776)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Jerald Wray

Champaign, IL 61821

EPA response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Regina Whitman (Doc. #2368, SBC-046900)

Dear Michael Regan,

The EPA has a fundamental and moral obligation to the General Public over the concerns and profits of big companies. A company that produces , sells and disperses harmful substances that get on our food, into our water supply and air that we breathe does not deserve any protection or

consideration . Over the health and safety of the people of this country. It is Paramount that you keep this mandate forward in your minds and decisions now and forever in the future .

Taking the first step to regulate PFAS in drinking water his commendable, but a small step at best.

It behooves the EPA to remember that once these harmful substances are in our environment, they are in humans for generations to come.

For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Regina Whitman

Queen Creek, AZ 85142

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Barbara Jennings (Doc. #2369, SBC-046777)

Dear Michael Regan,

THANK YOU for taking the first step to regulate PFAS in drinking water. PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment.

For decades, PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

We STRONGLY urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, and resisting industry's efforts to weaken them.

Sincerely,

Barbara Jennings

Wenonah, NJ 08090

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Catherine Cox (Doc. #2370, SBC-046420)

Dear Michael Regan,

I strongly support the proposed standards, and I urge EPA to finalize them as quickly as possible.

Please resist the industry's efforts to weaken them.

Sincerely,

Catherine Cox

Warrenville, IL 60555

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Roger Widenoja (Doc. #2371, SBC-046778)

Dear Michael Regan,

Get PFAS out of our drinking water.

Thank you for taking the first step to regulate PFAS in drinking water.

Sincerely,

Roger Widenoja

Silver Lake, OR 97638

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Carrie Anderson (Doc. #2372, SBC-046460)

Dear Michael Regan,

By issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water.

PLEASE finalize these standards, and implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Carrie Anderson

Spokane, WA 99203

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Elizabeth Perkins (Doc. #2374, SBC-046471)

Dear Michael Regan,

I commend you for proposing to regulate PFAS in drinking water. Your drinking water standards would provide important and long overdue protections against six of these toxic chemicals.

I urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Elizabeth Perkins

Grand Forks, ND 58201

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Diane Fails (Doc. #2375, SBC-046779)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. PFAS is implicated in increased rates of cancer, developmental and reproductive harm, and other serious diseases. I strongly support the proposed standards, and I urge EPA to finalize them as quickly as possible.

We need clean, safe water, and it's important to every living being that you resist industry's efforts to weaken rules to keep PFAS out.

Thank you.

Sincerely,

Diane Fails

Fremont, OH 43420

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Nancy McRae (Doc. #2376, SBC-046780)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

These chemicals are everywhere. I live in a small Massachusetts community which still has lots of open land and small family farms. However the PFAS problem has been an issue even here. Many households rely on well water and homeowners have been advised to do PFAS testing. Higher levels of PFAS were detected in one of the town's well just last summer and regular monitoring is now on a frequent basis. If PFAS are a concern where I live .. it is problem everywhere.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to

cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Nancy McRae

Pepperell, MA 01463

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Edward Main (Doc. #2377, SBC-046781)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. Please finalize the proposed standards as promptly as possible.

PFAS are a persistent and apparently hazardous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in human blood and organs, and apparently cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of

lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water.

Please promptly finalize these standards and issue rules that provide the needed human health and environmental protection.

Thank you for your service to our country.

Sincerely,

Edward Main

Houston, TX 77098

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Linda Agerbak (Doc. #2378, SBC-046782)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

Despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Linda Agerbak

Arlington, MA 02474

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Meghan Thompson (Doc. #2379, SBC-046783)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. I strongly support the proposed standards, and I urge EPA to finalize them as quickly as possible.

Despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Meghan Thompson

Seattle, WA 98117

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Ed Oberweiser (Doc. #2380, SBC-046524)

Dear Michael Regan,

EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals.

I support the proposed standards, and urge EPA to finalize them as quickly as possible.

PFAS are a highly dangerous class of chemicals. PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment.

They have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States.

EPA's proposed rule would provide safer drinking water for communities from coast to coast.

The proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

Sincerely,

Ed Oberweiser

Fort Bragg, CA 95437

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Alicia Mason-Miller (Doc. #2381, SBC-046784)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water by providing important and long overdue protections against six of these toxins. I urge EPA to finalize them as quickly as possible..

They are a public health threat, known as " forever chemicals," because once released into the environment, they build up in our blood and organs, compounding damage over the years. We can't excrete them. It's inexcusable that EPA has neglected to set limits on PFAS in drinking water because of industry pressure.

We as consumers can choose not to buy furniture and clothing that are water and/or stain resistant because their chemical coatings contain PFAS. We can avoid Teflon cookware and fast food with grease-resistant PFAS. But we have no choice when it comes to drinking water. We shouldn't be forced to consume PFAS because the producers of these chemicals don't want to own up to the harm caused to human health. Yet, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would establish strong limits on six widely detected PFAS. The proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling

its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water.

Please finalize this rule immediately.

Sincerely,

Alicia Mason-Miller

Ranchos De Taos, NM 87557

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Thomas Kemp (Doc. #2382, SBC-046785)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

Since PFAS are a large and dangerous class of chemicals, often called "forever chemicals," they persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. I urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Thomas Kemp

Garland, TX 75043

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Steve Sears (Doc. #2383, SBC-047499)

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Steve Sears

Hatboro, PA 19040

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kathryn Fox (Doc. #2384, SBC-046786)

Dear Michael Regan,

Both my daughter and I have had breast cancer and my husband, Alzheimer's Disease. I believe all the various polutants probably played a part in it. PFAs don't go away. Don't put them in our environment! Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Kathryn Fox

Salem, OR 97317

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Cindy Black (Doc. #2385, SBC-046787)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases.

THEREFORE I URGE YOU: PLEASE CONTINUE ALL EFFORTS TO GET THESE NASTY CHEMICALS OUT OF OUR WATER!!!!

Thank you.

Sincerely,

Cindy Black

Seattle, WA 98133

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Ralph Myer (Doc. #2386, SBC-046788)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases.

Among other cases, PFAS chemicals in fracking spotlights New Mexico: 80% of state residents get their drinking water from groundwater, making these "forever" chemicals particularly risky.

EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Ralph Myer

Seattle, WA 98146

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sasha Jackson (Doc. #2387, SBC-046789)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Sasha Jackson

Detroit, MI 48228

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Willem VandeKamp (Doc. #2388, SBC-046790)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Willem VandeKamp

Alameda, CA 94501

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Nancy Parkinson (Doc. #2389, SBC-046791)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

I am happy that you are limiting these six PFAS but you need to do much much more. Please make this only the beginning of protecting all of us from these chemicals.

Sincerely,

Nancy Parkinson

Warren, NJ 07059

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Nicholas Rattner (Doc. #2390, SBC-046898)

Dear Michael Regan,

Don't it feel good on a hot day to pour yourself a glass of water and cool off? Of course, we're a long way from the days when you could refresh yourself from a stream, but one step at a time. We have to ensure that drinking water, what we call it now, remains not just a possibility but an expectation. From there we can start to talk about cleaning our rivers and streams. Seems pretty basic. Really, what's the ethical case for not taking this action? But you have done what many others balked at. So, many many thanks for taking the first step to regulate PFAS in drinking water. Now, keep going!!!!

For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Nicholas Rattner

Houston, TX 77025

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

James Schmidt (Doc. #2391, SBC-046890)

Dear Michael Regan,

Thank you for beginning to regulate PFAS in drinking water. For decades, PFAS have contaminated our drinking water supplies, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. I strongly support the proposed standards, and I urge EPA to finalize them as soon as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

James Schmidt

Chicago, IL 60640

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Bonni McKeown (Doc. #2392, SBC-046554)

I urge EPA to swiftly implement drinking water protections against PFAS contamination.

We need national standards for PFAS. Expanding protections to six PFAS, as well as the combination of different PFAS, will protect our drinking water from this toxic contamination and keep countless Americans safe from enduring the health risks associated with these dangerous chemicals.

PFAS, which are used to manufacture a range of goods, break down very slowly over long periods of time and instead accumulate in people, wildlife, aquatic life, plants, and the environment. This contamination poses a direct threat to our health and our ecosystems. Also known as "forever chemicals," PFAS are pervasive contaminants that are linked to serious health conditions such as cancer, liver and kidney disease, reproductive issues, immunodeficiencies, and hormonal disruptions. No wonder a lot of Americans are suffering from poor health!

PFAS are everywhere! That is why we need to act fast and decisively. Finalizing these regulations would protect drinking water for countless humean communities. The ecology of rivers and lakes- support us and all living things..

Thank you,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Ann Mateo (Doc. #2393, SBC-046792)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water.

We URGE you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

ann mateo

Wyckoff, NJ 07481

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Buck Schall (Doc. #2394, SBC-046793)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water.

We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Buck Schall

Asheville, NC 28801

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Susan Kallman (Doc. #2395, SBC-046794)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals.

I strongly support the proposed standards, and I urge EPA to finalize them as quickly as possible.

Thank you for listening.

Sincerely,

Susan Kallman

Saint Paul, MN 55125

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Shawn Harris (Doc. #2397, SBC-046601)

Hello, my name is Shawn Harris, and I'm proud to serve as Board President for the Piney Woods Conservation Group (PWCG). PWCG is a conservation organization founded in 2018 in Hattiesburg, Mississippi, with the mission of conserving, promoting and protecting the open spaces and green places of environmental and scenic significance in the Pine Belt. Since its inception, PWCG has worked tirelessly alongside the Hattiesburg Tourism Commission, The City of Hattiesburg, Forrest County Board of Supervisors and other community and state partners – public and private – to establish the first blueways in the greater Hattiesburg area. With the recent expansion of 52.3 miles of navigable blueways, the organization has focused more emphasis on conservation-related projects including tactical cleanups in public parks and along the watershed.

We were recently part of a Consumer Reports project that tested the tap water in all 82 Mississippi counties, including my personal tap water. My household's PFAS level was 9.61 ppt, significantly above the interim updated levels issued by the EPA in June 2022. While the full statewide results are still being accumulated, initial discussions lead me to believe this is an issue statewide. I am writing today to urge EPA to swiftly implement drinking water protections against PFAS contamination.

We need national standards for PFAS. Expanding protections to six PFAS, as well as the combination of different PFAS, will protect our drinking water from this toxic contamination and keep countless Americans safe from enduring the health risks associated with these dangerous chemicals.

PFAS, which are used to manufacture a range of goods, break down very slowly over long periods of time and instead accumulate in people, wildlife, aquatic life, plants, and the environment. This contamination poses a direct threat to our health and our ecosystems. Also known as "forever chemicals," PFAS are pervasive contaminants that are linked to serious health conditions such as cancer, liver and kidney disease, reproductive issues, immunodeficiencies, and hormonal disruptions.

PFAS' ubiquity is why we need to act fast and decisively. Finalizing these regulations would protect drinking water for countless communities.

I urge your support for these badly needed regulations to better protect people and our rivers, oceans, lakes, and communities from PFAS contamination.

Thank you,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Susan Johnson (Doc. #2398, SBC-047565)

Clean water! I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Winifred Chambers (Doc. #2399, SBC-046795)

Dear EPA Environmental Protection Agency,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Ms Winifred Chambers

1051 Hillsboro Mile Apt 905 Hillsboro Beach, FL 33062-2129

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Margaret Miller (Doc. #2400, SBC-047066)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS. The EPA set out to ensure clean water for everyone in this country. No company or group of companies should be able to persuade the EPA to put industrial needs before people's lives.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Theresa Kardos (Doc. #2401, SBC-047067)

Dear Administrator Regan:

As an environmental educator and field biologist, a former public health worker with the New York City and New York State Health Departments, and a parent and grandparent who cares deeply about the health of our planet and all its inhabitants, I support the EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS. I may have written before on this issue, but the hazards of PFAS are so frightening and wide-ranging that I believe one cannot say too much on the subject.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is as effective as possible in protecting health, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Marilee Corey (Doc. #2402, SBC-047068)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

In my opinion, you all are in the position to prioritize making our water safe for all citizens and all crops and livestock. It is your obligation to protect your constituents, not the dirty industries albeit fossil fuel, chemical or Monsanto.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jeri Ramrath (Doc. #2403, SBC-047069)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS. Water is our most precious resource and our final frontier. This step to protect our water is crucial in its importance to our health and the health of the planet.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Carrie Palmer (Doc. #2404, SBC-047070)

Dear Administrator Regan:

Anything that harms fetuses/children should be given high priority. Children need a good immune system and they are being compromised before they are even born. How can people live with themselves if they don't do something to help?!

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joe Murphy (Doc. #2405, SBC-046519)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a great first step to protect our families and communities from PFAS.

As you know, PFAS have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for millions of people in communities across our nation where their drinking water is contaminated by PFAS. Additionally this proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

Please move quickly to finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and also begin addressing all other types of PFAS.

Thank you for your efforts.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Roland Goyette (Doc. #2406, SBC-047071)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jerry DiMarco (Doc. #2407, SBC-047072)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for 6 PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are notorious for their extreme persistence and widespread pollution, and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these 6 PFAS chemicals and implement a rule that is health protective. Then it will be time to begin addressing all other types of PFAS. Thank you for your consideration of this very serious matter.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Norma Sasseville (Doc. #2408, SBC-047073)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

We are not a third world nation...Clean drinking water should be a guarantee, not an issue that we have to fight for. Clean water should be at the top of our priorities, along with clean air.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Alan Hamilton (Doc. #2409, SBC-047074)

Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their widespread pollution.

The EPA's proposed rule would provide safer drinking water for people across the nation where the drinking water is contaminated by PFAS.

I urge you to pass the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Cherie Fernandez (Doc. #2410, SBC-047075)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS. These chemicals are proliferating much more rapidly than the technology needed to remove them from drinking water.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm. I cannot help but wonder if the severity of the pandemic was worsened due to seemingly healthy people having suppressed immune systems because of the presence of persistent pollutants lingering in their bodies.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Audrey Diehl (Doc. #2411, SBC-047076)

Dear Administrator Regan:

I am very happy to hear about the EPA's proposed national drinking water regulations for six PFAS chemicals. It's so important for our federal government to use its authority to protect communities from PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I hope that you will quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS present in the United States.

Thank you for all that you do to safeguard the health and safety of the American people!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Marcia Rankin (Doc. #2413, SBC-046470)

Dear Administrator Regan:

Thank you for The EPA's proposed national drinking water regulations for six PFAS chemicals.

The EPA's proposed rule would provide safer drinking water where the drinking water is contaminated by PFAS. It will save thousands of lives and prevent serious PFAS-related illnesses.

I hope that the EPA will also address protective

measures from other types of PFAS chemicals.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Ellen Henry (Doc. #2414, SBC-047077)

Dear Administrator Regan:

It's good to hear that the EPA has proposed national drinking water regulations for six PFAS chemicals. This is a welcome first step to protecting our families and communities from the scourge of PFAS.

I urge you to go ahead and finalize this proposal as quickly as possible since the contamination and adverse health impacts are widespread already, and PFAS are essentially non-degradable and hence stay in the environment "forever." Then there are many additional PFAS compounds whose toxicity must be addressed and their use curtailed ASAP.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Judith Fraser (Doc. #2415, SBC-047078)

Dear Administrator Regan:

Regulating PFAS in drinking water is long overdue. As time goes on we recognize that practices once accepted are no longer appropriate in today's world.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Thank you for your consideration and action.

Judith Fraser, Hamilton, MT.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sharron Coontz (Doc. #2416, SBC-047079)

Dear Administrator Regan:

I'm writing to support a quick finalization of the regulations for six PFAS chemicals.

As you know, PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

Please implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Carrie Acosta (Doc. #2417, SBC-046204)

I support strong safety standards and regulations regarding PFAS and other chemicals in our drinking water.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Stewart Knoepp (Doc. #2418, SBC-046239)

I am in support of legislation to regulate PFAS (and PFOS and PFOA) in our drinking water. This is a dangerous chemical that has been allowed to be used to carelessly and to spread too much in our water. Thank you

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Debra Hover (Doc. #2420, SBC-047080)

Dear Administrator Regan:

I am relieved to hear that the EPA is proposing national drinking water regulations for six PFAS chemicals to protect our families and communities from PFAS. This topic has been building over the last decade and I am concerned the more I read about it and how prevalent it is. Thank you for not waiting any longer to take action.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Dana Ayala (Doc. #2421, SBC-047081)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Please finalize and pass these regulations so all people can have safe water to drink that wont make us sick. It is worrisome these kinds of chemicals are in our water. Thank you for acting on behalf of us all.

Sincerely,

Dana Ayala/Greensboro NC

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2422, SBC-046198)

EPA needs to set strong regulations to protect the public from PFAS in drinking water

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Diane Dickinson Selvaggio (Doc. #2423, SBC-047082)

Dear Administrator Regan:

A safe drinking water supply is absolutely critical to our health and safety all across the nation. Presently, there are far too many chemicals on the loose in our overall environment that we have little understanding of. More are added constantly, meaning we are constantly playing catch-up, and our land, water, and air, our health and safety, our quality of life, our finances, our economy are always at risk.

PFAS chemicals are the current poster children for this problem. We have been using them for decades with warnings from knowledgeable scientists being ignored. The story repeats and repeats and repeats...

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the damages of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution. They have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm, while officials have been steadfastly ignoring the warnings.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

Please finalize the regulations of these six PFAS chemicals immediately, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Thank you very much.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sarah Edwards (Doc. #2424, SBC-046275)

Please help protect our waters and our children. We must find a solution to reduce and remove PFAS from our most necessary natural resource! I love living in Michigan and our abundance of water sports, but I am increasingly wary of spending so much time in and around the waterse that are likely poisoned with PFAS. Please regulate PFAS in our drinking water, and then move on to regulation on all PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

R Ricardo Garcia (Doc. #2425, SBC-046408)

Dear Administrator Regan:

Would you drink it yourself and serve it to your family?

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Carey Creed (Doc. #2426, SBC-047083)

Dear Administrator Regan:

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

These rules, enacted, would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. Acceptance of the whole proposal can save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Romalda Allsup (Doc. #2428, SBC-047084)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Ruth Shanen (Doc. #2429, SBC-047085)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

All new chemicals, created by humans for commercial or non-profit processes, should be reviewed and tested for potential dangers to living organisms, before being approved for commercial or any other useage, Humans are creating new materials, and all of these should be tested carefully before being released anywhere in our environment.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Deborah White (Doc. #2431, SBC-046190)

I'm in favor of these lower standards for PFAS chemicals.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Will Perry (Doc. #2432, SBC-047086)

Dear Administrator Regan:

Water is our most precious resource. Chemicals that harm people and other living things have no place in our water.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Margaret Kling (Doc. #2433, SBC-046796)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

People have been drinking toxic water in many areas for far too long. Our children, and all of us, deserve better. The right to clean safe drinking water is basic, and I urge you to take action now.

Sincerely,

Margaret Kling

Englewood Cliffs, NJ 07632

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Katherine Ansbro (Doc. #2434, SBC-047087)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

Richard Vogl highlights the fact that "Water is the medium of life" in his book A Primer of Ecological Principles. Without a doubt, that is the truth. Access to clean water is a basic human right.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Beverley Colgan (Doc. #2436, SBC-046213)

I support the EPA Draft regulations proposed for 6 PFAS chemicals. I urge you to pass these rules and add additional PFAS to the regulations.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Steve Erickson (Doc. #2437, SBC-046797)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water.

We need more at the local permitting level. We are seeing land use permits being considered and granted with no - zero - requirement that groundwater be tested before such permits are granted, even in areas where nearby tests have resulted in extremely high numbers of PFAS. Every department and agency says its not their problem. But of course it is everybody's problem. We seek direction from EPA, that in areas where groundwater is known or suspected to be contaminated, any development permit must be accompanied by 1) a determination that the source of potable water is not contaminated or 2) a requirement for installation of sufficient filters and 3) regular testing and reporting.

For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Steve Erickson

Langley, WA 98260

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Edith Couchman (Doc. #2438, SBC-046246)

Please take action immediately to protect the health of people and other living beings from PFAS exposure by regulating these and allied chemicals vigorously. At the very least, lower the permitted levels in drinking water and foods.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kristy Pace (Doc. #2440, SBC-046798)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. THEY ARE FOREVER POISONS AND WE NEED TO RID OUR BODIES, WATERWAYS AND ENVIRONMENT OF ANY FUTURE CONTACT WITH THEM.

I strongly support the proposed standards, and I urge EPA to finalize them as quickly as possible.

Sincerely,

Kristy Pace

Tarzana, CA 91356

kvpsummer@yahoo.com

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Melanie Hopkins (Doc. #2441, SBC-046237)

I strongly support the EPA draft regulations proposed for six PFAS chemicals. I urge you to finalize these rules as quickly as possible. These comments are in regard to Docket ID: EPA-HQ-OW-2022-0114.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Deborah Munitz (Doc. #2442, SBC-046281)

I have a private water well that already has PFAs found when testing. Water quality protection requires federal protection because safe water should be a US citizens right and water does not know of municipal and state boundaries. Polluted water can travel through clouds and across borders. This is exactly the kind of problem that requires a federal solution. It is time to get rid of PFA chemicals in the US. Please support strong EPA regulation of PFA chemicals.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. For specific information regarding private well water, please see section 1.4 of the EPA response in this *Response to Comments* document

Sri Grandmaster Hari Palacio (Doc. #2443, SBC-047500)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA’s proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry’s efforts to weaken them.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Gale Pisha (Doc. #2444, SBC-047278)

My comments are in regard to Docket ID EPA-HQ-OW-2022-0114.

I fully support the EPA's proposed federal regulations for six PFAS chemicals, which will "prevent thousands of deaths and reduce tens of thousands of serious PFAS-attributable illnesses."1

This action by the EPA is very important, as the U.S. has not regulated a single new contaminant in drinking water in nearly 30 years. The Agency's own research, released in June, 2022, showed that some PFAS chemicals are toxic over lifetime exposure at even the lowest detectable levels.2

The proposed regulations would set drinking water standards for PFOA and PFOS at 4 parts per trillion (ppt), and would set combined standards for four more PFAS (PFHxS, HGPO-DA and its ammonium salt, PFNA and PFBS). Filtration and removal would be mandated when levels exceed these thresholds.

I live in Rockland County, NY, where all but one of our water company's more than 60 water sources contain at least one PFAS chemical, with some being hundreds or thousands of times higher than the advisory levels of 0.004 ppt and 0.02 ppt for PFOA and PFOS respectively that EPA issued in June, 2022. New York State's Maximum Contaminant Level of 10 ppt for these two PFAS is higher than the proposed EPA standards of 4 ppt, so if these draft EPA regulations are accepted, more of our water sources in Rockland will be mandated to be cleaned up. While filtration is expensive, considering the human misery and billions of dollars in healthcare costs that result from exposure to single or multiple PFAS over lifetime exposure, these draft regulations are well worth adoption. I agree with the EPA Administrator that the benefits of regulation of these chemicals justify the costs.3

In addition to the proposed Maximum Contaminant Levels of 4 ppt for PFOA and PFOS, I support EPA's expedited approach to the four chemicals it regulates with a hazard index approach (PFHxS, HGPO-DA and its ammonium salt, PFNA and PFBS), which should help prevent cumulative impacts from exposure to multiple PFAS.

Ultimately, PFAS should be regulated as a class, since it takes many years to go through a regulatory process for individual chemicals meanwhile giving the chemical industry time to come up with substitutes with slightly different chemical formulas. The government also needs to ban the continued production and sale of these forever chemicals by not approving new ones and by banning their nonessential uses in consumer products.

The government also needs to restrict emissions from industrial sites into local air and water, not allow dumping of PFAS into wastewater systems (which will then require expensive treatment to

remove them), and limit exposure that comes from the spreading of biosolids (sewage sludge) on crops. This sludge has been proven to contain PFAS as well as other toxins and pharmaceuticals.

Just as with lead, mercury and asbestos, there is no known safe level of PFAS exposure. By banning lead in gasoline and paint, we were able to dramatically reduce blood levels of lead. We can do the same with PFAS, but it will take bold action by both the federal and state governments.

The current draft EPA regulations do not go far enough, but they are a good start, and I urge their adoption and implementation quickly.

Thank your the opportunity to comment.

1. https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas

2. https://www.epa.gov/sdwa/drinking-water-health-advisories-pfoa-and-pfos

3. https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0027

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Paula Morrow (Doc. #2445, SBC-046799)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. I strongly support the proposed standards, and I urge EPA to finalize them as quickly as possible.

Sincerely,

Paula Morrow

Chicago, IL 60606

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Robert Kecskes (Doc. #2446, SBC-046291)

I applaud the USEPA in its proposed PFAS National Primary Drinking Water Regulation Rulemaking. PFAS and its companion compounds are wreaking havoc on drinking water supplies and natural water resources in the United States and around the world. We must

expedite actions to clean up existing PFAS problems and eliminate the potential to require future contamination problems. Equal attention must be focused on the "pathways" that allows PFAS to make its way into the environment, as well as taking action against the producers of these contaminants.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joseph Truhon (Doc. #2447, SBC-047274)

· I strongly support the EPA draft regulations proposed for six PFAS chemicals. I urge you to finalize these rules as quickly as possible. These comments are in regard to Docket ID: EPA-HQ-OW-2022-0114.

· I live in Rockland County, where nearly all of our drinking water is contaminated with toxic PFAS chemicals. Many of our wells and reservoirs are contaminated with PFAS at levels below the current New York State drinking water standards. That means that filtration will not be required for the majority of Rockland's contaminated wells -- unless the draft EPA regulations are passed.

· Many of Rockland's drinking water sources are contaminated with multiple PFAS chemicals, possibly resulting in additive or synergistic health impacts. But New York State currently regulates only two chemicals. The draft EPA regulations are written for combined standards, which would require many more of these chemicals to be cleaned up.

· The New York State Dept. of Health is waiting for EPA's finalized regulations. If EPA's draft regulations are passed, it will make it possible for the states to build on EPA's science and direction to regulate even more PFAS.

· These regulations will send a strong signal to the chemical industry to invest in safe alternatives now.

· There are over 12,000 PFAS chemicals in all. Moving forward, EPA should extend these regulations as quickly as possible to cover PFAS chemicals as a class.

· EPA should immediately halt the approval of all new PFAS.

· While the costs of filtration and disposal are high, those costs are far outweighed by the billions of dollars in healthcare costs caused by the health impacts of PFAS chemicals.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joseph Ryan (Doc. #2448, SBC-046411)

Protect the environment.

If there is a future, it will need filtered water and the curtailment of the chemicals in question.

EPA Response: The EPA acknowledges this comment, and the notion of protecting the environment. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Perry Kendall (Doc. #2449, SBC-046560)

Dear Michael Regan,

Decades of contaminated water supplies makes your taking the initial step to regulate PFAS in our drinking water imperative. Millions of us rely on your action to avert the increased rates of cancer, developmental and reproductive harm, and other serious diseases PFAS cause. EPA's proposed drinking water standards would provide crucial long overdue protections against six of these toxic chemicals. We desperately need the EPA to finalize federal limits on PFAS levels to ensure our drinking water is potable.

Nationwide EPA's proposed rule would necessarily provide safe drinking water. Beneficially establishing strong limits on six widely detected PFAS. Annually this meaningful proposal saves 1000's of lives preventing tens of thousands of serious PFAS-related illness. The EPA acknowledges and addresses the cumulative impacts on communities exposed to multiple PFAS. Issuing such a proposal, takes us one step closer to fulfilling your commitment under the 2021 PFAS Strategic Roadmap beginning regulating PFAS in our drinking water. Posthaste we need you to finalize these standards, implementing a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Perry Kendall

Glenside, PA 19038

PearEmail@gmail.com

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Janice Gintzler (Doc. #2450, SBC-046800)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

It was years ago that I saw the film "Dark Waters" about the lawsuit in West Virginia against DuPont for killing animals and people along a creek that ran from the DuPont plant manufacturing PFAS. DuPont, I believe, changed its name following the lawsuit. In all these years, PFAS still are produced and are making us ill?

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Janice Gintzler

Crestwood, IL 60418

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

MV Tegel (Doc. #2451, SBC-046465)

I am in favor of your proposal to regulate six PFAS chemicals under the Safe Drinking Water Act (US Environmental Protection Agency, 2023). The EPA proposed to limit drinking water exposure to two PFAS chemicals at 4 parts per trillion (ppt).

This proposal covers only six -- we need to keep going farther on regulation of these toxins.

Sincerely,

MV Tegel

Exeter NH

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Victoria Oltarsh (Doc. #2452, SBC-046244)

With all the taxes I pay, and the money I spend l shopping, living, and paying high rent in Nyack, the least we deserve is fresh and healthy drinking water, not polluted with toxic waste and chemicals. This is a crime.

EPA Response: The EPA acknowledges this comment and agrees that communities deserve safe drinking water. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kristine Atkinson (Doc. #2453, SBC-046801)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. PFAS is contaminating drinking water supplies for millions of people across the country, many unaware that their water supply has caused increased rates of cancer, developmental and reproductive harm, and other diseases. Higher drinking water standards are long overdue protections against the top six of these toxic chemicals. We urge EPA to finalize the proposed standards as quickly as possible, and to ban use in products such as toilet paper, cosmetics and cleansers.

Despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water. We are far safer here in Massachusetts than elsewhere, and residents of states lagging behind should be protected. EPA's proposed rule would provide safer drinking water for communities from coast to coast. There is a cumulative effect on communities exposed to multiple PFAS: this proposal moves EPA one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water.

Please act quickly to finalize these standards, and be proactive in preventing the sale and use of products that are contaminating water supplies everywhere.

Sincerely,

KRISTINE ATKINSON

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joan Donovan (Doc. #2454, SBC-046885)

Dear Michael Regan,

Healthy drinking water is very important to me. EPA's proposed drinking water standards would provide important and long overdue protections. I support the proposed standards, and urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities by establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Joan Donovan

San Mateo, CA 94403

donvanbj@gmail.com

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Laurie Puca (Doc. #2457, SBC-046334)

I strongly support the EPA draft regulations proposed for six PFAS chemicals. I urge you to finalize these rules as quickly as possible. I live in Rockland County, where nearly all of our drinking water is contaminated with toxic PFAS chemicals. Many of our wells and reservoirs are contaminated with PFAS at levels below the current New York State drinking water standards. That means that filtration will not be required for the majority of Rockland's contaminated wells -- unless the draft EPA regulations are passed. Many of Rockland's drinking water sources are

contaminated with multiple PFAS chemicals, possibly resulting in additive or synergistic health impacts. But New York State currently regulates only two chemicals. The draft EPA regulations are written for combined standards, which would require many more of these chemicals to be cleaned up. The New York State Dept. of Health is waiting for EPA's finalized regulations. If EPA's draft regulations are passed, it will make it possible for the states to build on EPA's science and direction to regulate even more PFAS. These regulations will send a strong signal to the chemical industry to invest in safe alternatives now. There are over 12,000 PFAS chemicals in all. Moving forward, EPA should extend these regulations as quickly as possible to cover PFAS chemicals as a class. EPA should immediately halt the approval of all new PFAS. While the costs of filtration and disposal are high, those costs are far outweighed by the billions of dollars in healthcare costs caused by the health impacts of PFAS chemicals.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Donna Fine (Doc. #2458, SBC-047088)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

Having traveled to Africa and seen how much of a difference clean water access could make, it sickens me to think that we would not want our own citizens to at least have access to water that will not make them sick.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Pearl Gray (Doc. #2459, SBC-047663)

Clean water is a basic need for all creatures, including humans. Pfas is a toxic carcinogenic chemical that does not belong in our water, air, or land, yet it is there. Let's begin protecting the

citizens of our country and county from unregulated and unfettered pollution that is making our planet toxic to all life only for the purpose of profit. Humans can live without vast wealth, we can not live without vast clean water and vast clean air. It is imperative that the elected and appointed governing bodies protect the people who elected them from being exploited for the irrelevant dollar in a linear consumptive economy. Our planet, our water, is our legacy. Earth's good health and prosperity are irreplaceable and essential for life. Our wealth is in the prudent stewardship of the planet. Protecting and purifying our water without connection to profit is the most valuable decision that can be made with dividends that extend through generation or the debt that will be paid indefinitely.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mark Petzold (Doc. #2460, SBC-046802)

Dear Michael Regan,

Once again, industry has chosen profit over protection. Did we learn nothing from the DDT debacle ?

Once again, the EPA has failed to Protect.

PFAS is everywhere, the lake trout in Seneca lake have high levels and the NYS DOH is silent. Once you upgrade water standards, look at the other sources of PFAS in the food chain.

This overhaul is long overdue. I support the new standards and also call for a hold on approval of any new PFAS chemical, a comprehensive review of all existing chemicals paid for by the industries that use them, and product labeling so consumers know the risks.

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated

drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Mark Petzold

Tioga Center, NY 13845

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Rosemary K Coffey (Doc. #2461, SBC-047089)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step in protecting our families and communities from the scourge of PFAS.

PFAS, which are notorious for their extreme persistence and widespread pollution, have been linked to a long list of ill-health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation whose drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS. Thank you in advance for your attention to this matter!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Robert Essman (Doc. #2462, SBC-046803)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

The status quo of profit making and the willful ignorance and even the deliberate misinformation by corporations is creating a rapidly increasing toxic world. It is time for creative people to lead us out of this dark ideological mindset of chaos and fear of the future towards a sustainable healthy future for those not yet born.

Do your job while you can or find some one who can lead us out of desperate hateful grasping for straws.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Robert Essman

Stamford, CT 06906

mungwha@gmail.com

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Fred Malo (Doc. #2464, SBC-046804)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Don't be intimidated by the SCOTUS. W.V. v EPA & Sackett v EPA severely restricted your authority to protect the American people from dangerous pollutants, but it's what we should expect from this court. You look at the past decisions of the conservatives that have been appointed by a one-term, twice impeached president and they always rule in favor of large corporations over the people. Maintain your stance for the health and safety of the people.

Sincerely,

Fred Malo

Carbondale, CO 81623

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

V M (Doc. #2465, SBC-047660)

Studies on the impacts of chemicals in our environments have been ignored and slow walked until harms can no longer be ignored. Very little research has ever been done on the cumulative impact of the range of chemicals the human body attempts to adapt to and function amidst. Information about PFAS chemicals is clear. Yet, with all the political and media attention on health care, pandemic response, and climate change - and billions of dollars spent to support the pharmaceutical industry - there have been decades of underwhelming response to make sure our drinking water is free of these chemicals and other problematic toxins.

It is clear to me that the federal agencies tasked to protect the American public have been hijacked. Thankfully, there are still compassionate and intelligent people around the world who actually want to take actions that directly support the quality of health and life of everyone. Let us stand with each other.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lisa Kunkel (Doc. #2466, SBC-046805)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. I strongly support the proposed standards, and urge EPA to finalize them as quickly as possible.

EPA's proposed rule would provide safer drinking water for communities by establishing strong limits on six widely detected PFAS.

The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting any efforts to weaken them.

Sincerely,

Lisa Kunkel

Eagle, CO 81631

lisa_kunkel@yahoo.com

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Anonymous public comment (Doc. #2467, SBC-046335)

I am a resident of Rockland County, NY where our drinking water is contaminated with multiple PFAS chemicals. There is no question that the cumulative stress of environmental factors such as these chemicals considerably impacts our health. Chronic health issues in our children have been exponentially increasing since the mid 80;s. Little to no research has been done to effectively understand the cumulative harms of the range of chemicals we live amidst on a daily basis. In fact, New York State currently regulates only two PFAS chemicals. The draft EPA regulations are written for combined standards, which would require many more of these chemicals to be cleaned up. The New York State Dept. of Health is waiting for EPA's finalized regulations. If EPA's draft regulations are passed, it will make it possible for the states to build on EPA's science and direction to regulate even more PFAS. We need safe alternatives now!! All of us deserve this. There are over 12,000 PFAS chemicals in all. This is only one subset of chemicals. Not only should the EPA extend these regulations as quickly as possible to cover PFAS chemicals as a class, the EPA must immediately halt the approval of all new PFAS. This is common sense. The fact that ignoring these harms has become normalized is a symptom of incredible soullessness, greed, and an ongoing loss of integrity. While the costs of filtration and disposal are high, those costs are far outweighed by the billions of dollars in healthcare costs caused by the health impacts of PFAS chemicals. Stop displacing these corporate costs onto individual lives. This burden dims the entire world. Just stop now. Be someone who changes everything for the better.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sharon Kleppel (Doc. #2468, SBC-047267)

My name is Sharon Kleppel and I am a member of the Catholic Climate Covenant which is working to support the proposed EPA National Primary Drinking Water Regulation which sets enforceable limits on PFAS and other related chemical compounds in public drinking water.

I am concerned that not only for myself, but for all Americans, we do not have guaranteed access to clean drinking water that does not contain harmful PFAS levels. I am particularly concerned in light of the fiasco in Flint Michigan several years ago that many of our smaller cities and rural areas are permitting these chemicals to be in their water.

Therefore, I am writing in support of the NPDWR (EPA-HQ-OW-2022-0114-0027) and its stringent regulations on drinking water. The rule has the potential to lower the presence of dangerous chemicals in the water supply of over 110 million Americans. PFAS chemicals have been repeatedly connected to dangerous health conditions, and the EPA must do something to protect Americans from such contamination.

As a member of a faith community, I take the responsibility I have to creation, and to each other, very seriously. It is from that position that I advocate for this act as a way of bringing about more justice in our society. It is because the benefits of the rule are so great, and, according to the EPA, far outweigh the costs of implementation, that I believe it to be in the best interest of the United States to enact the National Primary Drinking Water Regulation. Thank you for the continued work of the EPA to create better living standards and a more harmonious relationship with nature.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sandy Kirkpatrick (Doc. #2469, SBC-046537)

Dear Michael Regan,

PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. This proposal would bring the EPA one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. I urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Sandy Kirkpatrick

Benicia, CA 94510

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joseph Hiss (Doc. #2470, SBC-046505)

Dear Michael Regan,

There are currently no federal limits on these levels in drinking water. EPA's proposed drinking water standards would protection against six of these toxic chemicals, presumably the most important ones. We urge you to finalize them as quickly as possible.

PFAS are often called "forever chemicals." They have contaminated drinking water supplies for approximately 200 million people in the United States.

The EPA is now one step closer to meeting its commitment under the 2021 PFAS Strategic Roadmap to start regulating PFAS in drinking water. We urge you to resist industry's efforts to weaken them.

Sincerely,

Joseph Hiss

Olympia, WA 98501

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Christine Schmitthenner (Doc. #2471, SBC-047273)

I strongly support the EPA draft regulations proposed for six PFAS chemicals. I urge you to finalize these rules as quickly as possible. These comments are in regard to Docket ID: EPA-HQ-OW-2022-0114.

· I live in Rockland County, where nearly all of our drinking water is contaminated with toxic PFAS chemicals. Many of our wells and reservoirs are contaminated with PFAS at levels below the current New York State drinking water standards. That means that filtration will not be required for the majority of Rockland's contaminated wells -- unless the draft EPA regulations are passed.

· Many of Rockland's drinking water sources are contaminated with multiple PFAS chemicals, possibly resulting in additive or synergistic health impacts. But New York State currently regulates only two chemicals. The draft EPA regulations are written for combined standards, which would require many more of these chemicals to be cleaned up.

· The New York State Dept. of Health is waiting for EPA's finalized regulations. If EPA's draft regulations are passed, it will make it possible for the states to build on EPA's science and direction to regulate even more PFAS.

· These regulations will send a strong signal to the chemical industry to invest in safe alternatives now.

· There are over 12,000 PFAS chemicals in all. Moving forward, EPA should extend these regulations as quickly as possible to cover PFAS chemicals as a class.

· EPA should immediately halt the approval of all new PFAS.

· While the costs of filtration and disposal are high, those costs are far outweighed by the billions of dollars in healthcare costs caused by the health impacts of PFAS chemicals.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Cynthia Hudley (Doc. #2472, SBC-046806)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. EPA's proposed drinking water standards provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

Despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water. Establishing strong limits on six widely detected PFAS would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. By issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Cynthia Hudley

Los Angeles, CA 90016

hudley@ca.rr.com

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

David Will (Doc. #2473, SBC-046807)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

Despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

David Will

Schulenburg, TX 78956

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Bonnie Bledsoe (Doc. #2474, SBC-046548)

Dear Michael Regan,

It's beyond common sense to have pure drinking water...who doesn't want to be healthy? Including all the creatures in nature.

Please regulate PFAS in drinking water. I strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

These "forever chemicals" are truly scary; they build up in. our body, and they last for decades.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge

you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Bonnie Bledsoe

Seattle, WA 98125

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mary Mathews (Doc. #2475, SBC-046602)

The EPA's PFAS Strategic Roadmap and its comprehensive approach in addressing PFAS through research, restriction, and remediation is an excellent plan to protect people and the environment. National regulations and enforcement are required to stop widespread polluting of our drinking waters and the adverse health effects caused by "forever chemicals".

This is especially necessary for environmental justice communities which already are burdened with so many other pollutants and possibly multiple sources for PFAS. One such community Waukegan, IL is near my own town. The drinking water for both communities is drawn from Lake Michigan. Currently, the measurable amount is not high, but without action, could be soon. My community is suing 3M for any costs associated with PFAS in the drinking water. Perhaps not all communities are included in the lawsuit, but all communities should receive equitable protection against public drinking water contamination.

Part of the plan, that I strongly support, is the EPAs proposal "Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation" which limits six PFAS. This crucial step will help keep these toxic chemicals out of our drinking water and curb some long-lasting harm to people and wildlife.

But that proposal is only a start. I urge the EPA to speed up its process and expand to include all PFAS chemicals, including ones currently classified as inactive. Contamination already is found worldwide, and levels of concentration will only grow until industries are forced to contain or stop their uses.

While some consumers have become aware of PFAS in everyday products such as nonstick pots and food wrappers and choose to avoid those, manufacturers have designed new applications and products where the presence and toxic nature of PFAS are unknown to the public.

An example of this is the use of artificial turf (plastic grass), a growing industry all over the country. My community approved installation of 10 acres of plastic grass next to a stream. Runoff from it and hundreds of thousands of other installations (private yards, school athletic

fields, professional sports fields, etc.) throughout the county will increase the contamination levels of PFAS.

Manufacturers have known about the deadly harm caused by their chemicals for years and have been able to avoid any consequences. This must not continue. Polluters must be held accountable. Please use every enforcement tool available.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

William Ashman (Doc. #2478, SBC-046808)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water! For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible!

Sincerely,

William Ashman

Virginia Beach, VA 23451

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jean Naples (Doc. #2479, SBC-047277)

Dear Administrator Reagan,

I am writing as a physician and public health/environmental protection advocate because I am very concerned by the latest news that our waterways that provide drinking water and habitat for wildlife including the belted kingfisher, are contaminated with highly toxic "forever chemicals", PFAS, that persist in our environment, our water, people, and wildlife for a long, long time. These chemicals, known as Per and Poly fluoroalkyl Substances, or PFAS, expose communities and beloved species to serious health risks, including cancers and impacts to the reproductive and immune systems.

Please understand that I strongly support the EPA draft regulations proposed for six PFAS chemicals. I urge you to please finalize these rules as quickly as possible. These comments are in regard to Docket ID: EPA-HQ-OW-2022-0114.

I live in the town of Suffern in Rockland County, where nearly all of our drinking water is contaminated with toxic PFAS chemicals. Many of our wells and reservoirs are contaminated with PFAS at levels below the current New York State drinking water standards. That means that filtration will not be required for the majority of Rockland's contaminated wells, unless the draft EPA regulations are passed.

I am very concerned because many of Rockland's drinking water sources are contaminated with multiple PFAS chemicals, with the possible result of additive or synergistic health impacts. However, as a physician and public health/environmental protection advocate, I am very disturbed because at this current time, New York State is only regulating ground water contamination of two PFAS chemicals. The draft EPA regulations are written for combined standards, which would require many more of these chemicals to be cleaned up.

Please understand that the New York State Dept. of Health is waiting for EPA's finalized regulations. If EPA's draft regulations are passed, it will make it possible for the states to build on EPA's science and direction to regulate even more PFAS.

At this time, I thank you for your consideration of my letter and my recommendations. It is vital for you to understand that EPA approval of these regulations will send a strong signal to the chemical industry to invest in safe alternatives now. I am also very disturbed by the fact that there are over 12,000 PFAS chemicals in all. Moving forward, I strongly urge the EPA to please extend these regulations as quickly as possible to cover PFAS chemicals as a class. It is also very important that the EPA should immediately halt the approval of all new PFAS.

While the costs of filtration and disposal are high, those costs are far outweighed by the billions of dollars in public healthcare costs caused by the health impacts of PFAS chemicals.

I strongly urge you to please acknowledge that persistent toxic pesticides must be considered to pose an "unreasonable risk to the environment," and these risks to our public health should result in cancellation of their registrations.

Sincerely,

Jean Marie Naples, MD-Ph.D.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sue Odierna (Doc. #2480, SBC-046332)

I moved to Rockland County 8 months ago and have just learned nearly all of our drinking water is contaminated with toxic PFAS chemicals. Many of our wells and reservoirs are contaminated with PFAS at levels below the current New York State drinking water standards. That means that filtration will not be required for the majority of Rockland's contaminated wells – unless the draft EPA regulations are passed

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Judy Schultz (Doc. #2481, SBC-046809)

Dear Michael Regan,

As a nurse, I want to thank you for taking the first step to regulate PFAS in drinking water. As you know, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. I strongly support the proposed standards, and I implore the EPA to finalize them as quickly as possible.

We simply cannot continue to allow the kind of harmful pollution that PFA's pose simply for the profits of the industries that manufacture and use them. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

As you know, the proposed rule would provide safer drinking water for communities from coast to coast and address the cumulative impacts on communities who are exposed to multiple PFAS. Please finalize these standards as soon as possible and implement a rule that is as robust as possible.

Thank you for your consideration.

Sincerely,

Judy Schultz

San Francisco, CA 94115

heyjudenf@gmail.com

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Norman Shepard (Doc. #2482, SBC-046810)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

We Gave Known About These Many Health Issues Connected To PFAS Chemicals For Years, Yet They Have Been Allowed To Be Put in Our Water Systems, Used On Our Cooking Pots & Pans & Other Places With Out Restriction !! It's Long Past Time They Were Totally Banned From Any Use That Could Affect Our Health. Please Get It Done - Water Is Just The 1st Step. Our Water Systems

Sincerely,

Norman Shepard

Girard, IL 62640

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Louise Nolta (Doc. #2483, SBC-046811)

Dear Michael Regan,

How can I thank you for taking the first step to regulate PFAS in drinking water? We have waited a long time for this to happen. Drinking water is so essential to every person, so this will make such a difference in the lives of people. It will save lives, it will make a safer environment and will prevent sicknesses. It will not prevent every sickness, but it will prevent what is preventable. I strongly support the proposed standards, and I urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

By doing this you can really make a difference in the lives of so many. Please do make a difference. Thank you

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Louise Nolta

Winnetka, IL 60093

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Long Island Civic Alliance (Doc. #2484, SBC-046299)

Thank you for proposing stricter standards for PFAs contamination. We are NY residents where the current Department of Environmental Conservation levels are 10 parts per trillion. That is 40% of the standards the EPA is proposing. We live near Republic Airport on Long Island, which has been implicated in PFAs contamination by the NYSDEC, but their potential clean-up will only mitigate contamination to their levels. Some NYSDEC mitigation involves paving over contaminated areas, which is completely unacceptable and very dangerous. We hope federal standards will be required of every state environmental agency. Please pass this regulation quickly. Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mary Ann Kadooka (Doc. #2485, SBC-046812)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

*** Living on the islands of Hawaii, I never dreamed I would have to worry about our pristine ground water quality. But now with the Navy fuel tanks leaking into our ground and the plastics

in the ocean, we need to be diligent about limiting pollutants from our drinking water. The economic health costs for our state has been devastating as our cost of living is one of highest in the country!

I implore you to regulate PFAS in our water!

Mahalo Niu loa"...

Sincerely,

MARY ANN KADOOKA

Honolulu, HI 96817

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jim Tappon (Doc. #2486, SBC-046813)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

As you are well aware, water is the lifeblood of all life - humans, animals, plants - and if continue to allow contaminants, we are in effect allowing all Living creatures to be poisoned. It is your job to be the 'watchdog' for all of us who depend on you and companies that may become more concerned about their bottom line than they are about life on our planet!

Sincerely,

Jim Tappon

Rochester, NY 14609

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Andrea Callan (Doc. #2487, SBC-047622)

I do the best I can to limit my family's exposure to PFAS by being an educated consumer, but it isn't enough. I am expecting my second child and recently read about a recent study documenting PFAS in breastmilk! Our bodies are totally contaminated, down to the most natural, life-giving parts of ourselves. It's hard to not feel hopeless that corporations will endlessly and carelessly harm us in the name of profits. Only government has the type of regulatory power needed to make a difference in truly limiting the harm these chemicals pose to our bodies and the wellness of our society.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Tim Peterson (Doc. #2489, SBC-046651)

Dear Administrator Regan,

This is a no brainer. So much of the free world/western culture live without the threat of PFAS. This country should not only join them, but be a leader in this important environmental and health issue.

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Emily Lewis (Doc. #2490, SBC-046679)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water. EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals.

Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Pete O'Malley (Doc. #2491, SBC-046652)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

Many people in my community are experiencing the effects of PFAS in our drinking water and it's tragic to know so many going through the same cancer treatments because of where we live.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

Peter O'Malley

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mary Chieffe (Doc. #2492, SBC-046273)

I strongly support cleaning our water so it is safe to drink, bathe and use for other household purposes. There is no place for toxic chemicals in our water. I want my children and grandchildren to be safe and healthy. Clean water is a must for our health and livelihood. Polluting companies are responsible for cleaning their toxic messes. The health and wellbeing of people comes before profit.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Marcus Maloney (Doc. #2493, SBC-046653)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government must act boldly to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals.

Placing the burden on our communities, our drinking water, and our health will not solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mark Olinger (Doc. #2494, SBC-046654)

Dear Administrator Regan,

The Environmental Protection Agency (EPA) has a chance to make drinking water safer for everyone!

PFAS are found in our drinking water, our air, our soil, and our bodies. Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

The EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

John Lovelace (Doc. #2495, SBC-047090)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

We will not get a second chance on this problem. Nature cannot heal when we put such large wounds on the system.

Very likely mankind is relying on your actions.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Daniel Vallero (Doc. #2496, SBC-047091)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Exposure to PFAS – known as "forever" chemicals because they are extremely resistant to breaking down in the environment – has been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

But every day, millions of people across the country drink water contaminated with PFAS. Unfortunately, PFAS are almost impossible to avoid. They are found in our homes, our offices, our supermarkets – practically everywhere. What's worse, manufacturers don't have to disclose to consumers that they're using them. It needs to stop.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Theresa Conk (Doc. #2497, SBC-047092)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS. As a parent and health advocate, there is no step I can take personally or advise that others take to minimize exposure. This must be addressed through regulation. This is an issue that affects us all but especially the most marginalized. Industries won't change unless you take action.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS. Thank you for the work that you do.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Cynthia Gerlinger (Doc. #2498, SBC-047093)

Dear Administrator Regan:

In commend your efforts to limit or even ban PFAS. The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

My family and I are very converned about PFAS persistence in the drinking water we use. As you know, these forever chemicals have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

My family and I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then continue to prioritize addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mary Jane Engh (Doc. #2499, SBC-047094)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

Of course you are familiar with the harmful effects of PFAS--and because these chemicals are so long-lasting, their effects accumulate every year that they are still used.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Cathy Farris (Doc. #2500, SBC-047095)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm. They should not be ingested by anyone!

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

No living creature should ingest PFAS. Stop the breeding!

Without population control, we are doomed! The earth cannot produce enough resources for our endless needs!

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Grace Bartlett (Doc. #2501, SBC-047096)

Dear Administrator Regan:

Clear drinking water is essential for life and health. As you know clean PFAS free water is not an optional extra. The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS. This is vital to the wellbeing of all. Thank you for your quick action.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Margaret Tilden (Doc. #2502, SBC-046415)

Dear Administrator Regan:

Please make sure the EPA's proposed national drinking water regulations for six PFAS chemicals is passed and enforced as quickly as possible. YOU know why!

Thank you!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kathleen Fenton (Doc. #2503, SBC-047097)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our

The EPA's proposal for regulating PFAS would be a step toward saving thousands of lives and preventing tens of thousands of serious PFAS-related illnesses each year.

Please quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Judy Hopkins (Doc. #2504, SBC-046551)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals are an important step towards protecting communities from these hazardous substances. It's crucial that such regulations are based on the latest scientific evidence and are robust enough to ensure safe drinking water for everyone.

Additionally, addressing all types of PFAS contamination is critical to protect public health. PFAS chemicals are widely used in many industries, and their persistence in the environment means that they can accumulate in the food chain and pose long-term risks. It's essential to have a comprehensive approach that includes not only regulating PFAS in drinking water but also addressing their use in manufacturing and other applications.

Overall, I agree with the NRDC's call to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS. This will require a coordinated effort from policymakers, industry, and the public to ensure that we can effectively address this urgent environmental and public health challenge.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Annetta Winkle (Doc. #2505, SBC-047098)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

The chemical companies have made enough money off of the blood of the people of this country and the world. GREED, GREED.\,GREED isa ll they are and it seems much off this country of insecure little white men haters are too.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Maureen Allen (Doc. #2506, SBC-047099)

Dear Administrator Regan:

EPA needs a LOT more money to eliminate mounting environmental threats!

THANK YOU for proposing national drinking water regulations for six PFAS chemicals!

Who even knew they exist? Or the harm they do? Cancer! Immune suppression! Developmental damage!

This first tranche of regulations is such a welcome first step to protecting us from the scourge of PFAS.

Obviously, the faster you can release the final rule, the more illnesses and deaths you will prevent.

Your team may already be working on regulations covering more types of the ubiquitous PFAS. I hope raising public awareness and requiring disclosure of PFAS by the companies who expose us to them are key components of both rules.

And I support EPA receiving budget priority in proportion to the importance of restoring a healthy environment!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Elizabeth Pingree (Doc. #2507, SBC-047100)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

Living in Maine, as my family does, PFAS chemicals have been in recent News reports, thus, very much on the collective minds of people who live here. It has not gone unnoticed just how prevalent, dangerous, and common these PFAS chemicals are in the broader landscape. There are troublesome areas around the state, certainly, but no place is completely immune. It's more than concerning, more like alarming to all of us living here.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Scott Schweizer (Doc. #2508, SBC-047101)

Dear Administrator Regan:

As a Republican I can tell you the environment is not a partisan issue. I urge you to take strong action to safeguard people and our water from forever chemical pollution.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Paul R. Ogushwitz (Doc. #2509, SBC-046417)

Dear Administrator Regan:

I urge you to quickly finalize the regulations of the six PFAS chemicals, implement a rule that is health protective, and then BAN ALL OTHER TYPES OF "PFAS".

Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Andrew Goldstein (Doc. #2510, SBC-047102)

Dear Administrator Regan:

The EPA is tasked with protecting our environment. I am happy to see you have proposed national drinking water regulations for six PFAS chemicals. That is a welcome first step to protecting our families and communities from the scourge of PFAS which will go on for generations.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals and implement a rule that is health protective. Then begin addressing all other types of PFAS. You have to start somewhere but please don't stop there. That is just the tip of the iceberg.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Andrea Doukas (Doc. #2511, SBC-047103)

Dear Administrator Regan:

Thank you for the EPA's proposed national drinking water regulations for six PFAS chemicals. This is a welcome first step to protect Americans from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Tom Schwegler (Doc. #2512, SBC-047104)

Dear Administrator Regan:

I am writing to you as a supporter of the Natural Resources Defense Council, Earth Justice, the Environmental Defense Fund, the Sierra Club and other environmental organizations.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to please quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Thank you considering this critical environmental protection and human health issue.

Sincerely,

Tom Schwegler

Kansas City, Missouri

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Rio Kerr (Doc. #2513, SBC-046499)

Dear Administrator Regan:

Thank you for quickly pushing through the EPA's proposed national drinking water regulations and standards for six PFAS.

This legislation is long overdue and urgently needed.

Any difficulties arising from the implementation of these standards are also needed to make people and polluters see and accept the insidiousness of these chemicals, and force better science to address them.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Thank you,

Rio Kerr

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Charles Beers (Doc. #2514, SBC-046183)

Protect US against PFAS!!!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Theresa Cromeans (Doc. #2515, SBC-047105)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

As a retired health scientist, I am highly concerned about this now and especially for future generations. We have no way to rid the environment of these chemicals and they are far too pervasive already.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Rebecca Wells (Doc. #2516, SBC-046196)

We really need this to come as soon as possible. Please see this through.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Nancy Borchert (Doc. #2517, SBC-047106)

Dear Administrator Regan:

Remove PFAS chemicals from use now! Stop contaminating our drinking water with chemicals that last forever and damage our bodies! Clean drinking water is a human right! Take action now.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Dave Councilman (Doc. #2518, SBC-047107)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Getting these chemicals out of our water is pro-health, pro-life and Prevention!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Nicholas White (Doc. #2519, SBC-047108)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

We are becoming aware that ghe extent of PFAS contamination has been hidden/underestimated/ underreported, and that municipal water supplies in the apparently safest districts are compromised. We know that agricultural land in New England is seriously polluted. It is time for fast strong action to stop things getting worse.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm. I fear that we will be linking this contamination with many more diseases in the next decade or so.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal

would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Pat Long (Doc. #2520, SBC-047109)

Dear Administrator Regan:

The EPA's proposed national drinking-water regulations for 6 PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these 6 PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jill Levin (Doc. #2521, SBC-047110)

Dear Administrator Regan:

How many requests, pleas and asks must be made to get you and other government agencies to act in the best interests of the American people. Don't keep delaying in protecting our drinking water. PROTECT IT.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jo Hersh (Doc. #2522, SBC-047111)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I consider this a critical public health issue, and urge you to quickly finalize the regulations of these six PFAS chemicals, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Susan Bramley (Doc. #2523, SBC-047112)

Dear Administrator Regan:

There is nothing more fundamental to life than water. But the water must be clear of substances that cause harm. Our industrial world is making it harder and harder to find good, toxin-free drinking water. Fortunately for our country the EPA is finally moving in the right direction.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Barbara Stone (Doc. #2524, SBC-047113)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a needed first step to protecting our families and communities from the scourge of PFAS.

PFAS are cannot be removed and degrade so slowly that they are termed 'forever' chemical pollution. Their widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Catherine Haskin (Doc. #2525, SBC-047114)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal

would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS. While you are working to finalize the regulations, I also urge you to continue to listen to the people who will benefit from these rules, not the producers.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Daria Flores (Doc. #2526, SBC-047115)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

It would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Catherine Cosman (Doc. #2527, SBC-047116)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protect families and communities from the PFAS scourge.

PFAS are infamous for their extreme persistence and widespread pollution and are linked to many health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for millions of people in communities across the USA where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Esther Garvett (Doc. #2528, SBC-047117)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Abigail Holmes (Doc. #2529, SBC-047118)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are well known for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

I live near a military facility where these were used firefighting. while water has been provided to some residents - this is in our ground water now. poisoned water - thats not what we should get from our taps in the US!

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

dont let this be where you stop - historically companies have simply replaced one PFAS with another. start by taking this great first step ,but then I call on you to protect us from future version - its crazy that in this country so many dangerous substances are simply allowed to remain in our water and environment.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Robert Droste (Doc. #2530, SBC-047119)

Dear Administrator Regan:

The sooner these "forever" chemicals are no longer added to the environment the better. Since once they are added they continue to accumulate and the problems they cause will only become worse.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Susan O'Rourke (Doc. #2531, SBC-047120)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. With water being something we can't live without it's quite shocking that this hasn't been taken care of before now!! How many humans, animals and all things dependent upon drinking water will have to possibly be stricken with a serious and maybe deadly ailment before drinking water is safer for all. Our politicians need to focus more on fixing America's real problems and QUIT FIGHTING WITH EACH OTHER AND NOTHING GETS DONE-we are waiting to see results and so far you are all failing Americans.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Thomas Beck (Doc. #2534, SBC-047121)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting us from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then address all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Arlene Renshaw (Doc. #2535, SBC-047122)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS. Human health is at risk all across our country.

Thank you for taking this dangerous water pollution problem seriously and seeking to address it meaninfully.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

N Yvonne Hamilton (Doc. #2536, SBC-047123)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS. My Husband died from Parkinson's and There have been several cases On this Block and I'm not well! Who is responsible?

This is inexcusable!

How many more have to die before it stops!

N Yvonne Hamilton

California

90275

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sharon Crossen (Doc. #2537, SBC-047124)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

We have had a wonderful, clean water source in the Dayton, Ohio area...until we have seen PFAS beginning to show up our test wells. Sources have been identified as fire foam both in use by the the city fire department and those at Wright-Patterson Air Base. Sadly,there are more sources being found. We have a wonderful son, daughter-in-law and precious grandson. We want then to have a safe, water source. PLEASE work in seeing that it a wish come true. Check the water in the areas of your family. You might be surprised by what you find. This isn't just a me problem, it is an US problem.

Thank you from a third generation Irishwoman and life long Democratic supporter.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lynne Mehalick (Doc. #2538, SBC-047125)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from pervasive exposure to PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm in humans, and probably all animal life.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year, greatly reducing the burden on the U.S. healthcare system.

PLEASE HELP ELIMINATE THIS VERY SERIOUS THREAT TO HUMAN HEALTH. There are still so many other human health risks to correct, such as pesticide and herbicide contamination in our food supply.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Samantha Herdman (Doc. #2539, SBC-047460)

The goal of the Safe Drinking Water Act of 1974 (SDWA) is to set health standards to protect people from contaminants in drinking water, whether man-made or naturally occurring. Unfortunately, the ability of the Environmental Protection Agency (EPA) to effectively wield the SDWA to respond to public health threats has been under fire (Weinmeyer et al. 2017). Implementing the proposed PFAS National Primary Drinking Water Regulation (NPDWR) is imperative for the safety of citizens across the United States and an excellent opportunity to combat the narrative that the EPA can't adequately protect public health from unsafe drinking water. However, there is more that EPA should do to protect the public from PFAS.

I support EPA's decision to set science-based MCLGs and MCLs for perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorohexane sulfonic acid (PFHxS), GenX chemicals, perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS), and mixtures of these PFAS (EPA 2023). After learning about the negative health effects of PFAS and their ubiquity in manufacturing, I became very concerned about using any products that may result in PFAS contaminated drinking water. I also felt a lot of frustration that protection against PFAS was state-dependent. EPA's decision to monitor these six PFAS is overdue, and I fully support EPA's plan to build upon existing state regulations (EPA 2023).

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mary Ferm (Doc. #2540, SBC-047126)

Dear Administrator Regan:

Tests have recently shown high levels of PFAs in the HOA well just uphill from us on San Juan Island in Washington State. We are very concerned about this issue and have paid for our own well to be tested, but have yet to receive the results.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Nicholas Saltmarsh (Doc. #2541, SBC-046814)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment

under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

It is somewhat insulting that these issues aren't taken more seriously. The EPA consistently brags and boasts about climate action but does little to help the everyday American from being exposed to toxic chemicals in their everyday life. The people of our country would recognize the great act of discernment once PFAS are more strictly regulated or banned.

Sincerely,

Nicholas Saltmarsh

Parsonsfield, ME 04047

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

LuAnn Glatzmaier (Doc. #2542, SBC-047127)

Dear Administrator Regan:

When the EPA was just starting as a government agency, my best friend was dating the person who was representing the water department. I was so happy that there was an agency that had been appointed to this most vital dimension of life. I was so proud that in this country that the EPA had emerged. I am still so thankful today that EPA is such an important dimension of our lives, in all aspects of it's protection, and what matters more to us than water, that sustains all life?

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Michelle Betz (Doc. #2543, SBC-047579)

I recently finished Erin Brokovich's book, Superman's Not Coming: Our National Water Crisis and What We the People Can Do About It, and am convinced we need stronger regulation around our water quality. Science now confirms the damaging health effects of 'forever chemicals', and the EPA must act to save communities from consuming these damaging toxins. These toxins accumulate over a lifetime and cause irreversible damage- the time to act is now!

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Peter Beckman (Doc. #2544, SBC-046425)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is essential!

I've been using a water filter for years which filters most contaminants but fails to properly filter PFAS!

Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Cecelia Carreon (Doc. #2545, SBC-047128)

Dear Administrator Regan:

As a young adult, I want to believe I have a future. I want to picture the wonderful prospects I might have in the future. It's not possible, though. Not if there is no clean water available. Not in the sweltering heat. Not when violent storms topple the roof of my house. Not when I won't live to be 40. I urge you to think about addressing climate change in consideration of not just you or your loved ones, but future generations. We, as a species, deserve to flourish in a world that was intricately designed for us. Please consider this message:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Candace Fujikane (Doc. #2546, SBC-047646)

I am an English professor at the University of Hawaii and a water protector.

Over the years I have seen so many threats to our aquifers, through overdevelopment, through the use of pesticides, through the construction of industrial complexes whose wastes leak into our aquifer. We must protect water. It is our most basic necessity. It also costs less to protect water than it will to lose that water to chemical toxins. We can look to places like Calcutta where people wait for hours in line for water, or in other places where people are dying for lack of water. I have heard of mothers giving their babies their saliva to keep them alive. We have the power to do something about the contamination of our waters, and we must do all we can to protect our waters.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sandra Kuritzky (Doc. #2547, SBC-046514)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a first step to protecting our families and communities from harmful PFAS, which are known for their persistence and widespread pollution. They have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Ashlea Romano (Doc. #2548, SBC-046202)

Please don't set my children up for failure by contaminating all their drinking water. Protect them!

EPA Response: The EPA acknowledges this comment and believes this PFAS NPDWR will result in increased public health protection from drinking water potentially contaminated with PFAS. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Stefan Pacin (Doc. #2550, SBC-046589)

Re: Proposed PFAS National Primary Drinking Water Regulation Rulemaking Docket ID: EPA-HQ-OW-2022-0114

Dear Administrator Regan,

Thank you for taking this historic step to keep our drinking water safe from PFAS contamination. For decades, PFAS chemicals have contaminated both public and private drinking water supplies across the country. PFAS contamination exposes communities to serious health risks, including cancers, impacts to the immune and reproductive systems, and other harms. The EPA's proposed drinking water standards would provide long overdue federal protections against six types of highly toxic PFAS.

I strongly support this proposed rule and urge EPA to move swiftly to finalize health-protective standards to reduce PFAS in drinking water.

The PFAS crisis is widespread, contaminating the blood of humans, fish, and wildlife worldwide.

EPA's proposal would significantly reduce exposure to PFAS in drinking water for millions of people by setting strong, science-based drinking water standards for six types of PFAS. While this proposal is an important first step towards addressing PFAS exposure, it is critical that EPA also expedite efforts to prevent these chemicals from entering our waters and environment in the first place, before it even reaches our taps.

These proposed regulations are long overdue and I fully support this first step of regulating six dangerous PFAS in drinking water. In addition, I encourage the EPA to take a comprehensive approach to regulating the entire class of chemicals in order to reduce overall PFAS exposure, and improve drinking water safety in thousands of communities across the country.

Thank you for your consideration.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Charming Evelyn (Doc. #2553, SBC-047585)

Evidence shows that under-served and under-resourced communities are the most likely to suffer from PFAS/PFOA contamination. It's time to reign in polluters and clean up water in these communities. Everyone no matter their economic circumstances, gender, skin color, including ecosystems and the life dependent on them deserve the right to clean, accessible, good quality water. It's time to make polluters pay to clean up their messes and to expedite the process.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

David Patton (Doc. #2554, SBC-047129)

Dear Administrator Regan:

I am fortunate to drink clean safe water but in the USA not everyone has this basic need met. This is unacceptable. Why do we have to try so hard to look and act like a 3rd world country? Environmental injustice.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal

would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Carl Albers (Doc. #2555, SBC-047302)

I think the proposed regulations are a step in the right direction. In the future I believe the whole class of forever chemicals should be regulated as a group.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Houman Sedaghat (Doc. #2558, SBC-046410)

Dear USA EPA:

I support setting the smallest possible limits for the amount of PFAS chemicals in our drinking water.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2561, SBC-046199)

Please help change the current regulations allowing PFAS in our water system. Thank you!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Grace Kailainathan (Doc. #2562, SBC-046286)

We must put communities ahead of corporations, corporations that pollute must be held to higher standards and fined for causing damage to our environment. Particularly the recent train derailments, the fast fashion industry (clothes made of micro plastics when put in the washing machine pollute the water supply) and coal industry MUST be regulated and adapt sustainable,

environmentally friendly practices. I support the Biden-Harris PFAS regulations. Keep our water clean, healthy, and safe!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joyce Bressler (Doc. #2563, SBC-046285)

I am writing in response to Docket ID EPA-HQ-QW-2022-0114. thank you for taking the time to read my comments. I urge you to follow through with the planned regulations of PFAS chemicals and clean-up in our water. these chemical have proven to be serious and dangerous to public health, producing cancers and other illnesses. Do not succumb to pressure from the industries that produce, manufacture and sell these chemicals in everyday products that end up in our water and inour bodies.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Zachary Bouricius (Doc. #2566, SBC-046655)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

How many Flint, Michigan's do we need before ? Its going to hurt you in the election if more people are POISONED! You were on a knife's edge in Michigan and Wisconsin. cmon'.

Sincerely,

Zach Bouricius

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Andrew Lazur (Doc. #2567, SBC-046656)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Additionally, to help educate consumers whose health is negatively affected by these contaminants, legislation requiring all products sold in the US to include distinct labelling notice of PFAS presence/content, should be established. Consumers, are unaware of the presence and risk associated with PFAS that is found in hundreds of products used daily. Laeblling will facilitate better informed decisions and selection of safer products, thereby in the long term signalling to manufacturers to remove PFAS from their products.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Diana Cowans (Doc. #2568, SBC-046657)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

I know of no other species that deliberately poisons itself. Clean water is required for all life on this planet and humans should be the responsible stewards of the environment.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use

and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Thank you for taking action to protect our water.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Linda White (Doc. #2570, SBC-046458)

I am an active-duty Army spouse, mother of three, voter and 20 year plus resident of Hawaii.

My family and I fully support regulating per- and polyfluoroalkyl substances in our drinking water without reservation, regardless of the financial costs of the state and corporations of adhering to such limits. Long overdue and I applaud the EPA for this.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Stephen Levine (Doc. #2573, SBC-046887)

Dear Michael Regan,

PFAS are so pernicious, they even exist in our raindrops.

As a cancer survivor, I feel really scared about the terrible damage these have been shown to do to us humans.

It's crucial we need to consider the life quality our grandchildren will inherit.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Stephen Levine

Overland Park, KS 66213

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Nancy Perez (Doc. #2574, SBC-046414)

Dear Administrator Regan:

I urge you to finalize the regulations of these six PFAS chemicals quickly, implement a health-protective rule, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Ed Dornheim (Doc. #2575, SBC-046659)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should quickly finalize these Safe Drinking Water Act regulations, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use, and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of the EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail the use of PFAS chemicals. Placing the burden on our communities, drinking water, and health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Michael Moran (Doc. #2576, SBC-046311)

I want to encourage the EPA to adapt as strict of limitations as possible on PFAS in our drinking water. I fear for the millions of American's that are unwittingly exposed to these pervasive, dangerous chemicals and what could be perhaps generational damage to our collective well-being. I can't accept the bargain plastics manufacturers propose - we should accept a certain amount of pollution in order to enjoy the use of plastics in our lives. The profits they earn through the manufacture and sale of plastics sully their voice in this conversation - we won't be able to count on them to pay for the damage caused to communities affected by PFAS. The recent train derailments and chemical spills are clear examples of inadequate regulation. Clean water is a fundamental right and we must do everything in our power to protect this right and to punish those that infringe upon it. Please protect our waters

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Leda Beth Gray (Doc. #2577, SBC-046815)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. I live in Maine and we are finding it in organic farmland and products, in wildlife and in wells and public drinking water. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. I strongly support the proposed standards, and we urge you to finalize them as quickly as possible.

I wish PFAS had never been approved for industrial uses-- they are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment

under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. I urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Leda Beth Gray

Blue Hill, ME 04614

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

SL Triolo (Doc. #2578, SBC-046272)

For too long the desires of corporations and their so-called "rights" to destroy nature and pollute people and animals have been primary. This PFAS regulation and all subsequent EPA evaluations of current practices should put people and the environment over corporate profits. Stop the madness! How can any practice that is a known harm be an "acceptable level of harm"? Come on!

EPA Response: The EPA acknowledges this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. For further information regarding the SDWA rulemaking process and how the EPA followed all requirements under SDWA, please see section 1.1 of the EPA response in this *Response to Comments* document.

Tristan Sophia (Doc. #2580, SBC-046816)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals.

We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

Sincerely,

Tristan Sophia

Butte, MT 59701

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Diana Bain (Doc. #2581, SBC-046817)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

There are currently NO federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Diana Bain

Bridport, VT 05734

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Emily Keltonic (Doc. #2582, SBC-046818)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

We need this protection to stop cororations and stock holder interests continuing to harm the future of our planet. As a former, microbiologist and middle school science teacher, I was always concerned about the safety of new chemicals on all life. DDT was a m perfect example!!!

Sincerely,

Emily Keltonic

Norwich, CT 06360

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mary Mathews (Doc. #2583, SBC-046819)

Dear Michael Regan,

We have to get rid of PFAs as quickly as possible. The harm they do is proven and universal. All of us are affected. We are killing ourselves and nature. I do not want my children and grandchildren to develop any of the health conditions associated with these forever chemicals. Right now, it is impossible to protect them from these toxic substances which are everywhere and don't need to be.

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections

against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Mary Mathews

Lake Forest, IL 60045

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Judy Harris (Doc. #2584, SBC-046820)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies

who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. By issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken it.

Sincerely,

Judy Harris

Richmond, TX 77469

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Richard Van Aken (Doc. #2585, SBC-046821)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge

you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

The science says these chemicals are deadly and are reluctant to break down causing all kinds of medical problems. The question is why has this been allowed to happen and what is the government going to do about the thousands of these chemicals now in use?

Sincerely,

Richard Van Aken

Southampton, PA 18966

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sharon Thompsen (Doc. #2586, SBC-046510)

Dear Michael Regan,

I am concerned about our drinking water having toxic chemicals (PFAS) in it. It's great that the EPA has proposed some limits on six PFAS that have been a problem for a long time. Too many people don't know of the bad effects these chemicals can have, such as contributing to the development of cancer and other serious illnesses, infertility, and immune system damage.

Thank you for taking this critical step to address the crisis around PFAS and to help communities remove these dangerous chemicals from their drinking water.

Please try to finalize these proposed standards as quickly as possible. And I urge you to oppose industry's efforts to weaken them. Thanks very much!

Sincerely,

Sharon Thompsen

West Chester, PA 19382

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Juli Kring (Doc. #2587, SBC-046822)

Dear Michael Regan,

As a mother and a grandmother, I am very concerned for the health and viability of the planet our children and future generations will inherit. We have a duty to our communities, families and

most importantly, children to ensure their safety and well being through environmentally sound and sustainable policies, including clean air, water, etc. That duty will always be more important than politics or profit.

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Juli Kring

Houston, TX 77099

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Ken Kurtz (Doc. #2588, SBC-046588)

Dear Michael Regan,

I wanted to discuss a topic that I think is important for all of us: regulating PFAS in drinking water.

PFAS, or "forever chemicals," have been contaminating our drinking water for decades, affecting millions of people and causing cancer, developmental and reproductive harm, and other serious diseases. It's alarming that despite these serious health risks, there are currently no federal limits on PFAS levels in drinking water.

That's why I'm grateful that the EPA has proposed drinking water standards that would provide long overdue protections against six of these toxic chemicals. This is a crucial step in the right direction, and I strongly support these proposed standards.

These chemicals are highly dangerous and can persist in the environment, building up in our blood and organs and causing harm for years to come. They have contaminated the drinking water of approximately 200 million people in the US, including newborn babies who are exposed in utero.

The proposed rule would provide safer drinking water for communities across the country and save thousands of lives by preventing tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges the cumulative impacts on communities exposed to multiple PFAS, and I believe it's time to take action to protect everyone's health.

So, I urge you to support these standards and to resist any efforts to weaken them. We need to take care of ourselves and each other, and regulating PFAS in drinking water is a crucial step in that direction. Thank you for listening, and let's work together to create a safer and healthier future.

Sincerely,

Ken Kurtz

Chandler, AZ 85249

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Martha King (Doc. #2589, SBC-047310)

PFAS have been known to be used since the 1940's. Health issues have resulted. It is now 2023 and it is being proposed that there be a "maximum contaminant level goal for the 6 PFAS" where there is "no known or anticipated negative effect on an individuals health". Knowing what we already know...there should be NO allowance for ANY PFAS in our water system. PFAS have no place in our communities. Placing a "rule on limiting any 'mixture' containing one or more of these chemicals" is only asking for further harm to the health of our citizens. Many, I dare say, most, of our water systems are under staffed and outdated. And even if the "hazard index" indicated a problem and the public was "notified" then the harm has already been done. The MCLG is "health based (what does that mean and who determines this?) and non-enforceable"

which is just another way of allowing another "loop hole" for companies to continue defiling our environment and harming our citizens.

EPA Response: The EPA acknowledges this comment in general support of regulating PFAS in drinking water, but that also cites some concerns with the proposed MCLG and Hazard Index. Please see section 1.3 of the EPA response in this *Response to Comments* document. In accordance with the SDWA, MCLGs are based on findings from the Toxicity Assessments supporting documents (USEPA, 2024a; USEPA, 2024b) and are health-based and do not account for other factors, including feasibility. Once MCLGs are determined, the EPA then determines feasibility (as defined in the SDWA). Feasibility includes an evaluation of the BATs and the costs for applying those BATs when trying to treat to the MCLGs. Unlike MCLGs, MCLs are enforceable. This NPDWR is setting enforceable levels of six PFAS in drinking water. For additional information on the MCLG determinations and health-based approach followed by the MCLs, please see section IV and V of the FRN.

Diane Ryerson (Doc. #2590, SBC-046823)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. I strongly support the proposed standards to regulate six of the most common PFAS contaminants of our waters. Because these long-lasting toxic chemicals accumulate in our bodies and have significant health impacts, I urge EPA to finalize these proposed standards as quickly as possible. Please serve the people by not letting the industry weaken the standards or prolong finalization. Thank you.

Sincerely,

Diane Ryerson

Arcata, CA 95521

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Alexa Ross (Doc. #2591, SBC-046501)

It is the duty of EPA to implement drinking water protections against PFAS contamination.

PFAS are ubiquitous in commerce, and accumulate in people, water, wildlife, aquatic life, plants, everywhere. It is outrageous that these toxic "forever chemicals," are allowed to contaminate us with cancer, liver and kidney disease, reproductive and immunity problems, and hormonal disruptions.

It is criminal to allow these poisons to proliferate when they are practically impossible to remove. Strict regulations are overdue to protect people and our rivers, oceans, lakes, and communities from PFAS contamination.

Thank you,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

John Acker (Doc. #2593, SBC-046431)

I am writing today to urge EPA to swiftly implement drinking water protections against PFAS contamination.

PLEASE support the badly needed regulations to better protect people and our rivers, oceans, lakes, and communities from PFAS contamination.

Thank you,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Juli Kring (Doc. #2594, SBC-046584)

As a mother and a grandmother, I am very concerned for the health and viability of the planet our children and future generations will inherit. We have a duty to our communities, families and most importantly, children to ensure their safety and well being through environmentally sound and sustainable policies, including clean air, water, etc. That duty will always be more important than politics or profit.

So I urge EPA to immediately implement drinking water protections against PFAS contamination.

We need national standards for PFAS. Expanding protections to six PFAS, as well as the combination of different PFAS, will protect our drinking water from this toxic contamination and keep countless Americans safe from enduring the health risks associated with these dangerous chemicals.

PFAS, which are used to manufacture a range of goods, break down very slowly over long periods of time and instead accumulate in people, wildlife, aquatic life, plants, and the environment. This contamination poses a direct threat to our health and our ecosystems. Also known as "forever chemicals," PFAS are pervasive contaminants that are linked to serious health conditions such as cancer, liver and kidney disease, reproductive issues, immunodeficiencies, and hormonal disruptions.

PFAS' ubiquity is why we need to act fast and decisively. Finalizing these regulations would protect drinking water for countless communities.

I urge your support for these badly needed regulations to better protect people and our rivers, oceans, lakes, and communities from PFAS contamination.

Thank you,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kathryn Ryan (Doc. #2595, SBC-046573)

I am writing today to urge EPA to swiftly implement drinking water protections against PFAS contamination.

We need national standards for PFAS. Expanding protections to six PFAS, as well as the combination of different PFAS, will protect our drinking water from this toxic contamination and keep countless Americans safe from enduring the health risks associated with these dangerous chemicals.

PFAS, which are used to manufacture a range of goods, break down very slowly over long periods of time and instead accumulate in people, wildlife, aquatic life, plants, and the environment. This contamination poses a direct threat to our health and our ecosystems. Also known as "forever chemicals," PFAS are pervasive contaminants that are linked to serious health conditions such as cancer, liver and kidney disease, reproductive issues, immunodeficiencies, and hormonal disruptions.

PFAS' ubiquity is why we need to act fast and decisively. Finalizing these regulations would protect drinking water for countless communities. These rules and regulations will help prevent further damage. We need to plan and figure out how these horrendous chemicals can be removed from our water. Also, those that perpetrated the damage need to clean. It. Up.

I urge your support for these badly needed regulations to better protect people and our rivers, oceans, lakes, and communities from PFAS contamination.

Thank you,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kathryn Burns (Doc. #2596, SBC-046561)

I am writing today to urge EPA to swiftly implement drinking water protections against PFAS contamination.

We need national standards for PFAS. Expanding protections to six PFAS, as well as the combination of different PFAS, will protect our drinking water from this toxic contamination and keep countless Americans safe from enduring the health risks associated with these dangerous chemicals.

PFAS, which are used to manufacture a range of goods, break down very slowly over long periods of time and instead accumulate in people, wildlife, aquatic life, plants, and the environment. This contamination poses a direct threat to our health and our ecosystems. Also known as "forever chemicals," PFAS are pervasive contaminants that are linked to serious health conditions such as cancer, liver and kidney disease, reproductive issues, immunodeficiencies, and hormonal disruptions.

We all must drink water. Allowing these chemicals to remain in our supply is inexcusable.

PFAS' ubiquity is why we need to act fast and decisively. Finalizing these regulations would protect drinking water for countless communities.

I urge your support for these badly needed regulations to better protect people and our rivers, oceans, lakes, and communities from PFAS contamination.

Thank you,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Beverly Richards-Smith (Doc. #2597, SBC-046579)

I am writing to urge EPA to implement protections for drinking water against contamination by per- and polyfluoroalkyl substances (PFAS) as quickly as possible. These ubiquitous chemicals include compounds known or suspected to cause cancer, infertility, birth defects, liver and kidney disease, immune deficiencies, and endocrine disorders in humans, livestock, and wild animals. (Their endocrine disrupting properties may be responsible for the increased incidence of transsexuality in younger human generations.) The carbon-fluorine bonds that are the defining property of these compounds, among the strongest bonds encountered in organic chemicals, make them highly resistant to degradation and thus persistent long-term in the environment -- thus their nickname, "forever chemicals."

National standards for PFAS are sorely needed. Expanding protections to six PFAS, as well as to combinations of PFAS, will help to reduce contamination of our drinking water by this toxic class of chemicals, and thus, our exposure to their health risks.

PFAS' ubiquity is the reason we need to act soon -- and decisively. Finalizing these regulations would protect drinking water for countless communities and would protect not only those of us living today, but future generations.

I urge your support for these badly needed regulations to better protect our rivers, oceans, lakes, wildlife, and human communities from PFAS contamination.

Thank you,

Beverly Ridhards-Smith

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mr.Derlin Clair (Doc. #2598, SBC-046576)

Dear EPA, Hello,I'm Mr.DerIin G.Clair.I am writing today to most Strongly please urge the EPA to Please Truswiftly implement drinking water protections against PFAS contamination.

We need national standards for PFAS. Expanding protections to six PFAS, as well as the combination of different PFAS, will protect our drinking water from this toxic contamination and keep countless Americans safe from enduring the health risks associated with these dangerous chemicals.

PFAS, which are used to manufacture a range of goods, break down very slowly over long periods of time and instead accumulate in people, wildlife, aquatic life, plants, and the environment. This contamination poses a direct threat to our health and our ecosystems. Also known as "forever chemicals," PFAS are pervasive contaminants that are linked to serious health conditions such as cancer, liver and kidney disease, reproductive issues, immunodeficiencies, and hormonal disruptions.

PFAS' ubiquity is why we need to Truly act fast and decisively. Finalizing these regulations would protect drinking water for countless communities.

Therefore,I most Strongly urge your honest to dear God total support for these badly needed regulations toTruly better protect people and our rivers, oceans, lakes, and communities from PFAS contamination.

Well Thank you,my dear friends,and God bless you.Mr.Derlin G.Clair,131 Beinville Dr.,Sldiell,La.70458;E-Mail:derlinclair@yahoo.com

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Maria Celia Hernandez (Doc. #2599, SBC-046582)

EPA

Sub: Expand Drinking Water Protections Against PFAS Contamination

With due respects,

Today, I am writing today to urge EPA to swiftly implement drinking water protections against PFAS contamination.

We need national standards for PFAS. Expanding protections to six PFAS, as well as the combination of different PFAS, will protect our drinking water from this toxic contamination and keep countless Americans safe from enduring the health risks associated with these dangerous chemicals.

PFAS, which are used to manufacture a range of goods, break down very slowly over long periods of time and instead accumulate in people, wildlife, aquatic life, plants, and the environment. This contamination poses a direct threat to our health and our ecosystems. Also known as "forever chemicals," PFAS are pervasive contaminants that are linked to serious health conditions such as cancer, liver and kidney disease, reproductive issues, immunodeficiencies, and hormonal disruptions.

PFAS' ubiquity is why we need to act fast and decisively. Finalizing these regulations would protect drinking water for countless communities.

I urge your support for these badly needed regulations to better protect people and our rivers, oceans, lakes, and communities from PFAS contamination.

Expand Drinking Water Protections Against PFAS Contamination because Everyone needs to drink clean water; Water is Live.

Thank you,

Ms. Maria Celia Hernandez 4-17-2023

54 Orleans St. Apt. 317

Boston, MA.02128

her84754@verizon.net

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mark Meeks (Doc. #2600, SBC-046660)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects. I strongly support stringent efforts to protect our environment from these chemicals. I fear our way of life is taking a quite harmful toll on the earth on which we depend and that will return in many harmful ways to impact our lives. I hope we can be far more diligent in limiting such impacts.

Indeed, the EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Bryn Hammarstrom (Doc. #2601, SBC-046661)

Dear Administrator Regan,

As a father and RN, thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects. In 1946 my father, a chemist, was working with vinyl chloride, and in 1947 I was born with an undescended testicle [a known result from my father's work with that chemical]. The EPA has a DUTY to protect OUR EARTH from PFAs and ALL harmful chemicals.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Susan English (Doc. #2602, SBC-046662)

Dear Administrator Regan,

My son lives in Wilmington, NC and we have been buying bottled water for him since he moved there because of concern about PFAS in the water.

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lynne Lambert (Doc. #2603, SBC-046663)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Don't let the companies who make plastic. And those that use it. Win against the public health of our country. They are called forever chemicals for a reason. Let help the next generation

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Ben Burrows (Doc. #2604, SBC-046193)

The PFAS chemicals are not biodegradable and must be eliminated

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Nadine Godwin (Doc. #2605, SBC-046511)

Please approve these proposed nationwide standards designed to significantly curtail our exposure to PFAS in our drinking water.

The New York Times, citing a 2020 study, reported that as many as 200 million Americans are exposed to PFAS in their tap water. Many of these people have been exposed to these so-called "forever chemicals" for a long time, making it urgent that these standards be implemented soonest.

I will just add that once we can put a lid on the amount of PFAS in our drinking water, we must also take steps to dramatically reduce the amounts of PFAS produced by industry and ensure that these chemicals are no longer dumped into our waterways as a byproduct of production or under any circumstance.

Thank you for making this proposal.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Marilyn Gooch (Doc. #2606, SBC-046467)

PFAS are harmful to human health. Seriously harmful. I believe we have an obligation to one another to do whatever we can to get dangerous pollutants out of our lives.

The current EPA proposal for minimum acceptable levels of PFAS in drinking water is one of those things we can and should do.

In fact, I think it is vital.

Please implement these proposed standards as soon as feasible.

Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Edward Thornton (Doc. #2607, SBC-046664)

Dear Administrator Regan,

See, what EPA actually is responsible to do is protect all Citizens. EPA can adopt policies that help industry to protect all Citizens. But what it cannot do is help industry but at the expense and harm of the rest of us. Thank you for moving forward on safe drinking water.

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Derlin Gerard Clair (Doc. #2608, SBC-046665)

Dear Administrator Regan, Hello,I,m Mr.Derlin G.Clair,a very,veyr concerned American citizen.Thank you kindly for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible,my dear Administrator Regan,including the Hazard Index approach for four PFAS chemicals.Thousands of PFAS chemicals are in use and many are very Unmfortunately found in mixtures in water around ourcountry.Therefore,EPA should Truly address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government Truly need to take equally bold action to stop PFAS pollution,Truly hold polluters accountable,and curtail uses of PFAS chemicals,my dear Adm.Regan.Just Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Margot Backus (Doc. #2609, SBC-046541)

Dear Administrator Regan,

I want to thank you for proposing limits on PFAS chemicals in drinking water that reflect the latest scientific information on the health effects of these chemicals!

The EPA needs to work quickly to finalize these Safe Drinking Water Act regulations. The one thing we know for sure about drinking water around the US is that we don't know how bad the situation is in how many communities. There are thousands of PFAS chemicals in use, and many are found in mixtures in water around the country. The EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is, as I am sure is apparent to everyone who gives thought to this issue, an appalling betrayal of the whole idea of a government that represents the interests of the people, not of corporations.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Rose Johnson (Doc. #2610, SBC-046666)

Dear Administrator Regan,

We have seen over and over the evidence that PFAS chemicals are harmful to human health. And it is scary that we may not even know the full impact these chemicals may be having. So, THANK YOU for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

I urge you to finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sarah Abbruzzese (Doc. #2612, SBC-046194)

Please stop this harmful substance from causing any more damage.

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Terry Skinner (Doc. #2614, SBC-046824)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water! For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. I strongly support the proposed standards, and I urge the EPA to finalize them as quickly as possible.

Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet, incredibly, despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water!

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment

under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. Please quickly finalize these standards and implement the rule (and please resist industry's efforts to weaken it). Thank you!

Sincerely,

Terry Skinner

Buena Park, CA 90620

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Marilyn Harris (Doc. #2615, SBC-046487)

Dear Administrator Regan,

Thank you for acting with the EPA to limit PFAS chemicals in drinking water, and thank you for listening to science on this.

Please finalize the Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for PFAS chemicals that are known to cause adverse health effects. Please lead the EPA in addressing the whole class of PFAS chemicals wherever possible.

Our drinking water, and our health (and that of those to come) is in your hands.

Sincerely,

Marilyn Harris

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

John Lent (Doc. #2616, SBC-046668)

Dear Administrator Regan,

As you know, PFAS chemicals are very dangerous for human health and they are everywhere. It is not acceptable that people must continue to be exposed to these dangerous chemicals in their daily lives. Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects. EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Karin Hemmingsen (Doc. #2617, SBC-047600)

I write as a family physician and public health professional who has watched for some decades now as the US government has allowed the greed of corporations to run roughshod over the public health of our citizens. We keep asking when will enough be enough in regard to guns (a very legitimate question), but there does not seem to be a similar urgency to the question when it concerns environmental pollutants that can harm us all and that have been accumulating for decades. The EPA needs to do its job.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Rachel Neurath (Doc. #2618, SBC-046669)

Dear Administrator Regan,

I am a mother and a scientist. I care deeply about safe water not only for my children but also for future generations. Water is one of our most valuable resources. All life depends on it. The overwhelming evidence to the dangers of PFAS and pervasiveness within our water make it clear that it is time - now - to act.

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Patrick Hughes (Doc. #2619, SBC-046527)

Dear Administrator Regan,

Americans' health begins with our environment. The food we eat, the air we breath, and the water we drink have been damaged by PFAS. First, stop the PFAS production as soon as possible. Then hold any producer that hid the dangerous effects of PFAS accountable. We should test our water regularly for PFAS and redesign any aspect of our production that cannot avoid PFAS. Americans are injecting huge amounts of PFAS, the physical & potential mental damage to our bodies may not be completely known for decades. It's imperative that we take all necessary steps to eliminate PFAS. Cleaning our drinking water is a step but only one step of a long journey. The journey becomes longer every day we allow the PFAS to continue to be produced. Please take all action to save the health and well being of all mankind. The PFAS are 'forever', we are not.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jondi Gumz (Doc. #2620, SBC-047299)

I reported on Santa Cruz County's epic fire, CZU lightning fire in August 2020 that destroyed more than 900 homes, for Scotts Valley Times. Fire retardant containing PFAS was dropped. This is a common practice. Eight of the 10 largest fires in California have taken place in the past 6 years. Dropping fire retardant containing PFAS is the go-to strategy. Huge swaths of the state are affected. https://en.wikipedia.org/wiki/List_of_California_wildfires

EPA Response: This comment is outside the scope of this NPDWR, please see section 15 of the EPA response in this *Response to Comments* document.

John December (Doc. #2622, SBC-046276)

I support the EPA enacting the proposed federal drinking water regulations (EPA-HQ-OW-2022-0114-0027). These are an essential first step in protecting the public from dangerous chemicals.

Support setting the maximum contaminant level in drinking water for the two most common PFAS compounds (PFOA and PFOS) at 4 parts per trillion (ppt) and create a health hazard scoring index to assess the cumulative risk from 4 other chemicals.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joan Janus (Doc. #2623, SBC-046266)

I'm urging you to protect public health by not backing down from regulations that will require harmful chemicals be removed from our drinking water. As drinkable water becomes more of a national and world wide issue these regulations are so important. I'm particularily concerned about the impact these chemicals have on infants and young children.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2624, SBC-046413)

After Flint and countless other water catastrophes, please just be on the right side of history here.

Clean water is a human right.

Finalize the drinking water standards.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2625, SBC-046208)

I wholeheartedly support this regulation. Please do the right thing and protect the public health of all Americans.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Aiden Finckbone (Doc. #2626, SBC-046428)

Dear Michael Regan,

I am in constant fear on how these chemicals will effect my life in the future. I'm fifteen years old and am told that forever chemicals are in everything and it's un-avoidable. Please help.

Sincerely,

Aiden Finckbone

Ypsilanti, MI 48198

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joelle Strom (Doc. #2627, SBC-046309)

I would like to voice my support, as a concerned citizen, of highly strict regulations on PFAS, both at the source of production and in water treatment. There are too many studies demonstrating evidence of direct harm by these chemicals to become lax in the amount we allow the population to be exposed to them. In addition to holding manufacturers accountable for keeping these compounds out of waterways, we should invest in upgrades to water treatment plants where necessary to remove as many PFAS from drinking water as possible, or educate citizens as to how they may protect themselves. I would appreciate as a form of penalty against violators of these regulations, an easily accessible list of ways I can use my consumer power to support companies that are maintaining their duty to protect our water supply by limiting their use of PFAS and/or properly disposing of these chemicals.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jerry Tobe (Doc. #2629, SBC-046670)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

May you do ONLY that which is truly best for the environment and the vast majority of people living in America as well as its territories and possessions, and cause those people as little harm as humanly possible.

Thank you for reading my comments and prayer.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Susan Baumgartner (Doc. #2630, SBC-046475)

Regarding Docket ID No. EPA-HQ-OW-2022-0114,

I ask the EPA to establish meaningful and actionable maximums for these chemicals in our water supplies.

We must limit their production and their release as a society. For those already loose in the environment, we must do what we can to remove them and/or restrict their affects.

Federal limits will push states to understand the importance of dealing with these chemicals and do so.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sharon Grinker (Doc. #2632, SBC-046513)

We need to protect our water supply. Human life can not be sustained without clean drinking water. This is the challenge of our era, to learn how to live healthfully with the planet and with our scientific knowledge and modern conveniences, without destroying ourselves. I believe that we are smart enough to do this. And I believe we are also smart enough to govern ourselves thoughtfully. A society is judged by how it cares for its most vulnerable citizens. All people need access to clean drinking water.

We need legislation to limit dangerous chemical contaminants (PFAS/PFOS and related) from our water. These chemicals are found throughout our waterways and we must do whatever we can to limit them so that we can continue to live healthful lives.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Eva Kranjc (Doc. #2633, SBC-046566)

Dear Michael Regan,

As a mother, I am extremely concerned about what PFAS means for the current and future health of my child, not to mention the health of my husband and I. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water.

There is no time to lose on these forever chemicals; please take action on this matter as soon as possible.

Sincerely,

Eva Kranjc

Westerly, RI 02891

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Susan Herold (Doc. #2634, SBC-046825)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades,

EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. I strongly support the proposed standards, and urge EPA to finalize them as quickly as possible.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment

under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. I urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Susan Herold

Kansas City, MO 64111

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

David Hempel (Doc. #2635, SBC-046496)

Dear Michael Regan,

Thanks for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

Sincerely,

David Hempel

Iowa City, IA 52245

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

KT Morice (Doc. #2636, SBC-046197)

Please protect the people, animals and invertebrates and pass this water regulation

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Caitlin Lisko (Doc. #2638, SBC-046315)

After years of inaction, the U.S. Environmental Protection Agency (EPA) has finally proposed health standards for 6 of the most widely detected PFAS chemicals in our drinking water. These

chemicals have contaminated the drinking water supply for over 200 million people nationally. They are so prevalent, that they are in the blood of every single American, including newborn babies. PFAS is known to cause increased rates of cancer, developmental and reproductive issues, and other serious diseases. The proposed federal drinking water regulations (EPA-HQ-OW-2022-0114-0027) are an important first step in protecting the public from these dangerous chemicals. EPA set the maximum contaminant level in drinking water for the two most common PFAS compounds (PFOA and PFOS) at 4 parts per trillion (ppt), and created a health hazard scoring index to assess the cumulative risk from 4 other chemicals. We need to take action now! Please take this concern seriously and make a change!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Robert Jones (Doc. #2639, SBC-046826)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Living in the most corrupt nation in human history, the Divided States of Corporate America, is an early death sentence for all life in it. If I had one wish, it would be to get the fuck as far away

from this piece of shit, shithole nation as quickly as possible. Death to the USA will be welcomed worldwide.

Sincerely,

Robert Jones

Salem, OR 97302

EPA Response: Please see section 1.3 of the EPA response in this *Response to Comments* document. Regarding the comment's statements about the United States, please see section 15 of the *Response to Comments* document for out-of-scope topics.

Mary Hood (Doc. #2640, SBC-046827)

Dear Michael Regan,

Due to a number of health issues, I drink only water--60 oz. per day. Because I'm an ardent environmentalist, I won't buy bottled water, the biggest scam of our lifetime. I drink Delco (Delaware County) water from my tap. Having clean, safe, pure water to drink matters intensely to me personally, and should be an inalienable right for every American.

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Mary Hood

Plain City, OH 43064

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Martha Booz (Doc. #2641, SBC-046828)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible, and to implement a rule that is the most health-protective. And you must resist industry's efforts to weaken them.

Sincerely,

Martha Booz

El Sobrante, CA 94803

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jane Hendley (Doc. #2642, SBC-046261)

Dear EPA, I am glad that the EPA is at least proposing strict regulations for some PFAS chemicals. They are so dangerous to health and persistent in the environment. But ALL the PFAS chemicals are dangerous and should be regulated also and no more allowed to be developed. Thank you for considering! Sincerely, Jane Hendley

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sandra Portko (Doc. #2643, SBC-046580)

Dear Michael Regan,

Hello, I want to thank all of you for working to protect our environment and urge you to stay strong in your actions. Push back hard against corporations whose greed is influencing many members of Congress to weaken regulatory standards. Enforcing necessary standards would improve the health of our planet and its inhabitants. Please continue to increase the regulatory standards to protect our water, soil, and land. The initial step to improve our water supply is appreciated and more is needed. Michigan is surrounded by 3 of the 4 Great Lakes and it is frightening to know that fish in all those lakes are contaminated with PFAs in addition to all our drinking water. However, realizing that all of our nation's (and other nations' as well) drinking water is filled with those same 'forever chemicals' is terrifying!

There is a large body of evidence that demonstrates the harm these chemicals cause in humans and animals ranging from developmental damage in growing organisms to various cancers in adult organisms. The only way to change this pattern is to implement stringent standards now, so that the level of contamination doesn't get any worse. I beg you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Sandra Portko, PhD

Developmental Psychologist and Child Developmental Specialist

Sincerely,

Sandra Portko

Grand Rapids, MI 49534

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Helen Fields (Doc. #2645, SBC-046270)

Please ban all PFAS and PFOA chemicals, as Europe has done, and lower the allowable amount to the lowest possible number. We have friends and coworkers who have lost homes, neighborhoods, and family members to this chemical in Bennington, Vermont. We do not need the chemicals; we have the right to "Protect the Common Welfare" of all; that is YOUR JOB. DO IT.

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document. This comment's discussion about the ban of PFAS and PFOA chemicals and Europe are outside the scope of this rulemaking. Please see section 15 of the EPA response in this *Response to Comments* document for out-of-scope topics.

Joan B Groff (Doc. #2646, SBC-047130)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Petrochemicals must be deterred more...they certainly are creating widespread pollution and breathing problems daily! We are intelligent human beings, able to adapt to using less plastic every day! Government seems to be needed to remind our of that!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Peter Macfarlane (Doc. #2647, SBC-047131)

Dear Administrator Regan:

Most of us have no access to data on the quality of the water we drink. The EPA's proposed national drinking water regulations for six PFAS chemicals are therefore a welcome first step to protecting us all from these toxins.

PFAS are infamous for their extreme persistence and have been linked to several adverse health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people across the nation for whom it is currently contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations regarding these six PFAS chemicals, and then begin addressing all other types of PFAS.

Thank you for your consideration.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Laura Kelly (Doc. #2648, SBC-046456)

Dear Administrator Regan:

I am glad to hear of the EPA's proposed national drinking water regulations for six PFAS chemicals.

With the PFAS cancer connection growing, it only makes sense to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Barbara Miller (Doc. #2649, SBC-047132)

Dear Administrator Regan,

EPA's proposed national drinking water regulations for six PFAS chemicals are a welcome first step to protecting Americans from the scourge of PFAS. PFAS are infamous for their extreme persistence and widespread pollution. They have been linked to many health issues, including cancer, immune suppression, and developmental harm.

EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Nancy Williamson (Doc. #2650, SBC-047133)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

These PFAS chemicals are probably hurting helpful insects like bees, birds & wild animals more than we will ever know. There is no need for these chemicals. Please enforce using safe alternatives.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Bob Edwards (Doc. #2651, SBC-047134)

Dear Administrator Regan:

The proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Margaret Binkley (Doc. #2652, SBC-047135)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Too many people are getting sick as a result of PFAS consumption. We urgently need to stop poisoning Americans.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Bruce Balan (Doc. #2653, SBC-047136)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Edmund Nespoli (Doc. #2654, SBC-047137)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Dana Duncan (Doc. #2655, SBC-047138)

I fully support the EPAs role in improving our environment. Please consider this a vote of that support and the need to continue to remove harmful substances which industry continues to throw into our environment for profit and with little consideration of the consequences to our health.

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Paul Flippen (Doc. #2656, SBC-046440)

Dear Administrator Regan:

The clear evidence that PFAS are exceptionally persistent is undisputed. Please protect our national drinking water by finalizing the EPA's proposed regulations. Protecting people, and our water, from these dangerous chemicals is the right thing to do.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jaimie Hunter (Doc. #2657, SBC-047139)

Dear Administrator Regan:

I am a cancer patient who has lived my life in fear of getting cancer taking every precaution and I believe it may have been caused by an environmental exposure which I had no co too over. Specifically, where I went to college in Pennsylvania has extremely high PFAS levels in the water. The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Judith Bentley (Doc. #2658, SBC-047140)

Dear Administrator Regan:

I am a cancer patient who has lived my life in fear of getting cancer taking every precaution and I believe it may have been caused by an environmental exposure which I had no co too over. Specifically, where I went to college in Pennsylvania has extremely high PFAS levels in the water. The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Bryant Wong (Doc. #2659, SBC-047141)

Dear Administrator Regan:

As an environmental engineer, I am writing you to express my support of the EPA's proposed national drinking water regulations for 6 PFAS chemicals.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Alison Boyle (Doc. #2660, SBC-047142)

Dear Administrator Regan:

We are all equally affected by these chemicals. Please do all that you can to outlaw them. I would like to also see filtration systems used universally to remove them.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Pat Egleston (Doc. #2661, SBC-047143)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS and it must be adopted immediately for the health of our country.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I strongly urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sharon Tkacz (Doc. #2662, SBC-047144)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

The EPA's proposed rule would provide safer drinking water for the millions of people.

I urge you to quickly finalize the regulations of these six PFAS chemicals.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kara Shaw (Doc. #2664, SBC-047145)

Dear Administrator Regan:

Please help protect our planet and our lives, this has gone too far! Please start with the suggestions below and DONT STOP until we have eliminated all toxic chemicals.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2665, SBC-046207)

This is such a great cause. I am glad we are taking steps towards providing clean drinking water for our country.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Bette Korber (Doc. #2666, SBC-047146)

Dear Administrator Regan:

Clean water for drinking and for our environment is a critical resource for our people now and in the future generations. Thank you for advancing these steps to safeguard our drinking water.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Teena Halbig (Doc. #2667, SBC-047510)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Renee Ewing (Doc. #2668, SBC-047147)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

This is an extremely important issue to me as PFA's are already being found in our bodies. We are killing ourselves and endangering future generations. Please take action to regulate these dangerous chemicals.

Thank you so much for your consideration in this matter.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mary Suagee-Beauduy (Doc. #2669, SBC-047148)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

I attended one of your listening sessions. From that I understand that public utility companies are exempt from monitoring for PFAS. I hope I am wrong about that. I tried to find out from my public utility what the PFAS levels are. They responded like I was speaking in a foreign language. They could not answer my question. Hence, I have no idea what level of PFAS I am consuming. Consumers should not be responsible for monitoring this! My immune system is compromised with an auto-immune disorder. Please, take the strongest actions possible to protect the public's health. Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Regarding the commenter's question around "public utility companies" and monitoring, the EPA clarifies that public water systems that meet the definition of a public water system under the SDWA must comply with and are not exempt from monitoring for PFAS as provided in this NPDWR. Under the final PFAS NPDWR, the EPA is adopting a three-tiered monitoring framework that public water systems must follow. Sampling tier and frequency is based on previous data, system type, and system size (population served). The EPA is finalizing the requirement that initial monitoring, or demonstration of previously collected data to satisfy requirements, must be completed within the first three years following promulgation of the rule. Based on this initial monitoring data, annual monitoring will occur at a specific tier. For further details on the monitoring required under this NPDWR, please see Section VIII.F of the FRN. Monitoring for PFAS outside of this NPDWR is outside the scope of this rulemaking. However, to learn more about ongoing monitoring for 29 PFAS contaminants and 1 metal (lithium) in PWSs under UCMR5, please visit the EPA website (https://www.epa.gov/dwucmr/fifth-unregulated-contaminant-monitoring-rule). Along with monitoring, this PFAS NPDWR requires public water systems to communicate information about distributed water to consumers. For more information on these required communications, such as the CCR and the PN requirements, please see Section IX of the FRN and section 9 of the EPA response in this *Response to Comments* document.

Keith Kisselle (Doc. #2670, SBC-047149)

Dear Administrator Regan:

I teach environmental studies and can say that students are often puzzled and concerned when we discuss what is and what is not regulated for our drinking water. many of them believe that EPA does it's best to protect citizens from environmental hazards. As a former post-doc research with EPA, I know that this goal is at the heart of the agency, but it can be better.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kathy Goings (Doc. #2671, SBC-047150)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I have lived where we have had contaminated drinking water, as well as bathing water.clean water should be an expectation in the US and SHOULD ALWAYS BE AVAILABLE. No company should be allowed to contaminate water!

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

William Coder (Doc. #2672, SBC-047151)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

My own residence's water supply relies on a PFAS/PFOA contaminated aquifer due to corporate malfeasance enabled by lax state environmental regulation and enforcement. We don't want this to happen to anyone else, and EPA 's science based approach is the best defense.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Andrea Reimers (Doc. #2673, SBC-047152)

Dear Administrator Regan:

My cousin has been directly impacted by PFAS in the drinking water in Wilmington, NC. My cousin and many of her friends (only in their 40s) have similar large lumps on their necks that they had to have surgically removed. As you know, PFAS affect your thyroid, and this is what happened to my cousin. I am worried that her daughter will be next.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Margaret Dyson-Cobb (Doc. #2674, SBC-047153)

Dear Administrator Regan:

I am grateful for the EPA's proposed national drinking water regulations for six PFAS chemicals. This is such a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS. It's time to move forward speedily to protect those alive (and inadvertently consuming PFAS chemicals), the coming generations, and our whole continuing environment. When our drinking water no longer has PFAS in it, we will be sending far less PFAS into our rivers, oceans, and water tables!

Thank you for following through on this essential first step!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Luana Rubin (Doc. #2675, SBC-047154)

Dear Administrator Regan:

3 generations of my family have been sickened by toxic chemicals/VOCs from the oil and gas industry. My friend who is a doctor says he's stopped testing for toxins in the blood because every single person he tests has such high levels of countless carcinogens in their blood samples. The administrators at the hospital tell the doctors not to tell the patients, because the polluters are donating to the hospitals. It is absolutely shameful that this continues, to enrich the few, and poison our communities.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Demaris Kenwood (Doc. #2676, SBC-046249)

Please act to regulate PFAS in the drinking water. PFAS have been proven to be dangerous and present a significant public health concern. As a mother and former teacher, I want drinking water to be safe for our children, families and all people.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Reilly Ruechel (Doc. #2677, SBC-046224)

Please stand up against industry pressure to weaken health standards for 6 of the most widely detected PFAS chemicals in our drinking water. We need safe drinking water!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Laura Mahony (Doc. #2678, SBC-046468)

Dear Assistant Administrator Fox,

There is mounting evidence that PFAS and other chemicals are causing many of our health issues. As someone with Parkinson's Disease I strongly support the EPA's proposed PFAS national primary drinking water regulations. I urge the EPA to finalize the standards as quickly as possible while simultaneously working to reduce PFAS pollution at the source.

Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Peter Ayres (Doc. #2679, SBC-047415)

I am glad to hear the EPA is addressing the PFAS in drinking water and adjusting the rules for drinking water to deal with this serious issue.

I support any new rules that will help rid the many types of PFAS that might get into our drinking water.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Bailee Jones (Doc. #2680, SBC-046448)

I am a young and active person who lives next to one of our Great Lakes, Lake Michigan. My community is seeing the devestating affects of PFAs in our fish and are worried about the long

lasting affects of PFAs in our drinking water. You must protect Americans by regulating this dangerous and damaging forever chemical.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Ariel Dahan (Doc. #2681, SBC-047276)

· I strongly support the EPA draft regulations proposed for six PFAS chemicals. I urge you to finalize these rules as quickly as possible. These comments are in regard to Docket ID: EPA-HQ-OW-2022-0114.

· I live in Rockland County, where nearly all of our drinking water is contaminated with toxic PFAS chemicals. Many of our wells and reservoirs are contaminated with PFAS at levels below the current New York State drinking water standards. That means that filtration will not be required for the majority of Rockland's contaminated wells -- unless the draft EPA regulations are passed.

· Many of Rockland's drinking water sources are contaminated with multiple PFAS chemicals, possibly resulting in additive or synergistic health impacts. But New York State currently regulates only two chemicals. The draft EPA regulations are written for combined standards, which would require many more of these chemicals to be cleaned up.

· The New York State Dept. of Health is waiting for EPA's finalized regulations. Many other states may be doing the same. If EPA's draft regulations are passed, it will make it possible for the states to build on EPA's science and direction to regulate even more PFAS.

· These regulations will send a strong signal to the chemical industry to invest in safe alternatives now.

· There are over 12,000 PFAS chemicals in all. Moving forward, EPA should extend these regulations as quickly as possible to cover PFAS chemicals as a class.

· EPA should immediately halt the approval of all new PFAS.

· While the costs of filtration and disposal are high, those costs are far outweighed by the billions of dollars in healthcare costs caused by the health impacts of PFAS chemicals.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Chad Thomack (Doc. #2682, SBC-046294)

It is a no-brainer that we are polluting our waters with chemicals that last well forever. They can not be taken out of the system and cause irreversible damage to human health. Water is something that all creatures need to survive and there for all have the right to clean water. We need to take action now that we are aware, the public is aware of the harmful effects of PFSAs. I urge you to take action now for the health of society. There has to be another way to keep people safe that benefit from PSFAs, it just might take some time and money, but in my mind it is worth it.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

David Payne (Doc. #2683, SBC-046829)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. Please, please, finalize them as quickly as possible.

As a large, long-lasting, and highly dangerous class of forever chemicals which persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment, they cannot be allowed to continue to be inflicted on us.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. I am aware of nothing more essential to human health and well being than clean, safe drinking water, with the possible exception of clean air which is not overburdened with CO2. Both are absolutely vital.

Again, please quickly finalize these standards and implement an essential health-protective rule that is not weakened by industry special interests.

Sincerely,

David Payne

Winter Park, FL 32792

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Keith Puntenney (Doc. #2685, SBC-046895)

Dear Michael Regan,

Thank you for taking the step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards could provide important and long overdue protections against six of these toxic chemicals. I strongly support the proposed standards, and urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released in the environment. PFAS have contaminated drinking water supplies for approximately 200 million people; the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, currently there are no federal or state limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities, from coast to coast. Establishing strong limits on six widely detected PFAS, this proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year, saving our health care systems millions in costs. The EPA acknowledges and has yet to address the cumulative impacts on communities who are exposed to multiple PFAS. By now issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap. This will begin regulating, and hopefully start a process to remove PFAS in US drinking water. I urge you to quickly finalize these standards, and implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Keith Puntenney

Boone, IA 50036

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Susan Mckay (Doc. #2686, SBC-046525)

Dear Michael Regan,

Please get all PFAs out of our drinking water! Thank you for taking the first step to regulate PFAS.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to

multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Susan Mckay

Columbus, OH 43212

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kelly Casey (Doc. #2687, SBC-046830)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

As a citizen of Minnesota, I have been working on our HF2310 to ban PFAs. I am sure you are aware of the work we are doing here. My friend Amara Strande died from cancer related to toxins in the water in her neighborhood. Please help to pass laws to ban the production and use

of PFAs. As a chaplain and a former teacher, I don't want to visit another child or family who is dying from the effects of poisoning environmental pollution.

Gratefully yours,

Kelly Casey

Sincerely,

Kelly Casey

Savage, MN 55378

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

George Goffe (Doc. #2688, SBC-046831)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

I heard about a study of blood and PFAS and the people doing the study had to go back in time to find a blood sample without PFAS. They found the blood in samples taken during the

WW2/Korea wars! For gods sake! I'm 75 now and am probably just jam packed tull of PFAS!!! What are you going to do about that?

Sincerely,

George Goffe

San Jose, CA 95124

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mary Wellington (Doc. #2689, SBC-046832)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Mary Wellington

Tucson, AZ 85704

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Linda Robertson (Doc. #2690, SBC-046833)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. I am a microbiologist who worked for a chemical company. While these chemistries have desired properties, they are a

significant problem. I stopped using teflon coated cookware when the first reports on the dangers of PFAS circulated in the scientific community.

For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Linda Robertson

Saint Charles, IL 60175

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Adam Pittner (Doc. #2691, SBC-046228)

Water is the most important resource on earth and we must do all we can to preserve it. Please keep and uphold the high standards for keeping pollutants out of our drinking water.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Paul Tippery (Doc. #2692, SBC-046834)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

Sincerely,

Paul Tippery

Decatur, NE 68020

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Maurine Canarsky (Doc. #2693, SBC-046835)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. EPA's proposed drinking water standards will provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule will provide safer drinking water for communities from coast to coast, save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. By issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We strongly urge you to finalize these standards, and implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Maurine Canarsky

Portland, OR 97214

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

John Savlove (Doc. #2694, SBC-046836)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water.

There are innovations to be tapped (pun intended). Clean water is a relative term. We want to ban PFAS through various methods in concert - including working with industry to better understand the promise of nature as nature intended - a self-cleaning operation that humans have the biology to do at our level.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water.

There is nothing helpful to populations or industry about waiting to strengthen and maintain regulations. The health care system is overworked. The economy is obviously imperiled, which means that the value of health is even more precious and will be ever more so. Money alone cannot buy a healthy populace. It is not too late to combine values, ethics, science, and common sense into one corrective mandate.

Thank you for taking these issues seriously and using your powers of office and diplomacy to strengthen our country's relationship with water.

Sincerely,

John Savlove

North Bennington, VT 05257

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Carol Newman (Doc. #2695, SBC-046451)

Dear Michael Regan,

Thank you for taking the first long overdue step to regulate PFAS in drinking water.

I join in supporting your proposed standards and opposing industry's efforts to weaken these necessary protections.

I urge EPA to finalize these standards as quickly as possible.

Sincerely,

Carol Newman

Astoria, OR 97103

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Christine Cotton (Doc. #2696, SBC-046837)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA

acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

When is our government going to stop poisoning and killing us? Why do we even need these chemicals in the majority of things that they're put in? And Roundup needs to be banned and taken off the shelves. People are killing their lawns which in turn is killing pollinators. Without pollinators we don't have food. It's as simple as that. Do your jobs and get this crap off of the shelves and out of our products!

Thank you,

Christine Cotton

Sincerely,

Christine Cotton

Ellsworth, ME 04605

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Scott Chase (Doc. #2697, SBC-046424)

Dear Michael Regan,

Thank you for moving to regulate PFAS in drinking water. These forever chemicals pose risks to us all.

We urge you to enact needed restrictions as soon sa possible.

Sincerely,

Scott Chase

Pine Plains, NY 12567

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Ruth Fink-Winter (Doc. #2698, SBC-046567)

I am writing today to urge EPA to swiftly implement drinking water protections against PFAS contamination. I'm concerned that I probably already have these chemicals in my blood and fat tissue. I want to make sure I don't get any more in my drinking water.

We need national standards for PFAS. Expanding protections to six PFAS, as well as the combination of different PFAS, will protect our drinking water from this toxic contamination and keep countless Americans safe from enduring the health risks associated with these dangerous chemicals.

PFAS, which are used to manufacture a range of goods from canned goods to frying pans, break down very slowly over long periods of time and instead accumulate in people, wildlife, aquatic life, plants, and the environment. This contamination poses a direct threat to our health and our ecosystems. Also known as "forever chemicals," PFAS are linked to serious health conditions such as cancer, liver and kidney disease, reproductive issues, immunodeficiencies, and hormonal disruptions.

PFAS' ubiquity is why we need to act fast and decisively. Finalizing these regulations would protect drinking water for countless Americans.

Please support these badly needed regulations to better protect people and our rivers, oceans, lakes, and communities from PFAS contamination.

Thank you,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mayra Rivera (Doc. #2699, SBC-047155)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

We want to leave a better future for our loved ones. There are "forever chemicals" because they can survive for years without really breaking down. This means that they can continue to build up in your blood as you drink them. And if you happen to drink water because you are human. According to Richard J. Vogl Book, A Primer of Ecological Principle (pg,140,#12) It is easier to prevent degradation, Contamination, invasion, or dysfunction that it is to stop, remove, restore, or repair abnormal conditions and damaged ecosystem.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Thank you

Sincerely,

Mayra Rivera

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Todd Snyder (Doc. #2700, SBC-046677)

As a stakeholder, I demand that the EPA finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Cindy Moeckel (Doc. #2701, SBC-046838)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

Sincerely,

Cindy Moeckel

Ashford, CT 06278

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joan Mabry (Doc. #2702, SBC-046839)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. Please remove them from our water! Thank you!

Joan Mabry, person who frequently drinks water.

Sincerely,

Joan Mabry

Manchester Township, NJ 08759

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Elizabeth Sexton (Doc. #2703, SBC-046461)

Dear Michael Regan,

As your constituent, I strongly support the proposed standards, to get rid of six toxic chemicals in our drinking water and ask that the EPA swiftly finalize the standards.

I am so unhappy that clean drinking water is not the top priority rather than bending to industry wishes. It's about time!!!!

Sincerely,

Elizabeth Sexton

Sedona, AZ 86336

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Tamera Luth (Doc. #2704, SBC-046840)

Dear Michael Regan,

It's appalling to me to see what has happened to our environment in my short lifetime. I'm 65. Now, drinking water isn't safe, our food isn't safe. Everything is touched by chemicals. EVERYTHING! Businesses and people have become accustomed to think with their wallets and base decisions upon profits first, health and long term affects are a distant second if they're considered at all. Act quickly, with your common sense and conscience. Please.

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

Sincerely,

Tamera Luth

Amarillo, TX 79119

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Marybelle Suczek (Doc. #2705, SBC-046841)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. But this action is long overdue. People are being sickened and dying from these chemicals. You know how dangerous and widespread they are, so act asap to save us from this profit driven catastrophe.

I'm already ninety, so I speak not for myself, but for others. Do your job to protect people.

Sincerely,

Marybelle Suczek

South Padre Island, TX 78597

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Taina Litwak (Doc. #2708, SBC-046842)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases.

EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. These "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water.

I urge you to QUICKLY finalize these standards, and implement a rule that is the most health-protective. PLEASE resist industry's massive lobbying efforts to weaken them.

Sincerely,

Taina Litwak

Gaithersburg, MD 20878

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Pamela A. Lowry (Doc. #2709, SBC-046902)

Dear Michael Regan,

We need stronger protections from PFAS in our drinking water. And EPA's proposed drinking water standards could provide that, which is why I strongly support the proposed standards and urge EPA to finalize them as quickly as possible.

For decades, PFAS have contaminated drinking water supplies for millions of us across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. Yet despite the serious health risks associated with them, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Pamela A. Lowry

Grand Junction, CO 81503

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Allen Wheeland (Doc. #2710, SBC-046843)

Dear Michael Regan,

I am very happy to thank you for taking the first step to regulate PFAS in drinking water. I must confess that I, personally, have been very concerned about these dangerous chemicals since I have become aware of how ubiquitous they were in my own life and the lives of my family and friends. PFAS have contaminated drinking water supplies for millions of people across the country for many years, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would begin to provide important and long overdue protections against six of these toxic chemicals. Many aware Americans have come to strongly support the proposed standards, and now we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. As so-called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. This is a curse on not just humans, but all life forms in the environment. PFAS have contaminated drinking water supplies

for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Allen Wheeland

Portland, OR 97217

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Andrea Thompson (Doc. #2711, SBC-047502)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to

multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Emma Allen (Doc. #2712, SBC-047504)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Shana McKeever (Doc. #2713, SBC-046234)

Please put first the health and well being of the American people over the financial interests of businesses and resist the pressure from companies aiming to weaken/prevent regulations regarding PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Arthur Fellows (Doc. #2716, SBC-047156)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal

would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kim Denardo (Doc. #2717, SBC-047157)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Deborah Cosentino (Doc. #2718, SBC-047158)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Carol Devoss (Doc. #2719, SBC-047159)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Richard Rousseau (Doc. #2720, SBC-047160)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jacqueline Clare (Doc. #2721, SBC-047161)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jane Worland (Doc. #2722, SBC-046844)

Dear EPA Environmental Protection Agency,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Ms Jane Worland

506 Woodview Cir Louisville, KY 40243-1055

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jennifer Abernathy (Doc. #2723, SBC-047162)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Yosleyri Flores (Doc. #2724, SBC-046845)

Dear EPA Environmental Protection Agency,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in

increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Mr Yosleyri Flores

2856 Indianapolis, IN 46224

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Vivian Cerny (Doc. #2725, SBC-047163)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Ann Riddel (Doc. #2726, SBC-046455)

Dear Administrator Regan:

Thank you for EPA's proposal to regulation six PFAS chemicals in our national drinking water.

PFAS are harmful to the human body and need to be regulated.

Please quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

N. Almazol (Doc. #2727, SBC-047164)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

NOTHING is needed in our drinking water except, perhaps, 4% Food Grade Hydrogen Peroxide, to deal with mold or mildew & micro-organisms. Everything else is superfluous, & dangerous, INCLUDING FLOURIDE, an Aluminum derivative, which is a central nervous system disrupting toxin!.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm. There is NO sane reason to have them in the water system.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The medical industry would STILL make PLENTY of money off food-borne illnesses without these poisons in the drinking water.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Cheri Bumgardner (Doc. #2728, SBC-047165)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

The most important part of finalizing the regulations is following through and making sure that these regulations are upheld. If you think self-regulation will work, I believe you are sadly mistaken. This issue can't be swept under the rug.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Elizabeth Frey (Doc. #2729, SBC-047166)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS. There is no amount of PFAS that is safe for human consumption, not to mention fish and other aquatic life. As you are well aware, toxic substances become concentrated higher in the food chain, so it is not just our water that is affected but the entire food chain.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal

would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jim Merkle (Doc. #2730, SBC-047167)

Dear Administrator Regan:

It's unknown what long time exposure to these chemicals will do to humans and I am very concerned that there will be some very negative repercussions. Please make the strongest protections that you can to get PFAS out of our drinking water.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Carmen Nichols (Doc. #2731, SBC-047168)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

The Environmental Protection Agency has proposed groundbreaking new regulations on six highly toxic PFAS chemicals found in drinking water. And while we need the EPA to do more to protect against PFAS, this is a crucial first step toward tackling this massive public health crisis. Push back against opposing industries' efforts to weaken these necessary protections.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lisa Johnson (Doc. #2732, SBC-047169)

Dear Administrator Regan:

Let's make clean and healthy air, water, plants and animals a top priority - RIGHT AWAY and keep our priorities that way forever and a day!

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sheila Rekdal (Doc. #2733, SBC-047170)

Dear Administrator Regan:

With Business Majors running Corporate interests it is not surprising that ALL these Chemicals have been allowed to be released into OUR Environment, as they are only interested in Bottomline...Sadly the real bottom line is the number of humans that are living very unhealthy lives dealing with cancer & other dastardly diseases caused by this plethra of chemicals that have been released in OUR environment!!!

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Eric Knight (Doc. #2734, SBC-047171)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

We don't need widespread pollution linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. We need to ban PFAS compounds to prevent any further pollution.

Finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Noelle Congdon (Doc. #2735, SBC-046225)

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mary Powers (Doc. #2736, SBC-047172)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Our entire community has been exposed to these toxic chemicals through our damaged city wide water system. This very likely will lead to health challenges for many citizens. It is time, to regulate these known cancer causing chemicals. It is your duty - no one is exempt.

Thank you

M.Powers

Wausau, WI

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Clara Brasseur (Doc. #2737, SBC-046305)

I am writing in support of the new EPA PFAS Drinking Water Regulation. The research is clear that PFAS compounds are harmful, and because of their longevity and compounding effects it is critical to lower their level in drinking water as quickly as possible. Because of the additive effect of small small levels building up over time, the decrease in overall PFAS pollution levels

will have a large positive effect on public health. I recognize the importance of setting achievable and enforceable maximum levels for these compounds, however given that there is no PFAS amount, however small, that is not harmful, once the targets laid out in this regulation have been reached it will be important to enact further measures to keep lowering PFAS levels in the water system.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sam Inabinet (Doc. #2738, SBC-046671)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

Your actions and inactions regarding this and all related concerns have been, are being and will be remembered by all of us who will live in the world that you are shaping with your decisions right now, in addition to being a matter of public record. We are all on it together. Environmental emergencies are affecting everybody's health and livelihood, and will do so for generations to come. All issues need to be considered as facets of the critical state of the biosphere.

Given the consistency with which each current and foreseeable crisis has been weaponized against the vulnerable majority of the population of the United States of America and the world, and the exceptional leniency shown toward – not to mention the overwhelming subsidization of – those industries that create and perpetuate these crises, any failure on your part to directly address and act upon these issues can only be seen as complicity in extinction and a clearly genocidal agenda.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Allison Nemenyi Shiozaki (Doc. #2739, SBC-047634)

The basic function of governance needs to address the needs of the people and also non-human life forms that our actions impact. The health of our society rests on this really basic understanding that the limited amount of drinking water that exists needs to be protected. Wastefulness and disrespect to this life force are not virtuous behaviors, and theres a reason. Water is life. No amount of these kinds of chemicals should ever go into the water. None, never. Yet, it keeps happening. Whats it going to take to stop this madness Please due your due diligence by protecting life here in Hawaii Nei and abroad. Repercussions to those who poison and pollute our water. Clean up, then cease and desist.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jim Worth (Doc. #2740, SBC-047173)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

You know that you cannot protect the environment from climate change when the congress refuses to acknowledge the problem but wants to push back on the President's beginning attempt to deal with it. You must use your budget and authority to educate (in fact shame) the congress into facing the truth and acting responsibly.

How else can you protect the environment?

If not now, WHEN?

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Breast Cancer Prevention Partners (Doc. #2743, SBC-047289)

PFAS is one of the most toxic compounds known and there is no known safe level of PFAS in food, air, and water. PFAS are persistent, bioaccumulative and negatively effects all organ systems of the body. Particularly concerning is the significant association between PFAS exposure and breast cancer, the incidence of which has risen in recent years. We urge you to consider cumulative and aggregate risks when it comes to drinking water contaminants and adopt the most stringent requirement possible to regulate and eliminate PFAS in the drinking water.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA acknowledges that there is some evidence that PFOA exposure may be associated with an increased breast cancer risk. For specific discussion on dose additivity and aggregate health effects, please see section IV of the FRN.

Matthew Granados (Doc. #2744, SBC-046545)

Water is the medium of life, and access to clean and safe drinking water is essential for the health and well-being of all living beings. Therefore, the EPA's proposed national drinking water regulations for six PFAS chemicals are a crucial step towards protecting our families and communities from the harmful effects of PFAS pollution.

As stated by Dr. R. Vogl in the Primer of Ecological Principles, "water is the medium of life," and any mismanagement or contamination of this precious resource can have devastating consequences. PFAS chemicals are persistent and widespread pollutants that have been linked to serious health effects. The EPA's proposed rule would provide millions of people in contaminated communities with safer drinking water, preventing tens of thousands of PFAS-related illnesses each year and saving thousands of lives.

I urge you to finalize these regulations swiftly and to continue addressing all other types of PFAS to ensure that all Americans have access to clean and safe drinking water. Thank you for your efforts to protect public health and the environment.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Debbie Ruiz (Doc. #2745, SBC-047174)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

It is really shocking that the greatest nation on earth can't assure that everyone has clean drinking water. Access to clean drinking water is a basic human right.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Karen Embertson (Doc. #2748, SBC-047175)

Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. It would save thousands of lives and prevent tens of thousands of PFAS-related illnesses each year.

Please finalize the regulations of these six chemicals, implement a rule that is health protective, then tackle all other types of PFAS until we all have pure, clean water.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jennifer Valentine (Doc. #2749, SBC-046599)

the proposed rule is important because:

Exposure to PFAS chemicals has been linked to severe health issues. The protection of public health is the primary concern at stake here. Ingesting or being exposed to PFAS chemicals has been linked to serious health concerns, including cancer, organ damage, and immune system suppression. In children, these chemicals have been shown to have negative impacts on development.

No level of PFAS chemicals are safe to drink. Even with very low levels of exposure, PFAS has still been shown to have toxic effects on the human body. While the industry argues that PFAS is used in many ways in our daily lives, this is no excuse for inaction. Given the known health risks, setting enforceable limits for PFAS as close to zero as possible is necessary to protect and preserve public and environmental health.

PFAS are "forever chemicals." PFAS essentially last forever in the environment, and can also bioaccumulate in fish, other animals, and humans. This poses a massive concern for exposure, since the chemical can remain and build up in the environment over years, and remain there for centuries. Moreover, the effects of PFAS are not always short-term, but after drinking contaminated water for months or years, the health impacts can be serious if not deadly.

Regulations encourage safer industry practices. Setting these regulations will encourage manufacturers and PFAS-producing industries at large to be more responsible in their use of PFAS. Ideally, industries would invest in safer alternatives for PFAS chemicals if they receive pressure from those in the regulatory and water supply sectors.

Regulations set legal standards for enforcement. Importantly, these standards create legal limits of PFAS chemicals in the water supply, meaning that legal action can be taken if the contaminants exceed these limits and are not addressed. The establishment of legal limits also provides clarification on the expectations for the use of PFAS chemicals and on the standards for providing safe, healthy drinking water for the public.

please protect ourselves and future generations from toxic forever chemicals!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Linda Jones (Doc. #2751, SBC-046555)

I am writing today to urge EPA to swiftly implement drinking water protections against PFAS contamination.

We need national standards for PFAS. Expanding protections to six PFAS, as well as the combination of different PFAS, will protect our drinking water from this toxic contamination and

keep countless Americans safe from enduring the health risks associated with these dangerous chemicals.

PFAS, which are used to manufacture a range of goods, break down very slowly over long periods of time and instead accumulate in people, wildlife, aquatic life, plants, and the environment. This contamination poses a direct threat to our health and our ecosystems. Also known as "forever chemicals," PFAS are pervasive contaminants that are linked to serious health conditions such as cancer, liver and kidney disease, reproductive issues, immunodeficiencies, and hormonal disruptions.

PFAS' ubiquity is why we need to act fast and decisively. Finalizing these regulations would protect drinking water for countless communities.

I urge your support for these badly needed regulations to better protect people and our rivers, oceans, lakes, and communities from PFAS contamination.

Thank you,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lara Villalobos (Doc. #2752, SBC-047176)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS which is important since as Dr. R. Vogl, Primer of Ecological Principles. 2014 stated: "water is the medium of life" and therefore should be protected and ensure to be save for consumption. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kelly Kulak (Doc. #2753, SBC-047177)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Paul Salazar (Doc. #2754, SBC-047178)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

As Richard Vogl, a professor from the California State University, Los Angeles says, "Water is the medium of life". We cannot allow toxic pollutants and forever chemicals to contaminate our water due to their health effects and potentially many more ecological effects.

Thank you,

Paul Salazar

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Marianne Nurmi (Doc. #2755, SBC-047441)

To whom it may concern,

The implementation of a PFAS regulation is a crucial step toward ensuring the safety of drinking water in the United States.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Michele Nihipali (Doc. #2756, SBC-046598)

Exposure to PFAS chemicals has been linked to severe health issues. The protection of public health is the primary concern at stake here. Ingesting or being exposed to PFAS chemicals has been linked to serious health concerns, including cancer, organ damage, and immune system suppression. In children, these chemicals have been shown to have negative impacts on development.

No level of PFAS chemicals are safe to drink. Even with very low levels of exposure, PFAS has still been shown to have toxic effects on the human body. While the industry argues that PFAS is used in many ways in our daily lives, this is no excuse for inaction. Given the known health risks, setting enforceable limits for PFAS as close to zero as possible is necessary to protect and preserve public and environmental health.

PFAS are "forever chemicals." PFAS essentially last forever in the environment, and can also bioaccumulate in fish, other animals, and humans. This poses a massive concern for exposure, since the chemical can remain and build up in the environment over years, and remain there for centuries. Moreover, the effects of PFAS are not always short-term, but after drinking contaminated water for months or years, the health impacts can be serious if not deadly.

Regulations encourage safer industry practices. Setting these regulations will encourage manufacturers and PFAS-producing industries at large to be more responsible in their use of PFAS. Ideally, industries would invest in safer alternatives for PFAS chemicals if they receive pressure from those in the regulatory and water supply sectors.

Regulations set legal standards for enforcement. Importantly, these standards create legal limits of PFAS chemicals in the water supply, meaning that legal action can be taken if the contaminants exceed these limits and are not addressed. The establishment of legal limits also provides clarification on the expectations for the use of PFAS chemicals and on the standards for providing safe, healthy drinking water for the public.

PFAS are not safe at any level and many lives will be saved when these are no longer in our water.

EPA Response: Please see section 1.3 of the EPA response in this *Response to Comments* document. Please see section V of the FRN and section 5 of the EPA response in this *Response to Comments* document for further discussion regarding the enforceable limits for PFAS.

Justine Dao (Doc. #2757, SBC-047179)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals are a welcome first step to protecting our families and communities from the scourge of PFAS.

As Dr. Vogl once stated, "Water is the medium of life" (Dr. R. Vogl, Primer of Ecological Principles. 2014). This principle is important to keep in mind because, for us, water is quite literally life. It's essentially what sustains us and we rely on its importance as a natural resource, while also assisting other forms of life and the planet in numerous ways. For these chemicals that are being found drinking water means an imminent danger is threatening our lives.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent thousands of serious PFAS-related illnesses each year.

I urge you to finalize the regulations of these six PFAS chemicals quickly, implement a health-protective rule, and then begin addressing all other types of PFAS.

Thank you,

Justine Dao

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Elizabeth Nguyen (Doc. #2758, SBC-046265)

I support the proposed limits to PFAS and PFOAs. We cannot control the amounts of these that enter our bodies through the food chain and products, but we can expect our municipalities to treat our drinking water to remove them, this reducing our exposure and the exposure of pregnant women and their babies to these know toxic substances.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Aidan Pacillas (Doc. #2759, SBC-047180)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. "Water is the medium of life." This means that water is the most important attribute to all of life and should be treated as the most important thing and should be cherished.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Marlon Harrington (Doc. #2760, SBC-047181)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

Not often considered is a concept mentioned by Richard Vogl in his book "A Primer Of Ecological Principals" where he says "As a result of the accumulative effects of certain actions or materials, the addition of relatively small amounts can trigger major chemical or ecological reactions"

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jessica McGeary (Doc. #2761, SBC-047182)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

I live in Boston, Massachusetts, which is infamous for the former filth of our water. I went to school in Cleveland, Ohio, where the river caught on fire. Both of these situations were cleared up by enforcement of the Clean Water Act, and I am eternally grateful. But that was not enough of a law on its own to deal with the chemicals we have only really come to understand now.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Ruth Katz (Doc. #2762, SBC-047183)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal

would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Addressing the PFAS inner water is probably one of the greatest contribution we can make to the health of humans and all life on this earth.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Linda Kennedy (Doc. #2763, SBC-047184)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

The very least we can expect is clean air and water. We rely on your agency to deliver on certain basic rights. This is one of them.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Deborah Izumi (Doc. #2764, SBC-046595)

Re: Proposed PFAS National Primary Drinking Water Regulation Rulemaking Docket ID: EPA-HQ-OW-2022-0114

Dear Administrator Regan,

Thank you for taking this historic step to keep our drinking water safe from PFAS contamination. For decades, PFAS chemicals have contaminated both public and private

drinking water supplies across the country. PFAS contamination exposes communities to serious health risks, including cancers, impacts to the immune and reproductive systems, and other harms. The EPA's proposed drinking water standards would provide long overdue federal protections against six types of highly toxic PFAS.

I strongly support this proposed rule and urge EPA to move swiftly to finalize health-protective standards to reduce PFAS in our drinking water.

The PFAS crisis is widespread, contaminating the blood of humans, fish, and wildlife worldwide. Communities of color and low-income communities are particularly impacted by PFAS exposure, where health impacts are often compounded because these communities tend to face cumulative effects from multiple environmental injustices and public health hazards.

EPA's proposal would significantly reduce exposure to PFAS in our drinking water for millions of people by setting strong, science-based drinking water standards for six types of PFAS. While this proposal is an important first step towards addressing PFAS exposure, it is critical that EPA also expedite efforts to prevent these chemicals from entering our waters and environment in the first place, before it even reaches our taps.

These proposed regulations are long overdue and I fully support this first step of regulating six dangerous PFAS in drinking water. In addition, I encourage the EPA to take a comprehensive approach to regulating the entire class of chemicals in order to reduce overall PFAS exposure, and improve drinking water safety in thousands of communities across the country.

Thank you for your consideration.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Suzanne Hungerford (Doc. #2765, SBC-046216)

It is imperative for the health of the nation (and world) that these chemicals be better regulated by industry and government. Time is running out.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Putnam Wendy Whetsel (Doc. #2766, SBC-047185)

Dear Administrator Regan:

Less than 2% of the water on this planet is potable. It supports ALL life on this planet including, human life, animal life, and plant life, all living creatures. We MUST PROTECT IT.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Vanessa Lemieux (Doc. #2767, SBC-046846)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. . . How will our civilization survive if we keep over polluting the water and land?

Train derailments, lab viruses, unearthly amounts of trash, sewage, PFAS, Fertilizer.

The cooperation's priorities are NOT in favor of people, I am all for profit, but at what cost?

Can responsibility be taken before it's too late for us all?

Sincerely,

Vanessa Lemieux

North Fort Myers, FL 33917

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Elizabeth Lewis (Doc. #2768, SBC-047186)

Dear Administrator Regan:

I live in an area that has been affected by these chemicals. At my address, we were never informed of the contamination and were not notified to stop drinking the tap water. After talking to neighbors all around my residence and learning they had all received these notices, I did

research. I found out that not only are there dry cleaning chemicals in our drinking water, it was discovered 12 years ago. Franklin Street Groundwater Contamination Superfund site. They haven't even begun to fix it. Luckily for me, I grew up on my own well in the country. But the last three years I have been in town on city water, I have seen the effects. I have developed dandruff, my hair is brittle and dry. We stopped drinking the tap water and our stomach issues we have been battling with for years were essentially cured. If you all don't have to live like this, why should we. My story is not even close to as bad as others across this country, who have been without clean drinking water for years. This is not the time to pass new regulations as a cop out. You need to fix and address these issues or you will have nobody left to make your money.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Betty Sabo (Doc. #2769, SBC-047187)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

Qquickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Paul Eldredge (Doc. #2770, SBC-047456)

USD is grateful for the resources provided to deliver safe drinking water and address emerging contaminants like per- and polyfluoroalkyl substances (PFAS), particularly through the

Infrastructure Investment and Jobs Act. At the same time, we would like to stress the scale of the proposed undertaking and the need for relief for many communities, especially those that are small, disadvantaged, and lacking in professional capacity. Otherwise, the costs risk falling disproportionately on vulnerable populations.

This is the first new contaminant to be regulated in drinking water in three decades and the first since Congress significantly amended the Safe Drinking Water Act (SDWA) in 1996. This is a new experience for many and will entail an additional learning curve especially given this is the first time EPA has chosen to use a Hazard Index for a federal drinking water maximum contaminant level (MCL).

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document. For concerns around communicating this NPDWR, including the Hazard Index, please see section 1.2 of the EPA response in this *Response to Comments* document. For additional discussion regarding funding, particularly for small and disadvantaged communities, please see section 2.4 of the EPA response in this *Response to Comments* document. Sections 13 and 14.10 of the *Response to Comments* document address the evaluation of costs and benefits of the NPDWR, including its impacts on disadvantaged communities.

Robert Frang (Doc. #2771, SBC-046187)

Please PFAS out of our water.

EPA Response: The EPA acknowledges and appreciates this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Gaila Dury (Doc. #2773, SBC-047188)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Aurora E Gonzalez (Doc. #2774, SBC-047189)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

Dr. R Vogl states in his book, Primer of Ecological Principles. 2014, "Water is the medium of life. Water is indeed the medium of life, and it is our collective responsibility to protect this vital resource for present and future generations. By prioritizing the implementation of health-protective regulations and subsequently addressing other types of PFAS, we can ensure the well-being of our communities and build a sustainable future.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

F. T. (Doc. #2775, SBC-047190)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joel McCormack (Doc. #2777, SBC-046508)

Dear Administrator Regan:

The Roman Empire suffered ill effects from lead in their water, coming from linings in their aqueducts to reduce leakage. At least they could plead ignorance.

We are, in some ways, dumber than people living 2000 years ago. We know the problems that many chemicals cause, but don't do anything to prevent their use. The family of PFAS are particularly nasty, given their longevity. And do we restrict them only to the most critical uses, where they cannot contaminate humans? No, we put them on fast food wrappers to prevent sticking!

I fully support the EPA's proposed regulations for six PFAS chemicals. Please implement this as soon as possible, and restrict the entire family of PFAS as soon as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Leslie O'Neil (Doc. #2778, SBC-047191)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

I fully support the proposed rule -- I very much want safer drinking water for the millions of people across the nation. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Carolyn Petrakis (Doc. #2779, SBC-046847)

Dear Michael Regan,

I am a mother and a retired clinical social worker who worked for decades in healthcare. I love nature and our only home, the earth. I fear our children and all living beings will be deprived of a healthy and safe future because of toxic pollution of our land, air and water. I am deeply concerned and angered about the toxic pollution of our waters with PFAS. Our family invests in expensive water filters for our home to protect us from PFAS. I know people from lower

incomes are unable to buy these filters ti protect themselves from the PFAS-saturated water. Action must be taken to insure that all Americans have clean, PFAS-free tap water.

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Carolyn Petrakis

Chicago, IL 60645

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Rebecca Smyth (Doc. #2780, SBC-046220)

PFAS should be regulated as a whole class but until they are any step we take to reducing the exposure and harm of individual PFAS is a positive and necessary one.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lisa Sweet (Doc. #2781, SBC-046557)

Docket ID: EPA-HQ-OW-2022-0114

I am heartened that the EPA announced the proposed National Primary Drinking Water Regulation (NPDWR) for six PFAS including perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO-DA, commonly known as GenX Chemicals), perfluorohexane sulfonic acid (PFHxS), and perfluorobutane sulfonic acid (PFBS). I understand that the EPA anticipates finalizing the regulation by the end of 2023 and that the EPA expects that if fully implemented, the rule will prevent thousands of deaths and reduce tens of thousands of serious PFAS-attributable illnesses.

I am an individual advocating for the health of my family and my neighbors. We live in an identified cancer cluster on the Seacoast of New Hampshire. Is it really too much to ask that the safety of chemicals be proven before releasing them into the environment? I do not want these chemicals in my food, water, clothing, dental floss, cosmetics - or anywhere. We should not have to bear additional risk because that is more convenient or easier for industry. If there is no level of exposure to PFAS that has been proven safe, then the limit should be zero.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joanna Meyer (Doc. #2782, SBC-047192)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation, saving thousands of lives and preventing PFAS illnesses.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Quinn Montana (Doc. #2783, SBC-046466)

The PFAS family of chemicals should be regulated stringently, with a goal of ending the production of ANY chemical in that family. They are known carcinogens. Every possible effort should be directed towards removing all extant PFAS from the environment. Your children's children will curse you for their illnesses from this abomination in their world.

Dr. Quinn Montana

Environmental Science, PhD

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document. The production of PFAS and PFAS in mediums other than drinking water are outside the scope of this rulemaking. Please see section 15 of the EPA response in this *Response to Comments* document for out-of-scope topics.

Mike Roche (Doc. #2785, SBC-046515)

This is literally and totally insane. I do not believe (at all) the USEPA and their toxicologists. After the Covid-19 debacle, the supposed "scientists" at the US government have exactly zero credibility.

The regulations are way ahead of the tox-science on this one. You are telling me that it is "ok" to drink water with 4.99 PPB of TCE, but it is "not ok" to drink water with 4.01 PPT of PFOA/PFOS??? I have absolutely no faith in the supposed "scientist-toxicologists" who "conducted" research on the "health" effects of PFAS. How in the hell have they determined that there are detrimental health effects at the single digit PPT exposure level that ARE NOT actually attributable to some other contaminant or exposure?

These proposed MCLs for PFAS should not be established

EPA Response: Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA disagrees with this comment, including the commenter's statements about the current state of the science supporting the EPA's decision to regulate PFAS in drinking water through a NPDWR in accordance the SDWA, as well as the questions around the health effects of PFAS. As required by the SDWA, the EPA used the best available, peer-reviewed science to finalize the PFAS NDPWR. The assigned MCLs for each of the individual PFAS were determined via a multi-step process consistent with the SDWA, including establishing MCLGs followed by setting an MCL as close to the public health goals as feasible while considering costs. For information regarding the health effects of PFAS compounds and the analyses that went into determining the MCLGs, please see the Toxicity Assessments support documents (USEPA, 2024c; USEPA, 2024d), as well as the summaries provided in the FRN section IV and V for setting MCLGs and MCLs, respectively.

Paula Schild (Doc. #2786, SBC-047193)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

One of my neighbor's developed testicular cancer because of PFAS

The EPA's proposed rule would provide safer drinking water in my community.

Please quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mary Matz (Doc. #2787, SBC-047616)

The new PFAS Standard must be finzalized as soon as possible at the RECOMMMENDED LEVEL! The health of our population is at stake due to the high toxicity and potential harm of these chemicals. Adopting the 6 mg PFAS in drinking water will positively impact the health of the US population as well as impact costs associated with the cancers and other significant negative impacts of higher exposure to these chemicals that are ubiquitous in our environment. EPA must adopt the scientifically determined thresholds and not bow to special interests.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA is unclear as to what the commenter is referring to regarding "adopting the 6 g PFAS in drinking water." For further information the MCLs that are set by this NPDWR, please see section V of the FRN and section 5 of the *Response to Comments* document.

Anonymous (Doc. #2790, SBC-046189)

I want this danger to the citizens of Michigan removed.

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document.

E. Cuenca (Doc. #2791, SBC-046672)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

Truly clean (uncontaminated) drinking water is the single most important factor for insuring our health, ahead of diet, exercise, sleep etc. Consuming contaminated water will inevitably lead to poor health consequences, even death.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mary Campbell Hart (Doc. #2792, SBC-046673)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge. That this problem has been known for years and nothing has been done to hold the responsible parties accountable what are we to think and what are we to do? What we take away is that we don't matter, the children don't matter, the animals on the planet don't matter. What

does matter? Money. Really? Can you drink it? Can your babies drink it? Can your dogs drink it without getting sick? Not for long.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Gerald Gladstone (Doc. #2794, SBC-047194)

Dear Administrator Regan:

I feel like we've all been poisoned for years without knowing it! NRDC's letter b elow is fine but need emphasis. The EPA must get these awful substances out of our drinking water!

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Judith Clinard (Doc. #2795, SBC-046322)

I live on the central coast of California near our county airport. In the past year the neighbors in my area were notified that PFAS were found in over 50 of the 60 domestic wells they tested. The contamination occured over a period of many years from the use of Fire fighting foam at the airport. The State water board of Calif issued a clean up draft to the airport and Cal Fire for a plan to clean up the ground water and to provide treatment to the homeowners wells. Sadly the county and Cal Fire both decided that they are not legally responsible for the clean up because they were only doing what Federal law imposed upon them . Now we homeowners are in limbo wondering when our water will be safe to use again. Litigation can take a long time for results and decisions to be made! Most of us have some sort of filtration for drinking water but we all live on rural parcels that we use for growing our own produce, raising livestock and poultry. No

one seems to be able to tell us if it is safe to continue consuming our home grown goods, and our animals ingest the grasses and water on our lands. We deserve to have our water safe for all uses not just what we drink. Some of the homeowners have PFAS levels in over 100- 4000 parts per trillion. The county has known about this for years and has spent 2 million dollars on investigations and in attorney fees but have yet to use the monies to install treatment systems at the well heads of the homeowners or to reimburse the homeowners for the thousands of dollars they have spent out of pocket trying to make their own water safe. While reverse osmosis may treat the water at the faucet it is still putting it right back into our septic systems and back into the ground and then recontaminating our ground water. In the meantime we are all wondering if our health has been or will be impacted from the many years of drinking this contaminated water. I am in total support of the EPA enforcing stricter standards for MCL in our water. If you know of anyone that could give us some guidance I would appreciate it! Thank you

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Skyler Principe (Doc. #2796, SBC-046681)

Dear Administrator Regan,

Thank you for proposing limits on PFAS chemicals in drinking water to protect our health that reflect the latest scientific information on their effects on our health.

EPA should finalize these Safe Drinking Water Act regulations as soon as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of the EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and reduce or stop uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Candice Hambrick (Doc. #2798, SBC-046205)

If we have evidence that these chemicals are harmful to health it seems common sense we would limit levels.

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2799, SBC-047436)

I am also deeply concerned about communication with vulnerable affected communities. A recent episode in Yuma, Arizona, illustrates the difficult problem of educating affected populations. Yuma County, Arizona, is a majority Hispanic population. Communication in the Spanish language is a necessary, but not sufficient, form of outreach. Online communications and mass media are not sufficient either. Door-to-door outreach to homes affected by PFAS contaminated drinking water is absolutely necessary as a component of effective public engagement.

Another difficult issue is the role of polluters who produced the PFAS in the first place. It is clear that this regulation cannot be left to polluters to enforce. Thus, despite the well-intended outreach of Marine Corps Air Station-Yuma to affected homeowners, that organization cannot be the lead agency in implementing these proposed rules.

Finally, education and training of staff of affected agencies will likewise be critical to successful implementation of this proposed regulation.

Thank you for this opportunity to comment.

EPA Response: The EPA acknowledges this comment. For concerns around communication to vulnerable and affected communities, as well as communication to staff of agencies via education and training materials, please see the discussion in section 1.2 of the *Response to Comments* document. Please see section 1.3 of the EPA response in this *Response to Comments* document regarding the issue of polluters.

Lana Fishkin (Doc. #2800, SBC-046184)

Need clean drinking water!

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kathy Garvey (Doc. #2801, SBC-046454)

Dear people,

It doesn't take a genius or even a scientist to realize that fresh clean drinking water is ESSENTIAL to life. So, I will keep this message short and to the point -- do everything humanly possible to maintain clean water for everyone! Your families and their families to come will be forever in your debt. Thank you,

Kathy

EPA Response: The EPA acknowledges and this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kevin Rolfes (Doc. #2802, SBC-047314)

I strongly support the proposed National Primary Drinking Water Regulation (NPDWR) to reduce polyfluoroalkyl substances (PFAS) and their mixtures: Perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO–DA) and its ammonium salt (also known as "GenX" chemicals), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS). The adverse health effects of per- and polyfluoroalkyl substances (PFAS), ranging from birth defects to cancer, have been clearly established in numerous studies. Unfortunately, these "forever" chemicals do not break down and are widely found in our environment, including in our drinking water.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Patricia Anne Hisler Skabla (Doc. #2805, SBC-046201)

We should have clean drinking water and clean soil. These chemicals kill by causing cancer.

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Patricia Guthrie (Doc. #2806, SBC-046586)

Every American has a right to safe drinking water.

For the health of Latinos and all Americans, I support EPA's plans to regulate and limit harmful PFAS in drinking water and the environment.

Considering the potentially devastating health impacts of PFAS exposure, it is unacceptable for these chemicals to be released into and remain in the environment at unsafe levels (https://salud.to/PFASbm).

While researchers have made strides in destroying PFAS in water, we must address PFAS contamination at the source with enforced regulations, as even undetectable levels of PFAS can pose human health risks including damage to fetal growth and increased cancer risk (https://salud.to/pfasdes).

PFAS affect everyone but may impact some populations more than others. For instance, Latino families are more likely to live in neighborhoods where there is a lack of clean and safe drinking

water (https://salud.to/nitrate) and where utility companies have less funding to meet community needs.

Therefore, environmental regulation of harmful PFAS is critical for all Americans, but especially those who are vulnerable to exposure, such as Latinos. I applaud EPA's proposed plans to regulate and limit PFAS chemicals in drinking water and the environment, which could help ensure a healthier future with less exposure to potentially harmful chemicals.

Are you not supposed ro be protecting us from these dangerous chemicals? Isn't the word "pretcetion" part of the name of your agency? Why then is it like pulling teeth to get you to do your jobs? Why are you allowing these dangerous chemicals into our water, air, land, and food?

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. Please see section 13.4-13.9 of the EPA response in this *Response to Comments* document that outlines the quantifiable and nonquantifiable benefits of this NPDWR that may address the commenter's concern of low levels of PFAS that can pose human health risks. In response to the comment that states that "environmental regulation of harmful PFAS is critical for all Americans, but especially those who are vulnerable to exposure", as part of its environmental justice analysis for this regulatory action, the EPA evaluated the distribution of baseline PFAS exposure in drinking water across demographic groups. For additional discussion on this topic, please see the EPA's EJ analysis in section 8 of the EA (USEPA, 2024a) and section 14.10 of the EPA response in the *Response to Comments* document.

Brenda Bell (Doc. #2807, SBC-046848)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of

lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

———

Shalom,

I am a servant of Lord Yahweh(God) Almighty and the Most High Yahweh in heaven, Lord Jesus Christ who is Lord Yahweh's son and the Messiah or the Anointed One and the Holy Spirit. I have been given the authority to speak on their behalf. Lord Yahweh has been aware of these chemicals none as PFAS. Your acknowledgement will only go so far. Keep the public aware of your intentions. Lord Yahweh is aware that it will take some but you are working on it. Thank you for taking the time to read my comments.

Truly

Sincerely,

Brenda Bell

Opelika, AL 36804

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Therese Argoud (Doc. #2808, SBC-047590)

Just as we have strong regulations and monitoring of chemicals for pesticide

Applications to plants, we should have at least equal if not greater regulations for regulating chemicals in water. Drinking water limits proposed by EPA is more than reasonable. It is necessary and vital to peopless health and the health and safety of animals, plants and our environment as a whole. Thank you for your attention to this critical matter and please expedite implementation.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Matthew Lilly (Doc. #2809, SBC-046517)

The adverse health effects of per- and polyfluoroalkyl substances (PFAS) have been clearly established in numerous studies, ranging from from birth defects to cancer, and unfortunately, these chemicals are widely found in our environment, including in drinking water.To maintain the public health benefits of the proposed rule as scientific knowledge and technical feasibility improves, EPA should regularly update the rule by modifying drinking water standards and adding more chemicals to the regulations.

The proposed regulation is a vital step in protecting public health from PFAS contamination. However, EPA must also separately and expeditiously facilitate solutions which address PFAS waste produced during treatment to avoid re-introduction of the contaminants into groundwater, soil, or air.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. For additional discussion around generated waste following treatment, please see section 10.4 of the EPA response in this *Response to Comments* document.

Robert Johnson (Doc. #2810, SBC-046259)

By restricting these other pf's, how much is this going to cost the consumer? These arbitrary restrictions and implementation costs will be passed to the end customers! More scientific data, research, and public opinions need to be considered prior to allowing the EPA from advancing any more legislation!

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document. For some information on available federal funding through the BIL, please see section II of the FRN, as well as additional discussion in section 2.4 in the *Response to Comments* document. Additionally, please see section 13.3 of the EPA response in this *Response to Comments* document for discussion of costs, including system costs, associated with the implementation of this NPDWR.

Desiree Rammon (Doc. #2811, SBC-046280)

I support the proposed U.S. Environmental Protection Agency National Primary Drinking Water Regulation (NPDWR) that would limit the levels of PFAS compounds and their mixtures in drinking water. PFAS compounds are in my drinking water, here in the suburbs of Philadelphia. These compounds are in much of the drinking water sources across the United States. It is the purpose of the USEPA to provide these regulations, and I support this regulation to limit PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Therese MacKenzie (Doc. #2812, SBC-046480)

I am horrified to think anyone, anywhere – but certainly in the United States – would drink less that 100% pure water. Please do everything possible to provide laws and policies and funding to make all drinking water completely safe.

I do not add supporting evidence as you must have plenty of it by now. What's needed is motivation to protect real people, especially children. Please make all water the quality you would want for yourself and your family.

Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Peter Wolanin (Doc. #2813, SBC-046571)

I thank the U.S. Environmental Protection Agency (EPA) for its sound research and effort that generated the proposed NPDWR. The adverse health effects of per- and polyfluoroalkyl substances (PFAS), ranging from birth defects to cancer, have been clearly established in numerous studies. Worse yet, these are persistent chemicals that do not break down and are widely found in our environment, including in our drinking water.

Because of this, I strongly support the proposed National Primary Drinking Water Regulation (NPDWR) to reduce polyfluoroalkyl substances (PFAS) and their mixtures: Perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO–DA) and its ammonium salt (also known as "GenX" chemicals), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS). The proposed drinking water limits are adequate to protect health, reasonable, and achievable.

To maintain the efficacy of the proposed rule, I ask that EPA continue reviewing data regarding the health effects of these compounds, adjusting the MCLs and HBWC values and adding more chemicals to the regulations as new data becomes available.

I firmly support the proposed NPDWR and look forward to seeing it implemented as a vital part of an overall strategy to protect public health from PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Tracy Feldman (Doc. #2814, SBC-046297)

Please make water quality rules as strong as possible, so that we the people have clean drinking water, and so the water we swim in is clean. This is one of the basic things we entrust to our government--clean water is one of the most fundamental needs of humans and all life on earth. Thus, I was very concerned when I heard about plans to weaken water quality rules, or changes to make it harder to safeguard our water. Please stand strong, and make sure the rules are in place to hold industry accountable for not polluting water. Make sure the standards are strict, as human health is not something to cut corners with.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lana Kelley (Doc. #2816, SBC-046543)

I support the proposed National Primary Drinking Water Regulation (NPDWR) to reduce polyfluoroalkyl substances (PFAS) and their mixtures. The adverse health effects of per- and polyfluoroalkyl substances (PFAS), ranging from birth defects to cancer, have been clearly established in numerous studies. Unfortunately, these "forever" chemicals do not break down and are widely found in our environment, including in our drinking water.

I ask that EPA continue reviewing data regarding the health effects of these compounds, adjusting the MCLs and HBWC values and adding more chemicals to the regulations as new data becomes available.

While the proposed NPDWR is a crucial step to protecting human health and the environment from the significant harms caused by PFAS, to be ultimately effective, EPA must expeditiously address the next step: facilitating effective and safe disposal methods of the waste material from PFAS removal.

I support the proposed NPDWR as a first step, and look forward to seeing it implemented as part of an overall strategy to protect public health from PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. For additional discussion around generated waste following treatment, please see section 10.4 of the EPA response in this *Response to Comments* document.

Riley Talbot (Doc. #2817, SBC-047266)

My name is Riley Talbot, and I am the Policy Associate for the Catholic Climate Covenant and a concerned citizen who is advocating for the proposed EPA National Primary Drinking Water Regulation which sets enforceable limits on PFAS and other related chemical compounds in public drinking water.

I am writing in support of the NPDWR (EPA-HQ-OW-2022-0114-0027) and its stringent regulations on drinking water. The rule has the potential to lower the presence of dangerous chemicals in the water supply of over 110 million Americans. PFAS chemicals have been repeatedly connected to dangerous health conditions, and the EPA must do something to protect Americans from such contamination.

As a member of a faith community, I take the responsibility I have to creation very seriously. Even more, I am a resident of New Orleans, with some of the most contaminated water in all of our country. I am concerned about my health and the health of my family and community members. It is from that position that I advocate for this act as a way of bringing about more justice in our society. These regulations would not only protect the health of humankind but will also benefit nature and wildlife. It is because the benefits of the rule are so great, and, according to the EPA, far outweigh the costs of implementation, that I believe it to be in the best interest of the United States to enact the National Primary Drinking Water Regulation. Thank you for the continued work of the EPA to create better living standards and a more harmonious relationship with nature.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jessica Berta (Doc. #2818, SBC-046233)

Please stand up against industry pressure to weaken these rules. I urge you to quickly finalize these drinking water standards to protect public health, our drinking water, and our communities.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Diane Tomkinson (Doc. #2819, SBC-047264)

My name is Sr Diane Tomkinson, and I am a supporter of the Catholic Climate Covenant which is working to support the proposed EPA National Primary Drinking Water Regulation which sets enforceable limits on PFAS and other related chemical compounds in public drinking water.

I am writing in support of the NPDWR (EPA-HQ-OW-2022-0114-0027) and its stringent regulations on drinking water. The rule has the potential to lower the presence of dangerous chemicals in the water supply of over 110 million Americans. PFAS chemicals have been repeatedly connected to dangerous health conditions, and the EPA must do something to protect Americans from such contamination.

As a member of a Franciscan faith community, I take seriously our responsibility to care for creation and bring about greater justice for the most vulnerable in our society. The faith and scientific communities agree on the urgency of addressing forever chemicals. These regulations

would not only protect the health of humankind but will also benefit nature and wildlife. It is because the benefits of the rule are so great, and, according to the EPA, far outweigh the costs of implementation, that I believe it to be in the best interest of the United States to enact the National Primary Drinking Water Regulation. Thank you for the continued work of the EPA to create better living standards and a more harmonious relationship with nature.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Anne Kelley (Doc. #2821, SBC-047195)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

And remember, producers of PFAS chemicals have known about the downside of these substances cause for decades but put profits above health of people and the planet again and again, suppressing and denying they were harmful pollutants. And they MUST be held responsible for the cost of clean up.

Please do the right thing!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. Regarding the commenter's statements about producers of PFAS, the EPA notes that only PWSs are regulated by this PFAS NPDWR and other entities, like PFAS producers, are outside the scope of this rulemaking.

Mary Smith (Doc. #2824, SBC-047262)

I am a supporter of the Catholic Climate Covenant which is working to support the proposed EPA National Primary Drinking Water Regulation which sets enforceable limits on PFAS and other related chemical compounds in public drinking water.

I am writing in support of the NPDWR (EPA-HQ-OW-2022-0114-0027) and its stringent regulations on drinking water. The rule has the potential to lower the presence of dangerous chemicals in the water supply of over 110 million Americans. PFAS chemicals have been repeatedly connected to dangerous health conditions, and the EPA must do something to protect Americans from such contamination.

As a member of a faith community, I take the responsibility I have to creation very seriously. It is from that position that I advocate for this act as a way of bringing about more justice in our society. These regulations would not only protect the health of humankind but will also benefit nature and wildlife. It is because the benefits of the rule are so great, and, according to the EPA, far outweigh the costs of implementation, that I believe it to be in the best interest of the United States to enact the National Primary Drinking Water Regulation. Thank you for the continued work of the EPA to create better living standards and a more harmonious relationship with nature.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

David Frazer (Doc. #2825, SBC-046230)

Please stand up against industry pressure to weaken these rules, and quickly finalize these drinking water standards to protect public health, our drinking water, and our communities.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Therese Patton (Doc. #2826, SBC-047196)

Dear Administrator Regan:

I doubt the Supreme Court gives a damn about clean drinking water as long as their select few don't have to worry about where their water comes from. I'm sure they all drink from single use plastic bottles all day long anyway.

But please fight to give the rest of us access to this #1 basic need to survive.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal

would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joann Edmonds-Rodgers (Doc. #2827, SBC-047197)

Dear Administrator Regan:

I support the the EPA's proposed national drinking water regulations to keep six PFAS chemicals out of our water. It's a welcome first step to protecting communities from the scourge of PFAS.

As you know, PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

This proposed rule would provide safer drinking water for millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

Please quickly finalize the regulations on these six PFAS chemicals, implement a health protective rule, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Michelle Parr (Doc. #2828, SBC-046212)

As a citizen, I believe this regulation is a step in the right direction for our health and safety. I fully support the revised regulations.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

John Pawlikowski (Doc. #2829, SBC-047263)

My name is Rev.Dr. John Pawlikowski, and I am a supporter of the Catholic Climate Covenant which is working to support the proposed EPA National Primary Drinking Water Regulation

which sets enforceable limits on PFAS and other related chemical compounds in public drinking water.

I am writing in support of the NPDWR (EPA-HQ-OW-2022-0114-0027) and its stringent regulations on drinking water. The rule has the potential to lower the presence of dangerous chemicals in the water supply of over 110 million Americans. PFAS chemicals have been repeatedly connected to dangerous health conditions, and the EPA must do something to protect Americans from such contamination.

As a member of a faith community, I take the responsibility I have to creation very seriously. Hence I support this act as a way of bringing about more justice in our society. These regulations would not only protect the health of humankind but will also benefit nature and wildlife. It is because the benefits of the rule are so great, and, according to the EPA, far outweigh the costs of implementation, that I believe it to be in the best interest of the United States to enact the National Primary Drinking Water Regulation. Thank you for the continued work of the EPA to create better living standards and a more harmonious relationship with nature.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

SheilaMarie Tobbe (Doc. #2831, SBC-047265)

My name is Sheila Marie Tobbe, and I am a supporter of the Catholic Climate Covenant which is working to support the proposed EPA National Primary Drinking Water Regulation which sets enforceable limits on PFAS and other related chemical compounds in public drinking water.

I am writing in support of the NPDWR (EPA-HQ-OW-2022-0114-0027) and its stringent regulations on drinking water. The rule has the potential to lower the presence of dangerous chemicals in the water supply of over 110 million Americans. PFAS chemicals have been repeatedly connected to dangerous health conditions, and the EPA must do something to protect Americans from such contamination. Clean water is essential for our health and the health of our children.

As a member of a faith community, I take the responsibility I have to creation very seriously. It is from that position that I advocate for this act as a way of bringing about more justice in our society. These regulations would not only protect the health of humankind but will also benefit nature and wildlife. It is because the benefits of the rule are so great, and, according to the EPA, far outweigh the costs of implementation, that I believe it to be in the best interest of the United States to enact the National Primary Drinking Water Regulation. Thank you for the continued work of the EPA to create better living standards and a more harmonious relationship with nature.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Susan Perry (Doc. #2833, SBC-046473)

PFAS National Primary Drinking Water Regulation Rulemaking

Please enact and enforce regulations to eliminate toxic PFAS in allprimary drinking water systems in the USA and its territories. The negative effect of PFAS in the nation's environment leads to a down hill landslide into unhealthy outcomes for all living beings. Save lives and expense by moving quickly to eliminate PFAS from our water and our environment.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA notes that not "all primary drinking water systems" are subject to this PFAS NPDWR, but only certain PWSs that meet the definition under SDWA are regulated by this rule. Please see section 1.4 of the EPA response in this *Response to Comments* document for the EPA's response of the scope of PWSs that are covered by this final rule.

Marilyn Green (Doc. #2835, SBC-046512)

I am a retired educator from Malibu, California. I am writing to thank you in advance for eliminating six extremely toxic PFAS chemicals from our drinking water through these regulations. I strongly support these new regulations for human health. Please put our health above corporate profits and give us these essential safeguards.

PFAS "forever" chemicals do not easily break down in the environment and can accumulate in the human body over time. Exposure to PFAS has been linked to a plethora of human health issues, such as cancer, immune suppression, reduced fertility, and developmental abnormalities. We do NOT want them in our water.

I have children and grandchildren who the EPA can protect by keeping forever chemicals out of our water.

Thanks.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mary Fitzpatrick (Doc. #2838, SBC-047260)

My name is Mary Fitzpatrick, and I am part of the Catholic Climate Covenant which supports the proposed EPA National Primary Drinking Water Regulation setting enforceable limits on PFAS and other related chemical compounds in public drinking water.

I am writing in support of the NPDWR (EPA-HQ-OW-2022-0114-0027) and its stringent regulations on drinking water. The rule has the potential to lower the presence of dangerous chemicals in the water supply of over 110 million Americans. The EPA must do something to protect Americans from this lasting contamination.

As a member of a faith community, I take the responsibility I have to creation very seriously. It is from that position that I advocate for this act as a way of bringing about more justice in our society. These regulations would not only protect the health of humankind but will also benefit nature and wildlife. It is because the benefits of the rule are so great, and, according to the EPA, far outweigh the costs of implementation, that I believe it to be in the best interest of the United States to enact the National Primary Drinking Water Regulation.

Thank you for the continued work of the EPA to create better living standards and a more harmonious relationship with nature.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Johanna Stoneking (Doc. #2839, SBC-047268)

My name is Johanna Stoneking, and I am a supporter of the Catholic Climate Covenant which is working to support the proposed EPA National Primary Drinking Water Regulation which sets enforceable limits on PFAS and other related chemical compounds in public drinking water.

The Pope has reached out to the world to show compassion for others. He's asking support for clean water, food, air & shelter. I'm disappointed the SCOTUS Catholics aren't showing empathy for their fellow man. They changed laws about abortion but they won't provide clean water for the children. Shame on them.

I am writing in support of the NPDWR (EPA-HQ-OW-2022-0114-0027) and its stringent regulations on drinking water. The rule has the potential to lower the presence of dangerous chemicals in the water supply of over 110 million Americans. PFAS chemicals have been repeatedly connected to dangerous health conditions, and the EPA must do something to protect Americans from such contamination.

As a member of a faith community, I take the responsibility I have to creation very seriously. It is from that position that I advocate for this act as a way of bringing about more justice in our society. These regulations would not only protect the health of humankind but will also benefit

nature and wildlife. It is because the benefits of the rule are so great, and, according to the EPA, far outweigh the costs of implementation, that I believe it to be in the best interest of the United States to enact the National Primary Drinking Water Regulation. Thank you for the continued work of the EPA to create better living standards and a more harmonious relationship with nature.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kathleen Gribble (Doc. #2841, SBC-047261)

My name is Kathleen Gribble, and I am a supporter of the Catholic Climate Covenant which is working to support the proposed EPA National Primary Drinking Water Regulation which sets enforceable limits on PFAS and other related chemical compounds in public drinking water.

I am writing in support of the NPDWR (EPA-HQ-OW-2022-0114-0027) and its stringent regulations on drinking water. The rule has the potential to lower the presence of dangerous chemicals in the water supply of over 110 million Americans. PFAS chemicals have been repeatedly connected to dangerous health conditions, and the EPA must do something to protect Americans from such contamination.

I take the responsibility I have to creation very seriously. It is from that position that I advocate for this act as a way of bringing about more justice in our society. These regulations would not only protect the health of humankind but will also benefit nature and wildlife. It is because the benefits of the rule are so great, and, according to the EPA, far outweigh the costs of implementation, that I believe it to be in the best interest of the United States to enact the National Primary Drinking Water Regulation. Thank you for the continued work of the EPA to create better living standards and a more harmonious relationship with nature.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lorraine marden (Doc. #2842, SBC-047270)

I strongly support the EPA draft regulations proposed for six PFAS chemicals. I urge you to finalize these rules as quickly as possible. These comments are in regard to Docket ID: EPA-HQ-OW-2022-0114.

· I live in Rockland County, where nearly all of our drinking water is contaminated with toxic PFAS chemicals. Many of our wells and reservoirs are contaminated with PFAS at levels below the current New York State drinking water standards. That means that filtration will not be required for the majority of Rockland's contaminated wells -- unless the draft EPA regulations are passed.

· Many of Rockland's drinking water sources are contaminated with multiple PFAS chemicals, possibly resulting in additive or synergistic health impacts. But New York State currently regulates only two chemicals.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kirven Blount (Doc. #2843, SBC-047275)

I strongly support the EPA draft regulations proposed for six PFAS chemicals. I urge you to finalize these rules as quickly as possible. These comments are in regard to Docket ID: EPA-HQ-OW-2022-0114.

I live in Rockland County, where nearly all of our drinking water is contaminated with toxic PFAS chemicals. Many of our wells and reservoirs are contaminated with PFAS at levels below the current New York State drinking water standards. That means that filtration will not be required for the majority of Rockland's contaminated wells -- unless the draft EPA regulations are passed.

Many of Rockland's drinking water sources are contaminated with multiple PFAS chemicals, possibly resulting in additive or synergistic health impacts. But New York State currently regulates only two chemicals. The draft EPA regulations are written for combined standards, which would require many more of these chemicals to be cleaned up.

The New York State Dept. of Health is waiting for EPA's finalized regulations. Many other states may be doing the same. If EPA's draft regulations are passed, it will make it possible for the states to build on EPA's science and direction to regulate even more PFAS.

These regulations will send a strong signal to the chemical industry to invest in safe alternatives now.

There are over 12,000 PFAS chemicals in all. Moving forward, EPA should extend these regulations as quickly as possible to cover PFAS chemicals as a class.

PLEASE immediately halt the approval of all new PFAS.

While the costs of filtration and disposal are high, those costs are far outweighed by the billions of dollars in healthcare costs caused by the health impacts of PFAS chemicals.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Christopher Lish (Doc. #2844, SBC-046674)

Sunday, May 28, 2023

U.S. Environmental Protection Agency

EPA Docket Center

Office of Ground Water and Drinking Water Docket

Mail Code 2822IT

1200 Pennsylvania Avenue NW

Washington, DC 20460

Subject: Act quickly to finalize the EPA's proposed national drinking water regulations for six PFAS chemicals -- Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation (Document ID: EPA-HQ-OW-2022-0114-0027)

Dear EPA Administrator Regan and PFAS NPDWR Team Lead Alexis Lan:

Thank you for proposing health-protective limits for perfluoroalkyls (PFAS) chemicals in drinking water that reflect the latest scientific information on their health effects. The Environmental Protection Agency's proposed national drinking water regulations for six PFAS chemicals is a welcome—albeit long-overdue—first step to protecting our families and communities from the scourge of PFAS. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. The Environmental Protection Agency's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. I strongly support the proposed standards and strongly urge the Environmental Protection Agency to finalize them as quickly as possible.

We need national standards for PFAS. PFAS are a large, long-lasting, and highly dangerous class of chemicals which are used to manufacture a range of goods. Because they break down very slowly over long periods of time, they are often called "forever chemicals." Thousands of PFAS chemicals are in use and PFAS can be found everywhere, including clothes, food packaging, and even Norwegian Arctic ice. PFAS persist in the environment, build up in plants and in the blood and organs of people, wildlife, aquatic life, and continue to cause harm decades after they are released into the environment. This contamination poses a direct threat to our health and our ecosystems.

These toxic substances have for too long been allowed to get into our drinking water, threatening the health of millions of Americans. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. The Centers for Disease Control and Prevention (CDC) has found these chemicals in the bodies of nearly every American it has

tested. PFAS have been linked to serious health conditions such as cancer, liver and kidney disease, reproductive issues, immunodeficiencies, and hormonal disruptions. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

The Environmental Protection Agency's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, as well as the combination of different PFAS, the proposal will protect our drinking water from this toxic contamination and would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The Environmental Protection Agency acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, the Environmental Protection Agency is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. This rule will especially benefit Black and brown communities who are disproportionately impacted by PFAS contamination.

The ubiquity of PFAS is why we need to act fast and decisively. All parts of Environmental Protection Agency and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Finalizing these regulations would protect drinking water for countless communities. I strongly urge you to quickly finalize these badly needed and long-overdue standards to better protect people and our rivers, oceans, lakes, and communities from PFAS contamination. Please implement a rule that is the most health-protective and resist industry's efforts to weaken the rule.

"The ultimate test of a moral society is the kind of world that it leaves to its children."

-- Dietrich Bonhoeffer

Thank you for your consideration of my comments. Please do NOT add my name to your mailing list. I will learn about future developments on this issue from other sources.

Sincerely,

Christopher Lish

San Rafael, CA

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Marcy Denker (Doc. #2845, SBC-047272)

I am writing as a resident of the VIllage of Nyack and the Chair of the Nyack Climate Smart Committee in full support of the EPA draft regulations proposed for six PFAS chemicals. These comments are in regard to Docket ID: EPA-HQ-OW-2022-0114.

The water in the Village of Nyack and most of Rockland County, is contaminated with toxic PFAS chemicals, and since we learned this several years ago we have also learned that many wells and reservoirs here in Rockland are contaminated with PFAS at levels below the current New York State drinking water standards. Many are also are contaminated with multiple PFAS chemicals, possibly resulting in additive or synergistic health impacts

The draft EPA standards will require filtration of the majority of Rockland's contaminated wells and are written for combined standards, which would require many more of these chemicals to be cleaned up.

If EPA's draft regulations are passed, it will make it possible for the states to build on EPA's science and direction to regulate even more PFAS. Moving forward, EPA should extend these regulations as quickly as possible to cover the over 12,000 PFAS chemicals as a class.

These rules will send a strong signal to the chemical industry to invest in safe alternatives now. I urge you to finalize these regulations as quickly as possible.

Marcy Denker

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. For a response regarding the scope of the PFAS NPDWR for PWSs that meet the definition under SDWA, see section 1.4 of the EPA response in this *Response to Comments* document.

Lynn Davis (Doc. #2847, SBC-046849)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

Please resist efforts to weaken the standards. Our family, like many, has suffered from cancer and other health challenges due to pollution, and the EPA is in the best position to protect our health and that of millions of others.

Sincerely,

Lynn Davis

Santa Ana, CA 92705

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Donna Yannazzone (Doc. #2848, SBC-046200)

These toxins need to be decreased and addressed properly for safe human water consumption.

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Rhoda Schlamm (Doc. #2849, SBC-046897)

Dear Michael Regan,

We need your help in protecting our drinking water from PFAS. If you don't use every means at your disposal to circumvent court decisions and legislation that would continue to allow pollution of our water supply, you are invalidating your mission to protect our environment and all who depend on it.

You have taken the first step to regulate PFAS in drinking water and we need you to continue to accelerate the pace to protect our water supply.. For decades, PFAS have contaminated drinking water for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to

multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Rhoda Schlamm

Woodside, NY 11377

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Liz Szabo (Doc. #2850, SBC-047506)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Judith Schafer (Doc. #2851, SBC-046245)

The dangers of PFAS are fact. We have got to protect our rivers, lakes and oceans. Our survival and that of the earth depend on clean waters. Please pass strong to keep our waters clean and to punish those who ignore them.

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Victoria Oltarsh (Doc. #2852, SBC-046333)

I live in Nyack, NY 10960 and I spend quite a bit of money on water purifier so my drinking water shower purifier, so my bathing water and then extra drinking vessels that contain ways to clean water. This is ridiculous. How could the water not be a top priority in the county like Rockland county? It's so so sad how many chemicals and toxic Materials are in drinking water, something we need to sustain ourselves and our health. When you can smell the water and taste how horrible it is that it's really bad and I've never had such bad water as living in Nyack. And it's getting progressively worse I've lived here for 20 years and in the last few years when I turn on the faucet in the morning, I am overwhelmed by the smell of what smells like chlorine, bleach, or mold, coming out of the top, does hasta be adjust ASAP! Above all else! What concerns me the most is that corporations and bureaucracy is allowed to rule over individual safety and needs of human beings and animals that depend on water. Just a thought that they made them forever chemicals back into the Hudson. It's so ridiculous that we even have to be discussing it as is keeping toxic horrible Pollutants in our drinking water

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Frederick Warwick (Doc. #2853, SBC-046850)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Frederick Warwick

Baltimore, MD 21210

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jane Twitmyer (Doc. #2854, SBC-046851)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Jane Twitmyer

Nellysford, VA 22958

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Alexandria Zielinski (Doc. #2856, SBC-046296)

As a nurse and teacher, I think it's extremely important to regulate our drinking water. We are studying and learning of the dangers in our water, particularly PFAS. Unfortunately, expecting everyone to be able to buy a reverse osmosis system for their home is impossible as so many cannot afford basic things like food and transportation. It is our duty to protect our environment and to protect each other, and it is not fair that our environment and our people have to deal with the mistakes and irresponsible nature of companies. Please pass this rule to keep our people and planet more healthy!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sherry Kessel (Doc. #2857, SBC-046852)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. EPA's proposed drinking water standards would provide important and long overdue protections against toxic chemicals. I strongly support the proposed standards, and I urge EPA to implement them.

PFAS in the environment affect our bodies, and harm years after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people. They are in everyone's blood--even in the blood of newborn babies who are exposed in utero. When are federal limits on PFAS going to be imposed for our drinking water? Doing so would save thousands of lives and avoid serious illnesses.

We need to begin regulating PFAS in drinking water. I urge you to immediately implement standards--no matter what the resisting industries say.

Sincerely,

Sherry Kessel

Boynton Beach, Florida

Sincerely,

Sherry Kessel

Boynton Beach, FL 33437

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

John Gau (Doc. #2858, SBC-046853)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water.

EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. As a cancer patient, i strongly support the proposed standards and urge EPA to finalize them as quickly as possible. Prevention is cheaper than attempting to cure cancer after the fact.

Sincerely,

JOHN GAU

Saint Paul, MN 55116

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Bruce Hlodnicki (Doc. #2860, SBC-046594)

Dear Michael Regan,

Thank you for taking a first step to regulate PFAS in drinking water.

For decades, PFAS have contaminated millions of people's drinking water all across the country. That by itself has increased rates of cancer, developmental and reproductive abnormalities, and other serious diseases. The Environmental Protection Agency has finally proposed drinking water standards to protect against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large class of compounds. They tend to be long-lasting, and biologically hazardous with high dosages or repetitive or prolonged exposures. Often called "forever chemicals," PFAS persist in the environment for very long periods. They accumulate in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million Americans and the blood of

nearly every individual in the United States, including newborn babies who are exposed in utero. Despite the serious health threats associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges the cumulative effects on communities exposed to multiple PFAS. With this, EPA is one step closer to keeping its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water.

I want you to quickly finalize these standards, and to implement the most stringent rule by resisting industry's efforts to weaken them!

Sincerely,

Bruce Hlodnicki

Indianapolis, IN 46226

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Erin D'Alessandro (Doc. #2861, SBC-046854)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Erin D'Alessandro

Lyons, CO 80540

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sharon Rogers (Doc. #2862, SBC-046855)

Dear Michael Regan,

Hello,

Nobody has a lack of PFAS in their bodies and I am grateful that the EPA is finally addressing this. There is irrefutable evidence that PFAS carry a direct link to many cancers. It is preventable, and this is a huge step in making our waters safe and out earth habitable.

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Sharon Rogers

Duluth, MN 55807

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Carolyn Petrakis (Doc. #2863, SBC-046856)

Dear Michael Regan,

I am a mother and a retired clinical social worker who worked for decades in healthcare. I am deeply concerned and angered about the harm we humans have done to our only home, the earth. I fear our children and all living beings are being deprived of a healthy future because of the climate crisis caused by toxic pollution of our air, land and water. We are poisoning ourselves. Clean water is essential for the survival of all living beings on this planet.

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Carolyn Petrakis

Chicago, IL 60645

chp9014@yahoo.com

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2864, SBC-046248)

We need to apply all regulations necessary to protect people and nature from PFAS. Water companies have to make sure pfas gets removed from drinking water and industry needs to stop using and dumping chemicals into the environment. Please act.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joanne Wheeler (Doc. #2865, SBC-046553)

Dear Michael Regan,

SAFE DRINKING WATER IS NECESSARY FOR ALL ON THIS GOOD EARTH to keep them healthy. The same applies to all in utero as what water is taken in by it's carrier, the mom, is equally important. WE NEED TO DO MORE TO PREVENT DISEASE CAUSING CHEMICALS OUT OF OUR DRINKING WATER. PLEASE DO WHAT IS NECESSARY TO KEEP THE SIX PFAS CHEMICALS AND OTHER CHEMICALS OUT OF OUR WATER. THANK YOU!

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Joanne Wheeler

Canton, MA 02021

condo23@comcast.net

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jennifer Nitz (Doc. #2866, SBC-046889)

Dear Michael Regan,

You have taken the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people nationwide, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide long overdue protections against six of these toxic chemicals. We support the proposed standards, and urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities nationwide. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. Quickly finalize these standards, and implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Jennifer Nitz

Missoula, MT 59802

grizzalo@hotmail.com

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Linda Rossin (Doc. #2867, SBC-046857)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in

increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. It's not right that chemical companies can get away with taking lives, but as an individual I cannot. There is something completely wrong with this! We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water. Again, I repeat: It's not right that chemical companies can get away with taking lives, but as an individual I cannot. There is something completely wrong with this!

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Linda Rossin

Lake Hopatcong, NJ 07849

lindarossin@mac.com

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Darcy Johnson (Doc. #2868, SBC-046858)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections

against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

#WaterisLife and we have the right to have clean drinking water.

Seattle's 1854 Oration -ver.1.

WHEN THE LAST REDMAN

HAS VANISHED FROM THE EARTH,

AND THE MEMORY IS ONLY THE SHADOW

OF A CLOUD PASSING OVER THE PRAIRIE,

THESE SHORES AND FOREST WILL

STILL HOLD THE SPIRITS OF MY PEOPLE,

FOR THEY LOVE THIS EARTH AS

THE NEWBORN LOVES ITS MOTHER'S HEARTBEAT.....

CONTINUE TO CONTAMINATE YOUR BED,

AND YOU WILL ONE NIGHT SUFFOCATE

IN YOUR OWN WASTE,

WHEN THE BUFFALO ARE ALL SLAUGHTERED,

THE WILD HORSES ALL TAMED,

THE SECRET CORNERS OF THE FOREST

HEAVY WITH THE SCENT OF MEN,

AND THE VIEW OF THE RIPE HILLS

BLOTTED BY TALKING WIRES,

WHERE IS THE THICKET? GONE.

WHERE IS THE EAGLE? GONE.

AND WHAT IS IT TO SAY GOODBYE

TO THE SWIFT AND THE HUNT?

THE END OF LIVING

AND THE BEGINNING OF SURVIVAL...

"CHIEF SEATTLE 1855"

Sincerely,

Darcy Johnson

Kittitas, WA 98934

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Michelle Williams (Doc. #2869, SBC-046859)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Michelle Williams

Mercer Island, WA 98040

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Cat Ransom (Doc. #2870, SBC-046860)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, and we don't even understand all the health damage they cause yet. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies in Prescott, Arizona, near my home and there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Cat Ransom

Cottonwood, AZ 86326

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Julianne Kever (Doc. #2871, SBC-046861)

Dear Michael Regan,

I have a friend whose husband is a firefighter and got cancer, most likely from the PFAS in their mandatory clothing. I have nine grandchildren and two great-grands, all of whom I wish the best health throughout their lives, but I'm very concerned about PFAS in turf fields where they play sports, clothing they may wear and even the floss they use to keep their teeth and gums healthy. The use of these 'forever chemicals' NEEDS to be banned NOW!

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Julianne Kever

Nantucket, MA 02554

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mary Holm (Doc. #2872, SBC-046862)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

We are killing the planet and ourselves with chemicals in our food, air, and water.

The real innocents; wildlife, plants, and our children result in a doomed planet.

Sincerely,

Mary Holm

Sun City West, AZ 85375

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Maryann Striegel (Doc. #2873, SBC-046863)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We STRONGLY SUPPORT the PROPOSED STANDARDS, and we urge EPA to finalize them as quickly as possible.

Despite the serious health risks associated with PFAS, there are CURRENTLY NO FEDERAL LIMITS on PFAS levels in drinking water!!

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of

lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water.

We urge you to quickly FINALIZE THESE STANDARDS, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Maryann Striegel

Davenport, IA 52807

maryannstriegel@gmail.com

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Daniel Davids (Doc. #2874, SBC-046419)

Dear Michael Regan,

I urge you to regulate PFAS in drinking water with all due haste. Please finalize the proposed standards and resist industry's efforts to weaken them.

Sincerely,

Daniel Davids

Woodinville, WA 98077

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Vivian Look (Doc. #2875, SBC-046864)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies of millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge you to finalize quickly.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. As you are no doubt aware, PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies of approximately 200 million people. PFAS are found in the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Despite the serious health risks associated with PFAS, there are no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities across the nation. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent thousands of serious PFAS-related illnesses each year.

The EPA acknowledges and addresses the cumulative impacts on communities exposed to multiple PFAS. In issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these rules and resist industry efforts to weaken them.

Sincerely,

Vivian Look

Galt, CA 95632

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sandra Przybylski (Doc. #2876, SBC-046865)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. I strongly support the proposed standards, and I urge EPA to finalize them as quickly as possible. Again, these limits on 6 PFAS in our drinking water are long overdue.

Thank you for your time.

Sincerely,

Sandra Przybylski

Kirksville, MO 63501

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Ken Kurtz (Doc. #2877, SBC-046597)

Dear Michael Regan,

I want to express my gratitude for your initiative in addressing the regulation of PFAS in drinking water. The contamination of drinking water supplies with PFAS has been an ongoing issue for many years, affecting countless individuals nationwide. It is alarming to see the increased rates of cancer, developmental and reproductive harm, and other serious diseases linked to these toxic chemicals.

The proposed drinking water standards by the EPA are crucial and long overdue. They offer much-needed protections against six of the most harmful PFAS compounds. I wholeheartedly support these standards and strongly urge the EPA to finalize them as swiftly as possible.

PFAS, often referred to as "forever chemicals," pose significant and long-lasting dangers. They persist in the environment, accumulate in our bodies, and continue to cause harm even decades after their release. It is distressing to note that approximately 200 million people have been affected by PFAS-contaminated drinking water, and nearly every individual in the United States carries these chemicals in their blood, including unborn babies exposed in utero.

Despite the clear health risks associated with PFAS, there are currently no federal limits on their levels in drinking water. This situation needs to change.

The EPA's proposed rule has the potential to provide safer drinking water for communities across the nation. By setting strong limits on the six most commonly found PFAS compounds, this proposal could save thousands of lives and prevent tens of thousands of PFAS-related illnesses each year. Moreover, the EPA acknowledges the cumulative impacts on communities exposed to multiple PFAS, showing a commitment to addressing this issue comprehensively.

I implore you to swiftly finalize these standards, ensuring they are the most health-protective measures possible. Let us not allow industry interests to weaken these critical rules. Together, we can make a significant difference in safeguarding the well-being of communities and future generations.

Sincerely,

Ken Kurtz

Chandler, AZ 85249

kkurtz123@msn.com

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Frances Walker (Doc. #2878, SBC-046422)

Dear Michael Regan,

Please do not allow polluting industries to eradicate PFAS in our waters. We need robust rules to protect our water supplies.

Sincerely,

Frances Walker

Sincerely,

Frances Walker

Gig Harbor, WA 98335

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Eleanor Saunders (Doc. #2879, SBC-046866)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country.,EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

You obviously know that PFAS have contaminated drinking water supplies for approximately 200 million people and are found in the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge

you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Eleanor Saunders

Hillsdale, NY 12529

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

James Boone (Doc. #2880, SBC-046569)

Dear Michael Regan,

Good for you! Thanks for taking the first step to regulate PFAS in drinking water.

For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards will provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. I urge you to quickly finalize these standards and implement a rule that protects health the most. Please resist industry's efforts to weaken them!

Thank you for aconsi9dering my comments.

Sincerely, James Boone

Sincerely,

James Boone

Portland, OR 97229

jameslboone@yahoo.com

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Carl B. and Pamela Lechner (Doc. #2881, SBC-046893)

Dear Michael Regan,

We appreciate your early efforts to date to regulate PFAS in drinking water. We know that for decades, PFAS have contaminated drinking water across the country. This abuse has resulted in increased rates of cancer, developmental and reproductive harm and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. These "forever chemicals," (PFAS) persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We ask you to finalize these standards as soon as possible and to implement a rule that is the most health-protective possible that will resist industry's efforts to weaken them.

Sincerely,

Carl B. and Pamela Lechner

Windsor, OH 44099

cblechner2@icloud.com

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Orrin and Jo Len Everhart (Doc. #2882, SBC-046867)

Dear Michael Regan,

For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. Thank you for taking the first step to regulate PFAS in drinking water. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

Sincerely,

Orrin and Jo Len Everhart

Bonners Ferry, ID 83805

gigatt37@gmail.com

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Brian Levo (Doc. #2883, SBC-046868)

Dear Michael Regan,

Greetings. Thank you for taking the first step to regulate PFAS in drinking water. I is my understanding that EPA's proposed drinking water standards would provide important and long overdue protections against toxic chemicals, or PFAS, which for decades, have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases.

Based on my research, PFAS are a large, long-lasting, and highly dangerous class of chemicals , often called "forever chemicals." PFAS, which persist in the environment, build up in our blood

and organs, and continue to cause harm decades after they are released into the environment. Unfortunately, despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

I believe EPA's proposed rule would provide safer drinking water for communities by establishing strong limits on six widely detected PFAS. In addition, the proposal would save lives and prevent serious PFAS-related illnesses each year. It has been reported that the EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap. I please urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Thank you for your consideration in this matter.

Sincerely,

Brian Levo

Falls Church, VA 22044

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sharon Tepe (Doc. #2884, SBC-046494)

Dear Michael Regan,

Thank you for doing something to regulate PFAs in our drinking water. These are terrible chemicals that get into our bodies through water and can persist forever. We need to limit these in our drinking water so that our children and families are safer. We need to establish limits at the federal level so that all states take this seriously and implement these changes consistently nationwide. Please get these finalized as soon as possible, as they are so important to families everywhere.

Thank you,

Sharon Tepe

Sincerely,

Sharon Tepe

Union, KY 41091

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

M. Lou Christ (Doc. #2885, SBC-046523)

Dear Michael Regan,

PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water. This is unacceptable.

So thank you for finally acknowledging & addressing the cumulative impacts on communities exposed to multiple PFAS, and for issuing this proposal, this first step to regulate six widely-detected PFAS in drinking water.

I urge you to quickly finalize these standards and to implement a rule that is the most health-protective as well as strong enforcement coverage-- regardless of industry's efforts to weaken or ignore them.

Sincerely,

m lou christ

Seattle, WA 98103

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Carolynn Kohout (Doc. #2887, SBC-046869)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water.

For decades,

PFAS have contaminated drinking water supplies

- for millions of people across the country, resulting in

- increased rates of cancer,

- developmental and reproductive harm, and

- other serious diseases.

EPA's proposed drinking water standards

- would provide important and long overdue protections

- against six of these toxic chemicals.

We strongly support the proposed standards.

We urge EPA to finalize them

- as quickly as possible!

PFAS are

1. a large, long-lasting, and highly dangerous class of chemicals

- "forever chemicals".

2. build up in our blood and organs and

-** continue to cause harm decades AFTER they are released into the environment**.

3. have contaminated

- drinking water supplies

- for approximately 200 million people and

4. contaminated the blood of nearly every individual

- in the United States,

- including newborn babies EXPOSED in-utero.

Despite the serious health risks associated with PFAS,

there are currently no federal limits

- on PFAS levels in drinking water.

EPA's proposed rule

- would provide safer drinking water

- for communities from coast to coast.

Strong limits on six widely detected PFAS,

would

- save thousands of lives and

- prevent tens of thousands of serious PFAS-related illnesses each year.

The EPA acknowledges and addresses the cumulative impacts

- on communities

- who are exposed to multiple PFAS.

By issuing this proposal,

EPA is one step closer to fulfilling its commitment

- under the 2021 PFAS Strategic Roadmap

- to begin regulating PFAS in drinking water.

Quickly finalize these standards and implement a rule

- the most health-protective,

- resisting industry's efforts to weaken them.

Sincerely,

Carolynn Kohout

Hillsboro, OR 97124

earthwindspirit9@gmail.com

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sharon Lynch (Doc. #2888, SBC-046675)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

What can be more important than drinking water which every child learns early in life is necessary for all life. Water as it was meant to be before pollution!

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Katherine Scott (Doc. #2889, SBC-047271)

I strongly support the EPA draft regulations proposed for six PFAS chemicals. I urge you to finalize these rules as quickly as possible. These comments are in regard to Docket ID: EPA-HQ-OW-2022-0114.

I live in Rockland County, New York, where nearly all of our drinking water is contaminated with toxic PFAS chemicals. Many of our wells and reservoirs are contaminated with PFAS at levels below the current New York State drinking water standards. That means that filtration will not be required for the majority of Rockland's contaminated wells – unless the draft EPA regulations are passed.

Many of Rockland's drinking water sources are contaminated with multiple PFAS chemicals, possibly resulting in additive or synergistic health impacts. But New York State currently regulates only two chemicals. The draft EPA regulations are written for combined standards, which would require many more of these chemicals to be cleaned up.

The New York State Dept. of Health is waiting for EPA's finalized regulations. Many other states may be doing the same. If EPA's draft regulations are passed, it will make it possible for the states to build on EPA's science and direction to regulate even more PFAS.

Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jeff Golliher (Doc. #2890, SBC-046331)

Rockland County and the State of New York should take strong and decisive action to protect people and ecosystems from PFAS contamination in water. Regulations must be effective and strongly enforced. This must be done immediately.

EPA Response: The EPA acknowledges this comment in general support of a final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Louis Pisha (Doc. #2891, SBC-047618)

I live in Rockland County, NY, which has been finding levels of PFAS in our drinking water wells, some at hundreds or thousands of times higher than EPA proposed limits. My neighbor died of kidney cancer, and we now find that kidney and testicular cancers are among the impacts of these forever chemicals.

Therefore, I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Michael Parietti (Doc. #2892, SBC-047630)

Lets not wait to find out decades down the road that PFAS have been poisoning people in many more ways than one. It is common sense that these industrial chemicals are detrimental to our water sources and potentially toxic and carcinogenic to human health. Don't allow private entities to take priority over the public interests in the name of easy and excessive profits. Enact these essential protections now so we have confidence in the purity of our water supply and the ability of our democratic system of government to strike the prudent and proper balance between the demand of industry and the common good.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Susan Hayes-Tripp (Doc. #2893, SBC-047509)

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Susan Hayes-Tripp

Placerville, CA 95667

iloathecomputers@comcast.net

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Dwight Johnson (Doc. #2894, SBC-046870)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water.

I urge you to quickly finalize these regulatory standards, and to implement rules that are most health-protective and to resist industry's efforts to weaken them.

Sincerely,

Dwight Johnson

Orinda, CA 94563

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joan Golden (Doc. #2895, SBC-046416)

Why should we-who pay whopping water rates to poison our children and grandchildren??

Have the EPA clean this horrible situation up. If the AR 25s don't get our kids the poisonous water will.

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sharon Tkacz (Doc. #2896, SBC-046442)

Dear Michael Regan,

We must regulate PFAS in drinking water. EPA's proposed drinking water standards would provide important protections against six of these toxic chemicals and provide safer drinking water.

Please finalize these standards.

Sincerely,

sharon tkacz

Novelty, OH 44072

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

James Ward (Doc. #2897, SBC-046607)

I am writing to you as a citizen concerned about the health effects of the group of chemicals known as PFAS. Their presence in our environment is pervasive and the negative health impacts are well documented. The general population is relatively unaware of this problem and continue to purchase products containing these chemicals often without knowing their hazards. There is also little to no recycling of PFAS and they don't breakdown in nature, therefore they remain in the environment virtually forever.

The first products containing PFAS were developed about eighty years ago. Now they are ubiquitous in the environment with little to no regulation. Companies have convinced consumers to purchase sports bras containing stain resistant PFAS despite their connection to birth related problems. Fire retardant foams containing PFAS are used at airports and seep into ground water. Fish and game in those areas are considered too toxic for human consumption. Food wraps and coatings containing PFAS are linked to high levels of cancer and other diseases. These are just a few examples of how the lack of regulation of PFAS is affecting our environment and human life.

I applaud the EPA for reaching out for comments on clean water standards. You are the only hope we have of protecting us from ourselves. In a perfect world those standards for PFAS in our drinking water would be zero. The larger issue is why we are still allowing the sale of products containing PFAS? Despite what the chemical industry claims, alternative safer solutions could be used in most cases and those that are truly essential should be tightly controlled. It could be part of a nationwide recycling program which our country badly needs. We need to control these chemicals at the frontend of their lifecycle and not just attempt to clean up their mess at the backend.

The second issue is who should pay for the clean up? If you developed the product or sold products containing PFAS without provision for containment, safety and efficacy, then you should bear the brunt of cost of cleanup. Local water departments or the taxpayers should not have to bear all those costs.

Other issues include education of the public. Many people don't read or don't watch news that covers issues such as PFAS contamination. A public campaign to educate people about PFAS and product labeling requirements that identify the presence and danger of PFAS in products is necessary. Water companies should publish PFAS content levels in their water. Funding should also be made available for new technologies to remove PFAS from our water.

The challenges you face are enormous. Those who should be held accountable have made a lot of money selling PFAS products and they can buy a lot of politicians to fight their battles. We spend a trillion dollars on finding cures for cancer and yet we know there is a link between PFAS and cancer and we won't regulate it! It would be insane to just set a weak standard for clean water quality as proposed and do nothing to prevent future contamination.

To summarize, (1) regulate all products containing PFAS family chemicals, (2) make polluters pay, (3) educate, disclose and label PFAS in products and (4) set clean water standards at zero with flexibility as practicable. In the real world reaching zero is improbable, but if you don't try for it you'll never come close.

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document. In response to the concern for educating the public on PFAS, please see section 1.2 of the EPA response in this *Response to Comments* document for additional discussion. For specific concerns on treatment, please see section 10 of the EPA response in this *Response to Comments* document. For the commenter's requests to "regulate all products containing PFAS family chemicals; make polluters pay; and educate, disclose and label PFAS in products", please see section 15 of the EPA response in this *Response to Comments* document for topics out of scope of this rulemaking.

Anya Contreras (Doc. #2898, SBC-046530)

Dear Michael Regan,

As you know, PFAS are a large, long-lasting, and highly dangerous class of "forever chemicals" that bioaccumulate in the tissues of living beings and cause harm decades after they are released into the environment.

PFAS have contaminated drinking water for over 200 million people resulting in increased rates of cancer, developmental and reproductive harm, and other life-threatening diseases. Despite the serious health risks associated with PFAS, there are currently no federal limits on levels of PFAS in drinking water.

The EPA's proposed limits on six widely detected PFAS would save thousands of lives and prevent tens of thousands of illnesses each year. We urge you to quickly finalize these standards, and implement aggressive health-protective policies, resisting industry's efforts to weaken human and environmental protections.

Sincerely,

Anya Contreras

Miami, FL 33176

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Virginia Cole (Doc. #2899, SBC-046247)

As a social worker in the health care system, I urge the EPA to adopt the Docket ID: EPA-HQ-OW-2022-0114 reducing these harmful carcinogens from our water supply. This will save many lives and and be a boon to our economy and public health.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sally Small (Doc. #2901, SBC-046871)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Sally Small

Indianapolis, IN 46219

sallyasmall@att.net

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Keith Lewison (Doc. #2902, SBC-047654)

I live on Cape Cod, MA where before 2016 the Hyannis public drinking water system had the highest PFAS levels of any in the state of MA. This was due to legacy toxic contamination from a county fire fighter training center and airport. A second major hot spot for PFAS in my region is located "downstream" from Joint Base Cape Cod. MA DEP instituted a drinking water mcl for 6 PFAS chemicals in 2020. Since then more and more towns are finding PFAS in regional drinking water supplies. Much tax payer / rate payer funds have been put into adding filtration systems. However, source areas have not been adequately cleaned up / addressed. This means that toxic PFAS are continuing to migrate through ground and surface waters affecting fish, shellfish, private drinking water wells, etc. The EPA's proposed drinking water limits on PFAS make Americans safer and healthier.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-

saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

John Commerford (Doc. #2903, SBC-046528)

Dear Michael Regan,

No conceivable cost-benefit analysis could result in the PFAS pollution plaguing the world. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water. Consequently, I strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

EPA's proposed rule would provide safer drinking water by establishing strong limits on six widely detected PFAS. The proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. Please finalize the rule as expeditiously as possible.

Sincerely,

John Commerford

Phoenix, AZ 85004

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joanne Szamreta (Doc. #2904, SBC-047198)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

All Americans need to be drinking safe water, the foundation for all our lives. Children are particularly at high risk. for toxic substances and this makes elimination of PFAS i drinking water especially important!

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Janet Alderton (Doc. #2905, SBC-047199)

Dear Administrator Regan:

A friend of mine who lives on San Juan Island has recently learned that her community well is contaminated with PFAS at a 10x higher level than the worst previously known contaminated water supplies in Washington State.

Immediate action is needed to avoid continuing to contaminate our environment with PFAS chemicals. All variants of PFAS must be immediately banned from production and removed from supply chains.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Rosemarie SantiEsteban (Doc. #2906, SBC-046429)

Round up and other PFAS have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm. And every day, millions of people across the country drink water contaminated with PFAS. Please ban their use.

Thank you.

EPA Response: The commenter requests EPA ban the use of PFAS. The EPA notes that request is outside the scope of this PFAS NPDWR. For topics outside the scope of this rule, please see section X of the *Response to Comments* document. Also, please see section 1.3 of the EPA response in this *Response to Comments* document.

Cheryl Citron (Doc. #2907, SBC-046547)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a first step to protecting our families and communities from harmful PFAS, known as "forever chemicals". .

PFAS are persistent (forever) and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

We urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.It is a start for our country to have safer water. We want it for my husband and I, but also for our daughter and our young grandson Jack. We want it for everyone else's mother, father, grandparents, children and grandchildren. Thank you,

Cheryl and Andy Citron

Raleigh, NC

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

R. Carbon (Doc. #2908, SBC-047200)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the deleterious effects of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to many serious health conditions, including cancers, immune suppression, and developmental harm.

The EPA's proposed rule would help provide safer drinking water to the millions of people in communities across the USA where the drinking water is contaminated by PFAS. This proposal could save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I am writing to urge you to finalize the regulations of these six initial PFAS chemicals as swiftly as possible, implement a rule that is health protective, and then begin supporting the research to address additional types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Paul Cremo (Doc. #2909, SBC-047201)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS. The US needs to catch up to other countries that have banned these dangerous chemicals and protect the health of its citizens.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Barry Fass-Holmes (Doc. #2910, SBC-046238)

I strongly urge you to quickly finalize regulations of the six highly toxic PFAS chemicals found in drinking water, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kathryn Fox (Doc. #2911, SBC-047202)

Dear Administrator Regan:

I'm one of those people who have suffered from the effects of carcinogens in our environment. I see many many people at the treatment centers suffering needlessly because we can't seem to clean up our air, water and food. This is another pollutant that there needs to be an alternative to. When it comes down to affecting loved ones or yourself, it really brings the problem home.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Alan Solomon (Doc. #2912, SBC-047203)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

My name is Alan Solomon. I live in southern California.

I completely agree with and strongly support the above statement/petition today and for many years and generations to come.

Thank you for your time Today.

Alan Solomon

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Julie Glover (Doc. #2913, SBC-047204)

Dear Administrator Regan:

PLEASE FINALIZE the regulations AGAINST six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome FIRST step to protecting our families and communities from the scourge of PFAS.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm. AS YOUR CONSTITUENT, I'M ASKING YOU TO DO SOMETHING ABOUT THIS!!!!!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Derek Benedict (Doc. #2914, SBC-047205)

Dear Administrator Regan:

How long is too long before we take stringent measures on ensuring that our next generation has a healthy environment to grow up in? We've known the science for over five decades, but very little has been done to make our country cleaner for our children.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Saundra Hodges (Doc. #2915, SBC-047206)

Dear Administrator Regan:

it is unfathomable that water, that is so vital to our survival is not yet subject to appropriate controls. A sincerely appreciate the action taken by the EPA to address the insufficient scrutiny that has been applied to PFAS. The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mel Ginsberg (Doc. #2916, SBC-047207)

Dear Administrator Regan:

I urge you to support the strongest regulations possible to protect us from PFAS chemicals.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Richard Swartz (Doc. #2917, SBC-047208)

Dear Administrator Regan:

We drink a lot of water, water that makes up a considerable portion of our body's weight. Now, water is increasingly contaminated by chemicals WE have allowed to infiltrate our aquifers. Stopping now would not magically "cleanse" our most important liquid, but would limit the extent of the pollution - which will otherwise continue to grow. The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Karen Mallam (Doc. #2918, SBC-047209)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

I am particularly concerned as I live in NC, where most of our water has been found to contain PFAS. I've already had thyroid cancer and had to have my thyroid removed.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Robert Williams (Doc. #2919, SBC-046186)

Forever affected. No escape.

EPA Response: Please see section 1.3 of the EPA response in this *Response to Comments* document.

Susan Hille (Doc. #2920, SBC-047210)

Dear Administrator Regan:

Considering all the chemicals that saturate our communities getting the worst ones out of the environment or at least preventing more from entering would help reduce disease and illness.

Rather than just limiting to 6 PFAS chemicals perhaps banning whole classes of them so there are fewer to contend with would make controlling them easier. Don't let industry control you.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Dawn Williams (Doc. #2921, SBC-047211)

Dear Administrator Regan:

We are ALL affected. Please do everything you can to get rid of the PFAs in our drinking water. The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Louan Fisher (Doc. #2922, SBC-047212)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

As my husband and I age we moved from our rural home and delicious well water to a development with water coming from a water treatment plant. We are concerned with ALL of the chemicals we are tasting in our water now and concerned about those we can't taste. PFAS are dangerous compounds that must be regulated now to keep us and our grandchildren safe! Please do what's right and require companies to reduce the use of PFAS and to disclose the amount of PFAS in their products.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Dion Duckett (Doc. #2923, SBC-047213)

Dear Administrator Regan:

We NEED EPA's proposed national drinking water regulations for six PFAS chemicals NOW.

It is a welcome first step to protecting our families and communities from the scourge of PFAS - infamous for their extreme persistence, widespread pollution and linked to cancer, immune suppression, and developmental harm.

Well Fracking Chemicals MUST BE NEXT! We are literally pumping PFAS into our water supply.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Carmen Rodriguez (Doc. #2924, SBC-047214)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and also widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS.

This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS. Thank you and thank you for reading -------- this.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lynne Grifo (Doc. #2925, SBC-047215)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is an essential and welcome first step to protecting our families and communities from the scourge of PFAS.

As I have been learning from many reputable scientific sources over the past several months, PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm. I am old and so I worry most about the exposure of children and youth over their lifetimes.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS. Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Melinda Merryfield-Becker (Doc. #2926, SBC-047216)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I spent my career working to protect groundwater in managerial roles at The Ohio EPA and the Los Angeles Regional Water Quality Control Board, and later lived in Minnesota where multiple municipal drinking water wells were closed because of PFAS contamination. We cannot afford to write off these important drinking water supplies, nor should we turn a bind eye to the potential health impacts of drinking water with lower concentrations of PFAS contaminants. The persistence of these pollutants is such that the only way to address future concerns is to prohibit manufacturing.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Dianne McCauley (Doc. #2929, SBC-047217)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal

would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

In conclusion, I honestly cannot believe that I have to send this letter in the 21st century to a first world country. For decades we have known the dangers of PFAS and yet, I still have to write a letter begging the government to fix the problem. This is embarrassing, disgraceful, and shameful!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Leslie Leslie (Doc. #2930, SBC-047218)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.please do the right thing. We have such a huge body burden to carry into the future ! Please help us have healthy children and a healthy planet.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mara Factor (Doc. #2931, SBC-047219)

Dear Administrator Regan:

I live near the Woburn, MA superfund site featured in the 1998 movie "A Civil Action". While the area has gone through mitigation, not all of the contaminated materials can or have been removed so we do occasionally have high levels of unhealthy chemicals in our water.

Preventing the contamination to begin with would have eliminated the need for very expensive mitigation.

Let's learn from the past...

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Imagine how much easier and less expensive preventing PFAS contamination would be than to mitigate it in the future.

Thank you

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Emily Jennings (Doc. #2932, SBC-047220)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

PFAS chemicals are an issue where I live in Michigan. Our drinking water meets current EPA standards, but those standards are too low. My partner and I have a filter on our sink to remove them, which shouldn't be necessary. Not everyone can afford a filter. Clean water should be free for everyone.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Hallie Bulleit (Doc. #2933, SBC-046492)

Dear Administrator Regan:

I am writing today to express my concern about PFAS in drinking water. I was encouraged to hear about the EPA's proposal for new national drinking water regulations for six PFAS chemicals, PFAS are already lurking in so many of the products we use & clothes we wear; Americans should not be worried about ingesting these disease-causing chemicals in our water.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Judith Porter (Doc. #2934, SBC-047221)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for millions in communities where drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joshua Kneidl (Doc. #2935, SBC-047222)

Dear Administrator Regan:

Thank you for proposing national drinking water regulations for several of the "forever" PFAS chemicals. They are an invisible scourge to public health.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kenneth Owens (Doc. #2936, SBC-047223)

Dear Administrator Regan:

I welcome the EPA's proposed national drinking water regulations for six PFAS chemicals as a first step to protecting consumers from PFAS.

PFAS are infamous for their extreme persistence and widespread presence in drinking water. They're linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would improve drinking water quality for millions of people in communities across the U.S. where PFAS.contamination is present. This proposal, if implemented, would prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations for six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Donna Wilson (Doc. #2937, SBC-047224)

Dear Administrator Regan:

Please stop letting companies poison us. Companies should have to prove a substance is safe before they can use it. Poisoning everyone and everything and than banning it (while better than nothing) really is ridiculous

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2938, SBC-046274)

I am writing in strong support of the proposed PFAS drinking water regulations. These regulations will prevent a great deal of human suffering and death. In addition, even a cost-benefit analysis that--by its own admission--underestimates or fails to monetize many of the benefits of these regulations, finds positive net benefits at a reasonable discount rate. Passing this regulation is a no brainer.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Eric Thompson (Doc. #2939, SBC-047225)

Dear Administrator Regan:

The idea that dangerous chemicals that are extremely resistant to breakdown should be released into our environment strikes me as a very questionable practice. Anything that is proven harmful to life should not be even allowed to be produced. The fact that this harm could last longer than we will makes that fact even more critical.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jim Powell (Doc. #2940, SBC-046439)

Dear Administrator Regan:

Your agency's proposed national drinking water regulations for six PFAS chemicals are a great start for protecting everyone from PFAS.

Please finalize the regulations as soon as possible so we can start getting rid of these and other PFAS.

Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kenneth Dunn (Doc. #2941, SBC-047226)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sheryl Kerby (Doc. #2942, SBC-047227)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

It should not be too hard to invent something that neutralizes the PFA's as we are the most intelligent nation in the world but it begs the question, how much will it cost? Answer: What price do you put on Human Life? Perhaps your own lives and those of your loved ones? Look beyond the money and look toward the future.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Benita Coffey (Doc. #2943, SBC-047228)

Dear Administrator Regan:

What we take into our bodies makes a difference...a huge difference to our health.. Please pay close attention to what follows and represent us , the common people who count on your service.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal

would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Patricia LeBeau (Doc. #2944, SBC-047229)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Keep chemicals out of our drinking water except fluorine which strengthens teeth and those that protect us from harmful bacteria or viruses.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Amy Vanderbilt (Doc. #2945, SBC-047230)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal

would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I respectfully urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS - AND - require manufacturers to begin listing all forms of PFAS and similar "forever chemicals" in their production and products.

The EPAs groundbreaking new regulations on six highly toxic PFAS chemicals found in drinking water is a crucial first step toward tackling this massive public health crisis – but we need the EPA to do more to protect against PFAS.

Unfortunately, PFAS are almost impossible to avoid. They are found in our homes, our offices, our supermarkets, our toiletries and cosmetics – practically everywhere! What's worse, manufacturers don't have to disclose to consumers that they're using them. It needs to stop!!!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Robert Commission (Doc. #2946, SBC-046559)

The Environmental Protection Agency (EPA) is committed to using and advancing the best available science to tackle per- and polyfluoroalkyl substances (PFAS) pollution, protect public health... you mean your committed to forcing other people against their will to tackle the supposed problem.

Just because a person in St Paul Minnesota area gets liver cancer in an area of elevated PFAS in the drinking water does not mean there is a connection between the water and the cancer. Thousands of others ingested the same water without getting the same cancer and thus common sense would say it is not from the PFAS.

99 percent of the water delivered to the customers is not ingested so it should not need to be treated for PFAS at the water utility but it should be the customers responsibility to remove it if the levels are deemed to be uncomfortable for them. The cost to remove the PFAS chemicals far exceeds the provable benefit and EPA is charged under the safe drinking water act with considering this.

The EPA is unconstitutional and should not be protecting public health. The EPA is a political weapon of the tyrants with an agenda that is not based on science or truth. EPA has twisted the definition of science and many other words.

EPA Response: Generally, please see section 1.3 of the EPA response in this *Response to Comments* document.

The EPA disagrees with this comment. First, the comment states that the commenter believes there is a general question about whether PFAS exposure in drinking water is linked to cancer. The EPA disagrees with this statement. The EPA has shown that the best available science supports the regulation of six PFAS, taking into consideration toxic effects as well as feasibility. The EPA has considered PFAS health effects information, evidence supporting dose-additive health effects from co-occurring PFAS, as well as national and state data for the levels of multiple PFAS in finished drinking water. Current scientific research and available evidence have shown the potential for harmful human health effects after being exposed to some PFAS. Drinking water is one of several ways people can be exposed to PFAS, as seen in drinking water data, and can be found together and in varying combinations as mixtures. Please see the PFAS NPDWR FRN for continued explanation of how the PFAS NPDWR meets statutory requirements and fulfills SDWA's purpose to protect public health by addressing contaminants in the nation's public water systems. For additional information specifically regarding health effects of PFAS, please see the Toxicity Assessments in the supporting documents.

Second, the commenter makes statements about the percentage of "water delivered to the customers [that] is not ingested" but not does not cite or provide underlying data or rationale for this factual assertion. Therefore, EPA is unable to respond to this part of the comment due to insufficient information provided by the commenter.

Third, the commenter states that the cost to remove PFAS exceeds the benefits. EPA disagrees with this statement. In the PFAS NPDWR FRN, the EPA provides how the agency has effectively evaluated the benefits and costs of the rulemaking as specified under the SDWA HRRCA requirements and the EPA Administrator has determined that the benefits of the NPDWR justify the costs. Please see section 13 of the EPA response in this *Response to Comments* document for additional discussion on the EPA's benefit and cost analysis. For those reasons, the EPA disagrees with the commenter's statement because the EPA determined that the benefits of the PFAS NPDWR justify the costs as required by the SDWA. Also, the EPA notes that the commenter does not cite or provide underlying data or rationale to support this statement.

Lastly, for topics outside the scope of this PFAS NPDWR, such as the commentors opinions of the agency, please see section 15 of the EPA response in this *Response to Comments* document.

Sarah Prados (Doc. #2947, SBC-046872)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Sarah Prados

Nokesville, VA 20181

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Julio Navarro (Doc. #2949, SBC-047231)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. This idea is reinforced by Dr. R. Vogl in his book, Principle of Ecological Principles, " Water is a key or limiting factor in the occurrence and distribution of organisms and ecosystems in soil, air and water" Dr. R. Vogl, Primer of Ecological Principles. 2014. What this represents is the fact that water is the important contributor to your well being, apart from warmth. Therefore this regulation would be directly benefiting not only our generation but the children of our children.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Linda Henson (Doc. #2950, SBC-047232)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. These illnesses and their causes are insidious, and their causation by PFAS are difficult to document. Yet scientific evidence supports the discovered chain of evidence. And would be extremely difficult to provide post-release remediation over large populations. So we must rely on preventing their release into our potable water sources.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. In response to the commenter regarding the scientific evidence for PFAS causation and illnesses, the EPA notes that it has considered PFAS health effects information, evidence supporting dose-additive health effects from co-occurring PFAS, as well as national and state data for the levels of multiple PFAS in finished drinking water. Current scientific research and available evidence have shown the potential for harmful human health effects after being exposed to some PFAS. Drinking water is one of several ways people can be exposed to PFAS, as seen in drinking water data, and can be found together and in varying combinations as mixtures. To clarify, this PFAS NPDWR is for removing PFAS in drinking water, and this rule does not regulate the release of PFAS into drinking water sources.

Mark Steuer (Doc. #2951, SBC-046509)

Dear Administrator Regan:

I support EPA's proposal to protect national drinking water supplies for six PFAS chemicals as a step toward protecting our communities from these persistent and harmful chemicals, which are linked to a litany of harmful health and environmental effects.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Matthew Explosion (Doc. #2952, SBC-047233)

Dear Administrator Regan,

Yeah okay so the message below is the canned NRDC message about PFAS, but I read and agree with everything here. We need the government's help to protect our selves and our families from these chemicals which, by all accounts, are quite dangerous. Given how long they take to break down, the longer we wait, the more danger we'll be in.

Thanks,

-Matt

NRDC message:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Thanks,

-Matt

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jean Schulz (Doc. #2953, SBC-047234)

Dear Administrator Regan:

I live in a state and a county that has open meetings of the Board of Public Utilities.

For over 2 years I monitored this Board for our chapter of The League of Women Voters. Because the meetings were open to the public, I, and any other citizen, could hear and see what was going on, what decisions were being made and how they were being paid for.

That does not happen in many states and counties. The EPA MUST oversee its regulations and standards in those areas where citizens do not know their areas may be harmed by regulators trying to save money at the citizens expense. (or maybe through ignorance.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lynne Atherton-Dat (Doc. #2954, SBC-047235)

Dear Administrator Regan:

We, the American Public, count on you to protect us from dangerous chemicals that shorten our lives and/or sicken us.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome First step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Hannah Lee (Doc. #2955, SBC-047236)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

All over Wisconsin city wells have had to be shutdown due to PFA pollution. Here in Madison, which prides itself on its beautiful four lakes, beaches can't open because the water is unswimmable due to PFAS. Fish from these lakes aren't safe to eat. And Madison is relatively clean compared to other cities in Wisconsin; ALL the wells in Wausau have been shut down!

This cannot continue. We are being poisoned by polluters, huge among them the U.S. Military.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Betty Merten (Doc. #2956, SBC-046489)

Dear Administrator Regan:

I'm writing in strong support of the EPA's proposed national drinking water regulations for six PFAS chemicals, an overdue first step toward making our water safe to drink.

As you know, PFAS have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm, and they persist!

I urge you to finalize without delay the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

Betty A. Merten

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Georgia Hickson (Doc. #2957, SBC-047237)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

I have been able to smell the chlorine the our city has added to our water. It is effecting my family. We have dry skin, dry hair, etc. I can't imagine what it is doing to our bodies. Our animals drink it all day long and it is harmful to them as well.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mary Seiden (Doc. #2958, SBC-047238)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Fritz Stumpges (Doc. #2959, SBC-047239)

Dear Administrator Regan:

I'm VP of a small water company and am trying to get our water test schedule to include Phthalates. So far it's not required. We had to install two huge "rubber bladders" lining our reservoirs to protect from animal bacteria but I worry about the Phthalates more! Glad we don't have PFAS! Please help with both of these regulations.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joshua Hassol (Doc. #2961, SBC-047240)

Dear Administrator Regan:

Even in today's divisive political climate, clean, safe drinking water should be something everyone can agree is important.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

I urge you to implement new rules to control and eliminate PFAS in our water.

Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Fred Cressman (Doc. #2962, SBC-047241)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS. The only way to do this is to ban PFAS. We banned DDT because of birds, we can ban PFAS because of people!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

John Fitzgerald (Doc. #2963, SBC-047242)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

I also urge you to require statea to report on the extent of PFAS contamination of all lands and waters by using a selective sampling method and tracking.

Please also report this year on your potential options for trade controls and liability and recovery from mfgrs as well as options if the US were to Ratify the treaties addressing such hazardous materials.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Blythe Clark-McKitrick (Doc. #2964, SBC-046873)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Blythe Clark-McKitrick

Portland, OR 97214

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Gena Cline (Doc. #2965, SBC-046874)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Gena Cline

Louisville, CO 80027

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Elaine Genasci (Doc. #2966, SBC-046875)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Elaine Genasci

San Luis Obispo, CA 93405

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Carolyn Pettis (Doc. #2967, SBC-046876)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Carolyn Pettis

Santa Clarita, CA 91350

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Fran Garb (Doc. #2968, SBC-046877)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Fran Garb

Cedar Knolls, NJ 07927

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Harvey Rosen (Doc. #2969, SBC-046878)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge

you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Harvey Rosen

Santa Fe, NM 87505

hrosen@harveyrosenlaw.com

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jennifer Russell (Doc. #2970, SBC-046459)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country.

Please finalize them as quickly as possible so our drinking water is safe from these dangerous chemicals.

Sincerely,

Jennifer Russell

Walnut Creek, CA 94595

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Nancy Campbell (Doc. #2971, SBC-046894)

Dear Michael Regan,

I'm grateful to you for having both the foresight and courage to take this first step in regulating dangerous PFAS in our drinking water!

We've known for decades that PFAS poison drinking water.

And the result is devastating.

Millions of Americans have increased rates of cancer, developmental and reproductive harm, and other serious diseases. THIS is why your actions are so vital.

EPA's proposed drinking water standards will give critical, long overdue protections against six of these toxic chemicals.

I STRONGLY SUPPORT THE PROPOSED STANDARDS.

I ALSO URGE EPA TO FINALIZE THEM ASAP.

PFAS are a large, long-lasting, and highly dangerous class of chemicals.

They're called "forever chemicals" for a very good reason!

PFAS stay in the environment for hundreds of years, build up in our blood and organs, and keep causing harm decades after they are released into the environment.

They have:

-- contaminated drinking water for approximately 200 million people

-- contaminated the blood of nearly every person in the United States, including newborn babies who are exposed in utero.

But in spite the serious health risks created by PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule will:

-- guarantee safer drinking water for communities from coast to coast

-- save thousands of lives

-- prevent tens of thousands of serious PFAS-related illnesses each year.

The EPA has acknowledged the cumulative impacts on the millions who have been exposed to multiple PFAS.

By issuing this proposal, EPA is one step closer to fulfilling its commitment to start regulating PFAS in drinking water -- a commitment made under the 2021 PFAS Strategic Roadmap.

I URGE YOU -- MOVE QUICKLY TO:

1. finalize these standards

2. implement a rule that is the most health-protective

3. resist industry's efforts to weaken the standards.

Sincerely,

Nancy Campbell

Kansas City, MO 64112

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sara Roderer (Doc. #2972, SBC-046883)

Dear Michael Regan,

As a rural senior citizen voter and ardent supporter and defender of our planet and anything that harms or damages humans, animals, our land, air or water. Please continue the fight to regulate PFAS in our drinking water. Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Sara Roderer

Heathsville, VA 22473

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joanne Conti (Doc. #2973, SBC-046882)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Joanne Conti

Sheffield, MA 01257

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Helene Zera (Doc. #2974, SBC-046476)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. And thank you for not stopping there!

You have a tough job fighting against wealthy and entrenched capitalist interests. But wouldn't it be deeply significant and appreciated if you could actually take a stand against them to purify our water supply and thereby save lives?!

Best Wishes,

Helene

Sincerely,

Helene Zera

New York, NY 10011

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Pamela Weaver (Doc. #2975, SBC-046881)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

The time to act is now! Please move as quickly as possible on this. For years we have known that many lakes, gravel pits and people's wells have been contaminated around Fairbanks, North Pole and Salcha. And please, do not allow north slope drillers in Alaska be allowed to continue using these chemicals.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment

under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Pamela Weaver

Fairbanks, AK 99709

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Gregory Grant (Doc. #2976, SBC-047667)

Our (The People's, not industry's) EPA needs to be stopping this pollution from the noted 6 PFAS chemicals and much, much more to protect everyone's health from the polluters. The polluters will not and, indeed, cannot voluntarily accomplish this on their own, since any one polluter acting on its own would simply be putting themselves out of business, to be replaced by some other business/source that has done nothing to avoid polluting our water.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Melissa Carlson (Doc. #2977, SBC-046879)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water.

FOREVER IS TOO LONG FOR A DANGEROUS CHEMICAL TO LAST IN DRINKING WATER. PLEASE FINALIZE THE STANDARDS QUICKLY. THERE IS NO NEED TO DUMB DOWN AND SICKEN THE HUMAN POPULATION, FOR SHORT TERM PROFIT OF A VERY FEW.

EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Melissa Carlson

Rochester, NY 14610

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Diego Carrasco (Doc. #2978, SBC-047312)

The Environmental Protection Agency (EPA) is requesting the public's input on the proposed rule about rules regulating six PFAS also known as chemicals that have been found to be harmful to humans since the 1940s. I think that the proposed rule for requiring the state and city public water systems to monitor these PFAS and notify the public when the levels of drinking water exceed the proposed standard is an excellent proposal that should have been created a long time ago. Giving the public access to the PFAS analytic tool will be very beneficial because it gives individuals information to make their own decisions. Governmental agencies should use this situation with the PFAS as a template for what should be done every time a chemical compound such as PFAS is created. This would allow them to have more control over the regulations and have updated data readily available for the citizens of this country.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

K Danowski (Doc. #2979, SBC-046546)

I urge EPA to swiftly implement drinking water protections against PFAS contamination.

We need national standards for PFAS. Expanding protections to six PFAS, as well as the combination of different PFAS, will protect our drinking water from this contamination and keep countless Americans safe from enduring the health risks associated with these dangerous substances.

PFAS, which are used to manufacture a range of goods, break down very slowly over long periods of time and instead accumulate in humans, wildlife, aquatic life, plants, and our environment. This contamination poses a direct threat to our health and our ecosystems. PFAS are pervasive contaminants that are linked to serious health conditions such as cancer, liver and kidney disease, reproductive problems, immunodeficiencies, and hormonal disruptions.

PFAS' ubiquity is why we need to act fast and decisively. Finalizing these regulations would protect drinking water for countless Americans.

I urge your support for these badly-needed regulations to better protect humans and our rivers, oceans, lakes, and wildlife from PFAS contamination.

Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Timothy Bardell (Doc. #2980, SBC-046880)

Dear Michael Regan,

I live in Minnesota, not far from the large plume of PFAS in ground water contaminated by 3M. It amazes me that we continue to allow corporations to introduce a new chemical into our environment, and eventually our bodies, without first proving that it is safe.

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every

individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Timothy Bardell

Minneapolis, MN 55416

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kathryn Wild (Doc. #2981, SBC-046903)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water and continuing to resist big industry's efforts to elevate profit over the heath of our blue planet.

Respectfully

Sincerely,

Kathryn Wild

San Diego, CA 92126

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Debra Dunson (Doc. #2982, SBC-046904)

Dear Michael Regan,

I am an organic chemist who is concerned about hazardous PFAS chemicals in our environment. I fully support the EPA's proposal to set concentration limits for PFAS in drinking water. 3M,

the world's largest manufacturer of PFAS have announced "3M will: Exit all PFAS manufacturing by the end of 2025: 3M will discontinue manufacturing all fluoropolymers, fluorinated fluids, and PFAS-based additive products". This is clear evidence that industry finally acknowledges that PFAS contaminates drinking water supplies of millions of people across the country. Furthermore, due to our exposure over decades of household use, we have ingested and breathed the vapors of these dangerous chemicals. Accumulation of PFASs in the human body has been correlated with the risks of disease and deformities, including various types of cancer and birth defects. Despite the serious health risks from PFAS, the latest EPA proposal is the first to impose federal limits on PFAS levels in drinking water. Please follow through and finalize the rules to institute long overdue protections against six PFAS chemicals found in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Debra Dunson

Spring Hill, TN 37174

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Melissa Quesinberry (Doc. #2983, SBC-047669)

Why do we have to ask the EPA to protect the environment and all life forms Keep up with the science and stop protecting corporate polluters and the chemical industry. Companies can adopt a B-corporation model of conscious capitalism or become obsolete. Our very survival and the future depends on how willing and courageous the EPA is to create and hold companies to a higher standard that does not harm ecological systems and life forms. We know have a better understanding of the impact of plastic on our oceans and our bodies. Companies managed to create and sell their products before we created plastic. This is not up for debate. Respect the science, not the dollar bill, and do your damn job!!

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-

saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Gay Mikelson (Doc. #2984, SBC-046905)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

Sincerely,

Gay Mikelson

Iowa City, IA 52246

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

David Cagle (Doc. #2985, SBC-046906)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. I strongly support the proposed standards, and I urge EPA to finalize them as quickly as possible.

I urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

David Cagle

Jacksonville, FL 32277

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Miriam Johnson (Doc. #2986, SBC-046907)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. I strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals,"PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Miriam Johnson

Salem, OR 97317

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Virginia Lee (Doc. #2987, SBC-046908)

Dear Michael Regan,

I am writing as a

- Utah Republican precinct chair (SLC074),

- biologist (1977 BS Biology, magna cum laude, Phi Beta Kappa, Utah Secondary Teaching Certificate 1977-1992),

- lawyer (1979 JD),

- member of the Union of Concerned Scientists, and

- member of Patriotic Millionaires.

Thank you for taking the first step to regulate PFAS in drinking water.

For decades, PFAS have contaminated drinking water supplies for millions of people across the country.

Contaminated drinking water has resulted in

- increased rates of cancer,

- developmental and reproductive harm, and

-mother serious diseases.

EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals.

We strongly support the proposed standards.

I urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals.

Often called "forever chemicals,"PFAS

- persist in the environment,

- build up in our blood and organs, and

- continue to cause harm decades after they are released into the environment.

PFAS have contaminated drinking water supplies

- for approximately 200 million people,

- and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero.

Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast.

By establishing strong limits on six widely detected PFAS, the proposal would

- save thousands of lives, and

- prevent tens of thousands of serious PFAS-related illnesses each year.

The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS.

By issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water.

I urge you to quickly finalize these standards.

I urge EPA to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Virginia Lee

Salt Lake City, UT 84105

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lorraine Wilson (Doc. #2988, SBC-046909)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water after decades of contamination resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. Your proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. I strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

Despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast by establishing strong limits on six widely detected PFAS, saving thousands of lives and preventing tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize these standards and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Lorraine Wilson

Lafayette, CO 80026

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Andrea Reimers (Doc. #2989, SBC-046910)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals,"PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

My cousin in Wilmington, NC, has been directly impacted by PFAS in the water. She had to have a large lump on her throat surgically removed, though she is only middle aged. (PFAS are known to cause thyroid problems.) Her Wilmington friends, also her age, are experiencing similar health threats.

We're talking about parents trying to raise their children.

Please protect families, not polluters.

Sincerely,

Andrea Reimers

Granite Falls, NC 28630

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mike Hobbs (Doc. #2990, SBC-046911)

Dear Michael Regan,

Our forefathers established a government 'of the people, by the people, for the people.' Not just some of the time but at all times. Your agency is the most important of all regulatory bodies. Without a healthy, sustainable ecosystem ALL other issues will not matter. Please protect US from the immoral, unscrupulous practices of the corporations that threaten our very lives.

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals,"PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

mike hobbs

Hanford, CA 93230

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lucinda R. Murphy (Doc. #2991, SBC-046912)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water.

I am in strong support of your proposed rule to reduce PFAS in drinking water. As a lung cancer survivor I am particularly concerned with the presence of any chemicals likely to cause cancer. Improving the quality of drinking water is an excellent step in the right direction.

For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals,"PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Lucinda R Murphy

Baltimore, MD 21214

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Barbara Bogart (Doc. #2992, SBC-047243)

Dear Administrator Regan:

We work hard here in Elgin to keep our water clean -- and to keep it available period. Many publications and organizations are currently seeking guidance and assistance with "forever"

chemicals." The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Vicki Berglund (Doc. #2994, SBC-047244)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from deadly, persistent PFAS.

I urge you to quickly finalize the regulations of the identified PFAS chemicals and implement a rule that protects the health of citizens and communities.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Norman Norvelle (Doc. #2995, SBC-047671)

I am a retired industrial chemist and a past longtime member of the American Chemical Society. In the last 50 years the number of new materials and compounds we have developed are amazing. But many of these are dangerous to us and the environment. Please develop new limits on these materials and especially on PFAS.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Stephanie Hysmith (Doc. #2996, SBC-046613)

Dear Assistant Administrator Fox,

It's inconceivable that the SCOTUS found in favor of West Virginia's Attorney General to undermine your authority. Patrick Morrissey has never had the health of our citizens in mind as he does all he can to support industry.

I have been following the history of these forever chemicals since they were first discovered in early 2000s in Parkersburg, WV coming from the DuPont Teflon manufacturing facility. At the time, I lived in Athens County, Ohio, one county north of Meigs whose residents were tested for C8 in their blood and whose health is carefully monitored. It's absolutely shameless that DuPont could get away with this.

My clipping file of newspaper articles includes all the findings and manipulations by DuPont at the time which have been meticulously documented and summarized in more recent articles and dramatized in the film, "Dark Waters."

Now that I'm living in West Virginia, I'm furious that these chemicals are still polluting the drinking water of WV citizens. It's dangerous and unforgivable.

Thank you for the opportunity to comment on the EPA's proposed National Primary Drinking Water Regulation for six per- and polyfluoroalkyl substances (PFAS). I support the EPA's proposal to set strong, science-based drinking water standards and commend the EPA's recognition that both individual PFAS and chemical mixtures of PFAS threaten human health. PFAS-contaminated water has harmed the health of West Virginians for decades; this is a critical and long overdue step to protect our public health.

Again, thank you for the opportunity to add my comments.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Todd Snyder (Doc. #2997, SBC-046614)

I support EPA's plans to regulate and limit harmful PFAS in drinking water and the environment.

Considering the potentially devastating health impacts of PFAS exposure, it is unacceptable for these chemicals to be released into and remain in the environment at unsafe levels (https://salud.to/PFASbm).

While researchers have made strides in destroying PFAS in water, we must address PFAS contamination at the source with enforced regulations, as even undetectable levels of PFAS can pose human health risks including damage to fetal growth and increased cancer risk (https://salud.to/pfasdes).

PFAS affect everyone but may impact some populations more than others. For instance, Latino families are more likely to live in neighborhoods where there is a lack of clean and safe drinking water (https://salud.to/nitrate) and where utility companies have less funding to meet community needs.

Therefore, environmental regulation of harmful PFAS is critical for all Americans, but especially those who are vulnerable to exposure, such as Latinos. I applaud EPA's proposed plans to regulate and limit PFAS chemicals in drinking water and the environment, which could help ensure a healthier future with less exposure to potentially harmful chemicals.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. Please see section 13.4-13.9 of the EPA response in this *Response to Comments* document that outlines the quantifiable and nonquantifiable benefits of this NPDWR that may address the commenter's concern of low levels of PFAS that can pose human health risks. In response to the comment that states that "environmental regulation of harmful PFAS is critical for all Americans, but especially those who are vulnerable to exposure", as part of its environmental justice analysis for this regulatory action, the EPA evaluated the distribution of baseline PFAS exposure in drinking water across demographic groups. For additional discussion on this topic, please see the EPA's EJ analysis in section 8 of the EA (USEPA, 2024a) and section 14.10 of the EPA response in the *Response to Comments* document.

Laurie Seeman (Doc. #2998, SBC-047279)

These comments are in regard to Docket ID: EPA-HQ-OW-2022-0114.

·I live in Rockland County, where nearly all of our drinking water is contaminated with toxic PFAS chemicals.

I have been aware ir rhis threat since it was first announced and seen the tremendous effort by countless people; citizens, researchers, government officials, organizational leaders to tackle this dilemma and to create a restoration response and pathways for a safe and healthy water and our future. It is more than impressive how cohesive this shared effort has been. And now the the best steps to take are before you, awaiting your vote and support. Please proceed with the proposed plan and begin the wide spread change. This will by virtue of best right action undoubtedly lead to other beneficial actions for human and planetary health going forward.

Many of our wells and reservoirs are contaminated with PFAS at levels below the current New York State drinking water standards. That means that filtration will not be required for the majority of Rockland's contaminated wells -- unless the draft EPA regulations are passed.

·Many of Rockland's drinking water sources are contaminated with multiple PFAS chemicals, possibly resulting in additive or synergistic health impacts. But New York State currently regulates only two chemicals. The draft EPA regulations are written for combined standards, which would require many more of these chemicals to be cleaned up.

·The New York State Dept. of Health is waiting for EPA's finalized regulations. Many other states may be doing the same. If EPA's draft regulations are passed, it will make it possible for the states to build on EPA's science and direction to regulate even more PFAS.

·These regulations will send a strong signal to the chemical industry to invest in safe alternatives now.

·There are over 12,000 PFAS chemicals in all. Moving forward, EPA should extend these regulations as quickly as possible to cover PFAS chemicals as a class.

·EPA should immediately halt the approval of all new PFAS.

·While the costs of filtration and disposal are high, those costs are far outweighed by the billions of dollars in healthcare costs caused by the health impacts of PFAS chemicals.

Thank you for your consideration of my thoughts and concerns. I am hopeful that together we can find the best ways forward.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jacquelyn Drechsler (Doc. #2999, SBC-047280)

We are very concerned about the level of toxic PFA's and PFOA's that contaminate our water here in Rockland County and now have an extra concern regarding the tiny PFA's that escape capture, which we understand are even more dangerous to people.

Industry always seems to find a way around regulations, for instance in creating alternatives to the PFA problem, which creates more problems.We can not allow the industry lobbyist to stop the EPA from instituting strong, strict standards for the health of the public.

Where I live in Rockland County, were are tied to Veolia Water, which took over from Suez - neither company has moved forward with the remediation plan for PFA's - always citing "supply chain issues".

PFA's - even at the lowest detectable levels are extremely dangerous especially for the health of fetuses, babies, children, pregnant women, immuno-compromised people and elders.PFA's are known carcinogens: birth defects, several types of cancer, auto-immune illnesses and fertility issues. The health consequesnce are enormous - and carries an enormous cost and burden to healthcare systems and individuals pocket books.

We need safe water in Rockland County and we only have wells, aquifers and Lake DeForest - we are not allowed to get water from outside of our borders.

Please do not let your draft regulation get watered down. Your draft regulations will promote safer drinking water standards that must be adhered to, to ensure less illnesses and diseases. If this draft does not pass, our horrible water company, Veolia - which wants a rate hike of 14% will not be forced to clean up our water.

The combined standard the EPA is proposing will really make a difference to public health. We know it is not possible in this exact moment in time to make regulations for all PFA's - which include up to 12,000 PFA's, but we feel that your regulations should be extended to cover ALL PFA's.

We also believe that the EPA should stop allowing any new PFA's to make their sneaky ways into our finaite water supply.

We appreciate this opportunity to comment.

Jacquelyn Drechsler and

Jocelyn DeCrescenzo

Valley Cottage, N.Y. 10989

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Victoria Eells (Doc. #3000, SBC-046913)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals,"PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Victoria Eells

Gold Beach, OR 97444

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Elaine Mayer (Doc. #3001, SBC-046914)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. Quickly finalize these standards, and resist industry's efforts to weaken them.

Sincerely,

Elaine Mayer

Minneapolis, MN 55447

mayerelaine57@gmail.com

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Stuart Knappmiller (Doc. #3002, SBC-046915)

Dear Michael Regan,

We both worked for 3M. I used DuPont polypropylene to make facemask and oil sorbent material. I wore a mask in our pilot plant room where the air was full of asbestos like white particles. My wife computerized the process I controlled with my hands and mind. My father polluted our rural church's well applying anhydrous ammonia to corn fields. I'm sure he would

have wanted to stop if he knew the damage he was creating while earning money to pay for our farm.

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals,"PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Stuart Knappmiller

Saint Paul, MN 55106

stuartknappmiller49@hotmail.com

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Fred Davis (Doc. #3003, SBC-046916)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS has contaminated drinking water for millions across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed

drinking water standards would provide essential and long overdue protections against six of these toxic chemicals. We strongly support the proposed measures and urge EPA to finalize them as quickly as possible.

PFAS is a significant, long-lasting, and hazardous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the atmosphere. PFAS has contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies exposed in utero. Yet despite the severe health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing solid limits on six widely detected PFAS, the proposal would save thousands of lives and prevent thousands of PFAS-related severe illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities that are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to finalize these standards quickly and to implement a most health-protective rule, resisting the industry's efforts to weaken them.

Respectfully I remain

FRED R DAVIS, ("MORTAL"- As Are We All)

Sincerely,

FRED DAVIS

Tampa, FL 33613

dfred0454@gmail.com

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Daniel Rostan (Doc. #3004, SBC-047353)

Because my health and that of my family and my neighbors will be affected by the outcome of regulations on this matter I write in strong support of the EPA draft regulations proposed for six PFAS chemicals. I urge you to finalize these rules as quickly as possible. In Rockland County, New York where I live, nearly all of our drinking water is contaminated with PFAS chemicals. Many of those wells and reservoirs are contaminated with PFAS at levels below the current New York State drinking water standards which means that unless the draft EPA regulations are passed filtration will not be required for the majority of Rockland's contaminated wells. If the draft EPA PFAS regulations are adopted unchanged, many more of Rockland's water sources

will be cleaned up, making our water supply far safer. Many of Rockland County's drinking water sources are contaminated with multiple PFAS chemicals. The combination of multiple PFAS could be resulting in additive or synergistic health impacts on Rockland's residents. But New York State currently regulates only two of these chemicals. The draft EPA regulations are written for combined standards (hazard index), and therefore make human health a higher priority than easy-to-meet regulations. The draft EPA regulations therefore would require many more of these chemicals to be cleaned up. The New York State Dept. of Health is waiting for EPA's finalized regulations. The Dept. of Health is required by law to regulate 23 additional PFAS, but they are waiting for the EPA regulations to be finalized first. Many other states may be doing the same. If EPA's draft regulations are passed, it will make it possible for the states to build on EPA's science and direction to regulate even more PFAS. The draft EPA regulations would require cleanup for no less than six (6) PFAS chemicals. The hazards posed by these six chemicals are well documented by dozens of human health studies and hundreds of experimental studies in animals. These regulations will send a strong signal to the chemical industry to invest in safe alternatives now. There are over 12,000 PFAS chemicals in all. Many scientists believe that the entire class of chemicals is toxic. We need a precautionary approach to protect human health and the health of the environment. Moving forward, EPA should extend these regulations as quickly as possible to cover PFAS chemicals as a class. EPA should immediately halt the approval of all new PFAS;

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kate Perkins (Doc. #3005, SBC-046917)

Dear Michael Regan,

Thanks for taking the first step toward regulating harmful PFAS in drinking water. For many decades, PFAS have contaminated the water supply for millions of people across the country, inflicting cancer, developmental and reproductive harm, and other serious diseases. The EPA's proposed standards for drinking water would provide important, overdue protections against 6 of these toxic chemicals. We strongly support the proposed standards and urge the EPA to finalize them as quickly as possible.

PFAS are a big, long-lasting, and highly dangerous class of chemicals. Also called "forever chemicals,"they persist in the environment, build up in human blood and organs, and continue to cause harm decades after they are released into the environment. They are in the blood of nearly every individual in the United States, including newborns who are exposed in utero. Yet despite the incredibly serious health risks associated with PFAS, there are currently NO federal limits on PFAS levels in drinking water!!

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of

lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Kate Perkins

Brooklyn, NY 11233

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Christina Bibeau (Doc. #3006, SBC-046918)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Thank you for finally taking action. I would believe that every person on the globe except for the industrial leaders and their stockholders would be unconditionally grateful. We never really have a say, but most of the world is trying to clean us up. Please help us. Big warning labels on all materials, pots, pans anything people would purchase. Give us a place and make it be known where to recycle old items. That is always lacking. I would be more than happy to assist if needed. I am grateful we are moving forward. Industry does not have a say. We want to live clean. If they know, shame on them. Let's go for it. Please also, make the public aware.

Sincerely,

Christina Bibeau

Mokena, IL 60448

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Susan Bishop (Doc. #3007, SBC-046919)

Dear Michael Regan,

Dear Administrator Regan

Please read this letter by starting at the end of it. I talk about a family member who is dead now because of of Teflon. Thank you!

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals,"PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to

multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

My sister-in-law, Kathy Novotny Bishop from LaGrange, Illinois got GIST cancer. It is a stomach cancer. She told us it was from "Teflon"and other similar compounds. She died so early in her life. Please don't continue to allow businesses to make and sell them! GIST is a horrible cancer!

Sincerely,

Susan Bishop

Louisville, AL 36048

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Bryan Burke (Doc. #3008, SBC-046615)

Dear Michael Regan,

We deserve clean drinking water!!

Sincerely,

Bryan Burke

Bellingham, WA 98229

EPA Response: The EPA acknowledges and appreciates this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Elizabeth Cramp (Doc. #3009, SBC-046920)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals,"PFAS persist in the environment, build up in our blood and organs, and continue to

cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

We must stop the scourge of cancer from killing Americans. My family members have been killed, young and old, by cancers. Where we know answers, like with PFA's, we must follow the science to protect people. Industry must understand that the EPA's job is to protect the environment for the safety and benefit of all Americans. This proposed rule will let them know that you will put people's safety over industry profits. Thank you.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Elizabeth Cramp

Clifton, VA 20124

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jean Naples (Doc. #3010, SBC-046616)

I am writing as a family physician and a public health/ environmental advocate that strongly opposes any exposure to or use of toxic PFAS or forever " chemicals.

Please be aware that PFAS or per- and polyfluoroalkyl substances, are a class of more than 12,000 chemicals that are used to make products water-, grease- and stain-resistant. I am very concerned because these chemicals have been found in crops, animals, water and even humans on farms where biosolids from sewage were used.

At this time, I strongly urge you to please designate perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS), including their salts and structural isomers, as hazardous substances. As companies have been producing and using these chemicals throughout the 20th century, it is imperative these chemicals are designated as hazardous so our country can begin

the clean-up process and hold industries and federal agencies accountable for the damage that has been done.

I am alerting you to the fact that industrial organizations are dumping toxic "forever chemicals" in our sewage. This sewage waste, is being turned into fertilizer and, according to recent findings, this sludge is spread on 20 million acres of land where farmers are growing our food.

I am very concerned because this practice represents a clear threat to our public health and protection for our environment, and this threat must stop now. It is crucial to understand that these PFAS chemicals never break down once they are sprayed in our environment.

Exposure to these chemicals has been associated with the development of immune issues, and birth defects. Any use of PFAS chemicals, which have been found in our drinking water, in cities across the US and in farm fertilizer, have been linked to the development of Hodgkin's lymphoma and kidney, testicular, prostate, breast, liver, and ovarian cancers.

I am very concerned about the fact that all Americans are exposed to PFAS in many aspects of our lives, through use of our everyday products, our food, and our drinking water. Please understand that these daily exposures to PFAS chemicals are placing us and our families at greater risk of development of serious disease. PFAS have polluted the tap water of at least 16 million people in 33 states and Puerto Rico, in addition to groundwater in at least 38 states. The water is contaminated through two main sources which include firefighting foam and industrial discharges.

At this time, I thank you for your consideration of my letter and my request. It is crucial for our country to hold the polluters accountable, especially as mounting research links PFAS to a wide range of health problems. For instance, PFAS have been linked to various types of cancer, birth defects, and have even been shown to reduce the efficacy of vaccines. Scientists have discovered unusual clusters of serious medical effects in communities with heavily PFAS-contaminated water, many of which are near military bases.

As a physician and public health advocate, I strongly urge you to please designate these toxic PFAS chemicals as hazardous and please remove them from exposure in our everyday lives!

Sincerely,

Jean Marie Naples, MD-Ph.D.

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA notes that many of the topics raised in this comment regarding PFAS regulation beyond drinking water under SDWA, including PFAS as a “hazardous substance” and PFAS in sewage, are outside the scope of this rulemaking. For more information on topics outside the scope of the final PFAS NPDWR, please see section 15 of the EPA response in this *Response to Comments* document. Section 15 of the *Response to Comments* document also discusses other actions that the EPA and other federal agencies are or may consider taking to address PFAS through a whole-of-government approach. In addition,

although outside the scope of this action, please see section 10.4.2 of the EPA response in this *Response to Comments* document for discussion of disposal of spent drinking water materials under possible future regulatory actions and costs.

Robert Tompkins (Doc. #3011, SBC-047281)

• I strongly support the EPA draft regulations proposed for six PFAS chemicals. I urge you to finalize these rules as quickly as possible. These comments are in regard to Docket ID: EPA-HQ-OW-2022-0114.

• I live in Rockland County, New York where nearly all of our drinking water is contaminated with toxic PFAS chemicals. Many of our wells and reservoirs are contaminated with PFAS at levels below the current New York State drinking water standards. That means that filtration will not be required for the majority of Rockland's contaminated wells -- unless the draft EPA regulations are passed.

• Many of Rockland's drinking water sources are contaminated with multiple PFAS chemicals, possibly resulting in additive or synergistic health impacts. But New York State currently regulates only two chemicals. The draft EPA regulations are written for combined standards, which would require many more of these chemicals to be cleaned up.

• The New York State Dept. of Health is waiting for EPA's finalized regulations. If EPA's draft regulations are passed, it will make it possible for the states to build on EPA's science and direction to regulate even more PFAS.

• These regulations will send a strong signal to the chemical industry to invest in safe alternatives now.

• There are over 12,000 PFAS chemicals in all. Moving forward, EPA should extend these regulations as quickly as possible to cover PFAS chemicals as a class.

• EPA should immediately halt the approval of all new PFAS.

• While the costs of filtration and disposal are high, those costs are far outweighed by the billions of dollars in healthcare costs caused by the health impacts of PFAS chemicals.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sherry Masiulaniec (Doc. #3012, SBC-047511)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Barry Fass-Holmes (Doc. #3013, SBC-046921)

Dear Michael Regan,

I strongly urge you to quickly finalize the EPA's proposed rule on PFAS chemicals that would provide safer drinking water for communities from coast to coast. Please implement a rule that is the most health-protective, and resist the chemical industry's efforts to weaken the rule.

Sincerely,

Barry Fass-Holmes

San Diego, CA 92108

b2fhsd@barryfhphd.com

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Erich Slimak (Doc. #3014, SBC-046922)

Dear Michael Regan,

I appreciate your proposals to limit forever chemicals in water sources. This is an imperative move towards safeguarding us and our way of life. The EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals,"PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite

the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Erich Slimak

Brooklyn, NY 11206

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Joey Mccutchan (Doc. #3015, SBC-046923)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water.

We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called

We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

JOEY MCCUTCHAN

Eureka, CA 95503

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Janet Gilbert (Doc. #3016, SBC-046924)

Dear Michael Regan,

As a grandmother of two adorable grandkids I am grateful that you are making positive change. I Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals,"PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them. We need safe non-toxic water to build healthy children. It is a needed investment in our children's future to clean up our environment. I implore you to create meaningful strong standards regulating PFAS to nil; such benefits us all. Thank you.

Sincerely,

Janet Gilbert

Crescent City, CA 95531

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Christine Williams (Doc. #3017, SBC-046925)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. The EPA's proposed drinking water standards would provide extremely important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals,"PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who were exposed in utero. Yet despite the very serious health risks associated with PFAS, there are currently NO federal limits on PFAS levels in drinking water. This cannot continue.

This needs to be changed immediately, before more Americans, like my parents, are harmed by PFAs. My dad suffered for years from early-onset Alzheimer's disease, which studies have partly linked to PFAs. My mother has recently been diagnosed with Parkinson's disease, which has also been partly linked to PFAs. I, myself, am in an 80% risk group for breast cancer, mostly due to genetics; however, I don't want my cancer risk increased more by exposure to PFAs.

I have owned a Pür brand pitcher for water filtration, for over 20 years, to help keep our drinking water safe while my son grew up. It filters dozens of things, including lead. Now I'm reading about PFAs in drinking water - and there is no filter for that. We are all at risk. Every single American.

The EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, the EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water.

My family, and countless others, urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, firmly resisting Big Industry's efforts to weaken these standards.

Please do everything in your power, very soon, to address this issue, which is so detrimental to American health and American lives. Thank you!

Sincerely,

Christine Williams

Nottingham, MD 21236

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Roger Martin (Doc. #3018, SBC-046926)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

When I was an Air Force bomber pilot on active duty, I responded to requests for bomber crewmembers to participate in firefighter exercises at an airplane. Sometimes, the firefighters would spray AFFF onto the ground, and we would have to walk through it. We were always told the foam was perfectly safe.

I have a degree in Biology. About a year ago, I had basal-cell carcinoma removed from just above the top-of-fling-boot line from my left calf. I doubt that cancer spot will be my last.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals,"PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Roger Martin

Tacoma, WA 98466

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Sally Davis (Doc. #3019, SBC-046617)

Dear Michael Regan,

PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

Sincerely,

Sally Davis

Fishers, IN 46038

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jennifer Ruiz (Doc. #3020, SBC-046618)

Dear Michael Regan,

We urge you to do something to stop PFAS from infecting the environment. Do something NOW. DO NOT WAIT ANY LONGER. Everyone's health depends on you to do something about this - EPA's proposed drinking water standards are a critical step toward addressing the PFAS drinking water crisis, and helping communities across the country remove these dangerous chemicals from their water,

Urging you to Act quickly to finalize EPA's proposed national drinking water regulations for six PFAS chemicals.

Sincerely,

Jennifer Ruiz

Madera, CA 93638

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Douglas Emery (Doc. #3021, SBC-046927)

Dear Michael Regan,

Let me first thank you for taking the first step to regulate PFAS in drinking water. PFAS have been a growing problem for our society but little serious containment has been initiated, let alone reduction. In fact, for decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases.

EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. My family strongly supports the proposed standards, and we urge EPA to finalize them as quickly as possible.

We have known for years now that PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals,"PFAS now persist in our environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment.

Today PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently still no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water.

My family urges you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's strong lobbying efforts to weaken them.

Sincerely,

Douglas Emery

Sebastopol, CA 95472

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Ann Finneran (Doc. #3023, SBC-047282)

I strongly support the EPA draft regulations proposed for six PFAS chemicals, and I urge you to finalize these rules as quickly as possible. These comments are in regard to Docket ID: EPA-HQ-OW-2022-0114

- An extraordinary number of locations in New York State, in particular the Hudson Valley and "downstate" areas, including my own residential town of Fallsburg, have PFAS drinking water levels exceeding proposed limits.

- The NYS Dept of Environmental Conservation (DEC) is looking to increase the permitting of the spreading of PFAS contaminated sewage sludge on croplands in the state, a practice the state of Maine has banned because the dairy cows' milk on such lands became contaminated with PFAS, destroying the cows' health and farmers' business. Sewage sludge spreading on crop fields will exacerbate the continual accumulation of PFAS in drinking water through runoff and leachate from such fields. The new regulations may help dissuade the NYS DEC from this very unwise plan.

- In the geographically small but densely populated county of Rockland, just north of New York City, nearly all of their drinking water is contaminated with toxic PFAS chemicals. Many of the Rockland wells and reservoirs are contaminated with PFAS at levels below the current New York State drinking water standards. That means that filtration will not be required for the majority of Rockland's contaminated wells — unless the draft EPA regulations are passed.

- Many of Rockland's drinking water sources are contaminated with multiple PFAS chemicals, possibly resulting in additive or synergistic health impacts. But New York State currently regulates only two chemicals. The draft EPA regulations are written for combined standards, which would require many more of these chemicals to be cleaned up.

- The New York State Dept. of Health is waiting for EPA's finalized regulations. Many other states may be doing the same. If EPA's draft regulations are passed, it will make it possible for the states to build on EPA's science and direction to regulate even more PFAS.

These regulations will send a strong signal to the chemical industry to invest in safe alternatives now.

- There are over 12,000 PFAS chemicals in all. Moving forward, EPA should extend these regulations as quickly as possible to cover PFAS chemicals as a class.

- EPA should immediately halt the approval of all new PFAS.

- The NYS Dept of Environmental Conservation is looking to increase the permitting of the spreading of PFAS contaminated sewage sludge on croplands in the state, a practice the state of Maine has banned because the dairy cows' milk on such lands became contaminated with PFAS, destroying the farmers' market products. Sewage sludge spreading on crop fields will exacerbate the continual accumulation of PFAS in drinking water through runoff and leachate from such fields. The new regulations may help dissuade the DEC from this very unwise plan.

- While the costs of filtration and disposal are high, those costs are far outweighed by the billions of dollars in healthcare costs caused by the health impacts of PFAS chemicals, which bio accumulate and are nearly impossible to destroy.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA notes that the topics raised in this comment regarding PFAS regulation beyond drinking water under SDWA, including "PFAS contaminated sewage sludge", are outside the scope of this rulemaking. For more information on topics outside the scope of the final PFAS NPDWR, please see section 15 of the EPA response in this *Response to Comments* document. Section 15 of the *Response to Comments* document also discusses other actions that the EPA and other federal agencies are or may consider taking to address PFAS through a whole-of-government approach. In addition, although outside the scope of this action, please see section 10.4.2 of the EPA response in this *Response to Comments* document for discussion of disposal of spent drinking water materials under possible future regulatory actions and costs.

Linda PaolinoPaolino (Doc. #3024, SBC-046336)

I live in Rockland County, where nearly all of our drinking water is contaminated with toxic PFAS chemicals. Many of our wells and reservoirs are contaminated with PFAS at levels below the current New York State drinking water standards. That means that filtration will not be required for the majority of Rockland's contaminated wells — unless the draft EPA regulations are passed.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Patrick Oharris (Doc. #3025, SBC-046928)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals,"PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Patrick Oharris

Ann Arbor, MI 48104

poharris@hotmail.com

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Justin Sweet (Doc. #3026, SBC-046325)

Please consider adopting or strengthening these regulations. In addition to the PFAS chemicals that need to be further regulated, the area where I live is in close proximity to New York City and has multiple other threats to our drinking water. Please act in the interest of the citizens you represent and not the corporations who continue to pollute our drinking water for profit. Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Cynthia Walter (Doc. #3027, SBC-046326)

I am a biologist with 35 years of experience teaching and writing about pollution sources, impacts and solutons. I learned today, the deadline, about the EPA plans re PFAs . I strongly encourage rules that indicate there is no safe level of many PFAs, such as goals for 0 MCL. Also, we need a low national standard for drinking water, because there are ways to meet those standards - my city installed such technologies. Finally, we need prohibitions on using PFAs , so we stop the releases in materials and exposures to workers in manufacturing. For decades, I have lectured about the substantial scientific evidence of serious health problems from PFAs; I am enouraged by this effort to begin to address this serious forever chemical.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response*

to Comments document. The EPA notes that the topics raised in this comment regarding PFAS regulation beyond drinking water under SDWA, including "prohibitions on using PFAS", are outside the scope of this rulemaking. For more information on topics outside the scope of the final PFAS NPDWR, please see section 15 of the EPA response in this *Response to Comments* document. Section 15 of the *Response to Comments* document also discusses other actions that the EPA and other federal agencies are or may consider taking to address PFAS through a whole-of-government approach.

Jennifer Studwell (Doc. #3028, SBC-046337)

It is crucial to the health of Rockland County's residents that the water supply is monitored closely & treated for the unacceptable, unsafe levels of PFAS. Please do not jeopardize the long term health of our babies, children & all vulnerable Nyers!!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Maria Coupe (Doc. #3029, SBC-047283)

Please be sure to say that your comments are for Docket ID: EPA-HQ-OW-2022-0114.

I strongly support the EPA draft regulations proposed for six PFAS chemicals. I urge you to finalize these rules as quickly as possible. As a long time Rockland County resident where I now work and raise my family I've grown increasingly concerned about the water available to drink.

I live in Rockland County, where nearly all of our drinking water is contaminated with toxic PFAS chemicals. Many of our wells and reservoirs are contaminated with PFAS at levels below the current New York State drinking water standards. That means that filtration will not be required for the majority of Rockland's contaminated wells — unless the draft EPA regulations are passed.

Many of Rockland's drinking water sources are contaminated with multiple PFAS chemicals, possibly resulting in additive or synergistic health impacts. But New York State currently regulates only two chemicals. The draft EPA regulations are written for combined standards, which would require many more of these chemicals to be cleaned up.

The New York State Dept. of Health is waiting for EPA's finalized regulations. Many other states may be doing the same. If EPA's draft regulations are passed, it will make it possible for the states to build on EPA's science and direction to regulate even more PFAS.

These regulations will send a strong signal to the chemical industry to invest in safe alternatives now.

There are over 12,000 PFAS chemicals in all. Moving forward, EPA should extend these regulations as quickly as possible to cover PFAS chemicals as a class.

EPA should immediately halt the approval of all new PFAS.

While the costs of filtration and disposal are high, those costs are far outweighed by the billions of dollars in healthcare costs caused by the health impacts of PFAS chemicals.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Scott Lauffer (Doc. #3031, SBC-046327)

I support the EPA draft regulations proposed for six PFAS chemicals. The EPA knows from its own studies that these chemicals are harmful to human health. These comments are in regard to Docket ID: EPA-HQ-OW-2022-0114.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Nancy Glassman (Doc. #3032, SBC-046929)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. I am a two time cancer survivor. My mother died from cancer, as did my grandmother and my cousin. My brother, (2 kinds of lymphoma and breast cancer), and my nephew have also survived cancer. My father died from a brain tumor.

Because I have held mistrust of non-stick pans, I have been careful to buy pans without the non - stick surfaces. I have looked in vain for cookie sheets without the non-stick coating, for 2 years.

For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals,"PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Corporations are not organized to protect the public. Only you can do that.

Sincerely,

Nancy Glassman

Searsmont, ME 04973

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Anonymous public comment (Doc. #3033, SBC-046338)

The water in Rockland County is terrible and definitely not safe to drink. Action needs to be taken to protect the residents. Everyone has the right to safe and clean drinking water. We should not have to worry about the harmful and toxic PFAS. Something needs to be done!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kara Brown (Doc. #3034, SBC-047284)

I strongly support the EPA draft regulations proposed for six PFAS chemicals. I urge you to finalize these rules as quickly as possible. These comments are in regard to Docket ID: EPA-HQ-OW-2022-0114.

I live in Rockland County, where nearly all of our drinking water is contaminated with toxic PFAS chemicals. Many of our wells and reservoirs are contaminated with PFAS at levels below the current New York State drinking water standards. That means that filtration will not be required for the majority of Rockland's contaminated wells — unless the draft EPA regulations are passed.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Victor Pytko (Doc. #3035, SBC-046328)

Outlaw production and use of PFAS rather than wasting our time and dollars in the courtroom or doctor's office.

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA notes that the topic raised in this comment regarding PFAS production and use are outside the scope of this rulemaking. For more information on topics outside the scope of the final PFAS NPDWR, please see section 15 of the EPA response in this *Response to Comments* document. Section 15 of the *Response to Comments* document also discusses other actions that the EPA and other federal agencies are or may consider taking to address PFAS through a whole-of-government approach.

Agnes Shehada (Doc. #3036, SBC-047285)

Please be sure to say that your comments are for Docket ID: EPA-HQ-OW-2022-0114. Here are some of the talking points you can use or modify:

I strongly support the EPA draft regulations proposed for six PFAS chemicals. I urge you to finalize these rules as quickly as possible. These comments are in regard to Docket ID: EPA-HQ-OW-2022-0114.

I live in Rockland County, where nearly all of our drinking water is contaminated with toxic PFAS chemicals. Many of our wells and reservoirs are contaminated with PFAS at levels below the current New York State drinking water standards. That means that filtration will not be required for the majority of Rockland's contaminated wells — unless the draft EPA regulations are passed.

Many of Rockland's drinking water sources are contaminated with multiple PFAS chemicals, possibly resulting in additive or synergistic health impacts. But New York State currently regulates only two chemicals. The draft EPA regulations are written for combined standards, which would require many more of these chemicals to be cleaned up.

The New York State Dept. of Health is waiting for EPA's finalized regulations. Many other states may be doing the same. If EPA's draft regulations are passed, it will make it possible for the states to build on EPA's science and direction to regulate even more PFAS.

These regulations will send a strong signal to the chemical industry to invest in safe alternatives now.

There are over 12,000 PFAS chemicals in all. Moving forward, EPA should extend these regulations as quickly as possible to cover PFAS chemicals as a class.

EPA should immediately halt the approval of all new PFAS.

While the costs of filtration and disposal are high, those costs are far outweighed by the billions of dollars in healthcare costs caused by the health impacts of PFAS chemicals.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

John Havrilla (Doc. #3037, SBC-047675)

See attached file(s)

I am writing to support the EPA in its effort to regulate six PFAS chemicals. This is a critical matter for the well being people in Rockland County, NY where a vast number of wells and water sources are contaminated with a host of PFAS. I applaud those who are making the effort to clean our water sources, and I challenge those who seek not to regulate these chemical because of a profit motive. While a profit motive is commendable, it cannot be at the expense of the health of the wider community.

Furthermore, I believe that the costs these contaminants are inflicting on the health of our people are far greater than the profit these chemicals produce. From a personal point of view, the well being of my grandchildren is paramount. I believe that they should be able to live in a community where the well being of all people is supported by community groups, corporations and government agencies. Because the profit motive is a strong impetus, the voice of the people must be heard through its elected officials and the structures of government in protecting our community. That is a central purpose of government-to protect our citizenry.

Therefore, I urge the EPA to adopt the proposed regulations of the six chemicals named. This is especially needed in New York State because only two PFSA chemicals are presently regulated. If adopted, this stance will be a platform for tackling the challenging effort to provide clean water sources for all people in our community and beyond by regulating even more PFAS chemicals. Because I live in a county where so much of the water supply has been violated by harmful chemicals, I urge the adoption of the EPA draft without delay, followed by NY State acting on an expanded plan that would require the clean-up of our water sources from all harmful chemicals.

Clearly, a comprehensive ban in NYS must be established so that the manufacture and sale of products containing PFAS ends. Further, PFAS as a class are to be regulated with Maximum Contaminant Levels for PFAS. Lastly, ensure the safe disposal of harmful chemicals that are removed from our drink water in such a way that the greater environment is not negatively impacted.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Susan Suggs (Doc. #3038, SBC-047462)

To Whom It May Concern,

I am writing in regards to the proposed rule for Per- and Polyfluoroalkyl Substances (PFAS) to be included into the National Primary Drinking Water Regulations.

On March 14, 2023, the EPA proposed the first ever national drinking standards with regards to PFAS in public drinking water. EPA is issuing a preliminary regulatory determination to regulate PFHxS, HFPO-DA (also known as GENX), PFNA, PFBS, PFOA, PFOS and a mixtures of these PFAS as contaminants under SDWA.

PFHxS, HFPO-DA (also known as GENX), PFNA, PFBS, PFOA and PFOS have all been found in large concentrations across North Carolina.

The Chemours plant in Bladen County produces GenX, and discharges upwards of 250 different PFAS chemicals into our drinking water.

The PFAS production at the site is responsible for groundwater and surface water contamination in the surrounding area, according to water samples from Chemours and the N.C. Department of Environmental Quality.

Since learning about our PFAS water contamination in 2017, we have learned how harmful PFAS are to populations that are exposed to "forever chemicals".

Pregnant women, young children, low income communities and people of color are extremely vulnerable.

PFAS are dangerous chemicals that bioaccumulate in the body's organs. Continuous small exposures can lead to larger health effects that can be harmful to people who are ingesting PFAS.

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Suzannah Glidden (Doc. #3039, SBC-046329)

I strongly support the draft regulations as written (instead of letting them be watered down by the chemical industry. We need to regulate PFAS NOW,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jeffrey Saunders (Doc. #3040, SBC-046930)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water.

For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Jeffrey Saunders

Philadelphia, PA 19107

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Tor Olsson (Doc. #3041, SBC-047464)

5/6/23

With regards to the proposed rule for Per- and Polyfluoroalkyl Substances (PFAS) to be included into the National Primary Drinking Water Regulations, Throughout my undergraduate education, I have been learning how harmful PFAS is to populations that are exposed to these "forever chemicals,"specifically harming communities of low income, people of color. As someone who lives only 6 miles from a 3M Cottage Grove historical dumpsite, I firmly and wholeheartedly support the adoption of these new regulations. For Amara Strande. For the thousands of 3M employees just at Cottage Grove. For the millions who are directly affected by PFAS. Towards accountability mechanisms for companies like 3M who have engaged in misinformation campaigns against the EPA, government, and us.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Dorothea Leicher (Doc. #3042, SBC-047245)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

My father was a chemist and so I have a high respect for the power of chemicals and great concern about our reckless use of chemicals without due regard for toxicity.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Robert Essman (Doc. #3043, SBC-047246)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

The science is clear as well as our hubris in thinking that we can continue to poison our children with these, now known, toxic chemicals. To continue to do so to help the profit margins of the chemical use industries and to avoid the hard lift of cleaning up our well intentioned ignorance of what we have done in the past or to remain comfortably ignorant is no longer a responsible option. Now that we see we are digging a deep toxic hole–please stop digging.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Faith Fusillo (Doc. #3044, SBC-046339)

I live in Rockland County, where nearly all of our drinking water is contaminated with toxic PFAS chemicals. Many of our wells and reservoirs are contaminated with PFAS at levels below the current New York State drinking water standards. That means that filtration will not be required for the majority of Rockland's contaminated wells — unless the draft EPA regulations are passed. Please hear us, please help us!

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Deena Craig (Doc. #3045, SBC-047465)

Copy and paste this statement to your EPA comment

To Whom It May Concern,

I am writing in regards to the proposed rule for Per- and Polyfluoroalkyl Substances (PFAS) to be included into the National Primary Drinking Water Regulations.

On March 14, 2023, the EPA proposed the first ever national drinking standards with regards to PFAS in public drinking water. EPA is issuing a preliminary regulatory determination to regulate PFHxS, HFPO-DA (also known as GENX), PFNA, PFBS, PFOA, PFOS and a mixtures of these PFAS as contaminants under SDWA.

PFHxS, HFPO-DA (also known as GENX), PFNA, PFBS, PFOA and PFOS have all been found in large concentrations across North Carolina.

The Chemours plant in Bladen County produces GenX, and discharges upwards of 250 different PFAS chemicals into our drinking water.

The PFAS production at the site is responsible for groundwater and surface water contamination in the surrounding area, according to water samples from Chemours and the N.C. Department of Environmental Quality.

Since learning about our PFAS water contamination in 2017, we have learned how harmful PFAS are to populations that are exposed to "forever chemicals".

Pregnant women, young children, low income communities and people of color are extremely vulnerable.

PFAS are dangerous chemicals that bioaccumulate in the body's organs. Continuous small exposures can lead to larger health effects that can be harmful to people who are ingesting PFAS.

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Robin Schnell (Doc. #3046, SBC-046931)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals,"PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Robin Schnell

Portsmouth, NH 03801

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Ann Payne (Doc. #3047, SBC-047247)

Dear Administrator Regan:

PFAS chemicals came to my attention decades ago when their presence in children's pajamas caused those garments to be removed from the shelves. Children were developing brain tumors as a result of exposure to those pajamas. We (and stores) had to discard that clothing. And yet today, our exposure to dangerous PFAS chemicals apparently continues unabated. We know the serious dangers. The time to act is far overdue.

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS. My family's water supply here is contaminated with PFAS. Imagine a nation feeling our government is actively protecting us . . .

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Erin Stephens (Doc. #3048, SBC-047248)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting people from the scourge of PFAS.

The EPA's proposed rule will provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS.

This proposal will save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

Quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Chantra Montoya-Pimolwatana (Doc. #3049, SBC-047249)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

I have an autoimmune disease that I am sure the tap water I drank since my childhood contributed to. I now have a young baby of my own and I don't want her exposed to the same toxins that I was growing up. Please help us and all of humanity.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Richard Wissler (Doc. #3050, SBC-047250)

Dear Administrator Regan:It is under your attention and "leadership" that we are fishing out AND polluting our oceans, atmosphere and land with chemicals, unusable animal waste and an unassailable stupidity to the extent that we are cancelling our ticket here on planet Earth.... Where are you going when this place is burnt down , flooded out or blown flat by the results of your version of "husbandry " ? - eh ? WHERE ?!

Your priorities amaze, sadden and disgust us .

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Tracy Weldon (Doc. #3051, SBC-047251)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

Everyone deserves clean water. I am worried about the children growing up now. Who knows what kinds of damage the chemicals in our water are doing to them. This affects not only all of us but generations to come.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Nancy Ihara (Doc. #3052, SBC-047252)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

While the chemical industry will forcifully push back on any regulations, it's the health of the people of this nation that will, I hope, always be uppermost in your mind. Thank you for bringing forth this proposal.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

J. Whiting (Doc. #3053, SBC-047253)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

The proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

PLEASE! I urge you--quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Carolyn Henne (Doc. #3054, SBC-047254)

Dear Administrator Regan:

as a resident of Michigan, the issue of PFAS and other forever chemicals has become an incredibly important concern. The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal

would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Priscilla Auchincloss (Doc. #3055, SBC-046620)

Dear Administrator Regan,

I'm writing to you from Upstate NY, where awareness of PFAS chemicals - their prevalence and the harms they cause - is growing, along with determination to end their use. It is great news that the EPA has proposed national drinking water regulations for six PFAS chemicals.

I urge you to move forward promptly to finalize the regulation of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS chemicals.

I'm sure you are aware that PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm. The question is - why haven't we done something about it?

I understand that the EPA's proposed rule would provide safer drinking water to literally millions of people in communities across the nation where the drinking water is contaminated by PFAS. Let's imagine the lives saved and health improved by enforcement of the EPA's proposal, and let that vision of vitality and health propel us to do even more to stop chemical contamination of our water, air, and soil across the U,S,

Thank you for your work and commitment.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Pamela A. Lowry (Doc. #3056, SBC-046932)

Dear Michael Regan,

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases.

EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Pamela A. Lowry

Grand Junction, CO 81503

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Clark Bell (Doc. #3057, SBC-046933)

Dear Administrator Regan:

I welcome EPA's proposed national drinking water regulations for six PFAS chemicals; this is a good first step in protecting our families and communities from PFAS.

I understand EPA's proposed rule would:

• provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS;

• save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

Because PFAS are known to be extremely persistent in the environment, very widespread, and linked to a long list of health effects, such as cancer, immune suppression, and developmental harm, I urge you to:

• quickly finalize the regulations of these six PFAS chemicals;

• implement a rule that is health protective;

• begin addressing all of the other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Lys Burden (Doc. #3058, SBC-047255)

To Administrator Regan:

My family and I (four taxpaying and voting residents of Washington State) applaud EPA's proposed national drinking water regulations for six PFAS chemicals as a welcome first step to protecting our families and communities from the everlasting and terrible impacts of PFAS.

We are well aware of PFAS for their extreme persistence and widespread pollution and their long list of health effects, including cancer, immune suppression, gender impacts and fetus developmental harm.

We support EPA's proposed rule that would provide safer drinking water for millions of people in communities across this nation where drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious and deadly PFAS-related illnesses each year.

We urge you to quickly finalize regulations for these six PFAS chemicals, implement rules that protect health, and then begin addressing all other types of PFAS and places where they contaminate our lives, such as in our food system through packaging, fast-food and processed food. It is imperative to address these extremely harm-inducing chemicals. They also harm our fish, wildlife and children and induce contamination of soil, solid waste stream, even the air we breathe. They are in our clothes, rugs, furniture and dust. PLEASE help our way of life become less contaminated by these "forever" chemicals.

Dan and Lys Burden

Mike and Dan Brant

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Marion Thorne (Doc. #3059, SBC-046621)

Dear Administrator

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Kathleen Doyle (Doc. #3061, SBC-047256)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protect our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution. They have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that protects health, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Marcee Silver (Doc. #3062, SBC-047257)

Dear Administrator Regan:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are causing enormous medical and household wealth problems. Not passing the proposed national drinking water regulations for the six PFAS chemicals will incur a huge ongoing cost for us all, so please get them in place ASAP.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mass comment campaign submitted by Karen Dukovich (Doc. #3063, SBC-046683)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge. It's easier to make improvements now than deal with more negative consequences later.

Sincerely,

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mass comment campaign submitted by Jerilyn Hall (Doc. #3064, SBC-046934)

Dear Michael Regan,

If we use and believe in Science that improves our lives medically and in many other areas of our lives, then we must accept that Science also tells us what to avoid in our environment to keep us safe and healthy.

Thank you for taking the first step to regulate PFAS in drinking water. For decades, PFAS have contaminated drinking water supplies for millions of people across the country, resulting in increased rates of cancer, developmental and reproductive harm, and other serious diseases. EPA's proposed drinking water standards would provide important and long overdue protections against six of these toxic chemicals. We strongly support the proposed standards, and we urge EPA to finalize them as quickly as possible.

PFAS are a large, long-lasting, and highly dangerous class of chemicals. Often called "forever chemicals," PFAS persist in the environment, build up in our blood and organs, and continue to cause harm decades after they are released into the environment. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in utero. Yet despite the serious health risks associated with PFAS, there are currently no federal limits on PFAS levels in drinking water.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Jerilyn Hall

Bonney Lake, WA 98391

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mass comment campaign submitted by Naia Mitchell (Doc. #3065, SBC-047673)

We deserve clean water and if companies are putting the publics health at RISK, they MUST be held responsible and barred from doing business ever again. We are not hard enough on entities that are putting us at risk, and its the EPA and the governments' job to keep us safe.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mass comment campaign submitted by Ellen Biemer (Doc. #3066, SBC-047258)

Dear Administrator Regan:

Please protect our water! It's essential for life, and we deserve not to be poisoned by it.

Now the form letter:

The EPA's proposed national drinking water regulations for six PFAS chemicals is a welcome first step to protecting our families and communities from the scourge of PFAS.

PFAS are infamous for their extreme persistence and widespread pollution and have been linked to a long list of health effects, including cancer, immune suppression, and developmental harm.

The EPA's proposed rule would provide safer drinking water for the millions of people in communities across the nation where the drinking water is contaminated by PFAS. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year.

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mass comment campaign submitted by Larry Menkes (Doc. #3067, SBC-046935)

Re: Proposed PFAS National Primary Drinking Water Regulation Rulemaking Docket ID: EPA-HQ-OW-2022-0114

Dear Administrator Regan,

Thank you for taking this historic step to keep our drinking water safe from PFAS contamination. For decades, PFAS chemicals have contaminated both public and private drinking water supplies across the country. PFAS contamination exposes communities to serious health risks, including cancers, impacts to the immune and reproductive systems, and other harms. The EPA's proposed drinking water standards would provide long overdue federal protections against six types of highly toxic PFAS.

I am am a victim of AFFF laced tap water. I have cancer, my wife and father-inlaw died of their cancer. Keep up the good work.

I strongly support this proposed rule and urge EPA to move swiftly to finalize health-protective standards to reduce PFAS in our drinking water.

The PFAS crisis is widespread, contaminating the blood of humans, fish, and wildlife worldwide. Communities of color and low-income communities are particularly impacted by PFAS exposure, where health impacts are often compounded because these communities tend to face cumulative effects from multiple environmental injustices and public health hazards.

EPA's proposal would significantly reduce exposure to PFAS in our drinking water for millions of people by setting strong, science-based drinking water standards for six types of PFAS. While this proposal is an important first step towards addressing PFAS exposure, it is critical that EPA also expedite efforts to prevent these chemicals from entering our waters and environment in the first place, before it even reaches our taps.

These proposed regulations are long overdue and I fully support this first step of regulating six dangerous PFAS in drinking water. In addition, I encourage the EPA to take a comprehensive approach to regulating the entire class of chemicals in order to reduce overall PFAS exposure, and improve drinking water safety in thousands of communities across the country.

Thank you for your consideration.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mass comment campaign submitted by Barbara Halpern (Doc. #3068, SBC-046622)

Every American has a right to safe drinking water.

For the health of Latinos and all Americans, I support EPA's plans to regulate and limit harmful PFAS in drinking water and the environment.

Considering the potentially devastating health impacts of PFAS exposure, it is unacceptable for these chemicals to be released into and remain in the environment at unsafe levels (https://salud.to/PFASbm).

While researchers have made strides in destroying PFAS in water, we must address PFAS contamination at the source with enforced regulations, as even undetectable levels of PFAS can pose human health risks including damage to fetal growth and increased cancer risk (https://salud.to/pfasdes).

PFAS affect everyone but may impact some populations more than others. For instance, Latino families are more likely to live in neighborhoods where there is a lack of clean and safe drinking water (https://salud.to/nitrate) and where utility companies have less funding to meet community needs.

Therefore, environmental regulation of harmful PFAS is critical for all Americans, but especially those who are vulnerable to exposure, such as Latinos. I applaud EPA's proposed plans to regulate and limit PFAS chemicals in drinking water and the environment, which could help ensure a healthier future with less exposure to potentially harmful chemicals.

The limit should be zero as these chemicals accumulate in the body they are forever chemicals. Water providers must be required to remove them from drinking water

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. Please see sections 13.4-13.9 of the EPA response in this *Response to Comments* document that outlines the quantifiable and nonquantifiable benefits of this NPDWR that may address the commenter's concern of low levels of PFAS that can pose human health risks. In response to the comment that states that "environmental regulation of harmful PFAS is critical for all Americans, but especially those who are vulnerable to exposure", as part of its environmental justice analysis for this regulatory action, the EPA evaluated the distribution of baseline PFAS exposure in drinking water across demographic groups. For additional discussion on this topic, please see the EPA's EJ analysis in section 8 of the EA (USEPA, 2024a) and section 14.10 of the EPA response in this *Response to Comments* document.

Mass comment campaign submitted by Carol De Angelo (Doc. #3069, SBC-047269)

My name is Carol De Angelo, and I am a supporter of the Catholic Climate Covenant which is working to support the proposed EPA National Primary Drinking Water Regulation which sets enforceable limits on PFAS and other related chemical compounds in public drinking water. I work with many groups who are concerned with the amount of PFAS in their drinking water. Once place is Rockland County where we have several retired Sisters of Charity living.

I am writing in support of the NPDWR (EPA-HQ-OW-2022-0114-0027) and its stringent regulations on drinking water. The rule has the potential to lower the presence of dangerous chemicals in the water supply of over 110 million Americans. PFAS chemicals have been repeatedly connected to dangerous health conditions, and the EPA must do something to protect Americans from such contamination.

As a member of a faith community, I take the responsibility I have to creation very seriously. It is from that position that I advocate for this act as a way of bringing about more justice in our society. These regulations would not only protect the health of humankind but will also benefit nature and wildlife. It is because the benefits of the rule are so great, and, according to the EPA, far outweigh the costs of implementation, that I believe it to be in the best interest of the United States to enact the National Primary Drinking Water Regulation. Thank you for the continued work of the EPA to create better living standards and a more harmonious relationship with nature.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Mass comment campaign submitted by Arthur Bell (Doc. #3071, SBC-047467)

Copy and paste this statement to your EPA comment

To Whom It May Concern,

I am writing in regards to the proposed rule for Per- and Polyfluoroalkyl Substances (PFAS) to be included into the National Primary Drinking Water Regulations.

On March 14, 2023, the EPA proposed the first ever national drinking standards with regards to PFAS in public drinking water. EPA is issuing a preliminary regulatory determination to regulate PFHxS, HFPO-DA (also known as GENX), PFNA, PFBS, PFOA, PFOS and a mixtures of these PFAS as contaminants under SDWA.

PFHxS, HFPO-DA (also known as GENX), PFNA, PFBS, PFOA and PFOS have all been found in large concentrations across North Carolina.

The Chemours plant in Bladen County produces GenX, and discharges upwards of 250 different PFAS chemicals into our drinking water.

The PFAS production at the site is responsible for groundwater and surface water contamination in the surrounding area, according to water samples from Chemours and the N.C. Department of Environmental Quality.

Since learning about our PFAS water contamination in 2017, we have learned how harmful PFAS are to populations that are exposed to "forever chemicals".

Pregnant women, young children, low income communities and people of color are extremely vulnerable.

PFAS are dangerous chemicals that bioaccumulate in the body's organs. Continuous small exposures can lead to larger health effects that can be harmful to people who are ingesting PFAS.

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Slingshot and National PFAS Contamination Coalition (Doc. #3072-14, SBC-046345)

Good afternoon, my name is Dana Colihan. I am co-Executive Director of Slingshot, and co-Facilitator of the National PFAS Contamination Coalition. I am testifying in support of the proposed EPA drinking water standards for six PFAS. Slingshot is an environmental justice organization working alongside communities most impacted by environmental health threats to take aim at polluters and build community power. We envision a PFAS-free world, where we do everything we can to address the horrific impact these chemicals have had on our communities and environment, which is why we strongly support these proposed drinking water standards. We also co-facilitate the National PFAS Contamination Coalition, which is comprised of 30 community groups from across the country who are directly impacted by PFAS. The coalition is fighting for a world where people are not exposed to any PFAS, where there is justice for the victims of PFAS exposure, and where laws and regulations prevent contamination and disasters like this from ever happening again. From this work, we have witnessed firsthand the impacts PFAS have had on our bodies, our families, and our environment. These standards are thanks to the tireless organizing of community members across the country. It reflects what these leaders

already knew to be true; that there are no safe levels of PFAS in our water. For too many Americans who live every day in the shadow of pollution, enough is enough. We commend the EPA for taking this long overdue step to protect millions of Americans from these dangerous chemicals in our drinking water. We applaud the acknowledgment that individual PFAS and PFAS mixtures can have an impact on our health. We believe using mixtures as a regulatory tool is an incredibly useful framework for regulating additional groups of PFAS. We hope to see the implementation of this as soon as possible, as we know all of these chemicals have a cumulative health impact on our bodies. We know there is a profound cost to inaction on PFAS. Delaying federal regulation of these chemicals will continue to take tolls on our bodies. We will get sick, we will not be able to work, we will incur medical expenses. It is not only morally and environmentally strategic to enact national PFAS drinking water standards, but also incredibly economically advantageous. We urge EPA to keep these standards as low and restrictive as possible. We seriously caution against any delays to implementation, or any standards that are less than health-protective or ignore the science. Ultimately, we also urge the EPA to regulate these chemicals as a class, turn off the tap of contamination by stopping the approval of any new PFAS chemicals, and ensuring that polluters are made to pay. We look forward to your swift and steadfast action to protect our communities and our environment from the horror of PFAS. Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Camp Grayling Restoration Advisory Board (Doc. #3072-15, SBC-046346)

Okay, I am Marcia Koppa, Wayne's wife. I don't know how that happened but I'm with the Camp Grayling Restoration Advisory Board. Camp Grayling is in Crawford County, which is in beautiful lower Northern Michigan. We started out primarily as a Michigan National Guard Training Camp and has expanded into even joining and training NATO troops. But we have three areas of contamination. One is the Grayling Army Airfield. That airfield had used Aqueous Film Forming Foam, AFFF, in the past, and that plume of groundwater is heading toward a trout fishing stream, the Au Sable River. And that river travels east passing Oscoda, which is another former Air Force base that is also contaminated, ends up in Lake Huron. Just a little ways west is the cantonment area, the main camp of Camp Grayling, which is on the south side of Lake Margrethe, which also has a lot of residential areas around it. It is also very contaminated. That lake drains into eventually Manistee River, which heads west to Lake Michigan. And so, we have an area that is affecting much of Northern Lower Michigan and its contamination. We are working very hard with the CERCLA group, and we are making progress, but we are a bit stymied at this point for bureaucratic reasons. So, we're very excited that EPA is deciding to make stricter standards and we really appreciate that. Anything you can do will be greatly appreciated. Thank you so much.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Integrated Resource Management (Doc. #3072-16, SBC-046347)

Great, thank you Rob. I would like to introduce myself as Bob Bowcock, I'm with Integrated Resource Management. I work with community groups and drinking water utilities virtually in all 50 states. I strongly support the proposed MCL and health index. I would like to thank staff for their many years of work that have gone into this proposed regulation. This is not something new, this is not a surprise. EPA and drinking water utilities have been working on these chemical contaminants for years. I encourage full implementation as soon as possible with the requirements of the Safe Drinking Water Act. There is no room for continued excuses or delays. Water utilities have known this was coming for years and no extension should be granted. I strongly encourage all systems, regardless of size, receive assistance to come into compliance sooner than later. Many of our small and very small systems are schools that are generally not receiving any information about this regulation or treatment techniques. This is where we send our children and many of the PFAS levels found in their source water are extremely high, like 80,000 parts, guys. Waste residuals must be subject to RCRA, and we must close the loop. As important as setting these MCLs as soon as possible, we must address continued discharges. We must immediately stop the practice of spreading contaminated biosolids from our wastewater treatment plants, stop the dumping of landfill leachate at wastewater treatment plants, and swiftly establish regulations for wastewater discharges. Thank you for this opportunity to provide public comment.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA notes that many of the topics raised in this comment related to the RCRA, biosolids, wastewater treatment plants, wastewater discharges, and landfill leachate, are outside the scope of this rulemaking. For more information on topics outside the scope of the final PFAS NPDWR, please see section 15 of the EPA response in this *Response to Comments* document. Section 15 of the *Response to Comments* document also discusses other actions that the EPA and other federal agencies are or may consider taking to address PFAS through a whole-of-government approach. In addition, although outside the scope of this action, please see section 10.4.2 of the EPA response in this *Response to Comments* document for discussion of disposal of spent drinking water materials under possible future regulatory actions and costs. Please see Section XI.D of the FRN and section 12 of the *Response to Comments* document for the EPA's response regarding extensions and the compliance date for this NPDWR.

NRDC (Doc. #3072-13, SBC-047366)

We certainly support EPA's MCLG of zero for PFOA and PFOS, and the one health MCLG for the health index for the other four PFAS. Best available technology is clear: it can achieve the

EPA proposed standards. There is granular activated carbon for some of the PFAS, ion exchange, reverse osmosis, so this is achievable, and we certainly urge EPA to move forward. The benefits far exceed the costs, even though that is not a required finding. It is feasible to achieve these standards. And the last point I wanted to emphasize is that the cost to industry of cleaning up Superfund sites or DOD cleanup sites is legally not relevant under the statute, and should not be a driver, and frankly would not be a lawful driver in this. So, we would urge EPA to withstand the pressure to try to consider such cost because they are not legally relevant. Thanks so much.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA agrees with the commenter's statements regarding not including the costs to cleanup PFAS-contaminated sites, like from industry or other federal government agencies, as part of the HRRCA requirements for MCL NPDWR in SDWA section 1412 and the Administrator's determination that the benefits of this rule outweigh the costs. For more information on the Administrator's benefit cost determination, please see section 13.8 of the EPA response in this *Response to Comments* document. Additionally, disposal costs are discussed in section 8 of the EA (USEPA, 2024a).

North Carolina Conservation Network (Doc. #3072-19, SBC-046349)

Hi, my name is Stephanie Bishop Schweickert, and I'm the senior campaign organizer with North Carolina Conservation Network. Thank you for the opportunity to give comments on the proposed drinking water standards, and I'd like to commend EPA for the proposed standards. NC Conservation Network started working on PFAS the day that news broke in 2017 that Cape Fear River Basin residents had been overexposed to forever chemicals for decades because of Chemours' pollution. Since then, I've met far too many community members and families with personal stories about how forever chemical pollution has harmed their lives. In this time, we've also found out that the problem extends far beyond the Cape Fear Basin, and have found PFAS in drinking water throughout our state. NC Conservation Network strongly supports the proposed drinking water standards for PFOS and PFOA, as well as the use of a hazard index for additional PFAS chemicals. I urge EPA to move swiftly to finalize this proposal. Further, we ask the EPA to add even more PFAS chemicals to the hazard index. Here in North Carolina, residents cannot afford one more drop of PFAS. Please protect our public health, and finalize these standards. Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Community Water Center (Doc. #3072-22, SBC-046351)

Thank you. My name is Eric Orellana. I'm a senior policy advocate with Community Water Center, an environmental justice organization who works in farmer communities to realize the human rights of water in California's Central Valley and Central Coast. Community Water Center is in strong support of the proposed legislation for the six PFAS chemicals. Many of the communities we conduct outreach and engagement in are served by water systems impacted by PFAS contamination, or have not been tested for PFAS because of their reliance on small water systems or private, domestic wells. We urge the Agency to adopt the proposed regulation, continue regulating other PFAS chemicals, hold responsible corporations accountable for putting profits over people, and provide small water systems across the country with the adequate support to treat for PFAS chemicals. I also urge the EPA to include a plan to support residents reliant on domestic wells to address PFAS contamination. Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

West Virginia Rivers Coalition (Doc. #3072-21, SBC-047369)

Thank you for the opportunity to be heard. My name is Heather Sprouse. I'm the Ohio River Coordinator with the West Virginia Rivers Coalition. I'm also an impacted resident of Hurricane, West Virginia, where levels of PFOA and PFOS contamination are 8.7 parts per trillion in the raw water of our source in Hurricane Creek near the Ohio River. I wholeheartedly support these MCLs and Hazard Index to protect my family, my community, and all who drink from the waters of the Ohio River Basin. My role as the Ohio River Coordinator is to connect with communities across West Virginia, listen to their water quality priorities, and amplify their concerns and desired solutions to decision-makers. I've spoken with residents and groups all along the 300 Ohio River miles in West Virginia, and what I hear is that people want PFAS out of their drinking water now, and that polluters need to pay for cleanup, not taxpayers or ratepayers.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Albemarle County Board of Supervisors and Rivanna Water and Sewer Authority Board of Directors, Virginia (Doc. #3072-28, SBC-046355)

Good afternoon. I am Ann Mallek. I represent the White Hall District on the Albemarle County Board of Supervisors in Virginia. I support the EPA regulation process for the six PFAS at the lowest possible regulatory level. I speak today about the concerns of citizens for their personal safety, for local governments for their permitting and purchasing decisions, and for local water systems who are expected to provide safe water to their customers. We all need your help at all

levels as soon as possible. Local water systems in Virginia are already facing high levels of PFAS contamination, which challenge their ability to clean up and also challenge their financial resources. Local governments need guidance for procurement to avoid future risk and to best protect the health and safety of our citizens. Citizens are concerned that those producers must pay for the cleanup or the citizens will have to. Yes, these chemicals are everywhere, but that should not be any excuse to move slowly. We need help now to prevent future contamination of drinking water from many sources, industrial discharges, compost and biosolids as examples. Yes, the producer's knew decades ago about the health impacts, yet they keep producing and selling. We need EPA to carry out your process for regulation without delay, to put a stop to production and sale and to require recall of contaminated products. Once these essential steps are taken, safe alternatives will be developed by the private sector. Yes, in my opinion, one can live without a non-stick pan. Stopping that sale should be easy. Alternative fire gear for protection is already available, yet fire companies around the country are waiting for regulation. Local governments are waiting for regulatory standards on which to base decisions. Every day, components of PFAS are entering drinking water supplies. Development of regulations will prevent bad chemicals from being replaced by equally bad ones about which we know little. The precautionary principles should be the basis of all government decisions as it is in other developed countries. I support designation of PFAS as a HAZMAT under Superfund. I support EPA to prioritize PFAS under TSCA. After these essential tasks are complete, please also repeal the grandfathering of existing chemicals which have proven after the fact to be so dangerous. Thank you for considering my views. Your work is important and needed ASAP.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA notes that the topics raised in this comment beyond drinking water under SDWA, including those related to the "production and sale" and "recall" of products containing or "contaminated with" PFAS and regulation of PFAS under CERCLA and TSCA, are outside the scope of this rulemaking. For more information on topics outside the scope of the final PFAS NPDWR, please see section 15 of the EPA response in this *Response to Comments* document. Section 15 of the EPA response in this *Response to Comments* document also discusses other actions that the EPA and other federal agencies are or may consider taking to address PFAS through a whole-of-government approach. In addition, although outside the scope of this action, please see section 10.4.2 of the EPA response in this *Response to Comments* document for discussion of disposal of spent drinking water materials under possible future regulatory actions and costs.

Savanna Science Co (Doc. #3072-30, SBC-046356)

Hello, I'm Kris Hansen. I have a PhD in chemistry and I have been a scientist for over 30 years, including five years in 3M's Environmental Lab between 1996 and 2001 during the "discovery" of PFAS in the blood of most humans and in the environment. I urge the EPA to implement the proposed rule as soon as possible and to continue efforts leading to the ban on PFAS excepting cases of critical use. All PFAS eventually reach a state of indestructibility in the environment and

given the complexity and understanding the effects of these human-made compounds, regulating PFAS individually is scientifically implausible. Further, allowing industry to self-regulate has proven ineffective. In the long history of PFAS, the fluorochemical industry has repeatedly demonstrated reluctance to share information transparently and to take accountability for their chemicals. These deficits have led to global human and environmental exposure to exceptionally long-lived chemicals with proven toxicity. Working at 3M in the 1990s, I understood that PFOS was "discovered" and characterized in the blood of the general population at that time. Nearly one year after the "discovery", I was told that scientists at 3M had made the same discovery of PFOS in the blood of the general population in 1975 over 20 years earlier. Even within the company there was lack of transparency and collaboration. As others have documented since 1975, 3M, DuPont and others have employed what social scientists called Unseen Science, Undone Science, and were active in manufacturing Dow. Thus, it's not surprising that it took over 20 years for the public disclosure of widespread PFAS contamination in humans and another 20 years for the health effects to be characterized. In the early 2000s, industry leaders announced their exit from manufacturing long chain PFAS and their decision to pursue a replacement strategy with short chain PFAS. Compounds they knew were environmentally indestructible, another lost opportunity. Studies have since demonstrated that short chain PFAS are widespread in the global environment and are associated with significant health effects. Despite nearly 50 years of PFAS revelations, the chemical industry has fought against accountability. Their claims that EPA's proposed regulations are too expensive and too complex are disingenuous and disrespectful. Their inability to understand and control their own products is no excuse for leniency. I live in a community with widespread groundwater contamination of PFAS. The anxiety within families who raise children on this groundwater and on city governments grappling with how to protect their citizens is of much greater concern than those of a multi-billion-dollar company claiming they lack funds to take accountability for their chemicals. Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Maine Organic Farmers & Gardeners Association (Doc. #3072-32, SBC-046357)

Good afternoon. I am Sharon Treat speaking on behalf of the Maine Organic Farmers and Gardeners Association in strong support of the proposed rule. For more than 50 years, MOFGA has worked to create a healthy, diverse and sustainable food system. We certified 535 organic farms in Maine and also processing operations. This rulemaking will improve the lives and health of Maine's farming families and communities. Since 2016, when PFAS was found contaminating water, soils and milk in a Maine dairy farm, the state has been acting to protect the public in the absence of enforceable federal rules. It's been a lonely and expensive journey with Mainers investing more than $100 million dollars to develop drinking water standards, test soil, water and food, install filtration systems, conduct research, fund farm assistance, and provide testing and monitoring for farmers and others with high PFAS levels in their blood.

Investigations so far show that 56 farms and more than 300 private drinking water wells are contaminated with PFAS, exceeding Maine's PFAS standard. Is Maine an outlier? We doubt it. Maine is the only state methodically investigating every site where sludge spreading may have occurred over the last 40 years, but PFAS contaminated sludge and compost is still being spread on fields across the nation. We support EPA setting an MCLG at zero for PFOA and PFOS. As testing technologies become more sensitive and reliable, the 4 parts per trillion MCL should ratchet down. We agree with EPA that the rules shouldn't be limited to PFOA and PFOS and support the Hazard Index approach for other PFAS. While PFOA and PFOS continue to contaminate water and soil even 30 years after sludge was spread, newer chemicals including GenX are also ubiquitous and pose health hazards. For example, a recent study in 16 states, which included Maine, detected 26 unique PFAS in water samples, including 12 not covered by current EPA testing methods. EPA's proposed rule will save lives and protect health and should be adopted without delay. Additionally, to prevent future contamination, EPA should ban wastewater sludge spreading as Maine has done and provide funding for safer disposal options. Thank you for your work and the opportunity to testify today.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA notes that the topics raised in this comment beyond drinking water under SDWA, including those related to wastewater sludge, are outside the scope of this rulemaking. For more information on topics outside the scope of the final PFAS NPDWR, please see section 15 of the EPA response in this *Response to Comments* document. Section 15 of the *Response to Comments* document also discusses other actions that the EPA and other federal agencies are or may consider taking to address PFAS through a whole-of-government approach. In addition, although outside the scope of this action, please see section 10.4.2 of the EPA response in this *Response to Comments* document for discussion of disposal of spent drinking water materials under possible future regulatory actions and costs.

Clean Cape Fear (Doc. #3072-33, SBC-046358)

Thank you for having me. My name is Emily Donovan. I'm co-founder of Clean Cape Fear. I want to thank everyone at the EPA who worked tirelessly to create this proposal and I implore the EPA to vigorously defend it from certain industry opposition. Three years after we moved to the Wilmington, North Carolina area, my husband developed a brain tumor. We may never know what caused his tumor, but when we learned about PFAS in our tap water, we couldn't help but wonder, is this why? Our state regulators and the utility servicing Wilmington, North Carolina knew about high levels of GenX in our tap water for a full year before the public was notified. The utility never alerted us because there was no legally enforceable mechanism in place requiring them to act. In 2017, we finally learned Chemours and DuPont for decades trashed our primary source of drinking water with literally hundreds of different PFAS compounds. Chemours's facility has contaminated the drinking water in eight counties, impacting over 6,000 private wells in several public water systems servicing over half a million residents. It's been six years and we still don't know the full scope of our crisis. My tap water is still contaminated with

some of the highest levels of PFAS in the nation per multiple tap water studies. I am still sending my children to school every day where the water fountains have unhealthy levels of PFAS. Without enforceable drinking water standards, we are left fending for ourselves. Not only are we paying for water we don't feel is healthy to drink, but we are also paying extra for in-home filtration to stop these chronic exposures. This has created inequity between the haves and the have nots. We are experiencing rare or re-occurring cancers at ages far too young to pass off as normal. Serious illnesses and diseases are common conversations. The amount of GoFundMe's I receive from medical related financial strain is alarming. There's also these hidden costs we continue to pay due to decades of federal inaction on PFAS. Access to healthy and affordable water is a fundamental human right protected under multiple international treaties, many of which the United States is legally bound to uphold. Failure to defend access to healthy water, we believe is a human rights violation and my community group, Clean Cape Fear, is currently seeking redress from the United Nations. These proposed drinking water standards must not be delayed or diluted. Had the EPA acted more swiftly years ago, my neighbor Amy would be here today making summer plans with her daughter. My friend Sarah and Tom would've watched their daughters complete their first year of college. For some of us, it's too late. For the rest of us, we are begging you do not extend the public comment period. Defend your work, implement these proposed standards swiftly and begin regulating PFAS as a class with a whole-of-government approach. Thank you for your time.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Zone 7 Water Agency (Doc. #3072-29, SBC-047376)

Good day. I'm also thanking you for the opportunity to speak. My name is Laurene Green. I live in Pleasanton, California, which is part of the Tri-Valley Area east of San Francisco. I'm a director on the board of the Zone 7 Water Agency. However, I'm not specifically speaking on the Agency's behalf, rather on behalf of myself and my constituents. We've had an ongoing discussion about PFAS and I'm very aware of the Tri-Valley residents' concerns, which I share. Although there are some thoughts on ways to improve the proposed MCLGs and MCLs for the first six PFAS chemicals, I trust my colleagues to articulate them and instead prefer to say, first, thank you. It's taken the better part of a century to recognize and grapple with this problem now via the roadmap and decades for the U.S. EPA to propose PFAS regulation. Thanks to the EPA for persevering and finally crossing that line. It appears to have been arduous at times, so thanks for putting the energy and resources and getting it done. Our Tri-Valley area and indeed the nation will be so much safer and healthier because of this effort.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

National PFAS Contamination Coalition (Doc. #3072-34, SBC-046359)

Hello. Thank you for letting me speak. My name is Sandy Wynn-Stelt and I'm from Belmont, Michigan. I am the co-chair of the Great Lakes PFAS Action Network, and I'm also a member of the leadership team of the National PFAS Contamination Coalition. My story began in 2016 when my husband Joel was diagnosed with liver cancer and died just three weeks later. I was devastated. I hate being a widow. While the grief changes over time, it never really leaves. I think about him every day and ironically, today is our anniversary and we would've been married 31 years. I start with this because this is just one of many stories that you hear from community members who have been impacted by this class of chemicals. Joel and I lived in our home for 23 years, drinking the water. I later learned that my water and the water of 25 square miles of my community was contaminated with PFAS at incredibly high levels from tannery waste from Wolverine Worldwide. I have some of the highest levels of PFAS in blood that's been seen, and I myself was diagnosed with thyroid cancer two years ago. I have neighbors who have experienced repeated miscarriages, who have kidney cancer, testicular cancer, and liver disease. I have seen children on my block with thyroid disease at three years old, with immune problems, and with vaccines that are not effective. We have no way to protect ourselves from these chemicals since we cannot see them or taste them in our water. The only protection we can get is from strong standards that are set federally. So, I applaud the EPA at taking these measures to put some impressive drinking water standards in place for some of these chemicals. It is a great start and they should be commended for following the science and working to protect the health and safety of our country. We do not have time to wait as any delay simply puts us at risk for further contamination. But please note, this is just the beginning. There are thousands more of these chemicals in a group that all need to be regulated. I look forward to working with the EPA to continue to protect the citizens in our country. Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Hope Grosse (Doc. #3072-35, SBC-046360)

Hi, my name's Hope Grosse, an affected community member and a Buxmont Coalition co-founder of Safer Water. I want to thank you for proposing these strict MCLs on some PFAS. I'm eager to hear when this will happen and grateful that you will continue to consider other PFAS chemicals to be added to the list as you move forward in an urgent manner. I was born in Warminster and lived directly across the street from the Warminster Navy Base the first 25 years of my life. My home was adjacent to a firefighting training center where firefighting foams containing PFAS were used and washed into the ground for over 50 years. 50 years. We watched the daily firefighting operations on my front porch. My family and others have private wells. Public water was not available to our homes, surrounding at the Navy base until 1996, when TCE and PCE and other volatile organic chemicals, heavy metals were found at high levels and the base was deemed a Superfund site. This was our first round of poisoning. Little did we know,

Round 2 PFAS, until 18 years later. Our well was in the front lawn of our property, 25 feet from the Navy's training area. We not only drank the contaminated water, we brushed our teeth in it, we swam in it in our pool, we showered in it, but most sickening was that my mother fed us baby formula mixed with this toxic chemical. I was one of six in my family, poisoned unknowingly. Growing up, all eight of our family pets died of tumorous cancers. Then in 1990, my father died from cancer at 52 years old. It wasn't just in my family. Our neighbor, he passed away from cancer three months prior to my father, and three months after burying my father, at age 25, I was diagnosed with Stage 4 cancer, which means this has been a lifelong sentence for me. During my treatments for cancer, doctors reportedly found and removed other rare tumors in my body. I've been dealt a lifelong cancer sentence, and this isn't the end. I just want to say that this is sickening and we need accountability as soon as possible. It's not just my town. We have so many people that are dying and ill from this poison, this invisible poison. So please act quickly. Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Newburgh Clean Water Project (Doc. #3072-36, SBC-046361)

Good afternoon and thank you for this opportunity to speak. My name's Jennifer Rawlison. I'm one of the 30,000 residents living in the City of Newburg. It's a historic city situated along the Hudson River in the beautiful Hudson Valley, New York, and with all that beauty we face the realities so many environmental justice communities are burdened with, the harmful industrial shadows of the past, and now present day, forever chemicals. I speak today as a member of Newburg Clean Water Project, a grassroots organization formed in response to the discovery that PFAS was running off our local Air National Guard Base and had contaminated our city's primary drinking water source and watershed for decades. I don't know how those decades of exposure to my family and neighbors have ultimately shaped my community. I cannot answer how different our lives may have been otherwise, but I can say our health and sense of security would've been stronger. Family and friends would still be here with us and our drinking water would be safe to drink. I speak today in support of the EPA and the proposed regulations and want to recognize they are long overdue. We know drinking water is a major form of exposure to PFAS and so establishing these regulations to prevent and reduce the exposure to these harmful chemicals is crucial. And as I listen to some bring up costs associated being used as debate or to have a pause, I can only say there is nothing more expensive than the disregard to the health and safety of communities across this nation. Our health cannot and should not be compromised, and therefore the chemical industry, utilities, and those responsible for the poisoning of our communities should bear the burden to clean up their messes and take responsibility for the harms they've caused. And lastly, I ask the EPA to recognize and regulate PFAS as a class, that way to ensure the most health protective steps for all Americans. Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Michigan League of Conservation Voters (Doc. #3072-38, SBC-046362)

Thank you so much for the opportunity to give public comment on these critical drinking water protections. My name is Bentley Johnson. In my day job, I work for the Michigan League of Conservation Voters, but today I'm really speaking as a resident of Ann Arbor, Michigan, which has had its source of drinking water contaminated with PFAS, the Huron River. And I really applaud and commend the EPA for proposing these strong limits on the six PFAS in our drinking water. It's long overdue. But these are really lifesaving protections and safeguards and I really encourage you to finalize them and make them as strong as possible as quickly as possible while also doing all your due diligence. In Ann Arbor, like I said, we've had harmful chemicals from a plating facility upstream in the Huron River watershed. We know that those chemicals continue to flow into the Huron River from that facility and other sources. And you know, we're blessed and we're privileged enough that we have the resources here in the city to take steps to filter the water. We need these national standards to ensure that every other community takes action. Even with the action at the city level at our water treatment plant, I'm still concerned. I have a seven-year-old and a four-year-old. I've gotten reverse osmosis filters at my house to make sure that my family is protected. But I think about it literally every day about what they might be consuming and what it might be doing to their health in the long term. So, these proposals and other proposals will literally save lives. We're really encouraged that EPA is proposing to use a hazard index on some of these to inform risks of chemical mixtures. And as you move forward, please take a comprehensive approach to regulating the entire class of chemicals and taking many other steps to prevent exposure from different pathways. Thank you so much and I stand ready to work with EPA to help move these along.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Great Lakes PFAS Action Network (Doc. #3072-39, SBC-046363)

Thank you. My name is Anthony Spaniola. I am a co-founder of the Need Our Water (NOW) PFAS Community Action Group in Oscoda, Michigan. I am also a co-founder and co-chair of the Great Lakes PFAS Action Network comprised of PFAS-impacted residents and groups across the Great Lakes region. I am also personally impacted by PFAS contamination from the former Wurtsmith Air Force Base in Oscoda, Michigan, the first publicly reported PFAS site in the nation, operated by the Department of Defense, the largest and worst known PFAS polluter in the United States. On behalf of my organizations, my community, and my family, I am here today to voice support in the strongest possible terms for the EPA's proposed PFAS National Primary Drinking Water Regulation and to call for its implementation with all deliberate speed.

PFAS contamination in my community of Oscoda, Michigan was first publicly reported more than 13 years ago. In our community, we have been living for a number of years under five separate PFAS public health warnings issued by our state health department. We know what it's like to be told that the fish we'd been eating for decades is unsafe. We know what it's like to be told that the water we'd been drinking for decades is unsafe. We've watched for years as cancers and other adverse health conditions have stricken our neighbors, our friends, and our families at alarmingly high rates. And we've watched for years as scientific gas lighters have tried to pretend it all away. The science is clear. The time for gaslighting and pretending is over. The EPA's proposed drinking water regulation will save lives. It will save productive human lives, human beings, real people like my neighbors, friends, and family, and those who have spoken before me here today, and millions of others across the nation. For those who devalue humanity, for those who look at this with only dollar signs in sight, I say in your terms, the costs of inaction is far greater than the costs and benefits of adopting and swiftly implementing the EPA's proposed regulation. We need safer drinking water. We need PFAS regulated as a class. We need all, but we need the current regulation adopted now. Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Faith Agarwal (Doc. #3072-40, SBC-046364)

Hello. Yes. So, I have two daughters and a son, and the PFAS chemicals that I've been drinking throughout my life has negatively affected their children. We know that this is a multi-generational toxin and needs to be swiftly regulated and stopped from our drinking water. So, I strongly support the proposed drinking water limits that the EPA has proposed for these six PFAS chemicals. And due to the slow pace of regulatory agencies, many Americans have been drinking these harmful amounts of PFAS chemicals for decades. So, the rules will speed the implementation of this lifesaving water treatment for communities across the U.S. Therefore, the Agency must finalize these rules as quickly as possible. In addition to the strong standards that the EPA's proposing for the PFOS and PFOA, I support EPA’s expedited action on the four chemicals that it's regulating with that Hazard Index approach. The method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals, and the EPA should extend this to include the other PFAS chemicals when your toxicological potency values are available. And consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in the water supplies for which that health information is more scarce. And next, the EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of the PFAS waste into the wastewater system, limit pollution caused by the biosolid sludge fertilizers, and set health-based limits for the PFAS in substance, fish, and other wild foods. I've seen people locally, young people getting sick, cancers, dying, teachers, people, you know, that we know and limiting this is very important work. Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA notes that the many topics raised in this comment beyond drinking water under SDWA, including emissions of "these and other PFAS chemicals from industrial sites and consumer products", the approval of new PFAS chemicals, PFAS in wastewater, biosolid sludge fertilizers, and "health-based limits of PFAS in substance, fish, and other wild foods", are outside the scope of this rulemaking. For more information on topics outside the scope of the final PFAS NPDWR, please see section 15 of the EPA response in this *Response to Comments* document. Section 15 of the *Response to Comments* document also discusses other actions that the EPA and other federal agencies are or may consider taking to address PFAS through a whole-of-government approach. In addition, although outside the scope of this action, please see section 10.4.2 of the EPA response in this *Response to Comments* document for discussion of disposal of spent drinking water materials under possible future regulatory actions and costs.

Northeastern University (Doc. #3072-42, SBC-046365)

Thank you very much. As a food safety expert and professor, I'm here to lend my support to the proposed National Primary Drinking Water Regulation that would establish minimum contaminant levels for PFAS in drinking water. The potential health effects of PFAS exposure are of great concern to us all, but are especially troubling for our youngest consumers. These substances have been linked to developmental issues, immune system dysfunction, cancer, and other concerns. Children are particularly vulnerable to the negative health effects of PFAS due to their small body size and developing organ systems. Thus, establishing legally enforceable levels for PFAS in drinking water is a critical step in protecting public health, especially for our children. Last year, the worldwide recall of powder infant formula resulting from a deadly outbreak of Cronobacter infections caused empty store shelves and desperation from worried parents looking for safe products to feed their infants. The safety of powder infant formula depends on the safety of the water parents use with the powder to feed their babies. If the water used to prepare infant formula contains high levels of PFAS, it can pose a serious risk of health to infants. Like earlier speakers, the risk of two infants through the food and water they need for nourishment and healthy development is something I know of from firsthand experience having buried my 16-month-old son, Riley, 30 years ago, due to high levels of pathogens in food that have since been further regulated. It is imperative that we set these standards for PFAS in drinking water to help prevent exposure to harmful contaminants that can have serious long-term health consequences from cradle to grave. I urge you to support the proposed regulation in favor of legally enforceable levels for PFAS in drinking water. By doing so, we can take an important step towards protecting the health and wellbeing of our communities and especially our young, most vulnerable consumers. Thank you for your work and for the opportunity to provide a statement for my support on this regulation. I give my time to fellow speakers.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Jonathan Needham (Doc. #3072-50, SBC-046370)

Yes. Thank you for your time. I just wanted to make a few brief comments. First of all, I wanted to congratulate the EPA on this groundbreaking paradigm-shifting effort. It is to be commended and supported. My concern is that things will take too long and we might get into a period of negotiation or reduction of the impact of this reducing levels, etc., so I would urge this to get wrapped up soon. And my final comment is to urge the EPA to consider extending these requirements. Obviously, drinking water is the #1 priority, but I would urge you to consider extending these requirements to include agricultural irrigation water as well as water used in industrial production processes. Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Bedford Citizen Representative on NH PFAS Commission & Bedford Town Councilor (Doc. #3072-52, SBC-046371)

Thank you, Mr. Willis. My name is Michael Strand. I currently serve as a Bedford New Hampshire Town Counselor as well as the local citizen, advocate, or representative on the New Hampshire PFAS Commission. I will be brief, I don't need the full two minutes. We'll bring it back locally. So, in New Hampshire we are an environment where our current MCL or standard is 0.12 or 12 parts per trillion. This unfortunately has led to large swaths of residential areas and wells that are slightly below that limit without any reimbursement, remuneration or remediation for PFAS contamination caused by a local private entity. It is my belief that should this regulation succeed and we actually have a viable standard for water that is safe and drinkable, that it will actually empower state regulatory bodies to probably recover and have more success at remediation and getting additional funds from the polluters who cause this. That's my primary concern. And I will also say, as much as I realize the cost associated with enforcing this seems prohibitive and scares folks with the spectrum of an unfunded mandate, I do believe that this has to be the first step without which we will have no ground to stand on or no ability to try and hold responsible parties more fiscally and ethically liable for what they cost. And I'll also say, we have recently seen, I think, some encouraging and promising results at the local level to improve municipal water treatment and standards working towards an MCL that actually is reflective of the value of clean water and public safety. Thank you very much.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Buxmont Coalition for Safer Water (Doc. #3072-56, SBC-046373)

Hi, my name is Joanne Stanton, co-founder of the Buxmont Coalition for Safer Water in Pennsylvania. I think it's really important that the EPA hears from impacted community members to understand the critical need to finalize these drinking water regulations. My personal PFAS story started when I was a young mother. I was naive. I thought if water came out of my kitchen faucet, it was safe. I had no idea that we had over 40,000 chemicals in consumer use with less than 10% of them ever tested for human health effects. We shouldn't have to worry that untested and unregulated chemicals like PFAS can easily make their way into our drinking water. Eight years ago, we learned that our community's drinking water was contaminated with PFAS for close to 50 years, with some of the highest levels of PFAS pollution ever detected from public drinking water wells. Our contamination source was two Department of Defense sites just outside Philly. As a mom, I started to read everything I could get my hands on about PFAS, and when I began researching the health effects, I learned that some of these chemicals can cross the placenta and affect a developing fetus, cause tumors, cancers, neural developmental problems, and even second-generation health effects. As I read this, my mind raced back to an earlier time when my son was diagnosed with cancer at age six. Back then, after my son's surgery, epidemiologist came into our hospital room and began asking my husband and me very pointed questions. Where do you live? Where was your early pregnancy? Have you or your husband ever worked with chemicals? They told us they found embryotic tissue in the center of my son's cancerous tumor, that meant it started to form during my pregnancy. There were three of us who grew up together on the same street within a few houses of each other, and all three of us had children with the same type of cancerous tumors with embryotic tissue found at the core. Our doctors immediately questioned our environmental exposures to chemicals and we eventually learned that we all drank PFAS contaminated water throughout entire childhood and during our pregnancies. As a mother, it was gut-wrenching for me to be told that my PFAS exposure might have caused my child's cancer. My story's not unique. We have families in my community and communities across this country that have been severely affected by PFAS. We have three-year-old's in town with kidney cancer and moms that don't feel they can safely breastfeed their babies because of the high levels of PFAS found in their breast milk. This is why we need to finalize without delay the proposed PFAS national drinking water regulation. It will save lives. I urge the EPA not to stop here. The EPA can prevent tens of thousands of cancer diagnoses across our country by simply requiring American manufacturers to adopt the precautionary principle where the burden of proof is on the emitter to prove a compound is safe before discharging it into the environment. Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Michigan League of Conservation Voters (Doc. #3072-57, SBC-046374)

Thank you for providing the opportunity to comment on these critical drinking water protections. My name is Jace Bylenga and I'm from Grand Rapids, Michigan and I applaud the Environmental Protection Agency for proposing strong limits on six widely detected PFAS in our drinking water. My great grandfather lived on the water in West Michigan and raised my grandfather and dad fishing on the Grand River, Spring Lake and Lake Michigan nearby, and my dad also raised me fishing there as well. I have recently learned that the levels of PFAS in fish in these bodies of water are very high and consuming one fish is as bad as drinking contaminated water for an entire month. These bodies of water are also downriver from the Wolverine World Wide PFAS contamination site, one of the worst in the nation in Rockford, Michigan. Many years ago, my dad was diagnosed with late-stage cancer, but he fought it and won at great cost, and although I can't say if there is a certain connection here, I know so many others have suffered so much from PFAS contamination in this same watershed and there is a very possible link. I doubt I will ever eat a fish out of those water bodies again and that is just heartbreaking. Would you feed your family one of those fish? That damage is priceless and arguments about the economics of this problem are ridiculous in the face of this toxicity and human suffering. Now I am a lifelong advocate for water protection and will continue to work with the Great Lakes PFAS Action Network and the Michigan League of Conservation Voters to ensure that strong protections for our families are put into place and enforced. We urge you to finalize these standards as quickly as possible. While this is an important first step, in order to fully protect the health of our people, communities, and the environment, we urge the EPA to move toward regulating PFAS as an entire class of chemicals instead of one by one. This proposal would save thousands of lives and prevent tens of thousands of serious PFAS related illnesses each year. These exposures are linked to serious health issues including increased rates of cancer, developmental and reproductive harm and other diseases. Thank you so much for instituting strong standards and thank you so much for your time.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Greenville Utilities Commission (Doc. #3072-53, SBC-047386)

PFAS compounds should be regulated at a point of use by the manufacturers. The proposed rule notes that these compounds are harmful to many systems, including cardiovascular and immune systems. These effects can be limited if the government will restrict the use of these compounds at the source rather than requiring the water industry to remove them once in the environment. Significant capital and annual operating costs will be needed to remove PFAS compounds to the proposed levels. The cost of the associated strategies to remove PFAS will increase due to the significant increase in demand for these strategies to meet the proposed compliance goals. The water industry is facing an aging infrastructure challenge that will require large investments to

ensure clean and safe water is provided to our customers. Funds should not be diverted from infrastructure needs to address contamination from multi-billion-dollar companies. Thank you.

EPA Response: The EPA acknowledges this comment. Please see section 1.3 of the EPA response in this *Response to Comments* document. The EPA notes the topic of regulating PFAS in manufacturing raised in this comment is outside the scope of this NPDWR rulemaking under SDWA. Please see section 15 of the EPA response in this *Response to Comments* document for topics out of scope of this NPDWR. Section 15 of the *Response to Comments* document also discusses other actions the EPA and other federal agencies are or may consider taking to address PFAS through a whole-of-government approach.

Clean Water Action (Doc. #3072-58, SBC-046375)

Yes, you did state my name correctly. Thank you. And I am speaking today on behalf of the thousands of members of Clean Water Action here in California. I am also a resident of San Jose, California, and my local water system has had to take my water supply offline after finding high levels of PFOS. On behalf of our members, we do support EPA's proposed regulation. California often gets overlooked in terms of the national picture because we do not manufacture PFAS in the state, yet after testing only 3% of our water systems, we know that the drinking water of 16 million people in this state have one or more PFAS in them. As monitoring expands, we know that number will go much higher, and a recent study showed that low-income communities of color served by smaller systems in domestic wells will bear an even greater burden. So, for us in this state, this is an environmental problem, a public health problem, and an environmental justice problem. So why do we support this proposal and what do we need moving forward? We support this because PFAS threatens lives at extremely low levels and as some of the people on this line have already indicated, no one wants to suffer health consequences because of their drinking water. We are sick of hearing about economic analyses and costs; cancer and other health effects are expensive and create tragedy. We support the hazard index approach because it is a first step to a class approach. We need this because we fear for inadequate treatment investments that don't capture other PFAS that will add cost to the future and send a false sense of safety in the interim. What we need as this regulation moves forward is for all of EPA to promote research on cost effective monitoring, treatment, and environmentally sound disposal of PFAS. Most of all, we need to stop this disaster from getting worse. While we in the state have made significant strides in eradicating uses of PFAS, we need to go bold and stop their use for all but a few essential uses and we need transparency as to the true scope of their use, and we're looking to EPA to do that as well. Thank you for this opportunity and we look forward to this moving forward.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Fountain Valley Clean Water Coalition (Doc. #3072-60, SBC-046376)

Hello, my name is Mark Anthony Favors. I'm a U.S. Army Vet, born and raised in Colorado Springs, Colorado. And my family has been exposed to PFAS for decades from Peterson Air Force Base in Colorado Springs without their consent and without their knowledge, until 2015. At least 16 of my family members have had cancer subsequently because of that, and many of them, you know, while serving in the U.S. Military as veterans. The CDC and the University of Colorado have found that the adults and children in the exposed areas have had significantly higher levels of PFAS in their blood when compared to people who weren't exposed. In fact, I had a cousin at age 14 who had sudden acute kidney failure and had to receive a new kidney and the doctors said it couldn't have been caused by genetics, so most likely environmental, and his mother had lived in the contamination area since she was age 10, because they believe our contamination started in the early 1970s. And like I said, many of my family members while serving combat tours for the United States Military had their families exposed here in the southern Colorado. In fact, my cousin PK who died of cancer last November, he was drafted during the Vietnam War and he reported, he didn't take any deferments and he reported and served in the military and he survived Vietnam, but only now to be buried in a U.S. military National Cemetery here in Colorado because he had been unknowingly drinking contaminated water by the government. So, you just think about that and there's several of our family members that died of cancer that are like that. They survived combat tours in either Vietnam, Korea, or the Middle East, but yet they survived that, but then now they're buried in military cemeteries after being poisoned by PFAS. And we all know it's all documented how the EPA and the Department of Defense have known for decades that these chemicals were toxic. So that's why I asked that the EPA, without any further delay, implement and regulate these PFAS chemicals quickly to save the lives of our adults and children all across the United States and military families and environmental justice communities. Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Raymond Choma (Doc. #3072-59, SBC-047390)

Hello, my name is Raymond Choma and I want to express my concern regarding the prevalence of PFAS chemicals in our drinking water. As a concerned citizen, I understand the impact that these forever chemicals can have on the environment and public health. I urge the EPA to finalize the PFAS National Primary Drinking Water Regulation to protect public health and deliver safe drinking water to all communities across America. As mentioned earlier, the EPA says there is no safe level of PFOA and PFOS, which are the most notorious forms of PFAS exposure. Exposure to PFAS chemicals can lead to several harmful health effects, including increased risk of cancer, decreased fertility rates, reduced immune system function, increased cholesterol levels, and developmental impacts to fetuses and infants. Implementing these new rules will help protect Americans and their communities. The impact, the EPA has a chance to

set a new and higher standard for safe tap water nationwide. Currently only seven states have enforceable drinking water standards for some PFAS. By enforcing stronger national protections, we can ensure that every community, especially those in lower income communities and communities of color, will be able to benefit.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Michigan League of Conservation Voters (Doc. #3072-63, SBC-046379)

Alright. Hello, my name is Madeleine Samuels. I work with the Michigan League of Conservation Voters and I would like to voice my support for the EPA's standards as I know how important it is that we set these boundaries for MCLs. I have sat in many meetings with community members impacted personally by PFAS contamination in West Michigan, namely the Rockford Belmont area. Corporations like Wolverine have been able to poison people and decimate their lives with contamination and it's time that they're held accountable. The steps that the EPA is taking are a great first step, but let's not forget that corporations have been putting people's lives in danger for generations with little to no accountability. I strongly urge you to do as much as you can to stop these greedy corporations from putting their profits over the lives of innocent people. Thank you for the opportunity to speak.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Midwest Environmental Advocates (Doc. #3072-65, SBC-046380)

My name is John Noonan, and I am here on behalf of Midwest Environmental Advocates to express our strong support for EPA's proposed National Primary Drinking Water Regulations for the PFAS in question. We support the promulgation of these proposed regulations because the substances meet the endangerment criteria set out in section 1412(b)(1)(A) of the Safe Drinking Water Act. Exposure to PFAS will likely be problematic for the health of persons. There's a substantial likelihood that PFAS contaminate public water systems at a frequency and level that is harmful to public health and the regulations present a meaningful opportunity to reduce public health risk. First, the PFAS chemicals may have adverse effects on the health of persons. EPA has provided enough scientific basis to support its findings. Second, there's a substantial likelihood that drinking water contamination will occur in public water systems at a frequency and level that is harmful to public health, and occurrence data in Wisconsin further supports EPA’s finding on this criterion. Currently, 20 communities across Wisconsin have detected PFAS in their public water systems. These include the City of Marshfield, a community of 18,000 people in West-Central Wisconsin, which detected PFOS concentrations as high as 101 parts per trillion in 2022. The City of Rhinelander, a community of over 7,700 people in northern

Wisconsin, which detected PFHxS concentrations at a high level of 90.1 parts per trillion in 2019, and the City of Madison in central Wisconsin where our organization is located. Madison serves around 235,000 people and there have been frequent detections of PFOS, PFOA, and PFHxS in this public water system since 2019. Third, these regulations present a meaningful opportunity for health risk reduction for persons served by public water systems. Thus far, more than 500,000 people comprising 20 communities in Wisconsin are served by public water systems that have detected PFAS chemicals in the recent past and will be helped by these regulations. We urge EPA to finalize this rulemaking expeditiously for the benefit of the public. My comments will be supplemented by written testimony. Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

GRS Inc. (Doc. #3072-67, SBC-046382)

Hello, I'm Jocelyn Lee, principal food safety consultant and director on the board of GRS Inc., involved in the food industry for 25 years and located in San Francisco Bay Area, California. I wholeheartedly support the EPA proposed rule. As a food safety consultant, my primary focus is on ensuring the safety of food products for public's consumption. Safe drinking water is also essential for maintaining public health, and it is important to consider the potential risks associated with water contamination. In particular, PFAS can accumulate in food products that are grown and raised using contaminated water as well as contaminated municipal water used as a raw ingredient and process aid, all which pose a risk to consumers. While verifying water quality via lab testing, water agency quality reports and certificates of analysis are a mandatory food safety code practice. PFAS is not in the testing criteria. Though a good many processors treat their site’s water, the PFAS level may not be reduced to acceptable levels. Processing sites need further PFAS mitigation and funding assistance to reduce and monitor the PFAS level in the water at the point of use within their sites according to the proposed MCL and standards proposed. Rapid PFAS tests for onsite monitoring and mitigation would be ideal for the food industry and our homes. PFAS contaminated water poses a significant risk to consumers leading to a range of illnesses and diseases. As such long overdue, it's never too late to implement important preventive controls and reintroduce monitoring programs to ensure that drinking water is safe for consumption and use in the food industry. It is critical that public health agencies and policy makers take swift action to address this issue and protect the public from further harmful effects of PFAS exposure. This must include implementing more stringent regulations and monitoring of PFAS in water sources, as well as providing resources for affected communities to address this issue. Please do not delay in enforcing this initiative. Our lives depend on this. And thank you for your work and opportunity to comment.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response*

to Comments document. For additional information regarding risk communication and resources, please see section 1.2 of the EPA response in this *Response to Comments* document.

Citizens Campaign for the Environment (Doc. #3072-64, SBC-047392)

Thank you. My name is Brian Smith and I'm the Associate Executive Director for Citizens Campaign for the Environment, an 120,000-member environmental advocacy organization working in New York State. We are grateful that EPA has taken this action and are supportive of adopting the proposed regulations with recommendations to further strengthen them. While New York State has been a national leader and an early adopter of MCLs for PFOA and PFOS, EPA's proposed regulations follow latest science and further enhance public health protections for New Yorkers and all Americans. With unprecedented investment in clean water infrastructure from the federal government as well as states such as New York, communities now have access to resources to install treatment technology needed to protect drinking water from PFAS. We support strong enforceable standards for PFOA and PFOS to what is likely the strongest, most health protective standard that is technically feasible at this point, at 4 ppt. Adopting these MCLs will help protect health of New Yorkers currently at risk. In fact, we analyzed the drinking water quality reports for just Long Island in New York State and found that 1.48 million residents were served by systems of levels of PFOA and/or PFOS lower than 10 ppt, which is New York's current MCL, but higher than EPA's proposed standard of 4 ppt. That's about a million and a half people that would receive additional protections with these regulations. We do support the Hazard Index for four additional PFAS chemicals, which addresses the combined impact of these chemicals. However, we do recommend the EPA include a mechanism to add additional PFAS chemicals to this Hazard Index to avoid lengthy delays associated with starting new regs from scratch.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. For additional details on incorporating additional PFAS into the Hazard Index, please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Clean Water Action (Doc. #3072-75, SBC-046385)

Hello, my name is Lynn Thorp and I'm the National Campaigns Director for Clean Water Action. We support EPA's proposal. EPA has appropriately analyzed health and occurrence information as well as feasibility of treatment to propose MCLs for PFOA and PFOS and to develop a Hazard Index approach for the four other PFAS chemicals. I wish we were not finding PFAS chemicals in drinking water around the country. We are likely to find more in data from the fifth round of unregulated contaminant monitoring going on right now. When this proposal is finalized, water systems will devote considerable effort and cost to comply with this regulation and their customers will help pay for that. However, knowing what we know about the wide range of public health risks from these chemicals, we cannot wait to take action to limit them in drinking water in keeping with all the statutory requirements. The federal government needs to

help water systems and communities hold PFAS manufacturers and users responsible for the drinking water contamination that has led us to this point. EPA estimates that drinking water can be 20% of our exposure to these chemicals. That means there are many other sources of exposure including food, air, products we handle like food packaging, workplace exposures and more. This proposal should, therefore, be a wake-up call. This National Primary Drinking Water Regulation proposal cannot be the only bold action taken in regard to PFAS. The Safe Drinking Water Act does not give EPA authority to keep chemicals out of drinking water, but we urge the Office of Groundwater and Drinking Water to do everything in its power to ensure that other parts of EPA and all federal partners are taking equally decisive action to reduce PFAS exposures and get these chemicals out of use. Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. Please see section 15 of the EPA response in this *Response to Comments* document for actions outside of the PFAS NPDWR under SDWA that the EPA and other federal agencies are or may consider taking to address PFAS through a whole-of-government approach.

Merrimack Citizens for Clean Water (Doc. #3072-68, SBC-047396)

Thank you. My name is actually Laurene Allen. I didn't realize that the Zoom was under my business name. I'm a clinical social worker. I am located right now in Milford, New Hampshire. I am the co-founder of Merrimack Citizens for Clean Water. We learned in 2016 that the water that we believe to be safe and pristine in our beautiful natural New Hampshire environment here was in fact contaminated and we had been drinking this water for decades. Our polluter is identified; it's Saint-Gobain Performance Plastics. The same travesties occurred in Hoosick Falls, New York, and in Bennington, Vermont. Discharges to environment have ruined our aquifers for miles. Currently, the investigation has expanded. We're seven years into this, we have over 100,000 impacted people at least that are acknowledged. And when we first learned about this, we were really minimized. You know, people looked around and shared stories. I thought about not only my personal observations, but my clinical work and all the health patterns I had seen that really puzzled me, neurologically, physically, etc. It matches all the research that we see. So, when you came out with your health advisory in June of last year, I was choked up. I was so validated. Everyone here just felt really seen by that acknowledgement that there is no safe level of PFOA and PFOS in a minimum. We also know we are exposed as a class, you know that also. I love the fact that you have taken this step for the hazardous index. It is brilliant. It is the way we need to go. We can't wait to prove what caused the illnesses that we see. And I will tell you what we see here in this community. The majority of people are at levels that were under that initial 70-part screening level and some of the homes in the area have relatively low exposure rates, yet their health patterns are similar to what we see absolutely everywhere. So, by setting this law, it's long overdue. You know, I really believed we had regulations to prevent this from happening, but unfortunately we have toxic chemicals that have evaded the label of toxicity for more than 20 years.

South Easton, MA 02375

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Clean Water Action (Doc. #3072-78, SBC-046387)

Thank you. My name is Jed Thorp and I'm the Rhode Island Director for Clean Water Action and we're pleased to have the opportunity to express our support for the EPA's proposed standards for PFAS in drinking water. As others have noted, these standards are long overdue. Just last year the Rhode Island General Assembly passed legislation setting state level standards for PFAS in drinking water, groundwater, and surface water. We've also banned PFAS in food packaging and legislation to ban non-essential uses of PFAS in a variety of consumer products is also currently under consideration, because we won't ultimately get PFAS out of our water or out of our bodies until we get PFAS out of products being sold. Many of the previous speakers have discussed the various health risks associated with PFAS exposure. We support the proposed 4 parts per trillion standard as it reflects the seriousness of those health risks. These proposed limits on PFAS in drinking water will prevent serious illness and they will save lives. As more testing is done over time, we'll likely find more and more sources of PFAS contamination, and we know that complying with these standards will be a challenge for some municipalities. While federal funding will help cities and towns meet these new standards, we hope that PFAS manufacturers will also be held financially accountable for contaminating drinking water, when the sources of contamination are clearly identified. While they may not give verbal testimony today, we know that the chemical industry and the folks responsible for this problem will be working hard to weaken these standards, but we urge EPA to do what you're charged to do, which is to protect the environment and public health and finalizing these proposed standards will do just that. Lastly, we urge EPA to work with other federal partners to think upstream, if you will, and take steps to get PFAS out of consumer products and ultimately to completely phase out their use. Thank you for your time.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

League of Conservation Voters (Doc. #3072-82, SBC-046391)

Good afternoon. My name is Lizzy Duncan, and I am with the League of Conservation Voters. LCV works to advance equitable policy solutions that ensure clean air, clean water, and access to our democracy are not a privilege but a right afforded to every community. Thank you for providing the time to speak today. I'm here today to urge the EPA to finalize the strongest possible standards for PFAS in drinking water. PFAS are extremely harmful forever chemicals that don't break down in the environment and are linked to serious health issues including liver

damage, cancer, asthma, and developmental harms. These health issues are often exacerbated in children. PFAS have been found to contaminate drinking water supplies of nearly 200 million people in the U.S. and this number is likely much higher because not every community is testing for PFAS. Even more frightening, more than 95% of the U.S. population already has PFAS in our bodies, which is unacceptable. The EPA's proposed rule to require monitoring, public notification and actions to eliminate and reduce PFAS exposure is critical and overdue. We are pleased to see that this rule has potential to prevent tens of thousands of PFAS related illnesses. Clean water is a basic human right. Our families and communities should be able to trust that the water coming out of the tap is safe. I'm urging EPA to do its duty of protecting the environment and safeguarding our health. Please move swiftly to finalize the strongest possible standards for PFAS in drinking water. Thank you.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Clean Water Action (Doc. #3072-84, SBC-046393)

Thank you all. Thanks for the opportunity to testify. My name is Cynthia Luppi and I'm the National Field Director for Clean Water Action. And I'm here today to reiterate that Clean Water Action supports EPA's proposed National Primary Drinking Water Regulations. Clear science and strong health imperatives support EPA's proposed action as many speakers have mentioned. We are driven to testify today on behalf of our members across the country and what they've experienced. This is a very local community-based issue for many of the grassroots leaders and members that we work with. And it's a very personal issue for families like that of Amara Strandis, who was diagnosed with Stage 4 liver cancer as a teenager. Growing up in Minnesota, she lived in the 3M plume and attended Tartan High School with other students directly affected by cancer. Amara spent the last weeks of her life urging action to comprehensively address PFAS pollution at all levels of government. Amara's story is a really powerful one and for all the Amaras and communities that are directly affected, we urge EPA to swiftly move forward with this proposed regulation. We know it's only a part of the PFAS action needed, but you know, clearly, we also need to ban PFAS in all but the currently or unavoidable uses in the many products in which it is found. But EPA's action today to pass the strongest possible rules are a central part of a protective PFAS agenda, and we thank you for moving forward in this way and again, thanks for the opportunity to testify.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Advisory Committee for Alachua County, Florida (Doc. #3072-102, SBC-046405)

Okay. Yeah. My name is David Moritz, I'm a resident of Florida and I'm a member of an advisory committee for Alachua County as well as being one of the people who started an amendment to the constitutional of Florida, petition at least to get it on the ballot. We haven't had much luck getting even where there is something that the EPA has put in place, getting the state to enforce it, and they seem to take away from the EPA whatever they can so they can enforce it themselves, so we kind of feel that the way to really go is to have state amendments, that green amendments, if you will, that essentially will give citizens the right to clean water, which means essentially that they can then go and sue their state government. Whether there's the governor or anyone in the Florida Department of Environmental Protection in our case, or any one of the other executive agencies in Florida that are responsible for enforcing the law. I agree with many of the comments made. I think the main problems are, the main problem is we found in Florida, you can't just leave this up to cleaning up the water after the fact, you've got to keep it out. You've got to get it to the source. And to that standpoint, you know, you just can't let these PFAS chemicals be made in the first place. They can't be put into products. They can't be distributed. They can't be allowed to be put back into the water when the companies have it in their waste system, waste stream. So that has to stop before we're going to be able to do anything with company. Otherwise, the utilities are going to be spending fortunes just to try and clean up after the companies and then as others have pointed out, we, the citizens will have to pay for it. The other thing I have a problem with is just limiting it to the six different specific PFAS chemicals when there's hundreds of them out there, and as soon you cut down on one, they're going to say, "Oh well, we'll we just move something over here, move this group over here, carbon or whatever we've got to do to get us to still work but be a different enough chemical that it is no longer regulated." Because you know that's what they're going to do. So, if we don't have something in place that takes the PFAS chemicals out as a class, as people have been saying and, we're not going to get anywhere with this. Thank you very much.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document. For additional discussion on incorporating additional PFAS into the Hazard Index, please see section 4.3.5 of the EPA response in this *Response to Comments* document. The EPA notes that the many topics raised in this comment beyond drinking water under SDWA, including the manufacturing, use, and distribution of PFAS and PFAS in wastewater, are outside the scope of this rulemaking. For more information on topics outside the scope of the final PFAS NPDWR, see section 15 of the EPA response in this *Response to Comments* document. Section 15 of the *Response to Comments* document also discusses other actions that the EPA and other federal agencies are or may consider taking to address PFAS through a whole-of-government approach.

Christine Géhant (Doc. #1871, SBC-047286)

Dear Michael Regan,

Merci d'avoir fait le premier pas pour réglementer les SPFA dans l'eau potable. Pendant des décennies, les SPFA ont contaminé les réserves d'eau potable de millions de personnes à travers le pays, entraînant une augmentation des taux de cancer, de dommages au développement et à la reproduction et d'autres maladies graves. Les normes proposées par l'EPA pour l'eau potable fourniraient des protections importantes et attendues depuis longtemps contre six de ces produits chimiques toxiques. Nous appuyons fermement les normes proposées et nous exhortons l'EPA à les finaliser le plus rapidement possible.

Les PFAS sont une classe de produits chimiques de grande taille, durables et très dangereuses. Souvent appelés « produits chimiques éternels », les SPFA persistent dans l'environnement, s'accumulent dans notre sang et nos organes et continuent de causer des dommages des décennies après leur rejet dans l'environnement. Les PFAS ont contaminé les réserves d'eau potable d'environ 200 millions de personnes et le sang de presque tous les individus aux États-Unis, y compris les nouveau-nés exposés in utero. Pourtant, malgré les risques graves pour la santé associés aux SPFA, il n'y a actuellement aucune limite fédérale sur les concentrations de SPFA dans l'eau potable.

La règle proposée par l'EPA fournirait de l'eau potable plus sûre aux communautés d'un océan à l'autre. En établissant des limites strictes pour six SPFA largement détectées, la proposition sauverait des milliers de vies et préviendrait des dizaines de milliers de maladies graves liées aux SPFA chaque année. L'EPA reconnaît et aborde les impacts cumulatifs sur les communautés qui sont exposées à de multiples PFAS, et en publiant cette proposition, l'EPA fait un pas de plus vers la réalisation de son engagement dans le cadre de la feuille de route stratégique 2021 des PFAS de commencer à réglementer les PFAS dans l'eau potable. Nous vous exhortons à finaliser rapidement ces normes et à mettre en œuvre une règle qui protège le mieux la santé, résistant aux efforts de l'industrie pour les affaiblir.

Sincerely,

Christine Géhant

25600

EPA Response: This comment was submitted in French, and the EPA translated it to English using Google to understand the comment. The EPA's response is in response to the Google translated version of the comment. The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Regula Hess (Doc. #2579, SBC-047287)

Dear Michael Regan,

Merci d'avoir fait le premier pas pour réglementer les SPFA dans l'eau potable. Pendant des décennies, les SPFA ont contaminé les réserves d'eau potable de millions de personnes à travers

le pays, entraînant une augmentation des taux de cancer, de dommages au développement et à la reproduction et d'autres maladies graves. Les normes proposées par l'EPA pour l'eau potable fourniraient des protections importantes et attendues depuis longtemps contre six de ces produits chimiques toxiques. Nous appuyons fermement les normes proposées et nous exhortons l'EPA à les finaliser le plus rapidement possible.

Les PFAS sont une classe de produits chimiques de grande taille, durables et très dangereuses. Souvent appelés « produits chimiques éternels », les SPFA persistent dans l'environnement, s'accumulent dans notre sang et nos organes et continuent de causer des dommages des décennies après leur rejet dans l'environnement. Les PFAS ont contaminé les réserves d'eau potable d'environ 200 millions de personnes et le sang de presque tous les individus aux États-Unis, y compris les nouveau-nés exposés in utero. Pourtant, malgré les risques graves pour la santé associés aux SPFA, il n'y a actuellement aucune limite fédérale sur les concentrations de SPFA dans l'eau potable.

La règle proposée par l'EPA fournirait de l'eau potable plus sûre aux communautés d'un océan à l'autre. En établissant des limites strictes pour six SPFA largement détectées, la proposition sauverait des milliers de vies et préviendrait des dizaines de milliers de maladies graves liées aux SPFA chaque année. L'EPA reconnaît et aborde les impacts cumulatifs sur les communautés qui sont exposées à de multiples PFAS, et en publiant cette proposition, l'EPA fait un pas de plus vers la réalisation de son engagement dans le cadre de la feuille de route stratégique 2021 des PFAS de commencer à réglementer les PFAS dans l'eau potable. Nous vous exhortons à finaliser rapidement ces normes et à mettre en œuvre une règle qui protège le mieux la santé, résistant aux efforts de l'industrie pour les affaiblir.

Sincerely,

regula hess

Dixon, CA 95620

EPA Response: This comment was submitted in French, and the EPA translated it to English using Google to understand the comment. The EPA's response is in response to the Google translated version of the comment. The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Laus Jacques (Doc. #2357, SBC-047288)

Dear Michael Regan,

Merci d'avoir fait le premier pas pour réglementer les SPFA dans l'eau potable. Pendant des décennies, les SPFA ont contaminé les réserves d'eau potable de millions de personnes à travers le pays, entraînant une augmentation des taux de cancer, de dommages au développement et à la reproduction et d'autres maladies graves. Les normes proposées par l'EPA pour l'eau potable

fourniraient des protections importantes et attendues depuis longtemps contre six de ces produits chimiques toxiques. Nous appuyons fermement les normes proposées et nous exhortons l'EPA à les finaliser le plus rapidement possible.

Les PFAS sont une classe de produits chimiques de grande taille, durables et très dangereuses. Souvent appelés « produits chimiques éternels », les SPFA persistent dans l'environnement, s'accumulent dans notre sang et nos organes et continuent de causer des dommages des décennies après leur rejet dans l'environnement. Les PFAS ont contaminé les réserves d'eau potable d'environ 200 millions de personnes et le sang de presque tous les individus aux États-Unis, y compris les nouveau-nés exposés in utero. Pourtant, malgré les risques graves pour la santé associés aux SPFA, il n'y a actuellement aucune limite fédérale sur les concentrations de SPFA dans l'eau potable.

La règle proposée par l'EPA fournirait de l'eau potable plus sûre aux communautés d'un océan à l'autre. En établissant des limites strictes pour six SPFA largement détectées, la proposition sauverait des milliers de vies et préviendrait des dizaines de milliers de maladies graves liées aux SPFA chaque année. L'EPA reconnaît et aborde les impacts cumulatifs sur les communautés qui sont exposées à de multiples PFAS, et en publiant cette proposition, l'EPA fait un pas de plus vers la réalisation de son engagement dans le cadre de la feuille de route stratégique 2021 des PFAS de commencer à réglementer les PFAS dans l'eau potable. Nous vous exhortons à finaliser rapidement ces normes et à mettre en œuvre une règle qui protège le mieux la santé, résistant aux efforts de l'industrie pour les affaiblir.

Sincerely,

Laus Jacques

70900

EPA Response: This comment was submitted in French, and the EPA translated it to English using Google to understand the comment. The EPA's response is in response to the Google translated version of the comment. The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Member of Congress (Doc. #3073, SBC-047676)

May 30, 2023

Administrator Michael S. Regan

U.S. Environmental Protection Agency

EPA Docket Center, OW Docket

Mail Code 28221T

1200 Pennsylvania Ave. NW Washington, DC 20460

Administrator Regan:

We write in strong support of the U.S. Environmental Protection Agency's (EPA's) proposed National Primary Drinking Water Regulations for per- and polyfluoroalkyl substances (PFAS). This proposal to regulate six types of PFAS, as individual chemicals and chemical mixtures, is critical to protecting our public health and environment. We are encouraged by the Biden administration's efforts thus far to address these toxic forever chemicals and strongly urge the EPA to finalize the standards as quickly as possible.

For far too long, the federal government has failed to set national standards to limit the concentration of PFAS in drinking water. PFAS chemicals pose grave danger to human health and our communities. They are persistent in the environment and human body, and many may be linked to serious health problems including thyroid, kidney, liver, heart and reproductive conditions.

Drinking water is a significant pathway of PFAS exposure, which is why we must address contamination before it reaches our communities' water systems. EPA estimates that 94 million Americans currently have drinking water contaminated by PFAS chemicals at levels above the limits proposed by EPA. Even at low levels of exposure, PFAS in drinking water may cause long term adverse health effects. We were pleased to see under EPA's proposal that drinking water utilities would be required to test water for PFOA and PFOS, as well as GenX, PFBS, PFNA, and PFHxS .

GenX, PFBS, PFNA, and PFHxS are among the thousands of forever chemicals that make up the class of PFAS, which have similar chemical structures and cause similar health effects. Testing for these chemicals as a mixture will provide a framework to address additional PFAS variations and mixtures of chemicals in the future.

As members of the bipartisan Congressional PFAS Task Force, we look forward to continuing our work with you to protect all Americans from harmful PFAS chemicals.

Sincerely,

Daniel T. Kildee

Member of Congress

Brian Fitzpatrick

Member of Congress

Debbie Dingell

Member of Congress

Michael V. Lawler

Member of Congress

Elissa Slotkin

Member of Congress

Mark Pocan

Member of Congress

Madeleine Dean

Member of Congress

Betty McCollum

Member of Congress

Haley M. Stevens

Member of Congress

Katie Porter

Member of Congress

Ro Khanna

Member of Congress

Brendan F. Boyle

Member of Congress

Jamie Raskin

Member of Congress

William R. Keating

Member of Congress

Jake Auchincloss

Member of Congress

Jerrold Nadler

Member of Congress

Bill Posey

Member of Congress

James P. McGovern

Member of Congress

Chellie Pingree

Member of Congress

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

Edward Cullen (Doc. #3075, SBC-047722)

Re: Docket ID No. EPA-HQ-OW-2022-0114, PFAS National Primary Drinking Water Regulation Rulemaking

I agree with the US EPA's plan to regulate per- and polyfluoroalkyl substances (PFAS) in US drinking water, as described in the March 29, 2023 Federal Register ("PFAS National Primary Drinking Water Regulation"; FR 88, 18638). I also urge the EPA to implement the new rules as soon as possible.

EPA Response: The EPA acknowledges and appreciates this comment in general support of the final PFAS NPDWR. Please see section 1.3 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045644)

[Attachment 2: Appendix A - Detailed Technical Comments on PFAS Toxicological Assessments : See Docket ID: EPA-HQ-OW-2022-0114-1759]

Appendix A

Detailed Technical Comments on PFAS Toxicological Assessments

Comments on the Proposed Regulation for Per - and Polyfluoroalkyl Substances (PFAS)

[Table of Contents: See Docket ID: EPA-HQ-OW-2022-0114-1759]

1. Introduction

This document provides comments on the science considered and technical methods and approaches applied in the development of the US Environmental Protection Agency's (USEPA) proposed National Primary Drinking Water Regulation (NPDWR) for six per- and polyfluoroalkyl substances (PFAS) including perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO-DA and its ammonium salt, commonly known as GenX Chemicals), perfluorohexane sulfonic acid (PFHxS), and perfluorobutane sulfonic acid (PFBS). Our review for these

comments includes the documentation of these methods and approaches in the following public comment drafts:

• Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctanoic Ace (PFOA) in Drinking Water (USEPA 2023a) and Appendices (USEPA 2023b);

• Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) in Drinking Water (USEPA 2023c) and Appendices (USEPA 2023d);

• Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation (USEPA 2023e) and Appendices (USEPA 2023f);

• Maximum Contaminant Level Goal (MCLG) Summary Document for a Mixture of Four Per- and Polyfluoroalkyl Substances (PFAS): HFPO-DA and its Ammonium Salt (also known as GenX Chemicals), PFBS, PFNA, and PFHxS (USEPA 2023g); and

• Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS) (USEPA 2023h).

EPA Response: The EPA acknowledges this comment. The EPA is addressing comments directly in other sections of the Response to Comments document organized by topic. Please see the applicable sections of the Response to Comments document responding to each detailed comment topic listed by the commenter. For an overview of how the EPA has met the requirements under the SDWA to promulgate this PFAS NPDWR, please see section 1.1 of the EPA response in this Response to Comments document. For additional high-level discussion of some of the points the commenter lists, please see section 1.3 of the EPA response in this *Response to Comments* document.

1.4 Entities to which the Action Applies

Summary of Major Public Comments and EPA Responses

The EPA has received comments related to applicability of this final PFAS NPDWR to various entities. Some commentors state that they believe the rule is unclear for whom it applies, with specific concerns around the applicability of this rule to wholesale and consecutive systems (also referred to as secondary systems). Some comments suggest that the rule should also apply to TNCWSs, or that the rule should apply to entities that do not meet the definition of a PWS under the SDWA. A few comments reflect concerns around private well owners and bottled water consumers.

Some comments request clarity around the definitions of systems that are included within this rulemaking, and to provide clarifying rationale as to why these systems are included or not. The EPA describes the entities in which this rule applies in section I.B in the preamble of the FRN. As defined under SDWA (42 USC 300f(4); 40 CFR 141.2), a PWS is "a system for the provision to the public of water for human consumption through pipes or, after August 5, 1998, other constructed conveyances, if such system has at least fifteen service connections or regularly

serves an average of at least twenty-five individuals daily at least 60 days out of the year". NPDWRs that are regulated under the SDWA only regulate PWSs if they meet these requirements. The EPA does not have the legal authority to regulate anything that is not defined as a PWS. PWSs can be classified as a community water system (CWS) or a non-community water system (transient and non-transient). Forty CFR 141.2 defines a CWS as a "public water system which serves at least fifteen service connections used by year-round residents or regularly serves at least twenty-five year-round residents;" and a non-transient non-community water system (NTNCWS) is defined as a "public water system that is not a community water system and that regularly serves at least twenty-five of the same persons over six months per year." As described in Section I.B of the final rule preamble, all CWSs and NTNCWSs are subject to the rule requirements under this PFAS NPDWR. Additional details regarding consecutive systems are included below.

Most comments provided in this section describe how the EPA has failed to differentiate the exact system classifications within the definition of a PWS that are required to monitor under this NPDWR. Because of this, commentors request that the EPA exempt consecutive systems, or systems that purchase from wholesale systems, from monitoring for the regulated contaminants within this NPDWR because it would be a waste of water system resources and would exacerbate existing laboratory capacity issues for these systems to test for PFAS, especially if the wholesale system is also already required to monitor under the NPDWR. Although no distinction for PWSs was included in the monitoring and compliance requirements (section VIII of the FRN), the EPA did provide clarifying language regarding consecutive systems in section I.B of the preamble and therefore believes that the language is clear. The requirements these consecutive systems must implement to comply with this regulation may be, and often are, much less extensive than for systems which draw untreated water from a given source water (i.e., non-consecutive systems).

For clarity, 40 CFR 141.2 defines a wholesale system as "a public water system that treats source water as necessary to produce finished water and then delivers some or all of that finished water to another public water system. Delivery may be through a direct connection or through the distribution system of one or more consecutive systems." Forty CFR 141.2 then defines a consecutive system as a "public water system that receives some or all its finished water from one or more wholesale systems." For finished water that is provided through a system interconnection (defined in 40 CFR 141.29 as the connection point between one or more PWSs), the wholesale system is responsible for conducting the PFAS NPDWR monitoring requirements at the EPTDS. Because the wholesale system will be conducting compliance monitoring for all regulated PFAS, and the EPA does not anticipate that concentrations of these PFAS will fluctuate between the wholesaler and purchasing systems or within the distribution system, the EPA will not require any monitoring to be conducted at a system interconnection point of a consecutive system. If an MCL violation does occur at an EPTDS, the wholesale system must notify their consecutive systems of this violation and the consecutive systems must provide PN to their customers. Wholesale systems must also provide any information on monitoring data and violations to their consecutive water systems. Those consecutive water systems must then

include this information in their CCR so their customers are informed about the quality of their water. In short, consecutive systems that receive all their finished drinking water from a wholesale system are not responsible for compliance monitoring for this NPDWR and are only responsible for providing their customers with a CCR regarding their water quality and PN if there is a violation of the NPDWR. This approach on consecutive system requirements, as well as for monitoring frameworks requiring entry point monitoring rather than distribution system monitoring, is consistent with other synthetic organic chemical (SOC) contaminants that the EPA currently regulates. For more information about the monitoring and compliance requirements, please see section 8 of the EPA response in this *Response to Comments* document. For more information about the CCR or the public notification requirements, please see section 9 of the EPA response in this *Response to Comments* document.

The EPA disagrees that this rule should apply to all public water systems, specifically TNCWSs. Forty CFR 141.2 defines a TNCWS as a "non-community water system that does not regularly serve at least 25 of the same persons over six months per year" (e.g., campgrounds, gas stations). TNCWSs are generally required to monitor for contaminants that exhibit an acute nature of exposure that results in immediate life-threatening health impacts, such as indicators for acute microbial contaminants like total coliforms (40 CFR Part 141.851) or nitrate and nitrite (40 CFR Part 141.23). Therefore, the EPA has determined that TNCWSs are to be excluded from this rulemaking, as exposure to the regulated PFAS in drinking water are not known to represent immediate acute health effects. This is consistent with the requirements under the Chemical Contaminants Phase II/V rules, (56 FR 3526 and 57 FR 31776, respectively), the Lead and Copper NPDWR (40 CFR Part 141 Subpart I), and most disinfection byproducts described in the Stage 2 Disinfectants and Disinfection Byproducts NPDWR (40 CFR Part 141 Subpart L), as examples. Importantly, the EPA allows primacy agencies (such as states or Tribes) to impose more stringent requirements than those described within NPDWRs. The EPA's NPDWR serves as the least stringent requirements and leaves room for primacy agencies to provide additional requirements for systems excluded by this rule, like for systems that are classified as transient but are serving schools or gas stations. Therefore, determination of system type can be done on a case-by-case basis. For additional discussion on why the six PFAS under this final regulation are determined to not represent immediately life-threatening health impacts, please see the section 9.2 of the EPA response in this *Response to Comments* document. For further discussion of the EPA's characterization of health effects from PFAS exposures, please see section 5.1.1 and 5.2.1 of the EPA response in this *Response to Comments* document for PFOA and PFOS, respectively; for health effects of the other PFAS subject to regulation under this rule, see section III.B of the preamble to the final rule. For comments that explicitly ask about protection for school systems and the EPA's response to those comments, please see the EPA response to comment Doc. #1473, SBC-042309 in section 1.4 in this *Response to Comments* document.

As previously described, the EPA only has the authority to promulgate a NPDWR for PWSs. Therefore, as noted above, this PFAS NPDWR only applies to PWSs that are CWSs and NTNCWs and does not apply to private wells or bottled water entities. The regulation of bottled water or management of private wells are outside the EPA's authority for promulgating an

NPDWR under the SDWA and therefore, outside the scope of this rulemaking. Though beyond the scope of the rulemaking, the EPA notes that the Food and Drug Administration (FDA) ensures that the quality standards for bottled water are compatible with the EPA's standards for public drinking water. See section 15 that discusses topics that are out of scope of this rulemaking. Please visit the EPA website to learn more about bottled water (https://www.epa.gov/sites/default/files/2015-11/documents/2005_09_14_faq_fs_healthseries_bottledwater.pdf) and private drinking water wells (https://www.epa.gov/privatewells).

Individual Public Comments

Jorge Diaz Castello (Doc. #1473, SBC-042309)

In closing schools have a responsibility to provide safe drinking water to their students and staff, and they should be held to the same standards as other public water systems. Furthermore, as children are particularly vulnerable to the effects of PFAS contamination, it is imperative that we take every possible step to protect them. By ensuring that schools are monitoring for PFAS and adhering to the MCLs, we can help to prevent the negative health impacts associated with these compounds.

Therefore, I urge you to directly address schools as NTNCWS for EPA's Proposed PFAS NPDWR.

Thank you for your consideration of this important issue.

Sincerely:

Jorge Diaz Castello diazcastello@gmail.com

786 381 8592

EPA Response: Many schools are served by CWSs and therefore the water they receive would be subject to the PFAS monitoring and MCLs at the CWS level. Schools that are NTNCWSs would also be subject to the PFAS monitoring and MCL requirements. A school that is not served by a CWS may be considered a NTNCWS if it meets the definition in 40 CFR 141.2. For schools that are not PWSs, the EPA does not have the authority to regulate them. As described in the section 1.4 of the EPA response in this *Response to Comments* document, the EPA only has the authority in a NPDWR to regulate a PWS so schools that are not considered a PWS are outside of the EPA's NPDWR authority. The EPA expects that the final rule would provide additional protection to both children and adults who consume drinking water supplied by the affected systems. The EPA also expects that the benefits of the final rule, including reduced health risk, will provide significant benefits to infants and children. SDWA Section 1412(b)3(C)(V) requires that in the HRRCA the EPA consider "[t]he effects of the contaminant on the general population and on groups within the general population such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other

subpopulations that are identified as likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population." For discussion of the benefits (including those for children) that were considered for the HRRCA of this NPDWR, please see section XII.E-G of the FRN and Section 6.2.2 of the EA. Consistent with SDWA Section 1412(b)(3)(C)(i)(V), when setting the MCLG, the EPA considers the effects of the contaminant on the general population and sensitive subpopulations, which includes for infants, children, and pregnant women. The PFAS NPDWR sets the MCLGs for PFOA and PFOS to zero and the MCL is set as close as feasible to these MCLGs. The NPDWR is protective against health effects in children that are described in more detail in sections IV and V of the FRN. Lastly, the EPA evaluated the environmental health or safety effects of the regulated PFAS found in drinking water on children and estimated the risk reduction benefits to children associated with the final rule to reduce these PFAS in drinking water, which is described further in the agency's analysis for *Executive Order 13045: Protection of Children from Environmental Health and Safety Risks* (section XIII.G of the FRN).

Jorge Diaz Castello (Doc. #1473, SBC-042307)

March 30, 2023

Ashley Greene

Standards & Risk Management Division

The Office of Groundwater & Drinking Water Environmental Protection Agency

1200 Pennsylvania Ave.

Washington, DC 20460

RE: EPA's Proposed PFAS NPDWR; Docket ID No. EPA-HQ-OW-2022-0114

Dear Mrs. Greene:

I am writing to express my support for EPA's Proposed PFAS NPDWR. As you may know, PFAS compounds have been linked to numerous health risks, and it is crucial that we take steps to limit exposure to these substances.

However, I urge you to consider directly addressing the applicability of schools as public water systems. While they may not fit the traditional definition of a public water system, they do meet the definition of a non-transient non-community water system (NTNCWS) as defined by the proposed regulation; an entity that provides water to at least 25 of the same people at least six months per year.

Schools must be responsible for ensuring that the water is safe for their students to drink. Given that children are particularly vulnerable to the effects of PFAS contamination, it is imperative that we take every possible step to protect them. By including schools in the regulation, we can

ensure that all children have access to safe drinking water, regardless of where they attend school.

EPA Response: The EPA acknowledges the commenter's support for the PFAS NPDWR rulemaking. Regarding applicability of the rule's requirements to schools, please see section 1.4 of the EPA response in this *Response to Comments* document, as well as the EPA response to comment Doc. #1473, SBC-042309 in section 1.4 in this *Response to Comments* document.

Jorge Diaz Castello (Doc. #1474, SBC-042310)

Applicability of proposed rule. See attached

March 30, 2023

Ashley Greene

Standards & Risk Management Division

The Office of Groundwater & Drinking Water

Environmental Protection Agency

1200 Pennsylvania Ave.

Washington, DC 20460

RE: EPA's Proposed PFAS NPDWR; Docket ID No. EPA-HQ-OW-2022-0114; Applicability to Non-transient, non-community water systems (NTNCWSs)

Dear Mrs. Greene:

Please address each scenario and advise if Proposed PFAS NPDWR applies:

1. Schools with more than 25+ students that also have drinking fountains or a cafeteria.

2. Office buildings with 25+ employees that also have drinking fountains, cafeteria, or kitchens.

3. Hotels with 25 employees that also have drinking fountains, cafeteria/restaurant.

4. Any facility with 25+ employees that also have drinking fountains, or cafeteria.

Let's get this right and leave out ambiguity.

Sincerely

Jorge Diaz Castello diazcastello@gmail.com

786 381 8592

EPA Response: Please see section 1.4 of the EPA response in this *Response to Comments* document. Regarding applicability of the rule's requirements to schools, please see section 1.4 of the EPA response in this *Response to Comments* document, as well as the EPA response to comment Doc. #1473, SBC-042309 in section 1.4 in this *Response to Comments* document. Whether individual schools and other facilities meet the legal requirements included in this rule are evaluated on a case-by-case basis. Many schools, office buildings, hotels, and other facilities with 25+ employees are served by CWSs and therefore the water they receive would be subject to the PFAS monitoring and MCLs at the CWS level. A school, office building, hotel, or other facility with 25+ employees that is not served by a CWS may be a NTNCWS if it meets the criteria in 40 CFR 141.2. Facilities that meet the definition for NTNCWSs would also be subject to the PFAS monitoring and MCL requirements. As described in section 1.4 of the EPA response in this *Response to Comments* document, the EPA only has the authority in a NPDWR to regulate a PWS so any of the listed facilities that are not considered a PWS are outside of the EPA's NPDWR authority.

Great Lakes Water Authority (GLWA) (Doc. #1558, SBC-042548)

Sampling Clarification

The proposed language currently uses Community Water System (CWS) terminology when defining systems required to sample. This language does not distinguish between treatment providers and receivers in consecutive systems. Therefore, each CWS would be required to sample for PFAS concentrations. Requiring samples by secondary systems is not warranted and only adds to the burden of sampling and analysis costs for our Member Partners while also straining laboratory capacity. GLWA further asserts that our member partners without connections to other water service providers should be eligible for sampling exemption status.

EPA Response: The EPA agrees that purchasing or consecutive systems are not subject to the rule's monitoring requirements. Regarding applicability of the rule's requirements to consecutive systems, please see section 1.4 of the EPA response in this *Response to Comments* document. For finished water that is provided through a system interconnection, wholesale systems will be responsible for conducting the monitoring requirements at the EPTDS. The final regulation does not require that any monitoring be conducted at a system interconnection point. For additional discussion on monitoring requirements, please see section 8.1.2 of the EPA response in this *Response to Comments* document. For more discussion on extensions and exemptions requirements, please see section 12 of the EPA response in this *Response to Comments* document.

Maine Water Utilities Association (MWUA) (Doc. #1567, SBC-042729)

Regulated Entities:

EPA proposes that Community Water Systems and Non-Transient, Non-Community Water Systems will be subject to this rule. If EPA is so concerned about drinking water as an exposure

pathway, MWUA believes that standards should also apply to Transient Non-Community Water Systems where employees could be drinking the water every day. More importantly, we additionally wonder why the Biden Administration is not moving forward with regulations (under the appropriate regulatory authority, if not EPA) to require testing of private wells. The inhabitants of a home drinking water from a private well are doing so in the same manner as customers served by a PWS. Similarly, the Food and Drug Administration should be regulating PFAS in bottled water. If PFAS is as dangerous as EPA is suggesting, we think that the EPA and the states' regulatory agencies should be as concerned about private well owners and bottled water consumers as they are about customers of PWSs and find the appropriate mechanisms to make all consumers aware of PFAS.

EPA Response: Please see section 1.4 of the EPA response in this *Response to Comments* document.

National Tribal Water Council-Tribal PFAS Working Group (NTWCTPWG) (Doc. #1598, SBC-042336)

Monitoring

On page 18734 of the FRN, it is stated that:

This action has tribal implications, it imposes direct compliance costs on tribal governments, and the Federal government will not provide funds necessary to pay those direct compliance costs. However, EPA notes that the Federal government will provide a potential source of funds necessary to offset some of those direct compliance costs through the BIL.

EPA has identified 998 PWSs serving tribal communities, 84 of which are federally owned. EPA estimates that tribal governments will incur PWS compliance costs of $5 million per year attributable to monitoring, treatment or non-treatment actions to reduce PFAS in drinking water, and administrative costs, and that these estimated impacts will not fall evenly across all tribal systems. The proposed PFAS NPDWR does offer regulatory relief by providing flexibilities for all water systems to potentially utilize pre-existing monitoring data in lieu of initial monitoring requirements and for groundwater CWSs and NTNCWSs serving 10,000 or fewer to reduce initial monitoring from quarterly monitoring during a consecutive 12-month period to only monitoring twice during a consecutive 12-month period. These flexibilities may result in implementation cost savings for many tribal systems since 98 percent of tribal CWSs and 94 percent of NTNCWs serve 10,000 or fewer people.

[In the above paragraphs, BIL indicates Bipartisan Infrastructure Law (Infrastructure Investment and Jobs Act; Public Law 117-58), CWSs indicates Community Water System, defined by EPA as a public water system that supplies water to the same population year-round, and NTNCWSs indicates Non-transient non-community water systems, which is defined by EPA as a public water system that regularly supplies water to at least 25 of the same people at least six months per year. Some examples of NTNCWSs given by EPA are schools, factories, office buildings,

and hospitals that have their own water systems. The following definitions are added for completeness. EPA defines a transient Non-Community Water System (TNCWS) as a public water system that provides water in a place such as a gas station or campground where people do not remain for long periods. Finally, a public water system provides water for human consumption through pipes or other constructed conveyances to at least 15 service connections or serves an average of at least 25 people for at least 60 days a year. A public water system may be publicly or privately owned. https://www.epa.gov/dwreginfo/information-about-publicwater-systems.]

The NTWC-TPWG recommends that language be included that recognizes the problems inherent in applying the (proposed) regulation to the numerous small tribal water systems that fail to meet the 25-person criterion for classification as a public water system and that speaks to monitoring guidance for such systems. This guidance could be located on a webpage hosted by EPA and be updated from time to time as PFAS understanding, experience and awareness improves, as compared to lodging the guidance as a static item in the (proposed) regulation.

EPA Response: The monitoring requirements of the final rule will be publicly available in the CFR. Water systems not defined as a PWS under SDWA, which are defined by the statute as providing water for human consumption to at least 15 service connections or serving an average of at least 25 people for at least 60 days a year, could consider using these monitoring requirements to inform the development of any voluntary sampling programs or processes, although they would not be required under the rule. As described in section 1.4 of the EPA response in this *Response to Comments* document, under SDWA, an NPDWR establishes requirements applicable to PWSs. Since the definition of a PWS is prescribed by statute in the SDWA, the EPA cannot amend that definition through an agency rulemaking. Further, NPDWR requirements for water systems that do not meet the requirements for a PWS, as defined in SDWA, are beyond the EPA's authority under the SDWA and therefore, outside the scope of this rulemaking. Regarding production of additional guidance and communication materials, please see section 1.2 of the EPA response in this *Response to Comments* document. For additional discussion around the EPA's pre-proposal Tribal consultation and outreach, please see section 14.6 of the EPA response in this *Response to Comments* document and section XIII.F of the final rule preamble.

The EPA acknowledges the challenges that the commentor has described regarding small Tribal water systems. Small water systems that do not meet the definition of a PWS as prescribed in the SDWA may receive assistance from the EPA's Training and Technical Assistance for Small Systems program (https://www.epa.gov/dwcapacity/training-and-technical-assistance-small-systems-funding), which provides support to small water systems as well as private well owners to improve water quality. Communities may request assistance from this and other EPA technical assistance programs using the WaterTA Request form (https://www.epa.gov/water-infrastructure/forms/water-technical-assistance-request-form). As described in the EPA response to comment Doc. #1784, SBC-045804 in section 14.10 in this *Response to Comments* document, the EPA is also working with Tribal drinking water systems to ensure they have resources to

address PFAS and other emerging contaminants. BIL has made substantial resources available to Tribes to help them identify and address PFAS and other Emerging Contaminants in drinking water through both the Drinking Water Infrastructure Grants Tribal Set-Aside and Emerging Contaminants in Small or Disadvantaged Communities Grant programs, with more information found here: https://www.epa.gov/tribaldrinkingwater and https://www.epa.gov/dwcapacity/emerging-contaminants-ec-small-or-disadvantaged-communities-grant-sdc. There are no cost-sharing requirements for these programs. Federally recognized Tribes are eligible to access these funds from both grant programs through the EPA Regional offices and are encouraged to reach out directly to the Regional Tribal Coordinators listed here to get more information on how to monitor for PFAS: https://www.epa.gov/tribaldrinkingwater/regional-tribal-drinking-water-coordinators.

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-042879)

Regulated Entities:

EPA proposes that Community Water Systems and Non-Transient, Non-Community Water Systems will be subject to this proposed regulation. Due to EPA's high level of concern regarding drinking water as an exposure pathway, MWWA believes that the standards should also apply to Transient Non-Community PWS where employees could be drinking the water every day. In addition, if reducing/eliminating public exposure to PFAS through drinking water is considered this urgent, MWWA wonders why the Biden Administration is not moving forward with regulations (under the appropriate agency's regulatory authority, if not EPA) to require testing and remediation of private wells. The inhabitants of a home where drinking water is supplied from a private well are utilizing water in the same manner as customers served by a PWS. Similarly, the Food and Drug Administration should be regulating PFAS in bottled water. If PFAS is as dangerous as EPA is suggesting, we contend that the EPA and the states' regulatory agencies should be as concerned about private well owners and bottled water consumers as they are about customers of PWSs and work with other governmental agencies to find the appropriate regulatory mechanisms to require PFAS protections for all water consumers.

EPA Response: Please see section 1.4 of the EPA response in this *Response to Comments* document, as well as the EPA response to comment Doc. #1567, SBC-042729 in section 1.4 in this *Response to Comments* document.

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-042900)

While private wells are not currently being regulated, homeowners may choose to remove PFAS from their private wells if they are aware of their presence. A point of entry treatment system currently costs approximately $6,000 in Massachusetts (this entails a sediment filter, water softener, and 2 carbon vessels). If the 311 private wells that had PFAS6 detections above 4 ppt were to install similar treatment that would amount to $1,866,000. The private well sampling that was conducted in Massachusetts represents a small percentage of these wells, so the magnitude

of costs would undoubtedly be more significant if every private well was tested. These systems will also have ongoing maintenance costs with the schedule of media replacement, largely dependent on the water use in a particular home.

EPA Response: Please see section 1.4 of the EPA response in this *Response to Comments* document. As discussed in that response to comment and acknowledged by the commenter, private wells are not covered by this rulemaking and beyond the scope of the EPA's authority to regulate public water systems through a NPDWR under the SDWA and this regulatory action.

Oakland County Water Resources Commissioner (WRC) (Doc. #1615, SBC-042929)

Additionally, the proposed regulations need clarifying language regarding the definition of a Community Water System (CWS) that is required to sample for PFAS concentrations. The current language does not distinguish between treatment providers and receivers that do not provide any treatment in consecutive systems. Without any distinction, each CWS is required to sample. For many of our customer communities, the Great Lakes Water Authority (GLWA) is the sole treatment provider. GLWA, as the treatment provider, should be required to sample for PFAS concentrations. However, water systems that directly receive treated water from GLWA, without connections to other water service providers, should be eligible for sampling exemption status or monitoring waiver. This would help reduce the financial burden of sampling and analysis costs and relieve strain on laboratory capacity.

Thank you for the opportunity to provide comments on this critically important matter. Please consider my office as an available resource as the EPA continues to develop the proposed regulations.

Sincerely,

Jim Nash

EPA Response: Please see section 1.4 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044090)

ASDWA recommends that EPA exempt water systems that purchase their water from other public water systems from monitoring requirements within the NPDWR.

The final rule should clarify and explain its reasoning on whether systems that purchase their drinking water from other public water systems will be required to monitor under the NPDWR. The Agency's proposed language uses the terms "ground water" and "surface water" when referring to both community water systems and non-transient non-community water systems, but terms are undefined. The Agency's definitions lack clarity regarding the inclusion of purchasing systems (or not). ASDWA recommends that EPA include an exemption from the monitoring

requirements for purchasing systems in the final rule, which would be consistent with existing exemptions for other chemical contaminants. Levels in the purchasing system would be controlled by the producing system, and there should not be an instance where the purchasing system would exceed the MCL if the producing system does not. Requiring purchasing systems to test for PFAS would be a waste of water system resources and exacerbate existing laboratory capacity issues.

EPA Response: Please see section 1.4 of the EPA response in this *Response to Comments* document.

Rural Community Assistance Partnership Incorporated (RCAP) (Doc. #1633, SBC-044145)

Additionally, the proposed PFAS NPDWR is applicable to public water systems but not private wells. We urge EPA and the President to work with Congress to ensure that the tens of millions of rural Americans served by both public water systems and private wells have the financial and technical assistance needed to protect themselves from these known carcinogens.

EPA Response: Please see section 1.4 of the EPA response in this *Response to Comments* document.

Citizens Against Ruining the Environment (CARE) (Doc. #1638, SBC-043444)

CARE further asserts that private well users should be protected from reduced home values that result from PFAS contamination of their groundwater.

EPA Response: Please see section 1.4 of the EPA response in this *Response to Comments* document. The impact of PFAS contamination on owners of homes served by private wells is beyond the scope of this regulatory action.

Citizens Against Ruining the Environment (CARE) (Doc. #1638, SBC-043455)

EPA Must Address Communities Excluded from the Benefits of the Proposal

Many CARE members reside in the Will County area where there is known PFAS contamination of groundwater and they rely on private wells to supply their drinking water. CARE understands that private well water regulation has historically been outside the scope of NPDWR, but nevertheless believes this is a critical environmental justice issue that should be addressed by EPA in this rulemaking. At this time, private well users are responsible for testing their well water for PFAS. This presents a financial burden and is time consuming for individual well users to navigate. Moreover, not all well users have the option to switch to a public system or a community well and those that do have the theoretical option often do not have the financial means to do so.

Thank you for your consideration of these comments.

Keith Harley, Attorney for Citizens Against Ruining the Environment

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EPA Response: Please see section 1.4 of the EPA response in this *Response to Comments* document.

National Rural Water Association (NRWA) (Doc. #1641, SBC-043269)

Lastly, NRWA requests clarification on the applicability of the proposed rule on consecutive water systems. Consecutive systems receive water that is understood to be compliant with the NPDWR standards. Consecutive systems should not be responsible for monitoring when they don't control the source. Most consecutive systems have little if any infrastructure. Installing any required treatment would be incredibly expensive.

EPA Response: Please see section 1.4 of the EPA response in this *Response to Comments* document.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044188)

9. NCDEQ recommends that EPA exempt water systems that purchase their water from other public water systems from monitoring requirements within the NPDWR.

The rule should clarify and explain its reasoning on whether systems that purchase their drinking water from other public water systems will be required to monitor under the NPDWR. The Agency's proposed language uses the terms "ground water" and "surface water" when referring to both community water systems and non-transient non-community water systems, but those terms are undefined. It is unclear whether the Agency's definitions include purchasing systems. NCDEQ recommends that EPA include an exemption from the monitoring requirements for purchasing systems within the final rule. Levels in the purchasing system would be controlled by the producing system, and there should not be an instance where the purchasing system would exceed the MCL if the producing system does not. Requiring purchasing systems to test for PFAS is unnecessary and will exacerbate existing laboratory capacity issues.

EPA Response: Please see section 1.4 of the EPA response in this *Response to Comments* document.

Inland Empire Utilities Agency (IEUA), California (Doc. #1666, SBC-043390)

Moreover, Section XIII Health Risk Reduction and Cost Analysis indicates that State and Tribal Agencies responsible for drinking water regulatory development and enforcement, and Public Water Systems (PWSs), such as Community Water Systems (CWSs) and Non-Transient, Non-Community Water Systems (NTNCWSs) will be affected by the proposed regulation. EPA does not mention utilities recharging recycled water as being impacted by new Federal MCLs upon adoption;

EPA Response: Please see section 1.4 of the EPA response in this *Response to Comments* document. Any system recharging recycled water must follow the SDWA. These systems would be subject to the MCL under this action if they meet the definition of a CWS or NTNCWS as defined by 40 CFR 141.2. For an overview of how water reuse is regulated at the federal level, please visit the EPA's Water Reuse Program's webpage at https://www.epa.gov/waterreuse/basic-information-about-water-reuse.

Arizona Corporation Commission (ACC) (Doc. #1735, SBC-045187)

SAMPLING CLARIFICATION

The current proposed language uses the term "Community Water System" (CWS) to define the systems that are required to conduct sampling. However, this language fails to differentiate between treatment providers and receivers in consecutive systems. As a result, every CWS, including secondary systems, would be obligated to perform sampling for PFAS concentrations and potential additional remediation. This requirement of sampling by secondary systems is unnecessary and imposes additional costs, while also putting pressure on already constrained laboratory capacity.

EPA Response: Please see section 1.4 of the EPA response in this *Response to Comments* document.

LSP Association (LSPA) (Doc. #1742, SBC-043602)

Slide 27: Costs are assessed as the expenses incurred by public water systems to monitor for the six PFAS included in the NPDWR, install and operate treatment technologies, inform consumers, and perform record-keeping and reporting responsibilities. State (or primacy agency) costs are assessed as expenses incurred to administer and implement the rule.

• One serious LSPA concern is the fact that roughly 15% of the US (over 40 million people, based on USGS data) use private residential wells to supply their water. USEPA's proposed regulations do not address these drinking water supplies. Many towns are already linking private well standards (which must be met after drilling a new well or, oftentimes, prior to a transaction of a home with an existing well) to federal or state drinking water standards for metals and organic compounds. Because residential drinking water wells are often present where on-site

septic systems are in use, a potential also exists for private well impacts as a result of PFAS discharges to residential septic systems. However, even private septic systems can result in concentrations of PFAS, particularly PFOA and PFOS, higher than the proposed PFAS MCLs. Public funds and grants are generally not available to private residents so costs for the installation, maintenance, and disposal of treatment materials would be borne by the homeowner.

EPA Response: Please see section 1.4 of the EPA response in this *Response to Comments* document.

LSP Association (LSPA) (Doc. #1742, SBC-043604)

The LSPA agrees with the MWWA in their May 26, 2023 comment letter regarding regulated entities (p. 8): "If PFAS is as dangerous as EPA is suggesting, we contend that the EPA and the states' regulatory agencies should be as concerned about private well owners and bottled water consumers as they are about customers of PWSs and work with other governmental agencies to find the appropriate regulatory mechanisms to require PFAS protections for all water consumers."

EPA Response: Please see section 1.4 of the EPA response in this *Response to Comments* document.

Environmental Protection Network (EPN) (Doc. #1773, SBC-043872)

EPN is concerned that the proposed rule does not specifically address monitoring requirements for seasonal non-transient non-community water systems (e.g., schools and camps/resorts) and seasonal sources (e.g., sources that are online as needed to handle peak or seasonal demand above normal levels). We strongly recommend the addition of these monitoring requirements to the final rule in order to ensure health protection.

EPA Response: Please see section 1.4 of the EPA response in this *Response to Comments* document. This rule applies to CWSs and NTNCWSs. If a seasonal system meets the definition of CWS or NTNCWS under 40 CFR 141.2, it would be subject to the requirements of this rule.

Neuse Regional Water and Sewer Authority (Doc. #1822, SBC-044569)

1. The Proposed Rulemaking should address how the regulation applies to water wholesalers who supply multiple independent water systems.

NRWASA asks EPA to revise the Proposed Rulemaking to address how operations similar to NRWASA's multi-system approach are covered. Specifically, we recommend that EPA clarify what category of system applies to water authorities. In addition, the final rule should address the location at which a water wholesaler must test its water before supplying customers.

The Proposed Rulemaking mentions systems with more than one water supply source, but not systems with more than one customer distribution system before water reaches consumers [FN2: EPA, PFAS National Primary Drinking Water Regulation Rulemaking, Federal Register Vol. 88, No. 60 page 18751.]. NRWASA has one source of water, the Neuse River, for distribution among eight system customers, and therefore asks EPA to ensure that the final rule provides clear and workable instruction on (i) whether NRWASA must test its water before supplying the water to each of its members; (ii) whether each of NRWASA's members must test after receiving supply from NRWASA and before distributing water to consumers; or, (iii) whether both NRWASA and its members must test NRWASA water.

EPA Response: For additional clarity on where within the CWS that monitoring will be required, please see section VIII of the FRN. To address the points listed, yes NRWASA will be required to test its water prior to providing water to its members. No, it is unlikely that each of NRWASA's members will be required to test the supplied water prior to distributing to their customers, unless the receiving members also have their own source of water that they use to supplement the NRWASA water. The final question on whether both NRWASA and its members must test NRWASA water depends on if the purchasing members supply or treat any of their own water as well. Please see section 1.4 of the EPA response in this *Response to Comments* document for additional clarity around the monitoring requirements for wholesale and consecutive systems, like NRWASA and its members.

New England Water Works Association (Doc. #1836, SBC-045380)

Regulated Entities:

EPA proposes that Community Water Systems and Non-Transient, Non-Community Water Systems will be subject to this rule. If EPA is so concerned about drinking water as an exposure pathway, NEWWA believes that standards should also apply to Transient Non-Community Water Systems where employees could be drinking the water every day. More importantly, NEWWA wonders why the Biden Administration is not moving forward with regulations (under the appropriate regulatory authority, if not EPA) to require testing and remediation of private wells. The homeowners drinking water from a private well are doing so in the same manner as customers served by a PWS.

EPA Response: Please see section 1.4 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #1953, SBC-047432)

My concern with regulating PFAS through the NPDWR, however, is that legal, enforceable standards only apply to public water systems. Consequently, many private sources of drinking water will not be held to a federal enforceable standard. Up to half of the US population is at risk of consuming unregulated and untreated waters from small, private systems (Weinmeyer et al.

2017, 1022). Such a risk potentially jeopardizes school children as some schools depend on independent systems.

Without federal oversight, we risk unregulated, PFAS contaminated drinking water to children. Children should not be victims of legal technicalities. Public schools cannot be exempt from regulating safe drinking water for their students. In these cases, public water drinking sources should be redefined to include the protection of public schools. We need to ensure that local, state, and federal agencies are fulfilling every possible step to protect children from PFAS contamination.

Thank you,

Concerned citizen.

References

Minnesota Department of Health. 2022. "Per- and Polyfluoroalkyl Substances (PFAS) and Health." September 6, 2022. https://www.health.state.mn.us/communities/environment/hazardous/docs/pfashealth.pdf

Weinmeyer, Richard, Annalise Norling, Margaret Kawarski, and Estelle Higgins. "The Safe Drinking Water Act of 1974 and its role in providing access to safe drinking water in the United States." AMA Journal of Ethics 19, no. 10 (2017): 1018-1026

EPA Response: Regarding applicability of the rule's requirements to schools, please see section 1.4 of the EPA response in this *Response to Comments* document, as well as the EPA response to comment Doc. #1473, SBC-042309 in section 1.4 in this *Response to Comments* document.

Duck River Utility Commission (Doc. #2310, SBC-046507)

This rule as written is extremely wasteful of utility funds and laboratory capacity. Only water producers need to test for PFAS compounds. There is no reason for the numerous utilities that purchase all of their water to test water they do not produce. It is testing the same water that the source utilities are already testing. PFAS is a source water contaminant. It only needs to be tested by utilities with source water. Utilities that purchase their water can get the results from their supplier utility. This duplication of cost is massive and also wastes laboratory capacity.

Please change the rule to only require utilities that produce water from a source to test for this contaminant. They can share those results.

EPA Response: Please see section 1.4 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2373, SBC-047425)

Comments on EPA's Proposed PFAS NPDWR

Docket ID: EPA-HQ-OW-2022-0114

While in general support of this new proposed regulation, there are still improvements that I believe could be made. The main issue I saw in this proposed rule is that it would not apply to all public water systems. All water systems (including transient non-community systems) should be required to meet this new PFAS standard to protect public health. At the very least, a cost-benefit analysis needs to be implemented. While the transient systems generally do not have the regular consumers in other water systems, I would argue it is still of great importance to enforce these same standards.

Our economy is highly dependent on businesses with transient water systems, and consumers should not question whether drinking water is safe for consumption or not. While I understand the perspective the EPA is coming from, I do not agree with not having any regulations for these transient systems. At the very least, there should be alternative limits that these systems have to meet instead of the more stringent requirements for other public water systems. However, I would still highly suggest that the proposed limits should be required for transient water systems since people are still consuming these waters regularly. What about the people who work at these businesses and consume their water on a regular basis? Collectively, this must account for many hundreds of thousands of people.

EPA Response: Please see section 1.4 of the EPA response in this *Response to Comments* document.

Sherry Hoffman (Doc. #2412, SBC-046502)

Docket ID No. EPA-HQ-OW-2022-0114

Our home is in Stone Meadow, Greenland, NH. We live one mile from Coakley Landfill Superfund site and with no access to town water; we have a well. For 17 years we have been to meetings, written letters, and lived very uncomfortably with extreme concerns for the status of our water. No level of PFAS exposure has proven to be safe. EPA's health advisories state that fact, advising that enforecment levels should be the lowest they can be. We implore you to hold that standard to reduce the risk with which we are living. This needs immediate support and attention.

Thank you,

Art and Sherry Hoffman

EPA Response: Please see section 1.4 of the EPA response in this *Response to Comments* document. For additional discussion regarding the final MCLs for this PFAS NPDWR, please see section 5 of the EPA response in this *Response to Comments* document.

Vanderbilt University Drinking Water Justice Lab (Doc. #3072-97, SBC-047410)

But Katie, you mentioned private wells, that is also a concern that private wells are not regulated by the Safe Drinking Water Act. So, if we find presence of PFAS in communities and we know that they are adjacent to communities that are using private wells, what do we do then? So, I know that would be an overhaul, congressional overhaul, the Safe Drinking Water Act, but we cannot continue to fail, the failure of not looking at drinking water quality in private wells. And I will close with, I really appreciate Paul DiLorenzo, your comments on these man-made chemical compounds. What's after PFAS? We know that was GenX, there's going to be something else. So, we also need to adopt, what was mentioned earlier, precautionary principles and get chemists involved to look at what chemical compounds are being used as part of U.S. manufacturing process because we have the ability to know what's dangerous and we need to create legislation to protect families like the Bryants. Thank you.

EPA Response: Please see section 1.4 of the EPA response in this *Response to Comments* document.

Great Lakes Water Authority (GLWA) (Doc. #1558, SBC-042550)

GLWA Responses to specific EPA Questions

In addition to the above GLWA concerns, EPA requested comment on many specific issues. GLWA responses to several issues are provided below.

Underlying assumptions that sufficient laboratory capacity will be available with the proposed MCLs; that demand will be sufficiently distributed during rule implementation to allow for laboratory capacity; and on the cost estimates related to these assumptions

The currently proposed language uses Public Water Supply (PWS)/Community Water Systems (CWS) terminology which includes secondary systems and requires sampling at the entry point to the distribution system (EPTDS). This language does not distinguish between treatment providers and receivers of consecutive systems and would require samples by the receiving communities. In the case of GLWA, that means 112 entities unnecessarily sampling water given that it has no opportunity to increase PFAS concentration following treatment and transmission.

Therefore, additional samples by secondary (or consecutive systems) is not warranted and only adds to the system's burden of sampling and analysis cost while also straining laboratory capacity. GLWA strongly requests that EPA consider defining the water treatment supplier as the only responsible sampler at the EPTDS.

EPA Response: Please see section 1.4 of the EPA response in this *Response to Comments* document regarding the terminology used for systems required to monitor for the NPDWR. For commenter concerns regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For cost

considerations when setting the MCL, please see section 5.1.3 of the EPA response in this *Response to Comments document*.

Section 1 References

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USEPA. 2021b. Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (CASRN 13252-13-6 and CASRN 62037-80-3). Also Known as "GenX Chemicals." EPA/822/R-21/010. Available on the Internet at:

https://www.epa.gov/system/files/documents/2021-10/genx-chemicals-toxicity-assessment_tech-edited_oct-21-508.pdf.USEPA 2024a, Office of Water Final Human Health Toxicity Assessment for Perfluorooctanoic Acid (PFOA). 815R24006.

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USEPA. 2024f. *OW Final Maximum Contaminant Level Goals (MCLGs) for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonic Acid (PFOS) in Drinking Water.* 815R24010

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2 Background

2.1 Definitions; What are PFAS?

Summary of Major Public Comments and EPA Responses

One commenter expressed strong support for the rule. Some commenters asked for clarification on the term "PFAS," which stands for Per- and Polyfluorinated Substances (PFAS), as well as which PFAS were being regulated by this action. PFAS is a general nonspecific name encompassing a group of substances. For the purposes of the fifth Contaminant Candidate List (CCL5), the EPA defined PFAS to include chemicals that contain at least one of these three structures: 1) R-(CF2)-CF(R′)R″, where both the CF2 and CF moieties are saturated carbons, and none of the R groups can be hydrogen 2) R-CF2OCF2-R′, where both the CF2 moieties are saturated carbons, and none of the R groups can be hydrogen, and 3) CF3C(CF3)RR′, where all the carbons are saturated, and none of the R groups can be hydrogen. The Organization of Economic Co-operation and Development (OECD), the United States Environmental Protection Agency (EPA), the World Health Organization (WHO), and the research community have all used various definitions as there is no singular consensus on exactly what features constitute the class of PFAS. The definition changes depending on the entity or regulatory body, scope, and application. An early definition was put forth by Robert Buck in a paper titled "Perfluoroalkyl and polyfluoroalkyl substances in the environment: Terminology, classification, and origins" which defined PFAS as "highly fluorinated aliphatic substances that contain 1 or more C atoms on which all the H substituents (present in the nonfluorinated analogues from which they are notionally derived) have been replaced by F atoms, in such a manner that they contain the perfluoroalkyl moiety C_nF_{2n+1}–." To address gaps in that definition, a more recent definition was put forth by the OECD in a paper titled "Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance," which wrote that "PFASs are defined as fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), i.e. with a few noted exceptions, any chemical with at least a perfluorinated methyl group (–CF_3) or a perfluorinated methylene group (–CF_2–) is a PFAS." As stated, PFAS is a very broad chemical class. For example, under the OECD definition, Fluoxetine, sold under various the brand names including Prozac, is a PFAS as well as many propellants used in inhalers and most anesthetic gases such as enflurane, isoflurane, desflurane, sevoflurane, and methoxyflurane. See section II.A of the proposal for a general description of PFAS. As explicitly stated in the rule proposal, this rule covers six specific PFAS in any form such as isomers, derivatives, or associated salts that may be created or identified. The exact technical definitions of the six regulated PFAS are found in section II.B of the rule proposal and in §141.2 of the Code of Federal Regulations (CFR) for the final rule.

Individual Public Comments

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-044879)

• DEP has identified several concerns related to definitions, including new proposed definitions in the rulemaking as well as terms that DEP believes should be defined. Specifically:

o EPA has not added a proposed definition for "PFAS." This acronym is used in the proposed definition for Hazard Index (HI) and in many other locations in the proposed rulemaking. DEP believes that it should be defined for clarity.

o EPA has not added a proposed definition for the term "regulated PFAS." This term is used throughout the proposed rulemaking and is not used consistently in all instances. This term may also have different meaning and significance than the acronym "PFAS" and should be defined separately. For example:

• [sec] 141.01(b)(l) states that analyses for "regulated PFAS" must be conducted by certified laboratories; it is implied that, in this case, it is referring to all six PFAS for which approved methods have been identified.

• The HI definition also uses the phrase "regulated PFAS," but PFOA and PFOS are not included in the HI calculation.

o DEP believes that the proposed definition for HI should include the calculation for determining compliance with the HI MCL. The calculation is only specified as a footnote to the tables in[sec] 141.50 and[sec] 141.61. DEP believes that it is inappropriate to only list this calculation in a footnote to a table.

o The proposed definition for HI also includes the phrase "regulated PFAS component" but does not identify the specific PFAS included in the HI MCL. Since PFOA and PFOS would also be considered regulated PFAS under the proposed rulemaking, this definition should clarify which PFAS are included, or the phrase "regulated PFAS component" should be defined.

o In the proposed definition for Hazard Quotient (HQ), DEP questions the use of the phrase "potential exposure to a substance" when it is actually the measured concentration used in the equation. DEP also suggests that instead of "the level at which no health effects are expected", the definition should refer to the health based water concentration (HBWC), which is also a newly defined term.

o In the proposed definition for HBWC, DEP suggests that instead of "levels protective of health effects" it should read "levels at which no health effects are expected".

EPA Response: Please see section 2.1 of the EPA response in this *Response to Comments* document. The six PFAS regulated by this rule are defined in §141.2 of the CFR and in the background section of the proposal preamble. Analyses for any/all of the six regulated PFAS must be conducted by certified laboratories. As the commenter notes, the requested

calculation is already included in a table footnote. The Hazard Index is comprised of four PFAS, (PFHxS, HFPO-DA, PFNA, and PFBS), which are defined in section 2. The proposal and the final rule clearly identify these four PFAS as the only components of the Hazard Index. The EPA notes that most water provided by utilities is not used for cooking or drinking so PFAS in drinking water that is used for example to water a lawn would not necessarily imply exposure despite it being a measured concentration. The EPA has updated the CFR §141.2 definition for the hazard quotient (HQ) with respect to the Health Based Water Concentration (HBWC) for additional clarity. The updated definition states that the HQ is the ratio of the measured concentration in drinking water to the HBWC (CFR § 141.2 Definitions).

Washington State Department of Health (DOH) (Doc. #1665, SBC-044391)

(1) General Comments

The Washington DOH strongly supports the EPA proposed PFAS drinking water standards. This is an important step in reducing exposure to PFAS to consumers of drinking water supplied by public water systems. There are areas within the proposed rule we would like to see clarification, additional information, further evaluation, and more specific guidance to help support successful implementation of the proposed PFAS rule at the state and local level.

• DOH requests that EPA provide clear definitions of all PFAS terms, including how they relate to levels of PFAS in drinking water.

EPA Response: The EPA refers the commenter to section 2.1 of the EPA response in this *Response to Comments* document noting that discussions of PFAS and definitions for the six regulated PFAS are provided in sections II.A and II.B of the proposed rule.

Thurston Public Utility District (PUD), WA (Doc. #1729, SBC-043583)

I would like to further ask, comment and request that:

1. The EPA provide clear definitions of all PFAS terms, including how they relate to levels of PFAS in drinking water.

2. The EPA clarifies language for health effects above the MCL and differentiates between health advisory language addressing potential health effects and lower PFAS levels.

EPA Response: Please see section 2.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1665, SBC-044391 from the Washington State Department of Health (DOH). Information on health effects of PFAS, including at concentrations above the Maximum Contaminant Levels (MCLs), may be found in sections 4 and 9.2 of the EPA response in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-044815)

Comments of the American Chemistry Council on Proposed National Primary Drinking Water Regulation for PFAS 88 Federal Register 18638

March 29, 2023

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52 Executive Summary

The Safe Drinking Water Act (SDWA) authorizes EPA to establish national drinking water standards for contaminants that it has determined may have an adverse health effect, are known or expected to occur in public water systems and for which there is a meaningful opportunity for health risk reduction. [FN1: 42 U.S.C. Section 300g-1(b)(1)A)] The Act outlines a multi-step process for data collection and evaluation of scientific, technical, and economic information with multiple opportunities for public comment and scientific peer review. Under its SDWA authority EPA has proposed to establish maximum contaminant levels (MCLs) and MCL goals (MCL Goals) for six per-and polyfluoroalkyl substances (PFAS) including perfluorooctanoate (PFOA), perfluorooctanesulfonate (PFOS), perfluorobutane sulfonate (PFBS), perfluorononanoate (PFNA), perfluorohexane sulfonate (PFHxS) and 2,3,3,3- tetrafluoro-2-(heptafluoropropoxy)propanoate (HFPO-DA). [FN2: Additional clarification is required on the definition of the materials covered by the proposed regulation. Although the proposal identifies the Chemical Abstract Service registration number for each substance, the definition for each also includes “any salts, derivatives, isomers or combinations thereof” for each.]

EPA Response: Please see section 2.1of the EPA response in this *Response to Comments* document. The EPA’s final rule includes data-driven drinking water standards that are based on the best available science and meet the requirements of the Safe Drinking Water Act (SDWA). The proposal identified one form that these chemicals are likely to be present in in drinking water however, as detailed in the rule proposal, “these PFAS may exist in multiple forms, such as isomers or associated salts and each form may have a separate CAS Registry number or no CAS at all.” The Chemical Abstract Service (CAS) was provided for the form most likely to be encountered in drinking water. For example, there are at least 11 substances with chemical formula $C_8HF_{15}O$ which have a CAS and at least 39 possible PFOA isomers that each may have many salts. The bullets presented here are addressed in various sections of this *Response to Comments* document. For additional discussion on the Maximum Contaminant Level Goals (MCLGs) and the EPA’s Health Risk Reduction and Cost Analysis (HRRCA), please see sections 4 and 13, respectively. Bullets related to the regulatory process are addressed in section 1of the EPA response in this *Response to Comments* document. Bullets related to the number of water systems affected are addressed in section 6 of the EPA response in this *Response to Comments* document.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044058)

36. General comment for consideration. Please clarify what is meant by HFPO-DA "and its ammonium salt". Using that language makes it seem as though it is an additional parameter that must be analyzed for and included in compliance calculations. Perhaps just drop this terminology, or clearly explain that it is not an additional/separate parameter.

EPA Response: Please see section 2.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1665, SBC-044391 from the Washington State Department of Health (DOH). Section II.B "Definitions" states that the six PFAS proposed for regulation may exist in multiple forms, such as isomers or associated salts and each form may have a separate CAS Registry number or no CAS at all. The regulation covers all salts, isomers and derivatives of the chemicals listed, including derivatives other than the anionic form that might be created or identified. EPA methods 533 and 537.1 measure the anionic forms that, at environmentally relevant pHs, these PFAS are expected to be in. The ammonium salt of HFPO-DA is expected to dissociate in water at environmentally relevant pHs and be measured as the anionic form.

2.2 Chemistry, Production and Uses, Human Health Effects

Summary of Major Public Comments and EPA Responses

Many commenters suggested that there should be universal PFAS restrictions and questioned why the EPA limited itself to these specific PFAS in one specific media (drinking water). The agency notes that the SDWA is one of multiple statutory authorities used by the EPA as a basis for actions to protect public health and the environment. SDWA applies specifically to drinking water and the EPA is promulgating this regulation under SDWA authority. Other actions may be taken by other agency programs to address other media using other statutory authority. Under SDWA, the EPA regulates contaminants that meet specific regulatory criteria as outlined in section 3 of this *Response to Comments* document. . This National Primary Drinking Water Regulation (NPDWR) addresses the removal of six PFAS (including HFPO-DA) known to cause adverse health effects as well as have a substantial likelihood to occur in public water systems (PWSs) with a frequency and levels of public health concern, consistent with the SDWA regulation criteria. As described in the EPA's *PFAS Strategic Roadmap*, the agency is committed to addressing PFAS contamination, including through the development of this PFAS NPDWR. The latter is a key action within this whole-of-agency approach (please see https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024 and section 15 of this document for discussion on the PFAS Roadmap). The EPA's approach considers the full PFAS lifecycle, and is based on getting upstream of the problem, holding polluters accountable, ensuring science-based decision making, and prioritizing disadvantaged communities. Specifically, the Roadmap sets timelines by which the EPA plans to take specific actions and commits to new policies to safeguard public health, protect the environment, and hold polluters accountable. The actions described in the PFAS Strategic Roadmap each represent important and meaningful steps to safeguard communities from PFAS contamination.

Cumulatively, these actions should lead to more enduring and protective solutions. In the Roadmap, the EPA notes that the agency "will bring deeper focus to preventing PFAS from entering the environment in the first place—a foundational step to reducing the exposure and potential risks of future PFAS contamination." Additionally, in the Roadmap, the EPA notes that "intervening at the beginning of the PFAS lifecycle—before they have entered the environment—is a foundational element of the EPA's whole-of-agency approach." PFAS manufacturing has been addressed via several significant new use rules and the agency's New Chemicals Program continues to review new PFAS before approving commercialization. More information on PFAS as a class is in section 2.3 of the EPA response in this *Response to Comments* document. Other EPA rules such as the as the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) designation are discussed in section 10.4.2, Treatment, of the EPA response in this *Response to Comments* document. The Office of Research and Development (ORD) as well as the Office of Science and Technology (OST) are evaluating and developing technologies for reducing PFAS in the environment to inform decisions on health effects, drinking water and wastewater treatment, contaminated site cleanup and remediation, air emission controls, and end-of-life materials management.

Additionally, the agency considers whether PFAS uses may be beneficial enough in specific applications or under appropriate controls to warrant use. As stated in the previous section, there is also no uniform agreed upon definition of PFAS and most definitions are written for specific purposes; as a result, there can be no perfect test method for PFAS as there is no fixed definition of what constitutes PFAS. This problem can compound if exemptions are made for beneficial uses. Additionally, current proxy methods such as a total organic fluorine test lack the analytical sensitivity to measure low enough concentrations to protect human health as these methods can reliably measure to approximately 100 ng/L and the health-based water concentrations for all but one of the PFAS species included in this rule are at least an order of magnitude below that. A total organic fluorine test also does not provide information on the specific constituents, so a 200 ng/L reading could either be very harmful to human health if it was composed of PFOS, for example but would not necessarily be harmful if it was PFBS for example. There may also be fluorinated chemicals that are not PFAS that this kind of test may measure. Imposing a rule without a mechanism to enforce or monitor will very likely not make a very effective rule for public health protection. Finally, there can be co-removal benefits where non-targeted PFAS are removed by default in trying to remove some of the targeted PFAS; this concept is discussed further in section 10.3 of the EPA response in this *Response to Comments* document as well as the final rule preamble. For more information on comments outside the purview of the SDWA please see section 15. For more information on the health effects, please see section 4 as well as the individual toxicity assessments.

Some commenters suggest that the EPA has dismissed thousands of PFAS as harmless to human health. Instead, the EPA, as it must by statute, has used the best available science in crafting this regulation. These are specific decisions that follow the regulatory process. For regulation under the SDWA, a contaminant must have an adverse health effect as well as be present at frequency and levels of public health concern in enough water systems that there is a meaningful

opportunity for public health risk reduction. In developing this rule, the agency considered the best available science on health effects, engineering, analytical methods, occurrence, and economics. The EPA also considered benefits and disbenefits from this regulation, as required under the SDWA. More information on the EPA's regulatory determinations can be found in section 3 of the EPA response in this *Response to Comments* document. More information on the health effects can be found in section 4 of the EPA response in this *Response to Comments* document. More information on how the EPA considered benefits and disbenefits can be found in section 13 of the EPA response in this *Response to Comments* document.

Some commenters suggested that the EPA is not moving quickly enough. The EPA is working as quickly as feasible under its statutory authority. More information on the SDWA rulemaking process including timelines can be found in section 1.1, the SDWA Rulemaking Process. Some commenters also stated that the EPA must move faster because their primacy agency is not moving quickly enough. The EPA creates a national baseline that others may build on. Primacy agencies may enact rules according to their authorities on their own timeline and are not precluded from enacting stricter rules than the EPA.

Some commenters pointed out there are other exposure pathways that the six PFAS included in this rule could follow to impact the health of Americans. For noncarcinogens, the EPA accounts for exposure to contaminants from non-drinking water sources by applying a relative source contribution (RSC) to the MCLG, health reference level (HRL), and HBWC. More information on RSCs is provided in sections 3 and 4.3 of the EPA response in this *Response to Comments* document.

Some commenters stressed the environmental justice (EJ) considerations in this rule. The EPA's EJ analysis for the final rule demonstrates that communities of color are anticipated to experience elevated baseline PFAS drinking water exposures compared to the entire sample population. However, the EPA believes that this action is likely to reduce existing disproportionate and adverse effects on people of color, low-income populations, and/or indigenous peoples. The EPA's EJ analysis finds that, across all health endpoints evaluated by the EPA, communities of color are anticipated to experience the greatest quantified benefits associated with the final rule. When examining costs anticipated to result from the final rule, the EPA finds that cost differences across both race/ethnicity and income groups are typically small, with no clear unidirectional trend in cost differences based on demographic group. To alleviate potential cost disparities identified by the EPA's analysis, there may be an opportunity for many communities to utilize Bipartisan Infrastructure Law (BIL) (P.L. 117-58) funding to provide financial assistance for addressing emerging contaminants. BIL funding has specific allocations for both disadvantaged and/or small communities and emerging contaminants, including PFAS. For more information on the EPA's EJ analysis, please see Chapter 8 of USEPA (2024a) and Appendix M of USEPA (2024b). For responses to comments related to the agency's EJ analysis, please see section 14.10 of the of the EPA response in this *Response to Comments* document. More information on BIL and EJ is in section 2.4.

Individual Public Comments

Anonymous (Doc. #1506, SBC-042578)

Although we believe EPA's regulations could be improved, there are some tradeoffs to these revisions. More stringent control over water regulation and compensation for those affected will result in a greater overall cost. However, we argue a lack of firm regulation now will result in greater medical costs in the future. Meaning spending more money on regulation upfront will be cheaper in the long run. PFAs also serve a useful role in our lives, contributing to the comfort and ease we experience as consumers. This means any regulation that inhibits the implementation of PFAs into these products will result in less convenience. We argue that comfort and convenience should not be prioritized at the cost of wellbeing. In addition, the durability associated with PFAs makes them difficult to eliminate from the environment (Darlington et al., 2018). However, we believe, although difficult, the effort to remove these chemicals has tremendous benefits. Overall, we highly encourage the EPA to modify their regulations to maximize well being and minimize harm for the entire ecosystem.

Resources:

Benesh, M. (2020). Why Are DuPont and Chemours Still Discharging the Most Notorious "Forever Chemical"?. Environmental Working Group. Www.ewg.org.https://www.ewg.org/news-insights/news/why-are-dupont-and-chemours-still-discharging-most-notorious-forever-chemical

Centers for Disease Control and Prevention. (2022). Per- and polyfluorinated substances (PFAS) factsheet. Centers for Disease Control and Prevention. https://www.cdc.gov/biomonitoring/PFAS_FactSheet.html

Darlington, R., Barth, E., & McKernan, J. (2018). The Challenges of PFAS Remediation. The Military engineer, 110(712), 58–60.

Morgenson, G. (2020). How DuPont may avoid paying to clean up a toxic "forever chemical." NBC News. https://www.nbcnews.com/health/cancer/how-dupont-may-avoid-paying-clean-toxic-fore ver-chemical-n1138766

Proposed Pfas National Primary Drinking Water Regulation. (n.d.). United States Environmental Protection Agency. https://www.epa.gov/system/files/documents/2023-03/PFAS%20NPDWR%20Public%20Presentation_Overview_3.16.23_508.pdf

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document.

Liliana Salcido (Doc. #1509, SBC-042582)

According to a journal written by Wendee Nicole, and published by Environmental Health Perspectives in the NCBI database, PFOA is found in the blood of 98% of Americans, and there is a strong association between PFOA exposure and 6 different diseases, most of which are

cancers (Nicole, 2013). Because most of the research has only been done in high exposure cohorts, it is extremely important for further research to be made amongst the general public as well.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document, which includes discussion of the EPA's PFAS Strategic Roadmap. Among the elements of the Roadmap is additional agency research.

Jon Raclin (Doc. #1511, SBC-042593)

This source adds some details as to why the chemicals cause sickness and what sicknesses. The article mainly focuses on the policy change and not the underlying issue at hand. I understood this not as a bias, but as a written perspective from the EPA.

From just reading the EPA article no, I do not know enough yet, however I do feel like I could guess where I would vote at the end.

Some additional evidence that I could find was in the National Institute of Health, the NIH, stating, "People are most likely exposed to these chemicals by consuming PFAS-contaminated water or food, using products made with PFAS, or breathing air containing PFAS". Also the NIH said, "The research conducted to date reveals possible links between human exposures to PFAS and adverse health outcomes. These health effects include altered metabolism, [Link: https://www.niehs.nih.gov/health/topics/agents/pfc/index.cfm#footnote2], fertility, [Link: https://www.niehs.nih.gov/health/topics/agents/pfc/index.cfm#footnote3], reduced fetal growth and increased risk of being overweight or obese, [Link: https://www.niehs.nih.gov/health/topics/agents/pfc/index.cfm#footnote4], increased risk of some cancers, and reduced ability of the immune system to fight infections. [Link: https://www.niehs.nih.gov/health/topics/agents/pfc/index.cfm#footnote5]".

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document.

Christian Garcia (Doc. #1513, SBC-042603)

PFAS are a group of chemicals used to make fluoropolymer coatings and products that resist heat, oil, stains, grease, and water. [FN1: CENTERS FOR DISEASE CONTROL AND PREVENTION, Per- and Polyfluorinated Substances (PFAS) Factsheet, https://www.cdc.gov/biomonitoring/PFAS_FactSheet.html (last visited Apr. 21, 2023).] PFAS are routinely referred to as "forever chemicals" because they breakdown extremely slowly, can move through soils and contaminate drinking water sources, and can build up (bioaccumulate) in people and animals. [FN2: National Institutes of Health, Perfluoroalkyl and Polyfluorinated Substances (PFAS), U.S. Dep't of Health and Human Svcs., https://www.niehs.nih.gov/health/materials/perfluoroalkyl_and_polyfluoroalkyl_substances_508.pdf (last visited Apr. 21, 2023).] Exposure to PFAS "increases the risk of cancer, harms the

development of the fetus and reduces the effectiveness of vaccines." [FN3: Sydney Evans, David Andres, Ph.D., Tasha Stoiber, Ph.D. & Olga Naidenko, Ph.D., PFAS Contamination of Drinking Water Far More Prevalent Than Previously Reported, https://www.ewg.org/research/national-pfas-testing (last visited Apr. 21, 2023).] Biomonitoring studies by the Centers for Disease Control and Prevention show that the blood of nearly all Americans is contaminated with PFAS. [FN4: CENTERS FOR DISEASE CONTROL AND PREVENTION, Per- and Polyfluorinated Substances (PFAS) Factsheet, https://www.cdc.gov/biomonitoring/PFAS_FactSheet.html (last visited Apr. 21, 2023)]

PFAS found in drinking water can make up a significant portion of a person's total PFAS exposure. [FN5: U.S. ENVIRONMENTAL PROTECTION AGENCY, EPA's Proposal to Limit PFAS in Drinking Water (March 2023),https://www.epa.gov/systems/files/documents/2023-04/Fact%20Sheet_PFAS_NPDWR_Final_4.4.23.pdf (last visited Apr. 21, 2023).]The Environmental Working Group has mapped PFAS contamination of drinking water or ground water in almost 1,400 sites in 49 states. [FN6: Sydney Evans, David Andres, Ph.D., Tasha Stoiber, Ph.D. & Olga Naidenko, Ph.D., PFAS Contamination of Drinking Water Far More Prevalent Than Previously Reported, https://www.ewg.org/research/national-pfas-testing (last visited Apr. 21, 2023).] As a result, the Environmental Working Group estimates that water supplies for over 110 million Americans may be contaminated with PFAS. [FN7: Id.] Such PFAS exposure, could lead to detrimental health effects. Most of the widely known adverse health effects include developmental effects affecting unborn children, breast cancer, thyroid disease, liver damage, kidney cancer, and increased cholesterol levels. [FN8: Suzanne E. Fenton et al, Per- and Polyfluoroalkyl Substance Toxicity and Human Health Review: Current State of Knowledge and Strategies for Informing Future Research, 40(3) ENVIRON. TOXICOL. CHEM. 606, 606-630 (2021).] According to recent studies, animals experience similar health effects. [FN9: Id.] Additionally, there may be further links adverse effects of PFAS on the nervous system, including reported neurotoxicity of PFAS in cell culture as well as altered behavioral responses and deficits in learning and memory ability. [FN10: Id.]

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document.

Daniel Varon (Doc. #1518, SBC-042722)

As it stands, the EPA has an advisory level of 70 ng/L maximum recommend levels in drinking for lifetime consumption. [FN8: JENNIFER L. GUELFO ET. AL., EVALUATION AND MANAGEMENT STRATEGIES FOR PER- AND POLYFLUOROALKYL SUBSTANCES(PFASS) IN DRINKING WATER AQUIFERS: PERSPECTIVES FROM IMPACTED U.S. NORTHEAST COMMUNITIES 2 (2018).] This means that over an individual's lifetime, if they drink water with 70 ng/L exposure daily, the EPA still thinks they will be protected from adverse health effects. The studies used to suggest a correlation between PFAS, and health consequences vary vastly from the EPA advisory level. [FN9: Id.]

The large studies that the CDC relies on in determining the "correlation" between PFAS and adverse health effects is the C8 Health Study. [FN10: AGENCY FOR TOXIC SUBSTANCE AND DISEASE REGISTRY, supra note 7.] These studies, self-admittedly "limited" in nature, yield interesting results. [FN11: Id.] First, some of the studies suggesting a strong correlation were shown with "high" levels of PFAS contamination—as high as 1700 ng/L. [FN12: Eva. M. Andersson, et al., High Exposure to Perfluorinated Compounds in Drinking Water and Thyroid Disease. A Cohort Study from Ronneby, Sweden, 176 ENV'T RSCH. 1 (2019).] Even if not to this extreme of a level, other studies evidencing correlation still showed levels above the EPA's recommended level. [FN13: GUELFO, supra note 8; Yiyi Xu, et. al., Inflammatory Bowel Disease and Biomarkers of Gut Inflammation and Permeability in a Community with High Exposure to Perfluoroalkyl Substances through Drinking Water, 181 ENV'T RSCH. 1 (2020).] Thus, the levels evidencing negative PFAS health consequences are above what the average American consumes.

Furthermore, studies indicated that 72% of PFAS detections comes from groundwater sources. [FN14: GUELFO, supra note 8] Groundwater is the water source for 33% of public water supplies, and 90% of the supplies in rural regions. [FN15: Id.] This indicates two things: (1) PFAS in contaminated water has a disparate impact across the United States, impacting rural regions more so than urban ones; and (2) perhaps attacking groundwater contamination could fight how PFAS end up in human's systems. Either option further shows that blanket regulation on every city's water systems may not be the most cost-effective policy.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. Commenter has cited 2016 EPA health advisory (HA) values, which were updated and lowered in 2022. For more information on this final rule and evaluation of health effects, including MCLGs and HBWCs, please see section IV of the final rule preamble.

Isabelle Dominguez (Doc. #1525, SBC-042625)

As the agency is well aware, per- and polyfluoroalkyl Substances (PFAS) are chemicals that are often used for their water- and oil-repellant properties. [FN1: Paul Frysh, PFAS: What to Know, WEBMD, https://www.webmd.com/a-to-z-guides/what-is-pfas (last reviewed June 16, 2022).] PFAS are used in fire repellants, electronics, and cookware, making them nearly omnipresent in today's society. [FN2: Id.] PFAS are known as "forever chemicals" because their carbonfluorine bonds make them "incredibly strong" and allow them to build up and "linger [in the environment] on geologic time scales." [FN3: Per- and Polyfluorinated Substances (PFAS), CDC, https://www.cdc.gov/biomonitoring/PFAS_FactSheet.html (last updated May 2, 2022) [hereinafter CDC PFAS].] This includes the buildup of PFAS in our drinking water. [FN4: Seen generally David Q. Andrews & Olga V. Naidenko, Population-Wide Exposure to Per- and Polyfluoroalkyl Substances from Drinking Water in the United States, 7 ENV'T SCI. TECH. LETTER 931 (2020).] This is the issue that the proposed regulation seeks to remedy.

There is conclusive evidence that PFAS exposure is rampant throughout the United States. Since 1999, "CDC scientists have found four PFAS (PFOS, PFOA, PFHxS…and PFNA) in the serum of nearly all people tested. This indicates widespread exposure to the PFAS in the U.S. population." [FN5: CDC PFAS, supra note 3. For the full report and data, see National Report on Human Exposure to Environmental Chemicals, CDC, https://www.cdc.gov/exposurereport/ (last reviewed Dec. 15, 2022).] Academic studies by independent institutions have come to the same conclusion. [FN6: See Andrews & Naidenko, supra note 4, at 933; see also Zhen Zaho et al., Perfuoroalkyl and Polyfuoroalkyl Substances (PFASs) in Groundwater: Current Understandings and Challenges to Overcome, 29 ENV'T SCI. AND POLLUTION RSCH. 49513, 49515-16 (2022); see also Elise M. Sunderland et al., A Review of the Pathways of Human Exposure to Poly- and Perfluoroalkyl Substances (PFASs) and Present Understanding of Health Effects, 39 J. EXPOSURE SCI. & ENV'T EPIDEMIOLOGY 131, 133-34 (2019).] Moreover, studies demonstrate that levels of PFAS have increased in accumulation in drinking water over the past few decades. [FN7: Xindi C. Hu et al, Tap Water Contributions to Plasma Concentrations of Poly- and PerfluoroalkylSubstances (PFAS) in a Nationwide Prospective Cohort of U.S. Women, 12(6) ENV'T HEALTH PERSPS. 067006-1, 067006-7 (2019).]

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document.

Water Environment Federation (WEF) (Doc. #1529, SBC-043313)

Research: Continued research is necessary in understanding the exposure impacts of PFAS from manufacturing, point of use, and fate and transport in the environment. Transparent and concise documentation of the results of the research and what it means to the public is essential.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document.

Robert Adamski (Doc. #1530, SBC-043333)

At the present time there is no strong link between the chemicals and any effects on human health. EPAs own Science Advisory Board said, "While the SAB agrees with the "likely" designation for PFOA carcinogenicity based on new evidence and prior evidence included in the 2016 HESD, a more structured and transparent "weight of evidence" discussion to support the rationale behind this designation is needed." Further the National Academy of Science states, "there is inadequate or insufficient evidence of many other health impacts."

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. The EPA also refers the commenter to the MCL and MCLG Derivation sections as well as the supporting documentation such as the *Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) in Drinking Water*, the *Final Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and*

Its Ammonium Salt (CASRN 13252-13-6 and CASRN 62037-80-3) Also Known as "GenX Chemicals," and other related supporting documents.

Linda Shosie (Doc. #1533, SBC-043964)

There is growing evidence that even at the lowest levels of exposure to PFAS can cause very large and varying sets of serious health effects, including cancer, reduced immune system function, and disrupt the human endocrine system and threaten the developing fetus. Furthermore, these toxic chemicals are highly persistent in the environment and accumulate in human bodies, and in the food chain, posing a significant threat to health, wildlife and ecosystems.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document.

Greenville Utilities Commission (Doc. #1534, SBC-042636)

May 1, 2023

Michael S. Regan

US Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington, DC 20460

RE: Comments for Docket ID #: EPA-HQ-OW-2022-0114; PFAS National Primary Drinking Water Regulation Rulemaking

Dear Administrator Regan,

The proposed Maximum Contaminant Levels (MCL's) of 4 parts per trillion (ppt) for PFAS compounds and the goal of 0 ppt are unprecedented regulatory actions and it will be extremely difficult and expensive for many water providers to meet. PFAS compounds are ubiquitous not just near known spills or contamination sites due to these compounds being used in many products encountered in our lives each day including food wrappers, cookware, personal care products, clothing, and cosmetics. Drinking water is only one of several routes of exposure to PFAS compounds, and the drinking water industry should not be disproportionately targeted by government's regulatory action to reduce PFAS exposure.

EPA Response: The EPA agrees that drinking water is only one route of exposure to PFAS. For noncarcinogens, the EPA accounts for exposure to contaminants from non-drinking water sources by applying a RSC to the MCLG, HRL, or HBWC. More information on RSCs is provided in section 3 and section 4.3 of the EPA response in this *Response to Comments* document. MCL derivation may be found in section 5 of the EPA response in this *Response to*

Comments document. The EPA also agrees that a holistic approach for handing these chemicals is required as outlined in the PFAS Strategic Roadmap. The EPA disagrees that the drinking water industry is disproportionately targeted by PFAS regulation. Please see the health risk reduction and accost analysis section. Please also see the summary of major public comments for this section.

Sarah Taylor (Doc. #1535, SBC-042640)

April 25, 2023

Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation: The Dangers of PFAS and a Proposal of How the EPA Can Help

Our nation's emergency response team have been exposed to PFAS provided medical resources for many decades. An example is our firefighting teams, using fire repelling spray foam every day to help our nation during devasting times; these foams are loaded with PFAS and cause exposure to our firefighters.

This leads to a chain reaction – although our firefighters are striving to help their community, they are also harming it along the way by contaminating the community with these PFAS each time they spray the foam. These contaminants end up in our soil and ground waters throughout their lifecycle, ultimately ending up in our drinking waters.

This is just one example of how PFAS end up in our environment, and ultimately in our bodies. PFAS are found in cosmetic products, cleaning products, clothing, papers, fabrics, shampoos, flosses, and even nonstick cookware (1). [FN1: https://www.dhs.wisconsin.gov/chemical/pfas.htm] The lifecycle of PFAS in these substances causes danger to human and environmental health.

Previous studies have indicated that PFAS in our bodies can lead to a plethora of health issues, including but not limited to increased risk of tumors, cancers, birth defects, reproductive harm, ulcerative colitis. Additionally, PFAS have been linked to decreasing thyroid function, liver function, kidney function, and infant birth weights.

The EPA website on PFAS states:

"Current peer-reviewed scientific studies have shown that exposure to certain levels of PFAS may lead to:

• Reproductive effects such as decreased fertility or increased high blood pressure in pregnant women.

• Developmental effects or delays in children, including low birth weight, accelerated puberty, bone variations, or behavioral changes.

• Increased risk of some cancers, including prostate kidney, and testicular cancers.

• Reduced ability of the body's immune system to fight infections, including reduced vaccine response.

• Interference with the body's natural hormones

• Increased cholesterol levels and/or risk of obesity" (2) [FN2: https://www.epa.gov/pfas/our-current-understanding-human-health-and-environmental-risks-pfas]

Additionally, research has been conducted on how these PFAS truly affect human health. Dr. Impinen and colleagues conducted a study analyzing the relationship between PFAS exposure and health outcomes. The study revealed a correlation between PFAS exposure in pregnant women and health ailments, such as diarrhea and airway infections (3). [FN3: Impinen A, Nygaard UC, Lodrup Carlsen KC, Mowinckel P, Carlsen KH, Haug LS, Granum B. 2018. Prenatal exposure to perfluoralkyl substances (PFASs) associated with respiratory tract infections but not allergy- and asthma-related health outcomes in childhood. Environ Res 160: 518–523.]

The evidence of how PFAS harm human health does not stop there. Dr. Kvalem and colleagues concluded that there is a relationship between PFAS exposure in infants/children and the development of immunosuppressive effects, ultimately leading to lower respiratory tract infections (4). [FN4: Kvalem HE, Nygaard UC, Lodrup Carlsen KC, Carlsen KH, Haug LS, Granum B. 2020. Perfluoroalkyl substances, airways infections, allergy and asthma related health outcomes—Implications of gender, exposure period and study design. Environ Int 134:105259] This data indicates that PFAS have a direct correlation to suppressing the human immune system.

Liver disease and cancer is also a primary concern regarding PFAS exposure. Long-chain PFAS primarily target the liver, leading to toxic hepatocyte infiltration (5). [FN5: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7906952/] This leads to the concerns of the development of carcinomas and adenomas. PFAS also cause the liver to produce higher level of liver enzymes (for example, alanine aminotransferase) resulting in a change in enzymatic liver behavior.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document.

Lawrence and Penelope Higgins (Doc. #1545, SBC-042863)

Exposure to PFAS can cause serious health effects, such as increased cholesterol levels, reduced immune system function, thyroid disease, liver damage and some forms of cancer. Chemical companies have continued to manufacture PFAS despite knowing for decades that they are unsafe, poisoning communities along the way. A 2018 study by the CDC showed that nearly all Americans have detectable levels of PFAS in their blood.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document.

Gabriella Thoppil (Doc. #1551, SBC-042699)

The Problem with PFAS

PFAS are a class of at least 9000, but potentially over 12,000, synthetic chemicals with unique properties that have led to their global use in consumer and industrial applications. [REF3: PFAS | NIOSH | CDC. Accessed April 20, 2023. https://www.cdc.gov/niosh/topics/pfas/default.html; REF4: Our Current Understanding of the Human Health and Environmental Risks of PFAS | US EPA. Accessed April 20, 2023. https://www.epa.gov/pfas/our-current-understanding-human-health-and-environmental-risks-pfas; REF5: Sunderland EM, Hu XC, Dassuncao C, Tokranov AK, Wagner CC, Allen JG. A Review of the Pathways of Human Exposure to Poly- and Perfluoroalkyl Substances (PFASs) and Present Understanding of Health Effects. J Expo Sci Environ Epidemiol. 2019;29(2):131. doi:10.1038/S41370-018-0094-1; REF6: Jha G, Kankarla V, McLennon E, et al. Per- and Polyfluoroalkyl Substances (PFAS) in Integrated Crop–Livestock Systems: Environmental Exposure and Human Health Risks. Int J Environ Res Public Health. 2021;18(23):12550. doi:10.3390/IJERPH182312550; REF7: Kurwadkar S, Dane J, Kanel SR, et al. Per- and polyfluoroalkyl substances in water and wastewater: A critical review of their global occurrence and distribution. Science of The Total Environment. 2022;809:151003. doi:10.1016/J.SCITOTENV.2021.151003; REF8: T Gaines LG, Linda T Gaines CG. Historical and current usage of per- and polyfluoroalkyl substances (PFAS): A literature review. Am J Ind Med. 2023;66(5):353-378. doi:10.1002/AJIM.23362; REF9: Glüge J, Scheringer M, Cousins IT, et al. An overview of the uses of per- and polyfluoroalkyl substances (PFAS). Environ Sci Process Impacts. 2020;22(12):2345-2373. doi:10.1039/D0EM00291G; REF10: CompTox Chemicals Dashboard. Accessed April 20, 2023. https://comptox.epa.gov/dashboard/chemical-lists/pfasmaster] Their unique properties involve resistance to natural erosion, chemical, physical, or biological degradation processes, high temperatures and pressures, and corrosive environments, which makes PFAS very versatile and useful in many various use cases like construction, military, aviation, textiles, medicine, household products, and even fire-fighting foams. [REF7: Kurwadkar S, Dane J, Kanel SR, et al. Per- and polyfluoroalkyl substances in water and wastewater: A critical review of their global occurrence and distribution. Science of The Total Environment. 2022;809:151003. doi:10.1016/J.SCITOTENV.2021.151003; REF8: T Gaines LG, Linda T Gaines CG. Historical and current usage of per- and polyfluoroalkyl substances (PFAS): A literature review. Am J Ind Med. 2023;66(5):353-378. doi:10.1002/AJIM.23362] Despite their incredible usefulness, the durability of PFAS directly translates to the extreme longevity in which they remain in the natural environment, as tests have detected traces of PFAS in air, water, soil, and sediment. [REF7: Kurwadkar S, Dane J, Kanel SR, et al. Per- and polyfluoroalkyl substances in water and wastewater: A critical review of their global occurrence and distribution. Science of The Total Environment. 2022;809:151003. doi:10.1016/J.SCITOTENV.2021.151003; REF8: T Gaines LG, Linda T Gaines CG. Historical and current usage of per- and polyfluoroalkyl substances (PFAS): A literature review. Am J Ind

Med. 2023;66(5):353-378. doi:10.1002/AJIM.23362; REF9: Glüge J, Scheringer M, Cousins IT, et al. An overview of the uses of per- and polyfluoroalkyl substances (PFAS). Environ Sci Process Impacts. 2020;22(12):2345-2373. doi:10.1039/D0EM00291G] With the combined exposure to PFAS from everyday products and the natural environment, it is no wonder that an astonishing 97% of Americans have traces of PFAS in their blood. [REF5: Sunderland EM, Hu XC, Dassuncao C, Tokranov AK, Wagner CC, Allen JG. A Review of the Pathways of Human Exposure to Poly- and Perfluoroalkyl Substances (PFASs) and Present Understanding of Health Effects. J Expo Sci Environ Epidemiol. 2019;29(2):131. doi:10.1038/S41370-018-0094-1; REF6: Jha G, Kankarla V, McLennon E, et al. Per- and Polyfluoroalkyl Substances (PFAS) in Integrated Crop–Livestock Systems: Environmental Exposure and Human Health Risks. Int J Environ Res Public Health. 2021;18(23):12550. doi:10.3390/IJERPH182312550] This is an alarming statistic because many scientific studies have demonstrated the adverse effects of specific PFAS like perfluorooctanesulfonate acid (PFOS) and perfluorooctanoic acid (PFOA) on human health, such as their link to liver and kidney disease, cancer, and complications related to the immune system, reproductive system, and child development. [REF5: Sunderland EM, Hu XC, Dassuncao C, Tokranov AK, Wagner CC, Allen JG. A Review of the Pathways of Human Exposure to Poly- and Perfluoroalkyl Substances (PFASs) and Present Understanding of Health Effects. J Expo Sci Environ Epidemiol. 2019;29(2):131. doi:10.1038/S41370-018-0094-1; REF6: Jha G, Kankarla V, McLennon E, et al. Per- and Polyfluoroalkyl Substances (PFAS) in Integrated Crop–Livestock Systems: Environmental Exposure and Human Health Risks. Int J Environ Res Public Health. 2021;18(23):12550. doi:10.3390/IJERPH182312550] Unfortunately, thousands of PFAS still remain undiscovered and untested, and unregulated in our ecosystem. [REF2: Fenton SE, Ducatman A, Boobis A, et al. Per- and Polyfluoroalkyl Substance Toxicity and Human Health Review: Current State of Knowledge and Strategies for Informing Future Research. Environ Toxicol Chem. 2021;40(3):606-630. doi:10.1002/ETC.4890; REF5: Sunderland EM, Hu XC, Dassuncao C, Tokranov AK, Wagner CC, Allen JG. A Review of the Pathways of Human Exposure to Poly- and Perfluoroalkyl Substances (PFASs) and Present Understanding of Health Effects. J Expo Sci Environ Epidemiol. 2019;29(2):131. doi:10.1038/S41370-018-0094-1] Though many countries have implemented regulations and bans on certain PFAS, many industries continue to utilize unregulated PFAS and develop newer compounds to replace legacy and regulated PFAS by the year. [REF7: Kurwadkar S, Dane J, Kanel SR, et al. Per- and polyfluoroalkyl substances in water and wastewater: A critical review of their global occurrence and distribution. Science of The Total Environment. 2022;809:151003. doi:10.1016/J.SCITOTENV.2021.151003] We simply cannot scientifically dismiss these thousands of unstudied PFAS as harmless to human health.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document.

Safe Healthy Playing Fields, Inc. (Doc. #1621, SBC-042941)

Safe Healthy Playing Fields Inc.

www.safehealthyplayingfields.org

27 May 2023

Public comments on Per- and polyfluoroalkyl substances (PFAS): Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) National Primary Drinking Water Regulation Rulemaking

Docket ID No. EPA-HQ-OW-2022-0114.

Submitted via https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0001

Thank you for this opportunity to participate in this vitally important conversation. These comments are submitted by Safe Healthy Playing Fields, Inc. (SHFPI), an all-volunteer 501-c-3 non-profit. Our constituency ranges from concerned individuals to community/civic organizations, legal, healthcare and science professionals, municipal leaders and state legislators.

On behalf of our members and chapters around the US and beyond, SHPFI hereby requests that the US EPA give urgent and serious consideration to a largely unrecognized source of PFAS contamination littered across our communities and country: The per- and polyfluoroalkyl substances (PFAS) in synthetic turf playing fields. Specifically, we request that the US EPA consider:

● The presence of PFAS in synthetic, plastic turf playing fields and other plastic turf applications that are known to leach into soil, air and water.

● The need to set standards at a level protective of both human and environmental health, as reflected by ability of commercial laboratories to detect PFAS at 2ppt.

● Regulation of PFAS as a class of chemicals.

PFAS [Link: https://dtsc.ca.gov/scp/treatments-with-pfass/] can cause multiple reproductive disorders [Link: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8743032/] (including a 40% decrease in female fertility; [Link: https://www.mountsinai.org/about/newsroom/2023/exposure-to-chemicals-found-in-everyday-products-is-linked-to-significantly-reduced-fertility] a decrease of 62.3% total sperm count in males) [Link: https://academic.oup.com/humupd/article/29/2/157/6824414?login=false]; Crohn's disease [Link: https://journals.lww.com/environepidem/Fulltext/2019/10001/Ulcerative_colitis,_Crohn_s_disease_and_other.1369.aspx#:~:text=Background%3A%20Per-%20and%20polyfluoroalkyl%20substances%20%28PFAS%29%20can%20act,Disease%20%28CD%29%20and%20other%20inflammatory%20bowel%20disease%20%28IBD%29]; breast [Link: https://www.bcpp.org/resource/pfas-forever-chemicals-pfoa-pfos/], testicular, kidney [Link: https://www.sciencedirect.com/science/article/abs/pii/S0013935120315899, prostate [Link: https://journals.sagepub.com/doi/10.1177/11786302221076707] and liver [Link: https://cdas.cancer.gov/approved-projects/2555/] cancers. They cross the blood brain barrier and are related to Autism Spectrum Disorder [Link: https://pubmed.ncbi.nlm.nih.gov/33387879/],

Attention Deficit Hyperactivity Disorder [Link: https://www.news-medical.net/news/20230328/ADHD-symptoms-linked-to-early-childhood-exposure-to-polyfluoroalkyl-substances.aspx#:~:text=The%20scientists%20found%20significant%20associations%20between%20PFAS%20exposure,second%20or%20third-quartile%20exposures%20compared%20to%20the%20first], increased deaths from Parkinson's and Alzheimer's diseases [Link: https://pubmed.ncbi.nlm.nih.gov/35921496/]; immunological effects [Link: https://www.healthandenvironment.org/webinars/96552]; increased serum cholesterol [Link: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7071576/]; effects on infant birth weights [Link: https://ehp.niehs.nih.gov/doi/10.1289/EHP9875]; impaired glucose metabolism, insulin resistance, dyslipidemia and adiposity in children and adolescents [Link: https://ehp.niehs.nih.gov/doi/10.1289/EHP11372]; thyroid hormone disruption [Link: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7851056/] (including neonatal) and thyroid cancer [Link: https://journals.sagepub.com/doi/10.1177/11786302221076707]. Because they are bioaccumulative, PFAS exposure can impact multiple generations [Link: https://vimeo.com/563823549].

The presence of PFAS in synthetic turf is beyond dispute. The volume of current, "retired" and planned playing fields and the rush to roll out plastic grass carpets by individuals, businesses and municipalities falsely believing it to be an answer to drought conditions, and the increasing frequency with which cities and boards of education are deliberately seeking to place plastic playing fields near or over waterways, single source aquifers and drinking water reservoirs speaks to the urgency that both the PFAS chemicals and the product itself must be regulated. SHPFI requests you be acutely aware of the human health ramifications of hundreds of thousands of children and athletes often exposed for multiple hours per day and multiple days per week. We ask you to employ the precautionary principle in regards to both the chemicals and the product.

The Environmental Justice considerations for the development of the Proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation (NPDWR) requires that you look beyond sports fields A petrochemical product, synthetic turf covers millions of acres of land: residential, commercial, daycare facilities, spas, batting cages, dog parks, landfill daily cover and closure turf, lining of storm drains and more. All of these applications create ongoing contamination [Link: https://www.youtube.com/watch?v=hoipI2Yj1DA] of air, soil and water.

To date, studies undertaken by US EPA, CDC, CPSC and California's OEHHA have looked only at the used-tire crumb infill – the only infill [Link: https://docs.google.com/document/d/18JSI1dofG6ENpiU5OV9ptjF-ZpsB9wLPIfZRoKyyEjE/edit] material used in synthetic turf for decades.

ALL [Link: https://docs.google.com/document/d/1B-ztYj_jw1p5BYISr5J6lHkW9h3wlshBTdiASI_W-s4/editsynthetic] turf tested to date contains per- and polyfluoroakyl substances- PFAS. The industry trade association, the Synthetic Turf

Council, admits to PFAS in plastic grass carpets, though they continue to attempt to greenwash the t rruth [Link: https://drive.google.com/file/d/1fJDsNTIPp-YMT_7aQ0TDvTaLg2lB5PMA/view?pli=1].

[Image: See Docket ID EPA-HQ-OW-2022-0114-1621]

The University of Notre Dame, Yale, the non-profit The Ecology Center in Ann Arbor, MI and Stockholm University have undertaken extensive research on PFAS in synthetic turf systems: the carpet backing, blades, shock pads and infills.

A partial list of PFAS found in synthetic turf and components (shock pads and plant based infill) to date (from public records):

- PFOS
- PFOA
- 6:2 FTSA
- GenX
- D3-N-MeFOSAA
- D2-N-EtFOSAA
- PFPeA
- PFHxA
- PFHpA
- PFBS
- PFBA
- PFNA
- PFDA
- PFHxS
- PPF Acid
- R-EVE
- PTFE
- PVDF
- 13C2-4:2 FTS
- 12C2-6:2 FTS

● 13C2-8:2 FTS

● 8:2 FTOH

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. See also section 14 of the EPA response in this *Response to Comments* document for discussion of EJ considerations. Use of PFAS in commercial products is beyond the scope of this current rulemaking.

National Association of Manufacturers (NAM) (Doc. #1655, SBC-043193)

EPA PFAS National Primary Drinking Water Regulation Rulemaking Preliminary Regulatory Determination and Proposed Rule

Docket ID No. EPA-HQ-OW-2022-0114 88 Fed. Reg. 18638 (Mar. 29, 2023)

Submitted on regulations.gov

May 30, 2023

Introduction

As the nation's largest manufacturing association, the National Association of Manufacturers (NAM) represents nearly 14,000 small, medium and large manufacturers in every industrial sector and in all 50 states. The NAM's members are committed to the communities in which they live and serve, and are dedicated to protecting the health, safety and vibrancy of those communities. The NAM appreciates the opportunity to comment on EPA's proposed rule.

Through constant innovation, investment and dedication, the NAM's members have become leaders in environmental stewardship and sustainability, while continuing to be the engine that drives our economic growth and prosperity. Today's domestic manufacturing sector is a clean and efficient operation that is technology driven and dedicated to the planet and its people. The NAM's members are committed to ensuring that progress continues.

Essentiality of PFAS substances

PFAS are a diverse group of chemicals that we rely on daily and that make modern life possible. They are critical to the NAM's members – without PFAS substances, we would not have modern infrastructure including water distribution systems and our current electric grid. Our country cannot make a clean energy transition without PFAS which supports batteries, electric vehicles, green hydrogen, semiconductors and solar components. Finally, PFAS substances are critical to national defense as aircraft, batteries for the warfighter, communications devices and many other functions are not possible without PFAS.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. This rule does not apply to all PFAS and it does not apply to all uses of

PFAS; the EPA encourages the commenter to submit comments in response to other proposed rulemakings, as appropriate.

Aurora Water, City of Aurora, Colorado (Doc. #1669, SBC-043729)

Health Impacts

As proposed, the rule suggests that by requiring water systems to treat their drinking water to an MCLG of 0 ppt all health impacts from PFAS will be mitigated. However, the chemical's presence in drinking water is only one small source of exposure for consumers. As indicated by the EPA, people can be exposed to PFAS through other sources such as eating PFAS contaminated fish, breathing PFAS contaminated air, swallowing contaminated dust, or using products made with PFAS chemicals. Commonly used products in the daily lives of consumers include food wrappers, household products, clothing and personal care products, to name just a few. It is also important that EPA considers sources other than PFAS for the health issues indicated by EPA as potential effects from exposure to PFAS.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. In publishing this rule, the EPA is not suggesting that "all health impacts from PFAS will be mitigated." As the commenter pointed out there are other exposure pathways that the six PFAS included in this rule could follow to impact the health of Americans.

American Dental Association (ADA) (Doc. #1671, SBC-043688)

May 30, 2023

U.S. Environmental Protection Agency

Office of Ground Water and Drinking Water

Mail Code 2822IT

1200 Pennsylvania Avenue NW

Washington, DC 20460

Re: Docket ID No. EPA-HQ-OW-2022-0114—PFAS National Primary Drinking Water Regulation

To Whom It May Concern:

On behalf of our 159,000 members, we would like to comment on the Environmental Protection Agency's proposal to reduce exposure to several per- and polyfluoroalkyl substances (PFAS) in drinking water. We offer these comments in response to your Federal Register notice of March 29, 2023 (88 FR 18638).

EPA has determined that several PFAS—colloquially termed ‘‘forever chemicals”—pose serious health risks at currently regulated exposure levels. These chemical compounds, which are exceedingly slow to degrade, are commonly found in everyday products (e.g., clothing, cosmetics, toilet paper) or are the unintended byproducts of certain manufacturing processes. Their widespread use has led them to now be found in blood, air, fish, soil, and other places, including drinking water.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document.

Association of California Water Agencies (ACWA) (Doc. #1675, SBC-044927)

I. Introduction

PFAS are a group of thousands of manmade chemicals that have been used extensively since the 1950s in consumer products, such as Teflon pans, fast food packaging, firefighting foams and other materials designed to be waterproof, stain-resistant, or non-stick. Although certain PFAS chemicals are no longer manufactured in the United States, these chemicals are still produced internationally and imported into the country through consumer goods.

EPA Response: Please see the summary of major public comments for this section.

Mass Comment Campaign sponsored by Slingshot. (email) (Doc. #1681, SBC-045709)

Exposure to PFAS can cause serious health effects, such as increased cholesterol levels, reduced immune system function, thyroid disease, liver damage and some forms of cancer. Chemical companies have continued to manufacture PFAS despite knowing for decades that they are unsafe, poisoning communities along the way. A 2018 study by the CDC showed that nearly all Americans have detectable levels of PFAS in their blood.

The EPA's proposed rule reflects what communities across the country already know to be true: There is no safe level of PFAS in our water. For too many Americans, especially those of us who live every day in the shadow of environmental pollution, including PFAS contamination, enough is enough.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document.

Mass Comment Campaign sponsored by Slingshot. (email) (Doc. #1682, SBC-045712)

Exposure to PFAS can cause serious health effects, such as increased cholesterol levels, reduced immune system function, thyroid disease, liver damage and some forms of cancer. Chemical companies have continued to manufacture PFAS despite knowing for decades that they are unsafe, poisoning communities along the way. A 2018 study by the CDC showed that nearly all

Americans have detectable levels of PFAS in their blood. We have been used as a toxic experiment by companies willing to poison our bodies and environment for profit.

The EPA's proposed rule reflects what communities across the country already know to be true: There is no safe level of PFAS in our water. For too many Americans, especially those of us who live every day in the shadow of environmental pollution, including PFAS contamination, enough is enough. It is well past time to turn off the PFAS tap and hold polluters responsible for the costs.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document.

Mass Comment Campaign sponsored by Slingshot. (email) (Doc. #1682, SBC-045718)

Exposure to PFAS can cause serious health effects, such as increased cholesterol levels, reduced immune system function, thyroid disease, liver damage and some forms of cancer. Chemical companies have continued to manufacture PFAS despite knowing for decades that they are unsafe, poisoning communities along the way. A 2018 study by the CDC showed that nearly all Americans have detectable levels of PFAS in their blood.

The EPA's proposed rule reflects what communities across the country already know to be true: There is no safe level of PFAS in our water. For too many Americans, especially those of us who live every day in the shadow of environmental pollution, including PFAS contamination, enough is enough.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document.

National Wildlife Federation et al. (Doc. #1702, SBC-043512)

The use of PFAS chemicals in everything from baby products and toothpaste to the water-proofing in outdoor clothing and the non-stick in pans, has exposed many communities to the toxic chemicals. PFAS chemicals can also enter our air, soil, crops, and waters through sources such as industrial discharges from manufacturing facilities, military bases, airports, wastewater treatment plants, petroleum refineries, and areas where PFAS-containing firefighting foams have been used. These long-lasting, toxic, “forever chemicals” can enter ground and surface water, contaminating our nation’s drinking water supplies, accumulating in fish and wildlife across the nation. They are found in the blood of nearly every individual in the United States.

PFAS contamination exposes people and wildlife to serious health risks, including cancers, impacts to the immune and reproductive systems, and other harms. Communities of color and low-income communities are particularly impacted by PFAS exposure, where health impacts are often compounded because these communities tend to face cumulative effects from multiple environmental injustices and public health hazards.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. See also section 14 of the EPA response in this *Response to Comments* document for discussion of EJ considerations.

Minnesota Center for Environmental Advocacy et al. (Doc. #1707, SBC-045721)

A. Minnesota has faced the brunt of PFAS contamination in the United States

The ubiquity of PFAS in our environment is well-documented. These synthetic chemicals have been detected in soils, [FN3: Ziyad Abunada et al., An Overview of Per- and Polyfluoroalkyl Substances (PFAS) in the Environment: Source, Fate, Risk & Regulations, 12 Water 3590 (2020), https://www.mdpi.com/2073-4441/12/12/3590/pdf.] drinking water, [FN4: Id.] and wildlife [FN5: Id.; Jacqueline Bangma et al., Understanding the Dynamics of Physiological Changes, Protein Expression, and PFAS in Wildlife, 159 Environmental International 107037 (2022), https://www.sciencedirect.com/science/article/pii/S0160412021006620/pdfft?md5=ca09c75b9d48c373a22e32a65e7b1203&pid=1-s2.0-S0160412021006620-main.pdf.] across the globe. Not even ice from remote glaciers in the arctic is safe from PFAS contamination. [FN6: https://www.sciencedirect.com/science/article/pii/S004896972300445X] But while PFAS have reached all parts of the globe, their impacts have not been evenly felt.

Minnesotans have been on the frontlines in the fight against PFAS for decades. 3M is an American multinational conglomerate based in Minnesota that operates in the fields of industry, worker safety, healthcare, and consumer goods. The company first developed perfluorochemicals in the late 1940s, and for decades 3M manufactured PFOA, PFOS, and other PFAS at facilities in the Twin Cities metropolitan area and shipped in products around the world. [FN7: Complaint at ¶¶ 7, 8, Minnesota v. 3M Co., No. 27-CV-10-28862 (Minn. Dist. Ct. Dec, 30, 2010), available at https://www.mncourts.gov/mncourtsgov/media/High-ProfileCases/27-CV-10-28862/Complaint-123010.pdf ¶¶ 7, 8.] 3M's manufacture of PFAS ceased only recently, and the company's disposal of waste from PFAS manufacturing at four locations in the East Metro is directly responsible for a nearly 100 square mile plume of contaminated groundwater that hundreds of thousands of Minnesotans rely upon every day for drinking water. [FN8: https://www.mncourts.gov/mncourtsgov/media/High-Profile-Cases/27-CV-1028862/Complaint-123010.pdf ¶¶ 6, 10. Id. at ¶¶ 6, 10.] As the state of Minnesota alleged in its 2010 lawsuit against the company, "3M is responsible for releasing [PFAS] into the Minnesota environment, causing pollution of groundwater, surface water, and sediments and resulting in injury, destruction and loss of natural resources of the State." [FN9: https://www.mncourts.gov/mncourtsgov/media/High-Profile-Cases/27-CV-1028862/Complaint-123010.pdf ¶ 19. Id. at ¶ 19.] 3M's actions devastated drinking water supplies in the region. And although Minnesota settled its lawsuit against 3M for $850 million, [FN10: Minnesota 3M PFAS Settlement, Minn. Pollution Control Agency, https://3msettlement.state.mn.us/ (last visited May 30, 2023).] communities in the East Metro continue to struggle to provide uncontaminated drinking water to their residents. [FN11: See, e.g.,

https://www.mprnews.org/story/2020/01/10/woodbury-takes-emergencyaction-to-tackle-water-contamination. See, e.g., Kirsti Marohn, Woodbury Takes Emergency Action to Tackle Water Contamination, MPRNEWS, Jan. 10, 2020, https://www.mprnews.org/story/2020/01/10/woodbury-takes-emergency-action-totackle-water-contamination (last visited May 30, 2023).]

Most significantly, 3M's illegal actions have led to tragic and avoidable public health impacts. Tartan High School, located in the East Metro city of Oakdale, has been at the center of a decades-long cancer cluster. [FN12: See Carrie Fellner, Toxic Secrets: The Town That 3M Built–Where Kids Are Dying of Cancer, SYDNEY MORNING HERALD (Jun. 15, 2018), https://www.smh.com.au/world/northamerica/toxic-secrets-the-town-that-3m-built-where-kids-are-dying-of-cancer20180613-p4zl83.html (last visited May 30, 2023).] The consumption of drinking water contaminated with PFAS has led to the death and lifelong ailments of many Oakdale children and families. These children have been left battling cancer with a persistent fear of remission well into adulthood, a fear that remains and resurfaces with each sip of tap water. These battles are felt by family and friends who observe the crippling effects of PFAS poisoning, who spend money on treatments and take time off work to provide care and transport, and who would give up everything to find a remedy. Minnesotans know all too well what the true social cost of PFAS is and why national drinking water standards are needed to ensure others across the country do not suffer the same fate. Some of these stories, told in greater detail below, explain the staggering costs borne by a few Minnesotans and their families, and justify the EPA's cost-benefit determination supporting the agency's proposed standards.

1. Amara Strande [FN13: Attachment 1, Declaration of Amara Dolore Strande, written by Dana Fath Strande and Michael Strande, May 5, 2023.]

Before her cancer diagnosis, Amara Strande did everything. She wrote music, she was in the theatre, she played sports, was in Girl Scouts, and was heavily involved with the Church. She dreamed of professionally composing music, of dating, of going out into the world to experience all the excitement of life. With the time that Amara had on this earth, she took it by storm.

Amara was full of light, song, and creativity. Kittens, rocks, music, and dark humor made her smile. She was loved and she loved fiercely in return. Through this grit, Amara made her world better, and she uplifted those around her. Before, during, and after cancer, Amara's presence affected change. When asked to describe Amara, one of the first stories her parents relayed was the reason that Amara called a refrigerator a "refrigerlater" is because "you put food in it to eat later."

Throughout Amara's life, the Strandes lived in Woodbury and St. Paul, Minnesota. Their water was supplied by local public drinking water systems, and they filtered it at home. Amara also drank the water at Tartan High School. For Amara's entire life, she was living above groundwater contaminated with PFAS from 3M's dumping. The Strandes were told that their water was safe and that the substances were non-cancerous.

In the fall of 2017, when she was just 15, Amara was diagnosed with a rare liver cancer called fibrolamellar carcinoma. This was after a year of misdiagnoses because her cancer was rare: so rare that the health insurance companies did not have a code for it. Amara swiftly started fighting. She underwent over 20 surgeries; she dealt with chemotherapy, radiation, and a host of treatments and therapies. But as Amara put it, cancer was a "whack a mole."

Through the pain, both physical and emotional, and compounded with becoming a teenager, Amara never stopped advocating and supporting others who needed their voices to be lifted and heard. She developed friendships and support groups for other Tartan High School students dealing with cancer, and she started support networks for children across the country. Because of the amount of time Amara and her family spent at hospitals, she put together a booklet for others on lessons learned in making hospital stays more manageable and less fearful. That booklet remains at the hospital, still helping others.

As Michael and Dana, Amara's parents, will tell you, cancer is not an experience that just affected Amara. As Dana puts it, when one person has cancer, the whole family has cancer. Nora, Amara's younger sister, spent her childhood and adolescence witnessing her sister's battles. As a result, Nora has been experiencing her own trauma, her own battle with loss and fear, and what it means to feel invisible to the outside world.

Dana, Michael, and Nora have lost so much from contaminated water. They fear the ability to build a retirement fund after having spent nearly all of what was saved to keep their family afloat. They have experienced job loss, missed time with their own aging parents, and uncertainty about how they will support Nora's future. There is concern that these same toxins that hurt Amara are running through Nora's body as well. And then there is simply the physical toll that stress and incremental loss takes on the bodies of loved ones, the emotional strain of continuing on when everything feels like it is falling apart.

When asked to approximate the financial expenses related to Amara's care, the Strande's estimated spending at least $50,000 annually over the course of Amara's five-year battle. They estimated that their insurance company spent at least $5 million for the innumerable surgeries, hospital visits, appointments, and other medical obligations attendant to cancer. Their first medical bill, of which there have been so many, was $900,000. And this is one person, one family affected by PFAS in drinking water.

Amara spent her life dealing with the true costs of PFAS. She spent her last few months battling its effects on her body. And she spent those final months advocating before the Minnesota Legislature to push for strict non-essential use ban on PFAS. Amara left this earth earlier this year, and her parents, Dana and Michael, provided the attached declaration. Dana and Michael have written these words to share with EPA who Amara was, what she stood for, and what PFAS contamination has cost them.

2. Senator Tou Xiong [FN14: Attachment 2, Testimony of Senator Tou Xiong, written in support of Minnesota's Legislative PFAS Disclosure and Ban on Non-Essential Use.]

Minnesota State Senator Tou Xiong also attended Tartan High School, and he witnessed first-hand what these substances do to communities. But more importantly, Senator Xiong saw how far families will go and expend to save their loved ones.

In 2005, when Tartan High School first realized the connection between PFAS and drinking water in the Oakdale community, no one wanted to talk about it. No one wanted to scare the students with news about cancer. But as Senator Xiong put it, there was no way to "hide the obvious." When Senator Xiong first moved to Oakdale, he did not fully understand why the school's end of year Relay for Life event was such a big deal in the community. The whole town, all the social groups, turned up for the event. And then it became clear: this was a step of action that the community could take to address the pain and suffering they had experienced all year long. Throughout Senator Xiong's four years at Tartan High School, he remembers the regular announcements the principal made. They let students know who to pray for, who had recently passed away, and when funerals would be held.

3. John Doe and Ben Rule [FN15: JD and Ben provided their consent to use the interviews they gave to Deena Winter at the Minnesota Reformer. See Deena Winter, There Must Be Something in the Water, MINN. REFORMER (Dec. 14, 2022), https://minnesotareformer.com/2022/12/14/there-must-besomething-in-the-water/ (last visited May 30, 2023).]

John Doe (JD) [FN16: To protect the confidentiality of this individual, their name has been changed to John Doe, or JD.] was first diagnosed with brain cancer at the age of 14. [FN17: JD provided testimony before the Minnesota Legislature's 2023 Session in support of the recently passed PFAS non-essential use ban. See Attachment 4.] JD's childhood home was just a few miles from where 3M dumped PFAS waste in an unlined pit. As a child, JD underwent extensive surgery to remove a tumor the size of a baseball from the back of his head. He had to relearn his basic motor skills, including walking. He still lives in Oakdale and remains constantly fearful of whether this experience with cancer will ever truly be over. He struggles with short-term memory retention. He may never be able to have children of his own. He watched friends die of cancer. He watched his friend's parents die of cancer. Cancer and PFAS have become a life-long battle for JD. It has become a part of his story.

JD's high school experience was immersed in cancer. Just as a typical high school has jocks, popular kids, and nerds, Tartan High School had another social class—the cancer kids. JD watched his classmates and neighbors receive their cancer diagnoses. He watched some of them die. In fact, JD considers himself to be one of the lucky ones because he did not have to undergo chemotherapy. Steroids were able to shrink the tumor to the point where surgery could remove it from his brain. But what he also lost were his memories. He lost the laughter with friends, the hugs from parents, and the adventures of youth. What JD kept is a permanent traumatic brain injury that leaves him susceptible to concussions and problems building new memories.

Ben Rule also grew up in Oakdale. [FN18: Attachment 3, Declaration of Benjamin Rule, May 19, 2023.] At 16, Ben learned that he had Acute Lymphoblastic Leukemia. Cancer cells were in

his blood and marrow. As Ben grew, so did his cancer. Pancreatitis led to the removal of his spleen. Complications from treatments led to Ben slipping into a coma for two weeks. He awoke up with Type 1 diabetes. Chemotherapy lasted five years. He needed to have his hip replaced. And Ben was not alone. Because of PFAS, Oakdale has a lymphocytic leukemia cancer rate nearly 30% higher than that of the rest of Minnesota.

Before cancer, Ben was a normal teenager. He was learning to drive, working his first job, and going to high school. He had no family history of cancer, no bad habits, no life factors that would lead to cancer. The days leading up to his diagnosis were full of pain. What Ben remembers from the day of his diagnosis, was the firm knowledge that his life would never be the same. He was correct; Ben has been suffering from severe depression as a result of coming into adulthood battling cancer. At a time when most kids are learning who they are, considering who to ask to prom, what colleges they want to apply to, and how excited they are to get out into the world, Ben was fighting for his life. He missed so many of the formative experiences that make a teenager into an adult. And he still feels lost in that purgatory of being an adult, but not having fully developed who he was during those life-shaping times.

4. The Others

When we tell the stories of how contaminants harm or kill people, we so often focus on those who are actively undergoing treatment or have lost their battle with the disease. But there are others. These are the ones who have had to watch; the ones who have caretaken, who have buried, and who have been silenced by the pain of those they love. They are the parents who are left with holes in their hearts after losing a child. They are the siblings who have grown up steeped in a whole family immersed in cancer battles—who have lost, who feel invisible, who grow up with an identity attached to sickness. They are children who will never get to know their parents as adults, as humans, because they have lost them to cancerous substances.

And then there's the burdensome financial costs that families and communities go through. The treatments, the travel, the hotel stays, the never-ending bills, the lost retirement wages, the time away from school and work that stalls a career path, the GoFundMe's, the future medical bills to keep the cancer at bay, the physical therapy, the mental health therapy, the wigs, the costs of a funeral, and the persistent fear of "who's next."

As we expand our knowledge of the harms of PFAS in our drinking water, we expand our fears. Parents, physicians, neighbors, siblings, all want change. They want action. They want their voices to be heard. And they want these stories to be a thing of the past, not a cautionary tale for the future.

EPA Response: The EPA thanks the commenter for submitting case studies regarding PFAS exposure and adverse human health effects. Please see section 2.2 of the EPA response in this *Response to Comments* document.

Environmental Working Group (EWG) (Doc. #1721, SBC-045403)

Contamination from the class of chemicals known as per- and polyfluoroalkyl substances, or PFAS, is an urgent public health crisis. The use of PFAS across multiple industries is ubiquitous, and experts have identified more than 1,400 individual PFAS in over 200 use categories. [FN1: Juliane Glüge et al., An Overview of the Uses of Per- and Polyfluoroalkyl Substances (PFAS), 22 ENV'T. SCI. PROCESSES 2345 (2020), https://pubs.rsc.org/en/content/articlepdf/2020/em/d0em00291g] A peer-reviewed analysis identifies a staggering 41,862 potential PFAS dischargers, many of which likely pollute sources of drinking water. [FN2: David Andrews et al., Identification of Point Source Dischargers of Per and Polyfluoroalkyl Substances in the United States, AWWA WATER SCI. 1252 (2021), https://doi.org/10.1002/aws2.1252.] EWG has identified 2,854 sites contaminated with PFAS in 50 states,[FN3:See Env't Working Grp., PFAS Contamination in the U.S., https://www.ewg.org/interactivemaps/pfas_contamination/ (last updated June 8, 2022).] and estimates that more than 200 million Americans may have PFAS in their drinking water. [FN4: David Q. Andrews & Olga Naidenko, Population-Wide Exposure to Per- and Polyfluoroalkyl Substances from Drinking Water in the United States, 7 ENV'T SCI. & TECH. LETTERS 931 (2020),https://pubs.acs.org/doi/10.1021/acs.estlett.0c00713.]

Exposure to PFAS is associated with a range of serious health harms including negative impacts on fetal growth after exposure during pregnancy, on other aspects of development, reproduction, liver, thyroid, immune function, and/or the nervous system; and increased risk of cardiovascular and/or certain types of cancers, and other health impacts. [FN5: PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18638, 18638 (March 29, 2023).] The six PFAS covered by the proposal have especially strong evidence of harm, as delineated in the proposal[FN6: Id. at 18645-18647.] and supplemented by additional technical comments to the proposal. [FN7: Earthjustice et al., Comments on PFAS National Primary Drinking Water Regulation Rulemaking, EPA-HQ-OW-2022-0114-0027, at 21-27.]

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document.

Chattahoochee Riverkeeper (CRK) (Doc. #1730, SBC-043561)

May 30, 2023

Michael S. Regan Administrator

U.S. Environmental Protection Agency

Washington, D.C.

RE: Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation (Docket ID: EPA-HQ-OW-2022-0114)

Dear Mr. Regan,

Chattahoochee Riverkeeper (CRK) would like to thank EPA for providing us the opportunity to comment on the proposed "Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation" (Docket ID: EPA-HQ-OW-2022-0114). We urge EPA to swiftly implement drinking water protections for per- and polyfluoroalkyl substances (PFAS) that will protect our water supply and keep countless Americans safe from enduring the health risks associated with these dangerous chemicals.

Established in 1994, Chattahoochee Riverkeeper (CRK) is an environmental advocacy and education organization in Georgia with nearly 10,000 members dedicated to making the Chattahoochee River a sustainable resource for the five million people who depend on it as a source of drinking water. Our mission is to advocate and to secure the protection and stewardship of the Chattahoochee River, its lakes, tributaries, and watershed, in order to restore and preserve their ecological health for the people and wildlife that depend on one of the Southeast's hardest working river. Our watershed is home to numerous landfills, land applications sites, carpet and textile manufacturers and military bases that are potential and known sources of PFAS contamination to the Chattahoochee River and its tributaries.

PFAS, which are used to manufacture a range of goods, break down very slowly over long periods of time and instead accumulate in people, wildlife, aquatic life, plants, and the environment. This contamination poses a direct threat to our health and our ecosystems. These "forever chemicals" are linked to increased incidence of cancer, liver and kidney disease, reproductive issues, immunodeficiencies, and hormonal disruptions. Though experts estimate that more than 200 million Americans are exposed to PFAS through drinking water, there are no binding, enforceable regulatory standards in place to protect the public and our nation's waters from this serious health hazard.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. The EPA notes that this rule will now be a binding, enforceable drinking water standard. The Clean Water Act (CWA) governs discharges to navigable waters of the United States and is outside the scope of this rulemaking.

Rio Grande Waterkeeper and WildEarth Guardians (Doc. #1732, SBC-045422)

I. PFAS in Drinking Water Poses a Serious Public Health Threat Warranting the Adoption of New Drinking Water Standards

There is no doubt in the scientific community that PFAS are harmful and incredibly widespread, accumulating in people, wildlife, and waterways. PFAS have been linked to cancer, liver damage, decreased fertility, and increased risk of asthma and thyroid disease. [FN1: Health Risks of Widely Used Chemicals May Be Underestimated, HARVARD T.H. CHAN SCH. OF PUB. HEATH, https://www.hsph.harvard.edu/news/hsph-in-the-news/pfas-health-risks-underestimated (last visited May 23, 2023).] As of June 2022, there are more than 2,800 sites known to be

contaminated by PFAS in the United States, according to the Environmental Working Group (EWG). [FN2: PFAS Contamination in the U.S., ENV'T WORKING GRP. (June 8, 2022), https://www.ewg.org/interactive- maps/pfas_contamination/.] A recent EWG analysis of newly available EPA data also found that more than 41,000 industrial and municipal facilities are known to use or are suspected of using toxic PFAS chemicals, including airports, sewage and wastewater treatment plants, and landfills. [FN3: Suspected Industrial Discharges of PFAS, ENV'T WORKING GRP., https://www.ewg.org/interactive-maps/2021_suspected_industrial_discharges_of_pfas/map/ (last visited May 23, 2023).' An extensive Waterkeeper Alliance study found that 83% of the 114 waterways tested across the US are contaminated by PFAS. [FN4: Invisible, Unbreakable, Unnatural, WATERKEEPER ALL., https://waterkeeper.org/pfas/ (last visited May 23, 2023).]

PFAS contamination of drinking water is a major source of human exposure to these toxic chemicals. A peer reviewed Ecotoxicology and Public Health study (2020) estimated that between 18 and 80 million Americans receive tap water with a PFOA and PFOS concentration at or above 10 ppt, more than double the EPA's proposed maximum contaminant level. Further, the study estimates that over 200 million Americans, almost two thirds of the nation's population, are likely to be receiving tap water with a PFOA and PFOS concentration at or above 1 ppt. [FN5: David Q. Andrews & Olga V. Naidenko, Population-Wide Exposure to Per- and Polyfluoroalkyl Substances from Drinking Water in the United States, ENV'T. SCI. & TECH. LETTERS (2020), https://pubs.acs.org/doi/10.1021/acs.estlett.0c00713.]

Currently, we are without substantive and universal restrictions on PFAS. There are no effective safeguards ensuring that our drinking water and everyday goods do not contain PFAS. Without comprehensive and effective standards to protect against the widespread threat of PFAS in the environment, our families, communities, and future generations remain at risk.

Of particular concern to Rio Grande Waterkeeper and WildEarth Guardians, PFAS contamination is a significant issue in the Rio Grande Basin with economic, environmental, and public health consequences. According to EWG's interactive map of PFAS contamination in the United States, PFAS are known to have contaminated water at least four military sites in New Mexico and it is likely there are many more contaminated sites. [FN6: PFAS Contamination in the U.S., ENV'T WORKING GRP. (June 8, 2022) https://www.ewg.org/interactive-maps/pfas_contamination/.] Two of these contaminated sites, Cannon Air Force Base (AFB) and Holloman AFB, have used PFAS-containing firefighting foam and have been discharging wastewater containing PFAS into the environment. Groundwater below Cannon AFB was found to be contaminated with PFOA and PFOS at combined concentrations as high as 26,200 ppt in 2018. [FN7: Groundwater War – New Mexico's Toxic Threat, N.M. PBS, https://www.newmexicopbs.org/productions/groundwater-war/timeline/ (last visited May 23, 2023).] PFAS contamination was also discovered in off-base wells supplying homes and dairies with water in Clovis. [FN8: PFAS Detected in Clovis Public Drinking Water System, N.M. ENV'T DEPT. (Feb. 10, 2020), https://www.env.nm.gov/wp-content/uploads/2020/02/2020-02-10-Clovis-PR-final.pdf.] In response to this groundwater contamination, the area's municipal

water provider took ten production wells off-line, and local dairy farmers were forced to euthanize thousands of cows contaminated with PFAS. [FN9: Theresa Davis, Cannon PFAS Destroyed Longtime Clovis Farmer's Dairy, ALBUQUERQUE J. (May 28, 2022), https://www.abqjournal.com/2503560/cannon-pfas-destroyed-longtime-clovis-farmers-dairy.html.] Separately, groundwater tested under Holloman AFB was found to contain PFAS levels of 1,294,000 ppt (18,000 times higher than the EPA's lifetime PFAS limit of 70 ng/L). [FN10: Laura Paskus, 2018 Report Shows Off-the-Charts Contamination in Holloman AFB Water, NM POL. REP. (Feb, 2, 2019) https://nmpoliticalreport.com/2019/02/02/2018-report-shows-off-the-charts-contamination-in-holloman-afb- water/.] Litigation between New Mexico and the Air Force about the discharge and cleanup of PFAS from Holloman AFB and Cannon AFB is ongoing. Meanwhile Cannon AFB continues discharging wastewater without taking precautions against PFAS contamination required by the NM Environment Department. [FN11: Megan Gleason, Battle Between New Mexico and US Air Force to Track Toxic Chemicals Drags On, SOURCE NM (Apr. 17, 2023), https://sourcenm.com/2023/04/17/battle-between-new-mexico-and-us-air-force-to-track-toxic- chemicals-drags-on/.]

PFAS has also been discovered at alarming levels in fish in the Middle Rio Grande just downstream from Albuquerque, which relies on the Rio Grande for its drinking water. [FN12: Where Our Water Comes From, ALBUQUERQUE BERNALILLO CNTY. WATER UTIL. AUTH.,https://www.abcwua.org/wp-content/uploads/Your_Drinking_Water-PDFs/Figure1_Where_Our_Water_Comes_From.pdf (last visited May 23, 2023).] Common carp in the Middle Rio Grande were found to contain 28,400 ppt of PFOS, and a total PFAS concentration of 43,183 ppt. [FN13: Forever Chemicals' in Freshwater Fish, ENV'T WORKING GRP. (Jan. 2023), https://www.ewg.org/interactive- maps/pfas_in_US_fish/map/.] This is concerning because eating even one fish at this level of contamination could be the equivalent of drinking water contaminated with PFAS above the EPA's new drinking water standard for months. [FN14: Nadia Barbo, et al., Locally Caught Freshwater Fish Across the United States Are Likely a Significant Source of Exposure to PFOS and Other Perfluorinated Compounds, 220 ENV'T RSCH. 115165 (Mar. 1, 2023). https://doi.org/10.1016/j.envres.2022.115165.] The discovery of PFAS-contaminated fish is also concerning as an indicator of PFAS contamination in the water that residents of New Mexico are drinking.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. As the commenter pointed out there are other exposure pathways that the six PFAS included in this rule could follow to impact the health of Americans. This rule does not apply to all PFAS and, consistent with SDWA, is focused on particular PFAS in drinking water.

<u>New Mexico Environment Department (NMED) (Doc. #1766, SBC-044247)</u>

Attachment 1:

Comments on EPA's Proposed PFAS National Primary Drinking Water Regulation

May 30, 2023

Introduction

The EPA has published a proposed rule designating four PFAS [FN1: The proposed rule addresses perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salt (also known as a GenX chemicals), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS), and mixtures of these PFAS.] as contaminants under the Safe Drinking Water Act, establishing a National Primary Drinking Water Regulation (NPDWR) and health-based Maximum Contaminant Level Goals (MCLG) for these four PFAS and their mixtures as well as for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS). PFAS have been used in food packaging, cleaning products, stain resistant carpet treatments, nonstick cookware and firefighting foam, among other products. Due to the widespread use of PFAS and the fact that they bioaccumulate, they are found in the bodies of people and animals all over the world, as well as ground and surface water and other natural resources.

The health effects of these contaminants are clear. Scientific research indicates that some PFAS affect reproductive health, increase the risk of some cancers, affect childhood development, increase cholesterol levels, affect the immune system, and interfere with the body's hormones. EPA and others have presented extensive documentation on PFOA and PFOS toxicity, mobility, persistence, and widespread presence in the environment, which result in substantial danger to public health and welfare and to the environment, including animals.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document.

Sierra Club of Hawai'i (Doc. #1771, SBC-044730)

Public Health

As the agency has reported, PFAS chemicals bioaccumulate in the environment and are linked to a variety of health problems including kidney and testicular cancer, damaged immune systems, and harm to the liver, thyroid, and pancreatic function. More than 200 million people in the United States are estimated to currently have unhealthy levels of PFAS in their drinking water, and nearly every American has some amount of PFAS in their bodies—even newborns. The long-term effects of ingesting these chemicals can be serious if not deadly. Indeed, no levels of PFAS in our water is safe to drink, and setting limits as close to zero is necessary to protect human health.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document.

Uttara Jhaveri (Doc. #1778, SBC-045439)

"TOXIC CHEMICAL LAW & ADVOCACY PRACTICUM"

FINAL PUBLIC COMMENT

TITLE OF ASSIGNMENT-

"PFAS National Primary Drinking Water Regulation Rulemaking"

SUBMITTED BY –

UTTARA JHAVERI

US Environmental Protection Agency Administrator

1200 Pennsylvania Avenue NW,

Washington, DC 20004

May 16, 2023

PFAS National Primary Drinking Water Regulation Rulemaking

Docket ID: EPA-HQ-OW-2022-0114

INTRODUCTION

Americans are exposed to Per- and poly-fluoroalkyl substances ("PFAS") through products such as food packages, carpets, non-stick cookware, and cosmetics, among other things. [FN1: Earthjustice, Breaking Down Toxic PFAS, EARTHJUSTICE, Oct. 19, 2021, https://earthjustice.org/feature/breaking-down-toxic-pfas.] PFAS are termed "forever chemicals" because they do not break down easily and persist in the environment and human bodies for decades. [FN2: Id.] Research has shown that PFAS has significant health effects on individuals, including negative impacts on fetal growth and child growth after exposure during pregnancy, impacts on the liver, thyroid, immune function, and/or the nervous system; and increased risk of cardiovascular and/or certain types of cancers. [FN3: Mindi F Messmer, Jeffrey Salloway, Nawar Shara, Ben Locwin, Megan W Harvey, Nora Traviss, Risk of Cancer in a Community Exposed to Per- and Poly-Fluoroalkyl Substances, NATIONAL LIBRARY OF MEDICINE (2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8842173/.]

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document.

PFAS Project Lab (Doc. #1786, SBC-044711)

Exposure to PFAS is associated with cancers, weakened immune response, developmental and reproductive harm, hormonal disruption, thyroid toxicity, and liver and kidney diseases, among other adverse health outcomes (ATSDR, 2021).

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document.

Mindi Messmer (Doc. #1788, SBC-044708)

3. Our children are already experiencing increasing rates of cancer (Ugai, et al, 2022) – we must do what we can to prevent additional cases and preserve the health and well-being of future generations.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document.

Peggy Kurtz (Doc. #1799, SBC-046046)

This is also the best way to cut future filtration costs: turn off the spigot. Stop producing the chemicals that are polluting our air and water.

I have a blood cancer, myself. I will never know what the source is, but it is not hereditary. I often wonder whether it could be from our drinking water. As a matter of fact, like everyone else over age fifty, many of the people I know have had some form of cancer – and of course, I know quite a few people who have died of cancer. It is long overdue that we take the threat of chemical pollution far more seriously.

We are poisoning ourselves and the wildlife around us. It is time for a precautionary approach.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document.

Peggy Kurtz (Doc. #1799, SBC-046041)

To: EPA

Re: Docket ID: EPA-HQ-OW-2022-0114, PFAS Regulations

Date: May 29, 2023

I am writing to ask the EPA to finalize as quickly as possible the draft PFAS regulations as proposed in Docket ID: EPA-HQ-OW-2022-0114. I want to thank the EPA for stepping up to take this strong action. The risks of at least some PFAS have been well researched and widely known to regulators at least since the early 2000s. This action is long overdue, but very welcome.

Since learning that our water is contaminated with PFAS, I've become involved with efforts to pass state legislation in New York State and to get stronger drinking water standards. I am the leader of Rockland Sierra Club and an appointed member of the Rockland County Water Task Force.

I live in Rockland County, New York. Nearly every single one of our public drinking water sources are contaminated with some level of PFAS chemicals.

Like about 90% of the county's residents, I am a customer of Veolia Water New York. According to a report by Riverkeeper, out of 63 different water sources managed by Veolia, all but one of them is contaminated.

New York State currently regulates only two PFAS: PFOA and PFOS. However, many of our wells are contaminated with multiple PFAS, eight different PFAS in all, so there is also the potential for additive or synergistic effects.

However, many of our wells and reservoirs are contaminated at levels below the NYS Maximum Contaminant Levels (MCLs). And six of the PFAS found in our drinking water are not regulated in NYS. So, approving the draft EPA PFAS regulations makes all the difference to us in Rockland County between continuing to drink water that is contaminated with PFAS – or not.

I am particularly concerned with the impacts on fetuses, infants, and children. It is just unacceptable to continue to expose children and babies to chemicals with known toxicity.

The New York State Department of Health is mandated by law to regulate 23 more PFAS, in addition to PFOA and PFOS. These regulations are now about one year overdue, past the mandated time frame for new regulations. However, the Department of Health told a group of environmentalists that they are waiting for the EPA regulations to move ahead. Many other states are likely doing the same. If EPA moves ahead with strong regulations, that will make it much easier for states to go even further to regulate additional PFAS, using the same science and the same principles.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document.

Millie Garcia-Serrano (Doc. #1803, SBC-044284)

ASTSWMO's PFAS Position Paper, drafted by the Association's Contaminants of Emerging Concern (CEC) Steering Committee, and updated and approved by our Board in November 2022, recommends that EPA evaluate classes of PFAS that have common characteristics, to more expeditiously designate PFAS compounds as CERCLA hazardous substances and RCRA hazardous constituents. However, the summary document (EPA-822-P-23-004) distributed for public comment on the combined Maximum Contaminant Level Goals (MCLGs) does not adequately explain why PFHxS, GenX chemicals, PFNA, and PFBS, four seemingly disparate PFAS, were selected. ASTSWMO recommends more careful consideration of PFAS functional groups, chain length, and toxic endpoints, and the use of a more-refined approach for the combined regulation of these chemicals.

EPA's promulgation of health-based MCLGs for the aforementioned PFAS compounds would advance federal and State efforts to compel responsible and potentially-responsible parties to investigate and remediate contamination nationwide, especially when private wells and public water supply systems are impacted. This is a critical step for impacted communities' access to financial resources for costly mitigation and cleanup.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. This regulatory action focuses on drinking water. Mitigation and cleanup are addressed under other statutes (e.g., CERCLA). For more information on why certain PFAS were selected, please see section 3.1 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046097)

I. EPA Must Expeditiously Finalize Health-Protective PFAS Drinking Water Standards

A. EPA Should Move Quickly to Finalize PFAS MCLs

As described by Dr. Patrick Breysse, the former Director of the Center for Environmental Health in the U.S. Centers for Disease Control and Prevention, PFAS present "one of the most seminal public health challenges for the next decades." [FN4: Pat Rizzuto et al., CDC Sounds Alarm on Chemical Contamination in Drinking Water, Bloomberg Env't (Oct. 17, 2017), https://news.bloomberglaw.com/environment-and-energy/cdc-sounds-alarm-on-chemical-contamination-in-drinking-water.] When Dr. Breysse made that statement in October 2017, he estimated that "up to 10 million Americans" could be drinking water with unsafe levels of PFAS. [FN5: Id.] Today, that estimate is approximately 200 million. [FN6: See Andrews & Naidenko (2020); Annie Sneed, Forever Chemicals Are Widespread in U.S. Drinking Water, Sci. Am. (Jan 22, 2021), https://www.scientificamerican.com/article/forever-chemicals-are-widespread-in-u-s-drinking-water/.] Impacted communities experience increased risks of cancer and other severe effects, with some exposed to PFAS levels that are tens of thousands of times higher than the levels that EPA has already determined present serious health risks. [FN7: See, e.g., EPA, Hoosick Falls, New York, Drinking Water and Groundwater Contamination, Frequently Asked Questions (Jan. 12, 2016), https://www.epa.gov/sites/default/files/2016-01/documents/hoosickfalls_faqs.pdf (describing PFOA detections of 600 parts-per-trillion (ppt) in drinking water in Hoosick Falls, New York—150,000 times higher than EPA's health advisory level of .004 ppt); WRAL News, Report: Extremely High Levels of GenX-like Chemicals in Wilmington Drinking Water for Years (Oct. 9, 2019), https://www.wral.com/story/report-extremely-high-levels-of-genx-like-chemicals-in-wilmington-drinking-water-for-years/18688129/ (describing GenX detections of 130,000 ppt in the Cape Fear River near Wilmington, NC, drinking water intake—13,000 times higher than EPA's health advisory level of 10 ppt).]

Because of their chemical structure, PFAS are highly persistent, "indicat[ing] the potential for long-lasting environmental and human exposure … that is difficult to control and reverse." [FN8: See, e.g., Ian T. Cousins et al., Why is High Persistence Alone a Major Cause of Concern?, 21 Env't Sci. Processes & Impacts 781 (2019), https://doi.org/10.1039/C8EM00515J.] Many PFAS also bioaccumulate in animals and people, with low-level exposures building up in people's bodies and causing serious harm. More than 98% of people tested in the United States have PFAS in their blood. [FN9: Antonia M. Calafat et al., Polyfluoroalkyl Chemicals in the U.S.

Population: Data from the National Health and Nutrition Examination Survey (NHANES) 2003–2004 and Comparisons with NHANES 1999–2000, 115 Env't Health Persp. 1596 (2007), http://doi.org/10.1289/ehp.10598.] Communities of color often experience the greatest PFAS exposures and risks; a recent study found that the "watersheds serving higher proportions of Hispanic/Latino and non-Hispanic Black populations had significantly greater odds of containing PFAS sources." [FN10: Jahred M. Liddie et al., Sociodemographic Factors Are Associated with the Abundance of PFAS Sources and Detection in U.S. Community Water Systems, Env't Sci. Tech. (2023), https://pubs.acs.org/doi/pdf/10.1021/acs.est.2c07255.]

The health risks associated with PFAS are well established and have been widely recognized by international scientific organizations, [FN11: See United Nations Env't Programme, UNEP/POPS/POPRC.2/17/Add.5, Report of the Persistent Organic Pollutants Review Committee on the Work of its Second Meeting add. 25–26 (Nov. 2006) (Risk Profile on Perfluorooctane Sulfonate), http://chm.pops.int/Portals/0/download.aspx?d=UNEP-POPS-POPRC.2-17-Add.5.English.PDF; United Nations Env't Programme, UNEP/POPS/POPRC.12/11/Add.2, Report of the Persistent Organic Pollutants Review Committee on the Work of Its Twelfth Meeting add. 24–26 (Oct. 2016) (Risk Profile on Pentadecafluorooctanoic Acid (PFOA, Perfluorooctanoic Acid), its Salts and PFOA-related Compounds), http://chm.pops.int/Portals/0/download.aspx?d=UNEP-POPS- POPRC.12-11-Add.2.English.PDF.] federal and state regulatory agencies, [FN12: Agency for Toxic Substances and Disease Registry, Toxicological Profile for Perfluoroalkyls, at 5–21, 26–29 (May 2021) ("ATSDR 2021"), https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf; Cal. Env't Protection Agency, Public Health Goals: Perfluorooctanoic Acid and Perfluorooctane Sulfonic Acid in Drinking Water (First Public Review Draft), Off. of Env't Health Hazard Assessment, at 62–166 (July 2021), https://oehha.ca.gov/sites/default/files/media/downloads/crnr/pfoapfosphgdraft061021.pdf.] and other leading scientific bodies. [FN13: Nat'l Acad. of Sci., Eng'g, & Med., Guidance on PFAS Exposure, Testing, and Clinical Follow-Up, at 6–8 (2022) ("NAS 2022"), https://nap.nationalacademies.org/catalog/26156/guidance-on-pfas-exposure-testing-and-clinical-follow-up; see also Arlene Blum et al., The Madrid Statement on Poly- and Perfluoroalkyl Substances (PFASs), 123 Env't Health Persp. A107 (2015), https://ehp.niehs.nih.gov/doi/epdf/10.1289/ehp.1509934 (statement of more than 250 scientists expressing "concern[] about the production and release into the environment of an increasing number of [PFAS]").] Individually, the PFAS covered by EPA's Proposed Rule are associated with cancer (PFOA, PFOS, and GenX), developmental harm (PFOA, PFOS, PFHxS, GenX, PFNA, and PFBS), reproductive harm (PFOA, PFOS, GenX, and PFNA), immune system toxicity (PFOA, PFOS, GenX, and PFNA), liver toxicity (PFOA, PFOS, PFHxS, GenX, and PFNA), thyroid toxicity (PFOA, PFOS, PFHxS, and PFBS) and kidney toxicity (PFOA, PFOS, GenX, and PFBS), among other adverse effects. [FN14: See Proposed Rule, 88 Fed. Reg. at 18,645–47, 18,656–63, 18,704, 18,718.] Because of these common health effects, people who are exposed to multiple PFAS—whether through their combined presence in drinking water or from other sources—face even greater risks of harm. Studies have shown that exposure to PFAS

mixtures alter critical biological processes in the developing fetus, infants, and children that are separately associated with an increased risk of developmental disorders, cardiovascular disease, and many types of cancer. [FN15: Jesse A. Goodrich et al., Metabolic Signatures of Youth Exposure to Mixtures of Per- and Polyfluoroalkyl Substances: A Multi-Cohort Study, 131 Env't Health Persp. Art. No. 27005 (2023), https://ehp.niehs.nih.gov/doi/epdf/10.1289/EHP11372.] Recent human birth cohort studies also reported associations between multiple PFAS exposures during pregnancy and adverse health outcomes, including an increased risk of gestational diabetes and altered glucose levels during pregnancy, altered levels of thyroid hormones in pregnant people and newborns, and liver injury in children. [FN16: Guoqi Yu et al., Environmental Exposure to Perfluoroalkyl Substances in Early Pregnancy, Maternal Glucose Homeostasis and the Risk of Gestational Diabetes: A Prospective Cohort Study, 156 Env't Int'l Art. No. 106621 (2021), https://pubmed.ncbi.nlm.nih.gov/33984575/. i: 10.1016/j.envint.2021.106621; Blanca Sarzo et al., Maternal Perfluoroalkyl Substances, Thyroid Hormones, and DIO Genes: A Spanish Cross-sectional Study, 55 Env't Sci. Tech. 11144 (2021), https://pubs.acs.org/doi/10.1021/acs.est.1c01452; Arash Derakhshan et al., Association of Per- and Polyfluoroalkyl Substances with Thyroid Homeostasis During Pregnancy in the SELMA Study, 167 Env't Int'l Art. No. 107420 (2022), https://www.sciencedirect.com/science/article/pii/S0160412022003476?via%3Dihub; Richard Christian Jensen et al., Higher Free Thyroxine Associated with PFAS Exposure in First Trimester. The Odense Child Cohort, 212 Env't Rsch. Art. No. 113492 (2022), https://pubmed.ncbi.nlm.nih.gov/35597289/; Jianqiu Guo et al., Umbilical Cord Serum Perfluoroalkyl Substance Mixtures in Relation to Thyroid Function of Newborns: Findings From Sheyang Mini Birth Cohort Study, 273 Chemosphere Art. No. 129664 (2021), https://pubmed.ncbi.nlm.nih.gov/33493812/; Qian Yao et al., Prenatal Exposure To Per- and Polyfluoroalkyl Substances, Fetal Thyroid Hormones, and Infant Neurodevelopment, 206 Env't Rsch. Art. No. 112561 (2022), https://www.sciencedirect.com/science/article/abs/pii/S0013935121018624?via%3Dihub; Nikos Stratakis et al., Prenatal Exposure to Perfluoroalkyl Substances Associated With Increased Susceptibility to Liver Injury in Children, 72 Hepatology 1758, 1758–70 (2020), https://onlinelibrary.wiley.com/doi/full/10.1002/hep.31483.] An accompanying analysis by Drs. Anna Reade and Katherine Pelch of the Natural Resources Defense Council discusses additional health effects that are linked to PFAS exposure, but which were not well described in EPA's toxicity assessments for PFOA and PFOS, such as disruption of mammary gland development and reduced duration of lactation. [FN17: Ltr. from Drs. Anna Reade and Katherine Pelch, Natural Resources Defense Council, re PFAS National Primary Drinking Water Regulation Rulemaking (May 30, 2023) ("Reade and Pelch 2023") (attached as Exhibit A).]

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. See also section 14.10 of the EPA response in this *Response to Comments* document for discussion of EJ considerations and section 4.2.1 of the EPA response in this *Response to Comments* document for discussion of noncancer health effects associated with PFOA and PFOS.

Environmental Working Group et al. (Doc. #1810, SBC-044686)

National standards to limit the concentration of PFAS in drinking water are long overdue. For decades, PFAS have been used in thousands of applications, and a peer-reviewed study estimates that PFAS may be present in the drinking water of more than 200 million Americans. EPA's proposal for six PFAS would set the national standard for PFOA and PFOS at the lowest detection level approved by the agency, and would establish limits on GenX, PFBS, PFNA, and PFHxS using a hazard index. EPA estimates that 94 million Americans currently receive drinking water contaminated by one or more these PFAS chemicals at levels above the limits proposed by EPA. The regulation of PFAS will improve drinking water safety for millions of Americans.

Not only are PFAS widespread in drinking water, these "forever chemicals" persist throughout the environment and pose risks to public health even in trace amounts. They are found in the blood of virtually everyone on Earth, and build up in our organs. Very low doses of PFAS in drinking water have been linked to suppression of the immune system [Link: https://www.atsdr.cdc.gov/pfas/health-effects/index.html] and are associated with an elevated risk of cancers and reproductive and developmental harms [Link: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8743032/], among other serious health concerns [Link: https://www.atsdr.cdc.gov/pfas/health-effects/index.html].

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document.

Sharon Levy (Doc. #1824, SBC-044275)

To Whom It May Concern,

I am writing in regards to the proposed rule for Per- and Polyfluoroalkyl Substances (PFAS) to be included into the National Primary Drinking Water Regulations.

On March 14, 2023, the EPA proposed the first ever national drinking standards with regards to PFAS in public drinking water. EPA is issuing a preliminary regulatory determination to regulate PFHxS, HFPO-DA (also known as GENX), PFNA, PFBS, PFOA, PFOS and a mixtures of these PFAS as contaminants under SDWA.

PFHxS, HFPO-DA (also known as GENX), PFNA, PFBS, PFOA and PFOS have all been found in large concentrations across North Carolina.

The Chemours plant in Bladen County produces GenX, and discharges upwards of 250 different PFAS chemicals into our drinking water.

The PFAS production at the site is responsible for groundwater and surface water contamination in the surrounding area, according to water samples from Chemours and the N.C. Department of Environmental Quality.

Since learning about our PFAS water contamination in 2017, we have learned how harmful PFAS are to populations that are exposed to "forever chemicals".

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document.

Plymouth Village Water & Sewer District (Doc. #1827, SBC-044557)

PVWSD supports NHDES's efforts, along with the necessary resources, to establish standards based on peer-reviewed scientific data regarding the health risks and a comprehensive understanding of the impact and practicality of the recommended standards. NHDES continues to research new health studies on PFAS compounds as well as risk management approaches that are scientifically valid that may address any compounding effects between chemicals.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document.

National PFAS Contamination Coalition (Doc. #1830, SBC-044551)

As you are aware, PFAS are highly persistent, toxic chemicals that pose significant health risks to humans and the environment. There is growing evidence that even the lowest level of exposure to PFAS is linked to a large and varying range of health problems, including various cancers, immune system dysfunction, and developmental delays. These chemicals are highly persistent in the environment and can accumulate in the food chain and our bodies, posing a significant threat to wildlife and ecosystems.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. See also section 14 of the EPA response in this *Response to Comments* document for discussion of EJ considerations.

Little Hocking Water Association (Doc. #1835, SBC-045505)

VIA ELECTRONIC SUBMITTAL

U.S. Environmental Protection Agency EPA Docket Center

May 30, 2023

Re: PFAS National Primary Drinking Water Regulation Rulemaking, Docket No. EPA HQ-OW-2022-0114

To Whom It May Concern:

These comments are submitted on behalf of the Little Hocking Water Association ("LHWA" or "Little Hocking") regarding the PFAS National Primary Drinking Water Regulation Rulemaking,

88 Fed. Reg. 18638 (March 29, 2023). LHWA, located at 3998 Newbury Road, Little Hocking, Ohio 45742, is a rural non-profit water system in southeastern Ohio.

Background and basis for comments

Little Hocking has first-hand knowledge of the immediate and future costs of failing to regulate and delaying regulation of PFAS. This perspective on the real cost of regulation, delay in regulation, and of the failure to regulate contribute to these comments.

LHWA's 45-acre wellfield in Ohio is located 1,300 feet across the Ohio River from the Chemours (formerly DuPont) Washington Works West Virginia plant. LHWA first started to learn about the extensive contamination of its wellfield in 2002. In contrast, DuPont knew by 1984, via testing it kept secret, that water from Little Hocking's wellfield contained PFOA contamination from the Washington Works plant. During DuPont's period of silence between 1984 and 2002, DuPont actually doubled its PFOA usage, despite, as litigation-obtained documents show, the internal fear of DuPont's business leaders that the health concerns about PFOA would cause the legal and medical arms of DuPont to terminate all PFOA use.

Following the 2002 revelation of the fact that PFOA was found in its wellfield, LHWA went on to learn that it held the dubious distinction of being the public water system with the consistently highest concentrations of PFOA of any known public water supply. Next, LHWA learned the levels of PFOA in the blood of its customers averaged 227.6 ug/L in 2005 -2006 and are displayed on a table on the ATSDR (2022) website as an example of a population severely affected by PFOA contamination. In addition, LHWA customers also had elevated levels of additional PFAS in their blood-including PFOS and PFHxS (ATSDR, 2022). See below (source: ATSDR, 2022). It took years for the social costs of this contamination to start to develop and that cost picture is still developing.

[Figure 1: see docket ID EPA-HQ-OQ-2022-0114-1835]

[Figure 2: see docket ID EPA-HQ-OQ-2022-0114-1835]

[Figure 3: see docket ID EPA-HQ-OQ-2022-0114-1835]

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. The EPA appreciates the submitted data.

Amigos Bravos (Doc. #1844, SBC-045398)

Administrator Michael S. Regan

U.S. Environmental Protection Agency

EPA Docket Center, OW Docket

Mail Code 28221T

1200 Pennsylvania Avenue NW

Washington, DC 20460

Submitted via EPA Docket Portal at https://www.regulations.gov/commenton/EPA-HQ-OW-2022-0114- 0027

May 30, 2023

Re: The Environmental Protection Agency's National Primary Drinking Water Regulation for PFAS (NPDWR) and PFAS in New Mexico Re: Docket ID No. EPA-HQ-OW-2022-0114

Dear Administrator Reagan,

Amigos Bravos is a statewide water conservation organization (based in Taos, NM) guided by social justice principles and dedicated to preserving and restoring the ecological and cultural integrity of New Mexico's water and the communities that depend on it. While rooted in science and the law, our work is inspired by the values and traditional knowledge of New Mexico's diverse Hispanic and Native American land-based populations, with whom we collaborate. Our areas of expertise and accomplishment include: broad-based advocacy campaigns; community organizing; the creation of effective socio-economically and culturally diverse coalitions; successful legal, regulatory, and legislative campaigns at the local, state, and federal level; community water quality monitoring programs; and, ecosystem restoration initiatives.

PFAS in New Mexico

Per- and poly- fluoroalkyl (collectively: PFAS) substances threaten the integrity of New Mexico's water quality and directly harms our land-based peoples, the Sovereign Native Nations that reside within New Mexico, as well as our traditional, cultural ways of life by the continuous introduction and exposure to these dangerous chemicals that enter into our agriculture and then into our citizens- from the food we eat to the milk and water we drink. These toxic substances also contaminate the air, soil, and water cycle that repeatedly cycles PFAS throughout our environment causing persistent and ubiquitous exposure via inhalation and ingestion. Amigos Bravos also cares about the health of the economy of New Mexico, which is also negatively impacted through PFAS contamination that come from every day items including equipment for food (e.g. pots and pans, etc.), clothing and textiles, and health care products that touch our bodies and that result in bio-uptake that may degrade our bodies.

Per- and poly- fluoroalkyl substances have negatively impacted the health of New Mexico's citizens, environment, and economy. PFAS have been found at Cannon and Holloman Air Force bases in New Mexico and in the surrounding groundwater. Subsequently, milk at dairies located near New Mexico Department of Defense (DoD) sites were found to have PFAS levels above the water health advisory, and milk tested above the limit was pulled from store shelves. According to the EPA: "There may still be some foam containing PFOS held or in use... around the country, including at airports, bulk fuel terminals and other locations which handle large quantities of liquid hydrocarbon fuels."

Concentrations of non-regulated PFAS have been found New Mexico's groundwater. The PFAS Groundwater Plume in Clovis, New Mexico, has migrated into the Ogallala Aquifer, which is one of the world's largest aquifers underlying eight U.S. states. The Ogallala Aquifer also provides over 21 million acre-feet of irrigation water for agricultural, traditional and cultural use.

Due to their chemical structure and physical properties such as oil and water-repelling capabilities, PFAS are manufactured extensively and used worldwide in industrial applications, and common household products and appliances.

PFAS have been found in New Mexico's:

• Air

• Drinking water

• Humans

• Irrigation water

• Land & water dwelling animals

• Rivers and lakes

• Soil

• Nearly all agricultural products–organic and otherwise–including plants and animals

PFAS do not simply vanish when they leave the source site, nor are they securely attached to any surfaces they coat. PFAS can aerosolize either from the source industry or from the object they coat thus travelling through the atmosphere and entering the air, soil, water cycle and infiltrate many pathways to human exposure without immediate noticeable detection unless monitored. When released, PFAS wash into water systems, and are not always captured by most wastewater treatment plants as they can slip past many filtration systems and structures. PFAS are released into rivers, lakes and oceans, and can accumulate in groundwater aquifers.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. See also section 14 of the EPA response in this *Response to Comments* document for discussion of EJ considerations.

Midwest Environmental Advocates +more (Doc. #1846, SBC-045820)

First, the scientific evidence supporting EPA's findings that these substances may pose adverse health effects is incontrovertible. Toxicity studies and epidemiological studies have linked these PFAS to a plethora of adverse health effects, including cancers. And, as shown below, the endangerment finding does not require certainty of harm, merely the possibility thereof.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document.

Mary Anderson (Doc. #1863, SBC-045843)

Due to widespread use of PFAS chemicals in numerous products and industries, PFAS chemicals have become ubiquitous in the environment, including our soil, air, and drinking water. Testing has revealed PFAS in water sources in communities across our nation.

Studies show that human exposure to PFAS is widespread and that nearly all people in the United States have some PFAS compounds in their blood. Exposure to PFAS can lead to higher rates of kidney and testicular cancer, higher cholesterol levels, thyroid problems, adverse developmental effects and decreased immune response in children, and other adverse health impacts.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document.

Laura Spilotros (Doc. #1864, SBC-045847)

Due to widespread use of PFAS chemicals in numerous products and industries, PFAS chemicals have become ubiquitous in the environment, including our soil, air, and drinking water. Testing has revealed PFAS in water sources in communities across our nation.

Studies show that human exposure to PFAS is widespread and that nearly all people in the United States have some PFAS compounds in their blood. Exposure to PFAS can lead to higher rates of kidney and testicular cancer, higher cholesterol levels, thyroid problems, adverse developmental effects and decreased immune response in children, and other adverse health impacts.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document.

Paula Okin (Doc. #1867, SBC-045859)

Due to widespread use of PFAS chemicals in numerous products and industries, PFAS chemicals have become ubiquitous in the environment, including our soil, air, and drinking water. Testing has revealed PFAS in water sources in communities across our nation.

Studies show that human exposure to PFAS is widespread and that nearly all people in the United States have some PFAS compounds in their blood. Exposure to PFAS can lead to higher rates of kidney and testicular cancer, higher cholesterol levels, thyroid problems, adverse developmental effects and decreased immune response in children, and other adverse health impacts.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document.

Katrina Rudmin (Doc. #1868, SBC-045863)

Due to widespread use of PFAS chemicals in numerous products and industries, PFAS chemicals have become ubiquitous in the environment, including our soil, air, and drinking water. Testing has revealed PFAS in water sources in communities across our nation.

Studies show that human exposure to PFAS is widespread and that nearly all people in the United States have some PFAS compounds in their blood. Exposure to PFAS can lead to higher rates of kidney and testicular cancer, higher cholesterol levels, thyroid problems, adverse developmental effects and decreased immune response in children, and other adverse health impacts.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #1877, SBC-047309)

The medical costs and debilitation associated with the treatment of these potential chronic illnesses and disorders far exceeds the costs of remediation. The affected population are victims. The polluters need to be held accountable to the highest extent of the law. There is much to do as far as policy such as requiring PFAS testing in routine blood work (PFAS is inherently stable in the blood with a half life of 6-10 years) particularly in those areas were drinking water is contaminated along with liver profiles especially in children so that parents and pediatricians can help make informed medical decisions. Infants/children drink more water per pound of body weight than older individuals leading to increased toxicity in their formidable years as their tissue/organs are developing. The schools need to make sure the water filter stations not only filter out lead but also these carcinogenic chemicals. There needs to be policies in place in the school systems as far the the water that the kids are consuming in the schools, the chemicals used for cleaning etc. Pregnant mothers, infants, children are victims to this with the great potential for adverse health outcomes in their lives. Non germ-line pediatric and adult cancers of endocrine glands, increased cancers in pets goes on and on. The molecular biological etiology as far as if PFAS is implicated either directly or indirectly in the damage or loss of the TP53 gene need to be further investigated as TP53 is the most frequently missing or damaged gene in 50% of cancers. Thank you. Thank you. Thank you.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on the health effects, see also section 4 of the EPA response in this *Response to Comments* document. The HBWC MCLGs are designed to protect the most vulnerable groups with an adequate margin of error.

Anonymous (Doc. #1927, SBC-047321)

In my opinion I believe that this proposed rule does not serve justice as it stands today. The reason for this is because although we can monitor, notify, and reduce the amount of PFAS in the

water supply we should also be limiting the amount that is put into our water supply in the first place. The companies with the new PFAS are not required to present studies that show whether these products are safe for the environment before production starts. They are also not presented with proper ways to dispose of these PFAS if they are potentially harmful. The majority of the PFAS are used to make industrial products and "aqueous film forming foams for firefighting" (Pelch, Reade, Wolffe, Kwiatkowski, p1). This makes it evident of how much PFAS are being processed in our daily lives. These chemicals are also known as "forever chemicals" since they are an alkyl chain with one or more fluorinated carbon atoms (Pelch, Reade, Wolffe, Kwiatkowski, p1). Knowing this about the atom bonds, it shows that this atom is hard to break down and explain the reason as to why they call these PFAS a "forever chemical." To conclude, based on this information these chemicals will never go away so disposing of these within our environment would be critical seeing these are not only harmful to the environment, but also for those living within it. You might be asking how this is affecting the individual's health of individuals who are being exposed to these PFAS. Well, PFAS can impact "cancer, immune function, metabolic outcomes, and neurodevelopment" of individuals within their body. This is crucial since these are major and important components of the human body or could be detrimental if they were to occur.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document. The EPA is taking a whole of agency approach to its response to PFAS as indicated in the PFAS Strategic Roadmap. Other EPA rules, such as the CERCLA designation, are discussed in section 10, Treatment, of the EPA response in this *Response to Comments* document.

Annabelle Ott (Doc. #1949, SBC-047455)

Some of my knowledge of the chemical PFAS comes from articles by NPR's Erika Ryan, Mary Louise Kelly, Patrick Jarenwattananon, and Nathaniel Rich of the New York Times.

In the NPR article Ryan, Kelly, and Jarenwattananon provide some general information about PFASs, also known as the "forever chemical" in the article PFAS 'forever chemicals' are everywhere. Here's what you should know about them. The information they provided states that even a trace amount of the chemical may impose threats on humanity. The article also uses a discussion between them and, biophysical chemist, Arlene Blum. She states that studies around PFAS have been deemed harmful and may affect the human body systems. These effects include increased cholesterol levels, testicular cancer, damage to the liver, high blood pressure in middle-aged people who were assigned females at birth, and general immune system issues.

Nathaniel Rich's article The Lawyer Who Became DuPont's Worst Nightmare goes down more of the story route. In the article, it is described that farmer Wilbur Tenant claimed his cows were quote "dying left and right" (Rich, Nathaniel, The Lawyer Who Became DuPont's Worst Nightmare). Tennant believed that the death of his cows was at the hands of DuPont, who had an

operating chemical sight in Parkersburg, West Virginia, not far from his farm. Tennant investigated and learned that DuPont dumped chemical waste into a river near where the cows grazed and that they started acting odd when DuPont first started doing such. The PFASs chemical was affecting their behavior and their lives. For example, Tennant describes deer and cattle, which had died with blood running from their noses and mouths, and the water they drank was bubbly with chemical waste. DuPont also affected. As part of the investigation, they had to submit files and documents to Taft's headquarters from their scientists. Interestingly to me, America has a not guilty until proven policy allowing companies like DuPont to produce these chemicals until proven unsafe. Even when they are, they are not regulated to extremes, and variants of these chemicals are still allowed due to chemical or chemical composition-specific rules. Because of this, I think the EPA's regulation is based more on what is efficient rather than what is safe for human and animal health. The EPA website also claims that there are still things that unknown about the chemical compound like how to detect and measure it in the air, water, soil, and fish/wildlife, how much exposure people have to it, how harmful it actually is, and how to manage/dispose of it. However, with the previous information shared it is my belief that the chemical compound poses threat and I, again, wish to have it regulated if not fully removed.

Sources supporting this argument:

Gardella, John P., PFAS Regulation: Business Should Plan Now for Financial Impacts, BloomBerg Law, 9, February 2021, https://news.bloomberglaw.com/environment-and-energy/pfas-regulation-business-should-plan-now-for-financial-impacts

Ryan, Erika, Kelly, Mary Louise, Jarenwattananon, Patrick, PFAS "˜forever chemicals' are everywhere. Here's what you should know about them, NPR, 23, June 2023, https://www.npr.org/2022/06/22/1106863211/the-dangers-of-forever-chemicals

Rich, Nathaniel, The Lawyer Who Became DuPont's Worst Nightmare, The New York Times, 6, January 2016, https://worldclass.regis.edu/content/enforced/299939-RSS_EC200_RU01_23SSEM/The%20Lawyer%20Who%20Became%20DuPont%E2%80%99s%20Worst%20Nightmare%20-%20The%20New%20York%20Times.pdf?_&d2lSessionVal=s6XHxbvhod68TVd49psvGVV6y

Environmental Protection Agency, PFAS Explained, Environmental Protection Agency, Last updated 28, April 2022, https://www.epa.gov/pfas/pfas-explained

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. PFAS is not an individual "chemical compound" but, as detailed in the background section of the proposal and in §141.2 of the CFR, a chemical class comprised of many differing chemical compounds. This rule regulates six of these chemicals in drinking water as requested by commenter. It is important to note that there is no singular consensus on exactly what constitutes PFAS and the definition changes depending on the entity or regulatory body, scope, and application of the definition. It is important to note that even within the EPA there is no singular definition as the meaning should be fit for purpose. The six PFAS regulated by this rule are defined in the background section of the proposal preamble and in §141.2 of the CFR.

For example, fluoxetine is on the WHO's List of Essential Medicines and contains a perfluorinated methyl group, so it could be considered PFAS but would not necessarily meet the definition here.

The EPA is required to take feasibility into account when setting MCLs (SDWA 1412(b)(4)(D)). In the SDWA 1412(b)(4)(D), "the term "feasible" means feasible with the use of the best technology, treatment techniques and other means which the Administrator finds, after examination for efficacy under field conditions and not solely under laboratory conditions, are available (taking cost into consideration)," so the EPA has done exactly this and indeed taken feasibility into account. The EPA has set the MCLs as close to the MCLGs as is feasible. Please see the summary of major public comments for this section.

Thomas Driscoll (Doc. #2074, SBC-047433)

April 28, 2023

Environmental Protection Agency

1200 Pennsylvania Avenue NW

Washington, D.C. 20004

Re: New Federal Drinking Water Standards for PFAS

To Whom It May Concern,

I am writing in support of your latest proposal that would raise federal drinking water standards for pre- and polyfluoroalkyl substances (PFAS). My name is Thomas Driscoll, and I am a Master of Public Policy (MPP) candidate at the University of Virginia.

During my time at U.Va., I have extensively studied environmental issues, including the growing body of research which suggests that exposure to PFAS, even in small doses, is associated with adverse health consequences. These include an elevated risk for developing the following conditions: certain cancers (most notably prostate, kidney, and testicular cancers), high cholesterol, obesity, decreased fertility, compromised immune system, reduced vaccine response, high blood pressure in pregnant women, and developmental delays in children. These findings are deeply alarming as it is estimated that more than 200 million people have tap water contaminated with a mixture of PFAS at concentrations of one part per trillion (ppt) or higher.

PFAS are a broad family of synthetic compounds that have been used since the 1940s in a wide array of commercial, industrial, and military applications. Their hydrophobic and oleophobic properties have made them a popular choice among manufacturers of waterproof and grease-resistant packaging. PFAS are also commonly found in nonstick cookware (e.g. Teflon), cleaning products, cosmetics, and paint sealants. However, it is these same hydrophobic and oleophobic qualities that have made it so challenging for officials to remove PFAS from the environment. In fact, these substances are commonly referred to as "forever chemicals" because they do not

naturally break down. Instead, they accumulate over time in contaminated areas such as rivers and streams as well as in the bodies of organisms that have been exposed.

It is for these reasons why it is so important for federal officials to regulate the concentration of PFAS in drinking water as repeated exposure to small doses, over time, can have lasting consequences.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document.

Mary Raven (Doc. #2435, SBC-047444)

Dear, EPA,

Regarding Docket ID No. EPA-HQ-OW-2022-0114, please set the allowable levels for PFOA and PFAS as low as they can be detected-- which means even lower than your current 4ppt.

I am asking you to do this because PFAS has probably had a profound negative impact on my life.

My husband, a 28-year resident of Merrimack, NH, where we know the water is contaminated with PFAS, had testicular cancer and I'm concerned that the PFAS chemicals in our water, which has been linked to testicular cancer, may have caused or contributed to it. Here is our story.

I noticed that something did not feel right with my husband's right testicle and mentioned that he should have it checked out. At least a month passed before he finally made a doctor's appointment, and he came home from that doctor's appointment white as a sheet and visibly upset.

"I have testicular cancer and tomorrow morning I need to get my right nut chopped off." We were both in shock. So soon? Right away? Doesn't a diagnosis usually take months?

Not with testicular cancer. It travels VERY quickly to other organs in the body. Once a diagnosis is made, an Orchiectomy (the technical term for having a nut chopped off) is done as soon as possible.

In our society, we have lots of euphemisms for testicles. Nuts, balls, the family jewels. But we don't talk seriously about testicles very much. It was really awkward even, to call his manager and tell him that he'd be out for a week because he had testicular cancer and had to have a "ball-ectomy."

After dropping our 2 children off at school the next morning we headed to the hospital. I will never forget the doctor coming out of surgery holding a big, white, metal pan with my husband's bloody testicle in it. It had been sliced in half. He showed me all the tumors. The worst part was, they were not sure they got everything – because it spreads so fast. He'd need radiation as well.

The radiation rendered him sterile. And he missed more work because the radiation made him very tired.

Testicular cancer had a profound effect on our family, our sex life, our relationship, and maybe even his career due to missed work.

We were fortunate that we already had 2 children so the fact that we could not have any more was not a huge blow to us, but it might be to some people. Testicular cancer can occur in any man at any age (compared to prostate which tends to occur with older men). Imagine if you were in your 20's and found out that this cancer made you unable to ever have children? Or, if the cancer spreads to both testicles and both need to be amputated, you'd never be able to get an erection. No amount of Viagra can help if you have no testicles.

Knowing if there are PFAS in your water can protect not only men from testicular cancer, but also women and children from other types of cancer.

How much are the "family jewels" worth? I think we'd all agree they are priceless. I am asking that you support legislation to provide notice of PFAS and other groundwater contamination in the purchase and sale of a property.

Thank you very much for hearing my story and considering my request.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document. Regulations regarding the purchase and sale of property are beyond the scope of this action.

Jondi Gumz (Doc. #2620, SBC-047420)

None of the fire agencies talks about the impact of PFAS, the forever chemical that doesn't break down in the environment or in our bodies, PFAS—resistant to water, grease, and heat. Studies have linked PFAS to cancers, high cholesterol, thyroid disease, liver damage, asthma, allergies, and reduced vaccine response in children. PFAS have also been linked with decreased fertility, newborn deaths, low birthweight, birth defects, & delayed development. We tossed our Teflon pans & stopped buying new carpet for this reason, but now PFAS can get into our water supply & soil where our food is grown. https://www.hsph.harvard.edu/news/hsph-in-the-news/protecting-against-forever-chemicals/

Companies should stop using PFAS. There must be alternatives. Use good science to find a safer alternative.

Clean drinking water is essential to human life, and reverse osmosis to filter wastes water, which in California is precious.

It's your job to protect us. Please.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document.

Marianne Nurmi (Doc. #2755, SBC-047442)

PFAS have been designed for long-term stability and therefore are meant to be difficult to destroy, meaning that they cycle through our environment and have been given the name of "forever chemicals" for this ability to remain intact (AAAS.org, 2023) This is a concerning fact when combined with research that has linked PFAS to health issues from "cancers and increased cholesterol levels to preeclampsia during pregnancy (AAAS.org, 2023). Not only are these chemicals extremely difficult to break down or destroy, but they are causing harm with little regulation.

I believe the use and exposure to chemicals such as PFAS must be limited until further research is available. A study by the Centers for Disease Control and Prevention found PFAS in the blood of 97% of Americans (NIEHS.NIH.gov, 2023). This is a concerning fact since the full effects of PFAS on humans, animals, and our environment are not fully understood. Until these effects can be further examined and researched, we need to err on the side of caution.

The regulations that are being proposed, such as this one, would help in providing protection to the public and our environment against dangerous chemicals such as PFAS and allow further research to be conducted to increase understanding and assess risk. Other studies conducted by the Centers for Disease Control and Prevention found that chemicals that were removed from consumer products in the early 2000s, such as PFOS and PFOA, have shown reduced levels in blood meaning that our bodies can work to reduce these types of chemicals when given the chance (NIEHS.NIH.gov, 2023).

It is the responsibility of the government to protect the citizens of the United States from companies putting profit over health and safety concerns. Though I understand any type of new regulation requires time to be implemented by those being regulated (in this case, water treatment plants, etc.) It is clear to me that chemicals such as PFAS have no place in our water and need to be regulated as soon as possible to keep the general public safe and allow the ability to fully research and analyze their effects.

Sincerely,

Marianne Nurmi

References

AAAS.org. 2023. "Per- and Polyfluorinated Substances in Drinking Water" . Last modified April 23, 2023. https://www.aaas.org/epi-center/pfas#:~:text=of%20health%20effects%3F-,Trace%20doses%20of%20several%20of%20the%20most%2Dresearched%20compounds%20have,immune%2C%20endocrine%20and%20metabolic%20systems.

CDC.gov. 2023. "Per- and Polyfluorinated Substances (PFAS) Factsheet" . Last modified May 2, 2022. https://www.cdc.gov/biomonitoring/PFAS_FactSheet.html

EPA.gov. 2023. "PFAS Explained" . Last modified April 10, 2023. https://www.epa.gov/pfas/pfas-explained

National Institute of Environmental Health Sciences. 2023. "Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS). Last updated March 9, 2023. https://www.niehs.nih.gov/health/topics/agents/pfc/index.cfm

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document.

West Virginia Rivers Coalition (Doc. #3072-3, SBC-047356)

Hello everyone, thank you for providing the opportunity for verbal comment. My name is Jenna Dodson, and I'm the staff scientist at West Virginia Rivers Coalition. West Virginia Rivers Coalition strongly supports EPA's proposal to set strong, science-based drinking water standards for six PFAS. In West Virginia, communities have suffered the health impacts from PFAS-contaminated water for decades. For over 50 years, communities near Parkersburg were exposed to dangerously high concentrations of PFOA discharged by a DuPont manufacturing facility into the Ohio River, which was the community's drinking water supply. Decades-long epidemiological studies have shown that these communities suffer from severe long-term health effects, including high rates of autoimmune disease, testicular cancer, and kidney cancer. In the Eastern Panhandle in Martinsburg, firefighting foam from the Shepherd Field Air National Guard station migrated through the groundwater and caused PFAS contamination to public and private wells. A 2022 exposure assessment by the Agency for Toxic Substances and Disease Registry found that affected community members have PFHxS blood levels 2.5 times higher than the national average. Although it's nearly impossible to fully recover from years of concealed truths and harm, the proposed drinking water standards is a concrete step towards protecting community health. That being said, the proposed regulations are just the first step.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document.

NRDC (Doc. #3072-13, SBC-047365)

Thank you very much. I would like to first of all thank EPA for issuing this historic proposal. It is a welcome change from a long history of delay on this issue, and we are urging EPA – I'm from the Natural Resources Defense Council – to finalize this rule as soon as possible without delay to get it out, and to get the public health protections out there to protect the up to 94 million people that EPA says may be drinking water that exceeds its proposed standards. We

commend EPA for quantifying and monetizing many of the benefits, such as cardiovascular disease, low birth weight, and renal cell carcinoma, as well as some of the additional benefits of reducing other co-occurring contaminants, such as disinfection byproducts, where bladder cancer and other health effects have been quantified. But we also urge EPA to take another second, hard look at quantifying and monetizing some of the additional health effects that the Agency and scientists around the world have recognized, including thyroid effects, immunotoxicity, some of the liver and/or hepatotoxicity issues, and lactation effects.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document. Discussion on the quantifiable and non-quantifiable health endpoints for this NPDWR can be found in the HRRCA section 13.4 of the EPA response in this *Response to Comments* document.

Alliance of Nurses for Healthy Environments (Doc. #3072-27, SBC-047375)

Very low doses of PFAS in drinking water have been linked to suppression of the immune system and are associated with an elevated risk of cancers and reproductive and developmental harms and other serious health concerns. And the National Academies of Science Engineering and Medicine has published in their guidance that there is sufficient evidence that certain PFAS are associated with health outcomes including decreased antibody responses, dyslipidemia, decreased infant and fetal growth, and increased risk of kidney cancer. EPA's proposed drinking water standards align with the Biden administration's commitment to advanced environmental justice, as communities of color and low-income communities have historically faced disproportionate exposure to pollution and cumulative adverse health effects for multiple co-occurring contaminants. As nurses and healthcare providers quickly educate themselves on how to adequately assess patients in communities for PFAS exposure and provide the necessary resources, we are relying on EPA to quickly finalize these drinking water standards and expedite efforts to prevent these forever chemicals from polluting the environment in the first place. We urge EPA to control industrial discharges, reduce unnecessary uses of PFAS, and we urge the EPA to implement a rule that is the most health protective, resisting industry's efforts to weaken them. Thank you.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document. See section 14 of the EPA response in this *Response to Comments* document for discussion of EJ considerations.

Clean Hall River Grassroots Advocacy Group (Doc. #3072-96, SBC-047407)

Good evening I'm Katie Bryant, the co-founder of Clean Hall River Grassroots Advocacy Group out of Pittsboro, North Carolina. I'm a trained microbiologist, the spouse of a retired forward military operator and a mother to two daughters. We get our water from the Hall River where

PFAS and other industrial contaminants have been coming downstream for over 40 known years from the textile industry out of Reedsville, Burlington, and Greensboro, and are responsible for polluting the entire Cape Fear River Basin. One of the largest contributors being Elevate Textiles in Burlington, who has been shown to be discharging PFAS at levels of 33,000 parts per trillion. We have industries discharging whatever they want into our drinking water. We have land applied biosolids and inline landfills leaching into the Hall River as well as firefighting foams. All of this is impacting our water quality. The GenX exposure study published data last year showing Pittsboro blood serum values are four times higher than the national average. We have adults so far off the charts and children with PFAS blood values higher than adults in our country, my children included. This should disturb you because there is a footprint here. The chemicals in these children match the exact chemicals used by industries upstream. Sadly, my community is suffering. Pittsboro water users check every box on a PFAS exposure checklist and show rare and reoccurring cancers and deaths. My children are sick. I can't keep them well enough for school. They have learning disabilities, developmental delays, digestive issues. My husband has lost his gallbladder, has increased cholesterol and is now showing signs of early liver disorder.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document.

Sophia Milone (Doc. #1487, SBC-042702)

My name is Sophia Milone. I'm studying Sustainability at Stockton University in NJ, and I have learned about PFAS and other "forever chemicals" for the last three years of my education. PFAS are known to have many adverse impacts on animal health and public health, as they can cause significiant medical issues in humans; they can also disrupting ecosystem functioning due to their persistence. It goes without saying that exposure to these compounds is not healthy, and should be avoided at all costs.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document.

Kaden Heldt (Doc. #1510, SBC-042590)

Another issue surrounding this decision is how only six of these PFASs have been regulated out of the thousands of them that exist. This regulation is undoubtedly positive, but more needs to be done (Underferth). The allowance of this continues the harm of citizens, putting millions of Americans at health risks. Exposure to PFASs can lead to health complications including immune system issues, hormone interference, reduced effectiveness of vaccines, high cholesterol, low birth rate, kidney cancer, liver damage, testicular cancer, and thyroid disease (Underferth).

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document.

Daniel Varon (Doc. #1518, SBC-042721)

PFAS are a group of chemicals used to make fluoropolymer coatings and products that resist heat, oil, stains, grease, and water. [FN1: CENTERS FOR DISEASE CONTROL AND PREVENTION, NATIONAL BIOMONITORING PROGRAM: PER- AND POLYFLUORINATED SUBSTANCES (PFAS) FACTSHEET, https://www.cdc.gov/biomonitoring/PFAS_FactSheet.html (last visited Apr. 20, 2023).] For this reason, they are most prevalent in cookware, clothing, carpets, and firefighting foam—all household products. [FN2: NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES, PERFLUOROALKYL AND POLYFLUOROALKYL SUBSTANCES (PFAS), https://www.niehs.nih.gov/health/topics/agents/pfc/index.cfm (last visited Apr. 20, 2023).] As these products are used and washed, PFAS can seep into sewers, soil, water, and air. [FN3: Id.] It is important to note that consuming PFAS contaminated water is only one method in which humans are exposed to PFAS, other methods include eating contaminated food—whether it be grains from contaminated soil or livestock eating contaminated grains—and also by breathing air containing PFAS. [FN4: AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, PFAS EXPOSURE AND YOUR BODY, https://www.atsdr.cdc.gov/pfas/health-effects/PFAS-exposure-and-your-body.html (last visited Apr. 20, 2023).] One study conducted by the CDC found that PFAS were in the blood of 97% of Americans. [FN5: NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES, supra note 3.]

Exposure to PFAS "may" lead to: increased cholesterol levels, changes in liver enzymes, small decreases in infant birth weights, decreased vaccine response in children, increased risk of high blood pressure or preeclampsia in pregnant women, and increased risk of kidney or testicular cancer. [FN6: AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, PFAS HEALTH EFFECTS, https://www.atsdr.cdc.gov/pfas/health-effects/index.html (last visited Apr. 20, 2023).] It is important to note that studies relied on merely "suggest" a correlation between PFAS and these health defects, and even then, the correlation is not "statistically significant." [FN7: AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, PFAS: AN OVERVIEW OF THE SCIENCE AND GUIDANCE FOR CLINICIANS ON PER- AND POLYFLUOROALKYL SUBSTANCES (PFAS) 8 (2019).]

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. The EPA agrees that drinking water is only one route of exposure to PFAS. More information about health effects, and about the EPA's use of the RSC to account for multiple PFAS sources, can be found in section 4 of this *Response to Comments* document and the MCLG Summary Document for a Mixture of Four PFAS (USEPA, 2024c).

Isabelle Dominguez (Doc. #1525, SBC-042627)

There are several serious health risks associated with PFAS exposure. [FN11: See generally Sunderland et al., supra note 6.] One such health risk is cancer; several studies have demonstrated that communities with higher levels of PFAS in drinking water have increased cancer risk, particularly in prostate, kidney, and testicular cancers. [FN12: Id at 138-39.] PFAS exposure also affects individuals' immune systems. For example, there is a well-established association between "higher PFAS exposure and suppressed immune response" to vaccination in populations of all ages. [FN13: Id. at 139-40.] Other health issues concern metabolic effects [FN14: Id. at 140-41 (discussing the effects of PFAS on cholesterol, thyroid function, cardiovascular disease, and body weight among other things.)] and neurodevelopment effects. [FN15: Id. at 141-42.] PFAS exposure is particularly dangerous for children [FN16: Id. at 138.] and pregnant people and their fetuses. [FN17: How PFAS Chemicals Affect Women, Pregnancy, and Human Development, INT'L FED'N OF GYNECOLOGY AND OBSTETRICS, (May 20, 2021) https://www.env-health.org/wp-content/ uploads/2021/05/FIGO-PFAS-Fact-Sheet-FINAL-5.20.2021.pdf.]

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document.

Samantha Matterson (Doc. #1527, SBC-042630)

However, I do not believe that this action gets at the root cause of the issue. PFAS are harmful not only to people but to the surrounding environment. The C8 (another term for PFAS) Science Panel's 2005-2013 study confirmed a probable link between PFAS and "diagnosed high cholesterol, ulcerative colitis, thyroid disease, testicular cancer, kidney cancer, and pregnancy-induced hypertension" (Fletcher et al., 2020). Additionally, PFAS are nicknamed forever chemicals for a reason. For example, the average half-life of PFHxS is 5.3 years, and these chemicals bioaccumulate over time and through the food chain (Li et al., 2017). Meaning that, not only is this affecting humans, but it's affecting animals and plants as well. Given the abundance of evidence for the harmful nature of these chemicals, I am concerned that this action does not do enough to satisfy the extent of the issue.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document. This NPDWR is designed to address drinking water as a specific exposure pathway. Other exposure pathways are addressed by other agency programs based on other statutory authority,

Cordell Spires Jr. (Doc. #1541, SBC-042660)

I. Background

Per- and polyfluoroalkyl substances (PFAS) are chemicals produced in the United States since the 1940s. [FN-1: PFAS in Drinking Water, ILLINOIS DEPARTMENT OF PUBLIC HEALTH,

https://dph.illinois.gov/topics-services/environmental-health-protection/private-water/factsheets/pfas-drinkingwater.html#:~:text=Exposure%20to%20high%20levels%20of,odds%20of%20women%20becom ing%20pregnant (last visited April 21, 2023).] They are used in a variety of ways ranging from firefighting to stain and waterproofing consumer products, such as carpet, clothing, and food packaging. [FN-2: Id.] Some PFAS are no longer made due to environmental and health concerns, but they persist in the environment and may contaminate surface waters and groundwaters near sites where they were made or used. PFAS, even those that are no longer made, continue to be detected in human blood. [FN-3: Id.] Meanwhile, new PFAS continue to be created. [FN-4: Id.]

II. Health Effects of PFAS

Exposure to PFAS in contaminated drinking water may result in: increased cholesterol levels, changes in liver enzymes, hormone disruption and increased risk for thyroid disease, decreased odds of women becoming pregnant, high blood pressure or pre-eclampsia during pregnancy, small decreases in infant birth weights, decreased vaccine response in children, and increased risk of kidney and testicular cancers. [FN-5: Id.]

III. Communities Impacted by PFAS Regulation

43% of U.S. Zip codes have had at least one water source where PFAS contamination was detected over the past 20 years. [FN-6: Amanda Hernandez & Mark Nichols, How PFAS are Entering America's Water Supply, ABC News (April 21, 2023, 5:01 AM), https://abcnews.go.com/US/pfas-entering-americas-watersupply/story?id=98479678.] In other words, at least 143 million Americans potentially could have been exposed to PFAS. [FN-7: Id.] PFAS contamination is also more prevalent in ZIP codes that are poorer and more racially diverse than the national average. [FN-8: Id.]Therefore, any regulation will have a significant impact on those communities.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document. See section 14 of the EPA response in this *Response to Comments* document for discussion of EJ considerations.

Alliance of Nurses for Healthy Environments (Doc. #1544, SBC-042668)

Not only are PFAS widespread in drinking water, these "forever chemicals" persist throughout the environment and pose risks to public health even in trace amounts. They are found in the blood of virtually everyone on Earth, and build up in our organs. Very low doses of PFAS in drinking water have been linked to suppression of the immune system [Link: https://www.atsdr.cdc.gov/pfas/health-effects/index.html] [FN5: Agency for Toxic Substances

and Disease Registry (ATSDR). (2022, November1). What are the health effects of PFAS? https://www.atsdr.cdc.gov/pfas/health-effects/index.html] and are associated with an elevated risk of cancers and reproductive and developmental harms [Link: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8743032/], [FN6: Rickard BP, Rizvi I, Fenton SE. (2022). Per- and poly-fluoroalkyl substances (PFAS) and female reproductive outcomes: PFAS elimination, endocrine-mediated effects, and disease. Toxicology, 465:153031. doi: 10.1016/j.tox.2021.153031. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8743032/] among other serious health concerns [Link: https://www.atsdr.cdc.gov/pfas/health-effects/index.html] [FN7: Agency for Toxic Substances and Disease Registry (ATSDR). (2022, November1). What are the health effects of PFAS? https://www.atsdr.cdc.gov/pfas/health-effects/index.html]

The National Academies of Science, Engineering and Medicine has published in their guidance that there is sufficient evidence [Link: https://nap.nationalacademies.org/catalog/26156/guidance-on-pfas-exposure-testing-and-clinical-follow-up] that certain PFAS are associated with health outcomes including:

- decreased antibody responses (in adults and children),
- dyslipidemia (in adults and children),
- decreased infant and fetal growth, and
- increased risk of kidney cancer (in adults). [FN8: Ibid (pp 6-7)]

According to ATSDR's 2019 publication providing guidance for clinicians [Link: https://www.atsdr.cdc.gov/pfas/docs/clinical-guidance-12-20-2019.pdf], human studies have found associations between exposure to PFAS and adverse health effects in many organ systems. [FN9: Agency for Toxic Substances and Disease Registry (ATSDR). (2019). PFAS: an overview of the science and guidance for clinicians on per- and polyfluoroalkyl substances (PFAS). Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service. https:// www.atsdr.cdc.gov/pfas/docs/ ATSDR_PFAS_ClinicalGuidance_12202019.pdf] EPA notes that "PFAS can accumulate and persist in the human body for long periods of time and evidence from laboratory animal and human epidemiology studies indicates that exposure to these compounds may lead to cancer, reproductive, developmental, cardiovascular, liver, and immunological effects. Many known and potential sources of PFAS contamination are near communities already overburdened with pollution."[FN10: EPA (2023, April 14). EPA Takes Important Step to Advance PFAS Strategic Roadmap, Requests Public Input and Data to Inform Potential Future Regulations under CERCLA.

https://www.epa.gov/newsreleases/epa-takes-important-step-advance-pfas-strategic-roadmap-requests-public-input-and-data].

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document.

Lecsy Gonzalez (Doc. #1561, SBC-042869)

Exposure to PFAS through drinking, or tap, water is a serious concern, as PFAS chemicals have been found in 99% of blood samples taken across the United States population between 1999 and 2012. [REF4: Crone, B.C., Speth, T.F., Wahman, D.G., Smith, S.J., Abulikemu, G., Kleiner, E.J. and Pressman, J.G., 2019. Occurrence of per-and polyfluoroalkyl substances (PFAS) in source water and their treatment in drinking water. Critical reviews in environmental science and technology, 49(24), pp.2359-2396.] This is a significant public health concern as even low drinking water concentrations of PFAS can remain in the human body for many years after exposure. [REF5: Domingo, J.L. and Nadal, M., 2019. Human exposure to per-and polyfluoroalkyl substances (PFAS) through drinking water: A review of the recent scientific literature. Environmental research, 177, p.108648.] PFAS exposure, as aforementioned, has been linked to increased liver enzymes, thyroid disorders, pregnancy-induced preeclampsia, reduced fertility, and testicular and kidney cancer. [REF1: Stoiber, T., Evans, S., Temkin, A.M., Andrews, D.Q. and Naidenko, O.V., 2020. PFAS in drinking water: an emergent water quality threat. Water Solutions, 1(40), p.e49; REF4: Crone, B.C., Speth, T.F., Wahman, D.G., Smith, S.J., Abulikemu, G., Kleiner, E.J. and Pressman, J.G., 2019. Occurrence of per-and polyfluoroalkyl substances (PFAS) in source water and their treatment in drinking water. Critical reviews in environmental science and technology, 49(24), pp.2359-2396]. As such, it is crucial to pass this regulation which would decrease PFAS in drinking water sources in a more equitable way.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document.

Wisconsin Conservation Voters (Doc. #1611, SBC-042859)

Every day, we hear more stories about the impact of PFAS contamination in Wisconsin. Across the state, Wisconsinites are worried about the serious, long-term health risks associated with PFAS. This includes an increased risk of complications with pregnancy, childhood obesity, learning and behavioral issues, thyroid disease, heart disease, diabetes, and testicular cancer.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document.

Safe Healthy Playing Fields, Inc. (Doc. #1621, SBC-042943)

Responding to testing results of a newly installed synthetic turf field in Portsmouth, NH, Dr. Graham Peaslee, University of Notre Dame, the leading researcher of PFAS in consumer products, wrote in an email to a colleague:

“Even their [external testing lab] "very low" levels measured from a piece of turf...if multiplied by the size of a field would contaminate significant amounts of surface/ground water above these new limits.

While the regulatory limits (when they come) will likely be set higher, this pronouncement of unsafe levels in drinking water mean[s] trouble for turf grass fields as sources of PFAS...even though the measurable load is only a few ng/L of a few PFAS, there is a lot of turfgrass out there, and this would represent a threat to the local ecology and humans if there were drinking water sources nearby.”

Recent research from the University of Stockholm [Link: https://chemrxiv.org/engage/api-gateway/chemrxiv/assets/orp/resource/item/624ea1cd5a] indicates that synthetic turf fields contain from 1 to 38 pounds of PFAS, per playing field. To date, all reported testing results have found PFAS in all components of synthetic turf fields: the carpet backing, blades, shock pad and infill. PFAS in synthetic turf has been shown to leach from the plastic grass carpet, contaminating soil, WATER [Link: https://www.youtube.com/watch?v=hoipI2Yj1DA] and air (@19:55).

The loss of degrading microplastic blades [Link: https://wjla.com/features/i-team/montgomery-county-sports-field-washing-away-in-rain] from synthetic turf is significant. The International Association for Sports and Leisure Facilities states (27 Aug 2019):

“mechanical wear from high tread loads – as arising during football or rugby – causes tiny particles or blades of artificial grass to break off. This amounts to 250 to 300 kg per year for modern sports pitches.”

That is 551-661 pounds of PFAS laden microplastics readily lofted into the air by field, washed down drains or embedded into soil due to activity or weather- per field, per year. With an estimated 32,400 - 35,000 plus current synthetic playing fields (based on industry statements and industry claims of new installations every three to four days) and a regulation sized field of 80,000 square feet, the estimated amount of synthetic turf playing systems is between 457,000,000 and 505,000,000 square feet of of PFAS containing synthetic turf covering parks and schools across the country. This, of course, is a gross underestimate as it is exclusive of other applications noted above. Additionally, many playing fields are 200,000 to 400,000 square foot installations.

Microplastic synthetic turf blades have been found in Lake Tahoe and the ocean. This makes synthetic turf clearly a major point source of PFAS pollution that cannot go unaddressed.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document. There can be many different contamination sources affecting drinking water; this rule is designed to ensure drinking water quality regardless of the source. Use of PFAS in commercial products is beyond the scope of this current rulemaking.

Association of Environmental Authorities (AEA) (Doc. #1635, SBC-042961)

We support comments submitted by NACWA, the Water Environment Federation (WEF), and the American Water Works Association (AWWA), and in particular, the following points:

PFAS chemicals are widespread in our environment – in water, in air, and in soil. PFAS chemicals are in fast food wrapping and dental floss, and they are water-proof clothing, make-up, and literally thousands of other items and products we use every day. Our member utilities are passive receivers of PFAS chemicals.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. The EPA agrees that drinking water is only one route of exposure to the six PFAS regulated by this rule, more information about the agency's use of RSC to account for the drinking water route can be found in section 4 of the EPA response in this *Response to Comments* document. It is also important to distinguish between a potential environmental release and a direct exposure. A PFAS release does not inherently imply human exposure and a release is not inherently risky to specific populations. A product that contains PFAS does not automatically imply risk or release.

Sharon Levy (Doc. #1824, SBC-044277)

PFAS are dangerous chemicals that bioaccumulate in the body's organs. Continuous small exposures can lead to larger health effects that can be harmful to people who are ingesting PFAS.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document.

Gujarat Fluorochemicals Limited (Doc. #1840, SBC-044851)

May 30, 2023

Docket ID: EPA-HQ-OW-2022-0114

Re: Proposed PFAS National Primary Drinking Water Regulation.

To Whom It May Concern:

Gujarat Fluorochemicals Limited ("GFL") respectfully submits these limited comments as pertinent information for the Proposed Rule posted on March 29, 2023: Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation. The Proposed Rule aims to regulate under the Safe Drinking Water Act perfluorooctanoic acid ("PFOA"), perfluorooctane sulfonic acid ("PFOS"), perfluorohexane sulfonic acid ("PFHxS"), hexafluoropropylene oxide dimer acid ("HFPO-DA") and its ammonium salt (also known as "GenX Chemicals") and other PFAS of Concern ("PFOC"). GFL and GFL Americas, LLC (a U.S.-based wholly-owned subsidiary) manufacture certain fluoropolymers used in critical applications necessary for functioning of

modern society. While fluoropolymers themselves are safe and non-toxic substances with high molecular weight, the use of toxic, small, water soluble, mobile and bio-accumulative PFAS molecules as polymerization/processing aids in their manufacture is a cause of concern to be addressed by the industry through the use of safer chemistry. To this end, GFL comments to share information on non-PFAS alternatives developed to replace the use of PFOA, HFPO-DA and other PFAS substances as polymerization aids in the manufacture of fluoropolymers.

In particular, GFL seeks to share information to supplement EPA's decision to strictly regulate HFPO-DA. As EPA states in the Proposed Rule, the "most common use for GenX Chemicals is for emulsion polymerization." The use of PFAS processing aids for this purpose is not necessary for a majority of fluoropolymers, and so GFL supports any regulation to minimize the use of these chemicals or mitigate the effect thereof. Viable alternate technologies exist to produce most fluoropolymers that are circulated in commerce without the use of PFAS processing aids. GFL itself uses such technology to produce four fluoropolymers – polytetrafluoroethylene ("PTFE"), polyvinylidene difluoride ("PVDF"), fluoroelastomer ("FKM") and perfluoroalkoxy alkanes ("PFA") – largely without PFAS processing aids, and by the end of this year will produce its entire fluoropolymer portfolio without the use of these aids. GFL is not alone; fluoropolymer manufacturers like Arkema, Solvay and Honeywell have developed non-PFAS alternatives and have committed to stopping the use of harmful PFAS as processing aids. Other manufacturers are also developing methods to replace PFAS polymerization aids with non-fluorinated aids. In fact, more than 50% of fluoropolymers do not require the use of polymerization aids at all during manufacturing. Of those fluoropolymers that are manufactured with the use of polymerization aids, few use PFAS polymerizations aids (and fewer need to). One study concludes that more than 80% of the fluoropolymers produced globally soon will be manufactured without the use of fluorinated polymerization aids [FN1: "Fluoropolymers: The Safe Science That Society Needs"; Jaime Sales, Francisco Hernández, Deepak Kapoor and Marcel van den Noort. [2022] ICRL. ISSN (Print) 2566-834X.]. Similarly, the International Chemical Regulatory Law Review recently published a special issue on regulatory updates on PFAS detailing this shift towards the use of non-PFAS polymerization aids [FN2: "Developments in Fluoropolymer Manufacturing Technology to Remove Intentional Use of PFAS as Polymerization Aids"; Bruno Ameduri, Jaime Sales and Michael Schlipf. [2023] ICRL. ISSN (Print) 2566-834X ISSN, (Online) 2566-8412.].

EPA Response: The SDWA regulates contaminants that meet specific regulatory criteria as outlined in section 3. This NPDWR will reduce six PFAS (including HFPO-DA) known to cause adverse health effects as well as occur in PWSs, consistent with the SDWA regulation criteria. As outlined in the PFAS Strategic Roadmap, the EPA plans on taking a holistic approach to managing PFAS risks and the EPA shares the goal of safeguarding human health and the environment. This is partially accomplished by evaluating new chemicals to ensure that they are in fact safer alternatives. Please see the summary of major public comments for this section.

Villanova University (Doc. #3072-10, SBC-046344)

Good afternoon, and thank you for this opportunity to provide comments. My name is Dr. Laura Anderko, I'm a registered nurse with a Ph.D. in Public Health at Villanova University. I've been a member of the Children's Health Protection Advisory Committee, the National Drinking Water Advisory Council, and co-author of the recent NASM report, "Guidance on PFAS Exposure, Testing, and Clinical Follow-Up." I'm here to strongly support EPA's proposed drinking water standards for PFAS and thank you, as these are long overdue. EPA's proposal for the six PFAS would set the national standard for PFOA and PFOS at the lowest detection level approved by the Agency, and would establish limits on GenX, PFBS, PFNA, and PFHxS using a Hazard Index. EPA estimates that 94 million Americans currently receive their drinking water contaminated by one or more of these PFAS chemicals above the limits proposed by the EPA. The proposed regulation of PFAS will improve the drinking water safety for millions of Americans, and protect the public's health. PFAS chemicals are found in the blood of virtually every American. Children are particularly vulnerable to these chemicals, with research reporting health effects such as decreased infant and fetal growth, dyslipidemia, and decreased vaccine response. Children are more susceptible to the health effects of water pollution because their bodies, brains, and organs are still developing, and damage from chemical exposure may last a lifetime. PFOS and PFOA are commonly found in breast milk and core blood. Research continues to explore the long-term health effects of these chemicals in children from these sources of exposure. It is encouraging to know that the Bipartisan Infrastructure Law will provide funding for drinking water infrastructure upgrades and other drinking water infrastructure needs for municipalities. Prevention of exposure is key to ensuring the public's health. Therefore, I also urge EPA to expedite efforts to prevent forever chemicals from entering the environment by controlling industrial and military discharges of PFAS into the water. In closing, I'd like to underscore that the proposed PFAS drinking water standards supports the mission of EPA to protect human health and the environment, and I urge the Agency to finalize the standards as quickly as possible. Thank you.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document. This rule focuses specifically on drinking water. Discharges to source water are addressed by other agency programs based on other statutory authority.

Jennifer Decker (Doc. #3072-91, SBC-046399)

My full name is Jennifer Decker, Morgan is a nickname. I would just like to invite us all to have moments of silence for those we've lost. I'm thinking about the people who've shared about family members who are gone. I just invite us all to reflect upon the babies who've had cancer. I am really thankful for all the people who've spoken out today on the issue of PFAS. I feel like this is a matter of trust in government. I urge us to follow the model of the European Union that Marguerite Adelman spoke about. I think we do need to follow the precautionary principle in

order to re-establish trust in government. The lack of trust in government has caused chaos in this country. If a foreign power wanted to poison and kill the U.S. public, we declare a war, but when the Department of Defense does it, we have to hold a hearing, and we're in an absurd position, sort of like the book Catch 22, where we're dealing with a government that is supposed to protect all of our life, liberty, and our pursuit of happiness, but instead is destroying that and then is allowed to negotiate. It doesn't make any sense. One of the things that I think is really important for us to consider is the neurological impacts of PFAS. That's something that we need to study more, but I think that we might have avoided a lot of problems in this country if people could have understood that it was these toxins that are causing things like autism and other neurological damage.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document.

Safe Healthy Playing Fields (Doc. #3072-93, SBC-046401)

Good afternoon, this is Diana Conway. I'm a Potomac, Maryland resident just outside of Washington DC. I'm also president of a nonprofit called Safe Healthy Playing Fields. We are 501(c)(3) established in 2019, after more than 10 years of advocacy on why artificial turf fields are a disaster. We knew they were a disaster for athletes, for heat, for injury, for general toxicity, just things like carcinogens or endocrine disruptors. But now we know that each one of those fields, about two acres per field, is loaded with PFAS and that it leaches off, of course. The gentleman who called in from Oak Bluffs on Martha's Vineyard, the town attorney I think, I was pleasantly surprised to hear him there because I know that Island, Martha's Vineyard, as well as Nantucket, are turning back artificial turf fields because they are the sole source aquifers, and if that water is contaminated, they're done. Never mind the tourist season that sustains those communities, they won't be able to drink a drop of their water. So, I'm calling in and I'm so pleased you opened the phones like this. I had no idea I could be able to jump in at the last minute. I really appreciate it. Everything everybody said made sense. Let's get the whole class regulated. Let's be much more aggressive about the regulation. Let's be ready and clear-eyed that the industry's going to come back and say, "Oh wait, oh wait, we have a better idea." This has been for decades. This has been a known problem and it's finally getting said out loud. I am so grateful to all the scientists and activists and the students who chimed in. What I really want to say is, artificial turf is one of the easy ones. A lot of these products that have PFAS in them are things that we may not be able to replace yet. Artificial turf, my goodness, it's two acres of PFAS and we have a classic replacement, it's called grass. It's good for the water, it's a carbon sink, it's a cooling effect instead of a heat island. And you're not rolling your children in chemicals from pre-K through college, and especially of course in PFAS. Montgomery County, Maryland is a suburb of Washington DC. There's a large area of farming community still there. They've had to close two of their only 13 municipal wells in Poolesville because of the excessive PFAS contamination. So, we're going to run out of water to drink. This should be a no-brainer and

artificial turf above all should be one of the first ones to go. We've got choices there. So, thank you again very much for this opportunity.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document. There can be many different contamination sources affecting drinking water; this rule is designed to ensure drinking water quality regardless of the source. Use of PFAS in commercial products is beyond the scope of this current rulemaking.

Virginia Clinicians for Climate Action (Doc. #3072-95, SBC-046402)

Hi, thanks very much. So, my name's Paul DiLorenzo. I'm a heart specialist and I am a member of the Virginia Clinicians for Climate Action and I have some interest in reducing health risk to the population as a whole. So, some of my suggestions or questions really are that there is a move to regulate six PFAS chemicals. Congratulations. Great job. I think that's wonderful. Anything is better than nothing at all. But as we know, there will be this negligent substitution or whack-a-mole. And I think you need legislation or rules within EPA to say that the companies must prove safety prior to making the next non-stick pan or that there will be substantial multi-million- or billion-dollar penalties if they're found to be negligent down the road. And then the next thing is I would go along with somebody earlier who looked at low-hanging fruit, foam, which has PFAS, obviously should be banned. Non-stick should be really carefully looked at by the EPA to determine if there are indeed any safe non-stick pans or non-stick pans should be banned. And then artificial turf, which I thought was an excellent suggestion. So, I think what I'm saying is the two things left out are new negligent substituted PFAS and basically ways to not only measure and reduce the water content, but to actually reduce the amount of PFAS that is going into our country. I thank you very much. I hope this was helpful. And by the way, the conference was great. Good job.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document. There can be many different contamination sources affecting drinking water; this rule is designed to ensure drinking water quality regardless of the source. Use of PFAS in commercial products is beyond the scope of this current rulemaking.

Kathy Michaels (Doc. #3072-104, SBC-046407)

Hi. Yeah. My name is Kathy Michaels and I'm in Maryland and I just wanted, I came on very late, but I wanted to point out the fact that a lot of PFAS chemicals are entering air, soil, and water from solid waste such as plastics, in particular synthetic carpeting and in particular the huge installations of synthetic turf, which it's like a Trojan horse for PFAS chemicals, and not just leaching out into the nearby soils and water, but because they break down, they form

microplastics that loft into the air and get deposited everywhere. So, they're basically a point source of a huge amount of PFAS pollution and they get discarded every eight years or so. So, they're just building up in the environment that way. So, thank you very much. I wanted to bring that to your attention.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document. There can be many different contamination sources affecting drinking water; this rule is designed to ensure drinking water quality regardless of the source. Use of PFAS in commercial products is beyond the scope of this current rulemaking.

Jorge Diaz Castello (Doc. #1473, SBC-042308)

Endocrine disruptors are chemicals that can interfere with the body's endocrine system, which is responsible for regulating hormones and other biological processes. PFAS compounds have been identified as endocrine disruptors, meaning that they interfere with the body's hormonal balance and cause adverse health effects.

In children, who are still developing both physically and hormonally, exposure to endocrine disruptors like PFAS can be particularly concerning. During early life stages, the body's systems are still maturing, and exposure to environmental contaminants can disrupt the normal processes of growth and development. This can lead to a wide range of negative health outcomes, including developmental delays, cognitive impairment, and increased susceptibility to disease.

Moreover, research has suggested that PFAS exposure during pregnancy may have long-lasting effects on a child's health. A study conducted by researchers at Harvard found that higher levels of PFAS in maternal blood were associated with lower birth weights and head circumferences in infants, as well as reduced immune function and increased risk of infection in early childhood.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document.

Shelley V.L. (Doc. #1555, SBC-042558)

Document ID: EPA-HQ-OW-2022-0114

Comments regarding: Per- and polyfluoroalkyl substances (PFAS): Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) National Primary Drinking Water Regulation

Thank you for the opportunity to provide public comments regarding this critical piece of legislation. I support the Environmental Protection Agency’s (EPA) proposal to regulate Per- and poly-fluoroalkyl substances (PFAS), such as Perfluorooctanoic acid (PFOA) and Perfluorooctane sulfonic acid (PFOS), in nation’s drinking water. The role and federal authority of the EPA is to

act on the behalf of the people, to "protect people and the environment from significant health risks … and enforce environmental regulations". PFAS or "forever chemicals" within our nations drinking water is well within the agency's authority to take measures to protect public health; moreover, establishing strict PFAS drinking water standards really should be considered the bare minimum of actions to be taken by the EPA.

PFASs are considered "forever chemicals" because it could take thousands of years to breakdown in the environment and, most importantly the chemicals can buildup and remain in the human body potential causing significant health issues. While there is still much more researched to be done to fully understand the adverse effects of PFAS, epidemiological studies have linked PFAS exposure to many adverse effects such as the following: immune and thyroid function, liver disease, lipid and insulin dysregulation, kidney disease, conception, pregnancy and infant development, and cancer. PFASs have been detected in the environment (e.g., groundwater, drinking water, air, and soil). In addition, these chemicals are prevalent in the manufacturing and distribution processes of our food, clothing, and other commercial uses. Given the enormous possibilities for people to be exposed to PFAS, it is prudent for the EPA to act with a sense of urgency in protecting people from these contaminants where possible.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document. There can be many different contamination sources affecting drinking water; this rule is designed to ensure drinking water quality regardless of the source. Use of PFAS in commercial products is beyond the scope of this current rulemaking.

Kristina Winter (Doc. #1559, SBC-042542)

Due to widespread use of PFAS chemicals in numerous products and industries, PFAS chemicals have become ubiquitous in the environment, including our soil, air, and drinking water. Testing has revealed PFAS in water sources in communities across our nation.

Studies show that human exposure to PFAS is widespread and that nearly all people in the United States have some PFAS compounds in their blood. Exposure to PFAS can lead to higher rates of kidney and testicular cancer, higher cholesterol levels, thyroid problems, adverse developmental effects and decreased immune response in children, and other adverse health impacts.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document.

Endocrine Society (Doc. #1579, SBC-042426)

The Endocrine Society enthusiastically supports the proposed National Primary Drinking Water Regulation for PFAS, with modifications as described above. This regulation is consistent with the accumulating evidence demonstrating that these chemicals act as endocrine disruptors, can accumulate in the environment and in the human body, and can result in adverse health effects in humans and wildlife. However, we note that there are thousands of other chemicals with similar structure, and presumably the same function, that will remain unregulated.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document.

Association of State and Territorial Solid Waste Management Officials (ASTSWMO) (Doc. #1583, SBC-042402)

Overall, as movement is made toward better regulation and oversight of these contaminants, ASTSWMO's membership recognizes a corresponding need for research, communication, and improved understanding within the following areas:

• development of human health and ecological toxicity values for PFAS;

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document.

Center for American Progress (CAP) (Doc. #1586, SBC-042385)

After nearly 70 years of widespread use in manufacturing, PFAS can be found virtually everywhere in our environment. They enter our water supply through industrial sites, fire response training sites, landfills, and wastewater treatment centers,[FN1: California State Water Resources Control Board, Division of Water Quality, "PFAS – Frequently Asked Questions" (Sacramento, CA: 2020), available at https://www.waterboards.ca.gov/pfas/docs/master_pfas_faq_mar.pdf] and are extremely resistant to breakdown and can stay in the environment for centuries. Humans are frequently exposed to these chemicals by drinking contaminated water directly, eating food—particularly fish—contaminated by PFAS, or breathing contaminated air. It is no surprise that 97 percent of Americans have at least some forever chemicals in their blood,[FN2: Ryan C. Lewis and others, "Serum Biomarkers of Exposure to Perfluoroalkyl Substances in Relation to Serum Testosterone and Measures of Thyroid Function among Adults and Adolescents from NHANES 2011–2012," International Journal of Environmental Research and Public Health 12 (6) (2015): 6098 – 6114, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4483690/], and depending on the level of exposure, the presence of these chemicals in humans can be very dangerous.

More research into the dangers of forever chemicals on human health is needed, but the existing science is clear: exposure to PFAS negatively impacts the human immune system, heart health, reproductive system, and childhood development, and it is associated with an increased risk of cancer. Studies have linked exposure to PFAS with decreased antibody response to disease in both adults and children, high cholesterol in adults and children, decreased fetal and infant growth, and increased risk of cancer in adults [FN3: National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Division on Earth and Life Studies; Board on Population Health and Public Health Practice; Board on Environmental Studies and Toxicology; Committee on the Guidance on PFAS Testing and Health Outcomes, "Guidance on PFAS Exposure, Testing, and Clinical Follow-Up"(Washington, DC: 2022) available at https://www.ncbi.nlm.nih.gov/books/ NBK584690/]. Evidence also suggests PFAS can be linked to an increased risk of breast cancer, testicular cancer, thyroid disease and dysfunction, inflammatory bowel disease, and pregnancy-induced high blood pressure [FN4: Ibid].

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document.

Mass Comment Campaign sponsored by Slingshot. (email) (Doc. #1682, SBC-045715)

As you are aware, exposure to PFAS can cause serious health effects, such as increased cholesterol levels, reduced immune system function, thyroid disease, liver damage and some forms of cancer. Chemical companies have continued to manufacture PFAS despite knowing for decades that they are unsafe, poisoning communities along the way. A 2018 study by the CDC showed that nearly all Americans have detectable levels of PFAS in their blood.

The EPA's proposed rule reflects what communities across the country already know to be true: There is no safe level of PFAS in our water. For too many Americans, especially those of us who live every day in the shadow of environmental pollution, including PFAS contamination. Enough is enough!

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document.

Public Employees for Environmental Responsibility (PEER) (Doc. #1683, SBC-044968)

Background. The adverse health impacts associated with ingesting PFAS are numerous and well-known. The proposed rule's Executive Summary states:

Current scientific evidence indicates that consuming water containing the PFAS covered in this proposed regulation above certain levels can result in harmful health effects. Depending on the individual PFAS, health effects can include negative impacts on fetal growth after exposure during pregnancy, on other aspects of development, reproduction, liver, thyroid, immune

function, and/or the nervous system; and increased risk of cardiovascular and/or certain types of cancers, and other health impacts…

Indeed, the preamble to the proposed rule states that, "EPA has determined that PFOA and PFOS are likely to cause cancer (e.g., kidney and liver cancer) and that there is no dose below which either chemical is considered safe" (emphasis added). PEER agrees that the adverse health impacts associated with these – and other – PFAS warrant strict regulation.

EPA has been attempting to grapple with certain PFAS contamination for decades. After a voluntary stewardship agreement with eight major PFAS manufacturers in 2006, [FN1: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/fact-sheet-20102015-pfoa-stewardshipprogram] EPA erroneously stated that it "believes all uses of PFOA and its salts were phased out by December 31, 2013." [FN2: Fed. Reg. at 2887] Because PFOA is still being manufactured in the United States, not to mention imported, nearly all Americans have PFOA in their blood. [FN3: https://www.health.ny.gov/environmental/investigations/hoosick/docs/pfoa_blood_sampling_q_and_a_6_7_17.pdf] Despite the ubiquity of PFAS in our environment and our bodies, and the adverse health impacts from these chemicals, this is the first time EPA is attempting to regulate certain PFAS in our drinking water.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document. The EPA notes that the text quoted by the commenter on PFOA and its salts is not a part of this PFAS NPDWR.

Wisconsin Department of Justice et al. (Doc. #1687, SBC-044441)

Background

PFAS are a class of synthetic chemicals that have been used in the United States since the 1940s and are still found in many common products. These chemicals have been widely used because they are resistant to water, heat, and stains. PFAS are highly stable and resistant to degradation—which is why PFAS are known as "forever chemicals." They have been used to produce countless consumer products, including textiles (like waterproof clothing, car seats, strollers, and stain repellent furnishings), non-stick cookware, and food packaging. Firefighting foam containing PFAS [FN5:Aqueous film-forming foam, or AFFF, has been in use since its development in the 1960s.] has also been used for decades by the United States military, airports, industrial facilities, and local fire departments. PFAS are detectable in the blood of most people in the United States. [FN6: Agency for Toxic Substances and Disease Registry, PFAS in the U.S. Population, https://www.atsdr.cdc.gov/pfas/health-effects/us-population.html.] Because of their widespread and long-term use and method of production, PFAS are typically found in mixtures in the environment.

Our states face substantial threats to public health and the environment from PFAS. Many states, including many of the undersigned, have repeatedly urged both Congress and EPA to take prompt and aggressive actions to respond to the unfolding national PFAS crisis. [FN7: See, e.g., Multistate Comments dated April 13, 2022 regarding EPA's Fiscal Year 2022 Spend Plan for PFAS, https://www.michigan.gov/ag/-/media/Project/Websites/AG/releases/2022/April/State_Comments_on_EPAs_PFAS_Spend_Plan_FINAL_751106_7.pdf?rev=761235fc045d4b9c995b1a4427a2ad3c&hash=DB08B30565068BCA058CB3E5C331694C; Multistate Comments dated September 27, 2021 regarding EPA's Proposed TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, 86 Fed. Reg. 33926 (June 28, 2021), https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0549-0086; Multistate Comments dated September 17, 2021 regarding EPA's Drinking Water Contaminant Candidate List 5 Draft, 86 Fed. Reg. 37948 (July 19, 2021), https://www.regulations.gov/comment/EPA-HQ-OW-2018-0594-0076; Multistate Comments dated May 10, 2021 regarding EPA's proposal to expand monitoring for PFAS under the UCMR5 (May 10, 2021), https://coag.gov/app/uploads/2021/05/510.21_PFAS_Comments.pdf; Multistate Letter to Congress dated July 16, 2021 regarding Support for 2021 PFAS Action Act, https://content.govdelivery.com/attachments/WIGOV/2021/07/23/file_attachments/1886815/Multi-State%20PFAS%20Letter%20071621.pdf; Multistate Comments dated June 10, 2020 regarding EPA's Preliminary Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List, 85 Fed. Reg. 14098, 14120 (Mar. 10, 2020), https://www.regulations.gov/comment/EPA-HQ-OW-2019-0583-0258; Multistate Comments dated April 17, 2020 regarding EPA's Supplemental Proposed Rule on Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule, 85 Fed. Reg. 12479 (March 3, 2020), https://www.regulations.gov/comment/EPA-HQ-OPPT-2013-0225-0217; Multistate Comments dated February 3, 2020 regarding Addition of Certain PFAS; Community right to Know Toxic chemical Release Reporting, 84 Fed. Reg. 66369 (Dec. 4, 2019), https://www.regulations.gov/comment/EPA-HQ-TRI-2019-0375-0086; Multistate Comments to Congress dated July 30, 2019 regarding need for comprehensive PFAS Legislation, https://oag.ca.gov/system/files/attachments/pressdocs/Multistate%20PFAS%20Legislative%20Letter_7.30.19_FINAL.pdf.] The science demonstrates that these chemicals are highly toxic to humans and animals, with even miniscule exposures over time associated with significant and diverse adverse human health effects. [FN8: See Pelch KE, Reade A, Kwiatkowski CF, Wolffe T, Merced-Nieves FM, Cavalier H, Schultz K, Rose K, Varshavsky J. 2021. PFAS-Tox Database, https://pfastoxdatabase.org/.] Moreover, PFAS in mixtures can have a dose-additive effect, which makes it critical to regulate combinations of PFAS in addition to individual chemicals, the approach the agency is pursuing in this rulemaking. [FN9: See e.g., Goodrum et al., Application of a Framework for Grouping and Mixtures Toxicity Assessment of PFAS: A Closer Examination of Dose-Additivity Approaches, Tox. Sciences (2021), https://doi.org/10.1093/toxsci/kfaa123.]

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document. The EPA is accounting for mixtures in the Hazard Index approach adopted under this rule. For more discussion on the Hazard Index approach, please see section 4.3.1 of this *Response to Comments* document.

Three Rivers Waterkeeper (3RWK) (Doc. #1689, SBC-044972)

I. PFAS are both dangerous and widespread.

Despite some remaining scientific uncertainty as to the precise medical effects of all PFAS on the human body, the most-studied PFAS are both widespread and associated with serious adverse health effects. [FN1: What Are the Health Effects of PFAS?, Agency for Toxic Substances and Disease Registry, https://www.atsdr.cdc.gov/pfas/health-effects/index.html (Last Accessed May 30, 2023).] Despite this dangerous combination of prevalence and toxicity, a 2021 analysis by the Environmental Working Group found nearly 30,000 new industrial sites known or suspected to be releasing PFAS into the environment, a twelve-fold increase from previous estimates. [FN2: Monica Amarelo, Twelvefold Increase in Suspected Industrial Dischargers of Forever Chemicals, Environmental Working Group, July 14, 2021, https://www.ewg.org/news-insights/news-release/2021/07/twelvefold-increase-suspected-industrial-dischargers-forever.] PFAS accumulate in people, in wildlife, and in waterways. They can be found at dangerous levels in rainwater around the world, on all seven continents. [FN3: Rainwater Unsafe to Drink Due to Chemicals: Study, phys.org, Aug. 10, 2022, https://phys.org/news/2022-08-rainwater-unsafe-due-chemicals.html.] An extensive Waterkeeper Alliance study found that 83% of the waters tested in the U.S. are contaminated with PFAS, but the full extent of PFAS contamination remains unknown. [FN4: Invisible Unbreakable Unnatural, Waterkeeper Alliance, https://waterkeeper.org/pfas/ (Last Accessed May 30, 2023).] Experts estimate that over 200 million Americans are exposed to PFAS through drinking water. [FN5: Id.] Even though we continuously learn more about the adverse health effects associated with PFAS, these chemicals continue to be widely used in both consumer products and industrial processes. [FN6: Id.]

The peer-reviewed studies used by the EPA suggest a wide range of potential health effects including:

● Reproductive effects such as decreased fertility or increased high blood pressure in pregnant women.

● Developmental effects or delays in children, including low birth weight, accelerated puberty, bone variations, or behavioral changes.

● Increased risk of some cancers, including prostate, kidney, and testicular cancers.

● Reduced ability of the body's immune system to fight infections, including reduced vaccine response.

● Interference with the body's natural hormones.

● Increased cholesterol levels and/or risk of obesity. [FN7: Our Current Understanding of the Human Health and Environmental Risks of PFAS, United States Environmental Protection Agency, March 16, 2023, https://www.epa.gov/pfas/our-current-understanding-human-health-and-environmental-risks-pfas.]

Their unique properties make them toxic even in small doses, which build up over time in the body and in the environment. Furthermore, these harmful effects are not distributed equally among the population. [FN8: Jahred M. Little, Laurel A. Schaider, and Elsie M. Sunderland, Sociodemographic Factors Are Associated with the Abundance of PFAS Sources and Detection in U.S. Community Water Systems, 57 Environmental Science and Technology 7902, 7909, May 15, 2023, https://pubs.acs.org/doi/10.1021/acs.est.2c07255.] Recent studies show disparities in PFAS exposure, with communities marginalized along racial and economic lines being more likely to have elevated PFAS concentrations in their drinking water sources. [FN9: Id.] Systemic socioeconomic factors can expose members of disadvantaged communities to PFAS and other toxins by pushing them into working hazardous jobs, or living downstream of hazardous runoff. This is a serious environmental justice issue, but at the same time, PFAS are so widespread that a 2015 report by the Centers for Disease Control "found PFAS in the blood of 97% of Americans." [FN10: Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS), National Institute of Environmental Health Science, March 9, 2023, https://www.niehs.nih.gov/health/topics/agents/pfc/index.cfm#footnote1.] They have been found in Antarctica [FN11: Green Science Policy Institute, It's Raining PFAS: Even in Antarctica and on the Tibetan Plateau, Rainwater is Unsafe to Drink, phys.org, Aug. 2, 2022, https://phys.org/news/2022-08-pfas-antarctica-tibetan-plateau-rainwater.html.] and in mothers' breast milk. [FN 12: Guomao Zheng et al., Per- and Polyfluoroalkyl Substances (PFAS) in Breast Milk: Concerning Trends for Current-Use PFAS, 55 Environmental Science and Technology 7510, 7513-17, May 13, 2021, https://pubmed.ncbi.nlm.nih.gov/33982557/.] PFAS are as inescapable as they are dangerous.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document. See section 14 of the EPA response in this *Response to Comments* document for discussion of EJ considerations.

Protecting Our Water, Environment, and Ratepayers (POWER) (Doc. #1714, SBC-045928)

I. INTRODUCTION

EPA has proposed a NPDWR for six PFAS chains: perfluorooctanoic acid ("PFOA"), perfluorooctanoic sulfonic acid ("PFOS"), perfluorohexane sulfonic acid ("PFHxS"), hexafluoropropylene oxide dimer acid ("HFPO-DA" commonly known as "GenX"), perfluorononanoic acid ("PFNA"), and perfluorobutane sulfonic acid ("PFBS"). Specifically, EPA seeks to set maximum containment level goals ("MCLG") and maximum containment

levels ("MCL") for the six proposed PFAS chains. EPA proposes MCLGs for PFOA and PFOS at zero and MCLs for PFOA and PFOS at four (4) parts per trillion (ppt). For the four additional chains, EPA is proposing, for the first time under the Safe Drinking Water Act, a hazard index ("HI") approach for both the MCLG and MCL, which would be exceeded with individual concentrations of GenX at 10 ppt, PFBS at 2000 ppt, PFNA at 10 ppt, and PFHxS at 9 ppt, or would be exceeded at far lower levels if multiple of these PFAS substances are present.

These substances are introduced into the water systems nationwide primarily through manufacturing and use of consumer products. Today, PFAS, including the six proposed chains, are found or used in many consumer products such as carpets, clothing, fabrics, cookware, firefighting foam, and many other products and textiles. These chains enter the environment, including drinking water systems, through the manufacturing plants, every home and business, and any place PFAS-containing firefighting foam is or has been used. POWER! believes it is important to move aggressively to stop the introduction of additional PFAS chains into the stream of commerce and the environment, and to develop cleanup, handling, transportation, disposal and/or destruction standards and technologies for each chain. However, without these standards and technologies in place, this proposed rule, as with other rules recently proposed by EPA [FN1: Environmental Protection Agency, Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances, 87 Fed. Reg. 54415 (proposed Sept. 6, 2022).], will cause many unintended consequences and costs for water and wastewater agencies and the public they serve, as described below.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document. This NPDWR is designed to address drinking water as a specific exposure pathway. Other exposure pathways are addressed by other agency programs based on other statutory authority. Other EPA rules such as the CERCLA designation are discussed in section 10, Treatment, of the EPA response in this *Response to Comments* document.

Coralie Pryde (Doc. #1781, SBC-043814)

Studies by the US Geological Service (USGS) have shown that wells across Delaware are contaminated with levels of PFAS above the 17 ppt level previously suggested by the EPA. There has been no indication that the state intends to address this contamination until mandatory levels are established. This means that a large number of residents are suffering from high blood serum levels of PFAS. This is particularly true in New Castle County, where I live.

A 2022 study shows that residents of New Castle County (NCC) have the highest levels of PFAS in their blood compared to the national average. [FN3: https://www.atsdr.cdc.gov/pfas/docs/PFAS-EA-Final-Report-Community-Summary-H.pdf] The total levels of all PFAS found there exceeded the levels at nine other sites selected for study by

the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) because they were known to have very high levels of contamination.

The extremely high levels of contamination for NCC may partially be the result of measurements on people who were exposed to the very high levels of contaminants found in the city of New Castle and areas near the National Guard air base.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document.

Silent Spring Institute (Doc. #1784, SBC-045797)

Chemicals in the PFAS family are of concern for many health endpoints, including breast development, lactation, and cancer.[REF1: National Academies of Sciences, Engineering, and Medicine. Guidance on PFAS Exposure, Testing, and Clinical Follow-Up. Washington, DC: The National Academies Press; 2022; REF2: Kay JE, Cardona B, Rudel RA, et al. Chemical Effects on Breast Development, Function, and Cancer Risk: Existing Knowledge and New Opportunities. Curr Environ Health Rep. 2022;9(4):535-562.] Silent Spring Institute previously published peer-reviewed studies on PFAS exposures associated with drinking water,[REF3: Schaider LA, Rudel RA, Ackerman JM, Dunagan SC, Brody JG. Pharmaceuticals, perfluorosurfactants, and other organic wastewater compounds in public drinking water wells in a shallow sand and gravel aquifer. Sci Tot Env. 2014;468:384-393; REF4: Hu XC, Andrews D, Lindstrom AB, et al. Detection of poly- and perfluoroalkyl substances (PFASs) in U.S. drinking water linked to industrial sites, military fire training areas and wastewater treatment plants. Environ Sci Technol Lett. 2016;3(10):344-350; REF5: Liddie JM, Schaider LA, Sunderland EM. Sociodemographic factors are associated with the abundance of PFAS sources and detection in U.S. community water systems. Environ Sci Technol. 2023.] food packaging,[REF6: Schaider LA, Balan SA, Blum A, et al. Fluorinated compounds in U.S. fast food packaging. Environ Sci Technol Lett. 2017;4(3):105-111.] diet,[REF7: Susmann HP, Schaider LA, Rodgers KM, Rudel RA. Dietary Habits Related to Food Packaging and Population Exposure to PFASs. Environ Health Perspect. 2019;127(10):107003.] and consumer products.[REF8: Boronow KE, Brody JG, Schaider LA, Peaslee GF, Havas L, Cohn BA. Serum concentrations of PFASs and exposure-related behaviors in African American and non-Hispanic white women. J Expo Sci Environ Epidemiol. 2019;29(2):206-217; REF9: Rodgers KM, Swartz CH, Occhialini J, Bassignani P, McCurdy M, Schaider LA. How Well Do Product Labels Indicate the Presence of PFAS in Consumer Items Used by Children and Adolescents? Environ Sci Technol. 2022;56(10):6294-6304.] Silent Spring scientists are currently leading or contributing to four federally funded research studies on PFAS: 1) the Massachusetts PFAS and Your Health Study, part of the larger CDC/ATSDR Multi-Site Health Study on health effects of PFAS exposures from drinking water, 2) PFAS-REACH, which is assessing the relationship between PFAS and pediatric immunotoxicity, 3) the STEEP Superfund Research Program, led by the University of Rhode Island, which is investigating environmental transport, exposure, and health effects of PFAS, and

4) a study funded by the National Science Foundation to investigate policy responses to PFAS at multiple levels of governance. Silent Spring scientists have also reviewed risk assessments that are a basis for drinking water standards proposed by various US states.[REF10: Cordner A, De La Rosa VY, Schaider LA, Rudel RA, Richter L, Brown B. Guideline levels for PFOA and PFOS in drinking water: the role of scientific uncertainty, risk assessment decisions, and social factors. J Expo Anal Environ Epidemiol. 2019.]

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document. For more information on occurrence, please see section 6 of the EPA response in this *Response to Comments* document.

Ohio Environmental Council (Doc. #1794, SBC-045322)

National standards to limit the concentration of PFAS in drinking water are long overdue. For decades, PFAS have been used in thousands of applications, and a peer-reviewed study estimates that PFAS may be present in the drinking water of more than 200 million Americans. EPA's proposal for six PFAS would set the national standard for PFOA and PFOS at the lowest detection level approved by the agency, and would establish limits on GenX, PFBS, PFNA, and PFHxS using a hazard index. EPA estimates that 94 million Americans currently receive drinking water contaminated by one or more these PFAS chemicals at levels above the limits proposed by EPA. The regulation of PFAS will improve drinking water safety for millions of Americans.

Not only are PFAS widespread in drinking water, these "forever chemicals" persist throughout the environment and pose risks to public health even in trace amounts. They are found in the blood of virtually everyone on Earth, and build up in our organs. Very low doses of PFAS in drinking water have been linked to suppression of the immune system and are associated with an elevated risk of cancers and reproductive and developmental harms, among other serious health concerns.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document. For more information on occurrence, please see section 6 of the EPA response in this *Response to Comments* document.

Safe Drinking Water Branch, Hawaii Department of Hawaii (Doc. #1801, SBC-043757)

The Interim Health Advisory

After the PFAS rule is finalized by the end of 2023, EPA should remove the Interim Health Advisory published in June 2022 to avoid the confusion among the public and make it for the state agency, and water purveyors to communicate with the public.

EPA Response: The SDWA authorizes the EPA to issue HAs for contaminants, even if they are not subject to a NPDWR (42 U.S.C. §300g-1(b)(1)(F)). A HA provides technical information on a contaminant that can cause negative human health effects and is known or anticipated to occur in drinking water (42 U.S.C. §300g-1(b)(1)(F)). HA's are non-enforceable and serve to provide technical information. The EPA issues an interim HA when a contaminant's associated health effects assessment is in draft form, but there is a pressing need to provide information to public health officials prior to finalization of the health effects assessment. That is why the EPA published interim HA's for PFOA and PFOS in June 2022, based on a robust assessment of the best available science at that time. On March 14, 2023, the EPA published a proposed NPDWR for PFOA and PFOS, as well as for four additional PFAS and their mixtures. This rule has considered additional updates to the science and is responsive to peer review feedback provided by the EPA's Science Advisory Board (SAB). In the proposed rule, the EPA presented updated noncancer toxicity values based on evaluating additional scientific information. These updated values are different from those used to calculate the 2022 interim HAs, which the EPA based on the best available science at that time. The EPA solicited public comments on its proposed NPDWR, including on the proposed MCLGs, other supporting information, and the draft 2023 toxicity values for PFOA and PFOS, which are based on the best available science. Note that the MCLGs in the proposed rule were zero. The EPA anticipates developing HAs for additional PFAS as the agency publishes toxicity assessments. The EPA's disposition of its HAs is beyond the scope of this action. The agency is considering options for the 2022 interim HAs for PFOA and PFOS.

Jeanne Forster (Doc. #1865, SBC-045851)

Due to widespread use of PFAS chemicals in numerous products and industries, PFAS chemicals have become ubiquitous in the environment, including our soil, air, and drinking water. Testing has revealed PFAS in water sources in communities across our nation.

Studies show that human exposure to PFAS is widespread and that nearly all people in the United States have some PFAS compounds in their blood. Exposure to PFAS can lead to higher rates of kidney and testicular cancer, higher cholesterol levels, thyroid problems, adverse developmental effects and decreased immune response in children, and other adverse health impacts.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document. For more information on occurrence please see section 6 of the EPA response in this *Response to Comments* document.

K Murphy (Doc. #1866, SBC-045855)

Due to widespread use of PFAS chemicals in numerous products and industries, PFAS chemicals have become ubiquitous in the environment, including our soil, air, and drinking water. Testing has revealed PFAS in water sources in communities across our nation.

Studies show that human exposure to PFAS is widespread and that nearly all people in the United States have some PFAS compounds in their blood. Exposure to PFAS can lead to higher rates of kidney and testicular cancer, higher cholesterol levels, thyroid problems, adverse developmental effects and decreased immune response in children, and other adverse health impacts.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document. For more information on occurrence please see section 6 of the EPA response in this *Response to Comments* document.

Alyssa Rodriguez (Doc. #1956, SBC-046611)

PFAS Regulation Comment:

The Environmental Protection Agency should be supported in their proposal to regulate PFAS nationally in drinking water. As the Environmental Protection Agency clearly outlines, PFAS cause significant health issues in several systems of the body. Maternal and fetal liver dysfunction increased significantly when PFAS were exposed gestationally to mice (Blake et al., 2022). PFAS disrupt many biological pathways and gene expression rates in these mouse trials showing a significant strain on mice ability to function as a whole (Blake et al., 2022). Trials such as these shed light on the hidden dangers that even a mild build up of these chemicals can have on communities throughout the US. Although Every disease is important, it is vital to stress the impact on the future generations especially when genetic damage proven probable. Virtually every way a PFAS can enter the body causes significant damage.

Furthermore, another concern of PFAS is the inherent risks associated with inhalation due to their burning in landfills or the inadequately neutralized PFAS being incinerated. A study done by the National Resource Defence Council reported in 2021 that approximately ninety percent of PFAS were under-reported because they were incinerated (NRDC, 2021). Incineration has not been proven to neutralize PFAS and these now air born PFAS can further spread without documentation. This resistance to being burned is evident by their use in Aqueous film forming foam which can put out fires and so on. Many of these airborne or not quite neutralized PFAS surely do end up in our water systems but the inhalation of these chemicals should also be regulated because inhalation of PFAS can be more readily absorbed by the body. As demonstrated by a research study that coated dust particles with PFAS and then exposed rats to the dust. The study collected several blood samples after PFAS dust exposure and samples of various organ tissues to measure the amount of PFAS on the rats compared to oral ingestion. The

researchers found that, "The Cmax following inhalation was four times higher compared to oral exposures. At 48 h post exposure, the levels of PFOA in the plasma, liver, and kidney were twice as high from inhalation exposures. This shows that PFOA is readily bioavailable and has a rapid systemic distribution following an inhalation or oral exposure to house dust coated with PFOA" (Gustasson et al., 2022). This demonstrates the necessity to not only combat PFAS in the ground water but add additional regulations on inefficient disposal methods as they may cause more harm than good such as incineration.

Although this argument is centered on a deontological sense of ethics focusing on our obligation to perform a task for the greater good, it is important to note that this PFAS cleansing does come at a cost. At least part of that cost should be contributed from the companies that produce them. An environmental safety tax could at the very least aid in the financial burden on states' financial needs to meet the proposed expectation of PFAS in their drinking water and may discourage the production of PFAS like material.

References

Blake, B., Miller, C., Nguyen, H., Chappell, V., Phan, T., Phadke, D., Balik-Meisner, M., Mav, D., Shah, R., & Fenton, S. (2022). Transcriptional pathways linked to fetal and maternal hepatic dysfunction caused by gestational exposure to perfluorooctanoic acid (PFOA) or hexafluoropropylene oxide-dimer acid (HFPO-DA or GenX) in CD-1 mice. Elsevier Inc. https://eds-s-ebscohost-com.dml.regis.edu/eds/detail/detail?vid=12&sid=5ecf8ae0-fd91-4773-b5e0-dd9c88a5b3ce%40redis&bdata=JnNpdGU9ZWRzLWxpdmUmc2NvcGU9c2l0ZQ%3d%3d#AN=S014765132201154X&db=edselp

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NRDC. (2021, October 22). New EPA PFAS Data Misleading: Huge Amounts of PFAS Chemicals Underreported, Burned. NRDC. Retrieved April 9, 2023, from https://www.nrdc.org/press-releases/new-epa-pfas-data-misleading-huge-amounts-pfas-chemicals-underreported-burned

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document. See section 10 of the EPA response in this *Response to Comments* document for discussion of some other EPA actions such as the CERCLA designations of PFOA and PFOS. An environmental safety tax is beyond the scope of this rule making action.

Kelly Casey (Doc. #2572, SBC-046658)

Dear Administrator Regan-

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects. The EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. The EPA should address the whole class of PFAS chemicals wherever possible.

I am also a citizen of the State of MN, and by now I am sure you are aware of the recent bill passed here banning PFAs. This bill is named Amara's Law, after my friend Amara Strande. Amara was just 2 days shy of her 21st birthday when she died from Fibrolamellar Hepatocellular Carcinoma. This complicated liver cancer is linked to the kind of toxic chemicals found in 3M's illegal dumping of PFAs in the neighborhood near her high school, Tartan High School in Oakdale, MN. That school has a disproportionate history of students and families with cancers, genetic abnormalities, and other illnesses associated with PFA exposure. Amara mustered all the strength she could in her final days to testify before both the MN House and Senate about the need to remove and ban these hazardous substances.

Amara was a gifted actor, musician, and composer. She formed the Teen Cancer Alliance for kids with cancer as part of her Gold Award in the Girl Scouts. She was a fierce fighter for the underdog, whether that be the planet, its animals, or its people. She had a low threshold for injustice.

Amara's mother, The Rev. Dana Fath Strande, is my parish priest. Dana, her husband Michael, and Nora, Amara's younger sister, continue their passionate work in Amara's memory to make the companies who invent and use PFAs and PFOs pay for the clean-up and the medical costs associated with these rare skin, blood, and other cancers and genetic anomalies. No one should go through what my beloved friends have. Please do not bend to industry and business when it comes to our safety. There must be consequences for those who flush the toilet upstream without caring for the effects of their actions downstream. 3M and others have destroyed the public trust. Please restore that public trust by holding these criminals and tycoons accountable.

All parts of the EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail the use of PFAS chemicals. Placing the burden on our communities, our drinking water and our health is not the right way to solve the PFAS challenge.

Thank you.

EPA Response: Please see section 2.2 of the EPA response in this *Response to Comments* document. For more information on health effects, see also section 4 of the EPA response in this *Response to Comments* document.

2.3 Statutory Framework and PFAS Regulatory History

Summary of Major Public Comments and EPA Responses

Some commenters stated that 60 days was not a long enough comment period and requested more time. The EPA is following the process outlined in the SDWA and regulating PFAS in drinking water is a significant step toward protecting the health of hundreds of millions of people. Moreover, the EPA anticipates that over many years this action will save thousands of lives and prevent tens of thousands of serious illnesses that would otherwise result from long-term exposure to PFAS. Therefore, it is an EPA priority that the agency finalize this regulation expeditiously to reduce PFAS exposure in communities across the country.

The EPA announced the proposed PFAS NPDWR on March 14, 2023. To provide the public with additional time to review and prepare comments on the proposed rule and key supporting documents, the agency simultaneously made publicly available a pre-publication version of the proposed rule Federal Register Notice (FRN) (USEPA, 2023a), as well as several of the significant underlying technical supporting documents, including the *Economic Analysis* (USEPA, 2023b) and Appendices (USEPA, 2023c)*, Toxicity Assessment and Proposed Maximum Contaminant Level Goal (MCLG) for PFOA* (USEPA, 2023d) and Appendix (USEPA, 2023e), *Toxicity Assessment and Proposed MCLG for PFOS* (USEPA, 2023f) and Appendix (USEPA, 2023g), *Framework for Estimating Noncancer Health Risks Associated with Mixtures of PFAS* (USEPA, 2023h), *MCLG Summary Document for a Mixture of Four PFAS* (USEPA, 2023i), and the *EPA's Response to Science Advisory Board Recommendations on Draft Documents for the Proposed PFAS NPDWR* (USEPA, 2023j). Subsequently, the proposed rule was published in the FR on March 29, 2023, officially initiating the public comment period. That period concluded on May 30th, 62 days later. Considering the agency's pre-publication announcement of the proposed rule, commenters had access to the proposed-rule text and these key supporting documents for a total of 77 days. During the proposed rule development period that occurred before the pre-publication announcement of the proposed rule, the EPA sought to actively involve stakeholders and members of the public in the rulemaking process, seek their input, and provide information through various consultations and engagements. The EPA greatly appreciates the feedback and information shared during this time, which meaningfully informed the proposed rule. Following the proposed-rule announcement, the EPA also offered opportunities for the public to learn more about the proposal, including through two public webinars that the EPA hosted on March 16, 2023, and March 29, 2023 for both general public and technical stakeholders. These webinars, as well as other supporting materials, were made available on the EPA's PFAS NPDWR website as a resource (https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas). Additionally, the EPA held a public hearing for the proposed NPDWR on May 4, 2023, where members of the public had the opportunity to share their comments with the EPA on the proposed rule. The EPA deeply values public input on its proposed rules. Based on the opportunities outlined presented above, the public comment period time provided for this particular action is reasonable, while also allowing the EPA to fulfill its

mission of protecting people and the environment from exposure to negative PFAS health effects as quickly as possible.

Some commenters suggested that there should be universal PFAS restrictions (i.e., regulations for all PFAS in all media). The SDWA regulates contaminants that meet specific regulatory criteria as outlined in section 3. For example, 42 U.S.C. § 300g–1 (b)(1)(A)(ii) includes the requirement that there is a substantial likelihood that contamination will occur in PWSs at a level of public health concern and 42 U.S.C. § 300g–1 (b)(1)(A)(i) requires an adverse effect on the health of persons. PFAS is a term encompassing a diverse group of substances. The Organization of Economically Developed Countries , the USEPA, the WHO, and the research community have all used various definitions as there is no singular consensus on exactly what constitutes PFAS. The definition changes depending on the entity or regulatory body, scope, and application of the definition. An early definition was put forth by Robert Buck in a paper titled "Perfluoroalkyl and polyfluoroalkyl substances in the environment: Terminology, classification, and origins," which defined PFAS as "highly fluorinated aliphatic substances that contain 1 or more C atoms on which all the H substituents (present in the nonfluorinated analogues from which they are notionally derived) have been replaced by F atoms, in such a manner that they contain the perfluoroalkyl moiety C_nF_{2n+1}–." To address gaps in that definition, a more recent definition was put forth by the OECD in a paper titled "Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance," which defined PFAS as "fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), i.e. with a few noted exceptions, any chemical with at least a perfluorinated methyl group (–CF_3) or a perfluorinated methylene group (–CF_2–) is a PFAS." For the purposes of CCL5, the EPA defined PFAS to include chemicals that contain at least one of these three structures: 1) R-(CF2)-CF(R′)R″, where both the CF2 and CF moieties are saturated carbons, and none of the R groups can be hydrogen, 2) R-CF2OCF2-R′, where both the CF2 moieties are saturated carbons, and none of the R groups can be hydrogen, or 3) CF3C(CF3)RR′, where all the carbons are saturated, and none of the R groups can be hydrogen. As stated, PFAS is a very broad chemical class. For example, under this definition, Fluoxetine, sold under various the brand names including Prozac, is a PFAS as well as many propellants used in inhalers and most anesthetic gases such as enflurane, isoflurane, desflurane, sevoflurane, and methoxyflurane. Other PFAS uses that may be considered critical are in labs, for example, in high performance liquid chromatography, safety/protective clothing, or other areas where high performance is necessary and limited by technology, such as by the National Aeronautics and Space Administration (NASA). For more information on why certain PFAS were selected for this rule, please see sections 3.1 and 2.2 of the EPA response in this *Response to Comments* document.

As described in the EPA's PFAS Strategic Roadmap, the agency is committed to addressing PFAS contamination, including through the development of this PFAS NPDWR. The latter is a key action within this whole-of-agency approach (please see https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024 and section 15 of the EPA response in this *Response to Comments* document for discussion on the PFAS Roadmap). The EPA's

approach considers the full PFAS lifecycle, and is based on getting upstream of the problem, holding polluters accountable, ensuring science-based decision making, and prioritizing disadvantaged communities. Specifically, the Roadmap sets timelines by which the EPA plans to take specific actions and commits to new policies to safeguard public health, protect the environment, and hold polluters accountable. The actions described in the PFAS Strategic Roadmap each represent important and meaningful steps to safeguard communities from PFAS contamination. Cumulatively, these actions should lead to more enduring and protective solutions. In the Roadmap, the EPA notes that the agency "will bring deeper focus to preventing PFAS from entering the environment in the first place—a foundational step to reducing the exposure and potential risks of future PFAS contamination." Additionally, in the Roadmap, the EPA notes that "intervening at the beginning of the PFAS lifecycle—before they have entered the environment—is a foundational element of the EPA's whole-of-agency approach." PFAS manufacturing has been addressed via several significant new use rules and the New Chemicals Program continues to review new PFAS before approving commercialization. Other EPA rules such as the CERCLA designation are discussed in section 10, Treatment, in this *Response to Comments* document. The ORD as well as the OST are evaluating and developing technologies for reducing PFAS in the environment to inform decisions on health effects, drinking water and wastewater treatment, contaminated site cleanup and remediation, air emission controls, and end-of-life materials management.

Additionally, the agency considers whether PFAS uses may be beneficial enough in specific applications to warrant use. As stated in section 2.2 of the EPA response in this *Response to Comments* document, there is also no uniform agreed upon definition of PFAS and most definitions are written for specific purposes; as a result, there can be no perfect test method for PFAS as there is no fixed definition of what constitutes PFAS. This problem can compound if exemptions are made for beneficial uses. Additionally, current proxy methods such as a total organic fluorine test lack the analytical sensitivity to measure low enough concentrations to protect human health as these methods can reliably measure to approximately 100 ng/L and the health-based water concentrations for all but one of the PFAS species included in this rule are an order of magnitude below that. A total organic fluorine test also does not provide information on the specific constituents, so a 200 ng/L reading could either be very harmful to human health if it was composed of PFOS, for example, but would not necessarily be harmful if it was PFBS, for example. There may also be fluorinated chemicals that are not PFAS that this kind of test may measure. Imposing a rule without a mechanism to enforce or monitor it will very likely not make a very effective rule.

Some commenters stated that the EPA was not working quickly enough or encouraged the EPA to work more quickly. EPA is working as quickly as feasible while maintaining statutory requirements, high quality analysis, and best available science. This rule is a key EPA priority under the *PFAS Strategic Roadmap* and the *PFAS Action Plan*. More information on the SDWA rulemaking process including timelines can be found in section 1.1, the SDWA Rulemaking Process, in this *Response to Comments* document. Some commenters also stated that the EPA must move faster because their primacy agency is not moving quickly enough. The EPA creates

a baseline that others may build on. Primacy agencies are welcome to enact rules according to their authorities on their own timeline and are not precluded from enacting stricter or quicker rules than the EPA.

Individual Public Comments

Emma Jenevein (Doc. #1514, SBC-042705)

April 20, 2023

Submitted via Regulations.gov

Michael Regan, Administrator

U.S. Environmental Protection Agency

1200 Pennsylvania Ave. NW

Washington, D.C. 20460-0001

RE: Docket ID No. EPA-HQ-OW-2022-0114, Environmental Justice Considerations for the Development of the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation (NPDWR)

Dear Administrator Regan,

Thank you for the opportunity to comment on the proposed National Primary Drinking Water Regulation (NPDWR). I am a resident of Dallas, Texas, as well as a student at SMU Dedman School of Law studying environmental law.

I would like to provide further support for concerns raised regarding EPA's proposed National Primary Drinking Water Regulation (NPDWR):

1. EPA should expand the definition of PFAS to cover the entire class of PFAS chemicals as regulation of individual fluorinated compounds is insufficient to protect public health.

EPA Response: Please see section 2.3 of the EPA response in this *Response to Comments* document, the SDWA regulates contaminants that meet specific regulatory criteria using the best available science as outlined in section 3 of the EPA response in this *Response to Comments* document. At this time, lacking a clear PFAS definition, it does not make sense to regulate all PFAS, as explained in the preambles to the proposed and final rule and elsewhere in these responses to comments. While some PFAS classes may warrant regulation in the future, at the present time this is not supported through the best available science and the SDWA regulatory process.

Emma Jenevein (Doc. #1514, SBC-042707)

In summary, I urge EPA to promptly finalize this proposal and establish a National Primary Drinking Water Regulation (NPDWR) that will require monitoring for the entire class of PFAS in public water systems and provide mechanisms to address exceedances that threaten public health. Please see below for additional details and pertinent literature.

Sincerely,

Emma C. Jenevein

EPA should expand the definition of PFAS to cover the entire class of PFAS chemicals

Per- and Polyfluoroalkyl Substances ("PFAS") are a class of synthetic chemicals characterized by chains of linked carbon and fluorine atoms; these carbon-fluorine bonds are among the strongest chemical bonds, as a result PFAS do not degrade easily in the environment. [FN1: NAT'L INST. OF ENV'T HEALTH SCI., PERFLUOROALKYL AND POLYFLUOROALKYL SUBSTANCES (PFAS) (March 09, 2023), https://www.niehs.nih.gov/health/topics/agents/pfc/index.cfm#footnote.] PFAS, sometimes referred to as "forever chemicals," can last eight years in the human body, leading to bioaccumulation; the most studied chemicals, PFOA and PFOS, will not naturally degrade in the environment. [FN2: Tom Johnson, Breaking down the Forever Chemicals –What are PFAS?, CLEAN WATER ACTION (Aug. 2, 2018), https://cleanwater.org/2018/08/02/breaking-down-forever-chemicals-what-are-pfas#:~:text=Some%20PFAS%20can%20last%208,naturally%20degrade%20in%20the%20environment.] Further, PFAS have been used in consumer products around the world since about the 1950s and overtime have leaked into the soil, water, and air. [FN3: NAT'L INST. OF ENV'T HEALTH SCI., PERFLUOROALKYL AND POLYFLUOROALKYL SUBSTANCES (PFAS) (March 09, 2023), https://www.niehs.nih.gov/health/topics/agents/pfc/index.cfm#footnote.] In 2012, the Centers for Disease Control and Prevention, using data from the National Health and Nutrition Examination Survey ("NHANES"), found PFAS in the blood of 97% of Americans. [FN4: Ryan C. Lewis, Lauren E. Johns, & John D. Meeker, Serum Biomarkers of Exposure to Perfluoroalkyl Substances in Relation to Serum Testosterone and Measures of Thyroid Function among Adults and Adolescents from NHANES 2011–2012, INT'L J. ENV'T RSCH. PUB. HEALTH (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4483690/.] PFAS represent a growing environmental concern because of their widespread presence in the environment and bioaccumulation in humans and other organisms. [FN5: Marco Parolini et al., A review of the bioaccumulation and adverse effects of PFAS in free-living organisms from contaminated sites nearby fluorochemical production plants, WATER EMERGING CONTAMINANTS & NANOPLASTICS (2022), https://www.oaepublish.com/wecn/article/view/5282.] The pervasiveness of PFAS in U.S. public water systems threatens public health [FN6: Xindi C. Hu et al., Detection of poly-and perfluoroalkyl substances (PFASs) in US drinking water linked to industrial sites, military fire training areas, and wastewater treatment plants, ENV'T SCI. & TECH. LETTERS (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5062567/. See also

ENVIRONMENTAL WORKING GROUP, PFAS CONTAMINATION IN THE U.S. INTERACTIVE MAPS (Oct. 4, 2021), https://www.ewg.org/interactive-maps/pfas_contamination/map/.] as this class of chemicals has been linked to many negative health outcomes, including increased cholesterol levels, decreased vaccine response in children, increased risk of high blood pressure or pre-eclampsia in pregnant women, and increased risk of kidney or testicular cancer. [FN7: AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, What are the health effects of PFAS? (Nov. 1, 2022), https://www.atsdr.cdc.gov/pfas/health-effects/index.html] EPA recognizes that PFAS pose significant risks to human health even at extremely low level of exposure. [FN8: U.S. ENV'T PROTECTION AGENCY, Our Current Understanding of the Human Health and Environmental Risks of PFAS (March 16, 2023), https://www.epa.gov/pfas/our-current-understanding-human-health-and-environmental-risks-pfas.] Therefore, the prompt establishment of a National Primary Drinking Water Regulation ("NPDWR") is essential to protect public health.

Nevertheless, due to the persistent, bioaccumulative, toxic, and pervasive nature of these chemicals, EPA should employ class-based approaches to regulate PFAS in the proposed NPDWR. For example, long-chain PFAS, such as perfluorooctane sulfonate (PFOS) and perfluorooctanoate (PFOA), have been demonstrated to pose an intrinsic threat to human and ecosystem health. [FN9: Grace M Wickham & Thomas E Shriver, Emerging contaminants, coerced ignorance and environmental health concerns: the case of per- and polyfluoroalkyl substances (PFAS), SOCIOLOGY OF HEALTH & ILLNESS (Feb. 26, 2021), https://pubmed.ncbi.nlm.nih.gov/33635569/.] As a result the production of long-chain PFAS has been phased out, and companies have shifted their production to short-chain fluorinated alternatives. [FN10: Gerald T. Ankley et al., Assessing the ecological risks of per- and polyfluoroalkyl substances: current state-of-the science and a proposed path forward, ENV'T TOXICOLOGY & CHEMISTRY (Nov. 6, 2020), https://pubmed.ncbi.nlm.nih.gov/32897586/.]

Not only are these short-chain fluorinated replacements and newly identified PFAS considered emerging compounds, whose environmental presence and potential toxicity are largely unknown, but the chemical structures and properties of alternative, short-chain PFAS are commonly treated as confidential information. [FN11: John W. Washington et al., Nontargeted mass-spectral detection of chloroperfluoropolyether carboxylates in New Jersey soils, SCIENCE (June 5, 2020), https://pubmed.ncbi.nlm.nih.gov/32499438/; Wendy E. Wagner & Steve C. Gold, Legal obstacles to toxic chemical research, SCIENCE (Jan. 14, 2022), https://pubmed.ncbi.nlm.nih.gov/35025638/.] Further, short-chain PFAS are also frequently found in drinking water. In 2019, a study conducted by EPA and the US Geological Survey detected short-chain PFAS such as PFBS, PFHxA, PFPeA, PFHpA, and PFBA in 100%, 100%, 96%, 92%, and 88%, respectively, of tap water collected from twenty-five water treatment plants (all located in different states). [FN12: J. Scott Boone et al., Per- and polyfluoroalkyl substances in source and treated drinking waters of the United States, THE SCIENCE OF THE TOTAL ENVIRONMENT (Feb. 25, 2019), https://pubmed.ncbi.nlm.nih.gov/30412881/.] EPA has identified over 12,000 chemical compounds classified as PFAS, [FN13: U.S. ENV'T PROTECTION AGENCY, PFAS MASTER LIST OF PFAS SUBSTANCES (Aug. 11, 2021),

https://comptox.epa.gov/dashboard/chemical-lists/PFASMASTER.] many of which are associated with industrial processes and consumer products. [FN14: Juliane Glüge et al., An overview of the uses of per- and polyfluoroalkyl substances (PFAS), ENVIRONMENTAL SCIENCE—PROCESSES & IMPACTS (Dec. 1, 2020), https://pubmed.ncbi.nlm.nih.gov/33125022/.] Given the size of this chemical family, it is not feasible to conduct human health risk assessments for each individual PFAS compound. Additionally, the persistence of PFAS makes it impossible to study the long-term health impacts of these chemicals, meaning that the health risks of PFAS may be underestimated. [FN15: See Health risks of widely used chemicals may be underestimated, HARVARD SCH. OF PUB. HEALTH, https://www.hsph.harvard.edu/news/hsph-in-the-news/pfas-health-risks-underestimated/.] The persistency of PFAS in the environment coupled with the sheer number of PFAS compounds requires a class-based approach for effective regulation.

EPA Response: Please see section 2.3 of the EPA response in this *Response to Comments* document, the SDWA regulates contaminants that meet specific regulatory criteria using the best available science as outlined in section 3 of the EPA response in this *Response to Comments* document. At this time, lacking a clear PFAS definition, it does not make sense to regulate all PFAS, as explained in the preambles to the proposed and final rule and elsewhere in these responses to comments. While some PFAS classes may warrant regulation in the future, at the present time this is not supported through the best available science and the SDWA regulatory process.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-044903)

Cleveland Water has some concerns with this proposed approach, some of which will be addressed later in these comments, but first and foremost, such a novel approach deserves more thought than a 60-day comment period can convey. Regulating groups or classes of PFAS will set a precedent unlike one seen in the past; therefore, EPA should be consulting with stakeholders on the best way to do so before making Regulatory Determinations and proposing regulations in such a rapid and expedited manner. The SDWA is very clear on not allowing backwards sliding in regulation, so it is paramount that the agency make well-informed decisions that include feedback from stakeholders and use up-to-date data. Additionally, this type of regulations will likely prove difficult for the public to understand. Considerable thought and attention should be given on how this information will be presented and explained in Consumer Confidence Reports.

EPA Response: Please see section 2.3 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045905)

D. To the extent health advisories are retained by EPA, the science is not reliable to support them

EPA has stated "[a]fter EPA has considered public comments and issues a final NPDWR, EPA will decide whether to update or remove the interim health advisories for PFOA and PFOS and the final health advisories for PFBS and HFPO-DA."[FN140: See EPA Technical Overview Webinar Presentation: Proposed PFAS NPDWR, March 29, 2023, at slide 35, available at: https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas.] As described in the comments above, the science in this proposal is so flawed that, if finalized, it should not be used to support even the existing health advisories for PFOA, PFOS, PFBS, and HFPO-DA chemicals. The compromised SAB review process and the short public comment period provided for this rulemaking do not allow for sufficient robust review of the science underlying this proposal.

For the reasons stated above, the information EPA uses to support its proposed MCLs for PFOA and PFOS do not represent the best available science. Therefore, relying on this information to regulate PFOA and PFOS would be contrary to SDWA requirements.

EPA Response: Please see sections 2.2 and 2.3 of the EPA response in this *Response to Comments* document. The EPA followed all requirements set forth in the SDWA using the best available science to fulfill its mission of protecting people and the environment from exposure to negative PFAS health effects as quickly as feasible. The SAB is addressed in section 14.11.1 of the EPA response in this *Response to Comments* document and the regulatory process is addressed in section 1.1 of the EPA response in this *Response to Comments* document. The best available science that underpins the health advisories is discussed further in section 4 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045951)

AMWA has some concerns with the proposed HI approach, some of which will be addressed later in these comments, but such a novel approach warrants longer than a 60-day comment period. Regulating groups or classes of PFAS will set a precedent unlike one seen in the past; therefore, EPA should be consulting with stakeholders on the best way to do so before making Regulatory Determinations and proposing regulations in such a rapid and expedited manner. SDWA is very clear on not allowing backward sliding in regulation, so it is paramount that the agency make well-informed decisions that include feedback from stakeholders and use up-to-date data.

EPA Response: Please see section 2.3 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045567)

As further detailed below, unless the issues outline in this letter are addressed, AWWA is concerned that any final rule would be legally vulnerable for not complying with the SDWA and the Administrative Procedure Act (APA).

EPA Response: In this comment, the American Water Works Association (AWWA) outlined the following issues: implementation challenges posed by the proposed three-year timeline to include training laboratory as well as technical operational capacity, determining if there is a problem, performing pilot testing, securing funding, and building; simultaneous compliance with other rules; and primacy agency capacity then suggested that without extension, the implementation timeline would violate the Administrative Procedure Act (APA) as arbitrary and capricious. The EPA is authorizing a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. More information on compliance with statutory and executive orders is in section 14 of the EPA response in this *Response to Comments* document. Laboratory capacity is addressed in section 7, information on treatment technology availability and capacity is addressed in section 10.6. Information on simultaneous compliance is discussed in section 10.4.2. Please see section 2.3 of the EPA response in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-045698)

X. THE PROPOSED RULE DOES NOT PERMIT MEANINGFUL NOTICE AND COMMENT IN VIOLATION OF THE SDWA AND THE APA

The APA requires notice-and-comment rulemaking for agency rules, 5 U.S.C. [sec] 553(b)(c). This notice-and-comment process is a "crucial" rulemaking requirement to ensure that "regulations are tested via exposure to diverse public comment" and "affected parties [have] an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review." Daimler Trucks N. Am. LLC v. EPA, 737 F.3d 95, 100 (D.C. Cir. 2013); see Miami-Dade Cty. v. EPA, 529 F.3d 1049, 1058 (11th Cir. 2008) (the purposes of notice requirements in notice-and-comment rulemaking under the APA are "(1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review"), quoting Envtl. Integrity Project v. EPA, 425 F.3d 992, 996 (D.C. Cir. 2005).

The D.C. Circuit has explained that an agency must "allow for meaningful commentary" not only as to the requirements that a proposed rule adopts, but also on the "technical basis for a proposed rule." N. Am.'s Bldg. Trades Unions v. OSHA, 878 F.3d 271, 301 (D.C. Cir. 2017); see also Owner-Operator Indep. Drivers Ass'n v. FMCSA, 494 F.3d 188, 199 (D.C. Cir. 2007) (the notice-and-comment requirement applies not only to the text of a rule but also to the "technical basis for a proposed rule" and the "critical factual material that is used to support the agency's position"). And the methods relied on by the agency must be made "available during the rulemaking." Am. Radio Relay League, Inc. v. FCC, 524 F.3d 227, 237 (D.C. Cir. 2008). An agency cannot withhold key elements of its analysis—methods and data—until the final rule, because that defeats the purpose of the notice and comment process.

Unless the agency promulgates a revised proposal in which it fully discloses the data and methods on which it relies, so that interested parties may comment on them, the public will learn of that "uncommented upon data and calculations," Am. Radio Relay League, Inc. v. FCC, 524

F.3d 227, 237 (D.C. Cir. 2008), only when the "final rule reveal[s]" them. CSX Transp. v. STB, 584 F.3d 1076, 1081 (D.C. Cir. 2009). That is not a permissible way to conduct rulemaking governed by the APA.

Here, basic transparency requirements have been blatantly violated, as demonstrated above. See Scientific Integrity Fast-Track Action Committee (2022), which states, "development of Federal regulations follows strict procedures that support transparency, e.g., through issuance of Notices of Proposed Rulemaking that solicit public input and establishment of regulatory dockets containing related information that are open for public inspection. Continued vigilance is necessary to ensure these procedures are followed and that all underlying documentation—including related scientific information—is made publicly available." The Agency's numerous failures to disclose underlying data and methods for its analysis are described throughout these comments.

3M has been prejudiced by the agency's non-disclosure of these key bases for the Proposed Rule. While it comments here on the errors in EPA's analysis, and on the gaps in the data and methods EPA used, what these comments cannot address is the substance of the missing material. See Horsehead Res. Dev. Co. v. Browner, 16 F.3d 1246, 1268 (D.C. Cir. 1994) ("While we have noted that insightful comments may be reflective of notice and may be adduced as evidence of its adequacy, we have rejected bootstrap arguments predicating notice on public comments alone. Ultimately, notice is the agency's duty because comments by members of the public would not in themselves constitute adequate notice. Under the standards of the APA, notice necessarily must come—if at all—from the Agency"). The only way to cure this serious procedural defect is for the agency to issue a new proposed rule in which it discloses all the data and methodology underlying its conclusions, on which interested parties may then comment.

EPA Response: Please see section 2.3 of the EPA response in this *Response to Comments* document. Contrary to commenter's assertion, key elements of the EPA's analysis were made available for a total of 77 days following the rule announcement to include the significant underlying technical supporting documents, including the *Economic Analysis* and Appendices, *Toxicity Assessment and Proposed MCLG for PFOA* and Appendix, *Toxicity Assessment and Proposed MCLG for PFOS* and Appendix, *Framework for Estimating Noncancer Health Risks Associated with Mixtures of PFAS*, *MCLG Summary Document for a Mixture of Four PFAS*, the *EPA's Response to Science Advisory Board Recommendations on Draft Documents for the Proposed PFAS NPDWR*, the *Best Available Technologies and Small System Compliance Technologies for PFAS in Drinking Water document*, the *Technologies and Costs for Removing Per- and Polyfluoroalkyl Substances from Drinking Water document*, and the Drinking Water Treatability Database, as well as a pre-publication version of the rule.

2.4 Bipartisan Infrastructure Law

Summary of Major Public Comments and EPA Responses

Many commenters stated that removing these six PFAS from drinking water will improve American health, particularly among those with special vulnerabilities. The EPA agrees and has described quantified and non-quantified benefits in the health risk reduction and cost analysis discussed in section 13 of the EPA response in this *Response to Comments* document.

Many commenters pointed out that there is a significant expense associated with this rule and expressed concerns that the costs would be borne by ratepayers. The EPA's final rule represents data-driven drinking water standards that are based on the best available science and meet the requirements of SDWA. Regulation of the PFAS covered by this NPDWR is vital toward protecting public health. The agency accounted for costs in its HRRCA and its evaluation of feasibility for the final MCLs. The agency anticipates that significant health benefits (attributable to reduced PFAS exposure) will be realized after the rule is promulgated. Additionally, the agency expects significant co-removal benefits (related to removal of other contaminants while removing PFAS) as a result of implementing the PFAS NPDWR. After considering both the nonquantifiable and quantifiable costs and benefits of the final PFAS NPDWR, the Administrator is re-affirming that the benefits of the MCL justify its costs. For additional information on the EPA's cost and benefit estimates for the final rule, please see section 13.3 and 13.4 of the EPA response in this *Response to Comments* document, respectively.

When establishing the MCLs, the EPA considered costs of treatment technologies that have been demonstrated under field conditions to be effective at removing the regulated PFAS and determined that the costs of complying with the MCLs are reasonable (please see section 5.1.3 for additional discussion on cost considerations when establishing the final MCLs).

The agency notes that funds are also available as a result of P.L. 117-58, the Infrastructure Investment and Jobs Act (IIJA), also referred to as the BIL, to assist many disadvantaged communities, small systems, and others with the costs of installation of treatment. BIL represents the single largest investment in clean and safe water that the federal government has ever made by providing $50 billion to the EPA, approximately $43 billion of which will flow to states, Tribes, and territories (and ultimately utilities and communities) through the Clean Water and Drinking Water State Revolving Funds (CWSRF and DWSRF). There is $4 billion specifically reserved to address PFAS and emerging contaminants and $5 billion in grants for small or disadvantaged communities. The EPA is working to ensure the funds are available to drinking water systems, especially those within disadvantaged communities.

Many commenters stated that the rule would not be affordable for low-income ratepayers. Some commenters expressed particular concern for ratepayers served by small PWSs. Additionally, a few commenters requested that the EPA consider implementation flexibilities for small and rural water systems and suggested that these types of utilities may not have staff capacity nor expertise to compete for funding to implement the rule. The EPA notes that it is authorizing a two-year

capital improvement extension, applicable to all PWSs subject to this rule, pursuant to SDWA 1412(b)(10). While issues surrounding competition for funding were not the basis for the EPA's decision to extend the compliance date, the agency believes that extending the compliance date will also provide ancillary benefits by giving smaller and rural water utilities more time to apply for funding under BIL. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation. See also section 12.1 of the EPA's response in this *Response to Comments* document for discussion on supply chain and labor challenges that may affect the compliance timeline.

Additionally, the EPA has incorporated flexibilities in the final rule that should alleviate some cost concerns (particularly for small systems) related to the monitoring requirements of the rule. In particular, the final rule includes the flexibility to use previously acquired monitoring data to satisfy some or all the initial monitoring requirements. For those groundwater systems serving 10,000 or fewer people that do not have this data, they will be required to only collect two samples at each entry point to the distribution system (EPTDS) to satisfy initial monitoring requirements.

With respect to cost concerns for small systems, the agency anticipates some increased costs to households served by PWSs, including small systems, that install treatment. However, the agency expects the availability of BIL funds to reduce some of these household costs (for more details, please see the EPA's affordability analysis in chapter 9.13, Tables 9-15 and 9-15 of the final Economic Analysis supporting the NPDWR).

The EPA also notes that there are some strategies that utilities may apply to help particular rate payers, such as the following: variable rate structures, which allow free or low-cost essential-use amounts, then scale for extra use; capping bills for low-income residents as a percent of income; discounts to low-income customers; aiding low-income consumers with correcting plumbing leaks as well as other repairs; consumer assistance programs; and grants or subsidies from the State Revolving Funds (SRFs).

The Financial Capability Assessment Guidance, originally designed for the CWA program, may also prove useful to PWSs, and organizations such as the Natural Resources Defense Council and National Consumer Law Center have provided toolkits on affordability and assistance programs, water efficiency and plumbing repair assistance, and equitable water rates as part of water affordability advocacy toolkits (see, for example, the EPA response to comment Doc. #1723, SBC-044469 in section 2.4 in this *Response to Comments* document).

The EPA's affordability analysis and discussion of small-system compliance technology can be found in sections 10.5 and 13 of the EPA response in this *Response to Comments* document.

In summary, the EPA believes that cost challenges, including those associated with small systems and low-income communities, are manageable using the approaches outlined above in this section essay and discussed elsewhere in the record for this rule.

Many commenters requested permission to use IIJA (BIL) funding for operations and maintenance costs (O&M costs). The EPA cannot offer this flexibility since 40 CFR 35.3520(f) explicitly prohibits DWSRF from being used for operation and maintenance expenses. The EPA notes that BIL funds are not meant to fully cover all capital costs associated with implementing the NPDWR and that there are significant quantifiable and non-quantifiable health benefits realized from implementing the rule.

If a water system or particular project cost is not eligible for funding under the DWSRF, it may be eligible under other programs, such as the following: the U.S. Department of Agriculture's Rural Development program; the U.S. Department of Housing and Urban Development's Community Development Block Grant program; the CWSRF; the newly-authorized Water Infrastructure Finance and Innovation Act (WIFIA) funding; or other federal, non-federal or state funding sources.

Initial filters, granular activated carbon, or anion exchange resin used to commission a project or as part of a substantial renovation are eligible for DWSRF money. While ongoing, routine monitoring is an ineligible O&M cost, initial, one-time monitoring associated with newly installed equipment as well as select special-purpose monitoring may be eligible for DWSRF money as set-aside expenses. More information may be found in the *Drinking Water State Revolving Fund Eligibility Handbook*.

Many commenters were concerned that restrictions associated with federal or state funds (e.g., the requirements described in the Build America Buy America Act (BABA)) would drive costs higher. Concurrently with BIL, Congress passed BABA. This domestic-preference program aims to create long-term opportunities for domestic manufacturing and the associated jobs as well as build resilient domestic supply. For SRF recipients, BABA expands existing American Iron and Steel (AIS) requirements that the EPA has implemented since 2014. AIS applies to all SRF projects, while BABA applies only to projects receiving federal dollars. In October 2023, the Office of Management and Budget (OMB) released the final guidance, the 2-CFR-184 and a clarifying memo, M-24-02. The EPA issued implementation guidance for BABA compliance for its federal water infrastructure funding programs. The EPA recognizes this is a new provision, and is working closely with states, Tribes, and territories on technical assistance and training.

The EPA plans to continue to provide detailed information on BABA compliance requirements, flexibilities, and processes; educate funding recipients about their eligibility for waivers; and assist with the waiver process. In accordance with Section 70914(b), there are three kinds of waivers: public interest (where applying the domestic-content procurement preference would be inconsistent with the public interest); non-availability (where materials are not produced in the United States in sufficient and reasonably available quantities or of a satisfactory quality); and unreasonable cost (where BABA requirements will increase overall project cost by more than 25 percent). Not all products are subject to BABA requirements; BABA only applies to items permanently incorporated into an infrastructure project. This means, for example, that temporary equipment and furnishings that are used only during construction or are not incorporated within the finished infrastructure project would be exempt from BABA.

Many commenters stated that PFAS manufacturers and distributors need to be held accountable for the costs of the damage that they have caused (including contamination of drinking water); many commenters recommended outright bans on PFAS as a class. These comments are outside the scope of the current rulemaking, since the SDWA and associated regulations apply to drinking water, and not manufacturing, distribution, and use of chemicals. Related to these concerns, though, see https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024 for discussion of the EPA's *PFAS Strategic Roadmap*. The roadmap describes the EPA's commitment to addressing PFAS contamination using a whole-of-agency approach. As such, the NPDWR must follow the legal requirements of the SDWA and therefore is not the appropriate forum to restrict chemical manufacture. Additionally, it is both the EPA's core mission and its responsibility under the SDWA to ensure that populations served by contaminated drinking water are not exposed to harmful concentrations of PFAS by developing and finalizing this regulation. The SDWA regulates contaminants that meet specific regulatory criteria as outlined in section 3 of the EPA response in this *Response to Comments* document. More information on PFAS as a class is in the summary of major comments for sections 2.2 and 2.3 of the EPA response in this *Response to Comments* document. Through the EPA's *PFAS Strategic Roadmap*, the agency is committed to addressing PFAS contamination, including through the development of the proposed PFAS NPDWR, which is a key action within this whole-of-agency approach (please see section 15 for discussion on the PFAS Roadmap). As outlined in the *PFAS Strategic Roadmap*, the EPA is committed to addressing PFAS, and the NPDWR is one aspect of that plan. The EPA cannot likely solve the problem of "forever chemicals" by tackling one route of exposure or one use at a time and has centered the PFAS approach on considering the full PFAS lifecycle, getting upstream of the problem, holding polluters accountable, ensuring science-based decision making, and prioritizing disadvantaged communities. Key actions for how this will happen can be found at: https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024. Specifically, the Roadmap sets timelines by which the EPA plans to take specific actions and commits to new policies to safeguard public health, protect the environment, and hold polluters accountable. The actions described in the PFAS Strategic Roadmap each represent important and meaningful steps to safeguard communities from PFAS contamination. Cumulatively, these actions should build upon one another and lead to more enduring and protective solutions. In the Roadmap, the EPA notes that the agency "will bring deeper focus to preventing PFAS from entering the environment in the first place—a foundational step to reducing the exposure and potential risks of future PFAS contamination." Additionally, in the Roadmap, the EPA notes that "intervening at the beginning of the PFAS lifecycle—before they have entered the environment—is a foundational element of the EPA's whole-of-agency approach." Manufacture has not continued unabated as several significant new use rules have been enacted on PFAS and the New Chemicals Program continues to review new PFAS before approving commercialization.

With respect to commenter concerns regarding EJ, the agency is committed to ensuring the fair treatment and meaningful involvement of all people with respect to environmental laws,

regulations, and policies. The EPA has conducted an EJ analysis for the final NPDWR, consistent with the EPA's *Technical Guidance for Assessing Environmental Justice in Regulatory Analysis* as well as existing Executive Orders such as EO12898 and EO14096, as described in section 14.10 of the EPA response in this *Response to Comments* document.

Some commenters stated that particular care needed to be taken for disadvantaged communities. A key BIL priority is to ensure that disadvantaged communities benefit equitably from these funds. Additionally, BIL funding prioritizes investment in local communities that are on the frontlines of PFAS contamination and that have few options to finance solutions through traditional programs and help them meet their obligations under this regulation. Disadvantaged communities typically experience, or are at risk of experiencing, disproportionately high exposure to pollution – whether in air, land, or water – and can include those with EJ concerns. The Justice40 initiative aims to ensure that federal agencies deliver at least 40 percent of benefits from certain investments to disadvantaged communities. Additionally, BIL mandates that 49 percent of DWSRF General Supplemental Funding must be provided as grants and forgivable loans to disadvantaged communities. The BIL also requires that not less than 25 percent of funds provided through the DWSRF Emerging Contaminants Funding be provided as grants and forgivable loans to disadvantaged communities or PWSs serving fewer than 25,000 people. For the CWSRF, the BIL mandates that 49 percent of funds provided through the CWSRF General Supplemental Funding must be provided as grants and forgivable loans to municipalities that meet affordability criteria (or municipalities that do not but seek supplemental funding), or entities implementing a process, material, technique, or technology that addresses water or energy efficiency, mitigates runoff, or encourages sustainable project planning, design, and construction.

Additionally, to support BIL implementation, the EPA is offering water technical assistance (WaterTA) to help communities identify water challenges and solutions, build capacity, and develop application materials to access water infrastructure funding (USEPA, 2023k). The EPA anticipates that new and existing EPA WaterTA programs for PWSs, including some aimed at small and/or disadvantaged systems, will be utilized to support effective implementation of the BIL. The EPA anticipates that some of these efforts will focus on identifying and addressing emerging contaminants, including PFAS NPDWR implementation. As stated in the March 2023 memo *Implementation of EPA Water Technical Assistance*, "EPA and technical assistance providers will collaborate to provide direct WaterTA to communities to facilitate access to CWA, SDWA and BIL SRF resources (and other relevant BIL funding opportunities, such as the Emerging Contaminants in Small or Disadvantaged Communities (EC-SDC) grant program), with a focus on disadvantaged and underserved communities, communities that have never accessed SRF funding before, and communities that are not currently receiving an equivalent kind of technical assistance." This focus encompasses many small drinking water systems. The EC-SDC grant program provides grant funding for small or disadvantaged communities, and it supports projects in which the primary purpose is to address the challenges of PFAS in drinking water, whether it is found in the PWS or in source water. There is no cost-share requirement for EC-SDC. Lastly, the EPA also receives approximately $25 million annually for the Small,

Underserved, and Disadvantaged Communities (SUDC) grant program. This is a noncompetitive program administered through the states with the purpose of assisting PWSs comply with the SDWA. This funding is available for a variety of project activities, and all projects must benefit communities that are underserved and small or disadvantaged.

Some commenters stated that the EPA was not working quickly enough or encouraged the EPA to work more quickly. The EPA is working as quickly as possible while maintaining adherence to statutory limits, high quality analysis, and best available science. This rule is a key EPA priority under the *PFAS Strategic Roadmap* and the *PFAS Action Plan*. More information on the SDWA rulemaking process including timelines can be found in section 1.1, the SDWA Rulemaking Process, in this *Response to Comments* document. Some commenters also stated that the EPA must move faster because their primacy agency is not moving quickly enough. The EPA creates a baseline that others may build on. Primacy agencies are welcome to enact rules according to their authorities on their own timeline and are not precluded from enacting stricter or quicker rules than the EPA.

Individual Public Comments

North Penn Water Authority (NPWA) (Doc. #1470, SBC-043292)

Costs

The cost to bring PFAS levels down this low will be exorbitant. Even if some grant money is made available from the federal or state governments, it will not be nearly enough to cover all the costs involved around the country. And this does not even take into account that grant money is a one-time lump sum to assist only with the initial construction and installation of treatment equipment. It does not include the additional cost required if water utilities need to buy into the capacity available from neighboring treatment plants. And there will be no grant money to fund the ongoing, annual costs to continuously operate these systems forever into the future. No government, federal or state, can provide such a continual funding stream that all water systems around the country will need for many years into the future. Certainly not when the federal government is already awash in many trillions of dollars in debt, before these new regulations even go into effect. So it is completely unrealistic to think that federal grant money will be falling freely from the sky like pixie dust, without the cost eventually falling on the shoulders of every American through higher taxes and higher water rates. In the end, this is yet another unfunded mandate. The question remains – is this added cost worth it, in terms of a measurable reduction in risk to human health impacts?

Also related to costs is the problem that the manufacturers and distributors of the PFAS material are not being held accountable for their role in introducing this hazardous material into the environment. Instead, it is the water utilities and their customers, who are on the receiving end of this problem, and are not responsible for the PFAS being found in the water supply, that are having these exorbitant costs imposed on them. This is a gross misapplication of blame and financial responsibility.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Kerri Sullivan-Leger (Doc. #1500, SBC-042569)

Re: Docket ID No, EPA-HQ-OW-2022-0114,

Proposed Per- and Polyfluoroalkyl Substances

National Primary Drinking Water Regulation

To the EPA,

Thank you for providing the opportunity to comment on Environmental Justice Considerations for the Development of the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation under the Safe Drinking Water Act. My name is Kerri Sullivan-Leger, and I am a graduate student in the Masters of Jurisprudence in Environmental Law at Tulane University in New Orleans, Louisiana. As a resident of Louisiana, I am a part of this expansive group of citizens that your rule will target because of the chemicals dumped and seeped into our drinking water supplies. In St. James Parish, we have historically been silenced and denied recourse on environmental matters that pertain to our community's contamination of chemicals in the air and our water. PFAS chemicals have filled our lakes and rivers used as drinking water sources.

I am writing to raise concerns over the failure of local and state regulatory agencies to address chemical exposures in our community. Until we as a country are genuinely committed to reducing forever chemicals and dismantling the industries that profit from them, health problems and other disparities will remain stubbornly intractable. If a state refuses to provide the most basic level of security for its poorest citizens, it has lost any justification for deference to agencies whose job is to protect all citizens. All that is left are empty slogans, well-drawn philosophies, and failed promises.

Recognizing the need for water monitoring stations and access to emergency financial support could provide low-income communities like mine with safe, clean drinking water. Please allow me to give context and foundational information in the following comment.

Highest Regards,

Kerri Sullivan-Leger

Tucked into the lower corner of Louisiana off the banks of the nation's second longest river, The Mississippi, was some of the most cherished lands in the south. Before 1860 Louisiana produced nearly all of the nation's sugar and a large amount of its cotton. Louisiana had approximately 25,000 slaveholders who were considered the wealthiest in the nation. The state was only second to Mississippi in per capita wealth. Sugar, cotton, and slave labor were Louisiana's economy. Pre-Civil War, Louisiana's enslaved population was well over 300,000. The Sugar Plantations

were valued at more than $200,000 during the Antebellum time. The large plantations along the river were recorded as the most expensive land in the country. The United States Census Bureau recorded in 1860 that ten percent of the land in Louisiana produced sugar at a value of $19 million just in agricultural equipment compared to Wisconsin's 70,000 farms that recorded $6 million. The sugar barons dominated south Louisiana. The Sugar Prince, John Burnside, owned a mansion in New Orleans and two plantations on the river, with 753 people on one and 187 in St. James Parish on the other. At the time of his death, he had accumulated nearly $3 million in assets which would be almost $80 million in 2023.

This same 85-mile stretch of land that held my ancestors in slavery is now home to the most carcinogen-ridden locations in America. An astounding 150 petrochemical companies operate in this small manufacturing corridor called "Cancer Alley." St. James Parish is our home, and it is where our ancestors took refuge after slavery ended. They stayed here to build homes and develop communities despite what they had gone through on those plantations. There was a time when fishing, hunting, and farming was typical pastime until the grand ole sugar and cotton plantations began to get raffled off to the highest bidder over 40 years ago. That is when everything changed—the land, air, and water began to make community members sick because of the unaccounted-for pollution. The remnants of once-enslaved populations were experiencing chemical retribution by petrochemical facilities allowed to develop products that could legally poison the air and water.

Louisiana Department of Environmental Quality failed to protect our communities. The politicians who control our parish seat are lobbied so well by the polluters that they ignore our complaints. Our right to water free of PFAS chemicals is not only a legal presumptive but also a human right. The roots of the water contamination and sanitation crisis can be traced to poverty, inequality, and unequal power dynamics exacerbated by socioeconomic challenges and depleting water resources. Yet, we continue to fend off wealthy chemical magnates who can afford teams of lawyers and advisers who tell us to "shut up and be quiet ."Today I ask the EPA what you will do to champion our cause. Will you stand up for communities like ours that are on the precipice of being plundered into extinction?

PFAS left undeterred, accumulates in the bloodstream, tissue, and vital organs. The endocrine system, made up of all the body's different hormones, regulates biological processes in the body from birth through old age, and plays a role in brain development, including nerve chemical transmission, reproductive organs, blood pressure, and sugar levels are disturbed and adversely affected by high levels of PFAS. PFAS chemicals simulate our fatty acids and perform as endocrine-disrupting chemicals (EDCs) in our hormones. A study by The Water Collaborative of Greater New Orleans conducted a study in the summer of 2022 on chemicals flowing in the Mississippi River. Most communities near the river use it as a source of drinking water. High levels of PFAS, the forever chemicals, were found in the water, increasing cancer risks within the community. PFAS levels were 200 to 268 times higher than what EPA, your agency, said was safe for our drinking water. The report emphasized the impact on the lives of African Americans, who are 75 percent more likely than white Americans to live in a community near a

chemical company that produces harmful chemical pollutants. The report also said that cancer deaths and other sicknesses in low-income communities are 12% higher than in communities above the poverty line that are not experiencing targeted, polluting infrastructure.

What could the EPA do to help socioeconomically challenged communities in Louisiana? Commit to the following:

•Require all unnecessary PFAS be eliminated from our drinking water reservoirs

•Enact a national safe PFAS drinking water standard

•Enact strict guidelines covering interstate borders to keep safe surface & groundwater safe from PFAS

•Provide necessary coverage of the SDWA that would include protection from PFAS in bottled water production

•Include recourse for states that decide not to comply with SDWA regulations in protecting all communities from PFAS

•Regulate PFAS as a single chemical class to reduce health risks and contamination and improve clean-up effort

We are all part of an assiduous shame of a chemical-driven discriminatory system that systematically relegates underprivileged communities into islands riddled with sicknesses and neglect. It is because there are those among us who benefit from maintaining these inequalities. This is why the EPA regulations for PFAS-free regulations have to speak for those who cannot. To be clear, clean drinking water is an enthusiastic beginning to correct the many historical injustices that have plagued impoverished communities in America. Maslow's hierarchy of needs reflects five categories that can dictate an individual's behavior. Those needs are physiological needs, the need to feel safe, experience love and community, and be valued, and self-actualization needs. Physiological needs are categorized as the basic requirements of life--food, water, housing, clothing, and rest. Security and protection from harm are second on the list, meaning a safe home, a safe community, and a secure environment are just as important as clean water and food.

It is insidious to pretend that the lingering effects of poverty and discrimination are not intertwined in our culture of classism and segregation that creates marginalized communities held captive by a hostile environment. There are no secrets; history exposes how we got to this point and emphasizes the extraordinary possibilities when charismatic visionary leaders stand up to enact policies that will bring about systemic change.

19th Judicial District Court held that LDEQ “must take special care to consider the impact of climate-driven disasters fueled by greenhouse gases on environmental justice communities and their ability to recover.”

Water Quality Testing Report Updated 02 23 23. pdf. The Water Collaborative. https://www.nolawater.org/water-testing-in-cancer-alley

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Follett, Richard J. The Sugar Masters: Planters and Slaves in Louisiana's Cane World, 1820–1860. Baton Rouge: Louisiana State University Press, 2005.

Agriculture of the United States in 1860: Agriculture https://www2.census.gov/library/publications/decennial/1860/agriculture/1860b-06.pdf

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EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. Information on health effects associated with the six regulated PFAS can be found in section 4. The EPA notes that the Food and Drug Administration (FDA) regulates bottled water as defined in 21 CFR 165.110 through the Federal Food, Drug, and Cosmetic Act (FFDCA); section 410 provides FDA with specific instructions for bottled water in response to developments at the EPA. FDA is required to establish a quality standard or find that such a regulation is not necessary to protect the public health (21 CFR 165.110). The FDA regulation must have the same effective date as the EPA regulation and FDA must publish its regulation no later than 180 days before the effective date (21 CFR 165.110). The EPA notes that this rule prescribes a national standard designed to address PFAS and provide for safe drinking water, as requested by the commenter. All community- and non-transient, non-community PWSs must comply with this SDWA-based regulation.

Kaden Heldt (Doc. #1510, SBC-042589)

One of the issues raised by this decision is cost. The costs of this decision could be damaging to municipalities who cannot afford the technology needed for regulating PFASs. The few technologies available for this process are revevrse osmosis, activated carbon, and ion-exchange resins. (Underferth). All of these processes are very costly, and on top of regular testing and maintenance costs, of the 200 million Americans that have PFASs in their drinking water many municipalities simply won't have the funds to keep up and protect their citizens (Underferth). This also doesn't even begin to cover households with wells, which also can contain PFASs (Underferth). This decision must be made in order to protect people from these harmful chemicals, but the issue surrounding the costs needs to be figured out.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. Households with private wells are not subject to SDWA provisions; rather, SDWA-based regulations apply to water systems that provide water for human consumption to at least 15 service connections or that regularly serve at least 25 people.

Jon Raclin (Doc. #1511, SBC-042592)

Our two focused dimensions are in:

https://www.epa.gov/system/files/documents/2023-03/PFAS%20NPDWR%20Public%20Presentation_Overview_3.16.23_508.pdf

1. The proposed actions moving forward (screen 4)

2. The proposed MCL levels (screen 5)

Our two additional resources I found:

a. https://www.pbs.org/newshour/science/4-questions-about-the-epas-proposed-pfas-drinking-water-standard-answered

b. https://www.niehs.nih.gov/health/topics/agents/pfc/index.cfm

Jon's Input :

This new policy change to many water systems in America, would cause the cost of living to go up. This affects the general public of both national and local. PBS states, "It's an important step in the right direction. But it's not over". This policy change was the correct step and first of many. Not only was this the right choice, but it should become the basis for more policies and investigations for our health benefits.

PBS uses the language that this new policy decision is necessary to protect our health as American citizens. I would agree with this perspective as the health of ourselves, and our loved ones, should be the leading reason. We can all benefit or scam, or even just straight up lie in life, but taking any negative health effects to our one life is not worth any price we can think of. This policy is protecting the length and quality we live in.

The restricted level of MCL parts/trilion the forever per- and polyfluoroalkyl substances. PBS added, "The EPA would cap PFOA and PFOS at 4 parts per trillion, essentially the lowest level at which "they can be reliably measured." Four other PFAS — PFNA, PFHxS, PFBS and GenX chemicals — would be

regulated as a mixture, which still tests for each one individually but assesses their risk in combination with one another".

Also another important fact worth adding in the cost of the changes that the EPA now says needs to happen. "To help pay for it, the EPA noted that $2 billion from the Bipartisan Infrastructure

Law was made available last month to "address emerging contaminants, including PFAS, in drinking water across the country."

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. More information on health effects from the six regulated PFAS can be found in section 4 of the EPA response in this *Response to Comments* document.

City of Alexandria, Virginia (Doc. #1523, SBC-042612)

While the proposed regulation details the significant expense required to remove these chemicals from our drinking water, we recognize that such an investment will improve the health and wellness of our residents, particularly those with health vulnerabilities. This investment is particularly timely given the substantial financial commitment to drinking water systems included in the Bipartisan Infrastructure Law.

As such, we urge the EPA to finalize these regulations without delay.

Thank you for the opportunity to provide comment.

Sincerely,

Justin M. Wilson, Mayor

City of Alexandria, Virginia

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Orange Water and Sewer Authority (OWASA) (Doc. #1524, SBC-042615)

• Cost

o Construction

*Rate impact of 1 to 2% depending on the year

*The expected construction cost is approximately 50% of our typical 5 year CIP costs.

*Reductions in other necessary CIP Spending to accommodate PFAS treatment (especially on this timeline).

*Has caused deferral of active projects due to overlap of expected construction and increased spending.

o Annual Operating Expenses

§ An additional $2-3M per year needed – this is an 30-40% increase

§ Laboratory costs for sampling (assume 5-10 samples per month = $50k-70K?

o Funding

§ OWASA has to commit to treatment implementation without full understanding of what funding opportunities will be available to authorities

§ DWSRF has $4B – if we assume everyone will have a similar cost to us (around $50M to implement treatment (and some will have higher or lower costs than this) this funding will only help 80 water systems. However, 25% of this funding is being slated towards disadvantaged communities so there may be more water systems helped – BUT OWASA will not qualify for that portion of the funding. Also the $5B to the EC-SDC grant program will also not be for OWASA since that is geared towards small, disadvantaged rural communities.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Robert Adamski (Doc. #1530, SBC-043336)

The cost to implement the proposed regulations has been severely underestimated by EPA at $772 million. AWWA puts it at $3.8 billion. EPA estimates the benefit to be around $1 billion which is not cost beneficial. The capacity of the industry i.e. consultants, contractors, manufacturers and operators is not available. Neither is the capacity of the agencies to hire, train and certify the operators and lab technicians to implement this rule. At present localities like Flint, MI the current utility operates with a $9 million annual deficit (not including significant capital expenditure needs) as a result of inadequate water rates and collections.

While EPA says there is money available in current federal programs there is not enough to cover all water related needs. AWWA's 2012 report Buried No Longer estimated the investment gap or needs at a trillion dollars. EPA estimates it at $625 billion over the next 20 years. Lead service line replacement has been estimated to cost $6 billion. There isn't enough money available for all these needs. In addition as the calls for balancing the budget and reducing spending these dollars might disappear.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. Treatment technology availability and capacity is addressed in section 10.6 of the EPA response in this *Response to Comments* document.

Greenville Utilities Commission (Doc. #1534, SBC-042639)

Significant capital and annual operating costs will be needed to remove the PFAS compounds to the proposed levels. The costs of the associated strategies to remove PFAS will increase due to the significant increase in demand for these strategies to meet the proposed compliance and goat levels. The water industry is facing an aging infrastructure challenge that will require large investments to ensure clean and safe drinking water is provided to our customers. Funds should not be diverted from infrastructure needs to address contamination from multi-million-dollar companies.

Thank you for your consideration,

David W. Springer, P.E.

Interim Director of Water Resources

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. Treatment technology availability and capacity is addressed in section 10.6 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce (Doc. #1537, SBC-042650)

Infrastructure Investment and Jobs Act (IIJA) funding is a solid benchmark to focus limited federal resources. We must have a balanced approach considering that the current resource levels in the IIJA. Setting such low MCL levels are well beyond the potential funding available and the ability of communities to afford. Our report suggests that if the MCL for PFOA and PFOS is set at less than 20 ppt the likelihood of outspending the $10 billion contained in the IIJA is significant. And this does not even contemplate the costs associated with the MCL for the other four PFAS.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Alliance of Nurses for Healthy Environments (Doc. #1544, SBC-042672)

While some water utilities have already installed water treatment technology capable of reducing

PFAS, many are not yet equipped to do so. To help communities, Congress passed the Bipartisan Infrastructure Law which provides $9 billion in funding for drinking water treatment upgrades, and an additional $11.7 billion for other necessary drinking water infrastructure needs. This funding will aid utilities in meeting EPA's proposed drinking water standards and improve drinking water safety.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL provided approximately $43 billion to CWSRF and DWSRF. This includes $4 billion specifically reserved to address PFAS and emerging contaminants and $5 billion in grants reserved to small or disadvantaged communities. While $15 billion is reserved for lead service line replacements, the rest can be used for various purposes, which could include installing PFAS treatment or source water protection.

Brooke Young (Doc. #1554, SBC-043969)

Some actions the EPA can do to address these challenges as part of the proposed PFAS drinking water regulation include:

• Ensure funding and incentives for the research and development of advancing technologies to remove PFAS from drinking water successfully.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. As part of the PFAS Strategic Roadmap, the EPA is evaluating and developing technologies for end-of-life materials management. This includes disposal and destruction technologies to further reduce PFAS in the environment in addition to their work on drinking water and wastewater treatment, contaminated site cleanup and remediation, air emission controls, and health effects.

Lecsy Gonzalez (Doc. #1561, SBC-042870)

Environmental health disparities exist across the United States but affect indigenous populations living in tribal nations disproportionally, as they experience a higher burden of disease and a lower life expectancy than non-Native individuals. [REF6: Indian Health Service. 2019. Disparities. https://www.ihs.gov/newsroom/factsheets/disparities/] Tribal drinking water systems already have well-documented issues, including high rates of unsafe inorganic contaminates and nitrates, and indigenous communities have also been historically excluded from PFAS action. [REF7: Mok, K., Salvatore, D., Powers, M., Brown, P., Poehlein, M., Conroy-Ben, O. and Cordner, A., 2022. Federal PFAS testing and tribal public water systems. Environmental health perspectives, 130(12), p.127701.] Indeed, tribal nations' water systems have been overlooked for systematic PFAS testing over the years, generating a large data gap. [REF8: Powers, M., Conroy Ben, O., Salvatore, D., Mok, K., Brown, P. and Cordner, A., 2021, August. PFAS in American Indian and Alaska Native Communities. In ISEE Conference Abstracts (Vol. 2021, No. 1).] Research suggests that even if PFAS was detected in tribal water systems, as per the suggested regulation, there is no current regulation for PFAS treatment and insufficient remediation funding. [REF7: Mok, K., Salvatore, D., Powers, M., Brown, P., Poehlein, M., Conroy-Ben, O. and Cordner, A., 2022. Federal PFAS testing and tribal public water systems. Environmental health perspectives, 130(12), p.127701.] Therefore, it is a primary concern to provide the funds needed not only to determine if PFAS is present in the water but also to correct their presence.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. This rule is a regulation for PFAS as the commenter requests, however, the rule does not proscribe how a water system must meet the rule; this means systems may choose treatment or non-treatment options as site-specific circumstances dictate. Additionally, BIL mandates that 49 percent of DWSRF General Supplemental Funding must be provided as grants and forgivable loans to disadvantaged communities (IIJA P.L. 117-58). The BIL also requires that not less than 25 percent of funds provided through the DWSRF Emerging Contaminants Funding be provided as grants and forgivable loans to disadvantaged communities or PWSs serving fewer than 25,000 people (IIJA P.L. 117-58). For the CWSRF, the BIL mandates that 49 percent of funds provided through the CWSRF General Supplemental Funding must be provided as grants and forgivable loans to municipalities that meet affordability criteria (or municipalities

that do not but seek supplemental funding), or entities implementing a process, material, technique, or technology that addresses water or energy efficiency, mitigates runoff, or encourages sustainable project planning, design, and construction (IIJA P.L. 117-58).

Lecsy Gonzalez (Doc. #1561, SBC-042871)

Many studies call for state and federal support for PFAS monitoring and remediation in tribal nations, as small tribal water sources do not have the financial resources to afront the remediation costs associated with PFAS. [REF7: Mok, K., Salvatore, D., Powers, M., Brown, P., Poehlein, M., Conroy-Ben, O. and Cordner, A., 2022. Federal PFAS testing and tribal public water systems. Environmental health perspectives, 130(12), p.127701] It is important to note that most (over 68%) water sources in tribal nations are considered "small," which compares to the 18.8% of systems serving non-tribal water systems. [REF9: U.S. EPA. 2022. Safe Drinking Water on Tribal Lands: Tribal PFAS Monitoring Results.https://sdwis.epa.gov/ords/sfdw_pub/f?p=SDWIS_FED_REPORTS_PUBLIC:TRIBAL_PFAS] Furthermore, it is important to revisit the 1908 Supreme Court decision in Winters v. United States, where the federal government guaranteed that land established as a reservation would be permanently owned by indigenous tribes. [REF10: Williams SM. 1997. Overview of Indian water rights. J Contemp Water Res Educ107(1):6–8.] This decision also guaranteed tribes the right to adequate amounts of water to meet the needs of the reservation. [REF10: Williams SM. 1997. Overview of Indian water rights. J Contemp Water Res Educ107(1):6–8.] As such, and with emphasis on this Supreme Court ruling, I suggest that "adequate amounts of water to meet the needs of the reservation" could, and should, be applied in the context of this water regulation ruling. If we are to achieve true health equity across the United States, which is the basis of this PFAS regulation, it is necessary for the federal government to provide additional help, in the form of funding, to tribal nations to meet the needs of their residents. In addition, tribal nations have also provided water rights to non-tribal entities, [REF10: Williams SM. 1997. Overview of Indian water rights. J Contemp Water Res Educ107(1):6–8.] which means that if this PFAS regulation passes and places a profound burden on tribal water systems, it will also hurt non-indigenous individuals.

According to this rule, the United States Federal government will not "provide funds necessary to pay direct compliance costs" to enact the PFAS monitoring and regulations in drinking water. [REF3: Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation. https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0027.] However, the Federal government funds the Indian Health Service, which states that one of their primary concerns is "environmental sustainability." [REF11: Indian Health Service. The Federal Health Program for American Indians and Alaska Natives. 2023. https://www.ihs.gov/] As such, and considering the public health impacts of PFAS contamination and the Winters v. United States ruling, it seems like this regulation could be easily edited to provide additional funding or other resources to tribal nations to deal with the monitoring and remediation that would be mandatory once passed. [REF3: Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation. https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0027.] Additionally, funding

tribal nations would not be a massive endeavor, as most water systems are considered to be small, and, therefore, less costly to monitor. [REF3: Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0027; REF9: U.S. EPA. 2022. Safe Drinking Water on Tribal Lands: Tribal PFAS Monitoring Results.https://sdwis.epa.gov/ords/sfdw_pub/f?p=SDWIS_FED_REPORTS_PUBLIC:TRIBAL_PFAS]

In conclusion, for PFAS contamination as a health issue to be genuinely addressed across the United States, this regulation needs to be reviewed to include additional funds for tribal nations. Most tribal nation water systems do not even have estimates of PFAS values since they have not been monitored, [REF8: Powers, M., Conroy Ben, O., Salvatore, D., Mok, K., Brown, P. and Cordner, A., 2021, August. PFAS in American Indian and Alaska Native Communities. In ISEE Conference Abstracts (Vol. 2021, No. 1).] which already incurs more expending than other state or local water systems. With this in mind, this regulation would be disproportionally more expensive for tribal nations that already have less funding and resources than the states. [REF7: Mok, K., Salvatore, D., Powers, M., Brown, P., Poehlein, M., Conroy-Ben, O. and Cordner, A., 2022. Federal PFAS testing and tribal public water systems. Environmental health perspectives, 130(12), p.127701.] Therefore, this regulation should include additional funds to help offset the difference and allow for a more equitable enactment of PFAS monitoring and removal.

Thank you for the opportunity to comment on this regulation,

Lecsy Gonzalez

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1. Stoiber, T., Evans, S., Temkin, A.M., Andrews, D.Q. and Naidenko, O.V., 2020. PFAS in drinking water: an emergent water quality threat. Water Solutions, 1(40), p.e49.

2. Kazwini, T., Yadav, S., Ibrar, I., Al-Juboori, R.A., Singh, L., Ganbat, N., Karbassiyazdi, E., Samal, A.K., Subbiah, S. and Altaee, A., 2022. Updated review on emerging technologies for PFAS contaminated water treatment. Chemical Engineering Research and Design.

3. Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation. https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0027.

4. Crone, B.C., Speth, T.F., Wahman, D.G., Smith, S.J., Abulikemu, G., Kleiner, E.J. and Pressman, J.G., 2019. Occurrence of per-and polyfluoroalkyl substances (PFAS) in source water and their treatment in drinking water. Critical reviews in environmental science and technology, 49(24), pp.2359-2396.

5. Domingo, J.L. and Nadal, M., 2019. Human exposure to per-and polyfluoroalkyl substances (PFAS) through drinking water: A review of the recent scientific literature. Environmental research, 177, p.108648.

6. Indian Health Service. 2019. Disparities. https://www.ihs.gov/newsroom/factsheets/disparities/

7. Mok, K., Salvatore, D., Powers, M., Brown, P., Poehlein, M., Conroy-Ben, O. and Cordner, A., 2022. Federal PFAS testing and tribal public water systems. Environmental health perspectives, 130(12), p.127701.

8. Powers, M., Conroy Ben, O., Salvatore, D., Mok, K., Brown, P. and Cordner, A., 2021, August. PFAS in American Indian and Alaska Native Communities. In ISEE Conference Abstracts (Vol. 2021, No. 1).

9. U.S. EPA. 2022. Safe Drinking Water on Tribal Lands: Tribal PFAS Monitoring Results. https://sdwis.epa.gov/ords/sfdw_pub/f?p=SDWIS_FED_REPORTS_PUBLIC:TRIBAL_PFAShttps://sdwis.epa.gov/ords/sfdw_pub/f?p=SDWIS_FED_REPORTS_PUBLIC:TRIBAL_PFAS

10. Williams SM. 1997. Overview of Indian water rights. J Contemp Water Res Educ107(1):6–8.

11. Indian Health Service. The Federal Health Program for American Indians and Alaska Natives. 2023. https://www.ihs.gov/

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA and BIL place increased investment in disadvantaged communities as a key priority as stated in the memorandum from Radhika Fox dated 8 March 2022 titled "Implementation of the Clean Water and Drinking Water State Revolving Fund Provisions of the Bipartisan Infrastructure Law." This can also be seen in various EPA initiatives such as Justice40 and the funding allocations to small and disadvantaged communities. More information on EJ can be found in section 14.10 of the EPA response in this *Response to Comments* document.

Michigan Farm Bureau (MFB) (Doc. #1562, SBC-043353)

EPA must also consider and find ways to address the cost of compliance for not only municipal water supplies of all sizes, but also for farms and agricultural product packers and processors who are often classified as public water supplies but who are not generally eligible or high-ranking in applications for state and federal financial support for upgrading testing and treatment systems.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA has carefully considered the cost for all systems that will be affected by the rule and has detailed the agency's assumptions. Please see section 13.3 of the EPA response in this *Response to Comments* document for additional discussion on costs.

Maine Water Utilities Association (MWUA) (Doc. #1567, SBC-042737)

It is also recommended that EPA and primacy states streamline their new technology review process to expedite grant approvals.

EPA Response: Permits for the installation of treatment facilities at water systems are generally addressed by state and local authorities. The EPA has developed supporting documents

such as the *Best Available Technologies and Small System Compliance for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water* document (USEPA, 2024d) that can be used to help permitting authorities become more familiar with these technologies. The agency plans to further consider suggestions from states, technical assistance providers, industry associations, and interested stakeholders as it develops technical materials that can assist water systems in complying with the regulations. More information on treatment technologies and permitting may be found in section 10 of the EPA response in this *Response to Comments* document.

Maine Water Utilities Association (MWUA) (Doc. #1567, SBC-042744)

GAC media costs have been increasing steadily as illustrated in the following chart. We are concerned that costs will continue to rise for all PWSs who use GAC for treatment when there is a rush to provide it to systems for PFAS remediation.

EPA states "To help communities on the frontlines of PFAS contamination, the passage of the Infrastructure Investment and Jobs Act, also referred to as the Bipartisan Infrastructure Law (BIL), invests over $11.7 billion in the Drinking Water State Revolving Fund (SRF); $4 billion to the Drinking Water SRF for Emerging Contaminants; and $5 billion to Small, Underserved, and Disadvantaged Communities Grants. These funds will assist many disadvantaged communities, small systems, and others with the costs of installation of treatment when it might otherwise be cost-challenging." While this funding is appreciated, it's not nearly enough for what PWS will need to address PFAS. MWUA strongly encourages EPA to establish and maintain communications with Congress on how to provide more funding to communities facing PFAS contamination. There must be committed attention not only to the initial capital costs that PWS will incur to install treatment, but also ongoing operations and maintenance costs such as for sampling, operation and maintenance of the treatment system, and media replacement. In some situations, the responsible party may pay for the capital costs. In most cases, municipalities will need to front the costs and chase the responsible parties for reimbursement. It is likely that many contaminated water supplies may not have an easily identifiable source or responsible party. Who will be responsible for these ongoing costs? Ratepayers should not have to bear this burden for harm caused by others.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. More information on treatment technology availability and capacity can be found in section 10.6 of the EPA response in this *Response to Comments* document.

Maine Water Utilities Association (MWUA) (Doc. #1567, SBC-042727)

Further, we are concerned that in the interest of rapid implementation of drinking water standards, the burden of paying for treatment will fall to ratepayers when it should be falling to the polluters to remediate the damage they have caused. When the Clean Water Act and the Safe Drinking Water Act were passed in the 1970s, Congress felt it so important to make progress

with regulatory compliance that there were robust grant programs (to the tune of 90% grants) to support the construction of treatment plants and treatment works. That same level of commitment does not exist today. The Biden Administration points to the funding available through the Bipartisan Infrastructure Law to lessen the burden; let us be very clear - it will NOT make a dent in what we anticipate our PWS will need in order to comply with the proposed PFAS rules. We have major backlogs of infrastructure needs which require significant investment to maintain public health. We call on Congress and the Biden Administration to fully fund the treatment and ongoing operations and maintenance costs necessary to remediate PFAS in our nation's drinking water and seek reimbursement from the polluters who have caused this problem.

EPA needs to carefully consider implementation challenges for PWS caused by regulatory efforts related to PFAS. MWUA is questioning whether EPA has invested enough time into this effort before moving forward with the proposed drinking water regulations. Without adequate consideration regarding these implementation challenges, public confidence in drinking water could be further jeopardized. EPA must address these challenges before finalizing the rule. We hope that EPA will strongly consider the information we are providing on behalf of Maine PWS and will craft a final rule that is reasonable in its expectations of implementation and schedule.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA has provided compliance flexibility through a two-year capital improvements extension of the MCL compliance deadline allowed by Section 1412(b)(10) of SDWA in response to challenges raised by commenters surrounding capital improvement. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 on extensions and exemptions and section 10.6 on treatment technology availability and capacity in this *Response to Comments* document. More information on compliance with related regulatory requirements is located in section 10.4.2 of the EPA response in this *Response to Comments* document.

National Special Districts Coalition (NSDC) (Doc. #1571, SBC-043000)

The capability to detect and treat PFAS in water systems and needed treatment to meet MCL remains as a concern. NSDC encourages the EPA to consider what is reasonable for small- and medium-size special districts and other utilities that already face significant challenges in upgrading infrastructure and implementing treatment technologies. As EPA approaches the primary drinking water standard, NSDC urges the agency offer adequate time and weigh funding considerations to water agencies to explore and implement appropriate treatment methods to meet the new standards. Adequate funding and resources will be necessary to support districts and other agencies' ability to meet these standards.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. SDWA Section 1412(b)(4)(E)(ii) requires the EPA to list technologies that small systems may reasonably use for rule compliance. The results of mandatory analysis may be

found in the *Best Available Technologies and Small System Compliance Technologies for PFAS in Drinking Water* document. Additional information on small system compliance technologies can be found in section 10.5 of the EPA response in this *Response to Comments* document. Additional information on availability and capacity of compliance technologies can be found in section 10.6 of the EPA response in this *Response to Comments* document.

Lakewood Water District (LWD) (Doc. #1574, SBC-042752)

Funding Support Exaggerated

The proposed regulations highlight the $11.7 billion of Drinking Water SRF funding contained in the Bipartisan Infrastructure Law (BIL). $4 billion of this appropriation is set aside for Emerging Contaminants like PFAS. While $4 billion is certainly a lot of money, the implication that this will largely offset the cost of compliance is misleading.

Table 66 shows that the annual cost of compliance with these proposed rules ranges from $705 million (on the optimistic side) to over $1.3 billion (on the more realistic side). At these rates, the BIL support will last at most about five years and, more likely, about three years.

The description of federal dollars fails to mention that this support could often be in the form of loans and is, therefore, not really funding but rather a financing option.

Further, whether federal dollars come in the form of a grant, forgivable loan, or loan, all federal money comes with multiple regulatory strings attached that increase costs (e.g., Buy America Build America requirements, American Iron and Steel requirements, recycled material requirements, disadvantaged business requirements, and more).

In addition to the imposition of additional costs, securing federal dollars takes an exceptionally long time and almost always lengthens the duration of a project, which also increases costs and diminishes the value of federal support.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

COMM Water Department (Doc. #1577, SBC-042436)

There is no where near adequate funding identified to help our PWS like ours address our basic infrastructure needs, never mind comply with these new standards. EPA's most recent estimate for Massachusetts was recently released, the 7th Drinking Water Infrastructure Needs Survey and Assessment [FN1: https://www.epa.gov/system/files/documents/2023-04/Final_FAQ_DWINSA_4.4.23.v1.pdf], and it shows $15 billion in need over the next 20 years to maintain public health protections. This estimate doesn't include any costs associated with complying with the proposed PFAS standards. Congress and the Biden Administration need to fully fund the treatment and ongoing operations and maintenance costs necessary to remediate PFAS in our nation's drinking water and seek reimbursement from the generators who have

caused this problem. The federal government has far more resources and abilities to pursue legal actions and seek reimbursements from PFAS manufacturers than do individual PWS or groups of PWS.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Washington Suburban Sanitary Commission (WSSC Water) (Doc. #1585, SBC-042779)

6. Financial support

Availability of funding assistance:

We suggest that EPA consider expanding the eligibility criteria for various funding opportunities that are currently available to support PFAS mitigation. While the Bipartisan Infrastructure Law (BIL) offers a major funding opportunity to support such efforts, it is important to note that this funding is limited to capital expenditures or related planning and design work. Unfortunately, funding for PFAS research, including synoptic studies, source water assessments, or treatment alternative studies and related pilot tests, remains scarce, and costs for operations and mitigation efforts thus fall on ratepayers.

Furthermore, it is imperative that EPA ensures that the funding allocated to support compliance costs aligns with the accurate cost estimates. Although we acknowledge EPA's pledge to support water systems, particularly those in disadvantaged communities, we note that the amount of funding falls short of the high costs of treatment and waste disposal. This inadequacy is primarily attributed to the inaccurate cost assessments presented in this rulemaking.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Water & Health Advisory Council (Doc. #1590, SBC-042789)

[Figure 1

Geometric Mean PFOS and PFOA Serum Concentrations for the U.S. Population, CDC National Health and Nutrition Examination Survey, 1999 – 2018.

[Figure 1: See Docket ID: EPA-HQ-OW-2022-0114-1590]

About 85 percent of Americans who receive water utility service are served by local governments that face continuous pressure to keep rates low. High PFAS testing, remediation, and/or removal costs are likely to crowd out water system investments that would yield greater public health benefits, such as investment in infrastructure necessary to improve reliability or address contaminants such as arsenic or lead in drinking water. Small water systems and water systems in disadvantaged communities who already struggle with underfunding and understaffing lack the necessary resources to address these proposed regulations. While the EPA

has designated PFAS-specific funds for these communities, the cost of implementation far exceeds the available funding. We must invest in small water systems and disadvantaged communities and not force them to address contaminants at such low levels and uncertain science, when this may not be the highest concern for their communities. The media creates intense concern regarding PFAS, but when it comes to public health, it is important to focus on addressing issues that most improve the safety of our nation's drinking water for the greatest number of people.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document and note that BIL contains a $15 billion dollar allotment to aid with lead service line replacement.

Water & Health Advisory Council (Doc. #1590, SBC-042791)

We urge the U.S. EPA to consider the unintended public health consequences associated with diverting water utility resources towards these low-level contaminants and away from known risks impacting drinking water. Municipal utilities may be forced to fund the compliance costs associated with the PFAS MCLs by cutting back on infrastructure replacement and maintenance, operational resiliency, and reducing other expenditures that would have more benefit to public health and provide better access to clean and safe water.

The Safe Drinking Water Act calls on our nation's leaders to take effective steps towards ensuring a safe, affordable, and reliable drinking water supply for everyone. We ask that you continue to apply a science-based, risk- and cost-benefit analysis when approaching regulating PFAS. Our Council stands ready to provide additional comment, testimony, or other ways that our expertise can be of value to this process. Thank you.

Sincerely,

Water & Health Advisory Council

Rob Renner, Council Chair, Former Chief Executive Officer at Water Research Foundation

Chad Seidel, Ph.D., President, Corona Environmental Consulting

Joseph Cotruvo, Ph.D., BCES President, Joseph Cotruvo & Associates

Joyce Dinglasan-Panlilio, Ph.D., Division Chair/Associate Professor in Environmental Chemistry at University of

Washington-Tacoma

Kathryn Sorensen, Director of Research at the Kyl Center for Water Policy, Arizona State University

Manuel Teodoro, Robert F. and Sylvia T. Wagner Distinguished Professor of Public Affairs at University of

Wisconsin-Madison

Janet Anderson, Principal Toxicologist, GSI Environmental Inc.

References:

CDC (2019) 'Fourth National Report on Human Exposure to Environmental Chemicals Updated Tables, January 2019, Volume One. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention.', p. 866.

COT (2022) 'Statement on the EFSA Opinion on the risks to human health related to the presence of perfluoroalkyl substances in food'. Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment. Available at: https://cot.food.gov.uk/sites/default/files/2022-11/COT%20PFAS%20%20Statement%20on%20EFSA%20Opinion_2022_04.22%20Acc%20V_0.pdf.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. More information on the health risk reduction and cost analysis can be found in section 13 of the EPA response in this *Response to Comments* document.

Greater North Dakota Chamber et al. (Doc. #1593, SBC-042805)

The broad impact of this proposal by EPA's own accounts may raise water bills for households in our communities by as much as $1,000 per month. These are real costs of our employees and customers that are avoidable should EPA select a more reasonable and defensible approach.

We stand ready to assist you as the MCL proposals moves forward. For any questions or further discussion, please contact Kevin Sunday, Director of Government Affairs for the Pennsylvania Chamber of Business and Industry, at (717) 487-3571 or ksunday@pachamber.org.

Sincerely,

Greater North Dakota Chamber

Idaho Association of Commerce & Industry

Indiana Chamber of Commerce

Iowa Association of Business and Industry

Kansas Chamber of Commerce

Kentucky Chamber of Commerce

Maine State Chamber of Commerce

Maryland Chamber of Commerce

Michigan Chamber of Commerce

Minnesota Chamber of Commerce

Missouri Chamber of Commerce and Industry

Nebraska Chamber of Commerce & Industry

New Jersey Business & Industry Association

New Mexico Chamber of Commerce

North Carolina Chamber

Ohio Chamber of Commerce

Oregon Business & Industry

Pennsylvania Chamber of Business and Industry

South Carolina Chamber of Commerce

Tennessee Chamber of Commerce & Industry

Virginia Chamber of Commerce

Wisconsin Manufacturers & Commerce

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that the monthly price increase quoted is significantly higher than the costs that the EPA has published in its analysis and is significantly higher than the EPA figures that are published on table 18 of the *Best Available Technologies and Small System Compliance Technologies for PFAS in Drinking Water* document. More information on cost and affordability analysis can be found in the *Best Available Technologies and Small System Compliance Technologies for PFAS in Drinking Water* and the *Technologies and Costs for Removing Per- and Polyfluoroalkyl Substances from Drinking Water* documents as well as section 13 of the EPA response in this *Response to Comments* document.

Michigan Department of Environment, Great Lakes, and Energy (EGLE) Drinking Water and Environmental Health Division (DWEHD) (Doc. #1597, SBC-042995)

A significant portion of this federal funding will be required to effectively support public water supply system upgrades, necessary to address the new limits proposed in this NPDWR. PFAS analytical testing alone represents a significant burden for many of our small supplies, especially those non-community water supplies operating as schools and childcare providers. To ultimately address PFAS contamination in source water may require additional challenges be met, including contamination investigation, engineering study, treatment design/permitting, consolidation efforts, or new well construction.

While EPA has taken steps toward providing funding opportunities to meet these challenges, it is likely that the need outweighs the current availability of federal resources. More is needed. It is the hope of EGLE DWEHD that EPA will remain an active partner for all states, in providing support and resources throughout implementation of the NPDWR and beyond.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Lehigh County Authority (LCA) (Doc. #1600, SBC-042825)

In addition, efforts should be made to find avenues to extend the availability of current funding streams so that support is available for utilities when they need it.

EPA Response: Please see section2.4 of the EPA response in this *Response to Comments* document. It is important to note that BIL Appropriations cover through at least FY2026 and the SRFs have successfully stewarded more than $200 billion since 1988 and should continue.

Lehigh County Authority (LCA) (Doc. #1600, SBC-042823)

5. Funding Capacity & Timing – The Infrastructure Investment and Jobs Act (IIJA) may be a vital resource for water utilities in their efforts to achieve compliance with the proposed PFAS rule. However, the $55 billion allotted for water infrastructure is set to expire in 2026, which is before the implementation date of the proposed rule. Further, the process for applying for and receiving IIJA or other funds through the Drinking Water State Revolving Fund (DWSRF) or the Water Infrastructure Finance and Innovation Act (WIFIA) can be time consuming.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-042901)

EPA states "To help communities on the frontlines of PFAS contamination, the passage of the Infrastructure Investment and Jobs Act, also referred to as the Bipartisan Infrastructure Law (BIL), invests over $11.7 billion in the Drinking Water State Revolving Fund (SRF); $4 billion to the Drinking Water SRF for Emerging Contaminants; and $5 billion to Small, Underserved, and Disadvantaged Communities Grants. These funds will assist many disadvantaged communities, small systems, and others with the costs of installation of treatment when it might otherwise be cost-challenging." While this funding is appreciated, it's not nearly enough for what PWS will need to address PFAS.

Additionally, the BIL funding has a sunset which will likely occur before many PWS are able to get through the monitoring and design process, preventing them from accessing these monies.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-042875)

We are concerned that in the interest of rapid implementation of drinking water standards, the burden of paying for treatment will fall to ratepayers when it should be falling to the polluters to remediate the damage they have caused. When the Clean Water Act and the Safe Drinking Water Act were passed in the 1970's, Congress felt progress toward regulatory compliance was of utmost importance and robust grant programs were established (to the tune of 90% grants) to support the construction of treatment plants and treatment works. That same level of commitment does not exist today. The Biden Administration points to funding available through the Bipartisan Infrastructure Law (BIL) as a means to lessen the burden. However, BIL funding will cover only a small fraction of what we anticipate our PWS will need in order to comply with the proposed PFAS rule. The total allocation of BIL funding proposed for Massachusetts was just $1.2 billion across all programs [FN12: https://www.mass.gov/doc/clean-water-and-drinking-water-state-revolving-funds-and-the-bipartisaninfrastructure-law-presentation/download] including Drinking Water State Revolving Fund Supplemental, Lead, Drinking Water Emerging Contaminants, Clean Water Supplemental, and Clean Water Emerging Contaminants. Lead funding for Massachusetts is now expected to be reduced by almost one-half because of reallocation after the 7th Drinking Water Infrastructure Needs Survey and Assessment.

Further, there are major backlogs of infrastructure needs in Massachusetts and across the country which require significant investment to maintain public health. EPA's most current estimate for Massachusetts was recently released, the 7th Drinking Water Infrastructure Needs Survey and Assessment [FN13: https://www.epa.gov/system/files/documents/2023-04/Final_FAQ_DWINSA_4.4.23.v1.pdf], and this report shows $15 billion is needed over the next 20 years; and this estimate doesn't include any costs associated with complying with the proposed PFAS standards. We will identify costs being incurred by PWS in Massachusetts later in our comments, but we call on Congress and the Biden Administration to fully fund the treatment and ongoing operations and maintenance (O&M) costs necessary to remediate PFAS in our nation's drinking water and seek reimbursement from the manufacturers who have caused this problem. The federal government has far more resources and abilities to pursue legal actions and seek reimbursements from PFAS manufacturers than do individual PWS or groups of PWS.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA has provided compliance flexibility through a two-year capital improvements extension of the MCL compliance deadline allowed by Section 1412(b)(10) of SDWA in response to challenges raised by commenters surrounding capital improvement. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 on extensions and exemptions and section 10.6 on treatment technology availability and capacity in this *Response to Comments* document. More information on simultaneous compliance with other regulatory efforts is located in section 10.4.2 of the EPA response in this *Response to Comments* document. More information on the health risk reduction

and cost analysis can be found in section 13 of the EPA response in this *Response to Comments* document.

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-042904)

MWWA strongly encourages EPA to establish and maintain communications with Congress on how to provide more funding to communities facing PFAS contamination. There must be committed attention not only to the initial capital costs that PWS will incur to install treatment, but also ongoing O&M costs such as for sampling, operation and maintenance of the treatment system, and media replacement. In some situations, the responsible party may pay for the capital costs. In most cases, municipalities will need to front the costs and file lawsuits against potentially responsible party(ies) (if any) for reimbursement. It is likely that many contaminated water supplies may not have an easily identifiable source or responsible party. Who will be responsible for these ongoing costs? Ratepayers should not have to bear this burden for harm caused by others. The proposed MCL represents an unfunded federal mandate unlike any other in the past under the SDWA and costs associated with complying with the rule need to be fully funded in perpetuity by the federal government.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-042899)

Massachusetts has already committed $209 million in State Revolving Fund (SRF) loans to fund just 24 PFAS treatment projects in the Commonwealth. Over the past year, SRF projects are routinely coming in 30% higher than what was originally committed, and we expect that trend will continue as we are experiencing inflationary pressure, supply chain challenges, and workforce shortages. With the limited public comment period, we do not have sufficient time to survey Massachusetts PWS to quantify private financing which many smaller, non-municipal PWS have had to utilize. MassDEP has also issued $11.8 million in targeted grant funding to assist PWS in their remediation activities. MassDEP recently issued the final Intended Use Plan for 2023 SRF funding and there are 29 communities on that list that have PFAS projects, and the projected 2023 funding is around $308 million. It's important to note that these PWS will still need local approval to enter into loan commitments for these projects to move forward. It is also important to note that several of these are multi-year projects with much higher price tags ($20 million+) which need to be funded over a multi-year period, as our SRF has a $15 million cap for funding given in any one year. As such, the loan commitments to date do not show the full extent of the needed expenditures for PFAS remediation. If all the 2023 projects move forward that will be more than $500 million expended in Massachusetts for just a fraction of systems who have exceeded the MMCL, which as we know is a much higher compliance value than EPA's proposal. It should also be recognized that SRF is primarily a financing mechanism that provides loans to PWS. Unless it is specified that all PFAS remediation projects are to be grant-funded, an SRF loan remains a burden on local ratepayers.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. More information on the public comment period and the EPA regulatory process can be found in section 2.3 of the EPA response in this *Response to Comments* document. More information on simultaneous compliance with other regulatory efforts is located in section 10.4.2 of the EPA response in this *Response to Comments* document.

Arlington County Virginia (Doc. #1603, SBC-043008)

4. The regulation as proposed inappropriately places the extraordinary financial burden of PFAS on rate payers, who were unwitting consumers of these compounds – the financial burden needs to fall on the companies that profited from the manufacture of these compounds

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Arlington County Virginia (Doc. #1603, SBC-043019)

Cost Burden

It is widely acknowledged that the presence of PFAS in source water systems (and nearly everything else) is a consequence of decades of manufacturing and commercial endeavors. The production of PFAS continues largely unabated today, and they therefore continue to accumulate in the environment. Water utilities bear no responsibility for the prevalence of PFAS, yet the proposed regulations place the entirety of the burden for removal upon water utilities and their customers.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

American Water Works Company Inc. (Doc. #1608, SBC-044007)

Low-Income Assistance

During the COVID-19 pandemic, Congress recognized that water and wastewater services could not be compromised by a customer's inability to pay their bill. A temporary low-income household water assistance program, or LIHWAP, was created as a stop-gap measure, offering $1.1 billion to customers and households across the U.S.

While this funding meant that the most vulnerable in our communities could continue to drink, bathe, and flush their toilet during the pandemic, it was only a short-term solution. Prior to the proposed PFAS rule, an independent report commissioned by five water sector associations that represent a cross-section of the 315 million Americans who rely on community water systems found the annual need for a federal assistance program to range between $2.4 billion and $7.9 billion in order to balance affordability with the need to accelerate investments in our infrastructure. We anticipate that the needs will only increase when the PFAS rule is finalized.

Therefore, we are calling for Congress and the Biden-Harris Administration to establish and fund a permanent federal low-income household water assistance program as quickly as possible.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

American Water Works Company Inc. (Doc. #1608, SBC-043979)

Treating or removing contaminants in water comes at a cost. To realize the health benefits of such, water utilities must have the financial resources to assure they can sustain the ongoing costs that will arise from constructing, operating, maintaining, and monitoring PFAS treatment systems for the safety and benefit of customers. States should treat these expenditures for regulated utilities as federally mandated requirements that are recoverable in customer rates through expedited means.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Prince William County Service Authority (Doc. #1609, SBC-042847)

6. The cost to implement PFAS treatment will be considerable and will be borne by utility ratepayers – the public. Drinking water affordability is already challenged by other new regulations, replacement of aging infrastructure, and price increases for chemicals, power, and supplies that far outpace overall inflation.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges please see sections 12.1 and 10.6 of the EPA response in this *Response to Comments* document. More information on simultaneous compliance with other regulatory efforts is located in section 10.4.2 of the EPA response in this *Response to Comments* document. More information on the health risk reduction and cost analysis can be found in section 13 of the EPA response in this *Response to Comments* document.

Marlene Ladderbush (Doc. #1612, SBC-042912)

• EPA has very much underestimated the costs to PWSs to comply with the proposed rule.

• There is no where near adequate funding identified to help our PWS or address our basic infrastructure needs, never mind comply with these new standards. EPA's most recent estimate for Massachusetts was recently released, the 7th Drinking Water Infrastructure Needs Survey and Assessment [FN1: https://www.epa.gov/system/files/documents/2023-04/Final_FAQ_DWINSA_4.4.23.v1.pdf], and it shows $15 billion in need over the next 20 years to maintain public health protections. This estimate doesn't include any costs associated with complying with the proposed PFAS standards. Congress and the Biden Administration need to

fully fund the treatment and ongoing operations and maintenance costs necessary to remediate PFAS in our nation's drinking water and seek reimbursement from the generators who have caused this problem. The federal government has far more resources and abilities to pursue legal actions and seek reimbursements from PFAS manufacturers than do individual PWS or groups of PWS.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. More information on the health risk reduction and cost analysis can be found in section 13 of the EPA response in this *Response to Comments* document.

Town of Lincoln Water Department (Doc. #1613, SBC-043023)

There is no-where near adequate funding identified to help our PWS like ours address our basic infrastructure needs, never mind comply with these new standards. EPA's most recent estimate for Massachusetts was recently released, the 7th Drinking Water Infrastructure Needs Survey and Assessment [FN1: https://www.epa.gov/system/files/documents/2023-04/Final_FAQ_DWlNSA_4.4.23.v1.pdf], and it shows $15 billion in need over the next 20 years to maintain public health protections. This estimate doesn't include any costs associated with complying with the proposed PFAS standards. Congress and the Biden Administration need to fully fund the treatment and ongoing operations and maintenance costs necessary to remediate PFAS in our nation's drinking water and seek reimbursement from the generators who have caused this problem. The federal government has far more resources and abilities to pursue legal actions and seek reimbursements from PFAS manufacturers than do individual PWS or groups of PWS.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. More information on the HRRCA can be found in section 13 of the EPA response in this *Response to Comments* document.

Oakland County Water Resources Commissioner (WRC) (Doc. #1615, SBC-042926)

First, the potential costs and liabilities associated with the proposed regulations, including cost associated with remediation and disposal, would cause a substantial financial burden for many of our customer communities, including the City of Pontiac and the Charter Township of Royal Oak. Water affordability is a top priority for my office. Through a state grant, we recently researched the topic, released a detailed report with our findings, and developed a comprehensive water affordability plan that can be found at www.wrc.com/affordability. A key finding in our report is that water affordability is not just a problem of the poor. As new water quality regulations emerge, the costs of regulatory compliance will be passed on through customer rates which drives up the number of households who struggle to pay for essential water services. This impacts the financial health of public utilities and results in tradeoffs to balance competing needs regarding proper investments in infrastructure, maintaining affordable rates, and long-term fiscal stability of the utility. Unfortunately, these tradeoffs lead to inequities.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. More information on the HRRCA can be found in section 13 of the EPA response in this *Response to Comments* document. More information on cumulative regulatory as well as disposal burden can be found in section 10.4.2 of the EPA response in this *Response to Comments* document.

Oklahoma Department of Environmental Quality (DEQ) (Doc. #1616, SBC-043048)

The cost to laboratories to obtain the instrumentation needed for analysis is substantial. In addition, there is need för laboratories to purchase redundant instruments to maintain capacity as well as test in matrices other than drinking water. The cost of peripheral equipment and maintenance contracts further adds to the cost of performing PFAS testing. The EPA should mandate that some portion of Bipartisan Infrastructure Law funds should be dedicated to laboratory support.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. More information on the HRRCA can be found in section 13 of the EPA response in this *Response to Comments* document. It is important to note that the DWSRF set-asides can be used to obtain test kits/laboratory equipment for systems to test for newly recognized contaminants of concern and training to use that equipment as mentioned in the memorandum from Radhika Fox dated 8 March 2022 titled "Implementation of the Clean Water and Drinking Water State Revolving Fund Provisions of the Bipartisan Infrastructure Law."

Oklahoma Department of Environmental Quality (DEQ) (Doc. #1616, SBC-043049)

Treatment, Small Systems, and Availability of Qualified Water Operators

DEQ suggests that EPA continue to fund and dedicate resources to technical assistance programs, programs to advance small water systems' technical, managerial, and financial capability, and operator recruitment programs.

Small system compliance with the PFAS MCL's will be challenging. Systems with no alternative source water will be faced with the challenge of installing treatment, and most small groundwater systems currently have minimal treatment installed.

In most cases, treatment for PFAS will require an increase in the level of certification for the water operator. The challenges for small and disadvantaged systems to hire and retain qualified operators will increase as systems install treatment to comply with PFAS MCL's.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The money committed to the SRFs represents continued dedicated assistance programs and those funds contain mandatory reserves for small or otherwise disadvantaged systems. More information on operator capacities can be found in section 10.6 of the EPA response in this *Response to Comments* document.

Aquarion Water Company (Doc. #1617, SBC-043375)

Federal funding, particularly through the Bipartisan Infrastructure Law (BIL), will defray some of these costs, but ratepayers will still bear the burden of much of the cost to construct solutions and all the cost to operate and maintain these solutions.

With these factors in consideration, Aquarion offers the following comment on the EPA's proposed regulation for the six PFAS.

1. EPA estimates the Annualized Quantified National Costs and Benefits of the proposed regulation are approximately $772 million and $1.23 billion, respectively (Table 66 in previously noted Federal Register), which indicates a net benefit of the proposed regulation. However, a recent study conducted by Black & Veatch on behalf of AWWA (WITAF 56 Technical Memorandum – PFAS National Cost Model Report) estimates the annualized national costs to be significantly higher at approximately $3.8 billion. As shown above, we estimate that our annualized capital costs to comply with the proposed regulation is approximately $14 million. Prorating this $14 million from our population served of 700,000 to the 316 million people served by community water systems across the country (see Table 4-4 in EPA's "Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation") yields an annualized national capital cost of $6.3 billion to comply with the proposed regulation. We recognize that this is a very rough approach to estimating the national costs of complying with the proposed regulation, and we're merely providing this input to show evidence that EPA should consider further evaluation of its cost estimates while finalizing the regulation.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA disagrees with many of the assumptions in AWWA's Black & Veatch's (B&V) report and the report's overall conclusions about the estimated national costs; see section 13.3.3 of the EPA response in this *Response to Comments* document for details.

Aquarion Water Company (Doc. #1617, SBC-043378)

4. To reduce the impact on water rates, we ask that regulatory agencies (and legislative bodies) consider providing more funding in the form of grants and loan principal forgiveness instead of the current approach of providing much of the funding in the form of low or no interest loans. While it's recognized and appreciated that the BIL requires states to distribute PFAS related funding entirely as forgivable loans or grants, in practice it seems that these funds will be spread over many individual loans, resulting in only partial principal forgiveness for the individual loans. The result is that ratepayers will have to cover the large portion of a loan that is not forgiven. More funding in the form of grants and/or increased principal forgiveness would further defray the impact on water rates.

We respectfully request that EPA take our comments under consideration when finalizing the regulation. Thank you for the opportunity to provide our comments.

Sincerely,

Aquarion Water Company

John P. Walsh, P.E.

Vice President, Operations (MA & NH), Water Quality, and Environmental Management

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Beaufort-Jasper Water & Sewer Authority (BJWSA) (Doc. #1618, SBC-042930)

May 26, 2023

U.S Environmental Protection Agency EPA Docket Center

Office of Ground Water and Drinking Water 1200 Pennsylvania Avenue NW Washington, DC 20460

Re:Docket ID No. EPA-HQ-OW-2022-0114

PFAS National Primary Drinking Water Regulation Rulemaking

To Whom It May Concern:

Thank you for the opportunity to comment on the USEPA's proposed PFAS National Primary Drinking Water Regulation . Beaufort-Jasper Water & Sewer Authority (BJWSA) is a political subdivision and a special purpose district of the State of South Carolina created by the state's legislature to provide water and wastewater services to residents in Beaufort and Jasper counties. The utility treats and delivers an average of 20 million gallons of drinking water each day to more than 65,000 retail customers, as well as numerous wholesale customers, for a total population served of approximately 150,000.

The major source of water supplying BJWSA's two water treatment plants is the Savannah River. Although this river is a very reliable source of water, it is impacted by low levels of PFAS chemicals. Neither treatment plant is presently equipped with treatment processes which remove these chemicals to levels below the proposed PFAS regulations. As a result, if the current proposal is finalized, BJWSA will be required to install treatment that is estimated to cost $80 million and budget for additional annual costs to operate and maintain the new treatment facilities and dispose of process residuals. This cost estimate is in alignment with that experienced by the Cape Fear, North Carolina Public Water Authority, which recently constructed and began operating a new granular activated carbon (GAC) facility to remove compounds such as PFAS. That project had a timeline of five years from study and pilot testing to facility startup, and annual operating costs for the Cape Fear facility are estimated at $5M in future years.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043067)

Securing Funding is a Slow Process

A crucial step for installing capital improvements is to identify and secure a source of funding. In announcing this rule, EPA highlighted the funds through the Bipartisan Infrastructure Law and more specifically the Drinking Water State Revolving Fund (DWSRF). Funding is also available through the Water Infrastructure Finance and Innovation Act (WIFIA) program. These programs provide an avenue for water systems to fund new treatment facilities; however, these programs can be time consuming and sometimes take several years to acquire approval, in addition to project design time. These programs may also impose additional requirements for funding to be approved that may limit procurement options and costs. Whether a system utilizes the DWSRF, WIFIA, or another program, the process may still be slow and will require financial planning for capital improvements outside of the typical Capital Improvement Program (CIP). Planning through a CIP helps to assure that capital improvements are staged in a way that minimizes water rate impacts.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

WaterPIO (Doc. #1624, SBC-043475)

Nationwide, the financial impacts of the EPA's proposed MCLs and HI will be in the tens of billions of dollars. AWWA commissioned a study on the financial costs of the proposed PFAS MCLs and Hazard Index [Link: https://www.awwa.org/Portals/0/AWWA/Government/2023030756BVFinalTechnicalMemoradum.pdf?ver=2023-03-14-102450-257]. The thorough work by Black and Veatch clearly shows how EPA exponentially underestimated the funding mandates created by these proposed regulations, financial burdens that are guaranteed to be passed on to the American people.

To show how absurd the cost burdens could be on the American people, here's an example using one of our clients. The water and wastewater utility is currently below the proposed MCLs for PFOA and PFOS at around three ppt each, and their main water source is a major river flowing through multiple states.

As we know from our experience with PFAS in North Carolina, PFAS levels jump in waterways during times of drought. When droughts have occurred for our "three ppt" client, their PFOA and PFOS levels have spiked to six, eight, and on occasion, to double-digit parts per trillion levels. This creates a situation where their running annual average could spike above the proposed MCLs of 4.0 ppt or throw them out of compliance with the HI's formula. What will be the result for this utility simply because it experienced a drought? An estimated construction cost of

approximately $1.5 BILLION dollars, with annual operation and maintenance costs in the tens of millions.

Without a definitive polluter on their waterway, guess who will be paying for these BILLION-dollar costs? The utility's customers, leaving many of them to decide if drinking their tap water is worth it anymore, especially since they'll be repeatedly told their water contains cancer-causing compounds while their rates are rising.

Is that really the world the EPA wants to create?

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs; see section 13.3.3 of the EPA response in this *Response to Comments* document for details. Compliance with this rule is calculated using a running annual average; we expect this to mitigate many of the concerns associated with temporary spikes in regulated PFAS concentration.

WaterPIO (Doc. #1624, SBC-043461)

2. The costs, grossly underestimated by the EPA, for meeting the proposed regulations will be astronomical. The largely unfunded mandates will cost in the tens, or even hundreds, of billions of dollars that water systems do not have.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044114)

ASDWA recommends that EPA continue funding research for the treatment of emerging contaminants in drinking water, especially treatment at small water systems.

Based on costs associated with the BAT, primacy agencies anticipate that small and disadvantaged water systems exceeding the MCL will face financial difficulties implementing any treatment options. While funding under the Bipartisan Infrastructure Law (BIL) may be available for some systems, each of the BAT are costly treatment methods with high operation and maintenance costs. For many systems, these costs will be passed on to ratepayers.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document and note that the EPA identified research as a key pillar in the *PFAS Strategic Roadmap.* The agency is funding research into new treatment technologies. More information on small system compliance technologies may be found in section 10.5 of the EPA response in this *Response to Comments* document and more information on the HRRCA can be found in section 13 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044106)

ASDWA strongly recommends that EPA invest funding into evaluations of these technologies by ORD, similar to the arsenic studies completed in the early 2000s or EPA's previously managed Environmental Technology Verification (ETV) program. Investment should particularly focus on treatment technologies at small water systems.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA has invested in evaluating and developing technologies for reducing PFAS in the environment to inform decisions on drinking water and wastewater treatment, contaminated site cleanup and remediation, air emission controls, and end-of-life materials management. Please see sections 10.1 and 10.2 of the EPA response in this *Response to Comments* document. The EPA's Environmental Technology Verification (ETV) Program concluded operations in early 2014 and there are currently no plans to reestablish it. The EPA is supporting the development of alternative technologies through various other programs such as the Innovative Water Technology Grant Program for next generation adsorbents and Small Business Innovation Research grants.

Illinois Farm Bureau (IFB) (Doc. #1630, SBC-043140)

[The most glaringly overlooked and/or underestimated data includes:]

• Infrastructure Investment and Jobs Act (IIJA) funding are limited federal resources. The investment needed to reach these low MCL levels moves well beyond the ability of communities to afford and beyond the potential funding available in the IIJA.

Please refer to more robust comments submitted by the American Farm Bureau Federation for a more detailed review our shared concerns.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Illinois Farm Bureau (IFB) (Doc. #1630, SBC-043142)

It will be infeasible for many rural communities to meet the standards outlined in the short timeframe identified and the exorbitant costs will inevitably be handed down to the water users. While federal funding may be available, our concern is there is not enough money to go around to cover the costs.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Rural Community Assistance Partnership Incorporated (RCAP) (Doc. #1633, SBC-044146)

Finally, because the financial burdens on small, rural, and tribal communities will be so great, EPA must work with utilities on a regional scale, encouraging partnerships between PWSs to help with compliance and cost-effective solutions.

RCAP thanks EPA for its efforts to protect public health in promulgating this proposed NPDWR and stands ready to assist the Agency with continued feedback and implementation support in the months and years to come.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. More information on the HRRA can be found in section 13 of the EPA response in this *Response to Comments* document, and more information on an affordability analysis can be found in section 10.5 of the EPA response in this *Response to Comments* document. Significant amounts of funding are reserved for small, rural, Tribal, or otherwise disadvantaged systems that are being distributed through the SRFs as a result of the EPA's commitment to productive partnerships and to maximize the impact of these funds.

Orange County Water District (OCWD), California (Doc. #1634, SBC-043235)

Securing funding for treatment or other means of compliance (e.g., drilling a new well) via programs such as the Bipartisan Infrastructure Act, Drinking Water State Revolving Fund (DWSRF), and or Water Infrastructure Finance and Innovation Act (WIFIA) requires significant time. It can take several years for funding to be approved through these programs, many of which impose procurement restrictions or reporting requirements which limit flexibility and further slow project progress.

EPA Response: The EPA has provided compliance flexibility by providing a two-year capital improvements extension of the MCL compliance deadline allowed by Section 1412(b)(10) of SDWA. For additional discussion on the compliance timeline, please see section 12 on extensions and exemptions. Please see section 2.4 of the EPA response in this *Response to Comments* document.

Town of Tewksbury, Massachusetts (Doc. #1637, SBC-043242)

There is nowhere near adequate funding identified to help our PWS like ours address our basic infrastructure needs, never mind comply with these new standards. EPA's most recent estimate for Massachusetts was recently released, the 7th Drinking Water Infrastructure Needs Survey and Assessment, and it shows $15 billion in need over the next 20 years to maintain public health protections. This estimate does not include any costs associated with complying with the proposed PFAS standards. Congress and the Biden Administration need to fully fund the treatment and ongoing operations and maintenance costs necessary to remediate PFAS in our nation's drinking water and seek reimbursement from the generators who have caused this

problem. The federal government has far more resources and abilities to pursue legal actions and seek reimbursements from PFAS manufacturers than do individual PWS or groups of PWS.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. More information on the HRRCA can be found in section 13 of the EPA response in this *Response to Comments* document.

Citizens Against Ruining the Environment (CARE) (Doc. #1638, SBC-043443)

One impacted Will County community, the City of Joliet, recently signed an agreement to purchase Lake Michigan water from the City of Chicago thirty-five miles away. The agreement will ensure clean drinking water for Joliet residents. Joliet currently uses a groundwater aquifer to supply community drinking water but will build the $1 billion pipeline infrastructure to transport treated Lake Michigan water in the future. [FN2: A.D. Quig, City of Chicago OK's 100-Year Water Deal with Joliet, Chicago Tribune (Apr. 19, 2023), https://www.chicagotribune.com/politics/ct-chicago-water-deal-with-joliet-council-2023-20230419-mpb635xftvgudf54vfw43322eu-story.html.] This is prohibitively expensive and infeasible for other Will County communities which have no choice but to continue using groundwater.

CARE asserts the costs associated with monitoring, reporting, and cleanup of PFAS should be borne by the parties responsible for the contamination, not private well users or water suppliers. CARE asserts that financial assistance for testing and filtration should be made available to middle class homeowners as well as low-income households. C

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. More information on the HRRCA can be found in section 13 of the EPA response in this *Response to Comments* document, and more information on an affordability analysis can be found in section 10.5 of the EPA response in this *Response to Comments* document.

California Municipal Utilities Association (CMUA) (Doc. #1639, SBC-043254)

I. CMUA Strongly Urges the EPA to Provide Financial Assistance that can be used in all Communities

Any new regulation comes with additional costs for public water agencies. Costs to monitor, notify, and treat at the proposed maximum contaminant levels (MCLs) for PFOA, PFOS, PFHxS, GenX Chemicals, PFNA, and PFBS may be infeasible for some agencies to bear, especially smaller agencies. Ultimately, those costs are borne by customers.

The proposed MCLs will require substantial investments for public agencies to monitor their water supplies to detect these contaminants at the proposed levels. It is also important to acknowledge the investments that public water agencies have already made in monitoring and detection equipment. The existing equipment may be able to detect at the currently proposed

standard, but if that standard is any lower, the extensive investments will be for naught since that equipment will not detect a lower standard. There is additionally the potential for false negatives or positives for the proposed trigger level of 1.3 parts per trillion for PFOA and PFOS. The lowest concentration that PFOA and PFOS can be reliably quantified within specific limits of precision and accuracy during routine laboratory operating conditions is 4 parts per trillion. Similarly, for some other agencies, past investments made in equipment will be insufficient to comply with the proposed MCLs, making those investments futile.

Thus, the EPA needs to consider ways to financially support public water agencies to comply with the proposed MCLs. Financial assistance must also be able to be accessed by agencies that serve differing populations. Water supplies are not distinguished between economic classes. A single water supply that contains PFAS may be used to deliver water to disadvantaged and non-disadvantaged communities. Providing financial assistance limited to a DAC would be a disservice to the non-DAC portions of a water agency's service territory and will not help the EPA achieve the goal of ridding water supplies of PFAS contaminants.

Therefore, CMUA urges the EPA to offer financial assistance without DAC limitation to public water agencies to comply with the Regulation.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. More information on the HRRCA can be found in section 13 of the EPA response in this *Response to Comments* document, more information on an affordability analysis can be found in section 10.5 of the EPA response in this *Response to Comments* document. It is important to note that the DWSRF set-asides can be used to obtain test kits/laboratory equipment for systems to test for newly recognized contaminants of concern and training to use that equipment as mentioned in the memorandum from Radhika Fox dated 8 March 2022 titled "Implementation of the Clean Water and Drinking Water State Revolving Fund Provisions of the Bipartisan Infrastructure Law." More information on analytical methods may be found in section 7 of the EPA response in this *Response to Comments* document. More information on monitoring and compliance requirements may be found in section 8 of the EPA response in this *Response to Comments* document, more information on trigger levels may be found in section 8.8 of the EPA response in this *Response to Comments* document. For concerns related to false negatives or positives, please see section 8.7 of the EPA response in this *Response to Comments* document. For commenter concerns regarding practical quantitation levels (PQLs), including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

National Rural Water Association (NRWA) (Doc. #1641, SBC-043263)

3. Available Funding

The State Revolving Fund (SRF) model has left many small, disadvantaged communities behind. The Infrastructure Investment and Jobs Act of 2021 (IIJA) appropriated $4 billion over 5 years

for projects that are Drinking Water SRF eligible whose primary purpose must be to address emerging contaminants, with a focus on PFAS. 25 percent of this BIL funding is targeted toward disadvantaged communities and/or communities of fewer than 25,000 people. Additionally, EPA recently announced the availability of $5 billion as part of the Emerging Contaminants in Small or Disadvantaged Communities grant program that can be used to reduce PFAS in drinking water in communities facing disproportionate impacts. The goal of the Emerging Contaminants in Small or Disadvantaged Communities grant program is for states to provide grants to public water systems in small or disadvantaged communities to address emerging contaminants, including PFAS. The proposed rule's financial analysis assumes 100% of water systems will receive financial assistance. Although this available funding is a good start, it does not go far enough to address the need. The total cost of capital improvements for all small systems across the United States is unknown. Additionally, most small systems have not begun to sample making it impossible to accurately forecast the cost to implement this rule. Controls must be established to ensure the smallest, and most disadvantaged communities will receive the funds needed. In many states the SRF funding is going directly to large, well-established communities.

Additionally, many states have struggled to spend their allocated SRF money. In a study published by Duke Nicolas Institute for Environmental Policy Solutions and the Environmental Policy Innovation Center, it is stated that "Nationwide there is $9.9 billion in SRF funding that states have not committed to projects." See Report Here [Link: https://nicholasinstitute.duke.edu/publications/uncommitted-state-revolving-funds#:%7E:text=States%20and%20the%20federal%20government,Revolving%20Fund%20(SRF)%20programs.] . There are many reasons why the SRF funding isn't being spent that are not the fault of the state SRF staff: capacity, staffing, resources, and funding. These challenges will be compounded by the influx of new money, further challenging the state staff.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA's national level cost analysis in the HRRCA does not assume 100 percent water systems will receive financial assistance, as was suggested by the commenter. The commenter may be referring to the EPA's supplemental affordability analyses that examined the impact of the rule when accounting for the financial assistance through BIL and other sources that are generally available to small systems. The EPA disagrees with commenters that stated this assumption was flawed; see section 14.11 of the EPA response in this *Response to Comments* document for more information.

National Rural Water Association (NRWA) (Doc. #1641, SBC-043278)

• EPA requests comment on the type of assistance that would help small public water systems identify laboratories that can perform the required monitoring, evaluate treatment technologies and determine the most appropriate way to dispose of PFAS contaminated residuals and waste the systems may generate when implementing the rule.

Response: Small public water systems are going to need technical assistance and funding to identify laboratories to perform monitoring, evaluate the best treatment technologies and determine the most appropriate and cost-effective ways to dispose of treatment residuals and waste. While a great deal of money has been appropriated – the greater challenge will be getting it out to the small systems - and doing so in a timely manner.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. For more information on technical assistance for Best Available Technologies, or their evaluation, please see section 10.1 of the EPA response in this *Response to Comments* document. For information on disposal of treatment residuals, please see section 10.4 of the EPA response in this *Response to Comments* document. For information on monitoring, including laboratories, please see section 8 of the EPA response in this *Response to Comments* document.

National Rural Water Association (NRWA) (Doc. #1641, SBC-043280)

Thank you for the opportunity to participate and comment. NRWA is very appreciative of the agencies' many public outreach opportunities. We believe our recommendations will result in a better rule once finalized. PFAS was not caused or created by our small, rural water systems. As such, these systems should not carry the financial burden of detecting, remediating, and monitoring PFAS. These costs will cripple the systems and negatively impact our most distressed communities. NRWA is ready to work with the EPA to responsibly remove concentrations of PFAS from drinking water in a manner that doesn't burden the systems, rate payers, and taxpayers that bear no responsibility in introducing PFAS into the environment.

If you have any questions, please contact NRWA's Senior Executive Policy Director, Charles Stephens (charles@nrwa.org).

Sincerely,

Matthew Holmes

Chief Executive Officer

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Raptor Pharm & Tox, Ltd (Doc. #1644, SBC-043414)

May 30, 2023

Following are public comments submitted by Raptor Pharm & Tox, Ltd. These comments are not on behalf of any other party. These comments are in response to EPA Docket EPA-HQ-OW-2022-0114-0027, the Per-and Polyfluoroalkyl Substances National Primary Drinking Water Regulation. These comments were prepared by our President and CEO, Dr. Lyle Burgoon, ATS. We would be happy to engage with EPA further with respect to our comments.

Raptor Pharm & Tox, Ltd (Raptor) is a North Carolina small business. Part of our expertise is regulatory toxicology. Raptor strives to ensure policies are based on the highest quality science, and has several outreach programs to help inform the public about both good quality and low quality science that is being talked about in the press, or is being used to formulate policy.

Raptor is concerned about the economic impacts of these Primary Drinking Water Standards on small businesses and the poor. Ultimately, these drinking water standards, at the levels being proposed, would significantly drive costs up at the point of water treatment. That means the water bills for America's small businesses and everyone with a tap at their house will significantly increase. At this time, America's small businesses are under immense pressure – from inflation driving our costs up, to inflation driving down spending, and from the Federal Reserve's actions further driving down consumer spending. These have cascading effects that ultimately hit America's small businesses the hardest of all businesses.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Raptor Pharm & Tox, Ltd (Doc. #1644, SBC-043415)

Not only that, but increasing costs for water, will disproportionately impact the poor. Water is necessary for life. Already today, there are poor individuals who have to choose which bill they will pay this month. As costs continue to increase on the poor individuals, including our grandparents, our senior citizens, those who cannot work, and children who have no say in any of this, we will further burden the poor, and further widen the wealth gap.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. More information on the HRRCA can be found in section 13 of the EPA response in this *Response to Comments* document, more information on an affordability analysis can be found in section 10.5 and 14.11 of the EPA response in this *Response to Comments* document.

GFL Environmental (Doc. #1648, SBC-043224)

• Funding shortfalls: The Building Infrastructure Law (BIL) provides a total of $10B for Emerging Contaminants, including $5 billion for the Emerging Contaminants in Small or Disadvantaged Communities (EC-SDC) grant program, which focuses on addressing emerging contaminants, such as PFAS in small or disadvantaged communities' drinking or source water. Funding shortfalls are anticipated as the cost to identify the presence, source, and extent in source water alone is substantial and with cost impacts associated with drinking water treatment alone anticipated to be as much as $60 billion, funding is inadequate.

Thank you for your consideration of our comments, and we look forward to continuing to partner with EPA to ensure the safe and effective management of waste streams containing PFAS.

Sincerely,

GFL ENVIRONMENTAL

Selin Hoboy | Vice President - EHS & Compliance 847-456-8889 | shoboy@gflenv.com

References

AWWA, 2023. WITAF 56 Technical Memorandum. PFAS National Cost Model Report. Published March 7, 2023.

ATSDR, 2018. PFAS MRLs and EMEGs. https://www.atsdr.cdc.gov/pfas/resources/mrl-pfas.html#:~:text=ATSDR%20Minimal%20Risk%20Levels%20(MRLs,result%20in%20adverse%20heal th%20effects. Published November 2018.

EPA, 2000. Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures. EPA/630/R-00/002. Published August 2000.

EPA, 2023. Statement on Proposed MCL for PFOA and PFOS. EPA Public Hearing. May 4, 2023.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document, particularly the amount of funding available, which the EPA notes is higher than suggested by the commenter.

New England Interstate Water Pollution Control Commission (NEIWPCC) (Doc. #1650, SBC-043146)

Finally, our member states are concerned that the rule will place a disproportionate burden on smaller community water systems. In general, small systems tend to contract with smaller laboratories for services. However, the smaller laboratories are less likely to be certified for PFAS. Those smaller laboratories, therefore, will likely subcontract the PFAS analyses out to other laboratories. As a result, small systems will incur higher cost. Small systems generally have fewer resources and, if privately-owned, may be ineligible for state financial assistance. Our member states anticipate that the financial challenges smaller systems have been experiencing will be compounded by the increased monitoring costs imposed by the rule. It, therefore, is imperative that EPA take into consideration the ability of smaller systems to carry this increased expense.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044196)

6. NCDEQ recommends that EPA continue funding research for the treatment of emerging contaminants in drinking water, especially treatment at small water systems.

Based on costs associated with the BAT, state agencies anticipate that small and disadvantaged water systems that exceed the MCL will face financial difficulties in implementing any of the

treatment options. While funding under the Bipartisan Infrastructure Law may be available for some systems, each of the BAT are costly treatment methods with high operation and maintenance costs. For many systems, these costs will be passed on to ratepayers. North

Carolina has a diverse and robust research community that could support such research needs. NCDEQ is available to work with EPA to develop collaborative partnerships between federal government, states, and academia to maximize the benefits of multiple funding sources.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA has invested in evaluating and developing technologies for reducing PFAS in the environment to inform decisions on drinking water and wastewater treatment, contaminated site cleanup and remediation, air emission controls, and end-of-life materials management. Please see sections 10.1 and 10.2 of the EPA response in this *Response to Comments* document.

Virginia Municipal Drinking Water Association (VMDWA) (Doc. #1657, SBC-043170)

Third, the construction project pricing recent experience for VMDWA Members projects is already adversely impacted by the currently high volume of engineering and construction work in the water sector (water, wastewater, stormwater), on road and bridge projects, and on other infrastructure projects. Relatedly, unemployment is low and inflation continues to run very high. Our Members have reported construction bid prices exceeding engineering estimates easily in the range of 2550% and the number of responsive bidders is relatively low compared to historical activity.

Fourth, with ongoing ARPA spending on infrastructure projects (with a 2026 completion deadline presently) and upcoming Bipartisan Infrastructure Law grant and loan projects, this situation is on track to get worse – and that is before adding in thousands of water treatment plants upgrades that EPA expects under this regulation.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA has provided compliance flexibility through a two-year capital improvements extension of the MCL compliance deadline allowed by Section 1412(b)(10) of SDWA. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 on extensions and exemptions in this *Response to Comments* document. More information on the HRRCA can be found in section 13 of the EPA response in this *Response to Comments* document.

Maryland Association of Municipal Wastewater Agencies (MAMWA) (Doc. #1658, SBC-043405)

Third, the construction project pricing recent experience for utility projects is already adversely impacted by the currently high volume of engineering and construction work in the water sector (water, wastewater, stormwater), on road and bridge projects, and on other infrastructure

projects. Relatedly, unemployment is low, and inflation continues to run very high. Our Members have reported construction bid prices exceeding engineering estimates easily in the range of 25-50% and the number of responsive bidders is relatively low compared to historical activity.

Fourth, with ongoing ARPA spending on infrastructure projects (with a 2026 completion deadline presently) and upcoming Bipartisan Infrastructure Law grant and loan projects, this situation is on track to get worse – and that is before adding in thousands of water treatment plants upgrades that EPA expects under this regulation.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1657, SBC-043170 from the Virginia Municipal Drinking Water Association (VMDWA).

National Association of Clean Water Agencies (NACWA) (Doc. #1659, SBC-043154)

EPA continues to point to the 2021 Bipartisan Infrastructure Law's (BIL) $9 billion allotment for drinking water investments to address PFAS and other emerging contaminants as a way to cover the increased costs. While the BIL funding is a historic federal water infrastructure investment—it is a mere drop in the bucket when considering the 66,000 public water systems that will be impacted by this proposed rulemaking. Some utilities are estimating they will need to spend billions of dollars at their facilities alone to treat PFAS over the next several decades. The sheer national scope and financial impact of EPA's proposed rule on public utilities far exceeds the investments provided by the BIL, which will be allocated and exhausted in a few short years.

Around the country, communities and their ratepayers are already facing heightened affordability challenges to cover the rising costs of water, wastewater, and stormwater services. To meet the MCLs proposed by this rulemaking, communities and ratepayers will bear the brunt of the treatment costs—further exacerbating the affordability gap disproportionately affecting low-income customers.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that significantly more money is available through BIL than suggested by the comments and notes that the estimated number of systems subject to the rule is stated directly in section VI.F of the proposed and final rule preamble at 4,100-6,700. For more information on numbers of systems subject to the rule, please see section 6 of the EPA response in this *Response to Comments* document.

Maine Organic Farmers and Gardeners Association (MOFGA) (Doc. #1660, SBC-043380)

The costs and scope of that taxpayer-funded assistance is taking shape through the Fund to Address PFAS Contamination, and it is proving to be an expensive proposition. Starting with an initial appropriation of $60 million, the PFAS Fund Advisory Committee's draft implementation plan currently estimates nearly $80 million will be needed over the next several years to mitigate

the devastating impact of PFAS on farmers' livelihoods, to purchase contaminated farmland, to pay for PFAS blood testing and health monitoring, to conduct research, and more. [FN3: https://www.maine.gov/dacf/about/commissioners/pfasfund/advisory-committee.shtml]

The $80 million figure is in addition to the millions of dollars the State is already paying to comprehensively investigate PFAS contamination of soils and water and to pay for water filtration for contaminated wells. Nor does this amount account for the cost to municipalities and their residents to properly dispose of PFAS-contaminated wastewater sludge residuals instead of continuing the polluting practice of land application of sludge and sludge-derived compost.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Water Supply District of Acton (Doc. #1662, SBC-043660)

Adequate funding has not yet been identified to help address our basic infrastructure needs, let alone to comply with these new PFAS standards. Our rate payers have already committed $35 million since 2009 to address water treatment upgrades to comply with state and federal requirements. EPA's most recent estimate for Massachusetts was recently released, the 7 th Drinking Water Infrastructure Needs Survey and Assessment [FN1: https://www.epa.gov/system/files/documents/2023-04/Final_FAQ DWINSA_4.4.23.v1.pdf], and it shows $15 billion in need over the next 20 years to maintain public health protections. This estimate doesn't include any costs associated with complying with the proposed PFAS standards. Congress and the Biden Administration need to fully fund the treatment and ongoing operations and maintenance costs necessary to remediate PFAS in our nation's drinking water and seek reimbursement from the generators who have caused this problem. The federal government has far more resources and abilities to pursue legal actions and seek reimbursements from PFAS manufacturers than do individual PWS or groups of PWS. Our actions to treat PFAS are a long-term commitment that will forever change our operating costs; any existing financial assistance available to the District is in the form of capital financing and limited principal forgiveness. EPA must look at the full cost implications of PFAS treatment and establish a fund to assist with the remedial costs in perpetuity.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Santa Clara Valley Water District (Valley Water) (Doc. #1664, SBC-043125)

Comment 1 – Valley Water Urges the EPA to Minimize the Burden on Ratepayers

Valley Water is committed to ensuring safe, clean water for the nearly two million residents of Santa Clara County. We will continue to take all action needed to ensure the treated water we deliver meets or exceeds all drinking water standards and to "aggressively protect groundwater from the threat of contamination" in accordance with our Board of Directors policy. Board

policy also directs us to "promote access to equitable and affordable water supplies" and we take that responsibility seriously.

Despite having no role in the production of PFAS or the release of these "forever chemicals" into the environment, water agencies must now find ways to remove them from local water supplies or identify alternative water supplies. Valley Water supports the EPA's efforts to limit PFAS in drinking water but encourages the EPA to minimize the financial burden on water agencies and ratepayers.

As described in the ACWA comment letter, nationwide water utility costs from the proposed rule will likely far exceed the EPA's cost estimate. While the Bipartisan Infrastructure Law provides much-needed funding, more will be necessary to address PFAS contamination in all communities. Valley Water supports a strong focus on financial support to address PFAS contamination in disadvantaged communities. However, PFAS will impact broad communities nationwide, as water supplies are not distinguished between economic classes, geographical, or demographic boundaries.

Like most other water utilities, Valley Water is already facing significant pressure on rates due to increased capital and operations costs, aging infrastructure, source water quality challenges, and new investments needed for continued water supply reliability. Valley Water encourages the EPA to hold polluters accountable and to consider ways to provide financial assistance to all impacted water agencies such that ratepayers are not unduly burdened with the costs for addressing PFAS contamination.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044395)

Costs to public water systems including funding treatment design and installation, operation and maintenance, availability of certified operators for implementing treatment options, and potential treatment supply chain product availability represent challenges especially to small water systems.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Inland Empire Utilities Agency (IEUA), California (Doc. #1666, SBC-043388)

Water and wastewater providers do not use PFAS in their process but are passive receivers. EPA's proposed regulation would result in significant cost increases on essential public service providers which would have severe negative impacts on the communities and residents they serve.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

City of Allentown and Lehigh County Authority (LCA), Pennsylvania (Doc. #1667, SBC-043683)

4. Funding Capacity & Timing -- Infrastructure Investment and Jobs Act (IIJA) may be a vital resource for water utilities in their efforts to achieve compliance with the proposed PFAS rule. However, the $55 billion allotted for water infrastructure is set to expire in 2026 which is before the implementation date of the proposed rule. Further, the water process for applying and receiving IIJA or other funds through the Drinking Water State Revolving Fund (DWSRF) or the Water Infrastructure Finance and Innovation Act(WIFIA) can be time consuming.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

City of Allentown and Lehigh County Authority (LCA), Pennsylvania (Doc. #1667, SBC-043685)

In addition, efforts should be made to find avenues to extend the availability of current funding streams so that support is available for utilities when they need it.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

City of Hillsboro, Oregon (Doc. #1668, SBC-043122)

Hillsboro Water greatly encourages EPA to increase the funding availability for infrastructure investments to allow utilities to implement and install the needed advanced treatment technology to ensure their drinking water meets the proposed MCLs and MCLGs.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-044912)

Cleveland Water supports EPA in protecting public health by ensuring safe, clean drinking water to the public at an affordable rate. This is why it is crucial EPA is using all the resources available to make the decisions that will have profound financial implications on the public. EPA always has the authority to strengthen drinking water standards when new data or science presents itself, but the agency is not able to walk back previously finalized standards if subsequently obtained data demonstrates that the occurrence of a contaminant is not as widespread as had been believed. This means that water system ratepayers would be permanently saddled with monitoring and treatment costs related to these low-occurrence contaminants –

funding that may be put to better use addressing improving infrastructure or addressing widespread contaminants that pose broad threats to public health.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that less occurrence than estimated would decrease estimated treatment costs and there would be more resources available to fewer communities providing treatment. Funding is also included to address leaded pipes and to supplement the DWSRF and CWSRF, which may be used to improve infrastructure or address widespread contaminants. Finally, it is important to note that occurrence is one piece of an important puzzle, more information on how the EPA regulates contaminants as well as the regulatory process can be found in sections 2.3 and 3 of the EPA response in this *Response to Comments* document.

Association of California Water Agencies (ACWA) (Doc. #1675, SBC-044931)

EPA points to funding provided in the Bipartisan Infrastructure Law (BIL) as the answer to the impending costs of this proposal. The BIL provides $9 billion to invest in drinking water systems specifically impacted by PFAS and other emerging contaminants through the Drinking Water State Revolving Fund (DWSRF) and Emerging Contaminants in Small or Disadvantaged Communities Grant Program.

ACWA appreciates this foundational funding to address PFAS contamination, however, the anticipated total costs of this proposal, including both capital and operation and maintenance costs, would greatly exceed this additional funding. Accurate cost estimates of proposed drinking water regulations are directly tied to whether the regulation is "feasible" under SDWA. As a result, ACWA believes the proposed rule is not feasible because the anticipated costs of this regulation have not been sufficiently evaluated.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that significantly more funding than suggested by the commenter is available through BIL, as noted in section 2.4 of the EPA response in this *Response to Comments* document. The EPA has published extensive details regarding its economic analysis (EA) as well as feasibility determination, and more information can be found in section 13 of the EPA response in this *Response to Comments* document as well as the rule supporting documents, such as the Best Available Technologies and Small System Compliance Technologies for PFAS in Drinking Water and the Technologies and Costs for Removing Per- and Polyfluoroalkyl Substances from Drinking Water documents.

City of Vancouver Water Utility, Vancouver, WA (Doc. #1684, SBC-044301)

May 30, 2023

Michael S. Regan

Administrator Environmental Protection Agency 1200 Pennsylvania Avenue, N. W.

Mail Code: 4607M Washington, DC 20460

RE: Docket ID No. EPA-HQ-OW-2022-0114 Comments - Draft PFAS Primary Drinking Water Regulation

General Comments:

Thank you for the opportunity to comment. The City of Vancouver Water Utility is in support of the development of a science based Per- and Polyfluoroalkyl Substances (PFAS) Primary Drinking Water Regulation that supports public health. The PFAS rulemaking and the assurance of providing a safe water supply and a safe environment for our residents are extremely important to the City of Vancouver. Protection of our natural resources and ultimately protection of the citizens is of the utmost concern.

However, there are substantial questions with EPA's current proposal. It is critical that EPA gets this right, as the costs that the proposed rule would impose are significant, and significantly underestimated, leading to several challenges to the water utilities. We urge EPA to conduct a more thorough analysis that more accurately captures the costs of compliance and if necessary, the agency collects more data to inform and address the gaps that currently exist. This should be a reasonable request given that the agency caveated its own work in the posting by listing a host of data limitations and uncertainties from a lack of modeling national costs for treatment.

Vancouver is committed to limiting exposure to PFAS and protecting the environment. At the same time, we want to ensure efforts do not impose unintended consequences by unnecessarily directing resources away from other water system priorities like noncompliance with existing pollutant MCLs, the lead service line inventory, cybersecurity, replacement of failing infrastructure, or conservation and resiliency efforts. The reallocation of resources to deal with a PFAS response at the proposed levels will mean deferring on maintenance, which could risk failure of water infrastructure and be ultimately more costly in terms of quality of life in dollars, public health, and the environment.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA's final rule represents data-driven drinking water standards that are based on the best available science, meet the requirements of SDWA, and regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. Funding is also included to address leaded pipes and to supplement the DWSRF and CWSRF, which may be used to improve infrastructure or address widespread contaminants. See section 13.3.3 on the EPA's response to comments on national treatment costs, and section 13.3.2 for the EPA's response to comments on the costs of the Hazard Index, specifically. Further, the EPA notes that it is best practice to identify known data limitations and uncertainties in any scientific or economic analysis, including this one (see e.g., USEPA Guidelines for Economic Analysis for more information). Finally, the EPA modeled national treatment costs of treating for PFOA, PFOS, and PFHxS. System level costs for treating PFNA, Gen X, and PFBS are discussed in detail in section13.3.2 of the EPA response in this *Response to Comments* document.

Massachusetts Coalition for Water Resources Stewardship (MCWRS) (Doc. #1691, SBC-044321)

More specific comments are as follows:

1. EPA's cost estimate for nationwide compliance with the proposed MCLs is significantly lower than estimates prepared by experts in the water profession. EPA's costs analysis suggests annualized compliance costs of up to $1.3 billion based on up to 6,300 water systems exceeding one or more of the proposed MCLs. The American Water Works Association (AWWA) had a cost estimate prepared by an engineering consulting firm experienced in the design of water treatment facilities. The AWWA estimate landed at $40-$55 billion for total compliance costs and annualized costs of $3.8 billion to $5.2 billion. Here in Massachusetts, the most recent Intended Use Plan for the State Revolving Fund found the state financing 24 PFAS drinking water treatment projects for a total of $209 million, or $8.7 million per project. The AWWA analysis and the Massachusetts SRF data suggest EPA's estimated costs are well below the mark. If the costs are underestimated then the cost benefit analysis would also be skewed and the federal funding through the Bipartisan Infrastructure Law (BIL), which is touted as the solution to the cost impact for PFAS compliance, will also be inadequate. Water ratepayers will carry the burden of funding PFAS MCL compliance unless federal grants are increased to cover the costs.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs; see section 13.3.3 of the EPA response in this *Response to Comments* document for details.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045011)

New Jersey also notes that the successful implementation of the proposed primary drinking water standards will require a sustained long-term investment in water and waste management infrastructure. While the Bipartisan Infrastructure Law has provided a historic level of investment, New Jersey's analysis of the projected cost of implementing the proposed primary drinking water standards has indicated that significant additional funding will be required. The cost of designing, installing, and maintaining treatment facilities for water systems to comply with the proposed standards, as well as for primacy agency oversight, will be significant, and ongoing and increased support from the federal government is essential to prevent the upfront cost of compliance from being borne solely on the shoulders of residents in the form of increased water bills.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Association of California Water Agencies et al. (Doc. #1701, SBC-043837)

Water systems are responsible for addressing various public health risks while also working to maintain affordable rates for their community. Regulations must not impose excessive financial burdens on ratepayers that drive rates beyond affordable levels for low-income households, as economic hardships can force difficult choices between water bills and essential needs. Our groups acknowledge the funding that the Bipartisan Infrastructure Law provides for PFAS, but given the estimates of organizations signing this letter, we reiterate to EPA and to Congress that this money is nowhere near enough to cover the cost of compliance.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Protecting Our Water, Environment, and Ratepayers (POWER) (Doc. #1714, SBC-045933)

The pass-through cost of implementation is very high and may prevent poor and rural communities from maintaining access to safe drinking water.

EPA's proposed NPDWR acknowledges that, in general, water agencies are able to pass through cost increases to their consumers. As such, it is important to adequately consider the actual costs to consumers to determine the proportionate impact and the feasibility of these changes. As of 2019, the average household spends $876/year on water. Table 22 [FN14: Proposed Rule, 88 Fed. Reg. at 18687.] has been revised to reflect the percent increase of cost for implementing the technologies necessary for PFAS treatment.

[Table 1: See Docket ID EPA-HQ-OW-2022-0114-1714]

GAC=Granular Activated Carbon; IX = Ion Exchange; RO=Reverse Osmosis; NF = Nano-filtration; POU = Point of Use

As shown by the amended table, implementing any of the technologies will substantially increase the average household cost of water with a disproportionate impact on rural communities or lower income families.

POWER! is concerned that many of the communities we serve will find it difficult to afford these pass-through costs for significant investments in new treatment infrastructure and treatment byproduct disposal in just three years. This will require water and wastewater agencies to rely on either limited federal funds to perform the treatment upgrades or take on substantial debt in a very short window. It will also increase water and wastewater agencies' operation and maintenance costs and the public's utility bills in perpetuity. In addition to our duties to serve clean water and wastewater, POWER! members each have a duty to ensure costs are reasonable and affordable for the public we serve.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Wyoming Department of Environmental Quality (WDEQ) (Doc. #1716, SBC-044763)

12. WDEQ Recommends EPA Provide Additional Training and Funding Opportunities for Small and Rural PWSs Due to the Increased Burden of Training to Implement Best Available Technologies (BATs) for PFAS Treatment of Drinking Water

The BATs presented in the proposed PFAS NPDW rule will require an increase in the PWS operator certification level. Recruitment of qualified operators is already a significant challenge in small and rural communities. The proposed BATs will result in an increased cost to small and rural PWSs by resulting in them needing to offer additional training and appropriate pay for existing operators or employ workers with the required certifications. EPA should provide additional training and funding opportunities for small and rural PWSs to help ensure that communities have available and trained workforces. Without EPA support, the costs will be passed on to consumers, who are already being impacted by cost-of-living increases.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA recommends states use the full DWSRF 2 percent small system technical assistance set-aside and the newly available CWSRF 2 percent technical assistance funds to enhance or build programs that proactively identify, reach out to, and provide assistance to rural, small, and Tribal publicly owned treatment works and drinking water systems, particularly in disadvantaged communities. The programs should be designed to help disadvantaged communities identify needs, develop projects, apply for funding, design and implement projects, build capacity, and create training and career pathways. The agency has been collaborating with states, technical assistance providers, industry associations, and interested stakeholders to provide technical materials that can assist water systems in complying with the regulations, as well as outreach efforts to help develop technical and operator capacities. More information on available operator and technology capacity can be found in section 10.6 of the EPA response in this *Response to Comments* document.

Monte Vista Water District (MVWD) (Doc. #1718, SBC-043529)

The cost to treat PFAS can vary depending on several factors, including the specific treatment method, volume and concentration of PFAS contaminants, the site characteristics, and local regulations. Estimates for PFAS treatment can reach several million dollars, requiring significant funding for such projects. Operational costs associated with compliance testing and disposal of spent media are also significant. Federal and state funding will be required to offset both capital and operational PFAS treatment costs, which would otherwise disproportionately affect the disadvantaged and low-income communities we serve.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA agrees that site-specific factors impact rule compliance cost.

Monte Vista Water District (MVWD) (Doc. #1718, SBC-043535)

The cost to treat PFAS can vary depending on several factors, including the specific treatment method, volume and concentration of PFAS contaminants, the site characteristics, and local regulations. Estimates for PFAS treatment can reach several million dollars, requiring significant funding for such projects. Operational costs associated with compliance testing and disposal of spent media are also significant. Federal and state funding will be required to offset both capital and operational PFAS treatment costs, which would otherwise disproportionately affect the disadvantaged and low-income communities we serve.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Thurston Public Utility District (PUD), WA (Doc. #1729, SBC-043588)

7. On page 18,639, funding should be provided by the EPA to Washington State to provide an effective implementation and data system support to implement the HI if approved.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. States can use a portion of the SRFs for administration of the funds.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045962)

AMWA supports EPA in protecting public health by ensuring safe, clean drinking water to the public at an affordable rate. This is why it is crucial EPA is using all the resources available to make these decisions that will have such profound financial implications for the public. EPA always has the authority to strengthen drinking water standards when new data or science presents itself, but the agency is not able to walk back previously finalized standards if subsequently obtained data demonstrates that the occurrence of a contaminant is not as widespread as had been believed. This means that water system ratepayers would be permanently saddled with monitoring and treatment costs related to these low-occurrence contaminants – funding that may be put to better use addressing improving infrastructure or addressing widespread contaminants that do pose broad threats to public health.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that less occurrence than estimated would decrease estimated treatment costs and there would be more resources available to fewer communities providing treatment. Funding is also included to address leaded pipes and to supplement the DWSRF and CWSRF which may be used to improve infrastructure or address widespread contaminants. Finally, it is important to note that occurrence is one piece of an important puzzle, more information on how the EPA regulates contaminants as well as the regulatory process can be found in sections 2.3 and 3 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045946)

May 30, 3023

Michael S. Regan Administrator

U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, NW Washington, D.C. 20460

Via electronic submission

Re: Docket ID #: EPA-HQ-OW-2022-0114; PFAS National Primary Drinking Water Regulation Rulemaking

Dear Administrator Regan,

The Association of Metropolitan Water Agencies (AMWA), an organization representing the largest publicly owned drinking water utilities in the United States, welcomes the opportunity to provide comments on the proposed National Primary Drinking Water Regulation of PFOA, PFOS, PFBS, HFPO-DA and its ammonium salts (known as GenX), PFNA, and PFHxS. AMWA strongly supports policies that protect public health and economic vitality via safe, affordable, and sustainable drinking water. AMWA appreciates the opportunity to lay out its concerns with elements of the rulemaking – particularly related to costs/affordability and compliance timeline, among many others.

Although AMWA supports regulating PFOA and PFOS in drinking water, AMWA disagrees with EPA's choice to place the lion's share of the financial burden of PFAS removal from drinking water on the American public rather than those producing and manufacturing these chemicals. EPA should be pursuing a polluter pays principle, where polluters are responsible for PFAS pollution prevention and remediation. EPA could mitigate these costs without compromising protection of public health by prioritizing water systems with the highest concentrations of PFAS. By doing so, these systems would gain expedited access to essential project resources including supplies, labor, and funding.

EPA's cost analysis vastly underestimates the real-world costs that this rulemaking will impose on public water systems, and ratepayers will bear those costs. Even worse, those costs will disproportionately affect economically disadvantaged and underserved communities. As EPA continues to work toward addressing environmental justice, the agency should be working to reduce burdens on these communities, not imposing further financial stresses. Given the numerous pressing priorities that public water systems are already grappling with, including challenges posed by aging infrastructure, compliance with various regulations, the impacts of climate change, and the current difficulties stemming from inflation, labor shortages, and disruptions in the supply chain, it is evident that more time than what is proposed in this rulemaking will be necessary for the implementation of PFAS treatment technologies. Projects of this magnitude can rarely be done in three years, but with the certainty of additional time, many water systems will be able to come into compliance by the deadline.

The association was able to provide the following comments to EPA in the short, 60-day comment period that was given for such an intricate and consequential rulemaking. In addition to real-world data and information AMWA collected from members who have explored or are currently exploring PFAS treatment, the association commissioned a report on the additional benefits and disbenefits of this proposed rule. This report can help EPA further explore the costs and benefits of its final rulemaking.

AMWA welcomes the opportunity to engage in continued dialogue regarding the effective implementation of this proposed rulemaking, with the overarching objective of enhancing public health protections in a manner that is financially feasible and accessible to all. If you have any additional questions, please contact Brian Redder (Redder@amwa.net), AMWA's Manager of Regulatory and Scientific Affairs.

Sincerely,

Tom Dobbins

Chief Executive Officer

Attachments

cc: Radhika Fox, OW Bruno Pigott, OW

Jennifer McLain, OGWDW

Eric Burneson, OGWDW

Ryan Albert, OGWDW

Alex Lan, OGWDW

Comments on Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

Docket ID No. EPA-HQ-OW-2022-0114

May 30, 2023

[Table of Contents, see docket ID EPA-HQ-OW-2022-0114-1738]

Section 1: Overarching comments

AMWA continues its strong support of regulation based on sound science that is protective of human health. Due to the significant risks of severe health effects and their persistent nature, AMWA agreed with EPA's 2021 final determination to regulate perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) in drinking water. Public water systems (PWSs) and EPA share the same goal of ensuring the delivery of clean, safe drinking water to the public, and AMWA welcomes continued dialogue with EPA on the best ways to accomplish this goal.

PWSs provide an important and valuable service to the public, and the burdens of pollution remediation should not be solely placed on these systems and their ratepayers. Foremost, EPA

should focus its resources on incentivizing pollution prevention and regulating per- and polyfluoroalkyl substances (PFAS) pollution where it is manufactured and/or used, rather than putting the entirety of burdens on passive receivers. It is much easier and more cost effective to prevent chemical discharges from entering the nation's waterways than trying to remediate pollution downstream. EPA must do more to hold polluters accountable and implement the "polluter pays" principle, where those causing pollution are responsible for the cost of clean-up. Relying solely on PWS ratepayers to finance the removal of contaminants shifts this responsibility to a "community pays" model, where the burdens of pollution removal are unfairly placed on the public.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. In the SRFs, funding is included to address leaded pipes and to supplement the DWSRF and CWSRF, which may be used to improve infrastructure or address widespread contaminants. Information on simultaneous compliance with other regulations is provided in section 10.4.2 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045979)

Another concerning aspect of these technologies is that the removal media does not maintain the same level of performance indefinitely and will require routine replacement or reactivation. For AIX, once the resin has been spent, there is no feasible way to reactivate it. GAC can be reactivated but only a finite number of times. With levels proposed at the PQL of 4.0 ppt, water systems that have already implemented one of these technologies for PFAS treatment will face increased costs and must revise treatment plans. To reliably treat down to the proposed level, which is half the level of the lowest state MCL, will require much more frequent replacement of media. In some instances, PWSs have indicated this will cut their media life in half. This will significantly increase operation and maintenance costs and will also require more frequent and distant transport by trucks of spent material to disposal sites or fossil-fuel-operated reactivation facilities, resulting in more contributions of greenhouse gas (GHG) emissions and quickly fill landfills. With only a select few GAC reactivation facilities in the country, significant transport costs, often time across state lines, will be required.

AMWA wants to reiterate that EPA and the association are both working toward the same goal of protecting public health by providing drinking water that is not only clean and safe but also affordable. Many utilities across the U.S. are struggling with the ability to maintain affordable rates in light of routine required capital and regulatory projects. Regulations must not put unnecessary financial burdens on ratepayers. Any economic hardship can cause individuals to have to make difficult choices like choosing between paying water bills and buying groceries. Access to safe, clean drinking water is a necessity, and it is important to develop regulations that do not unnecessarily compromise the abilities of PWSs to provide water access that is affordable and equitable.

While AMWA was and continues to be extremely supportive of the passage of the Bipartisan Infrastructure Law (BIL), the money provided will be insufficient to cover the cost of this rule. Between replacing lead service lines, addressing water scarcity, and upgrading aging infrastructure, there simply are not enough federal funds to offset large increases in water bills. It is difficult for utilities to justify rate increases when federal funds available are presented as grants and a catch-all fix to the affordability issue. EPA should use the momentum of recent federal legislation to highlight projects being done with federal funds but also illustrate the need for funding for projects that still need to be done.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. More information on Best Available Technologies is included in section 10. The EPA notes that while granular activated carbon (GAC) can be reactivated repeatedly, we estimate that roughly 20 percent will need to be replaced each activation cycle. While anion exchange (AIX) resins can be regenerated, the EPA expects that this will be unlikely for drinking water utilities based on our research. SRFs include set asides to address leaded pipes and to supplement the DWSRF and CWSRF, which may be used to improve infrastructure or address widespread contaminants. Greenhouse gases and the social cost of carbon were addressed in the economic analysis (EA), as described in section 13 of the EPA response in this *Response to Comments* document.

Del-Co Water Company, Inc. (Doc. #1744, SBC-043621)

Again, taking into account information provided in preceding sections of this document, Del-Co questions whether this funding could be allocated to other priorities (e.g., replacing lead service lines, upgrading cybersecurity, replacing aging infrastructure, and assuring sustainable water supplies) which would provide greater benefit, risk reduction, and public health protection to the ratepayers.

Thank you for the opportunity to provide comments on the proposed PFAS regulations. As mentioned previously, PWSs understand the importance of ensuring drinking water meets all Safe Drinking Water Act requirements and protects public health. Therefore, EPA has an obligation to address all stakeholder comments prior to finalizing the regulations. We look forward to working collaboratively with EPA and the state primacy agencies to ensure our PWSs can meet their mandate of continued protection of public health.

Respectfully,

Jeffrey Kauffman

Compliance Manager

6658 Olentangy River Road

Delaware, OH 43015

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. SRFs include set asides to address leaded pipes and to supplement the DWSRF and CWSRF, which may be used to upgrade cybersecurity, replace aging infrastructure, and assuring sustainable water supplies.

City of Thornton, Colorado (Doc. #1748, SBC-044799)

Thank you for considering these comments during the finalization of the PFAS NPDWR. Thornton is supportive of the EPA's efforts to protect consumers but strongly emphasizes that ratepayers should not be responsible for the cost burden of this proposed rule that protects public health from the pollution caused by decades of corporate and industrial malfeasance.

Sincerely,

Caleb Owen

Water Quality Administrator City of Thornton

9500 Civic Center Dr Thornton, CO 80229

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

City of Thornton, Colorado (Doc. #1748, SBC-044782)

In addition, EPA needs to work with Congress to increase funding for PFAS treatment beyond what has currently been established by the Bipartisan Infrastructure Law. EPA also needs to simplify the requirements for receiving these funds. While Thornton generally supports EPA's environmental justice considerations, Thornton also sees advantages to prioritizing funding towards systems that may not qualify as a disadvantaged but will see a greater benefit to public health because that funding will affect a greater number of people or address areas of higher contamination. Likewise, while Thornton as a whole does not meet requirements for a disadvantaged community, the City still contains many neighborhoods that would and also has a significant underrepresented population. Thornton believes it should receive funding from EPA to address PFAS.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. States have the flexibility to determine priorities and select projects for grant funding as well as establish a definition of disadvantaged communities that can receive additional subsidization. States may provide additional funds to municipalities that meet the state's affordability criteria, municipalities that do not meet the state's affordability criteria but seek additional subsidization to benefit individual ratepayers in the residential user rate class, or entities that implement a process, material, technique, or technology that addresses water or energy efficiency goals; mitigate stormwater runoff; or encourage sustainable project planning, design, and construction.

Las Cruces Utilities (LCU) (Doc. #1753, SBC-043924)

In response to Section XIII. Health Risk Reduction and Cost Analysis, EPA requests comment on whether factors such as anticipated Federal funding, the structure of PWSs relative to private enterprises, or the nature of the public health benefits should be further explored in the final rule analysis, including as it relates to the estimated range of impacts under the applied discount rates.

• Federal funding needs to be increased to cover implementation costs of this rulemaking, and the uncertainty regarding the availability of this funding should be further explored in the final rule analysis.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045641)

As part of this proposal, EPA proposes preliminary determinations for PFHxS, PFNA, HFPO-DA, and PFBS concurrently with a proposed drinking water standard for these compounds. The preliminary determinations for PFNA, HFPO-DA, and PFBS are not supported by the available occurrence data and the determination for the mixture of these PFAS is similarly lacking in co-occurrence data and is inconsistent with EPA guidance. Furthermore, the proposed regulation of these compounds concurrently with the preliminary determination is beyond EPA's authority under SDWA. EPA should (i) not finalize the preliminary determinations, (ii) evaluate and, if appropriate, re-issue the preliminary determinations following the availability of UCMR 5 data, and (iii) withdraw and re-issue a scientifically sound and adequately supported proposal to regulate the PFAS among these four which EPA can provide a sound basis for a positive determination to regulate.

With respect to the proposed drinking water standards for PFOA and PFOS, the docket does not support finalizing a rule, particularly a rule where attributable benefits outweigh quantifiable costs. The affordability of EPA's rule options is especially questionable for households served by small systems – systems which SDWA requires EPA give particular attention to in crafting a drinking water standard. If EPA moves forward with a final rule, setting MCLs for PFOA and PFOS at 10 ppt is the most appropriate option among the options EPA has analyzed. This option will prioritize water systems with the highest PFAS levels moving forward immediately.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. Information on occurrence data is contained in section 6 of the EPA response in this *Response to Comments* document. Section 3 of the EPA response in this *Response to Comments* document contains information on regulatory determinations and section 2.3 contains some information on the regulatory process. More information on how the MCLGs were determined is in section 4, and more information on MCLs is in section 5 of the EPA response in this *Response to Comments* document. The EPA has described its use of the best available science in the particular sections (e.g., section 10 for treatment technology information,

section 6 for occurrence, section 4 for health effects). The EPA determined that 4.0 ng/L is feasible (see section 5) and is as close to the MCLG as is feasible. The EPA accounted for costs in its HRRCA and its evaluation of feasibility for the final MCLs. When establishing the MCLs, the EPA considered costs of treatment technologies that have been demonstrated under field conditions to be effective at removing the regulated PFAS and determined that the cost of complying with the MCLs is reasonable (please see section 5.1.3 for additional discussion on cost considerations when establishing the final MCLs).

American Water Works Association (AWWA) (Doc. #1759, SBC-045555)

The responsibility of the Administrator is to ensure that regulatory actions are implemented in a cohesive manner for the effective protection of the environment and the public. It is imperative that the Administrator begin to advance these actions more meaningfully to minimize the role that communities play in addressing PFAS contamination that they were not responsible for causing. Advancing these actions in a more meaningful, cohesive manner has the potential to curb costly burdens on water system rate payers.

Ensuring Community Resources are Invested in High Priorities

In crafting NPDWRs, it is imperative that the abovementioned guiding principles be followed by the agency to ensure that community resources are invested in high priority risks. In crafting SDWA, Congress recognized the importance of addressing contaminants of greatest concern as part of the development of NPDWRs. EPA must consider the impact this final rule will have on communities as they are managing multiple priories for community investments to protect public health. Important examples include the replacement of lead service lines, enhancing cybersecurity protections, continuing to improve risk reductions related to disinfection byproducts (DBPs), and the continuous efforts to replace and maintain aging infrastructure to avoid the risk of water main breaks and other threats to public health. The benefits and costs of new standards must be carefully, and accurately, weighed to ensure the investments needed to meet new regulatory requirements do not inappropriately lead to reallocating available funds away from public health concerns of higher priority, causing unintended consequences.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. SRFs include set asides to address leaded pipes and to supplement the DWSRF and CWSRF, which may be used to upgrade cybersecurity, replace aging infrastructure, protect against disinfection byproducts (DBPs), and assure sustainable water supplies. The EPA has considered the rule's impact on communities, see sections 13 and 10.5 of the EPA response in this *Response to Comments* document.

New Mexico Environment Department (NMED) (Doc. #1766, SBC-044251)

PFAS Treatment Concerns

Complying with most drinking water contaminants can generally be achieved with modern treatment technologies. However, these treatment technologies are becoming increasingly unaffordable for many community water systems, especially those that are considered small and/or disadvantaged. These proposed PFAS regulations may require small and disadvantaged communities to fund and construct expensive advanced treatment systems in order to achieve compliance. Additionally, the overall operation and long-term maintenance of these advanced treatment systems may also require advanced level operations and increased utility rates that many small and disadvantaged communities may not be able to afford. On top of that, many community water systems are already struggling with failing infrastructure and may not have the capacity to fund multiple high dollar projects at the same time. NMED highly recommends that EPA consider a significant amount of easily accessible low cost, or no cost funding options for community water systems that may need advanced treatment or advanced level certified operators.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Eastern Municipal Water District (EMWD) (Doc. #1780, SBC-043825)

In addition to the comments herein, EMWD echos the comments on this Proposed Rule that were submitted by the Western Urban Water Coalition, the Association of California Water Agencies, and the WateReuse Association, and in addition would like to make the following comments. EMWD strongly supports efforts to address PFAS contamination and protect public health, however we feel strongly that water customers should not bear the cost of clean up and compliance.

Thank you for the opportunity to comment, and also for your consideration. If EMWD can be a resource as you evaluate next steps, please contact me at mouawadj@emwd.org.

Sincerely,

Joe Mouawad, P.E.

General Manager

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

National Ground Water Association (NGWA) (Doc. #1804, SBC-045465)

Laboratory Availability/Capacity - Does adequate lab availability to test to the MCL exist (this may apply to other contaminants as well as PFAS)? Actions that EPA should consider to enable more laboratory capacity are:

1. Provide funding to support an aggressive buildout of nationwide laboratory capacity.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. It is important to note that the DWSRF set-asides can be used to obtain test kits/laboratory equipment for systems to test for newly recognized contaminants of concern and training to use that equipment as mentioned in the memorandum from Radhika Fox dated 8 March 2022, titled "Implementation of the Clean Water and Drinking Water State Revolving Fund Provisions of the Bipartisan Infrastructure Law."

Florida Rural Water Association (FRWA) (Doc. #1806, SBC-044697)

Existing funding mechanisms will not cover costs such as ongoing sampling, bottled water, treatment system operation and maintenance, and additional operator certifications. Most of these smallest systems do not employ on-site operators and will need to pay increased visits and assistance from contract operations companies.

Zephyrhills, is a Florida community water system impacted by PFAS. Treatment costs are still adding up, but so far, millions have been spent on loss of supply, engineering, treatment, and remediation.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Office of Advocacy at the U.S. Small Business Administration (Doc. #1807, SBC-045479)

II. Advocacy's Small Business Concerns

A. Advocacy is concerned that small water systems will not have funding for timely compliance with EPA's proposed rule.

Overwhelming feedback indicates that small water systems do not currently have, nor will they have access to the funding required to comply with this rule, either at all or to ensure timely compliance. Advocacy is concerned that EPA did not adequately consider critical significant alternatives to reduce the significant economic burden on small entities.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. Regarding the EPA's evaluation of the impacts to small entities as required under the Regulatory Flexibility Act (RFA) / Small Business Regulatory Enforcement Fairness Act (SBREFA), see section 15.3 of the EPA response in this *Response to Comments* document. Additional information on impacts to small water systems can be found in sections 13 and 10.5 of the EPA response in this *Response to Comments* document.

Office of Advocacy at the U.S. Small Business Administration (Doc. #1807, SBC-045484)

b. EPA has overestimated its reliance on federal funding to defray compliance costs for small water systems.

Advocacy is concerned that EPA has overestimated its reliance on federal funding to help small water systems comply with its proposed requirements. EPA relies on anticipated federal funding to defray compliance costs for small water systems citing that "[t]he passage of the Infrastructure Investment and Jobs Act, also referred to as the Bipartisan Infrastructure Law (BIL), invests over $11.7 billion in the Drinking Water State Revolving Fund (SRF); $4 billion to the Drinking Water SRF for Emerging Contaminants; and $5 billion to Small, Underserved, and Disadvantaged Communities Grants."[FN13:88 Fed. Reg. at 18640.] The agency states that "[t]hese funds will assist many disadvantaged communities, small systems, and others with the costs of installation of treatment when it might otherwise be cost-challenging."[FN14: 88 Fed. Reg. at 18640.] EPA further explained that "these funds can also be used to address emerging contaminants like PFAS in drinking water through actions such as technical assistance, water quality testing, and contractor training, which will allow communities supplemental funding to meet their obligations under this proposed regulation and help ensure protection from PFAS contamination of drinking water."[FN15: Id. at 18644-45.] These funding opportunities may be available but there is no guarantee that it will be provided to the small water systems to comply specifically with this proposed rule. Moreover, the funding is likely to be insufficient because it only covers capital costs and will not alleviate the costly burden associated with the operation and maintenance costs (O&M). Finally, even if funding was available to small water systems, it is unlikely that it will be utilized efficiently to ensure timely compliance with the rule.

Federal funding referenced by EPA is not allotted specifically for compliance with this rule. Once that federal funding is dispersed to the states, availability to small public water systems may be limited due to other competing priorities and is often laden with stipulations. For example, during one of EPA's public hearings on the rule, a California stakeholder, who works with small and very small water systems, pointed out that available federal funding often gets encumbered once it gets to the states by being subjected to other priorities. This stakeholder recommended that the funds should be specifically designated for PFAS treatment and should be prohibited from being used for other requirements (e.g., state consolidation). A small entity representative of private primary schools in Wisconsin shared that without access to funding, either tuition will increase, or the school will close. Another commenter from EPA's public hearing, an Arizona water company, expressed that water utilities need additional opportunities to obtain funds to comply with the proposed regulations.

Given EPA's underestimated impacts of the rule (discussed above), the funding EPA relies on to defray the costs will not be sufficient. Especially, due to the number of systems that will likely need to implement treatment to comply with the low levels proposed, the funding sources cited by the agency will not be able to provide the compliance assistance required for the small water systems. In addition, as mentioned above, O&M costs will not be covered by the federal funding EPA references. These costs include labor, materials, energy, residual disposal/treatment, and other technology specific costs including trained personnel.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that significant funding is reserved for small systems.

Groundwater Resources Association of California (Doc. #1831, SBC-047714)

The regulations do highlight funds allocated in the Infrastructure Investment and Jobs Act for the Small, Underserved, and Disadvantaged Communities Grants. However, these funds may not be sufficient or difficult to access by CWS/SCWS. We encourage the EPA to work with local and State agencies to identify programs and funding opportunities for the CWS/SWS entities to comply with the EPA's sampling requirements. These opportunities should be paired with supporting access to affordable PFAS-free sampling materials and other external costs.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Pennsylvania Municipal Authorities Association (Doc. #1832, SBC-045781)

[PMAA's specific comments on the Proposal are as follows:]

4. As EPA is aware, many states, including the Commonwealth of Pennsylvania, have enacted various PFAS initiatives in advance of EPA's Proposal. In the case of Pennsylvania, a Safe Drinking Water PFAS MCL Rule was published in January, 2023, with MCLs for PFOA and PFAS less stringent than those proposed by EPA. Moreover, Pennsylvania's regulation contains many provisions that the regulated community are or will soon be required to comply with, including monitoring for the aforementioned PFAS chemicals. EPA's Proposal, when finalized, may require Pennsylvania to revise its program and MCLs to meet what appears to be a more stringent EPA regulation. The practical problem is that PMAA member authorities are or will be required to meet the mandates of Pennsylvania's regulation before EPA's PFAS regulation is finalized and, in so doing, will spend significant money to meet requirements that may no longer be applicable once EPA's PFAS regulation is finalized. Does EPA plan on meeting with representatives of Pennsylvania to address this issue, or is EPA going to allow PMAA member authorities to potentially spend significant ratepayer and taxpayer funds on state regulatory initiatives, some of which may be rendered moot upon the publication of a final PFAS Regulation by EPA.

[PMAA's specific comments on the Proposal are as follows:]

5. A final regulation based upon the Proposal and its associated compliance schedule will likely adversely impact the economic wherewithal of many municipal entities. If EPA enacts a final regulation towards the latter part of 2023, then most municipal entities will have a three-year compliance window under the Safe Drinking Water Act, with monitoring beginning during that three-year period. EPA should be aware that there may be tasks required to be implemented to meet the requirements of the Proposal, with such tasks possibly involving many separate and distinct phases, such as planning, design, budgeting and construction, which taken together would likely exceed the three-year window for compliance. Moreover, the timing of a final PFAS regulation based upon this Proposal will present an even more challenging economic environment for many municipal entities, in part because of concurrent regulatory initiatives,

such as the Lead and Copper Rule (and the Lead and Copper Rule Improvements). Although the federal government has earmarked funds for municipal entities to address PFAS, these funds are likely grossly insufficient to address many of the PFAS mandates, let alone compliance with other concurrent federal and state regulatory initiatives.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. Analyses conducted by the agency in support of an NPDWR undergo a significant public engagement and peer review process. The EPA notes that the EA for this rulemaking accounts for existing state standards at the time of analysis. Specifically, to estimate the costs and benefits of the final rule, the EPA assumed that occurrence estimates exceeding state limits are equivalent to the state-enacted limit. For these states, the EPA assumed that the state MCL is the maximum baseline PFAS occurrence value for all EPTDS in the state. Additionally, while states may establish drinking water regulations or guidance values absent federal regulation as they deem appropriate, the presence of state regulations does not preclude the EPA from setting federal regulations under the authority of SDWA that meets that statute's requirements. SRFs include set asides to address leaded pipes. Information on simultaneous compliance with other regulations is provided in section 10.4.2 of the EPA response in this *Response to Comments* document. More information on how the EPA consulted states can be found in section 14 of the EPA response in this *Response to Comments* document.

Corix Infrastructure Inc. (Doc. #1834, SBC-045365)

Likewise, Corix recommends that the EPA develop a residuals management plan that addresses disposal capacity, standardized analytical methodology, and ratification of a CERCLA exemption for drinking water systems before finalizing the rule to ensure additional liability and expense is not incurred by the public and the customers of water systems.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. Commenter's request for the agency to develop a "residuals management plan that addresses disposal capacity, standardized analytical methodology, and ratification of a CERCLA exemption for drinking water systems before finalizing the rule to ensure additional liability and expense is not incurred by the public and the customers of water systems" is beyond the scope of this rulemaking. For more information on how the EPA considered residuals management in context of the PFAS NPDWR, please see section 10.4.2 of the EPA response in this *Response to Comments* document. Analytical methodology is standardized and described in section 7 of the EPA response in this *Response to Comments* document.

New England Water Works Association (Doc. #1836, SBC-045375)

Further, we are concerned that EPA has vastly underestimated the cost of implementation [FN6: American Water Works Association WITAF 56 Technical Memorandum, PFAS National Cost Model Report, 2023]. In the interest of rapid implementation of drinking water standards, the burden of paying for treatment will fall to ratepayers when it should be falling to the polluters to

remediate the damage they have caused. A recent comprehensive study found that per-household costs would range from hundreds to thousands of dollars annually [FN7: American Water Works Association WITAF 56 Technical Memorandum, PFAS National Cost Model Report, 2023]. When the Clean Water Act and the Safe Drinking Water Act were passed in the 1970s, Congress felt it so important to make progress with regulatory compliance that there were robust grant programs (to the tune of 90% grants) to support the construction of treatment plants and treatment works. That same level of commitment does not exist today. The Biden Administration points to the funding available through the Bipartisan Infrastructure Law (BIL) as a means to lessen the burden—let us be very clear—it will NOT make a dent in what we anticipate our PWS will need in order to comply with the proposed PFAS rules. Nor does BIL funding adequately address the major backlogs of infrastructure needs which require significant investment in order to maintain public health. EPA's 7th Drinking Water Infrastructure Needs Survey and Assessment [FN8: https://www.epa.gov/system/files/documents/2023-04/Final_DWINSA%20Public%20Factsheet%204.4.23.pdf] released in April 2023 shows the enormous magnitude of costs facing our PWS before we even begin to address PFAS. These figures represent Drinking Water State Revolving Fund- eligible infrastructure projects that are necessary over the next 20 years for PWS to continue to provide safe drinking water to the public. For our region alone, this amounts to more than $24 billion in need (based on January 2021 dollars):

• Connecticut - $4,910,100,000

• Maine - $1,013,900,000

• Massachusetts- $15,192,800,000

• New Hampshire - $1,363,000,000

• Rhode Island - $1,029,000,000

• Vermont- $888,700,000

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. See section 13.3.3 of the EPA response in this *Response to Comments* document.

<u>Washington Association of Sewer and Water Districts (Doc. #1842, SBC-044770)</u>

Significantly Higher Costs than Estimated

The costs to clean up drinking water will be far more than EPA estimates. While hopeful that new technologies for cleanup being developed will lower costs, current technologies are not cheap.

One of our members, Lakewood Water District, has submitted a letter with details of their experience mitigating PFAS contamination from a nearby military base. They, along with other utilities, have experienced real world costs that are three to four times greater than the EPA estimates. These high cost facilities must be built into utility rates. EPA's underestimated costs for capital and operational expenses leads to an inappropriate conclusion about the impact on customers served by these utilities, with the greatest impact on smaller utilities that have fewer customers to share in the expense of the rule implementation and underserved communities who already have a hard time paying utility bills. We recognize that some money from government programs will be available, but Congress needs to know the real impacts to the constituents they represent. Underestimating implementation costs will impact the amount of funds that Congress makes available. Having a definitive MCL is helpful for utilities to know what to plan for, but without adequate funding support from Congress, the results will be unachievable without penalizing consumers who did not create the problem.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Metropolitan Washington Council of Governments (Doc. #1843, SBC-044756)

Third, while significant federal funding has been approved by Congress, additional direct federal funding for local governments and water utilities should be provided to help offset the high capital, operations, and maintenance costs expected at the local level. The cost of compliance is estimated by a recent AWWA study to be significantly higher than cost estimates developed by EPA. These potentially high expenses for PFAS treatment come at a time when local governments and water utilities are facing double and triple digit increases in the prices of essential supplies, equipment, and electricity. On top of that, we are also facing potentially high costs to address regional water security and resilience needs, mitigate climate change impacts, meet Chesapeake Bay TMDL restoration requirements, and more. Ultimately, all these costs will fall on ratepayers who are already facing higher costs for other basic necessities such as food, housing, and transportation.

We thank you for your consideration of these recommendations and look forward to continuing to work together on environmental restoration efforts.

Sincerely,

Maria Mackie

Chair, Chesapeake Bay and Water Resources Policy Committee

Cc: Radhika Fox, Assistant Administrator for Water

Adam Ortiz, EPA Region III Administrator

Catherine A. Libertz, Director, EPA Region III Water Division

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs; see section 13.3.3 of the EPA response in this *Response to Comments* document for details. SRFs include set asides to supplement the DWSRF and CWSRF, which may be used to upgrade cybersecurity, replace aging infrastructure, protect against DBPs, assure sustainable water supplies, address regional water security and resilience needs, mitigate climate change impacts, meet Chesapeake Bay Total Maximum Daily Load (TMDL) restoration requirements, and more.

Amelia Davis (Doc. #1929, SBC-047448)

When looking at the issue at hand it is clear that continuing to unregulated these forever chemicals can only cause further harm and damage to the living things throughout the world. Regulation of these PFAs is something that needs to be done to protect our environment and our health for generations to come. Understandably figuring out a way to regulate these chemicals becomes difficult and while I believe you are going in the right direction; I think that there is more to be done in order to protect our livelihood. The first two steps of the plan to first measure and monitor PFAs in public water systems and to make this information is the right first step in combating this issue. It's with the third step that issues arise.

Reducing the amount if PFAs in our water is known to be a difficult task and one that will cost a lot of money. At the moment the proposed rule change would have ratepayers in charge of paying for this filtering of water (Water Environment Foundations). This is something that should not become the burden of the citizens as they didn't have the knowledge necessary, and they are already responsible for other payments to clean water in other ways, like the Clean Water Act and the Safe Drinking Water Act. Having taxpayers provide funds to clean up a mess that was knowingly created can create issues for the common citizen, as an increase in taxes seems like an easy solution. The Water Environment Foundation also mentions that fact that money may be diverted from other clean water acts, which leads to an ineffective clean water system. It seems like the solution that would allow citizens to get clean water and to keep more of their income is to have the companies that knowingly put these PFAs in the water to pay for the reduction of their chemicals in the water. The amount of money that they have made from manufacturing these chemicals is more than enough to provide safe drinking water through the public water system. While this solution may cause economic issues for these businesses, it forces them to be held accountable and provide incitive to work on creating products that don't cause damage to the entire world.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. More information on the health impacts of these six regulated PFAS may be found in section 4 of the EPA response in this *Response to Comments* document. More information on monitoring and compliance may be found in section 8 of the EPA response in this *Response to Comments* document. More information on the regulatory process can be found in section 3 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #1944, SBC-047323)

The idea of having risk free drinking water is one that is seen to be unachievable due to the extreme cost of testing and cleaning the water. The cost of clean water will fall on those that the pollution most greatly affects in taxpayer dollars (Isaacs-Thomas, 2023). So why aren't the ones making the mess not picking up the mess? When corporations are linked to a mass amount of pollution, they are only forced to pay for part of the clean up, the rest is on us, the ones who are negatively affected by the pollution and had no say (Faye, 2021). When pollution cannot be linked to a corporation, instead of forcing corporations that only pay 21% of taxes in America and make 2.77 trillion dollars every year, the people are forced to pay for it (Faye, 2021). This is why just setting a bare minimum is not enough. There is a better option, it is attainable, we are just skirting around it making shortcut propositions like this. Go after the agencies, fund education, fund science, think about the future, if there is going to be one at this rate, and how they will historically look at this proposition. Would they think you guys went far enough for them or would they laugh, me personally, I'd laugh.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. More information on the rule making process can be found in section 3 of the EPA response in this *Response to Comments* document. More information on the health effects can be found in section 4 of the EPA response in this *Response to Comments* document. More information on feasibility can be found in section 5 of the EPA response in this *Response to Comments* document.

Anya Mulvaney (Doc. #1965, SBC-047450)

The EPA's Proposed National Primary Drinking Water Regulation of PFASs Policy attempts to establish legally enforceable levels for six PFAS in drinking water and it would "require [state and city] public water systems to (a) monitor for these PFAS; (b) notify the public of the levels of these PFAS; [and] (c) reduce the levels of these PFAS in drinking water if they exceed the proposed standards." This policy has both various positives and negatives. It could be damaging in some [or many] ways. State or local governments would pay for testing and potential clean-up or remediation, and this would show up in local taxes for citizens. While there is this financial cost, most citizens want to trust their water is safe, so arguably the benefit outweighs the cost. But the issue with this policy is who the cost and responsibility fall on. The question is if the responsibility should fall on the corporations that are disposing of these chemicals into the water, instead of responsibility falling onto the local government and therefore the citizens. This raises the question of how we charge the cost back to the corporations responsible. This issue is a complex one that is about more than what is legal or efficient, but also what is ethically and just.

What we know is 99% of humans have PFASs in their system. High concentrations have been connected to drinking water and have led to sickness. We don't necessarily know in what other ways we are being exposed to it due to the fact that PFASs are in so much of our environment. There are several stakeholders in this matter. Citizens are involved due to health risk; chemicals

companies hold a stake because if the tests proved their processes and products were dangerous it would turn back on them and could have major costs on them; and lastly, the local governments are stakeholders because the cost of testing and clean upfalls on them. The options for action are to test the water or do nothing. Within this, there are different creative ways to fund it. The way this policy has it set up is the local government pays. This would likely be through citizen taxes. Another option would be to hold the chemical companies responsible which could look like special taxes that hit companies or industries that rely on PFASs most. There are possible externalities, such as an increase in taxes and the potential increase in the cost of products containing chemicals.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Lance Freeman (Doc. #2132, SBC-047427)

There is also the issue of money, assuming there is a technology or method that can remove PFAS to the required level it is likely to be very expensive. While few would deny that making drinking water safer is a good use for taxpayer dollars there is the issue of those areas with a smaller population of people/a smaller economy might not have enough taxpayer dollars to afford it; The EPA talked about this themselves. Unless there is a way to help those smaller areas meet the cost criteria such as taking a certain amount out of every area's tax revenue and using any excess from larger economies to help the smaller areas, or maybe an exemption for smaller areas.

While there are likely other issues that I am missing or don't understand the significance of these two are my main concerns and if these two issues are addressed then I trust that the EPA will work out the smaller details sufficiently and they have my personal approval.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. More information on treatment technologies can be found in section 10 of the EPA response in this *Response to Comments* document.

Julia Wolny (Doc. #2313, SBC-047453)

While it is necessary to understand the dire need for federally regulating PFAS in drinking water, it is equally important to discuss how the regulation will be implemented and enforced. The primary feature of the NPDWR is to monitor the level of PFAS in drinking water to ensure they meet appropriate levels. Yet this raises many questions in regard to how violations will be dealt with in a way that holds appropriate parties responsible. Further, the EPA's proposal raises questions about what actions will be taken if PFAS exceeds permissible levels in drinking water. Although the proposal requires notifying the public of PFAS in drinking water if they exceed the proposed standards, it is unclear whether water treatment facilities will be entirely responsible for reducing PFAS in drinking water or if the responsibility will be placed on citizens. If notifying the public is not followed by swift action to reduce PFAS in drinking water, the burden

will inevitably fall upon citizens. This could have detrimental effects as home filters may not be affordable to all citizens and are often ineffective at reducing PFAS depending on the contamination levels. This leads me to echo the comments and concerns proposed by the Association of Metropolitan Water Agencies (AMWA) which calls for the EPA to consider how regulatory actions will affect water affordability for disadvantaged communities.

Once again, I would like to emphasize my support for the EPA's proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation. Yet I would also like to call attention to the need for a comprehensive analysis of how the regulation will be implemented in a manner that prioritizes all citizens' health and well-being. Logistics such as economic factors and access to resources must be taken into consideration. Failure to complete such examinations will likely decrease the effectiveness of the proposed regulation and disadvantage certain populations.

Sincerely,

Julia Wolny

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. More information on treatment technologies, specifically the use of filters, can be found in section 10 of the EPA response in this *Response to Comments* document. More information on monitoring and compliance can be found in section 8, and section 9 describes public notification requirements of the EPA response in this *Response to Comments* document.

Peter Ayres (Doc. #2679, SBC-047416)

I am concerned that many municipalities might not have the tech, infrastructure and money to implement the requirements that would be needed to meet the rules that are put in place. I know from a small town in Iowa where we have a house they are already trying to update sewer and water lines that are 100 years old at great cost and meet the rules and regs for water quality that are in place now So adding these rules is a good thing, but needs to be evaluated as to how realistic is it for water treatment plants thru out the nation to be able to comply or even afford to update again their filtration systems. I think of Dubuque Iowa's plant that deals with changes in quality of water sometimes every 15 minutes.

I hope something can be implemented.

Thanks

Peter Ayres

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. More information on feasibility can be found in section 5 of the EPA response in this *Response to Comments* document.

Westport Harbor Water Association (Doc. #2855, SBC-047294)

I am President of a rural water supply in Westport, MA. The Westport Harbor Water Association has currently 50 connections. Our PFAS/PFOS levels have been found to be less than 10 parts per trillion. We meet the regulatory limits as set by the Mass DEP but under the proposed rules will not meet the limits. The estimated cost for meeting the new rules would we over $50,000 in capital cost and the estimated yearly maintenance costs are estimated at $40,000. The rules will bankrupt the company and we may not be able to provide water to our members going forward. The State of Massachuesetts has indicated there is little money to help small systems.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Arizona Water Company (Doc. #3072-11, SBC-047363)

Good morning. My name is Andy Haas. I am the Vice President of Engineering with the Arizona Water Company, and we are a water utility that provides service to over 100,000 customers throughout the state of Arizona. I want to thank you for the opportunity to provide comments this morning. We rely on the EPA for their research and expertise to identify contaminants in drinking water and develop MCLs. We thank EPA for its aggressive stance to mitigate the effects of forever chemicals on the public through drinking water and other forms of exposure. The PFAS research, laboratory testing, and treatment technologies change quickly and frequently, so water utilities are doing their best to keep up. With concentrations this small, there is no room for human error in field sampling and laboratory testing. Many water utilities we have spoken with only sampled for PFAS chemicals under UCMR 3 about 10 years ago, and at the time, laboratory technologies did not have the ability to report results down to the levels in the proposed regulation now and if they're similar to us, we've sampled 10 years ago and had no water sources impacted by PFAS chemicals, but since then, we've continued to sample and may have more than 20 impacted sources. So, we believe other utilities may be similarly affected. As a result, EPA's estimates the number of affected water utilities, water supplies, and the construction and O&M costs may be significantly underestimated, and we expect the results of the UCMR 5 sampling to show a significant increase in the number of affected utilities. As a result, we request that there's additional funding opportunities made available for regulated utilities, not just municipal utilities, as water utilities will need sufficient funding opportunities and opportunities to timely recover their investment costs, while mitigating significant increases to customer water bills, so we can continue to provide safe, reliable, and adequate water supplies to our customers.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. More information on occurrence in water systems may be found in section 6 of the EPA response in this *Response to Comments* document. Information on analytical methods may be found in section 7, and information on monitoring requirements may be found in section 8 of the EPA response in this *Response to Comments* document.

West Virginia Rivers Coalition (Doc. #3072-21, SBC-047371)

For far too long, residents of the Ohio River Valley have unjustly beared the burden of health impacts from industries manufacturing and using these chemicals. These health impacts include the cost of care for PFAS-related diseases, as well as premature death. West Virginians already pay some of the highest rates for public drinking water in the country. There is simply not capacity for consumers to take on additional rate or tax burdens to clean up the mess of corporations that have benefited from their pollution for decades. Additionally, there is concern about paths for funding making its way into the communities that are most impacted. As we have seen with other federal funding recently made available to upgrade technology and infrastructure, many West Virginian communities do not have the capacity to secure and implement grant funding. Many grants are simply passing West Virginians by. This reality needs to be acknowledged as we explore best practices and work together to ensure that the citizens that are the most impacted by toxic pollution are first in line to receive funding to protect human health. The health of all people who depend on the Ohio River for their primary drinking water source deserve our best efforts to protect them. Thank you.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. More information on health effects can be found in section 4 of the EPA response in this *Response to Comments* document.

California Association of Mutual Water Companies (Doc. #3072-25, SBC-047373)

Secondly, we wanted to call your attention to the fact that even though the EPA is making funds available for this and having grants that are particularly targeted to small and disadvantaged communities, once they get to the state, they often get encumbered in other state priorities. And so if there is a way to make this allocation to California in a way that says this funding has to be separately available just for treatment for PFAS, and it can't be held hostage to a requirement to consolidate or other kinds of state priorities, that would be very helpful because what we're finding is that much of the EPA money that's in the State Revolving Fund right now is only accessible if our small systems are willing to agree to consolidation, and that's not reasonable. Thank you.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Zone 7 Water Agency (Doc. #3072-29, SBC-047377)

Second, I'd like to raise, again, the issue of funding. Although the U.S. EPA can only be part of the funding picture, I will take this moment to remind everyone that the roughly $50 million required to build a PFAS treatment system for just our agency is only part of the picture. The O&M costs in the subsequent decades as well as disposal costs will be significant. Also, one of the cities in our Tri-Valley area expects to incur similar amounts to either build their own system

and/or to pipeline into a nearby system so residents will get hit twice with rate hikes. Something needs to be done to help mitigate this. Although the Bipartisan Infrastructure Bill will help, it does not appear to be nearly enough to cover the capital costs nor the millions of dollars that our area will spend annually. I would ask the EPA to remind the administration and Congress that more robust funding will be needed to truly match the coming expenses. Further, I'd also ask that those that have started the process aren't penalized when funding becomes available, rather that there's retrospective funding. Thanks again for all your work on this issue. We're very happy to see these regulations at last and we hope the funding will follow through to make this available, and so we can finish the job that we started. Thank you and have a good day.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Massachusetts Water Resources Authority (Doc. #3072-49, SBC-047379)

This fails that test. EPA should be doing substantially more to eliminate these chemicals from production and use. Water systems should not be forced to pay to deal with contaminants they have nothing to do with. I agree with other commenters on the potential futility of trying to resolve the PFAS problem with a whack-a-mole approach, and believe the appropriate resolution is to keep those things out of our source waters. Speaking of cost, EPA's cost estimates are wildly too low based on what we've already seen here in New England. And while I'm sure water systems are grateful for the current additional federal funding, it's only a down payment, not nearly enough to meet these standards at a reasonable impact on our customers.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Raymond Choma (Doc. #3072-59, SBC-047391)

Furthermore, we have the technology necessary to remove PFAS from our drinking water. What we need is the political willpower to enact it at scale without putting the burden on individual households. I'm glad to know that the Bipartisan Infrastructure Law invests funds that will assist many disadvantaged communities, small systems, and others with the cost of installation of treatment when it might otherwise be cost challenging. In conclusion, safe drinking water is a fundamental human right that every American deserves. The new water filtering technologies will reduce cases of heart attacks, strokes, kidney cancer, and bladder cancer. I hope the EPA will finalize the PFAS National Primary Drinking Water Regulation quickly so we can have a healthier tomorrow. Thank you for listening. May the fourth be with you.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Steve Liska (Doc. #2355, SBC-047497)

Plus, the cost of containing this contamination is mounting. I just heard this morning that the Federal Government is going to spend 10 billion dollars to help "filter" some of these chemicals out of drinking water. Seems like it would be better to prevent the drinking water from being contaminated in the first place, as this is another tax-payer expense that could be better allocated.

I'm tired of billion dollar companies dictating policy that allows them to say what's important. It usually ends up being that they get record profits, and the consumer suffers health consequences.

Capitalists are ruining Capitalism. We need good government to put it right.

EPA's proposed rule would provide safer drinking water for communities from coast to coast. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. The EPA acknowledges and addresses the cumulative impacts on communities who are exposed to multiple PFAS, and by issuing this proposal, EPA is one step closer to fulfilling its commitment under the 2021 PFAS Strategic Roadmap to begin regulating PFAS in drinking water. We urge you to quickly finalize these standards, and to implement a rule that is the most health-protective, resisting industry's efforts to weaken them.

Sincerely,

Steve Liska

Chicago, IL 60625

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

National Center for Health Research (Doc. #3072-73, SBC-047402)

And fourth and last, we appreciate the law that provides funding for these efforts, but it's time to start shifting the costs to the companies that have made these chemicals. When companies are held financially responsible, they'll be less likely to inundate us with PFAS in products. Taxpayers are already stuck with the health risks. It's not fair for municipalities and taxpayers to get stuck with the work and the cost. Thank you very much for the opportunity to speak today.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

San Gabriel Valley Water Association (Doc. #3072-87, SBC-047404)

Additionally, the identified best available technologies may prove costly and inadequate if California and other states decide to adopt more stringent standards. Hazardous waste disposal, which may require transportation across state lines are also not included in the primary economic

analysis and can potentially double the total cost of meeting the MCL requirements. Although the BIL provides billions of dollars to assist water providers, it doesn't cover the ongoing cost of operating and maintaining water treatment systems. These expenses will have to compete with other EPA mandates, such as a Lead and Copper Rule Revisions and the newly introduced cybersecurity measures. We fear that this could lead to disparities between communities that can afford treatment methods and those that cannot. Thank you again for the opportunity to address you here today.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA has estimated that cost increases associated with managing drinking water treatment residuals as hazardous waste cost would be approximately $99M at the 2 percent discount rate as described in Appendix N.2 of the EA for the final rule. This represents 7 percent of the total estimated treatment costs of the rule. SRFs include set asides to address leaded pipes and augmentations to the SRFs can be used on cybersecurity measures. Information on simultaneous compliance with other regulations is provided in section 10.4.2 of the EPA response in this *Response to Comments* document. For more information on the EPA modeled costs, please see section 13 of the EPA response in this *Response to Comments* document.

Liliana Salcido (Doc. #1509, SBC-042586)

When it comes to the cost-benefit analysis, the cost of regulation may seem big now, but in the future, people will be healthy and not be hospitalized due to cancer or other diseases caused by PFAS. The American Water Works Association has expressed its concerns regarding consumers paying more for better water saying, "Advanced drinking water treatment systems for PFAS will require communities to make significant investment" (Isaacs-Thomas, 2023). However, it should not be a matter of "if," rather a matter of "when" citizens will pay more for their own well being and that of their neighbors. Decades have passed with countless cancer rates and deaths. Human beings can contribute to society if they are happy and healthy. Public health should be prioritized, especially if taxpayers will have to pick up most of the cost for these regulations.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. More information on how the EPA considered potential costs relative to potential health and other benefits may be found in section 13 of the EPA response in this *Response to Comments* document.

Southern Methodist University Dedman School of Law (Doc. #1512, SBC-042598)

(2) The EPA must take measures to ensure that adequate funding is available to all water utilities needing to improve their filtration equipment to meet new NPDWR standards.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Southern Methodist University Dedman School of Law (Doc. #1512, SBC-042600)

2. Funding for PFAS Reduction Efforts

An additional concern I have with the proposed NPDWR rulemaking has to do with the amount of funding available to local water utilities for necessary equipment upgrades. While I realize the Bipartisan Infrastructure Law has funding dedicated to PFAS reduction efforts, further economic analysis needs to be done to determine the financial impact the new rules may have on communities. Estimates need to be made to determine exactly how much it will cost to reach the Maximum Contaminant Levels (MCLs) dictated by the new regulation.

The reduction of PFAS has the potential to lessen costs incurred due to health problems and deaths caused by long term PFAS exposure. However, PFAS most severely impact poor and minority communities who may struggle to pay for upgraded water treatment equipment. [FN7: Udasin, supra, n.3] It would be inequitable for these communities to struggle to meet a MCL they cannot afford to reach. Therefore, I would like to see assurances that enough funding is in place to meet the MCL goals before the proposed NPDWR rules take effect.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. These requested analyses are part of the EA and affordability analyses; please see sections 13 and 10.5 of the EPA response in this *Response to Comments* document.

Cayro Bustos (Doc. #1517, SBC-042718)

Understandably, the government must consider cost and technological feasibility when considering undergoing any policy decision. New water treatment systems will be required for filtering PFAS from our water, and that will undoubtedly impact some communities more adversely than others. However, in February 2023 the EPA announced the availability of $2 billion from President Biden's Bipartisan Infrastructure Law to address emerging contaminants, including PFAS, in drinking water across the country. Future legislation like this will undoubtedly garner support if the public is educated and aware of the problems of PFAS contamination in their drinking water; many individuals have no idea what PFAS is, let alone its negative health effects. Cheryl Hogue, Why limiting PFAS in drinking water is a challenge in the US, Chemical & Engineering News (Jul. 13, 2020), https://cen.acs.org/environment/persistent-pollutants/limiting-PFAS-drinking-water-challenge/98/i27. Congress never seems to fail to find the budget necessary for what is politically popular; this is not only popular, but necessary for the health of our country.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that significantly more funding than that described by the commenter was made available.

Lecsy Gonzalez (Doc. #1561, SBC-042868)

Although the proposed water regulation would make great strides toward health equity for the general United States population, it places an additional burden on indigenous populations due to a lack of funding to implement these changes. [REF3: Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation. https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0027.] Due to this, I highly encourage to review the budget for this regulation and increase the funding for tribal nations.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043627)

Date: May 26, 2023

To: Michael Regan Administrator

Environmental Protection Agency 1200 Pennsylvania Avenue, N.W.

Mail Code: 1309

Washington, DC 20004

RE: Per- and polyfluoroalkyl substances (PFAS): Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) National Primary Drinking Water Regulation Rulemaking – Docket No. EPA-HQ-OW-2022-0114

Dear Administrator Regan,

First and foremost, the Water Works Board of the City of Birmingham (BWWB) would like to thank the USEPA for the opportunity to provide comments on the proposed PFAS National Primary Drinking Water Regulation (published on March 29, 2023) (i.e., the "PFAS Rule"). As the largest drinking water system in the State of Alabama, serving more than 15 percent of the population of the State, and employing more than 600 water professionals, we appreciate the chance to voice our perspective on this proposed regulation.

BWWB owns and operates four water filtration plants within the Birmingham metropolitan area namely: Shades Mountain Filter Plant, Western Filter Plant, Carson Filter Plant, and Putnam Filter Plant. Combined, these filtration plants delivered more than 111 MGD of drinking water to our customers in 2022. Each plant has received a series of awards from AWPCA, CDC, USEPA, and the Alabama Department of Environmental Management (ADEM) in recognition of treatment excellence and safe drinking water quality. As an innovative water leader in our state and nationally, BWWB prioritizes efficient operations, water quality, as well as environmental and community stewardship. In preparation of these comments, we assembled a team of internal

experts (licensed engineers and scientists) as well as our external independent engineer Arcadis US, Inc, and financial experts Raftelis.

Arcadis is a global company leading delivery of sustainable design, engineering, and consultancy solutions for built and natural assets. Arcadis has engaged several experienced national experts in drinking water regulation and water quality planning who have participated in the development of these comments—including their Director of Applied Research and several National Discipline Leaders.

Raftelis is a leading national financial and rate consulting firm that has contributed to major industry affordability research efforts, including completing an assessment of the Federal Low-Income Water Customer Assistance Program (LIWCAP) that was recently implemented by the federal government to help customers afford essential water and wastewater services, and to industry publications, including "Developing a New Framework for Household Affordability and Financial Capability Assessment in the Water Sector" prepared for AWWA, WEF, and NACWA, "Improving the Evaluation of Household-Level Affordability in SDWA Rulemaking: New Approaches" prepared for AWWA, and Affordability of Wastewater Service, a reference book published by WEF. In addition, Raftelis regularly provides affordability analysis and support to water utilities nationwide.

A brief summary highlighting BWWB's key points/concerns is provided within this letter. In support of the positions outlined in this summary, we have attached a series of appendices, detailed at the bottom of this letter.

Overall, BWWB believes that USEPA's proposed maximum limits for PFAS contaminants are the most stringent regulatory limits ever proposed for drinking water utilities. We also believe the proposed limits have not been demonstrated to be cost beneficial, and, if enforced, will have significant impacts on the affordability of drinking water for our customers and throughout the United States. Specifically, a significant portion of our customer base is already burdened with water bills equal to more than 2% of their household income. If implemented, this regulation is expected to push approximately 13,000 more Alabamans beyond this affordability threshold. A brief summary of BWWB's concerns is provided below:

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA's final rule represents data-driven drinking water standards that are based on the best available science, meet the requirements of SDWA, and regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. The agency accounted for costs in its HRRCA and its evaluation of feasibility for the final MCLs. After considering both the nonquantifiable and quantifiable costs and benefits of the final PFAS NPDWR, the Administrator is re-affirming the determination made at proposal that the nonquantifiable and quantifiable benefits of the MCL justify its nonquantifiable and quantifiable costs. For additional information on the EPA's cost and benefit estimates for the final rule, please see sections 13.3 and 13.4 of the EPA response in this *Response to Comments* document.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043643)

B. USEPA model considered costs in a vacuum without addressing the impact of other compliance and infrastructure needs (e.g., LCRR compliance, non-revenue water control, risk reduction and aging infrastructure).

Based on the existing utility challenges with aging infrastructure and other regulatory driven investments, the combined capital cost impact on BWWB for the next 10 years is estimated to be $180 million.

Please refer to Appendix B and Appendix C for BWWB's detailed impact analysis under a variety of regulatory scenarios; this analysis helps illustrate the likely impacts on BWWB capital and O&M expenses, as well as rate impacts on customers.

In summary, addressing the existing and emerging challenges facing BWWB over the next five years, excluding PFAS, could yield an average bill percentage of 2.74% of LQI and place a staggering 38.0% of households below the affordability threshold. When considering PFAS as well, the average water bill would represent 3.17% of the LQI and 40.0% of BWWB's customers would be below the affordability threshold by 2028.

It is recommended that USEPA reconsider the cost implications of the proposed PFAS rule on rate payers, particularly those in low-income communities.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The factors described by the commenter were considered in the EA and affordability analyses. Please see sections 13 for the cost analysis, 10.5 for an affordability analysis, and section 10.4.2 for simultaneous compliance concerns in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044070)

These increases in primacy agency responsibilities should be supported by a corresponding increase in the Public Water System Supervision (PWSS) Grant Program, recognizing EPA's limited ability to influence Congressional PWSS appropriations. Without additional PWSS funding, primacy agencies will have to make tough decisions on prioritizing support to existing programs. Limitations on primacy agency resources will result in fewer opportunities to work individually with water systems to improve compliance and protect public health.

On behalf of ASDWA's 57 members, we thank EPA for the opportunity to provide insightful comments on this critical rulemaking. ASDWA looks forward to further engagement with the Agency as we work together to implement this rule. Please feel free to reach out to me if you have any questions about these comments.

Sincerely Yours

J. Alan Roberson, P.E.

ASDWA Executive Director

Cc: Jennifer McLain – EPA OGWDW

Eric Burneson – EPA OGWDW

Ryan Albert – EPA OGWDW

Alex Lan - EPA OGWDW

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The implementation memorandum from Radhika Fox dated 8 March 2022 titled "Implementation of the Clean Water and Drinking Water State Revolving Fund Provisions of the Bipartisan Infrastructure Law" notes that states may use a portion of the SRF for administration of the funds from each funding stream in BIL.

Texas Commission on Environmental Quality (TCEQ) (Doc. #1632, SBC-044131)

State Program Funding

In state fiscal year 2023, Texas' Base Capitalization grant experienced a new loss of $31 million due to congressional earmarking. Although there is funding currently available through the Bipartisan Infrastructure Law, this funding is limited and will not remain available in perpetuity. Therefore, it is important to protect the long-term viability of the Drinking Water State Revolving Fund (DWSRF) base program funding for the additional resources needed to implement the PFAS NPDWR, and other newly promulgated federal regulations, and to ensure equitable funding access to all eligible public water systems and safeguard the intended self-sustaining nature of the DWSRF.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that $15,000,000,000 was set aside for Lead Service Line Replacement.

Rural Community Assistance Partnership Incorporated (RCAP) (Doc. #1633, SBC-044144)

Funding and Other Issues for Congress

While RCAP understands that it is the responsibility of Congress, not EPA, to fund the testing, compliance, enforcement, and technical assistance programs mentioned above, we would be remiss not to emphasize that more funding is needed for technical assistance, testing, and compliance, particularly for small, rural, and tribal systems. RCAP agrees with EPA that the Bipartisan Infrastructure Law (BIL) provides substantial funding for public water systems impacted by the proposed NPDWRs, and RCAP applauds this historic funding. Unfortunately, by the time the rule is implemented and enforced, around 2027, much of the BIL funding and time to access it will have already run out and will no longer be available for systems that need to install new treatment technologies.

We urge the President to work with Congress to increase federal investment in drinking water for small public water systems to comply with proposed PFAS NPDWRs and existing regulations under the Safe Drinking Water Act.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL funds are not meant to fully cover all capital costs associated with implementing the NPDWR and that there are significant quantifiable and non-quantifiable health benefits realized from implementing the rule.

American Farm Bureau Federation et al. (Doc. #1642, SBC-043487)

[They have identified the following areas of concern regarding the agency's development of this rule:]

• Infrastructure Investment and Jobs Act (IIJA) funding will be insufficient to cover the costs of compliance. The investment needed to reach these low MCL levels moves well beyond the ability of communities to afford and beyond the potential funding available in the IIJA. Simply put, the likelihood of outspending the billions of dollars contained in the IIJA is significant because the compliance costs are so high.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The factors described by the commenter were considered in the EA and affordability analyses. Please see sections 13 for the cost analysis and 10.5 for an affordability analysis.

American Farm Bureau Federation et al. (Doc. #1642, SBC-043501)

Federal Funding Is Limited

While the EPA touts the various federal funding streams that are available for drinking water utilities to adapt to this rule, they fail to recognize the difficulties that small, rural communities face in obtaining these monies. At a Small Business Environmental Roundtable on May 11, 2023, EPA staff highlighted the following funding opportunities that were authorized through the IIJA:

• $11.7 billion to the Drinking Water State Revolving Fund (SRF)

• $4 billion in SRF for emerging contaminants

• $5 billion to Water Infrastructure Improvements for the Nation (WIIN) Grants to address emerging contaminants

It is encouraging to see this level of investment in protecting our drinking water and addressing emerging contaminants, like PFAS chemicals. But, as previously mentioned, there is not enough money to go around to cover the costs of this rule for every water utility, and these resources are often devoted to projects that benefit large population areas. We have heard directly from rural

water communities who have expressed the challenges of accessing these federal dollars. The agency needs to ensure that these areas are not forgotten but rather prioritized, as they will experience the greatest challenges in meeting this proposed standard.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Water Supply District of Acton (Doc. #1662, SBC-043667)

Finally, the District wishes to acknowledge that the proposed PFAS regulations will impact other aspects of our community. The funding for our PFAS response is currently the sole responsibility of our rate payers. If utility bills continue to rise due to inflation, energy costs, and further regulation, we may see unintended consequences. The community may not support funding requests for PFAS treatment. Other priority projects in the community such as roadway safety improvements may garner support instead. The current model of local users paying the costs for a global PFAS issue is unreasonable and must be fully addressed in EPA's regulatory response and the federal government's financial assistance model.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

National Association of Water Companies (NAWC) (Doc. #1670, SBC-044160)

3. EPA must fully explain its approach to affordability to ensure that funding will be available to achieve the aims of the regulation.

EPA must do more in this rulemaking to assure that communities across the U.S. that are struggling to maintain affordable rates already due to currently planned and required capital and regulatory projects, have access to funds the communities and water systems can use to carry out the requirements of this rulemaking. As noted above, the costs of upgrading treatment systems to achieve reductions in the presence of PFAS chemicals in the water supply will be substantial and will significantly impact ratepayers. NAWC encourages EPA to maximize the opportunities for states and municipalities to spend funds from the Bipartisan Infrastructure Law (BIL) in a way that delivers the most benefit for communities, especially those with high levels of PFAS substances in their water supplies. NAWC again urges EPA to recognize with respect to affordability issues and funding that is provided, it is important that these rules and policies apply equally to all community water systems and wastewater treatment systems regardless of whether the systems are publicly or privately owned or operated.

Additionally, in setting the appropriate MCL levels EPA must recognize that the resources available from the Infrastructure Investment and Jobs Act (IIJA) are limited to $10 billion and that the lower the MCL is set, the more likely those funds will be insufficient to cover increased costs. In fact, reports provided to OMB by other organizations addressing this rulemaking point

out that if the MCL for PFOA and PFOS is set at less than 20 ppt, the likelihood of outspending the $10 billion contained in the IIJA is significant.

Access to safe, clean drinking water is a necessity and this action by EPA must ensure that this access is affordable and equitable.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Wisconsin Department of Justice et al. (Doc. #1687, SBC-044448)

4. We urge EPA to make technical and engineering resources available to public water systems so that the financial burden of removing PFAS does not unfairly fall on ratepayers and customers.

In the PFAS Rule, EPA examined the treatment options to achieve compliance with the proposed standards. EPA identified BATs, or Best Available Technologies, based on their high removal efficiency, history of successful use, general applicability, reasonable cost, compatibility with other water treatment processes, and the ability to bring all the water in a system into compliance. The proposed BATs for PFAS removal from drinking water are GAC, AIX, and high-pressure membranes such as RO and NF. [FN40: PFAS National Primary Drinking Water Regulation Rulemaking, 88 FR 18638-01 at 18684 to 18689.]

GAC and AIX are sorptive processes, which means that they involve substances attaching to other substances. Sorptive processes work by passing water through a vessel filled with a sorbent, which removes the contaminants. [FN41: Id. at 18684-85] High- pressure membranes are a separation process where water is split into two streams across a membrane. One stream has fewer contaminants, known as permeate, and the other stream contains concentrated contaminants, known as concentrate or retentate. The effectiveness of membrane systems is measured by flux, which is the amount of permeate produced per surface area and time. [FN42: Id. at 18685-86.]

Regardless of whether a water provider opts for sorptive processes or high- pressure membranes, the cost to build, operate and maintain the treatment will be substantial. [FN43: Id. at 18687-88 (analyzing costs of GAC, AIX, RO, and NF based on system size).] Even if the costs are very substantial, the benefits associated with the anticipated drinking water improvements justify such expenditures. EPA should nevertheless acknowledge and reflect in its rulemaking that the costs imposed on providers and their ratepayers are high.

The costs of installing additional treatment technologies should not fall to state and local governments and taxpayers. Further, the proposed regulation may create significant burdens on State regulatory agencies, and it is essential that EPA secure sufficient resources for states to be able to successfully implement and enforce the new MCLs. As some of our States have alleged in pending lawsuits, certain chemical manufacturers have broken the law in their manufacture, sale and distribution of PFAS and caused much of the contamination in our drinking water

supplies. For these reasons, we urge EPA to (1) provide substantial technical and engineering resources to water providers (including model plans); and (2) work with Congress to obtain and distribute federal funding for treatment, especially in underserved communities.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The implementation memorandum from Radhika Fox dated 8 March 2022 titled "Implementation of the Clean Water and Drinking Water State Revolving Fund Provisions of the Bipartisan Infrastructure Law" notes that states may use SRF funds to administer funding stream in BIL. As is typical after any rule promulgation, the EPA plans to provide support to utilities, primacy agencies, and other interested parties to ensure successful implementation of this PFAS rule. The agency notes that PFAS treatment will very likely often depend on site-specific factors; more information on this topic may be found in section 10 of the EPA response in this *Response to Comments* document.

Austin Water (AW), Austin, TX (Doc. #1688, SBC-044455)

The affordability of drinking water is a critically important factor in considering the proposed PFAS NPDWR. AW strives to maintain affordable rates for all customers as we conduct and complete necessary capital and other regulatory projects. Future regulatory actions should include ample time and easily accessible means to review, understand, and provide meaningful feedback on cost models used to estimate financial impacts on the community. They should not put unnecessary or significant financial burdens on ratepayers. Access to safe, clean drinking water is a necessity, and regulatory efforts moving forward should prioritize making this access affordable and equitable. Public water systems and their customers are the receivers of potential PFAS pollution, not the creators of these substances. More time should be given to allow for a careful evaluation of the cost burden on customers.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. More information on the EPA's rule development timeline can be found in section 2.3 and more information on the regulatory process can be found in section 3.1 of the EPA response in this *Response to Comments* document.

New Hampshire Department of Environmental Services (NHDES) (Doc. #1690, SBC-044333)

May 30, 2023

Michael S. Regan, Administrator

U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, N.W.

Washington, DC 20460

Subject: NHDES Comments for the Proposed PFAS National Primary Drinking Water Regulation Rulemaking Docket ID No. EPA-HQ-OW-2022-0114, Published March 29, 2023, Pages 18638-18754

Dear Administrator Regan:

We are writing to provide our comments on the United States Environmental Protection Agency's (US EPA) proposed Maximum Contaminant Levels (MCLs) for per- and polyfluoroalkyl substances (PFAS). As the primary environmental regulatory agency in our state, the New Hampshire Department of Environmental Services (NHDES) understands well the importance of protecting public health and the environment from PFAS contaminants. We have served as the principal responders to several drinking water contamination events, dating back to the 2014 discovery of PFAS contamination of a major public water supply well at the former Pease Air Force Base in Portsmouth, NH, and the 2016 discovery of widespread impacts in southern New Hampshire to both public and private drinking water wells from airborne emissions of PFAS from two manufacturing facilities. We have witnessed first-hand the impacts of PFAS contamination on our communities and the need for action to address this issue. Our agency and public water systems across our state continue to commit substantial financial and personnel resources to this problem each and every day. Sampling for PFAS in the state started in 2016 and has been conducted at over 1,400 public water system sources and over 10,000 private wells.

New Hampshire (NH) has had enforceable state MCLs for perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorononanoic acid (PFNA) and perfluorohexane sulfonic acid (PFHxS) since October 1, 2019. Community and non-transient, non-community public water systems have been required by NH administrative rule to complete compliance sampling for these four PFAS compounds since the fourth quarter of 2019. Based on the sampling results to-date, PFAS has been detected at approximately 30% of the public water system sources that have been sampled. However, exceedances of NH PFAS drinking water standards have only occurred at about 7% of those sources.

Since the initial discovery of PFAS contamination in our state, more than $300 million has been spent responding to this crisis. Much of that burden has been borne by state and local government, requiring significant reprogramming of and increases to capital and operating budgets in both sectors. As just one example of state-level impacts, in response to promulgating the state MCLs, in 2020 the NH legislature instituted the PFAS Remediation Grant & Loan Fund program that aids community water systems; non-profit, non-transient, non-community water systems; and municipalities with funding to remediate PFAS in drinking water that exceeds the state standards. The program was established offering $50 million in loan funds and $35 million in grant funding that are primarily funded with State monies. At this time, the grant funding is exhausted and approximately half the loan funding has been awarded to 33 projects at an anticipated cost of $55 million. Even with anticipated targeted federal funding, the need will outstrip available resources.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. More information about occurrence can be found in section 6 of the EPA response in this *Response to Comments* document.

Massachusetts Coalition for Water Resources Stewardship (MCWRS) (Doc. #1691, SBC-044323)

3. If EPA moves forward to implement the proposed MCLs then it is imperative that all capital and operational compliance costs be borne by the federal government. If the federal government cannot or will not provide full funding to public water systems then compliance with the MCL should not be mandated.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Ontario International Airport Authority (OIAA), California (Doc. #1693, SBC-043505)

Although the proposed MCL and the monitoring, treatment, and remediation regulations are aimed primarily at public water systems (PWSs), it is clear that the affected PWSs will not be able to feasibly afford the infrastructure required to treat the subject PFAS contamination to the concentration levels required under the proposed rule. Even those PWSs with advanced, state-of-the-art treatment facilities will be overwhelmed by the monitoring and disposal costs associated with PFAS removal from public water supplies. It is equally clear that the amount of federal assistance contemplated to assist PWSs in their compliance efforts will fall well short of what is needed, leaving the PWSs with no choice but to offset their costs by seeking to shifting liability toward those persons and entities which use PFAS-containing products – including large, public airports such as the Ontario International Airport (ONT).

Since 1988, the Federal Aviation Administration has required public airports such as ONT to maintain, store, and use Aqueous Film Forming Foam (AFFF) for purposes of fire suppression. Specifically, larger public airports like ONT (often referred to as "FAA Part 139 airports") are required to use AFFF with the molecular composition known as MIL-PRF-24385, which contains PFAS chemicals. For this reason, the proposed rule will make airports an easy target for any PWS seeking to deflect and reallocate costs it has incurred, or will incur, to comply with the 4 ng/L PFAS MCL that EPA now seeks to implement. Given that public airports were and remain required by federal regulation to use the very AFFF that results in potential discharges of PFAS into the environment, it would be prudent to exempt or otherwise shield such airports from liability under the proposed rule (or any other rule that EPA may propose on this topic). In short, it makes no sense hold public airports liable for a contaminant they were forced to use by federal regulation.

This is not to say that the OIAA is unsympathetic to PWSs striving to comply with the proposed rule. The costs of such compliance will be extraordinary. Further, they will be disproportionate to the operating and capital budgets of many of the affected PWSs, especially the smaller ones in rural areas. The cost-benefit analysis set forth in the proposed rule is deficient from a host of angles and provides little meaningful information on which to base a decision. For example, many of the cost items are deemed "unknown" or "uncertain", which means they were not factored into the analysis. This skews the results and hides the true costs of compliance. In

addition, the benefits of the proposed rule – and there are many – will be dispersed among the entire population, whereas the costs – and these are staggering – will be borne by a small number of public entities that already struggle to maintain balanced budgets. This disparity between who benefits and who pays undermines the proposed rule's cost-benefit analysis and renders it a complete fiction.

This defect in the proposed rule could be forgiven if the federal government were to provide an adequate pool of money to fund all necessary compliance efforts, thereby minimizing the economic pain felt by PWSs and, by extension, those third parties to whom PWSs may seek to shift liability. Unfortunately, this is not the case. The federal monies identified for this purpose in the proposed rule will not even come close to meeting what the PWSs will need. Again, this is what concerns the OIAA and other public airport operators. We do not wish to become the default funding source for PWSs seeking to comply with the proposed rule.

In light of these concerns, the OIAA recommends that EPA slow down and fully examine whether the proposed rule, including its rigorous (some might say draconian) MCLs for PFOA and PFOS, can feasibly and economically be implemented by the many and varied PWSs in the country. The OIAA also recommends that EPA exempt from liability any and all public entities which, by federal regulation, have been (or continue to be) required to use PFAS-containing substances, such as AFFF. Without such an exemption, public airports such as ONT may be forced to litigate with PWSs seeking to recoup costs incurred during their PFAS remediation efforts, leading to an unfortunate clash of public agencies and an unnecessary loss of local and federal public dollars.

Sincerely,

David P. Hubbard, Partner Gatzke Dillon & Ballance, LLP Counsel for the

Ontario International Airport Authority

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document, information on the health risk reduction and cost analysis can be found in section 13. Whereas the commenter suggests that the benefits of the rule will be distributed nationally while the costs are focused on those PWSs required to address elevated PFAS in their water, the benefits will very likely be seen specifically by those served by such PWSs. Regarding the consideration of uncertainty in the EA, the EPA provided a comprehensive uncertainty analysis in the PFAS NPDWR EA (see USEPA 2024b and the HRRCA section XII of the FRN for this action). Moreover, the EPA assessed all major sources of uncertainty in the EA using both quantitative and qualitative approaches, which is consistent with the OMB Circular A-4 guidance recommending that important uncertainties be analyzed and presented. For more information on the cost analysis, see section13.3 of the EPA response in this *Response to Comments* document. For more information on the EPA's uncertainty analysis and characterization, see section 13.9 of the EPA response in this *Response to Comments* document. The EPA makes CERCLA response decisions based on site-specific information, which includes evaluating the nature, extent, and risk to human health and/or the environment from the release.

Hazardous substance designations do not automatically result in CERCLA liability for any specific release. Whether an entity may be subject to litigation or held liable under CERCLA are site-specific and fact-dependent inquiries. Please see section 10.4.2 of the EPA response in this *Response to Comments* document for more information on how other statutes may interact with this rule.

City of Cottage Grove, Minnesota (Doc. #1696, SBC-044457)

May 30, 2023

Office of Water

U.S. Environmental Protection Agency 1200 Pennsylvania Avenue NW Washington DC, 20460

Re: PFAS National Primary Drinking Water Regulation Rulemaking (Docket EPA-HQ-OW-2022-0114)

To Whom It May Concern:

Thank you for the opportunity to comment on the US EPA's proposed PFAS National Primary Drinking Water Regulation . The City of Cottage Grove is located in the eastern Minneapolis-St. Paul Metropolitan Area (East Metro), which has a long history in dealing with PFAS groundwater contamination. The residents of Cottage Grove have been impacted by PFAS since its first detection in the City's municipal drinking water supply wells in the mid 2000's. Since that time, ever changing drinking water standards and guidance levels have continuously challenged the ability to meet the water supply needs of our community. Cottage Grove supports this proposed rulemaking to provide consistent, nationwide standards for PFAS.

Cottage Grove and its neighboring communities have been fortunate to be able to fund temporary PFAS treatment measures through the 2007 3M Consent Order, in addition to the upcoming construction of permanent treatment plants through 2018 3M Settlement Agreement. Having worked through the planning process and costs related to PFAS water treatment, Cottage Grove has firsthand experience with the magnitude of this endeavor. While communities in the East Metro have the funding to provide for water treatment, along with operations and maintenance for a period of time, these "forever chemicals" will impact all aspects of our water supply operations in perpetuity. The nationwide costs to meet these standards will be significant, and Cottage Grove supports new federal funding opportunities to assist public water suppliers as they take on this challenge.

Finally, the City of Cottage Grove supports the comments from the Minnesota Department of Health in their letter dated May 25, 2023, and the Minnesota Pollution Control Agency. These two agencies have been instrumental in addressing both PFAS contamination and fighting for clean drinking water in the State of Minnesota.

The·City of Cottage Grove appreciates the opportunity to submit these comments. Please contact Ryan Burfeind, Public Works Director, at 651-458-2899 or rburfeind@cottagegrovemn.gov should you have any questions or wish to discuss our comments in greater detail.

Sincerely,

Jennifer Levitt

City Administrator

City of Cottage Grove

C: Mayor and City Council

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Minnesota Center for Environmental Advocacy et al. (Doc. #1707, SBC-045727)

2. The Costs of Implementing the Proposed MCLs will Come Down With Time

Commenters also write to remind the Agency that the costs of compliance with the Proposed Rule will drop swiftly as technological advancements enter the market. With the Proposed Rule, EPA will require nearly 150,000 public water systems to monitor, test, and, potentially, take action to remediate PFAS contamination from the water supply. The sheer volume of water systems that will be required to engage in PFAS-related testing and action will invite resources into the market, which will spur innovation and drive costs down in the future.

The HRRCA requires EPA to analyze Quantifiable and nonquantifiable costs for which there is a factual basis in the rulemaking record to conclude that such costs are likely to occur solely as a result of compliance with the maximum contaminant level, including monitoring, treatment, and other costs and excluding costs resulting from compliance with other proposed or promulgated regulations. [FN43: 42 U.S.C. § 300g-1(b)(3)(C)(i)(III). Importantly, this statute means that EPA must not consider "costs associated with compliance with regulatory regimes other than the SWDA itself." City of Waukesha v. E.P.A., 320 F.3d 228, 243 (D.C. Cir. 2003). Thus, any comments complaining about alleged costs of compliance with the MCLs for purposes other than the SDWA—such as CERCLA, RCRA, or another statutory scheme—hold no weight.]

To meet this obligation, "EPA estimated costs associated with engineering, installing, operating, and maintaining PFAS removal treatment technologies, including treatment media replacement and spent media destruction." [FN44: PFAS National Primary Drinking Water Regulation Rulemaking, supra note 34, at 18692.] But absent from this calculation is any expected drop in engineering, installation, operating, or maintenance costs caused by advancements in technology or science that ease the financial burden for public water systems to comply with the Proposed Rule. Minnesota, for example, has already deployed PFAS removal technologies that, as of a few years ago, seemed like a pie-in-the-sky invention from the distant-future. [FN45: MPCA Brings

Cutting-Edge Technology to Minnesota to Remove PFAS from Water, Minn. Pollution Control Agency (Oct. 31, 2022), available at https://www.pca.state.mn.us/news-and-stories/mpca-brings-cutting-edgetechnology-to-minnesota-to-remove-pfas-from-water.] As public and private dollars are pumped into the PFAS space, innovation will follow, driving costs of compliance down. While the benefits of clean water and avoided public health outcomes will remain high, the costs of ensuring our public water supplies are not serving water laced with toxic levels of PFAS will drop substantially in the coming years. The Agency's conclusion that the ends justify the means is on sound footing.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA agrees with the commenter that costs of compliance may be reduced by advancements in treatment technologies in the future, though future costs are unknown. The EPA anticipates approximately 4,100-6,700 water systems would need to take action to come into compliance with the MCL and the entities regulated by this action are community water systems and non-transient non-community water systems , of which there are approximately 67,000. This rule does not affect the approximately 78,000 transient non-community water systems.

Philadelphia Water Department (PWD) (Doc. #1709, SBC-045736)

4. Despite historic infrastructure funding, it is still a possibility that customers will bear the cost of PFAS clean-up.

PWD applauds Congress for passing the historic Infrastructure Investment and Jobs Act (IIJA) and Drinking Water and Wastewater Infrastructure Act – known as the Bipartisan Infrastructure Law (BIL) – to invest more than $50 billion to improve the nation's water, wastewater, and stormwater infrastructure. PWD appreciates acknowledgement of the challenges that emerging contaminants, such as PFAS, pose to the water industry through the availability of $4 billion to the Drinking Water State Revolving Fund (SRF), with an additional $5 billion to support these efforts in small and disadvantaged communities. However, this funding will not be sufficient to cover the costs that will be incurred because of this proposed NPDWR. While these investments are unprecedented and commended by PWD, the proposed NPDWR may necessitate the nation's largest water infrastructure investment to date, requiring additional funding from either PWSs, state governments, or the federal government to close the anticipated funding gap.

Unfortunately, at this time, Philadelphia does not qualify for grant funding or principal forgiveness through Pennsylvania's SRF due to the size of our system, PWD's financial structure, and the applied affordability methodology. For Philadelphia and other communities impacted by these eligibility limitations, this translates to repaying the loans provided through BIL funding with the revenue generated from rate increases. In other words, PWD customers ultimately bear the cost of the treatment upgrades needed to remove PFAS from drinking water.

Like many major cities, citizens in Philadelphia have a higher poverty rate (22.8%, per the 2020 US Census) than the United States as a whole (11.4%, per the 2020 US Census). While PWD has

made great efforts to ease the financial burden on its most vulnerable ratepayers with the implementation of senior discounts and the tiered assistance program (TAP), [Link: https://water.phila.gov/cap/] the majority of the financial burden for implementing PFAS treatment technologies as proposed by the NPDWR will fall on ratepayers.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. States have flexibility in determining priorities and selected projects for grant funding as well as setting interest rates and repayment terms.

Philadelphia Water Department (PWD) (Doc. #1709, SBC-045754)

Conclusion

PWD applauds EPA for making strides to better protect residents across the country from exposure to PFAS. PWD fully supports the EPA's efforts to develop drinking water regulations for PFAS, however, PWD believes that further evaluation of the costs, benefits, and feasibility of reducing PFAS to concentrations less than the proposed maximum contaminant levels is needed. Like many systems across the country, PWD may have to make significant changes to its water treatment systems to comply with the proposed MCLs. Funding to implement the upgrades required must be made more financially accessible to ensure that PWD and water systems across the country have the same ability to treat or remove PFAS from drinking water. Given the challenges PWD has faced in acquiring federal infrastructure funding, PWD requests that EPA prioritizes providing clear and consistent funding guidelines to state revolving funds to ensure low-income communities can receive BIL funds regardless of their size.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. States have flexibility in determining priorities and selected projects for grant funding as well as setting interest rates and repayment terms for SRFs. For information on the feasibility analysis, please see section 5 of the EPA response in this *Response to Comments* document.

HRSD (Doc. #1719, SBC-043539)

May 30, 2023

U.S. Environmental Protection Agency

EPA Docket Center

Office of Ground Water and Drinking Water Docket

Submitted electronically to EPA-HQ-OW-2022-0114

RE: PFAS National Primary Drinking Water Regulation Rulemaking Dear Sir/Madam:

HRSD, a regional wastewater treatment provider serving southeast Virginia and approximately 1.9 million Virginians, appreciates the opportunity to provide comment on the proposed National Primary Drinking Water Regulation Rulemaking for PFOA, PFOS and for PFHxS, PFNA, PFBS, and HFPO-DA and its ammonium salt. What follows are specific comments from HRSD though we also support the comments of the Virginia Municipal Drinking Water Association (VMDWA).

HRSD is proud to offer One Water solutions to meet the growing water challenges faced by the communities we serve, implementing water management practices that prioritize investment in the programs and projects that provide the greatest environmental and public health benefits. This One Water management approach includes HRSD's Sustainable Water Initiative for Tomorrow (SWIFT), a managed aquifer recharge program which offers a sustainable supply of groundwater while reducing nutrient loading to the Chesapeake Bay. This program delivers multiple environmental and public health benefits, supporting a more affordable approach to meeting the compliance objectives of the Chesapeake Bay restoration plan for the region's wastewater and stormwater sectors. This allows local governments to prioritize investment in resiliency efforts to meet the increasing challenges of relative sea level rise throughout our region.

A One Water strategy necessitates the management of water quality and quantity to meet the varied water interests of the community. The SWIFT program, permitted through EPA Region 3's Underground Injection Control (UIC) program, recharges a potable groundwater source. As such, the program is required to meet the Safe Drinking Water Act's (SDWA) Primary Maximum Contaminant Levels (PMCLs) for all SWIFT Water™ that is recharged to the aquifer. The SWIFT Advanced Water Treatment (AWT) process includes Granular Activated Carbon (GAC) and is well positioned to meet the proposed MCLs for PFOA and PFOS as well as the MCL proposed for the combined effects of PFHxS, PFNA, PFBS, and HFPO-DA.

While HRSD is supportive of EPA's efforts to regulate PFAS in drinking water supplies, the costs and impacts to communities are not inconsequential, requiring a thoughtful, strategic approach to regulation that relies on the strength of science and leverages on-going federal and state efforts to reduce or eliminate PFAS at their source. While EPA has offered cost projections, those costs appear to be woefully underestimated, and communities already struggling with water challenges will be heavily burdened by the costs of controlling these chemical contaminants. Though oft repeated within our sector and by EPA itself, it is worth noting again that neither water/wastewater utilities nor the communities they serve manufactured these chemicals or profited from their use. It is critical, therefore, that the "Polluter Pays" model for clean-up of these contaminants serves as the basis for minimizing costs to communities.

Recognizing the importance of public health protection while minimizing economic burden to communities, we implore EPA to approach the PFAS drinking water regulation in a measured way, focusing on the strategies that provide that largest benefit to communities with the lowest cost burden.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Environmental Working Group (EWG) (Doc. #1721, SBC-045415)

EPA's proposed MCLs are affordable.

The EPA correctly determine that the benefits of the proposed rule outweigh the costs, even though SDWA does not explicitly require EPA to make that finding. While SDWA analysis of feasibility "tak[es] costs into consideration,"[FN58: 42 U.S.C. [sec] 300g–1(b)(4)(D).] it does not give more weight to cost over public health benefits or a finding that the benefits of outweigh the costs. [FN59: See S. Rep. No. 104-69 at 33 (Nov. 7, 1995) ("The Administrator is not precluded from … set[ting] a maximum contaminant level as close to the maximum contaminant level goal as feasible, even if the Administrator determines that the benefits of the MCL at this level do not justify the costs."); see also 42 U.S.C. [sec] 300g-1(b)(3)(C)(i) (requiring EPA to consider "nonquantifiable health risk reduction benefits" when establishing MCLs); City of Portland, Oregon v. E.P.A., 507 F.3d 706, 712 (D.C. Cir. 2007). See also Earthjustice et al., supra note 7, at 9.]

The costs of implementing the proposed rule are achievable. As explained above, there are off the shelf technologies which have been available for years. Many systems likely already have GAC installed, reducing the upfront costs of meeting the MCL. In fact, EPA's survey of drinking water infrastructure found an estimated $625 billion is needed over 20 years for water systems to continue providing safe drinking water to the public. [FN60: Env't Prot. Agency, Fact Sheet: 7th Drinking Water Infrastructure Needs Survey and Assessment (April 2023), https://www.epa.gov/system/files/documents/2023-04/Final_DWINSA%20Public%20Factsheet%204.4.23.pdf.] However, the proposal to regulate PFAS in drinking water would account for only approximately 2-3 percent of the total 20-year infrastructure investment need.

Additionally, unprecedented amounts of funding are already available to help systems meet the costs of upgrading. The Bipartisan Infrastructure Investment and Jobs Act, which was signed into law on November 15th, 2021, included $10 billion dollars to address pollution from emerging contaminants, including PFAS, through Safe Drinking Water Act and Clean Water Act grant programs. [FN61: The Infrastructure Investment and Jobs Act, H.R. 3684, 117th Cong. (1st Sess. 2021).]

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Natural Resources Defense Council (NDRC) et al. (Doc. #1723, SBC-044469)

Yet, many water systems have opposed the proposed MCLs based on the cost of compliance, which they say may make water bills unaffordable, especially for low-income customers. The

unavoidable implication is that communities experiencing PFAS contamination should resign themselves to drinking unsafe water if low-income residents cannot afford to pay higher water bills. This approach would only perpetuate existing inequities in access to safe drinking water—inequities that the Safe Drinking Water Act is meant to remedy. And it is based on a faulty premise that compliance with protective PFAS standards must come with the expense of unaffordable water bills.

First, opponents of the proposed standards often over-state the likely costs, as some of our organizations explain in separate comments submitted to the rulemaking docket. Second, as discussed further below, they often overlook steps that water systems, states, and EPA can take to fund compliance costs without relying exclusively on ratepayers, and without imposing unaffordable burdens on low-income residents.

In recent guidance under the Clean Water Act, EPA took a firm stand that communities must not be left with water that harms their health and the environment if their most vulnerable residents cannot afford increased water bills. EPA should take the same strong stand here, under the Safe Drinking Water Act.

Specifically, in the February 2023 Clean Water Act Financial Capability Assessment Guidance ("FCA Guidance"), EPA refused to accede to persistent utility demands to weaken standards whenever utilities raise concerns about affordability for low-income households. [FN1: See EPA, Clean Water Act Financial Capability Assessment Guidance (Feb. 2023), https://www.epa.gov/system/files/documents/2023-01/cwa-financial-capability-assessment-guidance.pdf.] Instead, EPA's guidance pushes utilities to pursue "strategies for lowering costs and reducing impacts on low-income households"[FN2: https://www.epa.gov/system/files/documents/2023-02/cwa-fca-questions-and-answers.pdf.] using tools that "ensure that a financial strategy is in place to support needed infrastructure upgrades without overburdening their most vulnerable ratepayers."[FN3:https://www.epa.gov/newsreleases/epa-announces-financial-capability-guidance-support-communities-and-ensureclean.] The guidance identifies "strategies for communities to support affordable utility rates while planning investments in water infrastructure that are essential to protecting clean water….Tools such as variable rate structures, consumer assistance programs, and grants or subsidies from the…State Revolving Fund are some of the tools outlined in the guidance."[FN4: https://www.epa.gov/system/files/documents/2023-02/cwa-fca-fact-sheet.pdf.] In releasing the guidance, EPA emphasized its commitment to work closely with state and utilities to deploy these strategies.

EPA should apply the same principles when adopting Safe Drinking Water Act standards for PFAS: adopt strong standards that are needed to protect human health and help water systems meet those standards without making bills unaffordable for low-income households.

In connection with adopting a final rule, EPA should highlight funding and financing strategies that water systems can use to achieve these objectives. EPA, the states, and water systems must all work to implement these strategies. We describe below several key strategies, including

maximizing use of available federal funding, especially for disadvantaged communities; holding polluters accountable for water systems' compliance costs; and adopting equitable rate structures and other programs that can increase rate revenues without burdening low-income customers.

1. Maximize the use of available federal funding, especially for disadvantaged communities.

To help communities meet new PFAS standards, Congress passed the Bipartisan Infrastructure Law (BIL). On top of federal and state funds available through "base" Drinking Water State Revolving Fund program, the BIL provides $9 billion in grants for water systems to address emerging contaminants such as PFAS, of which $5 billion is specifically for small, underserved, and disadvantaged communities, and of which $4 billion of which is only available as forgivable loans and grants to "eligible recipients," meaning disadvantaged communities [FN5: Pub. L. No, 117–58, 135 Stat. 429, 1402-03 (Nov. 15, 2021).]. The BIL also includes an additional $11.7 billion for drinking water infrastructure needs generally, of which 49% is for grants or principal forgiveness to disadvantaged communities. This funding will aid utilities in meeting EPA's proposed PFAS drinking water standards and improve drinking water safety.

Other BIL funding, though not eligible to be used for PFAS-related costs, indirectly supports water systems' ability to pay for PFAS compliance by reducing the need to rely on ratepayer funds for capital improvements. This includes $15 billion for drinking water systems for lead service line replacement. For water systems that function as combined water and wastewater utilities, the BIL's $12.7 billion in clean water infrastructure funds also offset capital improvement costs for wastewater and stormwater management, which would otherwise be passed on to ratepayers on their combined water and sewer bills. In addition, of course, there is funding available under the State Revolving Funds that have been federally capitalized and matched by state funds over the past two and a half decades, which continue to receive annual appropriations of about $1 billion or more. A significant portion of those funds also is reserved for grants and forgivable loans for disadvantaged communities.

Additionally, forty states have collectively dedicated almost $19 billion dollars in American Rescue Plan Act State Fiscal Recovery Fund monies towards water infrastructure, much of which is available to municipal water (and/or wastewater) systems [FN6: National Council of State Legislatures, ARPA State Fiscal Recovery Fund Database, https://www.ncsl.org/fiscal/arpa-state-fiscal-recovery-fund-allocations (last visited May 22, 2023).].

EPA should continue to bolster its technical assistance efforts to ensure that eligible communities can access all available grants and subsidized loans. Likewise, EPA should bolster its oversight of states' implementation of BIL funds, to ensure that funds designated for disadvantaged communities reach water systems with the greatest affordability challenges. EPA should closely track distribution of BIL funds (and other federal funds) and continue efforts to identify gaps in funding needs that can be identified for Congressional appropriators.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. After finalization of the PFAS NPDWR, the EPA also intends to provide

support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation.

Natural Resources Defense Council (NDRC) et al. (Doc. #1723, SBC-044471)

3. Adopt equitable rate structures and other programs to increase utility revenue without burdening low-income customers.

As stated above, EPA's FCA Guidance provides a toolkit of approaches that utilities can use to increase investment in water infrastructure without making bills unaffordable for low-income customers. In addition to securing grants and subsidized loans, which reduce the costs of capital improvements for all ratepayers, the guidance identifies many steps that utilities can take to reduce costs for low-income customers specifically. These include:

• capping bills for low-income residents at a percentage of income;

• adopting "lifeline" rates with a low charge for an initial amount of usage sufficient to meet each household's essential needs;

• offering bill discounts specifically to low-income customers;

• helping low-income customers repair plumbing leaks and replace old, water-guzzling toilets, which can both reduce utilities' water supply costs and provide ongoing bill reductions for low-income households.

There are water systems around the country using each of these approaches, to varying degrees. In addition to examples cited in the FCA Guidance, many of the best examples are collected in an extensive water affordability "toolkit" published last year by Natural Resources Defense Council and National Consumer Law Center [FN18: Natural Resources Defense Council and National Consumer Law Center, Water Affordability Advocacy Toolkit (June 2022), https://www.nrdc.org/resources/water-affordability-advocacy-toolkit. Three of the most relevant chapters of from this publication, entitled "Equitable Water Rates," "Affordability and Assistance Programs," and "Water Efficiency and Plumbing Repair Assistance," are submitted to the rulemaking docket as separate PDF files accompanying this letter.]. That toolkit also provides detailed recommendations on best practices and factors to consider when implementing these strategies.

The FCA Guidance states that technical assistance is available through EPA concerning these approaches. We urge EPA to ramp up its technical assistance offerings on these topics.

Additionally, we urge EPA to expeditiously complete the "needs assessment for nationwide rural and urban low-income community water assistance" required by the BIL, in which EPA is required to provide Congress with "recommendations of the Administrator regarding the best methods to reduce the prevalence of a lack of affordable access to water services."[FN19: Pub. L. No, 117–58, 135 Stat. 429, 50108 (Nov. 15, 2021)]

* * *

Thank you for your consideration of these comments. We look forward to a final rule from EPA, coupled with supporting resources, that will protect communities from toxic PFAS contamination while helping water systems achieve affordable bills for their customers.

Submitted on behalf of the following organizations:

National

Anthropocene Alliance

Children's Environmental Health Network

Clean Water Action

Earthjustice

Environmental Working Group

Green Science Policy Institute

GreenLatinos

League of Conservation Voters

National Consumer Law Center, on behalf of its low-income clients

Natural Resources Defense Council

River Network

Safer States

Sierra Club

Waterkeeper Alliance

Alabama

Alabama Rivers Alliance

Black Warrior Riverkeeper

Cahaba River Society

Alaska

Alaska Community Action on Toxics

California

Community Water Center

River in Action

Sacred Grounds TM

SEE (Social Eco Education)

Florida

Earth Ethics, Inc.

Great Lakes Region (multi-state)

For Love of Water (FLOW)

Louisiana

For a Better Bayou

Habitat Recovery Project

Justice and Beyond, Louisiana

Louisiana Bucket Brigade

Micah Six Eight Mission

The Water Collaborative of Greater New Orleans

Michigan

We the People of Detroit

Minnesota

Institute for Agriculture and Trade Policy

Lake Pepin Legacy Alliance

Northeast/Mid-Atlantic Region (multi-state)

Delaware Riverkeeper Network

Waterspirit

Vermont

Vermont Conservation Voters

Vermont Natural Resources Council

Vermont Public Interest Research Group

Wisconsin

Milwaukee Water Commons

[Attachment 2: see docket ID EPA-HQ-OQ-2022-0114-1723]

[Attachment 3: see docket ID EPA-HQ-OQ-2022-0114-1723]

[Attachment 4: see docket ID EPA-HQ-OQ-2022-0114-1723]

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA acknowledges the Financial Capacity Assessment (FCA) guidance recommended by the commenter and agrees that these strategies may be helpful for utilities to reduce costs for low-income customers. The "needs assessment for nationwide rural and urban low-income community water assistance" under BIL and providing Congress with "recommendations of the Administrator regarding the best methods to reduce the prevalence of a lack of affordable access to water services" are beyond the scope of the current rulemaking.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046003)

While EPA and AMWA have been extremely supportive of the Bipartisan Infrastructure Law (BIL) funds that are dedicated to addressing PFAS and other emerging contaminants, AMWA cautions EPA in using messaging that implies the dollars available are enough to cover the cost of this rulemaking. Such messaging creates a difficult situation for water systems and local officials who are forced to raise water rates to implement treatment in compliance with this proposed rule when the public is receiving messaging that available federal funding will fully cover PFAS treatment. The reality is that federal funding to date will be far from enough, and ratepayers will be the primary financiers of this proposed rule. Water systems need EPA's help to simultaneously acknowledge and applaud the BIL investment in drinking water while also urging for more, as the nation's water problems will need significant improvements in the coming years as our comments and assessment of costs (Attachment 1) indicate. EPA's most recent Drinking Water Infrastructure Needs and Assessment (DWINA) estimates that drinking water utilities will need more than $31 billion per year for the next twenty years for infrastructure to support drinking water regulatory compliance. AMWA therefore urges EPA to refrain from communicating to the public that federal investments alone will cover the costs of this proposed rulemaking.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL funds are not meant to fully cover all capital costs associated with implementing the NPDWR and that there are significant quantifiable and non-quantifiable health benefits realized from implementing the rule.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046026)

2. Federal Funding Analysis

The Drinking Water State Revolving Fund (DWSRF) is a federal-state program that provides funding and financing to CWSs drinking water infrastructure projects [FN133: U.S. Environmental Protection Agency, "Clean Water and Drinking Water State Revolving Funds and the Bipartisan Infrastructure Law," n.d.]. The Infrastructure Investment and Jobs Act (IIJA) provides $4 billion in funding to address emerging contaminants over five years (FY22- FY26). Eligible recipients include public and private community water systems serving at least 15 service connections used by year-round residents or regularly serving at least 25 year-round residents. Nonprofit non-community water systems including schools, publicly owned campgrounds, parks, and churches are also able to receive funding. Comparing the annual treatment cost to available federal funding is important because, while IIJA provides historic investment in PFAS treatment, the proposed rule's estimated costs far exceed this funding.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL funds are not meant to fully cover all capital costs associated with implementing the NPDWR and that there are significant quantifiable and non-quantifiable health benefits realized from implementing the rule.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045959)

Section 3.3: Simultaneous compliance

A major issue facing PWSs is simultaneous compliance. Water treatment is an extremely delicate process, and even the slightest change in the treatment train can have dramatic effects on water quality. Water utility managers are facing many challenges unique to their PWSs and are the most qualified individuals to make decisions on what is a priority for that system. Water systems must balance risk-risk tradeoffs to ensure maximum compliance and minimum risks of health effects.

PFAS is just one of many concerns water systems must navigate. PWSs are also addressing lead service line replacement requirements, where some are running into issues with funding and costs both on the public and private side of the service lines. Utilities across the country are working to prioritize the repair and replacement of aging infrastructure. The nation's headlines have shown the consequences of ignored infrastructure maintenance, and with limited resources, many projects must be put on the backburner to ensure compliance with regulations like the one proposed in this NPDWR. Many PWSs are extremely concerned about water scarcity and climate change impacts, which will require new and creative solutions that will likely come at high costs. These examples do not diminish the impact PFAS can have on public health but highlight the demand for resources and difficult decisions water systems must weigh to keep water both affordable and safe.

Water systems also must comply with the many current and future regulations. Even the smallest change in treatment can have negative impacts on other regulated and unregulated contaminants. The type and concentration of a contaminant to be treated with a new technology is extremely important information to have before designing and implementing a new treatment process as

these variables affect the size and components of the new system. Therefore, a treatment technique may be applicable to many contaminants, but the effectiveness of removing each of the contaminants can be dependent on how the process was developed. As EPA continues to revise or create new rules, water systems will have to make adjustments that could require more labor and increased costs than EPA originally assumed while drafting NPDWRs.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The agency acknowledges the concerns raised by the commenter on potential compliance challenges with the final NPDWR and other drinking water priorities in light of limited resources. As discussed further in section 13.4 of this *Response to Comments* document, the agency expects significant quantifiable and non-quantifiable health risk reduction benefits to be realized from implementing the PFAS NPDWR. To the extent that implementation overlaps with other rules, the EPA cannot evaluate costs that result from compliance with other regulations. Specifically, the agency notes that SDWA Section 1412(b)(3)(C)(i)(III) requires that the EPA include quantifiable and non-quantifiable costs that are likely to occur solely as a result of compliance with the rule at issue, including monitoring, treatment, and other costs, and excluding costs resulting from compliance with other proposed or promulgated regulations. Nonetheless, while operational adjustments may be necessary, the EPA has not identified any other drinking water regulations or requirements that will inhibit compliance with this regulation, nor should this regulation significantly impair compliance with other regulations, such as the lead and copper rules.

Environmental Council of the States (ECOS) (Doc. #1752, SBC-044503)

State Funding Needs

States will need additional funding for state capacity building to implement the final PFAS rule. ECOS has emphasized the need for EPA to provide states with funding and the flexibility to use it to manage PFAS. ECOS also acknowledges EPA's work to distribute funds from the Bipartisan Infrastructure Law to drinking water systems impacted by PFAS and other emerging contaminants.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Environmental Council of the States (ECOS) (Doc. #1752, SBC-044505)

ECOS members have also called on Congress to provide significantly more funding for state capacity building and infrastructure to implement and enforce

PFAS-related regulations that can protect and sustain our communities.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

El Paso Water (Doc. #1757, SBC-044523)

Ratepayers will bear the burden for cost increases. Our water sector trade associations are concerned that EPA has significantly underestimated the costs to PWSs and ratepayers for this testing. If a regulatory action will have a demonstrable health benefit, the return on investment is understood and can be communicated. However, in this case, costs to ratepayers will escalate with unreliable outcomes.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA has carefully considered the costs for all systems that will be affected by the rule and has detailed the agency's assumptions. Please see section 13.3 of the EPA response in this *Response to Comments* document for additional discussion on the rule costs.

El Paso Water (Doc. #1757, SBC-044527)

The EPA also should consider creating national fund that would assist PWSs in standing up these new treatment processes and not unfairly burden communities with these high costs.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Arizona Water Company (Doc. #1758, SBC-044534)

In the EPA's March 16, 2023 "General Overview Webinar on the Proposed PFAS NPDWR," the EPA mentions that nearly $21 Billion in Infrastructure Law and BIL DWSRF funding is available for drinking water systems specifically impacted by PFAS and other emerging contaminants. The Company, along with numerous other drinking water systems around the country, will apply for and use this funding to construct PFAS removal facilities. The Company recommends the EPA provide instruction on when and how utilities will be able to apply for this funding. The Company recommends providing funding options to all water providers, including private water utilities.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation.

American Water Works Association (AWWA) (Doc. #1759, SBC-045570)

Securing Financing is a Slow Process

A crucial step for installing capital improvement projects is to identify and secure a source of financing. In announcing this rule, EPA highlighted the funds through the Bipartisan

Infrastructure Law (BIL) and the Drinking Water State Revolving Fund (DWSRF). Financing is also available through the Water Infrastructure Finance and Innovation Act (WIFIA) program. These programs provide an avenue for water systems to finance new treatment facilities, but these programs are known be time consuming and sometimes take several years to acquire approval, which is in addition to the time to get to a project design that can be reviewed. These programs may also impose additional requirements for funding to be approved that may limit procurement options and costs. Whether a system utilizes the DWSRF, WIFIA, or through the market, the process may still be slow and will be independent of the typical financial planning process of developing a Capital Improvements Program. Planning through this program helps to assure that capital improvements are staged in a way that minimizes water rate impacts by staggering major investments within a community's water infrastructure.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Riverside Public Utilities, Riverside, CA (Doc. #1762, SBC-044229)

[The following comments are submitted for consideration in the proposed EPA rulemaking:]

Expand and Facilitate Funding

City staff looks for the U.S EPA and other State and Federal funding programs to expand and facilitate the process of accessing funding to allow utilities to cost-effectively achieve the benefits of the proposed regulations.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

New Mexico Environment Department (NMED) (Doc. #1766, SBC-044249)

State Staffing Resources and Overall Burden

Grants to states across EPA's portfolio should include additional funding to address known and unknown PFAS, PFOA and PFOS impacts and associated costs for compliance with the proposed regulation. EPA must meet the potential widespread prevalence of these compounds with appropriate funding increases and not simply pass these costs to states and communities.

Many states, including New Mexico rely heavily on federal grant dollars to help implement our state drinking water regulatory programs, specifically, the federal Public Water System Supervision (PWSS). Between 2015 and 2021, the last year for which award amounts are finalized, NMED's PWSS grant increased by 7% (from $2,055,000 to $2,192,000), lagging well behind inflation of nearly 12% in the same period. Beyond inflation, grant dollars are being stretched more thinly with increasingly complex and demanding workloads resulting from implemented regulations such as the Revised Total Coliform Rule, Disinfection Byproduct rules, Lead and Copper Rule Revisions, proposed Consumer Confidence Rule revisions and now PFAS

regulatory determinations. The overall resources required to effectively implement these rules have increased over the years; however, the federal grant dollars have not kept pace with those resource requirements.

Additionally, in New Mexico, almost 80% of our community water systems serve populations of less than 1,000 people. These small community water systems are often disadvantaged and underserved and require a significant amount of assistance from our drinking water program to achieve and maintain compliance with increasingly stringent drinking water regulations. Lastly, states are managing a significant increase in overall workloads due to additional factors such as the Bipartisan Infrastructure Law funding through the State Revolving Fund programs while facing retirements of technical staff and trained operators, putting states in the unreasonable and unsustainable position of being forced to do more with less.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. States have the flexibility to use a portion of the SRF funds to administer the SRF program.

Council of State and Territorial Epidemiologists (CSTE) (Doc. #1770, SBC-044262)

4. Funding Considerations: CSTE applauds the recognition by EPA that the passage of the Infrastructure Investment and Jobs Act, also referred to as the BIL, invests over $11.7 billion in the Drinking Water SRF; $4 billion to the Drinking Water SRF for Emerging Contaminants; and $5 billion to Small, Underserved, and Disadvantaged Communities Grants. These funds will assist many disadvantaged communities, small systems, and others with the costs of installation of treatment when it might otherwise be cost-challenging. These funds can also be used to address emerging contaminants like PFAS in drinking water through actions such as technical assistance, water quality testing, and contractor training, which will allow communities supplemental funding to meet their obligations under this proposed regulation and help ensure protection from PFAS contamination of drinking water. Despite these dollars, updating water infrastructure will likely exceed available funds. In addition, funding should be made available to private well owners. Funding will also need to be expanded to promote health equity in disadvantaged communities to comply with the updated regulation and avoid increases in water delivery costs for consumers or provide alternative water solutions as upgrades are made. CSTE recommends EPA further work with government partners including establishment of resource assessment teams to ensure that all funding needs are included in the prospective resources to support the regulation including needs associated with applied public health epidemiologists staffing and needs associated with conducting epidemiologic assessments and studies.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. As discussed in the section essay, the agency agrees that funding through BIL should help communities meet their obligations under the final NPDWR. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation. The EPA further notes that BIL

funds are not meant to fully cover all capital costs associated with implementing the NPDWR and that funds are intended to help utilities comply with the SDWA. Funding for "staffing and needs associated with conducting epidemiologic assessments and studies" are generally beyond the scope of BIL funding.

Uttara Jhaveri (Doc. #1778, SBC-045448)

The EPA must consider the costs of installation and operation of the proposed technologies by public water utilities. The high costs may be deemed "arbitrary" and not "economically feasible" under SDWA by stakeholders. [FN25: THE SAFE DRINKING WATER ACT, supra note 19.] Moreover, the costs may attract dissent from stakeholders and the public, especially because the entity bearing the burden of the costs is unclear from the proposed rulemaking. [FN26: Joseph J. Rolling & David P. Ruetz, EPA Proposes Regulatory Limits for PFAS in Drinking Water, NATIONAL LAW REVIEW, May 1, 2023, https://www.natlawreview.com/article/epa-proposes-regulatory-limits-pfas-drinking-water.] Therefore, the installation and operational costs must be properly justified, and the burden of said costs should be shifted to the polluters under the "Polluter Pays Principle" [FN27: OSPAR Commission, Polluter Pays Principle, https://www.ospar.org/convention/principles/polluter-pays-principle.] instead of the taxpayers or public entities.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA has considered cost to PWSs and primacy agencies in the agency's feasibility analysis of the final MCLs. Specifically, the agency considered the costs associated with implementation (e.g., costs for labor, materials, and construction of capital improvements) and compliance (e.g., costs to monitor) with the final MCLs. The EPA also considered costs of treatment technologies that have been demonstrated under field conditions to be effective at removing PFAS regulated under this NPDWR and determined that the cost of complying with the rule is reasonable. For additional discussion on the EPA's cost analysis, please see section 13.3 (methods for estimating cost) of the EPA response in this *Response to Comments* document.

Ohio Water Utility Council (OWUC), Ohio American Water Works Association (OAWWA) (Doc. #1782, SBC-044722)

These proposed drinking water standards are just one of the many current and upcoming regulatory rules where compliance is required or will be required for many PWSs in Ohio. The funding availability for these treatment and operational changes will only go so far, leaving a large cost to the water utility rate payers of Ohio. These funds will continue to be spread thin as more PWSs become aware of PFAS contaminants in their systems through the UCMR5 monitoring program. OWUC urges the EPA to thoroughly review the estimated costs and what funding will be made available to water systems as we tackle the treatment and removal of PFAS substances.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL funds are not meant to fully cover all capital costs associated with implementing the NPDWR and that there are significant quantifiable and non-quantifiable health benefits realized from implementing the rule.

National Ground Water Association (NGWA) (Doc. #1804, SBC-045453)

The National Ground Water Association submits its comments on Per- and polyfluoroalkyl substances (PFAS): Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) National Primary Drinking Water Regulation Rulemaking, EPA-HQ-OW-2022-0114, in the attached file. We appreciate the opportunity to review the proposed rule and submit these comments.

NATIONAL GROUND WATER ASSOCIATION COMMENTS ON: ENVIRONMENTAL PROTECTION AGENCY Proposed Rule: PFAS National Primary Drinking Water Regulation Rulemaking

Published: March 29, 2023

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Code of Federal Regulations: 40 CFR Parts 141 and 142

Docket/Agency Numbers: EPA-HQ-OW-2022-0114; FRL 8543-01-OW

Comments Due: May 30, 2023

Summary:

On March 29, 2021, EPA proposed a National Primary Drinking Water Regulation (NPDWR) and health-based Maximum Contaminant Level Goals (MCLG) for regulating specific Per- and Polyfluoroalkyl Substances (PFAS): perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) as contaminants with maximum contaminant levels and perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salt (also known as a GenX chemicals), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS), and mixtures of these PFAS as contaminants with hazard indicies under Safe Drinking Water Act (SDWA). EPA proposed to set the health-based value, the maximum contaminant level goal (MCLG), for PFOA and PFOS at zero. Considering feasibility, including currently available analytical methods to measure and treat these chemicals in drinking water, EPA proposed individual MCLs of 4.0 nanograms per liter (ng/L) or parts per trillion (ppt) for PFOA and PFOS. EPA proposed to use a Hazard Index (HI) approach to protecting public health from mixtures of PFHxS, HFPO-DA and its ammonium salt, PFNA, and PFBS because of their known and additive toxic effects and occurrence and likely co-occurrence in drinking water. EPA proposed an HI of 1.0 as the MCLGs for these four PFAS and any mixture containing one or more of them because it represents a level at which no known or anticipated adverse effects on the health of persons are expected to occur and which allows for an adequate margin of safety.

EPA has determined it is also feasible to set the MCLs for these four PFAS and for a mixture containing one or more of PFHxS, HFPO-DA and its ammonium salt, PFNA, PFBS as an HI of unitless 1.0.

Electronic Link: https://www.federalregister.gov/documents/2023/03/29/2023-05471/pfasnational-primary-drinking-water-regulation-rulemaking

National Ground Water Association Comments

Overarching Comments

Based on Environmental Protection Agency data, small public water systems are most significantly affected by PFAS compared to other system sizes. Additionally, small water systems may be least able to respond technically, financially and managerially to a complex rule requiring expensive treatment technology. [FN1: U.S. Environmental Protection Agency (USEPA). 2021. 18th Annual EPA Drinking Water Workshop: Small System Challenges and Solutions. Dr. Christopher Frey, EPA Deputy Assistant Administrator for Science Policy, message delivered to Session 1, Plenary, August 30, 2021. https://www.youtube.com/watch?v=ycVa5uG7izg (Accessed April 19, 2023).] This circumstance is also applicable to privately-owned household water systems that may be located near small water systems. NGWA is very concerned that Guelfo and Adamson (2018) [FN2: Guelfo, J.L. and D.T. Adamson. 2018. Evaluation of a national data set for insights into sources, composition, and concentrations of per- and polyfluoroalkyl substances (PFASs) in U.S. drinking water. Environmental Pollution vol. 236 (May), pp.505-513. Cited in U.S. Environmental Protection Agency, Regulatory Determination 4 Support Document; EPA 815-R-19-006, December 2019, p. 3-38.] examined PFAS results from the EPA's Unregulated Contaminant Monitoring Rule (UCMR) 3 program in detail and found that approximately 50 percent of samples with reportable levels of one or more PFAS detections contained at least two PFAS and 72 percent of detections occurred in groundwater. When detected, median total PFAS concentrations were higher in small public water systems (PWS) serving 10,000 or fewer persons (0.12 µg/L) than in large PWSs (0.053 µg/L). This PFAS level in small water systems is 30 times the proposed MCL of 4 ppt. This concern is highlighted by the fact that 76 percent (37,914) of all community water systems are primarily ground-supplied, and 96 percent of those groundwater-supplied systems are small water systems serving 10,000 or fewer people and have fewer resources to manage their water systems. Ninety-seven (97) percent (99,666) of nontransient and transient noncommunity water systems are groundwater-supplied. [FN3: U.S. Environmental Protection Agency. 2023. Drinking Water Government Performance Reporting Act Tool.

https://obipublic.epa.gov/analytics/saw.dll?PortalPages&PortalPath=/shared/SFDW/_portal/Public.]

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The commenter provides a summary of reportable detections referenced in Guelfo and Adamson (2018). The EPA notes that this study examined the third Unregulated

Contaminant Monitoring Rule (UCMR 3), which includes a PFAS compound that is not regulated under this final NPDWR (i.e., perfluoroheptanoic acid [PFHpA]). The agency also notes that detections do not necessarily equal MCL violations. In the final NPDWR, violations are assessed by running annual average and individual detections may not cause a system to be out of compliance (please see section 8.2 of the EPA response in this *Response to Comments* document for more information on PWS compliance and violations). Specifically in section 2.4 of the EPA response in this *Response to Comments* document, the EPA is finalizing flexibilities that should alleviate some cost concerns related to the monitoring requirements of the rule, including the flexibilities to use previously acquired monitoring data to satisfy some or all of the initial monitoring requirements and, for those groundwater systems serving 10,000 or fewer people that do not have this data, that they be required to only collect two samples at each EPTDS to satisfy initial monitoring requirements. With respect to PFAS occurrence, the EPA relied on multiple data sources, including UCMR 3 and state finished water data, to evaluate the occurrence of PFOA, PFOS, PFHxS, PFNA, and HFPO-DA, and probability of co-occurrence of these PFAS and PFBS. The EPA also incorporated both the UCMR 3 and some state data into a Bayesian hierarchical model, which supported exposure estimates for select PFAS at lower levels than were measured under UCMR 3. These results are discussed in more detail in section VI of the final rule preamble and section 6 of this *Response to Comments* document.

Florida Rural Water Association (FRWA) (Doc. #1806, SBC-044693)

RE: Comments on PFAS National Primary Drinking Water Regulation

As a representative of Florida's drinking water systems, the Florida Rural Water Association is providing feedback to EPA regarding PFAS regulation. We are proud that Florida is a national leader in protecting public health by regulating contaminants in drinking water. However, the financial impact of addressing contaminants on water utilities also poses a threat to public health. This is especially the case for our small, rural system members.

In particular, proposed regulations of PFAS place an undue burden on the resources of utilities that are impacted. Collecting the PFAS water sample requires extensive training or hiring a contractor. Sample analysis is expensive, especially since there are few labs within the state certified to perform EPA Methods 537 or 537.1. Those systems found to have PFAS levels exceeding the MCL will spend large amounts on engineering services and remediation in addition to the social consequences of issuing a Do Not Drink, public notice or messaging on "forever chemicals" in the water order to their customers. The consequences of the regulation will cause water rates to rise, which will often harm our most vulnerable populations.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. For laboratory and other analytic considerations in the agency's evaluation of feasibility for the final MCLs, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Environmental Working Group et al. (Doc. #1810, SBC-044691)

While some water utilities have already installed water treatment technology capable of reducing PFAS, many are not yet equipped to do so. To help communities, Congress passed the Bipartisan Infrastructure Law which provides $9 billion in funding for drinking water treatment upgrades, and an additional $11.7 billion for other necessary drinking water infrastructure needs. This funding will aid utilities in meeting EPA's proposed drinking water standards and improve drinking water safety.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

West Virginia Municipal Water Quality Association (Doc. #1816, SBC-044680)

VI. Federal Funding Impacts

EPA appears to assert that the BIL will solve all implementation issues. However, little of that funding over the first two years has been provided to the 6,000 community water systems that will have to install PFAS barrier technologies. The reality is that BIL money, with its competitive nature and limited grant percentage, is far from adequate to cover the unprecedented cost of PFAS barrier technology installations at thousands of water systems. Moreover, the States have already programmed a good bit of future BIL funding for supplemental projects unrelated to PFAS. Moreover, even if the BIL were adequate to cover PFAS costs, EPA and the States could not dedicate all (or even a major portion) of it to the exclusion of other significant public health-related drinking water and wastewater needs. For example, PFAS is taking away critical resources that could be used for lead service line replacements at the public water systems that need to continue to fund and implement removal of lead pipes from their systems.

The reality is that many affected water systems cannot afford to design and install PFAS barrier technology and even if they could, they cannot afford the significant operation and maintenance costs, especially if PFAS bearing residuals (such as spent GAC media) must be disposed of as hazardous waste. BIL funding does not address whatsoever these enormous annual operation and maintenance costs.

So even if EPA could cannibalize all other public infrastructure needs, it is highly unlikely that water systems can afford to implement and maintain current PFAS barrier technologies. That reality must be factored into EPA's feasibility analysis and further supports our proposed phased/tiered implementation approach.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL funds are not meant to fully cover all capital costs associated with implementing the NPDWR and that there are significant quantifiable and non-quantifiable health benefits realized from implementing the rule. With respect to a phased implementation approach and compliance timeframes, please see the section 12 of the EPA response in this *Response to Comments* document.

Association of Missouri Cleanwater Agencies (Doc. #1817, SBC-044658)

VI. Federal Funding Impacts

EPA appears to assert that the BIL will solve all implementation issues. However, little of that funding over the first two years has been provided to the 6,000 community water systems that will have to install PFAS barrier technologies. The reality is that BIL money, with its competitive nature and limited grant percentage, is far from adequate to cover the unprecedented cost of PFAS barrier technology installations at thousands of water systems. Moreover, the States have already programmed a good bit of future BIL funding for supplemental projects unrelated to PFAS. Moreover, even if the BIL were adequate to cover PFAS costs, EPA and the States could not dedicate all (or even a major portion) of it to the exclusion of other significant public health-related drinking water and wastewater needs. For example, PFAS is taking away critical resources that could be used for lead service line replacements at the public water systems that need to continue to fund and implement removal of lead pipes from their systems.

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So even if EPA could cannibalize all other public infrastructure needs, it is highly unlikely that water systems can afford to implement and maintain current PFAS barrier technologies. That reality must be factored into EPA's feasibility analysis and further supports our proposed phased/tiered implementation approach.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL funds are not meant to fully cover all capital costs associated with implementing the NPDWR and that there are significant quantifiable and non-quantifiable health benefits realized from implementing the rule. With respect to a phased implementation approach and compliance timeframes, please see the section 12 of the EPA response in this *Response to Comments* document.

NORTH CAROLINA WATER QUALITY ASSOCIATION (Doc. #1818, SBC-044636)

VI. Federal Funding Impacts

EPA appears to assert that the BIL will solve all implementation issues. However, little of that funding over the first two years has been provided to the 6,000 community water systems that will have to install PFAS barrier technologies. The reality is that BIL money, with its competitive nature and limited grant percentage, is far from adequate to cover the unprecedented cost of PFAS barrier technology installations at thousands of water systems. Moreover, the States have already programmed a good bit of future BIL funding for supplemental projects unrelated to PFAS. Moreover, even if the BIL were adequate to cover PFAS costs, EPA and the

States could not dedicate all (or even a major portion) of it to the exclusion of other significant public health-related drinking water and wastewater needs. For example, PFAS is taking away critical resources that could be used for lead service line replacements at the public water systems that need to continue to fund and implement removal of lead pipes from their systems.

The reality is that many affected water systems cannot afford to design and install PFAS barrier technology and even if they could, they cannot afford the significant operation and maintenance costs, especially if PFAS bearing residuals (such as spent GAC media) must be disposed of as hazardous waste. BIL funding does not address whatsoever these enormous annual operation and maintenance costs.

So even if EPA could cannibalize all other public infrastructure needs, it is highly unlikely that water systems can afford to implement and maintain current PFAS barrier technologies. That reality must be factored into EPA's feasibility analysis and further supports our proposed phased/tiered implementation approach.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL funds are not meant to fully cover all capital costs associated with implementing the NPDWR and that there are significant quantifiable and non-quantifiable health benefits realized from implementing the rule. With respect to a phased implementation approach and compliance timeframes, please see section 12 of the EPA response in this *Response to Comments* document.

South Carolina Water Quality Association (Doc. #1819, SBC-044614)

VI. Federal Funding Impacts

EPA appears to assert that the BIL will solve all implementation issues. However, little of that funding over the first two years has been provided to the 6,000 community water systems that will have to install PFAS barrier technologies. The reality is that BIL money, with its competitive nature and limited grant percentage, is far from adequate to cover the unprecedented cost of PFAS barrier technology installations at thousands of water systems. Moreover, the States have already programmed a good bit of future BIL funding for supplemental projects unrelated to PFAS. Moreover, even if the BIL were adequate to cover PFAS costs, EPA and the States could not dedicate all (or even a major portion) of it to the exclusion of other significant public health-related drinking water and wastewater needs. For example, PFAS is taking away critical resources that could be used for lead service line replacements at the public water systems that need to continue to fund and implement removal of lead pipes from their systems.

The reality is that many affected water systems cannot afford to design and install PFAS barrier technology and even if they could, they cannot afford the significant operation and maintenance costs, especially if PFAS bearing residuals (such as spent GAC media) must be disposed of as hazardous waste. BIL funding does not address whatsoever these enormous annual operation and maintenance costs.

So even if EPA could cannibalize all other public infrastructure needs, it is highly unlikely that water systems can afford to implement and maintain current PFAS barrier technologies. That reality must be factored into EPA's feasibility analysis and further supports our proposed phased/tiered implementation approach.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL funds are not meant to fully cover all capital costs associated with implementing the NPDWR and that there are significant quantifiable and non-quantifiable health benefits realized from implementing the rule. With respect to a phased implementation approach and compliance timeframes, please see the section 12 of the EPA response in this *Response to Comments* document.

Wet Weather Partnership (Doc. #1820, SBC-044592)

VI. Federal Funding Impacts

EPA appears to assert that the BIL will solve all implementation issues. However, little of that funding over the first two years has been provided to the 6,000 community water systems that will have to install PFAS barrier technologies. The reality is that BIL money, with its competitive nature and limited grant percentage, is far from adequate to cover the unprecedented cost of PFAS barrier technology installations at thousands of water systems. Moreover, the States have already programmed a good bit of future BIL funding for supplemental projects unrelated to PFAS. Moreover, even if the BIL were adequate to cover PFAS costs, EPA and the States could not dedicate all (or even a major portion) of it to the exclusion of other significant public health-related drinking water and wastewater needs. For example, PFAS is taking away critical resources that could be used for lead service line replacements at the public water systems that need to continue to fund and implement removal of lead pipes from their systems.

The reality is that many affected water systems cannot afford to design and install PFAS barrier technology and even if they could, they cannot afford the significant operation and maintenance costs, especially if PFAS bearing residuals (such as spent GAC media) must be disposed of as hazardous waste. BIL funding does not address whatsoever these enormous annual operation and maintenance costs.

So even if EPA could cannibalize all other public infrastructure needs, it is highly unlikely that water systems can afford to implement and maintain current PFAS barrier technologies. That reality must be factored into EPA's feasibility analysis and further supports our proposed phased/tiered implementation approach.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL funds are not meant to fully cover all capital costs associated with implementing the NPDWR and that there are significant quantifiable and non-quantifiable health benefits realized from implementing the rule. With respect to a phased

implementation approach and compliance timeframes, please see section 12 of the EPA response in this *Response to Comments* document.

Arkansas Department of Health (Doc. #1821, SBC-044573)

May 30, 2023

U.S. Environmental Protection Agency EPA Docket Center

Office of Ground Water and Drinking Water Docket Mail Code 2822IT

1200 Pennsylvania Avenue NW Washington, DC 20460

Re: Comments on the Proposed PFAS National Primary Drinking Water Regulation Rule Docket EPA-HQ-OW-2022-0114

Thank you for the opportunity to comment on the Proposed PFAS National Primary Drinking Water Regulation. The Engineering Section of the Arkansas Department of Health (ADH) is the primacy agency in Arkansas. As such, we work to ensure compliance with federal and state drinking water standards under the Safe Drinking Water Act. We support the proposal to regulate levels of PFAS chemicals in the National Primary Drinking Water Standards under the Safe Drinking Water Act. The proposed monitoring and corrective actions to identify and reduce PFAS exposure in drinking water will provide additional protections to public health.

The Association of State Drinking Water Administrators (ASDWA) provided comprehensive comments for this proposed Rule on behalf of all member Drinking Water Primacy Agencies. The Arkansas drinking water program fully supports the comments provided by ASDWA. It is imperative that the final Rule provides clear and achievable requirements for PFAS levels in drinking water without being overly burdensome on public water systems and the users they serve. We offer the following comments regarding the proposed Rule in addition to those provided by ASDWA.

We recommend that further evaluation be conducted regarding the costs and potential adverse impacts with compliance with other existing drinking water requirements and water system viability, especially for small water systems. In Arkansas, 94.3% of our 703 public water systems subject to this proposed Rule serve fewer than 10,000 people, with half of those systems serving communities with fewer than 1,100 people. These small water systems currently use minimal or conventional treatment processes and struggle to find properly qualified water treatment operators and adequate funding for their operations.

The capital and operation costs of installing treatment for PFAS are very high compared to the conventional water treatment processes currently being used. Additional treatment processes will require additional electrical and labor resources to operate properly compared to conventional treatment. In addition, these processes will require proper disposal of waste streams that contain concentrated levels of PFAS and other chemicals. The financial capacity of these water systems will be at significant risk to address the financial burden related to the installation of special

treatment equipment, increased costs of labor, power, and waste disposal for operation of the treatment.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA further notes that states can use the DWSRF set-asides to support operator certification programs. Set-asides are different than the loan portion of the program in that the funds do not go directly to the utility but are supporting the overall goals of the DWSRF. The set-asides can assist the state in ensuring that water systems have properly trained operators to operate and maintain drinking water infrastructure to supply safe water to consumers. This set-aside can, for example, fund state operator certification staff and the development of operator certification databases and data management programs to track operators' certification status. For more information, please visit: https://www.epa.gov/dwcapacity/about-drinking-water-state-revolving-fund-dwsrf-set-asides#overview

Neuse Regional Water and Sewer Authority (Doc. #1822, SBC-044568)

NRWASA'S STRUCTURE AND CONTEXT FOR CONCERNS

NRWASA supplies water to its eight member entities in Lenoir County and Pitt County, North Carolina. Our members are: Town of Ayden, Bell Arthur Water Corporation, Deep Run Water Corporation, Eastern Pines Water Corporation, Town of Grifton, City of Kinston, and North Lenoir Water Corporation. [FN1: Each member corporation is a North Carolina non-profit entity and the other members are municipalities.] As of July 2022, NRWASA's member entities supplied 41,127 active metered accounts serving approximately 125,000 people. NRWASA's smallest member serves 354 customers and its largest member serves 11,365 customers.

Each member manages its own water system and customer base independent of NRWASA and the other NRWASA members. In addition, each of the member entities draws water from the Central Coastal Plain Capacity Use Area ("CCPCUA") aquifer and treats such water at their respective plants. NRWASA draws its water from the Neuse River and treats that water at NRWASA's plant. The NRWASA water is then distributed to the member entities.

NRWASA was formed as regional public entity in response to the decreasing yields of well water in the CCPCUA. As a result of the decreasing well water, the State of North Carolina stepped in to regulate the allowable rate of groundwater withdrawals. The goal of these regulations is to limit groundwater withdrawals to a sustainable rate.

In 2000, NRWASA identified a solution to meeting this challenge. The plan was to continue to use a reasonable amount of groundwater in conjunction with a new water supply, the Neuse River, that NRWASA collects, treats, and distributes.

The NRWASA water treatment plant was completed in 2008 and can produce up to 15 million gallons of water per day. In addition, over 78 miles of water transmission mains were constructed across Lenoir and Pitt Counties to carry treated water to each member entity's water distribution system.

The NRWASA surface water supply project cost at least $146.4 million to complete. Design and construction work of the project was funded through grants and low-interest loans from the USDA, State of North Carolina, EPA, the North Carolina Rural Center, the Goldenleaf Tobacco Trust Fund, member entities, and other local sources. The bulk of the funding was through loans, and NRWASA has carefully budgeted expenditures around servicing the debt.

In addition, some members have undertaken extensive efforts to reduce their use of the aquifer by approximately 90% through reliance on NRWASA water, but all members use some groundwater. Member entities have paid increased rates over the exclusive use of well water (an average of 100%), in order to bring significant replenishment benefits to the CCPCUA aquifer.

Unfortunately, the relatively recent expenditure of such large sums of public funds did not predict the potentially devastating financial consequences of the Proposed Rulemaking.

NRWASA capital costs to comply with the Proposed Rulemaking to exceed $30 million if it is implemented as published, and NRWASA's operating costs will increase considerably to implement the Proposed Rulemaking. The PFOS annual operating cost could eventually exceed all of NRWASA's other routine annual operating costs. This will impose tremendous unbudgeted costs and could threaten the ability of NRWASA to fulfill its mission.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that the comment lacks sufficient detail (such as specifying whether these costs are capital or O&M) to compare the commenter's cost estimates to the results of the EPA's Work Breakdown Structure (WBS) models. See section 13.3.3 of the EPA response in this *Response to Comments* document for more information.

Neuse Regional Water and Sewer Authority (Doc. #1822, SBC-044572)

4. EPA's final rule should address regional public water systems serving economically distressed counties. Such systems should have access to federal funds for capital upgrades required by the Proposed Rulemaking and the rule should not penalize those water utilities for their inability to finance massive upgrades.

The Proposed Rulemaking references billions of dollars the federal government has set aside to assist disadvantaged communities and small systems in reducing PFAS contamination [FN9: EPA, PFAS National Primary Drinking Water Regulation Rulemaking, Federal Register Vol. 88, No. 60 page 18640.]. However, NRWASA itself does not qualify for much of this assistance because it is an independent governmental entity, despite North Carolina receiving a large share of the Bipartisan Infrastructure Law funds [FN10: See, e.g., EPA, Region 4 News Releases, https://www.epa.gov/newsreleases/biden-harris-administration-announces-61715000-bipartisan-infrastructure-law-funding-0, https://www.epa.gov/newsreleases/biden-harris-administration-announces-41876000-clean-water-infrastructure-upgrades#:~:text=RALEIGH%2C%20NC%20(Feb.,State%20Revolving%20Fund%20(CWSRF), and https://www.epa.gov/newsreleases/biden-harris-administration-announces-65-billion-

drinking-water-infrastructure-6.]. NRWASA requests EPA to delay the effective date of the Proposed Rulemaking until such funds are available for NRWASA and similarly situated entities.

NRWASA's customers live in Pitt and Lenoir Counties – both of which are in the North Carolina Department of Commerce's top tier of the most economically distressed counties in the state [FN11: N.C. Department of Commerce, County Distress Rankings (Tiers), https://www.commerce.nc.gov/grants- incentives/county-distress-rankings-tiers#AdditionalReferenceCountyAverageWages-497. These rankings compare counties by their average unemployment rate, median household income, percentage growth in population, and adjusted property tax base per capita.]. The Proposed Rulemaking estimates the total annual cost per household for a system serving between 3,301-10,000 people to be, at best, $133 to $235 a year [FN12: EPA, PFAS National Primary Drinking Water Regulation Rulemaking, Federal Register Vol. 88, No. 60 Table 22.]. NRWASA's analysis suggests the costs will be even higher for households, and the practical impact on economically distressed households will be far worse than for more urban, higher-income regions. Placing such compliance costs squarely on NRWASA and its members' customers will likely aggravate the challenging economic conditions this region of North Carolina already faces. NRWASA and its member systems will have to pass those costs down to consumers who are already living in economically challenged areas.

NRWASA respectfully requests EPA accept NRWASA's four recommendations for the Proposed Rulemaking. Incorporating each of these strategies into the Proposed Rulemaking will improve the regulation and help NRWASA eliminate PFAS substances from its water supply. EPA should ensure that the regulation is protective of public health and that it does not place an untenable burden on water utilities.

Sincerely,

Barry Sutton

Chair of the Board of Directors

Harold Herring

Executive Director

ND:4871-2574-3460, v. 1

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Plymouth Village Water & Sewer District (Doc. #1827, SBC-044556)

NH House Bill 1264 (HB1264), effective June 30, 2020, enacted RSA 485-H, which codified NHDES enforceable standards or Maximum Contaminant Level's (MCL's) for PFOA (12 parts

per trillion; ppt), PFOS (15 ppt), PFNA (11 ppt), and PFHxS (18 ppt), and provided for up to $50 million in loans for public water systems and wastewater facilities to address PFAS substances, including residential well owners. Based on existing state law NH requires NHDES to also adopt rules to establish Ambient Groundwater Quality Standards (AGQS's) that are the same as any MCL's established, impacting municipalities, businesses, and residents everyday essential needs; handling and recycling of solid waste and wastewater.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Plymouth Village Water & Sewer District (Doc. #1827, SBC-044558)

Please carefully consider the following points to help inform the pending rulemaking on this class of pervasive and persistent PFAS chemicals:

• With several thousand systems impacted by the proposed MCLs and roughly three-quarters of them serving 10,000 customers or less, the proposed MCLs will disproportionately affect small systems. Many smaller systems lack the financial, staff and management resources to implement the proposed rules. Today approx. 150 public water systems and every wastewater system in New Hampshire are impacted by PFAS above NH's regulatory levels, where approximately 200 additional public water systems will be impacted, the estimated capital costs of ~$170 million and annual O&M costs of $44 million do not account for inflation, manufacturing and supply chain issues, or professional labor shortages. In February 2023 the Biden-Harris Administration announced that $18,914,000 in BIL funding would go to NH for addressing PFAS contamination. As capital costs continue to increase, these funds will fall short. In addition, ongoing operation and maintenance (O&M) costs are large, growing, and of long (decades) duration. Even with proposed federal support, funds for PFAS treatment at current NHDES drinking water standards are inadequate.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL funds are not meant to fully cover all capital costs associated with implementing the NPDWR and that there are significant quantifiable and non-quantifiable health benefits realized from implementing the rule.

The District of Columbia Water and Sewer Authority (Doc. #1829, SBC-045764)

As a customer of the Aqueduct, DC Water has little control over treatment of our water, but ultimately bears 75% of the costs of compliance - both Capital and Operational. We support reasonable drinking water regulations and EPA's mission to protect and ensure the quality of drinking water in the U.S. The Proposal will place undue and unwarranted costs on our limited base of customers who are already struggling under the burden of having to pay for a $3 billion unfunded Consent Decree mandated program to alleviate combined sewer overflows to the District's waterbodies.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Pennsylvania Municipal Authorities Association (Doc. #1832, SBC-045783)

[PMAA's specific comments on the Proposal are as follows:]

7. Drinking water facilities, including PMAA member authorities, will need to know with certainty the costs to implement the requirements in the Proposal (and, ultimately, any promulgated PFAS regulation) in order to effectively budget for what appears to be a very significant expenditure. It is inevitable that PMAA members will need to spend an enormous amount of money to meet the requirements of the Proposal, even if such requirements can technically be met. Therefore, EPA and the federal government need to ensure that adequate funding is allocated, preferably through grants, to meet the economic expenditures required to meet the requirements of any promulgated EPA PFAS regulation. PMAA understands that certain monies may be available (e.g., Bipartisan Infrastructure Law), but these monies appear to be wholly insufficient, especially in light of other existing or prospective regulatory initiatives (e.g., EPA Lead and Copper Rule) that drinking water facilities in Pennsylvania must address.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL funds are not meant to fully cover all capital costs associated with implementing the NPDWR and that there are significant quantifiable and non-quantifiable health benefits realized from implementing the rule.

Pennsylvania Municipal Authorities Association (Doc. #1832, SBC-045785)

[PMAA's specific comments on the Proposal are as follows:]

9. Municipal entities will certainly require capital improvements and/or other expenditures to meet the mandates of the Proposal. The costs associated with the Proposal may actually increase in the near future due to other EPA regulatory proposals (e.g. designation of certain PFAS as CERCLA hazardous substances). EPA has acknowledged the possibility that such costs could increase by $30 million to $61 million per year if water systems are required to dispose of PFAS treatment as hazardous waste. (EPA PowerPoint from May 4, 2023 public hearing, slide 9). Municipal entities and their ratepayers should not be required to bear the burden of these costs, which will likely be a hardship for many municipal entities, and which expenditure by such municipal entities is wholly consistent with the "Polluter Pays" principle of EPA's PFAS Strategic Roadmap.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Columbia Water (Doc. #1833, SBC-045794)

By Electronic Submission: Docket EPA–HQ–OW–2022–0114

U.S. Environmental Protection Agency

May 30, 2023

EPA Docket Center

PFAS: PFOA and PFOS National Primary Drinking Water Regulation Rulemaking, Mail Code 28221T

1200 Pennsylvania Avenue NW

Washington, DC 20460

Dear Sir/Madam:

The City of Columbia, South Carolina (dba Columbia Water) appreciates the opportunity to comment on the USEPA's proposed National Primary Drinking Water Regulation (NPDWR) and health-based Maximum Contaminant Level Goals (MCLG) for PFOA and PFOS, as well as PFHxS, HFPO–DA and its ammonium salt, PFNA, and PFBS and their mixtures.

Columbia Water has been in the business of protecting the public health of the citizens of Columbia and the surrounding area for over 120 years. We take our responsibilities regarding the safety of the public water supply very seriously, and have an excellent record of compliance with all Federal and State drinking water regulations.

EPA's proposed MCLs for PFAS have the potential to impose the greatest compliance costs in the history of the Safe Drinking Water Act for our utility, both from a capital as well as ongoing operation and maintenance cost perspective. These costs will have to borne by the Columbia Water customers who are already dealing with the affordability challenges associated with meeting existing regulations, inflationary pressures, and aging infrastructure replacement. Such massive and far-reaching regulatory impacts are particularly unprecedented given that thousands of water plants will be impacted and affected utilities will have to plan, design, and construct newly developing PFAS barrier technologies at an unprecedented speed, all while PFAS blood serum levels in Americans have been dropping dramatically and are poised to plummet even farther due to the legislative, regulatory, and litigation pressure around these chemicals.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. More information on the EA can be found in section 13 of the EPA response in this *Response to Comments* document. The EPA has carefully considered the costs of all systems that will be affected by the rule and has detailed the agency's assumptions in section 13 of the EPA response in this *Response to Comments* document.

Corix Infrastructure Inc. (Doc. #1834, SBC-045361)

Corix works on a daily basis to protect our customers and communities by providing high quality drinking water that is compliant with the Safe Drinking Water Act. Corix respectfully submits the following comments in response to the EPA's request in addition to a request to review and revise elements of the proposed rulemaking to ensure the rule is feasible for all water providers. It is important that EPA carefully tailors its approach to reducing the levels of PFAS chemicals in water supplies without imposing unnecessary costs and restrictions because the costs and the impacts of reducing the presence of these chemicals in the water supply at the levels under consideration will be substantial and will place a heavy burden on communities, households and customers.

Corix urges the EPA to recognize in this rulemaking and in other actions related to removing PFAS chemicals from the water supply that EPA should ensure that all water and wastewater systems be treated equally regardless of whether the systems are publicly or privately owned or operated. All water and wastewater providers should have equal access to any and all federal and state funding related to treating PFAS chemicals.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that this rule applies to community- and non-transient, non-community PWSs across the country. It does not set regulatory requirements for wastewater systems nor private wells.

Little Hocking Water Association (Doc. #1835, SBC-045507)

PFASs are not naturally occurring and there are only a few companies (less than 10) responsible for the manufacture of PFAS in the United States. All costs of compliance with this proposed rule will be passed on to ratepayers. In the proposed rule, EPA recognizes that for communities of color, the costs of compliance with the proposed MCLs will be a burden and will compound burdens those communities already face, but concludes that these costs outweigh the benefits of reduced PFAS exposure. This ignores that water supplies in the United States were contaminated for decades while industry knew (and profited from delayed regulation of) the scope of the PFAS contamination and the public health risks of exposure. Accordingly, it is wholly inequitable and improper for individual households to pay to clean up the water they drink. EPA recognizes that federal funding is available under the Infrastructure Investment and Jobs Act. However, this funding is temporary and as EPA recognizes is only for installation costs, not operation. Considering that PFAS persists for thousands of years once in the environment, the operational cost burden likely exceeds the installation cost burden. Further, there is also no indication that there is enough funding for all environmental justice or low income communities to install PFAS water treatment. For these reasons, beyond the temporary federal funding, EPA needs to require the few manufacturers who made billions of dollars on PFAS to pay for any water treatment necessary for water suppliers to comply with the proposed MCLs in this rulemaking.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA reiterates its determination that the benefits of the rule justify its costs. The commenter mistakenly quoted the agency as suggesting the opposite. Please see section 13.8 of the EPA response in this *Response to Comments* document for additional discussion on the comparison of costs and benefits of the rule.

New England Water Works Association (Doc. #1836, SBC-047707)

EPA states "To help communities on the frontlines of PFAS contamination, the passage of the Infrastructure Investment and Jobs Act, also referred to as the Bipartisan Infrastructure Law (BIL), invests over $11.7 billion in the Drinking Water State Revolving Fund (SRF); $4 billion to the Drinking Water SRF for Emerging Contaminants; and $5 billion to Small, Underserved, and Disadvantaged Communities Grants. These funds will assist many disadvantaged communities, small systems, and others with the costs of installation of treatment when it might otherwise be cost-challenging." While this funding is appreciated, it's not nearly enough for what PWS will need to address PFAS.

NEWWA strongly encourages EPA to establish and maintain communications with Congress on how to provide more funding to communities facing PFAS contamination. There must be committed attention not only to the initial capital costs that PWS will incur to install treatment, but also ongoing O&M costs such as sampling, operation, and maintenance of the treatment system, and media replacement. In some situations, the responsible party may pay for the capital costs. In most cases, municipalities will need to front the costs and chase the responsible part(ies) for reimbursement. It is likely that many contaminated water supplies may not have an easily identifiable source or responsible party. Who will be responsible for these ongoing costs? Ratepayers should not have to bear this burden for harm caused by others.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

WASHINGTON STATE BOARD OF HEALTH (Doc. #1837, SBC-044265)

Early experience implementing the state's Group A rules for PFAS drinking water contamination suggests that agencies, water systems, communities, elected officials, and other interests will need significant technical and financial assistance navigating this complex, long-term public health crisis. Please couple action on this rulemaking with follow up on these diverse needs.

We encourage you to work with Congress and other interests to help marshal the needed resources to manage and, to the extent feasible, mitigate the public health effects and concerns associated with PFAS drinking water contamination.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Oklahoma Department of Environmental Quality (Doc. #3072-1, SBC-046340)

Hello everyone, I'm Shellie Chard. I'm the Water Quality Division Director for the Oklahoma Department of Environmental Quality (OK DEQ). Thank you, EPA, for allowing us to have this opportunity to provide comments. I think something that's really important that we all remember is that it's not the setting of standards that protects public health. We have to make sure our communities and water systems can implement and comply with these standards. In that vein, I think it's really important for EPA to provide as much guidance and guidance documents not only for water systems, but also to the primacy agencies, in order to assist our water systems in meeting these new regulations. It's fantastic that we have this huge influx of funding into our drinking water systems through the ARPA funding and BIL funding, but something important that we have to remember is that those are capital costs that are provided by that funding. We need to be thinking about how particularly small systems are going to secure funding for the continued capital or for the operation and maintenance costs and for paying appropriately trained operators to run this advanced technology that is going to be needed. We've touched a little bit on treatment technologies; I think it's important to highlight that we do have disposal costs of those wastes, and we need to be careful that we're not just moving PFAS from one media to the next, from drinking water into our landfill leachate which may then end up back in our wastewater treatment facilities, which we may then have PFAS going back into our surface waters which many times are source waters for drinking water. So, we need to keep those things in mind. I also think it's really important – the discussion of point-of-use filters for in-home or on-property use – that creates an issue where the current owner may be willing to operate and maintain those systems, but when the property is sold, or in the case of a landlord and tenant, sometimes those can be a little bit tricky. I know I'm at the end of my time. Thank you very much for allowing this opportunity to comment. The State of Oklahoma will be submitting to the docket more detailed written questions and comments. Thank you.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL funds are not meant to fully cover all capital costs associated with implementing the NPDWR and that there are significant quantifiable and non-quantifiable health benefits realized from implementing the rule. The EPA considered small system compliance technologies in the cost analysis, including point of use filters, and more discussion can be found in section 10.5 of the EPA response in this *Response to Comments* document. For additional guidance on training and implementation tools, please see section 1.2 of the EPA response in this *Response to Comments* document. For disposal concerns, please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Bob Johnson (Doc. #3072-24, SBC-046353)

Hi, my name is Bob Johnson, and I live in Anson County, North Carolina. I am a clean water and clean air activist. I was born and have lived in this county for 75 years. At present, we are a Tier 1 County in North Carolina. Our water and sewage system has reached its maximum life. Our county does not have money to repair or replace it so my question is, how could we go about

meeting the specifications of the EPA, of refining our water test, and filtering the water system when we have zero funds to do so? I know we're not the only county in the United States in that situation. I would hope that EPA takes into consideration that counties such as Anson requires federal grants and federal engineers, federal labs to test our water system and to make sure that it falls within the EPA guidelines. So, we are at this point at a standstill. We do not have the funds to even test our water on a regular basis, so I would like EPA to look into a special consideration for Tier 1 counties. We are in desperate need of clean water; we are in desperate need of clean air and we also host a regional landfill here in Anson County. Thank you for your time, and I appreciate this opportunity.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Piedmont Triad Water Authority (Doc. #3072-26, SBC-046354)

Hello, my name is Greg Flory. I'm the executive director of the Piedmont Triad Water Authority. We are a 14.7 million gallon a day surface water treatment plant on the Deep River in the Greensboro area of North Carolina. I just wanted to speak to the economic estimates in this proposal. We are currently in the midst of planning for PFAS treatment removal, and we have cost estimates for our facility as we expand to 26.7 million gallons. The cost of treatment will be around $100 million just for our facility and the ongoing cost for the maintenance of that system will be $2.5 million a year. It does appear that there is not adequate allocation of the funding requirements for this rule in EPA's funding formula, and I would request that they reevaluate that and prioritize funding to municipalities so that ratepayers aren't having to sustain these costs. That sums up my comments. Thank you.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL funds are not meant to fully cover all capital costs associated with implementing the PFAS NPDWR and that there are significant quantifiable and non-quantifiable health benefits realized from implementing the rule.

Great Lakes Water Authority (GLWA) (Doc. #1558, SBC-042547)

EPA requested comment on all aspects of its Environmental Justice analysis. GLWA has concerns that our progress towards affordability gained through the WRAP and other measures could be diminished or even eliminated given the potential impact of capital and legacy costs related to this proposed regulation.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Great Lakes Water Authority (GLWA) (Doc. #1558, SBC-042546)

Financial Implications

This proposed rule would impact many of GLWA's operations including water sampling, treatment and disposal. The potential costs and liabilities associated with the proposed rule is a significant concern to GLWA and its members and users of its water system.

GLWA has significant concerns about the potentially significant costs and liabilities that EPA's proposed rule will place onto water systems and subsequently local communities. GLWA has been steadfast in addressing issues of affordability. Toward that end, GLWA implemented the Water Residential Assistance Program (WRAP). This program provides income-based assistance for residential customers.

Based on our historical sampling results, GLWA is not expected to require capital improvements for additional water treatment processes to meet the proposed regulation. However, if PFAS concentrations emerge as a problem for us, the cost of treatment would not be confined to a single capital improvement investment. The legacy costs required by disposal or regeneration of the treatment waste streams would be systemic and are currently unknown due to other pending PFAS regulations (I.e., CERCLA and RCRA) regarding solids disposal. Public water utilities did not produce, regulate or discharge PFAS, but will be asked to continually contend with the cost of their disposal. GLWA strongly supports a "polluter pays" model where those who produced PFAS pollution bear the liability and costs of its remediation – not the public.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL funds are not meant to fully cover all capital costs associated with implementing the NPDWR and that there are significant quantifiable and non-quantifiable health benefits realized from implementing the rule. Please see section 13.3 of the EPA response in this *Response to Comments* document for the EPA's discussion on the agency's analysis of costs associated with the final NPDWR. For additional discussion on the EPA's affordability analysis, please see section 13.10 of the EPA response in this *Response to Comments* document. As outlined in the PFAS Strategic Roadmap, the EPA is committed to addressing PFAS and the NPDWR is one aspect of that plan. The EPA has centered the PFAS approach on considering the full PFAS lifecycle, getting upstream of the problem, holding polluters accountable, ensuring science-based decision making, and prioritizing disadvantaged communities. Key actions for how this will happen can be found at https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024. For additional discussion on the Roadmap, please see section 15.1 of the EPA response in this *Response to Comments* document.

Missouri Department of Natural Resources (Doc. #1563, SBC-042513)

With the increased cost for state agencies associated with this new rule, EPA should seek additional funding from Congress through the Public Water System Supervision Performance Partnership Grant to help offset the burden. The cost of the rule for Missouri will be significant. For the state, implementing this rule will require additional staff, equipment, laboratory capacity, and new tools for tracking and reporting all of the required elements included in the rule. In

addition, EPA is also adding to the state burden through other regulatory actions such as the Lead and Copper Rule Revisions, the soon to be proposed Lead and Copper Rule Improvements, the proposed Consumer Confidence Report Rule, and the establishing of additional requirements for states to assess cybersecurity as part of sanitary surveys. The burden that EPA is adding to states through these many regulatory actions is significant. States are ultimately responsible for the implementation of these requirements and will struggle to implement all of these new regulations, while continuing to implement existing requirements, without additional resources from EPA.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

San Antonio Water System (SAWS) (Doc. #1570, SBC-042482)

Small systems are highlighted in this rule and given exceptions. They are given easier sampling schedules and are more likely to receive funding. A PWS is supported by their rate payers regardless of size. A large system has more assets, more staff, and more problems to solve. Our rate payers do not want, nor are they more able to pay for the costs associated with compliance under this rule than anyone else. The EPA fails to acknowledge the practical impact of the rule and the fact that our budgets may be larger than a small system, but so are our costs.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA is finalizing a flexibility for all systems to use previously acquired monitoring data to satisfy some or all the initial monitoring requirements. This flexibility allows the use of data from the fifth UCMR (UCMR 5), which is being collected by all community water systems and non-transient non-community water systems serving 3,300 people or more, as well as a subset of smaller systems. The flexibility also allows the use of state-led or other appropriate monitoring data.

City of Wilmington, Ohio (Doc. #1572, SBC-042466)

Billions of dollars have been set aside by Congress to address PFAS and other infrastructure needs. More communities will become aware of PFAS problems as UCMR5 results become available. The money will not go far enough.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL funds are not meant to fully cover all capital costs associated with implementing the NPDWR and that there are significant quantifiable and non-quantifiable health benefits realized from implementing the rule.

Sammamish Plateau Water and Sewer District (Doc. #1573, SBC-042460)

The District notes that water utilities throughout the country are not the responsible parties for causing PFAS to enter the environment and contaminate drinking water. Rather, water utilities

and their customers, are the unfortunate recipients of the adverse impacts of PFAS contaminants in our water resources found through UCMR or independent proactive testing for PFAS. The proposed rules should orient towards supporting water utilities in a facilitative approach as they address potential health impacts and PFAS mitigation in drinking water. Rules that mandate PFAS reduction, and/or removal, should carry appropriate corresponding federal funding to offset capital expenditures mandated to reduce or remove PFAS from drinking water. Funding should be provided on an equal basis to all impacted water utilities regardless of demographics or economics.

Given that "EPA anticipates that if fully implemented the rule will prevent tens of thousands of PFAS-attributable illnesses or deaths", Federal appropriations should be administered in a manner which brings efficient access to funds so PFAS reduction can be implemented in an efficient and timely manner, absent of unnecessary red tape. As an example, in March 2022, our District was awarded a $1.585 million congressionally directed appropriation through Representative Schrier's office to assist in funding an $18.0-$20.0 million PFAS removal treatment plant. Efforts to access the funding have been frustrating to say the least. To date, we have not been able to access the appropriation, and it appears USEPA will be applying its requisites to the entire project, not just the elements funded by the appropriation. This has delayed our ability to build treatment. The $1.585 million is now controlling the entire project, and USEPA BABA, and AIS standards may increase the entire project cost by more than the appropriation.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Sammamish Plateau Water and Sewer District (Doc. #1573, SBC-042464)

Last, the rule states that for an exceedance of the proposed MCL, agencies may implement alternative water sources in lieu of treatment. Due to state regulation and water rights administration, alternative water sources will not exist or be available, thus defaulting in the need for treatment. Federal funding for treatment, available to all impacted water utilities, is an essential element of a holistic approach to PFAS management.

Thank you for the opportunity to comment and contribute in the rulemaking process.

Sincerely,

John C. Krauss

General Manager

cc: Sammamish Plateau Water Board of Commissioners

Judi Gladstone, Washington Association of Sewer and Water Districts

Ray Hoffman, Cascade Water Alliance

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL funds are not meant to fully cover all capital costs associated with implementing the NPDWR and that there are significant quantifiable and non-quantifiable health benefits realized from implementing the rule.

San Gabriel Valley Water Association (SGVWA) (Doc. #1580, SBC-042421)

Need to Help Small Systems and DACs: Despite efforts by the EPA and other agencies to improve access to government funding programs, small water systems and those serving disadvantaged communities still face challenges in applying for grants, managing reporting requirements, and completing projects. Even if successful in building a treatment system, many small and poorer systems cannot afford to maintain and operate them, as seen in past implementations of arsenic and nitrate standards where treatment systems stand idle.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

San Gabriel Valley Water Association (SGVWA) (Doc. #1580, SBC-042418)

Federal Funding Gaps: Although the Bipartisan Infrastructure Law provides billions of dollars to assist water providers, it does not cover all the expenses associated with the construction, operation, and maintenance of treatment systems. The proposed MCLs will require significant rate increases for most affected systems. Additionally, these expenses will compete with other EPA regulations that require funding, including the Lead and Copper Rule Revisions and the newly announced cybersecurity measures.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document, and note that BIL includes a specific set-aside of funds for lead service line replacements. The EPA notes that BIL funds are not meant to fully cover all capital costs associated with implementing the NPDWR and that there are significant quantifiable and non-quantifiable health benefits realized from implementing the rule.

Missouri River Public Water Supplies Association (MRPWSA) (Doc. #1581, SBC-042413)

Funding — To realize the health benefits of this proposed rule, water utilities must have the financial resources to assure they can sustain the ongoing costs that will arise from constructing, operating, maintaining, and monitoring PFAS treatment systems for the safety and benefit of customers. Low-income assistance must also be provided.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Center for American Progress (CAP) (Doc. #1586, SBC-042387)

The benefits of reducing forever chemicals in the water greatly outweigh the costs of its removal and to prevent future contamination. The EPA estimates bringing the nearly 66,000 water systems that will be subject to regulation into compliance will cost between $772 million to $1.20 billion, but the savings that the rule will generate in terms of avoided adverse health effects are greater, with estimates ranging from $908 million to $1.23 billion [FN6: United States Environmental Protection Agency, "Addressing PFAS in Drinking Water with the Drinking Water State Revolving Fund" (Washington, DC: 2019), available at https://www.epa.gov/sites/default/files/2019-03/documents/pfas_fact_sheet_and_case_studies_final.pdf]. Critically, local water systems will not shoulder the financial burden of coming into compliance alone, since the Biden Administration is making billions of dollars available to help them monitor and remove PFAS from the drinking water. Between the Drinking Water State Revolving Fund (DWSRF) and the Emerging Contaminants in Small or Disadvantaged Communities (EC-SDC) Grant Program, President Biden has made over $9 billion dollars available to state, local, and tribal governments.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Cape Fear Public Utility Authority (CFPUA) (Doc. #1588, SBC-042381)

Capital and operating costs vs. available funding

EPA has acknowledged federal funding assistance will be needed by public water systems to add treatment required to meet the proposed regulations. EPA points to billions of dollars available through the Bipartisan Infrastructure Law enacted in 2021, including $12 billion in Drinking Water State Revolving Funds (SRFs). CFPUA defers to comments from industry groups such as the American Water Works Association regarding EPA's overall cost estimates and the adequacy of available funding. We do believe our own experience provides useful context.

As noted above, the cost to design and construct CFPUA's new GAC filters needed to treat PFAS in our community's source water was approximately $46 million. Earlier this year, CFPUA shared this cost with members of the North Carolina Water Infrastructure Authority, which administers the State's SRF program. Shadi Eskaf, Authority member and director of the State's Division of Water Infrastructure, remarked that the cost just for CFPUA's GAC treatment exceeded the total amount of SRF funds available to public water systems statewide. In CFPUA's case, the cost to design and build the filters – and the estimated $5 million in recurring annual operating costs – continue to be borne entirely by CFPUA's customers. While federal and state funding may fully or partially offset costs to comply with the proposed NPDWR for some utilities, for many or even most water systems this burden will fall on their customers, who will be left to pay higher water bills to address a problem they did not create. We believe federal funding assistance will be woefully inadequate in offsetting this cost burden.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL funds are not meant to fully cover all capital costs associated with implementing the NPDWR and that there are significant quantifiable and non-quantifiable health benefits realized from implementing the rule.

Public Health, Seattle & King County (PHSKC) (Doc. #1594, SBC-042360)

Do not leave homeowners and rate payers responsible for the costs to remove, maintain, and dispose of PFAS in their drinking water. The number of contaminated drinking water sources in King County is unclear. UCMR 3 (2013-2015) testing revealed one major drinking water source was contaminated in King County. An expensive filtration system was installed to maintain the city's drinking water quality. Ongoing maintenance of the filtration system is expensive as is disposal of the PFAS that are removed by the filters. In 2021, the state of Washington developed State Action Levels (SALs) for 5 PFAS, and the Washington State Department of Health received funding to encourage water utilities to being testing prior to the 2025 date when testing is required. Many utilities are waiting for UCMR 5 to conduct their testing. Early testing revealed that at least 2 drinking water utilities exceed the state SALs, and we expect that additional utilities will be identified following UCMR 5 and when the EPA's drinking water standards are required. Some utilities that tested above the EPA health advisory or the WA SALs took their contaminated wells offline as they identify affordable ways to remove the PFAS contamination. Although EPA received a large amount of money to cover many costs to utilities for testing and remediation, the majority of costs for ongoing testing, remediation and hazardous waste removal will ultimately be passed on to the customers, as will the health costs associated with PFAS exposures.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. For additional discussion on disposal concerns for PFAS treatment, please see section 10.4.2 of the EPA response in this *Response to Comments* document. For additional discussion on monitoring costs, please see section 13.3.4 of the EPA response in this *Response to Comments* document. While remediation is beyond the scope for this NPDWR, please see section 15 of the EPA response in this *Response to Comments* document for related discussion.

Public Health, Seattle & King County (PHSKC) (Doc. #1594, SBC-042363)

Prioritize low-income and communities of color that are most impacted by contaminated drinking water and other stressors for federal assistance with testing, remediating, and maintaining healthy drinking water. EPA should identify ways to help low-income residents (both homeowners and low-income renters/landlords) to test and remediate PFAS contaminated private drinking water wells or group wells through technical and financial assistance, and should invest in research that will accelerate the development of methods that could be used to remove PFAS from private and small group drinking water wells.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. For PFAS contamination in private wells, please see section 15 of the EPA response in this *Response to Comments* document and note that private wells are not within the scope of the PFAS NPDWR.

National Tribal Water Council-Tribal PFAS Working Group (NTWCTPWG) (Doc. #1598, SBC-042337)

Similarly, funding is needed for PFAS monitoring of numerous small water systems in Indian Country not covered by the proposed regulation. We recommend that EPA at least speak to this in the regulation and identify possible strategies to alleviate this challenge going forward.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. All community- and non-transient, non-community PWSs are subject to this rule.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043641)

B. Federal funding is expected to defray many such PWS costs-- the available resources are listed below. However, reports of $10B available for PFAS treatment are misleading. The actual federal support available to local utilities can be considerably limited, as projects focusing on other contaminants are also eligible for the same funding. Some examples are provided below:

• Clean Water State Revolving Fund (CWSRF)

o $1 billon (over 5 years FY2022 – FY2026) allocation for PFAS and/or other emerging contaminants

o Eligible projects: wastewater, reuse, and stormwater

• Drinking Water State Revolving Fund (DWSRF)

- $4 billon allocation for PFAS and/or contaminants on the Contaminant Candidate List (CCL)

o Eligible projects: drinking water

• Emerging Contaminants in Small or Disadvantaged Communities Grant Program

o $5 billion allocation for PFAS and/or other contaminants

o Eligible projects: drinking water

It is recommended that significant additional federal funding (exclusively dedicated to PFAS Rule compliance) be provided to utilities to help address the gap between the likely national compliance cost and the available funding.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

American Water Works Company Inc. (Doc. #1608, SBC-044006)

Treating or removing contaminants in the water comes at a cost. To realize the health benefits of such, water utilities must have the financial resources to assure they can sustain the ongoing costs that will arise from constructing, operating, maintaining, and monitoring PFAS treatment systems for the safety and benefit of customers. States should treat these expenditures for regulated utilities as federally mandated requirements that are recoverable in customer rates through expedited means.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Rural Community Assistance Partnership Incorporated (RCAP) (Doc. #1633, SBC-044139)

Small, Rural Community Water Challenges

Central to RCAP's mission is the recognition that the availability of high-quality, affordable, and resilient water and sewer service is a key foundational building block necessary to spur economic development in rural communities. Of the approximately 150,000 public water systems across the country, 97 percent serve communities of 10,000 or less, and 72 percent serve communities of 500 or less. The average population of the communities RCAP has served in recent years is roughly 1,500, with a Median Household Income of half the national average. Each year, we have served more than 40 percent of America's persistent poverty counties, and roughly 300,000 individuals from indigenous communities.

The primary challenge for these small communities is spreading out the ever-increasing costs of operations over a smaller, and sometimes decreasing, base of customers. The price tag of necessary system upgrades, which may have minimal impact on a mid-sized or large community, can have a staggering effect on a system that serves only a couple hundred customers. Further, many small systems have very limited staffing. In a 2020 survey of the public water systems we serve, RCAP found that 43% had either 1 or 0 full-time employees, and instead supplement operations with part-time or volunteer staff.

It is of critical importance for EPA to recognize these cost and capability limitations for small, rural systems as it seeks to protect public health through implementation of the proposed NPDWR.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Aurora Water, City of Aurora, Colorado (Doc. #1669, SBC-043723)

Currently, EPA is considering the Bipartisan Infrastructure Law (BIL) funding to be sufficient for water systems' needs. However, BIL funds for emerging contaminants are not limited to PFAS. The available funding cannot cover the lengthy list of all the emerging contaminants

water systems are currently facing. Not only is there not enough available funding, but the process to be awarded any funding is also very complicated and lengthy. For water systems facing numerous complicated challenges, it is extremely straining for employees applying for funding opportunities. Aurora Water suggests EPA increases the available funding for emerging contaminants and simplifies the application process.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL funds are not meant to fully cover all capital costs associated with implementing the NPDWR and that there are significant quantifiable and non-quantifiable health benefits realized from implementing the rule.

National Association of Water Companies (NAWC) (Doc. #1670, SBC-044156)

NAWC members work on a daily basis to protect families and communities across the nation from the dangers posed by PFAS chemicals. While NAWC supports a rulemaking imposing limits on PFAS substances in drinking water, NAWC believes that EPA needs to revise and alter this proposed rulemaking in several respects outlined below to achieve a workable final rule that will be feasible and achievable. It is important that EPA carefully tailors its approach to reducing the levels of PFAS chemicals in water supplies without imposing unnecessary costs and restrictions because the costs and the impacts of reducing the presence of these chemicals in the water supply at the levels under consideration will be substantial and will place a heavy burden on communities, households and ratepayers.

NAWC urges EPA to recognize in this rulemaking and in other actions related to removing PFAS chemicals from the water supply, that EPA should ensure that all water and wastewater systems be treated equally regardless of whether the systems are publicly or privately owned or operated. All water and wastewater providers should have equal access to any and all federal and state funding related to treating PFAS chemicals.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that this NPDWR applies to all community- and non-transient, non-community PWSs across the country and does not set regulatory requirements for wastewater systems nor private wells.

North Jersey District Water Supply Commission (NJDWSC) (Doc. #1673, SBC-044202)

The recently proposed PFAS rules will require NJDWSC to make significant capital and long-term O&M investments that will ultimately result in onerous rate increases for its member communities. NJDWSC's current monitoring program has shown that PFOS and PFNA results are below the proposed MCLs, however PFOA is currently exceeding the proposed rules by a small margin, as sample results range from 2.28 - 5.08 ppt. Therefore, the member municipalities will incur this immense rate increase, but actually realize very minimal gain in water quality.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

California Association of Mutual Water Companies (Doc. #1676, SBC-043776)

2. Unreasonable Conditions on State Funding

CalMutuals additionally requests the EPA allocate or identify funding to support PFAS testing requirements and treatment in a manner that ensures that the funds are readily accessible to very small systems without unreasonable conditions, such as requiring involuntary consolidations. The State Board has in some situations denied much needed funding through the Drinking Water State Revolving Fund to small water systems which have been put on a list of systems to be consolidated – without any due process or determination as to the feasibility of such a consolidation. Further, the California SAFER program, which the State Board administers, has no plan for how to carry out consolidations in a methodical manner that includes identification of financial resources, public input, and process for implementation. The consequences of this policy are that small systems that do not wish to consolidate (including those that are well run but may face struggles with increasing regulation, increasing expenses and a small customer base) and those where consolidation is not feasible are being denied access to resources to address new regulations and are further penalized and stuck in a limbo of non-compliance without recourse.

In addition, it would be very helpful if access to any federal funding can be streamlined and facilitated without the need for engineering studies or grant writers, which in and of themselves are beyond the reach of most very small water systems.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

New York City Department of Environmental Protection (NYCDEP) (Doc. #1679, SBC-044210)

Cost Estimate

EPA has estimated the total annualized costs would range from $772 million to $1.2 billion, while the economic benefits would range from $908 million to $1.2 billion. However, a study conducted by Black and Veatch on behalf of the American Water Works Association found that the proposal would exceed $3.8 billion annually. Given that the cost of compliance will exceed any additional funding provided by the 2021 Bipartisan Infrastructure Law, costs associated with treatment, monitoring and public notifications will be passed on to ratepayers and communities rather than primary and secondary manufacturers and industrial users. Additionally, there are cost issues associated with lab capacity as discussed below.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL funds are not meant to fully cover all capital costs associated with implementing the NPDWR and that there are significant quantifiable and non-

quantifiable health benefits realized from implementing the rule. For additional discussion regarding lab capability and capacity for the final MCLs, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

City of Vancouver Water Utility, Vancouver, WA (Doc. #1684, SBC-044304)

The proposed MCLs may imperil the financial sustainability and affordability of some water systems, which will warrant greater assistance in terms of funding. To not clarify the extent of these costs now would be a grievous mistake as water systems and governments across all levels budget for the future and may be forced into competing for limited federal dollars.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Clean Water Action/Clean Water Fund (Doc. #1697, SBC-045004)

Decisive Actions to Address Burdens on Regulated Public Water Systems, State Primacy Agencies, and the Public

When EPA's proposed drinking water limits are final, communities around the country will need to invest in treatment and staff to comply with the regulations. While costs and effort will be higher where PFAS chemicals are found, all community water systems and non-transient noncommunity water systems will need to monitor for PFAS. New federal funding available as a result of the bipartisan Infrastructure Investment and Jobs Act and the Drinking Water State Revolving Fund will help, and water systems and communities should continue to seek to hold PFAS polluters accountable for contaminating drinking water wherever possible. Nonetheless, water systems and local governments will incur additional costs, people's water bills will often go up, state primacy agencies responsible for implementation will also incur new costs, and ongoing exposure to PFAS chemicals through food, air, and other routes of exposure will continue to pose public health risk.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

National Wildlife Federation et al. (Doc. #1702, SBC-043515)

As the Administration continues to address the PFAS crisis, it is critical that assistance for low-income communities and communities of color is prioritized, particularly since history shows us that vulnerable communities are often too under-resourced to quickly and comprehensively address toxic pollution. We must build on the investments made through the Infrastructure Investment and Jobs Act to provide additional assistance to communities that may be disproportionately impacted by PFAS and ensure that changing or implementing federal regulations do not negatively impact ratepayers or vulnerable communities by involving these communities in the decision-making process.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

The City of Columbus, Department of Public Utilities (Doc. #1703, SBC-045056)

Even with a historically high level of federal funding reaching billions of dollars, the proposed rule's estimated costs will far exceed available funding. NACWA's benefit-cost report projected that water utilities and their ratepayers will pay six times the amount allocated, plus operation and maintenance costs [FN5: Federal Funding Analysis, at page 67 of the Black and Veatch Study attached to NACWA's comment letter.]. While the federal funding will provide much needed assistance, it will not offset the necessary expenditure enough to prevent adverse outcomes for water utilities and ratepayers.

Utilities are struggling with maintaining affordable rates as they face an onslaught of mandated capital and regulatory projects [FN6: Impending regulatory challenges for water utilities are the Lead and Copper Rule Revision, Lead and Copper Rule Improvements, and CERCLA designation of PFAS. Additionally, water utilities are struggling with replacing aging infrastructure and meeting the challenges of climate change, including reducing greenhouse gas emissions while simultaneously preparing for its effects.]. Public water utilities are stewards of public funds and must choose how to best protect human health with limited resources. To accommodate the costs of new treatment, public water utilities will either have to devote fewer resources to ongoing operations, infrastructure repairs, and responses to other health priorities, or they will have to raise rates. Ratepayers—especially in our environmental justice communities—will feel the burden of higher utility bills. Regulating without proper consideration of cost will affect affordability and could result in negative outcomes in disadvantaged communities.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL funds are not meant to fully cover all capital costs associated with implementing the NPDWR and that there are significant quantifiable and non-quantifiable health benefits realized from implementing the rule.

California Farm Bureau Federation (Doc. #1704, SBC-045081)

Costs to Rural Households

Individual households will also experience financial impacts from this proposed rule. While financial impacts to individual households will vary by specific PFAS levels, system size, and other factors, we are specifically concerned about the impacts on rural households. As illustrated in the graph below, meeting the 4ppt standard would be significantly more expensive for public water systems that service less populated areas. AWWA estimates the annual costs of the proposed rule on communities with populations of less than 100 will cost between $10,000 and $11,000 per household, a significant increase for these households.

[Table 2: See Docket ID EPA-HQ-OW-2022-0114-1704]

Federal Funding is Limited

The agency has claimed that various federal funding streams are available for drinking water utilities to adapt to this rule. However, there remains a failure to recognize the difficulties that small, rural communities face in competing for and obtaining these monies. In a May 11th Small Business Environmental Roundtable, EPA staff highlighted the following funding opportunities that were authorized through the IIJA:

• $11.7 billion to the Drinking Water State Revolving Fund (SRF)

• $4 billion in SRF for emerging contaminants

• $5 billion to Water Infrastructure Improvements for the Nation (WIIN) Grants to address emerging contaminants.

While it is encouraging to see this level of federal investment in protecting our drinking water and addressing emerging contaminants like PFAS chemicals, there is not sufficient financial resources to cover the costs of this rule for every water utility. Additionally, these resources are often devoted to projects that benefit large population areas.

Conclusion

California Farm Bureau encourages EPA to reevaluate the proposed MCLs for these six PFAS chemicals so that the final rule includes an achievable standard that is not disproportionally burdensome to rural communities. If there are questions about these comments, please contact Kari Fisher at kfisher@cfbf.com.

Sincerely,

Jamie Johansson President

California Farm Bureau

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document for concerns regarding rate payers and small public water utilities. The EPA notes that BIL funds are not meant to fully cover all capital costs associated with implementing the NPDWR and that there are significant quantifiable and non-quantifiable health benefits realized from implementing the rule. The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. See section 13.3.3 of the EPA response in this *Response to Comments* document.

California Farm Bureau Federation (Doc. #1704, SBC-045071)

For example, the U.S. Chamber analysis highlights the following:

• Infrastructure Investment and Jobs Act (IIJA) funding will be insufficient to cover the costs of compliance. The investment needed to reach proposed MCL levels moves well beyond the

ability of communities to afford and beyond the potential funding available in the IIJA. Simply put, the compliance costs are too high.

There are a number of other issues associated with the proposed MCLs that deserve in-depth discussion, including the benefits identified by the agency, the health end points, and the possible conflict between other Administration policies. We hope that the EPA will consider all of these factors before finalizing this proposed rule.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL funds are not meant to fully cover all capital costs associated with implementing the NPDWR and that there are significant quantifiable and non-quantifiable health benefits realized from implementing the rule.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045095)

e. SRF eligibility for O&M expenses:

While there is funding currently available it does not cover all needs, all possible systems, and does not cover Operation and Maintenance (O&M) expenses. Initial designing, permitting, and construction is just the beginning, the on-going expenses are crippling and require the user base to cover increasingly expensive costs of disposal and replacement of media. Without loan or grant eligibility or other funding, these systems may become financially unstable. Additionally, there may be private schools or other for-profit Non- Community drinking water systems that are not eligible for funding but may have considerable expenses incurred.

EPA should establish a dedicated funding source for O&M expenses for small water systems who are disproportionately impacted by PFAS contamination.

EPA Response: With respect to BIL funding for operations and maintenance costs, please see the section 2.4 of the EPA response in this *Response to Comments* document.

Philadelphia Water Department (PWD) (Doc. #1709, SBC-045738)

5. In assessing the benefits and costs analysis for this rule, the EPA evaluated cumulative benefits on other regulatory programs but not the cumulative cost impacts resulting from this regulation on other ongoing regulatory activity, such as LCRR/LCRI implementation and compliance.

Currently, PWSs are facing simultaneous compliance issues for various ongoing regulatory changes at the EPA level such as the Lead and Copper Rule Revisions, revisions to National Pollutant Discharge Elimination System (NPDES) permit requirements for ammonia discharges, and combined sewar overflow discharge limits. Together, these current and upcoming regulations, in addition to the numerous other regulatory requirements to which PWSs are subject, represent a significant allocation of resources in the coming years. Given PWD's

inability to access SRF grant funding, as mentioned above, these burdens will be shouldered by our ratepayers. With the significant costs associated with the proposed PFAS NPDWR and other ongoing regulatory requirements, EPA should not be assessing the cost of this rulemaking in a vacuum. Rather, EPA's Economic Evaluation should be re- evaluated to consider the cost of this proposed rulemaking in the context of other ongoing regulatory requirements and the financial capabilities of utilities.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. To the extent that implementation overlaps with other rules, the EPA cannot consider costs that result from compliance with other regulations. Specifically, the agency notes that SDWA Section 1412(b)(3)(C)(i)(III) requires that the EPA include quantifiable and non-quantifiable costs that are likely to occur solely as a result of compliance with the rule at issue (including monitoring, treatment and other costs) and exclude costs resulting from compliance with other proposed or promulgated regulations. While operational adjustments may be necessary, the EPA has not identified any other drinking water regulations or requirements that will inhibit compliance with this regulation, nor does the agency expect this regulation to impair compliance with other regulations, such as the lead and copper rules.

Citizens Campaign for the Environment (CCE) (Doc. #1710, SBC-045127)

Now is the time to act. With unprecedented investment in clean water infrastructure from the federal government, through the Bipartisan Infrastructure Law, and from states such as New York, through the Clean Water Infrastructure Act, which has invested $5 billion since 2017, including $500 million in the state's recently adopted SFY 2023-24 budget, communities now have resources to install treatment technology needed to protect drinking water from emerging contaminants, including PFAS.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Citizens Campaign for the Environment (CCE) (Doc. #1710, SBC-045139)

• EPA should develop a grant program for low-income communities. Water suppliers that serve low to moderate income communities may need to obtain treatment technology for PFAS contamination. Low to moderate income communities would benefit from an EPA grant program so that clean, safe drinking water is available and affordable.

Thank you for your consideration of our comments.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045917)

E. EPA's reliance on other federal funding will not alleviate costs

EPA indicates that federal funding from the Bipartisan Infrastructure Law as a way to defray a small portion of the potential costs of installation and treatment when it "otherwise [might] be cost-challenging."[FN168: 88 Fed. Reg. at 18640.] However, its reliance on temporary federal funding to address a long-term unfunded mandate is flawed in several respects. First, because EPA underestimates costs, the amount of funding available to address PFAS treatment is a much lower percentage, making the "cost-challenging" comment highly relevant, as indicated in the Chamber's modeling. Second, EPA's reliance on available federal funding does not alleviate costs for water systems in the long term, or to cover O&M costs. The obligations of public water systems will far outlast the short- term funding available. Once funding through the Bipartisan Infrastructure Law runs out, public water systems will need a new source of revenue to continue operating the PFAS treatment, most likely by raising rates. Further, federal funding is certainly not guaranteed for every impacted public water system [FN169: The $11.7 billion funds are for investment in the Drinking Water State Revolving Fund (SRF), $4 billion to the Drinking Water SRF for Emerging Contaminants, and $5 billion for the Small, Underserved, and Disadvantaged Communities Grants. EPA details the process for water systems to be eligible and apply for these funds, which are administered by states: https://www.epa.gov/dwsrf/how-drinking-water-state-revolving-fund-works#tab-1.]. Water systems will have to apply for funding while, in the meantime, incurring compliance costs if and until federal funding is received. Also, the funding available will likely be competing for other important priorities like the lead pipe replacement requirements in the lead and copper rule revision, which could negatively affect environmental justice communities by slowing lead pipe replacement. Further, the fact that public water systems may not, in some circumstances, have to directly bear a portion of the cost does not mean it is not a cost at all. Additional public spending to address a regulatory mandate is a cost to taxpayers and the economy. Finally, the Bipartisan Infrastructure Law specified allocations of funding for certain purposes and did not specify that all of the funds must be used towards addressing PFAS [FN170: See "Bipartisan Infrastructure Law: A Historic Investment in Water," U.S. EPA: https://www.epa.gov/system/files/documents/2021-11/e-ow-bid-fact-sheet-final.508.pdf.]. \

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL funds are not meant to fully cover all capital costs associated with implementing the NPDWR and that there are significant quantifiable and non-quantifiable health benefits realized from implementing the rule. Finally, please also see section XIII.D of the final rule preamble for discussion on the EPA's consultation and analyses under current statutory and Executive Orders, including the Unfunded Mandates Reform Act (UMRA) in support of the final rulemaking.

Clean Air Council, et al. (Doc. #1731, SBC-043879)

Additionally, it should be noted that federal funding is available to help Public Water

Systems treat PFAS contamination. Indeed, $75 million of President Biden's Bipartisan Infrastructure Law was already allocated in February 2023 to Pennsylvania to address emerging contaminants—in particular PFAS—in drinking water [FN30: EPA, Biden-Harris Administration Announces $75 Million in Bipartisan Infrastructure Law Funding to Address Emerging Contaminants like PFAS in Drinking Water in Pennsylvania, https://www.epa.gov/newsreleases/biden-harris-administration-announces-75-million-bipartisan-infrastructure-law-funding (Feb. 14, 2023).]. Such funding would enable mitigation of costs, particularly in water systems serving economically disadvantaged communities.

In summary, enacting the proposed PFAS NPDWR in the Commonwealth of Pennsylvania is feasible both technically and economically. The existing, less stringent, Pennsylvania PFAS drinking water MCL will give PWSs in the Commonwealth a longer period of time to prepare and plan.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

U.S Conference of Mayors, National League of Cities and National Association of Counties (Doc. #1733, SBC-043900)

Conclusion

In conclusion, we urge EPA to adhere to the polluter pay model and to move forward in a way that will not shift the cost burden of this regulation onto local governments, water utilities or ratepayers. In developing this regulation, EPA should adequately examine emerging data in an effort to further scientific consensus regarding PFAS. Further, should EPA move forward on this regulation, we urge the Agency to establish a higher MCL for PFOA and PFOS and to provide local governments with maximum flexibility, longer compliance timeframes, and additional direct funding.

On behalf of the nation's mayors, cities and counties, thank you for considering the local government perspective on this important issue. If you have any questions, please contact us: Judy Sheahan (USCM) at 202-861-6775 or jsheahan@usmayors.org; Carolyn Berndt (NLC) at 202-626-3101 or Berndt@nlc.org; or Sarah Gimont (NACo) at 202-942-4254 or sgimont@naco.org.

Sincerely,

Tom Cochran

CEO and Executive Director

The U.S. Conference of Mayors

Clarence E. Anthony

CEO and Executive Director

National League of Cities

Matthew D. Chase

CEO and Executive Director

National Association of Counties

EPA Response: For funding concerns, please see section 2.4 of the EPA response in this *Response to Comments* document. For additional discussion on regulatory alternatives, please see section 5.1.3 of the EPA response in this *Response to Comments* document. For additional discussion on the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046005)

ECONOMIC IMPACTS

These social costs will fall heavily on low-income households and households served by small public water systems. Despite EPA's claims, recently enacted federal support for water utilities is insufficient to pay for even the capital costs of the proposal's requirements. As a result, ratepayers may pay a significant portion of the compliance costs of the rulemaking. Certain ratepayers are projected to pay hundreds of dollars per household per year due to this rulemaking.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL funds are not meant to fully cover all capital costs associated with implementing the NPDWR and that there are significant quantifiable and non-quantifiable health benefits realized from implementing the rule.

Defend Our Health (Doc. #1741, SBC-045197)

We would also like to urge the EPA to refrain from weakening the proposed standards due to arguments by water districts and others that this rule will cause an increase in water costs for taxpayers. Water districts across the country are making the argument that the draft MCLs, if implemented, will make water bills unaffordable, particularly for low-income residents. While we are sympathetic to increased costs for rate payers, water districts do have other options to fund compliance other than raising rates. Water districts also frequently overestimate the likely cost of compliance. The health impacts of PFAS are too great to allow communities to continue to be exposed. The EPA must resist attempts to weaken the draft MCLs.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

LSP Association (LSPA) (Doc. #1742, SBC-043609)

Slide 33: Bipartisan Infrastructure Law Funding for PFAS

• MassDEP data shows that 170 Public Water Suppliers (PWS) have detected PFAS above the state health standards, which is 20 ppt for the sum of six PFAS. That number is predicted to triple if USEPA's MCL is adopted. See the MWWA May 26, 2023 comment letter (pp. 6-7 and Graphic 3).

• The LSPA believes that USEPA is overestimating the ability of the Bipartisan Infrastructure Law (BIL) to fund the significant, ongoing costs of implementing this proposed rule. As the May 26, 2023 MWWA letter notes, "While this funding is appreciated, it's not nearly enough" for what is needed to address the PWS PFAS challenges. Pages 15 – 17 of the MWWA letter present more specific information.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL funds are not meant to fully cover the costs of the rule and that there are significant quantifiable and non-quantifiable health benefits realized from implementing the rule.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045241)

3. Capital improvements and workforce development will present considerable challenges, especially for small systems. CT DPH is already seeing increased demand for its Drinking Water State Revolving Fund (DWSRF). CT DPH is appreciative of the financial support the Biden Administration has already allotted through the BIL, the Emerging Contaminants DWSRF Award and the Emerging Contaminants in Small or Disadvantaged Communities Grant Program. CT DPH anticipates the need will grow and sustain well into the future as more PWS test for PFAS. In fact, applications to the DWSRF for funding assistance for projects to address PFAS already exceed CT DPH's FFY2022 BIL allotment for the Emerging Contaminants Capitalization Grant.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL funds are not meant to fully cover the costs of the rule and that there are significant quantifiable and non-quantifiable health benefits realized from implementing the rule.

West Virginia Rivers Coalition et al. (Doc. #1746, SBC-045252)

More funding is needed for rule implementation, particularly for small systems.

EPA has noted that passage of the Infrastructure Investment and Jobs Act (also referred to as BIL), invests over $11.7 billion in the Drinking Water State Revolving Fund (DW SRF), $4 billion to the DW SRF for Emerging Contaminants, and $5 billion to Small, Underserved, and Disadvantaged Communities Grants (SUDC). It is critical that EPA build on these investments to provide additional assistance to communities that may be disproportionately impacted by PFAS and ensure that changing or implementing federal regulations do not negatively impact ratepayers or vulnerable communities. Federal funding should cover all capital costs for treatment technologies, and strategies for operation and maintenance costs clearly communicated to states and water systems.

In West Virginia, even basic drinking water infrastructure investments are still gravely needed. Additional costs to install treatment technologies that remove PFAS will require even more funding, particularly because West Virginia is a hot spot for PFAS contamination from industry and military installations [FN4: https://www.ewg.org/interactive-maps/pfas_contamination/map/]. In FY 22, West Virginia was allotted $7.5 million in DW SRF for Emerging Contaminants. The entirety of this funding was used for one project, to upgrade the water treatment plant in Parkersburg, WV to remove PFAS from the source water, which was primarily contaminated by the Chemours Washington Works facility. Moreover, finished water data from 37 water systems show that 19 systems are in violation of the draft MCLs [FN5: https://dhhr.wv.gov/News/2023/Pages/DHHR-and-DEP-Announce-Drinking-Water-Test-Results.aspx]. Source water data from water systems across the state indicate that the total number of systems in violation of the draft MCLs is likely much higher. It is doubtful that West Virginia's allotment of BIL DW SRF and SUDC is sufficient to cover the hundreds of millions needed in capital costs to upgrade water systems, as well as basic infrastructure upgrades to ensure all West Virginians have access to safe drinking water.

Furthermore, it is imperative that ratepayers do not bear the burden of capital costs, nor the operation and maintenance costs. In tandem with the publication of a final rule, EPA should highlight funding and financing strategies water systems can use to ensure they can implement the final rule without making bills unaffordable, particularly for low-income customers. Strategies include maximizing use of available federal funding, especially for disadvantaged communities; holding polluters accountable for water systems' compliance costs; and adopting equitable rate structures and other programs that can increase rate revenues without burdening low-income customers.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL funds are not meant to fully cover all capital costs for treatment technologies, and strategies for operation and maintenance costs and that there are significant quantifiable and non-quantifiable health benefits realized from implementing the rule.

Riverside Public Utilities, Riverside, CA (Doc. #1762, SBC-044226)

May 30, 2023

The Honorable Michael Regan

Administrator

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue NW

Washington, D.C. 20460

Dr. Jennifer McLain

Director

Office of Ground Water and Drinking Water

U.S. Environmental Protection Agency

1201 Pennsylvania Avenue NW

Washington, D.C. 20004

Re: Comment Letter PFAS National Primary Drinking Water Regulation Rulemaking; EPA–HQ– OW–2022–0114; FRL 8543–01– OW

Dear Administrator Regan and Dr. McLain:

The City of Riverside (City) staff appreciates the opportunity to provide comments on the Environmental Protection Agency's (EPA) proposed PFAS National Primary Drinking Water Regulation (NPDWR). City staff strongly supports drinking water standards for PFAS that are based on sound science and robust analysis. This process will result in a landmark decision for water agencies. The U.S EPA's willingness to consider feedback from water agencies and stakeholders across the nation is greatly appreciated prior to the official rulemaking.

The City is the county seat of Riverside County with its own water, wastewater and electric utilities. The City provides high quality services to a population of more than 300,000. Approximately 34% of Riverside's population falls below 200% of the 2020 Federal Poverty Level. The City is committed to providing the highest quality water at affordable water rates to benefit the community and believes that future regulations must consider the financial burden on ratepayers.

The City's current treatment systems and blending capacity are reducing PFAS concentrations below the State's current notification levels; however, our initial analysis indicates that more advanced water treatment will be required to meet the proposed Federal regulations announced on March 14, 2023. Complying with the lower Federal PFAS limits will be more difficult, particularly during the high water demand summer period. During this time, water treated by the City's existing systems will likely exceed the proposed PFAS Federal limits, unless the City installs additional treatment, or resorts to turning off wells with high PFAS concentrations. Shutting down wells during peak summer water demand will reduce groundwater supplies and

may require the City to purchase more expensive imported water from the Metropolitan Water District of Southern California via Western Municipal Water District in order to meet the needs of its ratepayers.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Northwest Biosolids Association et al. (Doc. #1783, SBC-043800)

In addition, drinking water utilities will need federal funding and assistance to implement technologies capable of meeting any new limits for PFAS. Without federal assistance, the rate payers will suffer the burden of paying for the clean-up of upstream sources of PFAS.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Fairfax Water (Doc. #1789, SBC-045316)

6. The cost to implement PFAS treatment will be considerable and will be borne by utility ratepayers - the public. Placing the entire burden of PFAS removal on the drinking water public exacerbates the affordability issues many utilities face as we address new (Lead and Copper Rule Revisions) and future (Microbial and Disinfection Byproduct Rules) regulations, replace aging infrastructure, and address climate related resilience. Affordability is further challenged by cost increases for chemicals, power, and supplies that far outpace the overall rate of inflation. EPA should re-evaluate the costs of rule implementation to ensure the current realities of utility input costs and supply chain limitations are accurately reflected in its analysis.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that topics related to "new (Lead and Copper Rule Revisions) and future (Microbial and Disinfection Byproduct Rules) regulations, replac[ing] aging infrastructure, and address[ing] climate related resilience" are beyond the scope of the current rulemaking. To the extent that implementation overlaps with other rules, the EPA notes that it is not permitted to consider costs that result from compliance with other regulations per SDWA section 1412(b)(3)(C)(i)(III); please see section 12 of the EPA response in this *Response to Comments* document for additional information.

Fairfax Water (Doc. #1789, SBC-045307)

EPA frequently cites the funding made available for PFAS treatment in the Bipartisan Infrastructure Law (BIL), but those funds represent a fraction of what will be required to implement PFAS treatment at water utilities nationwide and many utilities are not eligible to receive those funds.

While infrastructure costs for PFAS treatment would be financed over time, the increase in annual operating expenses falls directly to the cost per gallon to customers. There is no federal funding to support ongoing operational expenses, nor is there any certainty that funding for the Low Income Household Water Assistance Program (LIHWAP) will continue.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL funds are not meant to fully fund "PFAS treatment at water utilities nationwide" and that there are significant quantifiable and non-quantifiable health benefits realized from implementing the rule.

Metropolitan Washington Council of Governments (COG) (Doc. #1791, SBC-043774)

Third, while significant federal funding has been approved by Congress, additional direct federal funding for local governments and water utilities should be provided to help offset the high capital, operations, and maintenance costs expected at the local level. The cost of compliance is estimated by a recent AWWA study to be significantly higher than cost estimates developed by EPA. These potentially high expenses for PFAS treatment come at a time when local governments and water utilities are facing double and triple digit increases in the prices of essential supplies, equipment, and electricity. On top of that, we are also facing potentially high costs to address regional water security and resilience needs, mitigate climate change impacts, meet Chesapeake Bay TMDL restoration requirements, and more. Ultimately, all these costs will fall on ratepayers who are already facing higher costs for other basic necessities such as food, housing, and transportation.

We thank you for your consideration of these recommendations and look forward to continuing to work together on environmental restoration efforts.

Sincerely,

Maria Mackie

Chair, Chesapeake Bay and Water Resources Policy Committee

Cc: Radhika Fox, Assistant Administrator for Water Adam Ortiz, EPA Region III Administrator

Catherine A. Libertz, Director, EPA Region III Water Division

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The agency notes that concerns regarding, "regional water security and resilience needs, mitigate[ing] climate change impacts, meet[ing] Chesapeake Bay TMDL restoration requirements" are beyond the scope of the current rulemaking.

Ohio Environmental Council (Doc. #1794, SBC-045327)

While some water utilities have already installed water treatment technology capable of reducing PFAS, many are not yet equipped to do so. To help communities, Congress passed the Bipartisan

Infrastructure Law which provides $9 billion in funding for drinking water treatment upgrades, and an additional $11.7 billion for other necessary drinking water infrastructure needs. This funding will aid utilities in meeting EPA's proposed drinking water standards and improve drinking water safety.

EPA Response: The EPA agrees that BIL funding can "aid utilities in meeting the EPA's proposed drinking water standards and improve drinking water safety." Please see section 2.4 of the EPA response in this *Response to Comments* document for additional discussion on BIL funding.

Vermont Rural Water Association (Doc. #1798, SBC-045332)

Existing funding mechanisms will not cover costs such as ongoing sampling, bottled water, treatment system operation and maintenance, and additional operator certifications. In Vermont, the sixteen systems with PFAS exceeding the state MCL include schools, fire districts, and small businesses in every corner of the state. Most of these systems do not employ on-site operators and must pay for increased visits and assistance from contract operations companies.

EPA Response: With respect to BIL funding for operations and maintenance costs, please see section 2.4 of the EPA response in this *Response to Comments* document.

Vermont Rural Water Association (Doc. #1798, SBC-045329)

From: Liz Royer <lroyer@vtruralwater.org>

Sent: Tuesday, May 30, 2023 11:59 AM

To: OW-Docket

Subject: Vermont Rural Water Comments on EPA-HQ-OW-2022-0114

Attachments: Vermont Rural Water Association EPA-HQ-OW-2022-0114.pdf

Please see the attached document for comments from the Vermont Rural Water Association on EPA-HQ-OW-20220114. Thank you.

Liz Royer

Executive Director

Vermont Rural Water Association

802-660-4988 x336 lroyer@vtruralwater.org

Rural Water…supporting water and wastewater systems in Vermont since 1982.

Date: May 30, 2023

To: US EPA

RE: Comments on Proposed PFAS National Primary Drinking Water Regulation

Docket ID: EPA-HQ-OW-2022-0114

As representatives of Vermont's small drinking water systems, the Vermont Rural Water Association is providing feedback to EPA regarding proposed PFAS regulation. We are proud that Vermont is a national leader in protecting public health by regulating contaminants in drinking water. However, the financial integrity of water utilities is also a threat to public health. This is especially the case for our small, rural system members.

Vermont's current PFAS regulations, established by Act 21, have already caused financial and technical burdens for over 600 public water systems in Vermont. Collecting the water sample requires training or hiring a contractor. Sample analysis is expensive, especially since there are no labs within the state certified to perform EPA Methods 537 or 537.1. Those systems found to have PFAS levels exceeding the state MCL have spent large amounts on engineering services and remediation in addition to the social consequences of issuing a Do Not Drink order to their customers. Additional regulations will likely cause water rates to rise, which will harm our most vulnerable populations.

EPA Response: With respect to funding concerns for disadvantaged communities, please see section 2.4 of the EPA response in this *Response to Comments* document.

Massachusetts Municipal Association (MMA) (Doc. #1800, SBC-043760)

Existing Regulatory Landscape in Massachusetts

In 2020, the Massachusetts Department of Environmental Protection (MassDEP) established an enforceable state maximum contaminant level (MCL) of 20 parts per trillion (ppt) for the sum of six PFAS compounds. These include perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorononanoic acid (PFNA), perfluorohexane sulfonic acid (PFHxS), perfluoroheptanoic acid (PFHpA), and perfluorodecanoic acid (PFDA). This regulatory standard was much more stringent than the EPA's health advisories for PFOA and PFOS at the time.

The Massachusetts MCL for PFOA, PFOS, PFNA, PFHxS, PFHpA, and PFDA, commonly referred to as "PFAS6," required our members to test, monitor, and remediate PFAS contamination in drinking water before a national enforceable regulation was proposed. 170 PWS in Massachusetts were impacted by this MCL and found detections above 20 ppt. To date, $209 million has been committed for just 24 projects to treat PFAS6 through State Revolving Fund (SRF) loans. Funding corrective actions and securing loans has been and will continue to be a complex system for municipalities to navigate.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. For additional discussion on existing state drinking water standards, please see section 5.1.5 of the EPA response in this *Response to Comments* document.

Massachusetts Municipal Association (MMA) (Doc. #1800, SBC-043763)

Communities in Massachusetts will face rising water rates as a result of this new regulatory standard, and it will be critical for the federal government to provide additional funding opportunities to support communities through this significant challenge. Investments through the Bipartisan Infrastructure Law (BIL) will assist in this process, but will not be sufficient alone to bear the financial burden this proposal creates for public water systems who are committed to providing safe, reliable service.

MassDEP estimates that 198 PWS across Massachusetts will be impacted should this proposal be finalized. The MMA has been in close communication with our member communities about the impact of this proposal, including many municipalities that have already been involved with significant remediation efforts to deal with PFAS contamination within the existing state standard.

EPA Response: For discussion on funding available to assist in the implementation of the PFAS NPDWR through the BIL, please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL is not intended to solely "bear the financial burden" of this NPDWR and that significant quantifiable and non-quantifiable health benefits are expected to be realized after implementing the rule.

Massachusetts Municipal Association (MMA) (Doc. #1800, SBC-043769)

Summary

The requirements to comply with the EPA's National Primary Drinking Water Regulation proposal go beyond the normal operating budgets of our cities and towns. Because of the tax-limited environment [Link: https://www.mass.gov/service-details/proposition-2-12-and-tax-rate-process] in Massachusetts cities and towns, many communities would be forced to consider an override to increase local property tax burdens, or be compelled to reduce funding for existing programs and services. That is the simple reality caused by unfunded mandates.

Public water systems are devoted to the provision of safe drinking water and will do what is necessary to ensure public trust and confidence in this resource. However, without supplemental funding and a practical timeline for this necessary work, municipalities will struggle to finance and implement corrective action, and this new burden will weaken the delivery of other vitally important services.

We welcome opportunities to work collaboratively with the EPA and EPA Region 1 staff as the regulatory process continues to ensure that municipal concerns and realities are taken into full consideration.

Thank you for considering our comments on the proposed National Primary Drinking Water Regulation. If you have any questions or desire further information, please do not hesitate to

have your office contact me or MMA Legislative Analyst Josie Ahlberg at jahlberg@mma.org at any time.

Sincerely,

Geoffrey C. Beckwith

Executive Director & CEO, MMA

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The agency also notes that individual state or local tax laws are outside the scope of the current rulemaking. Finally, please also see section XIII.D of the final rule preamble for discussion on the EPA's consultation and analyses under current statutory and Executive Orders, including UMRA, in support of the final rulemaking.

Safe Drinking Water Branch, Hawaii Department of Hawaii (Doc. #1801, SBC-043750)

Comment on the proposed PFSA Rule from Safe Drinking Water Branch, Hawaii Department of Hawaii

financial Burden

The cost of test, the construction and operation of the pilot treatment plant, the construction, the operation and maintenance costs of the treatment plant, the disposal cost of spent media will be a heavy financial burden to the water systems, especially those in the disadvantage community. How will EPA provide enough financial support for water purveyors in a long run?

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL provided approximately $43 billion to the CWSRF and DWSRF, with $4 billion specifically reserved to address PFAS and emerging contaminants and $5 billion in grants to small or disadvantaged communities. While $15 billion is reserved for lead service line replacements, the rest can be used for various purposes, which could include installing PFAS treatment or source water protection.

Midwest Environmental Advocates +more (Doc. #1846, SBC-045835)

EPA notes the availability of billions of dollars in federal funds through the BIL to help defray the compliance costs of the proposed rule. The availability of these funds is important context for the proposed rule and should not be ignored. In Wisconsin, around $13,000,000 in funding per year is available—through 2026—via the Safe Drinking Water Loan Program for Emerging Contaminants (SDWLP-EC) alone. [FN35: Wisconsin Department of Natural Resources, Bipartisan Infrastructure Law Funding: Clean Water and Drinking Water State Revolving Fund Programs, https://dnr.wisconsin.gov/aid/BILfunding] These funding sources allows water systems to lower their cost of capital and, thus, the estimated compliance cost forecasted with a 7% discount rate is overstated.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that BIL provided approximately $43 billion to the CWSRF and DWSRF, with $4 billion specifically reserved to address PFAS and emerging contaminants and $5 billion in grants to small or disadvantaged communities. While $15 billion is reserved for lead service line replacements, the rest can be used for various purposes, which could include installing PFAS treatment or source water protection.

Calie Mallory (Doc. #1935, SBC-046606)

It is unquestionable that we as a nation need to do something about the PFAS that are contaminating so much of our water and making so many sick. There is undoubtedly nothing bad that can come of addressing this issue, it would benefit the health of everyone in the long run and even the environment hopefully. Acting can only bring good in providing the EPA the necessary data to cause improvement. The recent Bipartisan Infrastructure Law Funding Grant and requiring PFA manufacturers to better provide toxicity data in broken down categories may be exactly what is necessary to address this issue. While it may seem like an incredibly great amount of money, $2 billion is an important investment for the E.P.A. to make to regulate the amount of PFAs that are seen in the water that is being supplied to citizens all over the country.1 Providing this to small and disadvantaged communities would be essential in taking initiative for this problem since it would start by directly targeting those that are most impacted by the presence of PFAS. Such as small farming communities that may not have much intervention in regulating their water toxicity for them and their farm animals, or disadvantaged communities that are not given the resources to keep their drinking water healthy. Disadvantaged communities such as Flint, Michigan. The people that would most be affected by this Bipartisan Funding is the taxpayers who are, in theory, providing the money for these grants. Some taxpayers may be upset that this is what their money is going to, but this should not be taken too harshly since helping them fund the grants will hopefully benefit them and their health in the future. Also, these taxpayers should feel confident that the money is being allocated appropriately by states and territories since they are going to have to actively collaborate with the E.P.A. regional offices in what they are doing to act. Looking at the Bipartisan Funding, it seems it will bring little harm and more benefit to everyone. Another action being proposed that may be effective in addressing PFAS and their regulation in water, is the new stricter data reporting that is being proposed.2 The proposed idea of all PFA manufacturers having to better provide toxicity data could be incredibly helpful in trying to produce solutions. Especially when it comes to getting very specific in the different PFA categories and breaking them down into smaller and more specific sub-groups that can allow better monitoring of health effects and possible solutions to regulating them. However, while this would be helpful and effective, it may not be very realistic since it will be hard for the E.P.A. to get all manufacturers of PFAS to accurately report their toxicity data. It may be possible that some manufacturers, when their toxicity data is not positive, may alter their numbers to look better which would not help in regulating that specific company or monitoring that PFA. If this is to be a method used in acting, there needs to be more specified details as to how PFA manufacturers are to be truly held accountable. When it comes to finding immediate

solutions and benefitting everyone, the Bipartisan Funding is the most beneficial and best option as of right now, the E.P.A manufacturer regulation may not be the most refined as it may need to be to properly taking effect.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. For additional discussion on the agency's plan for reducing PFAS exposure through the *PFAS Strategic Roadmap*, please see section 15 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2533, SBC-046303)

While I am all for banning, or at least severely regulating, PFAS chemicals because of their negative impacts on our health and the environment, I am wondering if the EPA has considered other relevant components to this proposal, such as its impact on the economy. PFAS are used in many consumer products from things like cleaning supplies to shampoo to life jackets. Regulating these chemicals will surely create an economic burden that will be shoved onto us as consumes of these products. Our health should obviously be our top priority, however, I think it should be considered that this economic burden could potentially make it difficult for those who are disadvantaged to pay for other serious health complications.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. Information on health effects associated with the six PFAS can be found in section 4 of the EPA response in this *Response to Comments* document, and economic impact is addressed in section 13 of the EPA response in this *Response to Comments* document under the health risk reduction and cost analysis. Regulation of consumer products is beyond the scope of this PFAS NPDWR.

Reid Biggs (Doc. #2565, SBC-046277)

Great work, thankyou. Please insist on the help of those that have manufactured, and profited from, items that have contributed to the PFAS buildup in our environment throughout this, and the last century. Please, don't let the blame and financial responsibility fall solely on the consumer. Maybe they should subsidize water filtration methods required to keep providing our descendants with plenty of clean, free, fresh, & safe drinking water.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. As part of the *PFAS Strategic Roadmap*, the EPA is committed to addressing PFAS contamination and the PFAS NPDWR is one key part of that strategy. For additional discussion on the *PFAS Strategic Roadmap*, please see section 15 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2311, SBC-047301)

Although there is Federal funding for infrastructure development, why is there no funding for operations and maintenance for rural/native communities, or otherwise economically and technically disadvantaged communities? Alaska has multiple rural communities that still lack running water and sewer service. They drink from rain catchment from their roofs, snow melt, rivers, or lakes and use 5-gallon buckets (aka "Honey buckets") as toilets. Millions of dollars have been spent to develop state of the art water treatment and sanitation facilities only for them to fall in disrepair because there is no funding to support operation and maintenance.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA and BIL place increased investment in disadvantaged communities as a key priority as stated in the memorandum from Radhika Fox dated 8 March 2022 titled "Implementation of the Clean Water and Drinking Water State Revolving Fund Provisions of the Bipartisan Infrastructure Law." This can also be seen in various EPA initiatives such as Justice40 and the funding allocations to small and disadvantaged communities. More information on EJ can be found in section 14.10 of the EPA response in this *Response to Comments* document.

Beaufort-Jasper Water & Sewer Authority (BJWSA) (Doc. #1618, SBC-042934)

The impact on customer rates will be substantial, especially when considering the national need to address aging water infrastructure coupled with the substantial increase in construction costs. Without additional federal funding to support PFAS treatment technology implementation and increased regulations on the polluters to decrease source water PFAS levels, water utility customers will b left paying the bill. In an attempt to try to keep water rate increases to feasible levels, utilities will need to delay other planned capital projects and defer necessary infrastructure repair and rehabilitation, which increases utility risk and could have severe public health consequences.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

California Association of Mutual Water Companies (Doc. #1676, SBC-043787)

5. Incentives for Larger Systems Helping Smaller Systems

CalMutuals recently has become the fiscal sponsor of an alliance of small to medium sized special districts that serve disadvantaged communities and have been advancing regional solutions to small-system challenges. We encourage the EPA to incentivize States to allocate a portion of the technical assistance set-aside within the State Revolving Funds to support and encourage larger systems in proximity to share technology and expertise to assist their smaller system neighbors as we work together to provide safe water to our shared communities.

Thank you for your consideration of CalMutuals comments.

Karina Cervantez

Managing Director

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Susan Gorman-Chang (Doc. #1705, SBC-045085)

6. Please add a statement that, pending future legislation to this effect, the costs of adherence to these regulations will be paid for, in whole or in part, by the chemical corporations that created these dangerous chemicals, those being DuPont, 3M, Chemours, Daikin, Arkea and Solvay. DuPont alone made this much money in the sales of its products in these years. Yes, that is TRILLIONs of dollars:

$25,000,000,000 in 1999

$28,200,000,000 in 2000

$27,000,000,000 in 2001

$24,700,000,000 in 2002

$24,000,000,000 in 2003

It is relevant to go even further back in time, since these products were developed in 1947-1949 so the above number reflect only SOME of the profits made off of the PFAS by DuPont.

In 2014 DuPont created a new corporation, Chemours, and here are the Net Sales per their 10-K for more recent years:

$6,345,000,000 in 2021

$4,696,000,000 in 2020

$5,526,000,000 in 2019

Plus, there are the additional corporations I mentioned at the beginning of this paragraph 6.

7. Please note that these sales figures, above, dwarf any figures of costs that will be borne by our federal government, by our local governments, and local water district which, of course means, it is born by we the taxpayers. Why should we the people pay for the poisons these corporations unleashed without conscience into OUR environment? These corporations have more than enough assets and income to pay for the cleanup of the poisons they released into the world. We even have a legal precedent for such a procedure with the Asbestos Trust Fund for past, present and future victims of exposure to asbestos. In these EPA Regulations, please include and require a PFAS Trust Fund be set up for the past, present and future health impacts of those exposed to

PFAS, with such trust fund paid for entirely by the above mentioned corporations. Additionally or alternatively, the PFAS Trust Fund could be used to help state and local water districts comply with their infrastructure requirements to filter and contain and dispose of the PFAs in their water systems.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Louisville Water Company (Doc. #1720, SBC-043551)

In that regard, we are providing the following comments on key issues that we think require consideration.

1. Louisville Water's urges EPA to focus its resources at preventing PFAS pollution at the source using the various tools the agency has available and its relationships with other federal and state agencies. We recommend EPA take actions that make it easier to identify sources of PFAS contamination in the environment and work to limit or eliminate these sources. Given the persistent nature of these chemicals in natural systems, the agency should prioritize prevention, as treatment costs are high and the long-term options regarding disposal are uncertain. We appreciate efforts already being made such as the addition of certain PFAS to the Toxics Release Inventory but urge the agency to do more to track and reduce PFAS discharges. Knowing the sources of PFAS will allow EPA and water utilities to work to address PFAS pollution at the source and hold those polluters accountable. Public water utilities provide an invaluable service to the public, but the burdens of pollution remediation should not be placed solely on water systems. We also recognize that the regulation of PFAS via a National Primary Drinking Water Rule establishes its own Environmental Justice dilemma. The proposed rule shifts the responsibility of remediating PFAS in drinking water to the water utilities and their rate payers; the poorest of our rate payers will be burdened the most significantly.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document. Topics related to assigning liability for PFAS pollution or addressing sources of PFAS contamination are beyond the scope of this rulemaking (please see section 15 of the EPA response in this *Response to Comments* document for additional discussion).

New Mexico Environment Department (NMED) (Doc. #1766, SBC-044253)

NMED highly recommends that EPA consider providing specific funding to community water systems and state primacy agencies to recruit, train, and retain a new generation of water and wastewater utility operators that will lead the effort in providing a safe and sustainable supply of drinking water for their communities.

EPA Response: Please see section 2.4 of the EPA response in this *Response to Comments* document.

Section 2 References

Guelfo, J.L. and D.T. Adamson. 2018. Evaluation of a national data set for insights into sources, composition, and concentrations of per- and polyfluoroalkyl substances (PFASs) in U.S. drinking water. *Environmental Pollution,* 236, 505-513. https://doi.org/10.1016/j.envpol.2018.01.066

USEPA. 2023a. PFAS National Primary Drinking Water Regulation Rulemaking. *Federal Register*. 88 FR 18638. March 29, 2023.

USEPA. 2023b. *Economic Analysis of the Proposed National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances.* EPA-822-P-23-001.

USEPA. 2023c. *Appendix: Economic Analysis of the Proposed National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances.* EPA-822-P-23-002.

USEPA. 2023d. *Public Comment Draft – Toxicity Assessment and Proposed Maximum Contaminant Level Goal (MCLG) for Perfluorooctanoic Acid (PFOA) (CASRN 335-67-1) in Drinking Water*. EPA-822-P-23-005.

USEPA. 2023e. *Public Comment Draft – Appendix: Proposed Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) (CASRN 335-67-1) in Drinking Water.*

USEPA. 2023f. *Public Comment Draft – Toxicity Assessment and Proposed Maximum Contaminant Level Goal (MCLG) for Perfluorooctane Sulfonic Acid (PFOS) (CASRN 1763-23-1) in Drinking Water.* EPA-822-P-23-007.

USEPA. 2023g. *Public Comment Draft - Appendix: Proposed Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) (CASRN 1763-23-1) in Drinking Water.*

USEPA. 2023h. *Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS).* EPA-822-P-23-003.

USEPA. 2023i. *Public Comment Draft – Maximum Contaminant Level Goal (MCLG) Summary Document for a Mixture of Four Per- and Polyfluoroalkyl Substances (PFAS): GenX Chemicals, PFBS, PFNA and PFHxS*. EPA-822-P-23-004.

USEPA. 2023j. *EPA Response to Final Science Advisory Board Recommendations (August 2022) on Four Draft Support Documents for the EPA's Proposed PFAS National Primary Drinking Water Regulation*. EPA-822-D-23-001.

USEPA. 2023k. *Water Technical Assistance (WaterTA).* Available on the internet at: https://www.epa.gov/water-infrastructure/water-technical-assistance-waterta

USEPA. 2024a. *Economic Analysis for the Final Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation.* 815R24001.

USEPA. 2024b. *Economic Analysis for the Final Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation Appendices.* 815R24002.

USEPA. 2024c. *Maximum Contaminant Level Goals (MCLGs) for Three Individual Per- and Polyfluoroalkyl Substances (PFAS) and a Mixture of Four PFAS.* 815R24004.

USEPA. 2024d. *Best Available Technologies and Small System Compliance Technologies Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water.* 815R24011.

3 Preliminary Regulatory Determinations

3.1 EPA's Preliminary Regulatory Determinations Summary for PFHxS, PFNA, HFPO-DA, and PFBS

Summary of Major Public Comments and EPA Responses

Many commenters expressed support for the EPA's preliminary regulatory determinations for PFHxS, PFNA, HFPO-DA, and PFBS, including that the EPA has appropriately determined that the three statutory criteria for regulation have been met for all four contaminants using the best available information. Many other commenters did not agree that the agency presented sufficient information to make a preliminary determination to regulate PFHxS, PFNA, HFPO-DA, and PFBS with some commenters recommending that that the agency withdraw the portion of the proposed rule associated with these four PFAS because in their view there is insufficient health effects and/or occurrence data at this time to support the EPA's action or there is a need to wait for future information, such as data from the fifth Unregulated Contaminant Monitoring Rule (UCMR 5), to become available to make a regulatory determination. For only some of the four contaminants, a few commenters stated that the EPA has not met the statutory criteria for regulation or that data suggests a determination not to regulate is more appropriate.

The Safe Drinking Water Act (SDWA) Section 1412(b)(B)(ii)(II) states, "A determination to regulate a contaminant shall be based on findings that the criteria of clauses (i),(ii), and (iii) of subparagraph (A) are satisfied. Such findings shall be based on the best available public health information, including the occurrence data base under section 1445(g)." The statute allows the EPA to determine the "best available public health information" for purposes of this provision and recognizes that the occurrence data may come from sources other than the database discussed in section 1445(g). Regarding PFHxS, PFNA, and HFPO-DA, the EPA disagrees with these commenters because there is this best available public health information to support individual regulation of PFHxS, PFNA, and HFPO-DA, based on the three statutory criteria as detailed in the EPA's responses within sections 3.1.1, 3.1.2, and 3.1.3 of this document and as demonstrated through's the EPA's evaluation of the best available information in sections III.B, C, and D of the final rule preamble. While the EPA recognizes there will be additional health, occurrence, or other relevant information for these PFAS and others in the future, the EPA has determined that there is sufficient information to make a positive regulatory determination in this action and the agency concludes that these three PFAS currently meet all of the statutory criteria for individual regulatory determination.

For the individual PFBS regulatory determination, after consideration of all the public comments on this issue, the agency is deferring the determination to individually regulate PFBS for further evaluation under the statutory criteria; consequently, the agency is also not promulgating an individual Maximum Contaminant Level Goal (MCLG) or National Primary Drinking Water Regulation (NPDWR) for PFBS in this action. This determination is informed by public comments suggesting that the three statutory criteria for individual regulation of PFBS,

particularly related to the occurrence criterion have not been met. The EPA will continue to consider other available occurrence information, including from UCMR 5, to determine whether the information supports a finding that there is a substantial likelihood that PFBS will individually occur in PWSs and at a level of public health concern. However, the record demonstrates that exposure to a mixture with PFBS may cause adverse health effects; that there is a substantial likelihood that PFBS co-occurs in mixtures with PFHxS, PFNA, and/or HFPO-DA in public water systems (PWSs) with a frequency and at levels of public health concern; and that, in the sole judgment of the Administrator, regulation of PFBS in mixtures with PFHxS, PFNA, and/or HFPO-DA presents a meaningful opportunity for health risk reduction for persons served by PWSs. Please see section III.A. of the final rule preamble for additional information.

A couple of commenters questioned the EPA's rationale for selecting PFHxS, PFNA, HFPO-DA, and PFBS for regulation, with some stating the EPA should not develop regulations that differ from state-developed regulations. The agency's process is allowable under SDWA and, as described within the section III of the final rule preamble, there is available health, occurrence, and other meaningful opportunity information for three PFAS (PFHxS, PFNA, and HFPO-DA) to meet the SDWA statutory criteria for regulation individually and four PFAS (PFHxS, PFNA, HFPO-DA, and PFBS) as a mixture. The EPA disagrees with commenters who suggested that the agency should not develop national regulations that differ from state-led actions. While states may establish drinking water standards for systems in their jurisdiction prior to regulation under SDWA, once an NPDWR is in place, SDWA 1413(a)(1) requires that states or Tribes adopt standards that are no less stringent than the NPDWR to maintain primacy. Moreover, the agency further notes that all four PFAS the EPA is regulating individually or as a mixture are currently regulated by multiple states as shown in table 4-17 of USEPA (2024a).

Individual Public Comments

Missouri River Public Water Supplies Association (MRPWSA) (Doc. #1581, SBC-042409)

Preliminary Determination to Regulate PFHxS, HFPO-DA, PFNA» and PFBS MRPWSA does not agree that U.S. EPA has sufficient information to make preliminary determinations on PFHxS, HFPO-DA, PFNA, and PFBS and recommends that the Agency withdraw the portion of the proposed rule associated with these four PFAS until such time as the data to support such action is available for one or more separate National Primary Drinking Water Regulations.

EPA Response: The EPA disagrees with the commenter. Please see section 3.1 of the EPA response in this *Response to Comments* document.

Michigan Department of Environment, Great Lakes, and Energy (EGLE) Drinking Water and Environmental Health Division (DWEHD) (Doc. #1597, SBC-042971)

A. EPA Preliminary Regulatory Determination for Additional PFAS

Having reviewed Section III of the proposed NPDWR, EGLE DWEHD agrees with EPA's findings that four additional PFAS compounds (HFPO-DA, PFBS, PFNA, and PFHxS) meet the statutory requirements for regulatory determination as established by the Safe Drinking Water Act. Furthermore, the inclusion of these four additional PFAS compounds is consistent with the regulatory determination established by the State of Michigan during the establishment of its own MCLs in 2020.

EPA Response: The EPA acknowledges commenter's agreement that HFPO-DA, PFNA, and PFHxS meet the statutory requirements for determinations to regulate. Please see section 3.1 of the EPA response in this *Response to Comments* document.

Consumer Reports (Doc. #1656, SBC-043183)

To summarize, we agree that EPA has met the criteria laid out in Sections 1412(b)(1)(A) and 1412(b)(1)(B) of the SDWA to make a preliminary regulatory determination that PFHxS, GenX chemicals, PFNA, and PFBS, and their mixtures are contaminants to be regulated as part of this proposed NPDWR.

EPA Response: The EPA acknowledges commenter's agreement that HFPO-DA, PFNA, PFHxS, and mixtures of these three PFAS and PFBS meet the statutory requirements for determinations to regulate. Please section 3.1 of the EPA response in this *Response to Comments* document.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044402)

Page 18729. Section III – Regulatory Determinations for Additional PFAS.

EPA requests comment on its preliminary regulatory determination for PFHxS and its evaluation of the statutory criteria that supports the finding. EPA also requests comment on if there are additional data or studies EPA should consider that support or do not support the Agency's preliminary regulatory determination for PFHxS, including additional health information and occurrence data.

• DOH supports the regulatory determination to regulate PFHxS. This PFAS co-occurs at very high levels with PFOS in drinking water supplies in Washington State. Impacted areas are mostly near fire training areas and military bases that used Aqueous Fire Fighting Foam (AFFF). The multistate ATSDR PFAS Exposure Assessment showed that a community in Washington State near Fairchild Airforce base had higher average serum levels of PFHxS than seven other sites included in the study. After PFOA and PFOS, PFHxS is the most common PFAS to occur above our state action levels in drinking water.

EPA Response: The EPA acknowledges commenter's support for the EPA's determination to regulate PFHxS. Please see section 3.1 of the EPA response in this *Response to Comments* document.

Horsham Water & Sewer Authority (HWSA) (Doc. #1686, SBC-043823)

An occurrence study performed in Pennsylvania, showed a maximum PFBS level found in drinking water of 13.0 ppt (well below the proposed health-based water concentration of 2,000 ppt) and a maximum PFNA concentration of 14 ppt (slightly above the proposed health-based water concentration of 10 ppt). Our experience is that PFHxS is among the PFAS compounds found in waters exposed to AFFF firefighting foam but that its occurrence level is always about half that of PFOA/PFOS and will be adequately covered by the PFOA and PFOS MCLs, as would PFNA if present as well as these are both long-chained PFAS compounds with similar performance to PFOA and PFOS when using GAC or Anion Exchange. GenX is a site-specific contaminant emanating from discreet sources that it is our understanding are already being regulated by EPA. Moving forward to regulate compounds without sufficient justification, especially when there may be little to no additional benefits that result, is not supportable.

Once again, thank you for the opportunity to comment on the Proposed Rule for Per- and

Polyfluoroalkyl Substances National Primary Drinking Water Regulation and if you have any questions regarding these comments, please contact Mike Pickel at (215) 672-8011 or at mpickel@horshamwatersewer.com.

For the Horsham Water & Sewer Authority,

Michael J. Pickel, P.E.

Director, Compliance & Regulatory Affairs

EPA Response: Please see EPA's response 3.1. The EPA disagrees that regulation of only PFOA and PFOS will fully protect against PFHxS or PFNA drinking water exposure, as well as exposure to HFPO-DA and PFBS. While PFHxS, PFNA, HFPO-DA, and PFBS have been demonstrated to often co-occur with PFOA and/or PFOS, in water systems where PFOA and PFOS are not present at elevated levels but PFHxS, PFNA, HFPO-DA, and/or PFBS are present, the EPA estimates in the final rule preamble that 100-300 PWSs will exceed the Hazard Index Maximum Contaminant Level (MCL) or PFHxS MCL without exceeding the PFOA or PFOS MCL. For persons served by those water systems, if the EPA were to rely solely upon regulation of PFOA and PFOS to reduce exposure, those consumers would continuously be exposed to potentially harmful levels of these other PFAS. Furthermore, the EPA agrees that the drinking water treatments used to remove PFOA and PFOS will have co-benefits for removal of PFHxS, PFNA, HFPO-DA, PFBS, and other PFAS, however those treatment systems must be designed and optimized for all of the contaminants that are present, accounting for site specific circumstances. Only designing a treatment system for PFOA and PFOS removal, rather than for the other PFAS which may be present in varying concentrations, may not be as effective for the

other PFAS or adequately public health protective. For comments and the EPA response to treatment co-removal, please see section 10.3 in this *Response to Comments* document.

Wisconsin Department of Justice et al. (Doc. #1687, SBC-044442)

Comments

1. EPA has authority to set PFAS drinking water standards because PFAS have known adverse health effects, are likely to occur in public water systems, and such regulation provides a meaningful opportunity for reducing risks to human health.

EPA is required to set enforceable drinking water standards if the EPA Administrator determines that a contaminant meets the following criteria: (a) it may have adverse human health effects; (b) it is known to occur or is substantially likely to occur in public water systems with a frequency and at levels of public health concern; and (c) its regulation presents a meaningful opportunity to reduce health risks for those served by public water systems. [FN10: 42 U.S.C. § 300g-1(b)(1)(A).] These criteria are met here.

EPA Response: The EPA acknowledges commenter's agreement of the EPA's decision that HFPO-DA, PFNA, PFHxS, and mixtures of these three PFAS and PFBS meet the statutory requirements for determinations to regulate. Please see section 3.1 of the EPA response in this *Response to Comments* document.

Clean Water Action/Clean Water Fund (Doc. #1697, SBC-045000)

The Preliminary Regulatory Determination and Proposed NPDWR for PFHxS, GenX, PFBA, and PFNS are consistent with EPA's Final Regulatory Determination for CCL 4

In the March 2021 Final Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List, EPA noted that commenters on the preliminary Regulatory Determination urged the agency to develop regulations for more PFAS chemicals and/or for PFAS chemicals as a class and stated:

EPA notes that although SDWA does not require the Agency to complete regulatory determinations for the contaminants on the fifth CCL until 2026, because of the significant progress related to developing new high-quality PFAS information, combined with the Agency's commitment in the PFAS Action Plan to assist states and communities with PFAS contaminated drinking water, EPA will continue to prioritize regulatory determinations of additional PFAS in drinking water. The Agency is committing to making regulatory determinations in advance of the next SDWA deadline for additional PFAS for which the Agency has a peer reviewed health assessment, has nationally representative occurrence data in finished drinking water, and has sufficient information to determine whether there is a meaningful opportunity for health risk reduction for persons served by public water systems. [FN3: Announcement of Final Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List,

Federal Register / Vol. 86, No. 40 / Wednesday, March 3, 2021 / Rules and Regulations, p. 12278-79]

EPA's proposal of preliminary Regulatory Determinations and proposed regulations for four PFAS chemicals is consistent with this statement of intention to move forward on additional PFAS chemicals if sufficient health effects and occurrence information became available.

EPA Response: Please see section 3.1 of the EPA response in this *Response to Comments* document. For the EPA's response related to the concurrent preliminary regulatory determination and proposed NPDWR actions, please see section 3.3 of the EPA response in this *Response to Comments* document.

Environmental Working Group (EWG) (Doc. #1721, SBC-045407)

The regulatory determinations for GenX, PFBS, PFHxS, and PFNA are necessary and appropriate.

Section 1412(b)(1)(A) of SDWA creates a three-part test for a determination to regulate a contaminant in drinking water. The EPA shall "publish a maximum contaminant level goal and promulgate national primary drinking water regulation for a contaminant" when:

(a) the contaminant may have an adverse effect on the health of persons;

(b) the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and

(c) in the sole judgment of the administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems. [FN19: 42 U.S.C. [sec] 300g-1(b)(1)(A).]

All six PFAS covered by the proposed rule meet these criteria. The EPA made the final regulatory determination for PFOA and PFOS in March 2021 under section 1412(b)(1)(B)(ii)(I), which requires that EPA make a regulatory determination for certain chemicals on the contaminant candidate list, or CCL, every five years. [FN20: 42 U.S.C. [sec] 300g-1(b)(1)(B)(ii)(I).] For the other four PFAS, the EPA is making the regulatory determination concurrent with the proposed maximum contaminant level goal and MCL.

EPA Response: The EPA acknowledges commenter's agreement that PFOA and PFOS and HFPO-DA, PFNA, PFHxS, and mixtures of HFPO-DA, PFNA, PFHxS, and PFBS meet the statutory requirements for determinations to regulate. Please see section 3.1 of the EPA response in this *Response to Comments* document.

PFAS Regulatory Coalition (Doc. #1761, SBC-046069)

3. EPA provides no rationale for why it is making regulatory determinations for the four additional PFAS.

It is not clear in the Proposal why EPA is making a regulatory determination for the four additional PFAS. EPA has recently issued health advisory levels (HALs) for PFBS and HFPO-DA, but the Agency has never issued HALs for PFNA or PFHxS. Additionally, EPA's targeting of these four PFAS is not correlated with state actions. Of the states that have issued MCLs, some have included some of these four PFAS in the state regulations, but we are not aware of any states that have singled out only these four substances for regulatory action. Looking to other EPA programs, this list also does not align with the longer list of PFAS compounds for which EPA is soliciting information as to possible designation as CERCLA hazardous substances. Advance Notice of Proposed Rulemaking, Addressing PFAS in the Environment, 88 Fed. Reg. 22399 (April 13, 2023) (the "CERCLA ANPRM"). EPA has provided no justification for why these four additional PFAS compounds have been targeted in this rulemaking. Understanding why EPA is focusing on these four compounds is also important for understanding how EPA has chosen to regulate them using a Hazard Index approach, as discussed further in Section C below.

EPA Response: The commenter is incorrect: EPA provides a rationale for why HFPO-DA, PFNA, PFHxS, and mixtures of HFPO-DA, PFNA, PFHxS and PFBS meet the statutory requirements for determinations to regulate. Please **s**ee section 3.1 of the EPA response in this *Response to Comments* document. Additionally, Health Advisories (HAs) are not a pre-requisite for an NPDWR under SDWA and there is nothing in the statute or the EPA's historical regulatory practice that suggests that the agency must or should delay regulation of a contaminant in order to develop an HA first. Furthermore, while beyond the scope of the rulemaking, through its PFAS Strategic Roadmap and associated actions, the agency is working expeditiously to address PFAS contamination in the environment and reduce human health PFAS exposure through all pathways using all of its available statutes. Nevertheless, the EPA disagrees that the contaminants the agency is proceeding with regulating under the SDWA are required to align with those under other EPA actions or statutes.

<u>San Diego County Water Authority, CA (Doc. #1779, SBC-045286)</u>

Preliminary Determination and Hazard Index

EPA is requesting comment on its preliminary determinations to regulate PFHxS, PFNA, PFBS, and GenX chemicals. The Water Authority supports EPA's preliminary determinations to regulate PFHXs, PFNA, PFBS, and GenX chemicals.

EPA Response: The EPA acknowledges commenter's support of the EPA's decision to regulate HFPO-DA, PFNA, PFHxS. Please **s**ee section 3.1 of the EPA response in this *Response to Comments* document.

<u>Midwest Environmental Advocates +more (Doc. #1846, SBC-045819)</u>

Pursuant to Section 1412 of the SDWA, EPA is required to regulate contaminants that (1) may have an adverse effect on the health of persons; (2) are known to occur or there is a substantial likelihood that they will occur in public water systems with a frequency and at levels of public

health concern; and (3) for which regulation presents a meaningful opportunity for health risk reduction in the sole judgement of the Agency. [FN3: 42 U.S.C. § 300g-1(b)(1)(A)] Here, due to the overwhelming evidence on the toxicity and occurrence of these six PFAS, EPA exercised its expert judgment to determine that these contaminants must be regulated to meaningfully reduce public health risks nationwide.

EPA Response: Please **s**ee section 3.1 of the EPA response in this *Response to Comments* document.

J.R. Simplot Company (Doc. #1661, SBC-044148)

Overview of Comments: EPA's Determination to Regulate PFNA, PFHxS, PFBS, and GenX Chemicals Is Pre-Mature

EPA proposes significantly lower, almost zero levels of these six PFAS in drinking water and employs a novel approach to setting an MCL for the mixture of four of the six PFAS without having gone through the required scientific, legal, or procedural requirements to justify the proposed rule. The shortcomings of skipping procedural requirements is that the necessary understanding of background conditions, analytical methods, critical review of health data (and benefits) and costs is not achieved. Examples include the following:

I. Available Occurrence and Health Data Do Not Support a Decision to

Regulate

Background/Occurrence

This rulemaking is on six specifics per- and polyfluoralkyl (PFAS) substances. However, as a broad group, PFAS substances are ubiquitous in the environment. As an example, recent data on PFAS concentration in rainfall has shown that PFAS concentrations range from approximately 0.9 to 13 nanograms per liter (ng/L). [FN1: Cousins, I.T., J.H. Johansson, M.E. Salter, B. Sha and M. Scheringer. 2022. Environmental Science and Technology. Outside the Safe Operating Space of a New Planetary Boundary for Per- and Polyfluoroalkyl Substances (PFAS). Vol. 56, p. 11172-11179.] Data for rainfall in the United States shows PFAS concentrations of approximately of 2-9 ng/L. EPA's proposed rule fails to discuss the widespread nature of these chemicals and how it relates to the MCL goals, health risks and benefits.

Health Risk Determination

EPA's preliminary determination is inconsistent with statutory criteria under Safe Drinking Water Act (SDWA) because the available health data and occurrence data do not support a decision to regulate, and the data does not demonstrate that this rulemaking is a "meaningful opportunity" for health risk reduction. EPA must ensure that its regulations are based on robust scientific evaluations and meet statutory criteria, which this proposal fails to do. A fundamental flaw is that EPA's preliminary determination to regulate rests on predictions of future occurrence and not actual data.

EPA Response: Please **s**ee section 3.1 of the EPA response in this *Response to Comments* document. For the EPA's response related to the concurrent preliminary regulatory determination and proposed NPDWR actions, please see section 3.3 of the EPA response in this *Response to Comments* document. For the EPA's response related to the regulatory determination statutory criterion on occurrence, please see sections 3.1.2 and 3.2.2 of the EPA response in this *Response to Comments* document. For the EPA's response related to the regulatory determination statutory criterion on meaningful opportunity, including other routes of PFAS human health exposure and sources of PFAS in the environment, please see sections 3.1.3 and 3.2.3 of the EPA response in this *Response to Comments* document. Related to this, while NPDWRs are intended to reduce the risks from contaminants specifically in drinking water, the EPA disagrees that the proposed rule failed to discuss the physical and chemical characteristics and widespread nature of these PFAS as this information was provided in section II.C of the preamble. Nonetheless, even if these PFAS are found in other media that does not preclude the EPA from implementing the SDWA and developing a drinking water regulation to reduce human health exposure from this particular source.

West Virginia Rivers Coalition et al. (Doc. #1746, SBC-045245)

The regulatory determination for additional PFAS is well supported and the use of a hazard index approach is warranted.

The EPA's preliminary determination that perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO-DA), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS) and their mixtures have adverse human health effects; there is substantial likelihood that PFHxS, HFPO-DA, PFNA, PFBS and mixtures of these PFAS, will occur and co-occur in PWSs with a frequency and at levels of public health concern; and regulation of PFHxS, HFPO-DA, PFNA, and PFBS, and their mixtures, presents a meaningful opportunity for health risk reductions for persons served by public water systems (PWSs) is well supported. In West Virginia, there is substantial evidence that PFHxS, HFPO-DA, PFNA, and PFBS occur and co-occur in PWSs with a frequency and at levels of public health concern, and we request these data be considered in EPA's preliminary regulatory determination.

EPA Response: Please **s**ee section 3.1 of the EPA response in this *Response to Comments* document. For the EPA's response related to the regulatory determination statutory criterion on occurrence, please sections 3.1.2 and 3.2.2 of the EPA response in this *Response to Comments* document.

The Chemours Company FC, LLC (Doc. #1845, SBC-046057)

IV. Conclusion

For the foregoing reasons, and those set forth in the attached technical comments and materials incorporated herein by reference, Chemours requests that EPA withdraw its proposed regulation

of HFPO-DA under the SDWA. Chemours also reserves its ability to raise any additional issues with respect to the rulemaking, particularly given the size of EPA's rulemaking docket and the limited time period provided for public comment. Chemours would welcome the opportunity to meet with EPA to discuss its concerns with the rulemaking and answer any questions EPA may have. Please feel free to contact me to arrange such a meeting.

Sincerely,

Brian D. Israel

Enclosures

Exhibit 1 – Technical Comments of Dr. Chad Thompson and Dr. Melissa Heintz

cc: Todd A. Coomes, Associate General Counsel, The Chemours Company

EXHIBIT 1

Technical Comments Regarding EPA's Proposed Hazard Index MCLG for HFPO-DA, PFBS, PFNA and

PFHxS

MAY 30, 2023

Technical Comments Regarding EPA's Proposed Hazard Index MCLG for HFPO-DA, PFBS, PFNA and PFHxS

MAY 30, 2023

PREPARED FOR:

Arnold & Porter Washington, DC

PREPARED BY:

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Thompson, Chad M., Ph.D., M.B.A.; Senior Consultant; ToxStrategies LLC

[Table of Contents: see docket ID EPA-HQ-OW-2022-0114-1845]

[Table of Acronyms: see docket ID EPA-HQ-OW-2022-0114-1738]

EPA Response: Please **s**ee section 3.1 of the EPA response in this *Response to Comments* document. For the EPA response related to the public notice comment period for the preliminary regulatory determination, please see section 17.1 in this *Response to Comments* document.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044403)

EPA requests comments on its preliminary regulatory determination for PFNA and its evaluation of the statutory criteria that support the finding. EPA also requests comment on if there are additional data or studies EPA should consider that support or do not support the Agency's preliminary regulatory determination for PFNA, including additional health information and occurrence data.

• DOH supports the regulatory determination to regulate PFNA and PFBS. Both occur in Washington State drinking water supplies. PFNA has been occasionally found at high levels in our state around firefighting facilities.

EPA Response: The EPA acknowledges commenter's support for the determination to individually regulate PFNA and to regulate PFBS as part of mixtures with PFNA, HFPO-DA, and PFHxS. Please **s**ee section 3.1 of the EPA response in this *Response to Comments* document.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044404)

EPA requests comment on its preliminary regulatory determination for PFBS and its evaluation of the statutory criteria that supports the finding. EPA also requests comment on if there are additional data or studies EPA should consider that support or does not support the Agency's preliminary regulatory determination for PFBS, including additional health information and occurrence data.

• DOH supports the regulatory determination to regulate PFNA and PFBS. Both occur in Washington State drinking water supplies. PFNA has been occasionally found at high levels in our state around firefighting facilities.

EPA Response: The EPA acknowledges commenter's support for the determination to individually regulate PFNA and to regulate PFBS as part of mixtures with PFNA, HFPO-DA, and PFHxS. Please **s**ee section 3.1 of the EPA response in this *Response to Comments* document.

American Water Works Company Inc. (Doc. #1608, SBC-043982)

Preliminary Determination to Regulate PFHxS, HFPO-DA, PFNA, and PFBS – American Water does not agree that the U.S. EPA has sufficient information to make preliminary determinations on PFHxS, HFPO-DA, PFNA, and PFBS and recommends that the U.S. EPA withdraw the portion of the proposed rule associated with these four PFAS until the data to support such action is available for one or more separate National Primary Drinking Water Regulations, using an MCL approach.

EPA Response: Please **s**ee section 3.1 of the EPA response in this *Response to Comments* document.

American Water Works Company Inc. (Doc. #1608, SBC-043989)

Preliminary Determination to Regulate PFHxS, HFPO-DA, PFNA, and PFBS

American Water does not agree that the U.S. EPA has sufficient information to make preliminary determinations on PFHxS, HFPO-DA, PFNA, and PFBS and recommends that the U.S. EPA withdraw the portion of the proposed rule associated with these four PFAS until the data to support such action is available for one or more separate National Primary Drinking Water Regulations, using an MCL approach.

In the preamble to the rule, the U.S. EPA cites occurrence data and potential impact on public health as key criteria for making a regulatory determination. American Water does not believe that adequate information exists to support positive regulatory determinations on the four PFAS included in the proposal, specifically:

• The majority of public health protection from this proposed rule comes from PFOA and PFOS. EPA should review the co-occurrence between the two analytes with proposed MCLs (PFOA and PFOS) and the four analytes proposed to be regulated under the Hazard Index (PFHxS, HFPODA, PFNA, and PFBS) and clearly articulate the additional protection being provided once systems anticipated to be impacted by PFOA and PFOS are removed from the calculation. This needs to be extended to cost estimates and into the cost-benefit analysis.

• The U.S. EPA needs to complete the toxicity assessments for PFHxS or PFNA before determining appropriate levels of concern in drinking water.

EPA Response: Please **s**ee section 3.1 of the EPA response in this *Response to Comments* document. For the EPA's response related to the toxicity assessments for PFHxS and PFNA, please see section 4.3.3 in this *Response to Comments* document. For the EPA's response regarding the regulatory determination statutory criterion on occurrence, please see sections 3.1.2 and 3.2.2 in this *Response to Comments* document. For the EPA's response pertaining to the cost estimates for the Hazard Index MCL regulation, please see section 13.3 in this *Response to Comments* document. Additionally, while PFHxS, PFNA, HFPO-DA, and PFBS have been demonstrated to often co-occur with PFOA and/or PFOS, in water systems where PFOA and PFOS are not present at elevated levels but PFHxS, PFNA, HFPO-DA, and/or PFBS are present, the EPA estimates in the final rule preamble that 100-300 PWSs will exceed the Hazard Index MCL or PFHxS MCL without exceeding the PFOA or PFOS MCL. For persons served by those water systems, if the EPA were to rely solely upon regulation of PFOA and PFOS to reduce exposure, those consumers would continuously be exposed to potentially harmful levels of these other PFAS. Furthermore, the EPA recognizes that drinking water treatments used to remove PFOA and PFOS will have co-benefits for removal of PFHxS, PFNA, HFPO-DA, PFBS, and other PFAS, however those treatment systems must be designed and optimized for all of the contaminants that are present, accounting for site specific circumstances. Only designing a treatment system for PFOA and PFOS removal, rather than for the other PFAS which may be present in varying concentrations, may not be as effective for the other PFAS or adequately

public health protective. For the EPA's response on treatment co-removal, please see section 10.3 in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045875)

II. EPA's Preliminary Determination To Regulate PFNA, PFHxS, PFBS, and HFPO- DA (and Mixtures of these PFAS) Is Inconsistent with the Requirements Under SDWA

In the proposed rule, EPA is issuing a preliminary regulatory determination to regulate perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO–DA) and its ammonium salt (also known as a GenX chemicals), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS), and mixtures of these PFAS as contaminants under SDWA.

As described in the final regulatory determination for PFOA and PFOS, EPA follows a three-phase process in making regulatory determinations: (1) data availability, (2) data evaluation, and regulatory determination [FN5: 86 Fed. Reg. 12272, 12274 (Mar. 3, 2021).]. In the first phase, the Agency applies criteria to screen out contaminants that "clearly do not have sufficient data to support a regulatory determination."[FN6: Id.] If sufficient data are available to characterize the potential health effects and likely occurrence in drinking water, then EPA determines whether the contaminant meets three statutory criteria for regulation:

1. The contaminant may have an adverse effect on the health of persons;

2. The contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and

3. In the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems [FN7: 42 U.S.C. [sec] 300g-1(b)(1)(A).].

Findings under these criteria must be based on the best available public health information, including the occurrence database [FN8: 42 U.S.C. [sec] 300g-1(b)(1)(B)(ii)(II).]. If EPA determines a contaminant meets the three statutory criteria (determination to regulate), EPA must publish a MCLG and promulgate a NPDWR for the contaminant.

As discussed below, EPA does not demonstrate that PFNA, PFHxS, PFBS, and HFPO-DA meet the three statutory criteria regulation under Section 1412(b)(1)(A) of SDWA. Therefore, EPA's preliminary determination to regulate these four PFAS is improper. The human health and occurrence data do not support a determination to regulate PFNA, PFHxS, PFBS, and HFPO-DA or their mixtures at this time. In fact, had EPA followed its typical process, these contaminants should have been screened out in the Office of Water's first phase of regulatory determination work as not having sufficient data. While the Chamber and the coalition continue to support the appropriate and science-based regulation of PFAS chemicals, EPA must ensure that its regulations are based on robust scientific evaluations and meet statutory criteria, which this

proposal fails to do. A fundamental flaw is that EPA's preliminary determination to regulate rests on potentially flawed predictions of future occurrence and not actual data, which does not meet SDWA requirements. In addition, the underlying science has not undergone the required review by the EPA Science Advisory Board (SAB).

EPA Response: Please see section 3.1 of the EPA response in this *Response to Comments* document. The EPA disagrees that it did not follow the required regulatory determination process under SDWA or that PFNA, PFHxS, HFPO-DA, and mixtures of these three PFAS and PFBS do not have sufficient information to meet the three regulatory determination statutory criteria. Please see sections 3.1.1 and 3.2.1 of the EPA response in this *Response to Comments* document regarding the health effects criterion, sections 3.1.2 and 3.2.2 regarding the occurrence criterion, and sections 3.1.3 and 3.2.3 regarding the meaningful opportunity criterion. Additionally, the EPA disagrees that it did not undertake the required review by the EPA Science Advisory Board (SAB) as described in sections 4.3.2 and 14.11.1 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045550)

2. The agency's preliminary determinations for PFNA, HFPO-DA, and PFBS and the mixture of PFHxS, PFNA, HFPO-DA, and PFBS are not sufficiently supported by the available data. Moreover the available data currently suggests a negative determination for these PFAS is appropriate. The agency should re-issue these preliminary determinations following the availability of national monitoring data currently being collected, as part of the Fifth Unregulated Contaminant Monitoring Rule (UCMR 5).

EPA Response: Please **s**ee section 3.1 of the EPA response in this *Response to Comments* document. Regarding the EPA's determination for mixtures of PFHxS, PFNA, HFPO-DA, and PFBS, please see section 3.2 of the EPA response in this *Response to Comments* document. Concerning UCMR 5, please see sections 3.1.2 and 6.8 of the EPA response in this *Response to Comments* document.

3.1.1 EPA's Preliminary Regulatory Determinations for PFHxS, PFNA, HFPO-DA, and PFBS – Statutory Criterion #1 Adverse Health Effects

Summary of Major Public Comments and EPA Responses

Many commenters expressed support for the EPA's determination that PFHxS, PFNA, HFPO-DA, and PFBS meet the statutory criterion for adverse health effects. Many commenters also supported the EPA's use of best available peer-reviewed science, specifically the use of the final, most recently published Agency for Toxic Substances and Disease Registry (ATSDR) minimal risk levels for PFHxS and PFNA as chronic toxicity reference values. Other commenters criticized the EPA for using ATSDR minimal risk levels and stated that they are inappropriate for SDWA rulemaking.

As discussed further in section 4.3.3 of the EPA response in this *Response to Comments* document, the EPA finds that the ATSDR minimal risk levels for PFHxS and PFNA currently represent the best available, peer-reviewed science for these chemicals. SDWA specifies that agency actions that are based on science must rely on "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices." At this time, the 2021 ATSDR Toxicological Profile for Perfluoroalkyls, which covers 10 PFAS including PFHxS and PFNA, represents the best available peer-reviewed scientific information on the human health effects of PFHxS and PFNA. ATSDR minimal risk levels for PFHxS and PFNA are appropriate for use under SDWA because ATSDR uses scientifically credible approaches, its work is internally and externally peer-reviewed and undergoes public comment, and its work represents the current best available science for these two chemicals. The 2021 ATSDR Toxicological Profile for Perfluoroalkyls underwent intra- and interagency review and subsequent external peer review by seven experts with knowledge of toxicology, chemistry, and/or health effects.

Some commenters questioned the EPA's external peer-review process for the four underlying final toxicity assessments used to calculate the Health Reference Levels (HRLs)/Health-Based Water Concentrations (HBWCs)[1] and for the HBWCs themselves. Some commenters noted that the EPA does not yet have completed Integrated Risk Information System (IRIS) assessments for PFHxS and PFNA, questioning the EPA's use of non-EPA assessments (see above). As discussed further in section 4.3.3 of the EPA response in this *Response to Comments* document, all four toxicity assessments containing the toxicity reference values (reference dose (RfD) or minimal risk level) used to calculate the HRLs/HBWCs underwent rigorous, external peer review (ATSDR, 2021; USEPA, 2021a; USEPA, 2021b). The EPA is not required under SDWA to exclusively use EPA assessments to support an NPDWR, and in fact, SDWA's clear direction in Section 1412(b)(3)(A)(i) is to use the best available, peer-reviewed science when developing NPDWRs. Final EPA assessments for PFHxS and PFNA are under development but are not currently available; final, peer-reviewed ATSDR assessments are available.

Other commenters offered critical comments on the HRLs/HBWCs for PFHxS, PFNA, HFPO-DA, and PFBS and raised technical and process concerns with the underlying human health assessments. Some commenters asserted that the human health toxicity values (EPA RfDs, ATSDR minimal risk levels) upon which the HRLs/HBWCs are based have too much uncertainty and are therefore inadequate to support a SDWA regulatory determination. The EPA disagrees with these comments. As discussed further in section 4.3.3 of the EPA response in this *Response to Comments* document, the HRLs/HBWCs are data-driven values based on toxicity reference values that incorporate uncertainty factors (UFs) based on the EPA guidance.

[1] The agency developed HRLs for PFHxS, PFNA, HFPO-DA, and PFBS as part of its regulatory determinations effort to identify the adverse effects each contaminant may have on the health of persons. In this instance, the EPA identified the HRL as the level below which adverse health effects over a lifetime of exposure are not expected to occur, including for sensitive populations and life stages, and allowing for an adequate margin of safety. The HRLs are also used as HBWCs in the calculation of the Hazard Index MCLG.

Individual Public Comments

Superfund Settlements Project (SSP) and RCRA Corrective Action Project (RCAP) (Doc. #1631, SBC-043435)

In addition to the comments set forth above, SSP and RCAP fully endorse the comments submitted by the United States Chamber of Commerce on behalf of several trade organizations, including SSP and RCAP. SSP and RCAP will not fully repeat those comments but emphasize three points.

First, EPA's lack of health and occurrence data and failure to adequately consider costs calls into question EPA's preliminary determination to regulate PFNA, PFHxS, PFBS and GenX. [FN59: See 42 U.S.C. § 300g-1(b).]

• EPA has not demonstrated that these substances may have an adverse effect on human health. EPA did not complete human health assessments for PFHxS and PFNA. EPA's assessments for PFBS and GenX were not subject to review by SAB or otherwise subject to adequate peer-review. Significant uncertainty factors and overly conservative assumptions in the face of a lack of data are inadequate to support a regulatory determination.

EPA Response: The EPA disagrees with these comments. See section 3.1.1 of the EPA response in this *Response to Comments* document, as well as section 4.3.3 of the EPA response in this *Response to Comments* document, and section III.B.6, section IV.B.1.b, and section IV.B.2.b of the preamble.

Consumer Reports (Doc. #1656, SBC-043180)

Section III: Preliminary Regulatory Determinations for Additional PFAS

Under the provisions of Sections 1412(b)(1)(A) and 1412(b)(1)(B) of the SDWA, the EPA can regulate substances/chemicals as a contaminant in drinking water if the contaminant(s) can meet three criteria: i) that it may have an adverse effect on the health of a person, ii) that it is known to occur or there is a substantial likelihood that it will occur in public water systems (PWS) and iii) the EPA Administrator determines that regulation of the contaminant presents a meaningful opportunity for health risk reduction for persons served by PWS.

EPA's review of the scientific literature clearly demonstrates that oral exposure to PFHxS, HFPO-DA, PFNA and PFBS may individually, and in mixture, each result in an adverse health effect, including disrupting multiple biological pathways that result in adverse effects a number of biological systems, including the endocrine, cardiovascular, developmental, immune, and hepatic systems1 [FN1: USEPA. 2023a. Maximum Contaminant Level Goal (MCLG) Summary Document for a Mixture of Four Per- and Polyfluoroalkyl Substances (PFAS): GenX Chemicals, PFBS, PFNA and PFHxS. EPA-822-P-23-004. At: https://www.epa.gov/system/files/documents/2023-03/PFAS%20HI%20MCLG%20Public%20Review%20Draft%20 09%20March%202023.pdf].

For each of the 4 PFAS, EPA has calculated a health-based water concentration (HBWC) which it defines as the "level protective of health effects over a lifetime of exposure, including sensitive populations." The EPA determined, based on the available science, that the HBWCs for PFHxS, GenX chemicals, PFNA and PFBS are 9 ppt, 10 ppt, 10 ppt and 2,000 ppt, respectively. We agree with EPA on the HBWCs for these four PFAS. For the Preliminary Regulatory Determination, the HBWCs were used as the Health Reference Level (HRL).

EPA Response: See section 3.1.1 of the EPA response in this *Response to Comments* document. In regard to calculating the HBWCs, please see section 4.3.3 of the EPA response in this *Response to Comments* document.

New York City Department of Environmental Protection (NYCDEP) (Doc. #1679, SBC-044208)

Toxicity

Two of the four chemicals included in the HI (PFNA and PFHxS) lack completed health assessments under the Integrated Risk Information System (IRIS) Program (p. 18664).

EPA Response: See section 3.1.1 of the EPA response in this *Response to Comments* document, as well as section 4.3.3 of the EPA response in this *Response to Comments* document and section III.B.6 of the preamble.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045879)

2. High uncertainty in the human health assessments for PFHxS, HFPO- DA, and PFBS makes them inadequate to support a determination to regulate

Even if the scientific assessments for PFHxS, HFPO-DA, and PFBS had been appropriately reviewed, all three of these assessments are low confidence. The three assessments each have an aggregate uncertainty factor (UF) value of 3000 assigned to the underlying Reference Dose (RfD). This is the maximum allowable aggregate UF value. Above this point, EPA guidance recommends, consistent with current EPA practice, that reference values not be derived [FN16: U.S. EPA, 2002. A review of the reference dose and reference concentration process, at page xviii and 4-41 where EPA states: "The Technical Panel recommends limiting the total UF applied for any particular chemical to no more than 3000 and avoiding the derivation of a reference value that involves application of the full 10-fold UF in four or more areas of extrapolation," available at: https://www.epa.gov/sites/production/files/2014-12/documents/rfd-final.pdf.]. The values derived for these three contaminants meet the criteria for low confidence. "Low confidence indicates the judgment that the data supporting the [Reference Dose] RfD may be of limited quality and/or quantity and that additional information could result in a change in the RfD."[FN17: See EPA Reference Dose (RfD): Description and Use in Health Risk Assessments, available at: https://www.epa.gov/iris/reference-dose-rfd-description-and-use-health-risk-assessments.]

EPA Response: The EPA disagrees with these comments. See section 3.1.1 of the EPA response in this *Response to Comments* document, as well as section 4.3.3 of the EPA response in this *Response to Comments* document and section III.B.6, section IV.B.1.b, and section IV.B.2.b of the preamble.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045884)

4. In addition, the flaws in the individual toxicity assessments make a regulatory determination for a mixture of the four contaminants inappropriate at this time

For the reasons described above, EPA has not met the statutory or scientific requirements to make a positive regulatory determination for PFHxS, HFPO-DA, PFNA, or PFBS. EPA has not demonstrated that these PFAS may cause adverse health effects at the levels that EPA believes may occur, and EPA has not conducted the requisite SAB review. As such, a determination to regulate a mixture of the four contaminants is also not supported.

EPA Response: The EPA disagrees with these comments. See section 3.1.1 of the EPA response in this *Response to Comments* document, as well as sections 4.3.2 and 4.3.3 of the EPA response in this *Response to Comments* document, and section III.B.6, section IV.B.1.b, and section IV.B.2.b of the preamble.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045881)

For PFHxS and HFPO-DA, while the assessments are lacking the typical statement about the confidence in the value, due to the UFs of 3000 applied in both assessments, it is not possible to characterize these assessments as anything but low confidence.

EPA Response: The EPA disagrees. See section 3.1.1 of the EPA response in this *Response to Comments* document, as well as section 4.3.3 of the EPA response in this *Response to Comments* document, and section III.B.6 of the preamble.

Wyoming Department of Environmental Quality (WDEQ) (Doc. #1716, SBC-044774)

1. EPA should wait to propose a NPDW rule for PFNA and PFHxS until Health Advisories are finalized for these compounds. EPA Should Complete the Human Health Toxicity Assessment/or PFHxS and PFNA

In the March 2023 Maximum Contaminant Level Goal (MCLG) Summary Document for a Mixture of Four Per- and Polyfluoroalkvl Substances (PFAS): HFPO-DA and its Ammonium Salt (also known as GenX Chemicals). PFBS, PFNA, and PFHxS. EPA states that there is no published EPA human health toxicity assessment for PFNA or PFHxS; however, EPA's Integrated Risk Information System program is developing a human health toxicity assessment for PFNA and PFHxS, which is expected to undergo public comment and external peer review in Fiscal Year 2023. Given the implementation costs of the proposed PFAS NPDW rule and how

quickly the human health toxicity assessments are expected to be released, EPA should first finalize the toxicity assessments, review and incorporate public comment, and use this as the basis to issue final Health Advisories for PFNA and PFHxS, prior to finalizing the PFAS NPDW rule for these compounds. This is particularly important given that the proposed PFAS NPDW rule for these compounds may change as a result of the human health toxicity assessment.

EPA Response: The EPA disagrees. See section 3.1.1 of the EPA response in this *Response to Comments* document, as well as section 4.3.3 of the EPA response in this *Response to Comments* document and section III.B.6 of the preamble. Also, HAs are not a pre-requisite for an NPDWR under the SDWA. There is nothing in the statute or the EPA's historical regulatory practice that suggests that the agency should delay regulation of a contaminant in order to develop an HA first.

HRSD (Doc. #1719, SBC-043541)

For PFNA and PFHxS, EPA has not yet completed its human health toxicity assessment. Further, the information that is available to derive the Health Based Water Concentration (HBWC) for these four PFAS utilizes uncertainty factors ranging from 300x – 3000x, resulting in compounding conservatism in the HI calculation. Occurrence data must be gathered, the EPA human toxicity assessment must be completed, and this new approach must be fully vetted before it is adopted as a regulation. The imposition of a regulation without fully understanding the need for or impacts of such a regulation has the potential to impose economic burden on communities without commensurate public health benefits.

EPA Response: See section 3.1.1 of the EPA response in this *Response to Comments* document, as well as section 4.3.3 of the EPA response in this *Response to Comments* document and section III.B.6 of the preamble.

3M Company (Doc. #1774, SBC-045666)

i. EPA's selection of reference values for the four PFAS for which it seeks to issue preliminary regulatory determinations (PFHxS, HFPO-DA, PFNA, and PFBS) is erroneous.

Putting aside EPA's violations of SDWA-mandated processes for public notice and peer review, the proposed standards for the HI PFAS are not consistent with EPA processes designed to ensure reliability and sound scientific practices. EPA relies on ATSDR for the PFHxS and PFNA reference values, and there is no evidence that EPA conducted an independent systematic review of the evidence base or assessed study quality for these compounds as recommended by the IRIS Handbook. Furthermore, because these four PFAS are considered together under the HI, EPA has not sufficiently discussed, as recommended in EPA's own RfD process recommendations (USEPA 2002), the implications of the collective uncertainty underlying all four reference values.

PFHxS. EPA's proposed reference value of 0.000002 mg/kg/day for PFHxS is based on ATSDR's (2021) Minimum Risk Level (MRL) [FN39: An MRL is a screening value used to identify potential environmental risk and is not a regulatory standard.], which is derived from Butenhoff et al. (2009). Butenhoff et al. (2009) observed that adult male rats exposed to PFHxS at 3 mg/kg-day exhibited thyroid follicular cell hyperplasia that may have been due to increased liver hypertrophy and induction of liver enzymes, which could in turn impact thyroid hormone metabolism. However, the authors did not measure thyroid hormones; therefore, the clinical significance of thyroid cell hyperplasia is unclear. Furthermore, in contrast to Butenhoff et al.'s (2009) findings, ATSDR (2021) concluded that liver effects in mice after exposure to PFHxS were not adverse. Had EPA evaluated Butenhoff et al. (2009) per systematic review guidance, that lack of adversity may have been identified and the study excluded.

In contrast, Chang et al. (2018), did measure thyroid stimulating hormone (TSH), and observed changes in neither TSH levels nor thyroid histopathology in mice at doses up to 3 mg/kg-day. Had EPA conducted an appropriate systematic review and assessed study quality per its IRIS Handbook, it may have considered this study, which is more reliable than Butenhoff et al. (2009) because it measured relevant endpoints. In other words, if EPA had conducted a truly independent systematic review of PFHxS toxicity studies, rather than rely on ATSDR's (2021) evaluation, it likely would have selected a different critical effect for PFHxS and therefore derived a different HBWC.

EPA also failed to comply with its guidance related to the application of uncertainty factors (USEPA 2002; USEPA ORD 2022). To derive the reference value for PFHxS, EPA applied a 10-fold uncertainty factor to ATSDR's MRL of 0.00002 mg/kg/day to extrapolate from subchronic to chronic exposure. This 10-fold uncertainty factor is in addition to the 30-fold uncertainty factor and 10-fold modifying factor that ATSDR applied its derivation of the MRL. The resultant combined uncertainty factor is 3,000, which highlights the substantial uncertainty of the evidence for the reference value. EPA's IRIS Handbook and EPA's recommendations on the RfD process (USEPA 2002) recommends that any composite uncertainty factor greater than 3,000 represents "excessive uncertainty" and should not be relied upon.

EPA Response: See section 3.1.1 of the EPA response in this *Response to Comments* document, as well as section 4.3.3 of the EPA response in this *Response to Comments* document and section III.B.6 of the preamble. Additionally, in response to the comment that if the EPA had conducted an independent systematic review of PFHxS toxicity studies instead of relying on ATSDR's evaluation, it likely would have selected a different critical effect for PFHxS—the EPA disagrees. As noted in section 4.3.3 of the EPA response in this *Response to Comments* document, at this time the 2021 ATSDR toxicological profile represents the best available peer-reviewed scientific information regarding the human health effects of PFHxS. ATSDR uses scientifically credible approaches and its work is internally and externally peer reviewed and undergoes public comment (the ATSDR toxicological profile underwent intra- and interagency review and external peer review by seven experts with knowledge of toxicology, chemistry, and/or health effects).

3M Company (Doc. #1774, SBC-045651)

The Proposed Rule is also based on profound uncertainty and assumptions, which EPA did not properly quantify and explain in its rulemaking documents. EPA defines "uncertainty" as "a lack of knowledge about factors affecting exposure or risk" (USEPA 2019, p. 1-7).. "Uncertainty factors" are "used in noncancer risk assessments when insufficient data are available to support the use of chemical-specific and species-specific extrapolation factors" (OEHHA 2008). Because uncertainty factors are used to address a lack of data, the higher the total uncertainty factors, the lower the confidence in the accuracy of the analysis. For its evaluations of HFPO-DA and PFHxS, EPA has assigned "uncertainty factors" totaling 3,000— the maximum that could be considered as the basis of a reference value according to EPA's IRIS Handbook. Had the uncertainty factors been any higher, EPA's own guidance would have precluded it from setting a reference value for those substances. In adopting a total uncertainty factor of 3,000, EPA implicitly acknowledges that its proposed RfDs for those substances are, at best, on the very edge of acceptability. This is important because "uncertainty factors" only account for specific sources of uncertainty in the Proposed Rule. They do not account for significant additional uncertainties, including uncertainties resulting from EPA's poor systematic review, inconsistent and non-transparent study quality evaluations, lack of an independent verification of underlying analyses of the selected points of departure, and the absence of peer review of the proposed hazard index MCLG. Accordingly, EPA's uncertainty factor of 3,000— already at the margins of acceptability—significantly understates the actual uncertainties inherent in EPA's proposal for those substances.

EPA Response: See section 3.1.1 of the EPA response in this *Response to Comments* document and section 4.3.3 of the EPA response in this *Response to Comments* document, as well as section III.B.6 of the preamble.

3M Company (Doc. #1774, SBC-045668)

PFNA. EPA's reference value for PFNA is based on ATSDR's (2021) intermediate MRL of 0.000003 mg/kg-day and is overly conservative as a result of EPA's improper data review processes. ATSDR's (2021) MRL is derived from Das et al. (2015), in which mouse pups exposed to PFNA at 3 mg/kg-day were observed to have decreased body weight and delays in development. Importantly, most of the PFNA-induced effects, including developmental effects, are directly linked to the PPARα pathway (Rosen et al. 2017; Wolf et al. 2010). As demonstrated in Wolf et al. (2010), there is a clear association between PPARα and delayed eye opening and decreased body weight in exposed mouse pups. Because the PPARα has limited relevance to humans, the selection of Das et al. (2015) as the primary basis of the MRL is improper.

Additionally, ATSDR's (2021) application of an uncertainty factor of 3 for interspecies differences was overly conservative and in violation of EPA's own guidance. As previously discussed, the limited application of PPARα to humans indicates that mice are the more sensitive species to the observed effects in Das et al. (2015) (i.e., PPARα is less active in humans than it is

in mice), such that an interspecies uncertainty factor of 1 would be consistent with guidance in EPA's IRIS handbook that allows for lower uncertainty factors considering differences in cross-species toxicokinetics and toxicodynamics are accounted for. Prior to the application of an interspecies uncertainty factor, the MRL was amply protective of human health. EPA (USEPA 2023l) also acknowledges that both ATSDR and EPA are reassessing the toxicity of PFNA via a revised MRL or new IRIS assessment, respectively. This further highlights the uncertainty in the reference value and lack of basis in the most up-to-date and systematically reviewed science.

Finally, another example of poor quality assurance in this proposed rulemaking, is in Section III.B.3 of the Federal Register Notice (USEPA 2023f), where EPA incorrectly refers to the HBWC for PFNA as both 100 ppt and 10.0 ppt.

EPA Response: For the EPA's response to comments related to uncertainty factors and human relevance of the critical effects, see section 3.1.1 in this *Response to Comments* document, as well as section 4.3.3 of the EPA response in this *Response to Comments* document and section III.B.6 of the preamble. Additionally, the agency has corrected the HBWC in the NPDWR. The correct HBWC for PFNA is 10 ng/L (ppt).

Public Health, Seattle & King County (PHSKC) (Doc. #1594, SBC-042357)

Lower the health-based water concentration (HBWC) used for PFBS to account for thyroid hormone disruption during early development. Washington and other states have selected lower values for PFBS to determine when action is needed to protect health. For example, the Washington State Action Level for PFBS is 345 ng/L whereas EPA's proposed HBWC (or health advisory level) is 2000 ng/L. Because thyroid hormone plays a critical role in early brain and skeletal development, PHSKC recommends that EPA lower the health advisory level set for PFBS to better protect pregnant women, infants and children.

EPA Response: The EPA disagrees. Washington State used the same RfD (3E-04 mg/kg-d) but a higher Drinking Water Intake Bodyweight-Adjusted (DWI-BW) to develop its Action Level for PFBS as compared to the EPA's HBWC (Washington State used the 95th percentile DWI-BW of 0.174 L/kg/day for infants, whereas the EPA selected the 90th percentile DWI-BW of 0.0354 L/kg/day for women of child-bearing age). The EPA disagrees that the infant DWI-BW is more appropriate for HBWC calculation. The EPA selected the thyroid hormone outcome (decreased serum total thyroxine in newborn mice seen in a developmental toxicity study) as the critical effect in its PFBS human health toxicity assessment (USEPA, 2021a). The RfD derived from this critical effect included application of a 10X uncertainty factor to account for lifestage-specific susceptibility (UF_H). To select an appropriate DWI-BW for use in deriving the HBWC for PFBS, the EPA followed its established approach of considering the PFBS exposure interval used in the developmental toxicity study that was the basis for chronic RfD derivation. In this study, pregnant mice were exposed throughout gestation, which is relevant to two human adult life stages: women of child-bearing age who may be or become pregnant, and pregnant women and their developing embryos or fetuses (Table 3-63 in USEPA,

2019). To be clear, the critical study exposed mice to PFBS only during pregnancy and not during postnatal development; newborn mice in early postnatal development, which would correspond to the human infancy life stage, were not exposed to PFBS. Of the two relevant adult stages, the EPA selected the 90th percentile DWI-BW for women of child-bearing age (0.0354 L/kg/day) to derive the HBWC for PFBS because it is the higher of the two, and therefore more health-protective. Please see additional information related to DWI-BW selection in section 4.3.3 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045880)

The PFBS assessment is very clear in stating that "[t]he overall confidence in the chronic RfD for thyroid effects is low,"[FN18: U.S. EPA Human Health Toxicity Values for Perfluorobutane Sulfonic Acid (CASRN 375-73-5) and Related Compound Potassium Perfluorobutane Sulfonate (CASRN 29420-49-3), at page 4, available at: https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=350888.] yet EPA relies on this endpoint and value for the health-based water concentrations (HBWC).

EPA Response: The EPA disagrees with this comment. Please see section 4.3.3 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045882)

It is worth noting that during the review of the PFBS assessment, one peer reviewer questioned why a single study could serve as the basis of U.S. national regulation. EPA responded that the "PFBS assessment is not a regulatory action but rather may in part inform risk remediation activities."[FN19: U.S. EPA, Response to Peer Review Comments on the Draft Human Health Toxicity Values for Perfluorobutane Sulfonic Acid (CASRN 375-73-5) and Related Compound Potassium Perfluorobutane Sulfonate (CASRN 29420- 49-3) October 2020, at page 16, available at: https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=350888.] Notwithstanding that earlier caveat, the single study in the PFBS assessment is indeed a critical driver in EPA's proposed regulation to regulate PFBS.

EPA Response: See the section 4.3.3 of the EPA response in this *Response to Comments* document, as well as section III.B.6 of the preamble. The EPA's 2021 PFBS Human Health Assessment included a systematic literature search and evidence mapping that resulted in identification of several human epidemiological and experimental animal studies. This landscape of hazard and dose-response information, associated primarily with oral exposures to PFBS, revealed a number of health outcomes of potential concern in several target organs or systems (e.g., thyroid, developmental, and the kidney). From among the candidate critical studies and critical health effects, a single study and effect were expertly identified by the assessment authors, consistent with the EPA human health risk assessment guidance and practice. In the derivation of a toxicity value, the identification of a single best study is necessary to qualitatively and quantitatively evaluate health effect dose –response. This is typically related to greatest

degree of confidence in the study/data. Importantly, this does not mean that other information from other studies were not considered for derivation purposes. Additionally, the commenter quotes only a small part of an EPA response to a peer-review comment on the PFBS toxicity assessment. The full EPA response states that the single study in question is a robust, high-confidence study that reports health outcomes consistent with a broader body of evidence demonstrating an exposure-effect relationship between oral PFBS and thyroid hormone perturbations. The identification of decreased thyroid hormone seen in this study as the critical effect is based on the entirety of the relevant study landscape (i.e., across rats and mice, different sexes, different exposure durations and lifestages); from amongst this body of evidence, the selected publication provided the highest confidence dose-response dataset on which to base identification of a point of departure (POD) for RfD derivation.

3M Company (Doc. #1774, SBC-045669)

PFBS. EPA relies on its RfD of 0.0003 mg/kg/day (USEPA 2021a) as the basis of the HBWC. EPA again failed to follow processes that would have ensured its RfD was properly supported. EPA relied on Feng et al. (2017), in which mouse pups exposed to PFBS were observed to have decreased serum thyroid hormone (thyroxine [T4]) levels compared to unexposed pups. The study's authors, however, expressed uncertainty as to whether the decreased serum T4 levels were toxicologically relevant; they further state that the decreased levels were not specifically related to development (Feng et al. 2017). A proper systematic review would have taken that uncertainty into account.

The selection of thyroid hormone changes in mice as the critical effect by EPA (USEPA 2021a) in and of itself is overly conservative but is further compounded by EPA's application of an uncertainty factor of 3 for interspecies differences. Multiple studies have shown that rodents are more sensitive to alterations in thyroid hormone compared to humans (NRC 2005; Bartsch et al. 2018; Parker and York 2014; Brown-Grant 1963). In other words, without the uncertainty factor, EPA's RfD may be protective of human health, but is made unduly conservative with it.

EPA Response: The EPA disagrees with these comments. Please see section 4.3.3 of the EPA response in this *Response to Comments* document,.

The EPA disagrees with the commenter regarding the application of the uncertainty factor for interspecies differences (UF_A). As noted in the EPA's toxicity assessment for PFBS (USEPA, 2021a), a UF_A of 3 was applied to account for uncertainty in characterizing toxicokinetic and toxicodynamic differences between mice and humans following oral K+PFBS/PFBS exposure (specifically, uncertainty in the relative cross-species sensitivity in toxicodynamics (e.g., thyroid signaling)). In the absence of chemical-specific data to quantify this uncertainty, the EPA's guidance recommends the use of a UF_A of 3.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044055)

33. EPA requests comments on the approaches we used to estimate each of the health impacts of exposure to the PFAS chemicals covered in this proposed rule, including the transparency of the assumptions we made and the impact of these assumptions on the magnitude of the risks avoided by the proposed regulatory action.

a. CWUC does not think the health impacts explained can be reliably linked to specific impacts of exposure to PFAS chemicals alone. There are many reasons a person could experience the health impacts discussed and they cannot be reliably linked to PFAS chemicals alone. Further, drinking water is typically only a very small exposure pathway of PFAS to an average person. Exposures are much greater to a typical individual from cosmetics and PCP, clothing, cookware, food wrappers, and many more products consumers use everyday.

EPA Response: The EPA disagrees with this comment. For the EPA's response to comments about approaches used to estimate health impacts of exposure to PFAS, please see sections 4.3.1, 4.3.2, and 4.3.3 of the EPA response in this *Response to Comments* document. Please also see the EPA's PFAS website (https://www.epa.gov/pfas) for links to resources and information about the established associations between PFAS exposure and adverse health effects. Additionally, please see section 4.3.3 of the EPA response in this *Response to Comments* document for information about relative source contribution (RSC) derivation, which takes into account potential PFAS exposure via non-drinking water routes.

U.S. Chamber of Commerce (Doc. #1537, SBC-042648)

There is limited understanding of risk at these levels. EPA's Reference Dose for PFNA, GenX Chemicals, PFHxS, and PFBS is based entirely on laboratory animal studies, even though EPA itself advises "Adequate human data are the most relevant for assessing risks to humans." There is significant uncertainty regarding the health risks at the proposed MCL levels for all six PFAS. WHO's recent study on potential guidelines for water quality, for example, proposed 100 ppt based on the most relevant public health data and seems to be consistent with known risk.

EPA Response: With respect to the use of animal studies, SDWA requires that the EPA use "the best available, peer reviewed science" to inform decision making on drinking water regulations. The HBWCs are based on the best available science—peer-reviewed, publicly available assessments for HFPO-DA (USEPA, 2021b), PFBS (USEPA, 2021a), PFNA (ATSDR, 2021), and PFHxS (ATSDR, 2021) provide the oral toxicity values (i.e., RfD or Minimal Risk Level) used to calculate the HBWCs; the DWI-BW selected for each of the four PFAS takes into account the relevant sensitive population(s) or life stage(s); and RSCs are determined based on a literature review of potential exposure sources of the four PFAS (USEPA, 2000a). Additionally, as noted in the EPA's *Staff Handbook for Developing IRIS Assessments* (USEPA, 2022) and *A Review of the Reference Dose and Reference Concentration Process* (USEPA, 2002), animal studies can provide the basis for toxicity reference values when adequate human studies are not available.

For the EPA's response to comments related to uncertainty factors, see section 3.1.1 in this *Response to Comments* document, as well as section 4.3.3 of the EPA response in this *Response to Comments* document and section III.B.6 of the preamble.

3.1.2 EPA's Preliminary Regulatory Determinations for PFHxS, PFNA, HFPO-DA, and PFBS – Statutory Criterion #2 Occurrence

Summary of Major Public Comments and EPA Responses

The EPA received many comments on the agency's evaluation of the second statutory criterion under Section 1412(b)(1)(A) of SDWA that the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur at a frequency and level of public health concern. The EPA notes that some comments discussing occurrence information are also contained within section 6 of this *Response to Comments* document. Many commenters supported the EPA's preliminary determination that PFHxS, PFNA, HFPO-DA, and PFBS meet the second statutory occurrence criterion under SDWA citing that the agency has used the best available information to determine that these PFAS are known to occur or there is a substantial likelihood that these PFAS will occur at a frequency and level of public health concern. Conversely, many other commenters did not agree that the agency presented sufficient occurrence information to make a preliminary determination to regulate PFHxS, PFNA, HFPO-DA, and PFBS at this time or that a determination not to regulate (i.e., negative determination) these four PFAS is more appropriate given the information provided by the EPA or a lack of available information. Other commenters stated that the EPA has not met the statutory criteria for regulation for only some of the four contaminants, primarily HFPO-DA, PFBS, and PFNA, while it has met the statutory criteria for others (e.g., PFHxS). Regarding PFHxS, PFNA, and HFPO-DA, the EPA disagrees with commenters that claim the EPA did not present sufficient occurrence information to satisfy the second statutory criterion or that a negative determination is more appropriate for these three PFAS. Within section III.C. of the final rule preamble, the EPA presents the best available information, consisting of both UCMR 3 and extensive state drinking water data, which documents the measured occurrence of PFHxS, PFNA, and HFPO-DA above their HRLs as well as other information to support the EPA's determination that there is a substantial likelihood that these contaminants will occur with a frequency and level of public health concern.

A couple of commenters claimed that the EPA does not have a robust understanding of available occurrence data that supports any of the regulatory determinations for the four PFAS in this rule. Additionally, some commenters suggested that the preliminary determinations were "rushed" and "non-scientific," and that the agency should wait until some or all of the UCMR 5 data is available and considered. The EPA disagrees because while the EPA recognizes there will be additional occurrence or other relevant information for these and other PFAS in the future, the agency has determined that there is more than sufficient occurrence information to establish a substantial likelihood of occurrence at frequencies and levels of health concern satisfying the statutory criterion to regulate PFNA, PFHxS, and HFPO-DA. Per the intent of the statute, the

agency used the best available data in an expeditious manner, which was also a very large dataset consisting of tens of thousands of samples and representing one of the most robust occurrence datasets ever used to inform development of a drinking water regulation of a previously unregulated contaminant. The agency also disagrees that the occurrence analyses undertaken and available in the proposed rule preamble as well as the technical support document for occurrence were non-scientific. Based on the publicly available information within the state data, the EPA verified that the very large majority of samples (at least 97 percent) were collected using EPA-approved methods; the slight percentage the agency was unable to verify would not result in different agency conclusions. Additionally, the EPA notes that the aggregated data were assessed using precedented statistical metrics and analyses. In addition, the Cadwallader et al. (2022) model uses a robust, widely accepted Bayesian statistical approach for modeling contaminant occurrence. Based on these analyses, the EPA has a clear understanding of the occurrence of the modeled contaminants. As discussed in the final rule preamble section III.C and USEPA (2024b), the EPA also has sufficient state data which consist of a greater number of total systems and samples than that included within the monitoring under UCMR 3, to confidently establish that there is a substantial likelihood of occurrence at frequencies and levels of public health concern. As discussed in section III of the final rule preamble and previously stated, the agency believes that the best currently available occurrence data demonstrate substantial likelihood of occurrence for the chemicals included in the final rule as they are demonstrated at frequencies and levels of public health concern. UCMR 5 data are being reported to the EPA while this final rule is being prepared. See section VI.G. of the final rule for more information on the preliminary results. While these data are too preliminary to provide the basis for the regulatory determination, these preliminary UCMR 5 results appear to confirm state data and model results.

Commenters both agreed and disagreed with the EPA's individual preliminary determination for PFBS. While PFBS occurs at significant frequency, in the final rule preamble, the EPA is making a final determination to regulate PFBS in mixtures with PFHxS, PFNA, and/or HFPO-DA, but is deferring the final individual regulatory determination for PFBS so that the agency can continue to evaluate this contaminant relative to the SDWA criteria for regulation, particularly related to its individual known or likely occurrence. However, the EPA maintains that there is a substantial likelihood that PFBS co-occurs in mixtures with PFHxS, PFNA, and/or HFPO-DA in PWSs with a frequency and at levels of public health concern, also meeting the other two statutory criteria and is finalizing regulation of PFBS as part of a mixture with PFHxS, PFNA, and HFPO-DA.

Several commenters requested that the EPA evaluate additional state occurrence data for PFHxS, PFNA, HFPO-DA, and PFBS to further inform its analysis for the preliminary regulatory determinations. In response to public comments on the proposal, the EPA evaluated updated and new state occurrence data available through May 2023. These additional occurrence data further confirm that the SDWA second criterion for regulation have been met for PFHxS, PFNA, and HFPO-DA as individual contaminants. The agency has included updated information in its occurrence analyses as described in section VI.B of the final rule preamble.

Several commenters disagreed that the available occurrence information supports a preliminary determination specifically for HFPO-DA, with a few citing limited or a lack of nationally representative data (such as through UCMR 3) and suggesting a delay until UCMR 5 data is collected. The EPA disagrees with these comments, as the extensive state monitoring data detailed in section III.C. of the final rule preamble and consisting of approximately 36,000 samples within 10,000 systems representing multiple geographic locations, demonstrates HFPO-DA occurrence in 13 geographically diverse states, including at 75 systems serving at least 2.5 million people, and at least 13 systems in 5 states within different geographic regions of the country serving a population of 227,000 people with reported concentrations above the HRL of 10 ng/L. Additionally, when evaluating only a subset of the available state data representing non-targeted monitoring, HFPO-DA was reported in approximately 0.48 percent of monitored systems; if these results were extrapolated to the nation and those system subject to the final rule requirements, the agency estimates that HFPO-DA would be detectable in over 320 PWSs serving 9.9 million people. If those results were further compared to the HRL for HFPO-DA (10 ng/L), HFPO-DA would be detected above the HRL in 42 systems with at least 495,000 people exposed. Moreover, there is no SDWA or other requirement that a contaminant must be monitored for under UCMR in order to make a determination to regulate and non-national datasets, particularly those of such size currently available through recent state data, may serve to demonstrate occurrence of a contaminant to warrant a positive determination and subsequent development of an NPDWR.

One commenter specifically stated that a regulatory determination for PFNA was unnecessary as they do not believe it occurred with frequency under UCMR 3 monitoring, and a couple of other commenters suggested that a negative determination was appropriate for PFNA citing occurrence levels. The EPA disagrees that a negative determination is appropriate for PFNA as discussed in section III.C. of the final rule preamble where the EPA's evaluation of the best available information demonstrated it to occur under UCMR 3 in approximately 0.28 percent of systems, serving 526,000 people in 7 states, Tribes, and U.S. territories, using a minimum reporting level of 20 ng/L. As this reporting level is two times greater than the health-based HRL of 10 ng/L, the EPA expects there is even greater occurrence and exposed population in the range between 10 and 20 ng/L. Additionally, through analysis of the extensive amount of state data, the agency found in occurred above the HRL of 10 ng/L in at least 52 water systems across 12 states. Furthermore, evaluating only a subset of the available state data representing non-targeted monitoring, PFNA was reported in approximately 3.6 percent of monitored systems and if those results were extrapolated across the country, PFNA would be detectable at any concentration in over 2,300 PWSs serving24.9 million people and detectable above the HRL of 10 ng/L in 228 systems serving 830,000 people.

Further supporting the final determinations for PFNA and HFPO-DA (as well as PFHxS), these PFAS are very stable and persistent in the environment. While PFNA has generally been phased out in the U.S. there are still detections as demonstrated through the EPA's evaluation of the best available information and legacy stocks may still be used, as well as products containing PFNA may still be produced internationally and imported to the U.S. (ATSDR, 2021). In the case of

HFPO-DA, however, it continues to be actively produced and used within the country and is generally considered to have replaced the production of PFOA. Since PFNA and HFPO-DA are both environmentally persistent, products containing PFNA are still in use and may be imported into the U.S., and HFPO-DA is still being actively produced and used, there is a substantial likelihood that environmental contamination of sources of drinking water will continue from the PFAS. To illustrate this point further, PFOA and PFOS, two of the most extensively sampled PFAS, are also very environmentally persistent and have been phased out in the U.S. for many years, though these two contaminants continue to often be found at levels of public health concern as discussed in section VI of the final rule preamble. Therefore, in consideration of factors relating to the environmental persistence of PFNA and HFPO-DA, their current and legacy production and use in commerce, and the observed occurrence of PFOA and PFOS as an indicator of likely future occurrence of PFNA and HFPO-DA, the EPA finds that there is a substantial likelihood PFNA and HFPO-DA occur or will co-occur at a frequency and level of public health concern.

A few commenters provided feedback on occurrence thresholds the agency should consider when evaluating the second statutory criterion for regulatory determinations. Particularly, these commenters recommended that the EPA should define a threshold for frequency and level of public health concern that warrants a specific regulatory determination. A few commenters cited other previous regulatory determinations where the agency made a determination not to regulate contaminants with similar or lower levels of occurrence suggesting that this should be the same for some or all of these four PFAS. Furthermore, some of these commenters stated that it would be arbitrary and capricious and conflict with the SDWA if the EPA did not use the level of adverse health effect (i.e., HRL) to represent the level at which a contaminant is considered a public health concern.

The EPA disagrees with these commenters and as demonstrated in the proposal and described in section III of the final rule preamble, for this regulatory determination, as well as past determinations, the agency did compare available occurrence data relative to the contaminant HRL as a factor in informing the occurrence level of public health concern. However, the level of public health concern for purposes of the second criterion is a contaminant-specific analysis that includes consideration of the HRL, as well as other factors and not solely based on the direct comparison to the HRL. There is not just one simple threshold used for public health concern for all contaminants. In the case of PFAS, this is particularly relevant given the dose additivity of mixtures. Furthermore, the EPA's evaluation of the second statutory criterion for regulation of PFHxS, PFNA, and HFPO-DA individually and regulation of combinations of these PFAS and PFBS in mixtures follows a similar process to previous rounds of regulatory determinations including the written Protocol developed under Regulatory Determination 3 (USEPA, 2014) and also described in detail in the Preliminary Regulatory Determination 4 (USEPA, 2020). Using the Protocol, and as conducted for the regulatory determinations in this action, the agency compares available occurrence data relative to the contaminant HRL as a preliminary factor in informing the level of public health concern. Consistent with the Protocol and similar to all past regulatory determinations, these regulatory determinations are also based on other factors, some

of which include the level at which the contaminant is found in drinking water, the frequency at which the contaminant is found and at which it co-occurs with other contaminants, whether there is an sustained upward trend that these contaminant will occur at a frequency and at levels of public health concern, the geographic distribution (national, regional, or local occurrence), the impacted population, health effect(s), the potency of the contaminant, other possible sources of exposure, and potential impacts on sensitive populations or lifestages" (USEPA, 2023a). It also includes consideration of production and use trends and environmental fate and transport parameters which may indicate that the contaminant would persist and/or be mobile in water. Appropriately, the EPA has considered these relevant factors in its evaluation that there is a substantial likelihood that PFHxS, PFNA, and HFPO-DA will individually occur and combinations of these three PFAS and PFBS will co-occur in mixtures in PWSs with a frequency and at levels of public health concern.

The EPA also disagrees with these commenters as SDWA does not define the occurrence level of public health concern for contaminants, nor does it prescribe the level of adverse health effects that must be used for a regulatory determination. In previous EPA regulatory determinations, the agency has considered the occurrence criteria unique to the contaminant it is evaluating and has made decisions not to regulate contaminants both where there was substantial likelihood of occurrence at frequency and/or at levels of public health concern and where there was limited or no substantial likelihood of occurrence at frequency and/or at levels of public health concern. Ultimately, the overall decision to regulate a contaminant considers all three statutory criteria, including the comprehensive assessment of meaningful opportunity which is in the Administrator's sole discretion. Moreover, consistent with this past regulatory history and the Administrator's authority under the terms of the statute, the decision considers all three criteria and cannot be determined in the exact same manner for different contaminants. While the EPA may have made negative determinations for other contaminants demonstrating occurrence at different frequencies and levels of public health concern, the basis for those decisions was specific to those contaminants and does not apply to these PFAS or any other future contaminants for which the EPA would make regulatory determinations. Therefore, the statute does not require, and the EPA does not use a minimum or one-size-fits-all occurrence thresholds (for either frequency or precise level) for regulatory determinations.

Individual Public Comments

American Water Works Association (AWWA) (Doc. #1759, SBC-045558)

The agency's preliminary determinations for PFNA, HFPO-DA, and PFBS are not sufficiently supported by the supporting documentation. The information included in the proposed rule docket does not suggest that there is a substantial likelihood of PFNA, HFPO-DA, and PFBS occurrence in drinking water with a frequency and at levels of public health concern. Instead, the available evidence indicates that a negative determination is appropriate. Similarly, the information on co-occurrence and overall occurrence of PFHxS, PFNA, HFPO-DA, and PFBS as a mixture also indicates that the agency only has supporting information for a negative

determination. Preliminary determinations for these compounds and their mixture should be re-issued following completion of the Fifth Unregulated Contaminant Monitoring Rule (UCMR 5).

EPA Response: Please **s**ee section 3.1.2 of the EPA response in this *Response to Comments* document. For the EPA's response related to the second statutory criterion for the regulatory determination of mixtures of PFHxS, PFNA, HFPO-DA, and PFBS, please see section 3.2.2 in this *Response to Comments* document. Concerning UCMR 5, please also see section 6.8 of the EPA response in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043097)

As part of this Proposal, EPA proposes preliminary determinations for PFHxS, PFNA, HFPO-DA, and PFBS concurrently with a proposed drinking water standard for these compounds. The determinations for PFNA, HFPO-DA, and PFBS are not supported by the available occurrence data.

EPA Response: Please **s**ee section 3.1.2 of the EPA response in this *Response to Comments* document.

American Farm Bureau Federation et al. (Doc. #1642, SBC-043482)

They have identified the following areas of concern regarding the agency's development of this rule:

• Lack of occurrence data at the proposed MCL level. EPA does not have a robust understanding of occurrence levels at the proposed MCL levels for PFOA and PFOS or the other four PFAS. This lack of occurrence data for a preliminary regulatory determination requires more thoughtful and thorough analysis.

EPA Response: Please **s**ee section 3.1.2 of the EPA response in this *Response to Comments* document. See section 6.2 of the EPA response in this *Response to Comments* document regarding state data used to inform PFOA and PFOS occurrence at MCL levels. Additionally, see PFOA and PFOS occurrence data results which are presented in section VI of the final rule preamble and the *Occurrence Technical Support Document* (USEPA, 2024b).

Consumer Reports (Doc. #1656, SBC-043181)

In terms of the occurrence of these four PFAS in drinking water, EPA analyzed data from the Unregulated Contaminant Monitoring Rule (UCMR) 3 sampling, which took place from 2013-2015, and from more recent data collected by states. The UCMR 3 study had 36,972 samples from 4,920 PWS that were analyzed for levels of PFHxS, PFNA and PFBS, but not GenX chemicals. The more recent data consisted of drinking water samples from 23 states that were also tested for PFHxS, PFNA, PFBS and GenX chemicals. The state data on detection frequency

and concentration results that EPA presents for PFHxS, GenX, PFNA, and PFBS vary widely between the four PFAS and across states.

That said, EPA notes that if you review the state data representing non-targeted monitoring, one or more of PFHxS, GenX chemicals, PFNA, and PFBS were reported in about 14% of the monitored systems. However, EPA also presents data to show that these four PFAS generally co-occur with each other, as well as with PFOA and PFOS. The state data also showed that for PFHxS, PFNA, PFBS, the levels found in drinking water often exceeded the HRLs of 9 ppt, 10 ppt, and 10 ppt, respectively. EPA made a determination that there is sufficient evidence of occurrence to support a preliminary determination that there is a substantial likelihood that PFHxS, GenX chemicals, PFNA, and PFBS will occur at frequencies and levels of public health concern. We agree with this assessment.

EPA Response: Please **s**ee section 3.1.2 of the EPA response in this *Response to Comments* document.

Wisconsin Department of Justice et al. (Doc. #1687, SBC-044444)

b. EPA's proposed PFAS drinking water contaminant levels are known to occur or substantially likely to occur in public water systems with a frequency and at levels of public health concern.

EPA appropriately determined that "there is a substantial likelihood that the [PFAS] contaminants [subject to the PFAS Rule] will occur and co-occur with a frequency and at levels of public health concern in [public water systems] based on EPA's evaluation of the best available occurrence information." [FN24: 88 Fed. Reg at 18647.] To reach this determination, EPA considered data collected under the Third Unregulated Contaminant Monitoring Rule (UCMR3) program as well as data collected by states. The state data, using newer analytical methods that have lower reporting limits than those under UCMR3, show "widespread occurrence of PFOA, PFOS, PFHxS, PFNA, and PFBS in multiple geographic locations." [FN25:Id. at 18648] State sampling demonstrated that millions of people drink water contaminated by the subject four PFAS. [FN26:Id. at 18651.] For example, Massachusetts data disclosed PFHxS in over 31 percent of finished water samples, South Carolina found PFBS in over 38 percent of finished water samples, and Kentucky found HFPO-DA in 13 percent of finished water samples. [FN27: Id. at 18949-50] The data show that PFHxS, HFPO-DA, PFNA, and PFBS, and mixtures of these PFAS, occur and co-occur at levels of public health concern as they are measured at concentrations above their respective individual health reference levels (HRLs) or, when considering their dose additive impacts, exceed these levels. [FN28: Id. Concentrations of PFBS, taken alone, did not exceed the HRL. But EPA determined that there is a substantial likelihood of its occurrence with a frequency and at levels of public health concern because of dose additivity with other PFAS found in mixtures and the elevated frequency with which PFBS occurrence has been observed over time. Id. at 18650.]

EPA Response: Please **s**ee section 3.1.2 of the EPA response in this *Response to Comments* document.

California Farm Bureau Federation (Doc. #1704, SBC-045066)

For example, the U.S. Chamber analysis highlights the following:

• Lack of occurrence data at the proposed MCL level. EPA does not have a robust understanding of occurrence levels at the proposed MCL levels for PFOA and PFOS or the other four PFAS. This lack of occurrence data for a preliminary regulatory determination requires more thoughtful and thorough analysis.

EPA Response: The EPA disagrees that the agency lacks occurrence data. In fact, the agency has tens of thousands of monitoring results for these six PFAS, many of which have reporting limits at or below the MCLs and many of which are for the PFAS EPA is making final regulatory determinations in this action. Please **s**ee section 3.1.2 of the EPA response in this *Response to Comments* document. See section 6.2 of the EPA response in this *Response to Comments* document regarding state data used to inform PFOA and PFOS occurrence at MCL levels. Additionally, see PFOA and PFOS occurrence data results which are presented in section VI. of the final rule preamble and the *Occurrence Technical Support Document* (USEPA, 2024b). In short, the EPA has a robust understanding of the occurrence of these PFAS and it is more than sufficient to determine that PFNA, PFHxS, and HFPO-DA and PFBS as part of a mixture with PFHxS, PFNA, and HFPO-DA are likely to occur with a frequency and at levels of public health concern.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045893)

5. EPA does not explain how it applied criteria to determine whether these four PFAS meet the occurrence factor

In the proposed rule, EPA fails to explain how it applied criteria in determining that the four PFAS meet the occurrence factor—the statutory finding that the contaminants are "known to occur or there is a substantial likelihood that the contaminants will occur in public water systems with a frequency and at levels of public health concern." EPA acknowledges that it does not have a "bright line" threshold for occurrence in drinking water that triggers whether a contaminant is of public health concern; rather, this determination is based on various factors. The considerations include: the level at which the contaminant is found in drinking water; the frequency at which the contaminant is found and at which it co-occurs with other contaminants; whether there is an sustained upward trend that these contaminant will occur at a frequency and at levels of public health concern; geographic distribution; the impacted population; health effects; the potency of the contaminant; other possible sources of exposure; and potential impacts on sensitive populations or life stages [FN50: 88 Fed. Reg. at 18647.].

EPA fails to explain why the data it relies on meets these factors for occurrence at levels and frequency of concern. EPA bases its determination for the occurrence factor on UCMR 3 data for PFNA, PFBS, and PFHxS (no data were monitored for HFPO-DA in UCMR 3) and recent PFAS drinking water data collected by 11 states, which are not representative [FN51: Id.]. The UCMR

data found that only 233 out of 36,972 samples had reported detections greater than or equal to the minimum reporting levels of at least one of the three PFAS. The percentage of systems where PFAS were found ranged from 0.1 to 56%. EPA does not explain why this data, which shows significant occurrence variability, and in some cases virtually no instances of occurrence, reflects a sufficient level of occurrence for all four PFAS to warrant regulation.

EPA Response: Please **s**ee section 3.1.2 of the EPA response in this *Response to Comments* document. Additionally, in the proposed rule preamble and the proposed rule *Occurrence Technical Support Document* (USEPA, 2023b), the EPA evaluated recent PFAS drinking water monitoring data from 23 states, not 11 states as incorrectly cited by the commenter. These datasets are representative of multiple geographic locations across the country and can be used to inform regulatory determinations. Based on public comment, for the final rule occurrence analyses, the EPA further updated this dataset to include new state occurrence data available through May 2023. These data include a very large dataset consisting of tens of thousands of samples from 32 states and representing one of the most robust occurrence datasets ever used to inform development of a drinking water regulation of a previously unregulated contaminant and further confirm that the SDWA second criterion for regulation have been met for PFHxS, PFNA, and HFPO-DA as individual contaminants. These updated state data are confirmatory of the data the EPA considered and discussed extensively during the rule proposal.

West Virginia Rivers Coalition et al. (Doc. #1746, SBC-045246)

In a 2022 study of raw-water samples at 279 public water systems across West Virginia, PFHxS was detected in 21% of samples with concentrations ranging from 0.8 to 81.4 ppt; HFPO-DA was detected in 10% of samples with concentrations ranging from 1.3 to 9.5 ppt; PFNA was detected in 3% of samples with concentrations ranging from 1.6 to 8.0 ppt; and PFBS was detected in 28% of samples with concentrations ranging from 0.49 to 24.5 ppt [FN1:https://www.sciencebase.gov/catalog/item/60db3fe9d34e596d2ba5c8f7]. Additionally, mixtures of these PFAS (at least two or more detections of PFHxS, HFPO-DA, PFNA, or PFBS) were found in 20% of samples. While these data are for pre-treated source water, it is likely that the frequencies and concentrations are generally reflective of finished water across the state as most public water systems only employ conventional treatment technologies, which are unable to remove PFAS to levels protective of public health.

In response to the above results, a follow up study was conducted to test for PFAS in the finished water at 37 public water systems identified to have PFOA and PFOS above laboratory reporting levels. These data show that PFHxS was detected in the finished water of 38% of systems with concentrations ranging from 1.94 to 22 ppt; HFPO-DA was detected in the finished water of 1 system with a concentration of 34 ppt; PFNA was detected in the finished water of 8% of systems with concentrations ranging from 3.9 to 6.51 ppt; and PFBS was detected in the finished water of 41% of systems with concentrations ranging from 2.09 and 8.49 ppt [FN2: https://www.sciencebase.gov/catalog/item/6401ff0dd34e6929881229c1]. Additionally, mixtures of these PFAS (at least two or more detections of PFHxS, HFPO-DA, PFNA, or PFBS) were

found in 32% of samples. Though these data are from targeted monitoring efforts and may not be representative of all PWSs in the state, we request that they be included in EPA's preliminary regulatory determination for PFHxS, HFPO-DA, PFNA, and PFBS.

EPA Response: Please **s**ee section 3.1.2 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045583)

Occurrence data for PFHxS is available not only through the UCMR 3 program but also as part of numerous state monitoring programs. Data is also currently being collected through the UCMR 5 program by 3,500 systems this year and more than 10,000 systems by the end of 2025 (EPA, 2021c). In review of the UCMR 3 data that is currently available, approximately 1.1% of water systems detected PFHxS at 30 ppt, more than 3 times higher than the proposed HBWC of 9.0 ppt. Additionally, data from California, Colorado, Pennsylvania, Vermont and Ohio show a similar trend of occurrence at levels above the proposed HBWCs (California Water Boards, 2023; CDPHE, 2023; Ohio EPA, 2023; PADEP, 2023; VTDEC, 2023). In review of the available occurrence data in comparison with the EPA's proposed HBWC, AWWA agrees that there is evidence that PFHxS occurs in drinking water at potential levels of concern.

EPA Response: Please **s**ee section 3.1.2 of the EPA response in this *Response to Comments* document. See section 6.2 of the EPA response in this *Response to Comments* document regarding the use of state datasets to support the final rule.

American Water Works Association (AWWA) (Doc. #1759, SBC-045581)

5. Preliminary Regulatory Determinations

The proposal includes preliminary regulatory determinations for four PFAS (and their mixture) concurrently with a proposed drinking water regulation of these compounds. AWWA supports the agency's interest in looking at PFAS beyond PFOA and PFOS for potential action and has previously recommended that the agency do so by applying adequate resources to fill data gaps (AWWA, 2020b).

Under the SDWA, EPA may only issue a NPDWR for a contaminant that is known to occur or there is a substantial likelihood that it will occur in public water systems at a level of public health concern. [FN15: 42 U.S.C. § 300g–1 (b)(1)(A)(ii).] In the preamble to the proposal, the agency notes that there is not a "bright-line threshold for occurrence in drinking water that triggers whether a contaminant is of public health concern". AWWA agrees that SDWA does not define a "bright-line threshold" that would define that a contaminant is of public health concern but given the statutory focus on the "adverse effect on the health of persons"16 [FN16: 42 U.S.C. § 300g–1 (b)(1)(A)(i).] it would be arbitrary and capricious and conflict with the SDWA if EPA did not use the level of adverse health effect to represent the level at which a contaminant starts to be considered a public health concern. AWWA also notes that EPA should consider its past

practices for determining whether a contaminant reaches a level of public health concern and ensure that its approach in any final rule is consistent with past practice or that it provides a reasoned explanation for any deviation from past practice. AWWA offers recommendations for each of these options, with this and other aspects in consideration. AWWA further notes that the best available health information indicates that a negative determination is appropriate for PFNA, HFPO-DA, and PFBS at this time.

EPA Response: Please **s**ee section 3.1.2 of the EPA response in this *Response to Comments* document.

San Antonio Water System (SAWS) (Doc. #1570, SBC-042475)

While it is problematic that there is such minimal data available for those PFAS substances tested for through UCMR3, the inclusion of GenX is wholly unsupported by any nationwide dataset since it was not a part of UCMR3.

EPA Response: Please **s**ee section 3.1.2 of the EPA response in this *Response to Comments* document. See section 6.2 of the EPA response in this *Response to Comments* document regarding the use of state datasets to support the final rule.

Alameda County Water District (ACWD) (Doc. #1595, SBC-042351)

3. Establishment of a standard for HFPO-DA prior to the collection of national level occurrence data

Monitoring for HFPO-DA was not conducted during the UCMR-3 monitoring and data is currently being collected as part of the UCMR-5 monitoring. UCMR 3 monitoring occurred between 2013 and 2015 and is currently the best available national dataset for any PFAS.

The occurrence of HFPO-DA is based on a limited data set from various state monitoring results. Using state monitoring results may not provide an accurate indication of occurrence data nationwide. As described above, UCMR-3 did not include sampling for HFPO-DA, and state monitoring orders may not have captured systems with HFPO-DA in source waters at all, nor systems with HFPO-DA at levels contemplated by the proposed MCL. EPA should allow for the completion of UCMR-5 monitoring to determine occurrence data for HFPO-DA prior to establishment of a standard, via the Hazard Index, for HFPO-DA.

We appreciate the opportunity to participate in the rule-making process. Should you have any questions about these comments, please feel free to contact Mike Wickham at (510) 668-6516, by email mike.wickham@acwd.com, or via U.S. mail at the letterhead address.

Thank you for your consideration.

Sincerely,

Ed Stevenson

General Manager

EPA Response: Please **s**ee section 3.1.2 of the EPA response in this *Response to Comments* document. See section 6.2 of the EPA response in this *Response to Comments* document regarding the use of state datasets to support the final rule.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043057)

2. The proposed positive regulatory determinations for perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO-DA), and perfluorobutanesulfonic acid (PFBS) is not supported by national occurrence data. EPA should either make a negative determination or re-propose the rule based on available occurrence data from Fifth Unregulated Contaminant Monitoring Rule (UCMR 5).

EPA Response: Please **s**ee section 3.1.2 of the EPA response in this *Response to Comments* document.

Philadelphia Water Department (PWD) (Doc. #1709, SBC-045741)

Similarly, PWD is not aware of a national dataset for HFPO-DA, and it was not a required analyte of the UCMR3 sampling program. While EPA has used state-level data, this information is regionally focused and includes an inconsistent suite of PFAS species for each state. It is unclear how EPA made a preliminary regulatory determination for this contaminant without having an indication as to its occurrence in public water systems across the country.

EPA Response: Please **s**ee section 3.1.2 of the EPA response in this *Response to Comments* document.

Philadelphia Water Department (PWD) (Doc. #1709, SBC-045744)

8. EPA should clearly define what threshold constitutes the determination that there is a "substantial likelihood that the contaminants will occur or co-occur with a frequency and at levels of public health concern".

Throughout section III.C and in the preamble for rulemaking reference USEPA 2023e ("Per- and Polyfluoroalkyl Substances (PFAS) Occurrence and Contaminant Background Support Document"), EPA states that the four HI compounds being discussed are found to have a "substantial likelihood [to occur] with a frequency and at levels of public health concern in drinking water systems across the United States". However, it is unclear what threshold was used to make this determination. For two of the HI compounds (PFNA and HFPO-DA), the percent of samples and systems with detects from most states was less than 10%. For all four of these compounds most states and systems had under 30-40% detections. PWD requests that EPA define what threshold it used to determine that each of these compounds have a "substantial likelihood" for occurrence.

EPA Response: Please see section 3.1.2 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045887)

2. UCMR 3 data and state data do not support a positive regulatory determination for HFPO-DA, PFNA, and PFBS

The existing data do not support a finding that the four contaminants of concern are occurring in drinking water with a frequency and at levels of public health concern. Furthermore, the detection levels used in UCMR 3 are significantly higher than the derived HBWCs, making data interpretation difficult.

There is no nationally representative data for HFPO-DA. In the past, EPA has determined not to regulate contaminants based on the lack of nationally representative occurrence data [FN33: 67 Fed. Reg. 38222, 38231 (Jun. 3, 2022) and 68 Fed. Reg. 42897, 42903 (Jul. 18, 2003). EPA determined not to regulate Acanthamoeba under the SDWA because EPA had no national monitoring data for Acanthamoeba occurrence in PWSs.]. While there is some non-representative state data (which likely suffers from self-selection bias), the majority of state samples detected HFPO-DA at occurrence levels below prior EPA determinations to regulate. Only three states had a percentage of detection that was above 0.5%, and the majority of states analyzed had detections below 0.3%. [FN34: 88 Fed. Reg. at 18649.] The statutory standard is simply not met based on the limited HFPO-DA occurrence data.

EPA Response: Please see section 3.1.2 of the EPA response in this *Response to Comments* document. Regarding quality assurance steps the EPA took to evaluate the available state PFAS data which are reported at levels significantly below UCMR 3 reporting limits, please see section 6.2 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenters assertion that the agency cannot make a determination to regulate a contaminant without UCMR or that SDWA requires a contaminant to be monitored for under UCMR to make a regulatory determination or establish an NPDWR assuming that the agency does have other non-national finished water datasets of sufficient size and scope to inform the determination to regulate. In addition, the EPA disagrees with the commenter's assertion that in the past the EPA has determined not to regulate contaminants based on the lack of nationally representative occurrence data. Specifically, in the case of acanthamoeba provided by the commenter, the agency further disagrees, because while there was no monitoring data for acanthamoeba to indicate occurrence in drinking water under UCMR or any other program, the EPA made the determination not to regulate acanthamoeba with an NPDWR since regulation would not present a meaningful opportunity for health risk reduction for persons served by PWSs. Moreover, as noted in the EPA's preliminary determination and affirmed in the final determination for acanthamoeba, "EPA finds that the disease incidence for acanthamoeba is extremely low and that exposure to acanthamoeba-related infections are not typically produced by ingestion of drinking water, inhalation during showering, or other standard uses of drinking

water. Rather, acanthamoeba related infections are typically associated with poor hygiene practices among contact lens wearers. Thus, the EPA finds that regulation of acanthamoeba does not present a meaningful opportunity for health risk reduction for persons served by PWSs" (67 FR 38232 and 68 FR 42903). In contrast, HFPO-DA does have a substantial amount of recently available state monitoring data covering a range of geographic locations demonstrating the substantial likelihood that it will occur at a frequency and level of public health concern and drinking water is known to be a significant route of human exposure.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045890)

The levels of detection from the best available sampling data simply do not support a listing for HFPO-DA, PFNA, and PFBS.

EPA has determined not to regulate the following substances at a national level on the basis that they did not occur at a frequency or level of public health concern:

• Nitrobenzene: UCMR 1 collected 33,576 finished water samples from 3,861 PWSs (serving ~226 million people) for nitrobenzene, and it was detected in only a small number of those samples (0.01%) above the HRL (10 μg/L), which is the same as the minimum reporting level (10 μg/L) [FN41: 86 Fed. Reg. at 12285.].

• RDX: UCMR 2 collected 32,150 finished water samples from 4,139 PWSs (serving ~229 million people) for RDX, and it was detected in only a small number of those samples (0.01%) at or above the minimum reporting level [FN42: Id. at 12286.].

In the above examples where EPA determined not to regulate the contaminants, the percentage of samples with detections were close to the percentage detection occurrence levels found for the four PFAS.

Further, in 2003, EPA made a determination that aldrin, a more hazardous substance than PFAS, did not occur at a frequency and a level of public health concern despite nationally representative data showing occurrence of aldrin above the health risk level in 0.2% of water systems [FN43: 85 Fed. Reg. at 43996.]. In that case, over one million people were being served by the water systems that had detections above the health risk level. The representative occurrence data for HFPO-DA (state data varied, some as low as 0%), PFNA (0.28%), and PFBS (0.16%) are similar or less than the percentage of detections in PWS for aldrin.

EPA Response: Please **s**ee section 3.1.2 of the EPA response in this *Response to Comments* document. As discussed previously, all regulatory determinations are a contaminant-specific decision and there is no one-size-fits-all determination. Regarding the comments provided on the EPA's regulatory determination for aldrin, in the EPA's preliminary regulatory determination, the EPA did find that aldrin occurred in PWSs at a very low frequency and at low levels, therefore regulation would not present a meaningful opportunity. Those levels, under Round 2 of Unregulated Contaminant Monitoring (UCM) indicated 0.02 percent of reporting PWSs had detections of greater than the HRL affecting 8,600 people, not 0.2 percent and over

one million people as incorrectly provided by the commenter. Further specific factors in the regulatory determination and consideration of meaningful opportunity for aldrin included that it was not considered to occur widespread nationally and the chemical was banned by the EPA for most uses nearly 30 years prior (i.e., 1974) to the EPA's regulatory determination. Thus, in consideration of these factors, and others, "It is likely that there will be so few people exposed to aldrin and dieldrin in their drinking water that a national regulation to control these two pesticides in drinking water would not provide a meaningful opportunity to reduce risk" (67 FR 38232). In contrast, HFPO-DA and PFNA have been demonstrated to occur or that there is a substantial likelihood that they will occur nationally with a much greater population exposure. Moreover, products containing PFNA and HFPO-DA are either still being actively produced and used or may be used through legacy products or imports into the U.S.

For the EPA's regulatory determinations on nitrobenzene and Royal Demolition Explosive (RDX), the agency again notes that these are contaminant specific determinations, and the EPA disagrees that these should serve as occurrence threshold examples for the regulatory determinations for HFPO-DA and PFNA or any other regulatory determinations. Further, the agency notes that for the nitrobenzene and RDX regulatory determinations, their occurrence was not geographically widespread as indicated by their UCMR 1 and UCMR 2 sampling results, respectively. RDX was not detected under UCMR 2 above its non-cancer HRL, and detected in only three systems nationwide above the Minimum Reporting Level (MRL) (which was higher than the cancer-derived HRL). Nitrobenzene was detected under UCMR 1 above its HRL in only two PWSs. Furthermore, as provided in the EPA's regulatory determination for nitrobenzene, "The EPA does not anticipate nitrobenzene occurrence meaningfully changing from the UCMR 1 monitoring period given that reported releases to surface water have generally decreased over time and detections of nitrobenzene in ambient waters and Six-Year Review monitoring data are at low levels" (85 CFR 14098). Therefore, in comparison to the occurrence data for HFPO-DA and PFNA demonstrated in section III.C. of the final rule preamble and the *Occurrence Technical Support Document* (USEPA, 2024b) which demonstrates many more than two or three PWSs with levels above the EPA's HRLs for HFPO-DA and PFNA, as well as the substantial likelihood of the continued or increasing occurrence of HFPO-DA and PFNA, regulation of RDX and nitrobenzene on a national scale would not have presented a meaningful opportunity for health risk reduction.

American Water Works Association (AWWA) (Doc. #1759, SBC-045584)

HFPO-DA

The UCMR 3 program did not include monitoring for HFPO-DA. Therefore, EPA is not able to determine the national occurrence of the chemical. While some states have conducted monitoring for HFPO-DA, these states provide only a limited understanding of national occurrence.

In review of the EPA's analysis, HFPO-DA monitoring was conducted in only 16 states and the data does not provide sufficient evidence that there is national occurrence of HFPO-DA. In two

states, North Carolina and Alabama, sampling data was available, but the extent of the program was unknown and so statewide occurrence levels can not be determined. In eight states, HFPO-DA was not detected in any systems and in another three states there was less than 0.2% of systems with detections of HFPO-DA, let at levels above the EPA's lifetime health advisory level of 10 ppt (EPA, 2022f).

The only state with a significant number of detections of HFPO-DA at systems was Kentucky. A total of 81 systems were sampled across the state. Of these 81 systems, eleven detected HFPO-DA. An in-depth review of this data shows that all of these systems, except one, rely on the Ohio River as a water supply source. The last system relies on the Ohio River Alluvium. This data suggests that HFPO-DA contamination in Kentucky is not widespread but rather linked directly to recent releases directly to the Ohio River. Specifically, it is anticipated that the Ohio River, and these systems, have been impacted by discharges of HFPO-DA from the Washington Works PFAS manufacturing plant in Parkersburg, West Virginia.

The Washington Works plant has long been a center for discussions on PFAS contamination. However, the EPA recently took landmark action against this plant for violations of the Clean Water Act related to discharges of HFPO-DA to the Ohio River (EPA, 2023c). With this action, it is anticipated that HFPO-DA levels in the Ohio River will drop, which will lead to a reduction in contamination of affected systems. Similar action has been taken by the North Carolina Department of Environmental Quality (NCDEQ) against the Fayetteville Works facility along the Cape Fear River. In 2019 NCDEQ issued a consent order that required the facility to begin taking mitigative measures against the release and contamination of HFPO-DA in the area surrounding the facility. Following EPA's publication of the lifetime health advisory level in 2022, this consent order was updated and now will limit discharges to a maximum of 10 ppt HFPO-DA. This action will reduce HFPO-DA contamination in the Cape Fear River.

Data is available on the production, use, and release of HFPO-DA from the EPA's supporting documentation and shows that HFPO-DA was released by five facilities in five states. According to the most recent TRI program data for HFPO-DA, 72% of the total HFPO-DA and its ammonium salt released was from the Fayetteville Works facility in North Carolina; the Washington Works facility in West Virginia accounted for 5.7% to the total releases (EPA, 2023d). Given that both of these facilities are reducing releases, as discussed above, this will reduce the total release of PFAS by as much as 77.7% from these two facilities alone. Further reductions are anticipated following the promulgation of the ELGs for manufacturers and metal finishers under the CWA, which has been identified by EPA as a part of the Effluent Guidelines Program Plan 15 (EPA, 2021b). Similar reductions may be anticipated as EPA and states work towards addressing PFAS as part of the National Pollutant Discharge Elimination System (NPDES), as directed by the agency in April and December of 2022 (EPA, 2022d; EPA, 2022e).

Overall, UCMR data is not currently available for HFPO-DA and the available state data is not sufficient to determine the national occurrence of HFPO-DA in drinking water. Furthermore, the limited occurrence observed by state monitoring programs and the limited extent of production shown by information from the TRI program data is not suggestive of a substantial likely of

HFPO-DA occurrence in drinking water with a frequency and at levels of public health concern. Instead, the available evidence indicates that a negative determination is appropriate for HFPO-DA.

EPA Response: Please **s**ee section 3.1.2 of the EPA response in this *Response to Comments* document. As shown in the final rule preamble section III.C. as well as the *Occurrence Technical Support Document* (USEPA, 2024b), the EPA disagrees that the state monitoring results demonstrate this is a local or regional issue only, given the documented drinking water occurrence both for detections at any concentrations and at levels above the HRL in 13 and 5 states, respectively, which is much more than the two states specifically documented by the commenter. Additionally, while the agency is taking appropriate actions to hold polluters of HFPO-DA accountable as detailed in this comment, and does show drinking water occurrence in some locations where the EPA has taken these actions due to known contamination, the EPA does not agree that these locations are the only areas where there is a substantial likelihood HFPO-DA will occur at a frequency and level of public health concern, nor that the agency should not take additional actions, such as the development of an NPDWR, when the statutory criteria are met. Furthermore, HFPO-DA continues to be actively produced and used throughout the U.S and is very stable and persistent in the environment; therefore, even if releases are reduced from certain facilities, the EPA anticipates that drinking water occurrence levels will continue to be found at least to the levels described in the final rule preamble.

Metropolitan Water District of Southern California (Doc. #1777, SBC-045430)

In addition, based on the California State Water Resources Control Board's GeoTracker PFAS database (2016-2023 data), there are insufficient occurrence data in California wells to support EPA's preliminary determination to regulate three of these contaminants (GenX chemicals, PFNA, and PFBS). While 558 wells statewide would be impacted by PFOA, 681 wells by PFOS, and 320 wells by PFHxS proposed MCLs, only 14 wells statewide would be impacted by PFNA above its health-based water concentration (HBWC). In addition, no wells are impacted by PFBS and HFPO (GenX) statewide. Accordingly, Metropolitan recommends EPA consider updated drinking water occurrence data that states have collected to inform its regulatory decision-making process.

EPA Response: Please **s**ee section 3.1.2 of the EPA response in this *Response to Comments* document. Additionally, as often observed, specific contaminant occurrence can be site-dependent, and while a contaminant may not occur as the same levels in all localities and states, the EPA has demonstrated that PFHxS, PFNA, and HFPO-DA occur or there is a substantial likelihood that they will occur with a frequency and level of public health concern across various geographic areas of the country. Furthermore, the EPA has demonstrated in section VI of the final rule preamble that PFOA and PFOS and the Hazard Index PFAS (PFHxS, PFNA, HFPO-DA, and PFBS) often co-occur and that the four Hazard Index PFAS often co-occur with each other (outside of their co-occurrence with PFOA and/or PFOS). Therefore, if PFOA, PFOS, and/or PFHxS are observed, there is a substantial likelihood PFNA, HFPO-DA,

and PFBS may also co-occur. Please see sections 3.2.2 and 6.3 of the EPA response in this *Response to Comments* document for more on PFAS co-occurrence.

The Chemours Company FC, LLC (Doc. #1845, SBC-046052)

ii. It is arbitrary and capricious for EPA to find that HFPO-DA occurs with a frequency and at levels of public health concern in the absence of any supporting data

In addition to violating the SDWA's express requirements, as described above, it is also arbitrary and capricious for EPA to find that HFPO-DA occurs in public water systems "with a frequency and at levels of public health concern" without data to support this finding. 42 U.S.C. [sec] 300g–1(b)(1)(A)(ii). It is especially arbitrary and capricious for EPA to rush into such a finding now when UCMR occurrence data for HFPO-DA will be available in the near future.

Preliminary UCMR occurrence data for HFPO-DA are expected to be published within months, and complete results will be available by 2026. [FN5: Occurrence Data from the Unregulated Contaminant Monitoring Rule, U.S. EPA, https://www.epa.gov/dwucmr/occurrence-data-unregulated-contaminant-monitoring-rule ("EPA anticipates posting the first set of preliminary UCMR 5 results in mid-2023 and expects to update the results approximately quarterly thereafter.").] EPA's decision to establish a NPDWR for HFPO-DA mere months before the data that should be central to EPA's analysis first become available is inexplicable, and suggests that EPA's decision to regulate this compound is detached from the underlying science.

Further, the data which are currently available demonstrate that the occurrence of HFPO-DA is limited to locations proximate to a small number of manufacturing facilities, and national regulations are therefore not appropriate. Thus, the occurrence data which EPA cites in its technical support document indicate that HFPO-DA does not occur at a frequency and level that supports national regulation. EPA first presents a compilation of HFPO-DA occurrence data from 16 states. [FN6: Per- and Polyfluoroalkyl Substances (PFAS) Occurrence and Contaminant Background Support Document, U.S. EPA, EPA 822-P-23-010 (Mar. 2023) at Exhibit 5-12.] The vast majority of detections came from a single state [FN7: Id. at Exhibit 5-13.]—North Carolina—which is also the only state with any detections above 30 ppt. [FN8: Id. at Exhibit 5-14.] Excluding North Carolina, HFPO-DA was detected in just a small fraction of samples, and in many states was not detected at all. [FN9: Id. at Exhibit 5-13; FN10: Detections of HFPO-DA in North Carolina are attributable to the Chemours Fayetteville Works facility. The Fayetteville Works facility is subject to a Consent Order with the North Carolina Department of Environmental Quality and Cape Fear River Watch, a non-governmental organization. Consent Order, North Carolina v. The Chemours Co. FC, LLC (N.C. Super. Ct., Feb. 25, 2019), https://deq.nc.gov/media/12453/download. The Consent Order was intended, and has had the effect, to drastically reduce emissions and discharges of HFPO-DA and other PFAS from the facility.]

In addition, the state data EPA has cited has numerous gaps and inconsistencies which demonstrate that it is not an adequate substitute for UCMR data when evaluating the occurrence of HFPO-DA at a national level. For example:

• Reporting thresholds varied between states, with some states failing to define any reporting threshold.

• Reporting thresholds varied within state data based on the particular laboratory analyzing the data.

• Some states reported at thresholds below laboratory practical quantitation limits ("PQLs"), while others reported at thresholds above EPA's NPDWR HBWC level for HFPO-DA.

• Some states failed to report the samples in which HFPO-DA was not detected. [FN11: PFAS Occurrence and Contaminant Background Support Document at Exhibit 5-12.]

The limited federal data that EPA presents in its technical support document also show nearly nonexistent occurrence of HFPO-DA. Department of Defense drinking water data showed only a single detection out of 994 samples. [FN12: Id. at Exhibit 5-16.] In ambient water, National Water Information System ("NWIS") data and EPA Storage and Retrieval ("STORET") data reported no detections of HFPO-DA across 336 samples. [FN13: Id. at Exhibits 5-17 and 5-18.]

Finally, Chemours has provided to EPA extensive data demonstrating that the occurrence of HFPO-DA is nonexistent or minimal outside of a small number of locations proximate to manufacturing facilities. For example, Chemours previously provided EPA 22 independent reports containing exposure data from the United States, Europe, and China which showed no significant levels of exposure to the general population from food, dust, air, soil, consumer products, firefighting foam, and ground and surface water. [FN14: Letter and Attachments from Sheryl Telford, Chemours, to Elizabeth (Betsy) Behl, U.S. EPA (May 31, 2022).] Further, Chemours previously presented to EPA a compilation of drinking water sample data submitted to EPA from the states and contained in EPA's ECHO database, which showed that HFPO-DA was not detected in 99.7% of drinking water samples. [FN15: Email and Attached Meeting Presentation from Sheryl Telford, Chemours, to Elizabeth (Betsy) Behl, U.S. EPA (April 29, 2022).]

EPA's rush to promulgate a NPDWR before UCMR data are available is without scientific or legal basis, and especially so given the data that do exist show minimal or nonexistent occurrence of HFPO-DA.

EPA Response: Please **s**ee section 3.1.2 of the EPA response in this *Response to Comments* document. The EPA disagrees that the state data cannot be used to inform the regulatory determination for HFPO-DA and took many quality control steps, as noted in the EPA's response 6.2, to ensure the data were accurately evaluated. As stated in the final rule preamble section III.C., the EPA disagrees that the state monitoring results demonstrate this is a local or regional issue only or that it only occurs near manufacturing facilities, given the documented drinking water occurrence both for detections at any concentrations and at levels

above the HRL in 13 and 5 states, respectively, which is more than the single state specifically documented in this public comment and that evaluates additional and newer data than that provided by the commenter. Moreover, of the 13 states with HFPO-DA detections and 5 states with detections above the HRL, the majority are in states that conducted non-targeted (i.e., not specifically conducted in areas of suspected or known contamination) monitoring efforts. Additionally, HFPO-DA continues to be actively produced and used throughout the U.S and is very stable and persistent in the environment; therefore, the EPA anticipates that drinking water occurrence levels will continue to be found at least to the levels described in the final rule preamble.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045888)

For PFNA, the UCMR 3 data showed that only 0.05% of all samples had detections above the quantitation limit, or MRL [FN35: U.S. EPA, PFAS Occurrence and Contaminant Background Support Document, 2023, EPA–822–P–23–010, at 160, available at: https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0037.]. These detections were found in 14 water systems that serve 526,341 people. [FN36: Id. at 162.] An MCL for PFNA seems to be unnecessary at a national scale.

EPA Response: Please **s**ee section 3.1.2 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045587)

Occurrence data for PFNA is available not only through the UCMR 3 program but also as part of numerous state monitoring programs. Data is also currently being collected through the UCMR 5 program by 3,500 systems this year and more than 10,000 systems by the end of 2025 (EPA, 2021c). In review of the UCMR 3 data that is currently available, less than 0.3% of water systems detected PFNA at 20 ppt (twice the level of the proposed HBWC of 10 ppt). Data from state monitoring programs showed similarly extremely low occurrence of PFNA in drinking water. Vermont, for example, required sampling of 1,794 water systems across the state and PFNA was detected above 10 ppt in only 12 systems, or 0.7% of systems (VTDEC, 2023). California monitoring, for example, found that 95% of samples with detections were below 3.2 ppt (California Water Boards, 2023). Monitoring data from Pennsylvania Department of Environmental Protection showed a maximum PFNA concentration of 14 ppt in the state, with a median PFNA level of 5.6 ppt (PADEP, 2023). Data from showed a similar trend of low to minimal occurrence at the HBWC (CDPHE, 2023).

The available data on the production, use, and release of PFNA from the EPA's occurrence analysis indicates that there are not significant sources of PFNA in the United States. While this could be due to inefficiencies in the reporting requirements under the EPA's authorities of the Emergency Planning and Community Right To Know Act's Toxics Release Inventory (TRI) program, the agency must rely on the best available data (AWWA, 2023). EPA recently

proposed rules that will require more improved data reporting on PFAS production, use, and release in the following years (EPA, 2022b).

In review of the available UCMR 3 data, state monitoring data, and manufacturing data for PFNA, the best available evidence does not suggest that there is a substantial likelihood of PFNA occurrence in drinking water with a frequency and at levels of public health concern. Based on the available evidence, and the SDWA statutory criteria, a negative determination is most appropriate for PFNA.

EPA Response: Please **s**ee section 3.1.2 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045889)

PFBS was also detected at only 0.05% of water samples in UCMR 3, and the population served by the water systems with detections was 349,933 people [FN37: Id. at 118-120 at exhibit 5-19 and 5-21.]. For PFBS, the highest level detected was 370 ppt, which is far below the HBWC of 2,000 ppt. It is also worth noting that there were no PFBS exceedances above 2000 ppt, and the available state data also showed no detections above 199 ppt. Similarly, Department of Defense drinking water sampling results from drinking water systems and private wells located in covered areas adjacent to 50 installations showed no detection above 362 ppt. Similarly, the USGS National Water Information System (NWIS) showed a maximum detection level of 109 ppt [FN38: Id. at 120-137.]. An MCL for PFBS seems to be unnecessary at a national scale. EPA even admits as much stating "EPA notes that PFBS concentrations do not exceed their HRL of 2000 ppt when considered in isolation."[FN39: 88 Fed. Reg. at 18650.] EPA then suggests that "dose additivity" is a reason to list PFBS [FN40: Id.]. This is not a valid reason to support a determination to regulate.

EPA Response: Please **s**ee section 3.1.2 of the EPA response in this *Response to Comments* document. As discussed in section 3.1 of the EPA response in this *Response to Comments* document, the EPA is deferring the individual final regulatory determination for PFBS to continue to evaluate the statutory criteria particularly related to its individual known or likely occurrence and, therefore, is also not promulgating an individual MCLG and NPDWR for PFBS in this action. However, regarding the commenter's statement that "dose additivity" is not a valid reason to support a regulatory determination, the EPA disagrees that the dose additive health concerns of PFBS, demonstrated co-occurrence of PFBS in combinations of mixtures with PFHxS, HFPO-DA, and PFNA at a frequency and level of public concern, and meaningful opportunity to reduce health risks from mixtures of these four PFAS (including PFBS) does not meet the statutory criteria for regulation within a mixture. Please see sections 3.2, 3.2.1, 3.2.2, and 3.2.3 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045589)

PFBS

The method reporting limits of the UCMR 3 program for PFBS provide sufficient clarity on occurrence at levels far below levels of health concern. For example, EPA's health advisory level is 2,000 ppt for PFBS and was only detected in less than 0.2% of systems above the reporting limit of 90 ppt under UCMR3 (EPA, 2022g) . Data from the state of Pennsylvania showed that the maximum PFBS level in drinking water was 13.0 ppt, with a median detected concentration of 4.2 ppt (PADEP, 2023). California monitoring data found that the maximum concentration across the state did not exceed 120 ppt and 95% of systems detected PFBS had levels below 15 ppt (California Water Boards, 2023). Monitoring data from several other states, including Ohio, Colorado, and Vermont show a similar trend (CDPHE, 2023; Ohio EPA, 2023; VTDEC, 2023).

Additionally, the available data on the production, use, and release of PFBS from the EPA's occurrence analysis indicates that there are not significant sources of PFBS in United States. While this could be due to inefficiencies in the reporting requirements of the TRI Program, the agency must rely on the available data. EPA recently proposed rules that will require more improved data reporting on PFAS production, use, and release in the following years.

In review of the available occurrence data, both from UCMR 3 and from state monitoring programs, it is apparent that PFBS does not occur in public water systems with a frequency, and at levels, of public health concern. The evidence from the production, use and release data that is available supports this conclusion. Therefore, at this time the best available public health information does not support a determination to regulate PFBS under the SDWA. In contrast, there is strong evidence that a negative determination is appropriate for PFBS and AWWA recommends that a negative determination be issued. EPA can revise its determination as to PFBS in the future, if new data indicates that such a determination is warranted.

EPA Response: Please **s**ee section 3.1.2 of the EPA response in this *Response to Comments* document.

PFAS Regulatory Coalition (Doc. #1761, SBC-046068)

2. There is a lack of occurrence data to support EPA's regulatory determinations for the four additional PFAS.

One of the key criteria for making a regulatory determination is that "the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern." SDWA Sec. 1412(b)(1)(A)(ii). EPA states that given the number of factors it considered it cannot identify a standard for occurrence data. But the statute provides the standard. Occurrence at levels of public health concern must be "known" or there must be a "substantial likelihood" of such occurrence. Clearly Congress intended that there be some levels and some frequencies that would be below the threshold of public health concern. EPA must articulate where it drew that line to allow for

meaningful comment. For example, in seven out of the eleven states with occurrence data on which EPA relied, HFPO-DA was not present in more than 1% of the systems. 88 Fed. Reg. 18648, Table 1. Extrapolating this ratio to all 50 states means that 32 states would have this compound in less than 1% of their systems. EPA's approach would lead to a result where a compound can be absent, or present in less than 1% of systems, in nearly two-thirds of the states, yet that would be enough to justify the occurrence criterion.

EPA's conclusion that PFHxS, PFNA, PFBS, and HFPO-DA meet this "occurrence" criterion is also based, in part, on an assumption of an upward trend in detections: "EPA anticipates that national monitoring with newer analytical methods capable of quantifying PFAS occurrence to lower levels, significant occurrence and cooccurrence of these PFAS are likely to be observed." 88 Fed. Reg. 18650. Anticipation of data is not a basis on which to make regulation. Moreover, according to the Agency for Toxic Substances and Disease Registry, levels of PFOS and PFOA in blood have declined by more than 85% for PFOS, and 70% for PFOA. See ATSDR, "PFAS in the U.S. Population," available at https://www.atsdr.cdc.gov/pfas/health-effects/us-population.html#print. EPA's "anticipation" cannot support a determination that the contaminants are "substantially likely" to be present "at levels of public health concern." UCMR 5 data are already being collected, so EPA should pause this rulemaking in order for the Agency to incorporate actual data, not supposition.

We also do not agree that PFBS meets the statutory "occurrence criterion." EPA acknowledges "that PFBS concentrations do not exceed their HRL [health reference level] of 2000 ppt when considered in isolation." 88 Fed. Reg. 18650. But instead of relying on this information to make its "occurrence" decision, EPA instead relies on an assumption that PFBS will co-occur with other PFAS to collectively reach levels of public health concern. This assumption is simply not supported by the data in EPA's Proposal. EPA reports the median sample range of the state sampling data as being between 1.99 – 7.26 ppt. Based on these results, the median contribution of PFBS to the Hazard Index ranges between:

1.99/2000 = 0.000995

7.26/2000 = 0.00363

If these very low levels are thresholds at which EPA believes co-occurrence can contribute to a public health concern, it is hard to imagine any substance that would not meet the "occurrence" test, an outcome that is clearly not supported by the language of the SDWA. Thus, EPA's determination that the data demonstrate that there is a "substantial likelihood" that PFBS will occur at levels of public health concern is not supported by the record.

EPA Response: Please **s**ee section 3.1.2 of the EPA response in this *Response to Comments* document. The EPA is deferring the individual final regulatory determination for PFBS to continue to evaluate the statutory criteria particularly related to its individual known or likely occurrence and, therefore, is also not promulgating an individual MCLG and NPDWR for PFBS in this action. However, regarding the commenter's statement that "it is hard to imagine any substance that would not meet the occurrence test" the EPA disagrees with this statement

because the agency has made regulatory determinations in the past where it found there was not a meaningful opportunity for health risk reduction of a contaminant both for contaminants occurring above and below frequencies and levels of public health concern. Moreover, as discussed in section 3.1.2 of the EPA response in this *Response to Comments* document, a regulatory determination decision is based on a number of factors and there is no one-size-fits-all occurrence threshold. In the specific case of PFBS when considered in mixture combinations with PFHxS, HFPO-DA, and PFNA, the EPA disagrees that the dose additive health concerns of PFBS, demonstrated co-occurrence of PFBS in combinations of mixtures with PFHxS, HFPO-DA, and PFNA at a frequency and level of public concern, and meaningful opportunity to reduce health risks from mixtures of these four PFAS (including PFBS) does not meet the statutory criteria for regulation within a mixture or is not supported by the best available data. Please see sections 3.2, 3.2.1, 3.2.2, and 3.2.3 of the EPA response in this *Response to Comments* document, as well as sections III and IV of the final rule preamble. The Hazard Index approach of considering these four PFAS in mixtures also recognizes these PFAS cause adverse health effects at differing potencies (e.g., the toxicity reference value for PFHxS is slower than the one for PFBS), and that, regardless of these potency differences, all co-occurring PFAS are included in the hazard calculation (i.e., the health effects and presence of lower toxicity PFAS are neither ignored nor are they over-represented).

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045885)

B. Existing occurrence data does not support the regulatory determination

1. SDWA requires collection of UCMR data in order for EPA to make the regulatory determination

To fulfill the second criteria under Section 1412(b)(1)(A) of SDWA, the act requires that EPA demonstrate it knows or "there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern."[FN28: 42 U.S.C. [sec] 300g-1(b).] Here, EPA has done nothing more than show that these PFAS may occur at levels of concern, falling short of the statutory requirement.

SDWA requires that once every five years, EPA issue a new list of unregulated contaminants to be monitored in drinking water,[FN29: 42 U.S.C. [sec] 300g-1(b)(1)(B).] known as the Unregulated Contaminants Monitoring Rule (UCMR). The contaminant occurrence data is a mechanism built into SDWA to obtain nationally representative occurrence data for contaminants in drinking water. Collecting data under the UCMR serves to better inform regulatory determinations, as contaminants are evaluated based on health effects and occurrence information [FN30: 87 Fed. Reg. 68060, 68062 (November 14, 2022).]. EPA has historically relied on the UCMR process to collect occurrence data on contaminants to support a determination on whether to regulate them. In previous regulatory determinations, where both state and UCMR data were available, EPA has determined that UCMR data "are the best available data" representing the national scale [FN31: See 85 Fed. Reg. 43990, 44001 (Jul. 21,

2020).]. EPA also notes this in the proposed rule as well [FN32: 88 Fed. Reg. 18672 states "UCMR 3 monitoring occurred between 2013 and 2015 and is currently the best nationally representative finished water dataset for any PFAS, including PFOA, PFOS, PFNA, PFBS, and PFHxS."].

EPA has simply not collected sufficient data to meet the statutory requirement of knowing or demonstrating there is a substantial likelihood that the four PFAS will occur in public water systems with a frequency and at levels of public health concern. EPA relies on limited UCMR 3 data and state data from only 11 states.

EPA Response: Please see section 3.1.2 of the EPA response in this *Response to Comments* document, as well as section 6.8 of the EPA response in this *Response to Comments* document regarding UCMR 5. Additionally, the EPA disagrees that the agency has circumvented the established process for developing NPDWRs. The EPA also disagrees that the agency has not collected sufficient data to demonstrate there is a substantial likelihood that these PFAS will occur in PWSs with a frequency and at levels of health concern. The EPA implements a monitoring program for unregulated contaminants (i.e., UCMR) under SDWA 1445(a)(2) that requires the EPA to issue a list once every five years of priority unregulated contaminants to be monitored by PWSs, however there is no statutory obligation that a contaminant must be on this list prior to making a determination to regulate, if the agency has sufficiently available information through other sources. The UCMR 3 dataset, along with additional state data and robust analyses, demonstrate sufficient likelihood of occurrence of the PFAS being regulated. As discussed in section 6.2 of the EPA response in this *Response to Comments* document, in addition to UCMR 3 data, the agency also considered occurrence data from 32 states, which provided the agency tens of thousands of additional PFAS monitoring results to inform the agency's decision. These data are summarized in section VI.F of the Federal Register Notice (FRN) and in the *Occurrence Technical Support Document* (USEPA, 2024b).

Midwest Environmental Advocates +more (Doc. #1846, SBC-045827)

Sampling results in Wisconsin indicate that the most concerning contaminants are PFOS, PFOA, PFHxS, and PFBS. These substances are frequently detected in community water systems in multiple geographic locations at levels of concern. The occurrence concentration levels for each contaminant individually and collectively found in community water systems across Wisconsin supports EPA's determination that these substances pose a public health concern. Below is a table summarizing some of the state's occurrence data of concern, focusing on the highest levels detected in each water system: [FN16: Additional information about each water system and its frequent PFAS detections are attached in Appendix A.]

[Table 1: See Docket ID EPA-HQ-OW-2022-0114-1846]

EPA Response: Please see section 3.1.2 of the EPA response in this *Response to Comments* document. The EPA acknowledges the commenter for provided information related to PFAS monitoring in Wisconsin. The agency considered data publicly available from the

Wisconsin Department of Natural Resources and the agency has considered these data prior to finalizing this regulation (please see the *Occurrence Technical Support Document* for more information).

Little Hocking Water Association (Doc. #1835, SBC-045511)

EPA requests comment "on if there are additional data or studies EPA should consider that support or do not support the Agency's preliminary regulatory determination for HFPO-DA, including additional health information and occurrence data." LHWA provides the following data on HFPO-DA occurrence that supports the regulation of HFPO-DA:

1. Chemours began testing for HFPO-DA in the LHWA water system influent water to the carbon treatment system on February 19, 2018. The reported concentration is consistently collected with the same three production wells providing water to the treatment plant. The reported concentration of HFPO-DA was 0.032 ug/L or 32 ppt on February 19, 2018. Attachment 3 shows a graph of the concentration of HFPO-DA since that time. The latest verified data point for April 10, 2023 shows a concentration of 0.49 ug/L or 490 ppt.

These data show the steep upward trend in HFPO-DA occurrence in the LHWA wellfield. Documentation of the data can be found in publicly-submitted data to the Ohio EPA (Chemours, 2023a).

2. For the nearby upstream Belpre water system, described above, recent analysis by Chemours (on March 20, 2023) for HFPO-DA shows a concentration of HFPO-DA of 2.3 ppt in the raw water to the GAC treatment plant (Chemours, 2023b). The concentration of HFPO-DA in the two lead beds of the GAC treatment plant were reported to be 2.6 ppt and 2.4 ppt. This is the first time that HFPO-DA data was available for the Belpre water system. Previous data for HFPO-DA is not available because, prior to this date, only results for PFOA were reported in publicly available information. As stated above, most data-gathering since 2002 focused on PFOA and PFOS. What relatively little data there is for HFPO-DA shows it has quickly spread in the environment and to water supplies.

3. The presence of HFPO-DA was shown to be widespread in surface water in the area around the LHWA wellfield primarily upstream and downwind of the Chemours Washington Works plant. Galloway et al., (2020) noted that HFPO-DA was found to be widespread in surface water up to four miles north of the Washington Works plant at concentrations greater than 100 ppt.

4. HFPO-DA was also found to be present in the most recent sampling of the Ohio River by the Ohio River Valley Water Sanitation Commission (ORSANCO). This is important to public water systems because the Ohio River serves both as a source of recharge to wellfields along the river as well as a direct source of water through river intakes along the river. ORSANCO sampled the Ohio River basin in 2021 and found detections of PFAS at every sampling station, with the highest measured concentration of HFPO-DA at 32.20 ppt (ORSANCO, 2022).

EPA Response: Please see section 3.1.2 of the EPA response in this *Response to Comments* document. Additionally, the EPA notes that the data submitted by the commenter support the EPA's conclusions that HFPO-DA is substantially likely to occur at a frequency and level of public health concern. The EPA anticipates that due to HFPO-DA's active production and use in the United States that similar or increasing levels will continue to be observed in drinking water for the foreseeable future.

Missouri Department of Natural Resources (Doc. #1563, SBC-042514)

Proposed Revisions to Part 141—National Primary Drinking Water Regulations

In the federal register notice for the proposed rule, EPA specifically requested comments on a number of aspects on the rule. You will find detailed comments from the Department related to many of those specific requests below.

EPA requests comment on its preliminary regulatory determination for PFHxS, HFPODA, PFNA, and PFBS and its evaluation of the statutory criteria that supports the finding. EPA also requests comment on if there are additional data or studies EPA should consider that support or do not support the Agency's preliminary regulatory determination for PFHxS, HFPO-DA, PFNA, and PFBS, including additional health information and occurrence data.

The Department believes that EPA is acting prematurely in making a preliminary regulatory determination for PFHxS, HFPO-DA, PFNA, and PFBS. The Department also believes that EPA should wait to make a determination for these compounds until after it is has completed the occurrence monitoring under UCMR 5 and has had the opportunity to evaluate the associated data. This pause would allow EPA to make a decision based on unbiased, consistently collected, national information rather than relying on data from a subset of states that varies in terms of quantity and coverage, and that includes data from targeted or site-specific sampling efforts where it may be expected to have higher detection rates, or not be representative of levels found in all public water systems (PWS) within a state. By delaying the final regulatory determination for these four PFAS until after completion of UCMR 5 occurrence monitoring, EPA will be able to better determine if the contaminants have widespread co-occurrence in drinking water supplies throughout the country.

EPA Response: Please see section 3.1.2 of the EPA response in this *Response to Comments* document. Additionally, regarding UCMR 5, please see section 6.8 of the EPA response in this *Response to Comments* document.

Maine Water Utilities Association (MWUA) (Doc. #1567, SBC-042728)

Occurrence:

EPA does not yet have a sense of occurrence of the suite of PFAS compounds in drinking water as the Unregulated Contaminant Monitoring Rule (UCMR5) program just commenced at the beginning of this year (2023). EPA's regulatory determination for PFNA, HFPO-D/GenX, and

PFBS are based on a very limited data set. UCMR testing has always been an important step in the EPA rulemaking process; waiting for UCMR5 results would provide a more robust data set for determining occurrence across the nation. EPA should delay promulgation of this rule until it has a chance to vet at least one full year of data obtained through UCMR5.

EPA Response: Please see section 3.1.2 of the EPA response in this *Response to Comments* document. Additionally, regarding UCMR 5, please see section 6.8 of the EPA response in this *Response to Comments* document.

Superfund Settlements Project (SSP) and RCRA Corrective Action Project (RCAP) (Doc. #1631, SBC-043436)

• With regard to occurrence data, at the very minimum, EPA should be waiting for the UCMR5 data. EPA's reliance on very limited UCMR3 and state data cannot support a determination that there is a substantial likelihood that the contaminants will occur in public water systems with a frequency and at levels of public health concern. That said, if EPA maintains that these data are sufficient (which they are not), they clearly do not support the regulatory determination to regulate individually or as a mixture.

EPA Response: Please see section 3.1.2 and 3.2.2 of the EPA response in this *Response to Comments* document. Additionally, regarding UCMR 5, please see section 6.8 of the EPA response in this *Response to Comments* document.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-044911)

Section 4: Regulatory Determinations for Additional PFAS

EPA has proposed issuing a regulatory determination for four additional PFAS concurrently with a proposed National Primary Drinking Water Regulations NPDWR for the same chemicals. Those additional PFAS are perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salt (also known as a GenX chemicals), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS).

To make this determination, EPA used older data from the Unregulated Contaminant Monitoring Rule (UCMR) 3 and more recent data from states as of August 2021. Some of the states where data was collected have gone through the process of promulgating their own regulation for certain PFAS that are included in this determination. For example, Michigan, a state included in Table 1, has regulated PFHxS, PFNA, PFBS, and GenX in 2020 [FN8: https://www.michigan.gov/pfasresponse/drinkingwater/mcl#:~:text=In%20August%202020%2C%20the%20Michigan,the%20Safe%20Drinking%20Water%20Act.]. This regulation would likely change the percent of samples with detections in those states as utilities presumably would have taken actions to address these detections and stay in compliance. Similarly, New Jersey regulated PFNA in 2018 [FN9: https://www.nj.gov/health/ceohs/documents/pfas_drinking%20water.pdf]. New Hampshire

(2020) [FN10: https://www.pfas.des.nh.gov/drinking-water], Massachusetts (2020) [FN11: https://www.mass.gov/lists/massachusetts-pfas-drinking-water-standard-mcl#massachusetts-pfas-standard-forpublic-drinking-water-supplies-], and Vermont (2019) [FN12: https://dec.vermont.gov/water/drinking-water/water-quality-monitoring/pfas] regulated PFHxS and PFNA. Each of these states are included in Tables 1 and 2, and have implemented measures to reduce concentrations and occurrence of specific PFAS.

An important part of Regulatory Determinations is having a holistic view of occurrence, or nonoccurrence, of these chemicals regionally and nationwide. While EPA does have some older data on occurrence, as mentioned above, this data may be out of date as a result of improvements due to recently promulgated state regulations. Additionally, data from many states is still missing. Fortunately, over the next two years, UCMR will be providing EPA with a large portion of data in the next nine months from UCMR 5 that will be able to fill in these gaps in our understanding of occurrence of these four PFAS chemicals. UCMR 5 will include data from all systems serving 3,300 people or more, and 800 representative public water systems serving fewer than 3,300 people [FN13: https://www.epa.gov/dwucmr/fifth-unregulated-contaminant-monitoring-rule]. This dataset is instrumental in assessing the occurrence of chemicals in our water systems. All four of these proposed additional PFAS are included on UCMR 5.

EPA should wait until it at least has the first year of UCMR 5 data to better assess the occurrence of these chemicals in drinking water systems at the current analytical levels we can achieve. Cleveland Water understands EPA's urgency in regulating PFOA and PFOS, and we strongly support regulation based on sound science and up-to-date data. That is why we believe at least the first year of UCMR 5 data will be crucial to giving the agency a better understanding of occurrence of these four additional PFAS. EPA will have the ability to include this information in a cost-benefit analysis that uses the most current data to calculate number of systems impacted and any additional health benefits associated with these chemicals at levels known to occur.

EPA Response: Please see section 3.1.2 of the EPA response in this *Response to Comments* document, as well as section 6.8 of the EPA response in this *Response to Comments* document regarding UCMR 5. Additionally, the EPA notes that it considers state promulgated standards as a part of its Economic Analysis (EA) for the proposed and final rule. Specifically, to estimate the costs and benefits of the PFAS NPDWR, the EPA assumed that all occurrence model estimates exceeding state limits were equivalent to the state-enacted limit. For these states, the EPA assumed that the state MCL is the maximum baseline PFAS occurrence value for all entry points in the state. This adjustment was made to the occurrence model PFAS estimates for PFOA, PFOS, and PFHxS in the EA. (See chapter 4 in USEPA, 2024a for additional information.)

New York City Department of Environmental Protection (NYCDEP) (Doc. #1679, SBC-044207)

Occurrence Data

EPA uses the UCMR to collect data for contaminants that are suspected to be present in drinking water and do not have health-based standards set under the Safe Drinking Water Act (SDWA).

Occurrence data are collected through UCMR to support the Administrator's determination of whether to regulate particular contaminants in the interest of protecting public health. In its current proposal, EPA intends to finalize these new drinking water MCLs in 2023, which is in advance of the Fifth UCMR sampling window. While occurrence data for PFOA, PFOS, PFNA, PFHxS and PFBS were collected under UCMR3, data collection for hexafluoropropylene oxide dimer acid (HFPO-DA or GenX) will not even begin until 2024 (i.e., these suspected contaminants are included even though EPA does not have data).

EPA Response: Please see section 3.1.2 of the EPA response in this *Response to Comments* document. Regarding UCMR 5, which the EPA clarifies is being conducted between 2023 through 2025, please see section 6.8 of the EPA response in this *Response to Comments* document.

Horsham Water & Sewer Authority (HWSA) (Doc. #1686, SBC-043819)

If it is only occurrence data that is insufficient, EPA will very soon have the results of the on-going 5th Unregulated Contaminant Monitoring Rule (UCMR5) and should wait for those results to be sure there is in fact sufficient cause to regulate. Based on existing occurrence information for these compounds, the delaying of setting MCLs for these compounds will not impact the desired health benefits much, if at all.

EPA Response: The EPA disagrees that occurrence data are insufficient to make regulatory determinations or inform this rule. Please **s**ee section 3.1.2 of the EPA response in this *Response to Comments* document. Additionally, the EPA disagrees that delaying these NPDWRs further would not impact the desired health benefits because these PFAS have been shown to result in a range of adverse health effects (e.g., developmental effects). Continuing to wait when there is sufficient data now would not only demonstrate that the EPA is not fulfilling its statutory obligations, but it will also allow for more people to potentially be impacted by these health effects.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045892)

4. EPA inappropriately uses anticipated occurrence findings rather than existing data in its preliminary determination

EPA must make the determination to regulate based on existing data. However, EPA seems to include anticipated findings in their determination. EPA states: “EPA anticipates that national monitoring with newer analytical methods capable of quantifying PFAS occurrence to lower

levels, significant occurrence and cooccurrence of these PFAS are likely to be observed."[FN48: 88 Fed. Reg. at 18650.] Yet EPA does not provide any citation or data to support this statement. EPA assumes that the UCMR 5 data will show that the four contaminants are known to occur [FN49: 88 Fed. Reg. at 18651.]. While that is one possibility, considering the costs and importance of this regulatory proposal, EPA should await the analysis of the UCMR 5 data to support its assumptions with respect to these four PFAS to determine whether there is representative data sufficient to demonstrate occurrence that would support a regulatory determination.

EPA Response: Please see section 3.1.2 of the EPA response in this *Response to Comments* document. Commenter is factually incorrect: the EPA did not base its regulatory determinations on "anticipated data." Rather, the final regulatory determinations were based upon actual, collected data because the EPA presented tens of thousands of samples from UCMR 3 and state monitoring efforts demonstrating there is a substantial likelihood of occurrence as required under SDWA.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045886)

SDWA contemplates EPA's reliance on UCMR data, and, because EPA is currently collecting data on 29 PFAS as part of the UCMR 5, it is premature to propose a regulatory determination for these substances. This data collection will provide national representative information on the occurrence of all four contaminants and will be more relevant for EPA to evaluate in its decision to regulate.

EPA Response: Please see sections 3.1.2 and 6.8 of the EPA response in this *Response to Comments* document. Additionally, the EPA implements a monitoring program for unregulated contaminants (i.e., UCMR) under SDWA 1445(a)(2) that requires the EPA to issue a list once every five years of priority unregulated contaminants to be monitored by PWSs, however there is no statutory obligation that a contaminant must be monitored under the UCMR program prior to making a determination to regulate, if the agency has sufficiently available information through other sources. Additionally, completion of monitoring for a contaminant under UCMR is not required prior to making a regulatory determination nor promulgation of the final rule. The UCMR 3 dataset, along with additional state data and robust analyses, demonstrate sufficient likelihood of occurrence of the PFAS being regulated.

Louisville Water Company (Doc. #1720, SBC-043552)

[In that regard, we are providing the following comments on key issues that we think require consideration.]

2. Having a holistic view of the occurrence of PFAS regionally and nationwide is a critical part of the regulatory determination process. Louisville Water is concerned that the agency is relying on a paucity of older data which may not reflect current conditions, and regional data that likely skews the occurrence data. Under the Safe Drinking Water Act (SDWA), the agency has until

September 2024 to promulgate this rule. We suggest that the agency consider holding off on finalizing the NPDWR for PFAS until the first year of UCMR5 data is available to the agency for review. Additionally, EPA has the option to move forward with the PFOA and PFOS rulemaking, but the statutory deadline of that Regulatory Determination only applies to those PFOA and PFOS. EPA may choose to regulate the four additional PFAS in an expedited manner after a Regulatory Determination is finalized utilizing UCMR 5 data. This latest UCMR5 dataset may also fill in some gaps in the cost-benefit analysis regarding this determination and proposal, which is currently missing. Furthermore, waiting for necessary occurrence data for PFNA, PFBS, PFHxS, and GenX is prudent with regard to making a Regulatory Determination. A pause in making a Regulatory Determination for PFNA, PFBS, PFHxS, and GenX would allow EPA the flexibility to further consider the best action based on best data and make the best decision possible regarding these four chemicals to protect the public's health by ensuring its decisions are well informed and the public does not incur unnecessary costs when it is already struggling with the affordability of water.

EPA Response: Please see section 3.1.2 of the EPA response in this *Response to Comments* document, as well as section 6.8 of the EPA response in this *Response to Comments* document regarding UCMR 5.

Florida Section American Water Works Association - Water Utility Council (FSAWWA WUC) (Doc. #1737, SBC-044491)

EPA' s positive determination for the four PFAS compounds relied on limited occurrence data (for example, Unregulated Contaminant Monitoring Rule, UCMR 3 detection limit s) and more information and analysis is needed to develop the future determinations. EPA should utilize the current UCMR 5 sampling results now underway to build upon its limited database to make a future regulatory determination.

EPA Response: Please see section 3.1.2 of the EPA response in this *Response to Comments* document, as well as section 6.8 of the EPA response in this *Response to Comments* document regarding UCMR 5.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045960)

Section 4: Regulatory Determinations for Additional PFAS

EPA has proposed issuing a regulatory determination for four additional PFAS concurrently with a proposed NPDWR for the same chemicals. Those additional PFAS are perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salt (also known as a GenX chemicals), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS).

To make this determination, EPA used older data from the Unregulated Contaminant Monitoring Rule (UCMR) 3 and more recent data from states as of August 2021. Some of these states where

data was collected have gone through the process of promulgating their regulation for certain PFAS that are included in this determination. For example, Michigan, a state included in Table 1, regulated PFHxS, PFNA, PFBS, and GenX in 2020 [FN8: Michigan PFAS Action Response Team. (2023). Maximum Contaminant Levels. https://www.michigan.gov/pfasresponse/drinking-water/mcl]. This regulation would likely change the percent of samples with detections in those states as utilities presumably would have taken actions to address these detections and stay in compliance. Similarly, New Jersey regulated PFNA in 2018 [FN9: New Jersey Department of Health. (2022, July). Per- and polyfluoroalkyl substances in drinking water. https://www.nj.gov/health/ceohs/documents/pfas_drinking%20water.pdf.]. New Hampshire [FN10: New Hampshire Department of Environmental Services. (2023). Drinking water. https://www.pfas.des.nh.gov/drinking-water.] and Massachusetts [FN11: Massachusetts Department of Environmental Protection. (2020). Massachusetts PFAS Drinking Water Standard (MCL). https://www.mass.gov/lists/massachusetts-pfas-drinking-water-standard-mcl#massachusetts-pfas-standard-for-public-drinking-water-supplies-] regulated PFHxS and PFNA in 2020, while Vermont regulated them in 2019 [FN12: Vermont Department of Environmental Conservation. (2023). PFAS & Drinking Water.https://dec.vermont.gov/water/drinking-water/water-quality-monitoring/pfas]. Each of these states is included in Tables 1 and 2 of the preamble and has implemented measures to reduce concentrations and occurrence of specific PFAS.

An important part of Regulatory Determinations is having a holistic view of occurrence, or nonoccurrence, of these chemicals regionally and nationwide. While EPA does have some older data on occurrence, this data may no longer be accurate as a result of recently promulgated state regulations. Additionally, data from many states is still missing. Fortunately, over the next two years, UCMR 5 will provide EPA with a large portion of data that will be able to fill in these gaps in the understanding of occurrence of these four PFAS chemicals, including data from all systems serving 3,300 people or more, and 800 representative public water systems serving fewer than 3,300 people [FN13: EPA. (2021, December 7). UCMR 5. https://www.epa.gov/dwucmr/fifth-unregulated-contaminant-monitoring-rule]. This dataset is invaluable in assessing the occurrence of chemicals in the nation's water systems. All four of these proposed additional PFAS are included in UCMR 5.

EPA should wait until it has the first year of UCMR 5 data to better assess the occurrence of the four HI chemicals in drinking water systems at current achievable analytical levels. AMWA understands EPA's urgency in regulating PFOA and PFOS, and the association strongly supports regulation based on sound science and up-to-date data. That is why AMWA believes at least the first year of UCMR data will be crucial to giving the agency a better understanding of occurrence of these four additional PFAS. With this additional occurrence information, EPA will have the ability to include this information in a cost-benefit analysis that uses the most current data to calculate the number of systems impacted and any additional health benefits associated with these chemicals at levels known to occur.

EPA Response: Please see section 3.1.2 of the EPA response in this *Response to Comments* document, as well as section 6.8 of the EPA response in this *Response to Comments* document regarding UCMR 5. Additionally, the EPA notes that it considers state promulgated standards as a part of its EA for the proposed and final rule Specifically, to estimate the costs and benefits of the PFAS NPDWR, the EPA assumed that all occurrence model estimates exceeding state limits were equivalent to the state-enacted limit. For these states, the EPA assumed that the state MCL is the maximum baseline PFAS occurrence value for all entry points in the state. This adjustment was made to the occurrence model PFAS estimates for PFOA, PFOS, and PFHxS in the EA. (See chapter 4 in USEPA, 2024a for additional information.).

American Water Works Association (AWWA) (Doc. #1759, SBC-045590)

Alternatively, given that the EPA is currently collecting occurrence data for PFBS in drinking water as part of the UCMR 5 program, EPA could consider re-issuing a preliminary determination for PFBS following the completion of this program.

EPA Response: Please see section 3.1.2 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045585)

However, given that the EPA is currently collecting occurrence data for HFPO-DA in drinking water as part of the UCMR 5 program, EPA could consider reissuing a preliminary determination for HFPO-DA following the completion of this program. This approach would ensure that the best available occurrence data is used.

EPA Response: Please see section 3.1.2 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045588)

However, given that the EPA is currently collecting occurrence data for PFNA in drinking water as part of the UCMR 5 program, EPA could consider re-issuing a preliminary determination for PFNA following the completion of this program. This approach would ensure that the best available data is utilized, not only occurrence data but also a forthcoming health assessment for PFNA under IRIS program (EPA, 2023b).

EPA Response: Please see sections 3.1.1 and 3.1.2 of the EPA response in this *Response to Comments* document.

Metropolitan Water District of Southern California (Doc. #1777, SBC-045429)

2. EPA should consider data from UCMR 5 and updated treated drinking water occurrence data from states for PFHxS, GenX chemicals, PFNA, and PFBS

As currently written, EPA proposes considering the UCMR 5 data to support the implementation of monitoring requirements under the proposed rule. However, UCMR 5 monitoring started in January 2023 and will not be completed until December 2025, and EPA expects to finalize this NPDWR Rulemaking by the end of 2023. [FN9: https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas; 88 Fed. Reg. at 18690.] It is unclear how EPA would access all the necessary UCMR 5 data before 2025 and finalize this NPDWR Rulemaking by the end of 2023, two years before UCMR 5 monitoring will be completed. Furthermore, as EPA states, "Additional nationwide monitoring data will be conducted between 2023-2025 under the UCMR 5. This data will serve to demonstrate whether the four PFAS are known to occur. [H]owever, EPA has sufficient evidence now to support a preliminary determination [that] there is a substantial likelihood that these PFAS will occur frequently and at concentrations where they are likely to exceed their respective HRLs based on the increased occurrence trends documented by available information."[FN10: 88 Fed. Reg. at 18651 (emphasis added).] Metropolitan recommends EPA wait until UCMR 5 data become available before making a final determination and proposing NPDWRs and MCLGs for PFHxS, GenX chemicals, PFNA, and PFBS.

EPA Response: Please see section 3.1.2 of the EPA response in this *Response to Comments* document, as well as section 6.8 of the EPA response in this *Response to Comments* document regarding UCMR 5. Please see section VIII of the final rule preamble for use of previously collected data, such as UCMR 5, to support the final rule's initial monitoring requirements.

New England Water Works Association (Doc. #1836, SBC-045378)

Occurrence:

EPA does not yet have a sense of occurrence of the suite of PFAS compounds in drinking water as the Unregulated Contaminant Monitoring Rule (UCMR5) program just commenced at the beginning of this year (2023). EPA's regulatory determination for Perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salt (also known as a GenX chemicals), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS) are based on a very limited data set. UCMR testing has always been an important step in the EPA rulemaking process; waiting for UCMR5 results would provide a more robust data set for determining occurrence across the nation, and establishing the extent of need and sources for funding compliance. EPA should delay promulgation of this rule until it has a chance to vet at least one full year of data obtained through UCMR5.

EPA Response: Please see section 3.1.2 of the EPA response in this *Response to Comments* document.

The Chemours Company FC, LLC (Doc. #1845, SBC-046051)

B. Regulating HFPO-DA under the SDWA would be premature, arbitrary, and capricious based on existing occurrence data showing limited detections and pending the forthcoming UCMR data

i. The SDWA requires EPA to base its decision to regulate a contaminant on occurrence data which are not yet available for HFPO-DA

EPA's decision to issue a national primary drinking water regulation ("NPDWR") for HFPO-DA at this time is premature and procedurally flawed. The SDWA establishes a two-step, data-driven process for EPA to determine whether to regulate unregulated contaminants. EPA's action here circumvents this well-established process under the SDWA and the statute's requirement that regulations be based on supporting scientific data. EPA has proceeded in a manner here that is at odds with the SDWA and that is arbitrary, capricious, and contrary to the principles of best available science.

Occurrence data are central to the statutory process for regulating a new contaminant under the SDWA. Every five years, EPA is required to publish a list of contaminants which may require regulation. 42 U.S.C. [sec] 300g–1(b)(1)(B)(i)(I). Contaminants included on this list are subject to certain reporting requirements under the Unregulated Contaminant Monitoring Rules ("UCMRs"). 40 C.F.R. [sec] 141.40(a); Id. [sec] Data collected under this rule are then published in an occurrence data base under 42 U.S.C. [sec] 300j–4(g).

Every five years, EPA must evaluate at least five contaminants on the UCMR list and issue determinations on whether or not to regulate the contaminants. 42 U.S.C. [sec] 300g–1(b)(1)(B)(ii)(I). A decision to regulate must be based on findings that:

(i) the contaminant may have an adverse effect on the health of persons;

(ii) the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and

(iii) in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

42 U.S.C. [sec] 300g–1(b)(1)(A).

Critically, these required findings "shall be based on the best available public health information, including the occurrence data base established under section 300j-4(g) of this title." 42 U.S.C. [sec] 300g–1(b)(1)(B)(ii)(II) (emphasis added). Even for contaminants which do not first appear on a UCMR list, EPA has the same obligations to base its findings on the best available public health information, including the occurrence data base. 42 U.S.C.

[sec] 300g–1(b)(1)(B)(ii)(III).

This two-step data-driven SDWA process has for decades ensured that EPA decisions to issue NPDWRs for new contaminants—decisions which often have major economic impacts—are based on the best available science. Indeed, Chemours is not aware of any other contaminant for which EPA has issued a NPDWR without first publishing UCMR occurrence data.

Yet for HFPO-DA, EPA proposes to issue drinking water regulations in the absence of any such data. HFPO-DA was first included in a UCMR list in December 2021. 86 Fed. Reg. 73,131 (Dec. 27, 2021). In that rule, EPA itself acknowledged that the SDWA requires EPA to "maintain UCMR data in the [National Contaminant Occurrence Database] and use the data when evaluating the frequency and level of occurrence of contaminants in drinking water at a level of public health concern." Id. at 73,136 (emphasis added).

The required monitoring period for HFPO-DA will run from 2023 to 2025, and no UCMR data for HFPO-DA was available at the time EPA issued its proposed regulations. As such, it is impossible for EPA to have "use[d] the data when evaluating the frequency and level of occurrence" of HFPO-DA or to have made its required findings to regulate "based on…the occurrence data base" as mandated by the SDWA. Id.; 42 U.S.C. [sec] 300g– 1(b)(1)(B)(ii)(II). Finalizing the proposed drinking water regulation for HFPO-DA at this time would therefore violate EPA's obligations under the SDWA.

Further, if EPA intends to consider UCMR data for HFPO-DA for a final rulemaking, EPA must repropose regulations in order to allow the public an adequate opportunity to comment on EPA's interpretation of that UCMR data. When determining whether additional rounds of notice and comment are required to comply with fair notice obligations under the Administrative Procedure Act, agencies should consider "whether a new round of notice and comment would provide the first opportunity for interested parties to offer comments that could persuade the agency to modify its rule." American Water Works Ass'n v. EPA, 40 F.3d 1266, 1274 (D.C. Cir. 1994). Indeed, an agency "must provide sufficient factual detail and rationale for the rule to permit interested parties to comment meaningfully." Nat'l Lifeline Ass'n v. Fed. Commc'ns Comm'n, 921 F.3d 1102, 1115 (D.C. Cir. 2019). Here, EPA is required to base its core findings to regulate HFPO-DA on UCMR occurrence data, but EPA has not yet published any such data for HFPO-DA. 42 U.S.C. [sec]300g–1(b)(1)(B)(ii)(II). [FN4: Further, the limited non-UCMR data summary that EPA does present, discussed in the subsection below, lacks clear references to the underlying data sets, preventing interested parties from conducting independent analysis.] If EPA intends for this rulemaking to rely on any such data, once it becomes available, EPA needs to provide the public with new notice and opportunity to comment in light of the essential information that such data would provide.

EPA Response: Please see section 3.1.2 of the EPA response in this *Response to Comments* document regarding the EPA's regulatory determination for HFPO-DA, as well as section 6.8 of the EPA response in this *Response to Comments* document and section VI.G of the final rule preamble regarding UCMR 5. Additionally, the EPA disagrees that the agency has circumvented the established process for developing NPDWRs or is acting arbitrarily. The EPA implements a monitoring program for unregulated contaminants (i.e., UCMR) under SDWA

1445(a)(2) that requires the EPA to issue a list once every five years of priority unregulated contaminants to be monitored by PWSs; however, contrary to the commenter's statement that the EPA has violated its obligations under SDWA, there is no statutory obligation that a contaminant must be monitored under the UCMR program prior to making a determination to regulate, if the agency has sufficiently available information through other sources.

Pertaining to the commenter's statement, "Chemours is not aware of any other contaminant in which the EPA has issued an NPDWR without first publishing UCMR data", the agency notes that it has completed multiple regulations since the passage of the 1996 SDWA amendments which did not have UCMR data, including the Revised Total Coliform Rule (RTCR), Long Term 2 Enhanced Surface Water Treatment Rule (LT2), and the Stage 2 Disinfectants and Disinfection Byproducts Rule. The robust amount of state occurrence data for HFPO-DA represents the current best available information and demonstrate sufficient likelihood of occurrence of the PFAS being regulated, as required under SDWA.

Specific to commenter's statements about the occurrence database under 42 U.S.C. [sec] 300j–4(g), although preliminary and partial UCMR 5 results appear in the 1445(g) database as of the date of this final rule, the EPA does not consider such results to be "best available" until the full monitoring cycle is complete because UCMRs are designed to yield statistically valid and nationally representative data that can be used to inform decisions once complete. Because at the time of the EPA's rule, UCMR 5 data are preliminary and partial, they are not considered "best available" and thus are not a basis for this final rule. The reference to "use of data" in the UCMR 5 FRN discussed by the commenter is referring to use of a complete and final UCMR 5 dataset.

The agency further disagrees with the commenter's claim that the non-UCMR data presented in the proposed rule lacked clear references to the underlying datasets as this information was transparently provided through references within the *Occurrence Technical Support Document* and available for review and opportunity for comment during the full public comment period. Specifically, in this document, the EPA cites at least 18 underlying datasets containing approximately 10,000 sample results of HFPO-DA in drinking water from 16 states with clear information and links how to access the datasets directly from that support document. The commenter's failure to review those datasets which were clearly available in the rule proposal is not grounds for delaying this regulation. In the final regulation, based on public comment, the EPA updated the occurrence information and final rule *Occurrence Technical Support Document* (USEPA, 2024b) to include over 35,000 sample results of HFPO-DA from 25 states. These updated results were confirmatory of the EPA's findings related to HFPO-DA occurrence and co-occurrence with other PFAS in the proposal.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045961)

To reiterate, AMWA was and is extremely supportive of the Regulatory Determination to regulate PFOA and PFOS. EPA has the option to move forward with the PFOA and PFOS rulemaking, as the statutory deadline of that Regulatory Determination only applies to those two

contaminants based on the timeline outlined under SDWA. EPA can still choose to regulate these four additional PFAS in an expedited manner after a Regulatory Determination is finalized utilizing UCMR 5 data, but AMWA stresses the importance of the UCMR 5 data EPA will soon receive. This UCMR 5 dataset will also fill in some gaps in the cost-benefit analysis regarding this determination and proposal, which is currently missing. Additionally, as the decision in NRDC v. Michael Regan [FN14: NRDC v. Michael Regan. No. 20-1335. U.S. Court of Appeals. (2023, May 9). https://www.cadc.uscourts.gov/internet/opinions.nsf/E8EC4867311BA7BA852589AA0052854F/$file/20-1335-1998466.pdf] demonstrated, once a positive determination is made, even if the UCMR 5 data later show very little to no occurrence, EPA cannot "backslide" or reverse its decision to regulate the contaminant(s). AMWA wants EPA to make the best decision possible on these four chemicals to protect the public's health by ensuring its decisions are well-informed and that the public does not incur unnecessary costs.

EPA Response: Please see section 3.1.2 of the EPA response in this *Response to Comments* document. Additionally, regarding UCMR 5, please see section 6.8 of the EPA response in this *Response to Comments* document.

Bowling Green Municipal Utilities (Doc. #1767, SBC-043928)

Inadequate Basis for Regulatory Determinations: EPA's positive regulatory determinations for perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO-D or GenX), and perfluorobutanesulfonic acid (PFBS) rely on very limited relevant occurrence data. Under Safe Drinking Water Act (SDWA), EPA has a responsibility to demonstrate that regulatory requirements are for contaminants that occur or are likely to occur at levels of public health concern in drinking water and that there is a meaningful opportunity for health risk reduction through a drinking water standard.

EPA Response: Please see section 3.1.2 of the EPA response in this *Response to Comments* document.

3.1.3 EPA's Preliminary Regulatory Determinations for PFHxS, PFNA, HFPO-DA, and PFBS – Statutory Criterion #3 Meaningful Opportunity

Summary of Major Public Comments and EPA Responses

The EPA received many comments on the agency's evaluation of the third statutory criterion under Section 1412(b)(1)(A) of SDWA. Most commenters supported the EPA's evaluation under the preliminary determination that individual regulation of PFHxS, PFNA, HFPO-DA, and PFBS presents a meaningful opportunity for health risk reduction and that the EPA has sufficiently justified this statutory criterion as well as the health and occurrence criterion. This included comments highlighting the extensive amount of work done by several states developing regulatory and non-regulatory levels for several PFAS compounds, including the PFAS for which the EPA is making regulatory determinations individually. These commenters also noted

the need for a consistent national standard for use in states where a state-specific standard has not yet been developed. Several commenters have also noted that although some states have developed or are in the process of developing their own state-level PFAS drinking water standards, regulatory standards currently vary across states. These commenters expressed concern that absence of a national drinking water standard has resulted in risk communication challenges with the public and disparities with PFAS exposure. Some commenters noted there are populations particularly sensitive or vulnerable to the health effects of these PFAS, including newborns, infants, and children. The EPA agrees with commenters that there is a need for a national PFAS drinking water regulation and that moving forward with a national-level regulation for PFHxS, PFNA, HFPO-DA, mixtures of these three PFAS and PFBS, as well as PFOA and PFOS, will provide improved national consistency in protecting public health and may reduce regulatory uncertainty for stakeholders across the country.

A few commenters expressed support for the EPA's evaluation of meaningful opportunity based on the treatment technologies which can remove the six PFAS for which the EPA is finalizing regulation. Furthermore, these commenters noted the meaningful opportunity to not only provide protection from the six regulated PFAS, but also other PFAS that will not be regulated as a part of this action.

Several commenters did not support the EPA's evaluation of the third statutory criterion, offering that in their opinion the EPA failed to justify there is a meaningful opportunity for health risk reduction for the PFAS individually and stating that the EPA should consider other factors such as costs. A few of these commenters wrote that the EPA provided limited rationale and factors for its meaningful opportunity determination. The EPA disagrees with these commenters that the agency failed to justify that there is meaningful opportunity for health risk reduction or that the EPA provided limited rationale and factors in its meaningful opportunity evaluation for these contaminants individually. As described in the EPA's March 2023 proposal and in section III.D. of the final rule preamble, the EPA fully considered many factors including individual contaminant toxicity and health effects, individual contaminant occurrence at frequencies and levels of public health concern, availability of similar treatment technologies to remove these four PFAS and analytical methods to measure them, and their individual chemical and physical properties leading to their environmental persistence. Additionally, the EPA notes in the proposed and final rule preamble, and as demonstrated through representative occurrence data, for the three contaminants individual occurrence is not only at a regional or local level, rather it covers multiple states throughout the country; therefore, a national level regulation is necessary to ensure all Americans served by PWSs are equally protected.

Some comments indicate that the health and occurrence information do not support that establishing drinking water standards presents a meaningful opportunity for health risk reduction The agency disagrees with the commenters' assertion that the health and occurrence information are insufficient to justify a drinking water standard as supported in sections III.B. and III.C. of the final rule preamble, and the agency finds that there is a meaningful opportunity for health risk reduction potential based upon multiple considerations including the population exposed to

PFHxS, PFNA, and HFPO-DA including sensitive populations and lifestages, such as newborns, infants and children.

Other comments assert that the EPA must evaluate the potential implementation challenges and cost considerations of regulation as part of the meaningful opportunity evaluation. The EPA disagrees with these commenters. The SDWA states that that the meaningful opportunity for health risk reduction for persons served by PWSs is in the sole judgement of the Administrator and does not require that the EPA consider costs for a regulatory determination. The SDWA does require that costs and benefits are presented and considered in the proposed rule's Health Risk Reduction Cost Analysis (HRRCA) which the EPA did for the proposal and has updated as a part of the final rule within section XII.

A few other commenters provided that due to all of the additional human health exposure pathways other than drinking water for these PFAS, that regulation of drinking water would not represent a meaningful opportunity for overall health risk reduction. While the EPA recognizes that drinking water is one of several exposure routes, the EPA disagrees with these commenters. Removing the PFAS that have been found to occur or are substantially likely to occur from drinking water systems will result in a significant improvement in public health protection. The EPA also notes that through its PFAS Strategic Roadmap and associated actions, the agency is working expeditiously to address PFAS contamination in the environment and reduce human health PFAS exposure through all pathways. While beyond the scope of this rulemaking, the EPA is making progress implementing many of the commitments in the Roadmap, including those that may significantly reduce PFAS source water concentrations.

Individual Public Comments

Superfund Settlements Project (SSP) and RCRA Corrective Action Project (RCAP) (Doc. #1631, SBC-043437)

• Based on the foregoing, EPA cannot reasonably conclude that regulation of these four PFAS would present a meaningful opportunity for health risk reduction, and the Proposed Rule fails in any effort to so justify. EPA has gotten ahead of the science and data and, consequently, has issued a Proposal that is premature and overly conservative

EPA Response: Please **s**ee section 3.1.3 of the EPA response in this *Response to Comments* document.

Consumer Reports (Doc. #1656, SBC-043182)

In terms of a meaningful opportunity to reduce the health risk of these 4 PFAS by regulating them, in addition to showing that the four PFAS and their mixtures cause adverse health impacts, and occur in the drinking water at frequencies and levels of public health concern, the data also show that PFHxS, GenX chemicals, PFNA, and PFBS and their mixtures are environmentally

persistent. In addition, there are validated EPA-approved methods to measure PFHxS, GenX chemicals, PFNA, and PFBS, and mixtures of these contaminants.

Finally, there are available technologies–including granular activated carbon (GAC), AIX resins, reverse osmosis (RO), and nanofiltration (NF)–that are capable of reducing PFHxS, GenX chemicals, PFNA, and PFBS. A number of these technologies, particularly the ones using sorptive and high-pressure membrane technologies, have been shown to remove PFHxS, GenX chemicals, PFNA, and PFBS, and their mixtures and have also been documented to remove other PFAS contaminants2 [FN2: McCleaf, P., Englund, S., Östlund, A., Lindegren, K., Wiberg, K., and Ahrens, L. 2017. Removal Efficiency of Multiple Poly-and Perfluoroalkyl Substances (PFASs) in Drinking Water using Granular Activated Carbon (GAC) and Anion Exchange (AE) Column Tests. Water Research, 120(2017):77–87. https://doi.org/10.1016/j.watres.2017.04.057; Sörengård, M., Östblom, E., Köhler, S., and Ahrens, L. 2020. Adsorption Behavior of Per-and Polyfluoralkyl Substances (PFASs) to 44 Inorganic and Organic Sorbents and Use of Dyes as Proxies for PFAS Sorption. Journal of Environmental Chemical Engineering, 8(3):103744. https://doi.org/10.1016/j.jece.2020.103744; Mastropietro, T.F., Bruno, R., Pardo, E., and Armentano, D. 2021. Reverse Osmosis and Nanofiltration Membranes for Highly Efficient PFASs Removal: Overview, Challenges and Future Perspectives. Dalton Transactions, 50(16):5398–5410. https://doi.org/10.1039/d1dt00360g]. Given that these removal/mitigation technologies can remove multiple PFAS, we agree with EPA that regulation of PFHxS, GenX chemicals, PFNA, and PFBS, and their mixtures will provide protection from PFAS that will not be regulated as part of this proposed NPDWR.

EPA Response: Please **s**ee section 3.1.3 of the EPA response in this *Response to Comments* document.

Wisconsin Department of Justice et al. (Doc. #1687, SBC-044445)

c. EPA's proposed PFAS drinking water standards present a meaningful opportunity for health risk reduction.

EPA correctly found that regulating the six PFAS subject to this rule presents a meaningful opportunity for health risk reduction for consumers of drinking water from public water systems. Four technologies are available to reduce the concentrations of these PFAS in water: granular activated carbon (GAC), aqueous ion exchange (AIX) resins, reverse osmosis (RO), and nanofiltration (NF). Because the four PFAS co-occur with other PFAS for which the Agency is not currently making a preliminary regulatory determination, regulation of the four PFAS represents a meaningful opportunity to reduce the overall public health risk from all other PFAS that co-occur and are co-removed with them. [FN29: 88 Fed. Reg at 18651.] In the rulemaking, EPA proposes these four technologies as Best Available Technologies, after considering: (1) the capability of a high removal efficiency; (2) a history of full-scale operation; (3) general geographic applicability; (4) reasonable cost based on large and metropolitan water systems; (5) reasonable service life; (6) compatibility with other water treatment processes; and (7) the ability

to bring all the water in a system into compliance. [FN30:Id. at 18683.] These technologies have demonstrated PFAS removal efficiencies that can exceed 99 percent, [FN31:Id. at 18684-85] with EPA finding GAC and AIX resins to be the most affordable technologies over a range of small water system sizes. [FN32:Id. at 18687-88.] The PFAS Rule is well justified because the standards present a meaningful opportunity to reduce human health risk.

EPA Response: Please **s**ee section 3.1.3 of the EPA response in this *Response to Comments* document.

City of Lancaster, Pennsylvania (Doc. #1695, SBC-044995)

4. Labeling the PFAS Chemicals as a Hazardous Chemical: By labeling this chemical family as hazardous there is a massive list of complications that need to be considered.

As stated by the EPA Technical Fact Sheet on PFAS, water is 20% of the PFAS exposure for most individuals and this regulation is clamping down on the water suppliers who received the contaminants from other point and non-point sources. 80% of the PFAS exposure comes from people's food sources and other products they live with in their daily lives. There have been studies showing that the wrappers for chocolate cake mix contain 1,700 ppt which is 425 times the water MCL. Many food products are known to have these chemicals, and this creates two distinct problems for the EPA.

Regulating prematurely is in effect penalizing the water industry that neither creates nor pollutes with PFAS. It will not stop the exposure of 80% of the contamination sources and it will not protect the citizenry of the US from exposing themselves to the major products/sources that contaminate with PFAS. This will have repercussions financially for many industries and create a cost that many industries will not be able to overcome. Irresponsible regulation has the potential to negatively impact the economy.

EPA Response: The EPA disagrees that regulation of these PFAS in public drinking water systems will not result in significant improvements in public health protection. Please see section 3.1.3 of the EPA response in this *Response to Comments* document. Regarding evaluation of the costs and benefits of the rule under the HRRCA, as required under SDWA, please see section XII of the final rule preamble and section 13 of this document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045894)

C. EPA has not demonstrated that this proposed regulation presents a "meaningful opportunity" for health risk reduction

Although the final element of the regulatory determination provides some discretion to define what constitutes a meaningful opportunity to address health risk reduction, that discretion is not unlimited. The Administrator's decision must be grounded on data, consider the costs of the decision, and have an articulable and understandable demonstration that the choice made is rationally related to the facts. It cannot be random choice without any reason or system.

EPA has failed to demonstrate with an adequate basis that the proposal to regulate PFNA, PFHxS, PFBS, and HFPO-DA (and mixtures of these PFAS) presents a meaningful opportunity for health risk reduction for persons served by the over 66,000 public water systems potentially impacted by this rulemaking. Keeping in mind that cost considerations are heavily imbedded in multiple elements of SDWA, those considerations are necessarily implicated in determining what is "meaningful." Failure to consider costs at this stage omits an essential element of the process that EPA must undertake before regulating these PFAS in public water systems, many of which are very small. EPA must also consider the downstream costs to the industries that rely on public water systems.

EPA provides very limited rationale for its meaningful-opportunity determination, primarily resting on speculative potential benefits. The proposal discusses the need to address the four PFAS due to the potential adverse human health effects, potential for co-exposures of these PFAS, and the availability of analytical methods to measure and treatment technologies (irrespective of costs) to remove them from drinking water. EPA does not enumerate a list of factors for its consideration of a meaningful opportunity for health risk reductions. In the past, EPA has looked to occurrence data and populations served by water systems to support a positive or negative determination based on the "meaningful opportunity" factor [FN52: 86 Fed. Reg. at 12283.]. As discussed, the health data and the occurrence data for the four PFAS do not support such a determination.

Further, EPA does not factor in costs in its justification that there are treatment technologies available to remove the PFAS from drinking water. Even if these technologies are available, there will be a limited supply of technologies available for the thousands of water systems that will suddenly need them all at the same time, and high costs for public water systems to implement and maintain the treatment technologies. EPA has not assessed the impact of a shift in demand on GAC, ion-exchange resin, and membrane markets. Compliance with the rule would be cost-prohibitive and may result in systems having to shut down or pass the high costs down to their ratepayers. EPA must consider the extraordinary compliance challenges and costs that this rule would impose on water systems, and those industries that rely on these water systems, for regulating the four PFAS because these factors impact whether this approach to regulate the PFAS is a "meaningful" opportunity to reduce health risk.

In conclusion, absent substantial evidence in the record to support the three statutory criteria of health effects, occurrence, and a meaningful opportunity for health risk reduction, EPA's preliminary determination to regulate PFNA, PFBS, PFHxS, and HFPO-DA is arbitrary and capricious and contrary to the requirements of SDWA.

EPA Response: Please **s**ee section 3.1.3 of the EPA response in this *Response to Comments* document. Section 1412(b)(1)(A)(2)(iii) provides that "in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems." Accordingly, the EPA has followed SDWA, and based on the available information, the EPA Administrator has, in their sole judgement and as provided explicitly through the statute, made this determination. The EPA has

thoroughly evaluated the commenter's concerns and information provided to consider whether the comments would impact the administrator's judgement; however, whether there is a meaningful opportunity for health risk reduction remains a determination in the sole judgement of the EPA Administrator. Importantly, the EPA disagrees with commenter's unfounded assertion that the Administrator's judgement for these regulatory determinations is "not grounded in data" or that "the choice was not rationally and related to the facts" as the commenter claims. Further, the EPA disagrees with the commenter's assertion that it does not enumerate a list of factors for its consideration of a meaningful opportunity for health risk reductions or that it did not provide information on the occurrence data and populations served by water systems to support the determination. The Administrator's reasoning is clearly articulated through the availability of this exact information in section III of the final rule preamble. Furthermore, the agency used its Protocol developed under Regulatory Determination 3 (USEPA, 2014) and also used in the Regulatory Determination 4. Hence, this evaluation is clearly not random as the commenter claims, and includes a comprehensive assessment of meaningful opportunity for each unique contaminant including the nature of the health effects, sensitive populations affected, including infants, children and pregnant and nursing women, number of systems potentially affected, and populations exposed at levels of public health concern, geographic distribution of occurrence, technologies to treat and measure the contaminant, among other factors. For the EPA's specific evaluation of the health and occurrence statutory criteria for regulation and the EPA's responses, please see sections 3.1.1 and 3.1.2, respectively, in this *Response to Comments* document.

Environmental Working Group (EWG) (Doc. #1721, SBC-045406)

The EPA should finalize the proposed drinking water standard as quickly as possible.

Drinking water standards for PFAS are long overdue. The EPA has known about the risks associated with PFAS since at least 1998 and was alerted to the presence of PFAS in drinking water by at least 2001. [FN10: Env't Working Grp., For 20-plus years, EPA has failed to regulate 'forever chemicals' (Jan. 9, 2020). https://www.ewg.org/research/20-plus-years-epa-has-failed-regulate-forever-chemicals.] For decades, millions of Americans have been exposed to unsafe levels of PFAS in their drinking water. The EPA's proposed MCLs and health-based water concentrations (HBWCs) show that PFOA, PFOS, GenX, PFBS, PFHxS, and PFNA are likely toxic at lower levels than all other regulated contaminants under the Safe Drinking Water Act (SDWA), including contaminants like ethylene dibromide, regulated at 50,000 ppt in drinking water,[FN11: Env't Prot. Agency, National Primary Drinking Water Regulations, https://www.epa.gov/ground-water-anddrinking-water/national-primary-drinking-water-regulations (last updated January 26, 2022).] and dioxin (2,3,7,8-TCDD), regulated at 30 ppt in drinking water. [FN12:Id.]

Treating PFAS in drinking water presents a meaningful opportunity to reduce exposure and consequent health risks. Quick action by the EPA to finalize the proposed MCLs will dramatically reduce levels of PFOA, PFOS, PFNA, PFHxS, PFNA, PFBS, and GenX in drinking

water. Drinking water is a major exposure pathway for PFAS chemicals, accounting for roughly twenty percent of exposure. [FN13: PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18638, 18654, 18664-65, 18670 (March 29, 2023).] In highly contaminated communities, drinking water likely accounts for an even larger percentage of exposure. Reducing exposure through drinking water will lower PFAS levels in blood, improving health outcomes. Levels of PFOA and PFOS in blood have dropped dramatically because of the EPA agreement with manufacturers to phase out the use of PFOA and PFOS by 2015. According to analysis of the National Health and Nutrition Examination Survey, which has measured PFAS in blood in the U.S. population since 1999, from 1999-2000 to 2017-2018 levels of PFOA in blood have declined more than 70 percent and levels of PFOS in blood have declined more than 85 percent. [FN14: Agency for Toxic Substances and Disease Registry, PFAS in the U.S. Population, https://www.atsdr.cdc.gov/pfas/health-effects/us-population.html (last reviewed Dec. 22, 2022).]

Epidemiological evidence also links reductions in PFAS in drinking water to lower PFAS blood levels. For example, a 2017 analysis looked at PFOA blood serum levels over time in both Cincinnati and in a Northern Kentucky suburb. Both communities are downriver from the Washington Works Plant in Parkersburg, West Virginia and use the Ohio River as a drinking water source. In 1992, Cincinnati began treating its drinking water with granular activated carbon, but Northern Kentucky did not adopt any treatment technologies that would reduce PFAS levels in finished tap water. The researchers noted that PFOA levels in blood serum went down during the 1990s in Cincinnati but rose in Northern Kentucky. The researchers concluded that difference in blood serum levels was likely attributable to the granular activated carbon technology adopted in Cincinnati, which is effective at filtering PFOA. [FN15: Robert L. Herrick et al., Polyfluoroalkyl Substance Exposure in the Mid-Ohio River Valley, 1991-2012, 228 ENV'T POLLUTION 50 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5540235/.]

PFAS are highly persistent in the environment, earning them the moniker "forever chemicals."[FN16: Joseph Allen, These Toxic Chemicals are Everywhere—Even in your Body. And They Won't Ever Go Away, WASHINGTON POST (Jan. 2, 2018), https://www.washingtonpost.com/opinions/these-toxic-chemicals-are-everywhere-and-they-wont-ever-go-away/2018/01/02/82e7e48a-e4ee-11e7-a65d-1ac0fd7f097e_story.html.] PFAS bioaccumulate in the blood [FN17: Half-life estimates range from over two years from PFOA and PFNA to 5.4 years for PFOS to 8.5 years for PFHxS. See ANNA READE, TRACY QUINN, & JUDITH S. SCHREIBER, NAT. RES. DEF. COUNCIL, SCIENTIFIC & POLICY ASSESSMENT FOR PER- AND POLYFLUOROALKYL SUBSTANCES IN DRINKING WATER at 12 (April 12, 2019), https://www.nrdc.org/sites/default/files/media-uploads/nrdc_pfas_report.pdf.] and other organs [FN18: Francisca Perez et al., Accumulation of Perfluoroalkyl Substances in Human Tissues, 59 ENV'T INT'L 354 (2013), https://pubmed.ncbi.nlm.nih.gov/23892228/.] where they can stay for long periods, even decades. For communities already devastated by decades of unwitting exposure through drinking water, relief cannot come soon enough. Although the EPA's statutory deadline is not until

September 2024, we urge the EPA to finalize the proposed rule well ahead of the deadline so that the proposed regulations can be implemented as quickly as possible.

EPA Response: Please **s**ee section 3.1.3 of the EPA response in this *Response to Comments* document.

Environmental Working Group (EWG) (Doc. #1721, SBC-045409)

It is appropriate and necessary for the EPA to make the additional regulatory determinations and propose the additional NPDWRs to address the urgent public health risks presented by PFHxS, PFNA, PFBS, and GenX. As detailed in the proposed rule, there is a significant body of scientific evidence associating adverse health effects with exposure to PFHxS, PFNA, PFBS, and GenX. [FN23: PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18638, 18645-47 (March 29, 2023).] Three of those four PFAS—PFBS, PFHxS, and PFNA—are widely detected at military bases [FN24: Melanie Benesh, The Pentagon Should Address All Types of PFAS on Military Bases, ENV'T WORKING GRP. (May 26, 2020), https://www.ewg.org/news-insights/news/pentagon-should-address-all-types-pfas-military-bases.] and all four have been detected in drinking water monitoring. [FN25: PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18638, 18671-80 (March 29, 2023).] Off the shelf technology is available to treat all four PFAS in drinking water—creating a meaningful opportunity for health risk reduction.

EPA Response: Please **s**ee section 3.1.3 of the EPA response in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-045675)

Moreover, EPA's decision to regulate the HI substances as a mixture led to an inflated sense of the opportunity for risk reduction. In the section on this criterion, the only factors considered discussed the substances as a group. There was no analysis of how, individually, the substances presented a meaningful opportunity to reduce risk to the public (Section VII). This omission violates the requirements for regulating new substances under the SDWA.

EPA Response: Please **s**ee section 3.1.3 of the EPA response in this *Response to Comments* document. The EPA disagrees that it only discussed the PFAS as a group as shown in section III.D. of the final rule preamble where it discussed both the regulatory determination for PFHxS, PFNA, and HFPO-DA individually and the regulatory determination for mixtures of these three PFAS and PFBS. For the EPA's responses related to meaningful opportunity of the determination to regulate mixtures of PFHxS, PFNA, HFPO-DA, and PFBS, please see section 3.2.3 of the EPA response in this *Response to Comments* document.

Ohio Environmental Council (Doc. #1794, SBC-045323)

Because drinking water is a significant pathway of PFAS exposure, addressing contamination before it reaches our taps is key to reducing associated health problems. The Safe Drinking Water Act requires that national drinking water standards present a meaningful opportunity to reduce health risks. EPA's proposal does just that – it would significantly reduce exposure to PFAS in drinking water and as a result, lower risks of related health impacts.

EPA Response: Please **s**ee section 3.1.3 of the EPA response in this *Response to Comments* document.

Environmental Working Group et al. (Doc. #1810, SBC-044687)

Because drinking water is a significant pathway of PFAS exposure, addressing contamination before it reaches our taps is key to reducing associated health problems. The Safe Drinking Water Act requires that national drinking water standards present a meaningful opportunity to reduce health risks. EPA's proposal does just that – it would significantly reduce exposure to PFAS in drinking water and as a result, lower risks of related health impacts.

EPA Response: Please **s**ee section 3.1.3 of the EPA response in this *Response to Comments* document.

Midwest Environmental Advocates +more (Doc. #1846, SBC-045828)

C. Regulation presents a meaningful opportunity to reduce the risk that PFAS poses to Wisconsin' residents.

Wisconsin's residents who rely on the state's public water systems for drinking water will benefit from the proposed regulation. As described above, these PFAS may cause adverse health effects and they occur frequently in public water systems throughout Wisconsin, often together, at levels that pose a serious risk to public health. The best available science and occurrence data from the state supports EPA's judgement about the pressing need to reduce health risks from PFAS exposure via drinking water. Thus, commenters support the proposed rule as a meaningful opportunity to reduce health risks to the people of Wisconsin and nationwide.

EPA Response: Please **s**ee section 3.1.3 of the EPA response in this *Response to Comments* document.

New York State Department of Health (NYS DOH) (Doc. #1677, SBC-044954)

16. EPA requested comment on the regulation of GenX compounds as part of this proposed rulemaking. Based on monitoring conducted in NYS to date, four public water systems are known to be above the health-based standard of 10 ppt. Although we do not oppose regulation of GenX compounds, the benefit of this regulation will not likely be widespread in New York.

EPA Response: Please see section 3.1.3 of the EPA response in this *Response to Comments* document. Additionally, as often observed, specific contaminant occurrence can be site-dependent, and while a contaminant may not occur as the same levels in all localities and states, the EPA has demonstrated that PFHxS, PFNA, and HFPO-DA occur or there is a substantial likelihood they will occur with a frequency and level of public health concern across various geographic areas of the country. For the EPA's response on the individual occurrence statutory criterion, please see section 3.1.2 in this *Response to Comments* document.

Alliance of Nurses for Healthy Environments (Doc. #1544, SBC-042669)

Because drinking water is a significant pathway of PFAS exposure, addressing contamination before it reaches our taps is key to reducing associated health problems. The Safe Drinking Water Act requires that national drinking water standards present a meaningful opportunity to reduce health risks. EPA's proposal does just that –instituting regulations with the capacity to significantly reduce exposure to PFAS in drinking water and as a result, lower risks of related health impacts.

EPA Response: Please see section 3.1.3 of the EPA response in this *Response to Comments* document.

Environmental Protection Network (EPN) (Doc. #1773, SBC-043841)

Preliminary Determination

The Safe Drinking Water Act (SDWA) requires EPA to consider the following three criteria when making a determination to regulate: 1) the contaminant may have an adverse effect on the health of persons; 2) the contaminant is known to occur or there is a high chance that it will occur in public water systems often enough and at levels of public health concern; and 3) in the sole judgment of the Administrator, regulation of the contaminant presents a meaningful opportunity for health risk reductions for persons served by public water systems.

EPA considered many scientific studies demonstrating that these four PFAS chemicals have adverse effects on multiple biological systems and functions, including thyroid hormone levels, lipid synthesis and metabolism, fetal and infant development, and immune and liver function. EPA also considered data from UCMR3 and twelve state monitoring programs showing that these four chemicals occur above levels of concern in public water systems serving millions of people. Clearly the Administrator can conclude that regulation of these four PFAS compounds presents a meaningful opportunity for health risk reductions for persons served by public water systems.

EPA Response: Please see section 3.1.3 of the EPA response in this *Response to Comments* document.

Missouri Department of Natural Resources (Doc. #1563, SBC-042516)

EPA requests comment on its evaluation that regulation of PFHxS, HFPO–DA, PFNA, PFBS, and their mixtures, in addition to PFOA and PFOS, will provide protection from PFAS that will not be regulated under this proposed rule.

As noted in our previous comment, the Department believes that regulation of PFHxS, HFPO–DA, PFNA, PFBS, and their mixtures should be deferred until after UCMR 5 data is evaluated for all 29 PFAS at the order of magnitude lower detection limits than those used during the UCMR 3 nationwide occurrence study. It makes sense that where a system installs treatment to address these proposed PFAS, it will also address other unregulated contaminants. However, it is unknown to what extent adding these four PFAS mixtures will have to increase protection without further study of the co-occurrence and health impacts of other unregulated PFAS mixture contaminants. In addition to evaluating whether the regulation of PFOA and PFOS and the four PFAS included in the hazard index will provide protection from unregulated PFAS, EPA should also evaluate whether regulation of PFOA and PFOS alone would produce similar protections from unregulated contaminants. States that have already required systems to install PFAS treatment will also have raw water data showing concentrations and mixtures of PFAS that caused the need for the treatment. The data from more than 23 states can then be used to show what effect treatment has on occurrence data obtained from UCMR 5.

EPA Response: Regarding meaningful opportunity to regulate PFHxS, PFNA, HFPO-DA, PFBS, and mixtures of these four PFAS, please see sections 3.1.3, and 3.2.3 of the EPA response in this *Response to Comments* document. Please see sections 3.1.2, 3.2.3, and 6.3 of the EPA response in this *Response to Comments* document regarding PFAS occurrence and co-occurrence.

3.2 EPA's Preliminary Regulatory Determination Summary – Mixture of Four PFAS

Summary of Major Public Comments and EPA Responses

As discussed in comments within section 3.1.1, several commenters expressed support for the EPA's preliminary regulatory determinations to individually regulate PFHxS, PFNA, HFPO-DA, and PFBS. The majority of these same commenters also expressed support to regulate mixtures of PFHxS, PFNA, HFPO-DA, and/or PFBS, including that the EPA has appropriately determined that the three statutory criteria for regulation have been met for mixtures of the four contaminants using the best available information. Conversely, many other commenters that did not agree that the agency presented sufficient information to make a preliminary determination for PFHxS, PFNA, HFPO-DA, and PFBS individually also did not agree that the EPA presented sufficient information to regulate mixtures of the four contaminants, with some commenters similarly recommending that that the agency withdraw the portion of the proposed rule associated with these mixtures because in their view there is insufficient health effects and/or occurrence data at this time to support the EPA's action. The EPA disagrees with these

commenters because there is information to support the regulation of mixtures of PFHxS, PFNA, HFPO-DA, and/or PFBS, based on the three statutory criteria as discussed in the final rule preamble in section III.B, C, and D.

The EPA received comments on its statutory authority to regulate mixtures of PFHxS, PFNA, HFPO-DA, and/or PFBS, specifically the agency's interpretation under Section 1401(6) that a mixture of two or more contaminants also qualifies as the definition of a contaminant under SDWA since a mixture itself meets the same definition. A few commenters disagreed and contended that a mixture does not meet the definition of being a single contaminant under SDWA, with some citing Toxic Substances Control Act's (TSCA) definition of a chemical substance. The EPA disagrees with these commenters. First, the EPA notes that TSCA's definitions are not relevant to SDWA's definition. Second, the SDWA definition of a contaminant does not specify that a contaminant is only a singular chemical. The SDWA definition is very broad, specifically stating that a contaminant is "any physical, chemical or biological or radiological substance or matter" (emphasis added) with no specific description or requirement for how it is formed. Matter for example, by definition, is comprised of either pure substances or mixtures of pure substances. A pure substance is either an element or compound, which would include any PFAS chemical. The statute encompasses matter which is a broad term that includes mixtures and therefore definitionally includes PFAS mixtures, comprised of a combination of PFAS (chemical substances), as itself qualifying as a "contaminant" under SDWA. Moreover, other provisions of the statute would be restricted in a manner inconsistent with Congressional intent if the EPA were to adopt the cabined approach to "contaminant" suggested by some commenters. For example, Section 1431 of SDWA provides important authority to the EPA to address imminent and substantial endangerment to drinking water supplies posed by "a contaminant" that is present in or threatened those supplies. Congress clearly intended this authority to be broad and remedial, but it would be significantly hampered if the EPA would be restricted to only addressing individual chemicals and not mixtures threatening a water supply. For these reasons, the EPA's interpretation of the definition of contaminant is the only reading that is consistent with the statutory definition and use of the term in context, and to the extent definition of contaminant is ambiguous, the EPA's interpretation represents the best interpretation of that term. Finally, even if a mixture is considered a group, as some commenters suggest, Congress clearly contemplated that the EPA could regulate contaminants as groups. See H.R. Rep. No 93-1185 (1974), reprinted in 1974 U.S.C.C.A.N. 6454, 6463-64 (noting the tens of thousands of chemical compounds in use commercially, with many more added each year, of which many will end up in the nation's drinking water and finding that "[i]t is, of course, impossible for EPA to regulate each of these contaminants which may be harmful to health on a contaminant-by-contaminant basis. Therefore, the Committee anticipates that the Administrator will establish primary drinking water regulations for some groups of contaminants, such as organic and asbestos.") Thus, the EPA has the authority to regulate a mixture as a contaminant under SDWA.

The commenters also suggested that the EPA has not followed its *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (USEPA, 2000a), specifically that the

agency did not use a "sufficiently similar mixture" where "components and respective portions exist in approximately the same pattern" and suggested that there has to be consistent co-occurrence of the mixture components. The EPA disagrees with these comments. For the EPA's response to these comments, please see section 4.3.2 of the EPA response in this *Response to Comments* document.

Many other commenters supported the EPA's interpretation of regulating a mixture as a "contaminant" that consists of a combination of certain PFAS, citing the EPA's broad authority under SDWA to set regulatory standards for groups of related contaminants and the EPA precedent for doing so under other NPDWRs including disinfection byproducts (DBPs; for total trihalomethanes [TTHMs] and the sum of five haloacetic acids [HAA5], (USEPA, 1979; USEPA, 2006)), as well as radionuclides (USEPA, 2000b) and polychlorinated biphenyls (PCBs). The EPA also noted some of these examples within the proposed rule. One commenter disagreed that these previous EPA grouping approaches are applicable to mixtures of the four PFAS, noting that TTHMs and HAA5 are byproducts of the disinfection process and are the result of naturally occurring compounds reacting with the disinfectants used in drinking water treatment; thus, their formation cannot be controlled and is dependent on the presence and amount of disinfectant. As a result of these factors, measuring them as a class is required; however, the four PFAS are not byproducts, and the presence of one PFAS does not change the presence of the other PFAS. Moreover, the commenter provided that related to radionuclides, alpha particles are identical regardless of their origination and using this example for PFAS is not supported since the four PFAS are fundamentally different. The EPA disagrees with this commenter. As noted above, the SDWA definition of contaminant is very broad ("any physical, chemical or biological or radiological substance or matter" (emphasis added)) with no limitations, specific description or requirement for how it is formed. The statute therefore easily encompasses a mixture, comprised of a combination of PFAS (chemical substances), as itself qualifying as a "contaminant" under SDWA. Moreover, as also noted above, to the extent the mixture is considered a "group," Congress clearly anticipated that the EPA would regulate contaminants by group. As a result, even if the PFAS "group" is different than other SDWA regulatory groupings, such a regulation is clearly authorized under the statute. Furthermore, it makes sense to treat these mixtures as a "contaminant" because the four PFAS share similar characteristics: it is substantially likely that they co-occur; the same treatment technologies can be used for their removal; they are measured simultaneously using the same analytical methods; they have shared adverse health effects; and they have similar physical and chemical properties resulting in their environmental persistence.

Individual Public Comments

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043072)

PFHxS, PFNA, HFPO-DA, and PFBS as a Mixture

As part of the Proposal, EPA sought public comment not only on the preliminary regulatory determination for PFHxS, PFNA, HFPO-DA, and PFBS individually but also as a mixture. Specifically, EPA highlights that Section 1401(6) of SDWA defines the term contaminant to mean "any physical, chemical or biological or radiological substance or matter in water" and therefore a mixture of two or more "contaminants" qualifies as a "contaminant" because the mixture itself is "any physical, chemical or biological or radiological substance or matter in water."

Aqua appreciates the Agency's interest in addressing multiple PFAS beyond PFOA and PFOS. However, the proposed approach to address these additional PFAS through a determination that these PFAS as a mixture meet the definition of being a single "contaminant" under SDWA is not appropriately supported. A chemical substance refers to a substance of similar chemical composition as opposed to similar constituents. Under the EPA's Toxic Substances Control Act (TSCA) a chemical substance may be a mixture of contaminants formed either naturally or through a chemical formulation process. EPA's "Supplemental Guidance for Conducting Health Risk Assessment of Chemical Mixtures," which EPA cites in crafting the risk assessment framework for the Proposal, specifically indicates that opportunities to infer hazard for a mixture must be from a "sufficiently similar mixture." The guidance goes on further to note that a mixture is sufficiently similar when the "components and respective portions exist in approximately the same pattern."

EPA Response: See section 3.2 of the EPA response in this *Response to Comments* document.

Protecting Our Water, Environment, and Ratepayers (POWER) (Doc. #1714, SBC-045939)

COMMENT 5 — THE PROPOSED HAZARD INDEX IS NOT SUPPORTED BY PRECEDENT OR SCIENCE.

The Safe Water Drinking Act precedent that EPA cites does not support grouping PFHxS, HFPO- DA, PFNA, and PFBS.

In the proposed rule, EPA justifies the novel Hazard Index approach by stating that it has a history of grouping compounds. Specifically, EPA points to regulating total trihalomethanes ("TTHM") and haloacetic acids ("HAA5") as a group in drinking water treatment and considering all alpha- particles together in the radionuclide rule. Though it is true that the EPA has considered compounds in groups before, that precedent does not support doing so for PFHxS, HFPO-DA, PFNA, and PFBS.

Although the grouping of the TTHMs and the HAA5 is similar to the proposed grouping of PFAS compounds, these examples are inapplicable to the proposed drinking water standard. TTHMs and HAA5 are byproducts of the cleanup process that are the result of naturally occurring compounds reacting with the disinfectants used in treatment. [FN22: https://www.epa.gov/sites/default/files/2014-04/documents/pn_haa5_mcl.pdf; https://www.epa.gov/sites/default/files/documents/PN_TTHM_MCL.pdf.] In other words, the concentration of HAA5 and TTHM depends on the amount of disinfectant. Because the amount of each of TTHM or HAA5 cannot be controlled and depends on the amount of disinfectant used, measuring them as a class is required. This is different from the situation for the four PFAS included in the Hazard Index. The four PFAS compounds are not byproducts of the treatment process and the presence of one PFAS does not change the presence of the other three. For these reasons, regulating these as a group is not justified by the EPA's previous actions.

Furthermore, the regulation of the PFHxS, HFPO-DA, PFNA, and PFBS as a class is different than measuring man-made and natural alpha particles together. Alpha particles are identical no matter where they come from. Therefore, it is logical to consider them together. Because the four PFAS compounds are fundamentally different, grouping them together is not supported by the radionuclide rule.

Although the EPA has grouped compounds together previously, fundamental differences between these groupings makes that precedent inapplicable to support grouping PFBS, PFNA, HFPO-DA , and PFHxS together.

EPA Response: See section 3.2 of the EPA response in this *Response to Comments* document.

Uttara Jhaveri (Doc. #1778, SBC-045442)

The proposal to not set a single proposed standard for PFNA, PFHxS, PFBS and GenX chemicals, but a limit for a mix of them is a reasonable consideration. [FN11: Id.] The limit for the mix of the PFNA, PFHxS, PFBS and GenX chemicals considers the public health aspect of the decrease in the relative concentrations of certain PFAS such as PFOA, PFOS, and PFNA due to their voluntary phase-out of production and replacement in the United States. [FN12: Id.] However, other PFAS such as PFBA, PFBS, and HFPO–DA may increase in concentration as their production, use, and discharge into source water continue in the United States. [FN13: Id.]

EPA Response: See section 3.2 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045958)

Section 3.2: PFAS mixture of PFBS, PFNA, GenX, PFHxS

EPA is proposing a HI of 1.0, equal to the MCLG, for the mixture of PFBS, PFNA, GenX, and PFHxS. Each PFAS in this mixture has a proposed HBWC: 10 ppt for GenX, 2000 ppt for PFBS,

10 ppt for PFNA, and 9 ppt for PFHxS. EPA proposed this action to account for dose-additive health impacts of these chemicals in co-occurrence.

As mentioned earlier, EPA has limited occurrence data for these additional PFAS and is in the process of developing a human health toxicity assessment for PFNA and PFHxS. The human health toxicity assessment should be done before a Regulatory Determination, and certainly before a proposed regulation, as this is paramount to assessing the impact on public health. In contrast, EPA in 2022 used a toxicity assessment from 2021 to develop a drinking water health advisory for PFBS, which is currently the basis for its HBWC. EPA should be using the same method to create the HBWC if it plans to group these PFAS into a HI.

EPA Response: Please see section 3.2 of the EPA response in this *Response to Comments* document. Regarding the EPA's evaluation of the second statutory criterion on occurrence data, please see sections 3.1.2 and 3.2.2 of the EPA response in this *Response to Comments* document. Regarding the EPA's evaluation of the first statutory criterion on health effects, please see sections 3.1.1 and 3.2.1 of the EPA response in this *Response to Comments* document.

<u>The Chemours Company FC, LLC (Doc. #1845, SBC-046050)</u>

I. EPA's proposed regulation of HFPO-DA does not comply with the legal requirements of the SDWA

A. The SDWA does not authorize EPA to regulate mixtures

EPA has proposed to regulate a mixture of four different compounds (PFHxS, HFPO-DA, PFNA, and PFBS) under a single MCL. EPA's approach—utilizing a so-called "hazard index" metric—is entirely unprecedented. Indeed, EPA concedes, "this is the first use of an HI approach for a SDWA National Primary Drinking Water Regulation." PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18638, 18669 (proposed Mar. 29, 2023).

But even more importantly, EPA's effort to regulate a mixture of compounds is illegal because EPA lacks authority to do so under the Safe Drinking Water Act. The SDWA allows EPA to set individual MCLGs and MCLs for a single contaminant only. EPA has no authority to set such levels for mixtures or multiple contaminants. Specifically, the SDWA provides that "for each contaminant" that EPA determines to regulate, EPA must publish maximum contaminant level goals and promulgate national drinking water regulations. 42 U.S.C. [sec] 300g-1(b)(1)(E) (emphasis added). The SDWA defines the term "primary drinking water regulation" as a regulation which specifies contaminants that may have any adverse health effect on persons and "specifies for each such contaminant . . . a maximum contaminant level" or treatment technique. 42 U.S.C. [sec] 300f(1) (emphasis added). Courts interpreting the SDWA's requirements also note that MCLGs and MCLs are to be set for "each identified contaminant." E.g., City of Portland, Oregon v. E.P.A., 507 F.3d 706, 709 (D.C. Cir. 2007) ("[The SDWA] requires EPA to set a 'maximum contaminant level goal' (MCLG) for each identified contaminant at a level at

which no known adverse health consequences will occur. It then requires EPA to set a 'maximum contaminant level' (MCL) for each contaminant as close to the MCLG as is feasible." (emphases added; internal citations omitted)). [FN2: EPA's proposed regulation of mixtures is also inconsistent with the SDWA's instruction to set the MCL for each contaminant as close to the MCLG as is "feasible." See 42 U.S.C. [sec] 300g-1(b)(4)(B). Whereas it is clear how that would be done for a single contaminant (based on the best feasible technology and treatment techniques for that contaminant, see id. [sec] 300g-1(b)(4)(D)-(E)), it is not at all clear how that would be done for contaminant mixtures where the threshold for one compound depends on the presence or absence of the others.]

The term "each" is not defined in the SDWA, and in the absence of such a definition, courts "construe a statutory term in accordance with its ordinary or natural meaning." F.D.I.C. v. Meyer, 510 U.S. 471, 476 (1994). Black's Law Dictionary defines the term "each" as "a distributive adjective pronoun, which denotes or refers to every one of the persons or things mentioned; every one of two or more persons or things, composing the whole, separately considered." Black's Law Dictionary (6th ed. 1990) (emphasis added). Thus, in using the term "each contaminant," the SDWA clearly states that contaminants should be separately considered when setting MCLGs and MCLs. Nothing in the SDWA suggests otherwise or supports EPA's HI approach for mixtures here.

EPA contends that the SDWA defines the term "contaminant" "very broadly to mean any 'physical, chemical, biological, or radiological substance or matter in water.'" Id. at 18664 (quoting 42 U.S.C. [sec] 300f(6)). EPA asserts that "[a] mixture of two or more 'contaminants' qualifies as a 'contaminant' because the mixture itself is 'any physical, chemical or biological or radiological substance or matter in water.'" Id. (emphasis in original). This unbounded definition is without support, particularly in light of the clear statutory language limiting EPA's authority to "each" contaminant (in the singular). If the term "contaminant" were intended to include a mixture, it would have been defined by Congress in the statute as such. EPA cannot enlarge or add a different meaning to a term that is expressly defined by statute. See Meese v. Keene, 481 U.S. 465, 484 (1987) ("It is axiomatic that the statutory definition of the term excludes unstated meanings of that term.").

Moreover, as EPA is well aware, Congress is quite capable of authorizing the regulation of chemical mixtures when it wishes to do so. EPA specifically relies on CERCLA as an example of EPA's use of the HI approach. PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18638, 18669 (proposed Mar. 29, 2023). But what EPA fails to mention is that CERCLA expressly defines a "contaminant" to include "any element, substance, compound, or mixture . . . ." 42 U.S.C. [sec] 9601(33) (emphasis added). Since, unlike CERCLA, the SDWA's definition of "contaminant" does not expressly include a mixture, EPA simply cannot add that word and does not have statutory authority to regulate mixtures or groups of contaminants together under the SDWA.

EPA's efforts to grant itself statutory authority where there is none are unavailing. For example, EPA notes that it has "a longstanding history of regulating contaminants in this manner (i.e., as

contaminant groups or mixtures)" and cites as examples the regulation of trihalomethanes, haloacetic acids, and radionuclides. PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18638, 18664 (proposed Mar. 29, 2023). First, the fact that EPA may have exceeded its statutory permission in some prior instance does not give it carte blanche authority to do so again. Either EPA has the authority or it does not. See Louisiana Pub. Serv. Comm'n v. F.C.C., 476 U.S. 355, 374 (1986) ("[A]n agency literally has no power to act . . . unless and until Congress confers power upon it."); Ball, Ball & Brosamer, Inc. v. Reich, 24 F.3d 1447, 1450 (D.C. Cir. 1994) ("An agency can neither adopt regulations contrary to statute, nor exercise powers not delegated to it by Congress."). Moreover, none of the federal register notices for EPA's regulation of trihalomethanes, haloacetic acids, and radionuclides under the SDWA discuss the HI approach, let alone provide any legal authority for regulating groups of contaminants together under the statute. [FN3: See National Interim Primary Drinking Water Regulations; Control of Trihalomethanes in Drinking Water, 44 Fed. Reg. 68624, 68624 (Nov. 29, 1979); National Primary Drinking Water Regulations: Disinfectants and Disinfection Byproducts, 63 Fed. Reg. 69390, 69392 (Dec. 16, 1998); National Primary Drinking Water Regulations: Stage 2 Disinfectants and Disinfection Byproducts Rule, 71 Fed. Reg. 388, 392 (Jan. 4, 2006); National Primary Drinking Water Regulations; Radionuclides; Final Rule, 65 Fed. Reg. 76708, 76732 (Dec. 7, 2000).] Thus, EPA's prior regulation of trihalomethanes, haloacetic acids, and radionuclides cannot be used to justify or authorize either the regulation of a mixture or the HI approach under the SDWA.

EPA also cites the statute's requirement that MCLGs be set at a level "which allow[s] for an adequate margin of safety." PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18638, 18654 (proposed Mar. 29, 2023). EPA states that the HI itself "provides an added margin of safety with respect to potential health hazards of mixtures of these PFAS." Id. This argument simply proves too much. As discussed above, there is no support in the SDWA for EPA's mixture approach, and EPA cannot shoehorn authority to regulate mixtures under the guise of an "adequate margin of safety." In fact, the U.S. Supreme Court has been abundantly clear on this point. For example, in the context of the Clean Air Act, the U.S. Supreme Court explicitly held that the statute's "adequate margin of safety" language did not permit EPA to consider implementation costs in setting national ambient air quality standards because it is "implausible that Congress would give to the EPA through these modest words the power to determine whether implementation costs should moderate national air quality standards." Whitman v. Am. Trucking Associations, 531 U.S. 457, 468 (2001). The same reasoning applies here—EPA cannot use the SDWA's "adequate margin of safety" language to justify regulating contaminant mixtures because such "vague" and "modest" words do not provide the clear congressional authorization required to regulate in that manner. See also Sackett v. EPA, No. 21-454, slip op. at 20 (U.S. May 25, 2023) ("We have often remarked that Congress does not 'hide elephants in mouseholes' by 'alter[ing] the fundamental details of a regulatory scheme in vague terms or ancillary provisions.'"); W. Virginia v. Env't Prot. Agency, 142 S. Ct. 2587, 2609 (2022) ("Extraordinary grants of regulatory authority are rarely accomplished through 'modest words,' 'vague terms,' or 'subtle device[s].' Nor does Congress typically use oblique or elliptical

language to empower an agency to make a 'radical or fundamental change' to a statutory scheme." (citations omitted)).

Finally, with regard to the hazard index approach itself, it is worth noting that EPA concedes, "this is the first use of an HI approach for a SDWA National Primary Drinking Water Regulation." PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18638, 18669 (proposed Mar. 29, 2023). As the U.S. Supreme Court has made clear, novel uses of regulatory power are inherently suspect. See Util. Air Regul. Grp. v. EPA, 573 U.S. 302, 324 (2014) ("When an agency claims to discover in a long-extant statute an unheralded power to regulate 'a significant portion of the American economy,' we typically greet its announcement with a measure of skepticism." (internal citation omitted)); accord NFIB v. Dep't of Labor, 142 S. Ct. 661, 666 (2022).

EPA's assertion that it has the statutory authority to regulate mixtures of contaminants under the SDWA also runs afoul of the major questions doctrine. Under this doctrine, an "extraordinary grant[] of regulatory authority" on an issue of "economic and political significance" requires an agency to "point to 'clear congressional authorization' to regulate in that manner." W. Virginia, 142 S. Ct. at 2608–09, 2614. For the reasons stated herein, there simply is no "clear congressional authorization" for EPA either to regulate mixtures of contaminants under the SDWA or to utilize their "novel" hazard index approach in doing so.

EPA Response: Please see section 3.2 of the EPA response in this *Response to Comments* document. The commenter's argument that the EPA's effort to regulate a mixture of compounds is illegal because the SDWA provides that "for *each* contaminant" that the EPA determines to regulate, the EPA must publish MCLGs and promulgate national drinking water regulations. 42 U.S.C. [sec] 300g-1(b)(1)(E) (emphasis added) ignores that the EPA has concluded that a mixture of two or more of the regulated PFAS itself qualifies as a "contaminant" because the mixture itself is "any physical, chemical or biological or radiological substance or matter in water" (emphasis added). In addition, the court decisions cited by commenters do not address the question of whether a mixture meets the SDWA definition of "contaminant." The EPA is thus promulgating national drinking water standards for "each" contaminant. The EPA's conclusion is based on the text of the definition in the SDWA; that Comprehensive Environmental Response Compensation and Liability Act (CERCLA) includes the word "mixture" does not narrow the SDWA's definition which includes "*any* physical, chemical, biological, or radiological substance or matter in water." 42 U.S.C. [sec] 300f(6) (emphasis added). Furthermore, contrary to commenter's assertion that it is not at all clear how to comport with the SDWA's instruction to set the MCL for each contaminant as close to the MCLG as is "feasible" for a contaminant that is a mixture, the final rule properly establishes an MCL for each contaminant, including the mixture that is a contaminant. Congress has clearly authorized the EPA to regulate mixtures [or "in this manner"] by defining contaminant broadly enough to include mixtures. This is confirmed by the SDWA's legislative history, in which Congress expressly anticipated that the Administrator would establish primary drinking water regulations for some groups of contaminants Moreover, regulation of a contaminant that is a

mixture simply is not an extraordinarily greater grant of authority than the authority to regulate singular chemical by singular chemical. As discussed in section 3.2 of the EPA response in this *Response to Comments* document, the EPA notes that it has previously regulated groups of contaminants in NPDWRs under SDWA. Similarly, the EPA (and states) regularly use the Hazard Index approach to inform potential health risks of chemical mixtures associated with contaminated sites/locations under CERCLA/Superfund Amendments and Reauthorization Act (SARA); as such, the application of the Hazard Index approach under a regulatory purview is not novel for the agency (see section VI.B of the proposed rule preamble). In addition, commenter mischaracterizes the preamble discussion regarding the definition of MCLG. The EPA's discussion in section IV.B of the proposed rule preamble (page 18654) explains the basis for the EPA's decision to select the Hazard Index approach to address mixtures and is not focusing on the definition of contaminant.

American Water Works Association (AWWA) (Doc. #1759, SBC-045591)

PFHxS, PFNA, HFPO-DA, and PFBS as a Mixture

As part of the proposal, EPA also sought public comment on the preliminary regulatory determination for PFHxS, PFNA, HFPO-DA, and PFBS as a mixture. Specifically, EPA highlights that Section 1401(6) of SDWA defines the term contaminant to mean "any physical, chemical or biological or radiological substance or mater in water" and therefore a mixture of two or more "contaminants" qualifies as a "contaminant" because the mixture itself is "any physical, chemical or biological or radiological substance or mater in water."

AWWA appreciates the agency's interest in addressing additional PFAS beyond PFOA and PFOS. However, the proposed approach to address these additional PFAS through a preliminary determination that these PFAS as a mixture meet the definition of being a single "contaminant" under SDWA is not appropriately supported. As recognized by the TSCA, any mixture is not considered a chemical substance, instead a mixture of contaminants formed either naturally or through a chemical formulation process may be considered a chemical substance (EPA, 2023e). EPA's "Supplemental Guidance for Conducting Health Risk Assessment of Chemical Mixtures", which EPA cites in crafting the risk assessment framework for the proposal, specifically indicates that opportunities to infer hazard for a mixture must be from a "sufficiently similar mixture" (EPA, 1986). The guidance goes on further to note that a mixture is sufficiently similar when the "components and respective portions exist in approximately the same pattern" (EPA, 1986).

EPA Response: Please see section 3.2 of the EPA response in this *Response to Comments* document.

3.2.1 Statutory Criterion #1 – Adverse Health Effects for Mixture of Four PFAS

Summary of Major Public Comments and EPA Responses

Many commenters expressed support for the EPA's determination that mixtures of PFHxS, PFNA, HFPO-DA, and/or PFBS meet the statutory criterion for adverse health effects using the best available information. Other commenters did not agree that the agency presented sufficient information to make a preliminary determination to regulate mixtures of PFHxS, PFNA, HFPO-DA, and/or PFBS, with some commenters recommending that that the agency withdraw the portion of the proposed rule associated with mixtures of these four PFAS because in their view, the EPA's mixtures assessment approach was flawed or there is insufficient health effects and/or occurrence data at this time to support the EPA's action. Commenters, both within this section and as described in sections 4.3.1, 4.3.2., and 4.3.3, raised concerns about the uncertainty factors applied for each of the four PFAS in the Hazard Index. Some commenters claimed that the EPA did not follow its guidance or SAB recommendations. For the EPA's responses to these comments, please see sections 4.3.1, 4.3.2, and 4.3.3 in this *Response to Comments* document.

Individual Public Comments

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043058)

3. The proposed positive regulatory determination, and concurrent regulation, of perfluorohexanesulfonic acid (PFHxS), PFNA, HFPO-DA, and PFBS are based on a scientifically flawed risk assessment approach to mixtures of PFAS that is not supported by the EPA's guidance materials. The Agency should re-propose the determination and regulation for additional PFAS following completion of UCMR 5 and a refinement of the hazard index approach.

EPA Response: See sections 3.2 and 3.2.1 of the EPA response in this *Response to Comments* document, as well as sections 4.3.1, 4.3.2, and 4.3.3 of the EPA response in this *Response to Comments* document regarding the regulatory determination health effects statutory criterion and risk assessments. Regarding UCMR 5, please see sections 3.1.2 and 6.8 of the EPA response in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043074)

Aqua does not support the regulatory determination of PFHxS, PFNA, HFPO-DA, and PFBS as a mixture. While EPA claims that mixtures of these PFAS may co-occur and represent a combined risk, the supporting information fails to create a sufficient record that this is the case. This is true both for evidence of occurrence and demonstration that these PFAS pose a combined risk. This lack of toxicological support for this approach is apparent in the Agency's proposed approach to use a hazard index for these compounds through a methodology that is contrary to federal agency guidance.

Aqua recommends that if EPA is interested in addressing additional PFAS through this rulemaking effort and through a regulatory determination for a mixture of PFAS, that EPA re-issue a preliminary determination for additional PFAS following the completion of the UCMR 5 program and further refinement of the hazard index approach. Delaying this action would also ensure that EPA may consider toxicological assessments for additional PFAS, which are currently in development.

EPA Response: See sections 3.2 and 3.2.1 of the EPA response in this *Response to Comments* document, as well as sections 4.3.1, 4.3.2, and 4.3.3 of the EPA response in this *Response to Comments* document regarding the regulatory determination health effects statutory criterion and risk assessments. Regarding the EPA's evaluation of the regulatory determination occurrence statutory criterion and UCMR 5, please see sections 3.1.2, 3.2.2, 6.3, and 6.8 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045594)

AWWA does not support the preliminary determination of PFHxS, PFNA, HFPO-DA, and PFBS as a mixture as the statutory factors under the SDWA to support a determination are not present. While EPA claims that mixtures of these PFAS may co-occur and represent a combined risk, the supporting information fails to create a sufficient record that this is the case. This is true both for evidence of occurrence and demonstration that these PFAS pose a combined risk. This lack of toxicological support for this approach is apparent in the agency's proposed approach to use a hazard index for these compounds through a methodology that is contrary to federal agency guidance. The preliminary determination for PFHxS, PFNA, HFPO-DA, and PFBS as a mixture is not sufficiently supported and the information for three of these compounds suggests a negative determination is most appropriate.

EPA Response: See sections 3.2 and 3.2.1 of the EPA response in this *Response to Comments* document, as well as sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document regarding the regulatory determination health effects statutory criterion and risk assessments. Regarding co-occurrence, please see sections 3.1.2, 3.2.2, and 6.3 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045607)

AWWA recommends that the EPA re-issue the preliminary determination for PFHxS, PFNA, HFPO-DA, and PFBS as a mixture and recommends that prior to re-issuing a preliminary determination for a mixture of PFAS work towards refining the proposed approach to align with guidance from federal agencies (including the agency itself) and recommendations from the SAB. Aligning the use of the hazard index with agency guidance and SAB recommendations is not only necessary for sound policy, but necessary to comply with both the SDWA and the APA. Further, EPA should follow its own guidance before finalizing any risk assessment for mixtures of PFAS, by EPA ensuring that appropriate peer review be conducted to confirm the agency is

relying on the best available science. [FN19: U.S. EPA, Peer Review Handbook, 4th edition, 2015, available at: https://www.epa.gov/sites/default/files/201510/documents/epa_peer_review_handbook_4th_edion_october_2015.pdf.] AWWA notes that EPA followed a more robust process in evaluating PFOA and PFOS and recommends that EPA apply at least the same level of rigor to its analysis of PFHxS, PFNA, HFPO-DA, and PFBS. Failing to do so, or failing to acknowledge this change, and providing a reasoned explanation for the change, would violate the APA.

EPA Response: See section 3.2.1 of the EPA response in this *Response to Comments* document, as well as sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document regarding risk assessment.

Wisconsin Department of Justice et al. (Doc. #1687, SBC-044443)

a. EPA's proposed PFAS drinking water standards are necessary to protect public health.

EPA's proposed MCL for PFOA and PFOS of four parts per trillion (individually), and the agency's proposed Hazard Index-based MCL for mixtures containing PFHxS, GenX, PFNA, and/or PFBS are strongly supported by health effects data. The MCLs reflect both EPA's well-supported analysis of that data and its commitment to protecting human health.

Data about how these six PFAS chemicals affect human health comes from human and animal studies examining how these PFAS enter our bodies and the associated health effects. Much of the research has focused on the health effects of specific PFAS chemicals in isolation, but there is also substantial data demonstrating the adverse health effects of PFAS chemicals as components of a mixture. [FN11: A coalition of nonprofits, research institutes and universities have created a database concerning PFAS toxicology called the PFAS-Tox Database that includes, among many others, studies on PFHxS, GenX, PFNA, and PFBS. In addition, the database contains at least 204 studies on PFAS mixtures. See Pelch KE, Reade A, Kwiatkowski CF, Wolffe T, Merced-Nieves FM, Cavalier H, Schultz K, Rose K, Varshavsky J. 2021. PFAS-Tox Database available at https://pfastoxdatabase.org/.] In fact, there is sufficient data concerning certain PFAS chemicals for EPA to assess their toxicity and publish detailed assessments about their safety. [FN12: See, e.g., United States Environmental Protection Agency, Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA), EPA Document Number: 822-R-16-005, May 2016, https://www.epa.gov/sites/default/files/2016-05/documents/pfoa_health_advisory_final_508.pdf; see, e.g., United States Environmental Protection Agency, Drinking Water Health Advisory for Perfluorooctane Sulfonate (PFOS), EPA Document Number 822-R-16-004, May 2016,https://www.epa.gov/sites/default/files/201605/documents/pfos_health_advisory_final_508.pdf.] These PFAS chemicals are associated with a wide range of serious adverse health effects when people ingest them through drinking water, including without limitation, various cancers, liver disease and damage, issues with growth and development like low birth weight, changes in hormone levels, weakened immune system, diabetes, and fertility issues. [FN13: See the

following illustrative examples of such studies. Studies concerning PFAS and Cancer: Jiang H., et al. Associations between Polyfluoroalkyl Substances Exposure and Breast Cancer: A Meta-Analysis. Toxics. 2022; https://doi.org/10.3390/toxics10060318; Keck School of Medicine of the University of Southern California, Synthetic "forever chemical" linked to liver cancer, https://keck.usc.edu/synthetic-forever-chemical-linked-to-livercancer/, (full study available at https://doi.org/10.1016/j.jhepr.2022.100550); Scott M. Bartell & Verónica M. Vieira (2021) Critical review on PFOA, kidney cancer, and testicular cancer, Journal of the Air & Waste Management Association, https://doi.org/10.1080/10962247.2021.1909668; Joseph J. Shearer, PhD, et al., Serum Concentrations of Per- and Polyfluoroalkyl Substances and Risk of Renal Cell Carcinoma, Journal of the National Cancer Institute, https://doi.org/10.1093/jnci/djaa143; Lisa M. Kamendulis et al., Exposure to perfluorooctanoic acid leads to promotion of pancreatic cancer, Carcinogenesis, https://doi.org/10.1093/carcin/bgac005; Imir OB, et al., Per- and Polyfluoroalkyl Substance Exposure Combined with High-Fat Diet Supports Prostate Cancer Progression. Nutrients. 2021; https://doi.org/10.3390/nu13113902. Studies concerning PFAS and the Liver: Elizabeth Costello et al., Exposure to per- and Polyfluoroalkyl Substances and Markers of Liver Injury: A Systematic Review and Meta-Analysis, Environ. Health Perspectives, https://doi.org/10.1289/EHP10092. Studies concerning PFAS and Development: Liew Z., et al., Developmental Exposures to Perfluoroalkyl Substances (PFASs): An Update of Associated Health Outcomes, Curr Environ Health Rep, https://doi.org/10.1007/s40572-018-0173-4; Bevin E. Blake, Suzanne E. Fenton, Early life exposure to per- and polyfluoroalkyl substances (PFAS) and latent health outcomes: A review including the placenta as a target tissue and possible driver of peri- and postnatal effects, Toxicology, https://doi.org/10.1016/j.tox.2020.152565; Kaberi P. Das, et al., Developmental toxicity of perfluorononanoic acid in mice, Reproductive Toxicology, https://doi.org/10.1016/j.reprotox.2014.12.012; Henrik Viberg, et al., Adult dose-dependent behavioral and cognitive disturbances after a single neonatal PFHxS dose, Toxicology, https://doi.org/10.1016/j.tox.2012.12.013; Silvia Manea, et al., Exposure to PFAS and small for gestational age new-borns: A birth records study in Veneto Region (Italy), Environmental Research, https://doi.org/10.1016/j.envres.2020.109282. Studies concerning PFAS and the Endocrine System: Jenny Carwile, et al., Serum PFAS and Urinary Phthalate Biomarker Concentrations and Bone Mineral Density in 12-19 Year Olds: 2011-2016 NHANES, The Journal of Clinical Endocrinology & Metabolism, https://doi.org/10.1210/clinem/dgac228. Studies Concerning PFAS and the Immune System: Haley Von Holst, et al., Perfluoroalkyl substances exposure and immunity, allergic response, infection, and asthma in children: review of epidemiologic studies, Heliyon, https://doi.org/10.1016/j.heliyon.2021.e08160; U.S. Department of Health and Human Services, National Toxicology Program, NTP Monograph: Immunotoxicity Associated with Exposure to Perfluorooctanoic acid and Perfluorooctane Sulfonate, September 2016, https://ntp.niehs.nih.gov/ntp/ohat/pfoa_pfos/pfoa_pfosmonograph_508.pdf. Studies Concerning PFAS and Diabetes: Gui, SY., et al. Association between per- and polyfluoroalkyl substances exposureand risk of diabetes: a systematic review and metaanalysis., J Expo Sci Environ Epidemiol, https://doi.org/10.1038/s41370-022-00464-3. Studies Concerning PFAS and Fertility. Mount Sinai, Exposure to Chemicals Found in Everyday Products Is Linked to Significantly

Reduced Fertility (2023), https://www.mountsinai.org/about/newsroom/2023/exposure-to-chemicals-found-ineveryday-products-is-linked-to-significantly-reduced-fertility (full study available at https://pubmed.ncbi.nlm.nih.gov/36801327/); Wei Wang, The effects of perfluoroalkyl and polyfluoroalkyl substances on female fertility: A systematic review and meta-analysis, Environmental Research, https://doi.org/10.1016/j.envres.2022.114718.]

PFOS and PFOA have been conclusively found to be highly harmful to human health even at miniscule levels of exposure, with both chemicals being linked to a wide variety of adverse health effects. The five health effects of PFOA and PFOS with the strongest human evidence are decreased vaccine response, delayed growth and development (e.g., decreased birth weight), increased cholesterol, increased levels of an enzyme that is an indicator of liver damage, and (for PFOA) kidney and testicular tumors. [FN14: Interstate Technology Regulation Council, Human and Ecological Health Effects and Risk Assessment of Per- and Polyfluoroalkyl Substances (PFAS) (Sept. 2022), https://pfas1.itrcweb.org/wp-content/uploads/2022/09/HH_Eco_PFAS_Fact-Sheet_082422_508.pdf.].

For PFHxS, PFNA, PFBS and GenX, there is likewise substantial evidence that all are individually harmful to human health. Each contaminant has been the subject of numerous animal and/or human health studies that show likely health effects. [FN15: Pelch KE, Reade A, Kwiatkowski CF, Wolffe T, Merced-Nieves FM, Cavalier H, Schultz K, Rose K, Varshavsky J. 2021. PFAS-Tox Database https://pfastoxdatabase.org/. Database listing 578 studies for PFHxS, 631 studies for PFNA, 150 studies for PFBS, and 29 studies for GenX.] In each case, EPA appropriately used such studies to set levels of protection called Health Based Water Concentrations (HBWC) for PFHxS and PFNA, PFBS and GenX, to provide appropriate protections against adverse health impacts. [FN16: PFAS National Primary Drinking Water Regulation Rulemaking, 88 FR 18638-01 at 18645-47.] For example, EPA based its HBWC for PFHxS on an Agency for Toxic Substances and Disease Registry (ATSDR) intermediate-duration oral Minimal Risk Level (MRL). [FN17:Id. At 18645-46.] The PFHxS MRL in turn was based on studies showing that PFHxS can harm the development of liver and thyroid tissue including a study on rats that showed risks to the thyroid at a certain level of exposure. [FN18: See, Agency for Toxic Substances and Disease Registry (ATSDR), Toxicological profile for Perfluoroalkyls, http://dx.doi.org/10.15620/cdc:5919.] Both ATSDR and EPA appropriately used this study to identify an exposure level without appreciable risk for humans, accounting for relevant factors like age and other sensitivities that may differ between species and including an uncertainty factor to account for chronic exposure through drinking water. [FN19: PFAS National Primary Drinking Water Regulation Rulemaking, 88 FR 18638-01 at 18645-46.]

Multiple PFAS are often present in drinking water and other sources of PFAS exposure, and as a result, in human blood serum. [FN20: See, e.g, California State Water Resources Control Board, Geotracker – PFAS Map, https://geotracker.waterboards.ca.gov/map/pfas_map (searchable map linking to test results in water throughout California with data showing PFAS mixtures in many sampling events); Biomonitoring California, Results for Perfluoroalkyl and Polyfluoroalkyl Substances (PFASs), https://biomonitoring.ca.gov/results/chemical/2183 (showing that the PFAS

at issue in this regulation are present in nearly all blood serum samples and in mixtures across several different cohorts).] To evaluate the impacts of exposure to multiple PFAS, researchers also consider PFAS mixtures and their impact on health. [FN21: See Pelch KE, Reade A, Kwiatkowski CF, Wolffe T, Merced-Nieves FM, Cavalier H, Schultz K, Rose K, Varshavsky J. 2021. PFAS-Tox Database https://pfastoxdatabase.org/ (listing 204 studies on "PFAS Mix").] For example, a recent study by the University of Southern California's Keck School of Medicine used human blood serum to examine the impacts of PFAS mixtures on the human thyroid and metabolism, and it found that exposure to a PFAS mixture is associated with an increase in a thyroid hormone. According to the researchers, this is especially concerning because thyroid hormones play an important role in child development during puberty, which can have important effects on a range of diseases later in life, including diabetes, cardiovascular disease and cancer. [FN22: Keck School of Medicine of the University of Southern California, Keck School of Medicine study finds "forever chemicals" disrupt key biological processes, https://keck.usc.edu/keckschool-of-medicine-study-finds-forever-chemicals-disrupt-key-biological-processes/,published study available at: https://doi.org/10.1289/EHP11372.] Another recent study concerning PFAS mixtures found lower odds of "attaining a clinical pregnancy within one year of follow-up and delivering a live birth when the combined effects of seven PFAS as a mixture were considered." [FN23: Mount Sinai, Exposure to Chemicals Found in Everyday Products Is Linked to Significantly Reduced Fertility (2023),https://www.mountsinai.org/about/newsroom/2023/exposure-to-chemicals-found-ineveryday-products-is-linked-to-significantly-reduced-fertility(study available at https://pubmed.ncbi.nlm.nih.gov/36801327/).] These studies illustrate both the need to regulate the six PFAS subject to the PFAS Rule and EPA's sound judgment in employing the agency's Hazard Index approach, with its rulemaking based on the risks to human health posed by PFHxS, PFNA, PFBS and GenX individually and in mixtures.

EPA Response: Please see sections 3.2 and 3.2.1 of the EPA response in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-045670)

EPA also violates its own guidance when it does not discuss the critical implications of the collective application of the uncertainty factors when considering these four PFAS together in the HI. The uncertainty factors when compared across PFHxS, HFPO-DA, PFNA, and PFBS are 3,000, 3,000, 300, and 300, respectively. Though the uncertainty factors across the four PFAS may not be purely multiplicative, EPA's own guidance (USEPA 2002) clearly recommends "limiting the total UF applied for any particular chemical to no more than 3000 and avoiding the derivation of a reference value that involves application of the full 10-fold UF in four or more areas of extrapolation" because uncertainty in four or five areas "may also indicate that the database is insufficient to derive a reference value." As stated previously, USEPA (2002) recommends "justification for the individual factors selected for each chemical," guidance that should also apply when considering uncertainty across multiple reference values under the HI. Taken together, in proposing the HI, EPA has failed to follow its own guidance, which

recommends that clear justification for the uncertainty factors, consideration of areas of overlapping uncertainty, and implications for the reliability of the reference values be provided.

EPA Response: See section 3.2.1 of the EPA response in this *Response to Comments* document, as well as sections 4.3.1, 4.3.2, and 4.3.3 of the EPA response in this *Response to Comments* document.

Protecting Our Water, Environment, and Ratepayers (POWER) (Doc. #1714, SBC-045942)

COMMENT 6 — BECAUSE THE RESEARCH TO DETERMINE THE TOXICITY LEVELS AND POTENTIAL HARMS RELATING TO THE COMPOUNDS INCLUDED IN THE HAZARD INDEX IS CURRENTLY BEING PERFORMED, THE PRELIMINARY REGULATORY DETERMINATION TO REGULATE THE MIXTURE OF PFHXS, HFPO-DA, PFNA, AND PFBS IS PREMATURE.

EPA has already laid out plans to review the toxicity and/or risk of PFHxS, HFPO-DA, PFNA, and PFBS. Given that the research and analysis intended to inform the drinking water regulations is currently being done, it is premature to make a regulatory determination to regulate the mixture of these compounds until that research and analysis is complete.

Setting the Hazard Index now prior to the human health toxicity assessment renders the human health toxicity assessment pointless.

The human health toxicity assessment "provides hazard identification, dose-response information, and derives toxicity values called oral reference doses ("RfDs") for chronic and subchronic exposures."[FN25: EPA, Human Health Toxicity Assessments for GenX Chemicals (last updated Dec. 27.2022) (https://www.epa.gov/chemical-research/human-health-toxicity-assessments-genx-chemicals)] Its purpose is to help policy makers consider if and when it is appropriate to reduce exposure to the compound. Therefore, the human health toxicity assessment is another tool that is necessary to inform and determine the potential risk of the compound.

In the proposed NPDWR, EPA acknowledges that the human health toxicity assessments for PFHxS and PFNA are currently ongoing and are supposed to undergo public comment this year. If the Hazard Index is finalized as written, the human health toxicity assessment, when complete, will be unable to inform policy makers of the potential risk.

POWER! therefore requests EPA delay setting MCLs for PFHxS and PFNA until the human health toxicity assessments are complete.

EPA Response: Please see sections 3.1.1 and 3.2.1 of the EPA response in this *Response to Comments* document. Additionally, see section 4.3.3 of the EPA response in this *Response to Comments* document related to ATSDR health assessments.

3.2.2 Statutory Criterion #2 - Occurrence for Mixture of Four PFAS

Summary of Major Public Comments and EPA Responses

The EPA received many comments on the agency's evaluation of the second statutory criterion under Section 1412(b)(1)(A) of SDWA. The EPA notes that some comments related to occurrence of the four PFAS are also contained within section 6 of this document. As demonstrated in comments within this section, section 3.1.2, and section 6, many commenters supported not only the EPA's preliminary regulatory determinations to individually regulate PFHxS, PFNA, HFPO-DA, and PFBS, but also expressed support for the EPA's preliminary determination that mixtures of these four PFAS meet the second statutory occurrence criterion under SDWA, citing that the agency has used the best available information to determine that there is a substantial likelihood that combinations of these PFAS will co-occur in mixtures at a frequency and level of public health concern. One commenter stated that the additional occurrence data presented by the EPA in the proposal for the Hazard Index PFAS supports the EPA's proposed determination that these PFAS should be regulated under the SDWA. Comments in section 6 also supported the EPA's co-occurrence analyses.

Conversely, many other commenters both in this section and in section 6 of this document did not agree that the agency presented sufficient occurrence information to make a preliminary determination for PFHxS, PFNA, HFPO-DA, and PFBS individually also did not agree that the EPA presented sufficient co-occurrence information to regulate mixtures of the four contaminants or that a determination not to regulate (i.e., negative determination) these four PFAS in mixtures is more appropriate. The EPA disagrees with these commenters that it has not met the second statutory criterion for mixtures of these four PFAS as demonstrated in sections III.C., VI.C, and VI.D of the final rule preamble, as well as the *Occurrence Technical Support Document*, all of which document measured co-occurrence of PFHxS, PFNA, HFPO-DA, and PFBS above their HRL, including that across 21 states there are at least 211 PWSs serving approximately 4.7 million people with results above a Hazard Index of 1 for mixtures with two or more of the Hazard Index PFAS. Specifically evaluating the presence of PFBS, in these same 211 systems where the Hazard Index was found to be greater than 1, PFBS was observed at or above its PQL in mixtures with one or more of the other three Hazard Index PFAS in at least 72 percent (152) of these systems serving approximately 4.5 million people. Additionally, as described in section III of the final rule preamble, PFHxS, PFNA, HFPO-DA, and PFBS are all very stable and persistent in the environment, and all are either still being actively used or legacy stocks may be used and imported into the U.S. Consequently, there is a substantial likelihood that environmental contamination of sources of drinking water from these PFAS will continue to co-occur to at least the levels described in the final rule preamble.

Specifically, a few commenters stated that there was not supporting evidence for the co-occurrence of the four Hazard Index PFAS. The EPA disagrees; the extent to which Hazard Index PFAS chemicals co-occur in the non-targeted state dataset is discussed extensively in the record for this rulemaking and made evident through the system level analysis in section VI.C. of

this preamble and also described in section III.C. As also discussed elsewhere in the record for this rulemaking, in both system level and sample level analyses where PFOA and/or PFOS were reported present and all four Hazard Index PFAS were monitored, two or more Hazard Index PFAS were reported present more than half of the time. Further, the odds ratios tables in Exhibit 11 of the final rule preamble provide a statistical examination of pairwise co-occurrence. The odds ratio is a statistic that quantifies the strength of association between two events. In the context described here, an "event" is the reported presence of a specific PFAS contaminant. The odds ratio between PFOA and PFHxS, for example, reflects the strength of association between PFHxS being reported present and PFOA being reported present. If an odds ratio is greater than 1, the two events are associated. The higher the odds ratio, the stronger the association. For every pair of PFAS chemicals included in the proposed regulation, the odds ratio was found to be statistically significantly greater than 1. This means there was a statistically significant increase in the odds of a PFAS being present if the other PFAS compound was detected (e.g., if PFOA is detected, PFHxS is more likely to also be found). In most instances the odds appeared to increase in excess of a factor of ten. Thus, based on the large amount of available data, the chemicals are clearly demonstrated to co-occur rather than occur independently of one another, further supporting the agency's determination for combinations of mixtures of the four PFAS. Related to PFAS co-occurrence, please also see section 6.3 of the EPA response in this *Response to Comments* document.

Individual Public Comments

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043073)

In review of the data presented by EPA there is not sufficient supporting evidence that these compounds co-occur significantly in drinking water systems to satisfy the requirement for the mixture of these compounds to be considered "sufficiently similar." First, there is a complete lack of national occurrence data for HFPO-DA. For HFPO-DA, PFBS, and PFNA the available data for occurrence shows that these compounds – if they do occur – occur at exceptionally low levels and rarely above levels of public health concern. Furthermore, an analysis of the co-occurrence for this mixture of PFAS demonstrates an apparent lack of supporting evidence that these compounds all occur at the same time and in similar proportions (if at all).

EPA's groupwise occurrence provides neither a clear nor transparent characterization of occurrence, nor co-occurrence, of PFNA, PFHxS, PFBS, and HFPO-DA. Most of the data tables in the analysis rely on a presentation of at least one of these compounds. This data does not provide necessary information to support a conclusion of co-occurrence given that it does not indicate the compound(s) that are detected and the level of the detected compound(s). This is an important consideration, as a detection of PFBS is likely to bias these results and represents a significantly different level of public health concern in comparison to a detection of PFOA or PFOS. With a detection limit for PFBS of 3.0 ppt, a sample with a detection of PFBS may be, and is likely to be, representative of a level that is less than one-hundredth of the level that a public health concern may begin.

EPA Response: Please see sections 3.1.2, 3.2.2, and 6.3 of the EPA response in this *Response to Comments* document. Additionally, the EPA disagrees that these PFAS do not co-occur as documented in sections III.C., VI.C, and VI.D of the final rule preamble and the *Occurrence Technical Support Document* (USEPA, 2024b), nor do they need to co-occur in similar proportions. Rather, the purpose of the Hazard Index is to consider varying proportions of the Hazard Index PFAS which can collectively co-occur in different combinations of mixtures resulting in dose additive adverse health impacts when they are simultaneously co-occurring in these mixtures. Since each of the component Hazard Index PFAS are individually compared to their respective HBWC value, their proportions to the overall Hazard Index are appropriately accounted for and one or more Hazard Index PFAS will not bias the results. Moreover, this approach also recognizes that exposure to the PFAS included in the Hazard Index is associated with adverse health effects at differing potencies (e.g., the toxicity reference value for PFHxS is lower than the one for PFBS) and that, regardless of these potency differences, all co-occurring PFAS are included in the hazard calculation (i.e., the health effects and presence of lower toxicity PFAS are neither ignored nor are they over-represented).

The EPA further disagrees that it does not present necessary information to indicate the levels of the detected compounds in its Hazard Index analyses, as these are transparently presented in sections III.C., VI.C. VI.D. of the final rule preamble and within the *Occurrence Technical Support Document* (USEPA, 2024b).

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043098)

The determination for the mixture of these PFAS is similarly lacking in co-occurrence data and is inconsistent with EPA guidance.

EPA Response: Please see sections 3.2.2 and 6.3 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045602)

Earlier in these comments, AWWA raised issues regarding the EPA's occurrence analysis and the proposal's lacking evidence for occurrence, let alone co-occurrence, of these four PFAS. Notably, EPA has not demonstrated that there is or "there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern" [FN18: 42 U.S.C. § 300g-1(b).] as required under the SDWA, and at most has shown that they may potentially occur at levels of concern.

EPA Response: Please see sections 3.2.2 and 6.3 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045592)

The occurrence analysis provided by EPA does not demonstrate that PFHxS, PFNA, HFPO-DA, and PFBS can be grouped together as a mixture within a manner consistent with well-established agency guidance. First, there is a complete lack of national occurrence data for HFPO-DA and the data for PFBS shows a significant lack of occurrence in drinking water. Furthermore, data for PFNA shows a very low level of occurrence on its own, let alone with the other three PFAS. EPA's groupwise occurrence provides neither a clear nor transparent characterization of occurrence, nor co-occurrence, of PFNA, PFHxS, PFBS, and HFPO-DA. The supporting documentation fails to illustrate a pattern of co-occurrence of these four compounds; in fact, most of the information on co-occurrence of these compounds is relative to PFOA and PFOS. Given that the determination is for PFHxS, PFNA, HFPO-DA, and PFBS the co-occurrence of these individual compounds with PFOA and PFOS does not demonstrate the other four compounds cooccur.

Furthermore, the information that is provided does not demonstrate occurrence of PFHxS, PFNA, HFPODA, and PFBS at or above levels of potential health risk. Instead, occurrence is consistently described as a function of detection. Unfortunately, this is also not useful in supporting a preliminary determination. Detections are not equivalent to potential risk, which is most easily demonstrated in comparing the meaning of a detection for PFBS and PFHxS. While a detection of PFHxS at 10 ppt is 100% of the proposed HBWC while a detection of PFBS at 10 ppt is only 0.5% of the proposed HBWC. Detection of PFBS is likely to bias these results and represents a significantly different level of public health concern in comparison to a detection with other PFAS.

To further investigate co-occurrence for the PFAS, AWWA conducted an analysis of PFAS occurrence data that was collected from nearly 8,000 water systems by Corona Environmental Consulting (Corona, 2021). The results of this analysis are shown in the table. While some systems may detect more than one of these PFAS, the occurrence of these PFAS together at levels above the HBWC are much more limited, if at all.

Table 4-1: Co-Occurrence of PFBS, PFHxS, and PFNA in Drinking Water (N=7,989) (Corona, 2021)

[Table 4-1: See Docket ID EPA-HQ-OW-2022-0114-1759]

While there are scientific studies evaluating the hypothesis that exposure to multiple PFAS may lead to adverse health effects, the proposal and its supporting documentation do not substantiate a preliminary determination nor a determination to regulate the mixture of PFHxS, PFNA, HFPO-DA, and PFBS. There is a lack of information showing co-occurrence and, therefore, co-exposure to these compounds.

EPA Response: Please see sections 3.1.2, 3.2.2, and 6.3 of the EPA response in this *Response to Comments* document. The agency disagrees that it also presented information on detections and does not consider the relative proportions of each of the four PFAS within the

Hazard Index. The purpose of the Hazard Index is to consider varying proportions of the Hazard Index PFAS which can collectively co-occur in different combinations of mixtures resulting in dose additive adverse health concerns when they are simultaneously co-occurring in these mixtures. Since each of the component Hazard Index PFAS are individually compared to their respective HBWC value, their proportions to the overall Hazard Index are appropriately accounted for and one or more Hazard Index PFAS will not bias the results. The EPA further disagrees that it does not present necessary information to indicate the levels of the detected compounds in its Hazard Index analyses, nor are the Hazard Index results presented biased – they are based on measured concentration samples with co-occurring Hazard Index PFAS.

The EPA disagrees with the commenter's claim that most of the information on co-occurrence of these compounds is relative to PFOA and PFOS and that the co-occurrence of the Hazard Index PFAS with PFOA and PFOS does not support demonstration of the Hazard Index PFAS co-occurring. As described in sections VI.C. and VI.D. of the final rule preamble because not as many states have monitored for the Hazard Index PFAS as compared to PFOA and PFOS, their occurrence information is less extensive than the occurrence information for PFOA and PFOS. Therefore, establishing co-occurrence of Hazard Index PFAS with PFOA and PFOS is important to better understand the likelihood of Hazard Index PFAS occurrence. The EPA evaluated this through its groupwise analysis (which was only a part of the agency's co-occurrence analyses), where results generally indicated that when PFOA and PFOS were found, Hazard Index PFAS were considerably more likely to also be present, and also concluded that when Hazard Index PFAS were found (with no consideration of PFOA and PFOS) it was more likely multiple Hazard Index PFAS were present than a single Hazard Index PFAS. In fact, when evaluating only a subset of the available state data representing non-targeted monitoring where either three or four Hazard Index PFAS were monitored, regardless of whether PFOA or PFOS were reported present, two or more of the Hazard Index PFAS were reported in approximately 12.1 percent of monitored systems. Additionally, for systems that only measured PFOA and/or PFOS and did not measure the Hazard Index PFAS, it can be assumed that the Hazard Index PFAS are more likely to be present in those systems, and that Hazard Index occurrence may be underestimated. Moreover, while PFOA and PFOS are not included within the Hazard Index PFAS or the determination to regulate mixtures of these PFAS, the pervasive occurrence of PFOA and PFOS shown in section VI of the final rule preamble is a strong indicator that these other Hazard Index PFAS are also more likely to be found than what has been reported in state monitoring data to date.

Regarding the PFAS occurrence analysis referenced by the commenter, the EPA evaluated this report and determined it uses a non-nationally representative set of systems to extrapolate to the nation. The set of systems included the 4,920 UCMR 3 systems but added an additional 3,069 systems from select states. New England accounted for about 70 percent of these additional systems (1,142 were in New Hampshire, 605 were in Vermont, 298 were in Massachusetts, and 73 in Rhode Island). An example of the impact of this approach is that New Hampshire went from representing less than 0.5 percent of systems in the nationally representative set of systems in UCMR 3 to representing over 14.6 percent of systems included in the Black & Veatch

extrapolation. Similarly, Vermont went from representing about 0.24 percent of UCMR 3 systems to representing about 7.7 percent of the systems in the final set of systems used for extrapolation. This indicates substantial bias in results that overrepresents the New England region. Thus, the agency asserts the results of this analysis would not be nearly as representative as the analysis conducted by the EPA and presented in the proposed and final rule preamble.

3M Company (Doc. #1774, SBC-045663)

b. EPA Has No Meaningful or Sound Occurrence Data for the HI MCL Substances

The SDWA requires that before it can promulgate an NPDWR, EPA must determine that, among other things, the substance is "known to occur or there is substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern.3 [FN33: SDWA [sec]1412(b)(1)(A)(i) and (ii).] Alleged co-occurrence of the four HI-PFAS is the basis for EPA's HI MCL. EPA's justification for the HI approach depends in part on the four HI-PFAS substances most frequently co-occurring as a mixture, rather than individually. [FN34: For PFHxS, the median sample concentrations range from 2.14 to 11.3 ppt. The HRL for this substance is 9.0 ppt. For HFPO-DA, the median sample concentrations range from 1.7 to 9.7 ppt. The HRL for this substance is 10.0 ppt. For PFNA, the median sample concentrations range from 2.1 to 7.46 ppt. The HRL for this substance is 10.0 ppt. For PFBS, the median sample concentrations range from 1.99 to 7.26 ppt. The HRL for this substance is 2000.0 ppt. The maximum sample did not even exceed the HRL for PFBS.] But EPA's analysis does not demonstrate that there is substantial likelihood that the four HI-PFAS co-occur with each other. Instead, EPA analyzed where any of the four HI-PFAS individual and either PFOA or PFOS co-occur.

Exhibit 6-3 summarizes co-occurrence of combinations of PFAS in the UCMR3 data. The combination of the four HI-PFAS is not listed. [FN35: Many of the combinations included in Exhibit 6-3 indicate PFHpA is detected, which is irrelevant to the proposed regulation of the four HI-PFAS as a mixture, given that PFHpA is not one of the four HI-PFAS.] Importantly, it appears there were no records in the UCMR3 data of the four HI-PFAS co-occurring.

Section 6 of the Background Support Document (USEPA 2023h) presents analyses of the co-occurrence rate of PFOA, PFOS and any of the four HI-PFAS, but does not specifically address co-occurrence of the four HI-PFAS proposed for regulation as a mixture using the HI approach. The analyses, discussion, and Exhibits 6-2, 6-4 and 6-5 also focus on co-occurrence of PFOA and PFOS with the four HI-PFAS, rather than co-occurrence of the four HI-PFAS with each other. That analysis is irrelevant to the decision to regulate the four HI-PFAS as a mixture, since neither PFOA nor PFOS is included in the group to be regulated as a mixture.

There are also significant issues with the sampling on which EPA relies that call into question the reliability of the data. Data are evaluated at the sample and PWS level, though it is not clear if sample counts represent unique locations or include multiple samples from the same location. Evaluating multiple samples from the same location within a system could overestimate the

frequency of co-occurrence. The co-occurrence data presented at the system level for detection of any HI-PFAS show wide variability among states (USEPA 2023h, p. 197). And the states with the most systems tested, Michigan and Ohio, show much lower frequency of detection of any HI-PFAS (i.e., 6.5 percent and 3.9 percent respectively) than states with fewer system tested (USEPA 2023h, p. 197). This observation suggests that data from states with fewer systems sampled may not be representative of occurrence in those states.

EPA's failure to include all states' data violates the fundamental scientific principle that one cannot selectively use data to generate a preferred outcome. The data set used covers 11 states and is described as "limited to samples from non-targeted monitoring efforts where at least one HI PFAS was analyzed and PFOS and PFOA were analyzed sufficiently to determine whether one was present." Although the state of Alabama analyzed for all four HI-PFAS and PFOA and PFOS, data from Alabama are not presented and no explanation for the omission is provided (USEPA 2023h, p. 11). Sampling efforts are ongoing in 6 of the 11 states presented (Illinois, Massachusetts, Michigan, New Hampshire, New Jersey, and Vermont); for these states, data collected after May 2021 are available but are not used by EPA for the co-occurrence analysis (USEPA 2023h, p. 11). EPA's PFAS Analytical Tools webpage (https://echo.epa.gov/trends/pfas-tools) lists data for several additional states (e.g., Oregon, Rhode Island) also not considered in EPA's co-occurrence analysis.

EPA also uses different data sets for the evaluations of co-occurrence and of affected systems, creating a fundamental disconnect such that one analysis cannot be used to inform the other. For example, in estimating the number of systems affected by the proposed MCLs, EPA uses an occurrence model that incorporates data from 17 states (USEPA 2023f, p. 18678). The 17 states include Arizona, California, Delaware, Georgia, Maine, and Pennsylvania (Cadwallader 2022). For these states, EPA considers the sampling "targeted" and omits them from the cooccurrence evaluation (USEPA 2023h, p. 11). Conversely, data from the state of Colorado are included in the co-occurrence evaluation but are not included in this modeling of affected systems. Different and unstated rationale for including state data for these two purposes suggest that those criteria were arbitrary.

EPA failed to include more recent samples that would improve the representativeness of the analysis. Specifically, EPA's analysis of co-occurrence does not include samples collected after May 2021 and uses different data sets than are used for EPA's occurrence modeling. The data set used to evaluate co-occurrence is limited to data available on public state websites through August 2021, which was limited to samples collected through May 2021.

EPA Response: See section 3.2.2 of the EPA response in this *Response to Comments* document. The commenter incorrectly states that the referenced support document (USEPA, 2023b) does not present co-occurrence of the Hazard Index PFAS without also considering co-occurrence with PFOA and PFOS, as these analyses are clearly provided in Exhibits 5-52, 5-53, 6-12, and 6-13 displaying the EPA's Hazard Index analyses and the EPA's pairwise odds ratios co-occurrence analyses of the extensive amount of available state data. Additionally, the EPA disagrees with the commenter that the EPA only analyzed where any of the Hazard Index PFAS

and either PFOA or PFOS co-occur as the EPA conducted multiple co-occurrence analysis, only some of which considered PFOA and PFOS co-occurrence with the Hazard Index PFAS. The EPA further disagrees with the commenter that consideration of co-occurrence of the Hazard Index PFAS with PFOA and PFOS does not support demonstration of the Hazard Index PFAS co-occurring or that it is an irrelevant analysis. As described in sections III.C, VI.C. and VI.D. of the final rule preamble because not as many states have monitored for the Hazard Index PFAS as compared to PFOA and PFOS, their occurrence information is less extensive than the occurrence information for PFOA and PFOS. Therefore, establishing co-occurrence of Hazard Index PFAS with PFOA and PFOS is important to better understand the likelihood of Hazard Index PFAS occurrence. The EPA evaluated this through its groupwise analysis (which was only a part of the agency's co-occurrence analyses), where results generally indicated that when PFOA and PFOS were found, Hazard Index PFAS were considerably more likely to also be present, and also concluded that when Hazard Index PFAS were found (with no consideration of PFOA and PFOS) it was more likely multiple Hazard Index PFAS were present than a single Hazard Index PFAS. In fact, when evaluating only a subset of the available state data representing non-targeted monitoring where either three or four Hazard Index PFAS were monitored, regardless of whether PFOA or PFOS were reported present, two or more of the Hazard Index PFAS were reported in approximately 12.1 percent of monitored systems Additionally, for systems that only measured PFOA and/or PFOS and did not measure the Hazard Index PFAS, it can be assumed that the Hazard Index PFAS are more likely to be present in those systems, and that Hazard Index occurrence may be underestimated. Moreover, while PFOA and PFOS are not included within the Hazard Index PFAS or the determination to regulate mixtures of these PFAS, the pervasive occurrence of PFOA and PFOS shown in section VI of the final rule preamble is a strong indicator that these other Hazard Index PFAS are also more likely to be found than what has been reported in state monitoring data to date.

The agency disagrees with the commenter's claim that there are significant issues with the sampling that call into question the reliability of the data. Appropriately, the EPA evaluates the data at both the sample and system level to ensure accurate representation of the available data and that it is not overestimated. In some instances, there may be unique locations that conducted multiple sampling efforts that EPA accounts for in its analyses. There is no scientifically valid reason why the EPA would not count these multiple results and include within its analyses since they are unique sampling events, however this is accounted for in the system level analyses where the system is included only once to ensure no over-representation. Further, while EPA agrees with the commenter there is variability across the states, using the two states referenced by the commenter, Michigan and Ohio, Table 13 in the final rule preamble which provides a summary of systems exceeding the Hazard Index (based on non-targeted state datasets only), shows that Michigan and Ohio have a higher percent of systems exceeding the EPA's final Hazard Index of 1 than over half of the states included within that table. This observation would instead suggest that due the variability noted by the commenter and agreed with by the EPA, there is no correlation between number of systems tested and frequency and/or level of detection.

The commenter claims that EPA failed to include all states' data and "selectively used data to generate a preferred outcome." The EPA strongly disagrees with the commenter's inaccurate assertion and, as described in section 6.2 of the EPA response in this *Response to Comments* document, the agency evaluated all best available state data which includes updated data for the final rule from 32 states through May 2023. The agency evaluated these data as they were presented directly by states, ensuring sufficient quality assurance; therefore, the agency did not selectively use the data and represented it transparently and accurately for its intended purpose. For some purposes, this was to separately present the non-targeted (or data not collected solely in areas of known or potential contamination) so as to not do exactly what the commenter claims and potentially over-represent or bias the data results. The agency clearly stated this intended purpose in the proposed and final rule preamble (see proposed rule sections III.B.5 and III.C.5 and final rule section III.C.). Additionally, for some states such as Alabama referenced by the commenter, which only reported data for detections, it would not have been appropriate to include frequency of detection as there could not be accurate representation of that dataset without also including the non-detection sample results. The commenter incorrectly states this explanation was not included as it was clearly articulated in the proposed and final rule preamble, as well as the proposed rule *Occurrence Technical Support Document* (see Exhibit 2-4; USEPA, 2023b).

Regarding the commenter's claim that the EPA did not include its rationale for using the state data differently for varying analysis purposes, as discussed previously in this response, the agency disagrees and within sections III and VI of the final rule preamble EPA clearly articulates its rationale which includes that "due to the reporting limitations of some of the available state data (e.g., reporting combined analyte results rather than individual analyte results), the EPA did not utilize all of these data in the subsequent occurrence analyses/co-occurrence analyses." Consequently, the criteria were not arbitrary as suggested by the commenter. Specific to the EPA's national occurrence model, please see section 6.5 of the EPA response in this *Response to Comments* document.

Little Hocking Water Association (Doc. #1835, SBC-045513)

Additional occurrence data for HI PFAS supports EPA's proposed determination that these PFAS should be regulated under the SDWA.

One statutory criterion for regulation under the SDWA is a determination that there is a substantial likelihood that contaminants at issue will occur and co-occur with a frequency and at levels of public health concern in public water supplies, based on EPA's evaluation of the best available occurrence information. In the proposed rule, EPA is proposing to determine that this statutory criterion has been met for PFHxS, HFPO-DA, PFNA and PFBS (the HI PFAS), and EPA is seeking public comment on whether additional data or studies exist which EPA should consider that support or do not support this preliminary decision. EPA also "requests comment on additional occurrence data the Agency should consider regarding its decision that PFHxS,

HFPO-DA, PFNA, and PFBS and their mixtures occur or are substantially likely to occur in PWSs with a frequency and at levels of public health concern."

Data on co-occurrence of PFHxS, HFPO-DA, PFNA and PFBS supports EPA's determination that the HI PFAS will occur and co-occur in public water supplies with a frequency and at levels that require regulation.

1) As discussed above in the section titled "Support of preliminary regulatory determinations for PFHxS, HFPO-DA, PFNA, and PFBS," Attachment 3 shows the presence of HFPO-DA in Little Hocking's raw water and the exponential increase of the concentrations of HFPO-DA since February 2018 (data from Chemours, 2023a).

2) Also as discussed above, the presence of HFPO-DA in the Belpre raw water as well as the two lead beds of its GAC filtration system were documented to be present at concentrations of 2.3 ppt, 2.4 ppt and 2.6 ppt, respectively (data from Chemours, 2023b). This data is from March 20, 2023 wherein Chemours began reporting for the first time in 17 years of testing for 18 PFAS analyzed using Method 537.1. The data for the monthly sampling in April 2023 is not yet publicly available, but, based on results from Little Hocking (which is 3.8 miles away), HFPO-DA will likely continue to be present and reported.

3) The table below shows concentrations of PFAS in Belpre raw water and the lead beds of its GAC System on and shows the presence of three of the four HI PFAS that are proposed to be regulated using the Hazard Index MCL (March 20, 2023 data from Chemours, 2023b). This table is the only data available for Belpre and shows that not only is HFPO-DA present in the raw water (at 2.3 ppt), but that concentrations of PFBS (at 24 ppt) and PFHxS (at 35 ppt) are also present. This data shows the co- occurrence of these chemicals and also shows that the concentration of PFHxS alone would exceed the hazard index of 1 (35/9 = 3.89, which is >1).

[Table 1: See Docket ID EPA-HQ-OW-2022-0114-1835]

4) The table above showing data for the occurrence of HI PFAS in the two GAC system lead beds for the Belpre water system also shows that even in the lead beds, calculation of the HI would result in an exceedance of the proposed hazard index. For example, the hazard index for 1N Lead would be calculated as follows:

[Table 2: See Docket ID EPA-HQ-OW-2022-0114-1835]

Similarly, lead bed 1S, would also exceed the proposed hazard index as follows:

[Table 3: See Docket ID EPA-HQ-OW-2022-0114-1835]

5) The four available dates for which Chemours has made data available for all 18 PFAS sampled under Method 537.1 show that of the four HI PFAS, only HFPO-DA is present. The table below (data source: Chemours, 2023a) shows additional PFAS that are not currently proposed to be regulated (PFHxA and PFHpA) are present in Little Hocking's raw water:

[Table 4: See Docket ID EPA-HQ-OW-2022-0114-1835]

And PFHxA and PFHpA were present in the east lead bed of Little Hocking's GAC plant on May 8, 2023, as shown in the below table (data source: Chemours, 2023a).

[Table 5: See Docket ID EPA-HQ-OW-2022-0114-1835]

However, due to the testing methodology used, the conclusion cannot be drawn that PFBS and PFHxS are absent in the raw water. Due to the elevated concentrations of PFOA in the raw water on the order of 7,000 ppt (see Attachment 1), Chemours has instructed the laboratory to analyze the raw water samples at a dilution of 5X and 50X. Although this is reportedly designed to protect the laboratory equipment for carry-over, the resulting reporting limit has ranged from 8.3 ppt to 9.5 ppt, thus effectively preventing detections of lower concentrations of other compounds of interest.

6) Co-occurrence of HI PFAS with PFOA and PFOS are not limited to the mid-Ohio Valley. In 2020, the Ohio EPA tested approximately 1500 public water supplies for six PFAS including PFOA, PFOS, HFPO-DA, PFBS, PFHxS and PFNA (data from which is reported in other sections of the proposed rule). Of the approximately 1500 public water systems tested, two public water systems were found to exceed the Ohio EPA action level of 70 ppt for PFOA or PFOS or the two combined. One of those systems, the Aullwood Audubon Center in Dayton, Ohio was served by a well that was contaminated and was ultimately connected to a public water supply that did not have measurable concentrations of PFAS that exceeded an Ohio Action Level.

7) Although the contamination was addressed in the public water system, the Ohio Department of Health was subsequently concerned that the area around the Aullwood Audubon Center was served by private water wells that utilized the same aquifer. Testing of 49 private wells for the same six PFAS (PFOA, PFOS, HFPO-DA, PFBS, PFHxS, and PFNA) showed the presence of PFAS in five of the private wells (Ohio Department of Health, 2021). The Ohio Health Department encouraged private well owners to have their wells tested.

8) A larger study of private wells in the area was conducted by Montgomery County, Ohio and Butler Township under a contract. As part of this contract, 155 wells were sampled for 18 PFAS by Method 537.1 in 2022 and 2023. The publicly-available portion of the results from the study are posted on the Butler Township Website (2023) and show that 70 of the 155 wells sampled had detections of at least one PFAS and two had concentrations of PFOA/PFOS that exceeded 70 ppt. Of the 18 PFAS that were tested for, there were detections of seven different PFAS, including three of the four of the HI PFAS proposed to be regulated under this proposed rule. The table below shows the maximum concentration of each of the detected PFAS (data source, Butler Township Website, 2023). Calculations showed that of the 70 private wells with detections, 34 locations would exceed the proposed MCLs for PFOA or PFOS. Calculations also showed that two additional wells that did not already exceed the proposed MCLs for PFOA and/or PFOS would exceed the proposed hazard index. If a private well exceeded the proposed MCL for PFOA and/or PFOS, the hazard index was not calculated separately, but some wells would also have exceeded the hazard index. Although this data was collected from private wells,

it is representative of the concentrations in the aquifer that was utilized by Aullwood Audubon and is still used by other smaller public water supplies.

[Table 6: See Docket ID EPA-HQ-OW-2022-0114-1835]

EPA Response: Please see section 3.2.2 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045891)

3. The co-occurrence data do not support a listing for the mixture of the four PFAS

To attempt to support its proposal to regulate these four PFAS as a mixture, EPA uses the UCMR 3 data to evaluate co-occurrence of PFAS [FN44: U. S. EPA, PFAS Occurrence and Contaminant Background Support Document, 2023, EPA–822–P–23–010, at 192-194, available at: https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0037.]. Focusing on detections (e.g., occurrences above the minimal reporting level), these data show 11 occurrences of PFNA, 27 occurrences of PFHxS, and 3 occurrences of PFBS. As presented, however, it is impossible to discern the co- occurrences of these four PFAS due to a lack of occurrences in the available data. If we include PFOA and PFOS in considering occurrence, only one occurrence also includes PFHxS and PFNA. As PFOA and PFBS only co-occurred twice, it is likely that PFBS never co-occurred with PFHxS, PFNA, PFOA, and PFOS. If it had, EPA likely would have presented those data. In the state data, there was co-occurrence of all six PFAS in only 0.3% of the samples [FN45: Id. at exhibit 6-8.]. While EPA relies on an analysis by Cadwallader et al., 2022, to evaluate co-occurrence, that study's model did not include PFBS and PFNA because the reported values from UCMR 3 were insufficient to fit a national model [FN46: Cadwallader, A., Greene, A., Holsinger, H., Lan, A., Messner, M., Simic, M., and Albert, R. 2022. A Bayesian Hierarchical Model for Estimating National PFAS Drinking Water Occurrence. AWWA Water Science, 4(3):1284. https://doi.org/10.1002/aws2.1284.]. It is also worth noting that Cadwallader et al., 2022, referred to the state datasets as being "insufficient" to act in place of UCMR data [FN47: Id.]

EPA Response: Please see section 3.2.2 of the EPA response in this *Response to Comments* document. The EPA disagrees that the co-occurrence analyses do not support the EPA's determination to regulate mixtures of the four Hazard Index PFAS as described in section VI.C. and III.C. of the final rule preamble and also within section 6.3 of the EPA response in this *Response to Comments* document. The commenter's co-occurrence analysis also only includes consideration of UCMR 3 data, and does not provide an evaluation using the extensive amount of available state data, which, as described in section 6.1 of the EPA response in this *Response to Comments* document, have significantly lower reporting limits than were available under UCMR 3. Consequently, the agency has supplemented these data with available state data to ensure consideration of all best available information. Furthermore, the EPA asserts that the mixture approach for the Hazard Index PFAS does not require all four Hazard Index PFAS to be present simultaneously to be health protective, and combined with this factor, as well as the lack of state

data considered, the commenter's analysis would not be representative of the best available occurrence information.

American Water Works Association (AWWA) (Doc. #1759, SBC-045595)

AWWA recommends that if EPA is interested in addressing additional PFAS through a regulatory determination for a mixture of PFAS, that EPA reconsider their approach to addressing PFAS as a mixture and delay re-issuing a preliminary determination until after the data collection activities for UCMR 5 are complete. Delaying this action would also ensure that EPA may consider health assessments for additional PFAS, which are currently in development (EPA, 2023b).

EPA Response: Please see sections 3.2.2, 3.1.2, and 6.8 of the EPA response in this *Response to Comments* document regarding the EPA's evaluation of the second regulatory determination statutory criterion on occurrence as well as UCMR 5. Please see sections 3.1.1, and 3.2.1 of the EPA response in this *Response to Comments* document pertaining to the EPA's evaluation of the first regulatory determination statutory criterion on health effects.

American Chemistry Council (ACC) (Doc. #1841, SBC-052933)

The proposal to address mixtures of the four PFAS also relies on an assumption that the substances co-occur in the nation's drinking water. As described in more detail below, however, EPA does not have national occurrence for PFBS, HFPO-DA, and PFNA.

EPA Response: Please see section 3.2.2 of the EPA response in this *Response to Comments* document. For additional information related to occurrence for PFBS, HFPO-DA, and PFNA, please see section 3.1.2 of the EPA response in this *Response to Comments* document.

3.2.3 Statutory Criterion #3 - Meaningful Opportunity for Mixture of Four PFAS

Summary of Major Public Comments and EPA Responses

The EPA received many comments on the agency's evaluation of the third statutory criterion under Section 1412(b)(1)(A) of SDWA. As demonstrated through comments within this section and section 3.1.3, most commenters supported not only the EPA's evaluation under the preliminary determination that individual regulation of PFHxS, PFNA, HFPO-DA, and PFBS meet the third statutory meaningful opportunity criterion, but also expressed support for the EPA's preliminary determination that mixtures of these four contaminants also presents a meaningful opportunity for health risk reduction and that the EPA has sufficiently justified this statutory criterion as well as the health and occurrence criterion. These commenters shared many of the same supporting factors of meaningful opportunity for both individual regulation of PFHxS, PFNA, and HFPO-DA, as well as mixtures of these three PFAS and PFBS. The EPA agrees with these commenters and refers to the comments and the EPA's response in section 3.1.3 in this *Response to Comments* document.

Specifically, a few commenters provided comment on the EPA's evaluation of meaningful opportunity of mixtures of these four PFAS based on the treatment technologies which can remove all of the six PFAS for which the EPA is finalizing regulation. The majority of these commenters noted the meaningful opportunity to not only provide protection from the six regulated PFAS, but also other PFAS that will not be regulated as a part of this action, with one commenter providing it was unclear if that is a reasonable assumption. The agency agrees with commenters that there is meaningful opportunity to simultaneously provide protection to PFAS other than the six being regulated under this final rule as the technologies that will remove these six PFAS can also remove other PFAS therefore it is reasonable to assume they will have some co-removal benefits. The EPA does acknowledge, however, that drinking water treatment systems will achieve greater removal efficiencies if the systems are developed and optimized to target specific PFAS.

Several commenters both in this section and section 3.1.3 did not support the EPA's overall evaluation of the third statutory criterion, also offering many of the same opposition factors and that the EPA failed to justify that there is a meaningful opportunity for both individual regulation of PFHxS, PFNA, and HFPO-DA, as well as mixtures of these three PFAS and PFBS. The EPA disagrees with these commenters that the agency failed to justify that there is meaningful opportunity for health risk reduction or that the EPA provided limited rationale and factors in its meaningful opportunity evaluation for these contaminants as mixtures. As described in the EPA's March 2023 proposal and in section III.D. of the final rule preamble, the EPA fully considered many factors specific to mixtures including dose additive toxicity and health concerns, co-occurrence of mixtures of these four PFAS at frequencies and levels of public health concern, availability of similar treatment technologies to remove these four PFAS and analytical methods to measure them, and their collective chemical and physical properties leading to their environmental persistence. Additionally, the EPA notes the proposed and final rule preamble, and as demonstrated through representative co-occurrence data, for mixtures of the four co-occurrence is not only at a regional or local level, rather it covers multiple states throughout the country; therefore, a national level regulation is necessary to ensure all Americans served by PWSs are equally protected.

Some comments indicate that the health and occurrence information do not support that establishing drinking water standards presents a meaningful opportunity for health risk reduction. The agency disagrees with the commenters' assertion that the health and occurrence information are insufficient to justify a drinking water standard as supported in sections III.B. and III.C. of the final rule preamble, and the agency finds that there is a meaningful opportunity for health risk reduction potential based upon multiple considerations including the population exposed to mixtures of PFHxS, PFNA, HPFO-DA, and/or PFBS including sensitive populations and lifestages, such as newborns, infants and children.

Other comments assert that the EPA must evaluate the potential implementation challenges and cost considerations of regulation as part of the meaningful opportunity evaluation. As stated in the EPA's response 3.1.3, the EPA disagrees with these commenters. SDWA states that that the

meaningful opportunity is in the sole judgement of the Administrator and does not require that the EPA consider costs for a regulatory determination. The SDWA does require that costs and benefits are presented and considered in the proposed rule's HRRCA which the EPA did for the proposal and has updated as a part of the final rule within section XII.

New York City Department of Environmental Protection (NYCDEP) (Doc. #1679, SBC-044204)

May 30, 2023

Michael S. Regan, Administrator

U.S. Environmental Protection Agency EPA Docket Center

Office of Ground Water and Drinking Water Docket Mail Code 28221T

1200 Pennsylvania Avenue NW Washington, DC 20460

(Via Federal eRulemaking Portal)

Re: Comment on EPA's Per-and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation

Docket ID No. EPA- HQ- OW- 2022- 0114

Dear Administrator Regan,

As the largest water supply in the nation, with both unfiltered and filtered systems, the New York City Department of Environmental Protection (DEP) supports the US Environmental Protection Agency's (EPA) goal of protecting public health by reducing exposure to per- and polyfluorinated substances (PFAS). In addition to having conducted monitoring for PFAS compounds at the entry points to the distribution system (EPTDS) as required by the third Unregulated Contaminant Monitoring Rule (UCMR), DEP conducts ongoing, proactive monitoring as part of an emerging contaminant monitoring effort. In 2016, New York State (NYS) became the first state in the nation to regulate perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS). In 2020, NYS set drinking water maximum contaminant levels (MCLs) for PFOA and PFOS at 10 ppt. NYS is also currently considering additional drinking water standards and notification levels for up to 23 PFAS.

Hazard Index

EPA's proposed National Primary Drinking Water Regulation (NPDWR) would establish Maximum Contaminant Level Goals (MCLGs) of zero and Maximum Contaminant Levels (MCLs) of 4.0 parts per trillion (ppt) for both PFOA and PFOS, which are more stringent than any current state regulation. The proposed action would also implement the use of a Hazard Index (HI) to consider the combined toxicity for perfluorononanoic acid (PFNA), GenX Chemicals, perfluorohexane sulfonate (PFHxS) and perfluorobutanesulfonic acid (PFBS). Hazard Indices have never been used for national drinking water regulations.

In section III.F. p. 18652, EPA seeks comment on "evaluation that regulation... will provide protection from PFAS that will not be regulated as part of the proposed PFAS NPDWR." It is not clear that this is a reasonable assumption. PFAS compounds seem to be tailored for specific industries, and, therefore, the assumption of co-occurrence seems less a result of the pollutant source and more a result of the ubiquitous nature of forever chemicals collecting in watersheds. As EPA identifies toxicity and occurrence data, other compounds should be regulated specifically as individual analytes or within an HI.

EPA Response: Please see section 3.2.3 of the EPA response in this *Response to Comments* document.

Aidan Cecchetti (Doc. #1640, SBC-044358)

We have developed the comments contained within this letter to address some of the issues we believe to be most important for EPA to consider when revising and promulgating a final PFAS NPDWR. Our most critical comments are summarized in Table 1.

Table 1: Summary of comments on the proposed PFAS NPDWR.

[Table 1: See Docket ID: EPA-HQ-OW-2022-0114-1640]

*In Docket ID: EPA-HQ-OW-2022-0114 contained within Federal Register Vol. 88, No. 60.

Additional details regarding the topics highlighted in Table 1, and other topics discussed in Docket ID: EPA-HQ-OW-2022-0114, are included in our full comments in the following section. As relevant, we have included the language of EPA's requests for comments from the Federal Register as well as page numbers to make clear to which requests we are responding. All page numbers are taken from Federal Register Vol. 88, No. 60.

Full Comments on EPA's Proposed PFAS NPDWR

• EPA requests comment on its evaluation that regulation of PFHxS, HFPO-DA, PFNA, PFBS, and their mixtures, in addition to PFOA and PFOS, will provide protection from PFAS that will not be regulated under this proposed rule (pg. 18652 Federal Register Volume 88, Number 60).

o The commenters agree with EPA's determination that the regulation of the listed PFAS will also provide some level of protection from PFAS not currently regulated in the proposed NPDWR. The most common treatment methods available for removal of PFHxS, HFPO-DA, PFNA, PFBS, PFOA, and PFAS (e.g., GAC, RO, and ion exchange) will also provide for some level of removal of non-regulated PFAS. However, the degree of public health protection provided to non-regulated PFAS is nonquantifiable without additional data on occurrence, toxicity, and effectiveness of treatments in removing those additional PFAS, particularly when PFAS are present in variable mixtures.

EPA Response: Please see section 3.2.3 of the EPA response in this *Response to Comments* document.

3.3 EPA's Concurrent Preliminary Regulatory Determination and Proposed NPDWR

Summary of Major Public Comments and EPA Responses

The EPA received several comments related to the EPA's interpretation in the proposal that the agency may, as it did here, issue a preliminary regulatory determination concurrent with a proposed NPDWR. Many stated that the EPA is authorized under SDWA to process these actions concurrently and agreed with the EPA's interpretation of the statute, noting that the EPA has followed all requirements under SDWA including notice and opportunity for public comment on both the preliminary regulatory determination and proposed NPDWR, and that simultaneous public comment periods are not precluded by SDWA. Several other commenters expressed disagreement with the EPA's interpretation. These dissenting commenters contend that the statute only allows the EPA to "publish such proposed regulation concurrent with the determination to regulate" (i.e., in their view, the final determination), not the "preliminary determination to regulate." Moreover, some of these commenters further indicated that they believe the EPA's final determination to regulate must precede the EPA's proposed regulation. The EPA disagrees with commenters who stated that the EPA cannot issue a preliminary determination concurrent with a proposed NPDWR. Section 1412(b)(1)(e) states that "[t]he Administrator shall propose the maximum contaminant level goals and national primary drinking water regulation for a contaminant not later than 24 months after the determination to regulate under subparagraph (B), and may publish such proposed regulation concurrent with the determination to regulate" (emphasis added). The EPA maintains its interpretation that "determination to regulate" in the second phrase of 1412(b)(1)(E) allows for concurrent processing of a preliminary determination and proposed rule, not a final determination and proposed rule.

The first clause of the provision provides an enforceable 24-month deadline for the EPA to issue a proposed rule once it has decided to regulate. Contrary to the suggestion of some commenters, the statutory language providing that the EPA "shall" propose an NPDWR "not later than 24 months after the determination to regulate" states when the 24 months to issue a proposed rule begins, i.e., the deadline is 24 months after making a final determination to issue a proposed regulation. The phrase "after the determination to regulate" here simply identifies when SDWA's deadline begins to run; there is no textual or other indication in the language that Congress meant it to constitute the beginning of an exclusive 24-month window in which the EPA is permitted to propose an NPDWR. Further, though the EPA's reading is clear on the face of the provision, it is also supported by language elsewhere in SDWA illustrating that when Congress intends to provide a window for action -- as opposed to a deadline for action -- it knows how to do so clearly. In fact, Congress did so in this very provision when it required the EPA to "publish a maximum contaminant level goal and promulgate a national primary drinking water regulation within 18 months after the proposal thereof." See also, 42 U.S.C. section 1448 (providing, among other things, that petitions for review of the EPA regulations under SDWA "shall be filed within the 45-day period beginning on the date of the promulgation of the regulation …")

(emphasis added). In addition, the phrase "not later than," expressly acknowledges that the EPA may issue a proposed rule concurrent with a final determination. And because this language only provides a deadline without a beginning trigger, the language in the first clause of this provision would also not preclude the EPA from issuing a proposed rule at any time prior to the expiration of the 24 months after a final regulatory determination, including issuing the proposed rule on the same day as the preliminary regulatory determination.

The second clause, which states that the Administrator "may publish such proposed regulation concurrent with the determination to regulate" should not be read to limit when the EPA can issue a proposed rule prior to a final determination. First, Congress's use of the phrase "determination to regulate" elsewhere in SDWA is not consistent, requiring the agency to discern its meaning based on statutory context. Second, reading "determination to regulate" to refer to a final determination would, without good reason, hinder Congress' goal in enacting this provision, to accelerate the EPA action under SDWA. Finally, the EPA's interpretation to allow for concurrent processes is fully consistent with, and indeed enhances, the deliberative stepwise process provided in the statute for regulating new contaminants.

Language throughout the statute demonstrates that Congress did not use the term "determination to regulate" consistently. In fact, "preliminary determination" only appears once in the entire provision, "final determination" is never used, and the remainder of the references simply refer to "determination." Specifically, section 1412(b)(1)(B)(ii)(I) expressly requires public comment on a "preliminary" regulatory determination made as part of the contaminant candidate listing process. The rest of section 1412(b)(1)(B)(ii) and (iii) as well as the title of the provision only refer to a "determination to regulate" or "determination." For example, 1412(b)(1)(B)(iii) states that "[e]ach document setting forth the determination for a contaminant under clause (ii) shall be available for public comment at such time as the determination is published."[2] Although this provision only refers to a "determination for a contaminant under clause (ii)," this language clearly refers to public comment on a preliminary determination and not a final determination to regulate. The EPA has interpretated "determination" in this paragraph to refer to "preliminary determination" because that is the best interpretation to effectuate Congressional intent to provide public comment prior to issuing a final determination. The EPA has done the same with Section 1412(b)(1)(E) here, as only a reading that allows for, in appropriate cases, concurrent processing of a preliminary determination to regulate and proposed NPDWR allows for rulemaking acceleration by the EPA as Congress envisioned. To the extent there is ambiguity, the EPA's reading of Section 1412(b)(1)(E) is the best one to effectuate these purposes.

The EPA could issue a proposed rule concurrent with a final determination; there is nothing in the statute or the Administrative Procedure Act (APA) that requires the EPA to wait. The SDWA

[2] Even the first clause of Section 1412(b)(1)(E) setting the 24-month deadline uses "regulatory determination" without further clarifying whether it is preliminary or final. Again, it is clear when viewed in context that the term refers to a final determination, as triggering a deadline to propose regulations on a preliminary decision to regulate would not be reasonable, as the agency may change its mind after reviewing public comment, obviating the need for a proposed NPDWR.

gives the EPA 24 months to act after a final determination but does not require the agency to wait 24 months. The "no later than" language in the first clause of Section 1412(b)(1)(E), expressly acknowledges that the EPA may issue a proposed rule concurrent with a final determination. Therefore, construing the second phrase of Section 1412(b)(1)(E) simply to authorize the EPA to issue a proposed rule concurrent with a final determination renders that provision of the statute authorizing the EPA to publish such proposed regulation concurrent with the determination to regulate a nullity. The well-known tools of statutory construction direct the agencies and courts not to construe statutes so as to render Congress's language mere surplusage, yet that it is what commenters' interpretation would do. The EPA's construction is the one which gives meaning to that language.

Moreover, the EPA's interpretation of "determination to regulate" in the phrase "may publish such proposed regulation concurrent with the determination to regulate" in section 1412(b)(1)(E) to be a preliminary determination best effectuates Congress' goal in enacting this provision, to accelerate the EPA action under SDWA when the EPA determines such a step is necessary and the EPA has, as it does here, a sufficient record to proceed with both regulatory determination and regulation actions concurrently. In addition to authorizing concurrent processes, Congress' intent to expedite regulatory determinations when necessary is evidenced more generally by the text and structure of Section 1412(b)(1)(B)(ii). The statute contemplates regulatory determinations could be made as part of the 5-year cycle for the contaminant candidate list under Section 1412(b)(1)(B)(ii)(I) but may also be made at any time under Section 1412(b)(1)(B)(ii)(III). The fact that Congress provided the EPA with express authority to make a regulatory determination at any time is a recognition that the EPA may need to act expeditiously to address public health concerns between the statutory periodic 5-year cycle. The EPA's interpretation of the relevant language in Section 1412(b)(1)(E) best effectuates all provisions of the statute because simultaneous public processes for off-cycle regulatory determinations and NPDWRs allow for administrative efficiency that may be needed to address pressing public health concerns.

Finally, the EPA's interpretation of the statute allowing for concurrent processes is fully consistent with the stepwise process for issuing an NPDWR set out by the statute. Here, the EPA provided for public comment on an extensive record for both the regulatory determinations and the proposed regulatory levels and it is not clear what further benefit would be provided by two separate public comment periods. This is especially true given the D.C. Circuit's ruling in National Resources Defense Council (NRDC) v. Regan, 67 F.4th 397 (D.C. Cir 2023), which held that the EPA cannot withdraw a final determination to regulate a contaminant. Thus, even if the EPA were to provide two separate comment periods, the information provided on a proposed rule cannot be used to undo a final regulatory determination. Indeed, although not required by the statute, the EPA in proposing actions concurrently provides commenters with much more information to evaluate the preliminary regulatory determinations. This is because the EPA has provided not just the information to support the preliminary determinations to regulate but also the full rulemaking record and supporting risk, cost, occurrence, and benefit analysis that supports the proposed MCLs. Further, the EPA has a much more comprehensive record for the

regulatory determinations to ensure that the final determination, which cannot be withdrawn, is based on the comprehensive record provided by the rulemaking and HRRCA development processes.

Washington Suburban Sanitary Commission (WSSC Water) (Doc. #1585, SBC-042768)

Regulatory determination for PFHxS, HFPO-DA. PFNA and PFBS:

EPA has requested comments on its preliminary regulatory determination of PFHxS, HFPODA, PFNA, and PFBS in this rulemaking. WSSC Water disagrees with EPA's interpretation of Section 1412(b)(1)(E) of SDWA, which allows for proposing a drinking water regulation concurrently with a determination to regulate. WSSC Water believes that the three statutory criteria - adverse health effects, occurrence, and meaningful opportunity for public health protection - must be met prior to the final determination to regulate, at which point EPA can propose a regulation. Additionally, since HFPO-DA was not included in the UCMR3 monitoring program, we recommend that EPA postpone the regulatory determination for this compound until a substantial amount of data has been gathered through the UCMR5 program.

EPA Response: Please see section 3.3 of the EPA response in this *Response to Comments* document. Regarding the EPA's evaluation of the second regulatory determination statutory criterion for HFPO-DA and UCMR 5, please see section 3.1.2 and 6.8 of the EPA response in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043099)

Furthermore, the proposed regulation of these compounds concurrently with the preliminary determination is beyond EPA's authority under SDWA. EPA is recommended to re-issue the preliminary determinations following availability of UCMR 5 data and to withdraw and re-issue the proposed regulation following a final determination.

EPA Response: Please see section 3.3 of the EPA response in this *Response to Comments* document. Regarding UCMR 5, please see sections 3.1.2 and 6.8 of the EPA response in this *Response to Comments* document.

Florida Section American Water Works Association – Water Utility Council (FSAWWA WUC) (Doc. #1737, SBC-044490)

XIV. Request for Comment on Proposed Rule: Section Ill-Regulatory Determinations for Additional PFAS, Section V-Maximum Contaminant Level Goal (MCLG) and Section VI Maximum Contaminant Level (MCL)

The Florida Water Sector recommends EPA remove preliminary regulatory determinations as well as the Hazard Index MCLG and MCLS for PFHxS, HFPO-DA, PFNA, and PFBS from a

final rule. We further recommend EPA obtain more data and information for the four compounds before releasing a potential new regulatory determination.

• We do not support EPA's approach to simultaneously release 4 new PFAS (PFHxS, HFPO DA, PFNA, and PFBS) preliminary regulatory determinations with a proposed MCLG and MCL Hazard Index. The term preliminary shows EPA still has significant questions about the determination themselves and make NPDWR development premature . For comparison, the PFOS and PFAS MCLGs and MCLs were developed two years from the time EPA made their positive regulatory determination and with considerably more information and data.

EPA Response: Please see section 3.3 of the EPA response in this *Response to Comments* document. For the EPA's evaluation of the regulatory determination statutory criteria for PFHxS, PFNA, HFPO-DA and mixtures of these three PFAS and PFBS, please see sections 3.1, 3.1.1, 3.1.2, 3.1.3, 3.2, 3.2.1, 3.2.2, and 3.2.3 of the EPA response in this *Response to Comments* document. Additionally, the term preliminary does not describe the substance of the regulatory determinations and so does not represent a conclusion that the EPA has significant questions about the determination themselves; preliminary here means these determinations are subject to notice and comment, as these were.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043077)

Additionally, the Agency has noted that SDWA provides EPA with the authority to concurrently propose a determination and to propose a drinking water regulation for these PFAS. In review of the statutory language, SDWA provides EPA with the authority to "publish such proposed regulation concurrent with the determination to regulate." A determination to regulate is distinctly different from a preliminary determination. Specifically, a preliminary determination applies to the proposed action while a determination to regulate applies to a final action. While this language authorizes EPA to propose regulation as part of the same action as a determination to regulate, it does not authorize that the proposed regulation be concurrent with a preliminary determination. This lack of authority further points to the need for the EPA to re-issue a proposed regulation for PFHxS, PFNA, HFPO-DA, and PFBS.

EPA Response: Please see section 3.3 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce (Doc. #1537, SBC-042651)

There are a number of other issues associated with the proposed MCLs that deserve in depth discussion, including the benefits identified by the agency, the health end points, and the possible conflict between other Administration policies, such as the energy intensity of the some of the proposed technology solutions and the possible creation of significant volumes of hazardous waste. There are procedural problems as well, as EPA bypassed an important step of the Safe Drinking Water Act two-step process for the four PFAS (other than PFOA and PFOS). EPA is

issuing the preliminary regulatory determination and the national drinking water standard at the same time for these contaminants.

EPA Response: Please see section 3.3 of the EPA response in this *Response to Comments* document. Regarding the rule benefits, please see section 13.4 of the EPA response in this *Response to Comments* document. Regarding the EPA's response on the first statutory criterion for regulatory determination, please see sections 3.1.1 and 3.2.1 of the EPA response in this *Response to Comments* document. The EPA notes that while commenter implies this drinking water regulation will result in hazardous waste as regulated under Subtitle C of RCRA, PFAS are not currently regulated as hazardous waste. The EPA included as part of a sensitivity analysis in its EA for this rule estimates of cost for disposal of water treatment residuals in Subtitle C landfills, not because they would be required, but because some entities might elect to use these facilities. As part of that effort, the EPA did an evaluation of the potential impact on hazardous waste landfill capacity and determined that even if water treatment facilities preferentially used Subtitle C landfills it would likely have a negligible impact on the national capacity. The EPA disagrees with the commenters characterization of "possible conflict between other Administration policies" and has followed the requirements of SDWA and all other required statutes in making the regulatory determinations and proposing and finalizing the NPDWRs.

Superfund Settlements Project (SSP) and RCRA Corrective Action Project (RCAP) (Doc. #1631, SBC-043441)

Based on the foregoing, EPA must withdraw its Proposed Rule and re-propose in strict compliance with the SDWA and upon an adequate record.

Sincerely,

/s/Laurie Matthews

Laurie Matthews

EPA Response: Please see section 3.3 of the EPA response in this *Response to Comments* document.

Superfund Settlements Project (SSP) and RCRA Corrective Action Project (RCAP) (Doc. #1631, SBC-043432)

I. EPA's simultaneous issuance of a preliminary regulatory determination and proposal of a MCLG and MCL circumvents the SDWA process.

Prior to this Proposal, EPA has not published a preliminary determination under the SDWA to regulate PFNA, PFHxS, PFBS and GenX. Notwithstanding, the Proposed Rule proposes MCLGs and MCLs for those substances simultaneously with a preliminary regulatory determination. This

is contrary to the statutory language and, accordingly, EPA must re-propose its determination and rescind its proposed MCLGs and MCLs as required by the SDWA.

Section 300g-1(b) of the SDWA sets forth the standards and procedures for regulating previously unregulated substances [FN4: 42 U.S.C. § 300g-1(b). EPA must determine: (1) a contaminant may have adverse health effects; (2) a contaminant is known to occur or substantially likely to occur in public water systems with a frequency and at levels of public health concern; and (3) there is a meaningful opportunity for health risk reduction through a national drinking water regulation]. First, EPA must issue a preliminary determination to regulate. Then, "after notice of the preliminary determination and opportunity for public comment" EPA then determines whether or not to regulate such contaminants [FN5: U.S.C. § 300g-1(b)(1)(B)(ii)(I) (emphasis added).]. EPA may propose MCLGs and MCLs concurrent with, or following, the final determination. Specifically, for any contaminant EPA determines to regulate, EPA shall publish MCLGs and NPDWRs not later than 24 months after the determination to regulate, and may publish such proposed regulation concurrent with the determination to regulate [FN6: 42 U.S.C. § 300g-1(b)(E).]. EPA must publish a MCLG and promulgate a NPDWR within 18 months after the proposal thereof or within the date of any extension. [FN7: Id]

The statutory intent is clear – EPA may propose MCLGs and NPDWRs only after or together with a final determination to regulate. [FN8: See Congressional Research Service, Regulating Contaminants Under the Safe Drinking Water Act (SDWA), R46652 at 11 (January 5, 2022) ("Once the Administrator determines to regulate a contaminant, SDWA requires EPA to propose a 'national primary drinking water regulation'").] If Congress meant otherwise, the allowance that EPA "may" publish an MCLG and NPDWR with the final determination to regulate would be unnecessary. Importantly, to do otherwise would deprive the public of the opportunity to comment on whether EPA's preliminary determination is appropriate and satisfies the regulatory criteria set forth at 42 U.S.C. § 300g-1(b)(1)(A).

This determination is not without regulatory import. In Nat. Res. Def. Council v. Regan, No. 201335 (D.C. Cir. May 9, 2023), the DC Circuit held that once EPA made a determination to regulate a contaminant, it may not withdraw that determination and is obligated to regulate that contaminant. The Court explained that the SDWA "frontloads" EPA's discretion in selecting contaminants for regulation following the procedure set forth in the statute. [FN9: Nat. Res. Def. Council v. Regan at 4.]. Following that, however, the SDWA sets forth a "strict, mandatory scheme governing the regulatory process." [FN10: Id.] Thus, the two-step process ensures that the public has an opportunity to comment, and EPA has an opportunity to consider those comments, prior to making a final regulatory determination and being committed to setting a MCLG and NPDWR.

EPA should not be seeking to compress the SDWA process into one proposal. EPA must reconsider its proposal of MCLGs and MCLs for the four PFAS and, instead, thoroughly consider public comments regarding the use of the best available peer-reviewed science, particularly in connection with its assessment of potential adverse health effects, whether the occurrence data are sufficiently robust and indicate a substantial likelihood of occurrence, and

whether regulation presents a meaningful opportunity for health risk reduction. Only after that should EPA develop proposed MCLGs and MCLs.

EPA Response: Please see section 3.3 of the EPA response in this *Response to Comments* document. As the EPA has explained, the agency has sufficient information to determine whether to regulate these contaminants and to propose the regulation. The public has been provided with an opportunity to comment on each of these proposals. For the EPA's evaluation of the regulatory determination criteria for both individual contaminant regulation and regulation of mixtures, please see sections 3.1, 3.1.1, 3.1.2, 3.1.3, 3.2, 3.2.1, 3.2.2, and 3.2.3 of the EPA response in this *Response to Comments* document. The EPA has requested and received additional data and information, for both the preliminary regulatory determination and the proposed rule, so an additional notice and comment opportunity is not required.

Western Urban Water Coalition (WUWC) (Doc. #1768, SBC-043949)

III. EPA's Proposed MCLs and MCLGs for PFHxS, GenX Chemicals, PFNA, and PFBS are Premature and Subject to Challenge

WUWC is also concerned that the issuance of a preliminary determination concurrent with proposed MCLs and MCLGs for PFHxS, GenX Chemicals, PFNA, and PFBS conflicts with the SDWA's established process for regulating drinking water contaminants and is vulnerable to legal challenges. The SDWA provides a two-step process for the regulation of drinking water contaminants. First, "after notice of the preliminary determination [to regulate contaminants] and opportunity for public comment," EPA must "make determinations of whether or not to regulate such contaminants."[FN32: SDWA § 1412(b)(1)(B)(ii); 42 U.S.C. §300g-1(b)(1)(B)(ii)] Second, EPA must "publish maximum contaminant level goals and promulgate, by rule, national primary drinking water regulations" for each contaminant EPA determines to regulate. [FN33: SDWA § 1412(E); 42 U.S.C. §300g-1(E)]

In the Proposed Rule, EPA claims that the SDWA allows it to publish a proposed drinking water regulation concurrent with its preliminary determination to regulate. [FN34: 88 Fed. Reg. at 18644 ("Section 1412(b)(1)(E) authorizes EPA to issue a preliminary determination to regulate a contaminant and a proposed NPDWR addressing that contaminant concurrently and request public comment at the same time.")] However, the statute only allows EPA to "publish such proposed regulation concurrent with the determination to regulate," not the "preliminary determination to regulate."[FN35: SDWA § 1412(E); 42 U.S.C. §300g-1(E); see also Nat. Res. Def. Council v. Regan, No. 20-1335, 2023 WL 3312344, at *1 (D.C. Cir. May 9, 2023) (stating that EPA must make a preliminary determination and then may make a final determination "[a]fter the comment period ends" for the preliminary determination).] EPA itself has published materials that document the normal SDWA regulatory process. [FN36: See e.g., U.S. EPA, SDWA Evaluation and Rulemss, https://www.epa.gov/sdwa/sdwa-evaluation-andrulemaking-process.] WUWC members appreciate EPA's sense of urgency to regulate PFAS under the

SDWA, but EPA should follow the procedures set forth in the SDWA to reduce the Proposed Rule's vulnerability to legal challenges.

EPA Response: Please see section 3.3 of the EPA response in this *Response to Comments* document.

California-Nevada Section American Water Works Association (CA-NV AWWA) (Doc. #1775, SBC-045278)

The Safe Drinking Water Act establishes a multi-step process for developing National Primary Drinking Water Regulations. This includes an incremental process for requiring a preliminary determination and public comment period prior to finalizing a regulatory determination. EPA should follow the standard process for PFHxS, PFNA, PFBS, and HFPO-DA (GenX), including a preliminary regulatory determination and full public review. This normal, stepwise process would permit a more thorough evaluation of occurrence, technological feasibility, and economic feasibility prior to proposing a final regulatory determination, and better appraisal of the complicated Hazard Index approach.

EPA Response: Please see section 3.3 of the EPA response in this *Response to Comments* document.

Wisconsin Department of Justice et al. (Doc. #1687, SBC-044446)

2. EPA has authority to issue a preliminary determination and simultaneously propose MCLs and MCLGs for PFAS in drinking water.

EPA's decision to issue a preliminary determination and simultaneously publish proposed MCLGs and national primary drinking water regulations for PFAS was proper and lawful. The SDWA, 42 U.S.C. § 300g-1(b)(1)(A), expressly authorizes EPA to proceed in this manner. Moreover, EPA has provided the required notice and opportunity to comment on its preliminary determination to regulate the subject four PFAS, in accordance with 42 U.S.C. § 300g-1(b)(1)(B)(ii). The Agency has also provided the required notice and opportunity for comment on its proposed rule publishing MCLGs and setting national primary drinking water regulations for the subject suite of six PFAS. [FN33: See 42 U.S.C. § 300g-1(b)(1)(E); 5 U.S.C. § 553(c).]

EPA also acted reasonably in scheduling the comment periods to occur simultaneously for the preliminary determination to regulate the four PFAS and for the proposed rule to establish MCLGs and setting national primary drinking water standards for the subject PFAS. Simultaneous, rather than sequential, comment periods are not precluded by the SDWA and here serve the purposes both of best promoting public health and furthering administrative efficiency. Indeed, the Act expressly states that EPA may propose such a regulation "concurrent with the determination to regulate," [FN34: 42 U.S.C § 300g-1(b)(1)(E).] and does not prohibit a proposal to set national primary drinking water standards made simultaneously with a proposed determination to regulate. And while the SDWA prescribes a deadline for EPA to propose a

regulation setting national primary drinking water standards (subject to notice and comment), being "no later than 24 months after the determination to regulate," [FN35:Id. (emphasis added).] the Act does not set a time before which the agency may set a national primary drinking water standard (subject, of course, to notice and comment). Thus, the SDWA allows for simultaneous comment periods here.

Given the need to promptly address the significant demonstrated risks to human health posed by the four subject PFAS, EPA was well within its discretion to schedule these simultaneous comment periods. Moreover, these simultaneous comment periods promote appropriately efficient decision-making by EPA because the standard for a determination to regulate matches the standard for issuing a national primary drinking water regulation. [FN36: See 42 U.S.C. §§ 300g-1(b)(1)(B)(ii)(II), 300g-1(b)(1)(A).] The standard for each turns on: (a) the contaminant's potential for adverse health effects, (b) the likelihood that the contaminant will occur sufficiently frequently in public water supplies, and (c) whether regulation of the contaminant presents a meaningful opportunity for health risk reduction. [FN37:Id.] These simultaneous comment periods facilitate fuller, more comprehensive, and more efficient consideration by EPA of its rulemaking in accordance with these standards.

EPA Response: Please see section 3.3 of the EPA response in this *Response to Comments* document.

Philadelphia Water Department (PWD) (Doc. #1709, SBC-045745)

9. Combining a preliminary regulatory determination within a notice of proposed rulemaking is inconsistent with EPA's established process for the promulgation of drinking water regulations under the SDWA.

Of the six PFAS included in the proposal, only PFOA and PFOS went through the established regulatory determination process as mandated in the Safe Drinking Water Act. PWD appreciates efforts to streamline the regulatory process, but not at the expense of scientifically sound regulations. It is recommended that EPA use the regulatory determination process to gather more data to inform the rulemaking for PFNA, PFHxS, PFBS, and HFPO-DA.

EPA Response: Please see section 3.3 of the EPA response in this *Response to Comments* document. The EPA disagrees that the regulatory determinations are not informed by the best health, occurrence and other data as described in sections 3.1 and 3.2 of the EPA response in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1711, SBC-044466)

[The Agency's proposal suffers from the following significant shortcomings –]

• The decision to propose an MCL/MCL Goal and preliminary regulatory determination concurrently for the four PFAS violates the requirements of the Safe Drinking Water Act, and

EPA Response: The EPA disagrees. Please see section 3.3 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045873)

Comments of the U.S. Chamber of Commerce and its Coalition

EPA PFAS National Primary Drinking Water Regulation Rulemaking Preliminary Regulatory Determination and Proposed Rule

Docket ID No. EPA-HQ-OW-2022-0114 88

Fed. Reg. 18638 (Mar. 29, 2023)

Submitted on regulations.gov

May 30, 2023

Executive Summary

Under the Safe Drinking Water Act (SDWA), EPA is required to regulate contaminants in drinking water by following a multi-step process established in the statute. The critical finding for preliminary and final determinations to regulate requires EPA use the best available public health information to show that a contaminant may have an adverse effect on human health, it occurs frequently enough to present a health concern, and there is a meaningful opportunity for health risk reductions by regulating public water systems. If EPA, based on SDWA's rigorous scientific standards, decides to regulate, the Agency must not impose maximum contaminant levels (MCLs) for regulation that are more stringent than feasible, considering costs to regulated entities.

In this proposed rule, EPA targets six per- and polyfluoroalkyl substances (PFAS) for regulation under SDWA: perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO–DA) and its ammonium salt (also known as GenX chemicals), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS). EPA expects this action to directly affect 66,000 public water systems across the country. But in EPA's rush to regulate these six PFAS and address a priority for the Agency, it deviates from its statutory procedures under SDWA. EPA proposes near-zero levels of these six PFAS in drinking water and employs a novel approach to setting an MCL for the mixture of four of the six PFAS without having satisfied the required scientific, legal, or procedural requirements to justify the proposed rule.

EPA Response: The EPA notes that this comment is the commenter's summary of how they perceive the key requirements of the rule and the EPA does not agree with their assertions. The EPA has responded to commenter's substantiative comments throughout this *Response to Comments* document. The EPA has used best available science to develop this regulation and the agency has met the legal and procedural requirements of SDWA and other obligations. Please

see section 3 of the EPA response in this *Response to Comments* document for discussion of Regulatory Determinations, section 4 on MCLGs, section 5 on MCLGs, and section 6 on Occurrence. In regard to the EPA following the SDWA statutory process and the commenter's claim that the EPA "deviates from its statutory procedures under SDWA", the agency disagrees and refers the commenter to see section 3.3 of the EPA response in this *Response to Comments* document. In regard to the Hazard Index MCL, please see section 5.2 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045895)

III. The Proposed MCL and MCLG for PFNA, PFHxS, PFBS, and HFPO-DA (and Mixtures of These PFAS) Is Legally and Technically Flawed and Cannot Be Finalized in Its Current Form

EPA proposes (simultaneously with its preliminary determination) a MCL and MCLG of "1.0 (unitless) hazard index" for PFNA, PFHxS, PFBS and HFPO-DA as a mixture. The proposed MCL and MCLGs for PFNA, PFHxS, PFBS, and HFPO-DA (and mixtures of these PFAS) cannot be finalized because the procedures EPA used to propose the MCLs and MCLGs for these four PFAS violate SDWA. And, the Hazard Index approach is inconsistent with SDWA requirements. Should, in the future, data from UCMR 5 identify occurrence of these four PFAS at levels of public health concern EPA can revisit whether regulation is necessary consistent with SDWA requirements.

In March 2021, EPA issued a final regulatory determination to regulate PFOA and PFOS as contaminants under SDWA. Now, EPA proposes a MCL of 4 ppt and MCLG of 0 for PFOA and for PFOS. As discussed, the scientific data EPA uses to support the proposed MCLs and MCLGs for PFOA and PFOS do not comport with SDWA's mandate for EPA to use the best available science in carrying out national drinking water regulations.

EPA Response: Regarding the EPA's concurrent preliminary regulatory determination and proposed NPDWR for PFNA, PFHxS, PFBS, HFPO-DA, and mixtures of these four PFAS, please see section 3.3 of the EPA response in this *Response to Comments* document. Specifically pertaining to the EPA's evaluation of the second regulatory determination statutory criterion on occurrence of PFNA, PFHxS, PFBS, HFPO-DA, and mixtures of these four PFAS, please see sections 3.1.2 and 3.2.2 of the EPA response in this *Response to Comments* document. The EPA disagrees that the Hazard Index approach is inconsistent with SDWA requirements as described in section 5.2 of the EPA response in this *Response to Comments* document. Additionally, the EPA disagrees that it has not used the best available science to support the proposed MCLs and MCLGs for PFOA and PFOS. Please see sections 5.1 and 4.1.2 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045897)

B. EPA failed to follow the process mandated by SDWA in proposing the preliminary determinations for PFNA, PFHxS, PFBS, and HFPO-DA simultaneously with their proposed MCL and MCLG

EPA has decided in this proposal to simultaneously issue a preliminary regulatory determination for PFNA, PFHxS, PFBS, and HFPO-DA and a proposed MCL and MCLG for these four PFAS. In doing so, it has side-stepped the statutory process for regulating contaminants under SDWA and deprived the public of sufficient time to provide public comments on the proposal.

SDWA requires that a preliminary regulatory determination be made prior to proposing an MCL:

For each contaminant that the Administrator determines to regulate under subparagraph (B), the Administrator shall publish maximum contaminant level goals and promulgate, by rule, national primary drinking water regulations under this subsection. The Administrator shall propose the maximum contaminant level goal and national primary drinking water regulation for a contaminant not later than 24 months after the determination to regulate under subparagraph (B),and may publish such proposed regulation concurrent with the determination to regulate. The Administrator shall publish a maximum contaminant level goal and promulgate a national primary drinking water regulation within 18 months after the proposal thereof. The Administrator, by notice in the Federal Register, may extend the deadline for such promulgation for up to 9 months [FN54: 42 U.S.C. [sec] 300g-1(b)(1)(E) (emphasis added)].

The "subparagraph (B)" referred to in this paragraph means the section of SDWA regarding EPA's determination to regulate contaminants "after notice of the preliminary determination and opportunity for public comment."[FN55: 42 U.S.C. [sec] 300g-1(b)(1)(B)(ii).] Therefore, the statutory procedure for regulation of contaminants is that EPA first issues a preliminary determination and provides an opportunity for comment. Then, after consideration of public comments, EPA may issue a final regulatory determination and concurrently (if the determination is positive) propose a NPDWR and MCLG for the contaminant for public comment. This statutory approach ensures that stakeholders could comment on the preliminary determination and then again after EPA makes a final determination on proposed MCLs and MCLGs for the contaminant. Indeed, this is the process that EPA has followed in the past.

In contrast to that usual course, EPA explains in the preamble that it interprets "determination to regulate" to mean the regulatory process for determining to regulate a contaminant, which begins with a preliminary determination. EPA thus claims that the statute allows it to issue a proposed regulation concurrent with a preliminary determination to regulate [FN56: 88 Fed. Reg. at 18644.]. This interpretation of SDWA is flawed because a preliminary determination is not a "determination to regulate." The entire scheme Congress set out in SDWA reflects a step-by-step process in which EPA collects data on contaminants, seeks public input and consultation with scientific authorities, proposes to regulate or not regulate the contaminant based on evaluation of the three statutory factors, and proposes (and accepts comment on) and adopts regulatory

limitations if it decides regulation is warranted. EPA's interpretation eliminates the distinction between preliminary and final determinations, upending Congress's intent to create multiple opportunities for public comment before EPA makes such an impactful decision. The text is clear, and EPA's proposed interpretation is not reasonable.

EPA justifies its corner-cutting with its goal to reduce these PFAS "expeditiously" and points to a "public urgency" to reduce PFAS concentrations in drinking water [FN57: 88 Fed. Reg. at 18652.]. But EPA's desire to rush to the finish line cannot overcome the statutory process. By short circuiting the procedures for regulating contaminants, the Agency failed to provide the public with the opportunity to comment on the preliminary determination for these four PFAS and provide EPA with necessary data, including occurrence data EPA acknowledges it does not have, to make the threshold decision on whether the statutory criteria are met to justify the proposal of a NPDWR or MCLG for the four PFAS. As proposed, stakeholders had only 60 days to provide comment not only on EPA's preliminary determination that these four PFAS must be regulated but also on the proposed MCL and MCLG Hazard Index—a completely novel approach to setting an MCL and MCLG.

To comply with SDWA requirements for regulating contaminants, EPA must withdraw its proposed MCL and MCLG for the four PFAS and, instead, first consider public input on the preliminary determination, i.e., whether the four PFAS warrant regulation at all. Then, to cure the legal defect in the proposal, EPA would have to re-propose the final determination and the NPDWR with an additional comment period before finalizing the regulatory limits on these substances [FN58: As EPA issued a previous regulatory determination for PFOA and PFOS, this comment is not applicable to the portion of the proposal setting MCLs for those substances.].

EPA Response: Please see section 3.3 of the EPA response in this *Response to Comments* document. The EPA is not rushing to the finish line and its actions are consistent with the statutory procedures. As the EPA has explained, the agency has sufficient information, including occurrence data, to determine whether to regulate these contaminants and to propose the regulation (see section 3 of the EPA response in this *Response to Comments* document regarding the EPA's preliminary regulatory determinations, as well as section 6 related to occurrence). The public has been provided with an opportunity to comment on each of these proposals. The EPA has requested and received additional data and information, for both the preliminary regulatory determination and the proposed rule, so an additional notice and comment opportunity is not required.

<u>Environmental Working Group (EWG) (Doc. #1721, SBC-045408)</u>

The EPA has clear legal authority to make a regulatory determination at any time, regardless of whether a substance appears on the CCL, so long as the contaminant meets the above-listed criteria. [FN21: 42 U.S.C. [sec] 300g-1(b)(1)(B)(ii)(III).] And while the EPA has 24 months to issue a national primary drinking water regulation after a regulatory determination, the EPA may

also issue NPDWRs "concurrent with the determination to regulate" [FN22: 42 U.S.C. [sec] 300g-1(b)(1)(E).] as it has done in this proposed rulemaking.

EPA Response: Please see section 3.3 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045552)

4. The agency's proposed regulation concurrent with preliminary regulatory determinations is not within the scope of authorities granted by the Safe Drinking Water Act (SDWA), does not fulfill the obligations under the Administrative Procedures Act, and is inappropriate. Proposed regulation of additional PFAS should not occur until a determination to regulate is issued.

We hope that these comments will help EPA finalize the rule by effectively leveraging science and the authorities of the Safe Drinking Water Act. If you have any questions regarding this correspondence, please contact me or Chris Moody at 202.326.6127 or cmoody@awwa.org.

Best Regards,

ON BEHALF OF THE AMERICAN WATER WORKS ASSOCIATION

G. Tracy Mehan III

Executive Director for Government Affairs

Attachment (1)

cc: Ryan Albert, EPA / OW

Eric Burneson, EPA / OW

Radhika Fox, EPA / OW

Jennifer McLain, EPA / OW

The American Water Works Association is an international, nonprofit, scientific and educational society dedicated to providing total water solutions assuring the effective management of water. Founded in 1881, the Association is the largest organization of water supply professionals in the world. Our membership includes more than 4,500 utilities that supply roughly 80 percent of the nation's drinking water and treat almost half of the nation's wastewater. Our 50,000-plus total membership represents the full spectrum of the water community: public water and wastewater systems, environmental advocates, scientists, academicians, and others who hold a genuine interest in water, our most important resource. AWWA unites the diverse water community to advance public health, safety, the economy, and the environment.

AWWA Comments on the Proposed "PFAS National Primary Drinking Water Regulation Rulemaking"

Docket ID No: EPA-HQ-OW-2022-0114 [Link: https://www.regulations.gov/docket/EPA-HQ-OW-2022-0114]

Prepared by the: American Water Works Association

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List of Appendices

[Table 1: See Docket ID EPA-HQ-OW-2022-0114-1759]

List of Tables

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List of Figures

[List of Figures: See Docket ID EPA-HQ-OW-2022-0114-1759]

List of Acronyms

[Table 2: See Docket ID: EPA-HQ-OW-2022-0114-1759]

EPA Response: Please see section 3.3 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045560)

Finally, the proposed regulation concurrent with preliminary determinations is not within the scope of the EPA's authority under SDWA. While EPA is authorized to issue a proposal concurrent with a determination to regulate, this is a distinctly different action from a preliminary determination.

EPA Response: Please see section 3.3 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045634)

Additionally, the EPA's statement that it has legal authority to concurrently propose a drinking water regulation with a preliminary determination is a misinterpretation of SDWA.

EPA Response: Please see section 3.3 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045608)

EPA stated that SDWA provides the agency with the authority to concurrently propose a preliminary regulatory determination and to propose a drinking water regulation for these PFAS, but this is not the case. SDWA provides EPA with the authority to "publish such proposed regulation concurrent with the determination to regulate". A determination to regulate is distinctly different from a preliminary determination. Specifically, a preliminary determination applies to the proposed action while a determination to regulate applies to a final action. While this language authorizes EPA to propose regulation as part of the same action as a determination to regulate, it does not authorize that the proposed regulation be concurrent with a preliminary determination.

EPA itself has distinguished between a preliminary and final regulatory determination, the latter of which it interprets to mean the "determination to regulate." [FN20: See 76 Fed. Reg. 7762, 7763 (Feb. 11, 2011) ("What is EPA's final regulatory determination on perchlorate and what happens next?" . . . . "the Agency has made a determination to regulate perchlorate in drinking water [and] EPA is initiating the development of a proposed NPDWR for perchlorate.").]

Second, SDWA Section 1412(b)(1)(B)(ii) specifically uses different terms for a determination to regulate and a preliminary determination:

"Not later than 5 years after August 6, 1996, and every 5 years thereafter, the Administrator shall, after notice of the preliminary determination and opportunity for public comment . . . make determinations of whether or not to regulate such contaminants." [FN21: 42 U.S.C. § 300g–1(b)(1)(B)(ii). See also NRDC v. EPA, No. 20-133, slip op. at 4 (D.C. Cir. May 9, 2023) ("After the comment period ends, EPA must make its final regulatory determination.") (emphasis added); id. at 11 ("[T]he preliminary determination precedes the notice and comment period. Once that period ends, the agency makes its regulatory determination, and that determination is final.").]

In addition, collapsing these steps into a single proposal undermines the SDWA's mandate that EPA use the best available public health information to make regulatory determinations in accordance with the three statutory criteria. While EPA is collecting public comment on the preliminary determination (and is seeking more studies and health information from the public), how would it know that regulation is warranted when it lacks a complete record? Instead, the notice and comment provisions exist to allow EPA to collect the data it needs to decide whether to regulate and to ensure the statutory criteria for it to do so are present. EPA's approach is also inconsistent with SDWA Section 1412(b)(4)(C), which states that "[a]t the time the Administrator proposes a national primary drinking water regulation under this paragraph, the Administrator shall publish a determination as to whether the benefits of the maximum contaminant level justify, or do not justify, the costs…" [FN22: 42 U.S.C. § 300g–1(a)(3).] EPA cannot reach such a decision while it is collecting public health data from the preliminary determination phase because it cannot simultaneously determine whether the benefits of regulation justify the costs. And notably, Congress knows how to direct simultaneous regulatory

actions under the SDWA when it intends to, but did not do so here. [FN23: For example, Section 1412(a)(3)) states: "Whenever a national primary drinking water regulation is proposed under subsection (b) for any contaminant, the maximum contaminant level goal for such contaminant shall be proposed simultaneously. Whenever a national primary drinking water regulation is promulgated under subsection (b) for any contaminant, the maximum contaminant level goal for such contaminant shall be published immediately."]

Because the SDWA does not provide EPA with the authority to propose a preliminary determination to regulate at the same time as a proposed regulation (and as a result it has not been agency practice to do so previously), EPA must re-issue a proposed regulation for PFHxS, PFNA, HFPO-DA, and PFBS after accepting public comment on its preliminary determination to regulate those substances in order to comply with its obligations under the SDWA and APA.

EPA Response: Please see section 3.3 of the EPA response in this *Response to Comments* document. Contrary to commenter's interpretation, the EPA's statement in the final regulatory determination on perchlorate that "the Agency has made a determination to regulate perchlorate in drinking water" is descriptive and not a preclusive interpretation of the phrase. The EPA maintains its interpretation that "determination to regulate" in the second phrase of 1412(b)(1)(E) allows for concurrent processing of a preliminary determination and proposed rule, not a final determination and proposed rule. As the EPA has explained, the agency has sufficient information, including health and occurrence data , to determine whether to regulate these contaminants and to propose the regulation (see section 3 of the EPA response in this *Response to Comments* document regarding the EPA's preliminary regulatory determinations, section IV related to MCLGs, and section 6 related to occurrence). The public has been provided with an opportunity to comment on each of these proposals. The EPA has requested and received additional data and information, for both the preliminary regulatory determination and the proposed rule, so an additional notice and comment opportunity is not required.

PFAS Regulatory Coalition (Doc. #1761, SBC-046067)

A. EPA's regulatory determinations for four additional PFAS are inappropriate.

1. The EPA Proposal fails to follow the procedures set forth in the Safe Drinking Water Act.

The Safe Drinking Water Act gives EPA the authority to establish national primary drinking water regulations "in accordance with the procedures established by this subsection." SDWA 1412(b)(1)(A). Yet, in the EPA Proposal, the Agency deviates from those procedures by combining three separate rulemakings into one – 1) drinking water standards for PFOA/PFOS; 2) regulatory determinations for four additional compounds; 3) drinking water standards for the four additional compounds.

The proposed drinking water standards for PFOA/PFOS first involved EPA, after what the Agency says was "careful consideration of public comments" (88 Fed. Reg. 18644), making a regulatory determination for these two compounds in a prior rulemaking in March 2021. More

specifically, on March 10, 2020, EPA published a preliminary regulatory determination for eight contaminants on the Contaminant Candidate List (CCL 4), two which were PFOA and PFOS. 85 Fed. Reg. 14098 (Mar. 10, 2020). On March 3, 2021, EPA made a final regulatory determination for only PFOA and PFOS and decided not to regulate the other six contaminants. 86 Fed. Reg. 12272 (Mar. 3, 2021). After deliberating for an entire year, EPA moved forward to the next stage of regulation for only two of the eight compounds for which it had made a preliminary regulatory determination.

Here, in contrast, EPA is making a regulatory determination for four compounds and moving forward with proposed drinking water standards in the same step. The consolidation of the Regulatory Determination and proposed drinking water standards for the four additional compounds is problematic in that it provides neither EPA nor the public with the time or information for appropriate consideration of the Regulatory Determination, as required by the Safe Drinking Water Act, instead assuming an outcome and proceeding directly to a proposed drinking water standard. EPA took a year to deliberate on the regulatory determination for PFOA and PFOS, yet is only giving the public 62 days to consider and comment not just on the regulatory determination for PFHxS, PFNA, PFBS, and HFPO-DA but also on the novel approach of using a Hazard Index (HI) as an MCL. This is especially problematic when, through a response letter EPA issued to the Coalition on May 5, 2023, EPA refused to grant an extension of the comment period.

EPA cites "public urgency" rather than consideration of best available science under the framework of the Safe Drinking Water Act as the rationale for this Proposal. 88 Fed. Reg. 18652. We understand that a sense of urgency is driving the Agency to move forward in this manner, but that must not be at the expense of due deliberation of the new and important issues raised in the EPA Proposal. EPA lacks authority to so sharply change course in setting MCLs. EPA's proposal to depart from its long-established MCL process and prior interpretations of its statutory authority is arbitrary and capricious.

EPA Response: Please see section 3.3 of the EPA response in this *Response to Comments* document. The commenter mischaracterizes the EPA's fourth regulatory determination, where the agency made a preliminary determination to regulate PFOA and PFOS and a preliminary determination not to regulate six other non-PFAS contaminants. After considering public comment, the EPA finalized determinations for all eight of these contaminants. Similarly, after considering public comment on the EPA's five preliminary regulatory determinations (PFHxS, PFBS, PFNA, HFPO-DA, and mixtures containing two or more of these PFAS), the EPA is finalizing four of those determinations. Additionally, the commenter mischaracterizes that the EPA cites "public urgency rather than consideration of best available science" as the rationale for its proposal to regulate PFHxS, PFNA, HFPO-DA, PFBS and mixtures containing two or more of these four PFAS. Though the EPA does acknowledge "public urgency to reduce PFAS concentrations in drinking water" in the proposal, the agency does so only after providing all of the necessary information and rationale to satisfy the statutory requirements and does not consider "public urgency" as a factor or in lieu of the requirements

under SDWA to consider the best available science (see section 3 of the EPA response in this *Response to Comments* document regarding the EPA's preliminary regulatory determinations). Regarding the commenter's request for an extension to the public comment period, please see section 17.1 of the EPA response in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-045653)

EPA's Proposed Hazard Index-Based MCL for PFHxS, PFBS, PFNA, and HFPO-DA Does Not Comply with the SDWA

EPA's proposed Hazard Index-based Maximum Contaminant Level (HI-MCL) for PFHxS, PFBS, PFNA and HFPO-DA is procedurally improper and substantively incorrect, for several reasons.

As an initial matter, the SDWA does not permit the Agency to simultaneously issue a notice of intent to regulate and a proposed MCLG and MCL. EPA may issue a decision to regulate at the same time that it proposes an MCLG and MCL, but it may not provide initial public notice that it is contemplating regulation at the same time it proposes the regulation. The failure to undertake the statutorily required two-step process undermines the validity of the EPA's proposals.

EPA Response: Please see section 3.3 of the EPA response in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-045662)

V. EPA'S PROPOSED STANDARDS FOR PFHxS, PFBA, PFNA, AND HFPO-DA ARE PROCEDURALLY AND TECHNICALLY FLAWED

a. The SDWA Does Not Permit Publication of a Preliminary Determination to Regulate at the Same Time as a Proposed NPDWR.

EPA issued its proposed NPDWRs for PFHxS, PFBA, PFNA, and HFPO-DA (the HI MCL) without adhering to the Congressionally prescribed procedure for setting MCLs under the SDWA. The Proposed Rule is therefore arbitrary and capricious and violates the SDWA. See Chevron USA Inc. v. Natural Resources Defense Council, 467 U.S. 837 (1984) ("[i]f the intent of Congress is clear… the agency… must give effect to the unambiguously expressed intent of Congress").

The SDWA requires EPA to make a "preliminary determination" to regulate a substance and provide notice and an opportunity for public comment on that preliminary determination. [FN31:42 USC [sec] 300g-1(b)(1)(B)(ii)(I)] The independent step of issuing notice of a preliminary determination reflects an intentional, discrete step in the regulatory process sanctioned by Congress. Once EPA has solicited and considered comment on that preliminary determination, EPA can make a final "determination to regulate." This two-step process is clearly reflected in the language of 42 USC [sec] 300g-1 (b)(1)(B)(ii)(I)-(b)(1)(B)(ii)(III).

Section (b)(1)(B)(ii)(I) states a "determination" to regulate a substance on the CCL "shall" only be issued "after notice of the preliminary determination and opportunity for public comment."

While the SDWA allows EPA to publish a proposed regulation "concurrent with the determination to regulate," id. at [sec] (b)(1)(E), it does not permit the EPA to skip the "preliminary determination to regulate" step, as it did here. To the contrary, the SDWA distinguishes between the process of issuing a "preliminary determination" that is subject to public comment (i.e., a proposed rule) and the "mak[ing of]" a final determination (i.e., a final rule). Id. Similarly, SDWA Section (b)(1)(B)(ii)(2) lists factors that must support the final "determination," not the "preliminary determination." Further, section (b)(1)(B)(ii)(III) states the same "determination" can be made even if the substance does not appear on the CCL, as required by (b)(1)(B)(ii)(I). These distinctions confirm that Congress intended a "determination to regulate" under the SDWA to mean a final determination and not a preliminary determination. Stated differently, EPA has the authority to promulgate a final decision to regulate in the same rulemaking as a proposal for additional drinking water standards. However, the SDWA does not give EPA the authority to issue a proposed NPDWR and a preliminary regulatory determination at the same time – but this is precisely what EPA did in this rulemaking.

EPA has recognized that "[t]he development of the CCL, regulatory determinations, and any subsequent rulemaking should be viewed as a progression where each process builds upon the previous process, including the collection of data and analyses conducted." [FN32: 85 Fed. Reg. at 14100] EPA's truncated regulatory determination in this case minimizes time for public-review and violates the plain language of the SDWA.

EPA Response: Please see section 3.3 of the EPA response in this *Response to Comments* document.

Metropolitan Water District of Southern California (Doc. #1777, SBC-045428)

1. EPA's proposed MCLs and MCLGs for PFHxS, GenX chemicals, PFNA, and PFBS are premature and should follow EPA's established regulatory process

As proposed, EPA is issuing a preliminary determination to regulate perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO–DA), and its ammonium salt (also known as GenX chemicals), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS), and mixtures of these PFAS as contaminants under the Safe Drinking Water Act (SDWA), while at the same time proposing a NPDWR and MCLGs for these four PFAS and their mixtures. However, pursuant to the SDWA, EPA must make a final determination to regulate prior to or concurrent with a proposed NPDWR.

Section 1412(b)(1)(B)(ii) of the SDWA explains the two-step process for how EPA regulates drinking water contaminants. The first step is that EPA must, "after notice of the preliminary determination [to regulate contaminants] and opportunity for public comment, . . . make determinations of whether or not to regulate such contaminants."[FN3: 42 U.S.C. §

1412(b)(1)(B)(ii)(I).] The second step is that for each contaminant EPA determines to regulate, EPA must "publish maximum contaminant level goals and promulgate, by rule, national primary drinking water regulations . . . ."[FN4: 42 U.S.C. § 1412(b)(1)(E).] The deadline for EPA to propose the MCLG and NPDWR is "not later than 24 months after the determination to regulate [FN5: 42 U.S.C. § 1412(b)(1)(E).]

EPA relies on Section 1412(b)(1)(E) to justify its ability to publish a proposed drinking water regulation concurrent with a preliminary determination to regulate. [FN6: 88 Fed. Reg. 18638, at 18644 (Mar. 29, 2023) ("Section 1412(b)(1)(E) authorizes EPA to issue a preliminary determination to regulate a contaminant and a proposed NPDWR addressing that contaminant concurrently and request public comment at the same time.").] But such language is not in Section 1412(b)(1)(E). Instead, Section 1412(b)(1)(E) states that EPA "may publish such proposed regulation concurrent with the determination to regulate." The "determination to regulate" is EPA's final determination to regulate, not its preliminary determination to regulate.

If Congress had meant that EPA could publish a proposed regulation at the same time as it issues a preliminary determination to regulate, Congress would have used the word "preliminary" (as it did in Section 1412(b)(1)(B)(ii)(I)), but Congress did not use the adjective "preliminary" to describe "determination to regulate" in Section 1412(b)(1)(E). [FN7: See, e.g., Reiter v. Sonotone Corp., 442 U.S. 330, 339, 99 S. Ct. 2326, 60 L. Ed. 2d 931 (1979) (the Court is "obliged to give effect, if possible, to every word Congress used").]

This interpretation is consistent with EPA's own explanation of its rulemaking process under the SDWA. According to EPA's SDWA Evaluation and Rulemaking Process, "EPA publishes preliminary regulatory determinations for public comment and considers those comments prior to making a final regulatory determination. If EPA makes a positive regulatory determination for any contaminant, it will begin the process to establish a national primary drinking water regulation, which typically includes a Maximum Contaminant Level (MCL)."[FN8: https://www.epa.gov/sdwa/sdwa-evaluation-and-rulemaking-process.] Accordingly, Metropolitan recommends that EPA follow the procedure set forth in the SDWA and first make a final determination to regulate PFHxS, GenX chemicals, PFNA, and PFBS before proposing NPDWRs and MCLGs for them, as was done for PFOA and PFOS. Otherwise, EPA's NPDWR Rulemaking could be subject to challenge, which would delay the process of establishing NPDWRs and MCLGs for these four PFAS.

EPA Response: Please see section 3.3 of the EPA response in this *Response to Comments* document. The EPA's description of its typical SDWA rulemaking process does not preclude the process it has undertaken in this rulemaking, consistent with the agency's interpretation of the SDWA.

Office of Advocacy at the U.S. Small Business Administration (Doc. #1807, SBC-045493)

Most importantly, Advocacy recommends that the agency proceed in a step-by-step manner contemplated by the statute by first issuing a preliminary determination for the four PFAS and then after the agency finalizes its determination, it can then propose the appropriate NPDWR.

EPA Response: Please see section 3.3 of the EPA response in this *Response to Comments* document.

Office of Advocacy at the U.S. Small Business Administration (Doc. #1807, SBC-045491)

III. Advocacy is concerned about the agency's concurrent proposal of a preliminary determination and the proposed regulation of four PFAS chemicals.

Advocacy is concerned about EPA's approach in issuing both a preliminary regulatory determination and national primary drinking water regulations for the four PFAS chemicals, (PFHxS, GenX chemicals, PFNA, and PFBS) in the same action. To support its justification for its concurrent proposal approach, EPA cites "[f]or each contaminant that the Administrator determines to regulate under subparagraph (B)…[EPA]may publish such proposed regulation concurrent with the determination to regulate."[FN18: 88 Fed. Reg.18644 citing 42 U.S.C. §300g–1 (b)(1)(E).] EPA's reliance, however, is misplaced because statutory language does not permit a proposed concurrent regulation with a preliminary determination; it only allows a concurrent proposal with a "determination to regulate." The agency equates the "determination to regulate" with a "regulatory process…that beings with a preliminary determination."[FN19: Id. at 18644]. "Determination" is defined as "the act of deciding definitely and firmly."[FN20: See, Merriam Webster Dictionary. Determination Definition & Meaning - Merriam-Webster (last visited May 30, 2023).] Therefore, it cannot be considered to be a preliminary process where a decision is being contemplated and is not yet decided. EPA further asserts that this provision authorizes a more expedited process. This is also incorrect. The SDWA includes a separate provision that allows for such an expedited process, to allow proposals concurrent with a preliminary determination because it allows EPA to "...promulgate an interim national primary drinking water regulation for a contaminant without making a determination for the contaminant…"[FN21: 42 U.S.C. §300g-1(b)(1)(D).].

EPA Response: Please see section 3.3 of the EPA response in this *Response to Comments* document.

Office of Advocacy at the U.S. Small Business Administration (Doc. #1807, SBC-045495)

Advocacy also recommends that EPA address small entity concerns with its proposed actions for PFHxS, GenX chemicals, PFNA, and PFBS, by issuing regulations in accordance with the SDWA.

If you have any questions or require additional information, please contact me or Assistant Chief Counsel Tayyaba Zeb at (202) 798-7405 or by email at tayyaba.zeb@sba.gov.

Sincerely,

/s/

Major L. Clark, III

Deputy Chief Counsel

Office of Advocacy

U.S. Small Business Administration

/s/

Tayyaba Zeb

Assistant Chief Counsel

Office of Advocacy

U.S. Small Business Administration

Copy to: Richard L. Revesz, Administrator

Office of Information and Regulatory Affairs

Office of Management and Budget

EPA Response: Please see section 3.3 of the EPA response in this *Response to Comments* document. The EPA maintains it has appropriately considered small system concerns in the proposed actions for PFHxS, HFPO-DA, PFNA, and PFBS as required under SDWA. Additionally, please see section XIII.D of the final rule preamble for the EPA's consideration of small entity concerns for this action as required under the Regulatory Flexibilities Act.

Office of Advocacy at the U.S. Small Business Administration (Doc. #1807, SBC-045477)

Advocacy also recommends that EPA address small entity concerns with its proposed actions for PFHxS, GenX chemicals, PFNA, and PFBS, by issuing regulations in accordance with the Safe Drinking Water Act [FN2: 42 U.S.C. §300f et seq. (1974).].

EPA Response: The EPA maintains it has appropriately considered small system concerns in the proposed actions for PFHxS, HFPO-DA, PFNA, and PFBS as required under SDWA. Additionally, please see section XIII.D of the final rule preamble for the EPA's consideration of small entity concerns for this action as required under the Regulatory Flexibilities Act.

American Chemistry Council (ACC) (Doc. #1841, SBC-044822)

[As outlined in these comments, the Agency's proposal suffers from a number of significant shortcomings, including the following –]

• The decision to propose an MCL/MCL Goal and preliminary regulatory determination concurrently for HFPO-DA, PFBS, PFHxS, and PFNA violates the requirements of the Safe Drinking Water Act, and

EPA Response: Please see section 3.3 of the EPA response in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-044812)

[The Agency's proposal suffers from the following significant shortcomings –]

• The decision to propose an MCL/MCL Goal and preliminary regulatory determination concurrently for the four PFAS violates the requirements of the Safe Drinking Water Act, and

EPA Response: Please see section 3.3 of the EPA response in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-044849)

SDWA Does Not Authorize EPA to Issue a Preliminary Regulatory Determination Simultaneously with a Proposed Standard

In proposing a preliminary regulatory determination for PFNA, PFHxS, PFBS, and HFPO-DA at the same time as it proposes national drinking water standards for these four substances EPA seeks to subvert the process clearly laid out in the SDWA. As part of this process, the Act instructs EPA to first collect data on the occurrence of contaminants, followed by the issuance of a preliminary determination to regulate and opportunity for public comment based on the "best available public health information, including the occurrence data," after which the Agency may issue a final determination to regulate which the Act notes shall be considered final agency action and subject to judicial review. Once a regulatory determination is made, the Act defines the process for establishing an MCL and MCL Goal, including the use of the best available science and an opportunity for public comment on the Agency's analysis of benefits and costs of the proposal.

EPA decision to propose a preliminary regulatory determination and regulatory standard for the four substances simultaneously is in violation of the Act. Although the Act allows EPA to propose a drinking water regulation "concurrent with the determination to regulate," [FN198: 43 U.S.C. Section 300g-1(b)(1)(E)] a preliminary determination cannot be considered a "determination to regulate." The Agency's interpretation ignores the Act's establishment of a two-step process – a preliminary regulatory determination followed by a final determination –

and eliminates a critical opportunity for public comment process laid out in the statute. The Agency's rationale that there is "public urgency" [FN199: 88 Fed. Reg. 18652] to reduce PFAS does not outweigh its statutory requirements.

Consistent with the statute, EPA should withdraw the current proposal for the four substances and conduct an evaluation to determine whether any of substances meet the criteria under Section 1421(b)(1)(A) for a preliminary determination to regulate. Such a determination likely will require the Agency to wait for occurrence data from the ongoing UCMR 5 national survey of water systems.

EPA Response: Please see section 3.3 of the EPA response in this *Response to Comments* document. Regarding the EPA's evaluation of the second regulatory determination statutory criterion on occurrence, please see sections 3.1.2 and 3.2.2 of the EPA response in this *Response to Comments* document. Additionally, please see section 6.8 of the EPA response in this *Response to Comments* document pertaining to UCMR 5.

Section 3 References

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4 Maximum Contaminant Level Goals (MCLGs)

4.1 MCLG Derivation for PFOA or PFOS

4.1.1 Systematic Review Protocol for PFOA and PFOS used to Determine the Weight of Evidence for Carcinogenicity and Cancer Classifications

Summary of Major Public Comments and EPA Responses

Several commenters expressed support or criticism of the EPA's systematic review protocol used in the cancer assessments for PFOA and PFOS, including specific topics such as the agency's approach for conducting study evaluations and weight of evidence determinations and the agency's use of epidemiological studies as supporting evidence for the cancer classifications consistent with the *Office of Research and Development* (*ORD) Staff Handbook for Developing IRIS Assessments* (USEPA, 2022a), hereafter referred to as the "IRIS Handbook" or "EPA peer-reviewed human health risk assessment methodology". The EPA's responses to these issues as well as others expressed by individual commenters are described in further detail below.

A few commenters agreed with the systematic review protocol the EPA used to evaluate the studies that supported the PFOA and PFOS cancer classification determinations in the draft toxicity assessments (USEPA, 2023f; USEPA, 2023a; USEPA, 2023b; USEPA, 2023c), with one commenter stating that the approach was "thorough and well-reasoned." Commenters stated that the systematic review protocol was clear because the EPA had addressed all concerns highlighted during the peer review process.

One commenter asserted that the EPA did not conduct a systematic review of the literature and did not follow the IRIS Handbook (USEPA, 2022a) to develop the toxicity assessments for PFOA and PFOS. This commenter stated the EPA lacked "a predefined protocol" and that the "systematic review methods lack[ed] transparency and consistency." The commenter took particular issue with the EPA's protocols for study quality evaluations, stating that they were inconsistent and not aligned with the IRIS Handbook (USEPA, 2022a). The EPA disagrees with this commenter's incorrect claims. The EPA adopted the overall approach and steps in the IRIS Handbook (USEPA, 2022a) and the *Systematic Review Protocol for the PFAS IRIS Assessments* (USEPA, 2021a) to develop PFOA- and PFOS-specific protocols that then formed the basis for performing study quality evaluations, evidence integration, and critical study selection in the toxicity assessments for PFOA and PFOS (USEPA, 2023f; USEPA, 2023a; USEPA, 2023b; USEPA, 2023c). The EPA did not put these predefined protocols out for public comment prior to the draft assessment development because these predefined protocols were largely consistent with the *Systematic Review Protocol for the PFAS IRIS Assessments* (USEPA, 2021a) which had already received public comment. Additionally, this predefined protocol was made available for public comment as Appendix A of the toxicity assessments at the time of rule proposal (USEPA, 2023b; USEPA, 2023c). Importantly, the EPA's Office of Water collaborated with the EPA's Office of Research and Development in conducting study quality evaluations, evidence

integration, and selection of critical studies to ensure consistency with the IRIS Handbook (USEPA, 2022a) and the *Systematic Review Protocol for the PFAS IRIS Assessments* (USEPA, 2021a).

Individual Public Comments

Washington State Department of Health (DOH) (Doc. #1665, SBC-044406 & SBC-044407)

Page 18729. Section V – Maximum Contaminant Level Goal.

EPA requests comment on the derivation of the proposed MCLG for PFOA and its determination that PFOA is Likely to be Carcinogenic to Humans and whether the proposed MCLG is set at the level at which there are no adverse effects to the health of persons, and which provides an adequate margin of safety. EPA is also seeking comment on its assessment of the noncancer effects associated with exposure to PFOA and the toxicity values described in the support document on the proposed MCLG for PFOA.

• DOH appreciates that EPA updated the literature review and added a systematic review of study quality for their determination of the PFOA and PFOS MCLGs.

EPA Response: Please see section 4.1.1 of the EPA response in this *Response to Comments* document. In response to Science Advisory Board (SAB) peer review, the EPA did update the literature search to identify new literature, reflected in the *Public Comment Draft – Toxicity Assessments and Proposed Maximum Contaminant Level Goals (MCLGs) for PFOA and PFOS* (USEPA, 2023f; USEPA, 2023a). However, the study quality evaluation step was not "added" but rather updated to reflect new literature in the draft assessments (USEPA, 2023f; USEPA, 2023a), in contrast to the commenter's suggestion. The EPA conducted study quality evaluation as part of the systematic review process *prior* to the 2022 SAB review, as reflected in the *Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for PFOA and PFOS in Drinking Water* (USEPA, 2021b; USEPA, 2021c) published for peer review in 2021. Study quality evaluations were conducted during the systematic review of the literature when the assessments were first initiated, consistent with the process described in the IRIS Handbook (USEPA, 2022a), and therefore, has been an integral part of and these draft assessments. Additionally, the protocols for study quality evaluations were externally peer reviewed by the Science Advisory Board (SAB) PFAS Review Panel.

Silent Spring Institute (Doc. #1784, SBC-053325)

Silent Spring Institute supports these evidence-based regulations and commends the EPA for their systematic review of the available scientific literature. We found the EPA's overall approach to determining the maximum contaminant level goals (MCLGs) for PFOA and PFOS to be thorough and well-reasoned.

EPA Response: Please see section 4.1.1 of the EPA response in this *Response to Comments* document. The commenter supports the "evidence-based regulations and commends the EPA for their systematic review of the available scientific literature."

Environmental Protection Network (EPN) (Doc. #1773, SBC-043842)

PFOA and PFOS MCLGs

EPA's Science Advisory Board (SAB) supported many of the elements of EPA's proposed PFOA and PFOS health-based values in the agency's 2022 interim drinking water health advisory document. However, the SAB expressed concerns over the systematic review process used to select the critical studies for health effects. EPA has addressed these concerns by providing additional clarity on the systematic review process and expanding the systematic review steps included in the health effects assessment. EPA has provided technical support documents for this rule that include the updated health effects literature search and new evaluations of models, methods, and data.

EPA Response: Please see section 4.1.1 of the EPA response in this *Response to Comments* document. The commenter supports the EPA's approach and states that the EPA has fully addressed the SAB panel's comments about the clarity regarding the systematic review protocol. However, the SAB did not review the 2022 interim drinking water health advisory (HA) document, but instead received the *Proposed Approaches* documents (USEPA, 2021b; USEPA, 2021c) for review, along with two other technical documents.

3M Company (Doc. #1774, SBC-053146& SBC-045650)

EPA Did Not Establish and Follow Required Procedures Designed to Ensure SDWA Compliance and Promote Regulation Based on the Best Available Science

EPA did not follow established best practices, including its own long-standing guidance, to conduct a systematic review of the relevant scientific literature. A proper systematic review is important to ensure that the Agency's conclusions are driven by science and are transparent to the public. Although EPA has long-standing guidance on how to conduct a systematic review, it did not follow it. Here, EPA's own SAB, in its Review of EPA's Analyses to Support EPA's National Primary Drinking Water Rulemaking for PFAS, "identified multiple inconsistencies and deficiencies in both the description and execution of the systematic review process utilized in the evaluation of both PFOA and PFOS." (USEPA SAB 2022, p. 3.) SAB also noted that EPA did not publish a pre-defined review protocol, did not have transparent criteria for study inclusion and exclusion, omitted studies that should have been considered, and improperly categorized studies, resulting in a review with "major deficiencies." (USEPA SAB 2022, p. 3.) These issues were so significant that at least one SAB member indicated EPA's systematic review did not "represent the state of practice."

As discussed herein, EPA did not meaningfully implement SAB's feedback. This resulted in an after-the-fact systematic review protocol that is contrary to the SAB's feedback and the Agency's own guidance. See e.g., ORD Staff Handbook for Developing IRIS Assessments, (USEPA ORD 2022, pp. xiv-xvii) ("The transparency and scientific rigor of the IRIS process is enhanced through the application of systematic review . . . The IRIS process applies a systematic review approach from the literature identification stage through the selection of studies for dose-response assessment"); USEPA SAB 2022 p. 3 ("Before initiating a systematic review process, it is essential to clearly define the study question to be addressed and to develop a protocol.") (emphasis added).

The absence of a rigorous, prescribed systematic review has had a serious impact on the rulemaking process. For example, the lack of a pre-defined review protocol led to outsized weight being placed on studies that have highly material deficiencies while underweighting higher-quality studies that do not support the proposed limits. Further, EPA reliance on cancer endpoints as the basis for a maximum contaminant level goal (MCLG) of zero for PFOA and PFOS is not consistent with the evidence EPA presents nor with its own guidance. Similarly, EPA did not establish review processes designed to ensure that the weight of evidence supports its new classification of PFOS as "likely" to be carcinogenic to humans.

EPA's derivation of its alternate, non-cancer reference doses (RfDs) for PFOA and PFOS are similarly in need of reconsideration and revision. In calculating the RfDs, EPA did not follow its own guidance documents including EPA's ORD Staff Handbook for Developing IRIS Assessments (USEPA ORD 2022). These procedures are important for transparency and reproducibility in study evaluation. An appropriate evaluation of the existing literature, consistent with EPA guidance, would have found many of the studies that EPA relied on to calculate the extremely low RfDs for these PFAS were low quality and at high risk of bias, therefore leading EPA to reach different conclusions.

EPA Response: Please see section 4.1.1 of the EPA response in this *Response to Comments* document. The commenter is incorrect in stating that the EPA did not follow its own guidance in conducting a systematic review for the toxicity assessments, that the EPA did not meaningfully implement SAB's feedback, and that the protocol published at the time of rule proposal was "after-the-fact." As outlined in section 4.1.1 of the EPA response in this *Response to Comments* document and described in more detail below, the EPA followed agency methodology in conducting a systematic review for the toxicity assessments (i.e., the IRIS Handbook (USEPA, 2022a)), responded to and implemented the SAB's feedback which mitigated the highlighted "deficiencies" (described in USEPA, 2023d) and established internal protocols *prior* to initiating the systematic review which were fully detailed in Appendix A of USEPA (2023f) and USEPA (2023a). Therefore, there is no basis for the commenter's claim that the "absence" of a systematic review has had a serious impact on the rulemaking process. Similarly, the EPA's conclusions on the carcinogenicity of PFOA and PFOS did follow agency guidance (USEPA, 2005) and long-standing practice of establishing the MCLG at zero under the

Safe Drinking Water Act (SDWA) (see USEPA, 1998; USEPA, 2000a; USEPA, 2001; *See* S. Rep. No. 169, 104th Cong., 1st Sess. (1995) at 3).

First, as the EPA noted in its response to SAB comments (USEPA, 2023d):

> "*EPA established internal protocols for the systematic review steps of literature search, population, exposure, comparator, and outcome (PECO) development, literature screening, study quality evaluation, and data extraction prior to initiating the systematic review for PFOA and PFOS. However, the agency recognizes that components of the protocols were not thoroughly included in the November 2021 draft Proposed Approaches documents. The EPA has since incorporated detailed, transparent, and complete protocols for all steps of the systematic review process into the updated versions of the Proposed Approaches documents, now named the Proposed MCLG documents (see Appendix A of both documents). Additionally, the protocols and methods have been updated and expanded based on SAB recommendations to improve the clarity and transparency of the process used to derive the MCLGs for PFOA and PFOS."*

The EPA emphasizes, again, that the PFOA and PFOS systematic review protocols were developed *prior* to initiating the literature searches and systematic reviews for the toxicity assessments of PFOA and PFOS. Additionally, the EPA did not put these predefined protocols out for public comment prior to assessment development because these predefined protocols were largely consistent with the Systematic Review Protocol for the PFAS Integrated Risk Information System (IRIS) Assessments (USEPA, 2021a) which had already received public comment. Therefore, the protocols published at the time of rule proposal were not developed "after-the-fact" as the commenter inaccurately claims but were improved to increase transparency and clarity as requested by the SAB PFAS Review Panel (USEPA, 2022b). The final protocols, which have again been updated to reflect public comment as well as the final literature searches and reviews, are available as Appendix A of the final toxicity assessments for PFOA and PFOS (USEPA, 2024a; USEPA, 2024b). The EPA provides specific responses to comments regarding methods of study quality evaluation and the cancer assessments and reference doses (RfDs) in sections 4.1.4, 4.2.1.2, 4.2.1.3, 4.2.1.4, and 4.2.1.5 of this response to public comment document.

Second, the EPA disagrees with the claim that it did not follow its own guidance when developing these assessments. Please see sections 4.1.1 and 4.1.2 of the EPA response in this *Response to Comments* document.

Finally, the EPA disagrees with the claim that it did not "meaningfully implement" the SAB PFAS Review Panel's feedback and notes that the commenter appears to have mischaracterized quotes from the SAB final report (USEPA, 2022b). For example, the commenter stated, "SAB also noted that the EPA did not publish a pre-defined review protocol, did not have transparent criteria for study inclusion and exclusion, omitted studies that should have been considered, and improperly categorized studies, resulting in a review with 'major deficiencies.'" In actuality, the SAB stated, "The lack of a protocol… was seen as a major deficiency of the reviews" and the

SAB asked that the EPA "provide additional clarification and corrections to the existing systematic reviews to fill in gaps about how specific tasks were completed" and to "establish protocols prior to beginning any new systematic review process" (USEPA, 2022b). As the EPA noted in the paragraph above, the toxicity assessments for PFOA and PFOS followed pre-established protocols drafted prior to systematic review initiation and mimicking components of the IRIS Handbook (USEPA, 2022a) and the *Systematic Review Protocol for the PFBA, PFHxA, PFHxS, PFNA, and PFDA (anionic and acid forms) IRIS Assessments* (USEPA, 2021a). These protocols were described briefly in the methods section of the *Proposed Approaches* documents (USEPA, 2021b; USEPA, 2021c). The EPA then implemented the SAB's recommendation by turning these pre-established protocols into a publicly available protocol document which described the systematic review approach used for the draft assessments (USEPA, 2023b; USEPA 2023c). Regarding how the EPA considered and implemented all of the SAB PFAS Review Panel's comments, please see section 4.1.3.

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A proper systematic review of the relevant scientific literature is the foundation for the agency to reach scientifically sound conclusions. As described by EPA's IRIS Handbook, EPA must review the full body of available scientific information, identify the subset of that information that is the best available, explain the basis for that decision, and then analyze that information to come to an ultimate conclusion (USEPA ORD 2022, EPA 2012). The agency cannot make its regulatory decision and selectively cite scientific studies that support the decision while ignoring equally valid but contradictory scientific information. For two of the six substances—PFHxS and PFNA—EPA did not conduct a systematic review and instead relied on the conclusions of the Agency for Toxic Substances and Disease Registry (ATSDR). For the remaining four substances, EPA has selectively cited studies to support its decision.

In reviewing EPA's draft documents, EPA's own SAB and numerous other commenters pointed out several major failings, including that EPA failed to publish a pre-defined review protocol. The SAB noted significant concerns that the reviews for PFOA and PFOS do not appear to have established a predefined protocol. The lack of a protocol led to a lack of clarity across each of the major systematic review steps for both chemicals and was seen as a major deficiency of the reviews. (USEPA SAB 2022, p. 3)

For example, the SAB "found that the inclusion and exclusion of epidemiologic and animal studies was inconsistent across endpoints, leading to confusion about the criteria being used." Similarly, the SAB found that EPA's literature review ignored studies that should have been considered, including some of those EPA relied on for its 2016 health advisory levels (HALs) for PFOA and PFOS, and some of which may have changed EPA's conclusions regarding the potential hazard of exposure to PFOA and PFOS at low levels.27 Indeed, the SAB concluded that "[t]he rationale for not considering studies, particularly human studies, that were included in the [2016 HALs] is not clear or supportable. There is no reason to conclude that the earlier studies are less relevant or of lesser quality than the newer studies." (USEPA SAB 2022, p. 5;

see also p. 14-15.) The SAB also "concluded that the decision to exclude literature published within the timeframe of the development of the 2016 health effects support document in the current literature search was unjustified." (USEPA SAB 2022, p. 5)

EPA's lack of a review protocol raises serious questions about the integrity of EPA's systematic review. It precludes clarity into how EPA decided which studies to review, how to weigh the studies it did review and, ultimately, how it decided which studies would form the foundation for its proposed levels. EPA also did not follow the same protocol across the multiple reviews it conducted, another major failure that the SAB identified (EPA SAB 2022).

EPA has not sufficiently addressed these and the SAB's other foundational concerns in the Proposed Rule. Instead, and as discussed below, EPA continues to pick and choose scientific studies based on unknown and non-transparent conditions (violating EPA's own procedures on conducting systematic reviews) which appears to have biased EPA's review to favor studies that support the low regulatory levels EPA has proposed and omit discussion of studies that do not support those levels. In short, EPA's systematic review was not grounded in "sound and objective scientific practices," a flaw it has not remedied.28 These classification and review protocol errors are identified throughout the comments herein as they relate to specific topics in the rulemaking.

EPA Response: The commenter repeats criticisms about the systematic review protocol and treatment of studies considered in its assessments of PFOA and PFOS, citing the final report produced by the SAB PFAS Review Panel (USEPA, 2022b). Please see the EPA responses to comment Doc. #1774, SBC-053146 and SBC-045650 in section 4.1.1 in this *Response to Comments* document. The EPA implemented recommendations from the SAB in the draft toxicity assessments released for public comment to address the SAB's concerns, and the EPA describes how every recommendation from the SAB was considered in its response to comment document (USEPA, 2023d). Please see section 4.1.1 of the EPA response in this *Response to Comments* document for additional details. The EPA did not "pick and choose scientific studies based on unknown and non-transparent conditions" as the commenter inaccurately suggested. The EPA describes all of the available evidence identified from the systematic literature searches and reviews, regardless of whether they support the "low regulatory levels" in Chapter 3 and provides rationale for study selection for reference dose (RfD) and cancer slope factor (CSF) derivation in Chapter 4 of the final toxicity assessments (USEPA, 2024d; USEPA, 2024c). The EPA followed the systematic review protocol for all studies including those identified from the 2016 *Health Effects Support Documents* (HESDs) (USEPA, 2016a; USEPA, 2016b). In contrast to the commenter's claims, the EPA did follow a systematic approach to identifying, screening, and assessing the quality of studies. Please see the EPA response to comment Doc. #1774, SBC-053425 in section 4.1.1 in this *Response to Comments* document for more detail.

Responses to comments regarding PFNA and PFHxS are provided in section 4.3 of the EPA response in this *Response to Comments* document.

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EPA did not provide sufficient information about why it excluded certain studies or which population, intervention, control, and outcomes (PECO) criteria the studies that it did exclude failed to meet, resulting in a lack of transparency regarding EPA's systematic review. The SAB, in response to charge question #1, recommended several changes to the evidence identification step of the PFOA and PFOS systematic reviews. EPA responded that a publicly accessible interactive flow diagram1 provides clarity about why EPA excluded specific studies at the title-abstract and full-text review steps. Although this flow chart is publicly accessible and provides high-level reasons for exclusion such as "Not PECO Relevant" it does not give insight to the particular PECO criteria that was not achieved. For example, according to the flow chart, McDonough et al. (2020) was excluded at the screening level. From a review of the title/abstract, it appears that McDonough et al. (2020) meets all PECO criteria outlined in Appendix A Table A-1 (EPA, 2023e).

EPA's methodology for study identification and inclusion is problematic and unclear.

· It is not clear why EPA excluded certain studies from consideration here that it had previously relied on for its 2016 Health Effects Support Documents (HESDs) for PFOA and PFOS (EPA 2016a, 2016b). In response to charge question #1 regarding the adequacy of EPA's systematic review methods, the SAB on August 22, 2022 recommended, "Earlier literature used for the 2016 HESDs must be included in the literature search and considered for both strength of evidence evaluation and dose response." EPA responded that it expanded the assessment to include epidemiological and animal studies identified in EPA's 2016 HESDs for PFOA and PFOS. The MCLG Assessment Protocol also states that EPA reviewed studies captured by the 2016 HESD. However, EPA does not describe in its protocol whether these were included based on subjective judgement or whether they were incorporated into the literature screening process applied to the other studies (i.e., evaluated against the PECO criteria). Further, Tables A-6 and A-7 state that 62 epidemiological and 11 animal studies identified in the HESD summary tables were included in EPA's MCLG assessments, respectively. However, in a query of the Interactive Reference Flow Diagram, it appears that only 58 studies total were included for review. Without the proper documentation, it is unclear whether the 15 unaccounted for studies were intentionally or erroneously excluded.

· EPA should not use filters as a means of exclusion without the use of quality control (QC) of title/abstracts excluded at this stage. In Appendix A of the draft toxicity assessments for PFOA and PFOS, the protocol states that the methodology includes use of SWIFT-Review and SWIFT-Active, which are well-known systematic review tools that can be used to implement machine-learning techniques. Here, SWIFTReview was used to apply "evidence stream filters" for human, animal (all), animal (human health model), [no tag], epidemiological quantitative analysis, and in vitro. The result of this is the automated exclusion of approximately 2200 studies. The validity and reliability of SWIFT-Review as a tool to exclude citations has not been studied (Howard et al., 2016; Pelch and Kwiatkowski, 2022) and is therefore unreliable as a basis to filter studies in the manner EPA applied here.

· EPA's review of and reliance on erratums is unclear. Inclusion criteria in Table A-9 of Appendix A states that "erratums and corrections were considered not relevant." This may have resulted in incomplete evidence identification as erratums and corrections could potentially contain updated information and inform study quality evaluation, impacting overall study rating and thus reliability. Further, although Table A-9 states that erratums and corrections were considered irrelevant, Table B-26 includes a reference to Shin et al., 2013 in context of "updated values in Erratum." It is not clear when or how this effort took place or whether it was systematic. It is also unclear whether corrigendum were included in this category of literature.

· It is unclear whether short-term studies reporting immune and neurological health outcomes were considered for weight of evidence (WOE) evaluation or tagged as supplemental. The protocol states different applications of criteria for short-term (<28 day) exposures. In Table A-8, it is stated that studies with <28 days of dosing will be tagged as supplemental except for reproductive, developmental, immune and neurological health outcomes. However, Table A-11 only states the same exception for developmental/reproductive outcomes. Due to the method of reporting exclusions and studies tagged as supplemental it is not feasible to ascertain whether there was consistent evaluation of short-term immunological and neurological health outcome studies.

EPA Response: The commenter incorrectly stated that the EPA did not provide enough information detailing the consistent application of screening criteria for individual studies that were excluded because they failed to meet the screening criteria. The commenter noted that the SAB PFAS Review Panel made several recommendations in response to charge question #1 during their evaluation of the *Proposed Approaches* documents (USEPA, 2021b; USEPA, 2021c; USEPA, 2022b). The commenter did not include the complete SAB recommendation, which was:

> *"[t]he Panel notes that the document's transparency would be enhanced through a diagram or flowchart depicting the overall process of study identification and inclusion," and "[a] list of excluded evidence after the full-text review should be developed and made publicly accessible. This may help provide clarity about why specific studies were excluded"* (USEPA, 2022b).

The EPA responded to the SAB recommendations by developing the Interactive Reference Flow Diagram, which exceeds both of these requests. This interactive diagram allows users to search for individual studies to identify whether studies were excluded and which step they were excluded. It specifies how the EPA identified the studies (e.g., the date range of the literature search update), which studies were screened for mechanistic and Absorption, Distribution, Metabolism, and Excretion (ADME)/toxicokinetic data, and which studies were extracted and reasons why certain studies were not extracted. The EPA's inclusion of this interactive flow diagram in the draft and final assessments has further enhanced the transparency of systematic review decisions by providing the ability to track at the individual study level. It also allows for tracking and sorting of thousands of studies through the assessment process.

The commenter incorrectly suggests that McDonough et al. (2020) was excluded from the assessment for seemingly unclear reasons. First, the commenter is not clear on which McDonough et al. (2020) publication they are referencing since there are two, but the EPA assumes the commenter is referencing the health effects study under Health and Environmental Research Online ID Number (HEROID) 6988474 since the other McDonough et al. (2020) study under HEROID 6512120 is about PFAS bioaccumulation only and therefore not PECO relevant. Second, in the assessments, the EPA has provided all the information required for a reader to understand how studies were screened and why studies were excluded. In this example, McDonough et al. (2020), can be previewed in the interactive flow diagram (including links to the Health and Environmental Research Online [HERO] page where the reference can be accessed), and the PECO criteria for inclusion and exclusion is located in Table A-1 of Appendix A (USEPA, 2024a; USEPA, 2024b). From the title alone ("Immunotoxicity of an Electrochemically Fluorinated Aqueous Film-Forming Foam"), a screener would note that the study may only pertain to PFAS mixtures, not PFOA or PFOS individually, a requirement for inclusion as dictated by the PECO in Table A-1 of Appendix A. Upon further evaluation of the abstract, the text clearly states, "[a]dult female and male C57BL/6 mice were given a commercial AFFF formulation for 10 days via gavage," and only received a single-dose of PFOA as a positive control (McDonough et al., 2020). In contrast to the commenter's assertion, this study clearly does not meet the PECO outlined in Table A-1 (USEPA, 2024a; USEPA, 2024b), though it would meet several supplemental tags of this assessment, including "Only One Exposure Group" and "Mixture Studies." The EPA recognizes that it may be unclear why this study was tagged as excluded instead of supplemental. When using SWIFT-Active (Sciome Workbench for Interactive Computer-Facilitated Text-Mining), the supplemental tag is included under the umbrella of exclude to train the model specifically for inclusion. To address this issue, the EPA has updated the Interactive Literature Flow diagram to reflect the studies tagged through the use of SWIFT-Active as supplemental instead of excluded.

The commenter mistakenly suggests that the EPA did not describe in the protocol how studies from the 2016 HESDs were included into the assessments (USEPA, 2016a; USEPA, 2016b). The EPA clearly stated in Section A.1.5.4 of both the PFOA and PFOS *Proposed MCLG* appendix documents that key studies from the 2016 HESD were reviewed and those studies that were considered relevant to one or more of the five main health outcomes were included in the toxicity assessment (USEPA, 2023b; USEPA, 2023c). These studies were listed in Tables A-6 and A-7 of the PFOA and PFOS *Proposed MCLG* appendix and can be tracked for their relevancy in the Interactive Reference Flow diagram. Specifically, the EPA reviewed the epidemiological studies that were included in the 2016 HESD summary tables and identified those that were relevant to one or more of the five main health outcomes (i.e., Developmental, Immune, Hepatic, Cardiovascular, and Cancer) (USEPA, 2016a; USEPA, 2016b). A total of 62 epidemiological studies were included and are listed in Table A-6 (USEPA, 2023b; USEPA, 2023c). The EPA focused on the HESD summary tables since the epidemiological studies were not considered quantitatively in the HESDs. The animal toxicological studies that were considered for dose-response in the 2016 HESDs were also incorporated into the current assessments. To address the

commenter's concern, the EPA has added additional detail to Section A.1.5.4 to clearly state how studies from the 2016 HESDs were incorporated into the final toxicity assessments (USEPA, 2024a; USEPA, 2024b).

For PFOA, the text for Table A-6 in the *Proposed MCLG* document indicates there were 62 epidemiological studies identified in the HESD summary tables that were included in the assessment (USEPA, 2023b). There was a minor error in the number of epidemiological studies for this table, as the total is actually 59 studies. To address this error identified by the commenter, the EPA has corrected the text above Table A-6 in the final PFOA toxicity assessment (USEPA, 2024a). Using the Interactive Flow Diagram[1], of these 59 studies, 45 were marked as relevant human and 14 were marked as did not extract. Of these 14 studies, 12 studies were listed as '*Low* confidence/*uninformative* study quality rating' and 2 studies were listed as 'Overlap with other study' as the reasons for not being extracted. The text for Table A-7 indicates there were 11 animal toxicological studies identified in the HESD summary tables that were included in the EPA's draft assessment. All 11 studies were considered relevant and included in the final toxicity assessment (USEPA, 2024d; USEPA, 2024a).

For PFOS, the text for Table A-6 in the *Proposed MCLG* document indicates there were 51 epidemiological studies identified in the HESD summary tables that were included in the assessment (USEPA, 2024b). There was a minor error in the number of epidemiological studies for this table, as the total is actually 47 studies. To address this error identified by the commenter, the EPA has corrected the text above Table A-6 in the final PFOS toxicity assessment (USEPA, 2024b). Using the Interactive Flow Diagram, of these 47 studies, 35 were marked as relevant human and 12 were marked as did not extract. Of these 12 studies, 10 studies were listed as '*Low* confidence/*uninformative* study quality rating' and 2 studies were listed as 'Overlap with other study' as the reasons for not being extracted. The text for Table A-7 indicates there were 9 animal toxicological studies identified in the HESD summary tables that were included in the EPA's draft assessment. Of these 9 studies, 8 were considered relevant and included in the PFOS draft assessment and 1 study was marked as '*Low* confidence/*uninformative* study quality rating' and was not extracted.

As indicated above, the EPA clearly explains the process for inclusion of the key studies from the 2016 HESD documents, the use of the literature screening process to determine relevancy, and the outcome of screening for each study in the Interactive Reference Flow diagram. All studies

[1] In tracking these studies through the Interactive Flow Diagram, it should be noted that as a publication moves through the systematic review steps in the Interactive Reference Flow diagram, the first three sections (e.g., Identification, Screening, and Eligibility) are identical for both the PFOA and PFOS diagrams. This is clearly indicated by the bold 'PFOA' and 'PFOS' in the 'References screened for PFOA and PFOS' and 'References assessed for eligibility for PFOA and PFOS' boxes. For the Eligibility section, a new option 'Relevant to PFOA/PFOS only' was added for increased clarity and indicate when a publication contained information for only one chemical. For the last section (e.g., Relevant), the 'To PFOA/PFOS' toggle button can be used to confirm whether or not the paper was considered relevant for the chemical of interest, tagged as containing mechanistic or toxicokinetic supplemental information, or was not extracted. If the publication was not extracted, hovering over the number in the 'Did Not Extract' box identifies the reason the publication was not extracted.

listed in Tables A-6 and A-7 of the PFOA and PFOS *Proposed MCLG* appendices were properly documented and accounted for (USEPA, 2023b; USEPA, 2023c).

The commenter stated that the EPA should not use evidence stream filters, such as those applied when screening with SWIFT-Review, to automate the screening process because the tool has not been studied and is unreliable. These claims are incorrect. First, the search filters of SWIFT-Review have been widely used in prior and ongoing IRIS assessments as an initial tool for problem formulation and to prioritize records for subsequent title-abstract screening with other software (USEPA, 2022a). Similarly, SWIFT-Active Screener has also been, "widely used in IRIS assessments for title and abstract screening, especially when there are many studies to screen (e.g., 2,000+) or there is time urgency," as was the case for the assessments of PFOA and PFOS under SDWA (USEPA, 2022a). Second, the EPA's use of SWIFT software was presented to the SAB PFAS Review Panel as part of the *Proposed Approaches* documents. In response to EPA's first charge question regarding study identification and inclusion, "[t]he Panel noted that the use of SWIFT and DistillerSR to sort the literature and process for quality evaluation and confidence determination were reasonable steps" (USEPA, 2022b). Third, the use of SWIFT-Review and SWIFT-Active Screener was also documented in the IRIS PFAS Systematic Review Protocol, which was published for public comment in 2019 and subsequently updated in 2020 and again in 2021 (USEPA, 2021a). Fourth, the citation provided by the commenter, Howard et al. (2016), is a peer-reviewed publication which describes the validity and reliability of the SWIFT-Review tool. Therefore, it is unclear why the commenter cites this publication to support the claim that the tool has *not* been studied. The EPA recognizes that when conducting a systematic review on a database as large as PFOA and PFOS, whether using active learning software or not, there is always a chance of the exclusion of relevant studies. This is one reason why the agency requested that both the SAB PFAS Review Panel (in 2021) and public commenters (in 2023) provide citations that they believed the EPA may have overlooked.

The commenter noted that the review and incorporation of errata in the draft toxicity assessments was unclear. The agency recognizes the confusion resulting from the quoted statement and has subsequently revised Appendix A of the toxicity assessments (USEPA, 2024a; USEPA, 2024c) to state: "Errata, corrections, and corrigenda were tagged to the original study and not considered a separate relevant record." More specifically, when an erratum, correction, or corrigendum to a study that met PECO criteria was identified, the EPA tagged them to the original study but did not treat them as unique, individual studies that met PECO. Errata, corrections, corrigenda were uploaded to the screening software (i.e., DistillerSR and SWIFT-Active Screener) along with all other search results identified in that literature update, uploaded in HERO, given a unique HEROID, and tagged as related to the original study. An example of this is the erratum published by Shin et al. (2013) which accompanied the original article (Shin et al., 2011), as the commenter mentioned. When an erratum or correction was identified, the EPA updated the information extracted from the original study, including information related to study quality evaluation metrics, with any corrections or additional information published in the erratum. Therefore, the EPA's draft assessments did have all relevant data incorporated using a systematic methodology.

Lastly, the commenter noted a minor discrepancy between Table A-8 and Table A-11 in the *Proposed MCLG* appendices (USEPA, 2023b; USEPA, 2023c). To address this comment, the EPA has revised Table A-11 to be consistent with Table A-8, which was correct. The EPA consistently evaluated short-term Immunological and Neurological health outcome studies and included animal toxicological studies with less than 28-day exposure durations as PECO-relevant for these health outcomes.

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EPA's methodology for study identification and inclusion lacks integrity and transparency. In response to SAB comments, EPA expanded its assessment to include epidemiological and animal studies identified in EPA's 2016 Health Effects Support Documents for PFOA and PFOS. However, it is unclear whether these studies were incorporated into the literature screening process applied to other citations or included based on subjective judgement. It is also unclear why 15 studies identified in the 2016 Health Effects Support Documents were not accounted for in the review.[FN29: See Tables A-6 and A-7 of the 2016 HESD summary tables and Interactive Reference Flow Diagram for PFOA & PFOS | Tableau Public.] EPA also implemented the use of SWIFT-Review [FN30: "SWIFT" is an acronym for Sciome Workbench for Interactive computer-Facilitated Text-mining. It is software that uses statistical modeling and machine learning to conduct automated document prioritization. See https://www.epa.gov/sites/default/files/2018-02/documents/d-4_swift_demo_abstract_-_nas_2018.pdf.] for a portion of study identification, which has yet to be validated for this purpose. This may have resulted in inadvertently excluding relevant studies. Additional study types that may have been inappropriately excluded from the review according to the reported methodology include erratums, corrections, and corrigendums. This issue is discussed in detail in Appendix A, Detailed Technical Comments on the Non-cancer Reference Doses (RFDs) and Economic Analysis for PFOA and PFOS.

Increased transparency in reporting is needed.

The SAB recommended changes to the evidence identification step of the PFOA and PFOS systematic reviews, including providing a more transparent reporting of output. EPA responded by providing a publicly accessible interactive flow diagram. That diagram, however, does not give insight into the specific Population, Exposure, Comparator, and Outcomes (PECO) criteria that EPA decided certain studies did not meet. PECO criteria define the objectives of the review and inform the "inclusion and exclusion criteria for a review, as well as facilitating the interpretation of the directness of the findings based on how well the actual research findings represent the original question."(Morgan et al. 2018) EPA's failure to identify the PECO criteria that excluded studies did not meet precludes independent appraisal of why those studies were excluded. This issue is discussed in detail in Appendix A.

EPA did not refine study quality criteria to the topic per standard IRIS systematic review guidelines.

To evaluate study quality and risk of bias in the PFOA and PFOS assessments, EPA said it used its IRIS assessment tool. EPA IRIS Handbook (USEPA ORD 2022) guidance states that to evaluate studies, chemical-, outcome- or exposure-specific considerations should be developed as needed to identify issues expected to result in critical biases and that should reduce the confidence rating of a study (ORD Handbook, p. 4-2). Contrary to EPA's own guidance, the only apparent modification EPA made to its IRIS assessment tool for study evaluation in this rulemaking was to the exposure assessment domain criteria. This modification is insufficient in that it fails to account for critical issues that could render studies unreliable for dose-response assessment – a critical part of EPA's analysis here. Critical omissions include lack of consideration of factors that are specific to exposure, outcome ascertainment, confounding factors that affect the association of interest, and sensitivity issues such as external validity and study construct. This issue is discussed in detail in Appendix A.

The study quality evaluation protocol used in EPA's assessments of PFOA and PFOS generated inconsistent study confidence ratings.

EPA did not correctly evaluate and rate studies for reverse causality, which is a type of bias where the health outcome affects physiological factors that moderate exposure measurement. (Andersen et al. 2021). If reverse causality is not accounted for in a study, the observed effects may not result from the exposure and could be mischaracterized as adverse. Although guidance provided for PFAS-Specific Exposure Measures states that concern for potential bias due to reverse causality with no direct evidence should be rated as 'deficient,' EPA did not consistently rate study design aspects that may impact reverse causality in the body of evidence it considered. In a review of crosssectional studies that fall into the category of "potential reverse causality," the Exposure Methods ratings were inconsistent and generally rated as adequate or good rather than deficient. Further, subjectivity introduced by the Guidance allows reviewers to increase confidence in studies reporting an effect if its confidence was reduced due to sensitivity only. How and when this was applied by EPA in its review here is not readily transparent. Lastly, the lack of transparency and objectivity in the study quality evaluation guidance also contributes vague overall study confidence ratings that do not appear to take the individual domain metric ratings into consideration. This issue is discussed in detail in Appendix A.

EPA's inconsistent systematic review methods violated its own guidance and resulted in exclusion of relevant studies and reliance on low-confidence studies that may be unsuitable for regulatory decision-making.

EPA Response: Please see section 4.1.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1774, SBC-053425 in section 4.1.1 in this *Response to Comments* document regarding the EPA's process of how each study in the PFOA and PFOS assessments are properly documented and the process of study inclusion and exclusion. The EPA maintains that there is enough information provided in the protocol and Interactive Flow Diagram for a reader to "independently appraise" individual studies and provides an example of this in the EPA response to comment Doc. #1774, SBC-053425 in section 4.1.1 in this *Response to Comments* document.

The commenter first incorrectly stated that the EPA "only" made modifications to one study quality evaluation domain (i.e., the exposure assessment domain). In fact, the EPA incorporated several outcome-specific modifications and PFAS-specific modifications. For example, the EPA stated in Section 3.4.4.1.2 of the draft toxicity assessments that, "For the Confounding domain, downgrading of studies occurred when key confounders of the fetal growth and PFAS relationship, such as parity, were not considered." Other alterations specific to the developmental health outcome are also described in that section. Additionally, as described previously, the EPA based the systematic review protocol used in these assessments on the *Systematic Review Protocol for the PFAS IRIS Assessments* (USEPA, 2021a). This resulted in the EPA's consideration and incorporation, when relevant, of the PFAS-specific alterations described in that protocol (e.g., in Section 6.2.1 ("Epidemiology Study Evaluation Criteria Specific to These Five Per- and Polyfluoroalkyl Substances (PFAS)") for the PFOA and PFOS toxicity assessments. Altogether, these examples clearly refute the commenter's assertion that the EPA "fails to account for critical issues that could render studies unreliable." The commenter also stated that the EPA's modification to the IRIS assessment tool for study evaluation was insufficient but did not make suggestions for specific modifications to study quality domains to support that assertion. Responses to specific health outcome study quality concerns have been made throughout this *Response to Comments* document, most notably in section 4.2.1.The commenter additionally incorrectly stated the study quality evaluation protocol used by the EPA generated inconsistent study confidence ratings, raising reverse causality and study sensitivity as specific concerns. The commenter states there was a lack of transparency and that individual domain metric ratings did not appear to be taken into account. The commenter also infers that all cross-sectional studies should be rated as *deficient* in the Exposure Methods domain. The EPA disagrees with these comments for the following reasons.

First, the EPA would direct the commenter to review the footnote in Table A-19 in the *Proposed MCLG* appendices (USEPA, 2023b; USEPA, 2023c), which defines reverse causality as a scenario where "the outcome of interest cause[s] a change in the measured exposure." Reverse causality is not inherent to a study design (e.g., not necessarily a concern in all cross-sectional studies simply because of their design), but issues with reverse causality may be raised about studies using certain study designs that analyzed outcomes that may affect PFAS metabolism. While evaluating studies, the EPA considered concerns regarding reverse causality on a health outcome- or endpoint-specific basis where consideration was supported by the established epidemiological literature (Radke et al., 2019). For example, health conditions, such as decreased renal function or diabetes, may affect clearance of PFAS from the body (Jain and Ducatman, 2019a), thus potentially resulting in a change in the measured PFAS exposure. Therefore, reverse causality was considered for these health outcomes.

Second, the EPA disagrees with the comment claiming that there was inconsistent application of criteria for Overall Study Confidence related to Study Sensitivity. The commenter partially cites a note included in the Overall Study Confidence rating criteria and then asserts that it is unclear when that note was applied by the EPA. The entirety of the note stated, "Reviewers should mark studies that are rated lower than high confidence only due to low sensitivity (i.e., bias towards

the null) for additional consideration during evidence synthesis. If the study is otherwise well-conducted and an effect is observed, the confidence may be increased" (USEPA, 2023b; USEPA, 2023cj; Table A-25). It is clear from this full excerpt that the EPA should consider this factor for studies rated lower than *high* confidence when the rating was lowered only because of a *deficient* study sensitivity rating. The EPA clearly provided all evaluation domain ratings for each study in figures within the draft toxicity assessments, including for studies with an overall confidence lower than *high* and a sole *deficient* rating for the Sensitivity domain (USEPA, 2023f; USEPA, 2023a), and also provided links to the Health Assessment Workplace Collaborative (HAWC) project page (hawc.epa.gov) that provides further detail on the basis of those ratings (e.g., when overall confidence was increased as a result of this note).

Lastly, the EPA disagrees that it "vaguely" or did not transparently conduct the study quality evaluations. The protocols in Appendix A explicitly describe factors considered during study evaluations (USEPA, 2023b; USEPA, 2023c; USEPA, 2024a; USEPA, 2024c). The EPA considered all individual domain ratings during study quality evaluations, the discussion for which are transparently and readily accessible through the health outcome heatmaps throughout the assessments and in the HAWC project page (https://hawc.epa.gov/assessment/100500248/), in contrast to the commenter's claim.

Regarding the EPA's consideration of agency guidance and methodologies, please see section 4.1.2 of the EPA response in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-053426)

To evaluate study quality and risk of bias, EPA used the IRIS assessment tool. EPA's ORD Staff Handbook for Developing IRIS Assessments (IRIS Handbook) guidance states that to evaluate studies, EPA should develop additional chemical-, outcome- or exposure-specific considerations as needed in order to identify issues that would be expected to result in critical biases and should reduce the confidence rating of a study (ORD Handbook 2022, p. 4-2). Although EPA stated that the methods used for its systematic review of the literature for health effects of PFOA and PFOS and toxicity assessment were consistent with those described in the IRIS Handbook, in Appendix A of the draft toxicity assessments for PFOA and PFOS, the only domain modified for the current topic was Exposure Measurement. This single modification to the exposure assessment domain is inadequate to evaluate biases effectively.

EPA modified the Exposure Assessment domain criteria to include specific considerations to rate the analysis of PFAS that directly measured exposure (blood, serum, plasma) vs. indirect measures (breastmilk, drinking water, residence, occupation) (EPA 2023a, B Appendix). EPA gave all exposure mediums a rating of "good" if well-established methods were used, or if less-established methods were used, they had to be supported by inter-method validation (one method vs. another) in the target population. EPA should further delineate the medium of exposure because PFAS measures in different mediums do not all have the same level of accuracy. Potential inaccuracies in exposure characterization due to measurement in various mediums may

also affect confidence in dose-response assessment and estimates of external dose. Further discussion of this is provided in Section 2.1.8 of this appendix.

EPA made only minor modifications to the assessment tool, and did not account for most factors that are specific to either the exposure, outcome ascertainment, confounding factors that affect the association of interest, and sensitivity issues including external validity and study construct. Transparency in the methods EPA used to evaluate overall study confidence and perform a formal critical appraisal of quality and risk of bias is vital for understanding the uncertainties in the risk assessment. Had EPA appropriately completed the critical appraisal by making recommended modifications to the assessment tool, EPA would have found much of the body of evidence to be of low quality and at high risk of bias. It is imperative that EPA follows the guidelines of IRIS when using its method for the systematic review and critical appraisal of the literature to understand the uncertainties surrounding the risk assessment.

EPA reportedly assessed seven evaluation domains for epidemiological study evaluation, including: participant selection, exposure measurement criteria, outcome ascertainment, potential confounding, analysis, selective reporting and study sensitivity. Guidance provided to the reviewers for the exposure measurement domain is presented in two tables in EPA's (2023a,b) Appendix A (Tables A-18 and A-19). It is unclear which of these were used by reviewers to develop ratings for the exposure measurement domain, or if they were meant to be complementary to each other. The use of both tables to guide a reviewer in the selection of the appropriate rating may introduce inconsistencies given the amount of information required to interpret the confidence in this metric for each publication.

Table A-19, which provides guidance for PFAS-Specific Exposure Measurements, states that a "deficient" rating should be given when there is concern for potential bias due to reverse causality with no direct evidence. Despite this guidance, study design aspects that may impact reverse causality are not rated consistently by EPA in the body of evidence. Inherent to their study design, cross-sectional studies assess the exposure and an outcome at a single point in time (in contrast to a prospective cohort study). Due to the nature of these studies, they would have fallen into the category of "potential reverse causality," though EPA did not rate any as deficient for this metric. EPA did not justify its reasoning for increasing confidence ratings. To exemplify these inconsistencies, Table 1 [see original comment] below shows a selection of studies evaluated for this domain along with their ratings and justification.

Further, study quality evaluation guidance in the protocol (Appendix A) introduces potential for subjective confidence ratings (EPA 2023a,b). This guidance directs reviewers in the following manner (PDF pgs. 110 [human], 135 [animal]): "Reviewers should mark studies that are rated lower than high confidence only due to low sensitivity (i.e., bias towards the null) for additional consideration during evidence synthesis. If the study is otherwise well-conducted and an effect is observed, the confidence may be increased." It is not clear how EPA applied this guidance in the assessments of PFOA and PFOS, nor does it appear consistent.

EPA Response: The commenter asserted that the EPA's exposure-specific modification to the IRIS study quality evaluation criteria was insufficient because the medium of exposure was not further delineated to account for varying levels of accuracy across different exposure media. The commenter further repeats that the EPA's modification to the "assessment tool" was minor and raises concerns about unaccounted factors, but the commenter does not mention which factors were of specific concern nor does the commenter provide any supplemental information or data to support these concerns. First, please see the EPA response to comment Doc. #1774, SBC-045661 in section 4.1.1 in this *Response to Comments* document.

The commenter does not provide an actual recommendation for how the EPA should delineate medium of exposure in addition to how the EPA already does delineate this factor, which is described in detail in the assessment in section Appendix A.1.7.1.2 (PFAS-specific exposure assessment criteria). For example, in this section the EPA states, "[s]tandard analytical methods of individual PFAS in serum or whole blood using quantitative techniques, such as liquid chromatography triple quadrupole mass spectrometry, are considered well-established methods." All of the studies the EPA considered for dose-response analyses reported serum concentrations as the exposure medium and used well-established methods as described in the protocol, thus negating the commenter's concern that, "inaccuracies in exposure characterization due to measurement in various mediums may also affect confidence in dose-response assessment." The commenter stated that further information was provided in Section 2.1.8 of the appendix document which does not exist ("Appendix A to 3M Comments on EPA Proposed National Primary Drinking Water Standard").

In contrast to the claim made by the commenter, the chemical-, exposure-, and outcome-specific modifications that the EPA made to the PFOA and PFOS systematic review protocols were sufficient, transparent, and based on the best available peer-reviewed science and methods. The EPA modified the systematic review protocol consistent with the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022a), as well as the *Systematic Review Protocol for the PFAS IRIS Assessments* (USEPA, 2021a), prior to initiation of the draft assessments. Exposure-specific modifications were appropriately made to the criteria in consultation with topic-specific technical experts to account for "chemical-specific knowledge or methodological concerns" (USEPA, 2022a). Further, the EPA considered additional chemical-, exposure-, and outcome-specific factors when reviewing studies for their use in quantitative analyses. For example, the EPA prioritized studies on birth weight (BWT) that measured PFAS serum concentrations during early pregnancy over those that reported PFAS serum concentrations in cord blood or later trimesters due to potential hemodynamics issues (e.g., increase in maternal blood volume over the course of pregnancy; see Section 3.4.4 of USEPA (2024a) and USEPA (2024b) for further discussion).

The commenter incorrectly stated that the EPA provided study quality reviewers with two different sets of exposure assessment criteria in Appendix A (Tables A-18 and A-19; USEPA, 2023b; USEPA, 2023c). The commenter further noted it was unclear which set was used by reviewers or if they were complementary. The commenter argued that the use of both tables as

complementary sets of criteria "may introduce inconsistencies given the amount of information" required to determine an exposure assessment rating. The commenter stated that the criteria listed in Table A-19 were not applied consistently, specifically regarding reverse causality in cross-sectional analyses. The commenter stated that the study evaluation guidance potentially introduces "subjective confidence ratings." The EPA disagrees with all of these comments and has provided clarifying information in the paragraphs below.

First, Tables A-18 and A-19 in Appendix A (USEPA, 2023b; USEPA, 2023c) were used as complementary sets of criteria for exposure assessment. The *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022a) lays out basic criteria and also states, "additional chemical-, outcome-, or exposure-specific considerations for evaluating studies are developed as needed in consultation with topic-specific technical experts." For this assessment, additional exposure-specific criteria were developed for PFOA and PFOS. The EPA disagrees that the use of complementary sets of criteria introduces inconsistencies in study quality evaluation. PFAS-specific criteria listed in Table A-19 (USEPA, 2023b; USEPA, 2023c) provide further exposure-specific considerations in addition to the standard exposure assessment criteria provided in the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022a), and there are no disagreements between criteria from the two tables. The EPA has added this additional detail to Section A.1.7.1 of Appendix A to make it clear that Tables A-18 and A-19 are complementary (USEPA, 2024a; USEPA, 2024c). Study quality evaluators rely on the criteria listed in Table A-18 for high-level conceptual questions regarding potential biases in exposure measurement, while Table A-19 provides evaluators additional specific criteria to seek out for answering the conceptual questions prompted by the criteria provided in Table A-18. While Table A-19 provides highly detailed criteria, information on these criteria helps the evaluator synthesize the study's whole exposure assessment protocol and determine whether the study can reliably distinguish between levels of exposure in a time window considered most relevant for an effect with respect to the development of the outcome. Regarding consistent application, some variation in justification is anticipated and accepted across a team of experts reviewing studies because scientific expertise and judgment is required to make decisions. In fact, the IRIS Handbook (USEPA, 2022a) notes that, "the use of scientific expertise and judgment is an inherent part of the process." Consistency across study evaluators is increased by the EPA's practice of conducting two independent review for primary evaluations and having a third, more experienced reviewer, conduct QC and finalize the study ratings across all evaluation domains.

Second, reverse causality is dependent on the outcome of interest and not inherent to a certain study design, as noted in the footnote of Table A-19 (USEPA, 2023b; USEPA, 2023c). This was previously described in the EPA response to comment Doc. #1774, SBC-045661 in section 4.1.1 in this *Response to Comments* document. While evaluating studies, the EPA considered potential for reverse causation on an outcome-specific basis, where consideration was supported by the established epidemiological literature (Radke et al., 2019). Certain health conditions, such as decreased renal function or diabetes, may affect clearance of PFAS from the body (Jain and Ducatman, 2019a); potential for reverse causality was considered in these cases. Thus, there are examples of cross-sectional analyses with exposure assessment rated as Deficient based on

reverse causality (e.g., Kataria et al., 2015) that were dependent on the outcome of interest (e.g., renal function). However, reverse causality is unlikely to be a concern in cross-sectional studies or studies of any other design for health outcomes unrelated to distribution or clearance of PFAS from the body. In these cases, cross-sectional measurements of PFAS were determined to be representative of past exposure due to the long half-lives of PFOA and PFOS in the body.

Lastly, the EPA disagrees that the guidance provided in the study quality evaluation protocol (Appendix A; USEPA, 2023b; USEPA, 2023c) introduces subjective confidence ratings. The specific piece of guidance the commenter cites describes scenarios where an overall study confidence was decreased solely due to a *deficient* rating in the Sensitivity domain. This would apply to studies of *low* or *medium* confidence. The guidance states an overall confidence rating may be increased if an effect was observed despite the limitations in sensitivity. The observed effect would be reported by the study authors and would not be based on a subjective decision of the reviewer. To the extent the commenter is raising concerns about subjectivity of the protocol, the IRIS Handbook recognizes that expert scientific judgment is an inherent part of the systematic review process (USEPA, 2022a); as described above, any differences in professional judgment are mitigated by the use of multiple reviewers and pre-established evaluation criteria.

Mike Pettit (Doc. #1542, SBC-043344)

This paper will merely highlight major issues and causes for concern that should be addressed before any type of rash decisions are made that would severely impact communities across the States. Page 244 and beyond are prime examples of these types of issues. Derived data can be useful however, derivations of derivations ultimately imbue a growing sense of error since they are, at their very core, speculations. Without properly controlled studies to accurately measure slopes of correlation, the amount of hidden error may not be realized at first and then incorrect conclusions may be drawn and imposed on the general populace. The very liberal usage of the term “estimate” in all of its tenses combined with the again, very liberal, usage of the term “suggestive” does not lend any form of certainty or gravity to the serious tone originally laid out in this memo.

By the memo’s own admission on pg 265, the weight of the terms and their relative strength is mentioned in this sentence: “discuss the weight of evidence supporting associations between PFOA or PFOS exposure with health outcomes as indicative (likely), inadequate, or suggestive.” That would immediately mean that the term “suggestive” is the weakest term of correlative strength and that heavy usage frankly does not lend any level of confidence. The term “suggest” and its tenses appears 51 times within the memo whereas “indicative” appears 8 times. That alone should speak for itself. The term “positive association” shows up 16 times however the strength of these associations are actually never delineated and the papers that are referenced really provide very weak positive associations or extreme circumstances such as acute, chronic exposure at levels far beyond what anyone in any normal situation would ever experience. In such instances, yes there would be an issue but the same could be said of vitamins, alcohol, and bananas. If anyone were to consume a huge amount of any of those things, there would be health

complications and concerns. That does not mean that those things are outlawed or even seriously regulated. Bananas have minimal regulations and if someone buys 100 pounds of them, that might raise a few eyebrows but nothing beyond that. Vitamins, again minimally regulated, and alcohol, the most regulated of these and a known carcinogen, is easy enough to buy with the right identification with no legal limits on how much a single individual can buy. So bananas (which are slightly radioactive), multivitamins (which can be overdosed), and alcohol (known carcinogen and major cause of vehicular death/homicide) are less regulated than a serious of non-reactive chemicals that have very little known issues and side effects.

The reason these chemicals are called “forever chemicals” to begin with is that they are mainly comprised of carbon-fluorine bonds which are the strongest bonds in organic chemistry and because of that bond, they are famously nonreactive. What this now means is that it is chemically inert, and will chemically barely react with anything within the body. The issue would then be not how the chemical reacts with the body but how the body reacts to the chemical, which is an entirely different animal and will vary from person to person. This has to do with genetics, genetic predispositions, community, living conditions, etc. It would be difficult at best to try to fully quantify the effects these chemicals would have without conducting long range, chronic studies that take into account a myriad of limiting factors. Extrapolation of data that does not or can not take these factors into full consideration should only be taken with the utmost caution. The amount of interfering factors that can be and are present would easily confound results into completely erroneous conclusions.

This brief digression has a purpose- of the 8 mentions of the term “indicative,” twice it was used as the definition and expanding the definition therein, once was used to explain why certain evidences were not used in the economic analysis, once mentioned that the evidence was indicative, but it could not be valued enough clinically to be included, another time it is mentioned that the slope implied only a small change in risk, twice it was used to say that there is moderate evidence to support a potential change as marked by elevated liver enzymes which are indicative of liver damage, and finally it was used to mentioned in the context of regulations of TTHMs. So of the 8 usages of the term, only two are directly used in reference to PFAS/PFOA but are later discounted, and two are loosely assigned with an idea that there is moderate evidence as shown by a secondary product that is indicative of liver disease and are thus not even fully linked together. Therefore, half of the strongest terms that could be used is not even used to support the evidence. This is a major cause of concern for the most obvious of reasons. There is a serious lack of sincerity and integrity showcased in this instance. There cannot be any strict, or even serious, type of regulations placed in this instance, such as enforcing 4 parts-per-trillion limit. If any are placed, this is either an error or has another reason behind it- it has nothing to do with the weight of the scientific evidence. If anything, this should prompt further, more focused research before anything is concluded. Surely this is a lesson that should have been learned with the advent of the first Covid-19 shot that caused severe and sometimes fatal after effects simply because the process was rushed which resulted in poor decisions being made and unnecessary suffering to occur. The short conclusion therefore of all of this, is that the vast majority of the claims are extrapolations that by their very nature cannot take into account all of the confounding

factors listed out in the previous paragraph. Again, this raises to the issue of drawing lines in the sand that scientifically cannot be drawn. The facts simply are not there.

EPA Response: The commenter suggests that the EPA's use of "derivations of derivations" introduces error, however the commenter does not define how the EPA used "derivations of derivations" and does not provide evidence that the studies used in the PFOA and PFOS toxicity assessments are improperly controlled. Please see section 4.1.2 of the EPA response in this *Response to Comments* document which details how the EPA used best available science and followed agency guidance in producing the PFOA and PFOS toxicity assessments.

The commenter took Issue with the language the EPA used to describe conclusions about the strength of evidence from reviewing the available in the health effects information. The commenter suggested that the ordering of the term "suggestive" last in the list of potential judgments led readers to believe this was the weakest term regarding supporting evidence. These terms are commonly used across agency assessments that follow the systematic review process outlined in the IRIS Handbook (USEPA, 2022a). The EPA's usage of terms such as "indicates" and "suggestive" was a direct result of the EPA responding to the SAB recommendation to "implement a structured, consistent process with consistent terminology for analyzing and synthesizing animal evidence, human evidence, and overall evidence" (USEPA, 2022b). The EPA used the same terminology in the toxicity assessments for evidence integration judgment terms that are defined in the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022a); these terms were also described in detail in Appendix A of the PFOA and PFOS draft toxicity assessments (USEPA, 2023b; USEPA, 2023c). In response to the concern raised by this commenter about the potential for confusion in the ordering of evidence judgments, the EPA has updated the quoted text to place the terms in the same order as described in the IRIS Handbook (USEPA, 2022a) and Appendices (USEPA, 2024a; USEPA, 2024b).

Additionally, the commenter incorrectly stated that the EPA described many positive associations observed in the literature but does not provide details on the relative strength of these associations. The EPA disagrees with these statements. The EPA used multiple methods to transparently describe and depict the available evidence, including descriptions of statistical significance where applicable, providing forest plots within synthesis sections, and tables of detailed study results (USEPA, 2023f; USEPA, 2023a). The magnitude of association between studies reporting effect estimates with different units (e.g., per ng/mL increase, per ln-ng/mL increase, per Interquartile Range [IQR] increase) are not directly comparable without transformation. The EPA demonstrated the strength of association across studies for the specific outcomes of concern for all relevant studies within each priority health outcome category (e.g., total cholesterol for Cardiovascular) by including forest plots which display effect estimates (i.e., regression coefficients, percent change, odds ratios (ORs), etc.). These are included in the human evidence synthesis sections for each priority health outcome (USEPA, 2024d; USEPA, 2024c): Hepatic (Sec. 3.4.1.1), Immune (Sec. 3.4.2.1), Cardiovascular (Sec. 3.4.3.1), and Developmental (Sec. 3.4.4.1). The EPA has also provided detailed results from all included studies in Appendix D of the final toxicity assessments for PFOA and PFOS (USEPA, 2024a; USEPA, 2024b).

The commenter also incorrectly claimed that the cited studies actually provide weak evidence of positive associations and that health effects are only observed under "extreme" circumstances. In fact, significant effects were observed in studies of impacted or high-exposure communities, as well as studies of the general population. Significant adverse effects associated with elevated PFOA exposure were observed in multiple general population studies for BWT (Chu, 2020; Wikström, 2020), Alanine Aminotransferase (ALT) (Lin, 2010; Salihovic, 2018), antibody response in children (Granum, 2013; Zhang, 2023), and total cholesterol in adults (Fan, 2020; Nelson, 2010; Dong, 2019). Similar significant adverse effects were observed in studies with general population exposure levels for PFOS: BWT (Bjerregaard-Olesen, 2019; Chu, 2020; Lauritzen, 2017; Luo, 2021; Wikström, 2020), ALT (Lin, 2010; Yamaguchi, 2013), antibody response in children (Granum, 2013; Zhang, 2023), and total cholesterol in adults (Nelson, 2010; Liu, 2018; Dong, 2019; Fan, 2020). These studies were described in detail in the draft toxicity assessments published at the time of rule proposal (USEPA, 2023f; USEPA, 2023a).

The commenter incorrectly claimed, without providing a citation, that because PFAS are "chemically inert" that they will not react with the body. The EPA disagrees with this statement that PFAS are chemically inert, and notes that there is sufficient toxicokinetic and mechanistic evidence to support the fact that PFOA and PFOS interact with biological processes in multiple organisms, including humans. As noted in the Toxicokinetic Synthesis, "PFOA binds to the liver fatty acid binding protein (L-FABP) [in liver cells] through polar and hydrophobic interactions (Luebker, 2002; Zhang, 2013; Yang, 2020)" (USEPA, 2023f, Sec. 3.3.1.2.2). Similar findings were observed for PFOS: "*in vitro* analyses found that plasma proteins can bind PFOS in plasma from humans, cynomolgus monkeys, and rats (Kerstner-Wood, 2003)." Additionally, "PFOS was highly bound (99.8%) to albumin and showed affinity for low-density lipoproteins (95.6%) with some binding to alpha-globulins (59.4%) and gamma-globulins (24.1%)" (USEPA, 2023a, Sec. 3.3.1.2.1). These documented findings demonstrate that PFOA and PFOS are not "chemically inert" in the body. There are additional findings of PFOA and PFOS interacting with biological processes that are summarized in the mechanistic syntheses for Hepatic (Sec. 3.4.1.3), Immune (Sec. 3.4.2.3), Cardiovascular (Sec. 3.4.3.3), and Developmental (Sec. 3.4.4.3) outcomes in the draft and final toxicity assessments (USEPA, 2023f; 2023a; 2024d; 2024c).

The commenter lastly stated that more research is needed prior to finalizing the PFAS National Primary Drinking Water Regulation (NPDWR). The EPA disagrees with this claim. Please see section 4.2.1 of the EPA response in this *Response to Comments* document.

Virginia Municipal Drinking Water Association (VMDWA) (Doc. #1657, SBC-043164)

Instead, EPA's proposal appears to rely heavily and near exclusively on extrapolation from lab animal studies (rats and mice). Given the American experience with well-known PFAS exposures, VMDWA believes the final MCLs would benefit from closer review and consideration of human health data as a complement to animal studies. VMDWA desires a final regulation that protects public health without misprioritizing limited public resources and causing unnecessary financial burdens on the public.

EPA Response: With respect to the commenter's suggestion that the EPA preferentially use human data over animal toxicological data to inform the MCLGs for PFOA and PFOS, the EPA considered all relevant data to inform the cancer classification determinations and evidence integration judgments for noncancer health outcomes associated with PFOA and PFOS exposures, consistent with agency guidance (USEPA, 2005) and the agency's peer reviewed human health assessment methodology (USEPA, 2022a). To support the PFOA and PFOS cancer classifications and evidence integration judgments for noncancer health effects, the EPA documented the integrated weight of evidence across the available epidemiological, animal toxicological, and mechanistic data (see Sections 3.4 and 3.5 of USEPA (2024a) and USEPA (2024b)). The available human data for PFOA and PFOS includes *high* and/or *medium* confidence epidemiological studies that showed consistent direction of effect and coherence with evidence presented in animal toxicological studies. Therefore, in contrast to the commenter's claims, the available human data was used to inform the conclusions of the toxicity assessments of PFOA and PFOS (USEPA, 2024d; USEPA, 2024c). Regarding the use of animal studies to serve as the basis of the MCLGs and Health-Based Water Concentrations (HBWCs) for PFNA, PFHxS, HFPO-DA, and PFBS, please see sections 4.3.2 and 4.3.3 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1642, SBC-043484 in section 4.3.3 in this *Response to Comments* document. Regarding the financial considerations of this rulemaking, please see sections 2.4 and 13.8 of the EPA response in this *Response to Comments* document.

Maryland Association of Municipal Wastewater Agencies (MAMWA) (Doc. #1658, SBC-043399)

Instead, EPA's proposal appears to rely heavily and near exclusively on extrapolation from lab animal studies (rats and mice). Given the American experience with well-known PFAS exposures, VMDWA believes the final MCLs would benefit from closer review and consideration of human health data as a complement to animal studies. VMDWA desires a final regulation that protects public health without misprioritizing limited public resources and causing unnecessary financial burdens on the public.

EPA Response: Please see the EPA response to comment Doc. #1657, SBC-043164 in section 4.1.1 in this *Response to Comments* document.

Mike Pettit (Doc. #1542, SBC-043350)

And while animal studies have been invaluable in advancing our understanding of biology and medicine, there are several potential flaws in extrapolating data from animal studies to humans. It is important to consider these limitations when interpreting the results of such studies:

• Species differences: Animals, especially non-human mammals, have distinct physiological, anatomical, and genetic differences compared to humans. These disparities may limit the applicability of findings from animal studies to human conditions

• Metabolic and immunological differences: Variations in metabolic pathways, immune responses, and drug metabolism between species can lead to different outcomes in animals compared to humans, reducing the reliability of animal studies for predicting human responses

• Behavior and cognitive differences: The cognitive and behavioral aspects of animals can differ significantly from humans, which can impact the interpretation and applicability of study results, particularly in the fields of psychology, neuroscience, and behavioral sciences

• Experimental conditions: The laboratory setting in which animal studies are conducted often differs significantly from real-life human environments. Factors such as housing, diet, and stress can influence the results and may not accurately represent human conditions.

• Limited genetic diversity: Laboratory animals often come from a small gene pool, which may not represent the wide genetic diversity found in human populations. This can lead to differences in susceptibility to diseases and treatment responses between animals and humans.

• Sample size and statistical power: Animal studies often have smaller sample sizes than human studies, which can limit their statistical power and lead to a higher risk of false positives or negatives.

• Overemphasis on positive results: Publication bias towards positive results may lead to an over-representation of successful animal studies, creating a skewed perception of the effectiveness of treatments and interventions when applied to humans

• Lack of standardization: Variability in experimental design, methods, and reporting among animal studies can make it challenging to compare and synthesize results across studies, limiting their applicability to human research.

Summary

As previously notated, there may very well be some potential health concerns for the general populace and in certain cases, severe concerns depending on genetic susceptibility. That said, there has not been near enough research that has been specifically targeted to the PFAS effects on humans and at what concentrations is to considered a level of concern. There is data from a singular study previously cited from rats but the serious problems of extrapolation have already been discussed. The issue lies in that there are serious regulations being expressed and potentially enforced that have very little scientific bearing and backbone. If the driving force is something other than science, then that needs to addressed in its own proper place, but leave the scientific claims out of it. If, and when there is any type of actual research of serious nature done, then more lines and conclusions can be drawn but as it stands currently there is little to no bearing that can be drawn from a scientific point of view. Regulations are understandable, and necessary in many cases, but making a law based on pure conjecture is foolish.

Clean water should be for everyone- that much is sure. Inane rulings that do nothing but cause needless headache and wasteful spending are for no one. The EPA needs to revise their current procedures and scientific work if they are going to use science as a claim for wasting money and

time. If the EPA wishes to use another reason for their ruling apart from scientific impetus, then that is up to the EPA's discretion. Unpacking all the reasons as to why there may be a drive to spend massive amounts of tax payer money is outside of the scope of this paper. This is a call to be better because the American people need it. Regardless of the agenda, priority, or reason, everyone needs to have water that is safe to drink. That is a fundamental need. Safe drinking water does not inherently mean pure water, as pure water is its own animal with potential risks. Realistically, proper definitions of what safe drinking water is and is not needs to be readily available for the public to avoid needless panic and misinformation.

Summarizing all of this, the EPA just generally needs to do better. There are claims, movements, and laws being proposed and enacted that have no actual bearing apart from lobbyists, unknown agendas, ignorance, and fear. Official and truthful statements need to be issued, actual studies done properly, and real, logical regulations put in place if necessary. Be better and do better.

EPA Response: Please see section 4.1.1 of the EPA response in this *Response to Comments* document for a discussion of the EPA's protocol related to systematic review methodology and see the EPA response to comment Doc. #1657, SBC-043164 in section 4.1.1 in this *Response to Comments* document regarding the EPA's consideration of human studies in the assessments for PFOA and PFOS. Please see section 4.1.2 of the EPA response in this *Response to Comments* document for a discussion of the EPA's use of the best available science and Agency guidance. The EPA disagrees with commenter's assertion that there is insufficient information to know the adverse effects associated with PFOA or PFOS exposure in humans and the concentrations of PFOA or PFOS that are associated with adverse effects. The results of the EPA's systematic review demonstrate that there are hundreds of *medium* and *high* confidence epidemiological studies that investigated and reported adverse health effects of PFOA and PFOS. See section 4.2.1 and the subsequent responses in sections 4.2.1.2, 4.2.1.3, 4.2.1.4, and 4.2.1.5 of the EPA response in this *Response to Comments* document. Please see section 4.2.2 of the EPA response in this *Response to Comments* document regarding the concentrations of PFOA and PFOS that result in these adverse effects and for more detail on extrapolating from animal studies to derive a CSF. Please see the EPA response to comment Doc. #1542, SBC-043345 in section 4.1.4.2 in this *Response to Comments* document for a response to the commenter's incorrect claim about the use of a singular study in rats to inform the PFOS cancer classification.

Regarding commenter's statements that "Inane rulings that do nothing but cause needless headache and wasteful spending are for no one" and "EPA just generally needs to do better," the EPA has developed a science-based, health protective, and implementable regulation. As discussed in the record for this rule, the PFAS NPDWRs were developed under the authority of the Safe Drinking Water Act, and are consistent with applicable requirements.

4.1.2 The EPA's Use of the Best Available Science, Agency Guidance, and EPA Data Quality Control Procedures to Make Conclusions in the EPA Toxicity Assessments for PFOA and PFOS

Summary of Major Public Comments and EPA Responses

A few commenters claimed that the EPA did not use the best available science when developing the draft toxicity assessments for PFOA and PFOS, asserting that the EPA did not follow its own guidance or data quality standards and that the EPA's systematic review process was flawed. Please see section 4.1.1 of the EPA response in this *Response to Comments* document regarding the systematic review process. The commenters appear to misunderstand what a systematic review is and the types of data that are used in a systematic review and toxicity assessment. As defined in the IRIS handbook, a systematic review is a "structured and documented process for transparent literature review using explicit, pre-specified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies" (USEPA, 2022a). This approach allows for the retrieval, organization, evaluation, synthesis, integration, and presentation of scientific information in a more structured and transparent manner (USEPA, 2022a). The process minimizes bias and improves accuracy through the establishment of protocols prior to initiating the systematic review, the use of multiple independent reviewers at the screening and study quality evaluation steps, and the engagement of a team of experts in different disciplines (e.g., epidemiologists, toxicologists, statisticians) to develop the toxicity assessments and perform independent QA of data extraction, evidence syntheses, evidence integration judgments and selection of critical effects and studies used for point-of-departure (PODD derivation.

As mentioned above, the purpose of a systematic review is to review the existing literature, not to generate original data such as those published in human epidemiological and animal toxicological studies. Further, the Handbook also describes the type of literature what that does is not provide original data, which includes "other agency assessments, informative scientific literature reviews, editorials, or commentaries" (USEPA, 2022a). The EPA uses original data provided in studies identified through literature searches for the systematic review, consistent with the IRIS Handbook (USEPA, 2022a). The commenter appears to misunderstand what constitutes "original data," which is not necessarily individual-level exposure or response data for each subject or animal. Original data can also be summary statistics based on individual-level data (e.g., mean, variance, regression coefficients). Having individual-level data for each subject is not required for inclusion in the systematic review process or use in toxicity value derivation (USEPA, 2022a). Additionally, the EPA does not generate original data through the systematic review process. Therefore, the commenter's claims about original data are moot. The EPA is consistent with the IRIS Handbook in identifying appropriate studies with original data for use in the systematic review. The core databases that were searched in the PFOA and PFOS toxicity assessments are the consistent with those outlined in the Handbook Section 2.3.2 (USEPA, 2022a). Additionally, the same types of studies and often the same exact studies are used in the recent draft IRIS PFAS assessments (e.g., Budtz-Jorgensen & Grandjean (2018), Sagiv et al.

(2018)). Further, the Handbook also describes what is not original data which includes "other agency assessments, informative scientific literature reviews, editorials, or commentaries" (USEPA, 2022a). Therefore, commenters who claim that the EPA did not use the best available science, did not follow agency methodology for systematic review, and did not adhere to data and quality control procedures for generating original data are incorrect.

One commenter stated that the EPA did not use the best available peer-reviewed science because the assessments did not follow methodological or statistical guidance. Specifically, this commenter stated that the EPA did not follow *A Review of the Reference Dose and Reference Concentration Processes* (USEPA, 2002) when selecting uncertainty factors and claimed the EPA did not follow guidance on data quality (USEPA, 2003a; USEPA, 2006a; USEPA, 2014a). The commenter stated they believed that the assessments contained flaws including exclusion of covariates in modeling, reliance on peer-reviewed studies published by non-EPA employees, and an inability to replicate results.

The EPA has provided all of the necessary information for replication of the modeling performed in these toxicity assessments to derive toxicity values. For example, all of the dose-response modeling inputs, outputs, assumptions, and equations are provided in Appendix E of the toxicity assessments (USEPA, 2024a; USEPA, 2024b). The pharmacokinetic (PK) models are also described in detail in section 4.1.3 and Appendix F of the toxicity assessments (USEPA, 2024d; USEPA, 2024c; USEPA, 2024a; USEPA, 2024b). Further, the code for the PK models was put on GitHub https://github.com/USEPA/OW-PFOS-PFOA-MCLG-support-PK-models) and the model code was thoroughly QA'd through the established EPA Quality Assurance Project Plan (QAPP) for Physiologically-Based Pharmacokinetic (PBPK) models (USEPA, 2018a). The EPA has followed statutory requirements to use the best available science in the development of the PFOA and PFOS toxicity assessments by 1) considering relevant peer-reviewed literature identified through performing systematic searches of the scientific literature or submitted through peer review or public comment; and 2) relying on peer-reviewed, and publicly available EPA human health risk assessment methodology (e.g., USEPA, 2002) as well as peer-reviewed systematic review best practices (USEPA, 2022a; USEPA, 2021a). These agency risk assessment guidance, methodologies, and best practices serve as the basis for the PFOA and PFOS health effects systematic review methods used to identify, evaluate, and analyze the available data. Not only did the EPA incorporate literature identified in previous assessments, as recommended by the SAB (USEPA, 2022b), but the EPA also conducted several updated systematic literature searches, the most recent of which was completed in February 2023. This approach ensured that the literature under review encompassed studies that were included in the 2016 HESDs (USEPA, 2016b; USEPA, 2016a) and more recently published studies. The results from most recent literature search provide further support for the conclusions made in the draft toxicity assessments for PFOA and PFOS (USEPA, 2023f; USEPA, 2023a) and are described in Appendix A of the final toxicity assessments (USEPA, 2024a; USEPA, 2024b). The EPA also reviewed and considered studies identified in public comments and provides discussion about consideration of these in section 4.2.6 of the EPA response in this *Response to Comments* document.

As described in section 4.1.1 of the EPA response in this *Response to Comments* document, the PFOA and PFOS systematic review protocol is consistent with the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022a) and further implemented PFAS-specific protocol updates outlined in the *Systematic Review Protocol for the PFBA, PFHxA, PFHxS, PFNA, and PFDA (anionic and acid forms) IRIS Assessments* (USEPA, 2021a). The EPA additionally followed peer-reviewed human health risk assessment methods for developing toxicity values (e.g., USEPA, 2002), conducting benchmark dose (BMD) modeling (USEPA, 2012), and other analyses. In the PFOA and PFOS toxicity assessments and the appendices, the EPA clearly describes the specific methods used and how those methods and decisions are consistent with current agency best practices and recommendations (i.e., through quotes and citations) described in various guidance documents (USEPA, 2024d; USEPA, 2024c; USEPA, 2024a; USEPA, 2024b).

Regarding data quality control, data quality objectives are an integral part of the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022a), and many of the data quality concepts considered in the agency documents cited by the commenter (USEPA, 2003; USEPA, 2006a; USEPA, 2006b; USEPA, 2014b) are addressed through the EPA's implementation of the IRIS Handbook (USEPA, 2022a) in the development of the PFOA and PFOS toxicity assessments. Furthermore, this work was conducted under a programmatic QAPP, which ensures that all agency data quality guidance is followed, including those cited by the commenter (ICF, 2024). Additionally, by developing and implementing a systematic review protocol consistent with the IRIS Handbook (USEPA, 2022a), the EPA reduced potential confirmation bias, a concern raised by another commenter, by conducting multiple independent evaluations of studies, relying on a data-driven, weight of evidence approach, and incorporating expertise from across the agency.

In many cases the commenters have misinterpreted the methods and decisions the EPA used to analyze the data or misinterpreted the guidance itself. For example, one commenter mistakenly suggested that the EPA did not consider covariates in its analyses of epidemiological studies; the EPA described which covariates were considered in each analysis in several sections of the draft toxicity assessments and appendices (USEPA, 2023f; USEPA, 2023a; USEPA, 2023b; USEPA, 2023c), including in descriptions of the studies in Section 3 and modeling of the studies in Appendix E. The EPA also notes that the primary studies that provide the data also describe covariate adjustments in their published analyses.

Individual Public Comments

3M Company (Doc. #1774, SBC-045649)

EXECUTIVE SUMMARY

As discussed below, EPA's proposed NPDWRs violate the Safe Drinking Water Act (SDWA) because they are not based on the "best available, peer-reviewed science," [[FN1: 42 U.S.C.A. [sec] 300g-1(b)(3)(A)]] and because EPA did not follow statutorily defined procedures and, in

many cases, its own well-established guidance in promulgating them. EPA did not appropriately establish and follow processes designed to help ensure its rulemaking reflects the weight of the evidence-based conclusions about potential consequences of exposure to the PFAS at issue, and the levels at which such consequences could be observed. The processes for collecting and evaluating scientific research are not matters of interpretation or preferred approach. They are foundational scientific practices and guidance, including, in many cases, the Agency's own guidance. Here, EPA has significantly deviated from those foundational practices. This has resulted in a proposal for incredibly low regulatory limits for PFOA, PFOS, and the Hazard Index (HI) substances (perfluorohexanesulfonic acid [PFHxS], perfluorobutane sulfonic acid [PFBS], perfluorononanoic acid [PFNA], and hexafluoropropylene oxide dimer acid [HPFO-DA]) in drinking water without showing that any benefits of such low limits are justified by their significant costs. The agency's flawed process has resulted in proposed NPDWRs that are arbitrary and capricious as they do not achieve the goal of appropriately balancing the costs of compliance against the expected benefits.

EPA Response: The EPA disagrees with these general statements which are not supported by specific citations to guidance and processes that the EPA failed to follow. Please see section 4.1.2 of the EPA response in this *Response to Comments* document and responses to the commenters specific concerns in the EPA response to comment Doc. #1774, SBC-045701, SBC-045680, SBC-045702, SBC-053418, and SBC-045681 in section 4.1.2 in this *Response to Comments* document. Regarding the Hazard Index for PFAS, please see section 4.3 of the EPA response in this *Response to Comments* document. Regarding the EPA's economic analysis, please see section 4.13 of the EPA response in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-053417)

EPA acknowledges significant uncertainty in the scientific literature, to the point that it incorporated uncertainty factors so high as to be the maximum that could be considered as the basis of reference value according to EPA's IRIS Handbook. EPA cannot cite scientific uncertainty as a basis for relying on subpar studies that fit its predetermined conclusion. [FN55: See City of Waukesha, 320 F.3d at 254.] Nor can EPA simply default to caution when scientific evidence directs the agency otherwise. [FN56: See Chlorine Chemistry Council v. EPA, 206 F.3d 1286, 1290-91 (D.C. Cir. 2000)] (EPA cannot "reject 'best available' evidence simply because of the possibility of contradiction in the future by evidence unavailable at the time of action – a possibility that will always be present.")

EPA Response: The commenter's statement that the EPA "incorporated uncertainty factors so high as to be the maximum that could be considered as the basis of reference value according to the EPA's IRIS Handbook" is incorrect. The EPA IRIS Handbook recommends the maximum composite uncertainty factors that can be applied without excessive uncertainty as 3,000 fold (USEPA, 2022a). For all candidate RfDs derived from the epidemiological data, including those selected as the basis of the overall RfDs for PFOA and PFOS, the composite uncertainty factor (UF) applied to the POD_{HED}s was 10 based on the intraspecies UF that

accounts for inter-individual or intraspecies variability in susceptibility across humans. For candidate RfDs derived from animal toxicological studies of PFOA and PFOS, none of the composite UFs exceeded 300. In short, this is a full order of magnitude (10 times) lower than the EPA's recommended maximum composite UF. The EPA's rationale for selecting uncertainty factors is provided in Section 4.1.5.5 of the final toxicity assessments (USEPA, 2024d; USEPA, 2024c). Further discussion on uncertainty factor selection is provided in the EPA Response to comment Doc. #1774, SBC-045702 in section 4.1.2 in this *Response to Comments* document. Additionally, the EPA disagrees that the agency relied on "subpar studies" to develop the assessment conclusions. The merits of critical studies are described in section 4.1.4 (cancer assessment) and 4.2.1 and 4.2.2 (noncancer assessment) of the EPA response in this *Response to Comments* document. In contrast to the commenter's claims, the EPA relied on the best available science published on or before the date of the final literature search for these assessments to support this rulemaking (see USEPA, 2024d; USEPA, 2024c; USEPA, 2024a; USEPA, 2024b); the agency did not rely on "future" evidence that is currently unavailable. The EPA is not "simply defaulting to caution when the scientific evidence directs otherwise" as the commenter suggests. As discussed in this rulemaking record, the EPA's determinations with respect to PFOA and PFOS are well supported and based on the best available peer reviewed science available at the time of this rulemaking. Unlike the situation in *Chlorine Chemistry Council v. EPA*, 206 F.3d 1286, 1290-91 (D.C. Cir. 2000), the EPA has maintained that PFOA and PFOS are *Likely to be Carcinogenic to Humans* from its proposal through this final rule and explained the bases for these classifications in the administrative record, including section 4.1.4 of the EPA response in this *Response to Comments* document, and the final toxicity assessments for PFOA and PFOS (USEPA, 2024d; USEPA, 2024c).

3M Company (Doc. #1774, SBC-045680)

VI. EPA's PROPOSED MCLGS AND MCLS FOR PFOA AND PFOS ARE NOT BASED ON BEST AVAILABLE SCIENCE

EPA's process flaws have resulted in a proposed NPDWR that does not comply with the SDWA's statutory requirement to rely only on "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices," rendering the proposed rule arbitrary, capricious, and in excess of statutory authority. [FN52: 42 U.S.C. § 300g-1(i).] An agency must be prepared to provide a "full analytical defense" of its approach. [FN53: Chemical Manufacturers Association v. EPA, 28 F.3d 1259, 1265 (D.C. Cir. 1994)] As many courts have noted, "[t]he deference accorded an agency's scientific or technical expertise is not unlimited." [FN54: Brower v. Evans, 257 F.3d 1058, 1067 (9th Cir.2001).]

First, as explained in Section III, EPA's evaluation of relevant scientific literature has serious procedural issues that raise significant questions regarding the Agency's scientific conclusions. For example, EPA did not follow basic principles or even its own guidance in conducting its review and evaluation analysis of studies, which resulted in the use of low-quality papers and

datasets that cannot be reproduced. Flaws in EPA's scientific approach that forms the basis of the standards proposed in this rulemaking are described in detail below.

As described in the sections below, EPA's proposed NPDWRs violate numerous foundational scientific practices such that it cannot represent the "best available, peer-reviewed science," in violation of both the SDWA and the Administrative Procedures Act's requirement that an agency's actions not be arbitrary.

a. EPA Did Not Follow Best Practice and Its Own Guidelines for Data Quality Control

EPA has published a series of quality control (QC) and best practice guidelines for program development and project development (USEPA 1992,2002a), data quality objectives (USEPA 2003, 2006), and good statistical practice (USEPA, 2006). EPA has also published approved methods and software for calculating benchmark doses (BMD) and their uncertainty (USEPA 2012, 2022c) which have been developed into an interactive web site. These guidelines are intended to ensure that the resulting decisions made by EPA meet the highest scientific standards, including reproducibility of results, appropriate data treatment, ensuring representative data, and accurate identification and quantification of true risk to human populations and environmental metrics. The IRIS Handbook and USEPA (2012) provide criteria for how to review literature studies and categorize them based on availability of data, study design, testing procedures, statistical methods, and deficiencies.

The methods and procedures EPA used to support the Proposed Rule did not follow these established procedures, and lack good data practice, sound statistical analysis practice, consistency of methods and models, and the ability to replicate analytical results. EPA has not proposed data quality objectives (DQOs) or Quality Assurance Project Plans (QAPP) for any data source chosen for the Proposed Rule, and/or associated findings used to establish the MCLG. DQOs are required for any research initiative in order to document and ensure that data are collected properly, data are treated using good statistical practice, and any findings can be replicated by scientists and data analysts not working at EPA. EPA's own documents provide guidance on DQOs, program planning, good data practice, and good statistical practice (USEPA 2003, 2006, 2014).

Nor has EPA followed its own requirements and guidance (as listed in the foregoing paragraph) for collecting and analyzing data. Rather, for the MCLG and associated analyses, EPA has largely relied on previously published studies conducted by non-EPA employees for which EPA has not verified data collection, data treatment, outlier detection, variance estimation, elimination of records, or good statistical practice. For example, EPA has selected papers where the data used to calculate BMDs and other measures of risk were not publicly available or were difficult and time-consuming to obtain (e.g., Budtz-Jørgensen and Grandjean, 2018; Shearer et al., 2021). The inability to replicate study findings violates a key principle of the scientific method. [FN57: This is a critical and highly relevant topic given that peer review is only as good as the information provided. Lack of transparency in publications and other related issues may limit the effectiveness of peer review and the ability to replicate results of the study. See, e.g.,

https://www.news-medical.net/life-sciences/What-is-theReplication-Crisis.aspx; see also Improving transparency and scientific rigor in academic publishing (Prager et al. 2019) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6346653/.] This action also is in direct violation of the IRIS Handbook (USEPA ORD 2022), which states that studies with no original data are "tracked for potential use in identifying missing studies, background information, or current scientific opinions," meaning they are not included in the quantitative IRIS assessment. Further, EPA's guidance for considering literature toxicity studies (USEPA ORD 2022) lists specific criteria for invalidation of studies, including "inadequate or missing analytical data," "deficiencies in reporting of study data," and "lack of appropriate statistical methodology." Had EPA's analysis comported with its guidance, many of the studies that EPA relied upon would have been categorized as invalid and therefore presumably not appropriate for use. Exclusion of significant studies, such as Budtz-Jorgensen and Grandjean (2018) and Shearer et al. (2021) would alter EPA's findings.

EPA Response: Please see section 4.1.2 of the EPA response in this *Response to Comments* document for general responses to three incorrect claims about the EPA's process to develop the toxicity assessments: 1.) that the EPA followed a flawed process and did not use the best available, peer-reviewed science when developing the proposed PFAS NPDWR; 2.) that the EPA did not follow guidance or methodologies (e.g., USEPA, 2012; USEPA, 2022a) in conducting its review and evaluation of studies, nor did the EPA follow established data quality practices, resulting in the use of low-quality data; and 3.) that the EPA did not propose data quality objectives (DQOs) or QAPPs for data supporting the proposed rule. The EPA's responses to more specific comments are provided below.

The EPA disagrees with the commenter's assertions that the EPA toxicity assessment development did not follow agency guidance and methodologies. The commenter appears to misunderstand the EPA's peer-reviewed human health risk assessment methodology and the IRIS Handbook (USEPA, 2022a). Specifically, the commenter incorrectly stated that the EPA relied on previously published studies from non-EPA authors that did not provide original data, an approach that the commenter incorrectly claims conflicts with the IRIS Handbook. Consistent with the IRIS Handbook and agency human health risk assessment practice, the EPA considered peer-reviewed, publicly available studies *regardless of authorship affiliations* (USEPA, 2022a). As outlined in the IRIS Handbook, systematic review is a scientifically sound process that is used to identify, evaluate, and integrate health effects data following chemical exposure based on a large body of evidence from peer-reviewed publications by authors with or without EPA affiliation. Systematic review enables the agency to follow a rigorous process designed to increase transparency, consistency, and the quality of health assessments. It allows the agency to make conclusions across the entire body of evidence according to a protocol in lieu of relying upon single studies to draw conclusions. The studies reviewed by the EPA were peer-reviewed publications and technical reports. To suggest that peer-reviewed publications do not have original data is fundamentally incorrect. This approach is consistent with current agency human health risk assessment methods (i.e., under the IRIS and Provisional Peer-Reviewed Toxicity Values (PPRTV) programs, the Office of Pesticides Program, and the Office of Pollution

Prevention and Toxics). The EPA followed protocols consistent with the IRIS Handbook (USEPA, 2022a) and the *Systematic Review Protocol for the IRIS PFAS Assessments* (USEPA, 2021a) to evaluate individual studies for relevance and study confidence, which included domains similar to the commenter's mentioned criteria for "invalidation of studies" (see Appendix A; USEPA, 2024a; USEPA, 2024b). Therefore, the EPA complied with its own guidance and has followed standard practice in its inclusion and evaluation of the available literature for PFOA and PFOS.

In the case of PFOA and PFOS, studies presenting original data (e.g., unique datasets, modeling results, statistical analyses) were used to draw hazard conclusions and derive quantitative values in the assessments. The EPA also notes that the commenter has incorrectly interpreted the definition of "original data" as described by the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022a), which provides examples of studies lacking original data as "other agency assessments, informative scientific literature reviews, editorials, or commentaries." Further, for all studies quantitatively considered in these assessments (e.g., used in BMD analysis), the EPA has made the information on the data used to calculate toxicity values and processes for obtaining additional information, when necessary, from study authors publicly available (see Appendix E of the toxicity assessments; USEPA, 2024a; USEPA, 2024b).

3M Company (Doc. #1774, SBC-053418 & SBC-045681)

b. EPA Did Not Follow Its Own Guidelines on Good Statistical Practice

Throughout the technical documents supporting the rule, EPA's statistical and modeling analyses conflict with guidance (USEPA 1992, 2002, 2003, 2006a, 2006b). This failure to follow the practices specified in EPA's guidance results in very low to negligible confidence in the quantitative findings on a consistent basis. Below are a few of the many examples of EPA's practices that are counter to the guidance on statistical and modeling practices cited above. Appendix A and Appendix B, EcoStat Comments on the United States Environmental Protection Agency's Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation, include more fulsome explanation of each of these issues.

· Frequently, EPA does not have the original data sets used by the authors in papers EPA considers of high quality. This directly contradicts the IRIS Handbook literature screening steps that exclude studies without provided data. Therefore, EPA and other scientists cannot replicate the results of the original authors, nor can EPA evaluate the authors' consideration of non-detects, outlier detection, sensitivity studies, or data transformations.

· When building statistical models, EPA often ignores fundamental covariates like gender, ethnicity, age, body weight, geographic region, etc. Papers selected by EPA may consider these variables and provide graphics, but the factors are not considered as fundamental covariates within the models that are used to estimate BMDs or to estimate public health risk When models are incorrectly built (e.g., leaving out key variables), the effect is to generate incorrect model

error estimates for hypothesis testing, which has the effect of overestimating the significance of PFAS concentrations in the model (Heinze et al 2018).

Because EPA frequently lacks the source data used in outside publications, and because these data are frequently unavailable to the public, EPA attempts to infer the statistical properties of the unavailable data for the purpose of model building. This approach is clearly a violation of EPA's QC guidelines (USEPA 1992, 2002). For example, EPA attempts to generate a "pooled variance" having only the 25th and 75th percentiles of a data set to infer the median and mean values. EPA states that "[i]f access to data and methods cannot occur, EPA should, to the extent practicable, apply especially rigorous robustness checks to analytical results and carefully document all checks that were undertaken." (USEPA 2002) Sound statistical practice recognizes that there are many (if not hundreds) of empirical distributions with the same 25 th and 75 th percentiles that result in different median and mean values. Accordingly, assuming any single distribution, without the ability to assess the original data, is inappropriate, unreliable, and subjective and does not adhere to the "rigorous robust checks" recommended in EPA's own guidance (USEPA 2002).

· EPA has selected papers and data sources to support the rule without establishing that the information is representative of national US populations. Therefore, findings from these papers cannot be inferred to the entire US population. Regional data, data from the Faroe Islands, data collected without a sampling frame, or data collected where sampling weights cannot be determined should not be used for setting a national standard.

· EPA has not included time-based effects in the models used to support the rule. 3M's assessment of NHANES data clearly demonstrates that changes in serum levels of PFOA and PFOS over time Hfluence the modeling results and should be considered in models for all human risk endpoints evaluated in the technical support documents.

EPA Response: The commenter incorrectly stated that the EPA did not have original data sets of peer-reviewed publications, and, therefore, the EPA is directly contradicting the IRIS Handbook literature screening steps that exclude studies without provided data (USEPA, 2022a). As noted in the response to comment Doc. #1774, SBC-045680 and in section 4.1.2 in this *Response to Comments* document, the commenter appears to misunderstand what constitutes "original data" as described by the IRIS Handbook (USEPA, 2022a). Please also see the EPA response to comment Doc. #1774, SBC-045701 in section 4.1.2 in this *Response to Comments* document regarding the commenter's claims about data availability.

The commenter incorrectly states without support that "[w]hen building statistical models, EPA often ignores fundamental covariates." First, the commenter incorrectly implies that the EPA built statistical models in the toxicity assessments for PFOA and PFOS. In actuality, the EPA uses peer-reviewed literature on the exposure-outcome relationship to inform dose-response modeling consistent with the IRIS Handbook (USEPA, 2022a). Second, the commenter does not identify the specific model at issue here.

Additionally, the EPA disagrees that the assessments ignore fundamental covariates because the agency addresses covariates throughout the systematic review process, specifically, when assessing study confidence (e.g., in the Confounding domain) and when selecting studies for toxicity value derivation (see chapters 4 and 7 of USEPA (2022a)). For example, potential for confounding by covariates was considered as a part of the study evaluation criteria for all epidemiology studies (USEPA, 2024a; USEPA, 2024b; Section A.1.7.1.5). Confounders are factors that are associated with both exposure and outcome but are not in the causal pathway (USEPA, 2022a). Lack of consideration of relevant confounders may bias the result toward or away from the null, depending on how the confounder impacts the exposure and outcome. Multiple approaches, including non-statistical approaches (e.g., directed acyclic graphs), for identifying confounders are important considerations as covariates may actually be mediators or factors related to unmeasured intermediates (USEPA, 2024a; USEPA, 2024b; Section A.1.7.1.5). The commenter also appears to misunderstand the impact of not including certain covariates, suggesting incorrectly that it would overestimate the effect of PFAS exposure, when in fact, overadjustment for these factors would generally bias estimates towards the null. As such, epidemiological studies do not require consideration of the same "fundamental" list of covariates and instead should only consider relevant covariates or "key" covariates, as stated by the commenter, that may influence the study results. The EPA evaluated each study analysis for how well it considered and addressed confounding holistically. Studies selected for POD derivation were rated at least *medium* confidence, and the EPA outlines specific considerations for selecting "studies with a design or analysis that addresses relevant confounding for a given outcome" in the assessment appendices (USEPA, 2024a; USEPA, 2024b; Section A.1.11.1).

The commenter incorrectly suggested that the EPA "violated" quality control guidelines by inferring statistical properties of unavailable data during model building. The commenter provided an example of the EPA deriving central tendency estimates from percentiles provided by study authors and alleged that a single distribution was assumed without providing evidence or justification. The commenter's characterization of the EPA's analysis is incorrect. For example, the EPA used the stated approach for statistical modeling of diphtheria and tetanus endpoints, not because the EPA assumed a "single distribution," but based on the knowledge of the log-normal distribution for diphtheria and tetanus antibody concentrations, which has been documented in multiple studies, including Timmerman et al (2021). Further discussion regarding calculations that facilitated modeling of epidemiological data is in section 4.2.2 of the EPA response in this *Response to Comments* document.

The commenter incorrectly suggests that the EPA should have used data from the U.S. population for setting a national standard and further, that the EPA did not consider the representativeness of study populations to the U.S. population. The EPA selected studies according to the protocol outlined in Appendix A of the toxicity assessments (USEPA, 2024a; USEPA, 2024b; Section A.1.11.1). Importantly, the EPA's established peer-reviewed human health risk assessment methods do not outline restrictions based on study or data source location, as this factor does not necessarily impact the inherent quality of studies (USEPA, 2022a).

Furthermore, in cases when data originating from the United States is limited, it is necessary to rely on studies conducted in other populations.

Regardless, the EPA considered the representativeness of study populations to the U.S. population when selecting studies for point-of-departure human equivalent dose (POD_{HED}) derivation. For example, one factor that contributed to the selection of Wikstrom et al. (2020) over Sagiv et al. (2018) was related to the comparability of study population exposure levels in the United States. Specifically, Sagiv et al. (2018) was conducted between 1999 and 2002, when PFOA and PFOS exposure concentrations in the United States were much greater. Wikstrom et al. (2020) conducted their study more recently, between 2007 and 2010, resulting in exposure levels that are more comparable to those observed in the United States today. The selection of Wikstrom et al. (2020) as the critical study was consistent with the IRIS Handbook to select studies with "exposures near the range of typical environmental human exposures" (USEPA, 2022a). These points are further discussed in section 4.2.2.2.3 of the EPA response in this *Response to Comments* document and section 4 of (USEPA, 2024d; USEPA, 2024c).

The commenter incorrectly stated that the EPA did not consider time-based effects in models, and the commenter suggested these changes over time in serum PFOA and PFOS exert a greater influence on the modeling results. The EPA disagrees with these claims. First, the EPA considered changes in serum PFOA and PFOS over time by modeling results for several time periods of National Health and Nutrition Examination Survey (NHANES) data (i.e., 1999–2018, 2003–2014, 2003–2018, and 2017–2018) (USEPA, 2024a; USEPA, 2024b; Section E.1.3.1). Second, as shown by the modeling results in Appendix E of the toxicity assessments, the estimated benchmark dose lower limits (BMDLs) are comparable across time periods (e.g., USEPA, 2024a; USEPA, 2024b; Table E-18), indicating that the changes over time in serum PFOA and PFOS concentrations do not have a significant impact on the conclusions of this rule.

<u>3M Company (Doc. #1774, SBC-045701)</u>

1. Lack of consistent quality control practice by EPA in the Proposed Rule and supporting documents negates the validity of key findings.

EPA has not proposed data quality objectives (DQOs) or Quality Assurance Project Plans (QAPP) for any data source chosen and associated findings used to establish the MCLG. EPA and National Institutes of Health (NIH) National Institute of Environmental Health Sciences (NIEHS) program offices, are required to generate quality assurance/quality control (QA/QC) plans that include the derivation of analysis-specific, and data-specific DQOs. Under standard quality control practices, DQOs are required for any research initiative in order to document and ensure that data are collected properly, data are treated using good statistical practice, and any findings can be replicated by scientists and data analysts not working at EPA. EPA's own documents provide guidance on DQOs, program planning, good data practice, and good statistical practice. (See e.g. USEPA 2003, 2006, 2014).

EPA has not followed its own requirements and guidance for collecting and analyzing data. Rather, for the MCLG and associated analyses, EPA has largely relied on previously published studies conducted by non-EPA employees for which EPA has no control over data collection, data treatment, outlier detection, variance estimation, elimination of records, or good statistical practice. For example, EPA has selected papers where the data used to calculate BMDs and other measures of risk, were not publicly available or difficult and time-consuming to obtain (e.g., Budtz-Jørgensen & Grandjean, 2018; Shearer et al., 2021). EPA has violated a key principle of statistical analysis, which requires that all studies and findings be available to the outside public and the findings replicated.

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EPA has established guidance that it should use DQOs as an insurance to create analyses of high caliber that are scientifically defensible. Here, EPA failed to establish DQOs, contrary to its own guidance.

EPA Response: Regarding comments on the EPA's data quality objectives and QAPP, please see section 4.1.2 of the EPA response in this *Response to Comments* document.

Regarding comments that the EPA did not follow its own requirements and guidance for data collection and analysis by relying on studies published by non-EPA entities, see the EPA response to comment Doc. #1774, SBC-045680 and section 4.1.2 in this *Response to Comments* document.

The commenter incorrectly states that the EPA selected studies that were not publicly available or were difficult to obtain and cannot be replicated. As outlined in Appendix A of the final toxicity assessments for PFOA and PFOS (USEPA, 2024a; USEPA, 2024b), the EPA followed a protocol for study identification that is consistent with the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022a) and the *Systematic Review Protocol for the PFAS IRIS Assessments* (USEPA, 2021a). These protocols include statements that the literature search should "identify full reports of primary studies (i.e., original data sources of health effects)" from databases such as PubMed and Web of Science, as well as gray literature sources. The EPA provided information regarding these studies on the HERO project page (https://heronet.epa.gov/heronet/index.cfm/project/page/project_id/2608). The EPA's study evaluation process reflects the confidence in the study conduct and data quality, including reporting, in each publication. This is the EPA's current best practice for transparency and reproducibility in human health risk assessment (USEPA, 2022a). It is not required that all studies and findings be available to the public. In fact, the individual-level data is typically not provided in published epidemiological studies often due to privacy concerns. Study authors provide the summary data that are needed for hazard identification and quantitation. In Appendix E of the final toxicity assessments, the EPA provided all of the publicly available data and presented the calculations needed to replicate the models used to derive PODs for each endpoint of interest (USEPA, 2024a; USEPA, 2024b).

Regarding comments related to the EPA's approaches for POD derivation, please see section 4.2.2, and specifically, subsection 4.2.2.3 and comment Doc. #1774, SBC-053446 in section 4.2.2.3 in in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-045702)

8. EPA is overly conservative in the calculation of RfDs.

EPA employs a series of highly conservative uncertainty and safety factors to generate an RfD. These values are not consistent with best practice for selection of such factors. EPA did not use robust statistical uncertainty techniques, as is expected as part of best available science, in order to replace the arbitrary safety and uncertainty factors with data-based measures of uncertainty. Model-based prediction uncertainty (for both statistical and toxicological models) approaches are available and should be used by EPA in place of overly conservative and subjective factors.

Classic safety factors and uncertainty factors are generally not based on models or data, which, as noted above does not meet EPA's own quality assurance guidelines. Any uncertainty used by EPA should be peer-reviewed, and based on actual data (e.g., uncertainty in BMD dependent on choice of model, BMR, p(0), etc.). Safety factors should be based on true data, and in particular, reflect the ability of others replicate EPA's results. EPA does not have actual data sets for many of the endpoints addressed in the rulemaking, and EPA did not oversee the work ensuring good quality control of the author's findings.

Without proper uncertainty analysis based on EPA's guidance on good statistical practice, the uncertainty and safety factors employed by EPA do not result in a scientifically defensible RfD value.

EPA Response: The commenter asserted that the EPA used conservative uncertainty and safety factors to derive an RfD, that these uncertainty factors are not consistent with best practice and do not meet the EPA's quality assurance guidelines, and that the EPA should replace the uncertainty factors with data- or model-based measures of uncertainty. The commenter's viewpoint is that safety factors should "reflect the ability of others [to] replicate EPA's results." The commenter incorrectly claims that the EPA's current approach does not result in a scientifically defensible RfD value. The EPA disagrees with all of these claims. The EPA followed agency best practices and guidance in applying uncertainty factors to derive RfDs for PFOA and PFOS (USEPA, 2002; USEPA, 2022a). The EPA has followed the same definitions of the applied uncertainty factors as has been used since the establishment of the 2002 agency document, *A Review of the Reference Dose and Reference Concentration Processes* (USEPA, 2002). This document has been applied repeatedly through its use in peer-reviewed agency assessments and is cited in more recent agency human health risk assessment methodology (USEPA, 2022a). The EPA cannot respond to the comment on the "model-based prediction uncertainty" and "data-based measures" of uncertainty due to a lack of detail in the comment (i.e., the commenter did not provide specific citations) for the EPA to review and evaluate. Regardless, the topics of "model-based prediction uncertainty" and "data-based measures" of

uncertainty have not been published in any peer-reviewed agency guidance or human health risk assessment documents. In fact, had the EPA used any approach other than the defined uncertainty factors, the EPA would be deviating from long-standing best practices and would be inconsistent with the agency's own methodologies (USEPA, 2002). In the PFOA and PFOS toxicity assessments, the EPA followed current best practices for setting uncertainty factors (USEPA, 2002; USEPA, 2022a).

Additionally, the commenter's belief that safety factors applied to the RfD should "reflect the ability of others [to] replicate EPA's results" is erroneous. Uncertainty factors are used in the derivation of RfDs to account for uncertainty (i.e., a lack of knowledge) and variability (i.e., heterogeneity and diversity) of the contaminant health effects database (USEPA, 2002); they are not related to replication of the EPA's analyses. Specifically, the EPA human health risk assessment practice is to consider the application of individual uncertainty factors account for "(1) the variation in sensitivity among the members of the human population (i.e., interhuman or intraspecies variability); (2) the uncertainty in extrapolating animal data to humans (i.e., interspecies variability); (3) the uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure to lifetime exposure (i.e., extrapolating from subchronic to chronic exposure); (4) the uncertainty in extrapolating from a LOAEL rather than from a no-observed-adverse effect level (NOAEL); and (5) the uncertainty associated with extrapolation from animal data when the database is incomplete" (USEPA, 2002).

Following these methods (USEPA, 2002; USEPA, 2022a), to derive RfDs for PFOA and PFOS from epidemiological studies, the EPA used relatively low composite (i.e., total) uncertainty factors of 10, in contrast to the commenter's claims that the EPA "employs a series of highly conservative uncertainty and safety factors to generate an RfD." The application of this 10x composite uncertainty factor was reviewed by the SAB PFAS Review Panel, who stated:

> *"The Panel generally finds these [uncertainty factor] values to be adequate and supported by the scientific rationale provided by the agency. The values were found to be appropriate and sufficiently protective, with rationale that was clearly described in the draft MCLG documents"* (USEPA, 2022b).

Overall, the EPA disagrees with the commenter's supposition that the approach to uncertainty factor application does not result in a scientifically defensible RfD. As discussed, the EPA followed longstanding agency human health risk assessment methods and received support from the SAB in its selection and rationale for the applied uncertainty factors (USEPA, 2002; USEPA, 2022a; USEPA, 2022b).

The commenter also stated that the "EPA does not have actual data sets for many of the endpoints addressed in the rulemaking, and EPA did not oversee the work ensuring good quality control of the author's findings." This claim is demonstrably incorrect. As described in previous responses (see the EPA response to comment Doc. #1774, SBC-045701 in section 4.1.2 in this *Response to Comments* document), the EPA provided all data and calculations needed to replicate the models used to derive PODs for each endpoint of interest in Appendix E of the draft and final toxicity

assessments (USEPA, 2023b; USEPA, 2023c; USEPA, 2024a; USEPA, 2024b). The EPA's study evaluation process reflects the confidence in the study conduct and data quality, including reporting, in each publication. Only studies of *high* or *medium* confidence were quantitatively considered in these assessments.

Raptor Pharm & Tox, Ltd (Doc. #1644, SBC-043417 & SBC-043418)

Based on EPA's handling and interpretation of these studies, it is clear to Raptor that EPA has not taken the due care to establish that there are adverse health outcomes in the studies being cited and used as the basis of the critical effect, PODs, and ultimately the RfD.

Raptor has identified that EPA exhibited a pattern, with respect to this drinking water standard, that do not uphold the high level of quality and scientific integrity required to generate a science-based policy.

Raptor suggests that EPA use the scientific approach outlined by the philosopher of science Karl Popper, and adapted by Raptor, when formulating a science-based policy. Raptor is concerned that EPA staff and management may have allowed their personal policy preferences and scientific biases to drive their assessment. In other words, the concern is that EPA succumbed to confirmation bias in looking for studies that supported the policy preferences of staff, management, and the administration. Popper identified confirmation bias as a significant problem in science, and he stated, in his book Conjectures and Refutations (1962):

"I found that those of my friends who were admirers of Marx, Freud, and Adler, were impressed by a number of points common to these theories, and especially by their apparent explanatory power. These theories appeared to be able to explain practically everything that happened within the fields to which they referred. The study of any of them seemed to have the effect of an [35] intellectual conversion or revelation, opening your eyes to a new truth hidden from those not yet initiated. Once your eyes were thus opened you saw confirming instances everywhere: the world was full of verifications of the theory. Whatever happened always confirmed it. Thus its truth appeared manifest; and unbelievers were clearly people who did not want to see the manifest truth; who refused to see it, either because it was against their class interest, or because of their repressions which were still 'un-analysed' and crying aloud for treatment."

And Popper also identified the solution:

"Confirming evidence should not count except when it is the result of a genuine test of the theory; and this means that it can be presented as a serious but unsuccessful attempt to falsify the theory."

Raptor concludes that US EPA did not take a refutation approach in developing this policy. US EPA did not critically analyze the scientific studies in order to refute those studies, or their underlying hypothesis that low levels of PFOS and PFOA cause adverse human health outcomes. In fact, one only needs to read US EPA's inappropriate explanation of why Budtz-Jorgensen and Grandjean was included to know that US EPA was fishing for studies – "Budtz-Jørgensen and

Grandjean (2018) was ultimately selected for the immune outcome because the response reported by this study reached statistical significance, this analysis considered co-exposures of other PFAS, and it was the more health-protective of the two vaccine-specific responses reported by Budtz-Jørgensen and Grandjean (2018)."

The reason this explanation is inappropriate is because US EPA was focused on "statistical significance". This is in direct violation of the advice given by the American Statistical Association when it stated that statistical significance should not be the driver of decisions. Rather, the effect size needs to be biologically meaningful (https://www.amstat.org/asa/files/pdfs/p-valuestatement.pdf).

EPA Response: The EPA disagrees with the commenter's incorrect characterization that the EPA "succumbed to confirmation bias," did not take a "refutation approach" in developing conclusions in the PFOA and PFOS toxicity assessments and that the EPA did not critically analyze the studies used to support the PFOA and PFOS toxicity assessments. Please see section 4.1.2 of the EPA response in this *Response to Comments* document.

The EPA has followed multiple steps within the systematic review process with one underlying purposes of reducing risks associated with confirmation bias At the EPA, achieving consensus on scientific issues is driven by following the current human health risk assessment methods and approaches (e.g., USEPA, 2002 and USEPA, 2022a). Policy preferences of staff, management and the administration are not considered within this systematic process. Here, the EPA used state of the art systematic review methods to critically analyze the health effects literature for PFOA and PFOS, methods that are consistent with the IRIS Handbook (USEPA, 2022a). Please see section 4.1.1 1 of the EPA response in this *Response to Comments* document.

Finally, the toxicity assessment for PFOA and PFOS underwent an independent, rigorous peer review by the EPA's Science Advisory Board PFAS peer review panel, which included 16 external scientists with expertise in human health risk assessment, including epidemiology and toxicology. Their conclusions, recommendations and report were later reviewed by more than 40 other scientists who serve on the Science Advisory Board (USEPA, 2022b). Among other things, when an SAB panel or subcommittee is formed, it is established while considering scientific credentials, disciplinary expertise in relevant fields, and background and experiences that would help members contribute to the diversity of perspectives on the committee, such as geographical, social, cultural, educational backgrounds, professional affiliations, and other considerations. The EPA's SAB has aa set of ethics requirements for panelists including disclosing financial information in order for the SAB to determine whether there are ethics issues with service on an advisory panel (https://sab.epa.gov/ords/sab/r/sab_apex/sab/ethicsreqsforadvisors?session=16384952239507).

As discussed elsewhere in this *Response to Comments* document and administrative record, the SAB provided a generally favorable review of the EPA's PFOA and PFOS draft toxicity assessments' conclusions (see section 4.1.3 of the EPA response this *Response to Comments* document). Where the SAB provided suggestions and feedback, the EPA considered

those recommendations and updated the assessments to respond to that input. By implication, if the results and findings of its toxicity assessments were merely driven by confirmation bias, as the commenter's unsubstantiated claim states, then the SAB's review would also fundamentally be driven by the confirmation biases of each of the diverse individual scientists on that panel. Such a conclusion is illogical and unsupported by any evidence. In short, many dozens of scientists from the EPA and outside organizations provided expert input on the EPA's draft PFOA and PFOS toxicity assessments.

Additionally, the commenter cited only one example to support their incorrect claim that the EPA "focused" on statistical rather than biological significance when selecting the critical study that serves as the basis of the candidate RfD for immune effects (i.e., Budtz-Jorgensen & Grandjean, 2018). Both statistical and biological significance were considered when evaluating studies for dose-response modeling. While statistical significance was not the sole factor, it is nonetheless one important factor considered by the EPA when selecting critical studies for POD derivation, determining evidence integration judgments, selecting model results, or to support other decisions made throughout the toxicity assessments. For the immune health outcome-specific RfD, the EPA selected Budtz-Jørgensen and Grandjean (2018) as the critical not only because it demonstrated a statistically significant effect, but also because this study's analysis considered co-exposures of other PFAS, unlike the other critical epidemiological studies which were the bases of the candidate RfDs for the immune health outcome (i.e., Timmerman et al. (2021) (PFOA and PFOS) and Zhang et al. (2023) (PFOS only)), and was a good estimate of 5 percent extra risk (USEPA, 2024d; USEPA, 2024c). Therefore, the commenter's claim that the EPA was "fishing for studies" is unsupported. While all of this information and rationale were presented in the draft toxicity assessments and the appendices published for public comment (USEPA, 2023f; USEPA, 2023a; USEPA, 2023b; USEPA, 2023c), the EPA recognizes that the information was not presented together in a single location in the public comment draft. Therefore, to clarify this issue, the EPA has updated the final toxicity assessments to present this rationale more clearly in one section, section 4.1 (USEPA, 2024d; USEPA, 2024c).

Raptor Pharm & Tox, Ltd (Doc. #1644, SBC-043424)

The US EPA improperly used studies that do not focus on adverse health outcomes. The US EPA did not use principles of sound science outlined by Karl Popper, the pre-eminent philosopher of science, and the architect of the modern approach to science. The US EPA appears to have succumbed to confirmation bias in its assessment and derivation of safe drinking water standards. However, with a re-analysis of the information that is available in the literature, and a more critical eye towards scientific integrity with respect to the studies themselves, especially a more critical eye to matters of study design, sample size, and actual falsification of the current prevalent theory of the safe levels of these chemicals, US EPA will generate a far more reasonable and scientifically-sound safe drinking water standard.

EPA Response: Please see the EPA response to comment Doc. #1644, SBC-043417 and SBC-043418 in section 4.1.2 in this *Response to Comments* document, as well as section 4.2.2.2.2 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045596)

6. Proposed Maximum Contaminant Level Goals

The derivation of a science-based maximum contaminant level goal (MCLG) is crucial because it means that it is both of public health and can transparently be communicated to inform decision-making for the public. EPA did not use the best available science in proposing the MCLGs (and MCLs) for these substances as required by SDWA. EPA must also ensure that the underlying science is review by the EPA SAB.

EPA Response: Please see sections 4.1.2 and 4.1.3 of the EPA response in this *Response to Comments* document.

4.1.3 Peer Review of the Science Underlying the Hazard Conclusions, Cancer Classifications and Toxicity Values for PFOA and PFOS

Summary of Major Public Comments and EPA Responses

A couple of commenters suggested that the toxicity assessments for PFOA and PFOS were not adequately peer-reviewed because changes were made post peer review (i.e., after publication of the final report by the SAB PFAS Review Panel (USEPA, 2022b)). The most significant change was the updated cancer classification for PFOS, but other changes included the addition of figures and mechanistic syntheses.

Some commenters also commented on the adequacy of the EPA's response to the SAB PFAS panel's recommendations. One stated that the EPA addressed the SAB's concerns regarding the systematic review protocol in the documents supporting the proposed rulemaking. A few commenters reiterated the importance of SAB recommendations, including to more thoroughly describe systematic review methods used in the assessment (e.g., study inclusion and exclusion criteria), incorporate additional epidemiological studies, provide rationale for critical study selection, and derive candidate toxicity values from both human and animal data. In contrast, a few commenters claimed that the EPA did not adequately consider several recommendations made by the SAB PFAS Review Panel in their final report (USEPA, 2022b), including that the EPA did not incorporate studies from the 2016 HESDs (USEPA, 2016b; USEPA, 2016a) or develop multiple CSFs. One commenter requested clarification on whether the EPA had implemented the feedback from the SAB.

The EPA disagrees that the toxicity assessments for PFOA and PFOS were not adequately peer-reviewed or that the agency did not "meaningfully implement" SAB feedback. The SAB recommendations on the draft toxicity assessments for PFOA and PFOS (USEPA, 2021b; USEPA, 2021c) and subsequent revisions by the agency greatly improved the scientific quality,

clarity, and transparency of the assessments supporting rule proposal (USEPA, 2023f; USEPA, 2023a; USEPA, 2023b; USEPA, 2023c) and this final rulemaking (USEPA, 2024d; USEPA, 2024c; USEPA, 2024a; USEPA, 2024b). The EPA agrees with commenters that highlighted the importance of the SAB's suggestions. As outlined in the *EPA Response to Final Science Advisory Board Recommendations (August 2022) on Four Draft Support Documents for the EPA's Proposed PFAS National Primary Drinking Water Regulation* (USEPA, 2023d), the EPA considered all of the comments and recommendations from the SAB prior to publishing the public comment draft assessments (USEPA, 2023f; USEPA, 2023a; USEPA, 2023b; USEPA, 2023c). The response to SAB document also describes how the agency addressed the recommendations made by the SAB in their final report (USEPA, 2022a; USEPA, 2023d). Specifically, improvements to the draft assessments included the addition of thorough and detailed descriptions of the methods used during assessment development, the inclusion of studies from the 2016 HESDs for PFOA and PFOS in the systematic review (USEPA, 2016a; USEPA, 2016b), updates to the literature, implementation of an evidence integration framework (USEPA, 2022a), expansion of rationale for critical study and model selection, development of toxicity values from both animal toxicological and epidemiological data, when warranted, and many other actions. In the very few instances where the EPA did not follow the recommendations of the SAB, the EPA described the rationale for these decisions in the response to SAB comments document (USEPA, 2023d). As described above, many commenters stated recommendations presented by the SAB in its final report (USEPA, 2022b) and requested that the EPA make these changes to the draft assessments. To reiterate, all of the recommendations made by the SAB were considered prior to rule proposal; therefore, many of the comments presented herein had previously been addressed.

Given the comprehensive review by the SAB, the EPA maintains that the PFOA and PFOS draft toxicity assessments, including the conclusions that are material to the derivation of the MCLGs, were adequately peer-reviewed by the SAB PFAS review panel (USEPA, 2022b). Notably, this panel "agreed with many of the conclusions presented in the assessments, framework and analysis" (USEPA, 2022b). The only toxicity assessment conclusion that changed and impacted MCLG derivation between the SAB review and rule proposal was the cancer classification for PFOS of *Suggestive Evidence of Carcinogenicity* was updated to *Likely to Be Carcinogenic to Humans* according to the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005). The rationale for this update was presented in materials published at the time of rule proposal, including the EPA's response to SAB comments (USEPA, 2023d), the draft toxicity assessment for PFOS (USEPA, 2023a) and is presented again in section 4.1.4 of the EPA response in this *Response to Comments* document, as well as in the final toxicity assessment for PFOS (USEPA, 2024c) and the PFOA and PFOS MCLG support document (USEPA, 2024e). USEPA, 2005USEPA, 2005No other major conclusions in either the PFOA or PFOS toxicity assessments changed that impacted MCLG derivation between SAB review and proposal.

In response to commenters who recommended another round of peer review, please see section 4.3.2 of the EPA response in this *Response to Comments* document.

Individual Public Comments

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045904)

C. Cancer classification and slope factors for PFOA and PFOS are not supported by the scientific evidence

EPA has significant irregularities in review and justification for the cancer classifications of PFOA and PFOS. EPA has moved ahead with a carcinogenicity determination for PFOS without SAB comment or approval, and EPA, without explanation, interpreted the same studies on PFOS in two different manners in a 2021 and a 2023 assessment. Now that EPA has developed frameworks for evaluating the scientific evidence, additional peer review is essential before finalization of this rulemaking. Additionally, EPA has failed to respond to SAB direction to develop appropriate multiple candidate cancer slope factors and relied on low confidence epidemiological data.

In the PFOA and PFOS Draft Assessments reviewed by the SAB in 2021, EPA proposed that PFOA was "likely to be carcinogenic" and for PFOS there was "suggestive evidence of carcinogenic potential." The SAB review provides, at best, tepid support for these findings, noting that EPA's rationale for the designations was not adequately provided and that EPA needed to provide a more structured framework to describe the criteria used for these designations [FN124: See SAB report to the EPA Administrator Aug. 22, 2022, at pages 32-38, available at: https://sab.epa.gov/ords/sab/f?p=100:18:16490947993:::RP,18:P18_ID:2601#report.]. For PFOS, the SAB report does not provide a recommendation for what the cancer classification should be. Because the documents provided to the SAB were not sufficiently transparent, the SAB was unable to directly respond to important charge questions and recommended significant changes, including a more structured framework, and inclusion and discussion of mechanistic data.

EPA Response: Please see section 4.1.3 of the EPA response in this *Response to Comments* document. Discussion regarding review of the evidence supporting the EPA's cancer classifications for PFOA and PFOS can be found under section 4.1.4 of the EPA response in this *Response to Comments* document. For responses regarding SDWA's requirements for SAB comment prior to proposal, please see section 4.3.2 of the EPA response in this *Response to Comments* document.

Michigan Farm Bureau (Doc. #1562, SBC-043354 & SBC-043355)

EPA requested the Science Advisory Board (SAB) review the agency's analysis of proposed MCLs, which it published in August of 2022.1 EPA took several steps outlined in the proposed rule to address the SAB's concerns, but several remain unresolved. These concerns are important to understanding and setting the stage for future regulations of PFAS, as well as ensuring that protection from the exposure and health risk from PFAS is reasonable, necessary, and feasible to implement.

The SAB recommended taking actions like ensuring more human studies are included in EPA's models of health outcomes, focusing on consistent frameworks for identifying disease, and synthesizing and integrating information. This is particularly important for the carcinogenic designations for some PFAS, which set a specific need for low concentrations of exposure. In the instance of carcinogenic designation, the SAB remarked it is especially important to include and discuss the strengths and limitations of epidemiological studies to make the agency's decision-making process clear. The SAB recommended further actions such as more clearly identifying reference doses in a dose metric equivalent value to more accurately convert dose to external exposures and water concentrations.

The SAB further pointed out that EPA was inconsistent in how it characterized cardiovascular risk, noting that EPA developed a cardiovascular risk document estimating that reductions in PFOS and PFOA exposure was linked to reductions in cardiovascular disease, but then determining in its proposed Maximum Contaminant Level Goal that the cardiovascular risk was not sufficient to form the basis of a reference dose for determining the exposure risk. EPA must provide more clarity on this and how the cardiovascular risk fits into the regulatory limit proposed for PFAS to help the regulated community understand exposure risk and reduction potential for that risk by implementing testing and treatment of drinking water.

Importantly, the SAB noted that EPA needs to provide more clarity on what forms of PFAS are being included in review of tests and studies, particularly of PFOS and PFOA. This is important because animal studies and human exposure studies, primarily of workers in PFAS-generating or industrial use situations, use different forms and salts of PFOA and PFOS to determine exposure which is then linked to expression of disease. It is crucial to make clear that EPA is comparing "apples to apples" when determining potential disease risk. Further, the SAB emphasized that if EPA declines to use a human health study in favor of animal studies, it must clearly explain its reasoning and establish what quality control and review methodology is used to determine inclusion or exclusion of particular studies. The SAB recommended including several studies including those on human exposure to EPA's list, which we strongly recommend EPA review and transparently indicate what decision-making process was used to include or exclude the findings of such studies.

EPA Response: Please see section 4.1.3 of the EPA response in this *Response to Comments* document. Additionally, see the EPA's Response to SAB Comment document (USEPA, 2023d) and the final toxicity assessments (USEPA, 2024d and USEPA, 2024c) where the EPA describes that changes in total cholesterol are a hazard and are the basis of a candidate RfD for PFOA and PFOS. Also see comments related to the cardiovascular disease (CVD) economic analysis in section 13.4.1 and more specifically, the EPA's response to comment Doc. #1759, SBC-053061 in section 13.4.1 in this *Response to Comments* document for discussion on consistency between the economic analysis and the conclusions on cardiovascular effects in the draft and final toxicity assessments for PFOA and PFOS.

Pennsylvania Municipal Authorities Association (Doc. #1832, SBC-045779 & SBC-045780)

PMAA's specific comments on the Proposal are as follows:

One of PMAA's primary comments with respect to a regulation impacting its members is that any final determination, decision or action made by any regulatory agency such as EPA must be based on the latest and best available health and scientific data and information. PMAA understands that there are a number of ongoing studies at the federal level regarding PFAS. What assurance can be given to PMAA members that the Proposal and the potential regulation of PFAS is based on all of the most recent and peer- reviewed health and scientific data and information?

As discussed herein, an issue of particular importance to PMAA is that the Proposal be based upon the latest and best available health and scientific data and information. However, there needs to be transparency not only as to the documents/studies/reports that were considered in the development of the Proposal, but also as to the documents/studies/reports that were available to the EPA, but not considered in the development of the Proposal, and the reason(s) that they were not considered. In other words, were there documents (e.g. health, toxicological, epidemiological) that the EPA or its Science Advisory Board reviewed, but for some reason, chose not to include in its evaluation process leading to the issuance of the Proposal? Moreover, the final Science Advisory Board consensus report provided recommendations to EPA, which the agency considered for the Proposal (See, EPA-SAB-22-008, August 22, 2022). Did EPA accept all of the aforementioned recommendations and, if not, please explain which recommendations were not accepted, and the rationale for not accepting such recommendations of the Science Advisory Board.

EPA Response: Regarding the EPA's use of the best available peer-reviewed science, please see sections 4.1.2 and 4.1.1 of the EPA response in this *Response to Comments* document. Briefly, the EPA has considered all relevant and peer-reviewed studies published through February 2023. Regarding the commenter's question about whether the EPA accepted the SAB's recommendations, please see section 4.1.3 of the EPA response in this *Response to Comments* document. Additionally, see EPA's Response to SAB Comment document (USEPA, 2023d). Regarding the commenter's questions about which documents, studies, or reports were considered in the development of this rulemaking, the commenter can refer to the systematic review protocol for study identification and relevancy screening in Appendix A of the toxicity assessments (USEPA 2024a; 2024b), as well as the Interactive Reference Flow Diagram, which transparently documents how and when individual studies were identified, as well as how they were categorized during the systematic review process. The studies identified from the literature searches are publicly available on the EPA HERO project page (https://hero.epa.gov/hero/index.cfm/project/page/project_id/2608).

4.1.4 The EPA's Determination that PFOA and PFOS are *Likely to Be Carcinogenic to Humans*

Summary of Major Public Comments and EPA Responses

Many commenters agreed that the available data indicate that exposure to either PFOA or PFOS is associated with cancer in humans and supported the EPA's determinations that PFOA and PFOS are *Likely to Be Carcinogenic to Humans* according to the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005). Multiple commenters agreed that studies published since the 2016 HESDs (USEPA, 2016b; USEPA, 2016a) have strengthened this conclusion. In particular, one commenter supported the EPA's conclusions regarding the human relevance of hepatic and pancreatic tumors observed in rats administered PFOS, citing their own independent health assessment conclusion that "several lines of evidence do not support a conclusion that liver effects due to PFOS exposure are PPARα-dependent" and therefore, may be relevant to humans (NJDWQI, 2018). The EPA agrees with these comments.

Several commenters disagreed with the EPA's determinations that PFOA and PFOS are each *Likely to Be Carcinogenic to Humans*. Two commenters claimed that the tumor types observed in rats (e.g., hepatic tumors) after PFOA or PFOS administration are not relevant to humans. Some commenters also stated that the human data do not support an association between PFOS exposure and cancer. One commenter specifically claimed that Shearer et al. (2021) does not provide sufficient evidence for changing PFOS's cancer descriptor from *Suggestive Evidence of Carcinogenicity* to *Likely to Be Carcinogenic to Humans* because it did not report associations between PFOS exposure and renal cell carcinoma (RCC) and others claimed that the EPA did not provide rationale for updating the cancer descriptor for PFOS. Two commenters stated that the EPA's discussion using structural similarities between PFOA and PFOS as a line of evidence to support the carcinogenicity of PFOS was inconsistent with the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005). A few commenters additionally questioned or disagreed with the determination that PFOA is *Likely to Be Carcinogenic to Humans* because of uncertainties in the epidemiological database and a lack of evidence indicating that PFOA is genotoxic.

The EPA disagrees with these comments. With respect to the relevance of the animal tumors observed in rats after chronic oral exposure to either PFOA or PFOS, the EPA considered all hypothesized modes of action (MOAs) and underlying carcinogenic mechanisms in its cancer assessments, including those that some commenters have argued are not relevant to humans (e.g., peroxisome proliferator-activated receptor α (PPARα) activation), the discussion of which is available in Section 3.5.4.2 of the toxicity assessments for PFOA and PFOS (USEPA, 2024d; USEPA, 2024c). After review of the available mechanistic literature for PFOA and PFOS, the EPA concluded that there are multiple plausible mechanisms, including some that are independent of PPARα, that may contribute to the observed carcinogenicity of either PFOA or PFOS in rats. Further confirmatory support for the EPA's conclusions regarding multiple plausible mechanisms of carcinogenicity comes from literature reviews published by state and global health agencies which concluded that the liver tumors associated with PFOA and/or PFOS

exposure may not entirely depend on PPARα activation and therefore may be relevant to humans (CalEPA, 2021; IARC, 2016; NJDWQI, 2017; NJDWQI, 2018).

The EPA reevaluated the cancer classification for PFOS, which was presented to the SAB PFAS Review Panel as *Suggestive Evidence of Carcinogenicity* (USEPA, 2021c), because in their final report, the SAB stated, "[s]everal new studies have been published that warrant further evaluation to determine whether the "likely" designation is appropriate" for PFOS and requested that the agency provide an "explicit description of why the available data for PFOS do not meet the EPA Guidelines for Carcinogen Risk Assessment (USEPA, 2005) criterion for the higher designation as 'likely carcinogenic" (USEPA, 2022b). Upon consideration of these comments, the EPA determined that PFOS met the criterion for the higher designation of *Likely to Be Carcinogenic to Humans* (USEPA, 2023a; USEPA, 2023d). This conclusion was based on four independent factors. First, the SAB's request that the EPA "reevaluate the 2012 Butenhoff study" and the EPA's subsequent agreement with the SAB after the EPA's reevaluation that the EPA's prior "interpretation of the hepatocellular carcinoma data from the Butenhoff (2012b) study in the 2016 HESD is overly conservative in dismissing the appearance of a dose-response relationship for this endpoint, particularly in females" (USEPA, 2022b). Second, the EPA's incorporation of mechanistic literature, as requested by the SAB, which served as the basis of the EPA's conclusions that multiple, potentially human-relevant modes of action (MOAs) may contribute to the hepatocellular tumors reported in PFOS toxicological studies of rats (USEPA, 2023a). This conclusion aligned with the SAB's comments that "multiple MOAs may be operative" in the reported hepatocellular tumorigenesis and that "the rodent liver tumors caused by PFOS do not appear to be PPAR−α dependent," (USEPA, 2022b). Third, the SAB's comment there were inconsistencies between the EPA's draft conclusions and "the California EPA conclusions based on the same human, animal, and mechanistic evidence presented in the EPA PFOS document," leading the EPA to re-review the California EPA's draft Public Health Goals for PFOA and PFOS technical document (CalEPA, 2021) and identify data indicating the occurrence of tumorigenesis in a second tumor site in male rats (i.e., pancreatic islet cell tumors) (USEPA, 2022b). Fourth, the EPA's identification of new supporting epidemiological literature resulting from the SAB's recommendation that the EPA update the literature search prior to finalization of the assessments (USEPA, 2022b). These factors and the EPA's conclusions were described in sections 3.5 and 6.4 of the draft assessment (USEPA, 2023a) and are presented in sections 3.5 and 5.4 of the final toxicity assessment (USEPA, 2024c). Additionally, the EPA did not rely on results reported by Shearer et al. (2021) as a rationale for updating the cancer classification for PFOS to *Likely to Be Carcinogenic to Humans* (USEPA, 2005) and acknowledges uncertainties in the results provided by this study, including that the effect in the third PFOS exposure quartile was null, the effects were attenuated (i.e., reduced in magnitude) when adjusted for exposure to other PFAS, and there was no association when Exposure to PFOS was considered as a continuous variable, rather than when PFOS levels were stratified by quartiles (USEPA, 2024c; USEPA, 2023a). As described in Sections 3.5.5 and 6.4 of the draft PFOS toxicity assessment (USEPA, 2023a) (Sections 3.5.5 and 5.4 of the final PFOS toxicity assessment; USEPA, 2024c), the available information exceeds the characteristics for the

descriptor of *Suggestive Evidence of Carcinogenic Potential* (USEPA, 2005) because there is statistically significant evidence of multi-sex and multi-site tumorigenesis from a *high* confidence animal toxicological study, as well as mixed but plausible evidence of carcinogenicity in humans, and mechanistic data showing potential human relevance of the observed tumor data in animals. The recently published studies reporting associations between PFOS exposure and hepatocellular carcinoma (HCC) in humans (Goodrich et al., 2022; Cao et al., 2022) strengthen the epidemiological database and support the cancer classification of *Likely to Be Carcinogenic to Humans* for PFOS.

Regarding commenters' claims that the EPA used the structural similarities between PFOA and PFOS as supporting evidence of the carcinogenic potential of PFOS, the EPA did not rely on structural similarities to draw conclusions about the cancer classification (see rationale listed above) but instead used this information as supplemental support for the *Likely* classification. Ie EPA originally included this supplemental line of evidence because the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005) explicitly states that "[a]nalogue effects are instructive in investigating carcinogenic potential of an agent as well as in identifying potential target organs, exposures associated with effects, and potential functional class effects or modes of action." PFOA and PFOS differ in their chemical structure by a single functional group. Nevertheless, since a full structure-activity relationship analysis was not conducted, the EPA removed discussion on this supplemental line of evidence from the toxicity assessment for PFOS (USEPA, 2024c).

Further, the EPA disagrees with comments stating that the epidemiological database for PFOA is too uncertain to support a classification of *Likely to Be Carcinogenic to Humans*USEPA, 2005. As described similarly in both the draft (USEPA, 2023f) and final toxicity assessments for PFOA (USEPA, 2024d), as well as the *Maximum Contaminant Level Goals for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonic Acid (PFOS)* document (USEPA, 2024j), the available epidemiological data support an increased risk of both kidney and testicular cancers associated with PFOA exposure. There is also evidence that PFOA exposure may be associated with an increased breast cancer risk, based on studies in populations with specific polymorphisms and for specific types of breast tumors. Taken together, these results provide consistent and plausible evidence of PFOA carcinogenicity in humans. Additionally, while genotoxicity is one potential MOA for carcinogenicity, there is no requirement that a chemical be genotoxic for the EPA to classify it as either *Carcinogenic to Humans*, *Likely to Be Carcinogenic to Humans*, or *Suggestive Evidence of Carcinogenic Potential* according to the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005). Importantly, the SAB PFAS Review Panel supported the rationale for the *Likely to Be Carcinogenic to Humans* designation for PFOA in its final report (USEPA, 2022b).

Individual Public Comments

4.1.4.1 General Comments

Rockbridge Area Conservation Council (RACC) (Doc. #1678, SBC-043736)

Comments on EPA Proposed National Primary Drinking Water Regulation (NPDWR)

(https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0027)

Rockbridge Conservation PFAS Working Group: Joe DiNardo, David Agnor, Sandra Stuart, Barbara Walsh

We would like to thank the EPA for their tremendous efforts and advances made in establishing guidelines to control the human and environmental impact of Per- and Polyfluoroalkyl Substances (PFAS) including perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS). With that said, we respectfully submit the following comments for EPA's review and consideration in light of the proposed National Primary Drinking Water Regulation (NPDWR):

1) EPA Statement:

"Following a systematic review of available human epidemiological and animal toxicity studies, EPA has determined that PFOA and PFOS are likely to cause cancer (e.g., kidney and liver cancer) and that there is no dose below which either chemical is considered safe (see section IV.A and V.A through B of this preamble for additional discussion). Therefore, EPA is proposing to set the health-based value, the MCLG, for both of these contaminants at zero."

We agree with EPA's safety assessment that PFOA and PFOS are likely carcinogenic to humans and with the conclusion that there is no dose that is safe and, therefore, setting an MCLG to "Zero" is warranted.

EPA Response: The comments provided by this commenter provide support for the final rule and toxicity assessments.

American Association for Justice (AAJ) (Doc. #1636, SBC-042968)

I. AAJ supports the EPA's science-based conclusion that there is no safe level of PFAS exposure.

An MCLG is defined in Section 1412(b)(4)(A) of the Safe Water Drinking Act (SWDA) as "the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety.'' EPA correctly recognized that scientific evidence widely supports a conclusion that PFOA and PFOS are carcinogenic to humans as well as causing other negative health effects, and therefore correctly proposed MCLGs for these chemicals of zero. AAJ agrees with EPA and the widespread scientific consensus that there is no safe amount of PFAS exposure and urges EPA to implement the proposed MCLGs.

EPA Response: The comments provided by this commenter provide support for the final rule and toxicity assessments.

Earthjustice et al. (Doc. #1808, SBC-046101)

B. EPA's MCLs for PFOA and PFOS are Consistent with the SDWA and Supported by the Record

i. EPA Correctly Determined That There is No Safe Exposure Level for PFOA or PFOS

EPA's proposed MCLGs for PFOA and PFOS are consistent with the SDWA's mandate to identify the "level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." [FN52: 42 U.S.C. § 300g–1(b)(4)(A).] EPA appropriately proposed MCLGs of 0 ppt based on its longstanding policy of "establish[ing] MCLGs of zero for carcinogens … where there is insufficient information to determine … a threshold dose below which no carcinogenic effects have been observed." [FN53: Proposed Rule, 88 Fed. Reg. at 18,659.] There is substantial evidence that both PFOA and PFOS are carcinogenic, with no known safe level of exposure. "The carcinogenicity of PFOA has been observed in both human epidemiological and animal toxicity studies." [FN54: Id. At 18,656.] EPA documented the evidence of PFOA's carcinogenicity in its 2016 PFOA Health Effects Support Document, and subsequent studies have only strengthened and reinforced that finding. [FN55: Id.] A 2022 report from the National Academies of Sciences, Engineering and Medicine ("NAS") found "that there is sufficient evidence for an association between PFAS," including PFOA, "and kidney cancer," [FN56: NAS 2022 at 74.] and the Agency for Toxic Substances and Disease Registry ("ATSDR") has reported "increases in the risk of testicular and kidney cancer associated with PFOA." [FN57: ATSDR 2021 at 523.] Similarly, human and animal studies of PFOS "reported elevated risk of bladder, prostate, kidney, and breast cancers after chronic PFOS exposure." [FN58: Proposed Rule, 88 Fed. Reg. at 18,660.] California's Office of Environmental Health Hazard Assessment ("OEHHA") has listed both PFOA and PFOS as chemicals "known . . . to cause cancer," based on its independent review of the scientific literature. [FN59: OEHHA, Notice to Interested Parties, Chemical Listed Effective February 25, 2022, As Known to the State of California to Cause Cancer: Perfluorooctanoic Acid (2022)("OEHHA 2022"), https://oehha.ca.gov/media/downloads/crnr/listingnoticepfoa022522.pdf; OEHHA, Notice to Interested Parties, Chemicals Listed Effective December 24, 2021, As Known to the State of California to Cause Cancer: Perfluorooctane Sulfonic Acid (PFOS) and Its Salts and Transformation and Degradation Precursors (2021), https://oehha.ca.gov/media/downloads/crnr/noticepfossandsaltstransdegradprecursor122421.pdf.] Additionally, OEHHA has published draft public health goals for PFOA and PFOS in drinking water based on their carcinogenicity. [FN60: OEHHA, Public Health Goals, Perfluorooctanoic Acid and Perfluorooctane Sulfonic Acid in Drinking Water (First Public Review Draft), at 10 (2021) ("OEHHA 2021"), https://oehha.ca.gov/sites/default/files/media/downloads/crnr/pfoapfosphgdraft061021.pdf. 61 Proposed Rule, 88 Fed. Reg. at 18,659–60.] EPA thus appropriately concluded that both PFOA and PFOS are "likely to be carcinogenic to humans." [FN61: Proposed Rule, 88 Fed. Reg. at 18,659–60.]

EPA's established practice, which has been endorsed repeatedly by EPA's Science Advisory Board, the NAS, and other leading authorities, assumes that cancer risks follow a linear dose

response curve, with no safe exposure threshold, in the absence of "scientific evidence demonstrating a threshold level of exposure below which there is no appreciable cancer risk." [FN62: Id. At 18,652–53; see also EPA, Guidelines for Carcinogen Risk Assessment, at 3-21–3-22 (2005).] Here, there is no evidence of a safe level for PFOA and PFOS, and accordingly no basis to depart from EPA's standard approach. Based on substantial evidence of their carcinogenicity and the absence of a safe exposure threshold, EPA appropriately determined that there is no safe level for either PFOA or PFOS.

EPA Response: The comments provided by this commenter provide support for the final rule and toxicity assessments. The commenter cites conclusions by the National Academies of Sciences, Engineering, and Medicine (NASEM, 2022), the Agency for Toxic Substances and Disease Registry (ATSDR) (ATSDR, 2021), and California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (CalEPA, 2021), all of which are cited in the EPA's toxicity assessments.

Environmental Protection Network (EPN) (Doc. #1773, SBC-052871, SBC-043843 & SBC-043845)

EPN supports EPA's finding that PFOA is likely to be carcinogenic and that the cancer slope factor should be based on a study of kidney cancer in human males. EPN also supports EPA's finding that PFOS is likely to be carcinogenic and that the cancer slope factor should be based on a study of liver cancer in male and female rats. As a result, there is no dose below which either chemical can be considered safe, and the MCLGs for PFOA and PFOS are appropriately proposed as zero.

EPA Response: The comments provided by this commenter provide support for the final rule and toxicity assessments.

Minnesota Center for Environmental Advocacy et al. (Doc. #1707, SBC-045723)

EPA's Carcinogenic Determination Accurately Reflects the Scientific Understanding

The SDWA directs EPA to set enforceable, nationwide standards for covered drinking water contaminants. [FN31: 42 U.S.C. §§ 300f to 300j-26.] EPA carries out its SDWA obligations by limiting the allowable level of covered contaminants for all public water systems through Maximum Contaminant Level Goals ("MCLG") and MCLs. The statute directs EPA to set the MCLG "at a level at which no known adverse health consequences will occur." [FN32: 42 U.S.C. § 300g-1(b)(4)(A).] EPA is then required to set a MCL as close to the MCLG as is "feasible." [FN33: Id. § 300g-1(b)(4)(B).] The SDWA explains that "feasible" means "feasible with the use of the best technology, treatment techniques and other means which the Administrator finds . . . are available (taking cost) into consideration." [FN34: Id. § 300g-1(b)(4)(D).] Where EPA sets the MCLG, while not an enforceable standard itself, is the floor the enforceable MCL must be based upon. Thus, the MCLGs play a vital role in determining the strictness for each contaminant regulated under the SDWA.

In the Proposed Rule, EPA determined, after "a systematic review of available human epidemiological and animal toxicity studies," that PFOA and PFOS "are likely to cause cancer. . . and that there is no dose below which either chemical is considered safe." [FN35: PFAS National Primary Drinking Water Regulation Rulemaking 60 Fed. Reg. 18638, 18639 (Mar. 29, 2023) (to be codified at 40 C.F.R. pts. 141, 142).] Accordingly, EPA's proposed MCLGs for PFOA and PFOS are zero, representing that there is no safe consumption level for these chemicals. [FN36: Id.] This is the correct conclusion. In prior years, scientists have identified causal links between certain cancers and PFOA and PFOS exposure. [FN37: See, e.g., Grandjean Mem.; see also https://www.tandfonline.com/doi/pdf/10.1080/10962247.2021.1909668 (summarizing scientific research on PFOA. See, e.g., Grandjean Mem. (explaining PFAS links to cancer).] In more recent times, those links have become clearer, with a recent survey of the research concluding that it is "difficult to attribute consistent observations of increased cancer risk in humans exposed to PFOA to chance, bias, or confounding." [FN38: Scott M. Bartell & Verónica M. Vieira, Critical Review on PFOA, Kidnery Cancer, and Testicular Cancer, 71 J. OF THE AIR & WASTE MGMT. Ass'n 663 (2021) (summarizing scientific research on PFOA), available at https://www.tandfonline.com/doi/pdf/10.1080/10962247.2021.1909668.] The association between PFOA and PFOS exposure and cancer is irrefutable. The Commenters urge EPA to adopt an MCLG of zero for PFOA and PFOS.

EPA Response: The comments provided by this commenter provide support for the final rule and toxicity assessments. The commenter cited one review of the cancer literature that the EPA has already included as supporting evidence in the cancer assessment for PFOA (USEPA, 2024d; Bartell and Vieira, 2021).

Consumer Reports (Doc. #1656, SBC-043184, SBC-043185 & SBC-043186)

For contaminants that are carcinogenic, EPA policy is to set the MCLG at zero, unless there is data to show that there is a threshold for a carcinogenic effect. We agree with EPA's conclusion that PFOA is Likely to be Carcinogenic to Humans, based on sufficient evidence of carcinogenicity in humans and animals and the lack of evidence that there is a threshold level of exposure to PFOA below which there is no appreciable cancer risk. We also agree with EPA that the weight of the evidence suggests that PFOS is Likely to be Carcinogenic to Humans. Thus, we support EPA setting the MCLG for PFOA and PFOS at zero.

EPA Response: The comments provided by this commenter provide support for the final rule and toxicity assessments.

West Virginia Rivers Coalition et al. (Doc. #1746, SBC-045248)

EPA appropriately concluded that PFOA and PFOS are "likely to be carcinogenic to humans," and "there is no dose below which either chemical is considered safe." West Virginians have been subject to studies investigating the health effects of PFOA for decades. Numerous studies and long-term health investigations provide evidence that PFOA exposure from the Washington

Works Teflon-manufacturing plant in Parkersburg, WV is associated with higher rates of cancers in mid-Ohio River valley residents [FN3: https://ehp.niehs.nih.gov/doi/10.1289/ehp.1306615; https://ehp.niehs.nih.gov/doi/10.1289/ehp.1205829; http://www.c8sciencepanel.org/index.html]. WV Rivers strongly supports the maximum contaminant level goal (MCLG) of zero for PFOA and PFOS, as any detection of PFOA or PFOS in drinking water can be harmful to human health.

EPA Response: The comments provided by this commenter provide support for the final rule and toxicity assessments. The commenter cited two peer-reviewed publications and a summary of the C8 Science Panel's conclusions on adverse health effects associated with PFOA exposure that the EPA has already included as supporting evidence in the cancer assessment for PFOA (USEPA, 2024d; Barry et al., 2013; Vieira et al., 2013; C8 Science Panel, 2012).

Silent Spring Institute (Doc. #1784, SBC-053330)

The MCLGs of zero for PFOA and PFOS are appropriate based on the weight of evidence for carcinogenicity and other adverse health impacts of PFOA and PFOS at very low exposures. The MCLs of PFOA and PFOS should be set as close to EPA's 2022 interim lifetime health advisories (LHAs) as possible to be protective of both cancer and non-cancer effects.

EPA Response: The comments provided by this commenter provide support for the final rule and toxicity assessments. The MCLs for PFOA and PFOS are set as close to the MCLGs as feasible, not the interim lifetime HAs for PFOA and PFOS. Please see Section 4.1.5 of the EPA response in this *Response to Comments* document regarding the EPA's MCLGs for PFOA and PFOS and section 5 of the EPA response in this *Response to Comments* document regarding the MCLs for PFOA and PFOS.

Mindi Messmer (Doc. #1788, SBC-044705)

PFOA and other PFAS are endocrine-disrupting chemicals (EDCs) that can disrupt hormonal balance and result in developmental and reproductive abnormalities like the delayed onset of puberty, interference with developmental hormone signaling, and reproductive organ malformation, etc. (Di Nisio et al., 2022; Tarapore & Ouyang, 2021).

Unlike other carcinogens, PFAS chemicals bioaccumulate in the human body with half-lives, or the amount of time needed to reduce the PFAS concentration in the body if all further exposure is halted, ranging from approximately 2 to more than 15 years (Kudo & Kawashima, 2003; Li et al., 2018; Russell et al., 2015) so with each exposure the risk of chronic disease increases.

Human exposure to PFAS is widespread through occupation, ingesting contaminated drinking water, and food that has been in contact with PFAS-coated packaging. Now, four PFAS (PFOA, PFOS, perfluoro hexane sulfonic acid [PFHxS], and perfluorononanoic acid [PFNA]) are detected in 99% of serum samples from humans over 12 in the United States (US), indicating nearly universal exposure (Calafat et al., 2007).

Studies of health outcomes in 69,000 people exposed to PFOA from DuPont's Washington Works plant in West Virginia concluded that PFOA exposure was "more probably than not" associated with testicular and kidney and renal pelvis cancers, ulcerative colitis, thyroid disease, hypercholesterolemia, and pregnancy-induced hypertension (C8 Science Panel, 2020).

Babies are exposed to PFAS in utero through prenatal transplacental transfer as well as early in life since PFAS transfers to breastmilk and contaminated bottled milk. Babies often have higher serum PFAS concentrations than their mothers and increasing PFAS serum levels with longer breastfeeding duration (Fromme et al., 2010; Gyllenhammar, et al, 2018; Papadopoulou et al. 2016; VanNoy et al., 2018). United States Environmental Protection Agency ("EPA") PFOA reference doses are based on concerns relating to developmental endpoints in young children (US Environmental Protection Agency, 2016b).

Previous research indicates that PFOA exposure is also associated with a variety of male and female reproductive outcomes, cancers, impaired developmental outcomes, reduced vaccine response, and more severe COVID-19 outcomes, etc. (see Table 1).

The evidence is clear that exposure to PFAS chemicals causes a wide variety of health effects. Prior research indicates that high levels of PFAS are associated with a variety of adverse health outcomes, including an increased risk of cancer. Researchers have stressed that "the goal is to have zero carcinogens in water" (McMenemy, 2015). We know that we can prevent up to 93% of all human cancers since they are non-hereditary…[but] caused by interaction with environmental factors. Only 7% of all human cancers are hereditary (Seto, et al, 2010).

EPA Response: The comments provided by this commenter provide support for the final rule and toxicity assessments. The commenter has provided several citations to support their conclusions. Please see section 4.2.6 of the EPA response in this *Response to Comments document* for information related to how the EPA considered references recommended during public comment.

<u>New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045015 & SBC-045016)</u>

Proposed PFOA and PFOS MCLGs of zero based on "Likely to be Carcinogenic to Humans" categorization:

EPA requested comment on its conclusions that PFOA and PFOA are Likely to be Carcinogenic to Humans. The DWQI (2022) agreed that current animal and human data indicate that PFOA should be categorized as a Likely to be Carcinogenic to Humans, and NJDEP concurs with this conclusion. Specifically, two recent studies add to the earlier evidence for carcinogenicity of PFOA. Shearer et al. (2021), cited in the proposed rule, is a human epidemiology study that reports an association of PFOA and kidney cancer within the general population. The National Toxicology Program (NTP, 2020), also cited in the proposed rule, is a chronic rat study that found that PFOA is a more potent carcinogen than two earlier chronic rat studies. Additionally,

NTP (2020) reported that PFOA caused malignant as well as benign tumors, while the earlier chronic studies reported only benign tumors.

The DWQI (2022) did not review EPA's determination that PFOS is Likely to be Carcinogenic to Humans because this conclusion was not publicly available when DWQI (2022) conducted its evaluation. NJDEP has reviewed the more recent EPA weight of evaluation for PFOS in the rule proposal and the draft "USEPA Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) in Drinking Water" (cited as USEPA [2023c] in the proposed rule). NJDEP agrees with EPA that the available scientific information indicates that it is appropriate to categorize PFOS as Likely to be Carcinogenic to Humans, as summarized in Table 3-26 of USEPA (2023c). NJDEP also agrees the evidence for carcinogenicity of PFOS exceeds the criteria for Suggestive Evidence of Carcinogenic potential, as summarized in Table 6-2 of USEPA (2023c).

NJDEP agrees with EPA's conclusion that the rat hepatocellular tumors caused by PFOS should be considered relevant to humans. Specifically, the USEPA (2023c) conclusions that PFOS is a relatively weak activator of peroxisome activated proliferator receptorα (PPARα) and that the primary mode of action for these tumors is not PPAR-alpha activation are consistent with the conclusions of earlier mode of action analyses by DWQI (2018) and NJDEP (2019). As stated in NJDEP (2019), "…carcinogenic and non-carcinogenic hepatic effects of PFOS have sometimes been assumed to occur through activation of PPARα. However, several lines of evidence do not support a conclusion that liver effects due to PFOS exposure are PPARα-dependent."

Additionally, USEPA (2023c) reports an increased incidence of an additional tumor type that was not considered in the DWQI (2018), NJDEP (2019) or USEPA (2016) PFOS evaluations. Specifically, the USEPA (2023c, Table 3-13) evaluation of tumor data from the chronic rat PFOS study (Thomford, 2002; Butenhoff et al., 2012) demonstrates a statistically significant dose-dependent positive trend for increased incidence of pancreatic islet cell carcinomas in males that was not reported by either Thomford (2002) or Butenhoff et al. (2012).

EPA Response: The comments provided by this commenter provide support for the final rule and toxicity assessments. The commenter agreed with the EPA's conclusions that current animal and human data indicate that PFOA should be categorized as *Likely to Be Carcinogenic to Humans* and noted that this is consistent with the New Jersey Drinking Water Quality Institute's (NJDWQIs) conclusions (NJDWQI, 2022). The commenter agreed that the studies by Shearer et al. (2021) and the National Toxicology Program (NTP) (2020), studies the EPA cited to support PFOA's cancer classification in the toxicity assessment (USEPA, 2024d), provide additional support for the cancer evidence database for PFOA,. The commenter similarly agreed that "the evidence for carcinogenicity of PFOS exceeds the criteria for *Suggestive Evidence of Carcinogenic Potential*" and that the rat hepatocellular tumors observed after PFOS exposure in rats should be considered relevant to humans. The commenter noted that the EPA's conclusions regarding the MOA for PFOS are consistent with similar analyses that were independently conducted by the NJDWQI (2018) and New Jersey Department of Environmental Protection (NJDEP) (2019).

PFAS Regulatory Coalition (Doc. #1761, SBC-053397)

As to the cancer endpoints that are discussed in the EPA Proposal, the studies that EPA cites did not adequately control for confounding factors. There are clear statements in those studies that PFOS effects were not separated from other cancer effects. For example, the effects of PFOS were not separated from the potential effects of PFOA.

EPA Response: The commenter states that the studies the EPA cites did not adequately control for confounding factors, particularly potential confounding by co-occurring PFAS. The EPA disagrees that confounding factors were not adequately addressed in the analysis of the epidemiological study data. Discussion of the results of the analyses of the epidemiological studies that support the cancer classifications for PFOA and PFOS and were considered for CSF derivation for PFOA address potential confounding was provided in the PFOA and PFOS draft toxicity assessments (USEPA, 2023f; USEPA, 2023a; Sec. 3.5 and 4.2.2). The EPA has provided further information on considerations for potential confounding by co-occurring PFAS in the EPA response to comment Doc.#1774, SBC-053428 in section 4.2.1.2 and comment Doc. #1774, SBC-053418 and SBC-045681 in section 4.1.2 in this *Response to Comments* document. Further, the cancer classifications for PFOA and PFOS are supported by *high* and *medium* confidence animal toxicological studies which demonstrate multi-site tumorigenesis for PFOA and PFOS (Butenhoff et al., 2012a; NTP, 2020; Biegel et al., 2001; Thomford, 2002; Butenhoff et al., 2012b). Since these animal toxicological studies only administered either PFOA or PFOS, there is no possibility of confounding by exposure to other PFAS.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045948)

Section 2: Maximum Contaminant Level Goal

EPA is proposing an individual Maximum Contaminant Level Goal (MCLG) for PFOA and PFOS and a separate MCLG for PFNA, PFHxS, GenX, and PFBS as a mixture. The MCLG is the level at which no known health effects are known to occur and allows for an adequate margin of safety. EPA conducted its analysis and consulted with the EPA Science Advisory Board (SAB) to determine the MCLGs for these chemicals.

Section 2.1: PFOA and PFOS

EPA is proposing MCLGs of zero for both PFOA and PFOS. These MCLGs stem from EPA designating PFOA and PFOS as "likely to be carcinogenic to humans," which historically has resulted in an MCLG of zero. The SAB supported this determination for PFOA, and EPA states that it "expects to conduct a final literature search update before the final rule is promulgated."

AMWA recommends one way to strengthen this determination would be for EPA to go further in its analysis to compare PFAS-linked health effect outcomes to population statistics. Such analysis should clearly present information to show the effects PFAS has on the national population by looking at health trends over time, particularly in relation to cancer rates.

EPA Response: The commenter suggested the EPA compare PFAS-related health outcomes to "population statistics" by looking at trends in cancer rates across time and that the EPA show evidence that geographic areas with relatively high PFAS concentrations show associations with health risks to strengthen its determinations that PFOA and PFOS are *Likely to Be Carcinogenic to Humans*. The commenter stated that there should be national trends of adverse health effects and potentially a decrease in life expectancy in areas of high PFAS exposure, due to their persistent and bioaccumulative properties. The EPA has concluded that there is sufficient information at this time to finalize this rulemaking using the best available, peer-reviewed science and supporting studies, as well as data collected by accepted methods or best available methods. Congress authorized the EPA to act when the agency has determined that it has sufficient information. As specified in SDWA Section 1412(b)(9), the agency addresses additional information that may be generated in the future in the six-year review.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045949)

This will serve to strengthen the MCLG analysis and would work to link PFAS exposure with certain health outcomes. Additionally, EPA should show that geographic areas with PFAS concentrations higher than the proposed MCLGs/MCLs see higher rates locally of certain PFAS-linked health risks.

This addition is important as it will affect the cost-benefit analysis. PFAS are persistent and bioaccumulative; therefore, one would expect to see national trends of associated adverse health conditions and potentially a steady decrease in life expectancy in areas of high PFAS exposure. There are, of course, other factors that would be associated with adverse health impacts and earlier life expectancy, specifically the COVID-19 pandemic and other events affecting the health of the public, but this analysis will strengthen the overall approach EPA has made in this determination.

EPA Response: The commenter suggested the EPA compare PFAS-related health outcomes to "population statistics" by looking at trends in cancer rates across time and that the EPA show evidence that geographic areas with relatively high PFAS concentrations show associations with health risks to strengthen its determinations that PFOA and PFOS are *Likely to Be Carcinogenic to Humans*. The commenter stated that there should be national trends of adverse health effects and potentially a decrease in life expectancy in areas of high PFAS exposure, due to their persistent and bioaccumulative properties. The EPA has concluded that there is sufficient information at this time to finalize this rulemaking using the best available, peer-reviewed science and supporting studies, as well as data collected by accepted methods or best available methods. Congress authorized the EPA to act when the agency has determined that it has sufficient information. As specified in SDWA Section 1412(b)(9), the agency addresses additional information that may be generated in the future in the six-year review.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-044901)

Section 2: Maximum Contaminant Level Goal

EPA is proposing an individual Maximum Contaminant Level Goal (MCLG) for PFOA and PFOS and a separate MCLG for PFNA, PFHxS, GenX, and PFBS as a mixture. The MCLG is the level at which no known health effects are known to occur and allows for an adequate margin of safety. EPA conducted its own analysis and consulted with the EPA Science Advisory Board (SAB) to determine the MCLGs for these chemicals.

Section 2.1: PFOA and PFOS

EPA is proposing MCLGs of zero for each of PFOA and PFOS. These MCLGs stem from EPA designating PFOA and PFOS as "likely to be carcinogenic to humans," which historically results in an MCLG of zero. This determination for PFOA was supported by the SAB, and EPA states that it "expects to conduct a final literature search update before the final rule is promulgated."

Cleveland Water recommends one way to strengthen this determination would be for EPA to go further in its analysis to compare these health effects to population statistics. This will clearly present that information to show the effects PFAS have on the national population by looking at health trends over time, particularly in relation to cancer rates. This will serve to strengthen the MCLG analysis and link PFAS exposure with certain health outcomes. Additionally, EPA should show that areas with PFAS concentrations higher than the proposed MCLGs/MCLs see higher rates locally of certain PFAS-linked health risks.

This addition is important as it will impact the cost-benefit analysis. PFAS are persistent and bioaccumulative, therefore one would expect to see national trends of certain adverse health conditions increasing, and potentially a steady decrease in life expectancy. There are, of course, other factors that play in, specifically the COVID-19 pandemic and other events affecting the health of the public, but this analysis will strengthen the overall approach EPA has made in this determination.

EPA Response: The commenter suggested the EPA compare PFAS-related health outcomes to "population statistics" by looking at trends in cancer rates across time and that the EPA show evidence that geographic areas with relatively high PFAS concentrations show associations with health risks to strengthen its determinations that PFOA and PFOS are *Likely to Be Carcinogenic to Humans*. The commenter stated that there should be national trends of adverse health effects and potentially a decrease in life expectancy in areas of high PFAS exposure, due to their persistent and bioaccumulative properties. The EPA has concluded that there is sufficient information at this time to finalize this rulemaking using the best available, peer-reviewed science and supporting studies, as well as data collected by accepted methods or best available methods. Congress authorized the EPA to act when the agency has determined that it has sufficient information. As specified in SDWA Section 1412(b)(9), the agency addresses additional information that may be generated in the future in the six-year review.

As a result of the systematic review, the EPA determined that there is sufficient information to support these cancer classifications and the MCLGs of zero for PFOA and PFOS (see sections 4.1.4 and 4.1.5 of the EPA response in this *Response to Comments* document and section IV of the rulemaking preamble).

Studies that were identified in this effort and were determined to be of sufficient quality that analyzed the association between individual-level concentrations of PFOA or PFOS and measured health outcomes (adjusting for relevant, individual-level covariates) provide data to characterize the effects associated with PFOA or PFOS exposure. The EPA used these studies to determine the health hazards as part of the toxicity assessment development process and documented this process in the final toxicity assessments for PFOA and PFOS (USEPA 2024a, USEPA 2024b). The commenter notes that areas of high-PFAS exposure should show increased rates of PFAS-associated health effects and potentially decreases in life expectancy. The EPA identified multiple peer reviewed studies of the C8 Health Project, which focused on a high-exposure PFOA community in the United States, reported significantly increased risks of kidney and testicular cancers with elevated exposure to PFOA (Barry et al., 2013; Vieira et al., 2013). The EPA incorporated these studies into the cancer classification determination for PFOA (USEPA, 2024d). The results of these studies and others conducted in highly exposed communities are important because there may be increased certainty that observed health effects in individuals from high-exposure communities are not confounded by other contaminant exposures.

PFOA and PFOS are included in the suite of contaminants measured in blood samples from a national population collected as a part of the National Health and Examination Survey (https://www.cdc.gov/exposurereport/index.html). Due to the individual nature of the data collected, studies based on data from NHANES can provide individual-level risk estimates as described in the paragraph above. However, the currently available literature reporting associations between cancer outcomes and PFOA or PFOS in blood as reported by the NHANES or other national surveys is limited. Two studies examined cancer in NHANES populations, however, both studies relied on self-reported cancer outcomes which limits confidence in the studies' conclusions (Fry and Power, 2017; Omoike et al., 2021). Omoike et al. (2021) reported significantly increased odds of ovarian and breast cancer with elevated exposure to PFOA and PFOS in continuous analyses and comparing the highest exposure quartiles to the lowest. The other study reported non-significant associations between elevated exposure to PFOA or PFOS and cancer incidence for numerous cancer types (Fry and Power, 2017). The EPA also relied on studies reporting NHANES data and noncancer health outcomes to support evidence integration judgments, POD derivation, and RfD derivation (e.g., Dong et al., 2019).

American Chemistry Council (ACC) (Doc. #1841, SBC-044831)

The available data do not support the determination that PFOA, PFOS or any PFAS are likely human carcinogens, especially at low environmentally relevant levels. Moreover, there is no evidence that PFOA, PFOS, or any PFAS are directly genotoxic. Therefore, regulating PFOA and

PFOS as likely carcinogens and setting the MCL Goal at zero is inconsistent with the best available science. USEPA's findings are also inconsistent with other federal agencies' toxicity assessments worldwide. Most recently, the independent scientific committee that advises the United Kingdom's governmental agencies and health departments concluded that there is "no evidence for a link between exposure to PFASs and cancer risk." [FN41: Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment. Statement on the EFSA Opinion on the Risks to Human Health Related to the Presence of Perfluoroalkyl Substances in Food. United Kingdom (2022). https://cot.food.gov.uk/Introduction%20-%20Statement%20on%20the%20EFSA%20Opinion%20on%20the%20risks%20of%20perfluoroalkyl%20substan ces%20in%20food (COT 2022)] The United Kingdom classifies long-chain perfluoroalkyl acids in their carcinogenicity "Category 2," which means that there is some evidence that exposures to these compounds causes cancer in laboratory animals, but that the information is insufficient to reach a conclusion related to human cancer risk. EPA should not regulate PFOA or PFOS as likely human carcinogens with an MCL Goal of zero, as this is unsupported by the available data.

EPA Response: The EPA disagrees with the comment that the available data do not support the determination that PFOA and PFOS are each *Likely to Be Carcinogenic to Humans*. Please see section 4.1.4 of the EPA response in this *Response to Comments* document regarding the EPA's determinations that PFOA and PFOS are *Likely to Be Carcinogenic to Humans* in accordance with the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005) and see section 4.2.6 of the EPA response in this *Response to Comments* document regarding differences between the EPA's conclusions in the toxicity assessments for PFOA and PFOS and the conclusions of other health agencies. The information supporting the EPA's cancer classifications for PFOA and PFOS are described in Section 3.5.5 of the final toxicity assessments (USEPA, 2024d; USEPA, 2024c).

Water & Health Advisory Council (Doc. #1590, SBC-042786)

The Safe Drinking Water Act requires that proposed regulations for our drinking water systems demonstrate a "meaningful opportunity for health risk reduction," which means evaluating risk to the public based upon clear exposure and health impact information. As of today, expert toxicologists' opinions and advisory levels for PFAS vary by over 100,000 -fold, indicating that there is no consensus regarding the toxicity of these compounds at drinking water levels. Numerous toxicologists, epidemiologists, and risk assessors worldwide have disagreed with the U.S. EPA technical review of PFOA and PFOS toxicity data. For example, the U.S. EPA's proposed strategy for regulating PFOA and PFOS as carcinogens with an MCL Goal of zero is in direct contrast with the United Kingdom's independent science advisory committee conclusion that there is "no evidence for a link between exposure to PFASs and cancer risk." (COT, 2022, p. 24). Additionally, all the noncancer health endpoints used by the U.S. EPA are based on "suggestive" evidence only; there is still no clear evidence that exposure to low levels of PFAS causes any human disease. We ask that the U.S. EPA take a more balanced approach to their interpretations of the potential human health risks associated with PFAS, consistent with

international agencies that have developed more practical approaches that consider the significant uncertainties within the available toxicity data.

EPA Response: The EPA disagrees that the available data do not support the determination that PFOA and PFOS are *Likely to Be Carcinogenic to Humans*. Please see section 4.1.4 of the EPA response in this *Response to Comments* document regarding the EPA's determinations that PFOA and PFOS are *Likely to Be Carcinogenic to Humans* in accordance with the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005) and section 4.2.6 of the EPA response in this *Response to Comments* document regarding differences between the EPA's conclusions in the toxicity assessments for PFOA and PFOS and the conclusions of other health agencies. Please see the EPA response to comments Doc. #1774, SBC-053196, SBC-053187, SBC-053190 in section 4.1.4.2 and the EPA response to comment Doc. #1774, SBC-045184 in section 1.2 in this *Response to Comments* document for more detailed discussion on the cancer classification and studies supporting the EPA's conclusions for PFOS and the EPA response to comment Doc. #1774, SBC-045682 and SBC-045683 in section 4.1.4.3 in this *Response to Comments* document for more detailed discussion on the cancer classification and studies supporting the EPA's conclusions for PFOA. As noted in that response, the EPA's determinations were supported by the EPA's Science Advisory Board (USEPA, 2022b), among others. Please see section 4.2.2 of the EPA response in this *Response to Comments* document for rebuttals to the incorrect claim that all of the noncancer health endpoints are based on "suggestive" evidence only. As described further in that section and in Section 3.4 of the PFOA and PFOS toxicity assessments (USEPA, 2024d; USEPA, 2024c), the EPA determined that the available *evidence indicates* there are likely associations between PFOA or PFOS and effects on the four prioritized noncancer health outcomes (i.e., developmental, hepatic, cardiovascular, and immune).

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-053386)

Cancer

While EPA cites multiple lines of evidence to support its carcinogenic finding, this section compares different agencies' conclusions concerning the epidemiologic evidence. Two studies involving participants in the C8 Health Project showed a positive association between PFOA levels (mean at 24 ng/mL) and kidney and testicular cancers [FN40: Vaughn Barry, Andrea Winquist, and Kyle Steenland, "Perfluorooctanoic Acid (PFOA) Exposures and Incident Cancers among Adults Living near a Chemical Plant," Environmental Health Perspectives, 2013.]. The C8 Science Panel concluded that a probable link existed between PFOA exposure and testicular and kidney cancer [FN41: C8 Science Panel, "C8 Probable Link Reports," 2012.].

In an occupational study in Italy, statistically significant increases in liver cancer mortality, malignant neoplasms of the lymphatic and hematopoietic tissue, and in all malignant neoplasms with cumulative serum PFOA exposure greater than 16,956 ng/mL-years. In another occupational study based on a West Virginia DuPont cohort, no significant associations with

incidence of cancers of the bladder, colorectal, prostate, and melanoma were observed when compared to the general population [FN42: Kyle Steenland and Susan Woskie, "Cohort Mortality Study of Workers Exposed to Perfluorooctanoic Acid," American Journal of Epidemiology, November 2012.].

Fifteen epidemiological and one animal toxicological study that investigated the association between PFOS and cancer were identified. Although the epidemiological evidence found mixed results across tumor types, EPA says that the available study findings support a plausible correlation between PFOS exposure and carcinogenicity in humans.

PFOS was associated with an increased risk of kidney cancer in a medium confidence study [FN43: Joseph Shearer et al., "Serum Concentrations of Per- and Polyfluoroalkyl Substances and Risk of Renal Cell Carcinoma," Journal of the National Cancer Institute, 2021.]. A case-control study within the National Cancer Institute's Prostate, Lung, Colorectal, and Ovarian Screening Trial reported a statistically significant positive trend in risk of renal cell carcinoma with pre-diagnostic PFOS serum levels.

One study also observed statistically significant increased odds of ovarian cancer both per ng/mL increase in PFOS and in the two highest quartiles of exposure, although the association was significantly inverse for the second quartile of PFOS exposure [FN44: Ogbedor Omoike et al., "Association between per and Polyfluoroalkyl Substances and Markers of Inflammation and Oxidative Stress," Environmental Research, May 2021.].

The evidence database for the carcinogenicity of PFOS is comprised of several epidemiological studies and a single chronic cancer. The available epidemiology studies report elevated risk of bladder, prostate, kidney, and breast cancers after chronic PFOS exposure. However, EPA notes that the study designs, analyses, and mixed results do not allow for a definitive conclusion on the relationship between PFOS exposure and cancer outcomes.

EPA explains that the low confidence sources are limited by selection bias, and confounders specific for cancer outcomes, including smoking and socioeconomic factors, were not addressed and behavioral risk factors could have differed. The EFSA, HC, and the WHO do not find the epidemiology evidence robust enough to support a causal link between PFOA exposure and cancer (see Table 38 and Table 39 in Appendix B).

In summary, since other competent public health agencies have reviewed the same scientific literature as EPA and have reached different conclusions on the existence and the strength of the associations between PFOS and PFOA exposure and disease, EPA must take this uncertainty into account. EPA must do so in a quantitative, reproducible uncertainty analysis as required by Circular A-4. Providing the range of potential benefits will also increase the public's understanding of the regulatory options.

EPA Response: Please see section 4.1.4 of the EPA response in this *Response to Comments* document. The EPA followed the agency's *Guidelines for Carcinogen Risk Assessment* in making its cancer determinations for PFOA (USEPA, 2005) and the EPA directs

the commenter to Section 3.5.5 of the toxicity assessments (USEPA, 2024d; USEPA, 2024c) which details the weight of evidence for PFOA and PFOS, and the EPA's rationale for ultimately determining PFOA and PFOS are *Likely to Be Carcinogenic to Humans* (USEPA, 2005).

The commenter points to the conclusions of other authoritative agencies (i.e., European Food Safety Authority (EFSA), the World Health Organization [WHO], Health Canada [HC]) and stated that they did "not find the epidemiology evidence robust enough to support a causal link between PFOA exposure and cancer." The EPA disagrees with the commenter that the conclusions cited differ from the EPA's conclusions. In fact, the EPA agrees that there is not adequate evidence from epidemiological studies supporting a causal association between PFOA exposure and increased cancer risk in humans. This is evident in the EPA's selection of the *Likely to Be Carcinogenic to Humans* cancer descriptor for PFOA (see Section 3.5.5; USEPA, 2024d) rather than the *Carcinogenic to Humans* descriptor (see Section 5.4; USEPA, 2024d). The EPA has clearly stated that, "[a] plausible, though not definitively causal, association exists between human exposure to PFOA and kidney and testicular cancers," in humans. The EPA makes similar conclusions regarding the lack of evidence from epidemiological studies supporting a causal relationship between PFOS exposure and cancer risk (USEPA, 2024c).

As described in the EPA's response to comments received on quantified uncertainties in the economic analysis (see section 13.9 of the EPA response in this *Response to Comments* document), the EPA assessed all major sources of uncertainty in the EA using both quantitative and qualitative approaches which is consistent with OMB Circular A-4 guidance. For some key sources of uncertainty, including model inputs for health effect exposure response slope factors, the EPA quantitatively assessed the uncertainty by evaluating the distribution of values for those inputs. See section 13.9 of the EPA response in this *Response to Comments* document, Chapter 6 of the EA (USEPA, 2024f), and section XII of the FRN for additional details on the EPA's uncertainty analysis and the presentation of uncertainty analysis results.

4.1.4.2 Comments Specific to PFOS

AWWA (Doc. #1759, SBC-045598)

As with PFOA, EPA is proposing to establish a MCLG of zero (0 ppt) for PFOS following a determination that PFOS is suggestive to be carcinogenic. As noted in comments in 2021, AWWA supports this determination (AWWA, 2021a). If EPA moves forward with a conclusion that PFOA is carcinogenic, AWWA agrees that the appropriate MCLG for a carcinogen is 0 ppt (zero).

EPA Response: In the proposed rule, the agency stated that PFOS is *Likely to Be Carcinogenic to Humans* in accordance with the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005) and therefore, the EPA set the proposed MCLG for PFOS at zero. The commenter mistakenly stated that "PFOS is suggestive to be carcinogenic," but agreed with the EPA's determination that an MCLG of zero is appropriate.

3M Company (Doc. #1774, SBC-045684)

ii. PFOS

The agency's conclusion that PFOS is likely to be carcinogenic to humans is likewise undermined by the lack of a reliable process for identifying and evaluating available evidence. As a result, EPA's conclusion is inconsistent with the evidence that EPA presents, as well as with fundamental scientific principles. In its November 2021 draft PFOS MCLG document submitted to SAB, EPA said there was "suggestive evidence of carcinogenic potential" of PFOS in humans. Now, without providing adequate justification, the Agency has switched its carcinogenicity determination for PFOS despite no new evidence and came to different conclusions about studies it had previously reviewed. The vast majority of the studies that EPA produced and analyzed reported no effects, no effects of statistical significance, or effects that are inapplicable for human risk assessment because of species differences. EPA's conclusion that the weight of evidence supports the classification that PFOS is likely to be carcinogenic to humans is inconsistent with the weight of the evidence to the contrary, as further detailed in this section Of critical importance, the PFOS cancer assessment as written was not reviewed by the SAB, counter to the Cancer Guidelines (USEPA 2005) that state, "[g]enerally, cancer risk decisions strive to be "scientifically defensible, consistent with the agency's statutory mission, and responsive to the needs of decision-makers" (NRC, 1994). Scientific defensibility would be evaluated through use of EPA's Science Advisory Board, EPA's Office of Pesticide Programs' Scientific Advisory Panel, or other independent expert peer review panels to determine whether a consensus among scientific experts exists." EPA's conclusions on the carcinogenicity of PFOS have been proposed without sufficient peer review, in violation of EPA's own Cancer Guidelines.

EPA Response: The EPA disagrees with the claim that the EPA's analyses and conclusions are inconsistent with either the evidence the EPA presents or fundamental scientific principles. As discussed throughout the administrative record and consistent with the SDWA, the EPA disagrees that there was a "lack of a reliable process" used to develop the toxicity assessments for PFOA and PFOS; the EPA has identified and used the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices and data collected by accepted methods or best available methods and considered internal review and external peer-review input in reaching conclusions (see sections 4.1.2 and 4.1.3 of the EPA response in this *Response to Comments* document). The commenter incorrectly suggests that the cancer assessment provided in the public comment draft toxicity assessment was not reviewed by the SAB and therefore lacks sufficient peer review. In fact, the SAB did review and comment on the cancer assessment as evidenced by the SAB's recommendation that the EPA provide an "explicit description of why the available data for PFOS do not meet the EPA *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005) criterion for the higher designation as 'likely carcinogenic'" and that the EPA was "overly conservative in dismissing the appearance of a dose-response relationship for [hepatocellular carcinoma], particularly in females…Given that multiple MOAs may be operative in this outcome, the Panel suggests that the EPA reevaluate the 2012 Butenhoff study" actually prompted the EPA's

reevaluation of the available data and subsequent reclassification of PFOS as *Likely to Be Carcinogenic to Humans* (USEPA, 2022b). During its reevaluation of the data, following the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005), the EPA concluded that the available data for PFOS do in fact surpass the designation of *Suggestive Evidence of Carcinogenicity*. The commenter also incorrectly stated that the EPA did not provide adequate justification for this revision to the cancer descriptor. In fact, a thorough description of the rationale for this determination can be found in Sections 3.5 and 5.4 of the final toxicity assessment (USEPA, 2024c) and sections 3.5 and 6.4 of the *Proposed MCLG* documents (USEPA, 2023a) available for public comment. Further, 68dditionditional epidemiological cancer studies included in the final toxicity assessment, which post-dated the SAB review, add to the weight of the evidence for carcinogenicity and strengthen the conclusion that PFOS is *Likely to Be Carcinogenic to Humans* (i.e., Goodrich et al., 2022 and Cao et al., 2022) as described below. The four overarching factors that the EPA used to support the decision to update the cancer descriptor for PFOS are presented in section 4.1.4 of the EPA response in this *Response to Comments* document. For responses regarding SDWA's requirements for SAB comment prior to proposal, see section 4.3.2 of the EPA response in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-053187)

B. Epidemiological Evidence

EPA is inconsistent in its presentation of epidemiological data regarding PFOS (USEPA 2023c). [FN64: EPA stated that it "identified 15 epidemiological" studies, of which "8 were classified as medium confidence, 6 as low confidence, and 1 was considered uninformative" (p. 3-260). In another section (p. 3-263), the agency states that, "of the 15 studies identified since the 2016 assessment (Figure 3-73), seven were considered medium confidence and six were low confidence," and that figure shows two studies as critically deficient.] EPA summarized epidemiological studies regarding PFOS and their reliability in USEPA (2023c). In a previous assessment that EPA conducted of pre-2016 epidemiology studies of PFOS for its 2016 Health Effects Support Document for PFOS (USEPA 2016), [FN65: See (USEPA 2023c at Figure 3-72, p. 3-262).] EPA concluded that Jørgensen (2011), Eriksen (2009) and Grice (2007) did not support EPA's new conclusion in the proposed NPDWR regarding PFOS carcinogenicity. [FN66: See (USEPA 2023c at 3-260-261).] Nonetheless, in EPA's weight-of-evidence conclusion for carcinogenicity, the agency misleadingly stated that Grice (2007) "observed that prostate cancers were among the most frequently reported malignancies." This directly contradicts the original authors' conclusions that they "observed no association between working in a PFOS-exposed job and several cancers, common health conditions, and birth weight" (Grice 2007).

The majority of the studies Identified by EPA as relevant for assessing whether PFOS is carcinogenic concluded no, or in one case, even a reduced risk of cancer from PFOS exposure, as follows:

· Bonefeld-Jørgensen et al. (2011): "the association was of a low magnitude and could not be separated from the effects of other perfluorosulfonated compound exposures" (p. 3- 283).

· Cohn et al. (2020):" maternal PFOS was associated with a decreased daughters' breast cancers risk" (p. 3-265).

· Ducatman et al. (2015): "No association between PFOS exposure and prostate cancer was reported […] in a study of the association between PFOS serum concentrations and prostate specific antigen (a biomarker of prostate cancer)" (p. 3-282).

· Eriksen et al. (2009): "No elevated bladder cancer risk was observed in a nested casecontrol study in a Danish cohort" (p. 3-261).

· Fry and Power (2017): "Cancer mortality based on Public-use Linked Mortality Files was not associated with PFOS exposure" (p. 3-266).

· Grice et al. (2007): "they did not reach statistical significance" (p. 3-261).

· Hurley et al. (2018):" A nested case-control study did not observe an association between breast cancer identified through California cancer registry and PFOS concentrations in serum" (p. 3-265).

· Shearer et al. (2021): "reported a statistically significant positive trend in risk of renal cell carcinoma" but "the association with PFOS was attenuated after adjusting for other PFAS […]. There was no association when evaluated on a per doubling of PFOS after adjusting for other PFAS" (p. 3-265).

In particular, there is a lack of confidence in EPA's review methodology, especially as it relates the Eriksen et al. (2009) study when compared to the Shearer et al. (2021) study. Both studies used the same methodology during the same time period. Both studies were published in the Journal of the National Cancer Institute. The Shearer et al. study originated from the PLCO screening trial study that enrolled approximately 150,000 individuals. These participants were enrolled between 1993 – 2001. Single measurement blood (serum) samples were collected at enrollment. At a later date, these samples were measured for PFOA and PFOS. A case control study was much later conducted of those who subsequently were diagnosed with kidney cancer (324 cases, 324 controls) and their archived serum sample for PFOS and PFOA. The Eriksen study originated from the prospective cohort Danish Diet, Cancer, and Health Study which had a cohort of 57,053 individuals aged 50 -65 years, born in Denmark with no previous cancer diagnoses. These participants were enrolled between 1993 – 1997. As with Shearer et al., there was only a single measure of blood (plasma) taken for each participant. Eriksen et al. followed the cancer experience in this cohort through mid-2006. Cases were ascertained through the Danish National Cancer Registry. A total of 713 prostate cancer cases, 332 bladder cancer cases, 128 pancreatic cancer cases, and 67 liver cancer cases were identified in this follow-up time period. A total of 772 noncancer cases were selected as controls. Archived plasma samples were measured for PFOA and PFOS. Eriksen concluded there was no clear differences in risk for these cancers in relation to plasma concentrations of PFOA and PFOS.

Unlike Shearer et al. (who assert that a single measurement can be used), however, Eriksen et al. wrote, "Consequently, misclassification may have occurred because the concentration may have occurred because the concentration at one moment in time may not reliably reflect the relevant plasma concentrations decades ago or at other times." Eriksen is the largest study, to date, to examine prostate, pancreas, and especially liver cancer, in the general population with PFOS exposure. (The Eriksen et al. study also analyzed for serum PFOA concentrations).

EPA judged both studies by Shearer et al. and Eriksen et al. to result in overall "adequate" confidence with confounding to be deficient in both studies (i.e., both had the same qualitative measurements for cigarette smoking). Given the same methodology, EPA considered Shearer et al. to have good metric scores for participant selection, exposure measurement, outcome, and analysis, whereas Eriksen et al. only received one good metric for participant selection. The mere fact that the EPA has considered PFOS to be likely carcinogenic (based on liver cancer in rats) but utterly failed to mention the Eriksen et al. study for its null liver cancer results in the PFOS final report illustrates inconsistency and apparent arbitrariness EPA's carcinogenicity assessment process.

In conclusion, EPA's process errors led it to reach a carcinogenicity determination that is contrary to the weight of epidemiological evidence in violation of EPA's own Cancer Guidelines.

EPA Response: As discussed throughout the administrative record and consistent with the SDWA, the EPA disagrees that there were process issues related to the development of the toxicity assessments for PFOA and PFOS; the EPA has identified and used the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices and data collected by accepted methods or best available methods and considered internal review and external peer-review input in reaching conclusions (see sections 4.1.2 and 4.1.3 of the EPA response in this *Response to Comments* document).

The commenter additionally stated several perceived issues with the epidemiological evidence presented to support the cancer classification for PFOS. First, the commenter points out a minor discrepancy in the study count for each confidence level between Sections 3.5 and 3.5.1.2 of the draft toxicity assessment (USEPA, 2023a). In response to this comment, the EPA has updated the confidence level counts to match Figure 3-74, including the addition of both studies identified in the updated 2023 literature search (Goodrich et al., 2022; Cao et al., 2022), which underwent systematic review steps and were included in the cancer synthesis of the final PFOS toxicity assessment (USEPA, 2024c, section 3.5).

Second, the commenter incorrectly claimed that the EPA mischaracterized study conclusions from Grice (2007) and raised additional concerns about studies evaluating associations between exposure to PFOS and cancer, citing studies that reported no association between PFOS exposure and cancer. The EPA disagrees that it mischaracterized the conclusions of Grice et al. (2007). Grice et al. (2007) reports non-significant but positive associations between PFOS and prostate cancer, and the author directly states "[m]elanoma (n=39), prostate cancer (n=29), and colon cancer (n=22) were the most frequently reported malignancies on the questionnaire." The EPA

maintains its position based on the publication's summary that prostate cancer was one of the most frequently reported cancers and disagrees that this statement contradicts the study publication's other conclusions that there was no statistically significant association between PFOS exposure and various cancer incidences; these two facts are not mutually exclusive. Additionally, a finding that lacks statistical significance can be used to support a conclusion of an effect (Wasserstein and Lazar, 2016; USEPA, 2022a); other factors, such as biological significance of the observed effect, also contribute to the EPA's conclusions regarding the effect.

The commenter also mistakenly combines results from multiple epidemiological studies assessing different target organs and cancer types (e.g., bladder, liver, prostate, breast) and also disregards study evaluation results to overstate null results observed in the PFOS epidemiological evidence stream. Critically, null results reported in one tumor site or study does not negate positive results reported in other tumor sites or studies. As stated in the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005), "Null results from epidemiologic studies alone generally do not prove the absence of carcinogenic effects because such results can arise either from an agent being truly not carcinogenic or from other factors such as: inadequate statistical power, inadequate study design, imprecise estimates, or confounding factors. Moreover, null results from a well-designed and well-conducted epidemiologic study that contains usable exposure data can help to define upper limits for the estimated dose of concern for human exposure in cases where the overall weight of the evidence indicates that the agent is potentially carcinogenic in humans."

For example, the commenter raised concerns about several studies on breast cancer (Bonefeld-Jørgensen et al., 2011; Cohn et al., 2020; Hurley et al., 2018) without providing further context. The EPA acknowledges evidence for an association between elevated exposure to PFOS and increased risk of breast cancer is mixed; there are factors related to study design that add a degree of uncertainty for this association. Several studies did not consider differences between breast cancer types (Bonefeld-Jørgensen et al., 2011; Cohn et al., 2020), which is especially important in light of other studies that consistently reported significantly increased risk of Progesterone Receptor Positive (PR+) and Estrogen Receptor Positive (ER+) breast cancer with elevated PFOS exposure (Mancini et al., 2020; Tsai et al., 2020). Analyzing all breast cancers combined, regardless of type, can limit specificity and the ability to draw conclusions about coherence between studies. Considering all available breast cancer studies identified by the EPA, five studies (5/13) reported an increased risk of breast cancer, which provides supports conclusions of a potentially increased risk of breast cancer with increasing PFOS exposure, but the overall evidence remains mixed due to study design issues, lack of replication of the results, and a lack of mechanistic understanding of the potential relationship between PFOS and specific breast cancer subtypes. The EPA considered all of these factors and others described in this response and in section 4.1.4 of the EPA response in this *Response to Comments* document, when developing conclusions about the weight of evidence for the carcinogenic potential of PFOS, in addition to statistical significance of the results.

The other studies mentioned by the commenter (Fry and Power, 2017; Ducatman et al., 2015) reported results for cancer outcomes that did not have a significant impact on the conclusion of the assessment. Fry and Power (2017) analyzed mortality due to any cancer type, thus combining all cancer types and providing an estimate of mortality risk that lacks specificity to a specific cancer type. Since the mode of action (MOA) can vary by cancer type, analyzing all-cause cancer mortality may dilute associations for specific types of cancer (e.g., liver or kidney cancer). Ducatman et al. (2015) examined associations between elevated PFAS exposure and changes in prostate-specific antigen (PSA), not incidence of prostate cancer. While PSA has historically been used for prostate cancer screening, Ducatman et al. (2015) acknowledge the complexities of using PSA as a screening tool due to other potential causes of elevated PSA (e.g., prostate hyperplasia, prostate inflammation, urinary retention, local trauma, and age). While the study was well-conducted, the uncertainty related to PSA's specificity as a biomarker of effect for prostate cancer and lack of a specific analysis of the association between elevated PFOS exposure and risk of prostate cancer limited the study's impact on the assessment's conclusions.

Fourth, the commenter raised concerns about and compared the results of Eriksen et al. (2009) and Shearer et al. (2021) to argue that the EPA's methodologies for evaluating studies were flawed. The commenter claimed that those two studies are similar for various reasons but received different ratings for several study evaluation domains: exposure measurement, outcome ascertainment, and analysis. In addition, the commenter mentions characteristics of the studies (such as the journal of publication) that are irrelevant to the risk of bias assessment (USEPA, 2022a). The EPA agrees that the studies are similar in quality, hence the overall determination of *medium* confidence for both. However, the study designs are different (case-control vs. prospective cohort), as is the level of detail reported in the studies that allows the reviewers to assess potential for bias. *Good* ratings are typically given to studies that provide detailed information regarding the domain under evaluation, such that the potential for bias can be thoroughly assessed or inferred (USEPA, 2022a). For example, for the exposure measurement domain, Shearer et al. (2021) provided details on blinding of laboratory staff and inclusion of matched case-control pairs within the same analytical batch to mitigate differences due to potential inter-batch variation, which resulted in a *Good* rating for this domain. For the outcome ascertainment domain, early-stage cases of cancer would be less likely to be missed in Shearer et al. (2021) since the study participants were routinely screened for cancer as a part of the Prostate, Lung, Colorectal, and Ovarian Screening Trial (PLCO) Screening Trial. Unlike Eriksen et al. (2009), the analysis presented in Shearer et al. (2021) also included exploration of non-linearity, stratified and sensitivity analyses, and an analysis including only those without evidence of diminished kidney function.

Finally, the commenter stated that the EPA failed to mention the null liver cancer results reported by Eriksen et al. (2009). While results from Eriksen et al. (2009) were generally imprecise, other evidence has since been identified supporting associations between PFOS serum concentrations and liver cancer in humans (i.e., Goodrich et al. (2022) and Cao et al. (2022)), thus also supporting the assessment conclusion of PFOS as *Likely to Be Carcinogenic to Humans* (USEPA, 2024c). A single epidemiological study reporting null results does not detract from

animal toxicological evidence of increased incidence of tumors due to contaminant exposure, regardless of whether the studies report on the same tumor site. The EPA relies on three evidence streams (i.e., epidemiological, animal toxicological, and mechanistic studies) to conduct hazard identification and support cancer classifications. The EPA also considers evidence across all tumor types when determining cancer classifications (USEPA, 2005). For liver cancer in particular, the EPA has provided additional discussion of all epidemiological studies reporting on incidences of liver carcinogenicity in the final toxicity assessment for PFOS (USEPA, 2024c).

The EPA classified PFOS as *Likely to Be Carcinogenic to Humans* based on evidence of carcinogenicity from animal studies and consistent mechanistic evidence of multiple potential MOAs for the tumors observed in animal studies, along with plausible but limited epidemiological evidence (USEPA, 2023a; USEPA, 2024c, Sec. 3.5.5). Although site concordance between human and animal studies is not always expected given biological differences between species (USEPA, 2005), the commenter correctly noted the importance of looking across studies reporting similar cancer types in humans and animal models. Two general population studies published since the 2016 HESDs and postdating the draft *Proposed MCLG* document (USEPA, 2023a) provide evidence of an association between PFOS and liver cancer in humans (Cao et al., 2022; Goodrich et al., 2022). A *medium* confidence nested case-control study of participants in the Multiethnic Cohort (MEC) Study in the United States observed significantly increased odds of non-viral HCC when comparing those above the 85th percentile of PFOS exposure to those below (OR = 4.50, 95% CI: 1.20, 16.00) (Goodrich et al., 2022). Results were similar in continuous analyses of PFOS exposure. A *low* confidence general population case-control study conducted in China observed significantly elevated odds of liver cancer incidence with increasing PFOS exposure (OR = 2.609, 95% CI: 1.179, 4.029, p-value for trend = 0.001) (Cao et al., 2022). Of the two studies reporting on liver cancer identified in the 2016 HESD (USEPA, 2016b), one study reported positive, non-significant evidence of an increased risk of liver cancer (Alexander et al., 2003). As noted by Alexander et al. (2003), some imprecision is expected due to a lack of individual exposure level measures or analyses (which could introduce exposure misclassification) and a lack of adjustment for potential confounders, such as smoking, both of which are common for standardized mortality ratio studies. The findings in a Danish population-based study (Eriksen et al., 2009) did not provide evidence of an increased risk of liver cancer and were generally imprecise, likely due to the small number of exposed cases. Another important difference between Eriksen et al. (2009) and Goodrich et al. (2022) is the specificity of the analysis for histological subtype. Eriksen et al. (2009) reported on all liver cancers, however, during the study's follow-up period, the incidence of HCC did not make up a large portion of liver cancers in the Danish population (Jepsen et al., 2017). More recently, the incidence of HCC has dramatically increased in the Danish population, and a follow-up study may be warranted (Jepsen et al., 2017). In response to this comment, discussion of these studies, including Eriksen et al. (2009), has been updated in the final toxicity assessment for PFOS (Section 3.5, USEPA, 2024c). Overall, the epidemiologic studies evaluating the association between PFOS exposure and liver cancer, provide sufficient evidence of an increased risk with increasing exposure (3/4). These findings further support the EPA's conclusion that

PFOS is *Likely to Be Carcinogenic to Humans* and provides tumor site concordance between the animal toxicological and human studies.

3M Company (Doc. #1774, SBC-053190)

2. Animal Evidence

EPA made similar process errors in determining that PFOS is "likely to be carcinogenic to humans" based on the results of neoplastic tumor data for the liver and pancreatic islet cells from a 2-year chronic dietary study (cited as Thomford, 2002 and Butenhoff et al. 2012, for the original study report and published peer-reviewed manuscript, respectively). While the original study data (by Thomford 2002) reported statistically significant increases in liver adenoma incidences in both male and female rats at the highest dose, it did not conclude such for the pancreatic islet cell tumors.

With regards to the hepatocellular tumor data observed in rats, EPA did not take the known biological plausibility into consideration as it related to human health and used two different models to interpret animal studies regarding PFOS carcinogenicity, which violates its own Guidelines for Carcinogenic Risk Assessment. In the draft PFOS appendix (USEPA 2023d), EPA states about data on hepatocellular adenomas and carcinomas in female rats, "the best fitting model was the Multistage Degree 1 model based on adequate p-values" (p. E-55 and p. E-58). It based its selection of a BMDL10 [FN67: BMDL10 is the benchmark dose level corresponding to the 95% lower confidence limit of a 10% change.] on this model. For data for hepatocellular adenomas in male rats, EPA stated "the best fitting model was the Multistage Degree 4 model based on adequate p-values" (p.E-47). EPA fails to explain the use of different models for studies involving male and female rats in evaluating the evidence of carcinogenicity. In doing so, EPA violates its 2005 Guidelines for Carcinogen Risk Assessment, which states, "goodness-of-fit to the experimental observations is not by itself an effective means of discriminating among models that adequately fit the data."

EPA deemed the study by Butenhoff et al (2012) a "high confidence study" (USEPA 2023c, p. 3-260), which should add to the importance of its correct interpretation and the representation of the study's result. However, EPA over-interpreted the importance of a "statistically significant trend of increased incidence of pancreatic islet cell carcinomas with increased PFOS dose" in male rats in the cancer classification section (USEPA 2023c, p. 3-296). It is important to understand that a trend, even if it is statistically significant, simply indicates a non-zero slope among data points. A trend is non-quantitative and does not imply that the magnitude of the increase in effect over increasing dose ever reaches biological significance, or that it would result in the observation of statistically significant increase in effects. A trend simply means that there is a consistent change within the observed parameters across the doses that were investigated. This does not necessarily mean that it continues to persist when additional experimental data is introduced, or that it ever reaches statistical or biological significance before reaching a

physiological maximum dose limit such as stomach capacity for dosing, or the natural lifetime of rats.

With regards to the pancreatic islet cells tumors, the EPA improperly employed an alternative statistical approach which led to a statistical significance in trend for the pancreatic islet cell carcinoma. Specifically, the original study report by Thomford (2002) calculated the total tumor incidence rate based on the total number of the tissues examined per specific dose group upon study termination at the end of two years. Given that age-related mortality is quite common among rodents in long-term studies, it is worth noting that the original statistical trend analysis (reported in Thomford 2002) did adjust for survival and survival was taken into account for the logistic regression of tumor prevalence and binary regression analyses. The EPA, on the other hand, calculated the tumor incidence rate based on the number of animals alive at the time when the tumor first occurred, which was an attempt to adjust for survival as well as excluding a subset of rats from control (n=10) and the highest dose group (n=10) that were sacrificed at week 52. While the EPA does not have any specific publication on how to analyze tumor incidence data, the guidance document from U.S. FDA Center for Drug Evaluation and Research (Lin 2007) summarizes various ways of analyzing tumor data in rodents by adjusting for intercurrent mortality, it did not, however, mention this particular approach taken by the EPA.

It was also not best practice to exclude subsets of rats from control (n=10) and the highest dose group (n=10) that were sacrificed at week 52 from the overall trend analysis for tumors, given that the trend test was adjusted for survival. All the animals in these two subgroups were subject to the same rigor in terms of specimen collections and pathology evaluations for potential presence or progression of tumor formations, if any. This was the ultimate purpose of the 2-year cancer study hence if anything, the interim evaluations (with proper survival time adjustment) did not "dilute", but rather, reflect additional statistical power to ascertain the likeliness of tumor outcome. Furthermore, in accordance with the guidance from the American Statistical Association (Wasserstein and Lazar 2016), a hard cut-off for statistical significance on its own should not be used to make scientific conclusions – "Scientific conclusions and business or policy decisions should not be based only on whether a p-value passes a specific threshold." Therefore, the interpretation should not be based on whether a p-value is above or below 0.05. On that note, the relationship between pancreatic islet cell carcinoma and PFOS treatment is further called into question because there was no increased incidence of pancreatic islet cell hyperplasia (Thomford 2002). This is important because an increase in islet cell hyperplasia is typically viewed as a continuum to develop islet cell neoplasm.

Lastly, best practice required consideration that it has been well-documented that there are substantial differences in pancreatic islet cells between rodents and humans in terms of anatomy, cellular components, gene expressions, and functional aspect of insulin secretion (Brissova et al. 2015; Steiner et al. 2010). For instance, human islet cells contain less β-cells and more α-cells relative to rodents; and the pancreas tissue in rats are highly vascular. The species difference in pancreatic islet architecture and composition begs the question regarding the interpretation and extrapolation of rodent data finding to humans.

EPA Response: As discussed throughout the administrative record and consistent with the SDWA, the EPA disagrees that there were process issues related to the development of the toxicity assessments for PFOA and PFOS; the EPA has identified and used the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices and data collected by accepted methods or best available methods and considered internal review and external peer-review input in reaching conclusions (see sections 4.1.2 and 4.1.3 of the EPA response in this *Response to Comments* document).

The commenter stated that the EPA failed to explain its use and selection of different models to quantify the observed hepatocellular tumors in male and female rats, which the commenter stated was inconsistent with the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005). The EPA disagrees. First, the quantification of the observed dose-dependent increase in hepatocellular tumors in males and female rats is inconsequential to the cancer classification applied to PFOS. The EPA concluded that PFOS is L*ikely to Be Carcinogenic to Humans* because of the observed multi-sex and multi-site tumorigenesis in response to PFOS exposure, including hepatocellular tumors (Thomford, 2002; Butenhoff et al. 2012a) in line with the 2005 Cancer Guidelines (USEPA, 2005). Regardless, the EPA disagrees that the agency did not provide further explanation aside from model fit as to why specific model outputs were selected; the EPA explained the selection of models in quantifying the hepatocellular tumors in male and female rats. For male hepatic adenomas, the EPA stated on page E-48 of the draft toxicity assessment for PFOS that all multistage models had "adequate fit (p-values greater than 0.1), [and] the BMDLs were sufficiently close (less than threefold difference)," however, "the Multistage Degree 4 model had the lowest AIC" (USEPA, 2023c). Similarly, for the hepatocellular adenomas and carcinomas in females, the EPA stated on page E-58 that all multistage models had "adequate fit (p-values greater than 0.1), [and] the BMDLs were sufficiently close (less than threefold difference)," however, "the Multistage Degree 1 model had the lowest AIC" (USEPA, 2023c). Therefore, the EPA did not rely solely on the p-values for model selection as the commenter suggests but did follow the recommendations provided in the EPA's *Benchmark Dose Technical Guidance* when considering and selecting models to derive PODs (Section 2.3.2, USEPA, 2012). In response to this comment, the EPA updated the language describing model selection in Appendix E and Section 4.2 of the final toxicity assessment for PFOS to ensure clarity (USEPA, 2024c; USEPA, 2024b). The EPA followed the standard, recommended approach "to prefer the multistage model for cancer dose-response modeling of cancer bioassay data (Gehlhaus et al., 2011). The multistage model (in fact a family of different stage polynomial models) is sufficiently flexible for most cancer bioassay data, and its use provides consistency across cancer dose-response analyses" (USEPA, 2012).

The commenter also mistakenly claimed that the EPA did not consider biological plausibility of hepatocellular tumors in rats when, in fact, the EPA did consider this factor in an extensive analysis of the MOA for hepatocellular tumors in rats (Section 3.5.4.2 of the draft toxicity assessment published for public comment; USEPA, (2023a)), as well as the final PFOS toxicity assessment (USEPA 2024b). In this section, the EPA addressed the question of human relevance of hepatocellular tumors in rats and concludes that "there is an absence of definitive information

supporting a single, scientifically justified MOA; in fact, there is evidence supporting the potential for multiple plausible MOAs." More specifically, the EPA determined that the MOA for hepatocellular tumors in rats was not entirely dependent on peroxisome proliferator-α activity, a MOA that this commenters and others claim may not be relevant to humans (Klaunig et al., 2003; Corton et al., 2014; Corton et al., 2018). The EPA identified several other potential modes of action for liver tumors that have human relevance (e.g., a cytotoxicity MOA) and may also play a role in the hepatic tumors resulting from PFOS exposure observed in rats. However, the EPA does not have adequate data to make a definitive conclusion about the mode(s) of action operative for PFOS-induced liver tumors, though a definitive conclusion about the MOA(s) underlying a particular tumor type are not required for determination of human relevance or to support the cancer classification for a contaminant. According to the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005), "[i]n the absence of sufficiently, scientifically justifiable mode of action information, EPA generally takes public health-protective, default positions regarding the interpretation of toxicologic and epidemiologic data; animal tumor findings are judged to be relevant to humans." This conclusion has since been strengthened by the publication of two epidemiological studies that show positive associations between PFOS and HCC in humans (Cao et al., 2022; Goodrich et al., 2022). Results of both studies are provided above in the EPA response to comment Doc. #1774, SBC-053187 in section 4.1.4.2 in this *Response to Comments* document. The EPA also describes the implications of these studies in section 3.5.1 of the final toxicity assessment for PFOS (USEPA, 2024c).

The commenter correctly stated that Thomford (2002) did not make conclusions about the pancreatic islet cell carcinomas observed in male rats. The commenter incorrectly argued that because the Butenhoff et al. (2012a) study was rated *high* confidence, the EPA should assume that the study authors correctly interpreted the pancreatic islet cell tumor data. Importantly, conclusions about the study confidence rating for the Butenhoff et al. (2012a) study are irrelevant to discussions on pancreatic islet cell tumors because the Butenhoff et al. (2012a) study does not include the pancreatic tumor data from the Thomford (2002) report. Therefore, the EPA cannot rely on the study author's conclusions regarding pancreatic islet cell tumors. Moreover, as part of the systematic review process, the EPA critically evaluates the available data through study quality evaluations and data extraction of individual studies as part of the systematic review process. Study quality evaluations are independent from the direction or magnitude of study findings (USEPA, 2022a). During the data extraction step, the EPA may extract the context surrounding study findings (e.g., the author's conclusions regarding an endpoint), although the study optimally provides quantitative dose-response data that can facilitate development of toxicity values (i.e., RfDs and CSFs), which the EPA extracts regardless of magnitude or direction of effect or of the author's conclusions about said data (USEPA, 2022a). The EPA analyzes the information provided in peer-reviewed studies as well as unpublished studies which contain data collected by accepted methods or best available methods (in this case, studies submitted under TSCA Section 4 (chemical testing results); Section 8(d) (health and safety studies); Section 8I (substantial risk of injury to health or the environment notices); and For Your Information (FYI) submissions consistent with USEPA,

2022a) to make data-driven, independent weight of evidence determinations regarding the conclusions of individual studies as well as conclusions about the entirety of evidence for an endpoint or health outcome.

The commenter described several other criticisms of the EPA's qualitative and quantitative analysis of the pancreatic islet cell carcinoma however, the commenter did not provide substantive scientific justification for why the EPA's approach should be adjusted according to the commenter's recommendations. The commenter first noted that "the original study report by Thomford (2002) calculated the total tumor incidence rate based on the total number of the tissues examined per specific dose group upon study termination at the end of two years." However, the commenter did not specify where in the Thomford (2002) report the data can be found. The EPA identified Table 38 or Text Table 5, as potentially having the information the commenter referred to, with limitations. In Table 38, Thomford (2002) provides incidence data for only the animals that survived to terminal sacrifice (week 104). If the EPA had used this data, it would have excluded several animals that presented with evidence of islet cell carcinoma formation upon necropsy at the time of premature death (i.e., prior to week 104). The inclusion of animals that die prior to the last day of chronic treatment in statistical analyses is standard practice at the EPA (e.g., USEPA, 2011; Jinot et al., 2017) and across health agencies, including the NTP (e.g., NTP (2020)) and California Environmental Protection Agency (e.g., CalEPA, 2021) and is an accepted and agreed-upon practice in the field (Haseman et al., 1984; Gart et al., 1979; Hoel and Walburg, 1972). In fact, Butenhoff et al. (2012a) reported a subset of data from the Thomford (2002) report, including the observed hepatocellular tumors, which included animals that died prematurely in the statistical analyses of other neoplastic lesions.

In Text Table 5, Thomford (2002) provides all reported incidences of pancreatic islet cell carcinomas in rats intended for the terminal necropsy (104 weeks; n = 50 per dose group) and the 53-week interim necropsy (n = 10 for control and high dose groups only). The number of animals presenting with tumors in each dose group reported in this table are the same as the number of animals the EPA used in its quantification of carcinogenic effects (i.e., PFOS CSF derivation; 1, 2, 2, 5, and 5 animals with pancreatic islet cell tumors in the 0, 0.5, 2, 5, and 20 ppm dose groups, respectively). However, in this table, Thomford (2002) combined the total number of animals examined across both the terminal and interim sacrifice time points. This led to an addition of 10 animals, none of which presented with pancreatic islet cell tumors, in the control (0 ppm) and high dose (20 ppm) groups. The EPA determined this approach to be biologically and statistically inappropriate. From a biological perspective, this approach was inappropriate because the prevalence and severity of lesions, particularly neoplastic lesions, is expected to be very different in animals that were administered PFOS for only half the exposure duration (i.e., 53 weeks) compared to the animals assigned to terminal sacrifice (i.e., 104 weeks). As stated in the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005), "[b]ecause of the often long latency period in cancer development, the likelihood of observing an effect also depends on whether adequate time has elapsed since exposure began for effects to occur." Indeed, there is no evidence to support that rats treated with PFOS according to the study design used by Thomford (2002) would present with pancreatic carcinomas after only 53 weeks of

exposure; the first reported incidence of pancreatic islet cell carcinoma in male rats was day 542 (approximately 77 weeks). From a statistical perspective, this approach is inappropriate because, in contrast to the commenter's claims that combining these groups "reflect[s] additional statistical power to ascertain the likeliness of tumor outcome," it decreases the percent of animals with tumors in the high dose group by adding animals that were highly unlikely to present with neoplastic lesions to the total number of animals examined, effectively biasing this response towards the null. While increasing the sample size of animals *treated in the same way* (i.e., administered PFOS for 104 weeks) would increase the statistical power of the response, combining groups that were treated very differently (e.g., when some animals were administered PFOS for half the exposure duration of another group) does not. This is supported by the observed decrease in the p-value associated with the trend test for this response reported by Thomford (2002): including the 10 interim animals in the control and high dose groups results in a p-value of $p = 0.0681$ while the p-value resulting from the EPA's independent analysis excluding the 10 interim animals in the control and high dose groups is $p = 0.0390$. Additionally, draft guidance from the Food and Drug Administration (FDA) states that in a situation when there are no observed tumors in animals from earlier time intervals, "the data for these intervals will not contribute anything to the test statistic, and these intervals may be ignored" (FDA, 2001). These biological and statistical implications are also the basis of the EPA's rationale for excluding rats that experienced premature mortality at a time prior to the first recorded occurrence of pancreatic islet cell tumors from statistical analyses and CSF derivation. As the EPA noted in both the draft and final PFOS toxicity assessments, "[e]xpressing incidence in this way quantitatively eliminates animals that died prior to the PFOS treatment duration plausibly required to result in tumor formation in the critical study" (USEPA, 2023a; USEPA 2024b). The EPA also notes that this is the same approach used for the cancer assessment of PFOS conducted by CalEPA (CalEPA, 2021) and has been used previously by the EPA (e.g., Jinot et al., 2017).

The commenter lastly questioned the significance of these tumors providing citations related to pancreatic hyperplasia and species-specific differences in pancreatic function. First, the commenter stated: "…there was no increased incidence of pancreatic islet cell hyperplasia (Thomford 2002). This is important because an increase in islet cell hyperplasia is typically viewed as a continuum to develop islet cell neoplasm." However, the commenter did not provide a citation supporting the claim that hyperplasia is a "continuum to develop pancreatic islet cell neoplasm" or that the observance of increased hyperplasia is necessary to consider the observed islet cell neoplasms significant. Second, the commenter stated that there are differences in pancreatic islet cells between rodents and humans and that these differences "begs the question regarding the interpretation and extrapolation of rodent data finding to humans." To address this issue, the EPA conducted a MOA analysis to identify information that may explain key events in the development of pancreatic islet cell tumors resulting from PFOS exposure. This discussion is available in Section 3.5.4.3 of the final toxicity assessment for PFOS (USEPA, 2024c). After review of the few available studies exploring the relationship between PFOS exposure and pancreatic tumors, the EPA determined there are currently no established modes of action for pancreatic islet cell carcinogenicity in humans or animals exposed to PFOS. As noted in a recent

review of the molecular mechanisms of pancreatic islet cell (i.e., neuroendocrine) tumors, "[a]lthough [pancreatic neuroendocrine tumors] originate primarily from aberrantly proliferating cells of the endocrine pancreas, they can also develop from pluripotent cells of the exocrine pancreas" (Maharjan et al., 2021). Some studies suggest a role for PPARα and PPARγ in rat and human pancreatic islet cell function (Sugden et al., 2001; Dubois et al., 2000; Roduit et al., 2000; Eibl et al. 2001), though PPARα activation has been argued to be related specifically to pancreatic acinar cell tumors rather than to islet cell tumors (e.g., Klaunig et al., 2003). Other studies have shown that PFOS exposure can lead to reduced pancreatic islet cell size and viability and can induce reactive oxygen species (ROS) (Qin et al., 2022). Considerable uncertainty remains in the underlying mechanisms of PFOS-induced pancreatic islet tumors. According to the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005), ""[i]n the absence of sufficiently, scientifically justifiable mode of action information… animal tumor findings are judged to be relevant to humans."

Additionally, Steiner et al. (2010), cited by the commenter, states that structural differences between the pancreas of various species may reflect "adaptation induced by altered physiological conditions, rather than inherent disparities between species." The authors provided an example of this in rodents, "the islets from diabetic *db/db* leptin receptor mutant mice display a random internal organization with a higher ratio of α-cells similar to that seen in humans," illustrating how physiological or genetic conditions may alter pancreatic cellular organization. Due to potential interindividual variability in human pancreatic structure, there remains significant debate over similarities with the rodent pancreas. Bonner-Weir et al. (2015) described this further and concluded "the human islet is similar to the rodent islet," regarding β-cell numbers, islet cell patterns, and blood vessel-islet structure and interactions, issues that were raised by the commenter.

Finally, the EPA's guidelines state that "site concordance is not always assumed between animals and humans," meaning that the occurrence of pancreatic tumors in rats may not necessarily translate directly to the occurrence of pancreatic tumors in humans (USEPA, 2005). The observation of pancreatic tumors in rodents reflects on the carcinogenic potential of PFOS in general, and not necessarily a particular tumor type expected to occur in humans.

3M Company (Doc. #1774, SBC-053196)

3. Mechanistic Evidence

EPA's processes also undermine its conclusion that PFOS is likely to be carcinogenic to humans based on mechanistic evidence. Mechanistic evidence is critical to support the relevance of data to carcinogenicity, with specific focus on relevance to carcinogenicity in humans. Mechanistic information is relevant to assess the applicability of findings in animals to human cancer risk. EPA (USEPA 2005) specifically emphasizes the importance of making "decisions about potential modes of action and the relevance of animal tumor findings to humans." As discussed below, profound uncertainties compromise the agency's following statement about hepatic tumors in

animals: “the available studies provide varying levels of support for the role of several plausible MoAs: PPARα activation, chimeric antigen receptor (CAR) activation, hepatocyte nuclear factor 4 alpha (HNF4α) suppression, cytotoxicity, genotoxicity, oxidative stress, and immunosuppression.” (USEPA 2023c, p.3-284). Each of these modes of action is discussed below.

PPARα Activation. EPA’s treatment of PPARα as a viable theory for carcinogenicity applicable to humans directly contradicts its own scientists’ conclusions. EPA scientists previously published a peer-reviewed article with the title “The PPARα-dependent rodent liver tumor response is not relevant to humans” (Corton 2018) (emphasis added), which EPA cites in the proposed NPDWR. The agency failed to acknowledge its own scientists’ key finding that “[t]he PPARα-dependent rodent liver tumor response is not relevant to humans.” EPA’s insistence on the relevance of this pathway with respect to PFOA and PFOS is further drawn into question by findings from EPA scientists who demonstrated last year (Evans et al. 2022) that the endogenous fatty acid oleic acid, which is also ubiquitous in the diet, is a more potent PPARα activator than are PFOA (by more than 1 order of magnitude) and PFOS (by more than 2 orders of magnitude). If PPARα activation were a relevant pathway to human liver tumors, that disease state presumably would be at epidemic levels, based on oleic acid alone.

In addition, EPA (Evans et al. 2022) reported concentrations of PFOS and PFOA that did not induce PPARα activity, which demonstrates that this alleged key MOA for carcinogenicity is, if anything, a proven threshold effect. Best practice would be to apply those insights to the carcinogenicity assessment of PFOS and PFOA and abandon the principle of a linear non-threshold dose response.

CAR Activation. In 2016, EPA referenced Hall et al.’s (2012) conclusion that, “CAR activation can lead to hepatocyte proliferation and hepatocarcinogenesis in animals. The human CAR receptor is relatively resistant to mitogenic effects and less likely to induce cancers through this mechanism.” EPA referenced the same publication elsewhere in the 2023 draft proposal for PFOS but neglected to report the same conclusion regarding the implausibility of CAR as MoA for PFOS carcinogenicity. EPA vaguely alluded to Hall’s conclusion on CAR in the PFOA draft proposal but failed to acknowledge its fundamental implications for human cancer risk.

Every event that is elicited by receptor binding is a threshold effect. A zero-effect threshold is inevitable at concentrations where insufficient numbers of activating molecules are present to trigger a biological signaling cascade and, thus, a response. Receptor-mediated theories warrant dismissal if proven inapplicable for human risk assessment; otherwise, they should be considered threshold effects. EPA did neither.

HNF4a Suppression. Beggs (2016) reported that concentrations of 10,000 nanomolar (nM) PFOA and PFOS had statistically significant impacts on HNF4α expression in primary human hepatocytes—and lower concentrations (i.e., 10, 100, 500, 1,000 nM) did not. This observation demonstrates the existence of a threshold below which no effect was observed. Best practice is to discontinue the use of a non-threshold approach for both PFOS and PFOA and instead use PBPK

modeling based on concentrations in drinking water to compare in vitro no-effect concentrations to expected concentration within human hepatocytes.

Cytotoxicity. In the draft document for PFOS (USEPA 2023c, p. 3-292), EPA states, "the available data indicate a parallel dose response for cytotoxicity and the formation of liver tumors as evidence in Table 3-24 and Table 3-25." It is unclear how EPA reached this conclusion from data that only show statistical significance for hepatocellular adenomas and combined hepatocellular adenomas and carcinomas, and for none of the other (cytotoxicity) endpoints. Variations on a cellular level cannot cause statistically significant tumor formation at a dose where those cellular changes are not also statistically significantly increased. A molecular event cannot be responsible for a pathological response if the dose-response curves are parallel and not intersecting. For PFOA, EPA presents evidence of cytotoxicity in vivo (i.e., "significantly increased single cell (hepatocyte) death and in necrosis in male and female was reported in Sprague-Dawley rats, with a significant dose-response trend"), but fails to conduct a dose-response assessment. Only effect concentrations of in vitro assays are mentioned in the draft document, none of which are lower than 10 µM. EPA lists non-cytotoxic concentrations but fails to use them as demonstrable no-effect levels to justify a threshold assessment of carcinogenicity.

The assessment of cytotoxicity lacks the diligence that is warranted if it is considered a key event in carcinogenesis. [FN68: It is inappropriate for EPA to set a MCLG at zero based on carcinogenicity when a substance does not have a linear mode of carcinogenic action. Chemistry Council v. EPA, 206 F.3d 1285, 1287 (D.C. Cir. 2000). When a substance exhibits a "cytotoxic" mode of action, no carcinogenic effects at low doses, a zero MCLG based on carcinogenicity is not in line with the goals of the SDWA. While there is uncertainty in the range at which no known or anticipated adverse effects on the health of persons occur, this does not mean that EPA can simply default to zero. Uncertainty allows EPA to choose the lowest MCLG within the window of uncertainty but it does not justify choosing an MCLG outside of the range of uncertainty. Id. At 1290.]

Genotoxicity. EPA concluded based on the available in vivo mutagenicity study (Wang et al. 2015) that "the evidence for mutagenicity of PFOS in vivo is negative" (USEPA 2023c, p. 3-269). Addressing DNA damage, the agency stated, "it is important to note that rat models could be ineffective for determining micronucleus formation if study authors do not use appropriate methodologies because the spleen will remove micronucleated cells" (USEPA 2023c, p.3-269). This draws the biological relevance of other models and findings into question because an effective removal of micronucleated cells implies the neutralization of this hazard. EPA should explain why said findings in other models are applicable for assessing potential human carcinogenicity.

Immunosuppression. EPA (USEPA 2023c, p.3-295) states that "the only available study in Sprague-Dawley rats […] does not indicate that immunosuppressive effects are occurring at or below doses that result in tumorigenesis." This finding demonstrates that there is no toxicological evidence that immunosuppression is a plausible MoA on the organism level because a mechanism that supposedly underlies a carcinogenic effect should occur at the same

doses that cause tumors. EPA ignores the fundamental logic that a response (e.g., cancer) that occurs at doses below the no-observable-effect-level (NOEL) of another response (e.g., immunosuppressive effects) cannot be linked to or caused by the latter. By insisting that both are linked, EPA violates the basic principle of dose-response. According to EPA's Vocabulary Catalog for Drinking Water Technical & Legal Terms (see https://sor.epa.gov/sor_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists/search.do?details=&vocabName=Drink%20Water%20Tech%2Flegal%202009), the NOEL is defined as a "dose level at which no effects are noted" and dose response is defined as "the quantitative relationship between the amount of exposure to a substance and the extent of toxic injury produced". If the extent of toxic injury from immunosuppression is zero, then it cannot be in a quantitative relationship with cancer that allegedly occurs below the NOEL of immunosuppression.

The perpetual inconsistency of EPA's findings and interpretations warrants a detailed analysis to compare and contrast reported dose-responses and clinical relevance of experimental models.

4. Structural Similarities EPA inappropriately attempts to rely on the structural similarity between PFOA and PFOS to conclude that its carcinogenicity determination PFOA applies to PFOS. EPA's reasoning of structural similarity for cancer risk read-across (USEPA 2023c, p. 3-296) between PFOA and PFOS is also not supported by evidence. EPA states in its publication by Patlewicz et al. (2019) that "the Environmental Protection Agency had the greatest experience in using readacross" but failed to apply any of the best practices – or even apply its own Generalized ReadAcross Tool (https://www.epa.gov/chemical-research/generalized-read-acrossgenra#:~:text=Chemical%20read%2Dacross%20is%20a,(e.g.%2C%20structural%20similarity). EPA also did not follow the seven key steps in the workflow: 1. Decision context 2. Data gap analysis 3. Overarching similarity rationale 4. Analog identification 5. Analog evaluation 6. Data gap filling 7. Uncertainty assessment. The two PFAS substances differ in a key functional group, in that PFOA is a perfluoroalkyl carboxylic acid and PFOS is a perfluoroalkyl sulfonic acid. Carboxylic acids and sulfonic acids possess different physical-chemical properties, which not only explains their different technical applications but also suggests differences in disposition and dynamics on biological receptor sites. The agency stated that a "similar set of non-cancer effects have been observed after exposure to either PFOA or PFOS in humans and animal toxicological studies," implying that those effects were of relevance for cancer risk assessment, when in fact, only the consideration of key events that actually lead to cancer is of relevance. By definition, non-cancer events are not applicable for cancer risk assessment.

EPA Response: As discussed throughout the administrative record and consistent with the SDWA, the EPA disagrees that there were process issues related to the development of the toxicity assessments for PFOA and PFOS; the EPA has identified and used the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices and data collected by accepted methods or best available methods and considered internal review and external peer-review input in reaching conclusions (see sections 4.1.2 and 4.1.3 of the EPA response in this *Response to Comments* document). Please also refer

to the EPA response to comment Doc. #1774, SBC-053190 in section 4.1.4.2 in this *Response to Comments* document for initial discussion on the human relevance of tumors reported in animal toxicological studies.

The commenter repeatedly made claims about "best practices" or recommended approaches that they did not substantiate with citations. Additionally, the commenter repeatedly stated that the EPA should use a non-linear (i.e., threshold) approach for both PFOA and PFOS, a recommendation which is inconsistent with the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005). The EPA concludes that the MOA for PFOS induced liver tumors cannot be determined based on the available evidence. Therefore, in accordance with agency guidance, "[n]onlinear approaches generally should not be used in cases where the mode of action has not been ascertained" (USEPA, 2005). As described further below, the commenter made numerous erroneous claims regarding the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005) and the EPA's analyses of the mechanistic literature underlying the carcinogenicity of PFOS and PFOA.

The commenter is incorrect in its interpretation of the EPA's conclusions on the relevance of PPARα-induced liver tumors. The EPA toxicity assessments do not include statements that PPAR-alpha induced hepatic tumors are relevant to humans. In fact, the EPA states, "some have argued that the MOA for liver tumor induction by PPARα activators in rodents has limited-to-no relevance to humans, due to differences in cellular expression patterns of PPARα and related proteins (e.g., cofactors and chromatin remodelers), as well as differences in binding site affinity and availability (Corton, 2018; Klaunig, 2003)." However, the assessment also discusses several studies which report activation of PPARα in human cell lines (see section 3.4.1.3; USEPA, 2024c). The commenter incorrectly stated that the EPA did not consider the discussion by Corton et al. (2018) in its evaluation of MOAs for liver tumors in rats. Rather, in Section 3.5.4.2.4 (Mode of Action for Hepatic Tumors) of the draft and final toxicity assessment for PFOS (USEPA, 2023a; USEPA, 2024c), the EPA cites Corton et al. (2018) several times when discussing the key events associated with PPARα-induced hepatic tumorigenesis. The EPA explicitly states: "Therefore, for PPARα activators that act solely or primarily through PPARα-dependent mechanisms (e.g., Wyeth-14,643, di-2-ethyl hexyl phthalate), the hepatic tumorigenesis observed in rodents may be expected to be reduced in frequency or severity or not observed in humans (Klaunig, 2003; Corton, 2014; Corton, 2018)." However, evidence exists that the liver tumorigenic responses to PFOS and PFOA are likely not entirely PPARα-dependent. Prior to the release of the public comment draft toxicity assessments published at the time of rule proposal, the EPA reviewed data related to other mechanisms of carcinogenesis in the liver and identified information related to key events in the development of hepatic tumors resulting from PFOS and PFOA exposures (Section 3.5.4.2, USEPA, 2023f; USEPA, 2023a). Evidence for MOAs for hepatic tumors other than PPARα activation, namely constitutive androstane receptor (CAR) activation and cytotoxicity, were reviewed in addition to the evidence for the PPARα activation MOA. The data related to these additional MOAs not only generally provide further mechanistic evidence supporting the potential for multiple MOAs underlying

PFOS and PFOA hepatic carcinogenicity, but also provide evidence that hepatic tumors caused by these contaminants may be relevant to humans.

The commenter also noted that there are concentrations of PFOS or PFOA that do not induce PPARα activity and argues that this demonstrates a threshold effect. The EPA disagrees with this claim because, as shown in Section 3.5.4.2 of the PFOA toxicity assessment (USEPA, 2023f; USEPA, 2024d), male rodents demonstrated PPARα activation at every dose evaluated ranging from 1.1 to 23 mg/kg/day, with the exception of 20 mg/kg/day. Section in the PFOS toxicity assessment (USEPA, 2023a; USEPA, 2024c) similarly shows that doses of PFOS of 0.312 mg/kg/day and greater led to PPARα activation in male and female rodents. While doses lower than 0.312 mg/kg/day of PFOS did not result in PPARα activation (or subsequent hepatic tumors), all data related to doses <0.312 mg/kg/day are from a single study (Butenhoff et al., 2012a; Thomford, 2002). Nonetheless, as stated above, without a definitive MOA for PFOA- or PFOS-induced hepatic tumors, "[n]onlinear approaches generally should not be used" (USEPA, 2005). Thus, the lack of PPARα activation at some doses in a single study does not alone support a threshold effect, considering the fact that PPARα activation is not the definitive MOA for PFOS-induced hepatic tumors.

The commenter cited Evans et al. (2022), a study that measured PPARα activation in *in vitro* human and rat ligand binding domain assays, to support their position that the PPARα MOA is not relevant to humans. It should be noted that Evans et al. (2022) stated in their abstract, "*In vitro* measures of human and rat PPARα and PPARγ activity did not correlate with oral doses or serum concentrations of PFAS that induced increases in male rat liver weight from the National Toxicology Program 28-d toxicity studies," and the authors later stated, "The *in vitro* endpoints measured here were poor predictors of *in vivo* liver weight changes in male rats from the NTP 28-day studies." Given that the *in vitro* data in Evans et al. (2022) did not correlate with *in vivo* studies, those data should not be used as evidence to establish either that PFOA or PFOS do not induce PPARα activity at lower doses or a threshold. A lack of a statistically significant response in an *in vitro* assay could be interpreted as the limits of the study's sensitivity, not that the chemical is not interacting with the receptor below that dose level. Comparisons between oleic acid and PFOA or PFOS based on the Evans et al. (2022) data should similarly be viewed with caution. The commenter illogically stated, "If PPARα activation were a relevant pathway to human liver tumors, that disease state presumably would be at epidemic levels, based on oleic acid alone." If this statement was correct, all cancers that involve nuclear receptor activation would be at epidemic levels because of endogenous ligands, which is not the case. For example, endogenous estradiol would induce widespread cancers due to estrogen receptor activation. The commenter's assertion ignored the state of the science regarding complexities of nuclear receptor signaling pathways (e.g., positive and negative feedback loops) and cancer formation. As stated in the *Guidelines for Carcinogen Risk Assessment*, "carcinogenesis involves a complex series and interplay of events" (USEPA, 2005). Additionally, "[a]lthough important information can be gained from *in vitro* test systems, a higher level of confidence is generally given to data that are derived from *in vivo* systems, particularly those results that show a site concordance with the tumor data" (USEPA, 2005). Reliance solely on *in vitro* data would result in neglecting the

impact that differences in toxicokinetic factors, bioaccumulation, and elimination rates have on *in vivo* PFAS toxicity, which is clearly pointed out by Evans et al. (2022) as a relevant confounding factor for both PFOS and PFOA.

The commenter questioned the relevance of the CAR activation-induced rodent liver tumor response to humans. Prior to rule proposal, the EPA reviewed the available data related to key events in proposed MOAs to understand the plausibility that hepatic tumors resulting from PFOA or PFOS exposure develop through MOAs including CAR activation (PFOA Section 3.5.4.2.4 (USEPA, 2024d) and PFOS Section 3.5.4.2 (USEPA, 2024c)). The key events for the CAR activation MOA and the evidence underlying them are summarized in those sections. The EPA demonstrates that for PFOS, evidence for the CAR activation key events is generally not reported *in vivo*, however, there is evidence that PFOS activates CAR in human cell lines, in contrast to the commenter's claim that CAR activation is an implausible MOA for PFOS-induced carcinogenicity in humans. Similarly, for PFOA there is evidence that CAR activation, and subsequent alterations in CAR target gene expression, occur in male rodents (USEPA, 2024d). While the CAR activation MOA for liver tumors may have less evidence than some other MOAs, the available data show it to be a plausibly human-relevant MOA.

The commenter stated, "Receptor-mediated theories warrant dismissal if proven inapplicable for human risk assessment; otherwise, they should be considered threshold effects." It is worth repeating that the *Guidelines for Carcinogen Risk Assessment* state, "Nonlinear approaches generally should not be used in cases where the mode of action has not been ascertained" (USEPA, 2005), which is the case for both PFOA and PFOS. Additionally, the commenter's unsubstantiated statement that all nuclear receptor-mediated events should be wholly considered threshold effects is not supported with a citation, and the EPA disagrees with this position. The *Guidelines for Carcinogen Risk Assessment* discuss receptor binding and activation as one biological mechanism of tumor induction, but the *Guidelines* do not assert that this mechanism results in non-linear carcinogenicity (USEPA, 2005). In fact, determining that a carcinogen acts through a threshold (i.e., non-linear) MOA is difficult because it requires studies designed so that there is not "a small risk that falls below an experiment's power of detection" (USEPA, 2005). While it is true that receptor-mediated effects are typically dose-dependent, a threshold response is not always certain because non-threshold dose-responses may also occur for receptor-mediated carcinogens (Melnick et al., 1996; Bosland 2019). For example, as shown in the PFOA toxicity assessment, no identified study measured both CAR activation and hepatic tumors in male rodents at the same dose (USEPA, 2024d). CAR activation was observed for doses of 3, 10, 19, and 23 mg/kg/day PFOA for 1, 7, and 28 days, and hepatic tumors were noted at doses both lower and higher than 3 mg/kg/day in 2-year studies. Thus, it is unclear from the animal evidence whether CAR activation at PFOA levels lower than 3 mg/kg/day contributes to hepatic carcinogenicity. While CAR activation was not directly measured for PFOS, gene expression indicative of CAR activation (Key Event #2 in the MOA) was observed at doses as low as 0.312 mg/kg/day and as high as 1 mg/kg/day, and hepatic tumors were observed at 0.984 mg/kg/day in male rats (USEPA, 2024c). In female rats, altered expression of CAR target genes was observed at 0.312 and 0.625 mg/kg/day at 28 days of exposure, while tumors were not measured at these

doses. At 1.251 mg/kg/day, the tumorigenic dose in female rats, CAR target genes were differentially expressed in a different study of pregnant females exposed during gestation. CAR activation and altered gene expression related to CAR activation (the first two molecular events in the MOA) were not evaluated in the tumorigenicity studies, nor at the same doses across studies; thus, it is not possible to conclude a threshold effect based on the available data.

The commenter made similar incorrect statements about threshold responses related to HNF4α. While the commenter is correct that the *in vitro* results from one study (Beggs et al., 2016) reported significant effects for PFOA and PFOS at 10,000 nM but did not report significant effects on HNF4α protein expression in primary human hepatocytes at concentrations of 1,000 nM or lower, these data are not the sole evidence of HNF4α suppression by PFOA and PFOS. In another *in vitro* study, gene expression microarray data demonstrated that PFOA exposure inhibited HNF4α function in primary human hepatocytes, as evidenced by changes in gene targets of HNF4α using upstream regulator analysis (Buhrke et al., 2015). These changes were statistically significant at 25 and 100 µM PFOA. An *in vitro* study in HepaRG cells exposed to 1–100 µM PFOS corroborated these findings, as downregulations in both HNF4α and its target gene CYP7A1 were observed (Behr et al., 2020). Additionally, the *in vivo* results from Beggs et al. (2016) demonstrated that hepatic HNF4α protein expression was decreased *in vivo* in mice treated with 3 mg/kg/day PFOA or 10 mg/kg/day PFOS for seven days. The results from Beggs et al. (2016) are described in Section 3.4.1.3 of the toxicity assessment (USEPA, 2024c). To increase transparency, the EPA has expanded the description of these results in the final assessments (see Section 3.5.4.2 of USEPA, 2024d; USEPA, 2024c).

The commenter asserted that, "Best practice is to discontinue the use of a non-threshold approach for both PFOS and PFOA and instead use PBPK modeling based on concentrations in drinking water to compare *in vitro* no-effect concentrations to expected concentration within human hepatocytes." The commenter does not provide any basis for this assertion and does not provide the methods by which the EPA would do this. Additionally, agency guidance does not support this practice (USEPA, 2022a; USEPA, 2014a). The EPA does not agree that a threshold approach should be taken for this single endpoint based on one (PFOS) or two (PFOA) *in vitro* studies, nor does this endpoint support the application of a threshold approach for the assessments of PFOA or PFOS carcinogenicity. The commenter again did not provide a citation substantiating their claim that best practice would be to use a modeling approach based on *in vitro* data. Furthermore, the commenter's approach is inconsistent with recommendations regarding interpretation of mechanistic data outlined in the *ORD Staff Handbook for Developing IRIS Assessments* (e.g., Section 6.2.1, USEPA, 2022a).

Further, HNF4α suppression represents only one possible mechanism that may be related to hepatotoxicity and hepatic carcinogenicity of PFOA and PFOS but does not alone represent an established MOA. The EPA has organized sections within the Section 3.5.4.2 (Mode of Action Analysis) of the toxicity assessments to highlight proposed MOAs for which data are available across multiple key events, in contrast to mechanistic evidence that does not currently "map" to a specific proposed MOA (USEPA, 2024d; USEPA, 2024c). HNF4α suppression does not alone

satisfy the criteria in the *Guidelines* that must be met for a nonlinear approach to be selected for dose-response analyses: "when there are sufficient data to ascertain the mode of action and conclude that it is not linear at low doses and the agent does not demonstrate mutagenic or other activity consistent with linearity at low doses" (USEPA, 2005).

The commenter questioned the EPA's characterization of cytotoxicity as a key event in hepatic carcinogenesis. In the proposed rule, the EPA conducted a MOA analysis to identify and organize evidence related to key events in the development of hepatic tumors resulting from PFOA or PFOS exposure (PFOA Section 3.5.4.2.4 (USEPA, 2024d) and PFOS Section 3.5.4.2 (USEPA, 2024c)). Specifically, the EPA summarized the evidence underlying the cytotoxicity MOA for hepatic tumors at several doses. As shown in the PFOA assessment, there are doses at which both cytotoxicity is significantly increased and hepatic tumors occurred in male rats (specifically at 2.2 and 4.6 mg/kg/day for PFOA and 0.984 mg/kg/day for PFOS; NTP (2020), Thomford (2002), and Butenhoff et al. (2012a), respectively). The commenter stated, "Variations on a cellular level cannot cause statistically significant tumor formation at a dose where those cellular changes are not also statistically significantly increased." The commenter did not provide support or a citation for this statement. The EPA disagrees with this unsubstantiated statement; while cellular changes measured at earlier timepoints may not reach statistical significance, this does not preclude the possibility of a cytotoxic MOA nor does it provide evidence against a cytotoxic MOA. In response to this comment, the evidence for the key events in the tables of the final assessments (USEPA, 2024d; USEPA, 2024c) now differentiate between evidence that is reported but not statistically significant (labeled as "–") and lack of data (labeled as "not reported" or "NR"). Because the term "parallel" appeared to confuse the commenter, the EPA updated the language to more clearly describe consistencies in the dose-response relationships of this MOA (USEPA, 2024d; USEPA, 2024c). The intent of the statement, "the available data indicate a parallel dose response for cytotoxicity and the formation of liver tumors," was to demonstrate that the dose-response curves for cytotoxicity and for hepatic tumorigenesis were both non-monotonically increasing with dose.

The commenter erroneously stated that the EPA did not conduct dose-response assessments of cytotoxicity endpoints. For PFOS, BMD modeling for Butenhoff et al. (2012a)/Thomford (2002) for hepatocellular adenomas is included in PFOS Appendix E for male and female rats, for combined hepatocellular adenomas and carcinomas in female rats, and for individual cell necrosis in the liver for male and female rats(USEPA, 2024c; USEPA, 2024b). For PFOA, BMD modeling for NTP (2020) is included in Appendix E.2.6 (USEPA, 2024a). The EPA modeled hepatocyte single cell death in male rats following post-weaning exposure, necrosis in the liver in male rats following postweaning exposure, hepatocellular adenomas in male rats following postweaning exposure, and hepatocellular adenoma or carcinoma in male rats following postweaning exposure. Finally, BMD modeling for the endpoints of focal necrosis and individual cell necrosis in male mice was modeled from Loveless et al. (2008).

The commenter's statements appear to call into question the biological relevance of genotoxicity findings across all model organisms and assays because of the EPA's discussion of the biological

limitations and methodological requirements associated with one assay measuring micronuclei formation in erythrocytes in the peripheral blood of rats. The EPA disagrees with the commenter's extrapolation from this assay to all genotoxicity data because this particular issue is an established limitation of the micronuclei assay in rats, as described in the reference provided in the draft toxicity assessments (Schlegel and MacGregor, 1984). For example, the cells with point mutations and deletions detected by the transgenic rodent assay reported in Wang et al. (2015) would not have been subject to splenic removal and, therefore, not subject to this limitation. The EPA also notes that there is available literature describing optimal and reliable methods for quantifying micronuclei formation in rats (Witt et al., 2000; WHO, 2020). Because the studies reporting micronuclei in rats following PFOS and PFOA exposures were conducted according to these standards, thereby avoiding the potential for false negative results, the text describing this issue has been removed from the toxicity assessments. In addition, it should be clarified that the potential hazard of genetic damage from exposure to a genotoxic agent is not "neutralized" in animals with a spleen. The identification of genotoxic agents is facilitated by assays that are simple, sensitive, and specific to detecting heritable genetic alterations. The endpoint of micronucleus formation in immature or mature erythrocytes in mammalian peripheral blood has become a standard of genotoxicity testing due to the ease of the collection and analysis of these cells and serves as a marker for genotoxic risk to all exposed tissues, provided appropriate test conditions are employed (e.g., OECD 474).

The commenter asserted that immunosuppression cannot be a plausible MOA for carcinogenicity and misleadingly cited an out of context excerpt of one sentence from the draft PFOS assessment (USEPA, 2023a) to support this assertion. The commenter neglected to acknowledge the full scope of evidence for immunosuppression already provided. The full context of that paragraph in the PFOS document states:

"Animal toxicological studies also report markers of immunosuppression, including reductions in natural killer cell activity. As described in Section 3.4.2.2, there are several reports of decreased natural killer cell activity in male and female, adult and F1 generation mice from short-term, subchronic, and gestational studies (Dong, 2009; Peden-Adams, 2008; Keil, 2008; Zhong, 2016; Zheng, 2009). While one short-term study in male mice reported increases in splenic T-helper (CD3+CD4+) and T-cytotoxic (CD3+CD8+) lymphocytes (Lv, 2015), two gestational studies reported reductions in thymic CD4+ cells in male offspring (Zhong, 2016; Keil, 2008). There is also limited evidence of immunosuppression in the form of reduced white blood cell counts (primarily lymphocytes) from two short-term rodent studies in male mice and rats, respectively (Qazi, 2009; NTP, 2019c). This short-term report is the only available study in Sprague-Dawley rats and does not indicate that immunosuppressive effects are occurring at or below doses that result in tumorigenesis (NTP, 2019c). However, it is difficult to discount immunosuppression as a potential MOA for PFOS, given the limited database for rats and stronger databases indicating immunosuppression in mice and humans."

Information presented throughout the toxicity assessments describes the immunosuppressive effects of PFOA and PFOS, including immunosuppression observed in human epidemiological

studies (USEPA, 2024d; USEPA, 2024c). The evidence profile tables for Immune Effects, show the weight of the evidence from evaluating and synthesizing multiple human and animal studies which provide evidence for immunosuppression following PFOA and PFOS exposure (Section 3.4.2; USEPA, 2024d; USEPA, 2024c). Therefore, the EPA maintains that immunosuppression represents a plausible underlying mechanism involved in PFOA- and PFOS-induced tumorigenesis.

Finally, the commenter criticized the EPA's discussion on the structural similarities between PFOA and PFOS when determining the weight of evidence for PFOS carcinogenicity. A response to this comment is provided in section 4.1.4 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-053421)

In response to the SAB requests, EPA presents in the Public Comment Draft Assessments a finding of "likely to be carcinogenic" for both PFOA and PFOS. This is striking because EPA did so without an SAB recommendation. The SAB Report did not recommend a "likely to be carcinogenic" classification for PFOS. This new classification for PFOS relies on the same exact data that EPA used in the Draft PFOS Assessment, but EPA has reinterpreted it to raise the classification. In the December 2021 Draft PFOS Assessment, EPA recommended the "suggestive" classification, explaining that "[t]he available epidemiological and animal toxicity data suggest a potential concern for carcinogenic effects in humans but are not sufficient for a stronger conclusion."[FN125: See Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) (CASRN 1763-23-1) in Drinking Water (PFOS Draft Assessment), at page 312, available at: .epa.gov/ords/sab/f?p=100:18:16490947993:::RP,18:P18_ID:2601.] Yet, in the March 2023 Public Comment Draft Assessment, after discussing the same studies considered in 2016 HESD [FN126: U.S. EPA (2016) Health Effects Support Document for Perfluorooctanoic Acid (PFOA). (EPA 822-R-16-003). (HESD) Washington, DC, U.S. Environmental Protection Agency, Office of Water. .epa.gov/sites/default/files/2016-05/documents/pfoa_hesd_final-plain.pdf.] and in the 2021 Draft Assessment, EPA states "EPA has now determined the available data for PFOS surpass many of the descriptions for Suggestive Evidence of Carcinogenic Potential."[FN127: See Public Comment Draft Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) in in Drinking Water (Public Comment Draft Assessments), at page 6-8, available at: .regulations.gov/document/EPA-HQ-OW-2022-0114-0034.] EPA appears to reinterpret the studies by Thomford 2002 and Butenhoff 2012 without explanation [FN128: Id. At Section 6.4. In contrast, in the 2021 Draft Assessment, at page 312, EPA states: "Additionally, the animal evidence for PFOS is limited to a single chronic cancer bioassay. Although liver adenomas were significantly increased in male and female rats at the highest dose and a positive trend was observed ($p = 0.03$), a dose-response pattern was not observed. Incidence of thyroid follicular tumors and mammary gland tumors also did not show a direct response to dose."]. EPA also adds a new criterion, which is not part of the EPA 2005 Guidelines for Carcinogens, and adds that "Structural similarities between PFOS and PFOA add

to the weight of evidence for carcinogenicity of PFOS."[FN129: Id. At page 3-296.] These findings also contradict EPA's 2023 Economic Analysis, which states "Evidence of a positive association between PFOS exposure and kidney cancer was inconclusive; the small number and limited scope of studies at the time were inadequate to make definitive conclusions (U.S. EPA, 2016e; U.S. EPA, 2023d)."[FN130: See EPA Economic Analysis of the Proposed National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances, 2023, at page 6-16.]

EPA's 2023 reinterpretation of the same studies it reviewed in 2016 and 2021, as well as EPA's addition of new considerations (e.g., a novel consideration of similarity to other chemistries), requires external peer review. This is not a minor change. The effects of a change from "suggestive to be carcinogenic" to "likely to be carcinogenic" for PFOS are highly significant to this rulemaking. Because of this higher cancer classification, EPA is now proposing an MCLG of zero for PFOS; whereas, if EPA had retained the cancer classification from the 2016 HESD and the 2021 Draft Assessment, the MCLG would be higher. While SDWA requires that EPA request comments from the SAB prior to proposing the MCLG,[FN131: 42 U.S.C. [sec] 300g-1(e).] there is no record from the SAB to support EPA's new determination for PFOS, nor is there any SAB review of the new structured framework that EPA developed to inform the most recent cancer classification. EPA's change in the cancer classification of PFOS without additional peer review of the new framework and its application to PFOS should not be finalized.

Further, until there is additional review and endorsement of EPA's proposed cancer classification for PFOS, EPA should not quantify the cancer effects of PFOS.

EPA Response: Please see section 4.1.4 of the EPA response in this *Response to Comments* document. The commenter misstates or mischaracterizes several of the EPA's conclusions and the SAB's recommendations. For example, the commenter's statements that the SAB did not recommend a *Likely to Be Carcinogenic to Humans* classification for PFOS and that the EPA did not explain its reinterpretation of studies cited in the 2016 HESD (USEPA, 2016b) or the 2021 *Proposed Approaches* (USEPA, 2021c) document leading to the agency's updated PFOS cancer classification are incorrect and are addressed in the EPA response to comment Doc. #1774, SBC-045684, SBC-053187, SBC-053190, and SBC-053196 in section 4.1.4.2 in this *Response to Comments* document. An explicit description of the EPA's rationale for updating the cancer classification for PFOS was provided in the public comment draft assessment (USEPA, 2023a) and is similarly presented in Section 5.4 of the final toxicity assessment (USEPA, 2024c).

The commenter additionally asserted that the EPA should not quantify the cancer effects of PFOS until there is endorsement of the proposed cancer classification. The EPA disagrees and in fact, the SAB did support and endorse quantification of cancer effects of PFOS (USEPA, 2022b). As described in the EPA response to comment Doc. #1774, SBC-045690 in section 13.4.1 in this *Response to Comments* document, the SAB PFAS Review Panel stated that the EPA was "overly conservative in dismissing the appearance of a dose-response relationship for [hepatocellular carcinoma], particularly in females…Given that multiple MOAs may be operative in this outcome, the Panel suggests that the EPA reevaluate the 2012 Butenhoff study" (USEPA, 2022b).

Therefore, the SAB endorsed both the EPA's reevaluation of the critical study (i.e., Butenhoff et al. (2012a)/Thomford (2002)) and the critical effect (i.e., hepatocellular tumors in female rats).

Additionally, even if the EPA had maintained the *Suggestive Evidence of Carcinogenicity* descriptor for PFOS, the EPA would have been consistent with agency guidance in quantifying a CSF according the 2005 *Guidelines for Carcinogen Risk Assessment*, which states that "when the evidence includes a well-conducted study, quantitative analyses might be useful for some purposes, for example, providing a sense of the magnitude and uncertainty of potential risks, ranking potential hazards, or setting research priorities" (USEPA, 2005). As the commenter notes, the Butenhoff et al., (2012a) is a *high* confidence study.

In addition, even if the EPA had maintained the draft *Suggestive Evidence of Carcinogenicity* descriptor for PFOS (USEPA, 2021c) and the MCLG was based on noncancer effects, calculating the MCLG based on the overall noncancer RfD for PFOS (1 x 10^{-7} mg/kg/day; USEPA, 2024c) would still result in an MCLG below the Maximum Contaminant Level (MCL) finalized in this rulemaking (4 ppt). For example, if the EPA had based the MCLG for PFOS on the critical effect of increased total cholesterol in adults, which is relevant to the population with the lowest bodyweight-adjusted drinking water consumption rate (USEPA, 2019) (i.e., the general population and not a vulnerable population such as formula-fed infants), the MCLG would be 0.6 ng/L (ppt). This example noncancer-based MCLG for PFOS is calculated as follows and summarized in the table below:

$$\mathbf{MCLG} = \left(\frac{\text{RfD}}{\text{DWI-BW}}\right) * \text{RSC}$$

$$= \left(\frac{0.0000001 \ \frac{\text{mg}}{\text{kg/day}}}{0.034 \frac{\text{L}}{\text{kg/day}}}\right) * 0.2$$

$$= 0.0000006 \ \frac{\text{mg}}{\text{L}}$$

$$= 0.6 \ \frac{\text{ng}}{\text{L}} \text{ or parts per trillion (ppt)}$$

Table 4-1. PFOS Noncancer-Based MCLG – Input Parameters and Value

Parameter	Value	Units	Source
Chronic oral RfD[a]	1E-07	mg/kg/day	RfD based on co-critical effect of increased total cholesterol in adults (Dong et al., 2019; USEPA, 2024c).
DWI-BW	0.034	L/kg/day	90th percentile 2-day average, consumer-only estimate of combined direct and indirect community water ingestion for adults 21 years and older based on 2005−2010 NHANES data (USEPA, 2019).

Parameter	Value	Units	Source
RSC	0.2	N/A	Based on a review of the available scientific literature on PFOS, potential exposure routes and sources exist but the available information is limited and does not allow for the quantitative characterization of the relative levels of exposure among these different sources (USEPA, 2024b).

Note: RfD = reference dose; DWI-BW = body weight-adjusted drinking water intake; HBWC = health-based water concentration; HFPO-DA = hexafluoropropylene oxide dimer acid; N/A = not applicable; NHANES = National Health and Nutrition Examination Survey; NTP = National Toxicology Program; RSC = relative source contribution.

[a] The RfD for PFOS is also based on the co-critical effect of decreased BWT in infants (Wikstrom et al., 2019; USEPA, 2024c). For the purposes of this calculation, the EPA based the MCLG on the co-critical effect of increased total cholesterol in adults in order to specify the target population needed for the selection of the DWI-BW term, which may change depending on the critical effect and critical study.

Additionally, establishing the MCLG for a chemical has historically been accomplished in one of three ways depending upon a three-category classification approach (USEPA, 1985; USEPA, 1991a). This approach was described in the proposed PFAS National Primary Drinking Water Regulation Rulemaking preamble (USEPA, 2023e). The starting point in categorizing a chemical is through assigning a cancer descriptor using the EPA's current *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005). Group C contaminants (USEPA, 1986) and contaminants with the descriptor of *Suggestive Evidence of Carcinogenic Potential* (USEPA, 2005) are in Category II. The EPA has historically set the MCLG for Category II contaminants based on noncancer effects, with the application of an additional modifying factor of 10 to account for uncertainties regarding the potential for carcinogenicity (USEPA, 1985; USEPA, 1991a). While not shown in the equation above, if the EPA were to derive a MCLG based on noncancer effects for PFOS, the EPA would consider this approach as well in order to ensure that the resulting MCLG includes an adequate margin of safety. The SAB also referred to this practice in their final report: "This approach is specified by USEPA (1985) for contaminants classified as "possible human carcinogens (Group C)" which is analogous to "suggestive evidence of carcinogenic potential" in the current terminology from the USEPA (2005) cancer risk assessment guidelines. An additional UF of 10 for potential carcinogenicity was incorporated into the RfDs for several USEPA MCLGs/MCLs including, for example, para-dichlorobenzene (USEPA, 1987)" (USEPA, 2022b).

Overall, the noncancer-based MCLG for PFOS would still be well below the MCL finalized in this rulemaking (4 ppt). Thus, there would be no change to the MCL for PFOS (see section V of the preamble and section 5 of the EPA response in this *Response to Comments* document for discussion on how the MCL is determined). Similarly, an MCLG for PFOA based on the noncancer RfD (3×10^{-8} mg/kg/day) would also be well below the MCL of 4 ppt:

$$\mathbf{MCLG} = \left(\frac{\text{RfD}}{\text{DWI-BW}}\right) * \text{RSC}$$

$$= \left(\frac{0.00000003 \ \frac{\text{mg}}{\text{kg/day}}}{0.034 \frac{\text{L}}{\text{kg/day}}} \right) * 0.2$$

$$= 0.0000002 \ \frac{\text{mg}}{\text{L}}$$

$$= 0.2 \ \frac{\text{ng}}{\text{L}} \text{ or parts per trillion (ppt)}$$

Table 4-2. PFOA Noncancer-Based MCLG – Input Parameters and Value

Parameter	Value	Units	Source
Chronic oral RfD[a]	3E-08	mg/kg/day	RfD based on co-critical effect of increased total cholesterol in adults (Dong et al., 2019; USEPA, 2024d).
DWI-BW	0.034	L/kg/day	90th percentile 2-day average, consumer-only estimate of combined direct and indirect community water ingestion for adults 21 years and older based on 2005−2010 NHANES data (USEPA, 2019).
RSC	0.2	N/A	Based on a review of the available scientific literature on PFOA, potential exposure routes and sources exist but the available information is limited and does not allow for the quantitative characterization of the relative levels of exposure among these different sources (USEPA, 2024a).

Note: RfD = reference dose; DWI-BW = body weight-adjusted drinking water intake; HBWC = health-based water concentration; HFPO-DA = hexafluoropropylene oxide dimer acid; N/A = not applicable; NHANES = National Health and Nutrition Examination Survey; NTP = National Toxicology Program; RSC = relative source contribution.

[a] The RfD for PFOA is also based on the co-critical effects of decreased BWT in infants and decreased antibody response to vaccination in children (Wikstrom et al., 2019; Budtz-Jorgensen and Grandjean (2018); USEPA, 2024d). For the purposes of this calculation, the EPA based the MCLG on the co-critical effect of increased total cholesterol in adults in order to specify the target population needed for the selection of the DWI-BW term, which may change depending on the critical effect and critical study.

Regarding the commenter's concern about the discussion on structural similarities between PFOA and PFOS, please see section 4.1.4 of the EPA response in this *Response to Comments* document. Regarding the commenter's concern that the toxicity assessments require a second round of peer review, please see section 4.1.3 of the EPA response in this *Response to Comments* document. Regarding the commenter's assertion that the findings of the toxicity assessment regarding the association between PFOS and kidney cancer contradict the EPA's economic analysis, please see sections 4.1.4 and 13.4 of the EPA response in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-052922)

[The Agency's conclusion that PFOS is a likely carcinogen relies on reports of liver tumors in a single laboratory rat study that was previously determined to not provide sufficient evidence for such a conclusion. [FN6: USEPA. Proposed Approaches to the Derivation of a Draft Maximum

Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) (CASRN 1763-23-1) in Drinking Water. External Peer Review Draft. EPA Document No. 822D21002. Office of Water (2021). (USEPA Draft PFOS MCLG Approaches 2021)] These errors, further described below, combine to result in a flawed assessment by the Agency and overly stringent proposed MCL Goals and MCLs.

EPA Response: Please see section 4.1.4 of the EPA response in this *Response to Comments* document, the EPA response to comment Doc. #1774, SBC-045684 and SBC-053190 in section 4.1.4.2 in this *Response to Comments* document, and the complete justification for the EPA's cancer classification for PFOS in Sections 3.5.5 and 5.4 of the final toxicity assessment (USEPA, 2024c).

American Chemistry Council (ACC) (Doc. #1841, SBC-052924)

The Human Data do not Support an Association Between PFOS Exposure and Increased Cancer Risk

Epidemiology studies have not reported a consistent or clear increase in cancers for occupational workers, impacted communities, or general population cohorts exposed to PFOS. The worker studies have focused on a fluorochemicals production facility in Alabama. Significant community studies include populations in France, Denmark, Sweden, Holland, Taiwan, and Greenland. These studies show no association of PFOS with liver, pancreatic, or prostate cancer or of cancers of the digestive, respiratory, lymphatic, or hematopoietic systems. While Alexander et al. (2003) reported an increase in bladder cancer in the worker population in Alabama, [FN27: Alexander et al. Mortality of employees of a perfluorooctanesulphonyl fluoride manufacturing facility. Occup Env Med 60:722-729 (2003).] a more detailed follow-up study found no association with bladder cancer and PFOS exposure. [FN28: Alexander BH and Olsen GW. Bladder cancer in perfluorooctanesulphonyl fluoride manufacturing workers. Ann Epidem 17:471-478 (2007).] No increase in breast cancer incidence was observed among 263 female employees at the production facility in Alabama, [FN29: Grice M et al. Self-reported medical conditions in perfluorooctanesulfonyl fluoride manufacturing workers. J Occup Environ Med 49(7):722–729 (2007).] although the number of cases was too small for further analysis.

No association with bladder, pancreatic, or liver cancer has been observed in non- occupational (community) studies of PFOS exposure. In fact, although EPA is inappropriately relying on Shearer et al. (2021) for their PFOA CSF, Shearer et al. also measured serum concentrations of PFOS and did not find an association with PFOS exposure and renal cell carcinoma (see Table 2 from Shearer et al. 2021). Eriksen et al. (2009) reported a possible increase in prostate cancer but no dose-response was observed, and the findings are not consistent with results from other studies. Notably, a case-control study of prostate cancer in Sweden suggests no association between PFOS exposure and risk of prostate cancer. [FN30: Hardell E et al. Case–control study on perfluorinated alkyl acids (PFAAs) and the risk of prostate cancer. Environment international, 63, 35-39. (2014).]

Several community studies have investigated the association with breast cancer and have reported mixed results, although the number of cases investigated in these studies has been relatively small. Two recent case-control studies have investigated the hormone receptor status among women with breast cancer in France and Taiwan. Both have suggested an association between PFOS exposure and estrogen receptor positive (ER+) tumors, the most commonly diagnosed tumor type. In both studies, the analysis was based on a single blood sample which, in the case of the study of French women, may have been collected several years before cancer diagnosis. PFOS levels vary widely between the two studies, with the blood collected in the Taiwan study between 2013 and 2015 – well after the voluntary phase out of PFOS in Japan, Europe, and the US. As a result, the relevance of the PFOS blood levels is uncertain. These studies are discussed below.

Mancini et al. (2020) investigated breast cancer incidence in 194 post-menopausal women (mean age of diagnosis – 68.8, range 58.3 to 84.9) diagnosed prior to 2013 for which a single blood sample had been collected between 1994 and 1999. [FN31: Mancini FR et al. Perfluorinated alkylated substances serum concentration and breast cancer risk: Evidence from a nested case-control study in the French E3N cohort. Intl J Cancer 146:917-928 (2020).] The association with ER+ tumors was only observed in adjusted Model 3 where the inclusion of so many covariables results in wide confidence intervals and limits the study's power. [FN32: Tumor hormone receptor expression was available for 158 of the 194 cases (81%). Of these, 132 tumors (83%) were ER+.] In a study of Taiwanese women, Tsai et al. (2020) observed an association between PFOS levels and the incidence of breast cancer overall and for ER+ tumors in woman less than 50 years old (mean age of 48.9 at diagnosis). [FN33: Tsai M-s et al. A case-control study of perfluoroalkyl substances and the risk of breast cancer in Taiwanese women. Environ Intl 142:105850 (2020).] Contrary to the results of the study by Mancini et al., there was no association with breast cancer or ER+ tumors in woman over the age of 50 – despite the fact these women were likely to have experienced higher overall exposure to PFOS.

EPA Response: The commenter incorrectly characterized the epidemiological evidence supporting an association between elevated exposure to PFOS and increased risk of cancer and asserted that epidemiological studies have not reported consistent evidence for several cancers (breast, bladder, liver, pancreatic, and prostate cancer; or cancers of the digestive, respiratory, lymphatic, or hematopoietic systems). Responses to these comments are provided in the EPA response to comment Doc. #1774, SBC-045684 and SBC-053187 in section 4.1.4.2 in this *Response to Comments* document. The EPA specifically refers the commenter to the discussion on recent studies reporting associations between PFOS serum concentrations and liver cancer in humans (see section 4.1.4 of the EPA response in this *Response to Comments* document). The commenter additionally raised concerns regarding the study selected for CSF derivation for PFOA (Shearer et al., 2021), which is discussed in the EPA response to comment Doc. #1774, SBC-045682 and SBC-045683 in section 4.1.4.3 in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-044830)

Based on EPA's own cancer risk assessment guidelines, the animal data evaluating PFOS carcinogenicity are "suggestive", at best, not definitive, and are not supportive of a "likely" classification for human cancer risk. [FN34: USEPA. Cancer Risk Guidelines] Only one chronic animal bioassay has been performed with PFOS – Butenhoff et al. (2012). The study exposed Sprague-Dawley rats to up to 20 parts per million (ppm) K+PFOS in their diet for 2 years. [FN35: Butenhoff et al. Chronic dietary toxicity and carcinogenicity study with potassium perfluorooctanesulfonate in Sprague Dawley rats. Toxicol 293(1-3):1-15 (2012).] A recovery group was also exposed to the high dose diet for the first 52 weeks and then fed with control diet. Carcinogenic effects in the study included tumors in the liver, thyroid, and mammary gland. Pancreatic islet cell carcinomas increased among males, but not females, and the increase was not statistically significant for adenomas or combined adenomas or carcinomas. Despite being publicly available since 2012, EPA has never previously determined that the data from this rodent cancer bioassay were adequate to support the derivation of a CSF for PFOS. In 2016, the Office of Water concluded that "the weight of evidence for the carcinogenic potential to humans was judged to be too limited to support a quantitative cancer assessment." [FN36: USEPA PFOS HESD 2016, at ES-2.] Nothing has changed with these data and no additional evidence supporting derivation of a CSF for PFOS is available, thus it is unclear on which evidence EPA is now basing its determination.

For the pancreatic islet cell carcinoma observed in Butenhoff et al., the Office of Water did not include consideration of these tumors in its 2016 analysis of the health effects for PFOS. [FN37: USEPA. Drinking Water Health Advisory for Perfluorooctane Sulfonate (PFOS). EPA 822-R-16-004. Office of Water (May 2016). (USEPA PFOS HA 2016)] Similarly, these tumors were not included in the evidence the Office presented to the SAB in late 2021 in which the Water Office declined to consider PFOS a likely carcinogen. [FN38: USEPA Draft PFOS MCLG Approaches 2021, at 312.]

Thyroid and mammary tumors also were observed in the study by Butenhoff et al. Thyroid follicular cell tumors (adenomas in males, and adenomas/carcinomas combined in females) were significantly increased in recovery group males and in the second highest exposure group in females, but not in the other exposure groups including the high dose group. In females, mammary fibroadenomas and combined fibroadenomas/adenomas were increased over controls only in the lowest dose group and showed a significant negative trenI.

The inIreased incidence of total hepatocellular adenoma, statistically significant at the highest dose, was observed in both sexes in rats exposed for 2 years, but not 52 weeks. The increased incidence of hepatocellular adenomas in the male and female rats and of combined adenomas/carcinomas in the females, however, did not display a clear dose-related response. A statistically significant increase in the incidence of hepatocytic necrosis and hypertrophy in both males and females observed in this study and in other short-term studies, combined with evidence of PPARα and activation of other nuclear receptors, [FN39: Elcombe CR et al. Hepatocellular hypertrophy and cell proliferation in Sprague–Dawley rats from dietary exposure to potassium perfluorooctanesulfonate results from increased expression of xenosensor nuclear

receptors PPARα and CAR/PXR. Toxicol 293(1-3):16-29 (2012).] suggests that the liver tumors observed by Butenhoff et al. may be of limited relevance to humans. The authors concluded that the liver effects were consistent with activation of PPARα, constitutive androstane receptor (CAR), and pregnane X receptor (PXR) and that the available human and animal data "do not provide support for cancer risk from exposure to PFOS."

EPA's analysis suggests the potential for PFOS to induce hepatic tumors via multiple MOAs in rodents but provides only limited evidence to support other potential MOAs. The available data show that liver tumors in rats exposed to PFOS are likely caused by the activation of nuclear receptors, such as PPARα, CAR, and PXR. [FN40: See for example: Elcombe et al. 2012.] Despite the lack of a dose-response in tumor incidence and evidence to suggest the MOA is based on threshold response of nuclear receptors, the Agency develops a CSF based on linear, multiple stage modeling of the combined adenomas and carcinomas in the female rats. Although the available epidemiological and animal toxicity data may suggest a potential concern for carcinogenic effects in humans, the evidence is not sufficient for a stronger conclusion.

Overall, the rodent liver tumors from Butenhoff et al. are of questionable human relevance due to potential species-specific mode of action considerations (non-human relevant mechanisms involving xenobiotic nuclear receptors, such as PPARα); the liver tumors noted with statistical significance were benign adenomas; no statistically significant increases in hepatocellular carcinomas were observed in either the male or female rats and no clear dose response was noted. These data are not strong enough to suggest that PFOS is carcinogenic to humans at low doses, and do not support a linear low-dose extrapolation and MCL Goal of zero.

EPA Response: The commenter stated that the evidence related to the carcinogenicity of PFOS does not support a designation of *Likely to Be Carcinogenic to Humans* according to the EPA's guidance and provided several explanations underlying this assertion. The EPA disagrees with the explanations provided by the commenter, as described here and in responses to other commenters. Specifically, comments regarding the weight of evidence for the carcinogenic potential of PFOS and where this was described in the draft and final PFOS toxicity assessments (USEPA, 2023a; USEPA, 2024c), statistical significance of the pancreatic islet cell tumors in male rats (Thomford, 2002), rationale for the EPA updating the cancer classification for PFOS, the biological relevance of reporting tumor results at 52 weeks, the suggestion that MOAs related to nuclear receptor activation should be considered threshold effects, the human relevance of hepatocellular tumors resulting from PFOS administration, and the EPA's guidance on determining conclusions about the MOA for contaminants (USEPA, 2005) are discussed in the EPA responses to comment Doc. #1774, SBC-045684, SBC-053187, SBC-053190, and SBC-053196 in section 4.1.4.2 in this *Response to Comments* document. Additionally, please see section 4.1.4 of the EPA response in this *Response to Comments* document regarding the commenter's assertion that "no additional evidence supporting a derivation of a CSF for PFOS is available." The EPA reevaluated the data underlying the CSF for PFOS (i.e., the hepatocellular tumors in female rats) and the other information supporting the EPA's cancer classification for PFOS based on a recommendation by the SAB (USEPA, 2022b).

The commenter additionally stated that the increased incidence of hepatocellular tumors in the male and female rats did not display a dose-related response, though the EPA developed a CSF "based on linear, multiple stage modeling." The EPA disagrees with this comment. A biologically significant incidence of a rare tumor type (i.e., HCC) was observed in female rats (NTP, 2020) in the highest dose group and there was statistical evidence of a dose-related response. Both statistical and biological significance were considered when determining the cancer classification and selecting studies and endpoints for dose-response modeling. Male and female high dose groups had significantly increased incidences of hepatocellular tumors compared to the control groups and there were statistically significant positive trends of the responses in both sexes, clearly indicating a dose-response relationship. The observed dose-response relationship was also supported by the SAB PFAS panel who stated that "the interpretation of the hepatocellular carcinoma data from the Butenhoff (2012a) study in the 2016 HESD is overly conservative in dismissing the appearance of a dose-response relationship for this endpoint, particularly in females" (USEPA, 2022b). Further, for all studies, the dose-response relationship is at least partly an artifact of the study design and may be influenced by study design characteristics or observed results such as sample size, mortality, and other factors. These factors influence study sensitivity and may affect the response (or lack thereof) seen at lower dose levels. Without evidence demonstrating a threshold response and considering the EPA's determination that there may be multiple potential MOAs contributing to the carcinogenicity of PFOS, the EPA correctly assumed a linear low-dose response and relied on the preferred multistage models to derive CSFs based on animal toxicological studies for PFOS (USEPA, 2005; USEPA, 2012).

Mike Pettit (Doc. #1542, SBC-043345)

This leads into the next major issue that needs to be addressed: carcinogen risk. Consider the following section from page 96: "EPA reviewed the weight of the evidence and determined that PFOS is Likely to Be Carcinogenic to Humans, as "the evidence is adequate to demonstrate carcinogenic potential to humans but does not reach the weight of evidence for the descriptor Carcinogenic to Humans." This determination is based on the evidence of hepatocellular tumors in male and female rats, pancreatic islet cell carcinomas in male rats, and mixed but plausible evidence of bladder, prostate, kidney, and breast cancers in humans. As previously noted, the results provided by one chronic cancer bioassay in rats exceeds the descriptor of Suggestive Evidence of Carcinogenic Potential as it provides evidence of multi-site and multi-sex tumorigenesis. Consistent with the statutory definition of MCLG, EPA establishes MCLGs of zero for carcinogens classified as Carcinogenic to Humans or Likely to be Carcinogenic to Humans, described in Section V.A. of this preamble above as the linear default extrapolation approach. EPA has determined that PFOS is Likely to be Carcinogenic to Humans based on sufficient evidence of carcinogenicity in humans and animals and has also determined that a linear default extrapolation approach is appropriate as there is no evidence demonstrating a threshold level of exposure below which there is no appreciable cancer risk and therefore, it is assumed that there is no known threshold for carcinogenicity. Based upon a consideration of the best available peer reviewed science and a consideration of an adequate margin of safety, EPA

proposes a MCLG of zero for PFOS in drinking water.” This makes sense until it is taken in the context that this is based off a singular study that does provide some evidence that at 200 mg daily dose to a rat for two years will cause issues. One might as well consume the entirety of a plastic 2-liter bottle every day, only to be surprised in several months that apart from crippling liver and kidney failure, there is also cancer potentially in their body now. The claim is obviously absurd. The sheer level of exposure should then be correlated to the toxicity equivalent for humans. A problem exists also in extrapolating from animal studies to humans can be problematic due to differences in the way humans and animals metabolize and eliminate chemicals. While one animal study has shown that PFAS exposure can cause tumors, others have not found a clear link between PFAS and cancer. For example, one study of workers exposed to PFOA found no increase in cancer risk, while another study of exposed workers found a possible association with prostate cancer but no clear evidence of an increased risk of other types of c’ncer. It's also worth noting’that EPA's designation of‘PFOS as "likely to be carcinogenic ”o humans" is not based on direct evidence of carcinogenicity in humans. R’ther, it's based on evidence of hepatocellular tumors in male and female rats, pancreatic islet cell carcinomas in male rats, and mixed but plausible evidence of bladder, prostate, kidney, and breast cancers in humans. The extrapolation of this evidence to humans is a complex process, and there are inherent uncertainties and limitations in such extrapolations.

Disregarding the issue that the dosage volumes have no extrapolation/correlation data given between rats and humans, the bigger issue lies within the fact there is only one study being used to lay the foundation of this classification. It is common practice that studies indicating something should be duplicated to ensure not only the integrity of the study, but also to add to the body of evidence to support the findings in the original study. The reason is obvious- studies need to be verified before full conclusions can be drawn so that appropriate civil actions can be enacted upon. This is not the case in the memo passed from the EPA. Therefore, drawing up the title “Likely to Be Carcinogenic to Humans” has only the basis of one study and is erroneously applied. No further duplication and verification of the findings in the original paper have been used or even cited, and this results in a premature label being added. Corrective action should be immediately taken to rectify this egregious error.

Something important to note, a threat of cancer is a fact of life for the most basic aspects of living. As anyone who has taken any form of biological class would know, cancer is merely a label for an aberrant cell that no longer functions in the way that a normal cell would. Cancerous cells are not even always inherently dangerous (which may be a shock to some). The creation of these incorrect cells occurs daily. These same cells are dealt with daily. Every person, creature, thing with more than 10 cells making up its body deals with cancer every single day. Anything and everything that can cause aberrations in making normal cells could technically be labeled as carcinogenic. Therefore using the term “cancer causing” on something that is normally nonreactive with minimal scientific evidence behind it is absurd. The lack of evidence is overwhelming and can only be used to stir up people who honestly do not know any better. It is clickbait in the first degree.

EPA Response: The commenter disagrees with the EPA's conclusions about the carcinogenic potential of PFOS. However, the commenter appears to misunderstand the EPA guidance related to carcinogens and fundamental concepts underlying these assessments, including the extrapolation from animal toxicological data to human exposure. Additionally, the EPA disagrees with the commenter's statements regarding the strength of evidence supporting the EPA's cancer classifications for PFOA and PFOS. Rebuttal to these comments is provided in the EPA response to comment Doc. #1774, SBC-045684, SBC-053187, SBC-053190, and SBC-053196 about PFOS in section 4.1.4.2 in this *Response to Comments* document and the EPA response to comment Doc. #1774, SBC-045682 and SBC-045683 about PFOA in section 4.1.4.3 in this *Response to Comments* document. For PFOS, evidence from recently published epidemiological studies show concordant associations between PFOS serum concentrations and HCC in humans (Goodrich et al., 2022; Cao et al., 2022), further supporting the evidence of hepatocellular tumors in animal models.

With respect to the designation of PFOS as *Likely to Be Carcinogenic to Humans*, the commenter is incorrect in stating that the designation is based on a singular study. As described in section 3.5 of the PFOS toxicity assessment (draft (USEPA 2023a) and final (USEPA, 2024c)), the cancer classification is supported by human, animal and mechanistic evidence, consistent with the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005). Importantly, the available mechanistic evidence supports the EPA's conclusion that multiple human relevant MOAs are operative in the hepatic and pancreatic tumorigenesis associated with PFOS exposure based on animal model study findings. Similarly, the International Agency for Research on Cancer (IARC) (Zahm et al., 2023) concluded that there is strong mechanistic evidence of carcinogenicity in exposed humans and that PFOS is immunosuppressive and induces epigenetic alterations in humans, induces oxidative stress in human primary cells and experimental systems and modulates multiple receptors. As described in the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005), "[i]n the absence of sufficiently, scientifically justifiable mode of action information, EPA generally takes public health-protective, default positions regarding the interpretation of toxicologic and epidemiologic data; animal tumor findings are judged to be relevant to humans, and cancer risks are assumed to conform with low dose linearity." The available mechanistic data does not support a single, scientifically justified MOA for PFOS-induced hepatic and pancreatic carcinogenesis; in fact, there is evidence supporting the potential for multiple plausible MOAs (USEPA, 2005). Therefore, the EPA followed its guidance in judging that the animal tumors are relevant to humans.

The EPA agrees that there can be uncertainties associated with the extrapolation of data from animal models to humans (see section 4.2.2 of the EPA response in this *Response to Comments* document), including several that the commenter highlighted above (e.g., toxicokinetic differences between species). However, the EPA disagrees that this precludes the agency from quantitatively relying on studies in animal models for the derivation of toxicity values. This practice has been used to support agency risk assessments for decades and has been repeatedly endorsed by agency guidance and methods (USEPA, 2002; USEPA, 2005; USEPA, 2014a; USEPA, 2022a). The EPA agrees that extrapolation from animal models to humans is complex,

but animal toxicological studies, regardless of study design characteristics such as dose levels, can be used to determine potential human health hazards and the exposure levels and internal doses (e.g., serum concentrations) that may be expected to cause adverse health effects in humans. With an understanding of how the chemical may behave differently in animals and humans (e.g., differences in excretion rates), the EPA can estimate the equivalent level of exposure that would pose a risk to human health and compare those values across any effects that could pose a hazard. In this way, the EPA can determine the minimum exposure level (e.g., RfD) that could result in a risk to human health. The pharmacokinetic approach the EPA used to estimate human equivalence doses from animal toxicological studies is available in Section 4.1.3 of the PFOA and PFOS toxicity assessments and is discussed further in Section 4.2.4 of this response to public comments document (USEPA, 2024d; USEPA, 2024c).

Finally, regarding the commenter's statement that "a threat of cancer is a fact of life for the most basic aspects of living," the EPA does not agree that exposure to cancer-causing agents in our drinking water is "imply a "basic aspect of living." The SDWA requires the EPA to set an MCLG at "a level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety" and the MCL be set at a level "as close as feasible" to the MCLG. The EPA is committed to providing Americans clean, safe drinking water, consumption of which should not cause undue risk to the health of persons. While cancer may impact Americans every day, exposure to harmful contaminants through drinking water should not increase that burden, and through the finalization of this PFAS NPDWR, the EPA anticipates meaningful reduction of cancer risk for millions of Americans.

PFAS Regulatory Coalition (Doc. #1761, SBC-046070)

B. The science does not support EPA's new classification of PFOS as a likely carcinogen.

In the Proposal, EPA has determined for the first time that PFOS is a likely carcinogen. EPA states that it has reviewed the weight of the evidence and determined that PFOS is Likely to Be Carcinogenic to Humans, as ''the evidence is adequate to demonstrate carcinogenic potential to humans but does not reach the weight of evidence for the descriptor Carcinogenic to Humans.'' 88 Fed Reg. 18663. Yet, before this Proposal, EPA had determined that PFOS was not a likely carcinogen, and it is not clear what "best available science" EPA is considering now in order to reach this new conclusion. Absent proper scientific support, EPA's new interpretation of largely the same data to reach different conclusions is arbitrary and capricious. EPA actually states at one point that reports preclude a definitive conclusion, but then in the next sentence, EPA points to only "one high confidence" study that found "associations" between PFOS and cancer before concluding that "available study findings support a plausible correlation between PFOS exposure and carcinogenicity in humans." 88 Fed. Reg. 18660, 18710.

It appears that EPA changed its classification of PFOS from "Suggestive Evidence of Carcinogenic Potential" to "Likely to be Carcinogenic to Humans" following the EPA Science Advisory Board's review of EPA's "Draft Proposed Approaches to the Derivation of a Draft

Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) (CASRN 1763-23-1) in Drinking Water." The SAB says: "The magnitude of the association between PFOS and kidney cancer was lower than that for PFOA, and after adjustment for other PFAS, the adjusted OR for the highest quartile was 1.14 and not statistically significant. However, these data should be presented clearly including a discussion of why the PFOS data from Shearer et al. (2021) were not considered sufficient for a higher designation of 'likely carcinogenic.'" Science Advisory Board Report, "Review of EPA's Analyses to Support EPA's National Primary Drinking Water Rulemaking for PFAS," at 36 (Dkt. No. EPA-HQ-OW-2022-0114-0078) (SAB Report).

The article referred to by the SAB Report is "Serum Concentrations of Per- and Polyfluoroalkyl Substances and Risk of Renal Cell Carcinoma," Shearer, J., et al., Journal of the National Cancer Institute, vol. 113, issue 5 (2021), at 580 (Dkt. No. EPA-HQ-OW2022-0114-0847). It is notable that the abstract for this article says:

"It remains unclear whether PFOA or other PFAS are renal carcinogens or if they influence risk of renal cell carcinoma (RCC) at concentrations observed in the general population."

Rather than improving the discussion of Shearer, et al. (2021), as recommended by the SAB, and despite the authors' conclusion quoted above, EPA's response to the SAB shows that EPA instead relied on this article to change its classification of PFOS to a "Likely Carcinogen." EPA Response to Final Science Advisory Board Recommendations (August 2022) on Four Draft Support Documents for the EPA's Proposed PFAS National Primary Drinking Water Regulation, at 26 (Dkt. No. EPA-HQ-OW-2022-0114-0043). That reliance, and the resulting determination of likely human carcinogenicity, are not supported by the best available science and not justified based on statements in that article itself.

In the Proposal, EPA concedes that scientific uncertainties exist surrounding the effects of PFOS exposure: "The available epidemiology studies reported elevated risk of bladder, prostate, kidney, and breast cancers after chronic PFOS exposure. While there are reports of cancer incidence from epidemiological studies, the study designs, analyses, and mixed results preclude a definitive conclusion about the relationship between PFOS exposure and cancer outcomes in humans." 88 Fed. Reg. at 18660. Also, EPA's Health Effects Support Document for Perfluorooctane Sulfonate (PFOS) EPA 822-R-16-002 states: (i) "Several human epidemiology studies evaluated the association between PFOS and cancers including bladder, colon, and prostate, but these data present a small number of cases and some are confounded by failure to adjust for smoking. The associations for most epidemiology endpoints are mixed," (ii) "The genotoxicity data are uniformly negative," (iii) "Human epidemiology studies did not find a direct correlation between PFOS exposure and the incidence of carcinogenicity in worker-based populations." In fact, results were so inconclusive that EPA cited 11 studies showing no association between increased serum PFOS and various types of cancer, and an additional two studies that showed a negative association between serum PFOS and breast or uterine cancer, indicating protective effect.

Facing this lack of clear evidence from human studies, EPA turned to one animal study for evidence of carcinogenicity in humans, as stated in the Proposal: "The one high confidence animal chronic cancer bioassay study provides evidence of multi-site tumorigenesis in both male and female rats" and the "single chronic cancer bioassay performed in rats is positive for multi-site and -sex tumorigenesis (Thomford, 2002; Butenhoff et al., 2012b)." 88 Fed. Reg. 18638. These statements do not support the conclusion that "evidence is adequate" as to human carcinogenicity. Moreover, observations of tumorigenesis in laboratory animals dosed at PFAS levels that are environmentally immaterial is not tantamount to risk of cancer in the general human population. Direct extrapolation down to 4 ppt (effectively the reporting limit for PFAS in water), based on animals dosed at PFAS levels much higher than those observed in the Unregulated Contaminant Monitoring Rule

3 (UCMR3) study is inconsistent with an understanding of human physiology and dictates a dose-response curve that is unsupported by science.

EPA Response: Please see section 4.1.4 of the EPA response in this *Response to Comments* document regarding how the EPA reached the conclusion that PFOS is *Likely to Be Carcinogenic to Humans*, in accordance with the Guidelines for Carcinogen Risk Assessment (USEPA, 2005). The EPA disagrees with the commenter's other erroneous claims and rationale and has provided rebuttals in section 4.1.4 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1774, SBC-045684, SBC-053187, SBC-053190, and SBC-053196 in section 4.1.4.2 in this *Response to Comments* document. The EPA also discusses uncertainties with the extrapolation of data from animal models to humans in the EPA response to comment Doc. #1542, SBC-043345 above.

Regarding evidence supporting the association between PFOA and kidney cancer, please see the EPA response to comment Doc. #1774, SBC-045682 and SBC-045683 in section 4.1.4.3 in this *Response to Comments* document. A single study was not used to support the agency's conclusions that PFOA exposure is associated with increased risk of kidney cancer in humans, nor is the commenter correct in stating that the EPA relied on Shearer et al. (2021) to update the cancer descriptor for PFOS (see section 4.1.4 of the EPA response in this *Response to Comments* document).

NCASI (Doc. #1651, SBC-043215)

In the proposed rulemaking, EPA has determined that PFOS is a likely carcinogen. EPA states "the evidence is adequate to demonstrate carcinogenic potential to humans but does not reach the weight of evidence for the descriptor Carcinogenic to Humans." (pg. 18663). As recently as in 2021, as noted in the "Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) in Drinking Water; Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanesulfonic Acid (PFOS) in Drinking Water", EPA had determined that the PFOS MCLG should be based on a non-carcinogenic endpoint , and it is not clear what new

information EPA is considering in order to make this new conclusion. EPA relies on "one high confidence" study before concluding that "available study findings support a plausible correlation between PFOS exposure and carcinogenicity in humans." (pg. 18660).

EPA's determination is put in the context of the scientific uncertainties that exist when evaluating the potential carcinogenicity of PFOS: "The available epidemiology studies reported elevated risk of bladder, prostate, kidney, and breast cancers after chronic PFOS exposure. While there are reports of cancer incidence from epidemiological studies, the study designs, analyses, and mixed results preclude a definitive conclusion about the relationship between PFOS exposure and cancer outcomes in humans." There are additional sources of substantive uncertainty cited in EPA's Health Effects Support Document for Perfluorooctane Sulfonate (PFOS) EPA 822-R-16-002 that indicates: "Several human epidemiology studies evaluated the association between PFOS and cancers including bladder, colon, and prostate, but these data present a small number or cases and some are confounded by failure to adjust for smoking. The associations for most epidemiology endpoints are mixed,"; "The genotoxicity data are uniformly negative,"; and "Human epidemiology studies did not find a direct correlation between PFOS exposure and the incidence of carcinogenicity in worker-based populations."

The single animal study relied upon by EPA for the carcinogenicity of PFOS is described as: "The one high confidence animal chronic cancer bioassay study provides evidence of multi-site tumorigenesis in both male and female rats" and "The single chronic cancer bioassay performed in rats is positive for multi-site and -sex tumorigenesis" (pg. 18638)12 [FN1: Thomford, P. 2002. 104-Week Dietary Chronic Toxicity and Carcinogenicity Study with Perfluorooctane Sulfonic Acid Potassium Salt (PFOS; T–6295) in Rats (pp. 1–216). 3M. Available on the internet at: https://www.ag.state.mn.us/Office/Cases/3M/docs/PTX/PTX2805. pdf] [FN2: Butenhoff, J.L., Chang, S.C., Olsen, G.W., and Thomford, P.J. 2012. Chronic Dietary Toxicity and Carcinogenicity Study with Potassium Perfluorooctane Sulfonate in Sprague Dawley Rats. Toxicology, 293:1– /doi.org/10.1016/j.tox.2012.01.003] This limited evidence is not sufficient to support the conclusion that "evidence is adequate" as to human carcinogenicity, particularly when considering that these observations of tumorigenesis are in excess of environmentally relevant concentrations of PFOS.

While EPA indicates that that these conclusions were arrived at with a systematic review, it is not clear whether the systematic review protocol was adequately developed to appropriately apply the noted sources of uncertainty into the conclusion of carcinogenic classification. Many of these issues could have been addressed by peer review/public comment on the systematic review protocol used in the MCL development. It is common practice among regulatory agencies to either publish or distribute for comment a proposed protocol that can be revised based on technical feedback as seen in other EPA program areas such as the Integrated Risk Information System (IRIS). Not only does this serve to enhance the transparency of the review process, but also provides additional perspectives on many of the criteria for risk of bias and evidence integration that must be detailed a priori to the actual review. NCASI supports the opportunity to provide technical comments on proposed systematic review protocols.

EPA Response: Regarding comments on the carcinogenicity assessment for PFOS, please see section 4.1.4 of the EPA response in this *Response to Comments* document and EPA response to comment Doc. #1774, SBC-045684, SBC-053187, SBC-053190, and SBC-053196 in section 4.1.4.2 in this *Response to Comments* document. Regarding comments on the systematic review protocol, please see section 4.1.1 of the EPA response in this *Response to Comments* document. Regarding comments on the peer review process for this rulemaking, please see section 4.1.3 of the EPA response in this *Response to Comments* document. Briefly, the EPA followed the agency's *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005) in determining that PFOS is *Likely to Be Carcinogenic to Humans*. The EPA additionally notes that the systematic review protocol for the toxicity assessments was released for public comment as Appendix A of the *Public Comment Draft Toxicity Assessments and Proposed Maximum Contaminant Level Goals for PFOA and PFOS in Drinking Water* (USEPA, 2023b; USEPA, 2023c).

Washington State Department of Health (DOH) (Doc. #1665, SBC-044408)

While there is solid evidence that PFOS is a rodent carcinogen, there is currently only weak and inconsistent epidemiological evidence that PFOS has caused cancer in humans. EPA classification of PFOS as a likely human carcinogen is reasonably supported by mechanistic data showing PFOS to have several characteristics of carcinogens, structural similarity to PFOA, and functional similarity to PFOA on other health endpoints.

EPA Response: Please see section 4.1.4 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1774, SBC-045684, SBC-053187, SBC-053190, and SBC-053196 in section 4.1.4.2 in this *Response to Comments* document regarding the strength of the epidemiological evidence supporting the cancer classification for PFOS. The EPA also directs the commenter to Sections 3.5.5 and 5.4 of the final toxicity assessments for PFOS which outline the rationale for the EPA's cancer classification for PFOS (USEPA, 2024c), which is based on recommendations from agency guidance (USEPA, 2005). The commenter provides additional supporting comments for other factors considered in the cancer assessment.

City of Vancouver Water Utility, Vancouver, WA (Doc. #1684, SBC-044305)

Is there clear evidence that PFOS is a human carcinogen? While there is solid evidence that PFOS is a rodent carcinogen, there is currently only weak and inconsistent epidemiological evidence that PFOS has caused cancer in humans.

EPA Response: Please see section 4.1.4 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1774, SBC-045684, SBC-053187, SBC-053190, and SBC-053196 in section 4.1.4.2 in this *Response to Comments* document.

4.1.4.3 Comments Specific to PFOA

Provencher Engineering, LLC (Doc. # 1564, SBC-042504)

More recently, the New Hampshire Department of Health and Human Services (NHDHHS) has conducted two important studies. One is a "MVD Community Exposure Assessment Report" (NHDHHS summary attached), which included PFOA blood sampling of 217 random MVD customers, which concluded that the average MVD customer's blood PFOA was 4 ug/L, double the national average of 2 ug/L from 2013-2014 (please refer to attached summary report). The second is a "Cancer Incidence Report for Merrimack, NH, January 2023" (attached), which based on Table 3 in that report, indicates a Standard Incidence Report (SIR) value for Merrimack, NH of 1.42, meaning that there is a 42% greater incidence of Kidney and Renal Pelvic cancers as compared to the rest of the state! That's what Table 3 represents, as presented by the DHHS itself. Combining the implications of the facts that: (1) Merrimack, NH is one of the worst cases of widespread PFOA contamination in the country due to air borne PFAS emissions from one or more polluters in and adjacent to Merrimack, that: (2) MVD customers' blood PFOA is double the national average, and that: (3) The Cancer Incidence Report in Merrimack indicates 42% more pelvic & renal cancers, it requires the application of common sense to be applied. These are not merely coincidences! It's time to take actions to reduce PFAS exposures, which includes treating more PFAS contaminated drinking water!

EPA Response: The commenter provided two reports which described the efforts of the New Hampshire Department of Health and Human Services (NHDHHS) to characterize PFAS exposure and associated cancer incidence in Merrimack, NH as evidence supporting the EPA's cancer assessment for PFOA. Given the EPA's cancer classification for PFOA and the resulting MCLG of zero, the EPA agrees that the available evidence indicates that there is no dose below which PFOA is considered safe in regard to cancer risk. Further, the EPA reviewed the information provided by the commenter regarding PFAS exposure and cancer incidence in Merrimack, NH (see section 4.2.6 of the EPA response in this *Response to Comments* document regarding how the EPA considered literature recommended in public comments). The EPA has identified a related peer-reviewed publication post-dating the updated 2022 literature search conducted prior to rule proposal (Messmer et al., 2022) that presents results from the NHDHHS report cited in this comment. The study findings and assessment implication for Messmer et al. (2022) has been added to the table of studies identified after the updated 2022 literature search (USEPA, 2024a, Sec. A.3). The ecological design of the study limits its utility for dose-response analysis; however, the report and associated publication (Messmer et al., 2022) are coherent with the EPA's conclusions that PFOA is *Likely to Be Carcinogenic to Humans* and that elevated PFOA exposure is associated with an increased risk of renal cancer.

3M Company (Doc. #1774, SBC-045682 & SBC-045683)

The MCLG of zero for PFOA is based on EPA's determination that PFOA is "likely to be carcinogenic to humans." EPA's conclusion is reportedly based on evidence of kidney and

testicular cancer in humans and testicular Leydig cell tumors ("LCTs"), pancreatic acinar cell tumors, and hepatocellular adenomas in rats. As discussed below, as a result of process failures, EPA's analysis of the evidence on which it relies is fundamentally flawed, rendering EPA's conclusion unreliable.

In determining whether a substance is a likely carcinogen, EPA follows its Guidelines for Carcinogen Risk Assessment (USEPA 2005). That Guidance directs EPA to evaluate relevant studies and make a "weight of evidence" determination, by "weighing all of the evidence in reaching conclusions about the human carcinogenic potential of agents" based on considerations of animal and human evidence, mechanisms of action and dose-response relationships (USEPA 2005, p. 1-11). Here, EPA's systematic review and evidence synthesis failures led it to inaccurately assess the weight of the evidence as it relates to PFOA. For example, tumors identified in animals have questionable relevance to humans because they have been shown to occur through the PPARα pathway, a mode of action with limited relevance to humans (Biegel et al., 2001; Corton et al., 2018). In addition, the LCT tumors observed in animals do not have a common mode of action with testicular germ cell tumors seen in humans (Klaunig et al. 2012). Additionally, an excess of renal tumors has not been reported in three rat studies (NTP 2020; Butenhoff et al. 2012; Biegel et al. 2001).

Despite the limited supporting evidence for renal carcinogenicity in animal studies, EPA relied primarily on the matched case-control study on kidney cancer (Shearer et al. 2021), even though other studies on humans evaluating associations between kidney cancer and PFOA exposure also have yielded inconsistent results and do not demonstrate consistent dose-response (Steenland and Woskie 2012; Barry et al. 2013; Raleigh et al. 2014).

Moreover, the study by Shearer et al. (2021) relied upon by EPA to derive the cancer slope factor (CSF) [FN58: A cancer slope factor is a value representing a relationship between increases in exposure dose and cancer risk.] for PFOA is undermined by the study's reliance on PFOA exposure measured at a single point in time almost a decade before cancer diagnosis. This discrepancy adds uncertainty to the associations of exposure and cancer outcomes, as discussed in more detail below. Furthermore, Shearer et al. (2021) insufficiently adjusts for confounding by key risk factors, including the very limited categorical data on smoking history, body mass index, and history of hypertension. EPA's Guidelines for Carcinogen Risk Assessment (2005) specifically discusses the importance of confounding factors and states, "[c]ommon examples include age, socioeconomic status, smoking habits, and diet" and further "[s]tatistical analyses of the bias, confounding, and interaction are part of addressing the significance of an association and the power of a study to detect an effect." EPA failed to follow its guidance when using Shearer et al. (2021) without consideration of these important variables.

Contrasts in PFOA levels in this study cohort were also modest—comparing the upper quartile of >7.3 µg/L PFOA to a lower quartile of <4.0 ug/L PFOA—and substantially smaller than exposure contrasts in more highly exposed populations that showed no significant difference in kidney cancer risk (e.g., Raleigh et al. 2014). The reference group (i.e., the least exposed group) in Shearer et al. (2021) also had fewer cases (47 cases) than the control group (81 controls),

which may have biased the statistical comparisons for the other exposure categories. This distribution of 81 controls and only 47 cases in the referent group is counterintuitive because one would expect a more similar distribution among the least exposed. Neither Shearer et al. nor EPA commented on this referent group, which becomes the main driver in the subsequent calculations for the other three exposure categories. This shortcoming another example of EPA's attempts to infer statistical properties as discussed in Section IV.b. Other scientific literature indicates no association between PFOA exposure and kidney cancer risk; for example, a significant association or exposure-response trend was not observed between PFOA exposure and kidney cancer incidence or mortality in several other human epidemiological studies, including those from highly exposed occupational cohorts (e.g., Barry et al. 2013; Raleigh et al. 2014). The fact that there was little to no association between exposure to PFOA in workers with occupational exposure to high levels of PFAS and kidney cancer should have been considered by EPA as strong evidence against carcinogenicity, but , as a result of its deficient review processes, EPA appears to have largely disregarded this evidence.

Finally, the mechanistic weight of evidence for carcinogenicity indicates that PFOA is more likely to act via a threshold mode of action. EPA concludes that "most of the evidence for mutagenicity is consistently negative." This means that best practice would be for EPA to identify a dose below which toxicity does not occur (the threshold) and, accordingly, set an MCLG based on that dose (rather than assuming a zero MCLG). EPA's overall conclusions, however, assume a linear-no threshold model of carcinogenicity based on default assumptions of EPA's Cancer Guidelines (USEPA 2005) rather than analysis of the weight of evidence. As detailed in the section below on evidence of PFOS carcinogenicity, many of the modes of action for carcinogenicity of PFOA identified in animals do not apply to humans (e.g., PPARα pathways) and best practice dictates that EPA's assessment of carcinogenic mode of action should be revised to reflect its conclusion that most of the evidence for mutagenicity is consistently negative, indicating the linear no-threshold model of carcinogenicity is not appropriate for PFOA.

EPA Response: Please see section 4.1.4 of the EPA response in this *Response to Comments* document. The commenter stated that the process and evidence the EPA used to determine that PFOA is *Likely to Be Carcinogenic to Humans* were flawed. The EPA disagrees with this statement because the EPA relied on Agency methodology to systematically identify, evaluate, and synthesize literature relevant to the carcinogenicity of PFOA, as well as determine the weight of evidence across epidemiological, animal toxicological, and mechanistic studies (USEPA, 2022a). The full protocols the EPA used to identify and synthesize relevant studies were available at the time of public comment as Appendix A of the toxicity assessments (USEPA, 2023b; USEPA, 2023c). These are consistent with systematic review protocols published in the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022a) and the *Systematic Review Protocol for the PFBA, PFHxA, PFHxS, PFNA, and PFDA (anionic and acid forms) IRIS Assessments* (USEPA, 2021a). The EPA followed the *Guidelines for Carcinogen Risk Assessment,* including the Mode of Action Framework, to determine the weight of evidence of carcinogenicity for PFOA from epidemiological, animal toxicological, and mechanistic studies

(USEPA, 2005). The commenter did not provide any additional studies that the EPA did not evaluate and document in its assessment. Responses to the commenter's specific comments are provided below. Regarding the commenter's asserted "process failures," please see section 4.1.2 of the EPA response in this *Response to Comments* document.

The commenter asserted that tumors identified in animals have "questionable relevance" to humans, that there are differences in MOAs of testicular tumors observed in rats and humans, and that renal tumors observed in epidemiological studies were not reported in studies of rats. The EPA discussed hypothesized and alternative MOAs for all tumor types reported in the epidemiological and animal toxicological literature in Section 3.5.4.2 of the PFOA toxicity assessment (USEPA, 2023f). Additionally, the EPA stated particularly for the PPARα activation MOA for hepatic tumors, which is generally understood to operate in a species-specific manner: "for PPARα activators that act solely or primarily through PPARα-dependent mechanisms (e.g., Wyeth-14,643 or di-2-ethyl hexyl phthalate), the hepatic tumorigenesis observed in rodents is expected to be infrequent and/or less severe in humans, or not observed at all {Klaunig, 2003, 5772415; Corton, 2014, 2215399; Corton, 2018, 4862049}." However, after review of the available literature, the EPA determined that "PFOA exposure is associated with several mechanisms that can contribute to carcinogenicity, including epigenetic changes and oxidative stress, which may occur in conjunction with or independently of PPARα activation. It is plausible that these mechanisms may occur independently of PPARα-dependent mechanisms. These observations are consistent with literature reviews recently published by state health agencies which concluded that the hepatotoxic effects of PFOA may not entirely depend on PPARα activation (CalEPA, 2021; NJDWQI, 2017; USEPA, 2023f; USEPA, 2024d). Moreover, IARC recently concluded there is strong mechanistic evidence of carcinogenicity in exposed humans and that PFOA is immunosuppressive, induces epigenetic alterations, induces oxidative stress, modulates receptor-mediated effects (via PPARα, CAR/Pregnane X Receptor (PXR), and PPARγ), and alters cell proliferation, cell death, and nutrient and energy supply (Zahm et al., 2023). The existence of multiple MOAs in addition to PPARα activation suggest that PFOA-induced liver cancer in rats may be more relevant to humans than previously thought. The EPA also noted that the evidence supporting the claim that PPARα agonism mediates tumorigenesis for the two other tumor types observed in animal species, pancreatic acinar cell tumors and Leydig cell tumors (LCTs), is limited and "not as strong as for other tumor types (i.e., hepatic tumors)." When conducting its assessment, the EPA considered all potential MOAs and underlying carcinogenic mechanisms, not just PPARα activation. The EPA discusses additional hypothesized MOAs that may be human relevant and may contribute to the hepatic, pancreatic, and testicular tumors observed in rodents in Section 3.5.4.2 of the final toxicity assessment (USEPA, 2024d). The commenter is also referred to the EPA response to comment Doc. #1774, SBC-053196 in section 4.1.4.2 in this *Response to Comments* document for discussion on the MOAs for PFOS that are also relevant to PFOA.

The commenter stated that LCTs "observed in animals do not have a common MOA with testicular germ cell tumors seen in humans." This statement is not demonstrably accurate because the MOAs for these tumors in humans or animals have not been determined; thus, it is

actually not clear whether the testicular tumors observed in humans and animals do not share an MOA or mechanism of action. Regardless, the EPA does not agree that this is a factor that would detract from conclusions regarding the carcinogenic potential of PFOA. The EPA's MOA analysis for LCTs (see Section 3.5.4.2.2, USEPA, 2024d) evaluated the evidence for six MOAs. Evidence from rodent studies supported hypotheses that PFOA may cause testicular tumorigenesis through some of these human-relevant MOAs (i.e., aromatase inhibition, estrogen agonism, and testosterone biosynthesis inhibition), and lacked evidence supporting other MOAs (i.e., 5α-reductase inhibition and androgen receptor antagonism). The available evidence does not indicate a singular, common MOA to explain the LCTs in animals but indicates that PFOA exposure leads to several key events across multiple MOAs. The EPA also notes in the assessment that "it is unclear whether these MOAs are relevant to testicular cancers associated with PFOA exposure in humans," owing in part to a lack of mechanistic data from human PFOA studies of testicular tumors (USEPA, 2024d). Further, the following text has been added to the final assessment (USEPA, 2024d) to clarify that although Clegg et al. (1997) concluded human relevance of several of these MOAs, the sensitivity varies across species: "The working group noted that sensitivity for the initiating events in these MOAs varies across species, with rodents being more sensitive relative to humans." Testicular tumors were observed in rodents at doses as low as 13.6 mg/kg/day after two years. Changes in key events in the LCT MOAs were observed at even lower doses (as low as 1 mg/kg/day), though many of the studies at lower doses were conducted for durations too short to measure tumor formation (e.g., 16 weeks); had those studies been extended to two years, more tumor incidence may have been observed. Finally, the EPA also notes that "site concordance is not always assumed between animals and humans," meaning that the occurrence of LCTs in rodents may not necessarily translate directly to the occurrence of testicular tumors in humans (USEPA, 2005). The observation of LCTs in rodents reflects more on the potential carcinogenic potency of PFOA, and not necessarily a particular tumor type expected to occur in humans.

The commenter also stated that renal tumors were not observed in three studies in rats. The EPA does not agree that this is a finding that detracts from conclusions regarding the carcinogenic potential of PFOA. It is important to note that the *Guidelines for Carcinogen Risk Assessment* also state that, "there is evidence that growth control mechanisms at the level of the cell are homologous among mammals, but there is no evidence that these mechanisms are site concordant. Moreover, agents observed to produce tumors in both humans and animals have produced tumors either at the same site (e.g., vinyl chloride) or different sites (e.g., benzene) (NRC, 1994). Hence, site concordance is not always assumed between animals and humans" (USEPA, 2005). The *Guidelines* further note, "positive effects in animal cancer studies indicate that the agent under study can have carcinogenic potential in humans… The option is supported by the fact that nearly all of the agents known to cause cancer in humans are carcinogenic in animals in tests that have adequate protocols (IARC, 1994; Tomatis et al., 1989; Huff, 1994)." Additionally, "[i]n the absence of sufficiently, scientifically justifiable mode of action information… animal tumor findings are judged to be relevant to humans" (USEPA, 2005). Given this guidance and the use of methods consistent with current best practices (USEPA,

2022a), the EPA correctly evaluated the weight of evidence across human, animal, and mechanistic data to inform its determination that PFOA is *Likely to Be Carcinogenic to Humans.*

The commenter cited three epidemiological studies of renal cancer (Steenland and Woskie 2012; Barry et al. 2013; Raleigh et al. 2014) that they claimed showed "inconsistent results." This claim is misleading. One of these studies was determined to be *low* confidence primarily because it lacked direct or modelled exposure to PFOA and is further discussed later in this response (Raleigh et al., 2014). Steenland and Woskie (2012) and Barry et al. (2013) both reported positive trends for kidney cancer (significant in Steenland and Woskie (2012)), which is consistent with the EPA's conclusions regarding associations between kidney cancer and PFOA exposure. In contrast to the commenter's claims, Barry et al. (2013) concluded, "PFOA exposure was associated with kidney and testicular cancer in this population." Furthermore, the commenters failed to acknowledge another *medium* confidence study that reports increases in kidney cancer with PFOA exposure (Vieira et al., 2013), a meta-analysis that also reports a positive association (Bartell et al., 2021), the recently published pooled analysis (Steenland et al., 2022) providing evidence that effects detectable at low exposures are concordant with effects seen in high-exposure studies. These studies are discussed in the draft and final toxicity assessments (USEPA, 2023f; USEPA, 2023a; USEPA, 2024d; USEPA, 2024c). Additionally, in a relatively recent review, Steenland et al. (2020) discussed the probable link between kidney cancer and PFOA exposure following the assessments of the C8 Science Panel. The exclusion of these studies indicate that the commenter has cherry-picked from the available evidence to support their narrative. Importantly and in accordance with the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022a), the EPA considers the full weight of evidence approach when characterizing hazard.

The commenter raised several concerns about the Shearer et al. (2021) study. First, the commenter incorrectly stated that use of Shearer et al. (2021) for POD derivation is undermined by the study's reliance on PFOA exposure measured at a single point in time almost a decade before cancer diagnosis. However, the EPA determined that the biomonitoring measures of PFOA levels in Shearer et al. (2021) were reliable measures of PFOA exposure due to the chemical's well-established long half-life (see Section 3.3 of the final toxicity assessment for PFOA (USEPA, 2024d)). As a result, PFOA levels in serum remain relatively stable over long periods of time (i.e., years). Additionally, adequate study of cancer outcomes requires consideration of the latency period of the disease. Cancer is generally not an acute outcome that develops immediately following chemical exposures (USEPA, 2005). The study's measurement of PFOA one decade prior to diagnoses was appropriate considering the nature of the outcome of interest.

The commenter misleadingly asserted that Shearer et al. (2021) insufficiently adjusted for "key risk factors," mentioning limited categorical analyses of smoking history, body mass index (BMI), and history of hypertension. However, this case-control study also used matching techniques (i.e., matched characteristics between cases and controls) to account for a number of additional confounders including age, sex, race/ethnicity, study center, and study year of blood

draw. Matching is a well-established and appropriate method of accounting for key confounders in case-control studies. As mentioned in a previous response, the EPA considered the author's approach to investigating, evaluating, and addressing confounding in this study to be adequate. The EPA also notes that the guidance referred to by the commenter (USEPA, 2005) clearly suggests "examples" of covariates to be considered and does not provide a "necessary and sufficient" list of covariates that need be included in an epidemiological study. Such a prescribed method would be inappropriate given the enormous breadth of epidemiological study designs, considerations of varying populations, exposure and outcomes, appropriate adjustment for and evaluation of potential confounders, and considerations of overadjustment bias.

Regarding the comment on "modest" PFOA levels in the Shearer (2021) study, the commenters referenced results that found no significant associations between PFOA and kidney cancer in an exposed study population from a *low* confidence study (Raleigh et al., 2014). However, Raleigh et al. (2014) presented results from an occupationally exposed population with different exposure patterns than those typically found in the general population, and the lack of association in this high exposure setting does not discredit associations found in other studies. Therefore, the EPA disagrees with the commenter's statement that this "should have been considered by EPA as strong evidence against carcinogenicity." In fact, associations found at lower levels of exposures, such as in Shearer et al. (2021), which are based on or are relevant to exposure levels in the general U.S. population, indicate that the general population is at risk. Additionally, Raleigh et al. (2014) was rated as *low* confidence and would not serve to discredit the results found in a study of higher confidence, such as Shearer et al. (2021). Raleigh et al. (2014) used modeled estimates of PFOA air concentrations in the workplace rather than biomonitoring measurements. This is a concern because the study lacks information about the degree to which inhaled PFOA is absorbed in humans and factors that may affect absorption. Additionally, PFOA exposure data in non-production workers was not based on actual measurements. Possible reasons that this study failed to identify the association between PFOA exposure and kidney cancer include relatively small numbers of cases, lack of information on adjustment for risk factors of kidney cancer such as smoking status and BMI, and the methods for exposure assessment. Finally, Raleigh et al. (2014) noted that their study had limited power to evaluate some cancers, and that case ascertainment from one study population was likely incomplete.

The commenter asserted that "the distribution of 81 controls and only 47 cases in the referent group is counterintuitive," it "may have biased the statistical comparisons for the other exposure categories," and it "becomes the main driver in the subsequent calculations for the other three exposure categories." However, the commenter did not substantiate these assertions with factual evidence or references. In contrast, the EPA concluded that the Shearer et al. (2021) study adequately defined the categories of PFOA based on the quartiles of serum PFOA *in the controls* which is best practice in analyses of case-control data (Breslow and Day, 1984; Velarde et al., 2022). Thus, it is unclear to the EPA what is "counterintuitive" about the particular case-control numbers in the reference group. The EPA also notes that there was evidence of an effect in the analysis of serum PFOA as a continuous variable (log2 transformed), thus rendering the commenter's assertion of "bias" unsubstantiated by the facts.

Finally, the commenter suggests that PFOA "is more likely to act via a threshold mode of action." In Section 3.5.4 of the final toxicity assessment for PFOA (USEPA, 2024d), the EPA determined "[t]he available data is limited in its ability to provide enough evidence to support conclusions about potential MOAs for PFOA-induced kidney and testicular tumors in humans. Similarly, there is limited data to support specific MOAs for PFOA-induced testicular and pancreatic tumors in rats… the available *in vivo* and *in vitro* assays provide considerable support that PFOA may induce tumorigenesis through multiple mechanisms that are considered key characteristics of carcinogens." The EPA provided discussion on the human relevance of tumors observed in animal models, noting that there is uncertainty associated with some of the potential MOAs, such as PPARα, but others should be considered relevant to humans (e.g., cytotoxicity, testosterone biosynthesis inhibition). Additionally, the EPA reiterates that tumors have been reported in human populations, clearly in contrast to claims that PFOA acts through MOAs that are entirely irrelevant to human biology. In combination, there is a lack of evidence to support a threshold (i.e., nonlinear) MOA for PFOA. To determine this, the EPA conducted a weight of evidence analysis and followed the MOA framework outlined in the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005), in contrast to the commenters claims that the agency relied on default assumptions rather than conducting an evidence-based analysis (available in Section 3.5.4; USEPA, 2024d). As stated in the *Guidelines*, "[n]onlinear approaches generally should not be used in cases where the mode of action has not been ascertained," as is the case for PFOA (USEPA, 2005).

While the commenter was correct in stating that the majority of the available literature that evaluates the potential mutagenicity of PFOA is negative, mutagenicity is not the only the determinant of whether a chemical acts through a nonlinear MOA. The commenter was incorrect in stating that a lack of evidence supporting mutagenicity results in the EPA identifying a dose below which toxicity does not occur and setting the MCLG based on that dose (i.e., the nonlinear dose-response approach). In fact, the *Guidelines* explicitly state two criteria that must be met for a nonlinear approach to be selected for dose-response analyses: "when there are sufficient data to ascertain the mode of action and conclude that it is not linear at low doses and the agent does not demonstrate mutagenic or other activity consistent with linearity at low doses" (USEPA, 2005). As described above, the EPA did not identify sufficient evidence supporting a nonlinear MOA and the commenter additionally did not provide literature to support this assertion. Therefore, the EPA maintains its position that there is insufficient evidence to support a nonlinear MOA for PFOA and the MCLG should be set at zero.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-053422)

For the PFOA cancer classification, EPA bases the determination "on the evidence of kidney and testicular cancer in humans and LCTs, PACTs, and hepatocellular adenomas in rats."[FN132: See EPA Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) (CASRN 335-67-1) in Drinking Water at page 3-306.] EPA is clear that "there is not convincing epidemiological evidence supporting a causal association between human exposure to PFOA and cancer," and notes state that "there is significant

uncertainty regarding the carcinogenic MOA(s) of PFOA, particularly for renal cell carcinomas and testicular cancer in humans" (emphasis added) [FN133: Id. At 6-8 to 6-9.]. The epidemiological literature is very inconsistent, particularly for kidney cancer,[FN134: See comments submitted by Nessa Horewitch Coppinger on behalf of the 3M Company, Feb. 10, 2022, at page 13, available at: https://sab.epa.gov/ords/sab/f?p=100:19:16404771425364:::RP,19:P19_ID:963.] yet EPA relies on the Shearer et al. 2021 study, which did not show statistically significant increases in kidney cancer after adjusting for other PFAS, to justify the "likely to be carcinogenic" classification. In its review, the SAB stated that EPA's rationale for the cancer designation was "not adequately provided" and that additional "weight of evidence" narrative was needed [FN135: See SAB report to the EPA Administrator Aug 22, 2022, at pages 32-33, available at: https://sab.epa.gov/ords/sab/f?p=100:18:16490947993:::RP,18:P18_ID:2601#report.]. Now that EPA has provided a new framework and justification, an additional SAB review is warranted. Without external peer review, stakeholders will not have the level of confidence that SDWA typically provides through the rigorous requirement for peer review. If more fulsome and complete documents had been provided to the SAB to inform its review, then additional peer review would not now be required.

EPA Response: Regarding comments on the evidence supporting the EPA's cancer classification for PFOA, please see section 4.1.4 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1774, SBC-045682 and SBC-045683in section 4.1.4.3 in this *Response to Comments* document. More specifically, the EPA followed agency guidance when determining the cancer descriptor for PFOA, which does not state that there must be evidence from epidemiological studies demonstrating causal associations between exposure and cancer risk or known MOAs for determinations that a contaminant is *Likely to be Carcinogenic to Humans* (USEPA, 2005). Regarding comments on the peer-review process for this rulemaking, please see section 4.1.3 of the EPA response in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-044827)

EPA Cannot Conclude that PFOA and PFOS are Likely to be Carcinogenic to Humans and Its Cancer Slope Factor Derivations are Flawed

EPA proposes to set the MCL Goal at zero for PFOA and PFOS based on the conclusion that both are likely to be carcinogenic to humans. As a consequence, and consistent with the Safe Drinking Water Act (SDWA), EPA proposes to set the enforceable MCL as close to the Goal as is determined to be feasible. In the case of PFOA, EPA's conclusion is based on elevated levels of kidney cancer (renal cell carcinoma, or RCC) reported by Shearer et al. (2021). [FN5: Shearer JJ et al. Serum concentrations of per-and polyfluoroalkyl substances and risk of renal cell carcinoma. J Natl Cancer Inst 113:580-587 (2021).] However, this finding is not supported by the results from other studies where the potential for exposure to PFOA was better characterized.

EPA Response: Please see section 4.1.4 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1774, SBC-045682 and SBC-045683in section 4.1.4.3 in this *Response to Comments* document. Similar to the EPA's response to this commenter's assertion about PFOS (comment Doc. #1841, SBC-044830), the EPA also disagrees that the cancer assessment conclusions resulted in an overly conservative MCLG for PFOA.

American Chemistry Council (ACC) (Doc. #1841, SBC-053414)

The determination of the potential carcinogenicity of PFOA relies on an epidemiology study that determines exposure based on a single blood sample, despite the existence of other, conflicting studies based on a more robust exposure assessment.

EPA Response: Please see section 4.1.4 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1774, SBC-045682 and SBC-045683 in section 4.1.4.3 in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-052923)

The Available Animal Evidence Does Not Support a Conclusion that PFOA is a Likely Carcinogen at Low Doses

Considering the uncertainty in the epidemiological database, it is important to look at the results of cancer studies in laboratory animals for biological plausibility and concordance with findings in humans. While several bioassays have been conducted, none have reported an increase in kidney cancer among the exposed animals. Reported cancers have included liver, pancreas, and Leydig cell (LC) cancers. The most recent of these studies was conducted by the National Toxicology Program (NTP). [FN24: NTP. Technical report on the toxicology and carcinogenesis studies of perfluorooctanoic acid administered in feed to Sprague-Dawley rats. Technical Report 598. Department of Health and Human Services. Research Triangle Park, North Carolina (2019). (NTP PFOA Bioassay Technical Report)] In addition, no plausible biological basis for the development of tumors from PFOA exposure has been reported. Without it, there does not appear to be sufficient information to establish causation.

A significant amount of genotoxicity and mechanistic data on PFOA is available to assist in evaluating the results of the epidemiology and animal bioassay results described above. Multiple in vivo and in vitro assays provide clear evidence that PFOA is not mutagenic and may only cause genotoxicity at cytotoxic concentrations. Consequently, it is generally agreed that PFOA causes tumors in laboratory animals via a non-genotoxic or epigenetic mechanism. [FN25: USEPA. Health Effects Support Document for Perfluorooctanoic Acid (PFOA). EPA 822-R-16-003. Office of Water. Washington, DC. (May 2016). (USEPA PFOA HESD 2016)]

The tumor types that have been reported consistently in rats exposed to PFOA – liver, LC, and pancreatic acinar cell (PAC) – have been observed with other substances that are peroxisome

proliferator-activated receptor alpha (PPARα) agonists. Because of key toxicodynamic and biological differences in responses between rodents and humans, PPARα activators are considered unlikely to induce tumors in humans. For liver tumors, this conclusion is based on minimal or no effects observed on growth pathways, hepatocellular proliferation and liver tumors in humans and/or species (e.g., Cynomolgous monkeys) that are more appropriate animal model surrogates than mice and rats. Several key studies provide support for the key events (Kes) in the proposed PPARα-activated mode of action (MOA) for rat liver tumors. These data are summarized by Klaunig et al. (2012) –

Analysis of gene expression changes elicited following short-term administration of PFOA demonstrated the up regulation of genes characteristic of PPARα activation, including genes involved in fatty acid homeostasis/peroxisomal proliferation as well as those related to cell cycle. In addition, PFOA has been shown to induce peroxisome proliferation in mouse and rat liver and causes hepatomegaly in mice and rats. While the liver growth caused by PFOA was predominantly attributed to a hypertrophic response, an increase in DNA synthesis following PFOA exposure was observed and predominated in the periportal regions of the liver lobule. Thus, the effect of PFOA on induction of cell cycle gene expression and the increase in DNA synthesis provide evidence in support of both [KE] 2 and 3 in the proposed MOA for liver tumor induction by PFOA. Empirical evidence also exists in support of the clonal expansion of preneoplastic hepatic lesions by PPARα activators (Step 4). Using an initiation-promotion protocol for induction of liver tumors in Wistar rats, PFOA was shown to increase the incidence of hepatocellular carcinomas in rat liver (33% in PFOA exposed rats vs. 0% in controls). [FN26: Klaunig JE et al. Mode of action analysis of perfluorooctanoic acid (PFOA) tumorigenicity and human relevance. Reprod Toxicol 33:410-418 (2012).]

EPA Response: The commenter stated that the evidence related to the carcinogenicity of PFOA does not support a designation of *Likely to Be Carcinogenic to Humans*. The EPA disagrees with the explanations provided by the commenter to support this claim. Comments regarding the epidemiological evidence for the carcinogenic potential of PFOA, the lack of kidney cancer incidence observed in the available animal toxicological studies, the "biological basis" (i.e., proposed MOA) for tumor development, the use of genotoxicity data to support cancer assessments and classifications, and the human relevance of various tumor types resulting from PFOA administration are discussed in section 4.1.4 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1774, SBC-045682 and SBC-045683 in section 4.1.4.3 in this *Response to Comments* document. The commenter does not provide supporting evidence for their claims that was not already considered and cited by the EPA in the agency's toxicity assessment of PFOA and in the PFOA and PFOS MCLG technical support document (USEPA, 2024d; USEPA, 2024e).

AWWA (Doc. #1759, SBC-045597)

According to the proposal, EPA is proposing an MCLG of 0 ppt (zero) for PFOA based on a determination that PFOA is likely to be carcinogenic. AWWA has previously reviewed the EPA's

determination that PFOA is carcinogenic and provided comments (AWWA, 2021a). Key aspects of those comments are shown below and can be found in more detail in Appendix A.

1. EPA cites Shearer et al (2021) as a key study showing that PFOA may be carcinogenic. This study may not be suitable as evidence to support this determination given that the study duration spanned less than 18 years. Given the half-life of PFOA, it is unlikely to accurately portray the exposure relevant to the development of kidney cancer.

2. In epidemiological studies of higher exposures there has been inconsistent evidence of increased cases of kidney cancer. For example, epidemiological studies of residents exposed to PFOA and other PFAS in contaminated drinking water have reported modest increases whereas occupational cohorts have shown increased and decreased risk of kidney disease, despite higher exposure and longer study durations.

If EPA moves forward with a conclusion that PFOA is carcinogenic, AWWA agrees that the appropriate MCLG for a carcinogen is 0 ppt (zero).

EPA Response: The commenter reiterated to two specific points that were initially described by the commenter in a document sent to the SAB for its consideration at the time of peer review regarding the EPA's use of Shearer et al. (2021) to support the cancer classification for PFOA and their perceived inconsistencies in the epidemiological database for kidney cancer and disease. Responses for these comments are available in section 4.1.4 of the EPA response in this *Response to Comments* document and in the EPA response to comment Doc. #1774, SBC-045682 and SBC-045683 in section 4.1.4.3 in this *Response to Comments* document. More specifically, the biomonitoring measures of PFOA levels in Shearer et al. (2021) were reliable measures of PFOA exposure due to the chemical's well-established long half-life (see Section 3.3 of USEPA (2024a)). As a result, PFOA levels in serum remain relatively stable over long periods of time (i.e., years). The commenter incorrectly states that the "study duration [of Shearer et al. (2021)] spanned less than 18 years." In fact, the Shearer et al. (2021) study reported that diagnoses of renal cell carcinoma occurred between 2-18 years after the pre-diagnostic serum samples were collected. Since the study reported diagnosed cases of RCC, it therefore had adequate study sensitivity (i.e., a follow-up period of 18 years or less adequately captured RCC incidence). Additionally, the study duration for epidemiological studies is not the same as the exposure duration; patients included in Shearer et al (2021) were likely exposed to PFOA and other PFAS throughout their lifetimes and were aged 55 years and older, which is an adequate exposure duration considering the latency of cancer as the outcome of interest (USEPA, 2005).

Regarding kidney disease, the EPA concluded the epidemiological evidence for renal health outcomes was slight, which was based on "evidence of decreased kidney function among children and adults, including increased uric acid and hyperuricemia and decreased eGFR," but there were uncertainties related to mixed results, study quality, and potential reverse causality (USEPA, 2024d, Appendix C.5). A lack of evidence reporting associations between PFOA exposure and kidney disease does not detract from epidemiological evidence of positive associations between PFOA exposure and kidney cancer.

The commenter additionally points the EPA to comments they present in Appendix A of their submission. Responses to those comments are available in sections 4.2 and 13 of the EPA response in this *Response to Comments* document, depending on the topic described.

The commenter supported the EPA setting an MCLG of zero if the EPA maintains the conclusion that PFOA is *Likely to Be Carcinogenic to Humans*. The EPA agrees with this statement.

4.1.5 The EPA's Proposed MCLGs of Zero for PFOA and PFOS

Summary of Major Public Comments and EPA Responses

Many commenters supported the EPA's proposed MCLGs of zero for both PFOA and PFOS, citing well-documented health effects, including cancer, resulting from exposure to either PFOA or PFOS as rationale for their support of the proposed rulemaking. Several commenters also agreed with the EPA's long-standing practice of establishing the MCLG at zero (see USEPA, 1998; USEPA, 2000a; USEPA, 2001; *See* S. Rep. No. 169, 104th Cong., 1st Sess. (1995) at 3) for known or likely linear carcinogenic contaminants, with one commenter stating that it is "appropriate based on the weight of evidence for carcinogenicity and other adverse health impacts of PFOA and PFOS at very low exposures."

Two commenters disagreed with MCLGs of zero for PFOA and PFOS, with one commenter claiming that the EPA's determinations were "not consistent with the evidence the EPA presents nor with its own guidance" (i.e., the EPA's cancer assessment was not consistent with assessment approaches recommended in the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005)).

To establish an MCLG for individual contaminants, the EPA assesses the peer-reviewed science examining cancer and noncancer health effects associated with oral exposure to the contaminant. For nonlinear carcinogenic contaminants, contaminants that are designated as *Suggestive Human Carcinogens* (USEPA, 2005), and non-carcinogenic contaminants, the EPA typically establishes the MCLG based on a noncancer RfD. An RfD is an estimate of a daily oral exposure to the human population (including sensitive populations) that is likely to be without an appreciable risk of deleterious effects during a lifetime. A nonlinear carcinogen is a chemical agent for which the associated cancer response does not increase in direct proportion to the exposure level and for which there is scientific evidence demonstrating a threshold level of exposure below which there is no appreciable cancer risk. For known or likely linear carcinogenic contaminants, where there is a proportional relationship between dose and carcinogenicity at low concentrations or where there is insufficient information to determine that a carcinogen has a threshold dose below which no carcinogenic effects have been observed, the EPA has a long-standing practice of establishing the MCLG at zero (see USEPA, 1998; USEPA, 2000a; USEPA, 2001; *See* S. Rep. No. 169, 104th Cong., 1st Sess. (1995) at 3). Section 1412(b)(4)(A) requires that the MCLG "be set at the level at which no known or anticipated adverse effects on the health of persons occur and which allows for an adequate margin of safety." The MCLG "incorporates a margin of safety to reflect scientific uncertainty and, in some cases, the particular susceptibility of some groups

(e.g., children) within the general population" (S. Rep. No. 169, 104th Cong., 1st Sess. (1995) at 3).The EPA's general practice and decision here to set the MCLGs for PFOA and PFOS at zero based on information presented in the record (USEPA, 2024d; USEPA, 2024c; USEPA, 2024e) ensures that the MCLG is set at a level of "no known or anticipated adverse effects on the health of persons occur" and also "allows for an adequate margin of safety", which is intended to reflect scientific uncertainty and also "allows for an adequate margin of safety." This level (0 ppt) both ensures that the statutory criterion is met, in light of and accounting for scientific uncertainty, and protects all populations, including vulnerable populations identified in the final toxicity assessments for PFOA and PFOS (USEPA, 2024d; USEPA, 2024c).

The EPA disagrees with commenters' assertions because there is sufficient evidence for carcinogenicity of both PFOA or PFOS exposures supporting classifications of *Likely to Be Carcinogenic to Humans* according to the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005) from the available epidemiological and animal toxicological studies. Consistent with the guidelines, the EPA provided a narrative to "explain the case for choosing one descriptor and discuss the arguments for considering but not choosing another" (USEPA, 2005) in the draft and final toxicity assessments (USEPA, 2024d; USEPA, 2024c; USEPA, 2023f; USEPA, 2023a). Please see also section 4.1.4 of the EPA response in this *Response to Comments* document.

Individual Public Comments

Petersburgh C8 (PFAS) Committee (Doc. #2714, SBC-047422)

To The EPA:

The amount of any PFAS/PFOS compound that we should be exposed to is zero. We live near Taconic Plastics, a SuperFund Site in Petersburgh, NY. This industry has released these toxins into our aquifer, our town water supply, our private wells, our soil, our air, and most likely our food that we grow in this rural area during the last 50 years.

We know that the long chain compounds previously used - and still in our water supply - are extremely toxic. We know that the factory is now using short chain compounds, though they won't tell us which ones; we know that these have also been proven to be toxic. We smell the emissions almost daily and have discovered that air deposition has contributed to water contamination in our community as well as others nearby. Since the information is proprietary, we have no idea of the compounds they are using and releasing.

EPA Response: The comments provided by this commenter support the final rule.

Natural Resources Defense Council (Doc. #3072-6, SBC-053424)

Appropriately, EPA has proposed MCLGs of zero and MCLs of 4 parts per trillion for PFOA and PFOS, limits that are both scientifically supported and technologically available with currently available water treatment systems.

EPA Response: The comments provided by this commenter support the final rule.

Joe DiNardo (Doc. #1725, SBC-045756)

EPA Proposed National Primary Drinking Water Regulation (NPDWR)
Comme//www.regulations.gov/document/EPA-HQ-OW-2022-0114-0027)

Joe DiNardo – Personal Care Products Toxicologist since 1976

I would first like to thank the EPA for their tremendous efforts and advances made in establishing guidelines to control the human and environmental impact of Per- and Polyfluoroalkyl Substances (PFAS). With that said, I respectfully submit the following comments for EPA's review and consideration in light of the proposed National Primary Drinking Water Regulation (NPDWR):

1) EPA Statement:

"Following a systematic review of available human epidemiological and animal toxicity studies, EPA has determined that PFOA and PFOS are likely to cause cancer (e.g.,kidney and liver cancer) and that there is no dose below which either chemical is considered safe (see section IV.A and V.A through B of this preamble for additional discussion). Therefore, EPA is proposing to set the health-based value, the MCLG, for both of these contaminants at zero."

I agree with EPA's safety assessment that PFOA and PFOS are likely carcinogenic to humans and with the conclusion that there is no dose that is safe and, therefore, setting an MCLG to "Zero" is logical.

EPA Response: The comments provided by this commenter support the final rule.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044019)

EPA requests comment on the derivation of the proposed MCLG for PFOA and its determination that PFOA is Likely to be Carcinogenic to Humans and whether the proposed MCLG is set at the level at which there are no adverse effects to the health of persons and which provides an adequate margin of safety.

a. It is standard for (potential) carcinogens to have an MCLG of zero.

EPA Response: The comments provided by this commenter support the final rule.

Suffolk County Water Authority (SCWA) (Doc. #1589, SBC - 043365)

Establishment of Maximum of Contaminant Level Goals Provides an Important Benchmark for Public Water Suppliers

SCWA bylaws provide that the SCWA's mission is to serve its customers "the highest quality water at the lowest possible cost with excellent customer service." Serving the highest quality

water means that the SCWA's mission is to treat water to the maximum contaminant level goal (MCLG) whenever feasible because that is the level at which there is no known or anticipated effects on the health of persons.

When the State of New York adopted MCLs for PFOA and PFOS, it did not adopt any MCLGs. Like 24 other states, New York does not currently utilize MCLGs as part of its public health law or its state sanitary code. Based upon SCWA's review of the regulatory record of the New York State Department of Health for PFOA and PFOS, it appeared that the MCLG for both contaminants would be zero if New York utilized MCLGs because they are likely human carcinogens, and there was insufficient information to determine if there was a threshold dose below which there were no carcinogenic effects. The EPA's proposal to establish MCLGs of zero for PFOA and PFOS provides confirmatory guidance to the SCWA regarding this important benchmark. [SB1] [EM2]

EPA Response: The comments provided by this commenter support the final rule.

Citizens Campaign for the Environment (CCE) (Doc. #1710, SBC-045131)

• Adopt the MCL Goal of zero for PFOA and PFOS

As suspected carcinogens, there is no safe level of exposure to these harmful PFAS chemicals. EPA's recent update of its health advisory for PFOS and PFOA has made clear that there is essentially no safe level of exposure to these chemicals in drinking water. CCE supports setting MCLG's at zero for a number of important reasons, including:

• Vulnerable populations, including infants, the elderly, and those with compromised immune systems may choose to only consume water that presents no known or anticipated adverse health effects.

EPA Response: This commenter supports the conclusions of the EPA's proposed rule and specifically highlighted the protection of vulnerable populations as rationale for adopting the MCLGs of zero. The EPA is issuing a final rule consistent with this comment; please also see section 4.1.5 of the EPA response in this *Response to Comments* document.

Kevin Korro (Doc. #1538, SBC-042654)

Individual Maximum Contaminant Levels (MCLs) for PFOA and PFOS were established at 4.0 nanograms per liter (ng/L) or parts per trillion (ppt), while the proposed Maximum Contaminant Level Goals (MCLGs) for PFOA and PFOS were set at zero. These are goals that have my complete support.

EPA Response: The comments provided by this commenter support the final rule.

A. O. Smith Corporation (Doc. #1674, SBC-043691)

Maximum Contaminant Level Goal

A. O. Smith supports the EPA's MCLG determinations for the six identified PFAS compounds and agrees that these chemicals are likely to create adverse health impacts in human beings at high exposure levels. Therefore, a goal of removing them from the nation's drinking water supply is appropriate.

EPA Response: The comments provided by this commenter support the final rule.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045017)

NJDEP also agrees that the proposed MCLGs of zero for PFOA and PFOS are consistent with the approach used by EPA since the 1980s for setting MCLGs for Category I contaminants (i.e., known and likely human carcinogens under the USEPA [2005] Cancer Risk Assessment Guidelines; Groups A, B1, and B2 under the earlier USEPA [1986, 1999] guidelines), as described on p. 186530 of the proposed rule. According to the USEPA (2005) cancer risk assessment guidelines, any level of exposure to a known or likely carcinogen is assumed to cause some risk of cancer unless a threshold mode of action has been demonstrated. As such, EPA sets MCLGs for known and likely human carcinogens at zero to ensure that "there are no anticipated adverse health effects with a margin of safety" unless a threshold for carcinogenicity has been established. Since a threshold mode of action for carcinogenicity has not been established for PFOA and PFOS, it is appropriate that the MCLGs for these two PFAS are set at zero.

EPA Response: The comments provided by this commenter support the final rule. Specifically, the commenter agreed with the proposed MCLGs of zero, stating that this approach is consistent with past precedent and conclusions regarding the carcinogenicity and MOAs of PFOA and PFOS. The EPA agrees with the commenter's conclusions.

3M Company (Doc. #1774, SBC-053427)

Further, EPA reliance on cancer endpoints as the basis for a maximum contaminant level goal (MCLG) of zero for PFOA and PFOS is not consistent with the evidence EPA presents nor with its own guidance.

EPA Response: The EPA disagrees with this comment. Please see sections 4.1.5 and 4.1.4 of the EPA response in this *Response to Comments* document regarding the EPA's determination that PFOA and PFOS are *Likely to Be Carcinogenic to Humans* (USEPA, 2005).

American Chemistry Council (ACC) (Doc. #1711, SBC-044458)

The Agency's proposal suffers from the following significant shortcomings –

The proposal to establish maximum contaminant level (MCL) goals of zero for both PFOA and PFOS is not consistent with the available cancer weight of scientific evidence for the substances.

EPA Response: The EPA disagrees with this comment. Please see sections 4.1.5 and 4.1.4 of the EPA response in this *Response to Comments* document regarding the EPA's determination that PFOA and PFOS are *Likely to Be Carcinogenic to Humans* (USEPA, 2005).

American Chemistry Council (ACC) (Doc. #1841, SBC-044816)

The Agency's proposal would establish MCL Goals for PFOA and PFOS of zero based on a conclusion that they are likely human carcinogens under the Agency's Cancer Risk Guidelines [FN3: USEPA. Guidelines for Cancer Risk Assessment. EPA/630/P-03/001F. Risk Assessment Forum (2005). (USEPA Cancer Risk Guidelines)] and a combined MCL Goal for PFBS, HFPO-DA, PFHxS, and PFNA based on a novel and unprecedented hazard index (HI) approach. While EPA proposes to set the enforceable MCL for the HI of the four substances at the MCL Goal, the MCL for PFOA and PFOS would be set at the minimum reporting level determined by the Agency for each substance. In support of its proposal, EPA has developed estimates of the costs of complying with the proposed standards and the expected benefits in public health that it predicts will be achieved as a result of the standards.

As outlined in these comments, the Agency's proposal suffers from a number of significant shortcomings, including the following –

The proposal to establish maximum contaminant level (MCL) goals of zero for both PFOA and PFOS is not consistent with the available cancer weight of scientific evidence for the substances.

EPA Response: The EPA disagrees with these comments. Please see sections 4.1.5 and 4.1.4 of the EPA response in this *Response to Comments* document regarding the EPA's determination that PFOA and PFOS are *Likely to Be Carcinogenic to Humans* (USEPA, 2005). Regarding the Hazard Index MCLG, please see section 4.3 of the EPA response in this *Response to Comments* document. Regarding the MCLs, please see section 5 of the EPA response in this *Response to Comments* document. Regarding the estimated benefits and costs, please see section 13 of the EPA response in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-044779)

May 15, 2023

The Honorable Michael S. Regan

Administrator

US Environmental Protection Agency

1200 Pennsylvania Avenue

Washington, DC 20460

Re: PFAS National Drinking Water Regulation Rulemaking; Preliminary Regulatory Determination and Proposed Rule, 88 Federal Register 18638 (March 29, 2023), EPA- HQ-OW-2022-0114

Dear Administrator Regan:

The American Chemistry Council (ACC) submits the enclosed comments on the preliminary regulatory determination for four per- and polyfluoroalkyl substances (PFAS) under the Safe Drinking Water Act (SDWA) and the proposal to establish national primary drinking water standards for these four substances, perfluorooctanoate (PFOA), and perfluorooctane sulfonate (PFOS) under the Act. The Agency's proposal suffers from the following significant shortcomings –

The proposal to establish maximum contaminant level (MCL) goals of zero for both PFOA and PFOS is not consistent with the available cancer weight of scientific evidence for the substances.

EPA Response: The EPA disagrees with this comment. Please see sections 4.1.5 and 4.1.4 of the EPA response in this *Response to Comments* document regarding the EPA's determination that PFOA and PFOS are *Likely to Be Carcinogenic to Humans* (USEPA, 2005). Regarding the regulatory determinations for four additional PFAS substances, please see section 3 of the EPA response in this *Response to Comments* document.

4.2 The EPA's Toxicity Assessments for PFOA and PFOS

Summary of Major Public Comments

The EPA requested comments on different aspects of the draft toxicity assessments of PFOA and PFOS. The EPA received comments on a variety of topic areas that fall outside the scope of the MCLG derivation, including comments on the noncancer health outcome conclusions, toxicity value derivations, relative source contribution (RSC), the pharmacokinetic modeling approach, non-prioritized health outcomes (e.g., endocrine), and others. Some commenters requested clarification on the information presented in the draft toxicity assessments. The EPA's responses to these issues as well as others expressed by individual commenters are described in further detail below.

4.2.1 The EPA's Conclusions on Noncancer Health Outcomes

Summary of Major Public Comments and EPA Responses

The EPA requested comment on its assessment of the noncancer effects associated with exposure to PFOA and PFOS. Some commenters supported and some commenters criticized the EPA's conclusions regarding noncancer health effects associated with PFOA and PFOS exposure.

Several commenters highlighted the multitude of adverse noncancer health outcomes that are associated with PFOA or PFOS exposure and the large volume of literature providing evidence supporting the regulation of these compounds. A few commenters specifically expressed support

for one or more of the four priority noncancer health outcomes (i.e., developmental, immune, hepatic, and cardiovascular) identified by the EPA in the toxicity assessments for PFOA and PFOS (USEPA, 2023f; USEPA, 2023a; USEPA, 2024d; USEPA, 2024c). These commenters are also in agreement with the SAB PFAS Review Panel, who stated, "[m]ultiple studies for each of these four effects are generally consistent in different populations and settings, and the total body of evidence indicates that these effects are present" (USEPA, 2022b).

A few commenters disagreed with the EPA's conclusions regarding the selection of four noncancer health outcomes prioritized in the PFOA and PFOS toxicity assessments. A few commenters stated that the human epidemiological evidence for one or more of the priority health outcomes was too inconsistent to support the EPA's strength of evidence determinations. A few commenters claimed that flaws in the EPA's approach (e.g., inconsistent study evaluations, selective consideration of epidemiological studies, improper evidence integration) resulted in the agency drawing incorrect conclusions regarding the strength of evidence for these noncancer health outcomes. A few commenters stated that they disagreed because the research is still ongoing and there is limited evidence for associations between PFOA or PFOS and adverse health effects in humans.

The EPA disagrees with the claim that the effects observed in the epidemiological databases for the four priority noncancer health outcomes are inconsistent. The EPA documented the weight of evidence in evidence profile tables, which organize and integrate evidence across the epidemiological, animal toxicological, and mechanistic data (see Section 3 of USEPA (2024d) and USEPA (2024c)) consistent with the ORD IRIS Handbook (USEPA, 2022a). This documentation is detailed, transparent, and clear. The epidemiological databases for each health outcome were determined to have moderate evidence of an association between PFOA or PFOS and the outcome of interest. This means that the evidence across studies supports a conclusion that the effect(s) results from the exposure being assessed (i.e., PFOA or PFOS) with only some uncertainty due to potential chance, bias, or confounding (USEPA, 2022a). More specifically, each critical effect was represented by multiple epidemiological studies of high and/or medium confidence that showed consistent direction of effect in the target population(s) and, importantly, coherence with evidence presented in animal toxicological studies. These factors, combined with the EPA's practice that "human data are preferred over animal data to eliminate interspecies extrapolation uncertainties" (USEPA, 2022a), support the EPA's decision to use human epidemiological studies for quantitative analyses.

As described in section IV of the Federal Register Notice, the EPA disagrees with commenters' claims that there were flaws in the assessment approach that resulted in the mischaracterization of hazards associated with PFOA and PFOS exposure. The EPA followed the state-of-the-art systematic review best practices from the ORD Staff Handbook for Developing IRIS Assessments (USEPA, 2022a) and the *Systematic Review Protocol for the PFBA, PFHxA, PFHxS, PFNA, and PFDA (anionic and acid forms) IRIS Assessments* (USEPA, 2021a) when developing the protocol used as the basis for study quality evaluations, evidence integration, and critical study selection, and followed other agency guidance as applicable. Additionally, the SAB

provided many recommendations to further strengthen the EPA's protocol and the EPA fully addressed the SAB PFAS panel's recommendations (USEPA, 2023d), resulting in scientifically sound toxicity assessments (USEPA, 2023f; USEPA, 2023a; USEPA, 2024d; USEPA, 2024c). Importantly, the SAB PFAS Panel "…agreed with many of the conclusions presented in the assessments," including the EPA's focus on "health outcomes that have been concluded to have the strongest evidence, including the liver disease, immune system dysfunction, serum lipid aberration, impaired fetal growth, and cancer" (USEPA, 2022b).

While the EPA acknowledges that there is ongoing health effects research for PFOA, PFOS, and PFAS as a class, the EPA disagrees with the characterization that there is limited evidence to support the findings and conclusions of this rulemaking. In fact, there is a substantial amount of evidence supporting the EPA's hazard characterizations for PFOA and PFOS as reflected in the Interactive Flow Diagram developed by the EPA to visualize the available literature in section 3.1 of the toxicity assessments (availablublic.tableau.com/app/profile/pfoapfos2023/viz/InteractiveReferenceFlowDiagramforPFOAPFOS_16615197966440/PFOAPRISMADiagram); there are hundreds of *medium* and *high* confidence published studies describing associations between PFOA and/or PFOS and adverse health effects. The strength of evidence supporting these association are summarized in the evidence profile tables found in sections 3.4.1.4 (hepatic), 3.4.2.4 (immune), 3.4.3.4 (cardiovascular), and 3.4.4.4 (developmental) of the toxicity assessments (USEPA, 2024d; USEPA, 2024c). Additionally, the studies identified in the final supplemental literature search conducted in February 2023 continue to support the conclusions of the toxicity assessments for PFOA and PFOS (USEPA, 2024a; USEPA, 2024b; Appendix A3).

Based on the results of the literature searches conducted through 2022, there was evidence of increases in total cholesterol (TC) concentrations (19/23 studies) associated with elevated exposure to PFOA in studies of adults (see Section 3.4.3 of USEPA, 2024d). Similarly, there was evidence of increases in TC concentrations (18/23 studies) associated with elevated exposure to PFOS in studies of adults (see Section 3.4.3 of USEPA, 2024c). Consistency for increases in TC concentrations in adults associated with elevated exposure to PFOA and PFOS was supported by additional studies identified from the EPA's supplemental literature search in 2023. Specifically, for PFOA, 10 out of 11) studies evaluating changes in TC reported increases in TC with elevated exposure to PFOA and 6 out of 11 reported statistically significant increases (Section A.3 of USEPA, 2024a). Similarly, for PFOS, 10 out of 11 studies evaluating changes in TC reported increases in TC with elevated exposure to PFOS and 8 out of those 11 reported statistically significant changes in TC (Section A.3 of USEPA, 2024b). Together, these studies support the EPA's conclusion that the evidence indicates elevated exposures to PFOA or PFOS are associated with adverse cardiovascular effects, specifically serum lipids, as well as EPA's selection of increased total cholesterol in adults for dose-response modeling.

Based on the results of the literature searches conducted through 2022, there were 30 studies reporting deficits in BWT (30/42) associated with elevated exposure to PFOA (see Section 3.4.4 of USEPA, 2024d). Similarly, there were 27 studies reporting deficits in BWT (27/39) associated

with elevated exposure to PFOS (see Section 3.4.3 of USEPA, 2024c). Consistency for decreases in BWT associated with elevated exposure to PFOA and PFOS was supported by evidence from studies identified from the EPA's 2023 supplemental literature search. Specifically, for PFOA, seven studies identified from the 2023 literature search evaluated changes in BWT (i.e., BWT and BWT for sex and GA), and 4 out of 7 studies reported decreases with three of these studies reporting significant decreases (Section A.3 of USEPA, 2024a). Similarly, for PFOS, eight studies identified from the 2023 literature search evaluated changes in BWT (i.e., BWT and BWT for sex and GA), and four studies reported decreases, three of which were statistically significant (Section A.3 of USEPA, 2024b). These studies provided additional support for the critical effect of decreased BWT in multiple geographic locations (i.e., Denmark, the United States, and China).

Based on the results of the literature searches conducted through 2022, there was consistent evidence for decreased antibody response in children, particularly tetanus, diphtheria and rubella, associated with elevated exposure to PFOA and PFOS (see Sections 3.4.2 of USEPA, 2024d; USEPA, 2024c)). Studies from the Faroe Islands provided consistent evidence of associations between elevated exposure to PFOA and PFOS and decreases in antibody responses against tetanus and diphtheria in children at birth, 18 months, age 5 years (pre-and post-booster), and at age 7 years, with some associations being statistically significant (USEPA, 2024d; USEPA, 2024c, Sec. 3.4.2.1.2.1). Evidence from multiple Faroe Islands studies was supported by another study which reported an increased risk of being below the level of protection for diphtheria in participants from Greenland with elevated exposure to PFOA or PFOS (Timmerman et al., 2021). Additional support for immunosuppression was also reported in studies on decreased rubella in children. Specifically, for PFOA 2/2 studies measuring rubella antibodies in different populations demonstrated a significant decrease (see section 3.4.2.1.1 in USEPA, 2024a). For PFOS, 2/2 studies measuring rubella antibodies in different populations demonstrated a significant decrease (see section 3.4.2.1.1 in USEPA, 2024c). Consistency for decreased antibody responses in children associated with elevated exposure to PFOA and PFOS was further supported by evidence from an additional study identified in the EPA's 2023 supplemental literature search (see Section A.3 of USEPA, 2024a; USEPA, 2024b). One study examined elevated exposure to PFOA and PFOS and changes in antibody response in adolescents, and an effect was observed for both PFOA and PFOS (Zhang et al., 2023). A significant inverse association was observed for elevated exposure to PFOS and rubella antibody response in the overall study population, while a significant inverse association was observed for elevated exposure to PFOA and rubella antibody response for participants in the lower folate group. Zhang et al. (2023) provided additional evidence for decreased vaccine response in children to a pathogen besides those already identified (i.e., tetanus and diphtheria) and added to the existing evidence (i.e., Granum et al.,2013, Pilkerton et al., 2018 (for PFOA) and Stein et al., 2016).

Based on the results of the literature searches conducted through 2022, there was consistent evidence for increased ALT concentrations in adults associated with elevated exposure to PFOA and PFOS (see Sections 3.4.1 of USEPA, 2024d; USEPA, 2024c). Specifically, for PFOA, 9 out of 11 studies demonstrated statistically significant increases in ALT with elevated exposure to

PFOA was observed across studies. Similarly, for PFOS, 6 out of 9 studies demonstrated increased ALT concentrations in adults was associated with elevated exposure to PFOS and 5 of those studies were statistically significant increases. Consistency for increased ALT concentrations associated with elevated exposure to PFOA and PFOS was further supported by evidence from additional studies identified from the EPA's 2023 supplemental literature search. For PFOA, 3 out of 4 studies examining ALT reported increases in ALT and two of those studies were statistically significant increases (see Section A.3 of USEPA, 2024a). For PFOS, 3 out of 4 studies examining ALT reported increased ALT with one of these studies demonstrating a statistically significant increase (see Section A.3 of USEPA, 2024b). Together, these studies support the EPA's conclusion that the evidence indicates elevated exposures to PFOA or PFOS are associated with adverse hepatic effects, specifically increased liver enzymes, as well as EPA's selection of increased ALT in adults for dose-response modeling

4.2.1.1 General Comments

Harris County Attorney's Office (Doc. #1751, SBC-045261)

The proposed standards are needed to safeguard the health of our communities.

As EPA has noted, exposure to PFAS has been linked to many known health impacts. These negative impacts include issues with growth and development, hormone and lipid levels, the nervous system and the immune system, reproduction, the liver, and cancer. As such, HCA is in support of measures that can reduce PFAS's negative health impacts.

The volume of literature on these negative health effects is rapidly growing and continually points to the need to regulate these compounds. For example, a study published in April of this year concluded that elevated plasma concentration of certain PFAS is associated with increased weight gain and obesity. [FN1: Phillippe Grandjean et al., Weight loss relapse associated with exposure to perfluoroalkylate substances, Obesity, Spring 2023, at 1.] A study published in February suggested PFAS can disrupt certain biological processes in youth, which is connected to an increased risk of a very broad range of diseases, including developmental disorders, cardiovascular disease, metabolic disease, and many types of cancer. This study also notes that exposure to a mixture of PFAS, rather than a single chemical, drove the disruption of these biological processes. [FN2: See generally Jesse A. Goodrich et al., Metabolic Signatures of Youth Exposure to Mixtures of Per- and Polyfluoroalkyl Substances: A Multi-Cohort Study, 131(2) Feb. 2023, at 027005-1-14; Hope Hamashige, Keck School of Medicine study finds "forever chemicals" disrupt key biological processes, Keck Sch. Med. USC, (Feb. 21, 2/keck.usc.edu/keck-school-ofmedicine-study-finds-forever-chemicals-disrupt-key-biological-processes/.] Another study published in February of this year linked PFAS exposure to a decrease in female fertility. [FN3: Nathan J. Cohen, Exposure to perfluoroalkyl substances and women's fertility outcomes in a Singaporean population-based preconception cohort, 873 Sci. of the Total Env't, 162267 (2023) ("Higher PFAS exposures may be associated with decreased fertility in women")] The frequency in which a new negative health consequence is linked to PFAS signals the necessity of these regulations.

EPA Response: This commenter supports the conclusions of the EPA's toxicity assessments for PFOA and PFOS and has provided several citations to support this stance. Please see the EPA Response to 4.2.6 for information related to how the EPA considered references recommended during public comment. No further response needed.

Earthjustice et al. (Doc. #1808, SBC-046102)

EPA's proposed MCLGs are further supported by PFOA's and PFOS's severe noncancer effects, which occur at levels far below those that can be detected in drinking water. As recognized EPA's toxicity assessments for both PFOA and PFOS, those contaminants cause immune system harm (including reduced vaccine effectiveness in children), developmental toxicity, and heart and kidney damage at levels ranging as low as 3 ×10–8 mg/kg/day (PFOA) and 1 ×10–7 mg/kg/day (PFOS).63 Those levels equate to drinking water toxicity in the parts-perquadrillion range, well below the detection limit for either chemical.64 While cancer risks alone are sufficient to support the proposed zero ppt MCLGs for PFOA and PFOS, their serious noncancer risks reinforce the need for EPA to reduce exposure to both chemicals as much as feasible.

EPA Response: This commenter supports the conclusions of the EPA's proposed rule and toxicity assessments for PFOA and PFOS. No further response needed.

Midwest Environmental Advocates et al. (Doc. #1846, SBC-045823)

The six PFAS subject to this regulation may cause significant adverse impacts on human health.

The SDWA "was enacted to ensure that public water supply systems meet minimum national standards for the protection of public health." [FN4: Nat'l Wildlife Fed'n v. U.S. EPA, 980 F.2d 765, 768 (D.C. Cir. 1992).] The statute therefore requires EPA to base NPDWRs on a finding that a contaminant may have an adverse impact on human health. [FN5: 42 U.S.C. §§ 300g-1(a)(3), (b)(1)(A)(ii), (b)(1)(B)(ii)(II).] While our knowledge on the health effects of PFAS continues to grow, the best available scientific information supports the endangerment finding that each of the six PFAS contaminants at issue may cause adverse health effects.

EPA reviewed toxicity studies of oral exposure in animals and other reliable scientific data to reach the sound conclusion that each of these PFAS may cause adverse impacts to human health. [FN6: 88 Fed. Reg. 18638, 18645-47.] The word "may" in the endangerment criterion delineates the degree of certainty for EPA's finding, and it unambiguously requires merely a show of evidence indicating the "possibility or probability" [FN7: May, Merriam Webster Diction//www.merriam-webster.com/dictionary/may (last visited May 22, 2022); see also May, Cambridge Dictiononary.cambridge.org/us/dictionary/english/may (last visited May 23, 2022) (defining "may" as "used to express possibility"); see also Parker v. Scrap Metal Processors, Inc., 386 F.3d 993, 1015 (11th Cir. 2004) (noting that the word "may" in the endangerment finding of Section 107 of the Resource Conservation and Recovery Act clearly requires only a "potential" for harm or threat of harm).] of adverse human health effects. The notion that the endangerment criterion requires a quantifiable threshold of certainty regarding health impacts has been rejected.

[FN8: See Nat. Res. Def. Council, Inc. v. U.S. EPA, 824 F.2d 1211, 1217-18 (1987) (rejecting argument that SDWA requires a preponderance-of-the-evidence threshold test for regulating contaminants and emphasizing that "[b]y its terms, the statute grants discretion to the Administrator to determine whether there is sufficient evidence to justify establishing a recommended level for a particular compound.").]

The evidence relied upon by the agency to support its endangerment finding indicates a strong correlation between oral exposure to PFOS, PFOA, PFBS, PFHxS, PFNA, and GenX and certain adverse health effects, including cancers. Any claim that EPA lacks the required scientific data to proceed with this rulemaking therefore disregards not only the robust toxicological data on these PFAS, but also the plain meaning of the endangerment criterion, the health-protective design of SDWA, and the discretion conferred on the Agency to reach this determination.

Commenters support EPA's endangerment determination as a decision based on the "best available, peer-reviewed science and supporting studies" [FN9: 42 U.S.C. § 300g-1(b)(3)(A)(i).] and consistent with the protective statutory scheme of the SDWA.

EPA Response: This commenter supports the conclusions of the EPA's toxicity assessments for PFOA and PFOS and the preliminary regulatory determination presented in EPA's proposed rule (USEPA, 2023e). The EPA is issuing a final regulatory determination consistent with the comment (see section 3 of the EPA response in this *Response to Comments* document). The commenter appears to be using the term "endangerment finding" or "engagement criterion" or "endangerment determination" to refer to the regulatory criterion at section 1412(b)(1)(A)(ii). The EPA addresses its findings regarding that criterion in section III of tthis rulemaking preamble and section 3 of this *Response to Comments* document.

Silent Spring Institute (Doc. #1784, SBC-045799)

1. There is strong evidence of harm from low-dose exposures to PFOA and PFOS, including for sensitive subpopulations such as pregnant women, children, and nursing individuals.

EPA Response: This commenter supports the conclusions of the EPA's toxicity assessments for PFOA and PFOS, specifically that sensitive populations may be at risk of adverse health effects. No further response needed.

Silent Spring Institute (Doc. #1784, SBC-053335)

Regardless of these omissions, EPA's conclusion of low-dose toxicity of PFOA and PFOS is consistent with the conclusion of the European Food Safety Authority in its 2020 assessment of four PFAS. In the revised opinion on joint exposures to PFOA, PFNA, PFHxS and PFOS, EFSA considered immunotoxicity as the critical effect and calculated a tolerable daily intake limit of 0.63 ng/kg-day.21 Using Lifetime Health Advisory formula from EPA, this intake limit corresponds to a health-based drinking water concentration limit of 2 ng/L for the sum of PFOA,

PFNA, PFHxS and PFOS. These data highlight the need to set the MCLs for PFOA and PFOS to levels as low as feasible to be protective of the most sensitive health effects.

EPA Response: This commenter supports the conclusions of the EPA's toxicity assessments for PFOA and PFOS and has cited conclusions by the EFSA (EFSA, 2020) to support their rationale. Please see the EPA Response to 4.2.6 below for information related to how the EPA considered conclusions from other health agencies when finalizing the toxicity assessments. No further response needed.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045013 & SBC-045014)

Derivation of Maximum Contaminant Levels and Hazard Index

MCLGs for PFOA & PFOS

EPA requested comment on the derivation of the proposed Maximum Contaminant Level Goals (MCLGs) for PFOA and PFOS. The proposed rule (88 Fed. Reg. 18652) states that, based on recommendations from the EPA Science Advisory Board (SAB), EPA's quantitative analysis for PFOA and PFOS focused on the five health outcomes with the strongest weight of evidence—liver, immune, cardiovascular, developmental, and cancer. The DWQI (2022) also concluded that these are the five health outcomes with the strongest evidence for PFOA and PFOS, and NJDEP concurs with this conclusion.

Use of human data as the basis for PFOA and PFOS toxicity factors:

The proposed rule (88 Fed. Reg. 18657) states: "…when both laboratory animal data and human data with sufficient information to perform exposure-response modeling are available, human data are generally preferred for the derivation of toxicity values." Regarding this point, the DWQI (2022) evaluated relevant information and agreed with EPA's conclusion that human data are an appropriate basis for the derivation of Reference Doses for non-carcinogenic effects of PFOA and PFOS and the cancer slope factor for carcinogenic effects of PFOA, and NJDEP concurs with the DWQI (2022) conclusion.

EPA Response: This commenter supports the conclusions of the EPA's toxicity assessments for PFOA and PFOS, specifically that the hepatic, developmental, immune, cardiovascular, and cancer health outcomes are those with the strongest supporting evidence and that human data are an appropriate basis for toxicity value derivation. No further response needed.

Steven Alt (Doc. #1724, SBC-044472)

The following represent my opinions and beliefs:

I support the EPA proposal to establish standards for PFAS in public drinking water supplies. I am a private citizen who believes strongly in learning from history. I read PFAS are endocrine

disruptors and the CDC stated “Endocrine disruptors are a particularly relevant environmental exposure, as exposure results in a decrease in testosterone and fewer males are conceived as a result.” [FN1: ,Hartnett KP, Marcus M. Can environmental or occupational hazards alter the sex ratio at birth? A systematic review. Emerg Health Threats J. 2011;4:7109.] A quick check of the Ccking.cdc.gov/DataExplorer on sex ratio led me to believe sex ratio skewing of humans has been occurring in WI counties deriving their drinking water supply from Lake Michigan which also supports my personal observation of more females seemingly being born than males in areas drawing drinking water from Lake Michigan.

I am disappointed in what I believe was the delay in the heeding of the possible warning signs, the first nearly 40 years ago and a second ~25 years ago. I do not know the level of communication between the EPA and State agencies such as Department of Natural Resources (DNR), but I believe strong warning signs of a new harmful pollutant (PFAS) in Lake Michigan might have been ignored in the past. I felt and still feel Great Lakes native aquatic species act much like the ‘canary in the coal mine’, a sentinel species, warning of possible environmental danger. The first warning, the Wisconsin Department of Natural Resources (WDNR) referenced in 1999 [FN2: The Great Lakes Fishery Commission; Lake Michigan Committee; Lake Michigan Management Reports, Lake Michigan Fisheries Team 1999. See Attachment2_WDNR_Manag_Rpt_1999], a document concerning Lake Michigan, page 12 “The substantial shift in sex ratios that has occurred since 1980 continued in the chub population sampled during 1998 from GMGN. In the early 80’s when younger fish (ages 2-5) dominated the chub population, the sex ratio was about 50:50. Now, with a greater range of year classes in the population, which older fish dominate, females predominate. The one advantage of the female dominated sex ratio to the industry is that commercial fishers have profited through the sale of eggs to the caviar market during the late fall and winter months”. I could not find any natural process which could explain this, nor could I find sex ratio skewing reported in Lake Michigan fisheries previously. I felt a chemical pollutant best explained this, but the list of past chemical contaminates such at DDT, Dioxin, mercury, etc. already being present for decades didn’t seem to result in fish skewing female so greatly and quickly, as chubs did in ‘the early 80’s’, while I believed PFAS could.

The second warning around the same time; in 1996 WI temporarily banned the netting of yellow perch in Lake Michigan [FN3: Excluding Green Bay (GB)] . Per perch surveys [FN4: Winter Graded-Mesh Assessments and or Statistical Catch At Age SCAA starting in 1986 for Lake Michigan (ex. GB)] , up until 1996 the yellow perch were skewing male most likely due to netting, as later supported by Lauer [brary.wiley.com/doi/abs/10.1111/j.1365-2400.2007.00567.x Changes in yellow perch length frequencies and sex ratios following closure of the commercial fishery and reduction in sport bag limits in southern Lake Michigan] . My fears of a chemical pollutant were further reinforced as can be seen from the Lake Michigan Yellow Perch Task Group 2021 report [mprey.org/pubs/lake_committees/michigan/yellow_perch/Status%20of%20YEP%20in%20LM%202019-2020%20(2021).pdf page 8 figure 2] , starting in 1997 the perch sex ratio immediately skewed female, a condition no longer hidden by the netting of female perch. Just as done

previously with chubs, the WDNR tried to spin this worrisome fact by stating “Since 2000 the sex ratio of the yellow perch population was shifted toward predominantly female and lasted until 2002. This trend was reversed again since 2003 with greater number of males, except for 2007. But recently the female proportion has increased markedly with 71% in 2010, 76% in 2011, 77% in 2012, and 76% in 2013. The data from 2008-2012 spawning assessment also indicated a decreased number male perch in the population. An absence of commercial harvest in Lake Michigan certainly has helped decrease the impact on fast growing larger female perch in the fishery, allowing them to spawn multiple years.” [FN7: Lake Michigan Management Reports – 2013 WdNR. Page 18. See Attachment3_WDNR_Manag_Rpt_2013.pdf] Spawning multiple years was never previously mentioned by the WDNR as being of concern. Also of possible interest to researchers, the stated 2003 ‘reversed trend’ coincided with the perch raised allegedly for a WDNR/UW Water Institute Yellow perch Broodstock program [FN8: See attachment5_Yellowperch1997broodstock.pdf] started in 1997 using yellow perch eggs removed from the Milwaukee reef. While the WDNR admits to UW Water Inst. Producing 195 liters (~16 million) Lake Michigan strain yellow perch eggs, the final disposition of those eggs and/or resulting fry [//dnr.wisconsin.gov/sites/default/files/topic/Fishing/LM_LakeMichiganYellowPerchSummitReport.pdf bottom page 21.] was withheld. This temporary pause of WI perch skewing female I believe was due to the unreported stocking of above perch in Lake Michigan (reported stockings [F//dnr.wi.gov/fisheriesmanagement/Public/Summary/Index In 1978 - 178,740 (inland strain) and 1981 - 200,000 (Green Bay strain) perch were stocked in Lake Michigan off Milwaukee Co.] led to the pervious perch recovery by 1986) and so offers a vein of investigation comparing the sex ratio of fish which spawn in Lake Michigan vs those which move up its tributaries to spawn.

I found the WDNR’s concern for the profits of apparent illegally subsidized commercial fishing [Fs://p.widencdn.net/2gge3j/Admin_FH039 Administrative Report No. 39 Lake Michigan Integrated Fisheries Management Plan 1995 – 2001 Feb 1995, page 38, ‘may not be appropriate’, i.e. illegal as it apparently violates WI Law of 1977 Act 418 (37) (d) 3 which requires ‘…an economically viable and stable commercial fishe/docs.legis.wisconsin.gov/1977/related/acts/418.pdf page 1799.] over the ecology of the lake, the health of a major fish species, such as chubs and perch, and possible danger to humans, worrisome, since a totally female population also leads to extinction.

One problem experienced in my private research into Lake Michigan’s fish skewing by sex ratio is and has been Wisconsin’s apparent lack of concern of laws [FN12: Law of 1977 Act 418 (37) (d) 3; reported again l//www.jsonline.com/story/sports/outdoors/2017/02/04/conservation-groups-urge-increases-licensefees/97360920/ paragraph 3, “The funding now comes from sportsmens' dollars”.] /statute [FN13: Sections 29.014(1), 29.041, and or 29.519 (1m) (b), Wis. Stats: commercial limits in excess of harvestabil/docs.legis.wisconsin.gov/code/register/2015/714B/register/rule_notices/cr_15_050_hearing_information/cr_15_050_rule_text - “... making the current Wisconsin harvest limit outdated and unsustainable”. Note: requested change was rejected, so limit is still outdated, unsustainable and/or in violation of law.]

/rules/agreement(s)s://docs.legis.wisconsin.gov/code/misc/chr/lrb_scanned/cr_96_098_final_rule_filed_with_lrb.pdf required a commercial limit of 7,140 in the future; money was paid but limit was raised starting in 2002, currently is 10,300.] concerning WI commercial fishing laws being violated, sciencettps://p.widencdn.net/cejkm3/03-01-NRB-minutes NRB meeting page 22-24. WDNR states a GB perch population of less than ~1.9 million requires a commercial limit of 20,000/yr. ,yet since 2008 with the population at less than 1.9 million the GB perch limit is at 100,000 lbs./yr. per WDNR GB perch SCAA dated 2022.] and/or data being ignored and/or purposely changed [FN16: 6 Attachment6_WDNR_GB_Population_estimates_from_SCAA_including_yearlings_1978-2013. WDNR SCAA's 2008-2013 Green Bay stated age-1 perch numbered 149,232,000 perch with a biomass of 12,004,700 lbs., making the 2008 age1 perch the largest in history of the SCAA. In 2016 the number was changed to just 860,410 age-1 perch reported and in 2022 reported 1,46,270 age-1 perch reported present instead.]. The WDNR downplays by 10 fold the past damage to the perch fisherylberglab.cbl.umces.edu/pubs/wilberg%20et%20al%20yellow%20perch%20dynamics%20NAJFM%202005.pdf by Wilberg 2tp://www.great-lakes.org/can_am.html], to the public, via a newspaper article [FN18: tps://www.jsonline.com/story/sports/columnists/paul-smith/2018/07/27/paul-smith-lake-michigan-yellow-perchdire-straights/834668002/ see graph labeled 'CPE of yellow perch – WI (GMA)', Note Y-Axis 'CPE per 1000 ft. of gillnet' is in units of 100 not the historically recorded 1,000] and/or their current management reportsps://dnr.wisconsin.gov/sites/default/files/topic/Fishing/LM_GLFCReport2022.pdf Figure 6 page 105.] both of which have a Y-Axis 'CPE per 1000 ft. of gillnet' in units of 100. Whereas the numbers on their websiteps://dnr.wisconsin.gov/topic/Fishing/lakemichigan/Yellowperch.html], past reports [FN21: One example: Attachment2_WDNR_Manag_Rpt_1999 page 29.] and shared with the Lake Michigan Yellow Perch Task Groualamprey.org/pubs/lake_committees/michigan/yellow_perch/Status%20of%20YEP%20in%20LM%202019-2020%20(2021).pdf] has CPE reported correctly, in 1,000's. The WDNR also underreported the WI commercial perch harvest for 2012 [FN22: See Attachment3_WDNR_Manag_Rpt_2013 page 15- 'In 2012, commercial fishers harvested a total of 57,845 pounds...']& 2013 [FN23: Attachment4_WDNR_Manag_Rpt_2014 page 5 of 49- "In 2013, commercial fishers harvested a total of 73,452 pounds (223,528 fish) of yellow perch using gill nets and drop nets, compared to 57,845 pounds in 2012 (Figure 4)".] to the public, but correct numbers to N.sciencebase.gov/catalog/item/5b99907ce4b0d966b4842829 Per noaa12.txt Lake Michigan perch harvest was 64,503 lbs. in 2012 and per noaa13.txt was 80,807 lbs. in 2013.]. Based on history I worry as to the accuracy and thereby the usefulness of any WDNR scientific findings in relation to any research involved with any federal agency, EPA, USFWS, etc. Due to the timing I also believe the Lake Michigan diporeia decline may also be due to sex ratio skewing.

I believe Great Lakes aquatics are sentinel species, and I fear their depletion since Lake Michigan fisheries numbers have declined up to 9

.glfc.org/pubs/lake_committees/common_docs/LM_Forage_Report_2021_For_Dissemination.pdf] since WI went to a commercial fishing quota system in 1989. There are basically no chubs, perch and smelt left in the lake to be used for surveys and science. I fear our denial of fish sentinels due to WI politics, such as 2011 ABttps://docs.legis.wisconsin.gov/2011/related/public_hearing_records/ac_natural_resources/bills_resolutions/11hr_ac_nr_ab0176_pt01.pdf AB176 repealed the minimum harvest requirement for WI commercial fishermen; AB176 did not make WI commercial fishing compliant with WI Law of 1977 Act 418 (37) (d) 3 though it was referenced, as was its being ignored (page 11)], which sought to protect too many WI commercial fishers from too few fish, instead of protecting the few fish left by upholding all WI laws. I don't know the scientific exchange between WI and EPA, if any, but I have a real fear that by ignoring laws and science WI might have contributed to the delay/accuracy of any investigation into the possibility of PFAS skewing fisheries, and humans, to female.

While I cannot find any research pointing to PFAS contributing or being responsible for some Lake Michigan fisheries skewing female, I believe removing PFAS from drinking water will be of help to future researchers by monitoring any changes in the sex ratios of fish, (and humans), such as perch using reefs near large metropolitan cities, like Milwaukee, where drinking water with lower levels of PFAS would be returned via city waste water, offering a comparison of pre vs post PFAS regulation of drinking water.

EPA Response: This commenter supports the conclusions of the EPA's toxicity assessments for PFOA and PFOS and has provided several citations to support this stance. Please see the EPA Response to 4.2.6 below for information related to how the EPA considered references recommended during public comment. Commercial fishing and/or fishery contamination by PFAS or other endocrine disruptors are beyond the scope of this drinking water regulatory action, as are Wisconsin's regulation of fisheries or their efforts to conduct biological surveys of fisheries. Additionally, historical contamination of Lake Michigan by potential endocrine disrupting chemicals is also beyond the scope of this drinking water regulatory action.

3M Company (Doc. #1774, SBC-045685)

d. EPA's Approach to Assessing the Overall Weight of Evidence for Non-Cancer Health Effects of PFOA and PFOS is Not Consistent with Guidance and Methods are Neither Transparent nor Reproducible

EPA likewise did not follow its own guidance in determining that PFOA and PFOS exposure is associated with numerous noncancer health effects including, but not limited to: "effects on the liver (e.g., liver cell death), growth and development (e.g., low birth weight), hormone levels, kidney, immune system, lipid levels (e.g., high cholesterol), the nervous system, and reproduction." For each type of health effect listed, EPA has not followed its own guidance (i.e., the IRIS Handbook) in evaluating the weight of evidence of the science, which shows, at most, inconsistent associations of the effects with PFOS and PFOA exposures. For several endpoints,

EPA improperly conflates changes in biomarkers (e.g., antibody response, cholesterol, liver enzymes) with increased risk of adverse disease outcomes in humans.

Agencies cannot disregard available scientific evidence that is better than the evidence on which it relies. [FN69: Kern County Farm Bureau v. Allen, 450 F.3d 1072, 1080 (9th Cir.2006).] However, this is exactly what EPA did in this Proposed Rule. As summarized below, EPA disregarded legitimate studies for reasons that are unclear or not justified in its Proposed Rule. [FN70: Ultimately, "[t]he presumption of agency expertise may be rebutted if the agency's decisions, although based on scientific experience, are not reasoned." Greenpeace v. NMFS, 80 F.Supp.2d 1137, 1147 (W.D. Wash. 2000).] Key scientific evidence and uncertainties for each health endpoint as well as EPA's failure to properly review and evaluate the evidence are summarized below, using immune system effects as an example.

In EPA's draft toxicity assessments for PFOA and PFOS (USEPA 2023a,b), EPA derived multiple candidate RfDs across four non-cancer health outcomes comprising four endpoints (i.e., decreased antibody response, low birth weight, increased total cholesterol, and elevated alanine transaminase (ALT) 71) from both epidemiological and animal toxicological studies that EPA deemed to have the "strongest weight of evidence" (USEPA 2023a,b). However, as described in Sections V.d – V.f above, EPA's process failures mean that none of these endpoints are, in fact, supported by the weight of evidence. Nonetheless, EPA determined that "candidate RfDs derived from epidemiological studies were all within 1 order of magnitude of each other (10-7 to 10-8 mg/kg/day), regardless of endpoint, health outcome, or study population . . . In fact, [for PFOA] candidate RfDs within the immune, developmental, and cardiovascular outcomes are the same value" (USEPA 2023a). EPA made similar conclusions for PFOS, as the candidate RfDs based on epidemiological studies "within the developmental and cardiovascular outcomes are the same value" (USEPA 2023b). As a result, EPA selected an overall RfD of 3 x 10-8 mg/kg/day for PFOA and 1 x 10-7 for PFOS.

As described in the following discussion, the range of estimated RfD values for PFOA that account for uncertainty is quite large. If uncertainties in each step of RfD derivation were estimated for each of the "co-critical endpoints" identified by EPA, it is unlikely that the resulting range of RfD values for each co-critical endpoint would be the same. To further increase confidence in the overall RfD, best practice would be to calculate ranges of RfD values that account for uncertainties within each of the endpoints identified as co-critical.

EPA Response: The EPA disagrees with the claims that the PFOA and PFOS toxicity assessment methods were inconsistent with EPA guidance and practice. Regarding the EPA's approach and methods used to conduct these assessments and how the EPA was consistent with agency guidance, see the EPA Response to 4.1.1 and 4.2.2. as well as the individual EPA responses to comment Doc. #1774, SBC-053146SBC-045649 & SBC-045650; Doc. #1774, SBC -045660; Doc. #1774, SBC-053425; Doc. #1774, SBC-045661; Doc. #1774, SBC-053426; Doc. #1542, SBC-043344, Doc. #1542, SBC-043350, Doc. #1774, SBC-045649, Doc. #1774, SBC-053417, Doc. #1774, SBC-045680, Doc. #1774, SBC-053418 & SBC-045681, Doc. #1774, SBC-045701, and Doc. #1774, SBC-045702. The EPA addresses concerns regarding the

consistency of the database and how the EPA evaluated individual studies in the EPA Response to 4.2.1.1 above and the EPA responses to specific endpoints below (see all of the EPA response in the following subheadings on low birth weight (LBW) (4.2.1.2), total cholesterol (4.2.1.3), antibody response (4.2.1.4), and ALT (4.2.1.5))), as well as the EPA response to the adversity of the selected critical effects in section 4.2.2.2.2.

The commenter incorrectly stated that the EPA derived candidate RfDs for only four endpoints from epidemiological and animal toxicological studies in the PFOA and PFOS public comment draft toxicity assessments (USEPA, 2023f; USEPA, 2023a). In fact, the EPA considered 9 different outcomes based on 26 different endpoints and studies (see Table 4-8 in USEPA, 2023f) in the derivation of PODs resulting in 15 candidate RfDs for PFOA (see Table 4-11 in USEPA, 2023f) and 10 different outcomes based on 24 different endpoints and studies (see Table 4-8 in USEPA, 2023a) in the derivation of PODs resulting in 14 candidate RfDs for PFOS (see Table 4-11 in USEPA, 2023f). These were clearly described in Section 4 of the PFOA and PFOS toxicity assessments (USEPA, 2023f; USEPA, 2023a). Based on an updated literature search and feedback from public comment, the EPA expanded the number of endpoints and studies considered for POD derivation to 30for PFOA (see Table 4-8 in USEPA, 2024d) and 29for PFOS (see Table 4-8 in USEPA, 2024c) resulting in 15 candidate RfDs for PFOA and 16 candidate RfDs for PFOS in the final toxicity assessments (USEPA, 2024d; USEPA, 2024b).

The commenter also recommended that the EPA calculate "ranges of RfD values that account for uncertainties within each of the endpoints identified as co-critical," claiming that this would be best practice. The EPA disagrees that the approach recommended by the commenter is standard or best practice for the agency and the commenter does not provide a citation verifying this claim. To derive the RfDs for PFOA and PFOS, the EPA followed established Agency methods and guidance, none of which describe a range of RfDs as "best practice" (USEPA, 2022a; USEPA, 2002a; USEPA, 2014a). The EPA accounted for uncertainties in the co-critical endpoints by deriving multiple PODs from multiple studies in varied populations, conducting sensitivity analyses, and deriving multiple candidate RfDs for each epidemiological endpoint and health outcome (see Appendix E and Section 4 of USEPA, 2023f; USEPA, 2023a; USEPA, 2024d; USEPA, 2024c). As described in Section 4.1.6 of the PFOA and PFOS toxicity assessments, "the candidate RfDs derived from epidemiological studies were all within 1 order of magnitude of each other, regardless of endpoint, health outcome, or study population," thus increasing the EPA's confidence in and decreasing uncertainty of these values and limiting how informative a "range" of RfDs would be (USEPA, 2024d; USEPA, 2024c). Responses to the commenter's suggestions of uncertainties for specific health outcomes are outlined in 4.2.1.2 Consideration of Decreased Birthweight as a Critical Effect, 4.2.1.3 Consideration of Serum Lipids as a Critical Effect, 4.2.1.4 Consideration of Decreased Antibody Response as a Critical Effect, and 4.2.1.5 Consideration of Increased ALT as a Critical Effect).

American Chemistry Council (ACC) (Doc. #1711, SBC-044459)

[The Agency's proposal suffers from the following significant shortcomings –]

The Agency's assessment of the non-cancer health effects of PFOA and PFOS inappropriately and selectively relies on data from a limited number of epidemiology studies, all of which provide limited support for a causal relationship between exposure and an adverse health impact

EPA Response: The commenter incorrectly stated that the EPA's assessment relied on "data from a limited number of epidemiological studies." As described in Sections 2, 3, and 4 of the PFOA and PFOS toxicity assessments (USEPA, 2023f; USEPA, 2023a), the EPA relied on three evidence streams to conduct hazard identification (i.e., epidemiological, animal toxicological, and mechanistic studies) and relied on both epidemiological and animal toxicological data, combined totaling hundreds of studies, to serve as the basis of the hazard conclusions. Through this approach, the EPA determined that the evidence indicates that PFOA and PFOS **likely causes** immune, developmental, hepatic and cardiovascular effects in humans consistent with the ORD IRIS Handbook (USEPA, 2022a). See section 4.2.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1738, SBC-047706 in section 13.4 of this *Response to Comments* document.

American Chemistry Council (Doc. #1841, SBC-044832)

EPA Overstates the Non-Cancer Risks Associated with PFOA and PFOS Exposure

EPA's assessment of non-cancer health effects for both PFOA and PFOS relies on the same set of eight epidemiology studies that have reported immune, developmental, cardiovascular, and hepatic effects. The analysis for immune effects focuses on reports of decreased antibody levels among children in genetically isolated populations that have not been associated with an increase in infection. Similarly, the reports of cardiovascular effects stem from reports of increased cholesterol levels in the absence of an association with heart disease and the reports of hepatic effects are based on changes in liver enzymes but not an increase in liver disease. Correlation to liver effects observed in animal studies is complicated by the likely contribution of a rodent-specific response that may not be relevant to human risk assessment. The results from studies of developmental effects are mixed, with the majority of studies reporting no association with the endpoint modeled by EPA. These types of endpoints – changes that may be reversible, potentially not adverse to humans, and that do not result in disease – are not suitable for drinking water MCL development, based on existing EPA health risk assessment guidance.

EPA Response: The commenter incorrectly claims that the EPA "relies on the same set of eight" epidemiologic studies in the assessment of non-cancer health effects hazards. This is incorrect because the EPA qualitatively relied on hundreds of studies to support the noncancer health conclusions of the PFOA and PFOS toxicity assessments as described in section 3 of the toxicity assessments (USEPA, 2023f; USEPA, 2023a). The EPA quantitatively considered nine epidemiological studies for candidate RfD derivation for PFOA, as illustrated in Figure 4-4 (USEPA, 2023f). The EPA additionally considered four different animal toxicological studies for candidate RfD derivation for both PFOA and PFOS (USEPA, 2023f; USEPA, 2023a).

Regarding "genetically isolated populations," the commenter does not provide any support as to how the population of the Faroe Islands would respond to PFOA or PFOS exposure differently than any other population. Please also see the EPA response to 4.2.2.1 1 Derivation of the Noncancer Reference Doses (RfDs) and EPA Responses to section 4.2.2.2.3. Regarding EPA's selection of critical effects, and particularly, the selection of biomarkers or precursor effects, please see Section 4.2.2.1 of the EPA response in this *Response to Comments* document and section 4.2.2.2.2 of the EPA response in this *Response to Comments* document. Responses to health outcome-specific comments, such as the human relevance of liver effects observed in animals (see section 4.2.1.5 of the EPA response in this *Response to Comments* document) and the evidence base for developmental effects (see section 4.2.1.2 of the EPA response in this *Response to Comments* document), are provided in the subsections below.

In contrast to the commenter's claims, the EPA followed established human health risk assessment methods (e.g., USEPA, 2022a) to review the available evidence for each health outcome, select critical effects and studies, and make conclusions regarding the potential adversity of effects (see EPA responses to 4.1.2 The EPA's Use of the Best Available Science, EPA Guidance, and Data Quality Control Practices). Regarding "rodent-specific response[s]," please see the EPA response to comment Doc. #1774, SBC-045682, Doc. #1774, SBC-045683, and Doc. #1774, SBC-053196.

American Farm Bureau Federation et al. (Doc. #1642, SBC-043502) (repeated by Illinois Farm Bureau (Doc. #1630, SBC-043143))

The Research on PFAS Is Still Ongoing

As we previously stated, our society cannot dismiss the health concerns related to PFAS exposure and the research in this space must continue. However, even EPA cannot definitively assert that PFAS exposure is leading to these adverse health outcomes. According to EPA's website: "Current scientific research suggests that exposure to high levels of certain PFAS may lead to adverse health outcomes. However, research is still ongoing to determine how different levels of exposure to different PFAS can lead to a variety of health effects. Research is also underway to better understand the health effects associated with low levels of exposure to PFAS over long periods of time, especially in children."

Additionally, the EPA states that the "health effects are difficult to determine." Given the costs that drinking water utilities must expend, which will ultimately land on the backs of American families, we believe EPA needs to improve the transparency of their review of studies and update their assessments based on availability of human studies to ensure the limit they regulate is both in line with the best science on health impacts but also takes into consideration the feasibility of implementation.

EPA Response: Please see the EPA Response to 4.2.1. Additionally, the commenter misleadingly quotes the EPA's website and statement on PFAS (https://www.epa.gov/pfas/our-current-understanding-human-health-and-environmental-risks-pfas) out of context. The full

quote states (emphasis added to text commenter omitted):
"Current scientific research suggests that exposure to certain PFAS may lead to adverse health outcomes. However, research is still ongoing to determine how different levels of exposure to different PFAS can lead to a variety of health effects. Research is also underway to better understand the health effects associated with low levels of exposure to PFAS over long periods of time, especially in children.

What We Know about Health Effects

Reproductive effects such as decreased fertility or increased high blood pressure in pregnant women.

Developmental effects or delays in children, including LBW, accelerated puberty, bone variations, or behavioral changes.

Increased risk of some cancers, including prostate, kidney, and testicular cancers.

Reduced ability of the body's immune system to fight infections, including reduced vaccine response.

Interference with the body's natural hormones.

Increased cholesterol levels and/or risk of obesity.

***Additional* Health Effects are Difficult to Determine**

Scientists at the EPA, in other federal agencies, and in academia and industry are continuing to conduct and review the growing body of research about PFAS. However, health effects associated with exposure to PFAS are difficult to specify for many reasons, such as:

There are thousands of PFAS with potentially varying effects and toxicity levels, yet most studies focus on a limited number of better known PFAS compounds.

People can be exposed to PFAS in different ways and at different stages of their life.

The types and uses of PFAS change over time, which makes it challenging to track and assess how exposure to these chemicals occurs and how they will affect human health."

The portion quoted by the commenter that implies all health effects are difficult to determine, is in fact an excerpt from a header that starts with the word "additional," after having listing numerous health effects associated with PFAS. The EPA also notes that PFOA and PFOS are two of the "limited number of better known PFAS compounds." Despite the commenter's misrepresentative claims otherwise, the EPA has determined that there are data available to make qualitative and quantitative conclusions about numerous adverse health effects associated with PFOA and PFOS exposure. PFHxS, PFNA, HFPO-DA, and PFBS also have been associated with numerous adverse health effects, as highlighted in USEPA, 2021d; USEPA, 2021e; ATSDR, 2021, and further discussed in section IV of the preamble of the PFAS drinking water regulation and section 4.3 of the EPA response in this *Response to Comments* document.

4.2.1.2 Consideration of Decreased Birthweight as a Critical Effect

3M Company (Doc. #1774, SBC-053211)

ii. EPA's assessment of developmental effects is flawed

In evaluating the impacts of PFOA/PFOS on development effects (namely, low birth weight), EPA did not appropriately employ methods described in the IRIS Guidance for evaluation of study quality and risk of bias.

EPA (USEPA 2023a,b) considered associations between PFOA and PFOS exposures and multiple developmental outcomes, including birth weight, birth length, head circumference, diagnosed condition of low birth weight,74 or small for gestational age, 75 gestational duration, or diagnosed conditions such as preterm birth. 76 EPA determined that there was moderate evidence of an association between PFOA or PFOS and developmental effects based on epidemiologic literature. As discussed below, this determination was not supported by the underlying evidence and appears to be based primarily on inconsistently observed decreases in birth weight.

EPA also did not appropriately consider uncertainties – most of which directly implicate bias in studies' results. These uncertainties include:

· Potential bias due to pregnancy hemodynamics and sample timing

· Mixed evidence for gestational duration, measured as gestational age or preterm birth

· Inconsistent evidence with rapid growth measures, including postnatal height and adiposity up to age 2

· Little evidence for increased fetal loss

· No evidence for increased birth defects

· Limited dose-response evidence in birth weight deficit studies

Additional details regarding the strength of evidence related to developmental outcomes are described in the EPA Evidence Stream and Summary Judgments (USEPA 2023a Table 3-10; USEPA 2023b, Table 3-12). EPA's determination of a "moderate" level of evidence is not supported by the findings presented. Decreases in birth weight have not been shown to represent adverse effects or other clinically meaningful health effects. In the appraisal of study quality and risk of bias, EPA did not evaluate studies consistently, which led to the selection of candidate studies for POD development with critical limitations. PODs are estimates of the dose levels at which an adverse response is not expected; they are typically derived near the low end of the observable range of data by using dose-response analyses within the selected studies. The PODs are then used as the basis for toxicity value calculations. Selection of reliable studies with limited bias is critically important for limiting the uncertainty in the derived POD and subsequent toxicity values.

1. Evidence integration of developmental outcomes demonstrated inconsistent evidence for an effect from PFOA/PFOS exposure.

EPA's categorization of the evidence regarding developmental outcomes is inconsistent with EPA's own criteria for an evidence synthesis judgement of "moderate" evidence in human studies. In order for evidence to be characterized as "moderate," the IRIS Handbook states that the evidence "includes at least one high or medium confidence study reporting an association and additional information increasing certainty in the evidence. For multiple studies, there is primarily consistent evidence of an association with reasonable support for adversity, but there might be some uncertainty due to potential chance, bias, or confounding or because of the indirectness of some measures" (USEPA ORD 2022, Table 6-4). IRIS guidance also states that supplementary evidence may address some of the uncertainty factors and raise a set of studies from "slight" to "moderate" evidence rating. Given the lack of consistency in the scientific literature, it is unclear how EPA concluded that there is "moderate" evidence that PFOA/PFOS affect developmental outcomes.

Moreover, EPA's determination of "moderate" evidence for developmental outcomes is a broad judgement that obscures the fact that such a designation is not consistent with EPA guidance for specific categories such as birth weight, birth length, head circumference, LBW, SGA, gestational duration, fetal loss, post-natal growth, and birth defects (USEPA 2023a Table 3-10; USEPA 2023a Table 3-12). EPA presented inconsistent or limited evidence of associations between PFOA/PFOS and each of the specific developmental outcomes, and did not provide judgements for any one of the specific developmental outcomes separately. Therefore, the strength of each evidence base is unclear.

In reviewing EPA's draft documents, the SAB stated that it was "not aware of evidence for associations of PFOA and PFOS with adverse consequences such as developmental delays in low birth weight/small for gestational age infants." (USEPA SAB 2023, p. 21). In short, EPA did not show consistent evidence that met the criteria for "moderate" evidence of an association between PFOA or PFOS exposure and developmental outcomes. Yet despite the uncertainties in the evidence of a relationship between PFOA or PFOS exposure and developmental outcomes, as acknowledged by EPA's own SAB, EPA selected decreases in birth weight as a critical endpoint and used it in POD derivation. Best practice is for EPA to follow its own guidance and determine evidence judgements for specific outcomes to select appropriate critical endpoints.

2. EPA did not appropriately consider the lack of consistency or plausibility demonstrated within the evidence base for decreased birth weight and incidence of adverse effects such as small for gestational age or low birth weight.

In reviewing EPA's draft documents, SAB recommended that EPA "clearly demonstrate that the endpoints selected for POD development are well established, sensitive, adverse or precursor to adverse"" (USEPA 2023c, p. 20). Due to the lack of evidence for associations between PFOA and PFOS exposure and developmental outcomes (e.g., fetal loss or birth defects), lack of consistency in evidence for outcomes of LBW or SGA, and lack of evidence that measured

decreases in birth weight are clinically relevant developmental outcomes, EPA has failed to meet the standard SAB deemed appropriate.

Two thirds of the studies (6 of 9) for PFOA showed some increased risk of either SGA or LBW, but did not have statistically significant results, meaning those studies are not reliable predictors of developmental effects. Critically, only 5 of the 11 examined PFOA in early pregnancy, which is the only period of exposure timing that is considered a lower risk of bias due to changes in pregnancy hemodynamics (Meng et al. 2018; Hjermitslev et al. 2020; ManzanoSalgado et al. 2017; Wikstrom et al. 2020; Chang et al. 2022). Of these 5 studies, only 2 identified statistically significant associations (Wikstrom et al. 2020; Chang et al. 2022). Of those, EPA selected one as a candidate study (Wikstrom et al. 2020). However, serum volume increases by about 50% during pregnancy, peaking at 30-35 weeks gestation (Salas et al. 2006), and glomerular filtration rate (GFR) increases similarly (40-50%) (Cheung and Lafayette 2013). These increases lead to a decrease in maternal serum PFAS concentration during pregnancy (Monroy et al. 2008; Steenland et al. 2018; Kato et al. 2014) and the magnitude of increases can be inversely correlated with birth weight. First trimester serum PFAS measures have less chance for bias from sample timing (USEPA 2023a, p. 3-212). Additionally, two meta-analyses by Dzierlenga et al. (2020) and Steenland et al. (2018) found that when PFOA was measured in early pregnancy, there was little to no association with LBW, suggesting that the timing of serum measurement is critical for accurate interpretation of study results.

While EPA described the collective evidence as "supportive" of an increased risk of LBW or SGA with PFOA/PFOS exposure, this is inconsistent with the fact that less than half of the studies reported statistically significant results, demonstrating that there was not consistent evidence of an association between PFOA/PFOS and these outcomes. Among the studies for PFOS, 5 of 10 studies examined PFAS measured in early pregnancy (Meng et al. 2018; Hjermitslev et al. 2019; Manzano-Salgado et al. 2017; Wikstrom et al. 2020; Chang et al. 2022), one of which was selected as a candidate study. Of the 5 studies, 2 reported statistically significant associations. Of the 7 high- or medium confidence studies, 2 reported statistically significant increased risks of SGA and only 2 of the 4 high- or medium-confidence studies reported increased risks of LBW (USEPA 2023b, p. 3-206-210).

EPA considered 6 high confidence studies of PFOA for POD development (Chu et al. 2020; Govarts et al. 2016; Sagiv et al. 2018; Starling et al. 2017; Wikstrom et al. 2020; Yao et al. 2021) (USEPA 2023a, p. 4-9). 2 of those were used for RfD determination because serum PFAS was measured in the first trimester (Sagiv et al. 2018; Wikstrom et al. 2020) (USEPA 2023a, p. 4-43). The agency also considered 6 high confidence studies of PFOS for POD development (Chu et al. 2020; Darrow et al. 2013; Sagiv et al. 2018; Starling et al. 2017; Wikstrom et al. 2020; Yao et al. 2021) (USEPA 2023b, p. 4-9), and the 2 that were used for RfD determination were the same as those chosen for PFOA (USEPA 2023b, p. 4-39).

For 5 of the studies, it is unknown if the study populations had clinically relevant changes in birth weights with PFOA or PFOS exposure (Sagiv et al. 2018; Starling et al. 2017; Wikstrom et al. 2020; Yao et al. 2021), because only mean or median birth weights were reported, none of

which were <2500 g. Among a Belgian birth cohort of 248 mother-infant pairs, the number of LBW infants was not reported, nor was the risk of LBW with PFOA or PFOS exposure examined, so it is unknown if there was an increased risk of an adverse effect in this population (Govarts et al. 2016).

The remaining 2 studies reported the risk of an LBW birth in the population. A study of the births among women in the C8 population of highly exposed individuals observed no significant associations between LBW births and PFOA or PFOS exposure (Darrow et al. 2013). In a study of 372 births in Guangzhou between July and October 2013 observed no significant associations between LBW and PFOA exposure. A statistically significant association was observed between LBW and PFOS (OR=2.43, 95% CI: 1.09-5.147), but not by quartiles of PFOS exposure. Authors also noted that the relationship between PFAS and birth outcomes was controversial due to concerns regarding effective dose, reverse causality, and sample timing. Based on the limited reporting on birth weights and inconsistent evidence of increased risk of LBW in the candidate studies, the evidence for an adverse effect with PFOA or PFOS exposure in that study is not clear.

EPA Response: The commenter incorrectly suggested that the EPA did not follow its own guidance while evaluating the impacts of exposure to PFOA or PFOS on changes to developmental health outcomes. The EPA disagrees and provides a detailed response on how these assessments applied the EPA peer-reviewed human health risk assessment methodology (USEPA, 2022a) in the EPA Response to 4.1.1 above. Responses to other specific criticisms are outlined below.

The commenter incorrectly stated the EPA did not follow its own guidance while concluding the evidence synthesis judgement for developmental health outcomes was *moderate*. First, the commenter is incorrect in calling the IRIS Handbook EPA guidance. It is not agency guidance but rather peer-reviewed human health risk assessment methodology. Though the IRIS handbook states that "[t]he handbook does not supersede existing U.S. Environmental Protection Agency (EPA) guidance and does not serve as guidance for other EPA programs," it does represent the state-of-the-art systematic review procedures and so the OW adhered to this peer-reviewed human health risk assessment methodology in developing the evidence synthesis judgement for the developmental health outcomes (USEPA, 2022a). The commenter outlines criteria for a *moderate* evidence synthesis judgement from the IRIS Handbook: "includes at least one high or medium confidence study reporting an association and additional information increasing certainty in the evidence. For multiple studies, there is primarily consistent evidence of an association with reasonable support for adversity, but there might be some uncertainty due to potential chance, bias, or confounding or because of the indirectness of some measures" ((USEPA, 2022a), Table 6-4)." The EPA disagrees that the evidence base for developmental effects, specifically decreases in BWT, does not align with the criteria for a *moderate* evidence synthesis judgement. For PFOA, deficits in mean BWT were observed in most studies (30/42) in the overall population. Additionally, 5 (Chang, 2022; Hjermitslev, 2020; Meng, 2018; Sagiv, 2018; Wikström, 2020) of 9 medium and high confidence studies reported evidence of reductions

in mean BWT based on early pregnancy biomarker samples. The majority of studies on changes in standardized BWT measures reported inverse associations (10/18), with most (7/10) of these being high and medium confidence studies which strengthens the confidence in this association. Similarly, most studies (12/17) observed either an increased risk of LBW or small for gestational age (GA) (see section 3.4.4.1 and 3.4.4.4.1 in USEPA, 2024d). For PFOS, deficits in mean BWT were observed in most studies (27/39) in the overall population. Additionally,5 (Bach, 2016; Hjermitslev, 2020; Meng, 2018; Sagiv, 2018; Wikström, 2020) of 8 medium and high confidence studies still reported evidence of mean BWT deficits based on early pregnancy biomarker samples. Most studies on changes in standardized BWT measures reported inverse associations (12/18) in the overall population or among boys or girls. Ten of 17 studies observed increased risk of LBW or small for gestational age (SGA) (see section 3.4.4.1 and 3.4.4.4.1 in USEPA, 2024c). The moderate evidence synthesis judgement for the developmental health outcome is further supported by consistency in other developmental effects. Specifically, for PFOS, increased risk of preterm birth was observed in 12 out of 17 studies (Section 3.4.4.4, USEPA, 2024c). These data clearly align with the IRIS evidence synthesis judgement criteria for *moderate*: "multiple studies [reporting] primarily consistent evidence of an association with reasonable support for adversity. *Moderate* evidence synthesis judgements may include "some uncertainty due to potential chance, bias, or confounding," and these issues have been outlined and discussed in detail in Sec. 3.4.4.4 (USEPA, 2023f; USEPA, 2023a). Further, supplemental evidence "may raise certainty in the evidence" base (USEPA, 2022a, Table 6-4), which included "several meta-analyses also support[ing] evidence of associations between maternal or cord blood serum PFOA and BWT or BWT-related measures {Johnson, 2014, 2851237; Verner, 2015, 3150627; Negri, 2017, 3981320; Steenland, 2018, 5079861}" (USEPA, 2023a, Sec. 3.4.4.4).

The commenter claimed studies observing non-significant increases in risk for SGA and LBW do not support the EPA's conclusion of *moderate* evidence for adverse developmental effects in humans, specifically reduced BWT. The EPA disagrees these studies do not support the EPA's *moderate* evidence synthesis judgement for developmental effects. Statistical significance is not the sole factor when making evidence synthesis judgements, and results that lack statistical significance can be used to support a conclusion of an effect (Wasserstein and Lazar, 2016; USEPA, 2022a). Despite non-significant findings, there was consistent evidence for PFOA and an increased risk of SGA or LBW in 12 out of 17 studies, and the "magnitude of the associations was typically from 1.2 to 2.8" (USEPA, 2023f; USEPA 2024d). Similarly for PFOS, 10 out of 18 studies reported non-significant "increased odds rang[ing] from 1.19 to 4.14" (USEPA, 2023a; USEPA 2024b). As mentioned above, these studies provide consistent evidence for effects in epidemiological studies that are coherent with LBW (i.e., SGA).

The commenter suggested evidence synthesis judgements should have been made for each unit of analysis within the developmental health outcome category. The EPA disagrees that evidence synthesis judgements are necessary for all unit of analyses and the EPA followed guidance outlined in the IRIS Handbook (USEPA, 2022a) as noted in the EPA Response above. First, the EPA states in the MCLG Appendix (A.1.10) that "strength-of-evidence judgments were made for each health outcome," which does not require a strength-of-evidence judgment for each

individual developmental endpoint (USEPA, 2023b; USEPA, 2023c; USEPA, 2024a; USEPA, 2024b). IRIS human health risk assessment methodology states that multiple judgements for a health outcome category may be made, but this is a pre-determined decision, and considering the breadth of the endpoints examined in all included developmental studies the EPA chose to make one evidence integration summary judgement for all developmental health outcomes. Regardless of separate or combined evidence integration summary judgements, the ORD IRIS Handbook states that "the strongest evidence judgement will typically be used to reflect certainty in the broader health effect category," in the event of multiple evidence integration summary judgements for one health outcome category (USEPA, 2022a). Additionally, the EPA's approach to the summary judgment for the developmental health outcome is consistent with the evidence integration summary judgments for recent draft IRIS PFAS assessments (USEPA, 2023h, USEPA, 2023g, and USEPA, 2024g).

The commenter stated it is unknown whether the observed decreases in BWT associated with exposure to PFOA or PFOS from the studies used for POD derivation are clinically relevant or adverse. The EPA disagrees with this comment. Please see the EPA Response to 4.2.2.Derivation of the Noncancer Reference Doses (RfD) below. Additionally, as previous research on lead exposure has found, although on an individual-level, changes in BWT may or may not have fallen below 2,500 g, small changes in mean BWT can result in substantial health impacts at the population level (Gilbert and Weiss, 2006). BWT is a significant factor in infant survival (Jacob, 2016); several studies have reported relationships between BWT and mortality (Almond et al., 2005, Ma et al., 2020, McIntire et al., 1999; Lau et al., 2013).

Detailed responses to the specific uncertainties from developmental studies raised by the commenter are discussed in the EPA response to comment Doc. #1774, SBC-053428 in section 4.2.1.2 in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-053428)

EPA's failure to conduct a transparent and consistent evaluation of the evidence base for developmental outcomes led to selection of candidate studies with critical limitations.

EPA (2023a,b) considered associations between PFOA and PFOS exposures and multiple developmental outcomes, including birth weight, birth length, head circumference, diagnosed condition of low birth weight,3 or small for gestational age,4 gestational duration, or diagnosed conditions such as preterm birth.5 EPA determined that there was moderate evidence of an association between PFOA or PFOS and developmental effects based on epidemiologic literature.

EPA did not appropriately consider uncertainties – most of which directly implicate bias in studies' results. These uncertainties include:

· Potential bias due to pregnancy hemodynamics and sample timing

· Potential confounding by other PFAS

· Mixed evidence for gestational duration, measured as gestational age or preterm birth

· Inconsistent evidence with rapid growth measures, including postnatal height and adiposity up to age 2

· Little evidence for increased fetal loss

· No evidence for increased birth defects

· Limited dose-response evidence in birth weight deficit studies

Additional details regarding the strength of evidence related to developmental outcomes are described in EPA Evidence Stream and Summary Judgments (EPA 2023a Table 3-10; EPA 2023b Table 3-12). The determination by EPA of a "moderate" level of evidence is not supported by the findings presented. In the appraisal of study quality and risk of bias, EPA did not evaluate studies consistently, which led to the selection of candidate studies for POD development with critical limitations. The evidence presented does not support PFOA and PFOS exposure and decreased birth weight as a critical endpoint.

Integration of developmental outcomes comprised inconsistent evidence.

As described above, EPA only provided evidence integration judgements for broad categories. EPA's determination of "moderate" evidence for developmental outcomes covers a broad category that includes specific categories such as birth weight, birth length, head circumference, LBW, SGA, gestational duration, fetal loss, post-natal growth, and birth defects (EPA 2023a Table 3-10; EPA 2-23b Table 3-12). EPA did not provide judgements for any one of these specific developmental outcomes separately, making it unclear how strong the evidence base was for each.

The underlying data across these types of effects do not support a categorization of "moderate" when properly evaluated according to EPA guidance and best practice. For example, in the summary of fetal growth restriction, EPA stated that the majority of studies that examined fetal growth restriction showed some evidence of associations with PFOA or PFOS. Head circumference and birth length were less consistent, with limited evidence of dose-response relationships. The agency concluded that, "despite some consistency in evidence across these fetal growth endpoints, some important uncertainties remain mainly around the degree that some of the results examined here may be influenced by sample timing. This source of uncertainty and potential explanation of different results across studies may indicate some bias due to the impact of pregnancy hemodynamics" (EPA 2023a p. 3-220; EPA 2023b p. 3-218).

EPA chose not to consider gestational duration outcomes for POD derivation including gestational age and preterm birth, stating "While overall there appears to be associations between PFOA/PFOS exposure and gestational duration, the inconsistencies in the database and lack of studies sampling in the first trimester of pregnancy reduce the level of confidence in the responses preferred for endpoints prioritized for dose-response modeling" (EPA 2023a,b). Fetal

loss and birth defects were also not considered as critical endpoints because of the limited number of studies available (EPA 2023a, p. 4-8; EPA 2023b, p. 4-8).

Given the lack of consistency in the scientific literature, it is unclear how EPA concluded that there is "moderate" evidence that PFOA/PFOS affect developmental outcomes. More specifically, this categorization is inconsistent with the criteria for an evidence synthesis judgement of "moderate" evidence in human studies.

EPA Response: The commenter incorrectly states the EPA did not adequately consider the following uncertainties while evaluating the evidence for developmental effects: potential bias related to pregnancy hemodynamics and exposure sample timing, potential confounding from PFAS co-exposures, mixed evidence for gestational duration, inconsistent evidence for postnatal growth, limited evidence for fetal loss and birth defects, and limited dose-response evidence for studies on BWT. Considerations of the uncertainties outlined above are described in each MCLG document (USEPA, 2023f; USEPA, 2023a, Sec. 3.4.4.1.2) and were discussed throughout the developmental synthesis (USEPA, 2023f; USEPA, 2023a, Sec. 3.4.4) and the discussion of study selection for developmental POD derivation (USEPA, 2023f; USEPA, 2023a, Sec 4.1.1.4). Specific considerations are described below.

Pregnancy hemodynamics were considered during study quality evaluation of developmental studies, with only *in utero* exposures being considered *Adequate* or better for Exposure Assessment (USEPA, 2023f; USEPA, 2023a, Sec. 3.4.4.1.2). Additionally, for studies on BWT, exposure sample timing was discussed in the results summaries. As described in the developmental synthesis, adverse effects on BWT were observed in studies with early pregnancy exposure samples. Additional studies with exposure samples from later pregnancy supported these findings. Although there are uncertainties related to pregnancy hemodynamics in the studies using later pregnancy samples, these uncertainties are not enough to explain the consistent effects observed across studies sampling in early and later pregnancy. In support of this, a recent meta-analysis for PFNA concluded that "deficits that were detected across all strata [i.e., early and later pregnancy] did not appear to be fully explained by potential bias due to pregnancy hemodynamics from sampling timing differences" (Wright et al., 2023). Given that there is no evidence that pregnancy hemodynamics would differ across PFAS, it is likewise unlikely that the decreases in birthweight observed for PFOA and PFOS can be fully attributable to pregnancy hemodynamics. Even so, further consideration of pregnancy hemodynamics and exposure sample timing occurred during study selection for quantitative analyses. Only *High* confidence studies utilizing early pregnancy exposure samples were considered for candidate RfD derivation (USEPA, 2023f; USEPA, 2023a, Sec. 4.1.5.4).

The EPA considered potential confounding by PFAS co-exposures during study quality evaluations and as part of the overall evidence stream judgment (USEPA, 2023f; USEPA, 2023a, Sec. 3.4.4.1.2 and Sec. 3.4.4.4). Further, the EPA has provided additional qualitative analysis examining the potential confounding by co-occurring PFAS (USEPA, 2024d; USEPA, 2024b, Sec. 5.1.1). This analysis supports the EPA's position that there is no consensus on best practices to account for potential confounding by multiple, concurrent PFAS exposures. Multi-pollutant

models may not perform as well when co-exposures are highly correlated, as is typical for PFAS mixtures. The degree of correlation between individual PFAS can lead to collinearity concerns, which may decrease precision. Multi-pollutant models may also lead to co-exposure amplification bias, where exposure measurement bias is amplified by the inclusion of multiple exposure terms with common but unaccounted for or unknown potential confounding. Other mixture analysis approaches, such as principal component analysis or elastic net regression, also have drawbacks, including difficulty interpreting effects for individual exposures and limited ability to examine non-linear associations. These challenges are also noted in the supplemental information to the *Toxicological Review of PFDA and Related Salts* (USEPA, 2023g, Sec. F.2), reflecting that analysis methods used to account for these co-exposures come with implementation challenges and introduce different uncertainties.

The EPA disagrees with the commenter's characterization of the evidence for gestational duration for PFOS. As outlined in the EPA response to comment Doc. #1774, SBC-05321, 8/10 high or medium confidence studies demonstrated a decrease in GA and 12/13 high or medium confidence studies demonstrated an increased risk of preterm birth. As described in 3.4.4.1.7.1 and 3.4.4.1.7.2, sample timing could not explain the consistency in the effects observed. This evidence helps to corroborate the observed decreases in birthweight (USEPA, 2023a; USEPA 2024b).

Regardless, and as stated above, positive associations or increased risk of adverse health outcomes (e.g., decreased birthweight) cannot be ignored, even if some inconsistency is present in the evidence base for other effects within the same health outcome (e.g., , inconsistent evidence of measures of postnatal growth). In fact, to do so would be in complete violation of agency human health risk assessment guidance (e.g., USEPA, 1991b) and the agency's peer-reviewed human health risk assessment methodologies (e.g., USEPA, 2002; USEPA, 2022a). Moreover, complete consistency within every health effect measured in a health outcome category is not necessarily an expectation of a body of observational studies in humans and does not necessarily result in a reduction in the overall confidence of this evidence stream. For example, for PFOA and PFOS, although multiple studies observed adverse effects on postnatal growth, thus supporting the evidence stream judgement, limitations in the evidence base for these endpoints included heterogeneity in outcome timing and characterization. Interpretation of effects observed across studies were difficult due to these limitations. The limited availability of directly comparable estimates for postnatal growth affected certainty of conclusions for these specific endpoints but did not impede the ability to draw conclusions for developmental effects overall. Likewise, a lack of evidence supporting an association between an agent and one endpoint (e.g., fetal loss, birth defects) does not necessarily influence the EPA's determination that there is an association between the agent and another endpoint (e.g., LBW) or influence the evidence stream judgment for that health outcome when there is abundant evidence supporting associations with other endpoints in that evidence stream, consistent with agency best practices (USEPA, 2022a).

Lastly, the EPA disagrees with the commenter's characterization of "limited dose-response evidence in birth weight deficit studies." As demonstrated in the forest plots of changes in mean BWT and odds of LBW, there was evidence of dose-response for BWT deficits (USEPA, 2023f; USEPA 2023a, Fig. 3-49–3-52 and Fig. 3-57). Categorical analyses of BWT generally reported linearly expressed associations, indicating BWT deficits with increasing exposure to PFOA or PFOS (USEPA, 2023f; USEPA, 2023a, Sec. 3.4.4.1.4.5). Due to the number of *high* and *medium* confidence studies observing BWT deficits with increasing exposure to PFOA (or PFOS), and in consideration with coherent adverse effects for other developmental outcomes (e.g., other measures of fetal growth restriction and gestational duration), BWT was chosen for dose-response analysis. This selection is consistent with the description of *moderate* evidence in human studies (USEPA, 2022a).

The commenter also states the EPA did not clearly communicate the strength of evidence for each developmental endpoint, limiting the transparency in the selection of a critical effect for POD derivation. The commenter suggests the evidence for fetal growth restriction does not support a categorization of *moderate* according to the methods provided by the EPA, specifically citing less consistent evidence for head circumference and birth length. The commenter disagrees with the *moderate* evidence integration judgment rating and cites as rationale the lack of consideration of gestational duration outcomes (e.g., preterm birth) as a critical effect. The EPA disagrees with these comments.

First, with respect to making evidence integration judgments for each developmental health outcome, see the EPA response to comment Doc. #1772, SBC-053428 in section 4.2.1.2 in this *Response to Comments* document. Briefly, regardless of separate or combined evidence integration summary judgements, assessment methodology from the ORD IRIS Handbook states that "the strongest evidence judgement will typically be used to reflect certainty in the broader health effect category," in the event of multiple evidence integration summary judgements for one health outcome category (USEPA, 2022a).

Second, the EPA disagrees that inconsistencies between data for BWT and data for other fetal growth measurements undermine a *moderate* evidence integration judgement. The EPA describes considerations of potential inaccuracies or imprecision of fetal growth measurements in section 3.4.4.1.2 of the assessments (USEPA, 2023f; USEPA, 2023a; USEPA, 2024d; USEPA, 2024c). Briefly, numerous studies have demonstrated that some fetal growth restriction measurements, such as birth length (Shinwell and Shlomo, 2003; Johnson et al., 1998; Johnson et al., 1999; Wood et al., 2013) and head circumference (Bhushan and Paneth, 1991), are more subject to measurement error compared to measures such as birthweight. Therefore, birthweight is a more accurate and precise measure of fetal growth restriction and there were numerous *high* confidence studies that provided data that were able to be modeled.

Third, the EPA disagrees that it is necessary to consider gestational duration outcomes as a critical effect for POD derivation in order to conclude a *moderate* evidence stream judgment rating from studies in humans. As described above, the evidence in gestational duration outcomes is consistent and helps to corroborates the observed decreases in birthweight.

However, the evidence base for mean BWT contains more medium and high confidence studies which increases confidence in the birthweight endpoint for POD derivation (USEPA, 2024d; USEPA, 2024c). It is not necessarily an expectation that effects related to gestational duration would be equivalent to effects on birthweight, as the etiology of the outcome may differ, or be augmented by other unknown factors. It is also not the expectation that every endpoint considered within an evidence stream judgment have the same strength of evidence to be considered *robust* or *moderate*. A judgment of *moderate* for epidemiological evidence can result from a single or multiple adverse effects or a single or multiple well-conducted studies (USEPA, 2022a). In addition, uncertainty of an association between chemical exposure and a health effect resulting in the EPA's determination not to quantify the association does not necessarily mean the association is non-existent, nor does it automatically result in a decrease in the level of certainty supporting evidence of the hazard. For example, the commenter cited the EPA's rationale for not deriving PODs for the endpoint of gestational duration "While overall there appears to be associations between PFOA/PFOS exposure and gestational duration, the inconsistencies in the database and lack of studies sampling in the first trimester of pregnancy reduce the level of confidence in the responses preferred for endpoints prioritized for dose-response modeling." In context, the EPA was comparing this endpoint to the endpoint of LBW, which had a more consistent evidence base and several *high* confidence studies with sample collection during early pregnancy, which is ideal to avoid uncertainty due to hemodynamics. Therefore, the EPA focused modeling efforts on the endpoint of decreased birthweight, as there was higher confidence in the database for this effect. This interpretation of the database and resulting judgment designation are supported by protocols outlined in the *ORD Staff Handbook for Developing IRIS Assessments* (See Table 6-3; USEPA, 2022a). The EPA has added additional detail to Section 4.1.1. to enhance the transparency of endpoint selection (USEPA, 2024d; USEPA, 2024c).

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046009)

Birthweight

Of the 32 studies that EPA used in its PFOA toxicity assessment, 21 reported some mean birthweight deficits in the overall population with limited evidence of exposure-response relationships [FN17: U.S. Environmental Protection Agency, "Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) in Drinking Water," March 2023, 3–205.]. Birthweight was found to have an inverse relation to PFOA concentration in a study of 293 infants at a mean PFOA concentration of 0.0016 micrograms per milliliters (µg/mL) [FN18: U.S. Environmental Protection Agency, 3–192.]. A 2012 study observed lower birthweights with increasing levels of maternal PFOA concentration (median concentration of 0.0037 µg/mL) [FN19: U.S. Environmental Protection Agency, 3–192; Mildred Maisonet et al., "Maternal Concentrations of Polyfluoroalkyl Compounds during Pregnancy and Fetal and Postnatal Growth in British Girls," Environmental Health Perspectives, 2012.].

Among the 21 studies showing some adverse associations in the overall population, there was a wide range of observed birthweight changes from –14 to –267 grams across both categorical and

continuous exposure estimates [FN20: U.S. Environmental Protection Agency, "2023b," 3–201.]. Among those with continuous PFOA results in the overall population, 14 of 20 studies reported deficits from –27 to –82 grams with increasing PFOA exposures. EPA notes, however, that there is limited evidence of exposure-response relationships and potential bias due to hemodynamic differences:

Three of the four smallest associations were based on earlier biomarker samples. Thus, some of these reported results may be related to pregnancy hemodynamic influences on the PFOA biomarkers during pregnancy. For example, 11 of the 12 largest mean BWT deficits (–48 grams or larger per unit change) in the overall population were detected among studies with either later pregnancy samples (i.e., maternal samples during trimesters 2, 3, or post-partum or umbilical cord samples) [FN21: U.S. Environmental Protection Agency, 3–201.].

EPA's caveat is important. Researchers have raised concerns with confounding and with possible reverse causation in studies taken late in pregnancy [FN22: Steenland, Kylea; Barry, Vaughna; Savitz, Davidb. Serum Perfluorooctanoic Acid and Birthweight: An Updated Meta-analysis With Bias Analysis. Epidemiology 29(6):p 765-776, November 2018. | DOI: 10.1097/EDE.0000000000000903]. Studies measuring concentrations in early pregnancy and prior to pregnancy do not show the same association.

For PFOS, one study found that birth weight, head circumference, and ponderal index were inversely associated with umbilical cord PFOS concentration in 293 infants [FN23: Benjamin Apelberg et al., "Cord Serum Concentrations of Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoate (PFOA) in Relation to Weight and Size at Birth," Environmental Health Perspectives, 2007.]. Deficits in mean birth weight per one natural logarithm (ln) increase in PFOS concentration were found. Another study evaluated fetal growth outcomes in female births and found that increased maternal PFOS concentration (median concentration 0.0196 μg/mL) was associated with lower birth weights [FN24: Maisonet et al., "Maternal Concentrations of Polyfluoroalkyl Compounds during Pregnancy and Fetal and Postnatal Growth in British Girls."]. A prospective cohort study in Japan found that their "fully adjusted model showed no significant negative correlation between PFOA levels and birth weight. In contrast, a log10-unit increase in PFOS levels correlated with a decrease in mean birth weight of 148.8 g (95% CI, 297.0 to 0.5 g) for PFOS in the fully adjusted model." [FN25: Noriaki Washino et al., "Correlations between Prenatal Exposure to Perfluorinated Chemicals and Reduced Fetal Growth," Environmental Health Perspectives, 2009.] Another study examined 429 mother-infant pairs from the Taiwan Birth Panel Study and found that umbilical cord blood PFOS concentration was inversely associated with gestational age, birth weight, and head circumference [FN26: Mei-Huei Chen et al., "Perfluorinated Compounds in Umbilical Cord Blood and Adverse Birth Outcomes," PLOS One, 2012.].

However, studies conducted in Canada and Japan did not find a statistically significant association between birthweight and PFOS concentration in maternal blood [FN27: Michele Hamm et al., "Maternal Exposure to Perfluorinated Acids and Fetal Growth," Journal of Exposure Science and Environmental Epidemiology, 2010; Health Canada, "Guidelines for

Canadian Drinking Water Quality: Guideline Technical Document – Perfluorooctane Sulfonate (PFOS)," December 2018.]. Similarly, an examination of 429 mother-infant pairs from the Taiwan Birth Panel Study did not find a significant association between umbilical cord blood PFOS concentration and birthweight [FN28: Mei-Huei Chen et al., "The Impact of Prenatal Perfluoroalkyl Substances Exposure on Neonatal and Child Growth," Science of the Total Environment, 2017.].

A Canadian study of 252 pregnant women found no statistically significant association between birthweight or gestation length and PFOS concentration measured in maternal blood, although mean birthweight increased slightly by increasing PFOS levels [FN29: Hamm et al., "Maternal Exposure to Perfluorinated Acids and Fetal Growth."]. In its Health Effects Support Document, EPA notes that low confidence studies are included for consistency in the direction of association [FN30: U.S. Environmental Protection Agency, "2023b," 3–195.]. As shown in Appendix B, agencies have recognized additional limitations in study data, including selection bias, small study sizes, and confounding. This is also true of other adverse effects included in EPA's assessment.

Health Canada explains that "more studies with better adjustments and follow-up in different populations would be needed to confirm the observed associations." [FN31: Health Canada, "Guidelines for Canadian Drinking Water Quality: Guideline Technical Document – Perfluorooctanoic Acid (PFOA)," December 2018, 46.] Similarly, for certain effects, EFSA mentions that more studies are needed to support causality. Specific to birthweight, EFSA said that while "a recent study seems to strengthen the causality, the decrease in birth weight after adjusting for confounders is not large and the potential longer term consequences of this decrease are unclear." [FN32: Dieter Schrenk et al., "Risk to Human Health Related to the Presence of Perfluoroalkyl Substances in Food" (European Food Safety Authority, September 2020), 7.] A Department of Health and Human Services toxicological profile cited by WHO concluded that "no studies found increases in the risk of low birth-weight infants" associated with maternal PFOS serum levels." [FN33: Agency for Toxic Substances and Disease Registry, "Toxicological Profile for Perfluoroalkyls" (US Department of Health and Human Services, May 2021), 479; World Health Organization, "PFOS and PFOA in Drinking-Water: Background Document for Development of WHO Guidelines for Drinking-Water Quality," September 2022, 32, https://www.cmbg3.com/library/WHO-Draft-Drinking-Water-Document.pdf.]

EPA Response: Please see the EPA response to comment Doc. #1774, SBC—0053211 above in this *Response to Comments* document for the developmental hazard determination and the EPA response to comment Doc. #1774, SBC-053428 in section 4.2.1.2 in this *Response to Comments* document for a discussion of pregnancy hemodynamics. Please see EPA response to 4.2.6 Consideration of conclusions of other state, federal, or international agencies for details related to why the EPA's conclusions may differ from those of other international agency assessments. As discussed by the commenter, the majority of studies examining associations between elevated exposure to PFOA or PFOS and BWT reported inverse associations, indicating decreased BWT with greater exposure. The commenter then points to 4 studies which do not

show an association between PFOS and decreased BWT. The EPA considered over 40 studies in making the determination that PFOS is associated with decreased BWT. EPA acknowledged that there is potential uncertainty related to pregnancy hemodynamics, however the overall weight of evidence indicating decreased BWT with greater exposure, including in studies with sample timing in early pregnancy, resulted in an evidence synthesis judgement of *moderate* evidence for decreased BWT. Additionally, the EPA further considered pregnancy hemodynamics during candidate RfD determination. Specifically, of the six (five for PFOA) studies selected for PODHED derivation, the two (Sagiv, 2018; Wikstrom, 2020) measuring exposure concentrations from first trimester maternal blood samples were selected for candidate RfD derivation as described in Section 4 of the assessments (USEPA, 2023f; USEPA, 2023a; USEPA, 2024d; USEPA, 2024c).

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-053368)

Similarly, EPA's justification for relying on birthweight as a critical adverse effect is also not supported by science. Public commenters have noted that this endpoint is not an established causal effect of PFOA or PFOS exposure,[FN117: See comments submitted by Nessa Horewitch Coppinger on behalf of the 3M Company, Feb. 10, 2022, avahttps://sab.epa.gov/ords/sab/f?p=100:19:16404771425364:::RP,19:P19_ID:963.] but the revised documents ignore this concern. The SAB pointed out that the Wikstrom et al. 2020 study and the Sagiv et al. 2018 study, on which EPA relied for PFOA and PFOS birthweight endpoints, did not consider confounding by co- exposure to other PFAS (and realistically, other unmeasured chemicals and other stressors) [FN118: See SAB report to the EPA Administrator Aug. 22, 2022, at page 54, avahttps://sab.epa.gov/ords/sab/f?p=100:18:16490947993:::RP,18:P18_ID:2601#report.]. This omission would lead to an overestimate of the impacts of PFOA or PFOS on birthweight, yet it remains unaddressed in the Public Comment Draft Assessments or the Proposed Rule. Despite the SAB concerns, EPA considered these studies to be "high confidence" and does not address the concerns related to potential confounding.

EPA Response: Please see the EPA response to comment Doc. # 1774, SBC-053211 and Doc. # 1774, SBC-053428 in this *Response to Comments* document. Additionally, the EPA responded to SAB concerns regarding Wikstrom et al. (2020) in the *EPA Response to Final Science Advisory Board Recommendations (August 2022) on Four Draft Support Documents for the EPA's Proposed PFAS National Primary Drinking Water Regulation* document (Section I.E5A.2; USEPA, 2023e). Additional discussion of the EPA response to SAB concerns is available in section 4.1.2 of this *Response to Comments* document.

Mike Pettit (Doc. #1542, SBC-052841)

Developmental effects: pg 266 reads "Exposure to PFOA and PFOS during developmental life stages is linked to developmental effects including but not limited to the infant birth weight effects that EPA quantified. SGA is a developmental health outcome of interest when studying

potential effects of PFOA/PFOS exposure because SGA infants have increased health risks during pregnancy and delivery as well as post-delivery. Epidemiology evidence related to PFOA/PFOS exposure was mixed; some studies reported increased risk of SGA with PFOA/PFOS exposure, while other studies observed null results. For PFOS, few patterns were discernible, and overall confidence of an association between the two factors was low. Similarly, ATSDR found no strong associations between PFOA or PFOS exposure and increases in risk of SGA infants."

It is important to note that the mechanism of PFOS-induced developmental effects is not well understood. PFOS may affect developmental processes through several pathways, including disruption of hormone signaling, oxidative stress, and immune dysfunction. However, the precise mechanisms of action are still unclear, and this limits the ability to develop targeted interventions to mitigate the effects. Also of note is that there may be confounding factors that affect the association between PFOS exposure and developmental effects. For example, studies have shown that maternal stress during pregnancy can also affect fetal development, making it difficult to attribute developmental effects solely to PFOS exposure. Also of note, is that by the EPA's own admission (highlighted) is that the exposure effects are mixed, which again does not lend itself to any kind of gravity or even usefulness. As previously stated, there needs to be more consistent results- if there are mixed results then further investigation needs to be instituted. Statements, let alone laws, cannot use the weight of scientific evidence if it is mixed. If it is used, then it is used in the most incorrect and crooked way.

EPA Response: The commenter stated that the mechanisms of action by which PFOS induces developmental effects are unclear. The EPA agrees with this statement and directs readers to Section 3.4.4.3 of the PFOS toxicity assessment (USEPA, 2023a) which describes available mechanistic evidence supporting the effects of PFOS on development. The EPA additionally notes that mechanistic evidence is generally used to support the relevance of animal effects to humans and provide biological plausibility for evidence integration judgments but a definitive understanding of the mechanisms of action are not required for hazard identification or characterization (USEPA, 2022a).In fact, the IRIS handbook states that "if the mechanistic evidence is insufficient to provide a mechanistic or biological understanding of coherence (or lack thereof), this will not change the interpretation of the results from the human or animal studies (i.e., there is no increase or decrease in certainty)" (USEPA, 2022a).

The commenter additionally stated that there may be confounding factors such as maternal stress which make it difficult to attribute developmental effects solely to PFOS exposure. While the EPA agrees that confounding factors may influence study results when not controlled for appropriately through study design or statistical methods, the consistent evidence of developmental toxicity reported by animal toxicological studies mitigates these concerns. As stated in the PFOS toxicity assessment (USEPA, 2024b), "evidence based on 16 *high* or *medium* confidence animal studies indicates that the developing fetus is a target of PFOS toxicity. Dose-dependent maternal and offspring effects were reported in mice, rats, and rabbits." The highly controlled environments of animal toxicological studies limits the potential for confounding

factors to influence results, thus providing supporting evidence of the developmental effects reported in humans.

The commenter also claimed that the EPA stated the evidence for the developmental effects after PFOS exposure was "mixed." This is a mischaracterization of the EPA's conclusions, which were: "The evidence of an association between PFOS and developmental effects in humans is *moderate* based on the recent epidemiological literature." Though evidence for some individual endpoints within the developmental health outcome may have had mixed results (e.g., birth defects), evidence for fetal growth restriction, including LBW, was consistent. The EPA's conclusions regarding the developmental health outcome can be found in Section 3.4.4.4 of the PFOS toxicity assessment (USEPA, 2024b). The commenter also references ATSDR's SGA findings for PFOA and PFOS. Additional discussion of the EPA's consideration of assessment conclusions from other agencies is available in section 4.2.6 of this *Response to Comments* document.

Lastly, the commenter stated that a lack of knowledge about mechanisms of action "limits the ability to develop targeted interventions to mitigate the effects" of PFOS exposure. This is incorrect. Mitigation of effects results from the reduction or removal of contaminant exposure, which will be accomplished with implementation of the PFAS NPDWR.

4.2.1.3 Consideration of Increased Serum Lipids as a Critical Effect

3M Company (Doc. #1774, SBC-053281)

iii. EPA's assessment of cholesterol [FN77: EPA's conclusions regarding cardiovascular disease appear to be driven by its finding of an association between cardiovascular disease and cholesterol, which was the result of a flawed process, as discussed herein.] is inconsistent with best practice

EPA similarly did not adequately address the SAB request for transparency in its selection of outcome-specific studies for cardiovascular disease POD derivation. EPA acknowledges that the evidence for most cardiovascular-related endpoints such as changes in blood pressure, hypertension, coronary heart disease, and stroke is inconsistent (USEPA 2023a, b). Despite this limited evidence, however, EPA selects total cholesterol as the basis of the POD for cardiovascular effects. A complete and rigorous risk of bias assessment is needed to address underlying uncertainties and limitations in the available evidence base for changes in serum lipids, such as cholesterol. Contrary to SAB recommendations, the IRIS Handbook, and its own statements, for cardiovascular disease (CVD) outcomes, EPA failed to consider high-confidence and medium-confidence studies, including those that did not support an association between PFOA and PFOS exposure and CVD. EPA states that "only well-conducted high or medium confidence human and animal toxicological studies were considered for POD derivation, as recommended in the IRIS Handbook {U.S. EPA, 2022, 10476098}" (USEPA 2023a,b; p. 4-1). EPA's statement misleadingly suggests that it considered both high-confidence and medium confidence studies. In fact, EPA considered three studies for derivation of a cardiovascular POD

for PFOA and PFOS (Dong et al. 2019; Lin et al. 2019; Steenland et al. 2009); these three studies are all described as "medium-confidence" in the draft assessment (USEPA 2023a,b; p. 4- 7). However, EPA identified additional medium and high confidence studies but did not consider them for POD derivation.

Although EPA provides some information regarding evidence integration, the agency does not address the SAB's request for explanation of why a specific study was selected for POD derivation among multiple comparable choices for CVD outcome evaluation. Specifically, EPA does not explicitly describe why the high-confidence (Gardener et al. 2021; Li et al. 2021) and other medium-confidence studies (Averina et al. 2021; Christensen et al. 2019; Domazet et al. 2016; Donat-Vargas et al. 2019; Fan et al. 2020; Han et al. 2021; Jain and Ducatman 2018; Jain 2019; Kang et al. 2018; Kobayashi et al. 2022; Lin et al. 2009, 2019, 2020; Liu et al. 2018, 2020; Mora et al. 2018; Papadopoulou et al. 2021; Skuladottir et al. 2015; Spratlen et al. 2020; Tian et al. 2021; Zare Jeddi et al. 2021; Eriksen et al. 2013; Fisher et al. 2013; Geiger et al. 2014; Nelson et al. 2010; Sakr et al. 2007; Timmermann et al. 2014; Winquist and Steenland 2014) were not further considered for POD derivation.

Specific information on the selection criteria used by EPA to pare down the list of medium- and high-quality studies described in the Study Evaluations is necessary to provide confidence in the CVD POD derivation and toxicity assessment. Some studies not considered for POD derivation have study design components that may provide more confidence in the observed exposure-response relationships, including longitudinal designs or collection of multiple serum measurements (e.g., Donat-Vargas et al. 2019, Convertino et al. 2018). EPA did not provide justification and transparently describe the process used to select the three studies that were considered for dose-response evaluation (Dong et al., 2019; Lin et al. 2019; Steenland et al. 2009). Further, additional clarification on how to interpret "multiple judgments" within the findings of the study evaluation process is needed. For example, Steenland et al. (2009) was considered deficient (or "Low Confidence") in some EPA judgments (USEPA 2023a,b; see Figure 3-33), but EPA ultimately treated it as having adequate or "Medium Confidence."

Another deficiency that is contrary to the IRIS Handbook's guidance for study evaluation is EPA's inadequate control for confounding or correlated exposures (e.g., diet, family history, or co-exposure to other PFAS). EPA did not follow best practice as described in the IRIS handbook in that it heavily weighted studies that failed to consider confounding factors, such as family history and dietary factors, which are established contributors to CVD and serum lipids. However, none of the three studies considered by the USEPA for CVD POD derivation (Dong et al. 2019; Lin et al. 2019; Steenland et al. 2009) adjusted analyses to account for family history. Additionally, Dong et al. (2019) and Steenland et al. (2009) do not adjust for dietary habits or cholesterol intake. Intake of saturated fats, trans-fats, polyunsaturated fats, and monounsaturated fats are typically controlled for in randomized controlled trials evaluating impacts of cholesterol intake on TC, LDL-C and HDL-C, as intake is known to affect serum lipoprotein levels (Vincent et al. 2019; Allen et al. 2016; Mensink et al. 2003). Cholesterol intake has also been shown to affect serum lipoproteins (Vincent et al. 2019). Because of these relationships between dietary

patterns and circulating lipoproteins, the National Academies and USDA Dietary Guidelines recommend limiting trans and saturated fats and dietary cholesterol (while maintaining a healthy diet) as a major focus for reducing TC and LDL concentrations (USDA and HHS 2020). Lin et al. (2019) adjusted for "percent of daily calories from fat" and daily fiber intake from a "semiquantitative food frequency questionnaire with 177 items that measured dietary habits over the previous year." In their longitudinal analysis, Lin et al. (2019) found that associations between baseline PFAS and TC did not translate to an increased risk of hypercholesterolemia or hypertriglyceridemia in the lifestyle intervention group, indicating an effect of diet and exercise. Through use of poorly controlled cross-sectional analyses as the basis for RfD development, EPA failed to account for the effects of diet and exercise, well known contributors to CVD outcomes, in its assessment.

1. Contrary to EPA's best practices for systematic review and guidance, EPA did not evaluate study quality consistently for CVD

EPA did not transparently document risk of bias in each domain for each endpoint to ensure that the study quality evaluations are relevant to the endpoint being evaluated, as requested by the SAB. The SAB noted that: a protocol for risk of bias assessment and, more importantly, how that approach was used in the synthesis of evidence for each particular health endpoint is not clearly presented; and therefore, the results cannot be confidently evaluated for accuracy or transparency, or for consistency across health endpoints. This is especially important when a proposed systematic review protocol has not been previously registered or published. (USEPA SAB 2022, p. 6)

EPA's own best practices, as described in the IRIS Handbook, require that individual studies be evaluated for risk of bias and rated according to the Health Assessment Workplace Collaborative (HAWC) database. Here, EPA failed to comply with that guidance and best practice by failing to evaluate the risk of bias for each endpoint within a study that evaluated multiple endpoints. EPA presents Study Quality Evaluation results for each study with CVD outcomes, including serum lipid changes (see USEPA 2023a,b Figures 3-30 to 3-36). According to EPA, each study was evaluated for risk of bias using multiple study domains, including participant selection, exposure measurement, outcome ascertainment, confounding, analysis, selective reporting, and sensitivity. Results from each of these domains are synthesized into a characterization of the overall confidence in the individual study. Although individual studies were evaluated for risk of bias within each of these domains, review of the justifications supporting the risk of bias ratings provided in the HAWC database indicates that the risk of bias ratings for each domain are not necessarily determined relative to each individual endpoint considered in a study.

For example, EPA rated the domains for outcome ascertainment and results in Lin et al. (2019) as "Good" for serum lipids because "blood samples were collected at baseline, annual, and semi-annual follow-visits" (see USEPA 2023d for details). However, Lin et al. (2019) only collected PFOA and PFOS concentrations at baseline and the TC measurements considered as the basis for POD derivation were also collected only at baseline. Therefore, this rating is misleading for the

TC measurements considered by EPA if repeated measurements are part of the justification for a "Good" rating.

In another example, EPA rated the domains for participant selection, exposure measurement, outcome, and analysis in Gardener et al. (2021) as "Good," and these individual domain ratings contributed to the overall confidence categorization as a "High Confidence" study. However, as described within EPA's HAWC documentation, Gardener et al. (2021) is a pilot study that uses a non-nationally representative sample of pregnant women in the Vanguard Pilot Study of the National Children's Study. Although Gardener et al. (2021) evaluated serum lipid concentrations in pregnant women, the EPA's justifications regarding the quality of the outcome, confounding adjustments, and endpoint analysis specifically refer to the gestational age and birth weight endpoints only. Justifications for the confidence ratings of serum lipids as an endpoint in Gardener et al. (2021) are not provided in EPA's HAWC documentation.

By not properly conducting a systematic review and assessing studies for bias within individual endpoints, EPA did not correctly determine which endpoints were suitable for further evaluation. Thus, relevant endpoints and data may have been excluded or unreliable endpoints were included because EPA rated the study overall instead of refining its rating based on a specific endpoint of interest.

EPA Response: The EPA first directs the commenter to discussions related to the EPA response to SAB recommendations and to the EPA's adherence to appropriate guidance are available in Section 4.1.3 and Section 4.1.2, respectively.

In addition, the EPA disagrees with the commenter's characterization of evidence supporting the cardiovascular health outcome. The EPA selected total cholesterol as an outcome for POD derivation based on consistent evidence of serum lipids responses in humans following exposure to PFOA and PFOS, as well as coherent results for perturbations in lipid homeostasis in animal models (USEPA, 2023f; USEPA, 2023a, Table 3-8; Table 3-11). The absence of robust, high confidence evidence for other cardiovascular effects does not equate with an absence of association with PFOS or PFOA, nor does it negate the consistent findings for serum lipids (see the EPA response to comment Doc. # 1774, SBC-053429 in section 4.2.1.3 in this *Response to Comments* document). In situations where evidence for some outcomes was limited or of low confidence, the EPA relied on outcomes for which the evidence base was more robust.

The EPA evaluated risk of bias for all studies considered in the evidence integration for cardiovascular outcomes consistent with the protocols described in the IRIS Handbook (USEPA, 2023b; USEPA, 2023c, Sec. A.1.7). Results from this evaluation (referred to as "study quality evaluation") for studies examining serum lipids are available in section 3.4.3.1.2.2 of the PFOA/PFOS assessments, with additional details available in HAWC. Study quality evaluations were taken into consideration in the evidence integration process. This comment is further addressed later in this response.

The EPA also disagrees with the statements that it did not consider all *high* and *medium* confidence studies for POD derivation and that it did not provide a rationale for ultimately

selecting Dong et al. (2019), Lin et al. (2019), and Steenland et al. (2009) for quantitative assessments. The EPA outlined the criteria for selecting studies for POD derivation in Appendix A, Section A.1.11.1 (USEPA, 2023b; USEPA, 2023c). These criteria include a preference for *high* or *medium* confidence studies over *low* confidence studies, suitability of the data for modeling and relevance of exposure levels, among other factors. Therefore, while all *high* and *medium* confidence studies examining total cholesterol were considered as possible inputs to POD derivation, three studies (Dong et al. 2019, Lin et al. 2019, and Steenland et al. 2009) were ultimately selected as best suited for POD derivation based on all criteria considered together. To further enhance transparency of critical study selection, the EPA has added additional detail in section 2 (methods) to explain that medium and high confidence studies which supported the evidence integration judgement were considered for POD derivation (USEPA, 2024d; USEPA, 2024c). Additionally, explicit rationale as to why other medium and high-quality studies demonstrating an association between PFOA or PFOS exposure and increased total cholesterol were not selected has been added to section 4.1.1.3 of the toxicity assessments (USEPA, 2024d; USEPA, 2024c).

With respect to the Donat-Vargas et al. (2019) study, though this study was rated as *medium* confidence, it was not selected for POD derivation because it was the only medium quality study, out of 19 for PFOA and 17 for PFOS, to report an inverse association between serum cholesterol and PFOA or PFOS levels. Because this study provided results which were inconsistent with the majority of the other general population TC studies, it was not considered for dose response analysis. Additionally, Donat-Vargas et al. (2019)had a smaller sample size (n = 187) than the studies selected for POD derivation (Dong et al., 2019 (n = 8,849); Lin et al., 2019 (n = 940); Steenland et al., 2009 (n = 46,494). Convertino et al. (2018) was rated as *low* confidence due to lack of consideration for potential confounding in the statistical analysis and was not considered for POD derivation as outlined in the methods section 2.2 and section 4.1 of the assessments (USEPA, 2023f; USEPA, 2023a; USEPA, 2024d; USEPA, 2024c).

Regarding the multiple confidence ratings reported for Steenland et al. (2009), this study included multiple outcomes of varying quality; thus, study confidence ratings were outcome-specific consist with the IRIS handbook (USEPA, 2022a) and as detailed in HAWC study evaluation (https://hawc.epa.gov/rob/study/101163917/). The rating of *low* confidence for overall study confidence pertains only to the test guideline (TG) and LDL-C outcomes. The TC outcome in Steenland et al. (2009), which was used as the basis for POD derivation, was rated *medium* confidence for overall study quality. This issue is further discussed in the EPA response to comment Doc. #1774, SBC-053429 in section 4.2.1.3 in this *Response to Comments* document.

Additionally, the EPA disagrees that the studies selected for cardiovascular POD derivation did not adequately address potential confounding. The EPA evaluated all studies for bias due to potential confounding during study quality evaluation (USEPA, 2023b; USEPA, 2023c, Table A-21). As described in Table A-21 (USEPA, 2023b; USEPA, 2023c), only studies in which the potential impact of residual confounding by such factors is judged to be minimal receive a rating of "adequate" for this evaluation domain. Regarding specific risk factors noted by the

commenter, confounding may occur only when a variable is associated with both the exposure and the outcome of interest. As such, while variables such as family history may be risk factors for TC, they would also need to be associated with PFOA or PFOS exposure in order to act as a confounder. The commenter provides no data to support this association. Additionally, regarding the issue of potential confounding by exercise, all three studies selected for POD derivation evaluated potential confounding by physical activity; thus, the claim that the EPA did not account for exercise is inaccurate. This issue is further discussed in the EPA response comment Doc. #1774, SBC-053429 in section 4.2.1.3 in this *Response to Comments* document.

The commenter provided additional concerns regarding the EPA's evaluation of the risk of bias for each individual endpoint within studies that included multiple health outcomes, which they characterized as a recommendation made by the SAB. The commenter based this statement on evaluations available in HAWC for two cardiovascular studies (Lin et al., 2019; Gardener et al., 2021). Regarding Lin et al. (2019), the commenter stated that the rating of "Good" in the outcome ascertainment domain for serum lipids was misleading, as only baseline TC measurements were considered in the analysis. Regarding Gardener et al. (2021), the commenter stated that the text in HAWC for the outcome, confounding, and analysis domains discussed GA and BWT but not serum lipids.

First, the EPA disagrees that individual health outcomes within a single study were not considered in study quality evaluation. As further discussed in the EPA response to comment Doc. #1774, SBC-053429 in section 4.2.1.3 in this *Response to Comments* document, the EPA provided information on how individual health outcomes were considered in Appendix A, Tables A-20 and A-24 of the assessments (USEPA, 2023f; USEPA, 2023a). Specifically, reviewers created multiple evaluations under the outcome ascertainment domain and multiple judgments for the overall confidence rating**,** if needed, to capture different health outcomes. In many cases, multiple judgments were not needed as the confidence across multiple endpoints was the same. All studies were independently evaluated using this protocol by two primary reviewers. A quality assurance reviewer resolved any conflicts and made final rating determinations, consistent with the IRIS Handbook (USEPA, 2022a).

Second, the EPA disagrees that the "Good" rating for serum lipids in the outcome domain of the study quality evaluation for Lin et al. (2019) is not appropriate. Under this domain, reviewers evaluate the extent to which the outcome measure(s) "reliably distinguish the presence or absence (or degree of severity) of the outcome" (Appendix A, Table A-20; USEPA, 2023f; USEPA, 2023a). As such, the justification for the "Good" rating in this domain is appropriately based on the methods used to measure serum lipids (e.g., laboratory methods), rather than timing of the outcome measurement relative to the exposure measurement. Furthermore, information regarding the choice to use data from Lin et al. (2019) on the cross-sectional association between baseline PFAS and baseline TC for POD derivation is provided in Appendix E, section 1.3.3 (USEPA, 2023f; USEPA, 2023a). While Lin et al. (2019) additionally included longitudinal analyses of the relationship between baseline PFAS and incident hypercholesterolemia and

hypertriglyceridemia, results were presented in the placebo and lifestyle intervention groups separately, thus limiting their use in POD derivation.

Third, regarding Gardner et al. (2021), although the main goal of the study was to evaluate developmental outcomes, the commenter expresses concern that cardiovascular outcomes were not originally described in the Outcome Ascertainment domain for study quality evaluation, though they were presented in the study evaluation heat maps and HAWC. Therefore, to ensure full completeness and transparency, the EPA has provided outcome-specific ratings in the Outcome Ascertainment domain for total cholesterol and triglycerides in the study quality evaluation for Gardener et al. (2021) (https://hawc.epa.gov/rob/study/101164025/).

Finally, the commenter mischaracterizes the SAB PFAS panel's quoted recommendations. In the quote provided by the commenter, the SAB suggested the EPA provide additional information on the risk of bias assessment process and its use in evidence synthesis, not that the EPA create independent evaluations for each health outcome within a study. In response to this guidance from SAB, the EPA added information on the relevant protocol in Section 2 of the toxicity assessments, as well as in the Appendices (USEPA, 2023f; USEPA, 2023a); this information was previously discussed in the EPA response to SAB comments document (USEPA, 2023d).

3M Company (Doc. #1774, SBC-053429)

EPA's failure to conduct a transparent and consistent evaluation of the evidence base for cardiovascular outcomes led to selection of candidate studies with critical limitations.

In its appraisal of study quality and risk of bias related to cardiovascular disease (CVD), EPA did not evaluate studies consistently, which led to the selection of candidate studies for POD development with critical limitations.6 EPA (2023a,b) determined that there is moderate evidence from the epidemiological literature for a relationship between PFOA and PFOS and serum lipids changes, with uncertainties stemming broadly from:

· Inconsistencies in TC results for PFOA in adults by sex and health status

· Mixed findings of significant increases in and no association with TC and HDL for PFOS

· Mixed findings of increases and decreases in TG associated with PFOS

· Mixed evidence for LDL for PFOA and PFOS

· Inverse associations for HDL and TG with PFOA in occupational populations, and

· Mixed evidence in children

The determination by EPA that there is a "moderate" level of evidence that PFOS/PFOA exposure are related to cardiovascular disease was made via a flawed process that rendered EPA's conclusion unreliable.

EPA did not transparently integrate evidence for cardiovascular outcomes.

EPA did not develop independent evidence stream judgments for each of the CVD effects identified as critical. EPA also did not transparently integrate animal and human information, or discuss the relative weight of each specific endpoint (e.g., serum lipids, hypertension, CVD, and atherosclerotic changes) considered in the Evidence Stream Judgment and the Evidence Integration Summary Judgments (EPA 2023a, Table 3-8, p. 3- 184 to 3-189; EPA 2023b, Table 3-11, pp. 3-176 to 3-182). EPA did not discuss its confidence in using risk factors for CVD effects, such as TC or LDL, in the absence of clear evidence of CVD outcomes. Accordingly, the public cannot meaningfully comment on whether EPA's treatment of animal information and weight accorded to each specific endpoint represents sound scientific methodology.

Despite failing to use transparent evidence judgments to evaluate these CVD outcomes, EPA confidently states 1) that there is no consistent evidence for associations between PFOA or PFOS and increased blood pressure in the general adult population, and 2) that "evidence for other CVD-related outcomes was more limited, and similarly inconsistent." (EPA 2023a p. 3-154; EPA 2023b p. 3-144). EPA states there is also no consistent evidence for associations between CVD-related outcomes or blood pressure in children, either. EPA stated that "Overall, the limited evidence available among children and adolescents was inconsistent and indicates PFOS is not associated with blood pressure in these age groups. The evidence for an association between PFOS and other CVD-related endpoints assessed in this study population was limited and inconsistent" (EPA 2023b, p. 3-140 to 3-141).7

Despite the admitted uncertain evidence for a relationship between PFOA and PFOS exposures and CVD outcomes, EPA selected changes in serum lipids as a critical endpoint for POD derivation. However, changes in serum lipids are not necessarily adverse on their own. The inconsistency and absence of strong evidence for observed CVD outcomes weakens confidence in the use of serum lipid changes as a critical effect (see Section 2.3.2). They are therefore not a valid critical endpoint for POD derivation.

EPA did not evaluate evidence regarding changes in serum lipids consistent with SAB recommendations.

EPA did not carefully consider the magnitude of the impact of PFOA and PFAS exposures and whether the changes in serum lipid measurements are clinically relevant. The SAB commented, "It is important to clearly demonstrate that the endpoints selected for POD development are well established, sensitive, adverse or precursor to adverse, and that endpoints from animal studies are relevant to humans" (EPA 2023c p. 20). Changes in serum lipids can be affected by many lifestyle and hereditary factors and there is a broad range of serum lipid measurements that are considered "normal." Therefore, best practice was for EPA to have accounted for such lifestyle and hereditary factors when using a risk factor or potential precursor of CVD for setting the POD, especially in the absence of clear CVD effects.

For example, Dong et al. (2019), the key study used for serum lipids POD derivation by EPA, calculated an estimate of 0.4 mg/dL (95% CI 0.06-0.6) increase in TC per 1 ng/mL PFOS and an estimate of 1.48 mg/dL (95% CI 0.2-2.8) increase in TC per 1 ng/mL PFOA. This suggests that

increases in serum TC associated with PFOA or PFOS exposures may not correspond to levels that are considered elevated (e.g., ≥ 240 mg/dL) per standard clinical practice and the American Heart Association's definition of hypercholesterolemia (NCHS 2019). As stated in Dong et al. (2019)'s discussion of study limitations, "the clinical significance of the elevated cholesterol levels was not investigated, which may inhibit the BMD/BMDL application in regulations [emphasis added]".

Although EPA used dose-response information from individual studies (Steenland et al. 2009; Dong et al. 2019; Lin et al. 2019) for POD derivation, EPA presents a meta-analysis, with sensitivity analyses evaluating inclusion and exclusion of low confidence studies, as part of the Economic Analysis for the proposed MCLs (see EPA, 2021b; Analysis of Cardiovascular Disease (CVD) Risk Reduction as a Result of Reduced PFOA and PFOS Exposure in Drinking Water). In that meta-analysis, EPA reports that "For PFOA, when all the studies were combined, EPA observed nonsignificant positive increases in TC of 0.003 (95% CI: −0.001, 0.006) mg/dL per ng/mL serum PFOA (p-value = 0.177, I2 = 89%) and for HDLC of 0.001 (95% CI: −0.001, 0.004) mg/dL per ng/mL serum PFOA (pvalue = 0.291, I2 = 71%). When the low-confidence studies were excluded, the results for both TC and HDLC were similar to the associations observed when all the studies were included in the meta-analysis, with 0.003 (95% CI: −0.003, 0.008) for TC (p-value = 0.321, I2 = 89%), and 0.002 (95% CI: −0.002, 0.005) for HDLC (p-value = 0.290, I2 = 58%)." (EPA 2023c p. 74, see Economic Analysis Appendix F, Table F-2 p. F-11). Nonsignificant increases in TC (p = 0.055) and HDLC (p = 0.631) were reported for PFOS when all studies were included (see Economic Analysis Appendix F, Table F-3 p. F-17). However, "when the analysis excluded the four higher ROB [risk of bias] studies, the association was significantly positive for TC (0.086, (5% CI: 0.001, 0.17, p-value = 0.047, I2 = 100%) and remained the same for HDLC (0.001, 95% CI: −0.001, 0.002, p-value = 0.606, I2 = 83%)" (EPA 2023c p. 74).

Given the lack of consistency in CVD outcomes, lack of evidence that serum lipid changes result in adverse CVD outcomes, and the lack of evidence that observed increases in serum lipids are clinically adverse, EPA needs to provide additional consideration of the clinical relevance of the serum lipid changes to justify selection of increased TC as a critical endpoint for POD development. Otherwise, its analytical process is fundamentally flawed.

EPA did not synthesize evidence in accordance with SAB recommendations or Agency Guidance; candidate study selection was not transparent and therefore PODs may have been derived without consideration of the full body of evidence.

To select endpoints for POD development, the SAB commented, "Internal inconsistencies in the criteria used for selection of endpoints for POD development should be addressed. It is also important to explain why a specific study of a health endpoint was selected when there are several possible choices." For CVD outcomes, EPA states that "only wellconducted high or medium confidence human and animal toxicological studies were considered for POD derivation, as recommended in the IRIS Handbook {U.S. EPA, 2022, 10476098}" (EPA 2023a,b; p. 4-1). Three studies were considered by the EPA for derivation of a POD for PFOA and PFOS

(Dong et al. 2019; Lin et al. 2019; Steenland et al. 2009); these three studies are described as "medium-confidence" in the draft assessment (EPA 2023a,b; p.4-7). However, EPA identified additional medium and high confidence studies but they were not considered by EPA for POD derivation.

EPA has not addressed the SAB's request for explanation of why specific studies were selected for POD derivation among multiple comparable choices for CVD outcome evaluation. Specifically, EPA does not explain why the high-confidence (Gardener et al. 2021; Li et al. 2021) and other medium-confidence studies (Averina et al. 2021; Christensen et al. 2019; Domazet et al. 2016; Donat-Vargas et al. 2019; Fan et al. 2020; Han et al. 2021; Jain and Ducatman 2018; Jain 2019; Kang et al. 2018; Kobayashi et al. 2022; Lin et al. 2009, 2019, 2020; Liu et al. 2018, 2020; Mora et al. 2018; Papadopoulou et al. 2021; Skuladottir et al. 2015; Spratlen et al. 2020; Tian et al. 2021; Jeddi et al. 2021; Eriksen et al. 2013; Fisher et al. 2013; Geiger et al. 2014; Nelson et al. 2010; Sakr et al. 2007; Timmermann et al. 2014; Winquist and Steenland 2014) were not further considered for POD derivation. These studies provide valuable information to the agency and represent some of the best available science on POD derivation in this context.

Some studies not considered for POD derivation have study design components that may provide more confidence in the observed exposure-response relationships, including longitudinal designs or collection of multiple serum measurements (e.g., Donat-Vargas et al. 2019 or Convertino et al. 2018). EPA did not transparently describe the process used to select the three studies that were ultimately considered for dose-response evaluation (Dong et al., 2019; Lin et al. 2019; Steenland et al. 2009). Additionally, EPA relied on one study, Steenland et al. (2009), that was considered deficient (or "Low Confidence") in some judgments (EPA 2023a,b; see Figure 3-33). Steenland et al. (2009) should not be considered as adequate or "Medium Confidence." Relatedly, EPA needs to clarify the meaning of "multiple judgments" within the findings of the study evaluation process. Specific information on the selection criteria used by EPA to pare down the list of mediumand high-quality studies described in the Study Evaluations is necessary to provide confidence in the POD derivation and toxicity assessment.

Transparency in the approaches used by EPA during incremental steps, such as evaluating and categorizing overall study confidence through a formal risk of bias assessment, is imperative for understanding the uncertainties in the ultimate toxicity assessment. If EPA had appropriately conducted a formal risk of bias assessment, the three studies the agency selected as candidates for POD derivation would have been found deficient or critically deficient and would have not been deemed acceptable for selection as candidate studies. Each of the three studies EPA considered (Dong et al. 2019; Steenland et al. 2009; Lin et al. 2019) were cross-sectional in nature, and the longitudinal components of Lin et al. (2019) were not evaluated. As noted by Dong et al. (2019), "The NHANES data are capable of examining the association but cannot address the issue of causality. Similar to other cross-sectional studies, this study cannot answer whether: 1) exposure to PFASs elevates the cholesterol level; 2) high cholesterol levels allow the storage of PFASs easier; or 3) joint factors simultaneously affect both PFASs and cholesterol" (p. 466). Steenland et al. (2009) notes that "Interpretation of these data is made difficult by our

cross-sectional design, which prohibits knowing whether an increase in cholesterol followed an increase in PFOA or PFOS." Therefore, use of these three studies for derivation of a POD is limited due to the nature of the study design, alone.

Other critical deficiencies that likely would have precluded the selected studies from consideration include inadequate control for confounding or correlated exposures (e.g., diet, family history, or co-exposure to other PFAS). Family history and dietary factors are established contributors to CVD and serum lipids. However, none of the three studies considered by EPA for POD derivation (Dong et al. 2019; Lin et al. 2019; Steenland et al. 2009) adjusted analyses to account for family history. Additionally, Dong et al. (2019) and Steenland et al. (2009) do not adjust for dietary habits or cholesterol intake. Intake of saturated fats, trans-fats, polyunsaturated fats, and monounsaturated fats are typically controlled for in randomized controlled trials evaluating impacts of cholesterol intake on TC, LDL-C and HDL-C, as intake is known to affect serum lipoprotein levels (Vincent et al. 2019; Allen et al. 2016; Mensink et al. 2003). Cholesterol intake has also been shown to affect serum lipoproteins (Vincent et al. 2019). Therefore, it is critical that a study consider the impact of diet and dietary factors on serum lipoproteins in each analysis.

Other critical considerations are the timing of serum lipid measurements. In the population assessed by Steenland et al. (2009), fasting blood samples were not consistently collected, and so a variable was added to the analysis to account for fasting in the 6 hours prior to blood sampling.8 Differences in fasting and non-fasting lipid samples will unnecessarily increase heterogeneity and uncertainty in the underlying outcome samples.

In summary, EPA did not adequately address the SAB request for transparency in its selection of outcome-specific studies for POD derivation, especiall,y when there are numerous studies to choose from. A complete and rigorous risk of bias assessment is needed to address underlying uncertainties and limitations in the available evidence base for changes in serum lipids.

EPA did not evaluate study quality consistently for CVD outcomes, in contrast to best practices in systematic review and guidance.

EPA presents Study Quality Evaluation results for each study with CVD outcomes, including serum lipid changes (see EPA 2023a,b Figures 3-30 to 3-36). According to EPA, each study is evaluated for risk of bias using multiple study domains, including participant selection, exposure measurement, outcome ascertainment, confounding, analysis, selective reporting, and sensitivity. Results from each of these domains are synthesized into a characterization of the overall confidence in the individual study.

As part of this process, the agency evaluated individual studies for risk of bias within each domain. The justifications supporting EPA's risk of bias ratings were provided in the Health Assessment Workplace Collaborative (HAWC) database. Those justifications indicate that the risk of bias ratings for each domain are not necessarily determined relative to each individual endpoint considered in a study. For example, EPA rated the domains for outcome ascertainment and results in Lin et al. (2019) as "Good" for serum lipids because "blood samples were

collected at baseline, annual, and semi-annual follow-visits" (see EPA 2023d for details). However, Lin et al. (2019) only collected PFOA and PFOS concentrations at baseline and the TC measurements considered as the basis for POD derivation were also collected only at baseline. Therefore, this rating is misleading for the TC measurements considered by EPA if repeated measurements are part of the justification for a "Good" rating.

In another example, EPA rated the domains for participant selection, exposure measurement, outcome, and analysis in Gardener et al. (2021) as "Good", and these individual domain ratings contributed to the overall confidence categorization as a "High Confidence" study. However, Gardener et al. (2021) is a pilot study that uses a nonnationally representative sample of pregnant women in the Vanguard Pilot Study of the National Children's Study. Although Gardener et al. (2021) evaluated serum lipid concentrations in pregnant women, EPA's justifications regarding the quality of the outcome, confounding adjustments, and endpoint analysis specifically refer to the gestational age and birth weight endpoints only. EPA did not provide justifications for the confidence ratings of serum lipids as an endpoint in Gardener et al. (2021) in the HAWC documentation.

Based on these examples of flawed reporting within HAWC, it is not clear that EPA evaluated the risk of bias for individual endpoints within each study, as recommended by the SAB. EPA did not transparently document risk of bias in each domain for each endpoint to ensure that the study quality evaluations are relevant to the endpoint being evaluated. Without such documentation, the public cannot have confidence that the agency properly evaluated each study for its quality with respect to each endpoint. This renders EPA's entire analysis suspect, and stands in stark contrast with fundamental principles of scientific integrity.

EPA Response: The commenter is directed to section 4.1.1 of the EPA response in this *Response to Comments* document for concerns about the systematic review process used. systematic review protocol for PFOA and PFOS assessments. The commenter suggested the EPA did not adequately address SAB recommendations or follow appropriate guidance for study evaluation. Discussions related to the EPA response to SAB recommendations and to the EPA's adherence to appropriate guidance are available in sections 4.1.3 and 4.1.2 of this *Response to Comments* document.

The commenter additionally stated that the EPA did not evaluate studies related to CVD risk consistently and raised concerns over inconsistencies in the evidence for PFOA and TC by sex and health status among adults, mixed evidence for associations between PFOS and several types of serum lipids (TC, High-Density Lipoprotein [HDL], and TG), mixed evidence for associations between both PFOS and PFOA and Low-Density Lipoprotein (LDL), inverse associations for PFOA and several types of serum lipids (HDL and TG) in occupational populations, and mixed evidence in children.

First, the EPA disagrees that it did not evaluate studies of CVD consistently. The EPA evaluated all studies following the protocol described in Appendix A, section A.1.7 (USEPA, 2023f; USEPA, 2023a). All studies were independently evaluated using this protocol by two primary

reviewers. A quality assurance reviewer resolved any conflicts and made final rating determinations, consistent with the IRIS Handbook (USEPA, 2022a) and the *Systematic Review Protocol for the PFAS IRIS Assessments* (USEPA, 2021a).

Second, as stated in the EPA response to comment Doc. #1774, SBC-053429 in section 4.2.1.3 in this *Response to Comments* document, complete consistency within a health outcome category is not an expectation of a body of observational studies in humans and does not necessarily result in a reduction in the overall confidence of an evidence stream. For example, variation in associations between PFOA and TC by sex within studies (e.g., Jain and Ducatman, 2019b, as summarized in Section 3.4.3.1.2.5 of the PFOA assessment (USEPA, 2023f) could reflect differing susceptibility between men and women. Variation in results by health status across studies, as was observed in Lin et al. 2019, Liu et al. 2020, and Donat-Vargas et al. 2019(PFOA assessment, Section 3.4.3.1.2.5 (USEPA, 2023f)), may similarly reflect differing susceptibility or could have arisen from differences in study methods. Regardless, the available evidence indicates an association between PFOA and increased TC, with 15 of 13 of 15 medium confidence studies in the general adult population reporting positive associations (USEPA, 2024d, Section 3.4.34).

Third, the EPA disagrees with the commenter's characterization of the evidence for PFOS and TC. Among adults, 13 of the 15 medium confidence studies reported evidence of a positive association between PFOS and TC (PFOS assessment (USEPA, 2024c), Section 3.4.3.4). Regarding associations between PFOS and both HDL and TG, the EPA agrees with the commenter's statement that findings were mixed (see PFOS assessment (USEPA, 2023a), Section 3.4.3.4). However, the evidence for TC and LDL was the main driver for the EPA's determination of moderate evidence for an association between PFOS and cardiovascular effects in humans. Lack of evidence supporting an association between an agent and one endpoint (e.g., TG) does not necessarily influence the evidence stream judgment for that health outcome when there is abundant evidence supporting associations with other endpoints in that evidence stream. Additionally, in the case of TG, serum levels are more subject to outcome misclassification than other serum lipid endpoints, such as TC, due to the potential effect of fasting on measurements, potentially contributing to heterogeneous results. This was explicitly noted as an outcome-specific factor that the EPA considered during study quality evaluation (Section 3.4.3; USEPA, 2023f; USEPA, 2023a).

Fourth, the EPA disagrees with the commenter's characterization of the evidence for LDL and both PFOS and PFOA. Among adults, the evidence supports positive associations with LDL (USEPA, 2024d Table 3-8; USEPA, 2024c Table 3-11). Specifically, in general population adults included in the public comment draft (USEPA, 2023f; USEPA, 2023a), 6 out of the 8 medium confidence studies reported positive associations between LDL concentrations and elevated PFOA, and 9 out of 11 medium confidence studies reported similar positive associations for PFOS (USEPA, 2024d; USEPA, 2024c). In addition to these studies, studies examining serum lipids identified after the 2022 updated literature search also reported evidence of increased serum LDL concentrations with elevated PFOA and PFOS (Appendix A.3; USEPA, 2024a;

USEPA, 2024b). These consistent findings are supportive of the moderate evidence stream judgment for the cardiovascular health outcome.

Fifth, the occupational studies measuring serum lipids and PFOA exposure are largely low confidence studies so the ability to draw conclusions in this population is limited (Section 3.4.3.4.1, USEPA, 2024d; USEPA, 2024c). Nevertheless, 8 out of the 10 occupational studies demonstrate a consistent association between PFOA exposure and increased TC (7/8) or increased risk of high cholesterol (1/2). Next, 4 of the 7 occupational studies that measured TG reported an increased association, though 6 put of those 7 studies were low quality for TG. The occupational studies that examined associations between PFOA and HDL were more mixed and mostly low quality. Considering human studies of PFOA and serum lipids as a whole, particularly the consistent associations between PFOA and increased serum lipids in the general adult population in higher confidence studies, the EPA's determination of moderate evidence is warranted.

Finally, regarding mixed evidence in children, expected changes in serum lipids during early childhood present methodological challenges for studying associations in this age group. Specifically, in the first two years, serum lipid concentrations tend to increase until they reach puberty, and then serum lipid levels subsequently decrease during puberty (Daniels et al., 2008). This age- and maturation-dependent fluctuation in serum lipids leads to difficulty in comparing results between different age groups in childhood. As such, the EPA based its determination of moderate evidence for an association between serum lipids and cardiovascular outcomes in humans primarily on studies conducted in adults (USEPA, 2024d Table 3-8; USEPA, 2024c Table 3-11). The EPA has added this rationale to the Serum Lipids Introduction (Section 3.4.3.1.2.1) and Study and Endpoint Selection for Cardiovascular effects (Section 4.1.1.3) (USEPA, 2024d; USEPA, 2024c).

The EPA emphasizes that the evidence stream judgment is for all **cardiovascular outcomes** (which includes CVD) and not specifically for CVD only, as the commenter incorrectly states. Overall, the evidence from epidemiological studies, particularly *medium* and *high* confidence studies conducted in adults from the general population and reporting LDL and TC, support a moderate judgment for this evidence stream.

The commenter additionally stated that the EPA did not develop an evidence stream judgment for each CVD endpoint, nor did the EPA describe how evidence for different endpoints was synthesized to arrive at Evidence Stream and Evidence Integration Summary Judgements. The commenter stated that the EPA did not provide a transparent description of its approach for integrating animal and human evidence. The commenter stated that the EPA did not provide a justification for using CVD risk factors (i.e., serum lipids) in POD derivation in the "absence of clear evidence" of effects on CVD endpoints and further states that serum lipids should not be used for POD derivation for this reason. The commenter also cited inconsistent or limited evidence for associations with blood pressure in the general adult population and other CVD-related outcomes as rationale for reduced confidence in the EPA's determination to use changes in serum lipids as a critical effect, as well as inconsistent evidence for associations with blood

pressure among children. The EPA disagrees with these statements and addresses each in detail below.

First, the EPA followed the evidence synthesis and integration approach in Appendix A (p. A-139 PFOS, A-116 PFOA) to arrive at a judgment for cardiovascular outcomes as a whole (USEPA, 2023f, USEPA, 2023a). The commenter appears to incorrectly conflate conclusions the EPA makes regarding studies of CVD and CVD-related outcomes in specific populations with the EPA's overall conclusions on the association between PFOA or PFOS and cardiovascular effects. The approach outlined in Appendix A does not require a strength-of-evidence judgment for each individual cardiovascular endpoint, nor does it require consistency across every study, population, or effect. Rather, this approach is based on the IRIS handbook which states that multiple, more granular evidence integration judgements can be made for a health outcome if the data allow, but this is generally a pre-determined decision based on manifestations of potential toxicity (e.g., creating separate judgements for immunosuppression and allergic response) (USEPA, 2023f). However, as stated previously, this is not a requirement of the IRIS Handbook evidence integration framework (USEPA, 2022a). The cardiovascular studies included in these two assessments examined a large breadth of related cardiovascular endpoints without clear, pre-determined differences in potential toxicity, and, as a result, the evidence integration judgement was made for the larger cardiovascular health outcome category. Cardiovascular endpoints with higher quality studies (and a larger quantity) drove conclusions for forming strength-of-evidence judgments. Judgments on endpoints with low quality or limited evidence may obscure coherent effects for endpoints within the same health outcome category with higher quality evidence. Regardless of separate or combined evidence integration summary judgements, guidance from the IRIS Handbook states that "the strongest evidence judgement will typically be used to reflect certainty in the broader health effect category," in the event of multiple evidence integration summary judgements for one health outcome category (USEPA, 2022a).

Second, the EPA describes how data from animal and human evidence streams were integrated in Table A-41 (USEPA, 2023f; USEPA, 2023a; USEPA, 2023f). In reference to the judgment rendered for cardiovascular outcomes, the table states that a judgment of *evidence indicates (likely)* is warranted in situations "with moderate human evidence supporting an effect and slight or indeterminate animal evidence, or with moderate animal evidence supporting an effect and slight or indeterminate human evidence." This judgment is appropriate given the moderate evidence for effects in both humans and animals (USEPA, 2023f, Table 3-8; USEPA, 2023a, Table 3-11). The EPA further described how the evidence from animal toxicological studies supports evidence from human studies in Section 4.1.1.3 of the final toxicity assessments for PFOA and PFOS (USEPA, 2024d; USEPA, 2024c).

Finally, the EPA disagrees that serum lipids are not a valid endpoint for POD derivation. While studies included in this assessment examined a range of CVD outcomes, evidence for most individual outcomes was limited as described in section 3.4.3.4 (USEPA, 2024d; USEPA, 2024c; USEPA, 2023f; USEPA 2023a). When evidence for some outcomes was very limited or of low quality (e.g., risk of stroke or hypertension in occupational studies), the EPA relied on outcomes

for which the evidence base was more robust (e.g., serum TC in adults). The absence of robust, high-quality evidence does not equate with an absence of association for these endpoints, nor does it negate the consistent findings for serum lipids. The consistent findings for serum lipids are also supported by evidence of associations with blood pressure in adult populations in *high* and *medium* confidence studies as was summarized in Tables 3-8 and 3-11 of the draft PFOA and PFOS toxicity assessments, respectively (USEPA, 2023f; USEPA, 2023a). While the commenter correctly pointed out that associations with blood pressure among children are inconsistent, this lack of consistency does not negate the consistent findings among the general adult population. Furthermore, it is not the expectation that every endpoint considered within an evidence stream judgment have the same strength of evidence for the overall determination to be considered robust or moderate. A judgment of *moderate* confidence for epidemiological evidence can result from a single or multiple adverse effects or a single or multiple well-conducted studies (USEPA, 2022a). In addition, uncertainty of an association between chemical exposure and a health effect resulting in the EPA's determination not to quantify the association does not necessarily mean the association is non-existent, nor does it automatically result in a decrease in the level of certainty supporting evidence of the hazard.

The EPA disagrees with the commenter's assertion that changes in serum lipid concentrations associated with PFOS or PFOA are not clinically relevant. Such serum lipid changes may or may not result in a concentration considered clinically elevated in a particular individual, however, given the distribution of individual concentrations within the population, small changes in average serum lipid concentrations can result in substantial health impacts at the population level (Gilbert and Weiss, 2006). For example, studies have shown that increases in lipid levels is one of the most important risk factors for CVD after menopause (Carr, 2000; El Khoudary, 2020). Similarly, the SAB PFAS Panel commented on this exact concern and stated that "[f]or the four most consistent endpoints [decreased antibody response, increased TC, increased ALT and decreased birthweight], most studies report relatively small changes in clinical biomarkers. While most of these studies did not evaluate the number of subjects with a clinically abnormal value for biomarkers, one or more studies, for each of the four effects, reported an association of PFOA and/or PFOS with increased risk of a clinically abnormal value…In studies where the number of subjects with clinically abnormal values was not specifically evaluated, an increase in the number of subjects with a clinically abnormal value is also expected from the overall change (shift in the distribution curve) in the abnormal direction. While the clinical relevance of exposure to PFOA or PFAS cannot be predicted on an individual basis, **the increased number of individuals within a population with clinically defined abnormal values is of public health concern"** (emphasis added) (USEPA, 2022b). To be responsive to public comments, the EPA has added discussion on this issue in Section 4.1.1.3 of the final toxicity assessments for PFOA and PFOS (USEPA, 2024d; USEPA, 2024c).

As described in the EPA response to comment Doc. #1774, SBC-053281 in section 4.2.1.3 in this *Response to Comments* document, the EPA evaluated potential confounders that could plausibly be associated with both PFOS/PFOA and health outcomes in humans (e.g., lifestyle) during study quality evaluation (Appendix A, Table A-21, USEPA, 2023f; USEPA, 2023a; USEPA 2024d;

USEPA 2024c)). As described in the table, only studies with minimal potential impact from residual confounding by such factors received a rating of "adequate" for this evaluation domain. Therefore, the EPA does account for "lifestyle and hereditary factors when using a risk factor or potential precursor of CVD for setting the POD," as the commenter recommended. Importantly, confounding may occur only when a variable is associated with both the exposure and the outcome of interest (USEPA, 2022a). As such, while variables such as family history may be risk factors for increased total cholesterol, they would also need to be associated with PFOA or PFOS exposure in order to act as a confounder. There is currently no evidence to support that family history of CVD impacts PFOA and PFOS exposure and the commenter does not provide any evidence to support this association.

Finally, the selection of TC as an endpoint for POD development is well-justified considering the potential for substantial population-level health impacts described above and the consistent evidence of adverse associations with serum lipids. As outlined in the EPA response to comment Doc. #1774, SBC-053281 in section 4.2.1.3 in this *Response to Comments* document, while evidence was limited for most CVD outcomes other than serum lipids, the absence of a robust evidence base for these outcomes does not equate with an absence of association, and, as such, does not negate the consistent findings for serum lipids. The SAB also stated, "elevated serum cholesterol is one of the better-established effects of PFAS exposure in humans," supporting the EPA's selection of serum total cholesterol as an endpoint for POD derivation (USEPA, 2022b).

The commenter stated that the EPA did not provide a rationale for the selection of three studies (Dong et al. 2019, Lin et al. 2019, Steenland et al. 2009) for POD derivation among other high and medium confidence studies. The commenter stated that Steenland et al. (2009) should not be considered a medium confidence study due to "deficient" ratings in some study quality evaluation domains. The commenter requested that the EPA clarify the meaning of "multiple judgments exist" within the study quality evaluation process. The commenter stated that the EPA did not conduct a formal risk of bias assessment for the studies selected for POD derivation and that such a formal assessment would have resulted in deficient ratings due to study design considerations. The commenter stated that the three studies selected for POD derivation did not account for family history (Dong et al. 2019, Lin et al. 2019, Steenland et al. 2009) and/or dietary habits or cholesterol intake (Dong et al. 2019, Steenland et al. 2009) and further states that these limitations should likely have precluded the three studies from further consideration. The commenter stated that fasting blood samples were not consistently collected in Steenland et al. (2009) and asserts that this lack of consistency may increase uncertainty in the measured outcomes. The EPA disagrees with these statements and detailed responses to each point below.

First, the EPA provided information on the process for selecting studies for POD derivation in Appendix A, Section A.1.11.1 (USEPA, 2023f; USEPA, 2023a). The criteria for selecting studies for POD derivation are related to, but distinct from, the study quality evaluation process. For example, studies that were rated high or medium confidence in study quality evaluation are preferred for POD derivation, but other factors, such as suitability for modeling and data availability (e.g., categorical exposure levels), are also considered. However, the EPA has added

explicit rationale for why these three medium studies were selected while other medium confidence studies were not to sections 4.1.1 of the final toxicity assessments (USEPA, 2024d; USEPA, 2024c). This rationale is provided below to address the studies listed by the commenter.

Importantly, for a study to be considered for POD derivation, the study must support the evidence integration judgement for cardiovascular outcomes. Therefore, the 4 medium quality studies which reported an inverse (Donat-Vargas et al. 2019) or null association (Fisher, 2013; Liu, 2020; Han, 2021) for serum lipids were not considered for POD derivation. The EPA determined that the overall evidence indicated an association between increased serum lipids and PFOA exposure and that this association was most evident in the general population as outlined earlier in this response (USEPA, 2024d, Section 3.4.3.4). Therefore medium quality studies in other subpopulations such as, pregnant women (Skuladottir et al. 2015; Gardener et al. 2021), occupationally exposed workers (Sakr et al. 2007; Winquist and Steenland 2014) and children (Li et al. 2021; Jain and Ducatman 2018; Averina et al. 2021; Domazet et al. 2016; Kang et al. 2018; Mora et al. 2018; Kobayashi et al. 2022; Lin et al. 2009; Papadopoulou et al. 2021; Spratlen et al. 2020; Geiger et al. 2014; Timmermann et al. 2014; Tian et al. 2021) were not further considered. Studies in pregnant women were limited, but 3 out of the 4 available studies show a positive association between TC and PFOA exposure, supporting the findings in the general population. Similarly, 7 out of 8 occupational studies reported positive associations between TC and PFOA exposure, supporting the findings in the general population, however the majority of these studies were low quality. As mentioned above, expected changes in serum lipids during early childhood present methodological challenges for studying associations in this age group (Daniels et al., 2008) therefore, EPA based its determination of moderate evidence for an association between serum lipids and cardiovascular outcomes in humans primarily on studies conducted in adults.

Four general population adult studies presented overlapping data from NHANES (Nelson, 2010; Liu, 2018; Fan, 2020; Dong, 2019). Of these four, Dong et al. (2019) was selected for POD derivation because the study included all NHANES cycles between 2003 and 2014, while the other three studies reported results for one or two cycles only and were therefore excluded. Similarly, two studies (Fitz-Simon, 2013; Steenland, 2009) presented data on the C8 Health Project population. Fitz-Simon et al. (2013) was excluded from POD derivation because it was a part of the short-term follow-up and was not as comprehensive as the population examined by Steenland et al. (2009). Therefore, Steenland et al. (2009) was also selected for POD derivation. Finally, Lin et al. (2019) was selected for POD derivation and represented adults from the Diabetes Prevention Program (DPP) population.

Other general adult population studies listed by the commenter were not selected for a variety of reasons. Two studies cited by the commenter (Eriksen, 2013; Lin, 2020) were excluded from POD derivation due to narrow age ranges (i.e., 50–65 years of age, 55–75 years of age, and 20–39 years of age, respectively) of the study populations that were less comprehensive than the age groups included by other studies and therefore, may not apply across the general adult population. One study {Jain and Ducatman, 2019b) was excluded from POD derivation because

the study reported findings stratified by BMI status without stratification by exposure Finally, the other studies listed by the commenter did not report TC measurements (Christensen et al. 2019; Li et al. 2021; Jeddi et al., 2021).

Second, the EPA disagrees that Steenland et al. (2009) should not be considered a *medium* confidence study. Steenland et al. (2009) was rated "deficient" in the outcome ascertainment domain and was rated "low" for overall study confidence only for the TG and LDLC outcomes. The other serum lipids in this analysis, including TC, which was used for POD derivation, were rated "adequate" in the outcome ascertainment domain and "medium" for overall study confidence (https://hawc.epa.gov/study/101163917/). A "low" study confidence rating for one endpoint does not necessarily reduce confidence for other endpoints reported in the same study.

Third, the EPA provided multiple judgments for studies when they included multiple health outcomes and reviewers judged that the different outcomes merited different ratings (Appendix A, Tables A-20 and A-24). This approach is outlined in the IRIS Handbook (USEPA, 2022a, Sec. 4.1 and 4.2.2) and was described at the beginning of each health outcome section as studies with *mixed* confidence ratings. The EPA used the language of *mixed* ratings for priority health outcomes (USEPA, 2023, Sec. 3.4.1, 3.4.2, 3.4.3, and 3.4.4) and multiple judgements for non-priority health outcomes (USEPA, 2023, Appendix C) in the public comment draft. The language for all health outcome sections has been clarified to *mixed* ratings.

Fourth, the EPA disagrees that a formal risk of bias assessment was not conducted for the studies selected for POD derivation and further disagrees that the design of these studies limits their use in this process. The EPA evaluated all studies consistently, including risk of bias, with the protocols described in the IRIS Handbook (Appendix A, section A.1.7). As part of this process, reviewers considered the timing of exposure measurement relative to the outcome within the specific context of each study (Appendix A, Tables A-18 and A-19). However, cross-sectional design alone does not justify rating a study deficient. Furthermore, the EPA reiterates that the process for selecting studies for POD derivation (Appendix A, Section A.1.11.1) is distinct from the process used to evaluate risk of bias and that cross-sectional design does not prevent selection of a study's for this purpose.

Fifth, the EPA disagrees that the use of the three studies selected for POD derivation is limited by their considerations of confounding. Reviewers evaluated the potential for confounding-related bias in each study by considering the approaches used to both identify and control for potential confounders (Appendix A, Table A-21). Not all risk factors for the outcome are considered confounders; rather, a risk factor must also be associated with exposure to be considered a confounder. As such, risk factors such as family history are unlikely to confound the association between PFOS/PFOA and serum lipids and the reviewer has not provided any references supporting an association between family history and PFOS/PFOA levels. Regarding cholesterol intake and dietary habits, the commenter notes and provides evidence that these factors "are typically controlled for in randomized controlled trials." The studies provided by the commenter relied on controlled trials only, specifically excluding observational studies (Vincent et al., 2019; Allen et al., 2016). The studies included in these meta-analyses controlled for dietary intake by

placing participants on specified, controlled diets. This approach is vastly different from controlling for dietary habits in statistical analyses through covariate adjustment, as the commenter is suggesting should have been done in Steenland et al. (2009) and Dong et al. (2019). The latter approach may be subject to recall bias and participants would be expected to have considerable differences in dietary intake of cholesterol or fatty acids as they are not on controlled diets. Additionally, the studies concluded that cholesterol intake was associated with changes in LDL-C, and specifically notes that the impact on HDL-C was less clear (Vincent et al., 2019). The evidence base consisted primarily of observational epidemiology studies which have risk-of-bias considerations distinct from controlled human exposure studies (USEPA, 2022a). For example, the IRIS Handbook suggests incorporation of aspects from other tools such as the Cochrane RoB tool for randomized trials (RoB 2) or the ROBINS-I tool when evaluating controlled human exposure studies (USEPA, 2022a).

Lastly, the EPA disagrees that the lack of fasting blood samples in Steenland et al. (2009) decreases confidence in the results. The EPA consistently rated the Outcome Ascertainment domain for studies without consideration of fasting status. Analyses of TC and HDL-C were not downgraded for lack of consideration of fasting status, however, due to susceptibility to postprandial effects, analyses of TG and LDL-C (which is commonly derived using TG) were downgraded if fasting status was not addressed. As the commenter points out, Steenland et al. conducted an analysis for triglycerides in which fasting status was included in regression models. Steenland et al. report that the inclusion of this variable in the analysis of TG resulted in differences, but for other serum lipid outcomes (e.g., TC) this had little impact on the results, strengthening confidence in the results for these outcomes. Furthermore, in a sensitivity analysis stratified by fasting status, Steenland et al. observed similar trends in both fasters and non-fasters. Therefore, the EPA maintains the confidence determination for Steenland et al. (2009) and continues to use this as a critical study to derive candidate RfDs for the endpoint of serum total cholesterol. For completeness and transparency, details on the sensitivity analyses for serum lipids has been added to the study quality evaluation for Steenland et al. (2009).

The commenter stated that the EPA did not consistently evaluate individual health outcomes assessed in a given study for risk of bias, which they characterize as a recommendation made by the SAB. The commenter based this statement on study quality evaluation data from HAWC for two cardiovascular studies (Lin et al. 2019, Gardener et al. 2021). Regarding Lin et al. 2019, the commenter states that the rating of "Good" for serum lipids in the outcome ascertainment domain is misleading, as only baseline TC measurements were considered in the analysis. Regarding Gardener et al. 2021, the commenter states that the text for the outcome, confounding, and analysis domains discuss GA and BWT but not serum lipids.

First, the EPA disagrees that individual health outcomes within a single study were not consistently evaluated in study quality evaluation. The EPA provides information on how individual health outcomes were considered in Appendix A, Tables A-20 and A-24. Specifically, if multiple judgments were needed to capture different health outcomes, reviewers created multiple evaluations under the outcome ascertainment domain and multiple judgments for the

overall confidence rating. All studies were independently evaluated using this protocol by two primary reviewers, and a quality assurance reviewer resolved conflicts and made final rating determinations, consistent with the IRIS Handbook (Appendix A, section A.1.7).

Second, the EPA disagrees that the "Good" rating in the outcome domain of the study quality evaluation for Lin et al. 2019 is not appropriate for serum lipids. Under this domain, reviewers evaluate the extent to which the outcome measure(s) "reliably distinguish the presence or absence (or degree of severity) of the outcome" (Appendix A, Table A-20). As such, the justification for the "Good" rating in this domain is appropriately based on the methods used to measure serum lipids (e.g., laboratory methods), rather than timing of the outcome measurement relative to the exposure measurement. Furthermore, information is provided in Appendix E, section 1.3.3 regarding the choice to use data on the cross-sectional association between baseline PFAS and baseline TC from Lin et al. (2019) in POD derivation. While Lin et al. (2019) additionally included longitudinal analyses of the relationship between baseline PFAS and incident hypercholesterolemia and hypertriglyceridemia, results were presented in the placebo and lifestyle intervention groups separately, thus limiting their use in POD derivation.

Third, regarding Gardener et al. 2021, although the main goal of the study was to evaluate developmental outcomes, the EPA recognizes the commenter's concern that cardiovascular outcomes were not originally described in the text, though they were presented in the study evaluation heat maps and HAWC. Therefore, for completeness and transparency, the EPA updated the text of Section 3.4.3.1.2.4 to describe confidence ratings and study results for the serum lipid outcome described in Gardener et al. (2021).

Finally, the commenter mischaracterizes the SAB's recommendation. In reference to this point, the commenter included a quote from the Study Evaluation section on page 6 of the SAB's final report (see the SAB's response to Charge Question #1; USEPA, 2022b): "a protocol for risk of bias assessment and, more importantly, how that approach was used in the synthesis of evidence for each particular health endpoint is not clearly presented; and therefore, the results cannot be confidently evaluated for accuracy or transparency, or for consistency across health endpoints." (USEPA, 2022b, page 6). In this quote, SAB is suggesting that the EPA provide additional information on the risk of bias assessment process and its use in evidence synthesis, not that the EPA create independent evaluations for each health outcome within a study. In response to this guidance from SAB, the EPA added information on the relevant protocol in Section 2 of the draft toxicity assessments as well as in the Appendices (USEPA, 2023f; USEPA, 2023a; USEPA, 2023b; USEPA, 2023c).

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-053367)

Consideration of clinical relevance is also important when evaluating EPA's reliance on cholesterol as a marker of cardiovascular disease. In commenting on the Dong et al. 2019 study, which EPA relied upon for PFOA and PFOS, the SAB could not discern why this study was chosen, stated that EPA's lack of information on the study did not appear to support its use, and

strongly recommended that EPA consider older studies [FN112: See SAB report to the EPA Administrator Aug. 22, 2022, at page 18, avahttps://sab.epa.gov/ords/sab/f?p=100:18:16490947993:::RP,18:P18_ID:2601#report.]. However, in the proposed rule, EPA continues to rely on the Dong et al. 2019 study. Importantly, the SAB notes that the epidemiologic literature that provides strong support for an effect of PFAS on cholesterol does not provide support for an effect of PFAS on the risk of cardiovascular disease [FN113: Id. at 102.]. Similarly, as pointed out by Steenland et al. 2020, in evaluating the C8 Science Panel data, while an association between PFOA and elevated cholesterol is plausible, there is no impact on the risk of cardiovascular disease [FN114: Steenland K, Fletcher T, Stein CR, Bartell SM, Darrow L, Lopez-Espinosa M-J, Ryan PB, Savitz DA. (2020) Review: Evolution of Evidence on PFOA and Health Following the Assessments of the C8 Science Panel, Environment International, Volume 145, 106125.]. In fact, the Proposed Rule states "EPA recognizes that the epidemiologic literature that provides strong support for an effect of PFOA and PFOS on cholesterol and blood pressure does not provide direct support for an effect of PFOA and PFOS on the risk of cardiovascular disease (CVD)." [FN115: 88 Fed. Reg at 18709.] Statements like these call into question why EPA continues to rely on this endpoint as a critical effect. In fact, additional recent studies continue to disprove any human CVD disease endpoint (such as stroke, myocardial infarction, or other measurable CVD), and highlight the overreach in attributing CVD to PFOA or PFOS [FN116: Schillemans T, Donat-Vargas C, Lindh CH, de Faire U, Wolk A, Leander K, et al. (2022) Per- and polyfluoroalkyl substances and risk of myocardial infarction and stroke: a nested case-control study in Sweden. Environ Health Perspect130(3):37007, available at: https://ehp.niehs.nih.gov/doi/10.1289/EHP9791.].

EPA Response: Regarding the use of the Dong et al. (2019) study for POD derivation, the EPA addressed all of the SAB's concerns related to selecting this study for POD derivation prior to releasing the draft toxicity assessments for public comment (USEPA, 2023f; USEPA, 2023a; USEPA, 2023d). First, the EPA provided rationale for why this particular study was chosen in section 4.1 of the assessments. The EPA also provided additional modeling details in Appendix E of the assessments in order to detail the modeling that was performed by EPA how the EPA used additional information provided by the study authors to perform hybrid modeling for this study (USEPA, 2023b; USEPA, 2023c). Additionally, the EPA did select multiple studies for POD derivation, including studies) that were published in the 2016 HESDs ((i.e., Steenland et al., 2009) for PFOA and PFOS, as recommended by the SAB. Finally, the EPA has added additional reasons for why other medium quality studies were not selected for POD derivation sections 4.1.1.3 of the toxicity assessments (USEPA, 2024d; USEPA, 2024c).

Importantly, the commenter mischaracterizes the SAB's support of the link between increased cholesterol and CVD. The SAB "support[ed] the overall approach to estimating reductions in cardiovascular disease (CVD) risk associated with reductions in exposure to PFOA and PFOS in drinking water" (USEPA, 2022b). Additionally, the SAB also supported the use of all four noncancer endpoints quantified in the draft, including increased cholesterol because "[i]n studies where the number of subjects with clinically abnormal values was not specifically evaluated, an increase in the number of subjects with a clinically abnormal value is also expected from the

overall change (shift in the distribution curve) in the abnormal direction. While the clinical relevance of exposure to PFOA or PFAS cannot be predicted on an individual basis, the increased number of individuals within a population with clinically defined abnormal values is of public health concern" (USEPA, 2022b).

Regarding the clinical relevance of the cholesterol endpoint, please see section 4.2.2 of the EPA response in this *Response to Comments* document, as well as the EPA response to comment Doc. #1774, SBC-053429 in section 4.2.1.3 in section 4.2.1.3 in this *Response to Comments* document. The latter response additionally describes the EPA's process for critical study selection, which was more transparently described in the PFOA and PFOS toxicity assessments as a result of the SAB comments described by the commenter (USEPA, 2022b; USEPA, 2023d). Please see the EPA response to comment Doc. #1841, SBC-044832 in section 4.2.1.1 in this *Response to Comments* document for a response to Schillemans et al. (2022).

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-053370)

1. EPA's evidence integration approach is flawed

EPA's approach and presentation of its evidence integration findings is flawed and does not represent the best available science or the best available scientific approach to evaluating evidence. For instance, for PFOS, as discussed in the Public Comment Draft Assessment, the 2016 HESD assessment did not assess evidence for associations between CVD diseases and PFOS, besides the review of its effects on serum lipids. Since the 2016 HESD, EPA identifies 45 new epidemiological studies that report on the association between PFOS and "cardiovascular disease" (with endpoints widely ranging from outcomes such as hypertension [in 19 of 45 new studies], CVD, congestive heart failure, microvascular diseases, to mortality). EPA determined that 4 of these studies were high confidence and 23 were medium confidence [FN120: Id. At 3-136.]. EPA has misplaced its emphasis on quantity of "CVD" studies rather than considering the underlying endpoint relevance when determining if in fact any of the endpoints are scientifically attributable to the action of PFOS (via MOA discussion) given the numerous confounders present in every study cited. EPA then concludes, "Overall, the findings from a single high confidence study and several medium confidence studies conducted among the general population provided consistent evidence for an association between PFOS and blood pressure." [FN121: Id. At 3-144.] The concern here is that EPA is not discussing the weight of evidence of all the studies evaluated but is instead drawing its conclusion on the positive studies only. It is clear that there are also medium quality studies that do not show any association, but EPA appears to ignore them when reaching its weight of evidence conclusion.

EPA does not array these data in tabular form, as one would present in a meta-analysis, which would make it easier for readers to discern how EPA is integrating the evidence. EPA's apparent approach of relying on just a few of the positive studies is a not a scientifically sound approach. This is but one example; EPA follows this similar structure and framework for the majority of the non-cancer endpoints assessed in the Public Comment Draft Assessments. EPA has not

sufficiently addressed the SAB concerns and has not provided a transparent and reproducible framework for evaluating the evidence.

EPA Response: The commenter's inadequately supported claim that the "EPA's approach and presentation of its evidence integration findings is flawed and does not represent the best available science or the best available scientific approach to evaluating evidence" shows a lack of understanding about the systematic review that the EPA performed and what constitutes best available science. Please see sections 4.1.1 1, 4.1.2, and 4.1.3 of the EPA response in this *Response to Comments* document. The commenter is also pointed to section 4.2.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1774, SBC-053211 and Doc. #1774, SBC-053428 in section 4.2.1.2 in this *Response to Comments* document regarding the EPA's consideration of all studies reporting cardiovascular effects, including serum lipids, while synthesizing and integrating evidence for the cardiovascular health outcome.

With respect to blood pressure, the commenter does not provide any evidence to support their claim that the EPA ignored medium confidence studies in determining that "[o]verall, the findings from a single high confidence study and several medium confidence studies conducted among the general population provided consistent evidence for an association between PFOS and blood pressure" (USEPA, 2023a). In fact, studies examining changes in blood pressure, including DBP and SBP, and risk of hypertension in general population adults showed consistent positive associations with increased risk of hypertension (4/7), positive associations for SBP (7/9) and DBP (7/8), including four medium or high confidence studies reporting significant increases (4/6) (Section 3.4.3.4, USEPA, 2024c).

The commenter incorrectly stated that the EPA did not array data on cardiovascular effects in a tabular form which makes it difficult for readers to understand how the EPA integrated the evidence. The EPA disagrees that the evidence is not presented clearly. The EPA provided figures of forest plots (in fact, to the commenter's point "as one would present in a meta-analysis") conveying associations between serum total cholesterol and PFOA or PFOS concentrations (e.g., see Figure 3-37 in USEPA, 2023f) and tables reporting associations in both serum lipids and other cardiovascular effects in Appendix D.5 (USEPA, 2023b; USEPA, 2023c). While the commenter critiques the EPA for not representing the "best available scientific approach to evaluating evidence," the commenter fails to recognize that this approach is based on and consistent with the agency's current gold standard for human health assessment methodology (USEPA, 2022a). The EPA also presented the integrated evidence in evidence profile tables (see Section 3.4.3.4.1, USEPA, 2023f; USEPA, 2023a). In addition, a meta-analysis for cardiovascular effects was presented in the *Economic Analysis of the Proposed National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances* (USEPA, 2023i), not in the public comment draft assessments.

American Chemistry Council (ACC) (Doc. #1841, SBC-052926)

PFOA and PFOS Exposure has not been Associated with Cardiovascular Disease in Multiple Epidemiology Studies

Despite a significant number of epidemiology studies investigating the potential association between exposure to PFOA and PFOS and an increased risk of cardiovascular disease (CVD), the evidence remains equivocal at best. As EPA notes, studies investigating CVD and atherosclerosis "reported mixed or primarily null [negative] results" and those evaluating blood pressure and hypertension "reported no effects or generally mixed associations." [FN55: USEPA. Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) in Drinking Water. Public Comment Draft. EPA Document No. 822P23005. Office of Water (2023), at 4-6. (USEPA PFOA MCLG Assessment 2023)], [FN56: USEPA. Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) in Drinking Water. Public Comment Draft. EPA Document No. 822P23007. Office of Water (2023), at 4-6. (USEPA PFOS MCLG Assessment 2023)] While there is evidence of an association between PFOS exposure and at least one measure of continuous blood pressure, there was not concordance among the endpoints within the study populations.

Although there is some evidence for an association with a modest increase in cholesterol and exposure to PFOA and PFOS, the increase does not correlate with increased CVD. Most recently a recent nested case-control study in Sweden study by Schillemanns et al. reported that exposure to five PFAS, including PFOA and PFOS, although associated with cholesterol levels, "did not associate with an increased risk of myocardial infarction, stroke or their composite endpoint." [FN57: Schillemans T et al. Per- and polyfluoroalkyl substances and risk of myocardial infarction and stroke: a nested case–control study in Sweden. Environ Health Persp 130(3):EHP9791.] While this study was published in early 2022, it was not identified by either EPA or the SAB. The lack of an association with CVD led the C8 Science Panel to raise the possibility that people with high cholesterol may retain PFOA, rather than PFOA being responsible for an increase in cholesterol. [FN58: Fletcher T et al. Probable Link Evaluation for heart disease (including high blood pressure, high cholesterol, coronary artery disease). C8 Science Pan http://www.c8sciencepanel.org/pdfs/Probable_Link_C8_Heart_Disease_29Oct2012.pdf]

Despite concluding that the epidemiology data do not support an association with PFOA and PFOS and CVD, EPA inexplicably develops an RfD for both substances based on evidence of an increase in total cholesterol.

EPA Response: Please see the EPA response to comment Doc. #1774, SBC-053211 and Doc. #1774, SBC-053428 in section 4.2.1.2 in this *Response to Comments* document regarding the EPA's consideration of studies reporting cardiovascular effects, including serum lipids, while synthesizing and integrating evidence for the cardiovascular health outcome. Regarding the EPA's selection of increased total cholesterol as a critical effect when data is limited for associations between PFOA or PFOS and CVD, please see section 4.2.2 of the EPA response in this *Response to Comments* document, as well as the EPA response to comment Doc. #1774, SBC-053429 in section 4.2.1.3 in this *Response to Comments* document. Regarding blood

pressure, please see the EPA response to comment Doc. #1713, SBC-053370 in this *Response to Comments* document. The agency did not conclude "that the epidemiology data do not support an association with PFOA and PFOS and CVD," but that the data were too limited to make conclusions regarding the association between PFOA or PFOS and CVD.

The commenter incorrectly claimed that the SAB and the EPA failed to identify a study published in 2022. First, Schillemans et al. (2022) postdated SAB review, which concluded in 2021, therefore it would have been impossible for the SAB to identify this study. Second, Schillemans et al. (2022) postdated the literature search conducted prior to public comment of the draft toxicity assessments, however the EPA has identified this study in the final updated literature review included in the final assessment (see section A-3 of the Appendix, USEPA, 2024d; USEPA, 2024c). The commenter misrepresented the findings from Schillemans et al. (2022) when suggesting that the study shows that although PFOA /PFOS were associated with cholesterol levels, there was no association with increased risk in other relevant cardiovascular endpoints (such as stroke, myocardial infarction, or other measures) in humans. The cholesterol levels and cardiovascular outcomes were not examined in the same subjects. In fact, the study shows that PFOS/PFOA were associated with increased cholesterol levels only in among the controls in the study (individuals without stroke or myocardial infarction). The risk of cardiovascular outcomes was analyzed comparing cases with stroke or myocardial infarctions and controls. Briefly, Schillemans et al. (2022) conducted population-based nested case-control study of Swedish adults (n = 1,528) within two cohorts: the Swedish Mammography Cohort-Clinical (SMC-C) and the Cohort of 60-year-old (60YO). In baseline cross-sectional analyses among 631 controls , baseline plasma PFOS was indeed associated with increased baseline TC (β per 1-SD-ln- ng/mL PFOS = 0.14, 95% CI: 0.06, 0.22), increased LDL-C (β = 0.13, 95% CI: 0.06, 0.20), increased HDL-C (β = 0.05, 95% CI: 0.01, 0.07), increased apolipoprotein A1 (β = 0.04, 95% CI: 0.02, 0.08), and decreased triglycerides (β = –0.11, 95% CI: –0.17, –0.05). In prospective analyses of the pooled cohorts, there were no significant associations between baseline PFOS and subsequent incidence of myocardial infarction, stroke, or CVD. Thus, this study evaluated associations between PFOS and elevated serum lipids among controls only; therefore, a conclusion about associations between PFOS and elevated CVD risk among individuals with elevated cholesterol levels cannot be made based on the study findings or data.

Mike Pettit (Doc. #1542, SBC-052837)

Cardiovascular effects: pg 267 reads "Epidemiology studies showed a positive association between PFOA or PFOS exposure and LDLC levels in children. In particular, the evidence suggested positive associations between serum PFOA and PFOS levels and LDLC levels in adolescents ages 12–18, while positive associations between serum levels and LDLC levels in younger children were observed only for PFOA. For instance, all five epidemiology studies evaluated in EPA's Proposed MCLGs for PFOA and PFOS in Drinking Water reported positive associations, although the association was only statistically significant in obese women. Available evidence regarding the impact of PFOA and PFOS exposure on pregnant women was too limited for EPA to determine an association."

A major issue is the lack of a clear mechanism by which PFoS exposure could lead to cardiovascular disease. While animal studies have suggested that PFOS exposure may lead to changes in lipid metabolism, inflammation, and oxidative stress, it is not yet clear how these effects may translate to humans or how they may contribute to cardiovascular disease. There is currently a lack of clear and consistent evidence linking PFOS exposure to cardiovascular effects in humans. While some studies have suggested an association between PFOS exposure and cardiovascular disease, others have not found a significant relationship. Additionally, animal studies have shown inconsistent results, with some indicating a link between PFOS exposure and cardiovascular effects, while others have not found any significant effects. A secondary thing of note, is that the only statistically significant finding was in obese women. There should be a red flag immediately brought up in this instance. This study does not take into account any of the other confounding factors having to deal with the potential reasons for heart disease in obese women. Clearly this claim should be taken into careful consideration.

EPA Response: The commenter stated that the mechanisms of action by which PFOS induces cardiovascular effects are unclear. The EPA agrees with this statement and directs readers to Section 3.4.3.3 of the PFOS toxicity assessment (USEPA, 2024c; USEPA, 2023a) which describes available mechanistic evidence supporting the effects of PFOS on the cardiovascular system. The mechanistic evidence is generally used to support the relevance of animal effects to humans and provide biological plausibility for evidence integration judgments but known mechanisms of action are not required for hazard identification or characterization (USEPA, 2022a).

Regarding the evidence for associations between PFOS and cardiovascular effects in humans, please see the EPA response to comment Doc. #1774, SBC-053211 and Doc. #1774, SBC-053428 in section 4.2.1.2 in this *Response to Comments* document. With respect to LDLC, the EPA disagrees that the only statistically significant finding was in obese women. Studies from the general population (Fan, 2020; Fitz-Simon, 2013; Lin, 2019 [PFOA only]) reported significant increases in LDL-C with elevated exposures to PFOA and PFOS. Additionally, studies published after our 2022 updated literature search have provided further evidence of significant associations between PFOS and LDL-C in adult populations (Batzella, 2022a; Batzella, 2022b; Cheng, 2022; Nilsson, 2022) (USEPA, 2024b, Sec. A-3). Additionally, a change or result that lacks statistical significance can be used to support a conclusion of an effect (Wasserstein and Lazar, 2016; USEPA, 2022a).

The EPA additionally disagrees with the commenter's assertion that the evidence from animal toxicological studies is inconsistent. As described in Section 3.4.3.4 of the PFOS toxicity assessment (USEPA, 2024a), alterations in serum lipids were reported in the majority of animal toxicological studies identified and reviewed by the EPA. These results are coherent with and support the evidence of altered serum lipids from human epidemiological studies.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-053387)

CVD

In a study described in the 2016 Health Advisory (HA), no association with hypertension in 1,655 children aged 12–18 years from the NHANES was found [FN34: Wen-Wen Bao et al., "Gender-Specific Associations between Serum Isomers of Perfluoroalkyl Substances and Blood Pressure among Chinese: Isomers of C8 Health Project in China," Science of the Total Environment, 2017.]. An occupational study reported an inverse association for mortality from heart disease among all cohort members.

Since publication of EPA's 2016 PFOA health effect support document, EPA found 49 new epidemiological studies report on the association between PFOA and CVD, including outcomes such as hypertension, CAD, congestive heart failure, microvascular diseases, and mortality.

Of the ten studies that examined blood pressure as a continuous measure, six reported statistically significant positive associations [FN35: U.S. Environmental Protection Agency, "2023b," 3–151.]. EPA also points to two NHANES-based studies examining CVD that reported significant associations between PFOA and CVS [FN36: Anoop Shankar, Jie Xiao, and Alan Ducatman, "Perfluorooctanoic Acid and Cardiovascular Disease in US Adults," Archives of Internal Medicine, October 2012.]. However, another study using a larger NHANES dataset did not observe an association nor a positive trend between quartiles of exposure and CVD incidence [FN37: Mengmeng Huang et al., "Serum Polyfluoroalkyl Chemicals Are Associated with Risk of Cardiovascular Diseases in National US Population," Environment International, 2018.].

Some findings were mixed and inconsistent across studies. For those examining strokes, for example, one found a slight positive association [FN38: Huang et al.], while another observed a significant inverse association [FN39: Robert Hutcheson, Kim Innes, and Baqiyyah Conway, "Perfluoroalkyl Substances and Likelihood of Stroke in Persons with and without Diabetes," Diabetes and Vascular Disease Research, 2020.].

EPA Response: Please see the first EPA response to comment Doc. #1774, SBC-053211, and Doc. #1774, SBC-053428 in section 4.2.1.2 in this *Response to Comments* document and Doc. #1713, SBC-053370 in section 4.2.1.3 in this *Response to Comments* document regarding further discussion of the EPA's characterization of studies on blood pressure and CVDs. The EPA disagrees with the commenter that findings regarding association between exposure to PFOA and cardiovascular health outcomes were inconsistent across available studies and notes that the critical effect determined from the EPA's toxicity assessment as changes in total cholesterol in adults (USEPA, 2024d; USEPA, 2024c; USEPA, 2023f; USEPA, 2023a). Briefly, the cardiovascular studies included in these two assessments examined a large breadth of related cardiovascular endpoints without clear, pre-determined differences in potential toxicity, and, as a result, the evidence integration judgement was made for the larger cardiovascular health outcome category, which included serum lipids such as TC. As noted in the PFOA assessment (Section 3.4.3.4.1; USEPA, 2023a), there was generally consistent evidence of increased blood pressure in studies of general population adults. The number of studies examining associations between elevated exposure to PFOA and PFOS and incidence of CVD or CVD mortality were fewer and

typically of lower quality. Most studies on CVDs provided risk estimates for unique, non-overlapping definitions of disease which make evaluating consistency and coherence between studies difficult. Cardiovascular endpoints with higher quality studies (and usually a larger quantity of studies) drove conclusions for forming strength-of-evidence judgments. Judgments on endpoints with low confidence or limited evidence may obscure coherent effects for endpoints within the same health outcome category with higher quality evidence, and the ORD IRIS Handbook states that "the strongest evidence judgement will typically be used to reflect certainty in the broader health effect category," in the event of multiple evidence integration summary judgements for one health outcome category (USEPA, 2022a).

4.2.1.4 Consideration of Decreased Antibody Response as a Critical Effect

City of Lancaster, Pennsylvania (Doc. #1695, SBC-044993)

PFAS Study Conflicting Results: Although the USEPA proposes a very stringent contaminant level in its regulations, reducing the levels in water will not eliminate exposure to PFAS species PFOA/PFOS. Please reference the article - Does regulating per- and polyfluoroalkyl substances represent a meaningful opportunity for health risk Reduction? as published by AWWA. Furthermore, testing referenced in these studies (Dong, G.H. (2011)) shows that levels of exposure to PFOS that result in significant response were not significant from the control until dosages went to 5 mg/kg dosage per day (over 1.25 million times greater than reference dosages proposed). Other impacts did not occur significantly until 50 mg/kg dosages (12.5 million times reference dosages) for several factors monitored in the study.

A toxicological study performed by the group referenced in the (L. Zheng et al (2011)) performed another study on PFOS toxicological behavior based on monitoring short term dosage varied responses. The results of their study showed their data was discordant and not matching previous studies. The following was also stated:

"These discordant results are not apparently isolated to PFOS only. In studies of the effects of PFOA (physiochemically similar to PFOS) on immune functions in female C57BL/6N mice, Dewitt et al. (2008) found that SRBC-specific IgM synthesis was dose- dependently suppressed by PFOA, whereas SRBC-specific IgG titers were increased at lower (and similar to controls at higher) doses of PFOA. In contrast, Yang et al. (2002a) reported that PFOA exposure markedly suppressed the formation of both IgM and IgG antibodies against horse red blood cells."- L.Zhen et al. (2011)

This shows there are significant conflicting dosage response results seen with PFOS and PFOA and these studies warrant more research before relying on them to solely justify a dramatic shift in regulatory strategy and resulting investment for water systems. The proposed MCL bulletin states there is still not enough data for an MCL for the rest of the PFAS species. With this lack of data, the proposed limits for water being recommended are not warranted.

More recent studies from the Environmental Toxicology and Chemistry _Volume 40, Number 3-PP. 550-563 by Gloria B Post, have also shown lower refence dosages used by various states. The primary new concern with the lower dosages is the effect on the immune systems from babies. Though it touches on this and various other sources of exposure, it makes the key point that they still do not know much about the health effects of many of these species and they are making assumptions in the way of their overall health impacts and how they are studying them.

When reviewing this research, the key math being overlooked is that the volume of water needed to be consumed to reach the reference dosage of 2 ng/kg/L for an adult weighing 70 kg would with a source having 15 ng/L for an adult weighing 70 kg would be around 9.3 liters of water. That is over 2 gallons, and that individual would likely die from that volume of water consumption alone. Even with a baby of 22 lbs or 10 kg, the consumption of 1 liter of water is the maximum recommended. So, if the baby is drinking only water (which is not likely) with 15 ng/L of PFAS, the reference dosage would still not be reached.

The data shows that the new limit of 4 ng/L for the water is overkill and is unjustly going to put a financial burden on the citizenry when the primary exposures are coming from other sources USEPA is allowing to continue.

EPA Response: The commenter stated that the reduction of PFAS levels in drinking water does not present a meaningful opportunity for health risk reduction. The EPA disagrees with this statement: please see Section III of the preamble for this regulation and sections 3.1.3 and 3.2.3 of the EPA response in this *Response to Comments* document. The EPA disagrees that there is insufficient information to establish MCLs for PFOA, PFOS, PFHxS, PFNA, HFPO-DA and mixtures of PFHxS, PFNA, HPFO-DA, and PFBS regulated utilizing a hazard index approach. Additionally, as required under the Safe Drinking Water Act, the EPA has set the MCLs as close to the MCLGs as feasible using the best available treatment technology and taking cost into consideration. The EPA does not believe setting the PFOA and PFOS MCLs at 4.0 ng/L, a level that is as close to the PFOA and PFOS MCLGs as feasible, is "overkill" as claimed by the commenter; rather, setting them as close to the MCLGs of 0 as feasible is the EPA's obligation under the SDWA statutory construction. See discussion in section V of the preamble of the PFAS NPDWR and section 5 of the EPA response in this *Response to Comments* document.

The commenter cited several animal toxicological studies as evidence that the immunotoxic effects of PFOA and PFOS are inconsistent and only occur at levels that are not relevant to human exposure. The EPA disagrees with these statements. The commenter appears to ignore the evidence of immunotoxicity from studies in humans (e.g., reduced antibody response to vaccination). As described in Sections 3.4.2.4 and 4.1.1.2 of the PFOA and PFOS toxicity assessments (USEPA, 2023f; USEPA, 2023a), results reported in animal toxicological studies are consistent with the observed immunosuppression in epidemiological studies. The epidemiological evidence consistently demonstrated reduced antibody response at median levels as low as 1.1 ng/mL PFOA. The commenter also ignores that the EPA quantified the immune health outcome RfD based on decreased antibody concentrations in children. Most importantly,

the commenter incorrectly stated that EPA relied on the cited immunotoxicity studies in animals "to solely justify a dramatic shift in regulatory strategy." The MCLGs are based on the determination that PFOA and PFOS are *Likely to be Carcinogenic to Humans,* not on an RfD derived from immunotoxicity data.

Further, the consistency of the animal toxicological database individually is presented in the evidence profile table in Section 3.4.2.4 (USEPA, 2023f; USEPA, 2023a; USEPA, 2024d; USEPA, 2024c). The commenter also appears to misunderstand extrapolation of data from dosed animal toxicological studies to human exposure. While the EPA agrees that there are uncertainties associated with the extrapolation of data from animal models to humans (see discussion in the EPA Response below), including several that the commenter highlighted above, the EPA disagrees that this precludes the agency from quantitatively relying on studies in animal models for the derivation of toxicity values. This practice has been used to support EPA products for decades and is repeatedly endorsed by the EPA guidance and methods (USEPA, 2002; USEPA, 2005; USEPA, 2014a; USEPA, 2022a). The EPA agrees that extrapolation from animal models to humans is complex, but animal toxicological studies, regardless of study design characteristics such as dose levels, are critical for determining potential human health hazards and the exposure levels and internal doses (e.g., serum concentrations) that may be expected to cause adverse health effects in humans. With an understanding of how the chemical exposure behaves differently in animals and humans, the EPA can estimate the equivalent level of exposure that would pose a risk to human health and compare those values across any effects that could pose a hazard. In this way, the EPA can determine the minimum exposure level (e.g., RfD) that could result in a risk to human health. The pharmacokinetic approach the EPA used to estimate human equivalence doses from animal toxicological studies is available in Section 4.1.3 of the PFOA and PFOS toxicity assessments (USEPA, 2023f; USEPA, 2023a). The EPA did not ignore this "key math" and in actuality implemented a more sophisticated approach than recommended by the commenter. There are fundamental toxicokinetic concepts which are ignored in the commenter's description of the volume of water required to reach the reference dose, such as the absorption, distribution, metabolism, and elimination of PFOA and PFOS in humans. PFOA and PFOS are both highly persistent chemicals with long reported half-lives generally ranging from 2 to 5 years in adults (USEPA, 2023f, USEPA, 2023a, Sec. B.4.5). Considering the length of the half-life for each substance (i.e., slow elimination), and that PFOA and PFOS both accumulate and are distributed in various tissues (USEPA, 2023f, USEPA, 2023a, Sec. B.2.2.1), calculating the amount of water necessary to reach a reference dose would not be as simple as the commenter suggests.

3M Company (Doc. #1774, SBC-053219)

v. EPA's assessment of immunotoxicology is inconsistent with agency guidance.

In assessing immune efforts, EPA did not appropriately employ methods described in the IRIS Handbook for evaluation of study quality and risk of bias in evaluating vaccine repose. EPA did not evaluate evidence consistently across studies, nor did it synthesize evidence according to

guidance. This omission again led to the selection of candidate studies for point of departure (POD) development with critical limitations. Selection of reliable studies with limited bias is critically important for limiting the uncertainty in the derived POD and subsequent toxicity values. If EPA had appropriately refined the study evaluation to the vaccine endpoint, thus accounting for aspects SAB recommended, a high level of uncertainty would have been found in the body of evidence. EPA failed to follow IRIS guidance to refine the study evaluation tool to the topic, including modifications to evaluation criteria to include factors specific to the exposure and outcome of interest, as well as potential confounders that specifically affect these associations. Such considerations would allow for the evaluation of specific factors critical to the overall study reliability conclusions. As a result of these process errors, the evidence presented does not support antibody response to vaccine as a critical endpoint and leads to a high level of uncertainty in the calculated toxicity values derived for this endpoint.

EPA (USEPA 2023a,b) considered multiple outcomes under the category of immune function, including vaccine response, infectious disease, immune hypersensitivity (allergy, asthma), and autoimmune disease. EPA determined that there was moderate evidence for an association between PFOA/PFOS exposure and immunosuppressive effects in human studies. This conclusion was based on its findings in PFOA studies of "largely consistent decreases in antibody response following vaccinations (against two different infectious agents: tetanus and diphtheria) in multiple medium confidence studies in children" (USEPA 2023a, p. 3-133), and a "largely consistent decrease in antibody response following vaccinations (against three different infectious agents) in multiple medium confidence studies in children" for PFOS (USEPA 2023b, p. 3-122). However, uncertainties in the conclusions for both PFOA and PFOS reflect:

· Inconsistent findings of decreased vaccine response in adult populations

· Inconsistent and/or imprecise findings of increased infectious disease

· Mixed findings of hypersensitivity, including allergy, asthma, and eczema

· Mixed findings for autoimmune disease

Additional details regarding the strength of evidence for outcomes related to immune function are described in the EPA Evidence Stream and Summary Judgments (USEPA 2023a, Table 3-7; USEPA 2023b, Table 3-10).

EPA Response: The commenter incorrectly stated the EPA did not appropriately employ study quality evaluation methods for evaluating vaccine response, consistently evaluate evidence across studies, or synthesize evidence according to guidance and SAB recommendations. Please see the EPA Responses to sections 4.1.1, 4.1.2 and 4.1.3 in this *Response to Comments* document.

The commenter suggested this led to the selection of studies inappropriate for POD derivation and incorrect conclusions about the body of evidence. The commenter raised uncertainties in the conclusions such as inconsistent findings of vaccine response in adults, inconsistent or imprecise

findings for infectious disease, mixed findings for immune hypersensitivity, and mixed findings for autoimmune disease. The EPA disagrees with these claims.

The EPA disagrees that modifications made to the PFOA and PFOS systematic review protocols were insufficient. As highlighted in responses to the same commenter under sections 4.2.1.2 and 4.2.1.3, the EPA modified the study quality evaluation criteria based on considerations described in the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022a), as well as the *Systematic Review Protocol for the PFAS IRIS Assessments* (USEPA, 2021a). Exposure-specific modifications were appropriately made to the criteria in consultation with a topic-specific technical expert. Due to the breadth and heterogeneity of outcomes evaluated in the evidence base, the EPA determined outcome-specific evaluation criteria were not necessary. It is unclear which SAB recommendation the commenter is referring to in suggesting the creation of vaccine response-specific evaluation criteria for Outcome Ascertainment and the EPA could find no such recommendation (USEPA, 2022b). The EPA considered additional chemical-, exposure-, and outcome-specific factors when reviewing studies for use in quantitative analyses consistent with ORD Handbook (USEPA, 2022a).

The EPA disagrees with the commenter's characterization of inconsistencies in studies of vaccine response in adults. There were a limited number of studies, especially High confidence studies, which analyzed vaccine response in adults. Specifically, there were only 5 studies that explored vaccine response in adults; three out of the five total studies were rated as Low confidence and each study analyzed different antibody titers (e.g., hepatitis A, hepatitis B, and influenza), which makes comparisons between studies difficult (Section 3.4.2.1, USEPA, 2024d; USEPA, 2024c; USEPA, 2023f; USEPA, 2023a). The difficulty in comparing these limited studies does not negate the findings from studies of vaccine response in children, especially considering the increased number of total studies (12), confidence in those studies (9 medium and 1 high confidence) and consistency of results observed in studies of children. Given these factors, the EPA maintains its position that vaccine response in children is an appropriate critical effect considered for quantitative analyses, a position that was supported by the EPA's SAB PFAS Review Panel (USEPA, 2022b).

Positive associations or increased risk of adverse health outcomes should not be ignored, even if some inconsistency is present in the evidence base. Complete consistency within an outcome category is not an expectation of a body of observational studies in humans, and some inconsistency is expected due to differences in study populations. For example, studies analyzing infectious disease examined numerous types of conditions, and, in some cases, analyzed "total infections," which may refer to various groupings of different infections. There were numerous infectious diseases examined in single studies, such as cytomegalovirus, Epstein Barr virus, hepatitis C and E, herpes simplex 1 and 2, HIV, Toxoplasma gondii and Toxocara species (Bulka, 2021). Even within a more granular category of infectious disease (e.g., respiratory tract infections) the studies still varied in their reporting of risk estimates, including for outcomes such as throat infection (Impinen, 2019), recurrent respiratory infection (Huang, 2020), lower respiratory tract infection (Kvalem, 2020; Impinen, 2018; Dalsager, 2021), upper respiratory

tract infection (Dalsager, 2021), syncytial virus and pseudocroup (Ait Bamai, 2020; Kvalem, 2020), or just "infections" generally (Abraham, 2020; Wang, 2022). The heterogeneity of how each study examined the presentation of infectious disease may lead to perceived inconsistencies in the evidence base, however, not all conditions described above can be directly compared. Other studies examined symptoms only (e.g., fever, diarrhea, coughing), which are difficult to attribute to a specific condition (Timmerman, 2020). The type of allergies examined in studies of hypersensitivity also included a wide variety of allergens and allergy tests conducted at various ages allergic rhinitis or rhinoconjunctivitis (Goudarzi, 2016; Ait Bamai, 2020; Impinen, 2018; Kvalem, 2020; Timmermann, 2017), skin prick test (Kvalem, 2020 and Impinen, 2018 at age 10 years; Timmermann, 2017 at age 13 years), and food or inhaled allergies(Kvalem, 2020, and Impinen, 2018, at age 10 years; Timmermann, 2017, at age 13 years}). Similar to infectious disease, if the number studies examining the same allergen or allergy test are limited, then direct comparability between studies is also limited. The availability of such studies is unrelated to the presence or absence of an adverse effect. Similarly, the evidence base for autoimmune disease examined a variety of different conditions (e.g., multiple sclerosis in Ammitzbøll, 2019; ulcerative colitis in Xu, 2020; and rheumatoid arthritis in Steenland, 2013), making comparisons across studies difficult. These considerations were outlined in the Evidence Integration for Immune studies (USEPA, 2023f; USEPA, 2023a, Sec. 3.4.2.4), including the Evidence Profile Table (Table 3-7).

3M Company (Doc. #1774, SBC-053430)

EPA's failure to conduct a transparent and consistent evaluation of the evidence base for immune outcomes led to selection of candidate studies with critical limitations.

Under the category of immune effects, EPA (2023a,b) considered multiple outcomes, including vaccine response, infectious disease, immune hypersensitivity (allergy, asthma), and autoimmune disease. EPA (2023a,b) determined that there was moderate evidence for an association between PFOA/PFOS exposure and immunosuppressive effects in human studies. This was based on its findings in PFOA studies of "largely consistent decreases in antibody response following vaccinations (against two different infectious agents: tetanus and diphtheria) in multiple medium confidence studies in children" (2023a, p. 3-133), and in PFOS studies a "largely consistent decrease in antibody response following vaccinations (against three different infectious agents) in multiple medium confidence studies in children" (EPA 2023b, p. 3-122). However, there were significant uncertainties in EPA's conclusions for both PFOA and PFOS due to:

· Inconsistent findings of decreased vaccine response in adult populations

· Inconsistent and/or imprecise findings of increased infectious disease

· Mixed findings of hypersensitivity, including allergy, asthma, and eczema

· Mixed findings for autoimmune disease

Additional details regarding EPA's assessment of the strength of evidence for outcomes related to immune function are described in the EPA Evidence Stream and Summary Judgments (EPA 2023a, Table 3-7; EPA 2023b, Table 3-10).

Despite this, EPA did not evaluate evidence consistently across studies, nor did it synthesize evidence according to its guidance. This led EPA to select candidate studies for POD development with critical limitations.

If EPA had appropriately refined the study evaluation for the vaccine endpoint, thus accounting for aspects SAB recommended, the agency likely would have found a high level of uncertainty in the body of evidence such that the use of vaccine response as a critical endpoint is not supported.

EPA did not appropriately explain whether or how it accounted for the lack of consistency or plausibility demonstrated within the evidence base for vaccine response and incidence of infectious disease.

EPA's summary of infectious disease incidence associated with PFOA or PFOS exposure indicated that results were not consistent across studies, finding that "Increased incidence of some infectious diseases in relation to PFOA exposure was observed, although results were not consistent across studies" and stating there is "limited evidence of an association between PFOS exposure and infectious diseases." (EPA 2023a, p. 3-106; EPA 2023b, p. 3-123).

Similarly, epidemiologic studies on hypersensitivity and autoimmune disease reported mixed associations with PFOA exposures (EPA 2023a, p. 3-134). Epidemiologic studies reported some evidence of sensitization and allergic responses with PFOS, but "notable limitations and uncertainties in the evidence base remain" (EPA 2023, p. 3-123). Specifically, EPA states "While there is some evidence that [PFOA and PFOS] exposure might also have the potential to affect sensitization and allergic responses in humans given relevant exposure circumstances, the human evidence underlying this possibility is uncertain and with limited support from animal or mechanistic studies." (EPA 2023a, Table 3-7; EPA 2023b, Table 3-10). Some evidence of an association between PFOS and asthma was observed, but EPA noted "considerable uncertainty due to inconsistency across studies and subgroups." (EPA 2023b, p. 3-123). EPA did not provide justifications or clearly state the strength of evidence for each of the immune endpoints, thereby limiting transparency in its selection of the critical effect for POD derivation. [FN2: Decreases in vaccine response can be a risk factor for infectious disease, but they are not necessarily adverse effects themselves. To be adverse, immunosuppressive effects must result in an increase in infectious disease incidence.]

EPA did not provide a transparent description of its approach to accounting for uncertainties and unsupportive toxicological studies in its evidence integration approach and methods. In addition, EPA failed to address the implications of the lack of clear mechanistic support and biological relevance and plausibility on its choice of vaccine response as a critical endpoint. The lack of such explanation is critical given that the underlying evidence does not demonstrate a clear or consistent relationship within the dataset, nor does it demonstrate a clear or consistent relationship with adverse outcomes (incidence of infectious disease). Without additional

explanation, the public cannot provide input regarding the agency's interpretation of the available evidence.

In contrast with best practices in systematic review, and in contrast with its own guidance, EPA did not evaluate study quality consistently for the immune evidence.

The SAB urged EPA to implement a consistent process with consistent terminology for analyzing and synthesizing evidence. In response, EPA said it expanded the systematic review steps to be consistent with the IRIS Handbook to ensure this was accomplished (EPA 2023c, p. 16). However, EPA did not follow guidance presented in the IRIS Handbook that asks the reviewer to re-read the studies after the initial evaluation of evidence for a particular health outcome and consider, "Have the evaluation judgments been consistently applied across the set of studies?" (EPA 2022). Rather, EPA's Study Quality Evaluation shows that the EPA inconsistently applied the risk of bias considerations. Within specific domains, some studies were downgraded for biases when other studies with similar characteristics were not (examples provided below).

As an example of EPA's inconsistent approach to the risk of bias in studies, the agency failed to equally evaluate temporality across all studies. In the IRIS assessment criteria for evaluating exposure measurement, a study should be given a rating of "critically deficient" for this domain if "There is evidence that reverse causality is very likely to account for the observed association" (EPA 2023d,e). Critically deficient studies should not be considered for a candidate study.

Based on this guidance, cross-sectional studies are of uncertain reliability because they measure exposure and outcome at the same time and cannot establish temporality between exposure and outcome. Reverse causation is a concern with these types of studies. EPA notes this concern and limitation for certain cross-sectional studies, such as Pilkerton et al. (2018), which examined serum PFOA/PFOS concentrations and vaccine response among NHANES participants. EPA stated that the analysis of adults in Pilkerton et al. (2018) "suffered from potential exposure misclassification due to concurrent exposure and outcome measurements and was also rated low confidence" (EPA 2023a, p. 3-104).

However, one of the candidate studies chosen was a cross-sectional study of Greenlandic children (Timmermann et al. 2022), which the agency gave an overall "medium" quality rating. This study is a cross-sectional study like Pilkerton et al. (2018). Therefore, it should have been considered critically deficient. The inconsistent application of confidence ratings based on the temporal limitations of cross-sectional analyses show that EPA did not consistently apply evidence judgements, as proscribed in the IRIS (EPA 2022) Handbook.

Biases in the assessment of exposure to PFAS were not consistently evaluated. EPA rated some studies as "Good" for this domain specifically because maternal samples were taken in early pregnancy and therefore had a low risk of bias. For example, the HAWC assessment details for Bjerregaard-Olesen (2019) state, "Exposure measurement error is expected to be minimal given the long half-life and high-quality exposure data that were collected (and analyzed); as such, the first trimester samples are anticipated to be appropriate to capture critical windows of interest." (EPA 2023f). Another study of PFAS and fetal growth outcomes analyzed PFAS measures taken

during each trimester and in cord blood during delivery, and was rated "Good" for Exposure Assessment because multiple samples across different trimesters was a strength. Further, EPA noted that primary analyses were performed with the earliest samples (trimesters 1-2), because these measures were reflective of critical in utero windows and minimal measurement error was anticipated (Chen 2021). Had the timing of the exposure measures been consistently evaluated, Grandjean et al. (2017) would not have been rated as Good", but rather "Deficient" in this domain, because maternal serum PFAS was measured in the third trimester and therefore has an increased risk of bias.

It is critical that EPA follow its own guidance and evaluate all studies consistently to determine the risk of bias and uncertainty within the body of evidence and choose appropriate candidate studies. EPA's failure to consistently apply critical appraisal ratings resulted in EPA choosing inappropriate or lesser confidence studies as candidate studies and therefore substantial uncertainties in toxicity value derivation.

EPA did not synthesize evidence in accordance with SAB recommendations or agency guidance because the agency omitted several studies from the body of evidence synthesis of vaccine response, and thus the endpoint was selected for POD derivation without consideration of the full body of evidence.

EPA did not follow the SAB's recommendation to consider the evidence from all medium confidence studies and provide reasoning for excluding any of those studies. The SAB recommended, "Consideration of all human studies is especially important because conclusions about the human health effects, which are generally observational rather than experimental, are based on the overall weight of evidence and should include all relevant data. [Emphasis added]" (EPA 2023c, p. 20). This recommendation was intended to help the agency make a sound scientific judgement on potential candidate studies after evidence integration. In response, EPA said it "revised the noncancer health effects synthesis and integration sections to provide a more detailed and consistent framework for study quality evaluation, evidence synthesis, and evidence integration for each health outcome following the IRIS Handbook." (EPAc, p. 20).

When synthesizing the evidence for vaccine response with PFOA exposure, EPA found, "largely consistent decreases in antibody response following vaccinations (against two different infectious agents: tetanus and diphtheria) in multiple medium confidence studies in children" (EPA 2023a, p. 3-133). Of the 6 medium confidence studies conducted in children, vaccines against 5 different infectious agents were investigated. It is unclear which studies EPA included in the evidence integration, but from the above statement, it was not all eligible studies.

Similarly for PFOS, the evidence integration concluded that there is a "largely consistent decrease in antibody response following vaccinations (against three different infectious agents) in multiple medium confidence studies in children." (EPA 2023b, p. 3-122). Of the 6 medium-confidence studies conducted in children (Grandjean et al. 2017a,b; Granum et al. 2013; Timmermann et al. 2020, 2022; Mogensen et al. 2015), vaccines against 5 different infectious agents were investigated. As with the PFOA evidence integration, it is unclear which studies

were included in the PFOS evidence integration, but again it appears it was not all eligible studies.

Thus, EPA did not synthesize all of the evidence, contrary to the SAB's recommendation and the SDWA's requirement that the agency consider the best available scientific information.

EPA also did not provide justification for its exclusion of some medium confidence studies on vaccine response when selecting a candidate study for POD derivation. This lack of explanation is contrary to the SAB's recommendation that the agency more clearly present the rationale and criteria for selection of endpoints and specific studies for POD development (EPA 2023c, p. 37). EPA responded that "multiple medium-confidence studies were considered for POD derivation: Budtz-Jørgensen and Grandjean (2018), Timmerman et al. (2021), Granum et al. (2013) and Looker et al. (2014)." (EPA 2023c, p. 37). However, the agency gave no explanation for why the remaining medium confidence studies in children that showed inconsistent evidence (e.g., Pilkerton et al. 2018; Timmermann et al. 2020; Mogensen et al. 2015) were not also considered. EPA cited Mogensen et al. (2015) in the list of Faroe Islands cohorts that had significant associations but ignored that significance was lost when other PFAS exposures were included in the models.

EPA's failure to follow SAB and IRIS Handbook guidance regarding consistent evidence integration resulted in inconsistent findings and biased choice of candidate studies. EPA did not provide sufficient discussion of the rationale for inclusion and exclusion of evidence from the final evidence integration and judgement for vaccine response as a critical endpoint.

EPA Response: The commenter stated there were significant uncertainties with the EPA's *Moderate* evidence stream judgement for immune effects in humans. The uncertainties cited by the commenter include inconsistent findings for vaccine response in adults, inconsistent or imprecise findings for infectious disease, mixed findings for hypersensitivity, and mixed findings for autoimmune disease. The commenter also claimed that the EPA did not consistently evaluate or synthesize evidence according to its guidance. The commenter stated that these factors combined suggest the EPA should not consider vaccine response as a critical endpoint. These comments are redundant with those provided by the commenter in another section; the EPA disagrees and provides an explanation as to why in the EPA response to comment Doc. #1774, SBC-053219 in section 4.2.1.4 in this *Response to Comments* document.

The commenter also asserted the EPA did not clearly state the strength of evidence for each immune endpoint, limiting the transparency of critical effect selection for POD derivation. however,, the EPA clearly states in the MCLG Appendix (A.1.10) that "strength-of-evidence judgments were made for each health outcome," which does not require a strength-of-evidence judgment for each individual immune endpoint (USEPA, 2023c; USEPA, 2023d). IRIS guidance states that multiple judgements for a health outcome category may be made, but this is a pre-determined decision, and considering the breadth of the endpoints examined in all included immune studies the EPA chose to make one evidence integration summary judgement for all immune health outcomes (USEPA, 2022a). Regardless of the decision to make separate or

combined evidence stream or summary integration judgements, assessment methodology from the ORD IRIS Handbook states that "the strongest evidence judgement will typically be used to reflect certainty in the broader health effect category," in the event of multiple evidence integration summary judgements for one health outcome category (USEPA, 2022a). In other words, this decision has no bearing on the overall conclusions for the immune or other health outcomes.

Further, the Evidence Profile Tables (EPTs) provided for each priority health outcome are completed in order of the strength of evidence and importance to the overall Health Outcome Category evidence summary judgment (i.e., Immunosuppression is discussed first, as the driving factor is antibody response). Coherence between immunosuppression, hypersensitivity, and autoimmune disease is not necessarily expected. There may be biological or mechanistic reasons for differences between immune endpoints and the commenter does not provide any evidence or citations to EPA guidance or best practices that coherence across every endpoint in necessary to conclude that the evidence indicates an association. Coherence between endpoints may also be restricted due to data limitations. For both PFOA and PFOS, the evidence base for autoimmune disease is comprised primarily of *low* confidence studies, which limits the EPA's ability to assess this endpoint.

Regarding consistencies between studies reporting on the same endpoint, the EPA disagrees with the claim that data from epidemiological studies were unable to demonstrate a clear relationship between exposure and the immune suppression. Differences in magnitude of effect or differences between categorical exposure groups may also depend on dose response curves that require further analysis, but do not negate the observed effect. Thus, complete consistency between studies using observational data is not realistic.

Second, the EPA provides descriptions on how data from all evidence streams, including mechanistic and toxicological studies, were considered in the evidence integration summary judgement located in Table A-41 (USEPA, 2023b; USEPA, 2023c). It is unclear how the commenter determined that toxicological studies were unsupportive of effects in humans and the commenter does not provide supporting evidence regarding this criticism. In Section 4.1.1.2 of the PFOA and PFOS assessments, the EPA stated: "Results reported in animal toxicological studies are consistent with the observed immunosuppression in epidemiological studies" (USEPA, 2024d; USEPA, 2024c; USEPA, 2023f; USEPA, 2023a). For both chemicals, there was coherent evidence of immunosuppression observed by several animal toxicological studies reporting results of functional assessments of immune responses (e.g., Natural Killer cell activity, immunoglobulin response, plaque-forming cell response).

Third, the EPA disagrees with the commenter's stated implication of the lack of mechanistic support. An explanation is provided in Appendix A Table A-41 (USEPA, 2023b; USEPA, 2023c) which states the determination of "evidence indicates (likely)" may be based on "moderate human evidence when strong mechanistic evidence is lacking." Further, according to the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022), mechanistic evidence "can provide support for the relevance of animal effects to humans and biological plausibility for

evidence integration judgments" or provide "information on potentially susceptible populations and lifestages or data that could inform the shape of the dose-response curve (i.e., if the available human data have substantial quantitative uncertainties)." For both PFOA and PFOS, there is coherent evidence of immunosuppression in both animal toxicological and human epidemiological studies, the epidemiological studies investigate a susceptible population (i.e., children), and there are not substantial quantitative uncertainties requiring strong mechanistic support. Therefore, limited insight into the know mechanisms of action does not impact the EPA's conclusions regarding the immunological effects of PFOA and PFOS.

Finally, regarding a consistent relationship with incidence of disease, the SAB panel noted "clinical manifestation of a disease is not a prerequisite for a chemical to be classified as an immunotoxic agent" (USEPA, 2023a, p. 4–5). Antibody response is a translatable outcome across species, and the SAB panel specifically stated "[d]ecreased antibody responses to vaccines is relevant to clinical health outcomes and likely to be predictive of risk of disease" (USEPA, 2022,a). The EPA has added additional justification regarding the adversity of the endpoint selected for POD derivation in Section 4.1.1.2 of the final toxicity assessments for PFOA and PFOS (USEPA, 2024d; USEPA, 2024c). Both the SAB PFAS Review Panel (USEPA, 2022) and the EPA agree that a reduction in the level of antibodies produced in response to a vaccine represents a failure of the immune system to respond to a challenge and, thus, should be considered an adverse immunological health outcome. The World Health Organization (WHO) has also concluded that "childhood vaccine failures represent a significant public health concern" (WHO, 2012).

The commenter additionally suggested the EPA did not follow its own guidance on study quality evaluation based on perceived discrepancies in applying risk of bias considerations within domains. The commenter provided an example of perceived inconsistent application of reverse causality in the exposure assessment domain by noting cross-sectional studies were not rated critically deficient when exposure and outcome were measured concurrently. The commenter provided another example of perceived inconsistent application of risk of bias considerations for exposure assessment, citing timing of exposure measurement in pregnancy for developmental and immune outcomes.

The EPA disagrees that it did not follow its own guidance on study quality evaluation. The study evaluation protocols used for the assessments of PFOA and PFOS were consistent with protocols provided in both the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022a) and the *Systematic Review Protocol for the PFAS IRIS Assessments* (USEPA, 2021a). Please also see the EPA response to section 4.1.1. Any perceived discrepancies in the EPA's application of risk of bias considerations is based on incomplete information and clarified in the following responses.

As discussed previously, the EPA disagrees that reverse causality is a concern in all cross-sectional studies. Reverse causality is dependent on biological considerations for the outcome of interest, as noted in the footnote of Table A-19 (USEPA, 2023b, USEPA, 2023c). In cross-sectional studies, outcomes that may impact the absorption, distribution, metabolism, or elimination of PFOA or PFOS in the body (i.e., the measured exposure) would elicit concern for

reverse causality. Examples of outcomes that impact the measured exposure levels of PFOA or PFOS have been described in the literature (Radke et al., 2019). Reverse causality is not directly relevant to immunotoxic effects, such as decreased antibody response observed in Pilkerton et al. (2018) and the commenter does not provide any evidence that reverse causality is a concern for immunotoxic effects. Furthermore, the evaluation for Pilkerton et al. (2018) was split by population, namely children and adults. The analysis of children was considered *medium* confidence, with justifications consistent with those described in the evaluation of Timmerman et al. (2021). The analysis of adults in Pilkerton et al. (2018) was considered *low* confidence due lack of information related to timing of vaccination or previous infection. Concurrent PFAS exposure measurements are representative of recent past exposure, however, for adults this may be less representative due to the large amount of time elapsed between vaccination (i.e., typically in childhood) and exposure measurement (i.e., ≥ 19 years of age). Additionally, there was no information on vaccination status, vaccination timing, prior infections, or variation in vaccination schedules, all of which may affect seropositivity in adults. Due to the considerable differences in potential for bias between adult and children in Pilkerton et al. (2018), separate ratings were justified and were not inconsistent with Timmerman et al. (2021).

The EPA also disagrees that considerations for exposure timing in pregnancy were inconsistently applied. The commenter appears to suggest that simply the presence of samples in a later trimester of pregnancy would automatically result in a "Deficient" rating for Exposure Assessment, which is incorrect. The PFAS-specific exposure assessment criteria (Table A-19) includes considerations for critical exposure windows based on the outcome: "exposure was assessed in a relevant time-window (i.e., temporality is established, and sufficient latency occurred prior to disease onset) for development of the outcome based on current biological understanding" (USEPA, 2023b; USEPA, 2023c). Study quality evaluations of studies investigating fetal growth restriction included judgements based on whether exposure measurement was representative of *"critical in utero windows,"* which is consistent with the study quality evaluation considerations outlined in the developmental synthesis (USEPA, 2023f, p. 3-193–194). Based on the estimated long half-lives of PFAS in humans (USEPA, 2023f, Sec. 3.3.1.4.5), exposure measurements taken during any trimester of pregnancy would be considered adequately representative. Bjerregaard-Olesen (2019) and Chen et al. (2021) had well described and documented exposure assessment methods, resulting in *Good* ratings for Exposure Assessment as a result. Likewise, Grandjean et al. (2017), had well described and documented exposure assessment methods and was also rated Good.

The commenter stated the EPA did not follow SAB's recommendation to consider all *medium* confidence studies in evidence integration. To demonstrate this, the commenter provided the example of the EPA's PFOA synthesis of tetanus and diphtheria vaccine response in children, suggesting the synthesis demonstrates that the EPA did not consider studies on vaccine response to other pathogens. A similar example for PFOS was provided. The EPA disagrees with these comments.

The studies identified by the commenter altogether address vaccine response to five different pathogens for PFOA (i.e., tetanus, diphtheria, rubella, influenza, and measles) and six for PFOS (i.e., tetanus, diphtheria, rubella, measles, and hepatitis A and B). However, for PFOA only three of those pathogens (i.e., tetanus, diphtheria, and rubella) were evaluated in more than one *medium* confidence study on children. Similarly, for PFOS, evidence for vaccine response to pathogens other than tetanus and diphtheria was only reported in two studies or less. In contrast to the commenter's claims, all available studies were synthesized in Section 3.4.2.1. Evidence integration for the immune health outcome also considered all studies addressing vaccine response in children, however, conclusions regarding the weight of evidence for this endpoint were based primarily on vaccine responses with multiple *medium* or *high* confidence studies, as these provided a stronger evidence base than responses with only one or two studies. Conclusions for vaccine responses to other pathogens besides diphtheria and tetanus (e.g., measles and Hib) were limited by the number of studies reporting an association and, in some cases, the confidence in the limited available studies.

The commenter also stated that the EPA did not provide adequate justification for the selection and exclusion of candidate studies reporting antibody responses for POD derivation. The EPA disagrees with this claim. The EPA outlined considerations for study selection (USEPA 2023f; USEPA, 2023a, Section A.1.11) which draws on guidance provided in the IRIS Handbook (USEPA, 2022a). The IRIS Handbook (USEPA, 2022a) outlines additional factors that can be considered during study selection beyond study confidence, including factors such as exposure timing and study design. The commenter provides examples of studies not considered by the EPA; these studies were considered but not selected for POD derivation for various reasons, including data availability for modeling (Pilkerton et al., 2018), lack of supporting evidence from additional studies on the specific response observed for that vaccine (e.g., measles for Timmerman et al., 2020), and overlapping populations with other studies (e.g., data from Mogensen et al., 2015 overlap with data from Grandjean et al., 2017). To increase transparency of these decisions, the EPA has provided additional discussion on candidate study selection to Section 4.1 of the final toxicity assessments for PFOA and PFOS (USEPA, 2024d; USEPA, 2024c). The IRIS Handbook also states that "consideration of the consistency in patterns of results does not require that all findings are statistically significant" (USEPA 2022a, p. 6–19).

<u>3M Company (Doc. #1774, SBC-053229)</u>

2. EPA did not appropriately employ methods described in the IRIS guidance for evaluation of study quality and risk of bias in evaluating vaccine response.

EPA's failure to follow its IRIS Handbook for evaluation of study quality and risk of bias led it to reach conclusions opposite those that would have been reached by an independent assessment of the evidence that did follow EPA's IRIS Guidance. According to IRIS guidance, additional chemical, outcome, or exposure-specific considerations for evaluating studies should be developed in order to identify issues that would be expected to result in critical biases and reduce the confidence rating of a study (USEPA ORD 2022, p. 4-2). Based on this guidance, the criteria

for assessing bias in several of the evaluation domains (exposure assessment, outcome ascertainment, confounding, and sensitivity) should have accounted for factors specific to the exposure and outcome of interest, as well as potential confounders that specifically affect these associations. Such considerations would allow for the evaluation of specific factors critical to the overall study reliability conclusions.

An independent assessment was performed by ToxStrategies for studies examining vaccine response and PFOA exposure using the same IRIS framework for systematic review and critical appraisal of studies used by the EPA in the draft toxicity assessment for PFOA (USEPA 2023a, p. 1-10). See Appendix A. The independent assessment followed the IRIS guidance to modify several of the evaluation domains specific to the topic in order to identify critical issues regarding study quality and risk of bias, including consideration of factors that are specific to either the exposure, outcome ascertainment, confounding factors that affect the association of interest, and sensitivity issues including external validity and study construct. In contrast, the only apparent modification EPA made to its tool was to the exposure assessment domain criteria. This and missed critical issues that could render studies unreliable for dose-response assessment.

After identification and critical appraisal of studies examining vaccine response and PFOA exposure in the independent assessment, all studies received an overall rating of "deficient" or "critically deficient." Each study had deficiencies in participant selection, timing of exposure and outcome measures, or confounding, which resulted in a body of evidence that was of low quality with a high risk of bias. Based on these findings, vaccine response was not considered a critical endpoint for PFOA exposure, and no studies qualified for POD development.

Significant additional flaws and limitations in EPA's assessment of immunotoxicology, including EPA's failure to consider the conclusions of other agencies regarding immune effects as a critical endpoint (and the Grandjean et al. (2012) study in particular), are described in further detail in Appendix A.

EPA Response: The commenter stated the EPA did not follow the EPA's IRIS guidance during study quality evaluation. The commenter stated chemical-, outcome-, and exposure-specific considerations should have been included in adapted study evaluation criteria. These comments are redundant with those provided by the same commenter in an appendix to their comment letter; the EPA disagrees and provided a rebuttal in the EPA response to comment Doc. #1774, SBC-053219, Doc. #1774, SBC-053430, and Doc. #1774, SBC-053229 in section 4.2.1.4 in this *Response to Comments* document.

The commenter stated they completed an independent assessment of vaccine response studies with modifications to evaluation domains such as exposure assessment, outcome ascertainment, and potential confounding, however, this independent assessment conducted by ToxStrategies does not appear to be included in the comment letter or attachments. The commenter stated they determined all studies received an overall confidence rating of *deficient* or *critically deficient*, and the commenter suggested this means no studies should have qualified for POD development. However, the specific modifications made by the commenter to the study quality evaluation

criteria and rationale for why the modifications were necessary were not provided in the main comment response or in Appendix A or B. It is not clear what modifications were made to each evaluation domain and whether those modifications were scientifically appropriate. Additionally, it is unclear if at least two independent reviewers performed study quality evaluation consistent with the IRIS Handbook (USEPA, 2022a). Additionally, no protocol for the study quality evaluation was provided. Without this explanation, documentation, and transparency, the EPA is unable to comment on the ToxStrategies conclusions for vaccine response studies. Therefore, the EPA maintains its position that vaccine response should be a critical effect considered for quantitative analyses, a position that was supported by the EPA's SAB PFAS Review Panel (USEPA, 2022b).

3M Company (Doc. #1774, SBC-053298)

7. Ignoring of the totality of NHANES immune and vaccine data

The Bulka, Avula, & Fry (2021) study used NHANES data to investigate the relationship between PFAS and possible immune effects investigated eight different pathogens (cytomegalovirus (CMV), Epstein Barr virus (EBV), hepatitis virus types C and E (HCV, HEV), human immunodeficiency virus (HIV), herpes simplex virus types 1 and 2 (HSV-1, HSV-2), Toxoplasma gondii (T. gondii), and Toxocara canis and Toxocara cati (Toxocara spp.)). No relationships between PFAS and these pathogens were found, until the authors constructed a composite measure to sum across all these pathogens. However, in 2020 these same authors, using NHANES data proposed lead exposures increased the risk of CMV infection and impair immune control of the virus in young adults. The usage of the same dataset to support radically different pathways for impairment represents p-hacking which is a form of data exploitation to discover patterns which would be presented as statistically significant, when in reality, there is no underlying effect.

EPA Response: The commenter suggests the statistical approach described in Bulka, Avula, & Fry (2021) was inappropriate and may result in misleading results. The connection of the commenter's concerns about this study to the toxicity assessments for PFOA and PFOS is unclear. The EPA's evidence stream judgement of immunosuppressive effects in humans is "based on largely consistent decreases in antibody response following vaccinations (against two different infectious agents: tetanus and diphtheria) in multiple medium confidence studies in children" (USEPA, 2023f, p. 3-133). The pathogens investigated in Bulka, Avula, & Fry (2021) are unrelated to tetanus and diphtheria vaccine responses in children, and vaccines for these pathogens do not exist or are not widely available. The EPA did not quantitatively consider results presented by Bulka, Avula, & Fry (2021) in these assessments. Qualitatively, the EPA reported the mostly null results the commenter describes above. As the results are not presented as statistically significant or used quantitatively, the EPA did not conduct "p-hacking" or "exploit" the data to "discover patterns… when in reality, there is no underlying effect."

U.S. Chamber of Commerce (Doc. #1713, SBC-053363)

There are also scientific concerns related to the choice of endpoints that are used for the candidate RfDs for PFOA and PFOS. The SAB review panel, which included only one panelist with expertise in immunology,[FN107: See SAB Determination Memo and List of Candidates where expertise of candidates is described. Only one chosen panelist, Dr. DeWitt, has expertise in immunotoxicology. Documents avahttps://sab.epa.gov/ords/sab/f?p=114:18:12110592892742:::RP,18:P18_ID:2601.] supported EPA's reliance on studies which evaluated anti- tetanus and anti-diphtheria antibody concentrations. But a recent publication that reviewed the weight of evidence for immunotoxicity of PFOA and PFOS concluded that, while there was moderate evidence from animal data for immunotoxic effects, species concordance and human relevance could not be established [FN108: Gregory J. Garvey, Janet K. Anderson, Philip E. Goodrum, Kirby H. Tyndall, L. Anthony Cox, Mahin Khatami, Jorge Morales-Montor, Rita S. Schoeny, Jennifer G. Seed, Rajeev K. Tyagi, Christopher R. Kirman & Sean M. Hays (2023): Weight of evidence evaluation for chemical-induced immunotoxicity for PFOA and PFOS: findings from an independent panel of experts, Critical Reviews in Toxicology, DOI: 10.1080/10408444.2023.2194913.]. This publication, which presented an analysis and review of the most recent immunotoxicology literature, included five panelists with immunotoxicology expertise [FN109: Id. at table 3.]. That expert panel also considered the clinical relevance of using vaccine antibody titer as a measure of immunotoxicity and noted limitations of relying on this as a critical endpoint. Steenland, et al., 2020, concluded that, despite a relatively large number of studies reporting that PFOA impairs immune function, the evidence that PFOA increases risk of human infectious disease is inconsistent [FN110: Steenland K, Fletcher T, Stein CR, Bartell SM, Darrow L, Lopez-Espinosa M-J, Ryan PB, Savitz DA. (2020) Review: Evolution of Evidence on PFOA and Health Following the Assessments of the C8 Science Panel, Environment International, Volume 145, 106125.]. In addition, public commenters, and the World Health Organization, relying on additional peer reviewed publications, have noted that the value used by EPA for benchmark dose modelling is clinically meaningless [FN111: See comments submitted by Nessa Horewitch Coppinger on behalf of the 3M Company, Dec. 30, 3021, avahttps://sab.epa.gov/ords/sab/f?p=100:19:16404771425364:::RP,19:P19_ID:963 and World Health Organization (WHO) PFOS and PFOA in Drinking-water, Version for public review Sept 2022, where WHO refers to the clinical relevance of these findings as "unclear", available at: https://www.cmbg3.com/library/WHO-Draft-Drinking-Water-Document.pdf.].

EPA Response: The commenter expressed concerns regarding the immune endpoint selected as a critical effect for candidate RfDs for PFOA and PFOS. Specifically, the commenter cited a recent review on the weight of evidence for the immunotoxicity of PFOA and PFOS (Garvey et al., 2023) and stated that the clinical relevance of the endpoint of antibody response to vaccination is unclear, citing a public comment from 3M to the SAB PFAS Review Panel and the WHO Public Review Draft *Background document for deriving Guidelines for Drinking-water Quality* (WHO, 2022). Regarding the clinical relevance of the immune endpoint, please see the

EPA Response to 4.2.2.1 below, as well as the EPA responses to comment Doc. #1774, SBC-053219 and Doc. #1774, SBC-053430 in section 4.2.1.4 in this *Response to Comments* document that contained similar statements as its comments sent to the SAB. The EPA additionally notes that the WHO has since removed the cited public review draft document from the related web pages (e.g., https://www.who.int/teams/environment-climate-change-and-health/water-sanitation-and-health/chemical-hazards-in-drinking-water/per-and-polyfluoroalkyl-substances) and it is no longer publicly available. However, other global, federal, and state health agencies agree with the EPA's stance regarding the clinical relevance of the antibody response endpoint (e.g., EFSA, 2020; NTP, 2016). Notably, the draft WHO background document conclusions (WHO, 2022) conflicted with the WHO's *Guidance for Immunotoxicity Risk Assessment for Chemicals* (WHO, 2012), which stated "although data from functional immune assays (e.g. the antibody response to vaccine) are generally not available in humans, such data represent the strongest evidence of an immunosuppression." As described in Section 4.1.1.2 of both the PFOA and PFOS toxicity assessments, "results reported in animal toxicological studies are consistent with the observed immunosuppression in epidemiological studies," and support the biological relevance of this endpoint.

Regarding commenter's statement about the SAB's expertise, the EPA disagrees with commenter's implied assertion that the SAB panel was missing either depth or breadth sufficient to provide a robust peer review because the commenter identified one reviewer where immunotoxicology is listed as their highlighted subspeciality. The PFAS review panel contained a wide variety of experts, including panelists with expertise in toxicology, epidemiology, biostatistics, medicine, and economics, among other things. Additionally, the SAB itself is composed of numerous experts, including those with expertise in microbiology and drinking water, epidemiology, toxicology, economics, and medicine, among other relevant fields. In short, despite commenter's attempt to allege otherwise, the SAB is among the premier scientific review boards in the United States, populated with ample diverse expertise to provide high quality, informed, and relevant review and recommendations on the four documents the EPA sought review.

American Chemistry Council (ACC) (Doc. #1841, SBC-052925)

The Available Epidemiology Data Do Not Support an Association Between PFOA and PFOS and Antibody Response

EPA uses data from reports of decreased vaccine response among children in remote communities that may not be generalizable to other populations. The interpretation of results of the first of these studies by Timmermann et al. [FN42: Timmermann CAG et al. Concentrations of tetanus and diphtheria antibodies in vaccinated Greenlandic children aged 7–12 years exposed to marine pollutants, a cross sectional study. Environ Res 203:111712 (2022).] is confounded by exposure to other pollutants, including polychlorinated biphenyls (PCBs), and report a weak association with blood levels of PFOA and PFOS among children in Greenland. As a result, it is not an appropriate basis for developing a reference dose (RfD).

The second study by Budtz-Jorgensen and Grandjean [FN43: Budtz-Jorgensen E and Grandjean P. Application of benchmark analysis for mixed contaminant exposures: mutual adjustment of perfluoroalkyl substances associated with immunotoxicity. PLoS ONE 13:e0205388 (2018).] reports two findings from the study of diphtheria and tetanus antibody concentrations associations among a unique, remote cohort of children of the Faroe Islands –

• An association between prenatal exposure to PFOA/PFOS and antibody concentrations at 5 years of age, and

• An association between PFOA/PFOS serum concentrations at age 5 and antibody concentrations at age 7. [FN44: The draft approaches select the benchmark dose modeling results for the serum levels at age 5 and antibody levels at age 7 from the cohort of children born between 1997-2000 to calculate the reference doses.]

In an earlier publication by Grandjean et al. (2012), [FN45: Grandjean P et al. Serum vaccine antibody concentrations in children exposed to perfluorinated compounds. J Amer Med Assn 307(4):391-397 (2012).] however, this research group did not observe an association between maternal PFOA/PFOS serum concentrations and antibody concentrations at age 5 in a cohort of children born between 1997 and 2000. Although the researchers reported an association in a cohort of Faroe Islands children born from 2007 and 2009, serum concentrations were lower than in the earlier cohort (see Table 3).

Table 3. Comparison of Serum Concentrations at Birth and 60 months in the Studies of Faroe Islands Children

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	Median Concentration (Interquartile Range)			
	1997-2000 Cohort[a]		2007-2009 Cohort[b]	
	At birth	At 60 months	At birth	At 60 months
PFOS (ng/ml)	27.3 (23.2,33.1)	16.7 (13.5,21.1)	n/a	4.7 (3.5,6.3)
PFOA	3.20 (2.6,4.0)	4.1 (3.3,4.9)	n/a	2.2 (1.8,2.8)

[a] Table 2, Grandjean *et al.* 2012; [b] Table 1, Grandjean *et al.* 2017a[46]

[Table 3: See Docket ID EPA-HQ-OW-2022-0114-1841] [FN46: Grandjean P et al. Estimated exposures to perfluorinated compounds in infancy predict antibody concentrations at age 5 years. J Immuno 14(1):188-195 (2017a). Maternal serum concentrations are not provided.]

Among 7-year olds, the Faroe Islands researchers did not find an association between serum concentrations and antibody levels at 7 after excluding children suspected of receiving additional

antibodies (i.e., no booster, ER visit, or unexplained antibody increase). [FN47: Grandjean P et al. Serum vaccine antibody concentrations in adolescents exposed to perfluorinated compounds. Environ Health Perspect 125:077018 (2017b).] Although the 2012 publication reports an association between serum levels of PFOA at age 5 and tetanus antibody concentrations at age 7, [FN48: No association is observed between PFOS serum concentrations at age 5 and diphtheria antibody concentrations at age 7, after adjusting for the antibody concentration at age 5.] the analysis does not control for children receiving additional antibodies between ages 5 and 7. Given the results of the prior analysis, this would appear to be a significant oversight that raises additional questions about the broad conclusion that exposure to PFOA or PFOS reduces vaccine response in children.

A recent independent, international expert panel was engaged using a double-blind process to review the available evidence relating to PFOA and/or PFOS exposure and immunotoxicity (Garvey et al. 2023). [FN49: Garvey GJ et al. Weight of evidence evaluation for chemical-induced immunotoxicity for PFOA and PFOS: findings from an independent panel of experts. Crit Rev Toxicol 53(1):34-51 (2023).] The panel concluded that while there may be some evidence that PFOA and PFOS are immunotoxic based primarily on laboratory animal studies, species concordance and human relevance cannot be established. Moreover, they also concluded that the human data, and specifically the use of reduced vaccine antibody titers as a critical effect, are inappropriate for use in deriving toxicity values and regulatory standards. This conclusion is consistent with other agency evaluations. [FN50: COT 2022; Agency for Toxic Substances and Disease Registry (ATDSR). Toxicological Profile for Perfluoroalkyls. US Department of Health and Human Services (May 2021). (ATSDR PFAS Tox Profile)]

The Evidence for Increased Infection Rates Among Children is Not Consistent

In its analysis, EPA suggests that a decrease in antibody concentrations may reduce the prevention of diphtheria and tetanus in children. Results of associations between PFOA and PFOS exposure and childhood infection are mixed, however, with studies reporting both increased and decreased associations with reported infections. [FN51: Steenland K et al. Review: Evolution of evidence on PFOA and health following the assessments of the C8 Science Panel. Environ Int 145: 106125 (2020).] As a result, NTP concluded that there is low confidence that exposure to either substance is associated with an increased incidence of infectious disease or a lower ability to resist or respond to infectious disease. [FN52: NTP. Immunotoxicity Associated with Exposure to Perfluorooctanoic acid or Perfluorooctane Sulfonate. NTP Monograph. US Department of Health and Human Services. (September 2016)]

The epidemiological evidence for an association between PFOA and PFOS exposure and hypersensitivity and autoimmune disease is also mixed. Studies that observed significant associations with “ever” or “current” asthma are seen primarily in sex- or age-specific subgroups but are null or insignificant in whole study analyses. For allergy and eczema outcomes, results were inconsistent across studies. Studies of PFOS exposure and autoimmune condition in humans are limited, and the results from studies of PFOA exposure and human autoimmune disease are mixed. While Steenland et al. report an association with ulcerative colitis, [FN53:

Steenland K et al. Ulcerative colitis and perfluorooctanoic acid (PFOA) in a highly exposed population of community residents and workers in the mid-Ohio valley. Environ Health Perspect 121: 900-905 (2013).] the analysis does not adequately control for confounding factors such as gastrointestinal infection and family history. [FN54: http://www.c8sciencepanel.org/study.html.]

EPA Response: The commenter raised concerns with the studies the EPA reviewed and considered in the determination of decreased antibody response in children as a critical effect. Please see the EPA Response to 4.2.2.1 below. Additionally, the commenter stated that Timmerman et al. (2021) was not appropriate for developing an RfD due to potential confounding by other pollutants. The EPA disagrees with this statement. While it is true there are other co-occurring exposures to organic pollutants in this population, as is the case for all studies in humans, the study authors still concluded that they "found decreased diphtheria concentrations after vaccination with increasing PFAS exposure, and higher serum concentrations of PFAS were associated with increased odds of not being protected against diphtheria after vaccination" (Timmerman, 2021). The EPA noted in Appendix E of the toxicity assessments for PFOA and PFOS that Timmerman et al., (2021) was chosen for comparison purposes as it represented another population—children from Greenland—compared to studies conducted in the Faroe Islands (USEPA, 2023b; USEPA, 2023c).

The commenter also raised concerns about the use of Budtz-Jorgensen (2018) for developing an RfD, citing the study setting, lack of significant findings in prior publications (i.e., Grandjean, 2012). Regarding the consistency of the antibody response epidemiological evidence base and epidemiological evidence reporting associations between PFOA or PFOS and other immune effects, please see the EPA response to comment Doc. #1774, SBC-053219 and Doc. #1774, SBC-053430 in section 4.2.1.4 of this *Response to Comments* document, and section 4.2.2.3.1 of the EPA response in this *Response to Comments* document. The commenter did not provide new rationale that the EPA had not already considered when selecting the health outcome-specific RfD for immune effects (see sections 3 and 4 of the toxicity assessments; USEPA, 2024d; USEPA, 2024c).

Regarding reasons why the EPA's conclusions may differ from those of other health agencies, please see the EPA Response to 4.2.6.

Mike Pettit (Doc. #1542, SBC-052839)

Immune effects: pg 268 reads "Some evidence suggests a relationship between PFOA exposure and immunosuppression; epidemiology studies showed suppression of at least one measure of the antibody response for tetanus and diphtheria among people with higher prenatal, childhood, and adult serum concentrations of PFOA. It is less clear whether PFOA exposure impacts antibody response to vaccinations other than tetanus and diphtheria. Epidemiology evidence suggests that children with preexisting immunological conditions are particularly susceptible to immunosuppression associated with PFOA exposure. Available studies supported an association between PFOS exposure and immunosuppression in children, where increased PFOS serum

levels were associated with decreased antibody production. However, the association between PFOS exposure and immunosuppression was not apparent in adults. Other potential associations with PFOS exposure with a high degree of uncertainty included asthma and infectious diseases (e.g., the common cold, lower respiratory tract infections, pneumonia, bronchitis, ear infections). Animal toxicology study evidence suggested that PFOA or PFOS exposure results in effects similarly indicating immune suppression, such as reduced response of immune cells."

Here there is a problematic factor- the immune system is a very complex machine that is not yet even close to being fully understood. As such it makes it difficult to accurately pinpoint if PFAS is ever truly interacting with the immune system or not, or if there is another confounding factor being measured. The high level of uncertainty indicated in the actual papers also points out that these studies do not take these potentially confounding factors into account. The levels of suppression are not spelled out in any way and what does higher serum levels entail? What are the levels? Are there preexisting conditions that need to be addressed. The sentence that children with immunecompromised systems are sensitive to PFOA is ridiculous. Obviously those with weak and compromised immune systems will be detected as weak and compromised when studied. Again, the liberal usage of the term 'suggestive' is folly. These values can be quantified with proper procedures and studies.

EPA Response: For concerns regarding uncertainty in the antibody response evidence base and consideration of confounding factors, please see the EPA response to comment Doc. #1774, SBC-053219 and Doc. #1774, SBC-053430 in section 4.2.1.4 in this *Response to Comments* document and section 4.2.2.3.1 of the EPA response in this *Response to Comments* document.

The commenter suggested it is too difficult to determine the effect of PFOA or PFOS on the immune system as it is too complex and "is not yet even close to being fully understood." The EPA disagrees the immune system is too complex to determine an effect. While there are still areas of research in immunology, it is a well-established field with a wealth of literature that has been applied in both medical and public health contexts, including the use of developmental immunotoxicology data for risk assessment (Dietert, 2008). The EPA identified and synthesized evidence from controlled animal toxicology studies and mechanistic studies which provided support for determining reduced antibody response in children as a critical effect (USEPA, 2023f, USEPA, 2023a, Sec. 3.4.2.2 and Sec. 3.4.2.3). This includes mechanistic evidence (NTP, 2016) demonstrating T-cell-dependent and T-cell-independent responses being reduced in mice treated with PFOA, suggesting a possible explanation for decreased antibody response in humans (USEPA, 2023f). Recent evidence from mechanistic studies also provide evidence for "PFOS-mediated suppression of adaptive immune responses includ[ing] PFOS-mediated effects on TH1/TH2-type cytokines and IgE titers in response to allergens in mice and humans (Zhong, 2016, 3748828; Zhu, 2016, 3360105), glycosylation of immunoglobulins in humans (Liu, 2020, 6833599), and lymphocyte toxicity *in vitro* (Zarei, 2018, 5079848)" (USEPA, 2023a, Sec. 3.4.2.3.2.7).

The commenter claimed the "levels of suppression" and what this means are not communicated. The EPA disagrees with this statement and directs the commenter to section 4.2.2.1 of the EPA response in this *Response to Comments* document for additional information on RfD derivation, as well as Appendix E (USEPA, 2023b; USEPA, 2023c, Sec. E.1.1.1) and Section 4 of the toxicity assessments (USEPA, 2023f; USEPA, 2023a) for discussion on setting a benchmark response (BMR) in accordance with biological and statistical guidance provided in the EPA's *Benchmark Dose Technical Guidance* (USEPA, 2012).

The commenter raised concerns about considerations for immunosuppressed or other pre-existing conditions. As mandated by SDWA, the EPA must consider sensitive subpopulations in its regulatory decisions. For instance, when making regulatory determinations, the Administrator is directed to prioritize contaminants that may impact sensitive subpopulations (see 1412(b)(1)(C)). Additionally, when conducting its health risk and cost analysis, the EPA shall consider "The effects of the contaminant on the general population and on groups within the general population such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations that are identified as likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population" (See SDWA 1412(b)(3)(C)(V)). As required under the SDWA, the EPA considered effects on potentially sensitive populations and subsequently recognized immunocompromised children as a population of concern. While it may be obvious to the commenter that immunocompromised individuals may be particularly sensitive to the immune effects associated with PFOA and PFOS exposure, the EPA attempts to ensure that the majority of the U.S. population can understand the various analyses and considerations that underly this rulemaking.

4.2.1.5 Consideration of Increased Serum ALT as a Critical Effect

3M Company (Doc. #1774, SBC-053217)

iv. EPA's assessment of liver effects is was not performed consistent with best practices.

EPA's assessment of liver effects of exposure to PFOA and PFOS is inconsistent with its own scientists' and the SAB's conclusions and again reflects EPA's failure to engage in a proper systematic review and evidence assessment process. As part of the hazard characterization and dose-response step, the IRIS Handbook states that EPA should consider the dose-response pattern in the relevant dose range and relevance of specific health outcomes in humans. In contrast to this recommendation, EPA cites animal studies showing liver effects which involve mechanisms of action with questionable relevance to humans, such as pathways moderated by peroxisome proliferator-activated receptor-alpha ("PPARα"). EPA also did not consider EFSA (2020), which noted there is evidence for elevated ALT due to PFOA exposure, but the adversity of this effect is uncertain because of the low magnitude of increases and no associations with liver disease. EPA even acknowledges that studies "have questioned the biological significance of relatively small increases in serum ALT (i.e., less than 2-fold) reported in animal toxicological studies (Hall. et al. 2012)." For PFOA and PFOS, EPA fails to characterize the biological relevance of changes in ALT or other liver biomarkers in the context of quantitative clinical outcomes. SAB similarly

noted that "the limited available information does not demonstrate an increase in liver disease" (USEPA SAB 2022).

As an example of its failures in conducting systematic review and assessing study quality, EPA inappropriately based its candidate PFOS RfD for elevated ALT on a study by Nian et al., (2019). This was a cross-sectional study from China that reported a 4.1 percent change (95% CI: 0.6, 7.7) in ALT for every 1 ng-mL increase in PFOS. Excluding individuals who were taking medications, this percent change was reduced to 3.8 which was not statistically significant (95% CI: -0.2, 7.8). Confounding variables were also not adequately controlled as most were described as binary (yes/no) which included alcohol, smoking and diet, which limits quantitative assessment. In addition, confounding from other PFAS were not adjusted for in the analysis of PFOS and PFOA. In EPA's section on Study Evaluation for Epidemiology Studies of PFOS and Hepatic Effects (page 3-25), EPA states that the Nian et al., (2019) approach to study participant selection and recruitment was not described in the paper. However, EPA still rates participant selection as "adequate." Given this information was not provided, EPA should have rated participant selection as "inadequate" based on its own criteria.

EPA Response: Regarding the commenters' statement about mechanisms of action in animal studies of liver effects, the non-cancer hepatic mechanistic evidence for PFOA is discussed in Sections 3.4.1.3 and 3.4.1.4 of the toxicity assessment (USEPA, 2024d; USEPA, 2024c; USEPA, 2023f; USEPA, 2023a) and focuses on several mechanisms such as nuclear receptor activation, lipid metabolism, transport, and storage, hormone function and response, xenobiotic metabolism, cell viability, growth, and fate, inflammation and immune response, and oxidative stress and antioxidant activity. While some of these mechanisms do involve PPARα, many of them do not involve peroxisome proliferator-activated receptors. The evidence also suggests a role for PPARα-independent pathways in the MOA for noncancer liver effects of PFOA. PFOA has been shown to activate a number of other nuclear receptors, including PPARγ, CAR/PXR, ERα, and HNF4α, which play an important role in liver homeostasis and have been implicated in liver dysfunction. In addition to the abundance of evidence related to hepatic nuclear receptors, PFOA also alters apoptosis and cell proliferation in the liver, indicating a cytotoxic mechanism of action. Further, the relevance of PPARα and species-specific differences in PPARα have already been addressed by the EPA in Section 3.4.1.4 of the draft toxicity assessments, which was available at the time of rule proposal (USEPA, 2023f; USEPA, 2023a. The molecular or cellular initiating events that do not involve PPARα and have been observed in vivo and in vitro are described in the mechanistic section of the Evidence Profile Table in 3.4.1.4 (i.e., increased apoptosis through a cascade of mechanisms, inflammation of the liver, induction of oxidative stress, and indirect evidence of alternative pathways following observations in knockout or humanized PPARα mice).

For hepatic cancer effects, in the absence of a clear MOA for PFOS carcinogenicity, the EPA considered all possible MOAs when evaluating the hepatic tumor evidence in rodents. The EPA considered the evidence for several potential underlying mechanisms and modes of action in addition to PPARα activation, such as pathways involving other nuclear receptors (e.g., CAR)

and cytotoxicity. The EPA mapped the available mechanistic evidence collected in rodent studies for all plausible MOAs in Section 3.5.4.2 Mode of Action for Hepatic Tumors. Evidence was identified for at least one key event in multiple MOAs (e.g., altered gene expression relevant to CAR activation, cytotoxicity, altered serum enzymes), while evidence was not identified for *all* key events in any MOA, including PPARα activation (USEPA, 2023f; USEPA, 2023a; USEPA, 2024d; USEPA, 2024c).

Second, to increase transparency, the EPA has added additional detail regarding the relevance of ALT to liver function and clinical disease in Section 4.1.1.1 of the PFOA and PFOS toxicity assessments (USEPA, 2024d; USEPA, 2024c). Further, the SAB PFAS Panel specifically supported the use of increased ALT as a critical endpoint (USEPA, 2022b). Regarding EFSA (2020), the authors' statement about the magnitude of association observed for ALT addresses only epidemiology studies examining the PFOS-ALT association. The authors did not draw conclusions about the clinical impact of small magnitude changes in ALT and incidence of liver disease. Studies examining the association between PFOS and liver disease were limited and primarily of *low* confidence (USEPA, 2023a, Sec. 3.4.1.4). Please also see section 4.2.6 of the EPA response in this *Response to Comments* document for additional discussion related to other agency assessments.

Regarding the relevance of small increases in serum ALT reported in animal toxicology studies, results can be supported by evidence of histopathological liver damage. This was the case for both PFOA and PFOS, for which animal toxicological studies reported increased incidence of liver cell death and necrosis (Section 3.4.1.2, USEPA, 2023f; USEPA, 2023a; USEPA, 2024d; USEPA, 2024b), confirming the potential relevance of relatively small changes in serum enzymes such as ALT. Regarding the quoted statement from USEPA SAB (2022b), the lack of *high* confidence studies examining PFOA and PFOS and liver disease outcomes does not equate to a known lack of association. The EPA further notes that in the same document, USEPA (2022b) acknowledged the public health importance of ALT increases associated with PFOA and PFOS exposure and recommended that the EPA include ALT as an endpoint for RfD derivation (p. 28, "The Panel recommends the use of ALT as endpoint in light of the numerous studies in the literature support an association between slight elevations in ALT and increased risk of morbidity and/or mortality"). Additional discussion related to the EPA's consideration of SAB recommendations is available in section 4.1.3 of the EPA response in this *Response to Comments* document. Please see section 4.1.2 of the EPA response in this *Response to Comments* document for discussion related to the use of agency guidance in the PFOA and PFOS toxicity assessments.

Third, the EPA disagrees that the use of Nian et al. (2019) for the PFOS RfD was inappropriate. The EPA provided information on the process for selecting studies for RfD development in Appendix A, Section A.1.11.1. These criteria are related to but distinct from the study quality evaluation process in which studies are evaluated for potential risk of bias due to the factors detailed by the commenter. In particular, studies that have been rated *high* or *medium* confidence during study quality evaluation such as Nian et al. (2019) are preferred, but other criteria such as suitability for modeling and data available are also considered when selecting a study for POD

derivation. Considering all of these criteria, Nian et al. (2019) was among the studies best suited for RfD development. In response to these public comments, the EPA has added additional rationale for POD study selection in section 4.1.1 of the final toxicity assessments (USEPA, 2024d; USEPA, 2024c).

Finally, the EPA disagrees that Nian et al. (2019) should not have been rated as "adequate" under the participant selection domain in study quality evaluation. As described in Appendix A, Section A. 1.7.1.1, a study merits a participant selection rating of "adequate" when there is enough information regarding the selection process that the reviewers judge there is no serious risk of bias. While some aspects of the recruitment process for government employees included in the study population were not described, study quality evaluators judged that selection bias was "unlikely based on available information," consistent with the criteria for an "adequate" rating.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-053369)

Similar concerns, regarding the adversity of the chosen critical effect, arise with EPA's choice of ALT as an RfD endpoint for PFOA and PFOS. In the Draft Public Comment Assessment, in discussing the association between PFOS and ALT, EPA states:

However, the associations were not large in magnitude, and it is unclear whether the observed changes are clinically adverse. Evidence for other liver enzymes and in children and adolescents is less consistent. Results for functional measures of liver toxicity, specifically histology results, are mixed. There is some indication of higher risk of liver disease with higher exposure, coherent with the liver enzyme findings, but there is inconsistency for lobular inflammation among the two available studies, which decreases certainty [FN119: See Public Comment Draft Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) in in Drinking Water (Public Comment Draft Assessments), at page 3-6e at: https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0034.].

EPA further states, "It is not possible to rule out potential confounding across PFAS with this evidence, but there is also no evidence that confounding can explain the observed associations." EPA's key supporting document for the proposed rule does not provide strong support for this chosen critical endpoint.

EPA Response: The commenter stated that the choice of ALT as a critical endpoint is not strongly justified. To support this point, the commenter raised concerns over whether observed changes in ALT are clinically significant, as well as over potential confounding by co-occurring PFAS. The EPA disagrees with these comments. Please refer to the EPA Response to 4.2.2.1 and the EPA Response to SBC-053217.

Additionally, the EPA disagrees that changes in ALT associated with PFOS or PFOA are not clinically relevant. As previous research on lead exposure has found, although small changes in an outcome (e.g., ALT) at the individual level may or may not reach a level considered clinically significant, such small changes can result in substantial health impacts at the

population level (Gilbert and Weiss, 2006). As described in Section 4.1.1.1 of the PFOA and PFOS Assessments, evidence from both epidemiologic and toxicologic studies indicates that elevated serum ALT is associated with clinical liver disease. The EPA also notes that potential confounding by other PFAS co-exposures was considered during study quality evaluation and as part of the overall evidence stream judgement (USEPA, 2023, Sec. 3.4.4.1.2 and Sec. 3.4.4.4). The EPA maintains there is no consensus on best practices to account for potential confounding by multiple, concurrent PFAS exposures. For further discussion of this issue, please see the EPA response to similar comments in Doc. #1774, SBC-053211 and Doc. #1774, SBC-053428 in section 4.2.1.2 in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-052927)

The Human Evidence for an Association Between Liver Disease and PFOA and PFOS is Lacking

EPA's estimate of potential risks of liver effects related to PFOA and PFOS exposure is based on findings of increased liver enzymes (primarily alanine aminotransferase, or ALT) in epidemiology studies. Although elevation of liver serum biomarkers in humans may be an indication of liver injury, it is not as specific as histological findings or functional tests for liver disease. The reported increase was small, however, and not considered indicative of hepatocellular injury. In analyzing liver enzymes in nearly 50,000 community residents and workers in the C8 Science Panel survey, the Panel noted the while the increase in enzyme levels may suggest small shifts in liver function, they are mainly within the normal physiologic range. [FN59: C8 Study Panel. Probable Link Evaluation for Liver 2012). http://www.c8sciencepanel.org/pdfs/Probable_Link_C8_Liver_29Oct2012.pdf] Based on its analysis, the Panel concluded that "there was no evidence of a positive association between liver disease and estimated PFOA exposure." While the epidemiological data are not as robust for PFOS, the information available on functional measures of liver injury is conflicting.

Although EPA initially determined that the data were not sufficient to support development of an RfD for liver health effects, [FN60: USEPA Draft PFOS MCLG Approaches 2021, at 308.] its decision to develop an RfD based on the liver enzyme data appears based on the review by EPA's Science Advisory Board (SAB). [FN61: USEPA SAB. Review of EPA' Analyses to Support EPA's National Primary Water Rulemaking for PFAS. EPA-SAB- 22-008 (2022). (USEPA SAB Review)] However, the SAB recommendation to consider changes in ALT is based on consistency with EPA's approach to other health endpoints. The Board explains its recommendation as follows -

The Panel noted that, although the magnitude of PfOA and/or PFOS's effect on ALT may not be large, the same may also be true for the magnitude of the PFOA and/or PFOS's effects on other human health endpoints such as, increased cholesterol and decreased birth weight. As such, if a [point of departure] is not developed for the ALT endpoint, an explanation should be provided as to why the magnitude of the effect was not sufficient for ALT but was sufficient for other effects of similar magnitude. [FN62: Ibid, at 24.]

In fact, the Board appears to be commenting on the weakness of data supporting several of the endpoints selected by EPA, rather than concluding that the liver data are sufficiently strong. Although the SAB points to EPA guidance on RfD development, the available data for PFOA and PFOS do not support a conclusion that the modest increase in ALT is a precursor to an adverse effect. The Board also provides a number of references on ALT, but as EPA correctly notes, none are specific to PFOA and PFOS. [FN63: USEPA. EPA Response to Final Science Advisory Board Recommendations (August 2022) on Four Draft Support Documents for the EPA's Proposed PFAS National Primary Drinking Water Regulation. Office of Water (2023). (USEPA Response to SAB)] In responding to the SAB, EPA provides no new evidence of liver disease. Rather the Agency explains how it conducted BMD modeling for the ALT endpoint. [FN64: EPA BMD analysis includes a BMR of 5 percent, despite the lack of evidence of liver disease and the recommendation of the BMD guideline to use 10 percent.]

As with the immune and CVD endpoints, EPA's analysis of effects focuses on a that is has not been linked to . In addressing this type of situation in updating its 2022 guidance for developing assessments under the Integrated Risk Information System, EPA notes that "[i]f the evidence base primarily includes outcomes or endpoints that are indirect measures (e.g., biomarkers) of the unit of analysis, certainty (for that unit of analysis) is typically decreased" particularly for "findings that have an unclear linkage to an apical or clinical (adverse) outcome." [FN65: USEPA. ORD Staff Handbook for Developing IRIS Assessment. EPA/600/R-22/268. Office of Research and Development, Washington, DC (2022). (USEPA IRIS Handbook)] EPA has chosen to rely on indirect measures in developing RfDs for immune, CVD, and liver effects of PFOA and PFOS – ignoring the weight of evidence available from human and animals studies in direct conflict with the SDWA requirement to use "best available, per-reviewed science." [FN66: 42 U.S.C. Section 300g-1(b)(3)(A).]

EPA Response: The commenter states that the information available on functional measures of liver injury is conflicting for PFOA and PFOS. The EPA disagrees with the statement and points to the EPA response to comment Doc. #1774, SBC-053217 in section 4.2.1.5 in this *Response to Comments* document and Section 3.4.3.4 of the toxicity assessments for PFOA and PFOS (USEPA, 2024d; USEPA, 2024c). These sections also describe how the EPA included evidence from human and animals in the evidence integration judgments, in contrast to the commenter's claims. The commenter is additionally misinterpreting the selected quote by the SAB PFAS Review Panel and ignoring the SAB's strong statement that, the "EPA should use Alanine Aminotransferase (ALT) as an endpoint in light of the numerous studies in the literature that support an association between slight elevations in ALT and increased risk of morbidity and/or mortality" (USEPA, 2022b). The EPA provides adequate rationale for consideration of the endpoint of increased ALT for dose-response analysis in Sections 3.4 and 4.1 of the toxicity assessments.

The commenter also states that has chosen to rely on indirect measures in developing RfDs for immune, CVD, and liver effects of PFOA and PFOS. The EPA disagrees with the implication

that the critical effects identified by the EPA are not biologically relevant. Please see section 4.2.2 of the EPA response in this *Response to Comments* document.

Mike Pettit (Doc. #1542, SBC-052838)

Liver effects: pg 268 reads "Epidemiology data provides consistent evidence of a positive association between PFOS/PFOA exposure and ALT levels in adults. Studies of adults showed consistent evidence of a positive association between PFOA exposure and elevated ALT levels at both high exposure levels and exposure levels typical of the general population. There is also consistent epidemiology evidence of associations between PFOS and elevated ALT levels, although the associations observed were not large in magnitude. Study results showed inconsistent evidence on whether the observed changes led to changes in specific liver disease. Toxicology studies on the impact of PFOS exposure on ALT in rodents also reported increases in ALT and other liver enzyme levels in rodents, though these increases were modest."

The mechanism by which PFOS may affect the liver is not clearly understood. Some studies have suggested that PFOS may cause liver effects by disrupting lipid metabolism, while others have suggested that PFOS may directly damage liver cells. It is also important to note there is a potential for bias in some of the studies linking PFOS to liver effects. For example, some studies may have included individuals with preexisting liver disease, which could bias the results. Additionally, some studies may have used non-standardized methods for assessing liver damage, which could lead to inaccurate or inconsistent results

EPA Response: The commenter stated that the mechanisms of action by which PFOS induces hepatic effects are unclear. The EPA agrees that there are several potential mechanisms by which PFOS may induce hepatic effects and there is not enough evidence to definitively conclude that one MOA is responsible for the reported hepatotoxicity. The mechanistic evidence supporting hepatic effects in humans and animals is available in Section 3.4.1.3 of the PFOS toxicity assessment (USEPA, 2024c; USEPA, 2023a). The EPA additionally notes that mechanistic evidence is generally used to support the relevance of animal effects to humans and provide biological plausibility for evidence integration judgments but known mechanisms of action are not required for hazard identification or characterization (USEPA, 2022a).

As described in Section 3.4.1.4 of the PFOS toxicity assessment, the coherent evidence across controlled laboratory studies in animals and the epidemiological studies in humans supports the EPA's conclusions that PFOS exposure is likely to cause hepatotoxicity in humans (USEPA, 2024c; USEPA, 2023a). The consistent evidence across studies in different species and populations with varying exposure histories reduces the potential uncertainties that may be raised due to individual study limitations *(e.g., non-standard methods).*

4.2.1.6 Consideration of Additional Endpoints

Silent Spring Institute (Doc. #1784, SBC-045800)

In its summary of noncancer health effects for PFOA and PFOS, EPA determined that oral exposure to PFOA and PFOS is associated with hepatic, immune, cardiovascular, and developmental effects. Beyond those endpoints, EPA's discussion of developmental effects misses impairments to mammary gland development and lactation.[REF2: Kay JE, Cardona B, Rudel RA, et al. Chemical Effects on Breast Development, Function, and Cancer Risk: Existing Knowledge and New Opportunities. Curr Environ Health Rep. 2022;9(4):535-562.] Current evidence from studies with rodent models demonstrate that low- dose PFOA exposures can lead to reduced mammary differentiation and altered milk protein gene expression.[REF11: Macon MB, Fenton SE. Endocrine disruptors and the breast: Early life effects and later life disease. J Mammary Gland Biol Neoplasia. 2013;18(1):43-61.; REF12: Tucker DK, Macon MB, Strynar MJ, Dagnino S, Andersen E, Fenton SE. The mammary gland is a sensitive pubertal target in CD-1 and C57Bl/6 mice following perinatal perfluorooctanoic acid (PFOA) exposure. Repro Toxicol. 2015;54:26-36.; REF13: White SS, Stanko JP, Kato K, Calafat AM, Hines EP, Fenton SE. Gestational and chronic low-dose PFOA exposures and mammary gland growth and differentiation in three generations of CD-1 mice. Environ Health Perspect. 2011;119(8):1070-1076.; REF14: White SS, Calafat AM, Kuklenyik Z, et al. Gestational PFOA Exposure of Mice is Associated with Altered Mammary Gland Development in Dams and Female Offspring. Toxicol Sci. 2006; 96(1):133-144.] We note that EPA derived a human equivalent dose reference dose (RfD) of 15 ng/kg- day based on impaired mammary gland development in its plan to develop the PFOA MCL.[REF15: U.S. EPA (U.S. Environmental Protection Agency). External Peer Review Draft: Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) (CASRN 335-67-1) in Drinking Water. EPA, Office of Water, Washington, DC; 2021.] This was a similar conclusion from the Texas Commission on Environmental Quality, which used a study of impaired mammary gland as its critical study in developing its 2016 Protective Concentration Level, deriving a RfD of 12 ng/kg-day.[REF16: TCEQ (Texas Commission on Environmental Quality). Toxicological Evaluation of Perfluoro Compounds. 2016.] In order to comprehensively describe health effects of PFAS chemicals, EPA's risk assessment should include a description of the mammary gland effects along with the other endpoints and demonstrate that the proposed risk assessment is protective for all of them. A similar discussion, for example, is included in the New Jersey Department of Environmental Protection (NJDEP) Health-Based MCL determination. NJDEP noted that delayed mammary gland development, along with increased liver weight, were the two most sensitive non-carcinogenic endpoints associated with PFOA exposure.[REF17: New Jersey Department of Environmental Protection. Health-Based Maximum Contaminant Level Support Document: Perfluorooctanoic Acid (PFOA). Trenton, NJ: New Jersey Drinking Water Quality Institute, Health Effects Subcommittee; 2017.] NJDEP concluded that the target serum concentration to be protective of delayed mammary gland development was below the median serum PFOA level in the general population and would correspond to an RfD of 0.11 ng/kg-day.[REF17: New Jersey Department of Environmental Protection. Health-Based Maximum Contaminant Level Support Document: Perfluorooctanoic Acid (PFOA). Trenton, NJ: New Jersey Drinking Water Quality Institute, Health Effects Subcommittee; 2017.] While NJDEP's

recommended MCL did not directly incorporate these mammary gland effects, NJDEP applied an extra uncertainty factor to account for this and other sensitive endpoints.

Evidence of impaired mammary gland development after PFOA exposure in rodent studies is consistent with findings in human studies that document effects on lactation, and potentially increased breast cancer risk.[REF2: Kay JE, Cardona B, Rudel RA, et al. Chemical Effects on Breast Development, Function, and Cancer Risk: Existing Knowledge and New Opportunities. Curr Environ Health Rep. 2022;9(4):535-562.] As noted by researchers at the Silent Spring Institute and others, altered mammary gland development may impair lactation and increase breast cancer susceptibility later in life.[REF1: National Academies of Sciences, Engineering, and Medicine. Guidance on PFAS Exposure, Testing, and Clinical Follow-Up. Washington, DC: The National Academies Press; 2022.; REF2: Kay JE, Cardona B, Rudel RA, et al. Chemical Effects on Breast Development, Function, and Cancer Risk: Existing Knowledge and New Opportunities. Curr Environ Health Rep. 2022;9(4):535-562. ; REF11: Macon MB, Fenton SE. Endocrine disruptors and the breast: Early life effects and later life disease. J Mammary Gland Biol Neoplasia. 2013;18(1):43-61.; REF18: Rudel RA, Fenton SE, Ackerman JM, Euling SY, Makris SL. Environmental exposures and mammary gland development: State of the science, public health implications, and research recommendations. Environ Health Perspect. 2011;119(8):1053-1061.] In humans, PFOA, PFOS, PFNA, and PFDA concentrations in serum were associated with shorter duration of breastfeeding in a cohort of mothers in the Faroe Islands[REF19: Timmermann CAG, Budtz-Jorgensen E, Petersen MS, et al. Shorter duration of breastfeeding at elevated exposures to perfluoroalkyl substances. Repro Toxicol. 2017;68:164-170.] and elevated serum PFOA was associated with early termination of breastfeeding in a cohort of U.S. mothers.[REF20: Romano ME, Xu Y, Calafat AM, et al. Maternal serum perfluoroalkyl substances during pregnancy and duration of breastfeeding. Environ Res. 2016;149:239-246.]

EPA Response: The commenter recommended the EPA reconsider its decision to exclude the critical effect of mammary gland development in rodents when selecting endpoints to serve as the basis of candidate RfDs for the developmental health outcome based on conclusions from other agency assessments. In response to these comments, the EPA reevaluated the evidence underlying this endpoint for both PFOA and PFOS. The EPA did not identify studies reporting on mammary gland development in animal models administered PFOS. For PFOA, the EPA has maintained the position the agency took when developing the 2016 HESD (USEPA, 2016a) and the public comment draft toxicity assessment for PFOA (USEPA, 2023f). More specifically, the EPA previously stated, “there is uncertainty related to the functional impact of this endpoint,” given a lack of evidence correlating mammary duct branching patterns and decreased ability to support pup growth during lactation (USEPA, 2016b). No new studies in animal models have been published since 2016 that would contradict this conclusion. In contrast to the commenter’s claims, the EPA did “include a description of the mammary gland effects along with the other endpoints” in Section 3.4.4.2.7 (“Mammary Gland Development”) of the PFOA toxicity assessment (USEPA, 2023f). As there was no evidence from the available animal literature supporting the hypothesis that altered mammary gland development results in decreased

lactational efficiency and subsequent reductions in offspring growth or survival, the EPA did not consider epidemiological studies reporting reduced breastfeeding duration, which was categorized under the non-priority health outcome of Reproductive effects, for POD derivation. The EPA instead focused on health outcomes that were coherent across epidemiological and animal toxicological studies (e.g., reduced offspring birthweight), and that have supporting evidence of adversity (e.g., reduced offspring survival).

The EPA additionally notes, regarding the commenter's request that the EPA "demonstrate that the proposed risk assessment is protective" of mammary gland effects, that an MCLG of zero based on cancer effects is the most protective value possible. Please see section 4.2.6 of the EPA response in this *Response to Comments* document for additional discussion related to how the EPA considered other agency assessments.

4.2.2 Toxicity Value Derivation

Summary of Major Public Comments and EPA Responses

The EPA requested comment on the derivation of draft toxicity values (i.e., RfDs and CSFs) for PFOA and PFOS. Many commenters supported the draft toxicity values derived for PFOA and PFOS. Other commenters noted uncertainties surrounding the extrapolation of data from animal toxicological studies to support the derivation of toxicity values for human exposure. A few of these commenters also noted the importance of epidemiological data to support quantitative dose-response assessments and MCLG derivation. In contrast, one commenter critiqued the EPA for relying on epidemiological data and the commenter claimed the EPA was "ignoring" high confidence data from animal studies. Some commenters provided comments specific to the RfDs or CSFs, further described below.

The EPA agrees that, when warranted by the chemical-specific database, the agency is supported in its use of epidemiological data for the derivation of toxicity values over data from animal toxicological studies because this approach eliminates uncertainties related to interspecies extrapolation (USEPA, 2022a). The EPA agrees with commenters who state the databases for PFOA and PFOS warrant this approach because there are numerous epidemiological studies of *high* or *medium* confidence for each critical effect that showed consistent direction of effect in multiple human populations, as well as coherence with evidence presented in animal toxicological studies (see the evidence profile tables and the weight of evidence discussion in Section 3 of USEPA (2024a) and USEPA (2024b)). The EPA disagrees with the commenter who claimed that the EPA ignored results from animal toxicological studies. Not only did the EPA rely on animal toxicological studies to determine the overall evidence integration summary judgments, but the EPA also selected animal toxicological studies to serve as the basis of candidate RfDs and CSFs (USEPA, 2024d; USEPA, 2024c). Consistent with methodologies in the IRIS Handbook, the EPA preferentially relied on epidemiological studies to limit the variability that is associated with extrapolation from animal to human exposure (USEPA, 2022a). However, the animal toxicological literature database was critical to the EPA's hazard

conclusions in the final toxicity assessment. See also sections 4.1.1 and 4.1.2 of this *Response to Comments* document.

A few comments, including one co-signed by many commenters, expressed support for the reference doses derived by the EPA. Specifically, commenters supported the use of epidemiological data to derive the RfDs for PFOA and PFOS, the selected uncertainty factors, and the selected critical effects. A few commenters provided specific arguments against the individual health effects prioritized by the EPA. Specifically, a few commenters stated that the agency improperly relied on changes in epidemiological biomarkers (i.e., antibody response, alanine aminotransferase (ALT), and total cholesterol (TC)) or effects (i.e., (LBW) which the commenters claimed are not clinically adverse and may be reversible, rather than disease outcomes, to serve as the basis for candidate RfDs. On the other hand, one comment representing thirty-six commenters provided supportive discussion on the biological significance of endpoints including ALT and antibody response to vaccination. A few commenters questioned whether studies reporting on effects observed in populations outside the U.S. with varying exposure histories (e.g., the Faroe Islands population) are relevant to the U.S. general population.

The EPA and the SAB PFAS Review Panel agree that the four selected critical effects (i.e., decreased antibody response to vaccination, increased serum ALT, increased TC, and decreased birthweight) are biologically significant effects and/or precursors to disease (e.g., CVD), which, according to agency guidance and methods, both warrant consideration as the basis of RfDs for PFOA and PFOS (USEPA, 2002; USEPA, 2005; USEPA, 2022b; USEPA, 2022a). The EPA describes rationale for these decisions in Section 4.1 of the toxicity assessments for PFOA and PFOS (USEPA, 2024d; USEPA, 2024c). Briefly, effects such as increased TC, increased ALT, decreased antibody response to vaccination, and decreased birthweight resulting from PFOS or PFOA exposure may or may not result in changes that would be considered clinically elevated in a particular individual. However, given the distribution of individual concentrations within the population, small changes in the average response of these endpoints can result in substantial health impacts at the population level (Gilbert and Weiss, 2006). The SAB PFAS Review Panel shared these sentiments and noted, "one or more studies, for each of the four [noncancer health] effects, reported an association of PFOA and/or PFOS with increased risk of a clinically abnormal value… In studies where the number of subjects with clinically abnormal values was not specifically evaluated, an increase in the number of subjects with a clinically abnormal value is also expected from the overall change (shift in the distribution curve) in the abnormal direction. While the clinical relevance of exposure to PFOA or PFAS cannot be predicted on an individual basis, the increased number of individuals within a population with clinically defined abnormal values is of public health concern" (USEPA, 2022b).

Unless data suggests otherwise, the EPA considers studies published outside of the U.S. as relevant to the U.S. population; the EPA's currently established methods and protocols do not outline restrictions based on study or data source location, as this factor does not necessarily influence the confidence in study conclusions (USEPA, 2022a; USEPA, 2021a). Further, none of the commenters provided any data to support that populations outside of the U.S. would respond

to PFOA or PFOS exposure differently than the U.S. general population or vulnerable populations. Additionally, whenever possible, the EPA considered results reported in populations from multiple geographic regions and varying exposure histories when synthesizing and integrating the available evidence and when selecting critical studies for dose-response modeling. For example, at the time of the proposed rule, data originating from the U.S. were limited for the antibody response endpoint. The EPA therefore considered studies in children from the Faroe Islands (Budtz-Jørgensen and Grandjean, 2018), Greenland (Timmermann et al., 2021), Norway (Granum et al., 2013), and Germany (Abrahams et al., 2020). The observation of consistent responses across varying populations is a strength of the database, not a weakness, as some commenters erroneously imply. Since publication of the draft toxicity assessments, a study reporting anti-rubella immunity in U.S. children has also been published, further supporting and strengthening the potential relevance and weight of evidence of antibody response as an endpoint for the U.S. population (Zhang et al., 2023).

A couple commenters expressed support for the CSFs derived by the EPA. Specifically, commenters supported the use of epidemiological data to derive the CSF for PFOA and/or the use of liver tumor data to derive the CSF for PFOS. A few commenters stated that the EPA should not have relied on Shearer et al. (2021) as the basis of the CSF for PFOA because they assert that it is low confidence (in contrast to the EPA's conclusion that it is a *medium* confidence study), reports only a single PFOA serum measurement, and is not supported by the other epidemiological studies of kidney cancer, among other concerns they expressed. A couple commenters criticize the CSF for PFOS because it relies on animal evidence (i.e., liver tumors) that they claim may not be relevant to humans.

The EPA determined that Shearer et al. (2021) is a *medium* confidence study after conducting study quality evaluation consistent with the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022a). The details of the study evaluation are publicly available (https://hawc.epa.gov/summary/visual/assessment/100500248/PFOA-Human-Study-Quality-Evaluations-Cancer/). The biomonitoring measures of PFOA levels in Shearer et al. (2021) were reliable measures of PFOA exposure due to the chemical's well-established long half-life in humans (see Section 3.5.1 of the Final Human Health Toxicity Assessment for PFOA (USEPA, 2024a)). Additionally, an adequate study of cancer outcomes requires consideration of the latency period of the disease (USEPA, 2005). Since cancer is not an acute outcome that develops immediately following chemical exposures, a measurement of serum PFOA one decade prior to diagnosis was appropriate. One commenter cited one *medium* and one *low* confidence studies that did not report statistically significant associations between PFOA and kidney cancer to support their claim of inconsistency in the database. The EPA disagrees with the commenter's characterization of the database because, unlike the EPA's discussion in the draft and final toxicity assessments for PFOA and PFOS (USEPA, 2023f; USEPA, 2023a; USEPA, 2024d; USEPA, 2024c), the commenter failed to acknowledge the entire body of evidence which includes another *medium* confidence study that reports increases in kidney cancer with PFOA exposure (Vieira et al., 2013) and a meta-analysis that also reports a positive association (Bartell et al., 2021). Additionally, Steenland et al. (2020) discusses the probable link between kidney

cancer and PFOA exposure. Importantly and in accordance with the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022a) and EPA's 2005 *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005), the EPA considers the full weight of evidence approach when characterizing hazard.

As described previously in this notice and in the toxicity assessments for PFOA and PFOS (USEPA, 2023f; USEPA, 2023a; USEPA, 2024d; USEPA, 2024c), and as supported by other commenters, the EPA maintains that the tumors observed in rats administered PFOA or PFOS may be relevant to humans. The EPA's rationale underlying mechanistic considerations of these tumor types is described further in responses to comments below and in section 4.1.4 of this *Response to Comments* document. Additionally, evidence from recently published epidemiological studies shows concordant associations between PFOS serum concentrations and HCCs in humans (Goodrich et al., 2022; Cao et al., 2022).

Individual Public Comments and EPA Responses

4.2.2.1 Derivation of the Noncancer Reference Doses (RfDs)

New York State Department of Health (NYS DOH) (Doc. #1677, SBC-044961)

Proposed Reference Doses and Cancer Potency Factors: The proposed rule identifies reference doses (RfDs) and cancer potency factors for both PFOA and PFOS. If the rule is adopted, it is critical for EPA to clarify the status of these toxicity values. Is the Agency planning to include the PFOA and PFOS RfDs and cancer potency factors on the Integrated Risk Information System, or use them as the basis for guidelines for various environmental media for other EPA programs? For example, the Regional Screening Levels for Chemical Contaminants at Superfund Sites [FN11: https://www.epa.gov/risk/regional-screening-levels-rsls-generic-tables] currently use the minimal risk levels (MRLs) for PFOA and PFOS (3 and 2 ng/kg/day, respectively) derived by the Agency for Toxic Substances and Disease Registry (ATSDR, 2021). These MRLs lead to residential tap water guidance values of 40 ng/L and 60 ng/L for PFOA and PFOS, respectively, which greatly exceed the proposed MCLs (4 ng/L). Adoption of the reference doses (0.03 and 0.1 ng/kg/day for PFOA and PFOS, respectively) and cancer potency factors (0.0293 and 3.95x10-5 per ng/kg/day for PFOA and PFOS, respectively) in the proposed rule will likely result in Regional Screening Levels at Superfund Sites being below the analytical levels of detection. It is critical for the Agency to describe how the underlying toxicological science will be applied consistently across programs.

EPA Response: The commenter requested clarification on the status of the draft toxicity values published at the time of rule proposal. These values are considered final upon publication of the final toxicity assessments for PFOA and PFOS (USEPA, 2024d; USEPA, 2024c). These values were not developed by the Office of Research and Development's IRIS and will therefore not be available on the IRIS website. The toxicity assessments and other materials supporting the rulemaking can be found in the docket EPA-HQ-OW-2022-0114. With the publication of the final toxicity assessments with this final rulemaking, other agency programs may choose to rely

on the final toxicity values for PFOA and PFOS published therein (USEPA, 2024d; USEPA, 2024c). Further discussion on the adoption of the final toxicity values for PFOA and PFOS across other agency programs is outside the scope of this rulemaking.

Consumer Reports (Doc. #1656, SBC-043187, SBC-043188 & SBC-043189)

The EPA considers noncancer effects when setting MCLGs. EPA can use the Reference dose (RfD), defined as the maximum acceptable oral dose of a toxic substance below which no adverse noncancer health effects should result from a lifetime of exposure. For PFOA, EPA followed the recommendations of the Science Advisory Board (SAB) to focus its review "on those health outcomes that have been concluded to have the strongest evidence, including liver disease, immune system dysfunction, serum lipid aberration, impaired fetal growth, and cancer." EPA identified four prioritized health outcomes from all the toxicity data on PFOA: immune (decreased antibody production in response to vaccinations), developmental (low birth weight), cardiovascular (increased serum total cholesterol), and hepatic (elevated ALT). The RfDs for the immune, developmental and cardiovascular effects were the same, i.e., 3 x 10-8 mg/kg/day, and are protective of effects that may occur in sensitive populations (i.e., infants and children). Thus, EPA set the overall RfD at 3 x 10-8 mg/kg/day for PFOA.

For PFOS, it turned out that EPA identified the same four prioritized health outcomes as for PFOA: immune (decreased antibody production in response to vaccinations), developmental (low birth weight), cardiovascular (increased serum total cholesterol), and hepatic (elevated ALT). The RfDs for the developmental and cardiovascular effects were the same, i.e., 1 x 10-7 mg/kg/day. Thus, EPA set the overall RfD at 1 x 10-7 mg/kg/day for PFOS.

We support EPA's proposed RfDs for PFOA of 3 x 10-8 mg/kg/day and for PFOS of 1 x 10-7 mg/kg/day.

EPA Response: The comments provided by this commenter support the final rule.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-053371)

2. EPA takes an inappropriate approach to average/weigh all endpoints equally

For PFOA, EPA relies on the immune, developmental, and cardiovascular outcomes as co-critical effects. For PFOS, EPA relies on developmental and cardiovascular outcomes as the co-critical effects. EPA chooses these values because they are the lowest of the values presented, and EPA finds that they will be protective of other effects and protective of effects that may occur in sensitive populations [FN122: 88 Fed. Reg. 18659 and 18663.]. EPA provides no scientific weight of evidence analysis and simply chooses the lowest numbers. If SDWA were a precautionary statute, then it would not direct EPA to use the best available public health information and data collected by the best methods. In this case, EPA ignores the statutory standard and picks the lowest numbers. SDWA also requires EPA to specify uncertainties, identify studies that would assist in resolving the uncertainties, and also reconcile inconsistencies

in the scientific data [FN123: 42 U.S.C. [sec] 300g-1(b)(3)(B)(iv).]. While EPA discusses uncertainties in the benefit and costs analysis, the proposed rule does not provide any substantive discussion of the uncertainties associated with the derivation of the RfD values. Finally, while the proposed rule notes inconsistencies in some of the data sets, as described for some of the endpoints in comments above, EPA makes no effort to resolve these inconsistencies.

EPA Response: The commenter disagreed with the EPA's approach to select co-critical effects to serve as the basis for the RfDs for PFOA and PFOS. The commenter stated that the EPA chose those values because they are the lowest presented and will be protective of effects in sensitive populations. The commenter stated the EPA did not provide a weight of evidence analysis and ignored the SDWA requirement to use the best available science. The commenter stated SDWA "requires EPA to specify uncertainties, identify studies that would assist in resolving the uncertainties, and also reconcile inconsistencies in the scientific data" and the EPA did not "provide any substantive discussion of the uncertainties associated with the derivation of the RfD values." The commenter lastly states that the EPA made no effort to resolve inconsistencies in the database. The EPA disagrees with these comments.

Regarding the selection of co-critical effects, the agency did not "average" the values across candidate RfDs; the candidate RfDs for immune, developmental, and cardiovascular (PFOA) and developmental and cardiovascular (PFOS) were the same when rounded to one significant figure. The EPA determined that it was appropriate to select co-critical effects to serve as the basis of the overall RfDs for PFOA and PFOS as a result of the weight of evidence analyses (i.e., evidence integration) presented in Section 3 for each health outcome (USEPA, 2024d; USEPA, 2024c), that the commenter incorrectly stated the EPA did not conduct. When considering data from epidemiological, animal toxicological, and mechanistic evidence streams, the EPA judged the immune, hepatic, developmental, and cardiovascular health outcomes to each have *evidence indicating* that PFOA or PFOS exposure is likely to cause adverse effects in humans under relevant exposure circumstances (see evidence integration protocols in Appendix A (USEPA, 2024a; USEPA, 2024b) and USEPA, 2022a). As such and considering the strengths of the modeled data for each health outcome and endpoint, described in Appendix E (USEPA, 2024a; 2024b), the EPA did not have evidence to distinguish one health outcome or endpoint over the other(s) when selecting an overall RfD. Therefore, the EPA selected co-critical effects to serve as the basis for the overall RfDs. This decision is in line with previous agency decisions to derive RfDs based on co-critical effects from varying health outcomes (e.g., IRIS PFBA assessment (USEPA, 2022c), 1,4-dioxane assessment (USEPA, 2013)). For further discussion on the EPA's use of the best available science, please see section 4.1.2 of the EPA response in this *Response to Comments* document.

Additionally, for PFOA, the overall RfD selected (3×10^{-8} mg/kg/day) was not the lowest possible candidate RfD derived (2×10^{-8} mg/kg/day, based on Timmerman et al., 2021). Similarly, for PFOS, the lowest possible candidate RfD for immune effects (1×10^{-7} mg/kg/day, based on Timmerman et al., 2021) was not selected as the immune health outcome-specific RfD (2×10^{-7} mg/kg/day, based on Budtz-Jorgensen & Grandjean, 2018). For these instances and

others where the EPA did not select the most health protective (i.e., lowest) possible candidate RfD, the EPA provided rationale in Section 4 and Appendix E (when the decision was related to POD derivation) of the draft and final toxicity assessments (USEPA, 2023f; USEPA, 2023a; USEPA, 2024d; USEPA, 2024c). Regardless, as the commenter stated, the EPA's overall RfDs are expected to be protective of effects that may occur in sensitive populations.

The EPA lastly disagrees with the commenter's assertions that the agency did not discuss uncertainties in the RfDs or inconsistencies in the database. Both of these factors are discussed throughout the toxicity assessments in the context of evidence synthesis and integration (Section 3), critical study and endpoint selection (Sections 3 and 4), PK and BMD modeling approaches (Section 4 and 5), and candidate RfD selection (Section 4), among other topics (USEPA, 2024d; 2024b). As described in Appendix A (USEPA, 2024a; USEPA, 2024b) and USEPA (2022a), inconsistencies in the database play a critical role in the EPA's evidence integration judgment, as well as selection of critical effects. For example, in the PFOS toxicity assessment, the EPA stated: "Although a few associations between other liver serum biomarkers [besides ALT] and PFOS exposure were identified in *medium* confidence epidemiological studies, there is considerable uncertainty in the results due to inconsistency across studies" (USEPA, 2023a). As such, the EPA did not consider liver serum biomarkers other than ALT for BMD modeling or candidate RfD derivation. Similar statements can be found throughout Section 3 of the PFOA and PFOS toxicity assessments for other endpoints and health outcomes (USEPA, 2024d; 2024b). Notably, the EPA identified generally consistent associations in *medium* and *high* confidence studies between PFOA or PFOS and the endpoints of decreased antibody response in children, decreased birthweight, increased serum ALT in adults, and increased serum TC in adults, as well as coherent and supportive evidence for these endpoints in animal toxicological studies. These findings facilitated the EPA's selection of these endpoints and associated studies for BMD modeling.

The EPA provided extensive discussion of several uncertainties related to the development of these assessments in Section 6 of the draft toxicity assessments for PFOA and PFOS (USEPA, 2023f; USEPA, 2023a). Specifically, the EPA discussed: uncertainties in the use of epidemiological studies for quantitative analyses; quantitative differences and uncertainties underlying comparisons between RfDs derived from animal toxicological and epidemiological studies; inconsistencies between approaches used in development of the 2016 HESDs (USEPA, 2016b; USEPA, 2016a) and the 2023 draft assessments (USEPA, 2023f; USEPA, 2023a); uncertainties in the cancer classification determination; uncertainties related to health outcomes with evidence bordering on "indicating" associations; uncertainties in modeling (i.e., animal internal dosimetry, human dosimetry, and BMD modeling); and uncertainties regarding sensitive subpopulations.

WV Municipal Water Quality Association (Doc. #1816, SBC-044664)

We question whether EPA has appropriately used the public health PFAS-related data available to it in lieu of extrapolating from literature values and animal studies.

We question whether EPA has adequately used the public health tracking data available to it from the various health tracking initiatives of individuals exposed to elevated PFAS levels from around the country.

To begin with, EPA has literally decades of actual human health PFOA-PFOS data available to it courtesy of the Food and Drug Administration. We understand that FDA has over twenty years of actual blood PFAS level sampling data for thousands of Americans as depicted in the chart below.

Rather than extrapolating from this wealth of human data, it appears that EPA chose to extrapolate from literature values and animal studies. Doing so resulted in EPA injecting an enormous margin of uncertainty multiplier into the criteria that we don't believe is warranted or justified.

[Figure 1: see docket ID EPA-HQ-OQ-2022-0114-1820]

For example, beyond FDA's data, EPA has available to it years of health monitoring data for impacted residents in Parkersburg/Vienna, West Virginia as well as other systems around the country such as Wilmington, North Carolina. States closely track public health clusters and yet we are not aware of any in these communities associated with elevated PFAS levels.

EPA must address this critical health data, along with its partners such as the West Virginia Department of Environmental Protection and Bureau of Public Health (regarding the Parkersburg/Vienna data) as well as the North Carolina Department of Environmental Quality (as to PFAS-related heath data for Cape Fear River communities).

More generally, EPA's 2023 proposed MCLs are based on a lifetime consumption of 2.5 liters per day for 70 years. In addition, the MCLs are based on rat/mice studies with a 300x uncertainty factor, comprising 10x for intraspecies variability, 3x for interspecies differences and 10x for database deficiencies. Note, that the study found no evidence to support lower birthrate at human serum levels included in the data sets.

[Figure 2: see docket ID EPA-HQ-OQ1820]

https://www.whitehouse.gov/wp-content/uploads/2023/03/OSTP-March-2023-PFAS-Report.pdf

[Figure 3: see docket ID EPA-HQ-OQ-2022-0114-1820]

[Figure 4: see docket ID EPA-HQ-OQ-2022-0114-1820]

Literature suggests that rats/mice are poor models for certain chemical health interactions in humans. The uncertainty factor is large and the basis for lifetime consumption wasn't validated. Given the prevalence of epidemiological studies and the breadth of available health information regarding PFOA and PFOS, it was error by EPA not to use human data to guide the proposed MCL regulation and EPA's failure is inconsistent with the approach taken by major health authorities in other developed nations.

EPA Response: The commenters appear to misunderstand several aspects of the science underlying the PFAS NPDWR, particularly the MCLGs for PFOA and PFOS. Please see sections 4.1.4 and 4.2.2 of the EPA response in this *Response to Comments* document. In contrast to the commenter's assertion, the EPA did use human data published in peer-reviewed epidemiological studies to develop toxicity values (i.e., RfDs and CSFs), when available. Data from human studies were significant to the EPA's determination that PFOA and PFOS are *Likely to be Carcinogenic to Humans* and subsequent determinations that the MCLGs for PFOA and PFOS should be set to zero. Further, the candidate RfDs derived from epidemiological studies incorporated a composite uncertainty factor of 10x, which is not "an enormous margin of uncertainty multiplier…" as the commenter suggests. Several epidemiological studies the EPA selected for candidate RfD derivation relied on data from NHANES, one source of "public health tracking data available" from the general U.S. population (e.g., Dong et al., 2019) and others relied on "individuals exposed to elevated PFAS levels" from impacted communities, such as the C8 Health Project subjects (e.g., Gallo et al., 2012).

The EPA considered all publicly available, peer-reviewed data, as well as data collected by accepted or the best available methods in the agency's assessments of PFOA and PFOS, including published studies of "public health clusters," in order to identify potential associations between these two chemicals and adverse health effects that may be observed in the U.S. population. The EPA is unaware of biomonitoring efforts undertaken by FDA that report PFOA and PFOS concentrations in human biological samples and the commenter did not provide a citation for their assertion. However, the EPA did incorporate monitoring of environmental media (e.g., food) conducted by FDA in its derivation of the relative source contribution (RSC), presented in Appendix G of the draft and final toxicity assessments (USEPA, 2023b; USEPA, 2023c; USEPA, 2024a; USEPA, 2024b).

The commenter also mistakenly stated that the "EPA's 2023 proposed MCLs are based on a lifetime consumption of 2.5 liters per day for 70 years." The EPA assumes the commenter is referring to the additional PFAS (i.e., HFPO-DA, PFBS, PFNA, and PFHxS) for this statement, as the MCLGs PFOA and PFOS were zero and did not incorporate assumptions regarding drinking water ingestion (see section 4.1.5 of the EPA response in this *Response to Comments* document). Regardless, the EPA described in the *Maximum Contaminant Level Goals (MCLGs) for Three Individual Per- and Polyfluoroalkyl Substances (PFAS) and a Mixture of Four PFAS.* (USEPA, 2024h) that drinking water consumption values were based on data presented in the 2019 edition of the *Exposure Factor's Handbook* (USEPA, 2019) and are specified for the target population presented in the critical study of interest. This does not equate to lifetime consumption of 2.5 L/day for 70 years in calculations of the HBWCs or MCLGs for any of the four additional PFAS considered in this rulemaking. The commenter also mistakenly asserts that all of the RfDs were derived with a composite uncertainty factor of 300x. As described above, the composite UF used in the overall RfDs for PFOA and PFOS was 10x (10x for intraspecies variability), while the composite uncertainty factor used in the RfD for HFPO-DA was 3,000x (10x for intraspecies variability, 3x for interspecies differences, 10x for extrapolation from a subchronic to a chronic dosing duration, and 10x for database deficiencies). These are reasonable

and standard uncertainty factors, applied based on the specific information available for each PFAS contaminant, consistent with long-standing EPA guidance and methods (USEPA, 2002; USEPA, 2022a).

The EPA disagrees that "literature suggests that rats/mice are poor models for certain chemical health interactions in humans" and the commenter does not provide citations to support this claim. While the EPA agrees that there are uncertainties associated with the extrapolation of data from animal models to humans (see discussion in section 4.2.2 of this *Response to Comments* document), the EPA disagrees that this precludes the agency from quantitatively relying on studies in animal models for the derivation of toxicity values. This practice has been used to support agency products for decades and is repeatedly endorsed by EPA guidance and methods (USEPA, 2002; USEPA, 2005; USEPA, 2014a; USEPA, 2022a). The EPA agrees that extrapolation from animal models to humans is complex, but animal toxicological studies, regardless of study design characteristics such as dose levels, are critical for determining potential human health hazards and the exposure levels and internal doses (e.g., serum concentrations) that may be expected to cause adverse health effects in humans. With an understanding of how the chemical exposure behaves differently in animals and humans, the EPA can estimate the equivalent level of exposure that would pose a risk to human health and compare those values across any effects that could pose a hazard. In this way, the EPA can determine the minimum exposure level (e.g., RfD) that could result in a risk to human health.

Association of MO Cleanwater Agencies (Doc. #1817, SBC-044642)

We question whether EPA has appropriately used the public health PFAS-related data available to it in lieu of extrapolating from literature values and animal studies.

We question whether EPA has adequately used the public health tracking data available to it from the various health tracking initiatives of individuals exposed to elevated PFAS levels from around the country.

To begin with, EPA has literally decades of actual human health PFOA-PFOS data available to it courtesy of the Food and Drug Administration. We understand that FDA has over twenty years of actual blood PFAS level sampling data for thousands of Americans as depicted in the chart below.

Rather than extrapolating from this wealth of human data, it appears that EPA chose to extrapolate from literature values and animal studies. Doing so resulted in EPA injecting an enormous margin of uncertainty multiplier into the criteria that we don't believe is warranted or justified.

[Figure 1: see docket ID EPA-HQ-OQ-2022-0114-1820]

For example, beyond FDA's data, EPA has available to it years of health monitoring data for impacted residents in Parkersburg/Vienna, West Virginia as well as other systems around the

country such as Wilmington, North Carolina. States closely track public health clusters and yet we are not aware of any in these communities associated with elevated PFAS levels.

EPA must address this critical health data, along with its partners such as the West Virginia Department of Environmental Protection and Bureau of Public Health (regarding the Parkersburg/Vienna data) as well as the North Carolina Department of Environmental Quality (as to PFAS-related heath data for Cape Fear River communities).

More generally, EPA's 2023 proposed MCLs are based on a lifetime consumption of 2.5 liters per day for 70 years. In addition, the MCLs are based on rat/mice studies with a 300x uncertainty factor, comprising 10x for intraspecies variability, 3x for interspecies differences and 10x for database deficiencies. Note, that the study found no evidence to support lower birthrate at human serum levels included in the data sets.

[Figure 2: see docket ID EPA-HQ-OQ1820]

https://www.whitehouse.gov/wp-content/uploads/2023/03/OSTP-March-2023-PFAS-Report.pdf

[Figure 3: see docket ID EPA-HQ-OQ-2022-0114-1820]

[Figure 4: see docket ID EPA-HQ-OQ-2022-0114-1820]

Literature suggests that rats/mice are poor models for certain chemical health interactions in humans. The uncertainty factor is large and the basis for lifetime consumption wasn't validated. Given the prevalence of epidemiological studies and the breadth of available health information regarding PFOA and PFOS, it was error by EPA not to use human data to guide the proposed MCL regulation and EPA's failure is inconsistent with the approach taken by major health authorities in other developed nations.

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044664 in section 4.2.2.1 in this *Response to Comments* document.

NC Water Quality Association (Doc. #1818, SBC-044620)

We question whether EPA has appropriately used the public health PFAS-related data available to it in lieu of extrapolating from literature values and animal studies.

We question whether EPA has adequately used the public health tracking data available to it from the various health tracking initiatives of individuals exposed to elevated PFAS levels from around the country.

To begin with, EPA has literally decades of actual human health PFOA-PFOS data available to it courtesy of the Food and Drug Administration. We understand that FDA has over twenty years of actual blood PFAS level sampling data for thousands of Americans as depicted in the chart below.

Rather than extrapolating from this wealth of human data, it appears that EPA chose to extrapolate from literature values and animal studies. Doing so resulted in EPA injecting an enormous margin of uncertainty multiplier into the criteria that we don't believe is warranted or justified.

[Figure 1: see docket ID EPA-HQ-OQ-2022-0114-1820]

For example, beyond FDA's data, EPA has available to it years of health monitoring data for impacted residents in Parkersburg/Vienna, West Virginia as well as other systems around the country such as Wilmington, North Carolina. States closely track public health clusters and yet we are not aware of any in these communities associated with elevated PFAS levels.

EPA must address this critical health data, along with its partners such as the West Virginia Department of Environmental Protection and Bureau of Public Health (regarding the Parkersburg/Vienna data) as well as the North Carolina Department of Environmental Quality (as to PFAS-related heath data for Cape Fear River communities).

More generally, EPA's 2023 proposed MCLs are based on a lifetime consumption of 2.5 liters per day for 70 years. In addition, the MCLs are based on rat/mice studies with a 300x uncertainty factor, comprising 10x for intraspecies variability, 3x for interspecies differences and 10x for database deficiencies. Note, that the study found no evidence to support lower birthrate at human serum levels included in the data sets.

[Figure 2: see docket ID EPA-HQ-OQ1820]

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[Figure 3: see docket ID EPA-HQ-OQ-2022-0114-1820]

[Figure 4: see docket ID EPA-HQ-OQ-2022-0114-1820]

Literature suggests that rats/mice are poor models for certain chemical health interactions in humans. The uncertainty factor is large and the basis for lifetime consumption wasn't validated. Given the prevalence of epidemiological studies and the breadth of available health information regarding PFOA and PFOS, it was error by EPA not to use human data to guide the proposed MCL regulation and EPA's failure is inconsistent with the approach taken by major health authorities in other developed nations.

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044664 in section 4.2.2.1 in this *Response to Comments* document.

SC Water Quality Association (Doc. #1819, SBC-044598)

We question whether EPA has appropriately used the public health PFAS-related data available to it in lieu of extrapolating from literature values and animal studies.

We question whether EPA has adequately used the public health tracking data available to it from the various health tracking initiatives of individuals exposed to elevated PFAS levels from around the country.

To begin with, EPA has literally decades of actual human health PFOA-PFOS data available to it courtesy of the Food and Drug Administration. We understand that FDA has over twenty years of actual blood PFAS level sampling data for thousands of Americans as depicted in the chart below.

Rather than extrapolating from this wealth of human data, it appears that EPA chose to extrapolate from literature values and animal studies. Doing so resulted in EPA injecting an enormous margin of uncertainty multiplier into the criteria that we don't believe is warranted or justified.

[Figure 1: see docket ID EPA-HQ-OQ-2022-0114-1820]

For example, beyond FDA's data, EPA has available to it years of health monitoring data for impacted residents in Parkersburg/Vienna, West Virginia as well as other systems around the country such as Wilmington, North Carolina. States closely track public health clusters and yet we are not aware of any in these communities associated with elevated PFAS levels.

EPA must address this critical health data, along with its partners such as the West Virginia Department of Environmental Protection and Bureau of Public Health (regarding the Parkersburg/Vienna data) as well as the North Carolina Department of Environmental Quality (as to PFAS-related heath data for Cape Fear River communities).

More generally, EPA's 2023 proposed MCLs are based on a lifetime consumption of 2.5 liters per day for 70 years. In addition, the MCLs are based on rat/mice studies with a 300x uncertainty factor, comprising 10x for intraspecies variability, 3x for interspecies differences and 10x for database deficiencies. Note, that the study found no evidence to support lower birthrate at human serum levels included in the data sets.

[Figure 2: see docket ID EPA-HQ-OQ1820]

https://www.whitehouse.gov/wp-content/uploads/2023/03/OSTP-March-2023-PFAS-Report.pdf

[Figure 3: see docket ID EPA-HQ-OQ-2022-0114-1820]

[Figure 4: see docket ID EPA-HQ-OQ-2022-0114-1820]

Literature suggests that rats/mice are poor models for certain chemical health interactions in humans. The uncertainty factor is large and the basis for lifetime consumption wasn't validated. Given the prevalence of epidemiological studies and the breadth of available health information

regarding PFOA and PFOS, it was error by EPA not to use human data to guide the proposed MCL regulation and EPA's failure is inconsistent with the approach taken by major health authorities in other developed nations.

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044664 in section 4.2.2.1 in this *Response to Comments* document.

Wet Weather Partnership (Doc. #1820, SBC-044576)

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[Figure 1: see docket ID EPA-HQ-OQ-2022-0114-1820]

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[Figure 2: see docket ID EPA-HQ-OQ1820]

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Literature suggests that rats/mice are poor models for certain chemical health interactions in humans. The uncertainty factor is large and the basis for lifetime consumption wasn't validated. Given the prevalence of epidemiological studies and the breadth of available health information regarding PFOA and PFOS, it was error by EPA not to use human data to guide the proposed MCL regulation and EPA's failure is inconsistent with the approach taken by major health authorities in other developed nations.

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044664 in section 4.2.2.1 in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-044825)

EPA's Assessment of the Human Health Effects is Flawed

EPA's proposed drinking water standards for the six PFAS relies on a selective analysis of the available health effects information that does not consider the entire full weight of available scientific evidence. This failure to consider all of the available evidence can be seen in the cancer slope factor (CSF) and multiple reference doses (RfDs) developed for PFOA and PFOS.

EPA Response: Please see section 4.2.2 of the EPA response in this *Response to Comments* document.

4.2.2.2 The EPA's Reliance on Epidemiological Data to Support RfD Derivation

4.2.2.2.1 Critical Study Selection

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045903)

B. Epidemiology data do not support an association for PFOA/PFOS immune, developmental, cholesterol, and hepatic (liver) endpoints

EPA has chosen to rely on epidemiology data for four critical endpoints for the development of the RfDs for the non-cancer effects of PFOA and PFOS and has inappropriately ignored high-quality animal data. An important comment made by the SAB was related to EPA's lack of transparent process for evidence synthesis and integration. SAB also directed EPA to consider multiple animal and human studies for a variety of endpoints [FN103: See SAB report to the EPA Administrator Aug. 22, 2022, in the cover letter to Administrator Regan, available at: https://sab.epa.gov/ords/sab/f?p=100:18:16490947993:::RP,18:P18_ID:2601#report.]. Yet, for quantitative derivation of the RfD values, EPA did not follow SDWA requirement to use "best available public health information," and instead relied on non-binding EPA guidance and used human data for all endpoints, even when higher confidence animal data existed [FN104: 88 Fed. Reg. 18661 (EPA states: "The focus of this FRN is on epidemiological studies for the four

prioritized health outcomes for which studies meeting this consideration were available, as human data are generally preferred 'when both laboratory animal data and human data with sufficient information to perform exposure-response modeling are available' (USEPA, 2022f).")]. This non-binding guidance sets a bar at "sufficient information," which is not consistent with SDWA requirement for "best available public health information."

EPA must develop a consistent, transparent, and peer-reviewed approach for deriving and choosing candidate RfD values which is based on SDWA requirements. This means that candidate RfD values should be developed based on concordance of both animal and human data, and EPA should take comment on them and rely on the highest quality evidence, with a robust and transparent scientific rationale [FN105: As discussed previously, SAB review is also required by the SDWA. EPA's new framework for evaluating evidence and the resulting values from animal and epidemiological data should be reviewed by the SAB.]. Instead, EPA relied on medium quality studies for three of the four endpoints and does not even present results from animal evidence in the Federal Register notice for the proposed rule. This choice made a material difference in the MCL levels. For instance, for hepatic effects of PFOS, if EPA had relied on the high quality animal data, rather than the medium quality human data, the resulting RfD would have been three orders of magnitude higher [FN106: See Public Comment Draft Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) in in Drinking Water (Public Comment Draft Assessments), at page 4-44, available at: https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0034.]. The approach provided in the proposed rule is not scientifically robust and not consistent with SDWA standards for scientific information.

EPA Response: Regarding the EPA's use of epidemiological data to serve as the basis of the overall RfDs and the commenter's claim that the EPA "ignored" animal toxicological data, please see section 4.2.2 of the EPA response in this *Response to Comments* document. Regarding the EPA's use of the "best available science," see section 4.1.2 of the EPA response in this *Response to Comments* document. Regarding how the EPA responded to SAB comments, see section 4.1.3 of the EPA response in this *Response to Comments* document and the Response to SAB Comments document (USEPA, 2023d). Regarding comparisons between RfDs derived from animal toxicological studies and epidemiological studies, please see the discussion that was provided at the time of rule proposal in Section 6.2 of the draft toxicity assessments (USEPA, 2023f; USEPA, 2023a; now Section 5.2 of the final assessments, USEPA, 2024d; USEPA, 2024c). Regarding the systematic review protocol used for this assessment, see section 4.1.1 of the EPA response in this *Response to Comments* document.

Additionally, there is no requirement, nor is it reasonable or practical for the expectation of one, that the agency "rely on the highest quality evidence," particularly considering how different study evaluation domains are across animal toxicological and epidemiological studies (see Appendix A (USEPA, 2024a; USEPA, 2024b) and USEPA (2022a)). Because different factors are considered with evaluating epidemiological and animal toxicological studies, it is difficult to make direct comparisons about study confidence ratings across the two evidence streams. The

EPA also must consider quantitative uncertainties with the extrapolation of data from animal studies to inform human health toxicity values. Finally, study selection guidance (Section 7.2) from the IRIS Handbook notes that "human are preferred over animal data to eliminate interspecies extrapolation uncertainties," and that animal studies "are considered the studies of primary interest when adequate human studies are not available" (USEPA, 2022a). The uncertainties associated with the use of animal toxicological studies and rationale for the selection of epidemiological studies to serve as the basis of the health outcome-specific and overall RfDs for PFOA and PFOS is described in Section 4.1.6 of the toxicity assessments (USEPA, 2024c; USEPA, 2024a).

3M Company (Doc. #1774, SBC-053431)

EPA was subjective and inconsistent in selecting key studies for BMD derivation.

In contrast to the systematic review practices recommended in EPA's IRIS Handbook, as well as best practice in risk assessment, EPA does not clearly describe the process for selection of key studies for use in BMD and BMDL derivation (see Section 2 for comments regarding study selection). Many studies judged as high- and medium-quality on CVD outcomes were not considered for POD derivation, including serum lipids, birth weight, and vaccine responses. EPA (2012) Benchmark Dose Technical Guidance states that, "The process of selecting studies for BMD analysis is intended to identify those studies for which modeling is feasible, so that BMDs can be calculated. All relevant studies should be considered for modeling…Sometimes combining several datasets may be an option [emphasis added]" (EPA 2012, p.14). However, EPA does not discuss why it did or did not consider specific studies, and thus the selection of the studies for BMD modeling appears to be subjective.

There are several examples in which EPA judged a study as medium- or low-confidence and contained data but did not model (or describe justification for not modeling) the available coefficients or dose-response information. For example, Mogensen et al. (2015) published an analysis on vaccine response at age seven within the Faroe Islands cohort; this analysis accounts for confounding and co-exposures to additional PFAS in the population through use of a Structural Equation Model (SEM). Mogensen et al. (2015) report that "When the three latent PFASs were mutually adjusted the associations became less apparent and only anti-tetanus antibody showed a borderline significant decrease by 29.6% (95% CI: -0.4%, 50.6%) at a doubling of PFOA exposure after this adjustment." Mogensen et al. (2015) also stated that their analyses "indicated that the causative dose is a long-term average where all three PFASs may contribute. Such an analysis would not be meaningful in standard regression models, as it would require that all exposure variables were included simultaneously as independent variables". Budtz-Jørgensen, in a 2007 article on the use of SEMs for estimation of benchmark doses, argues that dose-response modeling based on the assumed most sensitive outcomes "ignores other available data, is inefficient, and fails to account for multiple testing. Instead, risk assessment could be based on [SEMs], which can accommodate both a multivariate exposure and a multivariate response function" (Budtz-Jørgensen 2007). Budtz-Jørgensen (2007) argues "an

unbiased analysis can only be obtained in models that allow for measurement error" and proposes the use of SEMs for BMD analysis to account for and mitigate potential biases from measurement error. It is not clear why, based on the available evidence, EPA chose not to consider the findings from Mogensen et al. (2015) in addition to those from BudtzJørgensen and Grandjean (2018a) and Timmerman et al. (2021).

Lack of transparency in key study selection is not limited to the analyses of immune effects, however. EPA does not clearly describe its process for choosing the cross-sectional analyses by Dong et al. (2019), Steenland et al. (2009) and Lin et al. (2019) as the most appropriate studies for derivation of BMD(L)s for changes in serum lipids, nor does EPA provide justification of its selection of Chu et al. (2020), Govarts et al. (2016), Sagiv et al. (2018), Starling et al. (2017), Wikstrom et al. (2020), or Yao et al. (2021) for deriving BMD(L)s based on decreases in birth weight (see Section 2).

EPA Response: The commenter stated the EPA did not fully and transparently describe key study selection for POD derivation and that the process appeared to be subjective. The commenter provided one example, Mogensen et al. (2015), which reported an inverse association between PFOA and serum anti-tetanus antibodies in the Faroe Islands population. The commenter noted that Mogensen et al. (2015) used Structural Equation Modelling (SEM) analyses and cited a paper by Budtz-Jorgensen (2007) as supportive evidence. The commenter claimed that the EPA was not transparent in study selection for POD derivation across the serum lipid and LBW effects as well.

The EPA disagrees with the claim that critical study selection was not transparently described. In the health effects evidence synthesis and integration sections (sections 3.4 and 3.5 of the draft toxicity assessments for noncancer and cancer effects, respectively (USEPA, 2023f; USEPA, 2023a)), the EPA presented evidence integration judgments for each health outcome. The EPA used these judgments to determine which health outcomes and endpoints should be considered for quantitative analyses (i.e., only health outcomes with databases meeting criteria for evidence demonstrates or evidence indicates integration judgments were considered for dose-response assessment). In the dose-response assessment section of the documents (Section 4 of the draft assessments (USEPA, 2023f; USEPA, 2023a)), the EPA presented a description of each endpoint selected for quantitative analysis and the reasons for selection, the strength of the database in support of each endpoint, consistency of findings in the database, and the relevance of each endpoint to human health. The EPA lists the studies considered for POD derivation and provides confidence ratings for each study discussed. The EPA provides reasons for candidate study selection related to study design and analysis approach (Section 4.1.1, USEPA, 2024d; USEPA, 2024c) and follows the protocol outlined in the Appendix (Section A.1.11.1, USEPA, 2024a; USEPA, 2024b). The selected candidate studies were the best suited for POD derivation for multiple reasons, such as consideration of potential confounding factors, overall study confidence, study design and analysis, and suitability for modeling, among others described in the assessments. In response to public comments, the EPA has continued to improve the transparency and discussion related to candidate study selection, modeling, and RfD derivation

across each of the five priority health outcomes and critical effects, including increased total cholesterol, decreased BWT, increased ALT, and decreased antibody response to vaccination.

The EPA also disagrees with the commenter that the findings from Mogensen et al (2015) were not considered. As detailed in section 3.4.2.1.1.1 and Table 3-6 of the draft toxicity assessment for PFOA (USEPA, 2023f), the EPA clearly considered the findings from all the Faroe Island studies identified in the systematic literature review. The commenter asserted that the EPA should have considered using the estimates from structural equation modelling (SEM) provided in Mogensen et al. (2015) to "account for potential biases resulting from measurement error." The EPA agrees that SEM has the advantage of, if specified correctly, accounting for measurement error. However, both regression models (used in Budtz- Jørgensen and Grandjean (2018)) and SEMs ultimately estimate adjusted effects of one specific pollutant, while accounting for the others.

Mogensen et al. (2015) provides cross-sectional estimates of change in antibody levels at age 7 associated with changes in PFOS at age 7, with and without adjustment of PFOA and PFHxS. While this approach accounts for measurement error, it is more complex and it requires additional assumptions (e.g., assuming underlying latent variables) when modelling. Therefore, the modelling is only correct if the assumptions are met. Rather than Mogensen et al. (2015), the EPA selected the results from Budtz-Jørgensen and Grandjean (2018) Faroe Islands study for POD derivation. Budtz-Jørgensen and Grandjean (2018) is a *medium* confidence longitudinal study that relies on a standard statistical tool (regression models). Importantly, SEMs are not yet generally accepted for BMD modelling; the use of these estimates is not discussed in existing agency guidance (USEPA, 2012). Thus, the EPA determined that it is reasonable to rely on Budtz-Jørgensen and Grandjean (2018) for candidate RfD derivation over Mogensen et al. (2015).

American Chemistry Council (ACC) (Doc. #1841, SBC-052928)

Available Studies do not Provide Consistent Evidence of Low Birth Weight Among Infants Exposed to PFOA or PFOS In Utero

As noted in the draft documents, several human studies have investigated PFOA and PFOS exposure and birth outcomes, including birth weight. Most of these studies did not find an association between maternal serum levels and birth weight. [FN67: ATSDR PFAS Tox Profile, at 410.] Among the negative studies was an occupational exposure study in which female workers were exposed to high levels of PFOS. [FN68: Grice et al. 2007.] In many of those studies reporting an inverse relationship, moreover, the effect was small and limited to a single sex or exposure group.

Among the five studies for which EPA conducts benchmark dose modeling for developmental effects, two did not report a significant association with maternal serum concentrations of PFOA or PFOS – Govarts et al. 2016 [FN69: Govarts E et al. Combined effects of prenatal exposures to environmental chemicals on birth weight. Int J Environ Res Public Health 13:495 (2016).] and

Sagiv et al. 2017. [FN70: Sagiv SK et al. Early Pregnancy Perfluoroalkyl Substance Plasma Concentrations and Birth Outcomes in Project Viva: Confounded by Pregnancy Hemodynamics? Am J Epidemiol 187: 793-802 (2017). The association with PFOS was not significant after adjusting for potential confounders.] Moreover, Starling et al. (2017) [FN71: Starling AP et al. Perfluoroalkyl substances during pregnancy and offspring weight and adiposity at birth: Examining mediation by maternal fasting glucose in the healthy start study. Environ Health Perspect 125: 067016 (2017).] do not observe a significant association with serum concentration of PFOS and report an association only in the highest tertile of PFOA concentration. In the study by Chu et al. (2020), the association is not significant in the analysis by serum concentration quartiles for either substance or in the continuous serum concentration analysis for PFOA. [FN72: Chu C et al. Are perfluorooctane sulfonate alternatives safer? New insights from a birth cohort study. Environ Intl 135: 105365 (2020). While the OR for continuous serum concentration (per nanogram/milliliter) did not include 1, the confidence interval is quite wide (1.08, 5.47).] The final study by Wikstrom et al. (2019) [FN73: Wikström, S et al. Maternal serum levels of perfluoroalkyl substances in early pregnancy and offspring birth weight. Pediatric Res 87: 1093-1099 (2019).] report an association with PFOA and PFOS concentration in the highest quartile of girls; no association is observed in infant boys. Calculating an RfD from these epidemiology studies is inappropriate based on the higher degree of uncertainty in the findings and inconsistency across studies.

EPA Response: The commenter stated that most of the studies evaluating the association between BWT and PFOA or PFOS exposure did not find an association between maternal serum levels and BWT. The EPA disagrees with this comment. For PFOA, the majority of studies on changes in standardized BWT measures reported inverse associations (10/18), with most (7/10) of these being *high* and *medium* confidence (USEPA, 2024d). The forest plots also illustrate these associations. Similarly, the majority of studies (12/17) observed either an increased risk of LBW or small for GA. For PFOS, most evidence for deficits in mean BWT were reported from *high* or *medium* confidence studies (23/36; USEPA, 2024c). Studies on changes in standardized BWT measures reported inverse associations (12/18) in the overall population or specifically in one or both sexes. Ten of 17 studies observed increased risk of LBW or small for GA. These results are described in section 3.4.4.1 and summarized in section 3.4.4.4 of USEPA (2024a) and USEPA (2024b). Additionally, the commenter points to one occupational study, Grice et al. (2007), in which there was no association between PFOS and decreases in BWT in infants born to female workers exposed to high levels of PFOS compared to those born to females never exposed. The EPA conducted an evaluation of Grice et al., 2007 (see section 3.4.4 (USEPA, 2024c) and https://hawc.epa.gov/study/101163956/) and found this study was *deficient* for the BWT outcome. Therefore, confidence in the results from this particular study is limited. More specifically, comparing between women with "high levels" of PFOS and "never exposed" women is a crude comparison relative to studies comparing decreases in BWT per unit change in PFOS. However, the author notes that smoking was a modifying factor and "the reported birth weight for women who smoked during pregnancy compared with that for those who did not

smoke during pregnancy, adjusting for maternal age at birth and gravidity, was significant and therefore consistent with scientific knowledge (estimate -0.24 kg; 95% CI -0.12 to -0.37).

The EPA selected five (PFOA) and six (PFOS) *high* confidence studies for dose-response modeling of the decreased birthweight endpoint (USEPA, 2024d; USEPA, 2024c). The candidate epidemiological studies offer a variety of PFOA and PFOS exposure measures across the fetal and neonatal window. All studies reported their exposure metric in units of ng/mL and reported the β coefficients per ng/mL or ln(ng/mL), along with 95% CIs, estimated from linear regression models. The commenter asserted that some of the studies selected for POD derivation did not report significant associations. The EPA disagrees that using these studies is inappropriate. As stated in the EPA's *Guidelines for Developmental Toxicity Risk Assessment* (USEPA, 1991b), "Although statistical analyses are important in determining the effects of a particular agent, the biological significance of data is most relevant. It is important to be aware that with the number of endpoints that can be observed in standard protocols for developmental toxicity studies, a few statistically significant differences may occur by chance." The scientific consensus in the epidemiologic and systematic review community is that evidence of an association does not need to rely solely on statistical significance. As stated in the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022a), consideration of magnitude of the association and biological significance or adversity inform determination of associations. The nature of observational studies and potential sources of bias and systematic error that can impact statistical significance also make compelling cases for not relying solely on significance to determine whether the evidence supports an association or not.

4.2.2.2.2 Adversity of the Critical Effects

Raptor Pharm & Tox, Ltd (Doc. #1644, SBC-043416)

Raptor is concerned that EPA is violating the Safe Drinking Water Act by using scientific studies that do not demonstrate an adverse human health outcome. Although these comments focus on Steenland et al. 2009, Gallo et al. 2012, and Budtz-Jorgensen and Grandjean 2018, the EPA must reconsider all of the studies used to derive the RfD and clearly articulate how each study has identified an actual adverse human health outcome, rather than simply postulating that one could or may exist.

EPA Response: Please see section 4.2.2 of the EPA response in this *Response to Comments* document. While the commenter claims they are "concerned that EPA is violating the Safe Drinking Water Act," the commenter fails to note any action the EPA took that "violates" any specific SDWA statutory requirement. Although the commenter may want the EPA to conduct analyses in a certain way, it does not mean that the agency "violated" any SDWA obligation, nor does it place any requirement on the agency.

American Chemistry Council (ACC) (Doc. #1841, SBC-052921)

For non-cancer health effects, three of the RfDs for PFOA and PFOS rely on reports of slight changes in biomarkers in epidemiology studies in the absence of information to support that these changes are predictors of disease. The decision to generate an RfD for the fourth non-cancer endpoint ignores the results of several epidemiology studies that reported no adverse effects.

EPA Response: Please see section 4.2.2 of the EPA response in this *Response to Comments* document. The EPA assumes the commenter is referring to the endpoint of decreased birthweight when describing the "fourth non-cancer endpoint." The EPA responds to claims about inconsistencies in the database for this endpoint in the EPA response to comment Doc. #1774, SBC-053211 and SBC-053428 in section 4.2.1.2 in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-052929)

EPA's PFOA and PFOS Toxicity Evaluations are not Scientifically Justified

Given all the uncertainties and limitations of the available epidemiology data, the RfDs for PFOA and PFOS should be based on robust experimental animal data that is consistent, biologically plausible and relevant in humans, and shows a dose-response relationship. MCLs should be based on RfDs for endpoints that are adverse, more than transient and irreversible, and that truly can lead to human disease. While the human data may be useful as a qualitative line of evidence, the RfDs should be based on experimental animal data with observations that provide a clear dose-response and human relevant, biologically plausible, adverse endpoints.

EPA Response: Regarding the EPA's selection of epidemiological studies rather than animal studies to serve as the basis of the overall RfDs for PFOA and PFOS, as well as discussion on the adversity of the selected critical effects, please see section 4.2.2 of the EPA response in this *Response to Comments* document. Regarding the consistency of the database for each of the four epidemiological endpoints, please see sections 4.2.1.2, 4.2.1.3, 4.2.1.4, and 4.2.1.5 of the EPA response in this *Response to Comments* document.

4.2.2.2.3 Critical Study Populations

3M Company (Doc. #1774, SBC-053287)

2. EPA does not provide evidence that the study data sets used for BMD calculation represent the US population and even when appropriate datasets are selected, they are improperly analyzed.

(2A) EPA did not verify the representational nature of datasets selected for its BMD calculation

The data underlying several key studies EPA relies as the basis for its Proposed NPDWR are unavailable for review and evaluation (see for example Budtz-Jørgensen & Grandjean, 2018). Moreover, even where data is available, EPA did not address the representativeness of the data with respect to US national level populations.

Unless individual study findings can translate directly to the US population at large, the findings cannot be used to anticipate the impact of the rulemaking on human health risk in the US. Also, without a clear and quantitative understanding of how studies based on various nonrepresentative data sets were analyzed and treated, the costs and benefits of the proposed rule cannot be assessed properly.

EPA Response: The EPA disagrees with the commenter's erroneous statement that the agency did not consider whether studies were relevant to the U.S. general population. First, please see section 4.2.2 of the EPA response in this *Response to Comments* document and the EPA Response to this commenter (Doc. #1774, SBC- SBC-053296 in section 4.2.2.2.4 in this *Response to Comments* document) below. As a further example, one factor the agency considered when selecting critical studies for candidate RfD derivation was whether the serum PFOA or PFOS concentrations reported in the population examined in each study were comparable to serum PFOA or PFOS concentrations reported in the U.S. general population (see Section 4.1 of the toxicity assessments (USEPA, 2024d; USEPA, 2024c)). However, unless there are data available indicating that a non-U.S. study population may not be relevant to the U.S. population, it would not be best practices for the agency to exclude that study from the assessment or quantitative analyses.

For discussion of the methodology utilized for the economic analysis, including the various robust, peer-reviewed approaches for estimating benefits, please see the economic analysis for this final PFAS rulemaking action and section 13 of the EPA response in this *Response to Comments* document.

New Hampshire Department of Environmental Services (NHDES) (Doc. #1690, SBC-044337 & SBC-044338)

Comments by New Hampshire Department of Environmental Services (NHDES) For the Proposed PFAS National Primary Drinking Water Regulations

Docket ID No. EPA-HQ-OW-2022-0114

Published March 29, 2023, Pages 18638-18754

May 30, 2023

1. Page 18729, Column 3, Section V – Maximum Contaminant Level Goal

a. Section V, Part A.2c. Page 18,660, Column 1, 1st Paragraph - EPA is seeking comment on the derivation of the proposed MCLG for PFOA, its determination that PFOA is Likely to be Carcinogenic to Humans and whether the proposed MCLG is set at the level at which there are no adverse effects to the health of persons and which provides an adequate margin of safety. EPA is also seeking comment on its assessment of the noncancer effects associated with exposure to PFOA and the toxicity values described in USEPA (2023b).

Section V, Part B.2c. Page 18,663 Column 2, 1st Paragraph - EPA is seeking comment on the derivation of the proposed MCLG for PFOS, its determination that PFOS is Likely to be Carcinogenic to Humans and whether the proposed MCLG is set at the level at which there are no adverse effects to the health of persons and which provides an adequate margin of safety. EPA is also seeking comment on its assessment of the noncancer effects associated with exposure to PFOS and the toxicity values described in USEPA (2023c).

NHDES Comment - We applaud US EPA for reevaluating the human health risk assessments (HHRAs) of PFOA and PFOS since its prior assessment in 2016. The current HHRAs included in the proposed rule incorporated several new studies, as well as re-evaluated and reinterpreted previous animal toxicity studies and human epidemiological studies cited in the 2016 assessment (EPA, 2016). The re-evaluations recommend new Reference Doses (RfDs) and Cancer Slope Factors (CSFs) for PFOA and PFOS. We request that EPA provide additional clarification for several components of its HHRAs for PFOA and PFOS.

Relative to the non-cancer HHRAs (Page 18656, Column 2), EPA provided extensive details to support its benchmark dose model to derive the points of departure (PODs) for PFOA and PFOS. However, there remains a lack of clarity around EPA's justification for assuming the populations in several of the studies, especially the Faroe Island population, are representative of the broader population and not already representative of highly sensitive segments of a general population. While some might dispute the use of these study populations entirely, we do not agree that such confounding is justification for complete dismissal of epidemiological findings from uniquely designed studies. However, we are suggesting that EPA clarify its justification of assuming these populations are representative of the broader populations relative to the selection of benchmark responses. Improved transparency around EPA's interpretation of its own guidance for these chemicals will improve confidence in the recommendation for PFOA, PFOS, other PFAS, and likely other chemicals that EPA could apply such interpretations to. In a similar theme, EPA could improve clarity by providing examples of other contaminants where it has applied similar benchmarks to epidemiological studies with similar confounding factors.

EPA Response: The commenter supports the conclusions of the EPA's toxicity assessments for PFOA and PFOS but requested clarification on the EPA's rationale for study selection. The commenter particularly highlighted the study reporting reduced antibody response in Faroese children, specifically seeking clarification on representativeness of the study population. Descriptions of the EPA's considerations for other antibody response studies during study selection are provided in section 4.2.2 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1774, SBC-053296 in section 4.2.2.2.4 in this *Response to Comments* document and Doc. #1774, SBC-053430 in section 4.2.1.4 in this *Response to Comments* document. Additionally, the EPA outlined considerations for selecting studies for dose-response analysis in the draft and final toxicity assessment appendices (USEPA, 2023f; USEPA, 2023a; USEPA, 2024a; USEPA, 2024b; see Section A.1.11.1). At the time of rule proposal, there were a limited number of studies examining antibody responses in children from the United States, and those providing estimates of changes in antibody response in children did

not provide enough data to include in dose-response modeling (e.g., Pilkerton et al., 2018). Since publication of the draft toxicity assessments, a study reporting anti-rubella immunity in U.S. children has also been published, further supporting and strengthening the potential relevance and weight of evidence of antibody response as an endpoint for the U.S. population (Zhang et al., 2023). The EPA has since quantitatively considered this new study for POD derivation, as described in Section 4 and Appendix E of the Final Human Health Toxicity Assessment for PFOS (USEPA, 2024c; USEPA, 2024b).

4.2.2.2.4 Use of Studies Reporting NHANES Data

3M Company (Doc. #1774, SBC-053288)

(2B) Lack of appropriate analytical techniques when using NHANES to create population metrics

As described above, proper analysis of NHANES data requires the use of sample weights to produce correct estimates of means, percentiles, and other descriptive statistics. As acknowledged in an EPA supporting document (see e.g. page F-23 of USEPA 2023b) many of the papers forming the foundation of the potential association between PFOA/PFOS and serum cholesterol did not clearly indicate whether the required NHANES sampling weights were used in their analyses. Despite EPA acknowledging this fact, EPA did not appropriately classify these publications for study quality (see e.g., Figure 3-34 on pages 3-159 through 3-161 of USEPA, 2023d). Subsequent analyses use a number of studies with study quality (high/medium/low) as a metric for the degree of confidence that can be attributed to the study finding (see e.g. Table 3-8 on pages 3-185 through 3-189 of USEPA 2023d). EPA, for example when reviewing the Dong et al. 2019 study, ignored good data and statistical practice when assigning quality scores. An independent analysis of Dong et al. indicates the analysis approaches and data practices used by Dong were flawed and the findings unsupportable. See Section 6.5).

EPA Response: The commenter asserted that the EPA's study quality evaluations did not account for sampling weights for studies that used NHANES data. The EPA disagrees with this comment and points out that the Analysis domain specifically notes when weights were used in analyses (see Appendix A (USEPA, 2024a; USEPA, 2024b)). The EPA did not receive an independent analysis of Dong et al. (2019) from the commenter and therefore, the EPA cannot respond to the commenter's claims about this study. Further consideration of the EPA's use of Dong et al. (2019) study results are provided in section 4.2.2 of this *Response to Comments* document and the EPA response to comment Doc. #1774, SBC-053296 in section 4.2.2.2.4 in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-053207)

i. EPA relied on studies that used outdated and uncorrected NHANES data and did not conduct its own analysis or verify data accuracy

Many of EPA's conclusions related to non-cancer health impacts rely on previously published papers that used data sets that were ultimately rejected by the National Health and Nutrition Examination Survey (NHANES), the reporting entity, because they did not meet NHANES data quality requirements. EPA has largely relied on previously published statistical relationships between PFAS compounds and health outcomes that rely on NHANES data. NHANES regularly updates all its datasets, which in turn affects any previous quantitative analyses.72 In 2021 and 2022, the NHANES Biospecimen Program processes were reevaluated to monitor quality control after a procedural error was identified. Following a comprehensive review of all surplus sample datasets generated between 1999 and 2018, NHANES modified certain data files to remove 15-20% of PFAS records that were initially included in error because it said that data did not meet program standards. Revised files were released in April 2022 (CDC 2022). 73

While EPA notes the possibility of NHANES data updates, without conducting additional analyses, EPA cannot understand the ramification of these updates. EPA has not provided details on the data used in its analyses, or the year class of the data and it is thus very likely that EPA findings using NHANES are based on uncorrected data. Best practice is for EPA to provide details on the data updates incorporated into its models.

In short, any and all previously published analyses EPA relies on that use NHANES PFAS data contain an unknown number of errors, which invalidates the published statistical relationships.

EPA Response: The commenter misleadingly implied that all the analyses considered by the EPA for its "conclusions related to non-cancer health impacts" relied on datasets "rejected" by NHANES because they allegedly did not meet data quality requirements.

The commenter noted that NHANES updates its datasets and cited revised files published by the Centers for Disease Control and Prevention (CDC) in April 2022, which removed "15-20% of PFAS records." The commenter incorrectly implied that this had a large impact on data reported for PFOA and PFOS. In actuality, as the CDC/National Center for Health Statistics (NCHS) program states, "no data values were altered" as a result of this removal (e.g., see https://wwwn.cdc.gov/Nchs/Nhanes/2017-2018/SSPFAS_J.htM). The revisions affected various, but not all, NHANES cycles between 1999-2019 and "survey weights were adjusted" (https://www.cdc.gov/exposurereport/whats_new_121522_1.html). Data for PFOA and PFOS were not necessarily impacted by these revisions. In fact, "for each analyte included in this data file, it was determined that overall and for stratified sex, age, and race/Hispanic origin groups, the updated file using the new sample weights resulted in an estimate within the 95% confidence limit calculated using the original file and sample weights," which does not refer to PFAS serum concentrations at all. Thus, the EPA concluded that the presented data met agency data quality standards.

The commenter also claimed that CDC/NCHS revisions in 2021-2022 mean that data published before these revisions were inaccurate. According to the summary provided by CDC on the NHANES website linked by the commenter, revisions were only made to update rounding for imputed 2-(N-Methyl-perfluorooctane sulfonamido) acetic acid values (see

https://www.cdc.gov/exposurereport/whats_new_121522_1.html). These revisions were applied to the 1999-2000 and 2003-2004 cycles. Adjustments were not made to either PFOA or PFOS data; thus, the commenter's assertion that analyses were based on uncorrected data is not factually correct.

The commenter lastly incorrectly claimed that the EPA did not provide information on what NHANES data were used in its analyses. On the contrary, the EPA provided information on NHANES data included in dose-response analyses in Appendix E of the draft and final toxicity assessments for PFOA and PFOS (USEPA, 2023b; USEPA, 2023c; USEPA, 2024a; USEPA, 2024b). For example, section E.1.2 of PFOA Appendix E relays how PFAS biomonitoring data from cycle 2015-2016 of NHANES was used in dose-response analyses for LBW (USEPA, 2024a). Section E.1.3 in PFOA Appendix E describes the use of the updated NHANES data in dose-response analyses of cholesterol levels (USEPA, 2024a). Finally, section E.1.4 outlines the use of NHANES data in dose-response analyses for liver outcomes (USEPA, 2024a). All of the necessary information was provided for the commenter to understand how NHANES data were incorporated into the analyses. The EPA also notes that the MCLGs for PFOA and PFOS were not ultimately based on NHANES analyses, so the commenter's concerns regarding NHANES data are irrelevant to the MCLGs derived as part of this NPDWR (see section 4.1.5 of the EPA response in this *Response to Comments* document).

3M Company (Doc. #1774, SBC-045700)

The United States Environmental Protection Agency (EPA) has published a series of quality control (QC) and best practice guidelines for program development and project development (USEPA 1992, 2002), data quality objectives (USEPA 2003, 2006), and good statistical practice (USEPA 2006). EPA has also published approved methods and software for calculating benchmark doses (BMD) and their uncertainty (USEPA 2012, 2022) which have been developed into an interactive web site. These guidelines are intended to ensure that the resulting decisions made by EPA meet standards based on the best available science, including reproducibility of results, appropriate data treatment, ensuring representative data, and accurate identification and quantification of true risk to human populations and environmental metrics.

However, the methods and procedures used by EPA to support the National Primary Drinking Water Regulation Rulemaking (the "Proposed NPDWR") did not follow these established procedures, and lack good data practice, good statistical analysis practice, consistency of methods and models, and the ability to replicate analytical results.

In the following sections we provide specific examples of where EPA is lacking good practice in its selected quantitative approaches and provide examples of inappropriate practices and issues not addressed by EPA in the proposed rule.

Below, we demonstrate key statistical issues in the Proposed NPDWR using references to the rulemaking and supporting documents, describe how the issues impact the validity of the

Maximum Contaminant Level (MCL), reference EPA support documents with examples, explain that EPA is required to meet its own guidance and specifications, and provide examples from National Health and Nutrition Examination Survey (NHANES) illustrating the issue.

Background on NHANES

NHANES is a program of studies administered by the Centers for Disease Control and Prevention (CDC) to produce vital and health statistics for the United States. Since 1999, this cross-sectional survey has been a continuous program that examines a nationally representative sample of about 5,000 different people each two-year sampling period (located in 15 counties across the country). NHANES collects demographic, socioeconomic, dietary, and health-related data and conducts a comprehensive medical examination which consists of blood work, dental, and physiological measurements. Beginning with NHANES 1999–2000, PFAS and associated compounds have been measured in some (but not all) NHANES participants. NHANES employs a multiyear, stratified, clustered design to create a nationally representative sample of the US civilian, noninstitutionalized US population; however, NHANES purposely oversamples certain demographic groups to increase the reliability and precision of health status indicator estimates for those groups. This survey design results in each sampled person not having an equal probability of selection and thus sample weighting is needed to produce correct population estimates of means, percentiles, and other descriptive statistics.

Lack of appropriate analytical techniques when using NHANES data

As described above, proper analysis of NHANES data requires the use of sample weighting variables to produce correct estimates of means, percentiles, and other descriptive statistics. EPA acknowledged in its supporting document "Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation Appendices" (see (USEPA 2023b), page F-23) that many of the papers forming the foundation of EPA's analysis ofthe relationship between PFAS and serum cholesterol did not clearly indicate whether the required sampling weights were used in their analyses. Despite acknowledging this fact, EPA did not give these publications appropriate classifications for study quality (*see e.g.* Figure 3-34 on pages 3-159 through 3-161 of (USEPA 2023d)). EPA chose studies where data analyses did not meet EPA guidance and good practice guidelines. Therefore, these studies were of low quality. Subsequent analyses by EPA in the support documents use the number of studies with study quality (high/medium/low) as a metric of certainty of the relationship (*see e.g.* Table 3-8 on pages 3-185 through 3-189 of (U.S, 2023d)), giving an incorrect sense of the relationship between PFOS concentrations and cholesterol.
We highlight these misclassification errors of study quality for cholesterol but the same issue applies to any and all analyses that include NHANES data without confirming use of appropriate sample weighting variables and must be corrected.

EPA Response: The commenter claimed that the EPA did not follow its own guidance on best statistical and quality control practice, specifically using the EPA's treatment of NHANES

data as an example. Please see section 4.1.2 of the EPA response in this *Response to Comments* document. Additionally, the commenter stated that the EPA did not appropriately characterize NHANES studies in study quality evaluation due to lack of adjustment for sampling weights. While the EPA agrees consideration of sampling weights is an important aspect of NHANES data analysis, the EPA disagrees that these publications were not given appropriate study quality classifications. The EPA considered whether NHANES, or other studies using complex sampling strategies, appropriately accounted for sampling design in the Analysis domain (see Appendix A, USEPA, 2024a; USEPA, 2024b). Studies that did not describe their approach to address complex sampling strategies were rated as Deficient in the Analysis domain. The study quality evaluation framework was adapted from the *Systematic Review Protocol for the PFBA, PFHxA, PFHxS, PFNA, and PFDA IRIS Assessments* which notes that a reviewer's confidence judgment be made by considering all domains, and that there are "no predefined weights for the domains." (USEPA, 2021a). The IRIS Handbook further states "[w]hile limitations specific to the usability of the study for dose-response analysis are useful to note for informing those later decisions, they do not contribute to the study confidence classifications" (USEPA, 2022a). While studies that did not account for sampling strategies may not be appropriate for POD derivation, they are still informative to hazard ID. Additionally, the analytical approach to examining NHANES data is ubiquitous throughout the epidemiological literature, and a lack of description of adjusting for sampling weights does not necessarily mean they were unaccounted for in analyses.

3M Company (Doc. #1774, SBC-053290)

3. NHANES data important to PFAS and Health Outcomes are frequently changed and/or modified.

NHANES regularly updates datasets which have PFAS concentration variables, changing the values or excluding data that do not meet program standards. Some of these changes occur relatively soon after the datasets have been released and are posted on the NHANES news website (see https://www.cdc.gov/nchs/nhanes.htm and https://www.cdc.gov/nchs/nhanes/archive_new_nhanes.htm). In 2021 and 2022 the NHANES Biospecimen Program processes were reevaluated to monitor quality control after a procedural error was identified. Following a comprehensive review of all surplus sample datasets generated between 1999 and 2018, NHANES modified certain data files to remove records that were initially included in error and did not meet program standards and revised files were released in April 2022 (Source: Update to Tables Associated with Revised NHANES Biospecimen Program Data Files see https://www.cdc.gov/exposurereport/whats_new_121522_1.html)

From https://wwwn.cdc.gov/Nchs/Nhanes/2013-2014/SSPFAC_H.htm

Note: The NHANES Biospecimen Program processes were reevaluated in 2021 and 2022 to monitor quality control after a procedural error was identified. This error did not pose any risk of participant disclosure. Addressing this error resulted in the removal of some records from various stored biospecimen data files between 1999 and 2018 that did not meet program standards. After

a comprehensive review of all stored specimen datasets, this data file was modified to remove records (15-< 20% of records) that were initially included in error. No data values were altered. However, survey weights were adjusted. For each analyte included in this data file, it was determined that overall and for stratified sex, age, and race/Hispanic origin groups, the updated file using the new sample weights resulted in an estimate within the 95% confidence limit calculated using the original file and sample weights. However, not all possible analyses were performed. For any queries related to this dataset please email the Biospecimen Program at serumplasmaurine@cdc.gov.

While EPA notes the possibility of NHANES data updates, EPA does not provide details on the data used in its analyses, or the year class of the data. Additionally, EPA ignores that papers published prior to any updates must have used the incorrect values in their analyses and thus the conclusions are at a minimum inaccurate and at worst incorrect. EPA must provide details on whether and how data updates were incorporated into its models.

NHANES Cycle	PFAS Data First Published	PFAS Data Last Revised
1999-2000	Oct-06	Dec-22
2001-2002	-	-
2003-2004	Jul-07	Dec-22
2005-2006	Aug-09	Sep-12
2007-2008	Oct-10	Oct-13
2009-2010	Dec-11	Oct-13
2011-2012	Feb-14	Oct-14
2013-2014*	Jul-16	-
		Apr-22
2015-2016	Sep-18	-
2017-2018	Nov-20	-
*For 2013-2014, PFAS were in two different NHANES tables		

EPA does not provide sufficient detail on the data used in its analyses; therefore, it is difficult to know whether EPA is using outdated data. However, given the frequency of the updates in NHANES data, any and all publications that EPA is relying on and using NHANES PFAS data that have been previously published analyses contain an unknown number of errors. The ramification is that the analyses, the generated models, and conclusions based on uncorrected NHANES data are most certainly flawed. EPA must provide details on how the NHANES data updates were incorporated into its models, if they were incorporated at all and must update its analyses to use the most accurate datasets supplied by NHANES.

EPA Response: The commenter asserted that the EPA's analyses lacked detail on and used uncorrected NHANES data in its modeling. These assertions are inaccurate. The EPA provided detailed information at the time of rule proposal in Appendix E of the draft toxicity assessments for PFOA and PFOS (USEPA, 2023b; USEPA, 2023c). The EPA used "updated"

NHANES values, as specifically stated in Section E.1.3.1. (USEPA, 2023b; 2023c). Further other consideration on the EPA's use of NHANES data and evaluation of quality for studies using NHANES data are provided in section 4.2.2 of this *Response to Comments* document, as well as the EPA response to comment Doc. #1774, SBC-053207 and Doc. #1774, SBC-053296 in section 4.2.2.2.4 in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-053456)

Some studies use publicly available information, such as NHANES, and so the data should be accessible to EPA for re-analysis. For example, EPA stated that it "re-analyzed the data using the regression models from the Dong et al. (2019; 5080195) study, together with updated NHANES data, applied to a modified hybrid model" (EPA 2023a, p. E-298; EPA 2023b, p. E-26). However, EPA does not clearly document the methods regarding reanalyses and it appears that EPA obtained the updated coefficients from correspondence with the authors of Dong et al. (2019) rather than through re-modeling (EPA 2023a p. E298; EPA 2023b p. E-26). EPA states that, for its re-analysis "An important caveat is that these calculations assume that Dong's regression model is still applicable, or at least a good approximation, for all the time periods, for all adults and for adults taking cholesterol medications, and for the recently updated NHANES data." (EPA 2023a p. E-298; EPA 2023b p. E-26), which indicates a lack of re-analysis of the underlying data and development of models, de novo. EPA did not provide additional justification for why it did not re-analyze the publicly available data. Re-analysis of the underlying data, including application of non-linear models, may provide additional insight into the uncertainties regarding dose-response relationships. A full re-analysis of the NHANES data would bolster EPA's uncertainty analysis (described in Section 7) and may provide further justification or confidence in EPA's non-traditional use of regression coefficients for BMD(L) derivation.

EPA Response: The commenter incorrectly claimed that the EPA did not utilize publicly available NHANES data in the re-analysis of data used in the regression models published by Dong et al. (2019) and suggested that the EPA did not re-analyze the data using models from Dong et al. (2019). The EPA disagrees with these comments and the quotes provided by the commenter appear to be interpreted incorrectly. The EPA corresponded with Dong and colleagues to obtain the necessary details to build the same models for re-analysis (i.e., "After correspondence with the study author", USEPA, 2023b, Sec. E.1.3.1). The EPA obtained updated NHANES data (i.e., "together with updated NHANES data", USEPA, 2023b, Sec. E.1.3.1) which included NHANES cycles that were not included in the analysis reported by Dong et al. (2019). Dong et al. (2019) utilized NHANES data from 2003–2014 while the EPA expanded the scope of this analysis and provided analyses for the periods of 1999–2008, 2003–2014, 2003–2018, and 2017–2018, which is presented in Appendix E in contrast to the commenter's claims that the EPA did not document the reanalysis (USEPA, 2023b; USEPA, 2023c; USEPA, 2024a; USEPA, 2024b). Additionally, all data was updated data drawn directly from NHANES, a publicly available source. The quoted caveat provided by the commenter was added to address the point that the model used in Dong et al. (2019) was built using the 2003–2014 data, and an

assumption was made that the model was still a good approximation for other NHANES time periods considering all data were from the same source and collected in the same manner.

4.2.2.3 The EPA's Benchmark Dose (BMD) Modeling Approaches

3M Company (Doc. #1774, SBC-053230)

e. Significant Uncertainty in Benchmark Dose (BMD) Derivation Approaches Preclude Confidence in the Risk Values Calculated by EPA for Non-Cancer Endpoints

EPA also violated best practices and its own guidance when it failed to independently model and verify the underlying analyses to increase confidence and transparency in the BMDL derivation of each co-critical effect. Properly conducting BMD analysis is critical because the points of departure derived from the BMD analysis are the basis of EPA's proposed non-cancer RfDs. EPA does not transparently describe its process for key study selection or the impact of uncertainties in BMDL derivation arising from 1) the lack of consideration of pooled analyses, 2) reliance upon modeling assumptions, 3) model selection; or 4) benchmark response (BMR) 79 selection. These issues are discussed below and in detail in Appendices A and B.

i. EPA was not transparent and consistent in selecting key studies and models for BMD derivation

EPA's IRIS handbook and risk assessment best practice requires that the process for selection of key studies for use in BMD and BMDL derivation be clearly described, including identifying data quality objectives to ensure consistency and transparency. But here EPA did not propose data quality objectives, and it did not follow requirements for data quality assurance. As EPA itself has noted "[t]he strength of the DQA is that it is designed to promote an understanding of how well the data satisfy their intended use by progressing in a logical and efficient manner." (USEPA 2000c, p. 0-3). As a result of this process failure, key studies had critical deficiencies that preclude confidence in their findings and the subsequently derived regression coefficients or BMD(L)s. Dose-response models and BMD(L)s derived from poor quality or limited studies may not accurately describe the true exposure-response relationship and will therefore lead to inaccurate PODs and uncertainty in RfD derivation.

Additionally, when provided with multiple models from a given study or dataset, EPA provides minimal and inconsistent justification for selection of a single model for POD derivation. For some endpoints, EPA does provide limited justification for selection of individual models within a study; however, these justifications (e.g., selection based on p-values) are not statistically defensible nor do they align with EPA guidance for model selection (USEPA 2012). Other justifications, such as stated confidence in the BMDL or potential for confounding, are not transparently defined or consistently applied. As the range of BMD(L)s both within and among studies for a given endpoint can be uncertain, it is critical for the EPA to show a transparent model selection process to increase confidence that the POD is representative of the exposure-response and not biased towards an overestimation of risk. In other words, EPA's lack of

transparency in how it selected models could lead EPA to rely on models that overestimate risk or select PODs that are highly uncertain. In addition to the lack of transparent study and model selection, EPA did not validate or compare BMD(L)s derived from individual studies with BMD(L)s derived from pooled regression coefficients (when available). This issue is discussed in detail in Appendix A.

ii. EPA's BMD values have a high level of uncertainty

For derivation of BMD(L)s, EPA used a non-standard approach and relied on previously developed models or pre-defined regression coefficients as presented in the published literature. The use of non-standard approaches violates EPA's own guidance and means that its analyses do not accurately reflect the true underlying dose-response relationships. Traditionally, benchmark dose modeling is conducted by fitting dose-response models to mean or proportional responses at given exposures; EPA's (2012) BMDS guidance is designed for these traditional dose-response models. EPA did not independently validate or verify the published regression coefficients, nor did it transparently report the details of BMD modeling from the candidate studies. Key modeling information, as recommended in EPA's benchmark dose modeling guidance (USEPA 2012), is consistently absent from the published models, including analyses of model shape, model fit, the distribution or variance of the regression coefficients, and background [P(0)] responses. EPA did not critically evaluate the underlying response data to fill gaps in reporting of the modeling approaches or results. Therefore, EPA relied on assumptions regarding model shape, model fit, coefficient variance, model distribution, confounding, and background (or "zero-exposure") responses. Without verification of these factors, EPA cannot confirm that its assumptions are reasonable approximations of the underlying data, nor can it confirm that the estimated BMD(L)s accurately describe the dose-response. Moreover, EPA derived BMD and BMDLs from models with non-significant exposure parameters and with no consideration of model fit. EPA's benchmark dose guidance (USEPA 2012) states that modeled datasets should, at minimum, have a statistically or biologically significant dose-response trend. This issue is discussed in detail in Appendices A and B.

iii. EPA failed to demonstrate that use of a non-standard BMD approach is biologically appropriate

EPA discusses uncertainties in the draft toxicity assessments for PFOA and PFOS introduced through the use of regression coefficients (a non-standard approach) instead of response data for BMD modeling of epidemiological data. As noted above, the use of nonstandard approaches may have also led EPA to make erroneous conclusions about the relationships of exposure and effects observed in human epidemiological studies. EPA used the information from Steenland et al. (2009) to validate the use of regression coefficients; Steenland et al. (2009) was selected due to the accessibility of the mean response information underlying the regression coefficients. EPA states that the difference in BMDLs generated through use of regression coefficients instead of mean response information is less than 3-fold different and therefore acceptable; EPA has not, however, demonstrated that this relationship is consistent across PFAS compounds, endpoints, studies, or publicly available information such as NHANES. EPA did not evaluate additional

datasets with the raw data or mean response information in order to quantitatively justify that the BMDLs generated through this nontraditional approach are comparable to those generated through use of mean response information. Some of the publications relied upon by EPA, including the key study for total cholesterol (Dong et al. 2019), are based on NHANES or other publicly available information and, as such, further sensitivity analyses should have been performed using these additional studies and endpoints to provide confidence in the approach used to derive BMD(L)s for PFOA and PFOS. The uncertainty analysis conducted by EPA is not sufficient for validating its use of regression coefficients instead of response data. This issue is discussed in detail in Appendix A.

iv. EPA's BMR selections are neither adequately justified nor consistently applied

BMD modeling approaches used by EPA were non-standard and relied upon published regression coefficients. EPA did not address the inconsistency in methods and approaches used for BMD(L) calculation, nor did it thoroughly consider or evaluate the sensitivity of selected models to changes in biological cutoffs or alternative BMR assumptions. Each of the endpoints selected as critical effects by EPA (e.g., serum lipids, birth weight, and vaccine response) have widely accepted clinical cutoffs that are considered biologically significant. However, EPA did not establish that the underlying exposures are significantly associated with the measured outcomes, after accounting for confounding, or increased incidence of adverse responses such as infection or cardiovascular disease. EPA may be inappropriately applying BMRs to evaluate changes in adverse outcome probability for non-adverse effects. This means that EPA may be deriving MBDs based on arbitrary changes in responses that are not actually adverse. Additional transparency is needed in order to understand 1) the methods used by EPA to estimate background exposure and probability; 2) justifications for BMR selection; 3) the impact of using alternative BMRs based on clinical cut-points on BMD(L) derivation; and 4) consideration of the strength of association between exposure and response. Additionally, in order to derive studyspecific BMRs for Extra Risk, EPA relied on estimations of the study-specific intercepts of the study-reported regression coefficients, or slopes, in order to estimate response in an unexposed population; these estimations of the outcome probability in unexposed populations does not account for model uncertainty, variance in regression coefficients, or consideration of US population responses. Differences in BMR type, BMR sensitivity, and estimations of model intercepts (or hypothetical responses in unexposed populations) impact the estimation of the BMD(L) and subsequently derived RfD. This issue is discussed in detail in Appendix A.

v. EPA did not estimate the impact of modeling assumptions on derived BMDLs or how changes in these assumptions affect BMDL sensitivity

EPA used many assumptions to estimate BMD(L)s for changes in birth weight, immune response, and serum total cholesterol. Each assumption adds some quantifiable uncertainty to the derived BMD(L)s used for POD derivation. Using analyses of changes in birth weight as an example, variations in estimations of background exposure, BMR type, and background incidence of low birth weight may increase the derived BMDL by approximately 30% to 210%, depending on the study and assumptions. Uncertainty in the derived BMDLs, based on

assumptions required to conduct modeling, impacts confidence in the derived PODs. EPA did not quantify or discuss the potential uncertainty in the BMDLs used for POD derivation or the sensitivity of the BMDLs to changes in the underlying assumptions. This critical oversight means that the PODs EPA used to derive RfDs may have significant uncertainty making its assessment of non-cancer health effects unreliable. This issue is discussed in detail in Appendix A.

EPA Response: The commenter raised several concerns regarding the EPA's approaches to BMD derivation. The commenter stated that the assessments lacked transparency regarding selection of studies and models for POD derivation. The commenter also stated that the EPA did not propose data quality objectives, and it did not follow requirements for data quality assurance, resulting in selection of low quality studies for POD derivation and increased uncertainty. The commenter additionally stated that the EPA did not compare the derived BMDLs to those derived from pooled analyses. The EPA generally disagrees with these comments and first directs the commenter to section 4.1.2 of this *Response to Comments* document.

The EPA transparently provides an explanation of the protocol for BMD derivation and study selection in Section 2.2.1 and Appendix A section 1.11.1 of the toxicity assessments for PFOA and PFOS (USEPA, 2024d; USEPA, 2024c; USEPA, 2024a; USEPA, 2024b). Detailed explanation of the study selection and modeling approaches for each health outcome category are provided in Appendix E of the assessments (USEPA, 2024a; USEPA, 2024b). Additionally, when studies presented multiple models (see Appendix E section E.1 and Section 4.1.4; USEPA, 2024d; USEPA, 2024c; USEPA, 2024a; USEPA, 2024b), models were selected based on best fit rather than p-values, as the commenter incorrectly implies. Further information on model selection for the priority health outcomes can be found in Appendix E. In response to this comment, additional details regarding study selection have been added to Section 4.1.1 of the final toxicity assessments for PFOA and PFOS (USEPA, 2024d; USEPA, 2024b).

The commenter additionally stated that the EPA did not compare the derived BMDLs to those derived from pooled analyses. First, the EPA did not have access to pooled analyses of epidemiological data for the critical outcomes considered. Reliance on deriving BMDLs based on pooled regression coefficient (which would be obtained from a meta-analysis, rather than a pooled analysis as the commenter misleadingly implies) is not a requirement of the EPA *Benchmark Dose Technical Guidance* (USEPA, 2012). Confidence in the BMDLs used by the EPA is increased by the large number of studies considered that report the same effect and result in similar BMDL values across populations, as well as the various modelling approaches considered by the agency and presented in Appendix E (USEPA, 2023b; USEPA, 2023c; USEPA, 2024a; USEPA, 2024b).

The commenter additionally stated that the EPA did not validate the use of published regression coefficients and used non-standard modeling approaches to derive BMDLs, resulting in increased uncertainty in the modeling results. The EPA disagrees that the use of "non-standard" modeling approaches led the EPA to "erroneous conclusions about the relationships of exposure and effects observed in human epidemiological studies." It appears that the commenter

misunderstands the EPA's modeling approaches for epidemiology studies detailed in Appendix E of the draft and final toxicity assessments for PFOA and PFOS (USEPA, 2023b; USEPA, 2023c; USEPA, 2024a; USEPA, 2024b). The EPA also points out the use of regression coefficients for modeling dose-response and BMD calculation is hardly a "non-standard" approach and is standard practice when using epidemiological data for risk assessment. Analyses using regression coefficients to derive PODs were sent to the SAB PFAS Review Panel for their review (USEPA, 2021b; USEPA, 2021c); the SAB did not raise this as a concern in their final report (USEPA, 2022b). In fact, the SAB provided this statement in support of consideration of regression coefficients for POD derivation: "it would seem straightforward to apply the same methodology to derive the beta-coefficients ("re-expressed," if necessary, in units of per ng/mL) for antibody responses to vaccines and other health-effect-specific endpoints. Such a coefficient could then be used for deriving PODs" (USEPA, 2022b). This approach has also been recently used in other PFAS assessments, including the EPA's draft assessment for PFDA and the approach was discussed in a subsequent peer-review report (USEPA, 2023g; USEPA, 2023h).

The EPA conducted sensitivity analyses to compare BMDs produced by the reported regression coefficients with the measured response variable (i.e., mean total cholesterol and odds ratios of elevated total cholesterol), which were presented in Appendix E of the draft toxicity assessments (USEPA, 2023b; USEPA, 2023c). These sensitivity analyses showed that BMDLs estimated using the regression coefficient and using the measured response variable were within an order of magnitude in value, which *decreased* the EPA's uncertainty in this approach. The EPA disagrees that it is necessary to show consistency of these comparisons across compounds, endpoints, studies, or publicly available information such as NHANES.

The commenter also took issue with the assumptions the EPA made about the published data when conducting BMD modeling and that the EPA "modeled data with non-significant exposure parameters." As described elsewhere in this response to comments document and as even recommended by this commenter in other sections of their comment letter, the EPA does not rely solely on statistical significance to make qualitative or quantitative conclusions in these toxicity assessments. The commenter noted that "modeled datasets should, at minimum, have a statistically **or biologically significant** dose-response trend." Thus, the EPA's reliance on studies for quantitative analyses that do not show statistically significant dose-response trends does not violate EPA guidance or methods, particularly when the EPA determined there to be biologically significant effects, as is the case for all endpoints considered for toxicity value derivation in the assessments for PFOA and PFOS (see Section 4, USEPA, 2024d; USEPA, 2024c). The commenter also stated the EPA did not verify BMD modeling conducted in the published studies which is irrelevant as the EPA independently conducted BMD modeling to derive all BMDLs and did not rely on BMDLs published in peer-reviewed journal articles and PODs in the draft or final toxicity assessments for PFOA and PFOS (USEPA, 2023f; USEPA, 2023a; USEPA, 2024d; USEPA, 2024c).

The commenter stated the EPA did not evaluate the sensitivity of selected models to changes in selected BMRs and that they did not understand "1) the methods used by EPA to estimate

background exposure and probability; 2) justifications for BMR selection and 3) the impact of using alternative BMRs based on clinical cut-points on BMD(L) derivation." All of this information was presented in Appendix E of the draft toxicity assessments (USEPA, 2023b; USEPA, 2023c). For example, the EPA provided sensitivity analyses comparing different BMR selections for each endpoint of interest (e.g., 5 percent vs. 10 percent BMR for ALT, 1 vs ½ standard deviation [SD] for antibody response), and also provided rationale for BMR selection in these sections, as well as Section 4.1.2 of the toxicity assessments (USEPA, 2023f; USEPA, 2023a). The EPA provided rationale for why the agency did or did not use clinical cutoffs to determine BMRs for each endpoint in these same sections. The EPA also provided discussion on uncertainties in BMDL derivation due to various study-specific aspects in Appendix E of the toxicity assessments by providing BMDLs derived from multiple studies, populations, sexes, and ages (USEPA, 2023b; USEPA, 2023c). As mentioned above, the EPA disagrees that statistical significance is a prerequisite for modeled datasets, for reasons outlined earlier in this response. Regarding the adversity of the selected critical effects, please see section 4.2.2 of the EPA response in this *Response to Comments* document. In response to this comment, the EPA has improved discussion on modeling approaches in the final toxicity assessments for PFOA and PFOS (USEPA, 2024d; USEPA, 2024c; USEPA, 2024a; USEPA, 2024b).

More specific responses to this commenter's concerns for particular endpoints of interest (e.g., decreased birthweight) are provided in sections 4.2.2.3.1 (antibody response), 4.2.2.3.2 (total cholesterol), 4.2.2.3.3 (ALT), and 4.2.2.3.4 (birth weight) of the EPA response in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-053432)

Significant uncertainty in benchmark dose (BMD) derivation approaches preclude confidence in the toxicity values calculated by EPA for non-cancer endpoints.

As recognized by the SAB, the dose-response modeling approaches for non-cancer endpoints were not transparent and were not robust. For example, the SAB stated:

The Panel recommends that EPA provide supplemental data from the BudtzJørgensen and Grandjean (2018) publication used for BMD modeling as well the conclusions of EPA's review of the modeling in the publication, and additional rationale for the selection of specific BMDLs from this publication. Overall, it is essential that details of the BMD modeling that forms the basis of the PODs is transparently available for evaluation of the methods, approaches, and results (EPA Response to Final SAB Recommendations 2023, p. 41).

EPA did not sufficiently address SAB comments regarding dose-response modeling for Budtz-Jørgensen and Grandjean (2018a). Further, many of the uncertainties and issues described by the SAB for this particular dataset apply generally to the dose response modeling approaches applied to all key studies and co-critical endpoints. In response to SAB comments, EPA states that "EPA reviewed and reevaluated the modeling from BudtzJørgensen and Grandjean (2018) and elected to conduct additional modeling of data from this study, the results of which are provided in

Appendix E" (EPA Response to Final SAB Recommendations 2023, p. 41). EPA did not conduct additional modeling, although EPA did adjust the Benchmark Response (BMR) and approach for calculating the BMD and BMD lower limit (BMDL) based on a re-evaluation of the published models.

As part of its re-evaluation, EPA also considered additional PODs from co-critical endpoints: low birthweight and elevated serum cholesterol. However, the applied modeling approaches do not follow EPA's Benchmark Dose Technical Guidance (EPA 2012). In its derivation of PODs for immune, birthweight, and CVD effects, EPA failed to adequately consider or transparently describe several modeling considerations, including:

1) Impact of key study selection (Section 3.1)

2) Pooled or combined data analyses (Section 3.2)

3) Assumptions made due to inadequate reporting of modeling details, including (Section 3.3):

· Model shape (e.g., appropriateness of linear assumptions)

· Model fit

· Model variance or distribution of coefficients

4) Use of p-values to support model selection (Section 3.4)

5) Descriptions of model confidence and applications to key model selection (Section 3.5)

6) Impact of BMR selection (e.g., sensitivity and type; Section 3.6)

7) Impact of "zero exposure" assumptions on extra risk calculations (Section 3.7)

8) Sensitivity analyses to compare predicted versus observed extra risk (Section 3.8)

9) Approaches for selection of a single candidate BMDL for each critical endpoint (Section 3.9)

Each of these considerations impart uncertainty into model selection and impact confidence in the derived BMD(L)s.

EPA Response: The commenter incorrectly stated that the EPA did not conduct additional modeling of data reported by Budtz-Jorgensen and Grandjean (2018). In the *Proposed Approaches* documents sent to the SAB for review in 2021, (USEPA, 2021b; USEPA, 2021c), the EPA relied on the BMDLs derived in Budtz-Jorgensen & Grandjean (2018) as draft PODs for PFOA and PFOS. In response to SAB recommendations (USEPA, 2022b), the EPA reevaluated the methods used in this study and determined that they did not align with recommended methods in the *Benchmark Dose Technical Guidance* (USEPA, 2012). The EPA then conducted independent, new (i.e., "additional") BMD modeling of data from this source to derive BMDLs that were then used to develop candidate RfDs for the immune health outcome. These efforts were documented in Appendix E.1 of the draft toxicity assessments for PFOA and PFOS (USEPA, 2023b; USEPA, 2023c). The commenter noted several other perceived issues with the

EPA's modeling approaches which are presented in more detail, along with the EPA responses, under subsections 4.2.2.3.1 (antibody response), 4.2.2.3.2 (total cholesterol), 4.2.2.3.3 (ALT), and 4.2.2.3.4 (birth weight) below.

3M Company (Doc. #1774, SBC-053433)

EPA did not follow SAB recommendations regarding use of combined data analyses relative to single study estimates in developing RfD values; this is particularly impactful given the differential findings from meta-analyses relative to individual studies.

EPA did not transparently discuss its approach for selecting key studies for model consideration based on the underlying strengths and limitations, and did not validate or compare BMD(L)s derived from individual studies with BMD(L)s derived from the pooled regression coefficients (when available). Each of the key studies used for BMD(L) modeling has some uncertainty or deficiency tied to study design and analysis, limiting confidence in individual models. The SAB reflected this limitation in their recommendation that "the final choice of the health-effect specific RfDs and the overall RfD consider the strength and limitations of the data upon which each is based. A metaanalysis approach also should be considered" (EPA Response to Final SAB Recommendations 2023, p. 38).

In response to the SAB, EPA stated that it "performed a meta-analysis to evaluate associations between PFOA/PFOS exposure and effects on serum lipids, specifically total cholesterol (TC) and high-density lipoprotein cholesterol (HDLC). EPA also considered available meta-analyses while evaluating evidence of the associations between PFOA/PFOS and other health outcomes considered… EPA incorporated the results of recent meta-analyses as another line of evidence considered in the evidence integration" (EPA Response to Final SAB Recommendations 2023, p. 39). The findings of EPA's 2021 meta-analysis on serum lipids were not presented in the Draft Toxicity Assessment nor were the regression coefficients reported in the meta-analysis results considered for BMD(L) derivation.

Additionally, EPA did not consider or discuss for BMD(L) derivation pooled regression coefficients reported by meta-analyses on the effects of PFOA and/or PFOS on birthweight (Johnson et al. 2014; Verner et al. 2015; Negri et al. 2017; Steenland et al. 2018; Dzierlenga et al. 2020, as described in EPA 2023a, Table A-42 p. A-127 to A-128 and EPA 2023b, Table A-42 p. A-150 to A-151). As noted in the EPA's 2012 BMD Technical Guidance, "combining several datasets may be an option" (EPA 2012, p. 14). However, EPA did not explain its decision to evaluate individual studies instead of the pooled estimates that incorporate broader populations, increased dose ranges, and increased sample size. Although comparisons in the linear slope estimates of the EPA meta-analysis with those from Dong et al. (2019) and Lin et al. (2019) are presented in the Economic Analysis (Appendix K, Table K-3, p. K-5) in order to "assess the effects of using a key single study approach versus the meta-analysis approach to inform the exposure-response estimates" (EPA Response to Final SAB Recommendations 2023, p. 73), these comparisons neither account for the uncertainty in the slope estimates nor provide

justification for use of individual studies in lieu of the meta-analytic slope estimate for risk assessment purposes. This lack of consideration is a critical deficiency of the analyses, as the uncertainty in slope or variability in study selection may have significant impacts on BMD(L) and RfD derivation.

EPA Response: The commenter incorrectly stated that the EPA did not consider SAB recommendations to consider "combined" data analyses rather than single study estimates when deriving RfDs. Regarding how the EPA responded to SAB comments, please see section 4.1.3 of the EPA response in this *Response to Comments* document and the EPA's Response to SAB Comments document (USEPA, 2023d). Specifically, the EPA refers the commenter to response I.E5B.2 which discusses the EPA's meta-analysis for serum lipid effects (USEPA, 2023d). The EPA reiterates that the SAB stated, "A meta-analysis approach also *should be considered*," which the EPA has done; the SAB did not recommend a meta-analysis approach over single study estimates (USEPA, 2022b). The SAB similarly did not recommend the EPA "validate" BMDLs derived from single studies to BMDLs derived from "pooled regression coefficients," as incorrectly implied by the commenter (USEPA, 2022b).

The commenter additionally stated that the EPA did not provide justification for selecting PODs from individual studies over PODs derived from meta-analyses. The EPA has subsequently updated the final toxicity assessments for PFOA and PFOS and notes that the results from meta-analyses were not selected for POD derivation for several reasons, including lack of available meta-analyses for certain critical health outcomes, and uncertainty introduced when re-expressing regression coefficients based on combined analyses of multiple studies (e.g., estimated in the log-scale) to the normal scale for BMD and BMDL estimation (USEPA, 2024d; USEPA, 2024c). Additionally, in other analyses supporting this rulemaking, the EPA did use results from meta-analyses (see USEPA, 2024e). The EPA also refers the commenter to Appendix E.1.5 of the toxicity assessment for PFOA which outlines comparisons between pooled and single study CSF estimates (USEPA, 2024a).

The commenter briefly reiterated their assertion that the EPA did not adequately describe its approach for selecting key studies for model consideration, which are presented as more detailed comments, along with the EPA responses, under subsections 4.2.2.3.1 (antibody response), 4.2.2.3.2 (total cholesterol), 4.2.2.3.3 (ALT), and 4.2.2.3.4 (birth weight) below.

3M Company (Doc. #1774, SBC-053434)

The BMD values generated by EPA are associated with a high level of uncertainty; EPA should better address SAB recommendations, re-assess, and re-model BMD analyses to characterize and reduce uncertainties in model parameters, fit, and variance resulting from model assumptions.

As stated by the SAB, "it is essential that details of the BMD modeling that forms the basis of the PODs is transparently available for evaluation of the methods, approaches, and results" (EPA Response to Final SAB Recommendations 2023, p. 41). For derivation of BMD(L)s, EPA relied on previously developed models or pre-defined regression coefficients as presented in the

published literature. Although EPA responded to the SAB that "Based on recommendations from the SAB, EPA reviewed and reevaluated the modeling from Budtz-Jørgensen and Grandjean (2018) and elected to conduct additional modeling of data from this study" (EPA Response to Final SAB Recommendations 2023, p. 41), EPA did not conduct additional modeling of the Faroe Islands cohorts. "Regression coefficients (β) and their standard errors (SE) were computed by EPA from the published BMDs and BMDL based on a BMR of 5% decrease in the antibody concentration in Table 1 of Budtz-Jørgensen and Grandjean (2018, 5083631)" (EPA 2023a, p. E-269; EPA 2023b, p. E-1). EPA did not independently validate or verify the published regression coefficients using raw or mean response data from Budtz-Jørgensen and Grandjean (2018a), nor has it transparently reported the details of the BMD modeling based on this study. Additionally, EPA did not transparently report the details of BMD modeling from the candidate studies for other critical endpoints, including changes in serum TC or LBW.

Many of the key studies and published models used by EPA do not report critical modeling information, including analyses of model shape, model fit, or the distribution or variance of the regression coefficient. Despite EPA (2012) guidance, EPA did not critically evaluate the underlying response data to fill gaps in reporting of the modeling approaches or results. As stated by EPA BMD Guidance (2012), "for data evaluation in general, data (responses and doses) should be validated to the extent possible. For example, the original source should be examined, if possible, and any deliberate omissions of dose groups or subjects by the authors should be recognized and their basis understood." (EPA 2012 p. 14). Without validation of the modeling approaches and considerations, EPA may continue to replicate errors or omissions made in the original publications relied on for POD derivation. The lack of independent model validation, lack of access to information regarding the underlying data and model distributions, and lack of evaluation of the impact of these uncertainties limits confidence in the derived PODs.

Ideally, EPA would use raw or mean response data in order to perform independent doseresponse analysis. EPA BMD guidance states that, "from a modeling standpoint, the most desirable form for [continuous] data is by individual" (EPA 2012, p. 27). However, without access to the raw data, use of individual data is not possible and EPA used the uncertain regression coefficients instead. EPA noted, "BMD modeling of regression coefficients results in a nontraditional BMD, where the BMR is associated with a change in the regression coefficient of the response variable rather than the measured biological response variable. As a result, there is some uncertainty about the biological relevance of this non-traditional BMD associated with a regression coefficient." (EPA 2023a, p. 6-16; EPA 2023b, p. 6-14). EPA determined to use regression coefficients for POD derivation because it asserts that they are associated with changes in biological response and are biologically meaningful. EPA used uncertainty analyses in an attempt to address uncertainties regarding the biological relevance of the non-traditional BMD. However, as described further in Section 7, the uncertainty analysis (which evaluates the impact of using regression coefficients in lieu of response variables) is limited in scope and does not convincingly show concordance between BMD(L)s derived from the two approaches.

EPA Response: The commenter repeated their claims regarding modeling of Budtz-Jorgensen and Grandjean (2018), which the EPA responded to in the response to comment Doc. #1774, SBC-053432 in section 4.2.2.3 in this *Response to Comments* document. The commenter briefly reiterated concerns that the EPA did not adequately describe its approach for modeling critical studies, which are presented as more detailed comments, along with the EPA responses, under subsections 4.2.2.3.1 (antibody response), 4.2.2.3.2 (total cholesterol), 4.2.2.3.3 (ALT), and 4.2.2.3.4 (birth weight) below.

Responses to the commenter's repeated concerns regarding the EPA's use of summary statistics provided by peer-reviewed journal articles when conducting BMD modeling is also presented in these sections. Notably, if the EPA was able to derive RfDs from the critical studies, then all "critical modeling information" was provided, in contrast to the commenter's claims. If critical modeling information was missing, the EPA would not have been able to derive RfDs from those studies. This was actually the case for some *high* and *medium* confidence studies, which are discussed in Section 4.1 of the final toxicity assessments for PFOA and PFOS (USEPA, 2024d; USEPA, 2024c).

Regarding the EPA's use of the best available science and EPA guidance in these assessments, please see section 4.1.2 of the EPA response in this *Response to Comments* document. The commenter claimed that the EPA did not follow the *Benchmark Dose Technical Guidance* (USEPA, 2012) when deriving PODs, but provided an example, "deliberate omissions of dose groups or subjects by the authors should be recognized and their basis understood," that does not apply to any of the studies selected for POD derivation in these assessments (USEPA, 2024d; USEPA, 2024c; USEPA, 2024a; USEPA, 2024b).

3M Company (Doc. #1774, SBC-053435)

Because of its reliance on the published literature, EPA makes assumptions in the doseresponse modeling that stem from limitations in study reporting. Specifically, when using the reported regression coefficients as the basis for BMD(L) derivation, EPA must accept the assumption that a linear dose-response is most appropriate and therefore extrapolate risk estimates based on those linear assumptions. One exception includes the BudtzJørgensen and Grandjean (2018a) analyses, which include both linear and piecewise-linear models; the authors state that a logarithmic function was attempted "however, the steep slope at very low doses may be biologically implausible, and the logarithmic curve did not show a better fit to the data compared to the piecewise linear shape" (Budtz-Jørgensen and Grandjean 2018a). Without additional information regarding the underlying data or mean response, EPA cannot consider additional non-linear dose-response shapes that may better reflect the proposed mechanisms of action for each critical endpoint. EPA did not discuss available mechanistic information to inform or support the appropriateness of the linear dose-response shape assumptions. Linear models may be either under- or over- predicting risk, depending on the mechanism of action. Current methods in benchmark dose modeling are moving away from selection of single dose-response models and are instead moving towards the use of Bayesian Model Averaging (BMA) In order to account for

uncertainties in model determination and to reflect the underlying distribution of possible models (e.g., EFSA 2022). EPA guidance for BMD assessment notes that model averaging is a useful tool for "synthesis of risk estimates" and "may help to account for the impact of model uncertainty on risk estimates" but urges selection of a single "well-fitting and plausible model" due to challenges in application of model averaging (EPA 2012, p.36). Re-analysis of either the raw data or the mean response attributed to specific doses or dose ranges would enable EPA to consider multiple dose-response relationships with model averaging approaches to better reflect intra- and inter-model uncertainties.

An additional limitation in the approach used by EPA is the lack of consideration of model fit, especially in the region of the BMR and BMD(L). In response to an inquiry by EPA, the study authors have provided unpublished information and analyses, including relevant SAS code and model output for the linear and piecewise linear models shown in BudtzJørgensen and Grandjean (2018a). Notably, the model outputs (provided in BudtzJørgensen and Grandjean 2018b, 2022a, 2022b) reveal that the fitted models have adjustedR 2 values ranging from 1.0 – 3.7%, which indicates that 96-99% of the total variance in antibody response is not explained by the linear models. Furthermore, the PFAS exposures are only a subset of several predictors in the models suggesting that the percentage of variance explained by exposure alone is even smaller than 1.0-3.7%. Neither BudtzJørgensen and Grandjean (2018a) nor EPA address the low adjusted-R 2 values, and R2 information was omitted from the Budtz-Jorgensen and Grandjean (2018a) publication. Instead, EPA states that "no information was available to judge the fit of the model in the range of the BMDLs" (see e.g., EPA 2023a pp. E-274-275, E-277, E-282, E-285; EPA 2023b pp. E-5, E-8, E-13, E-16) for each of the diphtheria and tetanus response models presented by Budtz-Jørgensen and Grandjean (2018a). Given that the adjusted-R 2 values explain so little of the underlying antibody response, additional data visualizations and sensitivity analyses are needed to substantiate the modeling approach. Residual plots would be useful for assessing the existence of outliers and potentially influential observations that affect the slope (coefficient) estimates and resulting model fit. Examination of residuals and visual inspection of the fit of the models and underlying data are recommended by EPA BMD Technical Guidance (EPA 2012, p.39, 45, 50), and EPA recommends to "further reject models that apparently do not adequately describe the relevant low-dose portion of the dose-response relationship" based on those examinations (EPA 2012, p.39).

EPA Response: The commenter asserts that the EPA has to make certain assumptions about the shape of the dose-response because of reliance on the published literature. First, please see section 4.1.2 of the EPA response in this *Response to Comments* document. Additionally, the commenter themselves indicate by citing Budtz-Jørgensen and Grandjean (2018), that the published literature does report observations about the dose-response relationship. Further, analyzing the mean response data is not always feasible in epidemiology studies, unlike in most toxicology studies, hence reliance on regression slopes that come from models that might not necessarily be linear. While current methods are being developed that use Bayesian Model Averaging, these approaches are not necessarily standard approaches to agency human health

toxicity assessments, nor is there any implication they are a required consideration the *Benchmark Dose Technical Guidance* (USEPA, 2012).

The commenter stated that the EPA did not consider model fit, particularly in the region of the BMR and BMDL. The commenter claimed that the linear models do not account for 96-99 percent of the total variance in antibody response reported by Budtz-Jørgensen and Grandjean (2018). The commenter recommended additional analyses to substantiate the modeling approach, such as residual plots. The EPA disagrees with these comments as they appear to misinterpret the analyses that the EPA presented in Appendix E of the draft toxicity assessments for PFOA and PFOS (USEPA, 2023b; USEPA, 2023c).

More specifically, Budtz-Jorgensen and Grandjean (2018) fit three different model types, logarithmic, linear, and piece-wise linear models, for each PFAS and each antibody response. The EPA used the best fitting models for BMD estimation. Given that there was no indication of non-linear departure from the low-dose linear slopes, and that the BMDs and BMDLs were within the range of observed exposure values, there was no evidence of lack of fit in the low-dose region. Budtz-Jorgensen and Grandjean (2018) stated that,“"[a]ll dose-response models had normally distributed residuals with a homogeneous scatter”" This provides further evidence of support for the fit in the low-dose (i.e., BMR and BMDL) region as a lack of fit there would not be expected to yield such evidence. As such, the EPA should not reject these models as described in the *Benchmark Dose Technical Guidance* (USEPA, 2012) and does not require additional analyses to substantiate the approach.

Additionally, in the modeling the commenter describes above, R^2 is not simply a measure a model fit as the commenter seems to imply. Indeed, an R^2 statistic reflects the degree of variance in the outcome explained by the covariates in the model. Regardless of how good the model fit is, the R^2 statistic fluctuates with the number of covariates. What is important (and not reflected by the R^2 statistic) is the effect of the exposure on the outcome, adjusted for potential confounders, when modeled appropriately to ensure that the best model fits the data.

3M Company (Doc. #1774, SBC-053436)

EPA did not transparently describe its process for determining model confidence. Model diagnostic plots were not included in EPA’s draft toxicity assessments of PFOA and PFOS. These diagnostic plots would be useful to validate the model assumptions.

For some models, in order to use the reported regression coefficients for BMD(L) derivation, EPA needed to pool distributional information across cohorts, or make other assumptions regarding the standard deviation (SD) of the regression coefficients due to limitations in the author-reported coefficient variance. As noted by EPA in its 2012 guidance, “in some cases, a measure of variability is presented for the control group only and this information might be used for modeling by making an assumption, for example, that the variance in the exposed groups is the same as in the controls. However, this assumption may not be correct, and the modeling of the data and calculation of the confidence limits will not be as reliable or precise as when the

variance information is available for individual groups" (EPA 2012, p.13). Although the EPA guidance may not be directly applicable to the "non-traditional" approach used by EPA in this risk assessment, due to the lack of controls and traditional exposure groups, the risk of adding imprecision through assumptions of underlying variance still applies. As noted by BudtzJørgensen (2007), "benchmark calculations depend on a reliable estimate of the true response variation (Gaylor and Slikker 2004) and are therefore also sensitive to measurement uncertainty in the response" (Budtz-Jorgensen 2007). BMD(L)s derived for immune responses, changes in serum TC, and LBW are all impacted by these uncertainties. For example, in order to apply a BMR of 0.5 SD change in the distribution of log2 tetanus antibody concentrations reported by Budtz-Jørgensen and Grandjean (2018a), EPA pooled distributional information from two different cohorts reported by Grandjean et al. (2012, 2017). In order to derive the pooled SD, EPA made assumptions that the log2-transformed values are comparable to a normal distribution with a width of 1.35 SDs (EPA 2023a, Appendix E p. E-277). In other examples, EPA re-expressed β coefficients of Chu et al. (2020), Govarts et al. (2016), Sagiv et al. (2018), Starling et al. (2017), Wikstrom et al. (2020), and Yao et al. (2021) as a per ng/mL coefficient based on the reported study-specific medians and 25th and 75th percentiles (see summary in EPA 2023a Table E-15 and EPA 2023b Table E-13). As an example, in order to re-express the β coefficient into a usable form, EPA states that "Given the reported study-specific median…and the 25th and 75th percentiles…of the exposure from Chu et al. (2020, 6315711), EPA estimated the distribution of exposure by assuming the exposure follows a log-normal distribution… Then, EPA estimated the 25th -75th percentiles at 10 percentile intervals of the exposure distribution and corresponding responses of the β coefficient" (EPA 2023a, p. E-291-292; EPA 2023b, p. E-19). In other studies (e.g., Timmerman et al. 2021), the study findings are reported as a percent difference (given some magnitude of change in exposure) and EPA used assumptions to convert the percent change in response to an estimated slope. Although the approaches used by EPA for regression coefficient and variance estimation may be reasonable approximations, uncertainties in the BMD(L) derivation are introduced through this approach. EPA did not conduct sensitivity analyses to evaluate the impact of its pooling, transformation or re-expression of the underlying evidence on 1) the accuracy of the estimations used or 2) the sensitivity of the models to either small or large perturbations from each model assumption.

EPA Response: The commenter stated that the EPA did not provide information about how model confidence was determined and did not provide "diagnostic plots." The commenter also highlighted several quantitative assumptions the EPA made while conducting dose-response modeling of epidemiological data, incorrectly claiming that the EPA did not conduct sensitivity analyses to evaluate these assumptions and that there may be uncertainty associated with these assumptions. The commenter implied that the EPA was not following agency guidance when conducting these modeling efforts. The EPA disagrees with these assertions.

Many of the comments above are repeated by this commenter. Regarding modeling assumptions including pooled variances and percentiles, please see the EPA response to comment Doc. #1774, SBC-053296 in section 4.2.2.2.4 in this *Response to Comments* document. For discussion specific to critical studies modeled for the antibody response to vaccination endpoint and

decreased birthweight endpoint, including discussion on sensitivity analyses, please see the EPA responses in subsections 4.2.2.3.1 and 4.2.2.3.4, respectively. Regarding model confidence and diagnostic plots, see the EPA response to comment Doc. #1774, SBC-053437 in section 4.2.2.3 in this *Response to Comments* document.

Additionally, agency guidance recommends multiple approaches to data analysis in order to accommodate instances when the agency may not have the optimal data available (e.g., variance information available for individual groups; USEPA, 2012). The use of an approach using assumptions does not contradict agency guidance, nor should it be considered incorrect or flawed.

3M Company (Doc. #1774, SBC-053437)

EPA subjectively and inconsistently selected which dose-response models to carry forward in risk assessment; EPA should provide a more transparent and objective description for the selection of individual models from key studies.

When provided with multiple models for a given dataset, EPA provides minimal and inconsistent justification for selection of models within a study. EPA BMD guidance recommends provision of a rationale for study selection and for the selection of endpoints, stating, "thorough justification of the choices made to support the chosen approach and values should be presented." (EPA 2012, p.40). Similarly, EPA recommends providing the rationale for individual model selection, in addition to reporting the estimation procedure, model parameters, goodness-of-fit, log-likelihood, AIC, and standardized residuals (EPA 2012, p.40). EPA does not report these considerations in its rationales for model selection in the PFOA and PFOS documents.

In some examples, such as immune response, EPA states that it chose the models from the Budtz-Jørgensen and Grandjean (2018a) analysis that do not control for other PFAS based on a comparison of p-values for tetanus and diphtheria responses without consideration of other important factors (such as controlling for other PFAS) or model fit in the region of the BMD(L). Although EPA (2012) BMD Technical Guidance does not require or proscribe categorization of model confidence, EPA provided statements regarding its confidence in the BMD(L)s derived from some of the selected key studies; these statements are largely based on the estimated level of uncertainty in the BMD(L) attributed to confounding. However, EPA does not transparently describe its process for categorization of confidence in the derived BMD(L)s nor does it provide criteria for systematic and transparent judgment of model confidence. Additionally, EPA does not clarify how these determinations of confidence in the BMD(L) are defined or applied in the justification for model selection. Nor does EPA consistently provide these determinations of BMDL confidence for all models or endpoints (e.g., serum lipids or birth weight). The lack of transparency and consistency in EPA's approach for judging BMD(L) confidence limits may further preclude robust evaluation of EPA's decisions to select individual BMD(L)s from single studies for POD derivation.

Although there is no transparently described approach for determining model confidence, EPA does provide some limited justification for its determination of high, medium, or low confidence for the models based on the Budtz-Jørgensen and Grandjean (2018a) studies. For example, the dose-response between PFOS measured at five years and diphtheria responses was judged to be "medium" because "confidence was diminished by the potential confounding in the main effect – even though there was low confounding of the BMDL" (EPA 2023b, E-13). This statement is not informative regarding the types of confounding that are considered (by EPA) to be problematic. EPA does not provide reasoning for its judgment that the impact of confounding on the BMDL is "low", despite the knowledge that other unexplained factors play a significant role in the observed dose-response; in this example, the adjusted-R 2 of this model (see Budtz-Jørgensen and Grandjean 2018b, 2022a, 2022b) only accounts for 3% of the variability in diphtheria antibody response, regardless of whether or not PFAS is included in the model. Therefore, approximately 97% of the modeled response is explained by other factors, including potential confounders. In another example, EPA stated that confidence in the BMDLs derived from the model evaluating dose-response between PFOS measured at age five years and tetanus was "low" because "confidence was diminished by the non-significant fit for PFOS ($p = 0.12$) and stronger potential confounding in the main effect – even though there was moderate confounding of the BMDL" (EPA 2023b, E-6). EPA made a similar judgment in confidence based on the statistical significance for the POD derived from Timmerman et al. (2021); specifically, EPA states that the POD based on Timmerman et al. (2021) "is identified with lower confidence" because the BMDL is "based on a non-significant PFOA regression parameter" (EPA 2023a, p. E-279). These statements are problematic, as the statistical significance of the dose-response relationship, alone, should not be a driving factor for determination of study or POD quality. Rather, the lack of statistical significance should be considered as part of the overall weight of evidence to determine whether the endpoint is appropriate for consideration as a critical effect.

EPA did not provide transparent justifications for its judgements regarding study and BMD(L) quality, the potential for BMD(L) confounding, and the specific confounders that are being considered when making judgements regarding the potential for "low", "moderate", or "high" potential for confounding. It is assumed, based on current documentation, that EPA is using the impact of inclusion or exclusion of other PFAS in the models for determination of confounding potential, as these are the only explanatory variables that are clearly varied between models in the Budtz-Jørgensen and Grandjean (2018a) publication. EPA should not solely consider the inclusion or exclusion of other PFAS when evaluating the impact of confounding. However, if confounding by coexposure is the sole consideration when making judgments regarding the confidence in derived BMD(L)s, EPA is not applying these considerations consistently. For example, EPA judged the BMDL from the model evaluating PFOS exposures at age 5 in relation to tetanus antibodies as "low confidence" because the "effects of PFOS in the single-PFAS model are attenuated when log2[PFOA] is included in the model" (EPA 2023b, p. E-2). However, similar relationships were observed for PFOA exposures at age 5 in relation to tetanus antibodies, with EPA stating that "effects of PFOA in the single-PFAS model are attenuated when log2[PFOS] is included in the model" (EPA 2023a, p. E-270). But EPA judged the

confidence in the BMDLs of the latter comparison as "high". Therefore, EPA must consider other factors when judging confidence. Although EPA provided some partial justifications, EPA did not explicitly or transparently describe the process for deriving these judgments. Specifically, EPA notes the observed attenuation is potentially driven by confounding of PFOS on PFOA effect, however it postulates that physiological confounding (or the correlation between biomarkers measured from the same blood test) may also be a factor (see EPA 2023a, p. E-276 as an example). These additional confounders and limitations and their impact on model uncertainty and confidence are not clearly addressed.

Moreover, the confidence in the BMDLs derived from other publications for other endpoints (including the co-critical endpoints of CVD and birth weight) are not explicitly described. For example, EPA states that "Although the hybrid approach has several advantages {Crump, 1995, 2258}, few details were provided in Dong et al. (2019, 5080195) on several important aspects of this approach or on other key issues, including the definition of the unexposed reference group, the distribution of PFOS or TC values in this group, model fit (e.g., the fit of linear vs. non-linear models), the impact of potential confounders, or the potential role of reverse causality" (EPA 2023a, p.E-298;2023b p. E26). However, EPA does not provide any statement regarding the confidence in its BMD(L) derived from the models of Dong et al. (2019) and whether these limitations would reduce confidence in the derived POD.

EPA Response: The commenter asserted that the EPA provided inconsistent justification for model selection in BMD modeling. The EPA disagrees with this assertion as the agency provided modeling details and outputs for every modeled study in Appendices E of the draft PFOA and PFOS toxicity assessments (USEPA, 2023b; USEPA, 2023c). Model selection is specific to each critical outcome and each analysis, rather than a "one fits all" approach, which is why the discussion may appear inconsistent across endpoints. For transparency, the EPA added a table outlining the modeling approaches at the beginning of Appendix E of the final toxicity assessments (USEPA, 2024a; USEPA, 2024b).

After careful consideration of the commenter's point on the lack of consistent presentation of confidence in the derived PODs, to ensure the EPA's results are most readily understandable and interpretable by the scientific community, regulators, and members of the public, the EPA added descriptions of factors that could influence confidence in the derived PODs consistently across the modeled studies, including for Dong et al. (2019), in Section 4.1.4 and Appendix E of the final toxicity assessments for PFOA and PFOS (USEPA, 2024d; USEPA, 2024c; USEPA, 2024a; USEPA, 2024b) and removed language that unintentionally gave the impression of "prescribing" confidence to specific PODs. Some factors that the commenter claimed the EPA did not consider (e.g., confounding) were addressed during study quality evaluations (see Appendix A, USEPA (2024a) and USEPA (2024b)). For more information, see sections 4.1.1 and 4.1.2 of the EPA response in this *Response to Comments* document.

Regarding modeling of immune endpoints (i.e., from Budtz-Jørgensen and Grandjean (2018) and Timmerman et al. (2021)), see section 4.2.2.3 of the EPA response in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-053438)

EPA provided inadequate justification for BMR assumptions selected for its derivation of BMDLs.

EPA did not thoroughly consider or evaluate the sensitivity of selected models to changes in biological cutoffs or alternative BMR assumptions, despite its statement that they took "statistical and biological considerations into account to select the BMR" (EPA 2023a, p.4-14; EPA 2023b, p.4-13).

EPA states that it used methods for BMR selection consistent with the BMD Technical Guidance (EPA 2012). Specifically, "the BMD and 95% lower confidence limit on the BMD (BMDL) were estimated using a BMR intended to represent a minimal, biologically significant level of change. The Benchmark Dose Technical Guidance {U.S. EPA, 2012, 1239433} describes a hierarchy by which BMRs are selected, with the first and preferred approach being the use of a biological or toxicological basis to define what minimal level of response or change is biologically significant… For continuous responses, the preferred approach for defining the BMR was to use a preestablished cutoff for the minimal level of change in the endpoint at which the effect is generally considered to become biologically significant (e.g., greater than or equal to 42 IU/L serum ALT in human males {Valenti, 2021, 10369689}). In the absence of an established cutoff, a BMR of 1 SD change from the control mean, or 0.5 SD for effects considered to be severe, was generally selected." (p. 4- 14)" (EPA 2023a, p.4-14; EPA 2023b, p.4-13). Each of the endpoints selected as critical effects by EPA (e.g., serum lipids, birth weight, and vaccine response) have widely accepted clinical cutoffs that are considered biologically significant (described in detail in Section 2). For example, the World Health Organization (WHO, 2009, 2018), describes a minimum amount of circulating anti-tetanus or anti-diphtheria antibody that ensures protection from infection. This amount is dependent on the assay used to measure serum antibody levels (WHO, 2009, 2018). "It is assumed that a circulating diphtheria antitoxin level of 0.01 IU/mL, as determined by the neutralization test… provides basic clinical immunity against disease" (WHO, 2009) "whereas antitoxin concentrations of at least 0.1– 0.2 IU/mL are defined as positive [protective] when ELISA [enzyme-linked immunosorbent assay] techniques are used for the assessment" (WHO, 2018). However, because infections have occurred in people with antibody levels within the protected range, EPA made the conservative determination that "there is no accepted definition of an adverse level of change or clinical cut-off for reduced antibody concentrations in response to vaccination. Therefore, EPA performed the BMDL modeling using a BMR equivalent to a 0.5 SD change in log2-transformed antibody concentrations, as opposed to a fixed change in the antibody concentration distributions" (EPA 2023a, p. 4-15; EPA 2023b, p. 4-14). Additionally, birthweights below 2500g are clinically described as "low" by WHO (Cutland et al. 2017) and serum cholesterol >240 mg/DL is clinically considered "high" (NCHS 2019). EPA considers these clinical cutoff-points in its derivation of the BMRs and subsequent BMD(L)s for TC and birth weight effects, but not vaccine response. EPA describes the rationale for its selection of BMRs in Table 4-2 (EPA 2023a,b). However, the rationales for BMR selection for some critical endpoints are incomplete (i.e., the rationale for selection of a 5% extra risk

BMR for decreased birthweight associated with PFOA is incomplete) or poorly justified (e.g., selection of 5% extra risk because the standard BMR of 10% extra risk for TC would "result in a highly improbable doubling of risk"). At a minimum, careful descriptions of the rationale for derivation of BMRs, especially when deviating from the standard approach, and sensitivity analyses to consider the impact of consideration of clinical significance on vaccine response are needed. As an example, for changes in birthweight, use of an 0.5 SD change as the BMR instead of a 5% increase extra risk may increase the BMDL by up to 150-210%, depending on the study.

EPA Response: This comment repeats the commenter's claims that the EPA did not provide adequate rationale or follow agency guidance when selecting BMRs for dose-response modeling. The EPA disagrees and has provided substantial explanation and documentation in its peer-reviewed toxicity assessments. Please see section 4.1.2 of the EPA response in this *Response to Comments* document. Please also see the EPA response to comment Doc. #1774, SBC-053230. All rationale for BMR selection, including citations to the EPA guidance, are presented in Section 4.1.2 and Appendix E of the final PFOA and PFOS toxicity assessments (USEPA, 2024d; USEPA, 2024c; USEPA, 2024a; USEPA, 2024b).

3M Company (Doc. #1774, SBC-053439)

EPA did not account for a "zero exposure" or control group or the impact of using logarithmically transformed distributions when calculating "extra risk" BMRs.

Due to the limitations of reporting in the available epidemiolocal data, EPA may be overestimating background risk when calculating the BMR. EPA used BMRs of 0.5 SD for deriving BMD(L)s for immune responses and 5% extra risk (based on a hybrid approach) for deriving BMD(L)s based on low birth weight and increases in serum cholesterol. However, the BMR calculations are dependent on the probability or mean response at baseline, defined mathematically as "zero exposure". Therefore, EPA may not be appropriately accounting for background exposures to PFAS in their BMR and BMD(L) calculations.

Extra Risk is "a measure of the proportional increase in risk of an adverse effect adjusted for the background incidence of the same effect" (EPA 2012, p. 70). Extra risk calculated as a function of the probability of response at zero dose [P(0)] and the probability of response at a specified dose [P(d)]. The background probability [P(0)] is what is used to define the adverse response (i.e., a 5% or 10% change in probability or response from P(0)). Specifically, the equation used to estimate the BMR is:

Extra Risk = [P(d) – P(0)] / [1-P(0)]

Estimation of a BMR based on a standard deviation change in response is also based on the mean at zero dose. Specifically, a BMR based on standard deviation is defined as:

SD Response = m(0) + (BMRF x Standard Deviation)

where m(0) is the mean response at 0 dose and the BMRF is typically either 1 or 0.5, depending on the sensitivity of the chosen endpoint or BMR.

EPA acknowledges the potential impact of this assumption of zero exposure in the extra risk calculation in its comments to SAB, stating, "EPA selected the hybrid approach for POD derivation (Crump, 1995). The hybrid approach defines a benchmark response (BMR) for continuous outcomes, where the BMD corresponds to the dose yielding a specific increase in the probability of an adverse response, compared with zero background exposure [emphasis added]. The more commonly used standard deviation (SD)-definition of the BMR for continuous data is simply one specific application of the hybrid approach (U.S. EPA, 2012)" (EPA Response to Final SAB Recommendations 2023, p. 23).

EPA Response: The commenter incorrectly stated that the EPA's approach may not account appropriately for background exposures in using BMRs of 0.5 SD and 5 percent extra risk in hybrid approaches. The EPA disagrees with this comment. Please see the EPA response to comment Doc. #1774, SBC-053453 in section 4.2.2.3.4 in this *Response to Comments* document, which discusses this assertion in the context of decreased birthweight. This response applies across all endpoints for which the EPA used the hybrid modeling approach.

3M Company (Doc. #1774, SBC-053440)

For the immune and serum cholesterol effects, EPA does not describe use of an approach that is comparable to the one used for evaluating changes in birthweight; for these effects EPA does not evaluate or report the impact of background exposures on estimations of extra risk using an alternative tail probability. Calculation of an intercept based on a normal cumulative distribution function is described for the BMD(L) estimation from Dong et al. 2019; but this approach is not reproducible nor is it applied to the models for Steenland et al. (2009) or Lin et al. (2019). EPA does not describe why it considers this a potential limitation of the birth weight studies but not for other estimations of excess risk. An example of where this estimation is critical is in evaluation of the selected BMR for increases in TC. EPA states that a 10% BMR for calculating a BMDL based on increases in serum TC would be inappropriate for use because it would cause a "highly improbable doubling of risk" (see EPA 2023a,b; Table 4-2) because "the percentage of U.S. adults aged 20 and older with total cholesterol ≥240 mg/dL is 11.5%" (EPA 2023b, p. 4-15). However, EPA does not adequately account for background exposures and must use assumptions to estimate a "zero response" probability. Given the known impact of key factors such as diet, exercise, and genetics on cholesterol (see Section 2.3), any model that predicts a doubling of background hypercholesterolemia in the US population with 10% extra risk should be heavily scrutinized. EPA did not conduct additional analyses to adjust for background exposures to PFAS and the impacts those may have on derivation of BMRs based on extra risk for TC and for immune responses. Without these adjustments, there is a possibility that the BMRs based on an extra risk approach may be overestimating the probability of the outcome at the BMD.

In addition to the uncertainties associated with the potential impact of estimations of background exposure in BMD(L) derivation, there are additional uncertainties in the appropriateness of BMDLs derived from lognormally distributed data. As stated by EPA in its BMDS User Guide, "when response data is lognormally distributed, the BMR Types acquire different meanings… Using log-transformed responses in the analysis is not recommended" because "Data interpretation when using log-transformed responses will not be the same as when using the natural-scale response values. Indeed, the models— when "transformed back" to the natural scale—will not correspond to any of the standard BMDS models." (EPA 2018, p.20-219 ; EPA 2020, p. 5710; EPA 2022, p. 7511). Additionally, "interpretation of the BMD will not correspond to simple expressions (e.g., if the BMR is set equal to a relative deviation of 10%, that relative deviation will be assessed on the log-scale and so will not yield BMD or BMDL estimates that correspond to a 10% change in the original mean responses)" (EPA 2018, p. 21; EPA 2020, p. 5712; EPA 2022, p. 7513). Therefore, because EPA is using the log2-transformed BMD and BMDL reported by Budtz-Jorgensen and Grandjean (2018a) for derivation of BMDLs based on vaccine responses, extreme caution must be used when converting these values to un-transformed BMD(L)s and comparisons of extra risk for justification of individual BMD(L) selection. EPA did not re-evaluate its estimates of extra risk of immune responses by accounting for the lack of a true control and the log-normal transformation of the data.

EPA Response: The commenter asserted that the EPA did not use a modeling approach for TC and antibody response that is comparable to the one used for evaluating changes in birthweight. As noted in previous responses (Doc. #1774, SBC-053437), the EPA did not use the same method for BMD derivation across endpoints or studies. The approaches used by the EPA are dependent on the data and models available and on the critical outcome evaluated, including whether there are accepted clinical thresholds for adversity or biological significance. However, in response to this comment, the EPA improved discussion on the modeling approaches used for various studies (e.g., explanations for differences between modeling approaches for Dong et al. (2019), Steenland et al. (2009), and Lin et al. (2019)) in Appendix E of the final toxicity assessments (USEPA, 2024a; USEPA, 2024b).

The EPA also added detail in section 4.1.2.3 in the final toxicity assessments regarding BMR selection for cardiovascular effects (USEPA, 2024d; USEPA, 2024c). For the cardiovascular endpoint of increased serum TC in adults associated with PFOA or PFOS exposure, the BMD and the BMDL were estimated using a BMR of 5 percent extra risk from the biologically significant adverse serum TC concentration. The EPA presents PODs estimated using a 10 percent BMR for comparison purposes in Appendix E.1.3 (USEPA, 2024a; USEPA, 2024b).

Regarding the EPA accounting for extra risk and lack of "true control," please see the EPA response to comment Doc. #1774, SBC-053453 in section 4.2.2.3.4 in this *Response to Comments* document. Regarding how the EPA modeled specific endpoints, see sections 4.2.2.3.1, 4.2.2.3.2, 4.2.2.3.3, and 4.2.2.3.4 of the EPA response in this *Response to Comments* document.

With respect to uncertainties in using lognormally distributed data, the EPA clarifies that the BMD modeling for Budtz-Jørgensen and Grandjean (2018) utilized models with log-transformed

antibodies as the response variable, while PFAS exposure was untransformed and included additional covariates in the models. In this paper, they defined the BMR using percent relative deviation based on log-transformed antibodies. In contrast, EPA defined the BMR using standard deviation of log-transformed antibodies. These BMR definitions were constructed such that BMD and BMDL are solely functions of the regression coefficients of untransformed exposure. Importantly, these approaches allow for calculation of BMD/BMDL even in cases where raw data is not available. In the context of epidemiological studies where the raw individual participant data is unavailable and often protected, the BMR definition using log transformed responses is a solution. Because of this approach, the BMD and BMDL is calculated for log-transformed antibody responses. In other words, the goal is to determine the dose associated with a specific level of change in the log-transformed response, rather than the does related to a change in the original natural-scale response. The step of transforming back to natural scales is therefore deemed unnecessary. The commenter is also referred to the EPA response to SBC-053230.

3M Company (Doc. #1774, SBC-053441)

EPA did not consistently evaluate the impacts of BMR selection through sensitivity analyses of expected or extra risk or transparently describe its processes for evaluating the findings of its analysis, which may lead to inappropriate elimination of candidate studies.

Critically, EPA did not perform checks on extra risk estimations for all endpoints, or even for all studies or models considered within an endpoint. There is also no guidance for adjustment or consideration when these checks show that the conservative BMR selection is not a good estimate of 5% extra risk (e.g., the Timmerman et al. 2022 models). If these analyses are going to be used to justify selection of specific BMD(L)s, as is the case for the immune response models, EPA failed to transparently and consistently show the purpose of these assessments, describe the implications of their findings, and apply these assessments for all derived BMD(L)s.

EPA did not re-calculate many of these comparisons of the BMR with extra risk predictions, as EPA fails to account for critical factors in BMR derivation, including: 1) the lack of a true "control" or unexposed group and the impact of exposures in the background populations on extra risk calculations; and 2) the impact of use of log transformed data for modeling purposes and BMD derivation. Moreover, EPA made assumptions regarding the distributions of the populations with immune responses below the 0.1 IU/mL cutoff and did not independently verify the percentage of the population with values below the cutoff value with the raw data or study authors.

EPA Response: The commenter appears to misunderstand the modelling that the EPA conducted to support the PFOA and PFOS toxicity assessments. The extra check for the BMR selection is not applicable for endpoints where an clinical cutoff for extra risk already exists (e.g., ALT, BWT, and TC). In the case of modelling for tetanus, an endpoint for which an accepted clinical cutoff does not exist, these extra checks were performed for the study that

moved forward for RfD derivation in order to demonstrate that the selected BMR of ½ SD provides a reasonably good estimate if 5 percent extra risk. Additionally, these checks are just one factor in selection of the candidate studies and are not the sole determining factor. To further increase transparency, the EPA added rationale to explain selection of candidate RfDs (see section 4.1 of the final toxicity assessments for PFOA and PFOS (USEPA, 2024d; USEPA, 2024c)).

The commenter asserts that the EPA did not evaluate the impacts of BMR selection through sensitivity analyses. The EPA disagrees with the commenter and points to the sensitivity analyses presented in Appendix E of the assessments (USEPA, 2024a; USEPA, 2024b). For example, for the ALT and total cholesterol endpoints, BMD analyses were presented for two different BMRs. The EPA also disagrees with the commenter's claim that the EPA failed to account for "critical factors in BMR derivation." The EPA assumes that the commenter actually meant "BMD derivation." The intercept in a regression analysis represents the mean response in an unexposed population (see details in Section E.1 of USEPA (2024a; USEPA, 2024b)). To illustrate the impact of log transformed data for modelling purposes, the EPA added additional sensitivity analyses for total cholesterol and ALT modeling (see USEPA, 2024b).

In referring to assumptions regarding the distributions of the populations with immune responses below 0.1 International Standard UnitIU/mL, the commenter referred to an example the EPA included for illustrative purposes only, based on methods described in the *Benchmark Dose Technical Guidance* (USEPA, 2012). The purpose of this example is to illustrate how changes in the BMR relate to a shift in the population response compared to the 0.1 IU/mL antibody level. The calculations provided demonstrate that the EPA's selected approach to modeling is reasonable.

3M Company (Doc. #1774, SBC-053442)

EPA does not transparently describe its approach for selection of a single candidate BMDL for RfD derivation.

For each critical endpoint, EPA selects the BMDL used for derivation of outcome-specific RfDs from the range of modeled BMD(L)s. The process for selection of the outcomespecific BMDL for RfD estimation is not clearly described nor is systematic guidance provided. For example, EPA states that it used the BMDLs from models of anti-diphtheria responses in 7-year-old children from Budtz-Jorgensen and Grandjean (2018a) for derivation of the immune RfD for PFOS because "1) the response reported by this study reached statistical significance, and 2) the analysis considered co-exposures of other PFAS" (EPA 2023b, p. 4-47). For PFOA, EPA states that "EPA considered both [BudtzJorgensen 2018 and Timmerman 2021] as they both represented the low-dose range of effects across immunological endpoints and provided data regarding sensitive populations (i.e., children)" (EPA 2023a, p. 4-42). This statement is in direct contradiction with the summary of modeling results from Appendix E that states EPA selected POD of 3.47 ng/mL based on the model of anti-tetanus measurements at age seven from

BudtzJorgensen and Grandjean (2018a) because "the comparison POD of 2.26 ng/mL is considered lower confidence because it is based on a non-significant PFOA regression parameter" (EPA 2023a, p. E279). Based on these justifications, EPA may be placing undue importance on use of statistically significant regression parameters instead of considering the full weight of evidence, consistency, and the clinical relevance of the endpoints used for POD derivation. Moreover, EPA does not clearly describe how the disparate BMD(L)s derived from those two studies (shown in Table E-6), or within BudtzJorgensen and Grandjean (2018)'s models of multiple ages and considerations, are condensed to a single RfD. EPA does not consider the implications that, for the immune response, the BMDL derived from the Timmerman et al. (2021) model with non-significant associations (or regression coefficients) between exposure and response generated a BMD(L) that was more sensitive than those derived from Budtz-Jorgensen and Grandjean (2018a). This example shows why determination of confidence in the BMD(L)s based on statistically significant regression parameters is problematic. Judgments of BMD(L) confidence should not be based on the statistical significance of the regression parameters and should, instead, be based on the transparency and quality of the underlying doseresponse data.

For other endpoints, EPA uses the modeling confidence as the sole reason for selecting a BMD(L) for RfD derivation. As an example, "the RfD for increased TC from Dong et al. (2019, 5080195) was ultimately selected for the health outcome-specific RfD for cardiovascular effects as there is marginally increased confidence in the modeling from this study." (EPA 2023b, p.4-48). The process for determining confidence in the modeling is not clearly described or transparent, which reduces confidence in the resulting RfD if POD selections were based on poorly supported determinations of modeling confidence. EPA did not provide clarity and transparency in the process for making scientific judgments in order to increase confidence in the derived RfDs.

EPA Response: The commenter stated that the EPA did not transparently describe BMDL selection and that the EPA relied too heavily on statistical significance for BMDL selection. The EPA disagrees with these comments. The EPA, as illustrated in Appendix E, clearly used effect estimates that show both significant and null associations in modelling (USEPA, 2024a; USEPA, 2024b). The EPA also considered study confidence ratings in the study-specific statistical analyses (described in the study-specific risk of bias assessments available in Section 3 of the toxicity assessments (USEPA, 2024d; USEPA, 2024c)), when selecting a certain BMDL. The EPA agrees that judgments of BMD(L) confidence should not be solely based on the statistical significance of the regression parameters or models and should, instead, be based on many factors including but not limited to statistical significance, such as the transparency and quality of the underlying dose-response data (USEPA, 2012), which is exactly the approach that the EPA took in the PFOA and PFOS toxicity assessments. As the commenter pointed out, the EPA provided rationale across several parts of the draft toxicity assessments and appendices, primarily Chapter 4 and Appendix E (USEPA, 2023f; USEPA, 2023a; USEPA, 2023b; USEPA, 2023c), that described important assessment conclusions including critical study selection, model selection, POD selection, and RfD selection. In response to this comment, the

EPA has updated these sections in the final toxicity assessments to more clearly present this rationale (USEPA, 2024d; USEPA, 2024c; USEPA, 2024a; USEPA, 2024b).

The EPA discusses considerations of the weight of evidence, consistency, and the clinical relevance of the endpoints used for POD derivation in responses under subsections 4.2.2.3.1 (antibody response), 4.2.2.3.2 (total cholesterol), 4.2.2.3.3 (ALT), and 4.2.2.3.4 (birth weight), as well as section 4.2.2 of the EPA response in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-053443)

EPA failed to quantitatively assess uncertainty in the RfDs derived for PFOA and PFOS as requested by the EPA SAB.

EPA discusses uncertainties in the draft toxicity assessments for PFOA and PFOS that were introduced through the use of regression coefficients instead of response data for BMD modeling of epidemiological data (EPA 2023a,b). In addition, EPA provides a qualitative discussion of the uncertainties in the chemical-specific parameters used to model or calculate an external dose (i.e., human equivalent dose) from internal serum PFAS concentrations. Comments regarding the limitations in the EPA's uncertainty assessment of BMD and PBPK modeling are described below.

Uncertainties in estimation of PODs through use of BMD modeling

EPA's discussion regarding uncertainties in the POD estimates derived from BMD models is limited to a discussion of the use of regression coefficients instead of measured response variables (see Section 6.6.3 of EPA 2023a,b). Additional limitations described in Section 3 were not addressed, including the impacts of:

· Key study selection

· Selection of regression coefficients within key studies

· Background exposures

· BMR sensitivity and selection

· Linear assumptions

· Coefficient distribution assumptions

· Use of non-adverse outcomes (e.g., increases in TC instead of hypercholesterolemia)

· Use of log-transformed data or coefficients

EPA's uncertainty analysis is inadequate; EPA fails to prove that use of a non-standard BMD approach is biologically appropriate.

EPA Response: The commenter incorrectly stated that the EPA did not implement SAB feedback regarding RfD derivation and that the EPA did not quantitatively address uncertainty.

The EPA disagrees SAB feedback was not implemented, and further discussion of the EPA response to the SAB can be found in section 4.1.3 of the EPA response in this *Response to Comments* document. Quantitative analyses of uncertainty were presented at the time of rule proposal as sensitivity analyses in Appendix E and F of the draft toxicity assessments for PFOA and PFOS (USEPA, 2023b; USEPA, 2023c) and are still available in the final toxicity assessments (USEPA, 2024a; USEPA, 2024b).

The commenter claimed that the EPA did not consider various sources of uncertainty in BMD modeling of critical effects and critical studies. The EPA disagrees and directs the commenter to the EPA response to comment Doc. #1713, SBC-053371 in section 4.2.2.1 for discussion of how the EPA addressed uncertainties throughout the assessments, as well as section 4.2.2 of the EPA response in this *Response to Comments* document regarding the adversity of the selected critical effects. Please see the EPA response to comment Doc. #1774, SBC-053444 in section 4.2.2.3 in this *Response to Comments* document regarding modeling of regression coefficients.

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As described in Section 3, EPA relied on published regression coefficients to derive BMD(L)s for CVD, TC, and immune response effects. This approach of "modeling of regression coefficients results in a nontraditional BMD, where the BMR is associated with a change in the regression coefficient of the response variable rather than the measured biological response variable. As a result, there is some uncertainty about the biological relevance of this non-traditional BMD associated with a regression coefficient." (EPA 2023a p.6-16; EPA 2023b p.6-14). However, "EPA modeled these regression coefficients using the same approach that EPA used to model for studies that reported measured response variables" (EPA 2023a p. 6-16; EPA 2023b p.6-14). EPA tested this assumption that the regression coefficients were comparable to measured response variables through evaluation of a single study for which both regression coefficients and measured response data were available: Steenland et al.'s (2009) publication regarding increases in serum cholesterol associated with PFOA and PFOS exposures.

EPA used data provided by Steenland et al. to compare BMD(L)s generated through the reported regression coefficients with BMD(L)s generated through use of measured response variables (associated with deciles of exposure). For PFOS, the BMDL estimates were more than two-fold different, with measured BMDLs of 9.52 ng/L from the approach using regression coefficients and 26.39 ng/L from the approach using the measured response. EPA does not address these differences, and instead states that "The two BMDL estimates from the two approaches are within an order of magnitude, less than a 3-fold difference, and the RfD allows for an order of magnitude (10-fold or 1,000%) uncertainty in the estimate. Therefore, EPA is confident in its use [of] regression coefficients as the basis of PODHEDs" (EPA 2023b, p.6-14). However, for PFOA, EPA states that modeling of the response variable did not generate viable models, and therefore it could not make a quantitative comparison (see EPA 2023a, p. 6-16). EPA instead uses the findings from the PFOS comparison to justify comparability of the BMDLs for PFOA.

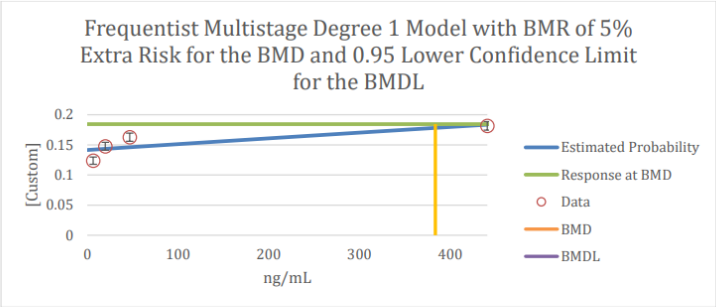
EPA does not discuss the limitations and adjustments made to enable comparison of the dose-response of the measured responses to traditional dose-response models using BMDS in the main documentation of the toxicity assessments (see 2023a p.E-301; 2023b p. E-29). For PFOA and PFOS, no viable models were identified when EPA modeled all 10 of the regression coefficients and deciles of exposure. To fit a dose-response, EPA used only the five lowest deciles and regression coefficients (EPA 2023a, Tables E-21 and E-22); however, EPA does not explain why it only considered five deciles of exposure. Upon review of the full range of reported regression coefficients (Table 3 of Steenland et al. 2009), the regression coefficient does not have a large magnitude of change between the fourth to tenth deciles of exposure range (coefficient range of 0.03 to 0.05). In order to generate a model based on a more traditional BMD approach, EPA modeled the measured response (incidence of hypercholesterolemia) reported by Steenland et al. (2009) for each quartile of exposure (EPA 2023a, Tables E-23 and E-24; EPA 2023b, Tables E-21 and E22). EPA does not explain why the measured response (hypercholesterolemia incidence) cannot be measured by decile of exposure to better match the models based on regression coefficients from the same underlying data. The measured response information is dichotomized, which means that the models used by EPA's BMDS are not directly comparable to those used for evaluation of the continuous regression coefficients. Models provided in the suite of continuous model options (e.g., exponential models) may also be more flexible and able to fit the sharp increase in response modeled in the lower dose regions (as reported by Steenland et al. 2009). An approach that would provide more confidence in model comparisons would be to compare BMD(L)s generated from the regression coefficients (by decile) with the mean TC (by decile).

Regardless, EPA states that none of the BMD(L)s generated through modeling of the measured responses for PFOA were viable, as the goodness of fit p-values were all < 0.001 (EPA 2023a, Table E-24). Recreation of the modeling approach used by EPA shows that the poor fit is in part driven by the small estimates of allowable variance in hypercholesterolemia incidence due to the relatively large sample size (n = approximately 11,400 per quintile of exposure); the large sample size limits the acceptable range of error in model prediction (see Figure 1 as an example). However, in contrast with EPA's statements, one model (the Dichotomous Hill model) does adequately fit the underlying data when a BMR of 5% Extra Risk is selected (P = 0.812; Figure 1). The BMDL05 generated for this model is 4.74 ng/mL PFOA, which approximates the BMDL05 of 4.25 ng/mL PFOA generated from the regression coefficients. This single fitted model does have high levels of uncertainty (e.g., a BMD/BMDL ratio >3), which accounts for the derivation of a comparatively low BMDL. These models indicate a potential for high model dependence, with all other models estimate BMDL05s ranging from 381 to 436 ng/mL PFOA (Figure 1). Critically, EPA does not report that the estimated BMD and BMDL for all models except the dichotomous hill are higher than the mean estimate of the largest quartile of exposure. This means that EPA is extrapolating beyond the range of observable data. Additionally, EPA's BMD Technical Guidance states that "in some cases, most of the available model fits may not appear to be adequate on the basis of goodnessof-fit p-values alone, i.e., p-values are less than 0.1. Some of these less adequate fits may be satisfactory when other criteria are taken into account (including the nature of the variability of the endpoint, visual fit, and residuals in the

most relevant region of the data range.); expert judgment is useful in these cases" (EPA 2012, p.33). In this example, the scaled residuals for the region near the BMD in each of the models are within acceptable ranges. EPA did not consider the impact of its non-traditional use of BMDS for analysis of epidemiological data with large sample sizes or discuss the fit of these models based on criteria other than goodness-of-fit.

Model selection creates another area of uncertainty in POD derivation, however EPA does not address the range of BMDLs generated through use of the mean or elevated serum models. For example, the range of BMDL0.5SD generated for TC from the regression coefficients ranged from 24.66 to 31.37 ng/mL PFOS (See EPA 2023b Table E-20) and the range of BMDL0.5SD generated from modeling the incidence of hypercholesterolemia in ranged from 14.27 to 40.29 ng/mL PFOS. (see EPA 2023b Table E-22). Note that the selected BMDL of 9.52 ng/mL PFOS, which is used for the uncertainty analysis comparisons and described in Table E-25 is not presented in the BMDS modeling summaries. EPA did not provide additional clarity on how it derived the value of 9.52 ng/mL. From the measured response models, EPA selected a BMDL05 of 26.39 ng/L PFOS based on the log-logistic model. No rationale for the model selection is provided. For these analyses, EPA did not consider use of model averaging to incorporate the full range of model uncertainty and avoid selection of a single model.

In order to make the current evaluation of Steenland et al.'s data more robust, EPA should have considered use of the mean TC measurements per decile of exposure to make a direct comparison with the exposure bands represented in the regression coefficient models. Use of the mean TC measurements per decile would allow direct comparison of the measured endpoint; as it currently stands, EPA's uncertainty analysis compares increases in serum TC measurements against the odds of having elevated TC. Use of mean TC (a continuous variable) would also allow EPA to consider the same suite of models between approaches including additional flexible model shapes (e.g., exponential models) that may better fit the observed dose-response.



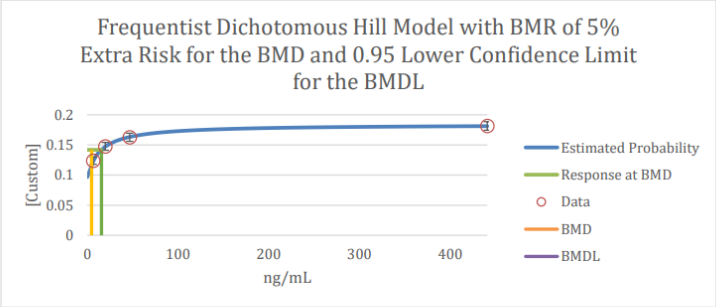


Figure 1. Benchmark-dose model examples from Steenland et al. (2009), with exposure measured in quartiles of exposure, show that the BMD(L) is highly model dependent and uncertain (BMD/BMDL ratio >3); response is incidence of hypercholesterolemia.

BMDS and other epidemiological models that dichotomize exposure measurements cannot account for the impact of ranges of exposures within the defined quartiles, deciles, or other categorical groupings of exposure. Inadequate consideration of the range of exposures associated with measured responses adds additional uncertainty. EPA did not use comparable dose ranges (e.g., deciles of exposure) in both analyses in order to improve comparability between the models used for testing and validating their approach; use of comparable dose ranges would minimize uncertainty in their comparisons of BMD derivation approaches. Additional analyses, such as the use of the Epidemiological Analysis function provided by BBMD (www.benchmarkdose.com), would allow for incorporation of uncertainties in exposure or consideration of exposure ranges provided within the epidemiological literature. Regardless of which modeling tool or approach is used, EPA did not consider the impacts of exposure uncertainty in BMD models based on epidemiological data.

EPA selected the information from Steenland et al. (2009) due to the accessibility of the mean response information underlying the regression coefficients. EPA states that the difference in BMDLs generated through use of regression coefficients instead of mean response information is less than 3-fold different and therefore acceptable, however EPA has not demonstrated that this relationship is consistent across endpoints, studies, or PFAS compounds. EPA did not evaluate additional datasets with the raw data or mean response information in order to quantitatively justify that the BMDLs generated through this nontraditional approach are comparable to those generated through use of mean response information. Some of the publications relied upon by EPA, including the key study for TC (Dong et al. 2019), are based on NHANES or other publicly available information. EPA did not conduct further sensitivity analyses based on these additional

studies and endpoints to provide confidence in the approach used to derive BMD(L)s for PFOA and PFOS.

EPA Response: The commenter made numerous incorrect or immaterial claims regarding the EPA's modeling of regression coefficients and specifically the sensitivity analysis the EPA conducted, particularly to compare various types of TC data reported by Steenland et al. (2009). In general, the EPA disagrees with these claims. The commenter appears misunderstand modeling approaches for POD derivation of epidemiologic studies.

The commenter first questioned why the EPA did not model the data using all reported deciles of exposure in Steenland et al. (2009) and claimed that the EPA did not include rationale for only including the lowest five deciles. The EPA stated "BMDS 3.3rc10 was used to fit the dose response data using all deciles, no viable models were identified. To further investigate, BMDS 3.3rc10 was used to fit the dose-response data in the lowest five deciles." Therefore, quantitative analyses could not be conducted when incorporating data from all deciles. This rationale was transparently presented in the Appendix E of the draft toxicity assessments for PFOA and PFOS (USEPA, 2023b; USEPA, 2023c).

The commenter then recommended the EPA "compare BMD(L)s generated from the regression coefficients (by decile) with the mean TC (by decile)." The commenter also incorrectly claimed that the EPA did not use mean TC data in its analyses. In fact, the EPA reported sensitivity analyses for Lin et al. (2019) and Steenland et al. (2009) that addresses both of those comments, by comparing PODs derived based on either mean serum TC or increased serum TC measures reported by quintile or quartiles of exposures (USEPA, 2023b; USEPA, 2023c). Such data were not available for Dong et al., (2019) and therefore, the agency could not conduct a similar analysis for this study.

The commenter additionally stated that the EPA incorrectly determined that there were no viable model fits to provide a quantitative comparison between the regression coefficient and measured response variable approaches. The commenter stated that one model (the Dichotomous Hill model) adequately fit the data. The EPA disagrees and illustrated this in Appendix E. 1.4.2.2.2. The commenter stated their analysis had "high levels of uncertainty (e.g., a BMD/BMDL ratio >3)." A model output with a BMD/BMDL ratio > 3 is not recommended for use as a POD in the benchmark dose software (BMDS). Therefore, the EPA does not rely on BMDLs with this type or magnitude of uncertainty and argues that this is evidence that the Dichotomous Hill model does not adequately fit the data as the commenter claimed.

The commenter claimed that the EPA did not report that the "estimated BMD and BMDL for all models except the dichotomous hill are higher than the mean estimate of the largest quartile of exposure" and claimed that subsequently, the EPA was "extrapolating beyond the range of observable data." The EPA disagrees with the comment. The estimated BMD and BMDL of 4.99 and 4.25 ng/mL for Steenland et al. (2009) were shown as sensitivity analyses, thus the EPA is not extrapolating beyond the observable data.

The commenter stated that the EPA did not consider the compatibility of BMDS for analysis of epidemiological data with large sample sizes. The EPA disagrees and points out that the data from Steenland et al. (2009) were only presented as sensitivity analyses for illustrative purposes. The commenter additionally discussed the EPA's model selection, claiming that the agency did not discuss the suitability of various models based on criteria other than goodness-of-fit and did not address the "range" of BMDLs produced from the different models. Comments regarding the EPA's rationale for model selection are addressed in the EPA response to comment Doc. #1774, SBC-053437 in section 4.2.2.3 in this *Response to Comments* document.

The commenter inaccurately stated that the EPA selected "the information from Steenland et al. (2009) due to the accessibility of the mean response information underlying the regression coefficients" and noted that the EPA did not conduct these sensitivity analyses across multiple studies or endpoints. The EPA provided rationale for selecting data for quantitative analyses of Steenland et al. (2009) in Appendix E1.4.2.2 (USEPA, 2023b; USEPA, 2023c). As noted in previous responses to comments about Steenland et al. (2009), the data from Steenland et al. (2009) were only presented as sensitivity analyses for illustrative purposes.

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EPA does not estimate the impact of modeling assumptions on derived BMDLs, or sensitivity of BMDLs to changes in these assumptions.

As discussed in Section 3, EPA uses many assumptions to estimate BMD(L)s for changes in birth weight, immune response, and serum TC, including:

· Background incidence of adverse outcomes associated with changes in these biometrics

· Estimates of model intercepts based on assumptions of background exposure and model shape

· BMR selections, including type (e.g., extra risk or SD) and magnitude (e.g., 5% or 10% extra risk, or 0.5 or 1 SD)

· Linear relationships between exposure and response

· Approximations of coefficient distributions

Each of these assumptions adds some quantifiable uncertainty to the derived BMD(L)s used for POD derivation. Using analyses of changes in birth weight as an example, variations in estimations of background exposure, BMR type, and background incidence of LBW may increase the derived BMDL by approximately a minimum of 30% and a maximum of 210%, depending on the study and assumptions. Uncertainty in the derived BMDLs, based on assumptions required to conduct modeling, impacts confidence in the derived PODs. EPA did not quantify or discuss the potential uncertainty in the BMDLs used for POD derivation or the sensitivity of the BMDLs to changes in the underlying assumptions.

EPA Response: The commenter states that the EPA did not estimate the impact of modeling assumptions in BMD derivation analyses and lists a number of assumptions that are common to dose-response modeling practices (USEPA, 2012). The EPA disagrees with this assertion and points to the tables in Appendix E where the EPA shows and explains the impact of modeling assumptions and provides BMDLs for various BMRs, models, or assumptions (USEPA, 2024a; USEPA, 2024b). The assumptions listed by the commenter were outcome, data and modeling approach specific, rather than global assumption for all analyses as the commenter suggests, and thus, sensitivity analyses to evaluate impacts of every single assumption are not always feasible or needed for every study. To the commenter's example of the BMD analyses for birthweight, for example, the impact of assumptions about background exposure is presented in in Section E.1.2 (USEPA, 2024a; USEPA, 2024b).

The EPA discusses additional considerations of the impact of modelling assumptions for specific endpoints under subsections 4.2.2.3.1 (antibody response), 4.2.2.3.2 (total cholesterol), 4.2.2.3.3 (ALT), and 4.2.2.3.4 (birth weight) of this response to public comment document, as well as in section 4.2.2 of the EPA response in this *Response to Comments* document.

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6. EPA's approaches to Benchmark Dose (BMD) are insufficient and inconsistent with accepted statistical standards.

EPA's approach to BMD calculations is lacking in appropriate sensitivity testing, choice of equation, and in some cases inappropriate use of information from the original publications. We discuss below the inappropriate information use and practice utilized by EPA for BMD calculations.

(6A) EPA does not properly address statistical significance

In Appendix E, Table E-1 (USEPA 2023c, e) displays BMDs in the Budtz-Jørgensen & Grandjean (2018) paper. In Table E-1, the slope coefficient which is used to calculate the BMD is clearly not significant, nor even close to significant. EPA states that the non-significant parameter can be used to calculate the BMD and BMDL. What is not shown is that the models in Table E-1 are poor representations of the original data (which are not available for review and testing) and fit the data poorly (they have a non-significant t-statistic). Therefore, the resulting non-significant slope is not correlated with the original data, and therefore is inconsistent with the underlying science inferred by the model. We note that the unavailability of the data negates the ability to rerun the model and thereby ensure the published results are reproducible and precise. No practicing statistician would agree that a BMD or a BMDL estimated from a non-significant model including a non-significant model parameter should be used to set a standard. EPA repeats this mistake throughout the BMD calculation process.

(6B) EPA's choices regarding statistical and/or biological properties of analyzed data are inconsistent with accepted practice.

EPA clearly states that selection of the BMR for the purpose of estimating a BMD involves making judgements about the statistical and biological properties of the data set. Yet, EPA provides no analysis of the sensitivity that these choices may have on the final BMD. The choice of BMR and the choice of "extra risk" (the p(0) term in the BMD calculation) simply will not withstand scientific review without a clear association back to clinical effects on the US population. As noted in the EPA QAPP guidelines, it is bad statistical practice to make judgement calls and subsequently calculate costs and benefits, without exploring the ramifications of and sensitivity of the results to these decisions in practice.

In summary (1) EPA has not conducted a sensitivity analysis of these arbitrary BMR and p(0) terms; (2) EPA provides no scientific basis for the choice of model equation; (3) EPA provides no scientific justification for (or against) specific BMR and p(0) choices, other than to state what EPA believes is commonly used; and most importantly,(5) EPA provides no explanation or examples of how the BMD calculations relate to actual human health risk. EPA must scientifically support how these calculations result in reduced mortality on a national scale.

For example, in the below table we demonstrate BMD and BMDL outcomes using two different BMD model equations (the Budtz-Jørgensen & Grandjean (2018) model, and the EPA Hybrid method used in Dong et al.(2019)). Models with three different sets of co-variates are fit (rows of the table) for NHANES total cholesterol data. (Dong et al., 2019). The appropriate NHANES weighting functions are used to generate the model estimates (there is no mention of weights in Dong et al. 2019). The choice of the extra risk term, and the choice of BMR make a significant difference in the resulting BMD and BMDL and could highly influence the final reference dose and ultimately the MCLG. Key co-variates that possibly affect the model parameter estimates should be included in all BMD calculations, which many of the papers selected by EPA do not do. These co-variates include the presence of a cholesterol lowering drug, age, ethnicity, gender, and BMI. Note in the analysis below the wide range of BMD and BMDL values found with relatively small changes in the BMR and p(0) terms. Also note that the slope parameter (the parameter multiplied by the total cholesterol concentration) is non-significant in every model. We supply this table only to show the range of BMD and BMDL values that can occur with arbitrary values of BMR and p(0). Good statistical and scientific practice requires EPA to relate the selected BMR and p(0) terms to the endpoints of interest, which according to EPA are severe disease or mortality estimates for the US population on a national basis. We also note that EPA claims the Dong et al. (2019) model included key co-variates like those above; however, this is not noted in the actual paper.

There are many BMD model forms and analytical approaches to choose from (Budtz-Jorgensen, Keiding, & Grandjean, 2001; Crump, 1995; Liu et al., 2016; USEPA 2012, 2022; Wheeler, Cortinas, Aerts, Gift, & Davis, 2022; Wheeler et al., 2023), including regression approaches, maximum likelihood approaches, and Bayesian approaches. How EPA chose from these differing approaches was not explained. Additionally, EPA did not robustly compare results from the various model forms and statistical paradigms. Without these explanations and comparisons,

EPA's decision-making and the scientific basis for its Proposed NPDWR are not transparent and prevent meaningful comment and analysis by reviewers.

Table 2 (below) provides an examination of the sensitivity of the BMD and BMDL calculations using two different model equations, and various values of BMR and p(0). Note that for any specific model and set of co-variates, the BMD and BMDL values vary tremendously. This results in a large variance in the resulting RfD. The equations are associated and follow a specific set of progressive calculations. Uncertainty at any specific level of the calculation hierarchy results in a compounded uncertainty in the final reference dose and ultimately the MCLG. EPA has not addressed this compounding of uncertainty in any of the technical documents or appendices. This issue is critical, because the cascading uncertainty sheds light on the lack of scientific integrity of the EPA proposed rule.

Table 2. Demonstration of range of BMD values with arbitrary choice of BMR and p(0): Total Cholesterol. Dong et al. (2019) reports BMD=10.5 mg/dL, BMDL=5.6 mg/dl.

Co-variates	(Budtz-Jørgensen & Grandjean, 2018) Method				Liu et al., 2016 Method			
	BMR=0.05		BMR=0.1		p(0)=.1 BMR=0.05		p(0)=.20 BMR=0.05	
	BMD	BMDL	BMD	BMDL	BMD	BMDL	BMD	BMDL
None	55.8	30.8	109.0	60.3	152.4	83.9	504.4	204.4
Age (<20, 21-80) Taking cholesterol drug (yes, no)	150.3	60.9	293.6	118.9	387.8	157.1	341.9	150.1
Age (<20, 21-80) Taking cholesterol drug (yes, no) Ethnicity Gender	102.7	45.4	200.6	88.6	262.0	115.2	341.9	150.1
Age (<20, 21-80) Taking cholesterol drug (yes, no) Ethnicity Gender BMI Category (healthy, obese, overweight, underweight)	103.6	45.0	202.5	87.8	262.0	113.7	345.9	150.1

The following comments (6C – 6F) are specific to USEPA 2023c, but likely also apply to USEPA 2023e.

(6C) EPA made repeated statistical mistakes contrary to accepted practice

In Table E-2 (page E-274) EPA repeats the mistake of excluding important co-variates and acknowledges in Table E-2 that no information is available to ascertain model fit. Again, without

the ability to replicate the Budtz-Jorgensen results and identify if the model from which the BMDL was derived has statistical validity, these results are invalid.

The fundamental statistical mistakes noted above continue with Table E-3 (E-275).

(6D) Inappropriate calculations to reproduce and/or calculate model parameters

(1) Note that EPA in "Selection of Benchmark Response" (following Table E-3) attempts to calculate a pooled variance using Log base 2 of the 25th and 75th percentiles, and uses these percentiles in an attempt to calculate a pooled variance. This calculation is unsupported. EPA acknowledges it does not have the original data, and therefore, it is not mathematically possible calculate a pooled variance. There are many distributions that could result in the same 25th and 75th percentile, but a pooled estimate based on actual data could be very different than what was calculated by EPA. This attempt to overcome lack of actual data is statistically inappropriate. In addition, EPA has no knowledge of how the 25th and 75th percentiles were generated, and cannot replicate these values without the original data set. Also, because the authors make no mention of it, EPA presumably does not know how the original authors treated issues with non-detected values, possibly dropped records, or dealt with sampling issues and weights. Again, EPA cannot use mathematical calculations to overcome the non-available data issue where the results cannot be repeated by the general public or other scientists. The outputs in Table E-4 are unsupported. Even EPA admits there is low confidence in the results, yet EPA continues to use the information. For example, in Section E.71 EPA states "[t]he Agency notes that the estimated models are potentially subject to omitted variable bias from other sources, such as income level, but EPA does not have adequate information to evaluate the impacts of this bias…"

(2) On page E-278, EPA seems to not have the original data for Timmermann et al. (2021) and attempts to back out a regression slope in order to calculate the BMD. This practice is mathematically indefensible, and could easily result in a wrong answer. Also, EPA is required under its own guidelines (USEPA 2003, USEPA 2006) to ensure that, consistent with the data, the original authors did not incorrectly treat the data (i.e., removal of outliers, etc.) prior to using the results for standard setting.

(3) The above inappropriate mathematical and statistical comments also apply to Section E.1.1.4, Modeling Results for Decreased Diphtheria Antibody Concentrations (page E279).

(4) In Section E.1.2.1. EPA again makes unsupported assumptions as to the mean and sigma estimates based on the 25th and 75th percentiles in Chu et al. (2020). EPA needs to obtain the original data, examine the original data using good data practices, and then calculate mean and sigma values. Using the ratio of percentiles reported in a paper is not in line with best statistical practice, and will most likely not represent values obtained using actual data.

(5) See sections E.1.2.2 – E.1.2.7 for continued statistical issues as described above.

(6) In each of the six high confidence studies for which EPA uses to calculate BMD/BMDLs (Sections E.1.2), EPA inappropriately uses the regression coefficients published in the paper, ignoring the fact that the published models incorporate co-variates in their final model. For

instance in Chu et al.(2020) the paper published in Table 2 adjusted regression coefficients for "gestational age, maternal age, maternal occupation, maternal education, family income, parity, and infant sex" (see page 4). When these types of adjustments are made, they are part and parcel of the final and the regression coefficient of interest. For example, b in Table 2 is only statistically valid in the presence of the covariates (also known as confounding variables). In this, and other sections of the report, EPA has repeatedly ignored the full model specification and instead only used the regression coefficient of interest, violating standard statistical principles.

(6E) Single variable regression models can overinflate the relationship to PFAS

Table E-9: EPA states that PFOS is significant in the single-PFAS model. As noted above, when a single variable regression model is applied to a larger data set, the basic tenants of hypothesis testing theory results in significant parameter estimates, simply due to sample size. However, we have showed in our comments that when critical co-variates like gender and age are included in the regression models, the coefficients on PFOA and PFOS are generally non-significant. This is a "signal and noise" problem, with the co-variates easily showing they are much more important to the endpoint (i.e., antibody titer) than PFOS and PFOA blood concentrations.

(6F) EPA's attempts to overcome missing information are inconsistent with accepted scientific practice

EPA's calculation of the "extra risk" in E.1.2.7 is not consistent with sound scientific practice. First, EPA does not know what the true background percentage of PFOS or PFOA is in the US. EPA has not evaluated a national-level exposure of these substances, which would vary tremendously on a national basis. Therefore, EPA's attempts to calculate an "alternative control group" response is not appropriate, and simply represents a statistical calculation that EPA has not defined explicitly. Without an exact understanding of background values (which EPA has not adequately addressed in this rule making), statistical calculations such as those in E.1.2.7 are inconsistent with sound and acceptable practice.

EPA Response: The commenter makes numerous claims regarding the BMD modeling of various critical effects and critical studies. The EPA disagrees with the majority of these claims and responds to the comments in the order they are presented above.

The commenter appears misunderstand how specific values were used in the assessments. As noted in a previous response, the non-significant BMDLs the commenters refer to in their comment 6A were provided for comparison purposes only, which is explicitly stated in Appendix E (USEPA, 2024a; USEPA, 2024b). They were not used to derive candidate reference doses as incorrectly claimed by the commenter. Additionally, none of the reference doses developed by the EPA were used to "set a standard," since the maximum contaminant level goals (MCLGs) were based on the EPA's determination that PFOA and PFOS are *Likely to be Carcinogenic to Humans* according to the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005); the MCLGs for PFOA and PFOS were not derived from non-cancer reference doses. Please also see sections 4.1.2, 4.1.4, and 4.1.5 of the EPA response in this *Response to Comments* document. Additionally, as described above, the original data is often not provided in published

epidemiological studies and study authors provide summary data that are needed for further assessment and calculations, as is the case with the Budtz-Jørgensen and Grandjean (2018). This study was a *medium* confidence study, reflecting the confidence in the study conduct and data quality, including reporting, in the published manuscript. In Appendix E of the draft toxicity assessments, the EPA provided all data and calculations needed to replicate the BMDL derivations (USEPA, 2023b; USEPA, 2023c).

The commenter erroneously claimed that the EPA did not illustrate impact of BMR or p(0) on BMDLs, or that the EPA did not transparently present how a modeling approach was selected. The EPA disagrees with these claims. As stated in the EPA responses to Doc. #1774, SBC-053437, and as is common practice, the EPA cited and referred to EPA guidance (e.g., USEPA, 2012) and used the available study-specific data and characteristics of the critical endpoint inform the choice of BMR, p(0) and modeling approach. The rationale is presented in Section 4 and Appendix E includes numerous sensitivity analyses that illustrate these points, in contrast to the commenter's claims (USEPA, 2024d; USEPA, 2024c; USEPA, 2024a; USEPA, 2024b). Please see section 13 of the EPA response in this *Response to Comments* document regarding the economic analyses conducted for this rulemaking.

The commenter made numerous repetitive statements regarding Dong et al. (2019), some of which were discussed in responses in subsection 4.2.2.3.2 below. The commenter erroneously claimed that the Dong (2019) paper did not include key covariates. However, as the EPA clearly states in Section E.1.3.1 in Appendix E (USEPA, 2023b; USEPA, 2023c) "the regression model applies to all adults 20 to 80 years old and was adjusted for age, gender, race, poverty income ratio, BMI, waist circumference, physical activity level, diabetes status, smoking status, and number of alcoholic drinks per day." The commenter did not present sufficient information supporting the analyses illustrated in Table 2 presumed to illustrate range of BMDs with "arbitrary" choices of BMR and p(0) for Dong et al. (2019) for the agency to respond to. The EPA's rationale for BMR selection for TC is presented in Section 4.2 of the final toxicity assessments for PFOA and PFOS (USEPA, 2024d; USEPA, 2024c). The commenter also did not provide explanation for the "Liu et al. (2016) Method" for the EPA to consider and respond to. The EPA further discusses these topics in the EPA response to comment Doc. #1774, SBC-053230 in section 4.2.2.3 in this *Response to Comments* document.

It is also clear from the Budtz-Jorgensen and Grandjean (2018), as well as the analyses presented in Appendix E that the models for this study controlled for age, gender, and booster type (USEPA, 2024a; USEPA, 2024b). The use of the Faroese study population inherently controls for socioeconomic status and ethnicity based on the characteristics of this population. Every model based on Budtz-Jorgensen and Grandjean (2018) that the EPA presents controls for these covariates and are referred to as "multivariate" models, indicating that more than one variable was accounted for in the modeling approach. The commenter is incorrect in stating that these "statistical mistakes" are repeated throughout the EPA's analyses. Additionally, the EPA describes in Appendix E how Budtz-Jorgensen and Grandjean (2018) fit three model types (i.e., linear, logarithmic, and piecewise) to the data, as well as analyses to determine the statistical validity

(i.e., model fit) (USEPA, 2024a; USEPA, 2024b). The EPA provided the results of these analyses and subsequently used the best fitting models for BMD estimation. For example, in Section E.1.1 in the PFOS Appendix, the EPA wrote, "Budtz-Jørgensen and Grandjean (2018) fit multivariate models of PFOS measured perinatally, against log2-transformed anti-diphtheria antibody concentrations measured at the five-year-old examination controlling for sex and age. Models were evaluated with additional control for PFOA (as log2[PFOA]), and without PFOA. Three model shapes were evaluated by Budtz-Jørgensen and Grandjean (2018) using likelihood ratio tests: a linear model of PFOS, a piecewise-linear model with a knot at the median, and a logarithmic function. The logarithmic functions did not fit better than the piecewise-linear functions Budtz-Jørgensen and Grandjean (2018). Compared to the linear model, the piecewise-linear model did not fit better than the linear model for either the PFOS exposure without adjustment for PFOA using a likelihood ratio test ($p = 0.55$; see Budtz-Jørgensen and Grandjean (2018) Table 3), or for the model that did adjust for PFOA (log2[PFOA]) ($p = 0.84$)," and provides Table E-9 with the corresponding statistical analyses (USEPA, 2023c; USEPA, 2024b). The commenter is incorrect in their assertions that the EPA did not provide this information.

The commenter expresses concern with the EPA's approach to calculating pooled variance using the data provided by the study authors. This calculation is a simple and standard practice, which allows for calculation of mean and standard deviation values based on reported 25th and 75th percentiles and known distribution of the data (Rosner, 2015). The EPA provided all calculations used to estimate pooled standard deviation in Appendix E (USEPA, 2023b; USEPA, 2023c). For example, in Section E.1.1.2.2 EPA states, "[t]he 25th and 75th percentiles of the diphtheria antibody concentrations in the earlier birth cohort at age five years in IU/mL were (0.05, 0.4). Log2-tranforming these values provides the 25th and 75th percentiles in log2(IU/mL) as (−4.32, −1.32). Assuming that these log2-transformed values are similar to the normal distribution, the [interquartile range] IQR is approximately 1.35 SDs, thus SD = IQR/1.35, and the SD of diphtheria antibodies in log2(IU/mL) is (−1.32−(−4.32))/1.35 = 2.22 log2(IU/mL)" (USEPA, 2024a; USEPA, 2024b). The calculations and assumptions the EPA uses to estimate pooled standard deviation follow basic statistical principles (Rosner, 2015) and are supported by publicly available information presented by the study authors. Thus, all computations are replicable.

The commenter misrepresents conclusions the EPA makes regarding individual modeling results and conflates them with the EPA's overall confidence in the immune evidence, antibody response to vaccination endpoint, and confidence in other modeled outputs. In situations where the EPA had relatively low confidence in the POD derived for a particular dataset, which is the case for the example the commenter provided (Table E-4 of the PFOS Appendix, USEPA, 2023c), the EPA does not advance the POD for candidate RfD derivation over PODs derived from other datasets reported by that study (USEPA, 2024c; USEPA, 2024b). The EPA may advance PODs from other studies with modeling results of lower confidence for comparison purposes, as was the case for PODs derived from Timmerman et al. (2021). These conclusions do not equate to the EPA's conclusions regarding the strength of evidence for the endpoint or health outcome, but to different factors specific to that one dataset, such as model fit, statistical associations between the

exposure and response variables, and potential confounding. Conclusions regarding the strength of evidence for each health outcome are presented in Section 3 of the final toxicity assessments (USEPA, 2024d; USEPA, 2024c).

The EPA is unsure where the commenter has identified the quote regarding estimated models. Neither the PFOA nor PFOS Appendices have a Section E.71, and the EPA was unable to identify the language the commenter supposedly quoted in any other section of the assessments or appendices. Therefore, the EPA cannot respond to this comment.

The commenter appears to have a misunderstanding of what data the EPA used from Timmermann et al. (2021) on tetanus or diphtheria antibody responses claiming that the EPA "attempts to back out a regression slope." While the EPA is unclear what the commenter's use of the expression "back out" refers to, the EPA points out that the approach used and described in Appendix E.1 is a simple and standard practice, using a basic mathematical equation which allows for calculation of a regression coefficient from a percent change coefficient reported in a study (USEPA, 2024a; USEPA, 2024b). Also, the EPA had no evidence that the study authors "incorrectly treat[ed] the data." In fact, unlike the commenter who does not provide any substantiating evidence to support this claim, the EPA performed a study quality evaluation of the study that did not result in any concern for data handling or statistical analysis in Timmermann et al., (2021) (see Section 3 of USEPA (2024d; USEPA, 2024c)).

The commenter states that the EPA must obtain the original data from Chu et al. (2020) to calculate mean and standard deviation used in subsequent calculations. The EPA disagrees with this claim. Typically, the original data is not provided in published epidemiological studies and study authors provide summary data that are needed for further assessment and calculations, as is the case with Chu et al. (2020). This study was a *high* confidence study, reflecting the confidence in the study conduct and data quality, including reporting in the published manuscript. The calculation that the commenter takes issue with is a simple and standard practice, which allows for calculation of mean and standard deviation (SD) values based on reported 25^{th} and 75^{th} percentiles and known distribution of the data. Briefly, the EPA used the fact that PFAS exposure follows a log-normal distribution; thus, ln(exposure) follows normal distribution. Since the distribution of exposure is assumed to be normal, the ln(mean) is equivalent to the ln(median), which was available from information provided by the authors. Further, the IQR, the difference between the 75th and 25th percentiles, of a normal distribution is approximately 1.35 SDs (Rosner, 2015). The SD is calculated as: SD = IQR/1.349 = [ln(q3) - ln(q1)]/1.349 = ln(q3/q1)/ 1.349, an equation which is provided in Appendix E (USEPA, 2024a; USEPA, 2024b).

The commenter states that the EPA incorrectly uses regression coefficients published in studies selected for POD derivation because they do not incorporate covariates into these values. The commenter appears to have misinterpreted the methods used in the modeled studies and by the EPA. Given there is no data (i.e., estimate of coefficients and covariance matrix) available for covariates, the EPA assumed the covariates and constant in the original adjusted model were another constant estimated as intercept *b*. The EPA has not ignored the full model specification, since the slopes adjusted for covariates are used in its calculations.

The commenter also stated that the EPA is not transparent in its rationale for including or excluding particular covariates. Additionally, the commenter appears to misinterpret the methods and results of the "single-PFAS model." The EPA disagrees with these claims, as described further below. The EPA clearly states which covariates were adjusted for in each model described. Again, using Budtz-Jørgensen and Grandjean (2018) as an example, the EPA states: "Budtz-Jørgensen and Grandjean (2018) fit multivariate models of PFOS measured at age five years, against log2-transformed anti-tetanus antibody concentrations measured at the seven-year-old examination **controlling for sex, exact age at the seven-year-old examination, and booster type at age five years**" (emphasis added) (USEPA, 2024a; USEPA, 2024b). Additionally, the commenter included Table 1 from Budtz-Jørgensen and Grandjean (2018), which also clearly states that gender, age, and booster type were controlled for. The EPA takes a similar approach for the other health outcomes and endpoints of interest, particularly noting when endpoint-specific covariates were incorporated (e.g., individuals taking cholesterol medication for the total cholesterol endpoint), in multiple locations in the documents, such as in Appendix E, in descriptions of the studies in Section 3 of the final assessment, and in Appendix D presenting detailed information from epidemiologic studies (USEPA, 2024d; USEPA, 2024c; USEPA, 2024a; USEPA, 2024b). To further increase transparency, the EPA has subsequently added descriptions of covariates controlled for in each model to the title or footnote of each of the pertinent tables in Appendix E (USEPA, 2024a; USEPA, 2024b).

The commenter misinterprets the meaning of the "single-PFAS model." A "single-PFAS model" is a model which includes only a single PFAS exposure *along with other covariates that are not PFAS exposures*. A multi-PFAS model includes at least two PFAS along with other covariates that are not PFAS exposures. The commentor may be referring to a univariate exposure model which uses a single PFAS exposure to predict antibody concentrations without control of any other covariate. The EPA did not use univariate exposure models in its assessment of PFOA or PFOS (USEPA, 2024d; USEPA, 2024c). To further increase clarity, the EPA has subsequently added a definition of "single-PFAS" and "multi-PFAS" models in the first mention of these terms in Appendix E (USEPA, 2024a; USEPA, 2024b).

The commenter claims the EPA has not defined variables in the statistical analyses used to examine the impact of background exposure and decreased BW incidence in the U.S. This is demonstrably incorrect. The EPA explicitly defined the variables and calculations used to conduct the modeling and sensitivity analyses presented in Appendix E.1.2 of the draft and final toxicity assessments (USEPA, 2023b; USEPA, 2023c; USEPA, 2024a; USEPA, 2024b). The EPA walks through each calculation used in the analyses and provides sources for the variables used. Specifically, the EPA cites the CDC Wonder site (https://wonder.cdc.gov/natality.html) as the source for the exact percentage of infants born below the public health definition of LBW and the America's Children and the Environment (ACE) Biomonitoring on Perfluorochemicals (https://www.epa.gov/americaschildrenenvironment/data-tables-biomonitoringperfluorochemicals-pfcs), based on NHANES data, as the source of background PFOA and PFOS serum concentrations in women of childbearing age. The EPA provides sufficient information for an individual to reproduce these analyses and has described

assumptions and decisions made for these analyses in several materials supporting the rulemaking, including this *Response to Comments* document and the final toxicity assessments for PFOA and PFOS (USEPA, 2024d; USEPA, 2024c; USEPA, 2024a; USEPA, 2024b).

3M Company (Doc. #1774, SBC-053446)

EPA did not address the inconsistent methods and approaches to BMD calculation in the selected papers and documents used to support the MCLG. This lack of consistency severely limits EPA's ability to reliably and accurately assess potential risk. Note the calculation approach used in (Budtz-Jørgensen & Grandjean, 2018) is completely different than that used by (Dong et al., 2019) (which incorrectly references (Liu et al., 2016)). Different statistical models will, simply based on different mathematics, provide differing results. This uncertainty, and the possible inaccuracy it would cause in the final rule, was not addressed by EPA. For example, EPA has accepted the slope produced by (Dong et al., 2019) when rerunning its BMD calculations yet ignores the fact that the slope is calculated with an incomplete data set, and data weights are not consistent with NHANES guidance. This is clearly a violation of EPA's quality principles and guidance.

EPA Response: This comment is repetitive of similarly incorrect statements provided by the same commenter. Please see the EPA response to comment Doc. #1774, SBC-053296 in section 4.2.2.2.4 in this *Response to Comments* document and the EPA responses to comments in section 4.2.2.2.4 (e.g., Doc. #1774, SBC-053207) for specifics as to why the statements made by the commenter are incorrect.

4.2.2.3.1 Comments Specific to Antibody Response Modeling

3M Company (Doc. #1774, SBC-053447)

EPA inappropriately uses differences in p-values to support selection of single-PFAS models in evaluation of immune responses.

EPA's BMD Technical Guidance states, "the preference in selecting suitable models is to use those that are consistent with the biological processes understood to operate in a particular case and to avoid models that are clearly inconsistent" and provides examples of biological processes include saturable or two-stage processes (EPA 2012 p. 26). EPA recommends use of a "global goodness-of-fit measure, usually a p-value" to "quantify the degree to which the dose-group means that are predicted by the model differ from the actual dose-group mean, relative to how much variation of the dose-group means one might expect." (EPA 2012, p.33). Therefore, the p-value indicates whether or not a model describes the underlying data and is, on its own, not an appropriate statistic for judging model fit in the region of the BMD(L) or making model comparisons. Specifically, EPA states in its BMD Technical Guidance that "P-values cannot be compared from one model to another since they are estimated under the assumption that the different models are correct" (EPA 2012, p. 33), and "Goodness-of-fit statistics are not designed to compare different models – in particular, a higher goodness-of-fit p-value for one model does

not necessarily indicate a better fit over another model with a lower p-value so alternative approaches to selecting a model to use for BMD computation need to be pursued" (EPA 2012 p. 36). Instead, EPA recommends the use of likelihood ratio tests "to evaluate whether the improvement in fit afforded by estimating additional parameters is justified" for models within model families or to the Akaike Information Criterion (AIC) for models within different families (e.g., lognormal versus normal). (EPA 2012, p. 36). Although EPA guidance specifically states that p-values cannot be used to compare different models, EPA here advanced the derivation of a POD for tetanus antibody responses associated with PFOA exposure measured in children at 5 years old based on the model that did not control for PFOS "because this model appeared to fit PFOA data better ($p = 0.02$ vs. 0.07) and there was little uncertainty due to potential confounding in the BMDL" (EPA 2023a, p. E277-278).

Although there are differences in the interpretation of the p-values calculated through traditional BMD approaches and the p-values describing the statistical significance of the models published in the literature, the general principle stands. In fact, as stated by EPA in its BMD Technical Guidance, "when there are other covariates in the models… the idea is the same, but the calculations are more complicated" (EPA 2012, p.33). Due to the complex nature of the multivariate models evaluating epidemiological data, statistics such as the AIC, likelihood ratio test (LRT), residuals in the region of the BMD(L), or adjustedR 2 (for linear models) are more appropriate for determination of comparative fit between models. EPA sets precedence for this type of approach through use of LRT to select use of the linear model instead of the piecewise-linear models reported by Budtz-Jørgensen and Grandjean (2018a) for RfD derivation.

Notably, EPA did not use considerations of comparative model fit (such as the AIC, LRT, or adjusted-R 2) to justify selection of the single-PFAS models reported by Budtz-Jorgensen and Grandjean (2018a). Although EPA justified model selection by noting that there was a small change in BMDL between the single- and multi-PFAS models reported by BudtzJørgensen and Grandjean (2018a) (e.g., the BMDL being 15-19% higher in the multi-PFAS models for 7- and 5-year diphtheria, respectively), this does not preclude the need for consideration of the impact of confounding and co-exposures. Evaluation of the adjustedR 2 for Budtz-Jorgensen and Grandjean's (2018a) models (Budtz-Jørgensen and Grandjean 2018b, 2022a, 2022b) confirms that EPA's comparison of the p-values does not indicate an improved fit of the single-PFAS model. The adjusted-R 2 values of 3.4% and 3.5% for the models with and without adjustment for PFOS, respectively, are comparable. Conversely, the comparison of p-values shows evidence of a potential for confounding by co-exposure with other PFAS. As described in Section 3.3, the fitted models have adjustedR 2 values ranging from 1.0 – 3.7% (Budtz-Jørgensen and Grandjean 2018b, 2022a, 2022b) which indicate that factors other than PFOA or PFOS exposures account for 96-99% of the total variance in antibody response in these models. Therefore, additional caution in model selection and further exploration of the implications of co-exposures to other PFAS on the biological and clinical significance on single-exposure models is necessary.

EPA Response: The commenter stated that the EPA used p-values as a basis for selecting a modeling approach and criticized the EPA's selection of a model that did not account for

exposure to other PFAS. The EPA disagrees with these comments. When possible, the EPA selects more parsimonious models that account for fewer variables as the approach to derive PODs. Accounting for a variable in a multivariable regression model that is not a significant predictor of the response variable reduces the degrees of freedom and effectively dilutes the significance of the other exposure variables that are predictors of the response. In the situation described by the commenter, the EPA stated, "The $BMD_{½\ SD}$ estimate from the multi-PFAS models is 7 percent lower than the $BMD_{½\ SD}$ estimate from the models with just PFOA, and the $BMDL_{½\ SD}$ estimates is 3 percent lower. The change in BMD estimates may, or may not, reflect control for any potential confounding of the regression effect estimates. While it is not clear which PFAS model provided 'better' estimate of the point estimate of the effect of PFOA, the two $BMDL_{½\ SD}$ estimates are comparable (3.35 ng/mL vs. 3.25 ng/mL) and the EPA advanced the derivation based on results that did not controls for PFOS because this model appeared to fit PFOA better (p = 0.02 vs. 0.07) and there was little uncertainty due to potential confounding in the BMDL" (USEPA, 2024d; USEPA, 2024a). These results showed that both models fit the response equally well, though the parameter for PFOA in the single PFAS model did have a lower p-value (p=0.02 vs. p=0.07 for the parameter for PFOA in the multi-PFAS model) and there was little uncertainty associated with the potential for confounding of multiple PFAS in the derived BMDL. Therefore, the EPA selected the BMDL from the more parsimonious model to serve as the basis for the candidate RfD.

The commenter seems to have a fundamental misunderstanding about the meaning and significance for adjusted R^2 values for model comparison. In this modeling scenario, R^2 is not just a measure a model fit as the commenter describes. Indeed, an R^2 statistic reflects the degree of variance in the outcome explained by the covariates in the model. Regardless of how good the model fit is, the R^2 statistic fluctuates with the number of covariates. What is important (and not reflected by the R^2 statistic) is the effect of the exposure on the outcome, adjusted for potential confounders, when modeled appropriately to ensure that the best model fits the data. Also of note, small R^2 values do not necessarily indicate "evidence of a potential for confounding by co-exposure with other PFAS" as the commenter seems to imply.

3M Company (Doc. #1774, SBC-053228)

1. EPA's Selection of Candidate Studies Was Neither Transparent Nor Consistent

The SAB provided specific guidance to EPA that in selecting endpoints for POD development, "[i]nternal inconsistencies in the criteria used for selection of endpoints for POD development should be addressed. It is also important to explain why a specific study of a health endpoint was selected when there are several possible choices." This guidance from the SAB related to all PODs EPA considered. EPA's response was that it presented evidence integration judgments for each health outcome, including the rationale for the selection of a particular study for POD derivation (USEPA 2023c, p. 20-21). Although EPA provided some discussion of evidence integration, it did not explain the choice of study for POD derivation among multiple medium-

confidence studies. The studies selected for POD development had critical deficiencies that should have excluded them from consideration.

First, the evidence base for vaccine response was not consistent. For example, the associations between vaccine response for tetanus or diphtheria with PFOA or PFOS exposures were not consistent either by age nor by vaccine type across several studies (Grandjean et al. 2012; Grandjean et al. 2017a,b; Mogensen et al. 2015; Shih et al. 2021). All of these studies were conducted based on cohorts from the Faroe Islands. Authors noted in 2012 that although negative associations were observed with vaccine antibodies, "the overlapping confidence intervals and the lack of comparative toxicology studies prevent inference in regard to causal attribution" (Grandjean et al. 2012). Similarly in 2017 they noted, "inter-correlations between serum-PFAS concentrations prenatally and at different ages make it difficult to determine accurately the possible age-dependent roles of individual PFASs in regard to immune function outcomes" (Grandjean et al. 2017b). The Agency did not adequately discuss the sporadic findings and uncertainties within the studies examining the Faroe Islands cohorts and to resolve those uncertainties before selecting a candidate study from this group of Faroe Islands cohorts (Butz-Jorgensen and Grandjean 2018).

The alternate candidate study selected by EPA also had critical limitations that should have been identified as part of a proper systematic review. Timmermann et al. (2021) was a cross-sectional analysis of vaccine response in Greenlandic children. Because the exposure and outcome are measured at the same time in a cross-sectional study, the study cannot determine if there is a temporal link between the exposure and the outcome. In addition, the timing of its exposure measurement is unclear compared to vaccination, as vaccination records were not available for nearly half (163/338 children) of the study population, which means the authors estimated the date of vaccination for purposes of evaluating antibody response. Notably, the authors acknowledged that using an estimated date of vaccination likely caused information bias, possibly due to long and varied time intervals since the most recent vaccination. [FN78: Timmermann et al. (2022) is also a poor choice because the children examined in that study had very different chemical exposure levels than American children. They had high levels of mercury and PCB concentrations compared to American children, and PFOS concentrations that were twice as high as American or Faroese children.]

EPA Response: The commenter stated the EPA's selection of critical studies for the antibody response endpoint was not transparent, citing SAB recommendations for providing additional information for selection of outcomes and studies for POD development. The commenter stated the EPA responded to this by providing evidence integration judgements, but the commenter suggested the EPA did not provide justification for decisions on which studies to include for POD derivation and that the EPA selected studies with critical deficiencies for modeling. The commenter raised specific concerns regarding vaccine response studies, suggesting the evidence base for the Faroe Islands population was not consistent across age or vaccine type and had issues such as confounding due to other PFAS and lack of comparable toxicological studies. The commenter also raised concerns about an alternate study, Timmerman

et al. (2021) selected for the EPA's sensitivity analysis, stating that this study should have been excluded because it had a cross-sectional study design, used an estimated date of vaccination for some of the children, and children had different exposure profiles compared to children in the United States. Please see section 4.1.3 of the EPA response in this *Response to Comments* document regarding how the EPA responded to SAB comments.

The EPA disagrees justifications were not provided for selection of studies for POD derivation. The commenter is incorrect in stating the EPA solely provided information regarding critical study selection in the evidence integration sections. The EPA outlined considerations made for study selection for the antibody response endpoint in several sections of the draft toxicity assessments (e.g., Section 4.1.1.2; USEPA, 2023f; USEPA, 2023a). While there were numerous *medium* and *high* confidence studies, the EPA selected studies that met criteria outlined in the Study Selection section, as well as those that met criteria outlined in the Appendices (Section A.1.11.1; USEPA, 2023b; USEPA, 2023c). Reasons for exclusion for other studies were additionally described in Table 4-1 (USEPA, 2023f; USEPA, 2023a). As described previously, the selected candidate studies were the best suited for POD derivation for multiple reasons, such as consideration of potential confounding factors, overall study confidence, study design and analysis, and suitability for modeling. In response to this comment, the EPA has continued to improve the clarity of the rationale for study selection in the final toxicity assessments for PFOA and PFOS (USEPA, 2024d; USEPA, 2024c; USEPA, 2024a; USEPA, 2024b).

The commenter claimed that the evidence base for reduced antibody response in children was not consistent, and that the studies selected by the EPA for POD derivation had critical deficiencies. The EPA disagrees that the evidence base for reduced antibody response in children was inconsistent. The commenter provided a limitation described by Grandjean et al. (2012), but does not consider the conclusions provided by the authors of each Faroe Island study. In each case, they conclude that PFAS are associated with reduced antibody response in children, with multiple significant associations reported for PFOA and PFOS (Grandjean et al., 2017; Grandjean et al., 2017; Mogensen et al., 2015; Grandjean et al., 2012,). Across the Faroe Island studies, few non-significant positive associations with tetanus and diphtheria antibody concentrations were observed for PFOA and PFOS, but these estimates were generally imprecise with wide confidence intervals (CIs) (USEPA, 2023f; USEPA, 2023a). In comparison, all other associations were inverse, and significant inverse findings were reported across multiple timepoints. The EPA disagrees that the studies selected for POD derivation had critical deficiencies. Specific to the antibody response endpoint, the two studies selected for modeling, Budtz-Jorgensen and Grandjean (2018) and Timmerman et al. (2021) were both considered *medium* confidence (see Section 3; USEPA, 2024d; USEPA, 2024c), meaning that they did not have critical deficiencies that would render them *uninformative* in accordance with study evaluation considerations outlined in the IRIS Handbook (USEPA, 2022a), the IRIS PFAS Systematic Review Protocol (USEPA, 2021a), or the protocols outlined in Appendix A of the toxicity assessments for PFOA and PFOS (USEPA, 2024a; USEPA, 2024b). Considerations for concerns raised by the commenter for Timmerman et al. (2021) are described later in this response.

Regarding co-exposure to other PFAS, the statement cited from Grandjean et al. (2017b) notes the difficulty in determining potential age-dependent roles of individual PFAS, but it does not question the adverse findings for individual PFAS observed in the study. Notably, Budtz-Jorgensen and Grandjean (2018) performed analyses with and without mutual adjustment for other PFAS and no notable attenuation of the effects were observed for either PFOA or PFOS. The EPA has added additional clarification regarding uncertainties related to potential confounding by co-occurring PFAS in the discussion of uncertainties related to epidemiological studies (USEPA, 2024d; USEPA, 2024c, Sec. 5.1.1). Regarding comparative animal toxicological studies, multiple studies reporting immunotoxic effects in rodent models (e.g., Dewitt et al., 2008; Loveless et al., 2008) were identified and included in the immune synthesis (USEPA, 2024d and USEPA, 2024c, Sec. 3.4.2.2). As noted in the evidence integration summary for immune effects, the immunomodulatory effects observed in these studies were consistent with a diminished antibody response in humans (USEPA, 2024d; USEPA, 2024c, Sec. 3.4.2.4).

The EPA disagrees with the commenter's claims about the Timmerman et al. (2021) study. This study does use a cross-sectional design, however, as PFOA and PFOS have relatively long half-lives in the body, a single measurement is adequately representative of exposure across time. The EPA acknowledged potential information bias in the analysis of all children, specifically those with estimated vaccination dates, reported in Timmerman et al. (2021). This is why analyses examining only those children with known vaccination records was considered the most scientifically accurate and as a result, were the basis for considering Timmerman et al. (2021) for POD derivation. The estimates drawn from Timmerman et al. (2021) used in the sensitivity analysis of tetanus and diphtheria responses in children were from the analysis of children with known vaccination records only. This information was clearly described in Appendix E (section E.1.1.3) of the draft toxicity assessments (USEPA, 2023b; USEPA, 2023c).

3M Company (Doc. #1774, SBC-053448)

Candidate study selection was not transparent.

The studies EPA selected for POD development had critical deficiencies that should have excluded them from consideration. To select endpoints for POD development, the SAB commented, "Internal inconsistencies in the criteria used for selection of endpoints for POD development should be addressed. It is also important to explain why a specific study of a health endpoint was selected when there are several possible choices." EPA's response was that evidence integration judgements were presented for each health outcome, including the rationale for the selection of a particular study for POD derivation (EPA 2023c, p. 20-21). However, EPA did not explain its choice of study for POD derivation among multiple medium-confidence studies.

First, EPA's evidence base for vaccine response was not consistent. For example, the associations between vaccine response for tetanus or diphtheria with PFOA or PFOS exposures in children were not consistent within each of the Faroe Islands studies, neither by age nor by vaccine type

(Grandjean et al. 2012; Grandjean et al. 2017a,b; Mogensen et al. 2015). Authors noted in 2012 that although negative associations were observed with vaccine antibodies, "the overlapping confidence intervals and the lack of comparative toxicology studies prevent inference in regard to causal attribution" (Grandjean et al. 2012). Similarly, in 2017 they noted "inter-correlations between serum-PFAS concentrations prenatally and at different ages make it difficult to determine accurately the possible age-dependent roles of individual PFASs in regard to immune function outcomes" (Grandjean et al. 2017b). Mogensen et al. (2015) also found that the association of PFOA was not statistically significant when adjusted for other PFAS and suggested that results from this study could not attribute effects of vaccine response to any individual compound.

Despite the inconsistency discussed above, EPA summarized the Faroe Island studies as finding "observed associations between higher levels of PFOA or PFOS and lower antibody levels against tetanus and diphtheria in children at birth, 18 months, age 5 years (pre-and post-booster), and at age 7 years, with some being statistically significant", and "There are a few results in the opposite direction for sub-analyses of the Faroe Island cohorts".

The alternate candidate study selected by EPA, Timmermann et al. (2022), is a crosssectional analysis of vaccine response in Greenlandic children that also had critical limitations that should have excluded it from consideration as a candidate study. Due to its cross-sectional design, this study cannot establish temporality between exposure and outcome. In addition, the timing of its exposure measurement is unclear compared to vaccination, as vaccination records were not available for nearly half (163/338 children) of the study population. This means the authors estimated the date of vaccination for purposes of evaluating antibody response. The authors acknowledged that using an estimated date of vaccination likely caused information bias, possibly due to long and varied time intervals since the most recent vaccination.

In the draft toxicity assessments for PFOA and PFOS, EPA noted that Timmermann et al. (2022) did not find consistent evidence of decreased vaccine response within the study population, and there was uncertainty due to "reported results that differed in direction of association based on the covariate set selected. The exposure measurement in these analyses may not have represented an etiologically relevant window." (EPA 2023a, p. 3- 104; EPA 2023b, p. 3-88). Despite no consistent evidence, EPA selected Timmermann et al. (2022) as a candidate study because it was the only study to report the odds of not being protected against diphtheria (based on antibody concentrations of <0.1 IU/ml) (EPA 2023a, p. 3-104; EPA 2023b, p. 3-88). These findings were not statistically significant for PFOA (OR=1.41, 95% CI: 0.91-2.19), but were significant for PFOS (OR=1.14, 1.04-1.26).

Timmermann et al. (2022) is also biased because the children examined in that study had very different chemical exposure levels than other populations. They had high levels of mercury and PCB concentrations compared to American children, and PFOS concentrations that were twice as high as American or Faroese children. Authors admitted that some of these additional compounds were highly correlated, making it difficult to separate their effects on vaccine response from the effects of PFOS/PFOA. Due to the number of associations tested, there was a high risk of finding

significant associations merely by chance. It is unclear why the study was selected by EPA when no significant findings for PFOA were reported. The study design inhibited causal interpretation of the results, and the population was a small population with unique characteristics that preclude any findings from being generalizable to the US population.

In short, both candidate studies contained limitations that EPA's own guidance indicates should have excluded them from consideration as candidate studies. EPA needs to be transparent in its critical appraisal of each study and rationale for the choices of candidate studies.

EPA Response: The commenter incorrectly states that the EPA did not explain its study selection for POD derivation among multiple *medium* confidence studies and that it selected studies for POD derivation that had critical deficiencies. The commenter suggests that the evidence base for vaccine response was not consistent for tetanus or diphtheria by age or vaccine type, and the commenter cites limitations described by each study author regarding their results, which are unrelated to age or vaccine type. The author critiques one critical study (Timmerman et al., 2021) for its design and study population.

The EPA disagrees with comments regarding a lack of rationale for critical study selection and that the selected studies have critical deficiencies. The EPA has explained in a previous response to this commenter (Doc. #1774, SBC-053228), as well as in descriptions provided in Section 4 and Appendix E of the final toxicity assessments (USEPA, 2024d; USEPA, 2024c), rationale for study selection for POD derivation. Rationale included strength of evidence for the specific booster type, confidence in modeling results, study confidence, availability of data appropriate for modeling, overlapping datasets, and others. Further, the EPA reported study evaluation results and noted limitations of each individual study, though no study selected for POD derivation had weaknesses so critical that they resulted in a *low* or *uninformative* confidence designation (USEPA, 2022a; USEPA, 2021a; USEPA, 2024a; USEPA, 2024b). Further, when considered together, as is the goal of the evidence integration process, the overall database showed consistent responses across multiple boosters and study populations (see Section 3, USEPA (2024a) and USEPA (2024b)). Consistency among age groups is not necessarily expected for this endpoint. The weaknesses of individual studies are overcome with support across the database, as is the case for epidemiological and toxicological studies indicating associations between PFOA or PFOS and immunosuppression.

The commenter noted limitations reported by Grandjean et al. (2012) as "overlapping confidence intervals" and a "lack of comparative toxicology studies." Similarly, the commenter cites another limitation described by a Faroe Islands study author (Mogensen et al., 2015), noting lack of statistical significance after adjustment for other PFAS. Regarding lack of comparative toxicological studies, multiple toxicological studies (Dewitt et al., 2008; Loveless et al., 2008; Zhong et al., 2016; Peden-Adams et al., 2008; Dong et al., 2009) observed decreases in globulin and immunoglobulin levels and other responses indicating immunosuppression after exposure to PFOA and PFOS, consistent with decreased antibody response observed in humans (USEPA, 2024d; USEPA, 2024c). Furthermore, mechanistic evidence (NTP, 2016) published after the Grandjean et al. (2012) study provided evidence of T-cell-dependent and T-cell-independent

responses being reduced in mice treated with PFOA, suggesting a possible explanation for decreased antibody response in humans (USEPA, 2024a). Regarding overlapping CIs and statistical significance after adjustment with other PFAS, the IRIS Handbook states that "consideration of the consistency in patters of results does not require that all findings are statistically significant" (USEPA 2022a, p. 6–19). Consistency of direction and magnitude of observed effects across the immune database were considered while drawing conclusions about vaccine response in children.

The agency had lower confidence (i.e., identified greater uncertainties) in PODs derived from Timmerman et al. (2021) compared to the selected PODs derived from Budtz-Jørgensen and Grandjean (2018) for multiple reasons, including some that the commenter quotes from Appendix E, as well as in Section 4 of the final toxicity assessments for PFOA and PFOS (USEPA, 2024d; USEPA, 2024c; USEPA, 2024a; USEPA, 2024b). The commenter did not provide new rationale that the EPA had not already considered when selecting the health outcome-specific RfD for immune effects. However, the EPA disagrees with the commenter's assertion that the EPA selected Timmerman et al. (2021) as a critical study because "it was the only study to report the odds of not being protected against diphtheria." The SAB recommended the EPA consider different populations in selecting studies for POD derivation (USEPA, 2022b, p. 35). Timmerman et al., (2021) was chosen for comparison purposes as it represented another population—children from Greenland—compared to studies conducted in the Faroe Islands. As the EPA noted in previous responses (e.g., Doc. #1774, SBC-045661), a cross-sectional study design does not preclude a study from quantitative consideration. Overall, the EPA relied on the most reliable modeling results and best-conducted studies available to serve as the basis for the health outcome-specific RfD for immune effects (Budtz-Jørgensen and Grandjean, 2018).

3M Company (Doc. #1774, SBC-053289)

(2C) EPA's removal of important modeling co-variates is not accepted practice and is inconsistent with study authors' conclusions.

EPA's improper analyses and lack of justification for alterations of previously published models lacks statistical rigor, are problematic, and leads to incorrect conclusions. An important modeling approach for assessing population phenotypes that aid in the assessment of representative models, is to include at least some basic population information like ethnicity, age, gender, socioeconomic status, and other components in the model. Here, EPA's failure to adjust BMD calculations for key co-variates results in incorrect BMD model generation which led to incorrect BMDL values.

In fact, the Budtz-Jørgensen & Grandjean (2018) study reveals, both in the SAS output and as clearly stated in the original paper (at 7), when co-variates like gender, age, and type of booster are included in the model, the relationship of PFOS or PFOA blood concentrations are shown to have a non-significant relationship with antibody titer changes (see Table 1, below reproduced from Table 1 of Budtz-Jørgensen & Grandjean, 2022). We provide other examples where models

are developed without inclusion of important statistically significant covariates arises later in the comments. For example, we will demonstrate that the PFOA and PFOS blood concentration relationships to selected response variables are very weak to non-existent when using US nationally representative data such as NHANES.

Table 1. PFOS Model Non-Adjusted Copied from Output Sent to EPA

PFOS Model Non-Adjusted	
Variable	Pr > t
Intercept	0.510
PFOS Parameter	*0.120*
sex	0.006
Age at 7 years	0.388
Booster type at age 5	0.860
From Table 1 of (Budtz-Jørgensen & Grandjean, 2022)	

In addition, EPA has not explained when or why co-variates are either included or excluded from the statistical models used by EPA to support the MCLG. This lack of scientific rigor in model development is clearly a violation of good statistical practices (Harrell 2016). When key population metrics are included in the model, these metrics dominate any relationship between the response variable and the model parameters. In such models, the parameter associated with either PFOA or PFOS is generally statistically insignificant.

EPA Response: The commenter incorrectly stated the EPA failed to adjust for covariates, including ethnicity, age, gender, and socioeconomic status (SES) in its modeling approach and BMD calculations and even "removed" covariates from analyses. The commenter particularly criticizes the results from Budtz-Jørgensen and Grandjean (2018), claiming that once covariates are incorporated into the modeling, associations between PFOA or PFOS and antibody response are no longer statistically significant. The EPA disagrees with all of these claims, as described further below.

First, the EPA did adjust for important covariates in its modeling. For example, results from Budtz-Jørgensen and Grandjean (2018), were adjusted for age, gender, and booster type. Ethnicity and socioeconomic status were not adjusted for given the nature of the Faroese population (i.e., the Faroese are a relatively homogenous population in terms of these two characteristics). The EPA also notes this statement from the SAB PFAS Review Panel on SES: "Assuming that any and all components of SES will always confound associations with PFAS is not supportable" (USEPA, 2022b). As suggested by the SAB, the EPA takes a case-by-case approach to determine which covariates should be considered in each analysis. Please also see the EPA response to comment Doc. #1774, SBC-053296 in section 4.2.2.2.4 in this *Response to Comments* document.

Second, regarding the results from Budtz-Jørgensen and Grandjean (2018), the table of results provided by the commentor accurately shows the PFOS regression output, which the EPA also

reports in Appendix E as p=0.12 (USEPA, 2024a; USEPA, 2024b). Further, the EPA clearly states, "PFOS is a non-significant predictor in the single-PFAS model (β = −0.0274; p = 0.12)." The commenter is not providing new information that the EPA did not already describe in its supporting documents. The EPA also provided rationale for its determination to model this data, noting, "…these data can be used to estimate a BMDL for completeness and to **allow comparisons across PFAS**" (emphasis added). The EPA did not bring BMDLs based on this data forward for RfD derivation and used them for comparison purposes only.

Finally, the commenter incorrectly states that regression coefficients were generally non-significant once covariates were incorporated into the models. Specifically for results from Budtz- Jørgensen and Grandjean (2018), all four models of PFOA (two for tetanus and two for diphtheria) were significant. Out of eight combinations (i.e., antibody type, sample timing, and single-PFAS vs multi-PFAS models) across PFOS and PFOA, six results were statistically significant. All of this information was clearly and transparently provided at the time of rule proposal in the appendices to the draft toxicity assessments (USEPA, 2023b; USEPA, 2023c) and contributed to the overall weight of evidence supporting the quantitative consideration of this endpoint. The EPA did not "remove covariates" but, as described in the EPA response to comment Doc. #1774, SBC-053447 in section 4.2.2.3.1 in this *Response to Comments* document, when possible, as was the case here, the EPA selects more parsimonious models that account for fewer variables as the approach to derive PODs.

3M Company (Doc. #1774, SBC-053449)

EPA also fails to consider potential complications from the use of simple univariate linear assumptions for estimation of regression coefficients from multivariate analyses. For example, "For the immune studies, where a clinically defined adverse level is not well defined, EPA used multivariate models provided in the studies and determined a BMR according to EPA guidance to calculate BMDs and BMDLs" (EPA 2023a, P. 2-16). When EPA computed the "Regression coefficients (β) and their standard errors (SE)… from the published BMDs and BMDL based on a BMR of 5% decrease in the antibody concentration in Table 1 of Budtz-Jørgensen and Grandjean (2018, 5083631)" (EPA 2023a, p. E-269; EPA 2023b, p. E-1), it may not have appropriately factored in the complexities of adjustments for other confounding or explanatory variables (including age, sex, or adjustment for other PFAS) and therefore may have uncertainties in the computed regression coefficients. Based on the statistical outputs provided in Budtz-Jørgensen and Grandjean (2018b, 2022a, 2022b) documentation, the regression coefficient for sex is up to 3-fold larger than the coefficient for exposure in the model based on PFOA exposure and tetanus antibody concentrations at age 7. Findings like these highlight the potential impact of confounding factors and indicate potential areas of uncertainty in simplistic extrapolations from reported BMD(L)s.

EPA Response: The commenter appears to misunderstand the modeling approach. Please see the EPA response to this commenter (Doc. #1774, SBC-053289) above.

3M Company (Doc. #1774, SBC-053450)

With respect to immune response outcomes, EPA argues that the statement from WHO (2018) that "a 'protective antibody concentration' may not be considered a guarantee of immunity under all circumstances" indicates an absence of a clear definition of an adverse effect. Regardless, "As a check, EPA evaluated how much extra risk would have been associated with a BMR set at a cutoff value of 0.1 IU/mL" (EPA 2023b, E-273). However, EPA does not describe the methods for derivation of a hybrid "extra risk" BMR with a cutoff of 0.1 IU/mL, nor does it describe the resulting BMD(L)s. Based on the limited reporting, it does not seem that EPA re-calculated a BMD(L)s based on the assumption of clinical protection at 0.1 IU/mL and, instead, used "the observed distribution of tetanus antibodies" to calculate the extra risk of values below the cutoff of 0.1 IU/mL. Additional transparency is needed in order to understand 1) the methods used and 2) the impact of using alternative BMRs based on clinical cut-points on BMD(L) derivation.

EPA Response: The commenter misunderstands the modeling approach described in the draft toxicity assessments for PFOA and PFOS (USEPA, 2023b; USEPA, 2023c). The commenter incorrectly claimed that the EPA did not adequately describe the methods for derivation of a hybrid "extra risk" BMR with a cutoff of 0.1 IU/mL and that the agency did not describe the resulting BMD(L)s. The extra risk analysis was a sensitivity analysis, the methods for which are described in agency guidance (USEPA, 2012), not an analysis that was meant to produce a BMDL. The extra risk check was meant for illustrative purposes that the use of ½ SD is a reasonable estimate of a 5 percent extra risk. However, the analysis does indicate that even if the agency had selected the hybrid approach using a cutoff of 0.1 IU/mL, there would likely be minimal impact on the BMDLs. The EPA presents rationale for why the hybrid approach was not used for this endpoint in Appendix E and Section 4 (USEPA, 2024d; USEPA, 2024c; USEPA, 2024a; USEPA, 2024b).

Raptor Pharm & Tox, Ltd (Doc. #1644, SBC-052845)

Budtz-Jorgensen and Grandjean 2018

This study did not demonstrate an adverse human health outcome. I have discussed issues with this study in detail elsewhere (https://toxictruthblog.com/epa-pfoa-and-pfos-health-advisories-violateguidelines-and-sdwa/). Briefly, if one looks at Figure 1, it is apparent that the Budtz-Jorgensen and Grandjean model only goes down to a diphtheria antibody concentration of 0.444 IU/mL – that's 44x larger than the basic immunity threshold of 0.01 IU/mL. What this means is that the Budtz-Jorgensen and Grandjean model is incapable of establishing that diphtheria antibody concentrations reach the level where adverse human health outcomes occur.

In addition, Budtz-Jorgensen and Grandjean is simply correlative. It is not causal. One cannot use this study to state that "but for PFOS/PFOA, the diphtheria antibody levels would be normal." There is no way for this study to make such a claim as it is not possible to test the counterfactual condition required to make the causal argument.

In addition, the BMDL identified in Budtz-Jorgensen and Grandjean violates the US EPA's Benchmark Dose Technical Guidance. In US EPA's Draft Approaches to the Derivation of an MCLG for PFOS in Drinking Water, US EPA echoes what Budtz-Jorgensen and Granjean state as a justification for their improper use of a 5% BMR when US EPA states: "for a developmental effect, a BMR of 5% is recommended. Given the range of health outcomes includes fatality and the effect on children, a BMR of 5% is a reasonable and appropriate choice." That is in violation of the Benchmark Dose Technical Guidance.

EPA misapplied the BMD guidance by confusing the data they actually have in Budtz-Jorgensen and Grandjean, which is continuous, for quantal data, thereby misapplying the quantal guidance to the continuous data.

Or more precisely, Budtz-Jorgensen and Grandjean are misapplying The Benchmark Dose Technical Guidance, and EPA is going along for the ride, but chooses to justify the 5% benchmark response (BMR) in a slightly different way.

What EPA and Budtz-Jorgensen and Grandjean did was to read the wrong part of the Benchmark Dose Technical Guidance; specifically they both are referencing the (dichotomous) data section "…most reproductive and developmental studies with nested study designs easily support a BMR of 5%. Similarly, a BMR of 1% has typically been used for quantal human data from epidemiology studies." BudtzJorgensen and Grandjean reasoned that a 5% BMR was more appropriate because it was the "lower BMR", which defies logic as a 1% BMR is also mentioned; however, more importantly EPA improperly concluded that a BMR of 5% is appropriate "[g]iven the range of health outcomes includes fatality and the effect on children…"

However, Budtz-Jorgensen and Grandjean data are continuous. That means EPA must apply the continuous data guidance, not the quantal data guidance. The continuous data guidance begins in the very next section and paragraph of the Benchmark Dose Technical Guidance. Therefore, as the data in Budtz-Jorgensen and Grandjean is continuous data, and not quantal data, EPA has misapplied the BMD Guidance, and has used an inappropriate BMR.

These points taken together demonstrate that EPA/OW has grossly misapplied the BMD process and has made a significant error.

What EPA should have done is clearly stated in the Benchmark Dose Technical Guidance because they have continuous data and a consensus basic immunity threshold for diphtheria antibodies (page 22):

The ideal is to have a biological basis for the BMR for continuous data, e.g., a consensus scientific definition of what minimal level of change in a continuous endpoint is biologically significant.

US EPA, Benchmark Dose Technical Guidance, page 22

This means that EPA, and not Budtz-Jorgensen and Grandjean, must use the consensus, clinically validated antibody threshold, established by the CDC, FDA, and the WHO in their benchmark dose analysis. That level is 0.01 IU/mL.

Bottom Line: EPA should have used the basic immunity threshold of 0.01 IU/mL as the BMR. Therefore, EPA erred when it stated that a 5% BMR is reasonable and appropriate.

EPA Response: Regarding the adversity of the antibody response critical effect, please see section 4.2.2 of the EPA response in this *Response to Comments* document. Additionally, the commenter stated that "the Budtz-Jorgensen and Grandjean model is incapable of establishing that diphtheria antibody concentrations reach the level where adverse human health outcomes occur." The EPA disagrees with this statement and the rationale provided by the commenter as support. Although the study did not demonstrate clinical cases of disease for the pathogens examined in Budtz-Jorgensen and Grandjean (2018), the EPA and the SAB agreed clinical manifestation of the disease was not necessary to demonstrate an adverse, immunotoxic effect:

"The SAB's PFAS review panel noted that reduction in the level of antibodies produced in response to a vaccine represents a failure of the immune system to respond to a challenge and is considered an adverse immunological health outcome {USEPA, 2022, 10476098}. This is in line with a review by Selgrade (2007, 736210) who suggested that specific immunotoxic effects observed in children may be broadly indicative of developmental immunosuppression impacting these children's ability to protect against a range of immune hazards—which has the potential to be a more adverse effect that just a single immunotoxic effect" (USEPA, 2023f; USEPA, 2023a, Sec. 4.1.1.2; see also USEPA (2022b))).

The EPA also notes that this one study was not the sole basis of the EPA's determination that the *evidence indicates* that there is likely an association between PFOA and PFOS and adverse immune effects in humans. For further discussion on the EPA's weight of evidence approach and systematic review of the literature, please see section 4.1.1 of the EPA response in this *Response to Comments* document, and for discussion specific to the antibody response effect, please see the EPA response to comment Doc. #1774, SBC-053430 in section 4.2.1.4 in this *Response to Comments* document.

The commenter incorrectly stated that the EPA used a BMR of 5 percent to estimate PODs for immune endpoints. As described in Appendix E.1 (USEPA, 2023b; USEPA, 2023c), the "EPA reevaluated the approach chosen by Budtz-Jørgensen and Grandjean (2018, 5083631) and determined that a different approach should be used to be consistent with EPA guidance {U.S. EPA, 2012, 1239433}, which recommends the use of a 1 or ½ SD change in cases where there is no accepted definition of an adverse level of change or clinical cut-off for the health outcome." The EPA ultimately selected a BMR of ½ SD change, which is described in Section 4.2 and Appendix E of the final toxicity assessments for PFOA and PFOS (USEPA, 2024d; USEPA, 2024c; USEPA, 2024a; USEPA, 2024b).

The commenter also stated that the EPA should have used the "clinically validated antibody threshold" of 0.01 IU/mL as the BMR for the antibody response endpoint modeling. As

discussed in Appendix E and Section 4.2 of the toxicity assessments, the EPA disagrees with this approach (USEPA, 2024d; USEPA, 2024c; USEPA, 2024a; USEPA, 2024b). More specifically, the EPA stated in the draft assessments (USEPA, 2023b; USEPA, 2023c) "[t]he amount of circulating antitoxin needed to ensure complete immunity against tetanus is not known for certain. Establishment of a fixed level of tetanus antitoxin does not take into consideration variable conditions of production and adsorption of tetanus toxin in the anaerobic area of a wound or a necrotic umbilical stump. A given serum level could be overwhelmed by a sufficiently large dose of toxin. Therefore, there is no absolute protective level of antitoxin and protection results when there is sufficient toxin-neutralizing antibody in relation to the toxin load (Passen and Andersen, 1986)."

Connecticut Department of Public Health (Doc. #1745, SBC-045208)

EPA requests comment on the derivation of the proposed MCLG for PFOA. EPA is also seeking comment on its assessment of the noncancer effects associated with exposure to PFOA and the toxicity values described in the support document on the proposed MCLG for PFOA.

The noncancer RfD of PFOA is based on the reduced antibody responses (anti-tetanus and anti-diphtheria) reported by Budtz-Jørgensen and Grandjean (2018). CT DPH recommends EPA to add more explanation on whether this health endpoint is significant in public health (i.e. how it may be related to the actual prevalence of tetanus and diphtheria). The clinical relevance is unclear for a 5% decrease in antibody responses to tetanus and diphtheria vaccines, a fact that EPA acknowledged in its draft proposed MCLGs for PFOA and PFOS (EPA 2021; Appendix B, Section B.1.1). In general, the lack of antibody responses to vaccinations does not equate to having an increased susceptibility to clinically significant disease; it is unknown whether persons that fail to mount sufficient antibody response (≤ 0.1 IU/mL) are at higher risk to acquire infections or develop disease (Weidermann et al. 2016). Moreover, there is no evidence that a reduction in serum antibody levels has any long-term effect (lifetime) on a person's health.

However, there is good evidence that the intensity of the humoral response to trigger the production of specific antibodies in response to a given stimulation is highly variable (Bil et al 2023) and influenced by a variety of factors that include age, gender, and genetics (Scepanovic et al 2018; Tsang et al. 2014; Ovysyannikova et al 2004). Such high variability in response to vaccinations was listed as one of the main reasons that researchers were unable to derive internal relative potency factors (RFPs) for the immunosuppressive effects of PFAS based on NHANES data in 12-19 year olds. A better understanding of the natural variation in human response to vaccinations is needed to support the use of immunomodulation associated with PFAS exposure as a point of departure for human risk assessment (Antoniuo et al 2022). CT DPH recommends EPA provide more explanation of the mechanisms by which PFAS alters the immune status, a necessary step to establish the validity of markers for predicting disease and the degree of their predictability.

CT DPH also encourages EPA to add more discussion on whether there is enough evidence that the findings in the studied population (Faroese children) is also representative of the general US population. Without such information, derivation of PFOA RfD based on this study may not be well supported to reflect the human health effects of PFOA exposure in the US through drinking water. The EPA risk analyses, based on geometric mean (g.m.) serum PFOA and PFOS levels in Faroese children at age 5 that are 3-fold (PFOA) to 4-fold (PFOS) higher than levels measured in the total U.S. population (NHANES 2017-2018), and the difference is likely greater for PFOS (up to 5-fold) if comparative data were available for U.S. children; NHANES (2013-14) data showed children aged 3 to 5 years had 1.5-fold lower PFOS levels than the those for the total U.S. population. Moreover, the immune effects measured in the Faroese children are likely impacted by their higher concentrations (compared to U.S. general population) of serum methylmercury (~10-fold higher) and PCBs. Both have been linked to developmental immunotoxicity in studies of experimental animals (methylmercury; Tonk et al. 2010) and in studies of this Faroese cohort: higher serum PCBs reduced antibody responses to diphtheria and tetanus vaccinations (Heilmann and Grandjean et. al. 2006; Heilmann and Budtz-Jorgensen et al. 2010), prenatal concentrations of mercury and PCBs were associated with lower autoantibodies (Osuna and Grandjean et al. (2014), while children's serum levels of PCBs and methylmercury at age 7 were associated with both an increase and decreased risk of allergic disease (Grandjean et al. 2010). Levels of serum PCBs (as well as DDE) have also been associated with reduced antibody response to infant tuberculosis vaccinations in Slovakian populations (Jusko et al 2016).

More recently, EPA IRIS (2023) derived an RfD for PFDA (0.004 ng/mg-d) that is 7.5-fold more conservative than the RfD (0.03) for the PFOA proposed MCLG, based on analyses of data from the same Faroese cohort that used the same endpoint (reduced Ab response to diphtheria and tetanus) and same BMD approach (0.5% SD BMR) as was used to derive the RfD for proposed MCLG for PFOA. The more conservative RfD for PFDA suggests that PFDA has a much greater impact on antibody response than PFOA and PFOS, and illustrates the difficulties of trying the disentangle the immune effects of individual PFAS from one another, notwithstanding the need to evaluate the impact of other immunotoxicants (methylmercury and PCBs) on antibody response in the Faroese population (there is no mention of methylmercury or PCBs in the proposed MCLGs for PFOA and PFOS).

The above listed points only scratch the surface of the complex issues and uncertainties surrounding the use of human data, and specifically antibody responses to vaccinations, as a critical endpoint in the risk assessment of PFOA and PFOS. Therefore, CT DPH recommends that EPA consider the use of other critical endpoints in its non-cancer risk assessment for PFOA and PFOS.

CT DPH also requests that EPA provide a more in-depth explanation of why it chose to use a different BMD model (linear) that resulted in chronic RfDs for PFOA and PFOS that are 20- and 25-fold higher than the respective RfDs derived using the BMD (piecewise linear) model

selected in the draft MCLGs for PFOA and PFOS because "the piecewise model tended to show slightly better fit values due to greater flexibility" (EPA 822D21001; December 2021).

EPA Response: The commenter appears to have been referencing earlier draft versions of the toxicity assessments (USEPA, 2021b; USEPA, 2021c) submitted by the EPA to the SAB for peer review, rather than the draft toxicity assessments that were published at the time of rule proposal (USEPA, 2023f; USEPA, 2023a) that were updated based on the feedback from the SAB (USEPA, 2022b). Therefore, many of the commenter's requests and concerns are no longer relevant. For example, the commenter recommended that the EPA "add more explanation on whether this health endpoint is significant in public health," which was available in Section 4.1 of the 2023 draft assessments (USEPA, 2023f; USEPA, 2023a). The commenter also requested clarification on the clinical relevance of a BMR of 5 percent for the antibody response endpoint, which was updated to a BMR of 0.5 SD in the 2023 draft assessments. Additionally, the EPA provided discussion on potential mechanisms of immune toxicity in Section 3.4.2.3 of the draft toxicity assessments for PFOA and PFOS (USEPA, 2023f; USEPA, 2023a) and the commenter quoted text from the 2021 draft versions of the PFOA and PFOS toxicity assessments that was no longer presented in the 2023 public comment drafts. The commenter requested the EPA consider the use of other critical endpoints in the agency's non-cancer risk assessment. Again, the agency did do this in the draft assessments published at the time of rule proposal (USEPA, 2023f; USEPA, 2023a). More specifically, the EPA selected co-critical effects of reduced antibody response to vaccination in children, increased serum total cholesterol in adults, and decreased infant BWT as the basis of the overall RfD for PFOA and co-critical effects of increased serum total cholesterol in adults and decreased infant BWT as the basis of the overall RfD for PFOS. For PFOS, antibody response to vaccination is no longer considered a co-critical effect, though the EPA presented a candidate RfD for this endpoint which serves as the basis for the PFOS immune health outcome-specific RfD. The EPA responds to portions of this comment that are relevant to the 2023 draft toxicity assessments below.

Regarding the adversity of the antibody response endpoint and comparisons between the Faroese and U.S. populations, please see section 4.2.2 of the EPA response in this *Response to Comments* document. Regarding the EPA draft PFDA assessment, a BMR of 0.5 SD (not 0.5 percent SD) was used for BMDL estimation, which is consistent with the EPA's BMR selection in the draft and final PFOA and PFOS toxicity assessments (USEPA, 2023f; USEPA, 2023a; USEPA, 2024d; USEPA, 2024c). The PFDA assessment also compared BMDLs determined based on regression coefficients from models with and without additional adjustment for PFOA and PFOS, and they were very similar (0.411 *vs.* 0.497 ng/mL in serum), indicating that potential confounding by PFOA and PFOS may not have a significant impact on that exposure-response relationship. The EPA disagrees that there is no mention of methylmercury or PCBs in the toxicity assessments for PFOA and PFOS. The EPA notes in Appendix D when studies controlled for methylmercury or PCBs, as well as in the study quality evaluations available in HAWC and Section 3 of the toxicity assessments (USEPA, 2024d; USEPA, 2024c; USEPA, 2024a; USEPA, 2024b). Again, the commenter may have been referring to the earlier versions of these assessments published in 2021 (USEPA, 2021b; USEPA, 2021c).

4.2.2.3.2 Comments Specific to Total Cholesterol (TC) Modeling

3M Company (Doc. #1774, SBC-053293)

4. NHANES cholesterol values changed significantly due to non-PFAS factors

NHANES determined that a change in assay methods was most likely responsible for changes in HDL cholesterol values in the NHANES cycles from 1999-2008 (Source: National Health and Nutrition Examination Survey, 1999-2000 Data Documentation, Codebook, and Frequencies Cholesterol L (Lab13) https://wwwn.cdc.gov/Nchs/Nhanes/1999- 2000/LAB13.htm). NHANES developed a formula to correct HDL values and re-posted the corrected data. It is very rare that papers document when data extracts were downloaded but it is not uncommon for papers to take more than two years from publication to data analysis and papers published with data prior to corrections will have inaccurate findings. The following table shows the original dates of data published for cholesterol as well as prescription drugs.

NHANES Cycle	Prescription Drugs		TC & HDL		LDL	
	First Published	Last Revised	First Published	Last Revised	First Published	Last Revised
1999-2000	-	-	Jun-02	Apr-10	Jun-02	Mar-07
2001-2002	-	-	Sep-04	Apr-10	Jun-05	Mar-07
2003-2004	Aug-07	Jun-09	Jun-06	Apr-10	Sep-06	May-08
2005-2006	Sep-08	Jun-09	Nov-07	Apr-10	Mar-08	
2007-2008	Apr-10		Sep-09	Feb-10	May-10	Sep-10
2009-2010	May-12		Sep-11		Dec-11	
2011-2012	Jul-14		Sep-13		Jan-14	
2013-2014	Dec-16		Oct-15	Mar-16	Mar-16	
2015-2016	Jan-19		Sep-17		Jan-19	
2017-2018	Mar-20		Feb-20		Dec-20	Mar-21
2017- Pre 2020	Sep-21		Aug-21		Oct-21	

Again, any and all analyses that EPA is relying on that included NHANES data must use the most accurate datasets supplied by NHANES.

EPA Response: The commenter suggested that NHANES HDL cholesterol values were corrected which resulted in the EPA relying on studies using inaccurate data in their analyses. The EPA disagrees that studies included in dose-response analyses utilizing NHANES data were inaccurate. Dong et al. (2019) was the only NHANES study the EPA modeled for total cholesterol. The study was published in 2019, and by the commenter's own estimation of two years between data analysis and publication, Dong et al. (2019) would have had access to updated NHANES data, which, according to commenter's table, were primarily adjusted in 2010 to account for the change in assay methods. Further, the EPA re-analyzed the data using the same model from Dong et al. (2019) with updated NHANES data from 2022 (USEPA, 2023c; USEPA,

2023b, Sec. E.1.3.1). Considering the timing of the publication of Dong et al. (2019) and the EPA's re-analysis presented in the draft toxicity assessments, NHANES updates over a decade prior would not be a concern. HDL cholesterol was not a modeled endpoint, nor was it considered a supporting factor for cardiovascular effects of PFOA or PFOS (USEPA, 2024d; USEPA, 2024b, Sec. 3.4.3.4.1).

3M Company (Doc. #1774, SBC-053295)

5. Dong et al., 2019, a key study upon which EPA relies, has serious methodological issues that render it unreliable.

EPA repeatedly cites Dong et al. (2019) in estimating Point of Departure (POD), reference dose (RfD), and benchmark dose (BMD) (USEPA 2023b, 2023d). The importance of this paper in EPA's analysis can be seen in particular on:

· Page F-10 of USEPA 2023b states "Although the datasets and models were not exactly the same in all NHANES-based studies, to avoid estimate dependency issues due to overlapping populations in the meta-analysis, EPA also performed a sensitivity analysis including only the data from the study covering the broadest range of NHANES cycles (2003–2014) (Dong et al.,2019)."

· Page K-4 of USEPA 2023b states "The use of single study-based TC effect estimates, rather than EPA meta-analysis-based effect estimates. To this end, EPA used estimates from a large NHANES study (Dong et al., 2019) …"

· Page E-298 of USEPA 2023c states that EPA re-analyzed the data using the regression models from the Dong et al., 2019 study, together with updated NHANES data, applied to a modified hybrid model to develop BMD and BMDL estimates for various time periods and assumptions.

Methodological issues with Dong et al.(2019) that seriously impact the veracity of the statistical associations found and alter the fundamental representational aspects of NHANES data include:

1. Dong et al. (2019) did not analyze the full NHANES dataset but rather excluded certain cholesterol and PFAS values. On page 463 the authors state, "to ensure no influential points heavily impact on the analysis results, the outliers for PFASs and cholesterol (data points more than 1.5 interquartile ranges (IQRs) below the first quartile or above the third quartile) were excluded."

2. Not only did the authors exclude portions of the original data for outliers, they also excluded based on age on page 464. The authors state, "The regression analysis was also conducted for adults [20-80 years] since most correlations observed for adolescents were insignificant." Data should only be excluded when they are known to be incorrect, due to laboratory measurement errors, etc. When data exclusion changes the results of the study or misrepresents the study, exclusion of the data is improper (Resnick 2000). EPA has not justified data exclusions by any of

the outside authors, and EPA has not internally rigorously evaluated data treatment nor established good data treatment guidelines that are consistent with DQOs.

3. The final regression models for BMD calculations published by the authors did not adjust for gender nor age despite the fact that these co-variates were found to be significant by their own analyses.

4. As recognized by EPA, Dong et al. (2019) did not explicitly state that the models generated used the appropriate NHANES weighting.

5. Dong et al. (2019) used custom code within a statistical software package (Matlab) to conduct a hybrid BMD calculation rather than using EPA approved BMD modelling software (e.g. BMDS (USEPA 2022))

Given these serious statistical and methodological issues, rating the Dong et al. (2019) study as a medium quality study, as EPA did here, is inconsistent with EPA statements on how it judged the merits of specific studies for the purpose of assigning a quality score. Additionally, given that the exclusion done by the authors removes the national representative nature of the NHANES dataset and introduces strong bias into the analysis, it is inconsistent with sound science and EPA's own guidance to use it as a basis for calculating BMDs.

Despite these significant issues with Dong et al., (2019) EPA retained the slope estimates and used these flawed estimates to calculate BMD and BMDL (see page E-298 of U.S, 2023c "where m is the slope, β, (from the Dong regression model) and b is the intercept."). It is not proper statistical practice to realize that a previous analysis used flawed methodologies and verify that with your own analyses as EPA did here, only to go ahead and use the incorrect values.

EPA has not followed its own QC guidelines when using findings from outside sources. EPA has not questioned many of the selected author's findings or taken steps to replicate them, nor has EPA reviewed the original author's poor data treatment. Given the deviation from sound practice and EPA guidance with respect to EPA's treatment of Dong et al. (2019), it is likely this lack of quality control and poor statistical practice has carried over to other data and statistical modeling activities throughout the technical portion of the Proposed NPDWR.

EPA Response: The commenter stated that the *medium* confidence rating for Dong et al. (2019), as well as its use in deriving PODs and candidate RfDs, is inconsistent with the EPA's guidance. Specific issues with this paper raised by the commenter included: the exclusion of outlier values of PFAS and cholesterol; the exclusion of NHANES participants under age 20; a lack of adjustment for age and gender in the regression models for BMD modeling; uncertainty regarding how the NHANES data were weighted (please see the EPA response to comment Doc. #1774, SBC-053293 in section 4.2.2.3.2 in this *Response to Comments* document); and how the EPA conducted hybrid BMD modeling using code the commenter characterized as not developed using "EPA approved BMD modelling software." The EPA disagrees with these statements.

First, the EPA disagrees that it did not follow its own guidance for study quality evaluation and BMD modeling. For additional discussion on the EPA's use of the best available science and

application of EPA guidance, see sections 4.1.1 and 4.1.2 of the EPA response in this *Response to Comments* document.

Second, the commenter points to a common and best-practice statistical approach of evaluating the impact of outliers on model performance and performing regressions excluding outliers from the analysis, if warranted by the data (Rosner, 2015). As illustrated in figure 1 in Dong et al. (2019) and as is typical in NHANES datasets, excluding outliers would not exclude a large proportion of the NHANES dataset as the commenter implied.

Third, the EPA disagrees with the statement that Dong et al. (2019) excluded data based on age. Rather, Dong et al. (2019) quantified correlations between PFAS and serum lipids separately in those age 12-19 and those age 20-80, then further explored associations among adults ages 20 and older in regression models based on the results of the correlation analysis. Conducting analyses for different subgroups of a study population (e.g., children versus adults) is a common best practice when associations are hypothesized to vary in magnitude and direction between groups, as is the case for serum lipid effects in children and adults. Furthermore, the age group included in the regression modeling in Dong et al. (2019) is aligned with the evidence judgement for PFOA/PFOS and serum lipids described in Section 3.4.3.4 of the toxicity assessments, which is primarily based upon significant findings in adults in the general population (USEPA, 2024d; USEPA, 2024c).

Fourth, the EPA disagrees that the final regression models in Dong et al. (2019) were not adjusted for age and gender. In describing the statistical analysis, Dong et al. (2019) state that "…age (12–80 yrs), gender (male or female), race (Mexican-American, other Hispanic, non-Hispanic white, non-Hispanic black or others), family income index (ratio of family income to poverty), body mass index (BMI), waist circumference (WC), physical activities (vigorous, moderate or low physical activity in the preceding 30 days) were included as confounding variables."

Finally, the hybrid modeling approach, described in the *Benchmark Dose Technical Guidance* (USEPA, 2012), cannot be conducted in the EPA's BMDS. Therefore, the EPA must use alternative statistical software to conduct these analyses. The commenter incorrectly implied that there is only one "EPA approved" statistical software. For additional detail on how the EPA conducted BMD modeling, including the use of software and the hybrid approach, see Appendix A, Section A.1.11.2 and Appendix E of the toxicity assessments (USEPA, 2024a; USEPA, 2024b).

Given the commenter's many erroneous claims regarding the quality of the Dong et al. (2019) study, the EPA maintains its position that this is a *medium* confidence study that is suitable for quantitative and qualitative consideration in the PFOA and PFOS toxicity assessments.

3M Company (Doc. #1774, SBC-053451)

EPA states that the sensitive BMR of 5% extra risk was selected for TC models instead of 10% extra risk because use of a 10% BMR would result in a "highly improbable doubling of risk" (see EPA 2023a,b; Table 4-2) because "the percentage of U.S. adults aged 20 and older with total cholesterol ≥240 mg/dL is 11.5%" (EPA 2023b, p. 4-15). In this calculation, EPA erroneously fails to consider the impact of a lack of true control, or "zero exposure" group, on the extra risk calculation since the general population is exposed to at least some measurement of PFAS (see Section 3.9). Before reducing the BMR for models measuring changes in serum TC, EPA did not consider the clinical impact, the confidence in the underlying findings, the biological significance, or the impact of the lack of a true control or "zero exposure" reference on the BMR calculation through extra risk methods. The estimate of 11.5% of US adults with TC ≥ 240 mg/dL may be an underestimate of background high cholesterol in the US; the CDC indicates that, between 2015-2018, 25% of US adults aged 20 or older have hypercholesterolemia or take cholesterol-lowering medications (CDC, 2023). Although EPA does provide the BMD(L)s based on a BMR of 1SD and 0.5SD for Lin et al. (2019; e.g., EPA 2023a, Table E-26) and Steenland et al. (2009; e.g., EPA 2023a, Table E-22), comparisons to a BMR based on a SD change are not provided for Dong et al. (2019, e.g., EPA 2023a, Table E-18), the key study used for POD derivation for TC. It is estimated that, should the EPA use a BMR of 0.5 or 1 SD for deriving a BMDL from Dong et al. (2019), the derived BMDL for PFOA may increase from the selected value of 5% extra risk BMDL of 2.29 ng/mL to 8.12 or 15.5 ng/mL, respectively. Notably, the provided comparisons of BMD(L)s from Lin et al. (2019) and Steenland et al. (2009) based on changes in BMRs do not include the selected BMR of 5% extra risk. It is not clear that EPA consistently used a BMR of 5% extra risk for evaluating all TC studies. Additionally, EPA did not provide justification for use of a 5% extra risk for changes in TC, not hypercholesterolemia incidence, instead of a BMR of 0.5 or 1SD.

EPA Response: The commenter appears misunderstand the modelling approaches for POD derivation used by the EPA. For a detailed response on selection of BMR of 5 percent and on consideration of background exposures, see previous responses to this commenter (e.g., Doc. #1774, SBC-053453) and the rationale the agency provided in the toxicity assessments for PFOA and PFOS (e.g., Section 4.2 of USEPA, 2024d; USEPA, 2024c).

The commenter claims that the EPA failed to provide a comparison of the BMDLs derived for total cholesterol for the critical study (Dong et al., 2019) using a BMR of 0.5 or 1 SD. This is based on an incomplete understanding from the commenter of when such an approach is needed. The modelling approach for Dong et al. (2019) was a hybrid approach using a BMR of 5 percent and the regression slopes from the study. The BMDS approach reported a sensitivity analysis for Lin et al. (2019) or Steenland et al. (2009) is based on mean serum TC or elevated serum TC measures reported by quintile or quartiles of exposures. Such data were not available for Dong et al. (2019) and therefore, this analysis was not conducted (see also the EPA response to comment Doc. #1774, SBC-053444 in section 4.2.2.3 in this *Response to Comments* document).

Raptor Pharm & Tox, Ltd (Doc. #1644, SBC-052846)

Steenland et al 2009

Steenland et al 2009 models predicted total cholesterol, HDL cholesterol, and LDL cholesterol as a function of median PFOA and PFOS levels. As summarized by PennMedicine, dangerous levels of cholesterol levels are: Total > 240mg/dL; LDL > 160mg/dL; HDL < 40mg/dL.

Steenland et al's models demonstrate levels of total cholesterol, LDL, and HDL that are all below the well-accepted dangerous levels. In fact, the levels tend to plateau suggesting that PFOA and PFOS will not drive the levels into dangerous levels at human-relevant concentrations.

This demonstrates that Steenland et al. 2009 has not identified any adverse health outcomes due to PFOA or PFOS exposure. This demonstrates that EPA is using a POD based on this study that is not biologically meaningful, and that PFOA and PFOS are not associated with any adverse health outcomes.

EPA Response: The commenter stated that Steenland et al. (2009) did not identify adverse alterations in serum lipid responses. The EPA disagrees with this comment. As detailed in section 4.2.2 of this *Response to Comments* document, while increases in serum lipid measures such as total cholesterol may not result in changes that would be considered clinically elevated in particular individuals, small changes in the average response of such endpoints can result in substantial health impacts at the population level given the distribution of individual concentrations within the population. The absence of clinically elevated cholesterol levels in Figures 2 and 3 of Steenland et al. (2009) does not imply that such levels would not be observed in the general population, as the model-predicted results in these figures are specific to a subset of relatively healthy individuals (e.g., never smokers, no alcohol use).

4.2.2.3.3 Comments Specific to Alanine Aminotransferase (ALT) Modeling

Raptor Pharm & Tox, Ltd (Doc. #1644, SBC-052847)

Gallo et al. 2012

Gallo et al. also failed to demonstrate an adverse health outcome. A quick review of Table 1 demonstrates that the ALT levels measured in the study are not beyond what is considered a normal ALT level for 87.5% of the population they measured. About 12.5% had an elevated ALT – this is in keeping with the average for the US population with an elevated ALT at any given time. However, it is important to note that an ALT higher than 45 IU/L is not necessarily an indication of any adverse health effect.

ALT by itself is not diagnostic of liver injury. Exercise is well-known to increase ALT levels. Hospital admission itself has been known to increase ALT levels (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC545762/). To be clear, we do not become truly concerned about ALT levels until the levels are very highly elevated (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC545762/).

In this study, the only other biomarkers that may inform on potential liver injury are bilirubin and GGT.

Bilirubin is generally considered a longer-term marker of liver injury, and it is a functional marker as well. In this case, 10x more people have ALT increases compared to the number with bilirubin increases. What we don't know is how many of the people with bilirubin increases also have ALT increases. If we assume they're the same, then this is a very tiny fraction of the overall subjects that have an adverse liver health outcome.

But even still, the models never approach the level of bilirubin, GGT, or ALT, that would be indicative of liver toxicity as a function of PFOA or PFOS. This demonstrates that Gallo et al. 2012 has not identified any adverse health outcomes due to PFOA or PFOS exposure.

This demonstrates that EPA is using a POD based on this study that is not biologically meaningful, and that PFOA and PFOS are not associated with any adverse health outcomes.

EPA Response: The commenter stated that Gallo et al. (2012) did not demonstrate an adverse health outcome associated with PFOS or PFOA and further states that this implies that the EPA is using a POD that is not biologically meaningful. To support this point, the commenter noted that the proportions of study participants with elevated levels of ALT and other liver enzymes were relatively small, and that factors such as hospitalization and exercise could contribute to increased ALT. The EPA disagrees that these points imply the absence of an adverse health outcome. First, as described in Section 4.1.1.1 of the PFOA and PFOS draft and final toxicity assessments, evidence from both epidemiologic and toxicologic studies indicates that elevated serum ALT is associated with clinical liver disease (USEPA, 2023f; USEPA, 2023a; USEPA, 2024d; USEPA, 2024c). Second, as detailed in section 4.2.2 of this *Response to Comments* document, small changes in the average response of endpoints such as ALT can result in substantial impacts at the population level given the distribution of individual concentrations within the population (Gilbert and Weiss, 2006). Finally, the presence of a relationship between non-chemical factors (e.g., hospitalization, exercise) and ALT does not imply that elevated ALT is not clinically significant. Additionally, the SAB was supportive of the EPA's consideration of this endpoint and stated, "EPA should use Alanine Aminotransferase (ALT) as an endpoint in light of the numerous studies in the literature that support an association between slight elevations in ALT and increased risk of morbidity and/or mortality" (USEPA, 2022b).

4.2.2.3.4 Comments Specific to Birth Weight Modeling

3M Company (Doc. #1774, SBC-053212)

3. Candidate study selection for developmental effects was not transparent

In reviewing EPA's draft documents, the SAB recommended "that additional clarification and detail be included to support the selection of the critical effect and why this effect, beyond having the lowest PODHED, is the most scientifically appropriate choice as well as being the most protective of public health." (USEPA 2023j, p. 38). In other words, SAB told EPA that it needed to show why critical studies were selected beyond simply having the lowest POD. EPA failed to do so with respect to its analysis of developmental effects.

The IRIS Handbook recommends that only well conducted high or medium confidence human and animal toxicological studies be considered for POD derivation (USEPA ORD 2022). EPA chose 6 studies for POD development for PFOA (Chu et al. 2020; Govarts et al. 2016; Sagiv et al. 2018; Starling et al. 2017; Wikstrom et al. 2020; Yao et al. 2021), and six for PFOS (Chu et al. 2020; Sagiv et al. 2018; Starling et al. 2017; Wikstrom et al. 2020; Darrow et al. 2013; Yao et al. 2021). EPA ultimately chose Wikstrom et al. (2020) for RfD derivation for both compounds. EPA did not describe why these studies were chosen among the multiple medium and high-quality studies for POD derivation, as the SAB requested. Over 30 medium or high confidence studies of birth weight and PFOA were available, and nearly 40 medium or high confidence studies of PFOS and birth weight. All of the studies selected as candidates were rated high confidence, though 4 of the studies measured PFAS later in pregnancy or after delivery, making them subject to biases from pregnancy hemodynamics (Chu et al. 2020; Darrow et al. 2013; Govarts et al. 2016; Starling et al. 2017; Yao et al. 2021). Had EPA's critical appraisal been conducted consistent with recommendations of the SAB and the IRIS Handbook and taken factors specific to PFAS measurement (like timing) into consideration, these studies likely would not have been considered high confidence due to this bias alone.

Both candidate studies selected for the derivation of the RfD for developmental effects measured PFAS in maternal serum taken in early pregnancy – Wikstrom et al. (2020) measured serum PFAS at a median of 10 weeks (range 3-27 weeks), and Sagiv et al. (2018) measured PFAS in a comparable time frame (median 9 weeks; range 5-19 weeks). The Sagiv study also adjusted for estimated glomerular filtration rate (eGFR) to account for blood volume increase and higher flow rate in pregnancy. Despite the additional adjustments for eGFR by Sagiv et al. (2018), Wikstrom et al. (2020) was ultimately used for RfD derivation instead. EPA's rationale for choosing the Wikstrom study over Sagiv is not clear. EPA stated: "The RfD for low birth weight from Wikström et al. (2020) was selected as the basis for the health outcome-specific RfD for developmental effects as it was the lowest and therefore most health protective candidate RfD from these two studies" (USEPA 2023a, p. 4-52, USEPA 2023b, p. 4-48). EPA offered this rationale despite the SAB's recommendation, "that additional clarification and detail be included to support the selection of the critical effect and why this effect, beyond having the lowest

PODHED, is the most scientifically appropriate choice as well as being the most protective of public health" (USEPA 2023j, p. 38).

EPA selected Wikstrom et al. (2020) as "the most scientifically appropriate choice," yet it is unclear whether there were clinically significant birth weight changes, and neither coexposures to other PFAS nor eGFR levels were accounted for in the study's analyses. Thus, EPA failed to follow the SAB's recommendation to provide additional clarification and detail in its justification for outcome-specific study selection other than having the lowest candidate RfD.

EPA Response: This comment is repetitive of others presented by the same commenter. Please refer to the EPA response to comment Doc. #1774, SBC-053452 in section 4.2.2.3.4 in this *Response to Comments* document and Doc. #1774, SBC-053428 in section 4.2.1.2 in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-053452)

Candidate study selection was not transparent.

EPA chose six studies for POD development for PFOA (Chu et al. 2020; Govarts et al. 2016; Sagiv et al. 2018; Starling et al. 2017; Wikstrom et al. 2020; Yao et al. 2021), and six for PFOS (Chu et al. 2020; Sagiv et al. 2018; Starling et al. 2017; Wikstrom et al. 2020; Darrow et al. 2013; Yao et al. 2021). EPA ultimately chose Wikstrom et al. (2020) for RfD derivation for both compounds. EPA did not describe why these studies were chosen among the multiple medium and high-quality studies for POD derivation, as the SAB requested.

Over 30 medium or high confidence studies of birth weight and PFOA were available, and nearly 40 medium or high confidence studies of PFOS and birth weight. All of the studies selected as candidates were rated high confidence, though four of the studies measured PFAS later in pregnancy or after delivery, making them subject to biases from pregnancy hemodynamics (Chu et al. 2020; Darrow et al. 2013; Govarts et al. 2016; Starling et al. 2017; Yao et al. 2021). Had EPA's critical appraisal been conducted appropriately and taken factors specific to PFAS measurement (like timing) into consideration, these studies would not have been considered high confidence due to this bias alone. EPA does not adequately explain its selection of Wikstrom et al. (2020) over Sagiv et al. (2018) or exclusion of the remaining studies.

There were additional critical deficiencies in the studies that EPA used for RfD derivation. EPA stated that although there is no consensus on how best to address PFAS co-exposures, that uncertainty was accounted for in the study quality evaluations and weight of evidence determination for birth weight. However, it was not included in the modifications to the IRIS study evaluation protocol presented in the draft toxicity assessment's Appendix documents and used for critical appraisal. Neither of the candidate studies chosen for RfD determination accounted for PFAS co-exposures in their analyses (Sagiv et al. 2018; Wikstrom et al. 2020), and EPA reviewers noted this limitation for both studies in the HAWC details of the study evaluations.

Despite this critical bias, each study was given an "adequate" rating for the confounding criteria. The authors of Wikstrom et al. 2020 found their single compound analyses to be a limitation, because of simultaneous influences by multiple environmental exposures on health outcomes. Corrections for multiple comparisons were felt to be overly conservative to be suitable for investigations of interrelated PFAS compounds, but the authors called for more carefully designed statistical models, such as mixture-based approaches, to be explored in further studies. EPA was not transparent whether it considered co-exposures to other PFAS as a serious potential bias in the study evaluations. Clear study evaluation criteria are necessary for a thorough appraisal of studies to ensure consistent application and consideration of important factors that may affect the certainty of the findings.

As discussed above, both candidate studies selected for RfD derivation measured PFAS in maternal serum taken in early pregnancy – Wikstrom et al. (2020) measured serum PFAS at a median of 10 weeks (range 3-27 weeks), and Sagiv et al. (2018) measured PFAS in a comparable time frame (median 9 weeks; range 5-19 weeks). The Sagiv study also adjusted for estimated glomerular filtration rate (eGFR) to account for blood volume increase and higher flow rate in pregnancy. Despite the additional adjustments for eGFR by Sagiv et al. (2018), Wikstrom et al. (2020) was ultimately used for RfD derivation instead. The rationale for choosing the Wikstrom study over Sagiv is not clear. EPA stated: "The RfD for low birth weight from Wikström et al. (2020, 6311677) was selected as the basis for the health outcome-specific RfD for developmental effects as it was the lowest and therefore most health protective candidate RfD from these two studies." (EPA 2023a, p. 4-52, EPA 2023b, p. 4-48). This rationale was given despite the SAB recommendation, "that additional clarification and detail be included to support the selection of the critical effect and why this effect, beyond having the lowest PODHED, is the most scientifically appropriate choice as well as being the most protective of public health." (EPA Response to Final SAB Recommendations 2023, p. 38).

EPA selected Wikstrom et al. (2020) as "the most scientifically appropriate choice", yet it is unclear whether there were clinically significant birth weight changes, and neither coexposures to other PFAS nor eGFR levels were accounted for in the study's analyses. Thus, EPA failed to follow the SAB's recommendation to provide additional clarification and detail in its justification for outcome-specific study selection other than having the lowest candidate RfD.

EPA Response: The commenter stated the EPA did not fully describe why the studies selected to derive PODs for PFOA and PFOS were chosen among other *medium* and *high* confidence studies. The commenter stated there were additional deficiencies of the critical studies, namely addressing hemodynamics and PFAS co-exposures, that were not appraised appropriately and should have resulted in a lower confidence rating for studies selected for POD derivation. The commenter stated that the EPA did not provide rationale for the selection of Wikstrom et al. (2020) as the critical study supporting the health outcome-specific RfD over Sagiv et al. (2018), citing model adjustment of estimated glomerular filtration rate (eGFR) as rationale for selecting Sagiv et al. (2018) as the basis for the health outcome-specific RfD. The

commenter stated that the EPA did not provide additional clarification for POD study selection, "beyond having the lowest PODHED," as requested by the SAB.

First, the EPA disagrees with the commenter's claim that the EPA did not provide rationale for why certain studies proceeded to POD_{HED} and candidate RfD derivation. The EPA provides reasons for candidate study selection related to study design and analysis approach (USEPA, 2024d and USEPA, 2024c, Sec. 4.1.1.4) and follows the guidelines outlined in the Appendices (USEPA, 2024a and USEPA, 2024b, Sec. A.1.11.1). The selected candidate studies were the best suited for POD derivation based on their consideration of potential confounding factors (e.g., pregnancy hemodynamics), while study designs and analyses from other *medium* and *high* confidence studies were not as well suited for modeling. Some studies did not present the data or analyses required for dose-response modeling. Due to the high number of *medium* and *high* confidence studies, multiple reasons for including the selected candidate studies were provided (USEPA, 2024d and USEPA, 2024c, Sec. 4.1.1.4). *Low* confidence studies were not considered for POD derivation due to reduced confidence in study results as a result of multiple biases and because there were numerous *medium* and *high* confidence studies to consider.

Second, the EPA maintains that there is no consensus on how best to address PFAS co-exposures, but the EPA included study quality considerations in the updated protocol as described in the toxicity assessment appendices (USEPA, 2024a and USEPA, 2024b, Sec. A.1.2). Further information on the EPA's considerations for potential confounding by co-occurring PFAS has been added to the discussion of addressing uncertainties related to modeling epidemiological studies (USEPA, 2024d; USEPA, 2024b, Sec. 5.1.1). The EPA provided rationale for this in the response to comment Doc. #1774, SBC-053428 in section 4.2.1.2 in this *Response to Comments* document. Briefly, PFAS co-exposures were considered in study quality evaluations, namely the *Confounding* domain (USEPA, 2022a). These considerations resulted in only a very small number of studies being rated *Good* for *Confounding*. Most studies examining birthweight that considered PFAS co-exposures had other deficiencies, such as exposure sampling in later pregnancy or post-delivery. The EPA agrees that sample collection later in pregnancy or post-delivery is a deficincy, which is cited as the rationale for why the EPA selected Wikstrom et al. (2020) and Sagiv et al. (2018) as critical studies for candidate RfD derivation over the others for which the EPA derived PODs (see Section 4.1.5, USEPA, 2024d; USEPA, 2024c). However, the EPA disagrees that it is a deficiency of a magnitude that would result in a reduction of the overall confidence judgment for those studies. The EPA maintains that all of the studies identified for POD derivation for the developmental health outcome should be rated as *high* confidence.

Third, the EPA disagrees Wikstrom et al. (2020) was chosen solely due to having the lowest POD_{HED}. The EPA clearly outlines rationale for the six candidate studies for PFOA and PFOS, as mentioned previously. the EPA specifically outlines why PODs derived from Wikstrom et al. (2020) and Sagiv et al. (2018) were chosen over PODs from other candidate studies (USEPA 2024d and USEPA, 2024c, Sec. 4.1). Selection of these two studies for candidate RfD derivation over the other candidate studies was not based solely on which RfD was most protective. Both studies collected maternal serum samples in early pregnancy, mitigating concerns for changes in

hemodynamics in later pregnancy. The distinction between these two *high* confidence studies relates to their comparability of exposure levels to those experienced in individuals in the United States. Sagiv et al. (2018) was conducted between 1999 and 2002, when PFOA and PFOS exposure concentrations in the United States were much greater. Wikstrom et al. (2020) conducted their study between 2007 and 2010, resulting in exposure levels more similar to those observed in the United States today. While the choice of Wikstrom et al. (2020) was the more health protective candidate RfD, it was also consistent with IRIS Handbook to select studies with "exposures near the range of typical environmental human exposures" (USEPA, 2022a). The EPA has added language clarifying this in the final toxicity assessments (USEPA, 2024d; USEPA, 2024c).

Finally, the EPA considered every comment provided by the SAB PFAS Review Panel. Please see section 4.1.3 of the EPA response in this *Response to Comments* document and USEPA (2023d). In response to public comments, the EPA has continued to improve the transparency and discussion related to candidate study selection, modeling, and RfD derivation. Updates related to these comments are available in Section 4 and Appendix E of the final toxicity assessments (USEPA, 2024d; USEPA, 2024c; USEPA, 2024a; USEPA, 2024b).

3M Company (Doc. #1774, SBC-053453)

For the models based on decreased birthweight, "EPA used the exact percentage (8.27%) of live births in the US in 2018 that fell below the cut-off of 2500 g as the tail probability to represent the probability of extreme ("adverse") response at zero dose." (EPA 2023a, p. E-294 to E-295; EPA 2023b, p. E-22). EPA acknowledges the limitations of using this exact background percentage as it "was calculated without accounting for the existence of background PFOS exposure in the U.S. population" and therefore not explicitly the probability at zero dose (EPA 2023a, p.E-295; EPA 2023b, p. E-22). To adjust for this, EPA estimated the study-specific intercepts of the slope based on the study-reported central tendencies of exposure (e.g., mean or median) and slope; these intercepts were then used to estimate the response in an unexposed population. Although this approach takes into consideration the limitations of having no true unexposed comparison group, it is still limited by assumptions that the model accurately identifies and describes the true intercept, or effect at zero dose. "In this alternative approach, P(0) is 9.86% if there is no background exposure" (EPA 2023a, p.E-295). EPA does not explain its scientific justification for rationalizing an estimated background probability at zero dose that is higher than the observed probability in the US population. This approach also does not fully consider or account for variations in exposure or uncertainties in the estimated slope. Notably, EPA uses the background incidence of LBW and PFAS exposures in the US population to make assumptions of background (or "zero exposure") response, however many of the studies, including the selected key study (Wikstrom et al. 2020) were not conducted in a US population and may have different background responses (e.g., the background LBW incidence in China may be as low as approximately 5%) and PFAS exposures. Regardless of these additional sources of uncertainty, EPA presents the BMD(L) results from these two approaches for decreases in birthweight: with and without the adjustment of the exact percentage of US

background response for background PFAS exposures (EPA 2023a, Table E-15; EPA 2023b, Table E-13). For some studies, the BMD(L)s varied widely with and without adjustment for background exposure (e.g., a range of BMDLs from 63.2 to 90.6 ng/mL for Yao et al. 2021 in the PFOA assessment). However, the BMDL selected for POD derivation for PFOA was not sensitive to adjustments in background exposure; the BMDLs calculated from Wikstrom et al. (2020) ranged from 2.2 ng/mL when the exact percentage of background response was used, as compared to 2.3 ng/mL when the adjusted background was used (EPA 2023a, Table E-15). Therefore, EPA did not make determinations regarding which approach was preferred and instead used the exact percentage estimate since it was the most conservative. For PFOS, the BMDLs calculated from Wikstrom et al. (2020) ranged from 7.7 ng/mL using the exact percentage of response to 9.4 ng/mL based on the alternative tail probability. EPA does not clearly describe why the BMDL from the exact percentage of response was selected, and so it is assumed that EPA again selected the most conservative BMDL. Additionally, EPA examined the impact of assumptions of background exposure on intercept and BMD(L)derivation based on Wikstrom et al. (2020) and show that the BMDL for PFOA could vary from 2.3 to 3.1 ng/mL based on changes in intercept (EPA 2023a, Table E-16). However, these results are not presented for the other considered studies, nor does EPA provide transparency in its reasoning for selecting the BMDL associated with the lowest assumptions of background exposure, even though these assumptions do not match the study-reported background of PFAS exposure of 1.6 ng/mL. Overall, changes in the assumptions regarding the US background of LBW incidence compounded with changes in the assumptions regarding background PFAS exposures could result in a 34-43% change in BMDLs. Additional transparency is needed to discern how this adjusted background approach is applied and incorporated into BMDL selection for the low birth weight POD. EPA did not consistently or transparently report sensitivity analyses used to test these assumptions regarding background incidence or exposure.

EPA Response: The commenter raised concerns with the approaches the EPA used to estimate points of departure from epidemiological studies reporting decreased birthweight. First, the commenter criticized the EPA's assumptions and analyses to account for background PFOA or PFOS exposure and questions differences between the actual and estimated background incidence of LBW. As described in Appendix E.1.2.2, the EPA uses a different set of assumptions to perform sensitivity analyses accounting for background incidence of LBW, as well as background PFOA and PFOS exposure (USEPA, 2024a; USEPA, 2024b). For example, the estimate accounting for background LBW incidence assumes a normal distribution of birthweight, though the actual birthweight distribution observed in the U.S. is slightly skewed (see Table 1 below based on results from CDC wonder site https://wonder.cdc.gov/natality.html). As expected, these differing assumptions result in minor differences between the exact incidence (8.27 percent) of live births falling below the public health definition of LBW and the estimate assuming normal distribution of birthweight (9.86 percent) if there is no background exposure.

Table 1. Birthweight summary based on CDC wonder 2018 data (https://wonder.cdc.gov/natality.html)

Birthweight (g)	Total # of births	# births below cutoff	Percentage of births below cutoff	Percentage of births below cutoff assuming normal (3,261.64, 590.66) quantiles
<2500	3,791,712	313,752	8.27%	9.86%
<3000	3,791,712	1,024,196	27.01%	32.89%
<3500	3,791,712	2,492,835	65.74%	65.67%
<4000	3,791,712	3,494,638	92.17%	89.44%
<4500	3,791,712	3,749,342	98.88%	98.20%

The EPA conducted an additional sensitivity analysis specific for the critical study (Wikstrom et al., 2020) that accounts for variation in exposure (see Appendix E of USEPA (2024a) and (2024b)). These analyses incorporated variation in exposure (i.e., 4.6 ng/mL for PFOA and 23.8 ng/mL for PFOS), as well as variation in the incidence of LBW (i.e., as low as ~5 percent). The uncertainty in the estimated slope was accounted for by the CI of the slope. Additionally, comparisons of BMDLs across different studies can provide insight into potential uncertainty in the estimated slope.

Second, the commenter notes that many of the studies modeled by the EPA were not conducted in the U.S. population which increases the uncertainty of conclusions based on these studies. The EPA disagrees with this commenter's conclusion. Please see section 4.2.2 of the EPA response in this *Response to Comments* document. Unless there are data showing otherwise, it is reasonable to assume that populations outside the U.S. would generally show similar responses (i.e., have a similar slope) as the U.S. population. The commenter does not provide a citation supporting their assumption that background LBW incidence in China is significantly different than background incidence in the U.S. However, given these uncertainties, the EPA derived multiple candidate BMDLs representing different study populations in both the draft and final toxicity assessments for PFOA and PFOS (USEPA, 2023f; USEPA, 2023a; USEPA, 2024d; USEPA, 2024c).

Third, the commenter criticizes the EPA's use of the exact LBW incidence in the agency's selected modeling approach. The commenter states the EPA selected BMDLs based on exact percentage because it is more conservative and was not transparent in its decision making. The EPA disagrees with these criticisms but has provided additional discussion in Appendix E to clarify the rationale (USEPA, 2024a; USEPA, 2024b). When the background PFOA or PFOS exposure is relatively high, the BMDL estimated from the alternative probability approach may be preferred as the background exposure should not be neglected in these populations. This is reflected in the differences between BMDLs derived for PFOA (but not PFOS as the exposure concentrations are relatively low) using the two approaches for the Yao et al. (2021) study, as raised by the commenter. As the PFOA exposure reported by Yao et al. (2021) is relatively high (median PFOA exposure of 42.8 ng/mL), the difference in the BMDLs produced by the two approaches is greater than for other studies reporting lower exposure levels. However, *because*

the PFOA exposure reported by Yao et al. (2021) is so high, EPA determined the PFOA levels were not comparable to the U.S. general population and therefore did not use BMDLs from Yao et al. (2021) as the basis of points of departure (PODs) for PFOA (see USEPA, 2024d; USEPA, 2024a). Studies such as Wikstrom et al. (2020) reported lower PFOA and PFOS exposure levels (median PFOA exposure of 1.6 ng/mL), which are comparable to the U.S. general population (i.e., compared to results from the ACE Biomonitoring on Perfluorochemicals program), and produced less variability between BMDLs. In cases where background exposure is unlikely to be driving the response (i.e., when background levels are relatively low), it is reasonable for the EPA to use the exact percentage in the U.S. population to support BMD modeling rather than the alternative model which relies on additional assumptions. Regardless, for studies reporting PFOA and PFOS levels similar to those seen in the U.S., the differences between BMDLs derived from the actual and alternative approaches are minimal (i.e., modeling of 4/6 PFOA studies results in BMDLs differing by ≤ 0.1 mg/L; modeling of 4/6 PFOS studies results in BMDLs differing by ≤ 1.7 mg/L).

Finally, the commenter notes that the EPA only provides additional analyses on the influence of background exposure from Wikstrom et al. (2020). In the draft toxicity assessments supporting the proposed rule, the EPA provided sensitivity analyses (see Table E-16 in PFOA (USEPA, 2023b) and E-14 in PFOS (USEPA, 2023c)) for Wikstrom et al. (2020), as it was ultimately selected as the critical study and served as the basis for the health outcome-specific RfD for developmental effects. After considering the commenter's input, the EPA has added similar analyses for each study considered for POD derivation to the final toxicity assessments. These analyses are now presented along analyses from Wikstrom et al. (2020) in Appendix E (USEPA, 2024a; USEPA, 2024b).

4.2.2.4 Derivation of Cancer Slope Factors (CSFs)

New Hampshire Department of Environmental Services (Doc. #1690, SBC-044339)

For the proposed CSFs for the HHRA (Page 18656, Column 2) as well as the Benefits Analysis (Section XIII-Health Risk Reduction and Cost Analysis – Page 18689, Column 3), EPA should further clarify the uncertainties about exposure levels used to estimate the CFSs for PFOA. EPA does not provide any analysis (e.g., sensitivity analysis) to determine the impact of its assumption that serum PFOA levels are stable over time between the onset of a disease and the time that single exposure measures are collected.

EPA Response: As described in the EPA response to comment Doc. #1774, SBC-053147 in section 4.2.2.4 in this *Response to Comments* document and section 4.2.2 of the EPA response in this *Response to Comments* document, the EPA maintains its conclusions that reliance on a single serum PFOA measurement is adequate to estimate the CSF for PFOA. This is because of the long half-life of this compound, which results in relatively stable serum concentrations over time. Discussion on the half-life and uncertainties in the available literature was presented in Section 3.3.1.4.5 of the PFOA draft toxicity assessment (USEPA, 2023f).

3M Company (Doc. #1774, SBC-053147)

1. Evidence for PFOA Carcinogenicity and Derivation of the Cancer Slope Factor

EPA failed to apply applicable guidance in evaluating the evidence of carcinogenicity and deriving a CSF for PFOA. EPA's IRIS Handbook indicates that "consistency across studies or experiment" should be considered as part of the evidence synthesis step. Additionally, EPA's Cancer Risk Assessment Guidelines (USEPA 2005) recommend that, "[w]hen multiple estimates [of cancer risk] can be developed, all datasets should be considered, and a judgment made about how best to represent the human cancer risk."

Contrary to this guidance, the proposed rule makes clear that EPA failed to consider all datasets relevant to potential cancer risk. As discussed below, in evaluating carcinogenicity, EPA incorrectly excluded several occupational exposure studies (Steenland and Woskie et al. 2012; Raleigh et al. 2014; Barry et al. 2013) which collectively demonstrate limited or no association with kidney cancers among workers with 10- to 100-fold greater exposure to PFOA than seen in the general population. Instead, EPA relies on Shearer et al. (2021), a matched casecontrol study on kidney cancer (324 cases, 324 matched controls) from the Prostate, Lung, Colorectal, and Ovarian Screening Trial (PLCO), which has critical flaws, as detailed below (e.g. a single serum measurement, potential reverse causation), that undermine the integrity of EPA's conclusion.

a. EPA incorrectly excluded occupational studies with greater exposures than Shearer et al. (2021)

Steenland and Woskie (2012) is an occupational cohort mortality study of DuPont workers (n = 5,791) with PFOA exposures, which reported a total of 12 kidney cancer deaths. This study observed significant elevated risk of kidney cancer death only in the highest exposure quartile. EPA identified this as a medium confidence study but stated that it did not consider it further because of the small number of observed cancer cases and because "information on a range of exposures more relevant to the general population were available from Shearer et al. (2021)" (USEPA 2023a). However, the range of exposures in Steenland and Woskie (2012) was actually 10 to 100 times higher than the general population, an indication that kidney cancer is not associated with general population-levels of exposure to PFOA.59

EPA also improperly excluded Barry et al. (2013), which is a community/worker cohort study of 32,254 residents (28,285 community members and 3,713 DuPont workers) with residential exposure to PFOA in their drinking water for which there were a total of 105 kidney cancer cases (87 from the community and 18 from the DuPont workers). This study also did not find a significant association of kidney cancer cases among workers who had serum concentrations that were 10-fold greater than the community population in Shearer et al. (2021). EPA stated Barry et al. (2013) was not suitable for dose-response analysis because it was performed in the same study area as Vieira et al. (2013) and may involve a number of the same participants. In addition, EPA stated that Barry et al. (2013) lacked the necessary exposure measurements for CSF calculation. However, a later study, Bartell and Vieria (2021), reports the necessary exposure data

from Barry et al. (2013), which EPA did not acknowledge or explain why these data did not make this study appropriate for inclusion in its analysis, and thus arbitrarily excluded Barry et al. (2013).

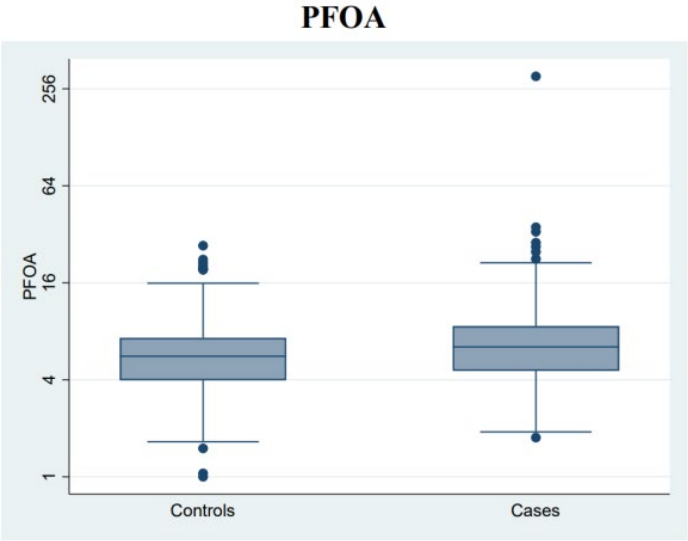
EPA also incorrectly excluded Raleigh et al. (2014), reportedly based on concerns of exposure assessment methods and study quality as well as the small number of cases (USEPA 2023a). Raleigh et al. (2014) is an occupational cohort mortality and cancer incidence study of 3M workers (n= 4,668) with exposure to the manufacture of the ammonium salt of PFOA (i.e., APFO) that reported 16 kidney cancer cases and was not confounded by TFE exposure. The authors did not find an excess of kidney cancer cases beyond what would be expected in the general population. EPA stated that it excluded this study because it used modeled estimates of PFOA air concentrations in the workplace rather than biomonitoring measurements and because of concerns about absorption of inhaled PFOA. However, EPA did not appropriately consider the totality of other studies that found that these workers did likely have high PFOA exposures consistent with the higher PFOA serum concentrations (Olsen et al. 2000, 2003; Raleigh et al. 2013, 2014). Other studies have also concluded that PFOA is efficiently absorbed in rodents following inhalation of PFOA (Griffith and Long 1980; Kennedy et al. 2004). Therefore, EPA mischaracterized the quality of the data from Raleigh et al. (2014), resulting in the arbitrary exclusion of this study.

EPA's failure to collectively synthesize evidence from the occupational exposure studies resulted in a misinterpretation of the weight of evidence. Though individually the three occupational studies may not have been suitable to calculate a CSF, EPA failed to consider that, collectively the PFOA exposures in these three worker studies were one to two orders of magnitude greater than the general population serum PFOA concentrations reported in Shearer et al. (2021) yet showed little to no association with kidney cancer.60 In Shearer et al. (2021), 324 kidney cancer cases originated from a cohort of 150,000 adults aged 55 – 74 with kidney cancer cases representing 0.22% of the cohort. In the three occupational cohorts by Steenland and Woskie (2012), Raleigh et al. (2014), and Barry et al. (2013) which had cohorts of 5,791, 4,668, and 3,713 (total = 14,172) workers respectively, there were a total of 52 kidney cancer deaths and cases representing 0.37% of the combined three cohorts. Though EPA labels each of these as small studies, they are collectively comparable to Shearer et al. (2021) in the percentage of kidney cancer cases.61

Therefore, among these three occupational analyses, which likely represent the highest exposed individuals based on overall reported biomonitoring data, only one analysis (Steenland and Woskie 2012) showed a statistically signficant associaton with kidney cancer, but this was confounded by the authors' decision to not adjust for TFE exposure. EPA did not synthesize the evidence across these studies, as is recommended by the IRIS Handbook and Cancer Guidelines, to inform its approach to the CSF and as a result did not appropriately assess the overall weight of evidence for carcinogenicity.

b. EPA did not properly assess Shearer et al. (2021) for flaws that undermine its reliability

Because EPA excluded the above occupational studies from consideration for the CSF, it instead inappropriately relied solely on Shearer et al. (2021) where a single measurement of serum PFOA was used to calculate the CSF.



Both EPA and Shearer et al. state the long half-life of elimination of PFOA indicates that a single serum measurement could be sufficient to provide an accurate and precise measurement of a person's long-term PFOA exposure. This assertion ignores the considerable uncertainty regarding the distribution, calculation, and measurement biases associated with the serum elimination half-lives of PFOA in humans as discussed in a series of publications (Dourson and Gadagbui 2021; Campbell et al. 2022a,b; Post et al. 2022). Shearer et al.'s (2021) conclusion that a single PFOA measurement is sufficient based on PFOA's long-half life in humans contradicts fundamental considerations of the connection between toxicodynamics, toxicokinetics, and time (Rozman et al. 1996). This highlights the limitations of using serum concentrations measured 2 to 18 years prior to the diagnosis of the disease. If the serum elimination half-life ranges from 0.5 to less than 3.0 years, then a PFOA measurement taken, on average, 8.8 years prior to the diagnosis of kidney cancer could be anywhere from 3 to greater than 5 half-lives from the diagnosis of kidney cancer. This discrepancy limits the accuracy of the reported serum concentrations in Shearer et al. (2021).

Shearer et al. (2021) also did not appropriately address reverse causation, which is a type of pharmacokinetic bias (Andersen et al. 2021) and occurs when a physiological outcome (e.g., estimated glomerular filtration rate [eGFR]), which affects the exposure assessment, has been moderated by the health outcome itself. The pharmacokinetic bias occurs when there is a sufficient window of time for the disease state to influence physiological factors that can bias the exposure assessment. EPA's IRIS Handbook recommends evaluating epidemiological studies for reverse causality and if reverse causality is a concern in the observed association of the exposure and health outcome, then a study should be labelled as deficient or critically deficient. In Shearer et al. (2021), the lack of an association between eGFR, PFOA, and kidney cancer does not

conclusively demonstrate a lack of reverse causation, but it should have been considered as a factor because the eGFR was measured, on average, 8.8 years prior to the diagnosis of kidney cancer. There is the possibility of pre-diagnostic conditions that result in declining renal function. EPA therefore violated its own guidance in suggesting the lack of an association between a single eGFR measurement, and the diagnosis of kidney cancer eliminates the concern about this type of pharmacokinetic bias in the association between the exposure to PFOA and kidney cancer.

c. EPA uses inconsistent methods to calculate the cancer slope factor resulting in an overly conservative value

The cancer slope factor (CSF) describes the relationship between dose and cancer risk. EPA considers the slope factor as the upper-bound estimate of risk per increment of dose that can be used to estimate risk of cancer for different exposure levels (USEPA 2005). Thus, a steeper slope, or greater CSF, indicates that cancer risks are expected to increase more per each unit increase in dose. EPA's Cancer Guidelines (USEPA 2005) state that CSFs are derived for substances that are assumed to have a linear no-threshold mode of action or as a default if a different mode of action cannot be identified. This means that EPA assumes that even at doses below a carcinogenic point of departure, there is a nonzero risk of cancer. CSFs can be derived from either animal or human studies but should be derived based on the best practices in EPA's Cancer Guidelines.

EPA's derivation of the CSF lacks transparency and EPA inconsistently selects studies and analysis techniques, resulting in a CSF that is not based on the best available data. EPA relied solely on the relative risk of renal cell carcinoma from Shearer et al. (2021) to calculate the CSF, which as described above has critical limitations that make it unreliable. EPA's CSF derivation is based on a simple regression model originally used by the California Office of Environmental Health Hazard Assessment (OEHHA) (CalEPA 2021; OEHHA 2004), which is used to estimate the dose-response between PFOA and renal cell carcinoma risk. The CSF is then calculated as the excess cancer risk associated with each ng/mL increase in serum PFOA (internal CSF).

Results of EPA's analysis of Shearer et al. (2021) are reported in Table E-42 in the PFOA MCLG Appendix excerpted below. PFOA dose levels in each quartile of exposure (represented as xi) were supposedly calculated as the midpoint of the reported PFOA range in ng/mL from Shearer et al. (2021). However, as seen in the second and third rows of excerpted Table E-42 below, the xi values of 2.75 and 4.4 are not within their respective PFOA ranges in the leftmost column. Thus, these values do not actually represent the midpoint of the categories used by Shearer et al. (2021).

Table E-42 from the PFOA MCLG Appendix demonstrating the odds ratios for PFOA serum concentrations and renal cell carcinoma from Shearer et al. (2021).

[Table E-42: see docket ID EPA-HQ-OW-2022-0114-1774]

Based on the analysis outputs in Table E-43 of the PFOA MLCG Appendix, EPA calculates the CSF of 0.00352 (ng/mL)-1 which represents the upper 95th percentile of the slope.

EPA also calculated CSFs based on Vieira et al. (2013) which is a study based on 58 kidney cancer cases exposed via drinking water and compared to greater than 7,000 controls. EPA calculates CSFs by either including or excluding the highest exposure level from that study (Table E-43 PFOA MCLG Appendix). EPA failed to explain why it chose not to use the regression model provided by California's Office of Environmental Health Hazard Assessment (OEHHA) and instead used the midpoint ranges of the Vieira et al. (2013) categorical data. This practice is inconsistent with the approach EPA applied to Shearer et al. (2021) to derive the CSF. This inconsistency of methods to derive a CSF from these two studies is arbitrary, lacks sufficient justification, and in the absence of a sensitivity analysis, prevents understanding of the ramifications of this arbitrary choice.

It is important to note that EPA's and OEHHA's approach to the derivation of the CSF are distinctly different and when followed with the same datasets, will result in different CSFs. OEHHA chose to use the central estimate of the slopes (i.e., the slopes themselves). This is because OEHHA combined the results of two separate studies (i.e., Shearer et al. 2021 and Vieira et al. 2013) to develop its final overall CSF. OEHHA determined this combination of different studies and different study sites would account for much of the variance likely to occur across different PFOA-kidney cancer sites and therefore using the geometric mean of the two slopes was a better representation of potential cancer risks across the general population. In contrast, because EPA did not appropriately synthesize the evidence, it only relied on Shearer et al. (2021) and instead based its estimate of the slope on the upper 95th percent confidence interval. Thus, California's CSF of 0.00178 (ng/mL)-1 is approximately half that of EPA's CSF of 0.00352 (ng/mL)-1 . Notably, the California CSF is nearly identical to the CSF derived from the pooled data analysis of the Shearer et al. (2021) and Barry et al. (2013) as published in Steenland et al. (2022). [FN62: Steenland et al. (2022), which calculated a CSF from pooled data from Shearer et al. (2021) and Barry et al. (2013), recognized that the CSF derivations from Shearer et al. and Barry et al. were statistically different due to differences in the dose-response relationship at different exposure levels.] Additionally, EPA's Cancer Guidelines allow for "combining data from different datasets in a joint analysis" (USEPA 2005, p. 3-25). Therefore, EPA should have considered this approach, which may better reflect the overall evidence base.

EPA Response: The commenter stated that the EPA did not follow its own guidance in evaluating the evidence base or deriving a CSF for PFOA. The commenter stated the EPA did not consider consistency across studies and cited the EPA guidance stating that multiple estimates of cancer risk should be developed when possible. The EPA disagrees with these claims. As described in the draft toxicity assessment (USEPA, 2023f), the EPA followed the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005) when conducting the cancer assessment for PFOA and protocols outlined in the *IRIS Handbook* (USEPA, 2022a) when synthesizing and integrating evidence across the epidemiological, animal toxicological, and mechanistic evidence streams. The EPA described and considered every study the commenter recommended and particularly noted consistencies across the evidence base (see Section 3.5, USEPA (2023f)). Additionally, the EPA developed multiple estimates of cancer risk (i.e., CSFs) for both epidemiological and animal toxicological studies. These candidate CSFs for kidney cancer in humans (Shearer et al., 2021;

Vieira et al., 2013) and hepatocellular, pancreatic, and LCTs in rats (NTP, 2020; Butenhoff et al., 2012) were presented in Section 4.2 (USEPA, 2023f). All of this information is similarly presented in the final toxicity assessment for PFOA (USEPA, 2024d; USEPA, 2024a).

The commenter stated that the EPA incorrectly excluded occupational studies providing results for kidney cancer, including Steenland and Woskie (2012), Barry et al. (2013), and Raleigh et al. (2014). The commenter specifically cited higher ranges of exposure reported in these three studies, and particularly by Steenland and Woskie (2012), as evidence that effects do not occur at ranges found in the general population. The commenter stated Barry et al. (2013) was improperly excluded from POD derivation because the study was included in a later meta-analysis (Bartell and Vieira, 2021). The commenter stated Raleigh et al. (2014) was inappropriately excluded, citing animal evidence for inhalation absorption of PFOA. The commenter stated that the EPA did not collectively synthesize evidence from these three occupational studies.

The EPA disagrees with the commenter's interpretation of results from Steenland and Woskie (2012). The commenter correctly points out the significant association between elevated exposure to PFOA and an increased risk of kidney cancer mortality (Steenland and Woskie, 2012). The commenter suggests that the fact the association reported by Steenland and Woskie (2012) is only observed in the highest exposure group reduces the impact of the associations observed at general population exposure levels (i.e., the significant increased risk of kidney cancer observed in Shearer et al. (2021)). However, there is an important difference between these two studies; namely, Steenland and Woskie (2012) reported associations between elevated PFOA exposure and kidney cancer mortality while Shearer et al. (2021) reports the risk for incident kidney cancer. Methods in the IRIS Handbook state that "data on incident cases are generally preferred over mortality data" (USEPA, 2022a) for exposure-response modeling. Further, according the EPA's *Guidelines for Carcinogen Risk Assessment*, analyses of cancer mortality can be improved by adjusting to reflect the incidence-mortality relationship because survival rates vary between cancers (USEPA, 2005), and Steenland and Woskie (2012) did not conduct such an analysis. Additionally, the commenter raised concerns with the study regarding potentially confounding exposures (i.e., TFE [Trifluroethanol]) and an error in the reporting of exposure ranges. The commenter stated the error in reporting of exposure ranges from Steenland and Woskie (2012) would result in exposure levels "more relevant to the general population." However, this directly contradicts the commenter's earlier claim that higher exposure levels would be "an indication that kidney cancer is not associated with general population-levels of exposure to PFOA." Both concerns raised in the footnote (i.e., potential confounding by TFE exposure and the reporting error) further provide support for the EPA's decision to not move the study forward for dose-response modeling (see USEPA, 2024d). Interestingly, the concerns raised by the commenter were drawn from a meta-analysis which concluded that there is a significant increase in risk with increasing exposure to PFOA (Bartell and Vieira, 2021), which is in agreement with the EPA's conclusion that PFOA is *Likely to be Carcinogenic to Humans* (USEPA, 2024d).

The EPA disagrees that Barry et al. (2013) was arbitrarily excluded from POD derivation. Vieira et al. (2013) was selected over Barry et al. (2013) due to the overlapping populations between the two studies; Vieira (2013) included the most complete and up-to-date data from this population. In addition, Barry et al. (2013) was not modeled because the study did not provide exposure levels for the entire population (exposure data were reported separately for the community participants and workers), which was necessary information to include in the CSF calculation (USEPA, 2023a, Sec. E.1.5). The EPA has provided additional discussion on candidate study selection to Section 4.1 of the final toxicity assessments for PFOA and PFOS which includes a discussion of studies with overlapping populations (USEPA, 2024d; USEPA, 2024b, Sec. 4.1). Because Vieira et al. (2013) provided updated data on the same population, the EPA did not also reach out to Barry et al. (2013) for combined exposure concentrations.

Regarding Raleigh et al. (2014), lack of biomonitoring data remains a concern and is justification for the EPA's determination that this is a *low* confidence study and therefore, should not be prioritized for POD derivation (USEPA, 2024d; USEPA, 2022a). As noted in the appendix (USEPA, 2024a) and Bartell and Vieira (2021), there is still a lack of information on determining human absorption of PFOA through inhalation. Additional information from Raleigh et al. (2014) would be required to estimate the absorbed dose in humans, thus resulting in the study being excluded from POD derivation.

The EPA disagrees that the agency did not collectively synthesize all three studies in the cancer assessment for PFOA. The EPA examined the weight of evidence across all studies reporting on cancer outcomes, and kidney cancer was selected for CSF derivation based on all the studies reviewed (USEPA, 2024d, Sec. 3.5.4). In contrast to the commenter's assertion that these studies did not provide consistent support for kidney cancer, all three studies observed either significant (Steenland and Woskie, 2012) or non-significant (Barry et al., 2013; Raleigh et al., 2014) increases in the risk of kidney cancer associated with PFOA exposure. A change or result that lacks statistical significance can be used to support a conclusion of an effect (Wasserstein and Lazar 2016; USEPA, 2022a). Additional evidence from a recent meta-analysis and a pooled analysis (Bartell & Vieira, 2021; Steenland et al., 2022) support the EPA's conclusion that PFOA exposure is associated with increased risk of kidney cancer.

The commenter stated numerous concerns regarding the EPA's decision to rely on Shearer et al. (2021) as the basis of the CSF for PFOA. However, the commenter criticized Shearer et al. (2021) but cites other peer-reviewed publications that quantitatively rely on this study as the basis of CSFs for PFOA in their rationale (CalEPA, 2021; Steenland et al., 2022). The commenter stated the CSF derived from the estimate reported in Shearer et al. (2021) was inappropriate because it was based on a single estimate of exposure. The commenter suggested this is inappropriate as the time between exposure measurement and average diagnosis was greater than the elimination half-life for PFOA. As stated in section 4.2.2 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1774, SBC-045682 and Doc. #1774, SBC-045683 in section 4.1.4.3 in this *Response to Comments* document, the EPA disagrees with the commenter's characterization of the representativeness of

single measurements for PFOA and PFOS. In addition, adequate study of cancer outcomes requires consideration of the latency period of the disease. Cancer is not an acute outcome that develops immediately following chemical exposures. The study's measurement of PFOA 2-18 years prior to diagnosis in adults aged 55 years and older was appropriate considering the nature of the outcome of interest.

The exposure levels reported in Shearer et al. (2021) were also analyzed in the California EPA's assessment to assess applicability to general population exposures (CalEPA, 2021). Based on historic PFOA production levels, data from smaller studies, and NHANES exposure concentrations, CalEPA concluded that serum PFOA concentrations collected in Shearer et al. (2021) were similar to those in the general U.S. population and representative of participants' peak exposure levels. Considering the latency period for most cancer diagnoses, the exposure levels reported in Shearer et al. (2021) would be representative of relevant exposure windows for the development of cancer.

The commenter stated that the lack of association between eGFR, PFOA, and kidney cancer prior to diagnosis does not preclude the presence of reverse causality in Shearer et al. (2021) and that the EPA did not accurately evaluate the study as a result. The EPA disagrees that reverse causality was not considered and addressed in the evaluation of Shearer et al., (2021). The EPA evaluated the study according to its own PFAS-specific exposure assessment criteria (USEPA, 2024a and USEPA, 2024b, Sec. A.1.7.1.3; USEPA, 2021a), which is reflected in the study quality evaluation for Shearer et al., (2021) (see Section 3.5 of USEPA, 2024d; USEPA, 2024c). Based on the analysis provided by the authors, there was no direct evidence that reverse causality was present or had not been mitigated by the study's design. Decisions to downgrade domains to *Critically Deficient* or studies to *Uninformative* are not based on indirect evidence or assumptions. Additionally, other studies reporting on kidney cancer did not consider eGFR as a potential confounder. As a result, Shearer et al., (2021) was the only study to demonstrate a lack of association between eGFR and incidence of kidney cancer at any point throughout the study. The commenter did not provide evidence supporting their assertion that reverse causality was a significant factor that impacted the findings of Shearer et al. (2021) or any other study of kidney cancer considered in this assessment.

The commenter stated the EPA's CSF was derived from a study, Shearer et al. (2021), with critical limitations and suggested that this makes the CSF unreliable. The EPA responded to the commenters concerns regarding Shearer et al. (2021) above and disagrees that these concerns result in an unreliable CSF.

The commenter additionally cited data from the EPA's analysis of Shearer et al. (2021) from the Appendix and suggested that a mistake had been made but in actuality mischaracterized the EPA's approach (USEPA, 2023b). Regarding the quartile midpoints, the EPA documented its approach in the Appendix (USEPA, 2023b, Sec. E.1.5.1.2). Specifically, "[s]ince the intercept of the regression is set at 1 for a dose of 0, the midpoint of the lowest quartile was subtracted from each of the midpoint of the upper quartiles." For example, the Quartile 1 xi value (2.0) was subtracted from the midpoint for Quartile 2 (4.75), yielding an adjusted midpoint value (2.75).

The commenter raised concerns with the EPA's derivation of a CSF based on data from Vieira et al. (2013), suggesting the EPA did not justify the decision to not use the same regression model as CalEPA's assessment (CalEPA, 2021) or the same approach as done with Shearer et al. (2021). The commenter appears to misunderstand how the EPA derived CSFs. First, the EPA did not rely on the regression model from CalEPA; the agency conducted its own modeling, as presented in Appendix E (USEPA, 2023b). The EPA disagrees that sufficient justification for modeling decisions related to deriving a CSF from Vieira et al. (2013) was not provided. The EPA used the same approach in modeling the data from Vieira et al. (2013) as the method used for modeling the data from Shearer et al (2021). The approach and results are presented in detail in Section E.1.5 of the PFOA Appendix (USEPA, 2024a).

The commenter incorrectly stated that the EPA did not consider a pooled analysis approach using data from Vieira et al. (2013) and Shearer et al. (2021) as was completed by CalEPA (2021). A sensitivity analysis combining the data was described in the Appendix (USEPA, 2023b, Sec. E.1.5.1.3). One approach included pooling the study-specific slopes using a random effects REML approach, and another approach was to take the geometric mean of the study-specific CSF_{serum}. However, as previously noted, there were considerable differences between Shearer et al. (2021) and Vieira et al. (2013), "including outcomes considered (RCC *vs*. any kidney cancer), exposure assessment (serum biomarker *vs.* modeled exposure), source population (multi-center nationally *vs.* Ohio and WV), study size (324 cases and 324 matched controls *vs.* 59 cases and 7585 registry-based controls)" (USEPA, 2023b, E.1.5.1.3). The EPA concluded that these differences limit the viability of deriving a CSF based on the pooled data (USEPA, 2024d). The commenter noted a similar approach taken by Steenland et al. (2022) to derive a pooled RfD between Shearer et al. (2021) and Barry et al. (2013). Considering Barry et al. (2013) was performed in the same study area as Vieira et al. (2013), likely involving many the same participants, the study was also considerably different from Shearer et al. (2021) and would similarly limit the viability of this approach.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-053423)

EPA also inappropriately developed slope factors for PFOA and PFOS. While the SAB agreed that robust human epidemiological data is preferable when available, it stated in its report to EPA that "for PFOA, there is an absence of 'high confidence' epidemiologic data as summarized by EpA." [FN136: Id. at 39.] One of the reasons for this lower confidence is that epidemiological data available (presented in a Shearer et al. 2021 study assessing kidney cancer risk) was not fully evaluated for the impacts of one individual in the study who had elevated serum PFOA levels. [FN137: Id.] For these reasons, and others described in the SAB report, the SAB recommended that EPA develop multiple candidate cancer slope factors (CSFs) including values based on animal cancer bioassays, and SAB did not endorse using the Shearer et al. study that EPA relied upon in the 2021 Draft Assessment. Despite the lack of endorsement from the SAB, and the concerns expressed by the SAB regarding how the slope factor from the human studies did not align with the animal evidence, EPA continues to rely on the Shearer et al. 2021 study. In this proposal, EPA does not provide a scientific explanation to address the SAB concerns

regarding the Shearer et al. study. Rather, EPA attempts to justify its choice by pointing to an EPA Office of Research and Development (ORD) Staff Handbook which states "when both laboratory animal data and human data with sufficient information to perform exposure-response modeling are available, human data are generally preferred for the derivation of toxicity values." [FN138: See Public Comment Draft Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) in Drinking Water, Mar. 2023, at page 4-49.] EPA's rationale is misleading. This ORD guidance is merely repeating the same general admonition acknowledged by the SAB that using human data is preferrable if it is available and robust. It by no means is forcing EPA to rely on the lower confidence Shearer et al. study. EPA should not finalize this proposal without squarely addressing the SAB recommendations to discuss the strengths and limitations of different CSFs [FN139: See SAB report to the EPA Administrator Aug. 22, 2022, at pages 42, available at: https://sab.epa.gov/ords/sab/f?p=100:18:16490947993:::RP,18:P18_ID:2601#report.].

EPA Response: The commenter stated that the SAB did not endorse the PFOA CSF based on the Shearer et al. (2021) epidemiological study and the EPA did not address the concerns raised by SAB regarding this study or the strengths and limitations of different CSFs. The EPA disagrees with these statements and the commenter's characterization of the SAB's feedback. In its final report (USEPA, 2022b), the SAB stated: "At least one new study, the general population nested case-control study conducted in the PLCO cohort (Shearer et al., 2021), supports previous positive associations with kidney cancer observed in individuals highly exposed to PFOA," and the SAB requested "a clear rationale for its selection as the sole basis for the CSF should be provided," as well as additional details regarding the modeling of this study. The SAB did not explicitly state that the EPA should not rely on the Shearer et al. (2021) but requested more rationale for the EPA's selection and modeling approach, which was provided in the draft toxicity assessment (Section 4.2; USEPA, 2023f), appendix (Appendix E; USEPA, 2023b), and the response to SAB comments document (USEPA, 2023d). The SAB panel also agreed that "toxicity values should only be derived from studies with at least 'medium' confidence," (USEPA, 2022b) which conflicts with the commenter's implication that because the EPA determined Shearer et al. (2021) to have a rating of *medium* confidence, it is not adequate for toxicity value derivation. The commenter implies that Shearer et al. (2021) was "lower confidence" because it did not account for an individual with an outlier PFOA concentration. The EPA disagrees that Shearer et al. (2021) was rated "lower confidence" due to this outlier. The study was considered *medium* confidence, consistent with agency systematic review methods (USEPA, 2022a; USEPA, 2021a; USEPA, 2024a; USEPA, 2024b) and the study authors provided multiple analyses, including continuous models of exposure as well as an analysis by quartile of exposure. Elevated ORs for the risk of RCC were observed for participants in the second and third quartiles of PFOA exposure compared to the first quartile of PFOA exposure, which would not include the outlier PFOA exposure concentration. The EPA also notes that the SAB recommended the EPA consider modeling other epidemiological studies reporting associations between PFOA and kidney cancer, indicating that they support the use of epidemiological data for toxicity value derivation (USEPA, 2022b).

The commenter stated the slope factor from the human studies did not align with the animal evidence. Discussion on comparisons between toxicity values derived from animal toxicological studies and epidemiological studies was presented in Sections 4.1.6 and 6.2 of the PFOA draft toxicity assessment (USEPA, 2023b; now Sections 4.1.6 and 5.2 of the final toxicity assessment, USEPA (2024a)). Though the former was in context of the candidate RfDs, the rationale is similarly applicable to derivation of candidate CSFs.

The EPA disagrees that the agency's rationale for the selection of a CSF based on an epidemiological study over the CSFs derived for animal studies was misleading and refers the commenter to section 4.2.2 of this *Response to Comments* document. The EPA concluded that the available data reported consistent positive associations between PFOA and kidney cancer in various study populations and therefore, the derivation of a CSF based on epidemiological evidence was warranted (USEPA, 2024a).

American Chemistry Council (ACC) (Doc. #1841, SBC-044828 & SBC-044829)

Shearer et al. Should Not be Used to Derive a Cancer Slope Factor for PFOA

Shearer et al. identified 324 cases of RCC among 75,000 participants of a multi-site study from medical centers in ten US cities. [FN7: The total population of 150,00 individuals was divided into two groups – screening and control. RCC cases and controls were identified from the screening group.] The subjects had baseline serum collected during 1993- 2002, although the samples were not analyzed for PFOA and other PFAS until 2018. The cases were diagnosed with RCC subsequent to serum collection. A control group of 324 individuals who had never had RCC was selected from among the same study participants – matched to the RCC cases by age (>50 years of age), sex, ethnicity, study center, and year of blood draw.

The researchers calculated odds ratios (ORs) for exposure quartiles and for continuous exposure, controlling for multiple potential confounding factors [FN8: These included body mass index, smoking status, hypertension, prior freeze-thaw cycle, year of blood draw, estimated glomerular filtration rate (eGFR), and exposure to other PFAS. Several of these confounders are on their own dose-response continuum, rather than a simple yes/no comparison, which further complicates the ability to pinpoint the effects of PFOA exposure.] in addition to the case-control matching factors. The quartiles were assigned based on serum concentrations of PFOA among controls, resulting in an uneven distribution in the ranges of the quartiles (see Table 1), which can skew the analyses for exposure-response trends. While several potential confounders were evaluated, it is unclear whether the covariates were addressed one at a time (varying each potential confounder, to see how the fit of the model changed) or all at once. No equation is presented in Shearer et al. to help understand their view of the interactions of all the confounders present when assessing the correlations with RCC.

As shown in Table 1 and as emphasized with shading, the data do not support a positive dose-response relationship (Confidence Interval includes 1.0) and would be considered not significantly elevated for the three higher exposure quartiles after adjusting for other PFAS

exposure. The results also do not suggest a dose-response pattern, and the p value for a positive trend was not statistically significant (p=0.13) according to the researchers.

[Table 1: See Docket ID EPA-HQ-OW-2022-0114-1841] [FN10: Continuous OR is in relation to a 1-unit increase in serum PFOA concentration on the log base 2 scale.]

Although the OR for the continuous exposure analysis was statistically significant, questions remain about the meaning of this finding. Of primary concern is whether the single serum measurement taken prior to RCC diagnosis (1993-2002) is representative of exposures over an extended period of time.

Conducting an analysis for continuous exposure, in addition to the quartile analysis, helps to address the disparity in the range of the exposures in the quartiles. However, questions remain about the distribution of exposures between the two groups. Steenland and Winquist point out that serum PFAS concentration contrasts in Shearer et al. study were relatively small, as they reflect general population levels (the lowest PFOA concentration quartile was <4 ng/ml, while the uppermost was >7.3–27.2 ng/ml). [FN11: Steenland K and Winquist A. PFAS and cancer, a scoping review of the epidemiologic evidence. Environ Res 194:110690 (2021).] The supplemental infhttps://academic.oup.com/jnci/article/113/5/580/5906528#supplementary-data] provided by Shearer et al. suggests that the range of serum levels was only slightly higher among the cancer cases compared to the controls, with the exception of a single serum level nearly 10 times the high end of the range in the case group. While this value may explain the use of a log base 2 scale for the continuous analysis, the authors do not explain the potential effect of this outlier on their results. However, the broad confidence interval in the highest exposure quartile suggests that such an explanation is necessary to adequately interpret the findings. Typical publications of this type will generally develop an equation that explains the relationship between the continuous variables, as well as provide a robust uncertainty or sensitivity analysis. These elements are missing from the Shearer et al. publication and would be considered “best practice” for epidemiology that is expected to become the basis for a public health regulation.

Although the researchers were able to use several factors to match controls to the RCC cases, the decision to select an equal number of controls may also limit the significance of the continuous exposure finding. The number of controls selected per case may vary, but it is common in the nested case-control literature to find four or five controls per case. [FN13: Ernster VL. Nest case-control studies. Prevent Med 23(5):94). https://doi.org/10.1006/pmed.1994.1093] The researchers do not provide an explanation for the decision to identify only 324 controls, particularly given the fact that they appear to have had such a large pool of individuals for whom a serum sample had been collected.

Finally, a key topic related to the variety of RCC subtypes that can be diagnosed is the differentiation in tumor type, by genetic basis. An analysis of the subtype of RCC has been a topic of recent interest [FN14: Wang Z et al. Cause-specific mortality among survivors from T1N0M0 renal cell carcinoma: a registry-based cohort study. Frontiers in O21). https://doi.org/10.3389/fonc.2021.604724] due to the variable survival rates and seemingly

different course of both development and treatment. Not all RCC are the same which raises concern that any study linking PFOA to generic RCC could be conflating correlation with causation artificially, by not evaluating by RCC subtype. Analysis of the raw data by subtype may yield a different conclusion, enable a reduction in the statistical uncertainty and also provide clues to where to look in the animal data for subtle mode-of-action data that could clear up the discordance between human and laboratory animal kidney disease attributed to PFOA.

These concerns are echoed by EPA [FN15: USEPA. Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) in Drinking Water. Public Comment Draft. EPA Document No. 822P23005. Office of Water (2023), at 3-265. (USEPA PFOA MCLG Assessment 2023)] which identified deficiencies in controlling for confounding and adequate confidence in selectivity and sensitivity in the study by Shearer et al. Based on "several limitations of the Shearer (2021) study," EPA's Science Advisory Board (SAB) questioned the decision to use its results as the sole basis for the cancer slope factor (CSF). [FN16: USEPA SAB. Review of EPA' Analyses to Support EPA's National Primary Water Rulemaking for PFAS. EPA-SAB- 22-008 (2022), at 38. (USEPA SAB Review)] Because the CSF derived from this study is two to three orders of magnitude more potent than that derived from experimental animal studies, SAB cautioned that "the decision as to what slope factor to recommend needs to be carefully considered and highly transparent." As discussed further below, this concern is compounded by the fact that the EPA's estimate of the benefits of the proposal is based in part on the CSF derived from Shearer et al.

Earlier Epidemiology Studies Provide Conflicting Results

Two other publications explore the incidence of kidney cancer among residents of the Mid- Ohio Valley exposed to PFOA in drinking water – Vieira et al. (2023) [FN17: Vieira VM et al. Perfluorooctanoic acid exposure and cancer outcomes in a contaminated community: a geographic analysis. Environ Health Perspect 121: 318-323 (2013).] and Barry et al. (2013). [FN18: Barry V et al. Perfluorooctanoic acid (PFOA) exposures and incident cancers among adults living near a chemical plant. Environ Health Perspect 121: 1313-1318 (2013).] The study by Barry et al. was conducted in the same study area as Vieira et al. and likely included many of the same participants. However, Barry et al. included information from additional years of follow-up and provides a more recent analysis of cancer incidence in the Mid-Ohio River Valley.

Also, as described in more detail below, Barry et al. includes a more comprehensive assessment of exposure. Moreover, Barry et al. included an analysis of cancer incidence among the workers of the manufacturing facility, whereas the previous study of these workers by Steenland and Woskie (2012) [FN19: Steenland K and Woskie S. Cohort mortality study of workers exposed to perfluorooctanoic acid. Am J Epidemiol 176: 909-917 (2012).] was limited to cancer mortality.

The cohort assembled by Barry et al. included 28,541 residents and 3,713 workers who participated in at least one of the follow-up surveys conducted between 2008 and 2011 and for whom an exposure estimate was available. A total of 105 cases of kidney cancer were identified with a complete data set within the cohort – 87 among the residents and 18 among the workers.

Barry et al. developed estimates of the cumulative PFOA serum concentration using the same model as Vieira et al., but accounted for each participant's reported residential history, drinking water source, tap water consumption, and workplace water consumption. [FN20: Based on measurements taken in 2005-2006, mean serum concentrations were 0.024 mg/L for community residents and 0.113 mg/L for workers.] The researchers calculated hazard ratios (HRs) for an increase in kidney cancer among residents, workers, and the combined group cohort for both continuous and quartiles of PFOA serum concentration. [FN21: The cutoffs for the exposure quartiles are not provided in the publication or supplemental material. The model was adjusted for the same potential confounders as in the analysis by Vieira et al.]

Table 2. Exposure quartiles and continuous log estimated cumulative PFOA serum concentration and risk of kidney cancer risk with a 10-year lag [FN22: Source: Barry et al. 2013 and supplemental materie at https://ehp.niehs.nih.gov/doi/suppl/10.1289/ehp.1306615.]

[Table 2: See Docket ID EPA-HQ-OW-2022-0114-1841]

As a result of the additional follow up, refined exposure assessment, and larger cohort size in the analysis by Barry et al., the association between PFOA exposure and risk of kidney cancer is substantially reduced (See Table 2.) Significantly, the hazard ratio is weakest for workers with a significantly higher median estimated exposure. This finding is consistent with the results of the study by Raleigh et al. who reported no evidence of elevated risk of kidney cancer at a manufacturing facility in Minnesota. [FN23: Raleigh KK et al. Mortality and cancer incidence in ammonium perfluorooctanoate production workers. Occup Environ Med 71:500-506 (2014).] These data raise significant question regarding EPA's decision to rely solely on Shearer et al. for its assessment of RCC risks, as noted by the SAB.

EPA Response: The commenter stated that Shearer (2021) should not have been used to derive a CSF for PFOA. The EPA disagrees that Shearer (2021) was an inappropriate choice for CSF derivation and has provided specific discussion of the commenter's points below. Please also see the EPA response to comment Doc. #1774, SBC-053147 in section 4.2.2.4 in this *Response to Comments* document. The commenter provides two additional studies (Vieira et al., 2013; Barry et al., 2013), suggesting they provide conflicting evidence to Shearer et al. (2021). The EPA disagrees that these studies provide conflicting evidence. As described in the Section 3.5.4 of the final toxicity assessment for PFOA (USEPA, 2024a), a recent critical review and meta-analysis of the epidemiological literature concluded that there was an increased risk for kidney (16 percent) and testicular (3 percent) tumors for every 10 ng/mL increase in serum PFOA (Bartell et al., 2021) (Appendix A, USEPA, 2024a). Although the authors concluded that the associations were likely causal, they noted that there were a limited number of studies and additional studies with larger cohorts could strengthen the conclusion. The recent pooled analysis of the National Cancer Institute (NCI) nested case-control study (Shearer et al., 2021) of 324 cases and controls, and the C8 Science Panel Study (Barry et al., 2013) of 103 cases and 511 controls provided evidence that effects detectable at low exposure are concordant with effects seen in high-exposure studies (Steenland, 2022).

For Shearer (2021), the commenter cites concerns about the use of continuous covariate measurements (e.g., BMI) which they state, "complicates the ability to pinpoint the effects of PFOA exposure." The EPA disagrees that the use of continuous covariates in regression models would negatively impact the ability to determine an effect of PFOA, and the commenter did not provide a citation or reasoning for their assertion. As discussed in section 4.1.2 of this *Response to Comments* document, the EPA followed statutory requirements to use the best available science, including the use of well-established EPA human health risk assessment methodology. As noted in the Potential Confounding domain for study quality evaluation of human studies, "consideration of the most relevant functional forms of potential confounders" was considered a criterion for a Good rating (USEPA, 2024a). The commenter suggests that dichotomization would be the most appropriate choice, however, this practice can commonly lead to additional residual confounding for continuous covariates such as BMI or eGFR by ignoring or obfuscating more complicated relationships between the confounder and outcome of interest (Groenwold, 2013). Additionally, the commenter raises issue with the fact that "no equation is presented" by Shearer et al. (2021) which demonstrates their understanding of interactions of all confounders in the analysis of RCC; however, the EPA disagrees that this is a critical flow for control for potential confounding. Presentation of an "equation" is not required nor is it considered in the evaluation of Potential Confounding (USEPA, 2024a).

The commenter raises concerns about lack of statistical significance in quartile analyses in Shearer et al. (2021). The EPA disagrees that the non-significant results from quartile analyses make the study inappropriate for CSF derivation. Results from quartile analyses, while not significant, were consistent with the continuous analysis. Statistical significance is not the sole factor when making evidence synthesis judgements, and results that lacks statistical significance can be used to support a conclusion of an effect (Wasserstein and Lazar, 2016; USEPA, 2022a).

The two studies (Vieira et al., 2013; Barry et al., 2013) provided by the commenter both examine the incidence of kidney cancer in the C8 Health Project Community. The commenter incorrectly suggests these studies provide conflicting evidence of an association between elevated exposure to PFOA and incidence of kidney cancer. Risk estimates from both studies were positive, indicating an increased risk of kidney cancer which does not conflict with the results of Shearer et al. (2021). The commenter points to a stratified analysis reported in Barry et al. (2013) which provides a null association for the risk of kidney cancer in an occupational sub-population. However, the commenter did not address the smaller number of cases when stratifying by occupational status, which would decrease the sensitivity of that particular analysis. Importantly, both studies provided by the commenter analyze kidney cancer without distinction of histological subtype. Shearer et al. (2021) analyzes renal cell carcinoma, which may be a more sensitive indicator. An additional study identified after the updated literature search has identified increased risk of renal cell carcinoma in the American Cancer Society's prospective Cancer Prevention Study II (Winquist et al., 2023).

The commenter provides other incorrect assertions about Shearer et al. (2021), including that the assignment of exposure quartiles based on serum PFOA concentrations in controls would skew

the analyses for exposure-response trends, whether the single PFOA measurement was appropriate for analyzing risk of RCC, and consistency with prior epidemiological evidence. The EPA disagrees with these assertions, and further discussion of these issues can be found in the EPA response to comment Doc. #1774, SBC-053147 in section 4.2.2.4 in this *Response to Comments* document. The commenter additionally states that the EPA did not implement SAB feedback on the use of Shearer et al. (2021) for the derivation of a CSF. The EPA disagrees SAB feedback was not implemented, and further discussion of the EPA response to the SAB can be found in section 4.1.3 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1774, SBC-045682 and Doc. #1774, SBC-045683 in section 4.1.4.3 in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-052920)

The CSF for PFOS relies on animal evidence for liver effects that may have little relevance to humans.

EPA Response: Please see the EPA response to comment Doc. #1774, SBC-053190 in section 4.1.4.2 in this *Response to Comments* document and section 4.1.4 of the EPA response in this *Response to Comments* document.

4.2.3 Characterization of Hazards for Non-Priority Health Outcomes

Mike Pettit (Doc. #1542, SBC-052840)

Endocrine effects: page 269 reads "There is suggestive evidence of a positive association between PFOA/PFOS exposure and thyroid hormone disruption. Epidemiology studies reported inconsistent evidence regarding associations between PFOA or PFOS exposure and general endocrine outcomes, such as thyroid disease, hypothyroidism, and hypothyroxinemia. However, studies reported suggestive evidence of positive associations for thyroid stimulating hormone (TSH) in adults, and the thyroid hormone thyroxine (T4) in children. Toxicology studies indicated that PFOA and PFOS exposure leads to decreases in thyroid hormone levels and adverse effects to the endocrine system. Despite uncertainty around the applicability of animal studies in this area, changes in thyroid hormone levels in animals did indicate adverse effects after PFOS and PFOA exposure that is relevant to humans."

Once again, there it exists the problem that there are serious inconsistencies within the studies and the results being produced. Thyroid pathways are very well documented and as such the interfering mechanisms should be decently simple to pinpoint and yet that pinpoint accuracy seems to be lacking. The results are inconsistent at best, and should be treated as such.

Metabolic effects: page 270 reads "Evidence suggests a direct association between PFOA exposure and leptin levels in the general adult population. Based on a review of 69 human epidemiology studies, evidence of associations between PFOS and metabolic outcomes appears

inconsistent, but in some studies, suggestive evidence was observed between PFOS exposure and leptin levels."

As some studies have reported a positive association between PFOS exposure and metabolic outcomes such as insulin resistance, dyslipidemia, and obesity, others have found no significant association. This inconsistency in results may be due to differences in study design, sample size, and population characteristics, among other factors. Also while cross-sectional and observational studies can provide useful information on the association between PFOS exposure and metabolic outcomes, they cannot establish causality. Randomized controlled trials, which are considered the gold standard for establishing causality, are not always feasible or ethical when studying environmental exposures. It is also important to consider the potential for reverse causation. Metabolic dysfunction may alter the way the body metabolizes and eliminates PFOS, leading to higher levels of PFOS in the body. Therefore, the observed association between PFOS exposure and metabolic dysfunction may actually be due to metabolic dysfunction leading to higher PFOS levels, rather than the other way around.

Reproductive effects: page 271 reads "The epidemiology evidence yields mixed (positive and nonsignificant) associations, with some suggestive evidence supporting positive associations between PFOA/PFOS exposure and both preeclampsia and gestational hypertension."

Firstly, many studies have focused on animal models, and there are significant differences in the way that PFOS affects animal and human reproductive systems. While animal studies can provide valuable insights into the potential effects of PFOS, it can be difficult to extrapolate these findings to humans. Of second note, many studies on human populations have relied on self-reported data or retrospective analyses, which can be subject to bias and inaccuracies. Additionally, many studies have relied on small sample sizes, making it difficult to draw firm conclusions about the potential reproductive effects of PFOS.

Musculoskeletal effects: page 271 reads "There is limited evidence from studies pointing to effects of PFOS on skeletal size (height), lean body mass, and osteoarthritis. Some studies found that PFOA/PFOS exposure was linked to osteoarthritis, in particular among women under 50 years of age. However, other reviews reported mixed findings on the effects of PFOS exposure including decreased risk of osteoarthritis, increased risk for some demographic subgroups, or no association."

There is limited evidence linking PFOS exposure to musculoskeletal effects, which can make it difficult to draw definitive conclusions about this association. Some studies have suggested that PFOS exposure may be associated with decreased bone density and an increased risk of bone fractures, particularly in older adults. Again however, other studies have not found a significant association between PFOS exposure and musculoskeletal outcomes. Studies on this association are relatively scarce, which can make it challenging to draw definitive conclusions about the effects of PFOS exposure on musculoskeletal health. Additionally, many studies have relied on self-reported outcomes, which may not be accurate or reliable indicators of actual musculoskeletal health.

EPA Response: The commenter raised concerns about several non-priority health outcomes (i.e., endocrine effects, metabolic effects, reproductive effects, and musculoskeletal effects), noting various perceived inconsistencies in the human and animal evidence. The EPA disagrees that these health outcomes were inappropriately synthesized. The evidence integration judgement for each of these outcomes noted that the *evidence suggests* adverse effects from elevated exposure to PFOA and PFOS, and the EPA identified uncertainties that led to these conclusions, including the quotes provided by the commenter (USEPA, 2023b; USEPA, 2023c; USEPA, 2024a; USEPA, 2024b). An evidence integration judgement of "*evidence suggests"* is typically made with a combination of *slight* or *indeterminate* evidence stream judgments for animal and human evidence (USEPA, 2022a, Table 6-7). The human evidence stream judgement for each outcome was considered *slight*, and the quotes and descriptions provided by the commenter do not deviate from the descriptions provided in the IRIS Handbook (USEPA, 2022a). For human evidence, a *slight* evidence stream judgment may be made when "one or more studies report an association between exposure and the health outcome, but considerable uncertainty exists" (USEPA, 2022a, Table 6-4). Additional research may provide further clarity regarding the effects of PFOA and PFOS on each health outcome, however, the health outcomes considered to have an "*evidence suggests"* evidence integration judgement were not considered for dose-response analyses and RfD derivation in the PFOA and PFOS toxicity assessments (USEPA, 2024d; USEPA, 2024c). Concerns regarding these health outcomes do not impact the EPA's conclusion that PFOA and PFOS are *Likely to be Carcinogenic to Humans* and the resulting MCLGs of zero (USEPA, 2024e).

4.2.4 Pharmacokinetic Modeling Approach

Washington State Department of Health (DOH) (Doc. #1665, SBC-052885)

DOH also appreciate that EPA added the modified Verner model to account for transplacental and trans-lactational exposure in developing children.

EPA Response: This commenter supports the approach used in the EPA's draft and final toxicity assessments for PFOA and PFOS (USEPA, 2023f; USEPA, 2023a; USEPA, 2024d; USEPA, 2024c).

3M Company (Doc. #1774, SBC-053233)

f. EPA Did Not Follow SAB Recommendations to Address Lack of Transparency, Lack of Reproducibility, and High Levels of Uncertainty in its Use of PBPK Models

PBPK models were used to simulate dosimetry during pregnancy and lactation for endpoints in human neonates and children. The SAB considered EPA's use of compartment based PBPK models to be reasonable but requested that details and assumptions required to run the model be documented sufficiently to allow reproduction of the simulations. EPA failed to address SAB comments regarding clarity of the PBPK model and EPA's lack of evaluation of the PBPK model

performance. EPA placed the PBPK model code on Github to allow reproduction of simulations but failed to provide sufficient documentation or a required header file ('linear_interp.h') needed to compile and run the code. As a result, the conversion of the point of departure (POD) to the POD human equivalent dose (PODHED) could not be reproduced and remains uncertain. These issues are discussed below and in detail in Appendix A.

From Appendix A: EPA did not provide required files or sufficient documentation to reproduce the conversion of the PODs to the PODHEDs.

The SAB recommend that EPA provide more details on model code, parameters, data and performance. In response, EPA posted the model code and supporting documentation on GitHub. As provided, users could not validate the code and the parameters because EPA failed to provide a required header file ('linear_interp.h') needed to compile and run the code. This means the public cannot assess data and performance. This, in turn, prevents the public from meaningfully commenting on EPA's approach.

EPA Response: The commenter noted that they were unable to download and run the code supporting the PK model. The commenter incorrectly concluded that the EPA failed to provide a required header file. Prior to rule proposal (March 14, 2023), the EPA ensured that the code was publicly available and usable by the public and could be accessed by following the instructions provided on the GitHub site by conducting two internal independent confirmations. The EPA has since confirmed that every required piece of code is available in the GitHub repository. The EPA did not write C code or headers that would require a file of the type "linear_interp.h" that would be necessary for the code to function; thus, the EPA did not fail to provide a file of this type as it is not needed. To ensure external stakeholders can effectively use the code, the EPA has since conducted a third independent test and found that individuals outside the EPA can access, download, and run the code. The EPA recognizes that software packages are frequently updated and may result in user error that would not be identified during internal QC. This is why the EPA explicitly stated in the "readme" file found in the GitHub repository, "if you need help with installing or executing the code, please contact us through a Github issue." The EPA did not receive issues reported to the repository during the public comment period and therefore was unable to assist the commenter. In short, the commenter's inability to correctly download and use the model and their decision not to contact the readily available Github contact and resource to remedy their technological issues did not result from an error by the agency. Additionally, the EPA has conducted a full review of the model code and performed minor modifications to improve compatibility on a wider variety of system configurations. These modifications are logged as comments in the GitHub repository.

3M Company (Doc. #1774, SBC-053237)

i. EPA failed to adequately perform sensitivity analysis for PBPK modeling and provide a quantitative assessment of model performance.

EPA also failed to address SAB's recommendation that EPA better characterize the uncertainty that results from different parameters/assumptions by considering sensitivity analyses or Monte Carlo simulations with a range or distribution of values. EPA did not perform a quantitative assessment of model performance and, as such, failed to address SAB's comment. Best practice frameworks recommend the use of global and local sensitivity analysis (Johnson et al. 2021). EPA only performed local one-at-a-time sensitivity analysis. The parameter(s) driving the output value (i.e., intake-based HED derived from a serum measurement) were not identified and sufficient quantification was not provided in EPA's one-at-a-time sensitivity analysis to fully assess the overall relative importance of all model parameters. This issue is discussed in detail in Appendix A.

From Appendix A:

The SAB stated EPA needs to better characterize the uncertainty caused by different parameters/assumptions by considering sensitivity analyses or Monte Carlo simulations with a range or distribution of values. This is consistent with best practice frameworks, which recommend the use of global and local sensitivity analysis (Johnson et al. 2021). EPA failed to address this comment because the agency did not perform a quantitative assessment of model performance. EPA only performed a single, local, one-at-a-time sensitivity analysis that failed to examine the interaction of model parameters. A global sensitivity analysis would consider those interactions and provide the agency with a better overall understanding of the impact of uncertainty factors on its conclusions.

Additionally, EPA did not identify the parameter(s) driving the output value (i.e., intake based HED derived from a serum measurement). EPA did not provide sufficient quantification in its one-at-a-time sensitivity analysis to fully assess the overall importance of all model parameters and adequately address SAB comments.

EPA used results from its one-at-a-time sensitivity analysis to identify the chemical specific parameters of Vd (volume of distribution) and half-life as sensitive parameters that influence serum and cord blood concentrations of PFOA or PFOS. However, the ranges chosen run contrary to those suggested by the best available science. Available literature provides ranges for both the Vd and half-life which would be more appropriate to consider than the mean values used by EPA. EPA compiled such ranges in values in its draft toxicity assessment Appendices for PFOA and PFOS. Notably, the mean half-lives for PFOA and PFOS used by EPA (i.e., 2.7 and 3.4 yrs, respectively) were from Li et al. (2018). The same Li et al. publication provided a 95% confidence interval for the half-life for both PFOA and PFOS (i.e., 2.5-2.9 and 3.1-3.7 yrs for PFOA and PFOS, respectively), which may be more appropriate to use as input values for half-life. Similarly, the Vd for PFOA and PFOS have been derived by a number of different

publications, whereas EPA used a single value from Thompson et al. (2010) (i.e., PFOA = 170 ml/kg and PFOS = 230 ml/kg). Within the draft Appendix for PFOA, for example, Table B-26 notes 10 values for Vd from 7 publications that range from 170-200 ml/kg.

The reported ranges for Vd and half-life could have a substantial impact on the subsequent PODHED value, which affects EPA's ultimate conclusions. In addition, the cord blood:maternal serum ratio parameter was also identified as a sensitive parameter. EPA used an average cord blood:maternal serum ratio estimated from values available in the peer-reviewed literature for PFOA and PFOS; however, the 95% confidence interval for PFOA values available in the peer-reviewed literature is 0.5819-1.441. The effect of the variability in the values for this sensitive parameter on PFOA and PFOS serum levels in children should be quantified in order to assess the appropriateness of the average value used for PBPK modeling.

EPA Response: The commenter stated that the EPA failed to address SAB's recommendation to better characterize uncertainty in the pharmacokinetic modeling approach. First, please see section 4.1.3 of the EPA response in this *Response to Comments* document and the EPA response to SAB comments document (USEPA, 2023d). The commenter also recommended a global sensitivity analysis (GSA) as an approach to meet the SAB's recommendation. The EPA disagrees with these claims. As noted by the commenter, the SAB recommended that the EPA perform sensitivity analyses *or* Monte Carlo simulations; as recommended by the SAB, the EPA performed those sensitivity analyses and the results were provided in Appendix F of the toxicity assessments for PFOA and PFOS at the time of rule proposal (USEPA, 2023b; USEPA, 2023c), thus addressing this recommendation. The EPA decided to conduct local sensitivity analyses because they are sufficient to understand how uncertainty in the parameters propagates to the model output for the PK approach used in these assessments. The EPA disagrees that a GSA approach is a better option for these analyses. If the EPA had used a full PBPK model approach, with a complex structure and parameter interaction that can often be unpredictable, then GSA could be an appropriate alternative approach to understand how simultaneous variation in parameters affect the model. In fact, this sentiment is supported by Johnson et al. (2021), which state that best practices "for any uncertain parameters within the pediatric PBPK model perform sensitivity analysis if they are likely to have a significant impact" are to conduct "global *and/or* local sensitivity analysis within PBPK platform" (emphasis added). However, for the EPA's PK modelling approach used to inform the toxicity assessments, use of the GSA adds unnecessary complexity and would not meaningfully address the variation in parameters used in the model. Regarding parameters that drive the output, the local sensitivity analyses conducted by the EPA will return the same results whether the model is run forwards (i.e., from serum measurement to human equivalence dose) as backwards (i.e., from human equivalence dose to serum measurement). Therefore, the local sensitivity analyses already "identify the parameter(s) driving the output value" and further GSAs are not needed.

The commenter raises concerns with values the EPA used for the PFOA and PFOS half-life, volume of distribution (Vd), and cord blood to maternal serum ratio (RCM) variables. The

commenter did not provide references supporting the claim that the EPA did not select values for Vd and half-life that reflect the best available science, nor did the commenter provide a recommendation for alternative values from the literature to consider instead of half-lives from Li et al. (2018), Vd estimates from Thompson et al. (2010), and a ratio of cord blood to maternal blood concentrations (RCM) based on average of values reported in the literature as was done in the original publication Verner et al. (2016). Additionally, the commenter recommends that the EPA use a 95% CI as the input for the RCM and half-life parameters. This approach is not statistically defensible and misinterprets the meaning of a CI. A CI is a range of values for which there is a specified probability that the true value of the parameter lies within it. In this modeling context, it is not intended to serve as a representation of the range of values for a population. As the commenter did not provide new information or a valid approach for the EPA to consider, the EPA has maintained the selected values for half-life, Vd, and RCM in the pharmacokinetic modeling approach for PFOA and PFOS.

3M Company (Doc. #1774, SBC-053238)

ii. EPA did not follow SAB's recommendation to use the Goeden et al. (2019) model as a more 'fit for purpose' model for deriving MCLGs

SAB recommended that EPA consider its use of the Verner et al. (2016) models and whether the Goeden et al. (2019) model that incorporates age-specific toxicokinetic and exposure factors would be more appropriate for deriving drinking water MCLGs. EPA compared use of the Verner and Goeden models and concluded that there was no "substantial improvement" in the outcome when modeled using either method. This statement was not supported by a side-by side comparison of results or sufficient information to allow for assessment and an understanding of whether the appropriate model was selected. Data should be presented to support how the decision to use constant daily dose versus age-specific toxicokinetic factors (e.g., volume of distribution) and exposure factors (milk and drinking water intake) affects the model outcome. This issue is discussed in detail in Appendix A.

From Appendix A: EPA did not follow the SAB recommendation to consider age-specific toxicokinetic and exposure factors and use the Goeden et al. (2019) model, which SAB said is more "fit for purpose" for deriving drinking water MCLGs. The Goeden model used an age-dependent adjustment for the volume of distribution (Vd) parameter instead of the constant Vd used by EPA. The SAB noted that the Goeden et al. (2019) appeared to have equal or better model fits as compared to the Verner et al. (2016) model.

EPA did not follow SAB's recommendation and instead asserted that there was no "substantial improvement" in the outcome when modeled using either method. However, EPA provided no side-by-side comparison or additional information to justify its selection of the Verner model. To improve transparency, EPA should provide quantification of the evidence to support the selection of a constant value for Vd parameters and the Verner model.

EPA Response: The commenter stated that the EPA did not follow the SAB PFAS Review Panel's recommendation to use the Goeden et al. (2019) model and did not provide quantitative comparisons or additional information to justify its selection of the Verner et al. (2016) model. The commenter is incorrect in stating that the SAB recommended the EPA "use" the Goeden et al. (2019) model instead of the Verner et al. (2016) model; in actuality, the SAB PFAS panel asked the EPA to "consider whether the Goeden et al. (2019) model is more appropriate for use in development of the PFOA and PFOS RfDs and MCLGs" (USEPA, 2022b). The EPA provided extensive rationale and quantitative discussion for the decision not to use the Goeden et al. (2019) model as the basis of the PK model in both the response to SAB comments document (USEPA, 2023d), the final toxicity assessments (see Section 5.7; USEPA, 2024d; USEPA, 2024c) and associated appendices (see Appendix F.2 for quantitative considerations; USEPA, 2024a; USEPA, 2024b).

Regarding the commenter's concern about the Vd parameter, the EPA provided a quantitative comparison of incorporation of the Vd from the Goeden et al. (2019) model with a constant Vd and determined that "[b]ased on mean relative error (for PFOA and PFOS combined) the model with constant Vd had better performance" (Appendix F.2; USEPA, 2023b; USEPA, 2023c). The EPA expanded the quantitative comparison with the addition of root mean square error (RMSE) in Appendix F.2 to address this concern (USEPA, 2024a; USEPA, 2024b). This additional comparison further supported the better fit to validation data using a model with a constant Vd. Rationale for the EPA's selection of the Verner et al. (2016) model, provided at the time of rule proposal, is available in Section 4.1.3 of the final toxicity assessments (USEPA, 2024d; USEPA, 2024c). Documentation of the evaluation of the Goeden et al. (2019) model for its use in these assessments is provided in Section 5 ("Human Dosimetry Models: Consideration of Alternate Modeling Approaches") and Appendix F.2 of the final toxicity assessments and Section I, Charge Question #4 in the EPA Response to Final Science Advisory Board Recommendations document (USEPA, 2023d; USEPA, 2024d; USEPA, 2024c; USEPA, 2024a; USEPA, 2024b).

3M Company (Doc. #1774, SBC-053240)

iii. EPA failed to account for life stage-specific variables in the PBPK model that impact the resulting PODHED

The PBPK model used by EPA does not account for life stage (maternal, fetal, infant) differences in parameters such as elimination and clearance rate, half-life, and volume of distribution (Vd), as recommended by the SAB. To clarify the uncertainty in life stage-specific variables, age-related differences in chemical-specific parameters should be considered to better explain the variability observed (i.e., lack of fit) in predicted child serum levels compared to reported child serum levels of PFOA and PFOS (see Figures F-15 and F-12 in draft Appendices for PFOA and PFOS, respectively). Consideration of life stage-specific variables may also impact the resulting PODHED. This issue is discussed in detail in Appendix A.

From Appendix A: The SAB recommended that model performance be documented for different life stages. However, the PBPK model EPA used failed to account for life stage (maternal, fetal, infant) differences in parameters such as elimination and clearance rate, half-life, and volume of distribution (Vd). To clarify the uncertainty in life stage-specific variables, EPA should consider age-related differences in chemical-specific parameters to better explain the variability observed (i.e., lack of fit) in predicted child serum levels compared to reported child serum levels of PFOA and PFOS (see Figures F-15 and F-12 in draft MCLG Appendices for PFOA and PFOS, respectively).

In addition, the PBPK model code (GitHub) has the functionality to allow the input values for these parameters to vary. Despite this, EPA's only uses an adult clearance rate value. The elimination rate, derived from clearance rate, is similarly a static value. EPA did not use the model functionality that allows clearance rate to be adjusted for the specific life stage (listed below) being modeled or provide information on the model variability that would occur with the use of life stage-specific values.

· 0 – 12.4y: Childhood / Pre-pubertal

· 12.4y – 24.25y: Puberty / Menstruation begins

· 24.25y – 26y: Pregnancy and breast feeding

· 26y – 50y: Adulthood / Menstruation

Therefore, the PBPK model used by EPA fails to capture sources of variability introduced by life stage as recommended by SAB.

EPA Response: The commenter stated that the PBPK model the EPA used did not account for lifestage differences in model parameters and recommended that the EPA consider age-related differences to explain the variability in predicted child serum levels compared to reported child serum levels for the literature. First, the commenter incorrectly described the approach used in the toxicity assessments for PFOA and PFOS, which was not a full PBPK model approach, but a PK model approach (see section 4.1.3; USEPA, 2024d; USEPA, 2024c). Further, upon review of the available literature, the EPA determined that the available data were too limited to inform lifestage-specific values (see descriptions of the available literature in Appendix B and human model validation Appendix F.3; USEPA, 2024a; USEPA, 2024b). The commenter did not provide any data or references to inform lifestage-specific values that contradict this finding. The EPA also did not identify data to inform clearance specific to children and therefore used the available data for total clearance for the general population as the model parameter. Additionally, the logic in the code is intended to turn on and off menstrual clearance coincident with puberty, pregnancy, and the end of lactation. The EPA's selected half-life value is derived from the observation of decreasing blood levels over time, which result in a measurement of total clearance, as opposed to data informing urinary clearance, to which menstrual clearance could or could not be added. Since the applied clearance value is from the general population it captures clearance from all sources. Further, adding ad hoc adjustments for

predictions of how clearance might change during childhood and pregnancy and/or lactation that is not based on available data would increase uncertainty in this case.

The EPA disagrees with the commenter's statement that there is a lack of fit in predicted and observed child serum levels. This is shown in the EPA's model validation discussions and analyses available in Appendix F (USEPA, 2024a; USEPA, 2024b). Briefly, for PK modeling, a common criterion for model validation are predictions within a factor of two of the validation data (Sager, et al. 2015). The models clearly fit all the validation data well within a factor of two. The EPA added guidance lines to the figure of predicted versus observed serum concentration to highlight the excellent fit of the model to the validation dataset in children. For additional proof of validation, the EPA added a table of root mean squared error (RMSE) values for the assessment model compared to the alternative models presented in Appendix F and discussed in Section 5.7 of the final toxicity assessments for PFOA and PFOS (USEPA, 2024d; USEPA, 2024c; USEPA, 2024a; USEPA, 2024b).

3M Company (Doc. #1774, SBC-053454)

Within the Effects Characterization section of the EPA draft toxicity assessments for PFOA and PFOS, EPA provides a qualitative uncertainty assessment for some of the chemical specific model parameters selected for PBPK modeling, including clearance rate, volume of distribution, and half-life. In addition, EPA discusses its consideration of alternate modeling approaches. However, despite SAB's recommendation to do so, a quantitative evaluation of model performance was not conducted by EPA; therefore, uncertainties in the resulting HED estimations were also not assessed by EPA.

EPA Response: The commenter incorrectly states that the EPA did not quantitatively evaluate the pharmacokinetic model performance and therefore, did not assess uncertainty in human equivalence dose estimations. The commenter is correct in stating that qualitative evaluations of model performance are described in the Effects Characterization section of the toxicity assessments (Section 6 of the public comment draft (USEPA, 2023f; USEPA, 2023a); now section 5 of the final toxicity assessments (USEPA, 2024d; USEPA, 2024c)), but the EPA also provides quantitative validations of both the animal and human pharmacokinetic models in Appendix F (USEPA, 2023b; USEPA, 2023c; USEPA, 2024a; USEPA, 2024b). Specifically, the EPA presented mean square log error (MSLE) analyses for both the training and test sets to evaluate animal model performance (see Figures F-4 and F-12 of USEPA, 2023b; USEPA, 2023c). Both the training and test data showed good agreement with model predictions using the male-specific parameters from Wambaugh et al. (2013), with MSLE for the adult training datasets and developmental test datasets under a half-$\log_{10}$ and about one $\log_{10}$ for the adult test datasets. Because experimental serum concentrations spanned many orders of magnitude, the EPA presented the unity line with +/- half-$\log_{10}$ to visualize the goodness of fit. The results of these analyses indicate that there were no systematic differences between the experimental data and the model predictions across species, strain, or sex, and the median model outputs uniformly appeared to be biologically plausible despite the uncertainty reflected in some of the 95th

percentile CIs. In general, the internal dose metrics used in these analyses were not sensitive to the parameters with the largest credible intervals following the Bayesian inference calibration. In other words, the results of the sensitivity analyses demonstrated that changing the most uncertain parameters from the modified Wambaugh et al. (2013) model did not impact the internal dose metrics.

For the human model, the model predictions shown in Figure F-12 of the draft assessments show the good qualitative fit of the model compared to the alternatives shown in Figures F-15 and F-16 (USEPA, 2023b; USEPA, 2023c). The EPA has addressed this comment by adding results of root mean squared error (RMSE) analyses for the human model to the assessments (see Appendix F; USEPA, 2024a; USEPA, 2024b). The results of this analysis quantitatively show that the EPA's model with the selected parameters performs better than other alternatives.

3M Company (Doc. #1774, SBC-053243)

iv. EPA failed to quantitatively characterize uncertainty for PBPK modeling and HED calculations

Monte Carlo simulations recommended by the SAB were not performed by EPA for PBPK modeling of co-critical endpoints including vaccine response and birth weight to inform the variability inherent in the modeling approach. In addition, the variability of chemical-specific parameters used to calculate the HED for total cholesterol was not quantified by EPA. Therefore, range of uncertainty in the resulting PODHED estimations were also not considered by EPA. This issue is discussed in detail in Appendix A.

From Appendix A: EPA did not thoroughly describe and quantify the uncertainty in each of the parameters used in the PBPK models or HED calculations. EPA did not perform Monte Carlo simulations recommended by the SAB for PBPK modeling of co-critical endpoints including vaccine response and birth weight to inform the variability inherent in the modeling approach and to provide a range of distribution of PODHED values. In addition, uncertainty in the HED used by EPA for total cholesterol was not evaluated. EPA did not provide a description or quantification of the variability in the chemical-specific parameters used to calculate the HED for total cholesterol. An understanding of the underlying variability in these parameters will inform the overall uncertainty in the resultant HED value for total cholesterol.

EPA Response: The commenter states that the EPA did not perform Monte Carlo simulations to evaluate uncertainty in each of the parameters. The SAB panel recommended the EPA consider sensitivity analyses *or* Monte Carlo simulations. The EPA elected to assess the model dependence on uncertainty and variability on individual parameters by performing local sensitivity analyses, the results of which are described in previous responses. Additionally, Monte Carlo simulation wouldn't increase our knowledge regarding model uncertainty because only parameter variability can be accounted for in this type of analysis, not model uncertainty. Monte Carlo simulation will only tell us population variability which is not useful if you want to know the central tendency of the distribution. In this case, the sensitivity analyses serve the same

purpose as the Monte Carlo simulations. This approach is fully consistent with the SAB recommendations.

The commenter also suggests providing a range of distribution of POD_{HED} values. The EPA disagrees with this approach, which has not been historically used by the agency in chemical assessments. In general, it is best to present one HED per endpoint that represents the best estimate of the POD_{HED}; providing a distribution of POD_{HED} estimates would potentially increase the uncertainty in the value as the EPA would likely consider using a measure of central tendency or similar as the overall POD_{HED} rather than selecting the most scientifically sound POD_{HED} as the EPA does in Section 4 of the final toxicity assessments for PFOA and PFOS (USEPA, 2024d; USEPA, 2024c).

Lastly, the commenter incorrectly states that the EPA did not evaluate or provide description of the variability in parameters used to calculate the HED for total cholesterol. The parameters used in the PK models to derive POD_{HED}s for total cholesterol are the same as those used to derive POD_{HED}s for all other health outcomes. Uncertainties in the selected approach, including uncertainty related to variability in the parameters used in the PK model are described in Sections 4.1.3.2 and 5.6.2 and Appendix F of the final toxicity assessments for PFOA and PFOS (USEPA, 2024d; USEPA, 2024c; USEPA, 2024a; USEPA, 2024b). Calculation of the POD_{HED} for total cholesterol is described in section 4.1.4.3 of the final toxicity assessments (USEPA, 2024d; USEPA, 2024c).

Anonymous (Doc. #2331, SBC-047414)

There has not been a large enough database of information on the levels in people's blood or liver over time to make statements that these chemicals accumulate in the body over time. New data is just lies from a politically motivated unconstitutional government bureaucracy. There is no proof that removing PFAS from drinking water will reduce cancer or any other health issues, it is all just modeling and extrapolation being pushed on us as facts.

Our organization has been treating water for potable use for over 40 years. This is an egregious leap into trying to make a problem and health concern where there is none.

EPA Response: The commenter is incorrect that there is not a database to demonstrate that PFAS accumulate in the body over time. The EPA directs the commenter to the Center for Disease Control's National Health and Nutrition Examination Survey (NHANES) website for decades of biomonitoring data confirming the presence of PFAS in human biological samples from the U.S. population (https://www.cdc.gov/nchs/nhanes/index.htm). Regarding potential biases, please see section 4.1.2 of the EPA response in this *Response to Comments* document. Please refer to the Final Regulatory Determination for PFOA and PFOS (USEPA, 2021f), section III of this rule and section 3 of this *Response to Comments* document for the EPA's rationale supporting the conclusion that regulating these compounds presents a meaningful opportunity for health risk reduction. The commenter provides no information to support their statement that "New data is just lies from a politically motivated unconstitutional government bureaucracy."

However, a substantial portion of the supporting information used to inform this rulemaking and these toxicity assessments were collected and analyzed by nongovernmental sources. Additionally, fabrication of data is a violation of the EPA's scientific integrity policy: it was not done here as falsely asserted by commenter with no evidence or information to support their unfounded, unwarranted, and misinformed claim.

4.2.5 Relative Source Contribution (RSC)

Summary of Major Public Comments and EPA Responses

Many commenters misunderstand the EPA's derivation of relative source contributions (RSCs) for the 6 PFAS covered under this rulemaking. Many commenters misinterpret the EPA's RSC determinations, incorrectly citing the 20 percent RSCs or the 80 percent of exposure expected to occur as a result of exposure to other sources out of context of the RfDs, HBWCs, Health Reference Levels (HRLs), or MCLGs. The RSC terms are derived for a specific purpose and are meant to be applied to the RfD. Specifically, the RSC is the "percentage of total exposure typically accounted for by the exposure source for which the criterion is being determined… [and] is applied to the RfD to determine the maximum amount of the RfD "apportioned" to that source" (USEPA, 2000c). As stated by the SAB PFAS Review Panel, "The RSC determination should not be based on the relative PFOA or PFOS water to non-water exposures, without the context of the RfD" and "the choice of the RSC depends on the numerical value of the RfD" (USEPA, 2022b). Therefore, comparisons made by commenters to the RSCs derived by other agencies (e.g., state health agencies) may only be relevant if those agencies used the same RfDs as the EPA. Similarly, comparisons of the RSCs to publications that attempt to quantify exposure without context of the RfD, the target population of interest, and policy considerations of the Exposure Decision Tree approach outlined by the *EPA Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (USEPA, 2000c) are not relevant and often are in direct contradiction to this peer-reviewed RSC methodology.

The Exposure Decision Tree approach considers several characteristics of the contaminant of interest, including the adequacy of available exposure data, levels of the contaminant in relevant sources or media of exposure, and regulatory agendas (i.e., whether there are multiple health-based criteria or regulatory standards for the contaminant). The EPA describes the data and decisions made to determine the RSCs for PFOA, PFOS, PFNA, PFHxS, HFPO-DA, and PFBS and walks through the Exposure Decision Tree for each chemical in the RSC Determination sections found across several supporting documents published at the time of this rulemaking (USEPA, 2024a; USEPA, 2024b; USEPA, 2024h). Several factors considered during this process are described further below as they relate to some of the public comments the EPA received on the proposed PFAS NPDWR.

Although the RSC may be entirely science-based in cases when the agency has the data required to conduct this "apportionment," frequently, as was the case for all 6 PFAS considered under this rulemaking, the agency must rely on risk policy factors outlined by the Exposure Decision Tree approach to determine the RSC (USEPA, 2000c). One example risk policy decision that is

described later in this response and is impactful for this rulemaking is the application of an 80 percent ceiling and 20 percent floor for the RSC. A quantitative RSC determination first requires "data for the chemical in question… representative of each source/medium of exposure and… relevant to the identified population(s)" (USEPA, 2000c). The term "data" is defined as ambient sampling measurements in the media of exposure, not internal human biomonitoring metrics. More specifically, the data must adequately characterize exposure distributions including the central tendency and high-end exposure levels for each source and 95% CIs for these terms. The 2000 *Methodology* additionally outlines factors to consider when determining whether a dataset is "adequate" (USEPA, 2000c). Notably, "monitoring study reports often fail to include background information or sufficient summary statistics (and rarely the raw data) to completely characterize data adequacy" (USEPA, 2000c).

The RSC determinations for PFOA, PFOS, PFNA, PFHxS, HFPO-DA, and PFBS are complex in that there is evidence supporting the occurrence of these 6 PFAS in numerous exposure media, which may result in potentially significant contributions to total exposure by media other than drinking water (USEPA, 2024a; USEPA, 2024b; USEPA, 2024h). A quantitative RSC derivation would therefore require adequate monitoring data for all of the potentially significant sources of exposure (USEPA, 2000c). The EPA presents the available monitoring data showing the presence of the 6 PFAS in environmental media including food, indoor and outdoor air, house dust, consumer products, and others (USEPA, 2024a; USEPA, 2024b; USEPA, 2024h). Many of the studies provide evidence of exposure and occurrence but are specific to certain locations and therefore may not be generalizable to the U.S. population as a whole or more specifically to the identified population(s) of concern. Other studies are limited in terms of data adequacy. For example, some studies present monitoring data in only a small number of products or samples and others do not present raw data. Data were even more limited when the agency specified monitoring relevant to susceptible populations such as infants, children, and pregnant individuals. Therefore, for all 6 PFAS, the agency determined that the data were inadequate to quantitatively derive the RSC (USEPA, 2024a; USEPA, 2024b; USEPA, 2024c). Additionally, commenters did not provide information that would allow the EPA to quantitatively derive the RSCs for any of the six PFAS included in this rulemaking.

When adequate quantitative data are not available, the agency relies on the qualitative alternatives of the Exposure Decision Tree approach. A "qualitative alternative" RSC is not based on monitoring data and therefore, the selected RSC is not necessarily the actual percent of contaminant exposure that the EPA expects to result from an exposure source or medium of concern. In reality, a qualitative RSC is an estimate that incorporates data and policy considerations and thus, is sometimes referred to as a "default" RSC (USEPA, 2000c). Many commenters misinterpreted the EPA's qualitative RSCs as conclusions about actual contribution of drinking water exposure to total exposure. To reiterate, references to the 20 percent allocation to drinking water or 80 percent allocation to other sources/media without the context of the RfD and policy considerations of the 2000 Methodology (USEPA, 2000c) are incorrect applications of the RSC and incorrect interpretations of the agency's conclusions about PFAS exposure.

As described in the *Methodology*, "The underlying objective is to maintain total exposure below the RfD (or POD/UF) while generally avoiding an extremely low limit in a single medium that represents just a nominal fraction of the total exposure. To meet this objective, all proposed numeric limits, for both quantitative and qualitative RSCs, lie between 80 percent and 20 percent of the RfD" (USEPA, 2000c). The 80 percent ceiling is protective of individuals whose total exposure is higher than average and is also protective of potential unknown sources of exposure. The EPA considers the 80 percent ceiling "If it can be demonstrated that other sources and routes of exposure are not anticipated for the pollutant in question," which, as described above, is not the case for any of the PFAS discussed in this rulemaking (USEPA, 2000c). Additionally, commenters did not provide evidence demonstrating this to be the case. Therefore, the EPA disagrees with commenters who recommend an 80 percent or higher RSC for any of the 6 PFAS.

The EPA disagrees with commenters who state that the 20 percent RSC determinations are too conservative. As stated by the 2000 *Methodology*, "When other sources or routes of exposure are anticipated but data are not adequate, there is an even greater need to make sure that public health protection is achieved" (USEPA, 2000c). Considering the evidence supporting the potential for other sources of exposure to PFOA, PFOS, PFNA, PFHxS, HFPO-DA, and PFBS besides drinking water and the lack of adequate monitoring data that would support quantification of the RSC for each of these chemicals, the agency is taking the health-protective approach in setting the RSCs at 20 percent. The selection of RSCs of 20 percent is also consistent with the definition of the MCLG. In addition, though the EPA did not ultimately rely on the noncancer/RfD approach to derive MCLGs for PFOA or PFOS, thereby not applying the RSC term to the RfD or incorporating the RSC into the MCLG calculation, the SAB PFAS Review Panel stated that, "there are non-drinking water exposures from other sources such as consumer products and house dust" and presented data from North America and Europe that support the EPA's selection of 20 percent RSCs for PFOA and PFOS (USEPA, 2022b).

The EPA disagrees with commenters who justify their stance that the cost of the EPA's rulemaking outweighs the benefits by citing to the RSC of 20 percent and stating that the PFAS NPDWR "will only help them to mitigate potentially 20%," of total exposure. As described above, this type of justification is a misinterpretation of the RSC and the 20 percent determination. Further discussion on the economic analysis supporting this rulemaking is presented in section 13 of this *Response to Comments* document.

The agency agrees with commenters who state that other actions must be taken to prevent and mitigate exposure to PFOA, PFOS, and other PFAS through sources other than drinking water. The EPA's multi-faceted approach to addressing PFAS exposure is outlined in the PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

See also Section 4.3.3 of the EPA response in this *Response to Comments* document.

4.2.5.1 Justification for the RSCs of 20% for PFOA and PFOS

New Hampshire Department of Environmental Services (NHDES) (Doc. #1690, SBC-044341)

EPA's discussion of its decision to apply a 20% Relative Source Contribution (RSC) was limited and should be expanded to clarify 1) why exposure estimates from multiple studies it cited could not be compared to the proposed RfDs and 2) why background exposures could not be estimated from NHANES studies or multiple biomonitoring studies that have been published in the peer-reviewed literature or by CDC's ATSDR (Page 18656, Column 2). Understanding exposure to background sources of PFAS, including PFOA, PFOS and their precursors, is crucial to providing an understanding of the impact of exposure reduction efforts that target drinking water. Accurate characterization of background exposures from non-drinking water sources is critical not only to the HHRA's selection of RSCs for PFOA and PFOS, but also to characterizing the uncertainties related to EPA's Benefit Analysis for potential disease burden (Section XIII-HRRCA – Page 18689, Column 3). EPA's HHRA documents for PFOA and PFOS acknowledge uncertainty about the linearity of the relationship between exposure and health effects. Better characterization and comparison of non-drinking water exposures at the proposed MCLs and health advisories would improve the understanding of the potential for overall exposure reduction relative to the RfDs and CSFs.

EPA Response: The commenter stated that the EPA's discussions supporting the RSC derivations for PFOA and PFOS were limited and requested the EPA expand this discussion to clarify why exposure estimates from the literature could not be compared to the RfDs and why background exposures could not be estimated from the available literature. The EPA provides a detailed description of RSC derivations for PFOA and PFOS, including how the data align with factors considered in the Exposure Decision Tree approach (USEPA, 2000c), in Appendix G (USEPA, 2024a; USEPA, 2024b). Please also see section 4.2.5 of the EPA response in this *Response to Comments* document. Additionally, as the EPA described in the Response to SAB Comments document (USEPA, 2023d), "biomonitoring data is not typically used to determine the RSC. While biomonitoring data provides valuable aggregate exposure information, the 2000 *Methodology for the Derivation of Ambient Water Quality Criteria* (USEPA, 2000c) does not describe an approach for deriving RSCs that use serum concentrations from the U.S. general population."

American Chemistry Council (ACC) (Doc. #1841, SBC-044836)

There have been several studies of dietary, dust, and inhalation exposure to PFOA and PFOS, none of which suggest that exposures other than drinking water are likely to add up to 80% of the allowable daily intake. [FN131: Sunderland EM et al. A review of the pathways of human exposure to poly- and perfluoroalkyl substances (PFASs) and present understanding of health effects. J Expo Sci Environ Epidemiol 29(2):131-147 (2019).] Additionally, most recently, Garnick et al. estimated an "actual RSC" for PFOA and PFOS of 0.95 based on the 95th percentile background exposures for women based on a 2011 study by Lorber and Egeghy

[FN132: Lorber M and Egeghy PP. Simple intake and pharmacokinetic modeling to characterize exposure of Americans to perfluoroctanoic acid, PFOA. Environ Sci Technology 45: 8006–8014 (2011).] and national serum concentration data from the National Health and Nutrition Examination Survey (NHANES). [FN133: Garnick L et al. An evaluation of health-based federal and state PFOA drinking water guidelines in the United States. Sci Total Environ 761:144107 (2021).] Correcting the RSC to appropriate data-driven values rather than the default would improve the defensibility of the resultant proposed MCLs. [Revision of the RSC can make a significant difference to the resulting HBWC.]

Overall Exposure to Legacy PFAS Has Declined Significantly Since 2000

As EPA is aware, four of the six substances – PFOA, PFOS, PFHxS, and PFNA - have been subject to significant new use rules (SNURs) issued by the Agency that date back as far as 2002. [FN134: SNURs addressing one of more of these four substances were issued in December 2002, October 2007, October 2013, and July 2020.] Most of these rules have followed voluntary commitments from US-based manufacturers to phase out the production and use of the materials. As a consequence, exposure to these four substances from the manufacture and use of products containing them has declined substantially. This is reflected in biomonitoring data collected by the Centers for Disease Control and Prevention (CDC) as part of its National Health and Nutrition Examination Survey (NHANES). [FN135: https://www.cdc.gov/exposurereport/index.html.]

[Figure 1: see docket ID EPA-HQ-OQ-2022-0114-1508]

Figure 1. Mean Serum levels of PFOA and PFOS (micrograms per Liter), 1999-2016 [FN136: Ibid.]

The CDC results suggest a nearly 75 percent drop in exposure to PFOA and about a 90 percent drop in PFOS exposure between 1999 and 2018. (See Figure 1.) [FN137: The graph does not include data from the 2017-18 NHANES survey which reported levels of 1.42 µg/L for PFOA and 4.25 µg/L for PFOS.] Although not as commonly used in manufacturing historically, exposures to PFHxS and PFNA have also declined over this time period (50 percent for PFHxS, 25 percent for PFNA) according to the NHANES data.

Dietary sources have been suggested as a major contributor to exposures to various PFAS. Data from the Food and Drug Administration's (FDA) Total Diet Study suggest, however, that exposure to PFOA, PFOS, PFHxS, and PFNA have been all but eliminated. [FN138: https://www.fda.gov/media/150338/download.] Of the 94 food products FDA sampled as part of a 2020 survey, PFOA and PFHxS were not detected in any samples and PFNA and PFOS were detected in only one. This further supports the notion that the RSC default is inappropriate as non-drinking water sources of these four PFAS are continuing to decline.

While exposures to these four PFAS from dietary sources, consumer products, ambient air, and household dust have declined over the past twenty years as a result of the phaseout of their manufacture, exposure from drinking water has gone largely unaddressed. As EPA notes in its

Economic Analysis, standard treatment methods employed by public water systems do not remove PFAS from source water. As a result, drinking water has likely become an increasingly greater contributor to overall exposures to these substances. The upcoming Unregulated Contaminant Monitoring Rule 5 (UCMR5) data, which should become availability within this next year, will help define the frequency of occurrence and concentrations of these PFAS in our Nation's public drinking water systems. The EPA should wait until this information is available to make judgements about PFAS drinking water exposure.

EPA Response: Please see section 4.2.5 of the EPA response in this *Response to Comments* document. The commenter cited two studies that discussed the relative contribution of various exposure media/sources to human PFOA or PFOS exposures. The studies cited did not derive RSCs using methods described in the *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (USEPA, 2000c), which explicitly states data requirements for quantitative data-driven RSC derivation. The EPA describes the data and rationale used to derive RSCs for PFOA and PFOS in Appendix G (USEPA, 2024a; USEPA, 2024b). The commenter additionally mischaracterized the conclusions of Sunderland et al. (2019) (see Table 1 of Sunderland et al., 2019).

The EPA also notes that the derived RSCs have no impact on the MCLGs for PFOA or PFOS finalized in this rulemaking because the MCLGs are zero based on the determination that PFOA and PFOS are *Likely to be Carcinogenic to Humans,* not on an RfD-based MCLG derivation approach (see USEPA, 2024e). However, even if the EPA had used an RfD-based approach and selected the least stringent RSC (i.e., the ceiling of 80 percent (USEPA, 2000c)), the MCLGs for PFOA and PFOS would still be below the MCL of 4 ppt. See the calculations presented in the EPA response to comment Doc. #1713, SBC-053421 in section 4.2.1.4 in this *Response to Comments* document. If the EPA had substituted a "0.8" for the "0.2" in the equations, the noncancer-based MCLGs for PFOA and PFOS would be 0.7 ng/L (ppt) and 2 ng/L (ppt), respectively.

See section 6.8 of the EPA response in this *Response to Comments* document for discussion related to data collected under UCMR 5.

4.2.5.2 PFAS Exposure Sources

Massachusetts Coalition for Water Resources Stewardship (MCWRS) (Doc. #1691, SBC-044324)

The public health benefits of the proposed MCL cannot be determined if there is no full understanding of PFAS exposure levels from various sources. It is well documented that PFAS is present, often in high concentrations, in household products, personal care products, food, dust, clothing, fabric, food wrappers and a multitude of materials to which people are routinely exposed every day. EPA assumed 20% of exposure is from drinking water but this is the default value, not an estimate, and not based on any data. It is not possible to claim massive public health benefits from the proposed MCLs when there is no understanding of exposure levels from

other common sources. Imagine if childhood lead poisoning had been handled in a similar fashion. If the approach to reducing lead exposure had been to just regulate drinking water then lead based paint, by far the greatest source of lead intake for children, would have been ignored and little progress would have been made addressing this very real health issue. For most Americans, PFAS intake from drinking water could be 1% or less of the total PFAS exposure. Spending $40 billion or more to reduce PFAS exposure by 1% does not appear to be a sound public health strategy or wise use of public monies.

EPA Response: Please see section 4.2.5 of the EPA response in this *Response to Comments* document, as well as documentation describing the rationale and process for the RSCs derived for PFOA (USEPA, 2024a), PFOS (USEPA, 2024b), and PFNA, PFHxS, PFBS, and HFPO-DA (USEPA, 2024h).

American Chemistry Council (ACC) (Doc. #1711, SBC-044461)

[The Agency's proposal suffers from the following significant shortcomings –]

• The Agency's assumptions about the contribution of drinking water to overall exposure to the identified substances ignores the available biomonitoring and food survey data,

EPA Response: Please see section 4.2.5 of the EPA response in this *Response to Comments* document. The commenter incorrectly states that the EPA ignores the available biomonitoring and food survey data. Biomonitoring data were discussed in Section 1.6.1 of the PFOA and PFOS draft toxicity assessments (USEPA, 2023f; USEPA, 2023a) and Section 1.4.1 of the final PFOA and PFOS toxicity assessments (USEPA, 2024d; USEPA, 2024c). Occurrence in food is discussed in Appendix G (USEPA, 2024a; USEPA, 2024b). According to established EPA methodology (USEPA, 2000c) and as described in the EPA response to SAB comments document (USEPA, 2023d), biomonitoring data are not generally used to determine the relative source contribution.

HRSD (Doc. #1719, SBC-043549)

Finally, and linking back to the earlier discussion on the criticality of source control, EPA needs to reconsider its choice of Relative Source Contribution (RSC) factor for each of the PFAS compounds. The selected RSC of 0.2 essentially puts the burden of controlling 80% of our PFAS exposure on the water sector, which equates to an unfair cost burden on the communities being served. EPA must work with other federal agencies to reduce the public exposures of PFAS and push impactful and cost- effective reductions in exposure. Forcing more stringent controls on the water sector to essentially compensate for the failure to control PFAS from other sources is simply unreasonable and infeasible. True public health protection requires a robust program of source control to mitigate public health exposures.

EPA Response: The commenter erroneously stated that the EPA's selection of a 20 percent RSC for each of the 6 PFAS considered under this rule effectively means that 80 percent

of the burden of PFAS reduction will be placed on the water sector. This statement reflects a fundamental misunderstanding of both what the RSC is and what the basis of some of the MCLGs and MCLs are for these PFAS. First, please see section 4.2.5 of the EPA response in this *Response to Comments* document. Additionally, the derived RSCs have no impact on the MCLGs for PFOA or PFOS because the MCLGs are based on the determination that PFOA and PFOS are *Likely to be Carcinogenic to Humans,* not on an RfD-based MCLG derivation approach. Please also see the EPA response to comment Doc. #1841, SBC-044836 in section 4.2.5.1 in this *Response to Comments* document.

4.2.6 Recommended Literature

Summary of Major Public Comments and EPA Responses

A few commenters expressed support of the EPA's effort to conduct a final literature search update prior to finalization of the toxicity assessments for PFOA and PFOS. Many commenters provided citations for the EPA to consider during finalization.

The EPA has reviewed and documented the literature identified from the updated search conducted in February 2023, in accordance with the systematic review protocols developed for the PFOA and PFOS toxicity assessments (see Appendix A.1 of USEPA (2024a) and USEPA (2024b)). Results of this effort are discussed in the final toxicity assessments (see Appendices A.3 and A.4 of USEPA (2024a) and USEPA (2024b)). Documentation for the EPA's review of references recommended by commenters is provided in a tabular format in the docket (EPA-HQ-OW-2022-0114) and is summarized in Section 3.1 of the final toxicity assessments (USEPA, 2024d; USEPA, 2024b).

Many commenters noted differences between the conclusions of the EPA's toxicity assessments for PFOA and PFOS and the assessments and conclusions published by other agencies or the EPA's previously published assessments (e.g., the 2016 HESDs). Commenters recommended the EPA consider publications by the ATSDR, World Health Organization (WHO), National Toxicology Program (NTP), EFSA, Food Safety Australia and New Zealand (FSANZ), the United Kingdom's Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT), HC, Texas Commission on Environmental Quality (TCEQ), NJDEP, and Michigan Science Advisory Workgroup, among others when finalizing its toxicity assessments for PFOA and PFOS.

There are several reasons why the EPA's conclusions may differ from those of other health agencies or from the agency's previous conclusions. For example, commenters questioned why the EPA's conclusions regarding the associations between adverse immunological endpoints and PFOA and PFOS exposure differ from the report on immunotoxicity of PFOA and PFOS developed by NTP (2016). First, the NTP (2016) report is approximately 8 years old and does not account for the more recent information the EPA considered in the final PFOA and PFOS toxicity assessments (USEPA, 2024d; USEPA, 2024c). As shown repeatedly through the EPA's literature searches conducted for these assessments, thousands of studies on PFOA and PFOS have been

published since that time; many of the critical studies the EPA considered postdate the 2016 NTP report, including the Timmerman et al. (2021), Zhang et al. (2023), and Budtz-Jørgensen and Grandjean (2018) critical studies. The EPA's conclusions regarding the immune health outcome reflects the best available peer-reviewed science. Another explanation for differing conclusions between health agencies are the differing methods and guidance used to develop the assessments. The EPA uses established systematic review practices (USEPA, 2022a) to identify, evaluate, synthesize, integrate, and quantify evidence in a chemical database. Other health agencies, including the WHO, do not follow these same practices and, as a result, may arrive at different conclusions. Additionally, the EPA followed agency guidance, such as the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005) to determine the cancer classifications for PFOA and PFOS. The classification systems used by other agencies (e.g., IARC, UK COT, CalEPA) differ from those used by the EPA; the application of different systems may result in different conclusions by other agencies. However, CalEPA's final public health goals are also generally supportive of the EPA's cancer classifications for PFOA and PFOS (CalEPA, 2024). As a final example, some agencies, such as the WHO have published guidance values that are not solely health based (i.e., they consider feasibility, analytical methods, etc.) and therefore, cannot be directly compared to the EPA's MCLGs, which are based solely on health effects information. The MCLs published in this rulemaking (described in section V of the rule preamble and section 5 of this *Response to Comments* document) may be more comparable to guideline values published by external agencies than the MCLGs described in this section.

Some comments pointed out differences between the EPA's and other agencies' conclusions, with references to specific cancer or noncancer effects. Please refer to section 4.1.4 of this *Response to Comments* document and Section 3.5 of the final toxicity assessments for PFOA and PFOS (USEPA, 2024d; USEPA, 2024c) regarding the EPA's conclusions about cancer effects. Please refer to section 4.2.1 of this *Response to Comments* document and Section 3.4 of the final toxicity assessments for PFOA and PFOS (USEPA, 2024d; USEPA, 2024c) regarding the EPA's conclusions about noncancer effects, including effects on the immune system, development, cardiovascular system, and liver.

Individual Public Comments and EPA Responses

Savannah River Nuclear Solutions LLC (Doc. #1647, SBC-043343)

The support document, Public Comment Draft Toxicity Assessment and Proposed Maximum Contaminant Level Goal for PFOA in Drinking Water publishes a PFOA overall reference dose (RfD) = 3E-08 mg/kg/day (page 4-53) and selects a CSF = 0.0293 (ng/kg/day)-1 (page 4-59). The EPA May 2023 regional screening levels (RSL) website publishes a RfD = 3E-06 mg/kg-day and a CSF (SFo) = 7E-02 (mg/kg-day)-1.

Further, support document Public Comment Draft Toxicity Assessment and Proposed Maximum Contaminant Level Goal for PFOS in Drinking Water publishes a PFOS overall RfD = 1E-07 mg/kg/day (page 4-49) and selects a cancer slope factor (CSF) = 39.5 (mg/kg/day)-1 (page 4-51). The EPA May 2023 RSL website publishes a RfD = 2E-06 mg/kg-day and a CSF (SFo) = none.

SRSNS requests that EPA explain why there is such a large difference between the toxicity values (RfD and CSF) published in the Draft Toxicity Assessments compared to those published in the most current EPA RSL website. In contrast, the RfDs for the PFAS mixtures (GenX, PFBS, PFNA, PFHxS) align with the values in the RSL website, minor exception is that PFHxS applies an additional sub-chronic to chronic uncertainty factor of 10 that is not considered in the RSL website (per the Public Comment Draft MCLG Summary for a Mixture of Four Per- and Polyfluoroalkyl Substances (PFAS): GenX, PFBS, PFNA and PFHxS).

EPA Response: The commenter requested clarification on why there are differences between the toxicity values presented in the EPA's draft toxicity assessments for PFOA and PFOS and those previously presented as the EPA Regional Screening Levels (RSLs). RSLs are not established under the authority of the Safe Drinking Water Act and instead are established as one of many tools to support Comprehensive Environmental Response Compensation and Liability Act (CERCLA) superfund implementation. The agency's Superfund program, in accordance with the 2003 memo "Human Health Toxicity Values in Superfund Risk Assessments" (USEPA, 2003b), generally uses final, peer reviewed, publicly available toxicity values (such as the ATSDR values) to calculate RSLs and RMLs. Draft toxicity assessments, such as those developed in support of the proposed PFAS NPDWR (USEPA, 2023f; USEPA, 2023a), are not used in calculating the RSL and RMLs. The finalized toxicity assessments for PFOA and PFOS (USEPA, 2024d; USEPA, 2024c) will be considered as part of the semi-annual update of RSLs and RMLs. The RSLs referenced by the commenter were based on toxicity assessments that predate finalization of the toxicity assessments for PFOA and PFOS. Further discussion on the RSL and RML update processes are outside the scope of this rulemaking.

Missouri Department of Natural Resources (Doc. #1563, SBC-042515)

EPA requests comment on whether there are other peer-reviewed health or toxicity assessments for other PFAS the Agency should consider as a part of this action.

While the Department has not evaluated the report, we were made aware of the following study which may or may not be relevant to this action: Henry, B. J., et al. "A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers", Integrated Environmental Assessment and Management. Volume 14, number 3, pages 316-334. May 2018.

EPA Response: Please see section 4.2.6 of the EPA response in this *Response to Comments* document.

New Hampshire Department of Environmental Services (NHDES) (Doc. #1690, SBC-044336)

Third, the EPA's human health risk assessment of PFOA and PFOS is a significant departure from its 2016 interpretation of similar studies. NHDES appreciates the growing body of scientific literature about the potential health impacts following PFAS exposure. However, the current technical support documents lack clarity about how the EPA's current approach is consistent with the assessment of previous chemicals with similar health endpoints. Similarly, it

is unclear how EPA has determined that this approach is reasonable for any and all chemicals with similar properties or how it will apply this level of conservatism to future chemical risk assessments. Furthermore, the assessments do not reflect existing evidence for the multiple sources of PFAS exposure from the environment and consumer products in addition to drinking water.

In conclusion, NHDES appreciates the opportunity to provide comments on the US EPA's proposed MCLs for PFAS. As a state that has been significantly impacted by PFAS contamination and has developed considerable expertise on the topic, we understand the importance of both science-based rulemaking and a thorough review of public comment provided by a broad array of stakeholders. We trust that our constructive comments will be incorporated as the EPA moves forward to advance this important rulemaking.

EPA Response: Please see section 4.2.6 of the EPA response in this *Response to Comments* document. Further, in 2016, the EPA had not yet adopted the currently established systematic review methodologies (i.e., USEPA, 2022a) used to develop the assessments supporting this rulemaking. In addition, hundreds of peer-reviewed epidemiological and animal toxicological studies on PFOA and PFOS have been published since the 2016 assessments as detailed in Section 3.1 of the toxicity assessments (USEPA, 2024d; USEPA, 2024c). The commenter does not provide specific instances where the EPA is inconsistent in its assessment of previous chemicals with similar health endpoints or which aspects of the current assessment are conservative.

The commenter additionally stated that the PFOA and PFOS toxicity assessments did not reflect existing evidence for multiple sources of PFAS exposure. This is incorrect. The EPA provides a detailed description of studies reporting the occurrence of PFOA or PFOS in various environmental media in Appendix G (USEPA, 2024d; USEPA, 2024c). In this appendix, the EPA also states that there are potentially significant sources of PFOA or PFOS exposure other than drinking water, including dietary sources, dust, consumer products, and air. This information is reflected in the EPA's derivation of relative source contributions (RSCs) of 20 percent for both PFOA and PFOS in drinking water. Regarding this topic, please also see section 4.2.5 of the EPA response in this *Response to Comments* document.

Michigan Farm Bureau (Doc. #1562, SBC-052842)

The different recommendations and regulatory limits on PFAS in drinking water and other media from different organizations and entities reflect the profound uncertainty and developing research on the potential for health impacts due to PFAS exposure. The Agency for Toxic Substances and Disease Registry (ASTDR) developed an overview of science and clinical guidance for PFAS, [FN2: ASTDR. 2019. PFAS: An Overview of the Science and Guidance for Clinicians on Per- and Polyfluoroalkyl Substances. Retrieved from: https://www.atsdr.cdc.gov/pfas/docs/clinical-guidance-12-202019.pdf.] noting that human studies on PFAS-associated health impacts have a lack of exposure monitoring data, limited analysis of other routes of exposure, and for many of

the predicted health impacts, no causal relationship has been established by these studies. ASTDR noted that the ability to quantify and associate incidence of health impacts for other PFAS was even less documented than PFOS and PFOA.

In a separate report, [FN3: ASTDR. 2021. Toxicological Profile for Perfluoroalkyls. U.S. Department of Health and Human Services. Retrieved from: https://www.atsdr.cdc.gov/ToxProfiles/tp200.pdf.] the ASTDR noted that differences in half-life of PFAS, mechanism of toxicity and endpoints, and differences in exposures created a high degree of difficulty in comparing animal studies to human health risks due to PFAS exposure. In particular, rats and mice used in experimental studies have more sensitive receptors that mediate a wide range of biological responses to chemical exposure that humans and other primates are far less sensitive to. Animal studies also predominantly focus on oral exposure without corroborating evidence collected for dermal or inhalation exposure, limiting the pathways for understanding of PFAS impacts from real-world contact. This is especially important for evaluating health impacts to other PFAS chemicals besides PFOA and PFOS, which have several human epidemiological studies to support and validate animal studies and models, making the establishment of hazard indices or limits to other PFAS problematic. Additionally, the study noted that "adverse health effects in studies in animals have been associated with exposure concentrations or doses that resulted in blood levels of perfluoroalkyls that were significantly higher than those reported in perfluoroalkyl workers or in the general population. [FN4: Id., p.7.] While not intended to cast doubt on whether PFAS exposure can have human health impacts, this study highlights the challenges in establishing meaningful MCLs and Maximum Contaminant Level Goals (MCLGs).

The U.S. Department of Health and Human Services' National Toxicology Program (NTP) performed a literature review [FN5: National Toxicology Program. 2016. NTP Monograph: Immunotoxicity Associated with Exposure to Perfluorooctanoic Acid of Perfluorooctane Sulfonate. U.S. Department of Health and Human Services. Retrieved from: https://ntp.niehs.nih.gov/ntp/ohat/pfoa_pfos/pfoa_pfosmonograph_508.pdf.] of health impact studies related to PFOS and PFOA and how the studies were both mechanistically analyzed and weighted for both potential bias of results and level of confidence in the evidence presented. The NTP concluded that while there was a high level of confidence in the evidence associating immune hazards in animals from exposure to PFOA and PFOS, there was only moderate confidence in associating immune hazards in humans from such exposure. While the NTP report concluded there is a high likelihood of health impact to humans from PFOS and PFOA exposure, their report highlights the difficulty of assigning risk to specific exposures because of a lack of epidemiological evidence on humans.

Similarly, research conducted on the European Food Safety Authority's assessment of PFAS risk [FN6: Antoniou E, Colnot T, Zeegers M, Dekant W. 2022. Immunomodulation and exposure to per- and polyfluoroalkyl substances: an overview of the current evidence from animal and human studies. Archives of Toxicology;96(8):2261-2285. doi: 10.1007/s00204-022-03303-4. Epub 2022 Jun 13. PMID: 35695909.] showed a weak relationship between PFAS blood serum levels and

immune response (which was the basis of the overall risk assessment), until blood serum levels are at several orders of magnitude higher than the geometric mean of European blood serum levels, which are 2.13 parts per billion (ppb) for PFOS and 0.97 ppb of PFOA. These values are compared to the geometric mean of general US population blood serum concentrations, which are 4.28 ppb for PFOS and 1.42 ppb for PFOA. [FN7: Centers for Disease Control and Prevention. 2022. Biomonitoring Data Tables for Environmental Chemicals. Retrieved from: https://www.cdc.gov/exposurereport/data_tables.html.]

The World Health Organization (WHO) reported [FN8: World Health Organization. 2022. PFOS and PFOA in Drinking Water: Background Document for Development of WHO Guidelines for Drinking-water Quality, Version for Public Review issued 29 September, 2022. WHO/SDE/WSH/XXXXXX. Retrieved from: https://www.cmbg3.com/library/WHO-Draft-Drinking-Water-Document.pdf] a wide variation in study results for varying health impacts from PFOS and PFOA exposure, finding that there was insufficient evidence for causal relationships between PFOA and PFOS and several health impacts studies have suggested are associated with PFAS. The health conditions tested with uncertain causal relationships to PFAS include: maternal hypertension/pre-eclampsia, pre-term birth and pregnancy loss (though PFOA had a stronger statistical association with this impact, making a causal relationship more likely), male reproductive fertility, neurodevelopmental abnormalities, overweight conditions in childhood, heart defects, neurotoxicity in adults, endocrine disorders, cardiovascular disease, diabetes, adult obesity, liver disease, chronic kidney disease, and PFOS impacts on cancer development. This report does not dispute the association between PFAS and health impacts, but further highlights the uncertainty surrounding health impacts from exposure. It additionally summarizes the range of PFAS health-based advisories and drinking water regulations, which go from 3 to 400 ppt for PFOS and 4 to 100 ppt for PFOA, noting that these standards used many different analytical methods to reach their concentration limits, and setting their own provisional guideline value of 500 ppt for all combined PFAS, and 100 ppt each for PFOA and PFOS.

The uncertainty noted in these reports is important because it highlights the need to develop robust and consistent tools to analyze data used to set health risk values and weight them appropriately against the feasibility of implementation and compliance with regulatory drinking water treatment standards.

EPA Response: For explanations of why the EPA's assessment conclusions may differ from other agency conclusions, please see section 4.2.6 of the EPA response in this *Response to Comments* document. For discussion on the use of epidemiological studies to support qualitative and quantitative risk assessments, please see section 4.2.2 of the EPA response in this *Response to Comments* document. For discussion on the other four PFAS considered in this rulemaking, please see section 4.3 of the EPA response in this *Response to Comments* document.

Mass Comment Campaign sponsored by Alliance for Risk Assessment (Doc. #1606, SBC-042828)

We read with surprise the recent action by EPA regarding the development of its PFOA MCL based in part on the development of its prior PFOA MCLG, and its associated reference or safe dose. EPA must know that its safe dose is over 100,000-fold lower than other international authorities, specifically FSANZ (2017), and significantly lower, although not quite as dramatically, with Health Canada (2018), WHO (2022), and more recently Burgoon et al. (2023). Moreover, all four of these expert groups concluded, in contrast to EPA, that the observational epidemiologic data do not constitute a reliable basis for estimating a reference dose for PFOA in the absence of mechanistic data that are relevant for humans at serum concentrations seen in the general population.

We encourage our EPA colleagues to seriously consider these other expert, international positions, and to engage colleagues associated with one or more of these groups in a resolution. Towards this resolution, a workshop is being planned for October of this year under the auspices of the Alliance for Risk Assessment (ARA), details of which will be forthcoming at https://www.tera.org/Alliance%20for%20Risk/ARA_Dose-Response.htm.

EPA Response: For explanations of why the EPA's assessment conclusions may differ from other agency conclusions, please see section 4.2.6 of the EPA response in this *Response to Comments* document. Regarding the EPA's quantitative and qualitative use of epidemiological data in these assessments, please see section 4.2.2 of the EPA response in this *Response to Comments* document.

Greater North Dakota Chamber et al. (Doc. #1593, SBC-042803)

There is limited understanding of risk at these levels. There is significant uncertainty regarding the health risks at the proposed MCL levels for all six PFAS. WHO's recent study on potential guidelines for water quality, for example, proposed 100 ppt based on the most relevant public health data and seems to be consistent with known risk.

EPA Response: For explanations of why the EPA's assessment conclusions for PFOA and PFOS may differ from other agency conclusions, please see section 4.2.6 of the EPA response in this *Response to Comments* document. Please see section 4.3 of the EPA response in this *Response to Comments* document for discussion on the other four PFAS considered under this rulemaking.

Aurora Water, City of Aurora, CO (Doc. #1669, SBC-043731)

The American Chemical Society (ACC) has voiced their concerns about the science behind EPA's proposed MCLs. Aurora Water agrees with their concerns about the excessively high health threshold for PFOA and PFOS. As noted by ACC, the World Health Organization (WHO) has stated they cannot set an official Health-Based Guidance Value with confidence. When determining the health impacts from PFAS the EPA should consider other organizations' positions about those impacts.

EPA Response: For explanations of why the EPA's assessment conclusions for PFOA and PFOS may differ from other agency conclusions, please see section 4.2.6 of the EPA response in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-053455)

EPA did not act on SAB recommendations to consider the conclusions of other agencies regarding immune effects as a critical endpoint, and in particular, the Grandjean et al. (2012) study.

EPA's use of human epidemiologic data as the sole basis for its calculations regarding vaccine response is a departure from the conclusions of other U.S. regulatory agencies. The SAB recommended that EPA review and potentially include conclusions from other agencies about immune outcomes. The EPA's response was that it "considered the conclusions from other health agencies about both the immune endpoints in general and the Grandjean et al. (2012) study in particular." However, EPA does not appear to have considered either the Agency for Toxic Substances and Disease Registry (ATSDR) or National Toxicology Program's (NTP) conclusions regarding immune endpoints. Both U.S. agencies raised questions regarding the reliability of human studies for the purposes of dose-response and risk assessment.

In addition to reviewing other agencies' conclusions regarding immune outcomes, the SAB also suggested that EPA should review the comments on Grandjean et al. (2012) and the studies of the Faroe Islands cohorts, in particular. It does not appear that EPA adequately addressed the SAB's suggestion.

In the NTP's review of the immunotoxicty of PFOA and PFOS, the agency stated that Grandjean et al. (2012) accounted for PCB exposure in analyses, but not PFAS. Therefore, "unless a study controlled for other PFAAs, studies were rated probably high risk of bias in accounting for potential confounders and modifiers because of the limited ability to differentiate effects of PFOA or PFOS from other PFAAs" (NTP 2016, p. 26). The NTP also noted that the findings may be due to chance, given the number of comparisons made in the analyses. Due to the non-significant results in the Mogensen et al. (2015) re-analyses of the Faroe Islands cohort, controlling for other PFAS, "Confidence in the body of evidence was not increased for dose-response for several reasons including the difficulty in attributing effects to individual compounds" (NTP 2016, p. 31).

ATSDR also pointed out that "Grandjean and associates also found an inverse association between serum polychlorinated biphenyls (PCBs) and serum antibody concentrations against tetanus and diphtheria in children living in the Faroe Islands (Heilmann et al. 2010)." ATSDR found that there was moderate confidence that exposure to PFOA is associated with suppression of the antibody response based on available human studies (ATSDR 2021, p. 327), and ultimately concluded that "the available epidemiological studies suggest associations between perfluoroalkyl exposure and several health outcomes; however, cause-and-effect relationships have not been established for these outcomes", including decreased antibody response to vaccines (ATSDR 2021, p. 6).

EPA failed to provide further consideration of the limitations of the Faroe Island studies identified by other agencies in its assessment of immune outcomes. These considerations would have informed EPA's decision regarding candidate studies as well as vaccine response as a critical endpoint.

EPA Response: The commenter states the EPA did not review and consider conclusions from other health agencies about immune endpoints. The commenter claimed the EPA did not follow recommendations of the SAB. The commenter provides limitations described by each health agency's documents characterizing immunotoxic effects of PFOA and PFOS, and the commenter suggests these limitations were not considered in the EPA's conclusion on immune effects. The EPA disagrees with these comments and first directs the commenter to sections 4.2.6 and 4.1.3 of the EPA response in this *Response to Comments* document.

Additionally, the commenter incorrectly characterizes the conclusions from both NTP's review (NTP, 2016) and ATSDR's *Toxicological Profile for Perfluoroalkyls* (ATSDR, 2021). Despite the limitations outlined by the commenter, NTP concluded that PFOA and PFOS are "presumed to be immune hazard to humans and to alter immune functions in humans," which was based on "a moderate level of evidence from studies in humans" (NTP, 2016, p. 86).

The ATSDR's *Toxicological Profile for Perfluoroalkyls* also identifies literature about the health effects of PFOA and PFOS and notes "epidemiological studies identify the immune system as a target of perfluoroalkyl toxicity," and that "the strongest evidence of the immunotoxicity of perfluoroalkyls in humans comes from epidemiological studies finding associations evaluating the antibody response to vaccines" (ATSDR, 2021). The ATSDR *Toxicological Profile* does not provide a classification or determination for PFOA and PFOS but notes the strength of the evidence base.

The commenter also mischaracterizes the SAB's conclusions about the immune endpoint and the Grandjean et al. (2012) study. In the final report, the SAB stated: "Overall, the Panel agreed with the selection of the critical study, Grandjean et al. (2012), and the critical effect, suppression of a vaccine response in children exposed during development, as appropriate for the derivation of chronic RfDs for PFOA and PFOS." The EPA considered all recommendations of the SAB when revising the assessments of PFOA and PFOS, including their overall conclusions on the EPA's assessments, as well as recommendations to consider the conclusions of other health agencies.

Additionally, the critical study selected for the immune health outcome-specific RfD was Budtz-Jorgensen & Grandjean (2018), which reflects updated analyses of the cohort studied by Grandjean et al. (2012).

PFAS Regulatory Coalition (Doc. #1761, SBC-053404)

Further, EPA is inconsistent in its decisions as to the toxicological endpoints that it wants to rely on. The HALs that EPA issued in 2022 were based on immune response, whereas the conclusions in the EPA Proposal appear to be based on cancer studies in mice and rats. Which endpoint does EPA think is appropriate to use? EPA does not provide any explanation of why it has chosen different endpoints for the HAL than in the current Proposal.

EPA Response: The EPA disagrees with the commenter's statement that the agency is "inconsistent in its decisions as to the toxicological endpoints that it wants to rely on." The commenter appears to misunderstand the processes used to develop the interim HAs for PFOA and PFOS and the final toxicity assessments and MCLGs for PFOA and PFOS.

In 2021, the EPA published and transmitted two draft documents, the *Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) (CASRN 335-67-1) in Drinking Water* (USEPA, 2021b) and the *Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) (CASRN 1763-23-1) in Drinking Water* (USEPA, 2021c), to the SAB PFAS Review Panel for peer review. Those documents were the basis for the qualitative and quantitative conclusions of the interim HAs for PFOA and PFOS, published in 2022. The 2022 interim HAs were based on noncancer endpoints (i.e., reduced antibody response to vaccination in children) and are non-regulatory HAs issued pursuant to a separate authority under SDWA that reflected the best available information at that time.

With the conclusion of the peer review process (see USEPA (2022b)), the EPA revised and improved the 2021 draft documents (USEPA, 2021b; USEPA, 2021c) and subsequently published updated draft toxicity assessments for PFOA and PFOS (USEPA, 2023f; USEPA, 2023a), as well as proposed MCLGs for PFOA and PFOS at the time of the PFAS NPDWR proposal (USEPA, 2023e). The proposed rule and draft toxicity assessments for PFOA and PFOS (USEPA, 2023f; USEPA, 2023a) were published for public comment at that time.

The proposed and final MCLGs are set to zero based on the EPA's cancer determinations that PFOA and PFOS are *Likely to Be Carcinogenic to Humans* in accordance with the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005) (see Section 4.1.5 of the EPA response in this *Response to Comments* document). The determinations of *Likely to Be Carcinogenic to Humans* are based on reviewing the weight of the evidence of the best available data from human epidemiology, animal toxicology, and mechanistic studies (see Section 4.1.4 of the EPA response in this *Response to Comments* document); in contrast to the commenter's statement, the MCLGs are not solely based on cancer studies in rodents.

At the time of rule proposal, the EPA communicated the differences in underlying toxicity values between the 2021 and 2023 draft toxicity values in this transparent note on the EPA's PFAS HA webpage (https://www.epa.gov/sdwa/drinking-water-health-advisories-pfoa-and-pfos). Specifically, the EPA stated, "In the proposed rule, EPA presents updated noncancer toxicity values based on evaluating additional scientific information. These updated values are different from those used to calculate the 2022 interim HAs, which EPA based on the best available science at that time." The 2023 toxicity assessments released as part of the rule proposal considered SAB recommendations and new scientific information. The EPA has considered information from an updated literature review and the information and studies reviewed were confirmatory of the EPA findings and conclusions in the PFOA and PFOS toxicity assessment drafts released for public comment at the time of rule proposal (USEPA, 2023f; USEPA, 2023a). The EPA final rule and final toxicity assessments for PFOA and PFOS (USEPA, 2024d; USEPA, 2024c) reflect the best available science and consideration of the public comments. As discussed in this *Response to Comments* document and throughout the administrative record for this action, the PFOA and PFOS MCLGs in the final rule are zero.

Anonymous (Doc. #1964, SBC-046609)

I would like to bring to the agency's attention new research that is highly relevant for the decision-making process regarding the proposed regulation Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation, Docket (EPA-HQ-OW-2022-0114).

The proposed regulation text cites that depending on the individual PFAS, health effects can include negative impacts on fetal growth after exposure during pregnancy, on other aspects of development, reproduction, liver, thyroid, immune function, and/or the nervous system; and increased risk of cardiovascular and/or certain types of cancers, and other health impacts when providing context for the following regulatory actions: proposing a National Primary Drinking Water Regulation (NPDWR) and health-based Maximum Contaminant Level Goals (MCLG) for these four PFAS and their mixtures as well as for PFOA and PFOS.

The related research summarized below supports the data presented by the agency...

This study childhood PFAS exposures may be associated with elevated serum lipid concentrations. This is a public health concern, as a detrimental lipid profile in childhood is a risk factor for later development of hyperlipidemia and cardiovascular disease.

There is strong evidence supporting a link between PFAS exposure and increased glucose levels and insulin resistance, with a strongest association in groups with multiple risk factors for diabetes. Although there appears to be variable associations, the conflicting data is often related to the specific PFAS examined and the gender of the subject affected.

The most consistently observed and strongest evidence for harmful impacts on human health is for immune suppression (such as decreased vaccination response), changes in liver function (such as higher cholesterol, elevated liver enzymes), and lower birth weight. In addition, PFOA

has also been associated with kidney cancer. Increased tumors were also observed in certain organs in animals exposed to very high doses of PFOA.

A comprehensive study estimates the societal costs for not regulating PFAS. The costs relate to health impacts of workers and the general population following PFAS exposure in addition to costs for cleaning up contaminated soil and water is estimated to be billions of Euros.

While we believe the immediate health risks for most people exposed to PFAS are low, the latest information indicates that fetuses and infants are more vulnerable. Long term exposure to PFOA, PFOS, and PFHxS leads to a buildup of these chemicals in women of child-bearing age that increases exposure to the fetus and breastfed babies. Breastfeeding provides many health benefits for mothers and babies.

The sources for the research cited above can be found at the end of this comment.

Please take this research into consideration when making any adjustments for the final regulation.

Sincerely,

Julien Tremblay and additional MD/MPH Degree Candidates

Sources:

Blomberg, A. J., Shih, Y. H., Messerlian, C., JÃ¸rgensen, L. H., Weihe, P., & Grandjean, P. (2021). Early-life associations between per- and polyfluoroalkyl substances and serum lipids in a longitudinal birth cohort. Environmental research, 200, 111400. https://doi.org/10.1016/j.envres.2021.111400

Roth, K., & Petriello, M. C. (2022). Exposure to per- and polyfluoroalkyl substances (PFAS) and type 2 diabetes risk. Frontiers in endocrinology, 13, 965384. https://doi.org/10.3389/fendo.2022.965384

Goldenman, G., Fernandes, M., Holland, M., Tugran, T., Nordin, A., Schoumacher, C., & McNeill, A. (2019). The cost of inaction"¯: A socioeconomic analysis of environmental and health impacts linked to exposure to PFAS. https://doi.org/10.6027/TN2019-516

Pdf: https://www.health.state.mn.us/communities/environment/hazardous/docs/pfashealth.pdf

EPA Response: Please see section 4.2.6 of the EPA response in this *Response to Comments* document.

Emma Nal (Doc. #2427, SBC-046449)

This is a great start but the regulation needs to go further to protect human health. Please read this research:

https://news.harvard.edu/gazette/story/2023/05/epas-new-rules-on-forever-chemicals-dont-go-far-enough-study-suggests/?utm_source=SilverpopMailing&utm_medium=email&utm_campaign=Daily%20Gazette%2020230517%20(1)

EPA Response: Please see section 4.2.6 of the EPA response in this *Response to Comments* document.

4.2.7 Recommendations for Additional Research

Millie Garcia-Serrano (Doc. #1803, SBC-044290)

Overall, as movement is made toward better regulation and oversight of these contaminants, ASTSWMO's membership recognizes a corresponding need for research, communication, and improved understanding within the following areas:

• development of human health and ecological toxicity values for PFAS;

EPA Response: The EPA agrees that development of human health and ecological toxicity values for PFAS are important. For all the ways the EPA is working to address PFAS pollution and exposure, please see the PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Anonymous (Doc. #1958, SBC-046295)

The EPA should do more research on how PFAS affects the human body in the long run. These chemicals have been proven to cause multiple health defects, such as cancer and liver problems. In addition, PFAS is a difficult compound for the human body to break down, so the more people consume it in drinking water, the more likely their health will deteriorate. Before putting this rule into law, the EPA should make efforts to do more experiments and conduct more research on these harmful chemicals so that a large portion of the population does not have their heath at risk when drinking water.

EPA Response: The EPA disagrees that more research needs to be done to finalize this PFAS NPDWR. The EPA is publishing Final Human Health Toxicity Assessments for PFOA and PFOS (USEPA, 2024d; USEPA, 2024c); these assessments consider hundreds of studies reporting adverse health effects that are associated with long-term exposure to PFOA and PFOS. Similarly, the agency has substantial information supporting NPDWR finalization for the four additional PFAS considered in this rulemaking (i.e., PFNA, PFHxS, HFPO-DA, and PFBS). See sections 4.3 and 5 of the EPA response in this *Response to Comments* document for information on the Hazard Index MCLG and MCLs, respectively.

Monte Vista Water District (MVWD) (Doc. #1718, SBC-043532 & SBC-043538)

In conclusion, MVWD's top priority is delivering safe drinking water, and we support EPA's efforts to ensure public health by monitoring and reducing exposure to PFAS contamination in drinking water. MVWD supports scientific research on potential health effects and exposure pathways to better understand the toxicity, bioaccumulation, and long-term health impacts of PFAS. MVWD recommends additional research, analysis, and monitoring efforts to better understand the extent of PFAS in drinking water to ensure science-based decision-making in support a more comprehensive PFAS National Primary Drinking Water Regulation.

EPA Response: Several of the comments provided by this commenter support the final rule. However, the EPA disagrees that more research needs to be done to finalize this PFAS NPDWR. The EPA is publishing Final Human Health Toxicity Assessments for PFOA and PFOS (USEPA, 2024d; USEPA, 2024c); these assessments consider hundreds of studies reporting adverse health effects that are associated with long-term exposure to PFOA and PFOS. Similarly, the agency has substantial information supporting NPDWR finalization for the four additional PFAS considered in this rulemaking (i.e., PFNA, PFHxS, HFPO-DA, and PFBS). See sections 4.3 and 5 of the EPA response in this *Response to Comments* document for information on the Hazard Index MCLG and MCLs, respectively. Please see the PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024) regarding the agency's other efforts to address PFAS pollution and exposure, including monitoring efforts conducted under the Fifth Unregulated Contaminant Monitoring Rule (UCMR 5) and ongoing human health toxicity or risk assessments under development by the various agency program offices.

4.3. MCLG Derivation for a PFAS Mixture (HI MCLG) and for Additional Individual PFAS

The EPA requested comment on the proposed general Hazard Index approach for MCLG derivation for a mixture of PFHxS, PFNA, HFPO-DA, and/or PFBS and whether the agency should consider individual MCLGs (and MCLs) for some or all of these PFAS.

Many commenters agreed with the EPA's scientific conclusions about the dose additivity of PFHxS, PFNA, HFPO-DA, and PFBS based on a common adverse health outcome instead of a common MOA as a health protective default assumption (please see section 4.3.1 of the EPA response in this *Response to Comments* document). Other commenters asserted that the EPA failed to establish that the four PFAS included in the Hazard Index (PFHxS, PFNA, HFPO-DA, and PFBS) are dose additive and questioned whether the EPA's approach was consistent with the recommendations of the EPA SAB and existing agency guidance (please see section 4.3.1 of the EPA response in this *Response to Comments* document).

Many commenters agreed with the EPA's approach to use the general Hazard Index MCLG approach for a mixture of PFHxS, PFNA, HFPO-DA, and/or PFBS (please see section 4.3.2 of the EPA response in this *Response to Comments* document). Other commenters asserted that the general Hazard Index was not justified, questioned the EPA's external peer review process, asserted that the EPA approach was inconsistent with its own guidance, disagreed with the use of

toxicity reference values based on different adverse effects for the four PFAS in the Hazard Index , and/or suggested other approaches to consider PFAS mixtures (please see section 4.3.2 of the EPA response in this *Response to Comments* document). Several commenters favored finalization of individual MCLGs (and MCLs) for some or all of the PFAS included in the proposed Hazard Index, with or without a Hazard Index approach to address mixtures of these PFAS (please see section 4.3.2 of the EPA response in this *Response to Comments* document).

Many commenters expressed support for the EPA's derivation of HRLs and HBWCs and use of best available peer-reviewed science, whereas others were critical of the agency's selection of toxicity reference values, body weight-adjusted drinking water intake rates (DWI-BWs), and/or relative source contributions (RSCs) (please see section 4.3.3 of the EPA response in this *Response to Comments* document). Some commenters supported the EPA's use of the final ATSDR minimal risk levels for PFHxS and PFNA as chronic toxicity reference values as best available, peer-reviewed science; other commenters criticized the EPA for using ATSDR minimal risk levels and asserted that these values are inappropriate for SDWA rulemaking (please see section 4.3.3 of the EPA response in this *Response to Comments* document).

Some commenters asserted that the human health toxicity reference values upon which the HRLs/HBWCs are based have too much uncertainty and are therefore inadequate to support a SDWA regulatory determination (please see section 4.3.3 of the EPA response in this *Response to Comments* document).

Some commenters opposed the EPA's application of a 20 percent RSC in the HRL/HBWC calculations and others disagreed with the DWI-BWs that the EPA used to calculate the HRLs/HBWCs.

Some commenters had questions or comments about the process for adding additional PFAS to the Hazard Index (please see section 4.3.5 of the EPA response in this *Response to Comments* document). Many commenters urged the EPA to consider making a determination to regulate for additional PFAS (in a mixture) or all PFAS as a class. A few commenters expressed concern that the EPA would add PFAS to the Hazard Index without undergoing regulatory determination and/or rulemaking process (please see section 4.3.5 of the EPA response in this *Response to Comments* document).

The EPA's responses to these issues as well as others expressed by individual commenters are described in further detail below.

4.3.1 Dose Additivity

Summary of Major Public Comments and EPA Responses

Many commenters supported the EPA's scientific conclusions about PFAS dose additivity and agreed that considering dose-additive effects is a health-protective approach. Many other commenters disagreed with the EPA's scientific conclusions regarding PFAS dose additivity and a few commenters questioned the agency's external peer-review process and whether the agency

sufficiently responded to SAB comments. For example, these commenters stated that the evidence base of PFAS mixture studies is too limited to support dose additivity for these four PFAS and recommended that the EPA re-evaluate its conclusion about dose additivity as new data become available. A few commenters stated that the EPA failed to adequately follow the SAB recommendation that "discussion of studies of toxicological interactions in PFAS mixtures in the EPA mixtures document be expanded to also include studies that do not indicate dose additivity and/or a common MOA [mode of action] for PFAS." A few commenters opposed the EPA's use of shared or similar health endpoints/outcomes rather than a shared MOA as a basis for assessing risks of PFAS mixtures. Some commenters questioned whether the EPA's approach to dose additivity for these four PFAS was consistent with agency guidance and practice. The EPA response to these issues, as well as others expressed by individual commenters, are described in further detail below.

PFAS dose additivity is well supported. Based on the administrative record for the final PFAS National Primary Drinking Water Regulation (NPDWR), there is substantial evidence that exposure to PFHxS, PFNA, HFPO-DA, and PFBS individually elicits similar health effects (but with differing potencies for effect(s)); that these four PFAS act in a dose additive manner when present in mixtures; and that exposure to mixtures of these PFAS may cause adverse health effects. Dose additivity means that when two or more chemicals (in this case, PFHxS, PFNA, HFPO-DA, and/or PFBS) exist in one mixture, the risk of adverse health effects following exposure to the mixture is equal to the sum of the individual doses or concentrations scaled for potency (USEPA, 2000b). Studies with PFAS and other classes of chemicals support the health-protective conclusion that toxicologically similar chemicals (i.e., those that elicit similar observed adverse effects following individual exposure, even if at different exposure levels) should be assumed to act in a dose-additive manner when present in a mixture unless data demonstrate otherwise. Experimental data demonstrate that PFAS elicit similar adverse health effects on several of the same biological systems and functions including thyroid hormone signaling, lipid synthesis and metabolism, development, and immune and liver function (USEPA, 2024c; see additional discussion below on "toxicological similarity"). Thus, exposure to these PFAS, at doses that individually would not likely result in adverse health effects, when combined in a mixture may pose health risks.

Numerous published studies across multiple chemical classes, biological effects, and study designs support a dose-additive mixture assessment approach for PFAS because they demonstrate that experimentally observed responses to exposure to PFAS mixtures and other chemical mixtures are consistent with modeled predictions of dose additivity (see the EPA's *Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances* (PFAS) (hereafter "PFAS Mixtures Framework;" USEPA, 2024c)). Since the EPA's draft PFAS Mixtures Framework underwent SAB review in 2021–2022, new studies from the EPA and others have provided robust evidence of combined toxicity of PFAS in mixtures, corroborating and confirming earlier findings (e.g., Conley et al., 2022b; 2023; see USEPA (2024c) for additional examples). Additionally, the National Academies of Sciences, Engineering, and Medicine (NASEM, 2022) recently recommended that clinicians apply an

additive approach for evaluating patient levels of PFAS currently measured in the National Health and Nutrition Examination Survey (NHANES) in order to protect human health from additive effects from PFAS co-exposure.

Data from *in vivo* studies that rigorously tested accuracy of dose additivity, Integrated Addition (IA), and Response Additivity (RA) model predictions of mixtures with components that disrupted the same pathways (i.e., were toxicologically similar) demonstrated that dose additivity models provided predictions that were better than or equal to IA and RA predictions of the observed mixture effects (Section 3.2 in USEPA (2024c)). In some circumstances the different additivity models provide highly similar predictions of mixture effects and thus are essentially equally effective. In situations where the models provide very different predictions, experimental data has demonstrated that dose additivity-based models consistently provide more accurate predictions of observed mixture effects than RA or IA. This strongly supports the use of dose additivity as the default method for estimating mixture effects of compounds that are toxicologically similar. The National Academy of Sciences (NAS) conclusions on phthalates (and related chemicals) (NRC, 2008) and systematic reviews of the published literature (Boobis et al., 2011 and Martin et al., 2021; see also Section 3.2 in USEPA (2024c)) support dose additivity as the default model for estimating mixture effects in some circumstances, even when the mixtures included chemicals with diverse MOAs (but the same target organs/effects).

Systematic reviews of mixture studies with chemical classes other than PFAS also indicate that departures from dose additivity are uncommon and rarely exceed minor deviations (~2-fold) from predictions based on dose additivity (Boobis et al., 2011; Martin et al., 2021). Boobis et al. (2011) examined literature from 1990 to 2008 that discussed synergy in mammalian test systems, with an emphasis on "low dose" studies. They found that of the 11 available studies with synergy data that reported the magnitude of the difference between the dose-additive estimates of toxicity and observed toxicity, six studies reported magnitudes of synergy that were generally small, and the authors concluded that deviations from dose additivity at low doses were not common. Additionally, Martin et al. (2021) reviewed more than 1,200 mixture studies and concluded that there was little evidence for synergy (greater than additive effects) or antagonism (less than additive effects) among chemicals in mixtures, and that dose additivity should be considered as the default model. This supports the health-protective conclusion that mixtures of PFHxS, PFNA, HFPO-DA, and/or PFBS should be assumed to act in a dose-additive manner unless data demonstrate otherwise.

Although some available *in vitro* studies do not provide conclusive evidence of dose additivity for PFAS mixtures, their results also do not justify drawing a conclusion other than dose additivity. For example, a study on PFAS cytotoxicity in a human liver cell line (Ojo et al., 2020) reported synergistic (greater than additive) effects (i.e., the combined effect(s) of the mixture components is greater than the sum of their individual effects) of mixtures of perfluoroalkyl acids (PFAAs; a type of PFAS) compared to a dose addition model, but also reported evidence of less than additive (antagonistic) effects. Other *in vitro* studies that have assessed PFAS mixture-based effects do not report these results; that is, they do not offer strong evidence for synergistic

or antagonistic effects, particularly at environmentally relevant concentrations. For example, Wolf et al. (2014) evaluated *in vitro* PPARα activation and reported that effects seen following exposure to combinations of different PFAS were consistent with dose additivity in the lower tested concentration ranges. Wolf et al. (2014) also reported slightly greater than additive effects at higher test concentrations (approximately 500 parts per billion to over 800 parts per million); however, in environmental media such as drinking water, PFAS are not likely to occur at these higher concentrations (e.g., see USEPA, 2024j). Carr et al. (2013) reported slightly less than additive effects for *in vitro* PPARα activation of binary mixtures of PFAAs including PFOA, PFNA, PFOS, and PFHxS. Addicks et al. (2023) evaluated mRNA transcription in primary human liver spheroids exposed to seven different PFAS mixtures and found that all tested mixtures produced effects that were consistent with effects predicted using dose addition. To summarize, the available *in vitro* data do not support a conclusion other than dose additivity for PFAS mixtures.

Available *in vivo* data on this subject similarly support dose additivity. Two studies with PFAS mixtures in zebrafish reported no indications of synergy (Ding et al., 2013; Menger et al., 2020). Additionally, recent EPA Office of Research and Development (ORD) studies provide robust evidence that PFAS behave in a dose-additive manner (Conley et al., 2022b; 2023; Gray et al., 2024). For example, results of a developmental toxicity study of exposure to PFOA and PFOS mixtures in rats showed that the observed results for almost all tested endpoints were consistent with dose additivity (Conley et al., 2022b). Likewise, a rat developmental study of a PFAS mixture of PFOS, HFPO-DA, and Nafion byproduct 2 (an emerging polyfluoroethersulfonic acid compound recently detected in human serum (Kotlarz et al., 2020)) found that multiple tested endpoints in both parental females and offspring conformed to dose additivity and no endpoints demonstrated synergy (Conley et al., 2023).

Additionally, as described in the final PFAS Mixtures Framework (USEPA, 2024i), over the past two decades, many *in vivo* experimental animal studies have been published in which toxicity of chemical mixtures has been systematically evaluated (e.g., Altenburger et al., 2000; Conley et al., 2022b, 2023; Crofton et al., 2005; Gennings et al., 2004; Hass et al., 2017; Howdeshell et al., 2015; Kortenkamp and Haas, 2009; Martin et al., 2021; Moser et al., 2005, 2012; Rider et al., 2008; 2009; 2010; Walker et al., 2005). These studies span different chemical classes, proposed MOAs, and health outcomes, but they generally show that chemicals in mixtures typically act dose additively. Even when mixture components with different MOAs/adverse outcome pathways (AOPs) are combined, they induce toxic effects consistent with dose additivity (e.g., Rider et al., 2009). This concept was further articulated in the National Research Council's 2008 report *Phthalates and cumulative risk assessment: The tasks ahead* (NRC, 2008), wherein that expert panel provided significant evidence that mixture components that elicit similar adverse health effects individually will demonstrate dose additivity when combined in a mixture, regardless of similarity in MOA.

This evidence base supports the longstanding recommendation in EPA chemical mixtures guidance for dose additivity as a default approach for evaluation of mixture toxicity (USEPA,

1986; USEPA, 2000b). This position is further supported and articulated in the newly published EPA Risk Assessment Forum's *Advances in Dose Addition for Chemical Mixtures: A White Paper* (USEPA, 2023j). (See additional discussion below on "toxicological similarity").

Comments from the SAB on dose additivity of PFAS mixtures. Importantly, the EPA's conclusions regarding dose additivity of PFAS were supported by the SAB during its 2021–2022 review of the EPA's draft *Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances*. The EPA directly asked the SAB for feedback on PFAS dose additivity as part of the SAB's review of technical materials supporting development of the PFAS MCLG and NPDWR. Specifically, the EPA asked the SAB to, "[p]lease comment on the appropriateness of this approach for a component-based mixture evaluation of PFAS under an assumption of dose additivity" (USEPA, 2022b). The SAB strongly supported the scientific soundness of this approach when evaluating PFAS and concurred that it was a health-protective conclusion. For example, the SAB said:

> "The SAB supports dose additivity based on a common outcome, instead of a common mode of action as a health protective default assumption and does not propose another default approach." (USEPA, 2022b)
>
> "…The information included in the draft framework supports the conclusion that toxicological interactions of chemical mixtures are frequently additive or close to additive. It also supports the conclusion that dose additivity is a public health protective assumption that typically does not underestimate the toxicity of a mixture..." (USEPA, 2022b)
>
> "The SAB Panel agrees with use of the default assumption of dose additivity when evaluating PFAS mixtures that have similar effects and concludes that this assumption is health protective." (USEPA, 2022b)
>
> "…dose additivity can provide an estimate of composite effects." (USEPA, 2022b)

While the SAB also noted that there remain some questions about PFAS interaction in mixtures (USEPA, 2022b), the available data justify an approach that accounts for PFAS dose additivity. As described above, studies that have assessed PFAS mixture-based effects do not provide support for a conclusion other than dose additivity (i.e., they do not offer strong evidence for synergistic/antagonistic effects) (USEPA, 2024i).

The four PFAS included in the Hazard Index MCLG are "toxicologically similar" because they elicit the same or similar adverse health effects. The EPA's approach is to evaluate risks from exposure to mixtures of PFAS based on similar adverse health effects (but with differing potencies for effect(s)) of the individual PFAS mixture components, rather than similar MOA. MOA describes key changes in cellular or molecular events that may cause functional or structural changes that lead to adverse health effects and can be a useful metric by which risk can be assessed. It is considered a key determinant of chemical toxicity, and chemicals can often be classified by their type of toxicity pathway(s) or MOA(s). PFAS are an emerging chemical class,

and MOA data are limited or entirely lacking for many PFAS. Although similarities among some PFAS have been shown at the level of molecular and cellular perturbations, no conserved MOAs have been identified across PFAS for noncancer health effects assessed thus far. Therefore, the EPA's approach for assessing risks of PFAS mixtures is based on the conclusion that PFAS that are "toxicologically similar"—that is, elicit the same or similar adverse health effects (but might have differing potencies for effect(s))—will produce dose-additive effects from co-exposures (see USEPA, 2024i).

Some commenters stated that the EPA did not provide sufficient evidence that the four PFAS included in the Hazard Index share key events or adverse outcomes. The EPA disagrees. Available epidemiological and animal toxicological data demonstrate that exposure to each of these four PFAS (PFHxS, PFNA, HFPO-DA, and PFBS) is associated with many of the same or similar adverse health endpoints and outcomes, and thus they are "toxicologically similar" (see Tables 1, 2, and 3 below). Further, these four PFAS are well-studied PFAS for which the EPA or ATSDR has developed human health assessments and toxicity reference values (i.e., RfDs, minimal risk levels). Available animal toxicological and/or epidemiological studies demonstrate that PFHxS, PFNA, HFPO-DA, and PFBS are documented to affect at least five (5) of the same major health outcomes: lipids, developmental, immune, endocrine, and hematologic (Table 1). Similarly, according to the 2023 Interagency PFAS Report to Congress (United States OSTP, 2023), available animal toxicological data show that PFHxS, PFNA, HFPO-DA, and PFBS significantly affect at least eight (8) of the same major health effect domains: body weight, respiratory, hepatic, renal, endocrine, immunological, reproductive, and developmental (Table 2). Furthermore, numerous *in vivo* and *in vitro* studies demonstrate that these four PFAS share many of the same health effects across diverse health outcome categories (e.g., developmental, immunological, and endocrine), and that they induce some of the same effects at the molecular level along biological pathways (USEPA, 2024h). Table 3 below shows specific endpoints shared across these four PFAS, including toxicologically relevant molecular perturbations (*in vitro*), and health effects (*in vivo*) from oral repeated-dose studies in rats and/or mice (note that this table is a summary of select studies for illustrative purposes and should not be construed to represent a systematic review or MOA analysis). Some commenters asserted that PPARα activation is not relevant to humans, but the EPA disagrees because although rodents do appear to be relatively more sensitive to peroxisome proliferators compared to humans, a large body of evidence supports the plausibility of PPAR-dependent MOAs in organ toxicity(ies) across species (for review, see Lai et al. (2004)). Further, in a mouse strain that expressed humanized PPARα, PFOA exposure resulted in dysregulation of genes controlling lipid homeostasis, increased liver mass, histopathological evidence of steatosis, and increased serum cholesterol levels in males and females (Schlezinger et al., 2020). Lastly, there are other shared molecular/cellular perturbations (e.g., CAR activation) across the four PFAS in addition to PPARα, and multiple shared adverse health effects (Table 3). In summary, there is substantial evidence that PFHxS, PFNA, HFPO-DA, and PFBS elicit many of the same or similar toxicological effects and thus are "toxicologically similar."

Table 1. Affected health outcomes in animal toxicological and/or epidemiological studies for the four PFAS included in the Hazard Index MCLG (adapted from Table 6-7 in USEPA, 2024e).				
Health Outcome	**HFPO-DA**	**PFNA**	**PFHxS**	**PFBS**
Lipids	X	X	X	X
Developmental	X	X	X	X
Hepatic	X	X	X	-
Immune	X	X	X	X
Endocrine	X	X	X	X
Renal	X	-	-	X
Hematologic	X	X	X	X

Notes: (X) Health outcome examined, evidence of association; (-) health outcome examined, no evidence of association.

Table 2. Affected health endpoints based on animal toxicological data for the four PFAS included in the Hazard Index MCLG (adapted from Table 4 in United States Office of Science and Technology Policy [OSTP, 2023).				
Health Endpoint	**HFPO-DA**	**PFNA**	**PFHxS**	**PFBS**
Body weight	X	X	X	X
Respiratory	X	X	X	X
Cardiovascular			X	X
Gastrointestinal		X	X	X
Hematological	X		X	X
Musculoskeletal			X	X
Hepatic	X	X	X	X
Renal	X	X	X	X
Dermal	X			
Ocular	X			X
Endocrine	X	X	X	X
Immunological	X	X	X	X
Neurological	X		X	X
Reproductive	X	X	X	X
Developmental	X	X	X	X
Other noncancer	X	X		

Notes: (X) Health outcome examined, evidence of association.

Table 3. Specific Endpoints Affected by One or More of the Four PFAS Included in the Hazard Index MCLG.				
Endpoint	**HFPO-DA**	**PFNA**	**PFHxS**	**PFBS**
Molecular/Cellular Perturbations				
PPAR alpha binding/activation	X (Evans et al., 2022; Nielsen et al., 2021)	X (Evans et al., 2022; Nielsen et al., 2021; Rosenmai et al., 2018;	X (Evans et al., 2022; Nielsen et al., 2021; Rosenmai et al., 2018;	X (Evans et al., 2022; Rosenmai et al., 2018; Wolf et al., 2012)

Table 3. Specific Endpoints Affected by One or More of the Four PFAS Included in the Hazard Index MCLG.				
Endpoint	**HFPO-DA**	**PFNA**	**PFHxS**	**PFBS**
Molecular/Cellular Perturbations				
		Wolf et al., 2012)	Wolf et al., 2012)	
PPAR gamma binding/activation	X (Evans et al., 2022; Houck et al., 2021)	X (Evans et al., 2022; Houck et al., 2021)	X (Evans et al., 2022; Houck et al., 2021)	X (Evans et al., 2022)
Liver gene induction (PPAR signaling pathway)	X (Conley et al., 2019; Blake et al., 2022)	X (NTP, 2019c; Rosen et al., 2017, 2013)	X (NTP, 2019b; Rosen et al., 2017, 2013; Chang et al., 2018)	X (NTP, 2019b; Rosen et al., 2013)
Liver gene induction (CAR signaling pathway)	-	X (NTP, 2019c)	X (NTP, 2019b)	X (NTP, 2019b)
Serum bile salts/acids (increased)	X (DuPont, 2010c)	X (NTP, 2019c)	-	X (NTP, 2019b)
Serum globulin (reduced)	X (DuPont, 2009, 2008a, 2008b)	X (NTP, 2019c)	X (NTP, 2019b)	X (NTP, 2019b)
Serum albumin:globulin (increased)	X (DuPont, 2009, 2008a, 2008b)	X (NTP, 2019c)	X ((NTP, 2019b; Butenhoff et al., 2009)	X (NTP, 2019b)
Health Effects				
Serum lipids (reduced cholesterol and/or triglycerides)	X (DuPont, 2009, 2008a, 2008b)	X (NTP, 2019c)	X (NTP, 2019b; Chang et al., 2018; Butenhoff et al., 2009)	X (NTP, 2019b)
Serum liver enzymes (increased ALT, AST, and/or Alkaline Phosphatase [ALKP])	X (DuPont, 2008b, 2010)	X (NTP, 2019c)	-	X (NTP, 2019b)
Serum thyroid hormones (reduced T4, T3)	X (Conley et al., 2019)	X (NTP, 2019c)	X (NTP, 2019b; Gilbert et al., 2021)	X (NTP, 2019b)

Table 3. Specific Endpoints Affected by One or More of the Four PFAS Included in the Hazard Index MCLG.				
Endpoint	**HFPO-DA**	**PFNA**	**PFHxS**	**PFBS**
Molecular/Cellular Perturbations				
Liver weight (increased)	X (DuPont, 2008a, 2008b, 2009; Blake et al., 2020; Conley et al., 2021, 2019; Rushing et al., 2017)	X (NTP, 2019c; Das et al., 2015)	X (NTP, 2019b; Chang et al., 2018)	X (NTP, 2019b; Lieder et al., 2009)
Liver histopathology (nonneoplastic effects)	X (DuPont, 200a, 2008b, 2010; NTP, 2019a)	X (NTP, 2019c)	X (NTP, 2019b; Chang et al., 2018)	X (NTP, 2019b)
Thymus weight (reduced)	X (DuPont, 2009)	X (NTP, 2019c)	-	X (NTP, 2019b)
Spleen weight (reduced)	-	X (NTP, 2019c)	-	X (NTP, 2019b; Lieder et al., 2009)
Kidney weight (increased)	X (DuPont, 2009, 2008a)	X (NTP, 2019c)	X (NTP, 2019b)	X (NTP, 2019b)
Reduced fetal/pup bodyweight	X (Conley et al., 2021; DuPont, 2010a, 2010b)	X (Das et al., 2015)	-	X (Feng et al., 2017)
Reduced fetal/pup survival	X (Conley et al., 2010)	X (Das et al., 2015)	X (Chang et al., 2018)	-
Reduced adult bodyweight	X (DuPont, 2013)	X (NTP, 2019c)	-	X (NTP, 2019b; Lieder et al., 2009)
Overt toxicity (lethality)	X (DuPont, 2009)	X (NTP, 2019c)	-	X (NTP, 2019b)
(-) indicates no statistically significant effect reported by study authors of cited studies at dose levels and dose interval used and/or effect not measured in cited studies.				

Background on concept of "toxicological similarity." This concept and application of dose additivity for "toxicologically similar components" in mixtures assessment is consistent with EPA mixtures guidance (USEPA, 1986; USEPA, 2000b) and the EPA Risk Assessment Forum's *Advances in Dose Addition for Chemical Mixtures: A White Paper* (USEPA, 2023j). Specifically, the EPA's *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (USEPA, 2000b) notes that although the shared MOA metric for application of dose addition is optimal, MOA data are not always available and that toxicological similarity in the context of mixtures risk assessment can be based on adverse effects observed at the organ or system level (USEPA, 2000b). This concept is further described in the EPA Risk Assessment Forum's *Advances in Dose Addition for Chemical Mixtures: A White Paper* (USEPA, 2023j): "The primary criterion for choosing between dose addition and response addition methods is toxicological similarity among the chemicals in the mixture [(USEPA, 2000b)]. "Toxicological similarity" is used here as an overarching concept with a wide range of specificity across levels of biological organization, allowing similarity judgments to be tailored to both the specific goals of the mixture risk assessment and the availability of hazard and dose-response information across components." Unless there are available data that suggest deviation(s) from dose additivity, mixture chemicals that are "toxicologically similar" (e.g., same/similar effect or profile of effect[s], regardless of differences in potencies) prototypically behave dose additively. This concept is depicted in Figure 1 below, which shows that dose additivity is the logical default approach for "toxicologically similar" components and that component-based mixture assessment approaches including Hazard Index (HI), relative potency factor (RPF), and mixture-benchmark dose (Mixture-BMD) are options for mixture assessment in such cases. (Please see section 4.3.2 of this *Response to Comments* document for a summary of comments and responses related to the EPA's use of the general Hazard Index approach to derive an MCLG for mixtures of two or more of PFHxS, PFNA, HFPO-DA, and PFBS).

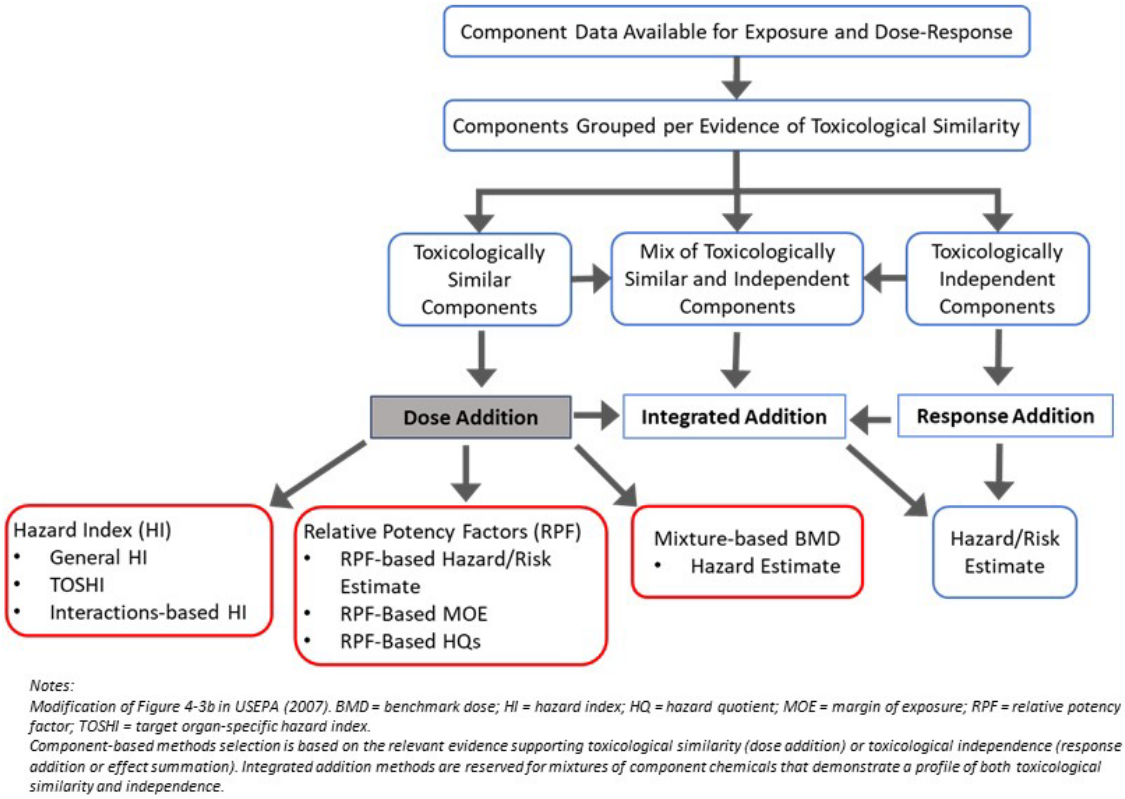


Figure 1. Flow chart for evaluating chemical mixtures using component-based additive methods. (Reproduction of Figure 2-1 from USEPA (2024i)).

Comments from the SAB on basing the concept of toxicological similarity for these PFAS on same/similar adverse effects in the absence of adequate MOA information. The SAB strongly supported the EPA's decision to focus on similarity of adverse health effects rather than similarity of MOA to assess risks of exposure to PFAS mixtures during its 2021–2022 review of the EPA's draft PFAS Mixtures Framework. Specifically, the EPA asked the SAB, "If common toxicity endpoint/health effect is not considered an optimal similarity domain for those PFAS with limited or no available MOA-type data, please provide specific alternative methodologies for integrating such chemicals into a component-based mixture evaluation(s)" (USEPA, 2022b). The SAB strongly supported the EPA's approach of using a similar toxicity endpoint/health effect instead of a common MOA as a default approach for evaluating mixtures of PFAS using dose additivity and did not recommend an alternative methodology. The SAB panel stated that: "The Panel agreed with use of a similar toxicity endpoint/health effect instead of a common MOA as a default approach for evaluating mixtures of PFAS. This approach makes sense because multiple physiological systems and multiple MOAs can contribute to a common health outcome. Human function is based on an integrated system of systems and not on single molecular changes as the sole drivers of any health outcome. The Panel concluded that rather than the common MOA, as presented in the EPA draft mixtures document, common physiological outcomes should be the

defining position" (USEPA, 2022b)."Furthermore, many PFAS, including the four used in the examples in the draft EPA mixtures document and others, elicit effects on multiple biological pathways that have common adverse outcomes in several biological systems (e.g., hepatic, thyroid, lipid synthesis and metabolism, developmental and immune toxicities)" (USEPA, 2022b).

Summary. The available scientific evidence supports the conclusion that PFAS that elicit similar adverse health effects following individual exposure (even if with differing potencies for effect(s)) should be assumed to act in a dose-additive manner when in a mixture unless data demonstrate otherwise. This means that individual PFAS, each at doses that are not anticipated to result in adverse health effects, when combined in a mixture may result in adverse health effects. (For a more complete discussion of the evidence supporting dose additivity as the default approach for assessing mixtures of PFAS, please see the final PFAS Mixtures Framework (USEPA, 2024i)). The EPA's conclusions regarding PFAS dose additivity were supported by the SAB during its review of the EPA's draft PFAS Mixtures Framework (USEPA, 2022b) and are consistent with longstanding agency chemical mixtures guidance (USEPA, 1986; 2000b) and a recent EPA white paper (USEPA, 2023j). The SAB also strongly supported the EPA's default assumption of dose additivity in the absence of other information and the EPA's approach of using similar toxicity endpoints/health effects instead of a common MOA for evaluating mixtures of PFAS (USEPA, 2022b). This approach of basing the concept of toxicological similarity on same/similar adverse effects in the absence of adequate MOA information is also consistent with the EPA's guidance (USEPA, 1986; 2000b) and a recent EPA white paper (USEPA, 2023j). The SAB also strongly supported the EPA's default assumption of dose additivity in the absence of other information and the EPA's approach of using similar toxicity endpoints/health effects instead of a common MOA for evaluating mixtures of PFAS (USEPA, 2022b). This approach of basing the concept of toxicological similarity on same/similar adverse effects in the absence of adequate MOA information is also consistent with the EPA's guidance (USEPA, 1986; 2000b) and the white paper (USEPA, 2023j). The EPA will consider new data and information that may become available on dose additivity and PFAS mixtures in the future.

Individual Public Comments and EPA Responses

Texas Commission on Environmental Quality (TCEQ) (Doc. #1632, SBC-044122)

Texas Commission on Environmental Quality (TCEQ) Comments on the United States Environmental Protection Agency's (EPA) Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

Docket ID Number EPA-HQ-OW-2022-0114

TCEQ provides the following comments on the proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation (NPDWR).

Hazard Index (HI)

The HI approach proposed for PFAS appears oversimplistic in assessing the potential for adverse health effects from four different PFAS with reference doses based on different critical effects and target organs of toxicity. An HI approach to evaluating risks from multiple chemicals involves considering the risk from each of the chemicals individually to derive a hazard quotient (HQ) for each, which is the concentration measured in drinking water/health-based water concentration, and then adding the HQs together to generate an HI for the chemical group. For this to be an appropriate method for determining risk from multiple chemicals, the dose of each chemical has to have an additive effect on a biological pathway, which is a mode of action (MOA), that contributes to effects in the same target organs. If the chemicals affect different biological pathways, then they will not have additive effects when a person is exposed to more than one of the chemicals at the same time.

The critical effect (i.e., the effect that occurs at the lowest exposure concentration) for the four PFAS are:

• Perfluorohexane sulfonic acid (PFHxS): Thyroid follicular epithelial hypertrophy/ hyperplasia in parental male rats;

• Hexafluoropropylene oxide dimer acid (HFPO-DA, GenX): Liver effects in female mice;

• Perfluorobutane sulfonic acid (PFBS): Decreased serum total thyroxine in newborn mice; and

• Perfluorononanoic acid (PFNA): Decreased body weight gain and delayed eye opening, preputial separation, and vaginal opening in mouse offspring.

These are different target organs and likely involve different MOAs. EPA appears to be proposing an HI approach for these PFAS simply because it is a conservative screening approach for potential health risk rather than an approach that has been established as a scientifically defensible one for predicting effects from combined exposure to these PFAS based on a common MOA for target organ effects. EPA states,

"Consistent with advice from the [Science Advisory Board] SAB, EPA considers it an appropriately health protective approach to assume dose additivity for PFAS co-occurring in mixtures as they share similar profiles of health effect domains (e.g., liver, thyroid, developmental, etc.). . . . To protect against the potential for dose additive health impacts from likely multi-chemical exposures of PFHxS, HFPO-DA, PFNA, and PFBS when they occur as mixtures in drinking water, the Agency is proposing to use the HI approach." [FN1: 88 Fed. Reg. 18638, 18668 (Mar. 29, 2023) (emphasis added).]

Thus, since these PFAS have several effects in common, dose additivity is simply being assumed because it is conservative, instead of EPA providing a scientifically defensible assessment that is based on the same shared MOA for a given target organ for the four PFAS. Although EPA states that dose additivity is the default assumption when considering effects seen with mixtures, [FN2: See, EPA, "PUBLIC REVIEW DRAFT: Framework for Estimating Noncancer Health Risks Associated with Mixture of Per- and Polyfluoroalkyl Substances (PFAS)," at 22, EPA Document

No. EPA-822-P-23-003 (Mar. 2023).] the following EPA statement confirms relaxation of this scientific standard,

"[T]he HI is used here as a decision aid, and determination of dose additivity among chemicals is relaxed from the level of common MOA to common target organ(s)/health outcome(s)." [FN3: 88 Fed. Reg. 18638, 18668 (Mar. 29, 2023) (emphasis added)]

EPA has stated that it proposes using the HI method because of concern regarding the potential dose additivity of the four PFAS,

"[W]hile EPA recognized that regulating these PFAS with individual [maximum contaminant levels] MCLs and [maximum contaminant level goals] MCLGs might be simpler to implement for some states or operators, if EPA were to regulate these PFAS individually and not under the HI MCL approach, it would not provide equivalent protection against potential dose additive impacts for these PFAS, nor would it establish a framework to consider potential dose additive impacts for future PFAS components or groups as EPA develops a better understanding of the adverse health effects of other PFAS." [FN4: 88 Fed. Reg. 18638, 18671 (Mar. 29, 2023).]

However, EPA should only evaluate dose additive effects when it has been scientifically demonstrated to be appropriate (e.g., common MOAs for target organ effects), and should not establish an HI framework just for the sake of having one, without scientific demonstration that it is appropriate. Such a framework can be established when EPA has demonstrated that a group of PFAS causes target organ effects through a common MOA; it would be scientifically inappropriate to establish an HI framework prior to that point in time and apply it to a group of PFAS for which this demonstration has not been made.

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-044837)

The Proposed Hazard Index is not Based on Health Effects in a Common Organ, Much Less Those Resulting from a Common Mode of Action

As described in the previous section, the HBWCs for the four PFAS included in the Agency's proposed HI MCL are derived from animal data reporting disparate health effects and target organs. While the HBWC for HFPO-DA is based on liver effects in adult mice, the value for PFHxS is derived from thyroid effects in adult rats. Although both the PFNA and PFBS are derived from effects in offspring of exposed mice, the endpoint for PFNA is body weight while that for PFBS is thyroid hormone levels. Although application of an HI is a common approach to assessing exposure to mixtures applied in the context of CERCLA remedial investigations and risk assessments, it assumes that there is a common response to exposure to the individual substances in the mixture such that the responses can be added together. EPA has not established that there is common response to exposure to the four PFAS. in fact, there is compelling scientific evidence instead against any common mode of action among these four chemicals.

In describing its conclusion that dose addition can be applied to evaluating mixtures of these four PFAS, EPA indicates that "it is considered a reasonable health-protective assumption that PFAS which can be demonstrated to share one or more KEs or adverse outcomes will produce dose-additive effects from co-exposure." [FN142: USEPA. Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS). Public Review Draft. EPA-822-P-23-003. Office of Water/Office of Research and Development (2023). (USEPA PFAS Mixtures Framework)] However, the Agency has not provided evidence to suggest that the four PFAS included in its HI approach share KEs or adverse outcomes. As described above, and as noted by the Agency, moreover, the most commonly reported molecular initiating event (MIE) reported in laboratory studies - activation of PPARα - is a rodent-specific response of limited relevance to humans. [FN143: Hall et al. 2012.] Another common response in rodents – reduction in circulating thyroid hormone concentrations – is not viewed by NAS as an adverse effect due to quantitative differences between rodents and humans. [FN144: NRC 2015.] Despite reaching the conclusion, that "there is potential for disparate MIEs in PFAS related adverse outcome pathways (AOPs) and there is a lack of mechanistic characterization for most PFAS-mediated effects," [FN145: USEPA PFAS Mixtures Framework, at 32.] EPA still maintains that dose addition is a reasonable assumption.

This conclusion contrasts sharply with EPA guidance for identifying evidence of toxicologic similarity in analyzing mixtures. In its 2000 mixtures guidance, the Agency identifies the following types of evidence for assessing toxicologic similarity (in order of most to least informative) -

• Identical or similar toxicodynamics,

• Shared syndrome,

• Shared apical outcome,

• Effect on the same target organ,

• Structural similarity, and

• Similarly shaped dose response curves in comparable toxicity studies. [FN146: USEPA. Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures. EPA/630/R- 00/002. Risk Assessment Forum (2000). (USEPA Supplementary Mixtures Guidance)]

Aside from limited structural similarity, EPA's MCL proposal fails to offer substantive evidence from this hierarchical list to support a conclusion of toxicologic similarity. There are currently less than a dozen published whole mixture or binary component toxicity studies with PFAS. [FN147: Goodrum PE et al. Application of a framework for grouping and mixtures toxicity assessment of PFAS: a closer examination of dose-additivity approaches. Toxicol Sci 179(2):262-278 (2021).] These studies suggest that dose-additivity assumptions for PFAS are not yet supported by the available whole mixture toxicity data.

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-052931)

The PFAS Mixtures Framework places considerable weight on the results of the 28-day studies of perfluoroalkyl carboxylates and sulfonates conducted by NTP. [FN148: NTP TR-096; NTP Technical Report on the Toxicity Studies of Perfluoroalkyl Carboxylates (Perfluorohexanoic Acid, Perfluorooctanoic acid, Perfluorononanoic Acid, and Perfluorodecanoic Acid) Administered by Gavage to Sprague Dawley (HSD:Sprague Dawley SD) Rats. Toxicity Report 97 (2019). (NTP TR-097)] In particular, the Agency notes the "rigorous exposure characterization and multiple endpoints spanning MIEs, KEs, and AOPs." [FN149: USEPA PFAS Mixtures Framework, at 31.] Yet, neither EPA nor NTP identify the events or pathways common to the four PFAS that support toxicologic similarity or the proposed HI approach.

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

Dylan Pilger (Doc. #1546, SBC-042676)

The EPA must consider possible synergistic effects of PFAS and adjust monitoring guidelines accordingly.

My first recommendation is that the EPA consider possible synergistic effects of PFAS and adjust guidelines accordingly. Current estimates in the proposed rule use an additive model. However, a review article published in 2021 found that animal and cell culture studies suggested that certain PFAS mixtures (including PFOS, PFOA, PFNA, PFDA, PFHxS, and PFHxA), may interact synergistically (Ojo et al., 2021). For example, Ojo et al. found that, PFOS has been found to have a synergistic inhibitory effect (cytotoxicity) with PFNA, PFHxS, and PFHpA in HepG2 human liver cells (Ojo et al., 2020). Therefore, an additive model for water monitoring may be insufficient for determining the safety of consuming water contaminated with different PFAS. PFBA, PFBS, PFHpA, PFHxA, PFHxS, PFOA, PFOS, PFPeA, and PFPeS have all been discovered in well water in the Kunia region of Oʻahu, the most populated island in Hawaiʻi (Hawaii DOH, n.d.-c). The Hawaiʻi State Department of Health has also detected PFHpS and 6:2 FTS in addition to the 9 PFAS just listed in another well in Kunia (Hawaii DOH, n.d.-b). These and other PFAS have been detected in areas across Oʻahu (Hawaii DOH, n.d.-a). This has generated great concern among people in my community, myself included, and it is crucial that the agency get this right.

EPA Response: Please see section 4.3.1 of the EPA response in this *Response to Comments* document.

Oklahoma Department of Environmental Quality (DEQ) (Doc. #1616, SBC-043039)

DEQ recommends that EPA reevaluate the default assumption of dose additivity as additional data become available.

EPA is proposing to use a Hazard Index (HI) approach with mixtures of PFHxS, HFPO-DA and its ammonium salt, PFNA, and PFBS. Dose-additivity is assumed for regulated co-occurring PFAS. The Science Advisory Board (SAB) agreed with the use of the dose additivity default assumption when evaluating PFAS mixtures that have similar effects. SAB recommended that EPA reevaluate the default assumption of dose additivity as additional data become available. DEQ recommends that EPA act in accordance with this recommendation from SAB.

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

Aidan Cecchetti (Doc. #1640, SBC-044361)

• EPA requests comment on the merits and drawbacks of the target-specific HI or RPF approach. EPA requests comment on the derivation of the HBWCs for each of the four PFAS considered as part of the HI (pg. 18664 Federal Register Volume 88, Number 60).

o The commenters note that the manner in which the HI approach described in EPA's proposed rule was developed does not conform with the recommendations of the SAB. The SAB specified the following: "The SAB PFAS Review Panel supports dose additivity based on a common outcome, instead of a common MOA as a health protective default assumption and does not propose another default approach." Although the commenters support the use of an HI approach for regulating mixtures of the four proposed PFAS based on common toxicological endpoints, EPA developed HBWCs for the four PFAS based on different adverse health outcomes. For example, HBWCs for PFHxS and PFBS were developed based on toxic effects on the thyroid, the HBWC for HFPO-DA was based on impacts to the liver, and the HBWC for PFNA was developed based on adverse developmental effects. The commenters do not believe that the approach of using data from different toxicological endpoints to produce a regulatory limit on mixtures conforms with the recommendations of the SAB regarding additive toxicity. EPA must provide additional substantiation for the use of toxicity data for different health outcomes or should produce a HI approach based on HBWCs developed from the same toxicological endpoints.

o Moreover, the commenters are particularly concerned about the possible error in the Federal Register indicating that PFHxS exposure data may have been used to develop the HBWC for PFNA (e.g., "The HBWC for PFNA is derived using a chronic reference value based on an ATSDR intermediate-duration oral Minimal Risk Level, which was based on developmental effects seen in mice after oral PFHxS exposure (ATSDR, 2021).") The commenters recommend that EPA clarify whether this is an erratum.

EPA Response: The EPA disagrees with the comment that HBWCs based on different endpoints is inconsistent with the SAB recommendations regarding dose additivity. For the EPA

response to this comment, please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

In response to the comment about a possible error in the Federal Register: there is a typographical error in the Federal Register Notice. The HBWC for PFNA was derived using data for PFNA, not PFHxS. The text quoted by the commenter should read, "The HBWC for PFNA is derived using a chronic reference value based on an ATSDR intermediate-duration oral Minimal Risk Level, which was based on developmental effects seen in mice after oral PFNA exposure (ATSDR, 2021)."

Aidan Cecchetti (Doc. #1640, SBC-044360)

Additionally, although there is a lack of data on the modes of action (MOAs) for the toxicity observed for many PFAS, the commenters agree with the Science Advisory Board opinion that "physiological outcomes should be the defining position" in determinations of additive toxicity, rather than MOAs. The SAB provides compelling evidence that dose additivity is a reasonable assumption for mixtures of chemicals with common toxicological endpoints but different MOAs. EPA has presented adequate substantiation that these contaminants produce adverse effects on common toxicological endpoints, which suggests that mixtures of those contaminants are likely to produce compounded effects on those endpoints and that basing the NPDWR on the assumption of additive toxicity should be health protective. Specifically, EPA has identified that the PFAS they are proposing to regulate using the HI approach produce adverse health effects on the liver (PFHxS, HFPO-DA, and PFNA), thyroid (PFHxS and PFBS), kidneys (HFPO-DA and PFBS), immune system (HFPO-DA and PFNA), reproductive systems (HFPO-DA and PFNA), and on development (all proposed HI PFAS).

EPA Response: This commenter supports the EPA's conclusion about dose additivity.

New York State Department of Health (NYS DOH) (Doc. #1677, SBC-044962)

25. Proposed Hazard Index Approach: The proposed rule would implement a framework for regulating a mixture of additional PFAS in drinking water through a hazard index approach rather than chemical-specific maximum contaminant levels (MCLs). However, the proposed approach is a departure from traditional risk assessment methods. The toxicity values for the four PFAS in the hazard index approach are based on disparate toxic endpoints (i.e., thyroid effects for PFBS and PFHxS, developmental effects for PFNA, and liver effects for GenX). This deviates from guidance on the use of hazard indices provided in the US EPA Risk Assessment Guidance for Superfund (US EPA 1989) and the US EPA Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures (US EPA 2000), which indicate that the premise of the hazard index is dose additivity where the component chemicals of the mixture have similar toxic effects on the same organ or biological system. The US EPA (1989) guidance further states that "application of the hazard index equation to a number of compounds that are not expected to induce the same type of effects or that do not act by the same mechanism could

overestimate the potential for effects..." A recent panel of independent experts deliberated on the most scientifically justified method of grouping PFAS for the purposes of human health risk assessment and regulatory actions and concluded that grouping PFAS together without data supporting common MOA and potency is inappropriate (Anderson et al., 2022). This panel of experts agreed that the HI dose additivity assumption for PFAS may be appropriate for screening (i.e., to determine if no risk or if further analysis is needed), but the data gaps currently present result in a high degree of uncertainty.

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

Three Rivers Waterkeeper (3RWK) (Doc. #1689, SBC-044975)

IV. Addressing the cumulative impact of PFAS is necessary to adequately address PFAS pollution.

Although 3RWK ultimately hopes that those living in the United States will one day no longer have to fear PFAS exposure at all, we support the EPA's decision to assume dose-additivity where PFHxS, HFPO-DA and GenX chemicals, PFNA, and PFBS (the PFAS addressed other than PFOS and PFOA) co-occur. Like PFOS and PFOA, these other PFAS compounds have a range of associated adverse health effects. This includes potentially affecting the growth and learning of children, interfering with the body's natural hormones, and increasing the risk of cancer. [FN17: Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) Frequently Asked Questions, Agency for Toxic Substances and Disease Registry Division of Community Health Investigations, Aug. 22, 2017, https://deq.nc.gov/media/9604/download.] They are often found together, and their health effects overlap.

EPA Response: This commenter supports the EPA's approach.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045018)

MCLGs for Mixtures of PFHxS, HFPO-DA, PFNA, and PFBS

EPA requested comments on the general Hazard Index (HI) approach for the mixture of four PFAS, and on the merits and drawbacks of the target organ specific HI or Relative Potency Factor (RFP) approach. NJDEP agrees that PFAS, including PFNA, PFHxS, PFBS, and HFPO-DA, cause similar toxicological effects and that it is reasonable to assume that dose additivity describes the toxicological interactions of these PFAS.

EPA Response: This commenter supports the EPA's approach.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045020)

EPA requested comment on the derivation of the HBWCs for the four PFAS included in the HI. Of the four PFAS (PFNA, PFHxS, PFBS, HFPO-DA) included in the HI, NJDEP has reviewed

the basis for the toxicity factor only for HFPO-DA. As stated in NJDEP (2022), the NJDEP Division of Science and Research "has reviewed the basis of the USEPA (2021) RfD [Reference Dose] of 3 ng/kg/day and concluded that it is scientifically justified and health protective."

Further, EPA requested comments on whether the Health Based Water Concentrations (HBWCs) should instead be proposed as stand-alone MCLGs in addition to or in lieu of the mixture MCLG. Use of HBWCs as stand-alone MCLGs in lieu of the mixture MCLG would not account for additive toxicity when mixtures of these PFAS are present in drinking water. Use of the HBWCs as stand-alone MCLGs in addition to the mixture MCLG would have no practical impact, since an exceedance of the HBWC for a specific PFAS would result in an HI above 1.0 even if none of the other PFAS included in the HI are detected.

EPA Response: The EPA agrees that the reference dose for HFPO-DA is scientifically justified and health protective.

For the EPA response to the comment about stand-alone MCLGs for the four PFAS, please see section 4.3.2 of the EPA response in this *Response to Comments* document. The EPA disagrees that deriving individual MCLGs in addition to the Hazard Index MCLG would have no practical impact; for the EPA's discussion on the establishment of stand-alone standards in lieu of or in addition to the Hazard Index MCL, please see section 5.2 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045899)

c. The dose additivity concept underpinning the Hazard Index approach is flawed because the underlying data already accounts for the co-occurrence of these chemicals

As discussed, EPA argues that the data support the co-occurrence of the four PFAS. In justifying the use of a dose-additive Hazard Index approach, EPA argues that it is a "reasonable health-protective assumption"[FN77: 88 Fed. Reg. at 18663.] because these PFAS have co-exposures. However, in each step of the derivation of the HBWC, EPA makes conservative assumptions that also account for the co- occurrence of these chemicals. For instance, despite the availability of information and data to inform a more realistic value, EPA chose the most conservative default value of 20% for the RSC. By combining multiple conservative assumptions, the Hazard Index approach is no longer tethered to actual data, which is not the best available science.

EPA Response: The commenter is incorrect in stating that the "underlying data already accounts for the co-occurrence of these chemicals." The toxicity assessments that serve as the foundations for the four HBWCs included in the Hazard Index MCLG do not consider chemical co-occurrence and are based on chemical-specific data (e.g., animal toxicology and/or epidemiology studies) for each of the four individual PFAS included in the Hazard Index. In developing the HBWCs, the EPA applied a chemical-specific RSC for each of the four PFAS to account for potential aggregate risk from exposures and exposure pathways other than oral ingestion of drinking water; that is, the RSC considers multiple exposure pathways from the

same chemical rather than co-occurrence of multiple PFAS. For more information, please see sections 4.3.1 and 4.3.3 of the EPA response in this *Response to Comments* document.

Protecting Our Water, Environment, and Ratepayers (POWER) (Doc. #1714, SBC-045940)

It is arbitrary to use a Hazard Index to group compounds that do not have similar harms.

EPA's decision to group PFHxS, HFPO-DA, PFNA, and PFBS in the proposed Hazard Index is arbitrary because EPA has failed to demonstrate, and instead merely assumes, that these compounds have a dose-additive effect. EPA explains that "a mixture of chemicals with similar apical effects should be assumed to also act in a dose additive manner unless data demonstrate otherwise." Here, the data provided by the EPA do not support, and in fact undermine, the assumption that the compounds are dose additive.

First, it is arbitrary to consider the dose-additive effects for PFHxS and PFNA because no Reference Dose has been finalized for these compounds. Because the level of harm caused to a specific body part has not been finalized, it is arbitrary to determine that there is an additive effect with the other compounds prior to this data getting finalized.

Even if the proposed effect is considered, asserting a dose-additive effect for PFHxS, HFPO-DA, PFNA, and PFBS is arbitrary because the compounds do not impact the same body parts. The finalized health advisories explain that PFBS causes thyroid issues and HFPO-DA has liver impacts. [FN23: Proposed Rule, 88 Fed. Reg. at 18644-45.] The interim findings assert that PFNA causes developmental delays and PFHxS causes thyroid issues. Although some of the harms overlap among some subsets of these four compounds, all of them do not overlap. Because there are substantial differences between thyroid and liver harms, it is arbitrary to consider all of these harms together and assume they are additive in the Health Index. The proposed rule asserts that it is considering a body-wide effect, but it has failed to point to a precedent where it has considered the effects of other compounds over the whole body rather than on an organ or biological system.

EPA Response: For the EPA response to comments on dose additivity, please see section 4.3.1 of this *Response to Comments* document. For the EPA response to comments on the toxicity reference values for PFNA and PFHxS, see section 4.3.3 of the EPA response in this *Response to Comments* document.

Wyoming Department of Environmental Quality (WDEQ) (Doc. #1716, SBC-044775)

2. EPA Should Reconsider the Hazard Index Approach/or PFHxS, GenX, PFNA, and PFBS
WDEQ recognizes that EPA's September 1996 Guidelines for the Health Risk Assessment of Chemical Mixtures state that "If sufficient data are not available on the effects of the chemical mixture of concern or a reasonably similar mixture, the proposed approach is to assume additivity." Moreover, as outlined in the preamble to the proposed regulations, EPA relayed that "If the Agency only established an individual MCLG, the Agency would not provide any

protection against dose-additivity from regulated co occurring PFAS." WDEQ also notes that the Science Advisory Board agreed "that the HI can be used as an indicator of potential health risk(s) associated with exposure to mixtures of PFAS." Finally, the in March 2023 Maximum Contaminant Level Goal (MCLG) Summary Document for a Mixture of Four Per- and Polvfluoroalkvl Substances (PFAS): HFPO-DA and its Ammonium Salt (also known as GenX Chemicals), PFBS, PFNA, and PFHxS, EPA describes that "The agency selected the HI approach for MCLG development because a HBWC for HFPO-DA, PFBS, PFNA, and PFHxS is available and can be calculated."

While helpful, these statements imply that EPA is proposing the HI for PFHxS, GenX, PFNA, and PFBS because they co-occur, HBWCs were available, and EPA wanted to protect against potential dose additivity. The rationale does not explain why, based on the similarity of human health effects, EPA selected PFHxS, GenX, PFNA, and PFBS for inclusion in the HI. This lack of an explanation is particularly concerning considering that Health Advisories have not been finalized for PFNA and PFHxS.

Considering the significance of the first proposed NPDW rule for PFAS and the potential costs incurred by affected PWSs and rate-payers, WDEQ notes that EPA's September 1996 Guidelines for the Health Risk Assessment of Chemical Mixtures also describe that "Dose addition for dissimilar effects does not have strong scientific support and if done, should be justified on a case by case basis in terms of biological plausibility," and "concerns with the use of interaction data on experimental mammals to assess interactions in humans is based on the increasing appreciation for systematic differences among species in response to individual chemicals. If systematic differences in toxic sensitivity to single chemicals exist among species, then it seems reasonable to suggest that the magnitude of toxicant interactions among species also may vary in a systematic manner." Finally, WDEQ notes that the HBWCs for PFNA and PFHxS are from the Agency for Toxic Substances and Disease Registry, which were developed for a different purpose than is being applied here.

Given that all the studies used to derive the HBWCs for PFHxS, GenX, PFNA, and PFBS were conducted in mice, a lack of any studies that evaluated dose additivity of these chemicals, and a lack of corresponding health effect data or dose additivity studies in humans, the uncertainties associated the health effects data appear to outweigh the benefits of implementing the HI as proposed.

EPA Response: For the EPA response to comments about dose additivity, please see section 4.3.1 of this *Response to Comments* document. For the EPA response to comments on the toxicity reference values for PFNA and PFHxS, see section 4.3.3 of the EPA response in this *Response to Comments* document. For the EPA response to the comment about inclusion of these particular four PFAS in the Hazard Index, see section 4.3.5 of the EPA response in this *Response to Comments* document.

In response to the comment about how HAs have not been finalized for PFNA or PFHxS: HAs are not a pre-requisite for an NPDWR under the SDWA. There is nothing in the statute or the

EPA's historical regulatory practice that suggests that the agency should delay regulation of a contaminant in order to develop a HA first.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045212)

USEPA should provide stronger evidence to support dose additivity of the four PFAS, which is the assumption the general HI approach based on. PFAS have some similar health effects, but they also differ more than just in potency. For example, the most sensitive health endpoints for both PFBS and PFHxS are thyroid while there is much less data indicating the same health effect of GenX and PFNA. Assumptions of PFAS additivity may vary by health endpoint (as shown in Conley et al. 2022a,b) and are not well supported by the limited available science in laboratory animals (Marques et al 2021) or in humans (Borghese et al 2020; Kim et al. 2018; Liu 2022; Preston 2020; Stratakis 2020). While additive effects have been demonstrated for certain PFAS and some specific outcomes in experimental in silico or in vitro studies, such effects were not confirmed by the first in vivo study to evaluate effects of perinatal exposure to a PFAS mixture. Marques et. al., 2022 reported that a PFAS mixture of PFOS, PFOA, and PFHxS had very distinct effects on mouse dams and pups when compared to a single compound treatment, and the effects varied by outcome. For example, the effect on liver weights from PFOA alone was analogous to the effects seen for the PFAS mixture (thus, not additive). Increases in liver triglycerides were seen for each of the three single PFAS treatments, but not for the mixture (thus, not additive, and suggestive of antagonism). The differential impacts of specific PFAS have also been observed in human studies. For example, in large prospective Canadian study that evaluated the associations between maternal first trimester serum plasma concentrations of PFOA, PFOS, and PFHxS and gestational hypertension (HTN) or preeclampsia, higher levels of PFHxS were associated with development of preeclampsia, but not with gestational HTN and neither PFOA nor PFOS were associated with either outcome. Mixtures were not specifically evaluated (Borghese et al., 2020). DPH is not aware of any animal or epidemiological studies that have evaluated the additivity of the four PFAS included in the HI approach. USEPA should also provide more discussion on the interaction (synergies vs. antagonism) of the PFAS in a mixture, as the type of interaction (antagonistic, additive, or synergistic) appears to vary across lower vs higher PFAS concentrations (Blake et al. 2022) and across different species (Dale et al 2022) and by type of outcome.

EPA Response: Please see section 4.3.1 of the EPA response in this *Response to Comments* document and the 'PFAS Dose Additivity' section (Section 3.4) in the EPA's PFAS Mixtures Framework (USEPA, 2024i). The EPA's PFAS Mixtures Framework describes additional recent published studies with PFAS mixtures which found that, *in vivo*, dose additivity is the more accurate model for predicting effects of mixtures. The Marques et al. (2021) study cited by the commenter is discussed in the EPA's PFAS Mixtures Framework document. The study has limitations (e.g., it did not address dose additivity vs. response additivity predictions, and in fact, the experimental design precluded any such calculation, and therefore the authors' conclusions of mixture interactions (e.g., synergy or antagonism) were speculative; see additional discussion in USEPA (2024i)). This study is discussed in the EPA's PFAS Mixtures

Framework document. The epidemiological studies cited by the commenter (Borghese et al., 2020; Kim et al., 2018; Liu, 2022; Preston, 2020; Stratakis et al., 2020) report associations between PFAS exposure and different effects, and some mention associations between effects and total PFAS concentration. Such epidemiological studies are interesting and important but are typically not useful for comparison of dose additivity vs. response additivity model predictions.

Additionally, the EPA notes that there are no published studies definitively showing synergy or antagonism of PFAS mixtures. Certainly, effects differ from species to species and type of outcome, but this does not refute that dose additivity should be the default model.

American Water Works Association (AWWA) (Doc. #1759, SBC-045600)

[In proposing this MCLG, EPA is making several key scientific determinations to support this decision:]

2. Co-exposure to a mixture of PFNA, PFHxS, HFPO-DA, and PFBS can lead to an aggregate health effect as a result of dose additivity, and

3. The dose additivity of PFAS can be applied through the hazard index with dissimilar health effects, or outcomes.

AWWA contracted with Ramboll Consulting U.S. to assist in reviewing the EPA's approach and to offer detailed recommendations to improve this work. Ramboll has provided a detailed letter with recommendations, which is included as part of Appendix A.

AWWA supports the agency's interest in taking a public health protective stance on PFAS. It cannot do so based on the assumption of dose additivity without sufficient evidence. There are numerous concerns regarding the agency's determination that these compounds co-occur and that their co-exposure has a dose-additive effect on dissimilar outcomes. Based on the information that EPA has currently provided and relied upon, EPA has not met the statutory or scientific requirements to make a positive regulatory determination for these substances individually or as a mixture.

EPA Response: Please see sections 4.3.1, 4.3.2, 6, and 3 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045605)

Additionally, the agency has failed to provide adequate information to support the proposed approach to apply the hazard index to these compounds using reference doses based on the compound-specific critical health outcome, not a similar health outcome. In review of the draft approach, the SAB provided EPA with support for the determination of "dose additivity based on a common outcome" while also noting that this was appropriate "instead of a common mode of action as a health protective default assumption" (SAB, 2022). Additionally, the support document for this MCLG states that "component-based approaches for assessing risks of PFAS

mixtures are focused on evaluation of similarity of toxicological endpoint/effect rather than similarity in MOA [mode of action]". The proposed approach is inconsistent with this statement and is contrary to the SAB recommendations.

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

Environmental Protection Network (EPN) (Doc. #1773, SBC-043857)

We further support EPA's selection of the relative source contribution and most sensitive person in calculating the health-based reference values for these four chemicals. We note that the revised PFAS Mixtures Framework provides strong support for the dose additivity of PFAS chemicals and the need for a HI approach.

EPA Response: This commenter supports the EPA's approach.

3M Company (Doc. #1774, SBC-045677)

ii. The hazard index approach is based entirely on unscientific assumptions of dose additivity

EPA's proposed general HI method is inconsistent with long-standing policy and science regarding chemical hazard additivity. As described below, EPA has not established that the HIPFAS share a mode of action (MoA) that is relevant for humans, which is required to regulate groups of chemicals. [FN45: See, e.g., (Anderson et al. 2022).] MoA information is critical to grouping PFAS and "[o]nly those PFAS that affect the same target organ/tissue/system should be grouped and assessed for dose additive or response additive approaches." [FN46: Id. at 5.] This is consistent with long-standing EPA guidance stating that multi-chemical cumulative non-cancer hazards should only be assessed for chemicals with RfDs that are based on an effect on the same target organ (USEPA 1986, 1989, 2000b.

EPA admits that the HI MCL lacks evidence of a common MoA. [FN47: See 88 FR 18668.] To the contrary, the reference value for PFHxS and the RfD for PFBS are based on different thyroid effects, the HFPO-DA RfD is based on a "constellation" of liver effects, and the PFNA reference value is based on changes to body weight and development. For PFHxS and PFBS, the same thyroid endpoints are not used as the critical effects – for PFHxS the critical effect is based on thyroid follicular epithelial hypertrophy/hyperplasia in parental male rats and for PFBS the critical effect is based on decreased serum total thyroxine in newborn mice after gestational exposure to the mother. These effects are likely occurring via different MoAs due to the different life-stages affected (parental versus offspring, respectively). EPA has also not established a shared MoA or considered relative potencies of the HI-PFAS. Because the HI-PFAS lack a common toxicity endpoint, summing potential hazards (as measured with a hazard quotient or HQ), contradicts long-standing EPA guidance and widely held scientific opinion.

These differences in target organs [FN48: A target organ is an organ in the body most affected by a specific substance.] and critical effects for the four HI-PFAS are precisely why EPA did not use

a target organ-specific HI approach and instead opted for the screening-level HI approach, despite its inability to accurately characterize the additivity of the four HI-PFAS. EPA guidance (USEPA 1989) recommends the use of the general HI approach as an initial screening to assess potential adverse effects and not for binding regulatory purposes. The approach assumes that simultaneous exposures to several chemicals occurring below their respective health-based thresholds could result in an adverse health effect, regardless of the chemicals' target organs or mechanisms of action. The HI is calculated as the sum of the ratios of each chemical's exposure relative to that chemical's respective health-based threshold. If the resulting general HI is less than 1, then an unacceptable hazard does not exist, and no further evaluation is needed. However, if the general HI exceeds 1, the guidance then recommends conducting a refined assessment by separating the HI evaluation by target organ and/or mechanism of action. EPA's proposed HI MCL omits the critical consideration for shared target organs and/or mechanism of action to determine potential hazard.

Because the four HI-PFAS do not share the same target organ, potential hazards calculated via the general HI method are not toxicologically accurate. EPA's proposed general HI method fails to use the target organ-specific RfDs in the most appropriate manner, resulting in a screening-level assessment when a refined target organ HI approach is available and is far more appropriate. [FN49: EPA wrongly refers to the general HI method as a more health protective indicator of risk and the target organ-specific HI approach as less health protective estimate of risk. Noncancer evaluations are based on threshold effects and, as a result, are either health protective or not. The contention that the general HI is "more" health protective stems from the misapplication of the long-standing approach for assessing the potential hazards associated with exposure to more than one noncarcinogen. The general HI method results in an inaccurate potential hazard calculation that unnecessarily increases uncertainty, reduces transparency, and hinders the risk communication process] This flaw results in inaccurate and overly conservative MCLs, combined with problematic risk communication due to their flawed scientific foundation and lack of transparency.

In short, EPA's reliance on the general HI method for PFHxS, HFPO-DA, PFNA, and PFBS is contrary to long-standing practices employed in human health risk assessments, well established and scientifically sound principles of toxicology, and EPA guidance. Further, the proposed general HI approach cannot be claimed as a more health protective method. Rather, it is an inaccurate method for assessing exposures and risks to compounds with different toxicological endpoints, and because of the method's inaccuracy, cannot be used to determine health protectiveness or margin of safety. Considering these fundamental shortcomings, the use of the general HI method in the proposed NPDWR is arbitrary.

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

The Chemours Company FC, LLC (Doc. #1845, SBC-046062)

1 EPA's justification for dose additivity of PFAS is inadequate; the weight of evidence from mixture studies is limited and does not support the assumption of dose additivity for these four PFAS.

In EPA's draft MCLG Summary Document for HFPO-DA, PFBS, PFNA, and PFHxS, the EPA cites findings from Conley et al. (2022) as a basis for their dose additivity assumption for these four PFAS (EPA 2023a). However, as stated in EPA's draft PFAS Mixtures Framework, "Limited work has been conducted on combined exposure to PFAS in experimental systems either in vitro or in vivo" (EPA 2023b). In fact, according to EPA (2023b), the Conley et al. (2022) study is the only published mammalian in vivo study available in the scientific peer-reviewed literature that has conducted mixture model-based analyses for PFAS. Further, data from Conley et al. (2022) are limited to two long-chain PFAS - specifically, PFOA and PFOS (individual and combined) effects in maternal and neonatal rats following exposure to relatively high dose levels. Notably, Conley et al. (2022) did not evaluate the four specific PFAS included in the HI MCLG.

In the draft PFAS Mixtures Framework, EPA mentions three other mammalian in vivo toxicity studies that have evaluated exposure to multiple PFAS, but notes that "these studies did not include individual PFAS dose response data or conduct any mixture model- based analyses, so it is not possible to ascertain if the mixtures behaved in a DA [dose additive] or RA [response additive] manner, or if interactions occurred" (EPA 2023b).

In addition, EPA (2023b) recognizes that only a "few in vitro studies have directly assessed the mixture-based effects of combined PFAS exposures," with in vitro studies reporting less than additive effects (Carr et al. 2013, Menger et al. 2020), effects consistent with dose additivity at low exposure concentrations (Wolf et al. 2014, Nielsen et al. 2022), synergistic and antagonistic effects (Ojo et al. 2020), or a mixture of interactive effects (Ding et al. 2013). Despite these inconsistent findings in vitro, EPA concluded evidence "for combined in vitro exposure to PFAAs [perfluorinated alkyl acids] demonstrate results that are either consistent with or have relatively minor deviations from predictions based on concentration additive models" (EPA 2023b). Importantly, EPA never defined "relatively minor" nor did it demonstrate that such deviations would not have significant impact.

EPA's Science Advisory Board (SAB) was charged with reviewing the 2021 draft PFAS Mixtures Framework. The SAB recommended that "discussion of studies of toxicological interactions in PFAS mixtures in the EPA mixtures document be expanded to also include studies that do not indicate dose additivity and/or a common MOA [mode of action] for PFAS" to "increase transparency and characterization of the uncertainties associated with the assumption of dose additivity" (EPA 2023c). Although a few studies were added in EPA's revised draft PFAS Mixtures Framework (EPA 2023b) that acknowledged non- additive interactions of PFAS, EPA failed to conduct a complete systematic review as part of its evaluation of the evidence base for PFAS mixtures to determine whether the weight of evidence supports dose additivity for these four PFAS. As a result, EPA failed to include several additional studies in its 2023 revised draft PFAS Mixtures Framework – specifically, EPA failed to include a number of in vitro studies demonstrating a lack of support for additivity of PFAS (Bjork et al. 2021, Fey et al. 2022, Hu et

al. 2014, Kjeldsen and Bonefeld-Jorgensen 2013). Therefore, based on the available studies examining PFAS mixtures, the overall weight of evidence does not support dose additivity for PFAS.

For the HI approach in the assessment of PFAS mixtures, EPA discusses dioxin-like chemicals (DLCs) and the toxic equivalence factor (TEF) approach as an example of a mixtures approach in the draft PFAS Mixtures Framework (EPA 2023b). However, there are important distinctions between DLCs and the four PFAS included in the proposed HI MCLG. Most notably, there are many toxicity studies specific to mixtures of DLCs. For example, a PubMed search of "(dioxin-like compounds and mixture) AND (toxicity)" yields 146 results. These results include a comprehensive mixtures study with a variety of DLCs conducted by the National Toxicology Program. Based on the extensive body of evidence, it was concluded that the results are consistent with the TEF approach and reflect dose additivity (Van den Berg et al. 2006, Walker et al. 2005).

Interestingly, despite the substantially larger body of evidence supporting dose additivity, and a common mode of action, for DLCs, EPA has only promulgated an MCL for a single DLC – specifically TCDD. There is no mixtures-based MCL for DLCs. While EPA could claim that the expectation is that utilities will calculate a total TEQ concentration that reflects detected concentrations of each DLC times its TEF, Van den Berg et al. (2006) (referenced in the PFAS Mixtures Framework) makes it clear that it is inappropriate to apply the TEFs to abiotic media, stating the following:

The expert panel emphasized that correct application of the present TEF scheme (see Table 1) and TEQ methodology in human risk assessment is only intended for estimating exposure to dioxin-like chemicals from consumption of food products, breast milk, etc. This limitation is derived from the fact that those REP studies that have been considered most relevant for the determination of the present TEFs are largely based on oral intake studies, often through the diet.

EPA Response: Please see section 4.3.1 of the EPA response in this *Response to Comments* document and 'Dose Additivity for PFAS' (Section 3) in the EPA's PFAS Mixtures Framework (USEPA, 2024i).

Regarding the comment on the need to define "relatively minor" deviations from dose additivity, this statement in EPA's PFAS Mixtures Framework (USEPA, 2024i) characterizes the findings of several *in vitro* studies which found that departures from dose additivity are uncommon and rarely exceed ~2- to 3-fold from predictions based on dose additivity. Such deviations in an experimental study are within the range of between-study variance that is expected for these types of *in vitro* and *in vivo* study designs in the literature (i.e., if an experimental mixture study was repeated multiple times, the observed mixture data would typically be expected to deviate ~2- to 4-fold greater than or less than the additivity prediction). This low-level deviation (~2- to 4-fold) from predictions based on dose additivity has been evaluated and described in several robust literature evaluation efforts across many chemical classes and study designs (see Boobis et al. (2011), Cedergreen et al. (2014), and Martin et al. (2021)) and thus the weight of evidence is

strongly in favor of dose additivity. Further, it has been determined that chemical mixture deviations from dose additivity most commonly occur at the highest experimental exposure concentrations, far exceeding those observed in human or environmental sampling data.

With respect to the SAB's recommendation to expand discussion of studies of toxicological interactions in PFAS mixtures, the EPA did update the PFAS Mixtures Framework to include the studies indicated in the SAB Report. The EPA also notes, however, that the mammalian PFAS mixture studies indicated in the SAB Report (Marques et al., 2021 and Roth et al., 2021) did not include individual chemical dose-response data or conduct any evaluation of mixture model predictions (i.e., dose addition versus response addition) compared to observed mixture effects. Thus, conclusions of mixture interactions (e.g., synergy or antagonism) were speculative and not supported by data published in those papers. The EPA also notes that in Nielsen et al. (2022), the generalized concentration addition (GCA) model of additivity has been developed for use with *in vitro* data that clearly identify full versus partial receptor activity (i.e., agonism or antagonism); however, there are no available data supporting the use of this model in estimating the *in vivo* effects from mixtures exposure. Regarding PFAS mixture studies of zebrafish, it has been clearly reported that fish peroxisome proliferator-activated receptors have low sequence homology to mammalian receptors and do not respond to many ligands that are active in mammalian systems; thus, the relevance of data reported from fish systems to the estimation of human health are unclear for PFAS. In regard to the additional *in vitro* mixture studies listed by the commenter, the Bjork et al. (2021) study inappropriately used a model of response addition (i.e., effect summation) instead of a dose addition model to evaluate additivity – thus the conclusion that the data did not fit additivity was in reference to response addition, not dose addition. The Fey et al. (2022) study was in zebrafish and used a non-human-relevant endpoint (swim bladder inflation), inappropriate dose-response modeling using a linear x-axis with widely spaced dose levels (log x-axis is appropriate), and the study does not report how mixture data analyses were conducted or what model of additivity was used for evaluation. Hu et al. (2014) evaluated binary and multi-chemical PFAS mixtures in vitro using a cell line that was erroneously identified as fetal liver but is now known to be HeLa cell-derived. That study reported non-monotonic J-shaped dose-response curves that included cell proliferation followed by cell death with disparate degrees of proliferation across the individual PFAS studied. The mixture models employed were not intended for use with component chemicals that display disparate maximum and minimum effect levels. Despite the difference in response functions, the observed mixture effects for cell death were well predicted using dose addition-based approaches (observed less than 2-fold different from predicted). Observed cell proliferation deviated from predictions; however, this was due to the discrepancy of effect magnitude across the component PFAS in the mixtures. In summary, there is limited information on PFAS mixture effects, but available high-quality published studies support dose additivity, as do multiple extensive literature analyses of mixtures of other classes of chemicals (see discussion in USEPA, 2024i).

Regarding the comment about application of toxicity equivalence factors (TEFs), which is a specialized form of relative potency factors (RPFs), 2,3,7,8-TCDD (referred to as 'dioxin') and associated dioxin-like compounds (DLCs) benefit from ample MOA data that demonstrate that

they all act through the same aryl hydrocarbon receptor (AhR) pathway to induce toxicity. This type of MOA information is not available for the vast majority of PFAS. Therefore, as described in section 4.3.1 of the EPA response in this *Response to Comments* document, the EPA's approach is to evaluate risks from exposure to mixtures of PFAS based on the fact that these PFAS elicit the same or similar adverse health effects (but may have differing potencies for effect(s)), an approach supported by the SAB and by EPA guidance.

The Chemours Company FC, LLC (Doc. #1845, SBC-046058)

Executive Summary

EPA's proposed maximum contaminant level goal (MCLG) for HFPO-DA, PFBS, PFNA, and PFHxS is based on a hazard index (HI) approach that assumes dose additivity for these four PFAS. In this proposed HI approach, a hazard quotient (HQ) is calculated as the ratio of exposure (i.e., measured drinking water concentration) to a health-based water concentration (HBWC) for each of the four PFAS. HQs for each of the four PFAS are then summed to yield the HI of the PFAS mixture. According to EPA, "a mixture HI exceeding indicates potential risk for a given environmental medium or site" (EPA 2023a). The following points represent key shortcomings in EPA's proposed HI MCLG for HFPO-DA, PFBS, PFNA, and PFHxS.

1) EPA's justification for dose additivity of PFAS is inadequate; the weight of evidence from mixture studies is limited and does not support the assumption of dose additivity for these four PFAS.

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

Lakewood Water District (LWD) (Doc. #1574, SBC-042754)

Hazard Index Approach is Flawed

The proposed Hazard Index (HI) approach is fundamentally flawed. Under the proposed HI approach, a water system could document that all four constituents of the Hazard Index are below the Health Based Water Concentrations (HBWCs) and still be characterized as hazardous. In fact, EPA shared this very scenario during several webinars with Example 2 of the HI calculations.

In EPA's Example 2, all four constituents are below the HBWC, yet the result was a HI above 1. This does not make sense. The HI concept should be significantly revised or discarded.

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

Lehigh County Authority (LCA) (Doc. #1600, SBC-042808)

2. Diversity of Health Impacts – The four PFAS compounds included in the Hazard Index have different health effects, including impacts on the liver, growth and development, hormones, kidney, immune system, lipid levels, nervous system, reproduction, and cancer. It is unclear how these health effects are related to each other, if at all. Therefore, it is unclear how combining them into a single Hazard Index will be protective of public health.

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

City of Allentown and Lehigh County Authority (LCA), Pennsylvania (Doc. #1667, SBC-043674)

[The treatment of these compounds in the proposed regulation is problematic for several reasons:]

3. Diversity of Health Impacts – The four PFAS compounds included in the Hazard Index have different health effects, including impacts on the liver, growth and development, hormones, kidney, immune system, lipid levels, nervous system, reproduction, and cancer. It is unclear how these health effects are related to each other, if at all. Therefore, it is unclear how combining them into a single Hazard Index will be protective of public health.

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

Orange County Water District (OCWD), California (Doc. #1634, SBC-043238)

Furthermore, EPA should address additional concerns raised by AWWA regarding the legality and scientific validity of the Hazard Index approach to regulate a chemical mixture under the SDWA before finalizing the rule.

EPA Response: Please see sections 4.3.1, 4.3.2, and 3 of the EPA response in this *Response to Comments* document.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044020)

4. EPA requests comment on the general HI approach for the mixture of four PFAS.

a. The inclusion of all of these compounds together using the proposed Health Index is not appropriate for a number of reasons. First, because they each have very different health impacts and EPA has previously mentioned in other guidance that they would not include chemicals with different toxic effects in a cumulative risk assessment. This also increases the difficulty in communicating health effects language to our customers. Customers are also comfortable with the "MCL" terminology they have seen for years in their CCRs; adding yet another concept and definition for HI will add to the complexity of the CCR. There are other better standardized

approaches for including multiple parameters under a chemical "umbrella", such as VOCs, SOCs, and DBPs.

EPA Response: Please see sections 4.3.1, 4.3.2, and 1.2 of the EPA response in this *Response to Comments* document. Also, the mixture risk assessment methods and applications in the final NPDWR and PFAS Mixtures Framework are not "cumulative risk assessment;" cumulative risk assessment is much broader in terms of the integration across multiple exposure routes/scenarios, and often includes stressors other than chemicals (e.g., physical conditions; microbial risks; nutritional status; socioeconomic factors; etc.) (see the EPA's PFAS Mixtures Framework, USEPA, 2024i).

WaterPIO (Doc. #1624, SBC-043474)

A quick note on the Hazard Index. Organizations more versed in the science than us have broken down the weaknesses of applying the HI approach for the first time to drinking water. We will simply point out one irrefutable fact that, again, shows how the EPA wants public water systems to fail.

If water providers test for the four PFAS that make up the Hazard Index – PFNA, PFHxS, PFBS, and HFPO-DA (GenX) – and find they are under the health-based concentrations for each one of the four, they should be in the clear for a possible drinking water violation, right?

Wrong.

Public water systems could still find themselves in violation of the HI if the total for all four PFAS in a mixture is above 1.0. So, water providers could be in good stead with the EPA's health-based concentrations for every one of the four compounds that make up the HI and still end up with a Notice of Violation that will also wreck public confidence in their drinking water.

Public water systems, again, are being put in a position to fail.

Some, especially in the activist community, are saying, "Why not set the regulations as low as possible? We know these chemicals are bad at higher levels," and one can reasonably agree that their argument has merit. No one in public water that we know is happy with these compounds being found in our source and drinking waters.

But that's not how we set regulations in this country. There are other factors involved, especially because setting regulations at these levels and using an HI is untenable and creates situations where water providers will have to pass on the astronomical costs of treatment to their customers. This will result in many of the very people activists are saying they are trying to protect turning to water sources that are not safer or to unhealthy beverages that pose a greater risk.

EPA Response: Please see sections 4.3.1, 4.3.2, and 5 of the EPA response in this *Response to Comments* document.

Southwest Regional Water District (Doc. #1772, SBC-044728)

Additionally, the District does not agree with the approach of the Hazard Index. Under the proposed rule, a utility could be below the individual limit for the four substances included in this value but using this method could still exceed the limit of 1 for the final HI value. The health effects of these compounds are not the same and therefore combining all into one value leans very conservatively in regulating these substances. For this reason, we urge the USEPA to eliminate this part of the proposed rule.

Thank you again for the opportunity to comment on these proposed rules. Should the USEPA have additional questions, the District is available for discussion. My contact information is below.

Sincerely,

Sarah Affrunti

Regulatory Compliance & Safety Manager Southwest Regional Water District
affruntis@swwater.org

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

Metropolitan Water District of Southern California (Doc. #1777, SBC-045434)

4. EPA should consider the consequences and impacts of using the proposed Hazard Index approach

EPA is proposing individual MCLs of 4.0 ppt for PFOA and PFOS, and a Hazard Index approach as the MCL for four other PFAS – PFHxS, GenX chemicals, PFNA, and PFBS. [FN18: 88 Fed. Reg. at 18638.] As currently written, EPA is setting the MCL for the latter four PFAS at a Hazard Index of 1. A running annual average Hazard Index greater than 1.0 is a violation of the proposed Hazard Index MCL. [FN19: EPA, Understanding the PFAS National Primary Drinking Water Proposal Hazard Index (Mar. 2023), click here, Link: https://www.epa.gov/system/files/documents/2023-03/How%20do%20I%20calculate%20the%20Hazard%20Index._3.14.23.pdf .] However, according to the online Hazard Index MCL calculation tool, only one of the four (PFHxS, GenX chemicals, PFNA, and PFBS) needs to be present to trigger the regulatory requirements. This essentially means that the Hazard Index is the de facto MCL for each constituent, without EPA conducting the full cost-benefit analysis for each of these constituents.

EPA Response: Please see sections 4.3.1, 4.3.2, and 13.8 of the EPA response in this *Response to Comments* document.

Ohio Water Utility Council (OWUC), Ohio American Water Works Association (OAWWA) (Doc. #1782, SBC-044723)

The Hazard Index calculation proposed in this rule is of additional concern to the OWUC. Under the proposed rule, a utility could be below the individual limit for the four substances included in Hazard Index, but using this method could still exceed the limit of 1 for the final HI value. The health effects of these compounds are not the same and therefore combining all into one value leans very conservatively in regulating these substances. For this reason, we urge the USEPA to eliminate this part of the proposed rule.

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

Greater Cincinnati Water Works (GCWW) (Doc. #1550, SBC-042695)

In addition to our concerns about the economic burden this regulation will place on our customers and the unrealistic compliance schedule, we also do not agree with the approach taken with the Hazard Index. Using this method, utilities can exceed the limit of 1 when all four of the compounds are well below their respective health reference values. Because the critical health effects are not the same for all the compounds included in the Hazard Index, using this additive approach is overly conservative. We believe USEPA should eliminate this component of the regulation.

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043076)

Additionally, the Agency has failed to provide adequate information to support the proposed approach to apply the hazard index to these compounds using PFAS-specific critical effects. In review of the draft approach, the Science Advisory Board (SAB) provided EPA with support for the determination of "dose additivity based on a common outcome" while also noting that this was appropriate "instead of a common mode of action as a health protective default assumption." Additionally, the support document for this MCLG states that "component-based approaches for assessing risks of PFAS mixtures are focused on evaluation of similarity of toxicological endpoint/effect rather than similarity in MOA [mode of action]." The proposed approach is consistent with this statement and is contrary to the SAB recommendations.

In addition, this approach conflicts with guidance on risk assessment for mixtures from the Agency itself and the ATSDR. ATSDR's Framework for Assessing Health Impacts of Multiple Chemicals and Other Stressors notes that the hazard index method is most appropriately "applied to components that cause the same effect by the same mechanism or mode of action" but "may be applied to components with different target organs as a screening measure." Additionally, ATSDR's Public Health Assessment Guidance Manual indicates that when "the health guideline for each contaminant is based on different target organs, health assessors will need to calculate a target-organ-specific HQ [hazard quotient] for each contaminant." In addition to ATSDR guidance, EPA's own guidance for risk assessment of mixtures clearly indicates that the use of

critical effects from multiple tissues in a hazard index is inappropriate, specifically noting that the index requires "similarity in target organ." In fact, the guidance states that "because the hazard index is tied to a specific effect, the underlying data should be on that effect." As part of this guidance, the Agency recommends that target organ toxicity doses as opposed to a critical effect dose, which is what is proposed in this action.

Aqua recommends that the EPA re-issue the preliminary determination for PFHxS, PFNA, HFPO-DA, and PFBS as a mixture and recommends that prior to re-issuing a preliminary determination for a mixture of PFAS work towards refining the proposed approach to align with guidance from federal agencies (including EPA), recommendations from the SAB, and through support from stakeholders.

EPA Response: The EPA's final regulatory determinations use the best available science and have been finalized consistent with the statutory requirements under SDWA. Please see sections 4.3.1, 4.3.2, and 3 of the EPA response in this *Response to Comments* document for further discussion.

Texas Commission on Environmental Quality (TCEQ) (Doc. #1632, SBC-044123)

EPA also uses an HI approach for remedial decisions at Federal Superfund sites, but in contrast to what is being proposed for the PFAS MCL, for remediation an HI greater than 1 is used as a screening level that may then be sorted by target organ and MOA. [FN5: See, EPA, "Risk Assessment Guidance for Superfund Human Health Evaluation Manual (Part A)," at 8-14 to 8-15, EPA Document No. EPA/540/1-89/002 (1989) (referred to as USEPA. 1989) (describing procedure for calculating the HI by effect and by mechanism of action). Briefly, if one of the effect-specific HIs exceeds a value of 1 (i.e., unity), consideration of the mechanism of action may be warranted. Segregation of HIs requires identification of the major effects of each chemical, including those seen at higher doses than the critical effect (e.g., the chemical may cause liver damage at a dose of 100 mg/kg-day and neurotoxicity at a dose of 250 mg/kgday). Major effect categories include neurotoxicity, developmental toxicity, reproductive toxicity, immunotoxicity, and adverse effects by target organ (i.e., hepatic, renal, respiratory, cardiovascular, gastrointestinal, hematological, musculoskeletal, and dermal/ocular effects).] Sorting by target organ and MOA is a process more consistent with the further evaluation contemplated by the SAB when they stated,

"In general, the screening level Hazard Index (HI) approach, in which Reference Values (RfVs) for the mixture components are used regardless of the effect on which the RfVs are based, is appropriate for initial screening of whether exposure to a mixture of PFAS poses a potential risk that should be further evaluated." [FN6: EPA, "EPA Response to Final Science Advisory Board Recommendations (August 2022) on Four Draft Support Documents for the EPA's Proposed PFAS National Primary Drinking Water Regulation," at 56, Section II.S2.1, EPA Document No. EPA–822–D–23–001 (Mar. 2023) (referred to as USEPA. 2023f) (emphasis added).]

Therefore, EPA's proposed HI approach is not scientifically defensible because it ignores both MOA and target organ differences among the four PFAS, yet nevertheless triggers action at a value greater than unity (i.e., 1). An alternative to the proposed HI approach is to use target-organ-specific hazard indices (TOSHI), which provide somewhat better information for decision-making about PFAS, or other chemical, contamination in drinking water or other media. The SAB recognized the TOSHI approach as more robust than a screening HI approach that ignores MOA and target organ (e.g., the one proposed by EPA) when they state,

"The TOSHI approach necessitates endpoint/health effect-specific reference values, not just overall reference values. . . . The TOSHI approach presents additional robustness compared to the Screening Level HI given the identification of human health/toxicity values that are effect/endpoint specific. . . . The TOSHI approach may merit consideration to be classified as a higher tier method compared to the Screening Level HI method for decision making purposes. This may also reflect current and future practices amongst states and others." [FN7: Id. At 58, Section II. S2.5.]

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document. Additionally, the text from *Risk Assessment Guidance for Superfund Human Health Evaluation Manual (Part A)* (USEPA, 1989) quoted by the commenter omits an important qualifier statement, which is that "Although higher exposure levels may be required to produce adverse health effects other than the critical effect, the RfD can be used as the toxicity value for each effect category as a conservative and simplifying step." This is a critical consideration supported by the EPA's guidance.

Aidan Cecchetti (Doc. #1640, SBC-044359)

• EPA requests comment on the general HI approach for the mixture of four PFAS (pg. 18655 Federal Register Volume 88, Number 60). EPA requests comment on its proposal of using an HI approach for PFHxS, HFPO-DA, PFNA, and PFBS, including whether it can be clearly implemented and achieves the goal of protecting against dose additive noncancer health effects (pg. 18666 Federal Register Volume 88, Number 60).

o The commenters agree with the EPA's decision to use an HI approach to regulate levels of PFHxS, HFPO-DA, PFNA, and PFBS. Due to the lack of toxicological data on PFAS mixtures to confirm the assumption of dose additivity, the commenters agree with the SAB's determination that "dose additivity can provide an estimate of composite effects" at the levels at which EPA is regulating the PFAS mixtures. Based on dose additivity data for other mixtures of contaminants, the commenters agree with SAB's suggestion that this approach is unlikely to underestimate the adverse health effects of contaminant mixtures and should therefore be health protective.

EPA Response: This commenter supports the EPA's approach.

NCASI (Doc. #1651, SBC-043227)

3.0 The Inappropriate Application of the Hazard Index Approach for Listed PFAS

In this rulemaking, EPA proposes a Hazard Index (HI) approach that substantially diverges from the intended justification and implementation of HI in standard human health risk assessment applications:

"An important aspect of the proposed 'general HI' approach is that it is based on the availability of a reference value regardless of the critical effect for each mixture component. Unlike a target organ specific Hazard Index which is typically based on either shared mode-of-action or shared health outcome of mixture components, the general HI is based on a non-cancer reference value (RfD or Minimal Risk Level) for the critical (usually the most sensitive) effect of each component."34 [FN3: USEPA. 2000a. Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures. EPA 630–R–00–002. Available on the internet at: https:// cfpub.epa.gov/ncea/risk/recordisplay. cfm?deid=20533.] [FN4: USEPA. 1989. Risk assessment guidance for Superfund. Vol. 1. Human Health Evaluation Manual (Part A). EPA/540/1–89/002.](pg. 18656)

An HI approach is only justified, in a toxicological sense, when two or more compounds elicit the same endpoint or act on the same biological mode of action in producing an adverse health effect that forms the basis of the health hazard for those substances. PFAS, as a group, includes thousands of substances with unique physio-chemical properties, unique fate and transport properties, and unique toxicological profiles. Broadly inclusive criteria are unlikely to produce standards or risk assessment approaches with a well characterized margin of safety or that accurately reflects the hazard posed by individual substances within the group. This has been evidenced in the scientific literature, even in studies that have evaluated PFAS of relatively similar chemical structure. As an example, Pizzurro et al. 2019 examined the toxicokinetics of several PFAS compounds and came to the following conclusions:

"Overall, our analysis provides one of the first syntheses of available empirical PFAS toxicokinetic data to facilitate interpreting human relevance of findings observed in animal studies and developing health-based criteria for PFAS from such studies. Our analysis highlighted several notable differences among the different PFAS regarding species and substance-specific tissue partitioning, half-life, and transfer to developing offspring via the placenta or lactation, as well as highlighted data gaps for certain substances….Lastly, the results of this analysis indicate that there are toxicokinetic differences among the different PFAS based on chain length, and these substances should not be regulated as a group without careful consideration of how the substance-specific toxicokinetics may impact potential toxicity, including differing specific target organ toxicity and overall body burden."5 [FN5: Pizzurro, Daniella M.; Seeley, Mara; Kerper, Laura E.; Beck, Barbara D. 2019. Interspecies differences in perfluoroalkyl substances (PFAS) toxicokinetics and application to health-based criteria. Regulatory Toxicology and Pharmacology 106 239–250.]

None of the listed substances under the HI approach in the proposed rulemaking are have RfDs based on the same critical effect, nor is there a link between a mode of action each substance

elicits that is related to all of the critical effects that form the basis of the individual RfDs. The EPA acknowledges the diversity of health outcomes exhibited from exposure to these listed PFAS:

"The adverse health effects observed following oral exposure to such PFAS are significant and diverse…"(pg. 18643)

A HI approach is not appropriate for compounds with different toxic modes of action and it's use in the proposed rulemaking is inconsistent with other EPA programs. EPA states that "the application of the HI approach under a regulatory purview is not novel," and EPA uses CERCLA as an example (pg. 18669). While the HI is not novel, in EPA's 2000 "Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures," EPA lays out three approaches to conducing risk assessments for mixtures, recognizing how the state of the science influences which approaches is appropriate. In the "Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures," an EPA Risk Assessment Forum Technical Panel, August 2000, further states that the "major concerns for the user are whether the available data are on components or whole mixtures, whether the data are composed of either similar components or similar mixtures that can be thought of as acting by similar toxicologic processes, and whether the data may be grouped by emissions source, chemical structure, or biologic activity." EPA, in the proposed rulemaking does not support that these four additional PFAS compounds act by similar toxicologic processes.

The Hazard Index (HI) approach requires confirmation of the fundamental assumption of dose additivity. Systemic toxicants should be confirmed as having the same mode of action prior to dose summation6 [FN6: USEPA 2000 Risk Assessment Guidance for Superfund (RAGS) (https://www.epa.gov/sites/default/files/201509/documents/rags_a.pdf]. The four PFAS species included in the proposed HI summation, PFNA, HFPO-DA, PFHxS, and PFBS, are dissimilar and do not seem to have confirmatory data that they adhere to the dose additivity model as they do not share critical effects as the basis for their individual RfDs. The Supplementary Guidance also explains that the "term additivity is used when the effect of the combination of chemicals can be estimated directly from the sum of the scaled exposure levels (dose addition) or of the responses (response addition) of the individual components." EPA's attempt to use additivity is not based on either of the approaches in the 2000 Guidance.

Further, EPA's additivity approach in the proposed rulemaking appears to assume conclusion on issues that EPA is still considering as to PFAS compounds in other programs. In the CERCLA ANPRM issued in April 2023, EPA is specifically soliciting feedback on whether future CERCLA action could group PFAS compounds, including on the basis of modes of toxicological action:

EPA is considering whether to initiate a future action that would potentially designate groups or categories of PFAS as hazardous substances. A group or category refers to a set of PFAS that share one or more similar characteristics. Characteristics of interest could include, but are not

limited to, chemical structure (e.g., carbon chain length, functional group), physical and chemical properties, mode of toxicological action, precursors or degradants, or co-occurrence.

EPA also gives an example of the TCSA Significant New User Rule (SNUR) where grouping was based on chemical structure.

In the TSCA program, EPA has developed Draft Principles for Cumulative Risk Assessment (CRA). In that document, EPA bases additivity on toxicological similarity: "Deciding, based on their toxicological similarity, which chemical substances to include in a cumulative chemical group that subsequently would be evaluated using dose additive models is an important element of a CRA." [FN7: Draft Principles for Cumulative Risk Assessment, EPA Document# EPA-740-P-23-001, Feb. 2023 United States Office of Chemical Safety and Environmental Protection Agency, Pollution Prevention, lines 458-460.]

These four additional PFAS are not toxicologically similar, so EPA grouping them under the MCL proposed rulemaking is inconsistent with how EPA would group chemicals under TSCA and CERCLA.

In light of the evidence that critical health endpoints for individual PFAS, including those listed under the HI approach in the proposed rulemaking, are unique and diverse the assumption of dose additivity is not valid and therefore the use of the Hazard Index as a risk management approach is not appropriate.

Feel free to contact me regarding these comments.

Respectfully submitted,

Giffe Johnson, PhD

Program Manager, Chemical Management and Health Effects

NCASI

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

<u>New York State Department of Health (NYS DOH) (Doc. #1677, SBC-044964)</u>

Grouping PFAS indiscriminately without considering toxic endpoint, mechanism of action or structural similarity is not necessarily the best precedent for EPA to take. We note that EPA's Science Advisory Board's (SAB) review of a mixtures framework for PFAS was in the context of the general hazard index approach (involving different reference value health endpoints) being an initial screening tool that would require further evaluation, rather than a regulatory tool for national drinking water standards (Final SAB Report, August 22, 2022 response to Charge Question #2, page 91). EPA needs to carefully evaluate the proposed hazard index approach both for scientific merit and regulatory precedent. There have been a variety of other PFAS grouping approaches taken in risk assessment and regulatory contexts including a proposed rulemaking

package in New York State in which PFAS were grouped on endpoint and structural grounds. We encourage EPA to reconsider how the critically important issue of PFAS mixtures should be addressed within a regulatory context.

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

Clean Air Council, et al. (Doc. #1731, SBC-043881)

b. The HI method proposed for PFHxS, HFPO–DA, PFNA, and PFBS is effective and better protects public health than individual MCLs.

The adverse health effects of these four compounds are well documented, as discussed for example in the proposed NPDWR [FN50: 88 Fed. Reg. 18638.]. However, unlike PFOA and PFOS, where their carcinogenic nature requires setting their MCLG at 0.0 ppt (the health-based goal, as opposed to the proposed enforceable 4.0 ppt MCI for PFOA and PFOS discussed in the previous sections), PFHxS, HFPO–DA, PFNA, and PFBS have not been classified as cancer-causing. As a result, there is some variability—which could be large—in the determination of their maximal safe level, as shown for example in the Table below:

[Table: see docket ID EPA-HQ-OW-2022-0114-1731]

Accordingly, Commenters ask that EPA continue reviewing data regarding the health effects of these compounds, and adjust the HBWC values as better understanding becomes available.

Addressing the additive effects of different PFAS is also crucial for protecting public health. As discussed in a recent EPA analysis, these compounds comply with EPA's definition of dose-additivity, which concludes that "PFOA and PFOS, as well as other PFAS with linear or branched alkyl or alkyl ether chains and sulfonic or carboxylic acid functional groups, share common toxicological impacts of exposure on multiple cellular receptors, tissues, life stages, and species (ATSDR, 2021; EFSA et al., 2018, 2020)." [FN54: EPA, Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS) 23 (Nov. 2021), available at https://sab.epa.gov/ords/sab/f?p=100:18:16490947993:::RP,18:P18_ID:2601, (emphasis added).] Accounting for the adverse health effects of mixtures of these compounds is essential, in particular since the probability of co-occurrence is high. For example, in the Pennsylvania drinking water sampling study approximately 70% of samples containing PFNA also contained at least one other PFAs species that is not PFOA or PFOS.

Some states approached the issue of dose-additivity by requiring that the sum of several PFAS species be below a certain value. For example, Massachusetts set a maximum of 20 ppt for the sum of PFOS, PFOA, PFHxS, PFNA, PFHpA and PFDA [FN55: MassDEP, Per- and Polyfluoroalkyl Substances (PFAS), https://www.mass.gov/info-details/per-and-polyfluoroalkyl-substances-pfas#drinking-water-standards-and-health-information- (last visited May 24, 2023).] Using this approach, however, neglects the differences in health impacts of the compounds. For

example, as can be seen in the Table, 10 ppt of PFNA are clearly harmful to public health, although PFBS at these levels will not likely have a large impact.

Therefore, the methodology of HI proposed by the EPA is an optimization that accounts for both dose-additivity, and the individual hazard posed by each of the four PFAS compounds: Like an MCL, exceeding the HBWC for an individual species (which would lead to an HI >1) would require water treatment in the same way as would an individually set MCL. However, additivity is accounted for in samples where several compounds are present at values that are below the individual HBWC but where HI >1, which indicates harmful effects of the total PFAS exposure and would similarly require water treatment.

Commenters strongly support the HI approach; However, HBWC values should be reviewed and adjusted to reflect the evolving understanding of the effects of these compounds on human health. Also, as understanding of the adverse health effects of other PFAS species becomes more clear, these should be added to the HI.

EPA Response: This commenter supports the EPA's conclusion about dose additivity and use of the Hazard Index approach. For the EPA response to the comment asking that the EPA continue reviewing data regarding the health effects of these compounds and adjust the HBWC values as better understanding becomes available, please see sections 4.3.1 and 4.3.2 of this *Response to Comments* document. For the EPA response to comments on the addition of other PFAS to the Hazard Index, see section 4.3.5 of the EPA response in this *Response to Comments* document.

Florida Section American Water Works Association - Water Utility Council (FSAWWA WUC) (Doc. #1737, SBC-044492)

The Florida Water Sector does not support the EPA' s Hazard Index as a MCLG and MCL. This tool is being misapplied as a NPDWR. In addition, the rationale and framework is too complex to us yet alone for the communities we are privileged to serve. For example, the scale difference between the Health Based Water Concentration (HBWCs) for PFBS (2000 parts per trillion, ppt) and the other three compounds (9.0 ppt for PFHxS, 10.0 ppt for HFPO-DA; 10.0 ppt for PFNA) seems inappropriate. It is also our understanding from American Water Works Association, the health endpoints are not the same for each compound which EPA states in the proposed rule their Scientific Advisory Board advised them to be necessary (Executive Summary, paragraph 6).

EPA Response: For the EPA response to comments about toxicity reference values based on different endpoints for the four PFAS, please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document. Please also see section 1.2 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045559)

Additionally, the agency's proposed drinking water standard for the mixture of PFHxS, PFNA, HFPO-DA, and PFBS poses several issues that must be addressed prior to further action. As discussed above, the underlying data to support a regulatory determination is insufficient and likely suggests that regulation does not represent meaningful opportunity to protect public health. The agency's approach to using a general hazard index with multiple health outcomes lacks support from risk assessment guidance and professionals (ATSDR, 2018; ATSDR, 2022; EPA, 1986; EPA, 2000; SAB, 2022).

EPA Response: For the EPA response to comments that the proposed regulation does not represent meaningful opportunity to protect public health, please see section 3 of this *Response to Comments* document. For the EPA response to comments about the use of a general Hazard Index based on different health outcomes, see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045606)

In addition, ATSDR and EPA guidance on risk assessment for mixtures recommends against the use of a common mode of action when using a hazard index. ATSDR's Framework for Assessing Health Impacts of Multiple Chemicals and Other Stressors notes that the hazard index method is most appropriately "applied to components that cause the same effect by the same mechanism or mode of action" but "may be applied to components with different target organs as a screening measure" (ATSDR, 2018). ATSDR's Public Health Assessment Guidance Manual indicates that when "the health guideline for each contaminant is based on different target organs, health assessors will need to calculate a target-organ-specific HQ [hazard quotient] for each contaminant" (ATSDR, 2022). Both ATSDR guidance and EPA's own guidance for risk assessment of mixtures clearly indicates that the use of critical effects from multiple tissues in a hazard index is generally inappropriate, specifically noting that the index requires "similarity in target organ" (EPA, 1986). In fact, the guidance states that "because the hazard index is ed to a specific effect, the underlying data should be on that effect." As part of this guidance, the agency recommends that target organ toxicity doses as opposed to a critical effect dose, which is what is proposed in this action.

Detailed comments and recommendations on the proposed hazard index approach for PFNA, PFHxS, HFPO-DA, and PFBS were prepared for AWWA by Ramboll US Consulting and can be found in Appendix A of these comments.

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045593)

Equally importantly, EPA's proposed approach to using the general hazard index is significantly flawed and is not supported by federal agency guidance nor recommendations from the Science Advisory Board (SAB) (ATSDR, 2018; ATSDR, 2022; EPA, 1986; EPA, 2000; SAB, 2022),

which collectively recommend that a common health outcome should be used as the basis for a hazard index in this context.

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-044826)

For the other four PFAS – HFPO-DA, PFHXS, PFNA, and PBFS – EPA proposes to establish health-based water concentrations (HBWCs) generated from studies in laboratory animal studies suggesting adverse effects in different target organs. The proposal to combine these disparate effects into a single HI assumes a common toxic endpoint and is inconsistent with Agency guidance and with accepted scientific practice, as well as the recommendations of peer reviewers. All of the values developed by EPA assume a relative source contribution (RSC) of 20 percent, despite the fact that PFOA, PFOS, PFHxS, and PFNA have been out of commerce for several years and available evidence suggests a significant decline in exposure.

EPA Response: For the EPA response to comments about a Hazard Index based on different adverse effects, please see sections 4.3.1 and 4.3.2 of this *Response to Comments* document. For the EPA response to comments about RSC derivation, please see section 4.3.3 of the EPA response in this *Response to Comments* document. Additionally, the commenter implied that the RSCs for PFOA, PFOS, PFHxS, and PFNA should not be 20 percent because these chemicals have been "out of commerce" for several years and evidence suggests a decline in exposure. The EPA disagrees. The unique physical and chemical properties that make some PFAS, including PFOA, PFOS, PFNA, and PFHxS, highly stable and resistant to degradation in the environment and human body, resulting in their colloquial name of "forever chemicals," indicates that exposure to these chemicals will continue regardless of their status of use in commerce. For example, PFOA and PFOS continue to be detected in environmental media (e.g., drinking water) as well as people's blood despite having been phased out of production years ago (the primary U.S. manufacturer of PFOS voluntarily phased out PFOS production by 2002 and in 2006; eight major PFOA manufacturers voluntarily agreed to phase out PFOA production by 2015).

The Chemours Company FC, LLC (Doc. #1845, SBC-046063)

2 The overall weight of the evidence does not support grouping these specific four PFAS.

The four PFAS in EPA's proposed HI MCLG consist of a mixture of short and long-chain carboxylated and sulfonated compounds. Recently, several research groups have demonstrated the importance of considering the chemical structures of PFAS when grouping PFAS together, as modes of action and toxicological profiles differ by chain length (i.e., short- versus long-chain) and functional groups (i.e., sulfonate or carboxylate) (Nielsen et al. 2022, Rericha et al. 2022, Goodrum et al. 2021, Colnot and Dekant 2022). Except for PFBS and PFHxS, the toxicity values developed for each PFAS in EPA's proposed HI MCLG are based on different endpoints (i.e.,

liver, thyroid or developmental effects). In addition, pharmacokinetic properties (e.g., serum elimination half-lives) and potential for bioaccumulation also differ between PFAS and should be considered when developing approaches for mixtures. For example, the serum and urine elimination half- lives for HFPO-DA in mammals are on the order of hours (Gannon et al. 2016), whereas the serum elimination half-life for PFBS in humans is on the order of days (Olsen et al. 2009) and urine elimination half-lives for PFHxS and PFNA are on the order of years (Zhang et al. 2013). Important toxicological differences exist between HFPO-DA, PFBS, PFNA, and PFHxS, therefore, application of EPA's general HI approach for these four PFAS is not appropriate based on the best available science.

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document. Additionally, in response to the commenter's assertion that pharmacokinetic properties should be considered, this is indeed accounted for in human health assessments and a given PFAS RfD does consider toxicokinetic differences. Specifically, toxicokinetic data such as clearance, plasma or serum half-life, and volume of distribution between experimental animals and humans are leveraged to calculate dosimetric adjustment factors (DAFs), which are used to adjust animal points of departure (PODs) to human equivalent PODs. These adjusted PODs are then used as the basis for RfD derivation. The four PFAS in the Hazard Index MCLG are "toxicologically similar" (see Tables 1, 2, and 3 and section 4.3.1 of the EPA response in this *Response to Comments* document).

GFL Environmental (Doc. #1648, SBC-043221)

Additional Technical Comments on the Proposed NPDWR

Based on our understanding of the HI approach as discussed with our consulting experts, regulating PFHxS, PFNA, PFBS, and GenX with this approach deviates from EPA's own standard practice for establishing MCLs and is not a scientifically sound approach for the following reasons:

• The HI approach is simplified and does not consider health effects on common organs. EPA's own risk assessment protocol (EPA, 2000) recommends summing only the chemical-specific hazards according to toxicological similarity (e.g., the same target organs or systems) because the toxicological effects associated with exposure to multiple chemicals, often through different exposure pathways, may not be additive.

• For health reference values, EPA relies on Health-Based Water Concentrations (HBWCs). EPA uses their Human Health Toxicity Assessments for GenX and PFBS but does not have published human health toxicity assessments for PFHxS and PFNA; EPA relies on Agency for Toxic Substances and Disease Registry (ATSDR) Minimum Risk Levels (MRLs) for these compounds. Per ATSDR, MRLs are screening levels and are not designed or intended to be used as public water standards (ATSDR, November 2018). EPA Human Health Toxicity Assessments have not been generated for PFHxS and PFNA and until they are, or more independent health hazard

information is adequately assessed by EPA, we propose that these chemicals should not be considered under the NPDWR.

• The HI approach is complex (i.e., it is not a value-to-value comparison) and will be difficult to communicate to the general public through publicly facing data portals.

EPA Response: For the EPA response to comments about the Hazard Index based on toxicity reference values for different adverse effects, please see section 4.3.2 of the EPA response in this *Response to Comments* document. For the EPA response to comments about the use of ATSDR minimal risk levels, please see section 4.3.3 of the EPA response in this *Response to Comments* document. For responses related to risk communication, see sections 1.2, 5.2.1, and 5.3.1 of the EPA response in this *Response to Comments* document.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043649)

5) Regulatory Unreasonableness and Continued Uncertainty

1. Hazard Index (HI) approach assumes that the impact of respective PFAS compounds relative to their relative disparate health effect endpoints (i.e., in this case: thyroid, liver, and developmental) are additive.

One limitation of the HI is that it does not consider the possibility of toxicological synergies or potentiation occurring as a result of multiple PFAS species being present in the sample at once. The HI is based on the assumption that "the dose response of multiple chemicals causing a common toxicological effect will follow dose addition models. Dose addition models assume that chemicals behave as if they were dilutions or concentrations of one another" (Price 2023). The HI is also unable to quantitatively predict the probability of specific adverse effects as all are combined into a single ratio (Price 2023).

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-052945)

• In the document titled Maximum Contaminant Level Goal (MCLG) Summary Document for a Mixture of Four Per- and Polyfluoroalkyl Substances (PFAS): HFPO-DA and its Ammonium Salt (also known as GenX Chemicals), PFBS, PBNA, and PFHxS, EPA states that the HBWCs for the four PFAS included in the HI MCL are based on the following non-cancer health effects: liver effects for GenX, thyroid effects for PFBS, developmental effects for PFNA, and thyroid effects for PFHxS. DEP concedes that a combined MCL may be most effective for implementation for PFAS with non-cancer health effects, but questions making assumptions about additive effects based on different health endpoints. In the EPA Science Advisory Board's (SAB) Review of EPA's Analyses to Support EPA 's National Primary Drinking Water Rulemaking for PFAS, the SAB stated that when health endpoints of a group of compounds is similar, the HI is "a reasonable approach for estimating the potential aggregate health hazards

associated with the occurrence of chemical mixtures in environmental media." However, as noted, the health endpoints for the four PFAS included in the HI are different, with the exception that PFHxS and PFBS both have thyroid effects. Therefore, DEP questions whether it is appropriate to use the HI approach to regulate these four PFAS.

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-053349)

While EPA notes it received a favorable review for developing the mixtures assessment approaches,[FN65: U.S. EPA. Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS). 2023, EPA–822–P–23–003, at page 4, available at: https://www.epa.gov/system/files/documents/202303/PFAS%20Mix%20Framework%20Public%20Review%20Draft%2009%20March%202023.pdf.] it concedes that the favorable review was for approaches "that rely on a health protective assumption of dose additivity based on a common health outcome, instead of a common mode of action (MOA)." [FN66: Id.] In this proposed rule, however, EPA is not applying a framework that relies on a common health outcome or a common mode of action. For the four PFAS, EPA is mixing and matching distinct endpoints. As a critical effect, EPA is relying on the thyroid endpoint for PFHxS and PFBS, bodyweight changes for PFNA, and liver lesions for HFPO-DA.

This approach, which combines disparate endpoints, appears to be unprecedented in a regulatory action. In its report to EPA, the SAB stated: "In general, the screening level Hazard Index (HI) approach, in which Reference Values (RfVs) for the mixture components are used regardless of the effect on which the RfVs are based, is appropriate for initial screening of whether exposure to a mixture of PFAS poses a potential risk that should be further evaluated." [FN67: U.S. EPA. Transmittal of the Science Advisory Board Report titled, ''Review of EPA's Analyses to Support EPA's National Primary Drinking Water Rulemaking for PFAS.'' EPA–22–008, 202, at page 92, available at: https://sab.epa.gov/ords/sab/f?p=114:12:15255596377846.] The approach EPA proposes as an MCL, in the words of the SAB, is an approach for "initial screening." And if potential risks are seen, they should be "further evaluated."

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

Ramboll US Consulting (Doc. #3072-55, SBC-046372)

Good afternoon. My name is Harvey Clewell, and I'm a principal consultant at Ramboll US Consulting. I've been conducting research on the pharmacokinetics mode of action of perfluoroalkyl substances for more than 20 years. I'm currently serving as a consultant of the American Water Works Association, but the opinions expressed today are my own. Over the last 30 years, I've assisted EPA on risk assessments for a variety of compounds, serving on the EPA's

fit for scientific advisory panel, EPA's scientific advisory board, and an external peer reviewer for EPA guidelines. I believe that the approaches used in the PFAS National Primary Drinking Water Regulation represent a return to the risk assessment process used in the 1970s and 80s when highly conservative default approaches were uniformly applied to all chemicals. However, in the 1990s under the leadership of William Farland, the EPA began the development of a new approach for conducting risk assessments that was based on a chemical's mode of action. In the current PFAS assessments, consideration of mode of action information to support the evaluation of studies and make qualitative decisions about the most appropriate risk assessment approach is completely inadequate. I was appalled to find that the EPA is proposing to use a hazard index approach for regulation of drinking water concentrations of four PFAS based on critical effects that are based on different endpoints and different target tissues. They attempt to defend this approach using supporting statements that are both inaccurate and contradictory. For example, they try to make an argument for a common mode of action that the diverse effects of various PFAS are all associated with a "common disruption of cellular signaling," while at the same time they indicate that it's necessary to use an approach based on common outcome rather than common mode of action due to the inadequate mode of action information on some PFAS. Inexplicably, the EPA then concludes that the inadequate mode of action data supports the hazard index approach that they use, which was based on different endpoints and different issues, not a common outcome. However, the use of hazard index based on a combination of endpoints for multiple target issues is not supported by any National Risk Assessment Agency except for the use in preliminary screening. The EPA risk assessment forum 2001 mixtures guidance states, "because the hazard index is tied to a specific effect, the underlying data should be on that effect. Substituting data on the critical effect introduces an unknown degree of conservatism so that the hazard index is inflated by an unknown amount."

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045647)

2. Comments on the Hazard Index Approach

USEPA has proposed the use of a General HI approach for regulation of drinking water concentrations of four PFAS: PFNA, PFHxS, PFBS, and GenX (USEPA 2023g, p.8-18). However, rather than following the recommendation of the SAB (USEPA 2022a) to conduct the assessment on the basis of common outcome, the Hazard Index for these 4 compounds are calculated using critical effects (RfDs or MRLs) that are based on different endpoints and target tissues:

• PFNA: Delayed development in mouse offspring.

• PFHxS: Thyroid follicular epithelial hypertrophy/hyperplasia in parental male rats.

• PFBS: Decreased thyroxine in mouse offspring.

• GenX: Liver toxicity in female rat dams.

USEPA attempts to defend this approach using arguments that are inaccurate and contradictory. Initially, USEPA tries to make a broad claim that the diverse effects of PFAS are all associated with a common mechanism involving disruption of cellular signaling:

"PFAS, including HFPO-DA, PFBS, PFNA, and PFHxS, disrupt signaling of multiple biological pathways resulting in common adverse effects on several biological systems and functions, including thyroid hormone levels, lipid synthesis and metabolism, development, and immune and liver function (ATSDR 2021; EFSA 2018, 2020; USEPA 2022c)." (USEPA 2023g, p.2)

However, the USEPA suggestion that PFAS causes common disruption of biological pathway signaling that results in common adverse effects is essentially an argument for a common mode of action. This argument is difficult to support, given the agency's determination that information to support a common mode of action for PFAS is inadequate:

"Because PFAS are an emerging chemical class of note for toxicological evaluations and human health risk assessment, mode of action (MOA) data may be limited or not available for many PFAS." (USEPA 2023g, p.3).

Moreover, in contradiction to the USEPA suggestion of a common mode of action across all PFAS, the agency concluded in the USEPA Toxicity Assessment for GenX (USEPA 2021a), one of the 4 chemicals included in the HI, that the liver effects of GenX are not consistent with there being a common mode of action for all PFAS:

"Although there is evidence for a PPARα MOA in the liver, particularly in the highdose groups in the available studies, data indicate that liver toxicity extends beyond a single PPARα-based MOA." (USEPA 2021a, p.84).

USEPA then makes a case for an assumption of dose additivity based on common outcome rather than common mode of action (USEPA 2023g, p.3), citing the USEPA (2000) mixtures guidance. Inexplicably, the USEPA applied a General HI approach across different outcomes for each chemical, apparently based on their assertion of a common mode of action (above), and despite the fact that the multi-outcome approach clearly ignores the recommendation of the SAB (USEPA 2022a). It is also inconsistent with existing USEPA guidelines.

USEPA Mixtures Guidance (1986) does not support the use of dissimilar effects in a Hazard Index: "Since the assumption of dose addition is most properly applied to compounds that induce the same effect by similar modes of action, a separate hazard index should be generated for each end point of concern. Dose addition for dissimilar effects does not have strong scientific support, and, if done, should be justified on a case-by-case basis in terms of biological plausibility." (USEPA 1986, p.9)

The USEPA Risk Assessment Forum (2000) Mixtures Guidance clearly indicates that the use of critical effects from multiple tissues in a Hazard Index is generally inappropriate. The guidance describes the HI method only in terms of similarity in target organ:

"The Hazard Index method has weaker assumptions and data requirements, is more generally applicable, and has more uncertainty in the resulting assessment. Instead of requiring knowledge of similar mode of action, the Hazard Index method requires only similarity in target organ." (USEPA 2000, p.71)

"One of the key desirable features is the constraint to use only data on the effect of concern. Because the Hazard Index is tied to a specific effect, the underlying data should be on that effect. Substituting data on the critical effect introduces an unknown degree of conservatism, so that the Hazard Index is inflated by an unknown amount." (USEPA 2000, p.85)

"The use of an acceptable level in the relative toxicity scaling factor (e.g. 1/RfD) may be overly health protective in that the RfD (or RfC) is based on the critical effect, defined as the toxic effect occurring at the lowest dose. When the Hazard Index is calculated for some different, less sensitive effect, the RfD will be too low, so the factor (1/RfD) will overestimate the relative toxicity and the Hazard Index will be too large. One alternative that avoids this critical effect conservatism is to use a toxicity-based exposure level that is specific to the target organ of interest and is derived similarly to an RfD (or RfC). For oral exposures, this value is called the target organ toxicity dose or TTD (Mumtaz et al., 1997)." (USEPA 2000, p.82)

Indeed, the use of a Hazard Index based on the combination of endpoints from multiple target tissues, apart from screening purposes, is not supported by any national risk assessment agency.

It is inconsistent with ATSDR guidance.

The ATSDR (2022) Public Health Assessment Guidance Manual indicates that when "the health guideline for each contaminant is based on different target organs, health assessors will need to calculate a target-organ-specific HQ for each contaminant. These target-organ HQs can now be added together to give a Tier 3 HI based on the same target organ." (ATSDR 2022, p.8)

The ATSDR Framework for Assessing Health Impacts of Multiple Chemicals and Other Stressors (2018) indicates that the use of different target organ toxicities is reserved for screening:

"Because it is based on the assumption of dose additivity, the hazard index method is most appropriately applied to components that cause the same effect by the same mechanism or mode of action. In practice, it may be applied to components with different target organs as a screening measure." (ATSDR 2018, p.43)

USEPA (2023g) does not provide any justification for failing to apply the Target-organ Toxicity Dose (TTD) methodology that ATSDR has developed specifically to address situations where there is an overlap in effects across a mixture of chemicals, but where the critical effects are different: "A Target-organ Toxicity Dose (TTD) for each end point of concern is calculated using appropriate MRL (or RfD) methodology, and then used in estimating the end-point specific HQs and hazard indices." (ATSDR 2018, p.45)

Use of the ATSDR methodology is particularly important in the case of this NPDWR, since the General HI used by the agency is based on the critical (lowest) effect for each chemical, regardless of target tissue. As pointed out by ATSDR, a HI based on TTDs will certainly be higher than one based on the General HI, indicating that the currently proposed General HI approach is overly conservative.

The draft mixtures framework (USEPA 2021b) referred to the HI based on multiple target tissues as a "Screening-Level HI" to differentiate it from a Target Organ Specific Hazard Index (TOSHI), which they indicated would be more consistent with the USEPA (2000) mixtures guidelines. The SAB specifically supported the USEPA Framework's use of the TOSHI rather than the Screening Level HI:

"The SAB supports dose additivity based on a common outcome, instead of a common mode of action as a health protective default assumption and does not propose another default approach." (USEPA 2022a, p.90)

However, the SAB indicated that the agency should avoid referring to the multiple target tissue HI approach as a "Screening-Level HI", to avoid the appearance of disparaging the work of states that have been using it in their regulations:

"Methods analogous to those classified by USEPA as 'Screening Level' or 'Tier 1' in the framework are potentially being used by states in a decision-making capacity. Issuance of this framework without recognition of that fact may create confusion for public water supplies and risk communication challenges for the public." (USEPA 2022a, p.3-94)

In response to this SAB concern, the revised Framework (USEPA 2023h) refers to the Screening Level HI as a "General HI". USEPA then applied the General HI approach rather than the TOSHI approach in deriving the MCLG for mixtures of 4 PFAS (USEPA 2023g). However, as pointed out above, the USEPA SAB (2022a) had clearly indicated that the USEPA should base their assessment on common outcome, which would require the use of the TOSHI approach.

2.1 Conclusions and Recommendations

• The proposed use of a HI based on different target organs or endpoints for estimation of a regulatory value has no support in existing agency guidelines or those of other national and international authoritative bodies.

• The agency should delay promulgating a HI-based assessment until they have developed the necessary Target Tissue Doses (TTDs) to support the use of the TOSHI approach.

• The TTDs can readily be derived using the existing ATSDR methodology (ATSDR 2018).

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document. In response to this comment, it is important to note a critical nuance to the Hazard Index variants, particularly in the context of application under SDWA. The general Hazard Index, selected for application to the four specified PFAS under this NPDWR, entails calculation of hazard quotients (HQs) using each chemical's RfD regardless of similarity in

critical effect. Application of the TOSHI (HI_{TO}) or a Hazard Index that uses Target Organ Toxicity-Dose (HI_{TTD}) would be less likely than the general Hazard Index to offer health protection against all potential effects.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-052955)

In table 42 of the preamble, EPA details the health outcomes associated with the PFAS compounds. EPA's reasoning for grouping these chemicals together was that they had additive health impacts. Cleveland Water seeks further clarification on this claim, and recommends EPA consider grouping these, and any future PFAS chemicals, based on similar health endpoints with the greatest support from data and science. The only row that has indication of potential health effects of all these four PFAS is birth weight, but two of the four chemicals have the subscript "5" and the chart indicates that, "evidence of the relationship between PFAS compound and the health outcome is not conclusive."

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-053382)

AMWA seeks further evidence on EPA's claim that HI PFAS have additive adverse health effects and recommends EPA consider grouping these, and any future PFAS chemicals, based on similar health endpoints with the greatest support from data and science. EPA's reasoning for grouping these chemicals was that they had additive health impacts. In Table 42 of the preamble, EPA details the health outcomes associated with the HI PFAS compounds. The only row that indicates the potential health effects of all four PFAS is birth weight, but two of the four chemicals have the subscript "5" which signifies that "evidence of the relationship between PFAS compound and the health outcome is not conclusive."

EPA Response: Please see section 4.3.1 of the EPA response in this *Response to Comments* document.

4.3.2 Hazard Index Approach

Summary of Major Public Comments and EPA Responses

Many commenters supported the EPA's proposal to regulate mixtures of PFAS and agreed with the EPA's scientific conclusions about PFAS dose additivity and the agency's use of the Hazard Index approach to develop an MCLG for mixtures of PFHxS, PFNA, HFPO-DA, and/or PFBS. Many commenters opposed the EPA's conclusion about dose additivity and the use of the Hazard Index approach to regulate co-occurring PFAS. Some commenters disagreed with the use of toxicity reference values based on different adverse effects to derive the HBWCs for the four PFAS to develop the Hazard Index MCLG. A few commenters questioned the EPA's use of the general Hazard Index approach and suggested alternative approaches such as development of

individual MCLGs or a target organ-specific hazard index (TOSHI). Some commenters claimed that the EPA did not appropriately seek review from the Science Advisory Board (SAB), particularly on the application of the general Hazard Index as an approach to regulate PFAS mixtures under SDWA. The EPA response to these issues, as well as others expressed by individual commenters, are described in further detail below. For comments and the EPA responses on dose additivity and toxicological similarity, please see section 4.3.1 of the EPA response in this *Response to Comments* document.

Background on the use of the general Hazard Index approach to develop an MCLG for mixtures of four PFAS. The EPA's final determination that mixtures of the four PFAS "may have an adverse effect on the health of persons" is based on the health-protective conclusion that chemicals that are toxicologically similar (i.e., have similar observed adverse health effects, regardless of potency differences) following individual exposure should be assumed to act in a dose-additive manner when in a mixture unless data demonstrate otherwise (USEPA, 2024i; see discussion of dose additivity and toxicological similarity in section 4.3.1 of this *Response to Comments* document, and also sections II and IV.B of the preamble). The scientific record shows that these four PFAS—PFHxS, PFNA, HFPO-DA, and PFBS—are toxicologically similar (see USEPA (2024h) and section IV.B of the preamble). Therefore, these four PFAS are assumed to act in a dose-additive manner when present in a mixture. This means that where drinking water contains any combination of two or more of the four PFAS that are the subject of this action—PFHxS, PFNA, HFPO-DA, and PFBS—the hazard associated with each PFAS in the mixture must be added together to determine whether the mixture exceeds a level of public health concern.

The SDWA requires the agency to establish a health-based MCLG set at "a level at which no known or anticipated adverse effects on the health of persons occur and which allows for an adequate margin of safety." The MCLG "incorporates a margin of safety to reflect scientific uncertainty and, in some cases, the particular susceptibility of some groups (e.g., children) within the general population." S. Rep. No. 169, 104th Cong., 1st Sess. (1995) at 3. In the context of this NPDWR, the general Hazard Index is the approach used to determine if a mixture of two or more of four PFAS in drinking water—PFHxS, PFNA, HFPO-DA, and PFBS—exceeds the level of health concern with a margin of safety. A general Hazard Index equal to 1 is the MCLG for any mixture of those four PFAS.

Based on the scientific record, each of these four PFAS has an HBWC, which is set at the level below which adverse effects are not anticipated to occur and allows for an adequate margin of safety (see USEPA (2024h) and section IV.B. of the preamble). The general Hazard Index approach accounts for the measured drinking water concentration of each of the four PFAS in the mixture, and the toxicity (represented by the HBWC) of each of the four PFAS. The general Hazard Index is derived by first calculating the ratio of the measured concentration of each of the four PFAS to its toxicity (the HBWC) to yield a "HQ" for each of the four PFAS. HQs are then added together to account for the dose-additive health concerns that these PFAS present. Adding the four HQs together yields the general Hazard Index. If the general Hazard Index exceeds 1,

then the hazard from the combined amounts of the four PFAS present together in drinking water exceeds a level of public health concern.

The EPA has determined that in the context of SDWA, the general Hazard Index is an appropriate methodology for determining the level at and below which there are no known or anticipated adverse human health effects with an adequate margin of safety with respect to certain PFAS mixtures in drinking water. The general Hazard Index approach is the most practical approach for establishing an MCLG for PFAS mixtures that meets the statutory requirements outlined in Section 1412(b)(1)(A) of SDWA. As noted above, the general Hazard Index assesses the exposure level of each component PFAS relative to its HBWC, which is based on the most sensitive known adverse health effect (based on the weight of evidence) and considers sensitive population(s) and life stage(s) as well as potential exposure sources beyond drinking water. The general Hazard Index also accounts for dose-additive health concerns by summing the hazard contributions from each mixture component. In this way, the general Hazard Index approach ensures that mixtures of two or more of these four PFAS are not exceeding the level below which there are no known or anticipated adverse health effects and allows for an adequate margin of safety.

Some commenters expressed support for the EPA's proposed general Hazard Index approach to regulating mixtures of two or more of the four PFAS in drinking water. The commenters also stated that occurrence and co-occurrence of these four PFAS in public water systems (PWSs), as well as individual and dose-additive effects of these PFAS, justify the general Hazard Index approach. The EPA agrees that the general Hazard Index approach is the most scientifically sound and health-protective approach to deriving a PFAS mixtures MCLG which considers both their dose-additive health concerns and co-occurrence in drinking water.

Consideration of the different mixture assessment approaches, and selection of the general Hazard Index approach. In selecting an approach to develop the MCLG for mixtures of two or more of four PFAS—PFHxS, PFNA, HFPO-DA, and PFBS—the EPA followed its *Guidelines for the Health Risk Assessment of Chemical Mixtures* (USEPA, 1986), *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (USEPA, 2000b, and *Risk Assessment Guidance for Superfund* (e.g., USEPA, 1991c). As described below and in USEPA (2024h), the EPA first considered whether data were available for the whole mixture or a "sufficiently similar" mixture, per agency guidance (USEPA, 1986; 2000b), and then considered several mixture component-based assessment methods (USEPA, 2024i), ultimately selecting the general Hazard Index approach for PFAS mixture MCLG derivation (USEPA, 2024h).

The EPA's guidance documents (USEPA, 1986; USEPA, 1991c; USEPA, 2000b) propose a hierarchy of mixtures assessment approaches, with the preferred approach being evaluation of health risk using hazard and dose-response data for a specific whole mixture of concern, or alternatively, a "sufficiently similar" mixture. Whole-mixture data are rare; there are often many chemical combinations and proportions in the environment (e.g., parent chemicals, metabolites, and/or abiotic degradants), introducing a level of complexity that complicates evaluation and characterization. The exponential diversity of PFAS co-occurring in different component

combinations and proportions makes whole-mixture evaluations complex and unfeasible. Due to differing fate and transport properties, biotic (metabolism) and abiotic (degradation) processes, pH, ultraviolet radiation, media temperature, and so on, chemicals commonly co-occur in the environment in an array of parent species, metabolites, and/or degradants, making characterization and evaluation of any given mixture complicated. In controlled experimental study designs, whole mixtures can be assembled with defined component membership and proportions, but the relevance of toxicity associated with exposure to a defined mixture in a laboratory setting may not be translatable to environmental mixtures of different component combinations and proportions across time and space in environmental media. The complexities associated with the diversity of PFAS co-occurring in different component proportions (see USEPA, 2024j) make evaluating each unique whole mixture of PFAS intractable. This is why component-based mixture assessment approaches are considered particularly useful and appropriate for addressing human exposure(s) to mixtures of PFAS (see Sections 5–7 in USEPA (2024i)). For a more detailed discussion on whole-mixture and component-based approaches for PFAS risk assessment, please see the final *PFAS Mixtures Framework* (USEPA, 2024i).

The EPA considered several component-based assessment approaches to develop an MCLG for mixtures of PFHxS, PFNA, HFPO-DA, and/or PFBS under an assumption of dose additivity. The approaches are described in detail in the EPA's *Framework for Estimating Noncancer Health Risks Associated with Mixtures of PFAS* ("PFAS Mixtures Framework," USEPA, 2024i) and include the general Hazard Index , the target organ-specific Hazard Index (TOSHI), the Relative Potency Factor (RPF) approach, and the mixture-BMD approach. As part of the technical support materials for the PFAS NPDWR, the EPA's draft PFAS Mixtures Framework (USEPA, 2021g) was submitted to the SAB for expert review. The SAB supported the EPA's proposed component-based approaches under the assumption of dose additivity in the absence of information to support a conclusion other than dose additivity (please see section 4.3.1 of the EPA response in this *Response to Comments* document). Following the SAB review, the EPA addressed the SAB's recommendations. Then, the EPA solicited public comment on the draft PFAS Mixtures Framework as part of the proposed NPDWR (88 FR 18638; USEPA, 2023e). The EPA evaluated potential component-based mixture assessment options, and ultimately proposed using the general Hazard Index approach as the most appropriate option based on available data and consistent with the statutory definition of MCLG.

Some commenters suggested that the EPA has not followed its guidance (USEPA, 2000b), specifically that the agency did not use a "sufficiently similar mixture" where "components and respective portions exist in approximately the same pattern," and suggested that there has to be consistent co-occurrence of the mixture components. The EPA disagrees with these comments. As described above, although use of data from whole mixtures or "sufficiently similar mixtures" is ideal in a theoretical sense, it is not practical, possible, or necessary for evaluating mixtures of PFAS in drinking water. Instead, the EPA is using the general Hazard Index approach, a longstanding component-based mixtures assessment approach which was endorsed by the SAB in the context of assessing risk associated with exposure to PFAS mixtures in drinking water (USEPA, 2022b), as discussed below. The goal of this component-based mixtures assessment

approach is to approximate what the whole-mixture toxicity would be if the whole mixture could be tested and relies on toxicity information for each individual component in a mixture (USEPA, 2000b). A whole-mixture approach for regulating mixtures of these four PFAS in drinking water is not possible because it would entail developing a single toxicity reference value (e.g., RfD) for one specific mixture of PFHxS, PFNA, HFPO-DA, and PFBS with defined proportions of each PFAS. Toxicity studies are typically conducted with only one test substance to isolate that particular substance's effects on test organisms, and whole-mixture data are exceedingly rare. There are no known whole-mixture studies for PFHxS, PFNA, HFPO-DA, and PFBS, and even if they were available, a toxicity reference value derived from such a study (i.e., a single RfD for a specific mixture of these four PFAS) would only be directly applicable to that specific mixture. Thus, a more flexible approach is necessary—one that considers the potential for the four PFAS to co-occur in different combinations and at different concentrations across time and space. The general Hazard Index approach affords this flexibility; the general Hazard Index indicates risk from exposure to a mixture and is useful to ensure a health-protective MCLG for PFAS mixtures that can be spatially and/or temporally variable. Given the variability of PFAS occurrence in drinking water across the nation (USEPA, 2024j), the general Hazard Index allows the EPA to regulate mixtures of these PFAS in drinking water by taking into account site-specific data at each PWS. HQs for the four different PFAS are expected to differ depending on the actual measured concentrations of each of the four PFAS at each PWS. The general Hazard Index approach thus allows for flexibility beyond a one-size-fits-all approach and is tailored to address risk at each PWS. Furthermore, the EPA's application of the general Hazard Index approach accounts for the dose additivity that was the basis for the EPA's final determination to regulate mixtures of two or more of these PFAS.

The general Hazard Index approach and the TOSHI. Some commenters opposed the EPA's use of a general Hazard Index as opposed to a target organ-specific Hazard Index (TOSHI) and suggested the use of a TOSHI instead. The EPA disagrees with these comments. The use of the general Hazard Index approach to develop an MCLG for mixtures of PFHxS, PFNA, HFPO-DA, and/or PFBS is scientifically sound, supported by external peer review (SAB), consistent with EPA guidance and guidelines (USEPA, 1986; USEPA, 1991c; USEPA, 2000b), and allows for the determination of an MCLG that is consistent with the statutory definition of an MCLG. Specific reasons why the general Hazard Index represents the more health-protective approach over the TOSHI are described below. A few commenters mentioned the RPF approach and agreed with the EPA that the general Hazard Index approach is preferred in this situation. The EPA did not receive comments on the mixture-BMD approach.

The EPA considered the two main types of Hazard Index approaches: 1) the general Hazard Index , which allows for component chemicals in the mixture to have different health effects or endpoints as the basis for their toxicity reference values (e.g., RfDs, minimal risk levels), and 2) the TOSHI, which relies on toxicity reference values based on the same specific target organ or system effects (e.g., effects on the liver or thyroid; effects on developmental or reproductive systems) (USEPA, 2000b). The general Hazard Index approach uses the most health-protective RfD (or minimal risk level) available for each mixture component, irrespective of whether the

RfDs for all mixture components are based on effects in the same target organs or systems. These "overall" RfDs (as they are sometimes called) are protective of all other adverse health effects because they are based on the most sensitive known endpoints as supported by the weight of the evidence. As a result, this approach is protective of all types of toxicity/adverse effects, and thus ensures that the MCLG is the level at and below which there are no known or anticipated adverse human health effects with an adequate margin of safety with respect to certain PFAS mixtures in drinking water.

The TOSHI produces a less health protective indicator of risk than the general Hazard Index because the basis for the mixture component toxicity reference values has been limited to a specific target organ or system effect, which may occur at higher exposure levels than other effects (i.e., be a less sensitive endpoint). In other words, a TOSHI may not be health protective compared to the general Hazard Index if available data for a mixture component show effects in other organs at lower exposure levels compared to the critical effect observed in the target organ used for the TOSHI. Additionally, since a TOSHI relies on toxicity reference values aggregated for the same specific target organ or system endpoint/effect, an absence or lack of data on the specific target organ or system endpoint/effect for a mixture component may result in that component not being adequately accounted for in this approach (thus, underestimating health risk of the mixture). A TOSHI can only be derived for those PFAS for which the same target organ or system endpoint/effect-specific RfDs have been calculated. For example, a TOSHI based on changes in thyroid effects illustrates why the target organ-specific approach underestimates risk in the context of these four PFAS in drinking water. To develop a thyroid effects-based TOSHI for mixtures of these four PFAS, only those PFAS with chronic toxicity reference values based on thyroid effects -- PFHxS (minimal risk level) and PFBS (RfD) – would be included in the TOSHI calculation; HFPO-DA and PFNA have chronic toxicity reference values based on other effects (i.e., liver and developmental effects, respectively) and thus would not be included in a thyroid effects-based TOSHI. Although thyroid effects are not the basis for the RfDs for HFPO-DA and PFNA, studies have shown that these two PFAS significantly affect the thyroid; for example, both have been shown to significantly affect serum thyroid hormone levels (reduced T4, T3) (Conley et al., 2019; NTP, 2019; please see section 4.3.1 of the EPA response in this *Response to Comments* document). According to the Interagency Report to Congress on PFAS, "Multiple studies on diverse species (developing rodents and fish) suggest that some PFAS (e.g., PFOS, PFOA, *PFNA, GenX chemicals*, PFHxS, PFDA, PFBA, PFBS, PFHxA) interfere with thyroid hormone signaling pathways and thyroid homeostasis through various mechanisms, including regulation of hepatic glucuronidation enzymes and deiodinases in the thyroid gland" (emphasis added, United States OSTP, 2023). Therefore, a thyroid-specific Hazard Index that excluded HFPO-DA and PFNA would underestimate the dose additivity concerns for thyroid effects from the total mixture.

The EPA's chemical mixtures guidance supports use of the general Hazard Index.
Many PFAS have data gaps in epidemiological or animal toxicological dose-response information for multiple types of health effects, thus limiting derivation of target organ-specific toxicity reference values; target organ-specific toxicity reference values for the same target for

all four PFAS are not currently available for PFHxS, PFNA, HFPO-DA, and PFBS. The EPA's *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* recognizes the potential for organ- or system-specific data gaps and supports use of overall RfDs in a general Hazard Index approach, stating, "The target organ toxicity dose (TTD) is not a commonly evaluated measure and currently there is no official EPA activity deriving these values, as there is for the RfD and RfC" … "Because of their much wider availability than TTDs, standardized development process including peer review, and official stature, the RfD and RfC are recommended for use in the default procedure for the HI" (USEPA, 2000b). Even if target organ-specific toxicity reference values (TTDs) were available for PFHxS, PFNA, HFPO-DA, and PFBS, the general Hazard Index approach would still be more appropriate for this specific application because it is protective of all adverse health effects rather than just those associated with a specific organ or system, consistent with the statutory definition of MCLG.

The EPA's risk assessment guidance for CERCLA assessments identifies the general Hazard Index approach as a health-protective and simplistic way to assess mixture risk: "Segregation of hazard indices requires identification of the major effects of each chemical including those seen at higher doses than the critical effect (e.g., the chemical may cause liver damage at a dose of 100 mg/kg-day and neurotoxicity at a dose of 250 mg/kg-day). Major effect categories include neurotoxicity, developmental toxicity, reproductive toxicity, immunotoxicity, and adverse effects by target organ (i.e., hepatic, renal, respiratory, cardiovascular, gastrointestinal, hematological, musculoskeletal, and dermal/ocular effects). *Although higher exposure levels may be required to produce adverse health effects other than the critical effect, the RfD can be used as the toxicity value for each effect category as a conservative and simplifying step*" (italics added for emphasis; pg. 8-15 from USEPA (1991c)).

The SAB supported the general Hazard Index approach. The EPA directly asked the SAB about the utility and scientific defensibility of the general Hazard Index approach (in addition to other methods, including TOSHI) during the 2021–2022 review of the EPA's draft *Framework for Estimating Noncancer Health Risks Associated with Mixtures of PFAS*. Specifically, the EPA asked the SAB to "Please provide specific feedback on whether the HI approach is a reasonable methodology for indicating potential risk associated with mixtures of PFAS. If not, please provide an alternative;" and "Please provide specific feedback on whether the proposed HI methodologies in the framework are scientifically supported for PFAS mixture risk assessment" (USEPA, 2022b). In its report (USEPA, 2022b), the SAB stated its support for the general Hazard Index approach:

"In general, the screening level Hazard Index (HI) approach, in which Reference Values (RfVs) for the mixture components are used regardless of the effect on which the RfVs are based, is appropriate for initial screening of whether exposure to a mixture of PFAS poses a potential risk that should be further evaluated. Toxicological studies to inform human health risk assessment are lacking for most members of the large class of PFAS, and mixtures of PFAS that commonly occur in environmental media, overall. For these reasons, the HI methodology is a reasonable approach for estimating the potential aggregate health hazards associated with the occurrence of

chemical mixtures in environmental media. The HI is an approach based on dose dose additivity that has been validated and used by the EPA. The HI does not provide quantitative risk estimates (i.e., probabilities) for mixtures, nor does it provide an estimate of the magnitude of a specific toxicity. This approach is mathematically straightforward and may readily identify mixtures of potential toxicological concern, as well as identify chemicals that drive the toxicity within a given mixture."

The EPA's use of the general Hazard Index under SDWA is well supported and not inconsistent with past application in other contexts. A few commenters stated that it is inappropriate to use the general Hazard Index in the context of a drinking water rule because it is a screening tool. In fact, the EPA initially proposed a tiered approach in its draft PFAS Mixtures Framework (USEPA, 2021g), whereby the general Hazard Index and TOSHI were considered Tier 1 (for screening purposes) and the more refined/data-intensive approaches (RPF and mixture-BMD) were proposed as Tier 2. During its 2021–2022 review of the draft PFAS Mixtures Framework, the SAB was critical of this proposed tiered approach for PFAS due to the paucity of data for these emerging chemicals and urged the EPA to restructure the PFAS Mixtures Framework to eliminate tiering/screening approach. One of the highlighted consensus recommendations from the SAB during its review of the draft PFAS Mixtures Framework was:

The "EPA should consider using a menu-based framework to support selection of fit-for-purpose approaches, rather than a tiered approach as described in the draft Mixtures document. Tiered approaches that require increasingly complex information before reaching a final decision point can be extremely challenging for data-poor chemicals such as PFAS" (USEPA, 2022b).

The SAB recognized the need for regulatory agencies to make decisions in the face of uncertainty to reduce exposures to PFAS. The SAB stated,

"Given the agency's desire to support fit-for-purpose approaches, not every PFAS mixture scenario will be one that warrants a tiered or hierarchical approach. In some instances, *an HI or target-organ-specific hazard indices (TOSHI) might provide enough information for decision-making about PFAS (or other chemicals) contamination in drinking water* (or other media). *Tiered approaches that require increasingly complex information before reaching a final decision point can be extremely challenging for data-poor chemicals such as PFAS. Data gaps identified in a such tiered methodologies could result in a bottleneck through which these chemicals may never emerge*…" (italics added for emphasis; USEPA, 2022b).

Further, the SAB did not say that the Hazard Index use was limited to screening, nor that the agency would or should be prohibited from considering its use in any regulatory or nonregulatory application. Indeed, the SAB concluded that:

"The HI methodology is a reasonable approach for estimating the potential aggregate health hazards associated with the occurrence of chemical mixtures in environmental media. The HI is an approach based on dose additivity (DA) that has been validated and used by the EPA…. This approach is mathematically straightforward and may readily identify mixtures of potential

toxicological concern, as well as identify chemicals that drive the toxicity within a given mixture" (USEPA, 2022b).

In response to SAB comments that were critical of the tiered/screening approach, the EPA restructured the PFAS Mixtures Framework as a data-driven, flexible approach to facilitate PFAS mixtures assessment in various decision contexts (see Section 4.2 and Figure 4-1 in USEPA, 2024i). In the final PFAS Mixtures Framework, the EPA included a discussion of key steps in the framework, including problem formulation and scoping, assembling information, evaluating data objectives, considering the data landscape to select component-based mixture assessment approach(es), and implementing component-based mixture assessment approach(es) (see Section 4.2 in USEPA, 2024i).

The general Hazard Index is a well-established methodology that has been used for several decades in at least one other regulatory context to account for dose additivity in mixtures assessments. The EPA routinely uses the Hazard Index approach to consider the risks from multiple contaminants of concern in the Remedial Investigations and Feasibility Studies for cleanup sites on the Superfund National Priorities List under CERCLA. Noncarcinogenic effects are summed to provide a Hazard Index that is compared to an acceptable index, generally 1. This approach assumes dose additivity in the absence of information on a specific mixture. These assessments of hazards from multiple chemical exposures are important factors to help inform the selection of remedies that are ultimately captured in the Superfund Records of Decision.

The use of the general Hazard Index MCLG as a risk indicator is consistent with SDWA. Some commenters claimed that the general Hazard Index was not appropriate for use in this SDWA context because it is an indication of appreciable risk, rather than an estimate of the concentration of the mixture in water that may result in adverse health outcomes after a specific period of exposure. On the contrary, under the SDWA, the MCLG is set at the level *at and below which* there are no known or anticipated adverse human health effects with an adequate margin of safety. Setting an MCLG at a level that may result in adverse health outcomes after exposure would be inconsistent with this statutory definition.

Relevance of guidance from other programs/agencies/panels. A few commenters stated that that the general Hazard Index approach is not consistent with mixtures guidance developed by other programs/agencies and under other statutes, including the EPA's *Draft Proposed Principles of Cumulative Risk Assessment under the Toxic Substances Control Act (TSCA)* (USEPA, 2023l) and ATSDR's *Framework for Assessing Health Impacts of Multiple Chemicals and Other Stressors* (ATSDR, 2018). The TSCA cumulative risk guidance defines cumulative risk assessment in general (i.e., not specifically for PFAS mixtures) within the requirements of TSCA. In addition, the Hazard Index MCLG for PFAS mixtures and the PFAS Mixtures Framework are not "cumulative risk assessment." Cumulative risk assessment is much broader in terms of the integration across multiple exposure routes/scenarios, and often includes stressors other than chemicals (e.g., physical conditions; microbial risks; nutritional status; socioeconomic factors; etc.) (see further discussion in the EPA's PFAS Mixtures Framework, USEPA, 2024i).

Regarding the ATSDR Framework, that document is a general framework and not specific to PFAS. Additionally, the ATSDR approach is a tiered approach similar to what the EPA originally proposed in its draft PFAS Mixtures Framework (USEPA, 2021g), which was criticized by SAB in the context of PFAS in drinking water (see above).

A few commenters claimed that the EPA's approach was inconsistent with the conclusions of a recent panel of independent experts (Anderson et al., 2022). Commenters mischaracterized the panel's findings by stating that "grouping PFAS together without data supporting common mode of action and potency is inappropriate." The full quote from Anderson et al. (2022) is as follows: "Ideally, PFAS groupings should be based only on common toxic MOAs **and/or target organs. Only those PFAS that affect the same target organ/tissue/system should be grouped** and assessed for dose additive or response additive approaches. Unfortunately, these data are the least likely to be available for the majority of PFAS. Added complexity noted is that individual PFAS are likely to have different MOA/AOP across tissues/organs" (emphasis added). As stated in section 4.3.1 of the EPA response in this *Response to Comments* document, the EPA's mixture assessment approach is based on similar adverse effects due to the absence of MOA data, an approach that was supported by the SAB in its review of the PFAS Mixtures Framework in the context of development of the PFAS NPDWR. The Anderson et al. (2022) panel agrees that grouping PFAS that affect the "same target organ/tissue/system" is supportable (see Fig. 1 in Anderson et al., 2022). These four PFAS affect many of the same target organs/tissues/systems (please see section 4.3.1 of the EPA response in this *Response to Comments* document).

The EPA appropriately sought comments from the SAB. The EPA disagrees with commenters that the agency did not seek adequate consultation from the SAB in the development of the MCLG and NPDWR. SDWA Section 1412(e) requires that the EPA "request comments" from the SAB "prior to proposal" of the MCLG and NPDWR. Consistent with this statutory provision, the EPA began its engagement with the SAB on December 12th, 2021, seeking guidance on several charge questions related to identifying and quantifying the health effects associated with PFOA and PFOS exposure; dose additivity and methods to assess mixtures of PFAS; and the agency's proposed methodology to determine avoided cases of CVD events. The proposed rule was signed on March 14, 2023. As discussed in the proposed rule, the SAB PFAS Review Panel met virtually via a video meeting platform on December 16, 2021, and then had three (3) subsequent meetings on January 4, 6, and 7, 2022 to deliberate on the agency's charge questions, which included a question specifically focused on the utility and scientific defensibility of the general Hazard Index approach in the context of mixtures risk assessment in drinking water. Another virtual meeting was held on May 3, 2022 to discuss the SAB PFAS Review Panel's draft report. Oral and written public comments were considered throughout the advisory process. The SAB provided numerous recommendations to the EPA which can be found in the SAB's final report (USEPA, 2022b). The EPA addressed the SAB's recommendations and described the EPA response to SAB recommendations in its *EPA Response to Final Science Advisory Board Recommendations (August 2022) on Four Draft Support Documents for the EPA's Proposed PFAS National Primary Drinking Water Regulation* (USEPA, 2023d) and also in this *Response to Comments* document which responds to public comments on the proposed

PFAS NPDWR (USEPA, 2023). Further discussion on the EPA consultations and stakeholder engagement activities can be found in section XIII of the preamble.

The agency also disagrees with commenters who contend that the EPA must seek advice from the SAB on all aspects of the MCLG and NPDWR. The statute does not dictate on which scientific issues the EPA must request comment from the SAB but instead states only that the agency must do so before proposal of an MCLG and NPDWR. The EPA disagrees with commenters who suggested that the EPA must go back to the SAB on issues prior to proposal or throughout the rulemaking process. As part of the development of a drinking water rule, the EPA typically considers and evaluates hundreds of scientific issues. SDWA reasonably provides the EPA with the discretion to use its technical expertise to choose which to send to the SAB for comment prior to the proposal. To read the SDWA's SAB comments requirement as broadly as some commenters urge would render compliance with SDWA's two-year proposed rule deadline an impossibility, as it would, among other things, require EPA to complete its complex scientific work before consulting with the SAB and to engage in a never-ending cycle of consultation.

In meeting the statutory mandate to request comment from the SAB, the EPA requests comment on the scientific questions that are the most critical to the EPA's derivation of the proposed MCLG and NPDWR. While the key questions vary with the contaminant at issue and timing of SAB review, they are often focused on issues or products on which there has not been extensive prior peer review and/or that employ novel approaches.[2] In this case, the EPA sought comments on four documents before proposal: *Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) in Drinking Water* (USEPA, 2021b); *Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanesulfonic Acid (PFOS) in Drinking Water* (USEPA, 2021c); *Analysis of Cardiovascular Disease Risk Reduction as a Result of Reduced PFOA and PFOS Exposure in Drinking Water* (USEPA, 2021l); and *Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of PFAS* (USEPA, 2021g). The first three focus on the MCLGs and NPDWRs for PFOA and PFOS, while as discussed elsewhere, the last was critical to the EPA's ability to derive an MCLG and NPDWR for a PFAS mixture. These two areas represent where the proposed PFAS MCLGs and NPDWRs posed critical issues that had not yet been subject to peer review where SAB commentary would be most valuable. In contrast, the ATSDR *Toxicological Profile for Perfluoroalkyls*, which covers 10 PFAS including PFHxS and PFNA, as well as the EPA toxicity assessments for PFBS and HFPO-DA had been externally peer reviewed prior to the SAB review of the EPA's four documents.

[2] For more information on the subsets of issues addressed in EPA's prior requests for comment from the SAB, see, e.g. Arsenic Rule Benefits Analysis: an SAB Review, https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=P1004JZG.txt (focusing SAB review on benefits of regulation, health endpoints, and uncertainties), and Perchlorate - Approaches for Deriving Maximum Contaminant Level Goals for Drinking Water, https://sab.epa.gov/ords/sab/r/sab_apex/sab/advisoryactivitydetail?p18_id=2221&clear=18&session=7288224619303 (SAB review focused on adverse effects during various life stages, approaches for deriving and MCLG, and strengths and limitations of available biomonitoring and epidemiological studies).

The four Hazard Index PFAS have the same or similar effects but with different potencies. Although these four PFAS elicit many of the same or similar adverse health effects, the most sensitive known endpoint for each of the four PFAS is different, and thus the toxicity reference values used to calculate the HBWCs in the general Hazard Index approach are different. Epidemiological and/or experimental animal studies have demonstrated that exposure to PFHxS, PFNA, HFPO-DA, and PFBS individually is associated with many of the same observed adverse health effects (e.g., effects on lipids, as well as developmental, immune, endocrine, and hematologic endpoints; please see section 4.3.1 of the EPA response in this *Response to Comments* document), but with differing potencies for effect(s). In other words, two or more PFAS may elicit the same or similar adverse effects, but at different exposure levels; for example, liver effects are associated with all four PFAS (PFHxS, PFNA, HFPO-DA, and PFBS; please see section 4.3.1 of the EPA response in this *Response to Comments* document) but HFPO-DA is the only one of the four for which liver effects represent the most sensitive known endpoint and serve as the basis for its toxicity reference value (i.e., RfD). The fact that the toxicity reference values (i.e., RfDs or minimal risk levels) for the four PFAS are based on different health endpoints does not mean that the four PFAS are not toxicologically similar; rather, it means that based on the available data, the most sensitive endpoint currently known is different for each of these PFAS. The general Hazard Index approach uses the most health-protective toxicity reference value available for each of the four PFAS to derive HBWCs, irrespective of whether they are based on effects in the same target organs or systems. Since each RfD (or minimal risk level) is based on the most sensitive known endpoint based on the weight of evidence (i.e., toxicity reference value selection is not limited to a specific organ or system), this approach is protective of all other adverse health effects. This approach of allowing for component chemicals in the mixture to have different health effects or endpoints as the basis for their toxicity reference values is consistent with EPA guidance (see examples in USEPA, 1991c; USEPA, 2000b) and was supported by SAB (see below).

A few commenters suggested that because the toxicity reference values for the four PFAS in the general Hazard Index approach are based on different endpoints, the approach is inconsistent with EPA guidance which indicates that the premise of the Hazard Index is dose additivity where the mixture components have similar toxic effects on the same organ or biological system. The EPA disagrees that the EPA's approach is inconsistent with its guidance. As described above and in the EPA Essay Response 4.3.1, these four PFAS do elicit the same or similar adverse health effects on many of the same organs and/or systems. The toxicity reference values for the four PFAS are not all based on the same endpoint because the most sensitive known endpoint is different for each of them. This does not mean that the four PFAS do not share many of the same or similar adverse health effects. Two things are true at the same time: 1) these four PFAS elicit many of the same effects in many of the same organs and systems; 2) the toxicity reference values are based on different effects because although the four PFAS affect many of the same endpoints, they do so at different exposure levels. Please see section 4.3.3 of the EPA response in this *Response to Comments* document for further discussion on HBWCs.

"Grouping" PFAS. Many commenters supported the EPA's interpretation of regulating a mixture as a "contaminant" that consists of a combination of certain PFAS, citing the EPA's broad authority under SDWA to set regulatory standards for groups of related contaminants and the EPA precedent for doing so under other NPDWRs including disinfection byproducts (DBPs; for total trihalomethanes [TTHMs] and the sum of five haloacetic acids [HAA5], (USEPA, 1979; 2006c)), as well as radionuclides (USEPA, 2000c) and polychlorinated biphenyls (PCBs). The EPA also noted some of these examples within the proposed rule. One commenter disagreed that these previous EPA grouping approaches are applicable to mixtures of the four PFAS, noting that TTHMs and HAA5 are byproducts of the disinfection process and are the result of naturally occurring compounds reacting with the disinfectants used in drinking water treatment; thus, their formation cannot be controlled and is dependent on the presence and amount of disinfectant. As a result of these factors, measuring them as a class is required; however, the four PFAS are not byproducts, and the presence of one PFAS does not change the presence of the other PFAS. Moreover, the commenter provided that related to radionuclides, alpha particles are identical regardless of their origination and using this example for PFAS is not supported since the four PFAS are fundamentally different. The EPA disagrees with this commenter. The SDWA definition of contaminant is very broad ("any physical, chemical or biological or radiological substance or matter" (emphasis added)) with no limitations, specific description, or requirement for how it is formed. The statute therefore easily encompasses a mixture, comprised of a combination of PFAS (chemical substances), as itself qualifying as a "contaminant" under SDWA. Moreover, to the extent the mixture is considered a "group," Congress clearly anticipated that the EPA would regulate contaminants by group (see section III.A.2 of the preamble). As a result, even if the PFAS "group" is different than other SDWA regulatory groupings, such a regulation is clearly authorized under the statute. Furthermore, it makes sense to treat these mixtures as a "contaminant" because the four PFAS share similar characteristics: it is substantially likely that they co-occur; the same treatment technologies can be used for their removal; they are measured simultaneously using the same analytical methods; they have shared adverse health effects; and they have similar physical and chemical properties resulting in their environmental persistence. Please see section III.A.2 of the final rule preamble and section 3.2 of the EPA response in this *Response to Comments* document for further information regarding the EPA's authority to regulate mixtures.

Form of MCLG/MCL. A couple of commenters suggested that the EPA set the PFAS mixture MCLG at a set concentration (e.g., 20 ppt). Setting one concentration nationally for all four PFAS combined would not account for the different potencies of the mixture components nor the spatial and temporal variability of PFAS concentrations in drinking water nationwide (USEPA, 2024j). As noted above, each PFAS within the mixture has an HBWC, which is set at the level below which adverse effects are not likely to occur and allows for an adequate a margin of safety. As described in USEPA (2024h), the HBWCs for PFNA, HFPO-DA, and PFHxS are each 10 ppt and the HBWC for PFBS is 2000 ppt. As indicated above, the general Hazard Index approach can be used to assess site-specific risk associated with variable mixtures of these four PFAS at individual PWSs.

The EPA disagrees with commenter assertions that the general Hazard Index approach is inconsistent with the SDWA and that the agency did not set a "maximum permissible level" and that it "is not actually a fixed standard." The statute does not require that the MCLG or MCL be a "fixed" level or standard. In any event, the MCLG and MCL are not variable: both are set at one (1). The exposure concentration (i.e., numerator in HQ) for each the four PFAS in the Hazard Index will vary over space and time, which is one reason the EPA is finalizing this approach to account for dose-additive health concerns. This approach is analogous to other NPDWRs regulated by an MCL where concentrations at sample locations can vary. Further, the underlying calculation is not mathematically different (i.e., summing up numbers and dividing) than a running annual average calculation which is used for determining compliance with many other contaminants, including synthetic organic contaminant (SOCs), volatile organic compounds (VOCs), most inorganic chemicals (IOCs), and disinfection byproducts. Based on occurrence data (USEPA, 2024j), the EPA expects that different PFAS mixtures at different PWSs will have different risk drivers (i.e., individual PFAS with the highest HQs) and so a one-size-fits-all approach with a set concentration for the total mixture of four PFAS is not appropriate. As stated above, this type of approach, i.e., setting one concentration nationally for all four PFAS combined, would not account for the different potencies of the mixture components or the spatial and temporal variability of PFAS concentrations in drinking water nationwide (USEPA, 2024j), and thus would be over-protective in some areas and under-protective in others.

Additionally, Section 1401(6) of SDWA defines the term ''contaminant'' to mean ''any physical, chemical or biological or radiological substance or matter in water.'' A mixture of two or more ''contaminants'' qualifies as a ''contaminant'' because the mixture itself is ''any physical, chemical or biological or radiological substance or matter in water.'' Section 1401(3) of SDWA defines the term "maximum contaminant level" to mean "the maximum permissible level of a *contaminant* in water which is delivered to any user of a public water system" (emphasis added). Therefore, in the general Hazard Index approach, mixtures of two or more of PFHxS, PFNA, HFPO-DA and PFBS constitute as a contaminant, and an MCL with Hazard Index value of 1 sets the maximum permissible level of that contaminant.

The agency also disagrees with some commenters' claims that dividing an exposure metric over a health metric (i.e., HQs in the general Hazard Index) is complex or difficult to understand. This calculation is similar to that used to determine the running annual average calculation (addition followed by division), which is used frequently for compliance calculations for other NPDWRs, including SOC's, VOCs, most IOCs, and disinfection byproducts. Regardless, to assist in the calculation of Hazard Index, the agency is developing a calculator tool for users. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation. For discussion on feasibility considerations for the Hazard Index MCLG, please see section 5.2.1 of the EPA response in this *Response to Comments* document. For additional discussion on the EPA's regulatory determination for mixtures of PFAS, please see section 3.2 of the EPA response in this *Response to Comments* document. For additional discussion on the Hazard Index MCL, please see section 5 of the EPA response in this *Response to Comments* document. For additional

discussion about the form of an MCLG/MCL, please see section 5.2.1 of the EPA response in this *Response to Comments* document.

Establishment of individual MCLGs for PFHxS, HFPO-DA, PFNA, and/or PFBS.
The EPA has determined that sufficient information is available to satisfy the statutory requirements for individual regulation of PFHxS, HFPO-DA, and PFNA (in addition to PFOA and PFOS). To support this determination, the EPA carefully examined the health effects information from available peer-reviewed final human health assessments as well as published studies, reviewed PFAS drinking water occurrence data collected as part of the UCMR 3 and state-led monitoring efforts, and considered public comments received. The EPA finds that oral exposure to PFHxS, HFPO-DA, or PFNA individually may lead to adverse health effects in humans; that each of these three PFAS have a substantial likelihood of occurring in finished drinking water with a frequency and at levels of public health concern; and that, in the sole judgment of the Administrator, regulation of PFHxS, HFPO-DA, and PFNA individually presents a meaningful opportunity for health risk reductions for persons served by PWSs. The EPA is setting the individual MCLGs for HFPO-DA, PFHxS, and PFNA at 10 ng/L (ppt) for each of these three PFAS based on information about each chemical's toxicity (i.e., RfD or minimal risk level) and exposure (i.e., drinking water intake rate or exposure factor; and relative source contribution, which is the proportion of a person's total exposure to the PFAS that is attributed to drinking water) (USEPA, 2024h). The MCLG for each of these individual PFAS is set, as defined in Section 1412(b)(4)(A) of the SDWA, at "the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety" (USEPA, 2024h).

The agency is deferring the final individual regulatory determination for PFBS to further consider whether occurrence information supports a finding that there is substantial likelihood that PFBS will individually occur in PWSs and at a level of public health concern. Therefore, no individual MCLG for PFBS is being established at this time. However, when evaluating PFBS in mixture combinations with PFHxS, PFNA, and/or HFPO-DA, the EPA has determined that based on the best available information it does meet all three statutory criteria for regulation when a part of these mixtures, including that it is anticipated to have dose-additive adverse health effects (see sections III.B and IV.B.1 of preamble); there is a substantial likelihood of its co-occurrence in combinations with PFHxS, PFNA, and/or HFPO-DA with a frequency and at levels of public health concern (see sections III.C, VI.C, VI.D of preamble) USEPA 2024j); and that there is a meaningful opportunity for health risk reduction by regulating mixture combinations of these four PFAS (see section III.D of preamble). Therefore, although the agency is deferring the individual final regulatory determination for PFBS, PFBS is included in the final determination to regulate mixture combinations containing two or more of PFHxS, PFNA, HFPO-DA, and PFBS. The establishment of individual MCLGs for PFHxS, PFNA, and HFPO-DA as well as a Hazard Index MCLG for mixtures of two or more of PFHxS, PFNA, HFPO-DA, and PFBS addresses potential health risks related to individual PFAS exposure as well as dose additive adverse health effects from exposure to mixtures of two or more of these four PFAS.

Suffolk County Water Authority (SCWA) (Doc. #1589, SBC-043705)

Establishing an MCLG for the four other subject PFAS that is greater than zero is also important information for public water suppliers. For the SCWA, this means that it does not necessarily need to treat these four PFAS to non-detectable levels in order to achieve the goal of having no adverse effect on the health of its customers. Instead, it only has to achieve the MCLG with an adequate margin of safety for operational purposes, typically half the MCLG.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document. In the context of the MCLG, an adequate margin of safety is incorporated into the MCLG, as indicated by Section 1412(b)(4)(A) of the SDWA, which states that the MCLG is set at "the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." The EPA notes that regulated PWSs must take action to reduce PFAS concentrations to meet or be below the MCLs; the MCLGs are non-enforceable public health goals. Public water suppliers must treat water to the MCL for a given contaminant. MCLs are set as close to MCLGs as feasible.

Aidan Cecchetti (Doc. #1640, SBC-044364)

• EPA requests comment on whether the HBWCs should instead be proposed as stand-alone MCLGs in addition to or in lieu of the mixture MCLGs. EPA requests comment on whether establishing a traditional MCLG and MCL for PFHxS, HFPODA, PFNA, and PFBS instead of, or in addition to, the HI approach would change public health protection, improve clarity of the rule, or change costs (pg. 18671 Federal Register Volume 88, Number 60).

The commenters agree with the EPA's decision not to propose the HBWCs for PFHxS, HFPO-DA, PFNA, and PFBS as stand-alone MCLGs. The commenters agree with the EPA determination that promulgation of individual MCLGs and MCLs for those contaminants would provide less public health protection than regulating these contaminants using the HI approach. Regulating these contaminants with individual MCLGs and MCLs would provide greater clarity and lower costs for public water systems but would not account for potential additive adverse health effects of contaminant mixtures. The commenters agree with the EPA determination to regulate these contaminants using the HI approach without individual MCLGs or MCLs. The commenters do not see the value to producing MCLGs for these contaminants in addition to the HI approach.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenter that there is no value in deriving individual MCLGs in addition to the Hazard Index MCLG. After a review of public comments, the agency is promulgating individual MCLs for PFHxS, PFNA, and HFPO-DA in addition to the Hazard Index MCL for mixtures containing two or more of these PFAS and PFBS. For additional discussion on the establishment of stand-alone standards in lieu of or in addition to the

Hazard Index MCL, please see section 5.3 of the EPA response in this *Response to Comments* document.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045024)

Hazard Index for PFHxS, HFPO-DA, PFNA, and PFBS

EPA requested comments on the proposed use of an HI approach for PFHxS, HFPO–DA, PFNA, and PFBS, including whether it can be clearly implemented and achieves the goal of protecting against dose additive noncancer health effects. As discussed in the comments above, NJDEP agrees that the proposed HI approach is protective for dose additive non-carcinogenic effects of the four PFAS that are included in the HI. NJDEP recommends the EPA continue to evaluate the potential addition of additional PFAS to the HI as appropriate.

Regarding whether establishing traditional MCLs for PFHxS, HFPO–DA, PFNA, and PFBS instead of, or in addition to, the HI approach as stated above, use of stand-alone MCLs in lieu of the mixture HI would not account for additive toxicity when mixtures of these PFAS are detected in drinking water. Use of stand-alone MCLs in addition to the mixture HI would have no practical impact, since an exceedance of the HBWC for a specific PFAS would result in an HI above 1.0 even if none of the other PFAS included in the HI are detected.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document. There may be a practical impact of these individual MCLs (for PFHxS, PFNA, and HFPO-DA) where one of these three PFAS occur in isolation (i.e., without one of the other four Hazard Index PFAS present) above their individual MCLs. The EPA notes that this regulatory structure is consistent with the intended effect of the proposed regulation, where as proposed, a single PFAS found in drinking water at a concentration above its HBWC would have caused an exceedance of the MCL. Based on public comment, the EPA has restructured the rule such that two or more of these regulated PFAS would be necessary to cause an exceedance of the Hazard Index and instead will regulate individual exceedances of PFNA, PFHxS, and HFPO-DA as individual MCLs to improve risk communication. Risk communication is an important focus for water systems and the EPA believes that finalizing individual MCLs for PFHxS, PFNA, and HFPO-DA can support risk communication as utilities and the public may be more familiar with this regulatory framework. Additionally, the final individual MCLs for PFHxS, PFNA, and HFPO-DA will address and communicate health concerns for these compounds where they occur in isolation. At the same time, since those individual MCLs do not address additional risks from co-occurring PFAS, the EPA is finalizing a Hazard Index MCL that provides a framework to address and communicate dose additive health concerns associated with mixtures of PFHxS, PFNA, HFPO-DA, and PFBS that co-occur in drinking water. For the EPA's discussion on the establishment of stand-alone standards in lieu of or in addition to the Hazard Index MCL, please see section 5 of the EPA response in this *Response to Comments* document.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045019)

As discussed in the proposed rule, the general HI approach, which considers non-carcinogenic toxicological effects in both the same and different target organs, is more protective than the target organ specific HI or RFP approaches, which only consider effects in the same target organ. As discussed in the proposed rule, while the general HI approach requires more assumptions than the target organ HI or RPF approach, there is often insufficient information (e.g., lack of target organ-specific toxicity factors) for use of the target specific HI or RPF approach. As such, as stated by EPA (p.18655) the choice of the general HI approach is a "reasonable policy choice for regulating a mixture of chemicals that are expected to adversely impact multiple health endpoints." As stated in the proposed rule the general HI approach "is protective against all health effects across component chemicals and therefore meets the statutory requirements of establishing an MCLG under SDWA."

EPA Response: This commenter supports the EPA's approach.

Public Health, Seattle & King County (PHSKC) (Doc. #1594, SBC-042353)

Yet PHSKC also supports the mixtures approach that EPA has taken for PFAS chemicals that frequently occur as mixtures and where health risks may be greater with exposures to multiple PFAS, as with GenX, PFABS, PFNA and PFHxS.

EPA Response: The commenter supports the EPA's approach.

Environmental Protection Network (EPN) (Doc. #1773, SBC-043859)

EPN finds that EPA's analysis of UCMR3 data and state data provides convincing evidence that these four PFAS chemicals co-occur in public water systems serving millions of people at a frequency justifying use of a mixtures approach. EPN agrees with EPA's statement that there should not be a bright line threshold for occurrence in drinking water that triggers whether a contaminant is a public health concern justifying a national drinking water standard. In addition to frequency of occurrence, the potency of the chemical, geographic distribution, impacted population, and type of health effects should be considered in deciding whether to regulate a drinking water contaminant. Based on all of those factors, EPN agrees that a HI of one is an appropriate MCLG indicating no appreciable risk.

EPA Response: The commenter supports the EPA's approach.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044032)

14. EPA requests comment on whether establishing a traditional MCLG and MCL for PFHxS, HFPO-DA, PFNA, and PFBS instead of, or in addition to, the HI approach would change public health protection, improve clarity of the rule, or change costs.

a. See number 4. CWUC is in support of establishing MCLs for any additional PFAS parameters.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044030)

12. EPA requests comment on its proposal of using an HI approach for PFHxS, HFPO-DA, PFNA, and PFBS, including whether it can be clearly implemented and achieves the goal of protecting against dose additive noncancer health effects.

a. See number 4. CWUC is more supportive of EPA establishing MCLs for these parameters.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044023)

6. EPA requests comment on whether the HBWCs should instead be proposed as stand-alone MCLGs in addition to or in lieu of the mixture MCLGs.

a. See number 4. Having a mixture MCL/G is problematic for communicating health effects language to our customers.

b. CWUC is in support of using the HBWCs to establish the MCLs for the four additional PFAS constituents.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document. Also, for the EPA response to the comment about communicating health effects language to customers, please see section 5.3 of this *Response to Comments* document.

PFAS Project Lab (Doc. #1786, SBC-044714)

The need for federal MCLs

EPA has long been aware of the scientific evidence pointing to harm from low-dose exposure to PFOA and PFOS, and regulations for these two compounds are long overdue. For example, EPA documented evidence of PFOA's carcinogenicity in its 2016 Health Effects Support Document, and following studies have strengthened that finding. Moreover, the scientific evidence supports regulating additional PFAS, including PFHxS, HFPO-DA, PFNA, and PFBS, and it is thus critical that they also be included. In 2021, ATSDR conducted a comprehensive assessment of PFHxS and PFNA in its toxicological profile for perfluoroalkyls, and it is justified that EPA uses the derived Minimum Risk Levels for these two compounds.

EPA Response: The commenter agrees with the EPA's approach.

Fairfax Water (Doc. #1789, SBC-045296)

EPA's proposal to use a Hazard Index calculation for PFNA, PFHxS, PFBS, and HFPO¬DA is an approach that has never been used under the Safe Drinking Water Act. The approach combines PFAS compounds with different health endpoints. Utilities could exceed the HI even if each PFAS compound is below the limits of health impacts. Further, the HI approach will be challenging to communicate to the public. Instead of the HI approach, EPA should establish MCL's for these PFAS compounds using reference doses (RIDs) and human health toxicity assessments when they are available.

EPA Response: Please see sections 4.3.1, 4.3.2, and 1.2 of the EPA response in this *Response to Comments* document.

Nebraska Department of Environment and Energy (NDEE) (Doc. #1653, SBC-043205)

The Department suggests disregarding the Hazard Index as this may lead to unnecessary and costly treatment for public water systems.

EPA Response: Please see sections 4.3.2 and 13, including section 13.3.2 (HFPO-DA, PFNA, PFBS National Costs), of the EPA response in this *Response to Comments* document.

Kevin Korro (Doc. #1538, SBC-042655)

In addition, I admire the use of the hazard index (HI) approach to protect against mixtures of PFHxS, HFPO-DA and its ammonium salts, PFNA, and PFBS in drinking water, with an HI of 1.0 being proposed as the MCLG for these four PFASs and any mixture containing one or more of them. This is something that I find very admirable. This is something that gives me a lot of cause for optimism.

On the other hand, I would like to suggest the MCLGs that have been proposed be made more severe to offer the maximum possible degree of protection for public health. It has been demonstrated beyond a reasonable doubt that PFAS are harmful and that they represent a risk to human health even when present in very low amounts. I would like to make it clear that I highly encourage the EPA to take into consideration making more cuts to the MCLG before they finalize the regulation.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document. Additionally, SDWA requires that to the degree that the EPA's action is based on science, the EPA must use "the best available, peer reviewed science" and "data collected by accepted methods or best available methods." The HBWCs/MCLGs are based on the best available science and data collected by accepted methods (see section III in the preamble and USEPA, 2024h). Specifically, peer-reviewed, publicly available toxicity assessments are available for HFPO-DA (USEPA, 2021e), PFBS (USEPA, 2021d), PFNA (ATSDR, 2021), and PFHxS (ATSDR, 2021) that provide the oral toxicity values (i.e., RfD or minimal risk level) used to calculate the HBWCs; the EPA selected the corresponding DWI-BW for the relevant sensitive population or life stage from the Exposure Factors Handbook (USEPA, 2019) based on the best

available, peer-reviewed science taking into account the relevant sensitive population(s) or life stage(s); and the RSCs are based on the best available, peer-reviewed science or best available methods taking into account the relevant sensitive population(s) or life stage(s) (USEPA, 2000d). The commenter did not present any information to support different values for the HBWCs/MCLGs.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-052980)

Application of potency subgroups to the Hazard Index

EPA should consider an alternative approach to calculating the HI based on potency subgroups that differ by factors of 3- or 10-fold rather than the current approach using individual HBWCs described in the Mixture document. The modest differences between the HFPO-DA HBWC of 10 ppt, PFNA HBWC of 10 ppt, and PFHxS HBWC of 9 ppt (10 ppt if calculated as above) for example are not supported as being distinct values given the differences in factors such as database extent, study execution, and inter-lab variability. The use of potency subgroups would better reflect the uncertainty in calculating PFAS drinking water values as well as simplify the calculation of the HI. As an example, for a drinking water system with detections of HFPO-DA, PFNA, and PFHxS, the current approach would require dividing the HFPO-DA drinking water concentration by the HFPO-DA HBWC, the PFNA drinking water concentration by the PFNA HBWC, and the PFHxS drinking water concentration by the PFHxS HBWC. For an approach based on potency subgroups, the HFPO-DA, PFNA, and PFHxS drinking water concentrations would all be divided by the same potency subgroup factor, as the HBWC values do not differ by more than a factor of 3-fold in the current draft Mixture document. This potency subgroup approach should also be applied to additional PFAS if added to the HI approach.

EPA Response: The EPA disagrees that segregating PFAS into potency subgroups that differ by factors of 3- or 10-fold is necessary or preferable. The fact that the HBWCs for HFPO-DA, PFNA, and PFHxS do not differ significantly should not necessarily be construed as a function of relative potency. RfDs (or minimal risk levels) for different PFAS may be derived using different health effects data (e.g., the RfD for HFPO-DA is based on liver effects; the minimal risk level for PFHxS is based on thyroid effects), and may be based upon different study types or dosing schedules (e.g., dietary or drinking water ad libitum versus daily oral gavage), exposure lifestages (e.g., adult versus developmental), and overall hazard evidence bases. Thus, the underpinning toxicity information considered in the assessment and derivation of a human health toxicity reference value from PFAS to PFAS is typically diverse and comes with different qualitative and quantitative uncertainties. Such considerations are directly addressed in the human health assessment for each PFAS, not the subsequent calculation of an HBWC. Further, calculation of HBWCs across PFAS includes other considerations (in addition to those discussed in a health assessment) such as bodyweight-based drinking water intake rates, which may be different (e.g., adult versus early(ier) lifestages) across PFAS mixture components. Using each individual mixture component chemical RfD (or minimal risk level) as the denominator in the calculation of a corresponding HQ is consistent with EPA chemical mixtures guidance and

practice; to aggregate or group based only upon quantitative convergence of HBWCs is unnecessary. In addition, as a practical matter, use of subgroups in the Hazard Index would be more complicated and difficult to communicate and would not result in any quantitative difference to the Hazard Index. In this hypothetical example, the Hazard Index is 4 either way:

The EPA approach:

$$HI\ MCLG\ = \left(\frac{[HFPO-DA_{ng/L}]}{[10\ ng/L]}\right) + \left(\frac{[PFBS_{ng/L}]}{[2000\ ng/L]}\right) + \left(\frac{[PFNA_{ng/L}]}{[10\ ng/L]}\right) + \left(\frac{[PFHxS_{ng/L}]}{[10\ ng/L]}\right)$$
$$=$$

$$HI\ MCLG\ = \left(\frac{[5_{ng/L}]}{[10\ ng/L]}\right) + \left(\frac{[1000_{ng/L}]}{[2000\ ng/L]}\right) + \left(\frac{[12_{ng/L}]}{[10\ ng/L]}\right) + \left(\frac{[20_{ng/L}]}{[10\ ng/L]}\right) = 4$$

Commenter suggested approach:

$$HI\ MCLG\ = \left(\frac{\left[HFPO-DA_{\frac{ng}{L}} + PFNA_{\frac{ng}{L}} + PFHxS_{\frac{ng}{L}}\right]}{[10\ ng/L]}\right) + \left(\frac{[PFBS_{ng/L}]}{[2000\ ng/L]}\right) =$$

$$HI\ MCLG\ = \left(\frac{\left[5\frac{ng}{L} + 12\frac{ng}{L} + 20\frac{ng}{L}\right]}{[10\ ng/L]}\right) + \left(\frac{[1000_{ng/L}]}{[2000\ ng/L]}\right) = 4$$

To assist in the calculation of these values, the agency is developing a calculator tool to easily determine Hazard Index calculations at individual PWSs. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation.

American Water Works Association (AWWA) (Doc. #1759, SBC-045603)

Additionally, the agency's approach is contrary to the agency's own guidance for assessing risks of mixtures, which states that it must be "sufficiently similar mixture" where "components and respective portions exist in approximately the same pattern" (EPA, 1986). As indicated in this guidance, a key feature of a mixture is the mixtures composition and consistent co-occurrence of the components (PFNA, PFHxS, PFBS, and HFPO-DA).

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043075)

Combined MCLG for PFNA, PFHxS, HFPO-DA, and PFBS

According to the Proposal, EPA is proposing to establish a combined MCLG for four PFAS set at a hazard index (HI) of 1.0. In proposing this MCLG, EPA is making several key scientific determinations to support this decision:

1. PFNA, PFHxS, HFPO-DA, and PFBS are likely to co-occur in water in a way that is a "sufficiently similar mixture,"

2. Co-exposure to a mixture of PFNA, PFHxS, HFPO-DA, and PFBS can lead to an aggregate health effect because of dose additivity, and

3. The dose additivity of PFAS can be applied through the hazard index with dissimilar health effects, or outcomes.

Aqua supports the Agency's interest in taking a public health protective stance on PFAS. However, EPA's assumption of dose additivity without sufficient evidence of the contrary is flawed. There are numerous concerns regarding the Agency's determination that these compounds co-occur and that their co-exposure has a dose-additive effect on dissimilar outcomes.

Aqua is concerned that the Agency's approach is contrary to the Agency's own guidance for assessing risks of mixtures, which states that it must be "sufficiently similar mixture" where "components and respective portions exist in approximately the same pattern." As indicated in this guidance, a key feature of a mixture is the mixtures composition and consistent co-occurrence of the components (PFNA, PFHxS, PFBS, and HFPO-DA). The EPA's occurrence analysis fails to sufficiently document co-occurrence of this mixture of PFAS.

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenter's claims that the EPA is making the determination that PFNA, PFHxS, HFPO-DA, and PFBS are likely to co-occur in water in a way that is a "sufficiently similar mixture." Please see section 4.3.2 of the EPA response in this *Response to Comments* document. Additionally, the EPA disagrees with the commenter's claim that the EPA's occurrence analysis fails to sufficiently document co-occurrence of these PFAS in drinking water. The EPA's evaluation of UCMR 3 data as well as data from state-led drinking water monitoring efforts shows that PFHxS, PFNA, and HFPO-DA each have a substantial likelihood to occur in finished drinking water and that these three PFAS and PFBS are also likely to co-occur in mixtures (USEPA, 2024j). Please see sections III and VI in the preamble and sections 3 and 7 of the EPA response in this *Response to Comments* document for additional discussion.

Environmental Protection Network (EPN) (Doc. #1773, SBC-043854)

EPN recommends the use of a HI for the drinking water standard in addition to individual MCLGs and MCLs because the HI accounts for dose additivity and is thus more health protective. We believe EPA should account for dose additivity in order to comply with SDWA's requirement to set drinking water standards with an adequate margin of safety. We recommend that EPA also provide individual MCLGs and MCLs for the four chemicals to improve rule clarity and maintain consistency with previous drinking water standards. EPN recommends against adding PFOA and PFOS to the HI because these chemicals differ from the other four PFAS chemicals in having MCLGs of zero, a level well below analytical quantitation levels, and their addition would obscure the risks posed by the four more-recently manufactured PFAS chemicals.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044416)

Page 18730. EPA requests comment on whether establishing a traditional MCLG and MCL for PFHxS, HFPO–DA, PFNA, and PFBS instead of, or in addition to, the HI approach would change public health protection, improve clarity of the rule, or change costs.

• DOH supports using both the traditional and HI approach for MCLs.

• These chemicals frequently occur in mixtures. When two or more are present, the HI approach effectively lowers the acceptable limit for each. Since PFAS health impacts are likely additive, a combined standard is appropriate.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044409)

EPA requests comment on the general HI approach for the mixture of four PFAS.

• DOH supports the HI approach.

EPA requests comments on the merits and drawbacks of the target- specific HI or RPF approach.

• DOH supports the HI approach.

EPA Response: This commenter supports the EPA's approach.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045950)

Section 2.2: PFAS mixture of PFBS, PFNA, GenX, PFHxS

AMWA recognizes the difficulty of addressing a class of compounds that includes thousands of chemicals with many uncertainties. PFOA and PFOS, being some of the most studied and well-known of the PFAS class, have individual proposed MCLGs while the additional four PFAS are proposed to be addressed as a mixture. EPA has proposed using a hazard index (HI) approach for PFBS, PFNA, GenX, and PFHxS, with an HI of 1.0 for the MCLG.

There have been past rulemakings when EPA has used the sum of certain chemicals in regulation. For example, in the Stage 2 Disinfectants and Disinfection Byproducts Rule, trihalomethanes (THMs) and haloacetic acids (HAA5) have an MCL for the sum of certain chemicals in these groups. The HI proposed by EPA is slightly different, as it uses a quotient of measured concentration in drinking water over a Health Based Water Concentration (HBWC). EPA proposes this measure to address the additive noncancer health effects of these compounds in a mixture. EPA declined to implement individual MCLGs for each compound, which AMWA is supportive of, as more data is needed for these chemicals to proceed with individual MCLGs.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document. For the EPA's discussion on the establishment of stand-alone MCLs for PFHxS, HFPO-DA, and PFNA in addition to the Hazard Index MCL, please see section 5 of the EPA response in this *Response to Comments* document. The health information available for PFHxS, PFNA, and HPFO-DA is sufficient to calculate individual MCLGs for each of these PFAS.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-044902)

Section 2.2: PFAS mixture of PFBS, PFNA, GenX, PFHxS

Cleveland Water recognizes the difficulty of addressing a class of compounds that includes thousands of chemicals with many more unknowns than knowns. PFOA and PFOS, being some of the most studied and well-known of the PFAS class, have individual proposed MCLGs while the additional four PFAS are proposed to be addressed as a mixture. EPA has proposed using a hazard index (HI) approach for PFBS, PFNA, GenX, and PFHxS, with an HI of 1.0 for the MCLG.

There have been past rulemakings when EPA has used the sum of certain chemicals in regulation. For example, in the Stage 2 Disinfectants and Disinfection Byproducts Rule, trihalomethanes (THMs) and haloacetic acids (HAA5) have an MCL for the sum of certain chemicals in these groups. The HI proposed by EPA is slightly different, as it uses a quotient of measured concentration in drinking water over a Health Based Water Concentration (HBWC). EPA proposes this measure to address the additive noncancerous health effects of these compounds in a mixture. EPA declined to implement individual MCLGs for each compound individually, which we are supportive of, as more data is needed individually for these chemicals to proceed with individual MCLGs.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document. For the EPA's discussion on the establishment of stand-alone MCLs for PFHxS, HFPO-DA, and PFNA in addition to the Hazard Index MCL, please see section 5 of the EPA response in this *Response to Comments* document. The health information available for PFHxS, PFNA, and HPFO-DA is sufficient to calculate individual MCLGs for each of these PFAS.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-052954)

Cleveland Water is concerned that this proposed HI would serve as a de-facto MCL for systems that have detected only one of the PFAS chemicals present in their system. These de-facto MCLs are equal to the HBWC EPA has proposed, but the agency is not officially proposing them as individual MCLs, an action we support. If EPA is addressing the issues these chemicals cause as a mixture and when they co-occur, then it would make sense that a water system would need to have a mixture and co-occurrence (more than one) present to do this calculation.

EPA Response: Please see sections 4.3.2, 3, and 5 of the EPA response in this *Response to Comments* document. The EPA is finalizing a Hazard Index of 1 (unitless) as the MCLG and MCL for any mixture containing two or more of PFHxS, PFNA, HFPO-DA, and PFBS.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-052956)

Cleveland Water is concerned that, once we have a holistic view of PFAS occurrence in drinking water from UCMR 5 data, it will become clear this approach may not have been the most appropriate, and more PFAS could potentially be candidates for regulation that do not have the same health effects. The addition of more PFAS to this HI will decrease the quotient threshold each quotient is allowed, without being more protective of public health. For example, right now each PFAS chemical can have a quotient of 0.25 (0.25+0.25+0.25+0.25=1), a value of ¼ of the HBWC and/or health advisories and still be compliant, but if one more PFAS chemical is added to make five, that quotient reduces to 0.2. At some point, the HI of 1.0 will not be attainable with additional PFAS, and EPA will have to evaluate its options on how to group and separate certain PFAS.

EPA Response: The commenter incorrectly interprets the Hazard Index approach as having four HQs equal to 0.25. In fact, HQs will differ across time and space depending on the actual measured concentrations of each of the four component PFAS. Regarding potential addition of PFAS, the EPA's final regulatory determination and final rule are limited to the mixtures that include two or more of PFNA, PFHxS, PFBS, and HFPO-DA. If there is any potential future inclusion of additional PFAS under this approach, such inclusion would be the subject of a potential future regulatory process. Additionally, pertaining to UCMR 5, please see sections 3.1.2 and 6.8 of the EPA response in this *Response to Comments* document. Also, please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

New York State Department of Health (NYS DOH) (Doc. #1677, SBC-044947)

9. The EPA's proposed approach to establish a HI as a way to address the additive health effects of mixtures is precedent setting for drinking water standards and presents implementation challenges. Regulators and public water systems will be required to provide education and communication on the new compliance concept, while also tracking and enforcing PFOA and/or PFOS MCLs in a more traditional way. Based on existing compliance data, the Department does not believe that the added complexity of the HI approach will provide significant additional public health protection, since monitoring conducted in New York State demonstrates that PFAS compounds used to calculate the HI typically co-occur with PFOA and/or PFOS. The Department supports establishing individual MCLs for GenX, PFBS, PFNA and PFHxS. As shown in Table 2, New York State expects 3 water systems to exceed the Hazard Index that do not have PFOA or PFOS greater than 4 ppt.

Table 2: Hazard Index 1m act Assessment

[Table 2: See Docket ID EPA-HQ-OW-2022-0114-1677]

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document. Also, in response to the comment that the Hazard Index approach is precedent-setting, there is precedent for the Hazard Index approach (see USEPA, 1991c) and that it is supported by the EPA's chemical mixtures guidance (USEPA, 1986; USEPA, 2000b). As noted by the SAB in its review of the EPA's draft PFAS Mixtures Framework, the Hazard Index approach for addressing potential health risks associated with exposure to a mixture of PFHxS, HFPO-DA, PFNA, and/or PFBS "is a reasonable approach for estimating the potential aggregate health hazards associated with the occurrence of chemical mixtures in environmental media. The Hazard Index is an approach based on dose additivity (DA) that has been validated and used by EPA" (USEPA, 2022b). Based on the EPA's evaluation of the best available occurrence data, the EPA has determined that there is a substantial likelihood that PFHxS, HFPO-DA, and PFNA individually, as well as mixtures of PFHxS, HFPO-DA, PFNA, and/or PFBS, will occur/co-occur in PWSs with a frequency and at levels of public health concern (see also sections 3.1.2, 3.2.2, and 6.3 of the EPA response in this *Response to Comments* document). Furthermore, the EPA disagrees that the Hazard Index will not provide significant additional public health protection or that regulation of PFOA and PFOS will protect against exposures to the Hazard Index PFAS. Please see the EPA response to comment Doc. #1686, SBC-043823 in section 3.1 in this *Response to Comments* document.

City of Vancouver Water Utility, Vancouver, WA (Doc. #1684, SBC-044309)

The hazard index approach for the PFAS other than PFOA and PFOS has never been used in setting an MCL, and it presents both technical and legal questions regarding its scientific basis as a health risk indicator. There is limited understanding of risk at these levels when these PFAS are combined together. EPA's Reference Dose for PFNA, GenX Chemicals, PFHxS, and PFBS is based entirely on laboratory animal studies, even though EPA itself advises "Adequate human

data are the most relevant for assessing risks to humans." Using a method that could ultimately cost rate payers billions of dollars with limited scientific basis is not acceptable per the Safe Drinking Water Act, which requires consideration of the costs and benefits. There is no way to determine the appropriate cost or benefits if limits are placed on these four PFAS utilizing the proposed hazard index approach. A traditional MCLG and MCL approach would improve clarity.

The shorter chain PFAS proposed in the HI break through current filtration treatment technologies (IX and GAC) significantly faster than longer chain PFAS like PFOS and PFOA. Setting a hazard index of 1.0 will have a significant cost impact on the ongoing O&M costs to ratepayers and it is essential that adequate data is collected to ensure an appropriate MCL is set if the HI approach is used for short chain PFAS. Did the EPA include the impacts of such a low hazard index when completing its benefit/cost analysis?

Provision must be placed in the rule to ensure additional PFAS cannot be randomly added to the hazard index calculation without following the required processes.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document. Also, with respect to the use of animal studies, SDWA requires that to the degree that the EPA's action is based on science, the EPA must use "the best available, peer reviewed science" and "data collected by accepted methods or best available methods." The HBWCs/MCLGs are based on the best available science and data collected by accepted methods (see section III in the preamble and USEPA, 2024h). Specifically, peer-reviewed, publicly available toxicity assessments are available for HFPO-DA (USEPA, 2021e), PFBS (USEPA, 2021d), PFNA (ATSDR, 2021), and PFHxS (ATSDR, 2021) that provide the oral toxicity reference values (i.e., RfD or minimal risk level) used to calculate the HBWCs; the EPA selected the corresponding DWI-BW for the relevant sensitive population or life stage from the Exposure Factors Handbook (USEPA, 2019) based on the best available, peer-reviewed science from publicly available, peer-reviewed studies taking into account the relevant sensitive population(s) or life stage(s); and the RSCs are based on the best available, peer-reviewed science or best available methods taking into account the relevant sensitive population(s) or life stage(s) (USEPA, 2000c). Additionally, as noted in the EPA's *Staff Handbook for Developing IRIS Assessments* (USEPA, 2022a) and *A Review of the Reference Dose and Reference Concentration Process* (USEPA, 2002a), animal studies can provide the basis for toxicity reference values when adequate human studies are not available.

For the EPA response to comments about the addition of PFAS to the Hazard Index calculation, please see section 4.3.5 of the EPA response in this *Response to Comments* document.

For the EPA response to comments about technical, scientific, and legal questions related to an MCL based on the Hazard Index approach, and comments related to cost, please see sections 5 and 13 of the EPA response in this *Response to Comments* document.

After considering public comments, the EPA has established individual MCLGs and MCLs for three of these PFAS in addition to the Hazard Index MCLG and MCL. For the EPA's discussion on the establishment of stand-alone MCLs for PFHxS, HFPO-DA, and PFNA in addition to the

Hazard Index MCL, please see section 5.2 of the EPA response in this *Response to Comments* document.

Wisconsin Department of Natural Resources (Doc. #1828, SBC-044801)

Hazard Index

WDNR supports the use of the hazard index for the four proposed PFAS. The hazard index approach is used in Wisconsin and our Drinking Water System database is programmed to calculate the index automatically when analytical results are submitted. The hazard index is a good method to weigh the risks to human health of both individual chemicals as well as mixtures.

EPA Response: This commenter supports the EPA's approach.

Wisconsin Department of Justice et al. (Doc. #1687, SBC-044447)

3. EPA's proposed Hazard Index approach to regulate PFHxS, GenX, PFNA, and PFBS is appropriate and justified to address the demonstrated adverse health effects of PFAS mixtures.

As previously discussed, infra at Comment 1.a., EPA's decision to regulate PFHxS, GenX, PFNA, and PFBS using a Hazard Index approach is amply supported by, among other studies, health effect studies concerning each chemical individually and from PFAS mixtures. As a result, EPA's Hazard Index approach, a method that employs a numerical value used in risk assessment to estimate the potential health risks associated with exposures to multiple chemicals or contaminants. The Hazard Index is determined by adding up the ratio of the concentration detected in drinking water to the HBWC for each of the four PFAS included in the Hazard Index. Here, the Hazard Index provides a scientifically sound way to evaluate the cumulative effects of exposure to the four subject PFAS and helps to determine whether the combined risk from multiple exposures is within acceptable levels or if further action is needed to protect human health. A Hazard Index greater than 1.0 indicates that the combined exposures may pose a potential risk to human health, while an index less than 1.0 suggests that the risks are likely to be low.

EPA's proposed use of a Hazard Index in this situation—where human exposure to a mixture of PFAS in drinking water is occurring simultaneously—is scientifically and technically sound and appropriate. Many States use Hazard Indices to address the risks of exposure to a mixture of contaminants. [FN38: Examples of states using Hazard Indices to assess the combined risk of mixtures of contaminants include: California (see https://dtsc.ca.gov/faq/how-are-the-toxicity-criteria-used-at-california-hazardous-waste-and-hazardous-substance-release-sites/); Minnesota (seehttps://www.health.state.mn.us/communities/environment/risk/guidance/gw/additivity.html); Oregon (see https://www.oregon.gov/deq/aq/cao/Documents/CAO-HIQuickLearn.pdf) and Wisconsin (see https://www.dhs.wisconsin.gov/publications/p03212.pdf).] In fact, one of the undersigned—Wisconsin—is currently using Hazard Indices for assessment of the hazards posed

by a mixture of PFAS in drinking water and has released an informative video describing its function. [FN39: See Wisconsin DHS, PFAS Hazard Index (March 2022), https://www.youtube.com/watch?v=vWyQgP7F0mM; see also https://www.dhs.wisconsin.gov/publications/p03212.pdf.] EPA's approach is well accepted both by regulators throughout the United States and by the scientific community and is appropriate and justified in addressing the demonstrated potential adverse health effects of PFAS mixtures in drinking water.

EPA Response: This commenter supports the EPA's approach.

Minnesota Center for Environmental Advocacy et al. (Doc. #1707, SBC-045724)

B. EPA Correctly Chose the Use a Hazard Index to Regulate Multiple PFAS Together

The Commenters also write to express their full support for the Agency's decision to use a Hazard Index to regulate PFHxS, GenX Chemicals, PFNA, and PFBS. While these PFAS pose serious risks to public health individually, the Hazard Index responds to the reality that these specific PFAS are commonly found together, and that the combination of these PFAS in drinking water poses elevated risks to human health. The Hazard Index is a simple dose additivity tool that safeguards against drinking water supplies contaminated with low concentrations of multiple PFAS.

In the East Metro, MDH has identified public and private drinking water supplies contaminated with low concentrations of PFHxS, PFNA, PFBS, and various other PFAS. [FN39: See PFAS Testing of Minnesota Community Water Systems, Minn. Dep't of Health, https://mdh.maps.arcgis.com/apps/MapSeries/index.html?appid=63515695237f425ea7120d1aac1fd09a (identifying water supply testing locations and results).] To ensure residents are protected from low levels of multiple PFAS substances, MDH uses a Health Risk Index ("HRI") to evaluate the "additive" risk of a group of PFAS that have similar adverse health impacts. [FN40: Minn. Pollution Control Agency & Minn. Dep't of Natural Res., Conceptual Drinking Water Supply Plan 25 (Aug. 2021), available at https://3msettlement.state.mn.us/sites/3msettlement/files/2023-02/Final-Planchapters-1-10.pdf.] In cities like Cottage Grove, multiple wells exceeded the HRI, prompting city officials to remove those wells from the water supply to ensure residents were not drinking toxic water. [FN41: Id. At 34.] Without the HRI, it is possible that the concentrations of individual PFAS substances present in the wells would not trigger an exceedance, meaning that the water would be considered "safe to drink" by regulators. But as MDH and EPA know, the additive risk of low concentrations of multiple PFAS is a serious threat to public health. The regulations must therefore be crafted to respond to this unique risk.

An HRI or Hazard Index does just that. It adds an additional layer of needed security to ensure the safety of our nation's drinking water. EPA is correct to use a Hazard Index to regulate this group of four PFAS compounds together

EPA Response: This commenter supports the EPA's approach.

American Chemistry Council (ACC) (Doc. #1711, SBC-044460)

[The Agency's proposal suffers from the following significant shortcomings –]

• The use of a hazard index (HI) as a basis for the MCL and MCLG Goal for the four other PFAS is unprecedented and contrary to Agency policy and the advice of the Agency's own Science Advisory Board

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-044808)

[The Agency's proposal suffers from the following significant shortcomings –]

• The use of a hazard index (HI) as a basis for the MCL and MCLG Goal for the four other PFAS is unprecedented and contrary to Agency policy and the advice of the Agency's own Science Advisory Board,

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-044817)

[As outlined in these comments, the Agency's proposal suffers from a number of significant shortcomings, including the following –]

• The use of an HI as a basis for the MCL and MCLG Goal for PFBS, HFPO-DA, PFHxS, and PFNA is unprecedented and contrary to Agency policy and the advice of the Agency's own Science Advisory Board,

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document.

Monte Vista Water District (MVWD) (Doc. #1718, SBC-043537)

Methodology

Testing water for PFAS can be complex and requires laboratory analysis, specialized equipment, and expertise to identify and measure specific PFAS compounds in the water sample. MVWD, a small water system, collects water samples which are then tested by a third-party laboratory with results returned to MVWD. Incorporating a Hazard Index (HI) to assess the potential health risks associated with exposure to multiple contaminants in water would require various components of data be factored into the laboratory data received: toxicological assumptions (and their impact on

certain populations), cumulative effects (how contaminants interact with each other), and sensitivity of population (variability in individual susceptibility to contaminants). The HI is based on scientific principles but should be considered a screening tool rather than a definitive measure of health effects. The HI has limitations and should be interpreted with caution. The HI assumes an additive effect of the contaminants, which may not accurately reflect the real-world interactions and complexities of chemical mixtures. Additionally, the HI relies on certain assumptions, such as the reference doses as thresholds for adverse effects and the absented of threshold effects for some contaminants.

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

Environmental Working Group (EWG) (Doc. #1721, SBC-045410)

The hazard index is a critical tool to address cumulative risks from mixtures of PFAS.

While the EPA set numerical levels as the maximum contaminant levels for PFOA and PFOS at 4 parts per trillion, the EPA applied a unitless hazard index of 1 to the other four PFAS. The EPA took this approach to protect the public from mixtures of GenX, PFBS, PFHxS, and PFNA, or the HI PFAS, "because of their known and additive toxic effects and occurrence and likely cooccurrence in drinking water."[FN26: Id. At 18639.]

As the EPA explains, a hazard index is "a commonly used risk management approach for mixtures of chemicals."[FN27:Id.] Under this approach, the EPA plans to calculate each PFAS's "hazard quotient," by dividing "an exposure metric," (in this case the amount measured in drinking water) by "a health reference value" (in this case the Health Based Water Concentrations the EPA has established for each of the four PFAS). [FN28:Id.] The hazard quotients, or ratios, for each PFAS are then "summed across the mixture to yield the [hazard index]", with a hazard index above 1 indicating increased risk to human health. [FN29:Id.]

The hazard index is a sound and practical approach for establishing an MCL and hazard indices have long been used by other EPA offices and endorsed by leading scientific authorities, including EPA's Science Advisory Board, as "a reasonable approach for estimating the potential aggregate health hazards associated with the occurrence of chemical mixtures in environmental media."[FN30:Id.] The hazard index is extensively discussed in the EPA's Guidelines for Health Risk Assessment of Chemical Mixtures, first released in 1986. [FN31: Guidelines for the Health Risk Assessment of Chemical Mixtures, 51 Fed. Reg. 34014 (Sept. 24, 1986).] The EPA regularly applies hazard indices under the Comprehensive Environmental Response, Compensation, and Liability Act to address exposures to multiple substances at a contaminated site and develop clean-up thresholds. [FN32: See Risk Assessment Guidance for Superfund: Volume I Human Health Evaluation Manual (Part A) at 8-11 – 8- 13 ("At most Superfund sites, one must assess potential health effects of more than one chemical … Estimating risk or hazard potential by considering one chemical at a time might significantly underestimate the risks associated with simultaneous exposures to several substances … To assess the overall potential

for noncarcinogenic effects posed by more than one chemical, a hazard index (HI) approach has been developed based on EPA's (1986b) Guidelines for Health Risk Assessment of Chemical Mixtures.") See also Earthjustice et al., supra note 7, at 13-15.] Hazard indices are also used under the Clean Air Act to calculate risk from groups of chemicals emitted from the same source category. [FN33: See National Emissions Standards for Hazard Air Pollutants: Cyanide Chemicals Manufacturing Residual Risk & Technology Review, 86 Fed. Reg. 3910-11 (Jan. 15, 2021).] As Earthjustice, the Natural Resources Defense Council, and other organizations point out in group comments filed to this docket:

hazard indices address the potential for 'low levels of multiple [chemicals] that individually would not likely result in adverse health effects … to result in adverse health effects' when combined in a mixture. This approach to calculating risk – also known as dose additivity – 'has found widespread acceptance as an assessment concept for combined exposures to multiple chemicals … and is extensively used by regulatory authorities as a protective default approach.'[FN34: See Earthjustice et al., supra note 7, at 19 (citing OECD, Considerations for Assessing the Risks of Combined Exposure to Multiple Chemicals: Series on Testing and Assessment No. 296, (Dec. 6, 2018), https://www.oecd.org/chemicalsafety/risk-assessment/considerations-for-assessing-the-risks-of-combined-exposure-to-multiple-chemicals.pdf).]

The hazard index pr449pposedhis rule aligns with a growing scientific movement to address cumulative risks from exposure to mixtures of environmental contaminants. The EPA has identified cumulative impacts research as "a priority to bolster the scientific basis for identifying actions that can improve community health and well-being"[FN35:ENV'T PROT. AGENCY, CUMULATIVE IMPACTS RESEARCH: RECOMMENDATIONS FOR EPA'S OFFICE OF RESEARCH AND DEVELOPMENT (2022) https://www.epa.gov/healthresearch/cumulative-impacts-research#Cumulative%20Impacts%20Report.] and dedicated funding to the "development of innovative approaches to assess the toxicity of chemical mixtures."[FN36: Env't Prot. Agency, Development of Innovative Approaches to Assess the Toxicity of Chemical Mixtures Request for Applications (RFA), https://www.epa.gov/research-grants/development-innovative-approaches-assess-toxicity-chemical-mixtures-request (last updated May 30, 2023).] The EPA also recently released draft principles of cumulative risk assessment under the Toxic Substances Control Act to address risks from mixtures of chemicals. [FN37: ENV'T PROT. AGENCY, DRAFT PROPOSED PRINCIPLES OF CUMULATIVE RISK ASSESSMENT UNDER THE TOXIC SUBSTANCES CONTROL ACT (2023), https://www.epa.gov/system/files/documents/2023-02/Draft%20Principles%20of%20CRA%20under%20TCSA_0.pdf.] In 2011, the European Chemicals Agency released an opinion and guidance document on toxicity and assessment of chemical mixtures,[FN38: EUROPEAN COMM'N, SCI. COMM. ON HEALTH & ENV'T RISKS, SCI. COMM. ON EMERGING & NEWLY IDENTIFIED RISKS, SCI. COMM. ON CONSUMER SAFETY, TOXICITY AND ASSESSMENT OF CHEMICAL MIXTURES (2011) https://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_155.pdf.] and in 2019 the European Food Safety Authority released guidance on risk assessment of

combined exposures from multiple chemicals. [FN39: Simon John More et al., Guidance on Harmonised Methodologies for Human Health, Animal Health and Ecological Risk Assessment of Combined Exposure to Multiple Chemicals, EFSA JOURNAL (2019) https://www.efsa.europa.eu/en/efsajournal/pub/5634.]

For the four HI PFAS, the hazard index is a meaningful opportunity to address combined risks from the four PFAS which national monitoring data suggest are substantially likely to "occur and co-occur with a frequency of public health concern."[FN40: PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18638, 18647 (March 29, 2023).] These four PFAS also pose similar health risks, "individually and in a mixture" such as "adverse effects on several biological systems including the endocrine, cardiovascular, developmental, immune, and hepatic systems" and "are anticipated to affect common target organs, tissues, or systems to produce dose-additive effects from co-exposures."[FN41: Id. At 18645.]

The use of the hazard index is also legally sound. The Safe Drinking Water Act does not specify the form that an MCL or MCLG must take. It only states that an MCLG must be "set at the level at which no known or anticipated adverse effects on the health of persons occur" and that the MCL must be "as close to the maximum contaminant level goal as feasible."[FN42: 42 U.S.C. [sec] 300g-1(b)(4).] In this case, the EPA has set an identical MCL and MCLG for the four HI PFAS by setting a hazard index "level" of 1 for both the MCL and MCLG.

EPA Response: This commenter supports the EPA's approach.

Clean Air Council, et al. (Doc. #1731, SBC-043858)

b. The HI method proposed for PFHxS, HFPO–DA, PFNA, and PFBS is effective and better protects public health than individual MCLs.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-053381)

AMWA is concerned that this proposed HI would serve as a de-facto MCL for systems that have detected only one of the PFAS chemicals present in their system. These de-facto MCLs are equal to the HBWC EPA has proposed, but the agency is not officially proposing them as individual MCLs, an action AMWA supports. If EPA is addressing the issues these chemicals cause as a mixture and when they co-occur, then it would make sense that a water system would need to have a mixture and co-occurrence (more than one) present to do this calculation.

EPA Response: Please see sections 4.3.2, 3, and 5 of the EPA response in this *Response to Comments* document. The EPA is finalizing a Hazard Index of 1 (unitless) as the MCLG and MCL for any mixture containing two or more of PFHxS, PFNA, HFPO-DA and PFBS.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-053383)

AMWA is concerned that once there is a holistic view of PFAS occurrence from UCMR 5 data, it will become clear the HI approach may not have been the most appropriate. The addition of more PFAS to this HI will decrease the quotient threshold each quotient is allowed, without being more protective of public health. For example, right now each PFAS chemical can have a quotient of 0.25 (0.25+0.25+0.25+0.25=1), a value of ¼ of the HBWC and/or health advisories and still be compliant, but if one more PFAS chemical is added to make five, that quotient reduces to 0.2. At some point, the HI of 1.0 will not be attainable with additional PFAS, and EPA will have to evaluate its options on how to group and separate certain PFAS.

Several AMWA utilities, based on their current monitoring data for PFAS, would be in noncompliance based solely on one or more of these PFAS chemicals in the HI. EPA assumes PFOA and PFOS will be the driving force in costs and decisions, but many utilities will have to make decisions primarily on the chemicals included in this HI. This is why EPA must have the best data and information necessary to make the most informed and science-supported decisions.

EPA Response: The commenter incorrectly interprets the Hazard Index approach as having four HQs equal to 0.25. In fact, HQs will differ across time and space depending on the actual measured concentrations of each of the four component PFAS. Regarding potential addition of PFAS, the EPA's final regulatory determination and final rule are limited to the mixtures that include two or more of PFNA, PFHxS, PFBS, and HFPO-DA. If there is any potential future inclusion of additional PFAS under this approach, such inclusion would be the subject of a potential future regulatory process. Also, please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

With respect to the comment about HAs as a basis for HBWCs: HAs are not a pre-requisite for an NPDWR under the SDWA and there is nothing in the statute or the EPA's historical regulatory practice that suggests that the agency must or should delay regulation of a contaminant in order to develop a HA first. Further, the Has for HFPO-DA and PFBS are not a basis or the starting point for their respective HBWCs. The EPA acknowledges that the Has and HBWCs have been set at the same level, but the EPA's HBWCs for HFPO-DA and PFBS represent its conclusions at the time of the rulemaking to calculate the HBWC using identified RfDs, to select the identified DWI-BWs, and apply the RSCs of 0.20.

American Water Works Association (AWWA) (Doc. #1759, SBC-045646)

The proposed approach for the regulation of these compounds includes the development of a hazard index (HI) that is used to determine if the combined levels of 4 PFAS pose a potential health risk. The use of this approach represents the first time a HI approach has been applied for a federal regulation; it has traditionally been applied as a screening tool to make initial decisions regarding chemical remediation. It is also important to note that the approach used by the agency in this case is inconsistent with existing regulatory guidelines; therefore, one of the main focuses of these comments are around the application of a HI outside of a screening approach and the challenges in finding support for this approach in the available science for PFAS.

As the proposed PFAS NPDWR is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review, an economic analysis is required under Executive Order 12866. The remaining comments focus on the USEPA's use of the available science related to PFAS exposure and selected endpoints, specifically low birth weight and cardiovascular disease (CVD) to attempt to demonstrate quantifiable and nonquantifiable health risk reduction benefits are likely to occur as the result of compliance with the proposed NPDWR.

EPA Response: Please see sections 4.3.2 and 13 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045635)

Finally, the hazard index approach is insufficiently substantiated by occurrence data and toxicological science.

EPA Response: Please see sections 4.3.1, 4.3.2, and 6 of the EPA response in this *Response to Comments* document.

Connecticut Section of the AWWA (CTAWWA) and Connecticut Water Works Association (CWWA) (Doc. #1763, SBC-044237)

Hazard Index

The proposed use of a Hazard Index is difficult to communicate to customers and the general public. Unlike a traditional MCL, the Hazard Index is a calculation and has proved challenging to explain to customers since the proposed PFAS Rule was released. We encourage the EPA to consider traditional MCLs, which would enable utilities and other drinking water professionals including regulators to effectively explain the PFAS Rule to customers.

EPA Response: Please see sections 4.3.2 and 1.2 of the EPA response in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-045676)

ii. The hazard index approach is not appropriate in the regulatory context

The use of the general HI approach as proposed by EPA is contingent on potential exposure information, compound toxicology, and an acceptable noncancer hazard. In short, the general HI method applies principles of human health risk assessment, but in an inherently flawed manner. The science of cumulative risk assessment of chemical mixtures has been the topic of research and policy making for decades, and as it pertains to PFAS, even EPA acknowledged that "there is currently no consensus on whether or how PFAS should be combined for risk assessment purposes" (USEPA 2023, p. 3) as also discussed in Section V.C of the proposed rule. Nonetheless, EPA arbitrarily employs the proposed general HI approach even though, by its own

admission, it is not a consensus method and is contrary to EPA's longstanding guidance and policy related to the application of risk assessment of chemical mixtures.

The general HI method is intended for "screening level" assessments that determine the need for further evaluation, rather than the basis for an expensive and complex NPDWR. In no fewer than three EPA risk assessment guidance documents, EPA refers to the general HI approach as "screening level," including: EPA's Guidelines for Health Risk Assessment of Mixtures (USEPA 1986), Risk Assessment Guidance for Superfund – Part A (USEPA 1989), Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures (USEPA 2000a).

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document. The EPA acknowledges that there remains a lack of "consensus on whether or how PFAS should be combined for risk assessment purposes." Under the statute, the EPA must act based on the "best available" science and information. Thus, the statute recognizes that the EPA may act in the face of imperfect information. It also provides a mechanism for the EPA to update standards as more science becomes available. For the PFAS covered by this rule, the EPA concluded that the state of the science and information has sufficiently advanced to the point to satisfy the statutory requirements and fulfill SDWA's purpose to protect public health by addressing contaminants in the nation's PWSs.

Uttara Jhaveri (Doc. #1778, SBC-045443)

EPA's proposal of an MCL for mixtures of PFHxS, HFPO–DA, PFNA, and PFBS expressed as an HI is important when considering the negative impact of PFAS mixtures on human health. [FN14: Id.] The relativity of the PFAS and increase or decrease in levels of certain PFAS may make the HI framework beneficial to inform the protection of human health for any source water PFAS, with available human health assessment values, still in production and use.

EPA Response: This commenter supports the EPA's approach.

Uttara Jhaveri (Doc. #1778, SBC-045444)

Moreover, with the HI approach, additional PFAS can be added over time once more information on health effects, analytics, exposure and treatment is available, and merits additional regulation as determined by EPA. Therefore, the framework is beneficial to address additional PFAS in the future by the Federal and State public health agencies.

EPA Response: The commenter supports the EPA's approach.

Silent Spring Institute (Doc. #1784, SBC-045802)

3. Regulating PFHxS, HFPO-DA, PFNA, and PFBS cumulatively using a hazard index approach is appropriate. It is a practical decision for addressing noncancer effects, and has been previously

applied in numerous regulatory settings such as CERCLA. We recognize the proposed rule as a step in the right direction toward a class-based approach.

We recognize EPA's decision to regulate PFHxS, HFPO-DA, PFNA, and PFBS cumulatively using a hazard index (HI) as a practical decision and likely protective against dose additive noncancer effects. The HI has not been employed in federal drinking water regulations before, which is likely due in large part to the fact that EPA has promulgated very few drinking water standards in the last few decades.

EPA has precedent in grouping chemicals with similar toxicological effects. In fact, the HI is a long- standing practice in EPA's own risk assessment guidelines [REF23: U.S. Environmental Protection Agency. Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS). Washington D.C. 2023.; REF24: U.S. EPA. Guidelines for the Health Risk Assessment of Chemical Mixtures. Washington D.C. 1986.; REF25: U.S. EPA. Risk Assessment guidance for Superfund. Vol. 1. Human Health Evaluation Manual (Part A). Washington D.C. 1991.; REF26: U.S. EPA. Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures. https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=20533. 2000.] and in other federal regulatory programs such as CERCLA. The HI is based on a grouping method that accounts for toxicological similarity while adjusting for relative potencies. EPA has used a similar grouping approach in developing MCLs for trihalomethanes and haloacetic acids, which assume equivalent potencies.

This HI approach also represents an important step forward in addressing PFAS as mixtures of chemicals. Silent Spring Institute supports a class-based approach to addressing PFAS.[REF10: Cordner A, De La Rosa VY, Schaider LA, Rudel RA, Richter L, Brown B. Guideline levels for PFOA and PFOS in drinking water: the role of scientific uncertainty, risk assessment decisions, and social factors. J Expo Anal Environ Epidemiol. 2019.; REF27: Kwiatkowski CF, Andrews DQ, Birnbaum LS, et al. Scientific Basis for Managing PFAS as a Chemical Class. Environ Sci Technol Lett. 2020;7(8):532-543.] Many authoritative state agencies, scholars, scientists, advocacy organizations, professional societies, and regulators in the European Union have upheld the importance of treating PFAS as mixtures of similar chemicals. For example, the American Public Health Association [REF28: American Public Health Association. Reducing Human Exposure to Highly Fluorinated Chemicals to Protect Public Health. 2016.] and a number of expert scientists including Dr. Linda Birnbaum, former head of the National Institute for Environmental Health Sciences, have called for treating PFAS as a class based on their shared chemical properties. Moreover, in 2019, the European Union recommended an action plan to eliminate all non-essential uses of PFAS as a class, indicating regulatory agencies are already moving in this direction.

EPA Response: This commenter supports the EPA's approach.

PFAS Project Lab (Doc. #1786, SBC-044715)

Moreover, EPA has undertaken toxicological evaluations of PFBS and HFPO-DA and it is thus critical that they also be included in current rulemaking given their adverse health outcomes. Communities are frequently exposed to these PFAS, as well as others, as mixtures in drinking water (Pelch et al. 2023) and scientific practice supports approaching the health risks posed by possible mixtures of PFHxS, HFPO-DA, PFNA, and PFBS as part of a Hazard Index. While EPA has adopted few MCLs in recent decades (and thus has not had much opportunity to employ this approach in drinking water regulation), Hazard Indices are commonly used by EPA, including in developing health protective clean-up goals under CERCLA.

EPA Response: This commenter supports the EPA's approach.

National Ground Water Association (NGWA) (Doc. #1804, SBC-045461)

Hazard Index (HI) · The "Mixture MCL" for PFNA, PFHxS, PFBS, and GenX makes technical sense, but may be confusing and esoteric to the public. Why would EPA not use an MCL consistent with the other contaminants? Use of the MCL is probably more easily understood by the public. Using the MCL for all contaminants clearly communicates whether a concentration is over or under the standard. NGWA recommends use of the MCL for all contaminants and not use of the Hazard Index.

EPA Response: Please see sections 4.3.2 and 1.2 of the EPA response in this *Response to Comments* document. After considering the comments, the EPA has established individual MCLGs and MCLs for three of these PFAS in addition to the Hazard Index MCLG and MCL. For the EPA's discussion on the establishment of stand-alone MCLs for PFHxS, HFPO-DA, and PFNA in addition to the Hazard Index MCL, please see section 5.2 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046106)

C. EPA's Proposed MCL for GenX, PFBS, PFNA and PFHxS is Consistent with the SDWA and Supported by the Record

i. A Hazard Index Is a Well Established and Appropriate Method of Addressing the Risks Posed by Mixtures of Multiple PFAS

For the HI PFAS, EPA proposed an MCLG and MCL using an approach that addresses the harms caused by each of those contaminants individually, as well as by their combined presence in drinking water supplies. This approach is well grounded in the SDWA, and it is needed to protect communities that have multiple PFAS in their drinking water supplies.

A hazard index is "commonly used" to measure and regulate risks from mixtures, or combinations, of contaminants that cause similar health effects. [FN79: Proposed Rule, 88 Fed. Reg. at 18,639.] Under this approach, EPA calculates each contaminant's "hazard quotient," or individual risk, by dividing the level of human exposure (i.e., the concentration of the contaminant in drinking water) by the level at which the contaminant presents risk to human

health (referring to be EPA as a Health-Based Water Concentration or "HBWC"). [FN80: Id.] A hazard quotient below 1 indicates an individual chemical is present below the level that is known to cause risk. To calculate the risk from the mixture, EPA adds the chemicals' hazard quotients to calculate a hazard index, with a hazard index above 1 generally indicating elevated risk to human health. [FN81: Id.] However, the use of a hazard index of 1 as an adequate health threshold relies on EPA's ability to address all of the harms associated with the chemicals at issue in their underlying toxicity assessments. Given the uncertainties inherent in the estimation of risk and the multitude of factors that are not included in EPA calculations– including the effects of non-chemical stressors and co-exposures to other PFAS that are not covered by the Proposed Rule – EPA should consider the use of a hazard index below 1 to provide the "adequate margin of safety" required by the SDWA. [FN82: 42 U.S.C. § 300g–1(b)(4)(A); see also Devon Payne-Sturges et al., Cumulative Risk Evaluation of Phthalates Under TSCA, 57 Env't Sci. & Tech. 6403, 6409 (2023), https://pubs.acs.org/doi/full/10.1021/acs.est.2c08364 (challenging the "traditional use of HI ≤ 1 as being 'safe' or acceptable for mixtures/multiple chemical exposures" and proposing "the use of a HI of 0.1–0.2 as a benchmark").]

Hazard indices have long been used by EPA offices and endorsed by leading scientific authorities, including EPA's Science Advisory Board. EPA calculates hazard indices under the Comprehensive Environmental Response, Compensation, and Liability Act to measure the cumulative effects of multiple contaminants at a Superfund site and to develop health-protective clean-up goals. [FN83: See EPA, EPA/540/1-89/002, Risk Assessment Guidance for Superfund: Volume I Human Health Evaluation Manual (Part A), Off. Of Emergency and Remedial Response, at 8-11–8-13, https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=2000KLZ9.txt ("At most Superfund sites, one must assess potential health effects of more than one chemical … Estimating risk or hazard potential by considering one chemical at a time might significantly underestimate the risks associated with simultaneous exposures to several substances … To assess the overall potential for noncarcinogenic effects posed by more than one chemical, a hazard index (HI) approach has been developed based on EPA's (1986b) Guidelines for Health Risk Assessment of Chemical Mixtures.")] They are also used under the Clean Air Act to calculate chronic risks from multiple chemicals released by a given source category. [FN84: See National Emission Standards for Hazardous Air Pollutants: Cyanide Chemicals Manufacturing Residual Risk and Technology Review, 86 Fed. Reg. 3906, 3910-11 (Jan. 15, 2021).] Hazard indices address the potential for "low levels of multiple [chemicals] that individually would not likely result in adverse health effects . . .to result in adverse health effects" when combined in a mixture. This approach to calculating risk – also known as dose additivity – "has found widespread acceptance as an assessment concept for combined exposures to multiple chemicals . . . and is extensively used by regulatory authorities as a protective default approach." [FN85: Org. for Econ. Coop. and Dev., ENV/JM/MONO(2018)37, Considerations for Assessing the Risks of Combined Exposure to Multiple Chemicals: Series on Testing and Assessment No. 296, at 19 (Dec. 6, 2018), https://www.oecd.org/chemicalsafety/risk-assessment/considerations-for-assessing-the-risks-of-combined-exposure-to-multiple-chemicals.pdf.]

Here, a hazard index is necessary and appropriate to address the harms associated with the HI PFAS. As EPA found, "PFHxS, [GenX], PFNA, and PFBS … result[] in common adverse effects on several biological systems including thyroid hormone levels, lipid synthesis and metabolism, as well as on development, and immune and liver function." [FN86: Proposed Rule, 88 Fed. Reg. at 18,647.] Exposure to mixtures of those chemicals poses greater risks than exposure to each chemical in isolation, such that setting individual chemical MCLs would not fully protect people who have combinations of the HI PFAS in their drinking water. EPA also found, based on nationwide monitoring data, that "there is a substantial likelihood PFHxS, [GenX], PFNA, and PFBS will occur and co-occur with a frequency of public health concern." [FN87: Id.] "When three or four HI PFAS were monitored, over 40 percent of systems reported detections of two to three of the HI PFAS." [FN88: Id. At 18,676.] An MCL that ignores those co-exposures could leave millions of people at risk. [FN89: See id. At 18,678]

This is the precise scenario that has justified prior, mixture-based MCLs. In its disinfection byproducts rule, EPA set a combined MCL for five THMs that are detected together in drinking water and cause similar health effects. [FN90: 90 44 Fed. Reg. at 68,624, 68,626-28.] Because of their combined effects, regulating each component of that mixture in isolation would "permit a substantial number of communities . . . to avoid any improvement of treatment practice and, by implication, water quality." [FN91: Id. At 68,628.] As described above, EPA also regulated all PCBs under a single MCL because individual isomer limits would understate their combined risks. [FN92: 56 Fed. Reg. at 3,546.] Here, too, EPA cannot protect communities with multiple HI PFAS in their drinking water unless its MCL accounts for the harms associated with those chemicals' mixtures.

EPA Response: This commenter supports the EPA's approach. The agency agrees that it has the statutory authority to regulate mixture combinations containing some or all of these four PFAS. Please see section III.A.2 of the final rule preamble, as well as section 3.2 of the EPA response in this *Response to Comments* document regarding this statutory authority.

Earthjustice et al. (Doc. #1808, SBC-046107)

ii. EPA Should Maintain its Hazard Index Approach to Setting the MCLGs and MCLs for the HI PFAS While Updating its Hazard Index Calculations to Reflect the Best Available Science

With appropriate inputs, a hazard index of 1 reflects "the level at which no known or anticipated adverse effects on the health of persons occur" from exposure to the HI PFAS, as required for an MCLG. [FN93: 42 U.S.C. § 300g–1(b)(4).] Because the HI PFAS cause a range of harmful effects at different exposure levels, simply setting a maximum concentration for their combined presence in drinking water, as EPA has done for prior contaminant mixtures, would not address their "known or anticipated" adverse effects. [FN94: Id.] By dividing each contaminant's exposure level by the lowest level at which the contaminant is known to pose harm, EPA can calculate hazard quotients that are tailored to each contaminant and that protect against effects that occur at higher exposure levels. And by adding those quotients to calculate the hazard index,

EPA can protect against adverse effects from mixtures of the HI PFAS and ensure that people who are exposed to multiple HI PFAS are not placed at risk. [FN95: As described below, EPA should update its toxicity values (or Health Based Water Concentrations) for the HI PFAS to reflect the latest available science on those chemicals' hazards. Those revisions would not change the MCL or MCLG; they would merely ensure that the calculations that EPA used to calculate the hazard index are fully protective of human health.] However, this approach requires EPA to set HBWCs—the denominators in its hazard quotient equations [FN96: Proposed Rule, 88 Fed. Reg. at 18,665.] —at levels that protect against all of a contaminants' adverse health effects, including effects to "subgroups . . . such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations[] that are identifiable as being at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population." [FN97: 42 U.S.C. § 300g–1(b)(1)(C).] As explained below, EPA's proposed HBWCs do not address the HI PFAS' increased risks to infants and must be revised in a manner consistent with the best available science. We urge EPA to use the reduced HBWCs recommended below when calculating the Hazard Index for the purposes of setting the HI PFAS MCLG.

A hazard index of 1 is also "feasible with the use of the best [available] technology," and is a proper MCL. Here, as well, EPA should revise the denominators for its hazard index calculations. Because the HBWCs proposed below are significantly lower than the practical quantitation level for the HI PFAS, laboratories may not be able to detect MCL exceedances that are based on those levels. Therefore, when calculating the hazard index for the purpose of setting and implementing the MCL, we recommend that EPA use the PQL for each HI PFAS as the denominator, similar to EPA's approach for PFOA, PFOS, and other chemicals that pose health risks below their respective PQLs. This would ensure that the HI PFAS MCL is feasible, because (1) laboratories can already detect each HI PFAS down to the PQL and (2) water systems can reduce levels of the HI PFAS below their respective PQLs by using the same treatment technologies that EPA has proposed to address PFOA and PFOS, including granular activated carbon and reverse osmosis. [FN98: Proposed Rule, 88 Fed. Reg. at 18,665-66.] Similar to PFOA and PFOS, many communities are already using those technologies to treat water contaminated with GenX and other HI PFAS.

The SDWA does not dictate the form of an MCL or MCLG; it merely requires the MCLG to be set at a health-protective "level" and the MCL to be set as close as feasible to that level. EPA's Proposed Rule, with the changes recommended herein, satisfies those statutory requirements. In the past, EPA has set MCLs based on the percentage of water samples that detected a class of contaminants (total coliforms), as opposed to a density-based limit, because "the presence-absence concept is simpler and mathematically more precise than the current density standard for total coliforms[.]" [FN99: Drinking Water; National Primary Drinking Water Regulations; Total Coliforms (Including Fecal Coliforms and E. coli), 54 Fed. Reg. 27,544, 27,548 (June 29, 1989).] Similarly, a hazard index provides a "more precise" estimate of the HI PFAS' effects than a concentration-based limit, consistent with the SDWA's mandate to minimize those contaminants' adverse effects to the extent feasible.

EPA Response: This commenter supports the EPA's approach to use a Hazard Index MCLG. Please see section 4.3.3 of the EPA response in this *Response to Comments* document for the EPA responses to comments related to modifications of the HBWCs. At the final HBWCs, there are no analytical measurement limitations since the final HBWCs are all above each of the respective PFAS' PQLs. For additional discussion about the form of an MCLG/MCL, please see section 5.2.1 of the EPA response in this *Response to Comments* document.

Environmental Working Group et al. (Doc. #1810, SBC-044688)

The PFAS addressed by EPA's proposal are among a class of thousands of forever chemicals. EPA's proposal to use a hazard index to address multiple co-occurring PFAS recognizes the risks associated with harmful chemical mixtures. Like many members of the PFAS class, PFBS, PFNA, GenX, and PFHxS have similar chemical structures and cause similar health effects. Many communities are exposed to, and harmed by, mixtures of those PFAS in their drinking water. EPA's approach provides a framework for addressing additional PFAS and mixtures of chemicals in the future, which would allow the Agency to move more rapidly to protect public health.

EPA Response: This commenter supports the EPA's approach.

Little Hocking Water Association (Doc. #1835, SBC-045510)

Support of preliminary regulatory determinations for PFHxS, HFPO-DA, PFNA, and PFBS.

LHWA supports regulation and adoption of MCLs for the four proposed PFAS chemicals HFPO-DA, PFHxS, PFNA, and PFBS through the use of a Hazard Index of 1.0. Further, LHWA supports a MCLG of 1.0 as a Hazard Index.

EPA Response: This commenter supports the EPA's approach. Please also see section 4.3.4 of the EPA response in this *Response to Comments* document.

Citizens Energy Group (Doc. #1838, SBC-044854)

Section V – Maximum Contaminant Level Goal

EPA requests comment on the general HI approach for the mixture of four PFAS.

Citizens supports the proposed Hazard Index as an appropriate approach to manage risks associated with this complex class of chemicals. The use of the Hazard Index is similar to the way that the Clean Air Act programs regulate dioxin/furan emissions from stationary sources, allowing emission units to demonstrate compliance based on the combined toxicity of the compounds, weighted for relative toxicity, rather than numeric limits for individual compounds.

EPA Response: This commenter supports the EPA's approach.

Alliance of Nurses for Healthy Environments (Doc. #3072-27, SBC-047374)

Good afternoon. My name is Sarah Bucic and I have been a registered nurse for over 20 years and I am here with the Alliance of Nurses for Healthy Environments. We're the only national nursing organization focused solely on the intersection of health and the environment and we support EPA's proposed regulation of PFAS in drinking water under the Federal Safe Drinking Water Act. By establishing strong limits on six widely detected PFAS, the proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses each year. National standards to limit the concentration of PFAS in drinking water are long overdue. EPA's proposal for the six PFAS would set the national standard for PFOA and PFOS at the lowest detection level approved by the Agency and would establish limits on GenX, PFBS, PFNA, and PFHxS using a hazard index. And because most people are exposed to mixtures of PFAS, EPA's proposal to use a hazard index to address multiple co-occurring PFAS recognizes the risks associated with harmful chemical mixtures.

EPA Response: This commenter supports the EPA's approach.

Massachusetts Water Resources Authority (Doc. #3072-49, SBC-047378)

Good afternoon and thank you. I'm Stephen Estes-Smargiassi, director of Planning and Sustainability at the Mass Water Resources Authority, today speaking for myself. I'll offer some very brief comments on key aspects of EPA's approach to this very important proposed regulation. National PFAS standard could reduce customer confusion associated with the very different state standards already in place. Unfortunately, components of this proposal failed to help with the confusion. The hazard index, most critically. Hazard index is typically used as a screening tool. It's relatively easy to calculate, but very difficult to explain to the typical lay audience we need to communicate with. Being able to communicate effectively about how we protect public health and how we determine what to invest in is key to public confidence.

EPA Response: Please see sections 4.3.2 and 1.2 of the EPA response in this *Response to Comments* document.

Alliance of Nurses for Healthy Environments (Doc. #1544, SBC-042666)

The PFAS class of chemicals includes over 12,000 different compounds with various chemical properties [FN4: National Academies of Sciences, Engineering, and Medicine (NASEM). (2022). Guidance on PFAS Exposure, Testing, and Clinical Follow-Up. Washington, DC: The National Academies Press. https://doi.org/10.17226/26156.] and most people are exposed to mixtures of PFAS such that specific effects are difficult to disentangle. However, the PFAS addressed by EPA's proposal are among this class of thousands of forever chemicals. EPA's proposal to use a hazard index to address multiple co-occurring PFAS recognizes the risks associated with harmful chemical mixtures. Like many members of the PFAS class, PFBS, PFNA, GenX, and PFHxS have similar chemical structures and cause similar health effects. Many communities are exposed

to, and harmed by, mixtures of those PFAS in their drinking water. EPA's approach provides a framework for addressing additional PFAS and mixtures of chemicals in the future, which would allow the Agency to move more rapidly to protect public health.

EPA Response: This commenter supports the EPA's approach.

Oregon Health Authority (OHA) (Doc. #1582, SBC-042757)

State of Oregon Comments on the Proposed PFAS Rule

Docket ID No. EPA-HQ-OW-2022-0114

Oregon Health Authority

May 25, 2023

XIV. Request for Comment on Proposed Rule: The Agency is requesting comment on this proposed National Primary Drinking Water Regulation (NPDWR) for PFAS. In the proposal, the Agency highlighted numerous areas where specific public comment will be helpful for EPA in developing a final rule. EPA specifically requests comment on the following topics within each section of this preamble.

As the state agency in Oregon with primacy for the Safe Drinking Water Act (SDWA), Oregon Health Authority (OHA) submits the following comments on the proposed NPDWR for PFAS for the following topics requested by EPA.

Section V – Maximum Contaminant Level Goal

• EPA requests comment on the general Hazard Index (HI) approach for the mixture of four PFAS.

OHA applauds the EPA for pursuing a class approach to four out of the six PFAS species proposed for regulation under the Safe Drinking Water Act. The HI approach acknowledges evidence suggesting that many PFAS species have similar biological targets and cumulatively affect toxicity in an additive fashion. While the proposed Health-Based Water Concentrations (HBWCs) for the four PFAS included in the HI approach are not all based on the same critical health effect, the proposed approach provides optimal public health protection in the face of scientific uncertainty

• EPA requests comment on the merits and drawbacks of the target-specific HI or relative potency factor (RPF) approach.

The merits of a target-specific HI or RPF approach include greater certainty about the additive nature of the cumulative impact of exposure to all four of these PFAS species. The main drawback is that the approach could result in residual risk if any of the included PFAS species have critical health effects at doses lower than the shared effects upon which their common-target HBWCs would be based. To protect against this, a target-specific HI approach would

require additional consideration of that residual risk on an individual PFAS species basis. That would add complexity to the process that is probably not warranted.

Therefore, OHA favors the simple HI approach proposed by EPA as there are no concerns about residual risk of critical effects for specific PFAS outside any shared target-organ effects. OHA encourages EPA to stick with the simple HI approach for the four included PFAS as proposed.

EPA Response: This commenter supports the EPA's approach. The EPA agrees that the TOSHI and RPF approaches would underestimate risk, and thus would not be consistent with the statutory definition of MCLG. Please see section 4.3.2 of the EPA response in this *Response to Comments* document.

Suffolk County Water Authority (SCWA) (Doc. #1589, SBC-043366)

3. Use of a Health Index for MCLs or MCLGs Will be Complicated and Confusing

While the use of a health index for determining dose additive health effects for selected PFAS may have merit from a technical perspective, utilizing a health index for a combined MCLG or MCL will be complicated and confusing for public water suppliers and their customers. A health index will add complexity for water systems trying to determine whether or not they have violated or are approaching an MCL at a particular location. Similarly, reporting PFAS health index analyses in a Consumer Confidence Report will likely not add to a consumer's confidence but only create consumer confusion.

For operational simplicity and customer communication purposes, contaminant specific MCLs and MCLGs would be preferred for the four PFAS for which EPA is considering a health index. However, if EPA wanted to maintain the PFAS health index as the MCLG, one alternative would be to set the MCLs for the four PFAS in the index at their respective health based water concentrations (HBWC). Thus, the MCLG would utilize the health index, but the enforceable MCL would be set at the respective HBWCs. Such a change would eliminate the vast majority of the complexity and confusion issues regarding a health index.

EPA Response: Please see sections 4.3.2 and 1.2 of the EPA response in this *Response to Comments* document. After considering the comments, the EPA has established individual MCLGs and MCLs for three of these PFAS in addition to the Hazard Index MCLG and MCL. For the EPA's discussion on the establishment of stand-alone MCLs for PFHxS, HFPO-DA, and PFNA in addition to the Hazard Index MCL, please see section 5.2 of the EPA response in this *Response to Comments* document.

Consumer Reports (Doc. #1656, SBC-043190)

For PFHxS, GenX chemicals, PFNA, and PFBS, and their mixtures, EPA has decided to use the Hazard Index (HI) methodology, which EPA regularly uses, for example in the Superfund program, to understand the health risks from chemical mixtures as the basis for setting a MCLG.

The HI approach assumes there is a dose additivity to the different chemicals in a mixture. This assumption of dose additivity is particularly clear in cases where each of the chemicals has a common mechanism of action and mainly affect the same human health endpoint. EPA considered two main types of HI approaches: 1) general HI which allows for each chemical in the mixture to have different health endpoints as the basis for the component chemical health-based reference value (e.g., RfD, HBWC) and 2) target-organ specific HI which relies on reference values based on the same organ or organ system (e.g., liver-, thyroid-, or developmental-specific).

The general HI is based on the overall RfD which is protective of all the effects for a given chemical regardless of organ or organ system, and thus a more protective estimate of risk, while the target-organ specific HI is a less protective estimate of risk since it focuses on only one target organ. For example, if a chemical has effects on multiple organs, the one target organ chosen for the HI may be one for which the effect may be less potent than on another organ or for which there may be significant currently unquantified effects due to lack of data. In addition, many PFAS lack human epidemiological or experimental animal hazard and dose-response data across a broad effect range which would limit determining target-organ specific values. EPA also considered the relative potency factor (RPF) approach, which represents the relative difference in potency of an effect/endpoint between a specific chemical and other chemicals in the mixture. The RPF approach has the same limitations as the organ-specific HI. EPA proposes to use the general HI as the most appropriate approach for considering PFAS mixtures, because the four PFAS chemicals frequently co-occur and can be expected to adversely impact multiple (but in many cases shared) health endpoints.

We agree with EPA that the general HI is the most appropriate approach for setting a MCLG for mixtures of PFHxS, GenX chemicals, PFNA, and PFBS since this approach adds an appropriate margin of safety for a class of contaminants that have been shown to co-occur in mixtures and for which there may be dose additivity since they share similar profiles of health effect areas (e.g., liver, thyroid, developmental, cardiovascular, etc.). Neither the target-organ HI approach nor the RPF approach will add an appropriate margin of safety.

The general HI is defined as the sum of the Hazard Quotient (HQ) for each chemical in a mixture. HQs are the ratio of potential exposure to a chemical and the level at which no health effects are expected. The HQ for a specific chemical is the exposure level (defined as its concentration in the drinking water) divided by the health reference value, in this case the HBWC (health-based water concentration) for that chemical. The MCLG for a mixture of PFHxS, GenX chemicals, PFNA, and PFBS is set at 1.

As noted previously, the HBWCs for PFHxS, GenX chemicals, PFNA, and PFBS are 9 ppt, 10 ppt, 10 ppt, and 2,000 ppt, respectively. Note that if the level of a specific chemical in drinking water exceeds the HBWC, then the HQ would be > 1, e.g., that specific chemical would exceed the “safe” level . Using the general HI approach, the levels of each chemical can be below their “safe” level (the HBWC), e.g., their HQ < 1, yet the HI could exceed 1 and so the mixture could be considered unsafe. For example, let’s say that levels of PFHxS, GenX chemicals, PFNA, and

PFBS in a drinking water sample are all 5 ppt, e.g., below the HBWC for each PFAS. The HI = (5 ppt/9 ppt) + (5 ppt/10 ppt) + (5 ppt/10 ppt) + (5 ppt/2,000 ppt) = .55 + .5 + .5 + .025 = 1.58. This shows the additive effect of the HI.

We agree with EPA that the MCLG for the mixture of PFHxS, GenX chemicals, PFNA, and PFBS should be the same as the HI and set at 1.

EPA Response: This commenter supports the EPA's approach.

Maine Organic Farmers and Gardeners Association (MOFGA) (Doc. #1660, SBC-043382)

We agree with EPA that the rule shouldn't be limited to PFOA and PFOS, and we support the hazard index approach for the other PFAS. While PFOA and PFOS continue to contaminate water and soil even 30 years after sludge was spread, newer chemicals including GenX are also ubiquitous and pose health hazards. For example, a recent study in 16 states (including Maine) detected 26 unique PFAS in water samples, including 12 not covered by current EPA testing methods. [FN4: Science in the Total Environment, https://www.sciencedirect.com/science/article/pii/S0048969723015966?via%3Dihub#bb0115]

EPA Response: This commenter supports the EPA's approach.

Citizens Energy Group (Doc. #1838, SBC-044859)

EPA requests comment on its proposal of using an HI approach for PFHxS, HFPO-DA, PFNA, and PFBS, including whether it can be clearly implemented and achieves the goal of protecting against dose additive noncancer health effects.

Citizens believes that it is appropriate to use the proposed Hazard Index (HI) for the group of four PFAS compounds and that the HI approach can be implemented by water systems. The proposed HI is parallel to approaches used in other media (dioxins/furans in air, for example), to acknowledge differences in toxic endpoints in a broad class of contaminants that may be present in mixtures.

EPA Response: This commenter supports the EPA's approach.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044169)

A. General Comments

1. NCDEQ supports EPA's efforts to collectively address PFAS as a group in a regulatory framework in addition to multiple individual maximum contaminant levels (MCLs).

NCDEQ supports EPA's decision to develop an NPDWR that addresses PFAS as a group in addition to MCLs for individual substances. PFAS are rarely found in the environment as a single chemical and the general public is demanding that cumulative health effects of multiple PFAS chemicals be considered. EPA's proposed standard method that accounts for health risks

associated with a group of PFAS based on available scientific data is a necessary first step for the long-term management of this class of chemicals.

EPA Response: This commenter supports the EPA's approach.

Horsham Water & Sewer Authority (HWSA) (Doc. #1686, SBC-043818)

While we stated earlier that we would not comment on the proposed PFOA and PFOS MCLs, we do wish to address the proposed Hazard Index (HI) MCL for the combination of PFBS, PFNA, PFHxS and GenX. We believe this HI is unnecessarily complicated and not appropriate. If EPA has occurrence data and health data that supports a regulatory determination for each of these compounds, then make that determination and move forward with individual MCLs.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document. After considering the comments, the EPA has established individual MCLGs and MCLs for three of these PFAS in addition to the Hazard Index MCLG and MCL. For the EPA's discussion on the establishment of stand-alone MCLs for PFHxS, HFPO-DA, and PFNA in addition to the Hazard Index MCL, please see section 5 of the EPA response in this *Response to Comments* document.

Clean Water Action/Clean Water Fund (Doc. #1697, SBC-045002)

The Hazard Index Proposal for Four PFAS

Although a hazard index approach has not been used in drinking water regulation, the concept of reducing public health risk from groups of chemicals is not new. Several NPDWRs address groups of contaminants, including regulations around disinfection byproducts and radionuclides. The concept of regulating drinking water contaminants as a class, rather than setting individual limits for every contaminant in the group or class, is also not a new one. One of the principles in EPA's 2010 Drinking Water Strategy was to "Address contaminants as a group rather than one at a time so that enhancement of drinking water protection can be achieved cost-effectively."[FN5: EPA Administrator Jackson Outlines New Vision for Clean, Safe Drinking Water, EPA press release, March 22, 2010] EPA's Science Advisory Board noted that it is "a reasonable approach for estimating the potential aggregate health hazards associated with the occurrence of chemical mixtures in environmental media."[FN6: Review of EPA's Analyses to Support EPA's National Primary Drinking Water Rulemaking for PFAS, EPA Science Advisory Board, August 22, 2022, p.91]

The Hazard Index approach, also addresses the dose additive impacts of exposure to multiple PFAS chemicals at low levels in a way that individual contaminant limits would not. Exposure to mixtures of PFAS chemicals can have health impacts that exposure to the individual chemicals at those low levels would not. This is a critical issue and Hazard Index approach allows for consideration of this dose additive characteristic of exposure to groups of PFAS chemicals at low levels. As noted in the proposal, the Hazard Index approach also allows for the addition of more

PFAS chemicals as information becomes available to develop the Health Based Water Concentration and to assess occurrence.

EPA Response: This commenter supports the EPA's approach.

Citizens Campaign for the Environment (CCE) (Doc. #1710, SBC-045134)

• Adopt EPA's Proposed Hazard Index of one unitless for four additional PFAS

CCE supports EPA's proposed Hazard Index of unitless one for perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO-DA, commonly known as GenX Chemicals), perfluorohexane sulfonic acid (PFHxS), and perfluorobutane sulfonic acid (PFBS). This is a critical step to better protecting the public from the suite of PFAS chemicals that may be present in drinking water. Exposure to multiple PFAS chemicals simultaneously has the potential to worsen health impacts. There is growing concern and scientific evidence on the combined synergistic effect exposure to multiple PFAS chemicals can have. A recent study evaluating the combined toxicological effects of PFOS, PFOA, PFNA, PFDA, PFHxS, and PFHpA on liver cells found that overall, the toxicological interactions of these PFAS chemicals had a synergistic effect especially at low to medium levels. [FN2: Combined Effect and Toxicological Interactions of Perfluoroalkyl and Polyfluoroalkyl Substance mixtures in Human Liver Cells. Atinuke F. Ojo, Cheng Peng, Jack C. Ng, 2020. https://www.sciencedirect.com/science/article/abs/pii/S0269749119361469?via%3Dihub] Given the potential for synergistic effects of PFAS chemicals, it is crucial that the EPA adopt this strong Hazard Index standard.

EPA Response: This commenter supports the EPA's approach.

West Virginia Rivers Coalition et al. (Doc. #1746, SBC-045247)

Taken together, PFHxS, HFPO-DA, PFNA, and PFBS occur and co-occur in both raw-water and finished water of PWSs in West Virginia with a frequency and at levels of public health concern. We support EPA's proposal of a hazard index (HI) to address the harms caused by each of these contaminants individually, as well as by their combined presence in drinking water. The use of such an index is most protective of public health, and needed to protect our communities exposed to multiple PFAS in their drinking water.

EPA Response: This commenter supports the EPA's approach.

Center for Environmental Health et al. (Doc. #1764, SBC-044243)

We agree with EPA's Hazard Index (HI) Approach to calculating MCLs for PFBS, PFHxS, PFNA, HFPO-DA and its ammonium salts. The hazard index, (HI) defined in the proposal as

[Equation 1: see docket ID EPA-HQ-OQ-2022-0114-1764]

where the Hazard Quotient, HQ is the ratio of the PFAS occurrence concentration, E, in mg/L and the reference value, RfV, is consistent with the prevailing scientific view that the health risks of these four PFAS are additive in mixtures, and therefore the presence of any one in a mixture could present significant health risks in drinking water. In the absence of best available scientific data EPA should continue exercising precautions to protect the most vulnerable populations while also requiring responsible parties, like the chemical industry, to fully fund independent human epidemiological studies on already overexposed populations.

We support the MCLs of the proposed NPDWS as calculated using the HI approach and urge EPA to quickly finalize them. We further urge EPA to continue updating its HI calculations by sourcing data collected using its authority under Section 4 of TSCA in addition to calculating RfVi from publicly available UCMR3 and State-level water data in the issuance of future drinking water standards.

EPA Response: This commenter supports the EPA's approach.

Environmental Protection Network (EPN) (Doc. #1773, SBC-043853)

Hazard Index MCLG

EPN commends EPA for using a general Hazard Index (HI) approach to address the additive effects of four co-occurring PFAS chemicals. We note that this approach has been used for years by EPA and the states under the Superfund program and is well-suited to address the thousands of PFAS chemicals in the environment. We believe that the general HI provides a framework for all future PFAS drinking water standards because additional compounds can be included as more information becomes available on their health effects, exposures, analytical methods, and treatment efficiency.

Due to widespread use and persistence, many PFAS compounds are known to co-occur in drinking water and the environment, often found in different combinations as mixtures. All the PFAS chemicals studied to date have been found to cause common adverse effects on several biological systems and functions, including thyroid hormone levels, lipid synthesis and metabolism, fetal and infant development, immune and liver function. The general HI allows for component chemicals to have different health effects or endpoints as the basis for their chemical reference values. A target-organ specific HI is less health protective when contaminants like PFAS impact multiple organs, and the target-organ is not the most sensitive endpoint for all the component chemicals.

EPA Response: This commenter supports the EPA's approach.

Minnesota Pollution Control Agency (MPCA) (Doc. #1569, SBC-042490)

Section V - Maximum Contaminant Level Goal (MCLG)

1) EPA requests comment on the general HI approach for the mixture of four PFAS.

MPCA response:

• MPCA supports the use of a general HI approach for the mixture of four PFAS given that there are limitations to deriving health effect-specific reference doses for many PFAS.

EPA Response: The commenter supports the EPA's approach.

New England Interstate Water Pollution Control Commission (NEIWPCC) (Doc. #1650, SBC-043151)

Hazard Index Approach

Generally, our member states are supportive of the proposed Hazard Index approach, albeit with an important caveat. Our member states note that the flexibility inherit with this approach allows for easier modifications in the future. Such modifications could include the refinement of the MCLs, the future addition of other compounds, and the removal of a compound for stand-alone regulation. We generally also prefer the Hazard Index approach over the summing approach some states are currently utilizing. Overall, we find that the Hazard Index approach more effectively considers the variation in MCLs across all PFAS compounds.

EPA Response: The commenter supports the EPA's approach.

Consumer Reports (Doc. #1656, SBC-043192)

The MCL for the mixtures of PFHxS, GenX chemicals, PFNA, and PFBS would be an HI = 1.0. The EPA has also determined that there are validated analytical methods (EPA Method 533 and 537.1) that can measure below the HBWC for each of these PFAS. EPA has determined that multiple technologies (i.e., GAC, AIX, RO and NF) are both available and have demonstrated PFAS removal efficiencies that may exceed >99 percent and that achieve concentrations below their PQLs (between 3.0–5.0 ppt) at a reasonable cost based on large and metropolitan water systems.

We support EPA's proposal to set the HI for the mixtures of PFHxS, GenX chemicals, PFNA, and PFBS at an HI = 1.0, since it is feasible to test drinking water at that level and multiple treatment technologies exist to reduce PFHxS, GenX chemicals, PFNA, and PFBS to below their specific HBWC at reasonable cost.

Best,

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EPA Response: The commenter supports the EPA's approach. Please also see section 4.3.4 of the EPA response in this *Response to Comments* document.

Greater North Dakota Chamber et al. (Doc. #1593, SBC-042802)

The novel hazard index approach. The hazard index approach for the PFAS other than PFOA and PFOS has never been used in setting an MCL, and it presents technical, scientific, and legal questions about how it would be implemented.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document. For the EPA response to comments about technical, scientific, and legal questions related to an MCL based on the Hazard Index approach, please see section 5 of the EPA response in this *Response to Comments* document.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-044883)

Proposed Hazard Index (HI) MCL

• DEP supports EPA's efforts to set a group MCL for PFAS. However, we do not believe that the use of a proposed HI is appropriate or feasible.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-052942)

• DEP has concerns regarding the use of the HI as a drinking water MCL as it is proposed. It is DEP's understanding that the HI is typically used as site-specific cleanup criteria, where the full range of contaminants likely to be present at a contamination site is known. Those contaminants, specific to an individual site, can be evaluated for overall risk based on several factors, including how they interact with one another, exposure factors, toxicity values, etc. By attempting to apply the HI concept as an across-the-board drinking water standard, it becomes an arbitrary evaluation of just those four contaminants included in the calculation. Any other contaminants that may be

present and may interact with the four HI PFAS are not accounted for. It is important to note that when used appropriately as cleanup criteria at a specific site, the HI would take into account not just other PFAS, but also any other type of interacting contaminant that may contribute to overall risk. As proposed, this HI MCL arbitrarily considers only the four HI PFAS, which DEP believes is not an appropriate application of the HI concept.

EPA Response: While it is recognized that any given site or exposure medium (e.g., water) may include a diverse landscape of environmental chemicals, in addition to PFAS, the expressed focus of the current NPDWR is on the PFAS indicated (i.e., HFPO-DA, PFBS, PFHxS, PFNA). Also, although component-based mixtures methods such as the Hazard Index have predominately been applied under site-specific assessment contexts (e.g., CERCLA), there is no indication in any existent EPA guidance that precludes application to other problem formulations under other authorities (e.g., SDWA). Additionally, the EPA disagrees that the Hazard Index MCL arbitrarily considers only the four PFAS because under the SDWA regulatory determination process, the EPA is required to evaluate contaminants using the three statutory criteria. As described within section III of the final rule preamble and in section 3 of this *Response to Comments* document, the agency has completed this evaluation and there is available health, occurrence, and other meaningful opportunity information for three PFAS (PFHxS, PFNA, and HFPO-DA) to meet the SDWA statutory criteria for regulation individually and four PFAS (PFHxS, PFNA, HFPO-DA, and PFBS) as a mixture. In addition, the commenter hasn't explained why the Hazard Index approach is not appropriate for regulation of a mixture under SDWA.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-052943)

• DEP also notes that the HI calculation included in the proposed rulemaking is a shortcut method to estimate HI that does not allow for an actual risk calculation. The proposed HI calculation uses HQs that are determined by comparing the measured concentration of a contaminant to the HBWC. As noted above, this calculation does not include values such as exposure factors and toxicity values that are typically included in HI determinations. Without that additional information, it is not possible to fully quantify the risk level with the HI. Therefore, it is not appropriate to introduce an HI MCL as a drinking water standard.

EPA Response: The EPA disagrees with this comment. The Hazard Index is not a "shortcut method … that does not allow for an actual risk calculation." On the contrary, the Hazard Index is a component-based mixture assessment approach that provides an indication of risk (USEPA, 1986; USEPA, 1991c, USEPA, 2000b; USEPA, 2023j). A Hazard Index greater than 1 (rounded to one significant digit) indicates that exposure from the combination of PFAS (i.e., in drinking water) exceeds the health-protective level (based on dose additivity), and thus, risk is indicated. A Hazard Index less than or equal to 1 indicates that occurrence of these four PFAS in drinking water does not exceed the health-protective level and is therefore generally regarded as unlikely to result in any appreciable risk (USEPA, 1986; USEPA, 1991c; USEPA, 2000b). In this application in the NPDWR, the Hazard Index does include exposure factors and

toxicity reference values to derive the HBWCs, which are subsequently used to calculate the Hazard Index (for a complete description of HBWC inputs, please see USEPA, 2024h). See also section 4.3.2 of the EPA response in this *Response to Comments* document.

Superfund Settlements Project (SSP) and RCRA Corrective Action Project (RCAP) (Doc. #1631, SBC-052849)

It is also indefensible to base a regulatory standard with broad applicability to 66,000 water systems and numerous contaminated sites across the country on a risk assessment tool developed for case-by-case application to ensure appropriate decision-making. [FN14: See, e.g., USEPA, Guidelines for the Health Risk Assessment of Chemical Mixtures, EPA/630/R-98/002 at vii (September 1986) (hereinafter, "Mixtures Guidelines") ("In particular, the guidelines emphasize that risk assessments will be conducted on a case-by-case basis, giving full consideration to all relevant scientific information. This case-by-case approach means that Agency experts review the scientific Information on each agent and use the most scientifically appropriate interpretation to assess risk."] Similarly, it is inappropriate to base a regulatory standard on the use of a tool that EPA guidance recommends only for screening. And further, the Proposal uses the HI approach in a manner contrary to EPA's guidance by seeking to add impacts based on different health effect end points based on only animal studies. [FN15: See, e.g., USEPA, Guidance for Identifying Pesticide Chemicals and Other Substances That Have A Common Mechanism of Toxicity (January 29, 1999).] While the preamble asserts that the health effects of these substances are additive, [FN16: See, e.g., 88 Fed. Reg. 18639 (exposure to a mixture of PFAS in drinking water "can be assumed" to act in a dose-additive manner); 88 Fed. Reg. 18645 (mixtures "are anticipated" to affect common organs, tissues and systems to produce dose-additive effects); 88 Fed. Reg. 18650 (PFAS "are likely" dose additive).] the proffered health effect endpoints on which EPA bases its HBWC differ – body weight gain and developmental delays in mice for PFNA, thyroid effects in male rats for PFHxS, thyroid effects in mice for PFBS and liver lesions in female mice for GenX. EPA admits that there is no consensus on whether or how PFAS should be combined for risk assessment purposes. [FN17: 88 Fed. Reg. 18654.] In addition, EPA is further adding more specificity to what should be a screening tool by setting the HI using two significant digits, contrary to EPA's guidance and longstanding practice as well as basic mathematical rounding rules.

EPA Response: The EPA disagrees with these comments. Please see sections 4.3, 4.3.2, and 4.3.4 of the EPA response in this *Response to Comments* document. Additionally, the EPA disagrees that "It is also indefensible to base a regulatory standard with broad applicability to 66,000 water systems and numerous contaminated sites across the country on a risk assessment tool developed for case-by-case application to ensure appropriate decision-making." The commenter is incorrect stating that it is "indefensible" to set an MCLG using the Hazard Index approach. In fact, given the temporal and spatial variability of PFAS occurrence in drinking water across the nation (USEPA, 2024j), it is not merely defensible, but appropriate to regulate these chemicals in drinking water by taking a flexible approach that considers site-specific data at each PWS. Component PFAS HQs are expected to differ across time and space depending on

the actual measured concentrations of each of the four PFAS. This approach allows for flexibility beyond a one-size-fits-all approach and is tailored to address risk from mixtures of these PFAS at each PWS. Furthermore, consistent with the statutory standard in SDWA, use of the Hazard Index ensures that the EPA sets an MCLG for mixtures of two or more of PFNA, PFHxS, HFPO-DA, and PFBS at a level at which there are no known or anticipated health effects on the health of persons, and allowing an adequate margin of safety.

The EPA acknowledges that there remains a lack of "consensus on whether or how PFAS should be combined for risk assessment purposes." Under the statute, the EPA must act based on the "best available" science and information. Thus, the statute recognizes that the EPA may act in the face of imperfect information. It also provides a mechanism for the EPA to update standards as more science becomes available. For the PFAS covered by this rule, the EPA concluded that the state of the science and information has sufficiently advanced to the point to satisfy the statutory requirements and fulfill SDWA's purpose to protect public health by addressing contaminants in the nation's PWSs.

Superfund Settlements Project (SSP) and RCRA Corrective Action Project (RCAP) (Doc. #1631, SBC-052850)

The HI approach should not remain in the final rulemaking. EPA guidance is clear on the point that the HI approach is a rough measure that should be used only as a screening tool. [FN18: EPA's use of the HI approach in connection with the Clean Air Act is similarly as a screening tool. See EPA, AirToxScreen Overview, available at https://www.epa.gov/AirToxScreen/airtoxscreen-overview.]

• "The hazard index provides a rough measure of likely toxicity and requires cautious interpretation." [FN19: Mixtures Guidelines at 9.]

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document. Also, the EPA acknowledges that the quoted statement is in Appendix A of its supplemental mixtures guidance (USEPA, 2000b); however, the guidance goes on to say the following (emphasis added):

"The hazard index is only a numerical indication of the nearness to acceptable limits of exposure or the degree to which acceptable exposure levels are exceeded. As this index approaches unity, concern for the potential hazard of the mixture increases. If the index exceeds unity, the concern is the same as if an individual chemical exposure exceeded its acceptable level by the same proportion."

This means that if the HI approaches 1 the potential hazard associated with the mixture increases, and when it is above 1, risk is indicated in the same way that it would be if an individual chemical exposure exceeded its acceptable level by the same proportion. An HI greater than 1 is generally regarded as an indicator of adverse health risks associated with a specific level of exposure to the mixture; an HI less than or equal to 1 is generally regarded as not being

associated with any appreciable risk (USEPA, 1986; USEPA, 1991c; USEPA, 2000b). Thus, in the case of this drinking water rule, an HI greater than 1 indicates that occurrence of two or more of the four component PFAS in a mixture in drinking water exceeds the health protective level(s) (i.e., HBWC(s)), indicating health risks. The EPA maintains that the HI MCLG is consistent with EPA chemical mixtures guidance (USEPA, 2000b) as well as the EPA's obligation under SDWA (Section 1412(b)(4)(A)) to set MCLGs at "the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." The EPA acknowledges that its AirToxScreen is a nonregulatory tool to provide communities with information about health risks from air toxics.

Superfund Settlements Project (SSP) and RCRA Corrective Action Project (RCAP) (Doc. #1631, SBC-052851)

• "[T]he act of combining all compounds, even if they induce dissimilar effects, is a screening procedure and not the preferred procedure in developing a hazard index." [FN20: Mixtures Guidelines at 26.]

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document.

Superfund Settlements Project (SSP) and RCRA Corrective Action Project (RCAP) (Doc. #1631, SBC-052852)

• "When used with components of unknown or dissimilar action, the hazard index is less accurate and should be interpreted only as a rough indication of concern." [FN21: Mixtures Guidelines at 27.]

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document. The EPA's chemical mixtures guidance (USEPA, 2000b) articulates that an ideal condition for evaluation of dose additivity of component chemicals is at the level of common mode of action (MOA; also referred to as 'toxic action'). However, the guidance also says that the dose additivity assumption can be relaxed to the level of toxicological similarity (i.e., same/similar adverse health effect) in order to use component-based mixture assessment methods such as the Hazard Index. This is captured in the Hazard Index section of the 2000 EPA chemical mixtures guidance as follows: "In practice, because of the common lack of information on mode of action and pharmacokinetics, the requirement of toxicologic similarity is usually relaxed to that of similarity of target organs" (USEPA, 2000b). This approach (i.e., relying on common health domains), was supported by the EPA Science Advisory Board review of the draft PFAS Mixtures Framework (USEPA, 2022b). Furthermore, the commenter pulled the quote from a response to public comments found in part B of Appendix A of the EPA supplemental mixtures guidance; this same text is not found or communicated in the body of that document.

Superfund Settlements Project (SSP) and RCRA Corrective Action Project (RCAP) (Doc. #1631, SBC-052853)

EPA guidance is also clear on the point that use of the HI approach for anything other than screening should be based on a single health outcome:

• "Dose additivity is based on the assumption that the components in the mixture have the same mode of action and elicit the same effects." [FN22: Mixtures Guidelines at 14.]

• "The biological basis for dose addition is the similarity of chemical components regarding toxicologic behavior, such as toxic mechanism, mode of action, or endpoint." [FN23: USEPA, Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures, EPA/630/R-00/002 at 80 (August 2000) (hereinafter "Supplementary Mixture Guidance").]

• "[D]ose additive models are not the most biologically plausible approach if the compounds do not have the same mode of toxicologic action." [FN24: Mixtures Guidelines at 8.]

EPA Response: Please see section 4.3.1 of the EPA response in this *Response to Comments* document. The EPA supplemental mixtures guidance (USEPA, 2000b) does indeed articulate that an ideal condition for evaluation of dose additivity of mixture component chemicals is at the level of common MOA (also referred to as 'toxic action'). However, the guidance document also posits that dose additivity interpretation can be relaxed to the level of toxicological similarity (sans MOA) and applied in component-based mixture assessment methods such as the Hazard Index. This is captured in the Hazard Index section (section 4.2) of the 2000 EPA supplemental mixtures guidance as follows: "In practice, because of the common lack of information on MOA and pharmacokinetics, the requirement of toxicologic similarity is usually relaxed to that of similarity of target organs." This approach (i.e., relying on common health domains) was supported by the EPA Science Advisory Board review of the draft PFAS Mixtures Framework (USEPA, 2022b).

Superfund Settlements Project (SSP) and RCRA Corrective Action Project (RCAP) (Doc. #1631, SBC-052854)

• "[T]he Hazard Index is then usually developed for each exposure route of interest, and for a single specific toxic effect or for toxicity to a single target organ." [FN25: Supplementary Mixture Guidance at 79.]

• "One of the key desirable features is the constraint to use only data on the effect of concern. Because the Hazard Index is tied to a specific effect, the underlying data should be on that effect." [FN26: Supplementary Mixture Guidance at 85.]

• "A separate HI should be calculated for each toxic effect of concern." [FN27: Supplementary Mixture Guidance at 86.]

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document. Also, the EPA supplemental mixtures guidance (USEPA, 2000b) also states:

"The default procedure for the HI has traditionally been to use the RfD or RfC (U.S. EPA, 1989a). Because of their much wider availability than TTDs, standardized development process including peer review, and official stature, the RfD and RfC are recommended for use in the default procedure for the HI." Further, the EPA's Risk Assessment Guidance for Superfund (RAGS) Volume I Human Health Evaluation Manual (Part A) states on pg. 8-15 "Segregation of hazard indices requires identification of the major effects of each chemical including those seen at higher doses than the critical effect (e.g., the chemical may cause liver damage at a dose of 100 mg/kg-day and neurotoxicity at a dose of 250 mg/kg-day). Major effect categories include neurotoxicity, developmental toxicity, reproductive toxicity, immunotoxicity, and adverse effects by target organ (i.e., hepatic, renal, respiratory, cardiovascular, gastrointestinal, hematological, musculoskeletal, and dermal/ocular effects). *Although higher exposure levels may be required to produce adverse health effects other than the critical effect, the RfD can be used as the toxicity value for each effect category as a conservative and simplifying step*." (italics added for emphasis).

Superfund Settlements Project (SSP) and RCRA Corrective Action Project (RCAP) (Doc. #1631, SBC-052855)

In summary,

[A] limitation with the hazard index approach is that the assumption of dose additivity is most properly applied to compounds that induce the same effect by the same mechanism of action. Consequently, application of the hazard index equation to a number of compounds that are not expected to induce the same type of effects or that do not act by the same mechanism could overestimate the potential for effects, although such an approach is appropriate at a screening level. [FN28: USEPA, Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual (Part A), EPA/540/1-89/002 at 8-14 (December 1989).]

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

Superfund Settlements Project (SSP) and RCRA Corrective Action Project (RCAP) (Doc. #1631, SBC-052856)

This conclusion is consistent with the conclusions of the SAB. While EPA relies on the review of the SAB to justify its use of an HI, EPA's reliance is misguided and inconsistent with the SAB input. [FN29: See, e.g., 88 Fed. Reg. 18639, 18654 (quoting SAB Report but ignoring immediate prior sentences identifying HI as a screening level approach and indicating that toxicological studies to inform human health risk assessment are lacking for most PFAS and mixtures of PFAS).] Importantly, the SAB did not review the HI approach in connection with it being an

MCL and MCLG. Rather, SAB concluded the HI approach is appropriate as a screening tool, as EPA's guidance also concludes. Specifically, SAB stated:

In general, the screening level Hazard Index (HI) approach, in which Reference Values (RfVs) for the mixture components are used regardless of the effect on which the RfVs are based, is appropriate for initial screening of whether exposure to a mixture of PFAS poses a potential risk that should be further evaluated. [FN30: USEPA, Science Advisory Board, Review of EPA's Analyses to Support EP''s National Primary Drinking Water Rulemaking for PFAS, FINAL REPORT (hereinafter "SAB Review Report") at 91 (August 22, 2022); see also 88 Fed. Reg. 18655 ""the SAB emphasized that using a HI in the context of developing regulations for PFAS should not be directly interpreted as a quantitative estimate of mixture risk. Rather the SAB agreed that the HI can be used as an indicator of potential health risk(s) associated with exposure to mixtures of PFAS""")]

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

Superfund Settlements Project (SSP) and RCRA Corrective Action Project (RCAP) (Doc. #1631, SBC-052857)

In fact, regardless of how it, and SAB's review of it, was painted in the preamble to the Proposed Rule, [FN31: See, e.g., 88 Fed. Reg. 18662] EPA's Framework for Estimated Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substance (PFAS) comes to the same conclusion, recognizing the differences and weaknesses of a screening-level HI versus a target-organ-specific HI. [FN32: See USEPA, Framework for Estimated Noncancer Health Risks Associated with Mixtures of Per-and Polyfluoroalkyl Substance (PFAS), EPA 822D-21-003 (November 2021) (hereinafter, "Framework").] The Framework highlights that the HI is only "an indication of potential hazard, not an estimate of the concentration of the mixture in water that may result in adverse health outcomes after a specific period of exposure" and that "[c]omparisons of HI estimates across different exposure scenarios can be misleading." [FN33: Framework at 41. Note that PFOA and PFOS might also be used as indicators of the same risk(s) posed by at least three of the four PFAS included in the HI approach, making the HI approach superfluous and unnecessary.]

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

Superfund Settlements Project (SSP) and RCRA Corrective Action Project (RCAP) (Doc. #1631, SBC-052858)

Further undermining the appropriateness of the HI approach is the lack of human toxicity data and the corresponding high uncertainty factors used to develop the HWBC, calling into serious question whether, even if a blended MCLG and MCL were appropriate, it would satisfy the SDWA's requirement to use the best available, peer-reviewed science. [FN34: See 42 U.S.C. §

300g-1(b)(3)(A).] EPA's reference dose for PFNA, GenX chemicals, PFHxS, and PFBS is based entirely on laboratory animal studies, even though EPA itself advises "[a]dequate human data are the most relevant for assessing risks to humans" [FN35: USEPA, A Review of the Reference Dose and Reference Concentration Processes, 630/P-02/002F at 4-12 (December 2002).] and to "use only data on humans for the exposure scenario of concern." [FN36: Supplementary Mixture Guidance at 85.] In addition, EPA has not finalized a human health toxicity assessment for either PFHxS or PFNA, and EPA's assessments for GenX and PFBS were not reviewed by the SAB or subject to appropriate peer-review, which has generally been required for all past MCLG and MCL proposals including those in this Proposal for PFOA and PFOS. High uncertainty factors can weight the HI to where knowledge is lacking most and evidence of additivity may be weakest, further demonstrating that this approach is not scientifically defensible. As these uncertainties are addressed, frequent revisions to the HI will be necessary, something not addressed in the Proposal.

Causing additional concern, the preamble to the Proposed Rule states that "additional PFAS can be added over time. . . . As such, this approach provides a framework for Federal and State public health agencies to consider using to address other PFAS in the future as needed." [FN37: 88 Fed. Reg. 18670.] EPA's guidance states that "as the number of compounds in the mixture increases, an assumption of additivity will become less reliable in estimating risk" [FN38: Mixture Guidelines at 26. This is particularly true where no common mode of action or target organ is required.] and "the uncertainty associated with the hazard index increases as the number of components increases, so that it is less appropriate for evaluating the toxicity of complex mixtures." [FN39: Mixture Guidelines at 27.] With estimates that there are thousands of PFAS substances, how and on what basis PFAS would be added to the HI calculation when the original four do not comply with EPA guidance demonstrates the arbitrary nature of this approach for these purposes. The HI approach results in an arbitrary and capricious "moving target" with an open-ended array of impossible compliance calculations and should be removed from the final rule.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document. Also, with respect to the use of animal studies, SDWA requires that to the degree that the EPA's action is based on science, the EPA must use "the best available, peer reviewed science" and "data collected by accepted methods or best available methods." The HBWCs/MCLGs are based on the best available science and data collected by accepted methods (see section III in the preamble and USEPA, 2024h). Specifically, peer-reviewed, publicly available toxicity assessments are available for HFPO-DA (USEPA, 2021e), PFBS (USEPA, 2021d), PFNA (ATSDR, 2021), and PFHxS (ATSDR, 2021) that provide the oral toxicity reference values (i.e., RfD or minimal risk level) used to calculate the HBWCs; the EPA selected the corresponding DWI-BW for the relevant sensitive population or life stage from the Exposure Factors Handbook (USEPA, 2019) based on the best available, peer-reviewed science from publicly available, peer-reviewed studies taking into account the relevant sensitive population(s) or life stage(s); and the RSCs are based on the best available, peer-reviewed science or best available methods taking into account the relevant sensitive population(s) or life stage(s)

(USEPA, 2000c). For example, the HFPO-DA and PFBS human health assessments underwent extensive peer-review, including internal EPA review, interagency review, independent external peer review, and public review and comment. As noted in the EPA's *Staff Handbook for Developing IRIS Assessments* (USEPA, 2022a) and *A Review of the Reference Dose and Reference Concentration Process* (USEPA, 2002a), animal studies can provide the basis for toxicity reference values when adequate human studies are not available. Further, in the calculation of HBWCs, the DWI-BW values selected for each of the four PFAS takes into account the relevant sensitive population(s) or life stage(s); and RSCs are determined based on a literature review of potential exposure sources of the four PFAS (USEPA, 2000c). As it pertains to the portion of the comment regarding applicability of the Hazard Index to mixtures with increasing numbers of component chemicals, the text to which the commenter refers from the 1986 EPA Mixtures Guidelines is actually referring to similarity in 'toxic action' in support of an assumption of dose additivity. This is determined at the level of shared mode of action, whereas the Hazard Index is commonly applied under an assumption of dose additivity relaxed to the level of shared health effect/endpoint when MOA data are lacking, as in this case.

Regarding potential addition of PFAS, the EPA's final regulatory determination and final rule are limited to mixtures that include two or more of PFNA, PFHxS, PFBS, and HFPO-DA. If there is any potential future inclusion of additional PFAS under this approach, such inclusion would be the subject of a potential future regulatory process. For the EPA response to comments about the addition of PFAS to the HI calculation, please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Superfund Settlements Project (SSP) and RCRA Corrective Action Project (RCAP) (Doc. #1631, SBC-043433)

The Hazard Index approach is contrary to statutory requirements and EPA guidance.

The Proposed Rule would set an MCLG and MCL for PFNA, PFHxS, PFBS and GenX using an HI approach. Such an approach, however, is indefensible, being contrary to statutory requirements and EPA guidance. While HI's may be a routine component of contaminated site risk assessment, use of the HI to set a regulatory standard as set forth in the Proposal is novel and unsupportable, particularly given that it would have very broad applicability.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document.

Superfund Settlements Project (SSP) and RCRA Corrective Action Project (RCAP) (Doc. #1631, SBC-043428)

Further, the novel HI approach proposed for these four PFAS is insupportable.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document.

National Association of Water Companies (NAWC) (Doc. #1670, SBC-044158)

Comments

1. The novel hazard index approach is not workable and should be withdrawn.

NAWC supports EPA's action to set MCL's for PFOA and PFOS at appropriate levels based on the available science while considering the costs to implement the MCL's because EPA's regulatory determination provides a basis for the proposed action. EPA's proposed preliminary determination to regulate four (4) additional PFAS chemicals, however, is based on a novel hazard index approach, lacks foundation, is inconsistent with the requirements of the Safe Drinking Water Act, sets a dangerous precedent, and should be withdrawn. EPA's preliminary regulatory determination to regulate: (1) PFHxS, (2) HFPO-DA and its ammonium salt (also known as a GenX chemicals), (3) PFNA, and (4) PFBS, and mixtures of these PFAS as contaminants under SDWA presents legal and technical questions about how it would be implemented.

Procedurally, EPA bypassed the important two-step process of the Safe Drinking Water Act by issuing the preliminary determination and the drinking water standard at the same time for these four contaminants. Moreover, the hazard index approach has never been used in settling an MCL and the proposed regulatory determination lacks factual support. The current health data do not support a proposed determination to regulate these four chemicals and their mixtures, either individually or as a mixture.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document. For the EPA response to comments on the regulatory determination for the four PFAS, please see section 3 of the EPA response in this *Response to Comments* document.

New Hampshire Department of Environmental Services (NHDES) (Doc. #1690, SBC-044345)

Additionally, throughout EPA's proposed rule it emphasizes that the use of a Hazard Index is consistent with EPA regulatory activities despite not using this approach for regulation of drinking water contaminants as an MCL. EPA should, at a minimum, provide examples of where EPA has applied a Hazard Index as a regulatory action (not a screening level tool) for drinking water or other media that is regulated with similar authority. Furthermore, EPA should explain why the Hazard Index approach will be solely limited to a single class of chemicals (i.e., PFAS) instead of inclusion for other chemicals with similar effects on target organ systems. In several cases, Hazard Index approaches are applied to a variety of chemicals found at a site and not exclusively to a single "class" as applied in this proposed rule.

EPA Response: Although the EPA recognizes that the general Hazard Index has been used for several decades in at least one other regulatory context, the EPA is under no obligation to demonstrate that such an approach has previously been used in order to use such an approach in a SDWA rule. In fact, such an expectation would preclude the EPA from implementing the plain language of the SDWA, which requires the agency to use "best-available science." As

science is updated and develops, setting an artificial standard of "has the EPA done it exactly this way before?" would prevent the EPA's regulatory approaches from evolving with the science, thereby precluding the agency from using the best available science. As discussed elsewhere throughout the administrative record of this rulemaking action, the EPA maintains its statutory authority to regulate mixtures of PFHxS, PFNA, HFPO-DA, and/or PFBS, and if a mixture is considered a group, as some commenters suggest, Congress clearly contemplated that the EPA could regulated contaminants as groups. Please see section III of the preamble and section 3.2 of the EPA response in this *Response to Comments* document for further discussion. In this case, the agency has determined that use of a general Hazard Index for regulating mixtures of two or more of PFHxS, PFNA, HFPO-DA, and PFBS constitutes best available science as it considers the relative toxicity of the PFAS, and that the approach meets the agency's obligation to set an MCLG at a level where there are no known or anticipated adverse effects on the health of persons, allowing an adequate margin of safety. While it is recognized that any given site or exposure medium (e.g., water) may include a diverse landscape of environmental chemicals, in addition to PFAS, the expressed focus of the current NPDWR is on the PFAS indicated (i.e., HFPO-DA, PFBS, PFHxS, PFNA). And, although component-based mixtures methods such as the Hazard Index have previously been applied under site-specific assessment contexts (e.g., CERCLA), there is no indication in any existent EPA guidance that it cannot be used under other authorities (e.g., SDWA), and in fact, use of the approach generally has been supported by the SAB (please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document). The strength of the Hazard Index approach is flexibility in its application for chemicals for which exposure information (e.g., water concentration) and toxicity reference values (e.g., RfDs) are available. See also section 3 of the EPA response in this *Response to Comments* document about why the EPA selected these four PFAS for inclusion in the Hazard Index MCLG.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-053345)

2. The Hazard Index does not meet SDWA's requirement to use best available science

a. The Hazard Index approach used is only appropriate for initial screening, not for regulation

The SAB was asked to review a mixtures framework, which contained multiple approaches for estimating the likelihood of noncancer risks associated with PFAS. EPA provided the SAB with descriptions of additivity-based approaches including the Hazard Index approach, a relative potency factor (RFP) approach, and a mixture-benchmark dose (M-BMD) approach. The framework document applied these approaches using a hypothetical mixture of five PFAS. EPA did not ask the SAB to review the framework as it is being applied in this proposed rule to PFNA, PFHxS, PFBS, and HFPO-DA as a mixture.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-053350)

A Hazard Index approach that relies on different effects is not endorsed or supported by the SAB as being scientifically robust for a regulation. EPA has not explained why this screening level analysis is appropriate for an MCL, particularly since it is being used in a quantitative manner, to inform an economically significant regulation. Furthermore, EPA's own policy, as recently stated by the EPA Office of Chemical Safety and Pollution Prevention, is that the appropriate approach to addressing risks found in a screening level evaluation is to refine the evaluation [FN68: See EPA's Draft Proposed Principles of Cumulative Risk Assessment under the Toxic Substances Control Act, Feb. 2023, in which, when referring to assessing cumulative risk, EPA states, at page 14, that a "hierarchical approach" is used in which tiered exposure and hazard assessments are conducted and that "refinements are typically made when lower tier cumulative 483 assessments that rely on highly conservative assumptions do not demonstrate an adequate margin of 484 exposure (MOE)." When applying these same concepts to a HI approach, and a screening level approach shows concerns, additional refinements are appropriate. In this case, EPA has not provided any refinements. Available at: https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0918-0008.]. It is not appropriate to use a screening level approach to inform regulation when additional information exists to inform the assessment.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-053351)

EPA also notes that a Hazard Index approach is not novel because EPA uses it in the Superfund program [FN69: 88 Fed. Reg. at 18,669.]. But EPA's proposed use of a Hazard Index approach is inconsistent with Superfund program guidance. According to EPA's Risk Assessment Guidance for Superfund, the Hazard Index approach is most properly applied to compounds that produce the same effect by the same mode of action. If that condition is not met, the Superfund program guidance specifies that the Hazard Index should be used a screening tool only, just as the SAB had recommended [FN70: See Risk Assessment Guidance for Superfund Volume 1, Human Health Evaluation Manual (Part A), EPA/540/1-89/002, at 8-14, available at https://www.epa.gov/sites/default/files/2015-09/documents/rags_a.pdf.].

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-053352)

b. The proposed Hazard Index approach is not appropriate because it blends different end points, is not best available science, and leads to illogical outcomes

The best available science with respect to setting a Hazard Index is to assess how the chemical affects a target organ, or an endpoint. Using this target organ-specific data within a Hazard Index framework is referred to as the TOSHI approach. In discussing this approach, the SAB stated: "The TOSHI approach presents additional robustness compared to the Screening Level HI given

the identification of human health/toxicity values that are effect/endpoint specific."[FN71: Id. at 92.] EPA nevertheless suggests that a TOSHI approach is less health protective [FN72: 88 Fed. Reg. at 18655.]. This is simply wrong. Target organ-specific reference values are derived to be protective against the adverse effect that occurs at the lowest level. If different contaminants have different target organ reference values, they can, and should, be evaluated separately. This is the scientifically robust approach to using the Hazard Index. The SAB recognized that target organ-specific information may be lacking for certain PFAS, which helped to inform why the approach EPA used was only recognized for initial screening. Even so, in the case of the four PFAS being proposed for regulation, EPA has target organ-specific data which the Agency could have used in a more refined manner. If the data are sufficient for setting HBWCs, then they should also be considered sufficient for a more refined Hazard Index approach [FN73: We note that a recent panel of independent experts deliberated on the most scientifically justified method of grouping PFAS for the purposes of human health risk assessment and regulatory actions and concluded that grouping PFAS together without data supporting common mode of action and potency is inappropriate. See Anderson, J.K. et.al., Grouping of PFAS for human health risk assessment: Findings from an independent panel of experts, Reg. Tox. Pharm, 2022, 134 (105226). Available at: https://www.sciencedirect.com/science/article/pii/S0273230022001131.].

Ignoring certain information available to it, EPA instead chose to use a screening level approach to derive an MCL and MCLG for mixtures of PFAS to inform this highly complex and economically significant proposed regulation. This, and the lack of presentation of this to the SAB, violates SDWA's mandate to use "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices."[FN74: 42 U.S.C. [sec] 300g-1(b)(3)(A)(i).] EPA's explanation that the screening level approach, which is referred to as "general HI approach," is "a more health protective indicator of risk"[FN75: 88 Fed. Reg. at 18655.] does not eliminate its obligation to use best available science. SDWA mandates a rigorous science-driven approach to ensure the protection of health. It does not permit EPA to substitute a "reasonable policy choice"[FN76: Id. at 18655.] and forego a more rigorous analysis using data that is available.

EPA's screening level approach also leads to illogical outcomes. The Hazard Index may not be greater than 1.0. But if any of the individual PFAS occur at their HBWC, the ratio for that individual PFAS would be equal to 1. So, if two PFAS are at their HBWC (or even at half their HBWCs), the Hazard Index would be exceeded. In other words, the approach EPA has developed is so "health protective" that if even one PFAS is detected above its HBWC, the Hazard Index will be exceeded. This defeats the purpose of a mixtures approach because there are exceedances at detection levels before any additivity is considered. EPA's efforts to be "health protective" have led to an approach that is so restrictive that it makes any scientific evaluation irrelevant.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document. Regarding the comment that the "EPA has target organ-specific data which the Agency could have used in a more refined manner," this is incorrect. TTDs/target-organ

specific RfDs are not available for these four PFAS, and even if they were, the general Hazard Index is still the best approach to meet the statutory definition of MCLG.

American Water Works Association (AWWA) (Doc. #1759, SBC-045551)

3. The agency misuses the hazard index as a maximum contaminant level given it is not supported by federal guidance for assessing risk from mixtures and other issues.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document.

PFAS Regulatory Coalition (Doc. #1761, SBC-046071)

C. Use of the Hazard Index is inappropriate.

1. A Hazard Index does not meet the definition of an MCL.

The Safe Drinking Water Act defines MCL to mean: "the maximum permissible level of a contaminant in water which is delivered to any user of a public water system." SDWA Sec. 1401(3). Under the Hazard Index approach in the Proposal, EPA does not give a set "maximum permissible level." Instead, there is a range of levels for each of the four compounds, up to their respective "health-based water concentration" (HBWC), that could be either acceptable or unacceptable. The Proposal discusses how EPA has authority to regulate mixtures as "contaminants," but the examples that EPA provides are mixtures for which EPA has established fixed numbers. See 88 Fed. Reg. at 18644. EPA claims that it has authority to use a Hazard Index approach (see e.g., 88 Fed. Reg. at 18663), but EPA does not explain how a Hazard Index meets the SDWA definition of "maximum contaminant level."

2. A Hazard Index is not appropriate for compounds with different toxic modes of action.

A Hazard Index is not appropriate for compounds with different toxic modes of action. In this respect, the Hazard Index approach used in the Proposal is inconsistent with the approaches that are used in other EPA programs. EPA states that "the application of the HI approach under a regulatory purview is not novel," and the Agency cites CERCLA as an example of where the approach is used. 88 Fed. Reg. 18669. We agree that the HI approach is not novel, but what is novel is the very simplified approach EPA is using here. In EPA's 2000 "Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures," EPA lays out three approaches to conducting risk assessments for mixtures, recognizing how the state of the science influences which approach is appropriate. "Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures," EPA Risk Assessment Forum Technical Panel, August 2000, at p. xi (hereinafter "Supplementary Guidance").

In that Guidance, EPA further states that the "major concerns for the user are whether the available data are on components or whole mixtures, whether the data are composed of either similar components or similar mixtures that can be thought of as acting by similar toxicologic

processes, and whether the data may be grouped by emissions source, chemical structure, or biologic activity." Id. at xiv. Yet, in the EPA Proposal, the Agency provides no rationale as to why these four compounds can be grouped for a risk assessment that forms the basis of an HI. The EPA Proposal offers no support for a finding that these four additional PFAS compounds act by similar toxicologic processes or that they can be grouped by "emissions source, chemical structure, or biologic activity."

According to EPA's Risk Assessment Guidance for Superfund, the Hazard Index approach is most properly applied to compounds that produce the same effect by the same mode of action. If that condition is not met, the Hazard Index should be used as a screening tool only. See Risk Assessment Guidance for Superfund Volume 1, Human Health Evaluation Manual (Part A), EPA/540/1-89/002, at 8-14, available at https://www.epa.gov/sites/default/files/2015-09/documents/rags_a.pdf). If, absent data showing that the mode of action is the same, a Hazard Index should not be used to characterize risk at a Superfund site. Therefore, it certainly should not be used to establish a regulatory threshold.

The four PFAS species included in the proposed HI summation, PFNA, HFPO-DA, PFHxS, and PFBS, are dissimilar, and EPA presents no data confirming that the dose additivity model applies to these compounds. In the Supplementary Guidance referenced above, EPA explains that the "term additivity is used when the effect of the combination of chemicals can be estimated directly from the sum of the scaled exposure levels (dose addition) or of the responses (response addition) of the individual components." Supplementary Guidance, at 10. EPA's Proposal merely assumes additivity without adhering to either of the scientifically supported analytical approaches set forth in the Supplementary Guidance.

Further, EPA's additivity approach in the Proposal appears to prejudge issues that EPA is still considering as to PFAS compounds in other programs. In the CERCLA ANPRM issued in April 2023, EPA is specifically soliciting feedback on whether future CERCLA action could group PFAS compounds, including on the basis of modes of toxicological action:

EPA is considering whether to initiate a future action that would potentially designate groups or categories of PFAS as hazardous substances. A group or category refers to a set of PFAS that share one or more similar characteristics. Characteristics of interest could include, but are not limited to, chemical structure (e.g., carbon chain length, functional group), physical and chemical properties, mode of toxicological action, precursors or degradants, or co-occurrence.

88 Fed. Reg. 22402-403 (emphasis added). EPA then gives an example of a Significant New Use Rule (SNUR) issued under the Toxic Substances Control Act (TSCA), in which grouping was based on chemical structure. 88 Fed. Reg. 22403.

In the TSCA program, EPA has developed Draft Principles for Cumulative Risk Assessment (CRA; Link: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/cumulative-risk-assessment-under-toxic-substances). In that draft document, EPA bases additivity on toxicological similarity: "Deciding, based on their toxicological similarity, which chemical substances to include in a cumulative chemical group that subsequently would be evaluated

using dose additive models is an important element of a CRA." Draft Principles for Cumulative Risk Assessment, EPA Document # EPA-740-P-23-001, Feb. 2023, United States Office of Chemical Safety and Environmental Protection Agency, Pollution Prevention, lines 458460, available at https://www.epa.gov/assessing-and-managing-chemicals-undertsca/cumulative-risk-assessment-under-toxic-substances. The four additional PFAS addressed in the EPA Proposal are not toxicologically similar, so EPA grouping them here is inconsistent with how EPA would group these chemicals under TSCA.

In sum, the Proposal provides no basis for grouping these four compounds through use of a Hazard Index. EPA tries to justify the grouping by co-occurrence, but that justification is not scientifically supported. As discussed in Section A.2 above, we do not believe that co-occurrence is supported by the data. Simply put, a Hazard Index of compounds that share nothing other than being part of a larger class is meaningless. Moreover, the inconsistency between EPA's Proposal and the rationale for the use of dose additivity in other programs, such as CERCLA and TSCA, supports that conclusion that use of an HI as a surrogate for an MCL for these four compounds is arbitrary and capricious.

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document. Additionally, commenter is incorrect that the EPA does not provide a specific permissible maximum contaminant "level" with the Hazard Index MCL. The Hazard Index is set at a unitless value or level of 1. The EPA provides clear regulatory instructions for how to calculate whether the mixture is in compliance with that level. Regarding the EPA's rationale for considering these four contaminants as a mixture and the statutory authority for regulation of mixtures, please see section III.A.2 of the final rule preamble and section 3.2 of the EPA response in this *Response to Comments* document. Furthermore, as discussed in section 3 of this *Response to Comments* document, the EPA disagrees that it has not provided the statutory basis for regulation of mixture combinations of these four PFAS and that this justification is not scientifically supported through the best available information informing the EPA's regulatory determination. Specifically pertaining to co-occurrence information, please see sections 3.2.2 and 6.3 of the EPA response in this *Response to Comments* document.

U.S. Poultry & Egg Association et al. (Doc. #1765, SBC-044548)

4. The use of a Hazzard Index to regulate "levels" of PFAS Mixtures

In the proposed regulation, EPA is requesting comment on a preliminary determination to regulate additional PFAS referred to as ''GenX Chemicals," PFNA, and PFBS. EPA proposes to use a "Hazard Index" (HI) approach to protecting public health from these mixtures because of their known and additive toxic effects and occurrence and likely co-occurrence in drinking water.

The Agency has indicated the HI will be established as the total of component PFAS HQs, calculated by dividing the measured component PFAS concentration in water by the relevant Health Based Water Concentration (HBWC.) In this proposal, EPA is using HBWCs of 9.0 ppt for PFHxS, 10.0 ppt. The proposed regulations states "EPA is proposing an HI of 1.0 as the

MCLGs for these four PFAS and any mixture containing one or more of them because it represents a level at which no known or anticipated adverse effects on the health of persons is expected to occur and which allows for an adequate margin of safety."

According to the National Drinking Water Regulations, contaminants that EPA regulates through the issuance of a final regulatory determination, the contaminant identified must be regulated by issuing a MCL or, "if it is not economically or technically feasible to so ascertain the level of such contaminate," to employ a treatment technique.

The Safe Drinking Water Act (SDWA) requires the use of MCLs and MCLGs with specified levels to provide regulated entities with the information it needs to comply with the regulation. The HI scheme EPA proposes provides no level to guide the adoption of a treatment technique. Rather the HI is a sum of component hazard quotients, calculated by dividing the measured regulated PFAS component contaminant concentration in water by the associated health-based water concentration. This approach would bring a high level of uncertainty to the regulated community because of the variability that will occur from revising the health-based water concentrations.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document.

American Water Works Company Inc. (Doc. #1608, SBC-043990)

Use of the Hazard Index Approach to Regulate PFHxS, HFPO-DA, PFNA, and PFBS

American Water does not support the use of the Hazard Index as proposed for regulating PFAS in drinking water and recommends the development of drinking water regulations that follow the MCL approach. We understand the U.S. EPA's effort to manage multiple PFAS analytes through a single approach, and the fact that this approach is used in other environmental programs, but American Water has concerns about the application within drinking water.

The U.S. EPA is proposing to use the general Hazard Index approach that essentially adds together all PFAS regardless of the method of impact or health endpoint. As the U.S. EPA indicates, this approach is more conservative but lends itself to potentially inappropriate addition of health effects that should not be combined.

The use of the target-organ specific Hazard Index is anticipated to be less conservative but would be more consistent with an actual dose additive approach since the approach "…relies on toxicity value aggregated by the "same target organ endpoint/effect…" (Page 18655). American Water also notes that the preamble indicates that the target-organ specific Hazard Index requires a health-specific reference dose (RfD) in order to be used, which is consistent with our earlier comments regarding the need for consistent health effects information.

The examples below illustrate how the preamble is unclear on whether the Science Advisory Board explicitly reviewed and opined on the general Hazard Index Approach as proposed or the concept in general. The U.S. EPA should be transparent on this matter in the final rule.

"EPA's Science Advisory Board (SAB) opined that where the health endpoints of the chosen compounds are similar, it is reasonable to use an HI as ''a reasonable approach for estimating the potential aggregate health hazards associated with the occurrence of chemical mixtures in environmental media.'' (USEPA, 2022a). (Page 18639)

"EPA's SAB opined that where the health endpoints of the chosen compounds are similar, ''the HI methodology is a reasonable approach for estimating the potential aggregate health hazards associated with the occurrence of chemical mixtures in environmental media. The HI is an approach based on dose additivity (DA) that has been validated and used by EPA'' (USEPA, 2022a)." (Page 18654)

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

American Water Works Company Inc. (Doc. #1608, SBC-043983)

Use of the Hazard Index Approach to Regulate PFHxS, HFPO-DA, PFNA, and PFBS – American Water does not support the use of the Hazard Index as proposed for regulating PFAS in drinking water and recommends the development of drinking water regulations that follow the MCL approach once data to support such action is available.

EPA Response: Please see sections 4.3.2 and 3 of the EPA response in this *Response to Comments* document.

Raptor Pharm & Tox, Ltd (Doc. #1644, SBC-043419)

Hazard Index Approach Is Not Yet Justified

Raptor believes US EPA's hazard index approach to dose additivity is highly inappropriate given the current state of the science. In order for a hazard index approach to be appropriate, the chemicals must have dose-response curves that demonstrate the same efficacy, and the same overall shape of the curve, with only the potency being different. In other words, the curves need to have a correlation coefficient very close to 1, with the same efficacy. Violations of these assumptions makes the hazard index overly-conservative or not conservative enough. In other words, violations of the assumptions make the hazard index not scientifically justifiable.

Rather, the US EPA must avoid the use of the hazard index approach, as the US EPA has not given sufficient evidence to justify the approach. Using the hazard index without scientific justification will be a violation of the Safe Drinking Water Act.

Instead, Raptor recommends that US EPA and its partners at the US National Toxicology Program put together a mixtures study at human relevant concentrations, and at concentrations

near the final drinking water standard (which Raptor will note should not be the ones being proposed by the US EPA in this draft; rather, the final ones should be much higher, more in line with the value calculated by an international collaboration of risk assessors that recently proposed a more appropriate value).

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document. Regarding the suggestion that "US EPA and its partners at the US National Toxicology Program put together a mixtures study at human relevant concentrations," the EPA's final rule represents data-driven drinking water standards that are based on the best available science and meet the requirements of SDWA. For the six PFAS, the EPA considered PFAS health effects information, evidence supporting dose-additive health concerns from co-occurring PFAS, as well as national and state data for the levels of multiple PFAS in finished drinking water. SDWA provides a framework for the EPA to regulate emerging contaminants of concern in drinking water. Under the statute, the EPA must act based on the "best available" science and information. Thus, the statute recognizes that the EPA may act in the face of imperfect information. It also provides a mechanism for the EPA to update standards as more science becomes available. For the PFAS covered by this rule, the EPA concluded that the state of the science and information has sufficiently advanced to the point to satisfy the statutory requirements and fulfill SDWA's purpose to protect public health by addressing contaminants in the nation's PWSs.

The commenter's supposition about "chemicals must have dose-response curves that demonstrate the same efficacy, and the same overall shape of the curve, with only the potency being different" is true for application of the general Hazard Index specifically when all components have MOA data for the same effect/endpoint; the general Hazard Index does not require this to be met for application of dose additivity to a mixture of chemicals. This clarification is captured in text box 2.6.1.1 in the EPA's 2000 Supplemental Mixtures Guidance (USEPA, 2000b) where "The 'common mode-of-action' assumption can be met by using a surrogate of same target organ."

3M Company (Doc. #1774, SBC-045674)

e. EPA's Unprecedented Hazard Index Approach Violates the SDWA and is Arbitrary

EPA's proposal to regulate drinking water concentrations for the HI PFAS using the so-called "general HI approach" is arbitrary, not based on sound scientific principles, and does not conform with long-standing risk assessment practices and toxicological principles detailed in EPA's human health risk assessment guidance (USEPA 1986, 1989, 2000b). Further, the use of the general HI approach is at odds with methods currently employed in some EPA regulatory programs, and the adoption of this approach for use in National Primary Drinking Water Regulations (NPDWR) would introduce conflicting outcomes depending on PFAS present and their relative concentrations.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document. Given the temporal and spatial variability of PFAS occurrence in drinking water across the nation (USEPA, 2024j), it is appropriate to regulate these chemicals in drinking water by taking a flexible approach such as the general Hazard Index that considers site-specific occurrence data at each PWS. Component PFAS HQs are expected to differ across time and space depending on the actual measured concentrations of each of the four PFAS. This approach allows for flexibility beyond a one-size-fits-all approach and is tailored to address risk at each PWS.

American Chemistry Council (ACC) (Doc. #1841, SBC-052932)

A recent panel of independent experts deliberated on the most scientifically justified method of grouping PFAS for the purposes of human health risk assessment and regulatory actions and concluded that grouping PFAS together without data supporting common MOA and potency is inappropriate (Anderson et al., 2022). This panel of experts agreed that the HI dose additivity assumption for PFAS may be appropriate for screening (i.e., to determine if no risk or if further analysis is needed), but the data gaps currently present result in a high degree of uncertainty.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-052934)

EPA Mischaracterizes the Recommendations of its Science Advisory Board on the Application of a Hazard Index

In its review of EPA's proposed approach to PFAS mixtures, the SAB identified several cautions that are not reflected in the Agency's current proposal for a HI approach for the four PFAS. Of primary importance is the Board's answer to the charge question regarding the approach to which it responded that it "agrees with the use of Hazard Index (HI) as a screening method and decision-making tool." The Panel further explains –

In general, the screening level HI approach, in which Reference Values (RfVs) for the mixture components are used regardless of the effect on which the RfVs are based, is appropriate for initial screening of whether exposure to a mixture of PFAS poses a potential risk that should be further evaluated. [FN150: USEPA SAB Review, at 91.]

In fact, the most recent HI approach guidance from the EPA, as well as other U.S. agencies and international authorities, is to utilize the default HI approach as a preliminary screening step of a more comprehensive tiered methodology. [FN151: USEPA. Concepts, Methods, and Data Sources for Cumulative Health Risk Assessment of 584 Multiple Chemicals, Exposures, and Effects: A Resource Document. EPA/600/R-585 06/013F. Office of Research and Development (2007).] If the preliminary screening indicates there is a potential for risk (i.e., if HI>1), further

evaluation is recommended using "Tier 1 or 2" approaches, which include using target organ-specific HIs or the Target Organ Toxicity Dose (TTD) HI approach.

Yet, the Agency is proposing to abandon the need for further evaluation and to use the HI based on different health endpoints as the basis for regulation. This approach is counter, not only to the Board's advice, but also to the Agency's 2000 Supplementary Mixtures Guidance, 2007 guidance of cumulative risk, and to the recently proposed principles for cumulative risk assessment under the Toxic Substances Control Act (TSCA). [FN152: USEPA. Draft Proposed Principles of Cumulative Risk Assessment under the Toxic Substances Control Act. Public Comment Draft. EPA-740-P-23-001. Office of Chemical Safety and Pollution Prevention (2023). (USEPA Draft TSCA Cumulative Risk Principles)] Meek et al. have outlined an appropriate framework for evaluating combined exposure to multiple chemicals, using a tiered approach that incorporates additional information with each tier. [FN153: Meek ME et al. Risk assessment of combined exposure to multiple chemicals: A WHO/IPCS framework. Reg Toxicol Pharma 60:S1-S14 (2011).]

Rather than focus on the Board's recommendation to use the proposed HI for the four PFAS as a screening tool, the Agency characterization of the "generally favorable review" from the Board is based on the following language -

The SAB PFAS Review Panel supports dose additivity based on a common outcome, instead of a common mode of action as a health protective default assumption and does not propose another default approach. [FN154: USEPA SAB Review, at 90.]

Other than offer generalized statements, EPA has provided no evidence to support a "common outcome" among the endpoints selected for the four PFAS. [FN155: Interestingly, EPA's draft TSCA Cumulative Risk Principles suggest that assessing mixtures based on an effect on the same target organ may introduce too much uncertainty to risk estimates. USEPA TSCA Draft Cumulative Risk Principles, at 10.] The Agency's statement that its proposed HI is "a more protective indicator of risk," is neither scientifically supportable nor consistent with long-standing EPA policy on mixtures.

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document.

Missouri Department of Natural Resources (Doc. #1563, SBC-042517)

Section V—Maximum Contaminant Level Goal

EPA requests comment on the general HI approach for the mixture of four PFAS. The Department has concerns with the general HI approach identified by EPA in the rule. The HI is a new concept for drinking water regulation and would add complexity to rules that are already significantly more difficult for small systems with limited resources to comply with. While the Department agrees that different PFAS could have a cumulative impact, EPA needs to ensure that the health effect endpoints for any PFAS included in the index are in the same order of

magnitude to have meaningful additive health effects. If EPA proceeds with the HI approach, the Department agrees with EPA's Science Advisory Board (SAB) where they opined, "where the health endpoints of the chosen compounds are similar, it is reasonable to use an HI as a reasonable approach for estimating the potential aggregate health hazards associated with the occurrence of chemical mixtures in environmental media." However, the proposed HI does not include similar health endpoints as three analytes have a health based water concentration (HBWC) near 10 ppt and one has a HBWC at 2000 ppt. Further, EPA has not shown the aggregate health hazards are at similar concentrations. It matters if the aggregate health hazards are at 50%, 10% or only 1% of the set HBWC which is calculated the same as a lifetime health advisory level.

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document. The EPA disagrees with the assertion that in order to establish a Hazard Index MCLG for the PFAS mixture, the HBWCs of the individual mixture components must have similar orders of magnitude. There is no scientific or mathematical basis to suggest that HBWCs must be similar in magnitude. The use of the most scientifically sound, health-protective HBWCs in the development of a Hazard Index, regardless of whether they differ in magnitude, is consistent with EPA chemical mixtures guidance (USEPA, 2000b) as well as the EPA's obligation under SDWA (Section 1412(b)(4)(A)) to set MCLGs at "the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." The commenter appears to misunderstand the definition of HBWC and the practical application of the general Hazard Index approach in the context of the NPDWR. The general Hazard Index accounts for the combined effects of the different mixture components and compares the exposure level of each component to that component's corresponding HBWC, which is based on the most sensitive known adverse health outcome (as supported by the weight of evidence) for that component. In this context, the HBWC is the level below which adverse health effects over a lifetime of exposure are not expected to occur, including for sensitive populations and life stages. This level also meets the statutory definition of an MCLG, which is the level of a contaminant below which there are no known or adverse effects with an adequate margin of safety.

The proposal defined a mixture as containing one or more of the four PFAS and therefore covered each contaminant individually if only one of the four PFAS occurred. Thus, the general Hazard Index as proposed ensures that the level of exposure to an individual PFAS remains below that which could impact human health because the exposure for that measured PFAS is divided by its corresponding HBWC. In the general Hazard Index approach, individual PFAS HQs are calculated by dividing the measured concentration of each mixture component PFAS in water (e.g., expressed as ng/L) by the corresponding HBWC for each component PFAS (e.g., expressed as ng/L), and the results are summed to derive a Hazard Index. The HBWC is akin to an MCLG in that it reflects a level below which there are no known or anticipated adverse effects over a lifetime of exposure, including for sensitive populations and life stages, and allows for an adequate margin of safety. The general Hazard Index approach ensures that the level of exposure to a PFAS mixture remains below that which could adversely impact human health. It

incorporates health protection afforded by the HBWCs for the individual PFAS mixture components as well as the resulting Hazard Index itself, which provides an adequate margin of safety with respect to potential health hazards of mixtures of these PFAS.

With respect to the comment about HAs as a basis for HBWCs: HA are not a pre-requisite for an NPDWR under SDWA and there is nothing in the statute or the EPA's historical regulatory practice that suggests that the agency must or should delay regulation of a contaminant in order to develop a HA first. Further, the HAs for HFPO-DA and PFBS are not a basis or the starting point for their respective HBWCs. The EPA acknowledges that the HAs and HBWCs have been set at the same level, but the EPA's HBWCs for HFPO-DA and PFBS represent its conclusions at the time of the rulemaking to calculate the HBWC using identified RfDs, to select the identified DWI-BWs, and apply the RSCs of 0.20.

Missouri Department of Natural Resources (Doc. #1563, SBC-042520)

EPA requests comment on whether the HBWCs should instead be proposed as stand-alone MCLGs in addition to or in lieu of the mixture MCLGs.

The Department views HBWCs as just a renaming of lifetime health advisory levels (HAL). As can be seen in the most recent 2018 health advisory tables (2018 Edition of the Drinking Water Standards and Health Advisories Tables (EPA 822-F-18-001) [Link-https://www.epa.gov/system/files/documents/2022-01/dwtable2018.pdf]), most analytes have a lifetime health advisory level equal to the MCLG. If EPA proceeds with a PFAS mixture MCLG, the individual PFAS analytes compared in the mixture must have similar orders of magnitude (e.g., not 10 ppt vs 2000 ppt) as part of the mixture.

EPA Response: Please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document. The HAs for HFPO-DA and PFBS are not a basis or the starting point for their respective HBWCs. The EPA acknowledges that the HAs and HBWCs have been set at the same level, but the EPA's HBWCs for HFPO-DA and PFBS represent its conclusions at the time of the rulemaking to calculate the HBWC using identified RfDs, to select the identified DWI-BWs, and apply the RSCs of 0.20.

The EPA disagrees with the assertion that in order to establish a Hazard Index MCLG for the PFAS mixture, the HBWCs of the individual mixture components must have similar orders of magnitude. There is no scientific or mathematical basis to suggest that HBWCs must be similar in magnitude. The use of the most scientifically sound, health-protective HBWCs in the development of a Hazard Index, regardless of whether they differ in magnitude, is consistent with the EPA's chemical mixtures guidance (USEPA, 2000b) as well as the EPA's obligation under SDWA (Section 1412(b)(4)(A)) to set MCLGs at "the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." The commenter appears to misunderstand the definition of HBWC and the practical application of the Hazard Index in the context of the NPDWR. The Hazard Index accounts for the combined effects of the different mixture components and compares the exposure level of

each component to that component's corresponding HBWC, which is based on the most sensitive known adverse health outcome for that component. In this context, the HBWC is the level below which adverse health effects over a lifetime of exposure are not expected to occur, including for sensitive populations and life stages. This level also meets the statutory definition of an MCLG, which is the level of a contaminant below which there are no known or anticipated adverse effects with an adequate margin of safety.

The proposal defined a mixture as containing one or more of the four PFAS and therefore covered each contaminant individually if only one of the four PFAS occurred. Thus, the general Hazard Index as proposed ensures that the level of exposure to an individual PFAS remains below that which could impact human health because the exposure for that measured PFAS is divided by its corresponding HBWC. In the general Hazard Index approach, individual PFAS HQs are calculated by dividing the measured concentration of each mixture component PFAS in water (e.g., expressed as ng/L) by the corresponding HBWC for each component PFAS (e.g., expressed as ng/L), and the results are summed to derive a Hazard Index. The HBWC is akin to an MCLG in that it reflects a level below which there are no known or anticipated adverse effects over a lifetime of exposure, including for sensitive populations and life stages, and allows for an adequate margin of safety. The general Hazard Index approach ensures that the level of exposure to a PFAS mixture remains below that which could adversely impact human health. It incorporates health protection afforded by the HBWCs for the individual PFAS mixture components as well as the resulting Hazard Index itself, which provides an adequate margin of safety with respect to potential health hazards of mixtures of these PFAS.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-052866)

2. Inconsistency of the health advisories (HA) for the regulated compounds: PFBS and GenX have HAs; PFOA and PFOS have "interim" HAs; and PFNA and PFHxS do not have HAs. However, MCLs based on health effects are proposed for all six PFAS compounds.

Although it is understandable that the development of HAs is an ongoing process, the inconsistency of HA status (i.e., HA, "interim" HA, no HA) amongst PFAS species may cause confusion amongst the public. Moreover, the public may need additional clarity on how the EPA has proposed MCLs based on health effects for the six (6) compounds in the proposed PFAS Rule, in spite of not having established HA's for each. It is recommended that the USEPA provide additional insight on how the MCL was determined per PFAS species.

EPA Response: The EPA disagrees with this comment. HAs are issued under a separate statutory authority and are not a pre-requisite for an NPDWR under the SDWA.

Horsham Water & Sewer Authority (HWSA) (Doc. #1686, SBC-043807)

We also have concerns to the appropriateness of the proposed Hazard Index MCL for the combination of perfluorohexanesulfonic (PFHxS), perfuorononanoic acid (PFNA),

perfluorobutanesulfonic acid (PFBS) and hexafluoropropylene oxide dimer acid (HFPO-DA or GenX).

EPA Response: Please see sections 4.3.2 and 5 of the EPA response in this *Response to Comments* document.

Protecting Our Water, Environment, and Ratepayers (POWER) (Doc. #1714, SBC-045941)

Even if the grouping were permitted, there is no authority for using a Hazard Index in this context.

The Hazard Index is traditionally used in the context of CERCLA to inform the target risk levels. Here, EPA is proposing to use a Hazard Index in the context of the SDWA, which has not been done before. In its proposed rule, EPA does not explain the authority for using the Hazard Index in the context of the SDWA and simply asserts that it should be allowed because this is not a new regulatory preview. Simply asserting that the Hazard Index is not new does not sufficiently explain the authority for the EPA to use the Hazard Index in setting an MCL and MCLG under a different statutory scheme.

The data needed to support the Hazard Index formation are not yet finalized.

The Hazard Index typically refers to the risk level as a sum of the Hazard Quotient ("HQ"). The HQ is the ratio of the exposure level of a simple substance to the Reference Dose ("RfD"). The RfD comes from the human health toxicity assessment."[FN24: EPA, Human Health Toxicity Assessments for GenX Chemicals (last updated Dec. 27.2022) (https://www.epa.gov/chemical-research/human-health-toxicity-assessments-genx-chemicals)]

In the proposed NPDWR, EPA acknowledges that the human health toxicity assessments for PFHxS and PFNA are currently ongoing and are supposed to undergo public comment this year. Because the human health toxicity assessment has yet to be released, neither PFHxS nor PFNA have a finalized RfD that can be used to calculate the HQ or the Hazard Index. Setting the Hazard Index with RfD information that is not finalized and is subject to public comment in the following months would be arbitrary.

The proposed Hazard Index is not supported by SDWA precedent or science. EPA should propose MCLs for PFHxS, HFPO-DA, PFNA, and PFBS only after it has taken and finalized the steps available under the SDWA to ensure the proposals are grounded in sound science.

EPA Response: Please see sections 4.3.2 and 4.3.3 of the EPA response in this *Response to Comments* document. Additionally, the EPA's final rule represents data-driven drinking water standards that are based on the best available science and meet the requirements of SDWA. For the six PFAS, the EPA considered PFAS health effects information, evidence supporting dose-additive health effects from co-occurring PFAS, as well as national and state data for the levels of multiple PFAS in finished drinking water. SDWA provides a framework for the EPA to regulate emerging contaminants of concern in drinking water. Under the statute, the EPA must

act based on the "best available" science and information. Thus, the statute recognizes that the EPA may act in the face of imperfect information. It provides a mechanism for the EPA to update standards as more science becomes available. For the PFAS covered by this rule, the EPA concluded that the state of the science and information has sufficiently advanced to the point to satisfy the statutory requirements and fulfill SDWA's purpose to protect public health by addressing contaminants in the nation's PWSs.

Louisville Water Company (Doc. #1720, SBC-043556)

[In that regard, we are providing the following comments on key issues that we think require consideration.]

6. Louisville Water is committed to providing its customers with the best water quality as is reasonably possible. We establish internal treatment goals well below regulatory thresholds and expectations. However, we strongly oppose the proposed approach of using the Hazard Index (HI) as a compliance standard because this approach is, in effect, more stringent than the Maximum Contaminant Level Goal (MCLG). We are concerned with the precedent being set regarding the agency using the HI to calculate the MCL for PFNA, PFBS, PFHxS, and GenX. It is questionable, if not fundamentally flawed, to use the HI as an MCL. HI is a risk-screening tool used to estimate the total health risk for a mixture of contaminants. The HI is the calculated sum of component hazard quotients (HQs). HQ is the component contaminant concentration divided by the associated HBWC. (The calculated HBWC is essentially the same as the MCLG.) Therefore, the HI is a MCLG-based matrix and is more stringent than individual MCLG. According to EPA's definition, the MCL is "the highest level of a contaminant that is allowed in drinking water and is established as close to MCLGs as feasible using the best available treatment technology and taking cost into consideration" (see below). In this case, using an HI as an MCL results in an MCL that is more stringent than individual MCLGs, which is not consistent with the definition and intention of the MCL. In addition, EPA chose a general HI which allows for component chemicals in the mixture to have different health effects or endpoints as the basis for the component chemical reference values (e.g., RfDs). This general HI approach is best used as a risk screening level and not as an enforceable standard. If the agency continues to use the HI approach, which we believe is fundamentally flawed and which we strongly oppose, EPA may consider the target- organ specific HI which relies on reference values based on the same organ or organ system (e.g., liver-, thyroid-, or developmental-specific). Finally, the four additional PFAS may require very different treatment approaches. The proposed HI/MCL for the four PFAS includes two long-chain PFAS (PFNA and PFHxS) and two short-chain PFAS (PFBS and HFPO-DA). We know that granular activated carbon and Ion Exchange (IX) are generally not cost-effective for removing short-chain PFAS due to the short bed life. Reverse Osmosis (RO) is effective for all PFAS treatment but is cost-prohibitive for use by many utilities. Louisville Water is concerned that using the proposed HI as an MCL sets an inappropriate precedent that contradicts the SDWA's intention with regarding the MCLs and the use of MCLGs. EPA's use of the HI as an MCL also fails to provide for consideration of feasibility/cost in rulemaking which is considered using a traditional MCLG/MCL approach.

EPA Response: Please see sections 4.3.1, 4.3.2, and 10 of the EPA response in this *Response to Comments* document. Regarding the commenter's statement that the Hazard Index MCL is more stringent than the Hazard Index MCLG, the agency disagrees because as discussed in section V of the final rule preamble, the Hazard Index MCLG is 1 and the Hazard Index MCL is being set as close a feasible to that level. In this case, based on the EPA's determination of feasibility, the Hazard Index MCL is set to the same level as the MCLG (Hazard Index value of 1), but it is not more stringent. The EPA also clarifies that within the Hazard Index the individual HBWCs and respective concentrations of each of the four PFAS are considered collectively to evaluate mixtures containing two or more of the Hazard Index PFAS; thus, they are not treated as individual MCLGs. For additional discussion on feasibility of the final MCLs promulgated in this NPDWR, please see sections 5.1, 5.2, and 5.3 of the EPA response in this *Response to Comments* document.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045175)

7. Evaluation of Toxicology and Scientific Basis for Standard Setting

MassDEP has several comments on EPA's proposed HI approach and the derivation of the MCLG, including comments on the draft document entitled "Maximum Contaminant Level Goal (MCLG) Summary Document for a Mixture of Four Per- and Polyfluoroalkyl Substances (PFAS): HFPO-DA and its Ammonium Salt (also known as GenX Chemicals), PFBS, PFNA, and PFHxS [FN1: EPA 2023a. Maximum Contaminant Level Goal (MCLG) Summary Document for a Mixture of Four Per- and Polyfluoroalkyl Substances (PFAS): HFPO-DA and its Ammonium Salt (also known as GenX Chemicals), PFBS, PFNA, and PFHxS, Public Review Draft. U.S. Environmental Protection Agency, Office of Water (4304T), Office of Science and Technology, Health and Ecological Criteria Division, Washington, DC 20460. EPA-822-P-23-004.]," (hereinafter referred to as the "Mixture document") which serves as a basis of EPA's proposed HI approach. Specifically, our comments address the following: (1) inclusion of additional PFAS in the HI; (2) use of body weight- adjusted drinking water intakes (DWI-BWs) in establishing the MCLG; (3) the calculation of the PFHxS health-based water concentration (HBWC); (4) the application of potency subgroups to the HI; (5) identification and use of the PQL in establishing the PFOS and PFOA proposed MCLs; and (6) the compliance averaging period.

EPA Response: Please see sections 4.3.2, 4.3.3, and 7, and 8 of the EPA response in this *Response to Comments* document.

LSP Association (LSPA) (Doc. #1742, SBC-043598)

The Hazard Index Approach is confusing to the lay person without risk assessment experience. The LSPA urges USEPA to consider using a summed concentration approach for PFNA, GenX, and PFHxS similar to that which MassDEP has employed for six PFAS compounds of similar toxicity (i.e., in Massachusetts, the MCL for the sum of the concentrations for these six PFAS

compounds is 20 ppt). For PFNA, GenX, and PFHxS, using the current EPA toxicity values, a summed concentration of 10 ppt would be roughly equivalent to a Hazard Index of 1.

EPA Response: Please see sections 4.3.2 and 5 of the EPA response in this *Response to Comments* document.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045211)

3. EPA requests comment on the general HI approach for the mixture of four PFAS.

CT DPH agrees that regulating co-occurring PFAS using the HI approach is more protective than regulating the individual PFAS. However, EPA should address the three points below, before using the HI approach in its final regulatory decision:

EPA Response: The EPA agrees that using the Hazard Index approach is more protective than regulating the individual PFAS alone. Please see section 4.3.2 of the EPA response in this *Response to Comments* document. (The EPA responses to the commenter's three points referenced above are included with other comments from this commenter).

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045213)

b) CT DPH is aware of the data gap to develop target-organ specific HIs and EPA's statement "a target-organ specific HI approach relies on toxicity values aggregated by the 'same' target organ endpoint/effect, and the absence of information about a specific endpoint may result in the contaminant not being adequately considered in a target-organ specific approach, and thus, underestimating potential health risk". However, this underestimation of risk is due to the data gap itself rather than the use of the target-organ specific HI approach. EPA excluded using a single target-organ specific HI for the regulation but did not discuss whether it is possible to evaluate multiple target-organ specific HIs collectively (i.e. making the MCL determination based on exceeding ANY of several target-organ specific HIs). For example, a HI based on thyroid effect can be calculated using the formula HIthyroid=HQthyroid[PFHxS]+HQthyroid[PFBS], PFNA and GenX do not need to be included in this calculation because there is less adequate data to indicate they have thyroid effect. The HIs based on developmental and liver effects (and other effects, if data availability allow), can be calculated in a similar manner. Any of the HIs larger than 1 would indicate a potential health risk.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document. The TOSHI produces a less health-protective indicator of risk than the general Hazard Index because the basis for the mixture component toxicity reference values in a TOSHI has been limited to a specific target organ or system effect, which may occur at higher exposure levels than other effects (i.e., be a less sensitive endpoint). Additionally, since a TOSHI relies on toxicity reference values aggregated for the same specific target organ or system endpoint/effect, an absence or lack of data on the specific target organ or system endpoint/effect for a mixture component may result in that component not being adequately accounted for in this approach

(thus, underestimating health risk of the mixture). A TOSHI can only be derived for those PFAS for which the same target organ or system endpoint/effect-specific RfDs have been calculated. Many PFAS have data gaps in epidemiological or animal toxicological dose-response information for multiple types of health effects, thus limiting derivation of target organ-specific toxicity reference values; target organ-specific toxicity reference values are not currently available for PFHxS, PFNA, HFPO-DA, and PFBS. The EPA's *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* recognizes the potential for organ- or system-specific data gaps and supports use of overall RfDs in a general Hazard Index approach, stating, "The target organ toxicity dose (TTD) is not a commonly evaluated measure and currently there is no official EPA activity deriving these values, as there is for the RfD and RfC" … "Because of their much wider availability than TTDs, standardized development process including peer review, and official stature, the RfD and RfC are recommended for use in the default procedure for the HI" (USEPA, 2000b).

The commenter's example of a TOSHI based on thyroid effects which only includes PFHxS and PFBS (and excludes HFPO-DA and PFNA) perfectly illustrates why the target organ-specific approach (TOSHI) underestimates risk. Studies show that HFPO-DA and PFNA significantly affect the thyroid (please see section 4.3.1 of this *Response to Comments* document). According to the Interagency Report to Congress on PFAS, "Multiple studies on diverse species (developing rodents and fish) suggest that some PFAS (e.g., PFOS, PFOA, *PFNA, GenX chemicals*, PFHxS, PFDA, PFBA, PFBS, PFHxA) interfere with thyroid hormone signaling pathways and thyroid homeostasis through various mechanisms, including regulation of hepatic glucuronidation enzymes and deiodinases in the thyroid gland" (emphasis added, United States OSTP, 2023). Therefore, a thyroid-specific Hazard Index that excluded HFPO-DA and PFNA would underestimate the dose additivity concerns for thyroid effects from the total mixture.

Pennsylvania Municipal Authorities Association (Doc. #1832, SBC-045793)

[PMAA's specific comments on the Proposal are as follows:]

18. PMAA has concerns with and questions EPA's approach in the Proposal related to the use of the Hazard Index for certain PFAS chemicals. This is the first time that such a Hazard Index is used within the context of the Safe Drinking Water Act, which is a tool used to evaluate potential health risks from exposure to chemical mixtures. More time is needed to fully evaluate and analyze this approach, and PMAA recommends that this Hazard Index approach be deleted from the Proposal, pending further review and evaluation of the appropriateness of using it in the context of a Safe Drinking Water Act PFAS regulation.

Once again, PMAA appreciates the opportunity to submit comments on this most novel and complex Proposal.

Very truly yours,

HAMBURG, RUBIN, MULLIN, MAXWELL & LUPIN

STEVEN A. HANN

SAH:ll

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document.

The Chemours Company FC, LLC (Doc. #1845, SBC-046054)

C. EPA's Hazard Index for mixtures of PFAS compounds including HFPO-DA is scientifically flawed

EPA's proposal to use a Hazard Index ("HI") approach for regulating mixtures of PFHxS, HFPO-DA, PFNA, and PFBS not only is not authorized by the SDWA, as discussed above, but also is not scientifically sound. First, as summarized in the preceding subsections, the 10 ppt level for HFPO-DA developed by EPA and included in the HI is deeply flawed. Second, there is no scientific basis for EPA's aggregation of HFPO-DA with the other three compounds in the HI. As set forth in further detail in the supporting technical comments prepared by Dr. Chad Thompson and Dr. Melissa Heintz (Exhibit 1), the science does not support EPA's HI approach for several reasons, including:

• Occurrence data demonstrate that HFPO-DA is detected infrequently in drinking water across the United States and also is detected infrequently with other compounds in the HI. This limited occurrence of HFPO-DA and limited co- occurrence with the other HI compounds demonstrate that it is unsupported for EPA to regulate all of these compounds together as a group.

• Toxicological studies do not indicate that the compounds in the HI have additive effects. EPA's speculation about "dose additivity" for these compounds is wholly unsupported. The one study (Conley et al. 2022) that EPA cites purportedly in support of dose additivity for mixtures of PFAS compounds addressed only PFOA and PFOS, not the HI compounds.

• Further, EPA fails to cite several studies that found no support for dose additivity for mixtures of PFAS compounds.

• While there is no support for dose additivity in general for the HI compounds, there is also no support for any additivity or increased or cumulative risk at the specific levels EPA has set for each compound. In other words, EPA's summation of the HBWC levels for each compound in the HI is inappropriate. The HBWC level for each compound in the HI is based on calculations by EPA that include orders of magnitude of uncertainty factors for each compound that result in a level below which no adverse effect is expected. The HI then further multiplies those uncertainty factors by aggregating all the HBWC levels together, resulting in an unprecedented extremely and excessively conservative approach that goes well beyond an "adequate margin of safety."

• The HBWC levels for the compounds in the HI are based on different toxicological endpoints with different modes of action in different organs in different animal studies for the different

compounds, such that there is no toxicological similarity to support aggregating these disparate HBWC levels into the same HI.

• The compounds in the HI also differ significantly in terms of their chemical structures and properties and their potentials for bioaccumulation. Plainly, there is no scientific basis for similarity to support EPA's grouping these compounds all into one HI here.

Finally, EPA has grossly mischaracterized the recommendations of its Science Advisory Board ("SAB") regarding the HI approach. The SAB stated in general terms that the HI approach "is appropriate for initial screening of whether exposure to a mixture of PFAS poses a potential risk that should be further evaluated" and expressed its support for "dose additivity based on a common outcome."[FN31: U.S. EPA SAB, Review of EPA's Analyses to Support EPA's National Primary Drinking Water Rulemaking for PFAS. EPA-SAB-22-008 (2022).] The SAB did not endorse the HI approach for regulating mixtures of PFHxS, HFPO-DA, PFNA, and PFBS. [FN32: Id.] And, contrary to the SAB's recommendations, EPA has grouped these four compounds in the HI based on different toxicological outcomes for each compound, rather than a "common outcome."

In conclusion, for the reasons summarized above and discussed in the attached technical comments, EPA's aggregation of HFPO-DA with the other three compounds in the HI is arbitrary, capricious, and scientifically unsound.

EPA Response: Please see sections 4.3.1, 3.1.2, 3.2.2, 6.3, and 4.3.2 of the EPA response in this *Response to Comments* document.

In response to the comment that "EPA's summation of the HBWC levels for each compound in the HI is inappropriate," the EPA disagrees. The Hazard Index MCLG reflects both the measured amount of each of the four PFAS in a mixture and the toxicity (represented by the HBWC) of each of the four PFAS. The PFAS mixture Hazard Index is an approach to determine whether any mixture of two or more of these four PFAS in drinking water exceeds a level of health concern by first calculating the ratio of the measured concentration of each of the four PFAS to the toxicity (the HBWC) of each of the four PFAS. This results in the "HQ" for each of the four PFAS. The four HQs are added together to derive the Hazard Index , and doing so produces a Hazard Index that accounts for dose-additive concerns associated with these PFAS when present in mixtures (USEPA, 2024i; see also section 4.3.2 of this *Response to Comments* document). If the Hazard Index exceeds 1, then the hazard from the combined amounts of the four PFAS in drinking water exceeds a level of public health concern.

Prince William County Service Authority (Doc. #1609, SBC-042846)

EPA should not utilize the Hazard Index approach for PFNA, PFHxS, PFBS, and HFPO-DA.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document.

Prince William County Service Authority (Doc. #1609, SBC-042832)

The proposal to use a Hazard Index calculation for PFNA, PFHxS, PFBS, and HFPO-DA is an approach that has never been used under the Safe Drinking Water Act. The approach combines compounds with different health endpoints. Utilities could exceed the HI even if each compound is below the limits of health impacts. Further, the HI approach will be challenging to communicate to the public. EPA should instead establish MCL's for these compounds using reference doses (RfDs) and human health toxicity assessments when they are available.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document.

Nebraska Department of Environment and Energy (NDEE) (Doc. #1653, SBC-043207)

The proposed rule is not clear regarding whether the Health Based Water Criteria (HBWC) used to calculate the HI are set values as part of this rulemaking or if they are independent values that can potentially be lowered at a later date. If the later is the case, that would increase the weight of given sample results raising the HI. The Department suggests EPA clarify this in the final rule and explain how the HBWCs could change in the future as more data and information is gathered.

EPA Response: Please see sections 4.3.2 and 5 of the EPA response in this *Response to Comments* document.

New York State Department of Health (NYS DOH) (Doc. #1677, SBC-044963)

A further anomaly in the hazard index approach concerns the way the hazard quotients are calculated. Hazard quotients are traditionally calculated as a ratio of equivalent measures of exposure. In other words, the contaminant exposure (usually in mg/kg/day) is typically compared to an unadjusted reference dose. The hazard quotients in the proposed rule are analogously calculated using water concentrations, but the water concentration representing the exposure of interest is compared to a health-based water concentration that is adjusted by a 20% relative source contribution. This is a departure from the traditional hazard quotient calculation used in risk assessment, biases the calculation toward non-compliance, and may overestimate the level of noncancer risk.

EPA Response: Regarding the comment on the calculation of the Hazard Index in terms of water concentration, as described in the EPA's PFAS Mixtures Framework (USEPA, 2024i), the HQs and the Hazard Index are unitless, so in the Hazard Index formula (Equation 5-1 in PFAS Mixtures Framework), E and the RfV must be in the same units. For example, if E is the oral intake rate (mg/kg-day), then the RfV could be the RfD, which has the same units. Alternatively, the exposure metric can be a media-specific metric such as water concentration, and the toxicity reference value is best represented as an HBWC or MCLG (i.e., the level below which adverse effects are not anticipated to occur and allows for an adequate a margin of safety).

In this case, the HQ is calculated as the ratio of PFAS water concentration (in mass/volume) to a HBWC (also in mass/volume), resulting in a unitless value. The Hazard Index accounts for the combined effects of the different mixture components and compares the exposure level of each component to that component's corresponding HBWC, which is based on the most sensitive known adverse health outcome for that component. In this context, the HBWC is the level below which adverse health effects over a lifetime of exposure are not expected to occur, including for sensitive populations and life stages, and allows for an adequate margin of safety. This level also meets the definition of an MCLG, which is the level of a contaminant below which there are no known or anticipated adverse effects with an adequate margin of safety. Regarding the comment on the inclusion of RSC in the HBWC calculation, the RSC is part of the HBWC calculation and is applied to ensure that potential exposure sources beyond drinking water are considered (please see section 4.3.3 of this *Response to Comments* document). The EPA has applied the RSC to calculate health-protective water values under the Clean Water Act and the Safe Drinking Water Act for decades and disagrees that inclusion of the RSC "biases the calculation toward non-compliance, and may overestimate the level of noncancer risk."

3M Company (Doc. #1774, SBC-045678)

f. The Hazard Index Fails to Provide Regulatory Certainty

The unprecedented HI-MCL "standard" is not actually a fixed standard. Instead, the "standard" is based on an unlimited combination of detections of the four HI-MCL substances, all of which can be below their respective HBWC, and still be considered a violation of MCL. Similar results where all four substances are below their HBWCs can have different regulatory outcomes. EPA has not set a single MCL for the HI-PFAS. Instead, the proposed HI-MCL is actually thousands of fluid standards.

Such unpredictable and inconsistent regulatory outcomes raise a host of issues, including fundamental issues regarding fairness, equity, and regulatory certainty. There is no evidence in the Proposed Rule or supporting materials that EPA considered these issues before proposing the HI-MCL. That lack of reasoned consideration is the hallmark of arbitrary agency action.

EPA Response: The EPA disagrees that the Hazard Index does not provide regulatory certainty. The Hazard Index MCL regulatory limits are clear and certain. Please see sections 4.3.2 and 5 of the EPA response in this *Response to Comments* document.

Minnesota Pollution Control Agency (MPCA) (Doc. #1569, SBC-052823)

4) EPA requests comment on whether the HBWCs should instead be proposed as stand-alone MCLGs in addition to or in lieu of the mixture MCLGs.

MPCA response:

• MPCA supports setting the MCLG for these four PFAS as a mixture HI as the most health protective approach.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document.

Water One – Water District No. 1 of Johnson County, Kansas (Doc. #1627, SBC-042327)

The Hazard Index (HI) concept is also new to drinking water regulations as it has typically only been used in the wastewater industry. It seems unlikely that appropriate Health Risk Assessments could have been performed and verified to support the numbers in the proposed regulation in such a short time span. Furthermore, the HI is a concern given there may be the instance where there is one compound that forces a violation when the other compounds assessed are in check. It simply does not have the same scientific level of scrutiny yet. It appears as though the EPA is entrenched with health advisory information and needs additional time to further develop the science behind the HI.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document.

The Chemours Company FC, LLC (Doc. #1845, SBC-046059)

2) The overall weight of the evidence does not support grouping these specific four PFAS.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document.

Association of State and Territorial Solid Waste Management Officials (ASTSWMO) (Doc. #1583, SBC-042396)

May 25, 2023

U.S. Environmental Protection Agency

EPA Docket Center

Mail Code 2822IT

1200 Pennsylvania Avenue, NW

Washington, DC 20460

RE: ASTSWMO Comments on U.S. EPA's Proposed PFAS National Priority Drinking Water Regulation; Docket ID No. EPA-HQ-OW-2022-0114

Dear Sir or Madam:

The Association of State and Territorial Solid Waste Management Officials (ASTSWMO) appreciates the opportunity to provide comments regarding the U.S. Environmental Protection Agency's (EPA) proposed Per- and polyfluoroalkyl substances (PFAS) National Primary

Drinking Water Regulation (NPDWR) Rulemaking. ASTSWMO is an association representing the waste management and remediation programs of the 50 States, five Territories, and the District of Columbia (States). Our membership includes State program experts from all States who manage State-run programs under both the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and the Resource Conservation and Recovery Act (RCRA).

ASTSWMO commends the EPA for taking this important step to regulate perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO–DA) and its ammonium salt (also known as GenX chemicals), perfluorononanoic acid (PFNA), perfluorobutane sulfonic acid (PFBS), and mixtures of these PFAS under the Safe Drinking Water Act (SDWA) and is pleased to offer comments on this proposed regulation.

ASTSWMO's PFAS Position Paper, drafted by the Association's Contaminants of Emerging Concern (CEC) Steering Committee, and updated and approved by our Board in November 2022, recommends that EPA evaluate classes of PFAS that have common characteristics, to more expeditiously designate PFAS compounds as CERCLA hazardous substances and RCRA hazardous constituents. However, the summary document (EPA-822-P-23-004) distributed for public comment on the combined Maximum Contaminant Level Goals (MCLGs) does not adequately explain why PFHxS, GenX chemicals, PFNA, and PFBS, four seemingly disparate PFAS, were selected. ASTSWMO recommends more careful consideration of PFAS functional groups, chain length, and toxic endpoints, and the use of a more-refined approach for the combined regulation of these chemicals.

EPA's promulgation of health-based MCLGs for the aforementioned PFAS compounds would advance federal and State efforts to compel responsible and potentially-responsible parties to investigate and remediate contamination nationwide, especially when private wells and public water supply systems are impacted. This is a critical step for impacted communities' access to financial resources for costly mitigation and cleanup.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document. Regarding the EPA's rationale for regulation of PFHxS, HFPO-DA, PFNA, and PFBS, as required under the SDWA, there is available health effects, occurrence, and meaningful opportunity information for three PFAS (PFHxS, PFNA, and HFPO-DA) to meet the statutory criteria for regulation individually, and for four PFAS (PFHxS, PFNA, HFPO-DA, and PFBS) as a mixture (please see section 3 of this *Response to Comments* document and section III of the final rule preamble for the agency's evaluation of this information). Furthermore, the EPA disagrees that these four PFAS are disparate because they share similar characteristics; it is substantially likely that they co-occur; the same treatment technologies can be used for their removal; they are measured simultaneously using the same analytical methods; they have shared adverse health effects; and they have similar physical and chemical properties resulting in their environmental persistence.

HRSD (Doc. #1719, SBC-043540)

We see the following recommendations as productive and protective strategies that EPA can utilize:

Proceed with regulation for PFOA and PFOS for which occurrence and toxicity data are more robust

Though we cannot comment on the appropriateness of the specific MCLs for PFOA and PFOS, the general MCL development approach for these two contaminants appears to be data driven. EPA's approach to regulating the mixture of PFHxS, PFNA, PFBS and HFPO-DA, however, utilizes a Hazard Index (HI) approach that is novel in the context of SDWA regulation. This is being proposed without the benefit of occurrence data that will be generated under the Unregulated Contaminant Monitoring Rule (UCMR) 5.

EPA Response: Please see sections 4.3.2 and 6 of the EPA response in this *Response to Comments* document.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-052877)

b. CWUC is more supportive of EPA establishing individual MCLs, utilizing the HBWCs.

b. If EPA does move forward with the HI approach, it seems ineffective to include PFBS at a level of 2000 because that parameter won't even be included in the HI value unless it is very high (at least 200 ppt in the finished water), levels we assume most facilities don't see.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document. As described in section III of the preamble, even though concentrations of PFBS are likely to be below its corresponding individual HRL when it occurs in a mixture, the record indicates that there is a substantial likelihood that it co-occurs with the regulated PFAS throughout PWSs nationwide. See section VI.C. of the preamble for further discussion. According to the 2023 Interagency PFAS Report to Congress (United States OSTP, 2023), PFBS has been shown to affect the following health domains: body weight, respiratory, cardiovascular, gastrointestinal, hematological, musculoskeletal, hepatic, renal, ocular, endocrine, immunological, neurological, reproductive, and developmental. Thus, including PFBS as a mixture component represents a meaningful opportunity to reduce PFBS' contributions to the overall hazard of PFAS mixtures and resulting dose additive health concerns. This is particularly relevant where the exposure levels of the other three PFAS in the mixture are also below their respective HRLs but when the hazard contributions of each mixture component are summed, the total exceeds the mixture HRL. In this scenario, the inclusion of PFBS allows for a more accurate picture of the overall hazard of the mixture so that PFBS can be reduced along with associated dose additive health concerns. In short, hazard would be underestimated if PFBS was not included in the regulated mixture. The EPA also considered potential situations where PFHxS, PFNA, or HFPO-DA exceed one or more of their corresponding HRLs and co-occur with PFBS below its corresponding HRL. Although in this case, the exceedance of the mixture

HRL is driven by a PFAS other than PFBS, PFBS is contributing to the overall hazard of the mixture and resulting dose additive health concerns. Including PFBS in the regulated mixture offers a meaningful opportunity to reduce dose additive health concerns because, when PFBS and other Hazard Index PFAS are present, PWSs will be able to better design and optimize their treatment systems to remove PFBS and any other co-occurring Hazard Index PFAS. This optimization will be even more effective with information about the presence and measured concentrations of PFBS in source waters.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-052879)

d. If EPA does move forward with the HI approach, they should consider an HI of 1.3. This would be the value obtained for having three of the parameters (not including PFBS because it doesn't affect the HI) at the PQL of 4.0 ppt. The trigger level should be set at 0.6, which would be a value obtained of 2.0 ppt for the three parameters. Values below two (and therefore a lower trigger level) are not accurate and should not be used for compliance.

EPA Response: Please see section 4.3.2 of the EPA response in this *Response to Comments* document. The EPA disagrees that any number other than 1 is appropriate for the Hazard Index MCLG. A Hazard Index greater than 1 is generally regarded as an indicator of potential adverse health risks associated with a specific level of exposure to the mixture; a Hazard Index less than or equal to 1 is generally regarded as not being associated with any appreciable risk (USEPA, 1986; USEPA, 1991c; USEPA, 2000b). Thus, in the case of this drinking water rule, a Hazard Index greater than 1 indicates that occurrence of one or more of these four component PFAS in a mixture in drinking water exceeds the health protective level(s) (i.e., HBWC(s)), indicating potential health risks. Additionally, the commenter's suggestion of a Hazard Index of 1.3 would round to 1 when using one significant digit so there would be no practical difference (please see section 4.3.4 of this *Response to Comments* document). For the EPA response to the comment on trigger levels, see section 8 of this *Response to Comments* document.

4.3.3 Derivation of the Four HRLs and HBWCs in the Hazard Index MCLG

The agency developed HRLs for PFHxS, PFNA, HFPO-DA, and PFBS as part of its effort to identify the adverse effects each contaminant may have on the health of persons. In this instance, the EPA identified the HRL as the level below which adverse health effects over a lifetime of exposure are not expected to occur, including for sensitive populations and life stages, and allowing an adequate margin of safety. The HRLs are also used as HBWCs in the calculation of the Hazard Index MCLG. This section summarizes public comments and the EPA responses related to the calculation of the HRLs and the HBWCs applied in the Hazard Index MCLG calculation.

Summary of Major Public Comments and EPA Responses (General)

Some commenters supported the EPA's derivation of the four HRLs/HBWCs for PFHxS, PFNA, HFPO-DA and PFBS. Many commenters expressed support for the EPA's derivation of HRLs/HBWCs based on the best available peer-reviewed science, specifically the use of the final, most recently published ATSDR minimal risk levels for PFHxS and PFNA as chronic toxicity reference values. Other commenters criticized the EPA for using ATSDR minimal risk levels and stated that they are inappropriate for SDWA rulemaking.

Some commenters questioned the EPA's external peer-review process for the four underlying final toxicity assessments used to calculate the HRLs/HBWCs and for the HBWCs themselves. Some commenters noted that the EPA does not yet have completed IRIS assessments for PFHxS and PFNA, questioning the EPA's use of non-EPA assessments.

Some commenters asserted that the human health toxicity reference values (EPA RfDs, ATSDR minimal risk levels) upon which the HRLs/HBWCs are based have too much uncertainty (e.g., inappropriately apply a composite uncertainty factor (UF) of 3,000) and are therefore inadequate to support a SDWA regulatory determination.

Some commenters opposed the EPA's application of a 20 percent RSC in the HRL/HBWC calculations and stated that it was a "conservative default" approach not supported by available information and that adequate exposure data exist to justify an RSC other than 20 percent (although commenters did not offer a suggested alternative RSC).

Some commenters disagreed with the DWI-BWs that the EPA used to calculate the HRLs/HBWCs and thought the selected DWI-BWs were too high (overly health protective). One commenter stated that the DWI-BW used in the calculation of the HRL/HBWC for HFPO-DA is inappropriate and that the EPA should have used a DWI-BW for general population adults instead of for lactating women. Other commenters urged the EPA to consider infants as a sensitive life stage for PFHxS, PFNA, and PFBS and use the DWI-BW for infants to calculate the HRLs/HBWCs.

Some commenters offered critical comments on the HRLs/HBWCs for PFHxS, PFNA, HFPO-DA, and PFBS and raised technical and process concerns with the underlying human health assessments. Some commenters questioned the EPA's reliance on animal data and its relevance to humans; for example, some commenters claimed that the liver effects observed in rats after exposure to HFPO-DA (the basis for the RfD for HFPO-DA) are not relevant to humans.

The EPA response to these issues as well as others expressed by individual commenters are described in further detail below.

Use of ATSDR Minimal Risk Levels for PFHxS and PFNA. The EPA disagrees with commenters who assert that it is inappropriate to use ATSDR minimal risk levels as toxicity reference values. The EPA finds that the ATSDR minimal risk levels for PFHxS and PFNA currently represent the best available, peer-reviewed science for these chemicals. SDWA specifies that an agency action that is based on science must rely on "the best available, peer-

reviewed science and supporting studies conducted in accordance with sound and objective scientific practices." At this time, the 2021 ATSDR *Toxicological Profile for Perfluoroalkyls*, which covers 10 PFAS including PFHxS and PFNA, represents the best available peer-reviewed scientific information on the human health effects of PFHxS and PFNA. ATSDR minimal risk levels for PFHxS and PFNA are appropriate for use under SDWA because ATSDR uses scientifically credible approaches, its work is internally and externally peer-reviewed and undergoes public comment, and its work represents the current best available science for these two chemicals. The 2021 ATSDR *Toxicological Profile for Perfluoroalkyls* underwent intra- and interagency review and subsequent external peer review by seven experts with knowledge of toxicology, chemistry, and/or health effects.

The agency acknowledges that ATSDR minimal risk levels and EPA RfDs are not identical. The two agencies sometimes develop toxicity values for different exposure durations (e.g., intermediate, chronic) and/or apply different uncertainty/modifying factors to reflect data limitations. Additionally, ATSDR minimal risk levels and EPA RfDs are developed for different purposes: ATSDR minimal risk levels are intended to serve as screening levels and are used to identify contaminants and potential health effects that may be of concern at contaminated sites, whereas EPA RfDs are used to support regulatory and nonregulatory actions, limits, and recommendations in various environmental media. However, an oral minimal risk level and an oral RfD both represent the level of daily oral human exposure to a hazardous substance below which adverse health effects are not anticipated to occur. The EPA has routinely used and continues to use ATSDR minimal risk levels in human health assessments when they represent the best available science—for example, in the context of Clean Air Act section 112(f)(2) risk assessments in support of setting national emission standards for Hazardous Air Pollutants (HAPs), developing Clean Water Act ambient water quality criteria, evaluating contaminants for the CCL, and site evaluations under the Resource Conservation and Recovery Act (RCRA) and CERCLA.

The EPA is not required under SDWA to exclusively use EPA assessments to support an NPDWR, and in fact, SDWA's clear direction in Section 1412(b)(3)(A)(i) is to use the best *available*, peer- reviewed science when developing NPDWRs (emphasis added). Final EPA assessments for PFHxS and PFNA are under development but are not currently available; final, peer-reviewed ATSDR assessments are available. The statute recognizes that the EPA may act in the face of imperfect information. It also provides a mechanism for the EPA to update standards as more information becomes available. For the PFAS covered by this rule, the EPA concluded that the state of the science and information has sufficiently advanced to the point to satisfy the statutory requirements and fulfill SDWA's purpose to protect public health by addressing contaminants in the nation's PWSs.

Peer Review. The EPA disagrees with comments that peer review was inadequate. The EPA notes that all four toxicity assessments underlying the HRL/HBWC calculations (i.e., the EPA human health toxicity assessments for HFPO-DA and PFBS (USEPA, 2021d; USEPA, 2021b) and the ATSDR toxicity assessments of PFNA and PFHxS (ATSDR, 2021)) underwent rigorous,

external peer review (ATSDR, 2021; USEPA, 2021d; USEPA, 2021e). The EPA is not required under SDWA to exclusively use EPA assessments to support an NPDWR, and in fact, SDWA's clear direction in Section 1412(b)(3)(A)(i) is to use the best available, peer-reviewed science when developing NPDWRs (emphasis added). Final EPA assessments for PFHxS and PFNA are not currently available; final, peer-reviewed ATSDR assessments are available.

Uncertainty. Some commenters asserted that the human health toxicity reference values (EPA RfDs, ATSDR minimal risk levels) upon which the HRLs/HBWCs are based have too much uncertainty (e.g., inappropriately apply a composite uncertainty factor (UF) of 3,000) and are therefore inadequate to support a SDWA regulatory determination. The EPA disagrees with these comments. The HRLs/HBWCs are data-driven values based on RfDs that incorporate UFs based on the EPA guidance and guidelines, and thus represent the levels below which adverse health effects are not expected to occur over a lifetime. According to the EPA guidelines and longstanding practices (USEPA, 2002a; USEPA, 2022a), UFs reflect the limitations of the data across the five areas used in current EPA human health risk assessment development: (1) human interindividual variability (UF_H); (2) extrapolation from animal to human (UF_A); (3) subchronic-to-chronic duration extrapolation (UF_S); (4) lowest-observed-adverse-effect level-to-no-observed-adverse-effect level (LOAEL-to-NOAEL) extrapolation (UF_L); and (5) database uncertainty (UF_D). In minimal risk level development, ATSDR also applies uncertainty factors as appropriate to address areas of uncertainty, with the exception of subchronic-to-chronic duration extrapolation (ATSDR, 2021). For the ATSDR minimal risk levels on which the HRLs/HBWCs for PFNA and PFHxS are based, ATSDR utilized UF_Hs, UF_As, and what ATSDR calls a modifying factor to address database deficiencies (equivalent to the EPA's UF_D) (ATSDR, 2021). The EPA carefully reviewed ATSDR's application of uncertainty and modifying factors for PFNA and PFHxS and applied additional uncertainty factors as warranted per the EPA guidelines. Specifically, the EPA applied an additional UF (UF_S) for PFHxS to extrapolate from subchronic to chronic duration per agency guidelines (USEPA, 2002a) and standard practice because the critical effect was not observed during a developmental lifestage (i.e., the effect was in parental male rats). A chronic toxicity reference value (i.e., RfD, minimal risk level) represents the daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime; the EPA is using chronic toxicity reference values to derive individual MCLGs (for HFPO-DA, PFNA, and PFHxS) and HBWCs for the PFAS mixture MCLG to ensure that each MCLG is set at a level at or below which no known or anticipated adverse effects on human health occur and allowing an adequate margin of safety. The MCLG "incorporates a margin of safety to reflect scientific uncertainty and, in some cases, the particular susceptibility of some groups (e.g., children) within the general population." S. Rep. No. 169, 104th Cong., 1st Sess. (1995) at 3. The EPA guidelines indicate that the composite (total) UF may be equal to or below 3,000; composite UFs greater than that represent "excessive uncertainty" (USEPA, 2002a; USEPA, 2022a). In the case of this final NPDWR, a composite UF of 3,000 was appropriately applied to derive toxicity reference values used to develop HRLs/HBWCs for two of the four PFAS (HFPO-DA and PFHxS) following peer-reviewed agency guidance and longstanding practice (see USEPA (2024h) for complete

discussion of UF application for all four PFAS). The EPA has previously developed an MCLG for a chemical that had a composite UF of 3,000 applied to derive a toxicity reference value (e.g., thallium [USEPA, 1992]). Further, a composite uncertainty factor of 3,000 has been applied in the derivation of oral RfDs for several chemicals that have been evaluated within the EPA's IRIS program (e.g., fluorene, cis- and trans-1,2-dichloroethylene, 2,4-dimethylphenol; please see the EPA's IRIS program website [https://www.epa.gov/iris] for further information).

With respect to the use of animal studies in general, SDWA requires that to the degree that the EPA's action is based on science, the EPA must use "the best available, peer reviewed science" and "data collected by accepted methods or best available methods." Additionally, as noted in the EPA's *Staff Handbook for Developing IRIS Assessments* (USEPA, 2022a) and *A Review of the Reference Dose and Reference Concentration Process* (USEPA, 2002a), animal studies can provide the basis for toxicity reference values when adequate human studies are not available. The HBWCs/MCLGs are based on the best available science and data collected by accepted methods (see section III in the preamble and USEPA, 2024h). Specifically, peer-reviewed, publicly available toxicity assessments are available for HFPO-DA (USEPA, 2021e), PFBS (USEPA, 2021d), PFNA (ATSDR, 2021), and PFHxS (ATSDR, 2021) that provide the oral toxicity reference values (i.e., RfDs or minimal risk levels) used to calculate the HBWCs/MCLGs; the EPA selected the corresponding DWI-BW for the relevant sensitive population or life stage from the Exposure Factors Handbook (USEPA, 2019) based on the best available, peer-reviewed science from publicly available, peer-reviewed studies taking into account the relevant sensitive population(s) or life stage(s); and the RSCs are based on the best available, peer-reviewed science or best available methods taking into account the relevant sensitive population(s) or life stage(s) (USEPA, 2000c).

Relative Source Contribution (RSC). The EPA disagrees with comments that the RSCs derived for one or more of the four PFAS are inappropriate. The EPA applies an RSC to account for potential aggregate risk from exposure routes and exposure pathways other than oral ingestion of drinking water to ensure that an individual's total exposure to a contaminant does not exceed the daily exposure associated with toxicity (i.e., threshold level or reference dose). Application of the RSC in this context is consistent with EPA methods (USEPA, 2000c) and long-standing EPA practice for establishing drinking water MCLGs and NPDWRs (e.g., see USEPA, 1989; USEPA, 2004; USEPA, 2010). The RSC represents the proportion of an individual's total exposure to a contaminant that is attributed to drinking water ingestion (directly or indirectly in beverages like coffee, tea, or soup, as well as from dietary items prepared with drinking water) relative to other exposure pathways. The remainder of the exposure equal to the RfD (or minimal risk level) is allocated to other potential exposure sources (USEPA, 2000c). The purpose of the RSC is to ensure that the level of a contaminant (e.g., MCLG) in drinking water, when combined with other identified potential sources of exposure for the population of concern, will not result in total exposures that exceed the RfD (or minimal risk level) (USEPA, 2000c). This ensures that the MCLG under SDWA meets the statutory requirement that it is a level of a contaminant in drinking water at or below which no known or anticipated adverse effects on human health occur

and allowing an adequate margin of safety. The EPA is only regulating certain PFAS in drinking water consistent with the definition of contaminant in SDWA section 1401(6).

To determine the RSCs for the four HRLs/HBWCs, the agency assessed the available scientific literature on potential sources of human exposure other than drinking water. The EPA conducted literature searches and reviews for each of the four PFAS to identify potential sources of exposure and physicochemical properties that may influence occurrence in environmental media (Deluca et al., 2022; USEPA, 2024h). Considering this exposure information, the EPA followed its longstanding, peer-reviewed Exposure Decision Tree Approach in EPA's Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (USEPA, 2000c) to determine the RSC for each PFAS. As discussed by the EPA in the Hazard Index MCLG document (USEPA, 2024h), the EPA carefully evaluated studies that included information on potential exposure to these four PFAS (PFHxS, PFNA, HFPO-DA, and PFBS) via sources other than drinking water, such as food, soil, sediment, and air. For each of the four PFAS, the findings indicated that there are significant known or potential uses/sources of exposure beyond drinking water ingestion (e.g., food, indoor dust) (Box 6 in the EPA Exposure Tree; USEPA, 2000c), but that data are insufficient to allow for quantitative characterization of the different exposure sources (Box 8A in USEPA, 2000c). The EPA's Exposure Decision Tree approach states that when there are insufficient environmental and/or exposure data to permit quantitative derivation of the RSC, the recommended RSC for the general population is 20 percent (Box 8B in USEPA, 2000c). This means that 20 percent of the exposure equal to the RfD is allocated to drinking water, and the remaining 80 percent is attributed to all other potential exposure sources.

Drinking Water Intake (DWI-BW). The EPA disagrees with comments that alternate DWI-BWs should be used for HBWC calculations for one or more of the four PFAS. Some commenters disagreed with the DWI-BWs that the EPA used to calculate the HRLs/HBWCs and thought the selected DWI-BWs were too high (overly health protective).

Other commenters urged the EPA to use the DWI-BW for infants to calculate the HRLs/HBWCs. The EPA disagrees with this comment. The EPA's approach to DWI-BW selection includes a step to identify the sensitive population(s) or life stage(s) (i.e., those that may be more susceptible or sensitive to a chemical exposure) by considering the available data for the contaminant, including the adverse health effects observed in the toxicity study on which the RfD/minimal risk level was based (known as the critical effect within the critical or principal study). Although data gaps can complicate identification of the most sensitive population (e.g., not all windows or life stages of exposure and/or health outcomes may have been assessed in available studies), the critical effect and point of departure (POD) that form the basis for the RfD (or minimal risk level) can provide some information about sensitive populations because the critical effect is typically observed at the lowest tested dose among the available data. Evaluation of the critical study, including the exposure window, may identify a sensitive population or life stage (e.g., pregnant women, formula-fed infants, lactating women). In such cases, the EPA can select the corresponding DWI-BW for that sensitive population or life stage from the Exposure Factors Handbook (USEPA, 2019a). DWI-BWs in the Exposure Factors Handbook are based on

information from publicly available, peer-reviewed studies, and were updated in 2019. In the absence of information indicating a sensitive population or life stage, the DWI-BW corresponding to the general population may be selected. Following this approach, the EPA selected appropriate DWI-BWs for each of the four PFAS included in the Hazard Index MCLG (see USEPA, 2024h). The EPA did consider infants as a sensitive life stage for all four PFAS; however, the agency did not select the infant DWI-BW because the exposure intervals of the critical studies supporting the chronic toxicity reference values did not correspond to infants. Instead, the exposure intervals were relevant to other sensitive target populations (i.e., lactating women or women of childbearing age) or the general population.

Another commenter suggested that DWI-BW should be identified from evaluation of the database as a whole, rather than solely based on the critical study for a particular PFAS, to better protect sensitive subpopulations in light of data gaps. The EPA disagrees with this suggested approach because the Agency has already taken into account data gaps through application of uncertainty factors, including a database uncertainty factor (UF_D). Each of the chronic toxicity reference values for the four PFAS included in the Hazard Index take into account the strength of the database as a whole: the HFPO-DA and PFBS RfDs each include a UF_D of 10, and the PFNA and PFHxS minimal risk levels each include a modifying factor (MF) of 10 for database deficiencies. (See also the EPA response to comment above, under "Uncertainty.") As described above, the EPA follows a data-driven approach to select an appropriate DWI-BW based on the exposure window associated with the critical effect from the critical or principal study.

Comments Specifically on PFNA. Some commenters questioned the human relevance of developmental effects observed in PFNA animal studies (i.e., decreased body weight gain, delayed eye opening, delayed sexual maturation) used to derive the ATSDR minimal risk level and the EPA's PFNA HRL/HBWC/MCLG. The EPA disagrees with this comment. At this time, the 2021 ATSDR Toxicological Profile for Perfluoroalkyls represents the best available peer-reviewed scientific information regarding the human health effects of PFNA. In addition, according to the March 2023 *Interagency PFAS Report to Congress*, PFNA is documented to affect the developmental health domain (United States OSTP, 2023), and a recently published meta-analysis (Wright et al., 2023) specifically supports decreases in BWT as an effect of PFNA exposure in humans. Published studies have shown that PFNA exposure results in statistically significant, dose-responsive developmental effects, including reduced fetal/pup bodyweight, reduced fetal/pup survival, changes in fetal/pup liver gene expression, increased fetal/pup liver weight, and delayed onset of puberty. Also, the EPA's 1991 *Guidelines for Developmental Toxicity Risk Assessment* (USEPA, 1991d; pp. vii-ix and pp. 1-2) states that, in the absence of clear evidence to the contrary, developmental effects observed in experimental animals are interpreted as relevant to humans.

Comments Specifically on PFBS. A few commenters suggested that the EPA lower the HRL/HBWC for PFBS to account for thyroid hormone disruption during early development and cited the Washington State Action Level for PFBS, which is 345 ng/L. Washington State used the same RfD (3E-04 mg/kg-d) but a higher DWI-BW to develop its Action Level as compared to

the EPA's HRL/HBWC (Washington State used the 95th percentile DWI-BW of 0.174 L/kg/day for infants, whereas the EPA selected the 90th percentile DWI-BW of 0.0354 L/kg/day for women of child-bearing age). The EPA disagrees that the infant DWI-BW is more appropriate for HRL/HBWC calculation. The EPA selected the thyroid hormone outcome (decreased serum total thyroxine in newborn mice seen in a developmental toxicity study) as the critical effect in its PFBS human health toxicity assessment (USEPA, 2021d). Notably, the RfD derived from this critical effect included application of a 10X UF to account for lifestage-specific susceptibility (UF_H). To select a DWI-BW for use in deriving the HRL/HBWC for PFBS, the EPA followed its established approach of considering the PFBS exposure interval used in the developmental toxicity study in mice that was the basis for chronic RfD derivation. In this study, pregnant mice were exposed throughout gestation, which is relevant to two human adult life stages: women of child-bearing age who may be or become pregnant, and pregnant women and their developing embryos or fetuses (Table 3-63 in USEPA, 2019a). To be clear, the critical study exposed mice to PFBS only during pregnancy and not during postnatal development; newborn mice in early postnatal development, which would correspond to the human infancy life stage, were not exposed to PFBS. Of the two relevant adult stages, the EPA selected the 90th percentile DWI-BW for women of child-bearing age (0.0354 L/kg/day) to derive the HRL/HBWC for PFBS because it is the higher of the two, and therefore more health-protective. Please see additional information related to DWI-BW selection above.

Other commenters stated that the EPA's human health toxicity assessment for PFBS is overly conservative, uncertain, and that the confidence in the chronic RfD is low. The EPA disagrees with these comments. Confidence in the critical study (Feng et al., 2017) and corresponding critical effect in newborn mice was rated by the EPA as 'High;' this rating was a result of systematic study evaluation and risk of bias analysis by a team of EPA experts. The Feng et al. (2017) study, the critical effect of thyroid hormone disruption in offspring, dose-response assessment, and corresponding RfD were subjected to extensive internal EPA, interagency, and public/external peer review. While confidence in the critical study was rated 'High,' the 'Low' confidence rating for the PFBS chronic RfD was in part a result of the lack of a chronic exposure duration study in any mammalian species; this lack of a chronic duration study was one of the considerations that resulted in the EPA applying a UF of 10 to account for database limitations (UF_D). Additional database considerations that warranted a 'Low' confidence ranking for the PFBS RfD included the lack of studies that evaluated neurodevelopmental, immunological, or mammary gland effects. Further, available toxicokinetic studies are limited (e.g., one mouse toxicokinetic study) and toxicokinetic data do not exist for PFBS at all life stages, including neonates, infants, and children. Lastly, studies are not available to estimate the relative cross-species sensitivity in toxicodynamics (e.g., thyroid signaling) between mice and humans. Based on the EPA's human health assessment practices, the lowest confidence rating across the areas of consideration (e.g., existent hazard/dose-response database) is assigned to the corresponding derived reference value (e.g., RfD). Thus, the EPA has high confidence in the critical study (Feng et al., 2017) and critical effect/thyroid endpoint, but the database is relatively limited. Although the PFBS RfD was based on best available peer-reviewed science, there is uncertainty as to the

hazard profile associated with PFBS after prolonged (e.g., lifetime) oral exposure. In the toxicity assessment for PFBS (USEPA, 2021d), the EPA noted data gaps in specific health effects domains, as is standard practice. Toxicity assessments for most chemicals identify data gaps; the issue of uncertainty due to toxicological study data gaps is not unique to PFBS. Data gaps are considered when selecting the UF_D because they indicate the potential for exposure to lead to adverse health effects at doses lower than the POD derived from the assessment's critical study. There is a potential that effects with greater dose-response sensitivity (i.e., occurring at lower daily oral exposures) might be discovered from a chronic duration exposure study. Due to this uncertainty, the EPA applied a UF_D of 10.

A few commenters questioned the human significance of thyroid hormone changes (T3, T4 levels) in newborn rodents to PFBS human risk assessment, with one commenter stating that the thyroid effects could have been secondary to liver effects. The EPA disagrees with this comment. As noted in the human health toxicity assessment for PFBS (USEPA, 2021d), PFBS-induced perturbation of the thyroid was consistently observed across two species, sexes, life stages, and exposure durations in two independent, high-confidence studies, and these perturbations involved a coherent pattern of hormonal changes. The toxicity assessment for PFBS (USEPA, 2021d) concluded that these changes in rodents are adverse and human-relevant, and appropriate for RfD derivation. Additionally, as it specifically pertains to the study/effect used as the basis of the PFBS RfD (USEPA, 2021d), a critical nuance is that T4 decrements occur during an early lifestage (e.g., in utero). So, while it is agreed that there are some key differences in thyroid hormone homeostasis between *adult* humans and rodents (e.g., carrier protein profile), these differences are effectively negated in a state of pregnancy. The placentas of both humans and rodents serve as a gatekeeper for transit of highly controlled levels of T4 to support proper TH-dependent tissue development across trimesters. That is, rodents and humans are more alike during pregnancy as compared to non-pregnant adults across species. So, the level of T4 available to offspring during in utero development is critical to proper development. This is indeed an adverse health scenario (i.e., too little T4/T3 especially in early pregnancy can have profound impacts on health of offspring). One of the most critical health outcomes consistently associated with decreased T4 (and T3) during in utero development is neurocognitive deficits. Further, as noted in the toxicity assessment for PFBS (USEPA, 2021d), "Although there are some differences in hypothalamic-pituitary-thyroid (HPT) regulation across species (e.g., serum hormone-binding proteins, hormone turnover rates, and timing of *in utero* thyroid development), rodents are generally considered to be a good model for evaluating the potential for thyroid effects of chemicals in humans (Zoeller et al., 2007). For more details pertaining to HPT dynamics and the similarities and differences associated with thyroid hormone economy between rodents and humans, please refer to *A Literature Review of the Current State of the Science Regarding Species Differences in the Control of, and Response to, Thyroid Hormone Perturbations. Part 1: A Human Health Perspective* (Regulatory Science Associates, 2019). The pattern of decreased thyroid hormones in the absence of a coordinated reflex increase in TSH and commensurate alterations in thyroid tissue weight and/or histology, observed in PFBS studies [e.g., Feng et al. (2017)], is consistent with the human clinical condition referred to as

"hypothyroxinemia," which is commonly associated with pregnancy in humans." For a full discussion of the human relevance of the thyroid hormone changes seen in rodents, please see USEPA (2021d).

One commenter questioned the EPA's approach to estimating the human equivalent dose (HED) from the animal data using toxicokinetic (TK) data rather than using default body-weight scaling and suggested that the default allometric approach is more appropriate for estimating an HED. The EPA disagrees with this comment. In human health risk assessment practice, the EPA considers a hierarchical approach to cross-species dosimetric scaling consistent with technical guidance to calculate HEDs (USEPA, 2011; see pp. X-XI of the Executive Summary in '*Recommended Use of Body Weight$^{3/4}$ as the Default Method in Derivation of the Oral Reference Dose*'). The preferred approach is physiologically based toxicokinetic (PBTK) modeling; however, there are rarely sufficient chemical-specific data to properly parameterize such a model. In the absence of a PBTK model, the EPA considers an intermediate approach in which chemical-specific data across species, such as clearance or plasma half-life, are used to calculate a DAF (USEPA, 2011). If chemical-specific TK data are not available, only then is a default approach used wherein allometric scaling, based on body weight raised to the ¾ power, is used to calculate a DAF. The human health toxicity assessment for PFBS invoked the intermediate approach, consistent with guidance, as TK data were available for humans and rodents.

Comments Specifically on PFHxS. Some commenters noted a typographical error in the HRL/HBWC calculation for PFHxS which was reported as 9.0 ng/L in the proposal. The agency has corrected the value in this NPDWR and within the requirements under 141 CFR Subpart Z. The correct HRL/HBWC for PFHxS is 10 ng/L.

Two commenters questioned the human relevance of thyroid effects (i.e., changes in tissue structure (e.g., enlarged cells; increased numbers of cells) in the thyroids of adult male rats) observed in the critical study used to derive the ATSDR minimal risk level and the EPA's PFHxS HRL/HBWC/MCLG because, as noted in the ATSDR *Toxicological Profile for Perfluoroalkyls*, this observed effect may have been secondary to liver toxicity and, therefore, the commenters state that its significance is unclear. The EPA disagrees with this comment. SDWA requires that to the degree that the EPA's action is based on science, the EPA use "the best available, peer reviewed science" to inform decision making on drinking water regulations. Although there is some uncertainty regarding the selection of thyroid alterations as the critical effect (as the ATSDR toxicological profile notes), at this time, the 2021 ATSDR toxicological profile represents the best available peer reviewed scientific information regarding the human health effects of PFHxS. As the most sensitive known effect as supported by the weight of the evidence, the thyroid effect was appropriately selected by ATSDR as the critical effect. Additionally, published studies in rats have shown that PFHxS exposure results in other thyroid effects, including decreases in thyroid hormone (primarily T4) levels in serum (NTP, 2018a; Ramhøj et al., 2018). Similarly, peer-reviewed final EPA assessments of other PFAS, including PFBS (USEPA, 2021d) and perfluorobutanoic acid (PFBA) (USEPA, 2021h), have concluded that these changes in rodents are adverse and human-relevant, and appropriate for RfD derivation.

Furthermore, it is appropriate to use other health protective (toxicity) values developed by other authoritative governmental agencies, including ATSDR minimal risk levels, if available, as these agencies use scientifically credible approaches and their work is peer-reviewed (the ATSDR toxicological profile underwent intra- and interagency review and external peer review by seven experts with knowledge of toxicology, chemistry, and/or health effects). The ATSDR minimal risk levels reflect the best available, peer-reviewed science.

Furthermore, the EPA's draft *IRIS Toxicological Review of Perfluorohexanesulfonic Acid (PFHxS) and Related Salts (Public Comment and External Review Draft)* (USEPA, 2023h), which is in the public domain, preliminarily provides confirmatory evidence that PFHxS significantly affects human development (emphasis added): "Overall, the available evidence indicates that *PFHxS exposure is likely to cause thyroid and developmental immune effects in humans*, given sufficient exposure conditions. For thyroid effects, the primary supporting evidence for this hazard conclusion included evidence of decreased thyroid hormone levels, abnormal histopathology results, and changes in organ weight in experimental animals. For immune effects, the primary supporting evidence included decreased antibody responses to vaccination against tetanus or diphtheria in children." Although the EPA did not rely on this draft IRIS toxicological review for PFHxS in this rulemaking, the draft is available to the public and offers confirmation that PFHxS elicits developmental effects in humans.

Comments Specifically on HFPO-DA. A few commenters submitted critical comments related to the adverse health effects associated with exposure to HFPO-DA and how these health effects are quantified to derive the RfD in the human health toxicity assessment for HFPO-DA (USEPA, 2021e), which was used to calculate the HRL/HBWC/MCLG. Commenters claimed that the RfD for HFPO-DA is not scientifically sound, and cited one or more of the following reasons why: 1) the selected critical effect (constellation of liver lesions) includes different liver effects that were not consistently observed across male and female mice and were not necessarily all adverse; 2) the hepatic effects in mice (the selected critical effect) are mediated by a rodent-specific MOA, peroxisome proliferator-activated receptor alpha (PPARα) activation, and therefore not relevant to humans; 3) the EPA incorporated results of a pathology working group which misapplied diagnostic criteria classifying apoptotic and necrotic lesions; and 4) the EPA misapplied uncertainty factors (UFs) (i.e., the subchronic to chronic UF and database UF), resulting in the maximum possible UF of 3,000 according to agency guidance (USEPA, 2002a; USEPA, 2022a). Another commenter thought that the interspecies UF should be further increased. Also, some commenters stated that the EPA did not properly consider all available epidemiological data, and one commenter stated that the DWI-BW used in the calculation of the HRL/HBWC for HFPO-DA is inappropriate. These comments are addressed below.

Overall, the EPA disagrees with the commenters and maintains that the final published peer-reviewed human health toxicity assessment that derived the RfD for HFPO-DA is appropriate and sound, reflects the best available peer-reviewed science, and is consistent with agency guidance, guidelines, and best practices for human health risk assessment. Notably, the EPA sought external peer review of the toxicity assessment *twice* (USEPA, 2018b; USEPA, 2021i),

released the draft toxicity assessment for public comment and provided responses to public comment (USEPA, 2021j), and engaged a seven-member pathology working group at the National Institutes of Health—an entirely separate and independent organization—to re-analyze pathology slides from two critical studies (USEPA, 2021e, Appendix D), all of which supported the EPA's conclusions in the toxicity assessment, including the RfD derivation.

Regarding critical effect selection: the EPA's approach to critical effect selection for the RfD derivation considers a range of factors, including doses at which effects are observed, biological variability (which can produce differences in effects observed between sexes), and relevance of the effect(s) seen in animals to human health. The EPA engaged a pathology working group within the National Toxicology Program (NTP) at the National Institutes of Health to perform an independent analysis of the liver tissue slides from the critical study and the pathology working group determined that the tissue slides demonstrated a range of adverse effects and that the constellation of liver effects caused by HFPO-DA exposure, which included cytoplasmic alteration, apoptosis, single cell necrosis, and focal necrosis, constitutes an adverse liver effect in these studies (USEPA, 2021e, Appendix D). The EPA evaluated the results of the pathology working group and determined that the effects were relevant to humans according to peer-reviewed, best available science (e.g., Hall et al., 2012). Additionally, the EPA convened a second independent peer-review panel of human health risk assessment experts to review the EPA's work on HFPO-DA, including critical effect selection. The panel unanimously agreed with the selection of the constellation of liver lesions as the critical effect, the adversity of this effect, and its relevance to humans (USEPA, 2021i).

The commenters' assertion that the hepatic effects observed in mice are not relevant to humans because they are PPARα-mediated is unsupported. Commenters claim that one specific effect—apoptosis—can be PPARα-mediated in rodents (a pathway that some data suggest may be of limited or no relevance to humans). However, in supporting studies cited by commenters, a decrease in apoptosis is associated with a PPARα-mediated MOA, with Corton et al. (2018) stating, "[t]he data indicate that a physiological function of PPARα activation is to increase hepatocyte growth through an increase in hepatocyte proliferation or a decrease in apoptosis or a combination of both effects" while HFPO-DA is associated with increased apoptosis (USEPA, 2021e). Therefore, the commenter's claim that apoptosis is associated with the known PPARα-mediated MOA is unsupported. Despite this, the critical study selected by the EPA, and indeed other studies as well, reported not only apoptosis but also other liver effects such as necrosis that are not associated with a PPARα-mediated MOA and therefore are relevant for human health (Hall et al., 2012). Further, according to the available criteria, effects such as cytoplasmic alteration in the presence of liver cell necrosis are considered relevant to humans (Hall et al., 2012).

Additionally, commenters asserted that a 2020 study by Chappell et al. reported evidence demonstrating that the rodent liver effects are not relevant to humans, and that the EPA failed to consider this study. It is important to note that although Chappell et al. (2020) was published after the assessment's literature search cut-off date (USEPA, 2021e, Appendix A; USEPA,

2022d), the EPA considered this paper initially through the Request for Correction process (USEPA, 2022d) and noted that this study specifically assessed evidence for PPARα-driven apoptosis and did not investigate other important potential modes of action or types of cell death, specifically necrosis. The authors state that they could "not eliminate the possibility that necrotic cells were also present." The EPA again considered Chappell et al. (2020), in addition to other studies submitted through public comment (Heintz et al., 2022; Heintz et al., 2023; Thompson et al., 2023), and determined that these studies are unable to explore a necrotic/cytotoxic MOA through transcriptomics with the methods used in these papers since Thompson et al. (2023) states that "there are no gene sets for assessing necrosis in transcriptomic databases." Though the study tests "a gene expression signature indicative of liver cytotoxicity…developed from short-term toxicity studies in rats," it is unclear whether this gene expression signature is indicative of liver cytotoxicity in mice or in studies longer than 4-14 days. This is important because the available HFPO-DA studies demonstrating a constellation of liver lesions are in mice exposed to HFPO-DA for 28 days and longer.

Finally, additional support beyond the data presented in a few transcriptomics-focused studies (Thompson et al., 2023 is a secondary analysis of Chappel et al., 2020 and Heintz et al., 2022 and Heintz et al, 2023 is a review of these three studies) are needed to conclude that PPAR-alpha activation is the sole definitive MOA for HPFO-DA-induced liver effects. For example, evaluation of the relationship between changes in mRNA abundance (gene expression) and functional protein expression for the same protein-coding genes would further the understanding of the downstream effects (i.e., changes in protein) of the predicted PPAR alpha activation and demonstrated PPARalpha binding. In the absence of changes to the PPARalpha gene, as presented in the studies, changes in protein indicators of PPARalpha activation (e.g., Cyp4a in mice, for which some (but not all) mRNA isoforms are differentially expressed in treated mice) could serve as surrogates, to support the predictions from transcriptomics data. It is known that mRNA levels generally explain protein levels in a "steady state" scenario, while it is also true that mRNA does not fully explain protein expression, as there are post-transcriptional and even post-translational events that influence protein expression (Liu et al., 2016). Relatedly, demonstration of alterations in proteins that are involved in the regulation of cell cycle and lipid metabolism that are expected following PPARalpha activation, whether via increased transcription resulting in increased translation or by other mechanisms (e.g., bioactivation or release of protein from cells) (Corton et al., 2014), would support the MOA, but were not measured in the studies. Targeted gene expression analysis of key genes involved in the PPARa signaling pathway to verify the findings from the non-targeted approach (e.g., qPCR) would also increase confidence in the results, albeit not as informative as protein expression.

Relatedly, confirmation of changes to predicted upstream regulators, specifically changes to PPARa at the protein level, has not been presented to accompany the predictions from upstream regulator predictive analysis. To conclusively link PPARa activation to all molecular effects, staining for PPARa in liver sections from animals used in these experiments to confirm that the protein is changed in localization or expression would strengthen the presented predictions. This is particularly important considering the overlap in gene targets of PPARa and other members of

the same nuclear receptor superfamily (e.g., PXR, CAR, and other PPARs (Elcombe et al., 2014)). It also should be noted that the gene set analyses conducted in these studies are based upon gene sets curated using data from publications from a variety of cell types. This is important because different cell types have different baseline transcriptomic landscapes (Zhu et al., 2016), and cell type-agnostic predicted pathways based upon inferences about the transcriptome may or may not be indicative of what is happening in the specific cell type being investigated in practice.

Thompson et al. (2019), Chappel et al. (2020), and Thompson et al. (2023) all demonstrate apoptotic cells which were lesions also identified by the NTP-PWG. Most importantly, the commenter and these cited studies fail to recognize that increased apoptosis is a key criterion to establish a cytotoxic MOA and, as noted above, is inconsistent with a PPARalpha MOA. As outlined in the toxicity assessment (USEPA, 2021e), Felter et al. (2018) "identified criteria for establishing a cytotoxicity MOA, which includes:…2) clear evidence of cytotoxicity by histopathology, such as presence of necrosis and/or increased apoptosis." Overall, following re-review of Chappell et al. (2020) as well as review of the other studies submitted through public comment, the EPA determined that these studies provide evidence for increased apoptosis, which is a key event of a cytotoxic MOA, and therefore they support the mechanistic conclusions of the 2021 HFPO-DA toxicity assessment "that multiple MOAs could be involved in the liver effects observed after GenX chemical exposure" including PPARα and cytotoxicity (USEPA, 2021e).

With respect to claims that the EPA misapplied diagnostic criteria classifying apoptotic and necrotic lesions: as mentioned above, the EPA engaged a pathology working group within the NTP at the National Institutes of Health to perform an independent analysis of the liver tissue slides. Seven pathologists—headed by Dr. Elmore, who was the lead author of the pathology criteria that the commenter cites (Elmore et al., 2016)—concluded that exposure to HFPO-DA caused a "constellation of liver effects" that included cytoplasmic alteration, apoptosis, single cell necrosis, and focal necrosis, and that this full "constellation of lesions" should be considered the adverse liver effect within these studies. The EPA then used the established Hall criteria (Hall et al., 2012) to determine that since liver cell death was observed, all effects, including cytoplasmic alteration, were considered adverse and relevant to humans. The NTP-PWG was comprised of 7 pathologists using the Elmore diagnostic criteria to systematically classify and reach consensus on the observed liver lesions, including Dr. Elmore herself. The analysis included multiple layers of quality control and peer review. The diagnostic evaluation conducted in Thompson et al., 2019 and Chappel et al., 2020 was completed by one pathologist with no quality control as described in the methods sections of those papers. The commenter states that the Thompson et al., 2023 publication "demonstrated that some of the hepatocytes putatively considered necrotic by the NTP-PWG, in fact, stain positive for molecular markers of apoptosis thereby calling into questions the NTP-PWG's diagnoses of necrosis;" however, it is known that apoptosis can lead to secondary necrosis and that this is mediated through Caspase 3 (Rogers et al., 2017), which is the same stain used in Thompson et al., 2023. Additionally, and as described above, the presence of increased apoptotic cells is more consistent with a cytotoxic MOA than with a PPARalpha MOA. For the reasons described above, the EPA is confident that the findings

of the seven-member pathology working group reflect an independent, unbiased, and comprehensive high-quality analysis.

The EPA disagrees with the commenters' assertion about UF application. As noted above, agency guidance (USEPA, 2002a; USEPA, 2022a) has established the appropriateness of the use of UFs to address uncertainty and account for data limitations. UFs reflect the limitations of the data across the five areas used in current EPA human health risk assessment development (referenced above); all individual UFs that are applied are multiplied together to yield the composite or total UF. The EPA guidance states that although a composite UF greater than 3,000 represents "excessive uncertainty" (USEPA, 2002a; USEPA, 2022a), a composite UF can be equal to 3,000. For HFPO-DA, a composite UF of 3,000 was appropriately applied to account for uncertainties, including variability in the human population, database uncertainties, and possible differences in the ways in which humans and rodents respond to HFPO-DA that reaches their tissues. Furthermore, the composite UF of 3,000 and specifically the database UF and subchronic-to-chronic UF used for HFPO-DA was peer-reviewed by a panel of human health risk assessment experts, and the panel supported the application of the database UF of 10 and the subchronic-to-chronic UF of 10 (USEPA, 2021h). Additionally, a UF_A of 3 was appropriately applied, consistent with peer-reviewed EPA methodology (USEPA, 2002a), to account for uncertainty in characterizing the toxicokinetic and toxicodynamic differences between rodents and humans. As noted in the toxicity assessment for HFPO-DA (USEPA, 2021e), in the absence of chemical-specific data to quantify residual uncertainty related to toxicokinetics and toxicodynamic processes, the EPA's guidelines recommend use of a UF_A of 3.

Some commenters claimed that the EPA did not consider available epidemiological evidence showing no increased risk of cancers or liver disease attributable to exposure to HFPO-DA. The EPA disagrees with this comment because the agency considered all available scientific evidence, including epidemiological studies (USEPA, 2021e). The exhibit submitted by the commenter presents an observational analysis comparing cancer and liver disease rates in North Carolina to rates in other states. It does not present the results of a new epidemiological study that included HFPO-DA exposure measures, health outcome measures, or an assessment of association between exposure and health outcome. The exhibit submitted by the commenter consists of a secondary analysis of disease rate information that was collected from various sources and does not provide new, high-quality scientific information that can be used to assess the impact of exposure to concentrations of HFPO-DA on human health.

One commenter stated that the DWI-BW used in the calculation of the HRL/HBWC for HFPO-DA is inappropriate and that the EPA should have used a DWI-BW for general population adults instead of for lactating women. The EPA disagrees with this comment. To select an appropriate DWI-BW for use in derivation of the HRL/HBWC for HFPO-DA, the EPA considered the HFPO-DA exposure interval used in the oral reproductive/developmental toxicity study in mice that served as the basis for chronic RfD derivation (the critical study). In this study, parental female mice were dosed from pre-mating through lactation, corresponding to three potentially sensitive human adult life stages that may represent critical windows of HFPO-DA exposure:

women of childbearing age, pregnant women, and lactating women (Table 3-63 in USEPA, 2019). Of these three, the highest DWI-BW, for lactating women (0.0469 L/kg/day), is anticipated to be protective of the other two sensitive life stages and was used to calculate the HRL/HBWC for HFPO-DA (USEPA, 2024h).

Individual Public Comments and EPA Responses

General Comments

Brian Hackman (Doc. #1539, SBC-042893)

By establishing the MCL's (maximum contaminant levels) and HI (hazard index) values using ASTDR (Agency for Toxic Substances and Disease Registry) data, USEPA has taken data that ASTDR has publicly recognized has not been equated to level of risk, i.e., concentrations above their values do not have a number of people vs. concentration correlation for risk of each and total health effects. By taking the MRL (minimum recommended level) data and reducing the ppt values by additional safety factors, the USEPA has presented an overly conservative maximum contaminant value, where the expectation appears to be that 0 people will be impacted if the MCL is met. However, USEPA has shown this approach is foolish because the Agency set a parts per quadrillion (ppq) standard as a health advisory, showing that the Agency has only emotions and no scientific basis other than simple math and models with numerous pages of assumptions considering absolute worst case values to base its decision making on. This dichotomy of the Agency's de minimus risk approach to protect public health while saying any concentration is a risk is pure insanity to determine, pay for, and enforce, even at the proposed MCL's and HI's in a rush to think that something needs to be done because something can be 'detected'.

EPA Response: Please see section 4.3.3 of the EPA response in this *Response to Comments* document. HAs are beyond the scope of this rulemaking action. They are non-regulatory HAs issued pursuant to a separate authority under SDWA that reflected the best available information at that time. The commenter acknowledges that the EPA uses peer-reviewed models and math to inform its decision-making. These models and math comprise best available science, which, among other science and information, inform the MCLGs and overall NPDWR.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045877)

Troublingly, EPA has not completed its own human health assessments for PFHxS and PFNA. Instead, it relies on assessments from the Agency for Toxic Substances and Disease Registry (ATSDR). EPA did not oversee the peer review process of the ATSDR document, which covered the assessment of 12 PFAS. ATSDR conducted a letter peer review, which is inconsistent with EPA's own best practices for the peer review of ISAs or HISAs. For instance, as described by ATSDR, the peer reviewers were not provided with any of the public comments before the review [FN11: ATSDR Peer Review Agenda for the Toxicological Profile for Perfluoroalkyls (PFAS), available at:

https://www.atsdr.cdc.gov/sites/peer_review/tox_profile_perfluoroalkyls.html.]. EPA's Peer Review Handbook recognizes that a letter review is appropriate when a work product is "not controversial" and also recognizes that, for HISAs, a panel review is a preferable approach [FN12: U.S. EPA, Peer Review Handbook, 4th edition, 2015, at pages 55-57, available at: https://www.epa.gov/sites/default/files/2015-10/documents/epa_peer_review_handbook_4th_edition_october_2015.pdf.]. The ATSDR health assessments are not a valid substitute for the rigorous SAB peer review that is required for a HISA. Equally important, in describing how to use the ATSDR minimal risk levels that EPA relies upon, ATSDR describes these values as "[i]ntended to serve as screening levels, are used by ATSDR health assessors and other responders to identify contaminants and potential health effects that may be of concern at hazardous waste sites. It is important to note that [Minimal Risk Levels] (MRLs) are not intended to define cleanup or action levels for ATSDR or other Agencies" (emphasis added by ATSDR) [FN13: See ATSDR description of minimal risk levels at: https://www.atsdr.cdc.gov/mrls/index.html.].

EPA Response: In regard to how the EPA considers the ATSDR assessments, please see section 4.3.3 of the EPA response in this *Response to Comments* document. Additionally, commenter mischaracterizes what constitutes Influential Scientific Information (ISI) or Highly Influential Scientific Assessment (HISA) and how the EPA manages peer review for ISI or HISA. The PFNA and PFHxS assessments are not HISA. A scientific assessment is considered HISA when the agency or the OMB Office of Information and Regulatory Affairs (OIRA) Administrator determines that the dissemination could have a potential impact of more than $500 million in any one year on either the public or private sector or that the dissemination is novel, controversial, or precedent-setting, or has significant interagency interest. Neither the EPA Administrator, the CDC director, nor the Administrator of OIRA have determined that the PFNA or PFHxS assessments are HISA. Therefore, the commenter is mistaken that these assessments are HISA. The PFHxS and PFNA toxicity assessments have been peer-reviewed. Letter peer review is consistent with the peer-review process for ISI.

Environmental Protection Network (EPN) (Doc. #1773, SBC-043855)

EPN supports the proposed use of ATSDR's intermediate-duration oral Minimal Risk Levels for PFHxS and PFNA and EPA's reference doses for HFPO-DA and PFBS as representing the best available science on the toxicity of these chemicals.

EPA Response: The commenter agrees with the EPA's approach.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-044910)

Section 3.2: PFAS mixture of PFBS, PFNA, GenX, PFHxS

EPA is proposing a HI of 1.0, equal to the MCLG, for the mixture of PFBS, PFNA, GenX, and PFHxS. Each PFAS in this mixture has a proposed HBWC; 10 ppt for GenX, 2000 ppt for PFBS,

10 ppt for PFNA, and 9 ppt for PFHxS. EPA proposed this action to account for dose-additive health impacts of these chemicals in co-occurrence.

As mentioned earlier, EPA has limited occurrence data for these additional PFAS, and is in the process of developing a human health toxicity assessment for PFNA and PFHxS. The human health toxicity assessment should be done before a Regulatory Determination, and certainly before a proposed regulation, as this is paramount to assessing the impact on public health. In contrast, a toxicity assessment from 2021 was used in 2022 to develop a drinking water health advisory for PFBS that is currently the basis for its HBWC. EPA should be using the same method to get to the HBWC if it plans to group these PFAS into a HI.

EPA Response: The EPA disagrees that the agency has limited occurrence data for PFBS, PFNA, HFPO-DA (GenX chemicals), and PFBS. For further discussion on this topic, please see sections 3 and 6 of the EPA response in this *Response to Comments* document. Additionally, the EPA notes that the EPA is using completed human health toxicity assessments for PFHxS, PFNA, HFPO-DA, and PFBS. Two of those assessments were completed by the EPA and two of them were completed by ATSDR. As noted in section 4.3.3 of the EPA response above, the EPA is not required under SDWA to exclusively use EPA assessments to support an NPDWR, and in fact, SDWA's clear direction in Section 1412(b)(3)(A)(i) is to use the best available, peer-reviewed science when developing NPDWRs.

Also, HAs are not a pre-requisite for an NPDWR under the SDWA and there is nothing in the statute or the EPA's historical regulatory practice that suggests that the agency should delay regulation of a contaminant in order to develop a HA first.

American Chemistry Council (ACC) (Doc. #1841, SBC-044834)

EPA has Not Completed an Ongoing Independent Health Hazard Assessment for PFHxS and PFNA and Use of ATDRS MRLs is Not Appropriate

EPA has not completed a toxicity assessment for either perfluorohexane sulfonate (PFHxS) or for perfluorononanoic acid (PFNA) and instead depends on an evaluation of the two substances conducted by the Agency for Toxic Substances and Disease Registry (ATSDR). [FN102: ATSDR. Toxicological Profile for Perfluoroalkyls (2021). (ATSDR PFAS Tox Profile).] However, as recently as February 2023, EPA has indicated that it will conduct assessments of these two chemicals under the Integrated Risk Information System (IRIS) over the next year or so. [FN103: IRIS Program Outlook, February 2023.] ATSDR explicitly states that their toxicity values (minimal risk levels (MRLs)) are "intended to serve as screening levels" (ATSDR 2021 p. 15) and "are not meant to support regulatory action" (ATSDR 2021 p. C-1). The peer review of the single ATSDR assessment, which covered the evaluation of 12 PFAS in one document, was conducted by letter review and was not consistent with EPA's own best practices for a peer review of influential scientific documents that are the basis for a regulation. [FN104: USEPA. Peer Review Handbook, 4th edition. EPA/100/B-15/001. Science and Technology Policy Council

(2025, at 55.] The ATSDR health assessment are not a valid substitute for the rigorous SAB peer review that is required for an influential scientific assessments.

Therefore, it is inconsistent with the intended use of ATSDR MRLs to use them in regulatory rulemaking under the Safe Drinking Water Act. Further, given EPA's stated intention to complete toxicity assessments for these substances in the next year or so, it is inappropriate for EPA to propose and seek comment on MCLs and MCLGs for these substances now, especially because it is not clear what process EPA would use to update the PFNA and PFHxS HBWC values in this proposal when EPA completes its assessment, particularly in light of the planned forthcoming IRIS assessments, for which systematic review protocols were issued for public comment in 2019 and assessments are well underway. [FN105: EPA's IRIS Handbook includes several references to the results of the systematic review for PFHxS and PFNA.] PFHxS and PFNA systematic review outcomes as examples, suggesting that an IRIS assessment for each of the chemicals was well underway.

Laboratory studies with PFHxS and PFNA suggest that the liver is a sensitive target, providing evidence of increased liver weight and centrilobular hepatocellular hypertrophy. Consistent with the criteria provided by Hall et al., however, ATSDR concludes that these effects are not appropriate endpoints for deriving minimum risk levels (MRLs) in the absence of other evidence of liver effects. ATSDR instead relies on reports of other effects in laboratory animal studies, despite evidence that these effects also may be of limited relevance to humans.

EPA Response: Please see section 4.3.3 of the EPA response in this *Response to Comments* document. The EPA notes that the draft EPA IRIS assessment RfD for PFHxS is significantly lower than the ATSDR minimal risk level. While the EPA is not relying on that draft assessment as it has not yet completed peer review, that assessment further demonstrates that PFHxS poses human health risk at low levels and further validates the EPA's determination that PFHxS may affect human health.

PFAS Regulatory Coalition (Doc. #1761, SBC-053399)

Also, EPA's reliance on studies from mice/rats is problematic. The non-cancer toxicological endpoints selected for PFNA, HFPO-DA, PFHxS, and PFBS, and used to support the MCL/MCLGs, are based on laboratory animal responses, which do not correlate with the potential for clinical effects in human populations. Effects seen in mice, such as delayed development and decreased hormone regulation, have highly uncertain relevance in terms of human health. Barring consistency between animals and humans (allowing the basis of the MCL to have positive concordance, which would comply with EPA guidance and policy), toxicological endpoints used in developing MCLs/MCLGs should preferentially rely on human studies and account for adverse PFAS effects leading to clinically-relevant impacts, or have a robust, peer-reviewed and SAB-endorsed rationale for relying solely on rodent results. [FN1: In this context, it should be noted that recent evaluations have raised concerns about the human and animal data that EPA is relying on in this rulemaking, including as to immunotoxicity effects of PFOA and

PFOS. See, e.g., Garvey, et. Al., "Weight of evidence evaluation for chemical-induced immunotoxicity for PFOA and PFOS: findings from an independent panel of experts," Critical Reviews in Toxicology, 53:1, 34-51, DOI: 10.1080.10408444.2023.2194913.]

EPA Response: Please see section 4.3.3 of the EPA response in this *Response to Comments* document. Additionally, please see sections 4.1.1 and 4.2.2 of the EPA response in this *Response to Comments* document regarding the EPA's use of human studies to support the assessments for PFOA and PFOS. For discussion regarding the EPA's conclusions on immunotoxicity associated with PFOA and PFOS, please see section 4.2.1.4 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045883)

3. The HBWCs are overly conservative and are not fit for purpose

EPA uses the following HBWCs for the four PFAS chemicals: 9.0 ppt for PFHxS, 10.0 ppt for HFPO-DA, 10.0 ppt for PFNA [FN20: We note that 88 Fed. Reg. at 18647, EPA refers to the PFNA HBWC as being 100 ppt.], and 2000 ppt for PFBS. For EPA's proposed hazard index approach (used to calculate the MCL for the mixture of these four PFAS), EPA is proposing to calculate the hazard index as the sum total of component PFAS hazard quotients (HQs), calculated by dividing the measured component PFAS concentration in water by these relevant HBWCs. The HBWCs are therefore critical to EPA's proposal to regulate these four PFAS. EPA derives HBWCs using three inputs: oral toxicity values (either the Reference Dose (RfD) or MRL), the body-weight adjusted drinking water intake level for the population of concern (DWI-BW), and the relative source contribution (RSC). However, as noted above, the science supporting the toxicity values for the four contaminants is highly uncertain, is not fit for purpose, and has not undergone the requisite SAB review. Thus, this input in the HBWC is flawed for all four contaminants.

In addition to using highly uncertain toxicity values, EPA uses a default RSC value (i.e., the amount of assumed exposure coming from drinking water) in each HBWC equation. EPA recognizes that "available data on PFHxS exposure routes and sources did not permit quantitative characterization of PFHxS exposure."[FN21: 88 Fed. Reg. at 18646.] Given that lack of data, EPA chose the most conservative default value for the RSC (20%). Combining this RSC with the highly uncertain toxicity values leads to HBWC values that are so low, they are untethered from any realistic measure of potential risk to human health.

In applying the 20% RSC, EPA refers to the EPA 2000 Exposure Decision Tree [FN22: U.S. EPA Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health, EPA- 822-B-00-004, available at: https://www.epa.gov/sites/default/files/2018-10/documents/methodology-wqc-protection-hh-2000.pdf.]. However, this decision tree allows flexibility and encourages the review of information, when available, to make a reasonable determination of exposure, with the goal that the default would not have to be used. For PFHxS, HFPO-DA, PFNA, and PFBS, EPA has not made a sufficient effort to review the existing

information to inform its use of the 2000 Decision Tree. For instance, HFPO-DA is used as a processing aid, and it is not found in consumer products. In determining that a 20% RSC is appropriate, EPA cites to the EPA 2021 HFPO-DA Human Health Toxicity Value Assessment [FN23: U.S. EPA Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (CASRN 13252-13-6 and CASRN 62037-80-3). Also Known as "GenX Chemicals." 2021; available at: https://www.epa.gov/chemical-research/human-health-toxicity-assessments-genx-chemicals.]. However, this assessment does not provide a robust discussion of potential human exposures, and it provides no justification for why a processing aid (chemical intermediate) that is not found in consumer products would warrant a default RSC of 20%. If EPA were to do a simple cursory review and follow its own 2000 Decision Tree, it would lead to the use of a RSC of 80% [FN24: See step 7 of the Exposure Decision Tree as described in U.S. EPA Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. EPA-822-B-00-004; available at: https://www.epa.gov/sites/default/files/2018-10/documents/methodology-wqc-protection-hh-2000.pdf, at page 4-8; and see also letter from Sheryl Telford, the Chemours Company, addressed to Elizabeth Behl, EPA, submitted to the Proposed Rule docket number EPA-HQ-OW-2022-0114, May 31, 2023 entitled Supplemental Data To Assist in the Development of Health Advisory.]. EPA has provided no information to support the choice of a 20% default for HFPO-DA.

EPA also chose a 20% RSC for PFHxS, PFNA, and PFBS without conducting a robust exposure review. For PFNA and PFHxS, EPA summarizes the occurrence data but still opts for a default of 20% [FN25: U. S. EPA. Maximum Contaminant Level Goal (MCLG) Summary Document for a Mixture of Four Per- and Polyfluoroalkyl Substances (PFAS): GenX Chemicals, PFBS, PFNA and PFHxS, 2023, EPA–822–P–23–004, available at: https://www.epa.gov/system/files/documents/2023-03/PFAS%20HI%20MCLG%20Public%20Review%20Draft%2009%20March%202023.pdf.]. By contrast, New Hampshire, Michigan, Minnesota, and Washington State all chose to use a RSC of 50% for PFHxS [FN26: See ECOS Paper: Processes and Considerations for Setting State PFAS Standards, 2023 Update, available at: https://www.ecos.org/documents/ecos-paper-processes-and-considerations-for-setting-state-pfas-standards-2023-update/.]. Similarly, for PFNA, New Hampshire, New Jersey, Michigan, and Washington state all chose to use a RSC of 50%.

EPA Response: Please see section 4.3.3 of the EPA response in this *Response to Comments* document. For a full discussion of data considered to derive the RSCs for the four PFAS included in the Hazard Index, please refer to USEPA (2024h).

Additionally, as noted by the SAB (USEPA, 2022b), RSC determination depends in part on the RfD value being used. Therefore, it is not necessarily informative to compare RSC derivations when the corresponding toxicity reference values are different (e.g., some of the states noted by the commenter used toxicity reference values for PFNA and/or PFHxS that were different from those used by the EPA). In its report, the SAB stated the following with respect to PFOA and

PFOS: "…because the RSC is based on the portion of the RfD that comes from non-drinking water sources, the choice of the RSC depends on the numerical value of the RfD. The RSC will decrease as the RfD decreases since the non-drinking water exposures represent a higher proportion of a lower RfD. Because the RfDs used in the 2016 EPA HAs and in state drinking water guidelines are several orders of magnitude higher than the RfDs presented in the draft MCLG documents, the RSCs used in the 2016 HESD and by states (discussed on p. 347-348 of the PFOA document) are not relevant to the selection of the RSC in the current draft MCLG documents."

Furthermore, the EPA followed its established process for RSC derivation, which is outlined in the EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (USEPA, 2000c). See information on RSC derivations for these four PFAS in USEPA (2024h). As noted in the EPA's exposure decision tree approach (USEPA, 2000c), exposure information relevant to the population of concern is a key element of RSC derivation. Following its methodology, the agency determined that for each of these four PFAS, data are insufficient to allow for quantitative characterization of the different exposure sources. Some of the states cited by the commenter (i.e., New Hampshire, Minnesota, New Jersey) appear to have selected a target population for one or more of the PFAS (e.g., breastfed/formula-fed infants) and calculated the RSCs by the subtraction method using predicted blood serum PFAS concentrations. The EPA, however, used the percentage method. As noted in USEPA (2000c), "The subtraction method is considered acceptable when only one criterion is relevant for a particular chemical. The percentage method is recommended in the context of the above goals when multiple media criteria are at issue. The percentage method does not simply depend on the amount of a contaminant in the prospective criterion source only. It is intended to reflect health considerations, the relative portions of other sources, and the likelihood for ever-changing levels in each of those multiple sources (due to ever-changing sources of emissions and discharges)."

<u>The Chemours Company FC, LLC (Doc. #1845, SBC-046065)</u>

4 The use of reference value (RfV) inputs with large disparities in composite uncertainty factors is likely to result in highly uncertain HI MCLG values and difficulties in the interpretation of risk indicated by these values.

In discussing the challenges of the general HI approach, EPA (2023b) notes that the HI can become "highly uncertain" in exposure scenarios where the constituent with the highest HQ has uncertainty in its exposure estimate or where the "RfV was derived using a large composite UF". As discussed above, EPA applied a maximum 3000-fold composite UF in its derivation of the RfD for HFPO-DA. This composite UF is an order of magnitude greater than the composite UF EPA applied to PFBS and PFNA (EPA 2023a). As discussed in Attachment A (Exhibit 3, Section 1), ~90% of IRIS RfD values have composite UF values below 3000. Because EPA considers the RfD for HFPO-DA (and PFHxS) to be so uncertain, the combining of PFAS with different levels of uncertainty can, according to EPA, result in difficulties in the interpretation of such highly uncertain HI MCLG values. As such, the combining of HFPO-DA, PFBS, PFNA, and PFHxS in

the general HI MCLG approach appears incongruent with the PFAS Framework (EPA 2023b). As previously noted, the SAB has not evaluated EPA's proposed implementation of the PFAS Framework to these four PFAS.

EPA Response: For the EPA response to comments on uncertainty, please see section 4.3.3 of the EPA response in this *Response to Comments* document. For the EPA response to comments on SAB review, please see sections 4.3.1 and 4.3.2 of this *Response to Comments* document.

The Chemours Company FC, LLC (Doc. #1845, SBC-046061)

4) The use of reference value (RfV) inputs with large disparities in composite uncertainty factors is likely to result in highly uncertain HI MCLG values and difficulties in the interpretation of risk indicated by these values.

Each of these issues are discussed in detail in the sections that follow.

EPA Response: Please see section 4.3.3 of the EPA response in this *Response to Comments* document.

The Chemours Company FC, LLC (Doc. #1845, SBC-053391)

3.2 The RfD and MRL values for PFBS, PFNA, and PFHxS potentially lack human relevance.

The RfD or MRL values for PFBS, PFNA, and PFHxS are respectively based on decreased serum total thyroxin, developmental effects (decreased bodyweight and delayed eye opening, preputial separation, and vaginal opening), and thyroid follicular cell hypertrophy/hyperplasia. Considering that some PFAS exhibit overlapping activity, PPARa activation might ultimately be involved in some or all of these endpoints and therefore the human relevance of the RfDs for PFBS, PFNA, and PFHxS may also be uncertain. For example, the PFHxS MRL (developed by ATSDR) is based on thyroid follicular cell hypertrophy/hyperplasia observed in male rats in a subchronic study by Butenhoff et al. (2009). There are well-documented MOAs for thyroid effects in rodents, some of which are widely believed to lack human relevance. One such MOA involves activation of nuclear receptors in the liver (viz., CAR and PXR) resulting in induction of liver enzymes that decrease circulating thyroid hormone levels thereby causing an increase in thyroid stimulating hormone (TSH) that promotes thyroid follicular cell hyperplasia that can, under prolonged circumstances, lead to thyroid tumors in rodents. Notably, ATSDR (2021) states, "There is some uncertainty regarding the selection of thyroid alterations as the critical effect. Butenhoff et al. (2009a) suggested that the histological alterations in the thyroid may be secondary to the liver effects (hepatocellular hypertrophy)." Prior to this statement, ATSDR also states, "Increased liver weight and centrilobular hepatocellular hypertrophy were also observed in the males at ≥3 mg/kg/day. Consistent with the Hall et al. (2012), the liver effects were not considered a relevant endpoint for humans. Although there is uncertainty regarding the exact, and possibly multiple, mechanism(s) for these liver effects, peroxisome proliferation is a likely

contributor, a mechanism that cannot be reliably extrapolated to humans (Hall et al. 2012)." Taken together, ATSDR was uncertain of the human relevance of the thyroid effects induced by PFHxS and clearly viewed a potential preceding effect (viz., hepatocellular hypertrophy) as "not relevant to humans". Notably, the liver effects not considered relevant to humans by ATSDR are similar to those serving as the basis of EPA's RfD for HFPO-DA. EPA adjusted the ATSDR MRL value down to 2E-6 mg/kg-day; similar to the RfD for HFPO-DA, the RfD for PFHxS is orders of magnitude lower than the Cramer Class III TTC (i.e., indicating potential problems with the toxicity value). Finally, EPA's RfD for PFBS is based on thyroid hormone effects (viz., decreased total thyroxine in newborn mice after gestational exposure via the mother) that might also be secondary to changes in the liver enzymes.

EPA Response: The EPA disagrees. Please see section 4.3.3 of the EPA response in this *Response to Comments* document.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-052944)

• The HBWCs appear to be calculated in the same way as MCLGs. Since they are calculated the same way, it is not clear why EPA introduced the new term HBWC instead of continuing to use the term MCLG. DEP requests clarification on what if any distinction exists between the terms MCLG and HBWC.

EPA Response: In this instance, the EPA identified the HRL to evaluate occurrence data and the likelihood of potential risk to human health for the PFAS for which the EPA is making an individual final regulatory determination and/or a final regulatory determination as part of a PFAS mixture. The EPA identified the HRL as the level below which adverse health effects over a lifetime of exposure are not expected to occur, including for sensitive populations and life stages, allowing an adequate margin of safety. Following this analysis, the agency determined that PFHxS, PFNA, and HFPO-DA meet the SDWA criteria to make individual regulatory determinations. The EPA also determined that combinations of these three PFAS and PFBS meet the SDWA criteria to make a regulatory determination for their mixtures.

The agency developed individual HBWCs for PFHxS, PFNA, HFPO-DA, and PFBS for inclusion in the Hazard Index equation to derive the final Hazard Index MCLG to protect against dose additive effects associated with exposure to mixtures of two or more of these four PFAS. The HBWC is akin to an MCLG in that it reflects a level below which there are no known or anticipated adverse effects over a lifetime of exposure, including for sensitive populations and life stages, and allows for an adequate margin of safety. The HBWCs are not MCLGs for purposes of the Hazard Index PFAS MCLG because the HBWCs are inputs in the equation to derive the MCLG for PFAS mixtures, but the HBWCs and MCLGs represent the same level of protection to meet the statutory definition of MCLG. For PFHxS, PFNA, and HFPO-DA, each of the three HBWCs are equivalent to their final individual MCLGs. The EPA edited the description of HRL and HBWC to clarify that they also meet the definition of MCLG.

The EPA is finalizing individual MCLGs for PFHxS, PFNA, and HFPO-DA as follows: PFHxS MCLG = 10 ng/L; HFPO-DA MCLG = 10 ng/L; and PFNA MCLG = 10 ng/L. The technical basis for why each of these levels satisfies the statutory definition for MCLG is described in section III of the preamble (and is the same technical basis the EPA used to explain the levels identified as the HBWCs). These MCLGs are expressed with one significant digit and are based on an analysis of each chemical's toxicity (i.e., reference dose/minimal risk level), appropriate exposure factors (i.e., DWI-BW), and consideration of exposure sources beyond drinking water (RSC) (USEPA, 2024h). The EPA is deferring its individual regulatory determination for PFBS and not finalizing an individual MCLG for PFBS at this time. However, since the EPA has determined that PFBS meets the SDWA criteria when considered in a PFAS mixture with PFHxS, PFNA, and/or HFPO-DA, PFBS is included (with an HBWC of 2,000 ng/L (ppt)) as an input value in the final PFAS mixture Hazard Index MCLG (USEPA, 2024h).

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045177)

Use of body weight-adjusted drinking water intakes (DWI-BWs)

EPA selected DWI-BWs for each PFAS included in the HI approach based on evaluation of the critical study used to derive the chronic reference dose. This led to selection of the DWI-BW for lactating women for HFPO-DA and PFNA, the DWI-BW for women of childbearing age for PFBS, and the DWI-BW for adults within the general population for PFHxS. MassDEP disagrees with this application of variable DWI-BWs. MassDEP recommends that EPA select the drinking water intake for the most sensitive population or life stage identified from evaluation of the database as a whole, rather than solely based on the critical study for a particular PFAS.

Two lines of evidence support the use of the DWI-BW for the most sensitive population or life stage for HFPO-DA, PFNA, PFBS, and PFHxS. First, EPA's 2023 Draft Toxicity Assessment and Proposed Maximum Contaminant Level Goal in Drinking Water documents for PFOA [FN2: EPA 2023b. Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) in Drinking Water, Public Comment Draft. U.S. Environmental Protection Agency, Office of Water (4304T), Health and Ecological Criteria Division, Washington, DC 20460. EPA-822-P-23-005.] and PFOS [FN3: EPA 2023c. Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) in Drinking Water, Public Comment Draft. U.S. Environmental Protection Agency, Office of Water (4304T), Health and Ecological Criteria Division, Washington, DC 20460. EPA-822-P-23-007], the PFAS with the largest databases, provide evidence for the similarity of noncancer health effects and effect levels across the life stages, health outcomes and endpoints. The candidate Reference Doses (RfDs) for PFOA and PFOS were developed from different health outcomes and endpoints evaluated at different life stages, yet the health outcome specific RfDs EPA developed for PFOA and PFOS were both within a factor of 2 across the four health outcomes with sufficient evidence for evaluation. PFAS with smaller databases may not have data to evaluate a full array of health outcomes, limiting the certainty that the critical effects to the most sensitive life stage have been sufficiently evaluated. Given the growing body of evidence

supporting a wide range of health outcomes across life stages, it is prudent to assume that, until demonstrated otherwise, PFAS may have effects at sensitive life stages.

Second, as described in the Mixture document, evidence supports dose-additive effects from co-exposure to PFAS. However, the relative contribution of any particular PFAS to produce additive response to any of the multiple health outcomes associated with different life stage sensitivities is not known.

While the difference in drinking water concentrations (MCLGs) derived using the lowest and highest DWI-BW is small, i.e., well within the margin of uncertainty assumed for the RfD, adopting the ingestion rate for the most sensitive population best represents the available evidence on the health effects of PFAS.

EPA Response: Please see section 4.3.3 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046115)

IV. EPA Should Strengthen its Proposed Rule to Protect the Public and Promote Compliance

A. EPA Should Revise its Health Based Water Concentrations ("HBWCs") to Fully Address the HI PFAS' Harms to Susceptible Populations

EPA's proposed MCLG and MCL for the HI PFAS incorporate HBWCs to indicate the levels at which PFBS, GenX, PFNA, and PFHxS pose no known adverse health effects. [FN144: As described above, EPA divides the measured concentration of each HI PFAS by its HBWC to calculate a hazard quotient, which is then added to the other HI PFAS' hazard quotients to calculate the hazard index.] When establishing MCLs, the SDWA requires EPA to consider contaminants' effects not only on the general population but also on "groups . . . such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations that are identified as likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water[.]" [FN145: 42 U.S.C. § 300g–1(b)(3)(C)(i)(V) (requiring EPA to assess health impacts on greater-risk populations when establishing MCLs).]However, EPA's proposed HBWCs fail to address risks to infants and other populations that experience the greatest risks from the HI PFAS, leaving those populations exposed to serious harm. In its final rule, we urge EPA to revisit and strengthen its HBWCs for each of the HI PFAS.

Developing infants and children are most at risk of the long-term effects of PFAS exposure. There are two reasons for this. First, the fetal and early childhood life stages are when the body's systems are being established and developed. Small changes that disrupt or permanently alter the course of development can increase the risk of later-life disease. Second, formula fed infants and lactating people consume more drinking water per unit of body weight. [FN146: EPA, EPA/600/R-18/259F, Update for Chapter 3 of the Exposure Factors Handbook: Ingestion of Water and Other Select Liquids, Off. of Rsch. and Dev., at 3-14, 3-23 (Feb. 2019),

https://www.epa.gov/sites/default/files/2019-02/documents/efh_-_chapter_3_update.pdf.] Infants, for example, may be exposed to PFAS via contaminated breastmilk and/or infant formula prepared with PFAS contaminated water. It is important that these factors are adequately accounted for in the MCL or health-based value calculation process, since developing children are both the most sensitive population as well as the population with the highest estimated exposure.

Unless there is substantial data showing that an endpoint studied in adults is not relevant in infants and children, it is EPA's responsibility to set standards that are protective of all populations. Furthermore, the assumption for PFAS should be that there is a need to protect infants and children. Given the similarity among PFAS, EPA does not require developmental studies each particular PFAS to conclude that infants and children are susceptible to harm from exposure. In this case, drinking water intake assumptions for infants and children should be used. As stated by EPA in the Drinking Water Health Advisory for PFBS, "[w]hen multiple potentially sensitive populations or life stages are identified based on the critical effect or other health effects data (from animal or human studies), EPA selects the population or life stage with the greatest [drinking water intake rate adjusted for body weight] DWI-BW" because it is the most health protective." [FN147: EPA, EPA/822/R-22/006, Drinking Water Health Advisory: Perfluorobutane Sulfonic Acid (CASRN 375-73-5) and Related Compound Potassium Perfluorobutane Sulfonate (CASRN 29420-49-3), Off. of Water, at 18–19 (June 2022), https://www.epa.gov/system/files/documents/2022-06/drinking-water-pfbs-2022.pdf.] Despite this strong statement and the potential for developmental effects from PFAS exposure in the Proposed Rule, EPA consistently failed to use the more protective DWI-BW for infants or children, even when the critical effect is developmental, as is the case for PFNA. EPA chose a DWI-BW for lactating women for PFNA and GenX, a DWI-BW for "women of childbearing age" for PFBS and a DWI-BW for the adult general population for PFHxS. [FN148: EPA, EPA-822-P-23-004, Maximum Contaminant Level Goal (MCLG) Summary Document for a Mixture of Four Per- and Polyfluoroalkyl Substances (PFAS): HFPO-DA and its Ammonium Salt (also known as GenX Chemicals), PFBS, PFNA, and PFHxS, Off. of Water, at 9 (Mar. 2023), https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0906.] The application of DWI-BW for these PFAS is not the most health protective and puts infants and children at risk.

Health protective approaches are used in other steps of risk assessment when evidence is lacking, for example, when deriving a chronic reference dose in the absence of a chronic study. Risk assessors often determine the risk of acute, subchronic, and chronic exposures to a chemical. For PFAS in drinking water, the most protective and realistic exposure scenario is typically a chronic exposure. However, since chronic exposure studies are not always available, EPA derives reference doses ("RfDs") for chronic exposure from subchronic studies by applying an uncertainty factor instead of improperly assuming a RfD based on a subchronic exposure is protective of chronic exposure.

Furthermore, NAS has recommended the use of an additional uncertainty factor of 10 to ensure protection of fetuses, infants and children groups which are often are not sufficiently protected

from toxic chemicals such as pesticides by the traditional intraspecies uncertainty factor. [FN149: Nat'l Acad. of Sci., Pesticides in the Diets of Infants and Children. National Research Council 361 (1993), https://www.ncbi.nlm.nih.gov/books/NBK236275/.] Congress adopted this requirement in the Food Quality Protection Act ("FQPA") for pesticides in or on foods. [FN150: 21 U.S.C. § 346a(b)(2)(C)(ii)(II).] The uneven application of this additional uncertainty factor to protect these vulnerable populations across EPA is concerning. Considering the many health effects linked to PFAS that affect these vulnerable populations and the substantial data gaps on exposure and toxicity of these compounds in complex mixtures, EPA must do a better job of protecting sensitive and vulnerable populations in its assessments and actions on all toxic chemicals, regardless of their regulatory context.

EPA Response: Please see section 4.3.3 of the EPA response in this *Response to Comments* document. With regard to the comment on the NAS recommendation for an additional uncertainty factor, each of the chronic toxicity reference values for the four PFAS included in the Hazard Index already take into account the strength of the database as a whole: the HFPO-DA and PFBS RfDs each include a UF_D of 10, and the PFNA and PFHxS minimal risk levels each include a modifying factor (MF) of 10 for database deficiencies.

Earthjustice et al. (Doc. #1808, SBC-053412)

We reiterate our support for EPA's use of a hazard index, or some other method that accounts for adverse effects associated with mixtures of the HI PFAS, when setting its MCLG and MCL. In order to comply with the SDWA and protect communities who are exposed to those PFAS mixtures, however, the HBWCs that EPA uses to calculate the hazard index must reflect the "best available science" on those chemicals' risks to infants and other susceptible subpopulations. EPA's proposed HBWCs would permit unsafe levels of the HI PFAS to remain in drinking water and diminish the protectiveness of EPA's proposed MCLs. We urge EPA to strengthen the HBWCs in its final rule.

EPA Response: Please see section 4.3.3 of the EPA response in this *Response to Comments* document.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-052997)

CT DPH also makes the following comments regarding the exposure factors used in EPA's preliminary regulatory determination for PFHxS, HFPO-DA, PFNA, and PFBS:

EPA selected DWI-BWs from three subpopulations- adults within the general population, lactating women, and women of child-bearing age- to derive the HBWCs for PFHxS, PFNA and PFBS, respectively. CT DPH recommends that EPA consider infants as a sensitive life stage for these PFAS and select the DWI-BW of infants to calculate the HBWCs. This is because the most sensitive health effects identified for the three PFAS were thyroid and developmental effects.

Infants are known to be more sensitive to these health effects, as recognized by USEPA's toxicological assessments. For example, although it was the female dams which were exposed to PFBS through ingestion in the critical study (Feng et al. 2017), the identified critical effect (developmental) is on the fetuses. Due to the lack of toxicokinetic information regarding lactational transfer rates, it is unclear whether the HBWC derived using the exposure factor for lactating women would also be protective to bottle-fed infant who consumes formula made with drinking water of the same PFBS concentration. For this reason, CT DPH has developed drinking water action levels for PFNA and PFHxS using infant ingestion rates. USEPA should also apply the infant water ingestion rate when calculating the HBWCs to protect the health of formula-fed infants.

CT DPH agrees that deriving HBWCs using upper percentiles of drinking water ingestion rates is protective for most of the general population. EPA used the exposure factors from the most recent Exposure Factor Handbook (Chapter 3), an appropriate source for this purpose. However, CT DPH recommends using 95th percentile instead of 90th percentile of the ingestion rate in the specified population to be more protective to the general population. This would also be consistent with the Exposure Factor Handbook's recommendations (Tables 3-1 and 3-3).

EPA Response: The EPA disagrees with this comment. The EPA selected the corresponding DWI-BW for the relevant sensitive population or life stage from the Exposure Factors Handbook (USEPA, 2019) based on the best available, peer-reviewed science taking into account the relevant sensitive population(s) or life stage(s). With respect to the comment about using the infant DWI-BW instead of the DWI-BW for women of child-bearing age for PFBS, the EPA notes that the agency followed its guidance for selecting an appropriate DWI-BW (see section 4.3.3 of the EPA response in this *Response to Comments* document). The EPA considered the PFBS exposure interval used in the toxicity study in mice that served as the basis for chronic RfD derivation (the critical study). In this study, thyroid effects (decreased serum total thyroxine) were observed in newborn mice following gestational exposure. To be clear, the critical study exposed mice to PFBS only during pregnancy and not during postnatal development; newborn mice in early postnatal development, which would correspond to the human infancy life stage, were not exposed to PFBS. Since dosing in the study did not continue beyond gestation, a DWI-BW for infants (which would represent exposure beyond gestation) would not appropriately correspond to the exposure window in the critical study and was therefore not selected. The exposure window in the study corresponds to two potentially sensitive human adult life stages: women of childbearing age, and pregnant women (Table 3-63 in USEPA, 2019). Of these two, the higher DWI-BW, for women of childbearing age (0.0354 L/kg/day), is anticipated to be protective of the other sensitive life stage and was used to calculate the HBWC for PFBS.

With respect to use of the 90th percentile DWI-BW, the EPA followed agency guidance (USEPA, 2000b), which recommends selection of the 90th percentile DWI-BW to be "protective of a majority of the population" (USEPA, 2000b). Using the 90th percentile DWI-BW is justified because it is a reasonable, appropriately conservative (health protective), high-end exposure assumption that results in protection of the general population as well as sensitive populations or

life stages (USEPA, 2000b,d), consistent with the statute's directive that the MCLG allows for an adequate margin of safety (1412(b)(4)(A)). The EPA has precedent for using the 90th percentile DWI-BW to develop MCLGs (e.g., USEPA, 2000c), and for routine SDWA statutory processes (e.g., Six Year Review, Regulatory Determination). Other EPA programs also use a default 90th percentile drinking water intake (DWI), for example when conducting human health assessments for Superfund sites (USEPA, 2014c) and developing human health criteria for ambient waters (USEPA, 2000c).

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045214)

c) The HBWCs, which are the denominators of the HQs that make up the HI, are not just different in terms of the health effect they represent (i.e. the HBWCs are based on different health endpoints). The HBWCs were also derived using different ingestion rates and target receptors (e.g. general adults, lactating women etc.) with different exposure durations. The various exposure assumptions the four HQs based on created a significant challenge when interpreting the meaning of the general HI, which leads to more challenging risk communication and management. For example, the risk message would need to target pregnant women as a sensitive population when the HQ for PFNA exceeds 1.0. This would be different from the risk message for a MCL exceedance solely triggered by GenX.

EPA Response: An HBWC represents the level below which adverse health effects over a lifetime of exposure are not expected to occur, including for sensitive populations and life stages and with an adequate margin of safety (as required by SDWA). Each of the HBWCs that make up the Hazard Index is based on the most sensitive known adverse health outcome (the critical effect) and a DWI-BW that reflects potentially sensitive populations or lifestages, based on available data for each contaminant. This approach ensures that each HBWC protects not only the general population but also sensitive populations and lifestages, resulting in a health-protective Hazard Index approach. Please see section 4.3.3 of the EPA response in this *Response to Comments* document for information about the EPA's approach to DWI-BW selection, and section 1.2 for additional discussion on PFAS risk communications.

Minnesota Pollution Control Agency (MPCA) (Doc. #1569, SBC-052822)

3) EPA requests comment on the derivation of the health-based water concentrations (HBWCs) for each of the four PFAS considered as part of the HI.

MPCA response:

• MPCA agrees with the methods used to derive HBWCs for the four PFAS considered as part of the HI.

EPA Response: The commenter agrees with the EPA's approach.

3M Company (Doc. #1774, SBC-045665)

The lack of peer review and submission to the SAB is significant. As noted above, it expressly violates the SDWA. The lack of peer review has even resulted in EPA making basic errors that would have been identified during the peer review process. For example, EPA makes an arithmetic error in its derivation of the HBWC for PFHxS (USEPA 2023l). Using EPA's inputs in Table 4 of the Hazard Index document (USEPA 2023l), the HBWC would be 12 ppt, and applying one significant figure, the final HWBC should be 10 ppt, not 9 ppt. This error must be corrected. This error also signals an absence of even basic quality assurance. All of EPA's calculations require comprehensive peer review before the NPDWR is finalized, and EPA must submit its proposed MCLG and NPDWR for the HI PFAS, including the HBWCs, to SAB for comment.

EPA Response: The commenter is incorrect. The toxicity assessments for PFHxS, PFNA, HFPO-DA, and PFBS have been peer reviewed. For the EPA response to comments on peer review, please see sections 4.3.1 and 4.3.2 of the EPA response in this *Response to Comments* document. The agency has corrected the PFHxS HBWC value in this NPDWR. The correct HBWC for PFHxS is 10 ng/L (ppt).

Silent Spring Institute (Doc. #1784, SBC-045801)

2. Setting standards for PFHxS, HFPO-DA, PFNA, and PFBS, in addition to PFOA and PFOS, is appropriate given strong evidence for adverse health effects and their prevalence in public water supplies.

We found the determination of the health-based water concentrations (HBWCs) for PFHxS, HFPO-DA, PFNA, and PFBS appropriate and protective of noncancer health effects. Overall, ATSDR concluded that there is strong evidence that links environmental exposures to these PFAS with a range of health effects, including elevated cholesterol, thyroid disease, ulcerative colitis, pregnancy-induced hypertension, obesity, impaired immune response to vaccinations, and cancer.[REF22: ATSDR. Toxicological Profile for Perfluoroalkyls. Atlanta, GA, 2021.] While many studies have focused on PFOS and PFOA, a growing number of studies have demonstrated similar effects from other PFAS compounds, including these.

In its toxicological profile for perfluoroalkyls, ATSDR documented evidence of low-dose PFHxS and PFNA toxicity and their high prevalence in U.S. water systems. ATSDR's derived Minimum Risk Levels are robust and authoritative, so the use of ATSDR's Minimum Risk Levels for PFHxS and PFNA as HBWCs is justified. These HBWCs are likely to be protective of health effects. The HBWCs are generally consistent with assessments by other expert authoritative bodies, such as MCLs developed by state health and environmental agencies. For example, New Hampshire established an MCL for PFHxS of 18 ng/L, and Michigan, Washington, and New Jersey each established MCLs for PFNA in the range of 6-13 ng/L. It should be noted, however, that ATSDR's Minimal Risk Levels for PFHxS (2 ng/kg-day) and PFNA (3 ng/kg-day) exceed EFSA's tolerable daily intake of 0.63 ng/kg-day for a group sum of PFOA, PFOS, PFHxS, and

PFNA. These data highlight the need to set the HBWCs for PFNA and PFHxS to levels as low as feasible to be protective of the most sensitive health effects.

EPA has conducted a thorough risk assessment of PFBS and HFPO-DA in their derivation of these HBWCs. Nevertheless, the appropriate HBWCs for PFBS and HFPO-DA could be lower than what EPA is proposing in order to account for PFAS's toxicokinetic variability across species, which can be accounted for in two ways: (1) using a PBTK approach to estimate an internal dose to account for toxicokinetic variability between rodents and humans, and (2) increasing the interspecies uncertainty factor (UFA) from 3 to 10, or possibly higher based on careful evaluation of all available data. These changes may result in lower HBWCs for PFBS and HFPO-DA.

EPA Response: For the EPA response to comments on the appropriateness of HBWCs and the use of ATSDR minimal risk levels, please see section 4.3.3 of the EPA response in this *Response to Comments* document. Additionally, as noted in the toxicity assessments for PFBS and HFPO-DA (USEPA, 2021d; USEPA, 2021b), the EPA followed its guidance (e.g., USEPA, 2002a; 2011; 2014a) to determine the most appropriate way to account for toxicokinetic variability across species. For both PFBS and HFPO-DA, the EPA determined that data were inadequate to support derivation of data-derived extrapolation factors. Therefore, consistent with EPA guidance, the default approach of the use of $BW^{3/4}$ scaling to obtain a human equivalent dose was used. Also, a UF_A of 3 was appropriately applied, consistent with peer-reviewed EPA methodology (USEPA, 2002a), to account for uncertainty in characterizing the toxicokinetic and toxicodynamic differences between rodents and humans. As noted in the toxicity assessments for PFBS and HFPO-DA (USEPA, 2021d; USEPA, 2021b), although this scaling addresses most aspects of cross-species extrapolation of toxicokinetic processes, there is some residual uncertainty for toxicokinetics and uncertainty around toxicodynamic processes. In the absence of chemical-specific data to quantify this uncertainty, the EPA's guidance recommends use of a UF_A of 3.

Illinois Farm Bureau (IFB) (Doc. #1630, SBC-043137)

The most glaringly overlooked and/or underestimated data includes:

• Significant uncertainty regarding the health risks at the proposed MCL levels for all six PFAS - EPA's Reference Dose–for PFNA, GenX, PFHxS, and PFBS chemicals is based entirely on laboratory animal studies, even though EPA itself advises "Adequate human data are the most relevant for assessing risks to humans." The World Health Organization's recent study on potential guidelines for water quality, for example, proposed 100 ppt based on the most relevant public health data and seems to be consistent with known risk. EPA's Science Advisory Bo'rd expressed these same sentiments and determined that EPA needs more transparency in how they assess studies, better information on the metrics of including specific studies or not, and they must include more human studies in their assessment.

[FN1:https://sab.epa.gov/ords/sab/f?p=114:0:6179756424602:APPLICATION_PROCESS=REPORT_DOC:::REPORT_ID:1105]

EPA Response: Please see the EPA response to comment Doc. #1642, SBC-043484 in section 4.3.3 in this *Response to Comments* document and section 4.3.3 of the EPA response in this *Response to Comments* document. Regarding the World Health Organization (WHO) guidelines, please see section 4.2.6 of the EPA response in this *Response to Comments* document.

American Farm Bureau Federation et al. (Doc. #1642, SBC-043484)

[They have identified the following areas of concern regarding the agency's development of this rule:]

• There is limited understanding of risk at these levels. EPA's Reference Dose for PFNA, GenX, PFHxS, and PFBS chemicals is based entirely on laboratory animal studies, even though EPA itself advises, "Adequate human data are the most relevant for assessing risks to humans." There is significant uncertainty regarding the health risks at the proposed MCL levels for all six PFAS. The World Health Organization's recent study on potential guidelines for water quality, for example, proposed 100 ppt based on the most relevant public health data and seems to be consistent with known risk. EPA's Science Advisory Board expressed these same sentiments and determined that EPA needs more transparency in how they assess studies, better information on the metrics of including specific studies or not, and they must include more human studies in their assessment. [FN3: https://sab.epa.gov/ords/sab/f?p=114:0:6179756424602:APPLICATION_PROCESS=REPORT_DOC:::REPORT_I D:1105]

EPA Response: The EPA disagrees. SDWA requires that to the degree that the EPA's action is based on science, the EPA must use "the best available, peer reviewed science." The HBWCs are based on the best available science—peer-reviewed, publicly available assessments for HFPO-DA (USEPA, 2021e), PFBS (USEPA, 2021d), PFNA (ATSDR, 2021), and PFHxS (ATSDR, 2021) provide the oral toxicity reference values (i.e., RfD or minimal risk level) used to calculate the HBWCs; the DWI-BW selected for each of the four PFAS takes into account the relevant sensitive population(s) or life stage(s); and RSCs are determined based on a literature review of potential exposure sources of the four PFAS (USEPA, 2000c). Additionally, as noted in the EPA's *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022a) and *A Review of the Reference Dose and Reference Concentration Process* (USEPA, 2002a), animal studies can provide the basis for toxicity reference values when adequate human studies are not available.

The EPA notes that the commenter took the SAB PFAS Review panel's comments out of context; the SAB's comments regarding transparency, study inclusion/exclusion, and epidemiological studies were specific to the draft documents and available data for PFOA and PFOS (USEPA, 2021b; USEPA, 2021k). These comments should not necessarily be applied to the HBWCs or MCLGs for HFPO-DA, PFBS, PFNA, or PFHxS.

Please see section 4.1.3 of the EPA response in this *Response to Comments* document regarding how the EPA accepted the SAB's recommendations for the PFOA and PFOS toxicity assessments. Additionally, see the EPA response to SAB Comment document (USEPA, 2023d). Regarding the conclusions of the WHO assessment, please see section 4.2.6 of the EPA response in this *Response to Comments* document.

California Farm Bureau Federation (Doc. #1704, SBC-045068)

[For example, the U.S. Chamber analysis highlights the following:]

• There is limited understanding of risk at these levels. EPA's Reference Dose for PFNA, GenX, PFHxS, and PFBS chemicals is based entirely on laboratory animal studies, even though EPA itself advises "Adequate human data are the most relevant for assessing risks to humans." There is significant uncertainty regarding the health risks at the proposed MCL levels for all six PFAS. The World Health Organization's recent study on potential guidelines for water quality, for example, proposed 100 ppt based on the most relevant public health data and seems to be consistent with known risk. EPA's Science Advisory Board expressed these same sentiments and determined that EPA needs more transparency in how they assess studies, better information on the metrics of including specific studies or not, and inclusion of more human studies in their assessment [FN2: See Science Advisory Board Letter to Administrator Regan, August 22, 2022, available at: https://sab.epa.gov/ords/sab/f?p=114:0:6179756424602:APPLICATION_PROCESS=REPORT_DOC:::REPORT_ID:1105].

EPA Response: Please see the EPA response to comment Doc. #1642, SBC-043484 in section 4.3.3 in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-045671)

ii. EPA's relative source contribution value for PFHxS, HFPO-DA, PFNS, and PFBS is not based on the best available science

The relative source contribution (RSC) term used to assign exposure contribution from drinking water is a key element of MCL derivation. The smaller the RSC, the more protective the drinking water regulatory limit is in order to account for other potential sources of exposure. EPA chose the 20 percent default RSC value for HFPO-DA, PFHxS, PFNA and PFBS to develop the HBWCs used in the HI-MCLG, citing insufficient data to calculate a substance-specific RSC. EPA guidance provides that the 20 percent default should only be used when data to characterize other exposure sources is insufficient.

In its comments on the PFOA and PFOS MCLG derivation, the SAB suggested the EPA more clearly justify the 20 percent default value, yet in the documentation for PFOA, PFOS and PFAS mixture, EPA continues to stress that data are not sufficient to characterize exposures for individual substances (USEPA 2023j). While EPA states there are not sufficient data to calculate

substance-specific RSC values for the various substances, the agency nonetheless presents several pages of scientific literature regarding substance occurrence in various media (e.g., dietary sources, indoor dust, soil, sediment) (USEPA 2023e, 2022a,b). The HFPO-DA RSC development documentation cites 52 studies, 14 "gray literature sources" and 3 additional references. For PFBS, 183 peer-reviewed and grey literature references were identified that characterized occurrence in drinking water, groundwater, surface water, dietary sources, consumer products, indoor dust, indoor air, ambient air, and soil (USEPA 2022b). For PFNA and PFHxS, 176 and 177 peer-reviewed studies, respectively, and at least 12 grey literature sources included occurrence data for ambient air, indoor air, consumer products, dust, food, groundwater, drinking water, surface water, sediment, soil, and human blood/serum/urine (USEPA 2023e). There is no clear explanation for why the numerous studies presented do not provide sufficient data to calculate substance-specific RSCs, as recommended by EPA's own guidance.

In addition to the studies presented by EPA for each of the four PFAS, other studies have directly characterized exposure sources for various PFAS. Ericson et al. (2008) determined that drinking water exposure to PFCs (including PFNA and PFHxS) may be as important as the dietary pathway. Vestergren et al. (2012) found that drinking water intake contributed 36–53 percent of the total exposure for PFHxS, PFHpA, and PFHxA.

Given the number of studies and breadth of exposure sources evaluated, inferences can reasonably be made about exposure from various sources using occurrence and concentration data presented. When the currently available data cited by EPA and the studies that directly show water is a primary contributor to exposure for each of the four HI-PFAS are considered collectively, there is likely sufficient support for chemical-specific RSC terms, similar to the chemical-specific values developed for PFOA by several states (Lindborg et al. 2022). EPA suggests that there were insufficient US-based studies, but 47, 50, and 59 of the studies presented for PFNA, PFHxS, and PFBS, respectively, were US-based (USEPA 2023e, 2022b). There is also no evidence that EPA evaluated the RSC based on these studies. Rather, EPA presented a summarized table of the concentration ranges, with no indication or evaluation of how the study findings relate to exposure contribution. This directly contradicts the intended application of EPA's Exposure Decision Tree methodology (USEPA 2000b).

EPA Response: please see section 4.3.3 of the EPA response in this *Response to Comments* document. Furthermore, the EPA followed its established process for RSC derivation, which is outlined in the EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (USEPA, 2000c). See information on RSC derivations in USEPA (2024h). As noted in the EPA's exposure decision tree approach (USEPA, 2000c), exposure information relevant to the population of concern is a key element of RSC derivation. Following its methodology, the agency determined that for each of these four PFAS, data are insufficient to allow for quantitative characterization of the different exposure sources.

<u>New Hampshire Department of Environmental Services (NHDES) (Doc. #1690, SBC-044343)</u>

Additionally, in the absence of a full review by EPA IRIS we suggest EPA include review of the RfDs for PFHxS and PFNA developed by other states. This includes those recommended by NHDES (NHDES, 2019; Ali et al., 2019), Minnesota Department of Health (MDH, 2020) and New Jersey Department of Environmental Protection (NJ DWQI, 2015).

• NHDES. (2019) Technical Background Report for the June 2019 Proposed Maximum Contaminant Levels (MCLs) and Ambient Groundwater Quality Standards (AGQSs) for Perfluorooctane sulfonic Acid (PFOS), Perfluorooctanoic Acid (PFOA), Perfluorononanoic Acid (PFNA), and Perfluorohexane sulfonic Acid (PFHxS). NHDES, Environmental Health Program. Link [Link: https://www.des.nh.gov/sites/g/files/ehbemt341/files/documents/r-wd-19-29-final.pdf] .

• Ali, J. M., Roberts, S. M., Gordon, D. S., & Stuchal, L. D. (2019). Derivation of a chronic reference dose for perfluorohexane sulfonate (PFHxS) for reproductive toxicity in mice. Regulatory Toxicology and Pharmacology: RTP, 108, 104452. Link [https://www.sciencedirect.com/science/article/pii/S0273230019302168?via%3Dihub]

• MDH. (2020) Toxicological Summary for: Perfluorohexane sulfonate. Health Risk Assessment Unit, Environmental Health Division. Link [https://www.health.state.mn.us/communities/environment/risk/docs/guidance/gw/pfhxs.pdf].

• NJ DWQI. (2015). Health-Based Maximum Contaminant Level Support Document: Perfluorononanoic Acid (PFNA). New Jersey Drinking Water Quality Institute Health Effects Subcommittee. Link [https://dep.nj.gov/pfas/standards/].

EPA Response: The EPA finds that the ATSDR minimal risk levels for PFHxS and PFNA currently represent the best available, peer-reviewed science for these chemicals. SDWA specifies that an agency action that is based on science must use "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices." At this time, the 2021 *ATSDR Toxicological Profile for Perfluoroalkyls*, which covers 10 PFAS including PFHxS and PFNA, represents the best available peer-reviewed scientific information on the human health effects of PFHxS and PFNA. ATSDR minimal risk levels for PFHxS and PFNA are appropriate for use under SDWA because ATSDR uses scientifically credible approaches, its work is internally and externally peer-reviewed and undergoes public comment, and its work represents the current best available science for these two chemicals. The 2021 *ATSDR Toxicological Profile for Perfluoroalkyls* underwent intra- and interagency review and subsequent external peer review by seven experts with knowledge of toxicology, chemistry, and/or health effects. The EPA notes that the state assessments suggested by the commenter pre-date the 2021 ATSDR toxicological profile for PFAS. See also section 4.3.3 of this *Response to Comments* document.

Michigan Department of Environment, Great Lakes, and Energy (EGLE) Drinking Water and Environmental Health Division (DWEHD) (Doc. #1597, SBC-042975)

In the case of PFBS and PFNA, Michigan established 2020 MCLs of 420 ng/l and 6 ng/l respectively, initially proposed by an independent panel of scientists.1 [REF1: Health-Based Drinking Water Value Recommendations for PFAS in Michigan, a Report by the Michigan Science Advisory Workgroup, July 2019.] These recommendations were developed based on a thorough review of the best available peer-reviewed scientific studies at the time and utilized in EGLE's subsequent rulemaking efforts. As these MCLs are below the MCLGs proposed by EPA in the NPDWR, EGLE DWEHD asks EPA to consider these lower values for calculating its proposed MCLGs/MCLs.

EPA Response: The EPA followed its guidance and process to determine MCLGs for PFBS and PFNA based on the best available, peer-reviewed science. Please see sections 4.3.1, 4.3.2, and 4.3.3 of the EPA response in this *Response to Comments* document, and please also see the Hazard Index MCLG support document for a complete description of MCLG derivation for PFBS and PFNA (USEPA, 2024h). The EPA notes that the state assessment suggested by the commenter pre-dates the EPA's PFBS toxicity assessment (USEPA, 2021d) and the 2021 ATSDR toxicological profile for PFAS (ATSDR, 2021). See also section 4.3.3 of the EPA response in this *Response to Comments* document.

PFBS

Washington State Department of Health (DOH) (Doc. #1665, SBC-044411)

EPA requests comment on the derivation of the HBWCs for each of the four PFAS considered as part of the HI.

PFBS

• DOH concurs with the RfD, but request EPA consider infants when selecting the drinking water intake rate for the PFBS Health-Based Water Concentration. Infants should be considered a sensitive life stage since neonatal thyroid function also supports infant growth and neurodevelopment. [FN3: Miller, M.D., et al., Thyroid-disrupting chemicals: interpreting upstream biomarkers of adverse outcomes. Environ Health Perspect, 2009. 117(7): p. 1033-41.] [FN4: Coperchini, F., et al., Thyroid Disrupting Effects of Old and New Generation PFAS. 2021. 11(1077). 228.] [FN5: Min, H., et al., Maternal Hypothyroxinemia-Induced Neurodevelopmental Impairments in the Progeny. Mol Neurobiol, 2016. 53(3): p. 1613-1624.] Thyroid tissue stores of T4 are low in newborn children making them less able than adults to compensate for reductions in T4. [FN6: Van den Hove, M.F., et al., Hormone synthesis and storage in the thyroid of human preterm and term newborns: effect of thyroxine treatment. Biochimie, 1999. 81(5): p. 563-70.] Washington State included infants as a sensitive group for this endpoint and used the 95th percentile water intake rates for infants (birth to <1 year old) to protect the developing child (see Table below). Michigan and California risk assessors also used infant drinking water intake rates to derive their state regulations for PFBS in drinking water based on this same endpoint.

[Table 1: See docket ID: EPA-HQ-OW-2022-0114-1665]

EPA Response: Please see section 4.3.3 of the EPA response in this *Response to Comments* document.

Environmental Working Group (EWG) (Doc. #1721, SBC-045417)

The EPA should lower the health-based water concentrations, especially for PFBS.

The EPA should maintain its hazard index approach for GenX, PFBS, PFHxS, and PFNA while also reassessing the toxicity values used to calculate the health-based water concentrations for each.

When developing an MCL, SDWA requires the EPA to consider not only health effects on the general population, but also "groups within the general population such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations that are identified as likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water."[FN64: 42 U.S.C. [sec] 300g–1(b)(3)(C)(i)(V) (requiring EPA to assess health impacts on greater-risk populations when establishing MCLs).] While the proposed rule includes a thorough accounting of health risks from the four HI PFAS, the analysis could be strengthened to include additional studies and considerations for vulnerable populations. Comments submitted by Earthjustice et al. include a detailed discussion of the science behind the HBWC calculation for each HI PFAS and suggests ways to strengthen each, particularly to better account for risks to sensitive populations like infants and children. [FN65: Earthjustice et al., supra note 7, at 21-27.]

In particular, the EPA should reassess and strengthen its proposed HBWC of 2000 ppt for PFBS. EPA's HBWC is significantly higher than the MCL of 420 ppt set by Michigan for PFBS in August 2020. [FN66: Michigan PFAS Action Response Team, Maximum Contaminant Levels (MCLs) https://www.michigan.gov/pfasresponse/drinking-water/mcl (last visited May 30, 2023).] It's also much higher than the notification level of 500 ppt adopted by California,[FN67: California Water Boards, PFAS: Per and Polyfluoroalkyl Substances, https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/pfas.html (last updated March 16, 2023).] Washington state action level of 345 ppt,[FN68: Washington State Dep't of Health, PFAS, https://doh.wa.gov/community-and-environment/contaminants/pfas (last visited May 30, 2023).] and Minnesota's health-based guidance value of 100 ppt. [FN69: Minnesota Dep't of Health, PFAS and Health https://www.health.state.mn.us/communities/environment/hazardous/topics/pfashealth.html (last updated March 02, 2023).]

EPA Response: Please see section 4.3.3 of the EPA response in this *Response to Comments* document.

West Virginia Rivers Coalition et al. (Doc. #1746, SBC-052998)

[In particular, we strongly support their calls for EPA to:]

• Revise the Health-Based Water Concentration for PFBS to 240 ng/L

EPA Response: The EPA disagrees that the HBWC for PFBS should be revised to 240 ng/L. The commenter did not cite underlying data or rationale for the argument/factual assertion it made. Please see section 4.3.3 of the EPA response in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-044835)

EPA's Toxicity Assessment for PFBS is Overly Conservative

Despite concerns about the relevance to human risk assessment, the HBWC for PFBS is based on changes in thyroid hormones in offspring of laboratory mice. [FN117: Feng X et al. Exposure of Pregnant Mice to Perfluorobutanesulfonate Causes Hypothyroxinemia and Developmental Abnormalities in Female Offspring. Toxicol Sci 155(2):409-419 (2017).] Although the elimination half-life is relatively short (estimated in humans at 25.8 to 44 days and in rodents to be only 4-5 hours), EPA's approach to estimating the human equivalent dose (HED) from the animal data relies on toxicokinetic (TK) data rather than using a traditional body-weight scaling. In light of the uncertainty over the volume of distribution and elimination half-life in humans, as detailed below, the use of the default allometric approach is more appropriate for estimating a HED. In addition, the HBWC includes a total uncertainty factor of 300, including an unnecessary UFD of 10, as discussed below. Reflecting these numerous uncertainties and EPA's conclusion that "[t]he overall confidence in the chronic RfD for thyroid effects is low," [FN118: USEPA. Human Health Toxicity Values for Perfluorobutane Sulfonic Acid (CASRN 375-73-5) and Related Compound Potassium Perfluorobutane Sulfonate (CASRN 29420-49-3). EPA/600/R-20/345F. Office of Research and Development (2021), at 4.] the Agency relies on this endpoint in calculating the HBWC.

The significance of changes in T4 levels in rodents to human risk assessment has been questioned by the National Academy of Sciences (NAS) [FN119: National Research Council. Health implications of perchlorate ingestion. Washington, DC National Academies Press. (2005). (NRC 2005). https://doi.org/10.17226/11202] and others because of the significant differences in binding proteins and affinities among species. In humans and other primates, thyroxine-binding globulin (TBG) is the principal protein that binds T4. [FN120: Dohler KD et al. The rat as model for the study of drug effects on thyroid function: Consideration of methodological problems. Pharmacol Ther 5(1-3):305-318 (1979).] Because of TBG's high affinity for T4, clearance of T4 from human serum is sharply reduced. Since TBG is not the primary carrier in adult rodents, most T4 in rodent serum is bound to albumin and transthyretin which have a binding affinity for T4 that is significantly lower than TBG. [FN121: USEPA PFBS Toxicity Assessment, at 83.] This difference contributes to a higher rate of T4 clearance in rodents which, in turn, contributes to the need for a higher rate of production of T4 per unit of body weight to maintain normal concentrations of T4. [FN122: Dohler et al. 1979.] Although EPA concludes that "significant differences in functional thyroid reserve capacity between human and rodent neonates are not

anticipated," the difference in T4 quantities in neonates [FN123: USEPA Final PFBS Toxicity Assessment, at 84.] suggests a need for caution in interpreting the rodent data.

These differences in binding proteins, binding affinities of the proteins for the hormones, turnover rates of the hormones, and thyroid stimulation suggest important quantitative differences between rodents and humans. NAS concludes, therefore, that –

[t]he committee does not agree that transient changes in serum thyroid hormone or TSH concentrations are adverse health effects; they are simply biochemical changes that might precede adverse effects. [FN124: Ibid, at 13]

In deriving the oral reference dose, EPA's final assessment uses a dose adjustment factor for estimating the HED despite the absence of information on clearance values. The Agency also acknowledges a nearly two-fold difference in the estimate of elimination half-live for PFBS (25.8 vs 44 days) but chooses the longer of the estimate in generating the HED. In light of the uncertainty in the data-derived extrapolation, use of the default body weight3/4 method is more appropriate for deriving the reference dose for PFBS. [FN125: USEPA. Guidance for applying quantitative data to develop data-derived extrapolation factors for interspecies and intraspecies extrapolation. EPA/100/R-14/002F. Risk Assessment Forum (2014).]

The analysis also applies a benchmark response (BMR) of a standard deviation (SD) of 0.5, based on the fact that the observed effects are "occurring in a sensitive life stage." [FN126: USEPA Final PFBS Toxicity Assessment, at 74.] According to its BMD guidance, however, a BMR of 1 SD is appropriate in the absence of information regarding the level of change that is considered biologically significant when assessing continuous data.

EPA's HBWC also includes a UFD of 10 based on concerns about developmental effects, particularly neurodevelopmental effects, the lack of chronic studies, and the absence of studies on immunotoxicity and mammary gland development. For PFBS, robust data are available on reproductive and developmental effects, including both a prenatal toxicity study and a two-generation reproduction study. Moreover, that developmental effects appear to be "less sensitive than thyroid hormone perturbations in developing mice" [FN127: USEPA Draft PFBS Toxicity Assessment, at 60.] Consequently, a toxicity value that protects against effects on thyroid hormones also will protect against developmental effects, particularly effects on neurodevelopment since EPA's stated concern is that perturbations in thyroid hormones may trigger neurodevelopmental effects. [FN128: It may also be possible to extrapolate from neurodevelopmental results results for PFHxS reported by Ramhoj et al.] After pointing out the connection between thyroid hormones and neurodevelopment, EPA provides no rationale for why neurodevelopmental effects should then be considered separately. Recent results from Ramhoj et al. who reported "no evidence of thyroid hormone-mediated neurobehavioral disruption in offspring" [FN129: Ramhoj et al. 2020.] after exposure to PFHxS may provide additional evidence for dropping the UFD based on concerns about neurodevelopmental effects.

EPA provides no rationale for the concern about mammary gland development other than a single reference to a study of mice exposed to PFOA. Effects on mammary glands in offspring,

moreover, were not reported in the prenatal toxicity and two-generation reproduction studies available for PFBS. The Agency's concern for the potential immunotoxicity of PFBS is based entirely on suggestions of immunotoxicity for other PFAS. In explaining the addition of the UFD, the Agency suggests that "immunotoxicity is an effect of increasing concern across several members of the larger PFAS family." In light of the limited amount of information on immune effects for PFBS, a UFD of 3 appears much more appropriate than the excessive factor of 10 used by the Agency.

EPA Response: The EPA disagrees with these comments. As noted in section 4.3.3 of the EPA response in this *Response to Comments* document, confidence in the critical study (Feng et al., 2017) and corresponding thyroid hormone critical effect in newborn mice was rated by the EPA as 'High;' this rating was a result of systematic study evaluation and risk of bias analysis by a team of the EPA experts. The Feng et al. (2017) study, the critical effect of thyroid hormone disruption in offspring, dose-response assessment, and corresponding RfD were subjected to extensive internal EPA, interagency, and public/external peer review. While confidence in the critical study was rated 'High,' the 'Low' confidence rating for the PFBS chronic RfD was in part a result of the lack of a chronic exposure duration study in any mammalian species; this lack of a chronic duration study was one of the considerations that resulted in the EPA applying a UF of 10 to account for database limitations (UF_D). Based on the EPA's human health assessment practices, the lowest confidence rating across the areas of consideration (e.g., existent hazard/dose-response database) is assigned to the corresponding derived reference value (e.g., RfD). Thus, the EPA has high confidence in the critical study (Feng et al., 2017) and critical effect/thyroid endpoint, but the database is relatively limited. Although the PFBS RfD was based on best available science, there is uncertainty as to the hazard profile associated with PFBS after prolonged (e.g., lifetime) oral exposure. In the toxicity assessment for PFBS (USEPA, 2021d), the EPA noted data gaps in specific health effects domains, as Is standard practice. Toxicity assessments for most chemicals identify data gaps; the issue of uncertainty due to toxicological study data gaps is not unique to PFBS. Data gaps are considered when selecting the UF_D because they indicate the potential for exposure to lead to adverse health effects at doses lower than the POD derived from the assessment's critical study. There is a potential that effects with greater dose-response sensitivity (i.e., occurring at lower daily oral exposures) might be discovered from a chronic duration exposure study. Due to this uncertainty, the EPA applied a UF_D of 10. Further, at the time the PFBS chronic RfD was developed, there were indeed indications from other structurally related PFSAs (e.g., PFOS) that more specialized health outcome domains, such as immunotoxicity, may be significantly more sensitive than other domains traditionally evaluated in repeat-dose studies (e.g., organ weights, histopathology, clinical chemistry, etc.). As such, in the absence of information as to the immunotoxicity potential of PFBS, this was also considered a data gap that warranted additional uncertainty. This is also true of some developmental endpoints such as mammary gland development (and anogenital distance) which is often observed on the lower end of dose-response(s) in many single- and/or multi-generation repro/dev studies. Unfortunately, an available two-generation reproductive/developmental toxicity study in rats available for PFBS (Lieder et al., 2009) did not include endpoints such as mammary gland

development in the evaluation of F1 or F2 pups. Therefore, the lack of data on endpoints that are known to be highly sensitive in repro/developmental studies, for those chemicals with endocrine disrupting activity, represents another data gap for PFBS which is why it was considered in the application of a UF_D of 10.

The EPA disagrees with the comment that the default allometric approach is more appropriate for estimating an HED. In human health risk assessment practice, the EPA considers a hierarchical approach to cross-species dosimetric scaling consistent with technical guidance to calculate HEDs (USEPA, 2011; see pp. X-XI of the Executive Summary in 'Recommended Use of Body $Weight^{3/4}$ as the Default Method in Derivation of the Oral Reference Dose'). The preferred approach is physiologically-based toxicokinetic (PBTK) modeling; however, there are rarely sufficient chemical-specific data to properly parameterize such a model. In the absence of a PBTK model, the EPA considers an intermediate approach in which chemical-specific data across species, such as clearance or plasma half-life, are used to calculate a DAF (USEPA, 2011). If chemical-specific TK data are not available, only then is a default approach used wherein allometric scaling, based on body weight raised to the ¾ power, is used to calculate a DAF. The human health toxicity assessment for PFBS invoked the intermediate approach, consistent with guidance, as TK data were available for humans and rodents.

Please see section 4.3.3 of this *Response to Comments* document for the EPA response to comments related to uncertainty factors.

Earthjustice et al. (Doc. #1808, SBC-053409)

ii. EPA Should Revise its HBWC for PFBS to 240 ng/L

EPA's highest, and least protective, HBWC is for PFBS, a chemical that is often "considered [as] a replacement for PFOS." [FN162: EPA, Drinking Water Health Advisories for PFAS Fact Sheet for Communities, at 2 https://www.epa.gov/system/files/documents/2022-06/drinking-water-ha-pfas-factsheet- communities.pdf.] EPA's proposed HBWC of 2000 ppt PFBS is significantly higher than toxicity values and drinking water standards adopted by California (500 ppt), Michigan (420 ppt), Washington (345 ppt), and Minnesota (100 ppt). [FN163; Cal. Water Boards, Notification Level Issuance, State Water Res. Control Bd. (Mar. 5, 2021), https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/pfas.html; Mich. PFAS Action Response Team, Maximum Contaminant Levels (MCLs), https://www.michigan.gov/pfasresponse/drinking-water/mcl (last accessed May. 25, 2023); Wash. State Dep't of Health, Recommended State Action Levels for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water: Approach, Methods, and Supporting Information (Nov. 1, 2021), https://doh.wa.gov/sites/default/files/2022-02/331-673.pdf; Minn. Dep't of Health, Per- and Polyfluoroalkyl Substances (PFAS) and Health, at 3–4 (Sept. 6, 2022), https://www.health.state.mn.us/communities/environment/hazardous/docs/pfashealth.pdf.]

In deriving a RfD for PFBS, EPA, California, Michigan and Washington used the same health effect (impaired thyroid development) and the same approach for calculating a human equivalent

dose, resulting in similar RfDs. [FN164: We support the use of a more chemical-specific dose adjustment factor in EPA's final toxicity assessment versus the allometric scaling performed in EPA's draft document.] However, EPA's PFBS Lifetime Health Advisory for drinking water, which serves as the foundation for EPA's proposed HBWC, deviated from state risk assessments most notably in the choice of DWI-BW (rate of water intake). In order to protect infants from harmful PFBS exposures, California, Michigan, and Washington selected a higher value for drinking water intake associated with infant drinking water consumption when deriving their drinking water limits for PFBS. [FN165: OEHHA, Notification Level Recommendation: Perfluorobutane Sulfonic Acid in Drinking Water, at 29–30 (Jan. 2021), https://oehha.ca.gov/media/downloads/water/chemicals/nl/pfbsnl121820.pdf; Wash. Dep't of Health, Recommended State Action Levels for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water: Approach, Methods, and Supporting Information, Off. Of Pub. Health Sci., at 80– 81 (Nov. 1, 2021), https://doh.wa.gov/sites/default/files/2022-02/331-673.pdf.] EPA, on the other hand, relied on a lower water intake rate associated with "women of childbearing age" [FN166: EPA, EPA-822-P-23-004, Maximum Contaminant Level Goal (MCLG) Summary Document for a Mixture of Four Per- and Polyfluoroalkyl Substances (PFAS): HFPO-DA and its Ammonium Salt (also known as GenX Chemicals), PFBS, PFNA, and PFHxS, Off. Of Water, at 12 (Mar. 2023), https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0906.] and thus failed to address PFBS' increased risks to infants, a "potentially susceptible life stage[] for the types of effects observed in animal testing with PFBS." [FN167: Wash. Dep't of Health, Recommended State Action Levels for PFAS, at 79.] Thus, EPA's HBWC for PFBS falls short of protecting one of the most "sensitive population(s) or life stage(s) (i.e., those that may be more susceptible or sensitive to a chemical exposure)." [FN168: EPA, MCLG Summary Document for a Mixture of Four PFAS, at 5.]

The thyroid harm identified by EPA resulted from decreased serum levels of T4 from PFBS exposure during a developmental life stage, effects that begin prenatally and continue into infancy. Decreased levels of T4 indicate dysfunction or underdevelopment of the thyroid gland. While a decrease in T4 affects the pregnant mice, those effects can also carry over to their offspring and "persist[] until the pubertal and adult periods." [FN169: Xuejiao Feng et al., Exposure of Pregnant Mice to Perfluorobutanesulfonate Causes Hypothyroxinemia and Developmental Abnormalities in Female Offspring, 155 Toxicological Sciences, 409, 417 (2017), https://doi.org/10.1093/toxsci/kfw219.] The authors of the study that EPA relied upon concluded that PFBS "may impair thyroid development in offspring, leading to permanent hypothyroxinemia" [FN170: Id. At 414.] Infants with hypothyroxinemia experience impaired growth and development because the thyroid orchestrates processes that are critical to their growth, including brain development. Thus, many infants with hypothyroxinemia experience intellectual disabilities and growth failures that require treatment through puberty and, in some cases, into adulthood. [FN171: See generally Noora Moog et al., Influence of Maternal Thyroid Hormones During Gestation on Fetal Brain Development, 342 Neuroscience 68, 68–100 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4819012/; Stanford Medicine, Congenital Hypothyroidism in Children, Childrens Health,

https://www.stanfordchildrens.org/en/topic/default?id=hypothyroidism-in-children-90-P01963.] While women of childbearing age are sensitive to developmental toxicity and persistent changes in thyroid hormone levels associated with PFBS, maternal thyroid hormones play a critical role in fetal and infant growth and neurodevelopment. Thyroid development and stores of T4 are especially important in infants whose T4 stores are lower and not as capable of offsetting declines. [FN172: Francesca Coperchini et al., Thyroid Disrupting Effects of Old and New Generation PFAS, 11 Frontiers in Endocrinology Art. No. 612320 (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7851056/; Hui Min et al., Maternal Hypothyroxinemia-Induced Neurodevelopmental Impairments in the Progeny, 53 Molecular Neurobiology 1613, 1613–1624 (2016), https://pubmed.ncbi.nlm.nih.gov/25666160/; Miller, M.D., et al., Thyroid-Disrupting Chemicals: Interpreting Upstream Biomarkers of Adverse Outcomes, 117 Env't Health Persp. 1033, 1033–41 (2009), https://pubmed.ncbi.nlm.nih.gov/19654909/.] Drinking water intake is a pertinent exposure factor that is "intended to protect sensitive populations and life stages within the general population from adverse effects." [FN173: EPA, Drinking Water Health Advisory: Perfluorobutane Sulfonic Acid Potassium Perfluorobutane Sulfonate, at 18.] EPA's failure to consider the increased drinking water intake of infants understates the exposure to PFBS and its health effects on a sensitive population. EPA's HBWC may provide protections for adults and fetuses but it ignores the risks that PFBS poses for infants and does not address "adverse effects can result from short or intermittent exposure during a critical period of development." [FN174: Id. At 17 (citing EPA, EPA/600/FR-91/001, Guidelines for Developmental Toxicity Risk Assessment, (Dec. 5, 1991), https://www.epa.gov/sites/default/files/2014-11/documents/dev_tox.pdf).]

Using the DWI-BW listed on Table 3 of the Drinking Water Health Advisory for PFBS [FN175: EPA, Drinking Water Health Advisory: Perfluorobutane Sulfonic Acid and Perfluorobutane Sulfonate, at 19.] for formula fed infants (0.249 L/kg/day), the HBWC for PFBS should be no more than 240 ng/L.

HBWC = (RfD/DWI-BW)*RSC

= ((0.0003 mg/kg-bw/day) / (0.249 L/kg-bw/day)) *0.2

= 0.00024 mg/L = 240 ng/L

EPA Response: Please see section 4.3.3 of the EPA response in this *Response to Comments* document.

Mississippi Farm Bureau Federation (Doc. #1826, SBC-044267)

May 30, 2023

Alexis Lan

Office of Ground Water and Drinking Water Environmental Protection Agency

1200 Pennsylvania Avenue NW Washington, DC 20460

Dear Ms. Lan,

On behalf of the Mississippi Farm Bureau Federation (MFBF), I appreciate this opportunity to submit comments and concerns in response to Docket ID No. EPA-HQ-OW-2022-0114, Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation. MFBF is a general agricultural organization representing over 180,000 farm families. Mississippi has approximately 300 municipal water supplies and over 800 rural water systems. The vast majority of our members live in rural communities and will be significantly impacted by the proposed regulations. Our comments here will be brief, but We urge you to please give special consideration to the more substantive comments submitted by the American Farm Bureau Federation on this important proposed rule.

MFBF supports safe and clean drinking water supplies and understands EP''s urgency to begin understanding and addressing the potential health effects of PFAS. As EPA moves forward, we are concerned that there is insufficient data on human health effects from some PFAS to support the ultra-low maximum concentration limits proposed. While we are confident that there is good scientific data around the longer 8-9 chain carbon PFAS, we are concerned that the agency may be""assumin"" similar health risk from the shorter (3-4 chain carbon) PFAS.

EPA Response: Please see section 4.3.3 of the EPA response in this *Response to Comments* document. The EPA did not assume that health risks for PFBS (the 4-carbon PFAS being regulated in this action) are similar to those of PFOA and PFOS (8-carbon PFAS). Rather, the agency conducted a separate toxicity assessment for PFBS based on experimental animal toxicological data for PFBS. The toxicity assessment was reviewed internally by EPA scientists, federal partners, external peer reviewers, and the public (USEPA, 2021d).

PFHxS

American Water Works Association (AWWA) (Doc. #1759, SBC-045582)

PFHxS

As part of the proposal, EPA has developed a HBWC using minimal risk levels that were developed by the Agency for Toxic Substances and Disease Registry (ATSDR) (ATSDR, 2021). AWWA supports the use of the proposed HBWC as a screening level for PFHxS in support of the regulatory determination as EPA's Integrated Risk Information System (IRIS) program works towards completing its health assessment (EPA, 2023b).

EPA Response: The commenter agrees with the EPA's approach.

Washington State Department of Health (DOH) (Doc. #1665, SBC-052893)

PFHxS

• WA concurred with state health risk assessors in Michigan in selecting Minnesota Department of Health's RfD of 9.7 ng/kg-day for PFHxS as the base for our state action on PFHxS. We think this is a better basis for the HBWC than the ATSDR MRL.

• The Minnesota Department of Health derived their RfD from a study by the National Toxicology Program (NTP) 2019. Specifically, a 28-day oral gavage study in adult male and female Harlan Sprague Dawley rats. The study measured growth and gross behavior, serum hormone levels, and evaluated all organs for gross and histopathological findings at the end of 28 days. Serum measurements of PFHxS were collected for assessment of internal dose at the end of the experiment. There was a dose-dependent decrease in serum thyroid hormone levels in both sexes with more marked reductions in T3, fT4 and tT4 in male [FN7: National Toxicology Program, NTP Technical Report on the Toxicity Studies of Perfluoroalkyl Sulfonates (Perfluorobutane Sulfonic Acid, Perfluorohexane Sulfonate Potassium Salt, and Perfluorooctane Sulfonic Acid) Administered by Gavage to Sprague Dawley Rats 2019, U.S. Department of Health and Human Services: Research Triangle Park, NC].

• These study results were supported by Ramhøj et al. 2018 experiments in pregnant Wistar rats. Oral administration of PFHxS produced marked, dose-dependent reductions in serum total T4 in pregnant and lactating dams and in pups [FN8: Ramhøj, L., et al., Perfluorohexane Sulfonate (PFHxS) and a Mixture of Endocrine Disrupters Reduce Thyroxine Levels and Cause Antiandrogenic Effects in Rats. Toxicol Sci, 2018. 163(2): p. 579-591.].

• WA also considered infants a sensitive group for thyroid hormone reduction (see reasons above under PFBS) and we encourage EPA to pair this lower RfD with a translactational exposure model that accounts for higher exposures of breastfed infants. In our model based on Goeden et al. 2019, infants had more than twice the PFHxS serum concentration of their mothers after breast-feeding exclusively for 6 months and then tapering their breastmilk consumption while introducing foods over the following 6 months.

EPA Response: The EPA disagrees with this comment. At this time, the 2021 ATSDR toxicological profile represents the best available peer-reviewed scientific information regarding the human health effects of PFHxS. The EPA used a chronic toxicity reference value for PFHxS of 2.0 ng/kg/day, which is slightly lower (more health-protective) than the RfD used in the Minnesota Department of Health's analysis (9.7 ng/kg-day). Additionally, the 2021 ATSDR minimal risk level is more current than the Minnesota Department of Health's analysis.

For information about DWI-BW selection, please see section 4.3.3 of the EPA response in this *Response to Comments* document.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-052977)

PFHxS Health-Based Water Concentrations

EPA appears to have an error in the calculation of the PFHxS HBWC in the Mixture document (Section 2.4.4, pages 16-17). The chronic reference value of 2x10-6 mg/kg-day divided by the

DWI-BW of 0.034 L/kg-day times the RSC of 0.2 should yield a value of 12 ng/L, not 9.2 ng/L rounded to 9 ng/L. The PFHxS HBWC should be corrected to reflect the values included in the document.

EPA Response: The agency has corrected the value in the final NPDWR. The correct HBWC for PFHxS is 10 ng/L (ppt).

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-053336)

In addition to the highly uncertain toxicity value, and the overly conservative RSC, EPA also appears to have erred in its calculation of the HBWC for PFHxS. Based on the inputs provided in the formula (which, as noted above, we do not support), the derived HBWC should be 12 ppt, not 9 ppt [FN27: U. S. EPA. Maximum Contaminant Level Goal (MCLG) Summary Document for a Mixture of Four Per- and Polyfluoroalkyl Substances (PFAS): GenX Chemicals, PFBS, PFNA and PFHxS, 2023, EPA–822–P–23–004, at pages 16-17, available at: https://www.epa.gov/system/files/documents/2023-03/PFAS%20HI%20MCLG%20Public%20Review%20Draft%2009%20March%202023.pdf.].

EPA Response: The agency has corrected the value in the final NPDWR. The correct HBWC for PFHxS is 10 ng/L (ppt).

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-052992)

CT DPH reviewed the following language“”The HBWC for PFNA is derived using a chronic reference value based on an ATSDR intermediate-duration oral Minimal Risk Level, which was based on developmental effects seen in mice after oral PFHxS exposure (ATSDR, 2021”” and“”As further described in USEPA (2023a), the HBWC for PFNA is calculated to be 100 pp”” regarding the HBWC for PFNA. USEPA should make the following corrections: 1)“”oral PFHxS exposur”” in the first sentence should be“”oral PFNA exposur””; 2)“”100 pp”” in the second sentence should be“”10.0 pp””.

EPA Response: The agency has corrected the PFHxS HBWC value in the final NPDWR. The correct HBWC for PFHxS is 10 ng/L (ppt) and it is derived using a chronic toxicity reference value based on a minimal risk level based on developmental effects seen in mice after oral PFNA exposure.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-052989)

4. EPA requests comment on the derivation of the HBWCs for each of the four PFAS considered as part of the HI.

CT DPH reviewed the HBWC for PFHxS but was not able to reach the same value (9.0 ppt) following the described calculation. The RfD, 0.000002 mg/kg/day, divided by the DWI-BW of

0.034L/kg/d, multiplied by the RSC of 20% would be 1.18e-5 mg/L (i.e. 11.8 ppt). USEPA should better explain how the 9.0 ppt was reached or correct the value if it is a miscalculation.

EPA Response: The agency has corrected the value in the final NPDWR. The correct HBWC for PFHxS is 10 ng/L (ppt).

West Virginia Rivers Coalition et al. (Doc. #1746, SBC-045257)

[In particular, we strongly support their calls for EPA to:]

• Revise the Health-Based Water Concentration for PFHxS to 2 ng/L

EPA Response: The EPA disagrees that the HBWC for PFHxS should be revised to 2 ng/L. The commenter did not cite underlying data or rationale for the argument/factual assertion it made. Please see additional information in section 4.3.3 of the EPA response in this *Response to Comments* document.

City of Thornton, Colorado (Doc. #1748, SBC-044793)

Thornton requests that the EPA reevaluate the HBWC for PFHxS and increase if possible. Data from Colorado utilities with PFAS treatment in-place indicate that PFHxS breaks through treatment processes before other PFAS compounds. Because of the concentrations in Colorado waters, many utilities may have to replace their treatment media to meet the HI MCL while that media is still protective of the higher risk PFOA/PFOS compounds leading to increased and unnecessary costs.

EPA Response: The EPA disagrees. Please see section 4.3.3 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-053408)

i. EPA Should Revise its HBWC for PFHxS to 2 ng/L

When calculating its HBWC for PFHxS, EPA relied on a RfD derived by ATSDR for thyroid follicular cell damage in adult male rats from a study by Butenhoff et al. [FN151: See ATSDR 2021 at 21, A54–A57 (citing John L. Butenhoff et al., Evaluation of Potential Reproductive and Developmental Toxicity of Potassium Perfluorohexanesulfonate in Sprague Dawley Rats, 27 Reprod. Toxicology 331, 331–334 (June 2009)).] However, in March 2022, OEHHA published a risk assessment analysis for PFHxS as part of its Notification Level Recommendation for PFHxS in Drinking Water. [FN152: OEHHA, Notification Level Recommendation: Perfluorohexane Sulfonic Acid in Drinking Water (Mar. 2022), https://oehha.ca.gov/media/pfhxsnl031722.pdf.] In its analysis, OEHHA evaluated the same studies as ATSDR and a newer toxicological study by the National Toxicology Program ("NTP"). [FN153: Id. at 15 (citing, inter alia, NTP, NTP Technical Report on the Toxicity Studies of Perfluoroalkyl Sulfonates (Perfluorobutane Sulfonic Acid, Perfluorohexane Sulfonate Potassium Salt, and Perfluorooctane Sulfonic Acid) (August

2019), https://cebs.niehs.nih.gov/cebs/publication/TOX-96)).] Ultimately, OEHHA derived Public Health-Protective Concentrations (equivalent to EPA's health-based water concentrations) for three sensitive endpoints because they occur in different populations. [FN154: Id. at 30.] In contrast, ATSDR only derived a single RfD. The analysis of multiple sensitive endpoints in deriving a final drinking water value is critical to ensure protection from all adverse health effects in all populations.

First, choosing the lowest human equivalent dose ("HED") to derive a RfD does not guarantee that the RfD will protect against all health effects. A less sensitive HED could reasonably result in a lower RfD due to differences in study design and overall application of uncertainty. The IRIS PFAS assessments follow best practices in calculating organ-specific RfDs for multiple identified health effects. [FN155: See, e.g., EPA, Toxicological Review of Perfluorohexanoic Acid and Related Salts, at 5–28.] OEHHA also followed these best practices and derived RfDs for decreased thyroxine (T4) (which is associated with thyroid toxicity) in adult male rats, decreased litter size in female mice, and increased relative liver weight in female rats. [FN156: OEHHA, Notification Level Recommendation: Perfluorohexane Sulfonic Acid in Drinking Water, at 26.] Whereas the lowest HED was for decreased litter size, the lowest RfD was identified as decreased total T4 due to the application of different uncertainty factors to the two outcomes. [FN157: Id. at 28.]

Secondly, choosing the lowest RfD to derive an HBWC does not guarantee that all health effects will be protected against. The influence of population specific drinking water exposure assumptions is also important to consider. In the case of OEHHA's analysis, the final health-protective concentration in drinking water was lowest for decreased T4 (2 ng/L), when protecting against possible health effects in infants. [FN158: Id. at 28–29.]

In its analysis, OEHHA states, "[f]or PFHxS, there are no developmental studies of thyroid hormone levels in animals, and no mouse studies reporting T4 or T3 levels. Despite this uncertainty, the point of departure ("POD") for decreased T4 in male rats is a suitable candidate for PFHxS HPC derivation due to the severity of possible developmental consequences of decreased T4 in humans." [FN159: Id. at 26.] Therefore, because infants are a sensitive group for decreased total T4, OEHHA applied a 0- to 6-month infant DWI-BW of 0.237 L/kg/day to derive a health-based water concentration.

We strongly support OEHHA's health-protective approach to the lack of developmental data on thyroid hormone disruption for PFHxS. There is no reason to assume that this health effect is limited to an adult male population. Rather, when data are available, decreased T4 during development has been identified as a sensitive endpoint for other PFAS. Importantly, OEHHA and IRIS have argued that even though decreased thyroid hormone levels appear less severe than classical hypothyroidism and are not associated with increased levels of thyroid- stimulating hormone (TSH), decreased T4 is correlated with neurodevelopmental and cognitive deficits in children, highlighting the importance of protecting the developing fetus, infants, and children against PFAS exposure. [FN160: See id. at 20.]

The analysis by OEHHA indicates that a HBWC of 2 ng/L should be set to protect the most vulnerable and sensitive populations. Because that level is lower than the PQL of 3 ng/L, when calculating the hazard index for the purpose of establishing and monitoring compliance with the PFHxS MCL EPA should rely on the PQL, as opposed to EPA's currently proposed and under-protective HBWC. [FN161: Proposed Rule, 88 Fed. Reg. at 18,680. Although we strongly recommend EPA adopt the analysis conducted by OEHHA, we acknowledge and support EPA's choice to apply an additional UF of 10 to adjust for subchronic-to-chronic duration (i.e., UFS), per agency guidance. Id. at 18,645–46.]

EPA Response: The EPA disagrees. Please see section 4.3.3 of the EPA response in this *Response to Comments* document for comments related to how HBWCs were derived.

3M Company (Doc. #1774, SBC-045656)

The absence of necessary peer review resulted in EPA making substantive errors that could have been identified and addressed before publication of the Proposed Rule. For example, EPA's selection of reference values for the four PFAS for which it is now issuing a preliminary regulatory determination contains important technical errors, including reliance on standards or studies that have been discredited and fail to account for numerous uncertainty factors. The proposed NPDWR also contains a math error in calculating the HBWC for PFHxS that resulted in EPA proposing an HBWC of 9 ppt instead of 10 ppt.

EPA Response: The agency has corrected the value in this NPDWR. The correct HBWC for PFHxS is 10 ng/L (ppt). Also, the commenter appears to claim that the toxicity reference values for the four PFAS rely on "standards or studies that have been discredited" but the commenter does not specify to which standards and/or studies the commenter is referring. For EPA responses to comments related to the toxicity reference values for HFPO-DA, PFNA, PFHxS, and PFBS, and how HBWCs for these four PFAS were derived, please see section 4.3.3 of the EPA response in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-053413)

The Relevance of Thyroid Hormone Changes in PFHxS Animal Studies is Uncertain

ATSDR bases its MRL for PFHxS on the results of a developmental toxicity study by Butenhoff et. al. [FN106: Butenhoff JL et al. Evaluation of potential reproductive and developmental effects of potassium perfluorohexanesulfonate in Sprague Dawley rats. Reprod Toxicol 27:331-341 (2009).] that reported thyroid effects (hypertrophy and hyperplasia of the follicular cells) in parental male rats treated with PFHxS for at least 42 days. The investigators noted that the observed changes in rats "are consistent with the known effects of inducers of microsomal enzymes where the hepatocellular hypertrophy results in a compensatory hypertrophy and hyperplasia of the thyroid." In light of this possible link to PPARα activation in the liver and the significant differences in thyroid function between rodents and humans, [FN107: Capen CC et al. Species differences in thyroid, kidney, and urinary bladder carcinogenesis. IARC Scientific

Publications 147:1-14 (1999).] there is some question about the relevance of the rat data to humans.

Although Butenhoff et al. do not report hormone levels, NTP reported decreases in thyroxine (T4) concentrations in a dose-response manner but not a consistent increase in thyroid stimulating hormone (TSH). Nor does the NTP study report any histopathologic changes in the thyroid gland. [FN108: NTP. Technical Report on the Toxicity Studies of Perfluoroalkyl Sulfonates (Perfluorobutane Sulfonic Acid, Perfluorohexane Sulfonate Potassium Salt, and Perfluorooctane Sulfonic Acid) Administered by Gavage to Sprague Dawley (Hsd:Sprague Dawley SD

) Rats. Toxicity Report 96 (2019). (NTP TR-96).] The report notes that the decrease in thyroid hormones may be related to the activation of PPARα and CAR that could accelerate degradation of thyroxine by the liver. In a study conducted by Chang et al. no alterations in TSH were observed in mice administered PFHxS prior to mating and during mating, gestation, and lactation; nor were there histological alterations in the thyroid gland of the animals. [FN109: Chang S et al. 2018. Reproductive and developmental toxicity of potassium perfluorohexanesulfonate in CD-1 mice. Reprod Toxicol 78:150-168 (2018).] These results are consistent with those of Ramhoj et al. who found that ”PFHxS lowered thyroid hormone levels in both dams and offspring in a dose-dependent manner, but did not change TSH levels, weight, histology, or expression of marker genes of the thyroid gland.” [FN110: Ramhoj L et al. Evaluating thyroid hormone disruption: investigations of long-term neurodevelopmental effects in rats after perinatal exposure to perfluorohexane sulfonate (PFHxS). Sci Rep 20:2672 (2020).]

The ATSDR MRL is based on a NOAEL of 1 milligram per kilogram per day (mg/kg-day) and a total uncertainty factor for 300, including a UFD of 10. To calculate the HBWC, EPA applied an additional UFS of 10. According to ATSDR, the decision to add a UFD of 10 is based on the limited number and scope of the available studies and the absence of information on immunotoxicity.

According to EPA guidance, a UFD is typically and properly applied in the absence of reproductive and developmental information. EPA’s guidance explains that a UFD is applied when reproductive and developmental toxicity studies are missing since they have been found to provide valuable information for establishing a LOAEL. [FN111: Dourson ML et al. (1996) Evolution of science-based uncertainty factors in noncancer risk assessment. Regul Toxicol Pharmacol 24:108–120 (1996).] The lack of a two-generation study for PFHxS would justify the use of a 3-fold uncertainty factor, based on EPA guidance. Any concerns about early life sensitivity are addressed by Chang et al. who report no treatment-related effects on postnatal survival of development in offspring exposed in utero through PND 36 and more recently by Ramhoj et al. (2020) who followed maternal exposure from early gestation (GD7) through lactation (PND22), and then again followed up after 4–5 months of age for the F1 females and 8–

9 months for the F1 males.. Although limited, Butenhoff et al. do not report evidence of immunotoxicity in rats exposed to up to 10 mg/kg per day by gavage for up to 56 days.

EPA Response: Please see section 4.3.3 of the EPA response in this *Response to Comments* document.

PFNA

American Water Works Association (AWWA) (Doc. #1759, SBC-045586)

PFNA

As with PFHxS, EPA also developed a HBWC for PFNA using data from ATSDR (ATSDR, 2021). AWWA supports the use of the proposed HBWC as a screening level for PFNA to guide this determination in the absence of a completed IRIS program health assessment (EPA, 2023b).

EPA Response: The commenter agrees with the EPA's approach.

Washington State Department of Health (DOH) (Doc. #1665, SBC-052897)

PFNA

• Consider amending the ATSDR MRL to account for a more recent estimate of serum half-life published after the ATSDR MRL: Yu, C.H., et al., Biomonitoring: A tool to assess PFNA body burdens and evaluate the effectiveness of drinking water intervention for communities in New Jersey, Int J Hyg Environ Health, 2021. 235: p. 113757. Yu et al. 2021 published a three-year biomonitoring study in a New Jersey community exposed to elevated PFNA in their drinking water. The geometric mean of the study group was five times higher than the mean PFNA levels in U.S. adults as measured in 2015-2016 by the CDC. The study collected three blood samples one year apart in 99 participants from 2017 to 2020. Residents ranged in age between 20 – 74 years old and were 68 percent female. Half-life estimates of PFNA in serum were 3.52 years for the 68 most highly exposed participants. DOH suggest that EPA consider the PFNA serum halflife in the more highly exposed members to minimize bias from ongoing background exposure to PFNA. Modifying the ATSDR MRL with the new half-life estimate of 3.52 years (1,285 days) from Yu et al. 2021, would result in:

• MRL (mg/kg-day) = POD (mg/L) x DAF (L/Kg-day) ÷ UF

o POD = 6.8 mg/L PFNA in serum

o DAF = Vd x (Ln(2)/T1/2) = 0.2 L/kg x (Ln(2)/1,285 days) =1.08 x 10-4 L/kg – day.

o UF = 300

• MRL = = 6.8 mg/L x 1.08 x 10-4 L/kg – day ÷ 300 = 2.45 x10-6 mg/kg-day (or 2.5 ng/kg-day)

EPA Response: The EPA disagrees with this comment. The EPA does not have authority to revise an ATSDR minimal risk level. Please see section 4.3.3 of the EPA response in this *Response to Comments* document.

West Virginia Rivers Coalition et al. (Doc. #1746, SBC-052999)

[In particular, we strongly support their calls for EPA to:]

• Revise the Health-Based Water Concentration for PFNA to 2 ng/L

EPA Response: The EPA disagrees that the HBWC for PFNA should be revised to 2 ng/L. The commenter did not cite underlying data or rationale for the argument/factual assertion it made. Please see additional information in section 4.3.3 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-053410)

iii. EPA Should Revise its HBWC for PFNA to 2 ng/L

In deriving a health-based water value for PFNA from ATSDR's RfD, EPA chose the drinking water intake estimate for lactating women (0.0469 L/kg-bw/day). [FN176: EPA, MCLG Summary Document for a Mixture of Four PFAS, at 15.]

However, the critical effects selected by ATSDR (decreased body weight and developmental delays including delayed eye opening, preputial separation and vaginal opening) occur during development. [FN177: Id. at 13.] Furthermore, a transgenerational toxicokinetic model for PFNA has been developed and used by some states which demonstrates a significantly higher level of exposure for breastfed infants. [FN178: Wash. Dep't of Health, Recommended State Action Levels for PFAS, at 21–24.] We recommend that EPA either evaluate and use this transgenerational toxicokinetic model or apply a drinking water intake rate for infants. Using the drinking water intake rate for formula fed infants (0.249 L/kg-bw/day) (see above), the health-based value goal for PFNA should be no more than 2 ng/L.

HBWC = (RfD/DWI-BW)*RSC

= ((0.000003 mg/kg-bw/day) / (0.249 L/kg-bw/day)) * 0.2

= 0.0000024 mg/L = 2 ng/L

The HBWC for PFNA should be no higher than 2 ng/L to protect the most vulnerable and sensitive populations. Because that level is lower than the PQL of 4 ng/L, when calculating the hazard index for the purpose of establishing and monitoring compliance with the PFNA MCL, EPA should rely on the PQL, as opposed to EPA's currently proposed and under-protective HBWC. [FN179: Proposed Rule, 88 Fed. Reg. at 18,680.]

EPA Response: The EPA disagrees. To select an appropriate DWI-BW for use in derivation of the HBWC for PFNA, the EPA considered the PFNA exposure interval used in the oral reproductive/developmental toxicity study in mice that served as the basis for chronic RfD derivation (the critical study). In this study, decreased body weight gain and impaired development (i.e., delayed eye opening, delayed sexual maturation) were observed in mice born to mothers that were orally exposed to PFNA during gestation (with presumed continued indirect exposure of offspring via lactation). This exposure window corresponds to three potentially sensitive human adult life stages that may represent critical windows of PFNA exposure: women of childbearing age, and pregnant women, and lactating women (Table 3-63 in USEPA, 2019). Of these three, the highest DWI-BW, for lactating women (0.0469 L/kg/day), is anticipated to be protective of the other two sensitive life stages and was used to calculate the HBWC for PFNA. Please see section 4.3.3 of the EPA response in this *Response to Comments* document for further discussion of how DWI-BWs were selected.

American Chemistry Council (ACC) (Doc. #1841, SBC-052930)

Developmental Effects Associated with PFNA Exposure are Not Relevant to Humans

ATSDR's intermediate MRL is based on reports of decreased body weight gain and developmental delays in the offspring of mice administered PFNA via gavage in a study by Das et al. [FN112: Das KP et al. Developmental toxicity of perfluorononanoic acid in mice. Reprod Toxicol 51:133-144 (2015).] These effects occurred concomitant with maternal toxicity and therefore, according to governing EPA guidelines, should not be used as the critical effect. [FN113: USEPA Developmental Toxicity Guidelines, at 6.] Moreover, Wolf et al. [FN114: Wolf CJ et al. Developmental effects of perfluorononanoic acid in the mouse are dependent on peroxisome proliferator-activated receptor-alpha. PPAR Res 2010 10.1155/2010/282896 (2010).] did not report changes in pup body weight or postnatal development in PPARα-null mice at 2 mg/kg- day, suggesting that these effects are rodent-specific responses to PFNA mediated by PPARα with little to no relevance to humans. [FN115: It appears that EPA as reviewed the available thyroid data as part of its ongoing IRIS assessment for PFNA but has not made the results of that review available as part of this rulemaking. See USEPA IRIS Handbook, at 5-18.] Reported liver effects in mice exposed to PFNA also may result from PPARα activation of limited relevance to humans.

In addition to concerns about study selection, ATSDR's decision to include a 10-fold UFD based on the limited and scope number of studies examining PFNA toxicity is unjustified. In particular, ATSDR suggests that reproductive toxicity may be a more sensitive endpoint than developmental toxicity and that data on immune function are lacking. [FN116: ATSDR PFAS Tox Profile, at A-66.] In the case of PFNA, developmental toxicity data do exist which suggest that effects are the result of PPARα activation. As noted by ATSDR, epidemiology studies examining a possible association between serum PFNA and immunosuppression or hypersensitivity have been negative or mixed. While animal data are lacking, existing human data do not suggest the potential for immune effects. Consequently, a UFD of 3 seems more appropriate given only the lack of data

on reproductive effects and acknowledging the existence of data on developmental and immune effects.

EPA Response: The EPA disagrees with this comment. Please see section 4.3.3 of the EPA response in this *Response to Comments* document.

HFPO-DA (GenX Chemicals)

Earthjustice et al. (Doc. #1808, SBC-053411)

iv. EPA Should Revise its HBWC for GenX to 2 ng/L

EPA finalized the Human Health Toxicity Assessment for GenX in October 2021. [FN180: See EPA, Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (CASRN 13252-13-6 and CASRN 62037-80-3), Also Known as 'GenX Chemicals at 86-88 (Oct. 2021), https://www.epa.gov/system/files/documents/2021-10/genx-chemicals-toxicity-assessment_tech-edited_oct-21-508.pdf. We support the changes to the draft document that were made in response to the public comment process. Specifically, we support the NTP Pathology Working Group findings on liver lesions, which were based on more contemporary pathology guidelines than were used in prior analyses. We further support the application of a full uncertainty factor to account for the use of a study with less chronic exposure and a full uncertainty factor for database deficiencies.] In the development of the Lifetime Health Advisory for GenX, EPA "identified three potentially sensitive life stages for GenX chemical exposure—women of childbearing age (13 to < 50 years), pregnant women, and lactating women." [FN181: EPA, Drinking Water Health Advisory: Hexafluoropropylene Oxide (HFPO) Dimer Acid (CASRN 13252-13-6) and HFPO Dimer Acid Ammonium Salt (CASRN 62037-80-3), Also Known as 'GenX Chemicals, Off. of Water, at 21 (June 2022), https://www.epa.gov/system/files/documents/2022-06/drinking-water-genx-2022.pdf.] In setting its HBWC, EPA ultimately chose the drinking water intake estimate for lactating women, stating that this would be protective of the other two populations as well (i.e., pregnant women and women of childbearing age). [FN182: EPA, MCLG Summary Document for a Mixture of Four PFAS, at 9.] However, there is no analysis to suggest that infants and young children would be sufficiently protected from liver or other developmental effects due to exposure during this critical stage.

Furthermore, the NOAEL for developmental effects linked to GenX exposure is within the same range as the NOAEL for liver effects (i.e., within one order of magnitude). [FN183: EPA, Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (CASRN 13252-13-6 and CASRN 62037-80-3) Also Known as 'GenX Chemicals,' (Oct. 2021) https://www.epa.gov/system/files/documents/2021-10/genx-chemicals- toxicity-assessment_tech-edited_oct-21-508.pdf] We therefore recommend that EPA apply a DWI-BW for infants. Using the DWI-BW listed on Table 3 of the Drinking Water Health Advisory for GenX for formula-fed infants (0.249 L/kg/day), the health- based value goal for GenX should be no more than 2 ng/L.

HBWC = (RfD/DWI-BW)*RSC

= ((0.000003 mg/kg-bw/day) / (0.249 L/kg-bw/day)) *0.2

= 0.0000024 mg/L = 2 ng/L

The HBWC for GenX should be no higher than 2 ng/L to protect the most vulnerable and sensitive populations. Because that level is lower than the PQL of 5 ng/L, when calculating the hazard index for the purpose of establishing and monitoring compliance with the GenX MCL EPA should rely on the PQL, as opposed to EPA's currently proposed and under-protective HBWC . [FN184: Proposed Rule, 88 Fed. Reg. at 18,680.]

EPA Response: The EPA disagrees with this comment. Please see section 4.3.3 of the EPA response in this *Response to Comments* document.

West Virginia Rivers Coalition et al. (Doc. #1746, SBC-053000)

[In particular, we strongly support their calls for EPA to:]

• Revise the Health-Based Water Concentration for GenX to 2 ng/L

EPA Response: The EPA disagrees that the HBWC for HFPO-DA should be revised to 2 ng/L. The commenter did not cite underlying data or rationale for the argument/factual assertion it made. Please see additional information in section 4.3.3 of the EPA response in this *Response to Comments* document.

The Chemours Company FC, LLC (Doc. #1845, SBC-046060)

3) EPA's HBWC calculations that are subsequently used in calculating the hazard index for HFPO-DA, PFBS, PFHxS, and PFNA are flawed because of the following critical issues:

a. The reference dose (RfD) value used in the HBWC for HFPO-DA lacks human relevance.

b. The RfD and minimum risk level (MRL) values for PFBS, PFNA, and PFHxS potentially lack human relevance.

c. The body weight-adjusted drinking water intake (DWI-BW) value used in the calculation of the HBWC for HFPO-DA is inappropriate.

EPA Response: Please see section 4.3.3 of the EPA response in this *Response to Comments* document.

The Chemours Company FC, LLC (Doc. #1845, SBC-046064)

3 EPA's HBWC calculations that are subsequently used in calculating the hazard index (HI) for HFPO-DA, PFBS, PFHxS, and PFNA are flawed.

In setting an MCLG for HFPO-DA, EPA has proposed to use a mixtures approach by combining HFPO-DA with PFBS, PFNA, and PFHxS. As part of this process, EPA derives a health-based water concentration (HBWC) for each constituent that requires a toxicity value such as a reference dose (RfD) or minimal risk level (MRL), a drinking water intake (DWI-BW), and a relative source contribution (RSC). Critical issues with the RfD and DWI-BW values for HFPO-DA result in a HBWC for HFPO-DA that is flawed. These issues are addressed below along with additional commentary on potential issues with the HBWC values for PFBS, PFNA, and PFHxS.

3.1 The RfD value used in the HBWC for HFPO-DA lacks human relevance.

Notwithstanding issues related to the scientific justification for using a mixtures approach for setting a MCLG for HFPO-DA and other PFAS (discussed above), any toxicity value (e.g., RfD or MRL) used in the derivation of drinking water standards (e.g., MCL or MCLG) should have human relevance. In the context of an assumption of dose additivity, it is critical that all the individual chemicals in a mixture of interest have meaningful, human relevant RfD values or else the underlying rationale for summing doses is nullified by the inclusion of some effects that do not occur in humans.

A major driver in the HBWC derivation for HFPO-DA is the RfD. The RfD EPA derived for HFPO-DA is technically flawed as a result of the selection of an inappropriate toxicological endpoint selected as the basis of the RfD, as well as the extrapolation to humans and the application of uncertainty factors. The toxicity endpoint that EPA used to derive its RfD was liver lesions in female mice in a subchronic oral gavage study (EPA 2021). In fact, EPA grouped multiple histopathological lesions in an unusual way that combined adaptive/non-adverse and potentially adverse effects as well as dose-responsive and non-responsive effects into a composite "constellation" of liver effects that were inappropriately subjected to quantitative dose-response modeling. Most toxicity criteria are derived from selecting among multiple candidate RfD (cRfD) values, each comprised of a single effect. As described in Attachment A (Exhibit 2), a National Toxicology Program (NTP) Pathology Working Group (PWG) was convened by EPA to review histological slides from several HFPO-DA studies and concluded that the various liver effects observed represented a "constellation" of effects that were adverse to mice. EPA overinterpreted this statement assuming 1) that these effects are relevant (i.e., adverse) to humans, 2) that early/adaptive responses could/should be combined quantitively with effects that are secondary (i.e., related) to the earlier events, 3) that all the effects are dose-related, and 4) that these combined effects could then be quantitatively modeled. Issues with these assumptions are discussed in detail in Attachment A (Exhibit 2, Section 2-5). In addition, one of the components of the constellation, hepatocellular single cell necrosis, was diagnosed by the NTP-PWG in a manner that appears inconsistent with well-accepted criteria or, at the very least, in a manner inconsistent with classic necrotic characteristics (Attachment A, Exhibit 2, Section 6). More recently, it was demonstrated that some of the hepatocytes putatively considered necrotic by the NTP-PWG, in fact, stain positive for molecular markers of apoptosis thereby calling into questions the NTP-PWG's diagnoses of necrosis (Thompson et al. 2023, see

Attachment B). These findings, in addition to transcriptomic evidence for apoptotic cell death, are consistent with a larger database indicating that HFPO-DA acts through a mode of action (MOA) that occurs in rodents but not in humans (see below).

In addition to the inappropriate grouping and modeling of the constellation of liver effects, several streams of data indicate that these liver responses in mice are consistent with a MOA involving peroxisome proliferator-activated receptor alpha (PPARa) activation that is widely regarded as lacking human relevance. As described in Thompson et al. (2019), HFPO-DA induces liver effects in rodents that are indicative of peroxisomal proliferators, including hepatocellular hypertrophy and hepatomegaly, induction of hepatic peroxisomal b-oxidation activity, as well as transcriptomic responses indicative of PPARa activation (albeit in limited studies ca. 2019). Prior to the release of the EPA final assessment for HFPO-DA (2021), EPA was made aware of unpublished transcriptomic data collected in liver tissues of mice exposed similarly to HFPO-DA as in the studies EPA selected as the basis for its RfD that indicated PPARa activation as the primary response in mouse liver. That work was published prior to the release of EPA's toxicological review but not cited by the EPA (Chappell et al. 2020)—indicating that EPA did not consider all of the available science prior to finalizing its toxicological review. Instead, EPA hypothesized that other MOAs might explain the liver effects in mice. Importantly, subsequent transcriptomic analyses in both primary hepatocytes and in liver samples from the same study that serves as the basis of EPA's RfD, further support PPARa activation as the operative MOA for HFPO-DA in mice and refute alternate MOAs proposed in the liver (Heintz et al. 2022; Klaren et al. 2023, see Attachments C and D). Attachment A (Exhibit 2, Section 2) summarizes much of the information supporting PPARa as the MOA responsible for the liver effects in rodents, which has recently been formalized and published in Toxicological Sciences (Heintz et al. 2023, see Attachment E). Critically, it has long been argued, and widely accepted (Felter et al. 2018), that some effects of PPARa activation in rodents (e.g., liver tumor formation) lack human relevance due to differences in rodent and human downstream signaling pathways (Corton et al. 2018; Klaunig et al. 2003). More recently, Heintz et al. (2023) have demonstrated that earlier non-neoplastic responses to HPO-DA are driven by PPARa activation and thus these effects similarly lack human relevance. As such, liver effects in mice should not be used as the basis of the RfD for HFPO-DA.

It is notable that EPA (2021) acknowledged that a PPARa MOA might have limited human relevance. EPA went on to suggest that the evidence for PPARa activation was inconclusive and hypothesized several alternative MOAs that might, if operative, have human relevance. As discussed in Heintz et al. (2023) and Attachment A (Exhibit 1, Section 3), the evidence for these alternative MOAs is weak at best. Chief among these alternative MOAs was that HFPO-DA induces liver effects through a cytotoxic MOA independent of PPARa activation. However, transcriptomic analyses in liver samples from the same study serving as the basis of EPA's RfD indicate PPARa activation as the most sensitive effect, without significant enrichment of molecular signatures for cytotoxicity with the potential exception of the highest exposure dose, which is likely secondary to PPARa-mediated changes (Heintz et al., 2023; Thompson et al., 2023). In addition, recent transcriptomic analyses of mouse, rat, and human primary hepatocytes

treated with HFPO- DA or positive control chemicals including known agonists of PPARa, PPARg, and known cytotoxic agents, demonstrate concordant transcriptomic responses between HFPO-DA and the PPARa agonist and a lack of concordant transcriptomic responses between HFPO- DA and the other positive control chemicals tested (Klaren et al. 2023, see Attachment D). Overall, histopathological and molecular data published since the release of the EPA (2021) toxicological review strengthen data published prior to the release of EPA (2021) that indicate a PPARa driven MOA in mouse liver that lacks human relevance.

In addition to selection of an endpoint lacking human relevance, EPA also misapplied uncertainty factors in the derivation of the RfD. After conducting interspecies dose adjustments by allometric scaling, EPA applied an unnecessary 3-fold interspecies uncertainty factor (UF_a) for potential pharmacodynamic sensitivities in humans. At the time of EPA's review, there was already data indicating the likely involvement of PPAR a mechanisms that are widely recognized as being more sensitive in rodents than humans. As such, there is no scientific basis to suggest that humans might be more sensitive to the liver effects induced by HFPO-DA in rodents (see Attachment A, Exhibit 3, Section 4.0). EPA also applied an unnecessary 10-fold uncertainty factor for the use of a subchronic study (UF_S) when it applied only a 3-fold UFS to liver effects in the same study in a prior draft review (EPA 2018). As described in detail in Attachment A (Exhibit 3, Section 2), quantitative analyses of liver effects in mice exposed to HFPO-DA for different durations do not provide evidence for a progression of effects warranting a full 10-fold UF_S, which is consistent with what EPA concluded in its 2018 draft review (EPA 2018).

Similar to the UF_S, EPA also applied a 10-fold database uncertainty factor (UF_D) in EPA (2021) but a 3-fold UF_D in its previous review (EPA 2018). This increase in uncertainty is inexplicable given the increase in mechanistic and toxicological studies published on HFPO-DA between 2018 and 2021. As described in detail in Attachment A (Exhibit 3, Section 1), EPA provided a list of reasons purportedly to support the 10-fold UF_D; however, many of the uncertainties could have been addressed by developing an array of candidate RfD (cRfD) values for different toxicities (or organ systems) and selecting the most sensitive effect. Despite the availability of numerous well-conducted studies, EPA only derived cRfD values for liver effects in mice. As shown in Attachment A (Exhibit 3, Sections 1.1-1.3), several additional cRfD values could have been derived but instead EPA "tacked on" additional uncertainty by increasing the UFD from 3 to 10. Attachment A (Exhibit 3, Section 1.4) demonstrates that the UFD applied in other contemporaneous PFAS assessments by EPA had 3-fold UFD values despite having less robust datasets—especially as it applies to reproductive and developmental toxicity studies (see Table 5 of Attachment A, Exhibit 3, Section 1.4). EPA also misinterpreted developmental toxicity data as indicating bioaccumulation of HFPO-DA in embryos, which EPA also stated as a reason for the 10-fold UFD. In fact, the apparent bioaccumulation was likely due to changes in body composition of the embryo/fetus over time that resulted in different levels of HFPO- DA partitioning to the fetus (see Attachment A, Exhibit 3, Section 1.5 for more detail).

Overall, EPA increased the composite UF in the RfD for HFPO-DA 10-fold from 300 to 3000 between 2018 and 2021. It is unusual for the uncertainty in a risk assessment for a chemical to

increase as more mechanistic and toxicological data become available. This increase in uncertainty is not supported. As shown in Table 2 of Attachment A (Exhibit 3, Section 1), the database for HFPO-DA is rather extensive and inconsistent with the use of a 3000-fold composite uncertainty factor that EPA has applied in only ~10% of IRIS risk assessments. EPA (2021) instead compounded various aspects of uncertainty in its RfD derivation for HFPO-DA.

As further evidence that EPA's RfD for HFPO-DA is flawed, the RfD of 3E-6 mg/kg-day is ~500-fold lower than the threshold for toxicological concern (TTC) value of 0.0015 mg/kg-day for Cramer Class III chemicals. Recent studies indicate that PFAS, which have not historically been included in the Munro TTC dataset, can be included among the structurally diverse Class III chemicals with minimal impact on the TTC value (Lea et al. 2022, see Attachment F). It should be noted that the fact that all Cramer Class III compounds have the same TTC value does not imply that they are equipotent or share common MOAs, target organ effects, structural moieties, or are dose additive or otherwise interactive. Importantly, EPA IRIS RfD values for Cramer Class III chemicals tend to be 6-fold higher than the Cramer Class III TTC (Pham et al. 2020). That the RfD for HFPO- DA is so much lower than the TTC implies problems in the RfD derivation, which is consistent with the many issues highlighted above.

EPA Response: The EPA disagrees with the commenter. Please see section 4.3.3 of the EPA response in this *Response to Comments* document. With respect to the commenter's comparison between the RfD for HFPO-DA and the threshold for toxicological concern (TTC) value of 0.0015 mg/kg-day for Cramer Class III chemicals: As noted in section 4.3.3 of this *Response to Comments* document, the final published peer-reviewed human health toxicity assessment that derives the RfD for HFPO-DA is appropriate and sound, reflects the best available peer-reviewed science, and is consistent with agency guidance, guidelines, and best practices for human health risk assessment. The EPA guidance does not allow generalized speculation of how the RfD for HFPO-DA compares to the TTC value of 0.0015 mg/kg-day for Cramer Class III chemicals. Altering an RfD or otherwise deviating from EPA guidance and guidelines in RfD derivation in order to achieve an RfD that is close to the TTC for Cramer Class II chemicals is not in line with EPA guidance.

With regard to the comment questioning why the EPA did not develop chronic RfDs for endpoints other than the liver (e.g., immune and hematological effects), these endpoints were not as consistently observed as the liver effects (see Section 7.1 in USEPA, 2021b). The EPA also did not derive an RfD based on developmental effects (e.g., placental lesions), due to data gaps, specifically, a two-generation reproductive toxicity study (see Section 7.1 in USEPA, 2021b). In addition, the EPA asked external peer reviewers if the agency should consider any other effects or studies for RfD derivation, and they unanimously supported use of the liver endpoint as the RfD.

<u>The Chemours Company FC, LLC (Doc. #1845, SBC-053395)</u>

3.3 The DWI-BW value used in the calculation of the HBWC for HFPO- DA is inappropriate.

In the derivation of a HBWC for HFPO-DA, EPA applied a DWI-BW for lactating women, arguing that this intake relates back to the RfD that was based on parental (F0) female mice exposed to HFPO-DA during premating, gestation, and lactation. EPA argued that DWI- BW for lactating women is highest and therefore should be protective of "women of child baring age, pregnant women, and lactating women". Critically, the RfD developed by EPA is already protective of all human lifestages as a 10-fold human variability factor (UFH) was applied in its derivation. Furthermore, EPA applied a 10-fold UFS for the use of a subchronic study, indicating that EPA did not consider the liver effects in the F0 female mice as a lifestage sensitivity. Had EPA considered the liver effects a lifestage sensitivity, then the endpoint would have been considered a reproductive toxicity endpoint and therefore not require a UFS per EPA guidance (EPA 1991). Nowhere in EPA (2021) are the liver effects in female mice characterized as a reproductive endpoint. In fact, EPA (2021) considered the same liver "constellation" endpoint in males as a candidate RfD but only selected females because it resulted in a slightly lower RfD. As further evidence that EPA did not consider the liver effects a reproductive endpoint, the RfD in the EPA (2018) draft review of HFPO-DA was based on liver effects in male F0 mice because it provided a slightly lower RfD than the same effect in females. As already discussed, it was only after inappropriately combining and modeling several liver effects into a "constellation" that the female liver effects provided a slightly lower RfD than male liver. As such, the appropriate DWI-BW value for the derivation of a HBWC for HFPO-DA (using EPA's flawed RfD) is that of an adult instead of a lactating woman. It is also notable that the SAB review of the PFAS Mixtures Framework specifically stated that use of ingestion rates for lactating women "is not likely to be appropriate" for PFBS or HFPO-DA "since there is no information to indicate that [they] are present in breastmilk" (EPA 2023c).

Using EPA's DWI-BW for lactating women (0.0469 L/kg-day), EPA reports a HBWC of 10 ppt. It is notable that the actual concentration is 12.8 ppt (0.000003 mg/kg-d ¸ 0.0469 L/kg-d ´ 20%). Given the extreme conservativism in EPA's RfD (e.g., endpoint lacking human relevance, application of a maximum 3000-fold composite UF) and use of an inappropriate DWI-BW, the rounding down as opposed to up, in this case reducing the HBWC by ~23% (10 ¸ 13), seems unnecessary. Using the adult DWI-BW (0.034 L/kg-d) results in a HBWC of 17.6 ppt (0.000003 mg/kg-d ¸ 0.034 L/kg-d ´ 20%), rounded to 18 ppt. In summary, notwithstanding the use of an inappropriate RfD for HFPO-DA, EPA has further erroneously calculated a HBWC for HFPO-DA that is almost 2-fold lower than it should be for the RfD EPA selected.

It is notable that EPA used an adult DWI-BW value for the derivation of the HBWC for PFHxS based on follicular cell hyperplasia in male rats. This clearly indicates that EPA does not apply DWI-BW values for lactating women as a matter of policy in their proposed HI approach. As discussed above, the liver effects serving as the basis of the RfD for HFPO-DA were observed in both sexes and the selection of the RfD was driven by numerical considerations as opposed to biological considerations as evidenced by EPA's selection of liver effects in males as the basis of the RfD in EPA (2018) and females in EPA (2021).

EPA Response: The EPA disagrees with this comment. Please see section 4.3.3 of the EPA response in this *Response to Comments* document.

In response to the commenter's statement that the HFPO-DA RfD is already protective of all human lifestages because of the UF_H that was applied: The commenter is conflating two separate elements—the RfD (a measure of toxicity), and the DWI-BW (a measure of exposure). The application of a UF_H to an RfD is to account for uncertainty related to intra-species variability with respect to toxicological response(s). The selection of an appropriate DWI-BW is a separate process during which the EPA considers the sensitive life stage(s) of exposure associated with the critical effect on which the RfD was based in order to apply an appropriate DWI-BW (please see section 4.3.3 of the EPA response in this *Response to Comments* document). As described in the HFPO-DA toxicity assessment (USEPA, 2021b), in the critical study, parental female mice were dosed for two weeks prior to pairing, throughout gestation, and through to lactation day 20 for a total dosing duration of 53 to 65 days. Therefore, exposure corresponded to three potentially sensitive adult female life stages: women of childbearing age, pregnancy, and lactation. The DWI-BW for lactation was appropriately selected because it is the highest (most protective) of the DWI-BWs for these three lifestages (please see section 4.3.3 of the EPA response in this *Response to Comments* document).

In response to the commenter's statement that "EPA applied a 10-fold UF_S for the use of a subchronic study, indicating that EPA did not consider the liver effects in the F0 female mice as a lifestage sensitivity"—the commenter is misunderstanding the purpose of the UF_S. The UF_S is intended to account for potential uncertainty related to using a study with a less-than-chronic exposure duration as the critical study. Its application has nothing to do with whether the critical effect was observed during a potentially sensitive lifestage or not.

In response to the commenter's statement that the SAB review of the PFAS Mixtures Framework specifically stated that use of ingestion rates for lactating women "is not likely to be appropriate" for PFBS or HFPO-DA "since there is no information to indicate that [they] are present in breastmilk"—the commenter is taking this quote out of context. The SAB was commenting on the fact that an example calculation in the draft PFAS Mixtures Framework uses HBWCs for PFOA and PFOS that use DWI-BWs for lactating women. The SAB was simply making the point that a DWI-BW for lactating women may not be appropriate for all PFAS. In fact, the sentence just before the text from the SAB report quoted by the commented reads, "ingestion rates for subgroups other than lactating women (e.g., infants, children, default adults) may be appropriate for HBWCs for other PFAS." At the time of its review and report, the HBWC for HFPO-DA (which uses a DWI-BW for lactating women) did not exist, and therefore, the SAB's general comment about HFPO-DA and the potential that a DWI-BW for lactating women may *not* likely be appropriate, was not made in the context of and/or with the knowledge of the HBWC for HFPO-DA.

In response to the commenter's statement about how the EPA used an adult DWI-BW value for the derivation of the HBWC for PFHxS based on follicular cell hyperplasia in male rats—this DWI-BW was appropriately selected to correspond to the lifestage of the animals that

were exposed and showed effects (i.e., adult male rats). Likewise, the DWI-BW for the critical effect for HFPO-DA was selected based on the lifestage of the animals that were exposed and showed effects (please see section 4.3.3 of the EPA response in this *Response to Comments* document and USEPA, 2024h).

American Chemistry Council (ACC) (Doc. #1841, SBC-044833)

The Reference Dose for HFPO-DA is Based on a Flawed Scientific Approach that has not Been Subject to Appropriate Scientific Review

EPA bases the HBWC for HFPO-DA on liver effects reported in a mouse reproductive/ developmental toxicity screening study, [FN74: E.I. du Pont de Nemours and Company. An oral (gavage) reproduction/developmental toxicity screening study of H-28548 in mice. U.S. EPA OPPTS 870.3550; OECD Test Guideline 421. Conducted by WIL Research Laboratories, LLC, Ashland, OH (2010). DuPont-18405-1037.] despite considerable evidence that the effects in the liver are rodent specific and an absence of supporting data from available epidemiology studies.

Moreover, the Agency chooses to focus on the results of a reproductive/developmental study rather than a 90-day subchronic study that provides additional, relevant hepatic measurements. [FN75: E.I. du Pont de Nemours and Company. H-28548: subchronic toxicity 90-day gavage study in mice. OECD Test Guideline 408. E.I. du Pont de Nemours and Company, Newark, DE. (2010). DuPont-18405-1307.] The EPA analysis also inappropriately combines four liver effects observed in the screening study into a new toxicological endpoint of questionable toxicological relevance. The analysis compounds these problems by applying overly conservative uncertainty factors to derive the HBWC.

The Rodent Liver Effects Underpinning the HFPO-DA Assessment are not Relevant to Humans

EPA's final Toxicity Assessment for HFPO-DA acknowledges that PPARα contributes to the liver effects observed in the laboratory animals and that the PPARα mediated effects "could be more relevant to rodents than humans." The Assessment attempts to provide evidence that other MOAs with potential human relevance could also contribute, including PPAR-gamma, cytotoxicity, and mitochondrial dysfunction, however, and that the liver effects should be considered relevant to humans. [FN76: USEPA. Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (CASRN 13252-13-6 and CASRN 62037-80-3). EPA Document No. 822R-21-010. Office of Water (2021), at 29. (USEPA HFPO-DA Toxicity Assessment)]

Of critical importance in assessing the MOA, the Agency's analysis fails to consider data available from a 2020 peer-reviewed publication by Chappell et al. that provides compelling evidence that the rodent liver effects underpinning EPA's Toxicity Assessment are mediated by PPAR-α and thus are not relevant to humans. [FN77: Chappell GA et al. Assessment of the mode of action underlying the effects of GenX in mouse liver and implications for assessing human health risks. Toxicol Path 48(3):494-508 (2020).] By conducting RNA sequencing of liver

sections from a 90-day subchronic toxicity study, Chappell et al. provide further evidence for activation of PPARα in the mouse livers following HFPO exposure leading to the alteration of cell growth pathways (increased apoptosis and cell proliferation). These two events are consistent with the MOA for PPARα-induced liver tumors which has been determined to be of little relevance to humans (Corton et al. 2018). [FN78: Corton JC et al. The PPARα-dependent rodent liver tumor response is not relevant to humans: addressing misconceptions. Arch Toxicol. 92(1):83119 (2018).] The analysis also provides important information to assess the potential for other MOAs.

Despite the compelling evidence in support of a PPARα MOA, EPA proposes that there may be alternative MOAs (e.g., PPAR-gamma, cytotoxicity, and mitochondrial dysfunction) to suggest effects potentially of greater relevance to humans. EPA analysis of these alternative MOAs lacks scientific rigor and, in some instances, is not supported by the very citations relied upon by the Agency. For example, EPA misinterprets the results of the Li et al. study, which concludes that HFPO-DA has little to no PPAR-gamma binding affinity in either humans or mice and causes minimal changes in PPAR-gamma gene expression. [FN79: Li CH et al. Adipogenic activity of oligomeric hexafluoropropylene oxide (perfluorooctanoic acid alternative) through peroxisome proliferator-activated receptor γ pathway. Environ Science & Tech 53(6):3287-3295 (2019).] EPA similarly misinterprets the findings of the Conley et al. (2019) by confusing PPAR-gamma signaling versus expression and does not consider evidence demonstrating that PPAR-gamma is not highly expressed in the liver. [FN80: Conley JM et al. Adverse maternal, fetal, and postnatal Effects of Hexafluoropropylene oxide dimer acid (GenX) from oral gestational exposure in Sprague-Dawley rats. Environ Health Perspect 127(3):37008 (2019).]

EPA's analysis of the evidence for cytotoxicity or mitochondrial dysfunction as potential MOAs fails to account for all of the available information for the substance. The Agency acknowledges that gaps exist in support for a cytotoxic MOA and that evidence for increased serum liver enzymes that may be clinically relevant is conflicting or contradictory. In addition, EPA's assumption of an increase in focal necrosis is not supported by the available data. Data likewise conflict with EPA's conclusions regarding mitochondrial dysfunction. Multiple studies have demonstrated that PPAR-α, and not mitochondrial dysfunction, mediates the expression of genes involved in mitochondrial beta-oxidation in rodent livers. [FN81: See for example: Cook WS et al. Less extrahepatic induction of fatty acid beta-oxidation enzymes by PPAR alpha. Biochem Biophys Res Commun 278(1):250-7 (2000).]

Available Epidemiological Evidence Does Not Support an Effect of HFPO-DA on Liver Disease in Humans

The evidence for the rodent-specific nature of the liver effects observed in laboratory studies is supported by the available epidemiological data which show no increased risk of liver disease or cancer in populations exposed to HFPO-DA. Notably, the North Carolina Department of Health and Human Services analyzed data from the North Carolina Central Cancer Registry and found no trends of increased cancer risk in the counties with water impacted by HFPO-DA originating from a PFAS manufacturing facility. [FN82: Summary of Selected Cancer Rates for Bladen,

Brunswick, New Hanover and Pender Counties, 1996– 2015, and Comparison to Statewide Rates. https://epi.dph.ncdhhs.gov/oee/pfas/Summary%20of%20Selected%20Cancer%20Rates_all%20counties_7 Nov2018.pdf.] This finding is supported by an analysis of data from the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) Program database that shows no increased cancer risk in the counties impacted by HFPO-DA when compared to the United States or the rest of North Carolina. [FN83: Chang ET. Epidemiology of Hexafluoropropylene Oxide Dimer Acid and its Ammonium Salt. Exhibit 5 of Request for Correction of GenX Chemical Toxicity Assessment pursuant to the Information Quality Act filed by Arnold & Porter (March 18, 2022). (Arnold & Porter HFPO-DA RfC)] This analysis also concluded that available epidemiological data "do not support an effect of HFPO-DA on liver disease in humans."

The Assessment's Toxicological Endpoint for HFPO-DA is Unprecedented and Its Use Misapplies Scientific Criteria

The error in the Agency's decision to focus on liver effects is further compounded by combining observations of four separate liver effects - cytoplasmic alteration, single-cell necrosis, focal necrosis, and apoptosis – into a new and unprecedented toxicological endpoint that does not follow evaluation criteria set forth in the peer-reviewed scientific literature. EPA's assessment relies on observations by a pathology work group convened by NTP (NTP PWG) [FN84: USEPA HFPO-DA Toxicity Assessment. Appendix D: NTP PWG Final Report on the Pathology Peer Review of Liver Findings – Final Report (December 4, 2019). (NTP-PWG Report)] to reanalyze pathology cell blocks from a reproductive/developmental study in mice [FN85: E.I. du Pont de Nemours and Company. 2010. An Oral (Gavage) Reproduction/Developmental Toxicity Screening Study of H-28548 in Mice. DuPont-18405-1037. U.S. EPA OPPTS 870.3550; OECD Test Guideline 421 (2010).] using criteria set forth by Elmore et al. [Elmore SA et al. Recommendations from the INHAND apoptosis/necrosis working group. Toxicol Path 44(2):173–88 (2016).] As summarized below, however, the NTP PWG misapplies the Elmore criteria and does not consider the information in the context of available information on the MOA. [FN87: Notably, the NTP-PWG concludes that the liver lesions observed are "indicators of adversity within the confines of this study," where "[a]dversity is a term indicating 'harm' to the test animal within the constraints of a given study design." (NTP-PWG Report, at D-22). The Work Group offered no conclusions as to the relevance of the findings to human risk assessment.]

The NTP PWG's observations do not properly distinguish two possible observed effects - single-cell necrosis, on the one hand, and apoptosis, on the other. As indicated above, the PPAR-α MOA, which is not relevant to humans, results in apoptosis. Pursuant to the criteria described by Elmore et al., necrotic cells have a pale cytoplasm, whereas apoptotic cells are hypereosinophilic. [FN88: Containing a high number of a certain type of white blood cells.] However, contrary to these criteria, the NTP PWG characterizes hypereosinophilic cells as necrotic, not as apoptotic. Further, while the Elmore criteria recognize that not all apoptotic cells

are small or rounded, the NTP PWG only characterizes small or rounded cells as apoptotic. Elmore et al. also note the importance of using biochemical markers to distinguish necrosis from apoptosis. Biochemical markers—including the caspase-3 immunostaining reported by Chappell et al. — confirm apoptosis following HFPO-DA exposure.

Additionally, there are important discrepancies in the NTP PWG's observations of focal necrosis (i.e., necrosis involving larger groups of functional cells within the liver). The focal necrosis observed by the NTP PWG lacked a dose-response relationship — focal necrosis was present in some control animals, there was no statistically significant increase in test animals, and a 10-fold increase in HFPO-DA dose resulted in minimal or no increase in focal necrosis. Moreover, it is well established that focal necrosis may be caused by biological processes other than direct chemical exposure and is not necessarily a progression from single-cell necrosis. [FN89: Hall AP et al. Liver hypertrophy: a review of adaptive (adverse and non-adverse) changes – conclusions from the 3rd international ESTP expert workshop. Toxicologic Pathol 40:971-994 (2012).]

EPA then combines the four liver effects observed by the NTP PWG into a never-before- used toxicological endpoint — a so-called "constellation of liver effects." Previously, EPA relied on single-cell necrosis as the toxicological endpoint but inexplicably pivoted to this new endpoint in its final Toxicity Assessment. Not only is EPA's "constellation of liver effects" unprecedented and a significant deviation from its standard toxicity assessment methods, but it is also at odds with the science. As described above, EPA misapplies the criteria from Hall et al. in determining whether liver effects observed by the NTP PWG are adverse effects. [FN 90: Ibid.] Had EPA properly applied these scientific criteria, the Agency would have instead correctly determined that dosing levels in treated mice did not generate effects relevant to humans.

EPA's HFPO-DA Analysis Inappropriately Rejects Results from a 90-Day Study

EPA bases its HBWC for HFPO-DA on liver effects reported in a mouse reproductive/ developmental toxicity screening study, [FN91: E.I. du Pont de Nemours and Company. An oral (gavage) reproduction/developmental toxicity screening study of H-28548 in mice. U.S. EPA OPPTS 870.3550; OECD Test Guideline 421. Conducted by WIL Research Laboratories, LLC, Ashland, OH (2010). (DuPont-18405-1037)] despite the fact that a 90-day subchronic study is available that provides additional, relevant hepatic measurements. [FN92: E.I. du Pont de Nemours and Company. H-28548: subchronic toxicity 90-day gavage study in mice. OECD Test Guideline 408. E.I. du Pont de Nemours and Company, Newark, DE (2010). (DuPont-18405-1307)] Hall et al. note the importance of considering available information on histological and clinical pathological changes when evaluating the relevance of rodent liver effects to humans. Both the reproductive/development and 90-day studies provide information on liver cell necrosis, but the 90-day study also includes information on key clinical chemistry – including alanine aminotransferase (ALT), alkaline phosphatase (ALP) and aspartate aminotransferase (AST). The elevation of these enzyme levels provides important clinical correlations to the observed changes in pathology. In its assessment, EPA dismisses the results from the 90-day study because of the smaller sample size [FN93: 10 animals/exposure group versus 24/group in the

reproductive/developmental study.] without addressing the other significant aspects of the two studies.

The consistency of the necrosis data with the liver enzyme results available from the 90-day study, provides a more complete picture of what is happening in the liver than the more limited data available from the reproductive/developmental study used in the assessment. EPA's concern about the statistical power of the 90-day study is further eroded by the fact that the authors did not observe necrosis in any of the animals exposed to levels of 0.5 mg/kg-day or less. The minimal necrosis reported at these levels in the reproductive/ developmental study may suggest an adaptive, non-adverse reaction in the mice or a response to other stressors for which no acknowledgement has been made.

The decision to reject the liver results from the 90-day study also raises concerns about the approach the Agency has taken in integrating data from the various studies as part of its systematic review. Both of the studies in question were assigned an overall quality level of "High" in the Agency's data evaluation tables. [FN94: USEPA HFPO-DA Toxicity Assessment, at 32.] In particular, both studies received the best possible weighted score of "1" in relation to the number of animals per group. [FN95: USEPA. Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (CASRN 13252-13-6 and CASRN 62037-80-3). Public Comment Draft. EPA-823-P-18-001. Office of Water (2018). Appendix B. (USEPA Draft HFPO-DA Toxicity Assessment)] Any concern about the number of animals in the 90-day study should have been reflected in the data evaluation and scoring, not as part of an arbitrary decision to choose one study over another based solely on generating a lower value.

Based on the liver effects reported in the 90-day study, the lowest observed adverse effect level (LOAEL) for single cell necrosis is 5.0 mg/kg-day and the no observed adverse effect level (NOAEL) is 0.5 mg/kg-day. [FN96: Arnold & Porter HFPO-DA RfC. Exhibit 3 - Issues with the Uncertainty Factors in USEPA Toxicity Assessment (2021). Prepared by ToxStrategies, at 15. ToxStrategies indicates that no Benchmark Dose Model fits the data.] Although EPA did not conduct benchmark dose modeling (BMD) for the data available from the 90-day study on the four effects included in its constellation of liver effects, the lower bound of the BMD at 10 percent risk is calculated to be 0.2 – well above the value derived by EPA from the reproductive-developmental study. [FN97: Ibid, at 16.]

The HFPO-DA Assessment Uses Inappropriate and Significantly Inflated Uncertainty Factors

EPA's use of a 3000-fold total uncertainty factor for HFPO-DA is inconsistent with the significant amount of toxicity data available for HFPO-DA and the Agency's approach to uncertainty for other chemicals. This includes a tenfold increase in total uncertainty factors between EPA's 2018 draft assessment [FN98: USEPA Draft HFPO-DA Toxicity Assessment.] and the final Toxicity Assessment attributed to increases in the database uncertainty factor (UFD) and the subchronic-to-chronic uncertainty factor (UFS), each from 3 to 10. Ten is the maximum possible value EPA could have selected for each of these uncertainty factors. EPA's selections of

10 for these uncertainty factors is not supported by the science. Additionally, the available information does not support EPA's selection of an interspecies uncertainty factor here.

In the final Toxicity Assessment, EPA claims that new data and studies have made the database of toxicity studies for HFPO-DA more uncertain with respect to potential reproductive or developmental effects. That additional data and studies could result in more uncertainty is plainly counterintuitive, and EPA has not reasonably explained how this could be the case here. Moreover, the new studies relied upon by EPA actually reduce, rather than increase uncertainty. The observed effects in these newly considered studies do not occur until levels of exposure that are significantly higher than the point of departure identified by EPA. It is not scientifically defensible to justify increasing the UFD based on these newer studies.

EPA also indicates that the UFD is based on limited testing of developmental toxicity and immunological responses. Although data from a 2-generation reproductive toxicity and additional immunotoxicity studies would be valuable, the available evidence suggests that any developmental and immune effects are likely to occur at exposure levels that are comparable to the liver effects that are the basis of the toxicity value. Two studies investigating developmental and reproductive effects are available – the mouse study previously discussed (Dupont-18405-1037) and a prenatal developmental toxicity study in rats. [FN99: E.I. du Pont de Nemours and Company. An Oral (Gavage) Prenatal Developmental Toxicity Study of H-28548 in Rats. U.S. EPA OPPTS 850.3700; OECD Test Guideline 414. Conducted by WIL Research Laboratories, LLC Ashland, OH (2010). DuPont-18405-841] While these studies have reported developmental effects, the LOAELs and NOAELs for the most sensitive effect (pup body weight in mice) are consistent with the liver results. Similarly, a study of immunological effects which suggests T cell-dependent antibody response (TDAR) suppression in mice treated with 100 mg/kg-day [FN100: Rushing B et al. Evaluation of the immunomodulatory effects of 2,3,3,3-tetrafluoro-2(heptafluoropropoxy)- propanoate in C57BL/6 mice. Toxicol Sci 156(1):179– 189 (2017).] – well above the NOAEL/LOAEL reported in the liver studies. Other studies reported decreases in spleen weight after 28 days, but again only when treated with 100 mg/kg-day. Based on these data, it is reasonable to conclude that toxicity value generated from the liver effects observed in the 90-day study will provide sufficient protection against potential developmental and immunotoxic effects and obviates the need to assign an additional uncertainty factor.

Further, EPA reasons that since its chronic toxicity value relies on effects in female mice in a reproductive/developmental study application of an uncertainty factor of 10 is appropriate for scaling from subchronic to chronic exposure (UFS). However, there is no strong indication of a progression of rodent liver lesions with longer exposure duration. Moreover, EPA guidelines indicate that there no UFS should be applied since the critical effects in female mice are from a maternal rodent toxicity study for which "an uncertainty factor is not [to be] applied to account for duration of exposure." [FN101: USEPA. Guidelines for Developmental Toxicity Risk Assessment. EPA/600/FR-91/001. Risk Assessment Forum (1991), at 42. (USEPA Development Toxicity Guidelines)]

EPA Did Not Seek Additional Public Comment Despite Making Significant Changes to its Draft Assessment for HFPO-DA

In light of the dramatic change in both methodology and results from Agency's draft assessment in 2018 and its final Toxicity Assessment for HFPO-DA in 2021, EPA should have provided additional opportunity for public comment before publishing the final version of the assessment. The failure to provide an opportunity for stakeholder input on these changes runs counter to the appropriate notice and comment process.

EPA Response: The EPA disagrees. Please see section 4.3.3 of the EPA response in this *Response to Comments* document.

Also, the commenter repeats concerns that they expressed and the EPA addressed during the public comment period for the draft HFPO-DA toxicity assessment. As stated in USEPA (2021b):

"The reproductive developmental study (DuPont-18405-1037, 2010) has greater statistical power than that of the 90-day subchronic study (DuPont-18405-1307, 2010) because of its greater sample size/group. In the reproductive/developmental study, DuPont evaluated 22–25 mice/dose group while the 90-day study in mice used 10 mice/dose group for liver endpoints. Additionally, one female mouse per HFPO dimer acid ammonium salt dose group died before study completion, bringing the sample size to nine mice/dose group in the 90-day toxicity study in mice (DuPont-18405-1307, 2010). The difference in the number of mice per dosing group between the 90-day study and the reproductive/developmental study might have an impact on statistical power (i.e., ability to observe liver effect levels in these studies). For example, in the 90-day study, adverse effects in the liver were observed in the high-dose 5 mg/kg/day group, yet there are indications of liver damage in the 0.5 mg/kg/day group. Specifically, absolute and relative liver weight increased relative to control mice in males by 12% and 11%, respectively, at 0.5 mg/kg/day. In males dosed with 0.5 mg/kg/day, 4/10 (40%) livers were observed to be discolored, compared to 0/10 (0%) for control mice. There were also increases in serum liver proteins at 0.5 mg/kg/day in males, although they did not differ significantly from control. AST, ALP, and ALT increased 35%, 40%, and 35%, respectively, compared to control (DuPont-18405-1307, 2010). Finally, histopathological liver effects were observed at 0.5 mg/kg/day in both sexes. Specifically, the NTP Pathology Working Group (PWG; see section 4.3 or appendix D of EPA, 2021a) noted that 10/10 (100%) male mice at the 0.5 mg/kg/day dose exhibited cytoplasmic alteration, compared to 0/10 (0%) in control. ACC also claimed that the longer exposure time in the 90-day study should have improved chances to observe necrosis despite the lower statistical power. However, this was not the case as evidenced by the NOAEL (0.1 mg/kg/day) from the reproductive/developmental study, which was lower than the NOAEL from the 90-day study (0.5 mg/kg/day) (see Table 12 in the assessment). The fact that liver enzyme data were not collected in the reproductive/developmental study does not negate the liver findings of cell death that were observed and recorded by the NTP PWG (appendix D in EPA, 2021a) as part of the adverse constellation of liver lesions. Although NTP classified cytoplasmic

alteration as part of the constellation of liver lesions that are considered adverse, no other liver lesions (i.e., single-cell or focal necrosis or apoptosis) were observed at the 0.5 mg/kg/day dose level in males. Consistent with the Hall criteria (Hall et al., 2012), EPA did not consider the cytoplasmic alteration alone as an adverse effect in this dose group. Additionally, 2/9 (22%) of the female mice in the 0.5 mg/kg/day dose group exhibited focal necrosis. Because 1/10 (10%) female mice in the control group also exhibited focal necrosis, a dose response was not observed for the constellation of liver lesions in the female mice in this study. Because of the significant uncertainties in the results of the 90-day study, EPA determined that the reproductive/developmental study was not only more sensitive for liver effects but also more completely represents the constellation of hepatic effects than the chronic."

Furthermore, the EPA sought external peer review of its selection and use of the reproductive developmental study (DuPont-18405-1037, 2010) as the critical study at two different times in the toxicity assessment development process. Specifically, the first letter peer review asked peer reviewers if "the selection of the critical study and critical effect for the derivation of the subchronic and chronic RfDs for GenX chemicals [was] scientifically justified and defensible" and to "provide rationale and detail an alternative critical study" if they did not agree with the use of DuPont 18405-1037, 2010 as the critical study (USEPA, 2018b). The five peer reviewers unanimously agreed with the selection of DuPont 18405-1037 (2010) as the critical study and none of the peer reviewers identified any study deficiencies. Similarly, the second external peer review asked the seven peer reviewers if "the selection of the oral reproductive/developmental toxicity study in mice (DuPont-18405-1037, 2010) for the derivation of the subchronic and chronic RfDs for GenX chemicals [is] scientifically justified and clearly described?" (USEPA, 2021i). Again, all seven peer reviewers found the use of DuPont-18405-1037 (2010) scientifically justified. Both peer-review panels unanimously approved the EPA's selection of the critical study for RfD derivation (USEPA, 2018b and USEPA, 2021i).

In response to the commenter's claim that the EPA's analysis of alternative MOAs is not supported and that the EPA misinterpreted the findings of Li et al. (2019) and Conley et al. (2019), the EPA disagrees. The Li et al. (2019) study reported data demonstrating that HFPO-DA does bind both mouse and human PPAR gamma, albeit with lower affinity than either PFOA or HFPO-TA (trimer acid). Further, Li et al. (2019) also reported statistically significant upregulation of PPAR gamma target genes and lipid accumulation from HFPO-DA exposure in human preadipocyte cells, again with similar or lower in vitro potency than PFOA and HFPO-TA. Subsequent publications from EPA, including Houck et al. (2021) and Evans et al. (2022), reported in vitro PPAR gamma activation by HFPO-DA. Further, Conley et al. (2019) reported quantitative expression of genes in maternal and fetal livers using a targeted PPAR signaling array with statistically significant upregulation of multiple PPAR gamma target genes including Lpl, Pck1, Aqp7, Scd1, Hsp1, Gk, and Txnip, among others that are putative targets of PPAR gamma. It is well documented in the literature that PPAR gamma is expressed in the liver, but to a lesser overall degree of expression than in adipose tissue. Overall, the available data indicate that HFPO-DA is able to activate the PPAR gamma receptor, which is present in the liver and other tissues, and potentially affect biological processes associated with that receptor.

HFPO-DA. EPA's (2021b) selection of an RfD of 0.000003 mg/kg/day for HFPO-DA is likewise nconsistent with sound scientific process and guidance. Not only is the study it selected unpublished (DuPont 2010a), but EPA also selected a critical effect of "constellation of liver lesions." The study, which was a reproductive and developmental study in mice, indicated that the various hepatic effects were not consistently observed in male and female mice. However, EPA inappropriately combined these effects in order to consider it as a single critical effect, in violation of its own guidance. The resultant no-observed-adverse-effect level (NOAEL) and lowest-observed-adverse-effect level (LOAEL) values are 0.1 mg/kg-day and 0.5 mg/kg-day, respectively. EPA's IRIS Handbook states that common endpoints are "the same specific outcome measurement, not just any endpoint in a common target organ" indicating that to be combined, the observed effects have to be the same.

Combining the observed liver effects is inappropriate because some of the liver effects considered in the "critical effect" were not clearly adverse; the effects were either adaptive changes or unclear in their adversity (e.g., hepatocellular hypertrophy, enlargement of liver cells, changes in cytoplasm of liver cells) (USEPA 2021b). These effects could occur through different modes of action or were not actually adverse effects (Hall et al. 2012), which makes combining them inappropriate per EPA's IRIS Handbook. Because differences between exposed and unexposed animals were only observed when all observed liver effects were combined, EPA could not have established a NOAEL and LOAEL based on any individual effect.

EPA also violated proper systematic review processes when it inexplicably disregarded other studies that did not find such a "constellation" of hepatic effects in rodents exposed to HFPO-DA. For instance, DuPont (2010b) reported a NOAEL of 0.5 mg/kg-day in a separate unpublished mouse study, rather than a NOAEL of 0.1 mg/kg-day applied by EPA. DuPont (2010b) was unable to establish a dose-response in female mice in this study (USEPA 2021b). Similarly, hepatic effects were not observed at such low doses in a DuPont chronic rat study (DuPont 2013). These scientifically flawed practices result in a critically flawed RfD value. EPA (2021b) itself demonstrates its uncertainty in the overall evidence base with its RfD by applying an uncertainty factor of 3,000. In other words, the significant uncertainty inherent in EPA's RfD highlights its unsuitability as the basis of a regulatory value. As noted for PFHxS, an uncertainty factor of 3,000 is the maximum that could be considered as the basis of reference value according to EPA's IRIS Handbook and USEPA (2002).

EPA Response: Please see section 4.3.3 of the EPA response in this *Response to Comments* document. Commenter incorrectly asserts that the final RfD for HFPO-DA in the EPA's 2021 final toxicity assessment for HFPO-DA (US EPA, 2021b) is "inconsistent with sound scientific process and guidance," in part, because the critical study used for RfD derivation is unpublished. The EPA disagrees. First, the study was submitted to the EPA Office of Pollution Prevention and Toxics under the Toxic Substances Control Act (TSCA) (Title 15 of the U.S.C. § 2601 et seq.) pursuant to a consent order concluding new chemical review of HFPO-DA. The

consent order specifies that the submitted studies must follow the Organization for Economic Cooperation and Development (OECD) Test Guideline (TG) 407 (OECD, 2008) and meet Good Laboratory Practices (GLP) standards. The study satisfied these requirements and was accepted by the EPA under the consent order.

The study subsequently underwent a quality evaluation (internal peer review) by the EPA Office of Water as part of its development of the HFPO-DA toxicity assessment. The process of selecting Dupont 18405-1037 (2010) as EPA's critical study for its HFPO-DA toxicity assessment involved a rigorous study review and quality evaluation of all dose-response studies according to the systematic review procedures outlined in the EPA's final *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022a). The EPA selected Dupont 18405-1037 (2010) as the critical study based on an adverse outcome at the lowest tested dose from a sufficient quality study (based on study quality evaluation as part of systematic review). Also, the study report was made publicly available by the agency as part of development of the HFPO-DA toxicity assessment.

Then, the EPA sought external peer review of the agency's draft HFPO-DA toxicity assessment, including its selection and use of the critical study, at two different times in the toxicity assessment development process. Specifically, the first letter peer review asked peer reviewers if "the selection of the critical study and critical effect for the derivation of the subchronic and chronic RfDs for GenX chemicals [was] scientifically justified and defensible" and to "provide rationale and detail an alternative critical study" if they did not agree with the use of DuPont 18405-1037 (2010) as the critical study (USEPA, 2018b). The five (5) peer reviewers unanimously agreed with the selection of DuPont 18405-1037 (2010) as the critical study and none of the peer reviewers identified any study deficiencies. Similarly, a second external peer review asked seven (7) peer reviewers if "the selection of the oral reproductive/developmental toxicity study in mice (DuPont-18405-1037, 2010) for the derivation of the subchronic and chronic RfDs for GenX chemicals [is] scientifically justified and clearly described?" (USEPA, 2021i). Again, all seven peer reviewers found the use of DuPont-18405-1037 (2010) scientifically justified. Both peer-review panels unanimously approved the EPA's selection of the critical study for RfD derivation (USEPA, 2018b and USEPA, 2021i).

To summarize, the study was conducted following established international guidelines and GLPs, was accepted by the EPA under TSCA, underwent a quality evaluation (internal peer review) by human health scientists in the EPA Office of Water, and was externally peer reviewed twice as the critical study in the HFPO-DA toxicity assessment (and made publicly available as part of assessment development). These review processes and standards are consistent with the EPA using the "best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data)" per SDWA. For the above-described reasons, it was appropriate for the EPA to consider DuPont-18405-1037 (2010) as the critical study.

The agency has a long history of using study reports produced by contractors or industry as critical studies in EPA human health risk assessments for pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and industrial chemicals under TSCA. These types of studies submitted by industry may be important for new and emerging chemicals for which there may not be a robust database of studies publicly available in peer reviewed journals. Additionally, the EPA notes that other recent toxicity assessments for PFAS (e.g., USEPA, 2023m; USEPA, 2023n) also rely on industry-conducted studies as the critical studies. The practice is also recognized by and consistent with the ORD Staff Handbook for Developing IRIS Assessments (Table 2-5) which indicates that strategies for literature identification can include the identification of "Unpublished studies, information submitted to EPA under TSCA Section 4 (chemical testing results); Section 8(d) (health and safety studies); Section 8(e) (substantial risk of injury to health or the environment notices)." For purposes of development of drinking water standards, any supporting information or studies would need to meet the requirements of Section 1412(b).

Regarding the commenter's claim that the EPA inappropriately combined the liver effects observed in the critical study in order to consider it as a single critical effect, in violation of its own guidance—the EPA disagrees. The text from the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022a) quoted by the commenter is from a section of the Handbook that describes possible considerations a risk assessor might consider when judging whether to perform dose-response modeling of data combined from multiple different studies. This quoted text from the Handbook is taken out of context and is not applicable to the critical study and effect selection for HFPO-DA, which did not combine data from multiple different studies, nor does the quoted text represent a requirement of the process outlined in the Handbook that must be followed. Also, as described above, two external peer review panels agreed with the use of the constellation of liver lesions as the critical effect.

<u>The Chemours Company FC, LLC (Doc. #1845, SBC-046053)</u>

II. EPA's proposed regulation of HFPO-DA is also arbitrary and capricious because it is based on substantial scientific flaws

As discussed above, EPA is proposing to regulate HFPO-DA as part of a Hazard Index for mixtures of multiple PFAS compounds, using a HBWC level of 10 ppt for HFPO- DA. To derive this 10 ppt level for HFPO-DA, EPA started with its 2021 Human Health Toxicity Assessment for GenX Chemicals ("HFPO-DA toxicity assessment") and the chronic reference dose it calculated therein, based on a "constellation" of liver effects observed in mice exposed to HFPO-DA multiplied by 3,000 times uncertainty factors. PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18638, 18646 (proposed Mar. 29, 2023). On top of that extremely conservative reference dose, EPA then applied a 20% relative source contribution ("RSC") factor based on the default assumption, not supported by the actual data, that 20% of HFPO-DA exposure occurs through drinking water and the remaining 80% occurs through other sources. Id. The resulting 10 ppt level for HFPO-DA is the same as EPA's 2022 drinking water

health advisory level for HFPO-DA. Id. Then, for this Proposed Rulemaking, EPA effectively ratcheted the level down even further by including it as part of a Hazard Index for mixtures of multiple PFAS compounds, such that lower levels of HFPO-DA could contribute to exceedances of the Hazard Index if other compounds in the Hazard Index are also detected. In fact, depending on the levels at which the other PFAS compounds are detected, the MCL for HFPO-DA could effectively be zero.

Chemours has previously made several submissions to EPA regarding the scientific flaws in EPA's HFPO-DA toxicity assessment, RSC, and health advisory, including:

• January 13, 2022 presentation slides from Chemours meeting with EPA Office of Water

• January 28, 2022 email from Sheryl Telford, Chemours, to Zach Schafer and Matthew Klasen, EPA, with attached meeting presentation

• March 18, 2022 Request for Correction Letter and Exhibits

• April 29, 2022 email from Sheryl Telford, Chemours, to Betsy Behl, EPA, with attached meeting presentation

• April 29, 2022 follow-up email from Sheryl Telford, Chemours, to Betsy Behl, EPA

• May 25, 2022 email from Sheryl Telford, Chemours, to Betsy Behl, EPA

• May 27, 2022 Request for Correction Supplement

• May 31, 2022 letter from Sheryl Telford, Chemours, to Betsy Behl, EPA, and attached studies

• February 7, 2023 email from Sheryl Telford, Chemours, to Betsy Behl, EPA, with attached studies

Chemours hereby incorporates these prior submissions into these comments and requests that they be added to the administrative record for this rulemaking.

Additionally, Chemours has filed a petition for review of EPA's HFPO-DA health advisory in the United States Court of Appeals for the Third Circuit, and that proceeding remains pending. Chemours v. U.S. EPA, Case No. 22-2287. Chemours incorporates into these comments its briefings filed in the Third Circuit proceeding, and requests that those briefings and the administrative record for that proceeding be added to the administrative record for this rulemaking. Chemours also requests that EPA's responses to Chemours' Freedom of Information Act ("FOIA") request for records concerning EPA's HFPO-DA toxicity assessment be added to the administrative record for this rulemaking.[FN16: FOIA Request No. EPA-2022-000577, available at https://foiaonline.gov/foiaonline/action/public/submissionDetails?trackingNumber=EPA-2022-000577&type=request.]

The subsections that follow provide a brief summary of the scientific flaws at every step of EPA's development of its proposed regulation of HFPO-DA—from its HFPO-DA toxicity

assessment and reference dose, to its default exposure assumptions and relative source contribution, to its aggregation of HFPO-DA with multiple other compounds in a Hazard Index. Further details are provided in the materials listed above and incorporated herein by reference, and in the supporting technical comments prepared by Dr. Chad Thompson and Dr. Melissa Heintz, attached hereto as Exhibit 1.

A. EPA's toxicity assessment and corresponding reference dose for HFPO-DA are scientifically flawed

EPA's HFPO-DA toxicity assessment, and the reference dose calculated therein, contains significant deviations from standard EPA toxicity assessment methods and is not supported by the weight of scientific evidence. For example, and as set forth in detail in Chemours' March 18, 2022 Request for Correction Letter and Exhibits and in the attached technical comments of Dr. Chad Thompson and Dr. Melissa Heintz:

• The rodent liver effects underpinning the assessment are peroxisome proliferator- activated receptor alpha ("PPAR-alpha") effects that are not relevant to humans.

• The assessment did not evaluate—or even acknowledge—a critically important 2020 peer-reviewed published study by Dr. Grace A. Chappell et al. that provides compelling additional evidence that the rodent liver effects underpinning the assessment are not relevant to humans.[FN17: See Chappell, G.A., C.M. Thompson, J.C. Wolf, J.M. Cullen, J.E. Klaunig, and L.C. Haws. 2020. Assessment of the Mode of Action Underlying the Effects of GenX in Mouse Liver and Implications for Assessing Human Health Risks. Toxicologic Pathology 48(3):494-508.]

• References in the assessment to non-PPAR-alpha modes of action are not supported by scientific data and are, in some cases, directly contradicted by the very sources relied upon by EPA.

• The assessment relies on observations by the National Toxicology Program Pathology Working Group ("NTP PWG") that do not follow evaluation criteria set forth in the peer-reviewed scientific literature.

• The assessment's new toxicological endpoint—a "constellation of liver effects"— is unprecedented, and misapplies scientific criteria in determining whether observed effects are in fact adverse effects in the context of a human health risk assessment.

• EPA did not take into account available epidemiological evidence showing no increased risk of cancers or liver disease attributable to exposure to HFPO-DA.

Further, EPA's HFPO-DA toxicity assessment uses inappropriate and significantly inflated uncertainty factors that are inconsistent with EPA's own guidance and practice in other toxicity assessments. In fact, one of EPA's external peer reviewers described EPA's uncertainty factors in the HFPO-DA toxicity assessment as "extreme" and "excessive."[FN18: U.S. EPA, EPA Doc. No. 822R-21-009, Response to Additional Focused External Peer Review of Draft Human Health

Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (GenX Chemicals) at 18 (Oct. 2021), https://www.epa.gov/system/files/documents/2021-10/epa_2nd- response-to-peer-review_genx_508.pdf (comments of David Alan Warren, MPH, Ph.D., Program Dir., Env't Health Sci., Univ. of S.C. Beaufort).]

Additional scientific research sponsored by Chemours and conducted since EPA's 2021 HFPO-DA toxicity assessment further underscores the assessment's scientific flaws. This research has already resulted in three studies, all approved for publication by independent, peer-reviewed journals, that provide further compelling and direct evidence that the rodent liver effects from HFPO-DA are mediated through the PPAR-alpha mode of action that is not relevant to humans.[FN19: Melissa M. Heintz et al., Evaluation of Transcriptomic Responses in Livers of Mice Exposed to the Short- Chain PFAS Compound HFPO-DA, 4 Front. Toxic. 1 (2022); Melissa M. Heintz et al., Assessment of the Mode of Action Underlying Development of Liver Lesions in Mice Following Oral Exposure to HFPO-DA and Relevance to Humans, 192 Toxic. Scis. 15 (2023); Chad M. Thompson et al., Assessment of Mouse Liver Histopathology Following Exposure to HFPO-DA with Emphasis on Understanding Mechanisms of Hepatocellular Death, Toxic. Pathology (Mar. 2023).] Additionally, the in vitro human and rodent hepatocyte study that Chemours is sponsoring is in the analysis phase, and publication of the results is expected to be forthcoming. The data collected from that study also show that the rodent liver effects from HFPO-DA are mediated through the PPAR-alpha mode of action and not the alternative modes of action hypothesized by EPA in its HFPO-DA toxicity assessment. The findings from this study provide additional compelling evidence that the rodent liver effects should not be used as the basis for the toxicity value for HFPO- DA, which underpins EPA's proposed regulation here.

B. EPA's default exposure assumptions and corresponding relative source contribution for HFPO-DA are scientifically flawed

On top of its flawed HFPO-DA toxicity assessment and corresponding reference dose, discussed above, EPA then applied a 20% relative source contribution ("RSC") factor (i.e., an additional fivefold downward adjustment) based on the default assumption, not supported by the actual data, that 20% of HFPO-DA exposure occurs through drinking water and the remaining 80% occurs through other sources.[FN20: This default assumption is not only unsupported by science, but also exceeded EPA's statutory authority under the SDWA, which is expressly limited to regulating contaminants "in water." 42 U.S.C. [sec] 300f(6). This constraint leaves no room for EPA to set levels based on other exposures covered by other regulatory regimes—much less to ground a MCL primarily (80%) on assumed non-drinking-water exposures.] As purported justification for selecting a 20% RSC for HFPO-DA, EPA cited to guidance it had issued under the Clean Water Act, which cabins the range of RSC values from a maximum of 80% to a minimum of 20%.[FN21: U.S. EPA, EPA Doc. No. 822-B-00-004, Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000), https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=20003D2R.txt.] But that guidance permits use of the 20% minimum as a "default" assumption only "when adequate exposure data do not

exist," and strongly cautions against using the minimum default when "available" information "more accurately reflects exposures than automatically using a default value."[FN22: Id.]

There is no indication that EPA has assessed the available data on potential sources of public exposure to HFPO-DA. But Chemours previously provided EPA with 22 independent reports containing exposure data from the United States, Europe, and China, which uniformly showed that the "only relevant exposure pathway for HFPO-DA is drinking water" and there are no significant levels of exposure from other sources such as food, dust, air, soil, consumer products, and firefighting foam.[FN23: Letter and Attachments from Sheryl Telford, Chemours, to Elizabeth (Betsy) Behl, U.S. EPA (May 31, 2022).] EPA has also had in its possession federally generated data, collected by the Agency for Toxic Substances and Disease Registry, which had monitored several separate "Exposure Assessment" sites and found that HFPO-DA "was not detected in any urine or dust samples" at any of the sites.[FN24: EPA Doc. No. ED_006421_00013324-00001, FOIA Request No. EPA-2022-000577, available at https://foiaonline.gov/foiaonline/action/public/submissionDetails?trackingNumber=EPA-2022-000577&type=request.] EPA has not, and cannot, explain why, despite all this data, it is appropriate to continue using the 20% default assumption for a nationwide regulation.

EPA's use of the 20% default assumption appears to reflect its underlying and incorrect view that public exposure to HFPO-DA will mirror that of PFOA, which was used far more extensively than HFPO-DA. For example, internal correspondence involving the Director of EPA's Health and Ecological Criteria Division stated (incorrectly) that HFPO-DA "may be used in the manufacture of the same or similar commercial fluoropolymer end products which formerly used PFOA."[FN25: EPA Doc. No. ED_006421_00011953-00001, FOIA Request No. EPA-2022-000577, available at https://foiaonline.gov/foiaonline/action/public/submissionDetails?trackingNumber=EPA-2022-000577&type=request] And in its HFPO-DA health advisory, EPA stated (again incorrectly) that "[s]ince GenX chemicals are substitutes for PFOA, products (e.g., some nonstick coatings, aqueous film-forming foam [AFFF]) that were previously made using PFOA may now rely on GenX chemicals."[FN26: U.S. EPA, Drinking Water Health Advisory: Hexafluoropropylene Oxide (HFPO) Dimer Acid (CASRN 13252-13-6) and HFPO Dimer Acid Ammonium Salt (CASRN 62037-80-3), Also Known as "GenX Chemicals" (2022), https://www.epa.gov/system/files/documents/2022-06/drinking-water-genx-2022.pdf.]

Chemours has previously explained to EPA multiple times that this assumption about HFPO-DA is incorrect.[FN27: See, e.g., Email from Sheryl Telford, Chemours, to Elizabeth (Betsy) Behl, U.S. EPA (May 25, 2022).] HFPO-DA was developed by one company as a replacement for PFOA's use as a polymerization aid; that industrial process is HFPO-DA's sole use by Chemours, and the only use for which it is legally authorized.[FN28: Id.] As a result, HFPO-DA did not replace PFOA's wide variety consumer-facing applications.[FN29: Id.] And in fact, studies show that no significant exposure levels of HFPO-DA have been found in such consumer-facing products.[FN30: Letter and Attachments from Sheryl Telford, Chemours, to Elizabeth (Betsy) Behl, U.S. EPA (May 31, 2022).]

In sum, there is simply no scientific basis for EPA's 20% RSC for HFPO-DA, as data overwhelmingly show that any HFPO-DA exposure occurs through drinking water and not through other sources. The data support the use of a RSC value of at least 80% within the context of EPA's guidance range.

EPA Response: Please see section 4.3.3 of the EPA response in this *Response to Comments* document. For comments related to dose additivity and the Hazard Index approach, please see sections 4.3.1 and 4.3.2, respectively, of the EPA response in this *Response to Comments* document.

With respect to Chemours' previous submissions to the EPA regarding the toxicity assessment, RSC, and HA, these submissions were not submitted to the EPA as part of this public comment process for this PFAS NPDWR and were instead provided to EPA by the commenter in a different context. Because they were not submitted during the public comment period and the commenter only referred to the documents and did not re-iterate the content of the referred documents in its comment letter for this rule, EPA is not obligated to address them as part of this rulemaking. Nevertheless, to the extent that the EPA could locate these referred documents, the EPA reviewed them and considered whether the issues within were addressed elsewhere in this *Response to Comments* document.

- January 13, 2022 presentation slides from Chemours meeting with EPA Office of Water.
    - The EPA has reviewed these slides related to development of the HFPO-DA RfD (e.g., regarding the critical effect, application of uncertainty factors, MOA), and all comments have been addressed. See EPA Essay Response 4.3.3 and preamble section III.
- January 28, 2022 email from Sheryl Telford, Chemours, to Zach Schafer and Matthew Klasen, EPA, with attached meeting presentation.
    - The EPA has reviewed these slides related to development of the HFPO-DA RfD (e.g., regarding the critical effect, application of uncertainty factors, MOA), and all comments have been addressed. See EPA Essay Response 4.3.3 and preamble section III.
- March 18, 2022 Request for Correction Letter and Exhibits.
    - The EPA reviewed this submission and responded as part of the agency's response to the Chemours request for correction (USEPA, 2022d).
- April 29, 2022 email from Sheryl Telford, Chemours, to Betsy Behl, EPA, with attached meeting presentation.
    - The EPA reviewed this submission which included studies relevant to RSC (see below EPA response to Part B).

- April 29, 2022 follow-up email from Sheryl Telford, Chemours, to Betsy Behl, EPA
    - The EPA was unable to locate this document.
- May 25, 2022 email from Sheryl Telford, Chemours, to Betsy Behl, EPA.
    - The EPA reviewed this email related to RSC. See below EPA response to Part B.
- May 27, 2022 Request for Correction Supplement
    - The EPA reviewed this submission which includes a study protocol related to MOA; see the EPA Essay Response 4.3.3 and preamble section III.
- May 31, 2022 letter from Sheryl Telford, Chemours, to Betsy Behl, EPA, and attached studies
    - The EPA reviewed this letter and attached studies related to RSC. See below EPA response to Part B.
- February 7, 2023 email from Sheryl Telford, Chemours, to Betsy Behl, EPA, with attached studies
    - The EPA reviewed this submission, which included four studies: Lea et al. 2022.; Heintz et al. 2022; Heintz et al. 2023; Thompson et al. 2023. The EPA has reviewed all of these studies; please see section 4.3.3 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1845, SBC-046064 in section 4.3.3 in this *Response to Comments* document.

Response to Part A of comment: As the commenter points out, their perceived issues with the HFPO-DA toxicity assessment related to non-PPAR-alpha modes of action, the NTP PWG's evaluation criteria, the constellation of liver lesions, supposed epidemiological evidence, and inflated uncertainty factors were detailed in the Chemours' March 18, 2022 Request for Correction Letter. However, the commenter fails to mention that the EPA denied Chemours' request for correction (which was submitted by Arnold & Porter (A&P) on Chemours' behalf) because "the scientific information described in this [request for correction] would not alter the conclusions of the GenX chemicals toxicity assessment. The EPA does not find that the A&P submission identified errors in the 2021 toxicity assessment or that the process used by EPA was flawed. The points raised by A&P have either been considered and addressed during the peer review process for the GenX chemicals toxicity assessment or would not meaningfully impact the assessment." It is important to note that the EPA provided detailed responses to each of these critiques in 2022 in EPA's Response to RFC 22001 (https://www.epa.gov/system/files/documents/2022-06/RFC_22001_Response_June2022.pdf). Please see section 4.3.3 of the EPA response in this *Response to Comments* document for EPA's reconsideration of these same issues as part of the rulemaking process.

With respect to the quoted language from Dr. Warren's response in the *second* external peer review of the HFPO-DA toxicity assessment, the EPA provided a detailed response to Dr. Warren in its response to peer review on pages 22-23 (https://www.epa.gov/system/files/documents/2021-10/epa_2nd-response-to-peer-review_genx_508.pdf). Additionally, Dr. Warren used comparisons between the values of the HFPO-DA RfD and the PFOA/PFOS RfDs derived in 2016 to justify his remarks that the application of a composite UF of 3,000 is "an extreme application of the precautionary principle." As the EPA pointed out at the time, "altering the UFs to achieve an RfD for GenX chemicals that is closer to the RfDs derived for perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS) is not in line with EPA guidance. It is not surprising that more uncertainty is associated with GenX chemicals given their more recent (2015) detection in drinking water. PFOA and PFOS have been extensively studied in the peer reviewed literature for at least the past 30 years and the toxicological data for these chemicals is quantitatively large and comprehensive when compared to the GenX chemicals toxicological database" (USEPA, 2021i). Additionally, the updated RfDs for PFOA and PFOS (USEPA, 2024i and USEPA, 2024k), which postdate the 2021 HFPO-DA toxicity assessment, are orders of magnitude lower than the HFPO-DA RfD, therefore making Dr. Warren's argument moot.

Finally, with respect to the additional scientific studies sponsored by Chemours, please see section 4.3.3 of the EPA response in this *Response to Comments* document.

Response to Part B of comment: Please see section 4.3.3 of the EPA response in this *Response to Comments* document as well as the Hazard Index MCLG support document (USEPA, 2024h) for a complete description of the RSC determination process for HFPO-DA, which was consistent with EPA methodology (USEPA, 2000c).

Regarding the comment criticizing EPA's reference to a Clean Water Act document describing EPA's standard procedure for considering the relative source contribution (USEPA, 2000c), that document explicitly stated that it was adopting EPA's use of relative source contributions under the SDWA to provide a uniform approach to risk assessment in the Office of Water. iIn response to the commenter's statement that the commenter previously provided the EPA with 22 documents (i.e., websites, slides, reports) containing exposure data for HFPO-DA: These 22 documents were not provided to the EPA as part of this public comment process for this PFAS NPDWR and were instead provided to EPA by the commenter in a different context; therefore, the EPA is not obligated to address them as part of this rulemaking. At the time when these 22 documents were provided to EPA, the EPA reviewed them for inclusion in the RSC analysis for HFPO-DA during the development of the draft HFPO-DA MCLG and HBWC for the PFAS rule proposal (US EPA, 2023). Nevertheless, the EPA considered these 22 documents a second time within this rule making context for potential inclusion in the RSC analysis. Ten of the 22 documents had already been considered as part of the EPA's RSC derivation process for the proposed HFPO-DA MCLG and HBWC. The EPA's re-review found that others were unsuitable for inclusion in the RSC derivation process for this final rule, as described in Table 4. Based on the EPA's re-review, three additional documents were included by the EPA as part of RSC

derivation for the final HFPO-DA MCLG and HBWC, but none made a quantitative impact on the RSC determination. The table below presents summary information about the 22 documents that were provided, and whether they were included in the RSC derivation process for HFPO-DA in the final rule.

Table 4. Disposition of the EPA's Review of 22 Documents Provided by Chemours in 2022

Document Citation	Included in Final HFPO-DA RSC Determination Process? Y/N; Reasons for Inclusion/Exclusion
Geosyntec. 2019. Offsite Human Health Screening Level Exposure Assessment (SLEA) of Table 3+ PFAS. Chemours Fayetteville Works. Geosyntec Project Number TR0795. www.deq.nc.gov/genx/consentorder/paragraph-16/fw-cap-final-12-31-2019-appendix-f/download Straková et al. 2021.Throwaway Packaging, Forever Chemicals: European wide survey of PFAS in disposable food packaging and tableware. 54 p. https://arnika.org/en/publications/throwaway-packaging-forever-chemicals-european-wide-survey-of-pfas-in-disposable-food-packaging-and-tableware Burkhard. 2020. Evaluation of Published Bioconcentration Factor (BCF) and Bioaccumulation Factor (BAF) Data for Per- and Polyfluoroalkyl Substances Across Aquatic Species. Environmental Toxicology and Chemistry. https://setac.onlinelibrary.wiley.com/doi/full/10.1002/etc.5010.	Yes; added to the studies considered in the RSC determination for HFPO-DA that was used to derive the final MCLG and HBWC; Included because these studies were relevant to HFPO-DA, were publicly available, and met the SDWA data quality requirements (i.e., data collected by accepted methods or best available methods).
US FDA. [webpage]. Analytical Results of Testing Food for PFAS from Environmental Contamination. (www.fda.gov/food/chemical-contaminants-food/analytical-results-testing-food-pfas-environmental-contamination). Last updated 9/29/23 Mengelers et al. 2018. Risk assessment of GenX and PFOA in vegetable garden crops in Dordrecht, Papendrecht and Sliedrecht. Risicobeoordeling van GenX en PFOA in moestuingewassen in Dordrecht, Papendrecht en Sliedrecht RIVM briefrapport 2018 0017. Brandsma et al. 2019. The PFOA substitute GenX detected in the environment near a fluoropolymer manufacturing plant in the Netherlands. Chemosphere. 2019;220:493 500. doi:10.1016/j.chemosphere.2018.12.135 Feng et al. 2021. External and internal human exposure to PFOA and HFPOs around a mega fluorochemical industrial	Yes; already included in the studies considered in the RSC determination for HFPO-DA that was used to derive the proposed MCLG and HBWC; Included because these studies were relevant to HFPO-DA, were publicly available, and met the SDWA data quality requirements (i.e., data collected by accepted methods or best available methods).

Document Citation	Included in Final HFPO-DA RSC Determination Process? Y/N; Reasons for Inclusion/Exclusion
park, China: Differences and implications. Environ Int. 2021;157:106824. doi:10.1016/j.envint.2021.106824 Galloway et al. 2020. Evidence of Air Dispersion: HFPO-DA and PFOA in Ohio and West Virginia Surface Water and Soil near a Fluoropolymer Production Facility. Environ Sci Technol. 2020;54(12):7175-7184. doi:10.1021/acs.est.9b07384 Li et al. 2021. First Report on the Bioaccumulation and Trophic Transfer of Perfluoroalkyl Ether Carboxylic Acids in Estuarine Food Web [published online ahead of print, 2021 Jul 23]. Environ Sci Technol. 2021;10.1021/acs.est.1c00965. doi:10.1021/acs.est.1c00965 Pan et al. 2017. First Report on the Occurrence and Bioaccumulation of Hexafluoropropylene Oxide Trimer Acid: An Emerging Concern. Semerád et al. 2020. Screening for 32 per-and polyfluoroalkyl substances (PFAS) including GenX in sludges from 43 WWTPs located in the Czech Republic - Evaluation of potential accumulation in vegetables after application of biosolids. Chemosphere. doi:10.1016/j.chemosphere.2020.128018	
2019 Risk Assessment of GenX and PFOA in Food Pt 1: Toxicity of GenX and PFOA and Intake through Contaminated Food of Animal Origin. Wageningen University and Research, National Institute for Public Health and the Environment	No (Note: A 2022 revised version of this report is available). Excluded because this risk assessment contains little detail about methodology, and the exposure data consists of a few paragraphs and one table of results. Sample size for exposure data is one (1) in some cases.
Holden et al. 2021. GenX and PFAS uptake by Food Plants. https://ncpfastnetwork.com/wp-content/uploads/sites/1328/2023/05/genx-and-pfas-uptake-by-food-plants.pdf	No; excluded because this is a presentation slide deck. The data cited in the slides (FDA--Ginualdi, deJager, Begley 2019) had already been included by the EPA in the RSC

Document Citation	Included in Final HFPO-DA RSC Determination Process? Y/N; Reasons for Inclusion/Exclusion
	derivation for HFPO-DA at the time of rule proposal.
Gebbink et al. 2020. Environmental contamination and human exposure to PFASs near a fluorochemical production plant: Review of historic and current PFOA and GenX contamination in the Netherlands. Environ Int. 2020;137:105583. doi:10.1016/j.envint.2020.105583 Xiao et al. 2017. Emerging poly- and perfluoroalkyl substances in the aquatic environment: A review of current literature. Water Research. https://doi.org/10.1016/j.watres.2017.07.024	Yes; already included in the studies considered in the RSC determination for HFPO-DA that was used to derive the proposed MCLG and HBWC. Each of these papers is a literature review and contains no original data. All original studies (in English language) cited in these reviews had already been included in the RSC derivation process for the proposed rule.
Miller et al. 2021. PFAS mass balance in retail biosolids fertilizers and what can be done about it. http://hdl.handle.net/2142/109875	No; excluded because this is a presentation slide deck, and it is not specific to HFPO-DA.
US FDA. [webpage]. Authorized Uses of PFAS in Food Contact Applications; https://www.fda.gov/food/chemical-contaminants-food/authorized-uses-pfas-food-contact-applications. Webpage content reportedly current as of 2/28/2024	No; excluded because this is not HFPO-DA-specific. The subject of the information on this webpage is FDA-authorized uses of PFAS.
Barzen-Hanson et al. 2017. Discovery of 40 Classes of Per- and Polyfluoroalkyl Substances in Historical Aqueous Film-Forming Foams (AFFFs)and AFFF-Impacted Groundwater. Environ Sci Technol. 2017;51(4):2047-2057. doi:10.1021/acs.est.6b05843	No; excluded because HFPO-DA is not mentioned in this paper.
Higgins and Luthy. 2006. Sorption of Perfluorinated Surfactants on Sediments. Environmental Science and Technology. DOI: 10.1021/es061000n Aro et al. 2021. Fluorine mass balance analysis of selected environmental samples from Norway. Chemosphere. doi:10.1016/j.chemosphere.2021.131200	No; excluded because HFPO-DA was not assessed.

Document Citation	Included in Final HFPO-DA RSC Determination Process? Y/N; Reasons for Inclusion/Exclusion
Wang et al. 2022. Concentrations of Hexafluoropropylene Oxide Dimer Acid (HFPO DA) in Environmental Media in the US (in prep). Wang et al. 2022. Concentrations of Hexafluoropropylene Oxide Dimer Acid (HFPO DA) in Environmental Media in China (in prep).	No; Excluded because these 5- to 6-page data reports, contain incomplete reporting descriptions of exposure findings and lack information about methods, and are not readily publicly available (i.e., only found online via exact title search, and hosted on website of unknown authority/reputability [static1.squarespace.com]).

With regard to the comment related to the use of HFPO-DA as compared to PFOA, HFPO-DA was developed by one company (Chemours) as a replacement for PFOA's use as a polymerization aid. For the Chemical Data Reporting for the 2020 reporting year, Chemours was the sole company that reported the manufacture or import of HFPO-DA, which was reported to be used as a processing aid. Chemical usage information may inform RSC derivation, and it is especially important when there are no occurrence data for a particular chemical. In the case of HFPO-DA, there is some occurrence information available, and these data suggest that there are several relevant HFPO-DA exposures and pathways beyond drinking water, including dietary consumption, incidental oral consumption via dust and soil or dermal exposure via soil and dust, and inhalation exposure via ambient air (USEPA, 2024h). Several of these may be potentially significant exposure sources to people in the US. Following the EPA's longstanding, peer-reviewed approach for deriving the RSC of the Exposure Decision Tree (USEPA, 2000c), the EPA determined that an RSC of 20 percent (0.20) was appropriate to calculate the HFPO-DA MCLG and HBWC.

4.3.4 Number of Significant Digits

Summary of Major Public Comments and EPA Responses

The EPA received comments on the number of significant digits used for the HBWCs and the Hazard Index MCLG (and MCL). Commenters noted the importance of clearly communicating the number of significant digits to be used in the documents, and that the choice of the number of significant digits could impact implementation of an MCL based on the Hazard Index. A few commenters did not support more than a single significant digit for the HBWCs and Hazard Index MCLG (and Hazard Index MCL), with some stating that using two or more significant digits for the Hazard Index contradicts the EPA chemical mixtures guidance (USEPA, 2000b and USEPA, 1991c). A few commenters supported the use of two significant digits for the HBWCs,

individual HQs, and the Hazard Index MCLG and stated that the use of two significant digits would not be expected to result in issues related to analytical methods precision. One commenter supported using all digits of precision in calculations but rounding to two significant digits for the final reported value of the Hazard Index, noting that the number of significant digits used only affects rounding during steps prior to the point at which a Hazard Index MCL is reached. The EPA response to comments on these issues, as well as others expressed by individual commenters, are described in further detail below. The agency further notes that since the Hazard Index level is set at the MCLG, the EPA responses to comments pertaining to the use of significant figures for the Hazard Index MCL are applicable to those commenters as well. For additional discussion on the PFAS Hazard Index MCL, please see section 5.2 of the EPA response in this *Response to Comments* document.

The EPA proposed a Hazard Index MCLG of 1.0, expressed with two significant digits. The EPA's proposal expressed the HBWCs to the tenths place, as follows: 9.0 ppt for PFHxS, 10.0 ppt for HFPO-DA; 10.0 ppt for PFNA; and 2000.0 ppt for PFBS. The EPA's draft Hazard Index MCLG support document expressed all of the HBWCs with one significant digit (9, 10, 10, 2000 ppt, respectively) (USEPA, 2023o).

For the final rule, the EPA agrees with commenters who did not support more than a single significant digit for the HBWCs and Hazard Index MCLG (and Hazard Index MCL). The EPA has determined that one (1) significant digit is appropriate for the HBWCs (i.e., 10 ng/L each for PFHxS, PFNA, and HFPO-DA and 2000 ng/L for PFBS), the Hazard Index MCLG (and Hazard Index MCL) (i.e., a Hazard Index MCL and MCLG of 1 rather than 1.0), and for the individual MCLGs (and individual MCLs) for PFHxS, PFNA, and HFPO-DA. The HBWCs/MCLGs have one significant digit because although there is sufficient analytical precision to measure to the tenths place in parts per trillion (nanograms per liter) (as described in section 5.1.7 of this *Response to Comments* document), the toxicity reference values (RfDs and minimal risk levels) used to derive these values have one significant digit. In this final rule, the EPA is following the generally accepted practice of rounding the number of significant figures at the end of a calculation to the same number of significant figures in the least precise parameter (in this case, the RfD) (USEPA, 2000a; APHA, 1992; Brinker, 1984). The general rule is that for multiplication or division, the resulting value (in this case, the HBWC/MCLG) should not possess any more significant figures than is associated with the factor in the calculation with the least precision (in this case, the RfD) (USEPA, 2000a). The agency also considered the requirement under SDWA that an MCL must be set as close as feasible to the MCLG. Specific to the Hazard Index, according to the EPA chemical mixtures guidance (USEPA, 2000b), "Because the RfDs (and by inference the TTDs) are described as having precision no better than an order of magnitude, the HI should be rounded to no more than one significant digit." This approach of using a Hazard Index of 1 is consistent with agency chemical mixtures guidance (USEPA, 1986; 2000b) and Superfund risk assessment guidance (USEPA, 1991c; USEPA, 2018c). The EPA's *Risk Assessment Guidance for Superfund Volume 1 Human Health Evaluation Manual* states, "For noncarcinogenic effects, a concentration is calculated that corresponds to an HI of 1, which is the level of exposure to a chemical from all significant exposure pathways in a given medium

below which it is unlikely for even sensitive populations to experience adverse health effects," and "The total risk for noncarcinogenic effects is set at an HI of 1 for each chemical in a particular medium" (USEPA, 1991c). Also, "Cancer risk values and hazard index (HI) values may express more than one significant figure, but for decision-making purposes one significant figure should be used" (USEPA, 2018c).

Individual Public Comments and EPA Responses

Philadelphia Water Department (PWD) (Doc. #1709, SBC-045748)

12. EPA requests comments on the derivation of the HBWC for each of the four PFAS considered and on significant figures.

In section IV.A, In the explanation for the determination of MCLG (and HBWC) values, EPA defines the formula for calculating the MCLG based on the Reference Dose (RfD), drinking water intake-body weight (DWI-BW), and Relative source criteria (RSC) as:

[Equation 1: see docket ID EPA-HQ-OQ-2022-0114-1709]

In section V.C.2 of the preamble of the proposed rule, EPA defines the RfD and DWI-BW for the four PFAS compounds included in the Hazard Index. The calculations are further detailed in rulemaking reference USEPA 2023a, with step-by-step calculation of each of the four HBWCs. Throughout the preamble of this rulemaking, supporting reference documents, and in the rulemaking itself, there is inconsistent use of significant figures for the HBWC values. In the proposed rulemaking, the proposed HBWC values are reported as 9.0 ppt, 10.0 ppt, 10.0 ppt, and 2000.0 ppt. However, in USEPA 2023a, the calculated HBWC values in mg/L are rounded to a single significant figure (i.e., for PFNA 0.000014 mg/L is rounded to 0.00001 mg/L). When the value is converted to ppt it is shown in USEPA 2023a as 10 ppt (equivalent to 0.000010 mg/L) and in the proposed rulemaking as both 10 ppt (equivalent to 0.000010 mg/L) and 10.0 (equivalent to 0.0000100 mg/L). EPA should remain consistent in their use of significant figures and not add additional significant figures after the number is rounded and converted to parts per trillion. The number of significant figures used in the rulemaking has significant impacts on how results are reported (always in mg/L) and how many significant figures are used and how rounding is handled. PWD requests that EPA remain consistent in its use of significant figures throughout the document and clearly define how many significant figures should be used when calculating compliance values. A few specific examples of significant figure inconsistencies are shown in Table 1.

Furthermore, using the values provided in section V.C.2 and USEPA 2023a and the equation shown above, the calculated MCLG/HBWC differ from those proposed in the rulemaking and those that are shown in USEPA 2023a. For example, in USEPA 2023a, the HBWC equation for PFHxS is shown on page 16 to be calculated as 0.0000092 mg/L (then rounded to 0.000009 mg/L and then converted to 9.0 ppt). However, when the numbers are calculated as shown in

USEPA 2023a, the correct output for the PFHxS HBWC is 0.000012 mg/L, which would round to 0.00001 mg/L (or 10 ppt) rather than 9.0 ppt.

PWD requests that if the HI requirement is kept in place, that the HBWC values be updated to match their correctly calculated values using a consistent number of significant figures.

Table 1 Examples of inconsistent significant figures for HBWC values throughout the rulemaking and supporting documents

[Table 1: See Docket ID EPA-HQ-OW-2022-0114-1709]

EPA Response: Please see section 4.3.4 of the EPA response in this *Response to Comments* document.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045210)

CT DPH also noticed that the number of significant figures EPA uses in the preamble for the same value is not consistent. For example, "In this proposal, the HBWCs that EPA uses to calculate the HI are proposed to be 9.0 ppt for PFHxS; 10.0 ppt for HFPO-DA; 10.0 ppt for PFNA; and 2000 ppt for PFBS (USEPA, 2023a). " (P18669) "the HBWC for HFPO–DA is 10.0 ppt; the HBWC for PFNA is 10 ppt; the HBWC for PFBS is 2000.0 ppt". If the differing use of significant figures is intentional, EPA should clarify whether they intend the same precision to be used for the analytical results when the results are used for HQ/HI calculation. If the levels of precision were not meant to be different, CT DPH recommends EPA use a consistent number of significant figures use for the same value.

EPA Response: Please see section 4.3.4 of the EPA response in this *Response to Comments* document.

Minnesota Pollution Control Agency (MPCA) (Doc. #1569, SBC-042492)

2) EPA requests comment on significant figure use when calculating both the HI MCLG and the MCL. EPA has set the HI MCLG and MCL using two significant figures (i.e., 1.0). EPA requests comment on the proposed use of two significant figures for the MCLG when considering underlying health information and for the MCL when considering the precision of the analytical methods.

MPCA response:

• MPCA supports the use of 2 significant figures for the MCLs/MCLGs.

EPA Response: Please see section 4.3.4 of the EPA response in this *Response to Comments* document.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044022)

5. EPA requests comment on significant figure use when calculating both the HI MCLG and the MCL. EPA has set the HI MCLG and MCL using two significant figures (i.e., 1.0). EPA requests comment on the proposed use of two significant figures for the MCLG when considering underlying health information and for the MCL when considering the precision of the analytical methods.

a. CWUC agrees that two significant figures is appropriate for all HI/MCLs. If the PQL, MCL, and trigger levels for all the other PFAS parameters use two significant figures, then the HI should also use two significant figures.

EPA Response: Please see section 4.3.4 of the EPA response in this *Response to Comments* document. For a discussion of significant digits for the PQLs, please see section VII of the final rule preamble; for the PFOA and PFOS MCLs, please see section V of the final rule preamble and section 5.1.7 of the EPA response in this *Response to Comments* document; for trigger level values, please see section VIII of the final rule preamble.

Nebraska Department of Environment and Energy (NDEE) (Doc. #1653, SBC-043206)

If the Hazard Index is retained in the final rule, the significant figure used in the HI should be consistent with the MCLs. Using one significant figure would be consistent with other chronic rules.

EPA Response: Please see section 4.3.4 of the EPA response in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-052935)

The numerical examples provided by the EPA to illustrate the application of the proposed MCLGs to an HI of two significant digits (i.e., 1.0) [FN156: 88 Fed. Reg. 18664-18665.] contradict the Agency's own long standing regulatory guidance and practice, and basic mathematical rounding rules.

The USEPA provides examples of applications of the PFAS HI method in which results are expressed and interpreted to two significant digits with the target threshold stated as Hazard Quotient(HQ) >1.0, rather than the standard HQ>1. [FN157: It is noteworthy that the PFAS Mixtures Framework document generally refers to HI>1 as the accepted threshold, except in the section where it introduces the examples.] This contradicts the Risk Assessment Guidance for Superfund, in which USEPA established that the rationale for rounding noncancer hazard quotients (HQ) to one significant digit is that the toxicity values (e.g., RfDs) are limited to one significant digit. [FN158: USEPA. Risk Assessment Guidance for Superfund (RAGS), Volume I, Human Health Evaluation Manual (Part A). EPA/540/I-89/002. Office of Emergency and Remedial Response (1989).] Furthermore, the exposure factors used in the calculation of the HBWQs are also rounded to one significant digit. Therefore, the use of two significant digits is inconsistent with EPA guidance and standard practice, and basic mathematical rules of rounding.

EPA should have recommended performing calculations with individual HQs expressed to 2 significant digits, but the final answer (HI) should be rounded to one significant digit.

EPA Response: The EPA agrees that the final Hazard Index should be rounded to one significant digit. Please see section 4.3.4 of the EPA response in this *Response to Comments* document.

Missouri Department of Natural Resources (Doc. #1563, SBC-052826)

EPA requests comment on significant figure use when calculating both the HI MCLG and the MCL. EPA has set the HI MCLG and MCL using two significant figures (i.e., 1.0). EPA requests comment on the proposed use of two significant figures for the MCLG when considering underlying health information and for the MCL when considering the precision of the analytical methods.

From the Department's review, it does not appear that EPA is consistent in their use of two significant figures when setting the MCLs. As stated in the preamble, "Under section 1412(b)(4)(B) of SDWA, EPA must generally establish an enforceable MCL as close to the MCLG as is feasible, taking costs into consideration. The Agency evaluates feasibility according to several factors including the availability of analytical methods capable of measuring the targeted compounds in drinking water and examining available treatment technologies capable of contaminant removal examined under laboratory and field conditions." In § 141.40 Monitoring requirements for unregulated contaminants, the EPA defines in CFR 141.40(a)(5)(iii) the minimum reporting level (MRL) as "the quantitation limit achievable, with 95 percent confidence, by 75 percent of laboratories nationwide, assuming the use of good instrumentation and experienced analysts". In establishing the MRL, EPA refers to the Unregulated Contaminant Monitoring Rule (UCMR 5) where EPA set the MRL for PFOA and PFOS with one significant figure at 0.004 µg/L. The preamble indicates 0.004 µg/L is equal to the two significant figures in 4.0 ppt, which is not accurate. It is also not accurate that EPA based the proposed 0.0040 µg/L MCL on meeting 95 percent confidence by 75 percent of laboratories nationwide. As stated in the UCMR 5 Laboratory Approval Manual, Version 2.0 from December 2021, seventeen labs participated in the LCMRL [Lowest Concentration Minimum Reporting Level] studies that generated the data in the Appendix B tables. The calculated MRL values in Appendix B, Table 19 were based on a minimum of three LCMRL values from the participating laboratories and appear to have only been based on eight or fewer labs out of 17, and not on required actual participation as defined in 141.40(a)(5)(iii) as 75 percent of labs nationwide.

EPA Response: Please see sections 4.3.4 and 5.2 of the EPA response in this *Response to Comments* document.

4.3.5 Incorporating Additional PFAS

Summary of Major Public Comments and EPA Responses

Commenters had questions or comments about the process for adding additional PFAS to the Hazard Index. Many commenters urged the EPA to consider making a determination to regulate for additional PFAS (in a mixture) or all PFAS as a class. A few commenters expressed concern that the EPA would add PFAS to the Hazard Index without making a determination to regulate consistent with the SDWA. The EPA response to comments on these issues, as well as others expressed by individual commenters, are described in further detail below.

The agency is required to demonstrate a contaminant meets the SDWA statutory criteria to make a regulatory determination. In addition to PFOA and PFOS which the EPA has already made a final determination to regulate individually, the agency is making final determinations for the four PFAS with sufficient information, including available health assessments, occurrence data, and meaningful opportunity information, to meet these statutory criteria individually and/or as part of mixture combinations. Using this available information, the agency followed the SDWA regulatory process and determined that three of these PFAS—PFHxS, PFNA, HFPO-DA, and mixtures of these three PFAS and PFBS—may cause adverse human health effects; are likely occur and/or co-occur in PWSs with a frequency and at levels of public health concern; and in the sole judgment of the Administrator, regulation presents a meaningful opportunity for health risk reductions for people served by PWSs. Some commenters suggested that the EPA consider regulating some additional PFAS, including perfluorobutanoic acid (PFBA), PFDA, PFHpA, and Perfluorohexanoic acid (PFHxA), as part of this rulemaking. As required under the statute, to make a regulatory determination the EPA must demonstrate that the three statutory criteria have been met which is informed by the best available information. The EPA focused on PFHxS, PFNA, HFPO-DA, and mixtures of these three PFAS and PFBS because there is sufficient information for these PFAS to allow for timely evaluation of them for regulation as part of this action. In addition, at the time of the EPA's review of available information, the EPA did not have adequate health and occurrence information to develop a total PFAS MCL.

The EPA's final regulatory determination and final rule are limited to mixtures that include two or more of PFNA, PFHxS, PFBS, and HFPO-DA. If there is any potential future inclusion of additional PFAS under this approach (e.g., individual PFAS or as a "class," precursor PFAS), such inclusion would be the subject of a potential future regulatory process under SDWA (please see section 5.1.6 of the EPA response in this *Response to Comments* document for more information). As information becomes available, the agency will continue to evaluate other PFAS for potential future preliminary regulatory determinations. Please see section 3 of the EPA response in this *Response to Comments* document and section III of the preamble for this action for further discussion about regulatory determinations.

Individual Public Comments and EPA Responses

Orange Water and Sewer Authority (OWASA) (Doc. #1524, SBC-042623)

• Future PFAS to be added to the regulation

o OWASA has to assume that other PFAS may be added to the regulation in the future and install treatment that not only works for PFOS and PFOA but shorter chain PFASs should they become regulated in the future too – we can't ask our rate payers to install $50M worth of treatment only to have it not be enough in the next few years when a new regulation may be passed

Ways to post our comments:

EPA Docket - https://www.regulations.gov/docket/EPA-HQ-OW-2022-0114/document

EPA May 4th public hearing -

WUC – Allison to send comments to Steve Via

EPA Response: Please see sections 4.3.5 and 13 of the EPA response in this *Response to Comments* document.

New York City Department of Environmental Protection (NYCDEP) (Doc. #1679, SBC-044206)

Additionally, it is assumed that the HI calculation will change over time to include more chemicals meeting the definition (a level at which no known or anticipated adverse effects on the health of persons is expected to occur, p. 18638). Typically, the water industry has produced occurrence data over a long period of record, allowing for assessment of trends and effectiveness of mitigations. As the HI calculation changes, the meaning of the HI will change, and not be available or appropriate for trend detection, compared to the more traditional regulatory approach.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Linda Shosie (Doc. #1533, SBC-043966)

We strongly believe that the establishment of new MCLs for PFAS is essential to ensure that our drinking water is safe. These new regulations will provide a clear standard for water utilities and other organizations to follow and will ensure that they are taking appropriate steps to remove PFAS from our water supply. With over 11,000 of these toxic chemicals in the PFAS class, we cannot do these one or two chemicals at a time. This will need to be done as a class.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Michigan Department of Environment, Great Lakes, and Energy (EGLE) Drinking Water and Environmental Health Division (DWEHD) (Doc. #1597, SBC-042972)

Consistent with Michigan's regulatory determination, EGLE DWEHD recommends that EPA consider including PFHxA, in addition to those four PFAS compounds proposed in the NPDWR, based on those same three statutory requirements established by the SDWA:

1. Some people who drink water containing PFHxA in excess of Michigan's MCL could experience adverse health effects. For the purpose of developing Michigan's PFHxA MCL, an independent panel of scientists determined that current toxicity data was sufficient and utilized a risk assessment based specifically on renal effects.1 [REF1: Health-Based Drinking Water Value Recommendations for PFAS in Michigan, a Report by the Michigan Science Advisory Workgroup, July 2019.]

2. Michigan's statewide PFAS survey results (2018 – 2020) indicate that PFHxA occurred in 10% of samples, and compliance monitoring results (2020 – present) indicate that PFHxA occurs in 4.1% of samples.

3. The regulation of PFHxA represents a meaningful opportunity for health risk reduction. EPA-approved analytical methods, treatment technologies, and achievable steps to manage drinking water all exist and are available to meet this challenge.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Lehigh County Authority (LCA) (Doc. #1600, SBC-042811)

4. Future Implications – As EPA is well aware, the family of PFAS compounds ranges in the thousands. How will the Hazard Index approach be adjusted over time to accommodate new PFAS compounds that are added to future regulations?

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044021)

e. Finally, any future additional parameters considered for inclusion in the HI (or MCL) must go through the required assessment evaluation and public input process.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

GFL Environmental (Doc. #1648, SBC-043222)

The EPA has stated they may consider the HI approach for additional PFAS as health hazard information becomes available, yet the formal process by which new PFAS are added to the HI has not been clearly defined and there is concern that the process is not as robust as that currently required by SDWA.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Blue Ridge Environmental Defense League (BREDL) (Doc. #1663, SBC-044381)

May 29, 2023

Docket ID No. EPA-HQ-OW-2022-0114

U.S. Environmental Protection Agency

EPA Docket Center

Office of Ground Water and Drinking Water Docket

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1200 Pennsylvania Avenue, NW

Washington, DC 20460

Comments on EPA Docket ID No. EPA-HQ-OW-2022-0114 PFAS National Primary Drinking Water Regulation Rulemaking

To Whomever it May Concern:

On behalf of Blue Ridge Environmental Defense League (BREDL) I am submitting these comments on the proposed drinking water limits for six PFAS compounds: PFOA. PFOS, GenX, PFBS, PFHxS, and PFNA (the six). This is an important step; however, PFAS must be regulated as a class in order to protect public health.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044405)

EPA requests comment on whether there are other peer-reviewed health or toxicity assessments for other PFAS the Agency should consider as a part of this action.

• PFBA has a completed toxicity value. EPA should consider adding it to the HI approach or as an individual MCL. This action should consider whether sufficient laboratory capacity is available since establishing an MCL for PFBA would force water systems to use test method 533. Method 531.7 does not measure PFBA.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Aurora Water, City of Aurora, Colorado (Doc. #1669, SBC-043709)

The current proposed rule allows for the addition of other PFAS compounds to the HI calculation as the EPA sees fit. Aurora does not agree with EPA having the ability to add new chemicals to the HI without the proper rulemaking process. Allowing for an open- ended HI definition is unfair to water systems as the rule would continue to change without proper notice or public input as prescribed under the Safe Drinking Water Act. Additionally, as more compounds are added, the HI ratios will need to be recalculated so compliance with the HI MCL can continuously be achieved. Aurora is insisting EPA follows proper procedure when adding any PFAS compounds to future HIs and they reconsider the ratios of compounds during each rulemaking process.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Rockbridge Area Conservation Council (RACC) (Doc. #1678, SBC-044299)

3) EPA Statement:

"The Hazard Index (HI) is a commonly used risk management approach for mixtures of chemicals (USEPA, 1986a; 2000a). In this approach, a ratio called a hazard quotient (HQ) is calculated for each of the four PFAS (PFHxS, HFPO-DA and its ammonium salt (also known as GenX chemicals), PFNA, and PFBS) by dividing an exposure metric, in this case, the measured level of each of the four PFAS in drinking water, by a health reference value for that particular PFAS. For health reference values, in this proposal, EPA is using Health Based Water Concentration (HBWCs) as follows: 9.0 ppt for PFHxS, 10.0 ppt for HFPO-DA; 10.0 ppt for PFNA; and 2000 ppt for PFBS (USEPA, 2023a). The individual PFAS ratios (HQs) are then summed across the mixture to yield the HI. If the resulting HI is greater than one (1.0), then the exposure metric is greater than the health metric and potential risk is indicated. EPA's Science Advisory Board (SAB) opined that where the health endpoints of the chosen compounds are similar, it is reasonable to use an HI as "a reasonable approach for estimating the potential aggregate health hazards associated with the occurrence of chemical mixtures in environmental media." (USEPA, 2022a)."

The idea of using a group "HI" for the chemicals noted above maybe useful for those four analytes, however, it does not address the other PFAS chemicals that can be identified in 98% of Americans blood, wildlife, consumer/industrial products, and/or the environment (land/water/air). With that said, using total PFAS levels in an HI calculation may be a much better choice, at least for the number of analytes used in the current EPA 1633 method. Realizing that not enough safety data may exist for all analytes to be included based on the ability to cause health effects … chemical toxicity can be estimated based on structurally similarities to other known toxic PFAS chemicals via carbon lengths, molecular weight, endocrine disruption activity … etc., to estimate a "no effect level". Additionally, using the current regulatory system(s) to review all 10,000+ PFAS analytes individually would be a task that would require generations to complete and would continue to allow PFAS to wreak havoc in people's lives. Regardless, of

how the PFAS materials are grouped, the issue of cumulative and/or synergistic interactions between PFAS chemicals – especially among those with endocrine disruptive activity - is ignored in this proposal.

Therefore, we respectfully request that using a total PFAS level in addition to or instead of the grouping of the 4 PFAS noted above, to add back some of the safety margins that have been removed by the analytical shortfalls adopted to justify the MCL of 4 ppt for PFOA/PFOS.

When dealing with estimating the adverse effects of PFAS or any other toxic chemical, it is always good to understand that toxicology and protection of public health require that a chemical be viewed as guilty until proven innocent, not the other way around. For compounds like PFAS that persist, bioaccumulate, and bioconcentrate in the environment, this is more than a best practice, it is essential. Wang, et al. (2017) observes that:

The most common current industrial practice of phasing out one PFAS is to replace it with another (or multiple other) structurally similar PFAS. Such a strategy is easier and less costly than identifying a nonfluorinated substance to be used in the same or similar process (i.e., chemical replacement) or inventing a new process that does not require PFASs (i.e., functionality replacement)..... [B]ut such a replacement strategy will not solve issues in relation to PFASs as a whole group—it will only increase the numbers of PFASs on the market and the difficulties in tracking them.

Promulgating individual PFAS compound standards until all 10,000+ compounds can be studied is an impossible task. Until there is an MCLG of zero for total PFAS in drinking water that disincentivizes the use of new or different PFAS without comprehensive health effect studies, the Agency cannot adequately control exposure to PFAS. We recommend that the PFAS MCLG of zero apply to all PFAS compounds that have no higher proven safe limit.

We hope that these comments will support EPA's admirable continuing advances in eliminating the impact of PFAS on human health and the environment.

Most sincerely,

Barbara Walsh, Executive Director Rockbridge Area Conservation Council (RACC)

Zhanyun Wang et al., "A Never-Ending Story of Per- and Polyfluoroalkyl Substances (PFASs)?," Environmental Science & Technology 51, no. 5 (March 7, 2017): 2508–18, https://doi.org/10.1021/acs.est.6b04806. Copyright 2017 American Chemical Society.

[Attachment 1: see docket ID EPA-HQ-OW-2022-0114-1678].

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Wisconsin Department of Justice et al. (Doc. #1687, SBC-044450)

6. After finalizing the PFAS Rule, EPA should consider drinking water standards for other PFAS both alone and in combination.

The States applaud EPA for taking this important step to regulate and set MCLs and MCLGs for PFOA, PFOS, PFHxS, GenX, PFNA, and PFBS. However, there are other PFAS that EPA should consider for regulation to protect human health. For example:

• The Massachusetts Department of Environmental Protection has adopted MCLs for six PFAS, including two PFAS not addressed by the proposed PFAS Rule: perfluorodecanoic acid (PFDA) and perfluoroheptanoic acid (PFHpA). [FN47: Development of a PFAS Drinking Water Standard (MCL) (mass.gov) (last visited May 4,2023)]

• The Wisconsin Department of Health Services recommended groundwater standards for the protection of public health for 12 PFAS in addition to the PFAS regulated in the proposed PFAS Rule. [FN48: https://dnr.wisconsin.gov/sites/default/files/topic/PFAS/DHSCycle11Letter20201106.pdf (last visited May 3, 2023).]

• New York has proposed drinking water standards for two PFAS not addressed by the proposed PFAS Rule: PFDA and PFHpA. [FN49: XLIV N.Y. Reg. 16-20 (Oct. 5, 2022).]

• The Michigan Department of Environment, Great Lakes, and Energy has adopted MCLs for seven PFAS, including all of those in EPA's proposed standards and one PFAS not addressed by the proposed PFAS Rule: perfluorohexanoic acid (PFHxA). [FN50: Michigan PFAS Action Response Team, Maximum Contaminant Levels (MCLs), https://www.michigan.gov/pfasresponse/drinking-water/mcl (last visited May 26, 2023).]

• EPA released or plans to release Integrated Risk Information System Toxicological Reviews for perfluorobutanoic acid (PFBA), PFHxA, and PFDA. [FN51: EPA, Toxicological Review of Perfluorobutanoic Acid (PFBA) and Related Salts (Final Report 2022), https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=356425; EPA, Toxicological Review of Perfluorohexanoic Acid (PFHxA) and Related Salts (Final Report 2023), https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=357314; EPA, Toxicological Review of Perfluorodecanoic Acid (PFDA) and Related Salts (Draft Report 2023),https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=354408.]

These regulatory actions support additional, broader federal drinking water regulations. EPA should actively review additional PFAS, and groups of PFAS, as viable targets for future enforceable drinking water standards, including setting MCLGs and MCLs for additional PFAS beyond the six in the proposed PFAS Rule. The undersigned States are available to work with the agency in considering for regulation additional PFAS that pose risks to human health through drinking water exposures.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

New Hampshire Department of Environmental Services (NHDES) (Doc. #1690, SBC-044342)

Section IV, Part B. Page 18,655, Column 2, 1st Paragraph. - EPA also considered setting individual MCLGs instead of and in addition to using a mixtures-based approach for PFHxS, HFPO–DA, PFNA, and/or PFBS in mixtures. … EPA is seeking comments on the merits and drawbacks of each of the approaches described above. As discussed later in this proposal, EPA is also seeking comment on whether to set MCLGs for the individual PFAS in addition to or instead of setting them for the mixture.

Section IV, Part C.1. Page 18,664, Column 1, 2nd Paragraph. - EPA is seeking comment on derivation of the HBWCs for each of the four PFAS considered as part of the HI.

NHDES Comment - The Hazard Index proposed by EPA includes 4 PFAS (PFBS, PFHxS, PFNA and GenX), but does not include other PFAS for which EPA has developed Reference Doses (RfDs) (i.e, PFBA, PFHxA and a draft for PFDA) (Section V-Maximum Contaminant Level Goal – Page 18656, Column 2). We suggest EPA improve its proposed rule by clarifying issues around 1) EPA IRIS's ongoing assessment of PFHxS and PFNA and 2) exclusion of other PFAS with EPA IRIS RfDs and addressing future PFAS.

EPA should clarify if EPA Office of Water's RfVs (functionally RfDs) for PFHxS and PFNA are essentially applicable as agency wide RfDs for other media, nullifying the necessity of the review process by EPA IRIS. If Office of Water's RfVs for these two PFAS are merely placeholders in the proposed rule, EPA should clarify how these will be updated when EPA IRIS finalizes RfDs and how the resulting Hazard Index would be impacted as EPA IRIS finalizes it assessments of PFHxS and PFNA. Additionally, EPA should clarify if these RfVs are unique only to characterizing toxicity from exposure via drinking water ingestion and whether the agency considers these oral toxicity factors applicable to other exposures via ingestion (e.g., food, dusts, or incidental soil ingestion).

EPA Response: Please see sections 4.3.5 and 4.3.3 of the EPA response in this *Response to Comments* document. With respect to clarifying the use of RfVs in various environmental media, as a general matter, RfVs can be used with exposure information and other important considerations to determine if, and when, it is appropriate to take action to reduce exposure to specific chemicals.

New Hampshire Department of Environmental Services (NHDES) (Doc. #1690, SBC-044344)

During the timeframe that EPA prepared this initial rule proposal, EPA finalized human health risk assessments for PFBA and PFHxA. In the proposed rule for a Hazard Index to cover 4 PFAS, EPA does not explain the exclusion of these two compounds specifically. Understandably, these were finalized while EPA prepared this initial release of a rule making document, but there is no justification relative to occurrence from UCMR 3 (e.g., occurrence was so infrequent that EPA determined regulation was not meaningful) or lack of evidence for dose-additivity for these two as to preclude them or other PFAS from future inclusion into the Hazard Index. As a part of

the response to comments, EPA should clarify how these two will be addressed, as well as other PFAS (e.g., PFDA) that are under review for toxicological assessment and that future UCMR or other occurrence data may report with lower detection/reporting limits. If exclusion of these or other future PFAS is simply a risk management decision, that should be explicitly stated and justified by EPA.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Philadelphia Water Department (PWD) (Doc. #1709, SBC-045746)

10. Potential for additional PFAS compounds not in proposed rule being added as individual MCL or to HI in final rule

In Section III, EPA requests comment on whether there is peer-reviewed information on additional PFAS that EPA should include in this rulemaking. PWD believes that EPA should not add PFAS as individual MCLs or in the HI that were not included in the proposed rule. Doing so would prevent stakeholders from commenting and reviewing the addition of these new compounds and circumvents the overall rulemaking process. PWD recommends that EPA use the standard regulatory determination process to inform rulemaking for any additional PFAS compounds.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Environmental Working Group (EWG) (Doc. #1721, SBC-045418)

After finalizing the rule, EPA should develop drinking water standards for other PFAS.

The EPA should expeditiously finalize the proposed rule, but then should also work to develop drinking water standards for additional PFAS.

An emerging body of evidence shows that many, and likely all PFAS, may cause adverse effects on the human health system. All PFAS persist in the environment and many PFAS build up in the blood and organs. Since 1999, the Centers for Disease Control has monitored at least 12 different PFAS chemicals in blood through the National Health and Nutrition Examination Survey. [FN70: Ctrs. for Disease Control & Prevention, Nat'l Biomonitoring Program, Per- and Polyfluorinated Substances (PFAS) Factsheet, https://www.cdc.gov/biomonitoring/PFAS_FactSheet.html (last updated May 02, 2022).] A 2013 study analyzed the concentrations of 21 different PFAS in autopsy samples from brain, liver, lung, bone, and kidney tissue and found PFAS in all human tissues. [FN71:Francisca Perez et al., Accumulation of Perfluoroalkyl Substances in Human Tissues, 59 ENV'T INT'L 354 (2013), https://pubmed.ncbi.nlm.nih.gov/23892228/.] A March 2020 analysis, led by EWG researchers, applied the Key Characteristics of Carcinogens framework for cancer hazard identification to 26 different PFAS and found that each PFAS displayed at least one of the key characteristics. [FN72: Alexis M. Temkin et al., Application of

Key Characteristics of Carcinogens to Per and Polyfluoroalkyl Substances, 17 INT'L J. OF ENV'T RESEARCH & PUBLIC HEALTH 1668 (2020), https://pubmed.ncbi.nlm.nih.gov/32143379/.] Studies by the National Toxicology Program show that many short-chain PFAS chemicals created to replace their long-chain predecessors are associated with the same or similar toxic effects. [FN73: Nat'l Toxicology Program, Per- and Polyfluoroalkyl Substances (PFAS), https://ntp.niehs.nih.gov/whatwestudy/topics/pfas/index.html (last updated May 19, 2023); See also Cheryl Hogue, Short-Chain and Long-Chain PFAS Show Similar Toxicity, US National Toxicology Program Say, CHEM. & ENG'G NEWS (Aug. 24, 2019), https://cen.acs.org/environment/persistent-pollutants/Short-chain-long-chain-PFAS/97/i33.]

The Agency for Toxic Substances and Disease Registry did a comprehensive study of 14 PFAS in 2018 and found several health effects associated with various PFAS. [FN74: Agency for Toxic Substances & Disease Registry, Toxicological Profile for Perfluoroalkyls (2018) https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf.] More than 20 states have determined that there is adequate health information to initiate regulations or develop health guidelines for various PFAS in drinking water including PFOA, PFOS, GenX, PFBA, PFBS, PFHpA, PFHxS, PFHxA, PFNA, and PFDA. [FN75:Emma Cormier, John Kindschuh, & Thomas Lee, PFAS Update: State-by-State PFAS Drinking Water Standards-February 2023, JD SUPRA (Feb. 21, 2023), https://www.jdsupra.com/legalnews/pfas-update-state-by-state-pfas-3060474/.] Many of the detected PFAS not covered by EPA's proposal are being evaluated by EPA's Integrated Risk Information System, or IRIS, and have toxicity values. The EPA has completed a draft evaluation and toxicity assessment of PFDA [FN76: Env't Prot. Agency, Integrated Risk Information System, IRIS Toxicological Review of Perfluorodecanoic Acid (PFDA) and Related Salts (Public Comment and External Review Draft) (April 2023), https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=354408.] and a final evaluation and toxicity assessment of PFBA [FN77: Env't Prot. Agency, Integrated Risk Information System, IRIS Toxicological Review of Perfluorobutanoic Acid (PFBA, CASRN 375-22-4) and Related Salts (Dec. 2022), https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0701tr.pdf.] and PFHxA. [FN78: Env't Prot. Agency, Integrated Risk Information System, IRIS Toxicological Review of Perfluorohexanoic Acid [PFHxA, CASRN 307-24-4] and Related Salts (April 2023), https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0704tr.pdf.]

Many PFAS not covered by the proposed rule are ubiquitous in the environment. A recent peer-reviewed, published study of tap water collected from 16 states, including more than 20 samples from public water supplies, detected 26 different PFAS, only six of which are covered by EPA's proposed rule. [FN79: Katherine E. Pelch, Taryn McKnight, & Anna Reade, 70 Analyte PFAS Test Method Highlights Need for Expanded Testing of PFAS in Drinking Water, 876 SCI. OF THE TOTAL ENV'T 162978 (June 2023), https://www.sciencedirect.com/science/article/pii/S0048969723015966.] In 2020, EWG tested 44 tap water samples from 31 states for 30 PFAS and found that all but one sample had detectable levels of PFAS. [FN80: Sydney Evans et al., New Detections of 'Forever Chemicals'

in New York, D.C., Other Major Cities, ENV'T WORKING GRP. (Jan. 23, 2020), https://www.ewg.org/research/national-pfas-testing.] EWG maintains and regularly updates a map with more than 2,800 sites contaminated with PFAS. [FN81:Env't Working Grp., PFAS Contamination in the U.S., https://www.ewg.org/interactivemaps/pfas_contamination/ (last updated June 08, 2022).] The EWG map contains data from the Unregulated Contaminant Monitoring Rule 3, state monitoring data, and Department of Defense monitoring. When the EPA begins releasing UCMR 5 data in mid-2023, there will be additional occurrence data on a wider range of PFAS.

However, SDWA allows for regulation not only where there is known occurrence, but also when there is a substantial likelihood that PFAS will occur in public drinking water at levels of public health concern. In addition to drinking water data, there is a wealth of data on PFAS contamination in surface and ground water. [FN82: 42 U.S.C. 300g-1(b)(1)(A)(ii).] Many of these surface water measurements are taken from or near sources of drinking water, making it likely that drinking water systems are also contaminated. A recent study of U.S. surface waters found 33 PFAS across 29 states and the District of Columbia, with one or more PFAS detected in 83% of the water bodies sampled. [FN83: Waterkeeper Alliance, Invisible, Unbreakable, Unnatural: PFAS Contamination of U.S. Surface Waters 13 (2022), https://waterkeeper.org/wp-content/uploads/2022/10/Waterkeeper-Alliance-PFAS-Report-FINAL-10.14.22.pdf.] A 2020 EWG analysis found that groundwater at military installations is frequently contaminated with eight different kinds of PFAS, including 4 not covered by the proposed MCLs, sometimes in very high concentrations. [FN84: Melanie Benesh, The Pentagon Should Address All Types of PFAS on Military Bases, ENV'T WORKING GRP. (May 26, 2020), https://www.ewg.org/news-insights/news/pentagon-should-address-all-types-pfas-military-bases.]

[Table1: See Docket ID EPA-HQ-OW-2022-0114-1721]

The EPA also has authority to develop MCLs for a class of chemicals, as it has done for total coliforms, haloacetic acids, trihalomethanes, chloramines, and PCBs. SDWA does not require detailed information about every member of a chemical class to develop NPDWRs to protect the public from their cumulative health effects. The EPA could follow the example of the European Union which has established a drinking water standard for "the totality of per- and polyfluoroalkyl substances."[FN85: Eur, Parliament & of the Council on Quality of Water Intended for Human Consumption, Directive (EU) 2020/2184 (Dec. 16, 2020), https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020L2184; see also Health Canada, Draft Objective for Per- and Polyfluoroalkyl Substances in Canadian Drinking Water: Rationale (Feb. 10, 2023), https://www.canada.ca/en/health-canada/programs/consultation-draft-objective-per-polyfluoroalkyl-substances-canadian-drinking-water/rationale.html (proposing 30 ppt drinking water limit for combined levels of 18 or more PFAS).]

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Joe DiNardo (Doc. #1725, SBC-045762)

3) EPA Statement:

"The Hazard Index (HI) is a commonly used risk management approach for mixtures of chemicals (USEPA, 1986a; 2000a). In this approach, a ratio called a hazard quotient (HQ) is calculated for each of the four PFAS (PFHxS, HFPO-DA and its ammonium salt (also known as GenX chemicals), PFNA, and PFBS) by dividing an exposure metric, in this case, the measured level of each of the four PFAS in drinking water, by a health reference value for that particular PFAS. For health reference values, in this proposal, EPA is using Health Based Water Concentration (HBWCs) as follows: 9.0 ppt for PFHxS, 10.0 ppt for HFPO-DA; 10.0 ppt for PFNA; and 2000 ppt for PFBS (USEPA, 2023a). The individual PFAS ratios (HQs) are then summed across the mixture to yield the HI. If the resulting HI is greater than one (1.0), then the exposure metric is greater than the health metric and potential risk is indicated. EPA's Science Advisory Board (SAB) opined that where the health endpoints of the chosen compounds are similar, it is reasonable to use an HI as "a reasonable approach for estimating the potential aggregate health hazards associated with the occurrence of chemical mixtures in environmental media." (USEPA, 2022a)."

The idea of using a group "HI" for the chemicals noted above maybe useful for those four analytes, however, it does not address the other PFAS chemicals that can be identified in 98% of Americans blood, wildlife, consumer/industrial products, and/or the environment (land/water/air). With that said, using total PFAS levels in an HI calculation may be a much better choice, at least for the number of analytes used in the current EPA 1633 method. Realizing that not enough safety data may exist for all analytes to be included based on the ability to cause health effects … chemical toxicity can be estimated based on structurally similarities to other known toxic PFAS chemicals via carbon lengths, molecular weight, endocrine disruption activity … etc., to estimate a "no effect level". Additionally, using the current regulatory system(s) to review all 10,000+ PFAS analytes individually would be a task that would require generations to complete and would continue to allow PFAS to wreak havoc in people's lives. Regardless, of how the PFAS materials are grouped, the issue of cumulative and/or synergistic interactions between PFAS chemicals – especially among those with endocrine disruptive activity - is ignored in this proposal.

Therefore, I respectfully request that using a total PFAS level in addition to or instead of the grouping of the 4 PFAS noted above, to add back some of the safety margins that have been removed by the analytical shortfalls adopted to justify the MCL of 4 ppt for PFOA/PFOS.

When dealing with estimating the adverse effects of PFAS or any other toxic chemical, it is always good to understand that toxicology is the direct opposite of democracy … a chemical should always be viewed as guilty until proven innocent … protecting public health "should be" priority one, not industrial profits!

[Attachment 1: see docket ID EPA-HQ-OQ-2022-0114-1725]

[Attachment 2: see docket ID EPA-HQ-OQ-2022-0114-1725]

[Attachment 3: see docket ID EPA-HQ-OQ-2022-0114-1725]

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Rio Grande Waterkeeper and WildEarth Guardians (Doc. #1732, SBC-045424)

II. EPA Should Act Expeditiously to Propose and Adopt New Drinking Water Regulations Addressing a Broad Swathe of PFAS Contaminants

While the proposed rule will begin to protect Americans from drinking these six PFAS substances from their tap, there are thousands more PFAS chemicals that the rule does not cover. As state and federal governments regulate specific PFAS chemicals, industry has and will continue to engage in "regrettable substitutions" by replacing the regulated chemical with an unregulated one that may be equally or more harmful. [FN17: Lindsey Konkel, The P-Sufficient Approach: A Strategy for Regulating PFAS as a Class, ENV'T HEALTH PERSPECTIVES (May 14, 2021), https://doi.org/10.1289/EHP9302.] While the health impacts of all the thousands of PFAS chemicals are not fully understood, scientists warn that limited data should not be used as a justification to delay regulation of replacement PFAS. [FN18: Sunderland, E.M., Hu, X.C., Dassuncao, C. et al., A Review of the Pathways of Human Exposure to Poly- and Perfluoroalkyl Substances (PFASs) and Present Understanding of Health Effects. J; OF EXPOSURE SCI. & ENV'T EPIDEMIOLOGY (Nov. 23, 2018), https://rdcu.be/dcPnE.] EPA needs to address this regrettable substitution problem by moving expeditiously to incorporate additional PFAS chemicals into federal drinking water standards and regulating the discharge of all PFAS chemicals.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Washington County Department of Public Health and Environment (Doc. #1739, SBC-043574)

Total PFAS MCL

In line with the MPCA, the county encourages EPA to consider development of a total (summed) PFAS MCL or similar type of regulatory value to account for exposures to PFAS in drinking water that do not have MCLs (and are unlikely to any time soon).

• A summed PFAS MCL would incorporate the detected concentrations of several PFAS, to be selected by EPA – possibly 10 or 20 of the most commonly detected PFAS chemicals that do not currently have risk evaluations, and provide guidance in situations where multiple PFAS are present in drinking water at concerning levels yet there is no MCL to evaluate the threat to human health.

• As an example, the European Union (EU) 2020 drinking water directive (DWD) includes drinking water standards for a defined sum of 20 PFAS at 100 ng/L or for a total PFAS at 500 ng/L.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document. The EPA notes that its research program is actively investigating many areas where better scientific or technical information is necessary prior to considering whether to develop a total PFAS regulation.

Arizona Water Company (Doc. #1758, SBC-044540)

PFAS Regulation and the Maximum Contaminant Level

In the EPA's Federal Register, Volume 88, No. 60, published Wednesday, March 29, 2023, the EPA stated "Depending on the individual PFAS, health effects can include negative impacts" on physical health. The current preliminary regulatory determination only regulates six PFAS contaminants. There are more than six PFAS present in drinking water (including, but not limited to, the 29 additional PFAS being monitored via UCMR 5). The Company recommends the EPA conduct further research into the regulation of PFAS contaminants prior to implementing or adjusting Maximum Contaminant Levels ("MCL").

Conclusion

The Company values the EPA's willingness to accept public comment on the proposed PFAS rule. Implementation of the proposed rule impacts public and private water utilities. As a private water utility, the Company would like to thank the EPA in advance for reviewing our comments and taking them into consideration.

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EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

PFAS Regulatory Coalition (Doc. #1761, SBC-046072)

3. The Coalition has concerns about the potential for expanded use of the Hazard Index approach.

The Coalition is concerned that use of the HI approach could be expanded. As discussed above, the Coalition doubts the validity of an HI as meeting the definition of an MCL, and the Coalition is opposed to use of the HI as presented in the Proposal, which adds across different modes of

action - especially for compounds where the co-occurrence conclusion is not justified by the data. These concerns are made even stronger when EPA states that "additional PFAS can be added over time once more information on health effects, analytics, exposure, and/or treatment becomes available, and merits additional regulation as determined by EPA." 88 Fed. Reg. 18670. EPA also says that "this approach provides a framework for Federal and State agencies to consider using to address PFAS in the future as needed." Id. The Coalition does not agree that the framework presented is appropriate for adding compounds over time or for other agencies to consider using.

EPA also does not make clear how, if at all, it would update the HI if there are updates to the science. The HI is based on HBWCs for each of the individual compounds. If there is an update needed to one or more of the HBWCs, would EPA update the HI through a future rulemaking? The current HI approach relies on HBWCs that are a combination of previously published Health Advisory Levels (for GenX and PfBS) and HBWCs that were separately developed as part of the MCL derivation (for PFNA and PfHxS). None of these is a regulatory value. The HBWCs for PFNA and PfHxS are even more uncertain: EPA acknowledges that there is no published EPA toxicity assessment for either of these chemicals, offering only that these assessments are under development and expected to undergo external peer review sometime in 2023. What happens to the HI if peer-review results in recommendations changes to these values? EPA has made dramatic swings in how it approaches PFOA and PFOS (see, e.g., the discussion in Section B, supra), so it would not be surprising if similar changes in EPA's approach were to occur with the other PFAS compounds as the science develops.

Similarly, if EPA wants additional PFAS compounds to be subject to an HI in the drinking water standards, would the Agency add them to those already included in the proposed HI, or would EPA create a new group with an additional HI? Again, as EPA has provided no sound basis for why it is combining these four PFAS compounds in a HI , the Coalition cannot meaningfully comment on that proposal. The Proposal also does not explain the basis EPA would use to update the HBWCs and how EPA would choose whether and which additional PFAS to include in this HI or a new HI, again depriving the Coalition of notice of EPA's regulatory approach and the opportunity to comment on it.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Silent Spring Institute (Doc. #1784, SBC-045805)

Considerations for future drinking water regulations

The proposed standards should be finalized without delay. Here we add supplementary comments for EPA to consider implementing after these PFAS standards have been finalized.

There is ample evidence that MCLs ought to be considered for PFDA (C10), PFUnDA (C11), and PFDoDA (C12). The health effects and toxicokinetic behavior of the C10-C12 compounds

show similarities to the behavior of PFNA, and the human half-lives for perfluorocarboxylates generally increase with chain length. Geometric mean human half-life for PFUnDA was 7.4 years, more than twice the estimated half-life for PFNA, which itself has concerning persistence.[REF33: Zhang YF, Beesoon S, Zhu LY, Martin JW. Biomonitoring of perfluoroalkyl acids in human urine and estimates of biological half-life. Environ Sci Technol. 2013;47(18):10619-10627.] As noted in the ATSDR Toxicological Profile, PFDA, PFUnDA, and PFDoDA have been associated with thyroid disorders and adverse birth outcomes in epidemiological studies.22 The ATSDR Toxicological Profile also shows that PFDA and PFUnDA have been linked with serum lipid outcomes, neurodevelopmental outcomes, and prostate cancer. PFUnDA and PFDoDA have been linked to suppressed antibody response to vaccines and decreases in childhood growth. PFDA has been linked with male reproductive outcomes and adverse pregnancy outcomes, and PFUnDA has been linked to diabetes. Mother-child transfer efficiencies for these compounds can be even greater than PFNA, as indicated by the low maternal-fetal and maternal- infant ratios reported in the ATSDR toxicological profile.

EPA should also consider incorporating a total PFAS and precursor assay as part of regular screening to address a wider set of PFAS chemicals than six alone. A one-by-one approach to regulating PFAS would be inefficient given the number of possible PFAS. EPA's own PFAS Master List contains over 12,000 possible PFAS compounds. Although this recommendation may be beyond the scope of the Safe Drinking Water Act, EPA should consider this option as part of the routine source water quality monitoring under the Groundwater Monitoring Rule, Surface Water Treatment Rule, or other applicable source water regulations.

A total PFAS and precursor assay test would better estimate and monitor the full extent of PFAS contamination. There are many other highly prevalent PFAS not covered by the rule. A 2016 study found that over 16 million U.S. residents were served by public water systems with detectable PFAS concentrations in the 2013-2015 UCMR3 cycle.[REF4: Hu XC, Andrews D, Lindstrom AB, et al. Detection of poly- and perfluoroalkyl substances (PFASs) in U.S. drinking water linked to industrial sites, military fire training areas and wastewater treatment plants. Environ Sci Technol Lett. 2016;3(10):344-350.] However, the UCMR3 underestimated the full extent of PFAS in public drinking water supplies, because the reporting limits ranged from 10 to 90 ng/L. These limits were well above concentrations that could be measured by analytical laboratories and above health guidelines established by some state health departments. A reanalysis by Eurofins Eaton Analytical of the UCMR3 samples concluded that, based on a reporting limit of 5 ng/L, nearly 30% of public water supplies likely contained at least one PFAS chemical above this level.[REF34: Eaton A. A Further Examination of a Subset of UCMR 3 PFAS Data Demonstrates Wider Occurrence. http://greensciencepolicy.org/wp-content/uploads/2017/12/Andy_Eaton_UCMR3_PFAS_data.pdf. Published 2017. Accessed 20 June 2018.] The Environmental Working Group extended this analysis and estimated that 110 million Americans may have > 5 ng/L PFAS in their drinking water.[REF35: Environmental Working Group. Report: Up to 110 Million Americans Could Have PFAS-Contaminated Drinking Water. 2018.] Another Environmental Working Group report found PFOA and PFOS in 43 out of 44 public water systems tested.[REF36: Environmental Working Group. PFAS

Contamination of Drinking Water Far More Prevalent Than Previously Reported. Washington, DC, 2020.] In addition, a 2018 study by the EPA and U.S. Geological Survey of 25 public water systems found PFOA in 100% and PFOS in 92% of treated water samples. Seven other PFAS compounds (PFBS, PFHxS, PFBA, PFPeA, PFHxA, PFHpA, and PFDA) were detected in at least 80% of treated water samples.

Finally, we recommend that EPA consider the rule's long-term commitment to addressing PFAS in drinking water. It will be important for EPA's PFAS drinking water standards to be responsive to a rapidly evolving scientific landscape. Currently, the proposed rule is unclear about how EPA will address emerging hazard data. EPA should articulate an efficient mechanism to incorporate PFAS that meet regulatory criteria into the hazard index or as a standalone MCL. There may be a need to add language that clarifies under what conditions should PFHxS, HFPO-DA, PFNA, and PFBS be removed from the hazard index and regulated as a standalone MCL like PFOA and PFOS. In the event that new evidence indicates a similar toxicological mode of action across multiple PFAS or a significant toxicological effect from PFAS mixtures, which is a current national research priority, it is unclear if EPA will adjust its grouping approach. All of this underscores the likely need for EPA to respond quickly to new toxicological data as they emerge.

Thank you for this opportunity to comment. Please contact us if you wish to discuss any of the above further.

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[Attachment 4: see docket ID EPA-HQ-OW-2022-0114-1784]

[Attachment 5: see docket ID EPA-HQ-OW-2022-0114-1784]

[Attachment 6: see docket ID EPA-HQ-OW-2022-0114-1784]

[Attachment 7: see docket ID EPA-HQ-OW-2022-0114-1784]

[Attachment 8: see docket ID EPA-HQ-OW-2022-0114-1784]

[Attachment 9: see docket ID EPA-HQ-OW-2022-0114-1784]

[Attachment 10: see docket ID EPA-HQ-OW-2022-0114-1784]

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

PFAS Project Lab (Doc. #1786, SBC-044720)

In conclusion, we emphasize the importance of adopting the proposed drinking water standards without delay given EPA's obligation to protect human health and the environment. We see this as the first step in addressing a long overdue lack of regulatory oversight over these chemicals of significant health concern. Given the number of PFAS in commerce (and the dozens of new PFAS awaiting EPA approval), EPA cannot fully protect public health and the environment until pursuing broader class-based action following the adoption of this proposed rule. Following this, we encourage separate rulemaking that takes a more comprehensive class-based approach to addressing additional PFAS not covered by EPA's proposal, yet found frequently in environmental media such as drinking water; EPA can look towards the European Union's work to establish a drinking water standard for "the totality of per- and polyfluoroalkyl substances" for guidance (E.U. 2022).

Respectfully,

Dr. Alissa Cordner, Associate Professor of Sociology, Whitman College, co-director of the PFAS Project Lab

Dr. Phil Brown, University Distinguished Professor of Sociology and Health Sciences, Northeastern University, co-director of the PFAS Project Lab

Dr. Jennifer Liss Ohayon, Affiliate Researcher at Northeastern University and member of the PFAS Project Lab

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EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Mindi Messmer (Doc. #1788, SBC-044709)

4. Please regulate these chemicals as a class. We are tired of playing whack-a-mole with the manufacturers who slightly modify the chemical structure to stay ahead of health studies.

5. Regulating PFAS chemicals as a group would also stop the use of precursors that readily convert to legacy PFAS chemicals. End the corporate welfare system that allows corporations to poison us for profit.

Thank you for your attention to this matter.

Mindi Messmer, MS, PG, CG Rye, NH

Table 1. Summary of PFAS-related exposure disease and illness in humans.

[Table 1: See Docket ID EPA-HQ-OW-2022-0114-1788]

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EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Mark Gearreald (Doc. #1792, SBC-044297)

3. Please regulate these chemicals as a class. We are tired of playing whack-a-mole with the manufacturers who slightly modify the chemical structure to stay ahead of health studies.

4. Regulating PFAS chemicals as a group would also stop the use of precursors that readily convert to legacy PFAS chemicals.

Thank you for your attention to this matter.

Sincerely,

Mark S. Gearreald

Mark Gearreald

sasgear@aol.com

5 Gold Post Road

Dover, New Hampshire 03820

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

James McConnell (Doc. #1793, SBC-044703)

3. Please regulate these chemicals as a class. We are tired of playing whack-a-mole with the manufacturers who slightly modify the chemical structure to stay ahead of health studies.

4. Regulating PFAS chemicals as a group would also stop the use of precursors that readily convert to legacy PFAS chemicals.

Thank you for your attention to this matter.

Best,

James W. McConnell

New Hampshire State Representative (2015-2018)

[name, if you wish]

[any other information you wish to provide]

James McConnell mcc988@icloud.com 42 Monadnock Highway

North Swanzey, New Hampshire 03431

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Peggy Kurtz (Doc. #1799, SBC-046045)

Ultimately, PFAS must be regulated as a class. This is the only way to control the ongoing pollution.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Massachusetts Municipal Association (MMA) (Doc. #1800, SBC-043762)

The four other PFAS chemicals – perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO-DA, commonly known as GenX Chemicals), perfluorohexane sulfonic acid (PFHxS), and perfluorobutane sulfonic acid (PFBS) – would be regulated as a mixture of chemicals through a hazard index (HI) calculation. Under the proposal, a running annual average hazard index value greater than 1.0 would be a violation of the proposed HI MCL. Two PFAS chemicals with a regulatory history in Massachusetts, PFHpA and PFDA, are left untouched by this NPDWR proposal.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

National Ground Water Association (NGWA) (Doc. #1804, SBC-045470)

[The steps identified in that letter include:]

• engaging experts to develop a public health risk assessment for PFAS beyond PFOA and PFOS to guide determining which PFAS or groups of PFAS should be targeted for future action,

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046096)

In a separate rulemaking, EPA should establish drinking water standards for the PFAS that are not covered by EPA's current proposal, including class-based standards that address the harms from additional PFAS mixtures. We urge EPA to use the full extent of its SDWA authority to ensure that no one suffers the harms associated with PFAS-contaminated drinking water.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046099)

B. EPA Should Pursue Additional, Class-Based PFAS Drinking Water Standards

While EPA's proposal marks an important step towards addressing the PFAS crisis, further action is needed to protect communities who are exposed to additional PFAS in their drinking water. A recent peer-reviewed, published study of tap water collected from 16 states, including more than 20 samples from public water supplies, detected 26 different PFAS, only six of which are covered by EPA's proposed rule. [FN19: Katherine E. Pelch et al., 70 Analyte PFAS Test Method

Highlights Need for Expanded Testing of PFAS in Drinking Water, 876 Sci. of the Total Env't Art. No.162978 (2023), https://www.sciencedirect.com/science/article/pii/S0048969723015966.] Another study of U.S. surface waters found 35 PFAS across 29 states and the District of Columbia, with one or more PFAS detected in 83% of the water bodies sampled. [FN20: Waterkeeper All., Invisible, Unbreakable, Unnatural: PFAS Contamination of U.S. Surface Waters, at 13 (Oct. 2022), https://waterkeeper.org/wp-content/uploads/2022/10/Waterkeeper-Alliance-PFAS-Report-FINAL-10.14.22.pdf.] Many of the PFAS detected but not covered by EPA's proposal, such as perfluorobutanoic acid ("PFBA") and perfluoroheptanoic acid ("PFHpA"), are associated with an increased risk of thyroid toxicity, liver damage, and developmental impairment, exacerbating the harms from the PFAS that are subject to EPA's proposed standards. [FN21: EPA, IRIS Toxicological Review of Perfluorobutanoic Acid (PFBA, CASRN 375- 22-4) and Related Salts, at 4-1–4-2 (Dec. 2022), https://www.epa.gov/system/files/documents/2022- 12/10945-%20PFBA%20ToxReview%20Final%20December%202022-HERO_partial-508%20%28updated%20page%20100%29.pdf; Health and Env't All., The Curious Case of PFHpA and Why This and All Forever Chemicals Should be Banned Under REACH (Dec. 13 2022), https://www.env-health.org/the-curious-case-of-pfhpa-and-why-this-and-all-forever-chemicals-should-be-banned-under-reach/.] Notably, PFBA, perfluorohexanoic acid ("PFHxA"), and perfluorodecanoic acid ("PFDA"), all have finalized or draft toxicity assessments performed by EPA's Integrated Risk Information System ("IRIS"). [FN22: EPA, IRIS Toxicological Review of Perfluorobutanoic Acid; EPA, IRIS Toxicological Review of Perfluorohexanoic Acid [PFHxA, CASRN 307-24-4] and Related Salts (Apr. 2023), https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0704tr.pdf; EPA, IRIS Toxicological Review of Perfluorodecanoic Acid [PFDA, CASRN 335-76-2] and Related Salts (Public Comment and External Review Draft) (Apr. 2023), https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=546623.]

Like GenX, PFBS, PFNA, and PFHxS (collectively, the "Hazard Index PFAS" or "HI PFAS"), these other detected PFAS also meet the three statutory criteria for regulation under the SDWA. [FN23: See 42 U.S.C. § 300g-1(b)(1)(A) (requiring EPA to develop MCLGs and national primary drinking water regulations for contaminants that EPA determines "may have an adverse effect on the health of persons," are known or substantially likely to occur in public water systems "with a frequency and at levels of public health concern," and present "a meaningful opportunity for health risk reduction for persons served by public water systems").] EPA has found that PFBA, PFHxA, and PFDA "may have an adverse effect on the health of persons," [FN24: Id. § 300g-1(b)(1)(A)(i).] and that they are associated with many of the same health effects observed following exposure to other PFAS, as summarized in Table 1 below. There are sufficient occurrence data from state monitoring efforts to support the need to protect against exposure to these PFAS in drinking water. [FN25: See id. § 300g-1(b)(1)(A)(ii).] Regulation of these PFAS in drinking water, individually and as a mixture with other PFAS, "presents a meaningful opportunity for health risk reduction for persons served by public water systems." [FN26: Id. § 300g-1(b)(1)(A)(iii).]

[Table 1: See Docket ID EPA-HQ-OW-2022-0114-1808]

[FN27: EPA, IRIS Toxicological Review of Perfluorobutanoic Acid, at xiii (Table ES-1. Evidence integration judgements and derived toxicity values for PFBA). FN28: Organ/system-specific oral reference dose. FN29: EPA, IRIS Toxicological Review of Perfluorohexanoic Acid [PFHxA, CASRN 307-24-4] and Related Salts, at xv (Apr. 2023). FN30: EPA, IRIS Toxicological Review of Perfluorodecanoic Acid (PFDA) and Related Salts (Public Comment and External Review Draft, at xvii-xviii (Apr. 2023).]

Health effects in bold were selected by EPA as the chronic or lifetime RfD.

Moreover, with more than 1,000 PFAS already in commerce and dozens of new PFAS awaiting EPA approval, EPA cannot fully protect public health or the environment by regulating individual PFAS (or even small sub-groups of PFAS) one at a time. Separate from its Proposed Rule, EPA should pursue a broader, class-based PFAS drinking water standard. Leading scientists have called for class-based standards [FN31: Carol F. Kwiatkowski et al., Scientific Basis for Managing PFAS as a Chemical Class, 7 Env't Sci. & Tech. Letters 532, 532–43 (2022), https://pubs.acs.org/doi/10.1021/acs.estlett.0c00255.] and the European Union has established a drinking water standard, which will take effect in January 2026, for "the totality of per- and polyfluoroalkyl substances." [FN32: Directive 2020/2184 of the European Parliament and of the Council of the European Parliament and of the Council of 16 December 2020 on the Quality of Water Intended for Human Consumption, 2020 O.J. (L 435), https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32020L2184; see also Health Canada, Draft Objective for Per- and Polyfluoroalkyl Substances in Canadian Drinking Water: Rationale, https://www.canada.ca/en/health-canada/programs/consultation-draft-objective-per-polyfluoroalkyl-substances-canadian-drinking-water/rationale.html (last updated Feb. 10, 2023) (proposing 30 ppt drinking water limit for "total PFAS in drinking water," using detection methods capable of measuring at least 18 PFAS).] Similarly, the Canadian government recently found that "a precautionary, class-based approach to addressing PFAS is needed to protect the environment and people from anticipated adverse effects." [FN33: Environment and Climate Change Canada and Health Canada, Draft State of Per- and Polyfluoroalkyl Substances (PFAS) Report at 113-114 (May 2023), https://www.canada.ca/content/dam/eccc/documents/pdf/pded/pfas/draft-state-pfas-report.pdf.] "Addressing PFAS as a class of chemicals would also reduce the chance of regrettable substitution," or the replacement of PFAS that regulated under the SDWA with equally toxic but less studied PFAS that are not subject to SDWA controls. [FN34: Id. at 116.]

The SDWA does not require detailed information about every member of the class to protect the public from their cumulative health effects. EPA previously established a class-based drinking water limit for polychlorinated biphenyls ("PCBs") despite acknowledging that "the toxicity of [the 209 possible PCB isomers] has not been fully characterized. [FN35: National Primary Drinking Water Regulations—Synthetic Organic Chemicals and Inorganic Chemicals; Monitoring for Unregulated Contaminants; National Primary Drinking Water Regulations Implementation; National Secondary Drinking Water Regulations, 56 Fed. Reg. 3,526, 3,546

(Jan. 30, 1991).] Here, too, the presence of multiple PFAS in the same drinking water supplies, as well as those chemicals' shared persistence and potential for common health effects, supports a class-based MCL. In addition to finalizing the Proposed Rule to protect communities with PFOA, PFOS, and the HI PFAS in their drinking water, EPA should also pursue a separate rulemaking process, beginning with a class-based PFAS regulatory determination, to establish drinking water standards that cover all mixtures of PFAS in drinking water.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Clean Water Action (Doc. #1813, SBC-045497)

Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Clean Water Action (Doc. #1852, SBC-045501)

Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

Sincerely,

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

National PFAS Contamination Coalition (Doc. #1830, SBC-044553)

However, this should be viewed as a first step. With over 11,000 of these chemicals in the PFAS class, we do not believe in a chemical by chemical approach. To adequately protect our communities, ultimately we will need to regulate these chemicals as a class. We also know that there is no safe level of PFAS in our drinking water. We have seen current technology with detection ability as low as 2 ppt, thus we would urge the EPA to implement a best-available technology based standard that would be lowered to 2 ppt and would continue to lower as detection technology improves.

We urge the EPA to act quickly and decisively in establishing new MCLs for PFAS. We cannot afford to wait any longer to address this critical issue. Thank you for your attention to this matter.

Sincerely,

The National PFAS Contamination Coalition

Signed:

Sandy Wynn Stelt, Co-Facilitator

Great Lakes PFAS Action Network

Belmont, Michigan

Dana Colihan, Co-Facilitator

Slingshot Portland, ME

Andrea Amico

Testing for Pease

Portsmouth, NH

Anthony Spaniola

Need Our Water (NOW)

Oscoda, MI

Arnie LeRiche

Wurtsmith RAB

Oscoda, MI

Ayesha Khan

Nantucket PFAS Action Group

Nantucket, MA

Brenda Hampton,

Concerned Citizens for WMEL Water Authority

Courtland, AL

Cathy Wusterbarth

Need Our Water (NOW)

Oscoda, MI

Cheryl Cail

SC Idle No More/SCIAC

Myrtle Beach, SC

Emily Donovan

Clean Cape Fear

Wilmington, NC

Hope Grosse

BuxMont Coalition for Safer Water

Landsdale, PA

Jaime Honkawa

Nantucket PFAS Action Group

Los Angeles, CA

Jennifer Rawlison

Newburgh Clean Water Project

Newburgh, NY

Joanne Stanton

BuxMont Coalition for Safer Water

Harleysville, PA

Katie Bryant

Clean Haw River

Pittsboro, NC

Laurene Allen

Merrimack Citizens for Clean Water

Merrimack, NH

Linda Shosie

Mothers Safe Air Safe Water

Force Tucson, AZ

Stel Bailey Fight for Zero

Cocoa, FL

Tanya Trevisan

Duxbury Safe Water Committee

Duxbury, MA

EPA Response: Please see sections 4.3.5 and 5.1.3 of the EPA response in this *Response to Comments* document.

Douglas Whitbeck (Doc. #1853, SBC-045504)

3. Please regulate these chemicals as a class. We are tired of playing whack-a-mole with the manufacturers who slightly modify the chemical structure to stay ahead of health studies.

4. Regulating PFAS chemicals as a group would also stop the use of precursors that readily convert to legacy PFAS chemicals.

Thank you for your attention to this matter. Our water is really all connected.

Douglas Whitbeck Mason, NH

Douglas Whitbeck

proddiebikes@gmail.com

756 Brookline Road

Mason, New Hampshire 03048

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

David McGraw (Doc. #1854, SBC-045523)

3. Please regulate these chemicals as a class. We are tired of playing whack-a-mole with the manufacturers who slightly modify the chemical structure to stay ahead of health studies.

4. Regulating PFAS chemicals as a group would also stop the use of precursors that readily convert to legacy PFAS chemicals.

Thank you for your attention to this matter. Best,

[name, if you wish]

[any other information you wish to provide]

David McGraw

dcmcgraw@myfairpoint.net

1163 NH Route 175

Campton, New Hampshire 03223

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Barbara Glassman (Doc. #1855, SBC-045526)

3. Please regulate these chemicals as a class. We are tired of playing whack-a-mole with the manufacturers who slightly modify the chemical structure to stay ahead of health studies.

4. Regulating PFAS chemicals as a group would also stop the use of precursors that readily convert to legacy PFAS chemicals.

Thank you for your attention to this matter. Best,

[name, if you wish]

[any other information you wish to provide]

Barbara Glassman

barbara.glassman@gmail.com

50 Barrington Ave. Unit 504

Nashua, New Hampshire 03062

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Elizabeth A. Trought (Doc. #1856, SBC-045529)

3. Please regulate these chemicals as a class. We are tired of playing whack-a-mole with the manufacturers who slightly modify the chemical structure to stay ahead of health studies.

4. Regulating PFAS chemicals as a group would also stop the use of precursors that readily convert to legacy PFAS chemicals.

Thank you for your attention to this matter.

Best,

[name, if you wish]

[any other information you wish to provide]

Elizabeth A Trought

batrought@gmail.com

188 Streeter Woods Rd

Dorchester, New Hampshire 03266-6315

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Kris Pastoriza (Doc. #1857, SBC-045532)

3. Regulate these chemicals as a class, which will also stop the use of precursors that readily convert to legacy PFAS chemicals.

kris pastoriza

easton nh

[name, if you wish]

[any other information you wish to provide]

kris pastoriza

krispastoriza@gmail.com

294 gibson road

easton, New Hampshire 03580

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Andrea Thorn (Doc. #1858, SBC-045535)

3. Please regulate these chemicals as a class. We are tired of playing whack-a-mole with the manufacturers who slightly modify the chemical structure to stay ahead of health studies.

4. Regulating PFAS chemicals as a group would also stop the use of precursors that readily convert to legacy PFAS chemicals.

Thank you for your attention to this matter.

Best,

[name, if you wish]

[any other information you wish to provide]

Andrea Thorn

dreathorn@gmail.com

17 Eagle Drive

Newmarket, New Hampshire 03857

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Jon Swan (Doc. #1859, SBC-045538)

3. Please regulate these chemicals as a class. We are tired of playing whack-a-mole with the manufacturers who slightly modify the chemical structure to stay ahead of health studies.

4. Regulating PFAS chemicals as a group would also stop the use of precursors that readily convert to legacy PFAS chemicals.

Thank you for your attention to this matter.

Best,

Jon Swan

Save Forest Lake

Dalton, NH

Jon Swan

saveforestlake@yahoo.com

25 Cashman Road

Dalton, New Hampshire 03598

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Steven Cea (Doc. #1860, SBC-045541)

3. Please regulate these chemicals as a class. We are tired of playing whack-a-mole with the manufacturers who slightly modify the chemical structure to stay ahead of health studies.

4. Regulating PFAS chemicals as a group would also stop the use of precursors that readily convert to legacy PFAS chemicals.

Thank you for your attention to this matter.

Best,

[name, if you wish]

[any other information you wish to provide]

Steven Cea

scea2014@gmail.com

137 6th Avenue

Nyack, New York 10960

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Kathy Malsbenden (Doc. #1861, SBC-045544)

3. Please regulate these chemicals as a class. We are tired of playing whack-a-mole with the manufacturers who slightly modify the chemical structure to stay ahead of health studies.

4. Regulating PFAS chemicals as a group would also stop the use of precursors that readily convert to legacy PFAS chemicals.

Thank you for your attention to this matter.

Best,

[name, if you wish]

[any other information you wish to provide]

Kathy Malsbenden

kmalsbenden@gmail.com

21 Bald Hill Road

Newmarket , New Hampshire 03857

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Michael Letendre (Doc. #1862, SBC-045547)

3. Please regulate these chemicals as a class. We are tired of playing whack-a-mole with the manufacturers who slightly modify the chemical structure to stay ahead of health studies.

4. Regulating PFAS chemicals as a group would also stop the use of precursors that readily convert to legacy PFAS chemicals.

End the corporate welfare system that allows corporations to poison us for profit.

Thank you for your attention to this matter.

Best,

[name, if you wish]

[any other information you wish to provide]

MICHAEL LETENDRE

maletendre877@comcast.net

140 Cass St Unit B

Portsmouth, New Hampshire 03801

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Mary Anderson (Doc. #1863, SBC-045845)

The proposed drinking water standards are a great first step to address these particular PFAS chemicals, however, I urge EPA to not stop here—it is critical that EPA next moves to regulate the full class of PFAS chemicals.

Thank you for your consideration.

Sincerely,

Mrs. Mary Anderson

110 Tamarack St Liverpool, NY 13088-5022

savicki7@gmail.com

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Laura Spilotros (Doc. #1864, SBC-045849)

The proposed drinking water standards are a great first step to address these particular PFAS chemicals, however, I urge EPA to not stop here—it is critical that EPA next moves to regulate the full class of PFAS chemicals.

Thank you for your consideration.

Sincerely,

Mrs. Laura Spilotros

23 Whispering Woods Dr Smithtown, NY 11787-1662

lspilotros1@gmail.com

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Jeanne Forster (Doc. #1865, SBC-045853)

The proposed drinking water standards are a great first step to address these particular PFAS chemicals, however, I urge EPA to not stop here—it is critical that EPA next moves to regulate the full class of PFAS chemicals.

Thank you for your consideration.

Sincerely,

Ms. Jeanne Forster

111 Upton Dr Sound Beach, NY 11789-2048

jeanneforster1@gmail.com

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

K Murphy (Doc. #1866, SBC-045857)

The proposed drinking water standards are a great first step to address these particular PFAS chemicals, however, I urge EPA to not stop here—it is critical that EPA next moves to regulate the full class of PFAS chemicals.

Thank you for your consideration.

Sincerely,

Mr K Murphy

100 MARSHALL Ave Lynbrook, NY 11563

cynnamon@aol.com

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Katrina Rudmin (Doc. #1868, SBC-045865)

The proposed drinking water standards are a great first step to address these particular PFAS chemicals, however, I urge EPA to not stop here—it is critical that EPA next moves to regulate the full class of PFAS chemicals.

Thank you for your consideration.

Sincerely,

Ms. Katrina Rudmin

416 N Aurora St Ithaca, NY 14850-4235

katrina@jackknife.org

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Great Lakes PFAS Action Network (Doc. #1870, SBC-045872)

These proposed regulations are long overdue and we fully support this first step of regulating six dangerous PFAS in drinking water. In addition, we encourage the EPA to take a comprehensive approach to regulating the entire class of chemicals in order to reduce overall PFAS exposure, and improve drinking water safety in thousands of communities across the country.

Thank you for your consideration.

[Table 1: See Docket ID EPA-HQ-OW-2022-0114-1870]

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Eri Higashi Durnell (Doc. #2048, SBC-047629)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Judith Moriarty (Doc. #2049, SBC-047637)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

The EPA MUST act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

I hope you will take my concerns, as well as those of thousands of others, seriously for even you might, someday, look back and appreciate the wisdom of protection a resource more valuable than any other for life itself.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Dorie Reisenweber (Doc. #2050, SBC-047587)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act posthaste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. BAN them. That is the only way to stop these forever toxins. Stop the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, END, not limit, pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

Remember these forever chemicals don't go away. Don't be like some ignorant politicians who discuss PFAs cleanup. If and when that is possible and affordable on mass scale, massive harm will have already been done. Limiting is a baby step. The health problems won't end until we BAN the production of PFAS and like chemicals. I urge the EPA to take that bold step and BAN PFAS and similar chemicals.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Chris Rauber (Doc. #2051, SBC-047607)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Edward Hyman (Doc. #2052, SBC-047659)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well established, as they are documented in dozens of human health studies, as well as in hundreds of experimental animal studies. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. This is an important "real life" model, since human bodies ingest, integrates and digests them all simultaneously . EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products.

EPA must cease approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, and limit pollution caused by biosolids/sludge fertilizers.

Further, it is of utmost importance that the EPA establish health-based limits for PFAS in subsistence fish and other wild foods ingested directly or indirectly by human beings.

EPA's adoption of these policies will begin to recognize our current understanding of the necessary inherent re-examination of various chemicals only viewed previously in isolation, yet which interact and affect the human species not independently, but with synergistic and interactive effects. Recognizing these interactive elements of the chemicals allows for more correct modeling of the impact on human subjects.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Cinda Flynn (Doc. #2053, SBC-047651)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the

potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Anthony Gatenby (Doc. #2054, SBC-047666)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

With the wide range of pollutants commonly reported in manure biosolids, the potential risks associated with long-term land application operations are concerning. In a recent study, PFAS in surface soils, deeper soils into the vadose zone, and immediately-underlying groundwater was measured at an agricultural station with a long record of biosolids applications. Twelve PFAS homologous were detected in every near surface soil sampled 030 cm depth below ground surface with multiple PFAS (especially short-chain) distributed through the soil profile.

Measured concentrations of PFAS in the soil profile (090 cm) show that these compounds have migrated to deeper soil depths (up to 9 m below the surface) with quantifiable concentrations in the soil and the immediate underlying groundwater located approximately 17 m below. Researchers across the globe have reported PFAS and related compounds in groundwater and soils following the application of PFAS-containing soil amendments including manure biosolids and compost (https://www.sciencedirect.com/science/article/abs/pii/S004313542101229Xvia%3Dihub).

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Lorene A (Doc. #2055, SBC-047593)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Andrea Thompson (Doc. #2056, SBC-047574)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Joy Schroeder (Doc. #2059, SBC-047572)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA’s expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Larry Menkes (Doc. #2060, SBC-047540)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Grason Weinstein (Doc. #2061, SBC-047653)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Alice Svendson (Doc. #2062, SBC-047613)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA’s expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS

chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Faith Moeller (Doc. #2063, SBC-047611)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Joey Lindsey (Doc. #2064, SBC-047546)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Andrew Kaufman (Doc. #2065, SBC-047657)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS

chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Brad Findlay (Doc. #2066, SBC-047595)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Jefferson Hall (Doc. #2067, SBC-047584)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Frederick Ellsworth (Doc. #2068, SBC-047518)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS

chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Tonda Bian (Doc. #2069, SBC-047550)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Jenny Walker (Doc. #2070, SBC-047564)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods is beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Elsa Obuchowski (Doc. #2071, SBC-047532)

The hazards of PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are documented by many studies with both humans and animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to strong regulation of PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Most important in my opinion, EPA needs to address ASAP the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval

of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods is beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Samantha Corte (Doc. #2073, SBC-047548)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Dawna Hammers (Doc. #2075, SBC-047526)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Charles Adelman (Doc. #2076, SBC-047576)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS

chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

N L (Doc. #2077, SBC-047645)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Katherine Weaver (Doc. #2078, SBC-047524)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Patricia Guthrie (Doc. #2079, SBC-047615)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS

chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Linda Schneider (Doc. #2081, SBC-047556)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Joseph Gibbs (Doc. #2085, SBC-047578)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Erin Kilpatrick (Doc. #2086, SBC-047560)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS

chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Alan Birmingham (Doc. #2088, SBC-047621)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Louise Usechak (Doc. #2089, SBC-047605)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Debra Johnson (Doc. #2090, SBC-047627)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS

chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Amy Mueller (Doc. #2091, SBC-047552)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Bill Johnson (Doc. #2093, SBC-047542)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Peter Beves (Doc. #2094, SBC-047514)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented. EPA has published an exhaustive analysis of the potency of these six chemicals and a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

EPA should also act with haste to address unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by

biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Barbara Lambdin (Doc. #2095, SBC-047554)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Israfel Mark Pafford (Doc. #2096, SBC-047643)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has

published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Shellee Davis (Doc. #2097, SBC-047599)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by

biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Perry Cogburn (Doc. #2099, SBC-047609)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Judith Allen-Leventhal (Doc. #2100, SBC-047558)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has

published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Donna Thomas (Doc. #2101, SBC-047662)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

We are counting on our EPA Reg 6.

I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals. Due to the slow pace of regulatory agencies, many Americans have been drinking harmful amounts of PFAS chemicals for decades. These rules will speed the implementation of life-saving water treatment for communities across the U.S. Therefore the Agency must finalize these rules as quickly as possible.

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Patrick Sharp (Doc. #2104, SBC-047568)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Rian Raby (Doc. #2105, SBC-047570)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Roland Hofman (Doc. #2106, SBC-047582)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Tina Masterson (Doc. #2109, SBC-047603)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Susan Adams (Doc. #2112, SBC-047528)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Lara Levison (Doc. #2113, SBC-047639)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Aileen Curfman (Doc. #2115, SBC-047625)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Doris Cellarius (Doc. #2116, SBC-047520)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked releases of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, stop allowing dumping of PFAS waste into the wastewater system, and ban land application of biosolids and sewage effluent because they all have been found to contain PFAS.

To address widespread pollution of waters and foods EPA must set health-based limits for PFAS in foods, fish and wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Mary Bautista (Doc. #2118, SBC-047516)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals.

I also support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Donna Brown (Doc. #2124, SBC-047597)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

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EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA

response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Tracy Frisch (Doc. #2119, SBC-047417)

Chronic exposures to PFAS chemicals found in drinking water can cause severe health problems, especially in young children and developing fetuses. I strongly support the proposed drinking water limits EPA has proposed for six PFAS chemicals.

But regulating 6 PFAS, while an advance forward, is far from sufficient to protect public health. EPA needs to regulate PFAS as a chemical class, rather than trying to regulate individual PFAS chemicals.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Melissa Tomlinson (Doc. #2262, SBC-047633)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the

EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Leslie Bennett (Doc. #2282, SBC-047530)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

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Elizabeth Becker (Doc. #2288, SBC-047589)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

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G. Paul Richter (Doc. #2332, SBC-047562)

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Cris Corley (Doc. #2333, SBC-047522)

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Lori Olinger (Doc. #2334, SBC-047544)

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Stephen Brown (Doc. #2335, SBC-047641)

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David Dow (Doc. #2336, SBC-047649)

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Susan Johnson (Doc. #2398, SBC-047566)

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Pearl Gray (Doc. #2459, SBC-047664)

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V M (Doc. #2465, SBC-047661)

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Andrea Callan (Doc. #2487, SBC-047623)

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Samantha Herdman (Doc. #2539, SBC-047461)

I am concerned, however, that EPA is only taking action to restrict, monitor and report six PFAS contaminants. There are more than 9,000 known PFAS chemicals, and at least 180 are considered toxic by the EPA because they are on the Toxic Release Inventory (CDC 2023; US EPA 2019). EPA acknowledges that PFAS act in a dose-additive manner, suggesting that combinations of the 9,000 PFAS may lead to health impacts generally associated with the class of chemicals, including cancer, negative impacts on fetal growth, development, reproduction, liver, thyroid, immune function, the nervous system and more. EPA should set class-based MCLGs or a Hazard Index score that encompasses all PFAS contaminants found in drinking water. Spending years studying the impacts of each individual PFAS contaminant will take decades, and in the mean-time the public will be at risk of exposure. A precautionary measure to protect the public health from PFAS contamination is justified by the available information about PFAS. Furthermore, restricting only some PFAS contaminants will likely lead to the adoption of other PFAS. This has already happened, when manufacturers replaced the well-studied PFOA and PFOS with alternative PFAS (EPA 2021a). Setting a class-based precautionary standard to regulate PFAS will be technologically difficult. However, the EPA already has access to technology to specifically identify at least 50 PFAS, according to the U.S. Government Accountability Office's technology assessment (2022).

I support EPA's proposal to set legally enforceable standards for six PFAS – but EPA should also do more. If those six PFAS are just replaced with similar, toxic replacements, the PFAS NPDWR will have a woefully inadequate result. EPA should set class-based restrictions to prevent Americans from drinking any dangerous PFAS contaminant.

CDC. 2023. "Per- and Polyfluoroalkyl Substances (PFAS)." January 11, 2023. https://www.cdc.gov/niosh/topics/pfas/default.html.

EPA. 2021a. "Our Current Understanding of the Human Health and Environmental Risks of PFAS." Overviews and Factsheets. October 14, 2021. https://www.epa.gov/pfas/our-current-understanding-human-health-and-environmental-risks-pfas.

———. 2021b. "PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024." Overviews and Factsheets. October 14, 2021. https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024.

———. 2023. "Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation." March 28, 2023. https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0027.

GOA. 2022. "Technologies for PFAS Assessment, Detection, and Treatment." U.S. Government Accountability Office. https://www.gao.gov/assets/gao-22-105088.pdf.

US EPA, OCSPP. 2019. "Addition of Certain PFAS to the TRI by the National Defense Authorization Act." Other Policies and Guidance. December 16, 2019. https://www.epa.gov/toxics-release-inventory-tri-program/addition-certain-pfas-tri-national-defense-authorization-act.

Weinmeyer, Richard, Annalise Norling, Margaret Kawarski, and Estelle Higgins. 2017. "The Safe Drinking Water Act of 1974 and Its Role in Providing Access to Safe Drinking Water in the United States." AMA Journal of Ethics 19 (10): 1018–26. https://doi.org/10.1001/journalofethics.2017.19.10.hlaw1-1710.

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Michelle Betz (Doc. #2543, SBC-047580)

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Candace Fujikane (Doc. #2546, SBC-047647)

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Charming Evelyn (Doc. #2553, SBC-047586)

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Waterkeeper Alliance (Doc. #3072-2, SBC-046341)

My name is Kelly Hunter Foster, and I'm a senior attorney and Clean Water Defense campaign manager for the Waterkeeper Alliance. We strongly support the regulation of PFAS in drinking water, and we commend EPA for proposing protective, scientifically-supported standards for six PFAS, and for also recognizing that both individual PFAS and chemical mixtures of PFAS pose very serious threats to human health at low levels. Given the widespread dispersion of PFAS in the environment, and the seriousness of the health effects posed by these chemicals, the adoption of national drinking water standards is long overdue, and we urge EPA to act quickly to finalize these standards. Waterkeeper groups across the country are seeing PFAS contamination of

surface water and groundwater, including public water supply source waters, and are concerned about the impacts of PFAS pollution on their communities, both in terms of contaminated drinking water, and the urgent need for standards and funding for public utilities, to properly treat wastewater and drinking water, and to safely manage contaminated treatment residuals. For example, last year Waterkeeper groups conducted PFAS testing in 114 waterways in 34 states and the District of Columbia. 83 percent of the waterways tested were found to contain at least one, but often many, of the 35 PFAS chemicals that were detected. In some places, the level of contamination was thousands to hundreds of thousand times higher than what is believed to be safe for drinking water. Unexpectedly, many lesser-known PFAS chemicals were detected with high frequency. For example, testing found PFHxA in 153 samples, PFPeA in 126 samples, and there are a lot of other examples of that. Multiple PFAS chemicals were detected in the majority of individual water samples, adding to the total concentration of PFAS in the waterways, and increasing the risk of harm. For example, a waterway in Pennsylvania was contaminated by 27 different PFAS chemicals and had a total concentration of 6,510.3 parts per trillion. This is one of the reasons that we support EPA's proposal to use a hazard index to address co-occurring PFAS that, like many other members of the PFAS class, have similar structures and present similar risks. Thank you for the opportunity to provide these comments to you today.

EPA Response: The commenter supports using the Hazard Index to regulate co-occurring PFAS. Please see sections 4.3.5 and 4.3.2 of the EPA response in this *Response to Comments* document.

Karin Hemmingsen (Doc. #2617, SBC-047601)

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EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Vermont PFAS/Military Poisons Coalition (Doc. #2715, SBC-047305)

I am the Coordinator of the VT PFAS/Military Poisons Coalition. Our Coalition believes that the EPA's proposed drinking water standards, while a step forward, are not comprehensive enough, take too long to enact, and don't set PFOA and PFOS at the limits needed to protect people and animals from harm. The EPA's chemical by chemical approach is not good enough to protect public health and the environment. We must regulate PFAS as a class of chemicals, and ban all but absolutely essential uses of these toxins and allow no new PFAS to enter the market.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Allison Nemenyi Shiozaki (Doc. #2739, SBC-047635)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids

management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Mary Matz (Doc. #2787, SBC-047617)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. In regard to discussion related to the Hazard Index, please see section 4.3.2 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Kevin Rolfes (Doc. #2802, SBC-047439)

For PFOA and PFOS, whose carcinogenic nature requires setting their Maximum Contaminant Level Goal at 0.0 parts per thousand (PPT), the proposed Maximum Contaminant Level (MCL) allowed in drinking water of 4 PPT is adequate to protect public health, reasonable, and feasible for both testing and treatment. PFHxS, HFPO-DA, PFNA, and PFBS have not been classified as carcinogens, but have been shown to affect health in a cumulative, additive manner. They often exist as mixtures in water, as found in the Pennsylvania drinking water sampling study where, for example, approximately 70% of samples containing PFNA also contained at least one other

PFAS species that is not PFOA or PFOS. EPA effectively addresses this issue of "dose additivity" by setting a Health Based Water Concentration (HBWC) value for the level of each chemical, and a Hazard Index (HI) for the mix. The proposed values are adequate to protect health, reasonable, and achievable.

To maintain the efficacy of the proposed rule, I ask that EPA continue reviewing data regarding the health effects of these compounds, adjusting the MCLs and HBWC values and adding more chemicals to the regulations as new data becomes available.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Therese Argoud (Doc. #2808, SBC-047591)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. In regard to discussion related to the Hazard Index, please see section 4.3.2 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Louis Pisha (Doc. #2891, SBC-047619)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

Finally, PFAS should be regulated as a class. Spending time going chemical by chemical when the industry is quickly coming up with replacements means we'll never stop being exposed.

Thank you fro considering my opinion in this proceeding.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. In regard to discussion related to the Hazard Index, please see section 4.3.2 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Michael Parietti (Doc. #2892, SBC-047631)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA’s expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the

potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. In regard to discussion related to the Hazard Index, please see section 4.3.2 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods is beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Keith Lewison (Doc. #2902, SBC-047655)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. In regard to discussion related to the Hazard Index, please see section 4.3.2 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild

foods is beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Gregory Grant (Doc. #2976, SBC-047668)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. In regard to discussion related to the Hazard Index, please see section 4.3.2 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Melissa Quesinberry (Doc. #2983, SBC-047670)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS

chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

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EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. In regard to discussion related to the Hazard Index, please see section 4.3.2 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Norman Norvelle (Doc. #2995, SBC-047672)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. In regard to discussion related to the Hazard

Index, please see section 4.3.2 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods is beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

John Lovie (Doc. #3060, SBC-046330)

EPA is proposing to use a Hazard Index (HI) approach to protecting public health from mixtures of PFHxS, HFPO-DA and its ammonium salt, PFNA, and PFBS because of their known and additive toxic effects and occurrence and likely co-occurrence in drinking water. Please consider drafting legislation and subsequent rulemaking around the criteria used to select and determine HBWCs for these compounds, rather than around the specific compounds meeting the criteria at the time. This way, other compounds meeting the criteria can be added without requiring modification of the legislation or rule.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document. Drafting legislation and potential future regulatory action to address additional PFAS is beyond the scope of this rulemaking action.

Mass comment campaign submitted by Naia Mitchell (Doc. #3065, SBC-047674)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The EPA acknowledges the commenters' support for this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. In regard to

discussion related to the Hazard Index, please see section 4.3.2 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Citizens Campaign for the Environment (Doc. #3072-64, SBC-047395)

The proposed EPA regulations are a great first step and should be implemented as quickly as possible to protect public health. However, there are thousands of PFAS chemicals with similar characteristics and health impacts. This should only be the start for EPA and the Agency should ultimately move to regulate PFAS as a class. Thank you again for the opportunity to comment.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Merrimack Citizens for Clean Water (Doc. #3072-68, SBC-047397)

I would urge you also to look at the chemicals that you're considering adding to CERCLA: PFBA, PFHxA, PFPeA, PFHpA, etc. You know the ones I'm talking about. Those are breaking through the GAC systems that we are currently paying for, immense amounts of money, and we really need the remediation to get this right. We can't wait, we don't have time here any longer. We have sick people and I would really love to see prevention for people across the country who do not know that they're being exposed as we didn't know for 20 years. Thank you so much.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

National Center for Health Research (Doc. #3072-73, SBC-047401)

Number two, we understand the Agency's desire to be flexible, but flexibility to satisfy monitoring requirements will likely generate a huge loophole. We ask EPA to have more explicit limits to prevent a weakening of these regulations. Number three, this proposed rule is an important first step, but it's long past time for EPA to define PFAS broadly, regulate them as a class and ban all non-essential uses.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Edith Couchman (Doc. #2083, SBC-047513)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has

published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. In regard to discussion related to the Hazard Index, please see section 4.3.2 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Clean Hall River Grassroots Advocacy Group (Doc. #3072-96, SBC-047408)

This has forced me to leave my town, sell my home, and purchase a home with a well. While I strongly support the EPA in their efforts, they are far too late for my family and fall short for my community. When we have way more than six PFAS coming downstream any given day. These six MCLs will not provide my town with what it needs. We need the entire PFAS class banned. There are over 9,000 individual chemicals in the PFAS family alone. And at this rate on a chemical-by-chemical basis, it would take the EPA 1,800 years to evaluate them for regulation at a five chemical per year rule. I urge you to use your powers, stand strong against chemical manufacturers who have demonstrated how pervasive their chemicals are, act swiftly with no delays, hold them accountable and make them pay for this cleanup. We're already sick and now have been dealing with water rate increases because of their lying by omission. My daughters, London and Berlin Bryant, ask you to show them the way and to battle for them. Thank you.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Paul Fishman and Mike Kurokawa (Doc. #2057, SBC-047538)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has

published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

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EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. In regard to discussion related to the Hazard Index, please see section 4.3.2 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Carl Zimmerman (Doc. #2084, SBC-047536)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

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biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. In regard to discussion related to the Hazard Index, please see section 4.3.2 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Linda Zahrt (Doc. #2087, SBC-047534)

The hazards posed by PFOS, PFOA, HFPO-DA, PFBS, PFHxS and PFNA are well documented by dozens of human health studies and hundreds of experimental studies in animals. EPA has published an exhaustive analysis of the potency of these six chemicals, as well as a detailed analysis of the economic benefits that will be realized by water limits.

In addition to the strong standards EPA is proposing for PFOS and PFOA, I support EPA's expedited action on the four chemicals it regulates with a hazard index approach. This method allows water managers to account for the additive impacts of exposure to multiple PFAS chemicals. EPA should extend this approach to include other PFAS chemicals when toxicological potency values are available, and consider ways that a hazard index can also account for the potential additive impacts of the hundreds of other PFAS chemicals found in water supplies for which health information is more scarce.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. In regard to discussion related to the Hazard Index, please see section 4.3.2 of the EPA response in this *Response to Comments* document. PFAS wastewater limits, biosolids management, and limits for subsistence fish and other wild foods are beyond the scope of this rulemaking. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

CleanEarth4Kids.org (Doc. #3072-44, SBC-046367)

Thank you. Good afternoon. My name is Suzanne Hume. I'm the educational director and founder of CleanEarth4Kids.org. CleanEarth4Kids.org supports the EPA's proposed PFAS National Primary Drinking Water Regulations for PFAS forever chemicals. But this rule only establishes criteria for six PFAS found in drinking water. PFAS must be banned and regulated as a class with the most stringent levels of protection for clean, safe water, for children's health, public health, fish, birds, wildlife, and entire ecosystems. As we speak, PFAS forever chemicals are entering our water. PFAS forever chemicals known to harm children's health and future. PFAS not only disrupt lipid and amino acid metabolism, but alter thyroid hormone function in children. An altered thyroid can fail to process proteins and fats, affecting every cell in the body. Long-term effects of PFAS in children include developmental issues in the brain and lifelong high blood pressure. Furthermore, PFAS in pregnant women can cause liver failure in infants, underweight newborns, failed vaccine response, and early onset, kidney cancer and on and on and on. Increased cancer, preeclampsia during pregnancy. So much, too many to mention in this very short time. So, it is very important that we ban PFAS as a class and use the most stringent regulations possible. PFAS forever chemicals will remain in the environment for thousands of years and continue to harm children, pregnant women, seniors and the public, our fish, wildlife and ecosystems. The EPA has responsibility to defend our environment and protect public health. So, it's vital to ban PFAS as a class. Scientists from all the world using numerous studies showing that managing PFAS as a class is the most effective approach to reducing the adverse effect on human and ecological health. And 67 scientists requested that EPA implement this ban as a class stating it would provide an orderly and expeditious process. And California DTSC determined regulation of individual PFAS is ineffective and California already regulates PFAS as a class and certain bills that can be found on our website. PFAS are contaminants that have been detected in drinking water throughout the U.S. and the cost of not banning PFAS as a class and the most stringent standards is criminal. A cost to our children, families, not to mention taxpayers, we should not have to bear. You know, investigations, health reports, medical problems, increased bills, workplace productivity, diminished mental health, all of this is affected. When our fish are too contaminated to eat, come on, it's past time. Thank you so much from CleanEarth4Kids.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Cape Fear River Watch (Doc. #3072-47, SBC-046369)

Thank you. My name is Dana Sargent. I am the executive director of Cape Fear River Watch, a nonprofit team of five in Wilmington, North Carolina, dedicating ourselves to this issue since we found out our Cape Fear River, the drinking water for 500,000 people, was contaminated for more than 40 years by DuPont and then Chemours. In addition, we found through court-ordered well sampling, after our organization sued Chemours, that around 10,000 wells and counting are highly contaminated. Also, from that order, we learned that Chemours alone has been dumping more than 300 unique PFAS into our drinking water supplies. This doesn't include the high levels

of legacy chemicals. I want to thank you all for providing Q&A session and I hope you continue that trend. My Q&A discussion has informed my comments. I want to be clear, Cape Fear River Watch is grateful that EPA has finally gotten the ball rolling on regulating PFAS, since the industry's own scientists knew these chemicals were toxic 50 years ago. We also appreciate the recognition that we're exposed to mixtures, again, more than 300 in our water. To that end, this rule is missing a vitally important piece. There needs to be a mechanism for adding additional PFAS to this rule's Hazard Index component. During my private Q&A written convo, it was suggested that EPA is not considering this, but instead will be gathering information through 2025 through the UCMR process and wait until after that to potentially propose completely new regulation and start this long process all over again. And they mention that the filtration required for the six in this proposal will work to remove other PFAS that is simply not the case. In our water for instance, PFMOAA is of the highest concentration, and it breaks through GAC sooner than all others in our water. So, systems that are regulated to catch the larger PFAS in this proposal could allow PFMOAA to break through before the carbon is required to be cleaned, for lack of a better word. Waiting until 2025 for EPA to start the regulation process on another PFAS or set of PFAS is unethical and dangerous. It may not even occur depending on who's leading the EPA in 2025 and beyond. We simply cannot wait for a one at a time approach. Again, we ask that EPA include a mechanism for adding additional PFAS to this rule's Hazard Index. It will not only save EPA time and resources, it could save lives. Also relative to this regulation, we ask that EPA include clear guidance on filtration to ensure that, for instance, spent carbon is managed without PFAS emissions or discharge and transport of PFAS containing filtration components is safe. Aside from this regulation, we of course request EPA work quickly to hold polluters accountable rather than taxpayers and utilities. Thank you very much.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Michigan League of Conservation Voters (Doc. #3072-62, SBC-046378)

Hi. Thank you for providing the opportunity to comment on these critical drinking water protections. I applaud the EPA for proposing strong limits on six widely detected PFAS chemicals in our drinking water. My name is Shannon Ervin and I'm a resident of Michigan where I studied freshwater science and has since held positions related to monitoring and educating the public on water quality. It has been my responsibility to bring PFAS to the public's attention. Due to the commonalities of these chemicals, it is bizarre, however, how unknown they are to the general public, especially when they have such a broad spectrum of health impacts. It is a relief that the EPA will be issuing protections on the public's behalf. However, damage has already been done. In regard to these proposed limitations, I urge you to act quickly on the entire class of chemicals rather than one by one. With an approximate 200 million people drinking contaminated water supplies, this proposal would save thousands of lives and prevent tens of thousands of serious PFAS-related illnesses yearly. In my line of work, I hear stories of individuals experiencing health problems by unknowingly consuming PFAS or knowingly consuming PFAS and not having a choice as there is no polluter pay or enforceable cleanup to

the polluters. This has built a community of people who represent the impacted communities in the Great Lakes PFAS Action Network. These impacted community members have been exposed to both individual PFAS and chemical mixtures of PFAS, which is why they are encouraging that the EPA propose to use a hazardous index on GenX, PFBS, PFNA, and PFHxS to inform risk of chemical mixtures. These proposed regulations are long overdue and fully support this first step of regulating six dangerous PFAS chemicals in drinking water. As the EPA moves forward and considers additional standards and actions, it is very important to take a comprehensive approach to regulate the entire class of chemicals. Addressing the entire class of PFAS will reduce overall exposure and improve drinking water safety for thousands of communities across the country. And since... Oh, and I'm out of time, thank you so much.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Michigan League of Conservation Voters (Doc. #3072-79, SBC-046388)

Hello, my name is Lena Swirczek, and I am a regional organizer for the Michigan League of Conservation Voters in southeast Michigan. I want to start by thanking the EPA for holding this hearing about strong proposed drinking water standards for its six PFAS chemicals. I am a resident of Oak Park, Michigan and I live in the Rouge River Watershed. In recent years, there have been growing concerns about elevated PFAS levels, especially in fish. Although I don't know of any current issues with my drinking water, I'm also aware that the blood of nearly every person in the United States contains PFAS, including likely myself. Whether or not I have a current water advisory, this issue is extremely important to me and others in my community who cannot be on this call today. PFAS chemicals present an extreme danger to every person in Michigan and the rest of the United States. Exposure to PFAS could prevent me from having children, cause cancer, and even hurt my immune system, which is especially terrifying as we continue to live with COVID. My heart breaks for everyone that has already faced these health effects from PFAS, especially knowing that proper regulation could have prevented this suffering in the first place. I appreciate that the EPA is finding the science that shows that virtually no levels of PFAS chemicals are safe to drink. This new standard is an important first step in protecting the public. However, we also need the EPA to move towards regulating the entire class of PFAS chemicals rather than on a one-by-one basis. Companies like 3M and DuPont have known that PFAS chemicals as a whole pose serious health threats since the 1950s. That is older than both me and my parents. I don’t want to be a grandmother by the time we take serious action towards addressing all of the PFAS chemicals that contaminate our water, food, soil, and air. This issue is long overdue, and we need action from the EPA to act broadly and boldly to protect the public. Addressing PFAS as a class of chemicals would save thousands of lives and hopefully prevent future contamination. Thank you for proposing this important first step and I hope to see further action from the EPA on additional PFAS chemicals soon.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Vermont PFAS Military Poisons Coalition (Doc. #3072-81, SBC-046390)

My name is Marguerite Adelman and I'm the coordinator of the Vermont PFAS Military Poisons Coalition. Our coalition believes that the EPA's proposed drinking water standards, while a huge step forward, are not comprehensive enough, take too long to enact, and don't set PFOA and PFOS at the limits needed to protect people and animals from harm. EPA's chemical-by-chemical approach is just not good enough to protect public health and the environment. We must regulate PFAS as a class of chemicals, ban all but absolutely essential uses of these toxins and allow no new PFAS to enter the market. The EPA should do with the European Union's Chemical Agency has done, ECHA. ECHA proposes to ban PFAS production and the import of over 10,000 forms of PFAS chemicals in the European Union. 108 European countries have committed to phasing out PFAS chemicals from products and processes and have joined in calling for comprehensive laws to deal with PFAS. The proposed EU ban on PFAS is extensive as opposed to the EPA's approach of regulating a few PFAS at a time. The EPA's proposal to regulate PFAS doesn't even include all of the 26 most common forms of PFAS found in drinking water. There are no pending proposed standards for 20 of these, and 12 of these PFAS are not included in current monitoring. Three of these PFAS fall outside the working definition for PFAS that the EPA adopted without any outside review. Finally, the laws won't even take effect until 2026. The EPA and all U.S. government agencies need to start using the precautionary principle, especially in regard to PFAS. Before a product goes on the market, a company must prove it is safe for our health and the environment, and all ingredients must be listed and known to consumers. We have the right to know. If there is any doubt, we must err on the side of caution and logical scientific assumptions and not allow the product on the market. We must protect future generations. Thank you.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Michigan League of Conservation Voters (Doc. #3072-83, SBC-046392)

Thank you for this opportunity. My name's Jessica Schick. I'm a student from Grandville, Michigan and I also work as a regional organizer for the Michigan League of Conservation Voters. I applaud the EPA for proposing strong limits on six widely detected PFAS in our drinking water. I live a couple minutes away from Millennium Park, which is the largest urban park in West Michigan. In 2021, PFAS was discovered in a former landfill within the park. As someone who grew up visiting Millennium Park multiple times a week, I was devastated to learn that water flowed from that landfill into the parks, lakes, and wetlands. Six of the park's seven lakes were affected by PFAS contamination, but by current standards, they were deemed still safe for people to use. Previous speakers have noted the long list of health issues caused by PFAS and that no level of PFAS is truly safe. The park is a popular place for local families. We swim and fish in those lakes. And Millennium Park is one of over 12 identified PFAS sites along the Grand River, which flows into Lake Michigan. Both the river and Lake Michigan are the main sources of drinking water for people in West Michigan. We urge you to finalize these

standards as quickly as possible. While this is an important first step, in order to fully protect the health of people, communities, and the environment, we urge the EPA to move towards regulating PFAS as an entire class of chemicals instead of one by one. Addressing the entire class of PFAS will reduce overall PFAS exposure and improve drinking water safety in thousands of communities across the country. Thank you.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Author (Doc. #3072-85, SBC-046394)

My name is Callie Lyons and I'm the author of "Stain-Resistant, Non-Stick, Waterproof and Lethal," the first book about this PFAS plague on our population. I want to commend the many students who we're hearing from today. Your time is well spent and much appreciated. I encourage you to visit the place where I live and see what has happened here. You see, I live near Parkersburg, West Virginia, and if you've seen the movie Dark Waters, you know our story. As ground zero in the public's awareness of this problem, many people, including local residents, believe this problem has been tackled and is behind us. They do not realize the poisoning continues. While some of our communities have filtration systems, many do not. Parkersburg, for instance, does not. I count more of my friends and neighbors as sick from exposure related illness than those who are not. And the people here who get sick don't just get one related illness, they often suffer through two or three or more before it ends their lives. Please regulate these dangerous substances as a class and do it with all haste, but please do it in a way that will not leave us behind. A very real concern is that the unintended consequences of these measures could easily lead to a situation where filtration materials and processes become so widely in demand that solutions would be available only to the highest bidder or the most populous areas. That would leave us in the same desperate situation we find ourselves in today. This proposed action regarding water is a start, but it is only a start as we will continue to be exposed in so many other ways. Since 2003, I've heard one comment more than any other when it comes to our pollution situation. If it was really a problem, the EPA would do something about it. Please do something about it and now. Make it meaningful and fulfill your promise to protect our people. Thank you.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

WWALS Watershed Coalition Inc. (Doc. #3072-86, SBC-046395)

Thank you. Yes. I'm John Quarterman. I'm the Suwannee Riverkeeper with WWALS Watershed Coalition Inc. trying to keep waters clean in the 10,000 square miles Suwannee River Basin in Georgia and Florida. I would like to urge EPA to rapidly complete the process of setting Maximum Contaminant Levels for the most toxic PFAS as well as total PFAS in drinking water. As others have noted, EPA needs to use PFAS classes since the manufacturers can avoid specific

chemicals by tinkering with the formula to change it slightly. We have previously requested and continue to request requiring producers to label products with each PFAS or PFOAS. Now we ask to add the class of each. While it's necessary to deal with point sources such as wastewater treatment plants, the rule also needs to deal with non-point sources such as human waste used as fertilizer, whether processed or not, such waste washes off into waterways. In tests we conducted last year in Georgia and Florida, we found PFAS in our Withlacoochee River, both upstream and downstream of the most relevant point sources, so we suspect some is coming from non-point sources. Back in 2014, PFAS was found in much higher levels in fish in our Alapaha River. It accumulates in fish, which are often eaten by people. EPA needs to require and Congress needs to find a way to fund waterway quality testing and fish testing for PFAS. As observed in Maine, PFAS can pass through cows who eat fodder fertilized that way and then may come out in milk or possibly even in meat. The food supply also needs to be tested and regulated for PFAS. Most importantly, EPA needs to strongly regulate the producers of these substances to radically cut down on this problem. Yet there's so much of it out there that all of the above is also necessary and EPA should require the PFAS producers to pay the cost of labeling, testing, additional wastewater processing, regulation, and cleanup. If EPA cannot do that, then Congress needs to ask. Thank you.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Michigan League of Conservation Voters (Doc. #3072-88, SBC-046396)

Hi. Thank you very much for the opportunity to speak to this today. My name is Victoria Stewart and I work with the Michigan League of Conservation Voters. I also reside in the state of Wisconsin where many community members have personally experienced health problems or live in health effected communities. We urge you to finalize these standards as quickly as possible. And while we know that this is an important first step in order to fully protect the health of people, communities, and the environment, we urge the EPA to move toward regulating PFAS as an entire class of chemicals instead of one by one. PFAS have contaminated drinking water supplies for approximately 200 million people and the blood of nearly every individual in the United States, including newborn babies who are exposed in the womb. This proposal will save thousands of lives and prevent tens of thousands of serious PFAS related illnesses each year, but we cannot wait to do this one by one. We know that if we continue to wait year by year, we will just have more communities and more individuals impacted by the negative effects of PFAS. I work with groups like the Great Lakes PFAS Action Network who represent PFAS impacted communities across the Great Lakes region, and these impacted community members have been exposed to both individual PFAS and chemical mixtures of PFAS, which is why this is so important. These proposed regulations are long overdue when we fully support this first step of regulating six dangerous PFAS in drinking water, and as the EPA moves forward and considers additional standards and actions, we urge you to take a comprehensive approach to regulating the entire class of chemicals. Addressing the entire class of PFAS will reduce overall PFAS exposure

and improve drinking water safety in thousands of communities across the country. Thank you very much.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Catherine Daligga (Doc. #3072-89, SBC-046397)

My name is Catherine Daligga and I'm a 65-year-old mother, grandmother, cancer survivor, climate and environmental activist and up. Every day of delay in imposing and enforcing these strict standards is a day lost to preventing future harm. Like others speaking today, I'm horrified by the scope of the problem and I consider it urgent lifelong resident of Southeast Michigan. Thank you for hosting this public comment period on water protection standards. I appreciate being in our virtual room with so many concerned and engaged citizens, and I'm grateful that the EPA is proposing limits for these six PFAS-related compounds in accordance with the scientific evidence, recognizing that basically no amount of these chemicals is safe to have in our water. My current hometown of Ypsilanti, Michigan is in the Huron River Watershed, already known to be impacted by PFAS contamination and thus affecting the Ann Arbor water system that does draw from the Huron. Since Ypsi is on the Detroit water system instead, as far as I know, I'm not personally at immediate risk from increased PFAS exposure, but we do have at least six other identified PFAS sites in Washington County near me. And I'm deeply concerned regardless about the risk of PFAS contamination for everyone in my local community, county, region, state, and country. According to the Michigan PFAS Action Response Team, there's currently more than 200 confirmed PFAS contamination sites in the state of Michigan alone, with more than 11,000 suspected PFAS sites throughout the state. We know that this class of chemicals is already so ubiquitous that we face a massive challenge in cleaning it to address it as quickly and completely as possible. Inaction and delay are not justifiable. We have already lost too much. Too many people like Amara Strande, too many residents of communities like Boston, Michigan and Parkersburg, West Virginia. This step should be merely the first of many taken by the EPA to regulate PFAS compounds as a class rather than considering them one by one. The time to act is now, not only to implement these new regulations, but to devise more comprehensive measures for eliminating these dangerous toxins as well as for holding the original manufacturers rather than the general public responsible for the cleanup costs. Thank you again for your time.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Hanaloa Hillela (Doc. #3072-92, SBC-046400)

Aloha. My name is Hanaloa Hillela, and thank you for giving me this opportunity to speak. I am from Oahu, Hawaii, and I am new to dealing with this PFAS, and it is coming on the tail end. I've become deeply involved in a water struggle here in Hawaii. As many of you know, the Red Hill

crisis, the Navy's underground storage facility leaking into our aquifer. And we thought if that wasn't bad enough, about a year after a major spill, the 11/20/2021 spill, about a year and nine days later in 2022, there was a spill of 1,300 gallons of AFFF concentrate, which has lots of PFAS in it, and this is right coming out of the Red Hill facility as well. So, we're highly concerned about these continuing spills and tests revealing more and more PFAS in our environment. Lately in the news we're finding out Kunia village, we're finding high levels of PFAS in their drinking water wells, Wahiawa we're finding. And we're often finding the PFAS is directly associated with military facilities. In central Oahu, the Kunia village situation, it seems like that is coming from the Schofield wastewater treatment facility, which I believe was privatized back in early 2000s by the military. But that's processing a lot of the wastewater out of the military bases, which we know that not only for firefighting foam but for de-greasing and other maintenance and service needs PFAS is extensively used. So, I would like to support most of the testimony that's been given that we have to treat this as a class rather than individual chemicals, which the chemical industries will find loopholes through. And I think that we need to go zero tolerance. I applaud.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Kristina Winter (Doc. #1559, SBC-042544)

The proposed drinking water standards are a great first step to address these particular PFAS chemicals, however, I urge EPA to not stop here—it is critical that EPA next moves to regulate the full class of PFAS chemicals.

Thank you for your consideration.

Sincerely,

Miss Kristina Winter

161 Oakland Ave Miller Place, NY 11764-3406 kristinawinterdesigns@gmail.com

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Minnesota Pollution Control Agency (MPCA) (Doc. #1569, SBC-042499)

MPCA strongly encourages EPA to continue developing MCLs for individual PFAS, groups of PFAS and their precursors, or other PFAS subgroups for drinking water regulations in the next round of regulatory determinations, including PFAS with completed IRIS assessments and considering development of a summed PFAS MCL or a similar means to address unregulated PFAS.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Minnesota Pollution Control Agency (MPCA) (Doc. #1569, SBC-042489)

The MPCA also urges EPA to take further steps to address PFAS in connection with this proposal. EPA should develop and adopt MCLs for additional PFAS with completed Integrated Risk Information System (IRIS) assessments (PFBA [Link: https://iris.epa.gov/ChemicalLanding/%26substance_nmbr=701] , PFHxA [Link: https://iris.epa.gov/ChemicalLanding/%26substance_nmbr=704] and soon, PFDA), either individually or as part of the HI-based PFAS MCL, in this rulemaking or as soon as possible. In addition, there is a need for a summed PFAS MCL or similar type of regulatory value to account for exposures to PFAS in drinking water that do not have MCLs (and are unlikely to any time soon, given the lack of toxicity data for the vast majority of PFAS).

We are aware that suggesting EPA develop an alternative and/or summed PFAS MCL is outside the bounds of "normal" with respect to the SDWA practice of developing individual MCLs. Nevertheless, the lack of toxicity data with which to develop traditional toxicity-based MCLs, and the serious human health impacts from PFAS that are being identified and verified (one resource is Kwiatkowski et al., 2020 and 2021), provide a strong driver for EPA to develop such an approach. Pelch et al. (2023) just published the results of a pilot study focused specifically on the Unregulated Contaminant Monitoring Program 5 or UCMR5, which will inform policy makers of the need to develop future PFAS MCLs. Pelch et al. suggest the design of the UCMR5, which is taking place now through 2025, will result in a number of gaps in detection of PFAS. A summed PFAS MCL is needed to better account for the variety of PFAS being detected in drinking water now, until a better approach can be formulated and promulgated.

Other entities have developed alternative and/or summed PFAS regulatory values. The European Union (EU) 2020 drinking water directive (DWD) includes drinking water standards for a defined sum of 20 PFAS at 100 ng/L or for a total PFAS at 500 ng/L. EU Member States have until 2023 to incorporate this into their national legislation. Bil et al. (2021) propose using a relative potency factor (RPF) that has PFOA as an index chemical. EPA itself is doing research to facilitate grouping PFAS chemicals regarding their toxicokinetic half-life, as a basis for prioritization (Dawson et al., 2023). While none of these approaches is likely fully developed or completely compatible with the dictates of the SDWA, they provide a basis for developing a summed PFAS MCL that has a scientific foundation and rationale to address the clearly demonstrated need.

Per EPA's Request for Comment (RFC), the MPCA has provided specific comments below, by section. Some, identified as such, respond specifically to the questions put forth by EPA in Section XIV of the RFC.

Section III- Regulatory Determinations for Additional PFAS

1) EPA asks: are there other peer-reviewed health or toxicity assessments for other PFAS the EPA should consider as part of this action?

MPCA response:

• The Integrated Risk Information System (IRIS) PFBA [Link: https://iris.epa.gov/ChemicalLanding/%26substance_nmbr=701] and PFHxA [Link: https://iris.epa.gov/ChemicalLanding/%26substance_nmbr=704] assessments are completed and should be considered for inclusion in this rulemaking, either for development of stand-alone MCLs/MCLGs or as part of the mixture of PFAS that are proposed to be regulated under the general Hazard Index (HI) approach, whichever would be most appropriate.

• Likewise, the IRIS PFDA [Link: https://iris.epa.gov/ChemicalLanding/%26substance_nmbr=702] draft assessment is out for public comment, EPA should consider whether this assessment will move towards finalization on a timeline where it could be incorporated into this rulemaking, either for development of a stand-alone MCL/MCLG or as part of the mixture of PFAS that are proposed to be regulated under the general HI approach.

2) EPA asks: will regulation of PFHxS, HFPO-DA, PFNA, PFBS and their mixtures, in addition to PFOA and PFOS, provide protection from PFAS that will not be regulated under this proposed rule?

MPCA response:

• MPCA does not believe regulation of PFHxS, HFPO-DA, PFNA, PFBS and their mixtures, in addition to PFOA and PFOS, provide protection from PFAS that will not be regulated under this proposed rule. That is why MPCA has urged EPA to adopt MCLs for additional PFAS with completed IRIS assessments (PFBA [Link: https://iris.epa.gov/ChemicalLanding/%26substance_nmbr=701] , PFHxA [Link: https://iris.epa.gov/ChemicalLanding/%26substance_nmbr=704] and soon, PFDA), either individually or as part of the HI-based PFAS MCL, in this rulemaking or as soon as possible. That is also why MPCA is urging EPA to consider development of a summed PFAS MCL or similar to account for exposures to PFAS in drinking water that do not have MCLs (and are unlikely to any time soon).

• If the HI-based PFAS MCL is exceeded, treating for PFHxS, HFPO-DA, PFNA, and PFBS will remove other PFAS that co-occur. However, the threshold for when treatment would be required is likely not low enough to protect public health from the occurrence of other PFAS. Inclusion of additional PFAS in the general HI approach could reasonably result in the HI being exceeded more often than if only four PFAS are included.

• Another possibility to improve the protectiveness of the HI-based PFAS MCL would be to add a “mixture factor” similar to a relative source contribution (RSC) adjustment with consideration of other unquantified PFAS in the drinking water. For example, a mixture factor of 80% would mean that there is 20% of the total quantified “toxicity” that is reserved for non-quantified PFAS.

• Note MPCA's previous comment about the need for a summed PFAS or similar type of MCL to protect for non-quantified or un-regulated PFAS.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document. Regarding the application of a "mixture factor," at this time, the EPA does not have the scientific basis for establishing or applying such a factor. Instead, the EPA is using the general Hazard Index method, which is supported by precedent in other regulatory contexts, agency chemical mixtures guidance, and the SAB review of the draft PFAS Mixtures Framework.

Minnesota Pollution Control Agency (MPCA) (Doc. #1569, SBC-042491)

There is a concurrent need for individual PFAS MCLs where completed IRIS assessments are available and/or where sufficient toxicological and toxico-kinetic data is available, per other comments in this letter.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Endocrine Society (Doc. #1579, SBC-042427)

We urge the EPA to build on the proposed regulation to advance more comprehensive solutions that regulate PFAS as a class of chemicals for the protection of public health and the environment. Thank you for considering our comments; if we can be of further assistance, please contact Joseph Laakso, PhD, Director of Science Policy at jlaakso@endocrine.org

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

American Public Works Association (APWA) (Doc. #1584, SBC-042392)

PFAS are a large, complex group composed of thousands of synthetic chemicals and testing for more and more of them would undoubtedly risk exacerbating other challenges. The lack of clarity on whether other PFAS might be slated for regulation as drinking water contaminants in the foreseeable future is also concerning especially as communities consider which treatment methods that may best capture a wider spectrum of PFAS chemicals.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Cape Fear Public Utility Authority (CFPUA) (Doc. #1588, SBC-042380)

As the most high-profile constituent of Chemours' PFAS contamination in the Cape Fear River, GenX remains a contaminant of concern for CFPUA and our customers. We commend EPA for including it in the proposed NPDWR, support the concept, and are grateful for the certainty it

brings to treatment standards. As CFPUA continues to evaluate EPA's proposal for regulating GenX, PFHxS, PFNA, and PFBS as components of a Hazard Index, we suggest that any future additions or modifications to the Hazard Index be introduced through formal rulemaking to ensure proper alignment with the public interest and the Administrative Procedures Act. As is the case with PFOA and PFOS, GenX and the other three hazard index compounds are being removed by CFPUA's new GAC filters to levels that, based on current raw water concentrations, will remain significantly below the proposed Hazard Index compliance threshold.

EPA Response: The commenter supports regulating GenX chemicals (referred to as HFPO-DA throughout this approach). In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Public Health, Seattle & King County (PHSKC) (Doc. #1594, SBC-042356)

Below are recommendations that PHSKC feels would strengthen the proposed protective actions:

Include additional PFAS found in drinking water in the MCL/MCLG derivations for PFAS mixtures in drinking water and develop a system that rapidly incorporates regulatory limits for new PFAS found in drinking water. We have continued concerns about additional PFAS that are found in drinking water and hope that EPA will continue to rapidly include additional PFAS on this list. Additional PFAS beyond the ones identified above have been detected in drinking water [FN1: Pelch et al. 70 analyte PFAAS test method highlights need for expanded testing of PFAS in drinking water. Science of the Total Environment (2023) 876: 16298]. The PFAS selected for possible regulation are a small number of those that found in drinking water. EPA should also conduct research to determine which PFAS remain following drinking water treatment that exceed any of the proposed MCLs to inform how protective remediation will be for other PFAS not included in the proposed regulatory actions.

EPA Response: In regard to regulating additional PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. In regard to PFAS treatment, please see section 10 of the EPA response in this *Response to Comments* document. For a description of numerous current EPA activities related to PFAS, including PFAS treatment, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

City of Allentown and Lehigh County Authority (LCA), Pennsylvania (Doc. #1667, SBC-043672)

[The treatment of these compounds in the proposed regulation is problematic for several reasons:]

2. Future Implications – PFOA and PFOS are the most common PFAS compounds found in the nation's drinking water and the family of PFAS compounds ranges in the thousands. The City

has a concern about the potential complexities with the Index when new PFAS compounds are added to future regulations.

EPA Response: Please see sections 4.3.2 and 5.2 of the EPA response in this *Response to Comments* document.

New York City Department of Environmental Protection (NYCDEP) (Doc. #1679, SBC-044209)

The HI excludes PFHpA (VII.e. p. 18678) based on a finding of no-toxicity (XIII.F.18719). PFHpA was included in the UCRM3 and has demonstrated occurrence data. The finding of no toxicity of PFHpA, which seems premature based on a "small number of studies investigating immunotoxicity," is used as rationale for exclusion from the HI. It would seem more appropriate to include this analyte in the HI with a high divisor level, rather than to exclude it from the HI altogether. The analyte is found using both approved methods, and data will be available at no additional cost (i.e., this suspected contaminant is excluded even though EPA has available data).

EPA Response: The EPA disagrees with this comment. The EPA did not state that the Hazard Index excludes PFHpA based on a finding of no toxicity. The commenter is citing excerpts from the *ATSDR Toxicological Profile for Perfluoroalkyls* that were cited by the EPA in the "Non quantifiable Benefits of Removal of PFAS Included in the Proposed Regulation and Co-Removed PFAS" section of the preamble to provide information about adverse health effects associated with exposure to unregulated co-occurring PFAS. Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Public Employees for Environmental Responsibility (PEER) (Doc. #1683, SBC-044969)

EPA needs to regulate more than six PFAS in drinking water. There are thousands of individual PFAS, depending on how they are defined [FN4: https://www.sciencedirect.com/science/article/pii/S2589004222002905]. When a particular PFAS comes under scrutiny, industry develops "regrettable substitutions" that are themselves toxic PFAS [FN5: https://www.env-health.org/wp-content/uploads/2023/04/Briefing-PFAS-biomonitoring-information-April2023.pdf]. When EPA finalizes this proposed rule, industry will likely turn to other PFAS with limited or nonexistent toxicity information, which will create additional human health and environmental concerns. Moreover, it is critical to note that this proposed rule does not take into account precursor compounds. PFAS compounds generally come in one of two forms: a precursor or a terminal form. EPA's proposed rule deal with six terminal compounds that do not degrade under normal environmental conditions. However, because unregulated precursor compounds can be transformed in the environment into the regulated terminal forms, regulating only the terminal compounds is not a solution. Indeed, Harvard University researchers recently found that roughly half of the PFAS found on a Cape Cod military base "consist of precursors that can transform into terminal compounds of known health concerns..." [FN6: https://pubs.acs.org/doi/full/10.1021/acs.est.3c00675].

Therefore, the only way for EPA to truly protect human health and the environment from PFAS is to: 1) define them broadly; 2) regulate them as a class; 3) ban all non-essential uses of PFAS; and 4) implement stringent disposal and cleanup standards. Regulating six PFAS in drinking water is a start, but it is the proverbial drop in the bucket.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Three Rivers Waterkeeper (3RWK) (Doc. #1689, SBC-044976)

The EPA's decision to base the MCLs for these four PFAS off of the Hazard Index (HI) approach expects and accounts for co-occurrence. By basing the MCL on the sum of each chemical's ratio of potential exposure to the level of exposure at which no health effects are expected, the EPA seems to have created a framework for the addition of further PFAS if and when new studies reveal those PFAS to be harmful. If in time it becomes necessary to regulate all PFAS as a class, we hope that this framework will help to determine the appropriate MCLs.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

City of Lancaster, Pennsylvania (Doc. #1695, SBC-044994)

3. USEPA Future Rule Making Shortcut: The USEPA has shown a new system/methodology of grouping future PFAS species directly into the hazard category without thorough testing of a chemical individually to determine its biological impact. Moreover, this ruling is being made without the UCMR5 study data which focuses on these compounds. It is a major issue when the known vetted rulemaking process is circumvented for ease in what appears to be a knee jerk reaction without proper scientific data to fully back up a decision. It shows a departure not only from the use of thorough scientific reasoning and methodology, but it can result in a significant chance for mislabeling and incorrectly assuming the risk/behaviors of the said chemical. The newer method of being able to link chemicals under the hazard grouping for PFAS without going through the appropriate rulemaking and analysis short circuits the ability to appropriately study and validate the results while potentially mischaracterizing a new chemical's potential risks and potential mitigation.

One critical example of this method having flaws is through the study of the periodic table of the elements. When you look at the group of elements 80-84 these all would be considered poisonous and deadly by the new grouping method being used by EPA. However, if that had happened then humanity would never have found that Bismuth (element 83), which is between two of the most poisonous elements known to man, is one of the best elements for helping human internal gut health when they are sick, and we would not have the universally known product of Pepto-Bismol.

EPA Response: Please see sections 4.3.5 and 4.3.2 of the EPA response in this *Response to Comments* document. Regarding the comment on bismuth, that topic is out of scope of this final NPDWR. Regarding UCMR 5 data, please see sections 3.1.2 and 6.8 of the EPA response in this *Response to Comments* document.

Susan Gorman-Chang (Doc. #1705, SBC-045082)

EPA-HQ-OW-2022-0114

Comments submitted by: Susan Gorman-Chang

I am appreciative of the EPA finally taking the threat of PFAS to human health seriously and these proposed regulations to regulate these harmful chemicals.

I have the following suggestions concerning these regulations:

1. Change the regulations to treat PFAS as a class of chemicals using regulation by class in the same manner as proposed by the Intergovernmental Organization for Economic Cooperation and Development and used by the members of the European Union. This would mean a comprehensive approach to the as many as 5,000 to 12,000 variations of PFAS chemicals and would provide more protection for the health of all human beings and wildlife.

2. I applaud your hazard index approach, as this can be a first step towards regulating PFAS as a class.

EPA Response: The commenter supports the use of the Hazard Index in this drinking water regulation. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045125)

Comment: Please explain how states can account for PFAS other than the four PFAS included in the Hazard Index equation.

Explanation: While the Department appreciates EPA's cumulative approach to four PFAS, the Hazard Index approach is not adequate to protect health. The Hazard Index approach does not offer a path to add additional PFAS. For example, the EPA IRIS program published final toxicity values for PFHxA on April 10, 2023. The EPA IRIS program has several additional PFAS toxicity values in development. Yet the Hazard Index equation does not offer flexibility to include additional PFAS as toxicity values become available. In addition, the Hazard Index equation does not adequately address PFAS as a class. As EPA methods for PFAS analysis improve and additional PFAS are included, we gain more and more information on our exposures to PFAS. Yet the Hazard Index equation does not include additional PFAS either with or without final toxicity values. This sends the message that other PFAS are not of public health concern.

Given what we know of PFAS, including those under assessment by IRIS, this is not a health-protective assumption.

EPA Response: In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Citizens Campaign for the Environment (CCE) (Doc. #1710, SBC-045138)

Regulate PFAS as a Class. The proposed EPA regulations are a great first step and should be implemented as soon as possible. However, there are thousands of PFAS chemicals with similar characteristics and health impacts as the PFAS chemicals covered by these regulations—this should only be the start for EPA and the Agency should ultimately move to regulate PFAS as a class.

EPA Response: The commenter supports this PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS rulemaking. In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Citizens Campaign for the Environment (CCE) (Doc. #1710, SBC-045135)

Recommendation to strengthen the Hazard Index: CCE recommends that EPA develop a process to add additional PFAS chemicals to the Hazard Index. We know that there are many thousands of PFAS chemicals, which have similar characteristics and cause similar adverse health impacts. As more information becomes available on additional PFAS chemicals, rather than starting a rulemaking process from scratch, which can take years to complete, EPA should develop a process to more efficiently add additional PFAS chemicals to this existing Hazard Index.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Private Citizen – General (Doc. #1722, SBC-043834)

3. Please regulate these chemicals as a class. We are tired of playing whack-a-mole with the manufacturers who slightly modify the chemical structure to stay ahead of health studies.

4. Regulating PFAS chemicals as a group would also stop the use of precursors that readily convert to legacy PFAS chemicals.

Thank you for your attention to this matter. Best,

Donna Reardon

Donna Reardon

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37 Curtisville Rd

Concord, New Hampshire 03301

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045176)

Inclusion of additional PFAS in the Hazard Index

EPA selected four PFAS for inclusion in an HI approach for MCLG development: hexafluoropropylene oxide (HFPO) dimer acid and its ammonium salt (also known as GenX chemicals), perfluorobutane sulfonic acid and its related compound potassium perfluorobutane sulfonate (PFBS), perfluorononanoic acid (PFNA), and perfluorohexanesulfonic acid (PFHxS). EPA identified these PFAS as having continued co- occurrence in drinking water and HBWCs that were available or could be calculated using recently published, peer-reviewed, publicly available assessments. MassDEP is supportive of the HI approach due to its ability to address co-exposures of PFAS in drinking water, but we recommend that EPA clarify its intent to incorporate additional PFAS into the HI. The EPA Integrated Risk Information System (IRIS) assessments for perfluorobutanoic acid (PFBA) and perfluorohexanoic acid (PFHxA) were finalized in December 2022 and April 2023, respectively, and could be used to derive HBWCs for inclusion in the HI approach. The IRIS Program also has assessments in development for perfluorodecanoic acid (PFDA), PFHxS, and PFNA that could be incorporated into the HI once finalized. Further, EPA should consider applying read across approaches to address additional PFAS with continued co-occurrence such as perfluoroheptanoic acid (PFHpA). EPA should clarify the inclusion criteria for PFAS compounds in the HI and the process for updating HBWCs as additional assessments and occurrence data become available to ensure that the MCLG and MCL are adequately protective of public health.

EPA Response: The commenter supports the Hazard Index in this regulation. In regard to regulating PFAS beyond those six regulated as part of this rulemaking, please see section 4.3.5 of the EPA response in this *Response to Comments* document.

North Carolina Conservation Network (Doc. #1728, SBC-043560)

In North Carolina, data from the Cape Fear River has indicated high levels of PFMOAA [FN1: See, for example, Cape Fear Public Utility Authority, website: Latest PFAS Test Results [Link: https://www.cfpua.org/779/Latest-PFAS-Test-Results], last visited May 30, 2023. The data indicates levels of PFMOAA and other PFAS in both raw and finished drinking water. See also, Frannie Nilsen, PFMOAA Summary [Link: https://www.deq.nc.gov/pfmoaa-summary-presentationpdf/download?attachment] (Presentation to the Secretaries' Science Advisory Board), February 8, 2023, slide 4 (noting that PFMOAA accounts for 67% of the total PFAS in the Cape Fear at the Huske Dam boat ramp, and 26% further downstream on the Cape Fear)]. We expect PFMOAA to have similar impacts on human health as other PFAS [FN2: Nilsen, slide 6 (summarizing toxicological indications for PFMOAA)]. As a short-chain PFAS, it breaks

through granular activated carbon treatment quickly. Because PFMOAA foils treatment so quickly, even where others of the four PFAS in EPA's proposed index are present, the index may not shield water system customers from exposure to PFMOAA. Where none of the six PFAS targeted by EPA's proposal are present, of course, the MCL will also not require drinking water treatment to remove PFMOAA or any other locally common PFAS.

We appreciate EPA's efforts to address PFAS nationally through the PFAS Strategic Roadmap [FN3: U.S. EPA, PFAS Strategic Roadmap [Link: https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf], October 2021]. We also understand that, because PFMOAA is not common across the country, the agency has not prioritized it as a target for research to develop a health value. Yet, PFMOAA remains a leading source of exposure here. In February 2023, North Carolina's Secretaries' Science Advisory Board considered whether existing published literature was sufficient to establish a health value for PFMOAA. The advisory body found inadequate literature at the time, but noted that studies in publication may well provide a suitable basis to develop a reference dose and derive a health value for PFMOAA this year.

EPA's draft rule includes this formula for the index portion of the proposed MCL:

GenX + PFBS + PFNA + PFHxS = Hazard Index Value, with the Index required to be kept below 1.

10 2000 10 9

We recommend adjusting the index formula to read:

GenX + PFBS + PFNA + PFHxS + [additional PFAS] = Hazard Index Value

10 2000 10 9 [adopted health value] for that PFAS

That is, we recommend that EPA build into the final rule a path for states to add locally significant PFAS to the index formula as health values become available for them [FN4: We note that the Safe Drinking Water Act (SDWA) does not preclude states from adopting their own drinking water standards. But, in this case, that would require a state to duplicate four-fifths of the existing index. States are far more likely to fit themselves into an EPA rule that makes room for them to add locally common PFAS.]. To finalize the rule in this form, EPA likely needs to cite criteria for judging when a health value is sufficiently robust. It may also be wise for the final rule to require that a state wanting to add a PFAS to the index formula do so through an official state decision, separate from the scientific process of generating a health value.

In concrete terms, for PFMOAA in North Carolina, this pathway could look like this: health studies are published on PFMOAA. The state scientific advisory body reviews the information and recommends that the state adopt a health value. Toxicologists at the NC Department of Health and Human Services derive a health value for PFMOAA. Then, the Commission for Public Health (CPH) proposes, based on the availability of a health value, to add PFMOAA to the index formula as applied in North Carolina. After notice and public comment, CPH finalizes

that decision. The Department of Environmental Quality's (DEQ) Public Water Supply program then begins to phase in the five-PFAS index within Safe Drinking Water Act implementation.

We recognize that this would not be a fast process. On the other hand, it would allow states to address PFAS that present a serious threat to their residents but that are so generally uncommon that EPA is not itself likely to develop a health value for them. In North Carolina, PFMOAA is a known example of this problem; we think it likely that there are other similar threats across the nation.

Thank you for considering this recommendation, and for working to protect all of us from unsafe exposures to this class of toxic compounds.

Stephanie Schweickert

Senior Campaign Organizer

Grady McCallie

Policy Director

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Defend Our Health (Doc. #1741, SBC-045199)

We recommend setting regulatory thresholds for the precursor PFAS which are known to transform into the regulated group of 6 PFAS. Finally, we recommend working towards regulating PFAS in drinking water as a class by adopting a total organic fluorine standard to supplement the regulation of individual chemicals.

Respectfully submitted,

Christopher D. Chavis

Vice President of Programs and Policy Defend Our Health

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document. While some states have promulgated drinking water standards for various PFAS prior to promulgation of this NPDWR, this rule provides a nationwide, health-protective level for PFOA and PFOS (as well as four other PFAS) in drinking water and reflects regulatory development requirements under SDWA, including the EPA's analysis of the best available and most recent peer-reviewed science; available drinking water occurrence, treatment, and analytical feasibility information relevant to the PQL; and consideration of costs and benefits. Regarding state flexibility to add PFAS to the Hazard Index, after the NPDWR takes effect, SDWA requires primacy states to have a standard that is no less stringent than the NPDWR. States with primacy can promulgate their own standards which could include additional PFAS as

long as the state regulation is no less stringent than the NPDWR. For further information, please see section 5.1.5 of the EPA response in this *Response to Comments* document.

Defend Our Health (Doc. #1741, SBC-045196)

The proposal fails to account for the presence of 'precursor PFAS' which are used in ongoing manufacturing, are present in consumer products and are frequent PFAS contaminants of drinking water. Precursors like PFOSA and EtFOSE/ MeFOSE have been demonstrated to degrade into PFOS [FN3: https://www.eurofins.se/media/1568225/top_precursor_short_facts_170613.pdf], and precursors like 8:2 FTOH and 8:diPAPS are known to degrade into PFOA [FN4: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9335875/]. These chemical transformations can happen in biological systems, including inside of the bodies of mammals [FN5: vhttps://www.sciencedirect.com/science/article/pii/S0045653520302095/pdfft?md5=78e162fdde8642140283640ef2f1cf5c&pid=1-s2.0-S0045653520302095-main.pdf]. As reported recently by Grist.org [FN6: https://grist.org/health/the-epas-proposed-pfas-regulations-ignore-a-major-source-of-drinking-water-contamination/], a recent study of Aqueous Film Forming Foam impacted sites by Environmental Science and Technology [FN7: https://pubs.acs.org/doi/10.1021/acs.est.3c00675] indicates that still other precursors transform into the PFAS chemicals PFBS and PFHxS, which the Agency proposes to regulate under a Hazard Index. It would be an astonishing missed opportunity to ignore precursors to the PFAS the EPA is proposing to regulate when we know they are present in solution in drinking water across the country and we know they can bio-transform inside the body into the very chemicals we are trying to protect people from.

Beyond the specific concern over precursors, the proposal's narrow focus on six specific PFAS chemicals fails to protect the public from the vast array of PFAS currently in the environment including the many new PFAS chemicals currently being manufactured for which there exists little toxicological data. EPA's CompTox dashboard identifies more than 14,000 individual PFAS chemicals [FN8: https://echo.epa.gov/trends/pfas-tools]. As a class, these chemicals share the characteristics of environmental persistence and mobility. The PFAS which been the subject of vigorous medical research have been demonstrated to be associated with toxic health impacts, so the EPA should move beyond the chemical-by-chemical approach and regulate the presence of all PFAS in drinking water to prevent ongoing harm to communities. The agency should adopt a total organic fluorine drinking water standard to supplement the existing proposal. This would protect people from ongoing exposure to understudied members of this toxic class of chemicals.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Defend Our Health (Doc. #1741, SBC-045194)

The Agency should expand the list of regulated PFAS to include precursors which are known to degrade into the any of the six PFAS proposed for regulation under the National Primary Drinking Water Regulations. And finally, EPA should use this proposal to move towards a class-based regulation for PFAS in drinking water.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045201)

2. CT DPH recommends the regulation of additional PFAS through their addition to the Hazard Index (HI). PFAS other than those included in the Proposed PFAS NPDWR contain chemical structural similarities and potentially may adversely impact human health. As further studies are published, the addition of PFAS that are shown to pose a threat to human health might be regulated by their inclusion in the HI. Such a streamlined approach for the further regulation of harmful PFAS would be beneficial toward the protection of human health.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045243)

EPA is proposing to regulate six out of thousands of PFAS chemicals; the additional nonregulated PFAS contain chemical structural similarities and potentially may adversely impact human health. As additional occurrence data, such as UCMR 5, and additional human health data are peer-reviewed and published, EPA should consider a streamlined approach to be able to regulate the chemicals. Detections of PFOA, PFOS, PFNA, PFHxS, PFBS, PFHpA, PFHxA, and PFDA have all been reported in the finished water supply of Connecticut public water systems, but only five of these chemicals are included in the proposed Rule. If future studies indicate occurrence and human health impacts from additional PFAS, adding each PFAS individually to the NPDWR will be a time and resource intensive process. CT DPH supports regulating PFAS mixtures with a Hazard Index if implemented appropriately. By being able to add PFAS to the mixture list through regular revision, as opposed to an individual rule, it will help speed up the process and ensure the regulated PFAS list is representative of the rapidly changing science and most protective of human health.

EPA Response: Please see the section 4.3.5 of the EPA response in this *Response to Comments* document.

West Virginia Rivers Coalition et al. (Doc. #1746, SBC-045256)

West Virginia communities have been exposed to PFAS for decades and bear the cost of contamination with our health. The proposed PFAS drinking water regulations are monumental for our communities, and we commend EPA for taking this step. We support the comments of

Earthjustice and the Natural Resources Defense Council, as well as the National Wildlife Federation. In particular, we strongly support their calls for EPA to:

• Pursue a broader, class-based PFAS drinking water standard

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Environmental Protection Network (EPN) (Doc. #1773, SBC-043862)

EPA should further commit to proposing a rule that sets a standard for them as a group using a novel approach currently under development by ORD.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Ohio Environmental Council (Doc. #1794, SBC-045324)

The PFAS addressed by EPA's proposal are among a class of thousands of forever chemicals. EPA's proposal to use a hazard index to address multiple co-occurring PFAS recognizes the risks associated with harmful chemical mixtures. Like many members of the PFAS class, PFBS, PFNA, GenX, and PFHxS have similar chemical structures and cause similar health effects. Many communities are exposed to, and harmed by, mixtures of those PFAS in their drinking water. EPA's approach provides a framework for addressing additional PFAS and mixtures of chemicals in the future, which would allow the Agency to move more rapidly to protect public health.

EPA Response: The commenter agrees with the EPA's approach.

Paula Okin (Doc. #1867, SBC-045861)

The proposed drinking water standards are a great first step to address these particular PFAS chemicals, however, I urge EPA to not stop here—it is critical that EPA next moves to regulate the full class of PFAS chemicals.

Thank you for your consideration.

Sincerely,

Ms. Paula Okin

10 Lake Dr New Hyde Park, NY 11040-1123

pokin@optonline.net

EPA Response: The commenter supports this regulation. In regard to potential future regulation of other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document.

North Carolina Conservation Network (Doc. #1869, SBC-045870)

Further, we ask that EPA moves rapidly to add even more PFAS chemicals to the hazard index, in order to protect North Carolina's public health.

Thank you.

Sincerely,

[Table 1: See Docket ID EPA-HQ-OW-2022-0114-1869]

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

North Carolina Conservation Network (Doc. #1869, SBC-045867)

Further, we ask that the EPA moves rapidly to add even more PFAS chemicals to the hazard index, in order to protect North Carolina's public health.

Thank you for your time and for the strong proposal to regulate PFAS in drinking water.

Sincerely,

Brittany Iery, Online Organizer

NC Conservation Network

234 Fayetteville Street, 5th Floor Raleigh, NC 27601

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #1913, SBC-046256)

A MCL for PFOA and PFOS is a good first step. However, short chain compounds such as PFBA will breakthrough conventional treatment technologies for PFAS such as GAC or IX well before PFOA or PFOS. If PFOA is present, PFBA is likely present as well. EPA needs to develop a MCL for PFBA too.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Michael Jones (Doc. #1962, SBC-046562)

The amount of any PFAS/PFOS compound that we should be exposed to is zero. We live near Taconic in Petersburgh, NY. This industry has released these toxins into our aquifer, our town water supply, our soil and most likely our food that we grow in this rural area during the last 40 years.

We smell the emissions almost daily. We have no idea of the compounds they are using and releasing into the air. Are they long or short chains? Are they both? Are these newer compounds safer, more dangerous or just as toxic than what has already been released into our community? The whole class of these chemicals should be regulated, all 14,000 of them. Why should the safety of these chemicals be tested on humans? Instead of spending money on treating our diseases, filtering our water and cleanup, stop these compounds from entering our bodies, our communities, our children, and our wildlife.

The proper MCL for this class of chemicals is as close to zero as possible. When a chemical from this group gets pulled out of use because people start getting sick, another is waiting to take its place. Industry is way ahead of our health, safety and regulations. We need strong policy from our government agencies charged with protecting our communities.

Thank you for your considersideration

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Titus Henry Presler (Doc. #2295, SBC-046214)

Thank you for your work! Please make sure the Environmental Protection Agency bans the entire class of PFAS chemicals from our drinking water.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Ellen Michele (Doc. #2488, SBC-046215)

I support a class-wide drinking water standard to include short and long-chain and polymerized forms rather than chemical by chemical regulation

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Kathryn Alessi (Doc. #2549, SBC-046591)

Thank you for the opportunity to comment on the proposed National Primary Drinking Water Regulation (NPDWR). I am a resident of New Jersey, and a fierce advocate for environmental justice. National standards to limit the concentration of PFAS in drinking water are long overdue. For decades, PFAS have been used in thousands of applications, and a peer-reviewed study

estimates that PFAS may be present in the drinking water of more than 200 million Americans. EPA's proposal for six PFAS would set the national standard for PFOA and PFOS at the lowest detection level approved by the agency, and would establish limits on GenX, PFBS, PFNA, and PFHxS using a hazard index, but this regulation does not cover the entire class of PFAS chemicals. EPA estimates that 94 million Americans currently receive drinking water contaminated by one or more PFAS chemicals at levels above the limits proposed by EPA. EPA's proposed National Primary Drinking Water Regulation (NPDWR) is needed, but it doesn't cover as much as it needs to for the health, safety, and well-being of everyone living in the United States. My further comments/suggestions for this proposed regulation are below.

1. EPA should expand the definition of PFAS to cover the entire class of PFAS chemicals as regulation of individual fluorinated compounds is insufficient to protect public health.

2. PFAS needs to be regulated at the source, in addition to remedial regulation of PFAS present in drinking water.

I urge EPA to promptly finalize this proposal and establish a National Primary Drinking Water Regulation (NPDWR) that will require monitoring for the entire class of PFAS in public water systems and provide mechanisms to address exceedances that threaten public health.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document. In regard to PFAS source control, please see section 10 of the EPA response in this *Response to Comments* document.

Coleen Wagner (Doc. #2551, SBC-046587)

Thank you for the opportunity to comment on the proposed National Primary Drinking Water Regulation (NPDWR).

National standards to limit the concentration of PFAS in drinking water are long overdue. For decades, PFAS have been used in thousands of applications, and a peer-reviewed study estimates that PFAS may be present in the drinking water of more than 200 million Americans. EPA's proposal for six PFAS would set the national standard for PFOA and PFOS at the lowest detection level approved by the agency, and would establish limits on GenX, PFBS, PFNA, and PFHxS using a hazard index, but this regulation does not cover the entire class of PFAS chemicals. EPA estimates that 94 million Americans currently receive drinking water contaminated by one or more PFAS chemicals at levels above the limits proposed by EPA.

EPA's proposed National Primary Drinking Water Regulation (NPDWR) is needed, but it doesn't cover as much as it needs to for the health, safety, and well-being of everyone living in the United States. My further comments/suggestions for this proposed regulation are below.

1. EPA should expand the definition of PFAS to cover the entire class of PFAS chemicals as regulation of individual fluorinated compounds is insufficient to protect public health.

2. PFAS needs to be regulated at the source, in addition to remedial regulation of PFAS present in drinking water.do

I urge EPA to promptly finalize this proposal and establish a National Primary Drinking Water Regulation (NPDWR) that will require monitoring for the entire class of PFAS in public water systems and provide mechanisms to address exceedances that threaten public health.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document. In regard to PFAS source control, please see section 10 of the EPA response in this *Response to Comments* document.

Jim Sandoe (Doc. #2556, SBC-046251)

PFAS must be regulated as a class! This is too important to do one at a time. My drinking water is not safe, but my town won't do anything until you act. The Pentagon won't do anything until you act. The states won't do anything until you act. We are out of time.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Liz Furkay (Doc. #2644, SBC-046209)

We need to ban ALL of the PFAS chemicals, not just some of them. Any chemical that is toxic to life on earth should not be permitted!

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Karen Anderson (Doc. #2684, SBC-046421)

Dear Michael Regan,

It is imperative that the EPA take on full removal of PFAS as swiftly as possible. The contamination of our water is criminal and completely unacceptable.

Sincerely,

Karen Anderson

Berkeley, CA 94702

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Scott Howell (Doc. #2746, SBC-046532)

I strongly believe that the current proposal to develop MCL's for six specific PFAS chemicals is inadequate. EPA needs to consider other PFAS chemicals that could occur due to breakdown products of larger chain PFAS chemicals. A case in point is my current water provider which is impacted by PFAS contamination has installed cation exchange treatment and is currently meeting or exceeding the MCL's for all six proposed PFAS contaminants. However they are showing breakthrough on PFBA AT 40 PPT And PFPeA AT 24 PPT. These PFAS chemicals have also been shown to be hazardous to human health but would not be regulated in the proposed rules. These are only a few of the potential PFAS chemicals that would theoretically be missed by the current proposed rules. Please consider a more inclusive MCL for all PFAS chemicals and their derivatives.

Thank you for the opportunity to comment on the proposed drinking water regulation.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Quinn Montana (Doc. #2784, SBC-046486)

In addition to working to prevent the production of ANY further PFAS family chemicals (all 9000+), and working to remove those that are already in the environment, the agency should work to also prevent "precursor" chemicals from being released into the environment. It's well past time for the agency to regulate PFAS and their precursors as a class, rather than trying to evaluate their hazards individually.

https://grist.org/health/the-epas-proposed-pfas-regulations-ignore-a-major-source-of-drinking-water-contamination/

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Ed Davis (Doc. #2788, SBC-046447)

Please regulate the entire class of 9,000+ PFAS chemicals, and their precursor chemicals, down to the minimum concentration capable of causing biological harm. Please similarly regulate PFAS allowed in food, water bodies, ground water, sewage, rivers, soil, etc.

Also require labeling of all products that contain PFAS.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Marc LeMaire (Doc. #2830, SBC-046253)

I am writing to urge you all to strictly regulate all PFAS as they are a proven danger to human health, not to mention all other life here on earth . You must not cave in to industry pressure on these pollutants. They must be heavvily regulated, now, not later or never. 730

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-052952)

• DEP notes that since PFAS are emerging contaminants and research is ongoing, there is the potential for more PFAS to be regulated in the future. With the proposed introduction of the HI approach for regulating PFAS in drinking water, it is not clear what approach will be taken in the future for regulating additional PFAS. If more PFAS are added to the HI calculation in the future, that would further reduce the contribution of each PFAS to the HI (i.e., if eight PFAS are included in the HI calculation, each one can be present at only 12.5% of its HBWC before the MCLG/MCL is exceeded). This would continue to drive down not only analytical requirements and capabilities, but also requirements for treatment capability. As such, this proposed regulation sets the stage for an even more significant implementation challenge in the future.

EPA Response: In regard to regulating other PFAS, please see section 4.3.5 of the EPA response in this *Response to Comments* document. In regard to discussion related to the Hazard Index, please see section 4.3.2 of the EPA response in this *Response to Comments* document. For a description of numerous current EPA activities related to PFAS, please see the EPA PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024).

Association of California Water Agencies (ACWA) (Doc. #1675, SBC-052957)

Additionally, ACWA would like clarity from EPA on whether the agency plans to use the Hazard Index to regulate additional PFAS in the future. ACWA is concerned that the Hazard Index approach will be used as an avenue to circumvent the stringent requirements of SDWA to regulate PFAS moving forward. The traditional SDWA approach is comprehensive and ensures full consideration of all aspects and impacts of regulatory development.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

Natural Resources Defense Council (Doc. #3072-6, SBC-046343)

Good afternoon, my name is Katie Pelch, and I am a scientist at the Natural Resources Defense Council (NRDC). Today I'd like to start by just thanking Andrea and the community members for their very impactful stories and their testimonies that they are sharing with us today. I'd also like to thank the U.S. EPA for its groundbreaking MCL proposal for PFOA and PFOS, and the use of a hazard index for four additional PFAS. The proposal is a much needed and long-awaited

first step for regulating PFAS chemicals in drinking water as a class. Thousands of studies have investigated the health and toxicological effects of PFAS exposure, and a significant body of evidence suggests that there is no safe level of exposure to PFAS. Appropriately, EPA has proposed MCLGs of zero and MCLs of 4 parts per trillion for PFOA and PFOS, limits that are both scientifically supported and technologically available with currently available water treatment systems. PFAS is a class of thousands of chemicals, and our recent study published in Science of the Total Environment indicated that EPA's validated method for measuring PFAS in drinking water are missing a significant portion of PFAS that is present. Regulating each of these chemicals one at a time will take decades and leave many communities unprotected. This is why we support EPA's development of a hazard index as a way to efficiently take first steps towards a class-based approach and protect against the additive effects of PFAS that millions of Americans are exposed to. EPA's IRIS office has now finalized the toxicological reviews of PFBA and PFHxA and released a draft review of PFDA. All of these have been detected in drinking water. Therefore, EPA should include these additional PFAS in the hazard index as well, and we will be submitting additional comments that indicate that the hazard index for the four PFAS that are included in the hazard index should be lowered, the health-based values. Importantly, the benefit of removing PFAS from the drinking water of 70 to 94 million people is significantly underestimated in EPA's economic analysis. Whereas uncertainties for the cost analysis are estimated and modeled, uncertainties in the benefits analysis result in the benefit not being quantified, and by default, are assigned a value of zero. We will provide written comments, detailing additional benefits EPA should have considered. Thankfully, the treatment technologies that will be required to remove PFAS will also remove other known and unknown synthetic organic contaminants, and the true benefits achieved by this regulation will make a difference in the lives of millions of Americans.

EPA Response: Please see section 4.3.5 of the EPA response in this *Response to Comments* document.

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5 Maximum Contaminant Levels

The EPA notes that a large majority of commenters who submitted feedback on the EPA's final Maximum Contaminant Levels (MCLs) did not distinguish between PFAS compounds in their comments. For example, many commenters cited their concerns for laboratory capability and capacity but often referred to "PFAS" generically and often did not distinguish between PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and/or PFBS. The structure of this section follows the final MCLs promulgated in this National Primary Drinking Water Regulation (NPDWR): 1) PFOA and PFOS (section 5.1); 2) Hazard Index PFAS (section 5.2); 3) Individual PFAS MCLs (section 5.3). The EPA notes that where commenters are specific on the regulatory construct, their comments are categorized accordingly in that section (i.e., specific comments on the Hazard Index were categorized into 5.2). Otherwise, the non-specific comments that covers all the MCLs (including the individual and Hazard Index MCLs) and agency responses for those issues can be found in the sub-sections under 5.1.

5.1 PFOA and PFOS

5.1.1 General

Summary of Major Public Comments and EPA Responses

The EPA received many comments that strongly support the final MCLs of 4.0 ppt (ng/L) and the agency's determination that the standards are as close as feasible to the Maximum Contaminant Level Goals (MCLGs). Many of these commenters request the agency finalize the standards as expeditiously as possible. Based on the EPA's feasibility analysis and consistent with these comments, the agency is establishing drinking water standards for PFOA and PFOS (and four other PFAS) to provide health protection against these contaminants found in drinking water.

Some commenters expressed concern with implementing the MCL for PFOA and PFOS at 4.0 ng/l. Some of the commenters state that compliance would be difficult for rural or smaller to mid-sized water systems due to limited expertise or financial resources. Section 1412(b)(4)(E)(ii) of the Safe Drinking Water Act (SDWA) requires that the agency identify small system compliance technologies (SSCTs), which are affordable treatment technologies, or other means that can achieve compliance with the MCL. The EPA identified SSCTs using the affordability criteria methodology developed for drinking water rules (USEPA, 1998) and identified technologies that are affordable for each small system size category listed in Section 1412(b)(4)(E)(ii). These analyses support the EPA's findings that affordable technologies are available for small systems to comply with the MCL. Funds are also available through the passage of the Infrastructure Investment and Jobs Act (IIJA), also referred to as the Bipartisan Infrastructure Law (BIL), to assist many disadvantaged communities, small systems, and others with the costs of installation of treatment when it might otherwise be cost-challenging. The EPA further notes that in accordance with section 1412(b)(10) of SDWA, the agency is extending the

compliance date for the PFAS MCLs, regardless of system size, to 5 years from the date of promulgation of the standard. See section 12.1 of the EPA response in this *Response to Comments* document for further discussion. While implementation concerns as they relate to funding for small and rural water systems did not form the basis for the EPA's decision to extend the compliance date for the PFAS MCLs, the agency believes that this extension may, among other things, provide opportunities for systems who are close to exceeding the MCLs to investigate sources of contamination and allow systems additional time to compete for funding to implement the rule. Please see section 12.1 for additional discussion on exemptions and extensions.

Individual Public Comments

Midwest Environmental Advocates +more (Doc. #1846, SBC-045831)

A. EPA's proposed MCLs for PFOS and PFOA are set as close as feasible to the corresponding health-based MCLGs.

Commenters strongly support EPA's proposal to set the MCLs for PFOS and PFOA at 4 ppt, in accordance with the requirements of the SDWA, and the Agency's evaluation of feasibility. EPA properly set the standard at the lowest concentration at which PFOA and PFOS can be reliably quantified given (1) the substances' carcinogenic potential, (2) the available analytical methods for accurate detection and measurement of these substances, and (3) the best available treatment technologies capable of removing these PFAS, taking cost into consideration. Both the 5 ppt and 10 ppt MCL alternatives would be unlawful standards given the SDWA's mandate to set MCLs "as close as feasible" to the corresponding MCLGs.

As explained above, EPA had to set a health-based goal at a level at which no known or anticipated adverse effects on the health of persons occur, allowing an adequate margin of safety. Here, Because PFOA and PFOS are contaminants likely to be carcinogenic to humans, EPA set the MCLG for each contaminant at 0 ppt. [FN19: 88 Fed. Reg. 18,659-60, 63; see also 88 Fed. Reg. 18,652 ("For linear carcinogenic contaminants, where there is a proportional relationship between dose and carcinogenicity at low concentrations, EPA has a long-standing practice of establishing the MCLG at zero.").] Subsequently, following the standard-development process of the statute, the Agency evaluated the feasibility of the proposed NPDWR and its alternatives, rightfully concluding that a 4 ppt MCL constitutes a level "as close as feasible" to the corresponding MCLGs.

The SDWA defines feasibility as "feasible with the use of the best technology, treatment techniques and other means which the Administrator finds, after examination for efficacy under field conditions and not solely under laboratory conditions, are available (taking cost into consideration)." [FN20: 42 U.S.C. 300g-1(b)(4)(D).] Here, EPA first evaluated the analytical methods available to measure PFOS and PFOA in drinking water and determined that 4 ppt is the lowest concentration at which PFOA and PFOS can be reliably quantified, within specific limits of precision and accuracy under routine laboratory operating conditions. [FN21: 88 Fed. Reg.

18,666.] EPA reasoned that a 4 ppt MCL is feasible because: (1) "for almost all laboratories, the proposed [MCLs] for PFOA and PFOS … are at least 4 times greater than the lowest calibration standard;" [FN22: 88 Fed. Reg. 18,667.] (2) "there will be sufficient laboratory capacity with the MCLs set at 4.0 ppt;" [FN23: Id.] and (3) EPA has promulgated and successfully implemented NPDWRs with MCLs equal to the contaminant's quantitation level limit. [FN24: 88 Fed. Reg. 18,666.]

Further, in its review of available treatment technologies, EPA determined that multiple available technologies are capable of effectively removing the regulated PFAS from water supplies. As part of its review and assessment, the Agency considered cost to large and metropolitan water systems as intended by Congress. [FN25: 88 Fed. Reg. 18,668.] Legislative history shows that "the Administrator's determination of what [treatment] methods are generally available (taking cost into account) is to be based on what may reasonably be afforded by large metropolitan or regional public water systems." [FN 26: A Legislative History of the Safe Drinking Water Act, Committee Print, 97th Cong., 2d Sess. (1982) at 550. Commenters note that despite EPA's required focus on large and metropolitan water systems in its feasibility analysis, the Agency provided a robust "affordability" analysis related to small public water systems pursuant to other provisions of the SDWA—which also supports the proposed regulation.] Thus, because the installation of treatment technologies for the removal of these PFAS is feasible for large and metropolitan water systems, a 4 ppt MCL is justified as a protective and feasible standard.

EPA's proposed MCLs for PFOS and PFOA are consistent with the statutory requirements of the SDWA, and reasonable, in light of the Agency's feasibility analysis. . EPA would violate its statutory duty to set MCLs for these substances "as close as feasible" to the corresponding MCLGs if it were to choose to adopt either of the higher levels—5 ppt or 10 ppt—analyzed by EPA as "alternative MCLs." Moreover, doing so would unnecessarily leave many Americans exposed to dangerous levels of PFOA and PFOS, and the myriad adverse health effects that such exposures may entail. Accordingly, Commenters urge EPA to adopt the proposed MCL of 4 ppt as a protective and feasible standard.

EPA Response: Please see section 5.1.1 of the EPA response in this *Response to Comments* document. The commenter notes that they believe the MCLs for PFOA and PFOS at 4.0 ppt are feasible and that setting an MCL higher is contrary to SDWA's requirement to set the MCL "as close as feasible" to the MCLG. The agency agrees that the MCLs for PFOA and PFOS at 4.0 ppt are as close as feasible to the MCLG. For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document. For additional discussion on cost considerations and regulatory alternatives, please see section 5.1.3 of the EPA response in this *Response to Comments* document.

National Special Districts Coalition (NSDC) (Doc. #1571, SBC-042999)

The National Special Districts Coalition (NSDC) appreciates the opportunity to provide comment on EPA's proposed PFAS National Primary Drinking Water Standard. Attached is NSDC's formal comment citing key concerns regarding.

NSDC is comprised of the Arizona Fire Districts Association, Association of Washington Public Hospital Districts, California Special Districts Association, Florida Association of Special Districts, Special Districts Association of Colorado, Special Districts Association of Oregon, South Carolina Association of Special Purpose Districts, Utah Association of Special Districts, Washington Association of Sewer and Water Districts, Washington Fire Commissioners Association, Washington Public Utility Districts Association, and Wyoming Special Districts Association.

See attached file(s)

May 28, 2023

U.S. Environmental Protection Agency (USEPA)

Office of Ground Water and Drinking Water

Mail Code: 4606M

1200 Pennsylvania Avenue, NW

Washington, DC 20460

SUBMITTED ELECTRONICALLY via Federal Rulemaking Portal: www.regulations.gov

RE: DOCKET ID NO. EPA-HQ-OW-2022-0114

The National Special Districts Coalition (NSDC), representing special district local governments that provide essential services in thousands of communities across ten states, welcomes the opportunity to submit comments on the U.S. Environmental Protection Agency's (EPA) proposed National Primary Drinking Water Regulation (NPDWR) covering six common forms of per- and polyfluoroalkyl substances (PFAS), published in the Federal Register on March 28, 2023.

A special district is a political subdivision of a State, with specified boundaries, created pursuant to general law or act of the State, for the purpose of performing limited and specific governmental or proprietary functions. Special districts are established by a community to provide a critical public service, or set of services, that other units of local government typically do not otherwise provide. They provide a wide variety of services to urban, suburban, and rural communities – including more than 5,000 special districts that provide safe and reliable drinking water to millions of Americans across the country.

The proposed NPDWR includes enforceable maximum containment levels (MCL) and maximum containment level goals (MCLG) for the six types of PFAS known as perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO-DA), perfluorohexane sulfonic acid (PFHxS), and perfluorobutane sulfonic acid (PFBS).

NSDC is particularly concerned with proposed enforceable MCL at 4 parts per trillion for each PFOA and PFOS with MCLG at zero. The ability for many special districts operating small- to mid-size public water systems to monitor and comply with the NPDWR would be a costly, burdensome challenge to monitor for such small quantities of contaminant – primarily due to availability and affordability of necessary technology to comply with the proposed regulation.

EPA Response: Please see section 5.1.1 of the EPA response in this *Response to Comments* document. For additional discussion on the EPA's affordability analysis, please see section 9 of the EPA response in this *Response to Comments* document. For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document. Regarding rule implementation and enforcement issues, please see section 11 of the EPA response in this *Response to Comments* document. The agency notes that the NPDWR finalizes monitoring flexibilities such as the use of historical monitoring results to satisfy initial monitoring requirements – please see section 8 of the EPA response in this *Response to Comments* document for more information.

National Ground Water Association (NGWA) (Doc. #1804, SBC-045454)

Specific Comments

Health Protective - If achievable, these maximum contaminant levels should be very protective of the public. Groundwater-supplied community water systems, typically serving small communities, are most impacted in incidence and in concentration for PFAS found previously.

Very small community water systems serving 500 or fewer people are 48% of all community water systems, 63% of all groundwater-supplied water systems, and 89% of all very small community water systems. Nearby private well owners may also be at risk. Small communities typically do not have the expertise and financial resources to manage their water systems sustainably for the delivery of safe drinking water. [FN4: U.S. Environmental Protection Agency (USEPA). 2021. 18th Annual EPA Drinking Water Workshop: Small System Challenges and Solutions. Dr. Christopher Frey, EPA Deputy Assistant Administrator for Science Policy, message delivered to Session 1, Plenary, August 30, 2021. https://www.youtube.com/watch?v=ycVa5uG7izg (Accessed April 19, 2023).] These small water systems need attention to treatment capabilities designed for their circumstances, including decentralized treatment that is both protective and affordable.

EPA Response: Please see section 5.1.1 of the EPA response in this *Response to Comments* document. For additional discussion on SSCTs, please see section 10.5 of the EPA response in this *Response to Comments* document. SDWA does not regulate private wells and this final rule does not set any requirements or standards for private well owners, the EPA acknowledges that people who consume water from private wells may be concerned about contamination of their drinking water by PFAS or other contaminants. The EPA has resources to help people who rely on private wells for their drinking water at: https://www.epa.gov/privatewells.

U.S. Chamber of Commerce (Doc. #1537, SBC-042652)

In addition, the low proposed detection levels, for these PFAS, including PFOA and PFOS send a misleading message about the real degree of known risk to members of the public – especially as compared to the known risks of other hazards. Finally, setting the levels as low as EPA has proposed would inevitably lead to diversion of resources from other water quality priorities.

Thank you for your attention. I am happy to answer any questions you may have.

EPA Response: Please see section 5.1.1 of the EPA response in this *Response to Comments* document. Note that the EPA has set the MCLs for PFOA and PFOS at the practical quantitation limit and not the detection limit. For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenter that at the practical quantitation levels (PQLs), or MCL levels, that PFOA and PFOS do not pose known risks. The best available peer-reviewed science indicates PFOA and PFOS pose significant risks above the MCLGs. See sections 4.1 and 4.2 of the EPA response in this *Response to Comments* document for further discussion. As discussed in the preamble for the final NPDWR, the EPA anticipates that this regulation will prevent tens of thousands of cases of serious disease and will save thousands of lives. With respect to risk communication and PFAS risk-communications with the public, please see section 1.2 of the EPA response in this *Response to Comments* document. The EPA recognizes that implementing a new NPDWR may cause systems to re-examine and, in some cases, prioritize expenditure of resources on implementing the new NPDWR. The EPA's final rule represents data-driven drinking water standards that are based on the best available, peer-reviewed science, meet the requirements of SDWA, and that regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water.

Kristina Winter (Doc. #1559, SBC-042543)

I urge the EPA to adopt the proposed enforceable limits for six PFAS chemicals in our drinking water. Specifically, I support proposed Maximum Contaminant Levels (MCLs) of 4 parts per trillion (ppt) for both PFOA and PFOS, as well as a Hazard Index (HI) of unitless 1 for PFNA, PFHxS, GenX, and PFBS.

EPA Response: Please see section 5.1.1 of the EPA response in this *Response to Comments* document. For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document. For additional discussion on the Hazard Index approach and regulation of additional PFAS, please see sections 5.2.1 and 5.3.1 of the EPA response in this *Response to Comments* document.

Citizens Campaign for the Environment (CCE) (Doc. #1710, SBC-045130)

CCE supports the proposed regulations, and offers the following specific recommendations:

• Adopt EPA's Proposed MCLs of 4ppt for PFOA and PFOS

PFOA and PFOS are a part of a group of man-made chemicals known as Per- or polyfluoroalkyl substances (PFAS). PFAS are often referred to as the "forever chemicals" due to their persistence in our environment and bodies—meaning that they don't break down and accumulate over time. PFAS has been detected in numerous water systems in New York, including high profile cases in Newburgh, Suffolk County, and Hoosick Falls. PFOA and PFOS in drinking water are a threat to public health and are associated with a host of significant adverse health impacts, including cancer, hormone disruption, liver and kidney damage, developmental and reproductive harm, changes in serum lipid levels, and immune system toxicity—some of which occur at extremely low levels of exposure.

Currently, New York's MCLs for PFOA and PFOS remains at 10 ppt, far higher than the EPA's proposed MCLs of 4 ppt for both PFOA and PFOS. We support strong, enforceable standards for PFOA and PFOS to what is likely the strongest, most health-protective standard that is technically feasible at this point in time—4ppt. Adopting the MCL's proposed by EPA would help protect the health of New Yorkers currently at risk. In fact, CCE analyzed drinking water quality reports for just Long Island in New York State and found that 1.48 million residents were served by water systems with levels of PFOA and/or PFOS lower than 10ppt (which is New York State's current MCL) and higher than EPA proposed MCLs of 4ppt. Therefore, the EPA standards would provide for additional public health protections for those 1.48 million people. That is a significant example of the importance of the 4ppt standard.

EPA Response: Please see section 5.1.1 of the EPA response in this *Response to Comments* document. The agency agrees with the commenter that the MCLs are "technically feasible at this point in time." For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 (for laboratory considerations) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document. For additional discussion on international and state drinking water standards, please see section 5.1.4 of the EPA response in this *Response to Comments* document.

Mary Anderson (Doc. #1863, SBC-045844)

I urge the EPA to adopt the proposed enforceable limits for six PFAS chemicals in our drinking water. Specifically, I support proposed Maximum Contaminant Levels (MCLs) of 4 parts per trillion (ppt) for both PFOA and PFOS, as well as a Hazard Index (HI) of unitless 1 for PFNA, PFHxS, GenX, and PFBS.

EPA Response: Please see section 5.1.1 of the EPA response in this *Response to Comments* document. For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 (for laboratory considerations) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document. For additional discussion on the Hazard Index approach and regulation of additional PFAS, please see sections 5.2.1 and 5.3.1 of the EPA response in this *Response to Comments* document.

Laura Spilotros (Doc. #1864, SBC-045848)

I urge the EPA to adopt the proposed enforceable limits for six PFAS chemicals in our drinking water. Specifically, I support proposed Maximum Contaminant Levels (MCLs) of 4 parts per trillion (ppt) for both PFOA and PFOS, as well as a Hazard Index (HI) of unitless 1 for PFNA, PFHxS, GenX, and PFBS.

EPA Response: Please see section 5.1.1 of the EPA response in this *Response to Comments* document. For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document. For additional discussion on the Hazard Index approach and regulation of additional PFAS, please see sections 5.2.1 and 5.3.1 of the EPA response in this *Response to Comments* document.

Jeanne Forster (Doc. #1865, SBC-045852)

I urge the EPA to adopt the proposed enforceable limits for six PFAS chemicals in our drinking water. Specifically, I support proposed Maximum Contaminant Levels (MCLs) of 4 parts per trillion (ppt) for both PFOA and PFOS, as well as a Hazard Index (HI) of unitless 1 for PFNA, PFHxS, GenX, and PFBS.

EPA Response: Please see section 5.1.1 of the EPA response in this *Response to Comments* document. For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document. For additional discussion on the Hazard Index approach and regulation of additional PFAS, please see sections 5.2.1 and 5.3.1 of the EPA response in this *Response to Comments* document.

K Murphy (Doc. #1866, SBC-045856)

I urge the EPA to adopt the proposed enforceable limits for six PFAS chemicals in our drinking water. Specifically, I support proposed Maximum Contaminant Levels (MCLs) of 4 parts per trillion (ppt) for both PFOA and PFOS, as well as a Hazard Index (HI) of unitless 1 for PFNA, PFHxS, GenX, and PFBS.

EPA Response: Please see section 5.1.1 of the EPA response in this *Response to Comments* document. For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document. For additional discussion on the Hazard Index approach and regulation of additional PFAS, please see section 5.2.1 and 5.3.1.

Paula Okin (Doc. #1867, SBC-045860)

I urge the EPA to adopt the proposed enforceable limits for six PFAS chemicals in our drinking water. Specifically, I support proposed Maximum Contaminant Levels (MCLs) of 4 parts per trillion (ppt) for both PFOA and PFOS, as well as a Hazard Index (HI) of unitless 1 for PFNA, PFHxS, GenX, and PFBS.

EPA Response: Please see section 5.1.1 of the EPA response in this *Response to Comments* document. For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document. For additional discussion on the Hazard Index approach and regulation of additional PFAS, please see section 5.2.1 and 5.3.1 of the EPA response in this *Response to Comments* document.

Katrina Rudmin (Doc. #1868, SBC-045864)

I urge the EPA to adopt the proposed enforceable limits for six PFAS chemicals in our drinking water. Specifically, I support proposed Maximum Contaminant Levels (MCLs) of 4 parts per trillion (ppt) for both PFOA and PFOS, as well as a Hazard Index (HI) of unitless 1 for PFNA, PFHxS, GenX, and PFBS.

EPA Response: Please see section 5.1.1 of the EPA response in this *Response to Comments* document. For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document. For additional discussion on the Hazard Index approach and regulation of additional PFAS, please see sections 5.2.1 and 5.3.1 of the EPA response in this *Response to Comments* document.

North Carolina Conservation Network (Doc. #1869, SBC-045869)

We strongly support the proposed drinking water standards for PFOS and PFOA, as well as the use of the hazard index for additional PFAS chemicals and urge EPA to swiftly finalize the proposal.

EPA Response: Please see section 5.1.1 of the EPA response in this *Response to Comments* document. For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document. For additional discussion on the Hazard Index approach and regulation of additional PFAS, please see sections 5.2.1 and 5.3.1 of the EPA response in this *Response to Comments* document.

A. O. Smith Corporation (Doc. #1674, SBC-043693)

2. Maximum Contaminant Level

Similar to the Company's position cited above on the EPA's proposed MCLG and HI approaches, A. O. Smith is supportive of the EPA setting an MCL for PFOA and PFOS and agrees that these chemicals create adverse health impacts in human beings at high exposure levels. What the Company cannot determine at this time is if 4 ppt is the correct value for public water systems to treat to, assuming corrective action is triggered under the SDWA by a public water system's sample testing demonstrating the presence of the targeted PFAS chemicals at or below 4 ppt.

The Company believes that context is important. As the EPA knows, 1 ppt is roughly the equivalent of one grain of sand in an Olympic-size swimming pool [FN2: One Olympic-size swimming pool holds 2.5 million liters of water or approximately 660,000 gallons of water.] or one drop of water in twenty Olympic-size swimming pools. [FN3: See, https://www.michigan.gov/-/media/Project/Websites/PFAS-Response/Images/PPT-Swimming-Pool.pdf] Compared with studies that demonstrated an average exposure to PFAS in food packaging between one and twenty parts per billion (i.e., 1 – 20 million ppt), the amount of PFOA and PFOS to be removed from drinking water supplies at 4 ppt is daunting. [FN4: Beyond paper: PFAS linked to common plastic packaging used for food, cosmetics, and much more, Environmental Defense Fund, July 7, 2021 (https://blogs.edf.org/health/2021/07/07/beyond-paper-pfas/#:~:text=The%20total%20level%20of%20the,had%201%20ppb%20or%20less.)] Moreover, when analyzing the daily water use in the United States relative to the amount of drinking water consumed daily (on average) by a typical household, the numbers demonstrate the significant policy and regulatory challenge the EPA is proposing to be implemented by the nation's public water systems to centrally treat their drinking water supply to a 4 ppt value for PFOA and PFOS. Along those lines consider the following:

• In 2015, the United States used 322 billion gallons of water per day (Bgal/day). [FN5: See https://www.usgs.gov/faqs/how-much-water-used-people-

unitedstates#:~:text=Since%201950%2C%20the%20USGS%20has,day%20(Bgal%2Fday).] The three largest water-use categories were irrigation (118 Bgal/day), thermoelectric power (133 Bgal/day), and public supply (39 Bgal/day), cumulatively accounting for 90% of the national total. [FN6: Id.]

• Of the 39.0 Bgal/d of total withdrawals for public water supplies, 61% percent were from surface-water sources. Public-supply systems deliver water to domestic, industrial, commercial, and other users, and 60% of public-supply withdrawals provided 87% of the United States population (283 million) for domestic indoor and outdoor residential uses. Other residences are self-supplied from wells or other sources; these withdrawals were about 1 percent (3.26 Bgal/d) of total withdrawals and provided water to about 13 percent (42.5 million) of the United States population. Groundwater was used for 98% of the self-supplied domestic withdrawals. [FN7: See, United States Geological Survey, Summary of Estimated Water Use in the United States in 2015 Fact Sheet 2018-3035, June 2018.]

• More than 97% of the nation's 156,000 public water systems are small systems that serve 10,000 or fewer people, which includes municipalities, small towns, homeowner's associations, schools, and campgrounds. [FN8: See, https://www.epa.gov/dwcapacity/learn-about-capacity-development]

• The average daily use of water in the typical American household varies between 300 to 82 gallons for a variety of uses (e.g., bathing, toilets, clothes and dishwashing). [FN9: Id.; see also https://www.epa.gov/watersense/how-we-use-water;.] Of these amounts 50 – 70 % of water in the home is used for watering lawns and gardens [FN10: See, Common Daily Water Usage, APEC Water.] and according to one source, water for hygiene and hydration on average is approximately 3.5 gallons a day. [FN11: See, Philadelphia Water Department Home-water-use-infographic 5, April 2020.]

Therefore, taken in context, the overwhelming majority of water that will be centrally treated by public water systems under the PFAS NPDWS will be for uses other than human consumption.

EPA Response: Please see section 5.1.1 of the EPA response in this *Response to Comments* document. For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 (for laboratory considerations) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document. There are several considerations the commenter notes regarding water usage in the United States and its relationship with the final MCLs. While the commenter factually points out statistics on processed water, most processed water is not treated to potable drinking water standards and is not used for human consumption, so these points do form a basis for how the agency considers feasibility when setting drinking water standards consistent with SDWA. Further, SDWA requires the agency to treat potable water to standards that are fit for human consumption. For additional discussion on certification standards and drinking water treatment technologies, please see section 10 of the EPA response in this *Response to Comments* document.

Bailey Smith (Doc. #1787, SBC-045814)

Lastly, with respect to EPA's request for comment on its "proposed determination to set MCLs at 4.0 ppt for PFOA and PFOS,"[FN48: Proposed Rule, supra note 3 at 18730.] this public comment agrees with the proposed MCLs the EPA has set (4.0 ppt).

EPA Response: Please see section 5.1.1 of the EPA response in this *Response to Comments* document. For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-044904)

Section 3: Maximum Contaminant Level

Like the MCLGs, EPA is proposing individual Maximum Contaminant Levels (MCLs) for PFOA and PFOS, and an MCL for PFNA, PFHxS, GenX, and PFBS as a mixture. Under section 1412(b)(4)(B) of the SDWA, EPA must establish an enforceable MCL, "which is as close to the [MCLG] as is feasible." Section 1412(b)(4)(D) subsequently defines "feasible" to mean "feasible with the use of the best technology, treatment techniques and other means which the Administrator finds … are available (taking cost into consideration)."

Section 3.1: PFOA and PFOS

EPA has proposed individual MCLs of 4.0 parts per trillion (ppt) for each of PFOA and PFOS. EPA also explored the costs of potentially proposing 5.0 ppt and 10.0 ppt, individually. EPA determined the Best Available Technologies (BATs) have the capability to bring PFAS levels down below the proposed 4.0 ppt MCL, on this point Cleveland Water concurs. However, the costs, supply chain and labor challenges affecting the compliance timeline, and current and future simultaneous compliance challenges, invite questions as to whether this standard is actually feasible under SDWA, as defined in Section 1412(b)(4)(D).

EPA Response: Please see section 5.1.1 of the EPA response in this *Response to Comments* document. For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 (for laboratory considerations) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document. For additional discussion on extensions and exemptions, please see section 12.1 of the EPA response in this *Response to Comments* document.

New Hampshire Water Works Association, Inc. (NHWWA) (Doc. #1576, SBC-042451)

Preliminary data indicate PFAS concentrations in precipitation may exceed the proposed 4.0 ppt MCL, making background exceedances widespread and intractable to treat.

EPA Response: Studies have demonstrated that PFAS can be transported through precipitation and atmospheric deposition, however the EPA disagrees that due to precipitation potentially containing PFAS that the final MCLs for PFOA and PFOS are not feasible. First, the EPA's final NPDWR regulates public water systems (PWSs) and does not pose treatment requirements to precipitation. Second, the EPA's analysis of PFAS occurrence in drinking water is already reflective of any wet weather deposition to source waters (i.e., if precipitation contains PFAS and are deposited into source waters, any change to source water concentrations of PFAS as a result of this deposition is already reflected in the data that the EPA evaluated to support the current rulemaking). Third, PFAS in precipitation does not preclude the EPA from following the SDWA and developing a NPDWR to reduce human health exposure from this particular source. With respect to the EPA's regulation of additional PFAS through a Hazard Index MCL, please see the section 5.2.1 of the EPA response in this *Response to Comments* document. For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 (for laboratory considerations) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document. With respect to additional individual PFAS MCLs for PFHxS, HFPO-DA and PFNA, please see section 5.3 of the EPA response in this *Response to Comments* document. For EPA's related to other routes of PFAS human health exposure and sources of PFAS in the environment, please see sections 3.1.3 and 3.2.3 of the EPA response in this *Response to Comments* document.

Wagner Engineering (Doc. #3072-9, SBC-047362)

Lastly, what is the suggested message to the public when asked why the MCL is set at 4 parts per trillion but EPA's health advisory is 1,000 times less than that at 0.004 parts per trillion? Thank you for allowing me to provide my comments.

EPA Response: Health Advisories (HAs) are beyond the scope of this rulemaking. The EPA's HAs are non-enforceable and non-regulatory and provide technical information to state agencies and other public health officials on health effects, analytical methods, and treatment technologies associated with drinking water contamination. MCLs are regulatory and enforceable standards that are set consistent with SDWA requirements, including that the MCL level is as close as feasible to the MCLG. For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document.

Philadelphia Water Department (PWD) (Doc. #1709, SBC-045743)

In the interest of transparency, PWD is requesting that the occurrence data used to inform the development of a HI be made available to the public.

EPA Response: The occurrence data used to inform the NPDWR was made available at the time of proposal for public comment. Please see the *Occurrence Technical Support*

Document (USEPA, 2023a), section 6 of this *Response-to-Comments* document, and section VI of the final rule preamble for additional discussion on occurrence.

Massachusetts Coalition for Water Resources Stewardship (MCWRS) (Doc. #1691, SBC-044325)

5. It is unclear why EPA has not approached PFAS regulation from a relative risk perspective as is done with other drinking water contaminants and public health risks in general. For the regulation of the PFAS compounds under the proposed MCLs there appears to be a desire to have risk-free drinking water. That intent is limited due to current laboratory detection capabilities and treatment technologies. Based on the documents provided through this rule-making process one can surmise that should detection levels and treatment technology improve the MCLs would be adjusted downward. The "no-acceptable risk" perspective is not applied to other drinking water contaminants, many of which have MCLGs of zero, but have MCLs well above their respective detection levels. Acceptable risk levels are present in all aspects of society otherwise there would be speed limits of 5 MPH, no playing of sports and no gathering of crowds. That PFAS in drinking water must somehow be risk free does not speak of science or enlightened thinking but of fear mongering and environmental advocacy gone haywire.

EPA Response: The commenter does explain the meaning nor does the commenter provide sufficient detail in explaining the contention that the final NPDWR is not approached from a "relative risk perspective as is done with other drinking water contaminants." The commenter also indicated that EPA has taken a "no-acceptable risk" approach; the agency is clarifying for the commenter that the agency has never stated this in the proposed rule materials. The EPA's final rule represents data-driven drinking water standards that are based on the best available, peer-reviewed science and meet the statutory requirements under the SDWA: please see sections 5.1.2, 5.1.3, and 5.1.4 of the EPA response in this *Response to Comments* document for the agency's evaluation of feasibility with respect to analytic, cost and treatment considerations, respectively. For how the agency may consider future science in the MCLs, please see section 5.1.6 of the EPA response in this *Response to Comments* document.

Office of Advocacy at the U.S. Small Business Administration (Doc. #1807, SBC-045494)

IV. Conclusion

Advocacy is concerned that small water systems will not have adequate funds to ensure timely compliance with EPA's proposed requirements. Therefore, Advocacy recommends that the agency consider alternatives standards and provide regulatory flexibilities to reduce the compliance burden on small water systems.

EPA Response: Please see section 5.1.1 of the EPA response in this *Response to Comments* document. With respect to funding concerns, please see section 2.4 of the EPA response in this *Response to Comments* document. Specifically, the agency expects funds available under the BIL to significantly reduce some of these household costs (see for example,

the EPA's affordability analysis Tables 9-15 and 9-20 of the final Economic Analysis [EA]). Finally, EPA firmly believes that all members of a community should have access to have safe water. There are strategies that utilities may take to help rate payers such as variable rate structures, which allow free or low-cost essential-use amounts then scale for extra use, capping bills for low-income residents as a percent of income, discounts to low-income customers, aiding low-income consumers with plumbing leaks as well as repairs, consumer assistance programs, and infrastructure grants as well as subsidized loans from the State Revolving Funds (SRFs). The EPA further notes that the agency is finalizing flexibilities in the final NPDWR such as the use of previously acquired monitoring data to support the initial monitoring requirements of the rule (please see section 8 of the EPA response in this *Response to Comments* document for additional details).

Office of Advocacy at the U.S. Small Business Administration (Doc. #1807, SBC-045476)

May 30, 2023

VIA ELECTRONIC SUBMISSION

The Honorable Michael S. Regan

Administrator

Environmental Protection Agency

Washington, DC 20460

Re: PFAS National Primary Drinking Water Regulation Rulemaking (Docket ID: EPAHQ-OW-2022-0114)

Dear Administrator Regan:

On March 29, 2023, the Environmental Protection Agency (EPA) published a proposed rule titled "PFAS National Primary Drinking Water Regulation Rulemaking."[FN1: 88 Fed. Reg. 18638 (March 29, 2023).] The Office of Advocacy (Advocacy) is concerned that small water systems will not have adequate funds to ensure timely compliance with EPA's proposed requirements. Therefore, Advocacy recommends that the agency consider alternative standards and provide regulatory flexibilities to reduce the compliance burden on small water systems.

EPA Response: Please see the EPA response to comment Doc. #1807, SBC-045494 in section 5.1.1 in this *Response to Comments* document.

Francesca S. (no surname provided) (Doc. #1472, SBC-042306)

Document ID: EPA-HQ-OW-2022-0114-0027

Federal Register Number: 2023-05471

PFAS and PFOS contaminants should have their MCLG be decreased to 4.0 ng/L or lower if possible. PFAS chemicals take multiple years to leave the human body, it is a slow process. However, if people are continuedly exposed and consuming high levels of these contaminants then it accumulates over time and it has an increased damaging effect on people's health. PFAS is known to cause a slew of different health conditions including cancer, liver disease, a decreased chance of women getting pregnant, and so on. A topic that should be of even more concern for the EPA and the FDA is that bottled water doesn't have a regulation on the levels of PFAS in their water. Comparing the two, the EPA according to this proposed rule is trying to get the MCLG of drinking water down to 4 parts per trillion, while there are brands out there such as the 365 Whole Foods bottled water brand that has nearly 140 parts per trillion of total PFAS in their water. Continuing with the example of the Whole Foods bottled water, that company makes billions of dollars per year, they have millions of customers so a large amount of Americans have consumed this beverage and yet there's still no regulations by the EPA or FDA on it. Bottled water PFAS levels should be a priority of the EPA's, however this proposed rule is focusing on drinking water in general, and lowering PFAS in any capacity is a good thing. It would be in the best interest of American's health for the EPA to have a goal of eventually creating a MCLG of 0 ppt of PFAS, but lowering it to 4 ppt currently is a good start. The Clean Water Act was a way to help protect people from the dangers of contaminants in drinking water since water is a necessity for human life, and people deserve the right to have a clean source of water so they can stay alive. Any organization that is permitting contaminants to continue to be in drinking water, when those said contaminants like PFAS cause diseases like cancer, should be striving continuously to work towards a future of no harmful contaminants being in the water.

EPA Response: The EPA is finalizing MCLGs for PFOA and PFOS at zero and enforceable MCLs at 4.0 ppt each based on the agency's feasibility analysis. For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations), 5.1.3 (cost considerations and alternative MCLs) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document. The Food and Drug Administration (FDA) regulates the safety of bottled water and is therefore beyond the scope of this rulemaking.

Town of Petersburgh, NY (Doc. #1521, SBC-042609)

RE: PFOA regulation public comment: Docket No: EPA-HQ—OW-2022-0114

On March 14, 2023, the Environmental Protection Agency ("EPA") proposed the first ever national drinking standards with regards to PFAS in public drinking water. Specifically, the EPA has proposed to regulate PFOA at a level they can reliably measure at 4 parts per trillion ("ppt"). The EPA requested input on the proposal from all stakeholders. This letter shall constitute a response on the proposal from the Town of Petersburgh, New York.

PFOA was found in large concentrations (from 100ppt to over 1000ppt) across Petersburgh in 2016. Since, then, our small, rural town has gone through proverbial hell in dealing with this

contamination. We have the health scars and death certificates to prove it!! A granular activated carbon treatment system was installed to treat the water in our municipal water district, and individual POET systems were made available for residents to treat the water from their private wells. According to our New York State DEC representatives, these systems provide potable water that meets or exceeds New York State drinking standards. However, this is not enough. No solution or technology exists today that will permanently remove the PFOA contamination from our surface water resources or groundwater aquifer's.

We are told to live with these existing treatment systems as a permanent solution. We flatly reject this assumption that we should just learn to live with PFOA contamination in our local water resources. Furthermore, we believe your proposed 4 ppt mcl standard is effectively an admission to hundreds, if not thousands, of communities across the country to "just live with it." There is no science that we are aware of that says exposure at 3ppt or 4ppt of PFOA is somehow safer than exposure at 5ppt or higher. Contrary, any long-term exposure to PFOA is a national health concern. The drinking water standard should be set as close to 0 ppt as possible. Treatment solutions are an interim option to deliver potable drinking water. Future research efforts and budgets should be focused on developing technologies that can remove the contamination directly from the water resources. "Just live with it" should be a mantra that is stricken from the thought processes of our environmental regulators. Accepting failure in cleaning up the environment by proposing a 4ppt mcl is not sufficient. We ask that you reconsider this standard.

Sincerely,

Katie Murray

Town Supervisor

Heinz Noeding

Town Board Councilman

Nathan Michaels

Town Board Councilman

Thomas Berry

Town Board Councilman

EPA Response: The agency acknowledges the commenter's concerns on the public health risks posed by PFAS in drinking water. While beyond the scope of this rulemaking, the agency is taking steps to address PFAS through a holistic, all-of-agency approach as discussed in the EPA's PFAS Strategic Roadmap; please see section 15.1 of the EPA response in this *Response to Comments* document for additional discussion.

City of Thornton, Colorado (Doc. #1748, SBC-044791)

Thornton does not support increasing the MCL to either 5 or 10 ppt even though it would reduce Thornton's capital and operational costs by 50% at an MCL of 5ppt and would eliminate Thornton's need for treatment at an MCL of 10ppt. Thornton believes that the EPA has demonstrated the health risks associated with these compounds and as such wants to protect the health of our consumers. There is a large amount, perhaps unduly earned, of fear in the general public about these compounds and their health risks due to messaging from the EPA, media, and environmental workgroups. Because of the EPA's revised HAL in 2022, Thornton's customers' perception is that there should be (essentially) zero PFAS in their water. It is difficult to explain to the public why the proposed regulated concentration is higher than those HALs; arguments of technological and economic feasibility are perceived as excuses when their health is at risk. It will be even more difficult to message an increase from the proposed MCL of 4 ppt to even higher levels of 5 or 10 ppt.

EPA Response: Please see section 5.1.1 of the EPA response in this *Response to Comments* document. Furthermore, the agency agrees that risk communication is important; please see section 1.2 of the EPA response in this *Response to Comments* document for additional discussion. The EPA notes that the Lifetime HAs are beyond the scope of this rulemaking. The MCLGs promulgated in this final NPDWR are based on the best available, peer-reviewed science and the agency's review of current scientific literature on human health effects; please see section 4 for additional discussion on health considerations for PFOA and PFOS when setting the MCLG. As required under the SDWA, EPA has set the MCLs for PFOA and PFOS at 4.0 ppt, which is as close to the MCLGs as feasible using the best available treatment technology and taking cost into consideration. See discussion in Section V of the preamble of the PFAS NPDWR for further discussion.

Anonymous (Doc. #1957, SBC-046600)

No science can prove or show that cancer or other illnesses is the result of water with PFAS at levels below 70 ppt. This is manipulated statistics not science. It is a means trying to justify an end. The cost to remove PFAS in well and surface water to below 15 ppt is unnecessary, unnecessarily expensive and will cost billions of dollars. Billions of dollars wasted just as all the money to remove lead service lines is a waste of money and energy and an inflation driver when zinc orthophosphate can contain the lead at a much more reasonable cost to below the 90th percentile.

Furthermore there is no proof that older people have more PFAS in their blood than younger people or whatever is driving the false narrative that the compounds build up in the blood over the years. That the amount in the blood is from drinking water as opposed to some other source is another fact of which there is no empirical evidence. This entire thing is politically driven as was the Covid protocols and the Covid shot. These are inert chemicals that don't break down easily in the environment and thus are not attacking the cells in the human body.

Hopefully the states will push back and sue the EPA over their false premises.

Testing for PFAS is expensive and should be once annually and not quarterly. 70 ppt for each chemical and 70 x the number of chemicals compounds should be the standard in drinking water if anything. Preferably these inert harmless chemicals will stay as just a health advisory where they belong and have been from past EPA's that weren't weaponized by the party currently in power. Your new data is just false twisting of data. There is no proof in the 5000 pages of manipulation that 50 ppt has any more effect on people than 4 ppt.

There is no reason for people to tell you about ourselves or our background and experience. People with common sense see what is going on with these new proposed standards and the further destruction of individual liberties and the cost to remove these chemicals in drinking water and the people oppose this new federal government over reach as injustice and not the role of the federal government under the constitution.

EPA Response: Please see section 5.1.1 of the EPA response in this *Response to Comments* document. The agency disagrees with the commenter on the human health hazards posed by the PFAS regulated through this NPDWR. As the record for this action demonstrates, and as is discussed in other parts of the rule, there are serious adverse health effects attributed to PFOA and PFOS exposure. See section 4 of the EPA response in this *Response to Comments* document. The EPA's final rule represents data-driven drinking water standards that are based on the best available science, peer-reviewed science, meet the requirements of SDWA, and that regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. Please see section 13 of the EPA response in this *Response to Comments* document for discussion about costs and benefits of the PFAS NPDWR. Please see section 13.3.4 of the EPA response in this *Response to Comments* document which discusses monitoring costs and steps EPA has taken to reduce monitoring burden. See also sections 8.3, 8.8, and 8.9 of the EPA response in this *Response to Comments* document about monitoring flexibilities designed to reduce burden. The demonstrated effectiveness of COVID-19 protocols or COVID-19 vaccines are beyond the scope of this PFAS NPDWR. Commenter provides no support or information how this rule does not meet SDWA requirements.

Kassidy Neuner (Doc. #2315, SBC-046321)

The EPA has installed a Maximum Level of Contaminant in Drinking Water (MLCG) for these PFOs or PFOAs so that they cause no harm to anyone, which is to the benefit of the consumer. The MLCG would only be a limit on water sent to the public water system. Recent findings have found that no dose of these PFOs is safe, therefore, it will need to be at a zero in all drinking water. These chemicals have been in use since the 1940s which means it has been contaminating water sources for many decades. Looser restrictions on products sold in stores for everyday use, such as insecticides, has been the root of most of our cancer-causing agents today. Silent Spring by Rachel Carson is a good source to know just how much damage insecticides with harmful

chemicals have caused to the environment in a short amount of time. It is plain to see the long-term effects decades later from lack of restriction from organizations like the EPA and FDA. However, resolving to limit the amount of PFOs and PFOAs to zero is a good initiative. Cancer is always on the rise in the United States, and to limit one's risk to cancer, by stripping every-day use items of cancer causing agents, is a good start. My only concern is how this will be dealt with. Atchison County, for example, still uses a single sewer system, meaning that both rain and fecal matter are mixed together and treated as one. This would mean that all water sources would need to be checked to make sure that the PFO and PFOA numbers are at zero. This would be time consuming and expensive for counties like Atchison County. Will this be up to the states to do, or will this be a federal job that uses tax dollars to fund? Will people be compensated for their general damages due to the chemicals in drinking water being at too high of a concentration, inevitability leading to cancer? These are important questions to consider. Overall, the phasing out of these chemicals in drinking water is a very good start to cleaning up the damage done by the government's once lax policies.

EPA Response: Please see section 5.1.1 of the EPA response in this *Response to Comments* document. As the record demonstrates and discussed in other parts of the rule (see section 4 of this *Response to Comments* document in particular), there are serious adverse health effects attributed to PFOA and PFOS exposure (as an example). The EPA's final rule represents data-driven drinking water standards that are based on the best available, peer-reviewed science, meet the requirements of SDWA, and that regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. Regarding funding concerns to support implementation of the NPDWR, please see the EPA's response in topic essay 2.4. Topics related to assigning liability for PFAS pollution or addressing sources of PFAS contamination are beyond the scope of this rulemaking (please see section 15.1 for additional discussion).

WaterPIO (Doc. #1624, SBC-043479)

The EPA's proposed MCLs and Hazard Index should not move forward without significant correction.

EPA Response: The EPA disagrees. The EPA's final rule represents data-driven drinking water standards that are based on the best available, peer-reviewed science, meet the requirements of SDWA, and that regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. Please see section 5.1.1 of the EPA response in this *Response to Comments* document. For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document. For additional discussion on the Hazard Index approach and regulation of additional PFAS, please see sections 5.2.1 and 5.3.1 of the EPA response in this *Response to Comments* document.

Texas Commission on Environmental Quality (TCEQ) (Doc. #1632, SBC-044136)

Underground Injection Wells

It is unclear if NPDWR MCLs would impact pollution prevention activities for Class V injection wells. The proposed rulemaking could impact certain types of Class V injection wells in the Underground Injection Control (UIC) Program, specifically aquifer storage and recovery (ASR), aquifer recharge (AR), and other Class V designations. Currently TCEQ regulations state that:

"No permit or authorization by rule shall be allowed where an injection well causes or allows the movement of fluid that would result in the pollution of an underground source of drinking water (USDW)." [FN10: Title 40 Code of Federal Regulations (CFR) Part 144; Title 30 Texas Administrative Code § 331.5(a) (Prevention of Pollution).]

For ASR and AR, TCEQ must consider whether the injection of water will comply with the standards set forth under the Federal Safe Drinking Water Act. [FN11: Title 42 U.S. Code § 300f.] Other Class V wells that may potentially be affected as MCLs have always been used as a guideline for compliance. The PFAS proposed regulation states that "EPA is proposing a National Primary Drinking Water Regulation (NPDWR) to establish legally enforceable levels, called Maximum Contaminant Levels (MCLs), for six PFAS in drinking water." It is unclear whether these MCLs would be established only for drinking water regulations or if these MCLs also would be used to comply with prevention of pollution under 40 CFR Part 144.

EPA Response: This commenter asks if MCLs promulgated in this NPDWR will be used to comply with pollution prevention activities under 40 Code of Federal Regulations (CFR) Part 144. The SDWA requires the EPA to promulgate regulations for state Underground Injection Control (UIC) programs with minimum requirements for effective programs to prevent endangerment to underground sources of drinking water (USDWs). 42 U.S.C § 300h(a)(1)&(b)(1). Underground injection endangers USDWs if it may result in the presence in USDWs of any contaminant, and "if the presence of such contaminant may result in [a public water] system's not complying with any NPDWR or may otherwise adversely affect the health of persons." 42 U.S.C § 300h(d)(2); see also 40 CFR 144.12(a) (regulatory non-endangerment provision); 40 CFR 145.11(a)(6) (requiring state 1422 UIC programs to implement provisions as stringent as 40 CFR 144.12). The PFAS NPDWR regulates PWSs, and as required under SDWA, this NPDWR and analyses supporting the rulemaking only include costs that "are likely to occur solely as a result of compliance with the MCL." Thus, the EPA's cost analyses focused on the compliance costs of meeting the MCL to PWSs that are directly subject to this regulation. Potential use of MCLs in other regulatory and nonregulatory contexts are beyond the scope of this rulemaking; please see section 15.1 of the EPA response in this *Response to Comments* document for additional discussion on comments outside the scope of this NPDWR.

GFL Environmental (Doc. #1648, SBC-043218)

May 30, 2023

Michael S. Regan Administrator

U.S. Environmental Protection Agency 1200 Pennsylvania Avenue NW

Mail Code: 4607M Washington, DC 20460

SUBMITTED ELECTRONICALLY TO REGULATIONS.GOV

RE: DOCKET ID NO. EPA-HQ-OW-2022-0114, COMMENTS ON THE DEVELOPMENT OF THE PROPOSED PER- AND POLYFLUOROALKYL SUBSTANCES (PFAS) NATIONAL PRIMARY DRINKING WATER REGULATION

Dear Administrator Regan,

GFL Environmental ("GFL") submits the following comments in response to the Proposed PFAS National Primary Drinking Water Regulation (NPDWR; EPA-HQ-OW-2022-0114). GFL is a diversified environmental services company in North America providing services in solid waste management and liquid waste management. Employing over 19,500 people company wide, GFL operates landfills [both municipal solid waste (MSW) and construction and demolition (C&D)] in 19 states in the US.

EPA is proposing a NPDWR to establish legally enforceable~~,~~ Maximum Contaminant Levels (MCLs)~~,~~ for six PFAS in drinking water: PFOA and PFOS as individual contaminants, and PFHxS, PFNA, PFBS, and HFPO-DA (commonly referred to as GenX Chemicals) as a PFAS mixture. The proposed MCL for both PFOA and PFOS is 4 nanograms per liter (ng/L) or parts per trillion (ppt). The MCL for the mixture of PFHxS, PFNA, PFBS, and GenX is proposed as a Hazard Index (HI) of 1.0. EPA is also proposing health-based, non-enforceable MCL Goals (MCLGs) of 0 ng/L for PFOA and PFOS.

GFL is pleased to be part of the long-term solution to PFAS management and recognizes the need to protect public health and the environment consistent with EPA's intentions. However, we are concerned about the unintended and disruptive consequences of this rule upon downstream or passive receivers of PFAS-containing waste. We are also concerned about the impacts that the new PFAS MCLs will have on other environmental programs and about the technical basis of the rule.

Trickle-Down Impact of MCLs

If promulgated, the application of these proposed MCLs may have impacts that extend well beyond safe drinking water. In other contexts, MCLs are used not just as standards at the point of water consumption but are also widely used to base groundwater and clean-up standards. While the PFAS MCLs are likely to present a challenge for water utilities, we believe that the application of these same standards to groundwater and remediation projects will present technical challenges that are not contemplated by EPA's proposal. These challenges include meeting the detection limit in the contaminated water or environmental media in question and then also treating the contaminated material to the MCLs. In addition, the new PFAS MCLs will likely be used as "Applicable or Relevant and Appropriate Requirements (ARARs) under

Section 121(d) of the Comprehensive Environmental Response and Compensation Liability Act (CERCLA) at clean-ups, which will itself present a host of additional technical issues, likely resulting in delays and added costs.

Given the current status of treatment options, unfortunately, groundwater restoration to the proposed MCLs is not practical or achievable. Risk-based clean-up standards are widely used in groundwater remediation projects and the absence of such standards for PFAS may drive clean-ups to meet the PFAS MCLs. There are no widely available in-situ groundwater remediation options and current options are anticipated to generate residuals that may also contain concentrated levels of PFAS and destruction technologies for residuals are not broadly available at commercial scale.

The ubiquitous and complex nature of PFAS is expected to complicate groundwater and surface water assessment activities from adjacent and pre-existing activities, due to the lack of targeted, accurate, and cost-effective 'fingerprinting' options to help characterize the source(s) of PFAS.

A similar concern arises with respect to the discharge of stormwater to a navigable water under a General National Pollutant Discharge Elimination System (NPDES) permit. While we understand that EPA will at some point be proposing pretreatment and effluent guidelines for PFAS under the Clean Water Act, we are concerned that the MCLs may become the default standard for discharges in the interim.

To help alleviate these unintended consequences, we recommend that EPA emphasize that the MCLs only apply to drinking water at the point of consumption and that EPA propose appropriate standards for other environmental media in subsequent rulemakings.

EPA Response: The EPA notes that consideration or reference to MCLs in non-drinking water programs (such as water quality criteria, National Pollutant Discharge Elimination System [NPDES], Effluent Limitation Guidelines, or Comprehensive Environmental Response and Compensation Liability Act [CERCLA] cleanups) is beyond the scope of this rulemaking; please see section 15.1 of the EPA response in this *Response to Comments* document for additional discussion on comments outside the scope of this NPDWR. For further discussion about CERCLA clean-up costs and benefits, please also see the section 5.1.3 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1631, SBC-043434 in section 5.1.3 in this *Response to Comments* document.

<u>The Ground Water Protection Council (GWPC) (Doc. #1654, SBC-043198)</u>

Date: May 30, 2023

To: U.S. Environmental Protection Agency Docket ID No. EPA-HQ-OW-2022-0114

Re: Per- and Polyfluoroalkyl Substances (PFAS) Proposed PFAS National Primary Drinking Water Regulation for Six PFAS

The Ground Water Protection Council (GWPC) appreciates the opportunity to provide comments and feedback to the U.S. Environmental Protection Agency (EPA) on the proposed National Primary Drinking Water Regulation (NPDWR) for six PFAS.

The GWPC's membership consists of representatives of state groundwater and underground injection control (UIC) regulatory agencies that mutually work toward the protection of groundwater nationwide. Our focus is specifically on protecting groundwater supplies, conserving groundwater resources for all beneficial uses, and recognizing groundwater as a critical component of the ecosystem. The GWPC is unique among state associations in that its members are the state officials who set and enforce regulations on groundwater protection and UIC.

The GWPC comments on the proposed rulemaking express the concerns of its state agency members, including anticipated impacts to UIC programs and facilities as well as groundwater quality concerns. A primary tenet of the federal UIC rules is its non-degradation standard for underground sources of drinking water (USDWs). Per the federal UIC rules in 40 CFR § 144.1 (g):

All owners or operators of injection wells must be authorized either by permit or rule by the Director. In carrying out the mandate of the SDWA, this subpart provides that no injection shall be authorized by permit or rule if it results in the movement of fluid containing any contaminant into USDWs, if the presence of that contaminant may cause a violation of any primary drinking water regulation under 40 CFR part 141 or may adversely affect the health of persons (§ 144.12).

• If the proposed MCLs and HIs for the 6 PFAS are adopted, these rules will impact the regulation and operations of UIC Class V injection wells, many of which inject into or above USDWs. UIC Class V injection wells include stormwater drainage wells, groundwater remediation wells, aquifer storage and recovery (ASR) projects, managed aquifer recharge (MAR) facilities, and non- hazardous waste disposal wells, among other subtypes. While federal rules allow Class V injection wells to be authorized-by-rule, many states review applications and issue permits for these wells. State agency UIC programs will need definitive guidance from EPA on how to address the new water quality standards in the context of authorizing/permitting and regulating UIC facilities, particularly UIC Class V facilities. There are an estimated 580,000 UIC Class V injection wells distributed across the nation, according to EPA's 2021 nationwide UIC well inventory. The financial impact of recharacterizing injected fluids for PFAS and monitoring potential impacts to injection zone groundwater for even 20% of these wells is mind-boggling. Agencies administering the UIC Class V program would need funding for additional staff and activities to address any new programmatic requirements related to PFAS that may be detected in the injection streams or the receiving groundwater.

• The GWPC is concerned that the proposed PFAS rulemaking will affect permitted operating ASR and MAR projects. Already, states are assessing whether existing ASR and MAR projects have measurable PFAS in the injected water and in the injection zone aquifer. GWPC is aware that in North Carolina, one operating ASR project storing public drinking water has been

terminated and the operator had to extract all the injected water, treat the water, and discharge the treated water back into the original surface water source (Cape Fear River). The rulemaking also has the potential to make new ASR/MAR projects infeasible due to costs associated analytical testing and with pre-injection and/or post injection (recovery) water treatment and disposal costs for the treatment residuals.

• The GWPC is concerned with the potential loss of reused treated municipal wastewater as a viable water source for ASR and MAR projects because of the costs associated with treating for and removing PFAS, as well as the costs of disposing the treatment residuals.

• Until cost-effective destruction technologies are in place for PFAS removal, the volume of PFAS- laden liquid wastes that are likely to be disposed into deep UIC Class I injection wells will increase, which will affect current disposal capacity.

• In conjunction with the proposed drinking water regulation, the GWPC has concerns that EPA's proposed CERCLA hazardous substances rulemaking and the anticipated EPA Resource Conservation and Recovery Act (RCRA) rulemaking for these PFAS wastes may result in new regulatory steps, extra time, and additional costs to the permitting process for UIC Class I wells receiving water/wastewater treatment plant residuals and other PFAS-laden wastes. If, upon promulgation of the proposed PFAS rulemakings, these PFAS-laden wastes are considered hazardous under RCRA, it is presumed that EPA will include disposal of these wastes under the RCRA hazardous waste land disposal ban. Because EPA is the administrator of the RCRA hazardous waste land disposal restriction (LDR) program, its region office UIC staffs would be consumed with work to process new UIC Class I hazardous waste disposal well no-migration permits to allow Class I wells to dispose of PFAS laden wastes. The same EPA Regional UIC Programs that would evaluate LDR no-migration petitions are currently backlogged with the ramp up of UIC Class VI carbon sequestration projects, both as a permitting agency and in the process of evaluating UIC Class VI primacy applications from states.

Thank you for the opportunity to provide these comments. Our members will be tasked with meeting all regulatory requirements and standards related to this rulemaking if it is adopted. We ask that EPA address our concerns prior to finalizing the proposed regulations.

If you have any questions or would like to follow up on any of these items, please contact Dan Yates, GWPC Executive Director, at (405) 516-4972 or dyates@gwpc.org.

Sincerely

Dan Yates Executive Director

The Ground Water Protection Council

EPA Response: Please see the EPA response to comment Doc. #1632, SBC-044136 in section 5.1.1 in this *Response to Comments* document. The PFAS NPDWR regulates PWSs. Application of MCLs in other contexts are beyond the scope of this rulemaking; please see section 15.1 of the EPA response in this *Response to Comments* document for additional

discussion on comments outside the scope of this NPDWR. With respect to potential cost concerns, the EPA notes that SDWA expressly states that EPA shall consider "quantifiable and nonquantifiable costs. . . excluding costs resulting from compliance with other proposed or promulgated regulations." Regarding disposal of PFAS laden waste as a result of drinking water treatment, the EPA notes that the likely disposal option for Reverse Osmosis/Nanofiltration Membrane (RO/NF) retentate is treatment and discharges through NPDES compliant facilities and, in limited circumstances, underground injection. Please see section 10.4 of the EPA response in this *Response to Comments* document for additional discussion on the management of treatment residuals.

National Association of Clean Water Agencies (NACWA) (Doc. #1659, SBC-043130)

May 30, 2023

The Honorable Michael Regan, Administrator

U.S. Environmental Protection Agency

Office of Groundwater and Drinking Water (Mail Code 2822IT) 1200 Pennsylvania Avenue NW

Washington, D.C. 20460

Submitted via Federal eRulemaking Portal: https://www.regulations.gov

Re: NACWA Comments on the U.S. Environmental Protection Agency's proposed PFAS National Primary Drinking Water Regulation Rulemaking (Docket ID No. EPA-HQ-OW-2022-0114).

Dear Administrator Regan:

The National Association of Clean Water Agencies (NACWA) appreciates the opportunity to comment on the U.S. Environmental Protection Agency's (EPA) proposed PFAS National Primary Drinking Water Regulation (NPDWR) rulemaking. NACWA has specific comments regarding EPA's plan to regulate perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) as per the regulatory determination from March 2021, and EPA's more recent preliminary regulatory determination to target perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid and its ammonium salt (HFPO-DA, or GenX chemicals), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS) and mixtures of these PFAS chemicals as drinking water contaminants under the Safe Drinking Water Act (SDWA).

NACWA represents the interests of more than 350 municipal clean water utilities, many of which are dual systems that provide safe drinking water supplies to their respective communities in addition to treating wastewater to high quality standards before beneficially reusing or discharging the water to surface waters. Many NACWA utilities also manage municipal stormwater. Our members are public health and environmental stewards that are anchor

institutions that provide a critical and essential function to their communities and strive each and every day to provide the highest level of service.

NACWA recognizes that the NPDWR is primarily an issue that impacts public water systems (PWSs) under the SDWA, and we know that our sister organizations in the water sector with substantial expertise in SDWA like the Association of Metropolitan Water Agencies (AMWA) and the American Water Works Association (AWWA) will provide EPA with valuable input during the rulemaking process.

However, the NPDWR also will impact wastewater and water recycling utilities primarily regulated under the Clean Water Act (CWA), particularly those that discharge to surface waters designated as drinking water supplies or to surface waters that overlie groundwater used or designated as drinking water supplies, as well as those that are engaged in innovative water recycling and reuse projects that sometimes require compliance with the SDWA's Maximum Contaminant Levels. EPA must also consider the potential interactions of the NPDWR with CWA regulations, including increasing imposition of PFAS monitoring requirements for clean water utilities at the same time that this NPDWR will impose new PFAS monitoring requirements on PWSs.

Further, EPA is developing ambient human health water quality standards that are based on the same reference doses developed during the NPDWR process. Clean water utilities will likely be required, in the not too distant future, to meet very stringent ambient human health water quality standards when there are no existing, affordable PFAS treatment techniques to manage or treat the significant volumes of wastewater and stormwater that clean water utilities manage on a daily basis.

EPA Response: The EPA notes that application of MCLs in non-drinking water programs (such as water quality criteria, NPDES) are beyond the scope of this rulemaking; please see section 15.1 of the EPA response in this *Response to Comments* document for additional discussion on comments outside the scope of this NPDWR. The EPA clarifies that this rule is applicable to PWSs and does not pose direct standards nor monitoring requirements for wastewater treatment facilities. To the extent these entities are facilities for potable reuse that is distributed directly to consumers, these entities would be classified as a PWS and the EPA has considered the cost of compliance for these systems (please see section 13.3 of the EPA response in this *Response to Comments* document for additional discussion).

Massachusetts Coalition for Water Resources Stewardship (MCWRS) (Doc. #1691, SBC-044326)

6. The proposed MCLs raise the specter of serious unintended consequences that could pose public health risks for water consumers. Some of these are:

a. Diversion of local finances to PFAS treatment/remediation and reduced spending on critical water system needs such as pipe replacement, sources protection, staffing and water system

maintenance. The outcome could be drinking water that fails to comply with multiple other MCLs and risk of water borne disease or health impacts.

EPA Response: Please see section 5.1.1 of the EPA response in this *Response to Comments* document. Please see section 13.3 of the EPA response in this *Response to Comments* document which discusses cost, and section 13.10 which discusses affordability. Please see also section 2.4 of the EPA response in this *Response to Comments* document which discusses the role of additional federal funding to offset some direct costs associated with this regulation. The EPA's final rule represents data-driven drinking water standards that are based on the best available, peer-reviewed science, meet the requirements of SDWA, and that regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water.

Thurston Public Utility District (PUD), WA (Doc. #1729, SBC-043579)

Our utility and our elected officials are committed to limiting exposure to PFAS and protecting the environment. At the same time, we want to ensure efforts do not impose unintended consequences by unnecessarily directing resources away from other water system priorities like noncompliance with existing pollutant MCLs, leak detection investment, replacement of lead service lines, cybersecurity, or conservation and resiliency efforts to address changes in climate such as increased droughts or flooding. The reallocation of resources by communities may also mean deferring on maintenance, which could risk failure of water infrastructure and be ultimately more costly in terms of quality of life in dollars, public health, and the environment.

EPA Response: Please see section 5.1.1 of the EPA response in this *Response to Comments* document. Please see section 13.3 of the EPA response in this *Response to Comments* document which discusses cost, and section 13.10 which discusses affordability. Please see also section 2.4 of the EPA response in this *Response to Comments* document which discusses the role of additional federal funding to offset some direct costs associated with this regulation. The EPA's final rule represents data-driven drinking water standards that are based on the best available, peer-reviewed science, meet the requirements of SDWA, and that regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water.

Kurt McCord (Doc. #2747, SBC-046590)

Tragic Recap: For decades, EPA has allowed wealthy businesses to poison our people and environment despite early warnings signs. All the while, advocates of these mega-polluters have been promoted as senior rank regulators and aided in this discrepantly disgusting affair. Even under the Biden administration, the leading defender of DuPont's PFOA production, Michael McCabe, gets appointed to the EPA agency review team. Our government continues to "let the fox in the hen house" at the expense of the people that it was created to protect.

So, I ask... what steps has EPA or in a broader context the US government taken to reduce the importation or disseminate of products containing PFAS? Are there programs in place to collect unused contaminated products for incineration? If not, why has an emphasis been placed on removal by utility owners without much effort to keep them out of the environment?

In general, I'm an advocate for clean water. However, an enormous burden has been placed on our public water providers (a recipient of the pollution) to the lowest MCLs ever proposed while profitable companies and poorly informed consumers continue to freely discharge these PFAS compounds into the environment. It's not a comprehensive approach. The recipients are penalized while the decrepit polluters get off easily. Ultimately, the American people (victims) have paid the price with pain, suffering, and the forfeiture of life. Furthermore, we will end-up paying to fix the problem with tax dollars and much higher water bills. Both then and now, the problem should've been stopped at its source by our appointed leaders. Unfortunately, it's another epic failure of the US government.

EPA Response: Please see section 5.1.1 of the EPA response in this *Response to Comments* document. The EPA's final rule represents data-driven drinking water standards that are based on the best available, peer-reviewed science, meet the requirements of SDWA, and that regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document. For additional discussion on the Hazard Index approach and regulation of additional PFAS, please see sections 5.2.1 and 5.3.1 of the EPA response in this *Response to Comments* document. Topics related to assigning liability for PFAS pollution or addressing sources of PFAS contamination are beyond the scope of this rulemaking (please see section 15.1 of the EPA response in this *Response to Comments* document for additional discussion).

National Ground Water Association (NGWA) (Doc. #1804, SBC-045471)

[The steps identified in that letter include:]

• actively engaging water systems and state agencies as well as other key stakeholders in the practical implementation of PFAS risk management,

EPA Response: After finalization of the PFAS NPDWR, the EPA intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation.

The City of Columbus, Department of Public Utilities (Doc. #1703, SBC-045054)

I. EPA should consider source control as it implements its PFAS Strategic Roadmap to avoid cost-shifting PFAS remediation to water utilities and ratepayers.

Working its way through its PFAS Strategic Roadmap, EPA is using CERLCA to address sites that are contaminated with PFAS, and the SDWA to address water that is contaminated with PFAS. One option that it did not consider is a direct campaign to eliminate additional PFAS load in our water and soil: to ban the manufacture and use of PFAS, except for in extraordinary circumstances with stringent controls. While most manufacturers voluntarily phased out PFOA and PFOS in the early 2000's for most uses, there is nothing being done to stop the active loading of new PFAS into our environment— onto our soil and into our water—from PFAS laden products that continue to be rolled out to consumers. At this very minute, manufacturers that produce and use PFAS are profiting from the pollution that ratepayers will be paying to clean out of their water for years to come. Water utilities can dedicate billions of dollars to treat water for decades but will never be able to tackle the source. And the source, those companies profiting from a product that is a known health concern, can continue to lawfully pump those pollutants into our world.

An MCL set without proper recognition of implementation, social, and opportunity costs shifts the financial burden of minimizing risk of human exposure to PFAS from private businesses to the public. The proposed drinking water regulation (as currently written) would shift the financial and technical responsibility from the manufacturers that create and use PFAS in their processes to downstream utilities. This burden will be borne by ratepayers.

The MCL should be set with the understanding that PFAS exists in the background of the environment and everyday life. The cost-benefit to achieve these regulatory requirements in the water industry needs to be weighed against the cost-benefit of removing it from food packaging, personal care products, clothing, and other direct and indirect exposure routes. The only way to address and stop the growing concentration of PFAS contaminants in the hydrological cycle is to stop introducing additional PFAS loads. EPA should re-assess the navigation of its PFAS Roadmap.

EPA Response: For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations), 5.1.3 (cost considerations and alternative MCLs) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document. For additional discussion on other actions the agency is taking related to the PFAS Strategic Roadmap (such as source reduction), please see section 15.1 of the EPA response in this *Response to Comments* document.

National Center for Health Research (Doc. #3072-101, SBC-046404)

Thank you very much and I appreciate so much, this chance for a second bite at the apple. Listening to this series of amazing passionate people with so much diversity of experience and so many different levels of personal story. I hope everybody who's still on will find a way to get the list of people who've testified here today and let's network on this. The EPA can only do so much. They're being hamstrung not only by a divided Congress, but of course, the Supreme Court is getting ready to crack down on administrative authority. So, I urge everyone on this call,

and it sounds like many already are, to work at your state and county levels. Here in Maryland, we've had individual bills that go after requiring no PFAS in food containers, and we're looking at AFFF and each state can start to push different municipalities and states and counties and towns are doing things all over the place. And it's going to take all these points of contact. So please everybody on this reach back out to each other. Let's get this network growing. There's a wonderful organization called Beyond Plastics, but I just want to remind people, Safe Healthy Playing Fields, we are a 501(c)(3) working to stop the PFAS of acres of plastic artificial turf that gets to 180 degrees that has massive injury rates that cost so much money that could be spent on grass and then cleaning up the PFAS that was there before. Thank you again so much for the second chance.

EPA Response: The EPA notes that the commenter did not provide specific comment on the PFAS NPDWR for the agency's consideration. Management of artificial turf is beyond the scope of this drinking water regulation.

Northwest Biosolids Association et al. (Doc. #1783, SBC-043793)

Science Based regulations. Enforcement and compliance of proposed standards are not practicable. Early regulatory actions should be focused on advancing scientific understanding and exploring PFAS treatment and source control options. Given the high uncertainties for monitoring, treatment, and destruction of PFAS, it is premature to establish maximum contamination levels (MCL) or treatment requirements at this time. We recommend that drinking water regulations for PFAS include actions that support scientific understanding and exploring implementation solutions that would include actions such as:

• Assessment of total risk and exposure pathways for human health.

• Data collection and monitoring

EPA Response: The EPA has utilized best available, peer-reviewed science and information to inform finalization of this regulation. For the PFAS covered by this rule, the EPA concluded that the state of the science and information has sufficiently advanced to the point to satisfy the statutory requirements and fulfill SDWA's purpose to protect public health by addressing contaminants in the nation's PWSs. While beyond the scope of this action, the EPA notes that agency is also evaluating and developing technologies for reducing PFAS in the environment to inform decisions on drinking water and wastewater treatment, contaminated site cleanup and remediation, air emission controls, and end-of-life materials management. Additionally, the EPA is developing additional health effect information for additional PFAS which aids in contaminant prioritization. For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations), 5.1.3 (cost considerations and alternative MCLs) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document.

Blue Ridge Environmental Defense League (BREDL) (Doc. #1568, SBC-042997)

Case Study: Roanoke, Virginia

Authorities fail to notify public about contaminated drinking water

On January 22, 2020, the Western Virginia Water Authority (WVWA) received water testing results that indicated the Spring Hollow Reservoir was contaminated with hexafluoropropylene oxide dimer acid (HFPO-DA), commonly known as GenX. This PFAS (per- and polyfluoroalkyl substances) was found to be 62 parts per trillion (ppt) in the Spring Hollow Reservoir and 61 ppt in the finished drinking water. The Spring Hollow Reservoir provides drinking water for part of the Roanoke Valley and nearby communities. The reservoir is fed by the Roanoke River.

Surprised by the results, WVWA conducted another test in February 2020. Those results came back showing a GenX concentration of 65 ppt at the Spring Hollow Reservoir and 62 ppt in the finished water. This confirmed to WVWA that there was contamination in the Roanoke area drinking water, yet the public and press were not notified. Unbeknownst to WVWA customers, some were consuming GenX contaminated drinking water. Meanwhile, internal communications obtained by the Virginia Freedom of Information Act, indicate that WVWA personnel were discussing plans on locating the source of the contamination.

In March 2020, the Virginia General Assembly passed bills regarding PFAS – directing a Virginia Department of Health (VDH) working group to study the occurrence of PFAS in Virginia water systems. WVWA voluntarily participated in this study.

In May 2021, the VDH working group began testing for 10 PFAS contaminants including GenX. WVWA received a result of 51 ppt of GenX at Spring Hollow Reservoir – Finished Water. WVWA's Carvins Cove, another source of drinking water for the Roanoke Valley, had no detection of GenX. The Salem Water Department, about 11 miles downstream from Spring Hollow, had no detection levels of GenX at its water intake on the Roanoke River.

On June 18, 2021, WVWA added a PFAS information page on its website. The webpage lists information about PFAS and GenX testing results. However, the general public and press were not informed and remained unaware of the contamination issue. After all, how many people are going to look at a public water source's website?

Meanwhile, WVWA continued testing for GenX. WVWA received a result of 57 ppt of GenX at Spring Hollow Reservoir – Finished Water on September 15, 2021.

On September 30, 2021, VDH made the summary of the VDH PFAS working group study available to the general public on its website. Once again, this went unnoticed by the general public and media in the Roanoke Valley.

On December 1, 2021, the VDH working group presented its report to then Governor Ralph Northam, the chairmen/chairwomen of the Virginia General Assembly House Committees on Agriculture, Chesapeake and Natural Resources; and Health, Welfare and Institutions, and

Senate Committees on Agriculture, Conservation and Natural Resources; and Education and Health. The VDH working group included, but was not limited to, several state water systems, VA Dept. of Environmental Quality, as well as at least two state environmental groups. The statewide PFAS testing showed that the Spring Hollow contamination was the highest PFAS concentration in the state at 54 ppt.

The next highest result was 14 ppt of PFPeA PFAS by the Fairfax County Water Authority. Despite all of these people knowing about the report and knowing that the Roanoke area had the highest PFAS concentration in the state, in the Roanoke area, the public and local media were still in the dark that our local drinking water was contaminated by GenX. Meanwhile, monthly testing was still showing GenX contamination. In December 2021, WVWA received a result of 47 ppt of GenX at Spring Hollow Reservoir – Finished Water.

Internal communications showed that on February 25, 2022, WVWA staff discussed the upcoming annual Water Quality Report (CCR) for 2022. This reports for the 2021 calendar year and any recent testing. One staffer reported that "Last year we reported UCMR-4 and noted that it was collected in 2019. I think the rule is if we test our water and report the findings to VDH, we have to include it in the report. I have asked Scott Shirley if the PFAS/Gen-X testing has to be reported or not." In other words, WVWA was in no hurry to report the GenX contamination and would not have done so in the 2022 annual report if the VDH was not involved in that May 2021 testing.

On June 9, 2022, WVWA staff discussed options: "anticipates that we will have to initiate a process where we reduce flow from Spring Hollow and find paths for blending from other sources including purchasing water from Salem and other options." Staff said they were working on a website to assist with public interest on the issue.

WVWA staff were well aware of the upcoming June 15, 2022 EPA announcement on the health advisory of 10 ppt for GenX. May and June 2022 testing results of Spring Hollow finished water was showing GenX concentrations 4 times the health advisory. WVWA should have immediately sent out a public notice and press release notifying the public that Spring Hollow was above this new EPA Health Advisory. But, they didn't. WVWA did prepare a document listing GenX Response Activities. Of course, notifying the public was not on that list of responses. EPA guidance on the health advisory to water systems stated, "Drinking water systems and public health officials should also provide consumers with information about the levels of PFAS in their drinking water" [FN4: 4 https://www.epa.gov/system/files/documents/2022-06/drinking-water-ha-pfas-factsheet-watersystem.pdf] . At this point, the source of the GenX contamination was still unknown.

On June 21, 2022, WVWA internal communications stated that "Staff are shifting daily production from Spring Hollow to other water sources. While not a viable long term solution, staff believes a 35% to 40% reduction is possible."

On June 30, 2022, WVWA publishes their 2022 Annual Water Quality Report (Consumer Confidence Report). It is posted on their website. This report, for the first time, includes a

concentration range of GenX – listed as HFPO-DA in the Spring Hollow section. There was no additional information included in the CCR report.

July 2022 testing finally indicated that GenX was in the Roanoke River – which feeds the Spring Hollow Reservoir – and not just in the Reservoir. A sampling result of 139 ppt was measured along the river at the Spring Hollow Reservoir. However, just 11 miles downstream, a Salem Water Dept. test from 5 days earlier found no detection of GenX. This WVWA testing result was not received by the authority until August 24, 2022. During this time, WVWA had discussed reaching out to Salem. In addition, WVWA had been in communications with Virginia Dept. of Environmental Quality in attempts to determine the source of the contamination.

On August 25, 2022 the public notification process finally begins – but not initiated by WVWA or any other authority. A BREDL staff member was searching the WVWA website for the latest Water Quality Report and came across their PFAS information page which mentioned GenX being found in Spring Hollow. The BREDL staffer contacted a local reporter at the Roanoke Times to alert him to this contamination issue. When contacted by the reporter, WVWA asked him to hold the story until they could brief the local governing bodies. Fortunately, the newspaper went ahead and published the article on August 29, 2022. [FN5: "Tests detect 'forever chemical' in Spring Hollow reservoir", Laurence Hammack, Aug. 29, 2022, https://roanoke.com/news/local/tests-detect-forever-chemical-in-spring-hollow-reservoir/article_dd6515b2-27ed-11ed-8540-ffa05c3c2aaa.html] On August 29, 2022, with the publishing of the newspaper article, WVWA finally posted a letter to their customers on the WVWA website – the letter was also mailed to affected customers. [FN6: https:// www.westernvawater.org/home/showpublisheddocument/13082/637976336776500000]

After nearly 3 years since the WVWA first discovered GenX contamination in the Spring Hollow Reservoir public drinking source, the public finally learned about it. It also took nearly 2.5 months after the EPA health advisory for the public to be notified. This was only after an article in the local newspaper informed the public. [Please see Appendix 1.]

Public Notification expedited discovery of contaminant source

The source for the GenX contamination was finally found in November 2022 after public notification had intensified the search for the source. Public notification was essential in keeping the pressure on officials to locate and stop the contamination. In mid-November 2022, it was disclosed that ProChem, Inc. in Elliston, Virginia was the source of the GenX contamination at Spring Hollow. ProChem has been periodically releasing GenX that has found its way into the Roanoke River since 2014, according to the company. One recent sample at the nearby Montgomery County Water Treatment Plant showed that ProChem had discharged through its sewer system GenX at a concentration of 1.3 million ppt. ProChem claims it was unknowingly releasing the GenX. Upon finding out, ProChem has allegedly stopped doing business with the source company – Chemours of West Virginia.

The Roanoke Times published an Editorial on November 20, 2022 titled: If only forever chemical source had been shut down faster highlights the importance of public notification of

contaminants in drinking water. The Editorial stated, “While it’s a relief that the source of the problem has been identified, hopefully preventing the kind of public health problems these chemicals have caused in other communities, the length of time between discovery and revelation underscores that there is room for improvement.” ProChem told a Roanoke Times reporter that they were unaware of the forever chemical contaminants on the equipment they were cleaning and that as soon as they were notified, they terminated the contract with the Chemours Company out of West Virginia. The Editorial concluded that “Given how ProChem responded, one can’t help but imagine that they would have ended the relationship with Chemours sooner had they been notified sooner, and perhaps Spring Hollow wouldn’t have ranked first in the state for the presence of forever chemicals. While the consensus on the health hazards posed by GenX and other forever chemicals continues to evolve, had officials aware of the problem taken action before government warnings and public exposure forced them to do so, everyone involved, especially water authority customers, would have been better off.” [Please see Appendix 2.]

Attempts to obtain list of waterworks currently testing under UCMR #5

At the moment, if waterworks systems discover PFAS in our drinking water they are not required to notify the public. If this is part of the Unregulated Contaminants Monitoring Rule (UCMR) #5, which is currently requiring testing for 29 PFAS contaminants, then those results will have to be released to the public. However, those results will not be released until the following June 30 after the previous year’s testing – and only online. Thus, if any of these PFAS contaminants are discovered in January or February during initial testing, the public will not know about it until a year and a half later, and only if the public goes to their waterworks website to download the annual water quality report (Consumer Confidence Report).

We strongly believe the public needs to be notified ASAP after PFAS is discovered in our drinking water. Therefore, we have attempted to obtain a list of the waterworks systems currently doing their annual testing for the UCMR. Our aim is to obtain drinking water testing results from some of these facilities to see if any PFAS has been discovered in the community’s drinking water.

For three years, nationwide waterworks will be monitoring for a year for 29 PFAS. Each year a different set of waterworks will be doing the monitoring. On February 22, 2023 we asked EPA if they could provide a list of the waterworks that will be testing for UCMR in 2023, in 2024 and in 2025. In a February 27, 2023 response, EPA would not provide the list citing that the information is “only accessible to EPA, States, and the PWS via SDWARS.” [Please see Appendix 3.]

On May 15, 2023, I sent an email request to the Virginia Department of Health (VDH) requesting a list of Virginia waterworks who are currently testing for the 29 PFAS as part of the UCMR #5. On May 17, 2023 I received a response from the VDH stating that they are “reviewing my request”. VDH did send us the requested list on May 22, 2023.

Public notification of PFAS contaminants in our drinking water is lacking and information can be cumbersome to obtain.

EPA Response: The EPA is finalizing SDWA Right-to-Know requirements for the final NPDWR, including requirements for both Public Notification (PN) and Consumer Confidence Reports (CCRs). Please see section 9 of the EPA response in this *Response to Comments* document for additional discussion.

Massachusetts Water Resources Authority (Doc. #1645, SBC-043290)

MWRA strongly urges EPA to, at the minimum, wait until UCMR5 data collection and data review is complete to finalize any PFAS NPDWR. In the interim, MWRA urges EPA to focus on source control, keeping PFAS out of our nation's waterways, removing PFAS from consumer products (including food packaging, stain- and water-repellent fabrics, nonstick products, polishes, waxes, paints, cleaning products, etc.), and establishing a system where the polluters are paying for the costs of treatment and disposal, not water utility ratepayers.

Thank you for your due consideration of the preceding comments. Respectfully submitted,

David W. Coppes, P.E.

Chief Operating Officer

cc: Fred Laskey, Executive Director

Joseph Favaloro, Executive Director, MWRA Advisory Board

EPA Response: The EPA disagrees with commenter that the agency needs to wait for additional information on the national occurrence of these substances in order to finalize the NPDWR at this time. The EPA currently has sufficient data and information to promulgate standards for the PFAS regulated through this NPDWR: please see section 6 of the EPA response in this *Response to Comments* document for additional discussion on occurrence information and Unregulated Contaminant Monitoring Rule (UCMR) and section 6.8 of the EPA response in this *Response to Comments* document specifically for discussion of UCMR 5. Topics related to assigning liability for PFAS pollution or addressing sources of PFAS contamination are beyond the scope of this rulemaking (please see section 15.1 of the EPA response in this *Response to Comments* document for additional discussion).

Massachusetts Coalition for Water Resources Stewardship (MCWRS) (Doc. #1691, SBC-044331)

[Alternative Approach-While MCWRS does not agree with the proposed MCLs, an alternative implementation plan is offered regardless of what the final MCLs may be. That plan would include:]

g. While UCMR 5 is being completed, work with other federal agencies to gather data on other PFAS exposure sources. This would allow critical information to be gathered in support of real public health protection.

EPA Response: The EPA disagrees with commenter that the agency needs to wait for additional information on the national occurrence of these substances in order to finalize the NPDWR at this time. The EPA currently has sufficient data and information to promulgate standards for the PFAS regulated through this NPDWR: please see section 6 of the EPA response in this *Response to Comments* document for additional discussion on occurrence information and UCMR and section 6.8 of the EPA response in this *Response to Comments* document specifically for discussion of UCMR 5. While EPA is developing new science, including by partnering with other entities such as federal agencies, the desire to develop new science is not a sufficient reason to suspend the use of best available, peer-reviewed science today to promulgate NPDWRs.

Oneida Nation (Doc. #1825, SBC-044274)

Further, we note that the list of benefits does not presently include the benefit of keeping these chemicals out of tribal subsistence resources – e.g., fish, wild game, plants and subsistence foods used by tribes. Tribal cultural and lifeway benefits derived from these resources surpass simple economic valuations and should be considered in rulemakings.

Conclusion

Thank you for the opportunity to submit comments. Please do not hesitate to reach out for additional information. You may contact me at thill7@oneidanation.org or 920.869.4420.

Sincerely,

Tehassi tasi Hill, Chairman Oneida Nation

EPA Response: Please see section 5.1.1 of the EPA response in this *Response to Comments* document. For additional discussion on non-quantifiable benefits of this final NPDWR, please see sections 13.5 through 13.7 of the EPA response in this *Response to Comments* document. While protection of Tribal subsistence resources such as fish is important, it is beyond the scope of this drinking water rulemaking.

National Tribal Water Council-Tribal PFAS Working Group (NTWCTPWG) (Doc. #1598, SBC-042335)

On behalf of the National Tribal Water Council and the Tribal PFAS Working Group, I am submitting a comment letter in regards to this proposed rule for PFAS National Primary Drinking Water Regulation.

May 26, 2023

Jennifer McLain, Director

Office of Ground Water and Drinking Water

US Environmental Protection Agency

1201 Constitution Avenue NW

Washington, DC 20004

Submitted via regulations.gov

RE: Comments on the Proposed National Primary Drinking Water Regulation (NPDWR) for six PFAS: perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO-DA, commonly known as GenX Chemicals), perfluorohexane sulfonic acid (PFHxS), and perfluorobutane sulfonic acid (PFBS) EPA Docket ID: EPA-HQ-OW-2022-0114

Dear Director McLain,

Early in 2020, the National Tribal Water Council (NTWC) formed an ad hoc working group named the Tribal PFAS Working Group (NTWC-TPWG) to assist in outreach on Per-and polyfluoroalkyl substances (PFAS) to tribes and tribal members and to advocate for inclusion of tribes and tribal lifeways in policy decisions on PFAS risks and risk management. The NTWC-TPWG is supported by and working in collaboration with the National Tribal Toxics Council (NTTC), the Tribal Science Council (TSC), National Tribal Water Council (NTWC), Tribal Waste and Response Steering Committee (TWRSC) and Tribal Pesticide Program Council (TPPC). The US EPA supports these tribal partnership groups (TPGs).

On April 14, 2022, the National Tribal Water Council-Tribal PFAS Working Group (NTWCTPWG) provided comments as input to EPA's development of a National Primary Drinking Water Regulation (NPDWR) for PFAS.

Select comments provided to EPA in April of 2022 are reiterated in this letter, as necessary and appropriate. In developing this comment letter, the NTWC-TPWG considered both EPA's request for specific comments, as summarized in Section 14 (pages 18729-18732) in the Federal Register Notice (FRN), and commented on other topics as well.

Compounded Health Impacts on Human Health from Drinking Water and Subsistence Food Practices

The FRN (page 18654) appears to indicate that setting the Maximum Contaminant Level Goal (MCLG) for a given drinking water PFAS contaminant takes into consideration both drinking water and food sources thereof. However, we find nothing in the FRN that indicates a similar joint treatment of drinking water-borne and food-borne sources when setting the Maximum Contaminant Level (MCL) for the same given PFAS contaminant. This contrast is of interest to the NTWC-TPWG as subsistence food practices in tribal communities result in a pathway of

considerable PFAS chemical exposure and uptake via ingestion of PFAS-contaminated subsistence food supplies, both terrestrial and marine (Aker et al., 2023a and 2023b). Aker et al. (2023b) determined that overall exposure to perfluoroalkyl acids was twice as high in subsistence Inuit populations as compared to the general Canadian population and specifically perfluorononanoic acid (PFNA) was sevenfold higher. We encourage EPA to take a second look at this and either justify the contrasting approaches or bring them into alignment so that both consider food sources.

EPA Response: The EPA notes that the MCLs, as required under SDWA, considers feasibility which takes into account limits of analytical detection, treatment technology effectiveness, and cost. The MCLGs promulgated in this action are set at a level at which no known or anticipated effects on the health of persons occur, allowing for an adequate margin of safety. Because of SDWA requirements, the MCLs are set as close as feasible to the MCLG. MCLGs based on noncancer effects consider all potential non-drinking water sources of exposure (see section 4 of the EPA response in this *Response to Comments* document). The MCLs for PFNA, PFHxS, and HFPO-DA, as well as the Hazard Index MCL are all equal to the MCLGs. Therefore, these MCLs also consider non-drinking water sources of exposure. For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 (for laboratory considerations), 5.1.3 (cost considerations and alternative MCLs) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document. For additional discussion on alternative regulatory standards (including lower PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document. For additional discussion on the MCLGs for PFOA and PFOS, please see section 4 of the EPA response in this *Response to Comments* document. While protection of Tribal food resources is important, it is beyond the scope of this drinking water rulemaking.

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-042874)

The proposed drinking water standards are based on the default assumption that 20% of a person's exposure is allocated to drinking water, while 80% is comprised of all other potential exposure pathways. We question why drinking water seems to be the sole focus of regulation while potentially higher PFAS exposures exist in consumer products (including food packaging [FN4: Susmann, H.P., L.A. Schaider, K.M. Rodgers, R.A. Rudel. 2019. "Dietary Habits Related to Food Packaging and Population Exposure to PFASs," Environmental Health Perspectives. DOI: 10.1289/EHP409], stain- and water-repellent fabrics [FN5: https://toxicfreefuture.org/wp-content/uploads/2022/08/toxic-convenience.pdf], nonstick products, polishes, waxes, ski wax [FN6: https://www.epa.gov/system/files/documents/2022-01/pfasskiwax.pdf], paints, cleaning products), food [FN7: https://www.fda.gov/food/process-contaminants-food/testing-food-pfas-and-assessing-dietaryexposure#:~:text=PFAS%20can%20also%20enter%20the,PFAS%20entering%20the%20food%20supply], personal care products/makeup [FN8: https://www.fda.gov/cosmetics/cosmetic-ingredients/and-polyfluoroalkyl-substances-pfas-cosmetics], pesticides, and dust [FN9: Schildroth, S., K.M. Rodgers, M. Strynar, J. McCord, G. Poma, A. Covaci, R.E. Dodson. 2022.

Per-and polyfluoroalkyl substances (PFAS) and persistent chemical mixtures in dust from U.S. colleges. Environmental Research. 206. https://doi.org/10.1016/j.envres.2021.112530. Article], and these potential sources of exposure are not simultaneously being regulated. Time magazine has an excellent graphic [FN10: https://time.com/6281242/pfas-forever-chemicals-home-beauty-bodyproducts/?utm_source=twitter&utm_medium=social&utm_campaign=editorial&utm_term=health_environment&linkId=215849297] depicting all these points of exposure (GRAPHIC 1).

[Figure 1: See Docket ID EPA-HQ-OW-2022-0114-1601]

GRAPHIC 1: There aren't many places in your home that are PFAS-free. Lon Tweeten for TIME; Getty Images

We note that there was a study [FN11: https://agu.confex.com/agu/fm19/meetingapp.cgi/Paper/568254, https://dnr.wi.gov/topic/Contaminants/documents/wispac/WSLHPresentation20200116.pdf] of rainwater conducted by the National Atmospheric Deposition Program and the highest total concentration of PFAS was nearly 5.5 parts per trillion (ppt) in a single sample from Massachusetts. We have higher concentrations of PFAS falling from the atmosphere than EPA's proposed drinking water standards. If we are to have meaningful health risk reduction shouldn't the Biden Administration be truly taking a whole of government approach in addressing PFAS exposure by identifying and regulating all means of PFAS exposure simultaneously? Addressing only 20% or less of a person's potential exposure while the remaining 80% of exposure is allowed to continue unfettered seems irresponsible and an ineffective public health strategy.

EPA Response: The EPA notes that the MCLs, as required under SDWA, considers feasibility which takes into account limits of analytical detection, treatment technology effectiveness, and cost. The MCLGs promulgated in this action are set at a level at which no known or anticipated effects on the health of persons occur, allowing for an adequate margin of safety. Because of SDWA requirements, the MCLs are set as close as feasible to the MCLG. For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations), 5.1.3 (cost considerations and alternative MCLs) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document. For additional discussion on alternative regulatory standards (including lower PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document. For additional discussion on the justification for the relative source contributions (RSCs) of 20 percent for the six PFAS considered in this rulemaking, please see sections 4.2.3 and 4.2.5 of the EPA response in this *Response to Comments* document. Please refer to section 15 of the EPA response in this *Response to Comments* document and the PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024) for discussion on other actions the EPA is taking to address PFAS pollution and exposure.

New England Water Works Association (Doc. #1836, SBC-045374)

May 30, 2023

Mr. Michael S. Regan, Administrator

U.S. Environmental Protection Agency

EPA Docket Center, OLEM Docket, Mail Code 28221T

1200 Pennsylvania Avenue, NW

Washington, DC 20460

RE: Docket ID No. EPA-HQ-OW-2022-0114 - National Primary Drinking Water Regulation Rulemaking for per- and polyfluoroalkyl substances (PFAS)

Dear Administrator Regan:

The New England Water Works Association (NEWWA) appreciates the opportunity to comment on the Environmental Protection Agency's proposed National Primary Drinking Water Regulation. NEWWA is a membership organization for those working or interested in the drinking water profession with more than 2,200 members who collectively serve more than 3 million water consumers across the six New England states. Headquartered in Holliston, Massachusetts, we bring together water utilities, consultants, manufacturers, vendors, regulators, academia, and other interested parties to network, educate, and advocate.

Let us state unequivocally for the record that public health protection is Public Water Systems' (PWS) primary mission and goal. PWS take this role very seriously and work hard to ensure that the water provided to residents across the region meets all Safe Drinking Water Act standards. As a testament to our success, we take great pride in the fact that according to the Environmental Protection Agency's (EPA) own statistics for Quarter 1 of 2023, 95% of community water systems in Region 1 met all applicable health-based standards and 93.8% of the population served by community water systems in Region 1 received drinking water which met all applicable health-based drinking water standards (Table 1).

[Table 1: See Docket ID EPA-HQ-OW-2022-0114-1836]

Table 1: EPA Safe Drinking Water Compliance Statistics – New England Public Water Systems
GPRA = Government Performance and Results Act

We are providing the following comments on EPA's proposed National Primary Drinking Water Regulation Rulemaking for per- and polyfluoroalkyl substances (PFAS). We note that EPA has engaged in rulemaking concurrently on several major rules that impact the water sector, with public comments all due within the past month, making it challenging to give each the thorough review it requires. This regulation is complicated, with new concepts not well understood by the drinking water profession. We are discouraged that EPA has denied requests to extend the public comment period to give more time for thoughtful review on a regulation which we well know

will have substantial impact on our industry. We fully support efforts to expand verified public health protections, but EPA needs to consider the challenges and costs associated with implementation of the proposed PFAS rule before finalizing these standards.

General Comments:

NEWWA and its members can offer technical expertise as it relates to the very real impact that new drinking water standards will have on PWS operations and related services, and the very significant cost burden it will have on our ratepayers – neither of whom have created this problem. However, our ability to offer comments and opinions on the scientific basis for setting the standards is limited. We are not toxicologists, nor epidemiologists, so we will leave it to other experts to comment on the appropriateness of the standards from a public health protection standpoint. We question why drinking water seems to be the sole focus of regulation at part-per trillion levels while potentially higher PFAS exposures may be happening due to PFAS concentrations in the part per billion and part per millions from a great variety of sources: consumer products (including food packaging [FN1: Susmann, H.P., L.A. Schaider, K.M. Rodgers, R.A. Rudel. 2019. "Dietary Habits Related to Food Packaging and Population Exposure to PFASs," Environmental Health Perspectives. DOI: 10.1289/EHP409], stain- and water-repellent fabrics [FN2: Microsoft Word - toxic-convenience.docx (toxicfreefuture.org)], nonstick products, polishes, waxes, paints, cleaning products), food, personal care products/makeup [FN3: Per and Polyfluoroalkyl Substances (PFAS) in Cosmetics | FDA], pesticides, and dust [FN4: Schildroth, S., K.M. Rodgers, M. Strynar, J. McCord, G. Poma, A. Covaci, R.E. Dodson. 2022. Per-and polyfluoroalkyl substances (PFAS) and persistent chemical mixtures in dust from U.S. colleges. Environmental Research. 206. https://doi.org/10.1016/j.envres.2021.112530. Article], and these potential sources of exposure are not simultaneously being regulated. We will note that there was a study of rainwater conducted by the National Atmospheric Deposition Program and the highest total concentration of PFAS was nearly 5.5 parts per trillion (ppt) in a single sample from Massachusetts [FN5: https://agu.confex.com/agu/fm19/meetingapp.cgi/Paper/568254]. With that said, we have higher concentrations of PFAS falling from the atmosphere than EPA's proposed drinking water standards. The proposed drinking water standards assume that 20% of a person's exposure is allocated to drinking water, while 80% is comprised of all other potential exposure pathways. In order to have meaningful health risk reduction the Biden Administration should be truly taking a whole-of-government approach to address PFAS exposure by regulating all means of PFAS exposure simultaneously. Addressing only 20% of a person's potential exposure while the remaining 80% of exposure is allowed to continue unfettered seems irresponsible.

EPA Response: The EPA notes that the MCLs, as required under SDWA, considers feasibility which takes into account limits of analytical detection, treatment technology effectiveness, and cost. The MCLGs promulgated in this action are set at a level at which no known or anticipated effects on the health of persons occur, allowing for an adequate margin of safety. Because of SDWA requirements, the MCLs are set as close as feasible to the MCLG. For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 (for laboratory

considerations), 5.1.3 (cost considerations and alternative MCLs) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document. For additional discussion on alternative regulatory standards (including lower PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document. For discussion on how the EPA considers other sources of exposure when setting the MCLGs, please see sections 4.2.5 and 4.3.3 of the EPA response in this *Response to Comments* document. Please refer section 15 of the EPA response in this *Response to Comments* document and to the PFAS Strategic Roadmap (https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024) for discussion on other actions the EPA is taking to address PFAS pollution and exposure. For additional discussion on comment period extensions, please see section 17.1 of the EPA response in this *Response to Comments* document.

5.1.2 Laboratory Considerations (including Capability and Capacity) and Practical Quantitation Levels

Summary of Major Public Comments and EPA Responses

Some commenters stated that setting the MCL at the PQL is technically and economically feasible and supports the EPA's rationale that the MCLs at 4.0 for PFOA and PFOS are as close as feasible to the MCLG under SDWA. The EPA agrees with these commenters based on the agency's feasibility analysis. As discussed in section IV of the preamble for this regulation and section 4 of this *Response to Comments* document, first, the agency is establishing non-enforceable MCLGs at zero for contaminants where no known or anticipated adverse effects to the health of persons will occur, allowing for an adequate margin of safety. For the feasibility analysis, the EPA then examined the treatment capability of Best Available Technologies (BATs) and the accuracy of analytical techniques as reflected in the PQL in establishing the closest feasible level. In evaluating feasibility, the agency has determined that multiple treatment technologies (e.g., Granular Activated Carbon [GAC], anion exchange [AIX]) "examined for efficacy under field conditions and not solely under laboratory conditions" are found to be both effective and available to treat PFOA and PFOS to the standards and below. The EPA also determined that there are available analytical methods to measure PFOA and PFOS in drinking water and that the PQLs for both compounds reflect a level that can be achieved with sufficient precision and accuracy across laboratories nationwide using such methods. Since limits of analytical measurement for PFOA and PFOS require the MCL to be set at some level greater than the MCLG, the agency has determined that 4.0 ng/L (the PQL for each contaminant) represents the closest feasible level to the MCLG and the level at which laboratories using these methods can ensure, with sufficient accuracy and precision, that water systems nationwide can monitor and determine compliance so that they are ultimately delivering water that does not exceed the maximum permissible level of PFOA and PFOS to any user of their PWS. The EPA evaluates the availability and performance of BATs for treating water to minimize the presence of the contaminant consistent with the MCLG as well as the costs of applying those BATs to large and metropolitan water systems when treating to that level. In consideration of these factors, the EPA is therefore establishing the MCL of 4.0 ng/L for both PFOA and PFOS. The

EPA further notes that the agency has determined that the costs of SSCTs to reach 4.0 ng/L are affordable for households served by small drinking water systems.

Many commenters assert that implementation of the PFOA and PFOS standard would be challenging because the MCLs are set at the PQLs for each compound, and some commenters recommended alternative standards (e.g., 5.0 ng/L or 10.0 ng/L). These commenters contend that by setting the MCL at the PQL, utilities would not be able to reliably measure when the concentration of contaminants in their drinking water is approaching the MCL. Some of these commenters suggest that having a buffer between the PQL and the MCL may allow utilities to manage treatment technology performance more efficiently because utilities generally aim to achieve lower than the MCL to avoid a violation and that this buffer would provide some level of operational certainty for systems treating for PFAS. The EPA disagrees that the PFOA and PFOS standard is not implementable because the MCL is set at its respective PQL. The EPA has promulgated, and both the EPA and water systems have successfully implemented, several NPDWRs with MCLs equal to the contaminant PQLs. As examples, in 1987, the EPA finalized the Phase I Volatile Organic Compounds (VOC) rule (USEPA, 1987), where the agency set the MCL at the PQL for benzene, carbon tetrachloride, trichloroethylene, vinyl chloride, and 1,2-dichloroethane (52 FR 25690). Other examples where MCLs were set at the PQL include benzo(a)pyrene, di(2-ethylhexyl) phthalate, dioxin, dichloromethane, hexachlorobenzene, and PCBs (see USEPA, 1991a and USEPA, 1992). Some commenters at the time stated they believed implementation would be challenging because the MCLs were set at the PQL in these examples; however, the EPA notes that those rules have been implemented successfully despite commenters initial concerns.

In the proposal, the EPA discussed how utilities may be able to use sample results below the PQL to determine analyte presence or absence in managing their treatment operations; however, a few commenters contend that this is not practical to determine compliance with the MCL as these values are less precise and violations may result in expensive capital improvements. Commenters are conflating two different issues. While commenters are referring to quantitation of a sampling result for compliance with the rule, the EPA discussion on results below the PQL refers to determining simple presence or absence of a contaminant for other purposes. Sampling results below the PQL may not have the same precision as a sampling result at or above the PQL but they are useful for operational purposes such as understanding that PFOA and PFOS may be present, which can inform treatment decisions and monitoring frequency. For example, a utility may use sampling results below 4.0 ng/L as a warning that they are nearing the PFOA and PFOS MCLs of 4.0 ng/L prior to an exceedance. Then, the utility can make informed treatment decisions about managing their system (e.g., replacing GAC). Additionally, EPA evaluated data submitted as part of the UCMR 5 Laboratory Approval Program (LAP) and found that 47 of 53 laboratories (89 percent) that applied for UCMR 5 approval generated a minimum reporting level (MRL) confirmation at 2 ng/L (one-half the proposed MCL) or less for Method 533. This suggests that the majority of laboratories with the necessary instrumentation to support PFAS monitoring have the capability to provide useful screening measurement results below the PQL.

The agency does not agree with commenters that operational flexibility is relevant for purposes of setting an MCL. Such considerations may be relevant to other parts of the rule, such as determining monitoring and compliance with the rule. First, for purposes of determining compliance with the MCL, water systems must calculate the running annual average (RAA) of results, which could allow some results to exceed 4.0 ng/L for single measurements if the overall annual average is below the MCL. In other words, there is a buffer built into determining compliance with the MCL. Second, when calculating the RAA, zero will be used for results less than the PQL which provides an additional analytic buffer for utilities in their compliance calculations. This monitoring and compliance framework allows for temporal fluctuations in concentrations that may occur because of unexpected events such as premature PFOA and PFOS breakthrough or temporary elevated source water concentrations. Thus, periodic occurrences of PFOA or PFOS that are slightly above the PQLs do not necessarily result in a violation of the MCL if other quarterly samples are below the PQL. The agency notes that in general, PQLs are set well above the limit of detection; for PFAS specifically, all the PQLs are well above their limits of detection. The PQL is also different than detection limits because the PQL is set considering a level of precision, accuracy and quantitation. Systems may be able to use sample results below the PQL to understand whether PFOA and PFOS are present. While the EPA has determined that results below the PQL are insufficiently precise for determining compliance with the MCL, results below the PQL can be used to determine analyte presence or absence in managing a system's treatment operations and used for determining monitoring frequency.

Some commenters contend that the PQLs for PFOA and PFOS are not set at an appropriate level (e.g., the PQLs are either too high or too low for laboratories to meet). Specifically, these commenters question whether enough laboratories have the ability to analyze samples at 4.0 ng/L and, as a result, contend it is not a "reasonable quantitation level". The EPA disagrees with commenters who suggest the PQLs for PFOA and PFOS are not set at an appropriate level. As discussed above and in the March 2023 proposal, the EPA derives PQLs that reflect the level of contaminants that laboratories can reliably quantify within specific limits of precision and accuracy during routine laboratory operating conditions. The ability to reliably measure is an important consideration for feasibility to ensure that water systems nationwide can monitor and dependably comply with the MCLs and deliver drinking water that does not exceed the maximum permissible level.

In the rule proposal (USEPA, 2023b), the EPA explained that the MRLs under UCMR 5 reflect "a minimum quantitation level that, with 95 percent confidence, can be achieved by capable lab analysts at 75 percent or more of the laboratories using a specified analytical method" (USEPA, 2022a). The EPA uses this definition to provide a statistical framework for predicting the lowest level a laboratory can achieve using a specified method and is not directly correlated to the total number of laboratories available to meet these limits. In other words, the definition applied in setting MRLs established for UCMR 5 (which serve as the basis for the PQLs in this rulemaking) does not mean that there are only 75 percent of laboratories available to meet these reporting levels and, conversely, that 25 percent of laboratories cannot. In practice, the number of available laboratories to meet these quantitation limits is likely much greater (USEPA, 1999; USEPA,

2001). For example (and described further below), all UCMR 5 approved labs were able to meet or exceed the PFOA/PFOS minimum reporting limits at 4 ng/L. The EPA further explains below that there are 53 labs for PFAS methods and the UCMR 5 LAP found that 47 of 53 laboratories (89 percent) that applied for UCMR 5 approval generated a MRL confirmation at 2 ng/L (one-half the MCLs) or less for Method 533. Based on the EPA's experience in implementing previous UCMRs and NPDWRs, the agency believes that these conditions are reflective of commercial and non-EPA laboratory performance and capacity (USEPA, 1999; USEPA, 2001). Additionally, laboratories may be operated by water utilities themselves or by commercial environmental laboratories, many of whom specialize in drinking water analyses. These labs contribute to an even more robust national network of laboratories with experience in PFAS drinking water analysis as demonstrated in the various state-led PFAS monitoring campaigns precluding the proposal of the PFAS NPDWR (USEPA, 2024a). The EPA expects the environmental laboratory community will continue to develop their capabilities for the PFAS drinking water analysis at the PQL as demonstrated in previous drinking water regulations (USEPA, 1999; USEPA, 2001).

With respect to the calculation of the MRLs for UCMR 5 (e.g., 4 ng/L for PFOA and PFOS) that serve as the basis for the PQLs in this NPDWR, the EPA calculated the UCMR 5 MRLs using quantitation-limit data from multiple laboratories participating in a MRL setting study. The technical basis for the MRL calculation is further described in (USEPA, 2010). The calculations account for differences in the capability of laboratories across the country. Laboratories approved to analyze UCMR samples must demonstrate that they can consistently make accurate and precise measurements of PFOA and PFOS at or below the established MRLs. As part of the final UCMR 5, the EPA noted in 40 CFR 141.40(a)(3) Table 1, Footnote 4, "If EPA determines, after the first six months of monitoring that the specified MRLs result in excessive resampling, EPA will establish alternate MRLs and will notify affected PWSs and laboratories of the new MRLs." Since implementation of the UCMR 5 monitoring program, the agency found that laboratories were routinely able to meet the MRLs on a regular basis and the EPA did not reconsider these levels when monitoring began in 2023, providing confirmatory evidence that the MRLs are appropriate to use as the basis for the PQLs in this rulemaking (USEPA, 2021a). Therefore, the EPA disagrees with commenters who find it inappropriate to use the UCMR 5 MRLs as the basis for the PQLs. The agency finds that the UCMR 5 MRLs are appropriate for using as PQLs for this rulemaking: the EPA estimates that laboratories across the nation can precisely and accurately measure PFOA and PFOS reliably at this quantitation level. After reviewing data from laboratories that participated in the MRL setting study under UCMR 5 and in consideration of public comment, the EPA finds that the MRLs set in UCMR 5 of 4.0 ng/L for PFOA and PFOS, that are also the PQLs, are as close as feasible to the MCLG. A few commenters contend that establishing a quantitation level "that is too low may result in recurring QC failures," thereby requiring repeat sample analyses and straining laboratory capacity. The agency disagrees; neither methods 533 nor 537.1 ver. 2.0 which are approved to meet the monitoring requirements of the final NPDWR have inherent quality control (QC) issues when followed. With respect to the analytic requirements of the EPA methods and for additional

discussion on PQLs, please see sections 7.1 and 7.2 of the EPA response in this *Response to Comments* document.

The EPA agrees with commenters that it is inappropriate to make potentially costly compliance decisions based on measurements below the PQL because they do not have the same level of precision and accuracy as results at or above the PQL. As previously discussed, for compliance purposes, results less than the PQL will be recorded as zero. For additional details on monitoring and compliance requirements, please see section VIII of the final rule preamble.

Some commenters disagreed with the EPA's determination that the rule is feasible under SDWA asserting that there is insufficient laboratory capacity and other analytic challenges to measure samples at these thresholds. In the agency's approach toward evaluating feasibility, the EPA assesses, among other things, (1) the availability of analytical methods to reliably quantify levels of the contaminants in drinking water and (2) the lowest levels at which contaminants can be reliably quantified within specific limits of precision and accuracy during routine laboratory operating conditions using the approved methods (i.e., the PQLs). This framework inherently considers both the capacity and capability of labs available to meet the requirements of the NPDWR.

Based on the EPA's analysis of these factors, the EPA disagrees with commenter assertions that there is insufficient laboratory capacity at this time to support implementation of the NPDWR. Currently, there are 53 laboratories for PFAS methods (Method 533 or 537.1) in the EPA's UCMR 5 LAP, more than double the participation in UCMR 3 (21 laboratories), with several laboratory requests to participate after the lab approval closing date. At a minimum, these 53 labs alone have already demonstrated sufficient capacity for current UCMR 5 monitoring, which requires monitoring for all systems serving above 3,300 or more persons and 800 systems serving less than 3,300 persons over a three-year period. Sufficient laboratory capacity for UCMR 5 is demonstrated by reviewing reported results submitted during 2023, the first year of UCMR 5 sampling, where 17,800 PFAS samples were analyzed by approved laboratories with 80 percent of those analyses conducted by 20 percent of the approved laboratories (11 of 53) (USEPA, 2024b). These results provide confirmatory evidence that sufficient laboratory capacity exists to support the monitoring requirements of the NPDWR; the laboratory capacity established for UCMR 5 will become fully available once UCMR 5 monitoring concludes in December 2025 for PWS to comply with the PFAS NPDWR monitoring requirements after the PFAS rule promulgation. Participating labs are spread throughout the country and many commercial labs support out-of-state clients for compliance drinking water analysis, as labs may be certified or accredited by states they are not geographically located in. Additionally, the NELAC Institutes' National Environmental Laboratory Accreditation Management System (TNI LAMS) database currently has 57 laboratories accredited for either Methods 533, 537.1, or both (NELAC Institute, 2024). This number is likely an underestimate as it doesn't include states that are not part of the NELAC Institutes (TNI) (Mass.gov, 2024). However, these additional laboratories accredited for the PFAS methods approved for the monitoring requirements of this rule provides further confirmatory evidence supporting the EPA's determination that there is sufficient

laboratory capacity, demonstrating an additional network of laboratories experienced in PFAS drinking water analysis. Additionally, the 21 laboratories participating in UCMR 3 provided more than sufficient capacity for that monitoring effort, which required monitoring for all systems serving greater than 10,000 persons and 800 systems serving less than 10,000 (USEPA, 2016). This further demonstrates that laboratory capacity has grown since UCMR 3 and the EPA's conclusion that even more labs (beyond the 53 approved for UCMR 5) will become certified to support compliance monitoring for the PFAS NPDWR. Further, a recent review of state certification and third-party accreditation of laboratories for PFAS methods provides confirmatory evidence that an additional 25 laboratories outside the UCMR 5 LAP with a certification or accreditation for EPA Method 533 or 537.1. Additionally, as has happened with previous drinking water regulations, the EPA anticipates laboratory capacity to grow once the rule is finalized to include an even larger laboratory community, as the opportunity for increased revenue by laboratories would be realized by filling the analytical needs of the utilities (USEPA, 1987; USEPA, 1991a; USEPA, 1991b; USEPA, 1992; USEPA, 2001). Finally, the EPA is aware of PFAS monitoring efforts by States and local communities across the country to better understand PFAS occurrence in drinking water, including both statewide drinking water monitoring actions, and targeted sampling at locations that have potentially been impacted by releases or where PFAS-containing materials are known to have been used (USEPA, 2024a). These ongoing efforts have contributed to an even more robust national network of laboratories experienced in PFAS drinking water analysis.

With respect to the number of samples laboratories may receive for compliance monitoring, the agency is finalizing monitoring requirements (such as the use of a reduced monitoring schedule to once every three years for eligible systems and the ability for systems that are reliably and consistently below the MCLs of 4.0 ng/L to only monitor once per year) such that the EPA anticipates that a large number of utilities may be able to take advantage of reduced or annual monitoring, and will not require a more frequent monitoring schedule, thus easing the burden of laboratory capacity as well. In addition, the EPA received comment from the American Council of Independent Laboratories (ACIL) that states "ACIL assures the Agency that they, on behalf of the commercial environmental testing community, do not expect laboratory capacity to be an ongoing concern." (see Doc. #1692, SBC-044736 in section 5.1.2). Further, the Environmental Monitoring Coalition reflected confidence to meet the needs of drinking water utilities to monitor PFAS provided that appropriate resources are in place (see Doc. #1625, SBC-043105 in section 5.1.2). In consideration of the available labs supporting a national monitoring program like the UCMR 5; the availability of labs identified in TNI LAMS database certified for PFAS methods (533, 537.1 or both); previous and on-going state efforts in monitoring and sampling for PFAS; the ability for water systems to leverage monitoring flexibilities in the NPDWR, the EPA finds that there is sufficient laboratory capacity supporting the final NDPWR.

The EPA also disagrees with commenter assertions that there is insufficient laboratory capability at this time. As discussed above and in the proposed rule preamble, the EPA proposed a PQL of 4.0 ng/L for both PFOA and PFOS based on current analytical capability and from the MRLs generated for the UCMR 5 program. The MCLs for PFOA and PFOS were also set at 4.0 ng/L as

a result of the analytical capability assessment under the MRL setting study for UCMR 5, as well as consideration of other factors (e.g., treatment, costs) as required under SDWA. For UCMR 5, all UCMR-approved laboratories were able to meet or exceed the PFOS and PFOA UCMR MRLs, set at 4 ng/L, the final MCL for both. The UCMR 5 MRLs of 4 ng/L for PFOS and PFOA are based on a multi-laboratory MRL calculation using lowest concentration minimum reporting level (LCMRL) data. The LCMRL and MRL have a level of confidence associated with analytical results. More specifically, the LCMRL calculation is a statistical procedure for determining the lowest true concentration for which future analyte recovery is predicted with 99 percent confidence to fall between 50 and 150 percent recovery. In other words, this procedure allows for the determination of a method quantitation limit through simultaneous incorporation of precision and accuracy in analytical measurements.

The multi-laboratory MRL is a statistical calculation based on the incorporation of LCMRL data collected from multiple laboratories into a 95 percent one-sided confidence interval on the 75th percentile of the predicted distribution referred to as the 95-75 upper tolerance limit. This means that 75 percent or more of participating laboratories will be able to set a MRL with a 95 percent confidence interval. The quantitation level of 4 ng/L has been demonstrated to be achieved with precision and accuracy across laboratories nationwide, which is important to ensure that systems can dependably comply with the MCL and deliver drinking water that does not exceed the maximum permissible level. The agency anticipates that these quantitation capabilities and capacity for labs will continue to improve over time, as technology advances and as laboratories gain experience with the PFAS Methods. The EPA's expectation is supported by the record borne out by the significant improvements in analytical capabilities for measuring certain PFAS, including PFOA and PFOS, between UCMR 3 and UCMR 5. For example, the MRLs calculated for UCMR 3 (2012-2016) were 40 ng/L and 20 ng/L for PFOS and PFOA, respectively, the MRLs calculated for UCMR 5 (2022-2025) were 4 ng/L each for PFOA and PFOS. Such advances not only imply scientific advances in instrumentation technology but also the availability of more sensitive instrumentation for laboratories to support implementation of the rule.

Additionally, the EPA is promulgating individual MCLs for PFHxS, PFNA and HFPO-DA at the same level as their respective MCLGs (which are equivalent to the Health-Based Water Concentration [HBWCs]). The EPA is finalizing individual MCLs as follows: HFPO-DA MCL = 10 ng/L; PFHxS MCL = 10 ng/L; and PFNA MCL = 10 ng/L. Concurrent with this action, the EPA is making the required determinations to support both the individual MCLs for PFHxS, PFNA, and HFPO-DA as well the Hazard Index MCL for mixtures of PFHxS, PFNA, HFPO-DA and PFBS. The PQLs for HFPO-DA (5.0 ng/L), PFHxS (3.0 ng/L), PFNA (4.0 ng/L), and PFBS (3.0 ng/L), like PFOA and PFOS, are also based on current analytical capability and from the MRLs generated for the UCMR 5 program. Considering that the non-PFOA/PFOS PFAS MCLs are significantly higher than their PQLs (between 2 to 667 times higher), the EPA disagrees that there are reliability concerns with results for these four PFAS. For discussion on PQLs for the PFAS regulated by the final NPDWR, including discussion on how the PQLs were established, please see the EPA section 7.2 of the EPA response in this *Response to Comments* document.

Several commenters raised concern regarding on-going laboratory capacity for this final rule in context of required testing under other environmental programs (for example, NPDES permitting requirements, evaluation of impacts to wastewater systems, or laboratory analysis under cleanup programs). These commenters express concern that laboratories must conduct analyses in various matrices and this rule may complicate their ability to provide results for complying with the final NPDWR in time. The EPA disagrees with commenters that testing for PFAS in other matrices would interfere with laboratories' ability to test for PFAS in drinking water matrices. First, as discussed elsewhere in this *Response to Comments* document, there are already a number of laboratories testing for PFAS in drinking water using EPA methods 533 and 537.1. Significant laboratory capacity has already been developed to support the UCMR 5 program and numerous state PFAS drinking ater regulatory and monitoring programs. Specifically, in regard to UCMR 5, as of January 2024, in the first 9 months of the UCMR 5 sampling program, these laboratories have already tested over 16,000 samples for all 29 PFAS monitored under that program (resulting in approximately 500,000 individual analytes reported). With finalization of this final PFAS NPDWR, as is typical in with past regulatory programs, the EPA expects the laboratories certified to collect these samples to increase, not decrease (see preceding discussion on laboratory capacity and capability). Secondly, the EPA notes that for labs that analyze both drinking water, wastewater, and/or other matrices' data, laboratories typically have dedicated equipment to support analyzing drinking water contaminants to avoid cross contamination, particularly for methods that have strict quality assurance/quality control (QA/QC) requirements and low PQLs such as those required for the six PFAS regulated by this drinking water regulation. Additionally, the EPA notes that there are many utility associated labs that are established solely to monitor for drinking water or wastewater (e.g., see Adams et al., 2023) or dedicate separate instruments to analyze drinking water versus non-drinking water samples as they don't want cross contamination. Third, commenters concerns are not supported by any basis in fact or factual information to the record. Specifically, the data on the volume of additional samples to manage from other state and federal programs was not provided by commenters and the EPA is generally unaware of sources that project specific future laboratory needs across all potential matrices. Hence, the EPA cannot estimate the potential additional demand that other analyses may create, nor what potential impacts, if any, there could potentially be on drinking water laboratory capacity. Finally, even if data were to be available, SDWA section 1412.b(3)(C)(i)(III) requires that EPA include quantifiable and non-quantifiable costs that are likely to occur solely as a result of compliance with the MCL, including monitoring, treatment and other costs and excluding costs resulting from compliance with other proposed or promulgated regulations." Testing for other matrices such as wastewater testing or testing for contaminated sites is not part of routine compliance sampling under this regulation. In summary, despite the concerns raised by commenters that there may be additional demands on drinking water laboratory capacity as a direct result of non-drinking water analytical needs, the EPA does not anticipate non-drinking water related sampling will meaningfully impact national laboratory capacity for analyzing PFAS in drinking water samples.

A few commenters expressed concern on enforcement actions or PN of violations resulting from delays in receiving analytical results from certified laboratories (e.g., prolonged laboratory turn-around times). In particular, these commenters state that on-going laboratory capacity challenges are resulting in backlogs that cause delays in analysis and delivery of results, even when samples are collected in a timely manner. Some of these commenters suggest that water systems should not be penalized in this scenario. As a general matter, it is incumbent on the water system to meet the monitoring and reporting requirements of any NPDWR and to get the analysis completed in a timely manner consistent with these requirements. In this vein, the EPA recommends that the primacy agency working with the system to schedule sample collection well before the end of the monitoring period to allow ample time for results to be reported. Further, it is important to note that if a sample is collected on time but laboratory analysis was delayed, this would constitute as a reporting violation and not a monitoring violation. See 40 CFR § 141.31(a) which states that "the supplier of water shall report to the State the results of any test measurement or analysis required by this part within (1) The first ten days following the month in which the result is received, or (2) the first ten days following the end of the required monitoring period as stipulated by the State, whichever of these is shortest." Moreover, states that gain primary enforcement authority would respond to violations of NPDWRs, however the EPA retains independent enforcement authority and may take federal actions as appropriate in specific situations. *See* the EPA's SDWA Enforcement Response Policy for an explanation of how the EPA typically pursues enforcement cases involving a water system's violations of the SDWA.

The EPA is promulgating a two-year capital improvement extension pursuant to SDWA section 1412(b)(10) in response to comments on the compliance timeframe. Although the EPA disagrees with commenter's assertions about laboratory capacity at this time to support implementation of the NPDWR, to the extent there are some initial implementation issues just after promulgation, extending the compliance date may also provide ancillary benefits toward addressing any such laboratory capability and capacity issues by allowing laboratories additional time to respond to short-term, increased demands to fill analytical needs of utilities to comply with the final NPDWR. Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Individual Public Comments

3M Company (Doc. #1774, SBC-045686)

VII. THE PROPOSED MCLs ARE NOT "FEASIBLE"

After determining to regulate a substance, EPA must set a "maximum contaminant level goal" (MCLG) for each identified substance at a level at which no known adverse health consequences will occur. [FN80: 42 U.S.C. [sec] 300g–1(b)(4)(A).] EPA must then set a "maximum contaminant level" (MCL) for each substance as close to the MCLG as is feasible. [FN81: Id.

[sec] 300g–1(b)(4)(B).] Under the statute, "feasible" means "feasible with the use of the best technology, treatment techniques and other means which the Administrator finds... are available (taking cost into consideration)." [FN82: Id. [sec] 300g–1(b)(4)(D)] Some basic factors such as insufficient lab capacity and inability to reliably measure samples at the ultra-low levels in the proposed NPDWR render the proposed MCLs infeasible, contrary to SDWA requirements.

EPA Response: The EPA disagrees with the commenter that the final MCLs are infeasible. The EPA's final rule represents data-driven drinking water standards that are based on a thorough analysis of feasibility consistent with requirements under SDWA. For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please also see section 5.1.2 of the EPA response in this *Response to Comments* document.

A. O. Smith Corporation (Doc. #1674, SBC-043695)

3. Laboratory Capacity and Testing Cost Considerations

Having reviewed and being familiar with USEPA Test Methods 573.1 and 533, the Company agrees that each test protocol when accurately conducted can reliably quantify and detect PFOA and PFOS to 4 ppt. The test protocols, again when accurately conducted, should also address concerns surrounding "false positives" and non-detects which can be a persistent challenge for PFAS analysis, which in turn can affect the detection limit of the methods.

EPA Response: The commenter's agree that test protocols, when accurately conducted, can reliably quantify PFOA and PFOS to 4.0 ppt. For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Robert Hollander (Doc. #1516, SBC-042709)

1. 88 FR 18667, 1st column

I agree it is appropriate to establish the MCL at the PQL for PFOA and PFOS. It would be not be acceptable for it to be lower for the reasons provided at 88 CFR 18667.

EPA Response: The commenter supports the feasibility of the final standards for PFOA and PFOS. For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

American Council of Independent Laboratories (ACIL) (Doc. #1692, SBC-044736)

As measurement experts, our comments will pertain solely to method/measurement aspects of the regulation. Our comments/requests for clarification are detailed below.

1. Proposed MCLs

ACIL agrees with the EPA that the measurement of the listed PFAS at the sensitivity needed to support the proposed MCLs is achievable by the laboratory community.

EPA Response: The commenter supports the feasibility of the final standards. For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Corix Infrastructure Inc. (Doc. #1834, SBC-045367)

[With regards to the specific items EPA has requested comment on, Corix provides below:]

• We support setting the MCL at the PQL for PFOA and PFOS.

EPA Response: The commenter supports the feasibility of the final standards for PFOA and PFOS. For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Las Cruces Utilities (LCU) (Doc. #1753, SBC-043905)

In response to Section VI-Maximum Contaminant Level of the Proposed Rules, EPA requests comment on its proposed determination to set MCLs at 4.0 ppt for PFOA and PFOS and whether 4.0 ppt is the lowest PQL that can be achieved by laboratories nationwide.

• LCU would like to express concern over the proposed determination to set MCL's at 4.0 ppt. While the EPA states the evaluation "determined that 4.0 ppt is the lowest concentration that PFOA and PFOS can reliably be quantified within specific limits of precision and accuracy during routine laboratory operating conditions," LCU questions the feasibility of the proposed limit in practical application.

This uncertainty is further warranted due to the following:

1. In 2016 until recent, 70 ppt was the health level of concern.

2. According to the European Chemicals Agency, "The proposal to establish a new 'group limit' value for PFAS of 0.5 µg/L (500 ng/L), in addition to limits for 16 individual PFAS of 0.1µg/L (100 ng/L) in drinking water under the recast of the EU Drinking Water Directive is currently under consideration at EU level."

LCU questions the public water suppliers' ability to meet the proposed limit in an environment in which EPA confirms the ubiquitous prevalence of PFAS; If drinking water accounts for 20% of PFAS exposure, what other points of exposure can affect sample validity? There are countless possible sources of external contamination. Contamination during sampling can be as simple as a dust particle in the air at the time of sampling on a windy day, or a part per trillion that adhered to a sampler's nitrile glove.

EPA Response: The EPA's final rule represents data-driven drinking water standards that are based on a thorough analysis of feasibility consistent with requirements under SDWA. For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 of the EPA response in this *Response to Comments* document. HAs are beyond the scope of this rulemaking. The PFAS NPDWR is informed by regulatory development requirements under SDWA and includes the EPA's analysis of the best available and most recent peer-reviewed science. There also may be several reasons why the EPA's conclusions may differ from those of other health agencies (such as the European Chemicals Agency). As an example, the EPA uses established systematic review practices (USEPA, 2022b) to identify, evaluate, synthesize, integrate, and quantify evidence in a chemical database. These protocols have been repeatedly peer-reviewed and improved upon over time. Other health agencies do not follow these same practices and, as a result, may arrive at different conclusions. For further discussion on international and state drinking water standards and guidelines, please see section 5.1.5 of the EPA response in this *Response to Comments* document. Regarding discussion on RSCs, please see section 4 of the EPA response in this *Response to Comments* document. Regarding analytical background contamination concerns, please see section 8.7 of the EPA response in this *Response to Comments* document.

Las Cruces Utilities (LCU) (Doc. #1753, SBC-043906)

In response to Section VI-Maximum Contaminant Level of the Proposed Rules, EPA requests comment on its proposed determination to set MCLs at 4.0 ppt for PFOA and PFOS and whether 4.0 ppt is the lowest PQL that can be achieved by laboratories nationwide.

• LCU would like to express concern over the proposed determination to set MCL's at 4.0 ppt. While the EPA states the evaluation "determined that 4.0 ppt is the lowest concentration that PFOA and PFOS can reliably be quantified within specific limits of precision and accuracy during routine laboratory operating conditions," LCU questions the feasibility of the proposed limit in practical application.

This uncertainty is further warranted due to the following:

1. In 2016 until recent, 70 ppt was the health level of concern.

2. According to the European Chemicals Agency, "The proposal to establish a new 'group limit' value for PFAS of 0.5 µg/L (500 ng/L), in addition to limits for 16 individual PFAS of 0.1µg/L (100 ng/L) in drinking water under the recast of the EU Drinking Water Directive is currently under consideration at EU level."

LCU questions the public water suppliers' ability to meet the proposed limit in an environment in which EPA confirms the ubiquitous prevalence of PFAS; If drinking water accounts for 20% of PFAS exposure, what other points of exposure can affect sample validity? There are countless possible sources of external contamination. Contamination during sampling can be as simple as a

dust particle in the air at the time of sampling on a windy day, or a part per trillion that adhered to a sampler's nitrile glove.

EPA Response: Please see the EPA response to comment Doc. #1753, SBC-043905 in section 5.1.2 in this *Response to Comments* document.

J.R. Simplot Company (Doc. #1661, SBC-044149)

II. Proposed MCL Values Have Considerable Analytical Uncertainty Associated with Measurements

Analytical Quantification/Precision

EPA has identified the following practical quantitation levels (PCL)

[Table 1: See Docket ID: EPA-HQ-OW-2022-0114-1661]

Table 1

PQLs for Regulated PFAS [FN2: Federal Register. 2023. Vol. 88 (60), p.18,680.]

There are two analytical methods approved by EPA for analyzing PFAS regulated under this proposed rule, USEPA Methods 537.1 and 533. In this evaluation, EPA determined that 4.0 parts per trillion (ppt) is the lowest concentration that PFOA and PFOS can be reliably quantified within specific limits of precision and accuracy during routine laboratory operating conditions.

These PQL values are problematic for several reasons. First, EPA is also proposing rule trigger levels for monitoring programs at 1/3 of the proposed MCLs. The use of the PQL as the MCL for PFAS substances tests the lower boundary of the accuracy of the test method when it is detected at very low concentrations, such as 4 parts per trillion or lower. So, the scientific certainty of a "trigger level" of measured 2.7 ppt is low. Furthermore, having the MCL set at the PQL significantly increases the possibility of false positives (i.e., exceeding the MCL when such an "exceedance" is due to the variation and limits of the analytical methodology. [FN3: EPA, in the Federal Register notice, describes the importance of Data Quality Objectives (DQO). EPA states that "DEQ should consider establishing reasonable quantification levels that laboratories can routinely meet. Establishing a quantitation level that is too low may result in recurring QC failures that will necessitate repeating sampling analyses, increase costs and potentially reducing laboratory capacity." However, by EPA "determining" that the PQL is 4 ng/L – that is exactly will happen. It is not certain that 4 ng/L is a "reasonable quantitation level" that laboratories can routinely meet. It is recommended that EPA further explain and seek comment on the appropriate PQLs for the contaminants listed in Table 1].

EPA Response: The EPA disagrees with the commenter that the PQLs are not set at a reasonable quantitation level. For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see

section 5.1.2 of the EPA response in this *Response to Comments* document. Furthermore, EPA notes that a single exceedance of the PQL may not result in an exceedance of the PFOA or PFOS MCL because compliance is determined based on an RAA. For more discussion, please see section 8.2 of the EPA response in this *Response to Comments* document and section VIII of the final rule preamble. Regarding the rule trigger levels for reduced triennial monitoring, please see section 8.8 of the EPA response in this *Response to Comments* document and section VIII of the final rule preamble. Lastly, for a discussion of potential "false positives," see section 8.7 of the EPA response in this *Response to Comments* document.

New York State Department of Health (NYS DOH) (Doc. #1677, SBC-044955)

17. EPA requested comments on implementation challenges and requested feedback on considerations for setting MCLs at the PQLs. New York State has been implementing enforceable MCLs for PFOA and PFOS since August of 2020. In that time, approximately 250 public water systems have exceeded the MCL. During that same period, the cost of equipment, including treatment vessels and media have been subject to periodic disruptions in the supply chain, and have significantly increased in cost. Shortage of human capital, such as engineering services, has also emerged as a challenge to effective implementation. As the workforce emerges from a global pandemic both regulating and regulated communities are working to fill the voids left through attrition, while navigating a new workforce paradigm.

In addition, it is challenging to enforce regulations at the PQL when there is uncertainty in the analytical method. Enforcing MCLs is a legal proceeding where the respondent is entitled to due process. It is conceivable that public water suppliers will appeal MCL determinations on the grounds that results are within the standard error of the analytical method, further straining state enforcement resources as well as Federal resources in states that do not immediately obtain primacy.

EPA Response: For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. With respect to responses to address uncertainty in the analytical method, the agency recognizes that any analytical method being used at a certified laboratory will have a degree of uncertainty, however, this is true for the measurement of any compliance parameter, not unique to PFAS measurements and results that pass QC requirements in the methods are defensible to enforce the regulations. With respect to responses that utilities may appeal MCL violations on the ground that results are within the standard error provided in the analytical methods, the agency disagrees with this commenter's assertions that analytical methods include defined standard error criteria that laboratories would include with measurement results. Analytical methods, like those approved for PFAS, specify QC requirements that laboratories must meet to demonstrate the validity of the reported results and document the laboratory's performance is in control, but these are not synonymous with standard error. For additional discussion on supply chain and labor challenges

that may affect the compliance timeline, please see section 12.1 of the EPA response in this *Response to Comments* document on extensions and exemptions.

American Council of Independent Laboratories (ACIL) (Doc. #1692, SBC-044741)

The ACIL is concerned that the EPA setting required PQLs at the MCL while also stating in the document that laboratories can and will report at 4-8X lower than the minimum stated PQLs risks sending mixed messages and causing confusion. For example, consider the case where the concentration of PFOS in a sample was 2.1 ng/L. Laboratory A reporting at the maximum allowed PQL of 4.0 ng/L with an MDL of 2.5 ng/L would report an ND for PFOS, below the trigger value, whereas laboratory B at a reporting limit of 1 ng/L would report a value of 2.1 ng/L above the trigger value from the same sample. We believe this confusion could be resolved by setting the reporting limits as defined by a definitive LCMRL, at least for PFOS and PFOA, and with examination of the data, for the other 4 PFAS as well, at 1/3rd the MCL, the trigger value, rather than at the MCL. This ensures that the data for determining sampling frequency triggers is reported at a known precision and accuracy. As the EPA states, "this reporting limit was possible given that under the UCMR5 application program, 49 of the 54 laboratories seeking EPA approval included a lowest PFAS calibration standard level at 1 ppt or lower, with the median lowest calibration level among all laboratories at 0.5 ppt"

EPA Response: The agency disagrees with the commenter that defining laboratory quantitation or detection limits are needed to support compliance monitoring for the rule; for additional discussion, please see section 7.1 of the EPA response in this *Response to Comments* document. For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For discussion of the trigger values, please see section 8.8 of the EPA response in this *Response to Comments* document.

American Council of Independent Laboratories (ACIL) (Doc. #1692, SBC-044739)

4. Clarity on Trigger Values and the MCL

The EPA has proposed an MCL of 4.0 ng/L for PFOS and PFOA, and 1.0 for the hazard index calculation that includes PFBS, PFHxS, PFNA and HFPO-DA. As the EPA mentions, laboratories can routinely support monitoring at these MCL values. The EPA sets minimum reporting requirements for laboratories in Table 19 (copied below)

[Table 19. See Docket ID EPA-HQ-OW-2022-0114-1692]

The EPA discusses at length the decision to set practical quantitation limits for PFOA and PFOS at the MCL rather than setting minimum reporting limits below the MCL in order to provide a buffer.

More cogently, the EPA proposes a trigger level that will result in increased monitoring if exceeded:

"While the values below the PQL will not be used to calculate compliance with the proposed MCLs under this proposed rule (see discussion above in Section VI of this preamble), values lower than the PQL are achievable by individual laboratories, and therefore lower levels can be used for purposes of screening and to determine compliance monitoring frequency. EPA is proposing the use of a rule trigger level for less frequent compliance monitoring under certain circumstances in which systems can demonstrate PFAS concentrations in finished drinking water are below: • one-third of the MCLs for PFOA and PFOS, i.e., 1.3 ppt; and • one-third of the HI MCL for the HI PFAS (PFHxS, HFPO–DA, PFNA, and PFBS), i.e., 0.33.

EPA Response: The agency disagrees that the trigger levels will result in increased monitoring if exceeded. On the contrary, results below the trigger levels can potentially decrease a system's monitoring frequency. For discussion of the rule trigger value, please see section 8.8 of the EPA response in this *Response to Comments* document. For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For discussion on the Hazard Index PFAS, please see section 5.2.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045021)

MCLs for PFOA and PFOS

EPA has proposed to set the practical quantitation limits (PQLs) for PFOA and PFOS at 4.0 ppt. EPA requested comment on the proposed determination to set the MCLs for PFOA and PFOS at the proposed PQLs. NJDEP is requesting EPA to evaluate if the analytical methods identified in the proposal can achieve the PQLs and trigger levels for all listed PFAS. For PFOA and PFOS, NJDEP has found that most certified laboratories used by public water systems (PWS) in New Jersey have lowest calibration standards between 1.0 and 2.0 ppt, so there is potential for EPA to lower the PQLs for PFOA and PFOS; however, this would result in a lower trigger level, which laboratories may not be able to achieve.

EPA Response: For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

The City of Columbus, Department of Public Utilities (Doc. #1703, SBC-045053)

May 30, 2023

FILED VIA FEDERAL eRULEMAKING PORTAL

Assistant Administrator Radhika Fox

Office of Water

Office of Ground Water and Drinking Water

Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington, DC 20460

RE: Proposed Rule, PFAS National Primary Drinking Water Regulation EPA-HQ-OW-2022-0114; 88 FR 18638 (March 29, 2023)

Dear Assistant Administrator Fox:

The City of Columbus, Department of Public Utilities ("CDPU") appreciates the opportunity to comment on EPA's proposed National Primary Drinking Water Regulation for PFOA, PFOS, and four other PFAS. CDPU operates drinking water and wastewater treatment plants serving over 220 square miles in the greater Columbus area. Our interest in PFAS stretches from the source water that feeds our drinking water plants to the effluent released from our wastewater plants, and everywhere in between. We are committed to improving water quality and protecting the environment, and we share EPA's concerns about the risks that PFAS chemicals pose to the public.

CDPU provides critical services to our community. The three drinking water plants operated by CDPU delivered over 50 billion gallons of clean, safe drinking water last year, averaging 145 million gallons daily, to over 1.3 million residents of the Greater Columbus area. The City of Columbus has many residents living in environmental justice communities including Linden, Franklinton, Hilltop, and Near South. CDPU uses a complex multi-barrier approach utilizing state of the art equipment and the latest treatment technologies to ensure all requirements of the Safe Drinking Water Act (SDWA) are continuously met. Ratepayers keep these plants running.

CDPU drinking water facilities do not use, produce, or profit from PFAS compounds. We passively receive source water into our facilities that may contain PFAS from industrial, commercial, and domestic sources. We treat and distribute water 24 hours a day, 7 days a week, 365 days each year. And we comply with our permits and protect public health and the environment by providing safe drinking water.

EPA requested comment on implementation challenges and considerations for setting the maximum contamination level (MCL) at the practical quantification level (PQL) for PFOA and PFOS, including on the costs and benefits related to this approach. EPA also asked for comment related to its evaluation of feasibility under the SDWA for the proposed PFOA and PFOS and hazard index MCLs. CDPU concurs with the comments made by the National Association of Clean Water Agencies (NACWA) and makes the additional comments below.

As a vested stakeholder with a duty to the public, CDPU supports EPA in its efforts to set its initial federal drinking water standard for PFAS at a protective, feasible (MCL). But CDPU urges EPA to consider the active loading of PFAS into water occurring through the manufacture and use of PFAS and PFAS containing products. CDPU also urges EPA to consider the accurate

costs and feasibility, consumer confidence, and regulatory alternatives before it mandates its first MCL at the PQL. Several states have established feasible state standards for PFOA and PFOS at twice the currently proposed federal standard. Those plans would result in the best use of limited resources because they address the greatest health risks by prioritizing systems with the highest concentrations of PFAS.

EPA Response: The EPA's final rule represents data-driven drinking water standards that are based on a thorough analysis of feasibility consistent with requirements under SDWA. For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please also see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding actions the agency is taking to "active loading of PFAS into water occurring through the manufacture and use of PFAS and PFAS containing products," the EPA notes that these actions are outside the scope of the current rulemaking but directs the commenter's attention to the EPA PFAS Strategic Roadmap that outlines the whole-of-agency approach to "further the science and research, to restrict these dangerous chemicals from getting into the environment, and to immediately move to remediate the problem in communities across the country" (USEPA, 2022c). For more discussion on the PFAS Strategic Roadmap, please see section II.F of the Federal Register Notice (FRN), section 15 of this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. For additional discussion on cost considerations for the MCL, please see section 5.1.3 of the EPA response in this *Response to Comments* document.

The City of Columbus, Department of Public Utilities (Doc. #1703, SBC-045060)

A. The MCL and the PQL are too close.

EPA requested comment on setting the MCL so close to the PQL and its effect on water utilities. In that discussion, EPA recognized that "[t]he agency must have a high degree of confidence in the quantified result as it may compel utilities to make potentially costly compliance decisions in order to comply with the MCL." It also recognized that water utilities operate conservatively to maintain water quality and "typically aim to achieve lower than the MCL to avoid a violation." In reality, this results in proactively adding treatment if there is any possibility of violating the MCL (as will play out at CDPU). But when the MCL is so low—measured in parts per trillion—and the difference between installing hundreds of millions of dollars of treatment, or not having to treat, is one drop in 20 Olympic size swimming pools, it is absolutely necessary to provide for quantitative reliability. The margins are too tight right now when the science is still emerging and the risks of overcommitting public money is high. The reality is that a water utility could graze the MCL level if the sampler applied deodorant that morning, wore a jacket while grabbing the sample, or used a typical sampling container [FN7: https://www.epa.gov/sites/default/files/2020-01/documents/pfas_methods-

sampling_tech_brief_7jan2020-update.pdf]. CDPU supports EPA in its decision that sample results below the PQL are to be recorded as zero. Setting the first ever PFAS MCL this low is not feasible (as discussed above) or reasonable when so much benefit can be realized with setting a higher MCL first to address the systems with significant PFAS contamination.

B. An overly-aggressive MCL for PFAS will shake consumer confidence.

Consumer confidence is key in any water regulation. Clean, safe drinking water is ultimately only as drinkable as the public understands it to be. In the case of PFAS, the science is clear on the risks of consuming high levels of the most damaging formulas of PFAS. Where science is still developing is in relation to the impacts and risks of health implications of low levels of less studied versions. Still further undeveloped is the science on how exposures vary between drinking water and the hundreds of other ways humans are exposed every day. What we know is that drinking water only accounts for 20% of human exposure to PFAS,[FN8: Relative Source Contribution (RSC) is an estimate that drinking water contributes 20% of total exposure to PFOA and PFOS. Other sources contributing 80% of exposure to PFOA and PFOS include but are not limited to air, foods, incidental soil/dust ingestion, and consumer products (U.S. EPA, 2016b) (U.S. EPA, 2016a).] but the risk that the public will be dissuaded from drinking safe tap water is increasingly high. This is especially true if the MCL is issued at the level proposed by EPA alongside the current compliance timeline. Widespread violations of the MCL may be triggered by EPA's proposed approach, and even if levels are close to the PQL and much lower than other sources of PFAS exposure, consumers will lose confidence in the safety of publicly supplied drinking water [FN9: Consumer confidence concerns affect low-income and underserved environmental justice area residents even more if they spend their limited resources on purchasing bottled water that is less-regulated.].

EPA Response: The EPA disagrees with the commenter that the PQLs are not set at a reasonable quantitation level and are "overly aggressive." For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For discussion on RSCs, please see section 4 of the EPA response in this *Response to Comments* document. For additional discussion on PFAS risk communication, please see section 1.2 of the EPA response in this *Response to Comments* document.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045098)

3) Implementation Challenges and Considerations for Setting MCL at PQL

While the proposed MCLs for PFOA and PFOS would increase public health protection, there is concern with setting a standard at a PQL which will be changing over time.

EPA Response: For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For additional discussion on how the EPA considers future science, please see section 5.1.6 of the EPA response in this *Response to Comments* document.

Wyoming Department of Environmental Quality (WDEQ) (Doc. #1716, SBC-044778)

4. EPA Should Not Set the MCL for PFOA and PFOS at the PQL

EPA's proposed NPDW rule for PFOA and PFOS establish the MCL at the PQL for USEPA Methods 537.1 and 533. While WDEQ recognizes that the SDWA requires EPA to set the MCL "as close as feasible" to the MCLG, there is too much uncertainty in values this close to the PQL to use them as the basis for an MCL. In addition, setting the MCL for PFOA and PFOS at the PQL implies that the MCLs should be modified as analytical detection and quantitation improve. Instead, EPA should establish the MCL somewhere above the PQL where PWS can be confident that their data either does or does not exceed the MCL.

WDEQ recognizes the significant amount of work that went into EPA's development of the proposed rule, and we appreciate the opportunity to submit these comments. We would welcome the opportunity to meet with EPA to discuss these issues in greater detail, and we look forward to our continued partnership with EPA as we implement both voluntary and regulatory programs to reduce PFAS and protect human health and the environment.

Sincerely,

Todd Parfitt, Director

cc: Jennifer Zygmunt, WQD Administrator

Suzanne Engels, SHWD Administrator

Nolan Rap, Office of the Governor

EPA Response: The EPA disagrees with the commenter that the PQLs are not set at a reasonable quantitation level. For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

City of Tulsa Water and Sewer Department (CoT WSD) (Doc. #1785, SBC-043779)

May 30, 2023

Michael Regan, Administrator U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, N.W.

Mail Code: 1309

Washington, DC 20004

TRANSMITTED ELECTRONICALLY

RE: PFAS National Primary Drinking Water Regulation Rulemaking

(88 FR 18638, EPA-HQ-OW-2022-0114)

Dear Administrator Regan,

The City of Tulsa Water and Sewer Department (CoT WSD) would like to present the following comments to the Environmental Protection Agency (EPA) regarding the preliminary regulatory determination and proposed rule for per- and polyfluoroalkyl substances (PFAS) National Primary Drinking Water Regulation. Underlined items are EPA's requested items for comment in the proposed rule (Federal Register document citation 88 FR 18638, document number 202305471; or Docket Document ID# EPA-HQ-OW-2022-0114-0027), with City of Tulsa Water and Sewer Department's response following.

1. 88 FR 18667 (also 88 FR 18730). EPA requests comment on if setting PFOA and PFOS MCLs at PQLs (4.0 ng/L) is implementable and feasible.

CoT WSD responds that setting the MCLs for PFOA and PFOS at the 4.0 ng/L PQL may cause some treatment and compliance issues for water systems. It is helpful to water systems that the MCL determination is by a running annual average and not individual sampling results.

EPA Response: For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For discussion about the RAA, see section 8.2 of the EPA response in this *Response to Comments* document.

PFAS Regulatory Coalition (Doc. #1761, SBC-046075)

D. Monitoring and compliance

1. It is not technically feasible to manage operations to meet a PQL.

Under the Safe Drinking Water Act, attainment of a MCL must be technologically feasible for public water systems. SDWA Secs. 1401(1)(i), 1412(b)(4). It is not feasible for public water

systems to manage a system so that it will always achieve contaminant levels at the Practical Quantitation Limit (PQL), as EPA is proposing. EPA appears to be unjustifiably dismissive of these concerns.

In considering whether to set an MCL at 25% above the PQL, EPA states that in its outreach consultations, a commenter suggested a MCL of 5.0 ppt because "water systems operate with a margin of safety and plan for performance that maintains water quality below quantitation levels." In the commenter's opinion, "having an increased buffer between the PQL and the MCL may allow utilities to manage treatment technology performance more efficiently because utilities typically aim to achieve lower than the MCL to avoid a violation". 88 Fed. Reg. 18670. EPA dismissed this idea and instead states: "For results between the detection limit and the PQL, EPA has determined that utilities would be able to reliably conclude analyte presence, though this detection is less precise regarding specific concentration." It is arbitrary for EPA to rely on this imprecise presence/absence approach for managing compliance, when facilities are potentially subject to civil and criminal penalties if they are judged to be in noncompliance.

Due to variability in samples, sampling technique, laboratories, etc., managing a drinking water treatment process to the PQL does not make operational sense. Drinking water providers try to make sure they are not just reaching the levels of the MCLs, but are well below those levels, to provide some level of additional operational certainty. Setting MCLs at the PQL does not allow operators to do this.

EPA Response: The EPA disagrees with the commenter that the final MCLs are not set at a feasible level and that it is "not technically feasible to manage operations to meet a PQL." Additionally, values below the PQL are not used for "managing compliance." For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Environmental Protection Network (EPN) (Doc. #1773, SBC-043851)

EPN agrees that EPA should set the MCL for PFOA and PFOS at the practical quantitation level of 4 ppt as implementable and feasible. EPA must be clear that this is not a health-based concentration. Four ppt is the lowest concentration that can be reliably quantified using EPA Methods 537.1 and 533 with specific limits of precision and accuracy during routine laboratory operating conditions. We recognize that 49 of the 54 laboratories seeking EPA certification to analyze UCMR5 samples can achieve a calibration standard of 1 ppt or lower, but we accept EPA's statement that there is not sufficient laboratory capacity nationwide if the quantitation level is set below 4 ppt. We support EPA's recommendation that water systems use measurements below 4 ppt as an early warning that treatment may need to be modified to ensure no exceedances of 4 ppt.

EPA Response: The commenter supports setting the MCLs for PFOA and PFOS at 4.0 ng/L. For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

California-Nevada Section American Water Works Association (CA-NV AWWA) (Doc. #1775, SBC-045268)

I. Technical problems are not adequately considered and are unworkable.

1. Establishing the MCLs for PFOA and PFOS at the analytical method Practical Quantitation Limit (PQL) prior to completing UCMR 5 monitoring (2023-2025) is premature.

The basis for establishing the proposed Maximum Contaminant Levels (MCLs) for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) at 4 nanograms per liter (ppt) is not sufficiently supported by technical laboratory capacity and data quality. We support EPA's position to ensure data quality across multiple laboratories and an expectation to report levels achievable across multiple laboratories nationwide at a 95% confidence interval using specified methods. Per the proposed regulation, the PQLs were developed for laboratories reporting PFAS data for the Unregulated Contaminant Monitoring Rule 5 (UCMR 5). Monitoring under UCMR 5 started in January 2023 and will continue through 2025 for a total of two years. During this time, EPA will be able to collect and evaluate quarterly monitoring data. In addition to providing EPA with occurrence information for 29 PFAS compounds, the reliability of the established analytical methods and the feasibility of reportable data at the PQLs will be better understood. This information is necessary to support the proper development of MCLs, particularly at the ultra-low detection levels of the analytical methods.

EPA Response: For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. The EPA disagrees with commenter assertions that the agency needs to wait for UCMR 5 results in order to finalize the NPDWR at this time. For additional discussion on how the EPA considers future science, please see section 5.1.6 of the EPA response in this *Response to Comments* document. For discussion about preliminary UCMR 5 results, please see section VI.G of the final rule preamble, section 6 of this *Response to Comments* document, and the *Occurrence Technical Support Document* (USEPA, 2024a).

Safe Drinking Water Branch, Hawaii Department of Hawaii (Doc. #1801, SBC-043754)

The MCL and PQL

The gap between the MCL and PQL is a potential loophole. Normally, the PQL is 5-30% of MCL, however, this time, the no-difference on the value between MCL and PQL leaves the lab

no room to have any error in the test. However, the instrumental, human, operational error is inevitable in the practice. EPA should either increase the MCL or decrease PQL.

[Table 1: See Docket ID EPA-HQ-OW-2022-0114-1801]

EPA Response: For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. The agency has determined that setting the MCLs at the PQLs for PFOA and PFOS is as close as feasible to the MCLG. Setting the MCL at the PQL has been demonstrated in other drinking water regulations: as examples, in 1987, the EPA finalized the Phase I VOC rule (USEPA, 1987), where the agency set the MCL at the PQL for benzene, carbon tetrachloride, trichloroethylene, vinyl chloride, and 1,2-dichloroethane.

Little Hocking Water Association (Doc. #1835, SBC-045509)

EPA also requests comment on its proposal to set MCLs at 4.0 ppt for PFOA and PFOS and whether 4.0 ppt is the lowest PQL (practical quantitation limit) that can be achieved by laboratories nationwide. EPA has specifically stated that many laboratories can reliably analyze PFAS to levels much less than the established PQL. Indeed, reporting limits for 18 PFAS under Method 537.1 are typically less than 2.0 ppt in datasets reported to LHWA. As a practical matter and given the concerns expressed by the agency in the proposed rule, LHWA does not object to a 4 ppt MCL. However, because many laboratories can reliably analyze PFAS to levels much less than the established PQL, because people have been unknowingly exposed to PFAS for decades, and because LHWA's customers have such high blood levels of PFOA, the MCLG must remain at zero and the MCL needs to be as low as possible.

EPA Response: The commenter does not object to the feasibility of the final standards for PFOA and PFOS. The agency notes that while some individual laboratories can potentially quantify to lower levels, the EPA's NPDWR is a standard that considers feasibility of laboratory capability nationwide. For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For additional discussion on the agency's derivation of the MCLGs, please see section 4 of the EPA response in this *Response to Comments* document.

Citizens Energy Group (Doc. #1838, SBC-044855)

Section VI – Maximum Contaminant Level

EPA requests comment on its proposed determination to set MCLs at 4.0 ppt for PFOA and PFOS and whether 4.0 ppt is the lowest PQL that can be achieved by laboratories nationwide.

Citizens supports the proposed determination to establish the MCL at a value achievable by laboratories. While 4.0 ppt might not be the lowest PQL that can be achieved by some

laboratories, the EPA's proposal recognizes that the method detection limit and the PQL will vary from analyst to analyst in a single lab, and from lab to lab across the network of commercial laboratories. While laboratories are incentivized to improve their analytical capabilities with lower MDLs and PQLs, at present, setting the MCL at values less than 4.0 ppt could risk some water systems using "J-flagged" estimated data to make compliance decisions.

EPA Response: The commenter supports the feasibility of the final standards for PFOA and PFOS. Estimated (i.e., J-flagged) data are not used to support compliance decisions. For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For additional discussion on monitoring and compliance requirements, please see section 8 of the EPA response in this *Response to Comments* document.

Aidan Cecchetti (Doc. #1640, SBC-047699)

The commenters agree with EPA's determination that utilities would still have an early warning that they may exceed the MCL prior to doing so when the MCLs for PFOA and PFOS are set at the PQL. Detections of PFOA and PFOS at concentrations below the PQL can provide utilities with the same type of information to make decisions related to monitoring frequency and treatment modifications, as measured concentrations between the PQL and 5.0 ppt would provide if the MCL were set at 5.0 ppt. However, the commenters encourage EPA not to consider imposing any uniform regulatory requirements for detections of PFOA or PFOS at concentrations below the PQL until and unless a uniform method detection limit below the PQL is required of analytical laboratories to become certified to perform these analyses. Otherwise, these requirements may lead to inequitable distribution of regulatory compliance requirements based on laboratory analytical capabilities.

EPA Response: For responses on the EPA's feasibility analysis, please see section 5.1.2 of the EPA response in this *Response to Comments* document. The agency is clarifying for the commenter that values below the PQL will not be used for compliance decisions in the NPDWR. For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please also see section 5.1.2 of the EPA response in this *Response to Comments* document.

Michigan Section American Water Works Association (MI-AWWA) (Doc. #1734, SBC-044476)

Feasibility

Another concern is the feasibility of reliable treatment methods at the proposed reporting levels. Sampling and analysis to such low levels also presents significant opportunities for cross contamination of samples and erroneous results. Setting the MCL at the MRL will present significant challenges because MRLs will continue to decrease overtime which will require treatment processes to achieve lower effluent concentrations to a point where PFAS removal is

cost prohibitive or not technically feasible. With that said, the cost of managing an ongoing problem versus routine monitoring will further impact the reliability of the treatment method employed.

EPA Response: For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding responses regarding the agency's evaluation of feasible treatment technologies for the final NPDWR, please see section 5.1.4 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenter that setting the MCL at the MRL will present significant challenges "because MRLs will continue to decrease overtime." The MCLs for PFOA and PFOS are set at the PQLs and the MCLs are not variable in implementing the NPDWR as finalized. If laboratory quantitation capabilities results in lower PQLs in the future, the agency could consider that information during the Six Year Review process under SDWA. For additional discussion on how the EPA considers future science, please see section 5.1.6 of the EPA response in this *Response to Comments* document.

North Penn Water Authority (NPWA) (Doc. #1470, SBC-043291)

March 24, 2023

Our Perspective on Proposed New PFAS Regulations

by Anthony J. Bellitto, Jr., P.E.

Executive Director

North Penn Water Authority, Lansdale, PA

With the newly proposed Maximum Contaminant Levels (MCL's) of 4 parts per trillion (ppt) for PFAS compounds, and a goal of "Non-detect," the federal Environmental Protection Agency (EPA) has taken an unprecedented regulatory action that will be extremely difficult and expensive for the water industry to meet. It will affect every water system around the country, since at these extremely low levels PFAS will be found everywhere, not just in areas that have had a known spill or contamination event.

Although the PFAS found at high levels in fire extinguishing foam around military bases is getting a lot of attention, PFAS is also found at much lower levels in many commonly used products that we use in our daily lives, including food wrappers, cookware, cosmetics, personal care products, and clothing, to name just a few. Its presence in drinking water is only one of several routes of exposure. Public water systems around the country should not be disproportionately targeted in the government's effort to reduce exposure to PFAS.

At these extremely low levels, it can be found in the environment all around us, even in the rainwater. In the approximately 150 years of water treatment history, there has never been a

regulatory standard set to such an infinitesimally small number, by any government anywhere in the world. Is it reasonable and justifiable to set a standard so low? That question needs to be answered before enormous amounts of money are expended to achieve this result.

To put this extremely low level in some comparative perspective, one part per trillion is the equivalent of one second in 32,000 years. The question remains – do levels that low have a measurable negative impact on human health? The scientific research on this matter has thus far not been conclusive, but there is good reason for skepticism. Is this recommendation from the EPA driven more by politics than by hard science?

Right now, several states have enacted water quality standards for PFAS that are quite different than what the EPA has proposed, yet both the federal government and the states have made the claim that their proposed standards were determined by rigorous scientific analysis. So which one is the correct science? They cannot all be right, as they each have arrived at different conclusions on what the acceptable number should be. It makes us wonder if maybe there is more politics at play here instead of science.

These extremely low levels, which have a questionable value, will unnecessarily frighten the average American citizen and cause an unjustified loss of confidence in the quality of the public water system. And the added costs could cause many publicly owned systems to be subjected to private takeovers, which inevitably leads to much higher rates charged to the customers.

There is also a lot of discussion that the goal for PFAS in water should be "Non-detect." But this is an unrealistic and unnecessary performance standard. No other water quality parameters are required to meet this standard. There are some measurable amounts of many parameters in all water, but those extremely low levels are well below the point where they would cause a negative health impact. Just because modern laboratory equipment can detect levels in the part per trillion range does not mean we can conclude that it causes harm to humans. "Non-detect" is a moving target, as new lab technology allows us to measure lower and lower amounts. Non-detect meant something quite different only 5 years ago, and it will likely mean something different 5 years in the future, as technology improves.

All of this is publicly reported by all water utilities across the country in their annual Water Quality Reports that are mandated for distribution to all its customers. For just one example, these reports show that the EPA's Maximum Contaminant Level (MCL) for lead is 15,000 parts per trillion (ppt), not "Non-detect." We hear people say "there is no safe level of lead" but really there is. The medical community has determined that any amount below 15,000 ppt in water is considered safe by scientific studies. This is quite appropriate, and the same kind of thinking should be applied in setting regulatory standards for PFAS.

EPA Response: The EPA disagrees with the commentor regarding the feasibility of the final standards. For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 (for PFOA and PFOS) and section 5.2.1 (for the Hazard Index PFAS) of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenter's assertions about the adverse health effects at low levels of PFOA and PFOS. The EPA's final rule

represents data-driven drinking water standards that are based on the best available, peer-reviewed science, meet the requirements of SDWA, and that regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water (see section II.D and III of the final rule preamble and section 3 of the EPA response in this *Response to Comments* document for discussion on the science informing the EPA's regulatory determinations). The EPA disagrees with the commenter's assertions that the MCL was set a "non-detect." The MCLG is based on the statutory standard (see section 4 of the EPA response in this *Response to Comments* document) and the MCL is based on the agency's feasibility assessment as discussed in section 5.1.2 of the EPA response in this *Response to Comments* document. For additional discussion on how the EPA considers future science, please see section 5.1.6 of the EPA response in this *Response to Comments* document.

Aidan Cecchetti (Doc. #1640, SBC-044365)

• EPA requests comment on its proposed determination to set MCLs at 4.0 ppt for PFOA and PFOS and whether 4.0 ppt is the lowest PQL that can be achieved by laboratories nationwide (pg. 18667 Federal Register Volume 88, Number 60).

o The commenters agree with EPA's determination that setting the MCLs at 4.0 ppt for PFOA and PFOS is technically and economically feasible and is therefore required pursuant to the SDWA requirement that EPA set the MCL as close as feasible to the MCLG. The commenters do not have expertise to provide feedback on whether 4.0 ppt is the lowest PQL that laboratories can achieve.

EPA Response: The commenter supports the feasibility of the final standards for PFOA and PFOS. For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Consumer Reports (Doc. #1656, SBC-043191)

Section VI. Maximum Contaminant Level

Under section 1412(b)(4)(B) of SDWA, EPA must establish an enforceable MCL as close to the MCLG as feasible, taking costs into consideration. EPA has approved two analytical methods, USEPA Methods 537.1 and 533, for measuring PFAS regulated under this rule. For PFOA and PFOS, EPA has determined that 4.0 ppt is the "practical quantitation level" (or PQL), or the lowest concentration that, with 95 percent confidence, can be achieved by analysts at 75 percent or more of the laboratories using Method 533 and 537.1, according to the UCMR 5 rulemaking. Indeed, laboratory calibration data submitted as part of the UCMR 5 Laboratory Approval Program found that "49 of the 54 laboratories seeking EPA approval included a lowest PFAS calibration standard level to 1 ppt or lower, with the median lowest calibration level among all laboratories at 0.5 ppt."3 [FN3: See pg 18667 in https://www.govinfo.gov/content/pkg/FR-2023-03-29/pdf/2023-05471.pdf] Thus, it appears that for virtually all laboratories, the PQLs for

PFOA and PFOS of 4.0 ppt are at least 4 times greater than the lowest calibration standard meaning that it is technically feasible to set the MCL at the PQL.

Section 1412(b)(4)(d) of the SDWA defines feasibility in part as "feasible with the use of best available technologies." EPA has determined that multiple technologies (i.e., GAC, AIX, RO and NF) are both available and have demonstrated PFAS removal efficiencies that may exceed >99 percent and that achieve concentrations below 4.0 ppt for PFOA and PFOS. EPA proposes to determine that it is feasible to treat PFOA and PFOS to 4.0 ppt because multiple treatment technologies are effective and available at reasonable cost based on large and metropolitan water systems4 [FN4: USEPA. 2023b. Technologies and Costs for Removing Per- and Polyfluoroalkyl Substances from Drinking Water. EPA– 822–P–23–011.] and because there are methods available to reliably quantify PFOA and PFOS at 4.0 ppt.

Given this, we support EPA's proposal to set the MCL for PFOA and PFOS at the PQL of 4.0 ppt since it is feasible to test drinking water at that level and multiple treatment technologies exist to reduce PFOA and PFOS below 4.0 ppt at reasonable cost.

EPA Response: The commenter supports the final standards for PFOA and PFOS. For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044412)

Page 18730. EPA requests comment on its proposed determination to set MCLs at 4.0 ppt for PFOA and PFOS and whether 4.0 ppt is the lowest PQL that can be achieved by laboratories nationwide.

• DOH cannot provide meaningful comment without reviewing the MDL/MRL studies used to determine the PQL.

EPA Response: For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. UCMR MRLs are determined using data from multiple laboratories that participate in the EPA's UCMR MRL-setting studies and is discussed in the proposed rule materials which the EPA solicited comment on. Nonetheless, this information has been published in the lab approval manual under UCMR 5, which is referenced in the PFAS NPDWR docket, included in the administrative record for this action, and cited here: https://www.epa.gov/dwucmr/fifth-unregulated-contaminant-monitoring-rule

Digamma Consulting (Doc. #3072-18, SBC-046348)

My name is Marco Troiani. I'm an organic chemist who's been doing water testing for a long time and my comments actually were very built on the comments of the last speaker of the

detection limits of 4 parts per trillion. There were two of them listed for PFOA and PFOS which are the two most well-known PFAS compounds, and we're seeing in the proposed regulations of 4 parts per trillion MCL which I guess is equivalent to sort of like the drinking water action level. And so, I know this isn't a place to make questions, but rather comments but I guess I'm commenting on that: what kind of levels are going to be seen for the other compounds, which is GenX and some of these other rare PFAS compounds that are not as well known that don't have specific numbers attached to them quite yet? And about that 4 parts per trillion number, I mean, it's a state-of-the-art number. The detection has not been able to do that up until very recently so this is pushing limits not just of water filtration and water management, but also analytical chemistry and testing. And from what I've spoken to people in the industry, they have developed quite a bit of techniques to improve the accuracy and repeatability of detections and concentrations down at these, up until previously, astronomically low levels. But I see that being a major challenge moving forward in implementing this act. Although, of course, it's going to be a necessary part of being able to get an accurate picture of how contaminated the American water table has become. And so obviously pushing the detections down as far as possible, it's critical, but I just want to make sure that there's a coordination between regulations and industry so that things that are being proposed are achievable and implementable in a sort of a reasonable time, and at a reasonable cost to the communities and the laboratories doing the testing. That's pretty much all I had. Thank you.

EPA Response: The commenter did not explain what it meant by "state-of-the-art number". Methods are available and there are at least dozens of labs nationwide that reach this PQL. For more information about analytical methods, please see section VII of the preamble and section 7 of the EPA response in this *Response to Comments* document. The EPA's final rule represents data-driven drinking water standards that are based on a thorough analysis of feasibility consistent with requirements under SDWA. For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please also see section 5.1.2 of the EPA response in this *Response to Comments* document.

Citizens Against Ruining the Environment (CARE) (Doc. #1638, SBC-047685)

PFOA and PFOS MCLs

CARE supports EPA's methodology and rationale in deriving the proposed MCLs for PFOA and PFOS. EPA's proposed MCLs for PFOA and PFOS as individual contaminants are 4 parts per trillion (ppt). [FN3: PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18638, 18639 (proposed Mar. 29, 2023) (to be codified in 40 C.F.R. pts. 141 and 142), https://www.govinfo.gov/content/pkg/FR-2023-03-29/pdf/2023-05471.pdf.] Following systematic review of both human epidemiological studies and animal toxicity studies EPA determined that PFOA and PFOS are likely carcinogenic. [FN4: Id.] As such, there is no dose below which either chemical can be considered safe within the meaning of SDWA. Therefore,

EPA's main consideration in setting its MCL for PFOA and PFOS is feasibility, including currently available analytical and treatment methods. [FN5: Id.]

EPA determined that 4.0 ppt is the lowest concentration that PFOA and PFOS can be reliably quantified within specific limits of precision and accuracy during routine laboratory operating conditions. [FN6: Id. at 18666.] This is known as a practical quantitation level (PQL). This reporting level is the minimum quantitation level that, with 95 percent confidence, can be achieved by capable analysts at 75 percent or more of the laboratories using a specified analytical method. [FN7: Id.] Furthermore, the PQLs provide for consistency in data quality from a diverse group of laboratories across the country and provide routine performance goals that many laboratories must strive to achieve. [FN8: Id.]

EPA Response: The commenter supports the feasibility of the final standards for PFOA and PFOS. For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045089)

Section VI – Maximum Contaminant Level

1) Determination to set MCL at 4.0 ppt and whether 4.0 ppt is the lowest PQL that can be achieved by laboratories nation-wide.

In Vermont's experience implementing our State MCL since 2019, the few laboratories that our systems have historically used can achieve a reporting level down to 2.0 ppt, we recognize, however, this reporting level is not currently consistently achieved by all laboratories across the country. Further, because this is a national standard, we have concerns about lab capacity moving forward, including the reliability and availability for laboratories to achieve even the proposed PQL of 4.0 ppt and meet the national demands for sample analysis. In other words, Vermont is concerned that we will have continued access to these established laboratories given the increased national demands. Vermont does not currently have in-state capacity for analysis as of the date of writing these comments.

As stated in the preamble, the PQL is set at the level that 75% of the laboratories can achieve 95% confidence. That is to say that 25% of those laboratories cannot achieve a level of 4 ppt. Given the strain on laboratories and the difficulty in implementing new analysis for PFAS in a new lab, 1 in 4 labs will not be able to achieve the PQL of 4 ppt.

EPA Response: For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges

to reliably measure samples for the final NPDWR, please also see section 5.1.2 of the EPA response in this *Response to Comments* document.

Water Environment Federation (WEF) (Doc. #1529, SBC-043306)

Testing: The demand for labs equipped to test PFAS will severely outweigh available lab capacity.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Robert Adamski (Doc. #1530, SBC-043335)

Further there is little laboratory capacity for testing. "But laboratory testing for PFAS isn't cheap. Or easy. Patrick Parsons, PhD, head of environmental health sciences at New York's Wadsworth Center [Link: https://wadsworth.org/]—the state public health laboratory—explained the hurdles. First is cost.

"The type of LC/MS/MS instrumentation for this analysis costs between $250-300K and a further $140K for the automated 96-well plate technologies for SPE for serum testing, and a further $40K for the automated SPE for water testing."

Older LC/MS/MS systems may be incapable of detecting PFAS at the low levels required, on the order of parts per trillion (ppt).

A second problem is contamination from PFAS already in the laboratory. Thus, sample introduction systems have to be stripped of Teflon® degassers, Teflon® SPE cartridges, PTFE vial caps and all other PFAS-containing components.

Of course, laboratories must also have staff experienced in mass spectrometry and assure additional, specialized training in trace analysis of the compounds."

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding responses regarding laboratory testing and potential contamination issues, please see section 8.7 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044086)

Analytical method requirements for temperature and timeframes to store and analyze PFAS samples may also require laboratories to significantly increase refrigeration storage. Primacy agencies have reported that some laboratories are currently unable to keep up with the volume of PFAS samples being run for UCMR 5 and other monitoring being conducted by primacy

agencies. The increased volume is creating delays in storing and processing samples while meeting the method requirements.

Additionally, some primacy agencies have found that systems are having problems meeting temperature and timeframe method requirements when shipping samples. Delays in shipping have caused water systems to take additional samples due to the inability to keep samples at temperature and ship them to the laboratory for processing in time to meet the method requirements.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding responses regarding laboratory testing and potential contamination issues, please see section 8.7 of the EPA response in this *Response to Comments* document. With respect to the analytic requirements of the EPA methods, please see section 7.1 of the EPA response in this *Response to Comments* document. The EPA notes that sample hold time and temperature requirement determinations (for both shipping and storage) were part of the PFAS method development; please see section 7.1 of the EPA response in this *Response to Comments* document for additional discussion on the validated analytical methods used to support the monitoring requirements of this final NPDWR.

American Farm Bureau Federation et al. (Doc. #1642, SBC-043494)

All drinking water stakeholders agree that testing availability presents a significant hurdle, and EPA must develop a plan to make this rule workable. While there may be an opportunity for large facilities to create an in-house testing method, that is certainly outside the realm of possibility for small operations. Since the proposed MCLs for PFOA and PFOS are incredibly low, we also remain concerned about the risk of contamination during the testing process. Essentially any interference with a testing sample could lead to inaccurate results and costly compliance measures.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding responses regarding laboratory testing and potential contamination issues, please see section 8.7 of the EPA response in this *Response to Comments* document.

Aurora Water, City of Aurora, Colorado (Doc. #1669, SBC-043717)

As a result of previous outsourcing of PFAS samples to local laboratories requiring significant time for analysis, Aurora Water has decided to invest in sampling equipment for in-house testing. This instrument is a significant up-front cost as well as long term investment for maintenance activities and the requirement of an additional analyst. An additional challenge with analyzing PFAS in-house is the ability to obtain the necessary reagents for the instrument since there will

be many labs looking to acquire the same thing. Aurora Water was concerned that the laboratories in the area would not be able to keep up with PFAS sampling demands and would cause the city to become out of compliance with this proposed rule.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. The EPA is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 13.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

A. O. Smith Corporation (Doc. #1674, SBC-043698)

A. O. Smith recommends that the EPA engage stakeholders to ensure that additional laboratory capacity, including the recruitment and training of certified laboratory technicians, is increased in a timely manner.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding concerns on laboratory training, please see section 8.6 of the EPA response in this *Response to Comments* document.

Massachusetts Coalition for Water Resources Stewardship (MCWRS) (Doc. #1691, SBC-044329)

[The proposed MCLs raise the specter of serious unintended consequences that could pose public health risks for water consumers. Some of these are:]

e. Nationwide laboratory capacity to support PFAS testing under the MCL while also providing testing under UCMR must also be scrutinized. With MCLs at the detection level the implications of overstressed laboratories making errors as they try to keep up with the demand cannot be overstated. There is no room for lab error but laboratories are being set up to fail if they are overburdened.

EPA Response: The EPA considered lab capacity issues relating to UCMR and the final rule. Under the final rule, data from the UCMR 5 program and other applicable monitoring programs can be used to satisfy the initial monitoring requirements. Additionally, the laboratory capacity established for UCMR 5 will become fully available once UCMR 5 monitoring concludes in December 2025 for PWS to comply with the PFAS NPDWR monitoring requirements after the PFAS rule promulgation For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments*

document. For additional discussion on monitoring and compliance requirements for the final rule, please see section 8 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045955)

In the preamble, EPA refers to other regulations that have been set at the PQL, specifically the phase 1 Volatile Organic Carbon (VOC) rule. AMWA would like to point out that the levels proposed for PFAS are in the ppt range, while the VOC rule includes compounds like Benzene, which has an MCL in the parts per billion range. When dealing with levels of parts per trillion of ubiquitous chemicals like PFAS, there is significant sensitivity and variability in analytical capabilities. Additionally, at such small concentrations, any sample container, and the handling and transport of samples, create the opportunity for interference or contamination.

EPA Response: Regarding commenter concerns for unit concentrations and analytical sensitivity, measurement sensitivity is relative. In other words, the methods approved for compliance monitoring for this NPDWR were developed and demonstrated to meet performance and QC expectations. The method development performance and QC evaluations are conducted as an assessment of method ruggedness, which is demonstrated through testing in multiple types of drinking water matrices, including assessments off-site at other laboratories by other analysts. Therefore, the agency has empirically determined assurances that the methods can perform adequately at the final MCL levels, regardless of unit concentrations.

For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please also see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding analytical background contamination concerns, please see section 8.7 of the EPA response in this *Response to Comments* document.

Environmental Caucus of the Democratic Party of Hawai`i (Doc. #3072-103, SBC-046406)

Thank you. Yes, my name is Melodie Aduja. And thank you for the second opportunity to provide oral testimony. I'm from Hawaii, and I'm following up with the comments of Susan Gorman-Chang also from Hawaii. We really have a problem here in the 50th state because we are in the middle of the Pacific and we are like the forefront of all the Pacific Basin. And of course, we've got the threats of the other countries coming in. And I think the problem with what we have here is that we just don't have a certified lab. So, there was some discussion that Susan brought up that it takes about 8 to 10 weeks before we even get our test results back. And apparently the way our Department of Health is working, it's at a snail’s pace. I can give you an example. They take a sample in September and then it goes to the mainland or through the continent for testing and then it comes back to Hawaii giving us 30 days before it comes back.

And then there is a confirmation test that's done. So, September to October, November, confirmation test, December, then we have the confirm sample of PFAS being in the water and then the Department of Health will give the public notice that the water is therefore contaminated with PFAS. Without a certified lab on the islands, we cannot have real-time testing and I'm not sure how we can really address that. It costs about $50 to $100 million for a certified lab. And I know with the military, they're all going through PFAS testing, and we seem to be the last in line in order to get our confirmation that we are being poisoned in our water. So please, I'm not sure what can be done, but we do need to have a lab and we need to have the EPA's help on this. Thank you very much.

EPA Response: Compliance samples for numerous other regulated parameters are frequently shipped from Hazard Index to certified drinking water laboratories within the US mainland and these results are reported within adequate timeframes to satisfy reporting requirements. Furthermore, the EPA disagrees with the statement suggesting "real-time testing" methods are currently available for PFAS testing as there are no published reports of such methods that provide immediate results. However, certified laboratories typically provide clients the option to request "quick turn-around" sample processing and reporting, which expedite the delivery of sample analytical results back to the client, effectively addressing the commenter's concerns.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-044907)

In the preamble, EPA refers to other regulations that have been set at the PQL, specifically the phase 1 Volatile Organic Carbon (VOC) rule. We would like to point out that the levels proposed for PFAS are in the ppt range, while the VOC rule includes compounds like Benzene, which has an MCL in the parts per billion range. When dealing with levels of parts per trillion of ubiquitous and widespread chemicals like PFAS, there is significant sensitivity and variability in in analytical capabilities. Additionally, at such small concentrations, any sample container, and the handling and transport of samples, creates the opportunity for contamination as well as other quality control problems.

EPA Response: Regarding commenter concerns for unit concentrations and analytical sensitivity, measurement sensitivity is relative. In other words, the methods approved for compliance monitoring for this NPDWR were developed and demonstrated to meet performance and QC expectations. The method development performance and QC evaluations are conducted as an assessment of method ruggedness, which is demonstrated through testing in multiple types of drinking water matrices, including assessments off-site at other laboratories by other analysts. Therefore, the agency has empirically determined assurances that the methods can perform adequately at the final MCL levels, regardless of unit concentrations.

For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response

in this *Response to Comments* document. Regarding analytical background contamination concerns, please see the section 8.7 of the EPA response in this *Response to Comments* document.

Water Quality Association (WQA) (Doc. #1694, SBC-044989)

Water Testing and Sampling

EPA should consider the risks of inaccurate water sample results when measuring at 4 ppt or below, considering the extensive use of PFAS in everyday products and those used under regular laboratory testing. EPA should refer to knowledgeable, experienced stakeholders on the best methods for water testing in the field and laboratory before and after treatment to help ensure results are accurate and are not compromised by cross-contamination.

Collecting samples for PFAS analysis requires advance planning. Specific shipping times, chilling temperatures, and other precautions must be taken when comparing testing with other contaminants to receive accurate results. It is important to note that normally sample collection, handling, storage, and testing are performed under very controlled laboratory conditions. Performing the same under field conditions as is proposed to be conducted to determine water system compliance will introduce significant challenges in producing reliable data.

EPA Response: Please see section 8.7 of the EPA response in this *Response to Comments* document.

Orange Water and Sewer Authority (OWASA) (Doc. #1524, SBC-042618)

• Laboratory Availability

o Turn around time for sampling – can we get the results back in time to meet the required monitoring and reporting requirements given the current strain on laboratory services

o In addition to regulatory monitoring, utilities will also be tracking PFAS breakthrough in media filters and this will add additional samples and this could impact turnaround time for regulatory sampling as well as impact our ability to track breakthrough in a timely manner.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. The EPA disagrees that large amounts of additional samples in performance monitoring will be required, and the commenter provided no data to support their assertion that this would be necessary. The EPA anticipates that many water systems will conduct a pilot test before implementing a full-scale treatment installation and that the operational results from the pilot test will be a sufficient indicator of performance; therefore, water systems should not have to collect large amounts of performance samples indefinitely during the full-scale operation of treatment technologies.

Please see section 13.3.3 of the EPA response in this *Response to Comments* document for additional details on how these considerations were factored into the EPA's cost estimates.

Missouri Department of Natural Resources (Doc. #1563, SBC-042525)

EPA requests comment on the underlying assumptions that sufficient laboratory capacity will be available with the proposed MCLs; that demand will be sufficiently distributed during rule implementation to allow for laboratory capacity; and on the cost estimates related to these assumptions.

The Department disagrees with many of the underlying assumptions EPA used for determining sufficient laboratory capacity. First, the Department believes that water systems will be incentivized to use labs that have a PQL/MRL no less than the proposed 4.0 ppt MCL, to avoid the potential for a "J Qualified" result to be used in their compliance determinations. This will allow any "J Qualified" result to be reported as a no detect (<4.0 ppt) and a zero would be used in the compliance determination, resulting in a higher likelihood of compliance. Second, labs are not required to report "J Qualified" data. As such, water systems that use a lab with a 4.0 ppt PQL/MRL may not be notified of an unquantified instrument estimated detection below the PQL/MRL. Finally, in addition to utilities "shopping" for labs based on their PQL preference, a capacity issue will develop as other media (e.g., soil, air, and clean water) and other environmental programs (e.g, Clean Water Act, RCRA/CERCLA, Solid Waste, etc.) begin monitoring for PFAS. The Department is already seeing an increase in demand for laboratory services with the beginning of UCMR 5 sampling and, our contract lab having issues with meeting our demand for PFAS sampling as we try to sample systems in our state not sampled under UCMR 5.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenter that water systems will be "incentivized to use labs that have a PQL/MRL no less than the proposed 4.0 ppt MCL, to avoid the potential for a "J Qualified" result to be used in their compliance determinations." The EPA allows water systems to select any certified laboratories that they may choose and acknowledges that laboratories may have different analytical capabilities. EPA notes that any result below 4.0 ppt for PFOA or PFOS would be treated as zero in their RAA compliance calculations. See section 8.2 of the EPA response in this *Response to Comments* document for further discussion. Additionally, as discussed in greater detail in section 8.8 of the EPA response in this *Response to Comments* document on rule trigger levels and in section XIII of the final rule preamble, water systems must demonstrate they are below the final rule trigger levels to be eligible for reduced triennial monitoring (i.e., utilities who only go to labs who can go as low as the MCL will not be eligible for reduced monitoring). Additionally, regarding concerns for laboratory capacity as it relates to other environmental programs and regulations, the commenter provided no verifiable information to support this claim. For instance, the commenter references UCMR 5 as a source

of capacity concern but the agency notes that utilities may be able to use data from UCMR 5 sampling to satisfy initial monitoring requirements in the final NPDWR.

Missouri Department of Natural Resources (Doc. #1563, SBC-042533)

EPA requests comment on other monitoring related considerations including laboratory capacity and QA/ QC of drinking water sampling.

As discussed previously, the Department believes EPA has significantly underestimated the resource needs that will cause lab capacity issues for drinking water sampling when other media and environmental programs begin monitoring at nearly the same time.

EPA Response: Please see the EPA response to comment Doc. #1563, SBC-042525 in section 5.1.2 in this *Response to Comments* document.

Maine Water Utilities Association (MWUA) (Doc. #1567, SBC-042731)

Certified labs have been challenged with analyzing the number of samples that PWS sends them. PWS can wait upwards of three weeks for sample results and then the primacy agencies must perform quality assurance evaluations, which can take several more weeks. Samples are expensive ($250-$350 per sample), with field blanks being run in many cases, thereby doubling the costs. Follow-up confirmatory samples will be needed to validate initial results. MWUA recommends that monitoring should be phased in by system size to reduce the resource burden on the labs and primacy agencies who must review and verify the quality of the data.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding initial monitoring timing, please see section 8.1.1 of the EPA response in this *Response to Comments* document. The agency notes that the EPA accounted for confirmatory samples in the cost analysis supporting the final NPDWR and the Administrator determined at proposal that the benefits of the rule justify its costs. Specifically, for any samples that have a detection, the system will analyze the field reagent blank samples collected at the same time as the monitoring sample. Systems that have an MCL exceedance may collect one additional sample from the relevant entry point to confirm the results (i.e., a confirmation sample), at the discretion of the primacy agency.

San Antonio Water System (SAWS) (Doc. #1570, SBC-042479)

o EPA recognizes most labs will not be able to reach the targets outlined in this proposal. The labs across the country are not ready for this regulation, and many will not be able to test with the accuracy necessary to provide dependable results for the proposed trigger level. The EPA's assumption that labs will reach analytical targets places PWSs in the precarious position of being able to prove compliance.

o EPA supports the proposed trigger level because 49 of the 54 labs who applied for the Laboratory Approval Program for UCMR5 were able to reach a lowest PFAS calibration standard level of 1 ppt or lower. While this may be sufficient for the 3,500 PWSs participating in UCMR5, it is not nearly enough for the nearly 150,000 PWSs in the country that will be required to verify compliance.

o Although the current list of accredited laboratories continues to grow there is concern that there are not enough labs accredited for PFAS to handle the influx of testing. Implementing new methods requires instrumentation, staff, training, and other resources that will take longer than the proposed timelines will allow for compliance.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding trigger levels, please see section 8.8. The EPA notes that this final rule will require monitoring from approximately 67,000 PWSs; not 150,000 PWSs as stated by the commenter. Additionally, the EPA estimates that approximately 10,300 systems will be collecting monitoring data under UCMR 5; not only 3,500 as claimed by the commenter. Finally, the EPA notes that many of the systems that are not required to monitor under the UCMR 5 program are small (<3,300 persons served) groundwater systems. These systems typically have fewer entry points to monitor than larger systems and they only have to monitor each entry point twice over the course of a year during their initial monitoring period, instead of four times per year for larger surface water systems. Hence, while there will be an increase in PFAS monitoring as a result of this rule, it will not be nearly as substantial as implied by the commenter. Please also see sections 8.1.1 and 8.3 of the EPA response in this *Response to Comments* document regarding the rule's initial monitoring requirements and use of previously collected data to satisfy monitoring requirements.

COMM Water Department (Doc. #1577, SBC-042438)

EPA needs to address laboratory capacity issues before finalizing the rule. Certified labs have been challenged with analyzing the number of samples that Massachusetts PWS send them. PWS can wait upwards of three weeks for sample results and then our primacy agency, MassDEP, must perform quality assurance evaluations, which can take several more weeks. EPA should do as Massachusetts did, and phase in monitoring by PWS size to reduce the resource burden on the labs and primacy agencies who must review and verify the quality of the data.

EPA Response: Please see the EPA response to comment Doc. #1567, SBC-042731 in section 5.1.2 in this *Response to Comments* document.

San Gabriel Valley Water Association (SGVWA) (Doc. #1580, SBC-042415)

May 25, 2023

Dr. Jennifer L. McLain

Director Office of Ground Water and Drinking Water

U.S. Environmental Protection Agency

1201 Constitution Ave NW Washington, DC 20004

Re: Docket ID No. EPA-HQ-OW-2022-0114

Dear Dr. McLain:

The San Gabriel Valley Water Association (SGVWA) represents municipal utilities, regulated utilities, special districts, and not-for-profit mutual water companies that supply water to nearly two million residents in the San Gabriel Valley of Los Angeles County, California. In response to the Environmental Protection Agency's request for public comment, the SGVWA is submitting this letter outlining the factors that must be addressed before the final adoption of the proposed per- and polyfluoroalkyl substances (PFAS) National Primary Drinking Water Regulations (NPDWR).

The SGVWA acknowledges that the proposed PFAS NPDWR does not mandate any actions until the four parts-per-trillion (4ppt) Maximum Contaminant Level (MCL) is approved or revised. However, the SGVWA is concerned about ensuring that the San Gabriel Valley water systems can comply with the final regulations. Several important factors negatively impact the economic feasibility of the proposed MCL for PFAS. Specifically, the proposed MCL presents significant challenges for water suppliers in the San Gabriel Valley in the following ways:

1. Transitions in the Laboratory Industry: The proposed standards for detecting and reporting PFOA and PFOS are very close to the limit. States will be responsible for certifying labs to ensure accurate compliance monitoring results. However, the initial monitoring requirements for over 70,000 systems conducting quarterly monitoring may exceed available lab capacity. In California, new accreditation requirements have caused a 25% decrease in public labs in the past two years, and commercial labs cannot meet the increased demand. As a result, the consolidation of California's laboratory industry has raised costs and limited access to water suppliers. Additionally, special procedures for collecting samples at such levels increase the risk of inaccurate results for certain volatile PFAS.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Association of State and Territorial Solid Waste Management Officials (ASTSWMO) (Doc. #1583, SBC-042401)

Analytical Laboratory Capacity: ASTSWMO anticipates an increase in sampling and analysis, warranting the need for sufficient analytical laboratory capacity to not only address the needs of the public water suppliers regulated under the SDWA, but also the needs of site discovery and cleanup programs managed under CERCLA, RCRA, and the States' cleanup programs, among

others. ASTSWMO recommends further communication between EPA and certified state and commercial laboratories to ensure that capacity issues do not impact PFAS analysis and site remediation.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Pennsylvania Chamber of Business and Industry (Doc. #1592, SBC-042794)

2. There Are Significant Laboratory Testing Constraints

There is a dearth of laboratory testing capacity to handle the volume of water and soil testing that will be needed for industries across the state and country to evaluate compliance with respect to PFAS.

EPA Response: Please see section 5.1.2 of the EPA response in this *Response to Comments* document for further discussion about laboratory capacity.

Michigan Department of Environment, Great Lakes, and Energy (EGLE) Drinking Water and Environmental Health Division (DWEHD) (Doc. #1597, SBC-042973)

It is the experience of EGLE DWEHD that laboratory capacity has been sufficient for Michigan's needs. Based on projected sampling under the proposed NPDWR, this would remain true even in a case where our state must rely solely on State of Michigan Laboratory capacity. However, this resource may not be available for all states and should be considered during rule development.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Lehigh County Authority (LCA) (Doc. #1600, SBC-042819)

Compliance & Implementation Challenges

There are several challenges that utilities like LCA will face in achieving compliance with this proposed rule, if approved as written.

1. Laboratory Capacity – Currently, there are only three commercial laboratories in Pennsylvania accredited to analyze drinking water via method EPA 533 or 537.1. While additional laboratories will certainly achieve accreditation in time, there will be a strain on the available laboratories to serve more than 9,000 public drinking water systems in Pennsylvania. Without ample laboratory capacity, water systems will have difficulty proactively preparing for and complying with the proposed regulation. In addition, not every laboratory that is accredited for methods EPA 533 or

537.1 will have the capability to reliably report PFAS results at levels less than the PQL. This will place additional strain on those selected labs that can report at lower levels, as many systems will be seeking the opportunity to achieve reduced monitoring.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding trigger levels for reduced monitoring, please see section 8.8 of the EPA response in this *Response to Comments* document.

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-042881)

Certified labs have been challenged with analyzing the number of samples that Massachusetts PWS send them. PWS can wait upwards of three weeks for sample results and then MassDEP must perform quality assurance evaluations, which can take several more weeks. Samples are expensive ($250-$350 per sample), with field blanks being run in most cases, thereby doubling the costs. Follow-up confirmatory samples will be needed to validate initial results. MWWA recommends that, as Massachusetts did, monitoring should be phased-in by system size to reduce the resource burden on the labs and primacy agencies who must review and verify the quality of the data. Nationwide laboratory capacity to perform the increased analysis also needs to be evaluated and additional laboratories will need to be approved and certified.

EPA Response: Please see the EPA response to comment Doc. #1567, SBC-042731 in section 5.1.2 in this *Response to Comments* document.

Town of Lincoln Water Department (Doc. #1613, SBC-043026)

EPA needs to address laboratory capacity issues before finalizing the rule. Certified labs have been challenged with analyzing the number of samples that Massachusetts PWS send them. PWS can wait upwards of three weeks for sample results and then our primacy agency, MassDEP, must perform quality assurance evaluations, which can take several more weeks. EPA should do as Massachusetts did, and phase in monitoring by PWS size to reduce the resource burden on the labs and primacy agencies who must review and verify the quality of the data.

EPA Response: Please see the EPA response to comment Doc. #1567, SBC-042731 in section 5.1.2 in this *Response to Comments* document.

Oklahoma Department of Environmental Quality (DEQ) (Doc. #1616, SBC-043042)

Based on the relatively low number of UMCR5 approved laboratories, laboratory capacity will be an issue when monitoring requirements are rolled out. To date no survey has been completed to determine how many samples each of these labs could accept for this complex testing. In addition, UCMR5 labs may not have the ability (instrumentation and staffing) to test non-drinking water matrices for PFOS/PFAS.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Furthermore, as discussed in section 5.1.2 of the EPA response in this *Response to Comments* document, the EPA notes that "test[ing] non-drinking water matrices for PFOS/PFAS" are out of scope of this rulemaking.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044042)

23. EPA requests comment on other monitoring related considerations including laboratory capacity and QA/QC of drinking water sampling.

a. Turnaround times (TAT) for PFAS may be upwards of 2 months per sample, during normal times. With increased sampling nationwide, these times may be longer. These long TAT do not help utilities make treatment process modifications. Laboratories are also experiencing issues getting analytical reagents and instrument parts. We need more companies making standard reference materials. In addition to the trained employees needed to run these complex analyses. Contract labs are not consistently fulfilling their contractual obligations, and may not have reliable capacity or staff. EPA also needs to consider lab certification timeframes for new instruments or facilities.

b. EPA also should require any PFAS results due by 10th of month after results received (not after sampling). And realize that there may not be enough time to resample within the monitoring timeframe with these long of TAT.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Please see section 9.6 of the EPA response in this *Response to Comments* document for laboratory certification considerations.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044029)

11. EPA requests comment on the underlying assumptions that sufficient laboratory capacity will be available with the proposed MCLs; that demand will be sufficiently distributed during rule implementation to allow for laboratory capacity; and on the cost estimates related to these assumptions.

a. Lab capacity (along with reagent and labor availability) is a concern due to volume of samples nationwide. Not only for compliance and standard monitoring samples, but the multitude of additional sampling for plants undergoing pilot studies or new treatments will be doing as well. There will be significant difficulties with the enormous amounts of samples that will be required to be analyzed. We anticipate there will be continued and worsening lab backups. And if the utility wishes to perform the analyses in-house, there are huge costs for instruments, reagents,

and certification processes, as well as the uncertainty of availability of qualified lab analysts. A higher MCL could contribute to less systems being required to continuously or more frequently monitor.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043066)

Laboratory Capacity is Lagging Behind Demand

As noted above, more than 67,000 water systems will be driven to comply with the initial monitoring requirements to determine their PFAS levels. Given the timeline of the rule, water systems that may not leverage previously collected PFAS sampling data, will need to perform initial monitoring during the 12-months immediately following the rule's promulgation. The result of this surge in water monitoring sampling will require laboratories to process more than 220,000 water samples collected by these systems.

This is in addition to ongoing monitoring activities by the water sector that include compliance monitoring for systems subject to state drinking water standards, performance testing by systems with treatment facilities, and samples to support pilot testing by systems investigating and designing new treatment facilities. This is also in addition to sampling being performed outside of the water sector for environmental investigations and the implementation of recent actions for effluent discharges, which will rely on the same laboratories. By comparison, approximately 20,000 water samples will be processed annually as part of the UCMR 5 program.

Over the past few years, the demand for the analysis of samples has continued to grow and has outpaced the increase in laboratory capacity. Water systems are currently reporting sampling challenges including longer processing and turnaround times, higher analytical costs, and lower reporting reliability. The surge of sampling activity, especially with an emphasis on lower reporting levels, will further strain the existing laboratory capacity.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenter that water systems will be required to perform initial monitoring in the 12 months following rule promulgation as this is incorrect and water systems will instead have 3 years to complete the final rule's initial monitoring requirements (please see section 8.1.1 of the EPA response in this *Response to Comments* document.). See also section 12.1 of the EPA response in this *Response to Comments* document regarding the two-year capital extension granted by EPA in the final rulemaking. Additionally, the EPA disagrees with the commenters' sampling estimates which are based in the incorrect assumption that all water systems subject to the rule's monitoring requirements will be required to conduct new initial monitoring sampling

or that they will be required to collect quarterly samples. Moreover, many water systems will be eligible to utilize previously collected data to satisfy some or all of these requirements and small groundwater systems serving 10,000 or fewer, which accounts for approximately 80 percent of the systems subject to the final rule monitoring requirements, will only be required to collect two initial monitoring samples. Please see sections 8.1.1 and 8.3 of the EPA response in this *Response to Comments* document regarding the rule's initial monitoring requirements and use of previously collected data to satisfy these monitoring requirements.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-044893)

DEP also notes that this estimated expenditure would be sufficient to add capacity for approximately 20 samples per week, at a maximum, using a manual extraction system. An automated extraction system could potentially increase this to up to approximately 40 samples per week but would add approximately $40,000 to the above cost estimates. Given the significant costs, it is not a given that more laboratories will seek to become accredited to add capacity for more samples.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For further discussion on the EPA's cost estimates as it relates to monitoring, please see section 13.3.4 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044064)

4. ASDWA recommends that EPA address anticipated laboratory capacity issues ahead of the final NPDWR. States continue to stress that the proposed rule will impact laboratory capacity. The number of laboratories that will be capable of sampling for PFAS in time to meet the new rule compliance demands is still uncertain. The number of samples that water systems will need to be analyzed will likely exceed laboratory capacity for all laboratories and each laboratory individually. ASDWA recommends that EPA further demonstrate the estimated sample demand and current national laboratory capacity to address this feasibility concern.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044087)

Laboratories have competing demands to analyze PFAS in other environmental media and, at the same time, meet other new and existing drinking water regulatory needs. PFAS detections in drinking water cause primacy agencies to launch investigations to find the source of the PFAS and other potential impacts, which typically include conducting sampling for surface water and

soils and nearby private wells. The LCRR and the future Lead and Copper Rule Improvements will likely create additional demands on laboratories, particularly if a significant number of systems will need to re-start initial monitoring based on revised compliance sampling locations. These revisions would significantly increase the number of lead and copper compliance samples.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. As discussed in the EPA response in section 5.1.2 of this *Response to Comments* document, there is sufficient laboratory capacity to the meet the compliance requirements of the PFAS NPDWR. Please also see section 12.1 of the EPA response in this *Response to Comments* document for a discussion on exemptions and extensions.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044084)

Laboratory Capacity

ASDWA recommends EPA stagger the initial monitoring requirements based on system size to help address anticipated laboratory capacity issues.

Despite EPA's assurance that laboratory capacity will not be a problem, laboratory capacity will clearly be impacted by several factors:

• Water systems will continue to test under the Fifth Unregulated Contaminant Monitoring Rule in 2024 and 2025;

• The time it takes to get a laboratory certified for PFAS methods;

• The number of laboratories that are currently capable of analyzing for PFAS and being able to manage the volume of samples;

• The method requirements for temperature and timeframes for laboratories to store and

• The competing demands for laboratories to analyze PFAS in other environmental media, while at the same time meeting other new and existing drinking water regulatory needs.

The additional time for more laboratories to get certified and prepare to analyze PFAS samples for the rule will impact laboratory capacity. Laboratories will need to purchase new equipment and instruments, set up, test, and validate the equipment, and hire new staff as part of this process. These needs will also impact the ability to get additional state laboratories certified and ready to analyze for PFAS because of inadequate funding. Laboratory capacity for analyzing PFAS in drinking water using EPA Methods 533 and 537.1 will also be impacted by laboratories concurrently getting ready to use EPA Method 1633 for analyzing PFAS in surface water, fish tissue, biosolids, and soils.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please

see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding initial monitoring requirements and timing, please see section 8.1.1 of the EPA response in this *Response to Comments* document.

Texas Commission on Environmental Quality (TCEQ) (Doc. #1632, SBC-044132)

Sampling Costs and Laboratory Capacity

The lack of laboratory capacity and increased sampling costs may limit rule implementation. TCEQ recommends EPA address anticipated laboratory capacity shortfalls and the cost of sampling ahead of the rule becoming final. TCEQ expects, within the first 12-month monitoring period, about 22,000 samples will be collected in Texas with an estimated $3 million in collection costs. The associated sample analysis cost for Texas' initial monitoring cycle is estimated to be another $7 million. These costs create an additional funding obstacle for TCEQ and Texas' public water systems to collect and analyze associated samples across the state.

Currently, only two Texas laboratories are approved by EPA to perform UCMR5 analysis for PFAS in drinking water samples. These two laboratories will not have sufficient capacity to analyze Texas' 22,000 samples. To gain more capacity, laboratories will need to invest time to acquire new equipment or infrastructure, hire and train staff, become approved for PFAS methods, and address ongoing supply chain and shipping delays. Capacity will be further impacted by the continued demand to perform analysis under UCMR5, competing demands to analyze PFAS in other media, and the need to meet method requirements for time and temperature.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For further discussion on the EPA's cost estimates as it relates to monitoring, please see section 13.3.4.

Association of Environmental Authorities (AEA) (Doc. #1635, SBC-042964)

Laboratory services are certain to be in much higher demand as a result of adopting the NPWDR. Like NACWA, we are concerned that laboratories will struggle to meet that increase in demand for their services. This has implications for the ability of utilities to comply with regulatory deadlines and for the cost of the laboratory services themselves.

EPA Response: Regarding responses regarding laboratory testing and potential contamination issues, please see section 8.7 of the EPA response in this *Response to Comments* document. For further discussion on the EPA's cost estimates as it relates to monitoring, please see section 13.3.4 of the EPA response in this *Response to Comments* document.

National Rural Water Association (NRWA) (Doc. #1641, SBC-043271)

• EPA requests comment on the underlying assumptions that sufficient laboratory capacity will be available with the proposed MCLs; that demand will be sufficiently distributed during rule implementation to allow for laboratory capacity; and on the cost estimates related to these assumptions.

Response: As previously stated, NRWA is not confident there will be sufficient laboratory capacity. Many states such as Kentucky do not have any certified laboratories. This will cause significant compliance challenges.

EPA Response: Regarding responses regarding laboratory testing and potential contamination issues, please see section 8.7 of the EPA response in this *Response to Comments* document. The EPA notes that states without in-state, certified laboratory services can seek those services in nearby states. Many PWSs use out-of-state laboratories to run their compliance monitoring so as long as the lab has a certification from that state. Many commercial laboratories have certifications from a number of states, either received directly or through reciprocity. Kentucky, for example, can start the process of certifying in-state labs after the NPDWR is promulgated and is adopted by the state.

American Farm Bureau Federation et al. (Doc. #1642, SBC-043493)

Testing: The availability of testing is a significant concern for all drinking water utilities—both big and small. We are already experiencing a shortage of testing laboratories, and this will only be exacerbated once these national MCLs go into effect. Water utilities already required to comply with state issued drinking water standards are experiencing long delays in getting results back from laboratories. According to the AWWA, there are 66 laboratories that are available nationwide for PFAS testing. Currently, these labs test between 20,000-25,000 samples annually. The initial monitoring requirements of this rule will trigger testing requirements on up to 66,560 systems. It is estimated that over a three-year period, 280,000 (plus) samples will need to be tested to determine initial status, sampling for piloting and performance testing. There is simply no way that the current laboratory network is equipped to deal with this amount of testing.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Savannah River Nuclear Solutions LLC (Doc. #1647, SBC-043328)

Additionally, there are still concerns with laboratory capacity in some areas of the country, especially since these laboratories will also be needed to verify the results of engineering and pilot- testing, in addition to routine monitoring. This could cause delays in analysis and increase costs to obtain compliance data.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

GFL Environmental (Doc. #1648, SBC-043220)

Laboratories are already at or beyond capacity for PFAS analysis, with standard turn-around times typically measured in months. With the proposed quarterly system monitoring requirements and other regulatory drivers for PFAS sampling (e.g., products, environmental media), national capacity for PFAS testing already falls well short of demand and the gap is only expected to grow. EPA has itself noted in the NPDWR proposal that they anticipate potential laboratory capacity and supply chain issues. Before its implementation, EPA must ensure that adequate national laboratory capacity exists to meet the demands of the rule.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

J.R. Simplot Company (Doc. #1661, SBC-044150)

Laboratory Certification

EPA requires that:

"Analyses under this section for regulated PFAS must be conducted by laboratories that have received certification by the State."

There are only a limited number of laboratories that are currently certified for EPA methods 533 and 537.1, which will make it difficult for these laboratories to have adequate capacity to provide analytical services for the monitoring requirements of PFAS NPDWR.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Water Supply District of Acton (Doc. #1662, SBC-043661)

EPA must address laboratory capacity issues before finalizing the rule. Certified labs have been challenged with analyzing the number of samples that Massachusetts PWS send them. PWS can wait upwards of three weeks for sample results and then our primacy agency, MassDEP, must perform quality assurance evaluations, which can take several more weeks.

EPA Response: Please see the EPA response to comment Doc. #1567, SBC-042731 in section 5.1.2 in this *Response to Comments* document.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044413)

Page 18730. Section VI – Maximum Contaminant Level

Page 18730. EPA requests comment on the underlying assumptions that sufficient laboratory capacity will be available with the proposed MCLs; that demand will be sufficiently distributed during rule implementation to allow for laboratory capacity; and on the cost estimates related to these assumptions.

• The 4.0 ng/L MCL/PQL should be high enough not to affect laboratory capacity. These proposed monitoring requirements and those already implemented by some states have helped create a new market for laboratories. In the proposed regulations, the overwhelming majority of UCMR 5 laboratory applicants had limits of quantitation (LOQ's) that were lower than 4.0 ng/L.

• The volume of samples required for quarterly monitoring may create laboratory capacity issues even as more laboratories are accredited for PFAS analysis. The preliminary testing in Washington has shown approximately 20 percent of sources have detections above 5 ppt. Using 1.3 ppt as the trigger will likely increase the number of water systems with detections required to monitor quarterly with no reduced monitoring options. Laboratories are already experiencing problems hiring and maintaining qualified staff.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding the rule trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044394)

Please consider short- and long-term solutions for insufficient laboratory capability and capacity. This rule could cause laboratories to be overburdened when the rule becomes effective and initial monitoring requirements trigger quarterly monitoring.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding initial and compliance monitoring requirements, please see section 8.1.1 and 8.1.2 of the EPA response in this *Response to Comments* document.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044424)

Given turnaround times for laboratories and lack of certified laboratories in Washington state, we are concerned that laboratory capacity may not match demand after implementation of this rule.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For concerns regarding in-state laboratory services, please see the EPA response to comment Doc. #1641, SBC-043271 in section 5.1.2 in this *Response to Comments* document.

City of Allentown and Lehigh County Authority (LCA), Pennsylvania (Doc. #1667, SBC-043680)

Compliance & Implementation Challenges: There are several challenges that utilities like our operator, LCA will face in achieving compliance with this proposed rule, if approved as written.

1. Laboratory Capacity – Currently, there are only three commercial laboratories in Pennsylvania accredited to analyze drinking water via method EPA 533 or 537.1. While additional laboratories will certainly achieve accreditation in time, there will be a strain on the available laboratories to serve more than 9,000 public drinking water systems in Pennsylvania. Without ample laboratory capacity, water systems will have difficulty proactively preparing for and complying with the proposed regulation. In addition, not every laboratory that is accredited for methods EPA 533 or 537.1 will have the capability to reliably report PFAS results at levels less than the PQL. This will place additional strain on those selected labs that can report at lower levels, as many systems will be seeking the opportunity to achieve reduced monitoring.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding rule trigger levels for reduced compliance monitoring, please see section 8.8 of the EPA response in this *Response to Comments* document.

City of Hillsboro, Oregon (Doc. #1668, SBC-043118)

May 30, 2023

Michael S. Regan Administrator

U.S. Environmental Protection Agency 1200 Pennsylvania Ave, NW Washington, DC 20460

RE: National Primary Drinking Water Regulations: Per- and Polyfluoroalkyl Substances Proposed Rule (Docket ID: EPA-HQ-OW-2022-0114)

Dear Mr. Regan,

The City of Hillsboro Water Department (Hillsboro Water) shares the Environmental Protection Agency's (EPA's) commitment to using and advancing the best available science to tackle per- and polyfluoroalkyl substances (PFAS) pollution, protect public health, and harmonize policies that strengthen public health protections to deliver safe drinking water. Hillsboro Water manages four public water systems: Hillsboro, Butternut Creek, Cherry Grove, and the Joint Water

Commission (JWC). Four agencies share ownership in the JWC including the Cities of Hillsboro, Forest Grove, and Beaverton and the Tualatin Valley Water District (TVWD). The JWC is the primary drinking water supplier in Washington County, Oregon, and is responsible for treating, transmitting, and storing potable water for approximately 400,000 customers. It is within this context that reflects the Hillsboro Water's comments and concerns as they pertain to the proposed National Primary Drinking Water Regulation (NPDWR) for PFAS.

Hillsboro Water supports the overall goals of the proposed NPDWR for PFAS, however, in its current form there are concerns for water utilities that should be addressed:

1. Sampling and Reporting

Hillsboro Water has concerns about the number of accredited laboratories that can reliably test for PFAS under the approved methods (EPA Methods 533 and 537.1) given the 70,000 utilities that will be triggered into sampling through the proposed NPDWR. Moreover, staff availability of these laboratories as well as a laboratory's ability to report results within the compliance monitoring period are added concerns given these strains. In addition to the regulatory monitoring, many utilities will voluntarily monitor more frequently to track PFAS breakthrough in media filters. These investigative samples are necessary for properly managing a water system's treatment efficacy but will greatly increase the already heightened demand on laboratories.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding concerns for voluntary sampling to monitoring treatment performance (i.e., performance monitoring), the EPA anticipates that many water systems will conduct a pilot test before implementing a full-scale treatment installation and that the operational results from the pilot test will be a sufficient indicator of performance; therefore, water systems should not have to collect large amounts of performance samples indefinitely during the full-scale operation of treatment technologies. Please see section 13.3.3 of the EPA response in this *Response to Comments* document for additional details on how these considerations were factored into the EPA's cost estimates.

<u>Aurora Water, City of Aurora, Colorado (Doc. #1669, SBC-043716)</u>

Aurora Water is concerned with the availability of laboratory capacity for analyzing PFAS samples. There will be about 67,000 water systems that will need to complete the initial monitoring period. For a conservative estimate if all these systems are sampling on a quarterly monitoring schedule that would result in 280,000 samples being sent to labs for analysis of PFAS all within a 1–3-year time period. This does not consider pilot testing, continued monitoring or anything outside of baseline testing. In comparison, the UCMR 5 sampling requirement led to 40,000 samples across 3 years to be analyzed. During this time, Aurora Water experienced an average of a 2-month turnaround time for those sampling results. This is unacceptable for

gaining any useful information with respect to optimizing treatment or protection of public health.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding voluntary sampling to monitoring treatment performance (i.e., performance monitoring), the EPA anticipates that many water systems will conduct a pilot test before implementing a full-scale treatment installation and that the operational results from the pilot test will be a sufficient indicator of performance; therefore, water systems should not have to collect large amounts of performance samples indefinitely during the full-scale operation of treatment technologies. Please see sections 13.3.3 of the EPA response in this *Response to Comments* document for additional details on how these considerations were factored into the EPA's cost estimates. Further, the EPA disagrees with the commenters' sampling estimates which are based in the incorrect assumption that all water systems subject to the rule's monitoring requirements will be required to conduct new initial monitoring sampling or that they will be required to collect quarterly samples. Moreover, many water systems will be eligible to utilize previously collected data to satisfy some or all of these requirements and small groundwater systems serving 10,000 or fewer, which accounts for approximately 80 percent of the systems subject to the final rule monitoring requirements, will only be required to collect two initial monitoring samples. Please see sections 8.1.1 and 8.3 of the EPA response in this *Response to Comments* document regarding the rule's initial monitoring requirements and use of previously collected data to satisfy these monitoring requirements.

California Association of Mutual Water Companies (Doc. #1676, SBC-043777)

3. Implementation Challenges – Lab Capacity

CalMutuals is concerned about implementation challenges that will impact small systems particularly hard. The initial monitoring requirements for over 70,000 systems to conduct quarterly monitoring will likely exceed available lab capacity. In California, due to new accreditation requirements, the number of public labs has shrunk by 25% in the past two years, and commercial labs cannot meet the demands. As a matter of supply and demand, rising lab fees will place additional financial burdens that will be hard for small systems to absorb.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

City of Vancouver Water Utility, Vancouver, WA (Doc. #1684, SBC-044312)

Furthermore, laboratories are already experiencing problems hiring and maintaining qualified staff.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

American Council of Independent Laboratories (ACIL) (Doc. #1692, SBC-044743)

6. Available Analytical Capacity

One issue that has been raised concerns the availability of the necessary analytical and field sampling capacity needed to implement the proposed rule. On behalf of the commercial environmental testing community, ACIL wants to assure the Agency that we do not expect laboratory capacity to be an ongoing concern.

EPA Response: The EPA acknowledges the comment regarding feasibility of the final standards as it relates to laboratory capacity.

California Farm Bureau Federation (Doc. #1704, SBC-045076)

Testing

Testing availability is a significant concern for all drinking water utilities regardless of size. National implementation of additional MCLs will further compound the shortage. Many water utilities are already having to comply with state issued drinking water standards and are experiencing long delays in getting results back from laboratories. According to the AWWA, there are 66 laboratories that are available nationwide for PFAS testing. Currently, these labs test between 20,000-25,000 samples annually. Should the proposed rule be finalized, initial monitoring requirements will trigger testing requirements on up to 66,560 systems. It is estimated that over a three-year period, upwards of 280,000 samples will need to be tested to determine initial status, sampling for piloting, and performance testing. We believe that testing availability presents a significant hurdle and EPA must develop a plan. Additionally, while there may be an opportunity for large facilities to create an in-house testing method, that will not be a universal option for smaller operations.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenters' sampling estimates which are based on the incorrect assumption that all water systems subject to the rule's monitoring requirements will be required to conduct new initial monitoring sampling or that they will be required to collect quarterly samples. Moreover, many water systems will be eligible to utilize previously collected data to satisfy some or all of these requirements and small groundwater systems serving 10,000 or fewer, which accounts for approximately 80 percent of the systems subject to the final rule monitoring requirements, will only be required to collect two initial monitoring samples. Please see sections 8.1.1 and 8.3 of the EPA response in this *Response to Comments* document regarding the rule's

initial monitoring requirements and use of previously collected data to satisfy these monitoring requirements.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045100)

5) Laboratory Capacity

In 2019 when Vermont was implementing its legislation and requiring systems to sample, other neighboring states were doing the same thing. We were required to reject multiple samples due to exceeded hold times at the laboratory. Unfortunately, many of the reports came to us with what appeared to be valid results, despite missing the respective hold time or both hold times for sample preservation or method run times, so it was up to program staff to wade through all reports (each 30-70 pages in length) prior to accepting the data. This was with just 3-4 local states vying for the same laboratories. While the number of available labs has grown, given national pressure, it is still unlikely that there are sufficient labs to perform the analysis. With additional resources to procure and retrofit analytic equipment and provide necessary training for analysts this could be more feasible. As discussed above, when considering the aspect of the need for well-trained, experienced analysts running the sample analysis, it will take time to grow that capacity to report out below 4 ppt. Also, regulating to the PQL is problematic for 25% of the labs in the country, as is discussed in the preamble where 75% of the labs can achieve 95% confidence; that means that 25% cannot.

Under 537.1 a field reagent blank is required for quality control. In Vermont we have required this blank. In our experience with busy labs and limited equipment, it can be difficult to meet hold times. Labs initially had intended to wait to analyze the field reagent blank until after the compliance sample was analyzed and then run the blank if there was a need from a quality control standpoint. The problem with this is that they were barely making hold times for the compliance sample, and once it went through validation/QC itself, it was too late to run the field reagent blank. To address this, the labs started analyzing the field reagent blanks at the same time as the compliance samples, doubling the cost to the water system. So, either the lab doubles the cost to the water system or they produce invalid samples, neither is system-friendly. As the need for samples goes up nationwide, it would be expected that the labs simply cannot accommodate the needs. The $1 million needed to get, retrofit, and implement equipment and then several month timeframe, at least, for procurement, installation, training and validating of equipment does not mean that a lab can simply add new staff and be able to accommodate more analysis. There need to be more laboratories and resources to provide this analysis nation-wide.

When applying for primacy, it states in 142.16 (i) that the initial monitoring plan must describe how systems will be scheduled during the initial monitoring period and demonstrate that the analytical workload on certified laboratories has been taken into account. In Vermont this would mean one staff tasked with the “Phase II/V” regulations would need to drop everything else to set schedules for nearly 600 systems, who already have at least 2 data points, if not 3 based on state-required sampling, and re-set monitoring schedules. This is a very large burden and would

require additional state resources. There are no labs within Vermont at this time who can perform PFAS analysis, so any assessment on lab capacity and lab feasibility is outside of our control and would be difficult to provide to EPA as part of the primacy application. If there were in-state capacity, it would be easier to forecast, but there would not be a mandate that systems would need to use the State lab, and for any one of several reasons, such as cost or logistics, systems may elect to not use the State laboratory.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please also see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding the circumstance described by the commenter regarding sample preservation times, the EPA notes that the six PFAS regulated by the NPDWR can be analyzed by either Method 533 or 537.1 and neither method has inherent QC issues when appropriately followed. For EPA Method 533, laboratories have 28 days to hold the sample prior to extraction, and then another 28 days to hold the extract before analysis. For EPA Method 537.1, laboratories have 14 days to hold the sample prior to extraction, and then another 28 days to hold the extract before analysis. This means laboratories have 56 and 42 days, respectively, to analyze samples that they receive. Based on the application of these methods for the UCMR 5 Program, it has been shown that the vast majority of laboratories approved for the UCMR 5 Program can meet these hold times. Any labs that were unable to consistently meet hold times were evaluated for inefficiencies in their sample processing and addressed on a case-by-case basis. The EPA also disagrees with the commenter claims' that "25% [of labs] cannot" meet the PQL; as discussed in the final rule preamble, the PQL reflects a minimum quantitation level that "with 95 percent confidence, can be achieved by capable analysts at 75 percent *or more* of the laboratories using a specified analytical method" (emphasis added). Greater than 75 percent of labs requesting participation in UCMR 5 were able to meet the PQLs/MRLs, and EPA anticipates the number of labs available for compliance monitoring to grow (see section 5.1.2 of the EPA response in this *Response to Comments* document). Regarding rule primacy requirements, please section 11.1 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. The EPA also notes that the use of pre-existing data, as the commentor discusses, can be used to meet the initial monitoring requirements and is discussed in section 8.3 of the EPA response in this *Response to Comments* document. See also section 13.3.1 of the EPA response in this *Response to Comments* document a discussion concerning primacy agency costs (including regulatory start-up).

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045107)

8) Monitoring related concerns including lab capacity and Qa/Qc of sample results

As has been discussed elsewhere in these comments, we have significant concerns about lab capacity. Vermont does not have a lab capable of providing PFAS analysis within the state, so samples must be sent out for analysis and thereby compete with neighboring states or nation-wide for laboratory capacity. When many New England states were implementing PFAS standards several years ago, there were several issues with laboratories not being able to meet hold times. Additionally, the equipment is so specialized and expensive that they often do not have redundancy or backup; if the sole piece of equipment goes down, it could seriously impact hold times and sample analysis. As we attempt to get analytic equipment and personnel in-state to perform the analysis, the time it takes to retrofit equipment, train staff, and receive necessary accreditation is not insignificant. We experienced situations where slight differences in the volume of water provided in the sample bottle dictated changes in the method reporting level, making it possible to drive up the reporting level by insufficiently filling the bottle.

EPA Response: Please see the EPA response to comment Doc. #1708, SBC-045100 in section 5.1.2 in this *Response to Comments* document.

Protecting Our Water, Environment, and Ratepayers (POWER) (Doc. #1714, SBC-045938)

Based on the information provided, it is unclear that the number of EPA certified water quality laboratories is sufficient to test the samples as required by the rule.

In the proposed rule, EPA states that there are 54 labs across the United States that submitted applications for EPA approval to analyze PFOA and PFOS to quantification limits of 4.0 ppt pursuant to EPA Analytical Method 533 and 537.1. [FN20: Proposed Rule, 88 Fed. Reg. at 18667.] Additionally, the proposed rule requires that large groundwater systems serving more than 10,0000 people and all surface water systems are required to test quarterly. [FN21: Proposed Rule, 88 Fed. Reg. at 18681.]

Methods 533 and 537.1 require testing of a large number of samples. Besides the field reagent blank sample, both Method 533 and 537.1 require a minimum of one Field Duplicate sample and if this is not possible, one Laboratory Fortified Sample Matrix Duplicate per sample. Given that the extraction batch for both Method 533 and 537.1 is 20 samples, each instrument will be able to analyze samples from 6 water systems a day assuming that there are only 2 samples from each water system. With 148,000 water systems and 54 labs running, each lab is required to have a minimum of 7 instruments running 260 days-a-year to complete the required samples. Although the rule proposes to allow reduced sampling requirements once the initial monitoring results show compliance, it is not clear that there will be sufficient approved lab capacity to meet the heightened testing load and it is also unclear how many water systems will qualify for reduced sampling, given the growing pervasiveness of PFAS in water supplies. At a minimum, EPA

should wait to implement the proposed rule until all required systems provide data under UCMR 5. .

This estimate is conservative and relies on two major assumptions that are likely inaccurate. First, it assumes that the samples are perfectly staggered in a way that would allow the samples to be prepared and ready without any overlap. Second, this assumes that there are only two samples per water system that are measured per day. If either of these two assumptions are improper, then additional labs or instruments would be necessary to handle the additional samples.

For these reasons, it would be premature to finalize the NPDWR without additional analysis and confirmation that there are enough approved labs nationwide to test to the required levels. And once the NPDWR is finalized, it should allow a longer time period for water and wastewater agencies to bring the significant investments online that are required to achieve compliance.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. The EPA disagrees with the commenter on their estimate of the number of systems subject to the rule's monitoring requirements, which is incorrectly cited as 148,000 systems. Instead, there are approximately 67,000 water systems many of which will not be required to conduct new initial monitoring as discussed in sections 8.1.1. and 8.3 of the EPA response in this *Response to Comments* document. For additional discussion on UCMR 5, please see sections 3.1.2 (under Preliminary Regulatory Determinations) and 6.8 (under Occurrence) of the EPA response in this *Response to Comments* document.

HRSD (Doc. #1719, SBC-043544)

Laboratory capacity is already limited and HRSD is experiencing delays in data turnaround of approximately 8 weeks.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045149)

Laboratory capacity

MassDEP believes that tripling the number of PWSs needing laboratory services, as the PFAS NPDWR is expected to do, will likely affect laboratory capacity. MassDEP recommends staggering the initial monitoring requirements across the three years between the effective and compliance dates of the final rule, as was done in the Stage 2 Disinfectants/Disinfection

Byproduct Rule, to avoid overwhelming laboratories. States are obligated, pursuant to 40 CFR § 142.16(e)(2)(i), to include a plan in their primacy applications that addresses scheduling of initial monitoring and "demonstrate[s] that analytical workload on certified laboratories has been taken into account", to identify and/or develop contingencies should capacity issues arise. While it is possible that this NPDWR will encourage more laboratories to establish PFAS analytical capabilities, EPA should work with the states to plan sufficient laboratory capacity until any such increased capacity is established.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. In addition, in response to this comment, to clarify the requirements for obtaining primacy, EPA notes that in the final rule, language has been added to clarify that the requirements of 40 CFR § 142.16(r) apply in lieu of the requirements of 40 CFR § 142.16(e). Finally, as noted in section 11.1 summary, in the final rule, there is no longer a requirement in § 142.16(r) for a monitoring plan that describes when systems will be scheduled to conduct initial monitoring and demonstrating that the analytical workload on certified laboratories has been taken into account. Regarding staggering initial monitoring schedules, see section 8.1.1 of the EPA response in this *Response to Comments* document.

U.S Conference of Mayors, National League of Cities and National Association of Counties (Doc. #1733, SBC-043895)

b. Inadequate Laboratory Capacity

Laboratories across the nation will need to be drastically scaled up in order to manage the surging demand from public water systems as they implement and comply with the proposed regulation. Compliance monitoring is only a small fraction of the number of samples that will need to be collected and analyzed as public water systems that have test samples above the limit will also need to monitor for PFAS while installing and operating treatment techniques.

Therefore, laboratory capacity must be able to not only handle initial compliance monitoring, but also monitoring from public water systems as they continue to operate and treat PFAS.

With such an increase in demand, we have serious concerns regarding laboratory capacity across the nation and the ability for public water systems to receive and process sample results in a timely and cost-efficient manner. Currently, public water systems are reporting wait times of up to three months to receive PFAS sample results. With the Agency's current proposal giving public water systems only three years to comply, water systems will be forced to move as expeditiously as possible, resulting in increased monitoring and longer sample response times than what is already being reported. As laboratories across the nation become overwhelmed, EPA should consider the importance of having reliable, accessible and affordable laboratory capacity as it relates to local governments' capability to work towards compliance.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Michigan Section American Water Works Association (MI-AWWA) (Doc. #1734, SBC-044478)

Finally, there are not sufficient laboratories in Michigan that are designed for this type of testing.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045972)

In the months following the promulgation of the rule, utilities with PFAS near or above the finalized MCLs will start the sprint toward treatment. Pilot studies will need to be conducted to determine the best treatment approach, how the treatment will affect other regulated and non-regulated contaminants, and the total efficacy of the treatment. As the investment in this treatment will be extremely significant, utilities need to be sure they are making the right long-term decision. This will result in many more samples being taken to assess what route a utility should take and what effect this will have on other elements of the treatment process.

Due to the cost compared to the other options and the success of granular activated carbon (GAC) and Ion Exchange (IX) at removing PFAS from drinking water, these will likely be options that many utilities choose. For these treatment techniques, water flows through a media that removes the PFAS from the water, leaving it in the media. While the media remove certain PFAS, media will become spent, requiring replacement or reactivation.

In the proposed rule, EPA estimates PWSs serving over 3,300 people will, at most, sample quarterly for initial and long-term compliance. While that timeline may be what EPA requires to show compliance, it is not the reality for many water systems. Because a water system needs to know how often it needs to replace its media, water systems will have to perform sampling throughout the column or bed to ensure PFAS is still being removed from the water and the media is still performing adequately. This will significantly increase the number of samples water systems have to take and, therefore, get analyzed by a lab. For example, one specific member serving over 2 million people has been consulting on the potential treatment they will need to comply with the rule. This system would have to install concrete 24 gravity contactors – 12 lead and 12 lag – that include four sample ports at different depths to assess GAC performance. This water system's sampling protocol to assess the efficacy of the GAC and switch between lead/lag arrangement would result in (12x4) + 12 = 60 samples per month on average, or 720 samples a year. That is significantly more than the four per year per entry point

required under the rule, is not unique to this singular utility, and is less than other utilities are projecting.

Another PWS, serving almost one million people, indicates that it plans on carrying out biweekly sampling of raw and finished water at all treatment plants for operational control and treatment performance, totaling approximately 415 samples per year. Additional testing for other aspects of treatment, such as developing dosage curves with specific carbon under varying water-quality conditions, carbon-type testing for procurement, and more uses, could result in around 50 more samples a year. Adding these to general compliance sampling, this PWS will have to process about 500 samples a year using EPA methods 537.1 or 533, or in some cases both. A final AMWA member serving around 400,000 people estimates that between UCMR/NPDWR samples, source water investigation (2-3 years), rapid small-scale column tests and pilot (2-3 years), and full-scale treatment applications, it will have to analyze at least 168 samples per year through 2026 at least, with only 8 of those being compliance/UCMR 5 monitoring samples.

EPA states in the proposal that 54 laboratories submitted applications for EPA approval to analyze PFOA and PFOS under UCMR 5. While more labs can become certified in the future once the rule is promulgated, the initial demand for sample analysis will be overwhelming. Using EPA's estimated number of systems, a mean of about 4,300, without factoring in required compliance monitoring, leads to an additional 258,000 samples a month. Split between 54 approved labs, each of them would have to process approximately 4,700 samples a month. Add in UCMR 5 and required monitoring under this proposal for every PWS, and that number increases. This is a back-of-the-envelope calculation, but these are additional strains EPA may not have considered and will be the reality for many water systems trying to get data back in a timely manner. This estimate also does not account for other wastewater and/or biosolids samples that will likely be competing for lab analysis.

Several AMWA members are looking into the creation of an in-house or affiliate lab to avoid the issues they currently or may face with limited lab capacity for PFAS samples. In-house labs are extremely costly to startup and require extensive operational and maintenance costs. Utilities who have explored this option, typically mid- and large-sized utilities, have seen a minimum equipment cost of $0.5 million, $400,000 for analytical instruments, and $100,000 for the autosampler and extraction system. This does not include space procurement, labor, and maintenance costs, which would likely be greater than the equipment cost. Additionally, the certification process can be time-consuming and tedious. Even with high start-up costs, PWSs are still considering it due to the ongoing issues with other labs and concerns about being held non-compliant for actions outside their control.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. Regarding concerns for voluntary sampling to access monitoring treatment

performance (i.e., performance monitoring), the EPA anticipates that many water systems will conduct a pilot test before implementing a full-scale treatment installation and that the operational results from the pilot test will be a sufficient indicator of performance; therefore, water systems should not have to collect large amounts of performance samples indefinitely during the full-scale operation of treatment technologies. Please see section 13.3.3 of the EPA response in this *Response to Comments* document for additional details on how these considerations were factored into the EPA's cost estimates. Further, the commenter states that, "In the proposed rule, EPA estimates PWSs serving over 3,300 people will, at most, sample quarterly for initial and long-term compliance." While the EPA agrees that some water systems will sample quarterly, the agency disagrees with the commenter's estimates and overall intent because both during initial monitoring and compliance monitoring, the majority of systems will not be required to conduct quarterly initial monitoring. The agency is allowing the use of previously collected data to satisfy the initial monitoring requirements and small groundwater systems, which account for approximately 80 percent of the systems subject to the final rule's monitoring requirements, will only be required to collect two samples (assuming they do not have available previously collected data which would further decrease this number of samples). For compliance monitoring, the EPA then anticipates based on national occurrence estimates that many water systems will be eligible for triennial monitoring.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045970)

Section 5.5: Lab capacity

EPA is requesting comment on the underlying assumptions: that sufficient laboratory capacity will be available with the MCLs set at 4.0 ppt; that demand will be sufficiently distributed during rule implementation to allow for laboratory capacity; and on the cost estimates related to these assumptions. AMWA has serious concerns over the ability of certified labs to not only reliably process the number of samples this rule will require, but also to evaluate the number of additional samples water systems will take for their own system evaluation purposes. While EPA has proposed some possible avenues to reduce the number of samples required under this proposed rule, the agency should also consider the number of samples beyond general compliance that will be generated due to the proposal.

AMWA members are currently underway with UCMR 5 sampling. UCMR 5 includes all six PFAS included under this proposed regulation. PWSs are already experiencing issues with getting data back in a timely manner, in addition to increased costs of sampling, sample transport, sample analysis, and even mishaps at labs where samples are thrown out before they can be retested. Many AMWA members rely on one commercial lab for PFAS analysis due to costs, availability, and access. Currently, AMWA members are waiting between one and three months for PFAS sample results. These issues are being seen during implementation of UCMR 5, even before other systems will have to start their initial monitoring.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

San Gabriel Basin Water Quality Authority (WQA) (Doc. #1743, SBC-043613)

3. EPA should evaluate whether there is an adequate number of certified laboratory service providers available to meet the potential increased demand for PFAS testing services. There have been many consolidations among the laboratories, and it appears that some are struggling to keep up with even the existing demand. EPA should also ensure that reliable and consistent results are being achieved at the proposed MCLs among the various laboratories.

WQA appreciates EPA's consideration of these comments. If you need additional information, I can be contacted at 626-338-5555.

Respectfully,

Randy Schoellerman Executive Director

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045218)

2. EPA requests comment on the underlying assumptions that sufficient laboratory capacity will be available with the proposed MCLs; that demand will be sufficiently distributed during rule implementation to allow for laboratory capacity; and on the cost estimates related to these assumptions.

CT DPH agrees that sufficient laboratory capacity will be available with the proposed MCLs, as all laboratories certified by the CT DPH ELCP are calibrating to concentrations less than 4.0 ppt. However, it is outside of the ELCPs scope to determine the capacity capabilities of individual laboratories. Additionally, ELCP cannot determine the capacity that will be needed to accommodate the testing for community and non-transient non-community public water systems in Connecticut. Currently, no instate laboratories are certified for EPA 533 but there are three in-state labs certified for EPA 537.1.

3. EPA requests comment on other monitoring related considerations including laboratory capacity and QA/ QC of drinking water sampling.

Laboratory capacity cannot be fully evaluated because of the change in monitoring requirements stemming from the trigger level.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding rule trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document.

Liberty (Doc. #1747, SBC-043623)

Upon review of the proposed rule, however, we have implementation considerations that should be addressed in order to ensure that industry can fully comply with the rule.

First, based on our experience, existing laboratory resources are not sufficiently available in the U.S. to meet the critical initial monitoring requirements outlined in the draft rule. For example, Liberty is currently engaged in UCMR5 monitoring for about one-third of our water systems. We must often ship samples to other states for processing, and have already experienced failed temperatures upon laboratory receipt despite following cooling protocols, as well as lost shipments. With well over 60,000 water systems that will need to collect initial monitoring samples within the first 12 - 18 months of promulgation, we believe access to laboratories that can provide timely, accurate, and cost-effective processing of these samples will be very challenging, if not impossible to find, for many utilities. EPA noted in the May 4, 2023, Public Hearing that it believes that there would be sufficient approved laboratory resources available to support initial monitoring by the time the regulation came to promulgation. Based on our experience, we respectfully disagree, and believe that the initial proposed monitoring timeline will lead to a tremendous burden on whatever qualified laboratories exist; an increase in processing and handling errors which could invalidate results; and higher prices for utilities, especially at those laboratories able to provide clients with reporting limits below the PQL.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenter that water systems will be required to perform initial monitoring in the 12-18 months following rule promulgation as this is incorrect and water systems will instead have 3 years to complete the final rule's initial monitoring requirements (please see section 8.1.1 of the EPA response in this *Response to Comments* document). Additionally, the EPA disagrees with the commenters' sampling estimates which are based in the incorrect assumption that all water systems subject to the rule's monitoring requirements will be required to conduct new initial monitoring sampling or that they will be required to collect quarterly samples. Moreover, many water systems will be eligible to utilize previously collected data to satisfy some or all of these requirements and small groundwater systems serving 10,000 or fewer, which accounts for approximately 80 percent of the systems subject to the final rule monitoring requirements, will only be required to collect two initial monitoring samples. Please see section 8.1.1 and 8.3 of the EPA response in this *Response to Comments* document regarding the rule's initial monitoring requirements and use of previously collected data to satisfy these monitoring requirements.

Las Cruces Utilities (LCU) (Doc. #1753, SBC-043911)

In response to Section IX-Monitoring and Compliance Requirements, EPA requests comment on other monitoring related considerations including laboratory capacity and QA/QC of drinking water sampling.

• It is likely that sample costs and turnaround times will increase significantly. In New Mexico, there are a limited number of State approved laboratories, so many systems must ship samples to the laboratory, incurring additional cost for proper packaging and shipping.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For further discussion on the EPA's cost estimates as it relates to monitoring, please see section 13.3.4 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045627)

As PFAS occurrence data are required to be collected and used to drive decision-making, there will be higher demand for laboratories that are able to analyze samples with a greater degree of reliability at single digit, part per trillion levels to minimize the risks of inaccurately higher sample results from interferences and other technical challenges. Increased demand for better laboratories will contribute to higher lead times, per sample costs, and more frequent recognition of sample analysis errors. The consequences of these pressures on the analytical services market, will most negatively impact smaller systems with less financial capacity to access more experienced and better performing laboratories. To the degree small systems have limited access to high quality laboratory service, it creates inequitable access to reliable sample analysis.

EPA Response: The commenter did not provide data to support claims that smaller systems will have "inequitable access to reliable sample analysis." For funding concerns, the agency notes that funds are also available through the passage of the IIJA, also referred to as the BIL, to assist many disadvantaged communities, small systems, and others with the costs of installation of treatment when it might otherwise be cost-challenging. Please see section 2.4 of the EPA response in this *Response to Comments* document for more discussion about currently available funding. For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045569)

Laboratory Capacity is Lagging Behind Demand

As noted above, more than 67,000 water systems will be driven to comply with the initial monitoring requirements to determine their PFAS levels. Given the timeline of the rule, as

described in the proposed rule preamble and reflected in the proposed rule text, water systems that may not leverage previously collected PFAS sampling data, will need to perform initial monitoring during the 12-months immediately following the rule's promulgation. The product of this surge in water monitoring sampling will require laboratories to process more than 220,000 water samples being collected by these systems.

This is in addition to ongoing monitoring activities by the water sector that include compliance monitoring for systems subject to state drinking water standards, performance testing by systems with treatment facilities, and samples to support pilot testing by systems investigating and designing new treatment facilities. Examples of sampling programs for testing new treatment facilities are laid out in detail in AWWA's "Drinking Water Treatment Selection Guide for PFAS" (AWWA, 2020a). This is also in addition to sampling being performed outside of the water sector for environmental investigations and the implementation of recent actions for effluent discharges, which will largely rely on the same laboratories (EPA, 2022d; EPA, 2022e). By comparison, approximately 20,000 water samples will be processed annually as part of the UCMR 5 program. Initial monitoring requirements will increase the demand for laboratory capacity by a factor of more than 11.

Over the past few years, the demand for the analysis of samples has continued to grow and has outpaced the increase in laboratory capacity. Water systems are currently reporting sampling challenges like longer processing and turnaround times, higher analytical costs, and less reliable reporting data quality. The surge of sampling activity, especially with an emphasis on lower reporting levels, will further strain the existing laboratory capacity. EPA will therefore create unavoidable compliance risks for public water systems unless it extends the implementation timeline to the maximum extent possible.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 on extensions and exemptions. The EPA disagrees with the commenter that water systems will be required to perform initial monitoring in the 12 months following rule promulgation as this is incorrect and water systems will instead have 3 years to complete the final rule's initial monitoring requirements (please see section 8.1.1 of the EPA response in this *Response to Comments* document.) Additionally, the EPA disagrees with the commenters' sampling estimates which are based in the incorrect assumption that all water systems subject to the rule's monitoring requirements will be required to conduct new initial monitoring sampling or that they will be required to collect quarterly samples. Moreover, many water systems will be eligible to utilize previously collected data to satisfy some or all of these requirements and small groundwater systems serving 10,000 or fewer, which accounts for approximately 80 percent of the systems subject to the final rule monitoring requirements, will only be required to collect two initial monitoring samples. Please see sections 8.1.1 and 8.3 of the EPA response in this

Response to Comments document regarding the rule's initial monitoring requirements and use of previously collected data to satisfy these monitoring requirements.

PFAS Regulatory Coalition (Doc. #1761, SBC-046077)

3. Concerns about laboratory capacity must be adequately considered and addressed.

The Coalition is concerned that there will not be adequate laboratory capacity to accommodate the enormous amount of testing across the country that would be required by the Proposal. Laboratories with PFAS analytical capabilities are already receiving increased demand for NPDES permit compliance testing, as well as for testing for remediation projects. Coalition members are already experiencing delays of six weeks to three months in turnaround times for PFAS analyses. The thousands of additional samples required under the Proposal would only exacerbate this problem. Even as more laboratories try to come on-line and offer PFAS analytical services, it takes time for them to do so and to provide consistent, reliable results. Laboratories are not immune to the challenges that other employers are facing in finding qualified and reliable personnel. EPA needs to fully consider these laboratory capacity concerns before proceeding further with this rulemaking. Without adequate laboratory capacity, attaining and maintaining an MCL is not technically feasible.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Note that EPA Method 533 and EPA Method 537.1 are solely drinking water methods. Any testing conducted for NPDES permit compliance testing would be using different methods than those listed here and may have different analysis time requirements.

U.S. Poultry & Egg Association et al. (Doc. #1765, SBC-044544)

1. EPA has not considered the technical expertise necessary, and costs associated with, collecting and interpreting laboratory analytical results for PFAS.

Compliance with the EPA's proposed MCLs for PFAS requires regulated entities to collect water samples for analysis by an accredited laboratory running Method 537.1: Determination of Selected Per- and Polyfluorinated Alkyl Substances in Drinking Water by Solid Phase Extraction (SPE) and Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS) [FN1:https://cfpub.epa.gov/si/si_public_record_Report.cfm?dirEntryId=343042&Lab=NERL]. EPA has not considered the level of education and training that will be necessary to appropriately collect the water samples and then accurately interpret analytical results from commercial labs. For many of the water suppliers subject to this regulation, this will be the first time they will be engaging with the more sophisticated commercial analytical laboratories. There are currently a limited number of commercial laboratories that are certified by EPA to run this method (see comment below), which causes significant concerns for timelines, hold times, and quality assurance. Moreover, as more commercial laboratories attempt to get NELAP certified,

there will inevitably be a learning curve, with quality assurance and quality control issues. The correct performance of Method 537.1 is technically challenging – and although procedures such as sample hold time, reagents, extraction, and interpretation of chromatograms will be documented by the analytical labs in detailed data packages, it is left up to the water provider to review and interpret the lab's procedures. Therefore, water suppliers will need to have on-staff expertise in the interpretation of Method 537.1 analytical results and in the review and analysis of laboratory quality assurance and data packages.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding training for EPA PFAS drinking water methods analysis, please see section 8.6 of the EPA response in this *Response to Comments* document.

U.S. Poultry & Egg Association et al. (Doc. #1765, SBC-044546)

2. EPA has not appropriately considered the lack of available accredited commercial laboratories capable of running Method 537.1, especially in the southern United States.

There are currently a limited number of commercial laboratories that are certified by the EPA to run this method (see comment below), which causes significant concerns for timelines, hold times, and quality assurance. According to the National Environmental Laboratory Accreditation Management System [FN2: https://lams.nelac-institute.org/SearchResults], there are currently only 49 labs accredited to run Method 537.1. Of those, only seven (7) are located within the southern U.S. While this number is certain to increase with market demand, there will be a significant learning curve and challenges with quality assurance with new labs. As discussed above, the burden to ensure appropriate laboratory quality assurance and quality control and data interpretation is on the water provider. With decision thresholds at the quantitation limit, there is no room for even minor biased high or low results. EPA has not adequately considered the lack of available accredited commercial laboratories capable of running Method 537.1, especially for water providers in the southern U.S. region. This lack of resources will put a significant additional burden on stakeholders located in the southern U.S., which includes some of the most vulnerable communities, and the largest concentration of non-transient, non-community water suppliers.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. The EPA notes there are two drinking water analytical methods approved for the monitoring provisions of this final NDPWR: the EPA Methods 537.1 and 533.

New Mexico Environment Department (NMED) (Doc. #1766, SBC-044255)

Lab Capacity

NMED requests that EPA address lab capacity issues ahead of final regulations including availability of existing labs certified to analyze PFAS and the logistics of sampling and transport in primarily rural states. Additionally, costs for training and certifications of laboratory personnel and sampling personnel, physical facility expansion requirements, and equipment procurements need to be factored into EPA's cost analysis.

The ability of labs to report their results electronically needs to be considered as additional costs will be incurred and resources required.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. In response to primacy agency costs and costs related to monitoring, please see section 13.3 of the EPA response in this *Response to Comments* document. In response to the commenter's recommendation that EPA should include the costs of establishing new laboratories and associated laboratory training costs in the economic analysis for the final rule, please see the EPA response to comment Doc. #1628, SBC-044091 in section 13.3.4 in this *Response to Comments* document. The EPA disagrees that those costs should be estimated and included. The sampling costs EPA included in the cost analysis are derived from a set of current labs and reflect the market price at the time of the survey. New labs entering the market would likely be competing with currently operating labs that have the option to expand their services. Expanding labs will likely lower their unit sample costs given the potential for shared existing overhead like billing platforms/other systems in general, floor space, or trained personnel, therefore potential new labs could not charge significant per sample rates above the current labs in the market. The costs to larger water systems considering creating a new lab would be equal to or less than the market rate charged by commercial labs already in the market.

Western Urban Water Coalition (WUWC) (Doc. #1768, SBC-043947)

B. Laboratory Capacity

WUWC is also concerned that EPA has overestimated the availability of laboratories with capacity to evaluate water systems' compliance with the Proposed Rule. [FN22: 88 Fed. Reg. at 18667–68 (requesting public comment on the underlying assumptions that sufficient laboratory capacity will be available with the proposed MCLs; that demand will be sufficiently distributed during rule implementation to allow for laboratory capacity; and on the cost estimates related to these assumptions).] Based on its experience certifying laboratories as part of the Fifth Unregulated Contaminant Monitoring Regulation (UCMR5) process, EPA assumes that "the commercial market for PFAS analysis is likely to remain strong and, in fact, grow as more laboratories develop the technical capacity."[FN23: Id. at 18667] EPA also assumes that, by

allowing existing PFAS monitoring data to meet initial monitoring requirements, the Proposed Rule mitigates the potential for a "sudden spike in laboratory demands."[FN24: Id. At 18667–68.]

From WUWC members' perspective, which is informed by decades of experience with drinking water sampling and analysis, the effects of new drinking water regulations on laboratory capacity are difficult to project. EPA has approved only 53 laboratories in the country to analyze UCMR5 samples by EPA Method 533 and/or EPA Method 537.1. [FN25: U.S. EPA, Laboratories Approved by EPA to Support UCMR5 (Mar. 1, 2023), available at https://www.epa.gov/dwucmr/list-laboratories-approved-epa-fifth-unregulated-contaminant-monitoring-rule-ucmr-5] Of those laboratories, seven do not offer commercial services. [FN26: Id.] Further, our members have reported a decrease in the number of accredited state labs in California of approximately 25 percent since 2020. [FN27: The California State Water Resources Control Board confirmed a decrease in the number of accredited labs during a workshop on Environmental Laboratory Accreditation Program Fees held on March 10, 2023.] Our members also report that recent typical laboratory turnaround times for internal and UCMR5 sampling have ranged widely from two to eight weeks. That range is likely to grow, because the Proposed Rule would increase the number of water systems obligated to test for PFAS beyond those subject to the UCMR5. Additional proposed regulations of other emerging contaminants, such as perchlorate, may soon follow that would further stress available laboratories. [FN28: See, e.g., NRDC v. Regan, No. 20-1335, 2023 WL 3312344(D.C. Cir., May 9, 2023)(overturning EPA's withdrawal of its prior determination not to regulate perchlorate in drinking water).] EPA should not assume that all water agencies in possession of existing UCMR5 data will elect to forego further sampling for the purpose of demonstrating compliance.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding use of previously collected data to satisfy the final rule's initial monitoring requirements (see sections 8.1.1 and 8.3 of the EPA response in this *Response to Comments* document), the EPA acknowledges that primacy agencies may require or water systems may choose to collect additional data even if they have available previously collected data. However, with this provision, the EPA is seeking to reduce burden and reduce potential laboratory capacity issues by allowing this flexibility and does make some reasonable assumptions, based on the overwhelming support from commenters on its use and allowance of this data will reduce burden for thousands of water systems, that water systems will choose to use this data if available. While beyond the scope of this PFAS regulatory action, regarding concerns related to perchlorate monitoring competing for laboratory space with PFAS monitoring, the EPA notes that the agency intends to propose the Perchlorate NPDWR by November 2025, and finalize that regulation by May 2027. Monitoring completed for perchlorate would, therefore, start after the initial monitoring period for this PFAS regulation.

3M Company (Doc. #1774, SBC-045687)

a. There is Insufficient Analytical Laboratory Capacity to Process the Quantity of Samples Required Under the Proposed Rule

EPA overstates the number of approved laboratories for the analysis of PFAS in drinking water and overestimates laboratory capacity. As of March 2023, there are 53 laboratories approved to support UCMR5, only 46 of which accept commercial samples (USEPA 2023g). As of April 21, 2023, the National Environmental Laboratory Accreditation Program (NELAP) Accreditation Management System lists only 38 total active laboratories certified to perform either EPA Method 533, 537.1, or both, and that accept commercial samples for drinking water (NELAP 2023).

Moreover, analytical capacity varies by laboratory and, for that reason, the number of approved laboratories is a poor indicator of overall capacity. The larger laboratory networks are currently at or near capacity for PFAS analyses in non-drinking water matrices (e.g., non-potable waters, soils); as a result, customers are experiencing considerable delays in receiving analytical results. In the past year, 3M has experienced several commercial testing labs move from standard 10 business day turnaround times for analysis of PFAS in water to straining to achieve turnaround times of less than 30 business days, despite adding equipment and other resources. This has impacted the ability to meet required timelines for regulatory-related obligations, as well as the operation, installation, and optimization of water treatment processes. The current PFAS testing capacity constraint is occurring prior to finalization of the EPA 1633 method, a more resource intensive test method than is currently employed by commercial contract testing labs. Further capacity constraints are expected after finalization and implementation of the EPA 1633 method. In fact, Metropolitan Council Environmental Services, which administers industrial discharge permits in Minnesota, notified 3M that there are only a small number of laboratories in North American that can perform EPA draft method 1633, and that turnaround times for analytical results can be as long as 4 months. It is not realistic to expect that growth in laboratory services will keep pace with increased demand, given all that is required to construct, permit, and staff an analytical laboratory.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. The EPA Method 1633 is not a drinking water method and, as such, may have different time and resource requirements than EPA Method 533 or EPA Method 537.1, ver. 2.0. As described above in the agency's approach toward evaluating feasibility, the EPA assesses (1) the availability of analytical methods to reliably quantify levels of the contaminants in drinking water and (2) the lowest levels at which contaminants can be reliably quantified within specific limits of precision and accuracy during routine laboratory operating conditions using the approved methods (i.e., the PQLs). This framework inherently considers both the capacity and capability of labs available to meet the requirements of the NPDWR. The EPA disagrees with commenter

assertions that there is insufficient laboratory capacity at this time to support implementation of the NPDWR. Based on the EPA's experience in implementing previous UCMRs and NPDWRs, the agency believes that current conditions are reflective of commercial and non-EPA laboratory performance and capacity, and the agency expects the environmental laboratory community will continue to develop their capabilities for the PFAS drinking water analysis at the PQL as demonstrated in previous drinking water regulations (USEPA, 1999; USEPA, 2001).

California-Nevada Section American Water Works Association (CA-NV AWWA) (Doc. #1775, SBC-045273)

4. Laboratory capacity should be considered and able to fulfill demands.

Initial monitoring requirements will trigger at least 70,000 public drinking water systems to conduct quarterly monitoring. Therefore, over 280,000 samples plus additional samples for pilot testing, performance testing, and other research by systems required to install treatment will be required during the first three years. EPA already acknowledged potential laboratory capacity issues, so if EPA were to promulgate MCLs, the Agency should also conduct a study to ensure sufficient laboratory capacity is available to fulfill demands. There are currently 49 laboratories approved to analyze UCMR 5 samples (by EPA Method 533) [FN4: https://www.epa.gov/system/files/documents/2022-01/ucmr5-approved-lab-list.pdf (accessed May 28, 2023).] Of those laboratories, 14 are public water system laboratories or state health department laboratories, which may not offer commercial services. It is not likely that thirty-five laboratories can meet the initial projected capacity demands.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenters' sampling estimates which are based in the incorrect assumption that all water systems subject to the rule's monitoring requirements will be required to conduct new initial monitoring sampling or that they will be required to collect quarterly samples. Moreover, many water systems will be eligible to utilize previously collected data to satisfy some or all of these requirements and small groundwater systems serving 10,000 or fewer, which accounts for approximately 80 percent of the systems subject to the final rule monitoring requirements, will only be required to collect two initial monitoring samples. Please see sections 8.1.1 and 8.3 of the EPA response in this *Response to Comments* document regarding the rule's initial monitoring requirements and use of previously collected data to satisfy these monitoring requirements. As described above in the agency's approach toward evaluating feasibility, the EPA assesses (1) the availability of analytical methods to reliably quantify levels of the contaminants in drinking water and (2) the lowest levels at which contaminants can be reliably quantified within specific limits of precision and accuracy during routine laboratory operating conditions using the approved methods (i.e., the PQLs). This framework inherently considers both the capacity and capability of labs available to meet the requirements of the NPDWR.

Based on the EPA's analysis of these factors, the EPA disagrees with commenter assertions that there is insufficient laboratory capacity at this time to support implementation of the NPDWR.

City of Tulsa Water and Sewer Department (CoT WSD) (Doc. #1785, SBC-043781)

3. 88 FR 18668 (also 88 FR 18730). EPA requests comment on the underlying assumptions that sufficient laboratory capacity will be available with the proposed MCLs; that demand will be sufficiently distributed during rule implementation to allow for laboratory capacity; and on the cost estimates related to these assumptions.

CoT WSD responds that while EPA's allowance of existing PFAS monitoring data (i.e. UCMR5 data) to meet initial monitoring requirements may help to lessen certified laboratory capacity overload for THIS rule, EPA does not take into account other PFAS monitoring that is occurring at the same time, e.g. monitoring for Clean Water Act (CWA). EPA is currently urging states, and local pretreatment programs, to use existing authorities to incorporate quarterly monitoring into NPDES permit requirements. Pretreatment Programs are monitoring certain Industrial Users that can be dischargers of PFAS to determine if their NPDES permits should be altered. POTWs are routinely sampling their influent, effluent, and biosolids. In addition to UCMR5 monitoring, PWSs are monitoring their raw water sources, treatment effluent and residuals for PFAS. All of the analytical work is performed by the laboratories that are certified for UCMR5 and that will be performing the work for this proposed NPDWR. It is our opinion that EPA severely underestimated the demand on laboratory capacity, and that this could have an effect on meeting compliance deadlines.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Safe Drinking Water Branch, Hawaii Department of Hawaii (Doc. #1801, SBC-043753)

Lab Capacity

How many labs can test PFSA? How many labs can EPA and each state certify by the end of 2023? After the PFSA rule is finalized, can water systems find a certified lab to send the PFSA samples? Can labs conduct the test within the holding time? If the answer to either question is No, we, as the state agent, will issue the violation letter to the innocent water systems which will cause the public panic.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and

exemptions. For responses on holding times, please see the EPA response to comment Doc. #1708, SBC-045100 in section 5.1.2 in this *Response to Comments* document.

Palm Beach County Water Utilities Department (Doc. #1802, SBC-045335)

Page 18667, VI.A. Third column first full paragraph," EPA received strong interest from a significant number of laboratories seeking UCMR 5 laboratory approval, demonstrating there is effective laboratory capacity to support the program. The commercial market for PFAS analysis is likely to remain strong and, in fact, grow as more laboratories develop the technical capability further enhancing lab capacity to analyze PFAS for drinking water rule compliance purposes.":

PBCWUD Comment: PBCWUD understands the EPAs conclusion that current strong interested by laboratory's in gaining approval will equate to an increase in lab capacity. However, current lab turn-around-time (TAT) for some UCMRS analysis ranges from 45 to 80 days indicating there is already a significant lack of lab capacity. Once this rule is implemented nationwide lab TAT will be even more strained. The EPA should consider the current backlog of lab resources when determining future lab capacity as effected by this proposed rule.

Page 18668, VI.A. First column first partial paragraph," sufficient laboratory capacity will be available with the MCLs set at 4.0 ppt; that demand will be sufficiently distributed during rule implementation to allow for laboratory capacity; and on the cost estimates related to these assumptions":

PBCWUD Comment: UCMRS is already putting a strain on lab capacity which will be increasingly affected by this proposed rule.

Page 18681, IX.A. Third column last paragraph, " feasibility of the proposed MCLs and more generally on laboratory capacity. As noted earlier, EPA anticipates laboratories will be able to adjust to demand (including possible price effects), which the Agency anticipates will be distributed across the implementation period":

PBCWUD Comment: Current lab TAT for some UCMRS analysis ranges from 45 to 80 days indicating there is already a significant lack of lab capacity. Once this rule is implemented nationwide lab TAT will be even more strained. The EPA should consider the current backlog of lab resources when determining future lab capacity as affected by this proposed rule.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Based on the EPA's experience in implementing previous UCMRs and NPDWRs, the agency expects the environmental laboratory community will continue to develop their capabilities for the PFAS drinking water analysis at the PQL as demonstrated in previous drinking water regulations (USEPA, 1999; USEPA, 2001).

Millie Garcia-Serrano (Doc. #1803, SBC-044289)

5. Analytical Laboratory Capacity: ASTSWMO anticipates an increase in sampling and analysis, warranting the need for sufficient analytical laboratory capacity to not only address the needs of the public water suppliers regulated under the SDWA, but also the needs of site discovery and cleanup programs managed under CERCLA, RCRA, and the States' cleanup programs, among others. ASTSWMO recommends further communication between EPA and certified state and commercial laboratories to ensure that capacity issues do not impact PFAS analysis and site remediation.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Laurens County Water and Sewer Commission (LCWSC) (Doc. #1805, SBC-043747)

Laboratory capacity is another compelling reason to delay this rulemaking. EPA tries to allay this concern by saying lab capacity will work itself out during rule implementation period. In a normal economic period, EPA may be correct that the lab services industry would build capacity after a couple of years to address the historic increase in testing services demand However, like most professions, the lab services sector is experiencing significant worker shortages that cannot be rectified in the near term. What EPA does not acknowledge is that the testing capacity simply is not there, particularly when considering the wastewater, biosolids, stormwater, and all other product and media PFAS-related testing that will be demanded in the years and decades to come.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Office of Advocacy at the U.S. Small Business Administration (Doc. #1807, SBC-045486)

In addition, during Advocacy's roundtable discussion on this proposed rule, a small entity representative stated that small systems will bear the brunt of limited laboratory capacity for foreseeable future due to high sample cost, long turnaround times, and diminishing access to quality laboratories.

EPA Response: The commenter does not provide supporting data regarding assertions that small systems will "bear the brunt of limited laboratory capacity for foreseeable future…" Funds are also available through the passage of the IIJA, also referred to as the BIL, to assist many disadvantaged communities, small systems, and others with the costs of installation of treatment when it might otherwise be cost-challenging; please see section 2.4 of the EPA response in this *Response to Comments* document for more information on funding. For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA

response in this *Response to Comments* document. Pertaining to the EPA's actions to fulfill requirements under the Regulatory Flexibility Act and consult with small entities, please see section XIII.C of the final rule preamble.

West Virginia Municipal Water Quality Association (Doc. #1816, SBC-044683)

IX. Laboratory Capacity & Delay

Laboratory capacity is another compelling reason to delay this rulemaking. Although EPA discusses the growing analytical capabilities of laboratories, see 88 Fed. Reg. at 18667, the amount of PFAS lab work that will be needed once the rule is finalized cannot be overstated. This ignores the fact of existing delays today with PFAS lab analytical result turnaround times. Recently, the New Jersey Association of Environmental Authorities issued an RFP for PFAS lab services for its members and only one lab responded. Several others reported that they did not have the capacity.

EPA tries to allay this concern by saying lab capacity will work itself out during the rule implementation period. In a normal economic period, EPA may be correct that the lab services industry would build capacity after a couple of years to address the historic increase in testing services demand. However, like most professions, the lab services sector is experiencing historic worker shortages that can't be rectified in the near term. See 88 Fed. Reg. at 18667-68. ("The commercial market for PFAS analysis is likely to remain strong and, in fact, grow…"). What EPA does not acknowledge is that the testing capacity simply is not there, particularly when considering the wastewater, biosolids, stormwater, and all other product and media PFAS-related testing that will be demanded in the years and decades to come.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Association of Missouri Cleanwater Agencies (Doc. #1817, SBC-044661)

IX. Laboratory Capacity & Delay

Laboratory capacity is another compelling reason to delay this rulemaking. Although EPA discusses the growing analytical capabilities of laboratories, see 88 Fed. Reg. at 18667, the amount of PFAS lab work that will be needed once the rule is finalized cannot be overstated. This ignores the fact of existing delays today with PFAS lab analytical result turnaround times. Recently, the New Jersey Association of Environmental Authorities issued an RFP for PFAS lab services for its members and only one lab responded. Several others reported that they did not have the capacity.

EPA tries to allay this concern by saying lab capacity will work itself out during the rule implementation period. In a normal economic period, EPA may be correct that the lab services industry would build capacity after a couple of years to address the historic increase in testing

services demand. However, like most professions, the lab services sector is experiencing historic worker shortages that can't be rectified in the near term. See 88 Fed. Reg. at 18667-68. ("The commercial market for PFAS analysis is likely to remain strong and, in fact, grow…"). What EPA does not acknowledge is that the testing capacity simply is not there, particularly when considering the wastewater, biosolids, stormwater, and all other product and media PFAS-related testing that will be demanded in the years and decades to come.

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044683 in section 5.1.2 in this *Response to Comments* document.

NORTH CAROLINA WATER QUALITY ASSOCIATION (Doc. #1818, SBC-044639)

IX. Laboratory Capacity & Delay

Laboratory capacity is another compelling reason to delay this rulemaking. Although EPA discusses the growing analytical capabilities of laboratories, see 88 Fed. Reg. at 18667, the amount of PFAS lab work that will be needed once the rule is finalized cannot be overstated. This ignores the fact of existing delays today with PFAS lab analytical result turnaround times. Recently, the New Jersey Association of Environmental Authorities issued an RFP for PFAS lab services for its members and only one lab responded. Several others reported that they did not have the capacity.

EPA tries to allay this concern by saying lab capacity will work itself out during the rule implementation period. In a normal economic period, EPA may be correct that the lab services industry would build capacity after a couple of years to address the historic increase in testing services demand. However, like most professions, the lab services sector is experiencing historic worker shortages that can't be rectified in the near term. See 88 Fed. Reg. at 18667-68. ("The commercial market for PFAS analysis is likely to remain strong and, in fact, grow…"). What EPA does not acknowledge is that the testing capacity simply is not there, particularly when considering the wastewater, biosolids, stormwater, and all other product and media PFAS-related testing that will be demanded in the years and decades to come.

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044683 in section 5.1.2 in this *Response to Comments* document.

South Carolina Water Quality Association (Doc. #1819, SBC-044617)

IX. Laboratory Capacity & Delay

Laboratory capacity is another compelling reason to delay this rulemaking. Although EPA discusses the growing analytical capabilities of laboratories, see 88 Fed. Reg. at 18667, the amount of PFAS lab work that will be needed once the rule is finalized cannot be overstated. This ignores the fact of existing delays today with PFAS lab analytical result turnaround times. Recently, the New Jersey Association of Environmental Authorities issued an RFP for PFAS lab

services for its members and only one lab responded. Several others reported that they did not have the capacity.

EPA tries to allay this concern by saying lab capacity will work itself out during the rule implementation period. In a normal economic period, EPA may be correct that the lab services industry would build capacity after a couple of years to address the historic increase in testing services demand. However, like most professions, the lab services sector is experiencing historic worker shortages that can't be rectified in the near term. See 88 Fed. Reg. at 18667-68. ("The commercial market for PFAS analysis is likely to remain strong and, in fact, grow…"). What EPA does not acknowledge is that the testing capacity simply is not there, particularly when considering the wastewater, biosolids, stormwater, and all other product and media PFAS-related testing that will be demanded in the years and decades to come.

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044683 in section 5.1.2 in this *Response to Comments* document.

Wet Weather Partnership (Doc. #1820, SBC-044595)

IX. Laboratory Capacity & Delay

Laboratory capacity is another compelling reason to delay this rulemaking. Although EPA discusses the growing analytical capabilities of laboratories, see 88 Fed. Reg. at 18667, the amount of PFAS lab work that will be needed once the rule is finalized cannot be overstated. This ignores the fact of existing delays today with PFAS lab analytical result turnaround times. Recently, the New Jersey Association of Environmental Authorities issued an RFP for PFAS lab services for its members and only one lab responded. Several others reported that they did not have the capacity.

EPA tries to allay this concern by saying lab capacity will work itself out during the rule implementation period. In a normal economic period, EPA may be correct that the lab services industry would build capacity after a couple of years to address the historic increase in testing services demand. However, like most professions, the lab services sector is experiencing historic worker shortages that can't be rectified in the near term. See 88 Fed. Reg. at 18667-68. ("The commercial market for PFAS analysis is likely to remain strong and, in fact, grow…"). What EPA does not acknowledge is that the testing capacity simply is not there, particularly when considering the wastewater, biosolids, stormwater, and all other product and media PFAS-related testing that will be demanded in the years and decades to come.

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044683 in section 5.1.2 in this *Response to Comments* document.

Mississippi Farm Bureau Federation (Doc. #1826, SBC-044269)

EPA should also consider the burden placed on the state regulato1y agencies, and the state chemical labs and ensure that they have the resources necessary to conduct a new testing program without significantly affecting other required testing programs.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Pennsylvania Municipal Authorities Association (Doc. #1832, SBC-045789)

[PMAA's specific comments on the Proposal are as follows:]

13. In Pennsylvania, a staggered monitoring program under the Commonwealth's PFAS Rule was developed to address concerns with laboratory availability and capacity. Similar laboratory issues could cause delays in the implementation of the Proposal's monitoring requirements, specifically as to the analysis of samples, and could significantly increase the costs to municipal entities to obtain compliance data required by the Proposal.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding the final rule's initial monitoring requirements and timing, please see section 8.1.1 of the EPA response in this *Response to Comments* document.

Corix Infrastructure Inc. (Doc. #1834, SBC-045368)

[With regards to the specific items EPA has requested comment on, Corix provides below:]

• With regards to the laboratory capacity being available, we note that the rule will overlap with the UCMR-5 requirements, putting more demand on labs to perform PFAS testing. Having challenges in finding laboratory ability recently, Corix assumes that EPA has worked with laboratories in developing plans to expand capacity for all water systems.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Citizens Energy Group (Doc. #1838, SBC-044858)

EPA requests comment on the underlying assumptions that sufficient laboratory capacity will be available with the proposed MCLs; that demand will be sufficiently distributed during rule implementation to allow for laboratory capacity; and on the cost estimates related to these assumptions.

Based on conversations with the commercial lab used by Citizens, we have been told that they are certifying additional lab facilities to the drinking water standards, which will improve the availability of labs certified to perform PFAS analysis in drinking water. However, as demand for PFAS analysis increases across the U.S., more and more water systems will rely on commercial labs creating an uncertainty with regards to total sample capacity. This increase in the demand for commercial lab analysis of PFAS compounds may lead to delays in receipt of analytical data, as most labs prioritize analysis in a "first in/first out" queue. Water systems should not be penalized if samples are collected in a timely manner and delivered to the certified lab, but backlogs in the lab result in delays in analysis and delivery of analytical results.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. The EPA notes that EPA Method 533 and EPA Method 537.1, ver. 2.0, require adherence to holding times for samples and extracts. Samples held beyond those prescriptive holding times would be considered invalid results.

San Gabriel Valley Water Association (Doc. #3072-87, SBC-047403)

Yes, my name is Karina Servantees, and I'm here on behalf of the San Gabriel Valley Water Association. We represent municipal and regulated utilities, special districts, and not-for-profit mutual water companies that supply water to nearly 2 million residents in the San Gabriel Valley of Los Angeles County, California. We share in many of the concerns highlighted today regarding the economic feasibility of the proposed MCL. Compliance with monitoring results is a concern due to transitions in the laboratory industry. California's new accreditation requirements have caused a significant decrease in the accessibility to public labs within the past two years, and commercial labs are unlikely to be able to meet the increased demand, leading to higher cost and limited access for water suppliers.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Marlene Ladderbush (Doc. #1612, SBC-042914)

EPA needs to address laboratory capacity issues before finalizing the rule. Certified labs have been challenged with analyzing the number of samples that Massachusetts PWS send them. PWS can wait upwards of three weeks for sample results and then our primacy agency, MassDEP, must perform quality assurance evaluations, which can take several more weeks. EPA should do as Massachusetts did, and phase in monitoring by PWS size to reduce the resource burden on the labs and primacy agencies who must review and verify the quality of the data.

EPA Response: Please see the EPA response to comment Doc. #1567, SBC-042731 in section 5.1.2 in this *Response to Comments* document.

Town of Tewksbury, Massachusetts (Doc. #1637, SBC-043244)

EPA needs to address laboratory capacity issues before finalizing the rule. Certified labs have been challenged with analyzing the number of samples that Massachusetts PWS send them. PWS can wait upwards of three weeks for sample results and then our primacy agency, MassDEP, must perform quality assurance evaluations, which can take several more weeks. EPA should do as Massachusetts did, and phase in monitoring by PWS size to reduce the resource burden on the labs and primacy agencies who must review and verify the quality of the data.

EPA Response: Please see the EPA response to comment Doc. #1567, SBC-042731 in section 5.1.2 in this *Response to Comments* document.

National Rural Water Association (NRWA) (Doc. #1641, SBC-043268)

The laboratory capacity needed to test samples represents another challenge. The list of laboratories approved by EPA [Link: https://www.epa.gov/dwucmr/list-laboratories-approved-epa-fifth-unregulated-contaminant-monitoring-rule-ucmr-5] for the Fifth Unregulated Contaminant Rule (UCMR5) is around 60 nationwide. Many states do not have a lab that is certified. It is assumed additional labs will seek certification and this number will increase but steps will need to be taken by EPA to incentivize these labs and create a streamlined approval process to meet demand.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Association of Public Health Laboratories (APHL) (Doc. #1646, SBC-043300)

Additionally, APHL has significant concerns that the national testing needs are underestimated and that there will be insufficient analytical capability and capacity without investment in laboratory infrastructure related to the addition of skilled analysts, acquisition of dedicated laboratory instrumentation (LC/MS, LC/MS/MS), training of laboratory scientists on the new technology and PFAS drinking water methodology and informatics solutions to support the proposed reporting requirements. We also anticipate additional and repeat testing will result from decreased method ruggedness at or near the proposed MCLs and PQLs and heightened public awareness of contamination. It will be a challenge for the commercial market to meet these demands.

APHL believes that establishing a small, coordinated laboratory network of state laboratories, Centers of Emerging Contaminants Testing, which work collaboratively with EPA programs and laboratories, would provide additional analytical expertise to transfer the technology to high-throughput laboratories quickly. This would be accomplished through investment in state laboratory infrastructure to acquire and maintain the necessary instrumentation, staffing, and supplies and by leveraging the existing expertise of the network to facilitate laboratory training

for PFAS and other emergent contaminants in water and other matrices. Modeled on existing, effective laboratory systems, The Centers of Emerging Contaminants Testing would provide dedicated resources available to refine, extend and validate analytical methods, expedite technology transfer through developing and delivering critical analytical training, and provide technical assistance to higher through-put laboratories. Without the burden of turning a profit, the network laboratories would have the dedicated resources to assist in increasing national capacity for quality PFAS measurements in support of the proposed regulations.

Thank you for the opportunity to comment. APHL welcomes any follow-up; please contact Julianne Nassif, Environmental Health Director, at Julianne.Nassif@aphl.org or 240.485.2737.

Sincerely,

Daphne Ware, Ph.D.

President, Board of Directors

Association of Public Health Laboratories Director, Missouri State Laboratory

Peter Kyriacopoulos

Chief, Public Policy Officer

Association of Public Health Laboratories

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding the commenter's suggestion for the establishment of a coordinated laboratory network, the agency intends to provide support to utilities, primacy agencies, and other interested parties after finalization of the PFAS NPDWR to ensure successful rule implementation and will consider the issues suggested by the commenter. The EPA further notes that many of the issues suggested by the commenter (such as refine, extend and validate analytical methods, provide technical assistance, or training of laboratory certification officers) are activities that the EPA is already engaged in and perform on a regular basis.

<u>New England Interstate Water Pollution Control Commission (NEIWPCC) (Doc. #1650, SBC-043145)</u>

Lab Capacity

Once finalized, water suppliers will have three years to implement the required monitoring and reporting, and extensions of up to an additional two years may be authorized by EPA on a case-by-case basis. In Section IX. Monitoring and Compliance of the proposed rule, EPA states that there are currently 54 laboratories certified to analyze PFOA and PFOS to the quantification limits of 4.0 ppt using EPA Method 533, and a "significant number of laboratories" expressing

"strong interest" in gaining such approval. Our member states are concerned that adequate laboratory capacity to implement the rule does not already exist, and it is not assured.

There are currently more than 148,000 public water systems in the United States, [FN3: EPA, 2022 (https://www.epa.gov/dwreginfo/information-about-public-water-systems)] over 16,000 of which are located in the Northeast. Currently, there are just five certified laboratories in the Northeast capable of analyzing PFAS. [FN4: EPA, Office of Water, 2023 (https://www.epa.gov/system/files/documents/2022-01/ucmr5-approved-lab-list.pdf)] In addition there are State-labs that analyze PFAS without UCMR5-certification. [FN5: https://health.ri.gov/programs/detail.php?pgm_id=1089] While these labs may assist with screening activities, analysis from a certified lab is required for public water systems.

Even after accounting for the use of existing PFAS monitoring data to meet the initial monitoring requirements of the rule, our member states anticipate a shortage of available laboratory capacity. This shortage could be further exacerbated by each states' analytical protocols. For example, some of our member states currently require duplicate sampling which increases the demand for services.

In Section IX. Monitoring and Compliance, EPA states, "[S]ystems with previously acquired data from outside UCMR 5, including State-led or other appropriate occurrence monitoring using EPA methods 533 or 537.1 will also not be required to conduct initial monitoring for regulated PFAS." This provision was included to reduce the burden on certified laboratories during the initial implementation period. However, the state-led monitoring programs vary significantly in design and implementation. We urge EPA to take into consideration whether the existing state strategies are sufficient to comply with the rule, as these state strategies could further contribute to laboratory demand if not.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. The EPA clarifies for the commenter that not all PWSs estimated by the commenter, i.e., "148,000 are subject to the final rule's monitoring requirements." Rather, EPA estimates that approximately 67,000 community water systems (CWSs) and non-transient non-community water systems (NTNCWSs) are subject to the monitoring requirements. The EPA acknowledges in the final rule that while it is allowing use of previously collected data to satisfy the final rule's initial monitoring requirements, not all systems will have some or all of this data available. However, the agency maintains that this allowance will significantly reduce monitoring burden for many water systems and allows any eligible data to be used and then supplemented with newer monitoring to meet the full requirement. Please see sections 8.1.1 and 8.3 of the EPA response in this *Response to Comments* document regarding the rule initial monitoring requirements and use of previously collected data.

NCASI (Doc. #1651, SBC-043226)

In addition to the inability to operationalize a risk management plan when action levels exist below the PQL, there may not be adequate laboratory capacity to accommodate the enormous amount of testing across the country that would be required under this proposed rulemaking. The PQLs described by EPA are achieved by cutting edge technology and may not be considered standard instrumentation across commercial laboratories. Additionally, laboratories with PFAS analytical capabilities are already receiving increased demand for NPDES permit compliance testing, as well as for testing for remediation projects. If MCL concentrations are promulgated that are reasonably above the PQL, it will broaden the accessibility of robust analytical evaluation for risk management, which would increase the feasibility of operationalizing risk management of drinking water under PFAS MCLs.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please also see section 5.1.2 of the EPA response in this *Response to Comments* document. As described above in the agency's approach toward evaluating feasibility, the EPA assesses (1) the availability of analytical methods to reliably quantify levels of the contaminants in drinking water and (2) the lowest levels at which contaminants can be reliably quantified within specific limits of precision and accuracy during routine laboratory operating conditions using the approved methods (i.e., the PQLs). This framework inherently considers both the capacity and capability of labs available to meet the requirements of the NPDWR.

Virginia Municipal Drinking Water Association (VMDWA) (Doc. #1657, SBC-043169)

Second, there is currently a well-known shortage of laboratory capacity for PFAS testing. VMDWA Members report 2-3 month delays in received test results pre-MCL. Upcoming UCMR5 and MCL testing mandates will exacerbate the current shortage. VMDWA expects test availability and turnaround times will get worse before they get better. Testing is the first step in the process and it appears destined for delays until a sufficient number of new labs to support the national program can be funded, permitted, constructed, staffed, and certified, assuming no backorders or supply chain issues exist for analytical instruments and consumables (e.g., reagents, etc.).

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please

see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Maryland Association of Municipal Wastewater Agencies (MAMWA) (Doc. #1658, SBC-043404)

Second, there is currently a well-known shortage of laboratory capacity for PFAS testing. MAMWA Members report 2-3 month delays in received test results pre-MCL. Upcoming UCMR5 and MCL testing mandates will exacerbate the current shortage. MAMWA expects test availability and turnaround times will get worse before they get better. Testing is the first step in the process, and it appears destined for delays until a sufficient number of new labs to support the national program can be funded, permitted, constructed, staffed, and certified, assuming no backorders or supply chain issues exist for analytical instruments and consumables (e.g., reagents, etc.).

EPA Response: Please see the EPA response to comment Doc. #1657, SBC-043169 in section 5.1.2 in this *Response to Comments* document.

National Association of Clean Water Agencies (NACWA) (Doc. #1659, SBC-043155)

EPA Failed to Consider Laboratory Capacity

With an increased regulatory focus on PFAS, interest has grown in understanding where these chemicals are in the environment and in what concentrations. However, laboratory capacity for EPA's approved PFAS analytical methods has not caught up with the sheer demand to investigate PFAS sources. With limited laboratories currently available to provide PFAS analysis, a significant backlog is already occurring often resulting in utilities waiting six or more weeks to receive results which can exceed permit reporting deadlines.

NACWA has serious concerns that when this rule goes into effect, there will be nearly 66,000 PWSs newly and simultaneously seeking limited laboratory analysis, further straining laboratories and creating longer wait periods for analysis and results. The demand could also significantly raise costs, which already range from around $300 to $600 per sample. On the CWA side, EPA also continues to urge states to incorporate quarterly monitoring into National Pollutant Discharge Elimination System (NPDES) permits and require utilities to routinely sample their influent, effluent, and biosolids. The federal and state regulatory push for the water sector to quantify PFAS concentrations absent the necessary laboratory capacity to do this type of sensitive chemical analysis will present a significant problem for PWSs and clean water utilities alike that need to meet legally enforceable compliance deadlines in a timely manner.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenters' assumption that all water systems subject to the rule's

monitoring requirements will be required to conduct new initial monitoring sampling. Moreover, many water systems will be eligible to utilize previously collected data to satisfy some or all of these requirements. Please see sections 8.1.1 and 8.3 of the EPA response in this *Response to Comments* document regarding the rule's initial monitoring requirements and use of previously collected data to satisfy these monitoring requirements.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045035)

Laboratory Capacity

The EPA seeks comment on laboratory capacity to meet the monitoring requirements of its proposal. NJDEP believes that laboratory capacity has been sufficient for the limited number of states that are requiring PFAS testing in drinking water so far. However, as states across the nation implement the proposed drinking water standards, this capacity will be strained. As of May 22, 2023, 26 laboratories are certified by NJDEP's Office of Quality Assurance to analyze for PFAS using EPA Method 537.1 and 13 laboratories are certified for EPA Method 533. A majority of these laboratories (22) are located outside of New Jersey. Once the proposed rules are implemented, New Jersey water systems will be competing with systems from across the nation for access to these laboratories.

It is reasonable to believe that laboratory capacity will increase after promulgation of these proposed NPDWRs. This was the case in New Jersey after the adoption of its PFAS MCLs. However, it is important for EPA to consider the time it will take for laboratories to purchase equipment, train staff, and obtain certification, as necessary, and to coordinate with public water systems to ensure samples are collected and reported in accordance with proposed requirements, thus, avoiding monitoring violations.

The EPA should consider that testing for matrices other than drinking water may also increase soon. This could be because of investigations into potential sources impacting public water systems, increased testing for contaminated site cleanups, or for evaluating impacts to wastewater systems, and may affect the laboratory capacity for all samples overall, as the same universe of laboratories conduct these analyses in all matrices. While demand will be distributed over three years, it may take that much time or more for certified laboratories that can handle both drinking water samples and other matrices to meet analytical demands in a timely manner.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Wyoming Department of Environmental Quality (WDEQ) (Doc. #1716, SBC-044759)

9. EPA Should Reevaluate Monitoring and Laboratory Analysis Capacity Impacts

According to the EPA's website, as of May 2023, only 53 UCMR 5 certified laboratories are capable of reaching EPA standards for UCMR 5 approved Analytical Methods 533 and 537.1. With over 70,000 PWSs across the United States anticipated to begin requiring analysis for regulated PFAS under the proposed PFAS NPDW rule, the demand placed on these laboratories will be tremendous. The method requirements for storage, temperature, and timelines to analyze make feasibility questionable given the anticipated demand. If demand outstrips the supply, the cost of the testing will increase.

WDEQ recommends EPA reevaluate its feasibility assessment of laboratory capacity in meeting the anticipated increased sample load.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenters' assumption that all water systems subject to the rule's monitoring requirements will be required to conduct new initial monitoring sampling. Moreover, many water systems will be eligible to utilize previously collected data to satisfy some or all of these requirements. Please see sections 8.1.1 and 8.3 of the EPA response in this *Response to Comments* document regarding the rule's initial monitoring requirements and use of previously collected data to satisfy these monitoring requirements.

Louisville Water Company (Doc. #1720, SBC-043555)

[In that regard, we are providing the following comments on key issues that we think require consideration.]

5. EPA has requested comment on the underlying assumptions that sufficient laboratory capacity will be available to implement the proposed rule. Our experience leads to concerns over the ability of certified labs to reliably process in an affordable manner the number of samples this rule will require, in addition to the samples utilities will generate for research and operational control purposes. UCMR5 presents an opportunity to assess nationwide lab capacity. Louisville Water recommends the agency consider holding off on finalizing the rule to make this assessment from UCMR5 metadata and then take the appropriate course of action.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding UCMR 5, please see sections 3.1.2 and 6.8 of the EPA response in this *Response to Comments* document.

Wisconsin Department of Natural Resources (Doc. #1828, SBC-044803)

Laboratory Capacity

WDNR recommends that EPA address anticipated laboratory capacity issues ahead of finalizing this PFAS rule. While WDNR notes that private labs will have three years to prepare and install instruments for PFAS analyses, the number of interested labs and interest in PFAS analyses should be assessed prior to rule implementation. Laboratories may not be interested in the large investment that would be necessary to establish PFAS analysis capability. Also, the limited PFAS monitoring frequency after initial monitoring requirements makes such an investment financially risky for smaller labs.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Clean Air Council, et al. (Doc. #1731, SBC-043884)

An additional issue raised during the comment period for Pennsylvania's PFAS drinking water MCL rule was the availability and capacity of accredited laboratories that could perform the testing. While some commenters may raise the issue with the proposed federal regulation, the schedule suggested in the NPDWR renders these objections invalid: The largest need for tests will take place during the initial period (12 months) of the proposed NPDWR, when quarterly or twice annual tests will need to be conducted by all PWSs (depending on the size of the population served). Following this initial period, compliance monitoring frequency will be reduced to once or twice every three years for the approximately 40% systems with PFAS below the trigger levels [FN67: 88 Fed. Reg. 18671–80. Note that the number of exempt systems may be higher since some of the studies used to identify the prevalence of PFAS in drinking water concentrated on areas where PFAS contamination was suspected. An example is Pennsylvania's sampling of PFAS in drinking water. 53 Pa.B. 533; Full PA Sampling Data]. EPA intends to alleviate the test load during the initial testing period by accepting data that was previously acquired. Therefore, PWSs in states where testing has already been conducted as part of a PFAS drinking water regulation (e.g. MA, MI, NY, NJ, NH, ME, PA) would not need to perform any additional tests. Testing of potentially contaminated PWSs finished water is also required in some states where no MCLs for drinking water have been set as yet (e.g. CA [FN68: Cal. Water Res. Control Bd., Section on PFAS, Drinking Water Resources, https://www.waterboards.ca.gov/pfas/drinking_water.html (last updated Mar. 1, 2023).]). Thus, a large number of PWSs will be able to present their previously acquired test data, receive exemptions, and then adopt the less frequent testing schedule. Reducing the total amount of testing needed across the nation increases the testing capacity available to PWSs in states that have not yet conducted testing because a PWS may send its samples to any accredited laboratory in the nation.

EPA Response: For additional discussion regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For the EPA's response related to use of previously collected data to satisfy the rule's initial monitoring requirements, please see section 8.3 of the EPA response in this *Response to Comments* document. For EPA's response related to initial monitoring requirements and timing, please see section 8.1.1 of the EPA response in this *Response to Comments* document. EPA clarifies for the commenter that the initial monitoring is required to occur in the 3 years following rule promulgation, not 12 months following rule promulgation.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043088)

If this data is required to be collected and used to drive decision-making, it will also lead to a higher demand for laboratories that are able to analyze samples with a greater degree of accuracy to these lower levels to minimize the risks of inaccurately higher sample results from interferences and other technical challenges. Increased demand for these laboratories will contribute to higher lead times, costs, and higher frequency of sample analysis errors. This will negatively impact smaller systems with less financial capacity to access these laboratories, creating inequitable access to nationally reliable sample analysis.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding rule trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-044892)

o EPA has noted an assumption that the demand for increased monitoring will trigger an increase in overall lab capacity because more labs will seek certification/accreditation in more states. However, DEP notes the significant expense of adding capacity for PFAS analysis for a laboratory. DEP estimates a total initial cost of over $542,000 to add PFAS analytical capacity, broken down as follows:

[Table 2: See Docket ID: EPA-HQ-OW-2022-0114-1626]

EPA Response: The EPA acknowledges the cost for analytical capacity submitted by the commenter. For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding the rule's cost estimates, please see section 13.3.4 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044085)

The number of laboratories that will be capable of analyzing for PFAS in time to meet the new rule compliance demands is still uncertain. The volume and number of samples that water systems will need to be analyzed based on expected occurrence and sampling frequency will likely exceed laboratory capacity for all laboratories and each laboratory individually. Laboratory capacity is a significant feasibility concern that should be further analyzed. Some primacy agencies have noted impacts on their laboratory capacity due to limited suppliers for PFAS standard reagents. Primacy agencies have also reported that laboratories have had to modify sample bottle lids to fit their auto extractors, where the standard bottles and lids are incompatible.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

New York State Department of Health (NYS DOH) (Doc. #1677, SBC-044944)

6. The Department notes that EPA has historically recognized that the precision and accuracy of analytical results are sacrificed as reporting limits are set closer to method detection limits (MDL). EPA has historically used the reduction in health risk as justification for the sacrifice in analytical precision and accuracy, though only three other organic contaminants that are regulated through NPDWR have MCLs at a similar multiple of the MDL proposed for PFOA and PFOS.

In addition, EPA has in the past highlighted vulnerability assessments and the availability of monitoring waivers to respond to concerns about laboratory proficiency and, therefore, laboratory capacity when MCLs are established at such low levels. We posit that in this case the concerns about laboratory capacity are consistent with similar concerns raised in the past, but that the relief afforded by waivers may not be available to offset the burden under the proposed rule.

EPA Response: The final MCLs for PFOA and PFOS are set at the PQLs; please see the section 5.1.2 of the EPA response in this *Response to Comments* document for additional discussion on PQLs and how they were set for the final NPDWR. For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please also see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding rule trigger levels for reduced triennial monitoring and monitoring waivers, please see sections 8.8 and 8.5, respectively, of the EPA response in this *Response to Comments* document.

New York City Department of Environmental Protection (NYCDEP) (Doc. #1679, SBC-044212)

In section IX.A., p. 18681, EPA requests comment on feasibility of the proposed MCLs and on laboratory capacity. EPA has recognized the challenging nature of this testing and expects the lab community to adapt. There are very few labs currently capable of producing data that meet the Data Quality Objectives required for this monitoring, and those are likely to be overwhelmed with new work. While those few labs that possess the resources to increase capacity will do so, the barriers to developing this complex testing will likely prevent more labs from entering the pool of labs. As a result of a lack of competition, this testing will continue to be expensive relative to other laboratory tests. The current price for each test by Methods 533 or 537.1 is between $550 and $600, which is almost double the amount shown in Table 34 (p. 18698).

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding the rule's monitoring cost estimates, please see section 13.3.4 of the EPA response in this *Response to Comments* document.

Metropolitan Water District of Southern California (Doc. #1777, SBC-045432)

While EPA intends to have a trigger level that is more protective in the long run, it may not be feasible without a reliable analytical method. In addition, lab capacity may also be an issue, particularly the availability of labs that can reliably measure at such low concentrations. This is especially a concern in California, where accredited state labs have decreased from 626 to 475, or nearly 25%. [FN12: California State Water Resources Control Board's 2023-24 Environmental Laboratory Accreditation Program fees workshop on March 10, 2023.] Also, EPA has approved only 53 laboratories to analyze UCMR 5 PFAS samples by EPA Method 533 and/or EPA Method 537.1. [FN13: https://www.epa.gov/system/files/documents/2022-01/ucmr5-approved-lab-list.pdf.] Of those laboratories, 7 do not offer commercial services. [FN14: Id.] It is unclear if EPA has considered this fact in its feasibility analysis.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding the rule trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document.

Missouri Department of Natural Resources (Doc. #1563, SBC-042534)

Additionally, the Department believes that it is a mistake to set a MCL at or near the PQL when a PQL has a ±50% Method QA/QC acceptance level. As additional research on toxicity and lab analytical ability improves, EPA will have the opportunity during six year reviews to possibly

lower MCL and/or PQL in the future. Until then, the Department believes that a PQL of 4 ppt with a MCL of at least 9 ppt is feasible and appropriate.

EPA Response: For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Please also see the EPA response to comment Doc. #1677, SBC-044955 in section 5.1.2 in this *Response to Comments* document for commenter claims on the 30 percent - 50 percent acceptance criteria in the reported result.

Missouri Department of Natural Resources (Doc. #1563, SBC-042521)

Section VI—Maximum Contaminant Level

EPA requests comment on its proposed determination to set MCLs at 4.0 ppt for PFOA and PFOS and whether 4.0 ppt is the lowest PQL that can be achieved by laboratories nationwide. EPA requests comment on implementation challenges and considerations for setting the MCL at the PQLs for PFOA and PFOS, including on the costs and benefits related to this approach. EPA requests comment on monitoring-related flexibilities that should be considered to further reduce burden while also maintaining public health protection including a rule trigger level at different values than the currently proposed values of 1.3 ppt for PFOA and PFOS and 0.33 for the HI PFAS (PFHxS, HFPO–DA, PFNA, and PFBS), specifically alternative values of 2.0 ppt for PFOA and PFOS and 0.50 for the HI PFAS. EPA also requests comment other monitoring flexibilities identified by commenters.

As described in the UCMR 5 Laboratory Approval Manual (Version 2.0 December 2021), the decision to have a PFOA and PFOS calculated minimum reporting level (MRL), also known as the lowest PQL, at 0.0040 µg/L (4.0 ppt) was based on a minimum of 3 LCMRL values from the participating laboratories. It appears from Appendix B this may have been done using only eight laboratories nationwide. While some states have reported using a lab that has the ability to reach near 2.0 ppt minimum reporting levels, not all labs are able to reach this MRL/PQL. Given such a small sample set from the UCMR 5 Laboratory Approval Manual, and the timing of this action being before the completion of UCMR 5, it seems premature to assume laboratories nationwide can achieve a lower result than 4.0 ppt. To do so, and be incorrect in the assumption, is setting up states to have lab capacity issues upon implementation of the rule.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please also see section 5.1.2 of the EPA response in this *Response to Comments* document. All UCMR 5 approved laboratories measuring for PFAS

were required to confirm that they could meet the UCMR 5 MRL using the MRL Confirmation procedures listed in EPA Methods 537.1, ver. 2.0 and 533. In other words, for UCMR 5, all UCMR-approved laboratories were able to meet or exceed the PFOS and PFOA UCMR MRLs, set at 4 ng/L. Regarding rule trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document.

Maine Water Utilities Association (MWUA) (Doc. #1567, SBC-042732)

Source Water and Analytical Variability:

Through the years of sampling that has been conducted by PWS, it is not uncommon for different labs to report a difference of several parts per trillion +/- in PFAS when analyzing the exact same source water. We question whether we are pushing the sensitivity of the equipment to a point where it cannot be reliably quantified. A sample is considered valid at +/-30%, when discussing regulatory compliance levels in the low parts per trillion, this is concerning. As a point of illustration, the following are split sample results for a utility in Massachusetts. The sample date was 12/11/2020, lab A's result was 12.7 ppt, while lab B's result was 20.56 – both were valid results, yet the swing was 7.86 ppt. This analytical variability is well over what EPA proposes as the MCL so PWS could be subject to noncompliance and enforcement due to analytical variability alone.

Some PWS have seen +/- parts per trillion variability in PFOS and PFOA concentrations when collecting monthly samples; even a 1-2 ppt variation can represent over 40% variability when close to the MDL. It is difficult to tell if this variability is attributable to changes of PFOS and PFOA concentrations in the source water or if it is linked to the variability of the analytical method (+/- 30%). Having a proposed Rule Trigger Level of 1/3, the PFOS and PFOA MCL or HI may have PWS and primacy agencies fluctuating back and forth on whether the PWS is eligible for a monitoring waiver and may impact the running annual average calculation. This uncertainty creates unnecessary complexity, increased level of effort, and continued erosion of public confidence.

We are also aware of several instances where it was found that lab instrumentation was not properly cleaned between sample runs, resulting in erroneous detections. It is paramount that labs are not doing cross matrix analysis on machines that analyze drinking water samples.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Please also see the EPA response to comment Doc. #1677, SBC-044955 in section 5.1.2 in this *Response to Comments* document for commenter claims on the 30 percent - 50 percent acceptance criteria in the reported result. The EPA further notes that neither methods 533 nor 537.1 v2 have inherent QC issues when explicitly followed. Regarding laboratory or background contamination considerations, please see section 8.7 of the EPA response in this *Response to Comments*

document. For discussion of rule trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document.

COMM Water Department (Doc. #1577, SBC-042434)

COMM Water Department •Our experience in Massachusetts has shown that there can be a wide range in results when different labs analyze the same source water. PWS professionals question whether we are pushing the sensitivity of the equipment to a point where it cannot be reliably quantified. A sample is considered valid at +/-30%, when discussing regulatory compliance, or Maximum Contaminant Levels (MCL), in the low parts per trillion, this is concerning.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Please also see the EPA response to comment Doc. #1677, SBC-044955 in section 5.1.2 in this *Response to Comments* document for commenter claims on the 30 percent - 50 percent acceptance criteria in the reported result.

New York Section American Water Works Association (NYSAWWA) (Doc. #1591, SBC-042368)

We are concerned that there are an inadequate numbers of labs with the capability to reliably report below 4 ppt, and feel strongly that this should not be a driver for regulatory framework.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding the EPA's rule trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document.

Minnesota Department of Health (MDH) (Doc. #1610, SBC-042851)

• Based on our experience with laboratories already confidently achieving RLs below 4 ppt and information from our Public Health Laboratory (PHL) and the Environmental Monitoring Coalition (EMC), it appears that 4 ppt is currently not "the lowest concentration of analyte that can be reliably measured within specified limits of precision and accuracy during routine laboratory conditions."

o MDH's PHL already has attained reporting limits (RLs), or limits of quantification (LOQ), for EPA Method 533 that are below 4 ppt – current RLs for all analytes are 1.6-1.8 ppt. MDH has also contracted with other laboratories for PFAS analysis, who are also currently attaining RLs between 1.8-2 ppt. Therefore, MDH is already receiving results without any "J-flagged" qualifiers for both PFOS and PFOA that are below 4 ppt.

o The Minnesota Environmental Laboratory Accreditation Program (MNELAP), a NELAC accreditation body, asked its accredited laboratories for RL data pertaining to EPA Methods 533 and 537.1. Of the 13 laboratories MNELAP queried, seven responded; six stating their RL was 2 ppt for the six applicable analytes while one has a RL of 1 ppt.

o MDH reviewed comments from the Environmental Monitoring Coalition (EMC), which stated that "most laboratories set the PQL as their MRL equal to the low calibration point which in Method 533 is 2 ng/L."

o In the future, more laboratories will be able to achieve lower RLs, but this proposed rule is not flexible with regard to future laboratory capabilities.

EPA Response: For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. The EPA disagrees that the final NPDWR "is not flexible with regard to future laboratory capabilities." Under SDWA, EPA is required to review NPDWRs at least once every six years and, if appropriate, revise them (i.e., the Six-Year Review Process). This evaluation considers any newly available data, information and technologies to determine if any regulatory revisions are needed to maintain or strengthen public health protection. This process allows the agency to consider future laboratory capability and other information in deciding whether existing NPDWRs should be identified as candidates for revision as required by SDWA.

Oklahoma Department of Environmental Quality (DEQ) (Doc. #1616, SBC-043043)

Additionally, the MCL being at the current detection limit of lab instrumentation requires a level of accuracy and precision that is not consistently attainable.

EPA Response: For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044052)

b. It is possible that some laboratories do not even have the report-generating capabilities to provide data for both the RL (PQL) and the MDL.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. A certified laboratory must be able to report results at or below the MCL or Hazard Index MCL. If a laboratory is required to provide multiple results, then they will need to have those report-generating capabilities. EPA further notes that using data submitted as part of the UCMR 5 LAP

as a reference point, the EPA notes that 47 of 53 laboratories (89 percent) that applied for UCMR 5 approval generated a MRL confirmation at 2 ng/L (one-half the proposed MCL) or less for Method 533. This suggests the majority of laboratories with the necessary instrumentation to support PFAS monitoring have the capability to provide screening measurement results at the revised trigger level of one-half of the MCL. This corresponds with commenters that provided their experience that laboratories are capable of reliably quantifying values below the PQLs, particularly to 2.0 ng/L for PFOA and PFOS. Regarding rule trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document.

Environmental Monitoring Coalition (EMC) (Doc. #1625, SBC-043105)

With the appropriate investment in laboratories (staffing, instrumentation, platform and method training), the laboratory community is confident they can meet the technical requirements for the testing to support drinking water utilities in their efforts to monitor PFAS.

EPA Response: The commenter supports the EPA's feasibility considerations in the final NPDWR as it relates to laboratory capability. For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-044894)

Even if labs make the above investment to seek to add capacity for PFAS analysis, there is no guarantee that the lab will be able to meet the extremely low reporting levels required by this proposed rule. If a lab is not able to meet the trigger level of one-third of the PQL for reporting, water systems will not be able to reduce their burden of monitoring frequency and will likely seek the services of a lab that can meet those lower reporting levels. This will likely further discourage labs from adding analysis capacity.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document. The commenter did not present evidence to support the assertion water systems will seek the services of a lab that can meet lower reporting limits and that this will "further discourage labs from adding analysis capacity."

Water One - Water District No. 1 of Johnson County, Kansas (Doc. #1627, SBC-042326)

Laboratory

The proposed Maximum Containment Levels (MCLs) of 4 parts per trillion (ppt) for PFAS is not based on sound science and is below detection limits of the EPA approved analytical methods originating from data collected for the PFAS compounds during UCMR 3. The analytical method that can achieve detection of these compounds at the proposed levels only became approved in

2020 and is just now being used in UCMR 5. There are a limited number of commercial laboratories with the capability to perform the analysis resulting in minimum turnaround times of 1-2 months that will be exacerbated when quarterly testing becomes required. Running this test internally, at our NELAC certified laboratory, would be a large investment ($500,000 or more) without a direct Return on Investment and likely take a year or more to become certified. Again, it should be reiterated that the proposed methodologies and regulation are premature and the laboratory infrastructure is not yet established to support this proposed rule.

Analyzing any compound at the part per trillion level is complicated at best and assigning health risks at values that low is even more challenging. Moreover, the risk of contaminated samples and analytical errors are extremely high at those levels. From a water utility perspective, those numbers are essentially zero as far as the public is concerned and other contaminant MCLs become more difficult to explain to the public.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. The commenter incorrectly cites that the proposed and final MCLs for PFOA and PFOS are below detection limits of the EPA approved analytical methods as they are instead equivalent to their PQLs which are distinctly different and significantly higher from the limits of detection. Regarding background contamination concerns, please see section 9.7 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044088)

Some primacy agencies have noted that the variation in sampling results at or near the PQL means that 25% or more of laboratories cannot meet below 4.0 ppt with a 95% confidence interval. This issue must be addressed before the final rule if EPA intends to maintain the proposed MCL of 4.0 ppt. Additionally, ASDWA's members have reported that some do not have state laboratories that can analyze PFAS samples, and even those with the capability do not necessarily analyze samples from water systems. Finally, since not all laboratories can provide results below 4.0 ppt, ASDWA's members anticipate a large influx of requests to those laboratories that can obtain results a lot lower than 4.0 ppt in order for systems to qualify for reduced monitoring. This will further strain laboratory capacity.

EPA Response: The EPA does not expect all laboratories to provide results below 4.0 ppt and disagrees that there is insufficient laboratory capacity at this time to support implementation of the NPDWR. For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs

to help operators manage their treatment operations, please also see section 5.1.2 of the EPA response in this *Response to Comments* document.

Association of Public Health Laboratories (APHL) (Doc. #1646, SBC-043302)

With the appropriate investment in laboratories (staffing, instrumentation, platform and method training), the laboratory community is confident they can meet the technical requirements for the testing to support drinking water utilities in their efforts to monitor PFAS.

EPA Response: The commenter supports the EPA's feasibility consideration in the final NPDWR as it relates to laboratory capability. For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Association of California Water Agencies (ACWA) (Doc. #1675, SBC-044936)

EPA states that "while EPA anticipates potential laboratory capacity issues if the Agency were to propose MCLs below 4.0 ppt, EPA believes there will be sufficient laboratory capacity with the MCLs set at 4.0 ppt." [FN29: 88 Fed. Reg. at 18,667.] ACWA disagrees with this belief and is concerned that there is already insufficient laboratory capacity. For example, during the California State Water Resources Control Board's (SWRCB's) recent 2023-24 Environmental Laboratory Accreditation Program fees workshop on March 10, 2023, and in e-mails afterward, SWRCB staff confirmed there had been a decrease of accredited state labs in California from 626 to 475, or nearly 25%.

EPA acknowledges this reality when it stated that "rigorous laboratory certification and quality assurance/ quality control procedures could limit the number of laboratories that can achieve lower quantitation levels and many water systems would not be able to secure the services of laboratories that are capable of consistently providing precise and accurate quantitation of concentrations of PFOA and PFOS at levels lower than 4.0 ppt." [FN30: 88 Fed. Reg. at 18.667.]

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding rule trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document.

Rockbridge Area Conservation Council (RACC) (Doc. #1678, SBC-043741)

EPA's rational for selecting the 4 ppt MCL levels for these chemicals may be a practical acknowledgement of the current inadequate analytical reality, however, it does not justify them toxicologically, nor does it 1) establish a timeline for EPA-certified commercial labs to improve their detection and quantification capabilities toward those commonly available in university and industry research labs – or 2) establish a parallel automatic adoption of the lower limits of quantification as MCLs. Both are needed to create the incentives for improving the degree of

protection of public health through investment in better lab technology and eliminate the undue burden on the Agency to repeatedly promulgate new MCL's for the same PFAS as those improvements are realized.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please also see section 5.1.2 of the EPA response in this *Response to Comments* document. The agency disagrees that establishing a "parallel automatic adoption of the lower limits of quantification as MCLs" is needed to improve public health protection. Under SDWA, EPA is required to review NPDWRs at least once every six years and, if appropriate, revise them (i.e., the Six-Year Review Process). This evaluation considers any newly available data, information and technologies to determine if any regulatory revisions are needed to maintain or strengthen public health protection. This process allows the agency to consider future improved laboratory capability and other information in deciding whether existing NPDWRs should be identified as candidates for revision as required by SDWA.

Private Citizen – General (Doc. #1722, SBC-043833)

2. Please pass the MCLGs as MCLs for PFAS chemicals. Labs can detect them much lower than 4 parts per trillion. For decades we have been exposed to these chemicals without our knowledge and we do not want to assume any additional risk - as scientists have been saying, there is no safe level of PFAS exposure.

EPA Response: For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Please also see section 5.1.3 of the EPA response in this *Response to Comments* document on alternative MCLs which includes a discussion on a lower MCL alternative.

Thurston Public Utility District (PUD), WA (Doc. #1729, SBC-043589)

8. On page 18,667, the document addresses laboratories. We had issues with laboratories not having the capability to adequately and accurately test the Washington State SAL level, let alone the very low MCL levels being considered by the EPA. Our utility had to send samples out-of-state for testing because there was not a lab available in Washington State that could test our samples. Not every laboratory applied to participate in UCMR5.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Thurston Public Utility District (PUD), WA (Doc. #1729, SBC-043585)

4. Please consider short-term and long-term solutions for insufficient laboratory capability and capacity. This rule could cause laboratories to be overburdened when the rule becomes effective and when initial monitoring requirements trigger quarterly monitoring.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045216)

Lab Methods & Capacity

1. EPA requests comment on its proposed determination to set MCLs at 4.0 ppt for PFOA and PFOS and whether 4.0 ppt is the lowest Practical Quantification Level (PQL) that can be achieved by laboratories nationwide.

Of the ten laboratories that the CT DPH Environmental Laboratory Certification Program (ELCP) currently has certified for EPA method 533, seven have calibrations established at concentrations less than 1.0 ppt, and the other three have calibrations established at 2.0 ppt. However, the current levels are being demonstrated on brand new equipment. At this time, it is difficult to determine if instrument sensitivity will decrease over time and if labs will have difficulty meeting these low levels in the future. However, setting the Maximum Contaminant Level (MCL) at the PQL limits the ability for PWSs to accurately monitor the annual running average of PFAS if the concentrations fluctuate near the MCL.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please also see section 5.1.2 of the EPA response in this *Response to Comments* document.

El Paso Water (Doc. #1757, SBC-044522)

Further, there are very few laboratories that currently have the capability to test at the new levels. In the state of Texas, we only have knowledge of one laboratory that can perform this testing. That could result in a monopoly situation, sky-high prices, and back-logs that create compliance challenges.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-045688)

b. Testing Methods Do Not Provide the Analytical Capacity to Identify or Distinguish Between the Ultra-low Levels at Issue in the Proposed Rule

The proposed MCLs for PFOA and PFOS are set at the practical quantitation level (PQL) of 4.0 ng/L and EPA proposes setting a rule trigger level of one-third the MCL to determine compliance monitoring frequency (USEPA 2023f, p. 18681). The PQL is defined as "the lowest concentration that PFOA and PFOS can be reliably quantified" (USEPA 2023f, p. 18666). By definition, measurement results less than the PQL are not reliably quantified and therefore not suitable for quantitative comparison against a standard. EPA notes that most of the laboratories seeking UCMR 5 approval included a calibration standard below the 4.0 ng/L PQL, while also noting that, "measuring PFOA and PFOS results below the PQLs may not be achievable from all laboratories" (USEPA 2023f, p. 18867). EPA also assumes the laboratory market for PFAS analyses will expand (USEPA 2023f, p. 18867). It is not safe to assume that as the market grows, new laboratories will have the same proficiency as existing experienced laboratories that already may not be able to measure below the PQL.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please also see section 5.1.2 of the EPA response in this *Response to Comments* document. Results below the PQL are only used in the determination of monitoring frequency and not compliance calculations. Additionally, as it was incompletely cited by the commenter, the EPA further clarifies that the PQL is defined as "the lowest levels at which contaminants can be reliably quantified within specific limits of precision and accuracy during routine laboratory operating conditions using the approved methods." For the purposes of determining whether a system can reduce their monitoring frequency, the values do not need the same level of precision and accuracy. Please see sections 8.2 and 8.8 of the EPA response in this *Response to Comments* document regarding the compliance calculation and rule trigger levels, respectively. The commenter also did not provide data or rationale to support their claims that "it is not safe to assume that as the market grows, new laboratories will have the same proficiency as existing experienced laboratories that already may not be able to measure below the PQL." As reflected in the PQL, 75 percent or more of participating laboratories will be able to set a MRL with a 95 percent confidence interval. As discussed in 5.1.2 of the EPA response in this *Response to Comments* document, the EPA's historical experience with other NPDWRs provides a record demonstrating that laboratory capacity is expected to grow once the rule is finalized as the opportunity for increased revenue by laboratories would be realized by filling the analytical needs of the utilities.

Northwest Biosolids Association et al. (Doc. #1783, SBC-043802)

Sampling and Laboratory Limitations. There are limited laboratories capable of testing water for PFAS at these reduced limits and arduous sampling protocols that require additional tools, instrumentation and very specific requirements of the person(s) doing the sampling (i.e. no laundered clothing can be worn, no showers for several days, no brushing of teeth, specific clothing). All these additional steps will require resources that clean water facilities are not currently funded for.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. The validated methods (Method 533 and 537.1 v2) used to support the final rule do not have inherent QC issues if appropriately followed; these methods do not include the sampling protocols such as "no showers for several days" as suggested by the commenter. For concerns related to sampling and background contamination issues, please see section 9.7 of the EPA response in this *Response to Comments* document. Regarding the rule trigger levels for reduced triennial monitoring, please see section 8.8 of the EPA response in this *Response to Comments* document.

Mindi Messmer (Doc. #1788, SBC-044707)

2. Please pass the MCLGs (from June 2022) as MCLs for PFAS chemicals. Labs can detect PFOA and PFOS in the range of 1 to 2 parts per trillion (ppt) now which is about half the proposed MCL. For decades we have been exposed to these chemicals without our knowledge and we do not want to assume any additional risk – as scientists have been saying, there is no safe level of PFAS exposure.

EPA Response: For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Please also see section 5.1.3 of the EPA response in this *Response to Comments* document on alternative MCLs which includes a discussion on a lower MCL alternative.

Fairfax Water (Doc. #1789, SBC-045309)

Inadequate Laboratory Capacity for PFAS Analysis

The EPA proposed MCLs for PFOA and PFOS are at the limits of detection. The ubiquity of PFAS in the environment and the extreme precautions that must be taken when collecting and analyzing PFAS samples to avoid cross-contamination, increase the risk of error in PFAS testing results. There is currently no EPA regulation for PFAS in drinking water and UCMR5 testing is just now beginning, yet utilities are experiencing longer and longer turnaround times for PFAS

analysis from certified laboratories. In our most recent rounds of sampling, Fairfax Water's turnaround times from contract laboratories have gone from weeks to months.

The capacity of certified labs to keep up with the increasing demands for PFAS testing for multiple regulatory tracks, e.g., UCMR5, drinking water, wastewater, and others is a significant concern.

No on-line instrumentation currently exists to monitor PFAS concentrations for process control in a water treatment plant. A utility using GAC for PFAS removal must instead rely on a series of routine samples analyzed in a laboratory to ensure that PFAS levels in the treated drinking water remain within compliance. Whether using pressure vessels or gravity contactors filled with GAC, in an operational setting water samples must be taken from various depths in the media on a regular basis and analyzed for PFAS. The results of these samples then provide an indication of where the PFAS breakthrough is within the GAC column, indicating remaining adsorptive capacity so that utilities know when they need to replace GAC media.

Consultants for Fairfax Water estimate that our Griffith plant would require the construction of twenty-four gravity GAC contactors to meet the proposed MCLs for PFOA and PFOS, operating in a lead-lag configuration. Once in service, on a monthly basis the lead contactors would each have to be sampled at four different levels within the filter column as well as at the individual contactor effluent. This equates to 60 PFAS samples per month (12x5) or 720 PFAS samples to be analyzed annually for process monitoring. That compares to 12 point of entry compliance samples specified in the proposed rule or a 60-fold increase in the number of samples that would have to be analyzed annually. The current laboratory turnaround times are unacceptable to support PFAS treatment operations. When the proposed rule is finalized the demand for laboratory analyses for PFAS will grow exponentially to support treatment operations. EPA should delay the compliance period for the rule to provide time for laboratories to develop the capacity necessary to support the significant increase in operational process control analyses for PFAS, otherwise operation of PFAS removal treatment trains will be adversely impacted.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please also see section 5.1.2 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenter that the MCLs are set at the limits of detection, but rather they are set at the PQLs which are distinctly different than the limit of detection and significantly higher. For concerns related to sampling and background contamination issues, please see section 9.7 of the EPA response in this *Response to Comments* document. Regarding concerns for voluntary sampling to monitor treatment performance (i.e., performance monitoring), the EPA anticipates that many water systems will conduct a pilot test before implementing a full-scale treatment installation and that the results from the pilot test will be a sufficient enough indicator of performance as well as break through

curves to inform operational monitoring; therefore, water systems should not have to collect large amounts of performance samples indefinitely during the full-scale operation of treatment technologies. Please see section 13.3.3 of the EPA response in this *Response to Comments* document for additional details on how these considerations were factored into the EPA's cost estimates. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Mark Gearreald (Doc. #1792, SBC-044296)

2. Please pass the MCLGs as MCLs for PFAS chemicals. Labs can detect them much lower than 4 parts per trillion. For decades we have been exposed to these chemicals without our knowledge and we do not want to assume any additional risk - as scientists have been saying, there is no safe level of PFAS exposure.

EPA Response: For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Please also see section 5.1.3 of the EPA response in this *Response to Comments* document on alternative MCLs which includes a discussion on a lower MCL alternative.

James McConnell (Doc. #1793, SBC-044702)

2. Please pass the MCLGs as MCLs for PFAS chemicals. Labs can detect them much lower than 4 parts per trillion. For decades we have been exposed to these chemicals without our knowledge and we do not want to assume any additional risk - as scientists have been saying, there is no safe level of PFAS exposure.

EPA Response: For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Please also see section 5.1.3 of the EPA response in this *Response to Comments* document on alternative MCLs which includes a discussion on a lower MCL alternative.

New England Water Works Association (Doc. #1836, SBC-045384)

Source Water and Analytical Variability:

Through the years of sampling by PWS across New England, it is not uncommon for different labs to report a variance of several parts per trillion +/- in PFAS when analyzing the exact same source water. We question whether we are pushing the sensitivity of the equipment to a point where it cannot be reliably quantified. A sample is considered valid at +/-30%, and when

discussing regulatory compliance levels in the low parts per trillion, this is concerning. As a point of illustration, the following are split sample results for a utility in Massachusetts. The sample date was 12/11/2020, lab A's result was 12.7 ppt, while lab B's result was 20.56 – both were valid results, yet the swing was 7.86 ppt. This analytical variability is well over what EPA proposes as the MCL so PWS could be subject to noncompliance and enforcement due to analytical variability alone.

Some PWS have seen +/- parts per trillion variability in PFOS and PFOA concentrations when collecting monthly samples; even a 1-2 ppt variation can represent over 40% variability when close to the Method Detection Limit (MDL). It is difficult to tell if this variability is attributable to changes of PFOS and PFOA concentrations in the source water or if it is linked to the variability of the analytical method (+/- 30%). Having a proposed Rule Trigger Level of 1/3, the PFOS and PFOA MCL or Hazard Index may have PWS and primacy agencies fluctuating back and forth on whether the PWS is eligible for a monitoring waiver, and may impact the running annual average calculation. This uncertainty creates unnecessary complexity, increased level of effort, and continued erosion of public confidence.

We are also aware of several instances where it was found that lab instrumentation was not properly cleaned between sample runs, resulting in erroneous detections. It is paramount that labs are not doing cross matrix analysis on machines that analyze drinking water samples.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For concerns related to sampling and background contamination issues, please see section 9.7 of the EPA response in this *Response to Comments* document. Regarding rule trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document. Please also see the EPA response to comment Doc. #1677, SBC-044955 in section 5.1.2 in this *Response to Comments* document for commenter claims on the 30 percent - 50 percent acceptance criteria in the reported result.

Douglas Whitbeck (Doc. #1853, SBC-045503)

2. Please pass the MCLGs as MCLs for PFAS chemicals. Labs can detect them much lower than 4 parts per trillion. For decades we have been exposed to these chemicals without our knowledge and we do not want to assume any additional risk - as scientists have been saying, there is no safe level of PFAS exposure.

EPA Response: For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Please also see section 5.1.3 of the EPA response in this *Response to Comments* document on alternative MCLs which includes a discussion on a lower MCL alternative.

David McGraw (Doc. #1854, SBC-045522)

2. Please pass the MCLGs as MCLs for PFAS chemicals. Labs can detect them much lower than 4 parts per trillion. For decades we have been exposed to these chemicals without our knowledge and we do not want to assume any additional risk - as scientists have been saying, there is no safe level of PFAS exposure.

EPA Response: For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Please also see section 5.1.3 of the EPA response in this *Response to Comments* document on alternative MCLs which includes a discussion on a lower MCL alternative.

Barbara Glassman (Doc. #1855, SBC-045525)

2. Please pass the MCLGs as MCLs for PFAS chemicals. Labs can detect them much lower than 4 parts per trillion. For decades we have been exposed to these chemicals without our knowledge and we do not want to assume any additional risk - as scientists have been saying, there is no safe level of PFAS exposure.

EPA Response: For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Please also see section 5.1.3 of the EPA response in this *Response to Comments* document on alternative MCLs which includes a discussion on a lower MCL alternative.

Elizabeth A. Trought (Doc. #1856, SBC-045528)

2. Please pass the MCLGs as MCLs for PFAS chemicals. Labs can detect them much lower than 4 parts per trillion. For decades we have been exposed to these chemicals without our knowledge and we do not want to assume any additional risk - as scientists have been saying, there is no safe level of PFAS exposure.

EPA Response: For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Please also see section 5.1.3 of the EPA response in this *Response to Comments* document on alternative MCLs which includes a discussion on a lower MCL alternative.

Kris Pastoriza (Doc. #1857, SBC-045531)

2. Pass the MCLGs as MCLs for PFAS chemicals. There is no safe level of PFAS exposure. You contain them.

EPA Response: For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Please also see section 5.1.3 of the EPA response in this *Response to Comments* document on alternative MCLs which includes a discussion on a lower MCL alternative.

Andrea Thorn (Doc. #1858, SBC-045534)

2. Please pass the MCLGs as MCLs for PFAS chemicals. Labs can detect them much lower than 4 parts per trillion. For decades we have been exposed to these chemicals without our knowledge and we do not want to assume any additional risk - as scientists have been saying, there is no safe level of PFAS exposure.

EPA Response: For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Please also see section 5.1.3 of the EPA response in this *Response to Comments* document on alternative MCLs which includes a discussion on a lower MCL alternative.

Jon Swan (Doc. #1859, SBC-045537)

2. Please pass the MCLGs as MCLs for PFAS chemicals. Labs can detect them much lower than 4 parts per trillion. For decades we have been exposed to these chemicals without our knowledge and we do not want to assume any additional risk - as scientists have been saying, there is no safe level of PFAS exposure.

EPA Response: For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Please also see section 5.1.3 of the EPA response in this *Response to Comments* document on alternative MCLs which includes a discussion on a lower MCL alternative.

Steven Cea (Doc. #1860, SBC-045540)

2. Please pass the MCLGs as MCLs for PFAS chemicals. Labs can detect them much lower than 4 parts per trillion. For decades we have been exposed to these chemicals without our knowledge

and we do not want to assume any additional risk - as scientists have been saying, there is no safe level of PFAS exposure.

EPA Response: For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Please also see section 5.1.3 of the EPA response in this *Response to Comments* document on alternative MCLs which includes a discussion on a lower MCL alternative.

Kathy Malsbenden (Doc. #1861, SBC-045543)

2. Please pass the MCLGs as MCLs for PFAS chemicals. Labs can detect them much lower than 4 parts per trillion. For decades we have been exposed to these chemicals without our knowledge and we do not want to assume any additional risk - as scientists have been saying, there is no safe level of PFAS exposure.

EPA Response: For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Please also see section 5.1.3 of the EPA response in this *Response to Comments* document on alternative MCLs which includes a discussion on a lower MCL alternative.

Michael Letendre (Doc. #1862, SBC-045546)

2. Please pass the MCLGs as MCLs for PFAS chemicals. Labs can detect them much lower than 4 parts per trillion. For decades we have been exposed to these chemicals without our knowledge and we do not want to assume any additional risk - as scientists have been saying, there is no safe level of PFAS exposure.

EPA Response: For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Please also see section 5.1.3 of the EPA response in this *Response to Comments* document on alternative MCLs which includes a discussion on a lower MCL alternative.

Idaho Environmental Coalition (Doc. #3030, SBC-047328)

Significant costs may be realized for laboratory analysis and treatment methods because sampling existing groundwater wells that contain equipment with PFAS components could indicate groundwater contamination when PFAS contamination is not present in the groundwater. Costs could also be significant if existing well equipment had to be removed and

replaced with equipment that is free of PFAS components, or if new wells were drilled to obtain background samples with PFAS-free well equipment. Existing laboratory contracts would need to be renegotiated to determine if the laboratory had the capability to report PFOA and PFOS at levels below the 4 ppt proposed MCL. Laboratories that state PFOA and PFOS detection levels of 1 to 2 ppt would most likely flag results below 10 ppt as J or UJ. Is it cost effective to implement treatment methods if a result of 8 ppt has a J flag? Can treatment methods be shown to meet the MCL if effluent data have J flags?

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Please see section 9.7 of the EPA response in this *Response to Comments* document regarding sample and background contamination issues. Additionally, under the EPA drinking water PFAS methods, laboratories are required to meet MRLs which are no less than any of the regulated PFAS PQLs. Therefore, any level above the PQLs is required to be quantified and would not be flagged as a non-quantifiable value. Furthermore, for the purpose of calculating MCL compliance, if a sample result is less than the PQL for a regulated PFAS, zero is used for that analyte solely to calculate the RAA. (see section 8.2 of the EPA response in this *Response to Comments* document), and water systems would not be required to take actions such as treatment for levels below the EPA's PQLs.

Citizens Energy Group (Doc. #1838, SBC-044865)

EPA requests comment on other monitoring related considerations including laboratory capacity and QA/QC of drinking water sampling.

Citizens is concerned with the long-term availability of certified drinking water laboratories to perform analysis for PFAS in a timely way given the limited number of laboratories certified and capable of performing the analysis under the Safe Drinking Water Act.

Constraints in the laboratory supply chain can lead to delays in receiving data. If a water system performs sampling as required (e.g., on a quarterly basis) but the analytical results are delayed beyond the end of the reporting period, water systems should not be subject to enforcement actions or public notifications for "failure to monitor".

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For a discussion of PN requirements, see section 9.2 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045953)

EPA creates some confusion when it states in the preamble, "Measuring PFOA and PFOS results below the practical quantification level (PQL) may not be achievable from all laboratories and may not have the same precision as higher-level measurements, nor does EPA believe it is appropriate to make potentially costly compliance decisions based on such lower-level measurements." However, EPA also states that it assumes water systems will treat to 80% of the proposed MCL to include "a margin of safety." Installing these treatment techniques will take several years, so a utility risks being in noncompliance at any moment if it is approaching detection at the proposed 4.0 ppt MCL, even though EPA has expressed that it is not "appropriate" to make costly decisions on these low-level measurements. Therefore, water systems with 3.2-4.0 ppt samples whose running annual average (RAA) is below 4.0 ppt will have to decide to install treatment in case there is seasonal variability or spikes that may put them out of compliance, potentially costing them, and therefore ratepayers, millions of dollars to get under this margin of safety that cannot be reliably measured.

Several AMWA members have detected PFOA and PFOS in the 3.0-5.0 ppt range and will have to make decisions on how to address PFAS (see Attachments 2, 3, and 4). Source control is an effective way for some water systems detecting PFOS and PFAS at these levels; however, it takes significant time to both identify the source and address the issue, and for levels to decrease in response to the action. Not only will source control save money for ratepayers in these service areas, but it will ease supply chain and labor demands for water systems with higher levels of PFAS that are a greater risk to public health. Source control will also address the problem of PFAS accumulation in the environment. PFAS are known as "forever chemicals" and are very persistent, so preventing PFAS pollution is more responsible and protective of public health than treating after PFAS are released into source waters.

EPA Response: For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. The EPA disagrees that a system would risk being out of compliance "at any moment if it is approaching a detection at the proposed 4.0 ppt MCL." This is because, for purposes of determining compliance with the MCL, the use of the RAA of results could allow some results to exceed 4.0 ng/L for single measurements if the overall annual average is below the MCL. In other words, there is a buffer built into determining compliance with the MCL. Second, when calculating the RAA, zero will be used for results less than the PQL which provides an additional analytic buffer for utilities in their compliance calculations. This monitoring and compliance framework allows for temporal fluctuations in concentrations that may occur because of unexpected events such as premature PFOA and PFOS breakthrough or temporary elevated source water concentrations. Thus, periodic occurrences of PFAS that are slightly above the PQLs do not necessarily result in a violation of the MCL if other quarterly samples are below the PQL. The EPA also notes that, for the PFAS regulated by the NPDWR, all the PQLs are well above their limits of detection. The

PQL is also different than detection limits because the PQL is set considering a level of precision, accuracy and quantitation. Systems may be able to use sample results below the PQL to understand whether PFAS are present. While the EPA has determined that results below the PQL are insufficiently precise for determining compliance with the MCL, results below the PQL can be used to determine analyte presence or absence in managing a system's treatment operations. In the example provided by the commenter, zero will be used for sample results below 4.0 ppt for PFOA and PFOS for purposes of compliance determinations and RAA calculations. For additional discussion on laboratory considerations and practical quantitation limits, please see section 5.1.2 summary, section 8.7 summary, and section 7.2 summary in this *Response to Comments* document.

The agency also acknowledges responses that it may be prudent for systems that are close to the MCL to have time to identify and address sources of PFAS in their watersheds rather than investing resources on treatment initially. Related to this matter, the EPA notes that the agency is exercising its authority under Section 1412(b)(10) of SDWA to implement a nationwide capital improvement extension to comply with the MCL such that the compliance date for the PFAS MCLs will be 5 years from the date of promulgation. While allowing time for source water investigation was not the basis for the agency's decision to extend the compliance date for the PFAS MCLs, the EPA believes that extending the compliance date may provide opportunities for systems who are close to exceeding the MCLs to investigate sources of contamination. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12.1 summary in this *Response to Comments* document on extensions and exemptions. The EPA also notes that the IIJA, also known as the BIL, has provided significant funding ($10 billion in total) available to PWSs through the SRFs and grant programs to reduce people's exposure to PFAS and other emerging contaminants through their drinking water, to help address discharges through wastewater, and to support source water protection efforts.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-044896)

DEP believes that performance monitoring for systems with PFAS removal treatment will be an implementation challenge with regard to the proposed MCLs. Demonstrating treatment efficacy over time is critical for systems with PFAS removal treatment. Monitoring results are a key data point for system operators in knowing when to switch between lead and lag units and when to change out media. However, the proposed MCLs complicate this effort, because it is not clear what is considered a detection or at what level breakthrough would occur. From a treatment design standpoint, operators need room between detection limits and MCLs in order to ensure continuous compliance and treatment efficacy. This is another implementation challenge caused by setting MCLs at levels such that any detection over the PQL will cause an exceedance.

EPA Response: For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of

sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

National Ground Water Association (NGWA) (Doc. #1804, SBC-045462)

The HI approach ends up eliminating a PFAS in the calculation of the HI if it is non-detect (assuming it is 0). How is analytical dilution accounted for? If the reporting limit (RL) for a sample is above the heath-based water concentration (HBWC) then it would be incorrect to assume that non-detects are not present above the HBWC. Replacing non-detects with 0 is a long-known concern in the public health/environmental field. There are methods to handle these censored data. It is against best practices defined by EPA itself in its Unified Guidance to replace non-detects with 0. [FN5: U.S. Environmental Protection Agency (USEPA). 2009. Statistical Analysis Of Groundwater Monitoring Data At RCRA Facilities; Unified Guidance. EPA 530/R-09-007. https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P10055GQ.txt (Accessed April 7, 2023)]

The HI approach is an annual averaging approach. For example, if quarterly samples are collected then the HI for each quarter is calculated and then the 4 HIs are then averaged and if that average is below the HI no exceedance is found, even if 1 of the quarterly HIs is above 1.0. For EPA regulatory programs such as RCRA, exceedances of the MCL are determined based on the upper confidence limit (UCL) of the mean not the mean itself. The UCL approach accounts for observed variability.

EPA Response: For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. With respect to responses on analytical dilution for purposes of compliance monitoring, the agency is clarifying that the HBWCs for PFHxS, PFNA, and HFPO-DA are 10 ppt each. For PFBS, the HBWC is at 2000 ppt. Since these HBWCs are well above the PQLs for each of these respective compounds (the PQLs are between 3 to 5 ppt), there is no concern for censoring data. For additional discussion on compliance and the use of values below the PQL for compliance calculations, please see section 8.2 of the EPA response in this *Response to Comments* document. Further, the EPA notes that applications of the MCL in other EPA regulatory programs (such as Resource Conservation and Recovery Act [RCRA]) is beyond the scope of this rulemaking. Nonetheless, the approved drinking water methods use the measured value and do not apply confidence intervals as variance with the reported result.

Superfund Settlements Project (SSP) and RCRA Corrective Action Project (RCAP) (Doc. #1631, SBC-043440)

As a final point, SSP and RCAP agree with the commenter from EPA's outreach consultations that advised "water systems operate with a margin of safety and plan for performance that

maintains water quality below quantitation levels" and, accordingly, "having an increased buffer between the PQL and the MCL may allow utilities to manage treatment technology performance more efficiently because utilities typically aim to achieve lower than the MCL to avoid a violation." [FN61: 88 Fed. Reg. 18670.] Remediation treatment system equipment is similarly difficult to reliably operate when the treatment goal is the PQL of the analytical method. At the very minimum, therefore, the PFOA and PFOS MCLs should be sufficiently higher than the PQL to allow for reliable operations.

EPA Response: For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Oklahoma Department of Environmental Quality (DEQ) (Doc. #1616, SBC-043054)

Whole-of-government Approach

DEQ recommends that EPA strengthen the source protection program to prevent PFAS from entering drinking water sources.

EPA should work to quickly finalize Draft Method 1633 for labs to analyze samples for surface water, ground water, and other media.

DEQ recommends that EPA use a holistic lifecycle approach that includes close coordination with other Federal agencies to administer all possible Federal statutory regulatory authorities to address PFAS concerns.

Using a holistic approach to reduce or eliminate the use of PFAS, and to prevent these compounds from entering the environment and drinking water sources throughout any part or all of the chemical's lifecycle, from manufacturing through processing, distribution, and disposal, is much more effective and less expensive than having to remove PFAS compounds once contamination has occurred.

Consideration should be given to potential impacts from disposal and incineration under each regulatory authority to ensure that the responsibility and cost for removing PFAS are not passed on from one media to another.

Thank you for this opportunity to provide comment. We hope these comments will be helpful to EPA in making a final decision on the rule. If you have any questions or would like to discuss these comments in more detail, please contact me or Shellie Chard at Shellie.Chard@deq.ok.gov and (405) 702-8157.

Sincerely,

Scott A. Thompson

Executive Director

Oklahoma Department of Environmental Quality

Scott.Thompson@deq.ok.gov

405-702-7161

cc: Jennifer McLain, OGWDW

EPA Response: The EPA's PFAS Strategic Roadmap lays out EPA's whole of agency approach to tackling PFAS. The PFAS Strategic Roadmap describes how EPA will get upstream of the problem and bring deeper focus to preventing PFAS from entering the environment in the first place—a foundational step to reducing the exposure and potential risks of future PFAS contamination. The EPA notes that the other actions to address sources of PFAS are highlighted in the agency's PFAS Strategic Roadmap and are beyond the scope of this rulemaking (please see section 15.1 of the EPA response in this *Response to Comments* document for additional information). For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. The EPA's Office of Water, in partnership with the Department of Defense's (DoD) Strategic Environmental Research and Development Program, has published Method 1633, "Analysis of Per- and Polyfluoroalkyl Substances (PFAS) in Aqueous, Solid, Biosolids, and Tissue Samples by LC-MS/MS," a method to test for 40 PFAS compounds in wastewater, surface water, groundwater, soil, biosolids, sediment, landfill leachate, and fish tissue. The EPA notes that Method 1633 is not a drinking water method and is not approved to meet the monitoring requirements of this final NPDWR. The EPA notes that the agency has provided *Interim Guidance on Destroying and Disposing of Certain PFAS and PFAS-Containing Materials* and that the agency is updating that guidance which outlines the current state of the science on techniques and treatments (including incineration) that may be used to destroy or dispose of PFAS and PFAS-containing material.

Environmental Monitoring Coalition (EMC) (Doc. #1625, SBC-043112)

3. Additional PFAS Analytes

Since the development of the original "Priority Pollutant" list in 1976, each EPA Program Office has developed their own unique monitoring list which tends to complicate cross media monitoring. As former EPA Assistant Administrator Paul Anastas stated in 2021:

While environmental chemistry has shown that chemicals move readily between media, the foundational U.S. environmental regulations do not. Many argue that controls on air pollutants, for instance, often result in the discharge of the same chemicals into the land or water without reducing the total number of harmful substances released into the environment. For example, the Clean Air Act requires most utilities that burn high-sulfur coal to use scrubbers to remove sulfur dioxide from their flue gases, but this type of air pollution control produces three to six tons of scrubber sludge for every ton of sulfur dioxide removed from the air. The limitations presented by this legal framing of environmental protection is reinforced and fortified by the analogous

organizational structure of the EPA, with offices closely aligned with each media/statute. There's an old design saying, "form follows function". The U.S. EPA perhaps has that saying backward because at the agency, function often follows form. Water standards are reviewed and enforced not because they are the greatest threat to human health of the environment but rather because it is simply what the Office of Water is legally mandated to do. Since EPA personnel have labored in an organizational structure where too often "form enables dysfunction," it is necessary to pursue new organizational models. In times of crisis, such as the 2010 oil spill in the Gulf of Mexico and the nuclear meltdown at Fukushima in 2011, the EPA draws together all of the capabilities and perspectives across the agency into the Emergency Operation Center. Together, all of the disciplines, skill sets, and resources of the agency are focused on the crisis at hand. This model is critically necessary now, at a time when we have numerous environmental and public health crises, some immediate and acute while others are slow and chronic, emerging in real-time, such as climate change resulting in wildfires throughout the American West; hurricanes increasingly devastating the American South; environmental injustice and health disparities in communities that are disproportionality poor and of color; and biodiversity resulting in degraded ecosystem health. While these crises may be chronic conditions resulting in acute impacts, and unfold over years rather than days, they are also crises that require an integrated and cohesive response that incorporates all of the talents across the EPA. The EPA's model must not continue to be fragmented, isolated, and myopically aligned with half-century old laws. It must instead break down old organizational barriers to create new agile, rapid response teams that are capable of addressing problems in the necessary time frame. This would require a complete restructuring of the EPAs organizational hierarchy. Instead of offices that are a reflection of outdated statutes, there would be a matrix that reflects the capabilities and resources within the agency. As problems are identified and prioritized, individuals from each of the "resource centers" would be assigned to work on that problem as part of a multidisciplinary team. These may range from small strike forces of a few individuals with the proper background for a short amount of time in discrete emergencies, to larger, complex teams that will be used to focus on an ongoing issue for years. All of these efforts would benefit from a matrix organizational structure that brings together the full capabilities of the agency and allows it to more effectively leverage and interconnect with other efforts in localities, states, and other federal entities. Of course, this activity could be decoupled from organizational structure and implemented while the longer-term process of reorganizing the agency is pursued. (Moving from Protection to Prosperity: Evolving the U.S. Environmental Protection Agency for the next 50 years, Environmental Science & Technology pubs.acs.org/est Policy Analysis https://dx.doi.org/10.1021/acs.est.0c07287 Environ. Sci. Technol. 2021, 55, 2779−2789)

Given that the EPA is increasing its scrutiny to more PFAS compounds, for example, the CERCLA Advanced Notice of Proposed Rulemaking published on April 13, 2023 (https://www.govinfo.gov/content/pkg/FR-2023-04-13/pdf/2023-07535.pdf) specifically addresses PFBA as becoming a "hazardous constituent" under CERCLA. In addition, the toxicity profile of PFBA is mentioned several times in the proposed drinking water rule. Furthermore, the EPA Clean Water Act and Resource Conservation and Recovery Act programs are also

developing methods 1633 and 8327 with their own lists of PFAS analytes, and the ORCR is also considering adding PFAS analytes to the Appendix VIII hazardous constituents in 40 FCFR 261.The EMC, therefore, recommends the Drinking Water program collaborate with other EPA program offices to come up with one standardized list. EMC seeks clarification on reporting additional PFAS analytes. EMC would note that some states have their own PFAS reporting lists.

EPA Response: The EPA is taking an all-of-agency approach toward addressing PFAS as discussed in the agency's PFAS Strategic Roadmap (please see section 15.1 of the EPA response in this *Response to Comments* document for additional information). For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. At the time of rule proposal, EPA did not have sufficient information to inform a regulatory determination for PFBA. The EPA notes that application of MCLs in non-drinking water programs (such as water quality criteria, NPDES, or CERCLA cleanups) is beyond the scope of this rulemaking; please see section 15.1 of the EPA response in this *Response to Comments* document for additional discussion on comments outside the scope of this NPDWR.

Association of Public Health Laboratories (APHL) (Doc. #1646, SBC-043320)

3. Additional PFAS Analytes

Since the development of the original "Priority Pollutant" list in 1976, each EPA Program Office has developed their own unique monitoring list which tends to complicate cross media monitoring. As former EPA Assistant Administrator Paul Anastas stated in 2021:

While environmental chemistry has shown that chemicals move readily between media, the foundational U.S. environmental regulations do not. Many argue that controls on air pollutants, for instance, often result in the discharge of the same chemicals into the land or water without reducing the total number of harmful substances released into the environment. For example, the Clean Air Act requires most utilities that burn high-sulfur coal to use scrubbers to remove sulfur dioxide from their flue gases, but this type of air pollution control produces three to six tons of scrubber sludge for every ton of sulfur dioxide removed from the air. The limitations presented by this legal framing of environmental protection is reinforced and fortified by the analogous organizational structure of the EPA, with offices closely aligned with each media/statute. There's an old design saying, "form follows function". The U.S. EPA perhaps has that saying backward because at the agency, function often follows form. Water standards are reviewed and enforced not because they are the greatest threat to human health of the environment but rather because it is simply what the Office of Water is legally mandated to do. Since EPA personnel have labored in an organizational structure where too often "form enables dysfunction," it is necessary to pursue new organizational models. In times of crisis, such as the 2010 oil spill in the Gulf of Mexico and the nuclear meltdown at Fukushima in 2011, the EPA draws together all of the capabilities and perspectives across the agency into the Emergency Operation Center. Together,

all of the disciplines, skill sets, and resources of the agency are focused on the crisis at hand. This model is critically necessary now, at a time when we have numerous environmental and public health crises, some immediate and acute while others are slow and chronic, emerging in real-time, such as climate change resulting in wildfires throughout the American West; hurricanes increasingly devastating the American South; environmental injustice and health disparities in communities that are disproportionality poor and of color; and biodiversity resulting in degraded ecosystem health. While these crises may be chronic conditions resulting in acute impacts, and unfold over years rather than days, they are also crises that require an integrated and cohesive response that incorporates all of the talents across the EPA. The EPA's model must not continue to be fragmented, isolated, and myopically aligned with half-century old laws. It must instead break down old organizational barriers to create new agile, rapid response teams that are capable of addressing problems in the necessary time frame. This would require a complete restructuring of the EPAs organizational hierarchy. Instead of offices that are a reflection of outdated statutes, there would be a matrix that reflects the capabilities and resources within the agency. As problems are identified and prioritized, individuals from each of the "resource centers" would be assigned to work on that problem as part of a multidisciplinary team. These may range from small strike forces of a few individuals with the proper background for a short amount of time in discrete emergencies, to larger, complex teams that will be used to focus on an ongoing issue for years. All of these efforts would benefit from a matrix organizational structure that brings together the full capabilities of the agency and allows it to more effectively leverage and interconnect with other efforts in localities, states, and other federal entities. Of course, this activity could be decoupled from organizational structure and implemented while the longer-term process of reorganizing the agency is pursued. (Moving from Protection to Prosperity: Evolving the U.S. Environmental Protection Agency for the next 50 years, Environmental Science & Technology pubs.acs.org/est Policy Analysis https://dx.doi.org/10.1021/acs.est.0c07287 Environ. Sci. Technol. 2021, 55, 2779−2789)

Given that the EPA is increasing its scrutiny to more PFAS compounds, for example, the CERCLA Advanced Notice of Proposed Rulemaking published on April 13, 2023 (https://www.govinfo.gov/content/pkg/FR2023-04-13/pdf/2023-07535.pdf) specifically addresses PFBA as becoming a "hazardous constituent" under CERCLA. In addition, the toxicity profile of PFBA is mentioned several times in the proposed drinking water rule. Furthermore, the EPA Clean Water Act and Resource Conservation and Recovery Act programs are also developing methods 1633 and 8327 with their own lists of PFAS analytes, and the ORCR is also considering adding PFAS analytes to the Appendix VIII hazardous constituents in 40 FCFR 261.The EMC, therefore, recommends the Drinking Water program collaborate with other EPA program offices to come up with one standardized list. EMC seeks clarification on reporting additional PFAS analytes. EMC would note that some states have their own PFAS reporting lists.

EPA Response: The EPA notes that the statutory authorities and organizational structure of the agency are outside the scope of this regulatory action. The EPA's Drinking Water Program regularly coordinates with the agency's Laboratory Enterprise Council on overarching analytical method and laboratory issues. The EPA further notes that the under the agency's PFAS Strategic

Roadmap the Office of Research and Development is leading the development and validation of methods to detect and measure PFAS in the environment, including additional targeted methods for detecting and measuring specific PFAS, non-targeted methods for identifying unknown PFAS in the environment, and exploring "total PFAS" methods. The development of these analytical methods must inherently consider the media being analyzed and the data quality objectives for the method. This may result in differing analytes for different methods. EPA has defined the reporting requirements for PFAS analytes under 40 CFR 141.904. Any current state reporting lists are outside the scope of this action. Please also see the EPA response to comment Doc. #1625, SBC-043112 in section 5.1.2 in this *Response to Comments* document.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044170)

2. NCDEQ recommends that EPA use all the Agency's regulatory and non-regulatory authorities to prevent PFAS from entering drinking water sources.

NCDEQ continues to support EPA's work to holistically address PFAS under the Agency's PFAS Strategic Roadmap. The Agency's approaches to "get upstream of the problem" and "hold polluters accountable" are paramount to the long-term protection of both surface and groundwater sources of drinking water.

The principle of 'control of pollutants at the point of generation' is established for other contaminants, both chemical and microbial. Therefore, leveraging a holistic approach to reduce or eliminate the use of PFAS and to prevent these compounds from entering the environment and drinking water sources throughout any part or all of the chemical's lifecycle - from manufacturing through processing, distribution, and disposal - is much more effective and less expensive than removing PFAS compounds once contamination has occurred. Protecting drinking water sources (and preventing contamination) is essential for sustaining safe drinking water supplies, protecting public health and the economy, and has many additional environmental benefits.

NCDEQ requests that EPA prioritize the Agency's work to establish PFAS effluent limitations guidelines for wastewater and stormwater discharges from ever expanding list of contributing sources and new emerging industries. NCDEQ stands ready to work with EPA, states, and the stakeholder community to characterize sectors, processes and activities that contribute to PFAS discharges and develop source reduction solutions that reduce such discharges.

Additionally, the Agency should work to finalize Dra Method 1633 promptly for laboratories to analyze samples for surface water, groundwater, and other media. NCDEQ is beginning to require monitoring for pollutants in surface water and groundwater and is developing water quality criteria. The availability of certified laboratories in the state will ensure the increased demand for testing PFAS is adequately met and consistent and reliable data are reported.

3. NCDEQ recommends that EPA use a holistic lifecycle assessment approach that includes close coordination with other Federal agencies to administer all possible Federal statutory regulatory authorities to address PFAS concerns.

The PFAS NPDWR is a necessary first step in addressing PFAS contamination. Numerous other regulatory decisions are made based on drinking water standards (e.g., ground water remediation determinations, National Pollution Discharge Elimination System (NPDES) permits, and surface water standards). This includes considering impacts from disposal and incineration under each regulatory authority to ensure that the responsibility and cost for removing PFAS are not passed on to other media.

EPA is already examining and taking actions on the agency's programs related to air, waste, and land management. We encourage EPA to continue using a holistic lifecycle approach to PFAS management such that the contamination is not transferred across different media without appropriate regulations in place. This also includes consistent messaging on PFAS to regulators, regulated entities, and the public.

Similarly, we encourage EPA to coordinate across other federal Agencies (i.e., the Department of Defense, the Food and Drug Administration, and Centers for Disease Control) to prevent and reduce PFAS contamination and exposure. A unified approach across all Federal agencies will ensure advancements in PFAS science and regulatory actions are made and consistent messaging and implementation of federal regulatory and non-regulatory programs are delivered to the public.

EPA Response: The EPA is taking an all-of-agency approach toward addressing PFAS as discussed in the agency's PFAS Strategic Roadmap (please see section 15.1 of the EPA response in this *Response to Comments* document for additional information). Please also see the EPA response to comment Doc. #1616, SBC-043054 in section 5.1.2 in this *Response to Comments* document for a discussion on the EPA's whole of agency approach to "get upstream of the problem" and "hold polluters accountable." EPA further notes that the agency is coordinating other Federal agencies. EPA is a member of the cross government Interagency Policy Committee (IPC) created by the Council of Environmental Quality to share information and collaborate on new policy strategies to support research, remediation, and removal of PFAS in communities across the nation. For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Tyson Foods, Inc. (Doc. #1750, SBC-043902)

Current technology to measure and detect the PFAS compounds at the proposed levels is not readily widely available nor is it affordable in comparison to other common testing requirements for our industry when scaled to the extent required by the proposed rule. Further, we strongly encourage EPA to convene an interagency working group with the Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA) to ensure alignment on regulatory

expectations of the stakeholders that are regulated by FSIS and/or FDA and EPA. This is critical as FSIS and FDA have regulatory requirements for water used in the food manufacturing.

Finally, Tyson Foods supports the comments provided by the North American Meat Institute, National Chicken Council, and the U.S. Chamber of Commerce. We respectfully request these points be considered before any modifications to the Proposed Rule are finalized.

Thank you for your consideration.

Sincerely,

Betsy Booren, Ph.D.

Managing Director, Regulatory Policy & Business Intelligence

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For a discussion of the EPA's work with other Federal Agencies to address PFAS, see the EPA response to comment Doc. #1652, SBC-044170 in section 5.1.2 in this *Response to Comments* document. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation.

<u>Protecting Our Water, Environment, and Ratepayers (POWER) (Doc. #1714, SBC-045929)</u>

POWER!'s comments on this proposed rule focus on three main concerns: (1) the rule is premature because EPA has not established the requisite technological standards and regulations; (2) the rule fails to adequately consider the costs of implementation; and (3) neither EPA Methods 533 nor 537.1 can be used to accurately and precisely determine compliance with the proposed standards for treatment or triggers for compliance monitoring.

EPA Response: For responses regarding feasibility of the final MCLs, please see sections 5.1.2 (laboratory considerations); 5.1.3 (cost considerations and alternative MCLs); and 5.1.4 (treatment considerations) of the EPA response in this *Response to Comments* document. Please also see section 8 (analytical methods) of the EPA response in this *response to Comments* document.

<u>Michigan Farm Bureau (MFB) (Doc. #1562, SBC-043356)</u>

Impacts of Setting Proposed Regulatory Limits

As stated above, EPA's proposed MCL rule sets MCL limits for six PFAS "[c]onsidering feasibility, including currently available analytical methods to measure and treat these chemicals in drinking water" [FN9: Fed. Reg. 18638.] based on the MCLG of 0 given the potential for carcinogenic effects of PFOS and PFOA. Essentially, this means EPA is setting PFOS and PFOA regulatory limits at or near the current technological capability of detecting PFOS and PFOA

based on approved analytical methods in order to get as close as feasible to 0, and a health index considering potential additive impacts of PFNA, PFBS, PFHxS, and GenX. In addition to the previously discussed uncertainty of health impacts and therefore assessment of meaningful MCLGs for PFAS, this "as close as technically possible to zero" proposal creates a huge burden and lack of clarity for water suppliers who must comply with the new regulations.

EPA Response: The commenter is incorrect that the NPDWR sets a MCLG of zero for six PFAS. Due to the carcinogenic potential of PFOA and PFOS, the EPA is promulgating MCLGs of zero for these two PFAS. For responses regarding feasibility of the final MCLs, please see sections 5.1.2 (laboratory considerations); 5.1.3 (cost considerations and alternative MCLs); and 5.1.4 (treatment considerations) of the EPA response in this *Response to Comments* document. For additional discussion on the hazard index, please see section 5.2.1 of this *Response to Comments* document.

5.1.3 Cost Considerations and Alternative MCLs

Summary of Major Public Comments and EPA Responses

Some commenters argue that the EPA did not sufficiently consider cost in the agency's feasibility analysis of the final MCLs and therefore disagreed with the EPA that the standards are feasible. In particular, these commenters suggest that the agency did not adequately consider costs associated with implementation (e.g., costs for labor, materials and construction of capital improvements) and compliance (e.g., costs to monitor) with the final MCLs. Based on these factors, many of these commenters suggest either raising the MCLs or re-proposing the standard in its entirety. The EPA did consider these costs and therefore disagrees with commenters' assertions that the agency did not consider these issues in establishing the proposed MCLs for PFOA and PFOS (USEPA, 2024d; USEPA, 2024e; USEPA, 2024f). The EPA considers whether these costs are reasonable based on large metropolitan or regional drinking water systems (H.R. Rep. No 93-1185 (1978), *reprinted in* 1974 U.S.C.C.A.N. 6454, 6470-71)[1]. The EPA considered costs of treatment technologies that have been demonstrated under field conditions to be effective at removing PFOA and PFOS and determined that the cost of complying with an MCL at the PQL of 4.0 are reasonable for large metropolitan water systems at a system and national level (USEPA, 2024c; USEPA, 2024d). To designate technologies as BATs, the EPA evaluated each technology against six BAT criteria, including whether there is a reasonable cost basis for large water systems. The EPA evaluated whether the technologies are currently being used by systems, whether there were treatment studies available with sufficient information on design

[1] To designate technologies as BATs, the EPA evaluated each technology against six BAT criteria, including whether there is a reasonable cost basis for large and medium water systems. The U.S. Census Bureau defines a metropolitan statistical area consisting of one or more counties that contain a city of 50,000 or more inhabitants or containing a Census Bureau-defined urbanized area and have a total population of at least 100,000. A "large system" system is one that generally serves a population of more than 10,000 people, so all metropolitan systems are included in the set of large systems.

assumptions to allow cost modeling, and whether additional research was needed (USEPA, 2024e). In considering the results of this information, the EPA determined that these costs are reasonable to large metropolitan water systems and supports the EPA's decision to finalize standards for PFOA and PFOS at 4.0 ppt. In response to responses on the EPA's cost analysis, the agency notes after considering public comment, the EPA has made a number of adjustments to the cost model and collectively these changes have increased the agency's estimated annualized costs. For additional discussion on the EPA's cost analysis, please see section 13.3 of the EPA response in this *Response to Comments* document.

The EPA notes that there is a strong record supporting the agency's feasibility analysis supporting the final standards. Specifically, within the record the EPA evaluated the accuracy of analytical techniques as reflected in the PQL, the availability and performance of BATs for treating water to minimize the presence of the contaminant consistent with the MCLG, as well as the costs of applying those BATs to large metropolitan water systems when treating to that level. In consideration of these factors, the EPA is therefore establishing the MCL of 4.0 ng/L for both PFOA and PFOS; individual MCLs for PFHxS, PFNA and HFPO-DA at 10 ppt; and a Hazard Index MCL of 1 for mixtures of PFHxS, PFNA, HFPO-DA and PFBS. Please see sections 5.1.2 and 5.1.4 of the EPA response in this *Response to Comments* document for additional discussion on how the agency evaluated feasibility with respect to analytic and treatment considerations, respectively, in the final standards.

Some commenters expressed concern that in their opinion the EPA is selecting the "least cost-beneficial" standard among the options considered. Additionally, some commenters suggest the EPA promulgate one of the regulatory alternatives presented at proposal (i.e., 5.0 ppt or 10.0 ppt). Some of these commenters contend that these levels are "more closely balanced" among the options that the EPA considered in terms of costs and benefits. Some of these commenters pointed out that quantified net benefits decreased with increasing MCL stringency. With respect to responses on the net benefits of the rule in comparison to the regulatory options, the EPA emphasizes that under SDWA, the EPA must consider whether the costs of the rule are justified by the benefits based on all statutorily-prescribed costs and benefits, not just the quantified costs and benefits (see SDWA 1412(b)(3)(c)(i)). In other words, SDWA does not mandate that the EPA establish MCLs at levels where the quantified benefits exceed the quantified costs. This was many commenters' justification for the recommendation to promulgate a standard of 10.0 ppt each for PFOA and PFOS in lieu of the proposed rule, and the EPA therefore disagrees that quantified costs and benefits can or should be the sole determinant of an MCL value. As detailed above, the EPA is required to set an MCL as close as feasible to the MCLG, taking costs into consideration.

Some commenters specifically pointed out the differences in the quantified net benefits of the proposed rule compared to Option 1a (PFOA and PFOS standard only at 4.0 ppt each), noting that the Hazard Index MCL "add(s) no significant net benefit." As EPA clearly discusses the proposed and final rule preambles, the Hazard Index is anticipated to result in significant non quantifiable benefits (for more information see section XII of the final rule preamble). The EPA

anticipates significant additional benefits that cannot be quantified that will result from avoided developmental, cardiovascular, liver, immune, endocrine, metabolic, reproductive, musculoskeletal, and carcinogenic effects as a result of reductions in the levels of the regulated PFAS and other co-removed contaminants. For example, elevated concentrations of both PFOA and PFOS negatively impact the immune and endocrine systems, impacts which the agency is unable to quantify at this time. As another example, EPA assessed the developmental benefits associated with PFNA exposure reductions semi-quantitively in sensitivity analysis, and the analysis demonstrates significant additional benefits associated with reductions in PFNA. There are other nonquantifiable benefits for other PFNA health endpoints, and numerous endpoints for PFHxS, HFPO-DA, PFBS, and other PFAS that are anticipated to be removed as a result of the final NPDWR. Additionally, there are benefits not quantified for removal of co-occurring contaminants for this regulation (e.g., certain pesticides, volatile organic compounds). Considering both quantifiable and nonquantifiable costs and benefits of the rule, the EPA is reaffirming the Administrator's determination at the time of proposal, that the quantifiable and nonquantifiable benefits of the final rule justify the quantifiable and nonquantifiable costs. See section 13.8 of the EPA response in this *Response to Comments* document on the Administrator's benefit cost determination and section XII of the final rule preamble.

Some commenters argue for a lower PFOA and PFOS MCL due to the underlying health effects of these contaminants. These commenters suggest the EPA establish MCLs lower than the agency's proposed standard of 4.0 ng/L due to the capability of some laboratories to quantitate lower concentrations. Some of these commenters also argue that since PFOA and PFOS are likely human carcinogens, the EPA should consider an MCL at zero. While the EPA agrees with the health concerns posed by PFAS that are the basis for the proposed health based MCLGs for these contaminants, the agency disagrees with commenters on these alternative MCL thresholds given the EPA's consideration of feasibility as required by SDWA. These commenters did not provide evidence demonstrating the feasibility of achieving lower MCL thresholds (including an MCL at zero) consistent with SDWA requirements in establishing an MCL. For example, commenters did not provide evidence to support a lower PQL that can be consistently achieved by laboratories across the country. They also did not provide arguments supporting why the EPA should accept less than 75 percent of participating laboratories will be able to set a MRL with a 95 percent confidence interval. Thus, the agency is finalizing the MCLs for PFOA and PFOS at 4.0 ng/L (at the PQL) as this is the closest level to the MCLG that is feasible due to the ability of labs using approved analytical methods to determine with sufficient precision and accuracy whether such a level is actually being achieved. The record supports the EPA's determination that the lowest feasible MCL for PFOA and PFOS at this time is 4.0 ng/L.

Some commenters argue for a higher MCL (such as the regulatory alternatives that the EPA proposed for PFOA and PFOS at 5.0 ppt or 10.0 ppt). Some of these commenters note that by adopting this approach, the agency can "phase-down" to a more stringent MCL as advancements in analytical technology progresses. As detailed above, the EPA is required to set an MCL as close as feasible to the MCLG, taking costs into consideration. Consistent with SDWA requirements in setting the MCL as close as feasible to the MCLG and after careful consideration

of public comment, the EPA is finalizing the MCL of 4.0 ng/L for both PFOA and PFOS; individual MCLs for PFHxS, PFNA and HFPO-DA at 10 ppt; and a Hazard Index MCL of 1 for mixtures of PFHxS, PFNA, HFPO-DA and PFBS. Please see section 5.1.2 and 5.1.4 of the EPA response in this *Response to Comments* document for additional discussion on how the agency evaluated feasibility with respect to analytic and treatment considerations, respectively, in the final standards.

Some commenters recommend the EPA regulate PFAS precursors or all PFAS as a class. As discussed above, the agency reiterates the SDWA requirements to establish an MCL. Specifically, the agency has not made a regulatory determination for specific PFAS precursors or the entirety of PFAS as a class and the commenters did not provide evidence to support a determination that PFAS precursors or the entire class of PFAS meet SDWA statutory criteria for regulation. For example, commenters did not provide evidence that the entire PFAS class may have an adverse effect on the health of persons; that the entire PFAS class is known to occur or there is substantial likelihood the contaminant will occur in PWSs with a frequency and at levels of public health concern; and in the sole judgment of the Administrator, regulation of the entire PFAS class presents a meaningful opportunity for health risk reductions for persons served by PWSs.

Regarding the EPA's decision to exclude PFOA and PFOS from the Hazard Index MCL, please see section 5.2.1 of the EPA response in this *Response to Comments* document.

Some commenters raised concerns that the EPA did not consider a sufficient range of regulatory alternatives. For example, a few commenters contend that the EPA violated 1412(b)(3)(C)(i) of SDWA because the agency did not identify and consider what they deem a reasonable number of regulatory alternatives for PFHxS, PFNA, HFPO-DA and its ammonium salts, and PFBS. Specifically, these commenters cite that the EPA only considered a single HBWC and did not consider any alternatives to the Hazard Index MCL of 1 itself. The EPA disagrees with these commenters. First, SDWA does not require the agency to consider any certain number of alternative MCLs or a range of alternatives. SDWA 1412(b)(3)(C)(i)(IV) only requires that in developing the Health Risk Reduction and Cost Analysis (HRRCA), the agency must consider the "incremental costs and benefits associated with each alternative maximum contaminant level considered." Second, the agency explicitly considered and took comment on more than one option for PFHxS, PFNA, HFPO-DA and its ammonium salts, and PFBS. First, the proposed rule included a Hazard Index MCLG and MCL for any mixture of one or more of PFHxS, HFPO-DA, PFNA, and PFBS. Second, the proposed rule EA explicitly considered multiple regulatory options that did not establish any MCLGs or MCLs for these four PFAS. And third and fourth, the agency explicitly sought comment on whether to regulate these four PFAS with individual MCLGs and MCLs instead of the Hazard Index (third) or regulate them with individual MCLs in addition to the Hazard Index (fourth). These are four specific regulatory scenarios for PFHxS, PFNA, HFPO-DA and its ammonium salts, and PFBS upon which the agency explicitly sought and received comment.

The final rule includes a Hazard Index MCLG and MCL for any mixture of two or more of PFHxS, HFPO-DA, PFNA, and PFBS. The final rule also includes individual MCLGs and MCLs for PFHxS, PFNA, and HFPO-DA. The EPA's cost analysis at proposal considered the costs associated with the individual MCLs for PFHxS, PFNA, and HFPO-DA because the proposed Hazard Index MCL would function as individual MCLs when these contaminants occur in isolation. While the rule structure has changed in the final NPDWR based on public comment received, the costing framework used at proposal is still fully applicable in the final rule: what was considered a Hazard Index MCL exceedance at proposal would be an individual MCL exceedance under the final rule should those contaminants occur in isolation. Further, the combination of a Hazard Index exceedance in the final rule (defined as two or more of PFHxS, PFNA, HFPO-DA, and PFBS) or an individual MCL exceedance for PFHxS, PFNA, or HFPO-DA is unchanged from a costing perspective to what the EPA proposed. Whether a system exceeds a Hazard Index MCL or individual MCL in the final rule, these costs are captured in the cost estimates the EPA considered and presented in Appendix N.3 of the EA (USEPA, 2024d).

To understand the totality of national-level cost impacts for the Hazard Index MCL, the EPA considered both the contribution of PFHxS (estimated as part of the national level cost analysis), as well as the costs for PFNA, HFPO-DA, and PFBS (estimated in the Appendix N sensitivity analysis). Together, these provide information on the costs for the Hazard Index MCL and the individual MCLs for PFHxS, PFNA, and HFPO-DA, as a whole.

To fully weigh the costs and benefits of the action, the agency considered the totality of the monetized values, the potential impacts of the nonquantifiable uncertainties, the nonquantifiable costs and benefits, and public comments received by the agency related to the quantified and qualitative assessment of the costs and benefits. For the final rule, the EPA is reaffirming the Administrator's determination made at proposal that the quantified and nonquantifiable benefits of the rule justify its quantified and nonquantifiable costs. Please see section 13 of the EPA response in this *Response to Comments* document for additional information on the agency's HRRCA.

In light of finalizing the individual MCLs for PFHxS, PFNA, and HFPO-DA, the EPA has separately presented national level marginal costs associated with the individual MCLs for PFHxS, PFNA and HFPO-DA in the absence of the Hazard Index MCL; see Chapter 5.1.3 and Appendix N.4 of the HRRCA for details. The EPA notes that these costs were considered in the proposed regulation under the proposed hazard index, where an exceedance of any one or more of these PFAS' HBWC would have resulted in an exceedance of the MCL. Therefore, the costs for the individual PFHxS, PFNA, and HFPO-DA MCLs have been considered both in the proposed and final rule. For more information on the agency's methodology, findings, and limitations of the EPA's updated analysis of costs associated with compliance with the Hazard Index, please see Appendix N.3 of the EA (USEPA, 2024c).

The agency also took comment on regulatory alternatives for solely PFOA and PFOS MCLs at 4.0, 5.0 and 10.0 ppt and further summarized quantified costs and benefits for these alternative options within the proposed rule preamble and economic analysis supporting the proposal. The

agency described the basis for these alternatives which included a 25 percent operational buffer above the PQL (for 5.0 ppt) and a level consistent with some state drinking water regulators (for 10.0 ppt), thereby providing a basis for comparison of the different regulatory approaches.

The EPA identified and analyzed a reasonable number of regulatory alternatives to determine the MCL requirement in the proposed rule as required by the Unfunded Mandates Reform Act (UMRA). UMRA's requirement to identify and consider a reasonable number of regulatory alternatives builds on the assessment of feasible alternatives required in E.O. 12866. OMB Circular A-4 describes that "the number and choice of alternatives selected for detailed analysis is a matter of judgment." Specifically, as described in the proposed rule, the EPA considered an alternative approach to the one proposed that only used the Hazard Index MCL. The proposal took comment on establishing individual MCLs instead of and in addition to using a mixture-based approach for PFHxS, PFNA, HFPO-DA, and/or PFBS in mixtures. In that notice, the EPA described how a traditional approach may be warranted should the EPA not finalize a regulatory determination for mixtures of these PFAS. Under this alternative, "the proposed MCLG and MCL for PFHxS would be 9.0 ng/L; for HFPO-DA the MCLG and MCL would be 10.0 ng/L; for PFNA the MCLG and MCL would be 10.0 ng/L; and for PFBS the MCLG and MCL would be 2000.0 ng/L." The agency requested comment on these alternatives for PFHxS, PFNA, HFPO-DA, and PFBS and whether these individual MCLs instead of or in addition to the Hazard Index approach would change public health protection, improve clarity of the rule, or change costs. Additionally, the EPA considered alternative mixture-based approaches such as a target-specific Hazard Index (TOSHI) or relative potency factor (RPF) approach. The agency requested comment on these approaches. Based on the EPA's technical expertise, the agency determined that the General Hazard Index is the most cost-effective and least burdensome alternative for purposes of UMRA because this approach for mixtures that achieves the objectives of the rule because of the level of protection afforded for the evaluation of chemicals with shared health endpoints. The EPA followed agency chemical mixture guidance (USEPA, 1986; USEPA, 1991b; USEPA, 2000a), which explain that when the Hazard Index value is greater than one (1) then risk is indicated (because exposure exceeds toxicity). The agency did not propose alternative Hazard Index values (i.e., higher Hazard Index values) because the EPA determined that a Hazard Index MCL of 1 is feasible: multiple treatment technologies are available to treat or below the MCL; the costs of applying these technologies to large and metropolitan water systems are reasonable; and there are analytical methods available to reliably quantify the four PFAS captured in the Hazard Index MCL (please see the EPA response in section 5.2.1 below for additional discussion on the EPA's feasibility analysis for the Hazard Index MCL). In addition, these alternative Hazard Index or mixture-based approaches would not provide sufficient protection against dose-additive health concerns from co-occurring PFAS. For example, a higher Hazard Index value (e.g., Hazard Index equal to 2) allows for exposure to be much greater than the toxicity and will not result in a sufficient health-protective standard that is as close as feasible to the MCLG, which is a level at which there are no known or anticipated adverse effects on human health and allows for an adequate margin of safety. The EPA notes that

commenters have not provided support justifying an alternative MCL standard for the Hazard Index.

Some commenters suggest that the EPA failed to consider the costs and impacts of the MCLs in non-drinking water contexts, such as its potential uses as CERCLA clean-up standards, its potential application as water quality objectives or groundwater recharge objectives, or its potential application in food and poultry industries. As required by SDWA, this rulemaking and analyses supporting the rulemaking only includes costs that "are likely to occur solely as a result of compliance with the [MCL]." Thus, the EPA's cost analyses focused on the compliance costs of meeting the MCL to PWSs that are directly subject to this regulation. The same provision expressly directs the EPA to exclude "costs resulting from compliance with other proposed or promulgated regulations." Thus, the EPA cannot consider the costs of use of the MCLs under other EPA statutes (such as CERCLA) as part of its EA (i.e., Economic Analysis or Health Risk Reduction or Cost Analysis) because SDWA specifically excludes such consideration (42 U.S.C. § 300g-1(b)(3)(C)(i)(III)). See also City of Waukesha v. EPA, 320 F.3d 228, 243-244 (D.C. Cir. 2003) (finding that SDWA excludes consideration of the costs of, for example, CERCLA compliance, as part of the required cost/benefit analysis). With respect to CERCLA clean-up costs, whether and how MCLs might be used in any particular clean-up is very site-specific and as a practical matter cannot be evaluated in this rulemaking. Nevertheless, it is inappropriate for the EPA to consider any potential CERCLA clean-up costs under a drinking water regulation as these are separate site-specific decisions on which applicable or relevant and appropriate requirement (ARAR) to use and represent different agency actions. In other words, the decision to clean up soil at sites is done under separate statutory authority and is not relevant when considering whether drinking water authorities should remove PFAS. Furthermore, an MCL is not a necessary prerequisite for clean-ups. Currently available Removal Management Levels (RMLs) and Regional Screening Levels (RSLs) inform site-specific decisions yield actionable levels close to the MCLs. To assess these impacts, the EPA would have to make assumptions about potential future, separate policy decisions regarding clean up. In short, these cost concerns are beyond the scope of this regulation.

Individual Public Comments

Little Hocking Water Association (Doc. #1835, SBC-045508)

Support of stand-alone MCLs for PFOA and PFOS.

LHWA supports the adoption of MCLs for PFOA and PFOS at 4 ppt or less and a MCLG of zero for PFOA and PFOS. "EPA requests comment on its proposed decision to establish stand-alone MCLs for PFOA and PFOS in lieu of including them in the HI Approach." LHWA provides the following data and comments in support of stand-alone MCLs for PFOS and PFOA:

1. Since 2002, when LHWA first started to become aware of the presence of elevated concentrations of PFOA in its water, only PFOA and PFOS (the chain length C-8) were discussed as a target for regulation. As a result, the focus of data-gathering efforts and research

was initially focused only on these two chemicals. More is known about these two PFAS than any of the other approximately 15,000 PFAS estimated to be documented today.

2. Data to date in LHWA's wellfield and raw water has similarly focused on PFOA. The concentrations of PFOA are significantly higher than other measured PFAS in the raw water. Attachment 1 shows the measured concentrations of PFOA in the raw water of LHWA from October 16, 2007 through April 10, 2023. This data shows concentrations of PFOA as high as 15,000 ppt in 2013 even after DuPont/Chemours reduced discharge of PFOA in 2009. Disturbingly, the concentrations of PFOA appear to remain relatively constant and do not show a significant downward trend with time.

3. Little Hocking also has information on the nearby Belpre, Ohio water system. The Belpre wellfield is located along the Ohio River and is approximately 3.8 miles upstream from LHWA and approximately 3.5 miles upstream of the Chemours Washington Works facility. Although concentrations of PFOA are less in the Belpre public water system raw water than in LHWA's raw water, the concentrations also show a disturbing upward trend of concentrations of PFOA (Attachment 2). This data demonstrates the persistence of PFOA in the environment and the importance of adopting a singular MCL for such a well-studied compound.

EPA Response: For additional discussion on alternative regulatory standards, please see section 5.1.3 of the EPA response in this *Response to Comments* document. Regarding the EPA's decision to exclude PFOA and PFOS from the Hazard Index MCL, please see section 5.2.1 of the EPA response in this *Response to Comments* document. Regarding the commenter's submission on occurrence trends, the EPA primarily considers finished drinking water data in the agency's occurrence analysis as this is the most reflective of conditions to determine whether a contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in PWSs with a frequency and at levels of public health concern. A comprehensive discussion of all the available state PFAS drinking water occurrence data is included in the *Occurrence Technical Support Document* (USEPA, 2024a). See also sections 3.1.2, 3.2.2, and 6 of the EPA response in this *Response to Comments* document for further discussion about available occurrence data and how it informed the EPA's decision making for this rule.

Arcadis (Doc. #3072-17, SBC-047367)

Good morning and good afternoon. Thanks to EPA and the team for welcoming public comments on such an important rulemaking. I strongly support this rulemaking. However, I do have two quick questions with regards to the proposed rule. In the year 2022, EPA announced interim health advisory limits of PFOA and PFOS. Based on the toxicology studies and those health advisory limits are significantly less than the proposed MCLs of 4 parts per trillion for PFOA and PFOS, respectively. I understand that the current available analytical methods cannot get that low enough to be notified health advisory levels and hence the reason for the MCLs. But it is conflicting to understand that the new rule is to safeguard the public, but there is still uncertainty whether the drinking water would contain below 4 parts per trillion for PFOA and

PFOS, for example, but yet be unsafe. That's a question mark. So, I would request EPA reconsider ways to address this gap.

EPA Response: For additional discussion on alternative regulatory standards, including discussion on lower MCLs for PFOA and PFOS, please see section 5.1.3 of the EPA response in this *Response to Comments* document. HAs are beyond the scope of this rulemaking. The EPA's HAs are non-enforceable and non-regulatory and provide technical information to state agencies and other public health officials on health effects, analytical methods, and treatment technologies associated with drinking water contamination. MCLs are regulatory and enforceable standards that are informed by regulatory development requirements under SDWA and includes the EPA's analysis of the best available and most recent peer-reviewed science. For additional information on how the agency considers feasibility when establishing the MCL, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Clean Air Council, et al. (Doc. #1731, SBC-043880)

2. The proposed PFOA and PFOS MCLs and the HI are protective of public health, and their implementation is feasible.

a. The proposed stand-alone PFOA and PFOS MCLs of 4.0 ppt are appropriate for the protection of public health.

The adverse health effects of PFOA and PFAS have been clearly established in numerous studies, ranging from from birth defects to cancer [FN31: See, e.g., Nat'l Cancer Inst., Section on What We Study, PFAS Exposure and Risk of Cancer, https://dceg.cancer.gov/research/what-we-study/pfas (last visited May 24, 2023) (listing multiple studies); Vladislav Obsekov, Linda G. Kahn, & Leonardo Trasande, Leveraging Systematic Reviews to Explore Disease Burden and Costs of Per- and Polyfluoroalkyl Substance Exposures in the United States, 15 EXPOSURE & HEALTH 373–94 (Jul. 26, 2022), available at https://doi.org/10.1007/s12403-022-00496-y; Si-Yu Gui, et al., Association Between Exposure to Per- and Polyfluoroalkyl Substances and Birth Outcomes: A Systematic Review and Meta-Analysis, 10 FRONTIERS IN PUB. HEALTH Article No. 855348 (Mar. 24, 2022), available at https://doi.org/10.3389/fpubh.2022.855348; Scott M. Bartell & Verónica M. Vieira, Critical Review on PFOA, Kidney Cancer, and Testicular Cancer, 71:6 J. of the AIR & WASTE MGMT ASSOC'N 663 (June 2021), available at https://doi.org/10.1080/10962247.2021.1909668; Xuejun Li, et al., Perfluoroalkyl Substances (PFASs) as Risk Factors for Breast Cancer: A Case–Control Study in Chinese Population, 21 ENVTL. HEALTH Article No. 83 (Sept. 9, 2022), available at https://doi.org/10.1186/s12940-022-00895-3. Additional studies are cited in the proposed NPDWR. 88 Fed. Reg. 18638.]. Yet, state Maximum Contaminant Level Goals ("MCLG") for PFOA and PFOS differ significantly in value: For example, the Commonwealth of Pennsylvania's analysis conducted by the Drexel PFAS Advisory Group recommended Chronic Non-Cancer MCLGs of 8 ppt for PFOA and 14 for PFOS [FN32: Drexel PFAS Advisory Group, Maximum Contaminant Level Goal Drinking Water Recommendations for Per- and Polyfluoroalkyl Substances (PFAS) in the Commonwealth

of Pennsylvania 74 (Jan. 2021), available at https://files.dep.state.pa.us/PublicParticipation/Public%20Participation%20Center/PubPartCenterPortalFiles/Environmental%20Quality%20board/2021/June%2015/03_PFAS%20Petition/01a_App%201%20Drexel%20PFAS%20Report%20January%202021.pdf.]. However, New Hampshire set the MCLG levels for both at 0.0 ppt [FN33: N.H. Code Admin. R. Env. 705.06(b), available at https://www.des.nh.gov/sites/g/files/ehbemt341/files/documents/env-dw-702-706-adptpstd.pdf]. These differences are in large part due to the main health condition considered and the reference dose ("RfD") values chosen, in addition to the methodology of calculation. For example, although both New Jersey and New Hampshire focused on the impact of PFOA on the liver when determining PFOA's MCLG, using the same Loveless 2006 [FN34: Scott E. Loveless, et al., Comparative Responses of Rats and Mice Exposed to Linear/Branched, Linear, or Branched Ammonium Perfluorooctanoate (APFO), 220 TOXICOLOGY 203 (Mar. 15, 2006), available at https://doi.org/10.1016/j.tox.2006.01.003.] study, they reached widely differing RfD values of 2 ng/kg/d and 6.1 ng/kg/d, respectively. Michigan and Pennsylvania chose skeletal effects based on Onishchenko 2011 [FN35: Natalia Onishchenko, et al., Prenatal Exposure to PFOS or PFOA Alters Motor Function in Mice in a Sex- Related Manner, 19(3) NEUROTOXICITY RES. 452–61 (May 29, 2010), available at https://doi.org/10.1007/s12640-010-9200-4.] and Koskela 2016, [FN36: A. Koskela, et al., Effects of Developmental Exposure to Perfluorooctanoic Acid (PFOA) on Long Bone Morphology and Bone Cell Differentiation, 301 TOXICOLOGY & APPLIED PHARMACOLOGY 14 (June 15, 2016), available at https://doi.org/10.1016/j.taap.2016.04.002.] calculating an RfD of 3.9 ng/kg/d.

For PFOS, most states focused on the immune system based on Dong 2011 [FN37: Guang-Hui Dong, et al., Sub-Chronic Effect of Perfluorooctanesulfonate (PFOS) on the Balance of Type 1 and Type 2 Cytokine in Adult C57bl6 Mice, 85 ARCHIVES OF TOXICOLOGY 1235 (Feb. 16, 2011), available at https://doi.org/10.1007/s00204-011-0661-x.] to calculate RfD in the range of 1.8–3 ng/kg/d. However, Massachusetts and Vermont used developmental issues, [FN38: Deanna J. Luebker, Marvin T. Case, Raymond G. York, John A. Moore, Kristen J. Hansen, & John L. Butenhoff, Two-Generation Reproduction and Cross-Foster Studies of Perfluorooctanesulfonate (PFOS) in Rats, 215 TOXICOLOGY 126 (Nov. 5, 2005), available at https://doi.org/10.1016/j.tox.2005.07.018; Deanna J. Luebker, Raymond G. York, Kristen J. Hansen, John A. Moore, & John L. Butenhoff, Neonatal Mortality from In Utero Exposure to Perfluorooctanesulfonate (PFOS) in Sprague-Dawley Rats: Dose-Response, and Biochemical and Pharmacokinetic Parameters, 215 TOXICOLOGY 149 (Nov. 5 2005), available at https://doi.org/10.1016/j.tox.2005.07.019.] reaching RfD values of 5 ng/kg/d and 20 ng/kg/d, respectively. To the best of our knowledge, despite being well documented, no state has used cancer risk as the main receptor to determine RfD and MCLG.

In contrast to the states, the Chemical Contaminant Rule requires that the MCLG for known cancer-causing contaminants be set to zero [FN39: EPA, Section on Drinking Water Requirements for States & Pub. Water Sys., Chemical Contaminant Rules, https://www.epa.gov/dwreginfo/chemical-contaminant-rules (last updated Nov. 15, 2022).] This rule regulates contaminants in three contaminant groups and applies to all public water systems.

Since both PFOA and PFOS have been designated as carcinogens, setting the federal MCLGs for PFOA and PFOS at 0.0 ppt is necessary and unavoidable.

Designating separate MCLGs for PFOA and PFOS (rather than including them in the HI) is important for several reasons:

First, these two compounds are the most prevalent PFAS species in water samples in the USA: As shown in the data compiled in the proposed NPDWR, PFOA and/or PFOS were detected in more than 30% of the drinking water samples reviewed, reaching astounding levels of more than 50% in South Carolina, Massachusetts, and New Hampshire [FN40: 88 Fed. Reg. 18673–74, Table 5.]. In Pennsylvania, extensive sampling data shows 25–27% of samples with PFOA or PFOS [FN41: 53 Pa.B. 335, Table 1.] Other PFAS compounds are less prevalent as a rule. The prevalence of PFOA and PFOS is also reflected in data from the Agency for Toxic Substances and Disease Registry ("ATSDR") of the Centers for Disease Control and Prevention ("CDC"). The concentrations of these two compounds in the United States population's blood are the highest when compared to other PFAS compounds [FN42: ATSDR, PFAS in the US Population, https://www.atsdr.cdc.gov/pfas/health-effects/us-population.html (last reviewed Dec. 22, 2022).]. EPA proposes to set the MCLs for PFOA and PFOS at 4.0 ppt. This is not the lowest practical quantitation limit ("PQL") that can be achieved by laboratories, as shown in the Table below for the EPA currently certified PFAS testing methods (533 and 537.1), and the in-development method 1633:

[Table: see docket ID EPA-HQ-OW-2022-0114-1731]

The feasibility of reliably detecting values lower than 4 ppt is demonstrated, for example, in the Pennsylvania drinking sampling data, where PFOA and PFOS were detected at levels as low as 1.7 ppt [FN49: 53 Pa.B. 335.] Also, as noted, current water treatment methods can remove these compounds to non-detectable levels, which means it would be possible to remove PFOA and PFOS down to the lowest detectable limits of at least 1.7 ppt.

Setting the MCLs for PFOA and PFOS below 4 ppt is therefore possible and would benefit public health. However, Commenters acknowledge that a lower value may be subject to fluctuations and difficult to implement, and therefore could place a heavy burden on public water systems. While the proposed MCLs are a reasonable compromise, Commenters urge the EPA to review these values periodically as the associated technology improves.

EPA Response: For additional discussion on alternative regulatory standards, please see section 5.1.3 of the EPA response in this *Response to Comments* document. Regarding the EPA's decision to exclude PFOA and PFOS from the Hazard Index MCL, please see section 5.2.1 of the EPA response in this *Response to Comments* document. The agency disagrees that a lower MCL is feasible for PFOA and PFOS due to analytical capabilities nationwide at this time; for additional discussion on alternative regulatory standards, including discussion on lower MCLs for PFOA and PFOS, please also see section 5.1.3 of the EPA response in this *Response to Comments* document. For additional discussion on how the agency considers analytic feasibility when establishing the MCL, please see section 5.1.2 of the EPA response in this *Response to*

Comments document. Regarding the agency's determination that PFOA and PFOS are Likely to be Carcinogenic to Humans, please see section 4.1.4 of the EPA response in this *Response to Comments* document.

Uttara Jhaveri (Doc. #1778, SBC-045440)

Recently, the U.S. Environmental Protection Agency (EPA) proposed the National Primary Drinking Water Regulations (NPDWR) for six PFAS, including perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO-DA, commonly known as GenX Chemicals), perfluorohexane sulfonic acid (PFHxS), and perfluorobutane sulfonic acid (PFBS). [FN4: Environmental Protection Agency, PFAS National Primary Drinking Water Regulation Rulemaking, (2023), .]

NATIONAL PRIMARY DRINKING WATER REGULATIONS: COMMENT

PROPOSED PFAS LEVELS IN DRINKING WATER

The EPA's proposal to regulate PFOA and PFOS at 4 parts per trillion (ppt) is a practical decision considering the analytical levels at which the existing technologies in the drinking water can accurately identify the chemicals. [FN5: Id.]However, considering that the current limit of PFAS in drinking water is 70 ppt, the regulations have considerably decreased the limits. [FN6: Id.]It is estimated that about 100 million Americans are drinking water that probably has PFAS levels exceeding the current limit of 70 ppt. [FN7: Karen Feldscher, Stricter federal guidelines on 'forever chemicals' in drinking water pose challenges, HARVARD T.H. CHAN SCHOOL OF PUBLIC HEALTH, .]Therefore, the EPA must consider that near 0 levels of PFAS may be unachievable with the state of the technology to detect PFAS in drinking water.

Further, individual states, such as Vermont, Massachusetts, New Hampshire, Michigan, California, and New Jersey, have lowered the limit of PFAS in drinking water below 70 ppt but remain higher than the limits EPA announced via its regulations. [FN8: Id.]The EPA guidelines could serve as a goal, with the reduced limits being a binding intermediate limit for PFAS for the short term, which is achievable with the current technology.

EPA Response: For additional discussion on alternative regulatory standards, including discussion on lower MCLs for PFOA and PFOS, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA is clarifying for the commenter that before this final PFAS NPDWR, there were no national "limits" for PFAS in drinking water. While some states have promulgated drinking water standards for various PFAS prior to promulgation of this NPDWR, this rule provides a nationwide, health protective level for PFOA and PFOS (as well as four other PFAS) in drinking water and reflects regulatory development requirements under SDWA, including the EPA's analysis of the best available and most recent peer-reviewed science; available drinking water occurrence, treatment, and analytical feasibility information relevant to the PQL; and consideration of costs and benefits. After the NPDWR takes effect, SDWA requires primacy states to have a standard that is no less stringent than the NPDWR.

Missouri Department of Natural Resources (Doc. #1563, SBC-042537)

Section XIII—HRRCA [Health Risk Reduction and Cost Analysis]

In the Economic Analysis, EPA presented estimated costs and benefits of regulatory alternatives for PFOA and PFOS if setting MCLs at 5.0 ppt and 10.0 ppt. EPA is requesting comment on its evaluation of these alternatives within the Economic Analysis.

The Department disagrees with EPA's conclusion that the regulatory alternative for setting the PFOA and PFOS MCL at 10.0 ppt does not meet a significant reduction in American's exposure to PFAS. The Department believes that EPA significantly underestimated the cost of reducing the MCL below 10.0 ppt.

EPA Response: The EPA did not conclude at proposal that "PFOA and PFOS MCL at 10.0 ppt does not meet a significant reduction in American's exposure to PFAS." Rather, the Administrator determined that for PFOA and PFOS, 4.0 ppt is as close as feasible to the MCLG and that the benefits of the rule justified the costs, for more information see section 5.1.3 of the EPA response in this *Response to Comments* document.

The EPA notes that the record supporting the agency's feasibility analysis supports final standards at 4.0 ppt. For additional discussion on the EPA's feasibility analysis with respect to analytic and laboratory considerations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For additional discussion on cost considerations when setting the MCL, please see section 5.1.3 of the EPA response in this *Response to Comments* document. Regarding responses regarding the agency's evaluation of feasible treatment technologies for the final NPDWR, please see section 5.1.4 of the EPA response in this *Response to Comments* document. Regarding responses regarding the agency's evaluation of compliance costs for the final NPDWR, please see section 13.3 of the EPA response in this *Response to Comments* document.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043629)

2. The USEPA has assessed the impact of different options of the Maximum Contaminant Levels (MCLs) for the two major PFAS compounds (PFOA and PFOS) in drinking water including 4, 5 and 10 ppt; however, USEPA's own analysis demonstrates that the option selected for the proposed rule (the most stringent of the options), is the least cost-beneficial of the options considered.

EPA Response: For additional discussion on benefit-cost considerations when setting the MCL, please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043639)

Furthermore, cost-benefit analyses of setting the MCLs at thresholds incrementally higher than 4 ng/L (e.g., 5 ng/L, 10 ng/L, etc.) revealed that more stringent MCLs resulted in lower net

benefits. The USEPA considered four scenarios – the results of each presented in the tables below:

1) PFOA and PFOS MCLs of 4.0 ppt and HI of 1.0 (the proposed option) (Table 1)

2) PFOA and PFOS MCLs of 4.0 ppt (Table 2)

3) PFOA and PFOS MCLs of 5.0 ppt (Table 3)

4) PFOA and PFOS MCLs of 10.0 ppt (Table 4)

The proposed MCLs of 4.0 ppt for PFOA and PFOS and an HI of 1.0 (the most stringent of the options and the one selected for the proposed rule) had the least net benefit (Table 1) compared to other options considered in the USEPA cost-benefit analysis shown below.

Table 1. Annualized Quantified National Costs and Benefits, Proposed Option (PFOA and PFOS MCLs of 4.0 ppt and HI of 1.0; Million $2021), adapted from USEPA.

[Table 1: See Docket ID EPA-HQ-OW-2022-0114-1602]

Table 2. Annualized Quantified National Costs and Benefits, (PFOA and PFOS MCLs of 4.0 ppt; Million $2021), adapted from USEPA.

[Table 2: See Docket ID EPA-HQ-OW-2022-0114-1602]

Table 3. Annualized Quantified National Costs and Benefits, (PFOA and PFOS MCLs of 5.0 ppt; Million $2021), adapted from USEPA.

[Table 3: See Docket ID EPA-HQ-OW-2022-0114-1602]

Table 4. Annualized Quantified National Costs and Benefits, (PFOA and PFOS MCLs of 10.0 ppt; Million $2021), adapted from USEPA.

[Table 4: See Docket ID EPA-HQ-OW-2022-0114-1602]

BWWB acknowledges that the regulation of PFAS is an important step towards protecting public health and minimizing risks. However, USEPA's own analysis demonstrates that the option selected for the proposed rule (the most stringent of the options), is the least cost-beneficial of the options considered. BWWB requests that USEPA consider proposing MCLs that are demonstrated to be both economically feasible and cost justifiable.

EPA Response: For additional discussion on benefit-cost considerations when setting the MCL, please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Aurora Water, City of Aurora, Colorado (Doc. #1669, SBC-043728)

If the MCL is increased to 10 ppt as Aurora has proposed, then the focus for treatment will shift to the removal of HI compounds instead of PFOA and PFOS. Aurora would be able to have fewer GAC material change outs which would mean lower annual costs and less waste produced.

Treating to 10ppt would result in annual costs of about $300,000 per year while treating to 4ppt would be about $670,000 per year. Not only would Aurora Water have fewer financial impacts by a higher MCL, but it is also estimated that in Colorado there would be 20 water systems that would exceed an MCL of 10 ppt versus an estimated 60 water systems that would exceed the proposed 4 ppt MCLs. The fewer systems that exceed the MCLs, the fewer that will have to change their treatment processes. This should also be considered in the cost estimates and feasibility studies through EPA.

EPA Response: To clarify, a NPDWR is a national rule that sets enforceable standards for PWSs across the country. As such, the agency analyzed the quantifiable and non-quantifiable costs and benefits of the rule at a national level. The commenter raises a scenario that if fewer systems exceed the MCLs, fewer systems will have "change their treatment processes" and that this factor should be considered in the cost estimates in the rule. The EPA has considered these cost considerations and alternative regulatory standards; please see section 5.1.3 of the EPA response in this *Response to Comments* document. As required by SDWA, the EPA has set the MCLs for PFOA and PFOS as close to their MCLGs as feasible, taking cost into consideration. For additional discussion on the EPA's feasibility analysis with respect to analytic and laboratory considerations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding responses regarding the agency's evaluation of feasible treatment technologies for the final NPDWR, please see section 5.1.4 of the EPA response in this *Response to Comments* document. Finally, the EPA Administrator has determined that the costs of the rule are justified by the benefits. See section 13.8 of the EPA response in this *Response to Comments* document for further discussion.

Aurora Water, City of Aurora, Colorado (Doc. #1669, SBC-043720)

Raising the proposed MCL would dramatically reduce costs for the water system. For Aurora, a change from removing PFOA/PFOS to 10 ppt instead of 4 ppt would mean a 10% increase in yearly costs versus a 200% increase and will serve as a balance for protecting public health while EPA works with manufacturers to remove PFAS sources. Additionally, raising the MCL would reduce the number of public notifications required, which is also an expense and degrades public confidence in their water. Bottled water companies are not required to disclose PFAS compounds in their water; however, some are reporting <5ppt. If consumers are turning to bottled water instead of tap, they may, unknowingly, be getting more exposure to PFAS.

EPA Response: Please see the EPA response to comment Doc. #1669, SBC-043728 in section 5.1.3 in this *Response to Comments* document. For additional discussion on cost considerations when setting the MCL and alternative regulatory standards, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA notes that bottled water is under the purview of the FDA and is out of scope for this NPDWR.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-044925)

Section 8: HRRCA for the proposed NPDWR

Section 8.1: Evaluation of Benefit-Cost Analysis: Regulatory Alternatives

In the Economic Analysis, EPA presented estimated costs and benefits of regulatory alternatives for PFOA and PFOS if setting MCLs at 5.0 ppt and 10.0 ppt. Cleveland Water asks EPA to carefully consider whether the benefits of finalizing the rule at 10 ppt better justifies the costs while still presenting a meaningful reduction in public health risks. Considering that the costs will be disproportionately borne by smaller systems and disadvantaged communities, EPA should explore what, if any, health benefits accrue from setting an MCL from 10 ppt to 4 ppt and consider if the social benefits and reduced overall costs of 10 ppt would be more appropriate. The limitations and uncertainties EPA acknowledges in its model application in the Economic Analysis warrant further investigation into quantified costs and benefits this rule will impose.

EPA Response: Please see the EPA response to comment Doc. #1669, SBC-043728 in section 5.1.3 in this *Response to Comments* document. For additional discussion on cost considerations when setting the MCL and alternative regulatory standards, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA is clarifying for the commenter that the agency did examine the health benefits and costs at each of the selected and alternative regulatory standards, and examined the quantifiable and non-quantifiable benefits that "accrue from setting an MCL from 10ppt to 4 ppt." The analysis is presented in the EPA's HRRCA for the final PFAS NPDWR and further discussed in section 13 of the EPA response in this *Response to Comments* document.

New York State Department of Health (NYS DOH) (Doc. #1677, SBC-044952)

14. NYS appreciates the fact that EPA has estimated the net cost/benefit of different regulatory thresholds, 4, 5 and 10 ppt. We note that the estimated net benefit of 4 ppt is only slightly greater than the net benefit at 10 ppt ($240M vs $200M at 3% discount rate) when focusing solely on the direct health benefits of PFOA/PFOS mitigation and not including co-benefits from the removal of disinfection byproducts. As noted, the overwhelming majority of water supplies expected to be impacted by this proposal in New York State will not benefit from co-removal of TOC. Thus, when considering the direct impact of PFOA/PFOS regulation, the Department is pleased to see that EPA's analysis supports a high degree of net benefit from the MCLs already in place in NYS since 2020, and that this is not substantially different than the estimated benefit at 4 ppt.

EPA Response: For additional discussion on cost considerations when setting the MCL and alternative regulatory standards, please see section 5.1.3 of the EPA response in this *Response to Comments* document. For EPA's *Response to Comments* on the disinfection by-product co-removal benefits anticipated as a result of the rule, see section 13.7 of the EPA response in this *Response to Comments* document. The EPA notes that under the SDWA, EPA must consider "Quantifiable and nonquantifiable health risk reduction benefits for which there is

a factual basis in the rulemaking record to conclude that such benefits are likely to occur from reductions in co-occurring contaminants that may be attributed solely to compliance with the MCL, excluding benefits resulting from compliance with other proposed or promulgated regulations" (See SDWA 1412(b)(3)(C)(i)(III). At a national level, the EPA has determined that total organic carbon (a Disinfection Byproduct [DBP] precursor) is a co-occurring contaminant that will be co-removed for those systems that elect to use granular activated carbon to remove PFAS. Since EPA has quantified benefits associated with DBP reduction due to total organic carbon (TOC) co-removal, it would be inconsistent with the SDWA statutory standards for EPA to exclude considering these benefits from consideration.

American Chemistry Council (ACC) (Doc. #1711, SBC-047703)

ACC further urges EPA to reconsider the proposed standards for PFOA and PFOS in light of the inability to determine that the benefits of the current proposal justify its costs, per Section 1412(b)(4)(C) of the SDWA.

Sincerely,

Steve Risotto

Stephen P. Risotto Senior Director

Enclosure

EPA Response: The EPA disagrees with commenter's statements regarding EPA's "inability to determine that the benefits of the current proposal justify the costs." In its proposed rule preamble, the Administrator determined the costs of the rule are justified by the benefits (see section XII of the final rule preamble). Furthermore, the EPA Administrator is re-affirming the decision made at proposal that the benefits of the final NPDWR justify the costs (see section 13.8 of the EPA response in this *Response to Comments* document and section XII of the preamble for the final rule for more information.) For additional discussion on benefit-cost considerations when setting the MCL and alternative regulatory standards, please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045992)

Section 8.7: Evaluation of benefit-cost analysis: regulatory alternatives

Given the underestimation of costs, partially due to the social cost of carbon and social costs generally, AMWA asks EPA to carefully consider whether the benefits of finalizing the rule at 10 ppt better justify the costs while still presenting a meaningful reduction in public health risks. In the Economic Analysis, EPA presented estimated costs and benefits of regulatory alternatives for PFOA and PFOS of setting MCLs at 5.0 ppt and 10.0 ppt.

Considering that the costs will be disproportionately borne by smaller systems and disadvantaged communities, EPA should explore what, if any, health benefits accrue going from an MCL of 10

ppt to an MCL of 4.0 ppt, and consider if the social benefits and reduced overall costs of 10 ppt would be more appropriate. The limitations and uncertainties EPA acknowledges in its model application in the Economic Analysis warrant further investigation into quantified costs and benefits this rule will impose.

EPA's analysis falls short of analyzing the full impact of the proposed rulemaking by only including engineering costs. Not including the social costs of carbon and other social costs hinders the Administrator from having all necessary information to set the PFOA and PFOS drinking water standard at a level that maximizes health risk reduction benefits at a cost that is justified, given those benefits.

Figure 8 in Attachment 1, and copied below, shows that the most benefits will occur for the population that has the highest exposure to PFOA and PFOS.

(PNG, 2023 Figure 8) Probability Distribution of HED by Disease Type for All Ages and Probability of Dose from Drinking Water for the Population

[Figure 8: see docket ID EPA-HQ-OW-2022-0114-1738]

The analysis by PNG replicated work by Chen et al and described in Attachment 1 aims to identify the most comprehensive evaluation of possible biologic changes in response to PFOS exposure. An adverse effect starts with biologic change; if there is little change in response to PFOS exposure at a certain dose, the likelihood of an adverse effect at that dose is greatly diminished. The Chen et al. and Chou et al. papers show the principal cellular and genomic changes in animal and human cells across a range of doses and cell types. For the most sensitive tissue and with the longest duration of PFOS exposure, the analysis identified 108 potential cellular and genomic changes and the dose that led to a 10 percent change in activity. A 10 percent change in activity does mean an adverse effect will happen – it is a benchmark commonly used by regulatory agency to mark when a chemical has a clear effect on the body. From these estimated benchmark doses, the analysis applied an additional safety factor of 30 to account for variation in responses in the human population. As a result, the analysis shows that below an internal dose of 20 ng/kg/day, there is little biological activity from PFOS exposure. Assuming a simple model of accumulation and excretion in the body, this dose translates to a 70 kg person drinking 2 liters a day of drinking water containing PFOS at 46 ppt.

Therefore, below a level equivalent to that concentration, very few if any adverse effects are expected. As a result, reducing existing state MCLs that range up to 15 or 20 ppt are expected to have minimal benefit, and EPA could set MCLs at 10 ppt without imposing any additional public health risks.

EPA Response: With respect to the commenter's recommendation to consider the social cost of carbon associated with this rulemaking, based on this and other comments, the EPA has included that analysis in the final rule; for additional details on this analysis, please see section XIII of the final rule preamble and section 13.11 of the EPA response in this *Response to Comments* document. With respect to considerations for other social costs, see section 13.9. For

additional discussion on benefit-cost considerations when setting the MCL and alternative regulatory standards, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The agency however disagrees that "reducing existing state MCLs that range up to 15 or 20 ppt are expected to have minimal benefit, and the EPA could set MCLs at 10 ppt without imposing any additional public health risks." The agency points to the fact that PFOA and PFOS are likely human carcinogens and that there is no level in drinking water below which no known or anticipated adverse effect on the health of persons would occur while allowing for an adequate margin of safety. Second, there are many states that currently do not have a state standard or health-based guideline value for any PFAS and as such, there is no requirement for systems to monitor and control for PFAS in their drinking water. In fact, based on individual state laws, some states are prohibited from adopting such as standard until the EPA promulgates one. As such, regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. Lastly, the EPA conducted a systematic review of all the available peer-reviewed literature reporting health effects associated with PFOS exposure..

The commenter is describing an approach to toxicity value derivation that is not commonly used by regulatory agencies and that is inconsistent with the currently established human health risk assessment methodologies and guidance developed by the EPA (e.g., USEPA, 2022b; USEPA, 2005, USEPA, 2002; USEPA, 2012). The commenter states that the analysis shows "that below an internal dose of 20 ng/kg/day, there is little biological activity from PFOS exposure. Assuming a simple model of accumulation and excretion in the body, this translates to a 70 kg person drinking 2 liters a day of drinking water containing PFOS at 46 ppt." The EPA disagrees with this analysis and with this approach to deriving a drinking water concentration. The EPA has shown that PFOA or PFOS exposures at doses several orders of magnitude lower are associated with multiple adverse health outcomes in humans (see section 4.2.2 of the EPA response in this *Response to Comments* document for how the EPA derived reference doses (RfDs) for PFOA and PFOS and section 4.2.1 of the EPA response in this *Response to Comments* document for the evidence supporting the critical effects that are the basis for the candidate RfDs derived in the final toxicity assessments (USEPA, 2024g; USEPA, 2024h)). The EPA has demonstrated that there is biological activity below the dose of 20 ng/kg/day recommended by the commenter. For more details on the EPA's MCLGs please see section 4 of the EPA response in this *Response to Comments* document.

LSP Association (LSPA) (Doc. #1742, SBC-043594)

See attached file(s)

Overall, while the LSPA absolutely believes that safe drinking water supplies are imperative, we urge USEPA to adopt the standard of 10.0 ppt (Option 1c) to more closely balance the costs and benefits of implementing this proposed rule. Simultaneously, the LSPA believes that the protection of public health will be much more effectively achieved by restricting the use of PFAS in consumer products.

Thank you for the opportunity to provide these comments.

EPA Response: The EPA Administrator is re-affirming the decision made at proposal that the benefits of the final NPDWR justify the costs. For additional discussion on benefit-cost considerations when setting the MCL and alternative regulatory standards, please see section 5.1.3 of the EPA response in this *Response to Comments* document.

LSP Association (LSPA) (Doc. #1742, SBC-043605)

Slide 29: EPA appreciates additional information and will use input received in public comments to inform the economic analysis for the final rule.

• In Section 2.1 of EPA-822-P-23-001, USEPA presents an evaluation of three alternatives for the enforceable MCL values for PFOA and PFOS:

o 4.0 ppt in Option 1a;

o 5.0 ppt in Option 1b, because it is 25 percent above the compliance quantitation limit of 4.0 ppt established for today's regulation; and at the level at which the benefits would justify the costs.

• In the tables provided in Section 7.0, only Option 1c results in a net benefit (for quantified factors) using both the 3% and 7% discount rates. As noted in other LSPA comments, a significant portion of the costs associated with the proposed MCLs (which will also dictate standards for private drinking water wells, groundwater, and leachable soil) is not quantified in the economic evaluation, which only includes public water supplies. These costs are not listed in Table 7-5 as non-quantified costs that were considered. As a result, LSPA urges USEPA to consider adopting the standard of 10.0 ppt (Option 1c) to more closely balance costs and benefits.

EPA Response: For additional discussion on cost considerations when setting the MCL and alternative regulatory standards, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The agency notes that while SDWA does not regulate private wells and this final rule does not set any requirements or standards for private well owners, the EPA understands that people who consume water from private wells may be concerned about contamination of their drinking water by PFAS or other contaminants. The EPA has resources to help people who rely on private wells for their drinking water at: https://www.epa.gov/privatewells. Standards for "groundwater" and "leachable soil," and any potential cost impacts, are not in scope of this NPDWR. SDWA Section 1412b(3)(C)(i)(III) requires that EPA include quantifiable and non-quantifiable costs that are likely to occur solely as a result of compliance with the rule including monitoring, treatment and other costs and excluding costs resulting from compliance with other proposed or promulgated regulations.

LSP Association (LSPA) (Doc. #1742, SBC-043610)

Overall, while the LSPA absolutely believes that safe drinking water supplies are imperative, we urge USEPA to adopt the standard of 10.0 ppt (Option 1c) to more closely balance the costs and benefits of implementing this proposed rule. Simultaneously, the LSPA believes that the protection of public health will be much more effectively achieved by restricting the use of PFAS in consumer products.

Thank you for the opportunity to provide these comments. Sincerely,

THE LSP ASSOCIATION, INC.

Charles P. Young, LSP, President

Wendy Rundle, Executive Director

cc:

Commissioner Bonnie Heiple, MassDEP

EPA Response: The EPA Administrator is re-affirming the decision made at proposal that the benefits of the final NPDWR justify the costs. For additional discussion on benefit-cost considerations when setting the MCL and alternative regulatory standards, please see section 5.1.3 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045564)

4. The results of the health risk reduction and cost analysis (HRRCA) are mixed and demonstrate the uncertainty of actual outcomes on communities. Under one analysis (3% discount rate), net benefits are expected for each rule option. Under the other analysis (7% discount rate), though, only one rule option (10 ppt PFOA and 10 ppt PFOS) has net benefits. EPA should recognize the significance of these conflicting results, in conjunction with the concerns regarding the cost analysis, prior to finalizing any rule.

EPA Response: The EPA Administrator is re-affirming the decision made at proposal that the benefits of the final NPDWR justify the costs. For additional discussion on benefit-cost considerations when setting the MCL and alternative regulatory standards, please see section 5.1.3 of the EPA response in this *Response to Comments* document. Additionally, the EPA disagrees with the commenter that results at proposal using the 3 and 7 percent discount rate were "conflicting." The results presented at 3 and 7 percent represent identical impacts, both costs and benefits of the regulation over the period of analysis. Positive net benefits at one discount rate and negative at the other discount rate simply demonstrates the impacts of adjusting the discount rate. See section 13.2 of the EPA response in this *Response to Comments* document for further discussion about discount rates. Further, as discussed in section 5.1.3 of the EPA response in this *Response to Comments* document, quantified positive net benefits at both 3 and 7 percent discount rates are not required to promulgate an MCL, nor are quantified costs and

benefits the only information considered in the Administrator's determination that the benefits of the rule justify its costs. As discussed in section 13.5 of the EPA response in this *Response to Comments* document, substantial nonquantifiable benefits of the rule are anticipated to be realized by rule implementation in addition to the quantified benefits discussed by the commenter. Additionally, see section 13.3 of the EPA response in this *Response to Comments* document on the cost analysis. Regulating PFAS and consumer products is outside the scope of this current rulemaking (please see section 15 of the EPA response in this *Response to Comments* document).

American Water Works Association (AWWA) (Doc. #1759, SBC-045633)

13. Alternative Regulatory Options for Drinking Water Standards

The proposal provides a detailed overview of the four regulatory alternatives that were considered by the Administrator to support this rulemaking. These options are laid out both in the preamble of the proposal and the economic analysis. The economic analysis frames both the costs and benefits of the proposed option and its alternatives. The proposed option is 4 ppt PFOA, 4 ppt PFOS, and a hazard index for PFHxS, PFNA, HFPO-DA, and PFBS of 1.0. Option 1a, 1b, and 1c propose MCLs for PFOA and PFOS each at 4 ppt, 5 ppt, and 10 ppt, respectively. Figures 13-1 and 13-2 depict the results of EPA's analysis based on both discount rates of 3% and 7%. Presentation of both discount rates to inform decision-making is consistent with Office of Management and Budget guidance for regulatory analyses.

A striking observation from both figures is the difference in annualized costs for the Proposed Option and Options 1a and 1b compared with Option 1c. Under both discount rates, the cost to implement the rule doubles from Option 1c to 1b. This is reflective of the significant number of systems that would be required to install PFAS treatment facilities to mitigate PFAS to comply with rule Option 1b compared to Option 1c. This difference is expected to impact systems that have PFAS levels ranging from 4 to 8 ppt, as EPA assumes that only systems within 80% of the MCL will make costly infrastructure investments.

These figures demonstrate that, regardless of the discount rate, there are minimal incremental benefits with the addition of the hazard index MCL for PFHxS, PFNA, PFBS, and HFPO-DA. This is substantiated by the available occurrence data, which demonstrates that very few systems would be required to install treatment for the PFHxS, PFNA, PFBS, and HFPO-DA MCL but not the PFOA and PFOS MCL.

[Figure 13-1: See Docket ID EPA-HQ-OW-2022-0114-1759]

Figure 13-1 : Annualized Costs and Benefits (7% Discount Rate)

[Figure 13-2: See Docket ID EPA-HQ-OW-2022-0114-1759]

Figure 13-2 : Annualized Costs and Benefits (7% Discount Rate)

To evaluate each regulatory option, AWWA considered the various concerns with the underlying analyses to support the rule that are discussed throughout this letter and the guiding principles for PFAS regulation that were noted earlier, and has determined that any rule will require a substantial level of work to improve the analyses that support the decision by the EPA. Furthermore, AWWA recommends that – if any rule is finalized based on the proposal – EPA finalize the MCLs for PFOA and PFOS at 10 ppt each. AWWA makes this recommendation for several reasons, laid out in more detail below.

EPA Response: The EPA agrees with the commenter that the agency presented discount rates in the proposed rule consistent with guidance in the A-4 circular. With respect to discount rates used in the proposed and final EA consistent with Circular A-4 Guidance, see section 14.1 of the EPA response in this *Response to Comments* document, Chapter 2 of the EA (USEPA, 2024d), and section 13.2 of the EPA response in this *Response to Comments* document. With respect to the incremental benefits of the Hazard Index MCLs, see Chapter 6 of the EA where EPA details the extensive nonquantifiable benefits of reduced exposure to PFAS beyond PFOA and PFOS, including the compounds in the Hazard Index. The EPA disagrees that the "rule will require a substantial level of work to improve the analyses that support the decision by the EPA." The agency has updated several analyses, including cost, benefit, and occurrence analyses, incorporating updated information suggested by commenters that all confirm the EPA's proposed rule finding. For more information about updates to the cost analyses, please see section 13.3 of the EPA response in this *Response to Comments* document; for updates to the benefits analyses, please see 13.4 of the EPA response in this *Response to Comments* document, and for updates to the occurrence analyses, please see section 6 of the EPA response in this *Response to Comments* document. All updated analyses are confirmatory of the EPA's conclusions in the proposed rule. For the final rule, the EPA Administrator is re-affirming the decision made at proposal that the benefits of the final NPDWR justify the costs. For additional discussion on benefit-cost considerations when setting the MCL and alternative regulatory standards, please see section 5.1.3 of the EPA response in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-045689)

VIII. EPA's BENEFITS ANALYSIS DOES NOT COMPLY WITH THE SDWA

The SDWA requires EPA to analyze the "[q]uantifiable and nonquantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur as the result of the treatment to comply" with each alternative level the Agency considers. [FN83: SDWA [sec]1412(b)(3)(C)(i)(I).] As discussed below, EPA's benefits analysis fails to comply with this requirement and is arbitrary, opaque, and counter to fundamentals of toxicology.

A. EPA's Selection of Alternative MCLs for PFOA and PFOS is Arbitrary

In promulgating NPDWRs since the 1996 SDWA Amendments, which first require consideration of alternatives, EPA has routinely considered at least four regulatory alternatives.

[FN84: See National Primary Drinking Water Regulations: Lead and Copper Rule Revisions, 84 Fed. Reg. 61684 (2019) (considering four alternative regulatory options); National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring 66 Fed. Reg. 6976 (2001) (considering four alternative MCL levels); and National Primary Drinking Water Regulations; Radon-222, 60 Fed. Reg. 59246 (1999) (considering seven alternative MCL levels).] As discussed below, in this rulemaking EPA considers only two theoretical alternatives to the proposed MCL of 4.0 ppt for PFOA and PFOS: 5.0 ppt and 10.0 ppt. EPA justifies its selection of regulatory alternatives not based on meaningful toxicological considerations, but instead on arbitrary comparisons to analytical levels and inapplicable state regulations. EPA states (USEPA 2023f) that it "considered an MCL of 5.0 ppt for PFOA and PFOS because it is 25 percent above the [practical quantitation limit] PQL of 4.0 ppt." EPA notes that this selection was based on input from a commenter in EPA's outreach consultations who "suggested the Agency consider a buffer of approximately 20 percent if the MCL is close to the quantitation level because water systems operate with a margin of safety and plan for performance that maintains water quality below quantitation levels." Thus, this value is intended to be a buffer between the PQL and MCL that could allow utilities to manage treatment approaches. EPA states that it disagrees that such a consideration is necessary but nonetheless applies the value yielded by the approach.

EPA (USEPA 2023f) also states that it "considered the MCL of 10.0 ppt to evaluate the national costs and benefits and whether the expected reduction in costs would change EPA's determination of the level at which the benefits would justify the costs (see Safe Drinking Water Act [SDWA] Section 1412(b)(6)(A))." The Agency maintains that this regulatory alternative level is consistent with State-enacted MCLs for certain PFAS, citing New York's PFOA and PFOS MCLs of 10 ppt. [FN85: EPA ignores that states have implemented a range of PFAS MCLs, some greater than 10 ppt., without further explanation for its use of 10ppt] There is no evidence that EPA considered different approaches nor the toxicological bases of various states' MCLs.

b. As a Matter of Toxicology, the "Alternatives" EPA Selected All Represent the Same Level of Exposure.

The alternatives EPA considered for PFOA and PFOS are meaningless, in violation of SDWA [sec]1412 (b)(3)(C)(i). EPA prepared a health risk reduction and cost analysis and quantified health outcomes in the benefits analysis for the proposed NPDWR, where it purported to distinguish between national benefits at drinking water concentrations of PFOS and PFOA at 4.0 ppt, 5.0 ppt, and 10.0 ppt (USEPA 2023i). It is not possible to determine how EPA conducted its benefits analysis because EPA did not make its model or important inputs into the model available in the public docket. What is clear is that EPA failed to acknowledge that chemical exposures from drinking water at 4.0 ppt, 5.0 ppt, and 10.0 ppt are toxicologically indistinguishable based on fundamental principles of toxicology and dose-response (Waddell 2008, 2010) and further detailed below. The numerically quantified health outcomes for those concentrations are not meaningful for public health.

Toxicology at its most fundamental level is based on the chemical reaction of a substance with a biological receptor. The activity of such chemical reactions is measured based on a logarithmic scale (Waddell 2008). Thus, dose-response relationships which describe the relationship of the amount of a substance to the effects from these biological reactions are assessed using a logarithmic scale. Consequently, when considering a logarithmic scale, only doses that differ by an order of magnitude (i.e., 10-fold) or more are biologically distinguishable. [FN86: The logarithmic nature of toxicology is also the reason why the dose selection for dose-response studies is generally advised to span two to four orders of magnitude (e.g., OECD, 2018 Test No. 408; USEPA, 2000 Health Effects Test Guidelines OPPTS 870.3050): it allows for an investigation of equidistant doses on the logarithmic scale in half-unit steps, e.g. log(1)=0, log(3.16)=0.5, log(10)=1, log(31.62)=1.5, log(100)=2, etc..] EPA even incorporates this concept into its own definition of a reference dose (USEPA 1993) "is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime." [emphasis added]. This definition highlights that it is not meaningful to distinguish between exposure doses occurring within an order of magnitude (i.e., 10-fold) of one another.

EPA's attempt to differentiate among health effects associated with the proposed MCL and the two regulatory alternatives—4.0 ppt, 5.0 ppt, and 10.0 ppt—is at best a theoretical exercise that lacks any toxicological relevance. This lack of relevance becomes obvious when human exposure doses are derived from the respective concentrations in drinking water and compared on a logarithmic scale.

However, the EPA (USEPA 2019) Exposure Factors Handbook provides information on drinking water intakes, and the following calculations can be conducted for any age group without yielding fundamentally different results. For this calculation (Table 7-1, Figure 7-2), the two-day average per capita estimates of combined direct and indirect water ingestion for all ages at the 95th percentile, which EPA listed as 37.1 ml/kg-d, was applied.

Table VII-1. Calculation of Hypothetical Exposure Doses (pg/kg-d) at Each Regulatory Alternative.

[Table VII-1: see docket ID EPA-HQ-OW-2022-0114-1774]

And displayed graphically:

[Figure VII-1: see docket ID EPA-HQ-OW-2022-0114-1774]

Figure. VII-1. Presentation of Exposure Doses Resulting from Proposed PFOA and PFOS Regulatory Alternatives.

The plots of daily exposures from drinking water that contains 4.0 ppt, 5.0 ppt, or 10.0 ppt of a substance (Figure 9-2) powerfully clarifies why dose should be considered on a logarithmic scale. In this figure, the y-axis is adjusted to a logarithmic scale to demonstrate that the three doses are actually all within one order of magnitude of each other (i.e., between 100 and 1000 pg/kg/d, a 10-fold range). In fact, the difference is within 2.5-fold. Accordingly, applying EPA's

definition of a reference dose, there would be no discernable differences between exposures occurring at 4.0 ppt, 5.0 ppt, or 10.0 ppt. Therefore, when presented on a toxicologically accurate scale, these three exposures cannot be expected to be biologically different from one another. Any hypothesized health benefits from choosing one of the proposed concentrations over the other are just that: hypothetical and speculative.

c. The Uncertainties in Parameters Used by EPA Thwart the Ability to Accurately Distinguish Between 4.0, 5.0, and 10.0 ppt.

Even though EPA listed numerous uncertainties in its benefits analysis, it failed to acknowledge that these uncertainties make it impossible to practically distinguish effects at concentrations of 4.0 ppt, 5.0 ppt, and 10.0 ppt. A slight change in assumptions within the spectrum of uncertainties might mathematically result in completely different concentrations in drinking water. In other words, the uncertainties in EPA's analysis are so great that they dwarf the difference between these toxicologically indistinct alternatives such that they are not true alternatives.

The calculations in Table 7-1 represent daily exposure doses. In contrast, EPA derived human equivalent internal doses using sophisticated models, which are based on numerous assumptions regarding intra- and interspecies variables in toxicokinetics (e.g., volume of distribution, half-life, tissue distribution), toxicodynamics (e.g., gender differences, age differences, susceptible life stages, differences in adverse outcome pathways), exposure (e.g., translation of concentration in rat chow into systemic exposure dose, relative source contribution assumptions, deterministic vs. probabilistic exposure modeling), and more. The six tables named "Limitations and Uncertainties" in the Economic Analysis draft (USEPA 2023i) further document the myriad assumptions that underpin EPA's analysis.

Every assumption used for these models and endpoints introduces uncertainty. Multiple uncertainties can have combinations of effects. Those effects can be additive, synergistic, potentiating, or antagonistic, which in turn introduces even higher levels of uncertainty regarding the accuracy of the predicted effects at the three alternative drinking water concentrations—without even considering the precision of said models. The compounding effects of multiple uncertainties far outweigh the de minimis differences of exposures on the logarithmic scale, which makes any attempt to distinguish between the health benefits of 4.0 ppt, 5.0 ppt, and 10.0 ppt not only futile but impossible.

D. EPA's Calculation of PFAS Serum Concentration Lacks Transparency

In the Economic Analysis, EPA (USEPA 2023i) states that it "developed single-compartment PK models for adult males and females to estimate blood serum PFOA and PFOS concentrations," noting that they are described in the MCLG documents. EPA then states that it compares the differences in serum concentrations at each regulatory alternative level to published coefficients of changes in serum concentrations that have been associated with health effects (e.g., reduced birth weight). Although EPA states the pharmacokinetics models are described in the PFOA and

PFOS MCLG documents (USEPA 2023a,b,c,d), neither these specific models nor the blood serum predictions are provided in the referenced material.

EPA's documents describe other pharmacokinetics models used for cross-species dosimetry or predicting points of departure to derive reference doses, but the "single-compartment pharmacokinetics models" used for predicting serum concentrations from drinking water – and subsequently for calculating benefits – are not described. EPA's entire benefits analysis hinges on these predicted serum data. It is the first parameter entered into the sequence of analyses that are used to estimate the health risk reduction benefits for the proposed MCL and the regulatory alternatives (e.g., Figure 6.1 of USEPA 2023i). EPA failed to clearly provide its predictions of the serum concentrations expected in populations consuming drinking water at the proposed MCL of 4.0 ppt and each regulatory alternative (5.0 ppt and 10.0 ppt) and identify if there are meaningful differences between the steady-state serum concentrations at each alternative. Importantly, there is no evidence that these pharmacokinetics models have been peer-reviewed. EPA's lack of transparency in model details, data outputs, assessment of uncertainty, and interpretation of results are underlying critical deficiencies. Such an analysis requires peer review before it is used to support regulatory decision-making. Moreover, EPA's lack of transparency is particularly important with respect to serum concentration calculations because the outputs of those calculations are used to determine difference in benefits at each regulatory alternative.

e. Demonstration of Overlap in Serum Concentrations at Each Regulatory Alternative

Though EPA does not make available either its model or its predictions of serum concentrations, EPA cites a first-order single-compartment model pharmacokinetics model (Bartell 2017; Lu and Bartell 2020) that it adapts to calculate PFNA serum concentrations from drinking water exposures (USEPA 2023k). To highlight the shortcomings in EPA's approach, this same model could be used to predict PFOA and PFOS steady state serum concentrations at the proposed MCL and each regulatory alternative. The following example analysis is intended to illustrate that the small, predicted differences in serum concentrations are not meaningful because they do not account for uncertainties and inherent variability in the model input parameters (e.g., half-life).

Table 7-2 demonstrates the model's outputs using NHANES geometric mean serum concentrations as the starting serum concentrations and assumes the model's defaults for other toxicokinetic and intake parameters. The half-life parameter was adjusted based on the range of half-lives reported by EPA to illustrate how altering only the half-life parameter impacts the modeled serum concentrations. EPA (USEPA 2023a,c) states that, in humans, the half-lives of PFOA can range from 1.7 years (Xu et al. 2020) to 4.4 years (Fu et al. 2016). For PFOS, halflives can range from 1.04 (Xu et al. 2020) to 60.9 years (Fu et al. 2016). For the calculation of points of departure, EPA (USEPA 2023a,c) selected a half-life of 2.7 years for PFOA (Li et al. 2017) and a half-life of 3.4 years for PFOS (Li et al. 2018), which is consistent with the model default (Lu and Bartell 2020).

As illustrated in Table 7-2, there is significant overlap in potential serum concentrations when inputting a range of half-lives for each regulatory alternative. For example, for PFOA, the predicted serum concentration at the 10.0 ppt and the shortest half-life (1.7 years) is 2.54 ng/ml which is less than the serum concentration of 2.64 ng/ml predicted at the longest half-life (4.71 years) and the lowest regulatory level (4.0 ppt). When EPA's selected half-lives are applied to the comparison of 4.0 ppt and 10.0 ppt, there is less than a 0.82 ng/mL difference in the predicted PFOA and PFOS serum concentrations (Table 9-2). These minimal differences in serum concentrations do not represent a meaningful difference in dose. Thus, there are likely not biologically relevant differences in effects between these regulatory alternatives.

Table VII-2. Predicted Steady State Serum Concentrations (ng/mL) at Each Regulatory Alternative Using Lu and Bartell 2020.

[Table VII-2: see docket ID EPA-HQ-OW-2022-0114-1774]

Notes:

Model Source: Lu S, Bartell SM. Serum PFAS Calculator for Adults, Version 1.2, 2020, www.ics.uci.edu/~sbartell/pfascalc.html.

Calculations assume a default starting serum concentration based on the NHANES geometric mean values for PFOA and PFOS (NHANES 2017-2018 Total Population https://www.cdc.gov/exposurereport/data_tables.html)

CI = confidence interval Half-life

Sources:

Model Default: PFOA is from Bartell et al. 2010 and PFOS is from Li et al. 2018 EPA: PFOA Li et al 2017 and PFOS Li et al 2018

The above analysis demonstrates that considerations of variability are critical in conducting an accurate scientific assessment of serum concentrations. EPA correctly notes that factors such as age and health status of individuals can impact toxicokinetic parameters such as half-lives (USEPA 2023a,c). However, it is not clear if or how such biological variability was accounted for in EPA's assessment of serum concentrations. EPA (USEPA 2023c) also states that "linear PFOS molecules exhibit longer half-lives than branched forms," but it is not clear if EPA considered those differences. Variability in other toxicokinetic parameters, such as volume of distribution or clearance rates, would add further uncertainty to the serum predictions. This inherent uncertainty in the alternatives analysis renders the overlap in serum concentrations at 4 ppt and the regulatory alternatives too great to be biologically distinct.

Additionally, EPA's apparent approach to predicting serum concentrations based on intake of drinking water contradicts its own statements in the MCLG documents (USEPA 2023a,c). In describing studies on half-lives for both PFOA and PFOS, EPA states, "there is insufficient data to correlate PFOS [and PFOA] intake measurements to serum/plasma and urine concentrations" [emphasis added]. Given this conclusion, it is unclear why EPA determined that predicting

serum concentrations as the basis of the benefits analysis was appropriate, in light of the significant population and biological variability in the underlying estimates of exposure and toxicokinetics. EPA's approach is not scientifically supportable.

These critical flaws in EPA's prediction of serum concentrations are then propagated through its benefits analysis, where EPA attempts to apply exposure-response relationships to assess associations with adverse disease outcomes and other estimates of impacted populations. There is simply no basis for distinguishing health outcomes across the regulatory alternative concentrations. Because there are no biologically meaningful differences between the serum concentrations at each regulatory alternative concentration (as explained above), the outputs of the benefits analysis also are neither meaningful nor valid. EPA has not chosen appropriate regulatory alternatives and there are likely no distinctly quantifiable health benefits at each of the alternatives.

EPA Response: The EPA strongly disagrees with the commenter that the benefits analysis does not comply with the SDWA and is "arbitrary, opaque, and counter to fundamentals of toxicology." The commenter raises several issues to which the agency is responding to below. First, the commenter contends that the EPA did not consider a sufficient range of regulatory alternatives and that only "two theoretical alternatives" were proposed. These claims are incorrect. As discussed in the topic essay to 5.1.3, the EPA first notes that SDWA does not require the agency to consider any certain number of alternative MCLs or a range of alternatives. Second, the agency identified, analyzed, and sought public comment on a reasonable number of regulatory alternatives which included establishing PFOA and PFOS MCLs (at 5.0 and 10.0 ppt) and individual MCLs for PFHxS, PFNA, HFPO-DA and PFBS instead of and in addition to using a mixture-based approach. Additionally, the EPA requested comment on the TOSHI or RPF approach as part of deriving the mixture MCLG that would then be used to set the MCL. Please see the topic essay 5.1.3 for further discussion on regulatory alternatives. In reference to the alternative of PFOA and PFOS MCL at 10.0 ppt, the commenter continues to say that there is "no evidence that EPA considered different approaches nor the toxicological bases of various states' MCLs." The EPA notes again that SDWA does not require the agency to consider different approaches or the toxicological bases of states' MCLs but only requires that in developing the HRRCA, the agency must consider the "incremental costs and benefits associated with each alternative maximum contaminant level considered." OMB Circular A-4 (OMB, 2003; OMB, 2023) further describes that "the number and choice of alternatives selected for detailed analysis is a matter of judgment." (please see topic essay 5.1.3 for further discussion). Based on the agency's technical expertise and judgment, the agency took comment on regulatory alternatives for PFOA and PFOS MCLs at 5.0 and 10.0 ppt and further summarized quantified costs and benefits for these alternative options within the proposed rule preamble and economic analysis supporting the proposal. The agency described the basis for these alternatives which included a 25 percent operational buffer above the PQL (for 5.0 ppt) and a level consistent with some state drinking water regulators (for 10.0 ppt), thereby providing a basis for comparison of the different regulatory approaches. For example, the state of New York has similar regulatory thresholds for PFOA and PFOS at the time of proposal (i.e., 10.0 ppt). While states may establish

drinking water standards for systems in their jurisdiction prior to regulation under SDWA, once an NPDWR is in place, SDWA requires that primacy agencies adopt standards that are no less stringent than the NPDWR.

The commenter contends that the alternatives the agency proposed all represent the same level of exposure and are not meaningfully different. First, the commenter is factually incorrect on assertions that the "EPA did not make its model or important inputs into the model available in the public docket." The model is cited in the EA and final tox assessment documents and the EPA provided the Pharmacokinetic (PK) model materials on the GitHub platform. The PK modeling approach used in the EA and the PFOA and PFOS toxicity assessments was peer reviewed by the EPA Science Advisory Board (SAB) (cite). The EPA does not provide blood serum predictions as this is not a requirement under SDWA. Regardless, these are estimated endogenously in the EPA's economic modeling and not programmed as an output. Second, the commenter states "definition [of an RfD] highlights that it is not meaningful to distinguish between exposure doses occurring within an order of magnitude (i.e., 10-fold) of one another." The commenter is incorrectly equating the definition of the RfD with the MCL. The MCLs for PFOA and PFOS are not based on a RfD. They are set as close as feasible to the MCLG, taking into account cost and feasibility (please see section 5.1.2, 5.1.3 and 5.1.4 of the EPA responses in this *Response to Comments* document for additional information). The purpose of the regulatory alternatives is not to distinguish between toxicological relevancy among the alternatives but to understand the incremental costs and benefits associated with each alternative MCL considered. See SDWA 1412(b)(3)(C)(i)(IV). Third, the commenter claims that 4.0 ppt, 5.0 ppt and 10.0 ppt are "toxicologically indistinguishable based on fundamental principles of toxicology and dose-response" and that the health outcomes quantified at these concentrations are not meaningful to public health. The commenter further provides a non-peer reviewed and hypothetical illustration of this point in sections (d) I (e) of their submission. The agency disagrees. As discussed in section IV of the final rule preamble and section 4 of the *Response to Comments* document, the EPA has determined that PFOA and PFOS are *Likely to be Carcinogenic to Humans* based on sufficient evidence of carcinogenicity in humans and animals (USEPA, 2024k). The EPA has also determined that a linear default extrapolation approach is appropriate as there is no evidence demonstrating a threshold level of exposure below which there is no appreciable cancer risk (USEPA, 2005). Therefore, *any* increase in exposure would result in a linear increase in cancer risk which would result in anticipated adverse health effects.

Further, as discussed in the topic essay to 5.1.3, SDWA 1412(b)(3)(C)(i)(IV) states that in developing the HRRCA, the agency must consider the "incremental costs and benefits associated with each alternative maximum contaminant level considered." Thus, the agency must conduct a cost-benefit analysis with each alternative MCL that is considered, if any. The agency has conducted a thorough cost-benefit analysis that are based on the best available, peer-reviewed science and meet the requirements of SDWA (please see the document titled "*Economic Analysis for the Final Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation"* supporting the final NPDWR and section 13 of the *Response to Comments* document for more information on the economic analysis). Additionally, the regulatory

alternatives of 5.0 ppt and 10.0 ppt are meaningful different from a treatment operations standpoint. The SDWA requires the agency to establish MCLs as close as *feasible* to the MCLG (emphasis added). Consistent with the statute, EPA considers cost as well as analytical limits of best available treatment technology, including availability of analytical methods, laboratory capability, capacity, and quantitation. An MCL at 5.0 ppt is different from an MCL at 4.0 ppt from a treatment operations, monitoring, compliance, analytic and implementation standpoint (please see discussion in 5.1.2 for discussion on laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, as well as practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations; additionally, see section 8 for monitoring and compliance requirements for the final NPDWR). These factors are also important for an MCL at 10.0 ppt. For example, media change-outs are less frequent when treating to a higher standard, thereby impacting cost and benefit (please see section 5.1.4 for additional considerations for treatment feasibility). With respect to concerns regarding the EPA's PK modeling approach, please see section 4.2.4 of the *Response to Comments* document. With respect to the how the EPA considered other agencies' (including states') assessments and why the agency's health conclusions may have differed, please see section 4.2.6. With respect to conclusions about the adversity of the non-cancer critical effects, please see section 4.2.2.

The EPA also disagrees with the commenter's assertion that the benefits analysis uncertainties "are so great that they dwarf the difference between these toxicologically indistinct alternatives such that they are not true alternatives." The EPA has quantitatively characterized the uncertainty concerning health effect serum slope factors used in benefits analysis and the uncertainty related to this (or any) data input does not discredit the estimated benefits under any of the regulatory alternatives. The EPA maintains that after taking all key modeling uncertainties into account, the regulatory alternatives described in the rule and assessed in the economic analysis are meaningfully distinct. Moreover, the EPA maintains that the regulatory alternatives are meaningfully different from both health effects and treatment perspectives. The EPA went to great lengths to characterize the uncertainty for all key benefits analysis inputs, which is described in section XII of the preamble and also USEPA (2024d). See section 13.9 in this *Response to Comments* document for the EPA's responses to comments received on quantified uncertainties in the economic analysis.

With respect to the commenter claiming that the EPA's approach to the benefits analysis being contradictory to a statement made in the MCLG documents, the EPA has edited the quoted sentence in section 3.3.1.4.5 to avoid any misinterpretation (USEPA, 2024i; USEPA, 2024j). When taken out of context, as the commenter has done here, the sentence appears contradictory to the approach used in the economic analysis. However, in context, the sentence was commenting on sources of variability in reported measurements of the PFOA/S half-life. While variability in the half-life measurements exists, it doesn't preclude the ability for the EPA to conclude that the half-lives of PFOA/S are within the range of reported values nor the use of a value within that range to estimate how changes in PFOA/S exposure will affect serum/plasma

concentrations. The EPA maintains that predicting serum concentrations as the basis of the benefits analysis is appropriate.

Finally, as discussed in this response, the EPA had strong reasons firmly grounded in analytical methods, engineering, and treatment feasibility, among other things, for considering the different regulatory options in this proposal (see 88 Federal Register [FR] 18638). In short, they are not "meaningless" as claimed by commenter. Furthermore, as commenter themselves acknowledges, one of these options for setting PFOA and PFOS MCLs at 5.0 ng/L was partially informed by early public input. The EPA considering public input in developing regulatory options is not arbitrary; in contrast, it is responsive to stakeholder input consistent with the goals of the various consultation processes. Additionally, while the commenter focuses on considerations related to toxicology and PKs, the commenter ignores issues related to that is described in the 5.1.3 response essay and in section V of the preamble of this rule that the EPA must consider when setting an MCL at a feasible level. While toxicological information is relevant to setting the MCLG, the language in the SDWA is clear: the EPA must set the MCL as close as feasible to the MCLG. And as discussed previously in this response and elsewhere in this *Response to Comments* document, based on best available, peer-reviewed science, the EPA determined that PFOA and PFOS are *Likely to be Carcinogenic to Humans*, and therefore set the MCLGs at zero.

3M Company (Doc. #1774, SBC-045673)

Not only is the failure to consider any alternatives to the HI-MCL itself a direct violation of the SDWA, it also led to EPA's failure to identify the level at which the costs of the HI-MCL justify the benefits. The HBWCs are purely health-based and should be calculated to have a margin of safety, similar to an MCLG. But EPA effectively set MCLs for these four substances at the HBWC without considering whether the same benefits could be achieved for lower costs because it did not consider any alternatives to the HBWCs as required by the SDWA. [FN44: See SDWA [sec]1412(b)(3)(C)(i).]

EPA Response: The SDWA does not require the EPA to consider or propose any certain or minimum number of alternative MCLs, MCLGs or a range of alternatives. Please see the section in section 5.1.3 of the EPA response in this *Response to Comments* document for further discussion. Furthermore, the EPA disagrees with the commenter that the agency "failed to consider any alternatives to the HI-MCL". The EPA notes that the agency proposed two options for the Hazard Index PFAS: option 1 which set the HBWCs set at 10.0 for PFNA, 9.0 ng/L for PFHxS, 10.0 for HFPO-DA (GenX chemicals), and 2000 ug/L for PFBS and a hazard index of 1.0; options 1a, 2, and 3 would not regulate these four PFAS for this action (therefore setting no MCLGs or HBWCs). As discussed in section 5.1.3 of the EPA response in this *Response to Comments* document and in the proposed rule preamble, the agency took comment on establishing individual MCLs instead of and in addition to using a mixture-based approach for PFHxS, PFNA, HFPO-DA, and/or PFBS in mixtures. Additionally, the EPA requested comment on alternative mixture-based approaches such as a TOSHI or relative RPF approach.

The EPA also notes that the HBWCs do include a margin of safety. The equation used to calculate an HBWC is the same as the equation used to calculate an MCLG and includes a toxicity reference value and a RSC as inputs. The RSC, along with uncertainty factors applied to the toxicity reference value, afford a margin of safety. For additional discussion regarding the MCLG derivation for a PFAS mixture and additional individual PFAS, please see section 4.3 of the EPA response in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-044823)

[As outlined in these comments, the Agency's proposal suffers from a number of significant shortcomings, including the following –]

• The Agency's choice of regulatory alternatives does not provide a reasonable basis for comparison of the possible regulatory approaches.

EPA Response: The EPA disagrees that the regulatory alternatives considered in the final NDPWR did not "provide a reasonable basis for comparison of the possible regulatory approaches." Please see the please see section 5.1.3 of the EPA response in this *Response to Comments* document for additional details and the EPA response to comment Doc. #1669, SBC-045689 and Doc. #1774, SBC-045673 in section 5.1.3 in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-044813)

[The Agency's proposal suffers from the following significant shortcomings –]

• The Agency's choice of regulatory alternatives does not provide a reasonable basis for comparison of the possible regulatory approaches.

EPA Response: The EPA disagrees that the regulatory alternatives considered in the final NDPWR did not "provide a reasonable basis for comparison of the possible regulatory approaches." Please see the please see section 5.1.3 of the EPA response in this *Response to Comments* document for additional details and the EPA response to comment Doc. #1669, SBC-045689 and Doc. #1774, SBC-045673 in section 5.1.3 in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-044850)

EPA has not Provided Information on an Appropriate Range of Regulatory Alternatives

EPA's economic analysis provides three alternatives to the current proposal to establish MCLs of 4 ppt for PFOA and PFOS and an HI MCL of 1.0 for PFBS, HFPO-DA, PFHxS, and PFNA. The alternatives include MCLs of 4.0 ppt, 5.0 ppt, and 10.0 ppt for PFOA and PFOS, with no MCL for the other four substances. As summarized in Table 6, EPA estimates essentially no difference in the number of systems impacted and the compliance cost by eliminating the HI MCL, a marginal reduction in impacts by increasing the MCLs to 5.0 ppt, and a significant reduction by

increasing the MCL to 10.0 ppt. The Agency's estimates for the total benefits achieved with each of the Options show a similar pattern.

Table 6. Comparison of Current Proposal and Alternatives

[Table 6: See Docket ID EPA-HQ-OW-2022-0114-1841]

The Agency's estimates for the three options likely suffer from the same shortcomings as the Agency's proposal, but there is not an independent analysis for each of the Options to use for comparison. We note, however, that the US Chamber of Commerce [FN200: The Chamber's analysis was submitted to the Office of Information and Regulatory Affairs of the Office of Management and Budget as part of an Executive Order 12866 meeting on November 1, 2022.] estimates a total cost of $16 billion to comply with MCLs of 10 ppt for PFOA and PFOS – which reflects an annualized cost well above the EPA estimate. [FN201: The Chamber's analysis does not provide an annualized estimate of costs.]

EPA has not provided a rationale for why the levels of 5.0 ppt and 10.0 ppt were chosen for its alternatives analysis. As the Agency readily acknowledges, it does not have actual occurrence data to determine the number of water systems likely to exceed each of these levels. While EPA has developed a statistical model to predict the number of exceedances, it has no way to validate the model until more sensitive occurrence data become available from UCMR 5. Consequently, it is not clear how accurately the model can predict differences among the small range of values that the Agency has chosen. In fact, a comparison of the Agency's modeling results with those from AWWA and the US Chamber of Commerce raises significant question about the model's reliability. Given the significant uncertainty, presenting information on a broader range of alternative values would be more instructive.

OMB's Circular A-4 offers guidance on the construction of regulatory alternatives. The following passages are particularly relevant for the proposed rule –

You should nevertheless explore modifications of some or all of a regulation's attributes or provisions to identify appropriate alternatives. . . You should study alternative levels of stringency to understand more fully the relationship between stringency and the size and distribution of benefits and costs among different groups. [FN202: OMB Circular A-4.]

To better understand this relationship, the Agency should at the very least provide a comparison of its proposal to an alternative based on the minimum reporting levels for PFOA and PFOS of the UCMR 3 survey data. [FN203: These levels were 20 ppt for PFOA and 40 ppt for PFOS.] This would provide the Agency and the stakeholders with a more accurate baseline for comparison with the current proposal.

EPA Response: For additional discussion on benefit-cost considerations when setting the MCL and alternative regulatory standards, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The commenter is factually incorrect when stating the EPA "has not provided a rationale for why the levels of 5.0 ppt and 10.0 ppt were chosen for its alternative analysis." Please also see section 5.1.3 of the EPA response in this *Response to*

Comments document for additional details. Regarding responses on the agency's occurrence analysis and consideration for UCMR 5 results, please see section 6 of the EPA response in this *Response to Comments* document. The agency also disagrees with the alternatives suggested by the commenter (20 ppt for PFOA and 40 ppt for PFOS); analytical accuracy and precision has improved since UCMR 3 data collection so these levels are not reflective of the current and best available, peer-reviewed science and supporting information which is a key consideration under SDWA. Proposing an option that's appreciably above current analytic capabilities will be disingenuous as the EPA fulfills these statutory requirements in promulgating a NPDWR. The EPA disagrees with the commenter's representation of costs in the report cited by this commenter. For more information, see the EPA response to comment Doc. #1537, SBC-042649 in section 13.3.3 in this *Response to Comments* document. In response to the commenter's reference to American Water Works Association Black & Veatch (AWWA B&V) estimates of national costs, EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. See section 13.3.3 of the EPA response in this *Response to Comments* document for more details. Importantly, the EPA notes that this analysis is not "independent" as characterized by the commenter. Rather, it is produced under contract to an organization that represents many of the entities that will be directly regulated under this rule.

The Chemours Company FC, LLC (Doc. #1845, SBC-046056)

EPA's analysis of the cost-benefit impact of the four-compound HI proposal is also flawed because EPA did not evaluate the costs and benefits of other options for regulating these four compounds. This stands in sharp contrast to the MCL proposal for PFOA and PFOS, where EPA analyzed the impacts of potential MCL levels of, respectively, 4.0 ppt,

5.0 ppt, and 10.0 ppt. But EPA did not analyze the impacts of setting the HI at levels other than 1.0.

EPA did analyze the option of setting the MCL for PFOA and PFOS at 4.0 ppt but with no MCL for PFHxS, PFBS, PFNA, and/or HFPO-DA. That analysis looks substantially similar to the analysis with PFOA and PFOS at 4.0 ppt and the HI of 1.0 included. The respective analyses are summarized in Tables 7-1 and 7-2 of the EPA Economic Analysis:

[Table 7-1: See Docket ID EPA-HQ-OW-2022-0114-1845]

[Table 7-2: See Docket ID EPA-HQ-OW-2022-0114-1845]

What these two tables show is that at a 3% discount rate, including the HI of 1.0 in the MCL would add no significant net benefit ($461.21 million annual expected value with the HI included compared to $460.26 million without it). And at a 7% discount rate, the costs would exceed the benefits by even more with the HI included (-$296.50 million compared to -$281.95 million). Of course, as discussed above, and recognized in the footnotes to Table 7-1, EPA's

analysis suffers from the critical uncertainty caused by the lack of occurrence data for HFPO-DA, PFBS, and PFNA.

Finally, EPA did not do a quantitative analysis of the costs and benefits of setting individual compound MCLs for each of PFHxS, PFBS, PFNA, and HFPO-DA. EPA recognizes its failure to do this analysis, but offers no explanation other than the conclusory statement that the HI approach would bring in more systems. Before embarking on use of an unprecedented multi-compound HI approach to ratchet down levels already set with multiple orders of magnitude of conservatism, sound public policy and the requirements of the SDWA necessitate an actual analysis of what the marginal costs and benefits will be.

In summary, EPA first promulgated a 10 ppt health advisory level for HFPO-DA, which it categorized as non-regulatory, without doing any cost-benefit analysis, asserting that none was required. Now when such an analysis is clearly required, EPA is again trying to avoid whether its proposal is justifiable by pointing to a lack of necessary occurrence data. EPA should never attempt to promulgate an MCL until it has the data it needs pursuant to the SDWA, and then should robustly evaluate other options. For all of the reasons set forth above, Chemours expects that a fully-informed cost-benefit analysis would show that regulating HFPO-DA at the levels proposed by EPA is neither warranted by the scientific evidence nor justifiable in light of the costs.

EPA Response: The agency disagrees with the commenter that the EPA did not consider a sufficient range of regulatory alternatives. The agency also provided an explanation as to why the EPA did not separately present changes in quantified costs and benefits for alternatives to the Hazard Index MCL. Please see section 5.1.3 of the EPA response in this *Response to Comments* document for additional information. Regarding responses on the agency's occurrence analysis, please see section 6 of the EPA response in this *Response to Comments* document. For responses on occurrence data for HFPO-DA and the agency's final regulatory determination, please see section 3.1.2 of the EPA response in this *Response to Comments* document.

The EPA disagrees with the commenter's assertion that the agency did not consider costs and benefits for the four Hazard Index PFAS. As required by SDWA, the agency considered both the quantifiable and nonquantifiable costs and benefits associated with compliance with the rule, including removal of the Hazard Index PFAS. For an overview of nonquantifiable costs and benefits considered by the EPA, including those associated with regulating the four Hazard Index PFAS, please see Tables 5-22, 6-48, and 7-6 of the EA (USEPA, 2024d). Please see section 13.3.2 of the EPA response in this *Response to Comments* document on the costs associated with the Hazard Index and Appendix N of the EA (USEPA, 2024c) for EPA's national level analysis of the costs associated with PFNA, HFPO-DA and PFBS. See Section 5.1.3 of the EA (USEPA, 2024d) for a summary of the EPA's annualized national cost estimates, which include costs associated with PFHxS. Please see Appendix K for the EPA's sensitivity analysis assessing the quantified benefits associated with PFNA effects on birth weight. Please see section 13.8 for discussion of the EPA's comparison of costs and benefits of the rule, including the Administrator's determination that the costs of the rule are justified by the benefits.

Additionally, the EPA disagrees with the commenter's statement that the "EPA first promulgated a 10 ppt health advisory level for HFPO-DA." The EPA published a health advisory under its authority provided in SDWA section 1412(F). The EPA maintains that its 2022 HA for HFPO-DA is not a legally enforceable federal standard and is not subject to the HRRCA requirements. For more information on the agency's health advisories, please see: https://www.epa.gov/sdwa/drinking-water-health-advisories-has. Therefore, the EPA disagrees with the commenter's assertion that the agency is "trying to avoid whether its proposal is justifiable," as the agency considered the quantifiable and non-quantifiable costs associated with the Hazard Index MCL, including HFPO-DA in EA for both the proposed and final rule, pursuant to SDWA.

El Paso Water (Doc. #1757, SBC-044525)

Keep MCL at current level

Like many utilities across the country, EPWater is concerned with any possible reductions in the MCL. Any such change would pose incredible financial cost to PWSs and be a strain on staffing for utilities such as ours.

A reduction in the MCL will be incredibly costly for any PWS and its ratepayers at a time when many systems are struggling to attract and retain qualified workers, and at a time when the cost of construction of new facilities remains stubbornly high. Adding to these costs would be the additional cost to dispose of PFAS tainted treatment media, which would be considered hazardous material.

Also, a reduction in the MCL will not be based on sound scientifically reliable data. The EPA's approach to gathering national PFAS contamination data to help develop proposed revisions was to take representative samples from a small number of systems nationwide. This is NOT representative of all of the approximately 140,000 systems throughout the nation. We urge the EPA to reconsider implementing costly lower MCL regulations.

EPA Response: For additional discussion on cost considerations when setting the MCL, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA disagrees that the final MCLs are not based on sound and scientifically reliable data (for additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document). The EPA also disagrees with the commenter that the agency did not consider a representative number of small systems nationwide. The agency relied on multiple data sources, including UCMR 3 (which includes a representative sample of small systems) and state finished water data, to evaluate the occurrence of PFOA, PFOS, PFHxS, PFNA, and HFPO-DA and probability of co-occurrence of these PFAS and PFBS. The EPA also incorporated both the UCMR 3 and some state data into a Bayesian hierarchical model which supported exposure estimates for select PFAS at lower levels than were measured under UCMR 3. The specific modeling framework used to inform this regulatory action is based on the peer-reviewed model

published in Cadwallader et al. (2022). Further, the commenter is incorrect in stating that "adding to these costs would be the additional cost to dispose of PFAS tainted treatment media, which would be considered hazardous material." First, disposal options for PFAS are currently available. These destruction and disposal options include landfills, thermal treatment, and underground injection. Systems are currently disposing of spent media, such as activated carbon, through thermal treatment, to include reactivation, and at landfills. Second, there are currently no federal regulations that designates PFAS (or treatment residuals that contain PFAS) as hazardous waste. Third, the EPA has estimated the treatment costs for systems both with the use of hazardous waste disposal and non-hazardous disposal options to assess the effects of potentially increased disposal costs. Specifically, the EPA assessed the potential impact on PWS treatment costs associated with hazardous residual management requirements in a sensitivity analysis.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045952)

Section 3: Maximum Contaminant Level

Like the MCLGs, EPA is proposing individual Maximum Contaminant Levels (MCLs) for PFOA and PFOS, and an MCL for PFNA, PFHxS, GenX, and PFBS as a mixture. Under section 1412(b)(4)(B) of SDWA, EPA must establish an enforceable MCL, "which is as close to the [MCLG] as is feasible." Section 1412(b)(4)(D) subsequently defines "feasible" to mean "feasible with the use of the best technology, treatment techniques and other means which the Administrator finds … are available (taking cost into consideration)."

Section 3.1: PFOA and PFOS

EPA has proposed individual MCLs of 4.0 parts per trillion (ppt) each for PFOA and PFOS. EPA also explored the costs of potentially proposing 5.0 ppt and 10.0 ppt, individually. EPA determined the Best Available Technologies (BATs) have the capability to bring PFAS levels down below the proposed 4.0 ppt MCL, which AMWA believes is true. However, the costs, supply chain, and labor challenges affecting the compliance timeline, and current and future simultaneous compliance challenges, invite questions as to whether this standard is actually feasible under SDWA, as defined in Section 1412(b)(4)(D).

EPA Response: For additional discussion on cost considerations when setting the MCL, please see section 5.1.3 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 10 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Western Urban Water Coalition (WUWC) (Doc. #1768, SBC-043937)

I. EPA Has Not Evaluated the Proposed MCLs for Economic Feasibility

WUWC is concerned with the methods and standards used to evaluate the economic feasibility of the proposed Maximum Contaminant Levels (MCLs). [FN3: 88 Fed. Reg. at 18668–69, 18730

(requesting public comment on EPA's evaluation of the economic feasibility of MCLs under the Proposed Rule).] The SDWA requires EPA to set primary drinking water standards as close to the MCL goals (MCLGs) as "feasible," taking account of both technical feasibility and economic feasibility. [FN4: SDWA § 1412(b)(4)(B); 42 U.S.C. § 300g-1(b)(4)(B); Congressional Research Service, Regulating Contaminants under the Safe Drinking Water Act (SDWA), 2, 13 (Jan. 5, 2022).] Separately, the SDWA requires that EPA prepare a Health Risk Reduction and Cost Analysis (HRRCA) that considers the costs of compliance with a proposed MCL. [FN5: SDWA § 1412(b)(3)(C); 42 U.S.C. § 300g-1(b)(3)(C).] Because the Proposed Rule is considered a significant regulatory action, EPA is required by Executive Order 12866 to prepare an Economic Analysis (EA) weighing the Proposed Rule's reasonably foreseeable costs and benefits.

In light with these latter two requirements, EPA completed an EA [FN6: U.S. EPA, Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation (Mar. 2023), EPA-822-P-23-001 (the "EA").] and HRRCA that comparatively evaluate the costs and benefits of the proposed MCLs and other less stringent potential MCLs not chosen under the Proposed Rule. EPA relies on the EA and HRRCA throughout the Proposed Rule wherever it references cost considerations. In this respect, EPA treats the requirement for economic feasibility analysis as equivalent to cost-benefit analysis and essentially procedural.

Instead, the economic feasibility analysis needed is both procedural and substantive. Procedurally, EPA cannot lawfully ignore entire categories of costs that necessarily will result from promulgation of a new MCL. Michigan recently ran afoul of this principle when a state court overturned its proposed state MCL for PFOA and PFOS. See 3M Company v. Mich. Dep't. of Env't, Great Lakes, and Energy, No. 21-000078 (Mich. Ct. Claims) (Nov. 15, 2022). The court faulted Michigan for preparing a Regulatory Impact Statement [FN7: The Regulatory Impact Statement required under Michigan law is akin to the requirements for an EA and HRRCA under federal law.] that failed to evaluate cleanup costs arising from the proposed MCL because existing Michigan law would have required the MCL to be used as a groundwater cleanup standard for aquifers contaminated with PFOA or PFOS "as a matter of law."

Substantively, the SDWA requires EPA to find that each proposed MCL is "technically possible and affordable." City of Portland v. EPA, 507 F.3d 706, 712 (D.C. Cir. 2007). California violated this principle in 2017 when a state court overturned its then-proposed MCL for hexavalent chromium under the California SDWA. See Cal. Mfrs. and Tech. Ass'n v. State Water Res. Control Bd., No. 34-2014-80001850 (Super. Ct. Cal.) (May 5, 2017). While acknowledging that the state's "cost estimates themselves [were] quite thorough," under the SDWA, the court found "simply coming up with cost estimates for seven MCLs and then selecting one of those MCLs is not equivalent to considering the economic feasibility of complying with the MCL." In particular, the court focused on the agency's failure to make findings concerning the affordability of the Proposed Rule to water utility customers.

EPA Response: For additional discussion on cost considerations when setting the MCL, please see section 5.1.3 for the EPA response in this *Response to Comments* document. The EPA disagrees with commenter that the EPA "treats the requirement for economic feasibility analysis

as equivalent to cost-benefit analysis and essentially procedural" and that the agency ignored "entire categories of costs that necessarily will result from promulgation of a new MCL." First, the commenter does not refer to any specific categories in its comment. Second, the EPA considered costs of treatment technologies that have been demonstrated under field conditions to be effective at removing the PFAS at issue and determined as part of its feasibility analysis that the costs of complying with an MCL at 4.0 for PFOA/PFOS, 10 ng/L for PFHxS, PFNA, and HFPO-DA, and the Hazard Index MCL of 1 is reasonable based on consideration of costs borne by large metropolitan PWSs. Please see sections 5.1.2, 5.1.3 and 5.14 for the EPA responses in this *Response to Comments* document for additional discussion on the agency's feasibility analysis with respect to laboratory considerations, cost, and treatment, respectively. In addition, the EPA used the HRRCA as the basis for its determination made under 1412(b)(4)(C) in the proposal and affirmed its final rule. The commenter's discussions of state law cases regarding adoption of state MCLs pursuant to state law prior to a federal standard are outside the scope of this rule.

West Virginia Municipal Water Quality Association (Doc. #1816, SBC-044684)

CONCLUSION

We believe that EPA must reevaluate its proposed MCLs. We think EPA must fully consider the extensive human health data available to it. EPA must also fully engage its state partners in assessing health benefits (lack of any health clusters) as well as implementation costs. After all, the states are the primary entities that track such information – especially on the cost side as the states administer the federal State Revolving Fund programs.

At a minimum, EPA should reevaluate its proposed criteria, consistent with our comments, and republish revised draft MCLs for further public comment. After all, this is the most significant federal Safe Drinking Water Act-based proposed rule in decades. In reconsidering its proposed rule, we urge EPA to consider our suggestion about phasing/tiering the MCLs. We believe that is a practical necessity that will allow significant benefits including the prioritization of PFAS barrier technology in environmental justice communities and communities with higher source water PFAS levels.

We are available to discuss our comments and to provide any additional information which EPA may require.

Sincerely,

F. Paul Calamita

General Counsel

C: WVMWQA Members

EPA Response: Please see section for 5.1.4 of the EPA response in this *Response to Comments* document. The EPA disagrees that the final MCLs are not based on sound and

scientifically reliable data (please see discussion in section 5.1.2 of the EPA response in this *Response to Comments* document on how the agency evaluated feasibility of the MCLs). For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 10 of the EPA response in this *Response to Comments* document on extensions and exemptions. For environmental justice considerations, please see section 14 of the EPA response in this *Response to Comments* document.

Association of Missouri Cleanwater Agencies (Doc. #1817, SBC-044662)

CONCLUSION

We believe that EPA must reevaluate its proposed MCLs. We think EPA must fully consider the extensive human health data available to it. EPA must also fully engage its state partners in assessing health benefits (lack of any health clusters) as well as implementation costs. After all, the states are the primary entities that track such information – especially on the cost side as the states administer the federal State Revolving Fund programs.

At a minimum, EPA should reevaluate its proposed criteria, consistent with our comments, and republish revised draft MCLs for further public comment. After all, this is the most significant federal Safe Drinking Water Act-based proposed rule in decades. In reconsidering its proposed rule, we urge EPA to consider our suggestion about phasing/tiering the MCLs. We believe that is a practical necessity that will allow significant benefits including the prioritization of PFAS barrier technology in environmental justice communities and communities with higher source water PFAS levels.

We are available to discuss our comments and to provide any additional information which EPA may require.

Sincerely,

F. Paul Calamita

General Counsel

C: AMCA Members

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044684 in section 5.1.3 in this *Response to Comments* document.

NORTH CAROLINA WATER QUALITY ASSOCIATION (Doc. #1818, SBC-044640)

CONCLUSION

We believe that EPA must reevaluate its proposed MCLs. We think EPA must fully consider the extensive human health data available to it. EPA must also fully engage its State partners in assessing health benefits (lack of any health clusters) as well as implementation costs. After all,

the states are the primary entities that track such information – especially on the cost side as the states administer the federal State Revolving Fund programs.

At a minimum, EPA should reevaluate its proposed criteria, consistent with our comments, and republish revised draft MCLs for further public comment. After all, this is the most significant federal Safe Drinking Water Act-based proposed rule in decades. In reconsidering its proposed rule, we urge EPA to consider our suggestion about phasing/tiering the MCLs. We believe that is a practical necessity that will allow significant benefits including the prioritization of PFAS barrier technology in environmental justice communities and communities with higher source water PFAS levels.

We are available to discuss our comments and to provide any additional information which EPA may require.

Sincerely,

F. Paul Calamita

General Counsel

C: NCWQA Members

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044684 in section 5.1.3 in this *Response to Comments* document.

South Carolina Water Quality Association (Doc. #1819, SBC-044618)

CONCLUSION

We believe that EPA must reevaluate its proposed MCLs. We think EPA must fully consider the extensive human health data available to it. EPA must also fully engage its state partners in assessing health benefits (lack of any health clusters) as well as implementation costs. After all, the states are the primary entities that track such information – especially on the cost side as the states administer the federal State Revolving Fund programs.

At a minimum, EPA should reevaluate its proposed criteria, consistent with our comments, and republish revised draft MCLs for further public comment. After all, this is the most significant federal Safe Drinking Water Act-based proposed rule in decades. In reconsidering its proposed rule, we urge EPA to consider our suggestion about phasing/tiering the MCLs. We believe that is a practical necessity that will allow significant benefits including the prioritization of PFAS barrier technology in environmental justice communities and communities with higher source water PFAS levels.

We are available to discuss our comments and to provide any additional information which EPA may require.

Sincerely,

F. Paul Calamita

General Counsel

C: SCWQA Members

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044684 in section 5.1.3 in this *Response to Comments* document.

Wet Weather Partnership (Doc. #1820, SBC-044596)

CONCLUSION

We believe that EPA must reevaluate its proposed MCLs. We think EPA must fully consider the extensive human health data available to it. EPA must also fully engage its State partners in assessing health benefits (lack of any health clusters) as well as implementation costs. After all, the states are the primary entities that track such information – especially on the cost side as the states administer the federal State Revolving Fund programs.

At a minimum, EPA should reevaluate its proposed criteria, consistent with our comments, and republish revised draft MCLs for further public comment. After all, this is the most significant federal Safe Drinking Water Act-based proposed rule in decades. In reconsidering its proposed rule, we urge EPA to consider our suggestion about phasing/tiering the MCLs. We believe that is a practical necessity that will allow significant benefits including the prioritization of PFAS barrier technology in environmental justice communities and communities with higher source water PFAS levels.

We are available to discuss our comments and to provide any additional information which EPA may require.

Sincerely,

F. Paul Calamita

General Counsel

C: WWP Members

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044684 in section 5.1.3 in this *Response to Comments* document.

Daniel Varon (Doc. #1518, SBC-042725)

The EPA should be concerned about the cost, especially given the economic situation the country currently finds itself in. The EPA's proposed cost summary has two estimates, one at 3% discount rate and another at 7% discount rate, of $772 million and $1.20 billion respectively. [FN19: Id.] Given the current increased interest rates, the implementation cost will likely be

closer to the latter than the former. This is also not considering a $30-$61 million potential yearly cost if PFAS are treated as hazardous waste. [FN20: Id.]

At the very least, I believe further investigations into PFAS should be conducted before rushing hastily into a costly project. Further research can indicate what level of PFAS we should actually be aiming for, or if there are certain geographic areas that should be focused in a resolution.

In conclusion, this would be no small project, and we must maximize the amount resources at hand. There are still a lot of unknowns surrounding PFAS, this is self-admitted by the CDC, EPA, and other governmental agencies. Given the unknowns, I do not think it is the best idea to rush into a costly implementation plan that sets extreme conditions, costly blanket rulings, and only impacts one source of PFAS contamination. Rather, I believe alternative, less costly and more targeted solutions should be explored further.

Thank you for taking the time to consider my comment.

Sincerely,

Daniel Varon

EPA Response: For additional discussion on benefit-cost considerations when setting the MCL, please see section 5.1.3 of the EPA response in this *Response to Comments* document.

The City of Columbus, Department of Public Utilities (Doc. #1703, SBC-045063)

V. CONCLUSION

CDPU looks to EPA to help ensure that access to the most basic human necessity—safe, clean drinking water—continues to be affordable and equitable. As EPA continues its determination on a final National Drinking Water Regulation related to these six PFAS, CDPU asks that EPA recognize that public water utility resources are limited as we try to rise to the challenge of meeting each increasingly stringent drinking water standard simultaneously. Additionally, CPDU asks that EPA's feasibility analysis include accurate costs for treatment, a quantification for the burden of opportunity costs, and the financial, human health, and environmental costs of increased greenhouse gas emissions, which will result from an MCL of 4 ppt. Finally, CPDU asks that EPA re-examine alternatives—regulations, timelines, and limits—that would provide a reliable, comprehensive benefit to the public by removing the greatest PFAS hazards, judicially using public funds, and ensuring the eventual end of the PFAS cycle.

The City of Columbus, Department of Public Utilities appreciates your consideration of these comments. Should you have any questions, please contact Kristin Atha at klatha@columbus.gov or call (614) 645-7541. Thank you again for your attention to and consideration of these comments.

Sincerely,

Kristin L. Atha Director

Columbus Department of Public Utilities

klatha@columbus.gov

Ecc: Alana Shockey, Deputy Director

Janean Weber, Assistant Director, Regulatory Compliance

John Newsome, Columbus CDPU, DOW Administrator

Matthew Steele, Columbus CDPU, DOW Assistant Administrator

Robert Priestas, Columbus CDPU, DOSD Administrator

Stacia Eckenwiler, Columbus CDPU, DOSD Assistant Administrator

EPA Response: For additional discussion on cost considerations when setting the MCL, please see section 5.1.3 of the EPA response in this *Response to Comments* document. For additional discussion regarding alternative MCLs, please also see section 5.1.3. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 10 of the EPA response in this *Response to Comments* document on extensions and exemptions. For EPA's response on additional social costs of the rule, including greenhouse gas emissions, see section 13.11 in this *Response to Comments* document.

California-Nevada Section American Water Works Association (CA-NV AWWA) (Doc. #1775, SBC-045279)

8. Economic feasibility and technical feasibility cannot be adequately considered due to information gaps about contaminant occurrence and constraints on capital and operational necessities.

Due to incomplete knowledge of the occurrence and co-occurrence of the PFAS discussed above, EPA cannot evaluate the economic feasibility of its proposed MCLs. Occurrence in small water systems or in disadvantaged communities is of particular concern, but without knowing where, and to what extent the contaminants occur, it is logically impossible to adequately address the economic feasibility of the regulation.

A similar problem comes from severely restricted options for disposal of treatment residuals (liquid brine or reverse osmosis reject water, or solid waste) containing PFAS. As noted above, PFOA and PFOS are already designated as hazardous under CERCLA, and few landfills will accept these materials; destruction of the substances by incineration or other methods is even more uncertain. Operating expenses like these are important factors to consider in the economic assessment of PFAS regulations and should be re-evaluated to gain a more complete understanding of the economic and technical feasibility.

Problems with sampling and laboratory capacity call into question the technical feasibility of the MCLs proposed in this rulemaking. Additionally, shortages of necessary treatment chemicals

such as granular activated carbon are very likely, resulting in price spikes that will exacerbate affordability issues for small systems. Infrastructure projects continue to be plagued by supply chain disruptions, and are further complicated by Buy America, Build America requirements when any federal funding is involved.

All the "unknowns" cited here support our concern that EPA has not and could not yet reasonably address the economic feasibility and the technical feasibility of this proposed regulation. More data and more thorough analysis are required, and the regulation should be pulled back or paused while these information gaps are filled.

EPA Response: For additional discussion on cost considerations when setting the MCL, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The agency disagrees with commenter assertions that economic and technical feasibility cannot be adequately considered because of stated occurrence information gaps. For PFOA and PFOS, the EPA issued final regulatory determinations for contaminants on the fourth Contaminant Candidate List (CCL 4) in March of 2021 (USEPA, 2021b) which included determinations to regulate PFOA and PFOS in drinking water. The EPA found that PFOA and PFOS may have an adverse effect on the health of persons; that these contaminants are known to occur, or that there is a substantial likelihood that they will occur, in PWSs with a frequency and at levels that present a public health concern; and that regulation of PFOA and PFOS presents a meaningful opportunity for health risk reduction for persons served by PWSs. The EPA also carefully considered drinking water monitoring data collected as part of the UCMR 3 and state-led monitoring efforts. The EPA finds that PFHxS, PFNA, and HFPO-DA each have a substantial likelihood to occur in finished drinking water and that these three PFAS and PFBS are also likely to co-occur in mixtures and result in increased total PFAS exposure above levels of public health concern. Therefore, the agency is determining that exposure to PFHxS, PFNA, or HFPO-DA individually, and any mixture of these three PFAS and PFBS, may have adverse effects on the health of persons; there is a substantial likelihood that PFHxS, PFNA, and HFPO-DA will occur and combinations of these three PFAS plus PFBS will co-occur in a mixture in PWSs with a frequency and at levels of public health concern; and in the sole judgment of the Administrator, individual regulation of PFHxS, PFNA, and HFPO-DA, and mixtures of the three PFAS plus PFBS, presents a meaningful opportunity for health risk reductions for persons served by PWSs. A comprehensive discussion of all the available state PFAS drinking water occurrence data is included in the *Occurrence Technical Support Document* (USEPA, 2024a). For additional discussion on the EPA'S final regulatory determinations, please see section 3 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 10 on extensions and exemptions. The commenter also incorrectly stated that PFAS are "designated as hazardous under CERCLA". There are currently no federal regulations that designates PFAS (or treatment residuals that contain PFAS) as hazardous waste. Further, disposal options and guidance on management of treatment residuals for PFAS containing waste currently exist; please see section 10.4 for the EPA's response in this *Response to Comments* document for additional discussion on the management of treatment residuals. Also see the EPA response to comment Doc. #1577,

SBC-042446 in section 5.1.4 in this *Response to Comments* document for a discussion of EPA's *Interim Destruction and Disposal Guidance.*

Greater North Dakota Chamber et al. (Doc. #1593, SBC-042800)

May 26, 2023

The Honorable Radhika Fox

Assistant Administrator

Office of Water

Environmental Protection Agency

Washington, DC 20020

RE: PFAS National Primary Drinking Water Regulation Rulemaking

EPA Docket ID: EPA-HQ-OW-2022-0114 FRL 8543-01-OW

Dear Assistant Administrator Fox:

We, the undersigned organizations representing a coalition of state chambers of commerce are pleased to provide comments for 1) EPA's proposed regulatory determination for PFHxS, HPFO-DA, GenX chemicals, and PFNA; and 2) EPA's proposed maximum contaminant levels (MCLs) and proposed maximum contaminant level goals (MCLGs) for PFOA and PFOS and also the four PFAS chemistries for which EPA is proposing a regulatory determination.

State Chambers of Commerce across our nation support a national drinking water standard for PFOA and PFOS based on the best science and risk. State environmental policymakers are pursuing aggressive requirements including drinking water standard, broad bans, and disclosure regimes. EPA action could be helpful in replacing this current patchwork.

However, there are substantial questions with EPA's current proposal. It is critical that EPA gets this right, as the costs that the proposed rule would impose are significant, and likely underestimated, leading to several challenges to the water utilities and other industries. For example, the proposed rule does not consider that maximum contaminant levels (MCLs) set in this regulation would have direct relationship to the costs of Superfund cleanups, given the pending CERCLA hazardous substance designation for PFOA and PFOS. SDWA sets the standard for using the "best available peer-review science." The proposed MCL must be changed to properly balance these costs and benefits, as the statute requires and EPA has done in setting prior MCLs.

Accordingly, we request that the agency withdraw the proposal and await the results of the UCMR 5 process:

EPA Response: Regarding cost concerns when setting the MCL, including impacts of the MCLs in non-drinking water contexts, please see section 5.1.3 of the EPA response in this *Response to Comments* document. Additionally, please also see section 6.8 of the EPA response in this *Response to Comments* document for additional discussion on UCMR 5. For the EPA's response on costs associated with the rule, please see section 13.3 in this *Response to Comments* document. Finally, the EPA disagrees with the commenter that the "MCL must be changed to properly balance these costs and benefits," as the EPA has reaffirmed the Administrator's determination at proposal that the benefits of the rule justify its costs. For more information see section 13.8 of the EPA response in this *Response to Comments* document.

Western Urban Water Coalition (WUWC) (Doc. #1768, SBC-043938)

The Proposed Rule commits both of these errors. The Proposed Rule nowhere accounts for the National Contingency Plan (NCP), adopted pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), which will require these new MCLs to be used as cleanup standards by operation of law. [FN8: 40 C.F.R. § 300.430(e)(2)(i)(B)-(C) (requiring attainment of MCLs where MCLGs have been set at zero and contaminated groundwater or surface water is designated as a current or potential source of drinking water).] WUWC has previously expressed its significant concerns to EPA and Congress that regulating PFAS could cause water utilities to incur cleanup liability at CERCLA sites, the costs of which would ultimately be borne by ratepayers. These additional costs to ratepayers of the Proposed Rule have not been considered.

EPA Response: Regarding cost concerns when setting the MCL, including impacts of the MCLs in non-drinking water contexts, please see section 5.1.3 of the EPA response in this *Response to Comments* document. For further discussion about CERCLA clean-up costs and benefits, please also see section 5.1.3 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1631, SBC-043434 in section 5.1.3 in this *Response to Comments* document.

Missouri Department of Natural Resources (Doc. #1563, SBC-047698)

The Department also believes that setting the MCL at 10.0 ppt would be appropriate and justifiable under the SDWA statutory criteria. An MCL of at least 9 ppt is necessary in order to allow detectable and reportable results for reliable and consistent compliance determinations. It will also allow utilities the opportunity to operate with a margin of safety and plan for performance that maintains water quality below quantitation levels. Having an increased buffer between the PQL and the MCL will also allow utilities to manage treatment technology performance more efficiently because utilities typically aim to achieve lower than the MCL to avoid a violation. With the MCL set at the PQL, utilities would not have the early warning that they may exceed the MCL prior to doing so.

EPA Response: For additional discussion on alternative regulatory standards, please see section 5.1.3 of the EPA response in this *Response to Comments* document. For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Aidan Cecchetti (Doc. #1640, SBC-044377)

• In the Economic Analysis, EPA presented estimated costs and benefits of regulatory alternatives for PFOA and PFOS if setting MCLs at 5.0 ppt and 10.0 ppt. EPA is requesting comment on its evaluation of these alternatives within the Economic Analysis (pg. 18670-18671 Federal Register Volume 88, Number 60).

o The commenters agree with the EPA determination that the reduced costs and reduced public health protection associated with a 5.0 ppt MCL for PFOA and PFOS are not justified by the purported increased buffer that may allow utilities to manage treatment technology performance more effectively.

EPA Response: For additional discussion on cost considerations when setting the MCL and alternative regulatory standards, please see section 5.1.3 of the EPA response in this *Response to Comments* document. For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Aidan Cecchetti (Doc. #1640, SBC-047700)

o The commenters agree with EPA's determination that the cost-reduction benefits of setting an MCL of 10.0 ppt for PFOA and PFOS do not outweigh the reduced public health protection associated with setting the MCL at that level. The commenters agree with EPA's determination that setting an MCL of 10.0 ppt for PFOA and PFOS would not be appropriate or justifiable under the SDWA statutory criteria.

EPA Response: Please see the EPA response to comment Doc. #1640, SBC-044377 in section 5.1.3 in this *Response to Comments* document.

The City of Columbus, Department of Public Utilities (Doc. #1703, SBC-045062)

IV. EPA should reconsider the proposed alternatives before setting its initial MCL at the PQL.

As it conducted its required analysis when crafting the proposed rule, EPA deliberated various options to reduce PFAS from drinking water. One option that was considered but not selected,

was to address the water systems with the most harmful, highest concentrations first with a MCL at 10 ppt. As discussed above, the feasibility analysis for that decision was flawed.

The crux of EPA's decision to set the MCL at 4 ppt instead of 10 ppt is that EPA found the former to be feasible. But that determination was erroneous because EPA did not accurately account for the cost of treatment and other social costs to environmental justice communities and from increased GHG emissions. Once EPA adjusts its calculation, if it determines that an MCL of 4 ppt is not feasible, then it will have an opportunity to revisit the regulatory alternative of 10 ppt and perform the analysis again with more realistic costs and benefits to determine if a higher MCL is appropriate and justifiable under the SDWA statutory criteria.

EPA has already acknowledged that a higher MCL would decrease the number of water utilities that will need to treat their water at this time. But it will would also result in targeted funding and treatment in the areas across the country that need it the most, which will protect our most vulnerable citizens from soaring utility bills that may threaten their food and housing stability. It will lessen the impact of such a large number of water utilities vying for limited treatment equipment, labor, and resources. It will give time for regulation or legislation to prevent further introduction of PFAS into our environment through consumer products. It will allow labs to develop the capability to test on a larger scale. It will allow public water utilities to have flexibility in their budgets to address the current, multiple regulatory challenges of PFAS, lead and copper, and aging infrastructure. And it will preserve consumer confidence in the safety of people's utmost necessity: drinking water.

EPA Response: The MCLs that the EPA proposed (and finalizing) is consistent with the statutory requirements under SDWA: please see the sections 5.1.2, 5.1.3, and 5.1.4 of the EPA response in this *Response to Comments* document for the agency's evaluation of feasibility with respect to analytic, cost and treatment considerations, respectively. The agency also disagrees that it did not account for the cost of treatment in the final rule: the EPA's strong record supports the agency's feasibility analysis supporting the final standards. Specifically, within the record and further discussed in sections 5.1.3 and 5.1.4 of the EPA response in this *Response to Comments* document, the EPA evaluated the accuracy of analytical techniques as reflected in the PQL, the availability and performance of BATs for treating water to minimize the presence of the contaminant consistent with the MCLG, as well as the costs of applying those BATs to large water systems when treating to that level. In consideration of these factors, the EPA is therefore establishing the MCL of 4.0 ng/L for both PFOA and PFOS; individual MCLs for PFHxS, PFNA and HFPO-DA at 10 ppt; and a Hazard Index MCL of 1 for mixtures of PFHxS, PFNA, HFPO-DA and PFBS. The reviewer is incorrect that the cost analysis fails to account for the environmental justice impacts of the final rule. In Section 8.4.2.2 of the EA (USEPA, 2024d), the agency reports the estimated incremental household costs across different system size categories and demographic groups. For further discussion on the agency's analysis of the social cost of carbon, please see section 13.11 of the EPA response in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-045672)

d. EPA Failed to Consider Any Alternatives to the HI-MCL, in Violation of SDWA [sec]1412 (b)(3)(C)(i)

EPA must consider a range of alternative MCLs but did not do so here in violation of the SDWA and the Unfunded Mandates Reform Act (UMRA). SDWA [sec]1412(b)(3)(C)(i) requires EPA to consider alternative MCLs. In promulgating other NPDWRs after the 1996 SDWA Amendments, EPA has routinely considered at least four alternatives. [FN40: See National Primary Drinking Water Regulations: Lead and Copper Rule Revisions, 84 Fed. Reg. 61684 (2019) (considering four alternative regulatory options); National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring 66 Fed. Reg. 6976 (2001) (considering four alternative MCL levels); National Primary Drinking Water Regulations; Radon-222, 60 Fed. Reg. 59246 (1999) (considering seven alternative MCL levels).] Additionally, the Unfunded Mandates Reform Act of 1995 requires EPA to consider alternative MCLs. [FN41:EPA identified that this rule is subject to the UMRA, see 88 Fed.Reg. 18733 (Mar. 29, 2023) ("This action contains a Federal mandate under the Unfunded Mandates Reform Act").] The Unfunded Mandates Reform Act of 1995 (UMRA). [FN42: 2 USC [sec] 1535 (1995)] UMRA requires any agency promulgating a rule with "Federal mandates" that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year to "identify and consider a reasonable number of regulatory alternatives and from those alternatives select the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule." [FN43:Id.]

Here, EPA did not consider a "reasonable number of regulatory alternatives." For PFHxS, HFPO-DA and its ammonium salts, PFNA, and PFBS, EPA considered a single HBWC, which effectively functions as substance-specific MCL. Nor did EPA consider any alternatives to the HI-MCL of 1.0 itself. Clearly, the analysis of only one regulatory option is not a consideration of "alternatives." The lack of alternatives considered for the PFAS covered in the Hazard Index violates both the SDWA and UMRA.

EPA Response: With respect to responses on the agency's evaluation of regulatory alternatives, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The agency disagrees with the commenter that the EPA did not consider a reasonable number of regulatory alternatives. Specifically, as discussed in section 5.1.3 of the EPA response in this *Response to Comments* document: The proposal took comment on establishing individual MCLs instead of and in addition to using a mixture-based approach for PFHxS, PFNA, HFPO-DA, and/or PFBS in mixtures. In that notice, the EPA described how a traditional approach may be warranted should the EPA not finalize a regulatory determination for mixtures of these PFAS. Under this alternative, "the proposed MCLG and MCL for PFHxS would be 9.0 ng/L; for HFPO-DA the MCLG and MCL would be 10.0 ng/L; for PFNA the MCLG and MCL would be 10.0 ng/L; and for PFBS the MCLG and MCL would be 2000.0 ng/L." The agency requested

comment on these alternatives for PFHxS, PFNA, HFPO-DA, and PFBS and whether these individual MCLs instead of or in addition to the Hazard Index approach would change public health protection, improve clarity of the rule, or change costs. Additionally, the EPA considered alternative mixture-based approaches such as a TOSHI or RPF approach. The agency requested comment on these approaches. Based on the EPA's technical expertise, the agency determined that the Hazard Index is the most cost-effective and least burdensome alternative for purposes of UMRA because this approach for mixtures achieves the objectives of the rule because of the level of protection afforded for the evaluation of chemicals with diverse (but in many cases shared) health endpoints. The EPA followed agency chemical mixture guidance (USEPA, 1986; USEPA, 2000a, RAGS), which explain that when the Hazard Index value is greater than one (1) then risk is indicated (because exposure exceeds toxicity). The agency did not propose alternative Hazard Index values (i.e., higher Hazard Index values) because the EPA determined that these approaches would provide sufficient protection against dose-additive health concerns from co-occurring PFAS. For example, a higher Hazard Index value (e.g., Hazard Index equal to 2) allows for exposure to be greater than the toxicity and will result in a standard that is not protective of public health.

Office of Advocacy at the U.S. Small Business Administration (Doc. #1807, SBC-045489)

a. EPA should consider finalizing one of the regulatory alternatives in the proposal and/or consider phasing in the proposed MCLs.

EPA should consider finalizing one of the alternative standards included in the proposed rule. Alternatively, EPA should consider a phase-in approach using the alternative standard values to require compliance with the proposed MCLs. In the proposal, the agency considered regulatory alternatives for PFOA and PFOS MCLs at 4.0, 5.0 ppt and 10.0 ppt without regulating the other four PFAS. As mentioned above, EPA did not present any MCL values to the SERs during the SBREFA panel, therefore, EPA has not considered small water systems' feedback on the proposed and regulatory alternative MCL values and its impacts and their ability to comply. Also, EPA only specifically identified regulating PFOA and PFAS and did not discuss the other four PFAS. The agency should conduct targeted outreach with small water systems on the feasibility of the proposed and alternative MCLs. Advocacy recommends that EPA give full consideration to any direct or written feedback in support of alternative standards presented by the agency or those recommended by small water systems, including a phased-in approach for compliance with the proposed standards.

EPA Response: For additional discussion on alternative regulatory standards, please see section 5.1.3 of the EPA response in this *Response to Comments* document. With respect to responses on the *Regulatory Flexibility Act* and how the agency considered advice from the Small Business Advocacy Review (SBAR) Panel, please see section 14.3 of the EPA response in this *Response to Comments* document. Specifically in regard to commenters' assertion that the EPA failed to provide specific MCLGs, MCLs, or other highly specific or specialized scientific information developed for the rule proposal, the EPA is not required under the RFA to provide

specific numerical regulatory standards, such as MCLs or MCLGs, to small entities during the SBAR Panel process. As a part of the development of the NPDWR, the EPA sought the input of the Small Entity Representatives (SERs) via the SBAR panel process to inform the proposed rule and its proposed regulatory requirements, specifically seeking ways to minimize the regulatory burden on small entities. The proposed regulatory requirements had not been determined at that time because the EPA specifically wanted to seek the input from the SBAR panel and from other mandated consultations prior to proposing any economically significant regulation. The EPA therefore appropriately waited to determine many of the specific requirements such as the MCLs until after seeking the SERs' and SBAR panel's input on such specific numerical regulatory standard values.

Cordell Spires Jr. (Doc. #1541, SBC-042663)

V. Conclusion

EPA's proposed rule continues the tradition of regulating individual PFAS chemicals, which has proven to be ineffective. Industries will continue to find structurally similar PFAS that are not subject to regulations yet likely pose the same health risks unless the entire class of PFAS is regulated. As a result, EPA should consider using a class-based approach to regulating PFAS.

Sincerely,

Cordell Spires Jr.

EPA Response: For additional discussion on alternative regulatory standards (including regulation of PFAS as an entire class), please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Greater Cincinnati Water Works (GCWW) (Doc. #1550, SBC-042694)

As an alternative to the proposed regulatory construct, we propose that the Agency consider a regulation based on tiered action. In such a construct, the agency could set an MCL at 10 ppt for PFOA and PFOS at which water utilities would need to install treatment. However, if a utility has concentrations between the PQL and 10 ppt for these compounds, the utility would initiate a source water investigation to determine the source of the PFAS and then work with the state to eliminate the sources. This construct would take advantage of the beneficial impacts of the other environmental regulations and would work with them to reduce exposure.

EPA Response: For additional discussion on alternative regulatory standards (including higher PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document. The agency's final MCLs are based on the EPA's analysis of feasibility and does not preclude a system to take actions recommended by the commenter (such as source water investigation).

Ann Cougle (Doc. #1557, SBC-042557)

No level of chemical substances in drinking water is safe.

Four PFAS PFOA, PFOS, PFHxS, and PFNA were detected in 99% of serum samples from humans over 12 in the US, indicating nearly universal exposure. (Calafat et al., 2007)

A ZERO limit is absolutely necessary unless you want everyone in the world to have cancer.

Analytical testing and in turn, our ability to detect and identify these manmade chemicals in our water has made significant advances. The EPA proposed limits are more than twice as high as laboratories can detect them (1 to 2 ppt) and 1,000 times higher than the EPA 2022 HA of 0.004 ppt. After decades of unknowingly being exposed to these dangerous chemicals, we need the agency to protect us, not the industry's bottom lines!!!

Thanks,

EPA Response: For additional discussion on alternative regulatory standards (including lower PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Missouri Department of Natural Resources (Doc. #1563, SBC-042518)

Further, in the Department's opinion, EPA should consider raising the MCL to a meaningful concentration level outside of the "at or near MRL" of 0.004 µg/L. As stated previously, EPA Method 533 Section 9.2.3.2 Evaluate Analyte Recovery "Results for analytes fortified at concentrations near or at the MRL [minimum reporting level also known as PQL] (within a factor of two times the MRL concentration) must be within 50–150% of the true value. Results for analytes fortified at all other concentrations must be within 70–130% of the true value. If the LFB [Laboratory Fortified Blank] results do not meet these criteria, then all data for the problem analytes must be considered invalid for all samples in the Extraction Batch." This difference in acceptance level identifies one of the key issues associated with proposing to set a MCL at the same value as the practical quantitation limit (PQL) or MRL. As noted previously, this issue is not one that can be solved by simply lowering the PQL/MRL to 2 ppt. Based on UCMR 5 lab approvals, it is already known that more than 25 percent of laboratories nationwide will not be able to meet a PQL lower than 4 ppt with a 95% confidence interval (CI). In addition to causing more issues with laboratory capacity nationwide, the number of samples that would be rejected under the method, and therefore requiring resampling, would increase even with a ±50% Method QA/QC acceptance level. If, for example, the PQL/MRL for PFOA and PFOS are set at 0.004 µg/L as is required by UCMR 5, then the MCL should be set at least greater than 0.008 µg/L (two times the MRL = 2 x 0.004 µg/L). Raising the MCL to a level that is quantifiable and above a "factor of two times the MRL", would equate to a MCL for PFOA and PFOS of at least 0.009 µg/L. An MCL at this level would allow reliable and consistent (R&C) compliance determinations to be made between the PQL/MRL of 0.004 µg/L and the MCL at 0.009 µg/L. The Department believes that the issues identified above, and in our previous comment regarding

the drawbacks to the HI approach, it is prudent for EPA to set the MCL at a level outside of a ±50% acceptance level. This would alleviate the need to rely on "J qualified" or data below the MRL for MCL calculation determinations, and would more closely follow the SOC standard monitoring framework for compliance determinations while relying on quantifiable results.

EPA Response: With respect to implementation concerns around variability around sample results, the agency disagrees with the commenter that excessive resampling would be required with MCLs at the PQLs and notes the following: First, the agency notes that quantitative sampling results do not have an estimate of standard error and therefore are generally not reported. Second, EPA does not expect laboratories to conduct intensive statistical analyses of their analytical results so there is no calculated error associated with their reported measurements. In effect, quantitated measurement values stand as a single reported result. Lastly, any laboratory that provides drinking water analyses on PFAS in support of the NPDWR are held to the same standard for reporting results per the analytical method. The EPA further notes that compliance with the MCL is determined by RAAs where individual sample results will not cause a system to be out of compliance (unless that result is 4x above the MCL in which they are in violation immediately). The EPA also disagrees with the commenter claims' that "25% [of labs] cannot" meet the PQL; as discussed in the final rule preamble, the PQL reflects a minimum quantitation level that "with 95 percent confidence, can be achieved by capable analysts at 75 percent *or more* of the laboratories using a specified analytical method" (emphasis added). Greater than 75 percent of labs requesting participation in UCMR 5 were able to meet the PQLs/MRLs, and EPA anticipates the number of labs available for compliance monitoring to grow (please see section 5.1.2 for the EPA response in this *Response to Comments* document for additional discussion on laboratory capacity and practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations). For additional discussion on alternative regulatory standards (including higher PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document. With respect to the analytic requirements of the EPA methods approved for meeting the monitoring requirements in the final NPDWR, please see section 7.1 of the EPA response in this *Response to Comments* document. Finally, the agency does not find MCLs at 0.009 µg/L for PFOA and PFOS to be feasible as close as feasible to the MCLG per SDWA requirements; the EPA estimates that laboratories across the nation can precisely and accurately measure PFOA and PFOS at quantitation levels of 4 ng/L and that levels below the PQL. Further, sampling results below the PQL may not have the same precision as a sampling result at or above the PQL but they are useful for operational purposes such as understanding that PFOA and PFOS may be present, which can inform treatment decisions and monitoring frequency.

<u>Missouri Department of Natural Resources (Doc. #1563, SBC-042508)</u>

The Department recommends that EPA strongly consider raising the proposed maximum contaminant level (MCL) for PFOA and PFOS to a level in the 9 to10 parts per trillion (ppt) range as further detailed in our comments below. An MCL at this level provides a significant

reduction in PFAS exposure, and is appropriate and justifiable under the SDWA statutory criteria. Increasing the MCL to 9 to 10 ppt will allow for reliable and consistent (R&C), quantifiable, and reportable detections of PFOA and PFOS at concentrations above the proposed practical quantitation limit (PQL) of 4 ppt.

EPA Response: Please see the EPA response to comment Doc. #1563, SBC-042518 in section 5.1.3 in this *Response to Comments* document. For additional discussion on alternative regulatory standards (including higher PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Missouri Department of Natural Resources (Doc. #1563, SBC-042523)

If, for example, the PQL/MRL are set at 0.004 µg/L for PFOA and PFOS as is required by UCMR 5, then the MCL should be set at least greater than 0.008 µg/L (two times the MRL = 2 x 0.004 µg/L). Raising the MCL to a level that is quantifiable and above a "factor of two times the MRL", would equate to a MCL for PFOA and PFOS of at least 0.009 µg/L. An MCL at this level would allow reliable and consistent (R&C) compliance determinations to be made between the PQL/MRL of 0.004 µg/L and the MCL at 0.009 µg/L. In addition, treatment added to remove PFOA or PFOS below 0.009 µg/L would also have the benefit of lowering mixtures of the PFAS identified for the hazard index to levels below the lowest HBWC of 0.009 µg/L for PFHxS.

The Department believes that the issues identified above, and in our previous comment regarding the drawbacks to the HI approach, it is prudent for EPA to set the MCL at a level outside of a ±50% acceptance level. This would alleviate the need to rely on "J qualified" or data below the MRL for MCL calculation determinations and would more closely follow the SOC standard monitoring framework for compliance determinations while relying on quantifiable results. Therefore, the Department recommends the EPA raise the MCL to at least 0.009 µg/L.

EPA Response: Please see the EPA response to comment Doc. #1563, SBC-042518 in section 5.1.3 in this *Response to Comments* document. For additional discussion on alternative regulatory standards (including higher PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document. For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For additional discussion on monitoring and compliance requirements, please see section 8 of the EPA response in this *Response to Comments* document.

Washington Suburban Sanitary Commission (WSSC Water) (Doc. #1585, SBC-042769)

MCL for PFOA and PFOS:

The proposed MCLs of 4 ppt for PFOA and PFOS are considerably lower than any other final or proposed MCLs established by states. According to a survey of state-enacted MCLs, final or

proposed MCLs for PFOA are set within a range of 8 — 14 ppt, and for PFOS within a range of 8 — 18 ppt. WSSC Water recommends that EPA conduct a review of the health risk reduction and cost analysis assessments conducted by the states to ensure that EPA's analysis is in line with the most accurate health effects and cost information.

In this rulemaking, EPA refers to certain contaminants under Phase I VOC rule as a basis for setting the MCL at the same level as practical quantitation level (PQL). While WSSC Water agrees that those rules have been implemented successfully, it should be noted that compliance management of PFAS at such low levels, near the analytical limit of precision and accuracy, will be much more challenging than VOCs, due to its environmental ubiquity and analytical sensitivity.

Regulatory alternatives:

EPA is soliciting comments on 5 ppt and 10 ppt as regulatory alternatives. WSSC recommends that EPA establishes the MCL at a level above the PQL of 4 ppt to provide adequate margin of confidence for water systems to better gauge relative risk levels with respect to MCL, and to identify and correct issues that could potentially impact compliance status. EPA may also consider a phased approach, in which MCLs are set at 10 ppt initially, then lowered to 5 or 4 ppt in the next six-year review cycle. Although 10 ppt is considerably higher than the MCLG, and it is technologically feasible to reduce PFOA and PFOS levels to 4 ppt, adopting this approach would provide more water systems with opportunities to prepare for mitigation measures and allow the EPA to gather more evidence to support lower MCLs in the future. As EPA correctly noted in reference to Phase I rule, advancements in analytical technology in the coming years will provide opportunities to lower the MCL closer to MCLG while maintaining an appropriate margin of confidence between the MCL and PQL.

EPA Response: For additional discussion on alternative regulatory standards (including higher PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA notes that the Six-Year Review process allows the agency to consider future information as appropriate in deciding whether existing NPDWRs should be identified as candidates for revision as required by SDWA; please see section 5.1.6 of the EPA response in this *Response to Comments* document for additional discussion.

Public Health, Seattle & King County (PHSKC) (Doc. #1594, SBC-042358)

Develop and quickly enact a class approach to regulate PFAS that are detected in water to avoid generations of regrettable substitutions and cleanups. The number and type of PFAS in drinking water are expected to change with time as manufacturers phase in new analogs to move away from those compounds that become regulated. Many of the replacement compounds may not yet have a significant amount of data available. It cannot be assumed that a lack of data on the large majority of PFAS means that they are safe, instead EPA should treat all PFAS as hazardous unless specific compounds are shown to be safe through substantial data and review.

EPA Response: Regarding commenter concerns for environmental ubiquity and analytical sensitivity, to the extent that challenges regarding ubiquity exist, the methods approved for compliance monitoring for this NPDWR were developed and demonstrated to meet performance and QC expectations with any such challenges present. The method development performance and QC evaluations are conducted as an assessment of method ruggedness, which is demonstrated through testing in multiple types of drinking water matrices, including assessments off-site at other laboratories by other analysts. Therefore, the agency has empirically determined assurances that the methods can perform adequately at the final MCL levels. In short, the methods are able to meet acceptable performance and QC acceptance criteria typical for drinking water methods in spite of any potential ubiquitous presence and background levels of PFAS. Please see sections 5.1.2 of the EPA response in this *Response to Comments* document for additional discussion on PQLs and laboratory capability considerations as well as sections 7.1 and 7.2 for additional discussion on the analytical methods approved for compliance monitoring for this NPDWR. For additional discussion on alternative regulatory standards (including regulation of PFAS as an entire class), please see section 5.1.3 of the EPA response in this *Response to Comments* document. With respect to considerations for state-enacted MCLs or other state drinking water standards and guidelines, please see sections 5.1.5 of the EPA response in this *Response to Comments* document. The EPA notes that the Six-Year Review process allows the agency to consider future information as appropriate in deciding whether existing NPDWRs should be identified as candidates for revision as required by SDWA; please see section 5.1.6 of the EPA response in this *Response to Comments* document for additional discussion.

Lehigh County Authority (LCA) (Doc. #1600, SBC-042816)

Based on AWWA's extensive research on this topic since the early 2000s, we support their recommendation that EPA set the standard for PFOA and PFOS at 10 ppt. This level is lower than the MCLs previously established by some states, including Pennsylvania, and is therefore highly protective of public health. Establishing MCLs of 10 ppt for PFOA and PFOS also addresses some of the concerns discussed above related to establishing the MCL at the PQL.

EPA Response: For additional discussion on alternative regulatory standards (including higher PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Safe Healthy Playing Fields, Inc. (Doc. #1621, SBC-042942)

On 15 June 2022, the US EPA issued non-binding drinking water health advisories for four of the above PFAS: PFOA, PFOS, PFBA and GenX. The advisories rendered no safe level of PFOA or PFOS. The standards for PFOA and PFOS issued on 13 March 2023 at 4ppt does not render "no safe level" for these legacy PFAS. The addition of PFNA and PFHxS to the proposed Health Index adds chemicals also found in synthetic turf.

EPA Response: Please see the EPA response to comment Doc. #1621, SBC-042944 in section 5.1.3 in this *Response to Comments* document. The EPA notes that the Lifetime HAs are beyond the scope of this rulemaking. The MCLGs promulgated in this final NPDWR are based on the best available, peer-reviewed science and the agency's review of current scientific literature on human health effects; please see section 4 of the EPA response in this *Response to Comments* document for additional discussion on health considerations for PFOA and PFOS when setting the MCLG.

Safe Healthy Playing Fields, Inc. (Doc. #1621, SBC-042944)

4ppt each for PFOA and PFOS are not protective and not reflective of the current state of technology. Currently available technology in commercial labs is capable of detecting PFAS at 2ppt and can reasonably be expected to improve further. Just as there is zero safe level of PFAS, there is zero social or environmental justice in essentially stating you will require less exposure and by doing so hope to cause less harm. Leading scientists and researchers [Link: https://www.youtube.com/watch?v=keBi8G2mDr8] agree 4ppt, as well as the proposed Health Index for a mixture of GenX, PFNA, PFBA and PFHxS are not protective of human or environmental health. To our knowledge, no one has ever given informed consent to be exposed to any chemicals in the PFAS family. Continuing to allow additional exposure to humans and the environment should not be tolerated.

The limits set for PFOA and PFOS should not be based on financial considerations when the societal cost globally is $17.5 trillion annually [Link: https://www.theguardian.com/environment/2023/may/12/pfas-forever-chemicals-societal-cost-new-report] for clean ups and health care of impacted individuals. The 8% of PFAS theoretically required for "essential" purposes must be exclusive of non-essential products, such as synthetic turf.

EPA Response: For additional discussion on alternative regulatory standards (including lower PFOA and PFOS MCLs), please see section 5.1.3.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044024)

7. EPA requests comment on its proposed determination to set MCLs at 4.0 ppt for PFOA and PFOS and whether 4.0 ppt is the lowest PQL that can be achieved by laboratories nationwide.

a. CWUC recommends that EPA consider an MCL of 8.0 ppt, based on analytical certainty. The trigger level should be set to the EPA established PQL of 4.0 ppt, and the MCL double that at 8.0 ppt. A PQL is set at a level that can accurately and consistently be measured, and any values obtained less than the PQL are suspect. Compliance cannot be based on suspect data. Setting the trigger level at the PQL is a more appropriate approach and gives systems the ability to address issues on more certain data, as well as provides the EPA opportunity to reevaluate levels at a later time as treatment and analytical technologies advance.

b. In calculating the MCLs, anything less than the Reporting Limit (or PQL) should be counted as zero.

EPA Response: For additional discussion on alternative regulatory standards (including higher PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document. The agency is clarifying for the commenter that for compliance calculation purposes, zero will be used for results below the PQL (see section 8.0 of the EPA response in this *Response to Comments* document for additional discussion on monitoring and compliance requirements).

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044053)

c. An improved and simpler solution is to raise the Trigger Level to the PQL of 4.0 ppt, and set the MCL at 8.0 ppt.

EPA Response: For additional discussion on alternative regulatory standards (including higher PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document. For additional discussion on trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document.

American Association for Justice (AAJ) (Doc. #1636, SBC-042969)

II. While AAJ supports EPA's proposal we are concerned that the proposed standard is inadequate in protecting human health. The EPA should set MCLs to zero which is the only safe exposure level and allow the MCL to be more impactful as detection methods improve.

Recognizing that PFOA and PFOS are carcinogenic and pose other health risks to humans, AAJ also broadly supports the imposition of MCLs. However, we are concerned that EPA's proposed MCLs do not go far enough to safeguard public health. Under Section 1412(b)(4)(B) of SDWA, EPA must generally establish an enforceable MCL as close to the MCLG as is feasible. Despite this, EPA has proposed MCLs for PFOA and PFOS of 4 parts per trillion (ppt). Given that EPA has correctly recognized there is no safe amount of PFAS exposure, these MCLs do not go far enough to protect human health.

EPA's public notice of the rule makes clear that it set the proposed MCLs at 4.0 ppt based on the minimum reporting level (MRL) for PFOS which is set in EPA testing Method 533 and 537.1. "The MRL is the lowest analyte concentration which demonstrates known quantitative quality."1 [FN1: David Munch and Phyllis Branson, Statistical Protocol for the Determination of the Single-Laboratory Lowest Concentration Minimum Reporting Level (LCMRL) and Validation of Laboratory Performance at or Below the Minimum Reporting Level (MRL), EPA, 1 (May 5, 2023), https://nepis.epa.gov/Exe/ZyPDF.cgi/P1005EAE.PDF?Dockey=P1005EAE.PDF] It is closely related to the Lowest Concentration MRL (LCMRL) which "is the lowest true concentration for which the future recovery is predicted to fall, with high confidence (99%), between 50 and 150% recovery."2 [FN2:Id] EPA Method 533 calculated an LCMLR for PFOA

of 3.4 ng/L and for PFOS of 4.4 ng/L. The fifth Unregulated Contaminant Monitoring Rule (UCMR 5) therefore set MCLs of 0.004 μg/L (equal to 4 ng/L) for both PFOS and PFOA. EPA has now taken these minimum reporting levels and adopted them as MCLs.

Essentially, EPA is setting the MCL at the level which it believes PFAS can be reliably tested for using present day technology. As EPA said in its public notice, "this reporting level is the minimum quantitation level that, with 95 percent confidence, can be achieved by capable analysts at 75 percent or more of the laboratories."3 [FN3: PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18, 666 (Mar. 29, 2023).] There are significant issues with this approach. EPA admits many laboratories can reliably detect PFAS at lower concentrations. As EPA Method 544 states, "[t]he values that a laboratory can obtain are dependent on the design and capability of the instrumentation used."4 [FN4: Laura Rosenblum and Steven C. Wendelken, Method 533: Determination of per- and polyfluoroalkyl substances in drinking water by isotope dilution anion exchange solid phase extraction and liquid chromatography/tandem mass spectrometry, EPA, 533-2 (May 5, 2023),https://www.epa.gov/sites/default/files/2019-12/documents/method-533-815b19020.pdf] So in practice, many detections will occur at levels which are dangerously unsafe, but which will not result in violations of the MCL. These events are contrary to the purpose EPA set out in the SWDA.

This problem will only grow worse over time. Broadly speaking, setting MCLs at the level of current laboratory competence is an overly conservative and ineffective approach. This approach means that as technology improves, EPA would have to take affirmative action to lower the MCL until eventually meeting the actual levels at which human health is endangered. A far more meaningful and forward-thinking approach is to set the MCL at the lowest safe human exposure, and then allow the current level of technological innovation to dictate whether a detection above that limit has occurred. In this way the effective MCL will shift downward as technology improves without the need for further EPA action.

Given that we know there is no safe human exposure level for PFAS, EPA should set MCLs to zero. Concerns over enforcement of the MCL are better addressed by imposing a confidence requirement in the result. For example, EPA could set the MCL at any level of PFAS above zero, where the confidence of the detection is 95% or higher. While in practice this may not result in meaningful difference in enforcement of the MCL today, it will result in the MCL having more meaningful impact as methods of detection and laboratory standards improve.

To the extent EPA wants to look for a middle ground, it should look to its own interim lifetime health advisories for PFOA and PFOS. EPA issued lifetime health advisories for PFOA and PFOS of 0.004 ppt and 0.02 ppt respectively. While these lifetime health advisories exceed the correctly determined MCLG of zero PFAS, they are far safer than EPA's proposed MCLs. At the proposed MCLs 4 ppt, PFAS could be present at levels 200 to 1000 times greater than EPA's lifetime health advisories, yet not violate the maximum contaminant level. This means humans will still experience significant risk of dangerous exposure to these chemicals despite the MCLs. This should not be allowed.

EPA has explained that "[h]ealth advisories provide technical information that federal, state, and local officials can use to inform the development of monitoring plans, investments in treatment solutions, and future policies to protect the public from PFAS exposure."5 [FN5: EPA, EPA Announces New Drinking Water Health Advisories for PFAS Chemicals, $1 Billion in Bipartisan Infrastructure Law Funding to Strengthen Health Protections, (2022), https://www.epa.gov/newsreleases/epaannounces-new-drinking-water-health-advisories-pfas-chemicals-1-billion-bipartisan.] EPA should follow its own lead on this point and inform its MCLs by its own health advisory levels.

Based on this reasoning, we strongly support the creation of MCLGs and MCLs for PFAS but urge EPA to set both the MCLG and MCLs at zero, or at most equal to the health advisory levels of 0.004 ppt for PFOA and 0.02 ppt for PFOS, rather than the much higher MCLs in EPA's proposal. An MCL of 4 ppt does adequately protect the public from the dangers of these chemicals.

AAJ strongly supports EPA's conclusion that there are no safe PFOA and PFAS exposure levels, we believe that the suggestions we have made can improve this proposed rule. The EPA should set MCL's at zero. This means that as methods of detection improve, the EPA will not have to undertake lengthy and expensive rulemakings to amend its standards. An MCL level above zero will expose humans to a significant and unnecessary level. If you have any questions, please contact Victor Diaz at Victor.Diaz@justice.org.

Respectfully submitted,

Tad Thomas

President

American Association for Justice

EPA Response: For additional discussion alternative regulatory standards (including lower PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA notes that MCLs of 0 ppt for PFOA and PFOS are not feasible within the meaning of SDWA for the reasons discussed in sections 5.1.2 and 5.1.3 of the EPA response in this *Response to Comments* document. The EPA notes that the Six-Year Review Process under SDWA allows the agency to consider information as appropriate in deciding whether existing NPDWRs should be identified as candidates for revision. As such, the agency will periodically review promulgated standards in the future as required by SDWA. Please see section 5.1.6 of the EPA response in this *Response to Comments* document for additional discussion on how the EPA may consider pending and future science. The EPA notes that the Lifetime HAs are beyond the scope of this rulemaking. The MCLGs promulgated in this final NPDWR are based on the best available science and the agency's review of current scientific literature on human health effects; please see section 4 for additional discussion on health considerations for PFOA and PFOS when setting the MCLG.

Citizens Against Ruining the Environment (CARE) (Doc. #1638, SBC-043451)

While the identified effective treatment technologies required by the proposed NPDWR may provide an ancillary benefit of removing other PFAS not covered in the NPDWR [FN56: Economic Analysis, EPA at 1-4.], that benefit still requires test results of the six PFAS to be above the MCL to be implemented. By not moving to control PFAS as a group the thousands of compounds not included in the NPDWR could be passing into our drinking water at levels far exceeding those proposed by the EPA for the six PFAS. CARE believes that EPA should consider taking an approach similar to the European Union.

EPA Should Adopt An Approach Like the The European Approach

Regulating PFAS as a class would not be a novel approach to protecting drinking water. As of January 12, 2021 the European Union recast its Drinking Water Directive, setting a limit of 500ppts for all PFAS and committing to phase out all PFAS, save for where "they are proven to be irreplaceable and essential to society." [FN57: Per- and polyfluoroalkyl substances (PFAS), European Chemicals Agency, https://echa.europa.eu/hot-topics/perfluoroalkyl-chemicals-pfas (last visited May 21, 2023).]

EPA Response: For additional discussion on alternative regulatory standards (including lower PFOA and PFOS MCLs or regulation of PFAS as an entire class), please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA has established this NPDWR under the authority of the SDWA, which has different requirements and considerations than those considered by the European Union when it established its Drinking Water Directive.

City of Allentown and Lehigh County Authority (LCA), Pennsylvania (Doc. #1667, SBC-043677)

Based on AWWA's extensive research on this topic since the early 2000s, the City supports consideration of their recommendation that EPA set the standard for PFOA and PFOS at 10 ppt. This level is lower than the MCLs previously established by some states, including Pennsylvania, and is therefore highly protective of public health. Establishing MCLs of 10 ppt for PFOA and PFOS also addresses some of the concerns discussed above related to establishing the MCL at the PQL.

EPA Response: For additional discussion on alternative regulatory standards (including higher PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Aurora Water, City of Aurora, Colorado (Doc. #1669, SBC-043732)

Communications

As proposed, water systems are required to publish a Tier 2 public notice if the NPDWR MCLs are exceeded. If the MCL is 4 ppt, this would result in more frequent - and expensive – Tier 2

public notifications, which would erode trust in water utilities nationally. Like all utilities, Aurora Water's operation system best practices ensures public notifications do not need to be sent. However, treating Aurora's water to a level under the proposed public notice level of 4 ppt may be the difference between increasing costs by nearly six-to-seven times, rather than setting the MCL to 10 ppt, which would still roughly double our treatment costs but would be more manageable. The higher the treatment costs, the more we would be forced to increase rates.

Additionally, with increased notifications, customers may be more likely to buy bottled water believing it has less risk, which, depending upon how the water is treated, may have higher levels of PFAS and has additional environmental impacts from plastic waste. Customers may also turn to expensive and often unnecessary in-home water treatment systems, which, if not properly maintained, may pose additional health risks and create issues with land disposal. These options would further increase costs to customers and provide a false sense of security. Aurora Water recommends the EPA consider setting the MCL at 10 ppt, which would lower GAC costs, the frequency of public notifications and help maintain community trust in their water utility.

EPA Response: For additional discussion on alternative regulatory standards (including cost considerations and higher PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA notes that the safety of bottled water is regulated by the FDA and is beyond the scope of this rulemaking. For additional discussion on PN requirements for the final NPDWR, please see section 9.2 of the EPA response in this *Response to Comments* document.

Rockbridge Area Conservation Council (RACC) (Doc. #1678, SBC-043739)

2) EPA Statement:

"Considering feasibility, including currently available analytical methods to measure and treat these chemicals in drinking water, EPA is proposing individual MCLs of 4.0 nanograms per liter (ng/L) or parts per trillion (ppt) for PFOA and PFOS" … "the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur is ZERO. Understanding that these chemicals have "NO SAFE LEVEL" and that the MCL of 4 ppt was selected based on what can be accurately identified analytically"

The interim life-time health advisory drinking water levels recently established by EPA, based on the existing toxicological data, for PFOA was to 0.004 ppt and 0.02 ppt for PFOS. These values are significantly below the MCL of 4 ppt causing a 1,000-fold decrease in safety for PFOA, a 200-fold decrease in safety for PFOS, and an unknown decrease in safety for the combination of PFAS compounds.

It is extremely unfortunate that current regulatory guidelines and the analytic technologies on which they are based for analysis of specific contaminants are between 50 - 70 years old. This has caused a large gap between identifying what can be identified conventionally, and determining whether the quantified dose is toxic or safe. Regardless, using this type of logic to

determine what is legally enforceable compared to what is "safe" is not a sound toxicological principle. Additionally, this logic goes against a variety of medical, philosophical, and legal practices that employ the "Precautionary Principle".

"The precautionary principle is a broad epistemological, philosophical and legal approach to innovations with potential for causing harm when extensive scientific knowledge on the matter is lacking. It emphasizes caution, pausing and review before leaping into new innovations that may prove disastrous."

EPA Response: For additional discussion on alternative regulatory standards (including lower PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document. Lifetime HAs are beyond the scope of this rulemaking. The MCLGs promulgated in this final NPDWR are based on the best available, peer-reviewed science and the agency's review of current scientific literature on human health effects; please see section 4 for additional discussion on health considerations for PFOA and PFOS when setting the MCLG. See section 1412(b) of SDWA for factors EPA considers when setting MCLs.

Public Employees for Environmental Responsibility (PEER) (Doc. #1683, SBC-044970)

The proposed MCLs are too high. EPA claims that it chose 4.0 ug/L as an MCL for PFOS and PFOA because, "4.0 ppt is the lowest concentration that PFOA and PFOS can be reliably quantified within specific limits of precision and accuracy during routine laboratory operating conditions." This is not true. Private laboratories like Eurofins can reliably measure down to 2.0 ppt in water. As defined by the SDWA, an MCLG is the "maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, allowing an adequate margin of safety." [FN7: 40 CFR § 141.2] The SDWA generally requires EPA to set an MCL "as close as feasible to" the MCLG. [FN8: 88 Fed. Reg. 18639] In this case, EPA is proposing a MCLG of zero for PFOA and PFOS, yet proposes an MCL of 4.0 ppt. An MCL of 2.0 ppt would be closer to the MCLG, EPA should consider reducing the proposed MCLs.

The Hazard Index (HI) will be difficult for public water suppliers to use. While PEER was pleased to see EPA propose to also regulate PFHxS, HFPO-DA, PFBS, and PFNA, use of the HI is unnecessarily confusing to the regulated communities. While we agree that it is important to account for the increased risk from mixtures of PFAS that may be found in contaminated drinking water, we fear that the HI will be difficult to implement. Because the HI is unitless, it is difficult to form messaging around these chemicals. There is currently an abundance of confusion over MCLs, clean-up standards, the PFAS definition, and a patchwork of regulations across the states; utilizing a HI instead of low MCLs will simply add to this confusion. As such, PEER urges EPA to consider low MCLs for PFHxS, HFPO-DA, PFBS, and PFNA, instead of using a HI.

Conclusion. PEER agrees with EPA that these PFAS chemicals are dangerous and must be regulated in drinking water; however, we do not believe that these proposed rules have gone far

enough. We urge you to consider defining PFAS consistent with the Organisation for Economic Co-operation and Development (OECD) definition, and regulating them as a class in drinking water.

Thank you for the opportunity to comment.

Sincerely,

Kyla Bennett, Director

Science Policy

Public Employees for Environmental Responsibility (PEER)

EPA Response: For additional discussion on alternative regulatory standards (including lower PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA promulgates standards that is achievable on a national scale (as reflected in the PQL). While some individual laboratories can achieve lower levels, this has not been demonstrated to be achievable at a national scale which the agency looks to when promulgation an NPDWR. The EPA finds that the Hazard Index approach is the most health-protective approach for PFAS that have dose additive health concerns and are known to co-occur as mixtures in the environment. The agency further notes that the hazard index calculation is also not mathematically different (i.e., summing up numbers and dividing) than a RAA calculation which is used frequently for compliance calculations for NPDWRs. Regardless, to assist in the calculation of these values, the agency is developing a calculator tool to easily determine your hazard index result. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation. After a review of public comment and considering this and other comments, the agency is promulgating individual MCLs for PFHxS, PFNA, and HFPO-DA in addition to the Hazard Index MCL for mixtures containing two or more of these PFAS and PFBS to aid in messaging, risk communication, and other factors. Please see section 5.3.1 of the EPA response in this *Response to Comments* document for additional discussion on these individual MCLs, including risk communication and feasibility concerns.

<u>The City of Columbus, Department of Public Utilities (Doc. #1703, SBC-045059)</u>

III. EPA should consider reliability and consumer confidence before setting its initial MCL at the PQL.

Issuing the initial MCL at the PQL has high consequences because once EPA sets the MCL, water utilities will have to start expending the billions of dollars to comply to meet it. Here, where there is scientific uncertainty and the proposed MCL is pushing the available treatment and sampling techniques to their physical extremes, EPA should set a MCL that meets the requirements of the SDWA that also can be supported as rational to the public. As more data

becomes available from UCMR 5 and other studies, there will be opportunities to issue a more stringent MCL.

EPA Response: For additional discussion on alternative regulatory standards (including higher PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA notes that the MCLs are not "initial" as the commenter describes; they are final standards that reflects the agency's analysis of feasibility consistent with SDWA requirements. For discussion on how the EPA considers future science, please see section 5.1.6 of the EPA response in this *Response to Comments* document.

Joe DiNardo (Doc. #1725, SBC-045760)

2) EPA Statement:

"Considering feasibility, including currently available analytical methods to measure and treat these chemicals in drinking water, EPA is proposing individual MCLs of 4.0 nanograms per liter (ng/L) or parts per trillion (ppt) for PFOA and PFOS" … "the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur is ZERO. Understanding that these chemicals have "NO SAFE LEVEL" and that the MCL of 4 ppt was selected based on what can be accurately identified analytically"

The interim life-time health advisory drinking water levels recently established by EPA, based on the existing toxicological data, for PFOA was to 0.004 ppt and 0.02 ppt for PFOS. These values are significantly below the MCL of 4 ppt causing a 1,000 fold decrease in safety for PFOA and a 200 fold decrease in safety for PFOS. Understanding EPA's rational for selecting the 4 ppt MCL levels for these chemicals may make sense analytically, however, it does not justify them toxicologically. It is extremely unfortunate that current regulatory guidelines, with respect to analytical identification of specific contaminants, are between 50 - 70 years old. This has caused a large gap between identifying what can be found in a substances and if that dose is toxic or safe. Regardless, using this type of logic to determine what is legally enforceable compared to was is "safe" is nonsensical in toxicology. Additionally, this logic goes against a variety of medical, philosophical and legal practices that employee the "Precautionary Principle".

"The precautionary prin16.0ciple is a broad epistemological, philosophical and legal approach to innovations with potential for causing harm when extensive scientific knowledge on the matter is lacking. It emphasizes caution, pausing and review before leaping into new innovations that may prove disastrous."

EPA Response: Please see the EPA response to comment Doc. #1678, SBC-043739 in section 5.1.3 in this *Response to Comments* document.

U.S Conference of Mayors, National League of Cities and National Association of Counties (Doc. #1733, SBC-043893)

Should EPA move forward, the Agency should establish a higher MCL, such as 10 ppt under Option 1 c in the proposed regulation. This will capture the systems where PFAS is more prevalent, without overburdening many more communities.

2. Practicality of Implementation

As mentioned above, local governments play a critical role in the effective implementation of federal regulations. Recognizing this, as the Agency moves forward with this regulation, we have serious concerns with several practical aspects that will impact local governments' capacity to effectively and economically achieve compliance, as outlined below. Many of these practical concerns can be minimized by establishing a higher MCL for PFOS and PFOA, which would prioritize systems with higher concentrations of the chemicals, and by granting a longer compliance timeframe.

a. MCLs for PFOS and PFOA set at detection levels

The Agency has proposed drinking water standards for PFOS and PFOA at 4 ppt, which is the lowest detection level at which the contaminant can be reliably measured. When comparing these MCL levels with other datasets in the international community, such as those from the World Health Organization, Australia, Japan and Canada, EPA's proposed standards are significantly lower. Additionally, several states have recently set their own drinking water standards for PFOS and PFOA. As proposed, EPA's standards are lower than any current international or state standard.

When taking into account that states as well as the international community have access to the same available science EPA used to develop its proposed regulation, there are questions about this wide discrepancy that requires further examination. Additionally, EPA's standards are set so strictly that thousands of systems will be in violation from the outset, necessitating immediate decision making and costly actions.

EPA Response: For additional discussion on alternative regulatory standards (including higher PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document. For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding responses on the compliance timeframe, the agency is authorizing a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. With respect to existing state and international drinking water standards, please see section 5.1.5 of the EPA response in this *Response to Comments* document.

Washington County Department of Public Health and Environment (Doc. #1739, SBC-043569)

[To address the issues described here, EPA should make one of the following changes to the proposed NPDWR for PFAS:]

• Raise the MCLs for both PFOS and PFOA to be above the PQLs so that results below the MCLs can be considered when calculating a QRAA for compliance.

EPA Response: For additional discussion on alternative regulatory standards (including higher PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document. For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Defend Our Health (Doc. #1741, SBC-045195)

The EPA's draft lifetime health advisories for PFOA (0.004 ppt) and PFOS (0.02 ppt) were developed in recognition of the impacts of those chemicals to the developing immune systems of young children. While the proposed Hazard Index approach to regulating GenX and PFBS is faithful to the draft Health Advisory Levels (HALs) published in 2022, the proposed MCLs for PFOA and PFOS are two to three orders of magnitude higher than the HALs for those chemicals. The stated justification for this discrepancy is that the HALs for PFOA and PFOS are well below the point of laboratory detection. But the commercial laboratories serving Maine drinking water testing routinely report results with a reporting limit of only 2 parts per trillion [FN1: https://alphalab.com/index.php/pfas-analysis].

The additional regulatory focus by EPA is already spurring innovation in PFAS detection. A mere three months after the EPA's published its proposed Lifetime Health Advisory Levels for PFOA and PFOS in 2022, Eurofins Lab announced that it had successfully improved existing laboratory analytical technology, and was able to detect PFOA and PFOS in the parts-per-quadrillion range of the proposed HALs. The EPA should support this innovative push by commercial laboratories by adopting an evolving, technology-based standard.

The failure to protect people whose water is contaminated between the current, commercially available level of detection of 2 ppt and the proposed 4 ppt PFOA and PFOS MCLs will have a real impact. In Maine, all non-transient community water systems have been required to test for PFAS and filter if the water exceeds the current drinking water standard. Almost 9% of community water systems (64 systems total) who have submitted their results to Maine Centers for Disease Control to date would fall into this unprotected gap [FN2: https://www.maine.gov/dhhs/mecdc/environmental-health/dwp/cet/documents/PFASallResults.pdf]. The people whose drinking water is supplied to them by at least 14 Maine municipal water districts would be left unprotected. The likely low-income residents of at least 13 Maine mobile home parks would be left unprotected. Especially

troubling given the documented impacts of low level PFOA and PFOS exposure to young children on which the HALS are based, there are at least 22 schools and day care facilities in Maine whose students would be unprotected to the effects of ongoing, documented exposure. It is unlikely that Maine is unique in the scope of its drinking water contamination. Millions of Americans would be left at risk of the toxic health impacts of ongoing PFOA and PFOS exposure by setting the MCLS at twice the commercially available point of detection.

In recognition of the current and rapidly improving analytical capacity to test for low level PFOA and PFOAS contamination and in recognition for the real medical harm experienced by communities exposed EPA should adopt an evolving, technology-based standard for PFOA and PFOS in drinking with an initial working regulation 2 parts per trillion for those two chemicals.

EPA Response: For additional discussion on alternative regulatory standards (including lower PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA promulgates standards that is achievable on a national scale (as reflected in the PQL). While some individual laboratories can achieve lower levels, this has not been demonstrated to be achievable at a national scale which the agency looks to when promulgation an NPDWR. For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For additional discussion on considerations for international and state drinking water standards and guidelines, please see section 5.1.5 of the EPA response in this *Response to Comments* document.

Defend Our Health (Doc. #1741, SBC-045193)

There is room for improvement in the EPA's proposal. We strongly urge the EPA to use a technology-based standard for PFOA and PFOS that correctly identifies the current, commercially available point of detection of 2 parts per trillion rather than 4 parts per trillion.

EPA Response: Please see the EPA response to comment Doc. #1741, SBC-045195 in section 5.1.3 in this *Response to Comments* document.

Defend Our Health (Doc. #1741, SBC-045198)

Defend Our Health supports the existing proposal to list regulate 6 PFAS of identified toxicity, which will likely protect millions of Americans from ongoing exposure to these chemicals. We recommend improving the existing proposal by adopting a technology-based standard for the detection and remediation PFOA and PFOS starting by regulating them to the current, commercially available point of detection of 2 ppt and evolving alongside improving commercially available analytical capability to further protect people from 'low level' contamination which exceeds HALs for those two chemicals.

EPA Response: Please see the EPA response to comment Doc. #1741, SBC-045195 in section 5.1.3 in this *Response to Comments* document.

National Center for Health Research (NCHR) (Doc. #1749, SBC-044496)

1. The PFAS limit should be changed to 2 parts per trillion (ppt).

We disagree with the EPA that 4 ppt is the lowest level that can be reliably tested and removed. Eurofins routinely and reliably measures 2 ppt in water and it is likely that 2 ppt will be widely usable to measure and remove PFOA and PFOS well before this rule is finalized. Since EPA acknowledges that no level of PFOA and PFOS is safe, the limit should be 2 ppt.

EPA Response: For additional discussion on alternative regulatory standards (including lower PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045636)

As with the EPA selected rule option, setting the nation's first drinking water MCLs for PFOA and PFOS at levels as low as 4 or 5 ppt will create a significant combination of implementation challenges. The effect of such a rule option selection will be to delay all water systems in installing treatment facilities and increase the burden on households to pay for doing so, rendering such levels infeasible. Instead, EPA should place an emphasis on higher-priority water systems by targeting those systems higher levels of PFAS first. Focusing on systems with higher levels of PFAS will ensure that communities with the greatest risk of exposure to PFOA and PFOS are able to control exposure via drinking water more cost-effectively and promptly. Setting the nation's first drinking water standard for PFOA and PFOS at 10 ppt does not preclude EPA from further reducing these standards as technology advances and available occurrence and toxicological data improve.

Ultimately, each of the proposed options is likely to represent a net cost to society (and drinking water consumers), requiring investments that will outweigh the benefits. These impacts will be most dramatically felt by smaller systems serving less than 10,000 people and the affordability analysis suggests that the costs to implement these treatment facilities will range from hundreds to thousands of dollars annually for individual households, significantly exceeding affordable margins for household expenditures for drinking water (i.e. drive the cost of water services beyond EPA's measure of affordable drinking water).

Consequently, EPA should significantly improve upon the analyses to strengthen any rule and to accurately capture the impacts on water systems and public health. The Administrator should reevaluate this rule with the improved analyses to determine if the benefits justify the costs and that the rule is feasible for small systems to implement. If any rule is finalized without the additional analysis and public review AWWA recommends that EPA utilize Option 1c and set MCLs of 10 ppt PFOA and 10 ppt PFOS. Option 1c affords the greatest opportunity for health

benefit for impacted communities while reducing affordability concerns associated with the rule. If EPA determines that regulation of additional PFAS is merited, the agency should propose a rule following a final determination to regulate, consistent with the authority provided by SDWA.

EPA Response: For additional discussion on cost considerations and alternative MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document. For additional discussion on the agency's cost analysis, the EPA has provided a robust discussion of the basis for the EPA's cost estimates in section XII of the final rule preamble and section 13.3 of the EPA response in this *Response to Comments* document. The agency notes that funds available under the BIL will significantly reduce some of these household costs for small systems (see for example, the EPA's affordability analysis Tables 9-15 and 9-20 of the final EA). With respect to the phased-in MCL approach, the EPA believes the monitoring and compliance requirements finalized in the PFAS NPDWR addresses high-risk systems (i.e., systems with elevated concentrations will require more frequent monitoring whereas systems without contamination or low levels of contamination will monitor less frequently). Based on these monitoring results, water systems may then be required to change their monitoring frequency if the results suggest increasing or decreasing concentrations (for additional discussion on monitoring and compliance requirements for the rule, please see section 8 of the EPA response in this *Response to Comments* document). In scenarios where elevated levels of PFAS are found in presumably "lower-risk" systems, a phased-in approach is not public health protective for systems that may experience spikes in PFAS concentrations. These fluctuations have been demonstrated in the agency's evaluation of PFAS occurrence in drinking water. Please see sections 12 and 13 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045557)

Summary of Key Recommendations

AWWA reviewed all aspects of the proposal and the supporting documentation, including the agency's occurrence analysis, cost analysis, benefits analysis, and household affordability analysis. The proposal includes several major actions for PFAS in drinking water, including:

1. Proposal for drinking water standards for both PFOA and PFOS;

2. Preliminary determinations for perfluorohexanesulfonic acid (PFHxS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO-DA), perfluorobutanesulfonic acid (PFBS), and the mixture of these four PFAS, and

3. Proposal for drinking water standard for PFHxS, PFNA, HFPO-DA, and PFBS as a mixture using a hazard index.

Based on the supporting documentation, and in consultation with drinking water technical experts, AWWA recommends that the agency consider withdrawing and re-proposing the drinking water standards for PFOA and PFOS given that the underlying analyses lack

transparency, are not consistent with use of best available science, and are not clear. However, if EPA issues a final rule setting standards PFOA and PFOS, the agency should set drinking water standards of 10 ppt PFOA and 10 ppt PFOS on the basis that these would be most defensible with the agency's current analysis.

EPA Response: For additional discussion on alternative regulatory standards (including higher PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document. The agency disagrees that the standards for PFOA and PFOS, as well as the Hazard Index MCL, are not based on the best available, peer-reviewed science and lacks transparency. The agency has made documentation supporting the NPDWR available for public comment and has described these analyses in detail in the proposed and final rule preamble. Specifically, please see the agency's proposed and final *Economic Analysis for the final PFAS NPDWR* and associated appendices (USEPA, 2023c; USEPA, 2023d; USEPA, 2024c; USEPA, 2024d).

American Water Works Association (AWWA) (Doc. #1759, SBC-045549)

In addition to providing feedback for improving the analyses to support the proposal, AWWA makes several key recommendations, which are further detailed in the comment letter.

These recommendations include:

1. The agency should consider withdrawing and re-proposing drinking water standards for PFOA and PFOS given the recurring issues with the underlying analyses. If the agency should finalize drinking water standards for PFOA and PFOS based on the current proposal, drinking water standards of 10 ppt, each, are most appropriate.

EPA Response: Please see the EPA response to comment Doc. #1759, SBC-045557 in section 5.1.3 in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-045657)

Finally, EPA also violated the SDWA when it did not consider any alternatives for the HI-MCL itself, or for the HBWCs that underpin it. Consideration of a reasonable range of alternatives is required by both the SDWA, and the Unfunded Mandates Reform Act. [FN4: SDWA [sec] 1412(b)(3)(C)(i); 2 U.S.C. [sec] 1535.] It also meant that EPA did not adequately consider the point at which benefits expected to result from the proposed HI-MCL outweigh its costs, as required by the SDWA.

EPA Response: For additional discussion on alternative MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The agency disagrees with the commenter that the EPA did not consider any alternatives for the Hazard Index MCL (see 5.1.3 of the EPA response in this *Response to Comments* document for additional discussion). The agency further notes that SDWA 1412(b)(3)(C)(i)(IV) only requires that in developing the HRRCA, the agency must consider the "incremental costs and benefits associated with each

alternative maximum contaminant level considered" if there are any. That provision does not require the agency to consider the HBWCs that are an input to the Hazard Index. Additionally, the commenter is incorrect in stating that the agency is required under SDWA to select an MCL where benefits "outweigh its costs"; the EPA emphasizes that under SDWA, the EPA must consider whether the costs of the rule are justified by the benefits (see SDWA 1412(b)(3)(c)(i)).

Fairfax Water (Doc. #1789, SBC-045301)

Instead of the proposed MCLs of 4 ppt, EPA should set the initial MCL at 10 ppt for PFOA and 10 ppt for PFOS to mitigate some of the pressures related to competition for limited resources and reduce the risk of further cost acceleration due to resource constraints.

EPA Response: For additional discussion on alternative regulatory standards (including higher PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046134)

14. The EA includes several alternative regulatory options, but all options are less stringent than the proposed option. Why were no more stringent regulatory options considered?

OMB's Circular A4 (2003) and EPA's (2014) economic guidelines suggest analyzing an array of alternative regulatory options, with at least one more stringent and one less stringent than the proposed option. The proposed PFAS NPDWR EA only includes less stringent alternative regulatory options. To strengthen the EA, EPA should evaluate a more stringent regulatory option or explicitly describe the rationale for not including a more stringent option. For example, Circular A4 (OMB 2003) states that more stringent regulatory alternatives are not required in cases where the proposed option is near or at the limits of what is technically feasible.

EPA Response: For additional discussion on alternative regulatory standards (including lower PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA did not propose more stringent MCLs for PFOA and PFOS given the EPA's consideration of feasibility as required by SDWA. For example, the agency does not have sufficient evidence to support a lower PQL that can be consistently achieved by laboratories across the country. After review of public comment, the agency is finalizing the MCLs for PFOA and PFOS at 4.0 ng/L (at the PQL) as this is the closest level to the MCLG that is feasible due to the ability of labs using approved analytical methods to determine with sufficient precision and accuracy whether such a level is actually being achieved. The record supports the EPA's determination that the lowest feasible MCL for PFOA and PFOS at this time is 4.0 ng/L.

West Virginia Municipal Water Quality Association (Doc. #1816, SBC-044682)

VIII. EPA is out of step with other health organizations around the world who have evaluated PFAS health issues.

As we noted at the outset, our members seek to serve the public in an affordable and cost-effective manner. We don't try to avoid necessary and appropriate requirements. To the contrary, we embrace them and prioritize them within our other infrastructure and operational requirements. However, EPA's proposed PFAS MCLs are so low that they give us pause – especially as we consider the fact that PFAS levels in our environment (and bodies) have been dropping dramatically and will plummet further given the intense focus on ending the use of these chemicals.

With this perspective, we are troubled that EPA's criteria are so much lower than other prominent health agencies. For example, the World Health Organization set a provisional guidance value in September 2022 of 100 ppt for PFOA/PFOS and 500 ppt for all other PFAS. WHO had the benefit of EPA's science when it adopted criteria five orders of magnitude higher for PFOA and four orders of magnitude for PFOS. This is an incredible difference between the world's two preeminent world health organizations.

WHO has not been alone in its repudiation of EPA's interim health advisory levels and now proposed MCLs. For example:

• The United Kingdom and European Union set their PFAS regulatory framework as follows:

<10ppt = no issue;

< 100ppt = research; and

>100ppt = action required.

• Australia set a standard of PFOS + PFHxS at < 70ppt and PFOA a < 560ppt (2022).

• Japan's standard for PFOS+PFOA is < 50 ppt.

• Canada's Guidelines for Canadian Drinking Water Quality, released in September 2022, show 600 ppt for PFOS and 200 ppt for PFOA. The application guidelines indicate the sum of PFOS and PFOA should not exceed 200 ppt. This remains much higher than the EPA proposal.

These are dramatic and, potentially, unprecedented differences between the PFAS standards of prominent health organizations and EPA's, which warrant significant caution on EPA's part. These differences also support our suggested phased implementation approach.

EPA Response: For additional discussion on considerations for international and state drinking water standards and guidelines, please see section 5.1.5 of the EPA response in this *Response to Comments* document. For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations), 5.1.3 (cost considerations and alternative MCLs) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document. With respect to a phased implementation approach, the EPA believes the monitoring and compliance requirements finalized in the PFAS NPDWR addresses high-risk systems (i.e., systems with elevated concentrations will require more frequent monitoring whereas systems without contamination or low levels of contamination will monitor less

frequently). Based on these monitoring results, water systems may then be required to change their monitoring frequency if the results suggest increasing or decreasing concentrations (for additional discussion on monitoring and compliance requirements for the rule, please see section 8 of the EPA response in this *Response to Comments* document). In scenarios where elevated levels of PFAS are found in presumably "lower-risk" systems, a phased-in approach is not public health protective for systems that may experience spikes in PFAS concentrations. These fluctuations have been demonstrated in the agency's evaluation of PFAS occurrence in drinking water. Please see section 12.1 and 13 of the EPA responses in this *Response to Comments* document.

Anonymous (Doc. #1950, SBC-046316)

PFAS and PFOS contaminants should have their MCLG be decreased to 4.0 ng/L or lower. As a resident in the Manorville area, approximately 1 mile from the Grumman site, now owned by the Navy, 64 residents in the surrounding area are dealing with contaminated well water. From Pfoa/Pfos to chemicals the average layman can not even pronounce. The Navy is not taking any responsibility, for the area outside the fence line where residents live. UNACCEPTABLE.. There are 22 out of 64 homes where residents have had, or have cancer, not to mention what can appear in the future for our children and animals. Lowering the acceptable number will hold businesses that have a responsibility to clean up the area before turning property over to someone else. It is the right of every American to have clean water. But there are sections in America that are the forgotten developments which is making people sick and or killing them. PLEASE lower the acceptable allowance numbers. If not for this generation, for our Childrens future

EPA Response: The EPA notes that MCLGs are public health goals and are not enforceable standards. For additional discussion on alternative regulatory standards (including lower PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Anne Schwartzman (Doc. #2203, SBC-046520)

Re: Docket ID No. EPA-HQ-OW-2022-0114

Water is needed for our lives. Clean water is necessary for humans and animals to live a healthy life. EPA's health advisories say no level of PFAS exposure is safe and so the enforcement levels should be the lowest they can be. People living on earth should not have to assume any additional level of risk to appease industry and trade organizations. The Chamber of Commerce does not speak for the health of all; please disregard their issues with it not being up to the polluters to curtail the PFAS created and used in products. Now is even late for us to be doing something; act now to do the decent thing in the USA.

Thank you,

Anne Schwartzman

Therefore, EPA should set regulations at the limit that the labs can detect rather than the proposed 4 ppt for PFOA and PFOS each.

EPA Response: For additional discussion on alternative regulatory standards (including lower PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2331, SBC-047291)

If it can not be proven definitively, and it can't that the health cost savings from 4 PPT removal is greater than the cost to remove to below 20 PPT then 20 PPT would be the MCL.

EPA Response: For additional discussion on alternative regulatory standards (including higher PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document. The Administrator has determined that the costs of this regulation are justified by the benefits: see section 13.8 of the EPA response in this *Response to Comments* document.

Mary Raven (Doc. #2435, SBC-047316)

Please set PFOA and PFAS levels as low as can possibly be detected -- lower than the current 4ppt.

EPA Response: For additional discussion on alternative regulatory standards (including lower PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Petersburgh C8 (PFAS) Committee (Doc. #2714, SBC-047423)

In addition, the whole class of these chemicals should be regulated as close to zero as possible, all 14,000 of them. Why should the safety of these chemicals be tested on humans? Instead of spending money on treating our diseases, filtering our water, and on cleanup, stop these compounds from entering our bodies, our communities, our children, and our wildlife. The research shows that this class of chemicals are dangerous and forever.

The proper MCL for this class of chemicals is as close to zero as possible. When a chemical from this group gets pulled out of use because people start getting sick, another is waiting to take its place. Industry is way ahead of our health, safety and regulations. We need strong policy from our government agencies charged with protecting our communities instead of letting industry profit from weaker regulations

Thank you for your consideration.

The Petersburgh C8 (PFAS) Committee

Petersburgh, New York

EPA Response: For additional discussion on alternative regulatory standards (including lower PFOA and PFOS MCLs or regulation of PFAS as an entire class), please see section 5.1.3 of the EPA response in this *Response to Comments* document.

West Virginia Rivers Coalition (Doc. #3072-3, SBC-047358)

In this light, we urge EPA to expedite the publication of human health criteria for PFAS. State agencies are waiting on EPA's guidance to implement policy levers to reduce PFAS pollution at the source. In accordance with recently passed legislation, the West Virginia Department of Environmental Protection will establish statewide limits on PFAS discharges upon EPA's issuance of those recommended criteria. Lastly, as demonstrated by the Maximum Contaminant Level Goal of zero, there is no safe level of PFOA or PFOS. As technologies continue to advance and PFAS detected at even lower levels, we urge EPA to lower the MCLs to levels protective of public health. Thank you.

EPA Response: For additional discussion on alternative regulatory standards (including lower PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA notes that "publication of human health criteria for PFAS" is beyond the scope of this rulemaking. For additional discussion on how the agency considers future science, please see section 5.1.6 of the EPA response in this *Response to Comments* document.

National Center for Health Research (Doc. #3072-73, SBC-047400)

I'm Dr. Diana Zuckerman, president of the National Center for Health Research. Our non-profit think tank focuses on the safety of medical and consumer products. We provide research-based information to Congress, federal agencies, and the public, and we do not accept funding from companies that make the products we evaluate. My comment today relies on my research experience at Yale and Harvard and in my current position, as well as my policy expertise from working in the house, the Senate, federal agencies, and the White House. We agree that this proposed rule will greatly improve public health, reducing cancer, heart disease, stroke, low birth weight, and other harms to adults and children. It will save lives. But we have recommendations to improve it. Number one, we disagree that 4 parts per trillion is the lowest level that can be reliably tested and removed. Eurofins routinely and reliably measures 2 ppt in water and it's likely that 2 ppt will be widely used, usable to measure and remove PFOA and PFOS well before this rule is finalized. Since EPA acknowledges that no level of PFOA or PFOS is safe, the limit should be 2 ppt.

EPA Response: For additional discussion on alternative regulatory standards (including lower PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document.

New Mexico Rural Water Association (Doc. #3072-98, SBC-047413)

Lastly, having an MCL is a concern because of the hammer that comes with violations. We suggest a treatment technique without penalties for systems that had no role in creating the contaminant, which we're trying to solve. Thank you for the opportunity to comment.

EPA Response: For additional discussion on alternative regulatory standards, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The agency notes that under SDWA, the EPA may establish a treatment technique in lieu of an MCL if it is not technologically feasible to ascertain the level of a contaminant in drinking water. The availability of analytical methods to monitor the targeted PFAS compounds in this NPDWR precludes the EPA from considering such a regulatory framework at this time. For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations), 5.1.3 (cost considerations and alternative MCLs) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document.

Daniel Varon (Doc. #1518, SBC-042724)

Further, the 4.0 ng/L seems too high of an allowable MCL. If the study conducted by the EPA used 30, 20, and 90 ng/L as threshold markers, why should the MCL not fall closer in line with this? I once again will mention that the studies linking PFAS to negative health consequences show correlation only at extremely high levels. If it becomes more costly to bring the MCL lower, it should be considered if there is a higher threshold that can yield comparable results. I note and am aware however, that if PFAS thresholds have little cost differences between a 30 ng/L threshold and a 4.0 ng/L threshold, then this point is not as significant.

EPA Response: For additional discussion on alternative regulatory standards, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA did not use a "study" nor propose alternative standards at "30, 20, and 90 ng/L as threshold markers."

Brian Hackman (Doc. #1539, SBC-042910)

Raising the MCL's and HI to more significant values, on the order of the initial 70 ppt Health Advisory concentrations, would allow the Agency to show health improvements are being achieved at a reasonable cost through this regulatory opportunity to chase after a real and mitigatable risk with effective solutions.

This statement is in objection to the current PFAS proposed MCLs being discussed as part of the USEPA Docket EPA-HQ-OW-2022-0114, in light of a standard that would prove to be more effective and demonstratable at higher concentrations.

Respectfully Submitted,

Brian L Hackman

EPA Response: For additional discussion on alternative regulatory standards (including higher PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Cordell Spires Jr. (Doc. #1541, SBC-042661)

IV. Why EPA Should Use a Class-Based Approach to Regulate PFAS

More than 12,000 PFAS chemicals have been identified, yet this regulation would only regulate 6 of them [FN-9: Id.] Therefore, this regulation does not go far enough in preventing the potential health effects associated with PFAS. Although PFAS exposure occurs in complex mixtures, at present, fewer than 50 PFAS are commonly measured. [FN-10: Carol F. Kwiatkowski et al., Scientific Basis for Managing PFAS as a Chemical Class, 7 ENV'T SCI. TECH. LETTERS 532, 533 (2020).] New testing methods have shown that humans are exposed to more PFAS than previously estimated. [FN-11: Id.] The most studied PFAS chemicals are PFOA and PFOS, which have been phased out by manufacturers. [FN-12: Id. at 534] Nonetheless, most industries have turned to structurally similar replacements and evidence suggests that these replacements are not safer alternatives. [FN-13: Id.]

Managing the risk of PFAS has focused primarily on regulating one chemical at a time or a small group of PFAS, and this approach has not been effective at controlling widespread exposure. [FN-14: Id.] The problem with this approach is that assessing each PFAS chemical individually or in small subgroups ignores the majority of PFAS and underestimates the overall risk, especially since most of the chemicals are not commonly measured and their risks are unknown. [FN-15: Id at 536.]

EPA Response: For additional discussion on alternative regulatory standards (including regulation of PFAS as an entire class), please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Cordell Spires Jr. (Doc. #1541, SBC-042659)

May 5, 2023

The Honorable Michael Regan

Environmental Protection Agency

Office of the Administrator, 1101A 1200 Pennsylvania Avenue, N.W. Washington, DC 20460

Re: Public Comment on the Proposed PFAS National Primary Drinking Water Regulation

(Docket ID: EPA-HQ-OW-2022-0114)

Dear Mr. Regan:

On March 14, 2023, EPA announced the proposed National Primary Drinking Water Regulation (NPDWR) for six PFAS including perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO-DA, commonly known as GenX Chemicals), perfluorohexane sulfonic acid (PFHxS), and perfluorobutane sulfonic acid (PFBS). I, a law student at Southern Methodist University Dedman School of Law, respectfully submit the following comment on the proposed regulation. I have an interest in this regulation because it will impact the future of our nation's water quality and I believe clean water should be the standard rather than the exception moving forward.

This regulation is a good start to regulating PFAS in drinking water, but it does not go far enough. Instead, EPA should regulate PFAS as a class of chemicals rather than regulating PFAS on a chemical-by-chemical basis.

EPA Response: For additional discussion on alternative regulatory standards (including regulation of PFAS as an entire class), please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Prince William County Service Authority (Doc. #1609, SBC-042845)

5. EPA should issue initial MCLs for PFOA and PFOS of at least 2-3 times higher than the proposed limits of 4 ppt.

EPA Response: For additional discussion on alternative regulatory standards (including higher PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Prince William County Service Authority (Doc. #1609, SBC-042831)

MCLs and Hazard Index

The proposed MCLs for the two PFAS chemicals are set at 4 parts per trillion (ppt), which is the lowest level that current technology can reliably detect and are lower than those enacted by every state that has regulated PFAS in drinking water thus far. The costs associated with the proposed regulation are likely to be substantial and the scientific basis for MCLs at levels this low has been called into question, thus raising the issue of whether the benefits outweigh the costs. The World Health Organization (WHO), based on its review of the relevant science, recently recommended a limit of 100 ppt for PFOA and PFOS in drinking water, a limit that is 25 times higher than that which EPA now proposes.

EPA Response: For additional discussion on alternative regulatory standards (including higher PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document. Regarding considerations for existing state and international PFAS standards, regulations and guidelines, please see section 5.1.5 of the EPA response in this *Response to Comments* document.

Minnesota Department of Health (MDH) (Doc. #1610, SBC-042854)

Raise the MCLs for both PFOS and PFOA to be above the PQLs so that results below the MCLs can be considered when calculating a QRAA for compliance.

EPA Response: For additional discussion on alternative regulatory standards (including higher PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document. For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Safe Healthy Playing Fields, Inc. (Doc. #1621, SBC-042946)

With babies being born pre-polluted with PFAS, [Link: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7530144/] support of manufacturers 3M, Chemours, Solvay, Daikin, Dow, Dupont, Honeywell, BASF, Merck, Orteck, Innovative Chemical Technologies, and Bayer's use of Confidential Business Information so that they can collectively make $4 billion annual return on their investments is unconscionable.

Just four years ago, there were an estimated 4,000 - 5,000 PFAS chemicals in existence. Today, the EPA toxicity database, DSSTox, lists 14,735 unique PFAS chemical compounds; PubChem reports approximately 6 million. There is no conceivable way to evaluate each chemical individually or even as mixtures as currently proposed. The EPA must act to regulate PFAS as a class. By not doing so, the US EPA is de-incentivising development of alternatives that are safe, not carcinogenic and are non-toxic.

The job of the US EPA is to protect human and environmental health, not the chemical industry. We ask that you not delay further in enacting human and environmental health protective MCLs and regulation of PFAS as a class.

Respectfully submitted,

Diana Conway, President

Dianne Woelke MSN, Board Member Safe Healthy Playing Fields, Inc.

https://www.safehealthyplayingfields.org SHPFI is an all-volunteer nonprofit 501-c-3

EPA Response: For additional discussion on alternative regulatory standards (including regulation of PFAS as an entire class), please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Maine Organic Farmers and Gardeners Association (MOFGA) (Doc. #1660, SBC-043383)

With as many as 14,000 chemicals in the PFAS family, setting standards one at a time will never succeed in protecting health and the environment. The high persistence, accumulation potential, and hazards of PFAS studied to date warrant treating all PFAS as a single class. [FN5: https://pubs.acs.org/doi/pdf/10.1021/acs.estlett.0c00255?src=getftr.] That should be EPA's next step.

EPA Response: For additional discussion on alternative regulatory standards (including regulation of PFAS as an entire class), please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046114)

Finally, EPA should evaluate a regulatory option that is more stringent than the proposed MCLs. Contrary to OMB Circular A4 and EPA's economic analysis guidelines, all the alternatives analyzed in the Draft EA are less stringent than the proposed option. EPA should evaluate a more stringent regulatory option in the final EA or, at a minimum, explain why such an analysis is not appropriate. [FN143: Id. at 10.]

EPA Response: Please see the EPA response to comment Doc. #1808, SBC-046134 in section 5.1.3 in this *Response to Comments* document.

CleanEarth4Kids.org (Doc. #3072-45, SBC-046368)

Good afternoon. My name is John Bottorff with the CleanEarth4Kids.org. We thank the EPA for this proposal, but it is not nearly enough. We ask the EPA to set MCLs for PFAS in drinking water at zero. It's essential to stop PFAS in drinking water. PFAS have been detected in drinking water and water sources throughout the United States. Exposure to PFAS through drinking water causes significant health risks to humans, like hormone disruptions, diabetes, pregnancy complications, and increased risk of thyroid disease along with kidney, liver, and testicular cancer. According to the EPA, the lower the levels, the lower the risk. While PFAS may be present in drinking water levels that cannot be currently measured, new testing procedures and filtering technologies are being developed and we must set the limit now to ensure public safety. The state of New York has set MCLs at 2.7 ppt for PFAS in drinking water, significantly lower than what the EPA is proposing. The EPA must lead the way as the top protection agency in the nation and take aggressive action by setting the limit at zero. PFAS must be regulated as a class using the broadest definition to cover the entire family of these toxic chemicals. Managing PFAS as a class is the only way to protect human and ecological health. There is no safe level of PFAS, the EPA must turn off the tap at the source. There is no limited or managed use of PFAS, the EPA must ban the use and manufacturer of all PFAS as a class and they must do it now and immediately stop the approval of any new PFAS. The U.S. regulatory process has completely failed to protect us from PFAS, and now must play catch up. Taxpayers are paying the health and

financial burden of PFAS toxicity despite their dangers being known for over 50 years. It is fundamentally wrong that people and communities have been burdened by the health impacts and now the cleanup cost of PFAS by corporations that have made billions and billions from these poisons. The EPA must hold companies like 3M and Dow accountable for the cost of testing, cleanup, and upgrading water treatment facilities. They knew PFAS were toxic in the 70s. Not only continued the use but hid their own research and have fought all regulations. Please take strong and immediate action to protect our health. Set limits at zero ppt in drinking water and ban all uses and manufacturing of PFAS as a class. No more extensions or delays. No more protecting profits instead of people. Please stop these poisons now. Thank you from CleanEarth4Kids.org.

EPA Response: For additional discussion on alternative regulatory standards (including lower PFOA and PFOS MCLs or regulation of PFAS as an entire class), please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Ira Share (Doc. #1900, SBC-046293)

Please set the PFOA family of chemicals as close to zero as possible. We live less than a mile from a SuperFund site that has ruined our community with these chemicals. Our town water supply is contaminated. Our private wells are contaminated. Our air is contaminated. We have had enough of these toxins. It has been 7 years since discovery and there has been no cleanup. BUT, our DEC and DOH knew about this problem long before 2016, neglecting to inform our town. So, please set these levels as slow as possible so other communities can avoid this tragedy.

EPA Response: For additional discussion on alternative regulatory standards (including lower PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Kathleen Share (Doc. #1901, SBC-046482)

Please determine that the MCL be 4.0 ppt or even better less as the recommendations have been .004 ppt.

I live in Petersburgh NY, a mile away from the Taconic Super Fund Site which has polluted the area with PFOA/PFAS for years. Our community was informed of the contamination years after Taconic and NYSDEC and NYSDOH were aware. More and more communities are finding contamination which could be avoided if the polluters knew the MCL was moving to EPA MCL.004. Next is GenX.

EPA Response: For additional discussion on alternative regulatory standards (including lower PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Don Treasure (Doc. #1909, SBC-046284)

Currently, EPA does not have data on the health effects (if any) of this entire group, and so cannot accurately support the extremely low level of regulation. The cost of this proposal far outweigh the low if any unknown risks of this level of exposure. Both Canada and the World Health Organization have more realistic (if still not well supported by data) levels. Rescind or at least substantially raise the allowed exposure levels from the unjustified levels proposed here.

EPA Response: For additional discussion on alternative regulatory standards (including higher PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA disagrees that it does not have "data on the health effects (if any) of this entire group." As discussed in section 4 of this *Response to Comments* document, the agency is promulgating MCLGs at zero for PFOA and PFOS, a Hazard Index MCLG of 1, and individual MCLGs for PFHxS, PFNA and HFPO-DA at 10 ppt based on the EPA's evaluation of scientific literature on human health effects. The EPA currently has sufficient data and information to promulgate standards for the PFAS regulated through this NPDWR: for additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations), 5.1.3 (cost considerations and alternative MCLs), 5.1.4 (for treatment considerations) and 5.2.1 (for feasibility considerations for the Hazard Index PFAS) of the EPA response in this *Response to Comments* document. Regarding considerations for existing state and international PFAS standards, regulations and guidelines, please see section 5.1.5 of the EPA response in this *Response to Comments* document.

Ira Share (Doc. #1923, SBC-046308)

The amount of any PFAS/PFOS compound that we should be exposed to is zero. I live near Taconic Plastics in Petersburgh, NY. They have ruined our aquifer, our town water supply, our soil and most likely our food that we grow in this rural area.. We smell the emissions daily. We have no idea of the compounds they are using and releasing into the air. Are they long or short chain? Are they both? The whole class of these chemicals should be regulated, all 14,000 of them. Why should the safety of these chemicals be tested on humans? Instead of spending money on treating our diseases and filtering our water, stop these compounds from entering our bodies. Zero is the proper MCL. When one of this group gets pulled out of use, another is is waiting to take its place. Industry is way ahead of our health and safety.

EPA Response: For additional discussion on alternative regulatory standards (including lower PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2321, SBC-046304)

EPA likely only has a biostatistical link if anything to PFAS and increased risk of cancer or any disease as a result of parts per trillion level exposer to PFAS chemicals. Likely "new data" you

are aspousing is made up as is the data on CO2 contributing to climate change. Therefore EPA should not be setting standard of removal at levels of 4 PPT. Removal down to 15 PPT is more easily and economically feasible for water utilities and therefore this is the MCL that should be set rather than 4 PPT along with the other combined PFX number. We doubt you can prove any health improvements solely attributable to reducing the levels to 4 PPT rather than 15 PPT and the certainly not for the massive increase in costs to utilities to achieve removal to 4 PPT

EPA Response: For additional discussion on alternative regulatory standards (including higher PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document.

June Fabre (Doc. #2430, SBC-046457)

I support the EPA's proposed new actions because no level of PFOAS exposure has been proven to be safe.

I would also like the EPA to set regulations at the limit that labs can detect if that is lower than 4 ppt for PFOA and PFOS EACH.

Health and safety are important to me as a mother, grandmother, and retired nurse. These new regulations are needed.

EPA Response: For additional discussion on alternative regulatory standards (including lower PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Anne Romney (Doc. #2557, SBC-046210)

I fully encourage the EPA to set regulations at the limit that the labs can detect rather than the proposed 4 ppt for PFOA and PFOS each.

EPA Response: For additional discussion on alternative regulatory standards (including lower PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Laura Fontaine (Doc. #2611, SBC-046667)

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

The standard limits should be ZERO as these chemicals stay in the body forever and accumulate. There is no safe level for PFAS. We have 16 positive test results for PFAS and PFOAs in our drinking water due to release of these chemicals from the St. Gobain Plant in Merrimack NH. They are not being held accountable for the pollution of our water due to the levels registered in

our well are under the recommended NH Ambient Groundwater Quality standards. The standards need to be ZERO. We have to pay for a water system due to this infiltration of PFAS into our well water. My husband was diagnosed with Prostate Cancer last year and had to have a radical prostatectomy at age 61. He had to miss work and now has a major lifestyle change. These chemicals are not safe at any level! NH has a high rate of breast cancer. Could it be from our polluted water?

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals. Thousands of PFAS chemicals are in use and many are found in mixtures in water around the country. EPA should address the whole class of PFAS chemicals wherever possible.

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge.

Sincerely,

Laura Fontaine

EPA Response: For additional discussion on alternative regulatory standards (including lower PFOA and PFOS MCLs or regulation of PFAS as an entire class), please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Wolf Creek Water and Sewer Improvement District (Doc. #2832, SBC-046612)

Thank you for the opportunity to comment on this proposed PFAS National Primary Drinking Water Regulation. I am an elected Board of Trustees member of the Wolf Creek Water and Sewer Improvement District in Eden, Utah, making this comment in that role, and as a private citizen.

Our District is a Public Water Supplier for approximately 1200 connections, and a similar number of connections for public sewer. The sewage is conveyed to a tertiary membrane bioreactor plant (MBR) and treated to a high standard. We then use the reuse water for landscape irrigation through a separate secondary water supply system. Northern Utah has many of these secondary water systems, and is increasing reuse of water.

We do not know whether we have any PFAS or GenX compounds in our water supply or sewage. Because our water supply is 3,000 year old mountain-sourced water (Utah Geological Survey Special Study 165, 2019), and we are in a fully residential setting, with no industry or fire training areas upgradient, we believe it is very unlikely that there would be PFAS etc occuring in our drinking water. However, consumer use of PFAS may well introduce them into our sewage, since we understand that toilet paper manufacturing equipment, fast food wrappers etc may contain PFAS. The removal effectiveness in our MBR plant is an unknown.

This leaves us with a situation where we may have to test for the compounds in both water streams (drinking and reuse), and if we find them, deal with the public concern that will follow.

Based on my 30 years of background in the environmental sciences (AIPG # 7148, and Registrations in KY, IN, and PA prior to retirement), I believe the value you are setting is too low. My reasoning is as follows.

*We have contacted the lab (ChemTech Ford, Salt Lake City) that provides the analyses for our water in accordance with the Utah Division of Drinking Water, which is a reflection of the Federal requirements. They are unable to provide reliable analysis below 40 ppt, even in a clean matrix sample.

*There is an extremely high probability of cross-contamination, laboratory generated outliers and other "stray" results when you push commercial laboratories down to levels of analysis below 1 part per billion.

*Further, although our water samples may be pristine, there is a very real chance of air transport cross-contamination. (Reference recent USGS analyses in soil in New Hampshire with results between 0.5 and 1 ppb in soil). Utah is a dusty place, particularly with increasing dust being transported off the Great Salt Lake, at its current low stand. There is a high probability of PFAS being present in that dust, since it is a closed basin with water from sewage treatment plants and industrial sources across densely populated Wasatch Front Area In other words the 4 nanograms/liter level proposed for PFOA and PFAS is an order of magnitude below current available services, there is a high risk of extraneous and inaccurate results, and the exposure from water sources is probably orders of magnitude below exposures from consumer goods and ingested dust.

The cost of water supply treatment, if it were deemed necessary would be extreme, due to the very low levels proposed.

We are further going to have to deal with this issue in our reuse water, with unknown complexities at this time, although the PFAS that might be therein are from consumer goods, and not from any source we can control.

In summary, this is a plea from the trenches that you reconsider setting such a low standard, and at this time set a "monitor only" standard, or a value above 50 ppt. This should remain in place until there has been more progress in removing the PFAS from consumer materials, manufacturing lubricants, and items such as recreational and racing ski wax (a local likely source). There should be a full human risk-based evaluation of the relative exposures from these sources, and the Drinking Water Primary Standard only finalized when there is concrete evidence that drinking water is a high impact to consumers through ingestion, in comparison to all the other routes of exposure. The value can be lowered from this interim value (50 ppt or higher) when there is clearer eveidence of the relative importance of drinking water as a route of exposure for consumers/humans.

We cannot afford as a country to deal with another PCB-type scare - without first dealing with the sources and primary routes of exposure. This should be tackled internationally, so that infants and children in particular are not exposed to PFAS etc from imported goods.

Thank you for your consideration

EPA Response: For additional discussion on alternative regulatory standards (including higher PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document. For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. With respect to responses on cross contamination/background contamination issues with analytical analysis, please see section 8.7 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #1944, SBC-047454)

We know these hazards through history have hardly been publicized, and when they are, it takes years to convict. If they are convicted, the company inevitably moves on to the next chemical they can get away with, due to the lack of funding in science in studying these chemicals (Rich, 2016). Following, the chemicals studied that have been made aware to those that have had the privilege of an education, are hardly regulated. People in power are now just getting to pick and choose which communities are "allowed" to be more affected than others (Erickson, 2022). Economically it makes sense as those in low-income communities can't afford lawyers to even begin to take action for themselves (Erickson, 2022).

The proposed National Primary Drinking Water Regulation does not nearly go far enough for these communities, and all communities. It's a step in the right direction, but it highlights the fact that our government will continue to do the bare minimum in order to put on a public front that they are doing something. You have a few choices. Do nothing about this, contributing to producing more fuel for angry citizens, allowing for more division in the United States. Do the bare minimum, such as setting a "maximum contaminant level" , which requires those who have the privilege of time and education to find the flaws. Or, you can actually do something and set regulations on where the problem is coming from firsthand, get rid of "maximum level" and replace it with NO levels, protecting all communities, especially vulnerable ones. Additionally directing more funding to education and science, this is the route least taken, evident in the proposed NPDWR.

With education, you know that PFAS, even in small increments, builds up in the human body, ecosystem, and other organisms over time with continual exposure (EPA, 2023). A maximum level does not mean no levels, it just means you're allowing for less exposure to occur, still resulting in the same problem just over a greater period of time. This proposal does nothing for the communities already disproportionately affected, continues to allow everyone to be exposed, and avoids the real problem. Additionally, looking at how the EPA handled the Flint water crisis, holding information from Flint citizens knowing they were using lead filled water, increases

distrust in citizens with the EPA (Bernstein, 2016). Why is it considered to be ok to have levels of anything hazardous in our drinking and bathing water and why should we trust a government agency to decide what composes safe drinking water when they have undoubtedly failed in the past?

EPA Response: For additional discussion on alternative regulatory standards (including lower PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA disagrees that the agency is doing the "bare minimum" in setting an MCL for the PFAS regulated under this NPDWR. The EPA's final rule represents data-driven drinking water standards that are based on the best available, peer-reviewed science, meet the requirements of SDWA, and that regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. The agency has conducted extensive analyses (see for example sections 3, 4, 6 and 10) and consultations (section 14) to support this final rulemaking.

Pennsylvania Chamber of Business and Industry (Doc. #1592, SBC-042796)

EPA Will Need to Provide Additional Resources to States for Compliance and Permitting Support

As discussed, the stringent MCL's being proposed will present a significant compliance burden on industry and will also present a major imposition on the staff and resources of state environmental agencies, who are already have significant challenges with respect to hiring and retaining qualified workers. This proposed rulemaking will have secondary regulatory impacts to brownfields cleanups, NPDES discharge permits, industrial stormwater permits, waste management permits for hauling, storage, and disposal at landfills, among others – all of which will require more staffing and resources for state and local agencies. States will need a substantial increase in federal funding to accommodate this mandate.

EPA Response: For additional discussion on cost considerations for the final MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The availability of BIL funding which can be used to support implementation of the final NPDWR (please see section 2.4 for additional information). For discussion related to costs, including costs to primacy agencies, please see section 13 of the EPA response in this *Response to Comments* document. The application of MCLs in non-drinking water programs (such as water quality criteria, NPDES, or CERCLA cleanups) is beyond the scope of this rulemaking; please see section 15.1 of the EPA response in this *Response to Comments* document for additional discussion on comments outside the scope of this NPDWR.

Aquarion Water Company (Doc. #1617, SBC-043374)

Much of this cost will be borne ratepayers, who are also facing increased water rates to address other important needs, such as replacing lead service lines and upgrading/replacing aging infrastructure.

EPA Response: For additional discussion on cost considerations for the final MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The availability of BIL funding which can be used to support implementation of the final NPDWR (please see section 2.4 of the EPA response in this *Response to Comments* document for additional information). Lead service line replacements and upgrading aging infrastructure is beyond the scope of this rulemaking.

Central Valley Clean Water Association (CVCWA) (Doc. #1619, SBC-042938)

May 26, 2023

Via the Federal eRulemaking Portal

U.S. Environmental Protection Agency EPA Docket Center

Office of Ground Water and Drinking Water Docket Mail Code 2822IT

1200 Pennsylvania Avenue NW Washington, DC 20460 https://www.regulations.gov/

Re: Docket ID No. EPA–HQ–OW–2022–0114

Comment Letter — PFAS National Primary Drinking Water Regulation Rulemaking

To the U.S. EPA Office of Ground Water and Drinking Water:

The Central Valley Clean Water Association (CVCWA) appreciates this opportunity to submit comments on the PFAS National Primary Drinking Water Regulation Rulemaking and the proposed Maximum Contaminant Levels (MCLs) for PFAS that are included in the proposed rule. CVCWA is a nonprofit association of publicly-owned treatment works (POTWs) located throughout the Central Valley region, including the southern Delta, that provide wastewater collection, treatment, and water recycling services to millions of Central Valley residents and businesses. We approach these matters from the perspective of balancing environmental and economic interests consistent with state and federal law.

California's water quality planning process requires the development, adoption, and amendment of Statewide Water Quality Control Plans and Regional Water Quality Control Plans (Basin Plans) that contain water quality objectives to provide protection of the beneficial uses of California's waters. Regional Water Quality Control Boards implement Basin Plans by issuing and enforcing waste discharge requirements (WDRs), which also serve as National Pollutant Discharge Elimination System (NPDES) permits issued under federal delegation for discharges to surface water. Water quality objectives are used to set effluent limitations in NPDES permits.

State-adopted MCLs are automatically enforceable water quality objectives in Basin Plans. Federal MCLs are likely to establish the floor for California MCLs for PFAS and are likely to be incorporated as enforceable numeric water quality objectives in a Basin Plan at some point. CVCWA has evaluated the estimated impact of the U.S. EPA's proposed MCLs for PFAS and has determined that significant wastewater costs (both financial and environmental) are likely to

occur when the proposed MCLs are adopted and incorporated as effluent limits in NPDES permits for PFAS.

California POTWs have worked to comply with numerous water quality regulations that are established to ensure that beneficial uses of our water resources are reasonably protected, as required under the California Water Code. To comply with these regulations, many POTWs in recent years have upgraded their treatment processes to tertiary levels of treatment (nitrification, denitrification, and filtration). To remove PFAS to meet the proposed MCL of 4 ppt and the proposed Hazard Index, most POTWs would need to again upgrade their treatment processes to include granular activated carbon, ion exchange or, more likely, reverse osmosis. Capital costs for reverse osmosis are estimated to be $4.0 billion dollars for all the NPDES- permitted POTWs needing to upgrade to meet new PFAS limitations in California's Central Valley. Annual operation and maintenance costs are estimated to be over $360 million for POTWs in the Central Valley. In addition to these financial costs, each treatment option will result in environmental and greenhouse gas impacts and should also be considered. Importantly, the Central Valley hosts a higher proportion of disadvantaged communities than the rest of California; these lower-income communities have limited resources to adapt to the expected economic and environmental burdens. CVCWA submits these comments to emphasize the critical need to ensure that environmental and human health benefits of U.S. EPA's proposed rule is commensurate with the financial and environmental (e.g., greenhouse gas emissions) impacts associated with new treatment facilities to meet new PFAS requirements.

As U.S. EPA prepares a proposed regulation implementing proposed MCLs for PFAS, we urge you to consider the direct or indirect financial and environmental costs for POTWs associated with complying with these regulations in the overall cost analysis for the proposed MCLs. If you have any questions, or if CVCWA can be of further assistance, please contact me at (530) 268-1338 or eofficer@cvcwa.org.

Sincerely,

Debbie Mackey Executive Officer

EPA Response: For additional discussion on cost considerations for the final MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The application of MCLs in non-drinking water programs (such as water quality criteria, NPDES, or CERCLA cleanups) is beyond the scope of this rulemaking; please see section 15.1 of the EPA response in this *Response to Comments* document for additional discussion on comments outside the scope of this NPDWR.

WaterPIO (Doc. #1624, SBC-043469)

For those of us who have worked in water for years, it's become painfully obvious that, because the EPA cannot achieve a variety of PFAS-related actions on the private polluters, it is consciously choosing to punish public water systems. The EPA cannot directly hand down

punitive actions against the private corporations that have polluted our waterways, in part of the loose regulations the EPA themselves helped set and in part because the large companies are backed by unlimited lobbying and legal resources. That's why the EPA is choosing to attack public water systems; they're the low-hanging fruit that doesn't have the staffs or the bankrolls to fight back against the EPA.

The case can also be made the EPA's goal isn't solely focused on cleaning up the nation's drinking water to safe levels because the MCLs and HI do not clearly follow PFAS-related science, as discovered by several states who have taken the time and money over the years to set their own drinking water standards. Instead, we believe the EPA is trying to create a groundswell of support for punitive actions against private polluters by slapping drinking water violations on thousands of public water systems that don't have any role in producing or illegally discharging PFAS into the nation's source waters. The systems are also not responsible for creating the millions of PFAS-laden products Americans use every day that make their way into our wastewater systems.

It must be said clearly and loudly. Not one public water system is responsible for putting PFAS in its drinking water or wastewater effluent. Not one. Yet the proposed MCLs and Hazard Index treat public water systems as if they are the polluters of the nation's source waters.

While a more-detailed public comment about the future of wastewater regulations is for another day, moves by the EPA also reveal the effort to punish public servants instead of polluters. If public wastewater service providers aren't provided exemptions under CERCLA during the drafting of new legislation, enterprising law firms will look to them as the first people to sue. After all, through the simple act of discharging effluent containing PFAS into a waterway, every wastewater system will technically become a polluter.

Again, since public water and wastewater systems won't have the legal teams and resources to fight back that the polluting corporations have, they will be the easy, first target of law firms all over the country. Public water systems will be forced to write settlement checks versus taking their cases to court because, without exemptions, they are almost guaranteed to lose in front of a judge or jury.

The total cost of these checks will likely be in the billions of dollars nationwide and public trust in their work will be devastated. After all, the settlements will make news and the dollar figures will be waved around as proof the wastewater utilities are polluters putting public health at risk. WaterPIO has sat on panels with EPA Region Administrators and lawyers from top firms and stated this as fact. No one on those panels disagreed, not in any way; we were even applauded for saying "the quiet part" out loud.

Add this potential reality to the price tags for drinking water compliance and the cost to the American consumer for basic water and wastewater services will exponentially jump to what, for many, will be unaffordable amounts.

EPA Response: For additional discussion on cost considerations for the final MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA notes that application of MCLs in non-drinking water programs (such as water quality criteria, NPDES, or CERCLA cleanups) is beyond the scope of this rulemaking; please see section 15.1 of the EPA response in this *Response to Comments* document or additional discussion on comments outside the scope of this NPDWR. The PFAS NPDWR is not designed to "punish" PWSs. Rather, it has been finalized to improve public health protection, consistent with the mandates and requirements of SDWA. See section III (final regulatory determinations) and IV (maximum contaminant level goals) of the preamble for this action for more information; see also section V for more information about the final rule's MCLs.

Citizens Against Ruining the Environment (CARE) (Doc. #1638, SBC-043450)

CARE Comment 4 - CARE Urges EPA to Regulate PFAS as a Class in Order to Address PFAS Contamination on a Broad Scale to Most Efficiently Protect Americans' Drinking Water

According to EPA's toxicity database, there are over 14,700 unique PFAS compounds as of August 2022. [FN52: PFAS|EPA: PFAS structures in DSSTox (update August 2022), EPA,

https://comptox.epa.gov/dashboard/chemical-lists/PFASSTRUCTV5.] EPA's proposed NPDWR only covers 6 of those chemicals. That is 0.04% of known PFAS. CARE is deeply concerned that regulating the thousands of PFAS chemicals on a case-by-case basis will take extraordinary time, effort, and resources. The time and energy wasted on EPA's current approach would likely lead to avoidable negative health effects for thousands of Americans and add burdensome and avoidable administrative costs in enacting such a multitude of individual regulations.

Furthermore, it was once believed that short-chain alternatives to long-chain, legacy PFAS were safe. [FN53: Anna Reade, PhD, The Scientific Basis for Managing PFAS as a Chemical Class, NRDC, (June 30, 2020) https://www.nrdc.org/bio/anna-reade/scientific-basis-managing-pfas-chemical-class.] Two of those short-chain alternatives include GenX Chemicals and PFBS, the very same compounds EPA holds are too dangerous at certain levels to be in our water in the current NPDWR proposal. As more and more research is conducted on PFAS, the more dangerous health effects and harms to our environment we find out. That is why sixteen PFAS experts recently published an article advocating for a robust and comprehensive classwide ban of PFAS. [FN54: Carol F. Kwiatkowski, David Q. Andrews, Linda S. Birnbaum, Thomas A. Bruton, Jamie C. DeWitt, Detlef R. U. Knappe, Maricel V. Maffini, Mark F. Miller, Katherine E. Pelch, Anna Reade, Anna Soehl, Xenia Trier, Marta Venier, Charlotte C. Wagner, Zhanyun Wang, and Arlene Blum, Environmental Science & Technology Letters 2020 7 (8), 532-543, https://pubs.acs.org/doi/10.1021/acs.estlett.0c00255.] These experts recommend eliminating the use of all PFAS save for chemicals considered essential and without safer alternatives. [FN55: Id.] They stress that "the high persistence, accumulation potential, and/or hazards (known and potential) of PFAS studied to date warrant treating all PFAS as a single class."

EPA Response: For additional discussion on alternative regulatory standards (including regulation of PFAS as an entire class), please see section 5.1.3 of the EPA response in this *Response to Comments* document.

National Chicken Council (NCC) (Doc. #1649, SBC-043217)

NCC supports efforts to protect the public health by ensuring Americans have access to safe drinking water. Water is critical to broiler chicken production and processing, and NCC member companies take great care to ensure the water they use is safe and that they return it to the environment clean. NCC also supports tailoring regulations carefully to minimize unintended consequences and unnecessary economic and nutritional impacts. We urge the Agency to consider the impact the proposed rule would have on chicken processors and other food manufacturing operations. In particular, United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) regulations require that processing plant water supplies meet National Drinking Water Standards. These standards set by EPA for drinking water will also affect all the nation's meat and chicken processors' ability to operate and could potentially affect food availability as well as the livelihoods of rural communities across the country.

It is important that the standards set do not inadvertently affect chicken processing plants or limit water availability for food processing, especially if, as NCC understands, the proposed standards are not based on food safety considerations. We believe that the proposed rule, as written, could negatively impact the ability for chicken producers to operate and put unnecessary strain on the food supply. As a result, should EPA proceed with this rulemaking, we urge the Agency to make the following changes to its proposal and to its process for this rulemaking:

1. EPA should work with its regulatory partners at FSIS to ensure EPA understands how EPA drinking water standards interact with FSIS regulations and, in turn, how changes to drinking water standards would impact chicken producers; develop a strategy to implement any new standards without disrupting the national food supply; and understand what, if any, food safety risks are posed by using water outside of the standards in the proposed rule in chicken processing.

2. EPA should structure any PFAS standards to apply only to water actually used for direct human consumption and not to water used in food production or other uses.

In support of these requests, we offer the following comments:

• The proposed rule directly impacts regulations governing chicken production and other food industries and has unintended consequences which would harm the chicken industry and U.S. food supply. Under FSIS regulations, 9 CFR 416.2(g), meat, poultry, and egg products establishments must have a supply of drinking water that complies with the National Drinking Water standards in 40 CFR 141. Chicken processing establishments must provide, upon request, a water report attesting to the "potability" of the water used in chicken processing.1 [FN1: 9 C.F.R. § 416.2(g)(1); see also USDA, "Public Q&A: Potable Water Certification,"

https://ask.usda.gov/s/article/What-documents-can-be-used-to-demonstrate-that-the-water-used-inthe-establishment-is-potable-fit-for-human-consumption.] Under the proposed rule, if a water source does not meet the proposed PFAS standards it would not comply with 40 CFR Part 141, and as a result, a chicken processing facility using that water source would not be able to satisfy its requirements under 9 CFR 416.2. Critically, whereas public drinking water sources may continue operating while implementing mitigation technologies – a process that can take years – and the water will remain available for drinking in the meantime, having a 40 C.F.R. Part 141-compliant water supply is a prerequisite for chicken processing establishment to operate. FSIS has numerous tools at its disposal to address regulatory noncompliances, including withdrawing inspection, which prevents a plant from operating. The proposed standard would place chicken processing establishments in an extremely precarious position, rendering them completely beholden to municipal water supplies' decisions on whether and how quickly to remediate any violations. Establishments supplied by well water face the same requirement and are equally at risk of having their fates decided by factors outside their control. It would be too much to place the burden entirely on FSIS to decide how to respond in each instance. This scenario will have major implications for the chicken industry and the U.S. food supply, and EPA should provide the necessary guidance to ensure that any National Drinking Standards do not undermine chicken processing operations and food manufacturing in general.

• It has not been determined that water with PFAS levels above the proposed threshold presents a food safety risk when used in food manufacturing. Before applying the proposed rule to chicken processing and food manufacturing, it should be determined if water with PFAS levels above the proposed threshold presents an actual food safety risk. FSIS has tested for PFAS substances in food products in the past and determined that the levels found did not present a consumer safety risk. The testing would have reflected any background levels of PFAS contributed by the facility's water supply. Given the potential disruption the proposed rule presents to the chicken industry, a robust and science-based risk assessment should be completed to fully understand whether a regulation like the proposed standard is needed to protect consumers from a legitimate food safety risk.

• Funding should be available for both city water facilities and chicken processing facilities whose water supplies are regulated by the proposed rule. The Agency discussed at both the technical meeting and the digital public hearing that state and local municipalities will have access to funding from infrastructure spending to help address needed improvements to water facilities. $1 billion in grant funding will be made available through the Infrastructure Law and an additional $5 billion through the Small or Disadvantaged Communities Grant Program, in addition to the $3.4 billion provided through the Drinking Water State Revolving Funds (SRFs) and $3.2 billion through the Clean Water SRFs. If they are affected by the proposed standard, either directly or indirectly through FSIS regulations incorporating the National Drinking Water Standards, food processing facilities should be able to access these funds to help expedite the implementation of improvements that will help ensure they have an available source of compliant water.

• NCC believes that the proposed rule will have significant economic impact on the chicken processing and food industries not fully captured by the Agency's analysis. Based on internal calculations, the costs of the proposed rule on the chicken industry would be significant. NCC estimates that PFAS water testing would cost about $1,200 per sample without considering the cost of the labor to collect the samples, the shipping of the samples, and analyzing the test results. To maintain compliance, around 112 samples are expected to be required annually per water source, meaning the testing of a single water source in a facility would cost approximately $134,000 annually. With some facilities using up to four different water sources, this cost will be significant. Laboratory capacity to handle the significant increase in testing demands simply do not exist today.

Moreover, EPA would need to consider the catastrophic effects that would follow if a chicken processing facility were shut down, temporarily or indefinitely, because it could not obtain a Part 141-compliant water source. Chicken processing facilities are expensive, capital-intensive operations. They take years to permit and build, and they are often the leading economic driver in their rural communities. Many chicken processing facilities produce millions of pounds of chicken each day. If a single chicken processing establishment's water source were to fail the proposal standard and the plant was not allowed to operate, it could negatively affect the chicken supply. Thousands of rural jobs could be lost, and the community would be unlikely to have enough jobs to reemploy those workers. Moreover, chicken processing facilities are supported by an extensive network of family farmers who raise the chickens to be processed, and those farms must be located within a reasonably close distance to the processing facility. The hundreds of family farms in that facility's live production network would lose a steady income source, and many of those farmers could go bankrupt. The lost output would significantly affect the nation's food supply, driving up protein costs and decreasing supply, placing economic and nutritional stress on American families on the on the federal and state nutrition assistance programs that rely heavily on affordable chicken to provide healthy meals.

NCC appreciates the ability to provide comments on such an important proposed rule. In consideration of the above comments, NCC asks that the Agency (1) extend the comment period for an additional 90-days, (2) engage with FSIS to ensure no unintended consequences result from the promulgation of this rule, and (3) if the proposed rule is finalized, the final rule should include an exemption for water used in food processing. These requests will help ensure that the Agency does not inadvertently undermine the food supply, food security, and the food industry while pursuing its goals for public drinking water.

Respectfully submitted,

Ashley B. Peterson, Ph.D.

Senior Vice President, Scientific and Regulatory Affairs

National Chicken Council

EPA Response: For additional discussion on cost considerations for the final MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The PFAS NPDWR regulate PWSs, defined as a system that provides water for human consumption to 15 or more connections or regularly serves 25 or more people daily for at least 60 days out of the year. The application of MCLs in non-drinking water programs is beyond the scope of this rulemaking; please see section 15.1 for additional discussion on comments outside the scope of this NPDWR. The EPA notes that the "the proposed standards are not based on food safety considerations" because this action does not regulate food or food safety, nor are there requirements under SDWA that the EPA should consider food safety for establishment of NPDWRs. Food and Food Safety are generally regulated by the FDA and/or the Department of Agriculture. The EPA further notes that the commenter presents a monitoring structure and associated costs that are not driven by this rulemaking. The EPA clarifies only regulated PWSs are required to monitor for the regulated PFAS in compliance with the rule. The commenter's contention that $1,200 per sample is high; the laboratory analysis per sample for the EPA method 537.1 (one of the validated methods to meet the monitoring requirements of the rule) is $309 (Method 537.1 version 2.0). See discussion in sections 8 and 13.3.4 of the EPA response in this *Response to Comments* document about the rule's mandated monitoring requirements and analytical costs, respectively. See section 17 of the EPA response in this *Response to Comments* document in regard to the request for extending the public comment period. In regard to the requested exemption for "an exemption for water used in food processing", as discussed above, this regulation directly applies to PWSs, and specifically a CWS or NTNCWS. If a food processing facility is considered a CWS or NTNCWS, then this regulation applies. If it is not, then the potential future application of other limits, including MCLs, to these systems by other regulatory agencies is beyond the scope of this rulemaking. See also the EPA response to comment Doc. #1839, SBC-046048 and Doc. #1839, SBC-047721 in section 5.1.3 in this *Response to Comments* document.

Horsham Water & Sewer Authority (HWSA) (Doc. #1686, SBC-043812)

Based on our experiences, there are a few other cases where EPA does not appear to fully appreciate the degree of impact the issues have on actual operating costs, and therefore are not adequately estimating costs appropriately. The first instance is regarding Simultaneous Compliance issues, in particular with the Lead & Copper Rule. Our state primacy agency, the Pennsylvania Department of Environmental Protection (PADEP) interpreted the Lead & Copper Rule to mandate that we had to be removed from reduced monitoring and returned to Initial Monitoring under the rule due to the installation of GAC. Having been on reduced monitoring (30 homes triennially) for years, we did not have 60 homes from our original approved sampling site list still available to us as many of the original customers have since moved. We therefore had to initiate a mass letter campaign to potentially eligible homes and then enter customer homes to sample and confirm the presence of lead solder during a pandemic. This put both our customers and our employees at risk, but we complied, nonetheless. Not surprisingly, there was no change in our 90th percentile lead and copper values. While the pandemic is over, the costs

and time of reestablishing a full Lead & Copper Rule sampling site list after being on reduced monitoring for years by canvassing customers, performing confirmation testing in homes, and then conducting two full sampling events are not inconsequential even in normal times and should not be overlooked.

EPA Response: For additional discussion on cost considerations when setting the MCL, please see section 5.1.3 of the EPA response in this *Response to Comments* document. Regarding responses on "simultaneous compliance challenges," please see section 12.1 of the EPA response in this *Response to Comments* document.

Citizens Campaign for the Environment (CCE) (Doc. #1710, SBC-045133)

The cost difference between treating a contaminant to the MCL and the MCLG can be significant, and when polluters can be identified, they should pay for the full cost to treat to levels where no known health effects are present.

EPA Response: For additional discussion on cost considerations when setting the MCL, please see section 5.1.3 of the EPA response in this *Response to Comments* document. MCLGs are public health goals and are not enforceable standards.

PFAS Regulatory Coalition (Doc. #1761, SBC-046088)

2. EPA should consider increased costs for remediation.

Under Section 121(d) of CERCLA, Superfund remedies must achieve MCLGs when remediating impacted groundwater and other drinking water sources. CERCLA 121(d)(2)(A). Further, once promulgated the MCLs would become applicable or relevant and appropriate requirements (ARARs) that Superfund remedies must attain. Id. No separate rulemaking or other process is needed. Therefore, it is this Proposal that would result in increased costs at Superfund sites, and EPA must consider those costs in this rulemaking.

The Department of Defense (DOD) PFAS remediation estimates demonstrate how significant these costs can be. As of July 2022, DOD summarized its PFAS remediation costs as follows: "Through September 30, 2021, DOD has obligated $1.46 billion to investigate and clean up PFAS. DOD anticipates obligating $409.4 million in FY 2022 and an additional $2.12 billion after FY 2022 to continue these efforts." Per- and Polyfluoroalkyl Substances (PFAS) Cleanup: Schedule, Status, and Cost Estimates, DOD Office of the Under Secretary of Defense for Acquisition and Sustainment (July 2022). DOD does not separate these costs by media, but assuming that even just half of these costs are for water/groundwater remediation leads to costs in the billions of dollars.

Further, this EPA action is likely to stimulate the adoption of PFAS cleanup standards under state law. OMB circular A-4 requires consideration of the costs of such additional state regulation as well as direct federal regulation. Circular A-4, at 6. EPA needs to address those costs for all parties anticipated to incur remediation costs. As noted elsewhere in these

comments, available estimates indicate that these new cleanup costs will amount to billions of dollars.

EPA Response: For additional discussion on cost considerations when setting the MCL, please see section 5.1.3 of the EPA response in this *Response to Comments* document. As required by SDWA, this rulemaking and analyses supporting the rulemaking only includes costs that "are likely to occur solely as a result of compliance with the [MCL]." Thus, the EPA's cost analyses focused on the compliance costs of meeting the MCL to PWSs that are directly subject to this regulation. The same provision expressly directs the EPA to exclude "costs resulting from compliance with other proposed or promulgated regulations." Thus, the EPA cannot consider the costs of use of the MCLs under other EPA statutes (such as CERCLA) as part of its EA because SDWA specifically excludes such consideration (42 U.S.C. § 300g-1(b)(3)(C)(i)(III)). See also City of Waukesha v. EPA, 320 F.3d 228, 243-244 (D.C. Cir. 2003) (finding that SDWA excludes consideration of the costs of, for example, CERCLA compliance, as part of the required cost/benefit analysis). For further discussion about CERCLA clean-up costs and benefits, please also see section 5.1.3 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1631, SBC-043434 in section 5.1.3 in this *Response to Comments* document.

Groundwater Resources Association of California (Doc. #1831, SBC-045353)

Second, National Pollutant Discharge Elimination System (NPDES) discharge sampling/reporting compliance will add costs to groundwater operations (e.g. new well construction) but will also

protect water bodies/aquifers from PFAS contamination. Third, the proposed MCLs will likely impact groundwater recharge operations and management decisions. For example, primary and even secondary MCLs are regularly adopted as thresholds for antidegradation analysis in groundwater systems or used as thresholds to assign assimilative capacity in groundwater. The addition of new MCLs for PFAS may impact past, current, and future investments in groundwater recharge and storage infrastructure, particularly where recycled water sources are used to recharge groundwater. If the proposed MCLs are adopted, they will likely be used to set new water quality objectives for PFAS in groundwater basins with subsequent restrictions on and additional costs for groundwater recharge of water containing PFAS in excess of the proposed MCLs. If MCLs are adopted as water quality objectives for groundwater, groundwater recharge projects may require treatment prior to recharge, increasing costs for groundwater recharge projects. Part of the cost-benefit analysis included inadvertent avoidance of disinfection byproducts (DBPs) due to anticipated changes in treatment type (e.g., decrease or discontinuation of chlorination and/or additional removal of organic matter). This benefit is not realized if MCLs are applied as water quality objectives in groundwater basins.

EPA Response: For additional discussion on cost considerations for the final MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA

notes that application of MCLs in non-drinking water programs (such as water quality criteria, NPDES, or CERCLA cleanups) is beyond the scope of this rulemaking; please see section 15.1 of the EPA response in this *Response to Comments* document for additional discussion on comments outside the scope of this NPDWR.

Citizens Energy Group (Doc. #1838, SBC-044853)

May 30, 2023

Via Electronic Submittal (www.regulations.gov)

U.S. Environmental Protection Agency

EPA Docket Center

Office of Ground Water and Drinking Water Docket

Mail Code 2822IT

1200 Pennsylvania Avenue NW

Washington, DC 20460

RE: PFAS National Primary Drinking Water Regulation Rulemaking Preliminary Regulatory Determination and Proposed Rule Docket Number EPA-HQ-OW-2022-0114

Dear Sir or Madam:

Citizens Energy Group ("Citizens") appreciates the opportunity to submit the following comments on the March 29, 2023, PFAS National Primary Drinking Water Regulation proposed rule, 88 Fed. Reg. 18,638. Citizens proudly serves safe and reliable drinking water to over 915,000 Hoosiers in Central Indiana and supports EPA's goal to protect public health through regulations under the Safe Drinking Water Act. Citizens offers these comments to share its perspectives and experiences as a regulated community water system.

In August 2011, Citizens acquired the assets of the drinking water system in the City of Indianapolis, Indiana and in March 2014, the assets of the drinking water system in Westfield, Indiana, and the assets of Southern Madison Utilities in 2013. Citizens' water systems reflect the mix of community water systems that will be regulated under this proposed rule, from the very small (Citizens South Madison, serving a population estimated at 65) to the very large (Citizens Water Indianapolis, serving a population estimated at 862,000).

Citizens' source of supply for its drinking water utilities is a combination of both groundwater and surface water. A network of over 100 groundwater wells provides approximately 30% of the annual finished water delivered to our customers while approximately 70% of the supply is derived from surface water sources. Surface water sources include: the White River, supplemented by Morse Reservoir; Fall Creek, supplemented by Geist Reservoir and Citizens Reservoir; and Eagle Creek Reservoir. The watershed is a mix of both agricultural and

urban/suburban development; surface waters receive the complex mix of point-source discharges from industrial facilities, stormwater discharges from MS4 systems and sheet flow runoff, and combined sewer overflows from communities upstream of the intakes on surface water.

Like many public water systems, Citizens participated in the assessment of PFAS in finished water through UCMR 3. More recently, however, Citizens has received more insight into the ubiquitous presence of PFAS in the environment through a PFAS-sampling program funded by the Indiana Department of Environmental Management ("IDEM"). Citizens has sampled the majority of its drinking water wells, the raw water intakes at four (4) surface water treatment plants and one hundred nineteen (119) groundwater wells, and a combined fourteen (14) entry points to the distribution system. In addition, Citizen has begun sampling in its water systems as required by UCMR 5.

Analytical results of samples collected under the IDEM-funded PFAS sampling program indicate low level detections of PFAS compounds, including PFBS and PFHxS, in the source of supply to our treatment plants. While Citizens understands the overarching goal of EPA's PFAS Strategic Roadmap to remedy the environmental impacts associated with the ubiquitous presence of PFAS in the environment, like other drinking water and clean water utilities, Citizens is concerned with the longer-term impacts of PFAS regulations on its operations. To that end, Citizens encourages EPA to continue to pursue a "polluter pays" model for remedying PFAS impacts on the environment, rather than shifting the financial burden to drinking water and clean water utility ratepayers.

In addition to the comments offered below, unless otherwise noted, Citizens endorses comments on this proposed rule submitted by the National Association of Clean Water Agencies ("NACWA") and the American Water Works Association ("AWWA").

EPA Response: For additional discussion on cost considerations for the final MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document. Assigning liability for PFAS pollution is beyond the scope of this rulemaking (please see section 15.1 of the EPA response in this *Response to Comments* document for additional discussion).

North American Meat Institute (Doc. #1839, SBC-046048)

May 30, 2023

Michael S. Regan, Administrator

Environmental Protection Agency

1200 Pennsylvania Avenue, N.W.

Washington, D.C. 20460

Re: Docket No. EPA-HG-OW-2022-0114; "PFAS National Primary Drinking Water Regulation Rulemaking."

Dear Mr. Administrator:

The North American Meat Institute (NAMI or the Meat Institute) appreciates the opportunity to submit these comments regarding the Environmental Protection Agency's (EPA or Agency) Preliminary regulatory determination and proposed rule; request for public comment; and notice of public hearing regarding "PFAS National Primary Drinking Water Standard," EPA-HG- OW-2022-0114, RIN 2040-AG18, 88 Fed. Reg. 18638 (March 29, 2023) ("Proposed Rule" or "PFAS Standard").

The Meat Institute is the United States' oldest and largest trade association representing packers and processors of beef, pork, lamb, veal, poultry, and processed meat products. The Meat Institute has 330 general members, operating more than 800 facilities subject to daily federal inspection by the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS). Some of our members also operate facilities that are subject to oversight by the Food and Drug Administration (FDA). Our members include not only the largest meat and poultry processors in the United States, but also many small businesses. In fact, more than half of our members have fewer than 100 employees. NAMI also has 200 supplier members, which provide a broad range of products and services ranging from large processing equipment to laboratory testing for food safety to packaging, all to help ensure Americans enjoy a safe and abundant supply of meat and poultry products. The U.S. meat and poultry processing industry produces nutrient-dense foods that play a unique role in healthy diets and are driving solutions for the environment, farmers' livelihoods, animal care, and more.

NAMI and our members have been, and continue to be, progressive in striving to protect the environment we operate and live in. NAMI and our partners in the Protein PACT for the People, Animals & Climate of Tomorrow are committed to accelerating progress and building momentum for public commitments in each of five focus areas: the environment, animal care, food safety, nutrition, and our workforce. Protein PACT is a commitment to continuous improvement toward a common set of ambitious goals across the industry. It empowers the animal protein industry to proactively meet the needs of its customers and consumers by accelerating continuous improvement across animal agriculture, transparently verifying progress toward ambitious targets, and proactively communicating that progress. Protein PACT unites partners committed to sustaining healthy people, healthy animals, healthy communities, and a healthy environment.

To achieve its Protein PACT targets, the Meat Institute pioneered creating a sector-wide dataset and published in October 2022 the first-ever data report measuring baselines and providing a snapshot of achievements to date. In its first year, the Meat Institute's data collection effort covered an estimated 90% (by volume) of meat sold in the United States. By 2030, 100% of Meat Institute members will report on all metrics.

Our member companies rely on clean water for slaughter and processing. NAMI and our members support reasonable regulation of substances that have potential human health impacts. However, we have significant concerns about the PFAS Standard. As detailed herein, we believe

the PFAS Standard may have unintended consequences that threaten the nation's food supply as certain regulations applicable to the food industry incorporate by reference the National Drinking Water Standard ("NDWS"). We are concerned that EPA has failed to engage other agencies to assess the potential impacts of the Proposed Rule and we are concerned that EPA's cost estimates do not adequately capture the impact of the Proposed Rule because they do not factor in costs created by unintended consequences. Finally, we share in the concerns expressed more fully in comments like those submitted by the U.S. Chamber of Commerce such as, but not limited to, the processed used to develop the PFAS Standard and adherence to statutory requirements, the scientific validity of the standard, the Agency's cost benefit analysis, and the state of potential monitoring and compliance options. We fully support all of the comments submitted by the U.S. Chamber of Commerce and incorporate them by reference into our comments. All of these concerns occur against the backdrop of a nation that is only beginning to recover from a period of historic inflation of all goods, including food, and at a time when we face raising interest rates and tremendous economic uncertainty.

EPA's Rulemaking:

On March 29, 2023, EPA published in the Federal Register a National Primary Drinking Water Regulation (NPDWR) to establish for the first time Maximum Contaminant Levels (MCL's) for six PFAS chemicals in drinking water [FN1: Per- and Polyfluoroalkyl Substances (PFAS) chemicals are a group of manufactured chemicals that have been used in industry and consumer products since the 1940s. They are useful in a variety of products, including nonstick cookware, waterproof clothing, and firefighting foam. EPA has found that they break down slowly in the environment and have the potential to accumulate over time. Many PFAS chemicals have been largely phased out due to health and environmental concerns, but EPA has determined that they may still be found in the environment and may make their way into drinking water.]. The six PFAS chemicals include perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO-DA, commonly known as GenX Chemicals), perfluorohexane sulfonic acid (PFHxS), and perfluorobutane sulfonic acid (PFBS). EPA is also proposing "health-based, non enforceable Maximum Contaminant Level Goals (MCLGs) for these six PFAS. EPA has stated that it anticipates finalizing the regulation by the end of 2023.

EPA's own description from its website at epa.gov regarding open questions the Agency has as it continues to push forward with this extremely costly, burdensome and complex rule is telling:

[Figure 1: see docket ID EPA-HQ-OQ-2022-0114-1839]

In addition to the five areas that EPA acknowledges that it does not "fully understand," we suggest there are at least three additional questions the Agency does not fully understand: (1) the interplay of the Proposed Rule with other federal regulatory standards; (2) the extreme shock that could result to the Nation's food supply because of impacts on regulations governing the food industry; and, (3) what the path forward is to coordinate with other Agencies to make sure the Proposed Rule does not result in these unintended consequences.

EPA's overview of the MCL for each of the PFAS, as presented in the Agency's March 29, 2023 Technical Overview Presentation regarding the Proposed Rule, is as follows:

[Figure 2: see docket ID EPA-HQ-OQ-2022-0114-1839]

The Proposed Rule will require public water systems [FN2: A public water system provides water for human consumption to at least 15 connections or serves an average of at least 25 people for at least 60 days a year.] to monitor for PFAS against the extremely low and barely testable level of 4 parts per trillion [FN3: In arriving at 4 ppt, EPA used Practical Quantitation Levels, which are the lowest concentration of a contaminant that can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions. EPA acknowledges that the Proposed Rule trigger levels are set at levels that are so low they are useful in determining whether the contaminant is present in a sample, but not to determine its specific concentration.], notify the public of the levels of these PFAS, and reduce the levels of the PFAS if they exceed the proposed standards. EPA has noted that PFAS can enter drinking water in numerous ways, including discharges to rivers and lakes from manufacturing and processing facilities, industrial and commercial use, or simple proximity to industrial sites, airports, military installations, and other sites where PFAS have been produced or used. EPA expects roughly 66,000 water systems to be subject to the rule, and expects approximately 3,400 - 6,300 systems to be in exceedance of one or more MCL. EPA's estimates are that the Annualized Quantified Rule Costs for public water treatment systems could be $1.2 billion at a 7% discount rate [FN4: EPA assessed costs as the expenses incurred by public water systems to monitor for the six PFAS, install and operate treatment technologies, inform consumers, and perform record-keeping and reporting responsibilities. Notably absent from the cost calculations are any attempt to quantify indirect costs to industries who may be impacted by regulations that tie their water standards to the National Primary Drinking Water Standard.]. In addition, if EPA ultimately determines that water systems must dispose of PFAS treatment as hazardous waste, EPA believes annual costs would increase by $30- $61 million per year.

Initial monitoring under the Proposed Rule must be completed in the three years between the rule promulgation date (currently expected to be the end of 2023) and the rule effective date (anticipated by the end of 2026). Initial monitoring requirements for public water systems include any combination of two or four samples collected at the system over one year, dependent on system population size and system type, or the use of recent, previously acquired PFAS drinking water data from the fifth Unregulated Contaminant Monitoring Rule, state-level drinking water occurrence monitoring, or an "other appropriate data collection program." EPA states that the initial monitoring results will determine the ongoing compliance monitoring requirements. Those requirements include quarterly monitoring as the normal frequency for all sampling locations and reduced monitoring flexibility to once or twice every three years for sampling locations where the result is below 1/3 of the MCLs. A system will be deemed in violation if monitoring results based on running annual averages exceed one of the MCLs.

If a system exceeds the MCL for one of the substances, EPA proposes that the system be required to issue public notification to consumers. The notification will be classified as a Tier 2

notification, which would require notice as soon as possible, but within 30 days of the violation. Community water systems will be required to include PFAS information in the Consumer Confidence Report distribution to customers, including the level of the regulated PFAS that is measured in their drinking water and the potential health effects of the regulated PFAS detected. Water systems with regulated PFAS above the MCLs will be required to install treatment or take other action to reduce regulated PFAS in their drinking water. EPA states that "the rule would allow water systems the flexibility to determine the best actions and approaches to their specific situation." EPA has identified granular activated carbon, anion exchange, and nanofiltration and reverse osmosis as the best available technologies, and has also noted that some water systems may be able to reduce PFAS levels without installing treatment by using an alternative source of water.

EPA Response: Please see the EPA response to comment Doc. #1839, SBC-047721 and Doc. #1649, SBC-043217 in section 5.1.3 in this *Response to Comments* document. In regard to treatment, please see section 10 of the EPA response in this *Response to Comments* document.

Regarding Figure 1 of this comment letter, which displays only a portion of the EPA's webpage "PFAS explained," the EPA is committed to providing meaningful, understandable, and actionable information on per- and polyfluoroalkyl substances – known as PFAS – to the American public. The information provided on this webpage is intended to explain some of the important background information needed to understand the details of specific actions the EPA takes to address PFAS, and not intended to relay all information pertinent to a specific rulemaking such as the NPDWR. As detailed extensively in the proposed and final rulemaking record, the EPA used the best available, peer-reviewed science related to the regulated PFAS in this action to support the regulatory determinations and the final rule, including MCLGs and feasible MCLs. See section 5.1.3 of the EPA response in this *Response to Comments* document for more information.

Regarding the commenter's three additional questions they contend the agency doesn't fully understand; the EPA disagrees with the commenter's statement that the agency has not considered the connections between this rulemaking and other federal regulatory standards and "[n]otably absent from the cost calculations are any attempt to quantify "indirect costs to industries who may be impacted by regulations that tie their water standards to the National Primary Drinking Water Standard." SDWA Section 1412(b)(3)(C)(III) states that the EPA shall consider "quantifiable and nonquantifiable costs. . . excluding costs resulting from compliance with other proposed or promulgated regulations." (emphasis added). Irrespective of the SDWA language, it is inappropriate for the EPA to consider costs to comply with other standards under a drinking water regulation, as these are separate agency actions and site-specific decisions (as applicable). Finally, the EPA notes that the agency does not estimate the costs or benefits of other agency actions. To assess these costs and benefits, the EPA would have to make assumptions about potential future, separate policy decisions under other statues. In short, these costs referred to by the commenter are beyond the scope of this regulation. Finally, the commenter asserts the agency does not fully understand "what the path forward is to coordinate

with other Agencies to make sure the Proposed Rule does not result in these unintended consequences." The EPA disagrees with this assertion, as the agency has worked with federal partners throughout the development of this regulation, including, most notably the federal agencies that participated in the Executive Order (EO) 12866 review of both the proposed and final rule and had the opportunity to provide their input during those reviews.

North American Meat Institute (Doc. #1839, SBC-047721)

Notwithstanding the huge economic impact of the Proposed Rule and its highly technical nature, EPA has allowed only a 60-day public comment period. On May 11, 2023, NAMI requested a 90-day extension of the comment period. We pointed out that the proposal raises numerous questions and seeks input on an array of complicated topics of interest to the meat industry and the food industry more generally. Given the interrelationship and potential impact of EPA's regulations with those of other federal, state and local agencies, NAMI requested additional time to allow ourselves and other stakeholders to comment effectively and in a constructive manner on this topic. Numerous other stakeholders have also requested extensions. NAMI's request for an extension was denied the next day, on May 12, 2023.

The Proposed Rule's Potential Unintended Consequences on the Meat and Poultry Industry and Related Concerns with the Agency's Cost Analysis.

Regulations Applicable to the Meat, Poultry and other Food Industries May be Impacted by the Proposed Rule

Meat [FN5: "Meat food product" means any product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats, excepting products which contain meat or other portions of such carcasses only in a relatively small proportion or historically have not been considered by consumers as products of the meat food industry, and which are exempted from definition as a meat food product by the Secretary under such conditions as he may prescribe to assure that the meat or other portions of such carcasses contained in such product are not adulterated and that such products are not represented as meat food products. This term as applied to food products of equines shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats. 21 U.S.C. § 601.] and poultry [FN6: Poultry is defined as any domesticated bird, whether live or dead. "Poultry product" means any poultry carcass, or part thereof; or any product which is made wholly or in part from any poultry carcass or part thereof, excepting products which contain poultry ingredients only in a relatively small proportion or historically have not been considered by consumers as products of the poultry food industry, and which are exempted by the Secretary from definition as a poultry product under such conditions as the Secretary may prescribe to assure that the poultry ingredients in such products are not adulterated and that such products are not represented as poultry products. 21 U.S.C. § 453.] establishments are subject to continuous inspection by FSIS under the authority granted to the Secretary of the U.S. Department of Agriculture (USDA) in the Federal Meat Inspection Act (FMIA) or the Poultry

Product Inspection Act (PPIA). FSIS is responsible for promulgating regulations to implement the FMIA and PPIA. One such regulation is 9 CFR 416.2, which sets standards for meat and poultry processing establishment grounds and facilities. Part 416.2(g) addresses water supply and water ice, and solution reuse and specifically requires:

(1) A supply of running water that complies with the National Primary Drinking Water regulations (40 CFR part 141), at a suitable temperature and under pressure as needed, must be provided in all areas where required (for processing product, for cleaning rooms and equipment, utensils, and packaging materials, for employee sanitary facilities, etc.). If an establishment uses a municipal water supply, it must make available to FSIS, upon request, a water report, issued under the authority of the State or local health agency, certifying or attesting to the potability of the water supply. If an establishment uses a private well for its water supply, it must make available to FSIS, upon request, documentation certifying the potability of the water supply that has been renewed at least semi-annually. (Emphasis added).

(6) Water that does not meet the use conditions of paragraphs (g)(1) through (g)(5) of this section may not be used in areas where edible product is handled or prepared or in any manner that would allow it to adulterate [FN7: The FMIA and PPIA define "adulterated" so as to include product that bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health. 21 U.S.C. § 453(g), 601(m). The Federal Food, Drug, and Cosmetic Act similarly provides that a food is "adulterated" if it bears or contains any "poisonous or deleterious substance" which may render it injurious to human health.] edible product or create insanitary conditions.

Regarding establishments that fall under the authority of the Food and Drug Administration, [FN8: FDA generally regulates product that does not fit the definition of meat, poultry and egg products regulated by USDA.] 21 CFR 117(a) states that “Any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality.” Though less prescriptive than FSIS regulations, it is common to demonstrate compliance by demonstrating water meets the NPDW standard.

The potential consequences on the food industry of the above-cited regulations are clear, given EPA's Proposed Rule and the new MCLs for certain PFAS chemicals. Meat and poultry establishments must have a supply of water that complies with the National Primary Drinking Water Standard. If the facility relies on water from a municipality exceeding the new PFAS MCLs, product from that facility could be deemed "adulterated" within the meaning of FSIS or FDA regulations. Once a food product is deemed adulterated, FSIS or FDA [FN9: State regulators typically have similar enforcement tools at their disposal to prevent the manufacture and distribution of "adulterated food."] have a broad array of enforcement tools, including: seizing and condemning the product; detaining imported product; enjoining persons from manufacturing or distributing the product; or requesting a recall of the product. FSIS has certain additional powers that are particularly relevant to much of the meat and poultry industry. FSIS

may suspend or withdraw federal inspection of an official establishment. Without federal inspection, an establishment may not produce or process meat or poultry products, and therefore must cease operations.

Simply put, the new PFAS MCLs could result in the destruction of food and the shuttering of a food manufacturing facility that is at the mercy of a municipal water supply that is out of compliance with the Proposed Rule. At a recent stakeholder meeting, FSIS stated there are no current plans to amend the regulations and establishments will need to ensure water meets the potable water standards set by EPA. NAMI and our members are concerned that EPA failed to adequately discuss the unintended consequences of the Proposed Rule with agencies, such as FSIS, that reference EPA standards.

It is also notable that while FSIS does not currently test water, but has tested meat and poultry products to understand whether there is a risk associated with these products for PFAS, with no findings of concern. FSIS has tested for 16 different compounds down to 0.5 ppb and is evaluating the feasibility of adding more compounds and increasing sensitivity, to align with fed partners, such as the Food and Drug Administration (FDA).

The result of this interplay between the regulatory regimes of EPA, USDA and FDA is striking -- both in its potential disruption to the nation's food supply, and in the illogical consequences it could create. As detailed earlier in these comments, there is no reason to suspect that EPA would immediately shut down a municipality's water supply on the basis of a sample that exceeds one of the MCLs. The Proposed Rule and EPA's various presentations on the topic archived at www.epa.gov make it clear that EPA will first require monitoring and public reporting, then if a water system has regulated PFAS above their proposed MCLs they will "be required to install treatment or take other action to reduce regulated PFAS levels in their drinking water and meet MCLs." EPA further states that the Proposed Rule "would allow water systems the flexibility to determine the best actions and approaches to their specific situation."

EPA at a minimum strongly implies they will work with municipalities and consider alternative actions and approaches to resolve exceedances. However, no such flexibility is expressly stated for food processing establishments that are at the mercy of public water systems for their supply of water. Moreover, EPA states that the Bipartisan Infrastructure Law provides $9 billion to invest in drinking water systems specifically affected by PFAS and other emerging contaminates and references the ability of states and communities to leverage an additional nearly $12 billion in BIL Drinking Water State Revolving Funds dedicated to making drinking water safer. Conspicuously absent is any reassurance that federal money will be available to food establishments impacted by the Proposed Rule. Some of our members treat and supply their own water for some of their plants, and when all shifts are factored in, that can add up to more than 20,000 employees using the water daily. This is a huge part of community exposure in those towns, larger than many municipal water supplies. Funds should be available to address that issue as well.

A simple example illustrates the absurd results potentially created by the interplay of the Proposed Rule and food safety regulations. A community that is home to a large meat processing plant could see that plant face repercussions as severe as FSIS pulling its federal grant of inspection and effectively shutting the plant down until either the municipality comes in compliance with the MCLs or the plant is able to source and install additional filtration in an amount sufficient to satisfy the food safety regulators that the plant had a potable water supply. That plant's employees, which could number in the thousands, would be unable to go to work. However, they would be able to drink the same tap water in their homes that caused the loss of their employment while EPA worked with the public water system to come within the MCLs. Their children could drink the same tap water in the public schools, but their school lunch program could be affected by the shock to the food supply system resulting from meat processing plants losing grants of inspection. Surely that is not the intended result of the Proposed Rule or of the FSIS and FDA regulations, but that is the reality of the black letter of the rules as currently written. We do not believe EPA adequately collaborated with other agencies to avoid such absurd results.

The Agency’s Cost Estimates are Inadequate Because They Do Not Account for Unintended Consequences.

As set forth earlier in these comments, EPA's cost estimates rest on financial costs that will be experienced by public water systems in meeting the PFAS Standard and disposing of treatment materials. NAMI believes the Agency has ignored indirect costs, which may ultimately be more significant that the direct costs to public water systems.

The study attached as Exhibit "1" from the Juday Group details some of the costs that could be borne by facilities in the food industry because of interruptions to operations or expenditures to bring incoming water into compliance with the PFAS Standard if FSIS or FDA imposed such a requirement. These costs could occur as: (1) lost revenue and sunk costs from potential temporary plant shut downs testing and compliance; (2) testing and compliance; and (3) capital outlays for new or upgraded water treatment systems. As background to this discussion, it is key to remember that these costs will not just be borne by large corporations. NAMI has members with fewer than 10 employees and whose operations can fit in a single large room. The impact of these costs could simply overwhelm a small business.

Consumer impacts are also a major concern. In addition to reduced availability of protein and higher prices at grocery stores and restaurants, the Proposed Rule could affect the operational viability of federal school nutrition programs and important federal contracts, such as those involving the Department of Defense. The Juday Group found that "without careful consideration in implementing these regulatory rules, the unintended consequences could result in a major economic disruption."

As discussed in more in the Juday Group study, the cost per day of a shutdown of a slaughter facility, varies depending on the animal involved, the size or type of plant, and the general value of wholesale meat. However, the Juday Group estimates per day costs based on a larger size

facility as follows: (1) Beef - $2 million; (2) Pork - $1.2 million; (3) Poultry - $400,000; (4) Prepared foods (further processing) - $400,000.

These numbers do not include the loss of purchased or integrator-owned animals to the plant. Unlike other manufacturing enterprises, meat and poultry processing plants involve live animals, and do not have the ability to build inventory of animals during a temporary closure and resume operations at a later date. The entire meat and poultry value chain is built to process large numbers of animals on a daily basis - - based on 2022 data, average daily slaughter was 127,037 head of cattle, 462,963 hogs, and 34.939 million broiler chickens. The sector generates economic activity and provides supplies under a just-in-time inventory system, which is necessary in handling live animals as a key input, and fresh, chilled meat as an output. These plants are not designed to house, nor feed, livestock or poultry for an extended period. In addition, animals kept on feed would continue to grow, and dependent on duration of plant closure and species, might become unsuitable for processing at the facility or for sale in the intended output market.

Through-put at a beef plant can range from 500 head per day at smaller plants, up to more than 5,000 head per day at a larger plant. Based on average livestock prices reported by USDA for 2022, the immediate loss of purchased animals delivered to the plant would be in a range from $950,000 and $9.5 million respectively. At a pork plant, daily through-put can range from 1,000 head per day up to 20,000 head per day. The immediate loss of those purchased or contracted animals would range between, $205,000 to $4.1 million.

Moving into a longer temporary shutdown lasting weeks to months, livestock losses would start to accrue to producers who lost the ability to market their animals for harvest. The effects of this dynamic were well chronicled during COVID, affecting every level from livestock producers to consumers.

In the least-worst case scenario for producers, livestock prices would drop from a lack of operational slaughter capacity. Shutdowns of smaller regional plants could have as significant an economic impact on the producers who supply it as the loss of operations at a large plant. In a worst case scenario, depending on the duration of a shutdown, producers could be forced to retain, rather than market, their animals over a period that is infeasible based on the biology of the animals they use. Hog producers particularly, due to both the biology of the animals and the physical infrastructure of the production systems, rarely have the physical capacity to maintain livestock indefinitely, which, depending on the duration of a plant shutdown could require depopulation, incurring a total economic loss.

Due to the integrated nature of the broiler chicken industry, animal loss for a temporary plant shutdown would be incurred entirely by the company. A smaller scale broiler slaughter facility may process 800,000 birds per week, at an average of 5.3 days per week. That is an average of about 151,000 birds per day. A large plan can slaughter 1.8 million birds per week, for a daily average of nearly 340,000 birds per day. Again, referencing USDA data on broiler price averaged in 2022, the daily bird losses would range between $1.2 to $2.6 million. A longer term interruption could result in a situation where contract growers would no longer receive chicks to

raise and thus lose revenue streams while still being responsible managing sunk costs and overhead in their operations.

In light of the huge economic loss that could occur in the event of plant closures, and with the uncertainty of adopting a "wait and see" approach to understand whether a public water system might have an issue that resulted in FSIS or FDA action at the processing plant, a facility might elect to do its own testing. That will represent significant costs. Water testing is an estimated $1,200 per sample. As companies will have to understand the baseline situation and attendant risk to operations, testing might have to occur frequently, such as seasonally or per quarter. Assuming baseline testing frequency of one week per quarter, four periods would result in a total testing cost of $33,600. Those cost estimates are for a single source of water. Most plants have multiple sources, ranging from four to 50 or more. The $33,600 cost estimate would be for each source, costing in aggregate between $134,400 to $1.68 million for a facility. Ongoing compliance monitoring would require sample testing based on the outcome of initial test findings. The best-case scenario would be one test per three-year compliance period, at $1,200. The worst case would be four sample testing per year for a three-year compliance period, at $14,400. Again, these costs would be felt not just by large processors, but also by small businesses.

Finally, depending on the situation with their public water system supply and Agency action, facilities might elect to install additional treatment systems. Cost estimates for treatment systems are uncertain, but empirical research suggests that treatment system costs are between $1 and $2 million. This estimate is for the system itself, not installation, retrofitting or other costs. Based on other experience within packing plants the yearly operating cost is assumed to be 50 percent of the capital investment cost of the system.

All of these costs assume supply chain availability of treatment and testing options. Supply chain constraints caused by nationwide attempts at compliance with the PFAS standard could increase these costs or the time needed to implement various measures. While the actual cost is necessarily an abstract exercise at this point and somewhat uncertain, one thing is certain: these are significant indirect costs caused by unintended consequences the Agency has failed to consider.

Consumers Will Feel the Cost of the Proposed Rule.

In addition to producer and processor impacts, again as experienced during COVID, the ultimate cost of this interruption in the supply chain would fall on consumers. The graphic from the Juday Study below helps clarify this result:

[Figure 3: see docket ID EPA-HQ-OQ-2022-0114-1839]

The magnitude of cost impacts to consumers is difficult to model given the uncertainty of what events might actually occur. However, there is ample empirical evidence from past shocks to the operational capacity of slaughter and processing which shows that major economic costs would

be incurred and felt by the consumer. What is even more apparent is that EPA has not taken these costs into account.

Conclusion

NAMI and our member companies are extremely concerned about the potential unintended consequences of the Proposed Rule and are equally concerned about what appears to be a lack of understanding by EPA of the implications of the PFAS Standard on other regulatory schemes, such as those governing the food industry. There appears to have been little or no interagency cooperation to address these concerns. We believe that USDA became aware of these concerns very late in the rulemaking process.

There are a number of steps the Agency could take to address these concerns. First, EPA should withdraw the Proposed Rule and include an express exemption or "carve out" in the PFAS component of the NDWS for water used in food processing. There is no scientific record that reducing process water to the levels envisioned by the PFAS Standard is necessary to avoid a food safety or human health issue. In fact, as mentioned earlier, FSIS has tested for PFAS in food and not found levels of concern. At a minimum, EPA should include language that a public water system that is undergoing a monitoring and remediation process in coordination with the Agency should not have its water deemed unfit for use in food processing. Second, prior to any implementation of the Proposed Rule, the Agency should engage in cooperative dialogue with FSIS, FDA and any other agencies that incorporate the NDWS by reference. This step is a minimum measure to discover and address unintended consequences and the resulting shock to the supply chain and the Nation's food supply. Dialogue between EPA and USDA and FDA would enable all agencies to better understand the correlation between potability in the various contexts those agencies regulate, could result in clear expectations and solutions for industry, and might produce useful information such as enforcement guidance for regulators and compliance guidance for all regulated entities, not just public water systems. EPA should provide more information on EPA-approved PFAS treatment options, including those that address the need for scalability of treatment technologies. Finally, public funding such as the funds outlined earlier in these documents should be made available to industries who suffer treatment costs as unintended consequences of these rules, and there should also be funding for private entity, non-transient/non-community water work systems.

NAMI appreciates the opportunity to submit these comments and stands ready to work with all agencies affected and other stakeholders to ensure that the Proposed Rule does not result in shocks to our Nation's food supply and the resultant harm to the very citizens the Proposed Rule seeks to protect.

Sincerely,

Bryan Burns

Vice President and Associate General Counsel

North American Meat Institute

Exhibit 1

Juday Group Study

Analysis: Potential Cost Impacts of EPA's Proposed PFAS/Drinking Water Rule

The potential cost impacts EPA's rule regarding per-and polyfluoroalkyl substances (PFAS) in the drinking water standards potentially would affect the meat and poultry in three ways: 1) testing and compliance, 2) capital outlays for new or upgraded water treatment systems, and 3) lost revenue and sunk costs from potential temporary shut downs. Aggregate costs could be massive and would be passed through the entire value chain both upstream to livestock producers and downstream to wholesales retailers, and ultimately consumers. Consumer impacts would also affect the cost, and even in some cases, the operational viability of federal nutrition programs. Without careful consideration in implementing these regulatory rules, the unintended consequences could result in a major economic disruption.

Temporary Plant Closure

The per day cost of a plant shut down depends on the size of the plant and the type of plant, i.e., beef, pork, or broiler chicken reflecting the general value of wholesale meat. Based on a larger capacity plant, the daily estimated cost for a plant shutdown is as follows.

Beef: $2 million Pork: $1.2 million Poultry: $400,000

Prepared Foods (further processing): $400,000

These estimates do not include loss of purchased animals delivered to the plant.

Unlike a goods manufacturing plant, meat and poultry packing and processing plants can not build nor hold inventory of livestock and birds during a temporary closure and resume operations at a later date. These plants are not designed to house, nor feed, livestock for an extended period. In sum, cattle and hog holding pens at the plant do not have the capacity to handle large volumes of animals who are not moved on to slaughter and processing. However, packing plants, and the entire livestock-meat value chain, are built to process large numbers of animals on a daily basis. The sector generates economic activity and provides supplies under a just-in-time (JIT) inventory system, which is necessary in handling live animals as a key input, and fresh, chilled meat as a major output. Industry wide, based on 2022 data, average daily slaughter was 127,037 head of cattle, 462,963 hogs, and 34.929 million broiler chickens.

Through-put at a beef plant can range from 500 head per day at smaller plants, up to more than 5,000 head per day at a larger plant. Based on average livestock prices reported by USDA for 2022, the immediate loss of purchased animals delivered to the plant would be in a range from $950,000 to $9.5 million respectively. At a pork plant, daily through-put can range from 1,000 head per day up to 20,000 head per day. The immediate loss of those purchased or contracted animals would range between, $205,000 to $4.1 million.

Moving into a longer temporary shutdown lasting weeks to months, livestock losses would start to accrue to producers who lose their ability to market animals for harvest. The effects of this dynamic were well chronicled during COVID, impacting every level of livestock producer, from grower/finishers of market ready animals back to breeders and seedstock producers.

In the least-worst scenario for producers, livestock prices would drop from a lack of operational slaughter capacity. It is important to note that shutdowns of smaller regional plants could have as significant an economic impact on the producers who supply it as the loss of operations at a large plant.

Under a worst case scenario, depending on the duration of a shutdown, producers could be forced to retain, rather than market, their animals, over a period that is infeasible based on the biology of the animals they raise. Hog producers particularly, due to both the biology of the animals and the physical infrastructure of the production systems, often do not have the physical capacity to maintain livestock indefinitely, which, depending on the duration of a plant shutdown could require depopulation, resulting in a total economic loss.

For the same reasons that scenario could also unfold in the poultry sector. Moreover, , due to the integrated nature of the broiler chicken industry, animal loss for a temporary plant shut down would be incurred entirely by the company. Contract growers would no longer receive chicks to raise and thus lose revenue streams while still being responsible managing sunk costs and overhead in their operations.

A smaller scale broiler slaughter facility may process 800,000 birds per week; at an average of 5.3 days per week. That is an average of about 151,000 birds per day. A large plant can slaughter 1.8 million birds per week, for a daily average of nearly 340,000 birds per day. Again, referencing USDA data on broiler price averages in 2022, the daily bird losses could range between $1.2 to $2.6 million.

Finally, again as experienced during COVID, down stream consumers would bear significant addition costs from an interruption in the supply chain caused by an indeterminant plant shutdown.

[Figure 4: see docket ID EPA-HQ-OQ-2022-0114-1508]

The scope and magnitude of cost impact is difficult to model for both up and down stream cost pass through but there is ample empirical evidence from past shocks to the operational capacity of slaughter and processing which support the proposition that major economic costs would be incurred.

EPA estimates there are 66,000 water systems in the country which would be subject to its proposed rule; the agency further assumes that 3,400 to 6,300 – or between 5 to 9.5 percent of all water systems – would initially prove out of compliance. Thus, it is feasible, if not likely, one or several meat or poultry plants would be serviced by a water system exceeding the proposed maximum containment level (MCL).

Assuming such a plant – or plants - was a major, or significant sized processor, and further assuming its operations may be offline for 3 to 6 months to source and install a new treatment system, the supply of meat produced (pork or beef) could be reduced by 5 to 10 percent. Such a dramatic shock to supply would be passed on to consumers in the form of significantly higher prices. Further, the inflationary impact would not be limited to the specific species harvested and processed at the plant where operations were suspended. Higher beef prices would influence pork and poultry prices; likewise higher pork prices would lead to higher beef and poultry prices. Based on estimated cross-price elasticities observed over time, up to one-third of the price inflation in one species could be passed on to another.

Treatment Systems

Cost estimates for treatment systems are uncertain, but empirical research suggests that treatment system costs are between $1 and $2 million. This estimate is for the system itself, not installation, retrofitting or other costs. Based on other experience within packing plants the yearly operating cost is assumed to be 50 percent of the capital investment cost of the system.

Testing and Compliance

Water testing is an estimated $1,200 per sample. As companies will have to understand the baseline situation and risk before compliance, testing would have to be conducted seasonally, each quarter. Assumed baseline testing is one week per quarter, or 7 days during four periods for a total testing cost of $33,600. Those cost estimates are for a single source of water. Most plants have multiple sources, ranging from four to 50 or more. The $33,600 cost estimate would be for each source, costing in aggregate between $134,400 to $1.68 million.

On going compliance monitoring would require sample testing based on the outcome of initial test findings. The best case scenario would be one test per three-year compliance period, at $1,200. A worst case would be four sample testing per year for a three-year compliance period, at $14,400.

For more information, contact

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EPA Response: Regarding the public comment period for this rulemaking, please see section 17.1 of the EPA response in this *Response to Comments* document. For additional discussion on cost considerations for the final MCLs, please section 5.1.3 of the EPA response in this *Response to Comments* document.

This commenter discusses the requirements or expectations under the United States Department of Agriculture's (USDA) and FDA's authorities to have a supply of running water that complies with the NPDWRs (40 CFR part 141). As detailed in the EPA response to comment Doc. #1839, SBC-046048 in section 5.1.3 in this *Response to Comments* document, costs associated with compliance with other regulations are outside the scope of this rulemaking. Further, in cases where the meat or poultry facility is itself a CWS or NTNCWS (i.e., a regulated entity under this rulemaking), the EPA has estimated the costs to PWSs associated with complying with the NPDWR, including implementation, monitoring, and treatment or non-treatment actions to comply with the rule, where applicable. In this case that would include costs to the facility to comply with the NPDWR. In cases where the meat or poultry facility is not a PWS and receives its water from a regulated PWS, the EPA reasonably anticipates that like all customers of PWSs, the meat and poultry facility will receive water compliant with all federal regulations, including the PFAS NPDWR. In the latter case, costs to supply water compliant with the standard will be incurred by the PWS but may be passed on to their customers. Again, this cost has been quantified and included in the EPA's cost analysis.

Regarding the commenter's claims of potential shutdowns, destruction of food, and other potential indirect impacts, enforcement actions by Food Safety and Inspection Service (FSIS) and FDA are outside of the scope of this rulemaking. Costs associated with these enforcement actions are likewise outside of the scope of this rulemaking. However, the EPA notes that in the final rule, the EPA is exercising its authority under SDWA § 1412(b)(10) to implement a nationwide capital improvement extension to comply with the MCL. All systems must comply with the MCLs by five years after the date of the promulgation. All systems must comply with all other requirements of the NPDWR, including initial monitoring, by three years after the date of promulgation. The EPA expects that customers of PWS, including meat and poultry facilities, will have information about PFAS occurrence at the PWS they are served by three years after the rule is promulgated due based on the monitoring schedule for the final rule. The five-year timeframe to comply with the MCLs is reasonably anticipated to provide sufficient opportunity for meat and poultry plants to obtain water compliant with the NDPWR.

Regarding funding, if, as provided by example by the commenter, the meat or poultry facility is a regulated PWS, there is no reason to think the water system would exclude from the BIL potential funding source. For concerns regarding BIL funding, please see section 2.4 of the EPA response in this *Response to Comments* document.

The EPA disagrees with the commenter's statements regarding the potential costs of sampling water, which the commenter states is $1,200 per sample and further suggests that a facility would test once a quarter for four years at a cost of $33,600. First, the EPA clarifies only regulated PWSs are required to sample in compliance with the rule. This commenter suggests that meat and poultry facilities may elect to do so while not being compelled by the NPDWR to better understand their water quality. Elective sampling at these facilities is not required under the rule and therefore not included in EPA's cost analysis. Further, the commenter overstates the potential costs of this elective sampling were it to be done. The commenter's cost per sample far

exceeds EPA estimates as well as estimates provided by public commenters, see section 13.3.4 of the EPA response in this *Response to Comments* document for more information and it is unclear how the commenter derived this estimate, as no supporting information or citations were included. Additionally, the commenter provides no justification for their estimated frequency of sampling described, the EPA expects that far fewer sampling results would provide a reasonable understanding of water quality from a given source, particularly, as in the hypothetical case described by the commenter.

Regarding the impact of supply chain issues on costs to comply with the rule, see section 13.3.3 of the EPA response in this *Response to Comments* document. Regarding EPA's work with federal partners, see the EPA response to comment Doc. #1839, SBC-046048 in section 5.1.3 in this *Response to Comments* document. EPA disagrees with the commenter's recommendation that the agency should withdraw the rule and include an exemption to "carve out" water used for food processing. EPA disagrees with this recommendation, as it is both not permissible under SDWA and further inconsistent with the agency's requirements for public health protection under SDWA. Specifically, SDWA does not include provisions under which the EPA could exempt water systems that serve certain industries from meeting the standard. The EPA also disagrees with the recommendation that "[a]t a minimum, EPA should include language that a public water system that is undergoing a monitoring and remediation process in coordination with the agency should not have its water deemed unfit for use in food processing," as EPA cannot dictate enforcement actions of other agencies and this recommendation is outside of the scope of this rulemaking. Please also see the EPA response to comment Doc. #1649, SBC-043217 in section 5.1.3 in this *Response to Comments* document.

Groundwater Resources Association of California (Doc. #1831, SBC-045351)

Groundwater is also a primary source for domestic wells and agricultural irrigation. Hence, the cost, benefit, and risk evaluations should give due consideration to the nation's groundwater resources and supplies (including untreated groundwater used for potable and non-potable purposes). For example, PFAS contamination can impact domestic wells (pumping from shallow groundwater systems) that are not part of PWS. Contaminated groundwater can also impact agricultural produce, in turn posing health risks to human populations consuming such produce. It is unclear if occurrence in and risks to groundwater resources was included in EPAs assessment. The following are additional cost-benefit-risk considerations that should be given to the direct and indirect impacts (costs and benefits) of the proposed MCLs on groundwater systems.

EPA Response: For additional discussion on cost considerations for the final MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The agency did consider occurrence data from both groundwater and surface water systems (as well as ambient water quality data) in the agency's occurrence analysis. The agency then evaluated finished drinking water to inform the agency's analysis on cost and benefits. Please see sections 7 (occurrence) or 13 (HRRCA) of the EPA response in this *Response to Comments* document.

Vermont PFAS/Military Poisons Coalition (Doc. #2715, SBC-047424)

The EPA should do what the European Chemicals Agency (ECHA) has done this year. ECHA proposes to ban PFAS production and the import of over 10,000 forms of PFAS chemicals in the European Union (EU). 108 European companies have committed to phasing out PFAS chemicals from products and processes and have joined in calling for comprehensive laws to deal with PFAS.

The proposed EU ban on PFAS is extensive, as opposed to the EPA's approach of regulating a few PFAS at a time. The EPA's proposal to regulate PFAS doesn't even include all of the 26 most common forms of PFAS found in drinking water. There are no pending proposed standards for 20 of these and 12 of these PFAS are not included in current monitoring. Three of these PFAS fall outside the "working definition" for PFAS that the EPA adopted without any outside review. Why would the EPA summarily adopt a definition that leaves out thousands of PFAS? Finally, the law won't even take effect until 2026.

The EPA and all US government agencies need to start using the Precautionary Principle, especially in regards to PFAS. Before a product goes on the market, a company must prove it is safe for our health and the environment. All ingredients must be listed and known to consumers. If there is any doubt, we must err on the side of caution and logical scientific assumptions and not allow the product on the market. Thank you.

EPA Response: For additional discussion on alternative regulatory standards (including regulation of PFAS as an entire class), please see section 5.1.3 of the EPA response in this *Response to Comments* document. The commenter does not provide information about the "26 most common forms of PFAS found in drinking water" or which PFAS the commenter believes these to be. EPA is regulating six PFAS with this NPDWR with specific Chemical Abstract Service Registry Number (CASRN) identifiers and does not specify a specific definition for PFAS. The definition that the commenter is referencing is used under the EPA's Toxic Substances Control Act (TSCA) and is outside the scope of this rulemaking. Additionally, the agency notes that consumer product regulation is beyond the scope of this regulation. Please see also the EPA response to comment Doc. #1638, SBC-043451 in section 5.1.3 in this *Response to Comments* document and section 5.1.3 of the EPA response in this *Response to Comments* document in regard to European limits.

Layla Cable (Doc. #2776, SBC-046243)

The precursors that turn into forever chemicals need to be addresses as well. Firefighting foam and military based release many more. Please include all PFAS and others turn into them in substances that need control.

EPA Response: For additional discussion on alternative regulatory standards (including regulation of PFAS as an entire class), please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Tracy Frisch (Doc. #2119, SBC-047418)

In addition, EPA should require Total Organic Fluroine be measured as a PFAS Hazard Index, until validated health data on individual chemicals determines an acceptable health risk to the public.

Next EPA should act with haste to address the unchecked emissions of these and other PFAS chemicals from industrial sites and consumer products. It must halt the approval of new PFAS chemicals, ban the production of all PFAS and use of PFAS in new products and as a manufacturing aid, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods.

EPA Response: For additional discussion on alternative regulatory standards (including regulation of PFAS as an entire class), please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA notes that actions related to "approval of new PFAS chemicals, ban the production of all PFAS and use of PFAS in new products and as a manufacturing aid, restrict dumping of PFAS waste into the wastewater system, limit pollution caused by biosolids/sludge fertilizers, and set health-based limits for PFAS in subsistence fish and other wild foods" are beyond the scope of this rulemaking; please see section 15.1 of the EPA response in this *Response to Comments* document for additional information.

Michigan Farm Bureau (MFB) (Doc. #1562, SBC-043361)

Additional Regulatory Impacts from MCLs

While MCLs fall under the statute and rules of the Safe Drinking Water Act, [FN18: 42 U.S.C. §300f, et. seq., 1974] setting MCLs and the science underpinning health impacts from contaminants crosses over into other regulatory programs, including the Clean Water Act. [FN19: 33 U.S.C. §1251, et. seq., 1972.] Pollutants regulated under the Clean Water Act, effluent limits, water quality standards set by states and approved by EPA all must consider and include human health parameters. Setting MCLs for PFAS, and the human health impacts affecting those regulatory standards, is thus an important step toward establishing water quality criteria for designated uses, National Pollutant Discharge Elimination Program (NPDES) effluent limits and other discharge regulations, and contaminated site cleanup.

All of these programs are vital to protecting the nation's waters, but all come at a cost of compliance. For instance, Michigan has used health data underpinning its MCLs among other studies including aquatic life, recreational activities, fish consumption and other designated uses to set water quality values for PFOS at 11 ppt for water used for drinking and 12 ppt for water not used for drinking, and for PFOA at 66 ppt for water used for drinking and 170 ppt for water not used for drinking. [FN20: Michigan Department of Environment, Great Lakes, and Energy. 2022. EGLE Establishes New Surface Water Values for Two PFAS Chemicals. Retrieved from: https://www.michigan.gov/egle/newsroom/mi-environment/2022/07/27/egle-establishes-new-

surface-water-values-for-two-pfas-chemicals.] Wastewater utilities are required to sample effluent and biosolids for PFOA and PFOS, meeting surface water quality values for discharges of effluent and meeting a limit of 125 ppb for biosolids land application. Industrial pre-treatment is required for facilities discharging to any wastewater facility with biosolids concentrations higher than 20 ppb of PFOS. [FN21: Michigan Department of Environment, Great Lakes, and Energy. 2022. Land Application of Biosolids Containing PFAS: Interim Strategy. Retrieved from: https://www.michigan.gov/pfasresponse/-/media/Project/Websites/egle/Documents/Programs/WRD/Biosolids/PFAS-Biosolids-Interim-Strategy-2022.pdf?rev=ef886f1fb9e047ab8c73f15c2c7d8c35&hash=D97B285D327B4906E22CADDE75B2BD5C.] These are necessary steps but also incur significant cost to regulated facilities: wastewater facilities are reporting additional compliance costs in the tens of millions of dollars each in capital costs, staff, testing, laboratory analysis, treatment, and disposal to address the PFAS requirements imposed at the state level. [FN22: Personal communication with members of the Michigan Water Environment Association, March 2023.]

EPA Response: For additional discussion on cost considerations for the final MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA notes that application of MCLs in non-drinking water programs (such as water quality criteria, NPDES, or CERCLA cleanups) is beyond the scope of this rulemaking; please see section 15.1 of the EPA response in this *Response to Comments* document for additional discussion on comments outside the scope of this NPDWR. For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document.

Illinois Farm Bureau (IFB) (Doc. #1630, SBC-043138)

[The most glaringly overlooked and/or underestimated data includes:]

• The Safe Drinking Water Act requires consideration of the costs and benefits. The estimated annualized costs for a proposed MCL of 4 ppt for PFOA and PFOS are approximately $1.8 billion annually and are more than twice as much as the EPA estimated costs in their economic analysis. The significant costs and impacts and their connection to other elements of the PFAS Strategic Roadmap, such as the proposed hazardous substance designation under CERCLA require further analysis and consideration.

EPA Response: For additional discussion on cost considerations for the final MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA notes that application of MCLs in non-drinking water programs (such as water quality criteria, NPDES, or CERCLA cleanups) is beyond the scope of this rulemaking; please see section 15.1 for additional discussion on comments outside the scope of this NPDWR. The EPA has carefully considered all public comments regarding the cost analysis and made numerous changes to the costs analyses as recommended by commenters. Specific changes made to EPA's cost analysis

for the file rule are detailed in sections 13.3.1 through 13.3.6 of the EPA response in this *Response to Comments* document. At a two percent discount rate, the EPA estimates the quantifiable annual costs of the final rule will be $1,548.64 million per year and the quantifiable benefits of the rule will be $1,549.40 million per year. For further discussion about CERCLA clean-up costs and benefits, please also see section 5.1.3 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1631, SBC-043434 in section 5.1.3 in this *Response to Comments* document.

American Farm Bureau Federation et al. (Doc. #1642, SBC-043485)

[They have identified the following areas of concern regarding the agency's development of this rule:]

• The Safe Drinking Water Act requires consideration of the costs and benefits. The estimated annualized costs for a proposed MCL of 4 ppt for PFOA and PFOS are exorbitant. The significant costs and impacts and their connection to other elements of the PFAS Strategic Roadmap, such as the proposed hazardous substance designation under CERCLA, require further analysis and consideration.

EPA Response: Please see the EPA response to comment Doc. #1630, SBC-043138 in section 5.1.3 in this *Response to Comments* document. For further discussion about CERCLA clean-up costs and benefits, please also see section 5.1.3 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1631, SBC-043434 in section 5.1.3 in this *Response to Comments* document.

Pennsylvania Municipal Authorities Association (Doc. #1832, SBC-045784)

[PMAA's specific comments on the Proposal are as follows:]

8. EPA's PFAS Strategic Roadmap, which lays the groundwork for EPA's response to various PFAS issues, focuses on a number of principles, one of which is to "Hold Polluters Accountable." However, directly contrary to the principles of the PFAS Strategic Roadmap, the Proposal will have severe consequences for PMAA member authorities that have absolutely no role in producing or placing PFAS chemicals into the stream of commerce; rather they are merely passive receivers of PFAS chemicals. Notwithstanding the aforementioned, EPA now seeks to impose significant additional technical and management costs on PMAA member authorities and their ratepayers/customers related to, among other things, the use of filtration and the management of biosolids. What justifies these additional costs, and did EPA specifically consider such costs in the Proposal? Moreover, why is EPA shifting costs to public entities, such as PMAA member municipal authorities, to address PFAS-related initiatives, when such "shifting of costs" is contrary to EPA's own principles set forth in EPA's PFAS Strategic Roadmap?

EPA Response: The EPA's final rule represents data-driven drinking water standards that are based on the best available, peer-reviewed science, meet the requirements of SDWA, and that regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. For additional discussion on cost considerations for the final MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document. Discussion on the EPA's cost estimates can be found in sections 13.3.1 through 13.3.6 of the EPA response in this *Response to Comments* document. Topics related to assigning liability for PFAS pollution or addressing sources of PFAS contamination are beyond the scope of this rulemaking (please see section 15.1 of the EPA response in this *Response to Comments* document for additional discussion).

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046001)

Section 8.12: Additional factors

EPA should focus its final analyses on the issues raised in these comments. AMWA believes that EPA's time and resources would be better spent by updating its cost analysis to reflect today's economic reality more accurately. EPA should work to portray the actual cost increases for labor, water treatment chemicals, lab analyses, materials, and construction that have been exacerbated since 2021. Additionally, the agency must include the social costs of carbon and additional energy usage and GHG emissions for GAC, IX, and RO treatments.

EPA Response: For additional discussion on cost considerations for the final MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA has carefully considered all public comments regarding the cost analysis and made numerous changes to the costs analyses as recommended by commenters. Specific changes made to EPA's cost analysis for the file rule are detailed in sections 13.3.1 through 13.3.6 of the EPA response in this *Response to Comments* document. At a two percent discount rate, the EPA estimates the quantifiable annual costs of the final rule will be $1,548.64 million per year and the quantifiable benefits of the rule will be $1,549.40 million per year.. Please also see section 13.11 of the EPA response in this *Response to Comments* document for additional discussion on the social costs of carbon.

Millie Garcia-Serrano (Doc. #1803, SBC-044285)

EPA needs to consider implementation of the proposed regulation, which poses financial, technological, logistical, and communication challenges that are of significant concern to the ASTSWMO membership, as follows:

1. Cost Concerns: EPA's cost analysis does not include costs that will be incurred under CERCLA or other remediation programs, which are likely to be significant. For example, for Superfund-financed sites, where there are no viable responsible parties, States will be responsible for cost-sharing obligations for remedial actions as well as 100% of the costs for long-term operation and maintenance of the remedies in perpetuity. Additionally, with this proposed

regulation, the number of sites to be remediated is likely to increase significantly, requiring additional resources for States to perform and/or oversee the remedial activities.

EPA Response: For additional discussion on cost considerations for the final MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document. See also the EPA response to comment Doc. #1630, SBC-043138 in section 5.1.3 in this *Response to Comments* document. The EPA has carefully considered all public comments regarding the cost analysis and made numerous changes to the costs analyses as recommended by commenters. Specific changes made to EPA's cost analysis for the file rule are detailed in sections 13.3.1 through 13.3.6 of the EPA response in this *Response to Comments* document. As required by SDWA, this rulemaking and analyses supporting the rulemaking only includes costs that "are likely to occur solely as a result of compliance with the [MCL]." Thus, the EPA's cost analyses focused on the compliance costs of meeting the MCL to PWSs that are directly subject to this regulation. For further discussion about CERCLA clean-up costs and benefits, please also see section 5.1.3 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1631, SBC-043434 in section 5.1.3 in this *Response to Comments* document.

Plymouth Village Water & Sewer District (Doc. #1827, SBC-044562)

[Please carefully consider the following points to help inform the pending rulemaking on this class of pervasive and persistent PFAS chemicals:]

• Public water system customers already face both real and perceived affordability issues. The substantial costs required to meet the proposed 4 ppt MCL will adversely impact individual and regional economies, especially in more financially disadvantaged communities. As noted above, EPA has underestimated the full life-cycle costs of treating PFAS to the proposed MCLs.

EPA Response: For additional discussion on cost considerations for the final MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA has carefully considered all public comments regarding the cost analysis and made numerous changes to the costs analyses as recommended by commenters. Specific changes made to EPA's cost analysis for the file rule are detailed in sections 13.3.1 through 13.3.6 of the EPA response in this *Response to Comments* document. For additional discussion on funding concerns and BIL, particularly for disadvantaged communities, please see section 2.4 of the EPA response in this *Response to Comments* document.

New Hampshire Water Works Association, Inc. (NHWWA) (Doc. #1576, SBC-042455)

Public water system customers already face both real and perceived affordability issues. The substantial costs required to meet the proposed 4 ppt MCL will adversely impact individual and regional economies, especially in more financially disadvantaged communities. As noted above, EPA has underestimated the full life-cycle costs of treating PFAS to the proposed MCLs.

EPA Response: Please see the EPA response to comment Doc. #1827, SBC-044562 in section 5.1.3 in this *Response to Comments* document.

Groundwater Resources Association of California (Doc. #1831, SBC-045354)

An assessment of these groundwater-related costs and available funding sources to offset costs should be included in determining the economic feasibility of the proposed MCLs. The justification for costs cites investments in the Infrastructure Investment and Jobs Act, but funds allocated under the Act are specifically for the Drinking Water State Revolving Funds (SRF), the Drinking Water SRF for Emerging Contaminants, and the Small, Underserved, and Disadvantaged Communities Grants. Groundwater management agencies that may not be directly associated with potable water treatment systems yet manage the critical drinking water source, may not be eligible for these funds but will incur significant costs due to the proposed MCLs.

EPA Response: For additional discussion on cost considerations for the final MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA has carefully considered all public comments regarding the cost analysis and made numerous changes to the costs analyses as recommended by commenters. Specific changes made to EPA's cost analysis for the file rule are detailed in sections 13.3.1 through 13.3.6 of the EPA response in this *Response to Comments* document. For additional discussion on funding concerns and other funding sources outside of BIL, please see section 2.4 of the EPA response in this *Response to Comments* document.

American Farm Bureau Federation et al. (Doc. #1642, SBC-043480)

May 30, 2023

Submitted via www.regulations.gov

Alexis Lan

Office of Ground Water and Drinking Water Environmental Protection Agency 1200 Pennsylvania Avenue, N. W.

Washington, DC 20460

Submitted via www.regulations.gov

Re: Docket ID No. EPA-HQ-OW-2022-0114, Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

The undersigned agricultural organizations appreciate the opportunity to submit these comments to the U.S. Environmental Protection Agency (EPA) in response to its proposed rule to set National Primary Drinking Water Regulations (NPDWR) for six PFAS chemicals [FN1:"Perfluoroalkyl or polyfluoroalkyl substance" (PFAS) means a non-polymeric

perfluoroalkyl or polyfluoroalkyl substance that contains at least 2 sequential fully fluorinated carbon atoms, excluding gases and volatile liquids, that is a hazardous substance (as defined in section 101 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9601))], including perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS). (March. 14, 2023).

Our organizations represent farm and ranch families working together to build a sustainable future of safe and abundant food, fiber and renewable fuel for our nation and the world. We support EPA's underlying goal of addressing widespread contamination of the environment caused by historic use of PFOA and PFOS. Unfortunately, EPA's proposed Maximum Contaminant Level (MCLs) of 4 ppt for PFOA and PFOS and the designation of a hazard index for PFNA, PFHxS, Gen X, and PFBS overlook potential widespread unintended consequences.

At the onset, it is worth emphasizing our shared concerns regarding the health impacts of PFAS exposure, even as research continues to examine claims of causation. This is personal for our membership, rural families that live near to or in the approximately 140,000 small communities in the US with drinking water systems. [FN2: United States Environmental Protection Agency, Small Drinking Water Systems Research and Development, fact sheet, updated February 2020, https://www.epa.gov/sites/default/files/202002/documents/scienceinaction_small_systems_research_2020.pdf] There are many factors that must be considered when developing regulatory limits and these comments will outline the challenges that we foresee with setting the drinking water MCL for PFOA and PFOS at the very low level of 4ppt, which is out-of-step with limits recommended by international standard-setting bodies. We fear that the enormous costs, estimated to be at least $5.2 billion annually, and implementation roadblocks outlined below will have a ripple effect throughout our economy, potentially hitting rural communities the hardest.

EPA Response: For additional discussion on cost considerations for the final MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA has carefully considered all public comments regarding the cost analysis and made numerous changes to the costs analyses as recommended by commenters. Specific changes made to EPA's cost analysis for the file rule are detailed sections 13.3.1 through 13.3.6 of the EPA response in this *Response to Comments* document.

U.S Conference of Mayors, National League of Cities and National Association of Counties (Doc. #1733, SBC-043891)

While we appreciate the recent significant investments in our nation's water infrastructure from BIL, it unfortunately is not enough to protect the health of our residents in the manner the Agency is attempting. We have serious concerns that not only will local governments be unable to afford the required costs to comply with this regulation, but also that the Agency has underestimated the cascading impacts this regulation will have on local communities, primarily in the form of higher water bills.

In general, local governments will be responsible, directly or indirectly, for a wide array of associated compliance costs, including for testing, monitoring and installing treatment. The proposed Maximum Contaminant Level (MCL) of 4 ppt will require 3,400-6,000 systems across the country to take action, significantly more than are currently doing so based on state-level standards or that would need to do so if the MCL was set at a higher level such as 10 ppt. Many of the roughly 66,000 water systems that will be subject to the regulation are small systems for which compliance will be even more challenging and the financial impacts more severe. Moreover, as the Agency moves forward with rulemakings designating PFOS and PFOA or other PFAS as hazardous substances under CERCLA, these costs will only increase as local governments will also be responsible for the appropriate removal and transport of hazardous chemicals.

As providers of public water, providing safe, clean and affordable drinking water to our communities is of utmost importance to local governments. It is worth emphasizing that local governments have limited financial resources to comply with a host of new and existing water-related mandates, including but not limited to testing for lead, removing lead service lines, upgrading cybersecurity and replacing aging infrastructure. Consequently, local utilities may be forced to fund the compliance costs associated with this new regulation by cutting back on infrastructure replacement and maintenance, reducing operational resiliency and reducing other expenditures that would otherwise benefit public health and access to clean and safe drinking water.

As local governments are forced to bear the brunt of the financial burden, an increase in water rates in communities across the nation is a near certainty. Indeed, this rising consumer cost for utilities to comply with the proposed MCL will be felt most harshly by the low-income households and small business community. The U.S. Census reports that local governments spent $80 billion in 2020 on water supply utilities. A $2.5-$3.2 billion new unfunded federal mandate will require a 3.125-4% increase in national spending that will be passed on to consumers through rate increases and long-term debt, particularly where advanced treatment is required for compliance. Given this regulation will currently impact approximately 3,400-6,000 systems, the burden on those communities will be dramatically higher. Many communities and residents are already experiencing significant and widespread financial burdens, and this proposed regulation will add to that burden.

Because of this, we urge the Agency to reconsider the financial impact this proposed regulation will have on individual consumers, particularly on environmental justice and disadvantaged communities. These communities are often disproportionately impacted by both increased costs for their water bills and risk exposure to emerging contaminants. In examining the financial impacts this regulation could impose upon individual households, costs will vary depending on several factors, such as the size of the public water system. In scenarios where new treatment facilities would need to be installed and operated, individual households may see increases in the amounts of hundreds of dollars to their water bills. For systems serving smaller communities, this number extends into the thousands, according to an AWWA study.

EPA Response: For additional discussion on cost considerations for the final MCLs and alternative MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document. EPA disagrees with commenter that the cost of the rule will be between $2.5-$3.2 billion per year. See the economic analysis for further discussion. For discussion related to household cost of the rule, please see section XII of the FRN and section 13.10 of the EPA response in this *Response to Comments* document. Additionally, EPA notes the availability of federal funding that can help offset some of the costs of implementing this regulation. For further discussion, see section 2.4. The EPA has carefully considered all public comments regarding the cost analysis and made numerous changes to the costs analyses as recommended by commenters. Specific changes made to EPA's cost analysis for the file rule are detailed in sections 13.3.1 through 13.3.6 of the EPA response in this *Response to Comments* document. The are also significant quantified and non-quantifiable benefits as a result of implementing this NPDWR.

U.S Conference of Mayors, National League of Cities and National Association of Counties (Doc. #1733, SBC-043889)

May 30, 2023

The Honorable Radhika Fox Assistant Administrator Office of Water

U.S. Environmental Protection Agency 1200 Pennsylvania Avenue NW Washington, DC 20460

RE: Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation, Docket ID No. EPA-HQ-OW-2022-0114

Dear Assistant Administrator Fox,

On behalf of the nation's mayors, cities and counties, we appreciate the opportunity to submit comments on the U.S. Environmental Protection Agency's (EPA) Proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation (NPDWR). Local leaders are dedicated to the health, well-being and safety of their residents and communities and are therefore highly interested and concerned regarding the public health impact that PFAS substances may have on our drinking water supplies and systems.

We appreciated the opportunity to submit comments to EPA in response to the Agency's Federalism Consultation briefing last year. However, we are disappointed to see that our recommendations are not reflected in this proposed regulation. Given this, we urge EPA to move forward cautiously, consult with local governments, gather and utilize additional and updated scientific data, and reexamine the cost-benefit analysis to best inform this regulation. Specifically, should EPA move forward, we ask that the Agency:

• Provide maximum flexibility for local governments, including longer compliance timeframes;

• Reconsider regulatory alternative Option 1 c, which would establish a higher MCL at 10 parts per trillion (ppt) for PFOS and PFOA; and

• Provide additional direct funding for local governments to comply with the proposed regulation to avoid creating an unfunded mandate that will disproportionately impact low- income residents and communities.

These measures are important to ensuring that local governments, water utilities and ratepayers are not unduly burdened in trying to fix a problem they did not create.

Our organizations represent the nation's 3,069 counties, 19,000 cities and the mayors of the 1,400 largest cities throughout the United States. For the past several years, all levels of government, including the counties and cities we represent, have become increasingly concerned about drinking water contamination from PFAS. Created by private industry for use in a variety of sectors and applications around the globe, these chemicals have made their way into drinking water systems across the country and are heavily concentrated in communities near military installations or industrial sites.

The presence of these human-made chemicals has spurred action by state and local governments across the country. We continue to urge the federal government to take holistic and comprehensive action to address PFAS contamination through pollution prevention, cleanup, research and development, scientific and public health analysis, and prevention of further exposure.

As passive receivers of materials containing PFAS, local water systems neither caused nor contributed to the pollution. We urge EPA to adhere to the polluter pays model and provide sufficient direct funding to comply with this regulation. Additionally, in developing this regulation, EPA should provide local governments with maximum flexibility and a longer compliance timeframe to avoid overburdening communities and ratepayers.

As coregulators in implementing federal statutes, including the Safe Drinking Water Act, and as partners in protecting public health, it is important that federal, state and local governments work together to craft reasonable and practicable rules and regulations to address PFAS contamination. In order to achieve these goals, it is essential that EPA provide local governments with a clear understanding of the rules' and regulations' requirements and a full and complete cost-benefit analysis.

In general, our organizations support provisions in the 1996 Amendments to the Safe Drinking Water Act that requires drinking water standards to be based on sound science, public health protection and the occurrence of contaminants in drinking water supplies at levels of public health concern in order to reduce risk while also balancing costs. Consequently, we believe the NPDWR for PFAS, and any regulatory or legislative initiative addressing PFAS in drinking water, should balance public health and environmental priorities with technological and economic feasibility. Any federal mandate on local governments should include additional federal financial resources, as well as offer local water systems flexibility in implementation and compliance options. Further, our organizations support programs for public education regarding safe drinking water and innovative solutions that approach this problem beyond traditional command and control.

Local governments fund the majority of water infrastructure investments

Local governments fund over 98 percent of all capital, operations and maintenance investment in drinking water and wastewater infrastructure in the United States, primarily through user fees and bonds. The most recent U.S. Census data shows that local governments spent over $142 billion on water and wastewater in 2020 alone, and, between 1993 and 2019, spent over $2.38 trillion, not adjusted for inflation. Even with this significant investment by and commitment from local governments, many communities struggle to upgrade their drinking water and wastewater systems.

During this same time period, the federal government only appropriated approximately $2 billion annually for both the Clean Water and Drinking Water State Revolving Loan Fund (SRF) programs. The SRF programs provide grants to states which, in turn, provide local governments with loans that must be repaid.

While we are pleased that the bipartisan Infrastructure Investment and Jobs Act (also known as the Bipartisan Infrastructure Law or BIL) provided record-high levels of funding for our nation's water infrastructure, including $10 billion over five years for grants to address PFAS and other emerging contaminants in drinking water and wastewater, this funding is insufficient for local governments to meet the requirements of this proposed regulation and/or other rules that the Agency is considering.

At a minimum, it must be acknowledged that the timelines for the availability of funding under BIL, which is through FY 2026, and the likely compliance dates for a new NPDWR for PFAS do not align. Therefore, it is uncertain if local governments will be able to use BIL funding specifically for compliance with this forthcoming regulation or for future rulemakings pertaining to PFAS.

Taking a holistic approach toward drinking water regulations

Considering EPA is simultaneously undergoing other rulemaking processes that pertain to local drinking water and wastewater infrastructure management, among others, it is important that these rules and regulations are not developed in silos within the Agency. We urge the Agency to take a holistic and integrated approach and consider the cumulative impacts that the rules and regulations will have on local governments in terms of costs, compliance, and implementation timelines. Additionally, EPA should examine other related consequences of proposed rules, such as the impact on efforts to reduce greenhouse gas emissions.

Specifically, we are concerned that the Agency's rulemakings around NPDWR for PFAS, Lead and Copper Rule Improvements, and regulating PFAS under CERCLA and RCRA will individually and combined, create additional unfunded mandates on local governments that will be economically significant and, in many communities, unaffordable. If EPA moves forward with these proposed rules and regulations, new funding sources must be created to assist local governments with compliance and implementation. Even with the increased funding from BIL for the SRF programs, as well as for reducing lead in drinking water and addressing PFAS

drinking water contamination, local governments will still face a significant water infrastructure needs gap that would exacerbate affordability and equity concerns for the many fixed- and low-income households that already spend a disproportionate amount of their income on water bills.

EPA Response: Please see the EPA response to comment Doc. #1733, SBC-043891 in section 5.1.3 in this *Response to Comments* document. With respect to BIL and funding concerns, please see section 2.4 of the EPA response in this *Response to Comments* document. The EPA notes that actions taken under other EPA programs (such as CERCLA and RCRA) and the Lead and Copper Rule Improvements (LCRI) are beyond the scope of this rulemaking.

Arizona Corporation Commission (ACC) (Doc. #1735, SBC-045179)

BEFORE THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

PFAS National Primary)

Drinking Water) Docket No. EPA–HQ–OW–2022–0114

Regulation Rulemaking)

COMMENTS OF THE ARIZONA CORPORATION COMMISSION

INTRODUCTION

The Arizona Corporation Commission ("ACC") appreciates the opportunity to provide the following observations regarding the Environmental Protection Agency's ("EPA" or "Agency") PFAS National Primary Drinking Water Regulation Rulemaking. The following responses address comments posed by the rulemaking that will impact Arizona's water companies and citizens.

The ACC is the state regulatory body responsible for the regulation of Arizona's public utilities, including utilities providing water service to the residents of Arizona. The ACC has broad authority over public service corporations under Article XV of the Arizona Constitution and Arizona Revised Statutes, Title 40.

COST OF COMPLIANCE

The Environmental Protection Agency's proposed per- and polyfluoroalkyl substances ("PFAS") rule will have various impacts on the utilities regulated by the ACC associated with the sampling, treatment, and disposal of PFAS. The ACC and its regulated utilities are greatly concerned about the potential costs and liabilities associated with the proposed rule. Respectfully, the ACC believes the EPA's estimates for national costs are extremely low and not supported by rigorous evaluations. The ACC suggests the EPA revisit its calculations. In view of the extensive testing and treatment costs that will be imposed on customers, it will be important for the EPA to conduct a thoughtful assessment of the economic consequences of its decision.

EPA Response: For additional discussion on cost considerations for the final MCLs and alternative MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA has carefully considered all public comments regarding the cost analysis and made numerous changes to the costs analyses as recommended by commenters. Specific changes made to EPA's cost analysis for the file rule are detailed sections 13.3.1 through 13.3.6 of the EPA response in this *Response to Comments* document. The are also significant quantified and non-quantifiable benefits as a result of implementing this NPDWR.

Virginia Municipal Drinking Water Association (VMDWA) (Doc. #1657, SBC-043163)

B. Favorable Trends in Declining PFAS Levels and Ongoing Industrial Source Reduction Efforts Further Support a Phased Approach to Water System Upgrades

As EPA is aware, extensive human health PFOA/PFOS data is available from the Centers for Disease Control and Prevention and the Food and Drug Administration. Fortunately, there are declining trend lines over 20 years of actual blood PFOA and PFAS levels as depicted in the chart below. The much improved and presumably still improving situation as compared to the situation only 20 years ago may further support reasons to phase-in treatment upgrades beginning with higher priority facilities, i.e., those experiencing relatively higher PFAS concentrations rather than all facilities with concentrations greater than the proposed MCLs.

[Figure 1: See Docket ID: EPA-HQ-OW-2022-0114-1657]

* Average = geometric mean

Data Source: Centers for Disease Control and Prevention. National Report on Human Exposure to Environmental Chemicals, Biomonitoring Data Tables for Environmental Chemicals. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention.

See ASTDR, PFAS in the U.S. Population, available at https://www.atsdr.cdc.gov/pfas/health-effects/us-population.html (last visited May 15, 2023).

It is unclear to what degree if any and in what manner EPA has directly considered human health impacts from areas around the Nation where there have been long-term PFAS exposure.

EPA is aware of situations where people in the U.S. have been exposed to levels of PFOA/PFOS for many years or decades at levels orders of magnitude higher than EPA's proposed MCLs. Known examples of source water contamination include the Parkersburg/Vienna, West Virginia area and the Wilmington, North Carolina (Cape Fear) area, where Chemours (formerly DuPont) facilities discharged PFAS chemicals for extended periods of time, as EPA is well aware.

These types of situations are especially concerning and may be instructive for regulatory development purposes. However, the MCL proposal does not appear to identify any health effect clusters as a result of these "hot spot" exposures, which presumably would be highly observable

given far lower levels of the proposed MCLs that EPA proposes are necessary to protect public health.

During an online Town Hall meeting regarding PFAS-related issues, we understand that North Carolina's health agency represented that it was not aware of any PFAS-related health effect clusters, despite what is believed to be long-term, high-concentration discharges of PFAS chemicals.

EPA Response: For additional discussion on alternative regulatory standards, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA considered human health impacts in high exposure communities where peer-reviewed human health effects studies were available for those communities. Multiple peer reviewed studies of the C8 Health Project, which focused on a high-exposure PFOA community in the United States, reported significantly increased risks of multiple health effects with elevated exposure to PFOA including elevated serum liver enzyme levels indicative of liver damage (Gallo et al. 2012 and Darrow et al., 2016) as well as kidney and testicular cancers (Barry, 2013,; Vieira, 2013). Further, the commenter referenced an exposure scenario in North Carolina that was recently uncovered; the EPA is not aware of any peer reviewed epidemiological studies studying adverse health effects in this community. Moreover, the EPA's occurrence analysis demonstrates that there is a substantial likelihood that the PFAS regulated through this NPDWR occurs and co-occurs in drinking water (see section 6 for additional discussion). The agency also disagrees that a "phased-in" MCL approach is necessary in light of the health effect concerns for PFAS; please see section 12.1 of the EPA response in this *Response to Comments* document for additional discussion.

Maryland Association of Municipal Wastewater Agencies (MAMWA) (Doc. #1658, SBC-043398)

Favorable Trends in Declining PFAS Levels and Ongoing Industrial Source Reduction Efforts Further Support a Phased Approach to Water System Upgrades

As EPA is aware, extensive human health PFOA/PFOS data is available from the Centers for Disease Control and Prevention and the Food and Drug Administration. Fortunately, there are declining trend lines over 20 years of actual blood PFOA and PFAS levels as depicted in the chart below. The much improved and presumably still improving situation as compared to the situation only 20 years ago may further support reasons to phase-in treatment upgrades beginning with higher priority facilities, i.e., those experiencing relatively higher PFAS concentrations rather than all facilities with concentrations greater than the proposed MCLs.

[Figure 1: See Docket ID EPA-HQ-OW-2022-0114-1658]

* Average = geometric mean

Data Source: Centers for Disease Control and Prevention. National Report on Human Exposure to Environmental Chemicals, Biomonitoring Data Tables for Environmental Chemicals. Atlanta,

GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention.

See ASTDR, PFAS in the U.S. Population, available at https://www.atsdr.cdc.gov/pfas/health-effects/us-population.html (last visited May 15, 2023).

It is unclear to what degree if any and in what manner EPA has directly considered human health impacts from areas around the Nation where there have been long-term PFAS exposure.

EPA is aware of situations where people in the U.S. have been exposed to levels of PFOA/PFOS for many years or decades at levels orders of magnitude higher than EPA's proposed MCLs. Known examples of source water contamination include the Parkersburg/Vienna, West Virginia area and the Wilmington, North Carolina (Cape Fear) area, where Chemours (formerly DuPont) facilities discharged PFAS chemicals for extended periods of time, as EPA is well aware.

These types of situations are especially concerning and may be instructive for regulatory development purposes. However, the MCL proposal does not appear to identify any health effect clusters as a result of these "hot spot" exposures, which presumably would be highly observable given far lower levels of the proposed MCLs that EPA proposes are necessary to protect public health.

During an online Town Hall meeting regarding PFAS-related issues, we understand that North Carolina's health agency represented that it was not aware of any PFAS-related health effect clusters, despite what is believed to be long-term, high-concentration discharges of PFAS chemicals.

EPA Response: Please see the EPA response to comment Doc. #1657, SBC-043163 in section 5.1.3 in this *Response to Comments* document.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045123)

Comments on EPA PFAS MCL by the Vermont Department of Health concerning Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) in Drinking Water (referred to as "document").

Comment: The Department of Health suggests that EPA provide a regulatory approach that is consistent with short-term exposures during pregnancy. Please explain how a regulation based on running annual average is protective of the developing fetus.

Explanation: The document describes the concerning developmental toxicity outcome of low birth weight, based on human studies. The points of departure from these studies are environmentally relevant serum levels, and as appropriate for human studies, the uncertainty factor used for reference dose derivation is 10.

EPA states the PFOA reference dose is applicable to both short-term and chronic risk assessment scenarios. This is at odds with the decision to regulate PFOA based on a running annual average. Doing so would expose a person who is pregnant during their entire gestation period. As pregnancy would be considered a short-term, rather than chronic situation, the decision to allow exposure throughout the pregnancy is not consistent with the agency's conclusion that the reference dose is applicable to short- term assessments. developing fetus.

EPA Response: While the EPA has characterized developmental effects, including immune impacts, associated with developmental PFAS exposure (i.e., during pregnancy and/or childhood) in addition to health effects that occur after chronic exposure (i.e., exposure over many years), the developmental and chronic effects associated with exposure to PFAS are not known to represent immediate acute health effects based on the currently available information. Exceedances for contaminants in other NPDWRs (such as nitrate, nitrite, or total nitrate and nitrite) can result in immediate life-threatening health impacts for infants (i.e., methemoglobinemia); this has not been demonstrated for the PFAS regulated in this NPDWR. The agency explains in CFR § 141.903(e) that in cases where there is elevated exposure scenarios such that a sampling result is high enough to cause the RAA to exceed an MCL (i.e., if the result is greater than four times the MCL), the systems is out of compliance immediately. Therefore, the agency finds the RAA appropriate for use in determining compliance with the MCLs. States and PWSs have to meet the requirements of the NPDWR however SDWA allows a state with primacy to require more stringent monitoring, compliance and PN requirements (e.g., such as more frequent sample collection or more stringent compliance calculations) if they deem necessary. For instance, if there are regional factors that suggest more frequent sampling is warranted by particular PWSs, the rule provides that primacy agencies may increase the required monitoring frequency, where necessary, to detect variations within the system (e.g., fluctuations in concentrations due to seasonal use or changes in water source). Finally, once the rule is finalized, the EPA will develop appropriate implementation guidance to assist in the understanding of violations and PN, among other rule requirements. For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations), 5.1.3 (cost considerations and alternative MCLs) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document. For additional discussion on alternative regulatory standards (including lower PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document. For additional discussion on the MCLGs for PFOA and PFOS, please see section 4 of the EPA response in this *Response to Comments* document.

WateReuse Association (Doc. #1712, SBC-043517)

May 30, 2023

The Honorable Michael S. Regan Administrator

U.S. Environmental Protection Agency William Jefferson Clinton Building 1201 Pennsylvania Avenue, N.W. Washington, D.C. 20460

Re: Docket ID No. EPA–HQ–OW–2022–0114

Dear Administrator Regan:

On behalf of the WateReuse Association (WateReuse), I am pleased to submit our comments on EPA's preliminary regulatory determination and proposed rule to establish Maximum Contaminant Levels (MCLs) for certain per- and polyfluoroalkyl substances (PFAS).

The WateReuse Association is a not-for-profit trade association for water utilities, businesses, non-profit organizations, and research entities that advocate for policies and programs to advance water recycling. WateReuse and its state and regional sections represent nearly 250 water utilities serving over 60 million customers, and over 200 businesses and organizations across the country.

Water reuse, also known as water recycling, is the process of intentionally capturing wastewater, stormwater, saltwater or graywater and cleaning it as needed for a designated beneficial freshwater purpose, such as drinking, industrial processes, groundwater replenishment, and watershed restoration. The fundamental principle of water reuse is using the right water for the right purpose, everywhere and all the time. By advancing water reuse, we protect and enhance public health and the environment while helping communities build resilience to drought, flooding, and other impacts of climate change. Across the country, water, wastewater, and stormwater managers have shown that water recycling can be a central feature in innovative, integrated approaches to solving water management challenges.

One common application of water recycling is the production of drinking water, either through indirect potable reuse or through direct potable reuse. In both cases, advanced treatment is typically used to meet drinking water standards. Through the use of technologies such as reverse osmosis (RO) and granular activated carbon (GAC), advanced water recycling projects are helping to remove PFAS from drinking water.

While water recycling facilities are helping to address PFAS contamination through the use of advanced treatment such as RO and GAC, the ubiquitous nature of PFAS contamination necessitates a strong focus by EPA and other government agencies on source control. We recommend that EPA take more proactive measures to identify where PFAS are originating and to control their introduction into commerce, as prevention is more cost-effective than attempting to clean up pollution later. A source control approach also maintains the polluter pays principle.

Advancing regulatory actions that provide source water protection will reduce the number of systems with PFAS contamination above the proposed drinking water standards. We therefore urge EPA and other federal agencies to work toward limiting the production and introduction of PFAS into commerce.

Sincerely,

Patricia Sinicropi

Executive Director

EPA Response: For additional discussion on cost considerations for the final MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document. With respect to responses on potable water reuse, the agency notes that NPDWRs apply to PWSs and does not pose direct standards or requirements for wastewater treatment facilities and advanced treatment facilities for potable reuse unless the water is for direct distribution (in this circumstance, these systems generally would be classified as PWSs). Typically, the process of using treated wastewater for potable water reuse involve a series of treatment steps after conventional wastewater treatment which then may get discharged to a surface water body, used for groundwater augmentation, or go directly to a PWS for additional treatment and distribution. At this last step, the PWS must meet the federal requirements outlined in the NPDWR. The agency's cost analysis specific for PWSs and primacy agencies implementing the PFAS NPDWR is further described in section 13.3 of the EPA response in this *Response to Comments* document. The EPA further notes that topics related to assigning liability for PFAS pollution or addressing sources of PFAS contamination are beyond the scope of this rulemaking (please see section 15.1 of the EPA response in this *Response to Comments* document for additional discussion). For additional discussion on treatment technologies, please see section 10 of the EPA response in this *Response to Comments* document. For general concerns around treatment discharges and waste residuals, as well as concern around water recovery or water reuse applications, please see section 10.4 of the EPA response in this *Response to Comments* document.

Florida Section American Water Works Association - Water Utility Council (FSAWWA WUC) (Doc. #1737, SBC-044489)

• Other Facility Operations

In addition to direct costs, other facility operations with permits containing MCL references could face cost increases. For example, some water reuse permits in the state of Florida reference MCLs and the facilities may need to change current treatment processes. Florida is a national leader in water reuse production with over 900 million gallons a day (please see https://floridadep.gov/water/domestic-wastewater/documents/2021-reuse-inventory-report). However, the time allowed for comments on EPA's proposed rule did not allow us to quant if y these potential cost estimates.

EPA Response: Please see the EPA response to comment Doc. #1712, SBC-043517 in section 5.1.3 in this *Response to Comments* document.

Los Angeles County Sanitation Districts (Doc. #1756, SBC-044515)

Implementation of the proposed MCLs could impede water recycling efforts in areas such as Southern California. Considering the interdependence of recycled water and drinking water for many public water systems, it is imperative that EPA evaluate the impacts of the proposed MCLs on the production and use of recycled water. This is increasingly true throughout the United States as water recycling is considered a climate-resilient water supply and is being implemented in an increasing number of areas. In California, for example, treated wastewater used for indirect or direct potable reuse projects must meet federal and state MCLs, so new federal MCLs for PFAS will apply to recycled water used for these purposes. While some potable reuse projects employ advanced treatment processes that may already reduce or remove PFAS, not all do. Moreover, unless designed to meet regulatory requirements for PFAS removal, these systems may not achieve newly adopted MCLs for PFAS, and new or modified treatment processes may still be necessary. The new MCLs may also affect the options available for management of the treatment residuals, as mentioned above. As an example, for groundwater replenishment projects, recycled water must meet MCLs before application to spreading basins that overlie the aquifer, and water reclamation plants (which typically have tertiary treatment that do not remove PFAS) will likely require new treatment technologies if and when they are required to meet the proposed PFAS MCLs, unless such treatment is already in place. The economic ramifications of these capital projects are enormous: multiple new technologies and treatment trains may be required at each water reclamation plant as one or more pretreatment steps prior to filtration or adsorption may be required. The energy requirements associated with the use of these technologies to treat tens of thousands of acre-feet of wastewater per year are also potentially huge and could include power for high-pressure pumping and other pumps, raw material manufacture and transport, thermal energy for regeneration/reactivation, and waste handling and transport. The energy consumption and associated greenhouse gas emissions of these technologies draw into question their sustainability and use for wastewater treatment. The high energy and financial costs of complying with low MCLs may discourage water recycling efforts and may deter or significantly delay expansion of existing projects and/or implementation of new projects. This would reduce these important climate resilient local water supplies. It is evident that the EPA has not fully considered nor evaluated the costs or energy and greenhouse gas impacts stemming from recycled water compliance with the proposed MCLs. The Sanitation Districts urge the EPA to address the impacts of the MCLs on water reuse and develop the appropriate regulatory frameworks that govern the operation of these projects while still promoting the use of this sustainable climate-resilient local water resource.

EPA Response: Regarding the agency's consideration for greenhouse gas impacts for the rule, please see section 13.11 of the EPA response in this *Response to Comments* document. For additional discussion on water reuse applications, please see the EPA response to comment Doc. #1712, SBC-043517 in section 5.1.3 in this *Response to Comments* document.

Water Replenishment District (WRD) (Doc. #1754, SBC-044220)

May 30, 2023

Administrator Michael S. Regan

United States Environment Protection Agency 1200 Pennsylvania Avenue, NW

William Jefferson Clinton Bldg Room; EPA East Room 1309 Washington, DC 20004

RE: Public Comment on EPA's Proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation (Docket ID: EPA-HQ-OW-2022-0114)

Dear Administrator Regan,

In response to the Environmental Protection Agency's (EPA) request for public comments regarding the proposed National Primary Drinking Water Regulation for per- and polyfluoroalkyl substances (PFAS), the Water Replenishment District (WRD) is submitting this letter to provide our comments regarding the proposed regulation. We believe that implementing the proposed limits without accompanying accessible remediation funding mechanisms could inhibit some local water purveyors (i.e., groundwater pumpers) from providing safe and affordable drinking water to their communities.

The Water Replenishment District (WRD) is the largest groundwater agency by population in the State of California, managing and protecting local groundwater resources for four million residents. WRD's service area covers a 420-square-mile region of southern Los Angeles County, the most populated county in the United States. WRD is committed to managing and protecting the Central Basin and West Coast Basin, two of the most utilized urban groundwater basins in the nation.

We urge you to carefully consider the issue of effective and accessible funding as you finalize the rule. While it is important to protect public health from PFAS contamination, it is also vital to ensure the human right to water. It has been our experience that the existing California funding programs are often inaccessible and unnecessarily cumbersome which leaves many smaller water purveyors at a disadvantage, even though the State of California statutorily recognizes that "every human being has the right to safe, clean, affordable, and accessible water adequate for human consumption, cooking, and sanitary purposes."

Detailed herein is information regarding our agency, our efforts to date to address PFAS contamination in local groundwater, and the anticipated financial impacts of the proposed regulation without an effective means of funding for PFAS remediation projects.

WRD BACKGROUND

WRD was formed in 1959 by a vote of the people and our mission is to provide, protect, and preserve safe and sustainable groundwater supplies within the Central Basin and West Coast Basin. The 43 cities in our service area, including a portion of the City of Los Angeles, and other

unincorporated parts of Los Angeles County use about 220,000 (72 billion gallons) of groundwater annually which accounts for nearly half of the region's water supply needs.

WRD owns three water treatment facilities: two advanced water treatment facilities and a groundwater desalter. Through the operation of WRD's two advanced water treatment facilities, WRD provides supplemental replenishment water for delivery to two Los Angeles County Public Works infrastructure systems: the Montebello Forebay Spreading Grounds located in the northeast portion of the Central Basin and the Seawater Barrier Project injection wells located along the coast. Traditionally, imported water from the Colorado River or Northern California Bay-Delta was used to supplement these systems. However, through technological and regulatory advancements, recycled water can now be used for 100 percent of replenishment purposes, supplemented by imported water only as needed to maintain barrier demands.

By utilizing local replenishment alternatives, WRD has secured groundwater sustainability and reliability while using water that would have otherwise flowed unused to the ocean. Additionally, costs remain affordable to ratepayers and energy savings from using less imported water yields a valuable environmental benefit of reduced carbon emissions.

WRD PFAS REMEDIATION PROGRAM

WRD has a legacy of identifying and treating unwanted substances before they spread in groundwater. Since its establishment in 1991, WRD's Safe Drinking Water Program (SDWP) and Disadvantaged Communities Program (DAC) provides financial and technical assistance to drinking water purveyors seeking to remediate their production wells. Through these programs, WRD has secured millions in State grant funding for well remediation and other water system projects. WRD established the PFAS Remediation Program in August 2020, and builds on the tremendous success of SDWP and DAC.

The PFAS Remediation Program is one of the first of its kind in California to award grant funding to treat PFAS-impacted drinking water wells. There are 1,740,000 residents in WRD's service area who are served by public water systems that have PFOA or PFOS levels above the current state Response Level. Furthermore, 35-45% of this population, or roughly 700,000 people, live within census tracts that are classified as disadvantaged or severely disadvantaged. As WRD's service area includes about 4 million residents, nearly 45% of the WRD population is affected by PFAS-impacted wells.

With a current Program budget of over $60 million that was funded by local water purveyors in the Central Basin and West Coast Basin, WRD's PFAS Remediation Program provides either grants for pumpers to install their own treatment systems, or for WRD to design and construct treatment systems for them. The purpose of the Program is to ensure remediation projects could be implemented immediately to prevent unnecessary closures of wells and ensure continued access to low-cost, high-quality groundwater by preventing the spread of PFAS contamination. Thus far, a total of 14 groundwater pumpers have applied for funding from the Program, and funding agreements have been executed between WRD and six (6) pumpers, for a total funding amount of over $27 million.

WRD assists groundwater pumpers with applications for grant funding from the State and other sources for their PFAS remediation projects. In many cases, water purveyors that serve economically disadvantaged communities lack the resources to prepare and submit successful applications for grant funding. In addition, it is not uncommon for the total cost of the remediation project to exceed the funding amount that can be provided from WRD's PFAS Program, and therefore the water purveyor requires additional funding to offset the cost of their project.

IMPACTS OF THE PROPOSED PFAS REGULATION

Perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) have been detected at concentrations greater than the proposed Maximum Contaminant Levels (MCLs) in drinking water wells, particularly those located in the northeast portion of the Central Basin, referred to as the Montebello Forebay (see attached Figure 1). The Montebello Forebay is critical to WRD's groundwater replenishment operations because it is a region where surface and recycled water infiltrate into the subsurface to directly recharge multiple unconfined drinking water aquifers. Contaminants in groundwater within this region can spread easily and quickly both laterally and vertically due to the nature of the underlying geology.

At the time when California established Response Levels (RLs) for PFAS, approximately 45% of the drinking water wells in the WRD service area exceeded the RLs. If the new MCLs are adopted, which are significantly lower than the RLs, the number of impacted drinking water wells would jump to approximately 70%, bringing the total of impacted wells to approximately 98 drinking water wells. Based on WRD's estimates, it would cost approximately $160 million (capital costs only) to remediate all 98 impacted drinking water wells. Without State or Federal funding assistance to offset remediation costs, it is cost prohibitive for many water purveyors in WRD's service area.

While the WRD PFAS Remediation Program offers a remedy for some of the water purveyors in the Central Basin and West Coast Basin, the funding for the Program places an undue and unsustainable burden on the groundwater pumping community. The pumping community came together and voluntarily contributed to a PFAS fund despite having no responsibility for the PFAS contamination. Furthermore, many of the impacted drinking water wells are located within Disadvantaged Communities (DACs) and Severely Disadvantaged Communities (SDACs), as depicted in the attached Figure 1.

CONCLUSION

WRD is concerned that without effective and accessible funding mechanisms for PFAS treatment in our service area, the proposed MCLs will likely result in the unintended consequence of prohibiting smaller water purveyors, especially those that serve DACs and SDACs, the use of the local groundwater supply and force them to rely on expensive and unsustainable imported water supplies.

Since WRD and its pumping community are not the responsible entities for contaminating the groundwater basins with PFAS, and presently no other party has been held accountable, it is critical that WRD and the pumping community receive timely funding assistance to address this very serious risk to basin water quality. Furthermore, to be effective, funding programs need to be streamlined to be accessible so that smaller water purveyors that are under resourced can receive funding in an expeditious manner.

WRD respectfully urges the EPA to consider the need for streamlined and accessible funding programs to implement in tandem with the proposed regulation. Without this funding structure in place, an undue burden will be placed on our most underserved and economically fragile communities. WRD appreciates and supports the EPA's commitment to protecting public health and leveraging the best available science to establish nationwide, health-protective standards for PFAS in drinking water.

Sincerely,

Stephan Tucker, MBA, PE, PMP

General Manager, Water Replenishment District

Attachment: Figure 1

Figure 1. PFOA/PFOS Detections in Drinking Water Wells in the Central Basin and West Coast Basin

[Figure 1: See docket ID EPA-HQ-OW-2022-0114-1754]

EPA Response: For additional discussion on cost considerations for the final MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document. For additional considerations on funding and BIL, please see section 2.4 of the EPA response in this *Response to Comments* document.

WaterPIO (Doc. #1624, SBC-043473)

(Of course, landing on 4ppt each makes the health advisories look even more ridiculous. The EPA set the HAs at parts per quadrillion (ppq) levels, 4 ppq for PFOA and 20 ppq for PFOS. The agency clearly ignored the error rate for testing at ppq levels; it can be as high as FIFTY percent. Because the numbers are so unreliable, ppq testing results are unreportable to the public, even when water systems could show their customers they are in the clear for PFAS.

Again, the EPA put public water in a position to fail.)

EPA Response: The EPA notes that the final MCLs consider feasibility: The EPA's final rule represents data-driven drinking water standards that are based on a thorough analysis of feasibility consistent with requirements under SDWA. For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations), 5.1.3 (cost considerations and alternative MCLs) and 5.1.4 (for treatment considerations) of the EPA

response in this *Response to Comments* document. Please see section 7 of the EPA response in this *Response to Comments* document for additional discussion on validated analytical methods to meet the monitoring requirements of this NPDWR. The commenter did not provide further explanation nor supporting information regarding claims that "the agency clearly ignored the error rate for testing at ppq levels; it can be as high as FIFTY percent." Further, HAs are beyond the scope of this action. HAs are not regulations and should not be construed as legally enforceable federal standards.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043657)

APPENDIX-B

Rate Impacts of BWWB's Ongoing and Emerging Compliance and Infrastructure Needs

(Excluding the PFAS Rule)

BWWB believes that USEPA's cost analysis was considered in a vacuum without addressing the impact of other compliance and infrastructure needs, such as:

• LCRR compliance

• Risk reduction and aging infrastructure (AWIA)

• Non-revenue water (NRW) control

The financial conditions of BWWB can be briefly described using three metrics: annual capital budget, annual O&M budget and planned annual revenue. Table B1 presents the baseline of BWWB's financial conditions. A preliminary estimate for the compliance and aging infrastructure costs in the next 5 years resulting from the three regulations mentioned above was added on the baseline to calculate the rate increase and affordability challenges BEFORE the proposed PFAS Rule. The results are presented in Table B1 on the subsequent page.

Table B1. Baseline Capital and O&M Budget with additional LCRR, AWIA and NRW Control Compliance Costs

[Table B1: See Docket ID EPA-HQ-OW-2022-0114-1602]

Table B2 below summarizes the impacts on BWWB's ratepayers in the next 5 years resulting from the ongoing and emerging compliance and infrastructure needs. Please refer to the Executive Summary Letter for the detailed explanation of Table B2.

Table B2. Impacts on ratepayers and BWWB by LCRR, AWIA and NRW Control Compliance

[Table B2: See Docket ID EPA-HQ-OW-2022-0114-1602]

EPA Response: For additional discussion on cost considerations for the final MCLs and alternative MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA has carefully considered all public comments regarding the cost analysis

and made numerous changes to the costs analyses as recommended by commenters. Specific changes made to EPA's cost analysis for the file rule are detailed in the sections 13.3.1 through 13.3.6 of the EPA response in this *Response to Comments* document. The agency also notes significant quantified and non-quantifiable benefits as a result of implementing this NPDWR. Evaluating aging water infrastructure and non-revenue water control are not part of routine compliance sampling in drinking water regulations and thus are not accounted for in the EPA's cost analysis. Moreover, SDWA section 1412(b)(3)(C)(i)(III) requires that EPA include quantifiable and non-quantifiable costs that are likely to occur solely as a result of compliance with the MCL. Therefore, actions taken in other rules (such as the Lead and Copper Rule Revisions) and other programs (replacement of aging water infrastructure) are beyond the scope of this rulemaking.

Water Works Operators' Association of Pennsylvania (WWOAP) (Doc. #1604, SBC-042827)

April 21, 2022

Environmental Quality Board

P.O. Box 8477

Harrisburg, PA 17105-8477 eComments

RegComments@pa.gov

RE: Regulation #7-569: Safe Drinking Water PFAS MCL Rule

Dear Environmental Quality Board:

The Water Works Operators' Association (WWOAP) (www.wwoap.org) is a nonprofit group of members dedicated to increasing the knowledge and expertise of those working at all levels and in all sectors of Pennsylvania's water supply industry. We provide information regarding public water supply design, construction, treatment, and management. For nearly a century, WWOAP has existed to help strengthen and promote the water industry.

The WWOAP supports the proposed rulemaking which will improve public health protection by setting maximum contaminant level goals (MCLG) and maximum contaminant levels (MCL) for two per- and polyfluoroalkyl substances (PFAS) – perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS).

The proposed amendments are intended to protect public health by setting state MCLs for contaminants in drinking water that are currently unregulated at the federal level. If the proposed amendments were adopted, Pennsylvania would move ahead of the federal Environmental Protection Agency (EPA) in addressing PFOA and PFOS in drinking water and join a small group of states that have set MCLs for select PFAS in drinking water.

In addition, the EPA is also moving forward with the MCL process as outlined in the federal Safe Drinking Water Act (SDWA) for perfluorooctanoic acid (PFOA) and perfluorooctane

sulfonate (PFOS). EPA expects to publish a proposed rule by Fall 2022 with a final rule expected Fall 2023. Therefore, Pennsylvania may need to adjust this proposed rulemaking if the EPA were to put forth its own rulemaking with conflicting or more stringent MCLs for PFOA and PFOS.

On July 29, 2021, a pre-draft version of the proposed rulemaking was presented to the Public Water System Technical Assistance Center (TAC) Board of which WWOAP is a member. The TAC unanimously voted to support the Department of Environmental Protection (DEP) moving forward in the rulemaking process to present a proposed PFAS Rule to the EQB. [FN1: Minutes of the July 29, 2021, Meeting – Public Water System Technical Assistance Center (TAC) Board https://files.dep.state.pa.us/PublicParticipation/Advisory%20Committees/AdvCommPortalFiles/TAC/2022/Draft_Minutes_Ju l_29_2021_TAC_meeting.pdf.]

Currently, EPA's health advisory limit (HAL) is 70 parts per trillion (ppt) for the combined concentrations of PFOS and PFOA. Since PFAS are unregulated, there is no MCL. However, our ability to detect has outpaced our ability to understand the significance.

DEP conducted a statewide sampling plan which began in June 2019. DEP identified 493 public water system sources as potential sampling sites because they met the criterion of being located within a half mile of a potential source of PFAS contamination, such as military bases, fire training sites, landfills, and manufacturing facilities.

Of those, DEP tested 372 targeted sites and 40 additional sites (for a total of 412) that were not located within a half mile of a potential source of PFAS contamination to establish a baseline.

Of the PFAS chemicals sampled, PFOS and PFOA were most common, being detected at 103 and 112 sites, respectively. Of the sites with detections, only eight PFAS were detected. The eight PFAS that were detected are: PFOS, PFOA PFNA, PFHxS, PFHpA, PFBS, Perfluorohexanoic acid (PFHxA), and Perfluoroundecanoic acid (PFUnA). Results were non-detect for the other 10 PFAS that were tested.

Of the 412 total samples, two of the results were above the EPA's HAL of 70 ppt for the combined concentrations of PFOS and PFOA: State of the Art, Inc. in Centre County, and Saegertown Borough in Crawford County.

The proposed rulemaking includes a proposed PFOA MCL of 14 ppt that is a 90% improvement in health protection as compared to the current EPA HAL of 70 ppt.

In addition, the proposed rulemaking includes a proposed PFOS MCL of 18 ppt that is a 93% improvement in health protection as compared to the current EPA HAL of 70 ppt.

Public water systems can treat source water with granular activated carbon (GAC), anion exchange (IX), and reverse osmosis (RO) (e.g., high-pressure membrane systems) to remove PFOS and PFOA from drinking water.

According to DEP's Table 16 (GAC Treatment Costs), "the average capital cost for the GAC treatment was $3,457,110 per million gallons per day (MGD) per entry point (EP) with an average annual operation and maintenance (O&M) cost of $171,970 per MGD per EP." [FN2:

Proposed Rulemaking – Safe Drinking Water PFAS MCL Rule, pg. 36, Table 16. GAC Treatment Costs http://www.irrc.state.pa.us/docs/3334/AGENCY/3334PRO.pdf]

Moreover, DEP's Table 17 (IX Treatment Costs), "the average capital cost for the IX treatment was $3,284,360 per MGD per EP with an average annual O&M cost of $155,666 per MGD per EP." [FN3: Proposed Rulemaking – Safe Drinking Water PFAS MCL Rule, pg. 36-37, Table 17. IX Treatment Costs http://www.irrc.state.pa.us/docs/3334/AGENCY/3334PRO.pdf]

In addition to treatment costs, the proposed rulemaking also imposes significant compliance monitoring costs. Specifically, the proposed rule requires initial quarterly monitoring for community and nontransient noncommunity systems serving a population of more than 350 persons beginning January 1, 2024. It also will require repeat compliance monitoring on a quarterly basis for any EPs at which either PFOA or PFOS is detected at a level above its respective minimum reporting limit (MRL), including those EPs at which one or both MCLs are exceeded. If the quarterly repeat monitoring results are reliably and consistently below the MCLs, the frequency of repeat monitoring may be reduced from quarterly monitoring to annual monitoring. Table 15 on page 35 of the proposed rulemaking summarizes the overall cost estimates for compliance monitoring costs in each of the first four years of rule implementation. According to DEP, "the average annual monitoring costs over the first four years are $4,397,916." [FN4: Proposed Rulemaking – Safe Drinking Water PFAS MCL Rule, pg. 35, Table 15. Compliance Monitoring Costs http://www.irrc.state.pa.us/docs/3334/AGENCY/3334PRO.pdf]. WOAP recommends that DEP consider accepting UCMR5 sampling results which begin in January, 2023 for many water systems. The UCMR5 sampling results should be accepted as the initial monitoring with reduced monitoring, as appropriate, beginning with the effective date of this regulation. Systems that do not detect PFAS or that have demonstrated through UCMR5 sampling to be consistently and reliably below the proposed MCLs should be able to discontinue quarterly sampling for another year after the UCMR5 sampling is completed. This would be a considerable cost saving to systems for compliance monitoring.

The WWOAP is concerned that the cost for monitoring and treatment will ultimately be much higher than those estimated for the proposed MCLs of 14 ppt for PFOA and 18 ppt for PFOS. The WWOAP is also concerned with the potential impact that the actual costs will have on community water systems, particularly small systems which make up the majority of our members. Therefore, it is imperative that the "Compliance Assistance Plan" [FN5: Compliance Assistance Plan, page 38 http://www.irrc.state.pa.us/docs/3334/AGENCY/3334PRO.pdf] be adequately funded to help community water systems offset the costs of this proposed rulemaking.

The WWOAP appreciates the opportunity to present these comments on this proposed rulemaking and respectfully requests the EQB's consideration.

Respectfully submitted,

Serena A. DiMagno

Legislative/Regulatory Affairs Committee Chairman

WWOAP

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EPA Response: For additional discussion on cost considerations for the final MCLs and alternative MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document. For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document. With respect to the agency's cost analysis, the EPA has carefully considered all public comments regarding the cost analysis and made numerous changes to the costs analyses as recommended by commenters. Specific changes made to EPA's cost analysis for the file rule are detailed in sections 13.3.1 through 13.3.6 of the EPA response in this *Response to Comments* document. The EPA notes that the agency did not propose standards (nor alternative MCLs) for PFOS at 14 or 18 ppt and subsequently did not consider these alternative thresholds in the EPA's cost analyses. With respect to funding concerns, please see section 2.4 of the EPA response in this *Response to Comments* document. Finally, considerations for international and state drinking water standards is further discussed in section 5.1.5 of the EPA response in this *Response to Comments* document.

Superfund Settlements Project (SSP) and RCRA Corrective Action Project (RCAP) (Doc. #1631, SBC-043434)

EPA failed to consider the costs of the Proposal at CERCLA and RCRA Corrective Action sites.

The SDWA requires EPA to conduct a Health Risk Reduction and Cost Analysis when proposing a NPDWR. [FN40: 42 U.S.C. § 300g-1(b)(3)(C)(i).] EPA is relying on its Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation [FN41: EPA-822-P-23-001 (March 2023).] (the "Economic Analysis") to fulfill this statutory mandate. The Economic Analysis, however, fails to consider a direct and substantial cost that will follow from the Proposal: costs in connection with remediation of contaminated

sites under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 ("CERCLA") [FN42: 42 U.S.C. §§ 9601 et seq.] and the Resource Conservation and Recovery Act. [FN43: 42 U.S.C. §§ 6901 et seq] Relatedly, the Economic Analysis fails to consider and recognize the very limited environmental benefit that would result from the Proposal.

CERCLA Section 121(d) requires that on-site remedial actions attain or waive federal environmental Applicable or Relevant and Appropriate Requirements ("ARARs"), or more stringent state environmental ARARs, upon completion of the remedial action. [FN44: 42 U.S.C. § 9621(d) et seq.] The 1990 National Oil and Hazardous Substances Pollution Contingency Plan also requires compliance with ARARs during removal and remedial actions at Superfund sites to the extent practicable. [FN45: 40 C.F.R. §300.400(g).] For water that is to be used for drinking, MCLs are clearly ARARs. [FN46: 40 C.F.R. § 300.430(e)(2)(i); see also USEPA, CERCLA Compliance with Other Laws Manual: Interim Final, EPA/540/G-89/006 at 4-8 (August 1988).] In addition, MCLs are relevant and appropriate as in situ cleanup standards where either surface water or ground water is or may be used for drinking water, which includes where an aquifer is considered to have any potential for use as drinking water but where no such use is currently occurring, planned, necessary or reasonably anticipated. [FN47:Id] In addition, to account for the potential future usability option, an MCL can come into play even for "unusable" groundwater (e.g., highly saline or having high total dissolved solids).

Consistent with CERCLA, the RCRA corrective action program bases cleanup levels on the maximum potential beneficial use of the groundwater. Thus, cleanup levels are generally set at a level that would be protective for drinking water use, with EPA adopting existing cleanup standards, generally MCLs or state drinking water standards. [FN48: See, e.g., 61 Fed. Reg. 19449.]

There are more than 1,300 Superfund sites and 3,700 RCRA corrective action sites. The Proposed Rule fails to identify these entities as affected; [FN49: See 88 Fed. Reg. 18642.] however, the sites would clearly be affected by the Proposal and the cost would be significant. Adding treatment of PFAS to the levels set forth in the Proposal will result in increased operating costs as well as longer remediation times, yet there would be no health risk reduction benefit. EPA already can set site-specific health-based clean up criteria. [FN50: See, e.g., National Contingency Plan, 40 C.F.R. Part 300; USEPA, Handbook of Groundwater Protection and Cleanup Policies for RCRA Corrective Action, EPA530-R-04-030 (April 2004).] Where the costs so expansively outweigh the benefit, a regulatory action cannot be justified.

This imbalance between cost/benefit is particularly troublesome at sites where PFAS had not been manufactured, used, disposed or discharged. It is reasonable to believe that, given that PFAS are ubiquitous, PFAS will be detected at numerous Superfund and RCRA corrective action sites and, at many of these sites, there would have been no manufacturing, use, disposal or discharge of PFAS at the site itself. By requiring responsible parties to remediate PFOA and PFOS at these Superfund and RCRA corrective action sites to the proposed MCLs, EPA will essentially be asking them to clean up to below background levels while nearby areas exhibit

similar levels at ambient conditions. The cost to treat groundwater to the proposed MCLs will have a substantial impact on remediation costs, costs EPA failed to consider in its Economic Analysis.

Importantly, for those sites where responsible parties are essentially cleaning up background PFAS groundwater contamination, there will be little to no environmental benefit since the site may essentially become an island in a sea of low-level PFAS contamination. Particularly at CERCLA sites, because of CERCLA's liability scheme, these extremely low MCLs will result in delays of the overall site cleanup such that these levels will be a detriment rather than benefit to the environment. Where a hazardous substance is present, CERCLA liability can attach, regardless of concentration. [FN51: See, e.g., A&W Smelter & Refiners V. Clinton, 146 F.3d 1107, 1110 (9th Cir. 1989).] CERCLA further creates a strict liability scheme that imposes liability regardless of whether the Potentially Responsible Party's ("PRP's") actions at the time of disposal were negligent, in accordance with the regulations in place at the time, or consistent with industry best practices. CERCLA also provides for joint and several liability: if there is more than one PRP, any one of those PRPs may be held liable for the entire site cleanup regardless of the number of other PRPs. [FN52: See Burlington Northern and Santa Fe Ry. Co. v. United States, 556 U.S. 599 (2009).] Nor is CERCLA temporally limited: although federal laws are generally not interpreted as having retroactive application absent an explicit statement that they should be applied retroactively, CERCLA has been interpreted to apply to both current and former PRPs and for past releases. [FN53: See, e.g., Commonwealth Edison Co. v. United States, 271 F.3d 1327, 1350-51 (Fed. Cir. 2001); United States v. Monsanto Co., 858 F.2d 160, 174 (4th Cir. 1988); United States v. Northeastern Pharm. & Chem Co., 810 F.2d 726, 734 (8th Cir. 1986). Note, however, that no court has considered whether Section 102(a) can be applied retroactively, an open question given the general position that retroactivity is not favored by the law. See, e.g., Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 208-09 (1988).]

EPA typically pursues a few "deep pocket" PRPs for whom they seek strict, joint and several liability. [FN54: Probst, Katherine N., Superfund at 40: Unfulfilled Expectations, Chapter 6, at 232 ("Unfairness can result from the way EPA implements the law as well. PRPs complain in particular that EPA often picks a subset of PRPs to target with a notice letter and ask to enter into a settlement at a site.")] EPA then leaves it to those PRPs to gain cooperation from others, and, when cooperation is not forthcoming, CERCLA provides a right to pursue contribution. [FN55: See 42 U.S.C. § 9613(f).] Where significant costs will be incurred to address substances for which no PRP is responsible, however, gaining cooperation will be extremely challenging. That, in turn, will result in delays in addressing contamination. The impact of setting MCLGs and MCLs at levels far below those needed for public health protection are especially concerning since a CERCLA "release" giving rise to such liability for a site surrounded by anthropogenic, ambient elevated concentrations will require significant investigation and remediation, all the while adding no further health benefit to the communities that the MCL was intended to protect.

The same is true for RCRA corrective action sites. While some of the same concerns regarding liability and allocation may not apply, RCRA corrective action has its own long arm and the

concerns regarding addressing contamination unrelated to a site and/or at ambient levels are the same. RCRA corrective action is required for all releases of hazardous waste or constituents from any solid waste management unit, whether permitted or not, on-site or off-site, and regardless of when the release occurred. [FN56: 42 U.S.C. § 6924(u), (v).]

EPA, at the discretion of the Administrator, may establish less stringent MCLs if achieving the MCL could result in an increase in health risks from other contaminants. [FN57: 42 U.S.C. § 300g-1(b)(5).] While this section is not directly applicable, this is the case here in connection with contaminated sites requiring remediation, and EPA should have considered this in its Economic Analysis.

If EPA finalizes the Proposal (whether in part or in whole), SSP and RCAP urge EPA to consider granting a nationwide variance to contaminated remediation sites using either SDWA Section 1415 or 1416 [FN58: 42 U.S.C. §§ 300g-4, 300g-5.] where site groundwater is not used for drinking water and adequate drinking water supply is present and reasonably expected to be present in the future. Alternatively, while not the purview of the Office of Water, another alternative way to address these significant issues would be to issue a blanket ARAR waiver at Superfund sites and similar policy for RCRA corrective action sites.

EPA Response: For additional discussion on cost considerations for the final MCLs and alternative MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document. SDWA § 1416(a) and (b)(2)(C) describe how the EPA or states may also grant an exemption for PWSs meeting specified criteria that provides an additional period for compliance. Regarding exemptions, please see section 12.1 of the EPA response in this *Response to Comments* document. Further, the EPA notes that application of MCLs in non-drinking water programs (such as water quality criteria, NPDES, or CERCLA cleanups) is beyond the scope of this rulemaking; please see section 15.1 of the EPA response in this *Response to Comments* document for additional discussion on comments outside the scope of this NPDWR.

Inland Empire Utilities Agency (IEUA), California (Doc. #1666, SBC-043391)

EPA also fails to acknowledge that these proposed MCLs may be considered when developing wastewater effluent limits as health-based water quality standards to protect water quality of receiving water that have municipal or domestic supply beneficial use or groundwater recharge opportunities.

As result, IEUA believes that EPA's economic assessment is incomplete and does not adequately capture increasing capital and operational costs for water, wastewater, and water recycling agencies required to meet compliance.

EPA Response: For additional discussion on cost considerations for the final MCLs and alternative MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA notes that application of MCLs in non-drinking water programs (such as water quality criteria, NPDES, or CERCLA cleanups) is beyond the scope of this rulemaking;

please see section 15.1 of the EPA response in this *Response to Comments* document for additional discussion on comments outside the scope of this NPDWR.

Aurora Water, City of Aurora, Colorado (Doc. #1669, SBC-043725)

There will also be increased energy demand as more treatment facilities are constructed and treatment material regeneration facilities are needed. Both activities will increase coal mining, which will have its own environmental impacts and should be considered in EPA's cost estimates.

EPA Response: For additional discussion on cost considerations for the final MCLs and alternative MCLs, please see section 5.1.3. The EPA has considered the costs or electricity usage and energy demand. For the EPA's response on greenhouse gas emissions associated with the rule, see section 13.11 in this *Response to Comments* document.

Northwest Biosolids Association et al. (Doc. #1783, SBC-043805)

Limits in any media, including drinking water, should be set with the understanding that it exists in the background of the environment and everyday life. To impose limits on the water industry to address PFAS, which is only a passive receiver of these compounds, while allowing the other industries that also use and provide products containing PFAS to consumers and the environment, is unbalanced and incomplete.

Humans and the environment as exposed to PFAS in many other media, and in much greater quantities. Therefore, the cost-benefit to achieve these regulatory requirements in the water industry needs to be weighed against the cost-benefit of removing it from food packaging, personal care products, clothing, and other direct and indirect exposure routes.

Sincerely,

Northwest Biosolids Association Midwest Biosolids Association Mid-Atlantic Biosolids Association Southeast Biosolids Association

Northeast Biosolids and Residuals Association Virginia Biosolids Council

James Dunbar

President

Northwest Biosolids

Albert Cox, PhD,

President

Midwest Biosolids

Mary Firestone

Executive Director

Mid-Atlantic Biosolids

Felicia Morrissette

Interim Executive Director

Southeast Biosolids Association

Janine Burke-Wells

Executive Director

Northeast Biosolids and Residuals

Robert G. Crockett

Executive Director

Virginia Biosolids Council

EPA Response: For additional discussion on cost considerations for the final MCLs and alternative MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA notes that removing PFAS in consumer products is beyond the scope of this rulemaking; please see section 15.1 of the EPA response in this *Response to Comments* document for additional discussion on comments outside the scope of this NPDWR.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045907)

EPA has seriously underestimated the costs of the proposed rule on regulated entities, and, by the Chamber's and others' estimates, the costs are expected to be significant. The significant costs of this rulemaking indicate EPA has failed to satisfy the SDWA requirements for feasibility in regulation, by failing to demonstrate that the proposed MCLs are as close to the MCLGs as "feasible" and that the combination of technology, treatment techniques, or other means required to meet the MCLs are not "more stringent than is feasible." EPA cannot finalize the rule as proposed without addressing these SDWA requirements.

EPA Response: The EPA disagrees with the commenter that the agency did not address SDWA requirements in setting the MCLs as close as feasible to the MCLG. Please see sections 5.1.2 (laboratory considerations, including capacity and capability), section 5.1.3 (cost considerations and alternative MCLs), and 5.1.4 (treatment considerations) of the EPA response in this *Response to Comments* document. Additionally, please see section 13 of the EPA response in this *Response to Comments* document.

Metropolitan Water District of Southern California (Doc. #1777, SBC-045437)

Since the proposed MCLs are almost certain to have a significant economic impact, Metropolitan recommends that EPA first decide whether to issue a final determination to regulate PFHxS, GenX chemicals, PFNA, and PFBS, in addition to PFOA and PFOS (see comment #1). If EPA decides to regulate some or all of these PFAS, it should then follow the required process of conducting an economic feasibility assessment for any proposed MCL(s) and consider all comments received in this NPDWR rulemaking and any future related rulemakings.

EPA Response: The EPA followed SDWA requirements in setting the MCLs as close as feasible to the MCLG. Please see sections 5.1.2 (laboratory considerations, including capacity and capability), section 5.1.3 (cost considerations and alternative MCLs), and 5.1.4 (treatment considerations) of the EPA response in this *Response to Comments* document. Regarding EPA's regulatory determinations for PFHxS, PFNA, HFPO_DA and mixtures of these three PFAS and PFBS, please see section 3 of this *Response to Comments* document.

5.1.4 Treatment Considerations

Summary of Major Public Comments and EPA Responses

Many commenters agree with the EPA's determination that feasible technologies exist to treat to the final MCLs based on their experience of full-scale use and/or existing case studies while some contend that feasible technologies are not available to support implementation of the final MCLs. With respect to the agency's feasibility analysis as it pertains to treatment technologies, the EPA evaluates the availability and performance of BATs for treating water to minimize the presence of the contaminant as well as the costs of applying those BATs to large metropolitan water systems when treating to that level (1412(b)(4)(E) and (5)). The definition of "feasible" means feasible with the use of best technology…"which includes consideration of the analytical limits of the best available treatment technology." *See* S. Rep. No. 169, 104th Cong., 1st Sess. (1995) at 3. To designate technologies as BATs, the EPA evaluated each technology against six BAT criteria, including whether there is a reasonable cost basis for large metropolitan water systems. The EPA evaluated whether the technologies are currently being used by systems, whether there were treatment studies available with sufficient information on design assumptions to allow cost modeling, and whether additional research was needed (USEPA, 2024e). In considering the results of this information, the EPA determined that these costs are reasonable to large metropolitan water systems. Please see section X of the final rule preamble and section 10 of the EPA's *Response to Comments* document for additional discussion on treatment technologies including BAT identification and evaluation.

Pursuant to SDWA § 1412(b)(4)(E)(ii), the agency also evaluated "technolog[ies], treatment technique[s], or other means that is affordable" for small PWSs. In this evaluation, the agency determined that the costs of SSCTs to reach 4.0 ng/L are affordable for households served by small drinking water systems. Additionally, the EPA notes that SDWA § 1412(b)(4)(D) states that "granular activated carbon is feasible for the control of synthetic organic chemicals" which

the agency lists as a BAT for this rule (section X). All PFAS, including PFOA and PFOS, are Synthetic Organic Chemicals (SOCs), and therefore, GAC is BAT as defined by the statute. For additional discussion on BATs and SSCTs, please see section X of the final rule preamble.

Individual Public Comments

Michigan Farm Bureau (MFB) (Doc. #1562, SBC-043357)

The WHO reported [FN10: World Health Organization. 2022. PFOS and PFOA in Drinking Water: Background Document for Development of WHO Guidelines for Drinking-water Quality, Version for Public Review issued 29 September, 2022. WHO/SDE/WSH/XXXXXX. Retrieved from: https://www.cmbg3.com/library/WHO-Draft-Drinking-Water-Document.pdf] on PFAS levels in drinking water from the Unregulated Contaminant Monitoring Rule third round update (UCMR-3), noting that in 2013-2015, average concentration of treated drinking water from groundwater sources was 45 ppt of PFOA and 199 ppt of PFOS, and from mixed groundwater/surface water sources was 33 ppt of PFOA and 47 ppt of PFOS. For comparison, the State of Michigan has regulated seven PFAS chemicals since 2020, setting MCL limits of:

• PFOA: 8 ppt

• PFOS: 16 ppt

• PFNA: 6 ppt

• PFHxS: 51 ppt

• PFBS: 420 ppt

• GenX: 370 ppt

• PFHxA: 400,000 ppt (this is not a chemical being proposed for MCL in EPA's rule)

The Michigan PFAS Action Response Team (MPART), a multi-agency work group tasked with coordinating on PFAS monitoring at a range of sources, reported utility treated drinking water mean concentrations across the state: [FN11: Means calculated from: Michigan PFAS Action Response Team. 2023. Statewide PFAS Survey of Public Water Supplies. Retrieved from: https://www.michigan.gov/pfasresponse/drinking-water/statewide-survey.]

• PFOA: 10.45 ppt (range: non-detect to 780 ppt)

• PFOS: 13.64 ppt (range: non-detect to 740 ppt)

• PFNA: 5.86 ppt (range: non-detect to 14 ppt)

• PFHxS: 9.81 ppt (range: non-detect to 67 ppt)

• PFBS: 9.85 ppt (range: non-detect to 230 ppt)

• GenX: no results reported

• PFHxA: 7.09 ppt (range: non-detect to 79 ppt)

This demonstrates that even with robust water treatment requirements already in place, some drinking water utilities will struggle to meet EPA's proposed PFAS MCL limits. MPART's surface water sampling in locations across the state also had significant variation in PFAS concentrations, with mean concentrations of: [FN12: Means calculated from: Michigan PFAS Action Response Team. 2023. PFAS Surface Water Sampling. Retrieved from: https://www.michigan.gov/pfasresponse/investigations/sites-aoi.]

• PFOA: 13.55 ppt (range: 0.19 to 7,700 ppt)

• PFOS: 46.37 ppt (range 0.28 to 11,000 ppt)

• PFNA: 1.00 ppt (range: non-detect to 97 ppt)

• PFHxS: 4.49 ppt (range: non-detect to 549 ppt)

• PFBS: 2.45 ppt (range: non-detect to 83.5 ppt)

• GenX: 1.33 ppt (range: non-detect to 14 ppt)

• PFHxA: 5.59 ppt (range: non-detect to 690 ppt)

While sampled surface water sites are weighted heavily toward site investigations with known or suspected PFAS sources entering the surface water, it is crucial to note that first, these results include sampling done after drinking water, surface water, and groundwater regulatory limits have already been set, and second, that particularly the concentrations of PFOA and PFOS are in some samples much higher than MCLs, making background or raw water concentrations of PFAS including PFOA and PFOS to be a significant challenge to treat to MCL levels of 4 ppt.

EPA Response: Regarding responses regarding the agency's evaluation of feasible treatment technologies for the final NPDWR, please see section 5.1.4 of the EPA response in this *Response to Comments* document. Regarding how the EPA considers state data, the agency relied on multiple data sources, including UCMR 3 and state finished water data, to evaluate the occurrence of PFOA, PFOS, PFHxS, PFNA, and HFPO-DA and probability of co-occurrence of these PFAS and PFBS. The EPA also incorporated both the UCMR 3 and some state data into a Bayesian hierarchical model which supported exposure estimates for select PFAS at lower levels than were measured under UCMR 3. The specific modeling framework used to inform this regulatory action is based on the peer-reviewed model published in Cadwallader et al. (2022). The EPA acknowledges that the available data were collected under varying circumstances; for example, targeted vs. non-targeted monitoring (i.e., monitoring not conducted specifically in areas of known or potential contamination). The EPA primarily considers finished drinking water data in the agency's occurrence analysis as this is the most reflective of conditions to determine whether a contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in PWSs with a frequency and at levels of public health concern. A comprehensive discussion of all the available state PFAS drinking water occurrence data is

included in the *Occurrence Technical Support Document* (USEPA, 2024a). For additional discussion on internal and state drinking water standards and guidelines, please see section 5.1.7.

The EPA acknowledges responses that while it may be challenging for some systems to treat to the MCL, the history of full-scale use of the designated BATs provide evidence that the BATs could treat to or below the MCL. Section 1412(b)(4)(E) of SDWA requires that the agency "list the technology, treatment techniques, and other means which the Administrator finds to be feasible for purposes of meeting [the MCL]," which are referred to as BATs. The EPA examined the following criteria for identifying feasible BATs: 1) The capability of a high removal efficiency; (2) a history of full-scale operation; (3) general geographic applicability; (4) reasonable cost based on large and metropolitan water systems; (5) reasonable service life; (6) compatibility with other water treatment processes; and (7) the ability to bring all the water in a system into compliance. Please see section 10 of the EPA response in this *Response to Comments* document for additional discussion on treatment technologies.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045036)

Treatment Technologies

An analysis of NJDEP records shows that facilities can reliably and consistently achieve levels of PFNA, PFOA, and PFOS close to or below detection levels (0.53 ppt to 5 ppt) through carefully designed and operated PFAS treatment. All detections of PFOA or PFOS were below New Jersey's MCLs of 14 ppt for PFOA and 13 ppt for PFOS for both GAC and AIX treatment technologies.

In addition to the 24 facilities with permanent treatment for PFAS, permits have been submitted to NJDEP for installation of PFAS treatment at approximately 90 additional facilities. These facilities are in various stages of completing the permitting process and constructing PFAS treatment. Records indicate that these facilities are designing their treatment systems to achieve finished water levels of PFOA and PFOS ranging from less than 1 ppt to 40 ppt.

EPA Response: The EPA acknowledges commenter's statement that, based on NJDEP records, "facilities can reliably and consistently achieve levels of PFNA, PFOA, and PFOS close to or below detection levels (0.53 ppt to 5 ppt) through carefully designed and operated PFAS treatment." Regarding the agency's evaluation of feasible treatment technologies for the final NPDWR, please see section 5.1.4 of this of the EPA response in this *Response to Comments* document. For additional discussion on treatment technologies, please see section 10 of the EPA response in this *Response to Comments* document.

Environmental Working Group (EWG) (Doc. #1721, SBC-045412)

EPA's proposed MCLS are feasible.

SDWA requires an MCL to "be as close to the maximum contaminant level goal as is feasible" and defines feasibility as, "feasible with the best technology…and other means which the

Administrator finds, after examination of efficacy under field conditions… are available."[FN47: 42 U.S.C. [sec] 300g-1(b)(4)(D).] SDWA further specifies that "granular activated carbon is feasible for the control of synthetic organic chemicals" and that any other technology "must be at least as effective …as granular activated carbon." [FN48: Id.]

EPA Response: The EPA agrees that the MCLs for this regulatory action are set as levels as close as feasible to the MCLG. Regarding the agency's evaluation of feasible treatment technologies for the final NPDWR, please see section 5.1.4 of the EPA response in this *Response to Comments* document. For additional discussion on treatment technologies, please see section 10 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046103)

ii. EPA's Proposed PFOA and PFOS MCLs are Feasible Using Readily Available Detection and Treatment Technologies

EPA's proposed PFOA and PFOS MCLs are "as close . . .as is feasible" to those chemicals' MCLGs, as required by the SDWA. [FN65: 42 U.S.C. § 300g-1(b)(4)(B).] The SDWA defines feasibility as "feasible with the use of the best technology" that has been tested under "field conditions" and is "available." [FN66: 42 U.S.C. § 300g-1(b)(4)(D).] When it amended the SDWA in 1986, Congress specified that "granular activated carbon is feasible for the control of synthetic organic chemicals," like PFAS. [FN67: Pub. L. No. 99-339, 100 Stat. 642, 644-645 (June 19, 1986) (currently codified at 42 U.S.C. § 300g–1(b)(4)(D)).] Congress added that "other means found to be the best available for the control of synthetic organic chemicals must be at least as effective in controlling synthetic organic chemicals as granular activated carbon." [FN68: Id.]

Here, EPA correctly found that granular activated carbon ("GAC"), anion exchange, and high pressure membranes such as those used in reverse osmosis systems "can achieve [PFAS] concentrations less than 4 [ppt]" and may "exceed >99 percent [PFAS removal]." [FN69: Proposed Rule, 88 Fed. Reg. at 18,684–86.] Those technologies are not only readily available, but they have been deployed and proven effective in communities across the country. The Cape Fear Public Utility Authority reported no PFAS detections in water treated by granular activated carbon at a Wilmington, NC drinking water treatment plant, despite high levels of PFAS in the water before treatment. [FN70: See WECT News, CFPUA: No PFAS Found in Water Treated by GAC Filters (Oct. 11, 2022), https://www.wect.com/2022/10/11/cfpua-no-pfas-found-water-treated-by-gac-filters/.] In nearby Brunswick County, another utility used reverse osmosis to reduce PFOA and PFOS to non- detectable levels. [FN71: Brunswick Cnty. Gov. Complex, Brunswick County Commissioners Receive Final Report Showing PFAS Not Detected in LPRO Treated Water (Apr. 17, 2018), https://www.brunswickcountync.gov/brunswick-county-commissioners-receive-final-report- showing-pfas-not-detected-in-lpro-treated-water/; CDM Smith, Advanced Treatment Options for the Northwest Water Treatment Plant: Brunswick County, App'x A (Apr. 2018), https://www.brunswickcountync.gov/wp-

content/uploads/2018/04/CDM-Smith-Brunswick- Final-Report-April-2018.pdf.] The use of granular activated carbon treatment in New Jersey yielded similar results:

Seven different GAC treatment plants operating for years . . . removed PFOA, PFOS, and other PFAS chemicals to nondetectable levels. Three of those GAC plants were treating groundwater with concentrations of PFOA or PFOS of >500 ppt to nondetectable levels. Since 2019, 12 New Jersey plants, seven that use GAC and five that use IEX, have been achieving nondetectable levels of PFOA and PFOS in >99.9% of treated water with detection limits ranging from 0.53 to 5 ppt. [FN72: Elizabeth Southerland & Linda S. Birnbaum, What Limits Will the World Health Organization Recommend for PFOA and PFOS in Drinking Water, 57 Env't Sci. & Tech. 7103, 7103–7105 (2023), https://doi.org/10.1021/acs.est.3c02260; N.J. Drinking Water Quality Inst., Treatment Subcomm., Recommendation on Perfluorinated Compound Treatment Options for Drinking Water, at 6–8 (June 2015), https://www.nj.gov/dep/watersupply/pdf/pfna-pfc-treatment.pdf.]

EPA Response: The EPA agrees that the PFOA and PFOS MCLs are as close as feasible to the MCLG. Regarding the agency's evaluation of feasible treatment technologies for the final NPDWR, please see section 5.1.4 of the EPA response in this *Response to Comments* document . For additional discussion on treatment technologies, please see section 10 of the EPA response in this *Response to Comments* document.

Environmental Working Group et al. (Doc. #1810, SBC-044690)

Under EPA's proposal, drinking water utilities will be required to test water for PFOA, PFOS, GenX, PFBS, PFNA, and PFHxS and install treatment technologies to reduce the concentrations of these chemicals to the level of EPA's proposed "maximum contaminant levels" or lower. Fortunately, proven technology is available that will not only reduce the presence of the six PFAS in EPA's proposal, but will also improve protection against other PFAS compounds and common contaminants.

EPA Response: The EPA agrees that treatment technology is available to reduce the six regulated PFAS to levels below their MCLs and that this regulation will also improve protection against other PFAS and non-PFAS contaminants. Please see section 5.1.4 o of the EPA response in this *Response to Comments* document for more information about the agency's evaluation of feasible treatment technologies for the final NPDWR. For additional discussion on treatment technologies, please see section 10 of the EPA response in this *Response to Comments* document.

Lance Freeman (Doc. #2132, SBC-047306)

The idea of lowering the amount of PFAS in water is inherently good in a vacuum. Fewer people dying because of dangerous chemicals in their drinking water is ideal. However, my concern does not come from the dislike of this idea, it comes from the uncertainty of logistics. The biggest question I have is if it is feasible technology-wise to effectively remove PFAS to this

level? That would be the first thing to determine. The EPA did state they were looking for comments on if it is feasible and what methods and technology would work best, I feel that the answers they get from those comments should be the top priority and even when they receive those answers they should be triple verified to make sure they work properly. Without the ability to remove PFAS effectively, it is unreasonable to assume this limit can be placed. Any water with PFAS in it would be unfit to be used as a resource and given that a large portion of the United States is experiencing water shortages as is, the removal of drinking water because it doesn't meet the new requirements might hurt more than it helps.

EPA Response: Regarding responses regarding the agency's evaluation of feasible treatment technologies for the final NPDWR, please see section 5.1.4 of the EPA response in this *Response to Comments* document. For additional discussion on treatment technologies, please see section 10 of the EPA response in this *Response to Comments* document. The EPA agrees that protecting public health and the environment by reducing PFAS contamination is important and that finalizing this NPDWR is an important step toward accomplishing that objective. After considering public comment, EPA reaffirms that there are feasible treatment technologies to remove PFAS to levels below the MCLs in this final regulation.

Anonymous (Doc. #2569, SBC-047292)

I have worked in the water treatment industry for nearly 30 years and to see such a drastic reduction to the proposed MCL of 4 ppt when the previous health advisory was 70 ppt seems unwarranted. This is in light of the fact that the FDA released a study in 2019 which identified PFAs was present in every food they tested, most of the time containing PFAs levels over 100 ppt and sometimes in the thousands. I work in a highly efficient treatment plant with multiple GAC contactors and we are able to get our levels down around 4 ppt. Most treatment plants will not be able to do that and will have to incur exorbitant capital costs to remove something that is already in the food supply. Since PFAs are already consumed daily, the level in the water can be 0 and everyone who eats will still consume hundreds if not thousands of ppt of PFAs every day. It doesn't make sense to have such stringent (4 ppt) number given the costs involved.

EPA Response: Regarding responses regarding the agency's evaluation of feasible treatment technologies for the final NPDWR, please see section 5.1.4 of the EPA response in this *Response to Comments* document. This final NPDWR is informed by the current and best available peer-reviewed science. For additional discussion on treatment technologies, please see section 10 of the EPA response in this *Response to Comments* document. For additional discussion on how costs were considered in setting the MCL, please see section 5.1.3 of the EPA response in this *Response to Comments* document. EPA has considered the RSC in informing the MCLGs for this regulation: please see sections 4.2.5 and 4.3.3 of the EPA response in this *Response to Comments* document.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044025)

8. EPA seeks comment on its PFOA and PFOS evaluation of feasibility for the proposal, including analytical measurement and treatment capability, as well as reasonable costs, as defined by SDWA.

a. An MCL of 4.0 ppt for PFOA and PFOS is not broadly feasible due to treatment installation costs, available treatment technologies and materials, product supply availability, manufacturing and disposal limitations, labor shortages and laboratory limitations.

EPA Response: Please see section 5.1.3 of the EPA response in this *Response to Comments* document. For additional discussion on treatment technologies, please see section 10 of the EPA response in this *Response to Comments* document. For additional discussion on extensions and exemptions, please see section 12.1 of the EPA response in this *Response to Comments* document.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045038)

NJDEP agrees and notes that of the 216 samples submitted by the 11 treatment plants that utilized GAC, only eight samples had detectable levels of PFOA (ranging between 2.1 ppt to 9.4 ppt, and no samples had detectable levels of PFOS. These facilities were able to reduce their levels of PFOA and PFOS to below the detection levels in 93% to 100% of samples. Detection limits for these samples ranged from 0.47 ppt to 5 ppt. All systems that have installed treatment for PFNA in New Jersey are utilizing GAC. These systems have reported non-detect for PFNA since the installation of treatment.

NJDEP notes that although the proposed MCLs seem to be achievable by treatment such as GAC, media changeouts may occur at an increased frequently as water systems look to meet the lower proposed MCLs.

EPA Response: Regarding responses regarding the agency's evaluation of feasible treatment technologies for the final NPDWR, please see section 5.1.4 of the EPA response in this *Response to Comments* document. For additional discussion on treatment technologies, please see section 10 of the EPA response in this *Response to Comments* document.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045022)

EPA requested comment on whether PWS can feasibly treat PFOA and PFOS to 4.0 ppt or below. Based on NJDEP's experience in implementing New Jersey's state-specific MCLs, water systems have demonstrated the ability to treat for PFOA, PFOS, and PFNA to 4.0 ppt. Based on NJDEP records, permits have been submitted to NJDEP for installation of PFAS treatment at approximately 90 additional facilities. These facilities are in various stages of completing the permitting process and constructing PFAS treatment. Twenty four facilities in New Jersey have installed permanent treatment for removal of PFAS. Of these, 11 facilities have utilized granular

activated carbon (GAC) treatment and 13 facilities have utilized anion exchange (AIX) treatment. Regulated drinking water systems began submitting standardized compliance data to the Department for PFOA and PFOS in January 2019. These compliance samples are collected post-treatment, prior to entering the water distribution system. Between January 23, 2019 and May 22, 2023, over 300 samples were submitted for PFOA and PFOS by the 24 facilities utilizing permanent PFAS treatment. An analysis of these data shows that these facilities were able to achieve levels of PFOA and PFOS below detection in the vast majority of treated water samples (>95%). Detection limits for these samples ranged from 0.47-5 ppt.

EPA Response: Regarding responses regarding the agency's evaluation of feasible treatment technologies for the final NPDWR, please see section 5.1.4 of the EPA response in this *Response to Comments* document. For additional discussion on treatment technologies, please see section 10 of the EPA response in this *Response to Comments* document.

Tyson Foods, Inc. (Doc. #1750, SBC-043901)

May 30, 2023

VIA ELECTRONIC SUBMISSION (www.regulations.gov)

Alexis Lan,

Office of Ground Water and Drinking Water

Standards and Risk Management Division

Mail Code 4607M

Environmental Protection Agency

1200 Pennsylvania Avenue NW

Washington, DC 20460

RE: PFAS National Primary Drinking Water Regulation Rulemaking [EPA– HQ–OW–2022–0114]; 88 Fed. Reg. (60): 18638 (March 29, 2023)

Dear Ms. Lan,

Tyson Foods, Inc. (Tyson Foods) is one of the world's largest food companies and a recognized leader in protein. As the world's population continues to grow and as we face a potential global food shortage, we need a food system that can support this population by providing nutritious protein and sustains our planet. This will require the global agriculture industry to become more efficient, productive, resilient, and sustainable – while keeping food affordable, nutritious, and accessible.

We appreciate the opportunity to comment on the Environmental Protection Agency' (EPA) proposed rule, PFAS National Primary Drinking Water Regulation Rulemaking (Proposed Rule or Proposal).

The Proposal as written poses a myriad of significant challenges to the meat and poultry industry. For instance, there is genuine concern based on available empirical data and analyses that the proposed levels cannot be achieved with existing treatment technology. Additionally, the draft rule proposes levels below those that can be reliably detected using existing EPA methods.

EPA Response: Regarding responses regarding the agency's evaluation of feasible treatment technologies for the final NPDWR, please see section 5.1.4 of the EPA response in this *Response to Comments* document. For additional discussion on treatment technologies, please see section 10 of the EPA response in this *Response to Comments* document.

responsesColorado Water Utility Council (CWUC) (Doc. #1622, SBC-044026)

9. EPA seeks comment on its evaluation of feasibility for the proposed HI MCL finding, including analytical measurement and treatment capability, as well as reasonable costs, as defined by SDWA.

a. Removal technologies for PFHxS may not be the same as what effectively removes PFOA and PFOS. Either way, EPAs cost estimates for PFAS removals are grossly underestimated.

EPA Response: Regarding responses regarding the agency's evaluation of feasible treatment technologies for the final NPDWR, please see section 5.1.4 of the EPA response in this *Response to Comments* document. This final NPDWR is informed by the current and best available peer-reviewed science. For additional discussion on treatment technologies, please see section 10 of the EPA response in this *Response to Comments* document. For additional discussion on how costs were considered in setting the MCL, please see section 5.1.3 of the EPA response in this *Response to Comments* document.

COMM Water Department (Doc. #1577, SBC-042446)

EPA needs to rapidly work toward finding permanent destruction technologies or we will continue to face the prospect of a never-ending cycle of moving PFAS around our environment.

EPA Response: Regarding responses regarding the agency's evaluation of feasible treatment technologies for the final NPDWR, please see section 5.1.4 of the EPA response in this *Response to Comments* document. The EPA notes that destruction technologies for PFAS is discussed in the updated *Interim Destruction and Disposal Guidance*. The interim guidance outlines the current state of the science on techniques and treatments that may be used to destroy or dispose of PFAS and PFAS-containing materials. However, the interim guidance is beyond the scope of this rulemaking.

Marlene Ladderbush (Doc. #1612, SBC-042922)

EPA needs to rapidly work toward finding permanent destruction technologies or we will continue to face the prospect of a never-ending cycle of moving PFAS around our environment.

EPA Response: Please see the EPA response to comment Doc. #1577, SBC-042446 in section 5.1.4 in this *Response to Comments* document.

Town of Lincoln Water Department (Doc. #1613, SBC-043034)

EPA needs to rapidly work toward finding permanent destruction technologies or we will continue to face the prospect of a never-ending cycle of moving PFAS around our environment.

EPA Response: Please see the EPA response to comment Doc. #1577, SBC-042446 in section 5.1.4 in this *Response to Comments* document.

Water Supply District of Acton (Doc. #1662, SBC-043665)

EPA needs to rapidly work toward finding permanent destruction technologies or we will continue to face the prospect of a never-ending cycle of moving PFAS around our environment.

EPA Response: Please see the EPA response to comment Doc. #1577, SBC-042446 in section 5.1.4 this *Response to Comments* document.

Nebraska Department of Environment and Energy (NDEE) (Doc. #1653, SBC-043209)

• EPA is requesting comment regarding PFAS treatment technologies.

o The Department regulates not only public drinking water systems but wastewater facilities as well. The identification of RO/NF as best available technologies (both full scale treatment and POUs) should be accompanied with a strong recommendation to evaluate the impact on wastewater treatment plant effluent and sludges due to the concentrated waste stream.

EPA Response: Regarding responses regarding the agency's evaluation of feasible treatment technologies for the final NPDWR, please see section 5.1.4 of the EPA response in this *Response to Comments* document. Regarding the impact of disposal of PFAS containing waste from RO/NF, see the EPA response to comment Doc. #1577, SBC-042446 in section 5.1.4 in this *Response to Comments* document for a discussion of the EPA's *Interim Destruction and Disposal Guidance*. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation.

City of Thornton, Colorado (Doc. #1748, SBC-044789)

Thornton is also concerned that an increase in landfill disposal of spent treatment media containing concentrated PFAS has a high potential to increase contamination of source waters or lead to contamination of new sources. Leachate from these landfills should be addressed by the EPA without leading to increased disposal costs for utilities.

EPA Response: Regarding responses regarding the agency's evaluation of feasible treatment technologies for the final NPDWR, please see section 5.1.4 of the EPA response in this *Response to Comments* document. The agency notes that addressing leachate from landfills is beyond the scope of this rulemaking (please see section 15.1 of the EPA response in this *Response to Comments* document for additional information). For additional discussion on cost considerations for the final MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Fairfax Water (Doc. #1789, SBC-045302)

Water Utilities Need a Comprehensive Understanding of EPA's PFAS Regulatory Framework to Support Decision Making for Capital Intensive Infrastructure

The drinking water treatment process results in several residual streams including process water from filter backwashes, sediments that are removed from source waters, and spent filter media. Utilities need to have clarity on the entire EPA PFAS regulatory structure, from source water to residuals, to make informed and cost-effective decisions on behalf of their ratepayers. EPA needs to provide clarity on how and when it will regulate sources of PFAS in the environment. There is currently no EPA regulatory mechanism to eliminate a PFAS source in a drinking water supply. EPA should reprioritize its PFAS regulatory focus so that sources are eliminated at the polluter's expense instead of PFAS remediation becoming the financial burden of the public.

EPA Response: Please see the EPA response to comment Doc. #1729, SBC-043581 in section 5.1.4 in this *Response to Comments* document for a discussion of how EPA's PFAS Strategic Roadmap sets timelines for specific actions. Regarding the impact of disposal of PFAS containing waste treatment residuals, see the EPA response to comment Doc. #1577, SBC-042446 in section 5.1.4 in this *Response to Comments* document for a discussion of the EPA's *Interim Destruction and Disposal Guidance*. Regarding responses regarding the agency's evaluation of feasible treatment technologies for the final NPDWR, please see section 5.1.4 of the EPA response in this *Response to Comments* document. Topics related to assigning liability for PFAS pollution or addressing sources of PFAS contamination are beyond the scope of this rulemaking (please see section 15.11 of the EPA response in this *Response to Comments* document for additional discussion).For additional discussion on the management of treatment residuals, please see section 10.4 of the EPA response in this *Response to Comments* document.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044190)

Additionally, NCDEQ requests that EPA continue its research into PFAS treatment, such as the planned PFAS demonstration projects by the Agency's Office of Research and Development (ORD), waste disposal technologies, additional investment into the capacity development program, and enhanced investment into the state agencies' programs who will oversee and implement this regulation.

EPA Response: Under EPA's PFAS Strategic Roadmap, the Office of Research and Development is evaluating and developing technologies for reducing PFAS in the environment to inform decisions on drinking water and wastewater treatment, contaminated site cleanup and remediation, air emission controls, and end-of-life materials management. Regarding responses regarding the agency's evaluation of feasible treatment technologies for the final NPDWR, please see section 5.1.4 of the EPA response in this *Response to Comments* document. With respect to responses regarding PFAS treatment and residuals management, please see section 10.4.1 of the EPA response in this *Response to Comments* document. For concerns on funding and BIL, please see section 2.4 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044104)

Additionally, ASDWA requests that EPA continue its research into PFAS treatment, such as the planned PFAS demonstration projects by the Agency's Office of Research and Development (ORD), waste disposal technologies, additional investment into the capacity development program, and enhanced investment into the primacy agencies' programs which will oversee and implement this regulation. Primacy agencies and systems will also need in-depth guidance and training on PFAS mitigation techniques before the final rule's compliance date.

EPA Response: Please see the EPA response to comment Doc. #1652, SBC-044190 in section 5.1.4 in this *Response to Comments* document.

Thurston Public Utility District (PUD), WA (Doc. #1729, SBC-043581)

The EPA should also reexamine its PFAS Strategic Roadmap and consider the chronology and speed of regulatory decision-making so that those subjected to new rules have sufficient time to adapt at each stage. EPA needs to clarify preferred and effective disposal and destruction procedures for spent materials used to remove PFAS from water and how to scale in an economic manner. PFAS in sewer systems needs to be addressed. Biosolids deserve consideration too since systems came to rely on them as a source of revenue, but now for many, they have turned into an additional expense. These actions should simultaneously help to clarify liability so that those undertaking improvements in treatment are not potentially subject in the future to avoidable legal risks particularly as EPA considers parameters for designating PFAS compounds as "hazardous substances" under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). If these efforts require additional research or

changes in law, we urge EPA to include that in communications such as budget requests with federal legislators so they can appropriate the resources necessary or legislate policy changes accordingly.

EPA Response: Reexamination of EPA's PFAS Strategic Roadmap, PFAS in sewer systems, biosolids, and the designation of hazardous substances under CERCLA is beyond the scope of this rulemaking. Please see the EPA response to comment Doc. #1577. SBC-042446 in section 5.1.4 in this *Response to Comments* document for a discussion of the *EPA's Interim Destruction and Disposal Guidance*. Regarding responses regarding the agency's evaluation of feasible treatment technologies for the final NPDWR, please see section 5.1.4 of the EPA response in this *Response to Comments* document. Topics related to assigning liability for PFAS pollution or addressing sources of PFAS contamination are beyond the scope of this rulemaking (please see section 15.1 of the EPA response in this *Response to Comments* document for additional discussion).For additional discussion on the management of treatment residuals, please see section 10.4 of the EPA response in this *Response to Comments* document.

Paul Eldredge (Doc. #2770, SBC-047458)

EPA should also reexamine its PFAS Strategic Roadmap and consider the chronology and speed of regulatory decision making so that those subjected to new rules can have sufficient time to adapt at each stage. EPA needs to clarify preferred and effective disposal and destruction procedures for spent materials used to remove PFAS from water and how to scale in an economic manner. These actions should simultaneously help to clarify liability so that those undertaking improvements in treatment are not potentially subject in the future to avoidable legal risks particularly as EPA considers parameters for designating PFAS compounds as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). If these efforts require additional research or changes in law, we urge EPA to include that in communications such as budget requests with federal legislators so they can appropriate the resources necessary or legislate policy changes accordingly.

This is especially pertinent at a time when wastewater agencies are still overcoming the compounding difficulties caused by workforce shortages, lingering supply chain issues, and inflation. Public works professionals balance public health and environmental concerns with doing what is best in the communities where we live and serve.

Thank you for your time and consideration of these comments.

EPA Response: Please see the EPA response to comment Doc. #1728, SBC-043581 in section 5.1.4 in this *Response to Comments* document.

American Public Works Assocation (APWA) (Doc. #1584, SBC-042394)

EPA should also reexamine its PFAS Strategic Roadmap and consider the chronology and speed of regulatory decision making so that those subjected to new rules can have sufficient time to

adapt at each stage. EPA needs to clarify preferred and effective disposal and destruction procedures for spent materials used to remove PFAS from water and how to scale in an economic manner. Biosolids deserve consideration too since systems came to rely on them as a source of revenue, but now for many they have turned into an additional expense. These actions should simultaneously help to clarify liability so that those undertaking improvements in water treatment are not potentially subject in the future to avoidable legal risks particularly as EPA considers parameters for designating PFAS compounds as "hazardous substances" under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). If these efforts require additional research or changes in law, we urge EPA to include that in communications such as budget requests with federal legislators so they can appropriate the resources necessary or legislate policy changes accordingly.

EPA Response: Please see the EPA response to comment Doc. #1729, SBC-043581 in section 5.1.4 in this *Response to Comments* document.

California Farm Bureau Federation (Doc. #1704, SBC-045079)

EPA's PFAS Strategic Roadmap only committed to meeting its statutory deadline of December 2023. This proposed drinking water standard of 4 ppt will require drinking water providers to treat drinking water sources for PFOA and PFOS and thus create more of a need for the management of treatment residues. Additionally, the Roadmap did not identify plans to address PFOA and PFOS under the Resource Conservation and Recovery Act (RCRA), which, among other things, would have required EPA to conduct a rulemaking to establish management, treatment, and disposal standards thmat would apply to all RCRA-regulated PFOA and PFOS waste anywhere in the United States. The absence of regulatory requirements, or at least clear guidance on management, treatment, disposal, and destruction guidelines, hampers the ability of drinking water utilities to develop the management infrastructure needed to address PFOA and PFOS contamination. Additionally, responsible parties lack places to send contaminated materials for appropriate management and disposal.

[Table 1: See Docket ID EPA-HQ-OW-2022-0114-1704]

EPA Response: Actions identified in the PFAS Strategic Roadmap regarding other agency programs (such as RCRA) are beyond the scope of this rulemaking; please see section 15.1 of the EPA response in this *Response to Comments* document. That said, the EPA PFAS Strategic Roadmap reference RCRA actions. In the Roadmap, the agency identified various authorities including the RCRA. The EPA also disagrees with the comment on the availability of disposal options. Disposal options and guidance on management of treatment residuals for PFAS containing waste currently exist; please see section 10.4 of the EPA response in this *Response to Comments* document for additional discussion on the management of treatment residuals. Also see the EPA response to comment Doc. #1577, SBC-042446 in section 5.1.4 in this *Response to Comments* document for a discussion of the EPA's *Interim Destruction and Disposal Guidance.* Regarding responses regarding the agency's evaluation of feasible treatment technologies for the

final NPDWR, please see section 5.1.4 of the EPA response in this *Response to Comments* document.

5.1.5 International and State Drinking Water Standards and Guidelines

Summary of Major Public Comments and EPA Responses

Many commenters compared the proposed MCLs to existing state and international standards, regulations and guidelines. In particular, these commenters reference several states who have conducted their own rulemakings to promulgate MCLs and use it as a point of comparison for the EPA's analysis. Further, some of these commenters ask the EPA to explain why certain states' cost-benefit analyses supported their respective levels and why the EPA's analysis is different. The EPA notes that potential differences in conclusions could arise from several factors, including from differences in the number of entities included in the analysis, baseline levels of PFAS contamination, estimation of health risk reduction benefits, and the estimation of costs. EPA's HRRCA for the proposal was based on the best available and peer-reviewed science, using data collected by accepted methods or best available methods, and the Administrator determined at proposal that the benefits of the rule justify its costs. For the EPA response to comments on the EPA's HRRCA, see section 13 in this *Response to Comments* document.

Regarding state PFAS regulations, some commenters point to state-led actions as a point of comparison for EPA's action and state that the agency's analysis is inconsistent with the approaches taken by states. While some states have promulgated drinking water standards for various PFAS prior to promulgation of this NPDWR, this rule provides a nationwide, health protective level for PFOA and PFOS (as well as other PFAS) in drinking water and reflects regulatory development requirements under SDWA, 'including requirements that EPA's action be based on the best available, peer-reviewed science; available drinking water occurrence, treatment, and evaluation of feasibility, including consideration of costs.. The state adopted MCLs identified by commenters were adopted prior to EPA's proposal and were adopted pursuant to relevant state authorities at the time. The fact that states have adopted less stringent MCLs under state law prior to EPA's proposal is not relevant to EPA's determination that its MCLs met applicable SDWA requirements. After the MCLs takes effect, SDWA requires primacy states to have a standard that is no less stringent than the MCLs.

The EPA notes that the EA for this rulemaking accounts for existing state standards at the time of analysis. Specifically, to estimate the costs and benefits of the final rule, the EPA assumed that occurrence estimates exceeding state limits are equivalent to the state-enacted limit. For these states, the EPA assumed that the state MCL is the maximum baseline PFAS occurrence value for all Entry Point to the Distribution Systems (EPTDSs) in the state. Additionally, while states may establish drinking water regulations or guidance values absent federal regulation as they deem appropriate, the presence of state regulations does not preclude the EPA from setting federal regulations under the authority of SDWA that meets that statute's requirements.

Regarding international PFAS guidelines and standards, some commenters point to these actions as a point comparison for the EPA's action and state that the agency's analysis is inconsistent with the approaches taken by international organizations. While some international entities (such as Australia, Japan, the United Kingdom and the European Union) have developed drinking water guidelines and standards for some PFAS, this NPDWR reflects the regulatory development requirements under SDWA, including requirements that the EPA's action be based on the best available, peer-reviewed science; available drinking water occurrence, treatment, and evaluation of feasibility, including consideration of costs. The international guidelines and state standards identified by commenters are relevant to those international authorities at that time. The fact that international organizations have adopted PFAS standards and guidelines is not relevant to the EPA's determination that its MCLs met applicable SDWA requirements.

Several commenters reference the World Health Organization's (WHO) Guidelines for Drinking Water Quality. The EPA notes that WHO provided a draft document that was offered for public comment in the fall of 2022 and that the WHO received a number of comments on that draft document. In the WHO's response to comments on the provisional draft value for PFOA and PFOS assessment, the WHO wrote the following. "The provisional guideline value of 100 ng/L for PFOA and PFOS proposed in the draft background document is not a health-based value and the draft background document does not suggest this is a safe level of exposure. Therefore, the WHO's proposed provisional guideline value should not be compared to health-based values established by other agencies. The draft background document found that high pressure membrane processes, adsorption and ion-exchange can reduce PFOS and PFOA contamination levels by ≥ 90 percent, and that these technologies can consistently and reliably reduce PFAS-contaminated waters to below 100 ng/L. However, the draft background document did not intend to suggest that these technologies couldn't reduce PFOS and PFOA contamination to concentrations lower than 100 ng/L. Therefore, the provisional guideline value should not be interpreted as the lowest concentrations of PFOA and PFOS that can be achieved with available treatment technologies; in fact, it is expected that well-operated treatment processes designed for PFAS removal are able to achieve concentrations well below this value." The WHO review and assessment of the PFAS group of substances is an ongoing process. The EPA does not believe it is appropriate to use the WHO's approach for determining PFOA and PFOS or other PFAS MCLs because it is inconsistent with the statutory requirements of the SDWA. The language in the SDWA is clear: the EPA must set the MCL as close as feasible to the health-based MCLG. In setting the MCLG, the EPA uses established systematic review practices (USEPA, 2022b) to identify, evaluate, synthesize, integrate, and quantify evidence in a chemical database. These protocols have been repeatedly peer-reviewed and improved upon over time. Other health agencies, including the WHO, do not follow these same practices and, as a result, may arrive at different conclusions. The EPA then considers non-health-based factors (such as analytic and treatment feasibility) when setting the MCL as close as feasible to the MCLG. For more information, please see section 4.2.6 of the EPA response in this *Response to Comments* document. Additionally, the WHO has stated, "In light of comments received and to ensure that the latest evidence is taken into account since the background document was drafted, WHO will

continue its review of PFAS. The updated assessment will consider, inter alia, the International Agency for Research on Cancer's (IARC's) carcinogenicity assessment on PFOS and PFOA," (https://www.who.int/teams/environment-climate-change-and-health/water-sanitation-and-health/chemical-hazards-in-drinking-water/per-and-polyfluoroalkyl-substances) indicating that their conclusions are subject to change.

With respect to the how the EPA considered other agencies' (including states') assessments and why the agency's health conclusions may have differed, please see section 4.2.6 of the EPA response in this *Response to Comments* document.

Individual Public Comments

Massachusetts Municipal Association (MMA) (Doc. #1800, SBC-043761)

Impacts of the Proposed NPDWR and Areas of Concern

The EPA's proposed regulation would establish legally enforceable thresholds, or maximum contaminant levels (MCLs), of 4 parts per trillion (ppt) for PFOA and 4 ppt for PFOS. This introduces a much stricter approach than the sum currently being utilized in the Commonwealth, which does not require specific action for one chemical's result unless the 20 ppt threshold is surpassed.

EPA Response: Regarding considerations for existing state and international PFAS standards, regulations and guidelines, please see section 5.1.5 of the EPA response in this *Response to Comments* document.

Clean Air Council, et al. (Doc. #1731, SBC-043874)

Regarding treatment, Eps in Pennsylvania would fall into three categories:

(i) Eps where levels of PFOA, PFOS, PFHxS, GenX, PFNA PFBS are below both the state rule MCLs and the proposed HI criteria in the NPDWR. Such systems would not need to implement water treatment under either state or federal regulations.

(ii) Eps with levels of PFOA and PFOS are below the state MCL, but where PFOA, PFOS, PFHxS, GenX, PFNA PFBS levels are above the proposed values in the NPDWR. As noted in the previous section, approximately 700 Eps in the Commonwealth of Pennsylvania are likely to fall into this category. Such systems would need to comply with the proposed federal rule in the same manner and under the same schedule as all other PWSs in the USA that exceed PFAS levels set in the NPDWR. However, they are not disadvantaged by the pre-existing state regulations. Indeed, due to the early availability of the monitoring data, these systems will identify the issues and will be able to plan accordingly.

(iii) EPs with levels of PFOA and/or PFOS that exceed the Pennsylvania MCL rules (and therefore also the proposed NPDWR). These approximately 200 EPs are required to treat the water in accordance with the Pennsylvania PFAS MCL and will have started setting up and

possibly running treatment processes for compliance with the less strict Pennsylvania rule by the time the federal regulations are in place. Some commenters on the Pennsylvania PFAS regulations questioned whether these facilities will be able to address compliance with the more strict NPDWR. However, as clearly stated in the Pennsylvania PFAS MCL rule, that concern is invalid; the PA-DEP expects that "[i]f the EPA's MCLs are more stringent, those PWSs that have installed treatment as required by this final-form rulemaking may need to make relatively minor operational adjustments, such as changing out the media more frequently, but large-scale design changes are not expected." [FN19: 53 Pa.B. 345.] The PFAS treatment methodologies endorsed by the PA-DEP are the ones certified by the EPA for addressing this contamination in drinking water. [FN20: See id. at 368.] These technologies have been tested and determined by the EPA to be capable of removing PFOA, PFOS and other PFAS(including those in the proposed NPDWR) to non-detectable levels [FN21: EPA, Per- and Polyfluoroalkyl Substances, https://tdb.epa.gov/tdb/contaminant?id=11020 (last visited May 24, 2023).] The equipment installed by the approximately 200 Pennsylvania entry points that are required by the Pennsylvania PFAS MCL rule to remove PFAS can therefore comply with the proposed federal requirements with only "minor operational adjustments."

EPA Response: The EPA does not disagree with commenter's classification of entry points in Pennsylvania. The EPA agrees that this regulation will require PFOA and PFOS be treated to lower levels than would have otherwise been required solely by the Pennsylvania drinking water rules. Regarding considerations for existing state and international PFAS standards, regulations and guidelines, please see section 5.1.5 of the EPA response in this *Response to Comments* document. For additional discussion on PFAS treatment technologies, please see section 10 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045954)

Several states and countries have implemented regulatory limitations of certain PFAS that differ significantly with EPA proposed limits. Some examples are Michigan, New Jersey, New Hampshire, Massachusetts, and Vermont, among several others. States must go through rigorous and thorough reviews of the science and data available to propose and finalize PFAS regulation. EPA's proposed MCLs are significantly lower than every state that has regulated PFOA and PFOS by at least half. This discrepancy makes it difficult to communicate whether water treated to these existing state standards is currently safe, and AMWA asks EPA to further explain why these states' cost-benefit analyses supported their respective levels and why EPA's analysis is different. Water systems must be able to explain to ratepayers why they are paying more for water after the implementation of this NPDWR, and having these differences complicates that task.

Other countries, such as Australia and Japan, as well as the United Kingdom (UK) and European Union (EU), have also approved limits on PFAS in drinking water that are higher than those the EPA has proposed. EPA's proposed limits are still much lower than every one of these. These countries have access to the same research that EPA does. In the UK, samples above 10 ppt

require more investigation if actions are needed, while samples over 100 ppt require immediate action [FN2: Drinking Water Inspectorate. (2022, July 7). Water Supply (Water Quality) Regulations 2016 (2018 in Wales) for Poly and Perfluorinated Alkyl Substances (PFAS). https://dwi-content.s3.eu-west-2.amazonaws.com/wp-content/uploads/2023/01/13123351/IL_03-2022_PFAS_Guidance-4-1.pdf.] Japan sets a provisional target of less than 50 ppt for PFOA and PFOS combined [FN3: The Mainichi. (2023 February 4). Japan must grasp full picture of chemical pollution amid PFAS detection.https://mainichi.jp/english/articles/20230204/p2a/00m/0op/008000c#:~:text=Since%202010%2C%20Japan%20has%20also,each%20of%20PFOS%20and%20PFOA.]

Australia similarly sets guidelines at 70 ppt for PFOA and PFOS combined [FN4: Australian Government National Health and Medical Research Council. (2023, April 28). Australian Drinking Water Guidelines. https://www.nhmrc.gov.au/about-us/publications/australian-drinking-water-guidelines.] AMWA supports regulation based on sound science and data and asks EPA to further explain how it came to different conclusions than every other state and country currently addressing PFAS in drinking water.

EPA Response: The EPA's final rule represents data-driven drinking water standards that are based on the best available, peer-reviewed science and meet the statutory requirements under SDWA. EPA has described, in detail, how it developed the MCLG and what science was used, in section IV of the final rule preamble. The EPA has described, in detail, how it determined the MCL in section V of the final rule preamble. Additional analyses outlined in the support documents used to inform these sections of the preamble go into greater detail; see for example: *Economic Analysis for the Final Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation and Appendices, Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS), Maximum Contaminant Level Goals (MCLGs) for Three Individual Per- and Polyfluoroalkyl Substances (PFAS) and a Mixture of Four PFAS, OW Final Maximum Contaminant Level Goals (MCLGs) for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonic Acid (PFOS) in Drinking Water, Best Available Technologies and Small System Compliance Technologies for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water, Technical Support Document - Technologies and Cost for Removing Per- and Polyfluoroalkyl Substances (PFAS) from Drinking Water, and Per- and Polyfluoroalkyl Substances (PFAS) Occurrence & Contaminant Background Support Document for the Final PFAS National Primary Drinking Water Regulation*. Regarding considerations for existing state and international PFAS standards, regulations and guidelines, please see section 5.1.5 of the EPA response in this *Response to Comments* document. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation. For additional discussion on PFAS risk communications, please see section 1.2 of the EPA response in this *Response to Comments* document.

PFAS Regulatory Coalition (Doc. #1761, SBC-046089)

3. EPA's analysis is inconsistent with the approaches taken by states that have been issuing standards.

Several states have conducted their own rulemakings to establish MCLs or similar drinking water standards. None of these states justified standards at the PQL levels proposed by EPA. The most recent state to adopt standards, Pennsylvania, conducted a robust cost/benefit analysis and promulgated MCLs of 14 ppt for PFOA and 18 ppt for PFOS, which are three to five times greater than what EPA is proposing. 53 Pa.B. 333, Jan. 14, 2023; available at: https://www.pacodeandbulletin.gov/Display/pabull?file=/secure/pabulletin/data/vol53/53-2/46.html. EPA's Proposal is inconsistent with the conclusions reached by Pennsylvania and the other states that have established their own MCLs.

EPA Response: The EPA's final rule represents data-driven drinking water standards that are based on the best available, peer-reviewed science and meet the statutory requirements under SDWA. Regarding considerations for existing state and international PFAS standards, regulations and guidelines, please see section 5.1.5 of the EPA response in this *Response to Comments* document. Please also see the EPA response to comment Doc. #1738, SBC-045954 in section 5.1.5 this *Response to Comments* document.

Clean Air Council, et al. (Doc. #1731, SBC-043871)

b. Enacting the proposed PFAS NPDWR in Pennsylvania is technically and economically feasible.

Compliance with the proposed federal PFAS regulations would not only be feasible, but also easier for states like Pennsylvania that already have existing regulations, even if their current regulations are less stringent.

There is a discrepancy between the Commonwealth's Safe Drinking Water PFAS MCL Rule of 2022 and the proposed NPDWR: Pennsylvania set the MCLs for PFOA and PFOS at values much higher than the proposed 4 ppt in the NPDWR (14 ppt and 18 ppt, respectively) [FN11: 53 Pa.B. 362.]. Moreover, the Pennsylvania regulation does not restrict levels of any other PFAS compounds in drinking water.

Similarly, the MCLs set in other states for PFOA and PFOS are higher than the proposed values in the NPDWR (see for example New York [FN12: NY State Health Dep't, Public Water Systems and NYS Drinking Water Standards for PFAS and Other Emerging Contaminants, https://www.health.ny.gov/environmental/water/drinking/Emerging_pfas_publicwater.htm (last updated Oct. 2022).]). In addition, to the best of our knowledge none of the states use the HI approach proposed by the EPA for other PFAS species. Either they set MCLs (see for example Michigan [FN13: Mich. PFAS Action Response Team, Maximum Contaminant Levels (MCLs), https://www.michigan.gov/pfasresponse/drinking-water/mcl (last visited May 24, 2023).]), or they define a maximum for the sum concentrations of several species (for example,

Massachusetts set a maximum of 20 ppt for the sum of PFOS, PFOA, PFHxS, PFNA PFHpA and PFDA [FN14: MassDEP, Per- and Polyfluoroalkyl Substances (PFAS), https://www.mass.gov/info-details/per-and-polyfluoroalkyl-substances-pfas#drinking-water-standards-and-health-information- (last visited May 24, 2023).]).

The differing standards can raise the question of whether the existence of state-level PFAS regulations for drinking water will impede compliance with the proposed federal rule. Indeed, a number of public comments submitted to PA-DEP on the Pennsylvania MCL PFAS rule raised this question. Yet, such concerns are invalid. States where some regulations already exist are better prepared, rather than less, to comply with the proposed NPDWR. As stated in the PA-DEP response in the final Pennsylvania rule:

However, when a final Federal rule is published, the regulations will go into effect 3 years after they are finalized. During this 3-year period, the Department will review the Federal rule and evaluate the supporting documentation to determine how the Federal rule compares to the Department's regulations. If the Federal rule is more stringent, the Department will follow the Commonwealth's rulemaking process to revise its regulation to address any discrepancies and to ensure the Department's regulations meet at least the minimum Federal requirements [FN15: 53 Pa.B. 345 (emphasis added).].

The testing methods required in the Pennsylvania PFAS rule (EPA Method 533, EPA Method 537.1 or EPA Method 537 Version 1.1) are the same as those certified by EPA and noted in the NPDWR. [FN16: Id. at 366; 88 Fed. Reg. 18750.] Tests required by PA-DEP will therefore be applicable for the initial monitoring requirements in the NPDWR [FN17: 88 Fed. Reg. 18683.]. This is also the case in other states where testing is required as part of a PFAS drinking water regulation (e.g. MA, MI, NY, NJ, NH, ME), as well as in states where some testing is required even though no MCLs for drinking water have been set there as yet (e.g. California [FN18: Cal. Water Res. Control Bd., Section on PFAS, Drinking Water Resources, https://www.waterboards.ca.gov/pfas/drinking_water.html (last updated Mar. 1, 2023).]).

EPA Response: The EPA agrees that the MCLs in this PFAS NPDWR are feasible. Regarding considerations for existing state and international PFAS standards, regulations and guidelines, please see section 5.1.5 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 10 on extensions and exemptions.

National Ground Water Association (NGWA) (Doc. #1804, SBC-045464)

State regulation – The development of the proposed rule needs to consider how the MCLs relate to and affect the patchwork of state drinking water PFAS regulations that have emerged, particularly those that are less stringent.

EPA Response: The EPA's final rule represents data-driven drinking water standards that are based on the best available, peer-reviewed science and meet the statutory requirements

under SDWA. Regarding considerations for existing state and international PFAS standards, regulations and guidelines, please see section 5.1.5 of the EPA response in this *Response to Comments* document. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation. For additional discussion on PFAS risk communications, please see section 1.2 of the EPA response in this *Response to Comments* document.

City of Concord Water Treatment Plant, New Hampshire (Doc. #1499, SBC-042568)

April 14, 2023

United States of America

Environmental Protection Agency

Subject: Proposed PFAS National Primary Drinking Water Regulation

EPA,

New Hampshire (NH) has been at the forefront of PFAS contamination since 2016.

NH established MCLs for PFOA, PFOS, PFHxS and PFNA in 2019. New Hampshire Department of Environmental Services (NHDES) had to consider the extent to which the contaminants are found in NH, the ability to detect them in public water systems, the ability to remove the contaminant from drinking water, and the costs and benefits to affected parties that will result from establishing the standard, and then develop a MCL for each compound that is protective of the most sensitive population at all life stages.

Included with the final rule making process, NHDES provided a summary technical report on the development of the drinking water standards (MCLs) including an explanation of the health risk assessment for each compound and information on cost, benefit, occurrence, and ability to detect and treat these chemicals.

The City of Concord believes that NHDES through its very thorough scientifically based process has set the appropriate MCL for PFOA at 12 ppt, and PFOS at 15 ppt.

We would ask that EPA set the proposed standards at the same limits that NH has established.

Respectfully,

Marco Philippon

Water Treatment Superintendent

Concord Water Treatment Plant

EPA Response: Regarding considerations for existing state and international PFAS standards, regulations and guidelines, please see section 5.1.5 of the EPA response in this *Response to Comments* document.

Daniel Varon (Doc. #1518, SBC-042723)

I highlight these facts to emphasize the uncertainty behind PFAS, and question whether the proposed regulation if the most efficient means to reduce PFAS containment in humans, or if the high standards proposed by the EPA are too stringent. The proposed MCL is 4.0 ng/L for PFOA and PFOS, and 1.0 ng/L for a combination of PFNA, PFHxS, PFBS, and HFPO-DA on all drinking water sources. [FN16: PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 60 (proposed Mar. 29, 2023) (to be codified at 40 C.F.R. pt. 141 & 142).] This is a calling for an enforceable minimum of 5% of what the EPA currently suggests is an allowable level. In determining the amount of PFAS in drinking water across the country, the EPA used a threshold amount of 30 ng/L, 20 ng/L, and 90 ng/L for PFHxS, PFNA, and PFBS respectively. Two of which numbers are still below the current EPA recommended level. [FN17: Id.] The EPA then found ranges of detectable PFAS from 0.1% to 38% across different states. [FN18: Id.] This is once again evidence that PFAS do not have an equal impact across the country, and all the reason that a blanket ruling, especially with such a high threshold, could overcorrect the situation and not maximize economic resources. Combine this with the fact that there are other sources of PFAS pollutants, such as food, that may have a large impact on human exposure and yet are not being addressed with this proposed action.

EPA Response: Regarding considerations for existing state and international PFAS standards, regulations and guidelines, please see section 5.1.5 of the EPA response in this *Response to Comments* document. The agency is clarifying for the commenter that the NPDWR applies to PWSs and does not regulate "all drinking water sources." The commenter incorrectly points out "threshold amounts of 30 ng/L, 20 ng/L, and 90 ng/L for PFHxS, PFNA, and PFBS respectively"; these are not the MCLs that the EPA proposed for regulation nor were they thresholds the EPA evaluated in the EPA's HRRCA.

New Hampshire Water Works Association, Inc. (NHWWA) (Doc. #1576, SBC-042448)

May 25, 2023

Email: Office of Water Dockets: OW-Docket@epa.gov

Comments: https://www.regulations.gov/commenton/EPA-HQ-OW-2022-0114-0027

Mail:

U.S. Environmental Protection Agency

EPA Docket Center

Docket ID: EPA-HQ-OW-2022-0114

Mail Code 28221T

1200 Pennsylvania Ave., NW

Washington, DC 20460

Subject: Docket ID: EPA-HQ-OW-2022-0114; proposed PFAS drinking water standards

Dear EPA Office of Water:

Our Association supports, represents, and advocates for public drinking water systems in New Hampshire. Our sector is committed to providing clean, safe, and affordable public water, using sound science to create practical policies that protect human health. As a national leader in the discovery, definition, regulation, treatment, and funding to reduce threats caused by PFAS chemicals, we are providing important input to EPA's proposed MCLs for six PFAS compounds.

New Hampshire has been at the forefront of this issue in the past decade, having experienced significant contamination issues with firefighting foam at a former airbase on the Seacoast and with a manufacturing facility in Merrimack. The New Hampshire Department of Environmental Services (NHDES) took a pro-active approach with sampling, outreach, community engagement and regulatory action. They have not only had public water systems sample for PFAS but have performed extensive testing of private wells, landfills, and other impacted sites (see where PFAS chemicals are found across the state [Link: https://nhdes.maps.arcgis.com/apps/View/index.html?appid=66770bef141c43a98a445c54a17720e2&extent=-73.5743%2C42.5413%2C-69.6852%2C45.4489]). NHDES requires regulated public water systems to continue monitoring for PFAS, with sampling frequencies based on initial occurrence analysis.

Effective October 1, 2019, NHDES has had science- and health-based, enforceable standards for PFOA (12 parts per trillion; ppt), PFOS (15 ppt), PFNA (11 ppt), and PFHxS (18 ppt). To develop a MCL for each compound protective of the most sensitive population at all life stages NHDES considered: the extent to which the contaminants are found in NH; the ability to detect and quantify PFAS in drinking water; the ability to remove the contaminant from drinking water; and the costs and benefits to affected parties that result from establishing the standard. NHDES provided a summary technical report [Link: https://www.des.nh.gov/sites/g/files/ehbemt341/files/documents/r-wd-19-29-final.pdf] on the MCL development that included a health risk assessment for each compound and information on cost, benefit, occurrence, and ability to detect and treat these chemicals. Based on this thorough and science- and health-based approach, in the state that leads the country in PFAS investigation and remediation, we suggest that EPA set the proposed standards at the same limits that NHDES has established.

EPA Response: Regarding considerations for existing state and international PFAS standards, regulations and guidelines, please see section 5.1.5 of the EPA response in this *Response to Comments* document.

WaterPIO (Doc. #1624, SBC-043472)

The EPA states their proposed MCLs and HI are tied to various studies, but those studies – which were also considered by the states over the years – somehow enabled the EPA to conveniently land where the states didn't, on the absolute lowest levels that public water can accurately test for today. While some would say we can test down to two parts per trillion with certainty, four ppt is where 100% confidence is agreed upon across the Water World. So that's where the EPA set its proposed MCLs.

EPA Response: Regarding considerations for existing state and international PFAS standards, regulations and guidelines, please see section 5.1.5 of the EPA response in this *Response to Comments* document.

Maryland Association of Municipal Wastewater Agencies (MAMWA) (Doc. #1658, SBC-043396)

2. WHETHER THE PROPOSED MCLS ARE SET AT APPROPRIATE LEVELS

A. EPA's Proposal Is Much More Stringent Than PFAS Values Approved by the World Health Organization and Other Nations

EPA's proposed PFAS MCLs are so low as to raise questions as to their appropriateness considering they appear to be far out of step with than other prominent health agencies such as the following:

• World Health Organization – WHO set a provisional guidance value in September 2022 of 100 ppt for PFOA/PFOS (compared to EPA's MCLs of 4 ppt). WHO had the benefit of EPA's science when it adopted its value. This is a 25-fold difference between two of the world's two preeminent health organizations.

• United Kingdom & European Union – The Europeans have set their PFAS regulatory framework as follows:

<10 ppt = no issue; 10 - 100 ppt = research; and >100 ppt = action required.

• Australia – This nation set a standard of PFOS plus PFHxS at <70 ppt and PFOA <560 ppt (2022).

• Japan – This nation set a standard for PFOS plus PFOA of <50 ppt.

These dramatic differences between and among EPA and other respected health organizations (much higher levels approved by the others) warrant consideration by EPA, including in connection with the health-based phased implementation approach we suggest below.

MAMWA is also concerned that adopting such low levels as MCLs will send a message to millions of Americans that their water is not safe to drink.

EPA Response: Regarding considerations for existing state and international PFAS standards, regulations and guidelines, please see section 5.1.5 of the EPA response in this *Response to Comments* document. For additional discussion on risk communications, please see section 1.2 of the EPA response in this *Response to Comments* document. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-044906)

Several states and countries have implemented regulation of certain PFAS, with PFOA and PFOS commonly targeted. Some examples are Michigan, New Jersey, New Hampshire, Massachusetts, Vermont and several others. States also must go through rigorous and thorough reviews of the science and data available to propose and finalize PFAS regulation. EPA's proposed MCLs are significantly lower than every state that has regulated PFOA and PFOS by at least half. This makes it difficult to communicate whether water treated to these existing state standards is currently safe. Cleveland Water asks EPA to further explain why these states' cost-benefit analyses supported their respective levels and why EPA's analysis is different. Water systems need to be able to explain to ratepayers why they are paying more for water, and having these discrepancies does not make that an easy task.

Other countries, such as Australia, Japan, and the United Kingdom (UK) as well as the European Union (EU) have also approved limits on PFAS in drinking water. EPA's analysis is still much lower than every one of these. These countries have access to the same research that EPA does. In the UK, samples above 10 ppt require more investigation to determine if actions are needed, while samples over 100 ppt require immediate action [FN2: https://dwi-content.s3.eu-west-2.amazonaws.com/wp-content/uploads/2023/01/13123351/IL_032022_PFAS_Guidance-4-1.pdf]. Japan sets a provisional target of less than 50 ppt for PFOA and PFOS combined [FN3: https://mainichi.jp/english/articles/20230204/p2a/00m/0op/008000c#:~:text=Since%202010%2C%20Japan%20has%20also,each%20of%20PFOS%20and%20PFOA]. Australia similarly set guidelines at 70 ppt for PFOA and PFOS combined [FN4: https://www.nhmrc.gov.au/about-us/publications/australian-drinking-water-guidelines]. Cleveland Water supports regulation based on sound science and data and asks EPA to further explain how it came to different conclusions than every other state and country currently addressing PFAS in drinking water.

EPA Response: Regarding considerations for existing state and international PFAS standards, regulations and guidelines, please see section 5.1.5 of the EPA response in this *Response to Comments* document.

Arlington County Virginia (Doc. #1603, SBC-043005)

Our concerns, detailed in the following paragraphs can be summarized as:

1. The proposed enforceable Maximum Contaminant Level (MCL) is imprudent

EPA Response: Please see the EPA response to comment Doc. #1603, SBC-043009 in section 5.1.5 in this *Response to Comments* document.

Arlington County Virginia (Doc. #1603, SBC-043009)

Proposed MCL Level

The proposed regulatory levels for the 6 PFAS compounds in drinking water are far more stringent than respected international health organizations and are orders of magnitude below levels which are observed in other exposure pathways.

The World Health Organization in September of 2022 set a provisional guidance value of 100 ppt for PFOA & PFAS, a value 25 times higher than the EPA's proposed MCL. The European Union and UK have established a regulatory framework of 100 ppt mandating response, with levels below 10 ppt deemed non-issues. Australia and Japan have likewise established limits that are substantially higher than the EPA's proposed 4 ppt.

Further, PFAS has been widely reported in organic pasta sauce at levels 5,000 times the proposed regulatory limit, plus similar or higher level in many common food packaging materials. Similarly, sampling of interior dust consistently finds levels of PFAS several orders of magnitude higher than the level proposed in drinking water.

There is currently insufficient science to understand the relative importance of various ingestion paths such as inhalation, food consumption, drinking water, and transdermal methods. However, the available science indicates that the concentrations of PFAS in dust, food and food packaging, and household products are several orders of magnitude greater than the levels proposed for drinking water.

By setting regulatory limits drastically below those of respected international health agencies and magnitudes lower than what consumers are exposed to in their environments, the proposed regulation will lead consumers to develop a misleading sense of the exposure and risks associated with PFAS from drinking water. Such confusion will serve to undermine confidence in public drinking water systems, which are recognized as pillars of public health.

EPA Response: The agency disagrees that the regulation "will lead consumers to develop a misleading sense of the exposure and risks associated with PFAS from drinking water." The MCLs promulgated in this NPDWR will establish national-level regulations for six PFAS in drinking water that are reflective of the best available, peer-reviewed science and supporting studies (please see section 5.1.5 of the EPA response in this *Response to Comments* document for additional discussion on considerations for international and state drinking water standards and guidelines). For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations), 5.1.3 (cost considerations and alternative MCLs) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document.

Fairfax Water (Doc. #1789, SBC-045295)

Risk Communication Challenges

EPA proposes MCL's for PFOA and PFOS that are lower than levels established by any state to date. They are also lower than proposed guidance from the European Union and the World Health Organization. All of these bodies have conducted their own rigorous analysis of scientific studies on potential health impacts of these compounds. It will be challenging for utilities to explain to the public the incremental health benefits provided by EPA's proposed standards relative to the lowest of the existing state standards, and further to explain the capital intensive treatment required to meet that marginally lower MCL. This will be particularly true for utilities that have already made capital investments as a result of a previously established state drinking water regulation for PFAS.

EPA Response: For additional discussion on considerations for international and state drinking water standards and guidelines, please see section 5.1.5 of the EPA response in this *Response to Comments* document. For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations), 5.1.3 (cost considerations and alternative MCLs) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document. For additional discussion on risk communications, please see section 1.2 of the EPA response in this *Response to Comments* document.

Association of Missouri Cleanwater Agencies (Doc. #1817, SBC-044660)

VIII. EPA is out of step with other health organizations around the world who have evaluated PFAS health issues.

As we noted at the outset, our members seek to serve the public in an affordable and cost-effective manner. We don't try to avoid necessary and appropriate requirements. To the contrary, we embrace them and prioritize them within our other infrastructure and operational requirements. However, EPA's proposed PFAS MCLs are so low that they give us pause – especially as we consider the fact that PFAS levels in our environment (and bodies) have been dropping dramatically and will plummet further given the intense focus on ending the use of these chemicals.

With this perspective, we are troubled that EPA's criteria are so much lower than other prominent health agencies. For example, the World Health Organization set a provisional guidance value in September 2022 of 100 ppt for PFOA/PFOS and 500 ppt for all other PFAS. WHO had the benefit of EPA's science when it adopted criteria five orders of magnitude higher for PFOA and four orders of magnitude for PFOS. This is an incredible difference between the world's two preeminent world health organizations.

WHO has not been alone in its repudiation of EPA's interim health advisory levels and now proposed MCLs. For example:

• The United Kingdom and European Union set their PFAS regulatory framework as follows:

<10ppt = no issue;

< 100ppt = research; and

>100ppt = action required.

• Australia set a standard of PFOS + PFHxS at < 70ppt and PFOA a < 560ppt (2022).

• Japan's standard for PFOS+PFOA is < 50 ppt.

• Canada's Guidelines for Canadian Drinking Water Quality, released in September 2022, show 600 ppt for PFOS and 200 ppt for PFOA. The application guidelines indicate the sum of PFOS and PFOA should not exceed 200 ppt. This remains much higher than the EPA proposal.

These are dramatic and, potentially, unprecedented differences between the PFAS standards of prominent health organizations and EPA's, which warrant significant caution on EPA's part. These differences also support our suggested phased implementation approach.

EPA Response: For discussion on considerations for international and state drinking water standards and guidelines, please see section 5.1.5 of the EPA response in this *Response to Comments* document. Please also see the EPA response to comment Doc. #1816, SBC-044682 in section 5.1.3 this *Response to Comments* document.

NORTH CAROLINA WATER QUALITY ASSOCIATION (Doc. #1818, SBC-044638)

VIII. EPA is out of step with other health organizations around the world who have evaluated PFAS health issues.

As we noted at the outset, our members seek to serve the public in an affordable and cost-effective manner. We don't try to avoid necessary and appropriate requirements. To the contrary, we embrace them and prioritize them within our other infrastructure and operational requirements. However, EPA's proposed PFAS MCLs are so low that they give us pause – especially as we consider the fact that PFAS levels in our environment (and bodies) have been dropping dramatically and will plummet further given the intense focus on ending the use of these chemicals.

With this perspective, we are troubled that EPA's criteria are so much lower than other prominent health agencies. For example, the World Health Organization set a provisional guidance value in September 2022 of 100 ppt for PFOA/PFOS and 500 ppt for all other PFAS. WHO had the benefit of EPA's science when it adopted criteria five orders of magnitude higher for PFOA and four orders of magnitude for PFOS. This is an incredible difference between the world's two preeminent world health organizations.

WHO has not been alone in its repudiation of EPA's interim health advisory levels and now proposed MCLs. For example:

• The United Kingdom and European Union set their PFAS regulatory framework as follows:

<10ppt = no issue;

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• Australia set a standard of PFOS + PFHxS at < 70ppt and PFOA a < 560ppt (2022).

• Japan's standard for PFOS+PFOA is < 50 ppt.

• Canada's Guidelines for Canadian Drinking Water Quality, released in September 2022, show 600 ppt for PFOS and 200 ppt for PFOA. The application guidelines indicate the sum of PFOS and PFOA should not exceed 200 ppt. This remains much higher than the EPA proposal.

These are dramatic and, potentially, unprecedented differences between the PFAS standards of prominent health organizations and EPA's, which warrant significant caution on EPA's part. These differences also support our suggested phased implementation approach.

EPA Response: For discussion on considerations for international and state drinking water standards and guidelines, please see section 5.1.5 of the EPA response in this *Response to Comments* document. Please also see the EPA response to comment Doc. #1816, SBC-044682 in section 5.1.3 in this *Response to Comments* document.

South Carolina Water Quality Association (Doc. #1819, SBC-044616)

VIII. EPA is out of step with other health organizations around the world who have evaluated PFAS health issues.

As we noted at the outset, our members seek to serve the public in an affordable and cost-effective manner. We don't try to avoid necessary and appropriate requirements. To the contrary, we embrace them and prioritize them within our other infrastructure and operational requirements. However, EPA's proposed PFAS MCLs are so low that they give us pause – especially as we consider the fact that PFAS levels in our environment (and bodies) have been dropping dramatically and will plummet further given the intense focus on ending the use of these chemicals.

With this perspective, we are troubled that EPA's criteria are so much lower than other prominent health agencies. For example, the World Health Organization set a provisional guidance value in September 2022 of 100 ppt for PFOA/PFOS and 500 ppt for all other PFAS. WHO had the benefit of EPA's science when it adopted criteria five orders of magnitude higher for PFOA and four orders of magnitude for PFOS. This is an incredible difference between the world's two preeminent world health organizations.

WHO has not been alone in its repudiation of EPA's interim health advisory levels and now proposed MCLs. For example:

• The United Kingdom and European Union set their PFAS regulatory framework as follows:

<10ppt = no issue;

< 100ppt = research; and

>100ppt = action required.

• Australia set a standard of PFOS + PFHxS at < 70ppt and PFOA a < 560ppt (2022).

• Japan's standard for PFOS+PFOA is < 50 ppt.

• Canada's Guidelines for Canadian Drinking Water Quality, released in September 2022, show 600 ppt for PFOS and 200 ppt for PFOA. The application guidelines indicate the sum of PFOS and PFOA should not exceed 200 ppt. This remains much higher than the EPA proposal.

These are dramatic and, potentially, unprecedented differences between the PFAS standards of prominent health organizations and EPA's, which warrant significant caution on EPA's part. These differences also support our suggested phased implementation approach.

EPA Response: For discussion on considerations for international and state drinking water standards and guidelines, please see section 5.1.5 of the EPA response in this *Response to Comments* document. Please also see the EPA response to comment Doc. #1816, SBC-044682 in section 5.1.3 in this *Response to Comments* document.

Wet Weather Partnership (Doc. #1820, SBC-044594)

VIII. EPA is out of step with other health organizations around the world who have evaluated PFAS health issues.

As we noted at the outset, our members seek to serve the public in an affordable and cost-effective manner. We don't try to avoid necessary and appropriate requirements. To the contrary, we embrace them and prioritize them within our other infrastructure and operational requirements. However, EPA's proposed PFAS MCLs are so low that they give us pause – especially as we consider the fact that PFAS levels in our environment (and bodies) have been dropping dramatically and will plummet further given the intense focus on ending the use of these chemicals.

With this perspective, we are troubled that EPA's criteria are so much lower than other prominent health agencies. For example, the World Health Organization set a provisional guidance value in September 2022 of 100 ppt for PFOA/PFOS and 500 ppt for all other PFAS. WHO had the benefit of EPA's science when it adopted criteria five orders of magnitude higher for PFOA and four orders of magnitude for PFOS. This is an incredible difference between the world's two preeminent world health organizations.

WHO has not been alone in its repudiation of EPA's interim health advisory levels and now proposed MCLs. For example:

• The United Kingdom and European Union set their PFAS regulatory framework as follows:

<10ppt = no issue;

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• Australia set a standard of PFOS + PFHxS at < 70ppt and PFOA a < 560ppt (2022).

• Japan's standard for PFOS+PFOA is < 50 ppt.

• Canada's Guidelines for Canadian Drinking Water Quality, released in September 2022, show 600 ppt for PFOS and 200 ppt for PFOA. The application guidelines indicate the sum of PFOS and PFOA should not exceed 200 ppt. This remains much higher than the EPA proposal.

These are dramatic and, potentially, unprecedented differences between the PFAS standards of prominent health organizations and EPA's, which warrant significant caution on EPA's part. These differences also support our suggested phased implementation approach.

EPA Response: For discussion on considerations for international and state drinking water standards and guidelines, please see section 5.1.5 of the EPA response in this *Response to Comments* document. Please also see the EPA response to comment Doc. #1816, SBC-044682 in section 5.1.3 this *Response to Comments* document.

Westport Harbor Water Association (Doc. #2855, SBC-047295)

The limits as set for our system are a hardship and we ask that the limits remain at the 20 parts per trillion for smaller systems that serve less than 500 people as set by the Massachusetts DEP. We also question the cost per lives saved as estimated by the EPA for the entire program. Our engineers and testing laboratory find the proposed limits as onerous to even measure on an accurate basis nor have we found any reasonable information as to harm caused by low levels of PFAS/PFOS.

EPA Response: Regarding considerations for existing state and international PFAS standards, regulations and guidelines, please see section 5.1.5 of the EPA response in this *Response to Comments* document. For additional discussion on alternative regulatory standards (including higher PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document. Please also see sections 5.1.2 (for laboratory considerations) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document.

Virginia Municipal Drinking Water Association (VMDWA) (Doc. #1657, SBC-043161)

2. WHETHER THE PROPOSED MCLS ARE SET AT APPROPRIATE LEVELS

A. EPA's Proposal Is Much More Stringent Than PFAS Values Approved by the World Health Organization and Other Nations

EPA's proposed PFAS MCLs are so low as to raise questions as to their appropriateness considering they appear to be far out of step with than other prominent health agencies such as the following:

• World Health Organization – WHO set a provisional guidance value in September 2022 of 100 ppt for PFOA/PFOS (compared to EPA's MCLs of 4 ppt). WHO had the benefit of EPA's science when it adopted its value. This is a 25-fold difference between two of the world's two preeminent health organizations.

• United Kingdom & European Union – The Europeans have set their PFAS regulatory framework as follows:

<10 ppt = no issue;

10 - 100 ppt = research; and >100 ppt = action required.

• Australia – This nation set a standard of PFOS plus PFHxS at <70 ppt and PFOA <560 ppt (2022).

• Japan – This nation set a standard for PFOS plus PFOA of <50 ppt.

These dramatic differences between and among EPA and other respected health organizations (much higher levels approved by the others) warrant consideration by EPA, including in connection with the health-based phased implementation approach we suggest below.

VMDWA is also concerned that adopting such low levels as MCLs will send a message to millions of Americans that their water is not safe to drink.

EPA Response: Regarding considerations for existing state and international PFAS standards, regulations and guidelines, please see section 5.1.5 of the EPA response in this *Response to Comments* document. For additional discussion on risk communications, please see section 1.2 of the EPA response in this *Response to Comments* document. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation.

David Dow (Doc. #2631, SBC-046603)

I am Dr. David Dow from East Falmouth, Ma. For over 30 years I have been engaged in the Superfund/Safe Drinking Water Act cleanup at Joint Base Cape Cod. In recent times the Air Force Civil Engineer Center added the Ma. DEP PFAS6 to the toxic contaminants of concern. This state mcl requires that the sum of 6 PFAS chemicals can't exceed 20 ng/l. The proposed EPA mcl contains many of the same isomers, but has different criteria for implementation which I don't fully understand. Recently EPA sought public comments under CERCLA to add additional PFAS chemicals for regulatory oversight.

The Fire Training Area-1 plume underlies the Yearling Meadows development where I reside and pollutes groundwater in Falmouth and Mashpee. This has required Granular Activated Carbon Filters on Public Drinking Water Wells in the two Cape Cod towns. The sources of the FTA-1 plume include the former fire training area and water/sediments of Ashumet and Johns Ponds. In addition, a PFAS6 plume from a former Massa. Army National Guard Training Range threatens Well #2 on the Upper Cape Water Supply Reserve (which lies on the northern 15,000 acres at JBCC). A recent EPA Region1 study of the UCWSR reported toxic chemical threats from the Massa. Army National Guard's proposed Multi-purpose Machine Gun Range. Falmouth and Sandwich receive public drinking water from the UCWSR as a replacement for Town Public Drinking Water Wells which had to be shut down because of JBCC Superfund plumes.

Given this situation, I wanted to know whether the EPA PFAS mcl was more protective of public health for sensitive populations than Ma. DEP's PFAS6 mcl. In addition, since JBCC and the local Mashpee Wampanoag Tribe appear on the Masaa. Executive Office of Energy & Environmental Affairs Environmental Justice Population maps, how will the proposed EPA mcl address these EJ concerns for drinking water and consumption of fish from the kettle hole ponds adjacent to JBCC which are contaminated at unsafe levels for sensitive populations (according to Massa. Dept of Public Health) ? EPA's Region1 Safe Drinking Water Act Branch explores toxic threats to the UCWSR, while its Superfund Branch deals the AFCEC cleanup of PFAS pollution sources and off base plumes. Ma. DEP has a similar complex regulatory approach which creates confusion amongst the concerned public and activists (some of whom I advise). Since the JBCC cleanup is being conducted under CERCLA/SDWA, which PFAS chemicals will be regulated by EPA Region 1 ?

It is hard for me to see the big picture solution strategy in addressing our local PFAS drinking water challenges

EPA Response: Regarding considerations for existing state and international PFAS standards, regulations and guidelines, please see section 5.1.5 of the EPA response in this *Response to Comments* document. The EPA acknowledges that some states, like Massachusetts, have established drinking water regulations for some PFAS prior to the PFAS NPDWR proposal. At the time of submission of this comment, the agency notes that PFAS NPDWR was a proposal for public comment. As such, the proposal did not require any actions for drinking water systems at that time and as such, a comparison of public health protection for sensitive populations cannot be ascertained. When the final NPDWR goes into effect, states will be required to have a standard that is no less strict than the NPDWR. For environmental justice considerations and the EPA's consultation with Indian Tribal governments for the final NPDWR, please see sections 14.10 and 14.6 of the EPA response in this *Response to Comments* document, respectively. The agency further notes that CERCLA actions are beyond the scope of the current rulemaking; please see section 15.1 of the EPA response in this *Response to Comments* document for further information. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation.

Association of State and Territorial Solid Waste Management Officials (ASTSWMO) (Doc. #1583, SBC-042399)

Consistency with State Standards: More than a dozen States have promulgated groundwater and drinking water protection standards for one or more PFAS. Some State standards use a similar "hazard index" approach for combinations of PFAS and regulate PFAS not included in the proposed MCLGs. EPA should confirm that the proposed federal MCLGs do not affect the applicability of State standards, in the context of their use as "Applicable or Relevant and Appropriate Requirements" (ARARs) in CERCLA cleanups.

EPA Response: The EPA notes that application of MCLs in non-drinking water programs (such as water quality criteria, NPDES, or Applicable, or Relevant and Appropriate Requirements for CERCLA cleanups) is beyond the scope of this rulemaking; please see section 15.1 for additional discussion on comments outside the scope of this NPDWR. Regarding considerations for existing state and international PFAS standards, regulations and guidelines, please see section 5.1.5 of the EPA response in this *Response to Comments* document.

Pennsylvania Chamber of Business and Industry (Doc. #1592, SBC-042793)

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VIA ELECTRONIC FILING

The Honorable Michael Regan, Administrator

May 26, 2023

Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington, DC 20460

RE: Proposed PFAS National Drinking Water Regulation (Docket ID: EPA-HQ-OW2022-0114)

Dear Administrator Regan,

On behalf of the Pennsylvania Chamber of Business and Industry, the largest, broad-based business advocacy organization in the Commonwealth, thank you for the opportunity to present comments with respect to the United States Environmental Protection Agency's (EPA) proposed National Primary Drinking Water Regulation for six PFAS compounds: PFOA, PFNA, HFPODA, PFHxS, and PFBS.

The PA Chamber represents nearly 10,000 members of all sizes and industry sectors. The PA Chamber and our members recognize that the development, use and stewardship of the water resources are essential to the health, success and vitality of every community, industry and enterprise. With that recognition, we understand that stewardship of our water resources requires a delicate, but essential, balancing of environmental and economic considerations.

With this in mind, we respectfully offer the following comments for your consideration.

1. EPA Should Recognize the Substantial Challenge a Federal Approach Will Present to Industry in States that Have Already Established an MCL for These Compounds

On January 14, 2023 the Pennsylvania Department of Environmental Protection published a final rulemaking establishing state drinking water maximum contaminant levels for PFOA at 14 ng/L and PFOS at 18 ng/L. These MCL's were established after an extensive, multi-year statewide sampling across hundreds of drinking water sources in the state, and, importantly, after a multiyear regulatory development process that, per state law, requires a demonstration that the regulation is effective with respect to costs and benefits. A federal MCL beneath these levels will, by our state environmental regulator's own evaluation, result in costs in excess of benefits for the state. Further, a federal MCL that is more stringent than Pennsylvania's will also result in significant challenges for the disposal of PFAS compounds, as well as challenges for industry with stormwater and discharge permits and the remediation and reuse of industrial sites. Such challenges will impede the stated policy goals of the administration and Congress to reshore and expand domestic manufacturing.

EPA Response: Regarding considerations for existing state and international PFAS standards, regulations and guidelines, please see section 5.1.5 of the EPA response in this *Response to Comments* document.

For additional discussion on cost considerations for the final MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Millie Garcia-Serrano (Doc. #1803, SBC-044287)

3. Consistency with State Standards: More than a dozen States have promulgated groundwater and drinking water protection standards for one or more PFAS. Some State standards use a similar "hazard index" approach for combinations of PFAS and regulate PFAS not included in the proposed MCLGs. EPA should confirm that the proposed federal MCLGs do not affect the applicability of State standards, in the context of their use as "Applicable or Relevant and Appropriate Requirements" (ARARs) in CERCLA cleanups.

EPA Response: Regarding considerations for existing state and international PFAS standards, regulations and guidelines, please see section 5.1.5 of the EPA response in this *Response to Comments* document. For additional discussion on cost considerations for the final MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA further notes that application of MCLs in non-drinking water contexts (such as

Applicable, or Relevant and Appropriate Requirements under CERCLA) are beyond the scope of this rulemaking.

U.S. Poultry & Egg Association et al. (Doc. #1765, SBC-044547)

3. EPA has not appropriately addressed the inconsistent messaging regarding PFAS human health risks across EPA program offices, other U.S. federal agencies, state agencies, and international agencies.

Chemical-specific toxicity information developed by EPA is often used not only across agency program offices, but also by other federal and state agencies. In fact, beginning with the initial EPA Risk Assessment Guidance for Superfund, agency guidance recommends selecting toxicity criteria based on the most recent data (USEPA 1989, p. 7-15). This recommendation has since been implemented in numerous EPA directives (USEPA 1993, 2003) that further establish a hierarchy and process for selecting toxicity criteria, all of which rely on the most recent and peer-reviewed source of information. It may be considered by some that the technical support documentation for the proposed MCLs represents the "most recent" assessment by the agency, and peer-review by the Science Advisory Board allows these values to be used across federal and state government agencies. Therefore, it is imperative that the Office of Water consider such additional applications of the toxicity information supporting its proposed drinking water regulations. Specifically, the oral noncancer toxicity values (reference doses, or RfDs) and cancer toxicity values (cancer slope factors or CSFs) for PFOA and PFOS are likely to be incorporated into the Regional Screening Level tables for CERCLA, and may be considered for wastewater discharge, effluent limitation guidelines or National Pollutant Discharge Elimination System permits. Additionally, many state-level remediation, property redevelopment, stormwater, and wastewater programs rely on toxicity information from EPA. The agency needs to clarify how the underlying toxicity information developed as supporting information for the proposed MCLs should and should not be used by other U.S EPA program offices and related state agencies. For public drinking water, states will be required to establish standards that are as strict as the federal regulations. It is not clear how other agencies and programs will incorporate this information.

In addition to EPA, several other federal agencies have authority over statues governing public health, such as the Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA), and the Centers for Disease Control and Prevention (CDC). Statements made by EPA regarding human health risks associated with exposure to PFOA and PFOS present inconsistencies with current positions by some of these agencies. It is not clear how EPA has coordinated its potential PFOA/PFOS risk information across the federal agencies. The deliberations during interagency review should be more transparent to the public. For example, when the FDA finds a detectable level of PFAS in the food supply, the agency conducts an assessment to evaluate whether the level detected presents a possible human health concern and warrants further FDA action. Currently, the FDA is using toxicity information from a mix of the Agency for Toxic Substances and Disease Registry (ATSDR) and EPA [FN3:

https://www.fda.gov/food/process-contaminants-food/testing-food-pfas-and-assessing-dietary-exposure]. Based on information from these sources, the FDA has made public determinations that extremely low levels of certain PFAS detected in food items does not present a risk to public health. However, EPA states in the agency's public FAQ document that "there is no level of these contaminants that is without a risk of adverse health effect." (Proposed PFAS National Primary Drinking Water Regulation FAQ for Drinking Water Primacy Agencies, p. 3). EPA must clarify that its specific statements apply to assumptions related to drinking water exposure and the agency must work with other federal agencies to ensure consistent and science-based messaging.

EPA has not taken into consideration the unintended consequences of such stringent and inconsistent messaging regarding potential human health risks associated with PFOA and PFOS. In addition to other U.S. federal agencies, EPA's position regarding health risks associated with PFAS is inconsistent with other international authoritative bodies, including Health and Environment Canada, Australia Department of Health, Food Standards Australia New Zealand, and the United Kingdom Committee on Toxicity [FN4: See the International portion of the ITRC PFAS "Water Table" factsheet found here: https://pfas-1.itrcweb.org/fact-sheets/]. The substantial inconsistency in human health risk estimates may pose significant problems when it comes to the import and export of items such as food commodities. This has economic implications and presents challenges for global companies with respect to corporate policies and risk management strategies. EPA needs to explicitly consider the implications related to inconsistencies within the public health and regulatory agencies within the U.S. and worldwide. Coordination across federal and state regulatory and public health agencies, and consideration of global impacts, has either not occurred or has not been transparent to the public.

EPA Response: Regarding considerations for existing state and international PFAS standards, regulations and guidelines, please see sections 5.1.5 and 4.2.6 of the EPA response in this *Response to Comments* document. The EPA notes that applications of MCLs (or the toxicity assessments that underpin the MCLGs promulgated in this NPDWR) in non-drinking water contexts or other agency programs is beyond the scope of this rulemaking. Regarding the coordination with other Federal Agencies on PFAS, EPA participates in the cross government IPC convened by the Council of Environmental Quality to share information and collaborate on new policy strategies to support research, remediation, and removal of PFAS in communities across the nation. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation. For additional discussion on PFAS risk communications, please see section 1.2 of the EPA response in this *Response to Comments* document. Regarding commenter concerns with any potential economic implications and challenges to the "import and export of items such as food commodities", any such concerns is not relevant to the EPA's determination that its MCLs met applicable SDWA requirements.

5.1.6 Considerations for Future Science

Summary of Major Public Comments and EPA Responses

Many commenters express concern with "MCLs changing over time" in light of new science and updated information (e.g., improvements in analytical methods, toxicity and/or future occurrence information including UCMR 5) and some contend that the EPA should "review and reduce" the MCLs as science improves. The EPA's final rule represents data-driven drinking water standards that are based on the best available, peer-reviewed science and meet the requirements of SDWA. The EPA agrees with commenters that the agency should periodically review promulgated standards. The EPA is required to review NPDWRs every six years and determine which, if any, need to be revised (i.e., the Six-Year Review Process). The purpose of the review is to evaluate current information for regulated contaminants and to determine if there is any new information on health effects, treatment technologies, analytical methods, occurrence and exposure, implementation and/or other factors that provides a health or technical basis to support a regulatory revision that will improve or strengthen public health protection. This process allows the agency to consider these and other information as appropriate in deciding whether existing NPDWRs should be identified as candidates for revision as required SDWA. For additional discussion on MCLGs, please see section 4 of the EPA response in this *Response to Comments* document; for additional discussion on occurrence, please see section 6 of the EPA response in this *Response to Comments* document; and for additional discussion on analytical methods, please see section 7 of the EPA response in this *Response to Comments* document.

Individual Public Comments

A. O. Smith Corporation (Doc. #1674, SBC-043694)

The Company does appreciate that acting on high concentration levels of PFAS chemicals in the nation's drinking water is critically important and a matter of public health. As the EPA is aware, many States acted under the color of their own authority to regulate PFAS in their drinking water systems prior to the EPA's proposed PFAS NPDWS. Some of those states overlap with the drinking water sampling data that was provided to the EPA as part of its analysis. These states and their respective PFAS MCLs include the following:

[Table: See Docket ID EPA-HQ-OW-2022-0114-1674]

Recognizing that the MCLs established by these states, as well as others, including some that were in development prior to the EPA issuing its proposed PFAS NPDWS, were all promulgated through a combination of legislative and regulatory processes. Those processes, among other things, examined medical literature, toxicological reports, state-based occurrence data, and the technical and cost feasibly of their public water systems to treat drinking water supplies to and none found an MCL at 4 ppt for PFOA and PFOS to be justified. Therefore, while the Company is not in a position to empirically state what the appropriate MCL level for PFOA and PFOS should be at this time, it would recommend that the EPA reconsider setting its value at 4 ppt

taking into consideration the dearth of health-effect data analyzing long-term human exposure at 4 ppt in drinking water and the pending review of UCMR5 occurrence data, which will assist in a potential revision of the cost-effectiveness analysis of setting the MCL at 4 ppt. [FN12: The Company recognizes that the EPA examined a 5 and 10 ppt option for the MCL, which may be more appropriate, but given the lack of toxicology analysis at these levels in humans for long exposure periods as well as occurrence data, the Company still cannot empirically state these are more appropriate levels than those independently promulgated by Maine, Massachusetts, Michigan, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont.]

EPA Response: For discussion on how the EPA considers future science, please see section 5.1.6 of the EPA response in this *Response to Comments* document. The EPA's record for this action supports finalizing the MCLs for PFOA and PFOS at 4.0 ng/L. However, because of supply chain and labor challenges that may affect the compliance timeline, the agency has promulgated a two-year extension of the compliance date for the MCLs. See section 12.1 of the EPA response in this *Response to Comments* document for further information. The EPA currently has sufficient data and information to promulgate standards for the PFAS regulated through this NPDWR and is not required under the statute to wait for another round of UCMR data to be collected before finalizing the regulation. Nonetheless, based on public comment and interest, the agency considered UCMR 5 data released as of July 2023 (USEPA, 2024l). While these data were not available for this rule's proposal and not a basis for informing the agency's decisions for the final rule, the EPA notes that they generally confirm the extensive occurrence analyses the agency has conducted: namely, that all six regulated PFAS occur in finished drinking water and that the six regulated PFAS co-occur with one another. For additional details, please see the *Occurrence Technical Support Document* (USEPA, 2024a) and section 6.8 of the EPA response in this *Response to Comments* document.

Richard Gelderman (Doc. #2820, SBC-047330)

2) There is no safe level of exposure to PFOA or PFOS. For that reason, the EPA must review and reduce the maximum contaminant level (MCL) for PFOA and PFOS as testing technologies advance.

EPA Response: For discussion on how the EPA considers future science, please see section 5.1.6 of the EPA response in this *Response to Comments* document.

Nancy Bouldin (Doc. #2822, SBC-047471)

Dear Assistant Administrator Fox,

I live in Monroe County in southern WV, where we are blessed with clean headwater streams, but significant karst terrain that makes our public and private drinking water sources highly vulnerable to surface contaminants.

Regarding EPA's proposed National Primary Drinking Water Regulation for six per- and polyfluoroalkyl substances (PFAS), I support the EPA's proposal to set strong, science-based drinking water standards and commend the EPA's recognition that both individual PFAS and chemical mixtures of PFAS threaten human health.

My husband grew up in Charleston and when I first went there in the 1970s, the Kanawha River and air were both polluted. Things seemed to improve but now are sliding back as the silent problems of PFAs have made their way into WV waters across the state. This is a critical and long overdue step to protect our public health.

I urge the EPA to consider the following comments to strengthen the proposed rule to further protect and prioritize public health:

1. As recognized by the EPA, there is no safe level of exposure to PFOA or PFOS. For that reason, the EPA must review and reduce the maximum contaminant level (MCL) for PFOA and PFOS as testing technologies advance.

EPA Response: For discussion on how the EPA considers future science, please see section 5.1.6 of the EPA response in this *Response to Comments* document.

Melda Clark (Doc. #2823, SBC-047473)

Dear Assistant Administrator Fox,

WV has very little clean drinking water. What is left of drinkable water in WV needs protection. MVP is also after WV. They own Land air and water straight through the middle of our state. MVP has 201 injection wells on the eastern side of Braxton County WV. Our water is greatly at risk. 5 million GALs of clean water, turns to fracked water with no one wanting the cancer causing waste. Don't let WV hold the waste of natural gas. Stop MVP and others from polluting our water .

Thank you for the opportunity to comment on the EPA's proposed National Primary Drinking Water Regulation for six per- and polyfluoroalkyl substances (PFAS). I support the EPA's proposal to set strong, science-based drinking water standards and commend the EPA's recognition that both individual PFAS and chemical mixtures of PFAS threaten human health. PFAS-contaminated water has harmed the health of West Virginians for decades; this is a critical and long overdue step to protect our public health.

I urge the EPA to consider the following comments to strengthen the proposed rule to further protect and prioritize public health:

1. As recognized by the EPA, there is no safe level of exposure to PFOA or PFOS. For that reason, the EPA must review and reduce the maximum contaminant level (MCL) for PFOA and PFOS as testing technologies advance.

EPA Response: For discussion on how the EPA considers future science, please see section 5.1.6 of the EPA response in this *Response to Comments* document.

Karen Valentine (Doc. #2834, SBC-047475)

Dear Assistant Administrator Fox,

Thank you for the opportunity to comment on the EPA's proposed National Primary Drinking Water Regulation for six per- and polyfluoroalkyl substances (PFAS). I support the EPA's proposal to set strong, science-based drinking water standards and commend the EPA's recognition that both individual PFAS and chemical mixtures of PFAS threaten human health. PFAS-contaminated water has harmed the health of West Virginians for decades; this is a critical and long overdue step to protect our public health.

I urge the EPA to consider the following comments to strengthen the proposed rule to further protect and prioritize public health:

1. As recognized by the EPA, there is no safe level of exposure to PFOA or PFOS. For that reason, the EPA must review and reduce the maximum contaminant level (MCL) for PFOA and PFOS as testing technologies advance.

EPA Response: For discussion on how the EPA considers future science, please see section 5.1.6 of the EPA response in this *Response to Comments* document.

Monty Fowler (Doc. #2836, SBC-047477)

Dear Assistant Administrator Fox,

I support the EPA's proposal to set strong, science-based drinking water standards and commend the EPA's recognition that both individual PFAS and chemical mixtures of PFAS threaten human health. PFAS-contaminated water has harmed the health of West Virginians for decades; this is a critical and long overdue step to protect our public health.

I urge the EPA to consider the following comments to strengthen the proposed rule to further protect and prioritize public health:

1. As recognized by the EPA, there is no safe level of exposure to PFOA or PFOS. For that reason, the EPA must review and reduce the maximum contaminant level (MCL) for PFOA and PFOS as testing technologies advance.

EPA Response: For discussion on how the EPA considers future science, please see section 5.1.6 of the EPA response in this *Response to Comments* document.

Steven Cole (Doc. #2837, SBC-047479)

Dear Assistant Administrator Fox,

Thank you for the opportunity to comment on the EPA's proposed National Primary Drinking Water Regulation for six per- and polyfluoroalkyl substances (PFAS). I support the EPA's proposal to set strong, science-based drinking water standards and commend the EPA's recognition that both individual PFAS and chemical mixtures of PFAS threaten human health. PFAS-contaminated water has harmed the health of West Virginians for decades; this is a critical and long overdue step to protect our public health.

I urge the EPA to consider the following comments to strengthen the proposed rule to further protect and prioritize public health:

1. As recognized by the EPA, there is no safe level of exposure to PFOA or PFOS. For that reason, the EPA must review and reduce the maximum contaminant level (MCL) for PFOA and PFOS as testing technologies advance.

EPA Response: For discussion on how the EPA considers future science, please see section 5.1.6 of the EPA response in this *Response to Comments* document.

John Doyle (Doc. #2840, SBC-047481)

Dear Assistant Administrator Fox,

Thank you for the opportunity to comment on the EPA's proposed National Primary Drinking Water Regulation for six per- and polyfluoroalkyl substances (PFAS). I support the EPA's proposal to set strong, science-based drinking water standards and commend the EPA's recognition that both individual PFAS and chemical mixtures of PFAS threaten human health. PFAS-contaminated water has harmed the health of West Virginians for decades; this is a critical and long overdue step to protect our public health.

I urge the EPA to consider the following comments to strengthen the proposed rule to further protect and prioritize public health:

1. As recognized by the EPA, there is no safe level of exposure to PFOA or PFOS. For that reason, the EPA must review and reduce the maximum contaminant level (MCL) for PFOA and PFOS as testing technologies advance.

EPA Response: For discussion on how the EPA considers future science, please see section 5.1.6 of the EPA response in this *Response to Comments* document.

Laurine Yates (Doc. #2900, SBC-047483)

Dear Assistant Administrator Fox,

Thank you for the opportunity to comment on the EPA's proposed National Primary Drinking Water Regulation for six per- and polyfluoroalkyl substances (PFAS). I support the EPA's proposal to set strong, science-based drinking water standards and commend the EPA's recognition that both individual PFAS and chemical mixtures of PFAS threaten human health.

PFAS-contaminated water has harmed the health of West Virginians for decades; this is a critical and long overdue step to protect our public health.

I urge the EPA to consider the following comments to strengthen the proposed rule to further protect and prioritize public health:

1. As recognized by the EPA, there is no safe level of exposure to PFOA or PFOS. For that reason, the EPA must review and reduce the maximum contaminant level (MCL) for PFOA and PFOS as testing technologies advance.

EPA Response: For discussion on how the EPA considers future science, please see section 5.1.6 of the EPA response in this *Response to Comments* document.

Mass comment campaign submitted by Jill Fischer (Doc. #3070, SBC-047485)

Dear Assistant Administrator Fox,

Thank you for the opportunity to comment on the EPA's proposed National Primary Drinking Water Regulation for six per- and polyfluoroalkyl substances (PFAS). I support the EPA's proposal to set strong, science-based drinking water standards and commend the EPA's recognition that both individual PFAS and chemical mixtures of PFAS threaten human health. PFAS-contaminated water has harmed the health of West Virginians for decades; this is a critical and long overdue step to protect our public health.

I urge the EPA to consider the following comments to strengthen the proposed rule to further protect and prioritize public health:

1. As recognized by the EPA, there is no safe level of exposure to PFOA or PFOS. For that reason, the EPA must review and reduce the maximum contaminant level (MCL) for PFOA and PFOS as testing technologies advance.

EPA Response: For discussion on how the EPA considers future science, please see section 5.1.6 of the EPA response in this *Response to Comments* document.

Wagner Engineering (Doc. #3072-9, SBC-047360)

Is it EPA’s intention to reduce the MCL in the future as testing capabilities improve, and the minimum detection limit decreases? If so, what assurances can EPA provide to the impacted water systems that the technologies being recommended and utilized today will meet future requirements, and not require additional capital expense that will have to be passed on to ratepayers?

EPA Response: For discussion on how the EPA considers future science, please see section 5.1.6 of the EPA response in this *Response to Comments* document.

Three Rivers Waterkeeper (3RWK) (Doc. #1689, SBC-044974)

III. 3RWK supports the strong MCLs for PFOS and PFOA, but notes that future developments in testing technology could render an MCL of 4.0 ppt obsolete.

The EPA's proposal to set the Maximum Contaminant Level Goal (MCLG) for PFOS and PFOA at zero is critical to protecting the health of our nation's waterways and the people who rely on them. PFOS and PFOA are already subject to restrictions and bans in a number of State and international jurisdictions due to the strength of the evidence suggesting their association with serious health impacts. 3RWK supports the EPA's decision to set a strong, cautious standard protecting public health.

3RWK believes that the enforceable MCL should be set as close as possible to the unenforceable MCLG. The EPA says that 4.0 ppt is the current limit at which PFOS and PFOA are reliably detectable, and that lower MCLs would likely lead to laboratory capacity issues. However, if there is no safe amount of PFOS and PFOA, then it follows that any detectable amount is unacceptable. As new monitoring technology becomes available and tests become more sensitive, the MCL of 4.0 ppt becomes obsolete. Furthermore, the limit of 4.0 ppt essentially tells communities that if PFAS is detected at the strength that 2023's testing equipment is capable of showing, then they have no recourse, even if they are likely exposed to a harmful concentration of PFAS.

EPA Response: The EPA's final rule represents data-driven drinking water standards that are based on the best available, peer-reviewed science, meet the requirements of SDWA, and that regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. For discussion on how the EPA considers future science, please see section 5.1.6 of the EPA response in this *Response to Comments* document. For additional discussion on how the agency considers analytic feasibility when establishing the MCL, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046105)

Despite acknowledging that existing technologies can reduce PFOA and PFOS levels below 4 ppt, EPA proposed a 4 ppt MCL based on those chemicals' practical quantitation levels ("PQL"), or the lowest level that can be detected "by capable analysts at 75 percent or more of the laboratories using a specified analytical method[.]" [FN73: Proposed Rule, 88 Fed. Reg. at 18,666–67.] Because no laboratories can currently measure PFOA or PFOS levels down to the 0 ppt MCLG and not all labs can reliably measure those chemicals below the PQL, "EPA often bases the MCL on the PQL." [FN74: EPA, EPA 810-R-16-002, Development of Estimated Quantitation Levels for the Third Six- Year Review of National Primary Drinking Water Regulations (Chemical Phase Rules), Off. of Water, at 1-3 (Oct. 2016), https://www.epa.gov/sites/default/files/2016- 12/documents/810r16002.pdf.] EPA's latest six-year review of National Primary Drinking Water Treatment Standards identified at least 14

contaminants for which EPA set MCLs based on the PQL, including benzo[a]pyrene, PCBs, and 2,3,7,8-Tetrachlorodibenzo-p-Dioxin. [FN75: Id. at 1-3 – 1-4.] Similarly, setting the PFOA and PFOS MCLs at the PQL is consistent with the SDWA and with EPA's past practice.

As testing technologies advance, however, EPA must review and reduce those MCLs. The SDWA provides that "not less often than every 6 years," EPA must "review and revise, as appropriate, each national primary drinking water regulation promulgated under this subchapter." [FN76: 42 U.S.C. § 300g–1(b)(9).] As EPA acknowledges, laboratory testing capacity "can improve over time," and "the Six-Year Review process is an opportunity to evaluate whether new information . . . shows that PQLs for carcinogens can be reduced, which introduces the possibility of reducing the MCLs[.]" [FN77: EPA, EPA 810-R-16-002, Development of Estimated Quantitation Levels for the Third Six- Year Review of National Primary Drinking Water Regulations (Chemical Phase Rules), at 1-2.] Many labs already have the ability to measure PFOA and PFOS well below the MCLs, and some emerging technologies can detect PFOA, PFOS, GenX, and PFBS in the parts- per-quadrillion range. [FN78: Phenomenex, Achieving Low Parts-per-Quadrillion Detection Limits for PFAS Analysis in Drinking Water (TN-1316), at 1, https://www.phenomenex.com/documents/2022/09/29/17/52/achieving-low-partsperquadrillion- detection-limits-for-pfas-analysis-in-drinking-water-tn1316.] EPA should reassess laboratories' PFOA and PFOS detection capacity during each six-year review period and decrease the MCL whenever new information supports a lower PQL.

EPA Response: The EPA's final rule represents data-driven drinking water standards that are based on the best available, peer-reviewed science, meet the requirements of SDWA, and that regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. For discussion on how the EPA considers future science, please see section 5.1.6 of the EPA response in this *Response to Comments* document. For additional discussion on how the agency considers analytic feasibility when establishing the MCL, please see 5.1.2 of the EPA response in this *Response to Comments* document.

American Farm Bureau Federation et al. (Doc. #1642, SBC-043503)

It is also worth noting that the World Health Organization (WHO) has recommended a limit of 100 ppt, individually, of either PFOA or PFOS in drinking water and a total cap of 500 ppt for combinations of up to 30 PFAS. When formulating this limit, the WHO looked at the same basic data that EPA evaluated in crafting this proposed rule—but reached very different conclusions. These guidelines represent the position of the United Nations regarding PFAS in drinking water and are likely to be adopted by many countries around the world. Meanwhile, the EPA has rushed to release proposed MCLs that will be extremely challenging to meet.

Conclusion

We strongly encourage the EPA to reevaluate the proposed MCLs for these six PFAS chemicals to ensure that it is an achievable standard and isn't unnecessarily burdensome to families

nationwide in the form of higher rates and entirely beyond reach – to implement or afford – for rural communities. The challenges that we have outlined in these comments regarding the feasibility of this rule mirror those of the thousands of small, rural drinking water utilities throughout the country. We hope that you will consider our concerns as you continue to work to make our drinking water safer, yet accessible for all American families.

American Farm Bureau Federation

American Horse Council

American Soybean Association

International Fresh Produce Association

National Association of State Departments of Agriculture

National Association of Wheat Growers

National Council of Farmer Cooperatives

National Milk Producers Federation

National Pork Producers Council

National Turkey Federation

U.S. Poultry & Egg Association

United Egg Producers

EPA Response: The EPA does not believe it is appropriate to use the WHO's approach for determining PFOA and PFOS or other PFAS MCLs because it is inconsistent with the statutory requirements of the SDWA. The language in the SDWA is clear: the EPA must set the MCL as close as feasible to the health-based MCLG. In setting the MCLG, the EPA uses established systematic review practices (USEPA, 2022b) to identify, evaluate, synthesize, integrate, and quantify evidence in a chemical database. These protocols have been repeatedly peer-reviewed and improved upon over time. Other health agencies, including the WHO, do not follow these same practices and, as a result, may arrive at different conclusions. The EPA then considers non-health-based factors (such as analytic and treatment feasibility) when setting the MCL as close as feasible to the MCLG. For more information, please see section 4.2.6 of the EPA response in this *Response to Comments* document. Additionally, the WHO has stated, "In light of comments received and to ensure that the latest evidence is taken into account since the background document was drafted, WHO will continue its review of PFAS. The updated assessment will consider, inter alia, the IARC's carcinogenicity assessment on PFOS and PFOA," (https://www.who.int/teams/environment-climate-change-and-health/water-sanitation-and-health/chemical-hazards-in-drinking-water/per-and-polyfluoroalkyl-substances) indicating that their conclusions are subject to change. The EPA's final rule represents data-driven drinking water standards that are based on the best available, peer-reviewed science, meet the

requirements of SDWA, and that regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. For discussion on how the EPA considers future science, please see section 5.1.6 of the EPA response in this *Response to Comments* document. For additional discussion on how the agency considers analytic feasibility when establishing the MCL, please see 5.1.2 of the EPA response in this *Response to Comments* document.

Illinois Farm Bureau (IFB) (Doc. #1630, SBC-043144)

It is also worth noting that the World Health Organization ("WHO") has recommended a limit of 100 ppt, individually, of either PFOA or PFOS in drinking water and a total cap of 500 ppt for combinations of up to 30 PFAS. When formulating this limit, the WHO looked at the same basic data that EPA evaluated in crafting this proposed rule— but reached very different conclusions. These guidelines represent the position of the United Nations regarding PFAS in drinking water and are likely to be adopted by many countries around the world. Meanwhile, the EPA has rushed to release proposed MCLs that will be extremely challenging to meet.

Conclusion

In light of the uncertain benefits and the economic hardships a new standard would cause to farmers in Illinois, the Illinois Farm Bureau encourages the EPA to continue to reevaluate the proposed MCLs for these six PFAS chemicals.

IFB appreciates your thoughtful consideration of these comments. If you wish to discuss any of these concerns or suggestions, please contact Lauren Lurkins, Director of Environmental Policy, at llurkins@ilfb.org or (309) 557-3153.

Sincerely,

Richard L. Guebert, Jr.

President

Illinois Farm Bureau®

1701 Towanda Avenue

Bloomington, IL 61701-2050

EPA Response: Please see the EPA response to comment Doc. #1642, SBC-043503 in section 5.1.6 in this *Response to Comments* document.

Washington Suburban Sanitary Commission (WSSC Water) (Doc. #1585, SBC-042767)

Comments by Washington Suburban Sanitary Commission:

Docket ID: EPA-HQ-OW-2022-0114

PFAS National Primary Drinking Water Regulation Rulemaking

1. Maximum Contaminant Levels

Hazard Index approach:

EPA is proposing an MCL for mixtures of PFHxS, HFPO-DA, PFNA, and PFBS expressed as a Hazard Index (HI). WSSC Water is concerned that regulating a group of contaminants in this complex manner will make future compliance incrementally difficult as additional PFAS chemicals that exhibit similar dose-additive health impacts are identified. This approach would practically lower the allowable Health Quotient for individual chemical each time new contaminants are added and regulated in the group. In contrast, under the Stage 2 DBP Rule, EPA successfully regulated a group of co-occurring contaminants by setting an implementable MCL supported by available analytical and treatment technologies. WSSC Water suggests that EPA explore an alternative approach to regulate PFAS chemicals as a class, in a sustainable and consistent manner. We also recognize that developing such a novel approach will require a significant amount of time, and urge that EPA set aside adequate amount of time for soliciting input from stakeholders and experts to ensure the legitimacy of the approach.

EPA Response: For discussion on how the EPA considers future science, please see section 5.1.6 of the EPA response in this *Response to Comments* document. With respect to the 60-day public comment process and comment period extensions, please see 17.1 of the EPA response in this *Response to Comments* document. For additional discussion on the feasibility of the hazard index MCL, please see section 5.2 of the EPA response in this *Response to Comments* document. For additional discussion on alternative MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Oregon Health Authority (OHA) (Doc. #1582, SBC-042759)

However, OHA encourages EPA to continue research to hopefully incorporate more species of PFAS into this HI class approach as toxicity information becomes available.

EPA Response: For discussion on how the EPA considers future science, please see section 5.1.6 of the EPA response in this *Response to Comments* document.

Citizens Campaign for the Environment (CCE) (Doc. #1710, SBC-045132)

As technology for water treatment and testing improves, MCL's can and should be strengthened to match MCLG's, thus treating drinking water to a level that is truly safe for consumption.

EPA Response: For discussion on how the EPA considers future science, please see section 5.1.6 of the EPA response in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1711, SBC-044467)

[The Agency's proposal suffers from the following significant shortcomings –]

• The Agency's choice of regulatory alternatives does not provide a reasonable basis for comparison of the possible regulatory approaches.

ACC urges the Agency to withdraw its preliminary regulatory determination and proposed standard for the four PFAS until its has collected additional information on the national occurrence of these substances.

EPA Response: For discussion on how the EPA considers future science, please see section 5.1.6 of the EPA response in this *Response to Comments* document. The EPA disagrees with commenter that the agency needs to wait for additional information on the national occurrence of these substances in order to finalize the NPDWR at this time. The EPA currently has sufficient data and information to make a regulatory determination for the PFAS regulated through this NPDWR: for additional discussion on the EPA's regulatory determinations, please see section 3; for additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations), 5.1.3 (cost considerations and alternative MCLs), 5.1.4 (for treatment considerations) and section 6 (for occurrence) of the EPA response in this *Response to Comments* document.

Environmental Working Group (EWG) (Doc. #1721, SBC-045419)

EPA should periodically update the MCLs and health-based water concentrations as new science emerges and detection methods improve.

SDWA requires that the EPA "shall, not less often than every 6 years, review and revise, as appropriate, each national primary drinking water regulation."[FN86: 42 U.S.C. [sec] 300g–1(b)(9).] As part of this six-year review, and more frequently if needed, the EPA should review both health data and laboratory capacity and adjust the MCLS appropriately.

The EPA proposed the 4 ppt MCL for PFOA and PFOS as the closest feasible MCL to the MCLG of 0 ppt based on the practical quantitation levels ("PQL") for those two PFAS. The PQL is the lowest level detectable "by capable analysts at 75 percent or more of the laboratories using a specified analytical method."[FN87: PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18638, 18666 (March 29, 2023).] However, as the EPA acknowledges, "the overwhelming majority of laboratories with the necessary instrumentation to support PFAS monitoring" can detect PFOA and PFOS below the PQL of 4 ppt and "49 out of 54 laboratories seeking EPA approval included a lowest PFAS calibration standard level at 1 ppt or lower."[FN88:Id.]

Because most laboratories can detect PFOA and PFOS well below the PQL it may only be a short matter of time before the PQL is below 4 ppt. Furthermore, many labs can also detect the four HI PFAS at levels well below the HBWCs assigned to each PFAS. We suggest the EPA

reassess the toxicity thresholds for the HBWCs as it prepares the final rule, but also continue to reassess those thresholds as new science emerges and as testing technologies advance.

Furthermore, because so many labs can detect PFAS below the PQLs and HBWCs, utilities should report all measurable detections when monitoring for PFAS. The EPA should not treat detections below the PQL as non-detects, especially when consumers have an interest in knowing about all measurable PFAS detections in their drinking water.

EPA Response: For discussion on how the EPA considers future science, please see section 5.1.6 of the EPA response in this *Response to Comments* document. For additional discussion on CCRs and reporting of detected values, please see section 9.1 of the EPA response in this *Response to Comments* document. For monitoring and compliance requirements and use of values below the PQL, please see section 8.8 of the EPA response in this *Response to Comments* document. For additional discussion on PQLs, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

West Virginia Rivers Coalition (Doc. #3072-21, SBC-047370)

These MCLs are a necessary step in the work to safeguard public health from PFAS contamination. However, these rules must be adaptive to technology as it advances. The MCLs are currently set at a detectable level, but detection technology will continue to advance throughout the coming years. We need rulemaking that can swiftly evolve alongside advances in science. These MCLs must be regularly reviewed and updated.

EPA Response: For discussion on how the EPA considers future science, please see section 5.1.6 of the EPA response in this *Response to Comments* document.

West Virginia Rivers (Doc. #3072-70, SBC-046384)

Thank you for the opportunity to speak this evening. My name is Maria Russo and I am the Clean Water Campaign Coordinator for the West Virginia Rivers Coalition. As we know, PFAS are carcinogens and exposure affects the immune and cardiovascular systems, as well as human development. When exposed over time, PFAS can lead to kidney cancer, pancreatic cancer, and death. I am from the eastern panhandle of West Virginia and it has been proven that my community, people I love, have been exposed to PFAS through contaminated drinking water. In a recent study completed by the United States Geological Survey, in cooperation with the West Virginia Department of Environmental Protection, along with other partners, at least one type of PFAS was detected at levels exceeding health advisories in 130 of our community water systems. My region in the eastern panhandle has some of the highest concentration of PFAS in raw water across the state of West Virginia. Blue Ridge Elementary School, which is less than 10 miles from my house, has PFOA and PFOS levels exceeding 14.8 parts per trillion. It is critical that we start addressing PFAS at the source such as product manufacturing so that we can make our collective work easier in addressing this massive public health issue. The EPA states that it is committed to using and advancing the best available science to tackle PFAS pollution and

protect public health to provide safe drinking water for all. While I recognize the EPA is proposing individual MCLs of 4.0 parts per trillion due to current technology, I urge EPA to continue to revisit those standards frequently as the technology continues to improve. I support the EPA setting the Maximum Contaminant Level Goals, MCLG, for PFOA and PFOS at zero. I hope that we can make that goal of zero a reality. The longer we wait to lower these standards, the longer our communities will continue to be exposed to these life-threatening forever chemicals. Thank you.

EPA Response: For discussion on how the EPA considers future science, please see section 5.1.6 of the EPA response in this *Response to Comments* document.

Prince William County Service Authority (Doc. #1609, SBC-042834)

Water Utilities Need a Comprehensive Understanding of the Future PFAS Regulatory Framework to Support Decision Making for Capital Intensive Infrastructure

The drinking water treatment process results in several residual streams including process water from filter backwashes, sediments that are removed from source waters, and spent filter media. Utilities need to have clarity on the entire EPA PFAS regulatory structure, from source water to residuals, to make informed and cost-effective decisions on behalf of their ratepayers. EPA needs to provide clarity on how and when it will regulate sources of PFAS in the environment. There is currently no EPA regulatory mechanism to eliminate a PFAS source in a drinking water supply. EPA should reprioritize its PFAS regulatory focus so that sources are eliminated at the polluter's expense instead of PFAS remediation becoming the financial burden of the public.

The proposed rule states that other PFAS compounds may be added to the proposed HI in the future. EPA also indicates that the MCLs for PFOA and PFOS could be lowered in future regulatory actions. EPA is moving forward with actions such as designating certain PFAS compounds as hazardous waste under CERCLA, which further introduces risk to utility ratepayers. EPA has been considering rules on PFAS in biosolids from wastewater treatment plants .

EPA Response: The EPA's PFAS Strategic Roadmap lays out EPA's whole of agency approach to tackling PFAS. The PFAS Strategic Roadmap describes how EPA will get upstream of the problem and bring deeper focus to preventing PFAS from entering the environment in the first place—a foundational step to reducing the exposure and potential risks of future PFAS contamination. The EPA notes that the other actions to address sources of PFAS are highlighted in the agency's PFAS Strategic Roadmap including the CERCLA hazardous waste designation are beyond the scope of this rulemaking (please see section 15.1 of the EPA response in this *Response to Comments* document for additional information). For discussion on how the EPA considers future science, please see section 5.1.6 of the EPA response in this *Response to Comments* document.

Prince William County Service Authority (Doc. #1609, SBC-042848)

7. Utilities need a comprehensive understanding of EPA's proposed regulatory structure for PFAS from sources of supply to residuals in order to make cost effective decisions and reduce rate impacts to our customers.

The Prince William County Service Authority appreciates the opportunity to comment on EPA's PFAS National Primary Drinking Water Regulation Rulemaking.

Sincerely,

Calvin D. Farr, Jr., P.E.

General Manager/CEO

EPA Response: Please see the EPA response to comment Doc. #1586, SBC-042384 in section 1.3 in this *Response to Comments* document.

Three Rivers Waterkeeper (3RWK) (Doc. #1689, SBC-044977)

V. The scientific understanding of PFAS and the legislative frameworks are in flux, necessitating an approach that can be adapted to changing circumstances.

Indeed, two of 3RWK's criticisms of the Pennsylvania DEP's PFAS regulations were the decision to not propose MCLs for PFAS other than PFOS and PFOA, and the decision to allow for unusually high cumulative MCLs for PFOS and PFOA.

Both government agencies and the industries that rely on PFAS must prepare for the eventual total phasing out of PFAS. The more the health effects of PFAS become clear, and the more we understand these chemicals, the more regulation of certain individual PFAS registers as insufficient. Recent studies for example have shown the importance of accounting for precursor chemicals as well, which are not addressed in this proposed rule. [FN18: Bridger J. Ruyle et al., Centurial Persistence of Forever Chemicals at Military Fire Training Sites, 57 Environmental Science and Technology 8096, 8103-04, May 15, 2023, https://pubs.acs.org/doi/10.1021/acs.est.3c00675. See also Paul Karoff, EPA's New PFAS Rules Don't Account for Major Source of Drinking Water Contamination, Harvard John A. Paulson School of Engineering and Applied Sciences News, May 15, 2023, https://seas.harvard.edu/news/2023/05/epas-new-pfas-rules-dont-account-major-source-drinking-water-contamination.] As mentioned previously, States such as Minnesota are passing increasingly strict PFAS rules, and the international community is pondering the possibility of banning them all. As important as PFAS have been to America's industrial history, there are alternatives that lack the extreme health and environmental impacts. [FN19: Cheryl Hogue, How to Say Goodbye to PFAS, 97 Chemical & Engineering News 47, Nov. 20, 2019, https://cen.acs.org/environment/persistent-pollutants/say-goodbye-PFAS/97/i46#.]

EPA Response: For discussion on how the EPA considers future science, please see section 5.1.6 of the EPA response in this *Response to Comments* document. Regarding considerations for existing state and international PFAS standards, regulations and guidelines, please see section 5.1.5 of the EPA response in this *Response to Comments* document. For additional discussion on regulation of additional PFAS, including PFAS precursors, please see section 5.1.3 of the EPA response in this *Response to Comments* document.

5.1.7 Significant Figure Usage

Summary of Major Public Comments and EPA Responses

The EPA received several comments related to significant figure usage in the rule proposal for MCLs, MCLGs, and HBWCs. Some commenters stated EPA's proposal regarding significant figure usage was unclear and/or displayed inconsistently throughout the proposed rule. The agency clarifies for these commenters that in the rule proposal the agency intended to express the PFOA and PFOS MCLs, as well as the Hazard Index MCLG and MCLs and the respective HBWCs for the four Hazard Index PFAS, to the tenths place in ppt (ng/L) (e.g., 4.0 ppt for PFOA MCL, 1.0 for the Hazard Index MCL and MCLG, and 10 ppt for the PFNA HBWC). In the proposal, the agency specifically requested comment on significant figure use when calculating both the Hazard Index MCLG and MCL using two significant figures (i.e., 1.0). For comments and a discussion on significant figure usage for the Hazard Index MCL and MCLG, HBWCs for the Hazard Index PFAS, and the individual MCLs and MCLGs for PFHxS, PFNA and HFPO-DA, which are all being finalized with one significant figure, please see the final rule preamble section IV.B.1.b and section 4.3.4 of the EPA response in this *Response to Comment*s document.

Commenters asked the EPA to clarify the use of significant figures concerned that results may affect compliance (i.e., RAA) calculations. These commenters note that sample results that are rounded to one versus two significant figures may affect compliance determinations particularly when the MCL is set at the PQL. The EPA agrees that the number of significant figures required and process for mathematical rounding can impact the compliance result but as described below, the agency maintains that it is establishing the most appropriate number based on available information and statutory requirements. For PFOA and PFOS, the EPA is finalizing MCLs using two significant digits. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation and will consider implementation topics (such as compliance calculations) as the agency develops implementation materials for the final NPDWR.

For all regulated PFAS, including the individual PFAS MCLs and the Hazard Index MCL, the EPA is finalizing the number of significant figures based on consideration of the precision of the analytical methods for the regulated PFAS and the precision of the underlying parameters used to derive the health-based values (i.e., MCLGs and HBWCs). Furthermore, under SDWA, the agency must set the MCL as close as feasible to the MCLG. EPA guidance states that all MCLs should be expressed in the number of significant digits permitted by the precision and accuracy

of the specified analytical procedure(s) and that data reported should contain the same number of significant digits as the MCL (USEPA, 2000b). Additionally, EPA methods 533 and 537.1, those authorized for use in determining compliance with the final PFAS MCLs, state that "[c]alculations must use all available digits of precision, but final reported concentrations should be rounded to an appropriate number of significant digits (one digit of uncertainty), typically two, and not more than three significant digits" (USEPA, 2009 and USEPA, 2019). Consequently, the EPA has determined that both methods 533 and 537.1 provide sufficient analytical precision to allow for two significant digits for all PFAS analyzed under these methods with the use of two significant digits being the most appropriate number given analytical uncertainty in allowing for more digits.

Specifically, regarding consideration of the derivation of the PFOA and PFOS MCLGs, as previously discussed in section IV of the final rule preamble, the health-based MCLGs for PFOA and PFOS are being finalized as zero because these two PFAS are likely human carcinogens. Based on EPA's MCL feasibility determination under SDWA described in section V.A of the final rule preamble, the MCLs for PFOA and PFOS cannot be set identical to these MCLGs. Therefore, unlike the PFHxS, PFNA, and HFPO-DA MCLs and the Hazard Index MCL where the underlying health information drove the decision for one significant figure for the MCLGs and HBWCs and the MCL must be set as close as feasible to the MCLG (see section IV.B.1.b and section 4.3.4 of the EPA response in this *Response to Comment*s document), the use of two significant figures for the PFOA and PFOS MCLs (i.e., 4.0 ng/L each) is the most appropriate number provided that both the precision of the analytical methods allows for this and this level is as close as feasible to the MCLGs (i.e., use of one significant figure (4 ng/L) would not be as close as feasible to the MCLG). This approach of using two significant figures is also consistent with other MCLs the EPA has set with carcinogenic contaminants with MCLGs of zero, including arsenic and bromate.

Individual Public Comments

PFAS Regulatory Coalition (Doc. #1761, SBC-046093)

The American Petroleum Institute (API) members are concerned that the commercial drinking water analytical laboratories may not have sufficient sensitivity and reporting precision to meet the proposed MCLs, HI, MCLGs, and trigger levels. API retained Environmental Standards, Inc. (Environmental Standard) to survey the commercial analytical laboratories accredited by The NELAC Institute (TNI) to perform PFAS analyses in drinking water utilizing the US EPA Methods 533, 537, and/or 537.1 to understand the analytical sensitivity and reporting precision currently being provided.

2.0 Brief on Environmental Standards

Environmental Standards is a consulting firm founded in 1987. Environmental Standards was acquired by Montrose Environmental Group in 2022. Environmental Standards' specialty consulting offerings include environmental chemistry, geosciences, environmental data

management, emergency response quality assurance oversight, and environmental health and safety auditing support.

Environmental Standards' chemistry staff includes B.S. through Ph.D. Chemists, six national Registry of Certified Chemists – Certified Environmental Analytical Chemists and one American Society of Quality – Certified Quality Auditor.

With respect to Environmental Standards' long rich history in fluorochemistry, our Chemists have been retained by several Future 500 Companies to provide chemistry quality assurance support for their perfluorinated compound (PFC, now PFAS) projects dating back to 2000. These projects have generated tens of thousands of commercial laboratory sample data representing drinking water, groundwater, surface water, wastewater, sediment, soil, tissues, and various other matrices (e.g., articles of commerce, fire debris, windshield washer fluid to name a few).

3.0 Surveyed Laboratories

Environmental Standards utilized the TNI Laboratory Accreditation Management System (LAMS) (https://lams.nelac-institute.org/) to search for environmental laboratories that are accredited to analyze PFAS analytes in drinking water by US EPA Methods 533, 537, and/or 537.1. Environmental Standards identified 51 facilities as being accredited to analyze drinking water for PFAS analytes by US EPA Methods 533, 537, and/or 537.1. Environmental Standards provided a survey to gather information on method detection limits (MDLs), practical quantitation limits (PQLs), lowest calibration standard concentration, and reporting significant figures. Environmental Standards received responses that represent 14 of the 51 facilities.

Environmental Standards noted that even though laboratories have retained TNI accreditation for US EPA Method 537, none of the 14 responding facilities offered this analysis to clients and provided US EPA Method 537.1 analysis instead. Of the 14 responding facilities, 12 of the facilities offer US EPA Method 533 analyses. A listing of the MDLs, PQLs and lowest calibration standard concentration is provided on Table 1.

4.0 Comments on Commercial Laboratory Sensitivity

Environmental Standards evaluated the provided information to understand if the commercial laboratory facilities can provide sufficient sensitivity and reporting precision (e.g., significant figures) to support/meet the proposed MCLs, HI MCLGs, and trigger levels.

Both US EPA Methods 533 and 537.1 indicate the laboratory must establish a minimum reporting level (MRL). The MRL is the lowest analyte concentration that meets data quality objectives and are generally equivalent to the lowest initial calibration standard concentration. US EPA Method 533 Section 12.2 specifies that the laboratory must report only those values that fall between the MRL (i.e., lowest calibration standard concentration) and the highest calibration standard.

Environmental Standards has summarized the MCLs, HBWCs, and trigger levels along with the lowest and highest MDLs, PQLs, and lowest initial calibration standards provided by the responding laboratories on Table 2.

Environmental Standards observed that the laboratory-provided PQLs for PFOA and PFOS were below the proposed MCLs of 4 ppt. However, in all cases, the PQLs reported were higher than the proposed trigger level of 1.3 ppt.

While MDL reporting is not acceptable for Methods 533 and 537.1, one of the laboratories had Method 537.1 MDLs for PFOA and PFOS that were above the proposed trigger level. In addition, Facility 350539 utilized only one significant figure (e.g., 2 ppt) for reporting results < 10 ppt and would not be able to provide sufficient significant figures to report to the proposed trigger level, which requires at least two significant figures (e.g., 1.3 ppt).

Based on the laboratory survey responses, under the current configuration, none of the commercial laboratories that responded will not be able to meet the sensitivity and reporting precision needed to comply with the US EPA-proposed MCL trigger levels. Even if MDL reporting allowed for future reporting, the prospect of reporting estimated data for trigger value compliance purposes is arguably unacceptable by any measure.

As a remedy, the hypothetical lowering of concentration of the lowest initial calibration standard may seem trivial; however, the measurements near the MDL are highly imprecise. As a practical matter, attempts to improve sensitivity of the analysis can be impacted by trace-contaminants in sample containers, reagents, laboratory equipment, and materials. Obtaining a sufficiently clean resource may become a challenge. On a final note, any such alterations to improve sensitivity will increase analytical costs, the number of repeated analysis due to quality control failures and will, accordingly, lengthen the time from sample receipt to reporting.

Published literature, as well as TNI, recommends that PQLs be approximately 3-times the calculated MDL. As such, commercial laboratories may be required to perform and potentially have to manipulate additional MDL studies to rationalize reported lower PQLs. Significant additional time and cost will be required to alter procedures, determine new MDLs. Technically achieving lower MDLs and PQLs will require revised/enhanced support system for sample handling, purchased reagents/standards, and protocols for laboratory equipment decontamination - this all with a currently, severely stressed PFAS analysis capacity issue.

The US EPA individual HBWC for PFHxS, HFPO–DA, PFNA, and PFBS were easily achieved based on the survey responses. The US EPA is proposing a health-based HI MCLG for PFHxS, HFPO–DA, PFNA, and PFBS of 1 (unitless). The proposed HI MCLG utilizes the following equation for the calculation.

HI MCLG = (HFPO-DA/10 ppt) + (PFBS/2000 ppt) + (PFNA/10 ppt) + (PFHxS/9 ppt)

Utilizing the lowest Method 533 or for Method 537.1 PQLs for PFHxS, HFPO–DA, PFNA, and PFBS (see Table 1 and Table 2), the calculated HI MCLG would be 0.600 ppt.

Utilizing the highest Method 533 PQLs for PFHxS, HFPO–DA, PFNA, and PFBS (see Table 1 and Table 2), the calculated HI MCLG would be 0.802 ppt. Utilizing the highest Method 537.1 PQLs for PFHxS, HFPO–DA, PFNA, and PFBS (see Table 1 and Table 2), the calculated HI MCLG would be 1.67 ppt.

The current PQLs for PFHxS, HFPO–DA, PFNA, and PFBS for some of the surveyed laboratories may be sufficiently sensitive to support the proposed HI MCLG; however, Environmental Standards anticipates that other laboratories will be required to adjust instrument calibration to meet reporting expectations based on the survey responses.

5.0 Concluding Statements

The surveyed laboratory responses indicated that the current laboratory sensitivity and reporting precision can meet the US EPA-proposed MCLs for PFOA and PFOS for drinking water. The surveyed laboratory response indicated that the current laboratory sensitivity and reporting precision will not be met by all accredited facilities for the US EPA-proposed trigger levels for PFOA and PFOS.

The surveyed laboratory responses indicated that the current laboratory sensitivity and reporting precision can meet the US EPA-proposed HBWCs for PFHxS, HFPO–DA, PFNA, and PFBS. The surveyed laboratory responses indicated that the current sensitivity demonstrated by the accredited laboratories may not be sufficient to meet the US EPA-proposed HI MCLG for combined PFHxS, HFPO–DA, PFNA, and PFBS.

Environmental Standards noted that Method 533 and 537.1 accredited commercial laboratories will require revised/enhanced support system for sample handling, purchased reagents/standards, and protocols for laboratory equipment decontamination - this all with a currently, severely stressed PFAS analysis capacity issue.

TABLE 1 SUMMARY OF METHOD DETECTION LIMIT, PRACTICAL QUANTITATION LIMIT, AND LOW STANDARD INFORMATION

Table 1: Summary of Method Detection Limit, Practical Quantitation Limit, and Low Standard

[Table 1: See Docket ID EPA-HQ-OW-2022-0114-1761]

TABLE 2: SUMMARY OF MCLs, HI, TRIGGER LEVELS, AND LABORATORY INFORMATION

Table 2: Summary of MCLs, HI, Trigger Levels, and Laboratory Information

[Table 2: See Docket ID EPA-HQ-OW-2022-0114-1761]

[Attachment 3: See Docket ID EPA-HQ-OW-2022-0114-1761]

[Attachment 4: See Docket ID EPA-HQ-OW-2022-0114-1761]

[Attachment 5: See Docket ID EPA-HQ-OW-2022-0114-1761]

[Attachment 6: See Docket ID EPA-HQ-OW-2022-0114-1761]

[Attachment 7: See Docket ID EPA-HQ-OW-2022-0114-1761]

EPA Response: Regarding usage of significant figures for the final NPDWR, please see section 5.1.7 of the EPA response in this *Response to Comments* document. Specifically pertaining to the commenter's claim that a laboratory would not be able to provide reported values to two significant figures, the agency disagrees because the standards and methods used for the analysis of the regulated PFAS are capable of including at least two significant figures and there is no rationale for not incorporating more than one digit of uncertainty. For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. The EPA notes that after evaluation of public comment, the NPDWR finalizes rule trigger levels at one-half the MCLs which is different from one-third of the MCLs that the EPA proposed. Regarding rule trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document. Additionally, the EPA clarifies for the commenter that the Hazard Index MCLG and Hazard Index MCL are both equal to 1 (unitless), not 1 ppt. As the commenter provides and the EPA confirms, laboratories can achieve the PQLs for the Hazard Index PFAS (PFBS, HFPO-DA, PFHxS, and PFNA) which are all at least one-half lower than the respective HBWCs for each of the four PFAS and at least half lower than the respective individual MCLs for PFHxS, PFNA and HFPO-DA; therefore, the Hazard Index MCL and MCLG, as well as the PFHxS, PFNA and HFPO-DA MCL and MCLGs, are feasible. With respect to the EPA's discussion on the validated analytical methods approved for meeting the monitoring requirements in the final NPDWR, please see section 7.1 of the EPA response in this *Response to Comments* document.

Michigan Department of Environment, Great Lakes, and Energy (EGLE) Drinking Water and Environmental Health Division (DWEHD) (Doc. #1597, SBC-042978)

However, in the case of analytical results the additional significant figure does represent a level of implied precision which has not been demonstrated by laboratories conducting EPA-approved drinking water analytical methods.

EPA Response: Regarding usage of significant figures for the final NPDWR, please see section 5.1.7 of the EPA response in this *Response to Comments* document.

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-042883)

Source Water and Analytical Variability:

Through the years of sampling that has been conducted by Massachusetts PWS, it is not uncommon for different labs to report a difference of several parts per trillion +/- in PFAS when analyzing the exact same source water. We question whether we are pushing the sensitivity of

the equipment to a point where it cannot be reliably quantified. A sample is considered valid at +/-30%. When discussing regulatory compliance levels in the low parts per trillion, this is quite concerning. As a point of illustration, the following are split sample results for a utility in Massachusetts. On a sample date of 12/11/2020, lab A's result was 12.7 ppt, while lab B's result was 20.56 – both were valid results, yet the swing was 7.86 ppt. This analytical variability is well over what EPA proposes as the MCL, so PWS could be subject to noncompliance and enforcement actions due to analytical variability alone. For this reason, we also do not recommend going to two significant figures to determine compliance values. MassDEP was initially going to count values below the Method Reporting Limit toward compliance with the MMCL but dropped that approach in its final rule. We recommend that EPA consider all results below the Practical Quantification Limit be considered 0 ppt.

Some Massachusetts PWS have seen +/- parts per trillion variability in PFOS and PFOA concentrations when collecting monthly samples. Even a 1-2 ppt variation can represent over 40% variability when close to the MDL. It is difficult to tell if this variability is attributable to changes of PFOS and PFOA concentrations in the source water or if it is linked to the variability of the analytical method (+/- 30%). Having a proposed Rule Trigger Level of 1/3 the PFOS and PFOA MCL or Hazard Index may have PWS and primacy agencies fluctuating back and forth on whether the PWS is eligible for a monitoring waiver. These variations may also impact the running annual average calculation. This uncertainty creates unnecessary complexity, increased level of effort, and possible erosion of public confidence. Importantly, the proposed approach to use results below the PQL, which are unreliable with questionable accuracy and not available to all PWSs due to the lab capacity, is inappropriate to determine reduced monitoring eligibility. This sets a precedent for using results that are inaccurate and not equally achievable for driving regulatory decisions. MWWA recommends following the Standard Monitoring Framework (SMF) where all results below the PQL are considered 0 ppt.

We are also aware of several instances where it was found that lab instrumentation was not properly cleaned between sample runs, resulting in erroneous detections. It is paramount that labs are not conducting cross matrix analysis on instruments that analyze drinking water samples.

EPA Response: Regarding usage of significant figures for the final NPDWR, please see section 5.1.7 of the EPA response in this *Response to Comments* document. With respect to implementation concerns relative to variability around sample results, the agency notes that the commenter is comparing +/- 30 percent QC criteria for accuracy to the evaluation of the precision of two reported results for the same sample analyzed at two separate laboratories. There are numerous factors that may contribute to high or low bias in a measurement result at any individual laboratory, and these factors are not unique to PFAS analysis or exclusive to low level measurement. The EPA further notes that compliance with the MCL is determined by RAAs where an individual sample result will not cause a system to be out of compliance (unless that result is 4x above the MCL in which they are in violation immediately). For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help

operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding laboratory or background contamination considerations, please see section 8.7 of the EPA response in this *Response to Comments* document. The EPA further notes that results below the PQLs will be considered 0 ppt for compliance determination purposes but note the use of results below the PQL can be useful in determining analyte presence/absence. For discussion of rule trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document. For discussion of monitoring waivers, which are not allowed under the final rule, please see section 8.5 of the EPA response in this *Response to Comments* document.

Marlene Ladderbush (Doc. #1612, SBC-042915)

Our experience in Massachusetts has shown that there can be a wide range in results when different labs analyze the same source water. PWS professionals question whether we are pushing the sensitivity of the equipment to a point where it cannot be reliably quantified. A sample is considered valid at +/-30%, when discussing regulatory compliance, or Maximum Contaminant Levels

(MCL), in the low parts per trillion, this is concerning. The analytical variability we routinely see in Massachusetts can be well over what EPA proposes as the MCL so PWS could be subject to noncompliance and enforcement actions due to analytical variability alone. For this reason, EPA should not go to two significant figures to determine compliance values.

EPA Response: Regarding usage of significant figures for the final NPDWR, please see section 5.1.7 of the EPA response in this *Response to Comments* document. Please also see the EPA response to comment Doc. #1612, SBC-042915 and #1601, SBC-042883 in section 5.1.7 in this *Response to Comments* document with respect to implementation concerns around variability surrounding sample results.

Town of Lincoln Water Department (Doc. #1613, SBC-043027)

Our experience in Massachusetts has shown that there can be a wide range in results when different labs analyze the same source water. PWS professionals question whether we are pushing the sensitivity of the equipment to a point where it cannot be reliably quantified. A sample is considered valid at +/-30%, when discussing regulatory compliance, or Maximum Contaminant Levels (MCL), in the low parts per trillion, this is concerning. The analytical variability we routinely see in Massachusetts can be well over what EPA proposes as the MCL so PWS could be subject to noncompliance and enforcement actions due to analytical variability alone. For this reason, EPA should not go to two significant figures to determine compliance values.

EPA Response: Regarding usage of significant figures for the final NPDWR, please see section 5.1.7 of the EPA response in this *Response to Comments* document. Please also see the EPA response to comment Doc. #1612, SBC-042915 and Doc. #1601, SBC-042883 in section

5.1.7 in this *Response to Comments* document with respect to implementation concerns around variability surrounding sample results. For additional discussion on the EPA's feasibility analysis with respect to analytic and laboratory considerations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For background PFAS contamination concerns, please see section 9.7 of the EPA response in this *Response to Comments* document.

COMM Water Department (Doc. #1577, SBC-042439)

Our experience in Massachusetts has shown that there can be a wide range in results when different labs analyze the same source water. PWS professionals question whether we are pushing the sensitivity of the equipment to a point where it cannot be reliably quantified. A sample is considered valid at +/-30%, when discussing regulatory compliance, or Maximum Contaminant Levels (MCL), in the low parts per trillion, this is concerning. The analytical variability we routinely see in Massachusetts can be well over what EPA proposes as the MCL so PWS could be subject to noncompliance and enforcement actions due to analytical variability alone. For this reason, EPA should not go to two significant figures to determine compliance values.

EPA Response: Regarding usage of significant figures for the final NPDWR, please see section 5.1.7 of the EPA response in this *Response to Comments* document. Please also see the EPA response to comment Doc. #1612, SBC-042915 and Doc. #1601, SBC-042883 in section 5.1.7 in this *Response to Comments* document with respect to implementation concerns around variability surrounding sample results. For additional discussion on the EPA's feasibility analysis with respect to analytic and laboratory considerations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For background PFAS contamination concerns, please see section 9.7 of the EPA response in this *Response to Comments* document.

Missouri Department of Natural Resources (Doc. #1563, SBC-042519)

Finally, laboratories must be able to show the ability to reliably and consistently report results to two significant figures if the final MCL includes two significant figures. As discussed previously, this has not been demonstrated by at least 75% of the labs nationwide as the UCMR5 MRL was set with one significant figure. The effect of setting the MCL at two significant figures and to four decimal places, instead of one significant figure and to three decimal places, is water systems being out of compliance at 0.0041 µg/L with two significant figures or 0.005 µg/L with one significant figure. For systems with PFAS at these low levels, such a difference due to significant figures could mean a significant difference from a true value that could result in significant expense if they are required to install and maintain treatment.

EPA Response: Regarding usage of significant figures for the final NPDWR, please see section 5.1.7 of the EPA response in this *Response to Comments* document. Specific to the UCMR 5 MRLs having one significant figure, the agency disagrees with the commenter that for the purposes of determining the MCLs for PFOA and PFOS that two significant figures have not

been demonstrated by at least 75 percent of laboratories nationwide because the UCMR 5 MRLs were determined under a multi-laboratory study which calculated the MRLs for all regulated PFAS to each have more than one significant figure (USEPA, 2020b). However, for the particular application of the UCMR program these MRLs are rounded to one significant figure though the agency notes that data is accepted from laboratories at or above the MRL which would include data at 4.0 ng/L (or 0.0040 ug/L) due to the precision of the methods and laboratory precision. Based on the considerations discussed in the EPA response 5.1.7, this same rounding would not be appropriate. Additionally, the EPA notes the commenter is incorrect in the examples they provide. Using the commenter's example for PFOA or PFOS (assuming an average of four quarterly samples): with one significant figure, a system is exceeding at 0.0045 µg/l and with two significant figures this exceedance occurs at 0.00405 µg/l. The numbers provided are both exceedances but they're not the cut-offs to which you exceed or not exceed. The EPA further notes that compliance with the MCL is determined by RAAs where individual sample results will not cause a system to be out of compliance (unless that result is 4x above the MCL in which they are in violation immediately).

Water Supply District of Acton (Doc. #1662, SBC-043662)

Our experience has shown that there can be a wide range of results when different labs analyze the same source of water. We question whether we are pushing the sensitivity of the equipment to a point where analyte values cannot be reliably quantified. Additionally, the interference of non-drinking water samples being processed on the same equipment at the lab, along with other chemicals and constituents in the water, may cause inaccurate results that overstate the PFAS concentrations in samples. These overstatements cause costly treatment upgrades, premature media replacement, and erosion in the public trust of public water systems. The analytical variability we routinely see in Massachusetts can be well over what EPA is proposing as the MCL. PWS could be subject to noncompliance and enforcement actions due to analytical variability alone. For this reason, EPA should not go to two significant figures to determine compliance values.

EPA Response: Regarding usage of significant figures for the final NPDWR, please see section 5.1.7 of the EPA response in this *Response to Comments* document. Please also see the EPA response to comment Doc. #1612, SBC-042915 and Doc. #1601, SBC-042883 in section 5.1.7 in this *Response to Comments* document with respect to implementation concerns around variability surrounding sample results. For additional discussion on the EPA's feasibility analysis with respect to analytic and laboratory considerations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For background PFAS contamination concerns, please see section 9.7 of the EPA response in this *Response to Comments* document.

Town of Tewksbury, Massachusetts (Doc. #1637, SBC-043245)

Our experience in Massachusetts has shown that there can be a wide range in results when different labs analyze the same source water. PWS professionals question whether we are

pushing the sensitivity of the equipment to a point where it cannot be reliably quantified. A sample is considered valid at +/-30%, when discussing regulatory compliance, or Maximum Contaminant Levels (MCL), in the low parts per trillion, this is concerning. The analytical variability we routinely see in Massachusetts can be well over what EPA proposes as the MCL so PWS could be subject to noncompliance and enforcement actions due to analytical variability alone. For this reason, EPA should not go to two significant figures to determine compliance values.

EPA Response: Regarding usage of significant figures for the final NPDWR, please see section 5.1.7 of the EPA response in this *Response to Comments* document. Please also see the EPA response to comment Doc. #1612, SBC-042915 and Doc. #1601, SBC-042883 in section 5.1.7 in this *Response to Comments* document with respect to implementation concerns around variability surrounding sample results. For additional discussion on the EPA's feasibility analysis with respect to analytic and laboratory considerations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For background PFAS contamination concerns, please see section 9.7 of the EPA response in this *Response to Comments* document.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-044891)

• DEP has several concerns with laboratory capacity considerations:

o Because there does not appear to be an initial compliance monitoring schedule identified in the proposed rulemaking, systems will likely wait until the last minute to complete their monitoring requirements, which will impact overall lab capacity. Therefore, DEP does not believe that it is safe to assume that lab capacity will be evenly spread out over initial monitoring.

O Because labs will be expected to meet very low reporting limits, the incidence of QA/QC failures will likely increase. This will result in a greater number of samples that will need to be resampled and reanalyzed. This adds to the burden on the laboratory and further reduces its capacity for additional samples.

O Many laboratories hold secondary accreditation in states other than the state in which they primarily conduct business. Those labs with secondary capacity are not able to accurately determine what percentage of their total capacity will be available to their state. This complicates the ability to estimate lab capacity.

O As noted previously, many labs will need to purchase standards in order to meet the significant figures required by the proposed rulemaking. This poses two complicating factors to overall lab capacity. One, the standards are very expensive, and two, there are a limited number of vendors from which to purchase those standards.

O Analysis of overall laboratory capacity needs to consider not only the additional drinking water compliance monitoring samples, but also performance monitoring for additional treatment systems that will be required , and monitoring of other environmental matrices that will likely increase as a result of this proposed rulemaking.

EPA Response: For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding usage of significant figures for the final NPDWR, please see section 5.1.7 of the EPA response in this *Response to Comments* document. For initial monitoring requirements and timing, please see section 8.1.1 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. With respect to performance monitoring, the EPA anticipates that many water systems will conduct a pilot test before implementing a full-scale treatment installation and that the operational results from the pilot test will be a sufficient indicator of performance; therefore, water systems should not have to collect large amounts of performance samples indefinitely during the full-scale operation of treatment technologies. Please see section 13.3.3 of the EPA response in this *Response to Comments* document for additional details on how these considerations were factored into the EPA's cost estimates.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-044889)

Laboratory and Analytical Method Considerations

• Regarding significant figures and decimal places, since the reporting limits are not clearly defined and appear to be missing from the proposed rulemaking, as already noted, DEP cannot comment on the missing information and can only make assumptions and comment on those assumptions. Since the PQLs for PFOA and PFOS and the four PFAS included in the HI have one decimal place (i.e., two significant figures), laboratories will need to be able to report to two decimal places (i.e.#.## ppt). This further means that laboratories will need to be able to read results to three decimal places. Labs will likely need to purchase the appropriate standards in order to meet the required number of significant figures, since they are not likely to be able to make their own standards. DEP notes that availability of standards for purchase, and the availability of vendors to supply those standards, are likely to be a limiting factor in laboratories' ability to read to this level.

EPA Response: Regarding usage of significant figures for the final NPDWR, please see section 5.1.7 of the EPA response in this *Response to Comments* document. The EPA also clarifies for the commenter that it does include information in the proposed rule 40 CFR141.902(9) on the levels that regulated PFAS must be reported. The EPA also disagrees with the commentor regarding the necessity of laboratories to purchase "the appropriate standards in order to meet the required number of significant figures, since they are not likely to be able to make their own standards." A fundamental responsibility of any analytical chemist is to accurately perform appropriate dilutions of certified reference standard solutions when following an analytical test method to measure ppt levels of PFAS.

Aurora Water, City of Aurora, Colorado (Doc. #1669, SBC-043710)

The proposed rule uses two significant figures for PFOA, PFOS and for the HI MCLs and MCLGs. Aurora Water suggests the use of one significant figure for PFOA, PFOS and HI MCLs and MCLGs.

EPA Response: Regarding usage of significant figures for the final NPDWR, please see section 5.1.7 of the EPA response in this *Response to Comments* document.

Aidan Cecchetti (Doc. #1640, SBC-044362)

• EPA requests comment on significant figure use when calculating both the HI MCLG and the MCL. EPA has set the HI MCLG and MCL using two significant figures (i.e., 1.0). EPA requests comment on the proposed use of two significant figures for the MCLG when considering underlying health information and for the MCL when considering the precision of the analytical methods (pg. 18666 Federal Register Volume 88, Number 60).

O Based on the PQLs promulgated by EPA for PFOA and PFOS, it is not appropriate to use two significant figures for an MCL that is set at the PQL (e.g., the proposed MCL for PFOA would be 4.0 ppt with a PQL of 4.0 ppt). The PQLs set by EPA indicates that the order of magnitude at which laboratories can produce measurements with adequate precision is at the ppt level. Therefore, significant figures at orders of magnitude below the ppt level cannot be reliably determined by analytical methods and should not be reported or used in compliance determinations. Compliance determinations are made based on averages of those measurements that are compared to the MCL. Averages of measurements cannot have significant figures at orders of magnitude lower than the least precise measurement. Therefore, the measurements and the averages calculated from them cannot be produced with sufficient precision for the MCL and MCLG to have significant figures below the ppt level.

EPA Response: Regarding usage of significant figures for the final NPDWR, please see section 5.1.7 of the EPA response in this *Response to Comments* document. For additional discussion on the EPA's feasibility analysis with respect to analytic and laboratory considerations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. With respect to the use of values below the PQL for the purposes of compliance determinations, see section 8.2 of the EPA response in this *Response to Comments* document.

Aidan Cecchetti (Doc. #1640, SBC-044363)

o Additionally, EPA should reconsider the significant figures used in the PQLs for these contaminants. As discussed above, a PQL of 4.0 ppt for PFOA and PFOS is inappropriate and should rather be 4 ppt.

o However, if there is much greater and widespread precision in laboratory measurement capabilities than the PWL would suggest, EPA should consider revising the PQLs and providing

a comparative analysis of how the use of one or two significant figures for the HI MCLG and the MCLs would impact costs and public health protection associated with the new rules. Without such a comparative analysis, the commenters are unable to provide adequate feedback on the benefits or drawbacks of using two significant figures for the HI MCLG and the MCLs.

EPA Response: Regarding usage of significant figures for the final NPDWR, please see section 5.1.7 of the EPA response in this *Response to Comments* document. For additional discussion on the EPA's feasibility analysis with respect to analytic and laboratory considerations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. With respect to the use of values below the PQL for the purposes of compliance determinations, see section 8.2 of the EPA response in this *Response to Comments* document. Finally, the agency considered a reasonable range of regulatory alternatives and disagrees that an analysis of one or two significant figures for the Hazard Index MCLG is needed to provide adequate feedback on the MCLs. The number of significant figures for the MCLG is based on the analytical precision of the method(s) as well as the magnitude of precision of the underlying health values used to inform the MCLG. The MCLs are then set as close a feasible to the MCLGs considering the analytical precision of the method(s). Thus, a comparative analysis of costs and public health protection is not a part of the determination of significant figures but rather that is considered in the cost-benefit analysis of the regulatory standard. Please see section 13 and section 5.1.3 of the EPA response in this *Response to Comments* document for additional discussion.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044092)

ASDWA recommends that EPA revise the use of significant figures to ensure accuracy and consistency throughout the proposed rule.

The proposed rule uses inconsistent significant figures for the proposed MCLs. For example, the footnote in the table at 141.50(b) states correctly that the HBWC for HFPO-DA is 10.0 ppt, but the formula used for the Hazard Index in that same footnote uses 10. This inconsistency continues for PFBS and PFNA. EPA should ensure that all references to the MCLs use the correct number of significant figures. ASDWA's members have also noted this issue in EPA's presentations and fact sheets. EPA should ensure that all materials the Agency releases use the correct number of significant figures.

EPA Response: Regarding usage of significant figures for the final NPDWR, please see section 5.1.7 of the EPA response in this *Response to Comments* document.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044179)

2. NCDEQ recommends that EPA revise the use of significant figures to ensure accuracy and consistency throughout the proposed rule.

The proposed rule uses an inconsistent number of significant figures for the proposed MCLs. For example, the footnote in the table at 141.50(b) states correctly that the health-based water concentration (HBWC) for HFPO-DA is 10.0 ppt, but the formula used for the hazard index in that same footnote uses 10. This inconsistency continues for PFBS and PFNA. EPA should ensure that all references to the MCLs use the correct number of significant figures. Additionally, this same issue has been found in EPA's presentations and fact sheets. EPA should ensure that all materials the Agency releases use the correct number of significant figures.

EPA Response: Regarding usage of significant figures for the final NPDWR, please see section 5.1.7 of the EPA response in this *Response to Comments* document.

5.2 PFAS Hazard Index: PFHxS, HFPO-DA, PFNA, and PFBS

5.2.1 General

Summary of Major Public Comments and EPA Responses

The EPA received many comments supporting the use of the Hazard Index approach and regulation of additional PFAS. Consistent with these comments, through this action, the agency is establishing drinking water standards for PFHxS, PFNA, HFPO-DA, and PFBS (as well as PFOA and PFOS) to provide health protection against these contaminants found in drinking water. The EPA considered PFAS health effects information, evidence supporting dose additive health concerns from co-occurring PFAS, as well as national and state data for the levels of multiple PFAS in finished drinking water.

Several commenters disagreed that the EPA's determination to set the MCL for the Hazard Index PFAS at the same level as the MCLG reflects what is feasible. Some of these commenters assert that technologies to remove the Hazard Index PFAS are not the same as those that effectively remove PFOA and PFOS. A couple of commenters were concerned that meeting the Hazard Index MCL may require more frequent media change-outs (e.g., GAC), thereby increasing operating costs such that the Hazard Index MCL of 1 is not feasible. The agency disagrees with these commenters that the BATs do not support the conclusion that those BATs could treat to at or below the Hazard Index MCL based on the history of full-scale use as documented in the BAT/SSCT document, the information in the proposed and final rule preambles, as well as in the comments that provided full-scale data as well as case studies. The best available treatment technologies available for PFOA and PFOS are the same for the PFAS regulated through the Hazard Index: all of the BATs (described in more detail in section 10 of the EPA response in this *Response to Comments* document and in the *Best Available Technologies and Small System Compliance Technologies for PFAS in Drinking Water;* USEPA, 2024e) have all been demonstrated to be effective in removing all six PFAS finalized for regulation as part of this rulemaking albeit to differing degrees. Additionally, the process integration for all BATs is similar. As described above in 5.1 of this section, the agency similarly considered feasibility as defined by SDWA for PFHxS, PFNA, HFPO-DA, individually and for mixtures of these three PFAS and PFBS. First, the EPA established a Hazard Index MCLG as a Hazard Index of 1 for

mixtures of two or more of PFHxS, PFNA, HFPO-DA, and PFBS. As part of setting the Hazard Index MCLG, the agency defined an HBWC for PFHxS, PFNA, HFPO-DA, and PFBS used in the calculation (see discussion in section IV of the final rule preamble). The EPA does agree that several site-specific factors will dictate the appropriate strategy for treatment and recommends pilot testing to aid in determining the best solution for a given location. The EPA further acknowledge that external factors such as limited space may dictate a different treatment train than the optimal engineering approach. For additional discussion on best available treatment technologies, please see USEPA (2024e). In considering the feasibility of setting the MCLs as close as feasible to the MCLG, the EPA first evaluated the (1) the availability of analytical methods to reliably quantify levels of the contaminants in drinking water and (2) the lowest levels at which contaminants can be reliably quantified within specific limits of precision and accuracy during routine laboratory operating conditions using the approved methods (i.e., the PQLs). The EPA determined that there are available analytical methods approved to quantify levels below these HBWC levels. In addition, the PQLs for PFHxS, PFNA, HFPO-DA, and PFBS (between 3.0 to 5.0 ng/L) are all lower than the respective HBWCs used in setting the Hazard Index MCLG for each of these PFAS (10 ng/L for PFHxS, PFNA, and PFHxS, and 2000 ng/L for PFBS). Thus, the PQLs are not a limiting factor in determining the MCL. Second, the EPA evaluated the availability and performance of BATs for treating water to minimize the presence of these contaminants consistent with the MCLGs (see section X of the final rule preamble and section 10 of the EPA response in this *Response to Comments* document for additional discussion on BATs) as well as the costs of applying those BATs to large metropolitan water systems when treating to that level. The EPA has found the same technologies identified for PFOA and PFOS are also both available and have reliably demonstrated PFAS removal efficiencies that may exceed >99 percent and can achieve concentrations less than the proposed Hazard Index MCL for mixtures of two or more of PFHxS, PFNA, HFPO-DA, and PFBS, and that the cost of applying those technologies is reasonable for large metropolitan water systems. For contaminants where the MCLG is higher than the PQL, the EPA sets the MCL at the MCLG if treatment is otherwise feasible because the PQL is not a limiting factor. In consideration of the availability of feasible treatment technologies, approved analytical methods to reliably quantify levels of the contaminants in drinking water, the EPA's cost analysis, and the fact that the PQLs are below the HBWCs used in setting the Hazard Index MCLG, the agency determines that setting the MCL at the same level as the MCLG for mixtures of PFHxS, PFNA, HFPO-DA and PFBS is feasible. Thus, the EPA is setting the Hazard Index MCL of 1 for mixtures of PFHxS, PFNA, HFPO-DA, and/or PFBS. For additional discussion and considerations surrounding BATs, please see section X.A of the final rule preamble and section 10 of the EPA response in this *Response to Comments* document. For more information about the EPA's cost estimates, please see section XII of the final rule preamble and 13.3 of the EPA response in this *Response to Comments* document.

The EPA notes additional detailed responses on the following topics as it relates to feasibility of the MCL within this section of the EPA response in this *Response to Comments* document: For additional discussion on feasibility with respect to laboratory capacity, capability, or other

analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. With respect to comments related to practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please also see section 5.1.2 of the EPA response in this *Response to Comments* document. With respect to cost considerations when setting the MCL, please see section 5.1.3 of the EPA response in this *Response to Comments* document. For additional discussion on the EPA's feasibility analysis as it relates to treatment considerations, please see section 5.1.4 of the EPA response in this *Response to Comments* document.

The agency also disagrees with commenters that the Hazard Index does not set a "level" as contemplated by the statute and that the Hazard Index approach is inconsistent with the SDWA mandate that MCLs be only as close as feasible to the MCLG. The statute does not dictate that the MCLG take a particular form; however, it must represent a "level" that meets the MCLG statutory definition. Given that the MCL must be "as close as feasible" to the MCLG, and that the MCL is defined as the "maximum permissible level of a contaminant in water which is delivered to any user of a public water system," the MCLG can take any form so long as it is a maximum level of a contaminant in water. SDWA defines an MCL as "the maximum permissible level of a contaminant in water which is delivered to any user of a public water system." Like the MCLG, SDWA does not dictate that the MCL take a particular form; however, given this definition, an MCL establishes a "maximum permissible level of a contaminant in water" and as a practical matter the identified "level" must be capable of being validated so that it can be determined whether that PWSs are delivering water to any user meeting or exceeding that "level." The EPA's MCL of 1 establish a "maximum permissible level of contaminant in water" because it is a limit for a mixture with PFAS components that must be met before the water enters the distribution system. PWSs use their monitoring results as inputs into the Hazard Index equation to determine whether they are delivering water to any user that meets the MCL.

Many commenters support excluding PFOA and PFOS from the Hazard Index MCL. The EPA agrees with these commenters as there are analytical limitations that would complicate including PFOA and PFOS in the Hazard Index. As discussed in section IV of the final rule preamble of the Hazard Index approach, individual PFAS hazard quotients (HQs) are calculated by dividing the measured concentration of each component PFAS in water (e.g., expressed as ng/L) by the corresponding HBWC for each component PFAS (e.g., expressed as ng/L). The HBWC is akin to an MCLG in that they reflect a level below which there are no known or anticipated adverse effects over a lifetime of exposure, including for sensitive populations and life stages, allowing an adequate margin of safety. Since PFOA and PFOS are likely human carcinogens, the MCLG (and if included in the Hazard Index, the HBWC) for each contaminant is zero. The only feasible way to represent PFOA and PFOS in the Hazard Index approach would be to only consider values for PFOA and PFOS at or above the PQL of 4.0 ng/L, however the level at which no known or anticipated adverse effects on the health of persons would occur is zero, which is well below the PQL. The Hazard Index is intended to capture the aggregate risks of the Hazard Index PFAS in a mixture when the monitored concentration of each mixture component is above the

PQL but below the HBWC. These risks are not relevant to mixtures with PFOA and PFOS given their PQLs. Because of the PQL considerations discussed in the preceding section V.A of the final rule preamble and section 5.1 of the EPA response in this *Response to Comments* document, the EPA is not including PFOA and PFOS in the final rule Hazard Index. Therefore, the EPA is finalizing individual MCLs for PFOA and PFOS but not including these contaminants in the Hazard Index addressing mixtures.

A few commenters provided feedback on the EPA's request for comment regarding the usage of significant figures to express the MCLs. See discussion on this issue in section 4.3.4 of the EPA response in this *Response to Comments* document. In summary, after considering public comment, the EPA agrees that one (1) significant digit is appropriate for the individual PFAS for PFHxS, PFNA and HFPO-DA (i.e., 10 rather than 10.0), and Hazard Index MCL (i.e., 1 rather than 1.0). For additional discussion on significant figure usage, please see section 4.3.4 and 5.1.7 of the EPA response in this *Response to Comments* document.

Some commenters asked about inclusion of other PFAS in the NPDWR (such as including in the Hazard Index) in future revisions. Although this final rule only addresses mixtures of the four PFAS, the agency believes the Hazard Index approach can be an adaptive and flexible framework for considering additional PFAS. As discussed above, the EPA is required to review NPDWRs every six years and determine which, if any, need to be revised (i.e., the Six-Year Review Process). The purpose of the review is to evaluate current information for regulated contaminants and to determine if there is any new information on health effects, treatment technologies, analytical methods, occurrence and exposure, implementation and/or other factors that provides a health or technical basis to support a regulatory revision that will improve or strengthen public health protection. This process allows the agency to consider these and other information as appropriate in deciding whether existing NPDWRs should be identified as candidates for revision as required by SDWA. The EPA notes that SDWA specifies a process that the agency follows to identify and list unregulated contaminants that may lead to the development of a NPDWR in the future. This listing currently includes PFAS as a structural class. Additionally, the EPA anticipates that the completed UCMR 5 dataset will be informative for considering potential future regulatory action regarding the 23 additional UCMR 5 PFAS that are not directly included in this final rule. The CCL listing and UCMR5 monitoring results may inform whether EPA should initiate a rulemaking process to develop an NPDWR for any specific contaminant in the future.

To understand the totality of national-level cost impacts for the Hazard Index MCL, the EPA considered both the contribution of PFHxS (estimated as part of the national level cost analysis), as well as the costs for PFNA, HFPO-DA, and PFBS (estimated in the Appendix N sensitivity analysis). Together, these provide information on the costs for the Hazard Index MCL and the individual MCLs for PFHxS, PFNA, and HFPO-DA, as a whole. Please see sections 5.1.2 and 13.3 of the EPA response in this *Response to Comments* document for additional discussion. Additionally, for more information on the agency's methodology, findings, and limitations of the

EPA's updated analysis of costs associated with compliance with the Hazard Index, please see Appendix N.3 of the EA (USEPA, 2024c).

Individual Public Comments

WaterPIO (Doc. #1624, SBC-043460)

Founded in 2017, WaterPIO is a public communications firm dedicated to helping water and wastewater utilities of all sizes improve their customer, media, and crisis communications. The company is now helping water providers in more than a dozen states, including several who called on us following discoveries of PFAS compounds in their drinking water. WaterPIO has conducted PFAS-related public communications in North Carolina, South Carolina, Georgia, Alabama, Illinois, Kentucky, Tennessee, Virginia, Ohio, Indiana, West Virginia, New York, Pennsylvania, Maryland, and Vermont.

After working as a DC-based national and local news producer for a decade, WaterPIO's President Mike McGill has led public communications for water utilities for 16 years. Before creating WaterPIO, he served as the former chief spokesperson for what is now WSSCWater and the former Chief Communications Officer for the Cape Fear Public Utility Authority (CFPUA), the water provider at the heart of the GenX discovery made during the mid-to-late 2010s.

During McGill's time at CFPUA, his counsel to notify the public about the results of Dr. Detlef Knappe's groundbreaking study – which CFPUA had fully cooperated with while McGill worked for the organization – went unheeded by its General Manager at the time. As a result, when the Wilmington StarNews report titled, "Toxin Taints CFPUA Drinking Water" hit the public space, CFPUA's reputation with its customers instantly hit an all- time low. McGill was re-hired to appear live on local newscasts, write op-eds, and develop public education campaigns to help the utility explain its PFAS-related actions.

News organizations from across the country came to Wilmington with the belief that it had become the next Flint, Michigan, a city with undrinkable tap water. Fortunately, thanks to the actions taken after the article, the Cape Fear Region did not get permanently tagged with such a distinction. And now, thanks to new management, an empowered staff, and a $43 million granular activated carbon project, CFPUA is fast becoming the drinking water industry's example of what to do when faced with a significant PFAS discovery.

CFPUA's roller-coaster of a response is a proper place to start for our comment because it clearly shows the years of reputation-related challenges PFAS discoveries can create for public water systems. CFPUA's failure wasn't due to the work of its employees; they had actually helped Dr. Knappe find the GenX in the Cape Fear River. The failure was due to their poor reaction to the initial discovery and horrific public communication-related decisions.

This comment is written more in an op-ed style because we work with leading water organizations who are making the scientific arguments far better than we can. What our comment hopes to achieve is a greater understanding of the impacts the EPA's proposed

Maximum Contaminant Levels (MCLs) and Hazard Index will have on the public after thousands of water systems across the country receive almost-certain notices of violations.

Simply put, what EPA is proposing is no less than the end of the nation's confidence in its drinking water. This is not hyperbole. This is fact. The public will never look at their tap water the same way again.

Based on our experience working with public water systems across the country that have been impacted by PFAS discoveries, WaterPIO believes the EPA's proposed MCLs and Hazard Index pose no less than eight, nearly impossible challenges for service providers, even if they don't have any PFAS detections in their drinking water:

1. The proposed MCLs were set at the lowest confirmable levels when the science on their impact on public health at numbers that low is not settled. In addition, the first-time use of a convoluted Hazard Index for drinking water will be difficult for water systems to meet and nearly impossible to explain to the public.

EPA Response: The commenter provides a claim that the regulation will be "no less than the end of the nation's confidence in its drinking water." The EPA finds the opposite to be true: promulgating a nationwide NPDWR will reduce exposures to these compounds which may cause harmful human health effects. The EPA's final rule represents data-driven drinking water standards that are based on the best available, peer-reviewed science, meet the requirements of SDWA, and that regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. The agency also disagrees that the "proposed MCLs were set at the lowest confirmable levels when the science on their impact on public health at numbers that low is not settled." The science is clear on PFAS human health effects based on the weight of evidence reviewed by the agency in promulgating the health-based MCLGs; please see section 4 for more information. Additionally, the MCLs (for PFOA and PFOS) are set at their practical quantitation limits and the MCLs for the Hazard Index PFAS includes individual HBWCs that are well above their respective PQLs. For discussion on feasibility considerations for the Hazard Index PFAS, please see the EPA section 5.2.1 of the EPA response in this *Response to Comments* document. Please also see section 5.1.2 of the EPA response in this *Response to Comments* document for more information on PQLs, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations. Regarding risk communication concerns. The EPA notes that after finalization of the PFAS NPDWR, the EPA intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation; please see section 1.2 of the EPA response in this *Response to Comments* document for more information.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-053343)

The Hazard Index approach is inconsistent with SDWA because it sets a limitation on a group of chemicals rather than the individual chemicals, and it does not set a "level" as contemplated by

the statute. The Hazard Index approach is not a "level" at all—it is a sum of component HQs, calculated by dividing the measured regulated PFAS component contaminant concentration in water by the associated health-based water concentration. A sum of those quotients greater than 1 constitutes an exceedance of the MCL. EPA thus transforms the typical MCL or MCLG into a complex mathematical equation that leaves uncertainty regarding compliance, absent additional efforts to measure, calculate, and combine fractions of each individual contaminant. Indeed, the Hazard Index is a highly variable equation that can change over time as inputs change (as the health-based water concentration may change).

This approach is also inconsistent with the SDWA mandate that MCLs be only as close as feasible to the MCLG [FN63: 42 U.S.C. [sec] 300g-1(b)(4)(B).]. Under the Hazard Index approach, it would be impossible to fulfill this requirement as the proposed MCL and MCLGs have the same unitless value [FN64: This novel approach to calculating a Hazard Index for a mixture of chemicals is not a treatment technique authorized by SDWA. See 42 U.S.C. [sec] 300g-1(b)(7)(A).].

EPA Response: The EPA disagrees that the Hazard Index is "inconsistent with SDWA because it sets a limitation on a group of chemicals rather than the individual chemicals." Section 1401(6) defines the term ''contaminant'' to mean ''any physical, chemical or biological or radiological substance or matter in water.'' A mixture of two or more ''contaminants'' qualifies as a ''contaminant'' because the mixture itself is ''any physical, chemical or biological or radiological substance or matter in water.'' Additionally, SDWA 1401(3) defines the term "maximum contaminant level" to mean "the maximum permissible level of a *contaminant* in water which is delivered to any user of a public water system" (emphasis added). Therefore, the Hazard Index approach, which captures mixtures of two or more of PFHxS, PFNA, HFPO-DA and PFBS, constitutes as a contaminant and a MCL with Hazard Index value of 1 sets the maximum permissible level of that contaminant.

The agency also disagrees that the Hazard Index does not set a "level" as contemplated by the statute and that the Hazard Index approach is inconsistent with the SDWA mandate that MCLs be only as close as feasible to the MCLG. The statute does not dictate that the MCLG take a particular form; however, it must represent a "level" that meets the MCLG statutory definition. Given that the MCL must be "as close as feasible" to the MCLG, and that the MCL is defined as the "maximum permissible level of a contaminant in water which is delivered to any user of a public water system," the MCLG can take any form so long as it is a maximum level of a contaminant in water. SDWA defines an MCL as "the maximum permissible level of a contaminant in water which is delivered to any user of a public water system." Like the MCLG, SDWA does not dictate that the MCL take a particular form; however, given this definition, an MCL establishes a "maximum permissible level of a contaminant in water" and as a practical matter the identified "level" must be capable of being validated so that it can be determined whether that PWSs are delivering water to any user meeting or exceeding that "level." The EPA's MCL of 1 establish a "maximum permissible level of contaminant in water" because it is a limit for a mixture with PFAS components that must be met before the water enters the

distribution system. PWSs use their monitoring results as inputs into the Hazard Index equation to determine whether they are delivering water to any user that meets the MCL.

The agency also disagrees that dividing an exposure metric over a health metric constitutes a "complex mathematical equation." This calculation is also not mathematically different (i.e., summing up numbers and dividing) than a RAA calculation which is used frequently for compliance calculations for NPDWRs. Regardless, to assist in the calculation of these values, the agency is developing a calculator tool to easily determine your hazard index result. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation. With respect to responses that the Hazard Index reflects a "variable equation that can change over time as inputs change," the EPA notes that the MCL is not variable. The inputs (i.e., exposure concentration) varies but that is analogous to any other NPDWRs regulated by an MCL where concentrations can change over time. Nonetheless, the MCL will be 1 unless or until the NPDWR changes. The agency is required to review NPDWRs every six years and determine which, if any, need to be revised. This review (i.e., the Six-Year Review Process) is not unique to this PFAS NPDWR. For discussion on feasibility considerations for the Hazard Index PFAS, please see the EPA section 5.2.1 of the EPA response in this *Response to Comments* document. For additional discussion on the EPA's regulatory determination for mixtures of PFAS, please see section 3.2 of the EPA response in this *Response to Comments* document. For additional discussion on the Hazard Index MCLG, please see section 4 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045898)

C. The Hazard Index approach is inconsistent with SDWA's statutory requirements for setting MCLs

For each contaminant that EPA determines to regulate, it must either issue an MCL or, "if it is not economically or technologically feasible to so ascertain the level of such contaminant," use a treatment technique [FN59: 42 U.S.C. [sec] 300g-1(b)(7)(A).]. The novel Hazard Index approach is neither an MCL nor a treatment technique. Therefore, EPA's use of this approach to regulate PFNA, PFBS, HFPO-DA, and PFHxS violates SDWA.

1. SDWA contemplates setting individual levels for each contaminant

The term "maximum contaminant level" means "the maximum permissible level of a contaminant in water which is delivered to any user of a public water system." [FN60: 42 U.S.C. [sec] 300f(3).] Notably, SDWA contemplates setting MCLs and MCLGs for each contaminant [FN61: 42 U.S.C. [sec] 300g-1(b)(E) ("For each contaminant that the Administrator determines to regulate under subparagraph (B), the Administrator shall publish maximum contaminant level goals and promulgate, by rule, national primary drinking water regulations under this subsection." (emphasis added)). See also City of Portland, Oregon v. EPA, 507 F.3d 706 (D.C. Cir. 2007): "[The SDWA] requires EPA to set a 'maximum contaminant level goal' (MCLG) for

each identified contaminant at a level at which no known adverse health consequences will occur" (emphasis added).] individually and with a specific level so that regulated entities can understand the levels that must be achieved for compliance. In this proposal, EPA proposes an MCL and MCLG for PFNA, PFHxS, PFBS, and HFPO-DA as a mixture and uses a Hazard Index approach rather than a specific concentration level (ppm or ppt). SDWA does not contemplate setting MCLs for a mixture, let alone using a complex equation. The term "mixture" appears only twice in the statute, and it is related to drinking water studies of complex mixtures [FN62: 42 U.S.C. [sec] 300j-18(b)(3).]. The statutory text thus reflects that Congress never intended for EPA to regulate mixtures of contaminants, rather than the individual contaminants themselves, using MCLs.

EPA Response: With respect to responses regarding why the EPA can use the Hazard Index to calculate an MCL/MCLG under SDWA, please see the EPA response to comment Doc. #1713, SBC-053343 in section 5.2.1 in this *Response to Comments* document. A mixture is a "contaminant" for purposes of the statute (please see section 3.2 of the *Response to Comments* document for additional discussion). The definition of a contaminant does not specify that a contaminant is only a singular chemical. The SDWA definition is very broad, specifically stating that a contaminant is "*any* physical, chemical or biological or radiological substance or matter" (emphasis added), with no specific description or requirement for how it is formed. Matter for example, by definition, is comprised of either pure substances or mixtures of pure substances. A pure substance is either an element or compound, which would include "any PFAS chemical. The statute encompasses "matter" which is a broad term that includes mixtures and therefore definitionally includes PFAS mixtures, comprised of a combination of PFAS (chemical substances), as itself qualifying as a "contaminant" under SDWA. Moreover, other provisions of the statute, would be restricted in a manner inconsistent with Congressional intent if the EPA were to adopt the cabined approach to "contaminant" suggested by some commenters. For example, Section 1431 of SDWA, provides important authority to the EPA to address imminent and substantial endangerment to drinking water supplies posed by "a contaminant" that is present in or threatened those supplies. Congress clearly intended this authority to be broad and remedial, but it would be significantly hampered if the EPA would be restricted to only addressing individual chemicals and not mixtures threatening a water supply. For these reasons, the EPA's interpretation of the definition of contaminant is the only reading that is consistent with the statutory definition and use of the term in context and at to the extent the definition of contaminant is ambiguous, the EPA's interpretation represents the best interpretation of that term.

Finally, even if a mixture is considered a group, as some commenters suggest, Congress clearly contemplated that the EPA could regulate contaminants as groups. See A Legislative History of the SDWA, Committee Print, 97th Cong. 2d Sess.(February 1982) at 542-3) (noting the tens of thousands of chemical compounds in use commercially, with many more added each year, of which many will end up in "the nation's drinking water and finding that "[i]t is, of course, impossible for EPA to regulate each of these contaminants which may be harmful to health on a contaminant-by-contaminant basis. Therefore, the Committee anticipates that the

Administrator will establish primary drinking water regulations for some groups of contaminants, such as organic and asbestos.") Thus, the EPA has the authority to regulate a mixture as a contaminant under SDWA.

Commenter states that the "mixture" appears only twice in the statute in 42 U.S.C. [sec] 300j-18(b)(3). EPA disagrees with commenter's assertion that this textual reference to mixture "thus reflects that Congress never intended for EPA to regulate mixtures of contaminants, rather than the individual contaminants themselves, using MCLs." Instead, the statute's reference to "mixture" is evidence that Congress understands that drinking water contains mixtures as a contaminant. Please see section 3.2 for more information on the EPA's rationale to regulate mixtures.

Clean Air Council, et al. (Doc. #1731, SBC-043844)

Introduction

The Environmental Protection Agency ("EPA") issued in March 2023 a proposed National Primary Drinking Water Regulation ("NPDWR") and health-based Maximum Contaminant Level Goals ("MCLG") for six per- and polyfluoroalkyl substances ("PFAS") compounds and their mixtures: Perfluorooctanoic acid ("PFOA"), perfluorooctane sulfonic acid ("PFOS"), perfluorohexane sulfonic acid ("PFHxS"), hexafluoropropylene oxide dimer acid ("HFPO–DA") and its ammonium salt (also known as "GenX" chemicals), perfluorononanoic acid ("PFNA"), and perfluorobutane sulfonic acid ("PFBS"). For PFOA and PFOS, EPA proposes MCLGs of zero nanograms per liter ("ng/L") or parts per trillion ("ppt"). Based on technical feasibility EPA proposes enforceable Maximum Contaminant Levels ("MCLs") of 4.0 ppt for PFOA and 4.0 ppt for PFOS.

EPA Response: With respect to the EPA's regulation of additional PFAS through a Hazard Index MCL, please see the section 5.2.1 of the EPA response in this *Response to Comments* document. With respect to the EPA's regulation of PFOA and PFOS, please see the section 5.1 of the EPA response in this *Response to Comments* document. With respect to additional individual PFAS MCLs for PFHxS, HFPO-DA and PFNA, please see section 5.3 of the EPA response in this *Response to Comments* document.

Clean Air Council, et al. (Doc. #1731, SBC-043856)

Summary of Comments

1. PFAS levels that exceed the proposed federal standards are prevalent in the Commonwealth of Pennsylvania, and Pennsylvania's compliance with the proposed federal standards is feasible.

a. PFAS are prevalent in Pennsylvania drinking water at levels above the proposed MCLs and HI.

b. Enacting the proposed PFAS NPDWR in Pennsylvania is technically and economically feasible.

2. The proposed PFOA and PFOS MCLs and the HI are reasonable and protective of public health, and their implementation is feasible.

a. The proposed stand-alone PFOA and PFOS MCLs of 4.0 ppt are appropriate for the protection of public health.

EPA Response: With respect to the EPA's regulation of additional PFAS through a Hazard Index MCL, please see the section 5.2.1 of the EPA response in this *Response to Comments* document. For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document. With respect to additional individual PFAS MCLs for PFHxS, HFPO-DA and PFNA, please see section 5.3 of the EPA response in this *Response to Comments* document.

New England Water Works Association (Doc. #1836, SBC-045387)

If a cumulative approach is taken by EPA using the Hazard Index, the potential for drinking water noncompliance from the presence of individual PFAS in single-digit ppt levels may also impose significant operational challenges for running PFAS treatment systems. Increased spent adsorptive media will be generated, requiring disposal or incineration from more frequent change-outs. With adsorptive media technologies that are commonly used for PFAS treatment, such as granular activated carbon (GAC) and anion exchange (AIX) resin systems, water is sampled from the different media bed depths to detect a breakthrough of PFAS, along with monitoring of the finished water level. When the breakthrough of the media is approaching the PFAS limit, the system requires a change-out with new media. Media change- outs are costly (although hopefully infrequent in well-designed systems), and therefore should be based on accurate analytical results. NEWWA is concerned that low parts-per-trillion accuracies will be difficult to achieve and may cause inefficient use of resources such as requiring an excessive number of PFAS samples to ensure accurate results.

EPA Response: For discussion on feasibility considerations for the Hazard Index PFAS, please see the EPA section 5.2.1 of the EPA response in this *Response to Comments* document. For more information on treatment technologies, please see section 10 of the EPA response in this *Response to Comments* document.

Maine Water Utilities Association (MWUA) (Doc. #1567, SBC-042735)

If a cumulative approach is taken by EPA using the Hazard Index, the potential for drinking water noncompliance from the presence of individual PFAS in single digit ppt levels may also impose significant operational challenges for running PFAS treatment systems. Increased spent adsorptive media will be generated requiring disposal or incineration from more frequent

change-outs. With adsorptive media technologies that are commonly used for PFAS treatment, such as granular activated carbon (GAC) and anion exchange (AIX) resin systems, water is sampled from the different media bed depths to detect a breakthrough of PFAS, along with monitoring of the finished water level. When the breakthrough of the media is approaching the PFAS limit, the system requires a change-out with new media. Media change-outs are costly (although hopefully infrequent in well-designed systems), and therefore should be based on accurate analytical results. NEWWA is concerned that low parts per trillion accuracy will be difficult to achieve and may cause inefficient use of resources such as requiring an excessive number of PFAS samples to ensure accurate results.

EPA Response: Please see the EPA response to comment Doc. #1836, SBC-045387 in section 5.2.1 in this *Response to Comments* document.

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-042886)

If a cumulative approach is taken by EPA using the Hazard Index, the potential for drinking water noncompliance from the presence of individual PFAS in single digit ppt levels will impose significant operational challenges for running PFAS treatment systems. Increased spent adsorptive media will be generated requiring disposal or incineration from more frequent change-outs. With adsorptive media technologies that are commonly used for PFAS treatment, such as granular activated carbon (GAC) and anion exchange (AIX) resin systems, water is sampled from the different media bed depths to detect breakthrough of PFAS, along with monitoring of the finished water levels. When breakthrough of the media is approaching the PFAS limit, the system requires a change-out with new media. Media change-outs are costly, and therefore should be based on accurate analytical results. MWWA is concerned that low parts per trillion accuracies will be difficult to achieve and may cause inefficient use of resources such as requiring an excessive number of PFAS samples to ensure accurate results.

EPA Response: Please see the EPA response to comment Doc. #1836, SBC-045387 in section 5.2.1 in this *Response to Comments* document.

PFAS Regulatory Coalition (Doc. #1761, SBC-046078)

4. Even accredited laboratories are not all able to meet the sensitivity and reporting precision required by the Proposal.

The concerns raised above regarding laboratory accuracy and capacity are further underscored by a laboratory survey recently conducted by Environmental Standards, Inc. for the American Petroleum Institute. Environmental Standards Survey, May 2023. Environmental Standards identified and surveyed 51 accredited laboratories for US EPA Methods 533, 537, and/or 537.1 and received responses from 14 of this facilities (27%). The results indicated that while the current laboratory sensitivity and reporting precision can meet the US EPA-proposed MCLs for PFOA and PFOS for drinking water, the current laboratory sensitivity and reporting precision

will not be met by all accredited facilities for the US EPA-proposed trigger levels for PFOA and PFOS.

Further, the current laboratory sensitivity and reporting precision can meet the US EPA-proposed HBWCs for PFHxS, HFPO–DA, PFNA, and PFBS, but the current sensitivity demonstrated by the accredited laboratories may not be sufficient to meet the US EPA-proposed Hazard Index MCLG for combined PFHxS, HFPO–DA, PFNA, and PFBS. This further demonstrates that the Proposal is technically infeasible with current laboratory capabilities.

EPA Response: The agency disagrees there is insufficient laboratory capability and capacity to support the monitoring requirements of this NPDWR. Using data submitted as part of the UCMR 5 LAP as a reference point, the EPA notes that 47 of 53 laboratories (89 percent) that applied for UCMR 5 approval generated a MRL confirmation at 2 ng/L (one-half the proposed MCLs for PFOA and PFOS) or less for Method 533. This suggests the majority of laboratories with the necessary instrumentation to support PFAS monitoring have the capability to provide screening measurement results at the revised trigger level of one-half of the MCL. For responses regarding feasibility with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For responses regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please also see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding rule trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document. EPA clarifies for the commenter that MCLGs are non-enforceable and are not required to be achieved by water systems, only MCLs are legally enforceable standards. Additionally, the EPA clarifies for the commenter that the Hazard Index MCLG and Hazard Index MCL are both equal to 1 (unitless), not 1 ppt.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045207)

8. CT DPH agrees with EPA's PFOA and PFOS evaluation of feasibility for the proposal and the feasibility for the proposed Hazard Index (HI) Maximum Contaminant Level (MCL) finding with respect to the analytical measurement and treatment capability. CT DPH agrees that setting the MCL at the Practical Quantitation Level (PQL) for PFOA and PFOS is implementable and feasible, as all laboratories certified by the CT DPH Environmental Laboratory Certification Program (ELCP) are calibrating to concentrations less than 4.0 ppt and have demonstrated their ability to justifiably report to concentrations below 4.0 ppt. CT DPH agrees that the HI MCL is feasible, as all laboratories certified by the CT DPH ELCP are calibrating to concentrations well below the Health Based Water Concentration (HBWC) that is used in the calculation. The best available technologies that EPA has described are proven to be effective at removing the proposed PFAS in drinking water.

Thank you for the opportunity to provide these comments regarding the EPA's preliminary determination.

Sincerely,

Lori J. Mathieu

Public Health Branch Chief

Environmental Health and Drinking Water Branch Connecticut Department of Public Health

C: Lisa M. Morrissey, MPH, Deputy Commission–r - DPH Graham Stevens, DEEP

EPA Response: The EPA acknowledges commenter's agreement that the PFOA, PFOS, and Hazard Index MCLs are all feasible. With respect to the EPA's regulation of additional PFAS through a Hazard Index MCL, please see the section 5.2.1 of the EPA response in this *Response to Comments* document. For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document. With respect to additional individual PFAS MCLs for PFHxS, HFPO-DA and PFNA, please see section 5.3 of the EPA response in this *Response to Comments* document.

Oklahoma Department of Environmental Quality (DEQ) (Doc. #1616, SBC-043037)

Maximum Contaminant Levels and Hazard Index

DEQ recommends consistency in the use of significant figures in the proposed rule.

In different places in the proposed rule, an inconsistent number of significant figures is used for the proposed MCLs. For example, the footnote in the table at 141.50(b) states correctly that the Health-Based Water Concentration for HFPO-DA is 10.0 ppt, but the formula used for the Hazard Index in that same footnote uses 10. EPA should ensure that all references to the MCLs use a consistent number of significant figures.

EPA Response: With respect to responses on significant figure usage for PFOA and PFOS, please see section 5.1.7 of the EPA response in this *Response to Comments* document. With respect to significant figure usage for the Hazard Index PFAS and individual PFAS MCLGs and MCLs (PFHxS, HFPO-DA and PFNA), please see section 4.3.4 of the EPA response in this *Response to Comments* document. With respect to rounding and compliance calculations, please see section VIII.B.3 of the final rule preamble. Please see also the EPA response to comment Doc. #1726, SBC-045150 in section 5.2.1 in this *Response to Comments* document.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045026)

EPA requests comment on the use of two significant figures (i.e., a value of 1.0) for the HI. NJDEP believes two significant figures would be appropriate for reporting and should not result in issues that could be caused due to precision of the analytical methods.

NJDEP notes that the use of one versus two significant figures (i.e., 1 versus 1.0) may impact implementation of an MCL based on the HI. An HI of 1 would not be exceeded unless the HI is calculated to be 1.5 or above, while an HI of 1.0 would be exceeded when the HI is calculated to be 1.05 or above. Also related to this point, it is noted that there is inconsistency in the presentation of the numerical values for the Health Based Water Concentrations (HBWCs) for the four PFAS with preliminary regulatory determinations throughout the rule proposal, and that EPA should clarify whether the HBWCs are intended to include a decimal point, since this can have important implications in implementation of these values.

EPA Response: With respect to responses on significant figure usage for PFOA and PFOS, please see section 5.1.7 of the EPA response in this *Response to Comments* document. With respect to significant figure usage for the Hazard Index PFAS and individual PFAS MCLGs and MCLs (PFHxS, HFPO-DA and PFNA), please see section 4.3.4 of the EPA response in this *Response to Comments* document. With respect to rounding and compliance calculations, please see section VIII.B.3 of the final rule preamble. Please see also the EPA response to comment Doc. #1726, SBC-045150 in section 5.2.1 in this *Response to Comments* document.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045088)

Section V – Maximum Contaminant Level Goal

1) Significant figures: In the presentations/guidance to states and operators, when assessing compliance with the Hazard Index for PFHxS, PFNA, PFBS, and GenX the respective health-based water concentrations are 10 ppt, 2000 ppt, 10 ppt, and 9.0 ppt. This creates confusion and complexity due to rounding and whole vs. decimal numbers. It also does not accurately reflect the regulation in that there are no decimals provided in any of the health-based water concentrations. Reference to the standards needs to be precise and guidance on how to round based on decimals must be provided.

EPA Response: Please see the EPA response to comment Doc. #1726, SBC-045150 in section 5.2.1 in this *Response to Comments* document.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045150)

EPA should revise the use of significant figures to ensure accuracy and consistency throughout the proposed rule and supporting materials.

The proposed rule uses an inconsistent number of significant figures for numeric values in the proposed rule. For example, the footnote to the table at 40 CFR § 141.50(b) shows the Health-Based Water Concentration (HBWC) for HFPO-DA as "10.0" ppt (three significant figures), but the formula used for the HI in that same footnote uses "10" (one significant figure). This inconsistency also occurs for PFBS ("2000.0" followed by "2000"). EPA's June 21, 2022, FR notice for the HAs upon which these HBWCs are based uses "10" (one significant figure) for GenX (HFPO-DA) and "2,000" (one significant figure) for PFBS. The same issue arises in the footnote to the table in § 141.61(c) where, in addition to the above examples, the HBWC for PFNA is shown as "10.0" and "10." EPA should ensure that all references to numeric values in the rule and all supporting materials, including presentations and fact sheets, use a consistent number of significant figures. As different labs may report results with different numbers of significant figures, it is important that EPA establish a consistent regulatory standard so that when results are used for compliance, appropriate rounding practices are applied. Compliance is often determined on a fine line between one value and another and will be even more so in this NPDWR as the MCL is being set so close to the limit of analytical capabilities.

EPA Response: With respect to responses on significant figure usage for PFOA and PFOS, please see section 5.1.7 of the EPA response in this *Response to Comments* document. The EPA notes that the PFOA and PFOS MCLs are finalized with two significant figures. With respect to significant figure usage for the Hazard Index PFAS and individual PFAS MCLGs and MCLs (PFHxS, HFPO-DA and PFNA), please see section 4.3.4 of the EPA response in this *Response to Comments* document. The EPA notes that the Hazard Index PFAS MCL and the individual MCLs for PFNA, PFHxS, and HFPO-DA are set to one significant figure. The EPA further notes that with respect to rounding in compliance calculations, any necessary rounding does not occur until the end of the calculation for an individual MCL, per § 141.903(f)(1)(i) of the regulations. For the Hazard Index, no rounding occurs until after the RAA Hazard Index is calculated, per section § 141.903(f)(2)(i) of the regulations. With respect to rounding and compliance calculations, please see section VIII.B.3 of the final rule preamble.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045200)

May 30, 2023

Via: Federal eRulemaking Portal: https://www.regulations.gov/

SUBJECT: Docket ID Number EPA-HQ-OW-2022-0114, PFAS National Primary Drinking Water Regulation Rulemaking

Dear Administrator Regan:

The Connecticut Department of Public Health (CT DPH) submits these comments in response to the United States Environmental Protection Agency's (EPA) Proposed PFAS National Primary Drinking Water Regulation (NPDWR). CT DPH is the primacy agency responsible for enforcing the federal Safe Drinking Water Act (SDWA) for the State of Connecticut and looks forward to

the implementation of the final PFAS NPDWR. CT DPH is supportive of the EPA's Proposed PFAS NPDWR as it will provide a framework for CT DPH to implement actions in Connecticut's Interagency PFAS Action Plan.

CT DPH has reviewed EPA'S Proposed PFAS NPDWR and respectfully provides detailed comments (attached) for EPA's consideration. Critical recommendations offered are outlined as follows:

1. CT DPH recommends EPA provide more details when explaining the significant figure use in the Hazard Index (HI) calculation. It is particularly important that EPA clarify this point because the Hazard Index is calculated as a sum of four ratios, which provides many more places where rounding can be done than in the traditional screening-level-based Maximum Contaminant level (MCL) approach, which is a single value. If rounding is done at multiple places in the HI calculation, it could have a significant impact on the result (and the determination of compliance with the MCL).

EPA Response: Please see the EPA response to comment Doc. #1726, SBC-045150 in section 5.2.1 in this *Response to Comments* document.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045209)

2. EPA requests comment on significant figure use when calculating both the HI MCLG and the MCL. EPA has set the HI MCLG and MCL using two significant figures (i.e., 1.0). EPA requested comment on the proposed use of two significant figures for the MCLG when considering underlying health information and for the MCL when considering the precision of the analytical methods.

CT DPH agrees that at least two significant figures need to be used when calculating the individual Hazard Quotients and the total Hazard Index. However, EPA should provide more details when explaining the significant figure use in the HI calculation. It is particularly important that EPA clarify this point because the HI is calculated as a sum of four ratios, which provides many more places where rounding can be done than in the traditional screening-level-based MCL approach, which is a single value. If rounding is done at multiple places in the HI calculation, it could have a significant impact on the result (and the determination of compliance with the MCL). Specifically, 1) USEPA should clarify whether the same level of precision (two significant figures) also applies to the PFAS drinking water analytical results when they are divided by the HBWC for HQ calculation (e.g. if the analytical result of PFHxS concentration is 4.2 ppt in the drinking water, should the HQ[PFHxS] be 4.2 ppt/ 10 ppt=0.42 or 4 ppt/ 10 ppt=0.4; and similarly, if the analytical result of PFBS concentration is 1981 ppt, should the HQ[PFBS] be 1981 ppt/ 2000 ppt= 0.99 or 2.0E+3 ppt/ 2000 ppt= 1.0). 2) USEPA should explicitly state whether the "two significant figures" refers to not just the HI but also the rounded HQ for each PFAS. CT DPH encourages EPA to incorporate the requirement on significant figure use into each relevant step of its HI calculation guidance.

EPA Response: Please see also the EPA response to comment Doc. #1726, SBC-045150 in section 5.2.1 in this *Response to Comments* document.

Corix Infrastructure Inc. (Doc. #1834, SBC-045366)

4. With regards to the specific items EPA has requested comment on, Corix provides below:

• We support the use of two significant figures when calculating both the HI MCLG and the MCL.

EPA Response: With respect to responses on significant figure usage for PFOA and PFOS, please see section 5.1.7 of the EPA response in this *Response to Comments* document. With respect to significant figure usage for the Hazard Index PFAS and individual PFAS MCLGs and MCLs (PFHxS, HFPO-DA and PFNA), please see section 4.3.4 of the EPA response in this *Response to Comments* document. With respect to rounding and compliance calculations, please see section VIII.B.3 of the final rule preamble.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044410)

Page 18730. Section V – Maximum Contaminant Level Goal.

EPA requests comment on significant figure use when calculating both the HI MCLG and the MCL. EPA has set the HI MCLG and MCL using two significant figures (i.e., 1.0). EPA requests comment on the proposed use of two significant figures for the MCLG when considering underlying health information and for the MCL when considering the precision of the analytical methods.

• DOH supports using all digits of precision in calculations, but rounding to two significant figures for the final reported value. Using the significant figure only changes how we round before an HI MCL is reached. A system would exceed the MCL with a RAA of 1.05 instead of 1.5 ppt.

EPA Response: Please see also the EPA response to comment Doc. #1726, SBC-045150 in section 5.2.1 in this *Response to Comments* document.

Michigan Department of Environment, Great Lakes, and Energy (EGLE) Drinking Water and Environmental Health Division (DWEHD) (Doc. #1597, SBC-042977)

Regarding EPA's proposed requirement to report to tenths of a part per trillion for the MCLGs, as well as the MCLs, EGLE DWEHD recognizes both the benefits and issues associated with this approach. By including this additional significant figure, RAA calculations may be compared to MCLs and associated trigger levels without the need for extra rounding, resulting in more straightforward compliance determinations.

EPA Response: Please see also the EPA response to comment Doc. #1726, SBC-045150 in section 5.2.1 in this *Response to Comments* document.

A. O. Smith Corporation (Doc. #1674, SBC-043692)

The Company does however have concerns related to the HI approach that the EPA is taking regarding mitigating four other PFAS compounds (e.g., PFHxS, HFPO–DA and its ammonium salt (also known as GenX chemicals), PFNA, and PFBS) in the context of the potential utilization of POU or POE solutions for small water systems. As a general proposition the HI is an approach that has not been utilized under the SDWA. Hence, while in theory the structure may be achievable the Company foresees potential execution and implementation challenges given no precedent exists in the drinking water context. Compounding the challenges is the inclusion of GenX chemicals in the HI. GenX chemicals in particular present a specific challenge for POU and POE manufacturers as a new consensus test method will need to be developed to address the new HI generally and specifically developing an effective treatment technology that takes into consideration GenX as compared to solely targeting PFOA, PFOS, PFNA, and PFBS. It is unclear if the HI will pose a challenge to large public water systems to implement considering the EPA is focused on treating incoming water down to the HI. However, for POU and POE manufacturers the current third-party NSF/ANSI test protocol considers 90th percentile occurrence data, which may have an impact on the effectiveness of treatment technology to address the mix of PFAS that the HI is attempting to address. A. O. Smith would recommend that the EPA remove GenX from the HI approach until a robust review of the pending GenX occurrence data from UCMR5 survey is completed.

EPA Response: The EPA's final rule represents data-driven drinking water standards that are based on the best available, peer-reviewed science, meet the requirements of SDWA, and that regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation. For discussion on feasibility considerations for the Hazard Index PFAS, please see the EPA section 5.2.1 of the EPA response in this *Response to Comments* document. With respect to point-of-use (POU) and point-of-entry (POE) devices, EPA is currently not listing them as best available treatment technologies and SSCTs because the MCLs require treatment to concentrations below the current National Sanitization Foundation International/American National Standards Institute (NSF/ANSI) certification standard for POU device removal of PFAS. The EPA is aware that the NSF/ANSI Drinking Water Treatment Unit Joint Committee Task Group is in the process of updating their standards; should these future standards meet the NPDWR, the EPA could revise the SSCT list to include POE/POU. For additional discussion on small system compliance technology identification and evaluation, please see section 10.5 of the EPA response in this *Response to Comments* document. The EPA also disagrees that the inclusion of HFPO-DA poses a specific challenge because the EPA's record demonstrates that the same technologies which remove the other chemicals can remove HFPO-DA (see USEPA, 2024l). The agency disagrees that the EPA

should wait for UCMR 5 to be completed before regulation. For considerations and use of pending and future science and for additional discussion on UCMR 5, please see sections 5.1.6 and 6.8, respectively, of the EPA response in this *Response to Comments* document.

Superfund Settlements Project (SSP) and RCRA Corrective Action Project (RCAP) (Doc. #1631, SBC-052848)

The SDWA definition of primary drinking water regulation requires EPA to specify "for each such contaminant" an MCL or treatment technique [FN11: 42 U.S.C. § 300f(1).]. The MCLG "shall be set at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." [FN12: 42 U.S.C. § 300g-1(b)(4)(A).]. For a contaminant for which an MCLG is established, EPA shall specify a MCL which is as close to the MCLG as feasible. [FN13: 42 U.S.C. § 300g-1(b)(4)(B).] The HI approach cannot meet these requirements. The HI does not specify "for each such contaminant" a single level but rather a sliding level that depends on the concentration of other substances. This has the practical effect of resulting in an HI exceedance of a combination of the four substances even where none individually is detected in concentrations that exceed the individual health-based water concentration ("HBWC") for any of the substances. Further, the end result would be inequitable: one water system with a certain concentration of one of the substances would have a treatment requirement while another with the same concentration of that substance would not.

EPA Response: The EPA disagrees with this comment. See the EPA response to comment Doc. #1713, SBC-053343 in section 5.2.1 in this *Response to Comments* document.

California Farm Bureau Federation (Doc. #1704, SBC-045067)

[For example, the U.S. Chamber analysis highlights the following:]

• The hazard index approach is problematic. The hazard index approach for PFNA, PFHxS, Gen X, and PFBS has never been used in setting an MCL, and it presents both technical and legal questions about how it would be implemented.

EPA Response: The EPA's final rule represents data-driven drinking water standards that are based on the best available, peer-reviewed science, meet the requirements of SDWA, and that regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation. As an example, the EPA intends to publish an on-line calculator tool to easily determine your Hazard Index result. For discussion on feasibility considerations for the Hazard Index PFAS, please see the EPA section 5.2.1 of the EPA response in this *Response to Comments* document.

Uttara Jhaveri (Doc. #1778, SBC-045445)

UNREGULATED CONTAMINANT MONITORING RULE (UCR)

The Fifth Unregulated Contaminant Monitoring Rule [FN15: Environmental Protection Agency, Fifth Unregulated Contaminant Monitoring Rule, (2021), https://www.epa.gov/dwucmr/fifth-unregulated-contaminant-monitoring-rule] requires sample collection for thirty chemical contaminants between 2023 and 2025 using analytical methods to provide EPA and other interested parties with scientifically valid data on the national occurrence of these contaminants in drinking water. [FN16: Id.] Many of the chemicals listed in the Monitoring Rule are PFAS and the EPA should consider including the other PFAS from the Unregulated Contaminant Monitoring Rule such as perfluorodecanoic acid (PFDA), perfluorododecanoic acid (PFDoA), perfluoro (2-ethoxyethane) sulfonic acid (PFEESA), and perfluoroheptanesulfonic acid (PFHpS). [FN17: Id.] Depending on the rate of occurrence and considering the negative ramifications on human health, their inclusion would promote public safety.

EPA Response: See section 6.8 of the EPA response in this *Response to Comments* document with respect to additional considerations for UCMR5. For discussion on potential regulation for additional PFAS in the future, please see the EPA section 5.2.1 and section 4.3.5 of the EPA response in this *Response to Comments* document.

responsesCalifornia-Nevada Section American Water Works Association (CA-NV AWWA) (Doc. #1775, SBC-045270)

2. EPA should seek public stakeholder input on the proposed Hazard Index (HI) approach and consider other methods to address PFAS mixtures.

CA-NV AWWA appreciates EPA's effort to attempt to address the potential cumulative health effects of PFAS mixtures, but we see multiple problems with the use and application of the Hazard Index (HI) to regulate perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO–DA) and its ammonium salt (also known as GenX chemicals), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS), and mixtures of these PFAS contaminants. The Hazard Index is overly stringent, confusing, and not supported by research or experience. Issuance of the proposed HI MCLs and MCLGs will create significant risk communication challenges for water systems, and confusion in the public. We support the recommendation [FN1: EPA-SAB-22-008. Transmittal of the Science Advisory Board Report titled, "Review of EPA's Analyses to Support EPA's National Primary Drinking Water Rulemaking for PFAS." August 2022] of the Science Advisory Board to use the HI approach as a "screening method and decision-making tool" instead of the proposed MCL and MCLG approach. The HI framework, as a Primary National Drinking Water Regulation needs further evaluation, research on the use and application of such an approach, and appropriate risk-based communication guidance before it can be implemented.

We strongly suggest eliminating the proposed HI-based MCLs and MCLGs for PFHxS, HFPO-DA, PFNA, and PFBS. We encourage EPA to work closely with water systems, including small water systems, and other stakeholders to fully consider this and other options for a useable mixture-based approach that can be practically applied. We support EPA's continued efforts to evaluate, prioritize, and develop MCLs for other high-risk individual PFAS compounds based on known toxicity, occurrence, and technical and economic feasibility. We also ask for transparency and early inclusion in efforts to address potential PFAS mixture concerns in drinking water.

EPA Response: The EPA's final rule represents data-driven drinking water standards that are based on the best available, peer-reviewed science, meet the requirements of SDWA, and that regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation. For discussion on feasibility considerations for the Hazard Index PFAS, please see the EPA section 5.2.1 of the EPA response in this *Response to Comments* document. Please also see section 1.2 for additional discussion on PFAS risk communications. Regarding the use of the Hazard Index as more than screening tool, please see section 4.3.1 of the EPA response in this *Response to Comments* document.

WaterPIO (Doc. #1624, SBC-043470)

Back to the proposed MCLs and Hazard Index, and how they will wreck the American people's confidence in their drinking water.

While the PFAS health advisories will be technically eliminated by the creation of MCLs and Hazard Index, the negative public perception they created will remain. Even if water providers meet the new MCLs and HI, because the health advisory language will still be out there in the Internet's permanent ink, systems will still find themselves accused of having drinking water containing PFAS at "unsafe" levels.

Far too many articles were written about the health advisories for them to simply go away following the imposition of the MCLs and HI. Heck, several pieces were written that stated the HAs were enforceable drinking water standards. Looking to the future using our experience as former network and local news producers, the press, activists, elected officials, and concerned customers will package the health advisories together with the MCLs and HI proposal to deliver a "double whammy" against public confidence in drinking water.

EPA Response: The HAs for PFOA, PFOS, HFPO-DA (GenX chemicals) and PFBS are beyond the scope of this rulemaking. The EPA's final rule represents data-driven drinking water standards that are based on the best available, peer-reviewed science, meet the requirements of SDWA, and that regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation. For discussion on

feasibility considerations for the Hazard Index PFAS, please see the EPA section 5.2.1 of the EPA response in this *Response to Comments* document. Please also see section 1.2 of the EPA response in this *Response to Comments* document for additional discussion on PFAS risk communications.

Citizens Against Ruining the Environment (CARE) (Doc. #1638, SBC-047686)

Hazardous Index MCL

CARE welcomes EPA's innovative move in regulating PFAS as a class. EPA's proposal to regulate PFNA, GenX, PFHxS, and PFBS is through a group based MCL called a Hazardous Index (HI). EPA did not include PFOA and PFOS in the HI because their individual proposed MCLGs are zero. [FN9: Id. at 18639.] The combined approach of the HI is due to the chemicals' additive toxic effects and likely co-occurrence in drinking water. [FN10: Id.] EPA's Science Advisory Board opined that a HI methodology is a valid and reasonable approach for estimating the potential aggregate health hazards from associated chemicals with similar health risk (health endpoints) when the chemicals regularly or easily mix in environmental media. [FN11: Id. at 18654.] This dose additivity means that low levels of multiple PFAS, that individually would not likely result in adverse health effects, are expected to result in adverse health effects when combined in a mixture. [FN12: Id. at 18639; 18647.]

Due to their widespread use and persistence, many PFAS are known to co-occur in drinking water and the environment—meaning that these compounds are often found together and in different combinations as mixtures. [FN13: Id.] EPA has determined that there is a substantial likelihood that PFHxS, HFPO–DA, PFNA, and PFBS, individually and as mixtures, will occur and co-occur with a frequency and at levels of public health concern in PWSs based on EPA's evaluation of the best available occurrence information. [FN14: Id. at 18647.] This preliminary determination is based on the most recent publicly available data, which includes UCMR 3 data and more recent PFAS drinking water data collected by several states. In general, the most recent state data using newer analytical methods than UCMR 3 show widespread occurrence of PFOA, PFOS, PFHxS, PFNA, and PFBS in multiple geographic locations. [FN15: Id. at 18648.]

For the proposed HI level, EPA developed Health Based Water Concentrations (HBWCs) for PFHxS, HFPO– DA, PFNA and PFBS. [FN16: Id. at 18645.] These HBWCs are defined as a level protective of health effects over a lifetime of exposure, including sensitive populations and life stages. In reaching the HBWCs, EPA utilized research from the Agency for Toxic Substances and Disease Registry (ATSDR) that viewed animal toxicity studies. [FN17: Id.]

These studies found that oral exposure to PFHxS, HFPO–DA, PFNA, and PFBS, individually and in a mixture, may result in adverse health effects including disruption of several biological systems including the endocrine, cardiovascular, developmental, immune, and hepatic systems. [FN18: Id.] These PFAS and their mixtures are also anticipated to affect common target organs, tissues, or systems to produce dose-additive effects from co-exposures. [FN19: Id.]

Economic Analysis for the Proposed PFAS NPDWR

In conjunction with the proposed PFAS NPDWR, EPA's Office of Management and Budget prepared an Economic Analysis (EA) that reviewed both the proposed rule and the Health Risk Reduction and Cost Analysis reports prepared by EPA. [FN20: Office of Water, Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation, EPA, 1-2 (March 2023), https://www.epa.gov/system/files/documents/2023-03/Proposed%20PFAS%20NPDWR%20EA_final_03_09_2023_0.pdf.] The EA compared the proposed MCL and HI levels against several regulatory alternative MCLs that were less stringent than the proposed 4ppt for PFOA and PFOS. EPA also compared the quantifiable and nonquantifiable health benefits expected against the costs from the proposed levels.

EPA determined that a final rule promulgation and implementation of the proposed NPDWR would reduce PFAS concentrations in drinking water distributed by PWS and result in reduced frequency of cardiovascular disease, bladder cancer, birth weight, and renal cell carcinoma. [FN21: Id. at 1-2; 6-6.] EPA also anticipates that the nonquantifiable human health benefits are substantial and may reasonably exceed the benefits the Agency was able to quantify for this regulatory proposal. [FN22: Id. at 1-3.] Quantified benefits include those likely to occur from reductions in co-occurring compounds that would be treated as a result of the identified effective treatment technologies required by the proposed NPDWR. [FN23: Id. at 1-4.]

Costs include expenses incurred by PWSs to 1) monitor for PFAS, 2) inform customers, 3) install and operate treatment technologies, and 4) perform record-keeping and reporting to comply with the NPDWR. [FN24: Id. at 1-2.] Install and operation costs include costs associated with engineering, installing, operating, and maintaining PFAS removal treatment technologies, including treatment media replacement and spent media destruction or disposal. [FN25: Id. at 5-9.] The EA also looked at certain non-treatment actions that some PWSs might take in lieu of treatment, such as constructing new wells in an uncontaminated aquifer or interconnecting with and purchasing water from a neighboring PWS. Lastly, costs incurred by states or other primary agencies to implement the rule, such as time spent to read and understand the rule, internal training for implementation, and reporting to EPA, were also examined. [FN26: Id. at 5-36.] Following a comparison of the associated benefits and costs to the proposed NPDWR, the Administrator determined that the quantified and nonquantifiable benefits justify the costs. [FN27: Id. at 7-7.]

After considering all these factors, CARE supports EPA's determination that the six PFAS and the mixtures listed in the HI should be regulated as contaminants under SDWA. CARE believes these determinations will protect human health and the environment and that the proposed MCLs are within EPA's statutory and regulatory authority prescribed by the Safe Drinking Water Act. CARE also welcomes EPA's first step in addressing PFAS as a class but, as explained in Issue IV, encourages EPA to broaden the HI to include more PFAS in future rulemakings. CARE wishes to underscore that the proposed NPDWR protects our drinking water at levels that are based on current feasibility limits and scientific knowledge while also asserting EPA should readdress the proposed levels as feasibility and scientific data evolve.

EPA Response: For discussion on feasibility considerations for the Hazard Index PFAS, please see the EPA section 5.2.1 of the EPA response in this *Response to Comments* document. The commenter supports the feasibility of the final Hazard Index MCL. The EPA is clarifying that the agency conducted and analyzed quantifiable and non-quantifiable costs and benefits of the regulation (and not the Office of Management and Budget); please see section 13 of the EPA response in this *Response to Comments* document for additional discussion on the agency's HRRCA. With respect to potential inclusion of additional PFAS compounds in the future, please see the section 5.1.6 of the EPA response in this *Response to Comments* document.

Clean Air Council, et al. (Doc. #1731, SBC-043846)

For PFHxS, HFPO–DA and its ammonium salt, PFNA, and PFBS, EPA is proposing using a Hazard Index ("HI") approach to account for their additive toxicity. Specifically, EPA is proposing Health Based Water Concentration ("HBWCs") of 9.0 ppt for PFHxS, 10.0 ppt for HFPO–DA; 10.0 ppt for PFNA; and 2000 ppt for PFBS. The sum of the individual hazard quotients (concentration in the water divided by the HBWC) yields the HI, where HI of 1.0 defines the MCL for these four PFAS.

The proposed NPDWR reflects current evidence regarding toxicity and health impacts of PFAS compounds. In particular, the HI addresses their confirmed dose-additivity, namely the cumulative effect when there is exposure to multiple PFAS species. Although the proposed MCLs and HBWCs are stricter than those in most of the states that have current regulations for PFAS in drinking water, this does not pose a conflict: States with existing PFAS drinking water standards will be well-positioned to meet the proposed NPDWR.

Commenters strongly support the proposed regulation as a strong step to ensuring public health and safety. The MCLs and HI/HBWC are adequate to protect public health based on current data, and are feasible for both testing and treatment. Commenters urge EPA to follow updated research and adjust the MCLs and NBWC values periodically and add more PFAS species to the HI to reflect new data.

EPA Response: For discussion on feasibility considerations for the Hazard Index PFAS, please see the EPA section 5.2.1 of the EPA response in this *Response to Comments* document. The commenter supports the feasibility of the final Hazard Index MCL. With respect to potential inclusion of additional PFAS compounds in the future, please see the section 5.1.6 of the EPA response in this *Response to Comments* document.

Clean Air Council, et al. (Doc. #1731, SBC-043882)

c. Laboratory detection methods can accurately measure the regulated PFAS species at the proposed PQL, MCLs, and HBWCs, and the proposed trigger levels are appropriate.

The proposed MCLs and HBWCs are well above the minimum detection limit ("MDL") of the leading EPA PFAS testing methods (533 and 537.1) as summarized in the table below. These

methods are broadly used by certified laboratories and accepted by current state regulations [FN56: See, e.g., 53 Pa.B. 343. Commercial laboratories also consider these to be accepted methods. See, e.g., Eurofins, PFAS Analysis, https://www.eurofinsus.com/media/1713837/pfas-user-Guide_221.pdf (last visited May 26, 2023); Assent, PFAS Guidance on Risk Assessment for Manufacturers, https://www.assent.com/resources/pfas-compliance/ (last visited May 26, 2023); Garden State Laboratories, Analytical Services, https://www.gslabs.com/?gclid=EAIaIQobChMIwb7n6ZLX_gIVi8vjBx1qBgrcEAAYAiAAEgLEL_D_BwE (last visited May 30, 2023).] Newly-developed methods such as EPA's method 1633 will also be able to determine the relevant PFAS compounds at the proposed levels [FN57: Draft Method 1633, supra note 46, at Table 6.]. Therefore, reliably identifying EPs where the regulated PFAS compound levels are above the values set by the proposed NPDWR is feasible.

EPA Response: For discussion on feasibility considerations for the Hazard Index PFAS, please see the EPA section 5.2.1 of the EPA response in this *Response to Comments* document. The agency acknowledges the comment supporting the feasibility of the final Hazard Index MCL. The agency notes that EPA Method 1633 is not a drinking water method and is not approved to meet the monitoring requirements of this final NPDWR for PFAS. For additional discussion on validated analytical methods, please see section VII of this *Response to Comments* document.

Environmental Protection Network (EPN) (Doc. #1773, SBC-043864)

Hazard Index MCL

EPN agrees that EPA's HI MCL of one is implementable and feasible, and we commend EPA for setting the MCL equal to the MCLG.

EPA Response: The commenter support the Hazard Index MCLG and MCL. For discussion on feasibility considerations for the Hazard Index PFAS, please see the EPA section 5.2.1 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce (Doc. #1537, SBC-042647)

[Accordingly, we are planning to provide comments to EPA and will request that the agency withdraw the proposal and should await the results of the UCMR 5 process:]

The novel hazard index approach. The hazard index approach for the PFAS other than PFOA and PFOS has never been used in setting an MCL, and it presents both technical and legal questions about how it would be implemented.

EPA Response: For discussion on feasibility considerations for the Hazard Index PFAS, please see the EPA section 5.2.1 of the EPA response in this *Response to Comments* document. For additional discussion on the agency's legal authority to regulate mixtures of PFHxS, PFNA, HFPO-DA and PFBS and discussion of the Hazard Index approach, please see section 3.2 of the EPA response in this *Response to Comments* document.

American Farm Bureau Federation et al. (Doc. #1642, SBC-043483)

[They have identified the following areas of concern regarding the agency's development of this rule:]

• The novel hazard index approach. The hazard index approach for PFNA, PFHxS, Gen X, and PFBS has never been used in setting an MCL, and it presents both technical and legal questions about how it would be implemented.

EPA Response: Please see the EPA response to comment Doc. #1537, SBC-042647 in section 5.2.1 in this *Response to Comments* document.

Oregon Health Authority (OHA) (Doc. #1582, SBC-042760)

Section VI – Maximum Contaminant Level

• EPA requests comment on its proposal of using an HI approach for PFHxS, HFPO-DA, PFNA, and PFBS, including whether it can be clearly implemented and achieves the goal of protecting against dose additive noncancer health effects.

OHA believes the HI approach, while a new concept in drinking water, is implementable at the state level.

EPA Response: For discussion on feasibility considerations for the Hazard Index PFAS, please see the section 5.2.1 of the EPA response in this *Response to Comments* document.

Safe Healthy Playing Fields, Inc. (Doc. #1621, SBC-042945)

The preliminary determination to regulate PFNA, PFBS, PFHxS and GenX as mixtures is a welcome first step. However, the concept of unitless actual measurements of summed fractions is not easily understood by the majority of the general population. It gives the appearance of creative bookkeeping that even the Wall Street Journal [Link: https://www.wsj.com/articles/epa-standards-miss-many-chemicals-in-drinking-water-study-says-eb748826] wasn't able to parse.

It is a generally accepted practice to write to a seventh grade level when providing health information. The National Institutes of Health [Link: https://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/clear-communication/clear-simple] notes:

"People with health literacy challenges are found among all ethnicities, races, and classes but there is a link between literacy and education and income levels. Many of the same populations at risk for limited health literacy also suffer from disparities in health status, illness (including heart disease, diabetes, obesity, HIV/AIDS, oral disease, cancer deaths, and low birth weight), and death."

The Health Index for PFNA, PFBS, PFHxS and GenX is unclear, instills fear and indicates a compromise with the chemical industry allowing them to continue to pollute both people and planet for multiple generations without a right to know or informed consent.

EPA Response: For discussion on feasibility considerations for the Hazard Index PFAS, please see the EPA section 5.2.1 of the EPA response in this *Response to Comments* document. The agency disagrees that dividing an exposure metric over a health metric will not be easily understood. This calculation is also not mathematically different (i.e., summing up numbers and dividing) than a RAA calculation which is used frequently for compliance calculations for NPDWRs. Regardless, to assist in the calculation of these values, the agency is developing a calculator tool to easily determine your hazard index result. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation. The commenter provides no explanation for its statement that a hazard index approach "instills fear and indicates a compromise with the chemical industry [by] allowing them to continue to pollute both people and planet for multiple generations without a right to know or informed consent." The EPA's final rule represents data-driven drinking water standards that are based on the best available, peer-reviewed science, meet the requirements of SDWA, and that regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. For additional discussion on risk communications as well as SDWA Right-to-Know requirements in the final NPDWR (including CCRs and PN), please see section 1.2 and 9, respectively, of the EPA response in this *Response to Comments* document.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044414)

Page 18730. EPA requests comment on its proposal of using an HI approach for PFHxS, HFPO–DA, PFNA, and PFBS, including whether it can be clearly implemented and achieves the goal of protecting against dose additive noncancer health effects.

• The HI approach is reasonable for regulating PFAS with additive toxicity. This will be challenging to implement as proposed due to the tracking of multiple compounds and automating this into existing data systems. DOH has limited IT resources to prepare for migration to SDWIS state. Timing will be a key consideration for successful implementation of this area of the

proposed PFAS rule. As written, this approach will have a considerable resource impact on compliance activities.

EPA Response: For discussion on feasibility considerations for the Hazard Index PFAS, please see the EPA section 5.2.1 of the EPA response in this *Response to Comments* document. With respect to data management systems, the EPA agrees that appropriate data management solutions are needed to effectively comply with SDWA requirements; however, the agency does not believe these systems must be available at the time of rule promulgation. Additionally, while beyond the scope of this rulemaking itself, the EPA is actively working on PFAS data management solutions, such as updating the SDWIS suite of applications to manage data

reported from this rule (please see section 11 of the EPA response in this *Response to Comments* document).

Washington State Department of Health (DOH) (Doc. #1665, SBC-044399)

(2) Specific Comments

Page 18639. Executive Summary: EPA is proposing to use a Hazard Index (HI) approach to protecting public health from mixtures of four PFAS: PFHxS, HFPO-DA, PFNA and PFBS because of their known and additive toxic effects and occurrence and likely co-occurrence in drinking water.

• Effective implementation and data system support is needed to implement the HI.

EPA Response: Please see the EPA response to comment Doc. #1665, SBC-044414 in section 5.2.1 in this *Response to Comments* document.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045025)

Regarding implementation, although a HI approach may be unfamiliar to non-toxicologists, this approach and its application to PFAS detected in drinking water are clearly explained in the proposed rule and are not conceptually difficult to understand. EPA has stated that it will post an online calculator that will determine the HI from the detected concentrations of the four PFAS considered in the HI. This online calculator will assist in the implementation of an MCL based on the HI.

EPA Response: For discussion on feasibility considerations for the Hazard Index PFAS, please see the EPA section 5.2.1 of the EPA response in this *Response to Comments* document. As the commenter notes, to assist in the calculation of these values, the agency is developing a calculator tool to easily determine your Hazard Index result. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation.

Missouri Department of Natural Resources (Doc. #1563, SBC-042526)

EPA requests comment on its proposed decision to establish stand- alone MCLs for PFOA and PFOS in lieu of including them in the HI approach. EPA requests comment on whether establishing a traditional MCLG and MCL for PFHxS, HFPO–DA, PFNA, and PFBS instead of, or in addition to, the HI approach would change public health protection, improve clarity of the rule, or change costs.

The Department agrees with the EPA decision to establish stand-alone MCLs for PFOA and

PFOS. At this time, the Department believes it is premature to establish MCLs for the other four PFAS.

EPA Response: For discussion on feasibility considerations for the Hazard Index PFAS, please see the section 5.2.1 of the EPA response in this *Response to Comments* document. For discussion on PFOA and PFOS MCLs, please see section 5.1 of the EPA response in this *Response to Comments* document.

Oregon Health Authority (OHA) (Doc. #1582, SBC-042758)

OHA supports excluding PFOA and PFOS from this HI approach since their proposed Maximum Contaminant Level Goals (MCLGs) are so much lower than the other four PFAS species proposed for regulation.

EPA Response: With respect to the EPA's decision to exclude PFOA and PFOS from the Hazard Index approach, please see section 5.2.1 of the EPA response in this *Response to Comments* document.

Michigan Department of Environment, Great Lakes, and Energy (EGLE) Drinking Water and Environmental Health Division (DWEHD) (Doc. #1597, SBC-042976)

Additionally, EGLE DWEHD requests that EPA further speak to the proposed use of a general hazard index for the four PFAS chemicals versus multiple target organ toxicity-specific indexes, and that EPA speak to the exclusion of PFOA and PFOS from hazard index calculations.

EPA Response: With respect to the EPA's decision to exclude PFOA and PFOS from the Hazard Index approach, please see the EPA response in 5.2.1 of the EPA response in this *Response to Comments* document. With respect to the agency's discussion on the application of the target organ specific hazard index approach, please see section 4.3.1 of the EPA response in this *Response to Comments* document.

Aidan Cecchetti (Doc. #1640, SBC-044366)

• EPA requests comment on its proposed decision to establish stand-alone MCLs for PFOA and PFOS in lieu of including them in the HI approach (pg. 18671 Federal Register Volume 88, Number 60).

o The commenters agree with EPA's decision to establish stand-alone MCLs for PFOA and PFOS in lieu of including them in the HI approach. The justification provided by EPA in their analysis is convincing because including PFOA and PFOS in the HI approach would not provide additional public health protection for those contaminants over setting MCLs at the PQL. Based on the co-occurrence data for PFOA, PFOS, and the HI PFAS, it is clear that including PFOA and PFOS in the HI approach would increase public health protection for the HI PFAS, but it would also significantly increase costs and the number of water systems required to treat for PFAS.

EPA Response: With respect to the EPA's decision to exclude PFOA and PFOS from the Hazard Index approach, please see section 5.2.1 of the EPA response in this *Response to Comments* document.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044415)

Page 18730. EPA requests comment on its proposed decision to establish stand- alone MCLs for PFOA and PFOS in lieu of including them in the HI approach.

• DOH supports this approach to compliance in the PFAS rule. Establishing MCLs is consistent with the current nationwide Standard Monitoring Framework implementation.

• EPA has set the MCLs for PFOS and PFOA at what the Agency determined are the PQLs for these compounds. Given that, it doesn't make sense to consider an approach where lower concentrations would contribute to the HI of a mixture.

EPA Response: With respect to the EPA's decision to exclude PFOA and PFOS from the Hazard Index approach, please see the section 5.2.1 of the EPA response in this *Response to Comments* document.

City of Vancouver Water Utility, Vancouver, WA (Doc. #1684, SBC-044308)

Hazard Index (HI) Approach:

Vancouver supports the decision to establish stand-alone MCLs for PFOA and PFOS in lieu of including them in the HI approach.

EPA Response: With respect to the EPA's decision to exclude PFOA and PFOS from the Hazard Index approach, please see section 5.2.1 of the EPA response in this *Response to Comments* document.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045023)

EPA requested comments on its proposed decision to establish standalone MCLs for PFOA and PFOS in lieu of including them in the HI approach. Since the proposed MCLs for PFOA and PFOS are set at the analytical minimal reporting levels, any detection of these PFAS above the minimal reporting limits of 4.0 ppt would result in an MCL exceedance, whether or not they are included in the HI approach.

EPA Response: With respect to the EPA's decision to exclude PFOA and PFOS from the Hazard Index approach, please see section 5.2.1 of the EPA response in this *Response to Comments* document.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045099)

4) EPA requests comment on its proposed decision to establish stand-alone MCLs for PFOA and PFOS in lieu of including them in the Hazard Index approach:

If EPA were to add PFOA and PFOS to the existing Hazard Index would be challenging and require additional supporting data and information due to the impact any reported level will have when compared with the respective health advisory number. Adjustment to the Hazard Index standard of 1.0 would need to be justified.

EPA Response: With respect to the EPA's decision to exclude PFOA and PFOS from the Hazard Index approach, please see section 5.2.1 of the EPA response in this *Response to Comments* document.

Missouri River Public Water Supplies Association (MRPWSA) (Doc. #1581, SBC-042410)

Use of the Hazard Index Approach to Regulate PFHxS. HFPO-DA. PFnA. and PFBS — MRPWSA does not support the use of the Hazard Index as proposed for regulating PFAS in drinking water and recommends the development of drinking water regulations that follow the MCL approach once data to support such action is available.

EPA Response: With respect to the EPA's regulation of additional PFAS through a Hazard Index MCL, please see the section 5.2.1.

Office of Advocacy at the U.S. Small Business Administration (Doc. #1807, SBC-045492)

Moreover, the agency is proposing to regulate the four PFAS chemicals under the novel HI approach. Many small entities and their representatives have expressed concerns about the validity of this approach. Advocacy encourages the agency to address the concerns raised by stakeholders on this topic.

EPA Response: With respect to the EPA's regulation of additional PFAS through a Hazard Index MCL, please see the section 5.2.1 of the EPA response in this *Response to Comments* document. The EPA has considered all public comments provided on the proposed NPDWR, including comments on the hazard index.

Austin Water (AW), Austin, TX (Doc. #1688, SBC-044454)

In addition to the proposal to regulate perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) with individual maximum contaminant levels (MCLs), the proposed PFAS NPDWR uses a "Hazard Index" approach for four substances: perfluorohexane sulfonic acid (PFHxS), GenX chemicals, perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS). This proposal is the first time the Hazard Index (HI) approach has been applied to drinking water regulations for public water systems under the SDWA framework. EPA has set

legal limits on over 90 contaminants in drinking water without using the HI approach. The HI approach differs considerably and is more nuanced and complex than regulations for MCLs or treatment technique (TT) requirements. Over the last four decades, community public water systems have developed a historical understanding of EPA's regulatory methodology employed under SDWA and the implementation of MCL and TT compliance requirements. The unforeseen introduction of a HI approach requires more time for water system staff to review and understand of the basis for and implementation of this application within our industry. As AW and other water systems are currently dedicating resources to meeting other new drinking water regulatory requirements, it is important to give water systems at least until the spring of 2024 to comprehend and incorporate the science behind the HI approach fully. This includes planning for potential impacts on compliance with proposed NPDWR regulations and being prepared to communicate with the public as needed. With these factors existing, it will be beneficial to allow additional time for further review and feedback on the use and effectiveness of the HI approach.

EPA Response: With respect to the EPA's regulation of additional PFAS through a Hazard Index MCL, please see the section 5.2.1 of the EPA response in this *Response to Comments* document. Regarding responses on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. While the agency acknowledges that the Hazard Index has not been used under SDWA to set an enforceable MCL, the Hazard Index approach has been used successfully by the EPA in other programs. The EPA further notes that the Hazard Index value is the MCL which represents the maximum level allowed of a contaminant or group of contaminants in water which can be delivered to any user of a PWS. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation.

Michigan Farm Bureau (MFB) (Doc. #1562, SBC-043352)

However, we have significant concerns about the feasibility of implementation and compliance with the proposed Maximum Contaminant Limits (MCLs) for six PFAS: 4 parts per trillion (ppt) for perfluorooctanoic acid (PFOA), 4 ppt for perfluorooctane sulfonic acid (PFOS), combined Health Index value for the total combined concentrations of up to 2000 ppt of perfluorobutane sulfonic acid (PFBS), 9 ppt of perfluorohexane sulfonate (PFHxS), 10 ppt of hexafluoropropylene oxide dimer acid and its ammonium salt (HFPO-DA, also known as GenX), and 10 ppt of perfluorononanoic acid (PFNA).

As EPA moves forward with its strategic plan and this important set of regulations, we urge the agency to carefully consider the impacts of setting these MCLs. EPA needs to ensure they are using the most recent, most accurate, and most transparent science in setting those regulatory limits. The agency needs to understand the larger impacts of drinking water regulations, not only because drinking water standards and the science behind them forms the basis of all other

regulatory standards for water, including surface and groundwater quality standards and designated uses, permitted discharge standards for NPDES and other program compliance, and contamination clean-up thresholds.

EPA Response: The EPA believes the MCLs are feasible and this is demonstrated by the Administrative record for this action. See sections 5.2.1., 5.1.2, and 5.1.4 of the EPA response in this *Response to Comments* document for further discussion. The EPA's final rule represents data-driven drinking water standards that are based on the best available science and are driven by the requirements of SDWA. In the administrative record, the EPA has described, in detail, how it developed the final rule's MCLs. See section V of the preamble for this NPDWR for information supporting development of the MCLs. With respect to commenter concerns on impacts of the NPDWR in non-drinking water contexts, such as NPDES or other permitting standards, these issues are beyond the scope of the current rulemaking. For additional discussion, please see section 5.1.3 and section 15.1 for the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045601)

First, AWWA notes that EPA's novel use of the hazard index approach in the proposal is not clearly permissible under the SDWA. The SDWA is designed for an individual assessment of contaminants and an individualized assessment of appropriate MCLG and MCL, as the statute uses the singular "contaminant" when defining "maximum contaminant level." [FN17: 42 U.S.C. § 300f(3).] The proposal runs counter to this statutory focus by a Hazard Index approach rather than a specific concentration level for proposing an MCL and MCLG for PFNA, PFHxS, PFBS, and HFPO-DA.

The Hazard Index approach is also arguably inconsistent with SDWA because it is not a "level" but instead a calculated sum of component hazard quotients using a highly variable equation that can change over time.

EPA Response: With respect to the EPA's regulation of additional PFAS through a Hazard Index MCL, please see the EPA response to comment Doc. #1713, SBC-053343 in section 5.2.1 in this *Response to Comments* document. Regarding EPA's statutory authority to regulate mixtures, please see section 3.2 of the EPA response in this *Response to Comments* document.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-044875)

Based on the substantial science and data used by DEP to promulgate our state PFAS maximum contaminant level (MCL) rule, DEP supports the decision to establish standalone MCLs for perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS), instead of including them in the hazard index (HI) approach. Additional comments relative to the proposed MCLs for PFOA and PFOS and the combined HI approach for additional PFAS are provided later in this letter.

EPA Response: Regarding the EPA's decision to exclude PFOA and PFOS from the Hazard Index MCL, please see section 5.2.1 of the EPA response in this *Response to Comments* document.

5.3 Individual PFAS MCLs: PFHxS, HFPO-DA, PFNA, and PFBS

5.3.1 General

Summary of Major Public Comments and EPA Responses

Commenters were mixed on the EPA's request for public comment on the establishment of stand-alone MCLs in lieu of or in addition to the Hazard Index MCL. Many of the comments were related to risk communications and messaging to consumers. While several commenters favored stand-alone MCLs in lieu of the Hazard Index to improve communications to their customers, several other commenters recommended stand-alone MCLs in addition to the Hazard Index MCL to achieve this purpose. Several commenters opposed individual MCLs for some or all of the PFAS because they believe it may complicate risk communication. Some commenters assert that the Hazard Index is novel and may confuse the public. The EPA notes that while the Hazard Index has not been used under SDWA to set an enforceable MCL, it has been validated and successfully used by other parts of the EPA as an effective approach to minimizing public health risks. After consideration of public comment, the agency agrees that risk communication is an important focus for water systems and primacy agencies, and the EPA believes that finalizing individual MCLGs and MCLs in addition to the Hazard Index framework to address mixtures may help support risk communication efforts because utilities and the public may be more familiar with individual MCLs when one contaminant is occurring. At the same time, since those individual MCLs do not address additional risks from mixtures of co-occurring PFAS, the EPA is finalizing a Hazard Index MCL to address dose additive health concerns associated with mixtures of PFHxS, PFNA, HFPO-DA, and PFBS that co-occur in drinking water. For additional discussion on the Hazard Index approach and other mixture-based approaches (e.g., TOSHI), please see section IV of the final rule preamble. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation. For additional discussion on PFAS risk communications, please see section 1.2 of the EPA response in this *Response to Comments* document.

In the final NPDWR, the EPA is promulgating individual MCLs for PFHxS, PFNA and HFPO-DA at the same level as their respective MCLGs (which are equivalent to the HBWCs). The EPA is finalizing individual MCLs as follows: HFPO-DA MCL = 10 ng/L; PFHxS MCL = 10 ng/L; and PFNA MCL = 10 ng/L. Concurrent with this action, the EPA is making the required determinations to support both the individual MCLs for PFHxS, PFNA, and HFPO-DA as well the Hazard Index MCL for mixtures of PFHxS, PFNA, HFPO-DA and PFBS (please see section III of the final rule preamble and section 3 of the EPA response in this *Response to Comments* document for additional discussion on the EPA's regulatory determinations).

The agency considered feasibility as defined by SDWA and notes that EPA's feasibility justification for these individual PFHxS, PFNA and HFPO-DA MCLs are the same as the Hazard Index MCL discussed in section 5.2 of the EPA response in this *Response to Comments* document and section V.B of the final rule preamble. The EPA further notes that the Hazard Index MCLG applies to the entire mixture but the EPA's technical justification for the underlying values (i.e., HBWCs) are the same as the individual MCLGs in this rule. In summary, the EPA has determined that it is feasible to set the individual MCLs at the MCLGs for PFHxS, PFNA and HFPO-DA current BATs can remove each contaminant to a level equal to or below their respective MCLGs. In addition, there are analytical methods available for these contaminants and the PQL for each contaminant is below the level established by the MCLG. The EPA also considered costs and determined that establishing an individual MCL of 10 ng/L for PFHxS, PFNA, and HFPO-DA is reasonable based on consideration of the costs to large metropolitan water systems. These considerations support a determination that individual MCLs of 10 ng/L for PFHxS, PFNA, and HFPO-DA are feasible and therefore the EPA is setting the MCL at the same level as the MCLG. For additional discussion regarding the derivation of the individual HBWCs and MCLGs, please see section III and IV of the final rule preamble.

In light of finalizing the individual MCLs for PFHxS, PFNA, and HFPO-DA, the EPA has separately presented national level marginal costs associated with the individual MCLs for PFHxS, PFNA and HFPO-DA in the absence of the Hazard Index MCL; for more information, please see sections 5.1.2 and 13.3 of the EPA response in this *Response to Comments* document. Additionally, please Chapter 5.1.3 and Appendix N.4 of the HRRCA.

Individual Public Comments

Pennsylvania Chamber of Business and Industry (Doc. #1592, SBC-042798)

EPA's Novel and Unprecedented Hazard Index Approach for PFAS Presents Significant Questions and Should be Reconsidered

In stark contrast to how all other MCLs have been established, which is determined in reference to health advisory limits, EPA is proposing in this rulemaking to regulate four PFAS combinations using a hazard index that may produce subjective determinations with conflicting interpretations between utilities and regulators. It is likely this approach will produce significant uncertainty to regulated communities and may be inconsistently applied across the country and not well understood by the public. As such, EPA should develop a workable MCL using traditional approaches.

EPA Response: After a review of public comment, the agency is promulgating individual MCLs for PFHxS, PFNA, and HFPO-DA in addition to the Hazard Index MCL for mixtures containing two or more of these PFAS and PFBS. The agency disagrees that it is likely that the Hazard Index approach will produce "significant uncertainty" to regulated communities, "may be inconsistently applied across the country" and "may product subjective determinations with conflicting interpretations between utilities and regulators" because the MCL of 1 is the

maximum level allowed of a contaminant in water which is delivered to any user of a PWS The hazard index calculation is not mathematically different (i.e., summing up numbers and dividing) than a RAA calculation which is used frequently for compliance calculations for NPDWRs. Please see the section 5.3.1 of the EPA response in this *Response to Comments* document for additional discussion on these individual MCLs, including risk communication and feasibility concerns. The EPA disagrees with commenter's assertions regarding MCLs and HAs. HAs and NPDWRs are different actions with different purposes that are conducted pursuant to different statutory authorities.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044017)

1. EPA requests comment on its preliminary regulatory determination for PFHxS and its evaluation of the statutory criteria that supports the finding. EPA also requests comment on if there are additional data or studies EPA should consider that support or do not support the Agency's preliminary regulatory determination for PFHxS, including additional health information and occurrence data.

a. PFHxS will likely become the PFAS problem for many utilities in their efforts to keep the HI below 1. This compound has been observed to breakthrough treatment media before PFOA and PFOS. PFHxS has a reference value of 9 in the new rule. CWUC is curious if EPA's treatment cost models are based on only PFOA and PFOS or all six compounds targeted in the new rule? CWUC recommends that the PFHxS reference value be re-evaluated and raised if possible (or consider establishing MCLs over the HI approach).

EPA Response: After a review of public comment, the agency is promulgating individual MCLs for PFHxS, PFNA, and HFPO-DA in addition to the Hazard Index MCL for mixtures containing two or more of these PFAS and PFBS. Please see the section 5.3.1 of the EPA response in this *Response to Comments* document for additional discussion on these individual MCLs, including risk communication and feasibility concerns. With respect to the commenter's question on if the cost models account for PFOA and PFOS, or all six compounds (specifically PFHxS), the EPA's cost models do account for PFHxS occurrence and removal. SafeWater Multi-Contaminant Benefit Cost (MCBC) calculates bed life using a system of equations that considers the percent removal required for each PFAS that occurs at an entry point and has an MCL or other limit in the regulatory option, even if the contaminant occurs at a concentration below the regulatory limit. See the EPA response to comment Doc. #1709, SBC-053307 in section 13.3.2 in this *Response to Comments* document about consideration of PFAS competition in the EPA's bed life equations. Further, please see Appendix N.3 of the EA (USEPA, 2024c) and section 13.3.2 of the EPA response in this *Response to Comments* document for discussion on the Hazard Index and individual MCLs for PFNA, PFHxS, and HFPO-DA costs at the national level. The EPA notes that in the final regulation, EPA has adjusted the MCL for PFHxS to 10 ng/L from 9.0 ng/L (please see the EPA response to comment Doc. #1774, SBC-045656 in section 4.3.3 in this *Response to Comments* document).

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-052953)

• The health effects required language for PN for an HI MCL exceedance in Appendix A to Subpart O of Part 141 will be confusing to the public. The required language does not sufficiently explain the HI and is likely to cause confusion and fear.

• The health effects required language for CCR reporting for the HI MCL in Appendix A to Subpart Q of Part 141 will be confusing to the public. The required language does not sufficiently explain the HI.

• DEP believes that communication of the HI MCL to the public will be a significant implementation challenge of the proposed rulemaking. As noted above, the required health effects language does not adequately explain the HI, how it is determined, what the significance is, or why it is unitless. This is likely to cause confusion and fear in the public. Communication to the public in a way that does not incite fear and misunderstanding is critical. One key point that will be important to communicate is the relative source contribution of drinking water and the numerous other potential routes of exposure to PFAS. For a public that is concerned about very low detected levels of PFAS in their drinking water, it is important to educate them on other ways to reduce their exposure, since drinking water is only considered a 20% relative source contribution to overall exposure.

• DEP notes that on page 18690 of the preamble to the proposed rulemaking, EPA states that it "has not separately quantified the benefits and costs for the alternative approach to regulate PFHxS, PFNA, PFBS, and HFPO-DA with individual MCLs instead of the HI." In other words, EPA did not show whether it is more cost effective or more feasible to regulate these four PFAS with traditional MCLGs and MCLs instead of the HI, and it did not clearly articulate the costs and benefits associated with regulating these four PFAS in a more traditional manner. As a result, it is not clear what impact eliminating the HI and regulating the four HI PFAS with traditional MCLGs and MCLs would have on overall costs. DEP believes that this missing information is critical in the evaluation of this proposed rulemaking and in determining the best way to regulate these PFAS, particularly since - as our previous comments detailed - the introduction of the HI MCL does not appear to be an appropriate application of the HI concept.

• Because of the significant implementation challenges noted above with the HI MCL, DEP suggests that it would be better to use an established approach for regulating these four additional PFAS. For example, using a treatment technique, combined MCL, or individual MCLs would be more feasible for implementation. As noted above, DEP believes that the HI MCL concept, as well as a water system's ability to demonstrate compliance, is likely to be confusing to the public. DEP believes that setting a traditional MCLG and MCL, either individually or combined, for the four HI component PFAS (PFHxS, PFNA, PFBS, and HFPO-DA) instead of using the HI approach would improve clarity for primacy agencies, regulated water systems, and the public. The traditional MCLG and MCL framework is an established framework that can be more readily comprehended.

EPA Response: After a review of public comment, the agency is promulgating individual MCLs for PFHxS, PFNA, and HFPO-DA in addition to the Hazard Index MCL for mixtures containing two or more of these PFAS and PFBS. Please see the section 5.3.1 of the EPA response in this *Response to Comments* document for additional discussion on these individual MCLs, including risk communication and feasibility concerns. Regarding risk communication, please see section 1.2 of the EPA response in this *Response to Comments* document. Regarding health effects required language for PN for a Hazard Index MCL, please see the section 9 of the EPA response in this *Response to Comments* document. The agency disagrees that the EPA "did not show whether it is more cost effective or more feasible to regulate these four PFAS with traditional MCLGs and MCLs instead of the Hazard Index, and it did not clearly articulate the costs and benefits associated with regulating these four PFAS in a more traditional manner." The EPA's cost analysis at proposal considered the costs associated with the individual MCLs for PFHxS, PFNA, and HFPO-DA because the proposed Hazard Index MCL would function as individual MCLs when these contaminants occur in isolation. While the rule structure has changed in the final NPDWR based on public comment received, the costing framework used at proposal is still fully applicable in the final rule: what was considered a Hazard Index MCL exceedance at proposal would be an individual MCL exceedance under the final rule should those contaminants occur in isolation. Further, the combination of a Hazard Index exceedance in the final rule (defined as two or more of PFHxS, PFNA, HFPO-DA, and PFBS) or an individual MCL exceedance for PFHxS, PFNA, or HFPO-DA is unchanged from a costing perspective to what the EPA proposed. Whether a system exceeds a Hazard Index MCL or individual MCL in the final rule, these costs are captured in the cost estimates the EPA considered and presented in Appendix N.3 of the EA (USEPA, 2024c) and discussed further in section 13.3 of the EPA response in this *Response to Comments* document.

While the EPA believes individual MCLs for these three PFAS will aid implementation, the EPA disagrees that solely regulating the additional PFAS using only individual MCLs would be better compared to the Hazard Index approach because the Hazard Index approach addresses dose additive health concerns from mixtures of PFHxS, PFNA, HFPO-DA and PFBS that is not addressed by individual MCLs alone. The EPA has assessed benefits associated with Hazard Index PFAS qualitatively in the HRRCA for the PFAS NPDWR. Specifically, as Hazard Index PFAS are reduced, the EPA anticipates additional public benefits from avoided cardiovascular, developmental, and immune effects. For further discussion of the quantitative and qualitative benefits associated with the PFAS NPDWR, see section 6.2 of the EA (USEPA, 2024d) and sections 13.4 through 13.8 of the EPA response in this *Response to Comments* document. For additional discussion on the HRRCA, please see section XII of the FRN, as well as section 14.7 of the EPA response in this *Response to Comments* document. The EPA discusses its rationale on the final NPDWR MCLs included in section V of the FRN, particularly V.B. and V.C. For high level implementation-related concerns, please see section 1.3 of the EPA response in this *Response to Comments* document.

PFAS Regulatory Coalition (Doc. #1761, SBC-046074)

5. Use of a Hazard Index approach complicates risk communication to the public.

Our members frequently have to address risk communication challenges regarding PFAS. The Environmental Council of the States (ECOS) has recognized these challenges for state agencies as well. In ECOS's White Paper "Processes & Considerations for Setting State PFAS Standards," the theme of needing improved risk communications regarding developing PFAS regulations appears throughout. ECOS, Feb. 2020, updated March 2023, at p. 8, 9. 36, 38, and 39, available at: https://www.ecos.org/documents/ecos-paperprocesses-and-considerations-for-setting-state-pfas-standards-2023-update/. To mitigate these challenges, the Coalition has long advocated for national standards, which allow for clearer risk communication than if there is a patchwork of state standards. It is difficult, for example, to explain to the public and other stakeholders why one state has MCLs for two PFAS compounds at certain levels, while another state regulates seven PFAS compounds at different levels. Uniform national standards allow for a more uniform understanding and clearer communication on these important issues. The use of a Hazard Index approach, however, frustrates the opportunity to provide clear communication to the public.

The Proposal demonstrates how unclear the HI approach is to communicate. EPA gives examples of how PFNA, HFPO-DA, PFHxS, and PFBS all can be below their respective HBWC, yet there is still an exceedance of the HI – which means there is an exceedance of the MCL. 88 Fed. Reg. at 18665 - 666. EPA adds to the confusion in its discussion of why only 4 compounds are included in the HI, and why it is not including PFOA and PFOS. The explanation that EPA gives as to why PFOA and PFOS are not part of the HI is that "the Agency believes doing so would not add meaningful health protection over setting an individual MCL." 88 Fed. Reg. at 18670. That statement is entirely inconsistent with the Agency's explanation of why it needs to use the HI approach. Further, this explanation is confusing and leaves the impression either an individual MCL or an HI may have more "meaningful health protection" than the other.

As recognized by ECOS and as experienced by our members, risk communication is vital with developing PFAS regulations. A national standard for drinking water should make risk communication easier, yet the HI approach makes it more difficult and confusing. This is yet another reason not to adopt an HI approach in drinking water standards.

EPA Response: After a review of public comment, the agency is promulgating individual MCLs for PFHxS, PFNA, and HFPO-DA in addition to the Hazard Index MCL for mixtures containing two or more of these PFAS and PFBS. Please see the section 5.3.1 of the EPA response in this *Response to Comments* document for additional discussion on these individual MCLs, including risk communication and feasibility concerns. Please see section 1.2 of the EPA response in this *Response to Comments* document for additional discussion on PFAS risk communications. The EPA disagrees that the Hazard Index approach should not be adopted in drinking water standards as adopting a Hazard Index approach will protect against dose additivity from mixtures of these four PFAS. The EPA's final rule represents data-driven

drinking water standards that are based on the best available, peer-reviewed science, meet the requirements of SDWA, and that regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation. For discussion on feasibility considerations for the Hazard Index PFAS, please see section 5.2.1 of the EPA response in this *Response to Comments* document. For discussion on the decision to use the general Hazard Index approach, please see section 4.3.1 of the EPA response in this *Response to Comments* document, as well as the rationale described in the Hazard Index MCLG and the Mixtures Framework support documents. Information on the Hazard Index mixtures MCL is included in section V.B of the FRN, as well as section 5.2 of the EPA response in this *Response to Comments* document The EPA further provides rationale for not including the PFOA and PFOS in the Hazard Index in section V.B.2 of the FRN and sections 4.3 and 5.2.1 of the EPA response in this *Response to Comments* document.

Bowling Green Municipal Utilities (Doc. #1767, SBC-043930)

Hazard Index is an Inappropriate MCL: EPA's proposed use of a "hazard index" is not only difficult to communicate to the public, but also a misapplication of the concept scientifically. Moreover, EPA's benefit-cost analysis recognizes that the hazard index does not accrue any actual benefit.

EPA Response: After a review of public comment, the agency is promulgating individual MCLs for PFHxS, PFNA, and HFPO-DA in addition to the Hazard Index MCL for mixtures containing two or more of these PFAS and PFBS. Please see the section 5.3.1 of the EPA response in this *Response to Comments* document for additional discussion on these individual MCLs, including risk communication and feasibility concerns. Please see section 1.2 of the EPA response in this *Response to Comments* document for additional discussion on PFAS risk communications. The commenter provides no explanation to support its statement that "this is a misapplication of the [hazard index] concept scientifically." Based on the agency's technical expertise, it was determined that the hazard index is the most cost-effective and least burdensome alternative for purposes of UMRA because this approach for mixtures achieves the objectives of the rule. For additional discussion about the hazard index, please see sections 4.3 and 5.2.1 of the EPA response in this *Response to Comments* document.

The EPA disagrees with the commenter regarding Hazard Index benefits. Contrary to the commenter's assertion, the EPA identified significant benefits associated with the Hazard Index and has assessed these benefits qualitatively in the EA for the PFAS NPDWR. Specifically, as PFHxS, PFNA, HFPO-DA and PFBS are reduced, the EPA anticipates additional public benefits from avoided cardiovascular, developmental, and immune effects. For further discussion of the quantitative and qualitative benefits associated with reduction of PFHxS, PFNA, HFPO-DA and PFBS that will result from the PFAS NPDWR, see section 6.2 of the EA (USEPA, 2024d) and

section 13 of the EPA response in this *Response to Comments* document. For additional discussion on the HRRCA, please see section XII of the FRN.

Corix Infrastructure Inc. (Doc. #1834, SBC-045369)

[With regards to the specific items EPA has requested comment on, Corix provides below:]

• With regards to whether the HI can be clearly implemented, Corix has concerns that the approach will be confusing for customers and other members of the public to understand and appreciate the complexities in the calculations. We request a standard approach to communicating and documenting compliance data.

EPA Response: After a review of public comment, the agency is promulgating individual MCLs for PFHxS, PFNA, and HFPO-DA in addition to the Hazard Index MCL for mixtures containing two or more of these PFAS and PFBS. Please see the section 5.3.1 of the EPA response in this *Response to Comments* document for additional discussion on these individual MCLs, including risk communication and feasibility concerns. Please see the section 1.2 of the EPA response in this *Response to Comments* document for additional discussion on PFAS risk communications.

The City of Columbus, Department of Public Utilities (Doc. #1703, SBC-045061)

Additionally, EPA's use of a hazard index adds another layer of confusion. If EPA includes a hazard index in the final version of the regulation, water utilities will be relying on EPA to develop a communication strategy to protect consumer confidence. Feasible standards with reasonable timelines will safeguard consumer confidence and protect our most vulnerable residents from additional burden.

EPA Response: After a review of public comment, the agency is promulgating individual MCLs for PFHxS, PFNA, and HFPO-DA in addition to the Hazard Index MCL for mixtures containing two or more of these PFAS and PFBS. Please see the section 5.3.1 of the EPA response in this *Response to Comments* document for additional discussion on these individual MCLs, including risk communication and feasibility concerns. Please see section 1.2 of the EPA response in this *Response to Comments* document for additional discussion on PFAS risk communications.

Lehigh County Authority (LCA) (Doc. #1600, SBC-042807)

PFHxS, HFPO_DA, PFNA, and PFBS

The proposed regulation includes a Hazard Index approach to address several PFAS compounds through a single measure: PFHxS, HFPO_DA, PFNA, and PFBS. To date, this approach has not been used in other drinking water regulations. The treatment of these compounds in the proposed regulation is problematic for several reasons:

1. Customer Communication – Water quality is a complex topic to begin with, and measures such as "parts per trillion" are sometimes difficult for customers to understand. However, units of measure can be explained with examples and other common-language descriptions. The complexity of the Hazard Index calculation does not lend itself to a simple explanation that customers will be able to understand.

EPA Response: After a review of public comment, the agency is promulgating individual MCLs for PFHxS, PFNA, and HFPO-DA in addition to the Hazard Index MCL for mixtures containing two or more of these PFAS and PFBS. Please see the section 5.3.1 of the EPA response in this *Response to Comments* document for additional discussion on these individual MCLs, including risk communication and feasibility concerns. Please see section 1.2 of the EPA response in this *Response to Comments* document for additional discussion on PFAS risk communications. For additional discussion on the use of the Hazard Index in other programs, please see section 4 of the EPA response in this *Response to Comments* document. The general Hazard Index is a well-established methodology that has been used for several decades in at least one other regulatory context to account for dose additivity in mixtures assessments. The EPA routinely uses the Hazard Index approach to consider the risks from multiple contaminants of concern in the Remedial Investigations and Feasibility Studies for cleanup sites on the Superfund National Priorities List under CERCLA. Noncarcinogenic effects are summed to provide a Hazard Index that is compared to an acceptable index, generally 1. This approach assumes dose additivity in the absence of information on a specific mixture. These assessments of hazards from multiple chemical exposures are important factors to help inform the selection of remedies that are ultimately captured in the Superfund Records of Decision.

City of Allentown and Lehigh County Authority (LCA), Pennsylvania (Doc. #1667, SBC-043671)

Water quality is a complex topic to begin with, and measures such as "parts per trillion" are difficult to understand; the complexity and change of the typical analysis into the Hazard Index calculation does not lend itself to a simple explanation.

EPA Response: After a review of public comment, the agency is promulgating individual MCLs for PFHxS, PFNA, and HFPO-DA in addition to the Hazard Index MCL for mixtures containing two or more of these PFAS and PFBS. Please see the section 5.3.1 of the EPA response in this *Response to Comments* document for additional discussion on these individual MCLs, including risk communication and feasibility concerns. Please see section 1.2 of the EPA response in this *Response to Comments* document for additional discussion on PFAS risk communications.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044082)

Hazard Index

From a communication perspective, ASDWA recommends that EPA retain the Hazard Index instead of establishing four additional MCLs.

EPA asked for comment on the decision to use solely a Hazard Index for the four PFAS mixture rather than a combination of a Hazard Index and MCLs. While ASDWA's members could not reach a consensus on the overall use of the Hazard Index, regarding the implications for public communication, ASDWA recommends that EPA only use the Hazard Index and not implement individual MCLs for the PFAS mixture compounds. ASDWA's members agree with EPA's reasoning that including a Hazard Index and four additional MCLs would create confusion without any obvious benefit.

EPA Response: After a review of public comment, the agency is promulgating individual MCLs for PFHxS, PFNA, and HFPO-DA in addition to the Hazard Index MCL for mixtures containing two or more of these PFAS and PFBS. Please see the section 5.3.1 of the EPA response in this *Response to Comments* document for additional discussion on these individual MCLs, including risk communication and feasibility concerns.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044072)

General Comments

ASDWA supports EPA's efforts to collectively address PFAS in a regulatory framework other than multiple individual maximum contaminant levels (MCLs).

Building upon previous comments, ASDWA generally agrees with EPA's decision to develop an NPDWR that addresses PFAS in groups rather than individual substances. Attempting to establish individual MCLs in the future for every PFAS that is shown to have detrimental health impacts would be time-consuming, cumbersome, and unrealistic for the long-term management of this class of chemicals. However, ASDWA's members could not reach a consensus on using EPA's proposed Hazard Index (HI) as the optimal regulatory framework.

EPA Response: After a review of public comment, the agency is promulgating individual MCLs for PFHxS, PFNA, and HFPO-DA in addition to the Hazard Index MCL for mixtures containing two or more of these PFAS and PFBS. Please see the section 5.3.1 of the EPA response in this *Response to Comments* document for additional discussion on these individual MCLs, including risk communication and feasibility concerns.

Texas Commission on Environmental Quality (TCEQ) (Doc. #1632, SBC-044124)

Risk Communication

The implementation of the proposed HI approach adds confusion about how to interpret an exceedance of the HI-based MCL. As noted in the proposed rule, different water systems will likely have different concentrations of each of the four PFAS, depending on what potential contaminant sources are nearby, and not all PFAS may exceed their individual health-based

water concentrations (HBWC). EPA does give examples of situations in which the HI of 1.0 is exceeded due to detection and measurement of one of the four PFAS, specifically PFHxS, in the HI equation. [FN8:88 Fed. Reg. 18638, 18666 (Mar, 29, 2023)] However, as noted above, the target organ of concern for PFHxS (i.e., thyroid follicular epithelial hypertrophy/hyperplasia in parental male rats) is different than the target organs of effect for the other three PFAS. While the HI value would indicate an exceedance of the MCL and MCLG for PFHxS, because there is a single MCL for all four PFAS, it also implies an exceedance for PFNA, GenX, and PFBS with their associated potential health effects.

Other examples are given in which none of the HWBCs are, [FN9: Id. At 18665.] yet the HI is larger than 1.0. If the HI is larger than 1.0 due to lack of exceedance of the HBWC for each PFAS, each with a different critical effect, then it is difficult to determine what potential risk should be communicated to the public. The default communication would be to state that there is a risk for each of the critical effects, even though none of the PFAS exceeded its individual HBWC and a common MOA has not been demonstrated, which would be misleading and create inappropriate concern. It is also not clear how to communicate the potential dose additive risk in the absence of a common MOA. Risk communication is a crucial part of implementing a drinking water standard and if EPA chooses to move forward with this scientifically unjustified HI approach, then it should also provide guidance on how to appropriately communicate risk from exceedances of the MCL to the public.

Due to the different critical effects, different target organs of toxicity, likely different MOAs for the critical effects of each of the four different PFAS in the HI approach, and the difficulty in communicating risk associated with an HI-based MCL, individual MCLs for PFBS, PFHxS, GenX chemicals, and PFNA would be more appropriate. Having a separate MCL for each contaminant would ensure that the regulated community understands the compliance calculations for these chemicals, would allow for precise public notice to customers with specific health-effects information, and allow the proposed rule to fit within established compliance processes and state data systems.

EPA Response: After a review of public comment, the agency is promulgating individual MCLs for PFHxS, PFNA, and HFPO-DA in addition to the Hazard Index MCL for mixtures containing two or more of these PFAS and PFBS. Please see the section 5.3.1 of the EPA response in this *Response to Comments* document for additional discussion on these individual MCLs, including risk communication and feasibility concerns. The agency agrees that risk communication is an important focus for water systems and primacy agencies, and the EPA believes that finalizing individual MCLGs and MCLs in addition to the Hazard Index framework may help support risk communication. With respect to the scenario of public notice of violations of individual MCLs and the Hazard Index MCL, the EPA agrees with the commenter and finds that issuing multiple for these violations may cause confusion as the adverse health effects and exposure concerns in this instance is not meaningfully different from either a Hazard Index or individual MCL perspective. To simplify implementation of PN in this scenario, the EPA is finalizing requirements in Appendix A to Subpart Q of Part 141 such that utilities who violate

the Hazard Index MCL and one or more individual MCLs because of the same compounds can issue one notification to satisfy the PN requirements for the multiple violations.

New York City Department of Environmental Protection (NYCDEP) (Doc. #1679, SBC-044205)

One concern about usage of the HI is that the constituent concentrations are essentially masked from direct reporting when compared to typical water industry MCLs for single analytes. As a new regulatory tool, the calculation of the HI will have to be explained to the public, as it may appear as though the water supplier is attempting to avoid reporting the HI constituent concentrations directly.

EPA Response: Please see the EPA response to comment Doc. #1632, SBC-044124 in section 5.3.1 in this *Response to Comments* document.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044031)

13. EPA requests comment on its proposed decision to establish stand-alone MCLs for PFOA and PFOS in lieu of including them in the HI approach.

a. It is appropriate to establish MCLs for PFOA and PFOS, with a recommended MCL of

8.0 ppt, and a trigger level at ½ the MCL of 4.0 ppt (at the established PQL). There could be a lot of pushback from communities if EPA does not establish MCLs for PFOA/PFOS. An option could be to continue with an additive MCL approach. CWUC also prefers establishing MCLs for the four other compounds.

EPA Response: After a review of public comment, the agency is promulgating individual MCLs for PFHxS, PFNA, and HFPO-DA in addition to the Hazard Index MCL for mixtures containing two or more of these PFAS and PFBS. Please see the section 5.3.1 of the EPA response in this *Response to Comments* document for additional discussion on these individual MCLs, including risk communication and feasibility concerns. For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations), 5.1.3 (cost considerations and alternative MCLs) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document.

Massachusetts Water Resources Authority (Doc. #1645, SBC-043285)

c. Hazard Index is Misplaced as a MCL

Maintaining public confidence in PWSs throughout the implementation of new regulations should be paramount. The unintended consequence of a lack of public confidence drives the public to less sustainable and less regulated sources of water, including bottled water. EPA's proposed use of a hazard index is extremely difficult to communicate to the public and is based on limited toxicology and occurrence data. MWRA recommends that EPA remove the hazard index MCL from this proposed rulemaking due to limited toxicological and occurrence data on

the four PFAS. More generally, MWRA asks EPA to reconsider the use of complicated and difficult to explain MCLs, such as a hazard index.

EPA Response: After a review of public comment, the agency is promulgating individual MCLs for PFHxS, PFNA, and HFPO-DA in addition to the Hazard Index MCL for mixtures containing two or more of these PFAS and PFBS. Please see the section 5.3.1 of the EPA response in this *Response to Comments* document for additional discussion on these individual MCLs, including risk communication and feasibility concerns. For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations), 5.1.3 (cost considerations and alternative MCLs) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044176)

2. From a communication perspective, NCDEQ recommends EPA retain the use of the hazard index in lieu of establishing four additional MCLs.

EPA asked for comment on the decision to solely use a Hazard Index for the four PFAS mixture rather than a combination of both a Hazard Index and MCLs. NCDEQ recommends that EPA retain only the Hazard Index approach and not implement individual MCLs for the PFAS mixture compounds. NCDEQ agrees with EPA's reasoning that including both a Hazard Index and four additional MCLs would create confusion without any obvious benefit.

EPA Response: After a review of public comment, the agency is promulgating individual MCLs for PFHxS, PFNA, and HFPO-DA in addition to the Hazard Index MCL for mixtures containing two or more of these PFAS and PFBS. Please see the section 5.3.1 of the EPA response in this *Response to Comments* document for additional discussion on these individual MCLs, including risk communication and feasibility concerns. For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations), 5.1.3 (cost considerations and alternative MCLs) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document.

Aurora Water, City of Aurora, Colorado (Doc. #1669, SBC-043707)

Comment Topics:

MCLs and Use of Hazard Index (HI)

Section VI

As proposed, the MCLs for PFOA and PFOS are 4 ppt with an MCLG of "non detect". Aurora Water urges EPA to consider an MCL of 10 ppt for PFOA and PFOS. With the current technologies for analyzing and treating drinking water, maintaining PFOA and PFOS levels below 4 ppt is not feasible. The prevalence of PFAS chemicals in the environment and the current available technology for treatment of PFAS in drinking water to non-detect levels would

be an astronomical effort. The cost of treatment to below 4 ppt would cost Aurora Water 190% more than what it would cost to treat to 10 ppt. Aurora believes that an MCL of 10 ppt would be adequately protective of public health based on the provided health studies. If EPA decides to use an MCL of 10 ppt now, it can be reviewed in subsequent rulemakings and lowered once treatment technologies are more advanced. Therefore, Aurora Water recommends the proposed 4 ppt MCL for PFOA and PFOS be increased to 10 ppt for each compound.

The hazard index (HI) is proposed as a calculation for a mixture of PFNA, PFHxS, PFBS, and GenX with an MCL of 1.0. Aurora Water is concerned about the use of an HI approach because it combines substances with different health impacts into a single index. EPA has previously noted, in their guidance "Identifying Pesticide Chemicals and Other Substances that Have Common Mechanisms of Toxicity," it would not use cumulative risk assessments for substances with largely different toxic effects or mechanisms of toxicity. We believe this statement applies to PFAS chemical compounds and EPA should apply the same reasoning to the PFAS mixture HI. Additionally, explaining an HI, which has three different critical health effects, to the public poses a scientific and communications challenge. Previously developed EPA guidance on cumulative risk for mixtures of chemicals does not support the idea of dose additivity for multiple compounds across different types of health effects. As a water utility, communicating a HI with multiple health effects to the public will be extremely difficult. Separating the hazard index chemicals and replacing with individual MCLs would simplify communication with the public. Therefore, Aurora Water argues for individual MCLs for each compound instead of a hazard index.

EPA Response: The EPA notes that the MCLG for PFOA and PFOS are not nondetect; rather, they are set at 0 (zero). Please see section 5.1.3 of the EPA response in this *Response to Comments* document for discussion around consideration of other PFOA and PFOS MCLs. After considering public comments, the agency is promulgating individual MCLs for PFHxS, PFNA, and HFPO-DA in addition to the Hazard Index MCL for mixtures containing two or more of these PFAS and PFBS. Please see the section 5.3.1 of the EPA response in this *Response to Comments* document for additional discussion on these individual MCLs, including risk communication and feasibility concerns. For additional discussion on cost considerations when setting the MCL and alternative regulatory standards, please see section 5.1.3 of the EPA response in this *Response to Comments* document. Regarding the comment on cumulative risk assessments for pesticides, the cited guidance was specifically developed to support pesticide risk assessments under the Food Quality Protection Act (FQPA) of 1996. The FQPA stipulates, among other things, that when determining the safety of a pesticide chemical EPA shall base its assessment of the risk posed by the pesticide chemical on: aggregate (i.e., total dietary, residential, and other non-occupational) exposure to the pesticide and available information concerning the cumulative effects to human health that may result from dietary, residential, or other non-occupational exposure to other substances that have a *common mechanism of toxicity* (italics added for emphasis). A mixture is a "contaminant" for purposes of SDWA; please see the EPA response to comment Doc. #1727, SBC-053343 in section 5.2.1 in this *Response to Comments* document for additional discussion. The EPA's approach to develop the Hazard Index

MCLG is supported by the best available peer reviewed science, the EPA chemical mixtures guidance, expert review by the SAB, and is consistent with the SDWA statutory language for MCLG (see section 4.3.2 of the EPA response in this *Response to Comments* document). With respect to responses on the general Hazard Index approach for PFAS that elicit similar effects following exposure and dose additivity, please see section 4.3.2 of the EPA response in this *Response to Comments* document.

National Rural Water Association (NRWA) (Doc. #1641, SBC-043272)

• EPA requests comment on whether establishing a traditional MCLG and MCL for PFHxS, HFPO–DA, PFNA, and PFBS instead of, or in addition to, the HI approach would change public health protection, improve clarity of the rule, or change costs.

Response: From a simplicity standpoint, introducing the HI will be problematic. Customers may understand MCL and MCLG's better due to its long-standing history. It is unclear at this point, due to the lack of data (sampling in systems under 10,000), whether the HI approach will change public health protection, improve clarity of the rule, or change costs. However, costs are certain to be excessive in small systems regardless of the approach.

EPA Response: After a review of public comment, the agency is promulgating individual MCLs for PFHxS, PFNA, and HFPO-DA in addition to the Hazard Index MCL for mixtures containing two or more of these PFAS and PFBS. Please see the section 5.3.1 of the EPA response in this *Response to Comments* document for additional discussion on these individual MCLs, including risk communication and feasibility concerns. For additional discussion on cost considerations when setting the MCL and alternative regulatory standards, please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Philadelphia Water Department (PWD) (Doc. #1709, SBC-045747)

11. EPA should consider a single approach to regulating PFAS, either through individual MCLs or considering the effects of PFAS mixtures.

PWD recognizes the unique regulatory challenges posed by a family of greater than 9,000 different chemical compounds. It has long been a subject of debate in the scientific community as to whether PFAS should be regulated as a class, like disinfection by-products, or as individual species, each with their own MCL. These contaminants together can pose a greater health risk than they do individually and PWD appreciates the EPA's proposal to capture site-specific risks from PFAS mixtures. However, promulgating regulations that include both an approach to regulate individual contaminants as well as mixtures may create confusion across the water industry, primacy agencies, and the general public.

PWD understands that EPA classifies PFOA and PFOS as carcinogens and employs a different policy established by the Safe Drinking Water Act to regulate those chemicals as close as feasible to an MCLG of 0 ppt. Given their carcinogenicity classification and how the HI is

calculated, those PFAS cannot be included in the proposed HI calculation. Because the nuances of EPA's methodology can be difficult to explain to customers, PWD is requesting that EPA provide clearer messaging to help our customers understand the different regulatory approaches and stay informed of the potential health effects from exposure to these contaminants. PWD recommends that the HI concept be removed from this NPDWR to reduce the complexity of the rulemaking.

EPA Response: After a review of public comment, the agency is promulgating individual MCLs for PFHxS, PFNA, and HFPO-DA in addition to the Hazard Index MCL for mixtures containing two or more of these PFAS and PFBS. Please see the section 5.3.1 of the EPA response in this *Response to Comments* document for additional discussion on these individual MCLs, including risk communication and feasibility concerns.

Wyoming Department of Environmental Quality (WDEQ) (Doc. #1716, SBC-044776)

WDEQ recommends that EPA consider issuing individual MCLs and MCLGs for GenX and PFNA until additional data and information is available to support the HI approach as currently proposed.

EPA Response: After considering public comments, the agency is promulgating individual MCLs for PFHxS, PFNA, and HFPO-DA in addition to the Hazard Index MCL for mixtures containing two or more of these PFAS and PFBS. Please see the section 5.3.1 of the EPA response in this *Response to Comments* document for additional discussion on these individual MCLs, including risk communication and feasibility concerns. For additional discussion on the EPA's feasibility analysis, please see sections 5.1.2 (for laboratory considerations), 5.1.3 (cost considerations and alternative MCLs), 5.1.4 (for treatment considerations) and 5.2.1 (for feasibility considerations for the Hazard Index PFAS) of the EPA response in this *Response to Comments* document.

PFAS Regulatory Coalition (Doc. #1761, SBC-046073)

4. If the four additional PFAS are to be regulated at all, it should be done by setting individual MCLs.

Given the concerns, questions and uncertainties regarding the Hazard Index that are set forth above, the Coalition suggests that if EPA is going to regulate the four compounds covered in the Hazard Index, it should instead develop individual MCLs for these compounds. The Coalition is not expressing an opinion as to whether the information that EPA has is sufficient to use in developing drinking water standards, but we would review and comment on that information if and when EPA issues such a rulemaking, following the process set forth in the Safe Drinking Water Act.

EPA Response: Please see section 5.3.1 of the EPA response in this *Response to Comments* document and response to comment Doc. #1716, SBC-044776 in section 5.3.1 in this

Response to Comments document for discussion of setting individual MCLs for PFHxS, PFNA, and HFPO-DA.

Fairfax Water (Doc. #1789, SBC-045315)

5. EPA should issue initial MCLs for PFOA of 10 ppt and PFOS of 10 ppt. EPA should not utilize the Hazard Index approach for PFNA, PFHxS, PFBS, and HFPO-DA.

EPA Response: Please see section 5.1.3 of the EPA response in this *Response to Comments* document for discussion of alternative MCLs for PFOA and PFOS. Please see section 5.3.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1716, SBC-044776 in section 5.3.1 in this *Response to Comments* document for discussion of setting individual MCLs for PFHxS, PFNA, and HFPO-DA.

Midwest Environmental Advocates +more (Doc. #1846, SBC-045832)

B. EPA's proposed MCL for PFBS, PFNA, PFHxS, and GenX expressed as a Hazard Index provides the required margin of safety but should include traditional individual levels to improve the clarity of the rule.

Commenters support the proposed Hazard Index (HI) approach as a feasible and protective level against dose additive impacts from PFBS, PFNA, PFHxS, and GenX. EPA's assumption "that a mixture of chemicals with similar apical effects should be assumed to also act in a dose additive manner unless data demonstrates otherwise" [FN27: 88 Fed. Reg. 18,664.] is consistent with the Agency's requirement to set (1) MCLGs allowing an adequate margin of safety and (2) MCLs as close as feasible to the health-based goals. [FN28: 42 U.S.C. §300g-1(b)(4).] Thus, we support this approach as a well-grounded action under the SDWA and necessary to protect communities exposed to multiple PFAS via drinking water.

Given the likelihood of co-occurrence of these substances, the well-grounded dose additivity assumption, and the feasibility of compliance, the HI MCL approach allows EPA to provide the required adequate margin of safety under the standard-development process of the SDWA. Thus, the Agency should not deviate from the proposed approach. However, to improve the clarity of the rule, EPA should consider establishing a traditional MCLG and MCL for each of these PFAS.

Establishing individual MCLs would not add any additional layer of public health protection because it functions the same as the HI MCL. As EPA rightfully noted, "a system cannot have MCL violations of an individually regulated PFAS without also exceeding the HI MCL." [FN29: 88 Fed. Reg. 18,671.] However, individual MCLs are clearer indicators to determine exceedances when only one of the PFAS is present in a drinking water system. Thus, we support the regulatory alternative considered by EPA where PFBS, PFNA, PFHxS, and GenX would expressly be subject to individual MCLs and the HI MCL for the mixture.

EPA Response: Please see section 5.3.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1716, SBC-044776 in section 5.3.1 in this *Response to Comments* document for discussion of setting individual MCLs for PFHxS, PFNA, and HFPO-DA.

Midwest Environmental Advocates +more (Doc. #1846, SBC-045830)

For the reasons detailed below, Commenters support EPA's proposed NPDWRs as health-protective, feasible, and cost-justified standards. For clarity, however, we urge the Agency to establish traditional levels for PFBS, PFNA, PFHxS, and GenX in addition to the proposed Hazard Index (HI) MCL.

EPA Response: Please see section 5.3.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1716, SBC-044776 in section 5.3.1 in this *Response to Comments* document for discussion of setting individual MCLs for PFHxS, PFNA, and HFPO-DA.

Anonymous (Doc. #2799, SBC-047435)

This is a public comment on the proposed PFAS National Primary Drinking Water Regulation. The Docket ID is EPA-HQ-OW-2022-0114.

This regulation has been carefully developed and its justification is especially detailed and thorough. The overriding goal of protecting public health, saving lives and preventing costly and destructive illness is paramount.

Rather than review this regulation's extensive documentation and methods, I will offer some brief critical comments intended to make this regulation more effective. I write from the perspective of a social scientist living in the rapidly urbanizing desert Southwest, with over thirty years of experience researching and teaching environmental issues.

The environmental justice component of this regulation is a critical benefit which can only be realized if adequate public communication and resources are provided.

I am deeply concerned that the proposed unitless "Hazard Index" is confusing to the public. The use of "parts per trillion" is much clearer and more understandable to all parties. It also highlights the important fact that even small amounts of these contaminants can cause great harm.

Therefore, I recommend that all six PFAS contaminants each be given a specific Maximum Contaminant Level, expressed in parts per trillion.

Thus, the MCL for PFOA and PFOS should be 4.0 ppt. The MCL for PFHxS should be 9.0 ppt, and the MCL for PFNA should be 10 ppt. For PFBS the MCL should be 2000 ppt, and for HFPO-DA the MCL should be 10 ppt.

Again, this change would make these legally enforceable standards more understandable to the public, and therefore easier to enforce.

EPA Response: Please see section 5.3.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1716, SBC-044776 in section 5.3.1 in this *Response to Comments* document for discussion of setting individual MCLs for PFHxS, PFNA, and HFPO-DA.

Suffolk County Water Authority (SCWA) (Doc. #1589, SBC-043367)

Another possibility would be to set contaminant specific MCLGs for these four PFAS at a lower level due to the likely co-occurrence of the other PFAS, e.g., one quarter of the HBWC for each four subject PFAS. The MCLs for each could then be set as close as feasible to the respective MCLGs. In any event, the SCWA, like other responsible public water suppliers, typically plans to install treatment systems once half the MCL level has been detected for a particular contaminant when the MCLG for the contaminant is greater than zero. Here, it would be one half of the MCLG because the EPA is proposing to set the MCL at the MCLG. This is done for operational reasons so that the possibility of an MCL violation during periods of high demand can be greatly limited or eliminated altogether. It is SCWA's goal to treat all locations that have detections of PFAS to levels below the MCLG and to non-detectable levels when the MCLG is zero.

EPA Response: The agency notes that MCLGs are public health goals and are not enforceable standards. After a review of public comment, the agency is promulgating individual MCLs (i.e., the enforceable standards) for PFHxS, PFNA, and HFPO-DA in addition to the Hazard Index MCL for mixtures containing two or more of these PFAS and PFBS. Please see the section 5.3.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1716, SBC-044776 in section 5.3.1 in this *Response to Comments* document for discussion of setting individual MCLs for PFHxS, PFNA, and HFPO-DA. Section 5.3.1 also includes discussion about risk communication and feasibility concerns. With respect to implementation of the PFOA and PFOS MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

LSP Association (LSPA) (Doc. #1742, SBC-043597)

Slide 5: EPA is requesting comment on preliminary determinations to regulate PFHxS, PFNA, PFBS, HFPO-DA (commonly referred to as GenX Chemicals), and mixtures of these four PFAS.

● It is unclear to the LSPA why PFBS, a short chain, "second generation" PFAS that is commonplace in groundwater and exhibits much lower toxicity relative to the other three PFAS compounds, was included in this grouped Hazard Index Approach. We do not think there is

technical justification for including PFBS in the Hazard Index Approach; the LSPA urges USEPA to consider setting an individual MCL for PFBS.

EPA Response: Please see section 5.3.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1716, SBC-044776 in section 5.3.1 in this *Response to Comments* document for discussion of setting individual MCLs for PFHxS, PFNA, and HFPO-DA. The agency is deferring its individual regulatory determination for PFBS at this time. The HBWC for PFBS is different than PFHxS, PFNA, and HFPO-DA. However, PFBS (as well as PFHxS, HFPO-DA and PFNA) have dose additive health concerns and are known to co-occur as mixtures in drinking water. The EPA, therefore, is moving forward with regulating mixtures of two or more of PFHxS, HFPO-DA, PFNA and PFBS through a Hazard Index MCL. Please see section 3 for additional discussion on the EPA's regulatory determinations.

Section 5 References

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6 Occurrence

6.1 UCMR 3

Summary of Major Public Comments and EPA Responses

Some commenters supported the EPA's use of the best available public health information including data from the third Unregulated Contaminant Monitoring Rule (UCMR 3) and state occurrence data. A few commenters criticized the use of UCMR 3 data, stating that the data suffer from limitations. These commenters expressed concern over the high minimum reporting levels (MRLs), the exclusion of many small systems, and the lack of national monitoring of HFPO-DA. Some of these commenters assert that UCMR 3 does not represent best available occurrence data for this rule. The EPA disagrees with these commenters. While UCMR 3 does have higher reporting limits than those available through current analytical methods, the data still constitute the best available nationwide occurrence dataset to inform the occurrence and co-occurrence profile for the regulated PFAS for which monitoring was conducted. These data are also a critical component of the EPA's model to estimate national level occurrence for certain PFAS and ensure it is nationally representative as described in section VI.E. in the final rule preamble. The EPA also disagrees that the UCMR 3 excludes small water systems as it included a statistically selected, nationally representative sample of 800 small drinking water systems. Regarding commenter concerns for lack of UCMR monitoring data on HFPO-DA, the agency notes that the EPA also examined recent data collected by states who have made their data publicly available. These data included tens of thousands of samples from over ten thousand systems for each of the six PFAS chemicals included in the final rule, including approximately 36,000 HFPO-DA samples, and used lower reporting limits than the data from the UCMR 3. These additional state data came from 32 geographically diverse states. The EPA disagrees that this dataset is insufficient. A discussion of these data and public comments on this information is presented in section III.C and in section VI.B of the preamble. Please see sections 6.2 and 6.4 of the EPA response in this *Response to Comments* document for further discussion of the additional state data and section 6.5 of the EPA response in this *Response to Comments* document for how the state data were used to support the national occurrence model.

Individual Public Comments

<u>San Antonio Water System (SAWS) (Doc. #1570, SBC-042471)</u>

Preliminary examination of PFAS was conducted via UCMR3. However, the PFAS detections for UCMR3 do not warrant regulation. Only 1.4% of UCMR3 samples were above detection nationwide. The contaminants were placed back on the CCL for UCMR5 at the same time regulation was developed circumventing the established process.

EPA Response: The EPA disagrees that the agency has circumvented the established process for developing National Primary Drinking Water Regulations (NPDWRs). The EPA

implements a monitoring program for unregulated contaminants (i.e., UCMR) under the Safe Drinking Water Act (SDWA) 1445(a)(2) that requires the EPA to issue a list once every five years of priority unregulated contaminants to be monitored by public water systems (PWSs). However, there is no statutory requirement that a contaminant must be on this list or that it cannot be listed more than once prior to making a determination to regulate. The EPA may make a determination to regulate if the agency has sufficiently available information through other sources. Please see section 6.1 of the EPA response in this *Response to Comments* document, the UCMR 3 dataset is one of the many sources of occurrence data the agency considered for this regulation. The agency also considered occurrence data from 32 states, which provided the EPA tens of thousands of additional PFAS monitoring results to inform the agency's decision. See discussion in section VI.B of the FRN for this action for further discussion. Please see section 6.8 of the EPA response in this *Response to Comments* document regarding UCMR 5. Completion of the UCMR 5 data collection effort is not required prior to making a regulatory determination nor promulgation of the final rule. The UCMR 3 dataset, along with additional state data and robust analyses, demonstrate sufficient likelihood of occurrence of the PFAS being regulated to justify the EPA's determination. Please see section 3.1.2 of the EPA response in this *Response to Comments* document regarding the EPA's regulatory determination and evaluation of the occurrence criterion.

Santa Clarita Valley Water Agency (SCVWA) (Doc. #1578, SBC-042431)

Additional Perspective:

SCV Water's monitoring program for PFAS Chemicals has demonstrated the ubiquitous nature of these chemicals in the environment and we believe that relying on UCMR 3 data collected in 2013 and 2015 supplemented with other sources grossly underestimates the impact of PFAS Chemicals nationwide.

EPA Response: Please see section 6.1 of the EPA response in this *Response to Comments* document and section VI of the FRN for this action, where PFAS occurrence is discussed in detail. Also please see section 6.5 of the EPA response in this *Response to Comments* document regarding the model used by the EPA to generate national estimates of PFAS occurrence. The EPA believes it has generated robust estimates of PFAS occurrence that represent the best available science.

Greater North Dakota Chamber et al. (Doc. #1593, SBC-042801)

Lack of occurrence data at the proposed MCL level. The current UCMR 3 occurrence data for PFOA and PFOS seems to indicate levels at between 20 ppt and 40 ppt. EPA does not have a robust understanding of occurrence levels at the proposed MCL levels for PFOA and PFOS or the other four PFAS. This lack of occurrence data for a preliminary regulatory determination requires more thoughtful and thorough analysis.

EPA Response: Please see section 6.1 of the EPA response in this *Response to Comments* document and section VI of the FRN for this action, where PFAS occurrence is discussed in detail. As discussed in section 6.1 of the EPA response in this *Response to Comments* document, the UCMR 3 dataset is one of the many sources of occurrence data the agency considered for this regulation. The EPA also considered occurrence data from 32 states, which provided the agency tens of thousands of additional PFAS monitoring results to inform the EPA's decision. Also please see section 6.5 of the EPA response in this *Response to Comments* document and section VI.E of the preamble regarding how UCMR 3 data and state data were used to inform the national extrapolation of PFAS occurrence. The EPA believes it has generated robust estimates of PFAS occurrence that represent the best available science. The agency has previously made a final determination that there is sufficient information to regulate PFOA and PFOS, and as demonstrated through the best available information in section III of the final rule preamble, has determined that PFHxS, PFNA, HFPO-DA, and mixtures of those PFAS with PFBS meet the statutory criteria for regulation. Please see section 3.1.2 of the EPA response in this *Response to Comments* document regarding the EPA's regulatory determination and evaluation of the occurrence criterion.

Alameda County Water District (ACWD) (Doc. #1595, SBC-042346)

1. Economic Impact Analysis – EPA's cost assessment does not capture the full costs that will be borne by water agencies and ratepayers.

a. Occurrence model relies on UCMR 3 data and publicly available state data

The proposed PFAS NPDWR economic impact analysis utilizes an occurrence model which relies on data collected during UCMR 3, as the primary source of nationwide occurrence data, and includes publicly available data from state PFAS monitoring efforts.

UCMR 3 monitoring only included 5 of the 6 PFAS compounds included in the NPDWR since HFPO-DA was not included in UCMR 3 monitoring and is included in the NPDWR. Additionally, the monitoring method 537 used during UCMR 3 also had much higher reporting levels than the levels included in the NPDWR, with Minimum Reporting Levels (MRLs) of 40 ppt (PFOS), 20 ppt (PFOA), 30 ppt (PFHxS), 20 ppt (PFNA), 90 ppt (PFBS). Using the UCMR 3 data to develop the economic analysis may result in unrealistically low-cost estimates.

EPA Response: Please see section 6.5 of the EPA response in this *Response to Comments* document regarding the Bayesian statistical model used to estimate national PFAS occurrence. Please see sections 6.1 and 3.1.2 of the EPA response in this *Response to Comments* document regarding available state data for HFPO-DA. The agency relied on additional occurrence data sources other than UCMR 3 when developing the Economic Analysis (EA). The agency has used the Bayesian statistical model described in Cadwallader et al. (2022) to support the EA for the proposed and final regulation by combining the available occurrence information from UCMR 3 and state datasets in a statistically robust and representative manner, utilizing those data to compute estimates of national occurrence for PFAS contaminants to levels below

UCMR 3 reporting limits, and providing estimates on the number of systems impacted by this final rule. These estimates directly informed the EA in USEPA (2024a). The EPA has generated robust estimates of PFAS occurrence that represent the best available science. For more information see the *Occurrence Technical Support Document* (USEPA, 2024b) as well as section VI of the Federal Register Notice (FRN).

City of Vancouver Water Utility, Vancouver, WA (Doc. #1684, SBC-044302)

PFAS Occurrence, Health Risks and MCL Justification:

The only significant water utility PFAS occurrence data currently available is from UCMR 3 and any additionally required testing by states, which is limited. Unfortunately, in the case of PFOS and PFOA, the reporting levels used during UCMR 3 with method 537 were higher than the proposed MCL. This increases the risk of wide gaps in the understanding and knowledge of occurrence.

The EPA does not have a robust understanding of occurrence levels at the proposed MCL levels for PFOA and PFOS or the other four PFAS. This lack of occurrence data for a preliminary regulatory determination requires more thoughtful and thorough analysis.

EPA Response: Please see section 6.1 of the EPA response in this *Response to Comments* document. The agency disagrees with the commenter. The EPA has generated robust estimates of PFAS occurrence that represent the best available science. While UCMR 3 does have higher reporting limits than those available through current analytical methods, the more recent state drinking water data reflect lower reporting limits than those in UCMR 3 and provide occurrence data at the Maximum Contaminant Levels (MCLs) for all six regulated PFAS. These additional state data included over ten thousand systems from 32 states. Additionally, the agency has used the Bayesian statistical model described in Cadwallader et al. (2022) which combines the available occurrence information from UCMR 3 and state datasets in a statistically robust and representative manner, utilizing those data to compute estimates of national occurrence for PFAS contaminants to levels below UCMR 3 reporting limits, and providing estimates on the number of systems impacted by this final rule.

Austin Water (AW), Austin, TX (Doc. #1688, SBC-044452)

May 30, 2023

U.S. Environmental Protection Agency EPA Docket Center

Docket ID: EPA-HQ-OW-2022-0114

Mail Code 28221T

1200 Pennsylvania Avenue, NW Washington, DC 20460

Submitted via Federal eRulemaking Portal: https://www.regulations.gov

Re: Docket ID No. EPA-HQ-OW-2022-0114, Proposed National Primary Drinking Water Regulation (NPDWR) for Six Per- and Polyfluoroalkyl Substances (PFAS)

Dear U.S. Environmental Protection Agency (EPA),

Austin Water (AW) appreciates the opportunity to comment on the proposed NPDWR for six PFAS as published in the Federal Register on March 29, 2023. These comments note some observations and considerations we offer as a community water system and utility regarding the timing and approach for the proposed PFAS NPDWR.

AW provides water service to a population of over one million with over 250,000 metered connections, and wholesale service to 17 surrounding water systems that serve in total approximately 55,000 people. We strive to maintain excellent water quality for our customers, and our staff work diligently around the clock to provide quality services to our customers. Our top priority is protecting public health and meeting federal and state drinking water standards at all times. We have been closely monitoring information on the emerging research about PFAS and public health. We recognize that the presence of these substances is ubiquitous and has caused significant environmental impacts that must be addressed.

The Safe Drinking Water Act (SDWA) framework includes the implementation of nationwide monitoring through the Unregulated Contaminant Monitoring Rule (UCMR). The SDWA framework is designed to use UCMR data to track and research substance/contaminant occurrences and to use these occurrence data to inform decisions on the Regulatory Determinations that are made in the development of NPDWRs. While the Third UCMR (UCMR3) included six PFAS in the 2013-2015 monitoring timeframe (five of which are included in the proposed NPDWR), it did not include monitoring for hexafluoropropylene oxide dimer acid and its ammonium salt (collectively, GenX chemicals) which is also included in the proposed NPDWR.

EPA Response: Please see sections 6.1 and 3.1.2 of the EPA response in this *Response to Comments* document for the EPA's responses related to UCMR 3 data and regulatory determinations, respectively. As discussed in section 6.1 of the EPA response in this *Response to Comments* document, in addition to UCMR 3 data, the agency also considered occurrence data from 32 states, which provided the EPA tens of thousands of additional PFAS monitoring results to inform the agency's decision. These data included samples of HFPO-DA from multiple states, which the EPA used to inform this regulation. Please see section 3.1.2 of the EPA response in this *Response to Comments* document as well as section III.C of the FRN for more information about how EPA considered occurrence data for HPFO-DA.

<u>Wyoming Department of Environmental Quality (WDEQ) (Doc. #1716, SBC-044749)</u>

3. Assessment of the Representativeness of the PWSs Sampled Under UCMR 3 Is Not Complete

EPA states that 4,920 PWSs were sampled for PFHxS, PFNA, and PFBS under UCMR 3, and specifically that a "statistically representative" population of small water systems serving 10,000

or fewer people was included; however, no explanation of the assumptions made or systems chosen is provided to support the determination that the UCMR 3 dataset is statistically representative of PWSs across the United States. With EPA proposing to issue NPDW regulations for six (6) PFAS prior to the completion of data collection and analysis under UCMR 5, it is critical that data being used to justify the proposed NPDW rule are in fact representative of the populations impacted by PFAS, the estimated number of affected PWSs, and the anticipated increased costs of operating affected PWSs. While EPA's website does not provide a numerical breakdown of how many PWSs are permitted within each category, the Center for Disease Control and Prevention (CDC) website states that there are over 155,000 PWSs in the United States, with 52,110 being Community PWSs and 18,239 being Nontransient non-community (NTNC) PWSs. UCMR 3 only required sampling from all PWSs serving more than 10,000 people and 800 representative PWSs serving 10,000 or fewer people. This suggests that the 4,920 PWSs sampled could represent less than 7% of the total assumed 70,349 combined Community and NTNC PWSs eligible for sampling under UCMR 3. Given the variables involved, it is uncertain whether this represents a statistically significant population size from which to draw conclusions. As the majority of PWSs in Wyoming are small systems serving rural communities with less than 10,000 people, an understanding of the representativeness of the data used to develop the rule is important to better assess the environmental and economic impacts to Wyoming.

Furthermore, an understanding of the distribution of PFAS in various media that may impact drinking water sources is not well developed, and those impacts are not evenly distributed throughout the United States. The WDEQ is concerned that the proposed rule relies primarily on data collected from eastern states; these data may not be representative of the PFAS sources and extent of potential PFAS contamination in rural western states.

WDEQ recommends that EPA provide details on how small PWSs were chosen for representation of all small PWSs across the United States under UCMR 3, whether the population size is statistically significant, and how this dataset accurately represents drinking water concentrations and distributions across the United States such that it provides a sound basis for proposing comprehensive NPDW regulation of PFAS.

EPA Response: A description of how small systems were representatively chosen for UCMR 3 monitoring is available in section 1. General Information of the Final UCMR 3 Rule: "Only a nationally representative sample of ''small'' community and non-transient non-community systems serving 10,000 or fewer people are required to monitor for the chemical analytes (see USEPA, 2001 for a description of the statistical approach for the nationally representative sample)." This statistical approach is outlined in *Statistical Design and Sample Selection for the Unregulated Contaminant Monitoring Regulation (1999)* (USEPA, 2001). The EPA refers the commenter to this resource for more details. Additionally, the EPA disagrees that the available data is not geographically representative of the nation because the agency presents its evaluation of available occurrence data from 32 states including many areas other than the

eastern part of the country, including Washington, California, Oregon, Idaho, North Dakota, and Colorado.

American Chemistry Council (ACC) (Doc. #1841, SBC-044839)

EPA Has Underestimated the Number of Systems That Will be Impacted by the Proposal

EPA's analysis of the systems expected to exceed the proposed MCLs relies on the data from the UCMR 3 national survey supplemented by more recent monitoring data from several states. In considering the state information, the Agency acknowledges that the USMR 3 data suffer from several limitations –

• The minimum reporting limits for PFOA, PFOS, PFHxS, and PFNA were above the proposed MCLs or HBWCs,

• Reported detections of PFNA and PFBS were too infrequent to provide a basis for analysis,

• Only a random sample of 800 systems serving 10,000 people or fewer were included in the survey, and

• HFPO-DA was not measured.

EPA Response: Please see section 6.1 of the EPA response in this *Response to Comments* document. Also please see section 6.5 of the EPA response in this *Response to Comments* document regarding potential underestimates in the number of impacted systems. The EPA disagrees that it has underestimated the number of impacted systems. The EPA also considered occurrence data from 32 states, which provided the EPA tens of thousands of additional PFAS monitoring results to inform the agency's decision. The agency used a Bayesian statistical model described in Cadwallader et al. (2022) for the proposed and final regulation by combining the available occurrence information from UCMR 3 and state datasets in a statistically robust and representative manner, utilizing those data to compute estimates of national occurrence for PFAS contaminants to levels below UCMR 3 reporting limits, and combining these results with findings from non-targeted monitoring data for the remaining PFAS to provide estimates on the number of systems impacted by this final rule. Additionally, the agency provides summary data tables in section VI of the FRN and in the *Occurrence Technical Support Document* (USEPA, 2024b), where the detection limits for most of the samples were at or below the PFAS MCLs finalized in this regulation. There were sufficient detections of PFNA and PFBS to inform development and finalization of this regulation. HFPO-DA data were also collected by numerous states.

Philadelphia Water Department (PWD) (Doc. #1709, SBC-045742)

The other three PFAS included in the preliminary regulatory determination (PFBS, PFNA, PFHxS) were collected during UCMR3 (2013-2015). However, at the time of the data collection and analysis, the minimum reporting levels (MRLs), or the lowest concentration that could be

reported, was much greater than it is currently. The HBWCs currently proposed for PFNA and PFHxS are less than the MRL from UCMR3, which makes the UCMR3 dataset questionable in assessing the occurrence of these compounds at the proposed HBWCs.

EPA Response: Please see section 6.1 of the EPA response in this *Response to Comments* document. Additionally, the UCMR 3 data remain relevant for their nationally representative selection and the insight they provide for occurrence at or above UCMR 3 minimum reporting levels (please see section 6.5 of the EPA response in this *Response to Comments* document), but they are not considered in isolation. As discussed in sections 6.1 and 6.2 of the EPA response in this *Response to Comments* document, in addition to UCMR 3 data, the EPA also considered occurrence data from 32 states, which provided the agency tens of thousands of additional PFAS monitoring results to inform the EPA's decision. Additionally, the agency provides summary data tables in section III.C and VI.B of the FRN and in the *Occurrence Technical Support Document* (USEPA, 2024b), where the reporting limits for most of the samples were at or below the PFAS MCLs finalized in this regulation. There were sufficient detections of PFNA, PFHxS, and PFBS to inform development and finalization of this regulation.

Philadelphia Water Department (PWD) (Doc. #1709, SBC-045740)

EPA should pursue a separate rulemaking determination from PFOA and PFOS for the constituents considered in the Hazard Index (HI) and should provide more data supporting its analyses:

7. EPA should remain consistent with the use of national occurrence data from the Unregulated Contaminant Monitoring Rule (UCMR) to determine if the contaminant occurs in public water systems at levels of public health concern.

The EPA's proposed rulemaking includes a preliminary regulatory determination for PFBS, PFNA, PFHxS, and HFPO-DA and its ammonia salt (trade name "GenX"). The notice also includes a proposed NPDWR and health-based Maximum Contaminant Level Goals (MCLGs) for a mixture of these chemicals. The use of a Hazard Index (HI) for the MCL and MCLG is proposed to account for the combined health risks from exposure to multiple PFAS in drinking water. The proposed HI compares measured exposure to PFBS, PFNA, PFHxS, and HFPO-DA to health-based reference values prior to combining them to see if they remain under the safe threshold value of 1 (unitless).

Regulatory determinations are made following the collection of nationwide data through the UCMR to determine whether regulation of a contaminant in drinking water presents a meaningful opportunity for public health risk reduction. Although data from 29 PFAS will soon be collected during the implementation of the Fifth Unregulated Contaminant Monitoring Rule (UCMR5), currently the Third Unregulated Contaminant Monitoring Rule (UCMR3) is the only national dataset to include PFAS. Of the six PFAS included in UCMR3, only PFOA and PFOS

resulted in a positive preliminary regulatory determination after considering the extent and degree of PFAS occurrence in public water systems.

National occurrence data generated from UCMR3 is insufficient to inform a National Primary Drinking Water Regulation for the proposed mixture of PFAS. It is unclear if EPA has sufficient national data to determine the extent of occurrence for HFPO-DA, PFNA, and PFHxS in drinking water at the proposed Health-Based Water Concentrations (HBWCs).

EPA Response: The EPA will not be pursuing a separate rulemaking for PFOA and PFOS and the Hazard Index PFAS as the agency currently has sufficient information to regulate the Hazard Index PFAS. Furthermore, the EPA has concluded it is most efficient and justified to regulate these six PFAS simultaneously. The agency has previously made a final determination that there is sufficient information to regulate PFOA and PFOS, and as demonstrated through the best available information in section III of the final rule preamble, has determined that PFHxS, PFNA, HFPO-DA, and mixtures of those PFAS with PFBS meet the statutory criteria for regulation. Please see section 6.8 of the EPA response in this *Response to Comments* document regarding UCMR 5 data. The EPA implements a monitoring program for unregulated contaminants (i.e., UCMR) under SDWA 1445(a)(2) that requires the EPA to issue a list once every five years of priority unregulated contaminants to be monitored by PWSs, however there is no statutory requirement that a contaminant must be on this list prior to making a determination to regulate. The EPA may make a determination to regulate if the agency has sufficiently available information through other sources. As discussed in section 6.1 of the EPA response in this *Response to Comments* document, in addition to UCMR 3 data, the agency also considered occurrence data from 32 states, which provided the agency tens of thousands of additional PFAS monitoring results to inform the EPA's decision. Please see the *Occurrence Technical Support Document* (USEPA, 2024b) for additional details. The UCMR 3 dataset, along with additional state data and robust analyses, demonstrate sufficient likelihood of occurrence of PFHxS, PFNA, and HFPO-DA. Please see sections 3.1.2 and 3.2.2 of the EPA response in this *Response to Comments* document regarding EPA's regulatory determination and evaluation of the occurrence criterion for these three PFAS and mixtures of these three PFAS and PFBS.

6.2 State Drinking Water Data

Summary of Major Public Comments and EPA Responses

Commenters generally supported the use of state datasets to inform the EPA's occurrence analyses. A few commenters discussed their own PFAS occurrence data, some of which were provided to the EPA, relative to the EPA's proposed regulatory levels and/or provided summaries of other monitoring efforts. Where possible, the EPA presents this information within its occurrence analysis – see the Other Data sections of USEPA (2024b). A few commenters recommended that the EPA expand the datasets used for the final rule to include additional and updated state sampling information. The EPA agrees with these suggestions to include additional and updated sampling information in order to evaluate PFAS occurrence in drinking water. Therefore, the agency has included updated information in its occurrence analyses as described

in section VI.B of the final rule preamble as well as the *Occurrence Technical Support Document* (USEPA, 2024b). The EPA notes that this information is consistent with the analyses contained in the proposal for this action and confirmatory of the EPA's original occurrence analyses.

A few commenters criticized the use of state datasets in occurrence analyses. These commenters claimed that the state datasets were insufficient for understanding PFAS contaminant occurrence and not dependable due to being collected under variable circumstances. These commenters expressed the need for enhanced quality control (QC) by the EPA to exclude data below reasonable reporting thresholds. The agency disagrees with commenters who contend that state datasets are insufficient. For both the rule proposal and this final action, the EPA took QC measures to ensure the EPA used the best available data for national extrapolation. For example, the EPA acknowledged in the proposal that states used various reporting thresholds when presenting their data, and for some states there were no clearly defined reporting limits. The EPA identified state reporting thresholds where possible and, when appropriate, incorporated individual state-specific thresholds when conducting data analyses. For other states, the EPA presented the data as provided by the state. Due to the reporting limitations of some of the available state data (e.g., reporting combined analyte results rather than individual analyte results), the EPA did not utilize all of these data in the subsequent occurrence analyses/co-occurrence analyses. Specific data analysis criteria (e.g., separation of non-targeted (i.e., monitoring not conducted specifically in areas of known or potential contamination) and targeted monitoring results were also applied. Additionally, the agency also verified that the vast majority of the data were collected using EPA Methods 533 and 537.1. Further, the EPA reviewed all available data thoroughly to ensure that only finished drinking water data were presented. A description of the scope and representativeness of the state data was provided in the proposal of this action in the PFAS Occurrence and Contaminant Background Support Document (USEPA, 2023a), as well as is available in updated *Occurrence Technical Support Document* for the final rule (USEPA, 2024b). These include describing the states the EPA found to have publicly available data, identifying the reporting thresholds where possible, and distinguishing whether monitoring was non-targeted or targeted (i.e., monitoring in areas of known or potential PFAS contamination). These QC measures ensured that the EPA utilized the best available data for each given analysis. Analyses aimed at extrapolation either utilized a robust statistical framework or were restricted to data from non-targeted monitoring to minimize bias.

State data that was collected to support the final rule included data from 32 states. Within this dataset, each PFAS chemical included in the final rule had tens of thousands of samples collected from over 10,000 PWS. Further, the vast majority of these state data utilized reporting limits on the order of single digit ng/L, lower than the minimum reporting levels in UCMR 3.

Individual Public Comments

San Antonio Water System (SAWS) (Doc. #1570, SBC-042473)

EPA put substantial weight in data collected at the discretion of the state's themselves under varying circumstances. The extrapolation of this limited data set is not a dependable or sufficient foundation for the broad and sweeping regulatory standards being imposed upon every state.

EPA Response: Please see section 6.2 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046037)

Water Quality

Aside from complying with UCMR3, which included monitoring for PFOA and PFOS, Newport News Waterworks (NNWW) began screening source waters and finished water for PFAS in 2019 in preparation for potential new MCLs. Data was needed to understand the sources, determine possible operational changes, and plan for treatment approaches in a highly variable coastal plain surface water system. Investigations confirmed multiple sources of PFAS in 4 of the 6 watersheds that supply water to the regional system. Years of data are beginning to yield basic trends and ranges for these contaminants, and the variability will be a challenge for operations, treatment, and compliance. An example from one of the storage reservoirs is provided below.

[Figure: see docket ID EPA-HQ-OW-2022-0114-1738]

With water quality variability within each of 4 watersheds (left graph is for Skiffes Creek Reservoir), the resulting variations at the WTP intakes will require extensive testing and modeling to ensure compliance with MCLs set at the analytical threshold.

The running annual average (RAA) for PFOA and PFOS in the finished water from both WTPs is depicted below and confirms that compliance at threshold-level MCLs will be difficult, even for diligent utilities, and will require substantial investment in PFAS-removing technologies (e.g., GAC).

[Figure: see docket ID EPA-HQ-OW-2022-0114-1738]

EPA Response: The EPA acknowledges the information on PFAS monitoring in the Newport News area submitted by the commenter. Please see section 5.1.2 of the EPA response in this *Response to Comments* document regarding the EPA's feasibility determination for the PFOA and PFOS MCLs.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046038)

Attachment 4

PFAS in Drinking Water – Compliance Outlook May 2023

WSSC Water's mission is to protect public health and safety by supplying safe, clean and reliable water to our 1.9 million customers. We are proud of our 105-year history of zero drinking water quality violations and remain committed to continuing this exceptional level of excellence.

[Figure: see docket ID EPA-HQ-OW-2022-0114-1738]

We draw the water we treat from two sources: the Patuxent and Potomac rivers. On the Patuxent River, we operate and maintain two reservoirs - Triadelphia and T. Howard Duckett. Our Patuxent Water Filtration Plant (WFP) draws water from the Duckett Reservoir and produces approximately 60 million gallons per day (MGD). Our Potomac WFP draws water straight from the Potomac River, producing between 100 and 120 MGD.

For several years, WSSC Water has been proactively testing for PFAS compounds in our drinking water, testing that went above and beyond federal and state requirements. In January of 2020 WSSC Water began monitoring for 18 PFAS compounds and expanded the monitoring in September of 2022 for 29 PFAS compounds that are included under the EPA's Fifth Unregulated Contaminant Monitoring Rule, also known as UCMR 5. The results of our testing are posted online (wsscwater.com/pfas).

[Table: see docket ID EPA-HQ-OW-2022-0114-1738]

[Figure: see docket ID EPA-HQ-OW-2022-0114-1738]

[Figure: see docket ID EPA-HQ-OW-2022-0114-1738]

EPA Response: The EPA acknowledges the results of PFAS testing provided by the Washington Suburban Sanitary Commission (WSSC) and their proactive efforts to understand and address PFAS contamination.

American Water Works Association (AWWA) (Doc. #1759, SBC-045578)

2. The agency's consideration of non-UCMR 3 data needs additional quality control to exclude system data that does not meet the necessary data quality for national representation, such as reported results that are below nationally reliable reporting limits, as recognized by EPA.

EPA Response: The agency disagrees that it should not consider all reported results as determined by individual state datasets and laboratories. While the EPA determines reporting levels based on nationally representative laboratory capabilities for the purposes of UCMR and for evaluation of feasibility as part of the establishment of regulatory standards under SDWA, individual laboratories and states may be capable of achieving lower levels and can set their own

reporting levels based on their own site-specific capabilities. Please see section 6.2 of the EPA response in this *Response to Comments* document regarding QC steps the agency took to ensure accurate and transparent representation of the available data.

American Water Works Association (AWWA) (Doc. #1759, SBC-045574)

Use of Non-UCMR 3 Data

EPA's occurrence analysis relies on data from both UCMR 3 and state monitoring programs. AWWA supports the consideration of the more recently collected data from state monitoring programs to improve understanding of occurrence, but there are several concerns about the agency's use of this data and the degree of quality control. These issues are discussed in more detail in the following paragraphs. As previously noted, the SDWA requires that EPA rely upon the best available public health information, including the occurrence database. [FN9: 42 U.S.C. § 300g-1(b)(1)(B)(ii)(II).] EPA must also provide sufficient information and explanation regarding the data selected and not selected as the basis of EPA's decision so that the public can meaningfully comment on the data selected as well as evaluate the data that EPA did not decide to rely upon.

It is unclear how data was screened for inclusion as part of the analysis. Several state monitoring datasets are documented to have reporting thresholds far below what is considered reliable for a national occurrence analysis; for example, reporting thresholds below 1 ppt are indicated for several states including New Jersey, Massachusetts, and California. In other cases, states did not indicate the applicable reporting thresholds. While the proposal acknowledges these data quality issues, the agency nonetheless elected to utilize this data without quality control. As AWWA noted in 2020, EPA should supplement monitoring data from UCMR 3 with high quality occurrence data (AWWA, 2020b). It is recommended that EPA re-evaluate the non-UCMR 3 data that is being leveraged and ensure that monitoring results that are neither achievable using the robust methods approved by EPA nor representative of high-accuracy data should not be considered as part of this analysis.

EPA Response: As discussed in section 6.2 of the EPA response in this *Response to Comments* document, the EPA took steps to assure that non-UCMR 3 data sources were the best available occurrence data of sufficient quality and accurately describe the steps taken to ensure data quality. Please see section 6.2 of the EPA response in this *Response to Comments* document as well as the *Occurrence Technical Support Document* (USEPA, 2024b) for more information. Additionally, the agency disagrees that it should not consider all reported results as determined by individual state datasets and laboratories after following the quality assurance (QA) steps documented. While the EPA determines reporting levels based on nationally representative laboratory capabilities for the purposes of UCMR and for evaluation of feasibility as part of the establishment of regulatory standards under SDWA, individual laboratories and states may be capable of achieving lower levels and can set their own reporting levels based on their own site-specific capabilities.

The District of Columbia Water and Sewer Authority (Doc. #1829, SBC-045767)

The use of PFAS data from multiple state monitoring programs is also problematic. There are differences in reporting thresholds, when reported, and the data itself has not been subjected to sufficient quality control measures.

EPA Response: Please see section 6.2 of the EPA response in this *Response to Comments* document.

Groundwater Resources Association of California (Doc. #1831, SBC-045348)

May 30, 2023

To:

Michael S. Regan, Administrator, U.S. Environmental Protection Agency

RE: GRA Comments on EPA's Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulations (Docket ID: EPA-HQ-OW-2022-0114)

TRANSMITTED ONLINE: https://www.regulations.gov/docket/EPA-HQ-OW-2022-0114/document

To whom it may concern

The Groundwater Resources Association of California (GRA [FN1: www.grac.org]) welcomes the opportunity to comment on the public review of the United States Environmental Protection Agency's (EPA) Proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulations (Docket ID: EPA-HQ-OW-2022-0114). GRA's vision is Sustainable Groundwater for All and our organization is dedicated to resource management that protects and improves groundwater supply and quality through education and technical leadership. GRA membership includes more than 1400 professionals located throughout California and the Western United States with technical, policy, and legal expertise on groundwater related matters.

The GRA acknowledges and commends the diligent and critical efforts made by the EPA and its technical experts in tackling one of the gravest challenges confronting our nation—the threat of PFAS contamination to our drinking water sources. Over the past couple of years, the EPA has demonstrated commitment and dedication to addressing this pressing issue. State agencies and local governments look to the EPA for regulatory leadership and guidance related to PFAS in our drinking water and the environment. EPA's proactive measures have set a worthy precedent on emerging contaminants, and we commend the EPA for taking the initial stride on this journey towards safeguarding our water resources. The path ahead entails collaboration and sustained efforts from all stakeholders to comprehensively tackle this multifaceted issue. The GRA firmly believes that by building upon the EPA's first steps, we can make significant strides in protecting the quality of our drinking water for generations to come.

Given GRA's groundwater focus, our comments on the proposed PFAS regulations are focused on the impacts these regulations will have on the availability, affordability, sustainability, and safety of drinking water sources derived from groundwater. Given the voluminous body of literature related to the referenced proposed regulations and the limited amount of time available for the public comment period (61 days), GRA is only providing comments on the primary regulatory document (Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation, Docket EPA- HQ-OW-2022-0114-0027). Based on our review of this document, GRA offers the following general comments and recommendations for consideration by the EPA as they finalize these regulations:

1. Request for Additional Clarity on Statewide PFAS Data: It is unclear from our reading of the report what statewide datasets were used to evaluate the occurrence, impacts, and costs of PFAS. The text states that data from 23 States was collected but the tables only show data from 10 States. We recommend that PFAS statistics from data collected across all 23 States be included. The Exhibit 2-4 in supporting document USEPA. 2023e (PFAS Occurrence and Contaminant Background Support Document. EPA-822-P-23-010) indicates that California data included testing for "Surface Water and Groundwater – Raw, Finished, and Unknown Water" and also states that "EPA reviewed the California PFAS data available online through April 2021. Finished water data were available from approximately 100 PWSs [Public Water Systems]. For analysis purposes, EPA only included results that were explicitly defined as being from treated water. Sampling in California is ongoing. California conducted sampling of 18 PFAS, including PFOS, PFOA, HFPO-DA, PFBS, PFHxS, and PFNA". The State Water Resources Control Board (SWRCB) of California and the United States Geologic Survey (USGS) have collected extensive PFAS data across the State as part of State Public Water Testing and Groundwater Ambient Monitoring and Assessment (GAMA) Priority Basin Project [FN2: https://www.waterboards.ca.gov/pfas/drinking_water.html; https://pubs.er.usgs.gov/publication/fs20213028]. This includes data from public supply and domestic water supply wells. As the State with the nation's largest population and highest Gross Domestic Product (GDP), PFAS occurrence, impacts, and costs in California would represent a significant proportion for the nation. Hence, we recommend that EPA reflects California data in the published regulatory documents and potentially expand the datasets to include the on-going state-wide testing and sampling programs, as outlined above.

EPA Response: The EPA acknowledges the information related to PFAS monitoring provided by the Groundwater Resources Association of California (GRA). As discussed in section 6.2 of the EPA response in this *Response to Comments* document, additional state data were collected after the rule proposal, where available. Depending on the intended purposes and describing the data accurately, some exhibits within proposed and final rule preambles and Occurrence Technical Support Document are limited to non-targeted monitoring results. In these instances, states with data produced through targeted monitoring efforts are not included. However, the EPA does present all state data collected through targeted monitoring efforts in the *Occurrence Technical Support Document* (USEPA, 2024b). Specific to California PFAS drinking water data, the EPA used all California data available through May 2023, taking QA

measures as described in the Technical Support Document to ensure it was representative of finished drinking water data only for drinking water rule analysis purposes.

Midwest Environmental Advocates +more (Doc. #1846, SBC-045826)

The most recent sampling data, however, has been collected by the Wisconsin Department of Natural Resources (WDNR or the state agency). In March of 2022, the state agency launched a voluntary program for municipal water systems to sample for PFAS during the second trimester of 2022. [FN14: Wisconsin Department of Natural Resources, Voluntary Drinking Water PFAS Sampling Project for Municipal Systems, https://dnr.wisconsin.gov/topic/PFAS/PWSampling.] In October of 2022, the WDNR began the enforcement of its initial monitoring requirements pursuant to the state's drinking water program. [FN15: Wisconsin Department of Natural Resources, NR 809 Safe Drinking Water Standards Update, https://dnr.wisconsin.gov/topic/DrinkingWater/NR809.html (The WDNR relies on laboratory analysis that use EPA Method 537.1 to test for 18 PFAS, including the ones subject to this rulemaking).] To date, the state agency has collected samples under the state drinking water program from approximately 187 community water systems representing a public drinking water population of about 3 million.

EPA Response: The EPA acknowledges the commenters' referral to information on PFAS monitoring in Wisconsin. As described in the final rule preamble and *Occurrence Technical Support Document* (USEPA, 2024b), finished drinking water occurrence data from Wisconsin has been considered as part of the agency's final rulemaking.

Edward Cullen (Doc. #3075, SBC-047723)

EPA has summarized credible data demonstrating the health risks to people of exposure through drinking water to numerous forms of PFAS (i.e., PFOA, PFOS, PFHxS, HFPO-DA, PFNA, and PFBS; see March 29, 2023 FR). EPA has also presented data showing that specific forms of PFAS have been measured in public drinking water at multiple sites in the US, and measured concentrations indicate a threat to public health.

For example, non-targeted surveillance of public water systems conducted by states showed that PFOA concentrations were greater than or equal to 5.0 ppt in 33.2% of systems in New Hampshire, 33.7% of systems in New Jersey, 36.6% of systems in Massachusetts, and 49.0% of systems in South Carolina (Table 8 FR 88, p. 18674). For reference, EPA is proposing a Maximum Contaminant Level (MCL) of 4.0 ppt for PFOA. Broadly similar results were reported for PFOS.

Preliminary surveillance data from 16 states for PFHxS, HFPO-DA, PFNA, and PFBS showed that there are at least 214 water systems that exceed the Hazard Index (HI) limit of 1.0 proposed by EPA for these contaminants (FR 88, p. 18678).

EPA Response: The EPA agrees that sufficient information has been utilized to inform the EPA's final regulatory determinations for PFHxS, PFNA, HFPO-DA, and mixtures of these three PFAS and PFBS, as well as the final NPDWRs for PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and mixtures of PFHxS, PFNA, HFPO-DA, and PFBS.

Clean Air Council, et al. (Doc. #1731, SBC-043867)

Comments

1. PFAS levels that exceed the proposed federal standards are prevalent in the Commonwealth of Pennsylvania, and Pennsylvania's compliance with the proposed federal standards is feasible.

a. PFAS are prevalent in Pennsylvania drinking water at levels above the proposed MCLs and HI.

In 2020–2021 the Pennsylvania Department of Environmental Protection ("PA-DEP") conducted an extensive survey to assess the presence of PFAS species in Public Water Systems ("PWSs"). The survey was conducted as part of the process of developing a Pennsylvania PFAS drinking water rule [FN2: Safe Drinking Water PFAS MCL Rule, 53 Pa.B. 333, 334–35 (January 14, 2023) (to be codified at 25 Pa. Code Ch. 109), available at https://www.pacodeandbulletin.gov/secure/pabulletin/data/vol53/53-2/53-2.pdf]. The survey was undertaken to generate statewide occurrence data, focusing on sampling of water entry points ("EPs") into water processing plants near identified sources of potential PFAS contamination, such as military bases, airports, or manufacturing facilities that may have used PFAS. Samples were collected from 412 entry points. 372 of those were targeted sites, and 40 were baseline sites in areas where PFAS contamination was deemed unlikely. Water testing was conducted for 18 PFAS species using the EPA–approved method 537.1.

Out of the more than 400 water systems sampled, approximately 250 did not show any detectable levels of the targeted 18 PFAS compounds [FN3: More details of the sampling plan are in the discussion of Pennsylvania's Safe Drinking Water PFAS MCL Rule. Id. at 334–36]. 102 samples exceed the EPA proposed 4 ppt limit for either PFOS or PFOA, and most of these samples exceed the limits for both. Some of the values recorded are quite high: For example, sample PWSID 477608- State of the Art (Centre County) had 62.1 ppt PFOS and 12.8 ppt PFOA. In sample 477075-Christman Lake Water System (Berks County), the water sampled contained 6.5 ppt and 59.6 ppt of PFOS and PFOA, respectively. Sample 477350-Saegertown Borough (Crawford County) recorded 187.1 ppt and 5.5 ppt of PFOS and PFOA, respectively. Samples with high levels of PFOA and PFOS were not localized in specific counties, but widespread throughout the Commonwealth [FN4: PA-DEP has made the the full sampling data available; see PA-DEP, Copy of BSDW_PFAS Sampling Project_All Results web edit.xlsx, https://files.dep.state.pa.us/Water/DrinkingWater/Perfluorinated%20Chemicals/SamplingResults/PFAS_Sampling_Final_Results_May_2021.pdf [hereinafter Full PA Sampling Data]].

PFOA and PFOS were the most prevalent PFAS species, found in approximately ¼ of the samples [FN5: Id. at 335, Table 1]. However, other PFAS species were found in a substantial fraction of entry points. For example, PFHxS was found in 13% of the samples, and PFBS in 16% [FN6: Id.]. These numbers are similar to data obtained in other states [FN7: See 88 Fed. Reg. 18648–49, Tables 1, 2]. Applying the EPA proposed methodology and associated values for determining the Hazard Index (HI) for PFHxS, HFPO–DA, PFNA and PFBS (Health Based Water Concentration of 9.0 ppt, 10.0 ppt, 10.0 ppt and 2000 ppt respectively, and a Hazard Index of 1 [FN8: See 88 Fed. Reg. 18665]) to the PA-DEP drinking water samples yields 13 samples with an HI > 1. All but one of these (Sample 410-15417-1 - Williamsport Mun Water Auth in Lycoming County) also contain PFOA and/or PFOS at values exceeding the proposed 4 ppt limit.

In the development of Pennsylvania's PFAS drinking water regulations, PA-DEP used the survey results as representative of all Public Water Systems ("PWS") in the Commonwealth [FN9: 53 Pa.B. 333]. Based on this assumption, the sampling data collected in the 2020–2021 survey by PA-DEP indicates that approximately 1⁄4 of the 3,785 entry points in the Commonwealth are contaminated with PFAS species at values that exceed the proposed PFAS NPWDR. The approximately 900 EPs with PFAS levels that were determined by EPA to be dangerous to public health, compared to the approximately 200 that exceed the PA-DEP MCLs, demonstrate that the proposed national standard would be more protective of public health in Pennsylvania [FN10: See Id.; Full PA Sampling Data, supra note 4].

EPA Response: The EPA acknowledges the commenter's referral to information on PFAS monitoring in Pennsylvania. The EPA notes occurrence information from the State of Pennsylvania is included within its occurrence analyses for the final rule as described in the final rule preamble and the *Occurrence Technical Support Document* (USEPA, 2024b).

Village of Woodbury (Doc. #1629, SBC-042958)

12. Additional PFAS compounds (i.e., PFHxS, PFNA, PFBS, HFPO-DA) do not have the same readily available occurrence data as far as we are aware.

EPA Response: The EPA disagrees that there is not sufficient occurrence data for PFHxS, PNFA, PFBS, and HFPO-DA to inform this regulation. The EPA evaluated tens of thousands of PFHxS, PFNA, PFBS, and HFPO-DA samples across more than 10,000 PWSs as a part of its rule occurrence analyses. Please see section 3.1.2 of the EPA response in this *Response to Comments* document regarding regulatory determinations and section 6.2 of the EPA response in this *Response to Comments* document regarding state datasets.

Midwest Environmental Advocates +more (Doc. #1846, SBC-045825)

Certain municipal systems have been testing for PFAS since 2013 under the Third Unregulated Contaminant Monitoring Rule (UCMR-3). Due to concerning results from the UCMR-3 sampling, several water systems proactively monitored for PFAS concentrations in their drinking

water. [FN13: See Wisconsin Groundwater Coordinating Council Report to the Legislature 4 (2022), https://dnr.wisconsin.gov/sites/default/files/topic/Groundwater/GCCGWQuality/PFAS.pdf ("In the UCMR-3 sampling, PFAS were detected in municipal water systems in La Crosse, West Bend, and Rhinelander … The data from UCMR-3 served as an initial indicator of the fact that both groundwater and drinking water supplies in Wisconsin have been impacted by PFAS. Voluntary sampling by a few municipalities (from 2019 through the first quarter of 2022) has shown additional impacts … in Madison, Eau Claire, Wausau and Rib Mountain.").]

EPA Response: The EPA acknowledges the information provided by the commenter related to PFAS monitoring in Wisconsin groundwater systems. The agency considered data publicly available from the Wisconsin Department of Natural Resources prior to finalizing this regulation. Please see the *Occurrence Technical Support Document* (USEPA, 2024b) for more information.

6.3 PFAS Co-Occurrence

Summary of Major Public Comments and EPA Responses

Some commenters agreed with the agency's conclusion in the March 2023 proposal that the PFAS included in the regulation meaningfully co-occur. However, some other commenters stated that they believed the data used to assess PFAS co-occurrence were too limited to make substantive conclusions. The EPA disagrees that the data were too limited or that the co-occurrence analysis was inconclusive. Based on the non-targeted state monitoring data used in the co-occurrence analysis for the proposed rule preamble (from 11 states), findings of the pairwise and groupwise analyses established a strong likelihood that these chemicals meaningfully co-occur in drinking water. This was observed through odds ratios statistically significantly greater than 1 in the pairwise analysis as well as frequency at which multiple chemicals were detected in the groupwise analysis. Based on public comment, the agency has updated its co-occurrence analyses to include more recent non-targeted state data that became publicly available after the proposal analyses were finalized. See section VI.C. of the rule preamble. This ensures that findings are up to date. The more recent data, which now include non-targeted monitoring data from 18 states and are presented in section VI.C. of the final rule preamble, confirm the proposal analyses.

Individual Public Comments

Michigan Department of Environment, Great Lakes, and Energy (EGLE) Drinking Water and Environmental Health Division (DWEHD) (Doc. #1597, SBC-042979)

C. Occurrence of 4 Additional PFAS

In response to EPA's request for occurrence information, and having reviewed Section VII of the proposed NPDWR, EGLE DWEHD has reviewed three years of PFAS MCL compliance monitoring data collected under Michigan's SDWA. This data indicates that 11 public water

supplies (8 community water supplies and 3 non-transient noncommunity water supplies) would potentially exceed the proposed HI-based MCL alone.

EPA Response: The EPA acknowledges the information provided by the Michigan Department of Environment, Great Lakes, and Energy (EGLE) on the number of systems expected to exceed the Hazard Index MCL and the agency has considered publicly available data from Michigan EGLE prior to finalizing this regulation.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044417)

Page 18730. Section VII – Occurrence

Page 18730. EPA requests comment on the number of systems estimated to solely exceed the HI (but not the PFOA or PFOS MCLs) according to the approach outlined in USEPA (2023e).

• Based on an initial and limited review of Washington water systems, a very small percentage of systems exceed the HI but not the PFOA or PFOS MCLs. Most systems with high levels of the other PFAS also have PFOA or PFOS as the drivers.

EPA Response: The EPA acknowledges the information provided by the Washington State Department of Health (DOH) on the number of systems expected to exceed the Hazard Index MCL. These data provide confirmatory information that Hazard Index PFAS often co-occur with PFOA and PFOS.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045087)

Section III – Regulatory Determinations for Additional PFAS

1) What are the impacts on compliance from PFHxS/PFNA?

In Vermont, we have been receiving water quality data under EPA Method 537.1 since July of 2019, with at least two samples per Non-Transient Non-Community (NTNC) and Community water systems. We regulate PFOA, PFOS, PFHxS, PFHpA and PFNA as a combination of compounds at 20 ppt. In our data, when compared with the proposed MCLs of 4.0 ppt for PFOA and PFOS, we did not have any systems with elevated PFHxS or PFNA (alone or combined) to the point where our MCL of 20 was exceeded and the PFOA and/or PFOS results were at or below 4 ppt each. This means that if there were elevated results sufficient to have high PFHxS or PFNA, there were much higher levels of either PFOA or PFOS so that those respective MCLs would have also been exceeded. We do not see elevated PFHxS or PFNA by themselves without the presence of PFOA or PFOS.

Based on our water quality results, relying often on a single sample and confirmation sample collected within 10 days (and not the Running Annual Average (RAA)), we did not have systems that exceeded the Hazard Index of 1.0 based on the respective proposed four compounds that

would not have otherwise either exceeded the proposed PFOA or PFOS MCL respectively already.

EPA Response: The EPA acknowledges the information provided by the Vermont Agency of Natural Resources and Department of Health on the number of systems expected to exceed the Hazard Index MCL. These data provide confirmatory information that Hazard Index PFAS often co-occur with PFOA and PFOS. Additionally, the agency maintains that individual regulation of PFHxS, PFNA, and HFPO-DA and regulation of mixtures of these three PFAS and PFBS will provide necessary public health protection to those exposed to elevated levels of these four PFAS that are not exposed to levels exceeding the PFOA and PFOS MCLs.

Philadelphia Water Department (PWD) (Doc. #1709, SBC-047688)

Given the extent of PFAS in the environment, the proposed HI represents less than 0.1% of PFAS. The EPA notice cites likely co-occurrence in drinking water as part of the justification for the public health protections of a Hazard Index. PWD is requesting that the EPA's analysis on the co-occurrence of PFBS, PFNA, PFHxS, and HFPO-DA be made publicly available as well.

EPA Response: The EPA's co-occurrence analysis and sources of the underlying data to support the analysis are publicly available in section VI.C of the final rule preamble and the *Occurrence Technical Support Document* (USEPA, 2024b).

American Water Works Association (AWWA) (Doc. #1759, SBC-045604)

The EPA's occurrence analysis fails to sufficiently document co-occurrence of this mixture of PFAS and AWWA's analysis of data from nearly 8,000 water systems does not demonstrate a pattern of co-occurrence.

EPA Response: The EPA disagrees. The data used in the EPA's co-occurrence analysis, including UCMR 3 and non-targeted state monitoring data, demonstrate co-occurrence of the six PFAS for which the EPA is finalizing regulation. PFAS co-occurrence has been documented in numerous peer reviewed publications (e.g., Guelfo and Adamson, 2018; Cadwallader et al., 2022; McMahon et al., 2022 (as cited in USEPA, 2024b)). Please see section 6.3 of the EPA response in this *Response to Comments* document.

Midwest Environmental Advocates +more (Doc. #1846, SBC-045821)

Second, occurrence data developed under the SDWA and state-led monitoring programs provide sufficient indication that the occurrence of these PFAS in water systems is of great concern. Below, Commenters provide occurrence data from Wisconsin's community water systems to support EPA's findings that the occurrence and likely occurrence or co-occurrence of these substances presents a significant public health concern given their frequencies and levels.

EPA Response: The EPA agrees that the PFAS included in this rule are likely to co-occur.

Midwest Environmental Advocates +more (Doc. #1846, SBC-045824)

B. Wisconsin's drinking water occurrence data further supports EPA's proposed regulation.

PFAS drinking water occurrence data from the State of Wisconsin supports EPA's finding that there is a substantial likelihood that the contaminants subject to this rulemaking occur or will occur in public water systems with a frequency and at levels of public health concern. Data thus far reveals that twenty-five community water systems across the state serving more than half a million people have detected levels of these PFAS at concerning frequencies and at levels higher than the proposed MCLs.

Wisconsin has 1,038 community water systems serving 69 percent of the state's population. [FN10: Wisconsin Department of Natural Resources, Wisconsin Public Water Systems 2021 Annual Drinking Water Report, Pub-DG-045 (2022) 6.] There are 610 municipal systems owned by cities, villages, towns, or sanitary districts that serve a population of approximately 4,026,471. [FN11: Id. at 6-7.] Most of these systems rely on groundwater, but a few of the largest systems obtain water from surface water. [FN12: Id. at 7-8.]

EPA Response: The EPA acknowledges the information provided by the commenter related to PFAS monitoring in Wisconsin and the agency has considered these data prior to finalizing the PFAS NPDWR.

Lehigh County Authority (LCA) (Doc. #1600, SBC-042810)

In addition, there appears to be limited data available to determine the prevalence of co-exposure to these compounds. Further review of the extent to which these compounds are likely to present themselves as a mixture would be beneficial prior to establishing a brand-new compliance approach such as the Hazard Index.

EPA Response: The EPA disagrees with the commenter that there is limited data to determine co-occurrence and co-exposure. Please see section 6.3 of the EPA response in this *Response to Comments* document, FRN sections VI.C and VI.G, and section 9 of the *Occurrence Technical Support Document* (USEPA, 2024b).

City of Allentown and Lehigh County Authority (LCA), Pennsylvania (Doc. #1667, SBC-043670)

In addition, there appears to be limited data available to determine the prevalence of co-exposure to these compounds. Further review of the extent to which these compounds are likely to present themselves, as a mixture, would be beneficial prior to establishing a brand-new compliance approach such as the Hazard Index.

EPA Response: The EPA disagrees with the commenter that there is limited data to determine co-occurrence and co-exposure. Please see section 6.3 of the EPA response in this *Response to Comments* document, FRN sections VI.C and VI.G, and section 9 of the *Occurrence Technical Support Document* (USEPA, 2024b).

6.4 Occurrence Relative to the Hazard Index

Summary of Major Public Comments and EPA Responses

The EPA received comments on the analyses presented in the proposal of occurrence relative to the Hazard Index. Many commenters agreed that the Hazard Index PFAS co-occurred in mixtures at levels of health concern. Two of these comments came from states that conducted monitoring of Hazard Index PFAS post-UCMR 3 and stated that those occurrence data supported the EPA's findings. Several state agencies provided a summarized analysis of the number of systems expected to exceed the proposed Hazard Index of 1.0 in their state. The EPA notes that these estimates were based on the proposed Hazard Index , which included two significant figures. Since the EPA has determined to finalize the Hazard Index with one significant figure, these estimations are likely high. Nonetheless, these state data and the analyses provided by commenters provide illustrative confirmatory insight of the EPA's Hazard Index analyses (please see section V of the final rule preamble for additional discussion on the usage of significant figures).

One commenter suggested that a national dataset and model complete with all four Hazard Index PFAS are necessary to accurately estimate the number of systems that may exceed the Hazard Index. The EPA disagrees with the commenter; as described in section VI.F of the final rule preamble, state data and model outputs were combined to estimate exceedance of the Hazard Index on a national level. This allowed the EPA to incorporate findings across 18 state datasets for non-targeted monitoring for the Hazard Index PFAS that were not modeled directly. Several commenters stated that there was a limited amount of available data to determine the prevalence of co-exposure of the Hazard Index compounds, and that further review would be needed prior to establishing the Hazard Index. The EPA disagrees with these commenters and believes that sufficient data were available to reasonably assess the co-occurrence of Hazard Index PFAS. An analysis of co-occurrence of Hazard Index compounds using a substantial amount of data encompassing tens of thousands of samples across over 10,000 systems is provided in section VI.C of the final rule preamble and demonstrates that the four Hazard Index PFAS co-occur with each other as well as with PFOA and PFOS. One commenter suggested that more systems may exceed the Hazard Index than the PFOA and PFOS MCLs, since current treatment technologies have been optimized for PFOA and PFOS and not for other PFAS. The EPA's analysis of state datasets clearly contradicts this claim; using the best available data and scientifically robust analytical approaches, the EPA estimates more systems will exceed the PFOA and PFOS MCLs (4,000-6,500 systems) than the Hazard Index MCL (300-700 systems). Of the systems anticipated to exceed the Hazard Index MCL, 100-300 were anticipated to not also be exceeding the PFOA or PFOS MCLs. Including state data from targeted and non-targeted monitoring, 211

systems across 21 states observed results exceeding the final Hazard Index of 1. The use of a single significant figure for the Hazard Index MCL in this final rule will further increase the likelihood of more systems exceeding PFOA or PFOS MCLs than the Hazard Index MCL.

Individual Public Comments

3M Company (Doc. #1774, SBC-045654)

In addition to being procedurally improper, EPA's development of the HI-MCL is also substantively flawed. EPA's approach assumes co-occurrence of the four PFAS included in the hazard index, but EPA has not provided meaningful occurrence data showing substantial likelihood that those substances co-occur. Further, EPA's discussion of potential co-occurrence is replete with examples of EPA relying on data from sources that EPA claims supports its argument while ignoring sources that clearly undermine it. For example, the co-occurrence data presented at the system level for detection of any relevant PFAS shows wide variability among states (USEPA 2023h, p. 197), and states with the most systems tested show much lower frequency of co-occurrence detections.

EPA Response: The EPA disagrees with the commenter's claim that the EPA's occurrence analysis fails to sufficiently document co-occurrence of these PFAS in drinking water. The co-occurrence analysis demonstrates both that the Hazard Index PFAS co-occur with each other as well as with PFOA and/or PFOS. As stated in III.C.5 of the final preamble, regardless of the presence of PFOA and/or PFOS, 12.1 percent of systems included in state datasets that conducted non-targeted monitoring and monitored for at least 3 of the Hazard Index PFAS reported the presence of multiple Hazard Index PFAS. When limiting this to systems that reported the presence of PFOA or PFOS, over 46 percent of systems reported multiple Hazard Index PFAS (this can be observed in section VI.C.3.a of the preamble). Further, as shown in section VI.C.3.b of the preamble and 9.2.2 of the *Occurrence Technical Support Document* (USEPA, 2024b), pairwise odds ratios among Hazard Index PFAS (as well as PFOA and PFOS) are significantly higher than 1 at the system level and sample level, indicating a statistically significant association between every unique pair of PFAS regulated by this final rule.

The EPA also disagrees that the agency has ignored data from sources that undermine its claims. It is common and anticipated for chemical occurrence to vary across states. This is also the reason the EPA includes results separated by state. Of 18 states that were included in the non-targeted analysis of state data, 8 states saw both PFOA and/or PFOS and Hazard Index PFAS at detectable levels in over 20 percent of systems. Most of the states with data available included hundreds of systems. States that included over 500 systems were MI, OH, MA, IL, NY, NJ, ME, and VT. The percent of systems in these states that reported the presence of both PFOA/PFOS and Hazard Index PFAS were 4.3, 1.8, 49.9, 6.3, 38.5, 43.5, 11.9, and 5.7 percent, respectively. Please see section 6.3 of the EPA response in this *Response to Comments* document, section VI.C of the FRN, and the *Occurrence Technical Support Document* (USEPA, 2024b) for more information on PFAS co-occurrence.

American Water Works Association (AWWA) (Doc. #1759, SBC-045599)

Combined MCLG for PFHxS, PFNA, HFPO-DA, and PFBS

According to the proposal, EPA is proposing to establish a combined MCLG for four PFAS set at a hazard index of 1.0. In proposing this MCLG, EPA is making several key scientific determinations to support this decision:

1. PFNA, PFHxS, HFPO-DA, and PFBS are likely to co-occur in water in a way that is a "sufficiently similar mixture"

EPA Response: The EPA refers the commenter to section 4.3.2 of the EPA response in this *Response to Comments* document regarding the Hazard Index approach and notes that a "mixture" can be any combination of two or more of the Hazard Index PFAS. The EPA's evaluation of UCMR 3 data as well as data from state-led drinking water monitoring efforts shows that PFHxS, PFNA, and HFPO-DA each have a substantial likelihood to occur in finished drinking water and that these three PFAS and PFBS are also likely to co-occur in mixtures (USEPA, 2024b). Please see section 6.3 of the EPA response in this *Response to Comments* document, section VI of the FRN, and the *Occurrence Technical Support Document* (USEPA, 2024b) for more information on PFAS co-occurrence.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045101)

Section VII – Occurrence

Based on the data from 2019 to date in Vermont we would not have a system exceed the MCL based on the Hazard Index calculation that would not already exceed the MCL for either PFOA, PFOS or both. Note that we calculate compliance based on an initial sample and confirmation sample, not the running annual average, however, assuming the results remain consistent, the data available are a good indicator for how the draft rule would play out in the State.

EPA Response: The EPA acknowledges the commenter for providing information on systems estimated to solely exceed the Hazard Index MCL and the agency acknowledges commenter's assertion that there would be no Hazard Index exceedances if there were not also exceedances of PFOA, PFOS, or both. The EPA notes that this information further supports that there is co-occurrence of Hazard Index PFAS with PFOA/PFOS.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045220)

Occurrence

1. EPA requests comment on the number of systems estimated to solely exceed the HI (but not the PFOA or PFOS MCLs) according to the approach outlined in USEPA (2023e).

Until a national data set and model are complete with all four HI PFAS, it will be difficult to accurately estimate the number of systems impacted or exceed the HI. However, with the data presented by the EPA, it does appear that these PFAS co-occur in mixtures and are present in the finished drinking water at health impacting levels.

EPA Response: Please see section 6.4 of the EPA response in this *Response to Comments* document. Additionally, the agency agrees that the Hazard Index PFAS co-occur in mixtures at a level and frequency of public health concern.

6.5 National Occurrence Model

Summary of Major Public Comments and EPA Responses

A few commenters stated that they believed the model was an overly complicated approach to characterizing chemical occurrence and found it difficult to understand. Further, a few commenters stated that they believed the model was not transparent. The EPA disagrees; the occurrence approach used by the agency in this rulemaking is based on a widely utilized and accepted statistical approach which is used in a variety of professional fields. The EPA used this model to better inform the agency's understanding of probable PFAS occurrence. For more information about Bayesian statistics and the wide variety of potential applications, see, for example, Hoff (2009); van de Schoot et al. (2021); Aguilera et al. (2011); and Messner et al. (2001). While the model uses an advanced statistical method and requires some statistical background to fully understand, Bayesian hierarchical models have previously been employed to assess occurrence for drinking water contaminants, as was discussed in the March 2023 proposal preamble as well as Cadwallader et al. (2022). Cadwallader et al. (2022) describes the model structure while the annotated model code and inputs were provided directly as supporting information alongside the manuscript. This information was incorporated into the docket for this rule's proposal. Sufficient information to replicate the model run was provided. Thus, the agency disagrees with the assertion that the model was not transparent.

Regarding the model complexity, the core structure of this specific model is comparatively simple among Bayesian hierarchical models. The model uses a multivariate normal distribution of system-level means (of log transformed data) for the four modeled PFAS. It also includes a parameter for small systems to assess whether they appear to have systematically different (higher or lower) concentrations than large systems. As stated in Cadwallader et al. (2022), the model extrapolates to the nation by sampling from the multivariate normal distribution and accounting for whether the system being simulated was small. The multivariate normal distribution and the parameter to distinguish small systems from large systems are two simple but important pieces of the model structure.

Many commenters stated that the model relied on insufficient data and produced substantial underestimates of the number of systems that would fail to meet MCL requirements. The agency disagrees both that the approach taken would systematically underestimate PFAS occurrence and that the data were insufficient to inform the model. The Bayesian approach used here makes a

precedented assumption about drinking water chemical contaminant occurrence distributions (lognormality) and uses the available data to generate iterative estimates of distribution parameters that capture uncertainty through Markov Chain Monte Carlo (MCMC) simulation. Across these iterations, the density of the posterior distribution for model parameters is proportionate to the likelihood that a given value would have produced the observed data. The subsequent national extrapolations also reflect this uncertainty. In response to commenters' concerns regarding underestimation of occurrence, the EPA has presented extrapolated preliminary UCMR 5 results alongside the EPA's estimates from the proposed rule and the final rule. Please see Figure 1 in section 6.8 of the EPA response in this *Response to Comments* document. Estimates of impacted systems and entry points from American Water Works (AWWA) report (AWWA, 2023) are also included, given that they were mentioned by several commenters. The preliminary UCMR 5 results indicate that the EPA's occurrence estimates are reasonable.

For the results presented in the March 2023 proposal preamble, the model was fit using 171,017 analytical results across the 4,920 UCMR 3 systems. This was a nationally representative set of systems. 147,887 of the analytical results were collected as part of UCMR 3 while 23,130 were aggregated from 17 subsequently collected state datasets. The model was designed to utilize both results reported as observed concentrations (8,209 results) and results reported as less than a reporting limit (162,808 results). While the UCMR 3 used higher reporting limits than are currently available, both reported concentrations and values reported as below the minimum reporting level cumulatively make substantial contributions to informing the model's estimates of the PFAS occurrence distribution because of this statistically robust framework. Due to this efficient use of data, and the steps taken to maintain a nationally representative set of systems, the agency believes that the over 170,000 analytical results were sufficient to generate reasonable estimates of occurrence for the modeled contaminants.

Several commenters expressed concern with model bias resulting from the supplemental state data that was incorporated when fitting the model. The hierarchical structure of the model minimizes the bias impact of introducing additional state data for only some UCMR 3 systems (those with additional data available) because the data are explicitly linked to their parent systems rather than being pooled with all other data informing the model. The primary impact that these data have is on the model's estimate of specific system means for those systems that had additional data and informing the within-system variability parameters in the model. Refinement of a single system's mean estimate has a much smaller impact on the high-level distribution of system-level means and such shifts are proportionate to the added evidence derived from the supplemental data.

The addition of data from systems not included in the UCMR 3 would pose a much greater concern for bias, since not all states have publicly available data. States with additional data would become disproportionately represented in the fit of the high-level distribution, since each system acts as a data point in fitting the distribution. The resulting high-level distribution would shift to resemble the states with higher system representation in the source dataset more closely.

This would also be reflected in the subsequent national extrapolation. This same bias concern applies to national extrapolation approaches where some fraction of systems in a subset are identified as exceeding a given threshold and the national inventory of systems is multiplied by that fraction to generate a national estimate of systems that would exceed the threshold. If certain states have a disproportionate number of systems included in the subset compared to in the nation as a whole, the national estimate will be biased towards the tendencies of those states. In addition to this bias, the simple example approach discussed above would not naturally reflect uncertainty. Thus, for the purpose of national extrapolation, a nationally representative set of systems is more appropriate, even if data from other systems are available.

While the EPA believes the model design and data selected for the analysis presented in the March 2023 proposal remain appropriate given the data availability at the time, the EPA has also continued to collect newly available data from publicly available state datasets, as the agency committed to in the proposed rulemaking (USEPA, 2023b). The aggregated state dataset used to inform the model now includes over 65,000 samples from 28 states. The Bayesian hierarchical model has been refit using the updated dataset with the same methods and criteria for data selection that were used for the analysis presented in the March 2023 proposal. Estimates from the updated model run support the EPA's prior conclusions with respect to occurrence of the modeled PFAS.

Individual Public Comments

New Hampshire Water Works Association, Inc. (NHWWA) (Doc. #1576, SBC-042450)

EPA lacks sufficient water quality occurrence data to accurately assesses the extent and degree of the problem – knowledge that is required to form the basis for a national standard. Statistical derivations of incomplete data sets are not a reasonable or defensible approach.

EPA Response: The EPA disagrees that the agency lacks sufficient occurrence data to "accurately assess the extent and degree of the problem." The EPA has used the best available information and best available science to establish robust national occurrence estimates. Please see sections 6.5 and 6.2 of the EPA response in this *Response to Comments* document for further discussion of the available data and how they were used.

American Water Works Company Inc. (Doc. #1608, SBC-044000)

American Water is aligned with the comments provided by AWWA on the U.S. EPA's occurrence analysis suggesting that the U.S. EPA should apply a 2-tier approach to the occurrence analysis to better leverage UCMR 3 and appropriate non-UCMR data and also utilize any available UCMR 5 data in a revised analysis before the rule is finalized.

Additionally, American Water believes that relying on PFAS data from recent monitoring programs may significantly underestimate the number of surface water treatment plants that will require treatment if the data is not statistically adjusted to consider the effects of low flow

conditions in surface water supplies during drought periods. Our available surface water data in several locations shows a clear seasonal effect, which is consistent with PFAS concentrations increasing when surface source water flows decrease during drier seasons. While we do not have enough historical data to accurately project PFAS concentrations within our surface water supplies across the full range of expected flows, we can reasonably assume that this seasonal effect will be even more exaggerated during drought events. This indicates that a number of facilities that have had historical PFAS sampling concentrations below the proposed MCLs and/or PQLs, and thus excluded from the U.S. EPA occurrence analysis, may yield PFAS concentrations at or above the proposed MCLs during even brief drought conditions.

EPA Response: For the EPA's responses to other commenters, please see their respective comments in this *Response to Comments* document. Regarding seasonal variability, exceedance of the MCLs presented in the final rule is based upon running annual averages (RAAs). Systems monitoring quarterly will have samples from each season equally contributing to their RAA calculation. This provides systems with flexibility compared to if compliance was based on individual sample results. UCMR 3 and state data that were used to inform the national model came from all quarters of the year.

Prince William County Service Authority (Doc. #1609, SBC-042833)

PFAS Occurrence Data Projections

EPA's use of a statistically generated occurrence model underestimates the number of utilities that will be required to implement PFAS treatment. The Unregulated Contaminant Monitoring Rule 3 (UMCR3) dataset that served as the baseline for this statistical generation uses data from a time when minimum reporting limits for these PFAS compounds were two to twenty times higher than today. The supplemental data EPA used comes from only 18 states. Regrettably, none of this data is from Virginia. Of further concern, the supplemental data includes PFAS monitoring from drinking water analysis methods that are not EPA approved.

EPA Response: Please see section 6.5 of the EPA response in this *Response to Comments* document. After considering public comment, the EPA collected additional state data as part of the final rule updates. The supplemental state data used to inform the national occurrence model now comes from 28 states, including Virginia. For the proposed rule, this state data had come from 17 states. For steps the EPA took to transparently ensure QC of the state data, please see section 6.2 of the EPA response in this *Response to Comments* document. The vast majority of the data were collected using EPA approved methods.

Prince William County Service Authority (Doc. #1609, SBC-042843)

3. In the absence of current national PFAS occurrence data for drinking water, which EPA will obtain in the recently initiated UCMR5 effort, we believe EPA's statistical model significantly understates the number of water utilities impacted by the proposed rule. As a result, the cost to implement the PFAS rule will likely greatly exceed EPA's estimates.

EPA Response: Please see section 6.5 of the EPA response in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043094)

Next, several of EPA's underlying analyses to support the rulemaking need improvement to be credible. The occurrence analysis lacks transparency on the levels of PFAS in communities nationally and criteria for data inclusion/exclusion is not clear. The approach to assessing national occurrence of PFAS is overly complicated.

EPA Response: Please see sections 6.5 and 6.2 of the EPA response in this *Response to Comments* document.

Orange County Water District (OCWD), California (Doc. #1634, SBC-043232)

To remedy the regulation's current occurrence estimate limitations, EPA should at least provide more transparent details of the Bayesian Model, including information on the model outputs with respect to the number and type of water systems impacted by the various regulatory options.

EPA Response: Please see section 6.5 of the EPA response in this *Response to Comments* document. Additionally, information about the Bayesian model is included in the docket for this rulemaking action.

Orange County Water District (OCWD), California (Doc. #1634, SBC-043230)

Estimated Cost

For several reasons, EPA has significantly underestimated the cost of the proposed regulation, including:

• An accurate estimate of nationwide occurrence of PFAS in drinking water underpins the entire regulation and is especially key to the cost estimates. Due to the current lack of reliable nationwide PFAS occurrence data in drinking water using detection limits relevant to the proposed maximum contaminant level goals (MCLGs), EPA has applied an opaque and overly complex Bayesian Hierarchical statistical model to estimate nationwide occurrence of PFAS. EPA's limited supporting information provided for the model, along with a single referenced scientific publication about the model, represents wholly inadequate technical documentation of such a foundational component of the regulation. The modeling effort requires many stated and unstated assumptions to utilize older, higher detection limit UCMR3 data with select recent state-level data collected from the same systems using lower detection limits. The wholesale exclusion of data from states like California, which have performed significant targeted PFAS drinking water monitoring is problematic and represents a lost opportunity for a more robust analysis. Similarly, the exclusion of non-UCMR3 sites from the state datasets analyzed represents an unnecessary and insufficiently justified limitation. Collectively, we believe these deficiencies

(and perhaps others) lead to a systematic underestimation of the number of systems impacted and thus an underestimate of the national costs of compliance. Furthermore, the occurrence and cost underestimates present inaccurate information to federal policymakers and elected officials assessing the scope of the problem and determining the amount of federal support available to affected systems.

EPA Response: Please see section 6.5 of the EPA response in this *Response to Comments* document for a response related to the Bayesian model and the supporting information that was provided with it. Please see section 13.3 of the EPA response in this *Response to Comments* document for responses related to the EPA's cost estimates. For information about how the EPA establishes a Maximum Contaminant Level Goal (MCLG), please see section IV of the preamble for this action. The EPA disagrees that California data was excluded from the model; see Cadwallader et al. (2022) which describes that supplemental state data from California was included to inform the model fit for the rule proposal. For the final rule, California is the state with most samples included from supplemental state data.

Massachusetts Water Resources Authority (Doc. #1645, SBC-043282)

2. MWRA Comments

a. Occurrence Analysis is Not Transparent and Based on Limited Data

As proposed in the NPDWR, EPA uses an overly complex statistical approach to characterize national low-level PFAS occurrence. The occurrence analysis and how it is used in subsequent analyses has not been adequately explained in the materials provided by EPA.

EPA Response: The EPA disagrees that the statistical model is overly complex. Bayesian statistical models are commonly used in multiple professional fields, including being previously used to inform prior EPA regulations. For further discussion, please see section 6.5 of the EPA response in this *Response to Comments* document.

Aurora Water, City of Aurora, Colorado (Doc. #1669, SBC-043708)

EPA is estimating that 5,000 water systems will be impacted by this proposed rule. The reality will likely be around 7,000 water systems that are impacted. One problem with EPA's estimates for how many systems are impacted and what the costs will be is that they have not completed their occurrence data assessment for PFAS chemicals. Since the UCMR 5 sampling program has not been completed it is clear EPA does not have a complete dataset for the PFAS levels across the country. Based on voluntary sampling for PFAS in public water systems in Colorado, it is estimated that there will be 60 water systems that will exceed the proposed MCLs for PFOA and PFOS.

EPA Response: Please see sections 6.5 and 6.8 of the EPA response in this *Response to Comments* document.

Massachusetts Coalition for Water Resources Stewardship (MCWRS) (Doc. #1691, SBC-044322)

2. EPA's estimate of impacted water systems falls at up to 6,300 with most being systems serving less than 10,000 people. This represents less than 10% of the 66,000 water systems subject to the proposed MCL rule. This appears to be extremely low given recent Massachusetts data based on a few years of PFAS monitoring. Massachusetts Department of Environmental Protection (MassDEP) reports that 29% of community and NTNC water systems will have to abandon sources, find new sources, connect with other systems or install treatment facilities to meet the proposed MCLs. This MassDEP figure likely underestimates the true number of water systems impacted in Massachusetts as it does not consider those systems that may see variable levels of PFOA and PFOS that could trigger an MCL violation in future testing rounds. Massachusetts is seeing PFAS in communities of all sizes and land use histories, from urban to rural areas, groundwater and surface water systems, towns with airports and military bases and those far removed from either. There is nothing unique about Massachusetts when it comes to PFAS in water supplies and no reason to believe that nationally only 9.5% of water systems will be impacted by the proposed MCL while Massachusetts will see nearly 30%.

EPA Response: The EPA disagrees that its PFAS occurrence estimates are extremely low. See section VI of the FRN and section 6.5 of the EPA response in this *Response to Comments* document for further discussion. Furthermore, Massachusetts was among the states with the most frequently reported the presence of PFOA and/or PFOS in non-targeted datasets (see section VI of the preamble). It is likely that MA is on the high end of the distribution for state-level occurrence frequencies. Further, available state data from MA were used to inform the national model fit for the proposed rule and additional data were collected to inform the final rule. It is among the states with the most available state data samples to inform the model.

Wyoming Department of Environmental Quality (WDEQ) (Doc. #1716, SBC-044755)

7. EPA Should Revise the Potential Number of PWSs That May Be Required to Address PFAS Contamination

EPA states that "The resulting range of systems estimated to be impacted by the proposed regulation of an MCL concentration of 4.0 ppt for PFOA and PFOS and an HI of 1.0 for a mixture of PFHxS, HFPO DA, PFNA, and PFBS was 3,400-6,300 systems serving a total population of between 70 million and 94 million people. Among these systems, between 100 and 500 were estimated to be systems exceeding the HI for PFHxS, HFPO-DA, PFNA, and PFBS that had not already exceeded the proposed MCLs for PFOA and/or PFOS." However, in its evaluation of non-targeted data from 12 states, EPA describes that "when evaluating only a subset of the available state data representing non-targeted monitoring, that one or more PFHxS, HFPO-DA, PFNA, and PFBS were reported in approximately 13.9% of monitored systems; if these results were extrapolated to the nation, one or more of these four PFAS would be detectable in over 9,000 PWSs." Considering that HBWCs are relatively close to the minimum

reporting limit of EPA Methods 533 and 537.1 for three of the four PFAS, which would result in a HI greater than 1.0, it seems reasonable to assume that EPA's estimation of the number of facilities impacted maybe an underestimate.

WDEQ recommends that EPA reevaluate the number of PWSs that may be required to address PFAS impacts above the proposed MCL concentrations and proposed HI value. This information is necessary for states to better understand potential impacts from the proposed rule.

EPA Response: In regard to Wyoming Department of Environmental Quality's (WDEQ's) recommendation to reevaluate the number of PWSs that may be above the MCLs for this action, please see sections 6.5 and 6.6 of the EPA response in this *Response to Comments* document. Based on this additional work triggered by this and other comments, the EPA's final estimates of the total impacted PWSs has increased slightly from the proposal; however, the general range is similar. Anticipated Hazard Index MCL exceedances at systems not already exceeding an MCL for PFOA or PFOS decreased due to the use of a single significant figure in the final rule as opposed to two significant figures in the proposed rule (please see section 6.4 of the EPA response in this *Response to Comments* document). See discussion in sections VI.E and VI.F of the preamble for this rulemaking action. Furthermore, state datasets used a variety of reporting limits, which are based on reporting practices as well as individual laboratory capabilities. The broader minimum reporting level used for the UCMR program is tailored to be achievable by the majority of laboratories nationwide. For this reason, there is a wider range of values that may be reported that remain under the Health-Based Water Concentrations (HBWCs). Please see section VI.D of the preamble for a direct discussion of occurrence relative to the Hazard Index. Additionally, of the 13.9 percent described in the proposal preamble, which depicts detections at any reported concentrations and not just at or above the HBWCs, 11.1 percent were systems that had also observed PFOA and/or PFOS and 2.8 percent were systems that had not also observed PFOA and/or PFOS. The fraction of systems reporting the presence of a Hazard Index PFAS is not a suitable proxy for the fraction of systems that will exceed the Hazard Index MCL without also exceeding an MCL for PFOA or PFOS.

Thurston Public Utility District (PUD), WA (Doc. #1729, SBC-043576)

A Government Accountability Office (GAO) study of drinking water data collected from six states showed at least 18 percent of 5,300 water systems studied had PFOA and/or PFOS exceeding the proposed MCLs of 4 ppt alone. Levels of initial noncompliance may be even higher than anticipated due to sampling bias since the proposed limits are the lowest level many laboratories can reliably detect, and many systems have not already pursued such sensitive testing for all six chemicals listed.

EPA Response: The six states in the Government Accountability Office (GAO) study include Massachusetts, New Jersey, and New Hampshire. These states were captured in the EPA's analysis as having elevated frequencies of detection (see preamble VI.B). In the GAO report, Massachusetts, New Hampshire, and New Jersey had 37 percent, 35 percent, and 40

percent of systems, respectively, observe an occurrence at or above 4 ppt (combining for 852 of the 978 systems that observed PFOA and/or PFOS at or above 4 ppt). Illinois, Ohio, and Vermont reported such occurrences in 4 percent, 3 percent, and 6 percent of systems in the study, respectively. Note that these percentages include systems that observed concentrations at the MCL, while compliance is assessed by exceeding the MCL. Further, observed occurrences do not necessarily indicate that a system would exceed an MCL since exceedances are determined by RAAs. For the EPA's analyses, supplemental state data from each of these six states were used to inform the national model fit.

Florida Section American Water Works Association - Water Utility Council (FSAWWA WUC) (Doc. #1737, SBC-044486)

The cost and timelines analysis should please consider the following:

• PFAS Nationwide Occurrence:

The Florida Water Sector believes EPA underestimated the amount of Public Water Systems (PWS) affected by the proposed rule. EPA used a "Bayesian hierarchical estimation model" fitted using PWS' Unregulated Contaminant Monitoring Rule, UCMR 3 data. However, the EPA UCMR 3 Minimum Reporting Level (please see https://www.epa.gov/dwucmr/third-unregulated-contaminant-monitoring-rule for PFOS (40 parts per trillion. ppt) and for PFOA (20 ppt) were an order of magnitude higher than the proposed maximum contaminant level (4 ppt). EPA should work with state primacy agencies to determine nationwide occurrence based on knowledge of current treatment methodologies' abilities to meet the proposed 4 ppt regulation and expected treatment changes to do so.

EPA Response: Please see section 6.5 of the EPA response in this *Response to Comments* document.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045221)

2. CT DPH agrees that EPA has demonstrated that the 6 proposed regulated "contaminants will occur and co-occur with a frequency and at levels of public health concern in PWSs." The EPA meets the second Statutory Criterion – Occurrence.

A preliminary analysis of the testing data that Connecticut public water systems voluntarily reported to the CT DPH is consistent with the national statistics in that the majority of MCL exceedances will be due to PFOA and/or PFOS concentrations. The limited drinking water results for Connecticut show that three of the four PFAS with proposed MCLs are often found as mixtures and co-occur in the sample with PFOA and PFOS.

The combined contamination occurrence model and state sampling evidence cited by EPA suggests a maximum of ~6,300 public water systems will be impacted by the proposed MCLs, or approximately one-tenth, of the ~66,000 public water systems impacted by these proposed MCLs. According to table 7, four states have measured PFOA and PFOS above the MCL at rates

higher than the maximum of the model. With UCMR3 data having relatively high reporting limits (20 or 40 ppt), the national data set is limited below the UCMR 3 reporting limit where "background" contamination of PFAS may impact PWS. It is possible that this model underrepresents the impact of PFAS on the finished drinking water, and this should be taken into account when calculating the costs of treatment.

EPA Response: Please see section 6.5 of the EPA response in this *Response to Comments* document. The upper end of the interval presented for the proposed rule does not constitute a maximum value. Rather, it is the upper end of a confidence interval. See subsection 10.3.2. of the *Occurrence Technical Support Document* (USEPA, 2024b) for further discussion. The majority of the supplemental state data from 28 states incorporated to inform the model utilized minimum reporting levels on the order of single digit ng/L. Regarding the EPA's regulatory determinations for PFHxS, PFNA, HFPO-DA, and mixtures of these three PFAS and PFBS, please see section 3.1.2 and 3.2.2 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045579)

3. Non-UCMR 3 data should be leveraged more effectively. Specifically:

a. The agency should leverage existing methodologies used to by the UCMR program to incorporate data from systems beyond the scope of UCMR 3 as part of the Bayesian Model in a way that maintains the national representation of the data and provides additional confidence.

b. If the agency determines that there are insufficient resources within the agency to do this, the non-UCMR 3 data that is excluded from the Bayesian Model should be used to evaluate the Model outputs.

4. The non-UCMR 3 data that is included in the Bayesian Model and considered to be nationally representative should be evaluated and EPA should substantiate the basis for its inclusion.

5. The agency should consider a 2-tier approach that relies on best-available, system specific data on PFAS levels and TOC levels and relies on a probabilistic distribution approach to the remaining systems without known PFAS and TOC levels.

EPA Response: Please see section 6.5 of the EPA response in this *Response to Comments* document. Non-UCMR 3 data from systems that were not used to fit the national occurrence model were used and presented in several other analyses that were presented in the preamble as well as the *Occurrence Technical Support Document* (USEPA, 2024b). Please see section 6.2 of the EPA response in this *Response to Comments* document for discussions about state data and the QC efforts taken by the EPA. Because the total organic carbon (TOC) levels for all systems are not available, the EPA used TOC data provided by states in response to the fourth Six-Year Review to derive TOC probability distributions for influent into a PFAS treatment process; one distribution for ground water systems and another for surface water

systems. For further discussion about the use of TOC data, please see section 13.7 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045577)

Distinguishing Between PFAS Detections and Levels of Health Risk Concern

The SDWA only allows EPA to regulate a substance when "the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern." [FN13: 42 U.S.C. § 300g–1 (b)(1)(A)(ii).] The agency's discussion about the occurrence of PFAS in drinking water frequently discusses the likelihood of detections of PFAS. While this is useful, it would be more relevant, and therefore beneficial, for EPA to provide information about PFAS occurrence at levels closer to the relevant health risk levels, particularly the proposed MCLGs or MCLs. While occurrence at any level is useful to understand, it is misleading to the public and it is important that occurrence be contextualized with the relevant levels of health concern, given that that is the proper statutory focus under the SDWA. A detection of PFBS at 5 ppt, for example, represents a level that is less than 0.25% of the EPA's lifetime health advisory level (HAL). In comparison, a detection of PFHxS at 5 ppt represents a level that is 55% of the EPA's proposed health-based water concentration (HBWC). Put plainly, a detection of PFBS represents a much different level of risk than a detection of PFHxS. For this reason, EPA should ensure that the occurrence analysis provides context on PFAS occurrence that is more useful than detection.

Providing Transparency of Occurrence Analysis Outputs

While it has been previous practice of EPA to depict the conclusions of its occurrence analysis by presenting the number of water systems (in addition to the population) impacted by the proposed rule and the rule options. EPA failed to follow that practice here and did so without providing a proper explanation for this change in its analytical approach, as required by the APA. Instead, EPA provided a breakdown of the population impacted along with a more limited set of information about the small systems that are impacted.

AWWA previously inquired about additional information on Bayesian Model in Fall 2022 and received a series of statistical outputs that did not assist AWWA in an understanding the PFAS occurrence at systems. Following the rule's publication to the Federal Register AWWA discussed the absence of this data in the Docket with EPA staff during a conference call; in discussion with staff, EPA clarified that the data, in their entirety, was not available as part of the supporting information provided for this rulemaking [FN14: Conference call on March 28, 2023, between AWWA and EPA staff]. AWWA made a written request for this data following this conference call and has not received the completed information (Moody, 2023).

It is important that relevant occurrence information underpinning a rulemaking analysis be made available for public comment and included in the record as part of any final PFAS rule, and for all future proposals for national primary drinking water regulations, so that the public can

understand the overall impact of the rule on communities and to confirm that the benefits and costs attributed to the rule are accurate.

Summary of Recommendations for Improving Occurrence Analysis

In order to comply with the requirements of the SDWA and APA, AWWA makes the following recommendations to improve quality and transparency of the occurrence analysis:

1. The agency should provide clearer and more transparent information on the intended approach of the Bayesian Model, including information on the model outputs with respect to the number and type (e.g., system size, source) of water systems impacted by the various regulatory options.

EPA Response: Please see section 6.5 of the EPA response in this *Response to Comments* document. The EPA disagrees that the occurrence analysis did not include discussion of system counts (and the population associated with them) exceeding certain PFAS occurrence thresholds. Observed PFAS occurrence relative to thresholds of interest are presented in section VII of the proposal preamble and have been updated in VI.B and VI.D of the final rule preamble. The estimated number of systems and the associated population anticipated to be impacted were presented in section VII.F of the proposal preamble (VI.F of the final preamble) as well as the *Occurrence Technical Support Document* (USEPA, 2024b).

The EPA disagrees with the commenter that the data used to inform the model was not provided. The full dataset used to inform the model run that was utilized in the proposal preamble was provided as publicly available supplemental information and uploaded to the proposal docket. Additionally, the separated dataset consisting only of supplemental state data was also provided; please see section 6.5 of the EPA response in this *Response to Comments* document for further discussion. Summary statistics for high level model parameters were provided as well. Separate UCMR 3 data is also publicly available. With the model code also provided as supplemental information, all necessary information to run the model was provided. As discussed in section 6.5 of the EPA response in this *Response to Comments* document, the EPA is confident that its methods represent best available science. While the EPA notes that assembling and conducting QC of the state datasets and developing and running the model represent thousands of hours of work, the results generated by the model are reproducible with publicly available information, provided experts in environmental statistics are available to recreate the results and invest the necessary time resources.

Summary materials for the updated model run that supported the final rule may be found in the docket.

American Water Works Association (AWWA) (Doc. #1759, SBC-045572)

4. Analysis of Occurrence Data

The SDWA requires that EPA rely upon the best available public health information, including the occurrence database [FN8: 42 U.S.C. § 300g-1(b)(1)(B)(ii)(II)]. EPA must therefore ensure

that the data on which it relies meets this standard. Because "best" is necessarily comparative, EPA must also provide sufficient explanation regarding the data selected and not selected as the basis of EPA's decision so that the public can meaningfully comment on the data selected as well as evaluate the data that EPA did not decide to rely upon.

According to the proposal, EPA applied a statistical modeling approach to characterize occurrence data for PFAS using a combination of both national occurrence monitoring data from the UCMR 3 and more recently collected state data. According to the proposal, EPA applied a statistical modeling approach to characterize occurrence data for PFAS using a combination of both national occurrence monitoring data from the UCMR 3 and more recently collected state data. While EPA typically relies on nationally representative occurrence data from the UCMR program to drive decisions for NPDWRs, the agency previously noted an interest in using data collected by state monitoring programs given the UCMR 3 database's high reporting limits relative to the potential levels of health concern (EPA, 2021e). While EPA typically relies on nationally representative occurrence data from the UCMR program to drive decisions for NPDWRs, the agency previously noted an interest in using data collected by state monitoring programs given the UCMR 3 database's high reporting limits relative to the potential levels of health concern (EPA, 2021e). AWWA appreciates the agency's interest in advancing this rulemaking by leveraging more recently collected data using improved methods. A detailed understanding of contaminant occurrence in drinking water across the country is a key factor for developing not only regulatory determinations, but also drinking water standards. In review of this approach, several opportunities to improve the analysis were identified.

Application of the Bayesian Statistical Model

The engine of the occurrence analysis for the proposal is the Bayesian hierarchical statistical model (the Bayesian Model), that uses PFAS occurrence data from more recent monitoring programs to provide improved understanding of the UCMR 3 data below the reporting limits. Similarly, the occurrence analysis is the engine of the entire rulemaking, informing the EPA's understanding of the regulatory impacts of the rule. For this reason, it is imperative that the Bayesian Model be utilized appropriately and with statistical confidence.

While the Bayesian Model approach is sophisticated technically, it is an overly complex approach for characterizing national occurrence. While the Bayesian Model approach is sophisticated technically, it is an overly complex approach for characterizing national occurrence. Bayesian models can be useful in many applications but there are some key challenges that arise with the use of these models that make it non-optimal for regulatory applications. The key challenge is that the selection of priors and the posterior conditions is a very subjective decision that is subject to the discretion of the statistician that is crafting the model. As such, it is expected that the assumptions around these decisions are documented clearly and in detail. While EPA has provided a copy of the code used for the Bayesian Model, along with a recent publication about the model, there is a lack of a non-technical description of the agency's intended approach. The lack of a clear explanation of intent regarding the model's

code leaves stakeholders unable to confirm that the code is accurately developed, and therefore unable to meaningfully comment on this aspect of the proposal.

EPA Response: Please see section 6.5 of the EPA response in this *Response to Comments* document. The Bayesian statistical model represents best available science for assessing PFAS occurrence data on the national scale. Inherently, the programming and use of the model does require specialized statistical expertise. The EPA has attempted to explain the model in less technical terms, but a minimum statistical background may be necessary to fully understand the methods and decisions made in the model. The EPA also has described the results of the model output in plain language throughout the record for this rule, and those key summaries are interpretable by a nontechnical audience.

Additionally, as stated in Cadwallader et al. (2022), weakly informative priors were used for the model. A posterior distribution is the result of combining a prior with information derived from the data that informs the model. When there is a large amount of data to inform the model, information from the data informing the model quickly "washes out" the influence of the weak prior. Gelman et al. (2013), as cited in Cadwallader et al. (2022), describes the general preference for the usage of weak priors as well as difficulties associated with the use of noninformative priors. The decision to use a weak prior was not a key challenge in the model development given the extensive dataset available and the precedent for the use of lognormal distributions to describe chemical occurrence in drinking water. Further, usage of a weak prior relative to a noninformative prior improves computational efficiency of the model (as stated in Cadwallader et al., 2022).

American Water Works Association (AWWA) (Doc. #1759, SBC-045638)

Several of the EPA's analyses underlying the rulemaking need improvement to be credible. The occurrence analysis lacks transparency on the levels of PFAS in communities nationally and criteria for data inclusion/exclusion is not clear. It is also an overly complicated approach to assessing national occurrence data for PFAS, which are currently being collected as part of the UCMR 5 program.

EPA Response: Please see section 6.5 of the EPA response in this *Response to Comments* document. The EPA affirms that its analyses are credible and represent the use of best available science. The EPA further notes that all of the available occurrence information and data sources were provided as a part of the proposed rule and are also available in in sections III.C. and VI of the final rule preamble and the *Occurrence Technical Support Document* (USEPA, 2024b). The EPA also documented the QC steps that the agency took to ensure the data were accurately and transparently presented (please see section 6.2 of the EPA response in this *Response to Comments* document).

American Water Works Association (AWWA) (Doc. #1759, SBC-045575)

Additionally, EPA has noted that the Bayesian Model's incorporation of state monitoring data excludes all non-UCMR 3 data that was collected by water systems that did not participate in UCMR 3. While EPA reanalyzes this decision by highlighting that the UCMR 3 program was designed to collect data that is nationally representative, this approach fails to realize an opportunity to leverage the vast quantity of non-UCMR 3 data that is available. A project was conducted by Corona Environmental Consultants for AWWA that collected PFAS monitoring data from both UCMR 3 and state monitoring programs (Corona, 2021). This work successfully aggregated data from these programs from nearly 8,000 public water systems from across the country. Of these systems, 668 systems had participated in UCMR 3 and had more recent data available through state monitoring programs. Additionally, data was available for more than 3,100 water systems had participated in state monitoring programs but not UCMR 3. More effective inclusion of this data would expand the more recent data set for PFAS occurrence by a factor of nearly 5, which could improve our understanding of occurrence for smaller systems significantly.

It is reasonable that the EPA is interested in leveraging the non-UCMR 3 data in a way that is nationally representative, but there are two aspects of the proposed approach that require a more detailed review. First, it is not clear why EPA is willing to leverage an overly complicated Bayesian Model to assess occurrence but at the same time is unwilling to develop a statistical approach to incorporating the additional non-UCMR 3 data in a manner that is nationally representative. EPA has existing experience under the UCMR program selecting small water systems for participation in the UCMR program that will be nationally representative. It is not apparent that EPA considered or attempted to leverage the significantly sized dataset of non-UCMR 3 data more effectively, especially to improve the occurrence analysis for smaller systems. In order to fulfill its obligations under the SDWA, EPA must likewise use a statical approach to the smaller water systems in order to make better use of this dataset.

Additionally, it is likely that the non-UCMR3 data that EPA used for the Bayesian Model is biased and not nationally representative. Consequently the data EPA used is likely not the best available public health information to support the rulemaking. Bias is present in the data collected after UCMR 3 is correlated to states with elevated concerns about statewide PFAS contamination following UCMR 3 detection and improved understanding of likely sources of PFAS in the state. While EPA notes that non-UCMR 3 data collected by systems that did not participate in UCMR 3 should be excluded because it may not be nationally representative, the agency did not determine whether the systems that were included are nationally representative. Unless EPA addresses its inconsistent treatment of available data before issuing any final rule, it risks violating both the SDWA and the APA.

Finally, the occurrence analysis was improperly used to project a probabilistic distribution of PFAS levels across all water systems in violation of the SDWA and APA. This approach may be appropriate for systems where there is not available data as that actual data is the best available

data. However, in taking this approach EPA cannot ignore data for specific system PFAS levels. These systems, that have previously collected data, should be captured in the occurrence analysis based on their previously collected data. Similarly, EPA should reflect actual data when available in its EPA's occurrence analysis of PFAS and total organic carbon (TOC). Besides ensuring that the costs for these systems are accurately reflected, this will ensure that any unique relationships that may exist between TOC occurrence and PFAS occurrence will be captured.

The SDWA explicitly provides a mechanism for EPA to obtain nationally representative occurrence data for contaminants in drinking water by requiring EPA issue a new list of unregulated contaminants to be monitored in drinking water every five years [FN10: 42 U.S.C. § 300g-1(b)(1)(B)]. This list is known as the UCMR. The UCMR serves to better inform regulatory determinations, as contaminants are evaluated based on health effects and occurrence information, and EPA has historically relied on the UCMR process to collect occurrence data on contaminants to support a determination on whether to regulate contaminants. The UCMR serves to better inform regulatory determinations, as contaminants are evaluated based on health effects and occurrence information, and EPA has historically relied on the UCMR process to collect occurrence data on contaminants to support a determination on whether to regulate contaminants. There are times when more recent or robust data may be available outside of UCMR collection, [FN11: Fed. Reg. 68060, 68062 (November 14, 2022)] and in such cases, EPA can appropriately rely on a combination of UCMR and non-UCMR data when available, so long as in doing so it provides a reasoned explanation for its approach and ensures that it is relying on the best available data for national occurrence. EPA has not done so here and must revise its data and provide greater transparency into its data in order to fulfill its obligations under the SDWA.

EPA Response: Please see section 6.5 of the EPA response in this *Response to Comments* document regarding model representativeness and data selection. The model was fit to a nationally representative set of systems and used to extrapolate across the country to generate national scale estimates. Incorporation of data from systems outside of this nationally representative set of systems would result in heavy bias of estimates towards states with additional data. The EPA disagrees that it ignored data from other systems. For analyses specific to state datasets, see the *Occurrence Technical Support Document* (USEPA, 2024b), section VI.B, and section VI.D of the final rule preamble. Regarding the dataset mentioned by the commenter, please see the EPA response to comment Doc. #1713, SBC-045902 in section 6.8 in this *Response to Comments* document. The set of nearly 8,000 systems mentioned by the commenter was developed without consideration for national representation. The set of systems included the 4,920 systems included in UCMR 3 with an additional 3,069 non-UCMR 3 systems with available data added. Of these additional systems, approximately 70 percent were from the New England region. This resulted in about 30 percent of the final set of systems being from New England. This is in comparison to the nationally representative UCMR 3 set of systems where New England's proportionate representation was closer to six percent. Thus, estimates generated by extrapolating from the set of 8,000 systems are likely heavily biased towards the New England region.

For discussion of UCMR 5, please see section 6.8 of the EPA response in this *Response to Comments* document. The EPA emphasizes that the agency must use best available science and information. Best *available* means what is currently available and not information that will be collected at some point in the future. The EPA has determined, as justified by the record for this rulemaking action, that there is sufficient information to regulate the six PFAS contained in this final regulation. Please see sections II.F and III of the FRN for further discussion.

American Water Works Association (AWWA) (Doc. #1759, SBC-046159)

4.0 Estimating National Occurrence

To estimate the costs of removing PFAS from drinking water nationally, national occurrence must be characterized. In parallel to this project, AWWA funded WITAF 057 to compile an occurrence database for PFAS in drinking water. In addition to data available for UCMR 3, WITAF 057 facilitated the collection of PFAS monitoring data from state databases and integrated these sources into a single data set. PWSs in this database included only active Community Water Systems (CWSs) and active Non-Transient Non- Community Water Systems (NTNCWSs). The inactive and transient non community water systems were eliminated from the dataset. Consecutive systems receiving all water from treated water wholesaler systems were not excluded from the database or from representation in the national cost estimation.

The WITAF 057 dataset consisted of 7,842 PWSs within these categories as compared to the 49,193 PWSs in the Safe Drinking Water Information System (SDWIS). To account for this incomplete occurrence data, the percent of systems impacted by a potential PFAS regulation within each system size category was multiplied by the active number of CWSs or NTNCWSs in EPA's SDWIS system at each size category to estimate the anticipated number of total water systems impacted in each size category. This methodology therefore assumed that existing occurrence data is representative of national occurrence. This assumption is considered conservative given a significant fraction of existing occurrence data came from UCMR 3, where the reporting limits of 20 parts per trillion (ppt) and 40 ppt for PFOA and PFOS, respectively, likely bias existing occurrence data to underrepresent true national occurrence that would be measured using the current reporting limits.

Monitoring data for PFAS compounds in the WITAF 057 database included more than 30 individual compounds but for this work was limited to the six PFAS covered by UCMR 3: PFOS, perfluoroheptanoic acid (PFHpA), PFHxS, PFNA, and PFBS. As compiled, the WITAF 057 database includes all monitoring results under UCMR 3 and various state monitoring programs, which may include multiple sample results for specific PFAS at a given PWS. Reported data were reviewed to ensure correct translation of reporting units; fields were included for PWS identification number, state, number of people served, source type, and system type. These data were analyzed to determine the maximum and average sample results for each PFAS at each PWS in the database.

EPA Response: Please see section 6.5 of the EPA response in this *Response to Comments* document. Also please see the EPA responses to comment Doc. #1759, SBC-045575 and Doc. #1713, SBC-045902 in sections 6.5 and 6.8, respectively, in this *Response to Comments* document regarding the substantial bias present in the dataset mentioned by the commenter.

Bowling Green Municipal Utilities (Doc. #1767, SBC-043927)

Occurrence Analysis is Not Transparent: An overly complex statistical approach is used to characterize national low level PFAS occurrence. The occurrence analysis and how it is used in subsequent analyses is not adequately explained. The Agency's commitment to a final rule publication in December 2023 (9 months in advance of the statutory deadline for promulgation), prevents EPA from considering Fifth Unregulated Contaminant Monitoring Rule (UCMR 5) monitoring data, that would dramatically improve the clarity and quality of the occurrence analysis.

EPA Response: Please see section 6.5 of the EPA response in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-045703)

9. Comments on Framework of a Bayesian Hierarchical Markov Chain Monte Carlo Occurrence Model (Appendix A, (U.S, 2023b))

(9A) EPA introduced bias in establishing PFOA/PFOS water concentrations

EPA states that small PWSs were selected using a population-weighted stratified random sampling design, in part because the data from these systems have lower detection limits. EPA states that non-detects are less informative than reported values. EPA states that if state data met certain specifications, then the data were comparable to UCMR 3 and could be used to inform the national occurrence model. Further, the state data were limited to those PWS already in the UCMR 3 data set.

The above approach by EPA is inconsistent with standard methods for selecting random samples for establishing an un-biased estimate of PFOA and PFOS water concentrations across the US. Limiting the state data to only those PWS selected by UCMR 3 imposes an artificial geographic restraint on the drinking water exposure distribution. EPA's logic results in only 17 states, which is likely unrepresentative of PFOS and PFOA water concentrations across the US. In fact, Table A-1 indicates that not only are few states selected, the number of systems included for each state are highly inconsistent. For example, only 1 PWS is available for the states of ME, GA, and ND; which effectively gives these states no influence on the final results, even though these states have many small communities representing a large number of populations and geographic factors.

Also, to generate an exposure distribution on a national level, a representative sample must be derived using metrics other than state population totals. The actual concentrations of PFOA or PFOS are a function of many factors, including distance from the PFAS source, topography, number of private drinking water wells in the area or state, climatology, distance to nearest large water and river systems, and other environmental factors. EPA's state data are clearly not representative of the PFAS exposure distribution on a national level. Therefore, any conclusions drawn based on these data do not represent the expected PWS concentrations across the US and cannot be used to support a MCL.

EPA does not explain what it means when it says that "… if the state data met certain specifications, EPA assumed that they were statistically comparable with the UCMR 3 data…" EPA must define what "certain specifications" means. For example, did EPA remove all PFOA or PFOS concentrations that were non-detects?

EPA uses a natural log of the PFAS concentrations. Many state-level data sets, especially those with a large number of non-detects, set the value to zero. Ln(0) is undefined. The results indicate that EPA removed all zero values from the data set because the use of a natural logarithm of zero does not exist. This approach arbitrarily deletes small values from the data set. According to best scientific practices, EPA should be using Ln(x+1) rather than the Ln(x) so as to not introduce bias into the analysis.

(9B) Conceptual Model Structure

EPA uses something called a "fixed factor shift" for small systems. This approach seems to increase the influence of small system data on the overall population mean. EPA does not explain why this adjustment is necessary (equation A-2). If the data are indeed representative of the US, no adjustment would be necessary. Equation A-2 seems to be an admission by EPA that the state data were not obtained using a pre-specified data collection plan containing DQOs, as required by EPA guidance documents. EPA must explain the degree to which equation A-2 influences the final answers.

EPA's use of small-system specific standard deviations is not clear, and it is not clear how EPA mathematically used these standard deviations. EPA states it uses within-system standard deviations pooled across size categories for PFHxS and PFHpA. Note, a within-system variance component for those systems with small sample sizes (and in particular when the small sample is composed predominately of non-detects) is unreliable at best. EPA must provide insight into the relative influence of this issue on the final results in order to assuage worries of veering from statistical best practices.

A Bayesian model is fully capable of estimating both within- and between- small system variances if the model is constructed correctly. There is no reason, outside of the model, to create covariance matrices or evaluate variance components independent of the full model. The beauty of a correctly constructed Bayesian Hierarchical Model is that the data inform the parameters and associated variance components at each level of the hierarchy. Therefore, EPA's approach as described in this section appears to be invalid.

As noted above, EPA did not include key geographic co-variates when building the Bayesian model (e.g., distance from the source, environmental metrics, climatology, etc.). These values should have been included in the model in an effort to correctly account for geographic variability among the water systems. Without these terms, or an attempt to build a model that explicitly accounts for geographic variance components, the outputs from the model are inaccurate and cannot be used to establish an exposure distribution for the US population.

EPA used "weakly informative prior distributions." EPA must provide the mathematical details of the prior distributions, and how the prior distributions were constructed. If indeed they are fully non-informative, EPA must provide the basis for using non-informative distributions. If the prior distributions do not account for natural geographic variability, then the prior distributions are incorrectly constructed and the resulting marginal predictive distributions are incorrectly constructed. Without this additional information, it is unclear whether EPA followed best available practices in the creation of its model.

EPA must provide the mathematical details of its calculations within the Bayesian model. EPA needs to provide mathematical equations showing the construction of the marginal mean distributions at each level of the hierarchy, the construction of marginal predictive distributions, the construction of the joint likelihood and prior distributions, etc. Without an explicit mathematical statement of the model, the model and its components cannot be fully evaluated.

EPA Response: Please see section 6.5 of the EPA response in this *Response to Comments* document and review Cadwallader et al. (2022). Contrary to the commenter's claim, the small systems used to fit the model were not selected because they had data with lower reporting limits. As plainly stated in Cadwallader et al. (2022) and section VI.E of the final rule preamble, they were selected because they were included in the nationally representative set of small systems incorporated into UCMR 3 sampling. The EPA disagrees with the commenter's statement that limiting data to those samples collected from systems that participated in UCMR 3 "imposes an artificial geographic restraint on the drinking water exposure distribution." UCMR 3 systems constituted a nationally representative set of drinking water systems. A description of how small systems were representatively chosen for UCMR 3 monitoring is available in Section 1. General Information of the Final UCMR 3 Rule: "Only a nationally representative sample of ''small'' community and non-transient non-community systems serving 10,000 or fewer people are required to monitor for the chemical analytes (see USEPA, 2001 for a description of the statistical approach for the nationally representative sample)." This statistical approach is outlined in *Statistical Design and Sample Selection for the Unregulated Contaminant Monitoring Regulation (1999)* (USEPA, 2001). The EPA refers the commenter to this resource for more details.

The commenter has not provided any information or support for the statement that "EPA's state data are clearly not representative of the PFAS exposure distribution on a national level." For the model fitting process, the objective of data selection for supplemental state data was to maintain a nationally representative set of PWSs that originated with UCMR 3. Cadwallader et al. (2022) explains the decisions that went into data selection for the model. Therein, treatment of non-

detects is clearly stated (taken as cumulative distribution functions up to the point of the reporting limit). Further, the commenter's assumption that non-detects were converted to zero is inaccurate and the posed recommendation (Ln(x+1)) would equate to assuming that the true concentration of non-detects is, at minimum, 1,000 ng/L. The EPA considers this to be likely inaccurate.

The commenter's claim that additional parameters are required for the model to be valid is incorrect. The purpose of the model was to generate national-scale estimates and it does so using a nationally representative set of PWSs with data available. If the objective of the model was to predict PFAS concentrations at specific systems that hadn't collected data, additional parameters would likely be necessary. However, this is not (and was never) the intended purpose of the model.

Cadwallader et al. (2022) explain the fixed-factor shift used in the model and the model as a whole. UCMR 3 included a census of large systems but a representative sample of small systems. Large systems make up a smaller fraction of the national inventory of systems than they make up of systems in UCMR 3. Not distinguishing between large and small systems in the model would result in a national extrapolation biased towards large systems.

The within-system variabilities are high-level parameters. They are estimated by pooling data from all systems in the relevant category and the uncertainties around them are explored across model iterations. Please see Cadwallader et al. (2022).

The commenter's remarks regarding Bayesian models are inaccurate. For chemicals suspected of co-occurring, it is particularly relevant to incorporate covariance in the model. Not doing so would produce drastically inaccurate results when extrapolating occurrence across the nation. The model naturally found that the chemicals co-occur but was not coerced into doing so.

Geographic variability was inherent to the set of PWS that were included in the model fit, given that it was a nationally representative set of systems. Regional parameters were thus not necessary to generate national estimates.

Non-informative priors are not the same as weakly informative priors. Weakly informative priors are what were used. Model code was provided as supplemental information to Cadwallader et al. (2022) and incorporated by reference into the rule proposal record. This code includes the priors used in the model. The nature of the model, being hierarchical, incorporates variability across the nation. This is why the model includes a high-level distribution of system-level means. Also please see the EPA response to comment Doc. #1759, SBC-045572 in section 6.5 in this *Response to Comments* document.

Fairfax Water (Doc. #1789, SBC-045313)

3. In the absence of current national PFAS occurrence data for drinking water, which EPA will obtain in the recently initiated UCMR5 effort, we believe EPA's statistical model significantly

understates the number of water utilities impacted by the proposed rule. As a result, the cost to implement the PFAS rule could greatly exceed EPA's estimates.

EPA Response: Please see section 6.5 of the EPA response in this *Response to Comments* document.

Fairfax Water (Doc. #1789, SBC-045298)

PFAS Occurrence Projections Underestimate the Cost to Implement

EPA's use of a statistically generated occurrence model underestimates the number of utilities that will be required to implement PFAS treatment. The Unregulated Contaminant Monitoring Rule 3 (UMCR3) dataset that served as the baseline for this statistical generation uses data from a time when minimum reporting limits for these PFAS compounds were two to twenty times higher than today. The supplemental data EPA used comes from only eighteen states. Regrettably, none of this data is from Virginia. Of further concern, the supplemental data includes PFAS monitoring from drinking water analysis methods that are not EPA approved.

EPA Response: Please see section 6.5 of the EPA response in this *Response to Comments* document. As part of the final rule updates, in response to this and other comments, the EPA updated the state data analyses to include available PFAS drinking water data from Virginia. The results of the updated analyses were confirmatory of the EPA's analyses to support the rule proposal. For steps the EPA took to transparently ensure QC of the state data, please see section 6.2 of the EPA response in this *Response to Comments* document. These steps included that the vast majority of the data were collected using EPA approved methods.

Earthjustice et al. (Doc. #1808, SBC-046131)

10. Are the state-level water quality data used to supplement the federal data when calibrating the Monte Carlo simulation models representative?

EPA relies primarily on federal water quality data to estimate point-of-entry concentrations of PFOA, PFOS, PFNA, HFPO-DA and its ammonium salt, PFHxS, and PFBS. EPA took an extra step and supplemented the federal data with state-level data from 11 states on point-of-entry concentrations. The state-level data are described as being useful because of the lower detection limits for identifying PFAS concentrations (pg. 4-20). At the same time, the EA would be strengthened with additional discussion regarding the representativeness of these state-level data. In particular, is there a potential selection bias to consider?

Additional qualitative discussion of this potential lack of representativeness may be sufficient. Or perhaps additional descriptive statistics can be provided to demonstrate the representativeness of the state-level data from these 11 states compared to the rest of the U.S.; perhaps by comparing PFAS concentrations across states with versus without state-level data based on the more widely available UCMR 3 federal data.

EPA Response: Please see section 6.5 of the EPA response in this *Response to Comments* document. For the proposed rule, supplemental state data for the model came from 17 states. For the final rule, supplemental state data comes from 28 states. The hierarchical nature of the model limits the bias impact. For the proposed rule, 11 states had non-targeted datasets. This has expanded to 18 non-targeted datasets. These results are presented separately from the model fit and findings.

Earthjustice et al. (Doc. #1808, SBC-046171)

[The analysis that follows shows that the $3.1 billion dollar difference in annualized cost can be explained by the following primary factors:]

2. Screening of occurrence datasets. Both EPA and AWWA relied on UCMR3 data collected by water utilities across the country. In addition, both approaches also used state data. EPA, as documented in Cadwallader et al., 2022, screened state data to only look at finished water samples and limited to UCMR3 water systems so occurrence samples would not be biased high due to non-PWS PFAS samples or PWS samples collected by water systems investigating known PFAS contamination sites (not necessarily used as drinking water sources). The inclusion of non-PWS samples resulted in higher median PFOA and PFOS data in the AWWA analysis and explains AWWA's 4,709 small systems required to comply vs EPA's 3,251 (Appendix B). The potential bias in the AWWA method indicates either the EPA approach is more appropriate, or the actual answer is somewhere between the two estimates. On the other hand, AWWA found a lower occurrence rate in large systems compared to EPA. This may be due to reliance on the UCMR3 data with higher detection limits for large system sampling. A model was described in Cadwallader et al., 2022 to fill in the non-detect median PFOA and PFOS levels. Developing a model may have been beyond the scope of the AWWA 2023 estimate, resulting in the difference in large systems exceeding the MCLs.

EPA Response: The EPA agrees with the commenter that the approach taken by the American Water Work Association (AWWA) introduces potential bias. The approach taken in the AWWA study referred to here was inherently different than the EPA's approach and utilized a simple extrapolation of a non-nationally representative set of PWSs. About 70 percent of the non-UCMR 3 PWSs included in the AWWA dataset were located in the New England region (please see the EPA response to comment Doc. #1713, SBC-045902 in section 6.8 in this *Response to Comments* document). The bias resulting from this sort of approach is also addressed in section 6.5 of the EPA response in this *Response to Comments* document.

Plymouth Village Water & Sewer District (Doc. #1827, SBC-044559)

[Please carefully consider the following points to help inform the pending rulemaking on this class of pervasive and persistent PFAS chemicals:]

• EPA lacks sufficient water quality occurrence data to accurately assess the extent and degree of the problem – knowledge that is required to form the basis for a national standard. Statistical

derivations of incomplete data sets are not a reasonable or defensible approach. In addition, EPA's proposed MCLs are vulnerable to excess false positive analytical results from factors such as Teflon-based materials commonly used in drinking water treatment systems.

EPA Response: Please see section 6.5 of the EPA response in this *Response to Comments* document. Regarding concerns related to background contamination and laboratory analysis, please see section 8.7 of the EPA response in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-044810)

[The Agency's proposal suffers from the following significant shortcomings –]

• EPA's estimate of the costs of its proposal relies on occurrence data for PFOA and PFOS that do not provide an appropriate baseline and is much lower than the costs predicted by an independent analysis,

[The Agency's proposal suffers from the following significant shortcomings –]

EPA Response: Please see section 6.5 of the EPA response in this *Response to Comments* document. For the EPA's response to comments on the number of water systems expected to be triggered into treatment, including the Black & Veatch (B&V) report see section 13.3.3 in this *Response to Comments* document. The EPA notes that the analysis referenced by the commenter is produced under contract by AWWA, an organization that represents PWSs that will be regulated by this rule. Hence, while the EPA acknowledges that different analyses have been conducted, and the EPA has considered those analyses prior to finalizing this regulation, it is inaccurate to consider this analysis as "independent," but rather, it should be considered as a different approach by another engaged stakeholder with equities in the outcome of the EPA's decisions. Please see the EPA response to comment Doc. #1713, SBC-045902 in section 6.8 in this *Response to Comments* document for more information about the bias in the dataset utilized in the analysis referenced by the commenter. The EPA's model that generated occurrence estimates for PFOA and PFOS for the final rule was informed by over 55,000 samples of both chemicals. For PFOA this included over 8,600 reported concentrations while for PFOS it included over 7,400 reported concentrations across the nation.

American Chemistry Council (ACC) (Doc. #1841, SBC-044819)

[As outlined in these comments, the Agency's proposal suffers from a number of significant shortcomings, including the following –]

• EPA's estimate of the costs of its proposal relies on occurrence data for PFOA and PFOS that do not provide an appropriate baseline and is much lower than the costs predicted by an independent analysis,

• EPA does not have sufficient occurrence data for PFBS, HFPO-DA, and PFNA to serve as a basis for estimating costs of compliance with its proposed HI MCL,

EPA Response: Please see section 6.5 of the EPA response in this *Response to Comments* document. The model that generated occurrence estimates for PFOA and PFOS for the final rule was informed by over 55,000 samples of both chemicals. For PFOA this included over 8,600 reported concentrations while for PFOS it included over 7,400 reported concentrations across the nation.

The EPA disagrees that it does not have sufficient occurrence data for PFBS, HFPO-DA, and PFNA. The EPA used occurrence data from 18 state datasets with non-targeted monitoring data to inform occurrence estimates for PFNA, HFPO-DA, and PFBS. More broadly, state data from 32 states informed the EPA's decisions in the final rule.

American Chemistry Council (ACC) (Doc. #1841, SBC-044840)

To account for these issues, EPA uses a model developed by Cadwallader et al. to estimate the national occurrence of three of the six substances included in the current proposal - PFOA, PFOS, and PFHxS. [FN164: Cadwallader A et al. A Bayesian hierarchical model for estimating national PFAS drinking water occurrence. AWWA Wat Sci 2022:e1284 (2022).] According to the Agency's description, state data on the occurrence and concentrations of the other three substances were then used to "superimpose PFNA, PFBS, and HFPO-DA concentrations onto the model output."

For their analysis, Cadwallader et al. modeled the data from 4,768 systems for which UCMR 3 data were available, supplemented by state data from 770 systems included in UCMR 3. It is likely that less than 10 percent of those modeled were systems serving less than 10,000 people. [FN165: EPA's accounting of the Safe Drinking Water Information System (SDWIS) as of January 2022 indicates a total of 4,482 CWSs serving 10,000 or more people. While the total number of systems appears to have changed somewhat between 2021 and the current proposal, that suggests that fewer than 300 systems serving under 10,000 people were included in the analysis conducted by Cadwallader et al.] As a result, the authors note that estimates for these smaller systems are "likely more uncertain." Based on this analysis, EPA concludes that 23.9 percent (22.1 to 25.9) of large systems (>10,000 people) would have an exceedance of one of the proposed MCLs while only 5.3 percent (3.4 to 7.6) of small systems (<10,000 people) would have an exceedance. [FN166: The numbers do not change significantly when considering just the MCLs for PFOA and PFOS.] Despite the cautions from Cadwallader et al., the proposal makes no effort to discuss the vast difference between the predicted impact on small vs large systems.

In contrast, the analysis by AWWA includes data from a larger number of systems (7,842) – nearly half of which serve less than 10,000 people. According to its analysis, AWWA estimates that 11 to 19 percent of small systems, and 7 to 16 percent of larger systems, will be impacted by the proposed MCLs for PFOA and PFOS. The analysis suggests that small systems are as likely, or perhaps more likely, to exceed the proposed MCLs for the two substances than large systems.

Since AWWA did not conduct an analysis for the four PFAS included in the proposed HI MCL, it is not possible to do a similar comparison for the potential impacts of that proposal. However,

a review of the available information provided by the Agency suggests a significant discrepancy in EPA's assessment. As part of its Economic Analysis, EPA provides estimates of the total number of systems impacted by the proposed option and the alternative Option 1a (PFOA and PFOS MCLs of 4 ppt only). A comparison of the two estimates indicates that EPA predicts that very few systems would be impacted by the HI MCL that would not also be impacted by the PFOA or PFOS MCLs (Table 4). According to this analysis, inclusion of the HI MCL would require fewer than 28 additional systems (<0.04 percent) to have an exceedance. This figure differs significantly from that provided in the Agency's analysis of occurrence data available in the Docket for this rulemaking. [FN167: USEPA. Per- and polyfluoroalkyl substances (PFAS) Occurrence and Contaminant Background Support Document. EPA 822-P-23-010. Office of Water (2023). (USEPA PFAS Occurrence Document).] This report estimates that between 700 and 1,300 systems would exceed the HI MCL, including between 200 and 400 systems not expected to exceed the proposed MCLs for PFOA and PFOS. [FN168: Ibid, at 206. In contrast, the text of the document indicates that the number is "approximately 100 to 500."]

Table 4. Comparison of Total Systems Impacted for Proposed Option (PFOA and PFOS MCLs = 4.0 ppt and HI of 1.0) and Option 1a (PFOA and PFOS MCLs = 4.0 ppt) [FN169: USEPA Economic Analysis, at 4-25 (Tables 4-18 and 4-19)].

[Table 4: See Docket ID EPA-HQ-OW-2022-0114-1841]

The reason for the 20+-fold difference in Agency estimates is not explained, or even acknowledged. Using this higher, and likely more accurate, estimate will have a substantial impact on the Agency's conclusions about the cost of the HI MCL proposal. The variability in the estimates of the number of additional systems that would be impacted by the proposed HI MCL, however, indicate a considerable amount of uncertainty about the Agency's analysis.

EPA Response: In contrast to the commenter's claim, the model discussed in Cadwallader et al. (2022) was fit to data from 4,920 systems. 16 percent (800) of these systems were small systems. The set of systems used for fitting was the full set of PWSs included in UCMR 3. This is clearly stated in Cadwallader et al. (2022). The added uncertainty surrounding small systems mentioned by the commenter is accounted for in the iterative nature of the Markov chain Monte Carlo model as it can be reflected as increased variability in parameter estimates (i.e., a wider spread in the posterior distribution). This uncertainty would be carried forward to subsequent analyses that maintain the iterative nature of the model. This uncertainty was also accounted for in the model design and justifies the use of parameters specific to small systems, such as the fixed factor shift and within-system variability.

The approach taken in the AWWA study referred to here was inherently different and utilized a simple extrapolation of a non-nationally representative set of PWSs. About 70 percent of the non-UCMR 3 PWSs included in the AWWA dataset were located in the New England region. The bias resulting from this sort of approach is addressed in section 6.5 of the EPA response in this *Response to Comments* document. The set of systems in the AWWA analysis is

inappropriate for national extrapolation. Please see the EPA response to comment Doc. #1713, SBC-045902 in section 6.8 in this *Response to Comments* document for further details.

The tables in section 4 referenced by the commenters show the number of water systems impacted by the proposed rule based on national occurrence model outputs for PFOA, PFOS, and PFHxS. At the time of proposal, the EPA estimated 528 water systems would exceed the Hazard Index based on PFHxS occurrence alone; these systems are not mutually exclusive with water systems exceeding the PFOA and or PFOS MCLs. As the EPA states in the FRN for proposal, the agency estimated between 100-500 were estimated to be systems exceeding the Hazard Index for PFHxS, HFPO-DA, PFNA, and PFBS that had not already exceeded the MCLs for PFOA and/or PFOS. This estimate by definition includes water systems that exceed the Hazard Index based on PFHxS occurrence alone, well as water systems that exceed the Hazard Index based on occurrence of the other compounds.

The commenter is incorrect in their assertion that the PFAS Occurrence Technical Support Document for the proposed rule (USEPA, 2023a) indicated between 200 and 400 systems were estimated to exceed the Hazard Index MCL without already exceeding an MCL for PFOS or PFOA. Exhibits 7-4 and 7-6 presented summaries of iterative results. Due to variability across iterations, these tables are not subtractive (e.g., the "Low" estimate for total systems impacted by any MCL in the rule cannot be subtracted by the "Low" estimate for systems impacted by either the PFOA or PFOS MCLs to determine the "Low" estimate for systems impacted by only the Hazard Index MCL). For this reason, the text explicitly, and correctly, describes this estimated range as 100-500 systems.

Orange County Water District (Doc. #3072-54, SBC-047387)

Good afternoon. My name is Jason Dadakis. I'm the executive director of Water Quality and Technical Resources with the Orange County Water District. We're a regional groundwater management agency located in southern California with a service area of 300 square miles and 2.5 million residents. Unfortunately, our groundwater basin, like many others around the country, has been profoundly impacted by PFAS. EPA's proposal will increase our number of impacted municipal wells from the current 58, due to state advisory exceedances, to over 100 impacted wells. This expansion requires several hundred million dollars more in treatment capital spending, above and beyond the several hundred million we've already committed, along with additional long-term operating costs. Based on our experience responding to PFAS impacts, we offer the following comments on EPA's proposed regulation. First, EPA has underestimated the cost of the proposed rule. Understanding nationwide PFAS occurrence is crucial to our robust cost-benefit analysis. EPA's statistical occurrence methodology is extremely complex, assumption heavy, and opaque. Furthermore, national cost models developed by AWWA as well as our own PFAS treatment project costs deviate significantly from EPA's projections. More accurate estimates of the Rule's costs are crucial for water systems and their rate payers as well as for policy makers weighing the appropriate level of federal support. Instead of rushing to finalize the proposed rule, we recommend EPA use the time it is afforded under the Safe

Drinking Water Act to review UCMR 5 PFAS data being collected right now to determine better national PFAS occurrence.

EPA Response: With regard to the EPA's national occurrence model, please see section 6.5 of the EPA response in this *Response to Comments* document. In regard to the EPA's cost analysis and how it compares to AWWA's analysis, the EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document and the EPA responses to comment Doc. #1713, SBC-045902 and Doc. #1759, SBC-045575 in sections 6.8 and 6.5, respectively, in this *Response to Comments* document. In regard to waiting for UCMR 5 data, please see section 6.8 of the EPA response in this *Response to Comments* document and section VI.G of the preamble for this regulation.

The District of Columbia Water and Sewer Authority (Doc. #1829, SBC-047687)

The Bayesian Model also excludes state monitoring data collected by public water systems that did not participate in UCMR3. This is because UCMR3 monitoring was designed to be nationally representative. However, the PFAS occurrence data that is available for systems beyond UCMR3 represents a significant expansion of water system data, especially for smaller systems that do not widely participate in this program.

EPA Response: Please see section 6.5 of the EPA response in this *Response to Comments* document.

The District of Columbia Water and Sewer Authority (Doc. #1829, SBC-045766)

Occurrence of PFAS in Drinking Water Supplies

There are major technical concerns regarding the Proposal that require EPA to take a fresh look at a rule that will impose enormous costs on non-profit public water systems like DC Water.

For example, EPA utilized a Bayesian statistical modeling approach to characterizing occurrence data for PFAS using a combination of both national occurrence monitoring data from the Third Unregulated Contaminant Monitoring Rule (UCMR3) and recently collected state data. EPA utilized the state data due to the high reporting limits in the UCMR3 database. This was done to develop a better understanding of PFAS occurrence in drinking water in U.S. public water systems – which is necessary for development of drinking water regulations.

The Bayesian Model is intended to provide improved understanding of PFAS occurrence at levels below the UCMR3 reporting limits. Bayesian models can be useful in many applications but there are some key challenges that arise with the use of these models that make it non optimal for regulatory applications. The key challenge is that the selection of prior and the posterior conditions is a very subjective decision and is at the discretion of the statistician that is crafting the model. While EPA provided a copy of the code used for the Bayesian Model, along with a recent publication about the model, there is a lack of a non-technical description of EPA's

intended approach. The lack of a clear intent of the model's code leaves stakeholders unable to confirm that the code is accurately developed.

EPA Response: Please see section 6.5 of the EPA response in this *Response to Comments* document. In regard to summarizing the model in non-technical terms, please see the EPA response to comment Doc. #1759, SBC-045572 in section 6.5 in this *Response to Comments* document.

6.6 Combining State Data with Model Outputs to Estimate National Exceedance of Either MCLs or Hazard Index

Summary of Major Public Comments and EPA Responses

One commenter stated that they believed it is difficult to determine whether the estimated number of systems exceeding the Hazard Index is a reasonable estimate until a complete national dataset is available. The EPA disagrees with this commenter. The agency believes that it has taken steps to produce reasonable estimates using a robust set of available data, and that the data and analyses are sufficient to inform the EPA's final regulatory decisions. Namely, this includes the use of non-targeted state datasets and multiple scenarios reflecting varying degrees of co-occurrence as described in section 10.3 of USEPA (2024b). Among other important uses for these data, the EPA considered them to inform the regulatory determination for the mixture of the Hazard Index PFAS and the EA. The EPA has used these data to clearly demonstrate that there is a substantial likelihood that combinations of the Hazard Index PFAS co-occur as mixtures in PWSs with a frequency and at levels of public health concern. See section III of the FRN for additional discussion. Additionally, these data support the EPA's EA, and considerations of costs and benefits consistent with SDWA's requirements. See section XII of the FRN for further discussion.

Individual Public Comments

Nebraska Department of Environment and Energy (NDEE) (Doc. #1653, SBC-043204)

EPA requested comment on the number of systems estimated to solely exceed the HI but not the MCLs. Without a full dataset to calculate the running annual average and given the issues with the PQL and allowable error rate noted above, this determination is difficult to provide.

EPA Response: Please see section 6.6 of the EPA response in this *Response to Comments* document.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044033)

15. EPA requests comment on the number of systems estimated to solely exceed the HI (but not the PFOA or PFOS MCLs) according to the approach outlined in USEPA (2023e).

a. It is possible that more systems may exceed the HI then the MCLs, due to current treatment technologies that are focused on removing PFOA and PFOS. Particularly when considering PFHxS.

EPA Response: Please see sections 6.6 and 6.4 of the EPA response in this *Response to Comments* document. Additionally, regarding treatment technology's ability to remove Hazard Index PFAS, including PFHxS, please see section 10 of the EPA response in this *Response to Comments* document as well as the *Best Available Technologies and Small System Compliance Technologies for PFAS in Drinking Water* document (USEPA, 2024c), the *Technologies and Costs for Removing Per- and Polyfluoroalkyl Substances from Drinking Water* document (USEPA, 2024d), and the *Drinking Water Treatability Database*.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045027)

Occurrence

As discussed above, NJDEP established an MCL of 13ppt for PFNA in 2019, and MCLs of 14 ppt and 13ppt for PFOA and PFOS, respectively, in 2020. In the time that these standards have been in effect and implemented, 17 New Jersey water systems have exceeded the MCL for PFNA, 56 water systems have exceeded the MCL for PFOA, and 44 water systems have exceeded the MCL for PFOS. Several water systems have had exceedances of more than one PFAS.

EPA has requested comments on the number of systems estimated to solely exceed the HI but not the PFOA or PFOS MCLs. NJDEP does not have complete data sets for all 4 PFAS included in the HI. The available data is from water systems submitting additional PFAS under method 537 and 537.1 during routine compliance monitoring. Based on available data, zero systems will exceed PFBS based on 750 water systems submitting data, and 41 systems will exceed PFHxS based on 759 systems submitting data. The NJDEP does not currently have data available on GenX chemicals. Four systems will exceed the HI MCL based on PFNA alone. The four systems that will exceed for PFNA do not include those New Jersey systems that exceeded New Jersey's MCLs and are currently in the process of installing treatment. To date, New Jersey has had 17 water systems receive violations for exceeding the MCL for PFNA.

EPA Response: The EPA acknowledges the New Jersey Department of Environmental Protection (NJDEP) for providing information on systems estimated to solely exceed the Hazard Index MCL.

6.7 Additional Occurrence Data

Summary of Major Public Comments and EPA Responses

The EPA received several comments related to additional occurrence information. These include comments from a private citizen, water utilities, and non-governmental organizations. As noted in the Occurrence Technical Support Document, data sources reviewed by the agency for

information on PFAS occurrence in drinking water included UCMR 3, state drinking water monitoring programs, and the Department of Defense PFAS drinking water testing, as well as additional studies from the literature. Some of these data sources were mentioned by commenters and have already been considered by the EPA. For the final rule, based on these and other comments, the EPA continued to aggregate data from known, publicly available sources after the proposed rule was released. These additional data were incorporated into updated summaries and analyses, as appropriate, and were generally confirmatory of the EPA's conclusions in the proposed regulation.

Individual Public Comments

Linda Shosie (Doc. #1533, SBC-043959)

The information was hard to come by, but after multiple requests, in 2018 Tucson Water- the city agency responsible for providing drinking water to Tucson residents disclosed that there were also very high levels of PFOA, and PFOS in our water supply.

In one location, Tucson Water detected 13,000ppt of PFOS in the groundwater- 650,000 times higher than the current EPA's Health Advisory Levels (HAL) of 0.02 ppt. Since 1994, Tucson Water sent treated drinking water from the Tucson Airport Remediation Process (TARP) Water Treatment Facility, Superfund Site, to over 50,000 of their costumers containing up to 30 ppt of PFAS, more than, 1,000 times higher than EPAs HAL for either PFOA or PFOS. Tucson Water was forced to remove drinking water wells from service following the detection of these extremely high levels of PFOA and PFOS, but elevated levels of both chemicals remain in our drinking water. ADEQ has also detected unsafe levels of PFAS in several drinking water monitoring wells and private drinking water wells in Tucson.

EPA Response: Please see section 6.7 of the EPA response in this *Response to Comments* document. The EPA considered occurrence data from Arizona in its proposed and final rulemaking. See the *Occurrence Technical Support Document* (USEPA, 2024b) for more information. As described in this rule, systems exceeding the MCLs for the regulated PFAS will be required to take action to protect public health.

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-042878)

Because Massachusetts has a drinking water standard, we have sampling results for PFAS detected under Method 537 or 537.1. A local media outlet, WBUR, created a map (GRAPHIC 2) which provides a good graphical representation of detections in Massachusetts; this is useful for looking at the extent of PFAS in Community (COM), Non-Transient Non-Community (NTNC), and Transient Non-Community (TNC) PWS across the Commonwealth [FN14: https://www.wbur.org/news/2023/02/14/pfas-pfoa-massachusetts-drinking-water-clean-up]:

[Figure 2: See Docket ID EPA-HQ-OW-2022-0114-1601]

GRAPHIC 2: Map produced by WBUR of maximum PFAS level detected in each Massachusetts Community based on results from the Executive Office of Energy and Environmental Affairs data portal.

Data shows that 170 PWS have detected PFAS6 above the MMCL. MassDEP has looked at Massachusetts PWS sampling results and determined that 29% of our Community and Non-Transient Non-Community PWSs could be impacted by the draft EPA PFAS MCL. Some PWS in Massachusetts have already addressed PFAS to comply with the MMCL of 20 ppt for PFAS6; however, they will likely have to do even more to comply with EPA's proposed PFAS standard, which are lower than the MMCL. Those numbers are not reflected in MassDEP's chart of the potential universe of impacted PWS. MassDEP acknowledged to MWWA in a phone conversation [FN15: Jennifer Pederson, MWWA Executive Director, phone conversation on April 21, 2023 with Margaret Finn, PFAS Lead for MassDEP's Drinking Water Program] that it may have underestimated the number of systems impacted if it was to revisit those PWS already in compliance with the MMCL. Here is the data that MassDEP presented in a webinar on April 10, 2023 (GRAPHIC 3) [FN16: https://www.mass.gov/doc/presentation-on-epa-proposed-mcls-for-pws/download].

[Figure 3: See Docket ID EPA-HQ-OW-2022-0114-1601]

GRAPHIC 3: MassDEP presentation slide showing the approximate number of Community (COM) and Non-Transient, Non-Community (NTNC) Systems impacted by EPA's proposed MCLs.

Further, because MassDEP requires PWS to ensure that their laboratory uses a lower Method Detection Limit (MDL) of 2 ppt, MassDEP stated that 317 COM, NTNC and TNC PWS have detected PFOA and/or PFOS > 2 ppt but < 4 ppt at one or more of their finished water sources.

Staff from the Massachusetts office of Kleinfelder analyzed the data from the Massachusetts Executive Office of Energy and Environmental Affairs data portal and found that 45% of COM PWS in Massachusetts had detections above 4 ppt of PFOA/PFOS. [FN17: Presentation by Ben Powers, EIT, Kleinfelder, "PFAS Treatment in New England: A Regional Survey," April 2023, New England Water Works Association, Spring Conference.]

MassDEP was instructed by the Massachusetts legislature to conduct sampling of private wells for PFAS. The agency concentrated its efforts in towns that are predominantly served by private wells and offered a voluntary sampling program. Of the private wells tested, there were 311 private wells that had PFAS6 detections above 4 ppt.

EPA Response: Please see section 6.7 of the EPA response in this *Response to Comments* document. The EPA considered occurrence data from Massachusetts in its proposed and final rulemaking. See the *Occurrence Technical Support Document* for more information (USEPA, 2024b).

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043646)

i. McMahon et al (2022) analyzed 254 samples collected from five aquifer systems to evaluate PFAS occurrence in groundwater used as a source of drinking water in the eastern United States. McMahon et al (2022) detected 14 (of the 24 PFAS species they analyzed for) in groundwaters and reported 60% of public-supplies and 20% of domestic wells, respectively, contained at least one PFAS detection.

Da Silva et al (2022) monitored for the presence of 51 PFAS species in the Pensacola Bay System in Florida. Surface water was collected and analyzed from 45 different sites. PFOA and PFHxA were present in all samples; moreover, at least eight or more PFAS species were quantified at each site analyzed.

EPA Response: Please see section 6.7 of the EPA response in this *Response to Comments* document. The EPA discusses the work by McMahon et al. (2022) in the *Occurrence Technical Support Document* for the proposed and final rule (USEPA, 2023a; USEPA, 2024b). As described in this rule, PWS that exceed the MCLs for the regulated PFAS will be required to take action to protect public health.

Prince William County Service Authority (Doc. #1609, SBC-042839)

The Service Authority PFAS Data and Costs of Treatment

The Service Authority's PFAS data from UCMR3 yielded non-detections on PFOA and PFOS. Since 2018, the Service Authority has been proactively and voluntarily monitoring for PFAS at our entry points. We also participated in the Virginia Office of Drinking Water (ODW) PFAS monitoring and occurrence study in 2021. Our monitoring data for treated water from Fairfax Water's Griffith Plant located in Lorton Virginia, which is sourced by the Occoquan Reservoir, has found a range of 4.3 ppt to 5.8 ppt for PFOA and 4.1 ppt to 5.9 ppt for PFOS, with average PFOA and PFOS concentrations of 5.3 ppt and 4.9 ppt, respectively. Monitoring data for treated water from Fairfax Water's Corbalis Plant, sourced by the Potomac River, found a range of non-detect to 2.2 ppt for PFOA and non-detect to 1.9 ppt for PFOS, with average PFOA and PFOS concentrations of 1.4 ppt and 0.6 ppt, respectively.

EPA Response: Please see section 6.7 of the EPA response in this *Response to Comments* document. In response to this and other comments, the EPA considered state drinking water occurrence data from Virginia in its final rulemaking. Those data supported the EPA's conclusions in the proposed regulation. See the *Occurrence Technical Support Document* for more information (USEPA, 2024b).

New Hampshire Department of Environmental Services (NHDES) (Doc. #1690, SBC-044346)

2. Page 18730, Column 2, Section VII—Occurrence

a. NHDES Comment - Please see the occurrence data below. The data are based on the most current water quality monitoring compliance sampling for PFAS that public water systems have completed to comply with NHDES's MLCs since October 2019. Please note that the summary provided below does not include PFAS results for over 100 sources of water that have either been deactivated or results from sources prior to having treatment installed to comply with NHDES' MCL. This means that the actual occurrence of PFAS in New Hampshire water systems was once much higher and contamination levels were also higher than reflected in the data below.

[Table: see docket ID EPA-HQ-OW-2022-0114-1690]

EPA Response: Please see section 6.7 of the EPA response in this *Response to Comments* document. In response to this and other comments, the EPA considered occurrence data from New Hampshire as part of its proposed and final rulemaking. Those data supported the EPA's conclusions in the proposed and final regulation. See the *Occurrence Technical Support Document* for more information (USEPA, 2024b).

PFAS Project Lab (Doc. #1786, SBC-044712)

Moreover, the mobility and persistence of PFAS released has resulted in widespread contamination of drinking water. In 2018, a joint USGS and EPA study measured 17 PFAS compounds in 25 paired samples of source and treated drinking water and found detectable levels of PFAS in 100 percent of samples (Boone et al. 2019). Furthermore, a 2020 analysis of public data sets of PFAS occurrence in drinking water in the U.S. revealed mixtures of PFAS are nearly ubiquitous in surface water, the predominate source of drinking water in the U.S., when testing with detection limits below 1 ng/L (Andrews & Naidenko 2020). It is estimated that over 200 million individuals receive drinking water with PFOA and PFOS levels at or above 1 ng/L (Andrews & Naidenko 2020), above EPA's proposed MCLGs for these compounds.

EPA Response: The EPA references the aforementioned study from Boone et al. (2019) in several sections of the *Occurrence Technical Support Document* (USEPA, 2024b) as an additional secondary drinking water study. With regard to the 2020 analysis mentioned in this comment, the EPA generally agrees that PFAS are ubiquitous in the environment. The agency's evaluation of finished drinking water data for the six PFAS included in this rule has found them at varying levels of detection with 4,100-6,700 PWSs serving a total population of 83-105 million people expected to exceed one or more of the final MCLs. As described in this rule, systems exceeding the MCLs for the regulated PFAS will be required to take action to protect public health.

Fairfax Water (Doc. #1789, SBC-045305)

Fairfax Water PFAS Treatment Evaluations and Cost Projections

Fairfax Water's PFAS data from UCMR3 yielded non-detections on PFOA and PFOS. Since 2021, Fairfax Water has been proactively and voluntarily monitoring for PFAS in our finished water on a quarterly basis and providing the results on our website. We also participated in the Virginia Office of Drinking Water (ODW) PFAS monitoring and occurrence study in 2021. Fairfax Water's monitoring data for treated water from its plant sourced by the Occoquan Reservoir has found a range of 3.7 ppt to 5.8 ppt for PFOA and 3.0 ppt to 5.1 ppt for PFOS, with average PFOA and PFOS concentrations of 5.1 ppt and 4.1 ppt, respectively. Monitoring data for treated water from our plant sourced by the Potomac River found a range of non-detect to 1.9 ppt for PFOA and non-detect to 2.6 ppt for PFOS, with average PFOA and PFOS concentrations of 0.6 ppt and 1.3 ppt, respectively.

EPA Response: Please see section 6.7 of the EPA response in this *Response to Comments* document. In response to this and other comments, the EPA considered state drinking water occurrence data from Virginia in its final rulemaking. Those data supported the EPA's conclusions in the proposed regulation. See the *Occurrence Technical Support Document* for more information (USEPA, 2024b).

New England Water Works Association (Doc. #1836, SBC-045379)

Because the New England states have been ahead of EPA in regulating PFAS, there is more complete occurrence data in the Northeast than would be available in the rest of the country. One of NEWWA's members, a consulting engineering company, performed a survey of New England utilities to determine costs associated with addressing PFAS. They presented their results at NEWWA's Spring Conference in April 2023. In their presentation, they highlighted the occurrence data for PFOA and PFOS on the following chart which was created with data obtained by the New England states and the EPA PFAS analytical tool. As you can see, nearly 30% of our community PWS will be affected if EPA finalizes its proposal as presented.

[Figure 1: see docket ID EPA-HQ-OQ-2022-0114-1836]

Figure 1: Community Water Systems in New England with detections over 4 parts per trillion, Kleinfelder 2023

EPA Response: Please see section 6.7 of the EPA response in this *Response to Comments* document. The EPA acknowledges the efforts of New England states and PWSs to proactively address PFAS drinking water contamination. In response to this and other comments, in its final rulemaking, the EPA considered state datasets from states in New England, including Maine, Massachusetts, New Hampshire, and Vermont. Those data supported the EPA's conclusions in the proposed regulation. See the *Occurrence Technical Support Document* for more information (USEPA, 2024b).

Midwest Environmental Advocates +more (Doc. #1846, SBC-045841)

Appendix A

1. City of Madison

Madison is located in the South Central Region of Wisconsin and its water utility serves approximately 235,000 non-transient people. All the system's drinking water comes from groundwater. There have been frequent detections of PFOS, PFOA, and PFHxS in this municipal water system since 2019. As a result of high detections, the water utility shut down one well.

Below is a more detailed account of the detections from this water system: [FN i: City of Madison, Water Utility: Perfluorinated Compounds, https://www.cityofmadison.com/water/water-quality/water-quality-testing/perfluorinated-compounds#:~:text=Madison%20Water%20Utility%20found%20a%20total%20PFAS%20concentration%20in%20Well,37%20ppt%20coming%20from%20PFBA; Wisconsin Department of Natural Resources, Drinking Water System Portal, https://dnr.wi.gov/dwsviewer/ ("WDNR Drinking Water System Portal").]

[Figure 1: see docket ID EPA-HQ-OW-2022-0114-1846]

PFHxS = 20 ppt PFOA 6.1 ppt PFOS = 5.9 ppt

[Figure 2: see docket ID EPA-HQ-OW-2022-0114-1846]

2. City of Eau Claire

Eau Claire is located in the West Central Region of Wisconsin and its water utility serves approximately a non-transient population of 66,060. All the system's drinking water comes from groundwater. There have been worrisome detections of PFOS, PFOA, and PFHxS in this water system. The highest PFAS concentration from this system's water wells are of PFOS at 60 ppt and PFHxS at 98 ppt, detected in July of 2021. As a result of high detections, the water system shut down four wells. Despite this action, levels of PFOS continue to be of concern as of April of 2023. Below is a more detailed account of the PFAS detections from this water system: [City of Eau Claire, PFAS Information: Test Results, https://www.eauclairewi.gov/government/our-divisions/utilities/pfas-information; WDNR Drinking Water System Portal.]

[Figure 3: see docket ID EPA-HQ-OW-2022-0114-1846]

[Figure 4: see docket ID EPA-HQ-OW-2022-0114-1846]

3. City of La Crosse

La Crosse is located in the West Central Region of Wisconsin and its water utility serves a non-transient population of approximately 53,000. All the system's drinking water comes from groundwater. There have been detections of PFOS, PFOA, PFBS, and PFHxS in this municipal water system. A more detailed account of recent detections from this water system is below: [FN iii: WDNR Drinking Water System Portal.]

[Figure 5: see docket ID EPA-HQ-OW-2022-0114-1846]

4. City of Wausau

Wausau is located in the West Central Region of Wisconsin and its water utility serves a non-transient population of approximately 39,106. All the system's drinking water comes from groundwater. There have been high detections of PFOS and PFOA. Below is a more detailed account of the detections from this water system: [FN iv: Wausau, Water Works: PFAS Sample Results, https://www.ci.wausau.wi.us/Departments/WausauWaterWorks/PFAS/PFASSampleResults.aspx ; DNR Drinking Water Portal.]

[Figure 6: see docket ID EPA-HQ-OW-2022-0114-1846]

[Figure 7: see docket ID EPA-HQ-OW-2022-0114-1846]

[Figure 8: see docket ID EPA-HQ-OW-2022-0114-1846]

5. City of West Bend

West Bend is in the Southeast Region of Wisconsin and its water utility serves approximately 31,861 non-transient people. All the system's drinking water comes from groundwater. There have been high detections of PFOA and PFOS in this municipal water system. The highest PFAS concentration found in West Bend's water system is of PFOA at 200 ppt in July of 2020. The water utility shut down operations of a well in June of 2022 to lower the overall concentrations of PFAS in its system. Recent sampling results continues to show concerning levels of PFOA. Below is a more detailed account of the detections from this water system: [FN v: City of West Bend, Water Utility FAQs: Where are PFAS detected in the City of West Bend, https://www.ci.west-bend.wi.us/departments/water/waterfaqs.php; WDNR Drinking Water System Portal.]

[Figure 9: see docket ID EPA-HQ-OW-2022-0114-1846]

[Figure 10: see docket ID EPA-HQ-OW-2022-0114-1846]

[Figure 11: see docket ID EPA-HQ-OW-2022-0114-1846]

[Figure 12: see docket ID EPA-HQ-OW-2022-0114-1846]

[Figure 13: see docket ID EPA-HQ-OW-2022-0114-1846]

[Figure 14: see docket ID EPA-HQ-OW-2022-0114-1846]

[Figure 15: see docket ID EPA-HQ-OW-2022-0114-1846]

6. City of Marshfield

Marshfield is in the West Central Region of Wisconsin and its water utility serves approximately 18,708 non-transient people. All the system's drinking water comes from groundwater. There

have been high detections of PFOS, PFOA, and PFHxS in this municipal water system. PFBS has also been frequently detected. The highest PFAS concentrations found in Marshfield's drinking water wells are of PFOS at 101 ppt and PFHxS at 95.6 ppt in May of 2022. Below is a more detailed account of the detections from this water system: [FN vi: WDNR Drinking Water System Portal.]

[Figure 16: see docket ID EPA-HQ-OW-2022-0114-1846]

7. City of Hartford

Hartford is located in the Southeast Region of Wisconsin and its water utility serves a non-transient population of approximately 16,076. All the system's drinking water comes from groundwater. There have been concerning detections of PFOS and PFOA in this municipal water system. Below is a more detailed account of detections from this water system: [FN vii: WDNR Drinking Water System Portal.]

[Figure 17: see docket ID EPA-HQ-OW-2022-0114-1846]

8. Village of Weston

Weston is in the West Central Region of Wisconsin and its water utility serves a non-transient population of approximately 15,045. All the system's drinking water comes from groundwater. There have been detections of PFOS, PFOA, PFBS, and PFHxS in this municipal water system. The highest PFAS concentrations found in this water system are of PFOS at 47.4 ppt and PFHxS at 28.1 ppt in May of 2022. A more detailed account of recent detections from this water system is below: [FN viii: WDNR Drinking Water System Portal.]

[Figure 18: see docket ID EPA-HQ-OW-2022-0114-1846]

9. Village of Pewaukee

Pewaukee is located in the Southeast Region of Wisconsin and its water system serves a non-transient population of 8,166. All the system's drinking water comes from groundwater. This municipal water system has detected concerning levels of PFHxS, PFOA and PFOS. The highest concentration detected is of PFHxS at 43 ppt in April of 2023. Below is a more detailed account of detections from this water system: [FN ix: WDNR Drinking Water System Portal.]

[Figure 19: see docket ID EPA-HQ-OW-2022-0114-1846]

10. City of Rhinelander

Rhinelander is in the Northern Region of Wisconsin and its water system serves approximately a non-transient population of 7,783. All the system's drinking water comes from groundwater. In this water system, PFHxS has been found at levels of concern and represents the most worrisome detection thus far. As early as September of 2019, this substance was detected at 35.9 ppt. In October of 2019, PFHxS was detected at its highest level so far at 90.1 ppt. Further, PFOA has been consistently detected at levels higher than the proposed MCL. More recent sampling results

continue to detect concerning levels of PFHxS and PFOA. Below is a more detailed account of the PFAS detections from this water system: [City of Rhinelander, Water and Wastewater Utility: PFAS, ; WDNR Drinking Water System Portal.]

[Figure 20: see docket ID EPA-HQ-OW-2022-0114-1846]

PFHxS = 35.9 ppt

[Figure 21: see docket ID EPA-HQ-OW-2022-0114-1846]

PFHxS = 90.1 ppt

[Figure 22: see docket ID EPA-HQ-OW-2022-0114-1846]

PFHxS = 12.1 ppt

[Figure 23: see docket ID EPA-HQ-OW-2022-0114-1846]

PFOA = 4.5 ppt

[Figure 24: see docket ID EPA-HQ-OW-2022-0114-1846]

[Figure 25: see docket ID EPA-HQ-OW-2022-0114-1846]

PFHxS = 9.4 ppt

[Figure 26: see docket ID EPA-HQ-OW-2022-0114-1846]

PFOA = 4.1 ppt

11. City of Prairie du Chien

Prairie du Chien is located in the South Central Region of Wisconsin and its water system serves a non-transient population of 6,005. All the system's drinking water comes from groundwater. This municipal water system has detected concerning levels of PFHxS and PFOS. Below is a more detailed account of detections from this water system: [FN xi: WDNR Drinking Water System Portal.]

[Figure 27: see docket ID EPA-HQ-OW-2022-0114-1846]

12. Town of Rib Mountain

Rib Mountain is a town adjacent to the City of Wausau with its own water system serving a non-transient population of 5,850. All the system's drinking water comes from groundwater. There have been detections of PFOS, PFOA, PFBS, and PFHxS. The highest levels found in this water system corresponds to PFOS at 85.6 ppt in November of 2021 and at 250 ppt in March of 2023, and to PFHxS at 75.5 ppt in December of 2021 and at 150 ppt in March of 2023. Below is a more detailed account of the detections from this water system: [FN xii: Town of Rib Mountain, PFAS Information,

https://www.ribmountainwi.gov/government/water___sewer_utility/pfas_information.php; WDNR Drinking Water System Portal.]

[Figure 28: see docket ID EPA-HQ-OW-2022-0114-1846]

PFOA = 8.09 ppt PFHxS = 63.6 ppt PFOS = 85.6 ppt

[Figure 29: see docket ID EPA-HQ-OW-2022-0114-1846]

PFOA = 4.9 ppt — PFOS = 6.56 ppt

[Figure 30: see docket ID EPA-HQ-OW-2022-0114-1846]

PFOA = 8.4 ppt PFBS = 16.5 ppt PFHxS = 75.5 ppt PFOS = 80.6 ppt

[Figure 31: see docket ID EPA-HQ-OW-2022-0114-1846]

PFHxS = 6.39 ppt PFOS = 7.13 ppt

[Figure 32: see docket ID EPA-HQ-OW-2022-0114-1846]

[Figure 33: see docket ID EPA-HQ-OW-2022-0114-1846]

PFBS = 27 ppt PFHxS = 150 ppt PFOA = 8.9 ppt PFOS = 250 ppt

13. Town of Sheboygan

Sheboygan is adjacent to the City of Sheboygan in the Southeast Region of Wisconsin and operates its own water utility serving a non-transient population of 4,596. All the system's drinking water comes from groundwater. This municipal water system has detected concerning levels of PFHxS. Below is a more detailed account of detections from this water system: [FN xiii: WDNR Drinking Water System Portal.]

[Figure 34: see docket ID EPA-HQ-OW-2022-0114-1846]

14. Village of Saukville

Saukville is located in the Southeast Region of Wisconsin and its water utility serves a non-transient population of approximately 4,424. All the system's drinking water comes from groundwater. There have been detections of PFOS, PFOA, PFBS, and PFHxS in this municipal water system. The highest PFAS concentrations found in this water system are of PFHxS at 34 ppt in June of 2022 and of PFOS at 33 ppt in September of 2022. Below is a more detailed account of detections from this water system: [FN xiv: WDNR Drinking Water System Portal.]

[Figure 35: see docket ID EPA-HQ-OW-2022-0114-1846]

15. Village of East Troy

East Troy is located in the Southeast Region of Wisconsin and its water utility serves a non-transient population of approximately 4,414. All the system's drinking water comes from groundwater. This municipal water system has detected PFOS, PFBS, and PFHxS. Below is a

more detailed account of detections from this water system: [FN xv: WDNR Drinking Water System Portal.]

[Figure 36: see docket ID EPA-HQ-OW-2022-0114-1846]

16. City of Prescott

Prescott is located in the West Central Region of Wisconsin and its water utility serves a non-transient population of approximately 4,258. All the system's drinking water comes from groundwater. This municipal water system has detected concerning levels of PFHxS. Below is a more detailed account of detections from this water system: [FN xvi: WDNR Drinking Water System Portal.]

[Figure 37: see docket ID EPA-HQ-OW-2022-0114-1846]

17. Village of Rothschild

Rothschild is located in the West Central Region of Wisconsin and its water utility serves a non-transient population of approximately 3,190. All the system's drinking water comes from groundwater. There have been frequent detections of PFOS, PFOA, PFBS, and PFHxS in this municipal water system. The most concerning detections relate to PFOS and PFOA. Below is a more detailed account of detections from this water system: [FN xvii: Village of Rothschild, Public Works, Utilities & Garbage: PFAS Information, https://www.rothschildwi.com/visitors/public_works_utilities___garbage/pfas_information.php.]

[Figure 38: see docket ID EPA-HQ-OW-2022-0114-1846]

PFOA = 7.42 ppt PFBS = 6.34 ppt PFHxS = 4.8 ppt PFOS = 12.2 ppt

[Figure 39: see docket ID EPA-HQ-OW-2022-0114-1846]

PFOA = 7.98 ppt PFBS = 6.39 ppt PFHxS = 3.42 ppt PFOS = 13.5 ppt

[Figure 40: see docket ID EPA-HQ-OW-2022-0114-1846]

PFOA = 6.73 ppt PFBS = 8.78 ppt PFHxS = 4.32 ppt PFOS = 11.9 ppt

[Figure 41: see docket ID EPA-HQ-OW-2022-0114-1846]

PFOA = 4.1 ppt — PFBS = 5.4 ppt — PFHxS = 4.2 ppt — PFOS = 9.9 ppt

18. City of Tomahawk

Tomahawk is located in the Northern Region of Wisconsin and its water system serves a non-transient population of 3,180. All the system's drinking water comes from groundwater. This municipal water system has detected concerning levels of PFOA. Below is a more detailed account of detections from this water system: [FN xxviii: WDNR Drinking Water System Portal.]

[Figure 42: see docket ID EPA-HQ-OW-2022-0114-1846]

19. Town of Brockway

Brockway is adjacent to the City of Black River Falls in the West Central Region of Wisconsin and operates its own water utility serving a non-transient population of 2,692. All the system's drinking water comes from groundwater. This municipal water system has recently detected concerning levels of PFOS. Below is a more detailed account of detections from this water system: [FN xix: WDNR Drinking Water System Portal.]

[Figure 43: see docket ID EPA-HQ-OW-2022-0114-1846]

20. City of Adams

Adams is located in the West Central Region of Wisconsin and its water utility serves a non-transient population of approximately 1,847. All the system's drinking water comes from groundwater. There have been frequent and high detections of PFOS and PFHxS in this municipal water system. The highest PFAS concentration found in this water system is of PFHxS at 43.3 ppt in May of 2022. Below is a more detailed account of detections from this water system: [FN xx: WDNR Drinking Water System Portal.]

[Figure 44: see docket ID EPA-HQ-OW-2022-0114-1846]

21. Village of Palmyra

Palmyra is located in the South Central Region of Wisconsin and its water utility serves a non-transient population of approximately 1,756. All the system's drinking water comes from groundwater. PFOS has been detected at high levels in water system. Below is a more detailed account of detections from this water system: [FN xxi: WDNR Drinking Water System Portal.]

[Figure 45: see docket ID EPA-HQ-OW-2022-0114-1846]

22. Village of Edgar

Edgar is located in the West Central Region of Wisconsin and its water utility serves a non-transient population of approximately 1,491. All the system's drinking water comes from groundwater. PFOA has been detected at high levels in this municipal water system. Below is a more detailed account of detections from this water system: [FN xxii: WDNR Drinking Water System Portal.]

[Figure 46: see docket ID EPA-HQ-OW-2022-0114-1846]

23. City of Mosinee

Mosinee is located in the West Central Region of Wisconsin and its east water system serves a non-transient population of 1,046. All the system's drinking water comes from groundwater. This municipal water system has detected concerning levels of PFOA and PFOS. The highest PFAS concentration detected is of PFOS at 29.4 ppt in May of 2022. Below is a more detailed account of detections from this water system: [FN xxiii: WDNR Drinking Water System Portal.]

[Figure 47: see docket ID EPA-HQ-OW-2022-0114-1846]

24. Village of Valders

Valders is located in the Northeast Region of Wisconsin and its water system serves a non-transient population of 967. All the system's drinking water comes from groundwater. This municipal water system has detected concerning levels of PFOA and PFOS. The highest PFAS concentration detected is of PFOS at 23 ppt in April of 2023. Below is a more detailed account of detections from this water system: [FN xxiv: WDNR Drinking Water System Portal.]

[Figure 48: see docket ID EPA-HQ-OW-2022-0114-1846]

25. Volk Field National Guard

The Air National Guard Volk Field is located in the West Central Region of Wisconsin near the Village of Camp Douglas. The military airport has its own water system serving a non-transient population of 400. PFHxS has been detected at high levels in this municipal water system. Below is a more detailed account of detections from this water system: [FN xxv: WDNR Drinking Water System Portal.]

[Figure 49: see docket ID EPA-HQ-OW-2022-0114-1846]

EPA Response: Please see section 6.7 of the EPA response in this *Response to Comments* document. In response to this and other comments, the EPA considered occurrence data from Wisconsin in its final rulemaking. Those data supported the EPA's conclusions in the proposed regulation. See the *Occurrence Technical Support Document* for more information (USEPA, 2024b).

6.8 UCMR 5

Summary of Major Public Comments and EPA Responses

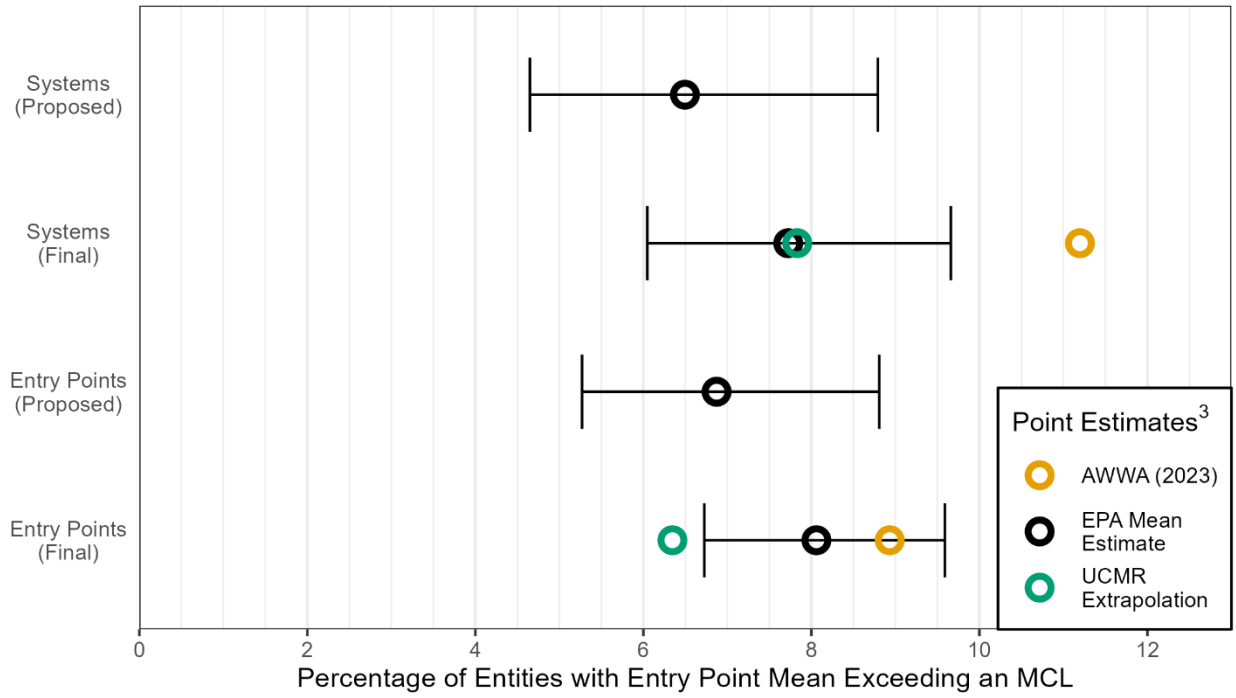
UCMR 5 occurrence data were not available to inform the proposal, but the agency discussed that additional nationwide monitoring data would be available for systems participating in the monitoring program. Some commenters called for the EPA to delay issuance of the final PFAS rule until the complete UCMR 5 occurrence dataset can be analyzed, and some commenters stated that rule promulgation should be delayed until at least a portion of the UCMR 5 data is obtained. The EPA disagrees with these commenters. The EPA is not required under the statute to wait for another round of UCMR data to be collected before proposing or finalizing a regulation; in this case, the completion of UCMR 5 data reporting is expected at the end of 2025, with the final dataset not being available until 2026. Rather, SDWA Section 1412(b)(1)(B)(ii)(II) expressly provides that the EPA must use the "best *available* public health information" in making a regulatory determination (emphasis added). The EPA has sufficiently robust occurrence information as documented in sections III.C. and VI of the final rule preamble and the Occurrence Technical Support Document to make regulatory determinations and promulgate a regulation for the six PFAS in this regulation. In addition to serving as a significant way for

helping many utilities reduce initial monitoring costs, the final full UCMR 5 dataset will also be valuable for informing future regulatory decisions for the 23 PFAS included in UCMR 5 that are not directly addressed by this proposed rulemaking. The agency believes that the best currently available occurrence data, including tens of thousands of samples per PFAS chemical in the final rule collected across 32 states, representing one of the most robust occurrence datasets ever used to inform development of a drinking water regulation of a previously unregulated contaminant, demonstrate sufficient occurrence or substantial likelihood of occurrence for the contaminants included in the final rule.

While the EPA is under no legal obligation to consider the preliminary, partial UCMR 5 dataset prior to rule promulgation, based on public comment and interest, the agency analyzed UCMR 5 data released as of February 2024 (USEPA, 2024e), though it did not serve as the basis for the agency's decision. See section VI.G of the FRN for the EPA's analysis of the UCMR 5 data, representing approximately three quarters of data and 24 percent of the anticipated final UCMR 5 dataset.

Figure 1 shows a comparison of national estimates derived from the preliminary UCMR 5 dataset with estimates developed independently of UCMR 5. The figure presents systems and entry points with entry point-level mean PFAS concentrations exceeding any of the PFAS MCLs. This includes estimates derived from the preliminary UCMR 5 dataset, national estimates from the EPA's proposed and final PFAS rule, and national estimates of impacted systems and entry points provided by AWWA, since the latter's estimates were referenced by several commenters. UCMR 5 data used for the extrapolation were limited to completed sample sets as well as entry points that included multiple complete sample sets. The entry point limitation was included to ensure that all results were based on a mean rather than a single sample result.

Figure 1: National Estimates[1] Compared to Preliminary UCMR 5 Results[2]



Notes:
[1]National estimates are shown with a mean estimate and an associated 90 percent confidence interval (error bars) and the values are as shown for the final rule in *Economic Analysis for the Final Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation* (USEPA, 2024a) and for the proposed rule in *Economic Analysis of the Proposed National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances* (USEPA, 2023c).
[2]The UCMR5 results include about 24 percent of the samples anticipated to be available in the completed dataset.
[3]The "UCMR Extrapolation" method weighs the results of currently available UCMR 5 data to account for the system size composition of the national inventory (e.g., large systems making up about 6.7 percent of systems in the national inventory and were adjusted accordingly). UCMR extrapolation also only uses complete sample sets and entry points with multiple complete sample sets. "AWWA (2023)" refers to the estimates provided in a study conducted by Black & Veatch on behalf of the American Water Works Association (AWWA, 2023).

Extrapolation of the preliminary UCMR 5 dataset indicates that 7.8 percent of systems and 6.3 percent of entry points would have an entry point-level mean exceeding a PFAS MCL. This is in comparison to estimates presented in USEPA (2023c) for the proposed rule which range from 4.6 to 8.8 percent of systems and 5.3 to 8.8 percent of entry points. For the final rule, occurrence estimates range from 6.0 to 9.7 percent of systems and 6.7 to 9.6 percent of entry points (USEPA, 2024a). The estimates derived from the UCMR 5 extrapolation indicate that the EPA occurrence estimate ranges are reasonable. The AWWA (2023) point estimates referenced by many comments are high compared to the UCMR 5 extrapolation (about 11.2 percent of systems and 8.9 percent of entry points). While the AWWA point estimate for entry points falls at the upper end of the EPA's estimated range, the AWWA point estimate for systems is beyond the upper end of the EPA's estimated range. The preliminary UCMR 5 dataset supports that the

EPA's occurrence analysis did not underestimate the number of systems that may have to take action such as treating drinking water to remove PFAS while the AWWA analysis likely significantly overestimated the number of systems that will have to take action. This overestimation would then result in inflated cost estimates. Since the UCMR 5 dataset is incomplete, extrapolated estimates may shift as additional data are collected.

Individual Public Comments

Water Environment Federation (WEF) (Doc. #1529, SBC-043304)

WEF asks that the following short-term and long-term impacts be taken into consideration with the proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation.

Short-term Impacts

Identify funding sources, not already accounted for, to support the water reclamation industry. Prioritize continued research and the proactive communication of these findings.

• Data: EPA is using the 3rd Unregulated Contaminant Monitoring Rule (UCMR 3) as the basis for the proposed NPDWR. If delayed to Summer 2024, EPA could analyze 2023 monitoring results from UCMR 5 to calibrate and confirm the results of the Bayesian Analysis. Also, as EPA recognizes, 'the minimum reporting levels (MRLs) were established based on the capacity of the analytical method, not based on a level established as "significant" or "harmful". In fact, the UCMR 3 MRLs are often a larger concentration than current "health reference levels" (to the extent that HRLs have been established).' [FN1: U.S. EPA The Third Unregulated Contaminant Monitoring Rule (UCMR 3): Data Summary, January 2017 https://www.epa.gov/sites/default/files/2017-02/documents/ucmr3-data-summary-january-2017.pdf.]

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document. Please see section 6.5 of the EPA response in this *Response to Comments* document regarding the EPA's national occurrence model. Regarding funding sources, please see section 2.4 of the EPA response in this *Response to Comments* document.

Greenville Utilities Commission (Doc. #1534, SBC-042637)

The Fifth Unregulated Contaminant Monitoring Rule (UCMR 5) will provide EPA with scientifically valid data on the national occurrence of 29 PFAS compounds in the nation's drinking water and at what levels. This data will ensure science-based decision-making and help prioritize protection of disadvantaged communities. Implementation of regulations before up-to-date information from UCMR 5 can be reported and analyzed does not follow sound scientific principles. The limited number of laboratories certified to analyze samples for UCMR 5 have caused ten-day turnaround times to become two month waits for data. Utilities will have to increase sampling to determine the effectiveness of potential treatment strategies which will further burden those laboratories.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document. Please see section 5.1.2 of the EPA response in this *Response to Comments* document regarding laboratory capacity.

U.S. Chamber of Commerce (Doc. #1537, SBC-042646)

Accordingly, we are planning to provide comments to EPA and will request that the agency withdraw the proposal and should await the results of the UCMR 5 process:

• Lack of occurrence data at the proposed MCL level. The current UCMR 3 occurrence data for PFOA and PFOS seems to indicate levels at between 20 ppt and 40 ppt. EPA does not have a robust understanding of occurrence levels at the proposed MCL levels for PFOA and PFOS or the other four PFAS. This lack of occurrence data for a preliminary regulatory determination requires more thoughtful and thorough analysis.

EPA Response: Please see sections 6.2, 6.5, and 6.8 of the EPA response in this *Response to Comments* document. The EPA disagrees that it does not have a robust understanding of occurrence levels for the PFAS which it is finalizing regulation for as demonstrated through the availability of tens of thousands samples from UCMR 3 and state monitoring data presented in the final rule preamble and *Occurrence Technical Support Document* (USEPA, 2024b). Regarding the EPA's regulatory determinations, please see section 3.1.2 of the EPA response in this *Response to Comments* document.

Missouri Department of Natural Resources (Doc. #1563, SBC-042510)

The Department also recommends that EPA complete the nationwide PFAS occurrence study under UCMR 5 before finalizing the Hazard Index for the other four PFAS that EPA has proposed to regulate. EPA will have significantly more PFAS occurrence data upon the completion of UCMR 5. The process EPA is now taking to make a regulatory determination and to establish a MCL for these four PFAS, with limited state occurrence data, seems rushed. The agency will have significantly more data available to it in the next few years to do a much more thorough analysis.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document. Regarding the EPA's regulatory determinations, please see section 3.1.2 of the EPA response in this *Response to Comments* document.

Missouri Department of Natural Resources (Doc. #1563, SBC-042527)

The Department recommends that EPA complete the nationwide PFAS occurrence study under UCMR 5 before finalizing the Hazard Index or an individual MCL for these four PFAS. EPA will have significantly more data on the occurrence of these four PFAS upon the completion of UCMR 5. The process EPA is now taking to make a regulatory determination and to establish a MCL for these four PFAS in this one action seems rushed. The agency will have significantly

more data available to it in the next few years to do a much more thorough analysis. Removing the Hazard Index will make the rule easier to implement, improve clarity, and reduce costs.

Section VII—Occurrence

EPA requests comment on the number of systems estimated to solely exceed the HI (but not the PFOA or PFOS MCLs) according to the approach outlined in USEPA (2023e). Completing the occurrence sampling under UCMR 5 would provide EPA the data to make a more informed decision on how to proceed with regulating PFAS. It would allow EPA to base its decision on unbiased, consistently collected, national information rather than relying on data from a subset of states that varies in terms of quantity and coverage, and that includes data from targeted or site-specific sampling efforts where it may be expected to have higher detection rates, or not be representative of levels found in all PWSs within a state.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document. Regarding the EPA's regulatory determinations, please see section 3.1.2 of the EPA response in this *Response to Comments* document.

San Antonio Water System (SAWS) (Doc. #1570, SBC-042474)

Since UCMR5 sampling has not been completed there is not a nationwide data set available to establish regulations. As such, proposed regulatory standards are not supported by concrete data and are premature. After a nationwide dataset has been completed, a thorough and comprehensive assessment through peer review and committee evaluation should occur, providing a more reliable scientific approach to establishing PFAS regulations.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document.

San Antonio Water System (SAWS) (Doc. #1570, SBC-042472)

While more detections are expected with the lower UCMR5 detection limits, there is currently not a dataset that proves the need for these regulations. The first sampling event for UCMR5 was not even completed for most Public Water Systems (PWSs) when the proposed rule was posted on the docket. UCMR5 sampling should be completed and evaluated prior to this rule being finalized.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document.

Security Water District, Security Water and Sanitation Districts/Enterprises (Doc. #1587, SBC-042784)

Back in 2016, there was a 6-week turn-around time to obtain PFAS sampling results. With the EPA Lifetime Health Advisory being issued on May 19, 2016, The Security Water District was

able to shut down all of its wells by September, 2016 — a remarkable accomplishment. During this time, however, we were making million-dollar decisions before we even had sample results back. There are many pitfalls that can result from making decisions based on incomplete information, and we fear that is what EPA is doing by promulgating this rule now. We feel that a better approach would be to wait at least until the July, 2023 UCMR-5 data is released, so that these important decisions are made based on the best information available. We feel that the best tactic would be to wait for the October, 2023 data, which would include 2 quarters of data, but would also include 3,500+ water systems. We feel that the latter alternative would dramatically improve the clarity and quality of the occurrence analysis.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document. For the final rule, the EPA has analyzed UCMR 5 data released as of February 2024. See section VI.G of the FRN. This includes approximately three quarters of data though it did not serve as the basis for the agency's decision.

Water & Health Advisory Council (Doc. #1590, SBC-042788)

The U.S. EPA has not justified the need for such extremely costly drinking water regulations for PFAS. Current U.S. population PFAS exposure levels are 70 to 90% lower than they were 25 years ago (see Figure 1 below) (CDC, 2019). The U.S. EPA's evaluations of risk include the assumption that drinking water is a minor contributor of exposures to PFAS relative to other pathways (default relative source contribution (RSC) of 20%), yet the agency is placing a great and costly burden on drinking water providers. In fact, the national drinking water occurrence database for PFOA and PFOS and other PFAS is very weak, and the data quality of the sources that have been assembled is not uniform. It does not provide a reliable basis for drinking water distributions and exposures, and economic impact analyses. The U.S. EPA should await the reports from the Unregulated Contaminant Monitoring Rule 5 (UCMR5) survey that is underway before making a regulatory decision. The first-round data will be available in less than a year. This occurrence data will likely show that communities nation-wide will have varying levels of PFAS in their drinking water; not all should be treated with the same level of urgency. The higher drinking water concentrations of PFOA and PFOS are mostly in groundwater supplies impacted by manufacturing and users' sites. In communities where high levels of PFAS exist, water utilities have and should continue to address drinking water exposures with urgency. However, communities with extremely low detections of PFAS that may also be facing well established public health risks from other sources such as elevated levels of other regulated chemicals, failing infrastructure, and reduced access to water supplies, should be able to utilize their resources to address those high priority concerns.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document. The EPA disagrees that this NPDWR is not justified. As described in sections II and III of this final rule, the EPA made determinations in accordance with the SDWA to regulate the 6 PFAS included in this rule. Briefly, in 2021, the EPA made a determination to regulate two PFAS—PFOA and PFOS—in drinking water under SDWA. The agency has

determined that PFHxS, PFNA, and HFPO-DA may have individual adverse health effects, and any mixture of these three PFAS and PFBS may also have dose-additive adverse effects on the health of persons; that there is a substantial likelihood that PFHxS, PFNA, and HFPO-DA occur individually with a frequency and at levels of public health concern and that mixtures of these three PFAS and PFBS occur and co-occur in PWSs with a frequency and at levels of public health concern; and that, in the sole judgment of the Administrator, individual regulation of PFHxS, PFNA, and HFPO-DA, and regulation of mixtures of these three PFAS and PFBS, presents a meaningful opportunity for health risk reduction for persons served by PWSs. Please see section 3.1 of the EPA response in this *Response to Comments* document for more information. Additionally, the EPA disagrees that the drinking water occurrence information used to inform this rule is "very weak." The agency used the best available data, consisting of tens of thousands of samples, and scientifically robust analytical approaches to inform its analyses. Further, the EPA disagrees that occurrence data suggests that PFOA and PFOS concentrations are higher in groundwater systems as supported by the available data the EPA used in its analyses, and the commenter did not cite any underlying data or rationale for this argument. Rather, based on available data, concentrations are observed to vary between different source water types and geographic locations, thus a national-level regulation is justified to protect those served by PWSs with levels of PFAS exceeding the EPA's MCLs.

Alameda County Water District (ACWD) (Doc. #1595, SBC-042347)

National occurrence data is currently being collected under UCMR 5 which uses EPA methods 533 and 537.1, with MRLs of 4 ppt (PFOS), 4 ppt (PFOA), 3 ppt (PFHxS), 4 ppt (PFNA), 3 ppt (PFBS), and 5 ppt (HFPO-DA). The lower detection levels possible using the newer method will result in a higher, and more representative, number of occurrences among water systems, providing a more refined basis for EPA to identify the needs for treatment and develop a more accurate cost assessment. EPA should base the Economic Impact Analysis on UCMR 5 monitoring results, to provide a more accurate representation of occurrences.

ACWD is in California, which conducted statewide PFAS monitoring for select water systems that were identified as being in proximity to potential sources of PFAS contamination. ACWD was not in the vicinity of potential PFAS sources and was not identified for monitoring by the state; additionally, ACWD had no PFAS detections during the UCMR 3 monitoring. ACWD believes in being proactive in the protection of public health and conducted PFAS monitoring on a voluntary basis at our groundwater sources. Our monitoring detected PFOS and PFOA concentrations at levels above the MCLs being proposed as part of the PFAS NPDWR, but below the UCMR 3 MRLs. Though ACWD's data was provided to the state, the monitoring we conducted was not required by the state. EPA should consider that there are most certainly other water systems which had no detections during UCMR 3 monitoring, and were not identified during statewide PFAS monitoring efforts, but do have PFAS concentrations above the proposed MCLs, and those agencies will not appear for the purposes of occurrence data and the economic analysis. EPA should base the Economic Impact Analysis on UCMR 5 monitoring results, which would better represent occurrence data by identifying systems in situations similar to our own.

EPA Response: Please see sections 6.8 and 6.2 of the EPA response in this *Response to Comments* document as well as section VI of the final rule preamble. The EPA collected and assessed state data from 32 states to support the final rulemaking that included reporting limits lower than the minimum reporting levels used for UCMR 3. These data support the EPA's estimates of national occurrence for the six PFAS, as well as the regulatory determinations for PFHxS, PFNA, HFPO-DA, and PFBS and mixtures of these four PFAS. Please see section 3.1.2 and 3.2.2 of the EPA response in this *Response to Comments* document regarding the EPA's regulatory determination and evaluation of the occurrence criterion for PFHxS, PFNA, HFPO-DA, and PFBS and mixtures of these four PFAS.

Lehigh County Authority (LCA) (Doc. #1600, SBC-042809)

3. Data Limitations – These four PFAS compounds have not been fully studied, and we believe setting a regulatory standard at this time is premature. EPA should consider delaying the establishment of regulatory standards for these PFAS compounds until full review of the results from the Unregulated Contaminant Monitoring Rule (UCMR 5) monitoring, which began this year.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document. The EPA disagrees that it is premature to regulate PFHxS, PFNA, PFBS, and HFPO-DA and the agency has concluded that all four have been sufficiently studied to regulate, consistent with the requirements of the Safe Drinking Water Act. Regarding the EPA's regulatory determinations, please see section 3.1.2 of the EPA response in this *Response to Comments* document.

Lehigh County Authority (LCA) (Doc. #1600, SBC-042813)

The addition of regulatory standards for other PFAS compounds, in addition to PFOA and PFOS, should be revisited upon completion of UCMR 5.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document.

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-042877)

Occurrence:

Testing under the Unregulated Contaminant Monitoring Rule (UCMR) program is and has always been an important step in the EPA rulemaking process. The occurrence data collected through this monitoring is used to support decisions to regulate particular contaminants in the interest of public health. The UCMR5 program just commenced at the beginning of this year (2023); therefore, EPA cannot possibly have a full sense of occurrence for the suite of PFAS compounds in drinking water. EPA's regulatory determination for perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salt (also

known as a GenX chemicals), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS) are based on a very limited data set and could only be enhanced by waiting for the results of UCMR5 to provide a more robust data set for determining occurrence across the nation. EPA should delay promulgation of this rule until it has an opportunity to vet at least one full year of data obtained through UCMR5.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document. Regarding the EPA's regulatory determinations, please see section 3.1.2 of the EPA response in this *Response to Comments* document.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043631)

5. The full impact of the proposed PFAS Rule remains uncertain as data collection for 29 PFAS species under UCMR5 is still ongoing. UCMR5 data collection is scheduled to be completed in December 2025. Therefore, imposing a rule now on six (6) PFAS species is unreasonable and premature. Under the current proposed regulation, systems could be required to install treatment technologies by 2026 and then subsequently be subjected to additional PFAS regulations.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document. For additional discussion on the compliance timeline, please see section 12.1 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043635)

A. UCMR3 data were used in the development of the USEPA economic analysis. Only six (6) PFAS species (PFOS, PFOA, PFNA, PFNxS, PFHpA and PFBS) were considered under UCMR3—five (5) of which are proposed for regulation under the PFAS rule (PFOS, PFOA, PFNA, PFNxS, and PFBS). UCMR5, however, will consider 29 species of PFAS (for data collected between January 1, 2023, and December 31, 2025); UCMR5 also includes consideration of GenX (HFPO-DA) which was not monitored in UCMR3 but is regulated in the proposed PFAS Rule. Moreover, UCMR5 PFAS have notably lower reporting limits as compared to UCMR3. A higher number of species being considered, in tandem with lower reporting levels, could increase the likelihood that more Public Water Systems (PWSs) will be impacted by the proposed rule. It is recommended that UMCR5 data be incorporated into the national occurrence model as well as USEPA's cost analysis as soon as its available, as this would help clarify the most appropriate regulatory framework and associated costs.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document. Regarding the EPA's national occurrence model, please see section 6.5 of the EPA response in this *Response to Comments* document. Regarding UCMR 3 data, please see section 6.1 of the EPA response in this *Response to Comments* document.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043642)

3) Utility Impacts

1. The USEPA model substantially underestimates the practical impact of compliance cost to individual utilities and the industry as a whole (which is supported by ratepaying consumers).

A. It is likely that the analysis undercounts the utilities nationwide that will have to add treatment to comply with the proposed PFAS Rule, which will be clearer after UCMR5 data are fully compiled.

i. It is possible that even UCMR5's monitoring may not be sufficiently indicative of industry-wide compliance, particularly with regards to small systems (i.e. specifically those serving fewer 3,300) as 800 will be randomly selected, subject to availability of appropriations and sufficient laboratory capacity. If EPA does not receive the appropriations needed each year, then a reduced number of small systems will perform monitoring.

ii. The Minimum Reporting Levels (MRLs) of PFAS species considered under UCMR3 (specifically those that are in the proposed PFAS Rule) range from 20 ng/L for PFOA to 90 ng/L for PFBS. The UCMR5 MRLs for the same species range from 3-4 ng/L (and 5 ng/L for GenX which is included in UCMR5, but not a part of UCMR3) illustrating a notable improvement in MRLs and also highlighting the potential that lower concentrations of these species could have been missed during the UCMR3 assessment—resulting in a likely underestimation of PFAS occurrence and utility impact. It is recommended that USEPA allow utilities time to complete UCMR5, for a clearer, and more refined understanding of national PFAS occurrence, ahead of the proposed rule.

Table 5: UCMR3 and UCMR5 PFAS Species MRL's, adapted from Crone et al (2019).

[Table 5: See Docket ID EPA-HQ-OW-2022-0114-1602]

The UCMR 3 MRLs were established based on the capability of the analytical methods (at the time), not based on a level established as "significant" or "harmful."

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document regarding UCMR 5, see section 6.5 of the EPA response in this *Response to Comments* document regarding the national PFAS occurrence model, and section 6.1 of the EPA response in this *Response to Comments* document regarding the usage of UCMR 3 data.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043645)

4) Treatability

1. If utilities are required to develop and implement systems to comply with the proposed Rule in the next three years, those systems may not be properly sized or function as intended if additional PFAS compounds are added to the regulation in the future.

A. UCMR3 captures occurrence data from 2013-2015 and only reflects six PFAS species, while UCMR5 will capture data from Jan 2023-Dec 2025 for 29 species of PFAS (inclusive of the six monitored during UCMR3), offering a better foundational understanding of occurrence to inform future regulation. Therefore, imposing a rule now on six (6) PFAS species is unreasonable and premature. Under the current proposed regulation, systems could be required to install treatment technologies by 2026 and then subsequently be subjected to additional PFAS regulations. It is recommended that USEPA give utilities time to complete UCMR5 for a better understanding of the occurrence prior to imposing the proposed PFAS rule.

B. According to the Crone et al (2019) analysis of the UCMR3 data, 4% of water systems reported at least one detectable PFAS compound. This percentage is likely to increase once UCMR5 data for all 29 species is completed by December 2025. This is likely true with regards to both surface and groundwater systems:

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document regarding UCMR 5 and section 6.1 of the EPA response in this *Response to Comments* document regarding UCMR 3 data.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043653)

7. Under the Safe Drinking Water Act, the USEPA has until September 2024 to finalize the new drinking water standards, 9 more months after the current plan (by the end of 2023). It is recommended that more time be given to PWSs to provide UCMR5 data to the national occurrence model and allow the model to estimate national occurrence for additional PFAS and help to evaluate national temporal trends in PFAS exposure (Cadwallader et al 2022).

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043071)

Inclusion of Data from Fifth Unregulated Contaminant Monitoring Rule

This year, drinking water monitoring for PFAS under the UCMR 5 began. UCMR 5 is expected to be the most comprehensive occurrence dataset for PFAS collected to-date. In accordance with UCMR 5, more than 10,300 systems will monitor for 29 PFAS using EPA Methods 533 and using single-digit minimum reporting limits. While a complete dataset will not be compiled until 2026, more than 3,400 water systems are actively collecting monitoring data this year. By the end of summer this year, all these systems will have collected at least one sample and EPA will have received these results. Previous research has shown that preliminary data collected from UCMR monitoring provides accurate insights about occurrence when compared to the complete dataset.

UCMR 5 data collected during the first half of 2023 would represent a significant increase in the available data that is nationally representative. Specifically, this dataset will provide information

on nearly 70% of the number of water systems that are typically represented by a UCMR program. While this data would not be a full UCMR sampling program, it would significantly expand the universe of nationally representative data at reporting levels that are presently appropriate. Given that the goal of the UCMR 5 program is to inform EPA on the occurrence of PFAS, EPA can ill afford to ignore this data, which would be of a much higher quality and value than existing data.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043059)

4. EPA's statistical approach to estimate occurrence of PFAS in drinking water is overly complicated and EPA would be ill-advised to finalize the rule without considering incoming data from more than 3,500 water systems currently collecting samples under the UCMR 5.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document regarding UCMR 5 and section 6.5 of the EPA response in this *Response to Comments* document regarding the national PFAS occurrence model.

Environmental Monitoring Coalition (EMC) (Doc. #1625, SBC-043106)

The Unregulated Contaminant Monitoring Rule 5 program is currently collecting additional data, at more utilities and at lower concentrations than UCMR3 on the occurrence of PFAS in drinking water. The first data sets should soon be available to the Agency. "Occurrence data are collected through UCMR to support the Administrator's determination of whether to regulate particular contaminants in the interest of protecting public health." However, this PFAS regulatory rule was proposed a few months before UCMR5 data are available. The UCMR process was designed specifically to collect occurrence data for EPA to use to assess the percent of the population potentially exposed and exposure levels as a basis for making regulatory decisions. Given that EPA could still meet its requirements through Congress to regulate PFAS by a certain deadline, EPA should consider how the first two quarters of UCMR5 data could be used to guide the development of these regulations.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document. Based on this and other comments, the EPA has presented results from approximately three quarters of UCMR 5 monitoring, and the agency notes that those results are consistent with the EPA's occurrence estimates.

Water One – Water District No. 1 of Johnson County, Kansas (Doc. #1627, SBC-042324)

Regulatory Process

The proposed PFAS regulation appears to completely bypass the EPA's established Unregulated Contaminant Monitoring Rule (UCMR) regulatory process and it is premature in the process particularly since it is superseding the collection and analysis of the UCMR 5 data.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document. The EPA disagrees that the agency has circumvented the established process for developing NPDWRs. The EPA implements a monitoring program for unregulated contaminants (i.e., UCMR) under SDWA 1445(a)(2) that requires the EPA to issue a list once every five years of priority unregulated contaminants to be monitored by PWSs, however there is no statutory requirement that a contaminant must be on this list prior to making a determination to regulate or that the agency must wait for this information if the agency has sufficiently available information through other sources. The UCMR 3 dataset, additional state data (please see section 6.2 of the EPA response in this *Response to Comments* document), and the EPA's robust analyses demonstrate sufficient likelihood of occurrence of the PFAS being regulated.

Orange County Water District (OCWD), California (Doc. #1634, SBC-043233)

Additionally, under the SDWA, EPA has until September 2024 to finalize these regulations, so the agency should strongly consider using at least some of this time to incorporate additional high-quality nationwide data from the ongoing UCMR5 monitoring that began in 2023, instead of rushing to implement a regulation based on an inadequate estimate of national occurrence.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document.

National Rural Water Association (NRWA) (Doc. #1641, SBC-043279)

• EPA requests comment on the underlying assumptions that, under UCMR 5, individual water systems would be able to request the full release of data from the labs for use in determining their compliance monitoring frequency and that PWSs may be able to use these lab analyses to demonstrate a ''below trigger level'' concentration using the UCMR 5 analyses by following up with the lab for a more detailed results report.

Response: Water systems should be allowed to use their UCMR 5 monitoring data to determine compliance monitoring frequency and demonstrate a "below trigger level" concentration. EPA should establish a standard that labs release two reports, the standard report, and a separate report with qualified data.

EPA Response: The EPA agrees with the commenter that, provided the data were collected using EPA method 533 or 537.1, water systems can utilize previously collected data, such as from UCMR 5, to satisfy the rule's initial monitoring requirements and determination of

compliance monitoring frequency. Please see section 8.3 of the EPA response in this *Response to Comments* document.

Massachusetts Water Resources Authority (Doc. #1645, SBC-043283)

EPA is also in the process of implementing the UCMR5. There are 29 PFAS included in UCMR5; sample collection for these 29 PFAS at thousands of PWSs began at the beginning of this calendar year and will continue through 2025. EPA's commitment to a final NPDWR publication in December 2023 (nine months in advance of the statutory deadline for promulgation), prevents EPA from considering any data collected as part of UCMR5. EPA's positive regulatory determinations for PFHxS, PFNA, HFPO-DA or GenX, and PFBS rely on very limited relevant occurrence data. Under the SDWA, EPA has a responsibility to demonstrate that positive regulatory determinations are for contaminants that occur or are likely to occur at levels of public health concern in drinking water and that there is a meaningful opportunity for health risk reduction through a drinking water standard. Waiting for the complete set of UCMR5 data to be available seems prudent given the potential financial and resource implications of this proposed regulation.

Using the UCMR5 PFAS data would dramatically improve the clarity and quality of EPA's occurrence analysis. MWRA recommends that EPA at least review UCMR5 data collected through June 2023 if EPA is intent on making a final NPDWR publication this December. Waiting until the complete UCMR5 data set is available for review and analysis in 2025, before finalizing a PFAS NPDWR would provide an even broader understanding of the occurrence of PFAS throughout the country.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document. Please see sections 3.1.2 and 3.2.2 of the EPA response in this *Response to Comments* document regarding the EPA's regulatory determination and evaluation of the occurrence criterion for PFHxS, PFNA, HFPO-DA, and PFBS and mixtures of these four PFAS.

Association of Public Health Laboratories (APHL) (Doc. #1646, SBC-043305)

The Unregulated Contaminant Monitoring Rule 5 program is collecting additional data, at more utilities and at lower concentrations than UCMR3. The first data sets should be uploaded soon. "Occurrence data are collected through UCMR to support the Administrator's determination of whether to regulate particular contaminants in the interest of protecting public health." However, this PFAS regulatory rule was proposed a few months before UCMR5 data are available. The UCMR process was designed specifically to collect occurrence data for EPA to use to assess the percent of the population potentially exposed and exposure levels as a basis for making regulatory decisions. Given that EPA could still meet its requirements through Congress to regulate PFAS by a certain deadline, EPA should consider how the first two quarters of UCMR5 data could be used to guide the development of these regulations.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document.

GFL Environmental (Doc. #1648, SBC-043219)

Other Important Factors to be Considered

EPA is using the third Unregulated Contaminant Monitoring Rule (UCMR 3) as the basis for the proposed NPDWR. If the proposed NPDWR implementation were delayed to the summer of 2024, EPA could analyze 2023 monitoring results from UCMR 5 to validate the impact of extrapolations assumed based on UMCR 3 data, which were collected using unvalidated testing methodology at significantly higher detection limits as compared to the UMCR 5 protocols.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenter that it used UCMR 3 as the only basis for the proposed NPDWR (see section 6.1 of the EPA response in this *Response to Comments* document). While the agency did use UCMR 3 results to inform the proposed rule and as the framework basis for the EPA's national occurrence model, the EPA also collected and analyzed an extremely robust dataset of state monitoring information consisting of tens of thousands of samples (please see section 6.2 of the EPA response in this *Response to Comments* document). Additionally, the EPA disagrees that UCMR 3 was collected using unvalidated testing methodology. PFAS data for UCMR 3 were collected using EPA Method 537, ver. 1.1, which was validated by the EPA, Office of Research and Development, National Exposure Research Laboratory. Method validation included both in-house performance data collection and a second laboratory demonstration using a minimum of two additional laboratories.

Inland Empire Utilities Agency (IEUA), California (Doc. #1666, SBC-043389)

The following are IEUA's comments on EPA's proposed rule.

Comment 1 – Cost Analysis – EPA's cost-benefit analysis should be updated to account for the cost to public water system and wastewater and water recycling utilities to upgrade treatment systems to comply with anticipated exceedances of one or more MCL.

In accordance with the Safe Drinking Water Act (SDWA) requirements, EPA has determined that the quantified and non-quantifiable benefits of the proposed PFAS NPDWR justify the costs. Costs are taken into consideration when establishing an enforceable Maximum Contaminant Level (MCL) as close as feasible to the Maximum Contaminant Level Goals (MCLG). In developing the financial impact EPA relied on multiple data sources including the Third Unregulated Contaminant Monitoring Rule (UCMR3) to estimate the PFAS occurrence and potential impact to public water systems. Since the analytical methods used by these data sources may have a minimum reporting level higher than the proposed MCL, we believe that more public water systems are anticipated to exceed one or more MCL and therefore, we recommend EPA to update the occurrence model and the cost-benefit analysis after the completion of the Fifth

Unregulated Contaminant Monitoring Rule (UCMR 5) in 2025. UCMR 5 will provide additional data that is a more accurate indication of current PFAS values at the proposed reporting levels which is critically needed to improve EPA's understanding of the frequency that PFAS are found in the nation's drinking water systems and at what levels. This data will ensure science-based decision-making and help to quantify the costs more accurately.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document. The agency would like to clarify that, for the proposed and final rule, the EPA assessed the costs to all entities subject to the rule, including PWSs that exceed the MCLs. For more information on the EPA's response to comments on the agency's cost estimates, see section 13.3 in this *Response to Comments* document. For the EPA's response to comments on the Administrator's determination that the benefits of the rule justify the costs, see section 13.8 in this *Response to Comments* document. For the EPA's response to comments on feasibility of the MCLs, see section 5 in this *Response to Comments* document.

City of Allentown and Lehigh County Authority (LCA), Pennsylvania (Doc. #1667, SBC-043669)

May 30, 2023

Michael S. Regan, Administrator

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Mail Code: 4607M

Washington, DC 20460

RE: Per- and polyfluoroalkyl substances (PFAS): Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) National Primary Drinking Water Regulation Rulemaking, Docket No. (Docket ID: EPA-HQ-OW-2022-0114)

Dear Administrator Regan,

We appreciate the opportunity to comment on the Environmental Protection Agency's proposed rule, PFAS National Primary Drinking Water Regulation Rulemaking – EPA-HQ-OW2022-0114. The City of Allentown supports and considers itself a partner in EPA's efforts to ensure safe drinking water for all citizens, all communities. The City of Allentown (City) is the third largest city in Pennsylvania and is the economic driver to the Lehigh Valley, the 68th-most populous metropolitan area in the United States. The City's water system serves approximately 200,000 people in the region. The City has reviewed the proposed rule and offers the following comments also contributed by the operator of the City's system, Lehigh County Authority (LCA) for your consideration.

PFHxS, HFPO_DA, PFNA, and PFBS: The proposed regulation includes a Hazard Index (Index) approach to address several PFAS compounds through a single measure: PFHxS, HFPO_DA, PFNA, and PFBS. To date, this approach has not been used in other drinking water regulations. The treatment of these compounds in the proposed regulation is problematic for several reasons:

1. Data Limitations – These four PFAS compounds have not been fully studied, and we believe setting a regulatory standard at this time is premature. We ask that the EPA consider delaying the establishment of regulatory standards for these PFAS compounds until full review of the results from the Unregulated Contaminant Monitoring Rule (UCMR 5) monitoring, which began this year.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document. Regarding the EPA's regulatory determinations, please see section 3.1.2 of the EPA response in this *Response to Comments* document.

City of Allentown and Lehigh County Authority (LCA), Pennsylvania (Doc. #1667, SBC-043673)

The addition of regulatory standards for other PFAS compounds, should be revisited upon completion of UCMR 5.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document. Regarding the EPA's regulatory determinations, please see section 3.1.2 of the EPA response in this *Response to Comments* document.

Austin Water (AW), Austin, TX (Doc. #1688, SBC-044453)

The analytical methods used to detect PFAS have become much more sensitive since the UCMR3 monitoring occurred and these enhanced methods are required by EPA for the sample analysis for 29 PFAS in the current Fifth UCMR (UCMR5). The UCMR5 is ongoing through 2025 and includes monitoring for all six PFAS listed in the proposed NPDWR, including GenX chemicals. AW had no detection of PFAS during our monitoring for UCMR3, and we are prepared to meet the monitoring requirements of UCMR5. Since UCMR5 will collect a considerable amount of additional data using analytical methods with increased sensitivity, the data from UCMR5 should be considered in the proposal for a final PFAS NPDWR. Using the UCMR5 sample result data would greatly improve the clarity and quality of the occurrence analysis and better inform any subsequent action on regulatory requirements for drinking water.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document regarding UCMR 5 and section 6.1 of the EPA response in this *Response to Comments* document regarding UCMR 3.

Massachusetts Coalition for Water Resources Stewardship (MCWRS) (Doc. #1691, SBC-044319)

MCWRS urges EPA to reconsider this approach, gather critical additional data, wait for the results of the upcoming UCMR 5 to be obtained and analyzed and delay any action on a final MCL until all of the needed information has been reviewed and many questions answered.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document.

Massachusetts Coalition for Water Resources Stewardship (MCWRS) (Doc. #1691, SBC-044330)

7. Alternative Approach-While MCWRS does not agree with the proposed MCLs, an alternative implementation plan is offered regardless of what the final MCLs may be. That plan would include:

f. Delay implementation until UCMR5 (already underway) is completed and the nationwide data analyzed. This would allow EPA to gain a better understanding of PFAS occurrence and levels in drinking water and is frankly the purpose of the UCMR program. Putting the MCLs in play prior to UCMR5 being completed defeats the purpose of having a UCMR program.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document. The EPA is under no legal obligation to delay the final rule until UCMR 5 is completed, as the UCMR 5 is not the basis for the rule and the agency currently has sufficiently robust occurrence information. In terms of implementation, the UCMR 5 data collection effort will be complete before the initial monitoring requirement deadline. Thus, the UCMR 5 data will support implementation without the need to delay because they will be available to satisfy initial monitoring requirements on the current timeline. For additional information on the final rule's initial monitoring requirements and the use of UCMR 5 data to support fulfillment of those requirements, please see sections 8.1.1 and 8.3 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045902)

4. The PFOA and PFOS MCLs are based on inadequate data

SDWA requires that data be collected by "best available methods (if the reliability of the method and the nature of the decision justifies use of the data)." [FN99: 42 U.S.C. [sec] 300g-1(b)(3)(A)(ii).] As discussed previously, UCMR data has always been and is still considered the most reliable data. As measurement methods have improved over time, the reliable quantitation limit, or minimum reporting levels for PFOA and PFOS have changed. In UCMR 3, the minimum reporting levels for PFOA and PFOS were 40 ppt and 20 ppt, respectively. In UCMR 5, the minimum reporting level for both PFOA and PFOS is 4 ppt, thus making the UCMR 5 data

far more relevant for the regulatory action EPA is considering. In addition to having greater relevance, because PFOA and PFOS are able to be detected at much lower levels, the UCMR 5 data also represents the best available methods.

Considering the potentially economically significant costs of the proposed rulemaking, EPA must use the best available methods as these provide the most reliable and relevant data. When UCMR 5 sample collection and analysis is complete, EPA will have data from all public water systems serving more than 3,300 [FN100: Note that transient noncommunity water systems (TNCWSs) (i.e., non-community water systems that do not regularly serve at least 25 of the same people over 6 months per year) are not required to monitor under UCMR 5.86 Fed. Reg. 73131, 73132 (December 27, 2021)]. The UCMR 3 data, due to the higher quantitation levels, is simply not sufficiently reliable. Nationwide UCMR 5 sampling will be complete in 2025 and these data will be the most reliable data to use to determine whether there is a substantial likelihood that these PFAS will occur frequently and at concentrations where they are likely to exceed their respective health risk levels. As proposed, EPA estimates that the number of impacted systems will be between 3,400 and 6,300 [FN101: 88 Fed. Reg. at 18680]. In fact, the number of impacted entities is almost double what EPA estimates [FN102: See PFAS National Cost Model Report, Black & Veatch Holding Company, prepared for the American Water Works Association, Appendix A (March 7, 2023): https://www.awwa.org/Portals/0/AWWA/Government/2023030756BVFinalTechnicalMemoradum.pdf?ver=2023-03-14-102450-257].

EPA Response: The EPA strongly disagrees with the commenter that the PFOA and PFOS MCLs are based on inadequate data. In regard to the EPA using the best available science and information, please see sections 6.8, 6.2, and 6.5 of the EPA response in this *Response to Comments* document. The EPA also disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document for more details.

The EPA's occurrence estimates represent best available science. Please see sections 6.5 and 6.8 of the EPA response in this *Response to Comments* document, as well as the EPA response to comment Doc. #1759, SBC-045575 in section 6.5 in this *Response to Comments* document. The Black & Veatch report relies on a non-nationally representative set of systems to extrapolate to the nation. The set of systems included the 4,920 UCMR 3 systems but added an additional 3,069 systems from select states. New England accounted for about 70 percent of these additional systems (1,142 were in New Hampshire, 605 were in Vermont, 298 were in Massachusetts, and 73 in Rhode Island). An example of the impact of this approach is that New Hampshire went from representing less than 0.5 percent of systems in the nationally representative set of systems in UCMR 3 to representing over 14.6 percent of systems included in the Black & Veatch extrapolation. Similarly, Vermont went from representing about 0.24 percent of UCMR 3 systems to representing about 7.7 percent of the systems in the final set of systems used for extrapolation. This indicates substantial bias in results that overrepresents the New England region. Thus, the agency asserts the results of this analysis would not be nearly as

representative as the analysis conducted by the EPA and presented in the proposed and final rule preamble. Additionally, the EPA disagrees that the UCMR 3 data are not "sufficiently reliable" and were not collected using best available methods (see section 6.1 of the EPA response in this *Response to Comments* document).

Protecting Our Water, Environment, and Ratepayers (POWER) (Doc. #1714, SBC-045936)

COMMENT 3 — A FINAL MCL WOULD BE ARBITRARY AND CAPRICIOUS UNLESS AND UNTIL THE PFAS PREVALENCE, AND THEREFORE THE MCL'S COSTS AND BENEFITS, ARE INFORMED BY DATA FROM UCMR 5.

On December 27, 2021, the EPA published UCMR 5, which requires sampling for 30 compounds between 2023 and 2025. UCMR data is intended "to support EPA's future regulatory determinations and, as appropriate, assist in the development of national primary drinking water regulations." [FN16: EPA, UCMR 5 Fact Sheet, available at https://www.epa.gov/system/files/documents/2022-02/ucmr5-factsheet.pdf.] Specifically, UCMR 5 is intended to "provide new data that is critically needed to improve EPA's understanding of the frequency that 29 PFAS (and lithium) are found in the nation's drinking water systems" to assist the EPA with making science-based decisions. [FN17: EPA, Revisions to the Unregulated Contaminant Monitoring Rule (UCMR 5) for Public Water Systems and Announcement of Public Meetings, 86 Fed. Reg. 73131, 73132 (Dec. 27, 2021) (Codified at 40 CFR Part 141).] The 29 PFAS in UCMR5 include PFOA, PFOS, and the four PFAS compounds in the proposed Hazard Index.

EPA states that UCMR 5 is intended to assist in making science-based drinking water regulations relating to the PFAS included in the Hazard Index. UCMR 5 was published in December 2021, and just began implementation this year, so most of the data has yet to be collected. EPA admits that the data from the UCMR 5 is not available for analysis of the proposed MCL at this time, but instead will be utilized for the "implementation of monitoring requirements under the proposed rule." [FN18: Proposed Rule, 88 Fed. Reg. at 18644.]

UCMR 5 is the first that requires monitoring for HFPO-DA or GenX. The other five PFAS were covered by UCMR 3 between 2013 and 2015, but they were only reportable at concentrations that were generally an order of magnitude higher than those in UCMR 5 or the proposed MCL. The proposed rule is therefore leapfrogging ahead of the very tool that is designed to inform EPA's assessment of contaminants' prevalence, and therefore the costs and benefits of promulgating an MCL.

To avoid acting arbitrarily, EPA should consider the monitoring data it receives from now through 2025, and provide the public an updated estimate of costs and benefits, before proceeding to a final MCL.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document. The EPA disagrees that the agency has "leapfrogged" the established

process for developing NPDWRs or is acting arbitrarily. The EPA implements a monitoring program for unregulated contaminants (i.e., UCMR) under SDWA 1445(a)(2) that requires the EPA to issue a list once every five years of priority unregulated contaminants to be monitored by PWSs, however there is no statutory requirement that a contaminant must be on this list, if the agency has sufficiently available information through other sources. Additionally, completion of the UCMR 5 data collection effort is not required prior to making a regulatory determination nor promulgation of the final rule. The UCMR 3 dataset, along with additional state data and robust analyses, demonstrate sufficient likelihood of occurrence of the PFAS being regulated.

Wyoming Department of Environmental Quality (WDEQ) (Doc. #1716, SBC-044767)

1. EPA Should Complete Collection and Analysis of UCMR 5 PFAS Data Prior to Finalizing the PFAS NPDW Rule

Developing a proposal to regulate PFAS under the SDWA prior to completion of ongoing UCMR 5 sampling efforts is inconsistent with EPA's integrated approach to PFAS (as stated in the Strategic Roadmap) to invest in research to increase understanding of PFAS exposures. UCMR 5 requires analysis for twenty-nine (29) PFAS compounds with a Minimum Reporting Limit (MRL) of 4.0 ppt, while UCMR 3 PFAS data represents concentrations of only six (6) PFAS with MRLs of 10 ppt to 90 ppt, from fewer PWSs overall. While EPA acknowledges that UCMR 5 data will not be available to inform this proposal, UCMR 5 data will be available to inform the implementation of monitoring requirements under the proposed PFAS NPDW rule. Additionally, more recent data collected by states and used by EPA to supplement UCMR 3 data shows that the continued occurrence of five of the six PFAS proposed for regulation "occur at lower concentrations and significantly greater frequencies than were measured under UCMR 3." However, the use of state-collected data is often not representative of PFAS impacts on PWSs due to those data being collected as a result of previously known PFAS impacts; thus, that data should not be used to model or predict the occurrence of anticipated concentrations nationwide. Developing and promulgating enforceable regulations prior to completing UCMR 5 misses an opportunity to expand our understanding of PFAS impacts on PWSs and subsequent human health exposures nationwide and to inform regulation development with higher quality data.

EPA Response: Please see sections 6.8 and 6.5 of the EPA response in this *Response to Comments* document. Additionally, the EPA disagrees with the commenter that the state data should not be used to evaluate occurrence. The EPA has presented the data that was collected under non-targeted frameworks and the data collected under targeted efforts (i.e., where it is collected in areas of known or suspected PFAS contamination) and utilized it appropriately based on this and other factors. See sections III and VI of the FRN and the *Occurrence Technical Support Document* (USEPA, 2024b) for extensive discussion of the data the EPA considered for this regulation.

Wyoming Department of Environmental Quality (WDEQ) (Doc. #1716, SBC-044771)

While WDEQ does not have comments in response to EPA's request for specific conditions that should be mandated for systems to be eligible for exemptions under SDWA § 1416(b)(2)(C), WDEQ does strongly recommend that UCMR 5 data collection and analysis be completed prior to finalization of the proposed PFAS NPDW rule, specifically to apply a more comprehensive understanding of PFAS occurrence and concentrations in PWSs to better inform financial and infrastructural implications for affected PWSs in Wyoming.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document.

Monte Vista Water District (MVWD) (Doc. #1718, SBC-043528)

Cost Analysis

EPA's financial impact used multiple data sources, including the Third Unregulated Contaminant Monitoring Rule (UCMR3), to estimate the PFAS occurrence and potential impact to public water systems. The analytical methods used by these data sources may have a minimum reporting level higher than the proposed MCL, and therefore public water systems may exceed one or more MCL's. MVWD recommends EPA update the occurrence model and the cost-benefit analysis after the completion of the Fifth Unregulated Contaminant Monitoring Rule (UCMR5) in 2025. UCMR5 will provide additional data that is a more accurate indication of current PFAS values at the proposed reporting levels which is critically needed to improve EPA's understanding of the frequency that PFAS are found in drinking water systems and at what levels. This data will ensure science-based decision-making and help to quantify the costs more accurately.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document in regard to UCMR 5 and section 6.5 of the EPA response in this *Response to Comments* document in regard to the national occurrence model. In regard to the EPA's cost estimates, please see section 13.3 of the EPA response in this *Response to Comments* document.

Monte Vista Water District (MVWD) (Doc. #1718, SBC-043534)

Cost Analysis

EPA's financial impact used multiple data sources, including the Third Unregulated Contaminant Monitoring Rule (UCMR3), to estimate the PFAS occurrence and potential impact to public water systems. The analytical methods used by these data sources may have a minimum reporting level higher than the proposed MCL, and therefore public water systems may exceed one or more MCL's. MVWD recommends EPA update the occurrence model and the cost-benefit analysis after the completion of the Fifth Unregulated Contaminant Monitoring Rule (UCMR5) in 2025. UCMR5 will provide additional data that is a more accurate indication of

current PFAS values at the proposed reporting levels which is critically needed to improve EPA's understanding of the frequency that PFAS are found in drinking water systems and at what levels. This data will ensure science-based decision-making and help to quantify the costs more accurately.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document in regard to UCMR 5 and section 6.5 of the EPA response in this *Response to Comments* document in regard to the national occurrence model. In regard to the EPA's cost estimates, please see section 13.3 of the EPA response in this *Response to Comments* document.

U.S Conference of Mayors, National League of Cities and National Association of Counties (Doc. #1733, SBC-043899)

3. Additional Scientific Data and Cost-Benefit Analysis

The Agency anticipates releasing updated data in its upcoming Fifth Unregulated Contaminant Monitoring Rule (UCMR 5), expected within the next nine months. According to EPA's website, "the monitoring provides EPA and other interested parties with nationally representative data on the occurrence of contaminants in drinking water, the number of people potentially being exposed, and an estimate of the levels of that exposure. These data can support future regulatory determinations and other actions to protect public health." Notably, this current dataset includes monitoring for 29 different PFAS chemicals, including for all six PFAS chemicals being considered under this proposal.

The information obtained from this monitoring dataset would be of great value to support the Agency as it develops its regulatory framework for proposing new drinking water standards for PFAS. This updated data will provide a deeper insight into the monitoring and testing capacities of public water systems and laboratories across the nation, as well as better inform the cost-benefit analysis. Setting the MCL levels at the detect level when more data has yet to be released denies the Agency the ability to adjust these levels in the future, making permanent strict compliance actions for which the costs may not be justified. Therefore, we urge the Agency to either propose a higher MCL standard such as 10 ppt for PFOS and PFOA, or consider waiting to finalize any MCL levels until at least this new dataset becomes available for EPA to utilize.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document. For the EPA's response related to the PFOA and PFOS MCLs and determination of feasibility, please see section V.A of the FRN, specifically V.A.2 regarding alternative MCLs.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045999)

Complete occurrence data from UCMR 5 will help EPA complete this cost analysis that the agency says currently is "unlikely to be substantially" underestimated. AMWA reiterates its

earlier comment that EPA should reconsider finalizing the regulatory determination of the HI PFAS as it collects and analyzes UCMR 5 data.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document regarding UCMR 5 data. Regarding the EPA's regulatory determinations, please see sections 3.1.2 and 3.2.2 of the EPA response in this *Response to Comments* document.

City of Thornton, Colorado (Doc. #1748, SBC-044784)

Without UCMR5 data, EPA is woefully uninformed about national PFAS occurrence and significantly underestimating costs there.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document. The EPA disagrees that the agency is uninformed about national PFAS occurrence, as the agency's analyses have produced scientifically robust estimates of national occurrence.

American Water Works Association (AWWA) (Doc. #1759, SBC-045576)

Inclusion of Data from Fifth Unregulated Contaminant Monitoring Rule

This year, drinking water monitoring for PFAS under the Fifth Unregulated Contaminant Monitoring Rule (UCMR 5) began. UCMR 5 is expected to be the most comprehensive occurrence dataset for PFAS collected to-date. Indeed Congress took the additional step of explicitly instructed EPA to include these substances in UCMR 5 as part of the National Defense Authorization Act for Fiscal Year 2020 (Congress, 2019). In accordance with UCMR 5, more than 10,300 systems will monitor for 29 PFAS using EPA Methods 533 and 537.1 using single-digit minimum reporting limits. While a complete dataset will not be compiled until 2026, more than 3,500 water systems are actively collecting monitoring data this year. By the end of summer this year, EPA will have at least one sample result from these 3,500 water systems. Previous research has shown that preliminary data collected from UCMR monitoring provides accurate insights about occurrence when compared to the complete dataset (Eaton et al, 2018).

UCMR 5 data collected during the first half of 2023 would represent a significant increase in the available data that is nationally representative. Specifically, this dataset will provide information on nearly 70% of the number of water systems that are typically represented by a UCMR program. While this data would not be a full UCMR sampling program, it would significantly expand the universe of nationally representative data at method reporting levels deemed appropriate in the proposed rule. As the goal of the UCMR 5 program is to inform EPA on the occurrence of PFAS, EPA can ill afford to ignore these data, which would be of a much higher quality and value than its current Bayesian Model approach.

The UCMR program is designed to collect national occurrence data on contaminants not currently subject to NPDWRs, and EPA "require[ed] collection of data under UCMR 5 to inform EPA regulatory determinations and risk-management decisions" (EPA, 2021c). Given that

Congress explicitly instructed EPA to include PFAS chemical in UCMR 5, Congress clearly intended for the national occurrence date resulting from UCMR 5 to inform EPA's regulatory determinations about these substances. This strongly suggests that EPA should wait to take final regulatory action on these substances until all UCMR 5 data has been collected so that that its decisions can be fully informed with the best available information. This is particularly true given that the SDWA's an-backsliding provisions will require continued regulation of these substances once EPA has issued a final NPDWR: EPA must make the most informed decision possible at this stage to fulfill its statutory obligations and prevent unnecessary and unjustified regulations. [FN12: See 42 U.S.C. § 300g-1(b)(9) ("Any revision of a national primary drinking water regulation shall be promulgated in accordance with this section, except that each revision shall maintain, or provide for greater, protection of the health of persons.").]

But even if EPA does not wait until all UCMR-5 data has been collected, it must at the very least incorporate and prioritize data already provided to the agency under UCMR-5 in making regulatory decisions under this proposal. Given that much of the UCMR 5 data has already been collected, EPA cannot meet the SDWA's directive to rely on the best available public health information without taking into account this most current and comprehensive set of data.

EPA Response: Please see section 3.1.2 of the EPA response in this *Response to Comments* document in regard to the EPA's regulatory determinations, section 6.8 of the EPA response in this *Response to Comments* document in regard to UCMR 5, and section 6.5 of the EPA response in this *Response to Comments* document in regard to the national occurrence model.

American Water Works Association (AWWA) (Doc. #1759, SBC-045563)

3. EPA's statistical approach to estimating occurrence of PFAS in drinking water is overly complicated and EPA would be ill-advised to move forward with a final rule without considering incoming data from more than 3,500 water systems currently collecting samples under the Fifth UCMR 5 (EPA, 2021c).

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document in regard to UCMR 5 data and section 6.5 of the EPA response in this *Response to Comments* document in regard to the EPA's modeling approach for estimating national PFAS occurrence.

American Water Works Association (AWWA) (Doc. #1759, SBC-045580)

6. EPA should not finalize the occurrence analysis without considering the availability of high-quality, nationally representative data from the UCMR 5 program to either improve the existing occurrence analysis or replace the analysis.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document.

Connecticut Section of the AWWA (CTAWWA) and Connecticut Water Works Association (CWWA) (Doc. #1763, SBC-044235)

Timeline for Finalizing the PFAS Rule

We recommend that findings from the fifth Unregulated Contaminant Monitoring Rule (UCMR5) monitoring period, specifically on the 29 PFAS compounds, be reviewed and incorporated into the PFAS Rule to ensure that it adequately limits risk. Nationwide monitoring results will provide greater insight into the occurrence of PFAS and guide the rule-making effort. We note that the EPA has committed to publishing the Final Rule in December 2023, which is nine months prior to the statutory deadline. This additional time could be utilized to analyze UCMR5 results.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document.

Environmental Protection Network (EPN) (Doc. #1773, SBC-043861)

EPN recommends that in the final rule, EPA commit to reviewing the results of UCMR5 as soon as data are available to identify any co-occurring PFAS.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document. Additionally, see VI.C. and VI.G. of the final rule preamble for the updated PFAS co-occurrence analysis.

California-Nevada Section American Water Works Association (CA-NV AWWA) (Doc. #1775, SBC-045269)

The importance of this issue recently came to our attention, when multiple water systems across the nation began reporting data quality issues with the methods for the first quarter of UCMR 5 monitoring (since January 2023), particularly with EPA Method 533 (for 25 PFAS). CA-NV AWWA urges EPA to complete the two-year UCMR 5 monitoring period, engage with stakeholders to develop a comprehensive assessment of the findings, and then use the results to inform and develop practical PFAS drinking water regulations. The benefits of this approach include a better understanding of laboratory capacity for trace level analyses, time to resolve technical issues with the analytical methods (including sample contamination and false-positives), more robust and consistent data to use for PQL development, and a realistic understanding of the analytical costs. Overall, EPA will have better and more reliable information by waiting. The collection of reputable data is a critical factor that must be completed prior to the development of the technical and economic impacts analyses.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document.

California-Nevada Section American Water Works Association (CA-NV AWWA) (Doc. #1775, SBC-045277)

EPA should adhere to the established SDWA regulatory process, and should adjust timeframes in the rulemaking and in the final regulation.

7. This rulemaking should be informed by additional occurrence data from UCMR 5 and State monitoring.

In this rulemaking, EPA has relied on data from UCMR 3 that provides an incomplete basis for the preliminary determination to set the MCLs proposed in this rulemaking. This shortcoming is especially true for small systems [FN9: In its Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation Appendices (EPA Document No. EPA-822-P-23-002, hereafter "Proposed PFAS Rule Economic Analysis"), the text notes, "Because UCMR 3 included only a sample of small systems, there is greater uncertainty in the occurrence estimates for small systems compared to large systems."], and for the four PFAS chemicals other than PFOA and PFOS, i.e., PFHxS, PFNA, PFBS, and HFPO-DA (GenX). Occurrence of these four PFAS is not sufficiently understood, and EPA needs to consider updated data available from states and to be collected under UCMR 5. In the Economic Analysis [FN10: Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation Appendices. USEPA, Office of Water, EPA-822-P-23-002. March 2023] a footnote states, "PFBS and PFNA were not included in the model because 19 reported values across the country from the primary dataset (UCMR 3) were insufficient for fitting the national model...." [FN11: Proposed PFAS Rule Economic Analysis, p. A-2]. Moreover, knowledge gaps about occurrence and the co-occurrence of chemicals included in the Hazard Index require additional data and new analysis for the Index to be valid.

EPA Response: The EPA has followed the SDWA regulatory process. Please see section 6.2 of the EPA response in this *Response to Comments* document in regard to the use of state data in addition to UCMR 3 data. Please see section 6.5 of the EPA response in this *Response to Comments* document regarding the national occurrence model and handling of small systems. Please see section 6.6 of the EPA response in this *Response to Comments* document regarding the combination of state data with national occurrence model output. See also section 10.3 of the PFAS *Occurrence Technical Support Document* (USEPA, 2024b). Please see section 6.3 of the EPA response in this *Response to Comments* document and preamble sections VI.C and VI.G regarding PFAS co-occurrence. Regarding costs associated with exceedances of the Hazard Index MCL, please see section 13.3.2 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenter that there is incomplete occurrence data or that it does not represent all sizes of water systems. The EPA collected PFAS data from 32 states, in addition to the UCMR 3 dataset, to inform the final rule. See VI. of the preamble for state data analysis, assessment of occurrence relative to the Hazard Index, and the assessment of PFAS co-occurrence. The *Occurrence Technical Support Document* presents additional analysis (USEPA, 2024b).

California-Nevada Section American Water Works Association (CA-NV AWWA) (Doc. #1775, SBC-045283)

11. Focus limited funding on the elimination of continued environmental loading.

Since the voluntary phase-out of PFOA and PFOS, the levels found in human blood serum have substantially declined, indicating that a preventative approach is effective [FN12: Hurley, S. et al. 2017. Time trends in per- and polyfluoroalkyl substances (PFASs) in California women: Declining serum levels, 2011-2015. Env. Sci. Tech 52(1)]. EPA estimates that human exposure primarily comes from food and air and estimates about 20% of PFAS exposure from drinking water. Advanced drinking water treatment comes at a significant economic, financial, and environmental cost (in terms of CO2 emissions and carbon use), which ultimately is paid for by the consumers, regardless of the water system size or demographic. Prior to requiring public water systems to employ advanced treatment to eliminate a continual supply of PFAS entering watersheds, EPA should fully understand the occurrence of PFAS in drinking water. The current UCMR 5 efforts will help inform that objective.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document.

San Diego County Water Authority, CA (Doc. #1779, SBC-045287)

EPA is also seeking comment on regulating the four PFAS as a mixture using a Hazard Index approach. The Hazard Index (HI) is a calculation used to evaluate potential health risks from chemical mixtures and would be the first use of this approach by EPA in setting drinking water standards. The HI assumes dose addition and co-occurrence among the chemicals. The Water Authority recommends that the Hazard Index based on these four chemicals be established after monitoring data is available under the Fifth Unregulated Contaminant Monitoring Rule (UCMR 5). The timing would align considering that EPA expects to finalize the rule at the end of 2023, after which water systems would have three years to comply. UCMR 5 data collection will occur from January 2023 through December 2025, and will provide significantly more data to be considered in establishing the HI. Additional data would also be available from states such as California that have required monitoring that was not considered by EPA in the proposed Rulemaking. For example, monitoring for Gen X was not part of UCMR 3 but is part of UCMR 5. Additionally, PFNA has been voluntarily phased out of production and use and may be less likely to cooccur. The availability of this additional data will allow for refinement of the Hazard Index approach to regulating the PFAS as a mixture.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document. State data from California, as well as 31 other states. were considered in the proposed rulemaking. These data are discussed in sections III.C. and VI.B. of the final rule preamble as well as the PFAS *Occurrence Technical Support Document* (USEPA, 2024b).

Safe Drinking Water Branch, Hawaii Department of Hawaii (Doc. #1801, SBC-043752)

The UCMR5 and the PFAS Rule

Normally, EPA conducts UCMR study to collect enough data first. After careful analysis of the test result, EPA then proposes the new regulation. However, this time the proposal of the PFAS rule and UCMR5 happen at the same time. It demonstrates that EPA made a rush decision without solid scientific evidence. It is very dangerous for EPA to establish such non-scientific precedent. It will impact the trust between EPA and the whole water industry.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document. Additionally, the EPA disagrees that the agency has made a "rush decision without solid scientific evidence." The EPA implements a monitoring program for unregulated contaminants (i.e., UCMR) under SDWA 1445(a)(2) that requires the EPA to issue a list once every five years of priority unregulated contaminants to be monitored by PWSs, however there is no statutory requirement that a contaminant must be on this list. The agency may make a regulatory determination if the agency has sufficiently available information through other sources. Additionally, completion of the UCMR 5 data collection effort is not required prior to making a regulatory determination nor promulgation of the final rule. The UCMR 3 dataset, along with additional state data and robust analyses, demonstrate sufficient likelihood of occurrence of the PFAS being regulated.

Office of Advocacy at the U.S. Small Business Administration (Doc. #1807, SBC-045480)

a. EPA has underestimated the impact of the rule on small water systems. Advocacy is concerned that EPA has underestimated the impact of the proposed rule on small water systems. More specifically, the agency underestimates the number of systems that will be required to comply. EPA's proposed MCLs are set at the lowest concentration that PFOA and PFOS can be reliably quantified in a laboratory (i.e., 4.0 ppt). As a result, many systems will be subject to the proposed requirements. Advocacy is concerned that EPA's estimates for the number of impacted public water systems is not based on the best available data. EPA decided not to wait for the fifth Unregulated Contaminant Monitoring Rule (UCMR 5) occurrence data to inform its analysis for the number of water systems that will be subject to the proposed rule. The collection of this data started this year and is expected to continue into 2025. Under UCMR 5, EPA published the method reporting limit (MRL) [FN8: The method reporting level (MRL) is the level at which the test can report a quantifiable value with high confidence] of 4.0 ppt each for PFOA and PFOS, same as the proposed MCLs. Instead, for the proposal, EPA used UCMR 3 and state data with levels above the proposed monitoring or compliance levels in this proposal. Because it represents a lower limit than UCMR 3, the results of UCMR 5 data will provide a more accurate accounting of water systems likely to be subject to EPA's regulations, an outcome not currently acknowledged or accounted for in EPA's analysis.

EPA Response: Please see sections 6.2 and 6.8 of the EPA response in this *Response to Comments* document. Also please see section 6.5 of the EPA response in this *Response to*

Comments document regarding how the national PFAS occurrence model incorporated both state data and UCMR 3 data. While the EPA clearly states in the proposed and final rule preamble that the UCMR 3 MRLs are higher than the proposed and final PFAS MCLs, the EPA disagrees that the analyses would systematically underestimate the impact of the final rule on small systems. State occurrence data that were used primarily had reporting limits on the order of single digits ng/L, often lower than the EPA's UCMR 5 MRLs. Since the EPA has considered these data, which are representative of all size water systems, and also used it in combination with UCMR 3 to model national occurrence estimates for small and large systems, the agency has concluded that it has reasonably estimated impacts to small systems.

The District of Columbia Water and Sewer Authority (Doc. #1829, SBC-045768)

Monitoring for PFAS under the Fifth Unregulated Contaminant Monitoring Rule (UCMR5) began this year. UCMR5 will be the most comprehensive occurrence dataset for PFAS collected to date. While a complete dataset will not be compiled until 2026, more than 3,400 water systems are actively collecting monitoring data this year. By the end of summer this year, all these systems will have collected at least one sample and EPA will have received these results. While this may not be a complete data set, it will significantly improve the understanding of PFAS occurrence in U.S. public water systems. We request that EPA delay issuance of the final PFAS standards until UCMR5 data can be used to better determine national PFAS occurrence and a more accurate assessment of the number of impacted systems, costs and benefits of the proposed rule can be completed.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document.

The District of Columbia Water and Sewer Authority (Doc. #1829, SBC-045774)

Monitoring for PFAS under UCMR5 began this year. UCMR5 will be the most comprehensive occurrence dataset for PFAS collected to date. EPA should delay issuance of the final PFAS standards until UCMR5 data can be used to better determine national PFAS occurrence and a more accurate assessment of the number of impacted systems, costs and benefits of the proposed rule can be completed.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document.

Pennsylvania Municipal Authorities Association (Doc. #1832, SBC-045788)

[PMAA's specific comments on the Proposal are as follows:]

12. PMAA believes that the results from the Fifth Unregulated Contaminant Monitoring Rule ("UCMR 5") will provide EPA with a more scientifically valid and robust database on the occurrence of PFAS chemicals in the nation's drinking water. This data will ensure that a

prospective PFAS final regulation will be based upon the best available science, and EPA should defer moving forward with the Proposal until such data is available, evaluated and subject to public review and comment. In fact, EPA recommends that data from UCMR 5 be used for initial monitoring requirements once the Proposal is finalized. (See, EPA PowerPoint from March 29, 2023 webinar on Proposed PFAS National Primary Drinking Water Regulation, slide 19).

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document.

Columbia Water (Doc. #1833, SBC-045795)

Due to the continued uncertainty of the effects on public health caused by PFAS chemicals, and EPA's apparently significant underestimation of the costs of making the capital and operational/maintenance investments necessary to treat water to the proposed standards, we believe EPA must withdraw the proposed MCL's for PFAS chemicals and make use of information to be gathered in the coming UCMR5 rule to inform additional future research into the prevalence and health effects of the PFAS chemicals.

Sincerely,

Clint Shealy, PE, Assistant City Manager for Columbia Water City of Columbia, South Carolina

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document. The EPA disagrees that there is uncertainty about the risks to public health caused from the six regulated PFAS: see section III and IV of the preamble for this action and sections 3.1.1, 3.2.1, and 4 of the EPA response in this *Response to Comments* document. The EPA also disagrees it has significantly underestimated the costs to treat water to the regulatory standards (see section 13.3 of the EPA response in this *Response to Comments* document),

Massachusetts Water Resources Authority (Doc. #3072-49, SBC-047381)

EPA also seems to have jumped out ahead of the logical regulatory process by making this proposal now while water systems are expending substantial effort and cost to collect the UCMR 5 PFAS data with appropriate detection levels. That data should have been in place before the rule was proposed to substantially refine its impact.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document.

Greenville Utilities Commission (Doc. #3072-53, SBC-047385)

Okay, thank you. Good afternoon. My name is Anthony Whitehead. I'm the water quality manager for Greenville Utilities Commission. The proposed MCLs for PFAS compounds will be extremely difficult and expensive for many water providers to meet. PFAS compounds are

ubiquitous, not just near known spill or contamination sites through these compounds being used in many products encountered in our lives each day, including food wrappers, cookware, personal care products, clothing, and cosmetics. Drinking water is the only one of several routes of exposure to PFAS compounds and the drinking water industry should not be disproportionately targeted by regulatory action to reduce PFAS exposure. UCMR 5 will provide EPA with scientifically valid data on the national occurrence of 29 PFAS compounds in the nation's drinking water and at what levels. This data will ensure science-based decision making and help prioritize protection of disadvantaged communities. Implementation of regulation before up-to-date information from UCMR 5 can be reported and analyzed does not follow sound scientific principles. The limited number of laboratories certified to analyze samples for UCMR 5 have caused 10-day turnaround times to become two month waits for data. Utilities will have to increase sampling to determine the effectiveness of potential treatment strategies which will further burden those laboratories.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document. Regarding laboratory capacity, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-047702)

Section 8.2: Cost of HI PFAS

Complete occurrence data from UCMR 5 will help EPA complete this cost analysis that the agency says currently is “unlikely to be substantially” underestimated. EPA should reconsider finalizing the regulatory determination of the HI PFAS as it collects and analyzes UCMR 5 data.

In Table 41 (88FR 18703) EPA states there are insufficient UCMR 3 data for PFBS and PFNA and that there are no UCMR 3 data for GenX available. If EPA does not have the data to support whether utilities will be out of compliance with the HI, how can it assume that these potential exceedances do not need to be part of the cost estimate? Cleveland Water disagrees with EPA that not including this information in the national cost estimates is insignificant.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document. The EPA notes that while UCMR 3 data for PFBS and PFNA were not included within the EPA’s national occurrence model as referenced by the commenter, nor was HFPO-DA included within the UCMR 3, as a part of its overall occurrence analysis the agency did evaluate and present UCMR 3 data on PFBS, PFNA, and PFHxS, and also evaluated a robust dataset of more recent state monitoring data for all of the PFAS which it is regulating, including HFPO-DA. Those data summaries and results are presented in the *Occurrence Technical Support Document* (USEPA, 2024b) and section VI of the preamble. Therefore, the EPA has sufficient data available for all PFAS which it is regulating and has included this information within its cost estimates. After considering recommendations from public commenters to further analyze the costs of the Hazard Index and the data available to support a quantitative analysis of the costs of the Hazard Index, the EPA decided to conduct a sensitivity analysis of the costs of the Hazard

Index at the national level. The results of the sensitivity analysis supported the EPA's assumption in the proposal that quantified national costs are marginally underestimated as a result of this lack of sufficient nationally representative occurrence data. For more information on the EPA's cost analysis, see section 13.3.2 of the EPA response in this *Response to Comments* document.

Loudoun Water (Doc. #1717, SBC-043522)

The Unregulated Contaminant Monitoring Rule is the critical path to provide EPA with nationally representative data on the occurrence of PFAS in drinking water, as well as the number of people potentially being exposed, and an estimate of the levels of that exposure. Loudoun Water believes that the collection of water system data in the fifth UCMR (UCMR 5) is likely to show that many more systems will be affected by the regulation than EPA has estimated.

EPA Response: Please see section 6.8 of the EPA response in this *Response to Comments* document.

Section 6 References

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7 Analytical Methods

7.1 Validated EPA Methods

Summary of Major Public Comments and EPA Responses

Several commenters note analytical differences between EPA Methods 533 and 537.1, such as differences in the quality control (QC) acceptance levels between the methods, sample preservation and holding times, as well as variability in sample and spike duplicates. In some instances, these commenters request specific modification to the methods, revisions to the EPA laboratory certification manual, or for the agency to develop guidance that laboratories and state accreditation/ certification bodies could use. These commenters note that while both methods are valid under the final rule, variability between the two may lead to differences in sampling results and may impact a water system's compliance status. The EPA agrees that Methods 533 and 537.1 have some differences that allow for analysis of varying chain lengths and molecular structures of PFAS. Method 533 generally captures "short chain" PFAS (i.e., those with carbon chain lengths of 4 to 12) and fluorotelomer sulfonic acids. Method 537.1 includes some overlap with Method 533's analyte list while including some longer-chain PFAS. However, the agency notes that all six PFAS finalized for regulation can be analyzed by either Method 533 or 537.1 and neither method has inherent QC issues that lead to significant variation in sampling results when followed. This is because the ability of the methods to meet QC is determined during method development, through both single and multi-laboratory validation. All laboratories, internal and external, are required to demonstrate that all QC criteria listed in Section 9.0 of the methods can be met. This ability to meet QC criteria also has been corroborated by laboratories participating in the fifth Unregulated Contaminant Monitoring Rule (UCMR 5) Laboratory Approval Program (LAP), where there was overwhelming success in meeting method QC acceptance criteria. While there are differences between the methods and how they measure their respective target analytes, both EPA Methods 533 and 537.1 utilize the same technologies (solid phase extraction (SPE) with liquid chromatography/mass spectrometry) and perform comparably as evidenced by the similar QC acceptance criteria and performance data provided in each method. The methods are clear and outline specific instructions regarding requirements that are needed for compliance monitoring measurements.

Some public commenters suggested that the EPA allow alternate analytical procedures or modifications to the two published EPA methods for meeting the monitoring requirements in the final rule. The EPA continues to specify the use of Methods 533 and 537.1 because consistent, reliable compliance data are necessary for implementation of the regulation at the Maximum Contaminant Level (MCL). However, the EPA recognizes that improvements in analytical technology and methodology occur. The EPA's Drinking Water Alternate Test Procedure (ATP) Program provides a mechanism for submission and review of alternative methods to measure a contaminant for nationwide use under 40 CFR 141.27. A method developer may apply for the EPA review of a method modification or a new method through the ATP Program. In the meantime, the agency has concluded that Methods 533 and 537.1 are reliable for use in

compliance monitoring with respect to accuracy and recovery (lack of bias) and precision (good reproducibility) at the MCL levels. With respect to improvements in analytical technology, the EPA further notes that the agency is required to review National Primary Drinking Water Regulations (NPDWRs) every six years and determine which, if any, are appropriate for revision (i.e., the Six-Year Review Process). The purpose of the review is to evaluate current information for regulated contaminants and to determine if there is any new information on health effects, analytical methods, occurrence and exposure, implementation, and/or other factors that provides a health or technical basis to support a regulatory revision that will improve or strengthen public health protection. This process allows the agency to consider these and other information as appropriate in deciding whether existing NPDWRs should be identified as candidates for revision as required by the Safe Drinking Water Act (SDWA).

Some commenters sought clarity on which methods are approved for use in compliance monitoring for the final PFAS NPDWR. Some of these commenters requested that only Method 533 be approved for monitoring under the final NPDWR, noting that it may be more suitable should additional PFAS analytes within its scope be targeted for regulation at the future date. Others requested that they be permitted to use Method 537, version 1.1. The EPA disagrees and reaffirms that Methods 537.1, version 2.0 and Method 533 are both applicable and suitable for use in compliance monitoring in the final rule. The EPA notes that the EPA Method 1633 is not a drinking water method and, as such, may have different time and resource requirements than the EPA Method 533 or Method 537.1, ver. 2.0. The EPA notes that HFPO-DA is one of the PFAS regulated under the final NPDWR and only Method 537.1, version 1.0 and version 2.0, and Method 533 support the collection of data for HFPO-DA. The agency notes that the primary difference between Method 537.1, version 1.0 and Method 537.1, version 2.0 is the field reagent blank (FRB) preparation: version 2.0 exposes the FRB to the preservative (Trizma) at the time of field sample collection. Version 1.0 combines the lab reagent water and the preservative together in the FRB prior to field sampling. Version 2.0 was created to more-closely mimic the FRB process used in Method 533. Additionally, Version 2.0 explicitly states that the SPE cartridge sorbents may not be modified with monomers other than styrene divinylbenzene (SDVB).

Several commenters requested that all laboratories be required to identify their quantitation limits (i.e., the smallest detectable concentration of an analyte greater than the detection limit where the accuracy (precision and bias) achieves the objectives of the intended purpose) and/or method detection limits (MDLs; i.e., the minimum result which can be reliably discriminated from a blank). Specifically, some commenters note if labs have to demonstrate they can get below the practical quantitation level (PQL), the EPA should establish reporting or detection limits demonstrating they can get to these levels. While the agency does not require laboratories to demonstrate that they can get below the PQLs, the EPA is finalizing rule trigger levels below the PQL to support the monitoring provisions discussed in section VIII of this preamble. The EPA disagrees with these commenters that such reporting is needed to support compliance monitoring for the rule and that such reporting would be a cost burden on laboratories. All labs are required per the approved methods to demonstrate whether laboratory reagent blank (LRB) QC samples have background concentrations of less than one-third the minimum reporting level (MRL; i.e.,

the minimum concentration that can be reported as a quantitated value for a method analyte in a sample following analysis). Therefore, for a laboratory to be compliant with the methods, they must be able to detect, not necessarily quantify, analytes at or above 1/3 the MRL.

After review of public comment, the EPA is establishing two approved methods to support the monitoring requirement of this NPDWR. These two liquid chromatography/tandem mass spectrometry (LC/MS/MS) analytical methods were developed by the EPA and validated to quantitatively monitor drinking water for targeted PFAS: the EPA Method 533: *Determination of Per- and Polyfluoroalkyl Substances in Drinking Water by Isotope Dilution Anion Exchange Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry* (USEPA, 2019) and EPA Method 537.1, Version 2.0: *Determination of Selected Per- and Polyfluorinated Alkyl Substances in Drinking Water by Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS)* (USEPA, 2020). All six PFAS compounds regulated by the NPDWR can be measured by both the EPA Methods 533 and 537.1, ver. 2.0 and both methods are acceptable for meeting the monitoring requirements of this regulation. These methods are incorporated by reference in the final rule (see 40 CFR § 141.901(a)) and are publicly available in the EPA's Docket ID No. EPA-HQ-OW-2022-0114. For additional discussion on analytical methods, please see section VII of the final rule NPDWR preamble. For additional discussion on the PQLs for the PFAS regulated under this final NDPWR, please see section 7.2 of the EPA response in this *Response to Comments* document. For discussion on feasibility of the MCLs with respect to laboratory capacity, capability, or other analytic challenges to reliably measure samples for the final NPDWR, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding commenter concerns about laboratory testing and potential contamination issues, please see section 8.7 of the EPA response in this *Response to Comments* document.

Individual Public Comments

Mike Pettit (Doc. #1542, SBC-043347)

Overall Critique of Method 1633

EPA Method 1633 is a method for the determination of per- and polyfluoroalkyl substances (PFAS) in drinking water using solid-phase extraction and liquid chromatography/tandem mass spectrometry (LC/MS/MS). While this method has been widely used for PFAS analysis, there are some critiques that can be made:

• Limitations in the number of PFAS analyzed: The method focuses on the analysis of only 14 PFAS compounds, which may not be enough to capture the full range of PFAS contaminants that may be present in the environment.

• Sample matrix effects: The method can be subject to matrix effects, which means that the presence of other compounds in the water sample can interfere with the analysis and affect the accuracy of the results

• Reliance on internal standards: The method relies on the use of internal standards to correct for matrix effects and other sources of variability, but the use of internal standards can introduce its own sources of variability and uncertainty

• Lack of standardized quality control criteria: While the method provides guidelines for quality control and quality assurance, there is no standardized set of criteria for assessing the quality of the results obtained using this method.

• Limited sensitivity: The method has a relatively high detection limit for some PFAS compounds, which means that it may not be sensitive enough to detect low levels of these contaminants in water samples.

Overall Critique of Method 533

Method 533 also has several glaring flaws:

• Limited detection range: EPA Method 533 has a lower limit of detection (LOD) of 0.05 ng/L for some PFAS compounds, which is lower than the LOD of previous methods. However, this LOD may still not be low enough to detect some of the newer, lower concentration PFAS compounds that are of concern.

• Limited sample volume: EPA Method 533 only allows for a maximum sample volume of 1 liter, which may not be sufficient to detect low-level PFAS contamination in larger water systems. This can be a particular issue for detection of PFAS in source waters that may be subject to contamination, as many water sources are larger than 1 liter

• Sample collection issues: Sample collection for PFAS analysis can be complicated by the unique properties of these compounds. PFAS compounds can adsorb to containers and tubing, which can lead to false negative results. Additionally, PFAS compounds can be found in a wide range of matrices, and the presence of other organic compounds or high levels of minerals in water can interfere with the analysis

• Limited scope of analysis: EPA Method 533 only covers a limited number of PFAS compounds, primarily those that have been detected in drinking water in the US. As new PFAS compounds are discovered, EPA Method 533 may need to be updated to ensure that all relevant compounds are being monitored.

EPA Response: With respect to clarification on which analytical methods are approved for meeting the monitoring requirements in the final NPDWR, please see section 7.1 of the EPA response in this *Response to Comments* document. The EPA notes that the EPA Method 1633 is not a drinking water method and, as such, may have different time and resource requirements than the EPA Method 533 or Method 537.1, ver. 2.0. Regarding commenter concerns about laboratory testing and potential contamination issues, please see section 8.7 of the EPA response in this *Response to Comments* document. The EPA also disagrees that EPA Method 533 has "glaring flaws" toward implementing the monitoring requirements of the final NDPWR; neither methods 533 nor 537.1 ver. 2.0 have inherent QC issues when explicitly followed. This is

because the ability of the methods to meet QC is determined during method development, through both single and multi-laboratory validation. All laboratories, internal and external, are required to demonstrate that all QC criteria listed in Section 9.0 of the methods can be met. This ability to meet QC criteria also has been corroborated by laboratories participating in the UCMR 5 LAP, where there was overwhelming success in meeting method QC acceptance criteria. Furthermore, EPA Method 533 does not require the calculation of a limit of detection (LOD), does not allow for samples greater than 250 mL, and is not applicable for the analysis of source waters.

Missouri Department of Natural Resources (Doc. #1563, SBC-042522)

Additionally, EPA Method 533 allows for quality assurance/quality control (QA/QC) samples to be ±50% at or near the MRL and not ±30% for all analytes as indicated in the preamble. From EPA Method 533 Section 9.2.3.2 Evaluate Analyte Recovery "Results for analytes fortified at concentrations near or at the MRL (within a factor of two times the MRL concentration) must be within 50–150% of the true value. Results for analytes fortified at all other concentrations must be within 70–130% of the true value. If the LFB [Laboratory Fortified Blank] results do not meet these criteria, then all data for the problem analytes must be considered invalid for all samples in the Extraction Batch." This difference in acceptance level identifies one of the key issues associated with proposing to set a MCL at the same value as the practical quantitation limit (PQL) or MRL. This issue is not one that can be solved by simply lowering the PQL/MRL to 2 ppt. Based on UCMR 5 lab approvals, it is already known that more than 25 percent of laboratories nationwide will not be able to meet a PQL lower than 4 ppt with a 95% confidence interval (CI). In addition to causing more issues with laboratory capacity nationwide, the number of samples that would be rejected under the method, and therefore requiring resampling, would increase even with a ±50% Method QA/QC acceptance level.

EPA Response: With respect to the analytic requirements of the EPA methods approved for meeting the monitoring requirements in the final NPDWR, please see section 7.1 of the EPA response in this *Response to Comments* document. The EPA also disagrees with the commenter claims' that "25% [of labs] cannot" meet the PQL; as discussed in the final rule preamble, the PQL reflects a minimum quantitation level that "with 95 percent confidence, can be achieved by capable analysts at 75 percent *or more* of the laboratories using a specified analytical method" (emphasis added). Greater than 75 percent of labs requesting participation in UCMR 5 were able to meet the PQLs / MRLs, and the EPA anticipates the number of labs available for compliance monitoring to grow. With respect to concerns on the feasibility of the PQLs, including discussion on how the PQLs were established for the NPDWR, please see section 7.2 of the EPA response in this *Response to Comments* document.

Maine Water Utilities Association (MWUA) (Doc. #1567, SBC-042733)

Analytical Methodology:

There must be leeway in the rule to utilize any current or future EPA approved analytical methods. We believe there will be advancements in analytical technology and the rule should be flexible enough to incorporate future approved methods for PFAS analysis.

EPA Response: With respect to alternate analytical procedures or modifications to the two EPA methods approved for meeting the monitoring requirements in the final NPDWR, please see section 7.1 of the EPA response in this *Response to Comments* document.

COMM Water Department (Doc. #1577, SBC-042441)

There must be leeway in the rule to utilize any current or future EPA approved analytical methods. In Massachusetts, our regulations are so prescriptive that PWSs have not been able to utilize Method 533 because it had not yet been approved by EPA at the time our regulations were drafted. We believe there will be advancements in analytical technology and the rule should be flexible enough to incorporate future approved methods for PFAS analysis.

EPA Response: With respect to alternate analytical procedures or modifications to the two EPA methods approved for meeting the monitoring requirements in the final NPDWR, please see section 7.1 of the EPA response in this *Response to Comments* document.

Association of State and Territorial Solid Waste Management Officials (ASTSWMO) (Doc. #1583, SBC-042404)

[Overall, as movement is made toward better regulation and oversight of these contaminants, ASTSWMO's membership recognizes a corresponding need for research, communication, and improved understanding within the following areas:]

• finalization of PFAS-specific analytical methods to facilitate analysis of PFAS in surface water, groundwater, and other media;

EPA Response: With respect to the EPA's discussion on the validated analytical methods approved for meeting the monitoring requirements in the final NPDWR, please see section 7.1 of the EPA response in this *Response to Comments* document. The development of new analytical methods in non-drinking water matrices is not in scope of the current NPDWR; please see section 15.1 of the EPA response in this *Response to Comments* document.

New York Section American Water Works Association (NYSAWWA) (Doc. #1591, SBC-042369)

We note that many labs in New York State are currently reporting at +/- 1.8 ppt for PFOA/PFOS. In order to ensure all water suppliers are measuring and reporting contaminants in the same way, we recommend that EPA methods establish standard Reporting Limits (RLs) for all labs.

EPA Response: With respect to commenter concerns on the identification of laboratory quantitation limits and/or MDLs, please see section 7.1 of the EPA response in this *Response to Comments* document.

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-042884)

Analytical Methodology:

There must be leeway in the rule to utilize any current or future EPA approved analytical methods. In Massachusetts, our regulations are so prescriptive that PWSs have not been able to utilize Method 533 because it had not yet been approved by EPA at the time our regulations were drafted. We believe there will be advancements in analytical technology and the rule should be flexible enough to incorporate future approved methods for PFAS analysis.

EPA Response: With respect to alternate analytical procedures or modifications to the two EPA methods approved for meeting the monitoring requirements in the final NPDWR, please see section 7.1 of the EPA response in this *Response to Comments* document.

Marlene Ladderbush (Doc. #1612, SBC-042917)

There must be leeway in the rule to utilize any current or future EPA approved analytical methods. In Massachusetts, our regulations are so prescriptive that PWSs have not been able to utilize Method 533 because it had not yet been approved by EPA at the time our regulations were drafted. We believe there will be advancements in analytical technology and the rule should be flexible enough to incorporate future approved methods for PFAS analysis.

EPA Response: With respect to alternate analytical procedures or modifications to the two EPA methods approved for meeting the monitoring requirements in the final NPDWR, please see section 7.1 of the EPA response in this *Response to Comments* document.

Town of Lincoln Water Department (Doc. #1613, SBC-043029)

There must be leeway in the rule to utilize any current or future EPA approved analytical methods. In Massachusetts, our regulations are so prescriptive that PWSs have not been able to utilize Method 533 because it had not yet been approved by EPA at the time our regulations were drafted. We believe there will be advancements in analytical technology and the rule should be flexible enough to incorporate future approved methods for PFAS analysis.

EPA Response: With respect to alternate analytical procedures or modifications to the two EPA methods approved for meeting the monitoring requirements in the final NPDWR, please see section 7.1 of the EPA response in this *Response to Comments* document.

Environmental Monitoring Coalition (EMC) (Doc. #1625, SBC-043111)

2. Differences in the Analytical Methods (including sample preservation and holding times)

EPA indicated that either EPA Method 533 or EPA Method 537.1, Version 2 would be "acceptable for meeting the monitoring requirements of this regulation." With the exception that Method 537.1 relies on post extraction internal standard calibration while Method 533 uses an extracted internal standard or isotope dilution calibration, both methods are comparable. However, there are many trivial differences between the two methods. In a 1987 Report to Congress, the Agency stated:

An evaluation of the monitoring programs established under the authority of major environmental laws, demonstrates that the analytical methods are sometimes unnecessarily different, as they relate to similar sample matrices, target analytes, and data quality objectives.

The unnecessarily different requirements between the wo methods make it difficult for laboratories to comply, especially since both methods state "Changes may not be made to sample preservation, the quality control (QC) requirements, or the extraction procedure."

Table 4 below summarizes some of the unnecessary differences found. The text which follows discusses these changes in more detail.

Table 4. Unnecessarily Different Changes between Methods 537.1 and 533

[Table 4: See Docket ID EPA-HQ-OW-2022-0114-1625]

The detailed comments below provide the EMC's thoughts on some of these unnecessary differences found. Ideally, the EMC would request EPA modify both methods as stated below. However, the EMC recognizes that process could be difficult in the expected time frame for this rule so alternatives could include 1) revising the certification manual or 2) coming up with other guidance that laboratories and state accreditation/certification bodies could use.

1. MDL. If EPA requires laboratories to report to the trigger level, , the EMC encourages EPA to require laboratories to establish MDLs that are below the trigger levels.

2. Sample Size. The EMC encourages EPA to allow flexibility in sample size to allow laboratories to go up to full volume of the 250 mL bottle for both methods with the prescribed 500 mg of sorbent.

3. SPE Sorbent, reagents and elution order. EPA apparently fixed the SPE step so they could reduce the level of validation required. The SVDB polymer defined in 537.1 does not perform as well as WAX does for the smaller PFAS (< 6 C). If method 537.1 were not defined by the SPE media, but rather was defined by the mode of calibration, then 537.1 could be used for smaller PFAS analytes. Accordingly, 533 was developed using the WAX sorbent which works well for small chain PFAS because it bases the binding on the pKA of the carboxylic and sulfonic moieties on the PFAS compounds. Thus, chain length doesn't matter. WAX binds C4-C18 with no problems.

4. Applying correction for low or irreproducible recovery because you are not using the best media for the analyte should not be the option. The EMC encourages EPA to allow flexibility in the selection of the SPE cartridge, reagents and elution step to allow improvements in this technology. The EMC further recommends EPA consider by-passing the SPE step completely and allow for direct injection without SPE or hydrophilic-interaction chromatography (HILIC) as an alternative separation technique.

5. Extract volume, solvent and storage. The EMC recommends the 80:20 ratio be used as this improves peak shape and to allow multiple injections from the same vial if sealed as stated in Method 533 or to allow self-sealing vials.

6. Second Source Quality Control Check. The EMC recommends the second source standard specified in 9.3.10 be required for Method 533 as well, especially for the six regulated analytes.

7. Sample Collection, Preservation and Holding Time.

a) The EMC supports the EPA statement that no changes to sample preservation should be allowed. However, the unnecessary differences in sample preservative, sample temperature, and holding time between the two methods makes it impossible for one bottle to be used for both methods and the current requirements present other challenges. The EMC recommends the ammonium acetate preservative as stated in Method 533.

b) The language in 537.1 could imply samples must be at 10 C the moment they are collected, which is impossible. The language in 533 is more appropriate.

c) Method 533 also allows for a 28-Day holding time (as shown in Table 15) and that should be allowed in 537.1 as well. A peer-reviewed article in the October 2019 issue of Environmental Science and Technology indicates that freezing is the preferred option for storage of samples and that samples stored in this manner are stable for at least 180 days. EMC request the Agency to consider this peer-reviewed science in revising the sample preservation and holding time requirements.

7. Scan Rate. EPA defined the minimum amount of data points across a peak allowed as 10 scans per second. Many modern Mass Spectrometers (MS) can collect the same quality of data at much faster scanning speeds so it is likely a modern (<5 yrs) MS can collect >20 data points with a 4-5 second peak width and so laboratories can easily run a 8-10 min method with same data quality compared to EPA's method done on older mass specs for EPA 533 and 537.1 validation that need >20 min.

8. Sample pH and peak asymmetry. The EMC supports the pH 6-8 range in Method 533. Verification of the narrow pH range in Method 537.1 does not improve the extraction efficiency and is harder to check in the laboratory. For 6 - 8 you can use wide range paper, for 6.5 - 7.5 you need narrow range paper. If the same elution and final solvent in Method 533, was allowed the peak asymmetry check would not be needed as the extra water would improve peak shape. Notice, however, that Method 537.1 indicates you cannot add extra water to improve peak symmetry.

9. Quality Control. The EMC also supports the EPA statement that no changes to the QC requirements are allowed but believes that changes to the extraction procedure should be allowed since the extraction procedures in Methods 537.1 and 533 are very different, and further advances in this technology are likely.

a. The requirement for an Initial Demonstration of Capability (IDC) and on-going QC should be sufficient to ensure reliable data are obtained with any modifications to the SPE extraction. However, assuring data in the modified procedure are equivalent or better than the data acquired using the existing extraction, equivalent or better would mean recovery of spikes in the IDC closer to 100%, with % RSD of < 10%. The EMC suggests the recovery limits for precision to be 10% and accuracy to be 90-110% instead of the required 20% and 70-130%.

b. The EMC also suggests adding a Certified Reference Material or single-blind Performance Evaluation sample to have an independent check as part of the IDC.

EMC believes either method is sufficiently accurate for regulating the six PFAS analytes in drinking water. However, the EMC would request EPA to either revise the methods as described above to be more consistent or to 1) alternatively revise the drinking water certification manual, or 2) develop other similar guidance that can be use by laboratories and state certification bodies to include the recommendations. Specifically, the EMC recommends EPA:

a) Revise Method 537.1 to use the same sample volume and bottles, the ammonium acetate preservative, the same temperature preservation, storage, holding time, and the pH 6-8 requirement to be consistent with 533.

b) Modify Method 533 to require a second source verification standard particularly for the regulated analytes as they are available.

c) Since the other unnecessarily different requirements in the table above are not listed in the items that cannot be changed, EMC believes laboratories can implement these requirements effectively. However, EMC is concerned that laboratory assessors working in state accreditation/certification programs might be less flexible. Accordingly, EMC recommends section 1.3 of both methods be modified to state:

The laboratory may select SPE media, LC columns, LC conditions, and MS conditions different from those used to develop the method. At a minimum, the internal standards specified in the method must be used, if available. The laboratory may select the aqueous sample volume within the range of 100–250 mL that meets their objectives. Changes may not be made to sample preservation, holding time, or quality control (QC) requirements. The chromatographic separation should minimize the number of compounds eluting within a retention window to obtain a minimum of 10, and preferably 15 - 20 scans across each peak. Instrumental sensitivity (or signal- to- noise) will decrease if too many compounds are permitted to elute within a MRM transition window.

Method modifications should be considered only to improve method performance, including increased productivity. In all cases where method modifications are proposed, the analyst must

perform the procedures outlined in the Initial Demonstration of Capability (IDC, Sect. 9.1), verify that all QC acceptance criteria in this method (Sect. 9.2) are met, and verify method performance in a representative sample matrix (Sect. 9.3.2).

EPA Response: The agency disagrees with the commenter that there are significant analytic differences between the two methods (533 and 537.1, ver. 2.0) that would make it difficult for laboratories to comply with the final NPDWR as neither method has inherent QC issues when explicitly followed and both can meet the monitoring requirements of the final rule. With respect to analytic differences between the EPA methods approved for meeting the monitoring requirements in the final NPDWR, please see section 7.1 of the EPA response in this *Response to Comments* document. Regarding method modifications not expressly permitted within the methods, such as the flexibility to select SPE cartridges different than those prescribed in the methods, the EPA notes that the procedures and requirements listed in the methods are based on empirical evidence collected during method development and performance data collection. Changes to those procedures and requirements may lead to unintended consequences leading to poorer data quality. As discussed in section 7.1 of the EPA response in this *Response to Comments* document, the agency notes that all six PFAS finalized for regulation can be analyzed by either Method 533 or 537.1. Modified methods may be submitted to the agency as ATPs and considered for approval, per the discussion in section 7.1 of the EPA response in this *Response to Comments* document.

Environmental Monitoring Coalition (EMC) (Doc. #1625, SBC-043116)

Revision 2.0 of Method 537.1

Finally, the EMC notes that a March 2020 revision 2.0 of Method 537.1 has been published by EPA. The only change appears to be related to the field reagent blank. The proposed rule cites the November 2018 version 1.0. EMC seeks clarity on which method EPA plans to approve.

EPA Response: With respect to the EPA's discussion on the validated analytical methods approved for meeting the monitoring requirements in the final NPDWR, please see section 7.1 of the EPA response in this *Response to Comments* document.

Environmental Monitoring Coalition (EMC) (Doc. #1625, SBC-043108)

1. Detection and Reporting Limits

EMC supports the MCLs proposed by EPA but has concerns over some of the other terms used in the proposed regulation and in EPA Methods 533 and 537.1. The table below summarizes a variety of terms used in the proposed rule, the methods, and from other sources.

Table 1. Maximum Contaminant Levels, Detection Limits, Lowest Concentration Minimum Reporting Limits, Minimum Reporting Limits, Practical Quantitation Limits, and Trigger Levels

[Table 1: See Docket ID EPA-HQ-OW-2022-0114-1625]

Method 537.1 uses an obsolete definition for Detection Limit. In 2017, as part of a Clean Water Act Method Update Rule, the Agency changed this definition to reflect the latest science. Because the MDL is widely recognized as the lowest concentration that indicates detection, and because the proposed rule may require reporting values below the MRL, EMC recommends the MDL be included in both methods, but updated to the current definition.

EPA Response: With respect to commenter concerns on the identification of laboratory quantitation limits and/or MDLs, please see section 7.1 of the EPA response in this *Response to Comments* document.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-044890)

• DEP supports inclusion of EPA Method 537 version 1.1 as an approved method for PFAS analysis. While DEP recognizes that EPA Method 537 version 1.1 does not include HFPO-DA (GenX) as an analyte, which would be a regulated PFAS compound under this proposed rulemaking, it is a valid, EPA-approved method for the other PFAS that EPA is proposing to regulate.

• In [sec] 141.01(a)(2)(ii), Method 537.1, version 1.0 from November 2018, is referenced as EPA document ID EPA/600/R-18/352. DEP notes that version 2.0 from March 2020, EPA document ID EPA/600/R-20/006 is not referenced in the proposed rulemaking. DEP has not been accrediting laboratories for version 2.0 because it contains more than just editorial changes from version 1.0. DEP requests clarification as to whether version 2.0 is an acceptable EPA-approved method for analysis of the regulated PFAS in the proposed rulemaking.

EPA Response: With respect to clarification on which analytical methods are approved for meeting the monitoring requirements in the final NPDWR, please see section 7.1 of the EPA response in this *Response to Comments* document.

Town of Tewksbury, Massachusetts (Doc. #1637, SBC-043247)

There must be leeway in the rule to utilize any current or future EPA approved analytical methods. In Massachusetts, our regulations are so prescriptive that PWSs have not been able to utilize Method 533 because it had not yet been approved by EPA at the time our regulations were drafted. We believe there will be advancements in analytical technology and the rule should be flexible enough to incorporate future approved methods for PFAS analysis.

EPA Response: With respect to alternate analytical procedures or modifications to the two EPA methods approved for meeting the monitoring requirements in the final NPDWR, please see section 7.1 of the EPA response in this *Response to Comments* document.

Association of Public Health Laboratories (APHL) (Doc. #1646, SBC-043319)

2. Differences in the Analytical Methods (including sample preservation and holding times)

EPA indicated that either EPA Method 533 or EPA Method 537.1, Version 2 would be "acceptable for meeting the monitoring requirements of this regulation." With the exception that Method 537.1 relies on post extraction internal standard calibration while Method 533 uses an extracted internal standard or isotope dilution calibration, both methods are comparable. However, there are many trivial differences between the two methods. In a 1987 Report to Congress, the Agency stated:

An evaluation of the monitoring programs established under the authority of major environmental laws, demonstrates that the analytical methods are sometimes unnecessarily different, as they relate to similar sample matrices, target analytes, and data quality objectives.

The unnecessarily different requirements between the wo methods make it difficult for laboratories to comply, especially since both methods state "Changes may not be made to sample preservation, the quality control (QC) requirements, or the extraction procedure."

Table 4 below summarizes some of the unnecessary differences found. The text which follows discusses these changes in more detail.

Table 4. Unnecessarily Different Changes between Methods 537.1 and 533

[Table 4: See Docket ID: EPA-HQ-OW-2022-0114-1646]

The detailed comments below provide the EMC's thoughts on some of these unnecessary differences found. Ideally, the EMC would request EPA modify both methods as stated below. However, the EMC recognizes that process could be difficult in the expected time frame for this rule so alternatives could include 1) revising the certification manual or 2) coming up with other guidance that laboratories and state accreditation/certification bodies could use.

1. MDL. If EPA requires laboratories to report to the trigger level, , the EMC encourages EPA to require laboratories to establish MDLs that are below the trigger levels.

2. Sample Size. The EMC encourages EPA to allow flexibility in sample size to allow laboratories to go up to full volume of the 250 mL bottle for both methods with the prescribed 500 mg of sorbent.

3. SPE Sorbent, reagents and elution order. EPA apparently fixed the SPE step so they could reduce the level of validation required. The SVDB polymer defined in 537.1 does not perform as well as WAX does for the smaller PFAS (< 6 C). If method 537.1 were not defined by the SPE media, but rather was defined by the mode of calibration, then 537.1 could be used for smaller PFAS analytes. Accordingly, 533 was developed using the WAX sorbent which works well for small chain PFAS because it bases the binding on the pKA of the carboxylic and sulfonic moieties on the PFAS compounds. Thus, chain length doesn't matter. WAX binds C4-C18 with no problems.

4. Applying correction for low or irreproducible recovery because you are not using the best media for the analyte should not be the option. The EMC encourages EPA to allow flexibility in the selection of the SPE cartridge, reagents and elution step to allow improvements in this

technology. The EMC further recommends EPA consider by-passing the SPE step completely and allow for direct injection without SPE or hydrophilic-interaction chromatography (HILIC) as an alternative separation technique.

5. Extract volume, solvent and storage. The EMC recommends the 80:20 ratio be used as this improves peak shape and to allow multiple injections from the same vial if sealed as stated in Method 533 or to allow self-sealing vials.

6. Second Source Quality Control Check. The EMC recommends the second source standard specified in 9.3.10 be required for Method 533 as well, especially for the six regulated analytes.

7. Sample Collection, Preservation and Holding Time.

a) The EMC supports the EPA statement that no changes to sample preservation should be allowed. However, the unnecessary differences in sample preservative, sample temperature, and holding time between the two methods makes it impossible for one bottle to be used for both methods and the current requirements present other challenges. The EMC recommends the ammonium acetate preservative as stated in Method 533.

b) The language in 537.1 could imply samples must be at 10 C the moment they are collected, which is impossible. The language in 533 is more appropriate.

c) Method 533 also allows for a 28-Day holding time (as shown in Table 15) and that should be allowed in 537.1 as well. A peer-reviewed article in the October 2019 issue of Environmental Science and Technology indicates that freezing is the preferred option for storage of samples and that samples stored in this manner are stable for at least 180 days. EMC request the Agency to consider this peer-reviewed science in revising the sample preservation and holding time requirements.

7. Scan Rate. EPA defined the minimum amount of data points across a peak allowed as 10 scans per second. Many modern Mass Spectrometers (MS) can collect the same quality of data at much faster scanning speeds so it is likely a modern (<5 yrs) MS can collect >20 data points with a 4-5 second peak width and so laboratories can easily run a 8-10 min method with same data quality compared to EPA's method done on older mass specs for EPA 533 and 537.1 validation that need >20 min.

8. Sample pH and peak asymmetry. The EMC supports the pH 6-8 range in Method 533. Verification of the narrow pH range in Method 537.1 does not improve the extraction efficiency and is harder to check in the laboratory. For 6 - 8 you can use wide range paper, for 6.5 - 7.5 you need narrow range paper. If the same elution and final solvent in Method 533, was allowed the peak asymmetry check would not be needed as the extra water would improve peak shape. Notice, however, that Method 537.1 indicates you cannot add extra water to improve peak symmetry.

9. Quality Control. The EMC also supports the EPA statement that no changes to the QC requirements are allowed but believes that changes to the extraction procedure should be allowed

since the extraction procedures in Methods 537.1 and 533 are very different, and further advances in this technology are likely.

a. The requirement for an Initial Demonstration of Capability (IDC) and on-going QC should be sufficient to ensure reliable data are obtained with any modifications to the SPE extraction. However, assuring data in the modified procedure are equivalent or better than the data acquired using the existing extraction, equivalent or better would mean recovery of spikes in the IDC closer to 100%, with % RSD of < 10%. The EMC suggests the recovery limits for precision to be 10% and accuracy to be 90-110% instead of the required 20% and 70130%.

b. The EMC also suggests adding a Certified Reference Material or single-blind Performance Evaluation sample to have an independent check as part of the IDC.

EMC believes either method is sufficiently accurate for regulating the six PFAS analytes in drinking water. However, the EMC would request EPA to either revise the methods as described above to be more consistent or to 1) alternatively revise the drinking water certification manual, or 2) develop other similar guidance that can be use by laboratories and state certification bodies to include the recommendations. Specifically, the EMC recommends EPA:

a) Revise Method 537.1 to use the same sample volume and bottles, the ammonium acetate preservative, the same temperature preservation, storage, holding time, and the pH 6-8 requirement to be consistent with 533.

b) Modify Method 533 to require a second source verification standard particularly for the regulated analytes as they are available.

c) Since the other unnecessarily different requirements in the table above are not listed in the items that cannot be changed, EMC believes laboratories can implement these requirements effectively. However, EMC is concerned that laboratory assessors working in state accreditation/certification programs might be less flexible. Accordingly, EMC recommends section 1.3 of both methods be modified to state:

The laboratory may select SPE media, LC columns, LC conditions, and MS conditions different from those used to develop the method. At a minimum, the internal standards specified in the method must be used, if available. The laboratory may select the aqueous sample volume within the range of 100–250 mL that meets their objectives. Changes may not be made to sample preservation, holding time, or quality control (QC) requirements. The chromatographic separation should minimize the number of compounds eluting within a retention window to obtain a minimum of 10, and preferably 15 - 20 scans across each peak. Instrumental sensitivity (or signal-to- noise) will decrease if too many compounds are permitted to elute within a MRM transition window.

Method modifications should be considered only to improve method performance, including increased productivity. In all cases where method modifications are proposed, the analyst must perform the procedures outlined in the Initial Demonstration of Capability (IDC, Sect. 9.1),

verify that all QC acceptance criteria in this method (Sect. 9.2) are met, and verify method performance in a representative sample matrix (Sect. 9.3.2).

EPA Response: The agency disagrees with the commenter that there are significant analytic differences between the two methods (533 and 537.1, ver. 2.0) that would make it difficult for laboratories to comply with the final NPDWR as neither method has inherent QC issues when explicitly followed and both can meet the monitoring requirements of the final rule. With respect to analytic differences between the EPA methods approved for meeting the monitoring requirements in the final NPDWR, please see section 7.1 of the EPA response in this *Response to Comments* document. Regarding method modifications not expressly permitted within the methods, such as the flexibility to select SPE cartridges different than those prescribed in the methods, the EPA notes that the procedures and requirements listed in the methods are based on empirical evidence collected during method development and performance data collection. Changes to those procedures and requirements may lead to unintended consequences leading to poorer data quality. As discussed in section 7.1 of the EPA response in this *Response to Comments* document, the agency notes that all six PFAS finalized for regulation can be analyzed by either Method 533 or 537.1. Modified methods may be submitted to the agency as ATPs and considered for approval, per the discussion in section 7.1 of the EPA response in this *Response to Comments* document.

Association of Public Health Laboratories (APHL) (Doc. #1646, SBC-043310)

1. Detection and Reporting Limits

EMC supports the MCLs proposed by EPA but has concerns over some of the other terms used in the proposed regulation and in EPA Methods 533 and 537.1. The table below summarizes a variety of terms used in the proposed rule, the methods, and from other sources.

Table 1. Maximum Contaminant Levels, Detection Limits, Lowest Concentration Minimum Reporting Limits, Minimum Reporting Limits, Practical Quantitation Limits, and Trigger Levels

[Table 1: See Docket ID: EPA-HQ-OW-2022-0114-1646]

Method 537.1 uses an obsolete definition for Detection Limit. In 2017, as part of a Clean Water Act Method Update Rule, the Agency changed this definition to reflect the latest science. Because the MDL is widely recognized as the lowest concentration that indicates detection, and because the proposed rule may require reporting values below the MRL, EMC recommends the MDL be included in both methods, but updated to the current definition.

EPA Response: With respect to commenter concerns on the identification of laboratory quantitation limits and/or MDLs, please see section 7.1 of the EPA response in this *Response to Comments* document. The detection limit calculation present in Method 537.1 is an optional determination. Other regulatory bodies may choose to employ other detection limit calculations, such as the MDL calculation from 40 CFR part 136, Appendix B at their discretion as a more stringent approach.

Association of Public Health Laboratories (APHL) (Doc. #1646, SBC-043299)

[Detailed recommendations are appended to this letter, but a few are emphasized below:]

• It is advisable to decrease the field blank testing requirement to one of the following, in priority order of preferred change:

• Updates are required to Method 533 to harmonize the sample volume and sorbent weight with that permitted in Method 1633 and enable use for regulatory compliance. Also, this method needs to be modified to permit self-sealing autosampler vials.

EPA Response: Please see the EPA response to comment Doc. #1646, SBC-043323 in section 8.7 in this *Response to Comments* document. The EPA notes that the commenter provides three options with respect to not requiring an FRB at each sampling site, however, the options provided are not viable toward maintaining the integrity of results since FRBs are a method QC requirement. This requirement is necessary to ensure that any detections are part of the field sample and not introduced during the sampling process. The suggestions made would not account for contamination at the time of sampling or contamination due to the conditions of the sampling site. FRBs are only required if target analytes are present in the field sample at or above the method MRL. Additionally, all holding times in the methods are based on storage stability study results conducted during method development. Further, the EPA notes that the EPA Method 1633 is not a drinking water method and, as such, may have different time and resource requirements than the EPA Method 533 or Method 537.1, ver. 2.0. The EPA further notes that neither method 533 nor 537.1 ver. 2.0 have inherent QC issues when explicitly followed. This is because the ability of the methods to meet QC is determined during method development, through both single and multi-laboratory validation. All laboratories, internal and external, are required to demonstrate that all QC criteria listed in Section 9.0 of the methods can be met. This ability to meet QC criteria also has been corroborated by laboratories participating in the UCMR 5 LAP, where there was overwhelming success in meeting method QC acceptance criteria. With respect to alternate analytical procedures or modifications to the two EPA methods approved for meeting the monitoring requirements in the final NPDWR, please see section 7.1 of the EPA response in this *Response to Comments* document.

Association of Public Health Laboratories (APHL) (Doc. #1646, SBC-043324)

Revision 2.0 of Method 537.1

Finally, the EMC notes that a March 2020 revision 2.0 of Method 537.1 has been published by EPA. The only change appears to be related to the field reagent blank. The proposed rule cites the November 2018 version 1.0. EMC seeks clarity on which method EPA plans to approve.

EPA Response: With respect to clarification on which analytical methods are approved for meeting the monitoring requirements in the final NPDWR, please see section 7.1 of the EPA response in this *Response to Comments* document.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-044908)

It is also worth mentioning that EPA method 533 and 537.1 allow for variability in sample and spike duplicates [FN5: https://cfpub.epa.gov/si/si_public_record_Report.cfm?dirEntryId=343042&Lab=NERL]. For samples measured below twice the MRL, i.e., below 8.0 ppt, the accepted relative percent difference (RPD) is 50% or less. To illustrate, suppose a sample is analyzed and found to have a concentration of 5.0 ppt. If the same sample is then reanalyzed and found to have a concentration of 3.0 ppt, the RPD calculation would be 50%, indicating that the laboratory's results are within the acceptable range. If a water sample can yield measurements of between 5.0 ppt and 3.0 ppt, the difference is roughly equal to one drop of PFAS in 10 Olympic sized swimming pools [FN6: https://dnr.mo.gov/monitoring/understanding-data], it demonstrates the variation allowed in results, and can significantly impact a water system's compliance status. This distinction is crucial because it can determine whether a water system would need to implement costly treatment techniques (5.0 ppt) or if it falls below the Maximum Contaminant Level (MCL) with a reasonable margin of safety (3.0 ppt), requiring no immediate action. There are significant cost differences for these results, but both would be valid under the proposed rule. Water utilities need to base costly treatment decisions on reliable data so that we do not ask customers to pay for expensive capital improvements that may not make an appreciable improvement in water quality.

EPA Response: With respect to analytic differences between the EPA methods approved for meeting the monitoring requirements in the final NPDWR, please see section 7.1 of the EPA response in this *Response to Comments* document. With respect to implementation concerns around variability around sample results, the agency notes the following: First, the agency notes that quantitative sampling results do not have an estimate of standard error and therefore are generally not reported. Second, the EPA does not expect laboratories to conduct intensive statistical analyses of their analytical results so there is no calculated error associated with their reported measurements. In effect, quantitated measurement values stand as a single reported result. Lastly, any laboratory that provides drinking water analyses on PFAS in support of the NPDWR are held to the same standard for reporting results per the analytical method. The EPA further notes that compliance with the MCL is determined by running annual averages where individual sample results will not cause a system to be out of compliance (unless that result is 4x above the MCL in which they are in violation immediately). For commenter concerns regarding PQLs, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

American Council of Independent Laboratories (ACIL) (Doc. #1692, SBC-044742)

5. Revision 2.0 of Method 537.1

ACIL notes that a March 2020 revision 2.0 of Method 537.1 has been published by EPA. The proposed rule cites the November 2018 version 1.0. ACIL seeks clarity on which method EPA plans to approve.

EPA Response: With respect to clarification on which analytical methods are approved for meeting the monitoring requirements in the final NPDWR, please see section 7.1 of the EPA response in this *Response to Comments* document.

American Council of Independent Laboratories (ACIL) (Doc. #1692, SBC-044738)

Choice of Method: 533 or 537.1

There are two 500 series methods available for the 6 PFAS that are the focus of the initial MCLs. While both method 537.1 and method 533 can report these 6 PFAS at a similar level of sensitivity, there are significant differences in the two methods.

1) EPA 533 is an isotope dilution method for 25 PFAS that includes all targets in consideration for the MCL, and short chain PFAS such as PFBA and PFPeA, and additional ether PFAS such as NFDHA, PFEESA, PFMPA and PFMBA not covered by EPA 537.1.

2) The use of the weak anion exchange column for preparation, and isotope dilution and recovery correction for quantification makes EPA 533 a preferable method conforming broadly to current PFAS best practice. The use of isotope dilution and recovery correction also improves method performance close to the method reporting limits. In ongoing use, our labs have documented fewer quality control issues with the use of 533 compared with 537.1. The analytical approaches in EPA 533 broadly mirror those in EPA 1633 draft for aqueous sample analysis indicating that the scope of EPA 533 can be expanded if needed.

3) The EPA is increasing its scrutiny to more PFAS, for example, the CERCLA notice EPA–HQ–OLEM–2022–0922; FRL–906401–OLEM] RIN 2050–AH25 posted to 40 CFR part 302 specifically addresses PFBA as needing measurement in solid waste. In addition, the toxicity profile of PFBA is mentioned several times in the MCL document. The preparation technique used in EPA 537.1 is not suitable for PFBA and PFPeA. We believe the use of 533 for drinking water will more than likely suit future alignment of PFAS targets across multiple regulatory needs better than 537.1 will. Given more targets are under consideration for addition to the PFAS MCL, potentially under the hazard index, 533 is a more suitable method. The EPA has also announced intentions to add PFAS targets to 533 at a future date.

For these reasons, the ACIL recommends that the EPA specify a preference for method 533 over 537.1. While costs of additional isotopically labeled standards is a consideration, the improvement in data quality, robustness, and alignment with EPA 1633 draft practices more than compensate.

EPA Response: With respect to clarification on which analytical methods are approved for meeting the monitoring requirements in the final NPDWR as well as discussion on analytic

differences between the EPA methods, please see section 7.1 of the EPA response in this *Response to Comments* document. The EPA notes that perfluorobutanoic acid (PFBA) and perfluoropentanoic acid (PFPeA) are not regulated as part of the final NPDWR and any potential analytic requirements for these PFAS are out of scope for this rulemaking.

Susan Gorman-Chang (Doc. #1705, SBC-045083)

3. Add to the regulations a phrase that states as testing technologies become more sensitive and reliable, the MCLs will be ratcheted down in response, and testing technologies will be reviewed annually by the EPA to identify the most sensitive and reliable methods and promulgate their use. This gives these EPA regulations the flexibility to evolve as our technology evolves. This is especially important for PFAS and PFOS as the EPA has found that NO level is safe for human consumption.

EPA Response: The agency disagrees that the language suggested by the commenter is necessary for the final NPDWR. Please see section 7.1 of the EPA response in this *Response to Comments* document for considerations on how the agency considers improvements in analytic performance when revising NPDWRs. Specifically, the agency is required to review NPDWRs every six years and determine which, if any, are appropriate for revision (i.e., the Six-Year Review Process). The purpose of the review is to evaluate current information for regulated contaminants and to determine if there is any new information on health effects, analytical methods, occurrence and exposure, implementation, and/or other factors that provides a health or technical basis to support a regulatory revision that will improve or strengthen public health protection. This process allows the agency to consider these and other information as appropriate in deciding whether existing NPDWRs should be identified as candidates for revision as required by SDWA.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045956)

It is also worth mentioning that EPA methods 533 and 537.1 allow for variability in sample and spike duplicates [FN5: EPA. (2020, June 6). Method 537.1.] and could have significant consequences for water systems' compliance. For samples measured below twice the MRL (i.e., below 8.0 ppt), the accepted relative percent difference (RPD) is 50% or less. To illustrate, suppose a sample is analyzed and found to have a concentration of 5.0 ppt. If the same sample is then reanalyzed and found to have a concentration of 3.0 ppt, the RPD calculation would be 50%, indicating that the laboratory's results are within the acceptable range. If a water sample can yield measurements of 5.0 ppt and 3.0 ppt, the difference between one drop of PFAS in 10 Olympic-sized swimming pools [FN6: Missouri Department of Natural Resources. (2023). Understanding data. https://dnr.mo.gov/monitoring/understanding-data], it demonstrates the variation allowed in results that can significantly impact a water system's compliance status. This distinction is crucial because it can determine whether a water system would need to implement costly treatment techniques (5.0 ppt) or require no immediate action as it falls below the MCL with a reasonable margin of safety (3.0 ppt).

EPA Response: Please see the EPA response to comment Doc. #1672, SBC-044908 in section 7.1 in this *Response to Comments* document**.**

Arizona Water Company (Doc. #1758, SBC-044539)

PFAS Contamination and Sampling

Certain contaminants have field sampling kits available for use in confirming laboratory results. Company operators use these kits to quickly check levels of contaminants in the field when continuous monitoring is not available. Company engineers recommend the EPA work with scientists and engineers to develop a field sampling kit for operator and management use.

EPA Response: With respect to the analytic requirements of the EPA methods, please see section 7.1 of the EPA response in this *Response to Comments* document. After finalization of the PFAS NPDWR, the EPA intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation. In addition to the analytical method sampling requirements, the EPA has developed guidance on PFAS analytical test methods and the recommended procedures for appropriate sample collection in the field. The EPA has not approved nor is aware of any PFAS "field sampling kits … to quickly check levels of contamination in the field."

American Water Works Association (AWWA) (Doc. #1759, SBC-045626)

As a matter of policy, EPA should not set a precedent for the use of analytical results that are not reliably achievable for all water systems as this would create an equity issue. Moreover, the current minimum reporting levels for EPA Methods 533 and 537.1 are appropriate based on ongoing experience with PFAS analytical results.

EPA Response: With respect to the analytic requirements of the EPA methods, please see section 7.1 of the EPA response in this *Response to Comments* document. The agency is clarifying for the commenter that the EPA is not "setting a precedent for use of analytical results that are not readily achievable for all water systems." With respect to concerns on the feasibility of the PQLs, including discussion on how the PQLs were established for the NPDWR, please see section 7.2 of the EPA response in this *Response to Comments* document as well as 5.1.2 for additional discussion on implementing MCLs at the PQLs.

Millie Garcia-Serrano (Doc. #1803, SBC-044292)

[Overall, as movement is made toward better regulation and oversight of these contaminants, ASTSWMO's membership recognizes a corresponding need for research, communication, and improved understanding within the following areas:]

• finalization of PFAS-specific analytical methods to facilitate analysis of PFAS in surface water, groundwater, and other media;

EPA Response: With respect to the EPA's discussion on the validated analytical methods approved for meeting the monitoring requirements in the final NPDWR, please see section 7.1 of the EPA response in this *Response to Comments* document. The development of new analytical methods in non-drinking water matrices is not in scope of the current NPDWR; please see section 15.1 of the EPA response in this *Response to Comments* document.

National Ground Water Association (NGWA) (Doc. #1804, SBC-045466)

[Actions that EPA should consider to enable more laboratory capacity are:]

2. Create a forum from the scientific and laboratory communities as well as other impacted stakeholders to review and fast-track/streamline analytical methods and processes while maintaining quality.

EPA Response: With respect to alternate analytical procedures or modifications to the two EPA methods approved for meeting the monitoring requirements in the final NPDWR, please see section 7.1 of the EPA response in this *Response to Comments* document.

New England Water Works Association (Doc. #1836, SBC-045385)

Analytical Methodology:

There must be leeway in the rule to utilize any current or future EPA-approved analytical methods. We believe there will be advancements in analytical technology and the rule should be flexible enough to incorporate future approved methods for PFAS analysis.

EPA Response: With respect to alternate analytical procedures or modifications to the two EPA methods approved for meeting the monitoring requirements in the final NPDWR, please see section 7.1 of the EPA response in this *Response to Comments* document.

Halff Associated Inc. (Doc. #3072-43, SBC-046366)

Good afternoon, everyone, and thank you for the opportunity to speak today. My name is Oscar Martinez. I'm with Halff Associates, Inc. I am an environmental contractor and I know we're speaking about the Clean Water and Drinking Water Act, but I also wanted to speak upon the test method, Method 1633 in particular. You know, it's for other matrices, for blood, solid waste, and the groundwater and surface water. I know that the EPA is working hard to do a multi-laboratory evaluation of the test procedure and I hope that this will propagate and that they will accept that test method. In addition to that, in order for that test method, in order for us to have clean water, we must also clean up the environment and that test method would greatly support the cleanup efforts that are currently working their way through CERCLA and RCRA as PFOS has both been, are now the public comment period for both CERCLA and RCRA also. So, I think we definitely need to make sure that those standards are in place. I know the public comment period

is coming up for the both of those also but without those cleanup standards we cannot have clean drinking water, and I'll see my time to somebody else. Thank you.

EPA Response: The EPA notes that the EPA Method 1633 is not a drinking water method and is therefore not validated for use under this final NPDWR. Additionally, cleanup actions are not in scope of this current rulemaking; for additional discussion, please see section 15.1 of the EPA response in this *Response to Comments* document.

Environmental Protection Network (EPN) (Doc. #1773, SBC-043866)

EPA's HI MCL of one is also implementable and feasible because EPA Methods 537.1 and 533 have quantitation levels (ranging from 3 to 5 ppt) below the health-based reference levels for these four PFAS chemicals. These low quantitation levels allow public water systems (PWS) to take early action to modify treatment if monitoring data indicate concentrations of the four PFAS are approaching the health-based reference levels

EPA Response: The EPA agrees that the final MCLs are implementable and feasible in part for reasons cited by the commenter that there are two validated methods available to support the rule: with respect to the analytic requirements of the EPA methods, please see section 7.1 of the EPA response in this *Response to Comments* document. With respect to PQLs, including discussion on how the PQLs were established for the NPDWR, please see section 7.2 as well as 5.1.2 of the EPA response in this *Response to Comments* document for additional discussion on implementing MCLs at the PQLs.

Village of Woodbury (Doc. #1629, SBC-042955)

9. In order to ensure all water suppliers are measuring and reporting contaminants in the same way, we recommend that EPA methods establish standard Reporting Limits (RLs) for all labs.

EPA Response: With respect to commenter concerns on the identification of laboratory quantitation limits and/or MDLs, please see section 7.1 of the EPA response in this *Response to Comments* document.

7.2 Practical Quantitation Levels (PQLs) for Regulated PFAS

Summary of Major Public Comments and EPA Responses

As discussed in the final NPDWR preamble, PQLs reflect the level of contaminants that laboratories nationwide can reliably quantify within specific limits of precision and accuracy during routine laboratory operating conditions and are based on a multi-laboratory assessment of analytical capacity. For purposes of a NPDWR, establishing PQLs are an important consideration for feasibility of MCLs in that they ensure water systems nationwide can monitor and dependably comply with such MCLs and deliver drinking water that does not exceed the maximum permissible level.

A few commenters critiqued how the proposed PQLs were established for the rule. Some of these commenters provided feedback on the feasibility of the proposed PQL and suggested that it may be too low, resulting in recurring QC failures that will necessitate repeat sample analysis, increased cost, and reduced laboratory capacity. Other commenters suggest that lower PQLs can be attainable by larger labs with advanced analytical instruments. After review of public comment, the agency disagrees that PQLs should be established at either a higher or lower level than that proposed. Based on the multi-laboratory data acquired for the UCMR 5 rule, the UCMR 5 MRLs reflect "a minimum quantitation level that, with 95 percent confidence, can be achieved by capable lab analysts at 75 percent or more of the laboratories using a specified analytical method" (USEPA, 2022). The EPA calculated the UCMR 5 MRLs using quantitation-limit data from multiple laboratories participating in a MRL setting study. The calculations account for differences in the capability of laboratories across the country. Laboratories approved to analyze UCMR samples must demonstrate that they can consistently make precise measurements at or below the established MRLs. After reviewing data from laboratories that participated in the MRL setting study under UCMR 5 and in consideration of public comment, the EPA finds that the following MRLs set in UCMR 5 are the most appropriate PQLs for the PFAS regulated by the final NDPWR (see also CFR Table 1 to § 141.903 (f)(1)(iv) of Subpart Z in the CFR that lists the PQLs for the PFAS regulated under this action). The EPA anticipates that over time, as technology advances and as laboratories gain experience with the PFAS Methods, laboratories will generally improve their capability to measure at lower levels.

Table 1: PQLs for Regulated PFAS

Contaminant	PQL (ng/L)
PFOA	4.0
PFOS	4.0
HFPO-DA	5.0
PFHxS	3.0
PFNA	4.0
PFBS	3.0

The final NPDWR does not require laboratories to demonstrate that they can get below the PQLs in order to comply with the rule. However, the final NPDWR discusses how utilities may be able to use sample results below the PQL to determine analyte presence or absence in managing their treatment operations. Additionally, the EPA is finalizing rule trigger levels below the PQL to support the monitoring provisions of the final NPDWR. While results below the PQL may not have the same precision as a sampling result at or above the PQL, they are useful for operational purposes such as understanding that PFOA and PFOS may be present, which can inform treatment decisions and monitoring frequency. For additional discussion on PQLs, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section V of the final rule NPDWR preamble and section 5.1.2 of the EPA response in this

Response to Comments document. For additional discussion on monitoring provisions of the rule more broadly, please see section VIII of the final rule NPDWR preamble, section 8 of the EPA response in this *Response to Comments* document, and section 8.8 in this *Response to Comments* document for trigger levels, specifically.

Many commenters requested that the EPA provide clarification on how laboratories and public water systems (PWSs) should report levels below the PQLs for monitoring frequency purposes. All results at or above the trigger level (which are below the PQLs for the PFAS regulated under this NPDWR) are to be reported as numeric values and used for determining monitoring frequency. The EPA intends to provide guidance materials on this to support successful implementation of the final rule.

Individual Public Comments

Missouri Department of Natural Resources (Doc. #1563, SBC-052827)

In addition, the Department is also concerned that the proficiency testing (PT) used to approve laboratories for UCMR 5 sampling was not sufficient to confirm a viable MRL. It is not clear from information that EPA has made publicly available to date, whether any of the 8 PT studies conducted included true values "at or near" the proposed MCL. In coordination with laboratories that EPA has approved for UCMR 5 analysis, we are aware that at least six of the eight PT studies had an average concentration of 55 ppt true value. Since EPA approves laboratories based on two PT tests, it is not clear how many approved laboratories have demonstrated proficiency "at or near" the proposed MRL and MCL of 4.0 ppt. Without the opportunity to review all of the proficiency testing data, it is difficult for interested parties to adequately comment on whether or not the MRL established was based on sufficient supporting evidence that laboratories could meet low-level true values around the MCL. The Department recommends that EPA make the PT study results from UCMR5 available, so interested parties can confirm that the use of a two significant digit MCL is appropriate and that there will be sufficient laboratory capacity to meet the demand with 75% of laboratories and a 95% confidence interval.

EPA Response: With respect to concerns on the feasibility of the PQLs, including discussion on how the PQLs were established for the NPDWR, please see section 7.2 of the EPA response in this *Response to Comments* document. While proficiency testing (PT) data for the UCMR 5 LAP are not made public due to the use of PT being used as laboratory audit tools throughout the UCMR 5 monitoring cycle, PT samples are not the tool for which laboratory MRLs were confirmed, but only a blind study to demonstrate overall lab efficiency. Laboratories must submit a Method application for each method they requested UCMR approval for through the LAP, containing an extensive Initial Demonstration of Capability (IDC), outlined in Section 9.1 of each PFAS Method, along with all raw data files that support the IDC. Each application IDC contains an MRL Confirmation, based on Method criteria, to verify that each lab participating in UCMR 5 meets the MRLs listed in the UCMR 5 Rule and the UCMR 5

Laboratory Approval Manual (LAM). These files are reviewed by EPA scientists to ensure all MRLs are met. As part of the UCMR 5 LAP application process, laboratories are required to confirm they can achieve the UCMR 5 MRLs for each analyte according to the procedure in 40 CFR 141.40(a)(5)(iii) and outlined in Sections 5.3.1 through 5.3.4 and Section 6.3.5, Table 4 of the UCMR 5 LAM. For additional discussion on implementing MCLs at the PQL, laboratory and analytic considerations when setting the MCL, or use of sample results below the PQLs to help operators manage their treatment operations, please see section V of the final rule NPDWR and section 5.1.2 of the EPA response in this *Response to Comments* document.

Missouri Department of Natural Resources (Doc. #1563, SBC-052825)

EPA requests comment on the merits and drawbacks of the target- specific HI or RPF approach.

The Department agrees the general HI approach "provides the most health protective endpoint for multiple PFAS in a mixture to ensure there would be no known or anticipated adverse effects on the health of persons." However, as noted in the federal register notice, most PFAS have a given health effect that is "poorly characterized or not studied at all." Additionally, "PFAS lack human epidemiological or experimental animal hazard and dose-response information across a broad(er) effect range thus limiting derivation of target-organ specific values." When setting a maximum contaminant level (MCL), there are more considerations than just the most health protective endpoint. EPA must also take into account the ability for water system customers to pay for the installation of treatment and the ongoing operation and maintenance costs associated with that treatment. Relying on a hazard index of "potential" unrelated additive health effects could cause an unnecessary increased cost of treatment that could cause a significant burden to small water systems who may struggle with maintaining technical, managerial, or financial capacity. Under the Safe Drinking Water Act (SDWA), the EPA must review its standards for drinking water every six years, and adhere to an anti-backsliding provision that requires each revision to drinking water standards to be at least as protective as the former regulation. Due to anti-backsliding provisions, it is prudent to set limits with known and quantifiable characterized health effects and allow the process of six-year reviews to strengthen limits, if and when, known and quantifiable health effects are shown to require a revision.

An additional drawback to the HI approach is that trigger levels under the approach are not quantifiable. EPA Method 533 allows for quality assurance/quality control (QA/QC) samples to be ±50% at or near the MRL and not ±30% for all analytes as indicated in the preamble. From EPA Method 533 Section 9.2.3.2 Evaluate Analyte Recovery "Results for analytes fortified at concentrations near or at the MRL [minimum reporting level also known as PQL] (within a factor of two times the MRL concentration) must be within 50–150% of the true value. Results for analytes fortified at all other concentrations must be within 70–130% of the true value. If the LFB [Laboratory Fortified Blank] results do not meet these criteria, then all data for the problem analytes must be considered invalid for all samples in the Extraction Batch." This difference in acceptance level identifies one of the key issues associated with proposing to set a MCL at the same value as the practical quantitation limit (PQL) or MRL. This issue is not one that can be

solved by simply lowering the PQL/MRL to 2 ppt. Based on UCMR 5 lab approvals, it is already known that more than 25 percent of laboratories nationwide will not be able to meet a PQL lower than 4 ppt with a 95% confidence interval (CI). In addition to causing more issues with laboratory capacity nationwide, the number of samples that would be rejected under the method, and therefore requiring resampling, would increase even with a ±50% Method QA/QC acceptance level. Likewise, EPA's conclusion that PWS would be notified of "J Qualified" results, which are results below the PQL/MRL, is not correct. The Laboratory Certification Manual does not currently require the reporting of data below the MRL. Therefore, "J Qualified" data would not always be available for use in MCL calculation determinations, and these compliance determinations would need to follow the SOC standard monitoring framework utilizing monitoring results that are quantifiable. For this reason, the Department recommends that EPA remove the hazard index at this time and proceed with the PFAS rule mirroring the SOC standard monitoring framework where a detection above the PQL triggers increased quarterly monitoring in lieu of a hazard index.

EPA Response: The EPA's final rule represents data-driven drinking water standards that are based on a thorough analysis of feasibility consistent with requirements under SDWA. For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 (for laboratory considerations) and section 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document. The EPA disagrees that the PQLs are not set at a reasonable quantitation level. The basis of this determination is included in section 7.2 of the EPA response in this *Response to Comments* document and includes discussion on how the PQLs were established. Please also see the EPA response to comment Doc. #1672, SBC-044908 in section 7.1 in this *Response to Comments* document for discussion on variability around sampling results. The EPA also disagrees with the commenter claims that "25% [of labs] cannot" meet the PQL; as discussed in the final rule preamble, the PQL reflects a minimum quantitation level that "with 95 percent confidence, can be achieved by capable analysts at 75 percent *or more* of the laboratories using a specified analytical method" (emphasis added). Greater than 75 percent of labs requesting participation in UCMR 5 were able to meet the PQLs/MRLs, and the EPA anticipates the number of labs available for compliance monitoring to grow.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-052948)

• DEP notes that in the example calculation on page 18665 of the preamble, which the text identifies as using the proposed PQLs as the measured values for each of the component PFAS, the numerical values entered for each PFAS are whole numbers with only one significant figure. In other words, the values used in the example calculation are 5 ppt for GenX, 3 ppt for PFBS, 4 ppt for PFNA, and 3 ppt for PFHxS. The calculated result of 1.2 for the HI is incorrect in this example, because with only one significant figure in the values used in the calculation, the result should also only have one significant figure and be 1 (not 1.0). However, as noted above, the PQLs as defined in the proposed rulemaking each contain two significant figures. This inconsistency is confusing and further supports DEP's comments that MRLs need to be clearly identified for each regulated PFAS, including the number of significant figures.

EPA Response: For discussion on PQLs for the PFAS regulated by the final NPDWR, including discussion on how the PQLs were established, please see section 7.2 of the EPA response in this *Response to Comments* document. The EPA is clarifying in the final NPDWR that the Hazard Index and individual PFAS for PFHxS, PFNA, and HFPO-DA Maximum Contaminant Level Goals (MCLGs) and MCLs are expressed to one significant figure (for additional discussion, please see section 4.3.4 of the EPA response in this *Response to Comments* document) whereas the PFOA and PFOS MCLGs and MCLs are expressed to two significant figures (for additional discussion, please see section 5.1.7 of the EPA response in this *Response to Comments* document). With respect to rounding and compliance calculations, please see section VIII.B.3 of the final rule preamble, as well as the EPA response to comment Doc. #1726, SBC-045150 in section 5.2.1 in this *Response to Comments* document.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-052950)

• With regard to the HI calculation, DEP notes that if each component PFAS is detected at a level equal to its PQL, the HI MCLG will be exceeded. Since the MCLG and the MCL are both set at 1.0, this means that the MCL would also be exceeded. This is confirmed by the example calculation on page 18665 of the preamble to the proposed rule, which shows that the resulting HI, when each of the four component PFAS are detected at their respective PQLs, would be 1.2. DEP believes that this low level for the HI MCL may present a significant implementation challenge. DEP recognizes that if compliance with the HI MCL is determined based on an RAA of quarterly HI calculated results, this may partially alleviate this concern, since one individual quarterly result over the HI MCL would not be an immediate violation. However, as noted above, it is not clear or consistently stated in the regulatory language how compliance is to be determined.

EPA Response: For discussion on PQLs for the PFAS regulated by the final NPDWR, including discussion on how the PQLs were established, please see section 7.2 of the EPA response in this *Response to Comments* document. The EPA clarifies for the commenter that the final NPDWR expresses the Hazard Index MCLG and MCL to one significant figure. Therefore, if each component PFAS is found at levels equal to its PQL, then the Hazard Index MCL will not be exceeded (assuming the results are the same after four quarterly samples). This is because the concentrations of each of the four PFAS at their PQLs would equal a Hazard Index of 1.2015 (unrounded), which would not be in violation of the MCL as this result would be rounded to a Hazard Index value of 1. Additionally, as the commenter notes, compliance is based on running annual averages to allow for additional operational flexibility and slightly elevated fluctuations. The EPA's final rule represents data-driven drinking water standards that are based on a thorough analysis of feasibility consistent with requirements under SDWA. For additional discussion on the EPA's feasibility analysis with respect to the Hazard Index MCL, please see section 5.2 of the EPA response in this *Response to Comments* document. For additional discussion on how compliance and violations are assessed in the final rule, please see section VIII (Monitoring and Compliance Requirements) of the final rule preamble, Subpart Z § 141.905

(Violations) of the Code of Federal Regulations (CFR), and section 8.2 of the EPA response in this *Response to Comments* document.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-052951)

• As previously noted, setting an MCL at a level such that a detection at the PQL would cause an MCL exceedance is not feasible. As noted above, detection of each of the HI PFAS at its respective PQL would cause an exceedance of the HI MCL according to the proposed regulation. This would not allow a water system to demonstrate compliance with the HI MCL unless one or more components are either not detected or detected below the PQL. However, as already noted, detections below the PQL should not be used for compliance determinations or other regulatory purposes and should be treated the same as non-detections. This would complicate a water system's ability to demonstrate compliance, and it also would complicate the public's understanding of this MCL. MCLs should be set at levels that allow for demonstration of continued compliance by allowing a buffer between the MCL and levels that are considered to be accurate and precise detections. The HI MCL should be set at a level that is higher than the MCLG of 1.0.

EPA Response: Please see the EPA response to comment Doc. #1626, SBC-052950 in section 7.2 of this *Response to Comments* document.

Mike Pettit (Doc. #1542, SBC-043349)

Testing Limitations

It is also important to consider the feasibility of the proposed lab analyses, specifically the requirement to monitor PFAS contaminants at a level as low as 4 parts per trillion (ppt). While this level may be attainable by larger labs with advanced analytical instruments, it may not be feasible for smaller labs with limited resources and capabilities. These labs may require significant investments in technology and training, which may not be feasible for many communities that rely on them for testing and analysis. Moreover, setting such a low threshold may also lead to false positives, as the sensitivity of testing instruments may not be sufficient to distinguish between trace amounts of PFAS contamination and background levels of naturally occurring organic compounds. This could result in unnecessary costs and resources being expended on remediation efforts that are not actually addressing a significant health risk. It is vital to note that testing at 4 ppt levels for PFAS compounds presents several challenges, particularly in terms of contamination and testing limits. PFAS compounds are ubiquitous, and there are numerous sources of contamination, including laboratory equipment, sample containers, and the environment. Therefore, it is crucial to maintain strict protocols to minimize contamination and ensure accurate test results. At such low levels, the analytical instrumentation used in the testing process can be pushed to its limit, and the probability of false positives or negatives increases. Additionally, some PFAS compounds have similar molecular structures, making it difficult to differentiate between them. As a result, the accuracy and reliability of test

results can be impacted, leading to potential errors in data interpretation and subsequent decision-making. Another significant challenge with testing for PFAS at such low levels is the limitations of the instrumentation used for analysis. Many instruments are simply not capable of reliably detecting PFAS at the parts-per-trillion (ppt) level without introducing significant levels of error into the analysis. For example, liquid chromatography-mass spectrometry (LC-MS), which is commonly used to analyze PFAS, can be highly sensitive but may also be subject to interference from matrix components, resulting in false positive or negative results. In addition, matrix effects can lead to variability in the measurements obtained, making it difficult to achieve reliable and consistent results. Furthermore, even if an instrument is capable of detecting PFAS at the ppt level, there is still a risk of contamination. Trace amounts of PFAS can be present in laboratory equipment, reagents, and even the environment, leading to false positives and making it difficult to distinguish between true detection and contamination. It is therefore vital for the EPA to consider the practicality and feasibility of the proposed lab analyses requirements, and to work with smaller labs to ensure that they have the necessary resources and support to meet these standards, or to develop alternative strategies that are both effective and feasible. This would require a collaborative effort from all stakeholders, including regulatory agencies, industry groups, and local communities, to ensure that the health and safety of all Americans are protected, while also promoting sustainable economic growth and development.

EPA Response: The EPA disagrees that the PQLs are not set at a reasonable quantitation level. For discussion on PQLs for the PFAS regulated by the final NPDWR, including discussion on how the PQLs were established, please see section 7.2 of the EPA response in this *Response to Comments* document. The EPA's final rule represents data-driven drinking water standards that are based on a thorough analysis of feasibility consistent with requirements under SDWA. For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 (for laboratory considerations) and section 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document. Regarding commenter concerns about laboratory testing and potential contamination issues, please see section 8.7 of the EPA response in this *Response to Comments* document. The EPA further notes that neither methods 533 nor 537.1 ver. 2.0 have inherent QC issues when explicitly followed (please see section 7.1 of the EPA response in this *Response to Comments* document for additional discussion).

New York Section American Water Works Association (NYSAWWA) (Doc. #1591, SBC-042370)

5. Messaging to consumers becomes complicated if a water supply has records of results that are below the PQL when labs provide results to their own internal limits and not the EPA's value of 4 ppt. When issuing Consumer Confidence Reports (CCRs), a supplier may be accused of lacking transparency should the results be stated as zero or "below detection" when the results are less than 4 ppt, despite having publicly recoverable records of reported values?

6. We are concerned that with the MCL set at the PQL, it suggests that USEPA will revise the MCL as soon as lab methods improve and a lower PQL is attainable. Thus, those systems that

are observing current trigger level concentrations could expect to be in violation of a lower MCL in the near future, making long range planning difficult.

EPA Response: With respect to commenter concerns on Consumer Confidence Reports (CCRs) and communicating results to consumers, for the purposes of reporting results in CCRs, "detected" is defined in § 141.151(d) to be at or above the levels prescribed in § 141.902(a)(5). The EPA agrees that reporting results in CCRs above the trigger level, or one-half of the MCL as defined in the final rule, promotes transparency for consumers. Consistent with the EPA response in section 7.2, results below the PQL can be useful in identifying that PFAS contaminants are likely present and can therefore help consumers make informed decisions related to their drinking water and can take additional actions, if appropriate. For additional discussion on CCR reporting requirements, see section 9.1in this *Response to Comments* document. For discussion on PQLs for the PFAS regulated by the final NPDWR, including discussion on how the PQLs were established, please see section 7.2 of the EPA response in this *Response to Comments* document. For additional discussion on how the EPA considers evolving science and revising NPDWRs, please see section 5.1.6 of the EPA response in this *Response to Comments* document.

New York Section American Water Works Association (NYSAWWA) (Doc. #1591, SBC-042367)

Jennifer McLain, Director

Office of Ground Water and Drinking Water

US Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Mail Code: 4601M

Washington, DC 20460

Re: Docket ID# EPA-HQ-OW-2022-0114-0027

Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

Comment Submittal

Dear Director McLain,

The New York Section American Water Works Association (NYSAWWA) represents drinking water utilities across New York State, providing safe, reliable, and affordable water to over 15 million residents. Our core principle is the protection of public health, and we take pride in New York State's leadership role in advancing these initiatives. Our diverse membership consists of leading experts in drinking water treatment, engineers responsible for designing and constructing our systems, academics at the forefront of innovative research, and pioneers driving the

development of emerging technologies. Together, we ensure that New York's water supply remains of the highest possible quality now and in the future. On behalf of NYSAWWA membership, I am writing to provide our comments and concerns regarding the recently proposed regulations by the United States Environmental Protection Agency (USEPA) regarding per- and polyfluoroalkyl substances (PFAS). As responsible water suppliers committed to providing safe and reliable drinking water to our communities, we appreciate the opportunity to contribute to the rulemaking process and share our perspectives on this critical issue.

We have carefully reviewed the proposed regulations and offer the following comments and recommendations:

1. We note that UCMR 5 data is only required to report down to the PQL of 4 ppt (for PFOS/PFOA specifically). Thus, for water that is at or below the proposed MCL and/or PQL, the data generated provides no actionable information relative to the extent of PFOS/PFOA. The UCMR effort appears in conflict with the sentiment expressed by EPA in the quotation below.

"This suggests the overwhelming majority of laboratories with the necessary instrumentation to support PFAS monitoring have the capability to provide screening measurement results above the proposed trigger level of 1/3 of the MCL (i.e., 1.3 ppt for PFOS or PFOA). Hence, a utility may use the lower-level measurements as a warning that they may be nearing the PFOA and PFOS MCLs of 4.0 ppt prior to exceeding them and can make informed treatment decisions about managing their systems (e.g., replacing GAC)."

We believe this is a key limitation to the development of the proposed rule. Bad (or limited) data does not produce good regulation.

2. We are concerned that establishing an MCL at the PQL could encourage poor practices. It becomes advantageous for water supplies to utilize labs who report only at the PQL (as is ongoing for UCMR 5 in accordance with USEPA direction). By doing so, water supplies who may have concentrations hovering below the PQL, but in detectable range by some labs could avoid reporting levels of PFOS/PFOA by simply reporting that results are below detection limits because they are utilizing a lab that can only report to the PQL.

EPA Response: The EPA disagrees that the PQLs are not set at a reasonable quantitation level. For discussion on PQLs for the PFAS regulated by the final NPDWR, including discussion on how the PQLs were established, please see section 7.2 of the EPA response in this *Response to Comments* document. The agency disagrees that the UCMR efforts conflict with the final NPDWR. This is because utilities may be able to use data from UCMR 5 sampling to satisfy initial monitoring requirements in the final NPDWR. With respect to commenter concerns that establishing an MCL at the PQL would "encourage poor practices," the agency also disagrees. The basis of this decision is discussed in greater detail in the EPA's response in section 8.8 on rule trigger levels and in section XIII of the final rule preamble, where water systems must demonstrate they are below the final rule trigger levels to be eligible for reduced triennial monitoring (i.e., utilities who only go to labs who can go as low as the MCL will not be eligible for reduced monitoring).

Michigan Department of Environment, Great Lakes, and Energy (EGLE) Drinking Water and Environmental Health Division (DWEHD) (Doc. #1597, SBC-042982)

5. EGLE DWEHD encourages EPA to consider including PQLs of 2.0 ng/l, consistent with Michigan's SDWA, considering these have been successfully employed since 2020.

6. Laboratory performance evaluation tolerances (70-130%) are concerning given the PQL = MCL for PFOS and PFOA. It seems there is no margin for error at this level. At the MCL for PFOS (4 ppt), the reported value could range from 2.8 to 5.2 ppt and be within QC tolerances but result in the sample being in or out of compliance, respectively.

EPA Response: For discussion on PQLs for the PFAS regulated by the final NPDWR, including discussion on how the PQLs were established, please see section 7.2 of the EPA response in this *Response to Comments* document. With respect to implementation concerns around variability around sample results, please see the EPA response to comment Doc. #1672, SBC-044908 in section 7.1 in this *Response to Comments* document.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043650)

3. Linking MCLs to PQLs: The MCLs for PFOA and PFOS are established at their respective practical quantitation limits (PQLs) usings Methods 533 and 537.1. However, improved laboratory performance and/or the development of more sensitive methods could lower the PQLs, which could conceivably open the door for lowering the MCLs, potentially resulting in thousands of treatment systems inappropriately designed/sized.

4. PQLs are not referenced in USEPA Methods 533 and 537.1. Instead, the EPA refers to the "Lowest Concentration Minimum Reporting Level (LCMRL)," which represents the lowest true concentration for which recovery is predicted to fall between 50% and 150%, at a confidence level of 99%. In USEPA Method 533, the LCMRL is 3.4 ng/L for PFOA and 4.4 ng/L for PFOS; while in Method 537.1, LCMRL is 0.82 ng/L for PFOA and 2.7 ng/L for PFOS (Table 7). It is unclear if/how these LCMRLs lead to PQLs 4.0 ng/L for PFOA and 4.0 ng/L for PFOS which inform the proposed MCLs. It is recommended that this relationship be explained more clearly.

Table 7: Lowest Concentration Minimum Reporting Level (LCMRL) Between USEPA Methods

[Table 7: See Docket ID EPA-HQ-OW-2022-0114-1602]

EPA Response: For discussion on PQLs for the PFAS regulated by the final NPDWR, including discussion on how the PQLs were established, please see section 7.2 of the EPA response in this *Response to Comments* document. For additional discussion on how the EPA considers evolving science and revising NPDWRs, please see section 5.1.6 of the EPA response in this *Response to Comments* document.

Minnesota Department of Health (MDH) (Doc. #1610, SBC-042853)

Reevaluate the PQLs to determine if they can be lowered, especially for PFOS and PFOA, based on current laboratory RLs and standards used for calibration.

EPA Response: For discussion on PQLs for the PFAS regulated by the final NPDWR, including discussion on how the PQLs were established, please see section 7.2 of the EPA response in this *Response to Comments* document.

Environmental Monitoring Coalition (EMC) (Doc. #1625, SBC-043109)

In Table 19, EPA used the term PQL as a regulatory term which is confusing to laboratories as most laboratories use the PQL as a Reporting Limit equal to the low calibration point, which in Method 533 is 2 ng/L. The methods use the MRL term instead of PQL. However, no MRLs are published in the methods. The methods do publish LCMRLs, but these values do not otherwise appear to be used in the methods.

EMC believes the MRL is the lowest concentration at which quantitative data can be reported and recommends the Agency use a different term in Table 19, such as Compliance Level, Consumer Confidence Reporting Level, or Detection Limit for Consumer Confidence Reporting. This way, a Public Water System (PWS) would not have to unnecessarily create concerns for their consumers, unless the MCL or HI was exceeded.

(Note: If Gen X, PFNS, and PFHxS are all not detected, PFBS could be as high as 600 ng/L and the HI would be below 1.0.)

EMC requests the Agency consider using consistent terminology for both the final rule and the methods and specifically requests the following:

• Include Method Detection Limit requirements in 533 and update the MDL section of 537.1.

• Publish MRLs in Methods 537.1 and 533.

• Replace PQL with Compliance Level, Consumer Confidence Reporting Level, or Detection Limit for Consumer Confidence Reporting in the final rule, or some other term that is not PQL.

EPA Response: For discussion on PQLs for the PFAS regulated by the final NPDWR, including discussion on how the PQLs were established, please see section 7.2 of the EPA response in this *Response to Comments* document. With respect to commenter concerns on the identification of laboratory quantitation limits and/or MDLs, please see section 7.1 of the EPA response in this *Response to Comments* document. The multi-laboratory Lowest Concentration Minimum Reporting Limit (LCMRL) calculation, used to generate the UCMR 5 MRLs, is a statistical calculation to determine an MRL value where the 75th percentile of laboratories can meet the 50-150 percent accuracy threshold. This is described in detail in Appendix A of USEPA (2010): An MRL is set after a statistical determination that 75 percent or more of laboratories will be able to meet that level with a 95 percent confidence interval (CI). The UCMR 5 MRLs

are not intended to represent the lowest achievable measurement level an individual laboratory may achieve. These MRLs are derived using the quantitation level results from multiple laboratories participating in an analytical study and account for differences in the capability of laboratories across the country. Note that EPA Methods 533 and 537.1, rev. 2.0 only require the confirmation of an MRL, whose concentration is determined based on the intended use of the method.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-044881)

Practical Quantitation Levels (PQLs) / Reporting Levels

• DEP recommends that EPA fully evaluate whether PQLs should be set any lower than 4.0 parts per trillion (ppt) for any of the PFAS included in the proposed rule. PQL is defined in 40 CFR [sec] 141.2 as "the minimum concentration of an analyte (substance) that can be measured with a high degree of confidence that the analyte is present at or above that concentration." This definition makes the PQL essentially equivalent to a repo1iing level. As part of our state rulemaking process, DEP conducted a survey of laboratories accredited in Pennsylvania for PFAS analysis. While many laboratories indicate that they may be able to detect and report PFAS compounds to approximately 2 ppt, the potential incidence of quality assurance (QA)/ quality control (QC) failures increase as repo1iing limits decrease. EPA states as much in the preamble to the proposed rulemaking, on page 18680: "Establishing a quantitation level that is too low may result in recurring QC failures that will necessitate repeating sample analyses, increase costs, and potentially reduce laboratory capacity." DEP has experience with this situation. During implementation of the DEP Bureau of Safe Drinking Water's PFAS Sampling Plan used to generate occurrence data and inform our state PFAS MCL rulemaking process, we utilized the services of two different laboratories. The lab with lower reporting levels, at approximately 2 ppt, experienced significantly more QC failures, and each location with an affected sample needed to be resampled and reanalyzed. The other lab used approximately 4 ppt as a reporting limit and had no QC failures. It is imperative to consistently define across all laboratories what is and is not a detectable level; using a PQL less than 4.0 ppt may not be feasible. EPA should investigate the incidence of QC failures at lower reporting levels before considering lowering the PQLs.

• DEP requests clarification on what levels are to be reported when a PFAS is detected below its respective PQL. DEP also suggests that an MRL should be clearly identified for each regulated PFAS and that MRL should be defined in [sec] 141.2. In [sec] 141.XX(a)(9), the proposed rule states that "a reportiable detection means at or above one-third of the levels described in the table outlined in ..." As noted earlier, DEP has identified inconsistencies and inaccuracies in the cross references and citations but believes that this table is referring to the PQLs. This seems to indicate that any detection over one-third of a PQL, or 1.3 ppt for PFOA or PFOS, would be reported as such. However, with the PQL set at 4.0 ppt for PFOA and PFOS, detections below that level would not be considered accurate or precise and would be counted as zero in the RAA calculation. It is critical for EPA to clarify what levels are to be repo1ied.

• Building on the previous comment, DEP believes that the definition of PQL suggests that detections below the PQL - or MRL if that term is defined and utilized - should be reported as not detected or zero since a detection below that level is not expected to be an accurate representation of the actual concentration. Results reportied at or above one-third the PQL and up to the PQL would be qualified data and would not be legally defensible as a true detection. Detections below the PQL should be reported as not detected or zero.

• DEP also believes it is confusing to say a reportable detection is "at or above one-third of the levels described in the table" instead of clearly listing the actual numbers for reporting. As noted earlier, the table referenced by [sec] 141.01(b)(2)(i) appears to be intended to list reportiing limits, but that table is missing from the proposed rulemaking. DEP cannot comment on information that is missing from the proposed rulemaking. Again, DEP believes this is an importiant component to include in the rulemaking to clarify reporting limits.

• Reporting levels for calculating MCL compliance and determining monitoring frequencies must be consistently applied and clearly defined. It is not implementable or appropriate to have different reporting levels for use in different parts of the proposed regulation.

MCLs and Trigger Levels for PFOA and PFOS

• DEP is concerned that the proposed MCLs may not be feasible and may result in significant implementation challenges. More specifically, DEP recommends that the MCLs for PFOA and PFOS should not be set at levels equal to the PQL. As noted above, PQL is defined in 40 CFR [sec] 141.2 as "the minimum concentration of an analyte (substance) that can be measured with a high degree of confidence that the analyte is present at or above that concentration." EPA-approved methods, Method 533 and Method 537.1, allow+/- 30% recovery for QC samples. In addition, the proposed regulation requires+/- 30% recovery for performance evaluation (PE) samples. By setting the MCLs equal to the PQL, if QC is biased high by up to 30%, which is acceptable, a low level detection in a sample that is just over the PQL/MCL may also be biased high. With a PQL of 4.0 ppt for PFOA and PFOS and a+/- 30 % QC allowance, any detection up to 5.2 ppt is within the acceptable analytical margin of error (30% of 4.0 is 1.2, and 4.0 +1.2 = 5.2). Therefore, with the PQLs set at 4.0 ppt, the lowest the MCLs should be set at is 6 ppt. By setting the MCLs for PFOA and PFOS at a level equal to the PQL, some water systems may exceed the MCL with low-level detections that are within the margin of analytical error. This is not a feasible level for implementation, and it presents significant implementation challenges.

EPA Response: For discussion on PQLs for the PFAS regulated by the final NPDWR, including discussion on how the PQLs were established, please see section 7.2 of the EPA response in this *Response to Comments* document. Further, the agency agrees that results below the PQL should not be used for compliance calculations (for discussion on how compliance and violations are assessed, please see section 8.2 of the EPA response in this *Response to Comments* document). The agency disagrees that “reporting levels for calculating MCL compliance and determining monitoring frequencies must be consistently applied and clearly defined.” The specific reporting levels for calculating MCL compliance and determination of monitoring

frequency is defined in the regulatory text of the final NPDWR; please see CFR 141.903 and 141.904 of the final NPDWR for regulated PFAS for compliance requirements and reporting and recordkeeping requirements, respectively. Furthermore, while results below the PQL, such as trigger levels, may not have the same precision as a sampling result at or above the PQL, they are useful for operational purposes such as understanding that PFOA and PFOS may be present, which can inform treatment decisions and monitoring frequency. For additional discussion on implementing MCLs at the PQL or use of sample results below the PQLs to help operators manage their treatment operations, please see section V of the final rule NPDWR preamble and section 5.1.2 of the EPA response in this *Response to Comments* document). With respect to implementation concerns around variability around sample results, please see the EPA response to Doc. #1672, SBC-044908 in section 7.1 of this *Response to Comments* document. The EPA provided more specificity on trigger levels in CFR § 141.902(a)(5).

Association of Public Health Laboratories (APHL) (Doc. #1646, SBC-043311)

In Table 19, EPA used the term PQL which is confusing to laboratories as most laboratories set the PQL as their MRL equal to the low calibration point, which in Method 533 is 2 ng/L. The methods use the MRL term instead of PQL. However, no MRLs are published in the methods. The methods do publish LCMRLs, but these values do not otherwise appear to be used in the methods. EMC believes the MRL is the lowest concentration at which quantitative data can be reported and recommends the Agency use a different term in Table 19, such as Compliance Level, Consumer Confidence Reporting Level, or Detection Limit for Consumer Confidence Reporting. This way, a PWS would not have to unnecessarily create concerns for their consumers, unless the MCL or HI was exceeded.

(Note: If Gen X, PFNS, and PFHxS are all not detected, PFBS could be as high as 600 ng/L and the HI would be below 1.0.)

EMC requests the Agency consider using consistent terminology for both the final rule and the methods and specifically requests the following:

• Include Method Detection Limit requirements in 533 and update the MDL section of 537.1.

• Publish MRLs in Methods 537.1 and 533.

• Replace PQL with Compliance Level, Consumer Confidence Reporting Level, or Detection Limit for Consumer Confidence Reporting in the final rule, or some other term that is not PQL.

EPA Response: Please see the EPA response to comment Doc. #1625, SBC-043109 in section 7.2 in this *Response to Comments* document.

NCASI (Doc. #1651, SBC-043225)

2.0 Laboratory limitations for Proposed Regulatory Limits and Action Levels

It is not clear that drinking water providers are able to manage a process to the levels of a Practical Quantitation Level (PQL), as EPA has assumed in their evaluation. Due to variability in samples, sampling technique, laboratories, etc., managing a drinking water treatment process for a variety of water treatment facilities (e.g., ranging from small private to large municipal) to the quantification level may be operationally infeasible. Drinking water providers manage risk by not only restricting concentrations to that of the MCLs, but also rely on action levels well below the MCLs, to provide some level of additional operational certainty. Setting MCLs at the PQL does not allow operators to do this.

The proposed rulemaking indicates trigger levels at 1/3 the MCLs, which equates to 1.3 ppt for PFOA/PFOS and a 0.3 HI for other listed PFAS. This means that action levels are not able to be reliably quantified. EPA recognizes the challenges of finding laboratories that can provide accurate quantitation below 4 ppt: "EPA anticipates there would not be sufficient laboratory capacity if the quantitation level were set at a level below 4.0 ppt. The rigorous laboratory certification and quality assurance/quality control (QA/QC) procedures could limit the number of laboratories that can achieve lower quantitation levels and many water systems would not be able to secure the services of laboratories that are capable of consistently providing precise and accurate quantitation of concentrations of PFOA and PFOS at levels lower than 4.0 ppt." (pg. 18667).

EPA Response: The EPA disagrees that the PQLs are not set at a reasonable quantitation level. With respect to these concerns on the feasibility of the PQLs, including discussion on how the PQLs were established for the NPDWR, please see section 7.2 of the EPA response in this *Response to Comments* document. For additional discussion on implementing MCLs at the PQL or use of sample results below the PQLs to help operators manage their treatment operations, please see section V of the final rule NPDWR and section 5.1.2 of the EPA response in this *Response to Comments* document. For additional discussion on trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document.

Aurora Water, City of Aurora, Colorado (Doc. #1669, SBC-043711)

PQLs

The current proposal sets the practical quantitation limit (PQL) at 4.0 ppt. PQLs are the lowest concentration of analyte that can reliably be measured within specified precision and accuracy during routine laboratory conditions. Aurora Water agrees with a PQL of 4 ppt and believes their in-house instrument should be able to reliably achieve this level. Aurora strongly disagrees with the consideration of using the proposed trigger level value instead of zero for any samples below the PQL when calculating the running annual average to determine compliance. Any data below the PQL is not considered reliable and would be extremely unfair to water systems if they must report anything below what is considered accurate for compliance calculations. However, EPA will use sample results below the PQL to determine water system monitoring schedules. The monitoring trigger level is set at 1.33 ppt, which is far below what has been determined to be

reliable measurement levels. Since any measurement below 4 ppt has been determined to be unreliable, Aurora Water argues that systems should not be required to report anything below that level or be held to any levels below that PQL. To resolve this PQL level issue Aurora Water is proposing an MCL of 10 ppt and a trigger level of 4 ppt.

EPA Response: For discussion on PQLs for the PFAS regulated by the final NPDWR, including discussion on how the PQLs were established, please see section 7.2 of the EPA response in this *Response to Comments* document. Further, the agency agrees that results below the PQL should not be used for compliance calculations (for discussion on how compliance and violations are assessed, please see section 8.2 of the EPA response in this *Response to Comments* document). For additional discussion on implementing MCLs at the PQL or use of sample results below the PQLs to help operators manage their treatment operations, please see section V of the final rule NPDWR preamble and section 5.1.2 of the EPA response in this *Response to Comments* document.

Protecting Our Water, Environment, and Ratepayers (POWER) (Doc. #1714, SBC-045943)

COMMENT 7 — NEITHER METHOD 533 OR METHOD 537.1 COULD ADEQUATELY OR RELIABLY MEASURE THE PROPOSED MCLS, PQLS, OR TRIGGER LEVELS.

EPA has not properly applied the meaning of the information provided in Method 533, 537.1 or UCMR5 to set the trigger level, Practical Quantitation Level ("PQL"), and MCL. Typically, the trigger level is less than the PQL, which is less than the MCL.

The trigger level, or the point where regulated entities industries need to take action, is generally set at or above the minimum reporting level ("MRL"), which is the lowest highly accurate reporting value that 75% of laboratories can satisfy. Typically EPA has set the trigger level at the MRL with the exception of lead. [FN26: HDR, One Water: Exploring Interconnectivity – Safe Drinking Water Act Wall Chart (17th Edition 2022) (https://www.hdrinc.com/sites/default/files/2022-05/hdr-sdwa-wall-chart-2022.pdf)] This makes sense because regulatory requirements should be based on a sound scientific determination that the sample is accurate and that the analyte is present.

The PQL is the minimum concentration at which an analyte can be measured with a high degree of confidence that the analyte is present or above the given concentration. The PQL is determined by performing a linear regression of the proficiency data or multiplying the Minimum Detection Level ("MDL") by between 5 and 10. [FN27: Analytical Feasibility Support Document for the Six-Year Review of Existing National Primary Drinking Water Regulations (Reassessment of Feasibility for Chemical Contaminants). EPA-815-R-03-003; EPA Office of Ground Water and Drinking Water: Washington, DC; 20003; https://www.epa.gov/sites/default/files/2014-12/documents/815b09003.pdf] The PQL is higher than the Minimum Detection Level (and thus the MRL) to account for variability and uncertainty that can occur near the Minimum Detection Level. In other words, the PQL is higher because it ensures that the measurements are reliable.

The MCL is informed by the PQL and is generally suggested to be 20% greater than the PQL. At the minimum, the PQL and MCL can be the same.

The method the EPA used to determine the PQL is improper and setting the PQL at the MRL will lead to imprecise results.

In creating this rule, EPA did not properly set the PQLs. Instead of setting the PQL at 5-10x the MDL for each compound, the EPA took the MRL from UCMR 5 and converted that to the PQL. This action is improper because it ignores the precision component of the data collection and does not indicate that the samples are repeatable. Furthermore, EPA has not pointed to an instance where it used the MRL as the PQL previously, nor has it explained how this action is permissible.

The EPA only addresses concerns with the PQLs by asserting that instrumentation is sufficient to measure these low proposed PQLs. Although the measurements could be accurate at this level, they are not precise or reliable. Because the MRL is not a level for which the results are repeatable, the proposed PQL is arbitrary and unsupported by the EPA's own documentation.

If the proper PQL calculation methods are used, neither Method 533 and Method 537.1 support the proposed PQLs.

The information available to the public on Method 533 does not support the claim that this method could determine if the concentrations of PFOA, PFOS, PFNA, PFBS, PFHxS, and HFPO-DA would meet the standards proposed by this rule. Specifically, Method 533 does not include an MDL or proficiency data which could be used to calculate the PQL. Therefore, there is insufficient information to determine if the proposed PQL is proper given the parameters of Method 533.

Method 537.1 includes MDLs for the 6 PFAS regulated under this proposed rule. Given the general rule of multiplying the MDL by between 5 to 10 to calculate the PQL, only the PQL for PFOA is within EPA's approved range as shown by the table below. For this reason, the proposed PQLs for PFOS, PFNA, PFBS, PFHxS, and HFPO-DA are arbitrary because they are calculated contrary to EPA's established methods. The proposed MCL for PFOS is also improper because it is also below EPA's approved range for PQLs.

[Table 2: See Docket ID EPA-HQ-OW-2022-0114-1714]

EPA Response: The EPA disagrees that the PQLs are not set at a reasonable quantitation level and further disagrees that they are "not precise or reliable" and that the PQLs were calculated "contrary to EPA's established methods." The reason for this is that the EPA's final rule represents data-driven drinking water standards that are based on a thorough analysis of feasibility consistent with requirements under SDWA. For discussion on PQLs for the PFAS regulated by the final NPDWR, including discussion on how the PQLs were established, please see section 7.2 of the EPA response in this *Response to Comments* document. For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 (for laboratory

considerations) and 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document.

Washington County Department of Public Health and Environment (Doc. #1739, SBC-043568)

[To address the issues described here, EPA should make one of the following changes to the proposed NPDWR for PFAS:]

• Reevaluate the PQLs to determine if they can be lowered, especially for PFOS and PFOA, based on current laboratory RLs and standards used for calibration.

EPA Response: For discussion on PQLs for the PFAS regulated by the final NPDWR, including discussion on how the PQLs were established, please see section 7.2 of the EPA response in this *Response to Comments* document.

Wisconsin Department of Health Services (Doc. #1823, SBC-044280)

Candidate reference doses considered in development of the proposed PFOA and PFOS maximum contaminant levels (MCLs) include health-based developmental outcomes, the Health-Based Water Concentrations (HBWCs) for PFNA and PFBS are based on developmental effects, and HFPO-DA and PFHxS are associated with similar toxicological endpoints as well. Because of this, exposures on timescales shorter than chronic exposure durations matter. Given that technical limitations already informed the selection of the practical quantitation limits (PQLs), exceedances of the PFOA and PFOS MCLs will be well above established health-based thresholds.

EPA Response: Compared to MCLs, "health-based thresholds," (i.e., MCLGs) do not account for analytic feasibility and can therefore be set at a level below these thresholds. The EPA's final rule represents data-driven drinking water standards that are based on a thorough analysis of feasibility consistent with requirements under SDWA. For discussion on PQLs for the PFAS regulated by the final NPDWR, including discussion on how the PQLs were established, please see section 7.2 of the EPA response in this *Response to Comments* document. For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 (for laboratory considerations) and section 5.1.4 (for treatment considerations) of the EPA response in this *Response to Comments* document.

American Council of Independent Laboratories (ACIL) (Doc. #1692, SBC-044737)

2. Terminology Used in Proposed Regulation

ACIL members have concerns over some of the terms used in the proposed regulation and in EPA Methods 533 and 537.1.

Method 537.1 uses an obsolete definition for Detection Limit. In 2017, as part of a Clean Water Act Method Update Rule, the Agency changed its previous definition to reflect the latest science.

Because the MDL is widely recognized as the lowest concentration that indicates detection, and because the proposed rule would require reporting values below the MRL, ACIL recommends the MDL be included in both methods, but updated to the current definition.

The Agency should employ the definition of Method Detection Limit found in 40 CFR Part 136, Appendix B (i.e., "The minimum measured concentration of a substance that can be reported with 99% confidence that the measured concentration is distinguishable from method blank results.").

In Table 19 and in Section VI, EPA used the term practical quantitation limit or PQL as the ''lowest concentration of an analyte that can be reliably measured within specified limits of precision and accuracy during routine laboratory operating conditions'' (USEPA, 1985). This is a subjective limit. The ACIL would prefer the limits to be stated in terms of objective, documented limits such as the Lowest Concentration Minimum Reporting Limit (LCMRL).

EPA Response: For discussion on PQLs for the PFAS regulated by the final NPDWR, including discussion on how the PQLs were established, please see section 7.2 of the EPA response in this *Response to Comments* document. With respect to commenter concerns on the identification of laboratory quantitation limits and/or MDLs, please see section 7.1 of the EPA response in this *Response to Comments* document.

Section 7 References

USEPA. 2010. *Technical Basis for the Lowest Concentration Minimum Reporting Level (LCMRL) Calculator.* EPA 815-R-11-001. December 2010. Available at https://www.epa.gov/dwanalyticalmethods/lowest-concentration-minimum-reporting-level-lcmrl-calculator.

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8 Monitoring and Compliance Requirements

8.1 General Monitoring Requirements

Individual Public Comments

Groundwater Resources Association of California (Doc. #1831, SBC-045349)

[Based on our review of this document, GRA offers the following general comments and recommendations for consideration by the EPA as they finalize these regulations:]

2. Equity, Affordability, and Resource Constraints Considerations for Community and Small Water Systems: California has approximately 2900 Community Water Systems [FN3: Community Water System (CWS): a public water system that serves at least 15 service connections used by yearlong residents or regularly serves at least 25 yearlong residents of the area served by the system. (California Health & Saf. Code, § 116275, subd. (i).)] (CWS), 1300 Small Community Water Systems [FN4: Small Community Water System: a CWS that has no more than 3,300 service connections or a yearlong population of no more than 10,000 persons. (California Health & Saf. Code, § 116275, subd. (z).)] (SCWS), and over 300,000 known domestic wells [FN5: 5https://www.ppic.org/blog/consolidating-small-water-systems-is-a-springboard-to-water-justice/ https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/documents/needs/2023needsassessment.pdf]. More than half of the CWS/SCWS have fewer than 100 connections [FN2: https://www.waterboards.ca.gov/pfas/drinking_water.html; https://pubs.er.usgs.gov/publication/fs20213028]. CWS/SWS providers suffer from limited staffing, are run by volunteer boards, and their rates do not cover long-term improvements [FN2: https://www.waterboards.ca.gov/pfas/drinking_water.html; https://pubs.er.usgs.gov/publication/fs20213028]. As such, it will be challenging for these water systems and agencies to comply with the proposed annual sampling requirements without significant external funding and resources. These CWS/SCWS may also have limited access to analytical laboratories that meet the standards established in the regulations, which may impact their ability to demonstrate compliance with the proposed regulations.

EPA Response: Regarding the compliance monitoring requirements, please see section 8.1.2 of the EPA response in this *Response to Comments* document. In addition, compliance monitoring frequency is based upon previous sampling results. Based on available occurrence information (see sections III.C and VI of the final rule preamble), the agency anticipates that many water systems will not be required to conduct monitoring more often than once every three years as they will not demonstrate levels of PFAS at or above rule trigger levels (see section 8.8 of the EPA response in this *Response to Comments* document for more information about those levels). For those that do have levels of regulated PFAS at or above the rule trigger levels, sampling must occur more frequently to ensure adequate public health protection and an understanding of current levels of regulated PFAS. For discussion of laboratory availability and

capability, please see section 5.1.2 of the EPA response in this *Response to Comments* document. The EPA intends to make resources available to support rule implementation. Additionally, as noted in section II.E of the preamble to the final rule, funding under the Infrastructure Investment and Jobs Act (IIJA), often referred to as the Bipartisan Infrastructure Law (BIL), will assist many disadvantaged communities, small systems, and others with the costs of addressing emerging contaminants, like PFAS, when it might otherwise be cost-challenging. Additionally, to support BIL implementation, the EPA is offering water technical assistance (WaterTA) to help communities identify water challenges and solutions, build capacity, and develop application materials to access water infrastructure funding (USEPA, 2023).

El Paso Water (Doc. #1757, SBC-044530)

We must oppose requirements for more stringent testing that is not reliable and produces no additional benefits for the consumer.

EPA Response: The EPA disagrees with the commenter that monitoring for regulated PFAS is not reliable and produces no additional benefits for the consumer. Please see sections 8.1.1. and 8.1.2 of the EPA response in this *Response to Comments* document regarding initial monitoring requirements and compliance monitoring requirements, respectively. These monitoring requirements ensure that public water systems (PWSs) are complying with the regulated PFAS Maximum Contaminant Level (MCLs) and that consumers of PWS are aware of the levels of regulated PFAS in their water systems.

Skippy McMuffins (Doc. #2110, SBC-046217)

We live in Alabama and want PFAS tested, reported, and removed. The water testing lab in Montgomery was closed. This is environmental racism. Do better ADPH.

EPA Response: The PFAS National Primary Drinking Water Regulations (NPDWR) will require all community water systems (CWSs) and non-transient, non-community water systems (NTNCWSs) to conduct monitoring of regulated PFAS to ensure compliance with the final MCLs. Please see sections 8.1.1 and 8.1.2 of the EPA response in this *Response to Comments* document regarding the final rule initial monitoring and compliance monitoring requirements, respectively. If the compliance monitoring results exceeds the final MCLs, water system will be required to take action to address regulated PFAS and reduce concentrations to at or below the MCLs. The final rule will also require reporting under the Consumer Confidence Report (CCR) rule to inform customers of levels of regulated PFAS (see section 9.1 of the EPA response in this *Response to Comments* document). The State of Alabama current sampling efforts are outside of the scope of this regulation.

8.1.1 Initial Monitoring Requirements

Summary of Major Public Comments and EPA Responses

The majority of comments the EPA received on the proposed initial monitoring requirements related to the number of initial samples systems would be required to collect and the intervals between required samples. Most commenters were generally supportive of the EPA's proposed initial monitoring requirements, including the flexibilities to use previously-acquired monitoring data to satisfy some or all the initial monitoring requirements and, for those groundwater systems serving 10,000 or fewer that do not have this data, that they be required to only collect two samples at each entry point to the distribution system (EPTDS) to satisfy initial monitoring requirements. For a discussion of comments and final rule requirements specific to the use of previously-acquired monitoring data to satisfy the initial monitoring requirements see section VIII.C of the preamble and section 8.3 below.

While most commenters were supportive of the number of initial monitoring samples the EPA proposed, a few commenters indicated they thought the EPA should not allow the flexibility for groundwater systems serving 10,000 or fewer to collect only two samples. Instead, they suggested that the EPA require quarterly samples to be collected by all systems to meet initial monitoring requirements, suggesting that this would be fully consistent with the Standardized Monitoring Framework (SMF) framework for other synthetic organic contaminant (SOCs). A couple of these commenters suggested that there are no data demonstrating that smaller systems are less likely to have elevated levels of PFAS than large systems or that groundwater systems are less likely to have elevated levels of PFAS than surface water systems. Additionally, other commenters generally suggested that two samples may not generate enough data to accurately capture the level of PFAS in drinking water and any potential seasonal variability. Related to potential seasonal changes in measured PFAS concentrations, some commenters from state agencies indicated that they have not observed seasonal variations in concentrations of PFAS measured by groundwater systems, whereas other commenters suggested the opposite and that they have seen changes seasonally based on their state's monitoring data.

The EPA disagrees with commenters that suggest two samples for small groundwater systems would not accurately capture the baseline level of regulated PFAS in drinking water. The EPA determined the initial monitoring requirements based on both source water type and system size considerations. First, from a national-level perspective, the EPA's model for estimating national PFAS drinking water occurrence (see section VI.E of the preamble) indicates that, regardless of source water type, small systems generally have lower mean PFAS concentrations and lower within-system variability than large systems. Further accounting for source water type, as compared to all groundwater systems, all surface water systems potentially have a larger number of sources of contamination and greater hydrology variability so more monitoring data is necessary to ensure an appropriately protective monitoring schedule. Both the differences in the occurrence estimations for large and small sized systems as well as the general source water characteristics of groundwater systems were collectively considered as part of establishing the proposed initial monitoring requirements for small groundwater systems. Consequently, the

agency expects that these small groundwater systems will be less likely to experience variations throughout a year and, where there may be seasonal variations, requiring the samples to be collected in different parts of a year will provide sufficient information to determine the appropriate compliance monitoring schedule. Given the different experiences cited by commenters, any seasonal variation is likely based on the specific geographic location and other localized factors. If there are regional factors that suggest more frequent sampling is warranted by particular PWSs, the rule provides that primacy agencies may increase the required monitoring frequency, where necessary, to detect variations within the system (e.g., fluctuations in concentrations due to seasonal use or changes in water source).

In response to comments about the alignment of the fifth Unregulated Contaminant Monitoring Rule (UCMR 5) sampling with initial monitoring requirements, some commenters indicated that requiring larger groundwater systems to collect four samples would translate into these systems needing to collect two additional samples beyond those collected for the UCMR 5 monitoring effort. The EPA acknowledges that while the initial monitoring requirements of this rule generally align with the UCMR 5 sampling requirements, groundwater systems serving greater than 10,000 would need to collect two additional samples within the three years following rule promulgation to supplement UCMR 5 results. As described previously, the model for estimating national PFAS drinking water occurrence indicates that larger systems have greater within-system variability than smaller systems, therefore it is appropriate that these larger groundwater systems collect four initial monitoring samples; this is consistent with initial monitoring requirements for groundwater systems under existing SOC NPDWRs.

In addition, a few commenters recommended that the number of required samples for initial monitoring be based on the results of the first two samples, with subsequent monitoring only required if regulated PFAS are detected in those earlier samples. The EPA recognizes there is some logic to this approach; however, there would be challenges implementing it. Specifically, it could be challenging for primacy agencies to track and implement the proposed approach, particularly for groundwater systems serving 10,000 or fewer which would require the additional samples to occur in quarters not represented by the first two samples. Furthermore, tracking this varying monitoring would result in additional administrative burden and oversight challenges for primacy agencies, rather than having a consistently defined schedule for monitoring requirements as is used for other SOCs.

The EPA also received several comments from state agencies about the required intervals associated with initial quarterly and semiannual sample collection. In its proposal, the EPA specified that samples be collected at least 90 days apart, whether the samples were required of a system monitoring on a quarterly basis or a system monitoring semi-annually. A small number of commenters noted that they believed that semiannual samples should be separated by more than 90 days to better capture seasonal variations (e.g., seasonal changes in the percent contributions of water blended from different sources, other fluctuations in concentrations). One commenter suggested semiannual samples should be collected at least 180 days apart, which would also be in better alignment with the required schedule for UCMR 5 semiannual sampling. The EPA

agrees with these comments. In the final rule, the EPA is requiring that the samples be collected 5 to 7 months apart for semiannual initial monitoring (see Table 2 to Paragraph (a)(4)(i)(B) of the regulations governing the UCMR program in 40 CFR Section 141.40).

With respect to the sample collection timing requirements for quarterly initial monitoring (for all surface water systems and groundwater systems serving greater than 10,000), a few commenters indicated that they were opposed to the proposed requirement for samples to be spaced at least 90 days apart. These commenters indicated that such a requirement was unnecessarily prescriptive and would make sample collection logistically challenging for PWSs. These commenters suggested the EPA change the required spacing in a way that still satisfies the EPA's intent to not have samples collected only a few days apart, but in different quarters, so that quarterly samples are more representative of fluctuations in concentrations over time. The EPA agrees with these comments and sees the value of systems being able to use four existing samples collected in separate quarters but also allowing flexibility that they are not all spaced at least 90 days apart. In the final rule, the EPA is modifying the required spacing of quarterly initial monitoring samples to be 2 to 4 months apart if samples are collected in a 12-month period. For systems that need to supplement previously-acquired data to satisfy all the initial monitoring requirements, the final rule requires that they must also be 2 to 4 months apart from the months of available pre-existing data. This will also better parallel the language outlining the required spacing of quarterly samples collected for the UCMR 5 monitoring effort.

Some commenters asked the EPA to clarify which systems would be subject to the initial monitoring requirements for surface water systems and which systems would be subject to the requirements for groundwater systems, in some cases presenting examples of specific scenarios. One example is when a system relies on surface water at some EPTDS and groundwater at other EPTDS. The EPA has modified the language of the final rule in Section 141.902(b)(1)(ii) to clarify that initial monitoring requirements are to be determined based on the type(s) of water serving as the source for a given EPTDS; thus, one system may have different initial monitoring requirements that apply to their different EPTDS. In response to questions, the EPA is clarifying in Section 141.902(b)(1)(iv) that, if an EPTDS uses water blended from multiple sources (some groundwater and some surface water), or if it uses different types of sources throughout the year, the system must follow the monitoring frequency for a surface water system (since water from surface water sources is used at least in part, for at least a portion of the year). This approach is more protective of public health because, as described earlier, generally surface water systems have more variable hydrology and potentially more sources of contamination so more monitoring data are necessary to ensure an appropriately protective monitoring schedule.

Some commenters asked for clarification about whether PWSs supplying groundwater under the direct influence of surface water (GWUDI) would qualify for semiannual initial monitoring at those EPTDSs. As noted in 141.902(b)(1)(iii), GWUDI systems follow the requirements for surface water systems. GWUDI systems may be as susceptible to contamination as surface water systems; thus, these systems must use the sampling requirements for surface water during the initial sampling phase to establish baseline levels of regulated PFAS.

In the proposal, the EPA requested public comment on the proposed initial monitoring timeframe, particularly for NTNCWS or all systems serving 3,300 or fewer. Many commenters expressed support for the EPA requiring initial monitoring as soon as possible with a few commenters explicitly supporting the EPA's proposed initial monitoring timeframe (noting it allows sufficient time for water systems to comply with the initial monitoring requirements). However, other commenters suggested that water systems would not be able to utilize the full three years following rule promulgation to perform initial monitoring and take actions to ensure compliance with the MCLs if monitoring results showed elevated levels of PFAS. While the agency agrees that it may be difficult to conduct initial monitoring and take necessary remedial actions (e.g., treatment installation) within three years, the EPA finds that it is practicable for all systems to complete their initial monitoring within three years. This is particularly the case since the large majority of systems serving greater than 3,300 will have sufficient monitoring data from UCMR 5 and many other systems will have at least some data to satisfy the rule's initial monitoring requirements. Moreover, the EPA is exercising its authority under Safe Drinking Water Act (SDWA) § 1412(b)(10) to implement a nationwide two-year capital improvement extension to comply with MCL. Consequently, water systems will have up to the full three years following rule promulgation to plan and conduct monitoring and still have two additional years to complete any actions needed to comply with the MCLs.

Several commenters suggested that the EPA consider a staggered initial monitoring timeframe by system size, such as those used in other previous NPDWRs, where, for example, larger sized systems conduct monitoring first followed by smaller systems. In the examples provided by commenters, this staggered monitoring could also allow systems to achieve compliance on a staggered schedule. A few commenters suggested that this is necessary to address potential laboratory capacity issues and to allow smaller systems additional time to plan and obtain resources to conduct the monitoring. The EPA disagrees that staggering the monitoring requirements to allow different compliance dates is necessary. SDWA 1412(b)(10) specifies that all systems must demonstrate compliance three years following rule promulgation except where a state or the EPA may grant an extension of up to two additional years to comply with MCL(s) if the EPA or the state (for an individual system) needs additional time for capital improvements. Therefore, the intent of the statute is to allow extensions to complete the capital improvements necessary to comply with the MCL. The EPA considers the three years sufficient for completing the rule's initial monitoring requirement. In response to some questions raised, the EPA added the date by which initial monitoring must be reported to the EPA (and other compliance dates) to 40 CFR § 141.900(b)(2). The EPA's allowance of previously-collected monitoring data will also significantly reduce the potential for laboratory capacity challenges. As noted above, the EPA has revised the required intervals between samples collected for initial monitoring under this rule to closely parallel the intervals required for UCMR 5, to promote the useability of existing data.

The EPA is not prescribing any staggering of monitoring (e.g., based on system size) but encourages primacy agencies to work with the systems they oversee to ensure their initial monitoring occurs and adjust schedules (within the three years following rule promulgation) as appropriate. Related to laboratory capacity considerations, see section 5.1.2; in addition to the

allowance of previously-collected data to satisfy initial monitoring requirements, as described in the rule proposal, the EPA anticipates that laboratories will be able to adjust to demand and that the demand will be distributed across the three-year implementation period.

Several commenters requested that the EPA clarify whether only samples collected under UCMR 5 would be allowed to fulfill initial monitoring requirements, or if data under other monitoring efforts, such as state monitoring, would also be acceptable. As provided in the proposal and final rule, a state may accept results from all appropriate monitoring efforts, as determined by the state, including, but not limited to, UCMR 5 and other state-led efforts. For a discussion of comments related to how existing monitoring data can be used to satisfy initial monitoring requirements, see section 8.3 below.

Individual Public Comments

Wisconsin Department of Natural Resources (Doc. #1828, SBC-044805)

Monitoring Requirements

WDNR supports ASDWA's comment regarding changing the 90-day monitoring reference to quarterly monitoring. The 90-day monitoring is problematic for Wisconsin's implementation process, which is evidenced by experience implementing the Stage 2 Disinfectants and Disinfection Byproducts Rule.

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document for a discussion of initial monitoring requirements, including revisions made in the final rule to the interval required between samples. Regarding discussion of compliance monitoring requirements, including the required intervals between sample collection, please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Wagner Engineering (Doc. #3072-9, SBC-047361)

Once the rule is finalized later this year, what will EPA's message be to water utilities that either are not participating in UCMR 5, or are not scheduled to take samples until 2024 or 2025? If these systems wait until they've completed UCMR 5 testing, they will not have time to implement any required treatment before the rule effective date in late 2026.

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document for a discussion of initial monitoring requirements and timing. See also section 12.1 of the EPA response in this *Response to Comments* document for a discussion of the nationwide 2-year extension for MCL compliance granted by the EPA to allow time for capital improvements, which would allow systems that sample in 2024 or 2025 additional time to implement treatment before the MCLs become effective, if needed.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045222)

Monitoring & Compliance

1. EPA is also proposing and taking comment on a modification to the Standard Monitoring Framework for Synthetic Organic Compounds in that groundwater systems serving 10,000 or fewer are initially required to only monitor twice for regulated PFAS within a 12-month period, each sample at least 90 days apart.

CT DPH agrees with reducing the sampling burden on these small systems and recommends that each sample be collected at least 180 days apart. Semiannual samples represent seasonal fluctuations in use and groundwater conditions that provide better representative samples of extremes in conditions as opposed to samples collected 90 days apart.

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document.

Ross Renick (Doc. #1553, SBC-042562)

Additionally, the sampling frequency proposed in the webinar during the initial monitoring period should be standardized, not based on the number of source users. Two samples in a 12-month period I do not believe will be sufficient in protecting the public from PFAS. Also, allowing a 3-year period to collect those samples does not seem feasible to be able to collect samples and then implement the proper technology to filter PFAS. If a public source waits until the final year of the 3-year window and samples twice towards the end of that calendar year, they will unlikely be able to implement the proper technology by the time the rule is in effect. If the timeline of enforceable MCLs is not advanced, I would urge you to require standardized sampling every year for all public water sources. This relates to environmental justice concerns as smaller populations would not be afforded the same protections with less infrequent sampling. I recognize that there is funding available through the EPA's Emerging Contaminants in Small or Disadvantage Communities Grant Program, which I believe should be utilized for additional sampling in smaller communities.

In closing, I thank you for the opportunity to comment on this proposed regulation. I would urge the EPA to take a precautionary approach to mitigating PFAS in our water supplies. This is still a new and emerging contaminant with limited available data. I believe it would be wise to have more stringent regulations early on in this process until either more data is available, or sources of PFAS can be contained and cleaned up.

Thank you,

Ross Renick

References:

Center for Disease Control and Prevention. N.d. "Per and Polyfluorinated Substances (PFAS) Factsheet. Last updated May 2, 2022. https://www.cdc.gov/biomonitoring/PFAS_FactSheet.html#:~:text=Many%20PFAS%2C%20including%20perfluorooctane%20sulfonic,bioaccumulate)%20in%20fish%20and%20wildlife.

EPA. N.d. "Webinar: Technical Overview of Proposed PFAS National Primary Drinking Water Regulation" Accessed May 10, 2023. https://www.youtube.com/watch?v=1uZ7KC9CmAM

Leighton, B. 2023. "PFAS Update: State-by-State Regulation of PFAS Substances in Drinking Water." Accessed. May 10, 2023. https://www.jdsupra.com/legalnews/pfas-update-state-by-state-regulation-4639985/

EPA Response: Please see section 8.1.1of the EPA response in this *Response to Comments* document. After the initial monitoring period, sampling frequency is determined by prior sampling results. Please see section 8.1.2 of the EPA response in this *Response to Comments* document regarding compliance monitoring requirements. Additionally, please see section 12.1 of the EPA response in this *Response to Comments* document for a discussion of the nationwide 2-year extension for MCL compliance granted by the EPA to allow time for capital improvements based on initial monitoring results.

American Water Works Association (AWWA) (Doc. #1759, SBC-045611)

[Examples of these systems may include:]

• Water systems scheduled for UCMR 5 monitoring in 2025: The proposal provides a 3-year timeline for water systems to comply with both the initial monitoring requirements and compliance with the MCL. Initial monitoring for the rule will need to begin immediately following promulgation of the rule to ensure that there is adequate time to take necessary action if PFAS levels exceed one or more of the MCLs. Given that the EPA's target date for a final rule is December 2023, all water systems without pre-existing data sufficient to meet these requirements will need to be monitored during 2024. This precludes the use of samples from 2025 under UCMR 5 program, as these results would give these systems less than a year to comply with the three-window for compliance, if treatment was needed.

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document for further discussion of initial monitoring requirements and section 8.3 of the EPA response in this *Response to Comments* document for discussion of the use of pre-existing data. Please see section 12.1 of the EPA response in this *Response to Comments* document for a discussion of the nationwide 2-year extension for MCL compliance granted by the EPA to allow time for capital improvements, which would allow systems that sample in 2025 additional time to implement treatment before the MCLs become effective, if needed.

Missouri Department of Natural Resources (Doc. #1563, SBC-042535)

EPA seeks comment on the Agency's proposed initial monitoring timeframe, particularly for NTNCWS or all systems serving 3,300 or fewer.

The Department recommends EPA look at a staggered initial monitoring timeframe such as used with the implementation of the Stage 2 Disinfecting Byproduct Rule. EPA established schedules (1-4) in that rule based on population, with Schedule 1 systems being larger and the first to start compliance monitoring. Large systems will have better Technical, Managerial and Financial (TMF) capabilities to provide treatment. They also serve larger populations and coincide with locations that typically have PFAS contamination issues based on UCMR3 data.

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document.

Oregon Health Authority (OHA) (Doc. #1582, SBC-042761)

Section IX – Monitoring and Compliance Requirements

• EPA requests comment on the proposed monitoring flexibility for groundwater systems serving 10,000 or fewer to only collect two samples at each entry point to the distribution system (EPTDS) to satisfy initial monitoring requirements.

OHA supports the proposed monitoring flexibility for groundwater systems serving 10,000 or fewer to only collect two samples at each EPTDS to satisfy initial monitoring requirements. This would allow groundwater systems that conducted UCMR5 monitoring or have previously acquired data to potentially use their results to comply with the initial monitoring requirements in the rule and reduce the burden on these water systems.

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document.

Michigan Department of Environment, Great Lakes, and Energy (EGLE) Drinking Water and Environmental Health Division (DWEHD) (Doc. #1597, SBC-042983)

7. EGLE DWEHD requests simplification of proposed rule language and proposes that EPA re-word 141.XX (Mon Req)(b)(i) to include GUDI and strike (b)(iii). We also suggest the following amended language for (i): "All surface water systems, all GUDI systems, and groundwater systems serving greater than 10,000 must take four consecutive quarterly samples …"

EPA Response: The EPA disagrees with this recommendation because moving the requirements for GWUDI systems from 40 CFR § 141.902(b)(iii) to § 141.902(b)(i) would entail rearranging where requirements are specified, but not any substantive difference to the requirements. The EPA is therefore retaining § 141.902(b)(iii). Further, referencing requirements for "systems" rather than all CWS and NTNCWS could be misconstrued as creating

requirements for transient non-community water systems (TNCWSs), which are not subject to this rule, and thus the EPA retained the reference to specific system types. Please see section 8.1.1 of the EPA response in this *Response to Comments* document.

American Water Works Company Inc. (Doc. #1608, SBC-044009)

Rule Implementation

Initial Monitoring

American Water supports the proposed initial monitoring scheme where surface water systems and groundwater systems serving over 10,000 people collect four (4) quarterly samples but groundwater systems serving 10,000 people or fewer would only be required to collect two (2) samples 90 days apart. This approach appropriately reduces the burden on the smaller groundwater systems.

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document.

Oklahoma Department of Environmental Quality (DEQ) (Doc. #1616, SBC-043046)

Compliance Deadlines

DEQ suggests EPA allow flexibility in the compliance deadlines to ensure feasibility, allowing staggered compliance deadlines depending on the system size.

Large and medium-sized water systems will have previously collected data from UCMR 5, while many small systems will be taking their first PFAS samples when the final PFAS NPDWR is implemented. If these small systems exceed the MCL, the three-year compliance timeline will be challenging to meet.

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044034)

16. EPA requests comment on the proposed monitoring flexibility for groundwater systems serving 10,000 or fewer to only collect two samples at each EPTDS to satisfy initial monitoring requirements.

a. Groundwater systems are the most likely to be contaminated with PFAS compounds.

EPA Response: The EPA disagrees that groundwater systems are the most likely to be contaminated with PFAS, based on the agency's model for estimating national occurrence which suggests otherwise (see section 8.1.1 of the EPA response in this *Response to Comments* document.). The commenter provided no supporting information or data for this claim.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043085)

Additionally, the timeline for the initial monitoring period of 3 years is appropriate. It is important to note, however, that this timeline is in concert with the compliance deadline for meeting or exceeding the MCLs. As such, water systems will not be able to wait until the third year of the compliance window to perform initial monitoring requirements because this would not leave time to comply with the MCLs, if elevated levels of PFAS are found.

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-044887)

In [sec] 141.XX, Table 1 to paragraph (b)(l)(iv) notes a population delineation for initial monitoring requirements of 10,000, but Table 2 to paragraph (b)(2)(iv) notes a population delineation of 3,300 for reduced monitoring level. DEP notes that this difference is confusing, and that it is further evidence that the population delineations are arbitrary, as noted in the previous comment.

EPA Response: The EPA clarifies that the first table the commenter referenced related to initial monitoring requirements and the second related to compliance monitoring requirements. The EPA disagrees that including requirements specific to systems of different sizes is arbitrary, and this approach has been used in other NPDWRs, including the monitoring requirements for other SOCs. Additionally, please see section 8.1.1 of the EPA response in this *Response to Comments* document, particularly the reference to data from the EPA's national occurrence model for PFAS in drinking water which indicates that larger systems have greater within-system variability. The EPA revised the compliance monitoring requirements, as discussed in section 8.1.2 of the EPA response in this *Response to Comments* document, to remove consideration of system size in light of the public comments received, which removes the potential for any similar confusion as raised by the commenter.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-044885)

• For initial monitoring, EPA proposes allowing groundwater systems serving 10,000 or fewer customers to only collect two samples at each EP instead of four consecutive quarterly samples. DEP recommends requiring all water systems to conduct monitoring for four consecutive quarters for initial monitoring. Allowing a reduction from four quarterly samples to only two samples is appropriate for regulated synthetic organic chemicals (SOCs) because monitoring would be required during the quarters in which those chemicals are most likely used and would affect water system sources. However, for PFAS chemicals, there may be seasonal variations, which would not be captured by allowing a system to reduce monitoring to only two samples.

• DEP requests clarification on which systems will be considered "groundwater systems" for the proposed monitoring flexibility allowing groundwater systems serving 10,000 or fewer

customers to only monitor twice for initial monitoring. If a system has their own groundwater sources, but also purchases finished water from a surface water system, will the purchasing system still be considered a groundwater system for the purposes of initial monitoring under this proposed rule?

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document. Initial monitoring frequency is based on the population served and on the source water type associated with each of the PWS's EPTDSs, regardless of whether the PWS is a "parent" system or "purchasing" system.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044098)

ASDWA recommends that the rule specify the date(s) by which initial monitoring must be completed.

The date specified in 141.XX(b)(1)(vi) only applies to monitoring that is needed to supplement previously acquired data to meet the initial monitoring requirements.

ASDWA recommends that EPA provide additional clarification to define the types of ground water systems for which the less frequent (1 sample every six months) initial sampling requirements apply.

The final rule should clarify and explain its reasoning on whether springs and ground water systems under the direct influence of surface water (GWUDI) can qualify for less frequent initial monitoring. The rule should also provide examples of ground water systems that would not be eligible for less frequent monitoring, such as water systems that mostly purchase surface water to provide drinking water to their customers but also have their own ground water wells.

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document. Less frequent (twice in 12 months) initial monitoring requirements apply only to PWSs serving 10,000 or fewer and any EPTDS within those PWSs that rely exclusively on groundwater.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044089)

To address these laboratory capacity concerns, ASDWA recommends that EPA include language within the final rule requiring initial monitoring to be staggered based on system size. Systems serving less than 3300 people should monitor last, as the majority of these systems will not have conducted UCMR 5 monitoring and will likely need the most time to budget for costs and meet monitoring requirements.

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document.

Texas Commission on Environmental Quality (TCEQ) (Doc. #1632, SBC-044133)

To alleviate the initial laboratory capacity issues and reduce public water system sampling costs, TCEQ supports:

• Allowing groundwater systems serving 10,000 or fewer people to monitor twice for regulated PFAS within a 12-month period instead of four samples within this period.

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document.

Aidan Cecchetti (Doc. #1640, SBC-044374)

• EPA seeks comment on the Agency's proposed initial monitoring timeframe, particularly for NTNCWS or all systems serving 3,300 or fewer (pg. 18681 Federal Register Volume 88, Number 60).

O It is the commenters' opinion that the proposed initial monitoring timeframes, in which water systems must complete the initial monitoring requirements within three years following rule promulgation, are appropriate and allow sufficient time for water systems to comply with the initial monitoring requirements. The commenters agree that the reduced monitoring requirements for NTNCWS and systems serving fewer than 3,300 persons offer significant burden reductions and sufficient time for rule compliance.

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document. The EPA notes that there are no reduced monitoring requirements or different initial monitoring timing requirements for NTNCWSs or systems serving fewer than 3,300 persons.

Aidan Cecchetti (Doc. #1640, SBC-044367)

• EPA requests comment on the proposed monitoring flexibility for groundwater systems serving 10,000 or fewer to only collect two samples at each EPTDS to satisfy initial monitoring requirements (pg. 18682 Federal Register Volume 88, Number 60).

O It is the commenters' opinion that the proposed monitoring flexibility for groundwater systems serving 10,000 or fewer is appropriate and consistent with other NPDWRs. The commenters do not foresee any challenges regarding implementation of this type of monitoring flexibility.

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document.

National Rural Water Association (NRWA) (Doc. #1641, SBC-043273)

• EPA requests comment on the proposed monitoring flexibility for groundwater systems serving 10,000 or fewer to only collect two samples at each EPTDS to satisfy initial monitoring requirements.

Response: Monitoring flexibility is essential for small systems

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044178)

F. Laboratory Readiness

1. NCDEQ recommends EPA consider staggering the initial monitoring requirements based on system size to help address potential laboratory capacity issues.

EPA should evaluate whether laboratory capacity required to support the PFAS NPDWR will be impacted, especially as water systems continue to test under UCMR 5 in 2024 and 2025. The factors that should be considered are the time it takes to get a laboratory certified for PFAS methods; the number of laboratories that are currently capable of analyzing for PFAS and being able to manage the volume of samples; the method requirements for temperature and time frames for laboratories to store and analyze the samples; shipping delays; and the competing demands for laboratories to analyze PFAS in other environmental media, while at the same time meeting other new and existing drinking water regulatory needs.

NCDEQ's current observation indicates that the number of laboratories capable of analyzing for PFAS in time to meet the new rule compliance demands is limited. The volume and number of samples that water systems will need to be analyzed based on expected occurrence and sampling frequency could exceed laboratory capacity for all laboratories and each laboratory individually. There may also be an impact on laboratory capacity due to limited suppliers for PFAS standard reagents. Analytical method requirements for temperature and timeframes to store and analyze PFAS samples may also require laboratories to significantly increase their refrigeration storage. Additionally, laboratories have competing demands to analyze PFAS in other environmental media and, at the same time, meet other new and existing drinking water regulatory needs. For example, the Lead and Copper Rule Revisions (LCRR) and the future Improvements will likely create additional demands on laboratories, particularly if a significant number of systems will need to re-start initial monitoring based on revised compliance sampling locations. These revisions would significantly increase the number of lead and copper compliance samples. We recognize that these demands could transform the way laboratories provide analytical services in the future, including adjusting their business operations to enable quicker and flexible services to meet increase in demand.

If EPA's evaluation concludes that capacity of laboratory at regional or national level is an issue, NCDEQ recommends that EPA consider providing additional time for more laboratories to get certified and prepare to analyze PFAS samples. EPA could include language within the final rule that would require initial monitoring to be staggered based on system size. Systems serving less than 3,300 people should monitor first, as the majority of these systems will not have conducted UCMR 5 monitoring.

EPA Response: Regarding staggering initial monitoring deadlines, please see section 8.1.1 of the EPA response in this *Response to Comments* document. Regarding the comments about laboratory availability and capabilities, see section 5.1.2 of the EPA response in this *Response to Comments* document.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044184)

5. NCDEQ recommends that the rule specify the date(s) by which initial monitoring must be completed.

The date specified in 141.XX(b)(1)(vi) only applies to monitoring that is needed to supplement previously acquired data to meet the initial monitoring requirements.

6. NCDEQ recommends that EPA provide additional clarification to define the types of ground water systems for which the less frequent (1 sample every six months) initial sampling requirements apply.

The rule should clarify and explain its reasoning on whether springs and ground water systems under the direct influence of surface water (GWUDI) can qualify for less frequent initial monitoring. The rule should also provide examples of ground water systems that would not be eligible for less frequent monitoring, such as water systems that mostly purchase surface water to provide drinking water to their customers but that also have their own ground water wells.

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document.

Nebraska Department of Environment and Energy (NDEE) (Doc. #1653, SBC-043200)

The Department would support allowing monitoring flexibility of two samples at each entry point to the distribution systems (EPTDS) with data collected previously for groundwater systems serving less than 10,000 to satisfy initial monitoring requirements. This would be consistent with previous rules.

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044418)

Page 18730. Section IX – Monitoring and Compliance Requirements.

EPA requests comment on the proposed monitoring flexibility for groundwater systems serving 10,000 or fewer to only collect two samples at each EPTDS to satisfy initial monitoring requirements.

• In Washington State, there are more detections in groundwater than in surface water. Detections are generally consistent over time with little seasonal variability.

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044425)

EPA seeks comment on the Agency's proposed initial monitoring timeframe, particularly for NTNCWS or all systems serving 3,300 or fewer.

• The initial monitoring of 2 samples in 90 days is acceptable.

• DOH has time and cost concerns over the impact from increased quarterly monitoring for detected results below the PQL, and the challenge in computing HI for PWS that have detections of other PFAS with MCLs.

EPA Response: Please see section 8.1.1. of the EPA response in this *Response to Comments* document for a discussion of initial monitoring requirements. Please see section 8.8 of the EPA response in this *Response to Comments* document for a discussion of the trigger levels established under this rule and use of values below the practical quantitation levels (PQLs) for the determination of monitoring frequency. Please see section 8.1.2 of the EPA response in this *Response to Comments* document for a discussion of compliance monitoring requirements. Section 8.1.2 contains a discussion of the annual monitoring tier added for PFAS in the final rule, akin to a tier available for other SOCs, which may help address the commenter's concern about time and costs required for systems that have detections of PFAS above trigger levels. Regarding calculating the Hazard Index, the EPA has explained the process in the final rule and intends to disseminate implementation materials about calculating the Hazard Index as part of a larger set of materials to aid with implementation of the rule.

New Hampshire Department of Environmental Services (NHDES) (Doc. #1690, SBC-044347)

3. Page 18730, Column 2, Section IX—Monitoring and Compliance Requirements

a. Page 18730, Column 2, Bullet 7 - EPA requests comment on the proposed monitoring flexibility for groundwater systems serving 10,000 or fewer to only collect two samples at each EPTDS to satisfy initial monitoring requirements.

NHDES Comment - NH would be a proponent of allowing monitoring flexibility for systems to only collect two samples at each EPTDS to satisfy initial monitoring requirements. However, we recommend that this flexibility be based on sample results rather than system source type or population served. For example, any system would be eligible to only collect two samples during the initial monitoring period if those two sample results were below the proposed rule trigger level. [Rule Reference: 141.XX (b)(1) (i) and (ii) – Page 18751, Column 3]

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045029)

NJDEP does not support EPA's modification to the Standard Monitoring Framework (SMF) for SOCs that would allow groundwater systems serving less than 10,000 customers to take two samples at each entry point to the distribution system (EPTDS) within a 12-month period, 90 days apart. Sampling twice in one year may not generate enough data to accurately capture the level of PFAS in drinking water being served by a system to the public. Public water systems with multiple wells may use some of these wells seasonally and depending on the sampling schedule, wells with elevated levels of PFAS may be offline during the sampling event. Second, as stated above, NJDEP has observed cases where water systems receive non-detect results initially, only to later exceed the MCL. Having the samples collected in close proximity on a temporal basis will potentially not fully capture potential violations. NJDEP recommends that EPA consider requiring all community and non-transient non community water systems to conduct initial quarterly monitoring. Of the 95 water systems in New Jersey that have received PFAS MCL violations for PFNA, PFOA, and PFOS, all have utilized groundwater sources at the treatment plants that exceeded the MCLs.

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document. Also, regarding the portion of the comment suggesting samples collected in close proximity temporally may not necessarily capture the range of possible concentrations of regulated PFAS in water, see section 8.1.2 of the EPA response in this *Response to Comments* document for discussion of ongoing compliance sampling requirements.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045102)

Section IX -Monitoring and Compliance Requirements

1) Proposed monitoring flexibility of GW <10,000 to only collect two Entry Point to Distribution System (EPTDS) samples to satisfy initial monitoring requirements.

While 10,000 is often a clear "line" to draw to separate systems, the data in Vermont do not support this distinction as having systems above that population or with a surface water source as having more vulnerability to PFAS contamination. There should be an initial framework by

which the system needs to collect 1 or 2 samples which then drives the future sampling, with options for quarterly, annual, and triennial sampling.

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document regarding initial monitoring requirements. Please see section 8.1.2 of the EPA response in this *Response to Comments* document regarding compliance monitoring frequencies, including the annual monitoring tier added in the final rule in response to public comments.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045230)

9. EPA seeks comment on the proposed initial monitoring timeframe, particularly for Non-Transient Non-Community public water systems or all systems serving 3,300 or fewer.

CT DPH has been encouraging all PWSs to test their water for PFAS since 2018, and have required all new source, including those for transient non-community public water systems, to test for PFAS prior to their activation. CT DPH agrees with EPA that community and non-transient non-community PWSs should test their systems. With UCMR5 and state monitoring programs, previously collected data should reduce the burden of testing for many systems.

Federal funds should be made available to assist initial sampling for the remaining small and very small community and non-transient non-community systems as those systems typically have fewer resources. CT DPH also recommends that EPA stagger the initial monitoring requirements based on system size.

EPA Response: Please see section 8.1.1. of the EPA response in this *Response to Comments* document for a discussion of initial monitoring requirements. For discussion of the use of existing data to satisfy initial monitoring requirements, please see section 8.3 of the EPA response in this *Response to Comments* document. As noted in section II.E of the preamble to the final rule, funding under the IIJA, often referred to as the BIL, will assist many disadvantaged communities, small systems, and others with the costs of addressing emerging contaminants, like PFAS, when it might otherwise be cost-challenging. Additionally, to support BIL implementation, the EPA is offering WaterTA to help communities identify water challenges and solutions, build capacity, and develop application materials to access water infrastructure funding (USEPA, 2023).

American Water Works Association (AWWA) (Doc. #1759, SBC-045621)

9. Monitoring Requirements

The agency is providing a compliance timeline of three years for water systems subject to the rule to perform initial monitoring requirements for PFAS at each entry point to the distribution system. The initial monitoring requirements may be waived for some systems that are either participant in UCMR 5 or have participated in eligible state monitoring programs since January 2019. Initial monitoring will determine if systems are eligible for a reduced monitoring

frequency under the proposed framework and if the system will need to install treatment (or take non-treatment action) to reduce PFAS to levels below the MCL.

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document. The EPA agrees with the majority of this statement, except for the portion suggesting that initial monitoring requirements of this NPDWR are being "waived" for systems with existing data. Instead, water systems may use existing data to satisfy the initial monitoring requirements of this NPDWR. The state can then use these data, provided within three years of rule promulgation, to determine the monitoring schedule required at the start of the compliance monitoring period. Regarding the use of previously collected data to satisfy initial monitoring requirements, please see section 8.3 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045624)

Additionally, the timeline for the initial monitoring period of three years is appropriate. It is important to note, however, that this timeline is in concert with the compliance deadline for meeting the MCLs. As such, water systems will not be able to wait until the third year of the compliance window to perform initial monitoring requirements because this would not leave time to comply with the MCLs, if elevated levels of PFAS are found.

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document. Please see section 12.1 of the EPA response in this *Response to Comments* document for a discussion of the nationwide two-year extension for MCL compliance granted by the EPA to allow time for capital improvements, which would allow systems additional time to implement treatment before the MCLs become effective, if needed.

New Mexico Environment Department (NMED) (Doc. #1766, SBC-044254)

Compliance

NMED recommends that EPA allow flexibility in the compliance deadlines to ensure feasibility, similar to the flexibility offered as a part of the final arsenic regulation that allowed staggered compliance deadlines depending on system size.

NMED appreciates and is supportive of EPA's efforts to regulate these forever chemicals and wants to work with EPA to achieve enhanced protection of public health through implementation of the more stringent regulations. However, if EPA doesn't address concerns being raised by state agencies and other organizations, the ability to successfully implement the regulations will be limited.

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document. Please see section 12.1 of the EPA response in this *Response to Comments* document for a discussion of the nationwide two-year extension for MCL compliance granted by

the EPA to allow time for capital improvements, which would allow systems additional time to implement treatment before the MCLs become effective, if needed.

Environmental Protection Network (EPN) (Doc. #1773, SBC-043869)

EPN strongly recommends that the final regulation require all PWS to conduct an initial round of monitoring unless explicitly waived in writing by the state.

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document. Water systems subject to this rule will need to conduct initial monitoring unless demonstrated to and approved by the state that they have previously-collected data to satisfy the NPDWR's initial monitoring requirements. Please see section 8.3 of the EPA response in this *Response to Comments* document for a discussion of the use of pre-existing data. For the portion of the comment referencing "all PWS," the EPA notes that CWSs and NTNCWSs are subject to this NPDWR. TNCWSs are not required to conduct monitoring under this NPDWR. For an explanation of the rationale for this decision, please see section 1.4 of the EPA response in this *Response to Comments* document.

Metropolitan Water District of Southern California (Doc. #1777, SBC-045435)

Furthermore, while the proposed rule allows systems to use previously collected monitoring data to satisfy the initial monitoring requirements, it is unclear what happens if agencies do not use previously collected monitoring data to satisfy the initial requirements, but their prior data shows they would be out of compliance. Monitoring and compliance of PFAS constituents significantly impact water agencies' day-to-day operations and financial standing. It is important to coordinate a stakeholder-driven assessment of use and application of a mixture-based screening tool prior to implementation of a Hazard Index-based MCL and MCLG. Metropolitan recommends that EPA carefully consider all the factors and provide clarification of these issues before requiring water agencies to collect monitoring data and trigger a compliance schedule.

EPA Response: The EPA has followed the regulatory development process as outlined under SDWA and considered all factors and comments in determining the final NPDWRs, including the monitoring requirements. For the final rule, no systems will be found to be out of compliance with the MCLs as a result of their initial monitoring results, whether those are determined through new sampling or through use of previously-collected data; rather, these data will be used to determine the ongoing compliance monitoring frequency. The EPA notes that while the agency is allowing use of previously-collected data as a monitoring flexibility in the final rule, water systems are not required to use, nor are states required to allow the use of, previously-collected data to satisfy the final rule initial monitoring requirements. Also, as a condition of using previously collected data to satisfy the initial monitoring requirements, the laboratory used by the water system must be capable of producing results at or below the MCLs. Please see section 8.1.1 of the EPA response in this *Response to Comments* document for more on initial monitoring requirements and section 8.1.2 of the EPA response in this *Response to*

Comments document for compliance monitoring requirements. Additionally, the EPA is planning to disseminate educational materials about calculating the Hazard Index as part of a larger set of materials to aid with implementation of the rule, with the goal of reducing challenges systems might have associated with computing the Hazard Index. For more on the Hazard Index MCL, please see section 5.2 of the EPA response in this *Response to Comments* document.

Citizens Energy Group (Doc. #1838, SBC-044868)

EPA seeks comment on the Agency's proposed initial monitoring timeframe, particularly for NTNCWS or all systems serving 3,300 or fewer.

Citizens believes that small systems (those serving fewer than 3,300 service connections) should be directed to collect the analytical data needed to support decision making. As offered in prior comments, if the data available to a small system provides sufficient information to support compliance with the proposed rule before the compliance date, there should not be obligations to sample just for the sake of collecting additional data. Each small system should collect sufficient data needed to ensure compliance and the delivery of water that meets the requirements of the Safe Drinking Water Act for their customers.

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document. The EPA clarifies that following initial monitoring, the frequency of monitoring will be determined by previous sampling results. For discussion of the compliance monitoring requirements, please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Paul Eldredge (Doc. #2770, SBC-047325)

We urge EPA to proceed carefully so as to ensure personnel are appropriately educated with the adoption of new well-developed standards in an efficient manner that minimizes costly mistakes such as the acquisition of unnecessary or insufficient equipment or usage of improper procedures. We want to ensure updates in standards not only strengthen public health protections and environmental safety but are enforced appropriately. We advise that new rules harmonize with other related requirements and allow for a thorough plan for phased implementation.

EPA Response: Regarding phased implementation, please see section 8.1.1 of the EPA response in this *Response to Comments* document. Regarding training, the EPA is developing guidance and training materials to aid states and systems in rule implementation. The EPA agrees that these new standards do strengthen public health protections, have been designed with an awareness of other related requirements, and will be enforced in a similar fashion as it is conducted under other NPDWRs. For a discussion of the modifications to the SMF for SOCs that the EPA made for PFAS, see section 8.1.2 summary.

Robert Hollander (Doc. #1516, SBC-042710)

2. 88 FR 18668, 1st column

If EPA sufficiently advertises and/or highlights the ability of water utilities to use data obtained from UCMR 5 monitoring to satisfy initial monitoring requirements, this will likely reduce demand for laboratory services prior to the compliance effective date.

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document on initial monitoring and section 8.3 of the EPA response in this *Response to Comments* document on the use of existing data to satisfy initial monitoring requirements.

Michigan Department of Environment, Great Lakes, and Energy (EGLE) Drinking Water and Environmental Health Division (DWEHD) (Doc. #1597, SBC-042984)

8. Regarding flexibility during initial monitoring for groundwater supplies serving a population less than 10,000, EGLE DWEHD generally does not have issue with EPA's proposed approach.

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document.

Little Hocking Water Association (Doc. #1835, SBC-045518)

Further, the proposed rule's monitoring requirements are not protective of health because the known difference between water systems that draw from surface water versus groundwater is not taken into account. Because levels of contamination in surface water vary much more than groundwater, systems that draw from surface water (or from groundwater influenced by surface water) should be subject to more stringent testing requirements. For systems whose source water contains widely varying levels of contamination, infrequent testing would miss times when concentrations are high. This is not protective of public health.

EPA Response: The EPA agrees that levels of some contaminants in surface water can vary more than levels in ground water, but this is not true for PFAS in all cases, as noted in some comments received in response to the proposed rule. Nevertheless, the EPA agrees with the commenter and is requiring surface water systems (and large groundwater systems) to conduct quarterly monitoring initially, which is a more stringent requirement than applies to groundwater systems serving 10,000 or fewer people that are required to collect two samples. Please see section 8.1.1 of the EPA response in this *Response to Comments* document for discussion of initial monitoring requirements. Following initial monitoring, monitoring frequency is based on previous sampling results not source water type, so if a sampling location demonstrates elevated levels of regulated PFAS, regardless of source water type, more frequent monitoring will be required. Please see section 8.1.2 of the EPA response in this *Response to Comments* document for discussion of compliance monitoring requirements.

Citizens Energy Group (Doc. #1838, SBC-044860)

Section IX – Monitoring and Compliance Requirements

EPA requests comment on the proposed monitoring flexibility for groundwater systems serving 10,000 or fewer to only collect two samples at each EPTDS to satisfy initial monitoring requirements.

Citizens supports EPA's proposal that imposes less stringent initial monitoring obligations on medium and small/very small systems. Offering flexibilities to these systems is appropriate given the limited resources (both personnel and budgets) that these systems typically have available.

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document.

New England Water Works Association (Doc. #1836, SBC-045383)

Certified labs have been challenged with analyzing the number of samples that PWS send them. PWS can wait upwards of 3 weeks for sample results and then the primacy agencies must perform quality assurance evaluations, which can take several more weeks. Samples are expensive ($250-$350 per sample), with field blanks being run in the majority of cases, thereby doubling the costs. Follow-up confirmatory samples will be needed to validate initial results. NEWWA recommends that monitoring should be phased in by system size to reduce the resource burden on the labs and primacy agencies who must review and verify the quality of the data.

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document. For discussion of compliance monitoring requirements, please see section 8.1.2 of the EPA response in this *Response to Comments* document. States determine confirmation sampling requirements for compliance sample purposes, although a system may voluntarily collect additional samples to provide it with more information. Regarding laboratory considerations, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

8.1.2 Compliance Monitoring Requirements

Summary of Major Public Comments and EPA Responses

Regarding the requirements for compliance monitoring, the comments the EPA received related primarily to the frequency with which sampling would occur under different circumstances, whether each EPTDS would be allowed to be on a different compliance monitoring schedule, and the trigger levels that would support decisions about reduced triennial monitoring. Regarding the latter point, commenters also addressed laboratory capabilities to measure levels below PQLs. Trigger levels, including the use of values below the PQLs, are addressed in section 8.8 of the EPA response in this *Response to Comments* document. Laboratory availability and

capability are also addressed in section 5.1.2 of the EPA response in this *Response to Comments* document.

The EPA proposed to allow systems eligible for reduced monitoring, and serving 3,300 or fewer, to collect one compliance monitoring sample triennially and to allow eligible larger systems to collect two samples during a three-year compliance period. The EPA specifically requested comment on whether all water systems, regardless of system size, should be allowed to collect and analyze one sample per three-year compliance period if the system does not measure any regulated PFAS in their system at or above the rule trigger level. Several commenters stated that they did not agree with a different number of triennial samples eligible systems must collect being based on the size of the population a system serves. These commenters suggested that one sample collected every three years is sufficient for systems of any size on reduced monitoring. The EPA agrees with these commenters that systems eligible for triennial monitoring should be allowed to collect one sample every three years, regardless of system size, especially considering other changes to the compliance monitoring framework, as described below.

Several commenters recommended that an annual sampling frequency tier be added to the required monitoring framework for various reasons including the mobility and persistence of PFAS in the environment, to ensure that systems that have previously demonstrated elevated levels of regulated PFAS are not allowed to move directly from quarterly to triennial monitoring, and based on their concerns that some laboratories may not be able to produce results at or below the rule trigger levels (resulting in some systems remaining on quarterly monitoring indefinitely even if they can consistently demonstrate they are below the MCLs). A few commenters supported offering three possible monitoring frequencies: quarterly, annually, and triennially, whereas many other commenters recommended against allowing triennial sampling at all and recommended that sampling be required no less than annually, to best protect public health. Those commenters supportive of allowing both annual and triennial monitoring, depending on prior sample results, suggested that annual monitoring should be an option for systems with regulated PFAS concentrations that are reliably and consistently below the MCLs. This modification would parallel the three tiers of monitoring allowed for other organic chemicals under the SMF.

A few commenters recommended that PFAS compliance sampling requirements mirror requirements for other SOCs under the SMF. The EPA agrees and has developed the PFAS NPDWR monitoring requirements generally based on the structure of the SMF for SOCs, which the agency anticipates will aid in successful understanding and implementation of the monitoring requirements. For example, the EPA agrees that an annual monitoring frequency should be available for PFAS, like other SOCs, and notes that the trigger levels for PFAS are analogous to the "detection limits" that determine a system's monitoring frequency for some other SOCs. But, as subsequently explained, the EPA does not agree with making the monitoring requirements for PFAS fully consistent with requirements for other SOCs. For example, PFAS are extremely persistent in the environment, and, as discussed in section 8.5 of this comment response document, the EPA has decided that no waivers for PFAS monitoring will be allowable. In

addition, the SMF for SOCs requires systems monitoring triennially to collect either one sample every three years or two samples every three years depending on the size of the population they serve, and, as noted above, the final PFAS rule will require systems monitoring triennially to collect only one sample regardless of their size.

The EPA does not agree with the comments suggesting that no systems should be allowed to sample triennially and that the longest sampling interval at any location should be one year. Based on the EPA's national occurrence estimates, most water systems subject to the rule's requirements will not have results for regulated PFAS that exceed the MCLs, and many will not identify PFAS at or above the triggers levels, thus allowing for reduced monitoring. These systems, after demonstrating results below the trigger level and therefore no or very little presence of regulated PFAS during the initial monitoring period or through ongoing compliance monitoring, should be able to reduce their monitoring burden and conduct triennial sampling, while still sufficiently maintaining public health protection. If a system monitoring triennially did have a sample result with elevated levels of a regulated PFAS (at or above the trigger level), it would be required to immediately initiate quarterly monitoring which would provide the primacy agency and water system with frequent sampling information to ensure compliance with the MCL and public health protection, as well as enable them to know whether treatment or other actions may be necessary to address regulated PFAS in that system's water. Additionally, the rule specifically provides that primacy agencies may increase the required monitoring frequency for compliance sampling for a variety of reasons, including to detect variations within specific systems (e.g., fluctuations in concentrations due to seasonal use patterns or changes in water sources). For any system that has regulated PFAS concentrations at or above the trigger level, but reliably and consistently below the applicable MCL, the EPA is introducing in the final rule an annual monitoring frequency within the compliance monitoring framework, consistent with the SMF for SOCs. A demonstration of reliably and consistently below the MCL would include consideration of at least four quarterly samples below the MCL. Annual samples would be collected during the quarter with the highest concentration measured during the prior round of quarterly sampling. The EPA expects this modification in the final rule to reduce the number of systems that are required to be on quarterly monitoring for extended periods of time, compared to the EPA's proposal, while still providing prompt information about PFAS levels in the water system to enable treatment or other actions should the regulated PFAS levels exceed the MCLs.

In adopting a three-tiered monitoring framework, the EPA is modifying the required sampling frequency from triennial to annual for systems determined by states to be reliably and consistently below the MCL and changing the threshold for this determination from the trigger level to the MCL. To further reduce monitoring, any system that transitions into annual sampling will be required to collect three years of annual samples each of which show concentrations of regulated PFAS below trigger levels (i.e., not an average of the three annual sample results) before then being eligible for triennial monitoring. If eligible for triennial monitoring, the sample collected triennially would need to be collected in the same quarter during which prior annual monitoring results were highest.

This additional, annual tier is intended to create a gradual step-down schedule for affected PWSs to confirm levels of regulated PFAS are remaining consistently low or decreasing. The modifications to the requirements for a reliable and consistent determination and the creation of the new annual sampling tier in the final rule make the requirements for regulated PFAS more consistent with the NPDWR requirements for SOCs. They also represent flexibilities that address concerns about laboratory capability. The EPA believes this three-tier approach, including the eligibility criteria for each outlined above, provides the best approach to protect public health and moderate the total cost of sampling borne by a system.

A few commenters were not supportive of the EPA's initial proposal to compare the running annual average (RAA) to trigger levels to determine eligibility for a "reliably and consistently below the MCL" determination that would allow the PWS to sample at the entry point triennially, after collecting at least four consecutive quarters of quarterly samples. In light of the public comments about the proposed threshold for a reliable and consistent determination and the incorporation of an annual monitoring frequency, the EPA removed the requirement to compare the RAA to the trigger levels to be eligible for such a determination. Instead, the EPA is specifying that a state must consider at least four consecutive quarters of data to make a reliable and consistent determination, with all four quarters required to demonstrate individual results below the MCLs (i.e., not the RAA result of the four quarters). States may establish additional criteria for making these determinations. In addition, the determination makes a system eligible for annual monitoring, not triennial monitoring, justifying the increased flexibility with respect to making this determination accorded to states in the final rule.

The EPA also received some comments about the practice by systems that have installed treatment for PFAS to regularly sample finished water to ensure the efficacy of their treatment media (e.g., filters), above and beyond what they would do for compliance monitoring. A few commenters suggested systems that have installed treatment would conduct this additional sampling voluntarily, typically for process control purposes. A few state agency commenters suggested that any system that is treating its water for PFAS should be required to sample more frequently than triennially (e.g., annually) no matter the levels of previous PFAS detections, since the effectiveness of treatment media may decline over time, if not replaced. The EPA disagrees with the commenters recommending a greater sampling frequency for systems that treat their water for PFAS and does not see a compelling reason to depart from the three-tier compliance monitoring program for a system that has installed treatment. In the final rule, the EPA is adding an annual tier of sampling for any system with concentrations reliably and consistently below the MCL but not consistently below the trigger level. The EPA believes this tier will likely apply to most systems treating their water for regulated PFAS, at least for the first three years of treatment, as the EPA estimates as part of its rule costs that systems needing to install treatment will adopt a treatment target of 80 percent of the MCLs. The majority of systems with elevated levels of regulated PFAS contamination are likely to sample quarterly, at least initially (unless they have treatment for PFAS in place prior to the collection of initial monitoring samples). In practice, the result is that most systems with PFAS contamination will likely not be eligible for triennial sampling unless their PFAS treatment is consistently optimized

and maintained. However, the rule provides that primacy agencies may increase the required monitoring frequency, where necessary to detect variations within the system, and this approach could be applied to those systems that have installed treatment. In addition, the EPA notes that, when systems are treating for other regulated chemicals pursuant to NPDWRs, no distinctions are made between the monitoring frequency required of a system that is treating for a chemical and a system that has not installed treatment. Thus, using the same monitoring frequency for systems regardless of whether they are treating their water for PFAS is consistent with existing NPDWRs.

The EPA requested comment on the proposed allowance for a water system to potentially have each EPTDS on a different compliance monitoring schedule based on specific EPTDS sampling results (i.e., some EPTDS being sampled quarterly and other EPTDS sampled only once or twice during each three-year compliance period), or if compliance monitoring frequency should be consistent across all of a system's sampling points. A few commenters recommended that all EPTDS used by a system monitor at the same frequency, or that doing so be optional, to reduce the complexity of monitoring requirements or the potential for mistakes to be made with respect to sampling windows. However, the overwhelming majority of those who commented on this topic indicated they supported allowing different sampling frequencies for different EPTDS. The EPA agrees that it would be beneficial to allow different sampling frequencies for different EPTDS because it would allow utilities to realize cost savings if only the EPTDS with elevated levels of PFAS are required to sample most frequently. In addition, the EPA notes it allows systems to use different sampling frequencies for different EPTDS for compliance with other NPDWRs.

To determine compliance monitoring frequency only, the EPA proposed a rule trigger level of one-third the MCLs (1.3 ng/L for PFOA and PFOS and 0.33 for Hazard Index PFAS (PFHxS, PFNA, HFPO-DA, and PFBS)) and invited comments on alternatives. If results for an EPTDS are below the trigger level, systems would be eligible for reduced triennial monitoring. Some commenters raised concerns about potential laboratory analytical and capacity issues associated with endeavoring to measure PFAS concentrations at levels below the PQLs and the rule trigger levels, which are discussed in detail in section 8.8, as well as section 5.1.2, of the EPA response in this *Response to Comments* document; see also section 7.2 of the EPA response in this *Response to Comments* document for further discussion of the PQLs. Some suggested that laboratories cannot achieve levels below the PQLs, which would result in water systems not being eligible for reduced monitoring based on not demonstrating results below trigger levels. The EPA recognizes that some laboratories may not be able to produce results at these lower levels with the same degree of accuracy and precision as results at or above the PQLs, and notes that there is not a requirement that they do so for these purposes of determining monitoring frequency.

Data below the PQL will be critical to ensuring that systems are monitoring at the correct frequency and whether a contaminant is present within a certain range. Moreover, while results near the trigger level may be less definitive than results at or above the PQL, such results are

appropriate for establishing monitoring frequency, as well as for reporting as part of the annual CCR. CCR reporting is based on detected contaminants and for the purposes of the PFAS NPDWR, 141.151(d) defines "detections" as results at or above the rule trigger levels (see section IX of the preamble for more information on CCR requirements.

Under the final rule, for monitoring frequency determination purposes, unlike the determination of compliance with the MCLs, systems are required to use all sample results, including those below the PQLs. The latter are not quantified with the same precision and accuracy as is associated with the compliance calculation determination, as discussed in subsection VIII.B of the preamble and section 8.2 of the EPA response in this *Response to Comments* document. Additionally, the determination of monitoring frequency is not based on an RAA result (for systems monitoring quarterly), but each individual sampling result. As an illustration of the approach, if a water system has quarterly sampling results at an EPTDS from initial monitoring for PFOA that are 2.0, 1.5, 5.0, and 1.5 ng/L, there are two results (i.e., 2.0 and 5.0 ng/L) at or above the EPA's final trigger level for PFOA (i.e., 2.0 ng/L). Thus, the water system would not be eligible for triennial monitoring at this EPTDS for all regulated PFAS when compliance monitoring begins. Providing a different example, if a water system that is currently required to conduct quarterly compliance monitoring has quarterly sampling results at an EPTDS for PFOA that are 2.0, 3.5, 2.5, and 1.5 ng/L, all results are below the MCL for PFOA (i.e., 4.0 ng/L), however three results are above the PFOA trigger level. In this case, because four quarters of data have been collected and assuming all other regulated PFAS sampling results are below their MCLs as well, the water system could be deemed reliability and consistently below the MCL by the primacy agency and be eligible to monitor annually at this EPTDS. For all frequencies of ongoing compliance monitoring, including quarterly, annual and triennial, this determination is to be done the same way where all sample results are used, even those below the PQLs.

Several other issues related to monitoring flexibilities were raised in public comments. One commenter asked, if a PWS has a result from an EPTDS for a single regulated PFAS at a concentration above the trigger level, but other regulated PFAS are below trigger levels, must the system initiate quarterly sampling for all regulated PFAS at the EPTDS or are they only required to initiate quarterly sampling for the specific PFAS observed at or above the trigger level. As described in the rule proposal, if any regulated PFAS is detected, which, for the purposes of the PFAS NPDWR the EPA considers results at or above a trigger level as "detections," the system must monitor quarterly at that sampling point for all regulated PFAS. This is appropriate as the same analytical methods are used for the analysis of all regulated PFAS (no extra analyses need to be performed to measure the other PFAS) and the regulated PFAS have been shown to significantly co-occur.

In addition, commenters questioned whether quarterly sampling would be triggered when a result is equal to but does not exceed the trigger level for systems monitoring triennially. One commenter pointed out that the language proposed for inclusion in § 141.905(b)(2) stated that systems monitoring triennially whose sample result is at or exceeds the trigger level must begin quarterly sampling, whereas § 141.902(b)(2)(ii) stated the trigger level must be exceeded before quarterly monitoring is required. The EPA is clarifying this point in the final rule to reflect the

EPA's intent that quarterly sampling would be triggered when a result is at or above the trigger level as prescribed in § 141.905(b)(2). This same approach has been used in other NPDWRs (e.g., for SOC trigger levels).

Individual Public Comments

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045153)

Does § 141.902(a)(8) require quarterly monitoring based on individual detections at or above the trigger level during initial monitoring, or does this evaluation occur once initial monitoring is completed comparing the average of either the two or four samples to the trigger levels? What does it mean to "monitor quarterly…beginning in the next quarter." If a PWS collects its initial monitoring in the first year after final rule promulgation and exceeds the trigger, must they immediately begin quarterly monitoring even though the compliance date is still two years away? If so, this will cause most PWS to delay initial monitoring until the last year prior to the compliance date. MassDEP recommends that EPA clarify that quarterly monitoring must begin on the compliance date of the final rule.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. The EPA agrees that compliance monitoring does not begin until three years after the date of rule promulgation and has deleted the proposed text for § 141.902(a)(8). Thus, a system that performs initial monitoring in the first year after the rule is promulgated and identifies levels of regulated PFAS that exceed trigger levels would not need to begin quarterly compliance monitoring until three years following rule promulgation.

Philadelphia Water Department (PWD) (Doc. #1709, SBC-045751)

15. EPA should clearly define when compliance monitoring would begin under the final rule

PWD supports EPA's decision to allow the use of monitoring data collected before the compliance date of this rulemaking (such as UCMR5) for initial compliance monitoring. However, PWD is requesting that EPA clearly define when compliance monitoring would begin after the compliance date of the final rule. If the final rule compliance date is in the middle of a calendar year, would compliance monitoring begin at the start of the next quarter or at the start of the next year? EPA should provide this clarification so that PWS and primacy agencies can properly plan for the start of compliance monitoring.

EPA Response: As noted under the summary for section 8.1.1, the EPA added specific dates under 40 CFR § 141.900(b)(2), including the date when compliance monitoring will begin, which is three years following rule promulgation rather than at the start of a calendar year or quarter. For discussion of the use of existing data to fulfill initial monitoring requirements, please see section 8.3 of the EPA response in this *Response to Comments* document.

Sammamish Plateau Water and Sewer District (Doc. #1573, SBC-042461)

The proposed rule is particularly unclear in the following areas, and should be revised to provide clarity to water utilities by addressing the following:

• The rule should provide clarity on what initial PFAS detection/limit would result in the need for ongoing monitoring. The rule should clarify whether this based on an exceedance of the proposed MCL or a percentage of the MCL. Additionally, regardless of the percentage of the MCL requiring a response (.3 versus .5 MCL), it would be helpful to provide clarity as to what levels will require the need for treatment.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. Under the final rule, all CWS and NTNCWS are required to conduct compliance monitoring at least every three years and potentially as often as quarterly. This frequency will be determined based on previous sampling results. Systems with RAA results above an MCL will be required to take actions, such as treatment, to reduce levels of regulated PFAS to at or below all MCLs to be in compliance with the rule.

Edward Cullen (Doc. #3075, SBC-047724)

EPA regulations should require providers of public drinking water to measure the levels of PFOA, PFOS, PFHxS, HFPO-DA, PFNA, and PFBS in drinking water, and to report the results to suitable authorities and to the public. Measurements should be made using available methods and sampling procedures approved by the EPA, as describe in the proposed rule (FR 88, 18638 (2023)). Also, for the sake of the health of US citizens and residents, the final EPA rule should require providers of public drinking water to remove PFOA, PFOS, PFHxS, HFPO-DA, PFNA, and PFBS whenever they are found to exceed the relevant Maximum Contaminant Level (MCL) or Hazard Index (HI), so that the drinking water meets the requirements of the rule.

I would like to congratulate and thank all the people at EPA who have worked on this program and put together the proposed rule.

Sincerely,

Edward Cullen

New Jersey

EPA Response: The EPA agrees with this commenter's recommendations, which are in alignment with the final rule. For more on the final rule compliance monitoring requirements, please see section 8.1.2 of the EPA response in this *Response to Comments* document. Additionally, the final rule requires systems to measure levels of the six PFAS the commenter identified using EPA-approved methods. (Analytical methods are discussed in section VII of the preamble to the final rule.) Public water systems are required to comply with NPDWRs, including meeting MCLs. For a discussion of how compliance is assessed and the EPA's

responses to comments on that topic, please see section VIII of the preamble to the final rule and section 8.2 of the EPA response in this *Response to Comments* document. The Public Notice Rule requires public water system to notify persons served when there is a violation or situation with potential to have adverse health effects, and the CCR Rule requires CWSs to provide consumers with information about detected levels of PFAS in their reports. For more information about public notice and CCR requirements, please see section IX of the preamble and section 9.1 of the EPA response in this *Response to Comments* document.

Portland Water Bureau (PWB) (Doc. #1769, SBC-044541)

May 30, 2023

Michael S. Regan, Administrator

U.S. Environmental Protection Agency

Mail Code 2822IT

1200 Pennsylvania Avenue, NW Washington, DC 20460

RE: Comments on EPA Proposed PFAS National Primary Drinking Water Regulation Rulemaking (Docket ID No. EPA-HQ-OW-2022-0114)

Dear Administrator Regan,

The Portland Water Bureau (PWB) in Portland, Oregon appreciates the opportunity to review and provide comments on EPA's proposed PFAS National Primary Drinking Water Regulation and supports EPA's efforts to reduce exposure from PFAS in drinking water. These comments were submitted electronically via regulations.gov.

The PWB is the largest drinking water utility in Oregon, serving nearly one million Oregonians every day. Portland is fortunate to have invested in two high quality water supplies and, to date, has not detected PFAS chemicals in our water supplies. Portland's primary drinking water source is the highly protected Bull Run Watershed, the largest drinking water supply in Oregon. Portland also has a secondary groundwater source, which is used as needed for seasonal supply augmentation and as a backup to the Bull Run surface water supply.

Portland is among many public water systems in the Pacific Northwest that operate seasonal and/or backup water supplies, such as aquifer storage and recovery wells, to balance out the wet winters and dry summers. For supplies/entry points used on an intermittent or seasonal basis, the draft rule is not clear how compliance is determined when quarterly monitoring is required. We would like to request clarification of monitoring and compliance requirements for intermittent use of supplies in the regulation.

EPA Response: Systems that use multiple sources and blend the water at one location before it is routed to a single entry point are to collect samples during time periods representative of standard operating conditions, according to 40 CFR § 141.902(a)(2). Thus, for systems that

use a supplemental source only for part of the year, if multiple samples are required to be collected every year, it would be reasonable for a state to require one or more sample be collected when the supplemental source used seasonally is in operation and others when the supplemental source is not in operation. For the small minority of systems that have entry points that only operate when a supplemental source of water is in operation, seasonally, the state would also work with the system to establish a monitoring schedule that meets the requirements in the regulations as closely as possible. If this source is on quarterly monitoring, compliance would be based on the quarters in which this seasonal entry point is in operation. For example, if the source operates only from March to August, the system would collect three quarterly samples (in Q1, Q2, and Q3), and the RAA calculation will be based on these results; as the source is not in operation from September to February, no samples would be collected in Q4. For additional discussion of initial monitoring requirements, please see section 8.1.1 of the EPA response in this *Response to Comments* document; for additional discussion of compliance monitoring requirements, please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Robert Hollander (Doc. #1516, SBC-042715)

8. 88 FR 18730, Section IX – Monitoring and Compliance Requirements, 3rd bullet

PWSs should be allowed to have each EPTDS on a compliance scheduled based on entry point sampling results, similar to what exists for current contaminant monitoring. This would provide the greatest level of public health protection for customers served by the EPTDS in question.

9. 88 FR 18730, Section IX – Monitoring and Compliance Requirements, 4th bullet

A two pronged approach would be appropriate here, where water systems can apply for monitoring waivers where both sampling results are consistently below trigger levels and vulnerability assessments indicate low risk to future contamination. This should be accompanied by updated vulnerability analyses, where feasible. If there is a potential change in vulnerability in the future (e.g., due to the addition of an industrial activity in the area), the vulnerability analysis should be revisited.

10. 88 FR 18730, Section IX – Monitoring and Compliance Requirements, 6th bullet

Yes, why not? See comment for 88 FR 18682, 2nd column, 1st paragraph, above regarding using previous monitoring results (e.g. UCMR 5 data).

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document for compliance monitoring schedule requirements. For discussion of monitoring waivers, please see section 8.5 of the EPA response in this *Response to Comments* document. For the EPA's response related to using previously-collected monitoring data to satisfy initial monitoring requirements, please see section 8.3 of the EPA response in this *Response to Comments* document.

Robert Hollander (Doc. #1516, SBC-042712)

5. 88 FR 18682, 2nd column, 1st paragraph

Regarding the EPA request for comment on EPTDSs having different compliance schedules based on previous monitoring data, this is already being done for SOCs. It is reasonable and understandable by systems already monitoring for SOCs. The proposed rule articulates individual EPTDSs will have different risks based on location with the system.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Missouri Department of Natural Resources (Doc. #1563, SBC-042528)

Section IX—Monitoring and Compliance Requirements

EPA requests comment on the proposed monitoring flexibility for groundwater systems serving 10,000 or fewer to only collect two samples at each EPTDS to satisfy initial monitoring requirements.

The Department believes that there is no need to modify monitoring from the synthetic organic contaminant (SOC) standard monitoring framework. The fact that PFAS are defined as being a class of man-made chemicals consisting of carbon and fluoride chemical bonds makes them synthetic and organic. There is also no reason to deviate from allowing the flexibility of reliable and consistent (R&C) determinations of results below the MCL for a minimum of two-four quarters for a groundwater system. There is an issue, however, with the language requiring "no less than 90 days" between quarterly samples. The intent for that requirement is to prevent a public water system from collecting a sample during the 1st quarter on March 31 and a second sample in the second quarter on April 1st, and consider those to be 2 "quarterly samples" when they are only separated by 1 day. The second intent is to allow for possible seasonal concentration changes. However, logistically it is nearly impossible for systems, and for states like Missouri that coordinate sampling for systems, to align quarterly monitoring to that level of precision. Having more than 90 days between quarterly sampling is not necessary to provide for seasonal variation. The Department recommends EPA revise this part of the rule to provide greater flexibility for collecting quarterly samples to a more acceptable range, such as no less than 30 days between samples.

EPA requests comment on the proposed allowance of a water system to potentially have each EPTDS on a different compliance monitoring schedule based on specific entry point sampling results (i.e., some EPTDS being sampled quarterly and other EPTDS sampled only once or twice during each three-year compliance period), or if compliance monitoring frequency should be consistent across all of the system's sampling points.

The Department recommends not changing source water sampling requirements, and continuing the practice of allowing groundwater sources within a PWS that also has surface water sources to

treat sampling the sources based on the source water risk. Groundwater sources continue to have less risk than surface water contamination.

EPA Response: Please see section 8.1.1 of the EPA response in this *Response to Comments* document for a discussion of initial monitoring requirements (including the required intervals between samples) and section 8.1.2 of the EPA response in this *Response to Comments* document regarding compliance monitoring requirements, including determinations that a sampling point is "reliably and consistently" below the MCL and differences between monitoring requirements for PFAS versus those for other SOCs. Additionally, in the final regulation, the EPA has specified that the requirements for a surface water system or groundwater system are dependent on the type of source water that is provided at an EPTDS.

Missouri Department of Natural Resources (Doc. #1563, SBC-042530)

EPA requests comment on if all water systems, regardless of system size, be allowed to collect and analyze one sample per three-year compliance period if the system does not detect regulated PFAS in their system at or above the rule trigger level.

The Department supports community and nontransient noncommunity water systems utilizing groundwater, regardless of size, to be allowed to collect a SOC/PFAS sample once every 6 years if results can be shown to be reliably and consistently (R&C) below the MCL, assuming the MCL is set above the PQL with a sufficient spread of limits. Due to the vulnerability of surface water systems to SOC/PFAS, the Department supports annual monitoring of systems with R&C results below the MCL.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. Please see section 5.1.2 of the EPA response in this *Response to Comments* document summary for a discussion of the relationship between MCLs and PQLs.

Oregon Health Authority (OHA) (Doc. #1582, SBC-042763)

• EPA requests comment on the proposed allowance of a water system to potentially have each EPTDS on a different compliance monitoring schedule based on specific entry point sampling results (i.e., some EPTDS being sampled quarterly and other EPTDS sampled only once or twice during each three-year compliance period), or if compliance monitoring frequency should be consistent across all of the system's sampling points.

OHA supports the proposed allowance of a water system to potentially have each EPTDS on a different compliance monitoring schedule based on specific entry point sampling results. This is consistent with current requirements for other regulated contaminants that are monitored at the EPTDS and reflects the fact that EPTDS may be served by sources that reflect different water quality characteristics, for example, groundwater wells in different aquifers or geographically distant from each other.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Michigan Department of Environment, Great Lakes, and Energy (EGLE) Drinking Water and Environmental Health Division (DWEHD) (Doc. #1597, SBC-042985)

However, for reduced compliance monitoring purposes, EGLE DWEHD proposes an approach based on source vulnerability rather than PWS size.

a) EPA proposes flexibility for groundwater supplies not detecting PFAS above the "Trigger Level," with those serving 3,300 or fewer permitted to sample once per three-year period AND those serving more-than 3,300 required to sample twice per three-year period. EGLE DWEHD proposes instead that EPA maintain a consistent requirement for sampling frequency across size categories in groundwater PWS.

b) Similarly, EGLE DWEHD proposes that surface water supplies and those groundwater supplies under direct influence (GUDI) not detecting PFAS above the trigger level also maintain a consistent sampling frequency requirement, although higher than that of groundwater supplies. EGLE DWEHD recommends EPA consider a reduced frequency of no less than annual sampling for these supplies.

By focusing on vulnerability as the determining factor, EGLE DWEHD posits that the proposed rule would be more protective of human health. In the case of surface water and GUDI supplies, unexpected changes in PFAS contamination may result from release events, changes in currents/weather patterns, or other environmental factors.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Lehigh County Authority (LCA) (Doc. #1600, SBC-042818)

Reduced Monitoring

The proposed rule uses trigger levels, set at one-third of the PQL, to determine if a system is eligible for reduced monitoring. EPA has requested comment on whether individual entry points should be allowed to achieve reduced monitoring status. LCA strongly encourages EPA to allow individual entry points to be placed on reduced monitoring. EPA as followed this protocol with other contaminants, and the same should be considered for PFAS.

A key benefit of allowing reduced monitoring by individual entry points is overall cost control. LCA's water systems consist of dozens of entry points. Laboratories in Pennsylvania are charging $800 or more per sample to test for PFAS, which will equate to nearly $100,000 in compliance sampling costs per year for our systems. Allowing for reduced monitoring on an individual entry point basis will ensure LCA's resources and compliance efforts are focused on the water sources that require more careful monitoring.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

American Water Works Company Inc. (Doc. #1608, SBC-044011)

American Water also supports the proposed regulatory approach that monitoring requirements will be determined independently for each entry point in a given water system, including reduced monitoring. This is consistent with implementation of other rules and recognizes the differences between water quality at different treatment plants.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044036)

18. EPA requests comment on the proposed allowance of a water system to potentially have each EPTDS on a different compliance monitoring schedule based on specific entry point sampling results (i.e., some EPTDS being sampled quarterly and other EPTDS sampled only once or twice during each three-year compliance period), or if compliance monitoring frequency should be consistent across all of the system's sampling points.

A. There is no problem with different sampling frequencies at different EPTDS, this already happens frequently. Keep it consistent with the other SDWA requirements.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044039)

20. EPA requests comment on if all water systems, regardless of system size, be allowed to collect and analyze one sample per three-year compliance period if the system does not detect regulated PFAS in their system at or above the rule trigger level.

a. One sample per 3 years with non-detects seems acceptable. However this could make an RAA approach problematic with only one or fewer sampling events in a year. CWUC disagrees with EPA's suggestion of determining compliance with the RAA using the trigger level. That is too complicated and does not afford the utility the opportunity to address and correct the issue, which we interpret to be the purpose of the trigger level. The RAA value should be the MCL (which we propose should be set at 8.0 ppt).

b. Please clarify in the rule, for establishing monitoring period frequencies, if the individual MCLs/His will be treated with individual compliance periods, or will they be lumped together? For instance, if the system meets the trigger level for HI and PFOA, but exceeds it for PFOS, will the system be on reduced monitoring for the prior two and standard monitoring for only PFOS? Or do they move to the same monitoring frequency for all elements as a group?

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. The RAA calculation only applies to systems conducting quarterly monitoring, as is the case with other SOCs, and is only used to evaluate compliance with the MCL (i.e., to judge whether the RAA is at or below the MCL). In light of the public comments about the proposed threshold for a "reliably and consistently" below the MCL determination (to determine compliance-monitoring frequency), the EPA deleted the proposed requirement to compare the RAA to the trigger levels. Instead, the state is to consider whether results from four consecutive quarters are below the MCL to justify a shift from quarterly to annual monitoring. Similarly, the state is to consider whether the results from three consecutive years of annual monitoring are below trigger levels to justify a shift from annual to triennial monitoring. Thus, the RAA is not compared to trigger levels in the final rule. Regarding establishing compliance monitoring schedules, samples will be analyzed for all PFAS on the same schedule, as noted in the final rule. Please see section 8.2 of the EPA response in this *Response to Comments* document for further discussion of determining compliance with the MCLs. This includes a description of how the MCL is the basis for compliance determinations. Values below the PQLs are not utilized in the calculation of RAAs (results below the PQL are treated as zero in that calculation). Please see section 5 of the EPA response in this *Response to Comments* document for further discussion of the final MCLs.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043062)

6. The use of the Standard Monitoring Framework (SMF) for PFAS is appropriate with the use of a trigger level that is one-half of the MCL to determine when PFAS levels are reliably below the MCL.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. For discussion of the trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043100)

Finally, the EPA's proposed approach to require monitoring under the Standard Monitoring Framework and the use of the one-half of the MCL as a trigger level is appropriate.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. For discussion of the trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-044886)

According to [sec] 109.XX(b)(2)(i) Table 2, reduced triennial monitoring for systems serving more than 3,300 persons consists of two samples per EP in a consecutive 12-month period during each three-year compliance period, at least ninety days apart; for systems serving 3,300 or fewer

persons, reduced monitoring consists of just one sample per EP per three-year compliance period. DEP does not agree with this distinction in monitoring frequency based on system population. While this appears to follow the reduced monitoring requirements for SOCs, there does not appear to be sufficient justification for requiring two samples at larger water systems. The differentiation of population is arbitrary.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-044877)

DEP supports compliance determinations that may allow different entry points (EP) at the same water system to be on different monitoring frequencies, based on monitoring results. Additional comments regarding determination of monitoring frequencies are provided later in this letter.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044096)

ASDWA recommends that EPA allows water systems to have different monitoring schedules for different entry points.

ASDWA recommends that EPA not require that all entry points be monitored on the same monitoring frequency. This flexibility in the final rule would allow systems to reduce analytical costs and would align with the current approach for chemical monitoring, especially for systems that have several sources.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044093)

Monitoring Requirements

ASDWA recommends using the standard monitoring framework (SMF) for Synthetic Organic Chemicals (SOCs) to provide consistency and clarification for PFAS monitoring requirements.

Using the SMF for quarterly monitoring and allowing water systems to stagger monitoring would provide clarification and consistency for PFAS monitoring requirements. The specification of the 90-day monitoring requirements, rather than requiring typical quarterly sampling per the SMF, is confusing. This confusion is exacerbated when, for example, the water system is seasonally operated and must retake a sample due to the sample being invalidated (but that was taken in the correct timeframe). This component of the rule needs more details and clarification. This every 90-day requirement was included in the Stage 2 Disinfectants and

Disinfection Byproducts Rule (DBPR), and some primacy agencies noted that their water systems were unable to meet the specific timing requirements. Based on EPA guidance, many primacy agencies allowed the samples to be taken within three calendar months. Some existing state PFAS drinking water regulations specify that the timeframe for compliance monitoring is restarted in the event that a sample is invalidated. In addition, the language in the proposed rule regarding staggered monitoring is vague and, as currently written, may not be evenly staggered. The language, as written, appears to allow water systems to test anytime within the three-year window, and all water systems could wait until the end of the monitoring period to conduct sampling. This timing could further stress laboratory capacity.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document for compliance monitoring requirements and timing. Regarding initial monitoring requirements and the proposed requirement that quarterly samples be collected during initial monitoring at least 90 days apart, please see section 8.1.1 of the EPA response in this *Response to Comments* document. As discussed in section 8.1.2 of the EPA response in this *Response to Comments* document, in the final rule, the EPA followed the model of the SMF for SOCs, but adjusted some aspects of the required compliance monitoring framework specific for PFAS. Pursuant to §141.902(b)(2)(vii) of the regulations, "Each public water system must monitor at the time designated by the State within each monitoring period." States are to make their expectations known to systems with respect to how to address special situations, such as those cited in this comment. For a discussion of laboratory capacity, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044180)

G. Monitoring Requirements

1. NCDEQ recommends using the standard monitoring framework (SMF) for Synthetic Organic Chemicals (SOCs) to provide consistency and clarification for PFAS monitoring requirements.

Using the SMF for quarterly monitoring and allowing water systems to stagger monitoring would provide clarification and consistency for PFAS monitoring requirements. The specification of the 90-day monitoring requirements, rather than requiring typical quarterly sampling per the SMF, is confusing. This confusion is exacerbated when, for example, the water system is seasonally operated and must retake a sample due to the sample being invalidated (but that was taken in the correct timeframe). This component of the rule needs more details and clarification. In addition, the language in the proposed rule regarding staggered monitoring is vague and, as currently written, may not be evenly staggered. The language, as written, appears to allow water systems to test anytime within the three-year window, and all water systems could wait until the end of the monitoring period to conduct sampling. This timing could further stress laboratory capacity, in addition to the other capacity factors previously mentioned.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document for compliance monitoring requirements and timing. Regarding initial

monitoring requirements and the proposed requirement that quarterly samples be collected during initial monitoring at least 90 days apart, please see section 8.1.1 of the EPA response in this *Response to Comments* document. As discussed in section 8.1.2 of the EPA response in this *Response to Comments* document, in the final rule, the EPA followed the model of the SMF for SOCs, but adjusted some aspects of the required compliance monitoring framework specific for PFAS. Pursuant to §141.902(b)(2)(vii) of the regulations, "Each public water system must monitor at the time designated by the State within each monitoring period." For a discussion of laboratory capacity, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Texas Commission on Environmental Quality (TCEQ) (Doc. #1632, SBC-044135)

[To alleviate the initial laboratory capacity issues and reduce public water system sampling costs, TCEQ supports:]

• Allowing each EPTDS's compliance monitoring schedule to be based on specific entry point sampling results as each EPTDS is supplied by a unique source and/or treatment and can have different levels of PFAS.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Citizens Against Ruining the Environment (CARE) (Doc. #1638, SBC-043446)

CARE Comment 2 – U.S. EPA Should Establish Clear and Protective Guidelines for State Implementation of the New MCLs.

Since regulations promulgated under SDWA will be implemented and enforced by State Primary Agencies, careful guidance and narrow guide rails from the EPA should be in place to ensure the proposed PFAS MCLs are enforced as intended. In particular, U.S. EPA should establish strict limits on Primary Agencies' authority to (1) reduce the frequency of PFAS monitoring and (2) grant exemptions for PFAS exceedances should be carefully drafted to minimize the variability in Primary Agency enforcement that might reduce the public health benefits of the proposed MCLs.

Monitoring and Compliance Requirements Must Be Strengthened

MCL values are protective only to the extent that they are supported by robust monitoring and enforcement. To ensure that the proposed MCLs have the intended effect of protecting human health, the proposed monitoring and compliance requirements must be strengthened.

Monitoring and compliance requirements should be designed in consideration of the physical properties of PFAS, including the limitations of current PFAS understanding. The mobility of PFAS chemicals in air, water, and soil is well established. [FN28: Addressing Challenges of PFAS: Protecting Groundwater and Treating Contaminated Sources, EPA (Sept. 20, 2021),

.epa.gov/sciencematters/addressing-challenges-pfas-protecting-groundwater-and-treating-contaminated-sources.] Its transport rate is dependent on numerous variables. [FN29: Goode, D.J., and Senior, L.A., 2020, Groundwater withdrawals and regional flow paths at and near Willow Grove and Warminster, Pennsylvania—Data compilation and preliminary simulations for conditions in 1999, 2010, 2013, 2016, and 2017: U.S. Geological Survey Open-File Report 2019–1137, p. 4.] PFAS have been found in groundwater plumes 24 kilometers from known point sources. [FN30: Drinking Water Health Advisory: Hexafluoropropylene Oxide (HFPO) Dimer Acid (CASRN 13252-13-6) and HFPO Ammonium Salt, Also Known as "GenX Chemicals", U.S. EPA, p. 8 (June 2022).] PFAS can travel long distances through the air before being deposited onto soil and surface waters, then finally migrating into subsurface soil and groundwater. [FN31: Drinking Water Health Advisory: Perfluorooctane Sulfanate (PFOS), U.S. EPA, p. 16 (May 2016).] Taking these factors into account, low quantities of PFAS in a given sample are not predictive of low quantities of PFAS in future samples because new or distant sources of PFAS that do not degrade continue to pose a threat as they migrate through the environment.

Monitoring Frequency Must Be Increased

CARE strongly disagrees with the provision in Proposed Rule Section IX that would allow all systems to analyze only one sample per three year reporting period if the system does not detect any regulated PFAS in their system at or above the trigger level. [FN32: PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. at 18730.] Given the known ability of PFAS to transport throughout environmental media and the variability in transport rates, sampling once every three years is inadequate. PFAS is known to persist for decades after initial release into the environment and to travel at different rates depending on the substrate and other conditions. It migrates from air to soil to water and will contaminate water both near and far from its initial source. These physical properties require ongoing vigilance by PWS to ensure that drinking water is free from PFAS and remains so.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. This NPDWR establishes the minimum requirements for sampling of regulated PFAS by a CWS or NTNCWS. Under SDWA, states cannot implement less stringent requirements and may institute requirements that are more stringent, so the EPA agrees that they would not be able to reduce the frequency of PFAS monitoring below what is required in this regulation. The requirements for a system to receive an exemption for this NPDWR as allowable under SDWA are consistent with requirements to be granted an exemption under other NPDWRs (see Subpart F of 40 CFR Part 141). For a discussion of comments related to exemptions and extensions, please see section 12.1 of the EPA response in this *Response to Comments* document.

Aidan Cecchetti (Doc. #1640, SBC-044369)

• EPA requests comment on the proposed allowance of a water system to potentially have each EPTDS on a different compliance monitoring schedule based on specific entry point sampling

results (i.e., some EPTDS being sampled quarterly and other EPTDS sampled only once or twice during each three-year compliance period), or if compliance monitoring frequency should be consistent across all of the system's sampling points (pg. 18682 Federal Register Volume 88, Number 60).

O The commenters agree with EPA's proposed reduced monitoring approach to allow lower-risk water systems to conduct compliance monitoring on different schedules at each EPTDS. This would be consistent with the implementation of monitoring schedules for other NPDWRs.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Aidan Cecchetti (Doc. #1640, SBC-044371)

• EPA requests comment on if all water systems, regardless of system size, be allowed to collect and analyze one sample per three-year compliance period if the system does not detect regulated PFAS in their system at or above the rule trigger level (pg. 18682 Federal Register Volume 88, Number 60).

O It is the opinion of the commenters that the proposed approach of allowing all water systems to collect one sample per three-year compliance period if the system does not detect regulated PFAS would be appropriate. This would be consistent with the manner in which the primary drinking water standards for other synthetic organic contaminants are applied and provides sufficient health protection for systems at low risk of detecting PFAS.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

National Rural Water Association (NRWA) (Doc. #1641, SBC-043275)

• EPA requests comment on the proposed allowance of a water system to potentially have each EPTDS on a different compliance monitoring schedule based on specific entry point sampling results (i.e., some EPTDS being sampled quarterly and other EPTDS sampled only once or twice during each three-year compliance period), or if compliance monitoring frequency should be consistent across all of the system's sampling points.

Response: If sample results are low – there is no reason to sample frequently and create a greater financial burden on the water systems.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Savannah River Nuclear Solutions LLC (Doc. #1647, SBC-043329)

SRNS SPECIFIC COMMENTS:

Comment 1

Section IX.A. Monitoring and Compliance Requirements (pg. 18682)

EPA is requesting comment on the allowance of a water system to potentially have each entry points to the distribution system (EPTDS) on a different compliance monitoring schedule based on specific entry point sampling results (i.e., some EPTDS being sampled quarterly and other EPTDS sampled only once or twice during each three-year compliance period). SRNS supports the flexibility that such an approach would provide water systems, however, there is a concern that having differing compliance monitoring schedules for different EPTDS might be complicated to implement and potentially lead to missing sampling periods, especially for those EPTDS that are only sampled once or twice during the three-year compliance period. SRNS recommends that compliance monitoring frequency should be consistent across all of the systems sampling points.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044182)

3. NCDEQ recommends that EPA allow water systems to have different monitoring schedules for different entry points.

NCDEQ recommends that EPA does not require that all entry points be monitored on the same monitoring frequency. This allows systems to reduce analytical costs and would align with the current approach for chemical monitoring, especially at systems that have several sources.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Nebraska Department of Environment and Energy (NDEE) (Doc. #1653, SBC-043201)

EPTDS should be on its own monitoring schedule based on prior monitoring results.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044398)

DOH supports the ability of public water systems with sources reliably and consistently (R&C) below PFOA and PFOS trigger levels to qualify for reduced monitoring.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044419)

EPA requests comment on monitoring-related flexibilities that should be considered to further reduce burden while also maintaining public health protection including a rule trigger level at different values than the currently proposed values of 1.3 ppt for PFOA and PFOS and 0.33 for the HI PFAS (PFHxS, HFPO–DA, PFNA, and PFBS), specifically alternative values of 2.0 ppt for PFOA and PFOS and 0.50 for the HI PFAS. EPA also requests comments on other monitoring flexibilities identified by commenters.

• A trigger for PFOA and PFOS of 2 ppt would place less burden on labs and PWSs while still allowing for public health protection. Since all results below the PQL for the HI PFAS are calculated as zero, it might make sense to use 0.5 as the trigger. Increasing these triggers would allow for some reduction in monitoring for sources that don't exceed the slightly higher trigger but are below the MCL. To ensure public health protection, EPA could also assign two years of annual monitoring or an R&C annual for sources with detections consistently below the MCL instead of having them remain on quarterly.

EPA requests comment on the proposed allowance of a water system to potentially have each EPTDS on a different compliance monitoring schedule based on specific entry point sampling results (i.e., some EPTDS being sampled quarterly and other EPTDS sampled only once or twice during each three-year compliance period), or if compliance monitoring frequency should be consistent across all the system's sampling points.

• While PFAS contaminant plumes can be extensive, they likely follow groundwater flow directions in such a way that timing monitoring in sources in distinctly different areas would be more burdensome than helpful. This is especially true for water systems where sources are spread across a wide area. For those systems which have been collecting quarterly samples there have not been significant differences in the concentrations temporally. Impacts were identified to surrounding/downgradient source concentrations when a large producing source was taken offline due to high PFAS detections while the PWS installed treatment. Systems assigned quarterly monitoring will likely collect samples at sources in a similar area at the same time to save on labor and shipping costs. DOH have also had multiple issues with lab analysis, which has required repeat samples be taken from sources; this could negate any timing attempts. This level of timing would only serve to make the rule more complex. Please ensure states continue to have the authority to increase monitoring as needed.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. The EPA agrees that a "reliably and consistently below the MCL" determination would appropriately allow a system to qualify for annual monitoring and has made that change in the final rule, along with stating that this determination would be based on a direct comparison to the MCL. Additionally, the rule provides that states may impose more stringent requirements. Regarding rule trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document.

City of Allentown and Lehigh County Authority (LCA), Pennsylvania (Doc. #1667, SBC-043679)

Reduced Monitoring: The proposed rule uses trigger levels, set at one-third of the PQL, to determine if a system is eligible for reduced monitoring. EPA has requested comment on whether individual entry points should be allowed to achieve reduced monitoring status. The City strongly encourages EPA to allow individual entry points to be placed on reduced monitoring. EPA has followed this protocol with other contaminants, and the same should be considered for PFAS.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Aurora Water, City of Aurora, Colorado (Doc. #1669, SBC-043713)

Additionally, Aurora Water agrees with the allowance for separate monitoring schedules based on sampling results at separate entry point locations. Aurora has several entry points into its distribution system that have varying sources of water. As a result, there are varying PFAS results at each entry point. Aurora has separate monitoring schedules for other contaminants based on entry point such as VOC, SOC, and nitrates. It is best if EPA stays consistent with other rules that are in effect by allowing different entry points to be on separate monitoring schedules and it will reduce costs while allowing the system to focus on the sample sites that are most concerning.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-044913)

Section 5: Monitoring and Compliance Requirements

Section 5.1: Monitoring

EPA has requested comment on several pieces related to monitoring requirements. The agency has proposed a monitoring regime based on the Standard Monitoring Framework (SMF) for Synthetic Organic Contaminants (SOC). Cleveland Water is supportive of using this framework to ensure uniformity among rules covering similar compounds. We also strongly support maximum flexibilities in monitoring that will reduce burdens on PWSs and still be protective of public health, as EPA has done with other chemicals with chronic health risks.

Cleveland Water is pleased EPA has considered situations in which reduced monitoring is appropriate. However, the agency is proposing a trigger level well below the Practical Quantification Level (PQL) for PFOA and PFOS. Under this proposal, a PWS qualifies for reduce monitoring if its RAA is below the trigger level of 1.3 ppt for PFOA and PFOS and a 0.33 HI for the additional PFAS. This allows water systems to sample once or twice in a three-

year period, depending on system size. Because the health effects of PFAS are chronic, we recommend EPA make this reduced monitoring uniform and require all systems, regardless of size, to sample once in the three-year period under this reduced monitoring framework. This would allow for further reduction in burdens on utilities while also not compromising public health.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. Regarding rule trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document.

New York State Department of Health (NYS DOH) (Doc. #1677, SBC-044946)

8. Although the Department recognizes the reasoning behind Entry Point to Distribution System (EPDS) monitoring for organic chemicals, the fate and transport of PFAS compounds, occurrence, and the low MCL makes this approach less conservative, and therefore less protective of public health.

Concentrations of PFAS compounds can vary significantly within a single well field within the same aquifer, and traditional methods of EPDS monitoring may not be appropriate. With a proposed MCL at 4 ppt, there are many instances where a single well that can be operated independently may exceed the MCL, while other wells within the aquifer remain below the standard. Although regulations specify typical operation, a public water system that has source water data can collect samples at EPDS during times when the lower concentration wells are in service to remain in compliance with the proposed standard. The complexity of many water systems makes it challenging for primacy agencies to be able to fully capture what happens during typical operation.

The Department currently requires monitoring at each source, however, we recognize that there may be opportunities to lower costs, particularly at small water systems, while concurrently obtaining a more robust dataset than we believe can be accomplished by entry point monitoring alone. The Department suggests EPA require 4 consecutive quarters of monitoring at each source if a public water system has an EPDS result greater than the trigger level for any PFAS compound during initial monitoring. Using an EPDS to determine compliance should be at the discretion of the primacy agency based on operational conditions of the water system that include but are not limited to number of sources, the presence of treatment to remove PFAS, number of EPDS, and the presence of source water monitoring data.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. The EPA agrees that there would be a considerably higher cost to systems if they were to sample at each drinking water source. Samples at those locations would not necessarily be representative of concentrations to which consumers are exposed. The NPDWRs focus on finished drinking water, and, for many NPDWRs on sampling at each EPTDSs, because it is the water that consumers drink and use for other domestic purposes.

New York City Department of Environmental Protection (NYCDEP) (Doc. #1679, SBC-044214)

In section IX. A., p. 18682, EPA requests comment on having different monitoring schedules for entry point based on trigger level status. PWSs already adapt to complicated monitoring schedules. Having different monitoring schedules is an added burden for sample scheduling that should be able to be adapted to. However, each testing event results in obtaining data for all PFAS in the method, regardless of schedule. P. 18682 states that the system must average all samples taken in the quarter. These samples will be taken on schedule, the analysis will be conducted by approved method, and results will be available for all PFAS included in the method. There is likely to be PFAS data collected outside of the intended monitoring schedule. How are the extra data to be handled? Is the supplier expected to request that the laboratory not report some PFAS data because they are not yet scheduled for monitoring? Will labs be in the position of knowing of an MCL issue and not reporting the level to the water supplier? Monitoring reductions do not actually save effort or reduce complications unless all PFAS chemicals follow the same schedule.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. The EPA has updated the language regarding the requirement to average multiple samples collected during a quarter (or other monitoring period) to indicate that the only samples to be included in the quarterly averages are compliance samples a system is directed to take by a state. See, for example, § 141.902(b)(2)(v), § 141.903(e), §§ 141.903(f)(1) and 141.903(f)(2), and Table 2 in § 141.904(b). Typically, these compliance samples would be limited to the sample for the monitoring period and any confirmation samples required by the state. Apart from these compliance samples, any other samples collected during a single monitoring period are not to be included in a quarterly, annual, or triennial average. Any extra samples collected voluntarily by a system are not required to be reported to the EPA or the state (unless the state provides otherwise). If the state requires reporting of results from voluntary sampling, those results should be managed separately such that only the results from compliance monitoring are included in RAA calculations.

City of Vancouver Water Utility, Vancouver, WA (Doc. #1684, SBC-044313)

Compliance Monitoring Frequency:

Vancouver agrees that each source should be allowed to have an independent compliance monitoring schedule and that it is not necessary to have compliance monitoring consistent across all system's sampling points.

Although Vancouver agrees that a PFAS MCL exceedance should be a Tier 2 violation given past practice for other bioaccumilating contaminants, the proposed limits will cause laboratories to become overburdened with sampling, which will lead to further delays and costs increases in what are already very expensive samples. Quarterly sampling is excessive given that the majority of utilities with PFAS issues do not see significant changes in levels within a 3-month period. This is especially true for water systems where sources are spread across a wide area. For those

systems which have been collecting quarterly samples there have not been significant differences in the concentrations temporally. Sampling twice a year is adequate.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. Please see section 9.2 of the EPA response in this *Response to Comments* document for a discussion of public notice requirements. Please see section 5.1.2 of the EPA response in this *Response to Comments* document for a discussion of laboratory availability.

New Hampshire Department of Environmental Services (NHDES) (Doc. #1690, SBC-044350)

d. Page 18730, Column 3, Bullet 2 - EPA requests comment on if all water systems, regardless of system size, be allowed to collect and analyze one sample per three-year compliance period if the system does not detect regulated PFAS in their system at or above the rule trigger level.

NHDES Comment - NH agrees that all water systems, regardless of system size, should be allowed to collect one sample per three-year compliance period if the system does not detect regulated PFAS in their system at or above the rule trigger level. Tracking and implementing a "2 samples in three years" schedule would be cumbersome with our current non-SDWIS database and would cause confusion for our water systems that are accustomed to monitoring frequencies of either triennial, annual, or quarterly. Frequencies based on sample results alone still maintains protection of public health for all consumers of public drinking water. [Rule Reference: 141.902 (b)(2)(i) – Page 18751, Column 3]

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045032)

NJDEP agrees with EPA's proposal to determine compliance at each EPTDS. NJDEP utilized this approach successfully in the implementation of New Jersey's MCLs for PFOA, PFOS and PFNA. Furthermore, NJDEP does not foresee issues implementing different compliance monitoring schedules at different EPTDS within the same system, as this is currently allowed under other existing rules.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045028)

Implementation

Monitoring and Compliance Requirements

EPA has proposed using the Standard Monitoring Framework (SMF) for Synthetic Organic Contaminants (SOCs) for PFAS. NJDEP recommends EPA develop a new monitoring

framework specifically for PFAS that utilizes a modified VOC framework that does not allow for reduction to triennial or use of monitoring waivers. The SOC framework as proposed allows for systems to be reduced to triennial monitoring after completion of their initial round of quarterly monitoring, includes a modification of the SOC SMF groundwater systems, and includes the option of monitoring waivers. Based on NJDEP's experience this framework may not be appropriate for PFAS.

For its MCLs, NJDEP had opted to utilize the VOC framework, which does not allow for immediate reduction to triennial but requires systems to collect three years of annual "non-detect" results to then be reduced to triennial. Based on NJDEP's experience, PWSs can detect PFAS, and in some cases exceed the New Jersey PFAS MCLs, following quarters of receiving non-detect or very low results. In New Jersey, 42 water systems have received MCL violations during the second or third year of data collection. Allowing a reduction first to annual monitoring as utilized in the VOC framework will provide a reduction for the systems but also give an added layer of protection to avert unintended PFAS exposure to impacted residents. While the reduction to triennial may be more economical to some systems, for most it will result in only one less sample event (two in one year every three years vs. one annually for three years).

Furthermore, NJDEP recommends that EPA consider removing the option to reduce systems to triennial monitoring. Based on NJDEP's experience, some water systems have detected PFAS, and in some cases have exceeded the New Jersey PFAS MCLs, following quarters of receiving non-detect results. Requiring water systems to continuously collect annual samples will provide assurance that public health protection is being met, particularly with the evolving nature of the science and analytical capabilities surrounding these contaminants. At the proposed levels, small variations in the dataset may result in an exceedance of the MCL and therefore, it is important to continue monitoring.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. The EPA notes that the allowance of monitoring waivers were not included in the proposed rule nor are they allowable under the final rule. Please see also section 8.5 of the EPA response in this *Response to Comments* document.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-047696)

5) 3-year sampling if initial monitoring was non-detect?

Vermont has at least two rounds of PFAS sampling at all PCWS and NTNC water systems, meaning systems have established a PFAS sampling history. Vermont is supportive of a system being placed into 3-year monitoring if the initial or state accepted existing sampling results are non-detect as discussed below. Given the importance of PFAS regulation, EPA should establish a health protective and unique monitoring framework for PFAS.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045104)

2) Monitoring-related flexibilities to reduce burden while protecting public health.

As discussed previously in these comments, there needs to be another sampling frequency in between quarterly or every 3-years and therefore graduated "tiers" of attention. It will place a considerable burden on the system and state staff to adhere to the draft provisions. There has been no discussion of the added workload, in fact the preamble incorrectly assumes that the states can accommodate this workload without an increase in hours or staffing. Our experience implementing our regulation in 2019 required 3 staff full-time for a year to train, set up SDWIS, work with labs, review data and get the program implemented. In a small state with a limited staff, this meant the majority of the compliance-related staff otherwise tasked with other responsibilities.

As it is written in the draft regulation, the sampling framework is too specific. The sampling frequency states "at least 90 days apart" when samples are to be collected under initial monitoring. Systems will not understand this very specific requirement, as they are only accustomed to sampling on a quarterly frequency, meaning anytime in a 3-month window. This same "flexibility" must be applied, otherwise systems and states would need to manage down to the specific DAY that the samples are required for subsequent samples. It is not likely that this was EPA's intent, so that must be remedied. Perhaps state that the samples must be collected in each respective calendar quarter, no less than 30 days between samples, that allows freedom to sample within the calendar quarter and will prevent someone sampling on the last day of quarter 1 and the first day of quarter 2, if that sampling behavior was sought to be eliminated by the "at least 90 days apart". Alternatively, perhaps the information should instead state "at most 90 days apart" which would then fall into more conventional quarterly monitoring.

3) EPTDS on its own schedule

Each respective entry point to the distribution should have its own schedule, it should not be regulated system wide. In Vermont we have small systems and there still may be multiple entry points many miles apart from one another. It does not make sense from a source contamination or source protection approach to "lump" all of the entry points in with one another. In Vermont our data indicate that PFAS exposure is quite localized, so systems with multiple wells in the same basic vicinity of one another may have one well with PFAS and one without. To say that 8 miles away a different entry point needs to sample more frequently does not make sense and will place a considerable undue burden on the water system.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. Please see section 8.1.1 of the EPA response in this *Response to*

Comments document for a discussion of initial monitoring requirements, including the revised requirements for the intervals between samples. Please see section 13.3 of the EPA response in this *Response to Comments* document related to estimating costs, including primacy agency costs, which are discussed in the section 13.3.1 summary.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045093)

The proposed sampling framework as established is confusing and burdensome on both water system and state resources. The routine sampling framework needs a step between quarterly and 3-year sampling, Vermont would support an annual sampling requirement for those systems with triggers/detections but below 4 ppt. In a situation where a system under 3,300 in population has consistent results of around 3.0 ppt for PFOA (a level to down to which Vermont receives data and have received data for nearly 4 years), the system would exceed the trigger of 1.3 ppt and be placed on quarterly monitoring. Then, after 4 quarters, the RAA would be 0 based on the calculation of (0 + 0 + 0 + 0)/4 = 0 since the results are below the PQL. So, the system could then transition to 3-year monitoring. There is no guidance or statement about how soon after the last quarterly sample was taken the next 3-year sample must be collected (for example, the Lead and Copper Rule sets the timeline by which the next sample must be collected when the sampling frequency changes). So, because of this, the logical thing to do would be to put the system on 3-year monitoring either immediately or sampling the next calendar year from the last quarterly sample. Alternatively, it could be a year from the last sample, but change would be made knowing what would happen next: the system will then have a result around 3.0 ppt and would be bumped back to quarterly monitoring for at least 4 quarters at which point this cycle would continue. We have approximately 30 systems that would be "stuck" in the unending loop, creating frustration, irregular sampling frequencies, and considerable manual oversight by the state. It would lead to non-compliance and missed samples. For watching results under 4, we would suggest doing so via annual monitoring to avoid confusion of the quarterly-to-3-year monitoring and/or longer timelines between samples when on 3-year monitoring.

b. Separation of Monitoring Schedules:

The water quality data in Vermont does not support the breaking out of separate monitoring schedules between surface water and groundwater or system size. There is no justification provided in the preamble as to why systems over 3,300 and surface water systems are treated the way they are with respect to PFAS vulnerability. The desire to slot PFAS into an existing framework makes sense on its face, but not in reality/practice. It would be perfectly understandable to create a PFAS-specific sampling framework outside of that of SOCs. PFAS are regulated to lower standards and have different responses than traditional SOCs, why would they be sampled under the same framework? Additionally, SOCs are easier to identify the source and have a solid regulatory framework and history under TSCA. This difference has not been taken into account and the clear differences between SOCs and PFAS are not considered. Under EPA method 537.1 - in Vermont, out of the approximately 615 systems having collected

samples, we have had detections of any of the 18 compounds reported at 107 systems. Six of those systems are surface water sources, the rest are groundwater. And of those six surface water systems, we have a total of 8 detections, with only one for PFOA and two for PFBS (the rest are for non-regulated compounds).

c. Water System Size and PFAS detections:

There also does not appear to be correlation between water system size and PFAS prevalence, in fact quite the opposite, where small schools and locations may have impacts from on-site septic or land use outside of the area of control, where many larger systems have better land use and source protection area regulations surrounding their sources.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. The EPA agrees that PFAS should not only follow the SMF for SOCs as this provides a consistent sampling approach, but also incorporate some PFAS-specific modifications as discussed in sections 8.1.1 and 8.1.2 of the EPA response in this *Response to Comments* document. With respect to the start date for the next sampling period when a system reduces its monitoring frequency, the EPA agrees this merits clarification and has specified in § 141.902(b)(2)(viii) that the next compliance sample must be collected in the monitoring period that begins the calendar year following state approval of a reduction in monitoring frequency. Regarding initial monitoring requirements and the differences in systems served by different source water types, please see section 8.1.1 of the EPA response in this *Response to Comments* document. For the determination of reduced monitoring and rule trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document. The EPA clarifies that monitoring frequency determinations are not based on an RAA and sample results below the PQLs are considered. Hence, water systems should not be "stuck in an unending loop" as suggested by the commenter.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045156)

The requirement in § 141.902(b)(1)(iv) to collect quarterly samples "at least ninety days apart" introduces an unnecessary complexity. If the intent is to space consecutive samples apart this can be done in several ways such as reducing this period to at least 30 or 60 days or by requiring all samples be collected in the middle month of the quarter. These options allow for flexibility within the quarter without potentially causing a monitoring violation if, for example, samples were collected a reasonable 80 days apart in separate quarters.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. Regarding initial monitoring requirements, including the revised requirements related to the intervals between samples, please see section 8.1.1 of the EPA response in this *Response to Comments* document.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045167)

MassDEP recommends that EPA allows water systems to have different monitoring schedules for different entry points.

MassDEP recommends that EPA does not require that all entry points be monitored on the same monitoring frequency. This allows systems to reduce analytical costs. This would align with the current approach for chemical monitoring, especially at systems that have several sources.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045964)

Section 5: Monitoring and Compliance Requirements

Section 5.1: Monitoring

EPA has requested comments on several pieces related to monitoring requirements. The agency has proposed a monitoring regime based on the Standard Monitoring Framework (SMF) for Synthetic Organic Contaminants (SOC). AMWA has been and still is supportive of using this framework to ensure uniformity among rules covering similar compounds (Attachment 5). AMWA also strongly supports maximum flexibilities in monitoring that will reduce burdens on PWSs and still be protective of public health, as EPA has done with other chemicals with chronic health risks.

AMWA is pleased EPA has considered situations in which reduced monitoring is appropriate. However, the agency is proposing a trigger level well below the Practical Quantification Level (PQL) for PFOA and PFOS. Under this proposal, a PWS qualifies for reduce monitoring if its RAA is below the trigger level of 1.3 ppt for PFOA and PFOS and a 0.33 HI for the additional PFAS. This allows water systems to sample once or twice in a three-year period, depending on system size. Because the health effects of PFAS are chronic, AMWA recommends EPA make this reduced monitoring uniform and require all systems, regardless of size, to sample once in the three-year period under this reduced monitoring framework. This would allow for further reduction in burdens on utilities while also not compromising public health.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. Please see section 8.8 of the EPA response in this *Response to Comments* document regarding rule trigger levels.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045967)

Section 5.2: Individual entry point compliance monitoring

EPA seeks comment on allowing water systems to potentially have entry points to the distribution system (EPTDS) on different monitoring schedules. This would allow a system with

multiple entry points to potentially be required to monitor quarterly at one entry point and qualify for reduced monitoring at another. AMWA agrees with this decision and believes that this reduction in sampling will save valuable resources for PWSs with more than one entry point that may have different RAAs for the proposed PFAS. It is important to note that it is also not mandatory that a water system participates in reduced monitoring if it qualifies, so a system does have the option to keep all its EPTDS on the same sampling schedule.

If EPA were to mandate a uniform monitoring schedule for all EPTDS, it would result in significantly more samples that utilities must collect, analyze, and report. However, this uniformity would not enhance public health protection if a particular entry point qualifies for reduced monitoring. The potential consequences of such a requirement, including increased costs and strain on laboratory capacity, lend substantial support to EPA's proposition of allowing different monitoring schedules based on individual EPTDS circumstances.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Washington County Department of Public Health and Environment (Doc. #1739, SBC-043572)

Frequency of Reduced Monitoring

Per Part XIV, Section IX of the rule proposal: "EPA requests comment on if all water systems, regardless of system size, be allowed to collect and analyze one sample per three-year compliance period if the system does not detect regulated PFAS in their system at or above the rule trigger level."

Comments:

The county, in line with MDH, supports allowing one sample per 3-year compliance period for all systems on reduced monitoring rather than requiring 2 samples per 3-year period for systems with >3,300 population. - Transient detections and significant seasonal variability are not typically observed with PFAS contamination based on our state's experience with past monitoring since PFAS is stable in the environment. Therefore, one sample is sufficient to determine if contamination is present.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

LSP Association (LSPA) (Doc. #1742, SBC-043601)

There is a significant difference between sampling every quarter and sampling once or twice every three years. The LSPA recommends that USEPA consider a more tiered approach to monitoring.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045224)

3. EPA is requesting comment on the allowance of a water system to potentially have each Entry Point to the Distribution System (EPTDS) on a different compliance monitoring schedule based on specific entry point sampling results.

CT DPH agrees with attempting to lower the sampling burden for low-risk PWS, and having EPTDS on different monitoring schedule is one possible way to do so. If a system cannot handle the administrative task of tracking compliance, the PWS could choose to increase sampling of all points to be on the same schedule.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

West Virginia Rivers Coalition et al. (Doc. #1746, SBC-045251)

Strengthen the reduced monitoring requirements to enhance public health protections.

We recommend EPA strengthen the compliance monitoring requirements in the proposed rule by limiting the reduced monitoring frequency to once every year for all PWSs. As proposed, PWSs eligible for reduced monitoring would conduct compliance monitoring only 1-2 times per three-year compliance period. Systems that serve 3,300 or fewer customers would only be required to analyze one sample for all regulated PFAS every three years. Due to the ubiquity, environmental persistence, and transport abilities of PFAS, infrequent monitoring may mask dangerous PFAS concentrations in drinking water and potential violations of MCLs. For example, in West Virginia, there are 325 small community water systems. Under the proposed rule, the 361,883 customers served by these water systems could potentially consume drinking water that may exceed of one of more PFAS MCLs for years before detected and treatment required. We urge EPA to modify its proposal such that all PWSs eligible for reduced monitoring be required to monitor annually. This would help ensure compliance with the proposed MCLs and maximize the potential health benefits of the rule.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Las Cruces Utilities (LCU) (Doc. #1753, SBC-043908)

In response to Section IX-Monitoring and Compliance Requirements, EPA requests comment on the proposed allowance of a water system to potentially have each [entry point to the distribution system] EPTDS on a different compliance monitoring schedule based on specific entry point sampling results (i.e., some EPTDS being sampled quarterly and other EPTDS sampled only once or twice during each three- year compliance period), or if compliance monitoring frequency should be consistent across all of the system's sampling points.

• Different compliance schedules would be preferred over defaulting to the stricter frequency across the entire PWS.

Consider if all 36 LCU wells are categorized as individual EPTDSs. PFAS samples at Hall can cost up to $500 each depending on the list of analytes requested. If LCU needs to sample all the wells quarterly due to one well exceeding the rule trigger level, the additional PFAS sample costs to LCU could be up to $72,000 each year. Other labor costs are incurred for collecting the samples, for review of results, and reporting. Allowing for different compliance schedules will allow for necessary sampling at areas that have exceedance without inducing excessive costs.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Las Cruces Utilities (LCU) (Doc. #1753, SBC-043910)

In response to Section IX-Monitoring and Compliance Requirements, EPA requests comment on if all water systems, regardless of system size, be allowed to collect and analyze one sample per three-year compliance period if the system does not detect regulated PFAS in their system at or above the rule trigger level.

• One sample per EPTDS per three-year compliance period is preferred, regardless of system size.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045565)

5. The use of the Standard Monitoring Framework (SMF) for PFAS is appropriate where a running annual average (RAA) below one-half of the MCL is considered to be reliably below the MCL. However, the agency's proposed approach to require reporting results below the practical quantification level (PQL) to calculate the RAA for reduced monitoring is inappropriate and will cause equity issues with respect to access to high quality laboratories. This will lead systems with less financial capacity to have more stringent monitoring requirements. EPA should move forward with the SMF, where all results below the PQL are considered 0 ppt.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. Additionally, regarding rule trigger levels for reduced triennial monitoring, please see section 8.8 of the EPA response in this *Response to Comments* document. Please see section 5.1.2 of the EPA response in this *Response to Comments* document for a discussion of laboratory capability and capacity.

California State Water Resources Control Board (Doc. #1760, SBC-044224)

[The State Water Board offers the following specific comments and recommendations for consideration regarding implementation of the rule:]

Recommend using the standard monitoring framework of quarterly monitoring utilized for synthetic organic chemicals rather than a specific 90-days between monitoring. Allowing public water systems flexibility to monitor within a quarter rather than a very specific schedule will ease implementation costs for water systems and yield data that is just as accurate. This will also allow for water systems to schedule with labs and help address lab capacity issues.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. Regarding initial monitoring requirements, including the revised requirements for the intervals required between samples, please see section 8.1.1 of the EPA response in this *Response to Comments* document. For laboratory availability, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Western Urban Water Coalition (WUWC) (Doc. #1768, SBC-043954)

D. Monitoring Schedule Flexibility is Appropriate

WUWC also supports allowing water systems the flexibility to place entry points to the distribution system on divergent compliance monitoring schedules based on specific entry point sampling results rather than mandating that compliance monitoring frequency proceed on the same schedule for all sampling points. [FN44: Id.] In WUWC members' experience, individual monitoring schedules are preferable to large urban water utilities from a cost and administrability perspective. Large water utilities are likely to have to monitor compliance at several points of compliance at once. Forcing uniform monitoring schedules would deprive WUWC members of the ability to adjust to site-specific considerations and result in redundant labor expense compared to a more adjustable schedule. WUWC reiterates its general comment that partially mitigating administrative burdens resulting from the Proposed Rule is insufficient to demonstrate economic feasibility.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Environmental Protection Network (EPN) (Doc. #1773, SBC-043868)

Monitoring Requirements

EPN agrees that the PFAS monitoring scheme should be based on the existing standard monitoring framework established for Synthetic Organic Compounds and other chemical regulations, which tailors the monitoring frequency to previous monitoring results. This reduces monitoring cost if the likely result is already known. The danger is that PWS may not monitor because they believe incorrectly that their monitoring has been waived. It is critical that the

primacy state communicates the required monitoring frequency to each PWS large and small and reports a monitoring/reporting violation to EPA and the public. If states fail to do this, there is a high likelihood of severe underreporting of monitoring violations.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. The EPA agrees that compliance monitoring frequency should be based on prior sampling results. Additionally, the EPA agrees that primacy agency and PWS communication on required monitoring frequency is critical to ensuring effective implementation and defers to the primacy agency to address this communication. The EPA clarifies for the commenter that the final rule includes monitoring and reporting violations per 141.905(c).

San Diego County Water Authority, CA (Doc. #1779, SBC-045291)

Entry Point to the Distribution System

The Water Authority supports EPA's allowance for water system to have different compliance monitoring schedules for entry points to the distribution system based on entry point sampling results. This approach is reasonable and would potentially provide resource savings for water systems without impacting public health.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

San Diego County Water Authority, CA (Doc. #1779, SBC-045289)

We request EPA also allow for reduced monitoring based on four quarters of sampling when results are lower than the detection limits.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. The EPA has adopted the use of trigger levels in this NPDWR. These are analogous to the "detection limits" that determine a system's monitoring frequency for some other regulated SOCs.

City of Tulsa Water and Sewer Department (CoT WSD) (Doc. #1785, SBC-043782)

4. 88 FR 18682 (also 88 FR 18730). EPA requests comment on water systems potentially having each EPTDS on different monitoring schedules based on specific entry point sampling results, or if compliance monitoring should be consistent across all the system's sampling points.

CoT WSD responds that it is our opinion that compliance monitoring should be consistent across all the system's sampling points. This will avoid the possibility that the system could actually have all sampling points on quarterly monitoring (past the initial monitoring timeframe) at different times within the year. This would cause confusion and continual sampling, pulling system field resources away from other required duties and monitoring for other NPDWR. In addition, proposed rule language at §141.903(a) (88 FR 18752) states, "If one sampling point is

in violation of an MCL, the system is in violation of the MCL (emphasis added)." All EPTDS sampling points represent the system, and one sampling point in violation of MCL causes the system to be in violation; therefore, monitoring frequency should apply to the system as a whole, which would include all sampling points on one monitoring schedule.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046119)

The SDWA requires NPDWRs to include monitoring requirements that will "[e]nsure compliance" with the relevant MCLs. [FN201: 42 U.S.C. § 300f(1)(D).] EPA's proposal does not satisfy this requirement insofar as it gives primacy agencies discretion to reduce required compliance monitoring to just 1–2 monitoring events per three-year compliance period if a system's initial year of monitoring documents PFAS concentrations below the proposed trigger level. [FN202: See Proposed Rule, 88 Fed. Reg. at 18,681; Economic Analysis at 5-32.] Indeed, EPA's proposal does not attempt to demonstrate that this reduced monitoring scheme would be adequate to "insure" compliance with the MCLs, [FN203: 42 U.S.C. § 300f(1)(D).] claiming instead that its proposal would "save resources" for purportedly "lower-risk water systems." [FN204: Proposed Rule, 88 Fed. Reg. at 18,682.] As explained below, existing PFAS monitoring data, as well as literature on PFAS toxicity and fluctuations in drinking water sources, indicate that EPA's proposal must be strengthened to ensure compliance with the MCLs.

Available data from PWSs that have tested for PFAS on a quarterly or more frequent basis demonstrate significant variation in PFAS detections and measured concentrations, which indicates that consistent monitoring is needed to ensure that PFAS levels remain below the MCLs. [FN205: See, e.g., Merrimack Vill. Dist. Water Works, Historical Charts for PFAS Water Sampling Test Resultwww.mvdwater.org/historical-water-sampling-charts/, and PFAS Results, Distribution Syswww.mvdwater.org/wp-content/uploads/2023/03/PFAS-Distribution- System-02-15-2023.pdf (distribution system notes); City of Ann Arbor, Mich., Drinking Water Sampling Datwww.a2gov.org/departments/water-treatment/Documents/PFAS-forweb- RESERVIOR-031523.pdf (updated Mar. 15, 2023); Orange Water and Sewer Auth., Trends in PFAS Detections in Finished Drinking Water (Quarterly Sample Results), Detections in Drinking Watewww.owasa.org/pfas-monitoring-program/ (scroll down to the "Complete Set of Historical PFAS Monitoring Data" and select "Raw Data." Review table on upper left corner titled "Finished Drinking Water").] For example, the Merrimack Village Water District reported non-detect results for PFOS at the Turkey Hill Road location within its drinking water distribution system during four sampling events between December 2, 2021, and July 27, 2022, then detected 15.20 ppt of PFOS during a subsequent sampling event on October 19, 2022, followed by another non-detect result on January 25, 2023. [FN206: Merrimack Vill. Water Dist. Water Works, PFAS Results, Distribution Sys., at 8.] Monitoring data from industrial PFAS dischargers likewise demonstrates the potential for significant intra-annual variation in PFAS discharges to drinking water sources, which will in turn impact the levels of PFAS in finished drinking water

from systems that have not installed PFAS treatment technology. [FN207: See, e.g., Colo. Dep't of Public Health & Env't, Suncor Water Quality Permits, Surface Water Suncor PFAS Data (Outfall 20phe.colorado.gov/suncor-water-quality-permits (updated Apr. 2023) (scroll down to the section titled "Resources and Pollution Data" and select "Toxic firefighting foam chemicals (PFAS)" from the drop drown menu. Select and view "Surface water Suncor PFAS data (Outfall 20)").] Peer-reviewed literature also documents significant intra-annual variation in PFAS concentrations in both source water and finished drinking water due to factors including variable flow rates, variation in industrial processes/production cycles, variable stormwater runoff from contaminated sites, mobilization of legacy PFAS contamination in sediment or groundwater, and the potential introduction of new sources of PFAS contamination. [FN208: See Minh A. Nguyen et al. Seasonal Trends of Per- and Polyfluouroalkyl Substances in River Water Affected by Fire Training Sites and Wastewater Treatment Plants, 308 Chemosphere Art. No. 136467 (2022doi.org/10.1016/j.chemosphere.2022.136467; M.-A. Pétré et al., Per- and Polyfluoroalkyl Substances (PFAS) in River Discharge: Modeling Loads Upstream and Downstream of a PFAS Manufacturing Plant in the Cape Fear Watershed, North Carolina, 831 Sci. of the Total Env't Art. No. 154763 (2022doi.org/10.1016/j.scitotenv.2022.154763.] Taken together, this evidence indicates that allowing compliance monitoring as infrequently as 1–2 times per three-year compliance period may mask dangerous PFAS concentrations in monitored drinking water and potential violations of the MCLs.

Further, as EPA acknowledges, PFAS subject to the proposed NPDWRs can pose health risks at concentrations substantially lower than the proposed trigger values. Indeed, in the Proposed Rule EPA acknowledges that PFOA and PFOS can cause adverse health effects at "near zero" levels. [FN209: Proposed Rule, 88 Fed. Reg. at 18,715.] While EPA has previously justified significant monitoring reductions on the grounds that "analytical results . . . below the MCL" for the contaminants at issue "do not pose a health threat," [FN210: 56 Fed. Reg. at 3,526, 3,562.] that logic is demonstrably inapposite for PFAS. Under EPA's proposal, exceedances of one or more PFAS MCL(s) could persist for years before they are detected and treatment is required, posing significant health risks for people served by the affected water system. And in situations where a water system has detectable PFAS concentrations below the proposed trigger values, EPA's proposal would deprive the public of information relevant to assessing health risks from consuming that PFAS-contaminated drinking water. [FN211: See 42 U.S.C. 300j-4(g)(6) (providing for inclusion in public database of "information on the detection of [regulated] contaminant[s] at a quantifiable level in public water systems (including detection of the contaminant at levels not constituting a violation of the maximum contaminant level for the contaminant).").]

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. Based on the totality of available occurrence data (see sections III.C and VI of the final rule preamble) and additional related public comments, the EPA determined the compliance frequencies are appropriate to enable sufficiently accurate detection of and response to regulated PFAS contamination in drinking water sources. Moreover, these frequencies are adequate as the regulated PFAS are associated with chronic human health effects. Regarding the

comment that "exceedances of one or more PFAS MCLs could persist for years before they are detected and treatment is required," the agency disagrees. Under the final rule water systems demonstrate their initial PFAS baseline levels over a consistent number of samples and then will be required to monitor at a frequency corresponding to those levels. Therefore, using these analytical results as the basis for potential PFAS contamination risk is a highly informative measure of how frequently a water system should be required to sample in order to demonstrate compliance with the MCLs, and if there are future changes in measured concentrations the water system will be required to change their sampling frequency as applicable. In water systems where there may be suspected new sources of PFAS contamination, the final rule also allows for primacy agencies to require more frequent monitoring. Additionally, please see sections 9.1 and 9.2 of the EPA response in this *Response to Comments* document, which discuss notification requirements to consumers under the CCR Rule and the Public Notification (PN) Rule. A CWS is required to include information on detected contaminants in its CCR, and a PWS must provide public notice when there is a violation or situation that has the potential to have adverse health effects. For further discussion of the MCLs, please see section V of the preamble to the final rule and section 5 of the *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046117)

C. EPA Should Strengthen the Proposed Monitoring Requirements to Comply with the SDWA and Enhance Public Health Protections

We urge EPA to strengthen the compliance monitoring requirements in the proposed rule by (1) relying on the MDL as the "trigger level" that can qualify a PWS for reduced monitoring where that value is lower than one-third of the PQL, and (2) requiring PWSs with consistent detections below the MDL to monitor annually for the regulated PFAS instead of triennially.

EPA's proposed monitoring requirements are insufficient to ensure compliance with the proposed MCLs, would undermine the potential health benefits of the rule, and would deprive the public of vital information regarding exposures to PFAS in drinking water at levels that threaten human health.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. Regarding rule trigger levels for reduced triennial monitoring, please see section 8.8 of the EPA response in this *Response to Comments* document. For discussions of CCR requirements and PN requirements, please see sections 9.1 and 9.2 of the EPA response in this *Response to Comments* document, respectively. The EPA-approved methods do not include Method Detection Limits (MDLs), but rather define and require the confirmation of Minimum Reporting Levels (MRLs) which are distinctly different from MDLs. For the PFAS NPDWR, the EPA did not define MRLs for PFAS contaminants, but established PQLs, as discussed in sections V and VII of the final rule preamble, to evaluate analytical feasibility for the determination of MCLs.

Corix Infrastructure Inc. (Doc. #1834, SBC-045370)

[With regards to the specific items EPA has requested comment on, Corix provides below:]

• We support EPA's approach to allowing the collection of one sample per three-year compliance period if the system does not detect regulated PFAS in their system at or above the rule trigger level.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Little Hocking Water Association (Doc. #1835, SBC-045516)

Quarterly testing frequency is not enough for all systems and decisions on less frequent monitoring needs to be made with knowledge of PFAS levels in pretreated water.

The proposed rule does not require any testing of pretreated water. LHWA understands that EPA is only concerned with finished water that goes to customers. LHWA strongly disagrees that this should be the only concern. It defies common sense that a regulator and the regulated water systems would respond to the PFAS crisis with only the knowledge of levels of contamination in finished water. If a water system does not know what levels of contamination are in its source water, then it cannot possibly react and solve the problem. Likewise, EPA cannot possibly develop and implement regulations protective of public health without knowing to what extent source waters need to be cleaned up.

The proposed rule requires monitoring frequencies and provides for relaxed monitoring frequencies that are not protective of health because the level of contamination in the pretreated water is not taken into account. For water supplies that are known to be highly contaminated with PFAS or are at a high risk of contamination, quarterly sampling is not enough. LHWA recommends initial sampling every 60 days.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. Regarding initial monitoring requirements, please see section 8.1.1 of the EPA response in this *Response to Comments* document. The NPDWR regulates PFAS levels in finished drinking water only as that is what is served to users of PWSs; this rule does not establish requirements applicable to drinking water sources. Treatment technologies installed between the source water and the finished water can reduce levels of PFAS and other contaminants to below levels of health concern in finished water. The EPA notes that the IIJA, also known as the BIL, has provided significant funding ($10 billion in total) available to PWSs through the State Revolving Fund (SRF) and grant programs to reduce people's exposure to PFAS and other emerging contaminants through their drinking water, to help address discharges through wastewater, and to support source water protection efforts.

Citizens Energy Group (Doc. #1838, SBC-044862)

EPA requests comment on the proposed allowance of a water system to potentially have each EPTDS on a different compliance monitoring schedule based on specific entry point sampling results (i.e., some EPTDS being sampled quarterly and other EPTDS sampled only once or twice during each three-year compliance period), or if compliance monitoring frequency should be consistent across all of the system's sampling points.

Citizens believes that it is appropriate for a water system to have each EPTDS on a different compliance monitoring schedule based on the sampling results. Citizens, for example, has multiple sources of supply to its system, including three reservoirs and multiple wellfields around the community. Each of these sources of supply has a unique 'fingerprint' when it comes to the raw water. Morse Reservoir, for example, is located in a primarily rural area, influenced by agriculture. Geist Reservoir is located in a highly urbanized area of the community, with active recreational uses in addition to agriculture in the headwaters of Fall Creek. Citizens' groundwater source of supply includes wellfields located in historically agricultural areas.

This difference in source of supply for each of the treatment plants should be recognized in sampling obligations imposed at the EPTDS. Water systems are responsible for implementing the standard monitoring framework for the suite of constituents regulated under the Safe Drinking Water Act, with monitoring obligations ranging from monthly to once every 10 years. Incorporating different schedules for PFAS-related monitoring obligations at the EPTDS can be managed by water systems.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Citizens Energy Group (Doc. #1838, SBC-044867)

Additionally, given the very low concentrations of PFAS that many water systems see in their analytical results, water systems should have the opportunity for confirmatory sampling if water samples at the EPTDS have detections for PFAS compounds that have not been previously detected in samples or if there are significant (unexpected based on historical data) changes in concentrations of PFAS before taking action that may alarm the general public.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. States may require systems to take confirmation compliance samples, but other samples collected voluntarily by a system (e.g., after an unusual detection) are not factored into calculations of the average for a quarter, year, or three-year period. With respect to the concern that a single high result might not be representative, the use of an RAA to determine MCL compliance (and PN related to MCL compliance), as discussed in section 8.2 of the EPA response in this *Response to Comments* document, does allow water systems to average samples collected over the course of four quarters accounting for potential fluctuations. Water systems must report detections from the previous year in their CCRs. Please see section 9 of the EPA

response in this *Response to Comments* document for a discussion of PN requirements; CCR requirements are addressed in section 9.1 and public notice requirements are discussed in section 9.2 of the EPA response in this *Response to Comments* document.

City of Fort Collins (Doc. #2320, SBC-046521)

I have a couple of questions about the relationship between the trigger level and reduced monitoring frequency in the proposed PFAS regulation, published on March 29, 2023.

The Hazard Index is only applicable to four (PFNA, PFHxS, PFBS, and HFPO-DA) of the six PFAS in this regulation, yes?

We have only one Entry Point to the Distribution System (EPTDS). If our initial quarterly EPTDS monitoring results exceed the trigger level for one PFAS but not for the other 5, is the system still eligible for reduced monitoring for the 5 parameters and then required to perform quarterly monitoring for the one PFAS? For example, if our initial running annual average for PFOS monitoring is 1.4 and the other 5 PFAS are less than the trigger level, can we analyze for the 5 PFAS twice every three years, but analyze for PFOS quarterly?

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. As it notes, the required monitoring frequency applies to all regulated PFAS. Regarding rule trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document. The commenter is correct that the Hazard Index only applies to four of the regulated PFAS (PFNA, PFHxS, PFBS, and HFPO-DA).

Richard Gelderman (Doc. #2820, SBC-047470)

4) The EPA should require quarterly monitoring of PFAS for all water systems. After a year of undetectable levels for the six PFAS, systems should reduce to annual monitoring, as opposed to monitoring just once or twice every three years.

I strongly support the EPA's proposed PFAS national primary drinking water regulations. I urge the EPA to finalize the standards as quickly as possible while simultaneously working to reduce PFAS pollution at the source.

Respectfully,

Richard Gelderman

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. Regarding initial monitoring requirements, please see section 8.1.1 of the EPA response in this *Response to Comments* document.

Nancy Bouldin (Doc. #2822, SBC-047333)

3. The EPA should require quarterly monitoring of PFAS for all water systems. After a year of undetectable levels for the six PFAS, systems should reduce to annual monitoring, as opposed to monitoring just once or twice every three years.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. Regarding initial monitoring requirements, please see section 8.1.1 of the EPA response in this *Response to Comments* document.

Melda Clark (Doc. #2823, SBC-047335)

3. The EPA should require quarterly monitoring of PFAS for all water systems. After a year of undetectable levels for the six PFAS, systems should reduce to annual monitoring, as opposed to monitoring just once or twice every three years.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. Regarding initial monitoring requirements, please see section 8.1.1 of the EPA response in this *Response to Comments* document.

Karen Valentine (Doc. #2834, SBC-047337)

3. The EPA should require quarterly monitoring of PFAS for all water systems. After a year of undetectable levels for the six PFAS, systems should reduce to annual monitoring, as opposed to monitoring just once or twice every three years.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. Regarding initial monitoring requirements, please see section 8.1.1 of the EPA response in this *Response to Comments* document.

Monty Fowler (Doc. #2836, SBC-047339)

3. The EPA should require quarterly monitoring of PFAS for all water systems. After a year of undetectable levels for the six PFAS, systems should reduce to annual monitoring, as opposed to monitoring just once or twice every three years.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. Regarding initial monitoring requirements, please see section 8.1.1 of the EPA response in this *Response to Comments* document.

Steven Cole (Doc. #2837, SBC-047340)

2. The EPA should require quarterly monitoring of PFAS for all water systems. After a year of undetectable levels for the six PFAS, systems should reduce to annual monitoring, as opposed to monitoring just once or twice every three years.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. Regarding initial monitoring requirements, please see section 8.1.1 of the EPA response in this *Response to Comments* document.

John Doyle (Doc. #2840, SBC-047342)

3. The EPA should require quarterly monitoring of PFAS for all water systems. After a year of undetectable levels for the six PFAS, systems should reduce to annual monitoring, as opposed to monitoring just once or twice every three years.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. Regarding initial monitoring requirements, please see section 8.1.1 of the EPA response in this *Response to Comments* document.

Laurine Yates (Doc. #2900, SBC-047344)

3. The EPA should require quarterly monitoring of PFAS for all water systems. After a year of undetectable levels for the six PFAS, systems should reduce to annual monitoring, as opposed to monitoring just once or twice every three years.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. Regarding initial monitoring requirements, please see section 8.1.1 of the EPA response in this *Response to Comments* document.

Mass comment campaign submitted by Jill Fischer (Doc. #3070, SBC-047346)

3. The EPA should require quarterly monitoring of PFAS for all water systems. After a year of undetectable levels for the six PFAS, systems should reduce to annual monitoring, as opposed to monitoring just once or twice every three years.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. Regarding initial monitoring requirements, please see section 8.1.1 of the EPA response in this *Response to Comments* document.

Student, Vanderbilt University (Doc. #3072-72, SBC-047398)

Good afternoon. My name is Siyuan. Thank you so much for this opportunity, and I'm a PhD student in environmental engineering at Vanderbilt University right now. Five years ago, when I was in North Carolina where the GenX issue happened, PFAS caught my attention, and right now it turns to be my research topic and I'm trying my best to contribute to this field. Even though studies showing the hazardous and the ubiquity of PFAS, it makes no sense to turn a blind eye on this issue. That's why this proposal from EPA is super essential. Well, based on my own research experience, I understand the technical difficulties of PFAS detection and separation, but this should not block the pace to protect public health from PFAS pollution.

Therefore, I will suggest a step-by-step action. The first is monitoring, a monthly or quarterly monitoring report should be conducted since people feel uneasy and anxious about the unknown PFAS pollution levels.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. Regarding initial monitoring requirements, please see section 8.1.1 of the EPA response in this *Response to Comments* document. Water systems must report detections from the previous year in their CCRs. Please see section 9 of the EPA response in this *Response to Comments* document for a discussion of PN requirements; CCR requirements are addressed in section 9.1 of the EPA response in this *Response to Comments* document and public notice requirements are discussed in section 9.2 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #1506, SBC-042576)

We also recommend that more strict testing and regulation measures are adopted in order to prevent high concentrations of PFAS from affecting residents. This means testing drinking water every 6 months to ensure acceptable levels of PFAS.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Minnesota Department of Health (MDH) (Doc. #1610, SBC-042857)

Frequency of Reduced Monitoring

Per Part XIV, Section IX of the rule proposal:

"EPA requests comment on if all water systems, regardless of system size, be allowed to collect and analyze one sample per three-year compliance period if the system does not detect regulated PFAS in their system at or above the rule trigger level."

MDH Comments:

· MDH supports allowing one sample per 3-year compliance period for all systems on reduced monitoring rather than requiring 2 samples per 3-year period for systems with >3,300 population.

· Transient detections and significant seasonal variability are not typically observed with PFAS contamination based on our state's experience with past monitoring since PFAS is stable in the environment. Therefore, one sample is sufficient to determine if contamination is present.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043086)

Use of Standard Monitoring Framework

The proposed approach to use the Standard Monitoring Framework (SMF) is appropriate.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Village of Woodbury (Doc. #1629, SBC-042953)

7. The EPA requested comments on allowing systems to monitor Entry-Point to Distribution Systems (EPTDS) at different schedules based on results received. This flexibility saves in costs for unnecessary sampling, which in our view is agreeable. Nonetheless, for systems to maintain compliance the required schedules should be clearly communicated with operators annually.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document. The EPA agrees that primacy agency and PWS communication on required monitoring frequency is critical to ensuring effective implementation. The EPA defers to the primacy agency to address this communication.

New York State Department of Health (NYS DOH) (Doc. #1677, SBC-044960)

23. The Department supports allowing systems with multiple entry points to the distribution system (EPDS) to have different monitoring schedules for each EPDS.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Citizens Energy Group (Doc. #1838, SBC-044863)

EPA requests comment on if all water systems, regardless of system size, be allowed to collect and analyze one sample per three-year compliance period if the system does not detect regulated PFAS in their system at or above the rule trigger level.

Citizens encourages EPA to incorporate monitoring flexibilities that can reduce the administrative burden into the final rule, including flexibilities that allow systems that do not detect regulated PFAS in their system to reduce their monitoring. Communities will face differing challenges with PFAS in the source of supply to their water systems, depending on the types of historical manufacturing and defense-related activities that occurred in the community's watershed. Those communities where PFAS is present at low levels (below the proposed trigger levels) given the ubiquitous nature of PFAS compounds in the environment should be given the flexibility to monitor less frequently. Allowing this flexibility reduces the overall burdens associated with implementation of the proposed rule without compromising public health.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Great Lakes Water Authority (GLWA) (Doc. #1558, SBC-042552)

Proposed allowance of a water system to potentially have each EPTDS on a different compliance monitoring schedule based on specific entry point sampling results (i.e., some EPTDS being sampled quarterly and other EPTDS sampled only once or twice during each three-year compliance period), or if compliance monitoring frequency should be consistent across all of the system's sampling points.

Different compliance monitoring schedules based on EPTDS locations makes sense for systems like GLWA that consist of more than one treatment facility and/or source water. Different compliance monitoring frequencies should be allowed.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Michigan Department of Environment, Great Lakes, and Energy (EGLE) Drinking Water and Environmental Health Division (DWEHD) (Doc. #1597, SBC-042986)

9. The proposed rule includes a required 90-day minimum interval for consecutive compliance samples. It is the opinion of EGLE DWEHD that this requirement presents a serious implementation issue. With quarters having between 90 and 92 days, a maximum of 2 days would be available for flexibility in quarterly sampling. Taking weekends and holidays into account, this represents a significant lack of flexibility and a likely source of schedule violations. Also note that, should a supply sample later in a quarter, they would be unable to mitigate this in the future as they would be forever required to sample at the end of each quarter to meet the 90-day requirement. EGLE DWEHD asks that EPA consider a timeframe that allows flexibility, while not permitting back-to-back sampling, such as a minimum of 30 days between sampling events.

EPA Response: In the proposed rule, there were two instances when samples were specified as needing to be collected "at least 90 days" apart. The proposed requirement, as it applied to compliance monitoring, was that any system serving at least 10,000 people that was following a triennial monitoring schedule would collect two samples every three years, at least 90 days apart. The requirements for triennial monitoring were changed in the final rule to require all systems to collect one sample every three years. Please see also section 8.1.2 of the EPA response in this *Response to Comments* document related to the compliance monitoring requirements. With respect to the proposed requirement to collect initial monitoring samples at least 90 days apart (for systems collecting quarterly initial monitoring samples), the final rule now specifies that such samples be collected within each quarter and two to four months apart. Please see also section 8.1.1 of the EPA response in this *Response to Comments* document.

New York State Department of Health (NYS DOH) (Doc. #1677, SBC-044941)

3. EPA solicited comment on establishing the proposed rule trigger level values of 1.3 ppt for PFOA and PFOS and 0.33 for the PFAS regulated by the Hazard Index (HI). Although the Department currently considers any detection above the method detection limit a "detect" and requires quarterly monitoring as a result, there is a mechanism for the water system to reduce monitoring to annually if they are reliably and consistently below the MCL of 10 ppt, The Department recommends that EPA consider allowing water systems with levels between the trigger level and MCL to be permitted to monitor annually if, after 4 quarters of monitoring, levels are consistently between the trigger level and the MCL.

EPA Response: Please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Robert Hollander (Doc. #1516, SBC-042711)

3. 88 FR 18677, paragraph after Table 14, end of 1st sentence

Correct Table 15 to read Table 14.

4. 88 FR 18682, 1st column, paragraph after 2nd bulleted paragraph

This is confusing. If a system shows results that are below the trigger levels, would that not be reliably and consistently below the MCL? Perhaps this should read "...the primacy agency may allow a system to move to a reduced monitoring frequency when the primacy agency determines that the system is below the rule trigger level and/or reliably and consistently below the MCL".

EPA Response: Regarding the comment about the paragraph after Table 14 in the preamble, the EPA corrected the sentence in the preamble that previously compared Table 15 to itself. The comparison at the end of the sentence has been changed to refer to the preceding table. In the final rule, those tables are Tables 13 and 12. Regarding the commenter's #4 comment, the EPA agrees that trigger levels are inherently below the MCLs. Please see section 8.1.2 of the EPA response in this *Response to Comments* document for a discussion of compliance monitoring requirements. In the final rule, "the system is below the rule trigger level" is no longer a criterion that must be met for a determination of reliably and consistently below the MCL and was removed from part IX of the preamble, as well as the regulatory text.

8.2 PWS Compliance and Violations

Summary of Major Public Comments and EPA Responses

Consistent with existing rules for determining compliance with NPDWRs, the EPA proposed that compliance would be determined based on the analytical results obtained at each sampling point (i.e., each EPTDS). For systems monitoring quarterly, compliance with the proposed MCLs would be determined by calculating RAAs for each sampling point. The agency received multiple comments on how the compliance determination and violations were proposed to be

assessed. Many commenters supported the EPA's approach to assess violations, including that violations are only assessed through an RAA for systems conducting quarterly monitoring. Some commenters suggested that in a scenario where a particular high quarterly sample (e.g., result greater than four times the MCL) would cause the RAA to exceed an MCL, the system should not be deemed out of compliance until the end of the quarter (to allow utilities to conduct additional monitoring during that quarter and average the results from the multiple samples). The EPA agrees that the results from confirmatory compliance monitoring specified by the primacy agency should be accounted for (in calculating an average for that quarter) but notes that additional voluntary sampling by the PWS may not be used in calculating the quarterly average. The final rule requires that a compliance sample be taken during each quarter for those systems conducting quarterly monitoring. Further, as prescribed under 141.902(b)(2)(v), the state may require a confirmation sample for any sampling results and, if this sample is required, the result must be averaged with the initial sampling results and used for the compliance determination.

A few commenters suggested changing the time periods for determining compliance (for both systems conducting quarterly monitoring and those conducting triennial monitoring). These recommendations included assessing compliance based on the results from eight consecutive quarterly samples (rather than four). For those systems conducting triennial monitoring, some commenters proposed that the compliance determination be based on one triennial sample result. For systems determining compliance through an RAA calculation, the EPA believes four consecutive quarterly samples is an adequate representation of the regulated PFAS levels while also assessing compliance in a timely manner. For systems conducting triennial monitoring, if a water system has a sample result at or above the EPA's trigger levels, the system will immediately be required to begin quarterly monitoring. This is consistent with monitoring requirements for other SOCs and, given the change in measured concentration, will provide additional information over a consistent and longer period of time to better assess the average level of regulated PFAS within the water supply and ensure the water system is reliably and consistently below the MCL.

In the proposal, when calculating the RAAs to determine compliance, if a sample result is less than the PQL for the monitored PFAS, the EPA proposed to use zero for that result. The EPA requested comment on whether the agency should consider an alternative to the approach of using zero when calculating the RAAs. Specifically, in the case where a regulated PFAS is detected but the result is below its proposed PQL, the proposed rule invited comment on whether the trigger level (proposed as one third of the PQL) should be used as the value in calculating the RAA for compliance purposes.

The EPA received numerous comments related to the proposed approach for calculating the RAA for compliance with the NPDWRs, particularly on the incorporation of sample results below the PQLs for the regulated PFAS (see sections V and VII of the preamble to the final rule for more information on PQLs.) Many commenters, including some states, supported the EPA's proposed approach to utilize zero for results below PQL to calculate the RAA and determine compliance. These commenters cited the definition of the PQL as "the lowest concentration of an

analyte that can be reliably measured within specified limits of precision and accuracy during routine laboratory conditions" and noted that this is a level that all laboratories should be able to achieve. Consequently, they suggested that values below these PQLs should not be used for the RAA compliance calculation. Several of these commenters expressed concern that using estimated or other values with less precision in the compliance calculation could result in utilities needing to take actions to address levels of regulated PFAS that are not well-quantified and may not be representative of regulated PFAS levels. Many commenters suggested that since some laboratories cannot achieve values less than the PQLs, this would result in equity issues with respect to disparate laboratories capabilities. Some also suggested that the approach could exacerbate any potential laboratory capacity issues.

The EPA agrees with these commenters that values below the PQLs for the regulated PFAS should not be used in the RAA compliance calculation. As cited previously by commenters and the EPA, in sections V and VII of the preamble, PQLs are the lowest concentration that can be reliably measured within specified limits of precision and accuracy during routine laboratory operations. As noted in the rule proposal, "the agency must have a high degree of confidence in the quantified result as it may compel utilities to make potentially costly compliance decisions in order to comply with the MCL." Moreover, because compliance with the MCL is determined by analysis with approved analytical techniques, the ability to analyze consistently and accurately for a contaminant is important to enforce a regulatory standard. The EPA recognizes the potential for minor analytical variabilities within sampling procedures and laboratory analyses below the PQL and this approach offers more operational certainty to utilities, provides better assurances of precision and accuracy in the concentrations at or above the PQL that are achievable for all laboratories, ensures more equitable access to all laboratories with comparable analytical capabilities for the purposes of compliance sample results, and reduces the potential for laboratory capacity issues.

Many other commenters did not support the EPA's proposed approach and offered that all sample results between MDLs and PQLs, even if estimated, should be included in the RAA and used to determine compliance. Alternatively, some suggested that any results that laboratories are able to quantify should be used in calculating the RAA for compliance. A subset of these commenters suggested that using zero (instead of an estimated or semi-quantitative value) biases the RAA compliance calculation, is even less precise and accurate than using the values below the PQLs, is contrary to the RAA compliance calculation for other SOC NPDWRs and demonstrates a reduction in public health protection. Some commenters also suggested that this could result in public communication challenges if laboratories are able to estimate or quantify values below the PQLs and zero is instead used in the calculation. Further, several commenters submitted that, in their experiences, some laboratories are capable of reliably and accurately reporting below the PQLs.

While the EPA recognizes that using zero for values below the PQL will result in a differing RAA compliance calculation result than if the values below the PQL were instead used, on a national scale, these values below the PQL do not consistently represent values with the

precision, accuracy, and reliability the EPA believes are necessary for compliance determination purposes. Therefore, the EPA's national approach to achieve consistency (recognizing that laboratories have varying analytical capabilities) is to judge compliance based on results at or above the PQL. Using values below the PQL may result in MCL compliance determination inequities across systems. The EPA notes that lower-level values (i.e., below the PQL) will be used for the determination of monitoring frequency. That determination is also based on individual sample results and not averages; therefore, systems with any PFAS results at or above the rule trigger levels will be required to monitor more frequently to ensure compliance with the MCLs (see sections 8.1.2 and 8.8 of the EPA response in this *Response to Comments* document related to compliance monitoring requirements and rule trigger levels, respectively).

The EPA agrees that some laboratories are capable of reliably measuring the regulated PFAS below the EPA's PQLs. This is supported by a subset of state PFAS monitoring data that represents some sampling with quantified values below the EPA's PQLs. Further, in the March 2023 proposal, the EPA recognized that "quantitation of the contaminants can be achieved between the method detection limit and the PQL" though the EPA also noted in the proposal that this is "not necessarily with the same precision and accuracy that is possible at and above the PQL." The EPA must set consistent requirements based on the circumstances of all PWSs and laboratory capabilities throughout the country. The agency notes that states must establish requirements at least as stringent as the EPA to maintain primacy; however, under SDWA, states with primacy may establish more stringent requirements. In instances where a laboratory can demonstrate it is capable of precisely and accurately quantifying values below the PQLs, some states may choose to establish their own requirements that are more stringent and use results below the agency's PQL for the compliance calculation.

The agency also received a few comments on the possible alternative approach of using the proposed trigger level as the value in calculating the RAA for compliance purposes when an estimated value is reported as between the trigger level and PQL. Most commenters did not agree with that approach and noted that using these values could result in inequitable implementation of the rule based on laboratory analytical capabilities.

After consideration of all these comments and for the reasons described previously, the EPA does not believe it is appropriate for the agency to require the use of trigger level values (or any other values below the PQL), as part of the RAA compliance calculation based on the information available to the agency as part of this final rulemaking. As described in section 8.8 of the EPA response in this *Response to Comments* document, the agency has concluded that results below the EPA's PQL (i.e., between the trigger level and PQL) are appropriate to determine if the contaminant is present (i.e., detected) and for the determination of reduced monitoring frequency, however the EPA concludes that values below the PQL would not consistently and reliably demonstrate the accuracy necessary for compliance determination purposes that can result in potentially costly expenditures, such as the installation of drinking water treatment, for PWSs.

A few commenters asked about how to account for regulated PFAS that are included in the Hazard Index when their concentrations are reported as "non-detect" and requested the EPA clarify what value to use in the Hazard Index calculation to evaluate compliance. The EPA confirms that when a laboratory reports that a result is below a PQL, the system is to use a zero in its calculation of the RAA Hazard Index MCL, similar to treating values below PQLs as zero in RAA compliance calculations for the PFAS with their own MCLs.

Individual Public Comments

Missouri Department of Natural Resources (Doc. #1563, SBC-052824)

Additionally, the Department does not agree with using the proposed hazard index approach as a trigger level indicator or for MCL compliance determinations. The HI does not follow the synthetic organic contaminant (SOC) standard monitoring framework (SMF) of basing decisions on reliable and consistent (R&C) analytical data as the HI levels are below the practical quantification limit (PQL). In order to make a R&C determination, decisions must be made on reportable results above the PQL.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. The EPA disagrees that the Hazard Index MCL does not follow the SOC standard monitoring framework; the approach is the same as for PFOA and PFOS, with the same modification made for other regulated PFAS contaminants. Regarding trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document. The EPA also disagrees that the trigger levels for the Hazard Index PFAS are below their respective PQLs. The trigger level for the Hazard Index is 0.5 and all of the Health Based Water Concentration (HBWCs) for the four Hazard Index PFAS (2000 ppt for PFBS or 10 ppt for the other Hazard Index PFAS) are at least twice their respective PQLs (3.0 ppt for PFHxS and PFBS, 4.0 ppt for PFNA, 5.0 ppt for HFPO-DA). Therefore, there are no pertinent analytical limitations for these four PFAS. Further, any measurements below the PQLs will not be utilized when determining Hazard Index MCL compliance. Additionally, please see section 8.1.2 of the EPA response in this *Response to Comments* document for a discussion of eligibility for different monitoring frequencies, including changes made to the criteria for determinations that a system is reliably and consistently (R&C) below the MCL. Under the final rule, the EPA has made changes to allow for measurable results below the MCL, but above the trigger level, to be sufficient for an R&C determination, which would allow a system to shift to annual monitoring.

Great Lakes Water Authority (GLWA) (Doc. #1558, SBC-042555)

Whether EPA should consider an alternative approach to what is currently proposed when calculating compliance with proposed MCLs. Specifically, in the case where a regulated PFAS is detected but below its proposed PQL, rather than using zero for the measurement value of the specific PFAS in the running annual average compliance calculation, that the proposed mile trigger levels (1.3 ppt for PFOA and PFOS and 0.33 of each of the HI PFAS PQLs (i.e.,

PFHxS=1.0, HFPO— DA=1. 7, PFNA=1.3, and PFBS=1.0)) be used as the values in calculating the running annual average for compliance purposes.

As previously stated, each of the trigger levels are below the PQL. We agree that detections below the PQL should be entered as a zero into the LRAA calculation due to the lack of certainty and precision.

Further, we suggest consideration that the trigger level requiring more frequent sampling be defined as a single exceedance using the LRAA calculation or health index value rather than an arbitrary concentration of a single sample. This would be more similar to the requirements of other drinking water regulations including the D/DBP Rule.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. For a discussion of the EPA's rationale for the trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document. In the final rule, as in the proposed rule, the trigger level is used to evaluate individual sample results to determine monitoring frequency. MCL compliance, on the other hand, is based on an RAA for systems that conduct quarterly monitoring. Please see section 8.1.2 of the EPA response in this *Response to Comments* document regarding compliance monitoring requirements. The EPA also clarifies for the commenter that while the PFOA and PFOS trigger levels are below their respective PQLs, the commenter incorrectly states that the trigger levels for the four Hazard Index PFAS (PFHxS, PFNA, HFPO-DA, and PFBS) are below their respective PQLs; the final rule trigger level for the Hazard Index is 0.5 and all of the HBWCs for the four Hazard Index PFAS (2000 ppt for PFBS or 10 ppt for the other Hazard Index PFAS) are at least twice their respective PQLs (3.0 ppt for PFHxS and PFBS, 4.0 ppt for PFNA, 5.0 ppt for HFPO-DA). Therefore, there are no pertinent analytical limitations for these four PFAS.

Missouri Department of Natural Resources (Doc. #1563, SBC-042532)

EPA requests comment on whether EPA should consider an alternative approach to what is currently proposed when calculating compliance with proposed MCLs. Specifically, in the case where a regulated PFAS is detected but below its proposed PQL, rather than using zero for the measurement value of the specific PFAS in the running annual average compliance calculation, that the proposed rule trigger levels (1.3 ppt for PFOA and PFOS and 0.33 of each of the HI PFAS PQLs (i.e., PFHxS=1.0, HFPO– DA=1.7, PFNA=1.3, and PFBS=1.0)) be used as the values in calculating the running annual average for compliance purposes.

The Department does not agree with using levels below the PQL for compliance purposes. The approach should be to raise the MCL to be sufficiently above the need of a ±50% Method QA/QC acceptance level so that reliable and consistent (R&C) reportable results above the PQL can be used for compliance determinations.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. The EPA clarifies for the commenter that levels below the PQLs will not

be used for compliance determination purposes. Regarding PQLs, please see section 7.2 of the EPA response in this *Response to Comments* document. For discussion of feasibility of PFOA and PFOS MCLs, please see section 5.1.1 of the EPA response in this *Response to Comments* document.

Minnesota Pollution Control Agency (MPCA) (Doc. #1569, SBC-042500)

In addition, and importantly, MPCA is concerned that EPA's proposal for evaluating compliance with the MCLs, which does not account for any analytical results below 4 ng/L for PFOS and PFOA, is not health protective and does not reflect the reality that most laboratories are providing results well below the 4 ng/L PQL, as is documented in the RFC. We urge EPA to revise this approach and allow the use of actual laboratory analytical results in evaluating compliance and the need for treatment of drinking water.

Thank you for this opportunity to comment.

Sincerely,

Katrina Kessler

This document has been electronically signed.

Katrina Kessler, P.E.

Commissioner

See References on next page

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EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

Minnesota Pollution Control Agency (MPCA) (Doc. #1569, SBC-042493)

Section VI - Maximum Contaminant Level (MCL)

1) EPA requests comment on its proposed approach for an alternative to using zero in the formula to determine compliance with the proposed MCLs. EPA's primary proposal for when a PFAS is detected at less than the laboratory PQL (practical quantitation limit), which also happens to be the MCL for PFOS and PFOA, is to use zero. EPA proposes an alternative that

utilizes the proposed rule trigger levels, set at one-third of the proposed MCL, in place of zero in situations where PFAS are detected but below their proposed PQLs.

MPCA response:

• The proposed use of zero when PFOS and PFOA are not reported above 4 ng/L is not health protective, especially when many labs will be reporting at PQLs well below 4 ng/L. EPA's proposed alternative of using the proposed trigger values in place of zero is a slight improvement.

• A much better approach, which MPCA urges EPA to adopt, is to allow the use of a laboratory's best available reporting limit and any detections of PFAS that are reported, even when below 4 ng/L. While laboratory reporting limits will vary from state to state and from lab to lab, this enables regulatory actions to reflect the actual analytical results and the best available technology, not an artificially set PQL/reporting limit that is judged to be universally achievable.

• Along with MPCA's preferred approach (described above), MPCA strongly encourages EPA to propose an MCL for the combined analytical result for PFOS and PFOA in drinking water (i.e. an additive MCL for PFOS and PFOA), to be set at 4 ng/L. This is needed when reporting limits of less than 4 ng/L are used, as MPCA urges, to address the situation where PFOS plus PFOA exceed the proposed MCL of 4 ng/L, but neither PFOS or PFOA exceed individually. For example, if a sample was reported to contain PFOS at 3 ng/L and PFOA at 3 ng/L - with the proposed individual MCLs, no treatment of the drinking water would be required. With a combined PFOS plus PFOA MCL, it would – resulting in a more health protective result that better reflects knowledge of the risks posed by these forever chemicals. For reference, PFOS and PFOA are included in Minnesota's existing process for evaluating cumulative risk from PFAS. The specific chemicals used in Minnesota's existing process include: PFOS, PFOA, PFBA, PFHxA, PFHxS, and PFBS.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. Please also see section 5.1.2 of the EPA response in this *Response to Comments* document regarding the relationship between PQLs and MCLs for PFOA and PFOS which have been determined by the agency as 4.0 ppt each for PFOA and PFOS. As discussed in section 8.2 of the EPA response in this *Response to Comments* document, for the determination of the RAA for MCL compliance purposes only, all results below these PQLs will use zero in the calculation. Therefore, a combined MCL for PFOA and PFOS of 4.0 ppt would not be feasible as a result of the analytical limitations described in section 5.1.2 of the EPA response in this *Response to Comments* document and the values below the PQLs (such as 3 ppt for PFOA provided in the commenter's example) will not be used in the determination of MCL compliance discussed in section 8.2 of the EPA response in this *Response to Comments* document. Additionally, please see section 5.1.3 of the EPA response in this *Response to Comments* document pertaining to PFOA and PFOS regulatory alternatives where the EPA discusses comments related to MCLs for PFOA and PFOS lower than 4.0 ppt.

San Antonio Water System (SAWS) (Doc. #1570, SBC-042480)

o To calculate the running annual average, EPA is allowing the use of a "0" for values below the PQL; however, the frequency of sampling events is predicated on quantifying those values. EPA should not use quantifiable values < PQL sometimes and not others. This inconsistency has the potential to increase PWS compliance sampling.

o There should be a consistent approach between running annual average and reduced monitoring. If the value is less than the PQL it should be a non-detect throughout the rule both for running annual average and monitoring requirements.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. Please see sections 8.8 and 8.2.1 of the EPA response in this *Response to Comments* document regarding rule trigger levels for reduced triennial monitoring.

Oregon Health Authority (OHA) (Doc. #1582, SBC-042765)

• EPA requests comment on whether EPA should consider an alternative approach to what is currently proposed when calculating compliance with proposed MCLs. Specifically, in the case where a regulated PFAS is detected but below its proposed PQL, rather than using zero for the measurement value of the specific PFAS in the running annual average compliance calculation, that the proposed rule trigger levels (1.3 ppt for PFOA and PFOS and 0.33 of each of the HI PFAS PQLs (i.e., PFHxS=1.0, HFPO-DA=1.7, PFNA=1.3, and PFBS=1.0)) be used as the values in calculating the running annual average for compliance purposes.

OHA supports using zero in calculating the running annual average for compliance purposes for results below the minimum reporting level (MRL) regardless of the MRL the lab can achieve (some labs may be able to achieve lower MRLs than the PQLs in the proposed rule), as long as the PQLs in the proposed rule are met. OHA believes that only quantified results (values at or above the MRL) should be used for compliance calculations. In cases where a regulated PFAS is detected but below its proposed PQL and below the lab's MRL, the proposed trigger levels should not be used since the trigger levels are not actual measured/quantified results. If a PFAS is detected above the lab's MRL but below the PQL, that actual value detected should be used, rather than zero.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

Washington Suburban Sanitary Commission (WSSC Water) (Doc. #1585, SBC-042773)

EPA is proposing that systems with existing monitoring data from UCMR5 will not be required to conduct separate initial monitoring for regulated PFAS. WSSC Water supports this approach. However, although some labs are capable of performing at a PQL of 2 ppt, the UCMR5 framework involves different QA/QC requirements than non-UCMR methods 537.1 and 533,

making it impossible for labs to report any quantifiable results below the required PQL of 4 ppt. This makes it impossible to evaluate UCMR5 results against trigger levels below the PQL. Considering these limitations, WSSC Water supports EPA's approach for any results below the PQL to be reported as zero in determining running annual average, consistent with the method used in Standard Monitoring Framework.

Running annual average approach:

EPA is proposing that compliance with the proposed MCLs for regulated PFAS will be determined by calculating running annual averages at the sampling point. PFAS is ubiquitous in the environment, and analysis of PFAS is subject to greater variability compared to other contaminants regulated as a running annual average under the Standard Monitoring Framework. A single monitoring result exceeding four times the MCL in a quarter will result in non-compliance, even if it is a false positive. WSSC Water recommends that EPA consider extending the period for calculating the running average from four quarters to eight consecutive quarters to ensure that compliance is based on a representative amount of data. In addition, EPA may consider allowing primacy agencies to invalidate false positive data meeting specific criteria. For instance, State of California has implemented repeat sampling protocols following a detection above the Notification Level. These protocols allow invalidation of original sample results if subsequent repeat samples indicate non-detect. Similarly, EPA has successfully implemented comparable procedures, as outlined in 40 CFR 141.21(c)(1)(ii), to grant states the authority to invalidate false positive bacteriological results based on the repeat sampling results. Incorporating a statistical measure in the compliance calculation method, such as procedures to remove outliers outside of the standard deviation, could also eliminate the impacts of false positive sampling results. Compliance calculation over a two-year period or removing false positive results would not adversely affect public health protection as the human health impacts of PFAS are based on lifetime exposure.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. Please see section 8.1.1 of the EPA response in this *Response to Comments* document for discussion of initial monitoring and section 8.3 of the EPA response in this *Response to Comments* document for a discussion of using existing data to meet the initial monitoring requirements. Related to the use of UCMR 5 data to satisfy the rule's initial monitoring requirements, the EPA clarifies that, while use of these data are allowable to satisfy the rule's initial monitoring requirements, water systems are required to collect the specified number of initial monitoring samples; therefore, large groundwater systems participating in UCMR 5 would have to collect two additional samples beyond those collected pursuant to UCMR 5 requirements. Additionally, while this previously-collected data can be used to satisfy some or all of the initial monitoring requirements, it is the results of the data that determine reduced monitoring eligibility. Along these lines, the EPA disagrees with the commenter's claim that a water system would not be able to use UCMR 5 data to demonstrate they may be eligible for reduced monitoring. Please see section 13.3.4 of the EPA response in this *Response to Comments* document for the discussion of how water systems can request UCMR 5 data below

MRLs from laboratories for use in satisfying some or all of the NPDWR's initial monitoring requirements and determination of compliance monitoring frequency.

The agency also refers the commenter to sections 8.8 and 8.2.1 in this *Response to Comments* document regarding rule trigger levels for reduced triennial monitoring and compliance monitoring requirements, respectively. Under the final rule, the EPA allows states to establish requirements for confirmation samples. In the event a system collects a confirmation sample required by the state, the system may average the two results (original and confirmation) and use the average in the compliance calculation. This approach (see § 141.902(b)(2)(v)) follows the precedent set for compliance samples and state-required confirmation samples collected to analyze most other chemical contaminants with chronic effects. Lastly, please see section 8.7 of the EPA response in this *Response to Comments* document for a discussion of background contamination concerns and potential "false positives."

Michigan Department of Environment, Great Lakes, and Energy (EGLE) Drinking Water and Environmental Health Division (DWEHD) (Doc. #1597, SBC-042981)

4. Michigan's SDWA requires a reporting limit of 2 ng/l for all seven PFAS compounds with MCLs. For running annual average calculations, would it be more appropriate to include numerical values for any detections below the PQL but above this RL in Michigan?

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

Lehigh County Authority (LCA) (Doc. #1600, SBC-042817)

A final point about the proposed MCLs for PFOA and PFOS is that compliance is proposed to be based on an annual running average. The proposed rule allows the use of a "0" (Zero) in the calculation when results are shown are below the PQL and MDL. The EPA is requesting comment on whether the proposed trigger level of 1.3 ppt should be used in lieu of "0." This approach would not be appropriate nor reliable. The EPA should not require arbitrary numbers to be used in a compliance calculation. Should a laboratory result be reported at a value less than the PQL and MDL, it is reasonable and appropriate to report that result as "0" (Zero).

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

American Water Works Company Inc. (Doc. #1608, SBC-044012)

Use of the Practical Quantitation Limits (PQLs)

American Water supports the proposed approach of using the PQLs as the limit for quantifying values when making compliance determinations. We agree that water systems will receive valuable information when results are provided to them below the PQLs, but strongly believe

that data should be used to assist in making treatment determinations. Concerns about accuracy and lab capacity support the PQLs as listed in the proposed rule.

American Water further supports using a value of zero (0) in compliance calculations for results below the PQLs. Choosing an arbitrary number such as one-half or one-third of the PQLs may lead to water systems being required to install costly treatment when actual levels do not support such actions.

American Water also cautions the U.S. EPA about the implications of making changes to the PQLs for PFAS analytes might have on this regulation. Any changes that would impact compliance determinations or monitoring requirements under this rule would need to be carefully considered and vetted through a new rulemaking process that clearly conveys the health risks that are being addressed and the associated costs and implementation challenges.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. Additionally, the EPA evaluates NPDWRs as part of the Six Year Review process. Any changes made to the regulations, including new PQLs, would follow this process outlined under SDWA.

Minnesota Department of Health (MDH) (Doc. #1610, SBC-042852)

· To address the issues described here, EPA should make one of the following changes to the proposed NPDWR for PFAS:

o Allow any results above laboratory RLs to be used for determining a QRAA for compliance and set a required RL for laboratories that is below the MCL and achievable, such as 2 ppt for PFOS and PFOA.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

Minnesota Department of Health (MDH) (Doc. #1610, SBC-042849)

May 25, 2023

Radhika Fox, Assistant Administrator

Office of Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue NW

Mail Code: 4101M

Washington, DC 20460-0001

RE: PFAS National Primary Drinking Water Regulation Rulemaking (Docket EPA-HQ-OW-2022-0114)

Dear Assistant Administrator Fox:

The Minnesota Department of Health (MDH) appreciates the opportunity to provide comment on the PFAS National Primary Drinking Water Regulation Rulemaking proposal. We further recognize the effort that U.S. EPA has made to reach this important milestone in addressing PFAS. As the primacy agency responsible Safe Drinking Water Act (SDWA) implementation in Minnesota, MDH offers its comments from the perspective of decades leading SDWA implementation, as well as years of experience in addressing PFAS. Our agency's comments integrate perspectives from our MDH Public Health Laboratory and well as our MDH Environmental Health Division, both of which have, and will continue to, play key roles in assessing and addressing the presence of PFAS in drinking water. MDH also is a member of the Association of State Drinking Water Administrators (ASDWA), and MDH staff participate in several ASDWA work groups focused on PFAS. As such, our comments herein are provided in addition to perspectives voiced in comments submitted by ASDWA. As described in ASDWA's comments, we would further emphasize that significant resources will be needed to implement this proposed rule in order to reduce PFAS exposure nationwide and here in Minnesota.

Please contact Sandeep Burman, MDH Drinking Water Protection Section Manager, at 651-201-4647 or sandeep.burman@state.mn.us should you wish to discuss our comments in greater detail.

Sincerely,

Tom Hogan, Director

Environmental Health Division

PO Box 64975

St. Paul, MN 55164-0975

Myra Kunas, Director

Public Health Laboratory Division

PO Box 64899

St. Paul, MN 55164-0899

cc: Jennifer McLain, Director, Office of Ground Water and Drinking Water

Minnesota Department of Health (MDH) Comment

PFAS NATIONAL PRIMARY DRINKING WATER REGULATION

RULEMAKING PROPOSAL (DOCKET ID EPA -HQ-OW-2022-0114)

The Minnesota Department of Health (MDH) is providing the following comments to the United States Environmental Protection Agency (EPA) regarding the proposed National Primary Drinking Water Regulation (NPDWR) for PFAS as published in the Federal Register on March 29, 2023.

Proposal to Treat Results Below the PQL as Zero for Compliance Purposes

In part IX, subpart B of the rule preamble, the following is stated:

"When calculating the running annual averages, if a sample result is less than the PQL for the monitored PFAS, EPA is proposing to use zero to calculate the average for compliance purposes. For example, if a system has sample results for PFOA that are 2.0, 1.5, 5.0, and 1.5 ppt for their last four quarters at a sample location, the values used to calculate the running annual average would be 0.0, 0.0, 5.0, and 0.0 with a resulting PFOA running annual average of 1.3 ppt. As described in sections VI and VIII of this preamble, EPA is proposing that values below the PQL will not be used to determine compliance with the proposed MCLs as these PQLs are the lowest concentration of analyte that can be reliably measured within specified limits of precision and accuracy during routine laboratory conditions. As such, quantifying concentrations below the PQL for compliance purposes may decrease the precision and accuracy of the measured value and may not be achievable for some individual laboratories."

MDH Comments:

• MDH asserts that any PFAS results from a certified laboratory that are above the laboratory RLs should be included when determining compliance with the MCLs.

o Due to the MCLs for PFOS and PFOA being set at the PQLs, and EPA's proposal to treat any result below the PQL as zero for compliance purposes, systems with valid data from laboratories showing they are out of compliance based on a traditionally-calculated Quarterly Running Annual Average (QRAA) will be treated as in compliance. This is problematic in regard to public perception, as it conflicts with how the QRAA for MCL compliance is typically determined for other contaminants (where results below the MCL are included in QRAA calculations), and moreover reduces the public health protection that could be provided under this proposed rule.

o The example used in the rule preamble is not informative for this issue. Instead, the following example should be considered: if a system has sample results for PFOA that are 3.9, 4.9, 5.0, and 5.1, which results in a QRAA of 4.7 ppt (above the MCL) when all results are included, the proposed rule would consider this for compliance as 0, 4.9, 5.0, 5.1, which results in a QRAA of 3.8 ppt (below the MCL). This difference is created by having just one single result below the PQL that is treated as zero. While this system is obviously not reliably and consistently below the MCL, the proposed rule would treat it as in compliance. MDH is not comfortable treating such a case as in compliance.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. The EPA notes it has included additional illustrative examples of compliance calculations in the final rule preamble section VIII.B.3.

Oklahoma Department of Environmental Quality (DEQ) (Doc. #1616, SBC-043045)

Compliance Calculations

If a sample result is less than the practical quantitation limit (PQL) for a regulated PFAS, zero is to be used for that analyte in calculations, and 141.903(f)(l)(i)(C) provides the PQL for the six regulated PFAS. Clarification is needed of what values would be used if the PQL's for these contaminants change.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. Additionally, the EPA evaluates NPDWRs as part of the Six Year Review process. Any changes made to the regulations, including new PQLs, would follow this process outlined under SDWA.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044041)

22. EPA requests comment on whether EPA should consider an alternative approach to what is currently proposed when calculating compliance with proposed MCLs. Specifically, in the case where a regulated PFAS is detected but below its proposed PQL, rather than using zero for the measurement value of the specific PFAS in the running annual average compliance calculation, that the proposed rule trigger levels be used as the values in calculating the running annual average for compliance purposes.

a. CWUC strongly disagrees with the use of any value other than zero for measurements below the PQL when determining compliance, because the reliability and accuracy of data below the PQL is not certain enough to use in a running annual average. This methodology is also inconsistent with all other chemical contaminant rules. Align this rule with SOC, VOC, DBPs. Include cumulative/additive MCLs over the HI, below detection are counted as zero, and less than half the MCL (ie the TL) qualifies the system for reduced monitoring.

b. This is yet another example of why raising the Trigger Level to 4.0 ppt and the MCL to 8.0 ppt is advisable. That data would be readily available and is confirmed to be accurate and reliable, and would negate the necessity to use j-flag data for compliance calculations.

c. CWUC also does not support using trigger levels to determine Running Annual Averages. That is not in alignment with any other rule. RAA should only be determined based on the MCL.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. Please see sections 8.8 and 8.1.2 of the EPA response in this *Response to Comments* document for discussion of rule trigger levels for reduced triennial monitoring and compliance monitoring requirements, respectively. The EPA clarifies for the commenter that in

the final rule, the RAA is not compared to the trigger levels or used to determine monitoring frequency, but is only compared to the MCLs for compliance determination purposes. Additionally, please see section 5.1.2 of the EPA response in this *Response to Comments* document for a discussion of the relationship between the PFOA and PFOS MCLs and PQLs.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043082)

Monitoring Requirements

The Agency is providing a 3-year timeline for water systems subject to the rule to perform initial monitoring requirements for PFAS at each entry point to the distribution system. The initial monitoring requirements may be waived for some systems that are either participating in UCMR 5 or have participated in eligible state monitoring programs since January 2019. Initial monitoring will determine if systems are eligible for a reduced monitoring frequency under the proposed framework and if the system will need to install treatment (or take non-treatment action) to reduce PFAS to levels below the MCL. According to the Proposal, compliance with the rule be determined using the running annual average (RAA) at each entry point to the distribution system. As part of the calculation of the RAA, EPA is also proposing that systems use zero ppt for results that are below the practical quantification limit (PQL) of 4.0 ppt. At the same time, EPA is proposing that to calculate the RAA for determining a system's eligibility for reduced monitoring, that only values below the detection limit be considered as zero ppt and all reported results above the detection limit be used. The following sections provide a detailed review of these requirements and their proposed alternatives.

In addition, the language in 141.903(f)(2)(i) is worded in a confusing way. It could be interpreted to mean that having an average Hazard index for a quarter over the MCL means that you are out of compliance with the MCL. This is not aligned with the 141.903(f)(1) that clearly states that compliance is determined via a running annual average of four quarters.

EPA Response: The commenter's characterizations of the requirements of the proposed rule are generally accurate, with one exception. The EPA clarifies that it is not the case that initial monitoring requirements are being "waived" for systems with existing data meeting the requirements specified under the NPDWR. Instead, a water system may submit previously-collected data consistent with the rule requirements and then the state can use these as initial monitoring data to determine the monitoring schedule required at the start of the compliance monitoring period. The EPA also clarifies that the RAA is used to judge compliance with the MCLs and is not relevant to determining monitoring frequency. Instead, eligibility for reduced monitoring is determined based on individual sampling results from prior rounds of monitoring, and a single sample result can prompt more frequent monitoring. This topic is discussed in more detail under section 8.1.2 of the EPA response in this *Response to Comments* document.

With respect to the comment about §141.903(f)(2)(i), the EPA has updated the language in the final rule to reflect that the RAA must exceed the MCL for there to be a MCL violation. Results equal to the MCL do not constitute a violation.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-044876)

DEP supports using zero in the running annual average (RAA) compliance calculation for PFAS levels detected below either a practical quantitation level (PQL) or minimum reporting level (MRL). By definition, the PQL is the lowest level that can be consistently measured with precision and accuracy; therefore, any detections below that level are not accurate or precise and should not be used for compliance determination or any other regulatory decision making. Additional comments relative to the proposed PQLs and detection and reporting limits are provided later in this letter.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. Please see sections 8.8 and 8.1.2 of the EPA response in this *Response to Comments* document for discussion of rule trigger levels for reduced triennial monitoring and compliance monitoring requirements, respectively.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044099)

ASDWA recommends that EPA clarify and revise conflicting language about the capability and expectation of laboratories to report PFAS detections at the lowest levels for reduced monitoring and compliance.

ASDWA's members could not reach a consensus on supporting the methods EPA has used to calculate the running annual average for determining both compliance and reduced monitoring. The PQL is defined as the "lowest concentration of an analyte that can be reliably measured within specified limits of precision and accuracy during routine laboratory operating conditions." Clarification is needed to explain how sample results with detections below the PQLs can or cannot be used for both reduced monitoring and compliance.

Some primacy agencies have highlighted that allowing the use of samples with PFAS detection levels lower than the PQL "for purposes of screening and to determine compliance monitoring frequency" conflicts with the definition and use of the PQL. The use of this language creates an expectation that laboratories can accurately report detection levels of 1.3 ppt. Primacy agencies have reported that some laboratories can reliably detect PFOA and PFOS as low as 1.8 ppt, but they cannot accurately detect them at 1.3 ppt. This information further supports setting the trigger levels for reduced monitoring at one-half (instead of one-third) of the MCLs.

Based on the rule proposal, it appears that the 1.3 ppt for PFOA and PFOS is meant to be used only for determining reduced monitoring, and that EPA is not expecting laboratories to be able to test to these low levels. If this is true, the rule should be clearer. Additionally, the current understanding is that any data below the PQL of 4.0 ppt will be used solely for calculating the running annual average for reduced monitoring and that anything deemed "non-detect" will count as "zero" for this calculation. Again, the proposed rule as written is unclear on this important issue, and it is unclear whether EPA is expecting a laboratory to be able to detect PFOA and PFOS at 1.3 ppt for that data to be eligible for reduced monitoring. ASDWA

recommends that EPA include an example of this calculation within the rule and supporting materials to reduce confusion.

Example of a running annual average calculation for initial monitoring to determine whether a system will qualify for reduced monitoring:

Quarter 1 Sampling – Non-Detect (0)

Quarter 2 Sampling - (2.2 ppt)

Quarter 3 Sampling – Non-Detect (0)

Quarter 4 Sampling – Non-Detect (0)

Running Annual Average: 0.55 ppt

Even when laboratories can test below the PQL, some primacy agencies have experienced significant issues with laboratory quality assurance and control for these results and question the legality of changing the monitoring frequency on levels below what laboratories can reliably and consistently report. In addition, some states with existing PFAS drinking water regulations only allow reduced monitoring for water systems that have samples with non-detects.

ASDWA's members could not reach a consensus on using either j-flag qualified or non-qualified data below the PQL of 4.0 ppt for compliance, noting some primacy agencies could not use jflag data, some want to use j-flag results below the 4.0 ppt PQL, and other primacy agencies reported some labs have the ability to report results around a 2.0 ppt MRL without the use of a j-flag. Some primacy agencies have highlighted that having the PQL set at 4.0 ppt for PFOA and PFOS in the proposed rule creates a protocol for laboratories to report any sample results with lower-level detections and non-detects as zeros. ASDWA recommends that EPA provide additional clarification regarding the Agency's expectations as to how laboratories will report levels below the PQL. Some of ASDWA's members have noted that primacy agencies may want the numerical results of these sampling events regardless of being below 4.0 ppt. Additionally, if EPA has lifetime health advisories for levels less than the PQL, the public will demand to see any data a system has below the PQL. Finally, primacy agencies have highlighted variations and inconsistencies in how laboratories report and primacy agencies accept (or do not accept) j-flag qualified data.

Some primacy agencies have asserted that using zeros for samples below 4.0 ppt does not calculate the RAA appropriately if the quarterly samples below 4.0 ppt have non-qualified detections just under 4.0 ppt (e.g., 3.9 ppt). These primacy agencies have noted that if a system's quarterly samples include non-qualified data below 4.0 ppt, that would result in a system being over the 4.0 MCL if included in the running annual average (rather than included as a "zero"), the system is not "reliably and consistently below the MCL" and should not be considered in compliance determinations based on the data reported to the primary agency.

Additionally, these primacy agencies noted that public communication surrounding the use of zeros for compliance calculations when there is a validated number from the laboratories will be

challenging for primacy agencies and water systems. These primacy agencies are particularly concerned with public communication when levels below 4.0 ppt may equate to a violation of the RAA when using zeros would not, as noted above.

Other primacy agencies have asserted that the rule should not allow either j-flag qualified data or non-qualified data below 4.0 ppt to be used in making compliance determinations, and these sample results should remain as "zero" within the calculations. These primacy agencies argued that if EPA can verify that most laboratories can reliably detect lower than 4.0 ppt, then EPA should lower the PQL within the regulation rather than using data below the PQL for compliance calculations. In this case, anything below 2.0 ppt would count as "zero" in a compliance determination. Some ASDWA members have highlighted that they have laboratories capable of reliably and accurately reporting down to 1.8 ppt.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. Please see sections 8.8 and 8.1.2 of the EPA response in this *Response to Comments* document for discussion of rule trigger levels for reduced triennial monitoring and compliance monitoring requirements including use of values below PQLs. In the final rule, the EPA has provided clarification on use of these values for their intended purpose, including several illustrative examples of compliance calculations and monitoring frequency calculations (see sections VIII.B.3 and VIII.A.2). The commenter is correct in their understanding that any data below the PQLs will be used solely to determine monitoring frequency; for the calculation of the RAAs that support compliance determination, results below the PQL are treated as zero. Additionally, monitoring frequency is not based on averages, but rather individual sample results. Regarding laboratory capacity and capability, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

For a response to the commenter's statements about "j-flag data" and "non-qualified data below the PQL," please see sections 8.2 and 8.8 of the EPA response in this *Response to Comments* document. With respect to the potential for the public to request "any data a system has below the PQL," every CWS is required to include information on detected contaminants in its CCR. Under this rule, 141.151(d) defines "detected" for the regulated PFAS. Moreover, the EPA considers results at or above the trigger levels as "detections." With respect to the concern that "having the PQL set at 4.0 ppt for PFOA and PFOS in the proposed rule creates a protocol for laboratories to report any sample results with lower-level detections and non-detects as zeros," the EPA has addressed this by specifying in § 141.901(b)(2)(iii) that laboratories must report data for concentrations as low as the trigger levels, if available. As the EPA develops implementation materials following final rule promulgation, the agency will consider additional resources to support states and water systems for notifying their customers.

Village of Woodbury (Doc. #1629, SBC-042954)

8. If the EPA opts to utilize a running annual average to calculate compliance, we believe it is appropriate for the calculation to include zero for concentrations that are below the detectable

limit. It would be inappropriate for the EPA to require suppliers to utilize the trigger level in these calculations knowing the trigger level is not based on actual detectable levels of contaminants within the water supply, but rather just the notable presence at any concentration.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

Aidan Cecchetti (Doc. #1640, SBC-044379)

The commenters have also prepared the following comments on topics related to the proposed PFAS NPDWR that were not specifically requested by EPA:

• The proposed requirements detailed in §141.903(f) of the new regulations appear to require all samples collected at a compliance location within a monitoring period to be included in compliance calculations (e.g., "If more than one compliance sample for the analyte is available in the quarter, systems must average all the results in a quarter…") The commenters request clarification from EPA on the meaning for "compliance sample" in this context. Does "compliance samples" refer to all samples collected from a compliance location? Might this encourage water systems to take multiple samples during a monitoring period to try to dilute the impact of a sample with a concerning result? The commenters suggest that EPA should consider requiring PFAS monitoring plans to be reviewed and approved by state primacy agencies that would indicate the number of samples to be collected during each monitoring period. The commenters contend that this type of approach may help avoid purposeful under- or over-sampling by water systems to obtain more advantageous average results. Other approaches may help achieve the intended result.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. The EPA does not define a compliance sample as a sample collected at a compliance location. Rather, the EPA defines a compliance sample as sample a system is directed to collect by a state or primacy agency. States identify the required monitoring schedule for a system and in what circumstances, if any, a system must collect and analyze a confirmation sample. Aside from a state-directed confirmation sample, additional samples collected by the system would be considered voluntary samples, not compliance samples, and the results of voluntary samples are not to be included in quarterly averages. In most circumstances, the EPA anticipates that a system would have no more than two compliance samples (the routine sample and a confirmation sample, if required) per quarter, and in both cases the sampling would occur at the direction of the primacy agency. This approach avoids the potential for problems associated with any "under- or over-sampling by water systems to obtain more advantageous average results," as the commenter states. The regulatory text has been revised as needed to specifically refer to the use of compliance-monitoring samples to demonstrate that MCLs are being met. With respect to the requirement for primacy packages to include a monitoring plan that addresses when systems will be scheduled to conduct initial monitoring, in light of public

comments, the EPA removed this requirement from the final rule. Please see section 11.1 of the EPA response in this *Response to Comments* document for more information.

Aidan Cecchetti (Doc. #1640, SBC-044373)

EPA requests comment on whether EPA should consider an alternative approach to what is currently proposed when calculating compliance with proposed MCLs. Specifically, in the case where a regulated PFAS is detected but below its proposed PQL, rather than using zero for the measurement value of the specific PFAS in the running annual average compliance calculation, that the proposed rule trigger levels (1.3 ppt for PFOA and PFOS and 0.33 of each of the HI PFAS PQLs (i.e., PFHxS=1.0, HFPO-DA=1.7, PFNA=1.3, and PFBS=1.0)) be used as the values in calculating the running annual average for compliance purposes (pg. 18682 Federal Register Volume 88, Number 60).

• The commenters agree with EPA's proposal to use zero to calculate RAAs for compliance purposes when a sample result is less than the PQL. It is the commenters' opinion that EPA should not at this time consider the alternative approach of using a trigger level that is set below the PQL in calculating RAAs when contaminants are detected below the PQL. This alternative approach would be inappropriate because it could lead to inequitable implementation of the rule based on laboratory analytical capabilities. EPA has determined that detections of PFAS below the PQL are not reliably quantifiable, but method detection limits for laboratories may be substantially lower than the proposed trigger levels. Therefore, it cannot be assumed that a PFAS detection below the PQL is necessarily greater than the trigger level or that quantified levels below the trigger level are of adequate precision to determine that the trigger level has not been exceeded. Unless EPA can demonstrate that laboratory analytical capabilities are already broadly precise enough that the trigger level of 1.3 ppt for PFOA and/or PFOS can be adequately detected and reliably distinguished from a detection of a lower concentration, it is inappropriate to use this value for compliance calculations. If EPA can demonstrate the above, EPA should consider lowering the PQL for PFOA and PFOS. In summary, it is the commenters' opinion that it would be inappropriate to require water systems to use any non-zero value in calculations of RAAs when compounds are detected below the PQL, even in the name of potentially increased public health protection.

• Alternatively, it may be appropriate to use a trigger level below the PQL in compliance determination calculations if there should be a requirement for regulatory agencies to include a minimum method detection limit for accreditation for laboratories to perform quantification of PFAS.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. Additionally, the EPA did not propose to establish a detection limit for PFAS in the proposed rule and has not done so in the final rule. For discussion of PQLs, please see section 7.2 of the EPA response in this *Response to Comments* document and section VII of the final rule preamble. Regarding rule trigger levels, please see section 8.8 of the EPA response

in this *Response to Comments* document. As discussed in the proposed and final rule preambles, results below the PQLs do not have the same precision and accuracy as those at or above the PQLs, and thus are not being utilized in the compliance calculation. The EPA has not stated that results below PQLs "are not reliably quantified." Moreover, the EPA notes that though the definition of the PQL is "the lowest level at which contaminant can be reliably quantified within specific limits of precision and accuracy during routine laboratory operating conditions using the approved methods", that does not suggest that measurements below the PQL should not be used to support monitoring frequency decisions, even if those results are associated with a lower level of precision and accuracy than higher-level results.

Aidan Cecchetti (Doc. #1640, SBC-044380)

• There do not appear to be separate compliance calculation requirements for systems that utilize treatment to remove PFAS. The commenters are concerned that requiring water systems that employ treatment to include all samples collected from a compliance location in the compliance calculations could discourage those water systems from taking investigatory samples out of fear of exceeding the new standards. The commenters encourage EPA to consider this and revise the proposed rule with additional provisions to help avoid discouraging systems from taking investigatory samples. As with the previous comment, requiring water systems to submit monitoring plans to primacy agencies for review and approval would help water systems and primacy agencies to clarify what samples must be included in compliance calculations to avoid these types of issues.

We thank EPA for their continued efforts toward implementing the federal SDWA and protecting public health. We hope that our input will help EPA to develop practicable and enforceable regulations that will be effective in limiting nationwide exposure to PFAS in drinking water. We encourage you to reach out to us at the contact information provided with this contact letter should EPA have any questions or require clarification on any of our comments.

Warm regards,

Aidan Cecchetti, PhD, PE

Scott E. Miller, PhD, PE

EPA Response: The EPA agrees that there are no separate requirements for systems that are treating their water for PFAS; please see section 8.2 of the EPA response in this *Response to Comments* document. However, the EPA disagrees that its regulatory framework discourages the collection of voluntary, investigatory samples because voluntary samples that go beyond the state-established requirements for compliance samples are not considered in the RAA or as part of establishing monitoring frequency. The EPA also disagrees that monitoring plans are needed specifically to clarify which samples will be included in compliance calculations; the agency has made it clear that only samples collected based on a primacy-agency requirement are to be used

to support compliance determinations. For samples collected during the initial monitoring period, the most recent data are to be used (see § 141.902(b)(1)). For further discussion of the proposed requirement for primacy packages to include a monitoring plan, which was removed from the final rule, please see section 11.1 of the EPA response in this *Response to Comments* document.

Massachusetts Water Resources Authority (Doc. #1645, SBC-043286)

d. Rule Requirements Must Employ High Quality Data

EPA's proposed approach to consider monitoring results below the practical quantification limits (PQLs) as zero is appropriate for the MCL. This approach should also be applied to criteria for reduced monitoring. PQLs represent nationally achievable and accurate reportable limits. Results below the PQL should not be reported for regulatory purposes, as not all laboratories and analytical equipment can reliably perform below the PQL. Analytical resources for implementing this proposed regulation will be in high demand. That demand may limit the availability of laboratory capacity to analyze samples; crafting a regulation that bases sampling requirements on levels below the PQL is impractical and unfair. Limited, highly sensitive analytical laboratory capacity may result in additional PWSs having to collect quarterly samplings, further increasing the overall cost for implementation of this regulation. MWRA recommends that EPA assume all monitoring results below the PQL are zero for the purposes of reduced monitoring.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. Regarding rule trigger levels and compliance monitoring requirements including use of results below PQLs for monitoring frequency determination purposes, please see sections 8.8 and 8.2.1 of the EPA response in this *Response to Comments* document.

Savannah River Nuclear Solutions LLC (Doc. #1647, SBC-043330)

Comment 2

Section IX.B. Monitoring and Compliance Requirements (pg. 18682)

SRNS supports EPA's proposal to utilize a running average annual approach to calculate compliance with the proposed rule. As proposed, a single occurrence of perfluorooctanoic acid (PFOA) or perfluorooctanoic sulfonate (PFOS) that is slightly above the proposed maximum contaminant levels (MCLs) would not result in an MCL violation, assuming other quarterly samples remain below the MCLs. SRNS also supports EPA's proposal to use zero (0) to calculate the average for compliance purpose when calculating the running annual averages if a sample result is less than the PQL for the monitored PFAS and allowing water systems to collect and analyze one sample per three-year compliance period if the systems does not detect regulated PFAS in their system at or above the trigger level.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. Requirements for systems to be determined eligible for triennial monitoring during the compliance monitoring period are discussed in section 8.1.2 of the EPA

response in this *Response to Comments* document, and requirements to be determined eligible for triennial monitoring after the initial monitoring period are discussed in section 8.1.1 of the EPA response in this *Response to Comments* document.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044185)

7. NCDEQ recommends that EPA clarify and fix conflicting language about the capability and expectation of laboratories to report PFAS detections at the lowest levels for reduced monitoring and compliance.

NCDEQ requests additional clarification on the methods EPA has used to calculate the running annual average for determining both compliance and reduced monitoring. The PQL is defined as the "lowest concentration of an analyte that can be reliably measured within specified limits of precision and accuracy during routine laboratory operating conditions." Clarification is needed to explain how sample results with detections below the PQLs can or cannot be used for both reduced monitoring and compliance.

Allowing the use of samples with PFAS detection levels lower than the PQL "for purposes of screening and to determine compliance monitoring frequency" conflicts with the definition and use of the PQL. The use of this language creates an expectation that laboratories can accurately report detection levels of 1.3 ppt. Some states have reported that many laboratories can reliably detect PFOA and PFOS at 2.0 ppt, but they cannot accurately detect them at 1.3 ppt.

Based on the rule proposal, it appears that the 1.3 ppt for PFOA and PFOS is meant to be used only for determining reduced monitoring, and EPA is not expecting laboratories to be able to test to these low levels, but the rule should be clearer. Additionally, the current understanding is that any data below the PQL of 4.0 ppt will be used solely for calculating the running annual average for reduced monitoring and that anything deemed "non-detect" will count as "zero" for this calculation. Again, the proposed rule as written is unclear on this important issue, and it is unclear whether EPA is expecting a laboratory to be able to detect PFOA and PFOS at 1.3 ppt for that data to be eligible for reduced monitoring. NCDEQ recommends that EPA include an example of this calculation within the rule and supporting materials to reduce confusion.

Example of a running annual average calculation for initial monitoring to determine whether a system will qualify for reduced monitoring:

Quarter 1 Sampling – Non-Detect (0)

Quarter 2 Sampling - (2.2 ppt)

Quarter 3 Sampling – Non-Detect (0)

Quarter 4 Sampling – Non-Detect (0)

Running Annual Average: 0.55 ppt

Even when laboratories are able to test below the PQL, there may be issues with laboratory quality assurance and control for these results and question the legality of changing monitoring frequency on levels below what laboratories can reliably and consistently report.

Having the PQL set at 4.0 ppt for PFOA and PFOS in the proposed rule creates a protocol for laboratories to report any sample results with lower-level detections and non-detects as zeros. NCDEQ recommends that EPA provide additional clarification regarding the Agency's expectations as to how laboratories will be reporting levels below the PQL. NCDEQ wants the numerical results of these sampling events regardless of being below 4.0 ppt. Additionally, if EPA has lifetime health advisories for levels less than the PQL, the public will demand to see any data a system has below the PQL.

Using zeros for any samples below 4.0 ppt does not calculate the RAA appropriately if the quarterly samples below 4.0 ppt have non-qualified detections that are just under 4.0 ppt (e.g., of 3.9 ppt). If a system's quarterly samples include non-qualified data below 4.0 ppt, that would result in a system being over the 4.0 MCL if included in the running annual average (rather than included as a "zero"), the system is not "reliably and consistently below the MCL" and should not be considered in compliance determinations based on the data reported to the primary agency.

Public communication surrounding the use of zeros for compliance calculations when there is a validated number from the laboratories will be challenging for state agencies and water systems. We are particularly concerned with public communication when levels below 4.0 ppt may equate to a violation of the RAA when using zeros would not, as noted above.

The rule should not allow either j-flag qualified data or non-qualified data below 4.0 ppt to be used in making compliance determinations, and these sample results should remain as "zero" within the calculations. If EPA can verify that most laboratories can reliably detect lower than 4.0 ppt, then EPA should lower the PQL within the regulation rather than using data below the PQL for compliance calculations. In this case, anything below 2.0 ppt would count as "zero" in a compliance determination.

In addition, the reporting and recordkeeping requirements for compliance within the rule should provide an option for not requiring the RAA to be reported by the laboratories if the state agency performs the RAA calculations for the water system.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. Please see sections 8.8 and 8.1.2 of the EPA response in this *Response to Comments* document for discussion of rule trigger levels for reduced triennial monitoring and compliance monitoring requirements including use of values below PQLs. In the final rule, the EPA has provided clarification on use of these values for their intended purpose, including several illustrative examples of compliance calculations and monitoring frequency calculations (see sections VIII.B.3 and VIII.A.2). The commenter is correct in their understanding that any data below the PQLs will be used solely to determine monitoring frequency; for the calculation of RAAs that support compliance determinations results below the PQL are treated as zero.

Additionally, monitoring frequency is not based on averages, but rather individual sample results. Regarding laboratory capacity and capability, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

For a response to the commenter's statements about "j-flag data" and "non-qualified data below the PQL," please see sections 8.2 and 8.8 of the EPA response in this *Response to Comments* document. With respect to the potential for the public to request "any data a system has below the PQL," every CWS is required to include information on detected contaminants in its CCR. Under this rule, 141.151(d) defines "detected" for the regulated PFAS. Moreover, the EPA considers results at or above the trigger levels as "detections." With respect to the concern that "having the PQL set at 4.0 ppt for PFOA and PFOS in the proposed rule creates a protocol for laboratories to report any sample results with lower-level detections and non-detects as zeros," the EPA has addressed this by specifying in § 141.901(b)(2)(iii) that laboratories must report data for concentrations as low as the trigger levels, if available. Regarding primacy agency reporting requirements and reporting of the RAA, please see section 11.3 of the EPA response in this *Response to Comments* document. As the EPA develops implementation materials following final rule promulgation, the agency will consider additional resources to support states and water systems for notifying their customers.

Nebraska Department of Environment and Energy (NDEE) (Doc. #1653, SBC-043208)

• EPA requested comment on an alternative approach to the proposed compliance calculation for MCLs where detects below the PQL use a zero value for the running annual average.

o The Department supports this idea and suggest the trigger level be set at one-half of the PQL which is consistent with standard assessment methods used in determining compliance with surface water quality standards under the Clean Water Act.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. Regarding rule trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document.

Nebraska Department of Environment and Energy (NDEE) (Doc. #1653, SBC-043203)

o A running annual average of quarterly monitoring results that may be less than the PQL and have a 50% error rate is expected to be cut in thirds and used to make compliance determinations. These factors significantly decrease the confidence in the monitoring to hold public water systems liable for the monetary ramification of compliance.

• The Department suggests removing the proposed triggers levels and using the PQL as the trigger. However, there are benefits of a trigger level that is less than the PQL as it allows the PWS to observe increasing levels of PFAS and more fully prepare to address PFAS contamination through increased monitoring.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. Regarding rule trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenter's claim that the monitoring results "have a 50% error rate" and refers to sections 5.1.2 and 7 of the EPA response in this *Response to Comments* document regarding laboratory considerations and analytical methods.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044422)

EPA requests comment on whether EPA should consider an alternative approach to what is currently proposed when calculating compliance with proposed MCLs. Specifically, in the case where a regulated PFAS is detected but below its proposed PQL, rather than using zero for the measurement value of the specific PFAS in the running annual average compliance calculation, that the proposed rule trigger levels (1.3 ppt for PFOA and PFOS and 0.33 of each of the HI PFAS PQLs (i.e., PFHxS=1.0, HFPO– DA=1.7, PFNA=1.3, and PFBS=1.0)) be used as the values in calculating the running annual average for compliance purposes.

• DOH is concerned with the concept of using estimated data to impact so significantly a utilities action and a laboratories ability to analyze at the proposed triggers. If a PFAS is detected above the MDL but below the PQL, then it would bias the running annual average downwards to tally as a zero. It appears that anything below the PQL is considered as an estimate, but that depends on where the laboratory MDL and LOQ are in relation the PQL. It is unclear whether laboratories can analyze with accuracy or precision at the triggers set in the proposed rule, especially for PFHxS and PFBS.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. Regarding rule trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document. The EPA also clarifies for the commenter that while the PFOA and PFOS trigger levels are below their respective PQLs, the trigger levels for PFHxS and PFBS (or any of the Hazard Index PFAS) are below their respective PQLs; the final rule trigger level for the Hazard Index is 0.5 and all of the HBWCs for the four Hazard Index PFAS (2000 ppt for PFBS or 10 ppt for the other Hazard Index PFAS) are at least twice their respective PQLs (3.0 ppt for PFHxS and PFBS, 4.0 ppt for PFNA, 5.0 ppt for HFPO-DA). Therefore, there are no pertinent analytical limitations for these four PFAS.

City of Allentown and Lehigh County Authority (LCA), Pennsylvania (Doc. #1667, SBC-043678)

A final point about the proposed MCLs for PFOA and PFOS is that compliance is proposed to be based on an annual running average. The proposed rule allows the use of a "0" (Zero) in the calculation when results are shown are below the PQL and MDL. The EPA is requesting comment on whether the proposed trigger level of 1.3 ppt should be used in lieu of "0." This approach would not be appropriate nor reliable. The EPA should not require arbitrary numbers to

be used in a compliance calculation. Should a laboratory result be reported at a value less than the PQL and MDL, it is reasonable and appropriate to report that result as "0" (Zero).

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

City of Hillsboro, Oregon (Doc. #1668, SBC-043119)

Furthermore, Hillsboro Water requests that EPA clarify the exact reporting needs for both the utility reporting to primacy agencies as well as how to address reporting in the CCR. For example, given that the Minimum Detection Level (MDL) for the approved methods is 4 ppt for PFOS and PFOA and the Maximum Contaminant Level (MCL) for the mentioned PFAS is also 4 ppt, but the trigger level for reduced monitoring is 1.3 ppt. Some laboratories may be able to detect PFAS at lower levels than the method MDL (often referred to as J-flagged data). This data means a substance was detected, but the value may not be accurate or precise because it is below the method MDL. Additionally, the proposed NPDWR specifies that the MCL is determined by a running annual average (RAA) calculation, but that detections must also be reported. For both RAA calculation and reporting in the CCR, will utilities report the official lab result (4ppt or greater), or will utilities be required to report detections (including J-flagged data), though they may be below the MDL? EPA specifically used the word "detected" in the proposed NPDWR; however, clarification is needed to differentiate a detection and a detection above the MDL.

Hillsboro Water request that EPA clarify these reporting requirements and provide utilities and primacy agencies with guidance on how to communicate to the public on these technical details.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. The EPA clarifies for the commenter that the EPA-approved methods do not include MDLs, as the commenter stated, but rather define and require the confirmation of MRLs which are distinctly different from MDLs. For the PFAS NPDWR, the EPA did not define MRLs for PFAS contaminants, but established PQLs, as discussed in sections V and VII of the final rule preamble, to evaluate analytical feasibility for the determination of MCLs. Data below these PQLs are not used for compliance determinations, which is calculated using a RAA, but these data are used for determining if a system is eligible for reduced monitoring (please see section 8.2.1 of the EPA response in this *Response to Comments* document for discussion of compliance monitoring requirements and section 8.8 of the EPA response in this *Response to Comments* document for rule trigger levels). The CCR Rule requires CWSs to provide consumers with information about detected levels of PFAS in their reports. CCR reporting is based on detected contaminants; for the purpose of CCR reporting, "detected" is defined as reported at a concentration equal to or exceeding a trigger level (please see section IX of the preamble to the rule and section 9.1 of the EPA response in this *Response to Comments* document for more information on CCR requirements). The concentrations reported to a system by a laboratory (for valid compliance samples) would be reported to the primacy agency, consistent with any primacy agency-specific requirements.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-044917)

Section 5.3: Compliance calculation

EPA is proposing a RAA approach to compliance calculation. PWSs must take quarterly samples, a minimum of 4 per year per EPTDS, and use the average the four. This is consistent with other regulation and would provide stability and familiarity with sampling calculations.

Cleveland Water also strongly supports EPA's proposal to report values below the PQL as 0 for the purpose of calculating the RAA. An alternate approach EPA considered in the proposal is using the trigger level (1/3 of the PQL), as the value when concentrations are below the PQL. If EPA were to adopt this version, no water system would be able to qualify for reduced monitoring. If a utility has all quarterly samples below 4.0 ppt, the proposed method will give them a RAA of 0, and they would be below the trigger level and qualify for reduced monitoring. That same utility under EPA's alternative approach would have a RAA of 1.3 ppt. The preamble states that water systems qualify for reduced monitoring if it "do[es] not detect regulated PFAS in their system at or above the rule trigger level." So being at the trigger level does not qualify a system for reduced monitoring.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. The final rule reflects that the RAA is only used to determine compliance with the MCLs, not to determine monitoring frequency (which, instead, is based on individual sample results). For the purposes of determining monitoring frequency only, all data (including laboratory results below the PQLs) from individual samples will be used. Please see section 8.1.2 of the EPA response in this *Response to Comments* document regarding eligibility for different sampling frequencies and section 8.8 of the EPA response in this *Response to Comments* document on rule trigger levels for reduced triennial monitoring.

Association of California Water Agencies (ACWA) (Doc. #1675, SBC-044934)

COMMENT 4 – TRIGGER LEVEL – The trigger levels should not be used for compliance purposes.

EPA is proposing the use of a trigger level for less frequent compliance monitoring under certain circumstances [FN25: 88 Fed. Reg. at 18, 681.]. EPA plans for the trigger level to be used both for calculating the running annual average (RAA) for compliance determination and for determining the frequency of compliance monitoring. ACWA supports the flexibility that EPA has introduced related to the trigger level, but ACWA has concerns about using any numeric value below the practical quantitation limits (PQL) [FN26: PQL is the lowest concentration that PFOA and PFOS can be reliably quantified within specific limits of precision and accuracy during routine laboratory operating conditions. (88 Fed. Reg. at 18,666).] for compliance purposes. Additionally, ACWA has concerns about laboratory capacity issues for values associated with requiring numeric values below the PQL.

EPA concluded "that 4.0 ppt is the lowest concentration that PFOA and PFOS can be reliably quantified within specific limits of precision and accuracy during routine laboratory operating conditions." [FN27: 88 Fed. Reg. at 18,666.]. ACWA agrees with the EPA that values below the PQL are less precise and accurate. As such, ACWA believes that values below the PQL should not be used for compliance purposes, including calculating the RAA. ACWA supports the current proposal to use zero for calculating RAA whenever a sample result is below its PQL. ACWA does not support using the trigger level for calculating RAA when PFAS are detected below their PQL.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. The final rule reflects that the RAA is only used to determine compliance with the MCLs, not to determine monitoring frequency (which, instead, is based on individual sample results). For the purposes of determining monitoring frequency only, all data (including laboratory results below the PQLs) from individual samples will be used. Please see section 8.1.2 of the EPA response in this *Response to Comments* document regarding eligibility for different sampling frequencies and section 8.8 of the EPA response in this *Response to Comments* document on rule trigger levels for reduced triennial monitoring.

New York State Department of Health (NYS DOH) (Doc. #1677, SBC-044959)

21. Please see 88 FR 18697, Section XIII.C(1)(f) which indicates that systems that have an MCL exceedance will collect one additional sample from the relevant entry point to confirm the results. This appears to be inconsistent with compliance monitoring prescribed for the running annual average calculation.

22. In accordance with Section 141.XX.c(b)(2)(iv) states may delete results of obvious sampling errors from the compliance calculations. It is not clear what constitutes an obvious sampling error, or if this latitude extends beyond sampling and also affords states the freedom to delete results due to obvious analytical errors or other circumstances. While we appreciate the discretion afforded to states, we believe that this provision is too broad, and provides an opportunity for inconsistent application. Analysis of the field reagent blank (FRB) should identify any sample contamination that occurred during sample collection. States should be given the ability to invalidate results with detections in the FRB as well as the ability to invalidate results with detections in the laboratory blanks.

EPA Response: The portion of the Federal Register Notice (FRN) cited in this comment (section XIII.C(1)(f)) is a summary of the method for estimating the costs associated with rule implementation. The commenter is correct that requirement for confirmation samples to be collected after an MCL exceedance is not found in the proposed Code of Federal Regulations (CFR) amendments and is therefore not binding on systems. Rather, the final rule does allow for confirmation samples. Whether and under what circumstances a confirmation sample might be required is a decision made by each primacy agency. However, in the location the commenter cited, for the purposes of analyzing potential costs, the EPA made one uniform assumption about

whether confirmation samples would be needed and described the assumption it used in its approach to modeling. Thus, as this is not a rule requirement, accounting for all systems taking an additional confirmation sample in the EPA's monitoring cost estimates would likely reflect an overestimate of real monitoring costs borne by water systems.

Regarding the comment on the proposed rule CFR section 141.XX.c(b)(2)(iv), the final-rule language about states having the discretion to invalidate results associated with obvious sampling errors is consistent with precedent, as there is parallel language in the portions of the regulations addressing most other chemical contaminants (see §141.23(f)(3), § 141.24(f)(13), and § 141.24(h)(9)). "Sampling" errors may include those that occur during sample collection and/or preparation. State regulations or guidance may provide additional clarity about the types of results that may be invalidated in that state. The EPA disagrees that it is necessary to provide additional clarity in the PFAS regulations, as the rules provide specific direction on invalidation options. The EPA requires that all samples pass method quality control (QC), including laboratory reagent blank (LRB) and field reagent blank (FRB) samples that would indicate contamination, and any results that do not pass acceptance criteria are considered invalid. The EPA agrees that samples identified as invalid by the laboratory should not be included in compliance calculations. Please see section 8.7 of the EPA response in this *Response to Comments* document regarding background contamination concerns.

New York State Department of Health (NYS DOH) (Doc. #1677, SBC-044942)

4. EPA requested comment on whether an alternative approach to calculating the running annual averages should be considered. The Department does not object to the compliance calculation as initially proposed, with results below the Practical Quantitation Limit (PQL) considered to be 0.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

New York City Department of Environmental Protection (NYCDEP) (Doc. #1679, SBC-044215)

In section IX. A., p. 18682, EPA requests comment on the proposal to use either zero or the trigger level for the purpose of calculating the running annual average. The usage of any value other than the laboratory reported value for performing calculations imparts a bias on the overall results. Replacing raw values with zero underestimates occurrence. Replacing values with the trigger level overestimates the occurrence. Additionally, replacement values add to the overall complexity of compliance reporting procedures.

Sincerely,

Paul V. Rush, Deputy Commissioner Bureau of Water Supply

cc: Lori Emery, Director, Water Quality & Innovation, BWS Charlene Graff, Director, Environmental Health and Safety, BWS Casey McCormack, BLA

Melinda Sherer, BLA

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

City of Vancouver Water Utility, Vancouver, WA (Doc. #1684, SBC-044310)

RAA Calculation:

Vancouver does not support the alternative method for calculating the running annual average where a regulated PFAS is detected but below its proposed PQL, rather than using zero for the measurement value of the specific PFAS in the running annual average compliance calculation, that the proposed rule trigger levels (1.3 ppt for PFOA and PFOS and 0.33 of each of the HI PFAS PQLs (i.e., PFHxS=1.0, HFPO– DA=1.7, PFNA=1.3, and PFBS=1.0)) be used as the values in calculating the running annual average for compliance purposes. 0 ppt should be used in the calculation in these cases.

This same comment applies when the levels are below the MRL and not detectable. 0 ppt should be used in this case as well.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

New Hampshire Department of Environmental Services (NHDES) (Doc. #1690, SBC-044352)

f. Page 18730, Column 3, Bullet 4 – EPA requests comment on whether EPA should consider an alternative approach to what is currently proposed when calculating compliance with proposed MCLs. Specifically, in the case where a regulated PFAS is detected but below its proposed PQL, rather than using zero for the measurement value of the specific PFAS in the running annual average compliance calculation, that the proposed rule trigger levels (1.3 ppt for PFOA and PFOS and 0.33 of each of the HI PFAS PQLs (i.e., PFHxS=1.0, HFPO–DA=1.7, PFNA=1.3, and PFBS=1.0)) be used as the values in calculating the running annual average for compliance purposes.

NHDES Comment – NH suggests using the actual value of any sample result above the recommended reporting limit of 2 ppt when calculating a running annual average (RAA). This will reduce the burden of implementing this rule for non-SDWIS States, as well as the confusion caused by replacing values with zeros for these calculations. In practice, using the actual value (if above the reporting limit of 2 ppt) may be more protective of public health because RAAs would be more conservative and representative of the actual amount of PFAS detected in drinking water, causing more water systems to be out of compliance with the MCL or HI and therefore performing public notification. [Rule Reference: 141.903(f)(1)(iii) – Page 18752, Column 3, 141.903 (f)(2)(iii) – Page 18753, Column 3 and 141.905(b)(2)(iii) – Page 18753, Column 2]

g. Rule Reference: 141.903 (d). Page 18752, Column 2 – (d) Systems monitoring triennially whose sample result equals or exceeds the trigger level of 1.3 ppt for either PFOS or PFOA, or a Hazard Index of 0.33 for PFNA, PFHxS, HFPO–DA, and PFBS must begin quarterly sampling. If the sample result exceeds an MCL, the system will not be considered in violation of the MCL until it has completed one year of quarterly sampling with the triggering sample used as the first quarter of monitoring for the running annual average calculation.

Rule Reference: 141.905(b)(2). Page 18753, Column 1 – (2) Systems monitoring triennially whose sample result is at or exceeds the trigger level as defined by § 141.902(a)(7) of this section must begin quarterly sampling. The system will not be considered in violation of the MCL until it has completed one year of quarterly sampling.

NHDES Comment – NH is against issuing an MCL violation only after a system has completed 1 year of quarterly monitoring following a triennial sample above the MCL. What we often see in NH is operators waiting to address treatment issues until they are notified that the system is in violation of an MCL, mostly due to the cost of replacing filters and resin. Therefore, in NH if a system is sampling annually or triennially and one sample is above the MCL, they are placed on quarterly monitoring and are also issued a notice of violation requiring public notification. We recommend compliance with an MCL be determined as soon as a triennial sample is above the MCL so that 1) operators take action to address treatment and 2) consumers are notified in a timely manner.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

Clean Water Action/Clean Water Fund (Doc. #1697, SBC-045003)

EPA has requested comment on alternative approaches to calculating running annual averages for compliance.

As noted in the comments we joined with NRDC, Earthjustice et al, using monitoring results above the Minimum Detection Level (MDL) to determine MCL compliance would be more consistent with existing NPDWRs and more protective of public health. The proposed procedure for calculating the running annual average in the proposal would use zero for any sample above the MDL but below the Practical Quantitation (PQL). EPA should revisit whether this aspect of the proposal since it discounts sample results that indicate the presence of regulated PFAS at levels that present public health risk.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045033)

EPA has proposed compliance with the MCLs to be determined based on running annual averages (RAAs) at each EPTDS. EPA states (88 Fed. Reg. 18682) that "if a system does not

collect required samples for a quarter, the running annual average will be based on the total number of samples collected for the quarters in which sampling was conducted." NJDEP strongly suggests EPA clarify and explain how this requirement should be implemented in scenarios where this may occur. Particularly, this could impact seasonal systems, missed samples, or a facility being placed offline. NJDEP advises EPA to develop guidance for states to ensure that compliance is determined consistently.

Regarding calculating the RAA to determine compliance with the proposed MCLs, NJDEP recommends that EPA be consistent in implementation of data assessment methodologies for monitoring reduction determinations and RAA calculations for compliance purposes. NJDEP recommends that EPA evaluates requiring laboratories to report data above trigger values but below the PQL. Analytical results at the proposed trigger value are considered reliable enough to determine whether a system can be placed on reduced monitoring; therefore, if a system's sample results are at or above the proposed trigger value, these results should be used in calculating compliance with the MCL.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. Regarding rule trigger levels for reduced triennial compliance monitoring, please see section 8.8 of the EPA response in this *Response to Comments* document. The portion of the comment, "if a system does not collect required samples for a quarter, the RAA will be based on the total number of samples collected for the quarters in which sampling was conducted," is consistent with similar language that applies to most other chemical contaminants with chronic effects. In the final rule, in response to public comments, the EPA updated the quoted language to read, "If a system fails to collect the required number of samples specified in § 141.902 (Monitoring requirements), this is a monitoring violation as described in § 141.905©, and compliance calculations must be based on the total number of samples collected." This revised language underscores the fact that only required compliance samples are considered in the compliance calculations. It is reasonable to assert that reasons for not collecting required samples during a quarter could include all three scenarios the commenter identifies; however, compliance for an active system will be based on those quarters in which samples are collected. If an entry point is not in operation during a specific quarter then no representative sample can be collected. As it develops implementation materials for the PFAS rule, the EPA will consider the suggestion that guidance cover this topic.

<u>State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045106)</u>

7) Way to calculate compliance, <PQL = 0

States should not use qualified/"j" flagged data to calculate compliance with the MCL because these results are estimates. Use of the Running Annual Average when results are quantified above the PQL to calculate compliance with the MCL makes sense if the health effects of PFAS are consistent with other primary drinking water contaminants with chronic health effects. However, using the trigger level of an estimated value to assess compliance does not make sense.

It is more likely that labs can achieve actual, verified concentrations down to 2 ppt, which would be half of the respective MCL for PFOA or PFOS, not 1.3 ppt which may be "j" flagged or qualified data as the result of an estimated concentration. Use of estimates in a regulatory framework is not an established practice under the Safe Drinking Water Act. These estimates would then be reported in CCRs and available to system users upon request, which would then require explanation of why 2.3 ppt is not "really" a number despite very much appearing to be a valid number. In our experience with our regulation since 2019, water system professionals have a difficult time understanding the difference between detection levels and reporting levels and now adding the practical quantification level into the mix, it will be increasingly difficult to convey information to users about water quality results, validity of samples, and comparison with the health advisories/MCLGs.

SDWIS is currently not set up to accommodate and accept both a method reporting level and estimated/qualified values pertaining to data to be used in screening. It is unrealistic for EPA to expect implementation of the MCLs without adequate tools to do so, because no other contaminant is managed the way EPA is proposing states manage PFAS yet it is expected to fit into an existing framework which is not a good fit.

Additionally, reporting of results below the respective reporting limits or PQLs sets a challenging precedent moving forward. Will this be expected of all compounds/chemicals reported? If so, has there been consideration as to how that is reported to the general public and/or included in CCRs? Opening the door to estimated values for compliance monitoring data reporting risks degrading the viability and the states' regulatory authority of every other established MCL. There are significant data management concerns and the inability to manage these consistently across the program and across states. If the number reported is below the reporting limit, then it should not be quantified, therefore whatever estimated result is reported should not be reflected as a number. While qualified data provides useful information including for the presence or absence of PFAS, there are challenges to using it in the regulatory compliance context as discussed here. Would SDWIS be built out to flag samples with qualifiers, or are states expected to manage the estimated results themselves without this capability being in SDWIS? This is a particularly urgent need for states that are already receiving compliance monitoring data for PFAS with the intent of using it to satisfy initial monitoring requirements. We cannot wait a year or more following the final PFAS regulation to receive the data management instructions. This needs to be sorted out before the final regulation is promulgated. If UCMR5 data can be used to count toward initial sampling, will the results be reported to the detection limit or reporting limit, and will they be "J" flagged?

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document, which discusses the use of concentrations below PQLs, which are not used in calculating RAAs. In addition, please see sections 8.1.2 and 8.8 of the EPA response in this *Response to Comments* document, which discuss rule trigger levels and compliance monitoring frequencies. The CCR Rule requires CWS to provide consumers with information about "detected" levels of PFAS in their reports, and, for this purpose, "detected" is defined as reported

at a concentration equal to or exceeding a trigger level (please see section IX of the preamble to the rule and section 9.1 of the EPA response in this *Response to Comments* document for more information on CCR requirements). As the EPA develops implementation materials following final rule promulgation, the agency will consider additional resources to support states and water systems for notifying their customers.

Concerning data management capabilities required to implement this rule, including potential changes to existing data management systems such as the Safe Drinking Water Information System (SDWIS), please see section 11.2 of the EPA response in this *Response to Comments* document. While beyond the scope of this rulemaking itself, the EPA is actively working on PFAS data management solutions, such as updating the SDWIS suite of applications to manage data reported from this rule. The EPA does not believe these data management systems must be available at the time of rule promulgation. Please see section 11.3 of the EPA response in this *Response to Comments* document for discussion of development of Data Entry Instructions. With respect to implications of this NPDWR on the NPDWRs that apply to other chemical contaminants, this rulemaking only applies to the specific chemicals identified in the rule.

Philadelphia Water Department (PWD) (Doc. #1709, SBC-045752)

16. EPA's requirement that any single point that would cause the LRAA to exceed the MCL would immediately trigger a violation

In Section 141.903(e) of the proposed rulemaking, EPA states "If any sample result will cause the running annual average to exceed the MCL at any sample point, the system is out of compliance with the MCL immediately." PWD believes that this is intended to capture any single results that are so high (i.e., greater than 4x the MCL) that would trigger an exceedance even if the remaining quarters are non-detect. While PWD does not oppose this stipulation, it believes that this stipulation as written will disincentivize systems from establishing routine monitoring at the entry point to distribution on a more frequent schedule than the regulatory requirement. An example: If PWS A is already over a year into compliance monitoring then a new LRAA will be generated every quarter. PWS A has established a monthly compliance monitoring program to provide more granular insight into PFAS levels in their system. Over the last three quarters, PWS A has had quarterly averages of 0 ppt, 0 ppt, and 4 ppt and their LRAA at the end of last quarter was calculated as 2 ppt (i.e., 0 ppt). This first monthly result of the next quarter was 12.5 ppt and would result in the subsequent LRAA being above the MCL if the LRAA was calculated after just this first quarterly sample. Based on the rule's current language, PWS A would be out of compliance before the remaining two monthly samples could be collected for the quarter, which could have resulted in the quarterly average being well below 12.5 ppt (as low as 4.2 ppt if the second and third month were below the PQL). This clause in the rulemaking may disincentivize systems from voluntarily implementing more than the minimum monitoring schedules to avoid situations like the example above.

EPA Response: In the final rule, the EPA has clarified the language to indicate that only compliance samples collected at the direction of a state (and any required confirmation samples) will be included in the RAAs used to determine MCL compliance. This removes any potential disincentive to systems to collect additional voluntary samples, in alignment with the commenter's request. Please see section 8.2 of the EPA response in this *Response to Comments* document for further discussion of compliance calculations.

Philadelphia Water Department (PWD) (Doc. #1709, SBC-045750)

14. Using the trigger level to calculate Locational Running Annual Averages (LRAA)

Under the current proposed rule, any results for PFOA and PFOS that are less than the respective PQLs would be included in the LRAA as zero. In section VI.A of the preamble, the EPA requested comment on using proposed trigger level for any results below the PQL in the calculation of the locational running annual averages. PWD recommends that EPA retain their current proposal to use zero in the calculation of the LRAA for results that are below the PQL. This would remain consistent with other regulations, such as the Stage 2 Disinfectant and Disinfection By-Products Rule, that utilize LRAA calculations for determining compliance which use zero in place of results less than the PQL/MRL.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

Citizens Campaign for the Environment (CCE) (Doc. #1710, SBC-045136)

Additional recommendation to strengthen EPA proposed regulations:

• EPA should determine MCL and Hazard Index violations quarterly, not annually as proposed. New York State currently determines violations quarterly. Doing this annually could result in the public being put at risk to drinking contaminated water for an unnecessarily long period of time. Increased frequency of determining violations, at least quarterly, will help protect public health from dangerous exposures.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. The EPA has determined that, consistent with precedent for most other chemical contaminants with chronic effects, violations will be determined on the basis of an RAA. This monitoring and compliance framework allows for temporal fluctuations in concentrations that may occur because of unexpected events such as premature regulated PFAS breakthrough or temporary elevated source water concentrations. Thus, periodic occurrences of regulated PFAS that are slightly above the PQLs do not necessarily result in a violation of the MCL if other quarterly samples are below the PQL. The EPA's use of a RAA to determine compliance is consistent with currently available information, that suggests that the developmental and chronic effects associated with exposure to the regulated PFAS are not

known to represent immediately life-threatening health impacts. Thus, the EPA has determined that its monitoring and compliance framework will be sufficiently protective of public health.

HRSD (Doc. #1719, SBC-043548)

Other policy decisions warrant careful consideration as they have direct implications for operational costs and burden on communities. One such decision revolves around the calculation of the Running Annual Average (RAA) for PFAS. EPA does appropriately propose that all analytical results less than the Practical Quantitation Limit (PQL) be treated as "0" for the purposes of calculating the RAA. This recognizes the high degree of uncertainty in analytical results below the PQL and yet still provides assurance of compliance with an MCL for which the risk calculation is predicated upon chronic exposures. This practice is consistent with the approach used for calculating RAAs for the other MCLs for which RAA is the means of evaluating compliance. Utilizing trigger values of 1/3 the PQL to substitute for values below the PQL in compliance calculations can result in greater operational costs with, as expressed by EPA, only a "slight increase" in public health protection. The potential increase in operational costs for uncertain values with only the potential for a "slight increase" in public health protection is not warranted and represents a potential misuse of public funds.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

Louisville Water Company (Doc. #1720, SBC-043553)

[In that regard, we are providing the following comments on key issues that we think require consideration.]

3. Louisville Water supports EPA's proposal of using a running annual average (RAA) to calculate compliance. We have noted some seasonality to the variation in our source water monitoring. Using the RAA is consistent with other regulations and provides a more earnest assessment of the chronic risks posed by PFAS.

[In that regard, we are providing the following comments on key issues that we think require consideration.]

4. Louisville Water supports EPA's proposal to report values below the PQL as zero for the purpose of calculating the RAA. However, we understand that the agency is struggling with this issue. For most labs, the method reporting limit (MRL) for PFOA and PFOS is 2.0 ng/L. We believe it would be appropriate to require that data values below the PQL but above the MRL be used for calculating the RAA, but not appropriate to use J-flagged data (<MRL).

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045164)

In § 141.903(f)(2)(ii)(B), the process to deal with multiple results for one or more of the HI PFAS during a quarter is not clear and doesn't appear to address the situation where multiple results exist for some but not all of the HI PFAS. MassDEP recommends that the set of results for each of the HI PFAS be averaged for the quarter and one set of Hazard Quotients (HQ) be derived to generate one HI (e.g., average all the PFBS results for the quarter, divide that average by the PFBS HBWC to get one PFBS HQ for the quarter add this to the other three HQs to obtain the HI for the quarter).

EPA Response: The paragraph referenced was removed from the final regulations because, as explained in section 8.1.2 of the EPA response in this *Response to Comments* document, the final rule does not provide for a situation when a system might collect two samples during a three-year compliance period. With respect to the possibility that there might be multiple samples to average in a quarter, the EPA has clarified that the only samples that are to be included in compliance calculations are compliance samples collected at the direction of the state. Further, each sample is to be analyzed for all regulated PFAS. Thus, the EPA would not anticipate a likely situation where multiple quarterly results would exist for some but not all of the regulated PFAS. Nonetheless, the final regulations would cover this situation, were it to occur, in a fashion consistent with the commenter's recommendation in § 141.903(b)(2)(i), which reads: "If the State requires one or more confirmation samples for an analyte in the quarter, systems must average these results for each analyte in that quarter and then determine the Hazard Quotient(s) from those average values, then sum the Hazard Quotients [to determine the Hazard Index for the quarter]."

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045171)

• Systems monitoring quarterly should not have a requirement to report whether the trigger level was met or exceeded. If a system is already subject to quarterly monitoring the relationship of its PFAS concentrations to the trigger would be meaningless because the only consequence of exceeding the trigger would be to be put on quarterly monitoring.

• Systems monitoring less frequently than quarterly should not have a requirement to report a Running Annual Average (RAA). According to § 141.903(d), a RAA isn't calculated unless a system is triggered into quarterly monitoring and then completes one year of quarterly monitoring.

EPA Response: The EPA retained the requirement for systems conducting quarterly monitoring to report whether the trigger level was met or exceeded because this information will provide states with a snapshot of systems that have experienced or are at risk of experiencing MCL exceedances. The EPA agrees that systems monitoring less frequently than quarterly should not be required to report an RAA. The agency clarified this in the final rule.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045162)

MassDEP supports EPA's proposal to substitute zero for sample results less than the PQL in both § 141.903(f)(1)(iii) and § 141.903(f)(2)(iii). MassDEP may consider establishing lower PQLs than are in the proposed rule, if appropriate.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045169)

The final rule should explicitly state that water systems that conduct UCMR5 monitoring do not need to conduct initial monitoring. While the UCMR5 only requires large groundwater systems to sample twice, this should be sufficient, even though the proposed rule requires quarterly sampling. Is EPA requiring UCMR5 laboratories to report qualified results, or nonqualified results where the lab used an MRL lower than that required by UCMR5, or are all results below EPA's MRLs reported as "<MRL?" This could affect whether MassDEP would allow the use of UCMR5 results to satisfy the initial monitoring requirements as we require lower MRLs than are being used in UCMR5.

Using zeros for any results below 4.0 ppt miscalculates the Running Annual Average (RAA) if these results are non-qualified detections. Such a system's RAA could exceed the MCL when these results are included. For example, the set of quarterly results: 4.2, 4.2, 4.1 and 3.8 exceeds the MCL when all four results are used (4.1) but does not (3.1) when zero replaces the lowest result. Public communication surrounding the use of zeros for compliance calculations when there is a quantified detection will be challenging especially where including such detections is the difference between a violation or not.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document for discussion of the compliance calculation. Please see sections 8.1.1 and 8.3 of the EPA response in this *Response to Comments* document for discussions of using existing data to meet initial monitoring requirements and for a description of the rationale for requiring large groundwater samples to collect four samples to satisfy initial monitoring requirements. The EPA notes it is not requiring UCMR 5 laboratories to report sample results below the UCMR 5 MRLs, but water systems can request UCMR 5 data below MRLs from their laboratories for use in satisfying some or all of this NPDWR's initial monitoring requirements and determination of compliance monitoring frequency. Please see section 13.3.4 of the EPA response in this *Response to Comments* document.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045173)

§ 141.905(2) states that "[s]ystems monitoring triennially whose sample result is at or [emphasis added] exceeds the trigger level as defined by § 141.902(a)(7) of this section must begin quarterly sampling." According to § 141.902(b)(2)(ii) the trigger level must be exceeded before

quarterly monitoring is required. Since there is inconsistent language throughout the proposal, it is unclear what EPA's intent is and therefore which sections need correction.

EPA Response: The EPA agrees that the language in the proposed rule was inconsistent and has remedied this in the final rule. The EPA's intent (as described in the final rule) is for a system to initiate quarterly monitoring if a sample result is equal to or exceeds the trigger level. This is consistent with the requirements in § 141.24(h)(7) for other SOCs. Please see section 8.1.2 of the EPA response in this *Response to Comments* document regarding compliance monitoring requirements.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045178)

Running Annual Average Approach

EPA's proposal in the NPDWR to utilize a RAA approach to calculate compliance with the proposed MCLs is not adequately protective of development effects. An alternative approach should be considered, such as the use of a shorter duration averaging period.

Setting the PFOA and PFOS MCL at a Practical Quantitation Limit

Setting the PFOA and PFOS MCL at a PQL, established at a level of 4.0 ppt, raises a number of issues. Extensive experience among states that are already regulating PFOA and PFOS support a current PQL of 2.0 ppt. That said, setting an MCL at a PQL raises a risk of compliance "yo-yoing", where systems with concentrations hovering near the PQL will bounce into and out of compliance simply based on analytical variability within the range that is acceptable for the method. To avoid that problem, we recommend setting the MCL at a level above the PQL that reasonably exceeds (say by a factor of 2-3) the acceptable method variability, based on a lower PQL.

Conclusion

MassDEP is committed to the protection of public health and the environment against the impacts of PFAS contamination and strongly supports EPA's efforts to establish drinking water standards for PFAS. We urge EPA to carefully consider our comments, which are based on three years of experience implementing one of the most stringent PFAS limits for drinking water in the nation, urge EPA to take swift action in implementing its own standards, and applaud EPA for its ongoing efforts to develop this NPDWR.

Sincerely,

Bonnie Heiple

Commissioner, MassDEP

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document regarding the compliance calculation determination and use of RAA. The use of the RAA will likely decrease the odds of systems "yo-yoing" as the commenter states,

since it allows some minor fluctuations in measured concentrations and likely accounts for a single outlier sample result. Please see section V of the preamble to the rule and section 5.1.2 of the EPA response in this *Response to Comments* document for discussion of MCLs for PFOA and PFOS. Further discussion of the PQLs can be found in section 7.2 of the EPA response in this *Response to Comments* document.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045158)

There is an inconsistency between § 141.902(b)(2)(ii) and (iii). The former states that quarterly monitoring is required when the trigger level is exceeded whereas the later states that systems that are at or exceed the trigger levels must conduct quarterly monitoring. MassDEP recommends that the trigger level must be exceeded to require increased monitoring. MassDEP also recommends that the same criteria apply to making the "reliably and consistently below the MCL" determinations in § 141.902(b)(2)(iii) – anything at or below the trigger level should be acceptable.

EPA Response: The EPA agrees that the language in the proposed rule was inconsistent about when quarterly monitoring is triggered. The EPA's intent (as described in the final rule) is for a system to initiate quarterly monitoring if a sample result is equal to or exceeds the trigger level. This is consistent with the requirements in § 141.24(h)(7) for other SOCs. Please see section 8.2 of the EPA response in this *Response to Comments* document. With respect to the state's ability to make a determination of R&C below the MCL, the EPA has removed the requirement for the RAA of at least four consecutive quarters to be less than the trigger level. The state must consider at least four consecutive quarters of data, and, at a minimum, the R&C determination must be supported by analytical results below the MCLs. If applicable, a state may apply its own additional criteria for R&C determinations.

Florida Section American Water Works Association - Water Utility Council (FSAWWA WUC) (Doc. #1737, SBC-044484)

With that overarching request, we now turn to the individual components of EPA's rule proposal:

IX. Monitoring and Compliance Requirements, A. What are the monitoring requirements?

• The Florida Water Sector supports EPA's proposed approach to monitoring results below the practical quantification limits as zero for the MCL. This approach should also be used in the reduced monitoring framework.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. For a discussion of rule trigger levels for reduced triennial monitoring, please see section 8.8 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045969)

Section 5.4: Compliance calculation

EPA is proposing a RAA approach to compliance calculation. PWSs must take quarterly samples, a minimum of 4 per year per EPTDS, and use the average of the four. This is consistent with other regulation and would provide stability and familiarity with sampling calculations.

AMWA also strongly supports EPA's proposal to report values below the PQL as 0 to calculate the RAA. An alternate approach EPA considered in the proposal is using the trigger level (1/3 of the PQL), as the value when concentrations are below the PQL. If EPA were to adopt this version, no water system would be able to qualify for reduced monitoring. If a utility has all quarterly samples below 4.0 ppt, the proposed method will give them a RAA of 0, and they would be below the trigger level and qualify for reduced monitoring. That same utility under EPA's alternative approach would have a RAA of 1.3 ppt. The preamble states that water systems qualify for reduced monitoring if they "do not detect regulated PFAS in their system at or above the rule trigger level," so being at the trigger level does not qualify a system for reduced monitoring.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

Del-Co Water Company, Inc. (Doc. #1744, SBC-043617)

II. Del-Co internal testing of PFOA would result in oscillating compliance around the 4.0 ppt MCL

Del-Co Water has been monitoring for PFAS chemicals since 2020. Over that time, background concentrations of PFOA have ranged between non-detectable to 5.8 ppt. During this time, and under certain circumstances, we would have exceeded the proposed MCL for PFOA. Under the proposed sampling scheme and running annual average calculation, this exceedance would only last for one quarter (or 3 months), after which our RAA would fall below the proposed PFOA MCL of 4.0 ppt. The manner in which we will oscillate below, then above the proposed MCL will lead to difficulties in compliance and in customer messaging and communication. It will lead to the unnecessary erosion of public confidence in our water quality.

This circumstance will likely occur at all surface water PWSs, as the national background PFOA concentration is approximately 4 – 5 ppt. This will place other drinking water utilities in the same situation as Del-Co, in that for the overwhelming majority of the time the PWS will be lower than the proposed 4.0 ppt for PFOA, but one high measurement could result in exceeding the proposed MCL, thus leading to millions in upgrades and difficult messaging to the customers.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. Since MCL compliance will be determined based on an RAA, the EPA

disagrees that the scenario described with one or two samples containing regulated PFAS at concentrations between non-detect and 5.8 ppt would result in an MCL violation assuming concentrations of regulated PFAS are below the PQLs in at least two quarters out of every four. As described in section 8.2 of the EPA response in this *Response to Comments* document, the use of the RAA allows for these type of temporary minor fluctuations and could, instead, reduce the number of times a system oscillates in and out of compliance. If the fluctuations were greater, to provide adequate public health protection and ensure compliance with the MCLs, it would be necessary to assess a violation, the water system to take necessary action to reduce the concentrations, and to notify the public. As the EPA develops implementation materials following final rule promulgation, the agency will consider additional resources to support states and water systems for notifying their customers.

Regarding the commenter's statement that "the national background PFOA concentration is approximately 4 – 5 ppt", the commenter does not provide any supporting information for this claim nor does the EPA agree based on available occurrence information presented in section III.C and VI of the final rule which is not demonstrative of this level.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045226)

CT DPH suggests that EPA utilize "J" flagged data consistently. For compliance, "J" flagged data is not accurate enough and a non-detect value of zero is used. However, this same data can be used as a present/absence indicator of a contaminant in the sample to trigger reduced monitoring and the actual numerical value matters and is used. "J" flagged data is an estimate. This can potentially create challenges to the rule if an estimate is used for regulatory compliance determinations. This inconsistent use of "J" flagged data makes messaging difficult for PWSs to communicate the results to customers, and the PWS must explain why the concentration is zero in some circumstances but the numerical value in others.

5. EPA is requesting comment on whether an alternative approach should be considered when calculating the running annual averages for compliance.

CT DPH agrees that the running annual average is an appropriate approach to monitor compliance as it has proven appropriate for other SOC contaminants. Using a similar approach will assist with Rule compliance for PWSs.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. Regarding compliance monitoring requirements, rule trigger levels, and associated data use and reporting, please see sections 8.1.2 and 8.8 of the EPA response in this *Response to Comments* document. As the EPA develops implementation materials following final rule promulgation, the agency will consider additional resources to support states and water systems for notifying their customers.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045217)

CT DPH requests EPA provide clarification on how to handle data below the PQL. There are three types of data that can occur below the PQL set by the EPA: qualified result, "J" flagged result, and non-detect result. The EPA makes no mention of qualified results below the PQL. Will states be required to use this qualified numerical data in the compliance running average, or will the data be treated as zero as "J" flagged data. Many states have reported that laboratories can reach below the PQL, and the fact EPA wants to use data below the PQL for trigger levels may indicate that the PQL is not set appropriately.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. Regarding rule trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045223)

2. EPA requests comment on the use of data below PQLs for reduced monitoring regarding feasibility of the proposed MCLs and more generally on laboratory capacity.

The EPA should utilize "J" flagged data consistently, and consistently apply either a non-detect (0) value for this data or utilize the numerical result. By definition, "J" flagged data is an estimate. Basing compliance decisions on estimated data could result in challenges that would further add to the impact on state primacy programs to implement the rule. Laboratory capacity cannot be fully evaluated because of the change in monitoring requirements stemming from the trigger level.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. Regarding rule trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document. Please see section 5.1.2 of the EPA response in this *Response to Comments* document for discussion of laboratory capacity.

West Virginia Rivers Coalition et al. (Doc. #1746, SBC-045250)

EPA must account for all PFAS detections when determining MCL compliance.

To ensure compliance with the MCL and to protect communities from dangerous PFAS exposures, EPA must consider all PFAS detections when calculating MCL compliance. EPA has proposed to utilize a running annual average over four consecutive quarters to calculate compliance with the proposed rule. When calculating the running annual average, if a sample result is less than the PQL - 4 ppt for PFOA, PFOS, and PFNA; 5 ppt for HFPO-DA; and 3 ppt for PFHxS and PFBS - EPA is proposing to use zero. In doing so, EPA is treating PFAS detections below the PQL but above the method detection limit (MDL) as if they were non-detects. This approach ignores measurable PFAS exposures and understates PFAS risks.

Instead, EPA should consider all PFAS detections above the MDL to calculate MCL compliance. Similarly, when calculating the annual running average of the HI PFAS to calculate the hazard index, EPA must consider all detectable levels of HFPO-DA, PFBS, PFNA and PFHxS. This is the approach used for regulations governing monitoring and analytical requirements for organic chemicals, as well as inorganic chemicals such as arsenic and mercury. EPA should apply the same, health-protective approach to the calculation of average PFAS concentrations. This will increase public health protection and provide PWSs greater forewarning that their results may exceed the MCLs.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

City of Thornton, Colorado (Doc. #1748, SBC-044794)

In determining compliance with the MCL, Thornton suggests that EPA revise its proposed approach for values below the PQL. First, EPA should reevaluate the PQL based on demonstrated lab feasibility; the contract laboratory that Thornton uses for PFAS analysis has a PQL of 1.9 ppt and MDLs around 0.5 ppt for most compounds. Data between the MDL and PQL, commonly referred to as J-flag data, is estimated at these levels from the calibration curve, peak integration, and analyst's technical expertise. In EPA's proposed compliance approach, zero is used for compliance calculations for samples below the 4 ppt PQL, this gives the public a false sense of security of how well protected they are from PFAS. In a hypothetical example where a utility regularly has samples of 3.8 ppt, their RAA will be zero. The public will believe that their water is free of PFAS, while their utility is actually very close to violating the MCL. EPA's alternative approach of using 1.3 ppt for compliance calculations for samples below the PQL is also flawed for the opposite reason. In a hypothetical example of a utility with GAC treatment targeting the MCLG with samples regularly below the MDL (0.5 ppt), the RAA will be 1.3 ppt. Customers will falsely believe their water has PFAS, when it might actually be PFAS free. Thornton suggests that the EPA allow utilities to use J-flag data for determining compliance with the proposed rule; data below the MDL should be considered zero for compliance calculations. This approach also allows utilities to show their progress towards treating down to the MCLG.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. The EPA notes that concentrations of regulated PFAS equal to or exceeding the trigger levels are required to be reported in the CCRs; please see section 9.1 of the EPA response in this *Response to Comments* document for a discussion of those requirements.

American Water Works Association (AWWA) (Doc. #1759, SBC-045622)

According to the proposal, compliance with the proposed rule will be determined using the RAA at each entry point to the distribution system. As part of the calculation of the RAA, EPA is also proposing that systems use 0 ppt for results that are below the practical quantification limit

(PQL) of 4.0 ppt. At the same time, EPA is proposing that to calculate the RAA for determining a system's eligibility for reduced monitoring, that only values below the detection limit be considered as 0 ppt and all reported results above the detection limit be used. The following sections provide a detailed review of these requirements and their proposed alternatives.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. The EPA has modified the requirements for a system to be eligible for reduced monitoring in the final rule, such that the RAA is no longer pertinent, instead requiring that individual sampling results be compared to the trigger levels. Please see section 8.1.2 of the EPA response in this *Response to Comments* document for further discussion of compliance monitoring requirements.

Bowling Green Municipal Utilities (Doc. #1767, SBC-043931)

Rule Requirements Must Employ High Quality Data: EPA's proposed approach to consider monitoring results below the practical quantification limits (PQLs) as 0 (zero) is appropriate for the MCL. This approach should also be applied to criteria for reduced monitoring. Results below the PQL should not be reported for regulatory purposes as not all laboratories and systems can reliably perform to or below the PQL.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. Regarding compliance monitoring requirements and rule trigger levels for reduced triennial monitoring, please see sections 8.1.2 and 8.8 of the EPA response in this *Response to Comments* document.

Western Urban Water Coalition (WUWC) (Doc. #1768, SBC-043950)

IV. Other Implementation, Monitoring, and Compliance Aspects of the Proposed Rule Warrant Additional Consideration

A. Below-PQL Samples Should be Counted as Zero

Under the Proposed Rule's monitoring requirements, when a public water system detects a regulated PFAS at a concentration below the practical quantitation limit (PQL), the rule stipulates that the value is counted as zero when calculating the running annual average for compliance monitoring. This methodology is entirely appropriate and consistent with existing law governing compliance determinations with drinking water standards. [FN37: Examples of rules adopted under SDWA that use zero when calculating locational running annual averages or running annual averages for results are less than the PQL include the Disinfectants and Disinfection Byproducts Rule, Synthetic Organic Compounds Rule, Volatile Organic Compounds Rule, and Radiological Rule.]

WUWC sees no reason to deviate from this standard practice. EPA requests comment on whether it should consider an alternative approach under which below-PQL detections would be counted at the proposed rule trigger levels (1.3 ppt for PFOA and PFOS and 0.33 of each of the

HI PFAS PQLs (i.e., PFHxS=1.0, HFPO– DA=1.7, PFNA=1.3, and PFBS=1.0)). [FN38: 88 Fed. Reg. at 18682] The Proposed Rule itself is premised upon EPA's finding that the PQL is the lowest feasible quantitation level. [FN39: Id. at 18639] By contrast, the proposed trigger levels are based upon EPA's view of laboratories' calibration limits. [FN40: Id. at 18667] These trigger levels are in the J value range and should not be considered reliable for the purpose of calculating a running annual average for compliance, especially since the Proposed Rule already proposes to set MCLs at the lowest quantitation level.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. Regarding compliance monitoring requirements and rule trigger levels, please see sections 8.1.2 and 8.8 of the EPA response in this *Response to Comments* document.

Environmental Protection Network (EPN) (Doc. #1773, SBC-043870)

The rule proposes running average concentrations to calculate compliance and proposes using zero if the sample result is less than the quantitation level even though labs can reliably measure lower than that level. EPN strongly recommends that EPA use a level that is 1/3 of the MCL (1.3 ppt for PFOA/PFOS, 1.0 ppt PFHxS, 1.7 ppt HFPO-DA, 1.3 ppt PFNA, 1.0 ppt PFBS) instead of zero for samples less than the quantitation level. The use of zero for these samples is not health-protective, as we show in our comments below on section 141.903.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

California-Nevada Section American Water Works Association (CA-NV AWWA) (Doc. #1775, SBC-045272)

3. EPA should be consistent and follow established and standardized procedures for compliance determination.

EPA's proposed approach to consider monitoring results below the practical quantitation limits (PQLs) as "not detected" and use of "0" (zero) for the calculation of annual average is an appropriate statistical approach for the regulation. This approach should also be applied to criteria for reduced monitoring and compliance reporting requirements. However, to be consistent with requirements stipulated in EPA's PFAS analytical methods, EPA should consider developing and using a Minimum Reporting Level (MRL) instead of the PQL. The MRL is the lowest concentration of an analyte that demonstrates both precision and accuracy. Results below the MRL are considered calculated estimates and they do not satisfy quality control requirements. EPA updated guidance for public water systems required to monitor under UCMRs in 1999, and in 2004 developed recommendations to assign a MRL for each contaminant and directed laboratories to report all occurrences of the contaminants at concentrations that are equal to or greater than the established MRL [FN2: US EPA. 2004. Statistical Protocol for the Determination of the Single-Laboratory Lowest Concentration Minimum Reporting Level (LCMRL) and Validation of Laboratory Performance at or Below the

Minimum Reporting Level (MRL); EPA 815-R-05-006; Office of Water: Cincinnati, OH, November 2004]. Based on EPA Method 533 [FN3: US EPA. 2019. Method 533: Determination of per- and polyfluoroalkyl substances in drinking water by isotope dilution anion exchange solid phase extraction and liquid chromatography/tandem mass spectrometry; Office of Ground Water and Drinking Water: Cincinnati, OH, November 2019.] for the analysis of 25 PFAS for UMCR 5, the procedure to determine the lowest concentration minimum reporting level (LCMRL) and validation of laboratory performance at or below the minimum reporting level (MRL), all results below the MRL should be considered "not detected" (ND) and reported as ND or less than the MRL (e.g., <2.0).

PQLs are based on data from a Performance Evaluation Study or by applying a multiplication factor to the analytical Method Detection Limit (MDL). EPA should use UCMR 5 data to develop MRLs for each PFAS they intend to regulate and compliance with MCLs should be determined based on the annual average at each sampling point for results that are at or above EPA's established MRLs for each PFAS. If EPA intends to use trigger levels, the use of a trigger level below the MRL, which is below the established analytical method's ability to reliably measure the target chemical, is inappropriate.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. Regarding the use of results below PQLs for determining monitoring frequency and rule trigger levels, please see sections 8.2.1 and 8.8 of the EPA response in this *Response to Comments* document, respectively. For a discussion of laboratory capability and the PQLs, please see section 5.1.2 of the EPA response in this *Response to Comments* document. As is often used for other NPDWRs, the EPA has adopted PQLs for PFAS instead of MRLs. These PQLs are based on the UCMR 5 MRLs. For a discussion of the PQLs, please see section VII of the final rule preamble and section 7.2 of the EPA response in this *Response to Comments* document.

Metropolitan Water District of Southern California (Doc. #1777, SBC-045433)

A related issue is EPA's following proposal: "[W]hen calculating the running annual averages, rather than using zero for sample results less than the PQL, EPA seeks comment on instead using the proposed rule trigger levels (i.e., 1.3 ppt for PFOA and PFOS) in the case where PFAS are detected but below their proposed PQLs. This would have the potential to be more protective in the long run than counting sampling results below the PQL as zero and provide PWSs greater forewarning that their results may exceed the MCLs."[FN15: 88 Fed. Reg. at 18667; see also 88 Fed. Reg. at 18682.] According to the SDWA, EPA typically assigns zero to samples below the method detection limit (MDL), not to samples below the associated PQL. [FN16: 66 Fed. Reg. 6990 (Jan. 22, 2001).] Metropolitan recommends that EPA consider EPA Region 3's Regional Guidance on Handling Chemical Concentration Data Near the Detection Limit in Risk Assessments for possible approaches to reporting non-detects, such as using half the detection limit. [FN17: https://www.epa.gov/risk/regional-guidance-handling-chemical-concentration-data-near-detection-limit-risk- assessments.]

EPA Response: The EPA agrees that under NPDWRs for some other chemical contaminants, values below a specified threshold (such as the "detection limit") are replaced with zeroes in compliance calculations. The EPA-approved methods do not include MDLs, but rather define and require the confirmation of MRLs which are distinctly different from MDLs. For the PFAS NPDWR, the EPA did not define MRLs for PFAS contaminants, but established PQLs, as discussed in sections V and VII of the final rule preamble, to evaluate analytical feasibility for the determination of MCLs. The EPA considered this feedback and the regional guidance document referenced before developing the final rule; the referenced guidance was prepared for the Hazardous Waste Management Division, not for the purposes of evaluating drinking water data. Please see section 8.2 of the EPA response in this *Response to Comments* document for more information about the EPA's decision that levels below the PQLs will be replaced with zeroes in compliance calculations. Additionally, the EPA notes that results below the PQLs will only be utilized for the determination of monitoring frequency (please see sections 8.1.2 and 8.8 of the EPA response in this *Response to Comments* document).

San Diego County Water Authority, CA (Doc. #1779, SBC-045290)

Running Annual Average

The Water Authority supports EPA's proposed approach of using a running annual average to calculate compliance. We also support using zero to calculate the average for compliance purposes if a sample result is less than the PQL. We believe this approach makes sense considering the reduced accuracy of testing at the very low concentrations in the proposed rule.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

Palm Beach County Water Utilities Department (Doc. #1802, SBC-045336)

Page 18682, IX.B. Third column last paragraph, "When calculating the running annual averages, if a sample result is less than the PQL for the monitored PFAS, EPA is proposing to use zero to calculate the average for compliance purposes. For example, if a system has sample results for PFOA that are 2.0, 1.5, 5.0, and 1.5 ppt for their last four quarters at a sample location, the values used to calculate the running annual average would be 0.0, 0.0, 5.0, and 0.0 with a resulting PFOA running annual average of 1.3 ppt.":

PBCWUD Comment: If calculating compliance based on the anything below the PQL of zero is used in the calculation, PBCWUD recommends using the MCLs levels to determine when to go on reduced monitoring, like as performed by inorganic standards. Once 4 quarters are below MCL, reduced monitoring can be approved.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. For a discussion of criteria to qualify for different monitoring frequencies

and rule trigger levels for reduced triennial monitoring, please see sections 8.1.2 and 8.8 of the EPA response in this *Response to Comments* document, respectively.

National Ground Water Association (NGWA) (Doc. #1804, SBC-045458)

EPA should create a management path of review for samples that fail the MCL but have previously met the standard. Follow up sampling should be considered before designating a water system as out of compliance.

NGWA has prepared "The Practical Guide for PFAS Sampling" to guide field sampling. This guide is published on the NGWA website at: https://my.ngwa.org/NC__Product?id=a18Ht00000ExtFaIAJ.

Compliance - The proposed rule is dynamic and potentially difficult to comply with, as different constituents may drive the risk from sampling event to sampling event. Furthermore, conditions may exist in which a water system is within standards for one sampling event only to be found above standards on the next, the difference being a small change in concentration. Process requirements of the regulation should provide for follow up sampling in such cases before finding a water system out of compliance, particularly for small systems which may have to invest substantially in treatment technology.

EPA Response: The EPA acknowledges the resource provided on PFAS sampling. Basing MCL compliance, which will likely drive treatment decisions, on an RAA appropriately accounts for variability in concentrations present in the same location on different dates and will likely alleviate the commenter's concern that "a small change in concentration" would result in noncompliance. Regarding follow-up sampling, states may require confirmation samples in situations they specify. Please see the section 8.2 of the EPA response in this *Response to Comments* document for a discussion of calculating the RAA and the samples that are considered when performing the calculation.

Earthjustice et al. (Doc. #1808, SBC-046116)

B. EPA Should Account for PFAS Detections Below the PQL When Determining MCL Compliance

To ensure compliance with the MCL and to protect communities from dangerous PFAS exposures, EPA must consider all PFAS detections when calculating MCL compliance. EPA has proposed determining initial MCL compliance based on a "running annual average," which considers a water provider's average PFOA concentration, PFOS concentration, or hazard index over four consecutive quarters to determine whether the provider has exceeded the MCL. [FN185: Id. at 18,667.] But when calculating the running annual average, EPA has proposed treating all PFAS detections below a chemical's PQL—4 ppt for PFOA, PFOS, and PFNA; 5 ppt for GenX; and 3 ppt for PFHxS and PFBS—as if they were non-detects. [FN186: Id. at 18,667; see id. at 18,680 (listing PQLs for different PFAS chemicals).] This approach ignores measurable

PFAS exposures and understates PFAS risks. For instance, if a water provider detected quarterly PFOA concentrations of 3.8 ppt, 3.8 ppt, 3.8 ppt, and 15 ppt, the mathematical average would be 6.6 ppt—more than 50 percent higher than the 4 ppt MCL. However, the average for the purpose of determining MCL compliance would be 3.75 ppt, since all of the 3.8 ppt detections would be replaced with zeros, meaning the provider would be considered in compliance with the MCL and no additional treatment would be required. EPA's discounting of sub-PQL detections is scientifically unsupported, contrary to longstanding SDWA regulations, and inconsistent with other parts of EPA's proposed rule.

As EPA acknowledges, "almost all laboratories" can detect the PFAS at issue at levels below the chemicals' respective PQLs. [FN187: Id. at 18,667.] The PQL reflects the capacities of some of the least sophisticated laboratories; it is, according to EPA, the "minimum quantitation level that . . . can be achieved by capable analysts at 75 percent or more of the laboratories using a specified analytical method." [FN188: Id. at 18,666.] In a prior rulemaking, EPA found that "49 of the 54 laboratories seeking EPA approval" to test PFAS in drinking water "included a lowest PFAS calibration standard level at 1 ppt or lower, with the median lowest calibration level among all laboratories at 0.5 ppt." [FN189: Id. at 18,667; see also id. (finding that "the overwhelming majority of laboratories with the necessary instrumentation to support PFAS monitoring have the capability to provide screening measurement results above … 1⁄3 of the MCL (i.e., 1.3 ppt for PFOS or PFOS)."] Given that "the overwhelming majority of laboratories" can detect PFOA, PFOS, and other PFAS below their PQLs, there is no reason for EPA to disregard those detections and treat PFAS-contaminated water as if it were PFAS-free when determining MCL compliance.

EPA's proposed approach is contrary to longstanding EPA regulations, which consider all detections above the method detection limit ("MDL"), a level that is distinct from—and lower than—the PQL. The MDL reflects the "minimum measured concentration of a substance that can be reported with 99% confidence that the measured concentration is distinguishable from method blank results." [FN190: 40 C.F.R. Part 136 App'x B; 40 C.F.R. § 141.2.] As a "general rule," EPA sets the PQL at a level that is 5–10 times greater than the MDL. [FN191: Id. at 18,666; National Primary Drinking Water Regulations; Volatile Synthetic Organic Chemicals, 50 Fed. Reg. 46, 902, 46,906 (Nov. 13, 1985) ("EPA believes that setting the PQLs in a range between 5 and 10 times the MDL achieved by the best laboratories is a fair expectation for most State and commercial laboratories.").] EPA's SDWA regulations governing monitoring and analytical requirements for organic chemicals, such as PFAS, state that "[i]f a sample result is less than the detection limit, zero will be used to calculate the annual average." [FN192: 40 C.F.R. § 141.24(f)(15)(v) (emphasis added).] Similarly, EPA's SDWA regulations governing inorganic chemicals, such as arsenic and mercury, provide that "any sample below the method detection limit shall be calculated at zero for the purpose of determining the annual average." [FN193: 40 C.F.R. § 141.23(i)(1) (emphasis added).] EPA acknowledges that the consideration of sub-PQL detections is "consistent with EPA's [National Primary Drinking Water Regulations] related to other [synthetic organic chemicals] and has the potential to . . . increase the public health

protection provided by this proposed regulation." [FN194: Proposed Rule, 88 Fed. Reg. at 18,682–83.] EPA should apply that same health-protective approach in its PFAS NPDWR.

EPA's justification for disregarding sub-PQL PFAS detections is unsupported and internally inconsistent. EPA claims that, even though most laboratories are able to detect PFAS below the PQL, "quantifying concentrations below the PQL for compliance purposes may decrease the precision and accuracy of the measured value." [FN195: Id. at 18,682.] But EPA's proposed approach is even less precise and accurate, since it would treat detectable PFAS levels as if they did not exist. Even if EPA has more confidence in PFAS detections above the PQL than below it, the relevant question is whether a detection above the MDL but below the PQL is more likely to reflect actual contamination or a false positive. EPA itself has acknowledged that "[f]or results between the detection limit and the PQL, EPA has determined that utilities would be able to reliably conclude analyte presence," meaning EPA's proposed approach of treating of all sub-PQL detections as zero understates real-world exposures and risks. [FN196: Id. at 18,670.] Moreover, elsewhere in its proposed rule, EPA considers detections at or below one-third of the PQL sufficiently reliable to "trigger . . . less frequent compliance monitoring." [FN197: Id. at 18,681.] In particular, EPA allows water systems to reduce their monitoring frequency from quarterly to once-every-three-years if their average PFAS concentrations are less than one-third of the MCL (i.e., 1.3 ppt for PFOA and PFOS and a hazard index of 0.33 for the HI PFAS). [FN198: Id.] In calculating that average, EPA considers PFAS detections that are well below the PQL. But there is no basis for considering sub-PQL detections to reduce water systems' monitoring obligations while ignoring those same detections when determining water systems' treatment obligations. For PFOA, PFOS, and the HI PFAS, EPA should instead consider all detections above the MDL to calculate a water system's annual running average and determine MCL compliance, including in hazard index calculations for HI PFAS.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document for a discussion of the use of results below the PQLs in calculating the RAA for compliance and sections 8.1.2 and 8.8 of the EPA response in this *Response to Comments* document for a discussion of the use of results below the PQLs for determining monitoring frequency and rule trigger levels. For further discussion of the PQLs, please see also section 7.2 of the EPA response in this *Response to Comments* document. The EPA-approved methods do not include MDLs, but rather define and require laboratory confirmation of MRLs which are quantifiable values and distinctly different from MDLs. For the PFAS NPDWR, the EPA did not define MRLs for PFAS contaminants, but established PQLs (based on the UCMR 5 MRLs), as discussed in sections V and VII of the final rule preamble, to evaluate analytical feasibility for the determination of MCLs. The agency maintains that using results below the PQLs for monitoring frequency determination purposes only will provide sufficient public health protection as it will require water systems to monitor more frequently if levels of regulated PFAS are detected at or above the rule trigger levels to ensure that water systems are not exceeding the MCLs (acknowledging that results below PQLs do not have the same level of precision and accuracy as the higher concentrations used to evaluate MCL compliance). Based on this, the EPA disagrees with the commenter that it is treating "detectable concentrations as if they did not

exist" because, the agency is, in fact, utilizing these values for their most appropriate purpose (i.e., to inform monitoring frequency).

Groundwater Resources Association of California (Doc. #1831, SBC-045356)

[Based on our review of this document, GRA offers the following general comments and recommendations for consideration by the EPA as they finalize these regulations:]

4. Clarity and Flexibility for PFAS Sampling and Monitoring Requirements: EPA is proposing PFOA/PFOS MCLs at their practical quantitation level (PQL) of 4 ppt with MCL goals (MCLGs) at zero. The Hazard Index based MCL for mixtures of PFHxS, HFPO-DA, PFNA, and PFBS is proposed at 1. The Hazard Index (HI) value is based on the additive ratio of the PFAS concentrations to each constituent's Health Based Water Concentration (HBWC), specified at 9 ppt, 10 ppt, 10 ppt, and 2000 ppt for PFHxS, HFPO-DA, PFNA, and PFBS, respectively. The PQL for PFHxS, HFPO-DA, PFNA, and PFBS are 3 ppt, 5 ppt, 4 ppt, and 3 ppt, respectively. Hence, the MCLs for PFHxS, HFPO-DA, PFNA, and PFBS are at 3x, 2x, 2.5x, and 667x the PQL for these constituents. The EPA's proposed regulations also define "trigger levels" at 1/3 of the MCLs based on the running annual averages from quarterly samples [FN6: Sampling frequencies may be reduced for small water systems or based on prior PFAS concentrations in relation to the trigger level and MCLs.]. Minimum Detection Levels (MDLs) for these PFAS range from 0.5 ppt to 1 ppt for PFOA/PFOS based on existing sampling and analysis standards. Section VI.A states that samples with concentrations less than the PQL would use a value of zero for their running annual average. We understand that the proposed approach allows for operational flexibility and reduces the impact from outliers or sampling/analysis errors. However, this approach makes it more difficult for PWS to track, report, and manage low levels of PFOA/PFOS at concentrations between the MDL and PQL. Ubiquitous low levels of PFAS [FN7: Recent studies indicate that certain PFAS can be present in rainwater at the proposed MCL concentrations, even in remote areas (https://pubs.acs.org/doi/10.1021/acs.est.2c02765)] complicate the sampling, monitoring, and management of PFAS. We recommend that EPA account for the MDL and PQL (same as the MCL for PFOA/PFOS) in the trigger levels established to make the distinction between PFOA/PFOS detections (above MDL but below PQLs) and non-detects (indicating the likely absence of PFOA/PFOS). One possibility would be to treat non-detects as zero and concentrations between MDL and MCL at half the MCL (MCL/2) or lower. Setting the MCLs higher than the PQL would also allow for operational flexibilities at low concentrations (at or below PQL). Setting the trigger levels for these constituents below the PQL will make it challenging for PWS to track, report, and manage low level PFOA/PFOS occurrences. In this regard, treating PFOA/PFOS concentrations below the PQL as zero would allow the PWS more operational flexibility and avoid undue sampling and monitoring costs due to erratic or erroneous PFAS data. Note that setting the concentrations at 0 for concentrations below PQL seems reasonable for PFHxS, HFPO-DA, PFNA, and PFBS as the HBWC (used for the HI calculation) for these contaminants is higher than the corresponding PQLs. As such, we recommend that EPA give due consideration to the balance between the

health protective, practical, and financial implications of setting the PFOA/pFOS MCLs and trigger levels at or below the PQLs for these contaminants.

EPA Response: Please see section V of the preamble and section 5.1.2 of the EPA response in this *Response to Comments* document regarding the PFOA and PFOS MCLs and their relationship to the PQLs. Please see sections 8.1.2 and 8.2 of the EPA response in this *Response to Comments* document for a discussion of the use of results below the PQLs and section 8.8 of the EPA response in this *Response to Comments* document for a discussion of rule trigger levels. The EPA notes that in the final rule, it made changes to the available monitoring frequencies and eligibility criteria for each. The final rule specifies that monitoring frequency is not determined based on an RAA concentration, rather they are based on individual sample results. The agency notes that sampling frequencies may be reduced for all sized water systems, not just small water systems (as incorrectly stated in the comment), based on sampling results being compared to the trigger levels and MCLs. The EPA disagrees with the commenter's concern that setting trigger levels below the PQLs would make it challenging for a PWS to track, report, and manage low level PFOA and PFOS occurrences. Laboratory results clearly indicate which PFAS were detected and which were not detected in a sample. The existence of trigger levels below the MCLs will increase a system's knowledge related to lower level PFOA/PFOS presence, even if the lower-level concentrations present are not known with as much precision and accuracy as higher values. For further information about data management infrastructure, please see also section 11.2 of the EPA response in this *Response to Comments* document. The agency notes that results for regulated PFAS equal to or exceeding the trigger levels are required to be reported by PWSs in their CCRs; please see section 9.1 of the EPA response in this *Response to Comments* document for a discussion of those requirements.

Pennsylvania Municipal Authorities Association (Doc. #1832, SBC-045792)

[PMAA's specific comments on the Proposal are as follows:]

16. EPA requested input on various issues in the Proposal, including whether it should consider an alternative approach to what is currently proposed for calculating compliance with MCLs. Specifically, EPA is requesting comment on situations where a PFAS chemical is detected, but the detection is below its proposed PQL. One option proposed by EPA is that, rather than using zero as the value of the specific PFAS chemical in the running annual average compliance calculation, the proposed trigger levels for the respective PFAS chemicals should be used in lieu of zero (1.3 ppt for PFOA and PFOS and 0.33 for each of the other four PFAS chemicals used in the Hazard Index approach – PFNA, PFHxS, PFBS and HFPO-DA, the latter of which are commonly referred to as GenX Chemicals). PMAA's position on this specific issue is that any detection of a PFAS chemical below its PQL should be entered as a zero in the running annual average calculation.

[PMAA's specific comments on the Proposal are as follows:]

17. The Proposal's requirements for monitoring and compliance indicates that most systems will not be in violation of an MCL until they have completed one year of quarterly sampling. However, in a situation where a quarterly sampling result will cause the running annual average to exceed an MCL, a system will be considered out of compliance with respect to that MCL immediately. This strict application ignores the practical impact of an anomalous sample during a particular quarter. PMAA believes that a better approach to addressing compliance would be to remove the "automatic" noncompliance determination from the Proposal. Rather, such determination should not be made until the end of a sampling quarter to allow municipal entities to take additional samples if, indeed, one sample provided an anomalous value. Such an approach would provide a more accurate picture of MCL compliance through a weighted approach, rather than sole reliance on a suspected anomalous sampling result.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. The final rule establishes that results below the PQLs will be treated as zeroes in calculating the RAA and this provides an additional analytic buffer for utilities in their compliance calculations. Additionally, the RAA calculation is intended to account for fluctuations (e.g., where a quarterly sample may be slightly above the MCLs, but other quarterly samples are below the MCLs). Per the final rule, a primacy agency may require a confirmation sample in certain situations it specifies (e.g., following an unusually high result), and, in those instances, compliance determinations are made based on the average of all results immediately following all compliance samples being reported for the quarter. However, the EPA notes that, aside from any primacy agency-directed confirmation sample, additional samples collected by the system are considered voluntary samples, not compliance samples. The results of voluntary samples are not to be included in quarterly averages. In most circumstances, the EPA anticipates that a system would have no more than two compliance samples (the original, routine sample and a confirmation sample, if required) per quarter, and in both cases the sampling would occur at the direction of the primacy agency. For a discussion of potential "false positives," please see section 8.7 of the EPA response in this *Response to Comments* document.

Little Hocking Water Association (Doc. #1835, SBC-045512)

Objection to the use of a zero for the measurement value for values below the proposed PQL in the running average compliance calculation.

"EPA requests comment on whether EPA should consider an alternative approach to what is currently proposed when calculating compliance with proposed MCLs. Specifically, in the case where a regulated PFAS is detected but below its proposed PQL, rather than using zero for the measurement value of the specific PFAS in the running annual average compliance calculation, that the proposed rule trigger levels (1.3 ppt for PFOA and PFOS and 0.33 of each of the HI PFAS PQLs (ie., PFHxS=1.0, HFPO-DA = 1.7, PFNA = 1.3, and PFBS = 1.0)) be used as the values in calculating the running annual average for compliance purposes." LHWA provides the following comments in objection to using a zero for the measurement value of a specific PFAS

in the running annual average compliance calculation wherein the specific PFAS is detected below its proposed PQL:

1. EPA has specifically stated that many laboratories can reliably analyze PFAS to levels much less than the established PQL. Indeed, reporting limits for 18 PFAS under Method 537.1 are typically less than 2.0 ppt in datasets reported to LHWA.

2. The EPA has established an interim health advisory for PFOA and PFOS at 0.004 ppt and 0.020 ppt, respectively as well as proposed a MCLG of 0 for PFOA and PFOS.

3. For compliance purposes, the proposed methodology already allows for water to be delivered to a customer with concentrations that exceed the proposed MCL of 4.0 ppt for PFOS and PFOA to allow for variable concentrations, according to EPA.

4. Therefore, it follows that in order to be protective of the health of persons that are being exposed to concentrations that can exceed not only the proposed MCLG of zero, but also exceed, at times, the MCL, a value other than zero should be used.

5. One example dataset would be quarterly concentrations of either PFOS or PFOA at 3.9 ppt, 4.6 ppt, 4.8 ppt and 5.7 ppt. The running average of this dataset using zero for the one value of 3.9 ppt would be 3.775 ppt. Therefore, this system would be in regulatory compliance, but deliver water over the MCL 75% of the time and 100% of the time over the MCLG. This would not achieve the goal of protecting human health.

6. If the proposed rule trigger level of 1.3 ppt for PFOA and PFOS is substituted for the example dataset in #5 above, the result is 4.1 ppt and the system would be determined to be out of compliance and above the MCL. This type of analysis is particularly important where there is an exposed population and the reduction of exposure to additional PFAS is critical.

7. LHWA objects to the use of zero in the calculation of annual running averages for compliance purposes where reported concentrations are below the proposed PQL of 4.0 ppt for PFOA and PFOS.

8. Similarly, LHWA objects to the use of zero in the calculation of annual running averages for compliance purposes where reported concentrations are below the proposed PQLs for HFPO-DA, PFHxS, PFNA and PFBS for the same reasons stated above.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. The EPA's use of an RAA to determine compliance is consistent with the currently available information that suggests that the developmental and chronic effects associated with exposure to the regulated PFAS are not known to represent immediate life-threatening health impacts. Additionally, the EPA clarifies that MCLs, not MCLGs, are the legally enforceable levels. MCLGs do not consider feasibility of treatment or analytical capabilities. Health advisories are also not legally enforceable levels, are distinctly different from an NPDWR, and do not account for feasibility of treatment or analytical measurement

capabilities. Please see section 5 of the EPA response in this *Response to Comments* document regarding MCLs and the determination of feasibility.

Citizens Energy Group (Doc. #1838, SBC-044856)

Citizens does not support using estimated results for compliance determination.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2311, SBC-047300)

Please provide guidance on how non-detect (ND) PFAS results will be handled when calculating the hazard index. EPA has failed to provide guidance on the handling of ND results for other contaminants regulated as total concentrations such as PCBs and dioxins leading to great conflict between regulatory agencies and responsible parties determining an approach. Some State regulatory agencies require the use of the limit of quantitation (LOQ) or 1/2 the detection limit (DL) be substituted for NDs for summations whereas most responsible parties prefer treating NDs as zeros, and most states do not have specific guidance on the matter making this a continuous source of contention. With commercial analytical laboratories barely meeting the proposed regulatory limits let alone the 1/3 trigger levels, this is going to be a big issue in determining compliance.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document for a discussion of determining compliance calculations. The final rule does not provide for replacing results below PQLs with a "limit of quantitation" or "half the detection limit" when calculating the Hazard Index for compliance determination purposes. For calculating compliance, such results would be treated as zero. Please see also section 8.1.2 of the EPA response in this *Response to Comments* document for a discussion of compliance monitoring frequencies and section 8.8 of the EPA response in this *Response to Comments* document for rule trigger levels to determine reduced triennial monitoring. Additionally, the EPA disagrees that commercial laboratories cannot consistently meet the proposed MCLs or trigger levels as the commenter claims. Please see section 5.1.2 of the EPA response in this *Response to Comments* document for a discussion of laboratory capability. Finally, the requirements for PCBs and dioxins are outside the scope of the final rule.

Richard Gelderman (Doc. #2820, SBC-047469)

Dear Assistant Administrator Fox,

I am writing to comment on the EPA's proposed National Primary Drinking Water Regulation for six per- and polyfluoroalkyl substances (PFAS).

I support the EPA's proposal to set strong, science-based drinking water standards and commend the EPA's recognition that both individual PFAS and chemical mixtures of PFAS threaten human health. PFAS-contaminated water has harmed the health of West Virginians for decades; this is a critical and long overdue step to protect our public health.

I urge the EPA to consider the following comments to strengthen the proposed rule to further protect and prioritize public health:

1) Compliance with the new drinking water standards should involve consideration of all detectable levels of PFAS, as opposed to treating all samples below the practical quantitation level as zero.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

Nancy Bouldin (Doc. #2822, SBC-047332)

2. When determining compliance with the new drinking water standards, the EPA should consider all detectable levels of PFAS, as opposed to treating all samples below the practical quantitation level as zero.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

Melda Clark (Doc. #2823, SBC-047334)

2. When determining compliance with the new drinking water standards, the EPA should consider all detectable levels of PFAS, as opposed to treating all samples below the practical quantitation level as zero.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

Karen Valentine (Doc. #2834, SBC-047336)

2. When determining compliance with the new drinking water standards, the EPA should consider all detectable levels of PFAS, as opposed to treating all samples below the practical quantitation level as zero.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

Monty Fowler (Doc. #2836, SBC-047338)

2. When determining compliance with the new drinking water standards, the EPA should consider all detectable levels of PFAS, as opposed to treating all samples below the practical quantitation level as zero.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

John Doyle (Doc. #2840, SBC-047341)

2. When determining compliance with the new drinking water standards, the EPA should consider all detectable levels of PFAS, as opposed to treating all samples below the practical quantitation level as zero.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

Laurine Yates (Doc. #2900, SBC-047343)

2. When determining compliance with the new drinking water standards, the EPA should consider all detectable levels of PFAS, as opposed to treating all samples below the practical quantitation level as zero.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

Mass comment campaign submitted by Jill Fischer (Doc. #3070, SBC-047345)

2. When determining compliance with the new drinking water standards, the EPA should consider all detectable levels of PFAS, as opposed to treating all samples below the practical quantitation level as zero.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

Citizens Campaign for the Environment (Doc. #3072-64, SBC-047393)

We also recommend EPA determine MCL and Hazard Index violations quarterly, not annually as proposed. Here in New York State, we look at these currently determined MCL violations quarterly. Doing this annually could result in the public being put at risk with contaminated drinking water for an unnecessarily long period of time.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. The EPA has determined that, consistent with precedent for most other

chemical contaminants with chronic effects, compliance will be determined on the basis of an RAA. This monitoring and compliance framework accounts for temporal fluctuations in concentrations that may occur (e.g., because of unexpected events such as premature regulated PFAS breakthrough or temporary elevated source water concentrations). Thus, periodic occurrences of regulated PFAS that are slightly above the PQLs do not necessarily result in a violation of the MCL if other quarterly samples are below the PQL and the resulting RAA value is at or below the MCL. The EPA's use of a RAA to determine compliance is consistent with currently available information that suggests that the developmental and chronic effects associated with exposure to the regulated PFAS are not known to represent immediate life-threatening health impacts. Thus, the EPA has determined that its monitoring and compliance framework will be sufficiently protective of public health.

Greater Cincinnati Water Works (GCWW) (Doc. #1550, SBC-042697)

Section IX (Monitoring and Compliance Requirements) states that a system will not be considered in violation of an MCL until it has completed one year of quarterly sampling except for when a quarterly sampling result will cause the running annual average to exceed an MCL. In this case the system will be considered out of compliance immediately. We propose this be changed such that the system would not be out of compliance with the MCL until the end of the quarter to allow utilities to average out an anomalous value with additional samples. Including additional samples in the quarterly averaging is already required if additional compliance samples are collected, so this approach is consistent with existing requirements. For example, if a sample is collected at the beginning of the quarter for PFOA or PFOS with a concentration of 17 ppt (more than 4 times the MCL) the utility would be in immediate non-compliance. However, if they believe this is an anomalous value, additional samples could be collected throughout the quarter. Expanding on the example, if they began conducting monthly sampling, and had levels of 5 the other two months, the quarterly average would drop to 8.3. If other quarterly samples are even lower, the system could stay in compliance. This approach safeguards against giving undue weight to a single anomalous value and still ensures long term exposure is not excessive.

Thank you for the opportunity to comment on this proposed regulation. If I can answer any questions, please feel free to contact me at Bruce.Whitteberry@qcww.cincinnati-oh.qov.

Sincerely,

Bruce Whitteberry

Assistant Superintendent

Water Quality & Treatment Division

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. The RAA calculation is intended to allow for fluctuations (e.g., where a quarterly sample may be slightly above the MCLs, but other quarterly samples are below the MCLs). Per the final rule, a primacy agency may require a confirmation sample in certain

situations it specifies (e.g., following an unusually high result), and, in those instances, compliance determinations are made based on the average of all results immediately following all compliance samples being reported for the quarter. However, the EPA would note that, aside from any primacy agency-directed confirmation sample, additional samples collected by the system are considered voluntary samples, not compliance samples. The results of voluntary samples are not to be included in quarterly averages. In most circumstances, the EPA anticipates that a system would have no more than two compliance samples (the routine sample and a confirmation sample, if required) per quarter, and in both cases the sampling would occur at the direction of the primacy agency. For a discussion of sampling contamination issues, please see section 8.7 of the EPA response in this *Response to Comments* document.

American Water Works Company Inc. (Doc. #1608, SBC-044010)

Determining Compliance

American Water supports the proposed regulatory approach of using a running annual average for determining compliance. This approach is consistent with the approach used for other contaminants that are sampled at the point of entry to the distribution system.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

Wyoming Department of Environmental Quality (WDEQ) (Doc. #1716, SBC-044750)

4. EPA Should Not Require Regulated PFAS Concentration Reporting Below the Practical Quantitation Limit (PQL) To Determine Monitoring Frequency

EPA has requested comment on the statement that EPA has "sufficient confidence that while measurements below the PQL may be slightly less precise and accurate, they are achievable by individual laboratories and appropriate for this intended purpose." However, EPA later states that "values below the PQL will not be used to determine compliance with the proposed MCLs as these PQLs are the lowest concentration of analyte that can be reliably measured within specified limits of precision and accuracy during routine laboratory conditions...and may not be achievable for some laboratories." EPA suggests that when calculating running annual averages for compliance assessment, any sample result less than the PQL of 4.0 parts per trillion (ppt) would be replaced by a zero concentration value. EPA also states that laboratory capacity issues would be anticipated if MCLs were proposed below 4.0 ppt. Consequently, EPA is requesting recommendations on alternative approaches for determining monitoring frequency and assessing PWS compliance. One approach EPA has suggested is using a Rule Trigger Level of one-third the MCL for PFOA and PFOS and one-third the HI for PFHxS, PFBS, PFNA, and HPFO-DA to determine monitoring frequency.

WDEQ is concerned that if the Rule Trigger Level approach is implemented as proposed, PWSs that report concentrations at or below the Rule Trigger Level may never be approved for reduced

compliance monitoring, due to the reduced precision and accuracy inherent in reporting analyte concentrations below their PQLs. Potentially, this could lead to rejected data, redundant sampling, and increased costs, even for systems below the PFAS MCLs. This in tum could lead to laboratory capacity issues while PWSs continue to submit samples that may not be quantifiable. Lab capacity issues would be further exacerbated by PWSs that hope to qualify for reduced monitoring submitting a high volume of samples to the few labs that can generate accurate, precise, quantifiable results at lower concentrations. This could potentially put at a disadvantage those PWSs that cannot realistically use those labs for their analysis, either because of increased cost or geography. Without access to qualified labs that can provide accurate data, small PWSs may ultimately implement more technical and expensive treatment technologies than are necessary to meet MCLs. Such technologies may not be feasible for small communities to install, much less operate and maintain over time. Additionally, WDEQ has concerns about setting a precedent for using analytical concentrations below PQLs for purposes of regulatory compliance, as the data is by definition lacking appropriate measurement precision and accuracy.

WDEQ recommends maintaining consistency with the proposed MCL concentrations for PFOA and PFOS and proposed HI calculation for assessing PWS compliance. WDEQ also recommends that monitoring frequency be based on MCL concentration values rather than setting a Rule Trigger Level of one-third the MCLs for determining compliance monitoring frequencies, due to the current inconsistency in PFAS analytical method precision and accuracy when measuring PFAS concentrations below 4.0 ppt. Doing so will meet the objective of protecting public health while ensuring that communities, particularly small communities, are not burdened with the implications and costs of obtaining data that lack precision and accuracy for purposes of regulatory compliance.

5. WDEQ Recommends Revising the Running Annual Average Calculation for Determining PWS Compliance with the Proposed PFAS NPDW Rule

EPA states, "a system will not be considered in violation of an MCL until it has completed one year of quarterly sampling, except in the case where, if a quarterly sampling result will cause the running annual averages to exceed an MCL at any sampling point (i.e. the analytical result is greater than four times the MCL). In that case, the system is out of compliance with the MCL immediately." If each entry point to the distribution system (EPDTS) is required to be a sampling point, the above statement assumes that each EPTDS provides an equal proportion of water to the total PWS distribution volume, which may not be realistic.

WDEQ recommends the running annual average calculations be revised to reflect the concentration of regulated PFAS from an EPTDS in context with the volume that that EPTDS provides to the PWS. This will prevent instances where an EPTDS with a PFAS MCL exceedance is of significantly lower volume that does not actually reflect a PFAS MCL exceedance in the PWS distribution as a whole, ensuring that a PFAS MCL violation and associated increased monitoring are not unnecessarily assigned to the PWS. Similarly, operator training will be critical to avoid quality assurance/quality control issues during sampling to ensure samples used in calculating annual averages are representative.

WDEQ also recommends that EPA clarify whether it will require periodic monitoring of the final distribution point of each PWS in addition to the EPTDS sampling points.

EPA Response: Regarding the use of values below the PQLs for the determination of monitoring frequency only and rule trigger levels, please see sections 8.8 and 8.2.1 of the EPA response in this *Response to Comments* document. For laboratory considerations, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

The EPA clarifies for the commenter that the RAA calculation will not utilize results below the PQLs as discussed in section 8.2 of the EPA response in this *Response to Comments* document, therefore no actions to address MCL exceedances will result from results below the PQLs. In the final rule, all results below the PQLs will be treated as zeroes in the compliance calculations, consistent with the commenter's recommendation.

The EPA disagrees with changing compliance calculations to account for the percentage of water a EPTDS provides to a PWS as a whole. As one EPTDS has the potential to provide water to a group of customers, the EPA has determined that compliance should be based on comparison of sampling results for each EPTDS to the MCL. As specified under § 141.905(b), if one sampling point is in violation of the MCL, the system is in violation of the MCL. This same approach is used in the regulations for other SOCs and VOCs. The EPA notes that there is no requirement to sample at the "final distribution point" of each PWS for regulated PFAS. Related to sampling issues, including background contamination concerns, please see section 8.7 of the EPA response in this *Response to Comments* document. As it develops implementation materials for the PFAS rule, the EPA will consider the suggestion that guidance cover operator training to reduce the potential for quality assurance (QA)/QC or sampling issues.

Wyoming Department of Environmental Quality (WDEQ) (Doc. #1716, SBC-044765)

14. Unclear Procedure Following a PFAS MCL Exceedance in a Regulated PWS

WDEQ recommends EPA provide clarification on the procedures that follow a PWS exceeding a proposed MCL. As written, the proposed PFAS NPDW rule is not clear on whether a PWS will be given a period of time to collect and provide confirmation samples or to adjust any PFAS treatment methods in place before the PWS is considered non-compliant. The WDEQ emphasizes the importance of quality assurance/quality control (QAQC) measures to ensure accurate and consistent data are obtained, and WDEQ encourages giving PWSs an opportunity to obtain confirmation samples to rule out QAQC issues if an exceedance is detected. The WDEQ recommends that EPA provide, for each PFAS with MCL values and PFAS with HI values, clarification on what PWSs can expect if a PFAS MCL exceedance occurs, what process will be followed to assess the exceedance and any potential QAQC issues, and how compliance will be measured, reported, and achieved.

EPA Response: Primacy agencies identify the required monitoring schedule for a system (consistent with the NPDWR) and in what circumstances, if any, a system must collect and

analyze a confirmation sample. Aside from a confirmation sample collected at the direction of a primacy agency, such as for a suspected QC issue, additional samples collected by the system would be considered voluntary samples, not compliance samples, and the results of voluntary samples are not to be included in quarterly compliance averages. In most circumstances, the EPA anticipates that a system would have no more than two compliance samples (the routine sample and a confirmation sample, if required) per quarter, and in both cases the sampling would occur at the direction of the primacy agency. With respect to an individual PFAS exceedance, at the national level, the EPA is not specifying the specific action that a water system must take, only that the water system is required to provide PN of the exceedance and take some action to reduce regulated PFAS concentrations to at or below the MCLs. MCL compliance is based on an RAA, as discussed in section 8.2 of the EPA response in this *Response to Comments* document, which is reassessed after every quarter. The exact timeframe for assessing MCL violations is determined by the primacy agency and will depend on whether a confirmation sample is requested. For a discussion of laboratory QA/QC concerns, please see section 8.7 of the EPA response in this *Response to Comments* document. A system achieves MCL compliance by providing drinking water at an EPTDS with RAA concentrations of regulated PFAS that are consistently no higher than the MCLs. MCL violations are assessed by the primacy agency, and the primacy agency reports the violations to the EPA. MCL violations also require public notice and must be summarized in CCRs. Please see sections 9.1 and 9.2 of the EPA response in this *Response to Comments* document for discussions of comments on CCR and public notice requirements, respectively. These requirements are discussed in section IX of the preamble to the final rule and are codified in Subparts O and Q of Part 141 in the CFR.

Wisconsin Department of Natural Resources (Doc. #1828, SBC-044807)

Laboratory Reporting Levels and Calculating the Running Annual Average

WDNR believes laboratories can reliably detect and report PFOA and PFOS at 2.0 ppt. Therefore, it is not appropriate to use zeros in the running annual average (RAA) for any samples below 4.0 ppt (e.g. 3.9 ppt would equal 0 ppt for purposes of RAA calculation in the proposed rule). Averaging zeros for quarters where the system was just below 4.0 ppt along with any quarterly results above 4.0 ppt would result in a system being under the 4.0 MCL for the RAA. However, if results between 2.0 ppt and 4.0 ppt are included in the running annual average (rather than included as a "zero") along with results that are above 4.0 ppt, the system would be determined to be above the MCL and would be out of compliance based on reported data.

WDNR looks forward to further engagement with EPA as we work together to implement this PFAS drinking water regulation.

Please contact me (steve.elmore@wisconsin.gov, 608-259-6100) if you have questions or would like to discuss these comments.

Sincerely,

Steven Elmore, Director

Drinking Water and Groundwater Program

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

Washington County Department of Public Health and Environment (Doc. #1739, SBC-043567)

Proposal to treat results below the PQL as zero for compliance purposes

Part IX, subpart B of the rule preamble discusses how to handle sample results that are less than the PQL for monitored PFAS.

Comments:

The county, in agreement with the Minnesota Department of Health (MDH), asserts that any PFAS results from a certified laboratory that are above the laboratory RLs should be included when determining compliance with the MCLs. Due to the MCLs for PFOS and PFOA being set at the PQLs, and EPA's proposal to treat any result below the PQL as zero for compliance purposes, systems with valid data from laboratories showing they are out of compliance based on a traditionally-calculated Quarterly Running Annual Average (QRAA) will be treated as in compliance. This is problematic in regard to public perception, as it conflicts with how the QRAA for MCL compliance is typically determined for other contaminants (where results below the MCL are included in QRAA calculations), and moreover reduces the public health protection that could be provided under this proposed rule.

It is our understanding that at least in Minnesota, laboratories already confidently achieving RLs below 4 ppt and information from our Public Health Laboratory (PHL) and the Environmental Monitoring Coalition (EMC), it appears that 4 ppt is currently not "the lowest concentration of analyte that can be reliably measured within specified limits of precision and accuracy during routine laboratory conditions."

To address the issues described here, EPA should make one of the following changes to the proposed NPDWR for PFAS:

• Allow any results above laboratory RLs to be used for determining a QRAA for compliance and set a required RL for laboratories that is below the MCL and achievable, such as 2 ppt for PFOS and PFOA.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. For discussions of the PQL and laboratory capabilities, please see sections 5.1.2 and 7.2 of the EPA response in this *Response to Comments* document, as well as sections V and VII of the preamble to the final rule. The agency clarifies for the commenter that the EPA has established PQLs for regulated PFAS, but no MRLs. Under both EPA-approved PFAS

drinking water analytical methods, a laboratory verifies its own MRL and the MRL can vary (see section 7 of the EPA response in this *Response to Comments* document).

City of Tulsa Water and Sewer Department (CoT WSD) (Doc. #1785, SBC-043780)

2. 88 FR 18667 (also 88 FR 18682, 18730). EPA requests comment on using zero for sample results less than PQL, or using alternative of one-third PQL for each PFAS.

CoT WSD responds that using zero for sample results less than PQL is consistent with current compliance calculations for other Synthetic Organic Compounds (SOC) NPDWRs at 40 CFR 141.24(h)(11)(v). The proposed PFAS compounds will be added to the table of SOC MCLs at §141.61(c) (see 88 FR 18748), therefore, the current SOC compliance calculation method should apply. EPA erroneously states at 88 FR 18682 that using one-third of the PQL is "largely consistent with EPA's NPDWRs related to other SOCs," but that is not what is in the regulation at this time.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. In the final rule, the PFAS MCLs are not added to the table of SOC MCLs in §141.61(c), but are presented in their own table Additionally, while the monitoring requirements are similar to the SMF for other SOCs, the regulated PFAS monitoring requirements are separate and included in their own Subpart Z.

Regarding the commenter's claim of an erroneous EPA statement in the proposed rule preamble (that using one-third the PQL is "largely consistent with EPA's NPDWR's related to other SOCs"), the agency notes the following as a more complete excerpted text, "While this approach may be more complicated to implement than using zero when below the PQL, it is largely consistent with EPA's NPDWRs related to other SOCs and has the potential to slightly increase the public health protection provided by this proposed regulation." The EPA notes this language was in the context of the agency requesting public comment on use of alternative values to zero in compliance calculations. For the PFAS NPDWR, the EPA has adopted the use of trigger levels, rather than "detection limits" as it done for some other regulated SOCs.

Jeniece Neville (Doc. #1924, SBC-046544)

Many communities in our local area of Northeastern Illinois have non-detectable levels of the newly proposed regulated PFAS constituents in drinking water, but some communities have a history of certain of the PFAS compound(s) hovering around the detection limit.

Since most lab methods (LC/MS/MS) per Methods 533 and 537.1 cannot detect PFAS constituents below approximately 2 ppt, my colleagues and I are wondering if, when calculating the H.I. ratios that pertain to each of the 4 H.I. PFAS chemicals, for N.D. levels of these chemicals, should we input a value of 2 ppt to account for the possibility of the constituents existing up to that amount without being detected in a sample? Or, should we simply assume a value of 0 ppt for the non-detected PFAS constituent?

We are specifically wondering about the cases where there have been detectable levels of the compound(s) in question in other tests that happen to hover around the detect limit. Otherwise, we would assume that a N.D. lab result would equate to a ppt of 0 to be factored into the reported H.I.

Thank you!

Jeniece Neville

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document. Compliance determinations rely exclusively on results at or above PQLs. If a laboratory result for a regulated PFAS is below the PQL, a value of zero would be substituted, whether calculating an RAA to compare to a single-PFAS MCL or to a Hazard Index MCL.

Jonathan O'Donnell (Doc. #2338, SBC-046260)

Treating concentrations of PFOA and PFOS that are less than 4 ppt as 0 ppt for compliance annual averages will allow many sites that are consistently above the trigger level but just below 4 ppt to avoid quarterly testing. I recommend treating concentrations that are less than 4 ppt as 2 ppt for compliance annual averages.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document regarding the determination of compliance and use of values below the PQLs. The use of results below the PQLs for establishing monitoring frequencies and trigger levels are discussed in sections 8.1.2 and 8.8 of the EPA response in this *Response to Comments* document. As results below the PQLs will be used in the determination of monitoring frequency, the EPA disagrees with the commenter that water systems with results between the rule trigger levels and MCLs will not be required to monitor more frequently because they will be required to conduct either quarterly or annual monitoring depending on the specific results.

Greater Cincinnati Water Works (GCWW) (Doc. #1550, SBC-042696)

EPA has requested comment on whether the proposed trigger levels (i.e. 1.3 ppt for PFOA and PFOS) should be used instead of zero when calculating the running annual averages for compliance when PFAS are detected but below their proposed PQLs. GCWW supports the currently proposed approach of using zero for compliance. Using the proposed trigger level is arbitrary and is essentially requiring compliance based on numbers which, by definition, cannot be reliably quantified by all laboratories. In section IX of the preamble (Monitoring and Compliance Requirements), the EPA states "...at the proposed trigger level, the measurement is primarily useful in determining whether the contaminant is present in a sample and for evaluating monitoring flexibilities, rather than to determine its specific concentrations." It is inappropriate to base compliance on measurements which are not useful in determining specific concentrations. This is overly conservative and will not result in significant health benefit.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-042889)

In some instances, Massachusetts PWSs have been advised to take sources out of service so that finished water PFAS concentrations are below the MMCL. This option will not be possible for most water systems. Some water systems have limited sources and those sources may be constrained by other regulatory programs that govern water withdrawal quantities (in Massachusetts, this is the Water Management Act). Flexibility for limited use of impacted sources during peak demand periods may be necessary for public safety (adequate pressure and fire protection) or to maintain reasonable operating costs while permanent solutions are implemented. For this reason, we support determining compliance on a running annual average.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document.

8.3 Previously-Acquired Data

Summary of Major Public Comments and EPA Responses

The EPA received many comments on the provision described in the proposed rule that allows PWSs to use previously-collected data to satisfy some or all of the initial monitoring requirements. This provision, under 141.902(b)(1)(vi), allows systems with appropriate historical monitoring data for each EPTDS, collected using EPA Methods 533 or 537.1 as part of UCMR 5 or a state-level or other appropriate monitoring campaign, to use that monitoring data to satisfy some or all of the initial monitoring requirements. The EPA proposed that data collected after January 1, 2023, be accepted for EPTDS samples, and data collected between January 1, 2019, and December 31, 2022, also be accepted if below the proposed rule trigger level. Additionally, the EPA proposed that if a system had conducted prior monitoring involving fewer than the number of samples required for initial monitoring under this PFAS NPDWR, then all surface water systems, GWUDI systems, and groundwater systems serving greater than 10,000 would be required to collect at least one sample in each quarter of a calendar year that was not acquired and groundwater systems serving 10,000 or fewer would be required to collect one sample in a different quarter of the calendar year than the one in which the previous sample was acquired.

Of commenters that provided input on this proposed allowance, nearly all supported the use of previously-collected data to support the initial monitoring requirements. The EPA agrees with these commenters that appropriate, previously-collected data should be allowed and notes that there will be significant data available from UCMR 5 monitoring and from the many states that have been proactively conducting PFAS drinking water monitoring. This will allow for a significant opportunity to reduce burden for numerous water systems, as well as decrease the potential for laboratory capacity issues. One commenter suggested that the use of this data may not be sufficiently representative of current PFAS concentrations in drinking water systems as

the laboratory analyses previously used may not have been sufficiently sensitive to detect the analytes, relative to the proposed PFAS regulatory standards. The EPA disagrees with this commenter as the analytical methods proposed for PFAS analysis were available for the majority of the time period (i.e., 2019 and after) in which data are allowed to be used to satisfy the initial monitoring requirements. Furthermore, the rule provides that a primacy agency may choose to not allow these data to satisfy initial monitoring requirements and may require more frequent monitoring on a system-specific basis. Additionally, the EPA clarifies that previous monitoring does not automatically qualify water systems for reduced compliance monitoring; rather it is the results from that monitoring that determine the eligibility for a reduced compliance monitoring schedule.

Many commenters suggested that the use of these data should be at the state's discretion and requested that the EPA provide additional flexibility to the primacy agencies in the determination of which data are allowed, including the number of samples and the QA requirements. Moreover, several commenters asked that the EPA clarify how much additional data would be needed to satisfy the initial monitoring requirements if a previous monitoring campaign included less sampling than required under the rule initial monitoring requirements. Specifically, a few commenters noted that, under the requirements of UCMR 5 monitoring, groundwater systems serving greater than 10,000 would have results from two sampling events, not the four needed to satisfy the initial monitoring requirements of this rule. Commenters requested that the EPA explain if these UCMR 5 systems would need to collect additional (supplemental) samples. A few commenters suggested UCMR 5 monitoring should sufficiently meet the requirements for all systems, even though the proposed rule requires quarterly sampling for all groundwater systems serving greater than 10,000. In the final rule under 141.902(b)(1)(viii), the EPA is maintaining that if a system has some previously collected results, but fewer than the number required to satisfy the initial monitoring requirements, they must conduct additional monitoring such that it, coupled with the previous monitoring, meets the requirements of this rule under 141.902(b)(1)(v). All surface water and GWUDI systems, and groundwater systems serving greater than 10,000, must collect the required additional samples 2-4 months apart from the months with available data, without regard to year, such that all quarters are represented. This would apply to all types of previously collected data, including from UCMR 5 systems. Please see section 8.1.2 for the EPA's responses regarding the initial monitoring requirements, specifically for groundwater systems serving greater than 10,000 that would need to supplement UCMR 5 data to satisfy the initial monitoring requirement.

Several commenters requested that the EPA clarify whether only samples collected under UCMR 5 would be allowed to fulfill initial monitoring requirements, or if data under other monitoring efforts, such as state monitoring, would also be acceptable. As provided in the final rule, a state may accept results from all appropriate monitoring efforts, as determined by the state, including, but not limited to, UCMR 5 and other state-led efforts.

Several commenters provided various comments related to QA requirements for previously collected data, including data analysis methods, MRLs, and data collection timeframe. A few

commenters expressed that the EPA should allow the use of results from modified EPA methods and/or other state-developed analytical methods. The EPA disagrees with these commenters. While there are other methods that have been used for data collection and analysis, the EPA is requiring that any data used for this rule be collected and analyzed using Methods 533 and 537.1 to ensure consistency across analytical results, as well as to align with the final rule analytical method requirements described in 141.901. A few commenters requested that the EPA provide additional information on reporting level requirements of the data, with one commenter suggesting that the EPA should not allow this data to be used for initial monitoring purposes if the reporting limits of the laboratory are higher than the EPA's proposed PQLs. The rule provides that the available data can be used regardless of reporting or detection limits to satisfy the initial monitoring requirements; however, given these factors, the results may not support determinations for reduced compliance monitoring. Regarding data collection timeframes, a few commenters questioned why data collected prior to 2023 would not be accepted where the laboratory was not able to produce results below the proposed rule trigger levels. In response, the EPA has modified the rule to allow data from January 1, 2019, and later to satisfy initial monitoring requirements, even if the laboratory is not able to produce results below the final rule trigger levels if it meets all other requirements (including being analyzed using Methods 533 and 537.1). Data collected prior to 2019 may not be representative of water quality conditions and likely would not have been analyzed using these methods (given when they were published). The EPA notes if the results exceed the final rule trigger levels the system will not be eligible for a reduced monitoring schedule at that EPTDS.

Individual Public Comments

Great Lakes Water Authority (GLWA) (Doc. #1558, SBC-042554)

Allow the use of previously acquired monitoring data to satisfy initial monitoring requirements including the data collection timeframe requirements and if other QA requirements should be considered.

Proactive utilities that have already been monitoring their systems should not be required to go backwards because USEPA is catching up with states that have regulated. Additionally, most QA/QC issues involved with sample collection and analysis are more likely to yield a false positive or higher concentration reported than the opposite. Therefore, previously acquired monitoring data should be able to satisfy initial monitoring requirements.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document.

Missouri Department of Natural Resources (Doc. #1563, SBC-042531)

EPA requests comment on its proposal to allow the use of previously acquired monitoring data to satisfy initial monitoring requirements including the data collection timeframe requirements and if other QA requirements should be considered.

The Department supports the use of previously acquired monitoring data at the state's discretion. This includes QA requirements. For instance, the Department used a modified 537 method (no field blanks) to decrease the cost of sampling during our occurrence screening. For systems with no detections, this would have no impact on the validity of the data and this data should be acceptable for initial monitoring. For systems with detections, the Department collected and analyzed confirmation samples using both approved methods without modification. The Department believes that all of this data should be valid for purposes of initial monitoring and the rule should provide flexibility to allow this.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document.

American Water Works Company Inc. (Doc. #1608, SBC-044014)

Using Previously Collected Data

American Water agrees with the U.S. EPA's intention to reduce the burden on groundwater systems serving 10,000 or fewer people by only requiring two samples within a ninety-day period for initial monitoring. We also appreciate the proposed use of previously collected data to fulfill initial monitoring requirements, but urge the U.S. EPA to:

• Review the regulatory language to ensure that it accurately reflects the intent of the preamble language that any samples collected after January 1, 2023, that were collected consistent with the methods described under UCMR 5 would be acceptable to be used as previously collected data. As currently written, the regulatory language could be misinterpreted to only allow data specifically required and collected under UCMR 5 to qualify, which does not appear to be the intent based on the preamble.

o Regulatory language: "Such data may only be used if it was collected in accordance with § 141.40 and that such samples were collected starting on or after January 1, 2023." (Page 18751)

o Preamble language: As proposed, systems would be allowed to use previously collected monitoring data to satisfy the initial monitoring requirements. In general, a system with appropriate historical monitoring data for each distribution system entry point, collected using EPA Methods 533 or 537.1 as part of UCMR 5 or a state-level or other appropriate monitoring campaign, could use that monitoring data to satisfy initial monitoring requirements. EPA is proposing that systems with previously acquired monitoring data from UCMR 5 will not be required to conduct separate initial monitoring for regulated PFAS. To satisfy the initial monitoring requirements for these systems using UCMR 5 data, data collected after January 1st, 2023, can be used for entry point samples. While EPA expects most systems serving 3,300 or greater will have UCMR 5 data, EPA is also proposing that systems with previously acquired monitoring data from outside UCMR 5, including State-led or other appropriate occurrence monitoring using EPA methods 533 or 537.1 will also not be required to conduct separate initial monitoring for regulated PFAS. This addition may allow systems serving fewer than 3,300 to

satisfy the initial monitoring requirements. Data collected after January 1st, 2023, can be used for entry point samples. Data collected between January 1st, 2019, and December 31, 2022, may also be used if it is below the proposed rule trigger level of 1.3 ppt for PFOA and PFOS and an HI of 0.33 for PFHxS, HFPO–DA, PFNA, and PFBS. The additional analytical requirement for older data is to ensure the use of these data is adequately representative of current water quality conditions. If systems have multiple years of data, the most recent data must be used." (Page 18683)

• Acknowledges that UCMR 5 sampling for groundwater systems serving over 10,000 people will not be adequate to qualify for reduced monitoring. The U.S. EPA should review cost estimates to confirm that the inability of these systems to qualify for reduced monitoring is accurately captured.

Further, using previously collected data is appropriate for reduced monitoring but not for determining compliance, as water systems may have made treatment changes or other changes to impact the quality of the water reaching their customers.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document. For the EPA response related to the EPA's sampling cost estimates, please see section 13.3.4 of the EPA response in this *Response to Comments* document.

Minnesota Department of Health (MDH) (Doc. #1610, SBC-042856)

Use of Previously Acquired Data to Meet Initial Monitoring Requirements

Per Part XIV, Section IX of the rule proposal:

"EPA requests comment on its proposal to allow the use of previously acquired monitoring data to satisfy initial monitoring requirements including the data collection timeframe requirements and if other QA requirements should be considered."

MDH Comments:

· Minnesota, and many other states, have proactively completed PFAS monitoring at public water systems in order to better identify systems with elevated PFAS levels and allow for communication and action in advance of rule finalization. The ability to use this previously collected data, as well as UCMR 5 data, provides an opportunity for the efficient use of public resources where the state already possesses appropriate information on PFAS presence. As such, we support the use of previously collected to satisfy initial monitoring requirements. Our further comments seek both clarification and some flexibility in how this data is used.

· The rule proposal does not clearly define how much previous data needs to be collected to satisfy initial monitoring. In part IX, subpart C of the rule preamble, the following is stated: "EPA is proposing that systems with previously acquired monitoring data from UCMR 5 will not be required to conduct separate initial monitoring for regulated PFAS." However, previously in part IX, subpart A, it is stated that "EPA is proposing that, consistent with the SMF for SOCs,

groundwater systems serving greater than 10,000 and all surface water systems are initially required to monitor quarterly within a 12-month period." Since groundwater systems are only sampled twice under UCMR5, it is unclear if UCMR5 sampling is sufficient to meet initial monitoring requirements for large groundwater systems or if additional data would be needed in between UCMR5 sampling events.

· For small groundwater systems not sampled under UCMR5, it is unclear how much previously acquired state monitoring data is needed to satisfy initial monitoring. Minnesota conducted statewide PFAS testing between 2020 and 2023, but most systems were only tested once.

· MDH requests that EPA allow states flexibility to determine if previously acquired monitoring data satisfies initial monitoring for these small systems. For example, if a system was tested only once under our statewide PFAS sampling effort, but there were no detections for any PFAS – and detection limits were below the trigger level – MDH would like the opportunity to consider those results for use in satisfying initial monitoring and starting the system on reduced monitoring.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044040)

21. EPA requests comment on its proposal to allow the use of previously acquired monitoring data to satisfy initial monitoring requirements including the data collection timeframe requirements and if other QA requirements should be considered.

a. See 19.b and 32. Consider allowing up to 5 years of previous data as long as the PQL of 4.0 ppt has been met. However...EPA has to allow labs to provide UCMR5 results down to the MDL (ie "j-flag" data) which currently isn't allowed. Contract laboratories performing UCMR5 analysis have been directed by EPA to not report any data below the established PQL of 4.0 ppt. This would be an incredible burden on labs to re-send every single report to every single system and this time include the MDL data.

b. This is another example of why raising the Trigger Level to 4.0 ppt and the MCL to

8.0 ppt is advisable. That data would be readily available and is confirmed to be accurate and reliable.

c. Another QA requirement to consider is that with updated EPA regulation on MDL calculations, MDLs are likely to be higher and to fluctuate year to year and with new and expanding equipment/facilities. Therefore, the EPA should only utilize data to determine compliance using established reliable and accurate PQL data, and do not utilize any data below 4.0 ppt for compliance determinations.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document. For the EPA's response related to trigger levels please see section 8.8 of

the EPA response in this *Response to Comments* document. For the EPA's response related to compliance determinations, please see section 8.2 of the EPA response in this *Response to Comments* document.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044038)

b. Up to 5 years of previously acquired data should be allowed to be used for initial compliance, as long as the current established PQL of 4.0 ppt has been met. For this reason, EPA must immediately allow contract laboratories to report UCMR5 PFAS results to the MDL.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document. For the EPA's assumptions that water systems can request UCMR 5 data below MRLs from laboratories for use in satisfying some or all of the NPDWR's initial monitoring requirements and determination of compliance monitoring frequency, please see section 13.3.4 of the EPA response in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043083)

Initial Monitoring: Use of Existing Data and Timeline

Aqua appreciates the Agency's interest in reducing public water system monitoring burdens, especially where existing monitoring data exists. The Agency's proposed approach to accept data collected since January 1, 2019, is appropriate. While it is uncertain what magnitude of impact this will have on water systems, this will be a welcome relief for water systems already working to understand PFAS levels in their water. This is especially true, given that the use of this data will be subject to state primacy agency approval and the overall quality and scope of the previous data collection. For example, many states may have data for PFOA, PFOS, PFHxS, and PFNA but not PFBS and HFPO-DA. In other cases, water systems may not have received results for PFAS below the proposed PQL.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-044874)

DEP supports allowing water systems to use previously collected data for initial compliance as one potential way to minimize costs. Additional questions and comments relative to the use of previously collected data are provided later in this letter.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-044884)

Compliance Monitoring Considerations

• DEP supports allowing water systems to use data collected for compliance with state PFAS MCL rules, including the Commonwealth's PFAS MCL rule, to meet the initial compliance monitoring requirements of EPA's proposed rule. Allowing systems to use this data would provide significant cost savings and reduce burden while maintaining health protection.

• DEP requests clarification on specifically what "previously collected" data will be acceptable to count for initial monitoring.

o Currently, it appears that state data in general was excluded as a grandfathering option for previously-collected data. DEP believes that more data that falls outside the scope of the state grandfathering allowance in the proposed rule needs to be included.

o DEP also believes that the rules for previously-collected data need to be consistent. If data for the Fifth Unregulated Contaminant Monitoring Rule (UCMR 5) does not need to meet the proposed trigger level, other data should similarly not be required to meet that low level.

o The trigger level of 1.3 ppt for PFOA and PFOS is too low for the allowance of previously-collected data. As noted previously, laboratories are generally not capable of accurately detecting PFAS to that level.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044065)

5. ASDWA recommends that EPA clarify and allow maximum flexibility to use previously acquired state sampling data for determining initial monitoring and waivers. States support the maximum flexibility for using existing state data to determine initial monitoring that was not included under the Fifth Unregulated Contaminant Monitoring Rule (UCMR 5) and for allowing waivers utilizing both state and UCMR 5 data. Clarification in the final rule is necessary to provide the details of the requirements for using previous state sampling and the number of samples necessary to meet the initial monitoring requirements.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044097)

ASDWA recommends that EPA clarify and allow maximum flexibility to use previously acquired state sampling data for determining initial monitoring and allowing waivers.

ASDWA recommends that maximum flexibility be allowed for using existing state data that was not included to meet the initial monitoring requirements and for allowing waivers using both state and UCMR 5 data. This flexibility should include providing primacy agencies with the ability to refrain from allowing water systems to use UCMR 5 data in lieu of initial monitoring. Clarification is needed in the final rule on the requirements for using previous state sampling and

the number of samples needed to meet the requirements for initial monitoring with the necessary stipulations for PFAS detections. Additionally, the final rule should explicitly state that water systems that conduct UCMR 5 monitoring do not need to conduct initial monitoring. While the UCMR 5 only requires large ground water systems to sample twice, this should be sufficient, even though the proposed rule requires quarterly sampling.

The final rule should answer the following questions in a way that allows the maximum flexibility for primacy agencies to make determinations about using existing data, to know what additional data the state may want to acquire before the rule goes into effect, and preemptively fill the gaps by taking additional samples to meet rule requirements for existing data, and for data reporting.

• Would one sampling event with no detections (done for statewide sampling using EPA Method 533) be allowed for initial monitoring? Or does the state data for water system samples have to be from four consecutive quarters?

• Will state data count if the primacy agency used a modified method when the only part that was modified was not running a field reagent blank, and instead, the laboratory did confirmation samples?

• How do varying reporting limits among the different primacy agencies affect this decision?

• Will it be up to the primacy agency to decide whether existing water system sampling data can be used for waiver requirements and reduced monitoring?

• How will primacy agencies verify and share the sampling data when it has not been entered into SDWIS?

• Will the CCR create SDWIS reporting for PFAS?

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document. For SDWIS reporting and recordkeeping, please see sections 11.2 and 11.3 of the EPA response in this *Response to Comments* document. The EPA will develop tools to assist PFAS reporting in the CCR. For responses related to CCR requirements, please see section 9.1 of the EPA response in this *Response to Comments* document. Revisions to the CCR rule and responses to public comments received on that proposed rule will be addressed as part of a separate action, see www.regulations.gov, Docket ID: EPA-HQ-OW-2022-0260, and are outside the scope of this action.

Texas Commission on Environmental Quality (TCEQ) (Doc. #1632, SBC-044134)

[To alleviate the initial laboratory capacity issues and reduce public water system sampling costs, TCEQ supports:]

• Allowing previously collected monitoring data to satisfy initial monitoring and allowing reduced monitoring requirements if the system has historical monitoring data for each entry point

to the distribution system (EPTDS), analyzed using EPA Methods 533 or 537.1 if collected after January 1, 2023, for UCMR5 or state-led monitoring program.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document.

Aidan Cecchetti (Doc. #1640, SBC-044372)

• EPA requests comment on its proposal to allow the use of previously acquired monitoring data to satisfy initial monitoring requirements including the data collection timeframe requirements and if other QA requirements should be considered (pg. 18683 Federal Register Volume 88, Number 60).

o It is the opinion of the commenters that EPA should allow the use of previously collected data to satisfy initial monitoring requirements if those data meet specific QA requirements. For example, data in which the method detection limit reported by the laboratory exceeds EPA's PQL should not be accepted for the initial monitoring requirements.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document.

National Rural Water Association (NRWA) (Doc. #1641, SBC-043276)

• EPA requests comments on its proposal to allow the use of previously acquired monitoring data to satisfy initial monitoring requirements including the data collection timeframe requirements and if other QA requirements should be considered.

Response: Previously acquired monitoring data should absolutely be allowed to satisfy initial monitoring requirements.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document.

Savannah River Nuclear Solutions LLC (Doc. #1647, SBC-043332)

Comment 3

Section IX.C. Can Systems Use Previously Collected Data To Satisfy The Initial Monitoring Requirement? (pg. 18683)

SRNS supports EPA's proposal to allow systems with previously acquired monitoring data from Fifth Unregulated Contaminant Monitoring Rule (UCMR 5) collected after January 1st, 2023 to not be required to conduct separate initial monitoring for regulated PFAS for entry point samples. This will allow systems to avoid duplicative and costly sampling and analysis and will further reduce burden on analytical laboratories.

SRNS seeks further clarification on whether monitoring data collected pursuant to the proposed rule (if promulgated) can be used to satisfy the monitoring requirements for UCMR 5.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document. The EPA clarifies that it is allowing the use of UCMR 5 results, or other appropriate monitoring data, to satisfy some or all the PFAS NPDWR initial monitoring requirements. While required under separate actions, data collected to satisfy the initial monitoring requirements of this NPDWR may or may not meet the requirements for UCMR 5 monitoring. Should a PWS wish to conduct "dual purpose" monitoring (to comply with both UCMR 5 and the PFAS NPDWR), the PWS should carefully consider the requirements of each rule and discuss questions with the EPA or the primacy agency as needed.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044183)

4. NCDEQ recommends that EPA clarify and allow maximum flexibility to use previously acquired state sampling data to satisfy initial monitoring requirements and qualify for waivers.

NCDEQ recommends that maximum flexibility be allowed for using existing state data that was not included in UCMR 5 to meet the initial monitoring requirements. Clarification is needed in the rule to explain the requirements for using previous state sampling and the number of samples needed to meet the requirements for initial monitoring with the necessary stipulations for PFAS detections. The final rule should explicitly state that water systems that conduct UCMR 5 monitoring do not need to conduct initial monitoring. While the UCMR 5 only requires large ground water systems to sample twice, this should be sufficient, even though the proposed rule requires quarterly sampling. The final rule should answer the following questions in a way that allows the maximum flexibility for state agencies to make determinations about using existing data, to know what additional data the state may want to acquire before the rule goes into effect, and preemptively fill the gaps by taking additional samples to meet rule requirements for existing data, and for data reporting.

• Would one sampling event with no detections be allowed for initial monitoring? Does state data for water system samples have to be from four consecutive quarters?

• Will state data count if the state agency used a modified method?

• Will it be up to the state agency to decide whether existing water system sampling data can be used for waiver requirements and reduced monitoring?

• How will state agencies verify and share the sampling data when it has not been entered into SDWIS?

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document. For SDWIS reporting and recordkeeping, please see sections 11.2 and 11.3 of the EPA response in this *Response to Comments* document.

Santa Clara Valley Water District (Valley Water) (Doc. #1664, SBC-043127)

Comment 3 – Prior Voluntary Sampling Should be Allowed to Support Compliance with the NPDWR Provided it is Consistent with Certain Criteria

Valley Water as a wholesaler is exempt from participating in the Fifth Unregulated Monitoring Contaminant Rule (UCMR 5), which requires monitoring for 29 PFAS. In addition, state-sponsored monitoring campaigns focused primarily on groundwater. Valley Water believes in being proactive in the protection of public health and conducted PFAS monitoring on a voluntary basis at its surface water drinking water treatment plants influent and treated water, which is the entry point to the wholesale transmission system. Valley Water used approved EPA methods when conducting voluntary monitoring. Though Valley Water's data was provided to the state, the monitoring we conducted was not required by the state. We request that EPA expand the criteria listed in Part C of Section IX. Monitoring and Compliance Requirements, to include historical data that was acquired through voluntary monitoring to satisfy the initial monitoring requirements, provided that appropriate analytical methods were used.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044421)

EPA requests comment on its proposal to allow the use of previously acquired monitoring data to satisfy initial monitoring requirements including the data collection timeframe requirements and if other QA requirements should be considered.

• DOH supports the use of previously acquired monitoring data to satisfy initial monitoring requirements. In Washington State, approximately 698 public water systems participated in a PFAS sampling pilot project in 2022 and approximately 1,136 sources were sampled for PFAS. Under Washington's current regulation all community and non-transient non-communities must complete initial PFAS monitoring by December 31, 2025.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document.

Aurora Water, City of Aurora, Colorado (Doc. #1669, SBC-043715)

The proposed rule allows for the use of previously acquired monitoring data collected during the UCMR 5 rule monitoring. This monitoring rule uses EPA analytical method 533, which has a minimum reporting level of 4 ppt. If a system decides to use data collected during this time for the initial monitoring requirements in the new proposed rule, that water system would automatically not be eligible for reduced monitoring. This is another example as to why the proposed trigger level and MCLs need to be adjusted. Any system that applies for reduced monitoring would be unable to use past measurements if the trigger level is set to 4 ppt.

Therefore, Aurora Water supports using previously acquired data but believes it is irrelevant unless the trigger levels and MCLs are adjusted.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document. For the EPA's response related to trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-044916)

Section 5.2: Initial compliance monitoring

EPA is proposing to allow PWSs to use previously acquired monitoring data from UCMR 5, state-led, or other applicable monitoring programs using EPA Methods 533 or 537.1 as the initially monitoring data for determining compliance. We strongly agree with this decision and recognize the initial monitoring burdens this will erase for systems that would have been required to conduct a separate sampling campaign. We support the utilization of UCMR and other monitoring data whenever possible, as this will help with lab capacity and sample analysis costs.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document.

New York State Department of Health (NYS DOH) (Doc. #1677, SBC-044958)

20. In accordance with Section 141.CC.c(b)(1)(v), data collected between January 1, 2019, and December 31, 2022, may also be used if it is below the rule trigger level of 1.3 ppt for PFOA and PFOS and below an HI of 0.33. It is not clear why results above the trigger level couldn't also be used to satisfy the initial compliance period.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document.

New Hampshire Department of Environmental Services (NHDES) (Doc. #1690, SBC-044351)

e. Page 18730, Column 3, Bullet 3 - EPA requests comment on its proposal to allow the use of previously acquired monitoring data to satisfy initial monitoring requirements including the data collection timeframe requirements and if other QA requirements should be considered.

NHDES Comment - NH requests that all State-led PFAS monitoring data from 2019-2022 be used for the initial monitoring period, regardless of sample results. When NH first implemented the State PFAS MCLs (2019), we set the laboratory reporting limit at 2 ppt. That reporting limit was consistent with what laboratories were accurately able to report at the time. Any value lower than 2 ppt was reported to the State as a "non-detect" (or zero). We have systems that haven't sampled since 2020 or 2021 because PFAS was not detected (below 2 ppt) in their initial monitoring results, so they were set to a triennial monitoring frequency. It would be an undue

burden for those systems to have to repeat initial monitoring when their initial State-led monitoring showed such low levels of PFAS detected, if at all. [Rule Reference: 141.XX (b)(1)(v) – Page 18751, Column 1]

In addition, NH requests that EPA consider allowing the use of sample results that were analyzed using State-accredited proprietary methods such as Isotope Dilution. NH pushed the accredited laboratories to develop these methods when we first began regulating PFAS, which was prior to EPA methods being available. Many of our early results were analyzed with these methods.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045031)

EPA requested comment on its proposal to allow the use of previously acquired monitoring data to satisfy initial monitoring requirements. NJDEP recognizes that, nationwide, water systems may have collected PFAS monitoring data and recommends EPA provide maximum flexibility to primacy agencies to determine use of previously collected data. However, NJDEP is concerned that this historical data may not be useful to assist in evaluating compliance in all cases, as the laboratory analyses used previously may not have been sufficiently sensitive to detect the analytes to the regulatory standards in this proposal. While data from New Jersey may be sufficient, additional monitoring may be necessary in many cases.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045105)

6) Use of previously acquired data to satisfy initial monitoring requirements including timeframe and other QA considerations:

Existing pre-2023 data should be accepted if the data was through a certified laboratory, using approved EPA methods 537.1 or 533, and the data were accepted by the State. Drawing the arbitrary line of "pre-2023" does not make sense when in fact all of our data in Vermont since 2019 has met the same "current" standard. Either reliance on certification of the EPA Method or data collected under a state framework that is at least as stringent as the existing requirements. The need to have a PQL of 1.3 for data prior to 2023 is arbitrary and not based in science or supported by the data present. Existing data, regardless of when it was collected and how close the samples were collected, such as 2 calendar quarters from the same calendar year, must be allowed. Requiring 2 samples in a 12-month period is arbitrary and may not capture potential seasonal variability in the sample results the way annual sampling would. State data received according to an EPA method should be allowed to "count" for the initial monitoring requirements. Many systems in Vermont have extensive data that would not qualify for

consideration as initial sampling because they were not taken within one calendar year. To reduce the burdens on states and water systems, existing data following EPA methods documenting low/reduced risk should count toward the initial sampling requirements of the proposed regulation. Drawing the line at January 1, 2023 is arbitrary and our data is the same quality from 2019 – 2023 as it will be beyond 2023.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045103)

The proposed regulation of accepting UCMR 5 data is inequitable for those systems required to sample and pay for the sampling out of their own budgets. EPA should accept valid data from certified laboratories on-file with states to meet the demands of the initial sampling requirements with pre-2023 data or otherwise provide an equitable path forward where some systems' samples are not subsidized.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045168)

MassDEP recommends that EPA clarify and allow maximum flexibility to use previously acquired state sampling data to satisfy initial monitoring.

MassDEP recommends that maximum flexibility be allowed for using existing state data to meet the initial monitoring requirements and for allowing the use of both state and UCMR5 data.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045968)

Section 5.3: Initial compliance monitoring

EPA is proposing to allow PWSs to use previously acquired monitoring data from UCMR 5, state-led, or other applicable monitoring programs using EPA Methods 533 or 537.1 as the initial monitoring data for determining compliance. AMWA strongly agrees with this decision and recognizes the initial monitoring burdens this approach will erase for systems that would have been required to conduct a separate sampling campaign. AMWA supports the utilization of UCMR and other monitoring data whenever possible, as this will help with lab capacity and sample analysis costs.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document.

Washington County Department of Public Health and Environment (Doc. #1739, SBC-043571)

Use of Previously Acquired Data to Meet Initial Monitoring Requirements

Per Part XIV, Section IX of the rule proposal: "EPA requests comment on its proposal to allow the use of previously acquired monitoring data to satisfy initial monitoring requirements including the data collection timeframe requirements and if other QA requirements should be considered."

Comments:

Minnesota, and many other states, have proactively completed PFAS monitoring at public water systems in order to better identify systems with elevated PFAS levels and allow for communication and action in advance of rule finalization. Our state department of health, MDH, works closely with the many affected communities to regularly monitor wells for PFAS, in addition to sampling of private wells. The ability to use this previously collected data, as well as UCMR 5 data, provides an opportunity for the efficient use of public resources where the state already possesses appropriate information on PFAS presence. As such, we support the use of previously collected to satisfy initial monitoring requirements. Our further comments seek both clarification and some flexibility in how this data is used.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045228)

7. Additionally, EPA is requesting comment on allowing similar monitoring waivers to be granted based on previously acquired monitoring data.

CT DPH agrees with attempting to lower the sampling burden on systems and supports the use of previously collected data for compliance. EPA should provide clarification on allowable data.

• For trigger levels, does the laboratory minimum reporting limit need to be below the trigger level, or just any numerical values, such as "J" flagged results?

• Data collected under UCMR 5 has a minimum reporting limit of 4 for PFOA and PFOS, but the proposed MCL is 4.0. What is an acceptable minimum reporting level for results outside of the UCMR 5 data?

• Do any specific quality assurance or quality control tests need to be included? For example, does a field blank need to be analyzed for every sample?

It is important to have consistent accurate data for initial monitoring, but flexibility is important. The greater number of previously analyzed samples allowed will reduce the pressure on the laboratories and limit the financial burden to PWSs.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document. The approved analytical methods list the quality control samples and acceptance criteria required for sample analysis. Please see section 8.7 of the EPA response in this *Response to Comments* document regarding the frequency of FRB analysis. For monitoring frequency determinations, please see section 8.1.2 of the EPA response in this *Response to Comments* document. For rule trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045623)

Initial Monitoring: Use of Existing Data and Timeline

AWWA appreciates the agency's interest in reducing public water system monitoring burdens, especially where existing monitoring data exists. The agency's proposed approach to accept data collected since January 1, 2019 is appropriate. Reduced regulatory monitoring demands will be a welcome relief for water systems already working to understand PFAS levels in their water, but it is uncertain what magnitude of impact this will have on water systems.

It is difficult to estimate the magnitude of the reduced monitoring impact because data will be (i) dependent on fully fulfilling the initial monitoring requirements and the quality control that they require and (ii) subject to state primacy agency approval. For example, many states may have data for PFOA, PFOS, PFHxS, and PFNA but not PFBS and HFPO-DA. In other cases, water systems may not have received results for PFAS below the proposed PQL. Another challenge for systems to use previously collected data, such as data from UCMR 5, is that the results may not have been reported at the necessary level to be used for EPA's monitoring and will likely not be feasible for all water systems to acquire data below the PQL.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document. For the EPA's assumptions that water systems can request UCMR 5 data below MRLs from laboratories for use in satisfying some or all of the NPDWR's initial monitoring requirements and determination of compliance monitoring frequency, please see section 13.3.4 of the EPA response in this *Response to Comments* document.

California State Water Resources Control Board (Doc. #1760, SBC-044222)

The State Water Board offers the following specific comments and recommendations for consideration regarding implementation of the rule:

Recommend that EPA clarify and allow maximum flexibility to use previously acquired sampling data for determining initial monitoring and waivers. California public water systems have already performed extensive monitoring, and more will precede the establishment of this

rule. EPA should allow for the maximum flexibility for using existing data to determine initial monitoring that was not included under the Fifth Unregulated Contaminant Monitoring Rule (UCMR 5) and for allowing waivers utilizing both state and UCMR 5 data. Clarification is needed within the rule to explain the requirements for using previous sampling data and the number of samples necessary to meet the requirements for initial monitoring. The State Water Board recommends the broadest allowance possible for usage of existing data as this will save on implementation costs by not requiring repeat samples that will provide essentially no additional information and help alleviate expected lab capacity issues when nationwide testing begins.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document.

Western Urban Water Coalition (WUWC) (Doc. #1768, SBC-043951)

B. The Option to Leverage Existing Monitoring Data Will Not Necessarily Accelerate Compliance or Increase Feasibility

WUWC supports EPA's proposal to allow the use of previously acquired monitoring data obtained during UCMR5 or similar state-led monitoring to satisfy initial monitoring requirements. [FN41:Id. at 18683.] WUWC partly agrees with EPA's assertion that allowing water utilities to utilize existing sampling results will result in a "significant burden reduction" and "sufficient timing to take necessary actions and ensure rule compliance." [FN42:Id.]

However, EPA should not assume for the purpose of its economic feasibility evaluation that water utilities will choose to utilize existing data and forego additional sampling. Many public water systems should be expected to elect to perform additional sampling where UCMR5 or state data could result in a finding of noncompliance. As noted above, EPA's assumption that the existing data provision will result in reduced burdens for laboratories is not a foregone conclusion.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document. The agency is confident that allowing use of this data will result in burden reduction and alleviate laboratory demand. Under the final rule, primacy agencies may require or water systems may choose to collect additional data even if they have available previously collected data. However, with this provision, the EPA is seeking to reduce burden and reduce potential laboratory capacity issues by allowing this flexibility. The agency makes some reasonable assumptions, consistent with the overwhelming support from commenters, that the allowance of this data will reduce burden for thousands of water systems and that water systems will choose to use this data if available. Furthermore, if the available data (supporting initial monitoring requirements) were to demonstrate that a water system has results above the MCLs, it would be both required under the final rule (per initial monitoring requirements under 141.902(b)(1)(vi)) and in the interest of the water system to conduct additional monitoring. This would allow the system to identify necessary actions to ensure they are providing drinking water to their customers that meets all NPDWRs in advance of the MCL compliance date.

Pennsylvania Municipal Authorities Association (Doc. #1832, SBC-045791)

[PMAA's specific comments on the Proposal are as follows:]

15. EPA should permit the use of monitoring data generated prior to any final PFAS regulation to satisfy the initial monitoring requirements set forth in the Proposal. Municipal entities that proactively monitored their systems or did so pursuant to a state regulation or mandate should not be required by EPA to undertake additional sampling simply because EPA issued the Proposal after states developed their respective PFAS- related initiatives.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document.

Corix Infrastructure Inc. (Doc. #1834, SBC-045371)

[With regards to the specific items EPA has requested comment on, Corix provides below:]

• We strongly support the use of previously acquired monitoring data as long as the MDLs are low enough and appropriate EPA methods are used.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document.

Citizens Energy Group (Doc. #1838, SBC-044864)

EPA requests comment on its proposal to allow the use of previously acquired monitoring data to satisfy initial monitoring requirements including the data collection timeframe requirements and if other QA requirements should be considered.

The timing of UCMR 5 activities for water systems in the U.S., as well as state- or local-lead PFAS monitoring activities that exist, provide data that can be used to satisfy initial monitoring requirements. These data inform water systems of whether they will achieve compliance with the proposed MCLs at the effective date of the rule (3 years following publication of the final rule in the Federal Register). Those water systems that detect PFAS compounds at their EPTDS during this initial monitoring period may choose to conduct additional sampling to better inform their engineering and design of treatment plant modifications.

Those systems that, based on the suite of data available to them, do not have PFAS compounds at their EPTDS that indicate potential compliance challenges, should not be obligated to monitor just for the sake of monitoring during the initial 3-year period ahead of the compliance date. Doing so risks adding to the overall burden facing water systems without any benefit to the customers.

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document. Additionally, the EPA clarifies that as provided in the final rule, water

systems are only required to either provide previously collected data or conduct initial monitoring in one 12-month period during the three years following rule promulgation. Following that initial monitoring, compliance monitoring is required beginning three years following rule promulgation.

Alicia Jacobs (Doc. #2396, SBC-046279)

Question on behalf of Kentucky EEC and Kentucky Rural Water Association: How will UCMR5 sampling results be used as preliminary monitoring to determine sample schedule (i.e., proving that results do not exceed 1/3 of MCL or HI) when labs are simply using non-detect if result is below 4.0 ppt? Some UCMR5 laboratories will show actual value while others indicate a ND. How can we show we are below 1/3 of the MCL if laboratories can only measure to 4.0 ppt?

EPA Response: Please see section 8.3 of the EPA response in this *Response to Comments* document. If initial monitoring data do not show that a laboratory confirmed that results are below trigger levels (see section 8.8 of the EPA response in this *Response to Comments* document on rule trigger levels), then a state would assign a system to conduct quarterly sampling at the start of the compliance monitoring period. Regarding availability of UCMR 5 results below the trigger level, as well as the EPA's assumptions that water systems can request UCMR 5 data below MRLs from laboratories for use in satisfying some or all of the NPDWR's initial monitoring requirements and determination of compliance monitoring frequency, please see section 13.3.4 of the EPA response in this *Response to Comments* document.

8.4 Composite Sampling

Summary of Major Public Comments and EPA Responses

The EPA proposed that compositing of samples would not be allowed as part of the rule's monitoring framework. The EPA received a few comments related to composite sampling. The majority of these commenters agreed with the EPA's proposal to not allow samples to be composited due to analytical limitations and the increased potential for background contamination, along with the physical and chemical characteristics of PFAS. One commenter noted grab samples as more appropriate and suggested that individual systems be permitted to request alternative sampling methodologies if needed. One other commenter suggested that compositing samples from varying EPTDS should not be allowed. Conversely, a few commenters suggested that composite sampling could be implemented and would reduce the cost of analyses. Further, it was suggested that with proper guidelines and procedures for analyzing samples, possible contamination issues could be mitigated and asserted that issues with false negative and positive samples also impact discrete samples (i.e., that they are not unique to composite sampling).

For commenters who offered that composite sampling could be implemented, the EPA agrees it would potentially decrease sampling analysis costs and that sampling errors can occur when

handling and analyzing discrete samples. However, the compositing of samples necessarily involves additional handling, opening, and transfer steps than are required for the collection and analysis of individual samples. Therefore, the combining of samples that must be done for composite sample analysis represents an increased risk of sampling error, which could result in decreased public health protection and additional sampling costs. The agency also does not agree that alternative sampling methodologies should be permitted and requires the use of EPA Methods 533 and 537.1 for monitoring per the requirements of the rule. Please see section VII of the final rule preamble for more information on methods.

The agency received input from consulting with state regulators and small business entities (operators of small PWSs) noting that PFAS are ubiquitous in the environment at low concentrations, which necessitates robust laboratory analytical precision at these low concentrations. The EPA agrees with these concerns, and based on this input, as well as in considerations of the public comments, the EPA maintains in the final PFAS NDPWR that composite sampling is not sufficiently public health protective. The agency, therefore, is not allowing the use of composite samples to satisfy the final rule monitoring requirements.

Individual Public Comments

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044059)

37. CWUC agrees with EPA that composited sampling for PFAS should not be allowed, as this increases the risk of contamination. Grab samples are more appropriate for sampling. Individual systems can request alternative sampling methodologies if needed.

CWUC also wishes to acknowledge and support comments submitted by AWWA and NACWA. Thank you again for the opportunity to engage with this important rulemaking.

Sherry Scaggiari, Chair Colorado Water Utility Council sscaggia@auroragov.org

303-739-7390

EPA Response: Please see section 8.4 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044095)

In addition, ASDWA agrees with EPA's proposed deviation from the SMF for SOCs to not allow samples to be composited based on the low concentrations of PFAS that must be analyzed from different entry points.

EPA Response: Please see section 8.4 of the EPA response in this *Response to Comments* document.

Wyoming Department of Environmental Quality (WDEQ) (Doc. #1716, SBC-044752)

6. Justification for Disallowing Composite Sampling of all EPTDS for a PWS under the proposed PFAS NPDW Regulation Is Not Clear

EPA states that "incidental contamination from or adherence to surface laboratory equipment may artificially lower contaminant concentrations or result in false negatives." These risks apply to any sample collected-composited across multiple PWS EPTDS or individually sampled from each EPTDS-and is insufficient justification for not allowing composite samples to be submitted for compliance monitoring. Similarly, EPA's statement that "PFAS are demonstrated to be ubiquitous in the environment such that the risk for false positives may increase when combining samples for composite analysis" also does not provide sufficient justification. The ubiquitous nature of PFAS in the environment, risks of sampler-introduced contamination, and risk of ambient environment introduction of PFAS to a sample exists in either sampling method. These risks are controlled for by proper training prior to sampling for PFAS, the use of proper Personal Protective Equipment (PPE), proper sampling materials and sampling protocols (including the use of laboratory provided PFAS-free field blanks that should be collected at every location sampled for PFAS), and proper sample shipping protocols, regardless of whether composite or individual samples are collected. Justification for the apparent claim that compositing samples increases the risk of false positive results for PFAS has not been provided, and further discussion of this proposed departure from the previously implemented Standardized Monitoring Framework for Synthetic Organic Compounds should occur prior to finalizing the PFAS NPDW regulation.

WDEQ is not advocating for or against composite sampling. As stated in comment #5 above, if EPTDSs are sampled, a flow-weighted approach is important to ensure one higher-concentration, low-flow sample doesn't skew results for the distribution system as a whole. However, if EPA disallows composite sampling in the final rule, we encourage EPA to provide a stronger justification. WDEQ notes that standardized PFAS sampling training and guidance from EPA will be critical for both types of sampling, composite or individual, to ensure high-quality data is obtained. Guidance materials along these lines will need to be provided to all PWSs affected by the proposed PFAS NPDW rule for consistency of implementation.

EPA Response: Please see section 8.4 of the EPA response in this *Response to Comments* document.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045160)

MassDEP supports EPA’s proposal to not allow samples to be composited.

EPA Response: Please see section 8.4 of the EPA response in this *Response to Comments* document.

Groundwater Resources Association of California (Doc. #1831, SBC-045357)

Section IX. D states that the proposed regulations do not allow for composite sampling of PFAS to avoid risk of false positives when combining samples for composites analysis from the contributing entry points. Composite sampling can potentially reduce analytical costs because the number of required analyses is reduced by combining multiple samples into one and analyzing the composited sample. Not allowing composites reduces the operational flexibility and increases the costs for PFAS sampling. Moreover, this may be unduly restrictive if the different samples all feed into the same delivery system (hence, the water at the receptor points would be mixed anyway). Proper guidelines and care in collection and compositing procedures can allow the composite sampling approach to be implemented to reduce the cost of analyses. Issues with false positives due to the ubiquitous low level PFAS concentrations impact discrete samples as well. With proper guidelines and care in collecting and compositing procedures, a composite sampling approach can be implemented to reduce the cost of analyses. As such, we recommend that EPA allow for composite samples under proper guidance and revised standards. With these guidance and standards, EPA may allow PWS to composite samples if they demonstrate proper sample collection and compositing procedures and if the samples collected feed into a common water delivery system.

EPA Response: Please see section 8.4 of the EPA response in this *Response to Comments* document.

8.5 Monitoring Waivers

Summary of Major Public Comments and EPA Responses

The EPA did not include a provision to allow primacy agencies to grant monitoring waivers as a regulatory flexibility in the proposed rule. Several commenters agreed that monitoring waivers should not be allowed for this rule. Several additional commenters cited the persistence and mobility of PFAS in the environment and advised that reduced monitoring frequencies should be no less than every three years on the basis that drinking water consumers in unmonitored areas may unknowingly be exposed to these PFAS. Furthermore, many other commenters suggested that PFAS contamination can migrate significantly over a three-year period.

Many other commenters were supportive of monitoring waivers for this rule under certain circumstances similar to those applicable to other SOCs. Several commenters indicated that waivers would be appropriate if they were based on monitoring results. A few commenters recommended that if monitoring waivers were to be allowed, they should not be based solely on a traditional vulnerability assessment. A couple of commenters stated that waivers based on vulnerability alone should not be allowed during the initial monitoring period. One commenter recommended waiting until UCMR 5 monitoring is complete before allowing monitoring waivers to be granted through vulnerability assessments. A few commenters suggested that waivers be considered if they are based on a combination of vulnerability and monitoring results, while one other commenter suggested that assessing watershed characteristics to demonstrate

eligibility for monitoring waivers would be protective of chronic health risks. One commenter noted that merely allowing waivers to be granted would not necessarily reduce public health protection under the rule, as primacy agencies will retain the ability to deny waiver applications.

After consideration of these comments which raised significant concerns about the use of waivers for PFAS, and due to the specific mobility and persistence characteristics of the regulated PFAS as compared with other NPDWRs, the final rule does not allow monitoring waivers and establishes triennial monitoring as the least frequent monitoring timeframe. These specific properties of the regulated PFAS and their observed ubiquity in both drinking water and many other sources make waivers impractical and complicate the ability to maintain public health protection. Moreover, the EPA is not confident that allowing monitoring any less frequently than every three years or conducting vulnerability assessments will accurately capture potential concentration variations over the long term or protect against risks from new contamination sources.

Individual Public Comments

Great Lakes Water Authority (GLWA) (Doc. #1558, SBC-042553)

Allowance of monitoring waivers of up to nine years if after at least one year of sampling results are below the proposed rule trigger.

If the proposed language is not modified to distinguish between water producers and receivers in consecutive systems, then it is even more critical that the monitoring waivers of up to nine years be permitted to decrease the burden on both secondary systems which do not provide treatment.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document. For consecutive-system requirements under the final rule, please see section 1.4 of the EPA response in this *Response to Comments* document.

Great Lakes Water Authority (GLWA) (Doc. #1558, SBC-042556)

Whether there are specific conditions that should be mandated for systems to be eligible for exemptions under 1416 to ensure that they are only used in rare circumstances where there are no other viable alternatives and what those conditions would be.

If the proposed language is not modified to distinguish between water producers and receivers in consecutive systems, then it is critical that the monitoring waivers be allowed to decrease the burden on both secondary systems which do not provide treatment.

Further, the model used by EPA to simulate EPTDS assumed within-system concentrations are … distributed and variability in concentrations is entirely across entry points (p. 44 of rule). This assumption infers that unlike DBP, LCR or TCR there is no change in PFAS concentration associated with time of travel in the distribution system and most notably between the water supplier and any secondary utilities.

Thank you again for the opportunity to provide comments on this critically important matter.

Sincerely,

Suzanne Coffey

Chief Executive Officer

Cc: William Wolfson

Cheryl Porter

Randal Brown

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document. For consecutive system requirements under the final rule, please see section 1.4 of the EPA response in this *Response to Comments* document. Regarding exemptions under SDWA 1416, please see section XII of the final rule preamble and section 12.1 of the EPA response in this *Response to Comments* document.

Missouri Department of Natural Resources (Doc. #1563, SBC-042529)

EPA requests comments on whether water systems should be permitted to apply to the primacy agency for monitoring waivers. Specifically, EPA is requesting comment on the allowance of monitoring waivers of up to nine years if after at least one year of sampling results are below the proposed rule trigger level. Similarly, EPA also requests comment on whether allowance of monitoring waivers of up to nine years should be permitted based on previously acquired monitoring data results that are below the proposed rule trigger level. Additionally, EPA is also requesting comment on the identification of possible alternatives to traditional vulnerability assessments that should be considered to identify systems as low risk and potentially eligible for monitoring waivers.

The Department does not recommend monitoring waivers based solely on traditional vulnerability assessments. Experience has shown PFAS contamination occurs mainly through improper disposal or concentration of PFAS through traditional landfill leachate, air deposition miles from the source, wastewater effluent discharge, or biosolids land application. Often these contamination occurrences can only be detected through sampling. However, a system in a rural community surrounded by farmland, forests, mountains, or deserts have minimal risk that would affect groundwater wells. For this reason, the Department supports PFAS waivers with sampling at least once in a 9-year compliance cycle.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

Oregon Health Authority (OHA) (Doc. #1582, SBC-042764)

• EPA requests comments on whether water systems should be permitted to apply to the primacy agency for monitoring waivers. Specifically, EPA is requesting comment on the allowance of monitoring waivers of up to nine years if after at least one year of sampling results are below the proposed rule trigger level. Similarly, EPA also requests comment on whether allowance of monitoring waivers of up to nine years should be permitted based on previously acquired monitoring data results that are below the proposed rule trigger level. Additionally, EPA is also requesting comment on the identification of possible alternatives to traditional vulnerability assessments that should be considered to identify systems as low risk and potentially eligible for monitoring waivers.

OHA supports the allowance of 9-year monitoring waivers where both monitoring data and susceptibility assessment indicates PFAS exposure to customers is low, and requests that EPA consider incorporating this flexibility into the monitoring requirements in the final rule. Oregon, like many other states, developed criteria for identifying public water systems that may be vulnerable to exposure to PFAS contamination as part of a targeted PFAS sampling project in 2021/2022. As part of this project, Oregon developed a geographic information system (GIS) database and screening tool that identified known and potential sources of PFAS contamination within a water system's drinking water source areas that could be used to assess eligibility for 9-year waivers under this rule. OHA believes that in Oregon PFAS contamination is localized and associated w/ certain known activities, for example, airports, defense/military sites, fuel storage/transport and regulated terminals, rail facilities, fire stations with potential aqueous film-forming foam (AFFF) training, landfills, environmental cleanup sites that may involve PFAS sources, and wastewater facilities with potential PFAS sources within the service area based on industry type indicating potential PFAS use (NAICS business codes). Oregon's PFAS screening and assessment criteria, along with evaluation of aquifer susceptibility and well construction for groundwater, consideration of time-of-travel from upstream potential PFAS discharges to downstream surface water intakes, and PFAS monitoring results (at least one round of initial PFAS monitoring under the rule or previously acquired such as voluntary, state sampling, or UCMR5 data that meets the rule requirements) could be used to evaluate water system eligibility for 9-year waivers. OHA believes that under these circumstances, waivers could be granted with a reasonable degree of confidence that the risk of PFAS exposure to customers is low.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

National Tribal Water Council-Tribal PFAS Working Group (NTWCTPWG) (Doc. #1598, SBC-042338)

On page 18370 of the FRN, it is stated that:

EPA requests comments on whether water systems should be permitted to apply to the primacy agency for monitoring waivers. Specifically, EPA is requesting comment on the allowance of

monitoring waivers of up to nine years if after at least one year of sampling results are below the proposed rule trigger level. Similarly, EPA also requests comment on whether allowance of monitoring waivers of up to nine years should be permitted based on previously acquired monitoring data results that are below the proposed rule trigger level. Additionally, EPA is also requesting comment on the identification of possible alternatives to traditional vulnerability assessments that should be considered to identify systems as low risk and potentially eligible for monitoring waivers.

Tribes remain concerned that existing monitoring data are insufficient for understanding the risks of PFAS to tribal resources from upstream water and wastewater systems. The proposed regulation indicates that EPA continues to consider monitoring waivers for systems that can claim that PFAS has not been used in the area or that the area or its water sources are not susceptible to PFAS contamination. It should be acknowledged by EPA in the regulation that there are data in the literature (Butt et. al. 2014) that suggest long-chain PFAS such as PFNA can be generated by degradation of fluorotelomer alchohols (FTOH), thus complicating claims about the source of potential contaminants. If waivers from monitoring are granted to water systems, downstream populations should be notified and granted an opportunity to challenge the waiver. Vulnerability assessments used to request waivers should consider all exposure pathways that the release of persistent bioaccumulative toxic contaminants have on downstream tribes that practice subsistence lifeways.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044037)

19. EPA requests comments on whether water systems should be permitted to apply to the primacy agency for monitoring waivers. Specifically, EPA is requesting comment on the allowance of monitoring waivers of up to nine years if after at least one year of sampling results are below the proposed rule trigger level. Similarly, EPA also requests comment on whether allowance of monitoring waivers of up to nine years should be permitted based on previously acquired monitoring data results that are below the proposed rule trigger level. Additionally, EPA is also requesting comment on the identification of possible alternatives to traditional vulnerability assessments that should be considered to identify systems as low risk and potentially eligible for monitoring waivers.

a. CWUC believes that discussing a 9-year reduced monitoring schedule is a premature request as the nation has just begun sampling these parameters for UCMR5. Once the magnitude of the occurrence of PFOA and PFOS are truly established, then this determination can be better made. There is just not enough information to make this decision right now. Since PFAS originate from human factors, and not environmental factors, the fluctuation in presence and levels can vary drastically from one sample to the next. With any typical system being at equal risk of having a detection for the compounds at any given time, CWUC believes that reduced monitoring should

be at the most 3 years. Monitoring should be allowed no less than annually for facilities with specific PFAS treatment in place.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document. Related to monitoring requirements for systems that install treatment to address PFAS drinking water contamination, please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-044888)

• DEP recommends not allowing nine-year monitoring waivers for any regulated PFAS compounds, regardless of the basis for the waiver determination. Allowing nine-year monitoring waivers assumes that changes in contaminant levels are not expected over a long period of time. However, PFAS are still considered emerging contaminants because researchers are still learning more about their fate and transport in the environment. As such, DEP believes it is inappropriate to make that assumption with these contaminants.

• DEP also recommends not allowing any type of vulnerability waiver for PFAS. Since PFAS do not readily break down in the environment, they are considered forever chemicals, and the vulnerability of a water source cannot be assessed. If any waivers are to be allowed, DEP support is only allowing use waivers, where the public water system must document that PFAS have not been used, stored, or transported in their source water protection area. Refer to DEP's waiver criteria in 25 Pa. Code Chapter 109 for more information.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044094)

ASDWA does not recommend allowing solely vulnerability assessments for monitoring waivers during the initial monitoring period and does not recommend using composite samples.

The final rule should not allow monitoring waivers solely based on vulnerability assessments during the rule's initial monitoring period. States that have conducted monitoring have found PFAS in drinking water sources that were not expected due to the location and proximity to potential sources of PFAS. Knowledge is lacking on PFAS occurrence and transport, and insufficient data is available to make these determinations. New sources of PFAS contamination are being found on a consistent basis across the country. Vulnerability assessments may be appropriate in the future as water systems obtain more data.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document. Regarding composite sampling, please see section 8.4 of the EPA response in this *Response to Comments* document.

Citizens Against Ruining the Environment (CARE) (Doc. #1638, SBC-043457)

Primary Agency Authority to Grant Monitoring Waivers Must Be Strictly Limited

CARE opposes allowing Primary Agencies to grant monitoring waivers to PWS for up to nine years after one year of data showing that the PWS is below the trigger level. The NPDWR regulations after which that proposed rule appears to be modeled were written for the inorganic contaminants antimony, arsenic, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, selenium and thallium. [FN33: 40 C.F.R. 141.23(c).] Those contaminants, their sources, fate, and environmental transport are well understood and generally predictable based on the large body of accumulated research and experience related to them. Reliable risk models are available to assess a system's vulnerability to contamination from those contaminants, including the age and composition of the system and the types of industry and waste in the area. [FN34: National Primary Drinking Water Regulations, EPA,https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations#Inorganic (Jan 6, 2023).]

PFAS monitoring should not mirror that for the above-named inorganic contaminants because PFAS do not have the same physical properties, are not as predictable, and have much broader source categories than the other inorganic contaminants. As an example, if a system is not contaminated by selenium from petroleum refinery activity, one can infer that it will not later be contaminated by selenium unless petroleum refinement has begun in that watershed. With that in mind, the potential to waive monitoring for selenium for up to nine years is appropriate. Conversely, PFAS contamination comes from all manner of sources, is ubiquitous in household products, consumer goods, commercial applications, and can migrate into water systems along numerous pathways. Absent a more sophisticated and sensitive risk assessment model to predict a system's vulnerability to PFAS contamination, Primary Agencies cannot predict whether a waiver from monitoring would be appropriate.

It would be reckless to permit a State Primary Agency to approve waivers from PFAS monitoring for up to nine years. This is an excessive duration of time and unsupported by the research and documentation provided by the EPA to support its proposed rule.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

Aidan Cecchetti (Doc. #1640, SBC-044370)

• EPA requests comments on whether water systems should be permitted to apply to the primacy agency for monitoring waivers. Specifically, EPA is requesting comment on the allowance of monitoring waivers of up to nine years if after at least one year of sampling results are below the proposed rule trigger level. Similarly, EPA also requests comment on whether allowance of monitoring waivers of up to nine years should be permitted based on previously acquired monitoring data results that are below the proposed rule trigger level. Additionally, EPA is also requesting comment on the identification of possible alternatives to traditional vulnerability

assessments that should be considered to identify systems as low risk and potentially eligible for monitoring waivers (pg. 18683 Federal Register Volume 88, Number 60).

o It is the opinion of the commenters that it would be appropriate for EPA to allow primacy agencies to grant monitoring waivers up to once per 9-years. This is consistent with the regulatory framework for other synthetic organic contaminants and provides adequate public health protection for systems at low risk of exceeding the trigger levels, the MCLs, or the HI.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044181)

2. NCDEQ does not recommend solely allowing vulnerability assessments for monitoring waivers during the initial monitoring period and does not recommend the use of composite samples.

The rule should not allow monitoring waivers solely based on vulnerability assessments during the rule's initial monitoring period. There is currently not enough known about PFAS occurrence and transport, and not enough data are available to make these determinations. Vulnerability assessments may be appropriate in the future as water systems obtain more data. In addition, NCDEQ agrees with EPA's proposed deviation from the SMF for SOCs to not allow samples to be composited based on the low concentrations of PFAS that must be analyzed from different entry points.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document. Regarding composite sampling, please see section 8.4 of the EPA response in this *Response to Comments* document.

Nebraska Department of Environment and Energy (NDEE) (Doc. #1653, SBC-043199)

May 30, 2023

Submitted via www.regulations.gov

U.S. Environmental Protection Agency Office of Ground Water and Drinking Water 1200 Pennsylvania Avenue NW Washington, D.C. 20460

Attention: Jennifer McLain, Director

EPA Office of Ground Water and Drinking Water

RE: Nebraska Department of Environment and Energy Comments Docket No. EPA-HQ-OW-2022-0114

Dear Director McLain:

Thank you for the opportunity to submit comments on the proposed National Primary Drinking Water Rule to regulate per- and polyfluoroalkyl substances (PFAS). The Nebraska Department of Environment and Energy (Department) offers the following comments to enhance the clarity and effectiveness of the proposed rule.

• EPA requested comment on allowing all public water systems (PWS), regardless of size be allowed to collect one sample per three-year compliance period if PFAS is not detected at or above the trigger level. The current monitoring framework allows nine-year waivers.

• The Department would support the flexibility for all PWS to utilize a three-year compliance period and when appropriate, a nine-year waiver.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044401)

Page 18683. IX. Monitoring and Compliance Requirements. E. Can primacy agencies grant monitoring waivers?

• DOH supports allowing for provisions for systems to apply for monitoring waivers based on source vulnerability combined with sampling results that show PFAS below trigger levels or non-detects. One sample per source is appropriate for source(s) in low-risk areas with a documented history of no PFAS detections.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044396)

While DOH agrees with EPA that source vulnerability should not allow a waiver for initial monitoring of PFAS, DOH supports the use of monitoring waivers if appropriate safeguards are in place for public water system sources. If both sampling history, source vulnerability, and geographic location indicate no historical PFAS detections, and there are no potential PFAS sources that could impact public water system sources. Allowing public water systems to apply for monitoring waivers is consistent with EPA's approach previously implemented for other drinking water contaminants.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044420)

EPA requests comments on whether water systems should be permitted to apply to the primacy agency for monitoring waivers. Specifically, EPA is requesting comment on the allowance of

monitoring waivers of up to nine years if after at least one year of sampling results are below the proposed rule trigger level. Similarly, EPA also requests comment on whether allowance of monitoring waivers of up to nine years should be permitted based on previously acquired monitoring data results that are below the proposed rule trigger level. Additionally, EPA is also requesting comment on the identification of possible alternatives to traditional vulnerability assessments that should be considered to identify systems as low risk and potentially eligible for monitoring waivers.

• EPA and states have provided waiver opportunities for other contaminants as well and still provide public health protection. States can develop a waiver model that allows sources that are less vulnerable and susceptible, and have non-detect PFAS, can reduce monitoring to a 6 or 9 year schedule while still providing public health protection. Our current waiver model allows us to rescind waivers if conditions change. Please allow states the flexibility to develop and provide waivers.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-044915)

Cleveland Water urges EPA to reconsider its decision decline monitoring waivers or reduced monitoring based on reduced risks and watershed characteristics, such as proximity to contaminant sources or previous uses within the watershed. Omitting this is not consistent with other contaminants with chronic health impacts. While we understand the nature of PFAS chemicals are persistent and transportable, for a system that cannot prove it is below the trigger level due to lab reporting constraints, it will never be able to stay in the reduced monitoring schedule. This is because once a system qualifies for reduced monitoring based on their RAA, if it cannot prove it maintains concentrations below the trigger level, the system is automatically thrown back into quarterly monitoring. This can result in systems repeatedly going back and forth between monitoring schedules with no option for providing stability in monitoring timelines unless the system chooses to stick to quarterly monitoring, increasing total costs and resources.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document. Regarding the rule trigger levels and eligibility for reduced triennial monitoring, please see section 8.8 of the EPA response in this *Response to Comments* document.

New York State Department of Health (NYS DOH) (Doc. #1677, SBC-044943)

5. While we support regulatory flexibility for those public water systems that have demonstrated an absence of these compounds, their ubiquitous nature makes developing and implementing science-based criteria to assess a source's vulnerability to contamination impractical. If waivers are considered, we recommend that eligibility is based on at least 4 consecutive quarters of monitoring data at each source rather than an assessment of vulnerability.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

City of Vancouver Water Utility, Vancouver, WA (Doc. #1684, SBC-044314)

EPAs proposal to allow water systems to apply to primacy agencies for monitoring waivers of up to nine years seems too long. Reducing this waiver allowance time period will ensure protection of public health.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

New Hampshire Department of Environmental Services (NHDES) (Doc. #1690, SBC-044349)

c. Page 18730, Column 3, Bullet 1 - EPA requests comments on whether water systems should be permitted to apply to the primacy agency for monitoring waivers. Specifically, EPA is requesting comment on the allowance of monitoring waivers of up to nine years if after at least one year of sampling results are below the proposed rule trigger level. Similarly, EPA also requests comment on whether allowance of monitoring waivers of up to nine years should be permitted based on previously acquired monitoring data results that are below the proposed rule trigger level. Additionally, EPA is also requesting comment on the identification of possible alternatives to traditional vulnerability assessments that should be considered to identify systems as low risk and potentially eligible for monitoring waivers.

NHDES Comment - Due to the widespread use of PFAS in commercial, industrial, institutional, and domestic settings and the possibility of still unknown occurrences in the environment, NH does not believe there is any basis to allow monitoring waivers based on sampling results.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045030)

NJDEP disagrees with the use of monitoring waivers for PFAS contaminants. Based on its experience in implementing the New Jersey-specific MCLs, NJDEP notes that some New Jersey water systems have incurred MCL violations after multiple years of quarterly monitoring which may have included observed values that were at/or below the proposed trigger level. Water systems may have multiple sources that contribute to one EPTDS and the impact of these different sources varies operationally and seasonally, which can be seen in the analytical results.

If EPA were to consider a monitoring waiver for nine years, NJDEP recommends EPA consider utilizing data collected at both the EPTDS as well as source water data. Furthermore, NJDEP does not support the use of vulnerability assessments for use in determining eligibility for monitoring waivers. In addition to water system compliance monitoring, NJDEP has added

PFAS monitoring to NJDEP's ambient surface water monitoring and groundwater monitoring networks, and New Jersey's Private Well Testing Act. Based on these data the presence of PFAS is widespread throughout the state and often is not able to be attributed to any known source or potential source in the environment. Therefore, vulnerability assessments may not result in accurate assessment of potential impact of PFAS on drinking water systems. NJDEP recommends decisions for consideration of reduced monitoring be based on monitoring data.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-047695)

4) Monitoring waivers – up to 9 years if initial monitoring is below the trigger level.

The standard SOC monitoring framework proposed by EPA does not seem to be a good fit for PFAS as discussed above. A protective framework should be part of the final regulation.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

Thurston Public Utility District (PUD), WA (Doc. #1729, SBC-043587)

6. The EPA should allow the Washington State Department of Health Office of Drinking Water the authority to grant waivers of monitoring if both sampling history, source vulnerability, and geographic location indicate a wavier is warranted.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

Thurston Public Utility District (PUD), WA (Doc. #1729, SBC-043591)

9. On Page 18,683, relating to Monitoring and Compliance Requirements, the EPA should authorize and provide the Washington State Department of Health the flexibility of allowing systems to apply for monitoring waivers based on source vulnerability combined with sampling results that show PFAS below trigger levels or non-detects. One sample per source is appropriate for source(s) in low-risk areas with a documented history of no PFAS detections.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

Arizona Corporation Commission (ACC) (Doc. #1735, SBC-045189)

Allowance of monitoring waivers of up to nine years if after at least one year of sampling results are below the proposed rule trigger.

The ACC strongly supports waivers of up to nine years if after sampling results are below the proposed rule trigger.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045966)

AMWA urges EPA to reconsider its decision to not grant monitoring waivers or reduced monitoring based on reduced risks and watershed characteristics, such as proximity to contaminant sources or previous uses within the watershed. Omitting this is inconsistent with other contaminants with chronic health impacts and introduces unnecessary costs. Furthermore, a PWS that cannot prove it is below the trigger level due to lab reporting constraints would never be able to stay in the reduced monitoring schedule. This is because once a system qualifies for reduced monitoring based on its RAA, if it cannot prove it maintains concentrations below the trigger level, the system is automatically thrown back into quarterly monitoring. This can result in systems repeatedly going back and forth between monitoring schedules with no option for providing stability in monitoring timelines unless the system chooses to stick to quarterly monitoring, increasing total costs and resources.

Allowing systems to use watershed characteristics and demonstrations of reduced risk to qualify for reduced monitoring or monitoring waivers would still be protective of the chronic health risks of PFAS. Utilities could demonstrate their reduced risk through a growing abundance of resources and tools. For example, EPA released its PFAS Analytic Tools to bring together multiple sources of information on PFAS sources in one spot with mapping, charting, and filtering functions [FN15: EPA. (2023, May 22). PFAS Analytic Tools. https://echo.epa.gov/trends/pfas-tools.]. Another tool by Azimuth provides information on PFAS-contaminated sites throughout the country that could be used to show a system is not located in these risk areas [FN16: Azimuth. (2021, April 07). How data science provides a new view into PFAS contaminated sites. https://www.azimuth1.com/blog/pfas].

Additionally, more data continues to be available on PFAS occurrence as EPA takes actions to identify and report PFAS industrial discharges and sources. A PWS would still be sampling at a reduced rate to check for detections of PFAS but will lessen the burdens and confusion of qualifying for reduced monitoring based on RAA and then being disqualified for an individual sample they cannot accurately demonstrate is below the trigger level.

AMWA appreciates EPA's consideration of reducing burdens on PWSs in the proposed rule and believes the above recommendations will achieve that goal without compromising any health benefits. Allowing PWSs with lower concentrations and risks to have a reduced monitoring schedule will ease burdens of costs and labor on the utility while still requiring the system to show continued low concentrations and risks.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document. Regarding the rule trigger levels and eligibility for reduced triennial monitoring, please see section 8.8 of the EPA response in this *Response to Comments* document.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045229)

8. EPA is seeking comment on the identification of possible alternatives to traditional vulnerability assessments that should be considered to identify systems as low risk and potential eligibility for monitoring waivers.

CT DPH does not support the use of vulnerability assessments as a possible alternative to identify low risk PWSs. In 2018 and 2019, CT DPH required all community public water systems that serve more than 1,000 individuals (84 PWSs) to assess potential PFAS generators within their public drinking water source water areas. While useful in helping PWSs prioritize sources for PFAS testing, there have been several instances where a PWS detected PFAS through voluntary sampling at sources where no apparent generator was identified.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045227)

6. EPA is considering and taking comment concerning waivers based on sampling results. Specifically, EPA is requesting comment on whether water systems should be permitted to apply to the primacy agency for a monitoring waiver of up to nine years (one full compliance cycle) for these proposed PFAS if after at least one year of quarterly sampling the results are below the rule trigger level, or for systems that may be monitoring less frequently than quarterly if at least two consecutive three-year compliance period sample results are below the rule trigger level.

Due to PFAS persistence and mobility in the environment, CT DPH suggests limiting the reduced monitoring frequency to no more than every three years. CT DPH agrees with EPA's desire to reduce sampling on PWSs that have consistently demonstrated non-detect PFAS concentrations or concentrations below the trigger level; however, PFAS contamination can significantly migrate over a three-year period. Due to the wide range of potential pathways into the environment, measurement for PFAS once every nine years may not be protective of human health as conditions can significantly change during that period.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045202)

3. CT DPH recommends vulnerability assessments not be used as the sole determinant to identify low risk public water systems that might be granted a waiver. In 2018 and 2019 CT DPH

required all community public water systems that serve more than 1,000 individuals (n=84) to assess potential PFAS generators within their public drinking water source water areas. While useful for prioritizing areas for PFAS testing, there were several instances where a public water system detected PFAS through voluntary sampling at sources where no apparent generator could be identified. This suggests that in Connecticut PFAS contamination may not correlate to assessed vulnerability.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

City of Thornton, Colorado (Doc. #1748, SBC-044796)

Thornton recommends that EPA does not grant monitoring waivers of 9 years to systems below the trigger level. Without appropriate occurrence data, it is inappropriate to grant this long of an extension. Likewise, because PFAS source contamination is not well understood and typically originates from discharges or seepages, the fluctuations in PFAS compounds and concentrations could drastically change within the proposed monitoring waiver framework. A system that believes they are free of PFAS and on reduced monitoring could suddenly have a new upstream contamination that they are unaware of and unprepared to treat, leading to up to 9 years of unprotected public health. Likewise, utilities that implement a PFAS treatment technique must monitor for breakthrough of PFAS; an extended monitoring waiver could result in utility complacency and lack of replacement of treatment media thus endangering public health. Thornton urges EPA to adopt monitoring waivers with a sampling frequency of no less than annually. If EPA does allow for reduced monitoring extending past annually, they must also clarify how the RAA will be calculated.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document. Regarding the rule compliance monitoring requirements and the compliance calculation, please see sections 8.1.2 and 8.2 of the EPA response in this *Response to Comments* document, respectively.

Las Cruces Utilities (LCU) (Doc. #1753, SBC-043909)

In response to Section IX-Monitoring and Compliance Requirements, EPA requests comments on whether water systems should be permitted to apply to the primacy agency for monitoring waivers. Specifically, EPA is requesting comment on the allowance of monitoring waivers of up to nine years if after at least one year of sampling results are below the proposed rule trigger level. Similarly, EPA also requests comment on whether allowance of monitoring waivers of up to nine years should be permitted based on previously acquired monitoring data results that are below the proposed rule trigger level.

Additionally, EPA is also requesting comment on the identification of possible alternatives to traditional vulnerability assessments that should be considered to identify systems as low risk and potentially eligible for monitoring waivers.

• Waivers should be granted. With respect to alternatives to traditional vulnerability assessments, EPA could consider proximity to other PWSs that do not have PFAS detections.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

Western Urban Water Coalition (WUWC) (Doc. #1768, SBC-043955)

E. State Primacy Agencies Should Have the Authority to Grant Monitoring Waivers in Appropriate Circumstances

Last, WUWC supports an adjustment to the Proposed Rule to allow state primacy agencies to issue monitoring waivers under circumstances where a public water system observes covered

PFAS for at least one year below the corresponding rule trigger level. [FN45: Id. at 18683.] Traditional vulnerability assessments in line with existing SDWA regulations that evaluate the potential for a water system to be susceptible to PFAS contamination should be utilized to support such waivers. [FN46: Cf. 40 C.F.R. § 141.24]

The Proposed Rule does not currently contemplate state primacy agency waiver authority based on EPA's belief that "due to the ubiquity, environmental persistence, and transport abilities of PFAS, granting waivers based on these conditions would be challenging." [FN47: Id.] WUWC disagrees because the Proposed Rule would set MCLs for PFOA and PFOS at 4 ppt, the lowest feasible quantitation level according to EPA's own findings. Under the Proposed Rule, assuming it is even feasible to implement, there would be very low potential for monitoring to result in false negatives.

Moreover, while the covered PFAS are indeed ubiquitous and persistent in the environment, the mere existence of a state primacy agency waiver authority would not result in under-monitoring. State primacy agencies would share EPA's interest in protecting public health and would simply deny monitoring waiver requests under circumstances where public water systems have not demonstrated appropriate circumstances. In the unlikely event that a state primacy agency was found to consistently grant monitoring waivers in inappropriate circumstances, EPA would also have authority to revoke its grant of state primacy. [FN48: See generally 40 C.F.R. § 142, Subpart B] Therefore, WUWC does not agree with EPA that the ubiquity or pervasiveness of these PFAS substances presents a sound justification for depriving states of monitoring waiver authority that is common under the SDWA.

* * *

Our members are experienced, on-the-ground partners with EPA and the states in the implementation of the SDWA and other related authorities. WUWC recognizes the importance of regulating PFAS in line with WUWC's mission to ensure that western water agencies and their customers are assured a public water supply that is reliable, affordable, and safe for consumption. Based on this experience, WUWC wants to work with EPA, other federal and state

regulatory agencies, and members of Congress to address this important issue. We look forward to continued dialogue and collaboration on legislative and regulatory initiatives affecting PFAS and water quality.

Thank you for the opportunity to provide these comments. For more information, please contact me at (303) 739-7378 or mbrown@auroragov.org, or WUWC's national counsel, Ted Boling, at (202) 661-5872 or TedBoling@perkinscoie.com.

Very truly yours,

Marshall P. Brown Chairman

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

Uttara Jhaveri (Doc. #1778, SBC-045451)

Granting Waivers under 40 CFR 141.24 Subpart C

The grant of waivers under 40 CFR 141.24 Subpart C based on the proximity of the system to contaminant sources (i.e., susceptibility to contamination) and previous uses of the contaminant within the watershed (including transport, storage, or disposal) would not be a fair decision. [FN32: Environmental Protection Agency, supra note 4.] PFAS are "forever chemicals" and can be transported to substantial distances in the atmosphere, groundwater, surface water, and soil. [FN33: Earthjustice, supra note 1.] Therefore, granting waivers based on certain exceptional conditions may lead to transportation and contamination of a nearby source and defeat the purpose of the proposed regulation. Instead, an effort to bring down the levels of certain contaminant sources over a period of time would be more aligned with the purpose of the proposed regulations.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046118)

At the outset, we support EPA's proposal to disallow monitoring waivers as part of the PFAS NPDWR in light of the "ubiquity, environmental persistence and transport abilities of PFAS." [FN199: Id. at 18,683.] But as explained below, these same factors—as well as the toxic effects of PFAS at very low concentrations—undermine EPA's proposal for reduced monitoring requirements for systems with initial PFAS detections below EPA's proposed trigger level of one-third the relevant MCL. [FN200: Id. at 18,681.]

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document. Regarding the EPA's compliance monitoring requirements, please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Sharon Levy (Doc. #1824, SBC-044278)

One aspect of the proposed rule is granting monitoring wavers to certain areas.

All communities must be monitored and protected. People should know what they are being exposed to, and the potential acute or chronic effects that can come from these chemicals.

Reduced monitoring will only lead to the potential risk of health effects associated with PFAS. Even small exposures can lead to health effects that can be harmful to people who are ingesting PFAS, especially if their community isn't being monitored.

In summary, The EPA must act urgently to protect vulnerable communities by shifting costs to polluters and monitor all communities for PFAS.

Sincerely,

Sharon Levy

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

Wisconsin Department of Natural Resources (Doc. #1828, SBC-044806)

The ASDWA comment raises important issues regarding monitoring requirements.

The WDNR does support the application of vulnerability assessment processes for monitoring waivers. States have varying vulnerability assessment processes which may warrant the application of waivers. Public water supply systems operate in numerous geological and hydrogeological environments where, along with well construction criteria, evaluation of potential contaminant sources and analytical history, provide justification for the implementation of a vulnerability assessment process.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

Little Hocking Water Association (Doc. #1835, SBC-045517)

Further, water supplies that are known to be highly contaminated with PFAS or are at a high risk of contamination should not be eligible for monitoring waivers, especially a waiver allowing monitoring only once every nine years. At the very least, eligibility for waivers for less frequent monitoring needs to be made with knowledge of the levels of contamination in pretreated waters, which is likely to show that less frequent monitoring would not be protective of public health.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2312, SBC-047428)

3/29/2023

RE: Docket ID No. EPA-HQ-OW-2022-0114, Environmental Justice Considerations for the Development of the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

I am currently a student at Loyola University Chicago who is researching contaminants in drinking water and their regulations. One aspect of the proposed rule that I have seen other people comment on is the idea of granting monitoring waivers to certain areas. I believe that reduced monitoring will only lead to more exposure to PFAS and is unfair to those living in the unmonitored areas. I fear that through the use of waivers, low income areas will be disproportionately affected by the lack of monitoring.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

Susan Suggs (Doc. #3038, SBC-047463)

One aspect of the proposed rule is granting monitoring wavers to certain areas.

All communities must be monitored and protected. People should know what they are being exposed to, and the potential acute or chronic effects that can come from these chemicals.

Reduced monitoring will only lead to the potential risk of health effects associated with PFAS. Even small exposures can lead to health effects that can be harmful to people who are ingesting PFAS, especially if their community isn't being monitored.

In summary, The EPA must act urgently to protect vulnerable communities by shifting costs to polluters and monitor all communities for PFAS.

Copy and paste this statement to your EPA comment

To Whom It May Concern,

I am writing in regards to the proposed rule for Per- and Polyfluoroalkyl Substances (PFAS) to be included into the National Primary Drinking Water Regulations.

On March 14, 2023, the EPA proposed the first ever national drinking standards with regards to PFAS in public drinking water. EPA is issuing a preliminary regulatory determination to regulate PFHxS, HFPO-DA (also known as GENX), PFNA, PFBS, PFOA, PFOS and a mixtures of these PFAS as contaminants under SDWA.

PFHxS, HFPO-DA (also known as GENX), PFNA, PFBS, PFOA and PFOS have all been found in large concentrations across North Carolina.

The Chemours plant in Bladen County produces GenX, and discharges upwards of 250 different PFAS chemicals into our drinking water.

The PFAS production at the site is responsible for groundwater and surface water contamination in the surrounding area, according to water samples from Chemours and the N.C. Department of Environmental Quality.

Since learning about our PFAS water contamination in 2017, we have learned how harmful PFAS are to populations that are exposed to "forever chemicals".

Pregnant women, young children, low income communities and people of color are extremely vulnerable.

PFAS are dangerous chemicals that bioaccumulate in the body's organs. Continuous small exposures can lead to larger health effects that can be harmful to people who are ingesting PFAS.

One aspect of the proposed rule is granting monitoring wavers to certain areas.

All communities must be monitored and protected. People should know what they are being exposed to, and the potential acute or chronic effects that can come from these chemicals.

Reduced monitoring will only lead to the potential risk of health effects associated with PFAS. Even small exposures can lead to health effects that can be harmful to people who are ingesting PFAS, especially if their community isn't being monitored.

In summary, The EPA must act urgently to protect vulnerable communities by shifting costs to polluters and monitor all communities for PFAS.

Sincerely,

Susan Suggs

1101 Herford Ct

Wilmington, NC 28411

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

Deena Craig (Doc. #3045, SBC-047466)

One aspect of the proposed rule is granting monitoring wavers to certain areas.

All communities must be monitored and protected. People should know what they are being exposed to, and the potential acute or chronic effects that can come from these chemicals.

Reduced monitoring will only lead to the potential risk of health effects associated with PFAS. Even small exposures can lead to health effects that can be harmful to people who are ingesting PFAS, especially if their community isn't being monitored.

In summary, The EPA must act urgently to protect vulnerable communities by shifting costs to polluters and monitor all communities for PFAS.

I have metastatic breast cancer. At the time of my diagnosis I had very high estrogen levels despite being age 64, post menopausal and being born with just one ovary. I drank water contaminated with GenX/PFAS for many years. I asked my oncologist if PFAS could cause high estrogen levels and he immediately said yes. He was from Parkersburg, WV where DuPont dumped carcinogens in their water. GenX is essentially what was dumped in the water in Parkersburg but designed to clear the bloodstream (not be detectable) in a short period of time. Yet PFAS is a forever chemical, its effects remaining in the body for many years.

DuPont Chemours has a history of placing profits over people.

Please protect us and monitor the levels of GenX, PFAS and other forever chemicals.

Sincerely,

Deena Craig

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

Mass comment campaign submitted by Arthur Bell (Doc. #3071, SBC-047468)

One aspect of the proposed rule is granting monitoring wavers to certain areas.

All communities must be monitored and protected. People should know what they are being exposed to, and the potential acute or chronic effects that can come from these chemicals.

Reduced monitoring will only lead to the potential risk of health effects associated with PFAS. Even small exposures can lead to health effects that can be harmful to people who are ingesting PFAS, especially if their community isn't being monitored.

In summary, The EPA must act urgently to protect vulnerable communities by shifting costs to polluters and monitor all communities for PFAS.

Sincerely, Art Bell

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

Groundwater Resources Association of California (Doc. #1831, SBC-045358)

Finally, EPA is considering not granting any waivers for monitoring requirements. We suggest that if a water system conduct a study to evaluate all the points of entry to the system for potential PFAS sources, and the consecutive monitoring results for one year have shown no MCL exceedances, then the primacy agency shall have the authority to waive the monitoring requirements. If the study finds no potential for PFAS sources to enter to the system and the monitoring results confirm that for a set period of time, then the waiver could be granted.

EPA Response: Please see section 8.5 of the EPA response in this *Response to Comments* document.

8.6 Laboratory Certification Requirements

Summary of Major Public Comments and EPA Responses

A few commenters requested that the EPA develop guidance and training for drinking water laboratory certification programs to evaluate laboratories seeking certification. The EPA agrees that training for laboratory certification officers is appropriate. The EPA will develop training materials and guidance for drinking water certification programs to evaluate laboratories to ensure adherence to the requirements of EPA Methods 533 and 537.1.

One commenter requested that the EPA establish reciprocity between laboratory certification programs to utilize all potential laboratory capacity available. As described in the EPA's Manual for the Certification of Laboratories Analyzing Drinking Water, laboratory certification programs may recognize drinking water laboratory certifications (or comparable "accreditation") from other laboratory certification programs, by reciprocity (USEPA, 2005). Most laboratory certification programs do utilize the practice of reciprocal certification. For purposes of supporting this NPDWR, reciprocal certification can only be granted to laboratories utilizing EPA Methods 533 and 537.1.

Individual Public Comments

Association of Public Health Laboratories (APHL) (Doc. #1646, SBC-043298)

Detailed recommendations are appended to this letter, but a few are emphasized below:

• The Laboratory Drinking Water Certification Manual must be updated to provide clear guidance to certification bodies and laboratories if these 6 PFAS are regulated.

EPA Response: Please see section 8.6 of the EPA response in this *Response to Comments* document. The EPA is currently working on a revision to the Laboratory Certification Manual.

National Ground Water Association (NGWA) (Doc. #1804, SBC-045467)

[Actions that EPA should consider to enable more laboratory capacity are:]

3. Provide training for needed additional laboratory staff certification

[Actions that EPA should consider to enable more laboratory capacity are:]

4. Establish reciprocity of certification across states to utilize all potential capacity available

EPA Response: Please see section 8.6 of the EPA response in this *Response to Comments* document.

Oklahoma Department of Environmental Quality (DEQ) (Doc. #1616, SBC-043053)

• EPA needs to expand their drinking water laboratory certification program to include PFOS/PFAS testing via LCMSMS technology (EPA methods 533, 537.1, and 1633). Currently, TNI is the only option to ensure laboratory competency and compliance for this type of analytical testing.

• PFOS/PFAS testing requires a unique and uncommon knowledge and skill set that requires extensive training and experience. Funding and training options to advance expertise on such applications for both laboratory scientists and lab assessors is very limited.

EPA Response: Please see section 8.6 of the EPA response in this *Response to Comments* document.

Rockbridge Area Conservation Council (RACC) (Doc. #1678, SBC-044298)

[With that said, we would respectfully request that:] (4) establish a timeline for lowering the limit of quantification for EPA lab certification with a parallel automatic reduction in the MCL.

EPA Response: Please see section 8.6 of the EPA response in this *Response to Comments* document. Additionally, the EPA evaluates NPDWRs as part of the Six Year Review process. Any changes made to the regulations, including changes to PQLs and/or MCLs, would follow this process outlined under SDWA.

Missouri Department of Natural Resources (Doc. #1563, SBC-042509)

In addition, the Department is concerned that the proficiency testing (PT) used to approve laboratories for Unregulated Contaminant Monitoring Rule (UCMR 5) sampling was not sufficient to confirm a viable minimum reporting level (MRL), also referred to in the rule as a practical quantification limit (PQL). It is not clear from information that EPA has made publically available to date whether any of the 8 PT studies conducted included true values "at or near" the proposed MCL. In coordination with laboratories that EPA has approved for UCMR 5 analysis, we are aware that at least six of the eight PT studies had an average concentration of 55

ppt true value. Since EPA approves laboratories based on two PT tests, it is not clear how many approved laboratories have demonstrated proficiency "at or near" the proposed MRL and MCL of 4.0 ppt. Without the opportunity to review all of the proficiency testing data, it is difficult for interested parties to adequately comment on whether or not the MRL established was based on sufficient supporting evidence that laboratories could meet low-level, true values around the proposed MCL.

EPA Response: Please see section 8.6 of the EPA response in this *Response to Comments* document. Laboratories that wish to be certified under this rule will need to participate in new proficiency testing (PT) studies to apply for certification from the state certification programs. This rule requires laboratories to pass at least one performance evaluation (PE) study (or PT study) per method and analyte on an annual basis. In addition, as part of state certification for methods EPA 533 and EPA 537.1, Version 2.0, laboratories must demonstrate proficiency at the laboratory reporting limit, per method reporting limit confirmation requirements. Laboratories will be required to submit initial demonstration of capability data to the state certification programs prior to the state program conducting an assessment of the laboratory. These data include a passing PE/PT result.

<u>The NELAC Institute (Doc. #1575, SBC-042458)</u>

Comments on PFAS National Primary Drinking Water Rulemaking (03/29/2023)

Docket ID. No: EPA–HQ– OW–2022–0114

May 22, 2023

Prepared by: The NELAC Institute

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The NELAC Institute (TNI) is a 501(c)(3) non-profit organization whose mission is to foster the generation of environmental data of known and documented quality through an open, inclusive, and transparent process that is responsive to the needs of the community. Among other matters, TNI manages a national proficiency testing (PT) program for environmental laboratories that covers drinking water, non-potable water, and hazardous wastes.

TNI appreciates the opportunity to comment on the proposed PFAS National Primary Drinking Water Rulemaking (03/29/2023). This comment requests changing the proposed Performance Evaluation sample acceptance limits outlined in Table 2 Paragraph (b)(2)(iii)(B).

141.901 Sub part Z. Section B states, "… the laboratory must achieve quantitative results on the PE sample analyses that are within the following acceptance limits:"

Table 2 to Paragraph (b)(2)(iii)(B) shows these acceptance limits as 70-130 percent recovery of true values. TNI requests these acceptance limits be adjusted to 60-140 percent recovery of true values to be consistent with UCMR 5 Performance Evaluation Sample acceptance criteria. Making this change would ensure data quality objectives for analysis completed in support of this rule would be consistent with UCMR 5 regarding Performance Evaluation data evaluation. Performance Evaluation sample data has not been gathered outside of UCMR and can thus not be evaluated to determine if limits of 70-130% would be supported. Furthermore, performance evaluation samples are not at a set true value. The true value of the compounds of interest can vary within the range specified in PT Provider instructions or Fields of Proficiency Testing (FoPT) Tables. These concentrations are randomly assigned according to the TNI PT standards. In reviewing Laboratory Fortified Blank (LFB) criteria in PFAS analytical methods, there is a percent recovery range specified at the Method Reporting Limit (MRL) level as well as the mid/high level. As PE (PT) samples could potentially incorporate multiple compounds spiked into one sample, recovery acceptance limits of 60-140% would be more inclusive to account for this range.

As specified in EPA Method 533 regarding LFB criteria:

9.2.3.2 Results for analytes fortified at concentrations near or at the MRL (within a factor of two times the MRL concentration) must be within 50–150% of the true value. Results for analytes fortified at all other concentrations must be within 70–130% of the true value. If the LFB results do not meet these criteria, then all data for the problem analytes must be considered invalid for all samples in the Extraction Batch.

As specified in EPA Method 537.1 regarding Laboratory Fortified Blank criteria:

9.3.3. Results of the low-level LFB analyses must be 50-150% of the true value. Results of the medium and high-level LFB analyses must be 70-130% of the true value. If the LFB results do not meet these criteria for method analytes, then all data for the problem analyte(s) must be considered invalid for all samples in the extraction batch.

Thank you for your consideration,

The TNI Proficiency Testing Program Executive Committee

Stacie Crandall, Chair

SCrandall@hrsd.com

EPA Response: Please see section 8.6 of the EPA response in this *Response to Comments* document. The PT portion of the UCMR 5 laboratory approval program differed from previous UCMR laboratory approval programs. When the EPA implemented the UCMR 3 laboratory approval program, PT acceptance criteria were indeed 60-140 percent for the perfluorinated compounds included in UCMR 3 monitoring program. The criteria were set wider than the laboratory fortified blank (LFB) acceptance criteria in UCMR 3, primarily because the analytical techniques used in the methods approved under UCMR 3 were new to the certified

laboratory community. Under UCMR 5, the EPA used PT acceptance criteria of 70-130 percent in the UCMR 5 laboratory approval program. Additionally, laboratories participating in the UCMR 5 laboratory approval program were required to pass two PT studies prior to becoming approved to analyze samples for UCMR 5. The EPA conducted eight PT studied prior to sample collection for UCMR 5, using the 70-130 percent acceptance criteria. Even while utilizing this tighter criterion for PTs, there was an overall passing rate for individual analytes of 97.8 percent. The UCMR 5 PT data and the UCMR 5 laboratories' Initial Demonstrations of Capability support the criteria proposed in this rule.

8.7 Other Laboratory Considerations

Summary of Major Public Comments and EPA Responses

Many commenters suggested the potential for false positives to misrepresent actual levels of the regulated PFAS within the drinking water sample due to the ubiquity of PFAS and the possible background interference. The EPA is aware of the potential for background contamination. The EPA agrees that PFAS sampling at very low levels is highly sensitive and there is potential for sample contamination. However, with proper training tools and communications, that potential can be mitigated, though not sufficiently enough to allow for composite sampling as discussed in section 8.4 of the EPA response in this *Response to Comments* document. For example, the UCMR program has released several sampling guidance documents and a small-systems sampling video to assist small and medium utilities with the PFAS sampling. These products have also been distributed to the UCMR laboratory community, which has been encouraged to share them with their PWS clients.

Also, Method 533 and Method 537.1 require the analysis of a Laboratory Reagent Blank (LRB) with each extraction batch. If method analytes are detected in the LRB at or above 1/3 the MRL, suggestive of background contamination, all positive field sample results associated with that extraction batch are invalid for the impacted analytes. Both methods also require the analysis of a FRB (a blank that is prepared at the sampling location) when any PFAS are detected above the MRL in field samples. The use of laboratory and field blanks were incorporated into the methods as QC to reduce the potential for false positives due to background contamination. Additionally, in the instance where there is evidence that the PFAS may be a result of background contamination and not representative of the drinking water, the final rule, at 141.902(b)(2)(v), allows a primacy agency to invalidate results associated with obvious sampling errors and/or require an additional confirmation sample to be taken if necessary.

Individual Public Comments

Mike Pettit (Doc. #1542, SBC-043348)

Sample Collection

PFAS (per- and polyfluoroalkyl substances) are synthetic chemicals that have been used in a wide range of industrial and consumer products for decades, including non-stick cookware, waterproof clothing, stain-resistant carpets, and firefighting foam. Due to their widespread use and persistence in the environment, PFAS are now found in soil, water, air, and biomes across the globe. The ubiquitous nature of PFAS molecules can create challenges for sample collection and analysis. One major challenge is the potential for contamination of samples during collection, handling, and analysis. PFAS are known to adhere strongly to laboratory equipment, such as tubing and containers, which can lead to false positives or elevated concentrations. As such special precautions need to be taken during sample collection, including the use of PFAS-free equipment and taking care to avoid cross-contamination. Another challenge is that PFAS can be present in a wide range of sample matrices, including water, soil, sediment, and biomass, and can exist in various forms, such as dissolved, particulate-bound, or adsorbed onto organic matter. This variability in PFAS form and distribution in samples can lead to differences in detection limits and biases in sampling results. Therefore, it is important to carefully select sampling and extraction methods that are appropriate for the specific sample matrix and analyte. To address these challenges, some potential solutions include using pre-cleaned or disposable sampling equipment, optimizing sampling and extraction methods, and using quality control measures, such as field and laboratory blanks, and reference materials. Additionally, it is important to carefully document sampling and analysis procedures to ensure data quality and reproducibility. Overall, careful consideration and attention to sampling and analysis procedures are critical for obtaining accurate and representative data on PFAS contamination in the environment

EPA Response: Please see section 8.7 of the EPA response in this *Response to Comments* document.

Maine Water Utilities Association (MWUA) (Doc. #1567, SBC-042730)

Sampling Protocols & Training:

PFAS sampling requires unique protocols that are extremely sensitive to prevent cross-contamination. Our PWS have been instructed to take precautions such as avoiding use of sharpie markers, sticky notes, and plastic clipboards; not to wear waterproof or stain-repellant clothing; not to use fabric softener on clothing to be worn in field, do not use cosmetics, moisturizers, hand cream, sunscreen, or other personal care products the morning of sampling, do not use plastic clipboards, etc. All these precautions cause us to believe that samples may easily be contaminated. When considering enforceable regulatory limits in the low parts per trillion, barely above a laboratory's capability to reliably detect and quantify these compounds, cross contamination must be considered. EPA must have protocols in place to invalidate samples with PFAS detections that may be a result of human error through sample collection, improper shipping practices, or other avenues. EPA and primacy states must ensure that PWS have training on proper sampling protocols and provide the appropriate technical assistance and outreach to PWS once the rule is implemented.

EPA Response: Please see section 8.7 of the EPA response in this *Response to Comments* document.

Lehigh County Authority (LCA) (Doc. #1600, SBC-042814)

PFOA and PFOS

The proposed regulation sets a Maximum Contaminant Level (MCL) of 4.0 parts per trillion (ppt) for PFOA and PFOS. The laboratory methods approved for analysis are methods EPA 533 and 537.1, which have a Practical Quantification Limit (PQL) and Method Detection Limit (MDL) of 4.0 ppt. PQLs are defined as "the lowest achievable level of analytical quantitation during routine laboratory operating conditions within specified limits of precision and accuracy" (50 Federal Register 46902, November 13, 1985). Thus, the PQL reflects both the physical limitation of approved analytical methods and the practical limitations of variability in laboratory performance.

While other analytes' MCLs have been set at the PQL (such as heptachlor, chlordane, or thallium), the likelihood of cross-contamination or interference was not as likely to occur in those cases. Conversely, PFAS compounds are known to be present in many everyday products such as cosmetics, food packaging, fabrics, etc. Every day, it seems, a story is published in the news media about PFAS being found in more products and in our natural environment in seemingly unlikely places.

To address the issue of potential cross-contamination of water samples from external sources, some states have established PFAS regulatory protocols that allow for samples to be invalidated based on obvious sampling errors. EPA should consider taking this approach in the final rulemaking, so utilities (and the communities they serve) are not unnecessarily penalized for a cross-contaminated sample. The very low limit, set at the PQL, and the ubiquitous nature of PFAS compounds make cross-contamination of water samples as very real concern for all utilities.

EPA Response: Please see section 8.7 of the EPA response in this *Response to Comments* document. Although the commenter correctly states that the PQLs for PFOA and PFOS are 4.0 ppt, the EPA-approved methods do not include MDLs as the commenter provided. Rather, the methods require the confirmation of MRLs which are distinctly different from MDLs. For the PFAS NPDWR, the EPA did not define MRLs for PFAS contaminants, but established PQLs, as discussed in sections V and VII of the final rule preamble, to evaluate analytical feasibility for the determination of MCLs.

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-042880)

Sampling Protocols & Training:

PFAS sampling requires unique protocols that are extremely sensitive to prevent cross-contamination. Our PWS have been instructed to take precautions such as avoiding use of

sharpie markers, sticky notes, and plastic clipboards; not to wear waterproof or stain-repellant clothing; not to use fabric softener on clothing to be worn in field, not to use cosmetics, moisturizers, hand cream, sunscreen, or other personal care products the morning of sampling, etc. All these precautions cause us to be concerned that samples may easily be contaminated. When considering enforceable regulatory limits in the low parts per trillion, barely above a laboratory's capability to reliably detect and quantify these compounds, cross contamination must be considered a significant problem. EPA must have protocols in place to invalidate samples with PFAS detections that may be a result of human error through sample collection, improper shipping practices, or other avenues. EPA and primacy states must ensure that PWS have training on proper sampling protocols and provide the appropriate technical assistance and outreach to PWS once the rule is implemented.

EPA Response: Please see section 8.7 of the EPA response in this *Response to Comments* document.

Environmental Monitoring Coalition (EMC) (Doc. #1625, SBC-043113)

4. Background Contamination

Regarding the background contamination level, there appears to always be an impurity in the isotope dilution standard. The compounds in the isotope dilution standard are labeled versions of the analytes, usually 13C, and there is always a small impurity of unlabeled analyte present. Since the isotope dilution standard is added to every sample, and always in the same amount, there will be the potential to have this contamination in every sample. When the reporting limit is driven to ever lower levels, this small impurity becomes a larger factor. For UCMR 5, the concentration of the isotope dilution standard is equivalent to 40 ppt in sample. So even a 1% impurity represents 0.4 ppt in the sample. Generally, laboratories see less than 1%, but it could be an issue.

There is also always systematic background in the laboratory reagent or extraction blanks. This background contamination can vary by laboratory, by compound, and between lots of reagents and other consumables used in each test. Even with tight control, by the laboratory, to minimize contamination the prevalent use of PFAS in manufacturing processes and consumer products means that this source of laboratory contamination will always be present. When using a MRL of 2 ng/L as most labs currently do, the 1/3 of the MRL blank requirement is possible (~0.66 ng/L), however, if laboratories attempt to lower the MRL to the trigger level of 1.3 ng/L the blank requirement will not be met resulting in a QC failure.

EPA Response: Please see section 8.7 of the EPA response in this *Response to Comments* document. Unlabeled analyte interferences from isotopic standards are not expected to be significant and would be accounted for by method quality control samples.

Association of Public Health Laboratories (APHL) (Doc. #1646, SBC-043321)

4. Background Contamination

Regarding the background contamination level, there appears to always be an impurity in the isotope dilution standard. The compounds in the isotope dilution standard are labeled versions of the analytes, usually 13C, and there is always a small impurity of unlabeled analyte present. Since the isotope dilution standard is added to every sample, and always in the same amount, there will be the potential to have this contamination in every sample. When the reporting limit is driven to ever lower levels, this small impurity becomes a larger factor. For UCMR 5, the concentration of the isotope dilution standard is equivalent to 40 ppt in sample. So even a 1% impurity represents 0.4 ppt in the sample. Generally, laboratories see less than 1%, but it could be an issue.

There is also always systematic background in the laboratory reagent or extraction blanks. This background contamination can vary by laboratory, by compound, and between lots of reagents and other consumables used in each test. Even with tight control, by the laboratory, to minimize contamination the prevalent use of PFAS in manufacturing processes and consumer products means that this source of laboratory contamination will always be present. When using a MRL of 2 ng/L as most labs currently do, the 1/3 of the MRL blank requirement is possible (~0.66 ng/L), however, if laboratories attempt to lower the MRL to the trigger level of 1.3 ng/L the blank requirement will not be met resulting in a QC failure.

EPA Response: Please see section 8.7 of the EPA response in this *Response to Comments* document. Unlabeled analyte interferences from isotopic standards are not expected to be significant and would be accounted for by method quality control samples.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044423)

Page 18730. Section IX-Monitoring and Compliance Requirements Continued.

EPA requests comment on other monitoring related considerations including laboratory capacity and QA/ QC of drinking water sampling.

• Increased emphasis on meeting all method required QC would help ensure consistent data quality and aid state Primacy agencies.

EPA Response: Please see section 8.7 of the EPA response in this *Response to Comments* document.

A. O. Smith Corporation (Doc. #1674, SBC-043696)

However, in the Company's view this challenge is addressed and documented in the methods themselves, including the quality assurance and quality control measures (i.e., QA/QC) that must be followed to ensure the sensitivity of the measurement instruments and laboratory settings. The

key, however, will be ensuring that the drinking water samples sent to the certified laboratories are free of any PFAS cross-contamination.

EPA Response: Please see section 8.7 of the EPA response in this *Response to Comments* document.

New York City Department of Environmental Protection (NYCDEP) (Doc. #1679, SBC-044211)

Laboratory Capability

In section VIII., p. 18681, the discussion of analytical methods excludes any mention of or assessment of contamination and positive bias. As PFAS are ubiquitous contaminants, it seems likely that the existing historic data will include positive bias resulting from contamination. Was this evaluated for the UCMR3 occurrence data? Notably, on p. 18697, EPA notes that blanks will be considered going forward. It is unclear if positive bias exists in the occurrence or toxicity data used as a basis for the levels stated in the rule.

EPA Response: Please see section 8.7 of the EPA response in this *Response to Comments* document.

U.S. Poultry & Egg Association et al. (Doc. #1765, SBC-044545)

There is a long list of potential interferences that can cause inaccurate reporting and interpretation of Method 537.1 results (falsely biasing results either high or low). Currently, the best standards of practice for collecting water samples and then interpreting results received from the lab are not well known by most water providers, especially non-transient, non-community water providers that typically do not have this level of experience and expertise on staff. Importantly, PFAS contamination may occur during sample collection, and robust procedures are necessary to elimination cross-contamination (e.g., nitrile gloves, use of the correct sample bottles and caps, appropriately flushing the system, adding the buffering agent correctly, use of sample blanks, appropriate shipping temperature and holding times). Specially trained personnel are needed to appropriately collect samples and interpret results obtained from the laboratories. Due to the low detection limit and the fact that decision thresholds are at the detection limit, the collection and analysis of samples will be extremely costly, time intensive and laborious, and mistakes will be extremely costly. EPA has not adequately considered the lack of properly trained personnel, especially for non-transient and non-community water providers that will be subject to this regulation.

The need to hire and/or train personnel to learn the best practices for selecting a lab certified in running Method 537.1, sample collection, and laboratory data interpretation has not been appropriately factored into the EPA costs and economic impact analysis.

EPA Response: Please see section 8.7 of the EPA response in this *Response to Comments* document. Regarding laboratory certification, please see section 8.6 of the EPA response in this *Response to Comments* document. The EPA disagrees that it has not

appropriately considered all costs associated with monitoring required by the final rule (please see section 13.3.4 of the EPA response in this *Response to Comments* document).

National Ground Water Association (NGWA) (Doc. #1804, SBC-045456)

Sample Bias – NGWA is concerned that the potential for sample bias and cross contamination is amplified based on the very low (stringent) criteria for sample test results as well as the sensitivity at ng/L levels.

EPA Response: Please see section 8.7 of the EPA response in this *Response to Comments* document.

New England Water Works Association (Doc. #1836, SBC-045382)

Sampling Protocols & Training:

PFAS sampling requires unique protocols that are extremely sensitive to prevent cross-contamination. Our PWS have been instructed to take precautions such as avoiding use of sharpie markers, sticky notes, and plastic clipboards; not to wear waterproof or stain-repellant clothing; not to use fabric softener on clothing to be worn in field; not use cosmetics, moisturizers, hand cream, sunscreen, or other personal care products the morning of sampling; to not use plastic clipboards, etc. All these precautions highlight the need for broader regulation but also cause concern that samples may easily be contaminated. When considering enforceable regulatory limits in the low parts per trillion—barely above a laboratory's capability to reliably detect and quantify these compounds—cross contamination must be considered. EPA must have protocols in place to invalidate samples with PFAS detections that may be a result of human error through sample collection, improper shipping practices, or other avenues. EPA and primacy states must ensure that PWS have training on proper sampling protocols and provide the appropriate technical assistance and outreach to PWS once the rule is implemented.

EPA Response: Please see section 8.7 of the EPA response in this *Response to Comments* document.

Citizens Energy Group (Doc. #1838, SBC-044866)

Further, the ubiquitous nature of PFAS compounds in the environment and the risk of low- level contamination of samples given the presence of these PFAS compounds in clothing, personal care products, etc., consideration should be given for "outliers", or analytical results that are inconsistent with prior sampling events.

EPA Response: Please see section 8.7 of the EPA response in this *Response to Comments* document.

New Hampshire Water Works Association, Inc. (NHWWA) (Doc. #1576, SBC-042452)

In addition, EPA's proposed MCLs are vulnerable to excess false positive analytical results from factors such as Teflon-based materials commonly used in drinking water treatment systems.

EPA Response: Please see section 8.7 of the EPA response in this *Response to Comments* document.

City of Allentown and Lehigh County Authority (LCA), Pennsylvania (Doc. #1667, SBC-043675)

PFOA and PFOS: The proposed regulation sets a Maximum Contaminant Level (MCL) of 4.0 parts per trillion (ppt) for PFOA and PFOS. The laboratory methods approved for analysis are methods EPA 533 and 537.1, which have a Practical Quantification Limit (PQL) and Method Detection Limit (MDL) of 4.0 ppt. PQLs are defined as "the lowest achievable level of analytical quantitation during routine laboratory operating conditions within specified limits of precision and accuracy" (50 Federal Register 46902, November 13, 1985). Thus, the PQL reflects both the physical limitation of approved analytical methods and the practical limitations of variability in laboratory performance. While other analytes' MCLs have been set at the PQL (such as heptachlor, chlordane, or thallium), the likelihood of cross-contamination or interference was not as likely to occur in those cases. Conversely, due to proposed limits, cross contamination during PFAS sampling is highly likely as PFAS compounds are known to be present in many everyday products.

To address the issue of potential cross-contamination of water samples from external sources, some states have established PFAS regulatory protocols that allow for samples to be invalidated based on obvious sampling errors. We request that EPA consider adopting this approach in the final rulemaking, so utilities (and the communities they serve) are not unnecessarily penalized for a cross-contaminated sample. The exceptionally low limit, set at the PQL, and the ubiquitous nature of PFAS compounds make cross-contamination of water samples a very real concern for all utilities.

EPA Response: Please see section 8.7 of the EPA response in this *Response to Comments* document.

California Farm Bureau Federation (Doc. #1704, SBC-045077)

Accuracy also remains a concern given the proposed MCLs for PFOA and PFOS are incredibly low. There is a high risk of contamination during the testing process and inaccurate results has the potential to result in costly compliance measures.

EPA Response: Please see section 8.7 of the EPA response in this *Response to Comments* document.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045159)

Criteria for sample invalidation needs to be added to accommodate issues such as Quality Control failures including but not limited to detections of target analytes in the FRB, as well as whether replacement samples must be collected along with a timeline for doing so.

EPA Response: Please see section 8.7 of the EPA response in this *Response to Comments* document.

Pennsylvania Chamber of Business and Industry (Doc. #1592, SBC-042795)

At the extremely low levels being proposed, it will be extremely difficult for commercial and public laboratory testing facilities to keep the testing areas, as well throughout the chain of custody, pure of any residual PFAS contamination that will result in inaccurate testing.

EPA Response: Please see section 8.7 of the EPA response in this *Response to Comments* document.

Environmental Monitoring Coalition (EMC) (Doc. #1625, SBC-043115)

While EMC acknowledges that current screening technology sensitivity levels are not adequate to help for these proposed PFAS MCL levels, it would be useful for EPA to investigate potential screening technologies versus analyzing all samples through LC/MS/MS or HRMS. This would help address laboratory capacity issues.

To also help address laboratory capacity issues, EMC believes it would be useful to decrease the field blank testing requirement by changing the current requirement of one field blank per site to one of the following, in priority order of preferred change:

1. Collect a field blank only when resampling to confirm detect/violation.

2. Collect a field blank, but only analyze it if the analyte is detected above the MCL. Since PFAS do not break down for long periods of time, is it necessary to have holding times for field blanks?

3. Collect a field blank once per collection event, versus every site. Then the laboratory could test the field blank (within the hold time requirement) if the result warrants examining whether the collection process was the contamination source. This would be similar to how it is approached with VOCs.

EPA Response: Please see section 8.7 of the EPA response in this *Response to Comments* document. Consistent with the commenter's point, the EPA is not aware of screening technology with the sensitivity that would be needed to support this NPDWR. Lastly, the EPA notes that the methods specify when laboratories are to analyze FRBs; the method approach was designed to limit the number of FRBs that are ultimately analyzed.

Association of Public Health Laboratories (APHL) (Doc. #1646, SBC-043323)

While EMC acknowledges that current screening technology sensitivity levels are not adequate to help for these proposed PFAS MCL levels, it would be useful for EPA to investigate potential screening technologies versus analyzing all samples through LC/MS/MS or HRMS. This would help address laboratory capacity issues.

To also help address laboratory capacity issues, EMC believes it would be useful to decrease the field blank testing requirement by changing the current requirement of one field blank per site to one of the following, in priority order of preferred change:

1. Collect a field blank only when resampling to confirm detect/violation.

2. Collect a field blank, but only analyze it if the analyte is detected above the MCL. Since PFAS do not break down for long periods of time, is it necessary to have holding times for field blanks?

3. Collect a field blank once per collection event, versus every site. Then the laboratory could test the field blank (within the hold time requirement) if the result warrants examining whether the collection process was the contamination source. This would be similar to how it is approached with VOCs.

EPA Response: Please see section 8.7 of the EPA response in this *Response to Comments* document. Consistent with the commenter's point, the EPA is not aware of screening technology with the sensitivity that would be needed to support this NPDWR. Lastly, the EPA notes that the methods specify when laboratories are to analyze FRBs; the method approach was designed to limit the number of FRBs that are ultimately analyzed.

Water Quality Association (WQA) (Doc. #1694, SBC-044983)

EPA should consider the risks of inaccurate water sample results when measuring at 4 ppt or below, considering the extensive use of PFAS in everyday products and those used under regular laboratory testing. EPA should refer to knowledgeable, experienced stakeholders on the best methods for water testing in the field and laboratory before and after treatment to help ensure results are accurate and are not compromised by cross-contamination.

EPA Response: Please see section 8.7 of the EPA response in this *Response to Comments* document.

8.8 Trigger Level Values

Summary of Major Public Comments and EPA Responses

To determine compliance monitoring frequency only, the EPA proposed a rule trigger level of one-third the MCLs (1.3 ng/L for PFOA and PFOS and 0.33 for Hazard Index PFAS (PFHxS, PFNA, HFPO-DA, and PFBS)). If results for an EPTDS are below the trigger level, systems

would be eligible for reduced monitoring. The EPA requested comment on monitoring-related flexibilities that should be considered to further reduce burden while also maintaining public health protection, including setting a rule trigger level at different values than the proposed values of 1.3 ng/L for PFOA and PFOS and 0.33 for the Hazard Index PFAS (PFHxS, PFNA, HFPO-DA, and PFBS). Alternative values of 2.0 ng/L for PFOA and PFOS and 0.50 for the Hazard Index PFAS were identified as possibilities. The EPA received numerous comments on the proposed rule trigger levels. Comments addressed the proposed values, specifically for PFOA and PFOS, and their intended purpose for determination of compliance monitoring frequency. Several commenters suggested that the proposed values (i.e., 1.3 ng/L for PFOA and PFOS and 0.33 for the Hazard Index) are too high and the EPA should instead set lower trigger level to ensure greater public health protection. Many other commenters suggested the opposite, stating that the proposed levels are too low, that laboratories will not be able to achieve these levels, and that it may exacerbate any laboratory capacity issues. Consequently, some of these commenters were concerned that water systems would be ineligible for reduced monitoring based on their laboratory's analytical limitations. Several commenters suggested that the proposed values are inconsistent with the SMF for SOCs.

Many who commented on the subject were fully supportive of the EPA's proposed alternative trigger level values of 2.0 ng/L for PFOA and PFOS and 0.50 for the Hazard Index, while others expressed support for the inclusion of trigger levels only if these higher levels were incorporated. Some noted that these higher trigger levels (i.e., one-half the MCL) would better align with current laboratory capabilities and allow greater use of previously collected drinking water data (to demonstrate systems are eligible for reduced triennial monitoring under the rule's initial monitoring requirements). A few commenters recommended alternative values of 70-80 percent of the MCLs be used as the trigger levels.

The EPA agrees with commenters that the trigger levels should be finalized as one-half of the MCLs (i.e., PFOA and PFOS at 2.0 ng/L each, PFHxS, PFNA, and HFPO-DA at 5 ng/L each, and Hazard Index at 0.5). Using data submitted as part of the UCMR 5 Laboratory Approval Program as a reference point, the EPA notes that 47 of 53 laboratories (89 percent) that applied for UCMR 5 approval generated an MRL confirmation at 2 ng/L (one-half the proposed MCL) or less for Method 533. This suggests that most laboratories with the necessary instrumentation to support PFAS monitoring have the capability to provide screening measurement results at the revised trigger level of one-half of the MCL. This corresponds with other comments described in section VIII.C of the final rule preamble that provided their experience that laboratories are capable of reliably quantifying values below the PQLs, particularly to 2.0 ng/L for PFOA and PFOS.

Additionally, based on the EPA's evaluation of state drinking water data, updating the final rule trigger levels (to one-half of the MCL) will result in a considerable number of additional water systems significantly reducing their ongoing monitoring frequency from quarterly or annual monitoring to triennial monitoring. Although this modification from one-third of the MCLs to one-half of the MCLs may provide slightly less information on a water system's measured PFAS

levels as a result of their less frequent monitoring, the trigger levels for the final rule (i.e., one-half of the MCLs) are sufficiently low that they will ensure that the monitoring frequency will provide primacy agencies, water systems, and the public with information well below the MCLs and inform any decisions regarding actions to address elevated levels of regulated PFAS when appropriate, while also reducing monitoring burden for water systems.

Many other commenters stated that either trigger levels should be removed from the rule entirely or that trigger levels should not be set to any levels below PQLs since these represent the level that can be reliably measured with a high degree of precision and accuracy across all laboratories. Several of these commenters suggested that data below the PQL are unreliable, would result in higher costs, and should not be used as the basis for any regulatory decisions. Thus, they suggested that if trigger levels are incorporated, they should be the same as the PQLs. These commenters also cited laboratory challenges in achieving measurement below the PQLs and suggested that water systems would not be eligible for reduced triennial monitoring as a result of these limitations. Additionally, some of these commenters suggested that decision making based on any values below the PQLs may exacerbate laboratory capacity issues, claiming that such trigger levels would result in errors, such as false positives, which would lead to increased monitoring where samples need to be re-tested.

The EPA emphasizes that the use of trigger levels set at values below the MCLs is consistent with other SOCs under the SMF and not novel for drinking water regulations (as described in the subsequent paragraph). Their use allows water systems the opportunity to reduce their monitoring schedule and burden where it can be demonstrated through sampling results that they are at low risk of PFAS contamination. In the absence of trigger levels, or some other below-MCL threshold, all water systems would be deprived of the opportunity for reduced monitoring even where there is little or no risk of PFAS contamination. At a national level, were the EPA to eliminate reduced monitoring options, this would result in a significant increase in costs to utilities without any corresponding increase in health benefits because there is little or no risk to public health associated with PFAS in the water from these water systems. Consequently, the EPA is choosing to incorporate these levels to allow flexibility and reduce burden for water systems while maintaining health protection.

For commenters that suggest the trigger levels should be identical to the PQLs, particularly for PFOA and PFOS, the EPA disagrees as the agency must have greater assurance that the levels are below the regulatory standard, the systems are actually lower risk, and a reduced monitoring schedule is appropriate. Specifically, in the case of PFOA and PFOS, the EPA believes it would represent an unacceptable public health risk to set trigger levels at the PQLs because the EPA is setting the MCL at the PQL which means that it represents the "maximum permissible level." Moreover, the approach of considering measured levels lower than PQLs for determining monitoring frequency is not novel but has been part of the drinking water standards for many years. Many of the EPA's other drinking water standards use an MDL, which, by definition, is lower than the PQL. Under the SMF for SOCs, for example, results both at or below detection limits and between detection limits and the MCL are utilized for monitoring frequency

determination. Additionally, 40 CFR § 141.24(h)(7) prescribes the monitoring frequency for organic contaminants based on sample results relative to detection limits (as defined in in paragraph (h)(18) of the same section). In each of these cases, detection limits are below their PQLs (often by a factor of 10). The approach in this rule – using levels lower than the PQL to determine monitoring frequency – is consistent with the EPA's approach for other NPDWRs.

As described earlier, some commenters raised concerns about potential laboratory analytical and capacity issues. For more on laboratory capability and capacity, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Some suggested that laboratories cannot achieve levels below the PQLs, which would result in water systems not being eligible for reduced monitoring based on not demonstrating results below trigger levels. The EPA recognizes that some laboratories may not be able to produce results at these lower levels with the same degree of accuracy and precision as results at or above the PQLs, and notes that there is not a requirement that they do so for these purposes. The EPA uses the PQL to inform the MCL feasibility determination and the same level of precision and accuracy is not required to determine monitoring frequency.

Along these lines, several commenters questioned if the sample results must be quantified to be used for the determination of monitoring frequency, given the proposed trigger level values were set below the PQLs, requesting further clarity from the EPA on how to interpret and utilize quantified and non-quantified data. Furthermore, some commenters suggested that if values below the PQLs are used, only quantified results should be used for determining monitoring frequency. Other commenters stated there should not be a numerical value associated with results below the PQL (e.g., results between the trigger levels and the PQLs) and instead such results should only be reported on an absence/presence basis.

The EPA agrees that results below the PQL may not have the same precision and accuracy as higher-level measurements; however, results below the PQL can be sufficiently determined for particular purposes. Data below the PQL will be critical to ensuring that systems are monitoring at the correct frequency and whether a contaminant is present within a certain range. Moreover, while results near the trigger level may be less definitive than results at or above the PQL, such results nonetheless provide sufficient information with adequate reliability that they are appropriate for establishing monitoring frequency, as well as for reporting as part of the annual CCR. CCR reporting is based on detected contaminants and for the purposes of the PFAS NPDWR, 141.151(d) defines "detections" as results at or above the rule trigger levels (see section IX of this preamble for more information on CCR requirements).

Under this final rule, for monitoring frequency determination purposes, systems are required to use all compliance sample results, including those below the PQLs and not quantified with the same precision and accuracy as is associated with the MCL compliance determination. Additionally, the determination of monitoring frequency is not based on a running annual average result, but each individual sampling result. As an illustration of the approach, if a water system has quarterly sampling results at an EPTDS from initial monitoring for PFOA that are 2.0, 1.5, 5.0, and 1.5 ng/L, there are two results (i.e., 2.0 and 5.0 ng/L) at or above the EPA's

final trigger level for PFOA (i.e., 2.0 ng/L). Thus, the water system would not be eligible for triennial monitoring at this EPTDS for all regulated PFAS when compliance monitoring begins. Providing a different example, if a water system that is currently required to conduct quarterly compliance monitoring has quarterly sampling results at an EPTDS for PFOA that are 2.0, 3.5, 2.5, and 1.5 ng/L, all results are below the MCL for PFOA (i.e., 4.0 ng/L), however three results are above the PFOA trigger level. In this case, because four quarters of data have been collected and assuming all other regulated PFAS sampling results are below their MCLs as well, the water system could be deemed reliability and consistently below the MCL by the primacy agency and be eligible to monitor annually at this EPTDS. For all frequencies of ongoing compliance monitoring, including quarterly, annual and triennial, this determination will be done the same (i.e., all sample results are used, even those below the PQLs).

Many commenters requested that the EPA provide clarification on how laboratories and PWSs should report levels below the PQLs for monitoring frequency purposes. All results at or above the trigger level are to be reported as numeric values and used for determining monitoring frequency. Under the EPA approved analytical methods discussed in section XII of the final rule preamble, numeric values as low as the rule trigger levels will be available because of the need to meet ongoing QC requirements of the method for blanks, demonstrating no background contamination. Within each analytical batch of samples, the laboratory must document passing blank QC criteria by attaining qualitative measurements of the regulated PFAS that are no higher than one-third of the laboratory's reporting limit, which must be at or below the PQL. The EPA intends to provide guidance materials with details and examples on this to support successful implementation of the final rule.

Some commenters suggested the potential for confusion related to the differences in how results less than PQLs are used in monitoring frequency determination and the MCL compliance determination. Several commenters suggested that there should be a consistent approach. Most commenters suggested that the approach should follow that of the MCL compliance determination, where zero is used in the calculation of annual averages when measured values are below PQLs. To alleviate possible confusion, the EPA intends to provide communication materials to support successful implementation of the final rule. Nevertheless, the difference in approach (between data used for compliance monitoring determinations and data used to determine monitoring frequency) reflects the most appropriate application of the data for each of the intended purposes. As a result, water systems will monitor with a frequency based on the system's sampling results which are most demonstrative of their risks, ensuring that any regulated PFAS contamination is detected promptly, and enabling the water system to provide any needed reduction in PFAS levels as required by this rule. The EPA's rationale is described in detail in subsection VIII.B of the final rule preamble.

Individual Public Comments

Town of Lincoln Water Department (Doc. #1613, SBC-043028)

EPA should abandon its plans to have any trigger below the MCL and revert to the Standard Monitoring Framework which considers all results below the Practical Quantification Limit to be considered 0 ppt.

EPA Response: The EPA disagrees with the commenter's claim that under the SMF all results below the PQL are considered zero as this is incorrect and described in section 8.8 of the EPA response in this *Response to Comments* document. Please see section 8.2 summary of the EPA response in this *Response to Comments* document for a discussion of using values below PQLs in compliance calculations.

Town of Tewksbury, Massachusetts (Doc. #1637, SBC-043246)

EPA should abandon its plans to have any trigger below the MCL and revert to the Standard Monitoring Framework which considers all results below the Practical Quantification Limit to be considered 0 ppt.

EPA Response: The EPA disagrees with the commenter's claim that under the SMF all results below the PQL are considered zero as this is incorrect and described in section 8.8 of the EPA response in this *Response to Comments* document. Please see section 8.2 summary of the EPA response in this *Response to Comments* document for a discussion of using values below PQLs in compliance calculations.

COMM Water Department (Doc. #1577, SBC-042440)

EPA should abandon its plans to have any trigger below the MCL and revert to the Standard Monitoring Framework which considers all results below the Practical Quantification Limit to be considered 0 ppt.

EPA Response: The EPA disagrees with the commenter's claim that under the SMF all results below the PQL are considered zero as this is incorrect and described in section 8.8 of the EPA response in this *Response to Comments* document. Please see section 8.2 summary of the EPA response in this *Response to Comments* document for a discussion of using values below PQLs in compliance calculations.

Water Supply District of Acton (Doc. #1662, SBC-043663)

EPA should abandon its plans to have any trigger level below the MCL and revert to the Standard Monitoring Framework which considers all results below the Practical Quantification Limit to be considered 0 ppt.

EPA Response: The EPA disagrees with the commenter's claim that under the SMF all results below the PQL are considered zero as this is incorrect and described in section 8.8 of the EPA response in this *Response to Comments* document. Please see section 8.2 summary of the EPA response in this *Response to Comments* document for a discussion of using values below PQLs in compliance calculations.

Marlene Ladderbush (Doc. #1612, SBC-042916)

EPA should abandon its plans to have any trigger below the MCL and revert to the Standard Monitoring Framework which considers all results below the Practical Quantification Limit to be considered 0 ppt.

EPA Response: The EPA disagrees with the commenter's claim that under the SMF all results below the PQL are considered zero as this is incorrect and described in section 8.8 of the EPA response in this *Response to Comments* document. Please see section 8.2 summary of the EPA response in this *Response to Comments* document for a discussion of using values below PQLs in compliance calculations.

Great Lakes Water Authority (GLWA) (Doc. #1558, SBC-042551)

Monitoring related flexibilities that should be considered to further reduce burden while also maintaining public health protection including a rule trigger level at different values than the currently proposed values of 1.3 ppt for PFOA and PFOS and 0.33 for the Hazard Index (HI) PFAS.

Trigger levels for PFOA and PFOS as defined by the proposed language are well below the PQL. GLWA strongly believes that if a trigger level is used to require more frequent sampling, it should be used as an absence/presence test for PFAS rather than a numerical value.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Missouri Department of Natural Resources (Doc. #1563, SBC-042538)

EPA requests comment generally on its estimation of sampling costs. The Agency is also specifically requesting comment on the ability of systems to demonstrate they are reliably and consistently below 1.3 ppt for PFOA and PFOS and 0.33 ppt for PFAS regulated by the HI in order to qualify for reduced monitoring.

As discussed in detail previously, demonstration of reliable and consistent (R&C) results can only be achieved with detectible results that are quantifiable (i.e., not estimated). As 1.3 ppt and 0.33 ppt are below available analytical technologies these values cannot be used as detections that are considered R&C below a PQL. As such, the HI is not implementable. Additionally, PFHxS has a HBWC of 2000 ppt. Regardless of a 0.33 ppt or 0.5 ppt HI level to trigger

increased quarterly monitoring, a reportable detected concentration of 667-1000 ppt would keep systems monitoring unnecessarily without being close to the HBWC level.

EPA Response: The EPA disagrees with this commenter that reliably and consistently below the MCL results must be quantifiable for the purposes of determining a system may be eligible for monitoring at an annual frequency. Please see section 8.1.2 of the EPA response in this *Response to Comments* document for additional information regarding compliance monitoring requirements. Pertaining to the EPA's trigger levels for reduced triennial monitoring, please see section 8.8 of the EPA response in this *Response to Comments* document. The EPA further disagrees with the commenter because all of the PFAS within the Hazard Index (PFHxS, PFNA, HFPO-DA, and PFBS) all have HBWCs that are equal to or greater than one half of their HBWC, therefore there are no analytical limitations and those values, while not required for monitoring frequency determination purposes, can be quantified as needed. The commenter also incorrectly cites that the HBWC for PFHxS is 2000 ppt, as it was proposed as 9.0 ppt and is being finalized at 10 ppt, and the PQL for PFHxS is 3.0 ppt. Thus, the PQL is clearly less than one-half of the HBWC.

San Antonio Water System (SAWS) (Doc. #1570, SBC-042476)

• The Practical Quantitation Limit (PQL) represents what can reasonably and accurately be measured between different labs across the nation. The proposed trigger level is substantially lower than the PQL and relies on a lowest calibration standard. This is a departure from standard practice. PWSs will be regulated based on a value that most labs will not be able to reach. EPA recognizes this and states that the values lower than the PQL will not have the required precision but will serve as a "warning" that the PWS may have a PFAS issue, as described in the following:

o It is not reasonable to require a PWS to increase their sampling 6-fold based on a trigger level lower than the PQL.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Lakewood Water District (LWD) (Doc. #1574, SBC-042753)

Trigger Level Inappropriate

The proposed regulation clearly documents that the minimum Practical Quantitative Limit (PQL) for PFOA and PFOS is 4 ppt. Contrary to this fact, EPA proposes using a value of one-third of the PQL to trigger monitoring requirements for water systems. It is inappropriate and unreasonable to base regulatory decisions on data that, by definition, is unreliable.

Further, using two different regulatory levels will create massive risk communication challenges for water purveyors like LWD. No values below PQL should be used for regulatory purposes.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Oregon Health Authority (OHA) (Doc. #1582, SBC-042762)

• EPA requests comment on monitoring-related flexibilities that should be considered to further reduce burden while also maintaining public health protection including a rule trigger level at different values than the currently proposed values of 1.3 ppt for PFOA and PFOS and 0.33 for the HI PFAS (PFHxS, HFPO-DA, PFNA, and PFBS), specifically alternative values of 2.0 ppt for PFOA and PFOS and 0.50 for the HI PFAS. EPA also requests comment other monitoring flexibilities identified by commenters.

OHA believes it may be confusing for primacy agencies and public water systems to consider values above detection but below quantitation for the purposes of monitoring frequency. It is OHA's opinion that only quantified results (values at or above the minimum reporting level or MRL) should be used for determining monitoring schedule frequency. Setting the trigger at 1.3 ppt would be below the MRLs that most labs can achieve at this time. Using unquantified data for decision-making is a risky precedent and states would need more clarity on how the data should reported, interpreted, and entered (OHA has a policy of not accepting J-flagged drinking water data for compliance).

If EPA keeps the trigger levels below the practical quantitation limit (PQL), OHA recommends that EPA change the trigger levels to one-half the MCLs (2.0 ppt for PFOA and PFOS and to 0.50 of the MCL for the Hazard Index) for determining monitoring frequency. Many labs can achieve MRLs of 2.0 ppt at this time and making the trigger a demonstrated quantifiable number (mostly in regard to PFOA and PFOS) may provide an incentive for other labs to work toward lower MRLs, and it is likely that more labs will be able to achieve lower MRLs over time anyway.

If EPA decides to set the trigger level below the PQL and below the MRLs some labs can achieve, states may be receiving both quantified and unquantified results. If this is to be the case, OHA requests that EPA provide guidance for how lab results should be reported for purposes of uniformity and clarity.

Lastly, OHA also believes that water systems that can reliably and consistently show PFAS results below the MCL should be eligible for annual monitoring just as for other organic chemicals. A small groundwater system serving 25 people with PFOS in their drinking water below the MCL but above the trigger (for example 2.4 ppt) would be on quarterly monitoring in perpetuity under the currently proposed rule and subject to the monitoring costs associated with analyzing a sample plus a blank for PFAS each quarter which seems overly burdensome.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document. Regarding compliance monitoring requirements, including annual

monitoring, please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Washington Suburban Sanitary Commission (WSSC Water) (Doc. #1585, SBC-042772)

Trigger Levels:

EPA set trigger levels at one third of the proposed MCLs: 1.3 ppt for PFOA and PFOS, and 0.33 for PFAS regulated by the HI (PFHxS, HFPO-DA, PENA, and PFBS). Trigger levels are used to determine monitoring requirements: after one-year initial monitoring, systems with PFAS less than the trigger levels are eligible for reduced monitoring. Systems already under reduced monitoring must revert to standard monitoring after one incidence of PFAS exceeding the trigger level.

Proposed trigger levels for PFOA and PFOS are not supported by the PQL of 4 ppt established by EPA for this rule and UCMR5, making it difficult for water systems to obtain quantifiable data at these levels. WSSC Water recommends that EPA establish the trigger level for PFOS and PFOA at 4 ppt or another reliable quantifiable level supported by current analytical technologies. This aligns with WSSC Water's earlier proposal to set the MCL initially at 10 ppt, providing sufficient margin of confidence. As analytical technology advances in the future, EPA can reconsider the feasibility of lowering MCLs and trigger levels.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Alameda County Water District (ACWD) (Doc. #1595, SBC-042350)

2. Establishment of a Trigger Level Criteria that is below the PQL to qualify for reduced monitoring

EPA is proposing a "trigger level" that will be set at levels below the Practical Quantitation

Level (PQL), for less frequent compliance monitoring in systems which can demonstrate PFAS concentrations in drinking water are below 1.3 ppt for PFOA and PFOS and 0.33 for the Hazard Index PFAS. EPA states that these lower monitoring levels are achievable by individual laboratories, and therefore, these low levels can be used for screening purposes and to determine compliance frequency.

The PQL is defined as the lowest concentration of an analyte that can be reliably measured within specified limits of precision and accuracy during routine laboratory operating conditions. EPA has determined that establishing a PQL at 4.0 ppt for PFOA & PFOS, which were derived from laboratory participation in establishing UCMR-5 MRLs, to be appropriate in this proposed rulemaking.

Until more laboratories upgrade their instrumentation, achieving lower values than the PQL may be a challenge. Additionally, the data that would be collected would need to be qualified as not

meeting the method requirements and there may not be any means to attach a qualifier to such (compliance) data. To avoid potential issues with producing qualified data at levels below the PQL, commercial laboratories may need to change their lowest calibration levels to the trigger levels. It is unlikely that such a change could be implemented in the middle of the current UCMR-5 monitoring program, where these have already been set at the PQLs.

ACWD appreciates EPA's inclusion of a criteria to qualify for a reduction in required monitoring. Given the challenges with reliably achieving precise and accurate monitoring results at levels below the PQL, establishing the levels to qualify for reduced monitoring far below the PQL, and below the MRLs will make it challenging for systems to qualify for the reduction in monitoring frequency and potential relief from the associated costs. EPA should consider establishing trigger levels for reduced monitoring at the PQL.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Michigan Department of Environment, Great Lakes, and Energy (EGLE) Drinking Water and Environmental Health Division (DWEHD) (Doc. #1597, SBC-042980)

D. Monitoring and Compliance Requirements

Having reviewed Section IX of the proposed NPDWR, EGLE DWEHD presents the following comments for consideration:

1. EGLE DWEHD requests clarification regarding how the proposed "Trigger Level" will be used, both during initial monitoring and ongoing compliance monitoring. The language in Section IX appears to present this threshold as a single point in time, for which a detection above would lead to a monitoring decision. Is this the case, or would the "Trigger Level" instead be calculated using a running annual average?

2. "Trigger Level" is a new definition within the SDWA. EGLE DWEHD proposes using "detection above X% of the MCL" to identify the threshold, rather than establishing an additional definition.

3. EPA proposes a "Trigger Level" at 1/3 of each MCL. This is presented as appropriate based on the ability of individual laboratories to detect at levels well below the practical quantitation limit (PQL). However, it is unlikely all laboratories are capable of this level of reliable detection, given their requirement to meet the 4.0 ng/l PQL threshold. Regulations should be based on values all laboratories can and are expected to meet. Otherwise, it may present an inequity for supplies, and their ability to potentially reduce monitoring. EGLE DWEHD proposes a "Trigger Level" of 1/2 each MCL, to alleviate this and to maintain consistency with other portions of the SDWA.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document. Regarding initial monitoring and compliance monitoring requirements,

please see sections 8.1.1. and 8.1.2 of the EPA response in this *Response to Comments* document, respectively, as well as section VIII.A. of the final rule preamble. For monitoring frequency determination purposes, the frequency is based on single sample results, not averages. The EPA acknowledges the suggestion provided by the commenter on the definition of the trigger level. The agency believes it has clearly defined what the trigger levels are and has updated them to be one-half of the MCLs for final rule, as recommended by the commenter.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043655)

9. The EPA is requesting comment on establishing the proposed rule trigger at 1/3 versus 1/2 of the proposed MCL for all PFAS species. There are cost implications associated with a lower trigger level (i.e., possible additional sampling) that need to be considered in trigger level determination.

It is recommended that EPA use 1/2 of the MCL as the trigger, as this level better aligns with most laboratory reporting limits (which are typically around 1.9-2.0 ng/L for PFAS species currently).

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EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

American Water Works Company Inc. (Doc. #1608, SBC-044013)

Reduced Monitoring

American Water supports including provisions that allow water systems to reduce their monitoring requirements. A trigger level of one-half the associated MCLs, not one-third as proposed, using results below the PQL as zero (0), would be an appropriate approach. It is

critical that the final approach be achievable and reliable, so water systems are able to attain reduced monitoring, where appropriate, and retain that status.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document. Values below the PQLs are treated as zero only for compliance determination purposes, and not for monitoring frequency purposes . Please see section 8.2 of the EPA response in this *Response to Comments* document regarding the determination of compliance and violations.

Minnesota Department of Health (MDH) (Doc. #1610, SBC-042850)

Since the rule proposal's trigger levels are set to 1/3 the MCLs, laboratories must report data below the PQLs for PFOS and PFOA. States and PWSs will receive this data in laboratory reports as public record, demonstrating a clear disconnect in how data is considered for compliance versus monitoring schedule purposes.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Oklahoma Department of Environmental Quality (DEQ) (Doc. #1616, SBC-043044)

Reduced Compliance Monitoring

DEQ recommends that EPA clarify and fix conflicting language related to the capability and expectation of laboratories to report PFOA and PFOS detections at low levels for reduced monitoring.

DEQ supports reduced monitoring when the compliance monitoring running annual averages for PFOA and PFOS are each less than the respective practical quantitation limit of 4.0 ppt, and when the Hazard Index is one-half (instead of one-third) of the MCL, i.e., 0.5. Setting the Hazard Index trigger level at one-half of the MCL would fit the Synthetic Organic Contaminant (SOC) standard monitoring framework.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-044882)

• DEP does not support using the proposed trigger level of 1.3 ppt in the RAA calculation for compliance determinations instead of zero when PFOA and/or PFOS are detected at a level below the PQL. As already noted, detections below the PQL would be reported as qualified data and would not be legally defensible. Using the proposed trigger level of 1.3 ppt in the RAA calculation instead of zero is arbitrary and assigns a value that is not based on actual defensible analytical results for a compliance determination.

• Trigger levels should not be set at levels lower than the PQL. Trigger levels for PFOA and PFOS are specified in [sec] 141.XX(b)(2)(iii) as one-third the MCL, which is also equal to one-third the PQL, or 1.3 ppt. As already noted, by definition, the PQL is the lowest level that can be accurately and precisely measured. Therefore, at a level below the PQL, the measured concentration may not be accurately quantified. It is not feasible to implement drinking water standards based on data that is not accurate or precise and, therefore, not legally defensible. EPA acknowledges in its FAQs for Drinking Water Primacy Agencies that "measurements below the PQLs may be less definitive," but then goes on to argue that those low levels are "appropriate for determining if PFAS are present and establishing monitoring frequency." However, it is not appropriate to use data that is not legally defensible in any way in a regulation. DEP does not agree with regulating PFAS monitoring frequencies based on levels detected lower than the PQL as a presence/absence detection.

• The use of 1.3 ppt as a trigger level for monitoring frequency for PFOA and PFOS is inconsistent within the proposed rulemaking. [sec] 141.XX(a)(7) defines the trigger levels as ppt for PFOA and PFOS and 0.33 for the HI but does not clarify whether these are based on discrete sample results or an RAA. In [sec] 14 I.XX(a)(8), the trigger level appears intended to be used as a calculated value to determine reduced monitoring frequency based on a RAA calculation for systems on a quarterly initial monitoring frequency. However, the trigger level also appears to be used as a discrete value (i.e., "reliably and consistently below the MCL") to trigger increased monitoring frequency back to quarterly([sec] 141.903(d)). DEP disagrees with using 1.3 ppt as a trigger level for monitoring frequency determination for PFOA and PFOS for several reasons:

o Based on information gathered by DEP during a survey of laboratories accredited in Pennsylvania to inform our state rulemaking process, and confirmed by the DEP Bureau of Laboratories, very few (if any) laboratories are capable of detecting PFAS at a level of 1.3 ppt. It is therefore not feasible to use the trigger level of 1.3 ppt in a single sample to require an increase to quarterly monitoring.

o In addition to the lack of laboratory capabilities to detect PFAS at such a low level, detections due to cross contamination should be considered. Because PFAS are generally considered to be ubiquitous, such low-level detections may not be indicative of actual water quality.

o Data reported below the PQL would be reported as qualified data, notated with the "J" qualifier. J-qualified data are considered to be a detection that is an estimated value. Qualified data is not acceptable for compliance determinations. Therefore, it is not appropriate to make regulatory decisions based on J-qualified data, even for monitoring frequency determinations.

• Instead of using the proposed trigger levels of one-third the MCLs for determining monitoring frequencies, DEP recommends using levels that are "reliably and consistently below the MCL" (R&C), to be consistent with existing regulations for chronic contaminants. As per 40 CFR, Part 141, the federal R&C criteria for nitrate (an acute contaminant) is set at 50% of the MCL. EPA defers to the states to set R&C criteria for chronic contaminants. For example, for chronic contaminants, DEP uses a R&C level of 80% of the MCL. Since DEP agrees that PFAS are

chronic contaminants, the R&C level for PFAS should be set at a level more appropriate for chronic contaminants. DEP suggests that it would be inconsistent for EPA to set the R&C criteria for a chronic contaminant such as PFAS lower than the R&C criteria for an acute contaminant. However, it is important to note that, if the MCLs for PFOA and PFOS are set at 4.0 ppt, which is the same as the PQL, then even 80% of the MCL, or 3.2 ppt, is still at a level that is below the PQL, which is not feasible. This further supports DEP's earlier comment that the MCLs should be set at a level that is a minimum of 30% above the PQL.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document. Regarding initial monitoring and compliance monitoring requirements (including the determination of reliably and consistently below the MCL), please see sections 8.1.1. and 8.1.2 of the EPA response in this *Response to Comments* document, respectively, as well as section VIII.A. of the final rule preamble. For monitoring frequency determination purposes, the frequency is based on single discrete sample results, not averages (e.g., for an EPTDS to be eligible for annual compliance monitoring, all quarterly samples results must be below the MCLs). Additionally, values below the PQLs are treated as zero only for compliance determination purposes. Please see section 8.2 of the EPA response in this *Response to Comments* document regarding the determination of compliance and violations. Pertaining to the commenter's concerns on cross contamination, please see section 8.7 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044102)

ASDWA recommends that EPA change the trigger levels to one-half the MCLs for determining compliance monitoring frequency.

The proposed rule is not clear regarding whether EPA expects that some laboratories will be able to reliably test as low as 1.3 ppt. Setting the trigger levels at one-half (instead of one-third) of the MCLs will help alleviate this misconception. Additionally, increasing the trigger level will allow more states to use previously collected data for determining systems that qualify for reduced monitoring and help with laboratory capacity, as well as the previously stated challenges with laboratory QA/QC for sample results at 1.3 ppt for PFOA and PFOS and 0.33 for HI PFAS - perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPODA) and its ammonium salt, perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS). For the proposed MCL of 4.0 ppt, this would change the trigger level to 2.0 ppt for PFOA and PFOS and 0.5 of the MCL for the Hazard Index (HI).

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044066)

6. ASDWA recommends that EPA change the trigger levels to one-half the MCLs for determining compliance monitoring frequency. Setting the trigger levels at one-half (instead of

one-third) of the MCLs would alleviate confusion regarding using the 1.3 parts per trillion for PFOA and PFOS, which some may incorrectly assume means laboratories can accurately test to that level. Setting the trigger levels for reduced monitoring at one-half (instead of one-third) of the MCLs would improve laboratory capacity and allow more states to use previously collected data for determining reduced monitoring.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Village of Woodbury (Doc. #1629, SBC-042948)

2. Following the initial monitoring period, if samples reach a "trigger level", which is currently proposed as 1/3 of the proposed MCL, then public water suppliers will be required to monitor for contaminants quarterly. The EPA utilized Practical Quantitation Limits (PQLs) to determine the MCL. The PQL is the concentration of a contaminant that can be reliably detected during normal laboratory testing. For some laboratories, the "trigger level" as one-third of the MCL is only useful for detecting whether a contaminant is present in a sample. The EPA requested comments on this or suggested alternate trigger level. In our view, anything less than the MCL based on the PQL is useful for only establishing the presence of the compound. Accordingly, one-third or one-half which is not reliably quantified has no bearing.

EPA acknowledges that measuring PFOA and PFOS results below the PQLs may not be achievable from all laboratories and may not have the same precision as higher-level measurements, nor does EPA believe it is appropriate to make potentially costly compliance decisions based on such lower-level measurements. Yet, trigger levels are proposed at 1/3 the PQL, which will be suggestive of required action (cost) and suggest that the level of reduction from the established NYS MCL of 10 ppt, is impractical and provides no significantly greater degree of public health protection.

We recommend the trigger rule be set to the proposed MCL's established based on reliable detection and the MCL's be raised. Alternatively, the current NYS MCL should be adopted as the Federal MCL.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document. Regarding the EPA's determination of MCLs for PFOA and PFOS, please see sections 5.1 and 5.1.5 of the EPA response in this *Response to Comments* document.

Citizens Against Ruining the Environment (CARE) (Doc. #1638, SBC-043456)

Trigger Values for Reduced Monitoring Frequency Must Be Lowered

CARE strongly opposes setting the trigger values for reduced monitoring at 1.3 ppt for PFOA and PFOS and 0.5 HI for PFNA, GenX, PFHxS, and PFBS. Monitoring frequency should not be reduced when the values are so high above the MCLG of 0.0 ppt and 1.0 HI and when that trigger value is disconnected from a risk analysis. Monitoring should continue without exception

because there is no risk or vulnerability analysis available to predict which systems are likely to exceed the PFAS MCLs in the future.

A reduced monitoring frequency triggered by 1.3 ppt PFOA and PFOS or 0.5 HI for PFNA, GenX, PFHxS, and PFBS would allow too much time to pass without water quality data when there is known and detectable PFAS contamination in the system. Rather than triggering reduced monitoring frequency, system values of 1.3 ppt and .5 HI should be a trigger for ongoing monitoring to ensure the system values do not increase further towards the 4.0 ppt and 1.0 HI MCLs.

Monitoring frequency should not be reduced at any trigger level until more information is available about where and how quickly PFAS may enter each system. That information would allow a more sophisticated risk analysis to be completed for each PWS before determining eligibility for reduced monitoring frequency.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document. Regarding the commenter's concerns about reduced monitoring frequency, please see section 8.1.2 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1808, SBC-046119 in section 8.1.2 in this *Response to Comments* document.

Aidan Cecchetti (Doc. #1640, SBC-044368)

• EPA requests comment on monitoring-related flexibilities that should be considered to further reduce burden while also maintaining public health protection including a rule trigger level at different values than the currently proposed values of 1.3 ppt for PFOA and PFOS and 0.33 for the HI PFAS (PFHxS, HFPO-DA, PFNA, and PFBS), specifically alternative values of 2.0 ppt for PFOA and PFOS and 0.50 for the HI PFAS. EPA also requests comment other monitoring flexibilities identified by commenters (pg. 18682 Federal Register Volume 88, Number 60).

o It is the commenters' opinion that setting trigger levels below the current PQL is inappropriate. Although EPA asserts there is broad laboratory capability to detect the regulated PFAS at least down to those trigger levels, EPA has not chosen to reevaluate the PQL to a lower value. This suggests to the commenters that there is not sufficient evidence to demonstrate broad laboratory capability to reliably quantify at those values. If laboratories cannot reliably quantify below the PQL, they would not have the capability to distinguish between a trigger level of 1.3 ppt and a level of 2.0 ppt for PFOA or PFOS, meaning there would be no meaningful difference or added monitoring flexibility in setting the trigger level at either value. If laboratories already have the capacity to quantify down to levels of 1.3 ppt, EPA should consider revising the PQL for those contaminants. Alternatively, it may be appropriate to set a trigger level below the PQL if there should be a requirement for regulatory agencies to include a minimum method detection limit for accreditation for laboratories to perform quantification of PFAS.

o However, the commenters agree that a trigger level of 0.5 for the HI PFAS would be appropriate to allow a larger number of water systems to reduce their monitoring frequency. This would be analogous to the way nitrate is regulated in California in groundwater sources (e.g., a 5.0 mg/L as nitrate-N trigger level requires greater monitoring, which is half the level of the 10 mg/L MCL), which has been demonstrated to provide sufficient flexibility for water systems to reduce monitoring frequency without resulting in insufficient assurance of the regulated levels or decreased public health protection. Additionally, a level of 0.5 for the HI PFAS would not have the same issues described above for PFOA and PFOS because the HBWCs for all the HI PFAS compounds are a minimum of twice the PQLs for those contaminants.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

National Rural Water Association (NRWA) (Doc. #1641, SBC-043274)

• EPA requests comment on monitoring-related flexibilities that should be considered to further reduce burden while also maintaining public health protection including a rule trigger level at different values than the currently proposed values of 1.3 ppt for PFOA and PFOS and 0.33 for the HI PFAS (PFHxS, HFPO–DA, PFNA, and PFBS), specifically alternative values of 2.0 ppt for PFOA and PFOS and 0.50 for the HI PFAS. EPA also requests comments on other monitoring flexibilities identified by commenters.

Response: One-half of the MCL is the EPA precedent for a trigger level. We don't believe trigger levels are necessary nor advisable for this rule, but if EPA includes them in a final rule then one-half the MCL makes sense.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044187)

8. NCDEQ recommends that EPA change the trigger levels to one-half the MCLs for determining compliance monitoring frequency.

Seng the trigger levels at one-half (instead of one-third) of the MCLs would alleviate confusion about the use of the 1.3 ppt and one-third levels in general, as well as the previously stated challenges with laboratory QA/QC for sample results at 1.3 ppt for PFOA and PFOS and 0.33 for HI PFAS - perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPODA) and its ammonium salt, perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS) . For the proposed MCL of 4.0 ppt, this would change the trigger level to 2.0 ppt for PFOA and PFOS and to 0.5 of the MCL for the Hazard Index (HI).

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Nebraska Department of Environment and Energy (NDEE) (Doc. #1653, SBC-043202)

• The proposed Hazard Index (HI) levels were set below the practical quantitation limit (PQL) with an allowable error rate of 50% using two significant figures.

o The proposed trigger levels are set at one-third of the maximum contaminate level (MCL) and HI, however, EPA suggested changing this to one-half in order to reduce burden while also maintaining public health. If trigger levels are required, the Department supports setting these levels at one-half or 2 ppt for the MCLs and .5 for the HI and allowing States to build escalation triggers into their enforcement policies.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document. Regarding the Hazard Index, the EPA clarifies that the commenter incorrectly stated that the HBWCs for the four PFAS included with the Hazard Index (PFHxS, PFNA, HFPO-DA, and PFBS) are below their PQLs. All PQLs for these four PFAS are less than one-half of their respective HBWCs.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044400)

Page 18667. Paragraph 2. Measuring PFOA and PFOS results below the PQLs may not be achievable from all laboratories and may not have the same precision as higher-level measurements, nor does EPA believe it is appropriate to make potentially costly compliance decisions based on such lower-level measurements". Nonetheless, the ability to know that PFOA and PFOS may be present within a certain range at these low concentrations (i.e., below the PQLs) can be used to inform decisions for already installed treatment (e.g., a utility can evaluate when break though is most likely to occur or is imminent) and to judge appropriate monitoring frequency".

• Not every laboratory applied to participate in UCMR5. Assuming 1.3 ppt is an achievable target nationwide may not be appropriate. Using an analytical result below the PQL only indicates that PFAS is present. Very little, if anything, is known about the actual concentration of PFAS in this instance. Relying upon low concentrations below the PQL for ongoing monitoring, reduced monitoring or compliance monitoring is not appropriate. Using a trigger level greater than or equal to 2.0 ppt for PFOS and PFOA would be preferred, as well as using 0.5 for the hazard index. This will allow laboratories flexibility, balance variability in the measurement, and allow for reduced monitoring for systems with sample results at or below 50% of the MCL.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044397)

DOH supports using the EPA suggested alternative values of 2.0 ppt for PFOA and PFOS and 0.5 for the HI PFAS as the trigger level. This alternative trigger level is more consistent with trigger levels previously used in EPA's Standardized Monitoring Framework.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Aurora Water, City of Aurora, Colorado (Doc. #1669, SBC-043712)

Monitoring Requirements

Trigger Level Sections VIII and IX

As proposed, the trigger level for monitoring is one-third of the proposed MCLs (1.33 ppt for PFOA and PFOS). The proposal states that labs cannot report values below 4 ppt. This means a value of 1.33 ppt is not reportable and not reliable. It follows that any system below 4 ppt is automatically ineligible for reduced monitoring. If a lab reports numbers below the PQL of 4 ppt, this could present issues with consistent and reliable data reporting. This unfairly disqualifies some water systems from obtaining reduced monitoring if they cannot analyze their samples to the proposed trigger levels. On page 30 of the proposed regulation, when justifying the MCL of 4 ppt for PFOA and PFOS the EPA states that the rigorous laboratory certification procedures "limit the number of laboratories that can achieve lower quantitation levels and many water systems would not be able to secure the services of laboratories that are capable of consistently providing precise and accurate quantitation of concentrations of PFOA and PFOS at levels lower than 4.0 ppt." This EPA statement confirms any measurements below 4.0 ppt are unreliable. Therefore, using a trigger level for monitoring below 4 ppt is unfair for any water systems who are trying to achieve a reduced monitoring schedule.

In summary of statements above, with an MCL of 10 ppt as suggested by Aurora Water, setting a trigger level of 4 ppt would be much more reliable than what is currently proposed and within the PQL level. This would create more reliable data and a reduced monitoring schedule could be reliably determined.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenter that the rule proposal stated that "labs cannot report values below 4 ppt." The EPA proposal did not state this and instead discussed that the PQLs represent the lowest levels at which contaminants can be reliably quantified within specific limits of precision and accuracy during routine laboratory operating conditions using the approved methods; accordingly, the EPA utilized these values in its MCL feasibility determination. However, values below the PQLs may be reported by a laboratory (albeit with lesser precision and accuracy than that for results at higher levels) and used for certain purposes (such as the determination of monitoring frequency and reporting in CCRs).

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-044914)

Cleveland Water has strong concerns with EPA proposing a trigger level below the PQL. As defined in the preamble, the PQL is "the lowest concentration of an analyte that can be reliably measured within specified limits of precision and accuracy during routine laboratory operating conditions." For EPA to consider using values below this would mean using unreliable and potentially inaccurate data to make monitoring decisions. This could lead to costly monitoring requirements at a system that in reality meets safe water standards, but laboratory results do not reflect that due to inaccuracy.

Because of the difficulties mentioned above with a proposed 1/3 MCL trigger level, if EPA moves forward with a 4.0 ppt MCL, Cleveland Water recommends EPA go with the alternate route discussed in the preamble where the trigger level is 50% of the MCL, or 2.0 ppt individually for PFOA and PFOS, and 0.5 for the HI PFAS. Water systems who qualify for reduced monitoring based on RAA's from UCMR 5 will still need to show they are below 2.0 ppt to continue the reduced monitoring schedule. While this would alleviate some of the burdens for PWSs that do receive sample information below 1.3 ppt, the proposed trigger level, Cleveland Water stresses that this level is not readily available to all PWSs, particularly those with less resources and limited budgets.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Association of California Water Agencies (ACWA) (Doc. #1675, SBC-044935)

COMMENT 5 – ALTERNATIVE TRIGGER LEVEL – ACWA supports the alternative trigger levels values but is concerned trigger levels may exacerbate laboratory capacity issues.

EPA is proposing the use of a trigger level for less frequent compliance monitoring under certain circumstances in which systems can demonstrate PFAS concentrations in drinking water are below 1.3 parts per trillion (ppt) for PFOA and PFOS and 0.33 for the Hazard Index PFAS [FN28: 88 Fed. Reg. at 18, 681.]. ACWA supports the flexibility offered by trigger level values including reduced monitoring and allowance of different compliance monitoring schedules at each entry point to the distribution system. These provisions save resources for many water systems. However, we have concerns with the accuracy of testing at levels below the PQL as well as the added burden on laboratory capacity nationwide.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Association of California Water Agencies (ACWA) (Doc. #1675, SBC-044937)

Many laboratories have only shown reliable detection of PFAS compounds down to 2.0 ppt.

Setting any trigger levels below 2.0 ppt would introduce a greater potential for unreliable results and variability which would not be preferred when water systems must make decisions in order to meet new MCL monitoring requirements.

EPA recognizes this issue and poses the alternative trigger levels of 2.0 ppt for PFOA and PFOS and 0.50 for the Hazard Index PFAS [FN31: 88 Fed. Reg. at 18,682]. ACWA supports the alternative trigger level values of 2.0 ppt for PFOA and PFOS and 0.50 for the Hazard Index PFAS, however, we maintain our concerns about the trigger levels impact on laboratory capacities.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

New York City Department of Environmental Protection (NYCDEP) (Doc. #1679, SBC-044213)

Monitoring

In section VIII.A., p. 18681, and section IX. A., p. 18682, EPA proposes to set a monitoring trigger level at 1.3ppt for PFOA and PFOS and 0.33 for HI. This level is about one third of the MRLs stated in the required analytical methods EPA 537.1 and 533 (which range from 3.5-4 ppt depending on chemical). EPA has underestimated the level of noise in the analytical methods at the trigger level. The data quality objective for a trigger level should not be established where the variability of the data is extreme, as it is below the MRL. The definition of the MRL in EPA method 537.1 is stated as having recovery of 50-150%. At 1/3 the MRL, the recovery will be more variable than 50-150% and will include a higher likelihood of both false negatives and false positives. Essentially, EPA is setting a trigger level that is based on random noise, perhaps inclusive of contamination and bias. Increased false negatives contribute to concerns for the primary objectives of the rule. Increased false positives are associated the unnecessary public concern, increased monitoring, and unwarranted treatment changes.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenter that it is "setting a trigger level that is based on random noise." While the agency fully agrees that there is less precision and accuracy in results below the PQL, the EPA maintains that it is appropriate to use these values for the determination of whether water systems should be allowed to monitor less frequently where there is a demonstrated lower risk of PFAS contamination. Such results do not require the same level of precision that should accompany a determination that treatment or other action is needed to reduce PFAS exposure; the latter determination triggers potentially much more costly action and should be based on more precise and reliable analytical measurements as the EPA is implementing in the final rule. Regarding the commenter's concerns on sampling contamination, please see section 8.7 of the EPA response in this *Response to Comments* document.

City of Vancouver Water Utility, Vancouver, WA (Doc. #1684, SBC-044311)

Trigger Level:

Relying upon low concentrations below the PQL for ongoing monitoring, reduced monitoring or compliance monitoring is not appropriate. The proposed regulation will set a trigger level at one-third of the MCL for PFOS and PFOA (1.3 ppt). With a MRL of 2 ppt, how will any utility meet the requirement for reduced sampling? The trigger level should be set at ½ of the MCL and hazard index to allow utilities that are non-detect to reduce sampling frequency and therefore decreasing the burden on water systems and labs.

EPAs use of trigger levels set at 1/3 the PQL increases the estimated cost of sampling while increasing variability in sampling data. Setting the trigger at ½ the PQL would increase the number of laboratories that can meet QA/QC levels bringing down the cost of sampling and provide better data for decision making. Washington supports using the EPA's suggested alternative trigger level of ½ the PQL. Currently laboratories are charging for both the PWS sample, and if there are detections, for testing the field reagent blank, effectively doubling the cost for PWSs with detections. It is unclear if EPA considered this in their cost estimates.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

New Hampshire Department of Environmental Services (NHDES) (Doc. #1690, SBC-044348)

b. Page 18730, Column 2, Bullet 8 - EPA requests comment on monitoring-related flexibilities that should be considered to further reduce burden while also maintaining public health protection including a rule trigger level at different values than the currently proposed values of 1.3 ppt for PFOA and PFOS and 0.33 for the HI PFAS (PFHxS, HFPO–DA, PFNA, and PFBS), specifically alternative values of 2.0 ppt for PFOA and PFOS and 0.50 for the HI PFAS. EPA also requests comment other monitoring flexibilities identified by commenters.

NHDES Comment - NH supports a rule trigger level of ½ the compliance levels (2 ppt for PFOA and PFOS and 0.5 for the HI PFAS). After reaching out to NH accredited laboratories and reviewing their reporting limits, we don't believe these laboratories can confidently report values as low as 1.3 ppt. Setting a reporting limit of 2 ppt will be more feasible for the laboratories and reduce the monitoring burden for more systems, while maintaining public health protection. [Rule Reference: 141.902 (a)(7) – Page 18751, Column 2]

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Philadelphia Water Department (PWD) (Doc. #1709, SBC-045749)

EPA should provide additional clarification and support around compliance and implementation:

13. PWD recommends reducing rule complexity by removing the proposed trigger level

The proposed MCLs for PFOA and PFOS are at, or very close to, laboratories' measurement capability. The application of a trigger level less than the proposed PQLs for PFOA and PFOS creates confusion since measured concentrations greater than the method detection limit but lower than the reporting (or quantitation) limit are only considered estimates by the labs making those measurements. EPA states in this proposed rulemaking that "EPA has sufficient confidence that while measurements below the PQL may be slightly less precise and accurate, they are achievable by individual laboratories…". It is stretching the limits of the analytical technology to base actionable triggers on concentrations that are so low that they are only considered to be estimated concentrations. Additionally, EPA states in section VI.A that it "anticipates there would not be sufficient laboratory capacity if the quantitation level were set at a level below 4.0 ppt". If EPA does not expect there to be sufficient lab capacity for analyzing PFOA and PFOS below the PQL, then it should not be considering setting trigger levels or screening thresholds below these levels as this will have disproportionate negative impacts on underfunded systems and all PWSs.

Establishing the trigger level below the determined PQL will also result in confusion regarding the enforcement of the trigger level between PWSs and primacy agencies. Some primacy agencies, such as PADEP, will not allow PWSs or laboratories to report qualified results that are reported below the MRL. It is unclear in this rulemaking how PWSs should report and qualify these results to primacy agencies in order to assess whether a system is able to move to reduced monitoring. This may result in some states enforcing their current reporting requirements and no system in that state are able to move to reduced monitoring not because they are above the trigger level, but because the primacy agency will not allow them to report results below the MRL. For some primacy agencies, results below the MRL are instructed to be reported as zero. PWD recommends that results below the MRL should be reported as zero.

EPA has previously established a "trigger level" in the LCRR. The proposed trigger level in the LCRR has created a large amount of confusion both for water utilities and the public in how to interpret sample results. As a part of the on-going review of the LCRR and the solicitation for comments related to the development of the LCRI, the EPA is already considering removing the trigger level to "reduce rule complexity" before the compliance date for the LCRR has even passed. PWD recommends that EPA avoid causing similar confusion in this PFAS MCL rulemaking and remove the proposed trigger level altogether. Reduced monitoring should be implemented if a system can reliably demonstrate that results are below the PQL.

In Section IX.A, EPA requests comment on whether alternate values should be used for the trigger level, specifically 2.0 ppt for PFOA and PFOS and 0.50 for the HI PFAS. PWD, as stated above, believes that EPA should remove the trigger level altogether and not rely on results below the PQL.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045900)

3. The trigger levels EPA proposes for the six PFAS cannot be reliably measured

In setting MCL levels EPA must also ensure that the Proposed Rule's trigger levels are also feasible. EPA proposes trigger levels that are one-third of the MCL for PFOA and PFOS (1.3 ppt), while also acknowledging that this is below the practical quantitation limit (PQL). Similarly, EPA proposes a trigger level that is 0.33 for the hazard index for PFHxS, HFPO-DA, PFNA, and PFBS. It is not realistic or feasible to set a national standard where measurement at the required trigger level is not reliably obtainable [FN78: See comments submitted by the PFAS Regulatory Coalition, submitted to the Proposed Rule docket number EPA- HQ-OW-2022-0114, May 31, 2023 which provide the report entitled "Survey Summary of Commercial Drinking Water Analytical Laboratories to Support the Proposed National Primary Drinking Water Maximum Contamination Levels (MCLs) for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonoic Acid (PFOS) and Proposed Hazard Index For Perfluorohexane Sulfonic Acid (PFHxS), Hexafluoropropylene Oxide Dimer Acid (HFPO-DA), Perfluorononanoic Acid (PFNA), and Perfluorobutane Sulfonic Acid (PFBS)."].

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document. Specifically, regarding the Hazard Index, because the PQLs for the four PFAS included with the Hazard Index (PFHxS, PFNA, HFPO-DA, and PFBS) are all less than one-half of their respective HBWCs, there are no analytical limitations.

Protecting Our Water, Environment, and Ratepayers (POWER) (Doc. #1714, SBC-045944)

Because the proposed trigger levels are lower than many of the method LCMRLs or UCMR 5 MRLs, the samples that would induce action under the trigger levels are insufficiently accurate.

Besides the issue with the PQLs, the trigger levels of 1.3ppt for PFOA and PFOS and 0.33 for the HI are unreasonable considering the both the LCMRLs described in Method 533 and 537.1 and the MRLs described in UCMR5. Typically the EPA has set the trigger level at the MRL with the exception of lead. [FN28: HDR, One Water: Exploring Interconnectivity – Safe Drinking Water Act Wall Chart (17th Edition 2022) (https://www.hdrinc.com/sites/default/files/2022-05/hdr-sdwa-wall-chart-2022.pdf)] Even for lead, the trigger level is above the MRL or LCMRL to ensure that the data points are accurate. [FN29: See e.g. trigger level for nitrate is 5mg/L (https://www.epa.gov/sites/default/files/2021-01/documents/wsg_213_nitrate_wsg_11-30-2020_signed_508-compliantfinal.pdf) which is higher than the LCMRL which were between 25 -39 ug/L. (https://pubs.acs.org/doi/pdf/10.1021/es072456n); Method 200.5 Determination of trace Elements in Drinking Water by Axially Viewed Inductively Coupled Plasma – Atomic Emission Spectrometry, Revision 4.2, EPA-600-R-06-115; EPA National Exposure Research Laboratory Office and Research and Development, Cincinnati OH, 45268; https://nepis.epa.gov/Exe/ZyPDF.cgi/P10096US.PDF?Dockey=P10096US.PDF]

Here, both Method 533 and 537.1 have LCMRLs that are above the trigger level, which indicates that samples that could require action are not accurate. Method 533 establishes a LCMRL of 3.4ppt for PFOA and 4.4ppt for PFOS, both of which are above the proposed trigger level. Additionally, the Method 533 LCMRL of just PFHxS, PFNA, or HFPO-DA individually would exceed the trigger level of the Hazard Index independently. Method 537.1 presents similar issues since the LCMRL for PFOS is 2.7 ppt and the LCMRL of just HFPO-DA would exceed the trigger level of the Hazard Index. Therefore, the samples that could trigger action include a high degree of inaccuracy.

Furthermore, the UCMR 5 MRLs for these compounds are higher than the proposed trigger levels. UCMR 5 establishes that the MRLs for PFOA and PFOs are 4.0 ppt. Additionally, the UCMR5 MRL of just PFHxS, PFNA, or HFPO-DA individually would exceed the trigger level of the Hazard Index independently.

Samples that are below the LCMRL and MRL have a known high degree of inaccuracy. Setting the trigger level far below this standard is arbitrary and capricious and will lead to inaccurate results and regulatory requirements unsupported by reliable evidence or sound science.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document. As discussed in this response, the EPA both disagrees that these levels have a "known high degree of inaccuracy" and that setting these trigger levels below the PQLs is "arbitrary and capricious" as the commenter claims. The agency fully agrees that the measurements do have less precision and accuracy than those at or above the PQLs; however, they are sufficiently reliable to indicate the presence of PFAS and thus to support less frequent monitoring where sampling results demonstrate a lower risk of PFAS contamination, which is their intended purpose as previously described in the preamble and this document. Furthermore, the approach of considering measured levels lower than PQLs for determining monitoring frequency is not novel but has been part of the drinking water standards for many years.

Louisville Water Company (Doc. #1720, SBC-043554)

In this same vein, Louisville Water believes that establishing the trigger level below the MRL is problematic because it would rely on J-flagged data. In a sense, the trigger level is a compliance threshold as it affects monitoring frequency and may inform treatment decisions. We believe it is inappropriate to use J-flagged monitoring data for compliance-related requirements and recommend that trigger level be established at the MRL (2 ng/L) or 50% of the PQL.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Thurston Public Utility District (PUD), WA (Doc. #1729, SBC-043590)

Assuming that 1.3 ppt is an achievable target nationwide may not be appropriate or reasonable. Using an analytical result below the PQL only indicates that PFAS is present. Very little, if

anything, is known about the actual concentration of PFAS in this instance. Relying upon low concentrations below the PQL or ongoing monitoring, reduced monitoring or compliance monitoring is not appropriate. Using a trigger level greater than or equal to 2.0 ppt for PFOS and PFOA would be preferred, as well as using 0.5 for the hazard index. This will allow laboratories flexibility, balance variability in the measurement, and allow for reduced monitoring for systems with sample results at or below 50 percent of the MCL.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Clean Air Council, et al. (Doc. #1731, SBC-043883)

EPA also proposes trigger values as a practical uniform stand-in for the 'zero' or 'not detected' designations currently used (which may vary depending on the laboratory conducting the tests) [FN58: For example, in Table 1 of the Pennsylvania PFAS rule, values of zero are followed by the designation "ND," meaning "not detected." 53 Pa.B. 335, Table 1.] The trigger values would be used to identify the presence of a compound in the water tested since detection down to zero is not feasible. As discussed in the proposed regulation, trigger levels will not be used in a quantitative sense or to determine compliance. Rather, their role is to identify systems that can be exempted from the standard monitoring frequency, which would be any system with levels below the trigger value [FN59: 88 Fed. Reg. 18681–82.]. Therefore, although the trigger values are for some compounds below the MDLs, they are reasonable and appropriate.

[Table: see docket ID EPA-HQ-OW-2022-0114-1731]

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Arizona Corporation Commission (ACC) (Doc. #1735, SBC-045188)

RESPONSES TO SPECIFIC EPA QUESTIONS

Monitoring related flexibilities that should be considered to further reduce burden while also maintaining public health protection including a rule trigger level at different values than the currently proposed values of 1.3 ppt for PFOA and PFOS and 0.33 for the Hazard Index (HI) PFAS.

The proposed trigger levels for PFOA and PFOS (1.3 PPT) are set well below the PQL [FN4: Practical Quantitation Limit ("PQL") means the value established as a target value by the EPA that is the lowest concentration of a substance that can be consistently determined within +/- 20 percent of the true concentration by 75 percent of the laboratories tested in a performance evaluation.] (4.0 PPT) threshold. As the trigger level is lower than the PQL, the ACC questions how to reliably determine concentrations below the PQL. The ACC highlights an example where a Class A utility, despite testing for PFAS, could only detect concentrations as low as 1.7 PPT, which is above the trigger level. Therefore, the alert level should be a concentration that can be

consistently detected using currently available detection technology. Alternatively, the EPA could consider an absent/present approach. Under this approach, if a utility's PFAS or PFOA concentration is below the PQL of 4.0 PPT, that system would be considered to have a concentration of 0 and would only need to undergo PFAS testing once or twice at EPTDS [FN5: Entry point to distribution system.] every three years.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045965)

AMWA has strong concerns with EPA proposing a trigger level below the PQL. As defined in the preamble, the PQL is "the lowest concentration of an analyte that can be reliably measured within specified limits of precision and accuracy during routine laboratory operating conditions." For EPA to consider using values below this would mean using unreliable and potentially inaccurate data to make monitoring decisions. This could lead to costly monitoring requirements at a system that in reality meets these conditions, but laboratory results do not reflect that due to inaccuracy.

PWSs may encounter many difficulties acquiring sampling results required by this proposed rule. Several AMWA members currently have contracts with commercial labs that provide information down to 4.0 ppt, or in some instances 2.0 ppt, depending on the contract details and lab. For those labs to provide any more information, many PWSs would have to amend or renegotiate their established contracts, likely adding costs. Labs are also not always willing to provide information they deem unreliable or inaccurate, meaning values below the lab's own PQL may not be available to many water systems. A prominent commercial lab used by many PWSs has told AMWA members that if they are on UCMR 5 contract and want to see results below 4.0 ppt, they would need an entirely separate sampling event due to quality assurance and quality control (QAQC) differences between UCMR 5 methods and regular EPA methods 537.1 and 533. This would require water systems to sample twice and pay twice to still only be able to see results between 2.0 and 4.0 ppt.

Because of the difficulties associated with a proposed 1.3 ppt trigger level, if EPA moves forward with a 4.0 ppt MCL, then AMWA recommends EPA set the trigger level at 50% of the MCL, or 2.0 ppt individually for PFOA and PFOS, and 0.5 for the HI PFAS. Water systems that qualify for reduced monitoring based on RAAs from UCMR 5 will still need to show they are below 2.0 ppt to continue the reduced monitoring schedule. While this would alleviate some of the burdens for PWSs that do receive sample information below 1.3 ppt, the proposed trigger level, the association stresses that this level is not readily available to all PWSs, particularly those with fewer resources and limited budgets.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document. For an explanation and support for the EPA's assumptions that water systems can request additional UCMR 5 data below MRLs from laboratories for use in satisfying

some or all of the NPDWR's initial monitoring requirements and determination of compliance monitoring frequency, please see section 13.3.4 of the EPA response in this *Response to Comments* document.

Washington County Department of Public Health and Environment (Doc. #1739, SBC-043570)

Proposed Trigger Level for Determining Monitoring Schedules

Per Part XIV, Section IX of the rule proposal, in line with MDH, the county supports the alternative trigger values of 2.0 ppt for PFOA and PFOS and 0.50 for the HI PFAS.

• Based on the state's experience with laboratory RLs for EPA Method 533, most laboratories have RLs for PFOA and PFOS above 1.3 ppt. Therefore, setting the trigger level at 1/3 of the MCL will require laboratories to report results below their RLs as qualified "J-flagged" data. This may be an additional burden on laboratories and is not typically done for compliance monitoring.

• If any results below the PQLs will be treated as zero for compliance as proposed in the rule, it is not necessary to increase to quarterly monitoring based on a trigger level that is significantly below the PQL. As an example, if a system has a PFOA detection at 1.4 ppt, then collects quarterly samples with PFOA results of 1.5, 2.0, and 2.5, all of these results would be treated as zero. Increased sampling at this level is not needed for determining compliance unless results below 4 ppt are allowed to be used in the QRAA calculations. As proposed, the rule's trigger level will cause undue burden with regards to sampling, which also increases the laboratory capacity necessary to handle these samples.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

LSP Association (LSPA) (Doc. #1742, SBC-043600)

Slide 21: EPA is requesting comment on establishing the proposed rule trigger levels at 1/3 of the proposed MCLs and on alternative trigger levels such as 1/2 of the proposed MCLs.

• The trigger level of 1.3 ppt for PFOS/PFOA is below typical Reporting Levels for laboratories (which are generally 2 ppt). USEPA indicates that this trigger level is intended to determine presence/absence rather than a specific concentration; however, the trigger is established as a discrete value. It is not scientifically defensible to establish a threshold value well below the practical quantitation limit (PQL) where precision and accuracy cannot be reliably achieved. Typical Acceptance Criteria for PFAS surrogates are 70 to 130%. The LSPA requests that USEPA consider establishing a trigger value that is 70% of the MCL (2.8 ppt for PFOS/PFOA if the MCL is set at 4 ppt), which would provide reasonable certainty that the compound is not present at a concentration exceeding the MCL and is above typical analytical reporting limits.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045225)

4. EPA is also requesting comment on establishing the proposed rule trigger level values of 1.3 ppt for PFOA and PFOS and 0.33 for the PFAS regulated by the HI (PFHxS, HFPO–DA, PFNA, and PFBS). EPA is seeking comment on establishing the trigger level at other levels, specifically alternative values of 2.0 ppt for PFOA and PFOS and 0.50 for the HI PFAS.

CT DPH is seeking clarification on what data can be used to trigger reduced monitoring. Can PWS only use laboratory data where the method reporting limit (MRL) is below the trigger level? If this is the case, very few water systems will be able to qualify for reduced monitoring. As the EPA argues in setting the PQL, the majority of labs cannot reach MRLs below 4 ppt in normal laboratory operation. If any non-detect value from a lab meeting the PQL can be used to trigger the reduced monitoring, this will encourage PWS to seek out laboratories that only report to the PQL or do not report "J" flagged detections. This could lead to backlogs at certain laboratories and PWSs not getting the most complete data.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

West Virginia Rivers Coalition et al. (Doc. #1746, SBC-045258)

[In particular, we strongly support their calls for EPA to:]

• Set the trigger value at the MDL where that value is lower than one-third the MCL

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Las Cruces Utilities (LCU) (Doc. #1753, SBC-043907)

In response to Section IX-Monitoring and Compliance Requirements, EPA requests comment on monitoring-related flexibilities that should be considered to further reduce burden while also maintaining public health protection including a rule trigger level at different values than the currently proposed values of 1.3 ppt for PFOA and PFOS and 0.33 for the HI PFAS (PFHxS, HFPO–DA, PFNA, and PFBS), specifically alternative values of 2.0 ppt for PFOA and PFOS and 0.50 for the HI PFAS. EPA also requests comment other monitoring flexibilities identified by commenters.

• LCU recommends a rule trigger level of 2.0 ppt. Hall Environmental Analysis Laboratory (the State approved laboratory, located in Albuquerque, NM) standard limits for method 537.1 are 2.0 ppt. Until laboratories have developed the methodology to detect PFAS to less 1.3 ppt, then this rule trigger level is impossible to implement.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

El Paso Water (Doc. #1757, SBC-044521)

Heightened testing and treatment could increase costs with questionable benefits for ratepayers

The requirement for a PWS to conduct testing beyond the current trigger levels raises concerns for the utility as it will mandate testing at a level the does not produce reliable or at times even readable results. The reduction in the trigger for testing from 4 ppt to 2 ppt could force utilities to double their testing costs while receiving test results that are not reliable due to the small amount of testable material.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

El Paso Water (Doc. #1757, SBC-044524)

The EPA should revise the testing requirement trigger to remain at the current level unless PFAS has already been detected at current levels, in which case, certain PWSs should be required to do further investigation to understand the extent or scale of the problem. For utilities that have had no or negligible detection, the cost is an undue burden on the PWS and ratepayers.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document. Please see section 8.1.2 of the EPA response in this *Response to Comments* document regarding compliance monitoring requirements.

California State Water Resources Control Board (Doc. #1760, SBC-044223)

[The State Water Board offers the following specific comments and recommendations for consideration regarding implementation of the rule:]

Recommend that EPA change the trigger levels to one-half the MCLs for determining compliance monitoring frequency. Setting the trigger levels at one-half (instead of one-third) of the MCLs would alleviate confusion regarding using the 1.3 parts per trillion for PFOA and PFOS, which some may incorrectly assume means laboratories can accurately test to that level. This change would also improve laboratory capacity by allowing more states to use previously collected data for determining reduced monitoring. Also, we believe that a one-half trigger level is appropriate for MCLs that are being set at the parts per trillion level.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

PFAS Regulatory Coalition (Doc. #1761, SBC-046076)

2. It is not appropriate to set trigger levels below the PQL.

The Proposal suggests trigger levels at 1/3 the MCLs, which equates to 1.3 ppt for PFOA/PFOS and a 0.3 HI. EPA should not set trigger levels below what can be accurately measured.

In the Proposal, EPA itself recognizes the challenges of finding laboratories that can provide accurate quantitation below 4 ppt: "EPA anticipates there would not be sufficient laboratory capacity if the quantitation level were set at a level below 4.0 ppt. The rigorous laboratory certification and quality assurance/quality control (QA/QC) procedures could limit the number of laboratories that can achieve lower quantitation levels and many water systems would not be able to secure the services of laboratories that are capable of consistently providing precise and accurate quantitation of concentrations of PFOA and PFOS at levels lower than 4.0 ppt." 88 Fed. Reg. 18667.

In our members' experiences, laboratories do not routinely report data below the PQL. If a laboratory does report this date in response to a client's request, the data is typically qualified as "estimated." Estimated values should not be used for regulatory reporting due to the high levels of uncertainty when reporting below the PQL. In addition, when calibrating analytical instrumentation, most laboratories use their PQL as the lowest calibration standard. Therefore, any reported values below the PQL are outside the laboratory's calibration range. Again, this introduces significant uncertainty into the reliability of these results. In fact, Coalition members have received false positive results from laboratories.

There is no logical reason that EPA should allow a lesser level of confidence for trigger levels than it does for MCLs. Incorporating data with inherently lower levels of accuracy also further complicates risk communication. Given the additional regulatory obligations for monitoring and compliance that would apply if sampling results are above the trigger level, values below the PQL should not be used.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Western Urban Water Coalition (WUWC) (Doc. #1768, SBC-043953)

C. Less Restrictive Trigger Values are Warranted

WUWC supports setting rule triggers at more lenient values of 2.0 ppt for PFOA and PFOS and 0.50 for the HI PFAS, consistent with EPA's request for comments on alternative values. [FN43: d. at 18730.] In WUWC members' experience, trigger values of 2.0 ppt and 0.50 ppt would fall in line with laboratories' current calibration limits for measuring PFAS constituents. WUWC agrees that adopting these more lenient trigger values would potentially result in reduced burdens to water utilities in the form of less frequent reporting. Similar to other comments above,

WUWC reiterates its view that partially mitigating the administrative burdens resulting from the Proposed Rule is insufficient to demonstrate that the Proposed Rule is economically feasible.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document. Regarding the EPA's economic analysis and cost-benefit determination of the final rule, please see section 13.8 of the EPA response in this *Response to Comments* document.

California-Nevada Section American Water Works Association (CA-NV AWWA) (Doc. #1775, SBC-045274)

5. EPA's proposed trigger level criteria below the PQL to calculate compliance or qualify for reduced monitoring is incoherent and impracticable. The trigger level for reduced monitoring should not be set below the PQL.

EPA defines the PQL (a more appropriate term should be the "Minimum Reporting Level" or MRL – see comment #3 above, with footnote) as the lowest concentration of PFOA and PFOS that can be reliably quantified in drinking water within specified limits of precision and accuracy during routine laboratory operating conditions. EPA has also determined a PQL at 4.0 ppt, each, for PFOA and PFOS, to be appropriate in this proposed rulemaking. These levels were derived from laboratory participation in establishing UCMR 5 minimum reporting levels (MRLs) for EPA methods 531.7 and 533. EPA then proposes using values based on 1/3 of the PQLs as "trigger levels" for determination of either more or less frequent compliance monitoring, depending on routine monitoring results. EPA also proposes to use trigger levels of 1.3 ppt, each, for PFOA and PFOS or a HI of 0.33 for PFNA, PFHxS, PFPO-DA, and PFBS, instead of zero, for calculating annual averages and compliance determination. However, EPA explains that the MCL for PFOA and PFOS should be 4.0 ppt because "this is the lowest concentration that PFOA and PFOS can be reliably quantified within specific limits of precision and accuracy during routine laboratory operating conditions." Therefore, if current analytical methods cannot reliably quantify at the proposed trigger levels, such as 1.3 ppt for PFOA and PFOS, as supported by EPA's reasoning for setting the MCL at 4.0 ppt, it does not make sense to require trigger levels below the levels that can be reliably quantified. Setting the trigger levels below the PQLs may lead to false positives and excessive, unnecessary monitoring and reporting, which will create confusion and diminish public confidence.

EPA also proposes trigger levels for less frequent compliance monitoring under certain circumstances in which systems can demonstrate PFAS concentrations in drinking water are below 1.3 ppt for PFOA and PFOS and 0.33 for the Hazard Index PFAS. EPA states that lower monitoring levels "are achievable by individual laboratories, and therefore lower levels can be used for purposes of screening and to determine compliance monitoring frequency." As explained above, use of the proposed trigger levels is arbitrary, and it is inappropriate to base compliance on theoretical measurements. Moreover, this approach is overly conservative and not likely to provide significantly better health protection benefits over the proposed conservative trace level MCLs.

Achieving reliable values lower than the PQL may require laboratories to upgrade their equipment and technology at significant cost and cause additional strain on already limited laboratory capacity to handle all the testing demand. Given the challenges with reliably achieving precise and accurate monitoring results at levels below the PQL, establishing the levels to qualify for reduced monitoring far below the PQL, and below the MRLs will make it challenging for systems to qualify for the reduction in monitoring frequency and potential relief from the associated costs. CA-NV AWWA requests EPA consider establishing trigger levels for reduced monitoring no lower than the PQL.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Metropolitan Water District of Southern California (Doc. #1777, SBC-045431)

3. Current analytical methods cannot reliably quantify PFOA and PFOS at the proposed trigger level of 1.3 parts per trillion (ppt)

EPA proposes using practical quantitation limits for the six PFAS of between 3.0 to 5.0 ppt, and to use values based on 1/3 of the MCL for trigger levels. The trigger levels would be 1.3 ppt, each, for PFOA and PFOS, or a Hazard Index of 0.33 for PFNA, PFHxS, PFPO-DA, and PFBS, and could be used by primacy agencies to reduce the monitoring frequency if monitoring results are below the trigger level. However, EPA explains that the MCL for PFOA and PFOS should be 4.0 ppt because "this is the lowest concentration that PFOA and PFOS can be reliably quantified within specific limits of precision and accuracy during routine laboratory operating conditions."[FN11: 88 Fed. Reg. at 18666.] Current analytical methods cannot reliably quantify at the proposed trigger level of 1.3 ppt for PFOA and PFOS, as supported by EPA's reasoning for setting the MCL at 4.0 ppt, because PFOA and PFOS cannot be "reliably quantified" at 1.3 ppt. In the absence of a reliable analytical method, setting the trigger level at 1.3 ppt may lead to false positives.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Uttara Jhaveri (Doc. #1778, SBC-045441)

The EPA also recommends a proposed "trigger level" for PFOA or PFOS. [FN9: Environmental Protection Agency, supra note 4.] Water utilities may use the proposed trigger level as a "warning that they may be nearing the PFOA and PFOS MCLs of 4.0 ppt prior to exceeding them" and can make informed treatment decisions about managing their systems. [FN10: Id.] The trigger levels are an interesting addition to the regulations and may be beneficial to guide the utilities to adjust their technology and filtration systems when they hit the trigger level. The warning would help utilities adapt their systems and reduce the risk of exceeding the proposed limit of PFAS in drinking water.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

San Diego County Water Authority, CA (Doc. #1779, SBC-045288)

Trigger Values

EPA has proposed trigger levels as a basis to reduce monitoring frequency for large public water systems. EPA is requesting comment on setting trigger levels at 1/3 of the proposed maximum contaminant level s(MCLs) and on alternatives such as 1/2 of the proposed MCLs. Of the two proposed alternatives, we request EPA set trigger levels no lower than 1/2 Proposed MCLs. However, we are concerned that setting trigger levels below minimum reporting levels would introduce additional inaccuracy in measurements and provide inconsistency between laboratories. EPA set the proposed MCLs for the six PFAS using Practical Quantitation Levels (PQLs), which are already the lowest concentrations that can be reliably achieved within specified limits of precision and accuracy during the routine laboratory operating conditions.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

City of Tulsa Water and Sewer Department (CoT WSD) (Doc. #1785, SBC-043783)

5. 88 FR 18681-18682 (also 88 FR 18731). EPA requests comment on proposed trigger level values of 1.3 ppt for PFOA and PFOS and 0.33 for the PFAS regulated by the HI (PFHxS, HFPO–DA, PFNA, and PFBS), and if systems will be able to demonstrate they are reliably and consistently below 1.3 ppt for PFOA and PFOS and 0.33 ppt for PFAS regulated by the HI in order to qualify for reduced monitoring.

CoT WSD responds that there should be more reservation by EPA in utilizing analytical measurements below PQLs, which are the lowest level of reliable, quantifiable measurement of an analytical method. EPA admits multiple times within the preamble that these measurements are less precise and less accurate, even stating that it doesn't believe "it is appropriate to make potentially costly compliance decisions" based on these measurements; however, those are exactly the decisions that will be made using these measurements as trigger levels. Media replacement and other operational decisions, as well as monitoring frequency are set to be determined by these non-quantifiable measurements. EPA should look at setting MCLs at one of the alternative higher levels to allow trigger levels to be within the quantifiable limits of the analytical method.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document. Regarding the EPA's MCL determinations, please see sections 5.1 and 5.2 of the EPA response in this *Response to Comments* document.

Safe Drinking Water Branch, Hawaii Department of Hawaii (Doc. #1801, SBC-043755)

The Trigger Level of the Quarterly Monitoring

As PQL of PFSA compounds is 3.0 to 5.0 ppt, the 1.3 ppt ppt (for PFOS and PFOA) of trigger-level is lower than PQL which indicates it cannot be reliably achieved during the routine laboratory operating conditions. It is a potential loophole and an invitation of lawsuits. EPA should consider increasing the trigger-level to 2 ppt which major labs can achieve as the minimum report level.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Palm Beach County Water Utilities Department (Doc. #1802, SBC-045334)

May 29, 2023

RE: Palm Beach County Water Utilities Department On-Line Submission of Comments Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

Docket: EPA-HQ-OW-2022-0114-0027

Federal Register, March 29, 2023 (88 FR 18638) (FRL-8543-01-OW) Start End Page: 18638-18754 https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0027

Dear EPA

Palm Beach County Water Utilities Department (PBCWUD) appreciates this opportunity to submit comments pertaining to the proposed EPA Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation. This rule is important for the protection of our water supply. There are several components of the proposed rule for which we respectively submit the following comments:

Page 18667, VI.A. First column first full paragraph," .... Method 537.1 ":

PBCWUD Comment: Laboratory results reported by the approved methods like EPA 537.1, are considered estimated between the MDL and PQL and are qualified appropriately; some labs will not be able to achieve reliable data less than the PQL. This would pose a problem with the criteria to achieve reduced monitoring where the results have to be <1.3 ppt or 1/3 MCL.

Page 18667, VI.A. Second column first full paragraph," in the case where PFAS are detected but below their proposed PQLs…":

PBCWUD Comment: Method 537.1 laboratory results are estimated between the MDL and PQL; so many labs will not be able to achieve reliable data. This would interfere with reduced monitoring where the results have to be <1.3 ppt or 1/3 MCL.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046120)

Finally, as discussed above, EPA's proposal to allow reduced monitoring based on PFAS detections below the trigger values, which in some cases are substantially below the relevant PQL, is inconsistent with EPA's proposal to zero-out all detections below the PQL for purposes of demonstrating MCL compliance. This approach is also inconsistent with EPA's assertion that detections "at the proposed rule trigger level" are "primarily useful in determining whether the contaminant is present in a sample . . . rather than to determine its specific concentration." [FN212: Proposed Rule, 88 Fed. Reg. at 18,681–82.]

To address these issues, EPA should modify its proposal to (1) set the trigger value at the MDL where that value is lower than one-third of the MCL, and (2) provide that systems with four consecutive quarters of non-detects for the 6 PFAS may reduce to annual monitoring. Lowering the trigger value would better align the proposal with EPA's Standardized Monitoring Framework for Synthetic Organic Compounds [FN213: See 40 C.F.R. § 141.24(f)(11)(i) (requiring quarterly monitoring for organic contaminants detected above 0.0005 mg/L).] as well as monitoring requirements in state- level PFAS MCLs. [FN214: See N.J. Admin. Code § 7:10-5.2(a)(5)(i)(2), (ii)(2) (requiring quarterly monitoring for PFOA, PFOS, and PFNS when detected above 0.002 ppt); N.Y. Comp. Codes R. & Regs. tit. 10 § 5-1.52 (establishing MDL as trigger value for reduced PFAS monitoring).] Allowing annual, instead of triennial, monitoring for PWSs with consistent detections below the trigger value also would align the federal requirements with existing requirements in multiple states. [FN215: See N.J. Admin. Code § 7:10-5.2(a)(5)(ii)(3), (iii)(3); N.Y. Comp. Codes R. & Regs. tit. 10 § 5-1.52; Mich. Admin. Code R 325.10717d(9), (11).]

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document. Regarding compliance monitoring requirements, please see section 8.1.2 of the EPA response in this *Response to Comments* document. The EPA has added a tier of annual monitoring in the final rule in response to public comments.

Citizens Energy Group (Doc. #1838, SBC-044861)

EPA requests comment on monitoring-related flexibilities that should be considered to further reduce burden while also maintaining public health protection including a rule trigger level at different values than the currently proposed values of 1.3 ppt for PFOA and PFOS and 0.33 for the HI PFAS (PFHxS, HFPO-DA, PFNA, and PFBS), specifically alternative values of 2.0 ppt for PFOA and PFOS and 0.50 for the HI PFAS. EPA also requests comment other monitoring flexibilities identified by commenters.

Citizens appreciates EPA's consideration of monitoring-related flexibilities, including those that can reduce the regulatory burden for communities where PFAS contamination does not originate

as a result of historical manufacturing, but rather in low levels (at or near detection limits, for example) as a result of the ubiquitous nature of PFAS in the environment.

Given the detection limits of the analytical methods, Citizens also encourages EPA to adopt the proposed alternative values in the rule trigger level to reduce the monitoring obligations. These alternative values do not compromise public safety, but rather give water systems the flexibility to leverage analytical results that fall in the range between the method detection limit (MDL) and the practical quantitation limit (PQL) – "J-flagged" data – to reduce the burdens associated with this rule, while at the same time ensuring that public health is safe- guarded.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Arcadis (Doc. #3072-17, SBC-047368)

And the second one is, I'm a little confused with the proposed trigger level. If the laboratories are able to measure precisely and accurately at 4 parts per trillion or more, how come the same laboratory can measure concentrations less than 4 parts per trillion with the same confidence level? I heard one of the speakers earlier explain but the language in the current docket is confusing, but what the speaker mentioned earlier was quite clear. So, I would request EPA clarify that better in the revised edition. That's all I have. Thank you very much.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Suffolk County Water Authority (SCWA) (Doc. #1589, SBC-043369)

4. Use of Trigger Levels Below Practical Quantitation Levels Will Add Unreliabilty to Implementation of Regulation

The SCWA's drinking water laboratory has been analyzing PFAS for several years, and it has established a New York minimum reporting level of 2 ppt for each of the PFAS proposed for EPA regulation. SCWA's minimum reporting level is likely what EPA would consider its practical quantitation level (PQL). With proposed MCLs for PFOA and PFOS of 4.0 ppt, the SCWA would be supportive of trigger levels of 1/2 of these proposed MCLs because they are within the PQL of the SCWA's laboratory. SCWA would have concerns about a trigger level set at 1/3 of the proposed MCLs for PFOA and PFOS because it would be below SCWA PQLs and therefore unreliable.

Since the SCWA's 2 ppt PQL for the other four PFAS are less than 1/3 of the HBWCs that would make up the proposed health index based MCL, SCWA would be supportive of either a 1/3 or 1/2 of the proposed MCL for these PFAS. However, as set forth above, SCWA would prefer contaminant specific MCLs and MCLGs for these four PFAS over a health index.

Notwithstanding the foregoing, it may be imprudent to set trigger levels below PQLs. A PQL is defined as the "lowest concentration of an analyte that can be reliably measured within specified limits of precision and accuracy during routine laboratory operating conditions." The basis for setting PQLs includes quantitation, precision and accuracy. Because the proposed PQLs for PFOA and PFOS are the same as the proposed MCLs, the proposed trigger levels will necessarily be unreliable. The same could be true if trigger levels are set at 1/3 of the MCL for PFNA and GenX Chemicals under the proposed PQLs for those chemicals depending upon the levels of other PFAS proposed for the health index.

This issue can be resolved by utilizing a 1/2 MCL trigger level and either raising proposed MCLs for PFOA and PFOS or by lowering their respective PQLs. Since EPA is required to set the MCL as close as feasible to the MCLG, perhaps the best course of action would be to lower the proposed PQLs for PFOA and PFOS accordingly.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document. Regarding the MCL determination for PFOA and PFOS, please see section 5.1 of the EPA response in this *Response to Comments* document. For discussion of the Hazard Index MCL and contaminant specific MCLs and MCLGs for the four Hazard Index PFAS, please see sections 5.2 and 5.3 of the EPA response in this *Response to Comments* document.

Minnesota Department of Health (MDH) (Doc. #1610, SBC-042855)

Proposed Trigger Level for Determining Monitoring Schedules

Per Part XIV, Section IX of the rule proposal:

"EPA requests comment on monitoring-related flexibilities that should be considered to further reduce burden while also maintaining public health protection including a rule trigger level at different values than the currently proposed values of 1.3 ppt for PFOA and PFOS and 0.33 for the HI PFAS (PFHxS, HFPO-DA, PFNA, and PFBS), specifically alternative values of 2.0 ppt for PFOA and PFOS and 0.50 for the HI PFAS."

MDH Comments

· MDH supports the alternative trigger values of 2.0 ppt for PFOA and PFOS and 0.50 for the HI PFAS.

o Based on our experience with laboratory RLs for EPA Method 533, most laboratories have RLs for PFOA and PFOS above 1.3 ppt. Therefore, setting the trigger level at 1/3 of the MCL will require laboratories to report results below their RLs as qualified "J-flagged" data. This may be an additional burden on laboratories and is not typically done for compliance monitoring.

o If any results below the PQLs will be treated as zero for compliance as proposed in the rule, it is not necessary to increase to quarterly monitoring based on a trigger level that is significantly below the PQL. As an example, if a system has a PFOA detection at 1.4 ppt, then collects quarterly samples with PFOA results of 1.5, 2.0, and 2.5, all of these results would be treated as

zero. Increased sampling at this level is not needed for determining compliance unless results below 4 ppt are allowed to be used in the QRAA calculations. As proposed, the rule's trigger level will cause undue burden with regards to sampling, which also increases the laboratory capacity necessary to handle these samples.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

American Council of Independent Laboratories (ACIL) (Doc. #1692, SBC-044740)

The trigger level is set at 1/3 the minimum reporting level, and exceedance above this trigger levels results in increased monitoring requirements for drinking water utilities, which has significant financial implications for the utilities. The EPA discusses this issue at length in section VI and states on page 18667:

"Therefore, for almost all laboratories, the proposed PQLs for PFOA and PFOS of 4.0 ppt are at least 4 times greater than the lowest calibration standard. This suggests the overwhelming majority of laboratories with the necessary instrumentation to support PFAS monitoring have the capability to provide screening measurement results above the proposed trigger level of 1⁄3 of the MCL (i.e., 1.3 ppt for PFOS or PFOS). Hence, a utility may use the lower-level measurements as a warning that they may be nearing the PFOA and PFOS MCLs of 4.0 ppt prior to exceeding them and can make informed treatment decisions about managing their systems (e.g., replacing GAC)"

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document. The final rule approach to monitoring frequency provides prudent information that the water systems can and should use to inform optimal drinking water treatment operations.

Wisconsin Department of Natural Resources (Doc. #1828, SBC-044804)

Trigger Level

WDNR recommends that EPA change the compliance monitoring frequency trigger level for PFOA and PFOS to be half the proposed Maximum Contaminant Level (MCL) (2.0 ppt). The one third trigger level (1.3 ppt) is not readily achievable by laboratory analysis and does not match the standard monitoring framework for synthetic organic compounds.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Travis Voorhees (Doc. #2928, SBC-046531)

Good morning. I would like to submit a couple comments regarding the trigger levels (IX. Monitoring and Compliance Requirements):

I believe that increasing the number of trigger level exceedances before being required to return to regular monitoring frequency from one (1) to three (3), would be more indicative of a PFAS presence/trend. There are many variables that could cause a single detection/trigger level exceedance, including contamination by the samplers. Multiple exceedances would significantly increase confidence that there was a presence and something to be further investigated.

Additionally, I believe increasing the trigger level to at least one half the PQL would be logical, especially given that the EPA has acknowledged on multiple occasions that detections under the PQL may not be reliable/accurate.

Thank you for the opportunity to comment, really appreciate it.

Respectfully,

Travis Voorhees

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document. Regarding compliance monitoring requirements, please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Environmental Monitoring Coalition (EMC) (Doc. #1625, SBC-043110)

Based on customer specifications, laboratories typically have two different ways of reporting results. The first option is to report any result below the MRL not detected as Not Detected. The other option is to report any result between the MDL and MRL as an estimated value. (Note: Method 533 does not have published MDLs.) This issue is further complicated by a requirement in the methods that blanks do not contain concentrations of any PFAS compounds above 1/3 the MRL. The proposed trigger levels create a third option, and as summarized in the table below, EMC seeks clarity on how laboratories should report data.

Table 2. Reporting Options for Laboratories

[Table 2: See Docket ID EPA-HQ-OW-2022-0114-1625]

As discussed above, the language is confusing. Option 1 is typically how drinking water results are reported but does not meet the Agency's goal of screening for concentrations below the MCL. Option 2 is how laboratories typically report results for other EPA programs. Option 3 would significantly change how laboratories report data and may represent a challenge for some laboratories' Laboratory Information Management Systems (LIMS). Option 4 would be an acceptable alternative to Option 2 as EPA indicated 48 of 53 laboratories can quantitate to this level. Option 5 may present similar problems to Option 3. Option 6 is also possible. There is a possible Option 7 relative to blanks being < 1/3 the MRL which would also create LIMS issues, but the EMC believes blank contamination is a Quality Control (QC) issue and not a reporting issue.

All of these options are possible, and EPA should provide clear, consistent requirements and guidelines to achieve those requirements.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Association of Public Health Laboratories (APHL) (Doc. #1646, SBC-043314)

Based on customer specifications, laboratories typically have two different ways of reporting results. The first option is to report any result below the MRL not detected as Not Detected. The other option is to report any result between the MDL and MRL as an estimated value. (Note: Method 533 does not have published MDLs.) This issue is further complicated by a requirement in the methods that blanks do not contain concentrations of any PFAS compounds above 1/3 the MRL. The proposed trigger levels create a third option, and as summarized in the table below, EMC seeks clarity on how laboratories should report data.

Table 2. Reporting Options for Laboratories

[Table 2: See Docket ID: EPA-HQ-OW-2022-0114-1646]

As discussed above, the language is confusing. Option 1 is typically how drinking water results are reported but does not meet the Agency's goal of screening for concentrations below the MCL. Option 2 is how laboratories typically report results for other EPA programs. Option 3 would significantly change how laboratories report data and may represent a challenge for some laboratories' Laboratory Information Management Systems (LIMS). Option 4 would be an acceptable alternative to Option 2 as EPA indicated 48 of 53 laboratories can quantitate to this level. Option 5 may present similar problems to Option 3. Option 6 is also possible. There is a possible Option 7 relative to blanks being < 1/3 the MRL which would also create LIMS issues, but the EMC believes blank contamination is a Quality Control (QC) issue and not a reporting issue.

All of these options are possible, and EPA should provide clear, consistent requirements and guidelines to achieve those requirements.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045154)

§ 141.902(a)(9) requires reporting of detections at or above 1/3 the PQL, which by definition is below the concentration that can be confidently quantified. Estimated concentrations should not be used to establish the compliance monitoring frequency or to trigger quarterly monitoring under § 141.902(b)(2)(ii) and § 141.903(d).

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document. The referenced requirement has been updated in the final rule. This item,

now listed as § 141.902(a)(7) instead of § 141.902(a)(9), requires that, "For purposes of this section, each water system must ensure that all results provided by a laboratory are reported to the State and used for determining the required sampling frequencies. This includes values below the practical quantitation levels defined in § 141.903(f)(1)(iv); zero must not be used in place of reported values." See also section 8.1.2 for a discussion of the use of data below PQLs for establishing monitoring frequencies. Please see section 8.2 of the EPA response in this *Response to Comments* document regarding the use of values below PQLs in compliance calculations.

San Antonio Water System (SAWS) (Doc. #1570, SBC-042477)

The cost and effort that will be required for data that is below nationally established precision is substantial. EPA should not consider any limits below a PQL.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document. Regarding the use of levels below the PQLs in the compliance calculation determination, please see section 8.2 of the EPA response in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043090)

It is recommended that EPA eliminate the use of analytical results below the PQL and instead use zero ppt for all analytical results below the PQL. Additionally, Aqua recommends that one-half the MCL be used to determine if PFAS levels at an entry point are reliably below the MCL.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document. For compliance monitoring requirements, including the determination of reliably and consistently below the MCL under this rule, please see section 8.1.2 of the EPA response in this *Response to Comments* document. For discussion of using values below the PQLs in RAA compliance calculations, please see section 8.2 of the EPA response in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043117)

However, the proposed approach to use reporting results below the PQL is inappropriate and will cause equity issues with respect to access to high quality laboratories. This will lead systems with less financial capacity to have more stringent monitoring requirements. EPA should move forward with the SMF, where all results below the PQL are considered 0 ppt.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document. Additionally, regarding compliance monitoring requirements, please see section 8.1.2 of the EPA response in this *Response to Comments* document. For discussion of using values below the PQLs in RAA compliance calculations, please see section 8.2 of the EPA response in this *Response to Comments* document. Please see also section 5.1.2 of the EPA

response in this *Response to Comments* document for a discussion of laboratory capability and capacity.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043101)

However, the use of reporting results below the PQL is inappropriate as it requires water systems to rely on unreliable data to determine monitoring requirements as part of the regulatory requirements. As a result of this requirement, to minimize the risk of inaccurate results triggering quarterly monitoring, water systems will be driven to pay higher monitoring costs to have access to laboratories with the ability to reliably achieve reporting results below the PQL.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document. Additionally, regarding compliance monitoring requirements, please see section 8.1.2 of the EPA response in this *Response to Comments* document. For discussion of using values below the PQLs in running annual average compliance calculations, please see section 8.2 of the EPA response in this *Response to Comments* document. Please see section 5.1.2 of the EPA response in this *Response to Comments* document for a discussion of laboratory capability and capacity.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044035)

17. EPA requests comment on monitoring-related flexibilities that should be considered to further reduce burden while also maintaining public health protection including a rule trigger level at different values than the currently proposed values of 1.3 ppt for PFOA and PFOS and 0.33 for the HI PFAS (PFHxS, HFPO- DA, PFNA, and PFBS), specifically alternative values of 2.0 ppt for PFOA and PFOS and 0.50 for the HI PFAS. EPA also requests comment on other monitoring flexibilities identified by commenters.

a. The trigger values should be set to 4.0 ppt, 1/2 the MCL of 8.0 ppt. Values below 4.0 ppt could present issues with consistent and reliable data reporting, and may not be precise or accurate. The HI trigger level should be raised to 0.5. Data review of concentrations below the MRL begin to shift towards qualitative and results below these levels can be suspect and unreliable. Values below the reportable limit should not be used for compliance.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document. For a discussion regarding treating values below the PQL as zero in RAA compliance calculations, please see section 8.2 of the EPA response in this *Response to Comments* document. For discussions of the MCLs, see section 5 of this document, including section 5.1.2 where the MCLs and PQLs for PFOA and PFOS are discussed.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043087)

In review of the Proposal, however, there are significant concerns surrounding the proposed approach requiring water systems to consider low quality, unreliable analytical results below the

PQL. Specifically, the EPA is proposing that 1.3 ppt PFOA and PFOS and one-third of the hazard index be used as a trigger level for reporting for the purposes of determining reduced monitoring eligibility under the SMF. The EPA also requested input on the use of 2.0 and one-half the hazard index.

Aqua believes the use of any data below the PQL to drive regulatory requirements, is unacceptable and scientifically inappropriate. The PQLs for PFOA and PFOS are set at 4.0 ppt each in the Proposal, which is consistent with the currently active UCMR 5 monitoring program's minimum reporting limits. In finalizing the UCMR 5 monitoring program in 2021, the EPA recognized that while EPA Methods 533 and 537.1 can both be used by laboratories to achieve lower reporting limits but concluded that the available lab capacity could not support establishing lower reporting limits to collect national occurrence data. Data below this level is less accurate and is not achievable by all water systems.

As a matter of policy, it is not recommended for EPA to set a precedent to use results that are not nationally achievable for all water systems as this would create an equity issue.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document. For discussion of compliance monitoring requirements, please see section 8.1.2 of the EPA response in this *Response to Comments* document. Regarding laboratory capability and capacity, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Texas Commission on Environmental Quality (TCEQ) (Doc. #1632, SBC-044126)

Practical Quantitation Limits (PQL)

Data below the PQL is only an estimation and this data should not be used to determine reduced monitoring frequency. EPA has defined the PQL as the "lowest concentration of an analyte that can be reliably measured within specified limits of precision and accuracy during routine laboratory operating conditions."

Due to the uncertainty and estimated values below the PQL, use of this data to determine monitoring frequencies will create doubt in the reliability of data used to make compliance decisions. As required by accreditation quality standards, results on laboratory analytical reports will specify the result is an estimate. For all chemical analytes, TCEQ requires reporting the PQL and the determined result, as well as reporting that the reported result is below the laboratory's PQL. TCEQ views all results below the PQL as a non-detection when determining compliance. When calculating a public water system's running annual average, if non-qualified data below 4.0 parts per trillion is included in the calculation—rather than included as a "zero"—it could result in the system not meeting the "reliably and consistently below the MCL" requirement to be considered in compliance. To be consistent with other NPDWR standards, TCEQ recommends that PFAS data below the PQL be reported as a non-quantifiable detection and have a compliance value of "zero."

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document. Regarding compliance monitoring requirements and frequencies, please see section 8.1.2 of the EPA response in this *Response to Comments* document. For a discussion regarding treating values below the PQL as zero in RAA compliance calculations, please see section 8.2 of the EPA response in this *Response to Comments* document. For further discussion of PQLs, please see section 7.2 of the EPA response in this *Response to Comments* document.

Santa Clara Valley Water District (Valley Water) (Doc. #1664, SBC-043128)

Comment 4 – The Proposed Trigger Level Criteria to Qualify for Reduced Monitoring Will be Challenging for Laboratories to Achieve

EPA is proposing a "trigger level" for less frequent compliance monitoring under certain circumstances in which systems can demonstrate PFAS concentrations in drinking water are below 1.3 parts per trillion (ppt) for PFOA and PFOS and 0.33 for the Hazard Index PFAS. EPA states that lower monitoring levels "are achievable by individual laboratories, and therefore lower levels can be used for purposes of screening and to determine compliance monitoring frequency."

The Practical Quantitation Level (PQL) is defined as the lowest concentration of an analyte that can be reliably measured within specified limits of precision and accuracy during routine laboratory operating conditions. EPA has determined that establishing a PQL at 4.0 ppt for PFOA & PFOS is appropriate in this proposed rulemaking. This PQL was derived from laboratory participation in establishing UCMR 5 method reporting limits (MRLs) using EPA Methods 537.1 and 533. Achieving lower values than the PQL is a technological challenge and requires laboratories to make significant financial and other resource investments to upgrade their analytical equipment.

Given the challenges with reliably achieving precise and accurate results at levels below the PQL, establishing the levels to qualify for reduced monitoring far below the PQL, and below the MRLs will make it challenging for systems to qualify for the reduction in monitoring frequency and potential relief from the associated costs. Valley Water requests EPA consider establishing trigger levels for reduced monitoring at the PQL.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document. Regarding compliance monitoring requirements and frequency, please see section 8.2.1 of the EPA response in this *Response to Comments* document.

Clean Air Council, et al. (Doc. #1731, SBC-043860)

c. Laboratory detection methods can accurately measure the regulated PFAS species at the proposed PQL, MCLs, and HBWCs, and the proposed trigger levels are appropriate.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045625)

Use of Standard Monitoring Framework

The proposed approach to use the SMF as a basis for triggering reduced monitoring is appropriate. In review of the proposal, however, AWWA has significant concerns surrounding the proposed approach to require water systems to consider low quality, unreliable analytical results below the PQL. Specifically, the EPA is proposing that 1.3 ppt PFOA and PFOS and one-third of the hazard index be used as a trigger level for reporting for the purposes of determining reduced monitoring eligibility under the SMF. The EPA also requested input on the use of 2.0 and one-half the hazard index.

AWWA recommends against the use of any data below the PQL to drive regulatory requirements. Data should likewise not be used to determine nor treatment, or more frequent monitoring. For the reasons detailed below, use of this below-PWL data would be arbitrary and capricious.

The PQLs for PFOA and PFOS are set at 4.0 ppt each in the proposal, which is consistent with the currently active UCMR 5 monitoring program's minimum reporting limits. In finalizing the UCMR 5 monitoring program in 2021, EPA recognized that while EPA Methods 533 and 537.1 can both be used by laboratories to achieve lower reporting limits but concluded that the available lab capacity could not support establishing lower reporting limits to collect national occurrence data. Data below this level is less accurate and is not achievable by all water systems.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document. As discussed in this response, the EPA disagrees that data below PQLs should not be used for the determination of monitoring frequency or that use of this data is "arbitrary and capricious" as the commenter claims. The agency fully agrees that the measurements do have less precision and accuracy than those at or above the PQLs, however they are appropriate for their intended purpose of determining whether water systems should be allowed to monitor less frequently where sampling results have demonstrated lower risk of PFAS contamination as previously described in the preamble and this document. Furthermore, the approach of considering measured levels lower than PQLs for determining monitoring frequency is not novel but has been part of the drinking water standards for many years. Regarding the determination of how MCL compliance is to be determined, please see section 8.2 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045642)

EPA's proposed approach to require monitoring under the Standard Monitoring Framework and the use of the one-half of the MCL as a trigger level is appropriate. However, the use of reporting results below the PQL is inappropriate as it requires water systems to rely on unreliable data to determine monitoring requirements as part of the regulatory requirements.

EPA Response: Please see section 8.8 of the EPA response in this *Response to Comments* document. Regarding compliance monitoring requirements and frequency, please see section 8.1.2 of the EPA response in this *Response to Comments* document.

8.9 Other Monitoring Flexibilities

Individual Public Comments

California Municipal Utilities Association (CMUA) (Doc. #1639, SBC-043256)

III. The Regulation Needs to Take Unintended Consequences into Consideration

There are certain unintended consequences of the Regulation that need to be taken into consideration before the EPA adopts the Regulation.

General practice for many public water agencies is to take a water supply offline if that supply gets to 50% of an enforceable drinking water standard. That water supply is then treated and brought back online once it no longer tests at 50% of the enforceable drinking water standard. When supplies are offline, the water agency is forced to rely more heavily on other water supplies to meet customer needs. For agencies with multiple water sources, this practice may mean they must import more water, divert more water, or use stored water. Smaller agencies, on the other hand, are less likely to have more than a few water sources. Suppose a smaller agency has to take a groundwater well offline because the testing shows 50% or more of the PFAS MCLs. In that case, the agency has fewer other sources to rely on and will be disproportionally impacted. Accommodations should be made for agencies that follow that practice and work to remain compliant but are nonetheless struggling to meet customer needs.

EPA Response: The EPA notes that NPDWRs require systems to meet the MCLs and do not require a system to take a water source offline if it contains concentrations exceeding half of any MCL. Water systems seeking assistance with achieving compliance with regulatory requirements are encouraged to coordinate with the applicable primacy agency. The commenter does not specify examples of accommodations it is seeking or a clear rationale for these accommodations that cites precedents under other NPDWRs. The SDWA permits the EPA or primacy agencies to grant extensions, exemptions, or variances under certain circumstances. Regarding exemptions and extensions, please see section 12.1 of the EPA response in this *Response to Comments* document and section XII of the final rule preamble. Additionally, as noted in section II.E of the preamble to the final rule, funding under the IIJA, often referred to as the BIL, will assist many disadvantaged communities, small systems, and others with the costs of addressing emerging contaminants, like PFAS, when it might otherwise be cost-challenging. Finally, to support BIL implementation, the EPA is offering WaterTA to help communities identify water challenges and solutions, build capacity, and develop application materials to access water infrastructure funding (USEPA, 2023).

National Center for Health Research (NCHR) (Doc. #1749, SBC-044497)

2. This is an important first step in PFAS regulation, but it needs to be strengthened in several ways to protect human health.

• We understand the agency's desire to be flexible, but flexibility in monitoring requirements will likely generate a huge loophole. EPA needs more explicit limits to prevent a weakening of these regulations.

EPA Response: The commenter requested "more explicit limits," but did not make a specific recommendation. Most elements of this rule related to compliance monitoring and determining MCL compliance are similar to the NPDWR requirements for other chemical contaminants. For any monitoring flexibilities offered, the EPA has utilized a data-driven rationale. Initial monitoring requirements, compliance monitoring requirements, and compliance determinations are discussed in sections 8.1.1, 8.1.2, and 8.2 of the EPA response in this *Response to Comments* document, respectively. The EPA disagrees that more explicit limitations are needed. The requirements are explicit, and the agency is promulgating this rule based on the extensive record discussed in this document and the final rule preamble that support the EPA's findings that the final MCLs and monitoring schedules will be protective of public health but will at the same time not impose unnecessary burdens on systems where the risk of PFAS contamination is minimal.

Section 8 References

USEPA. 2005. *Manual for the Certification of Laboratories Analyzing Drinking Water, Fifth Edition*. EPA 815-R-05-004. Available on the Internet at http://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=30006MXP.txt

USEPA. 2023. *Water Technical Assistance (WaterTA).* Available on the internet at: https://www.epa.gov/water-infrastructure/water-technical-assistance-waterta

9 SDWA Right-to-Know Requirements

9.1 Consumer Confidence Report Requirements

Summary of Major Public Comments and EPA Responses

A few commenters requested clarification of the health effects language included in the Consumer Confidence Report (CCR). Specifically, a couple of commenters said the proposed standard health effects language included in the CCR for a Hazard Index Maximum Contaminant Level (MCL) exceedance was not clear. One commenter suggested that the EPA utilize "plain language' explanations about the Hazard Index and the way that the EPA has framed the calculations based on risk" (Doc. #1838, SBC-044870). Another commenter asserted that "the required language does not sufficiently explain the HI" (Doc. #1626, SBC-052953). The EPA has considered this input and revised the health effects language associated with PFAS exposure, including the Hazard Index. The change is responsive to the commenters' concern regarding clarity because the EPA has provided additional text in the health effects language which describes how PFAS included in the Hazard Index can result in adverse health effects when combined in a mixture in drinking water. In response to these comments, the agency has also added a definition of the Hazard Index in 40 CFR 141.153(c)(3)(v) to provide further clarity.

A few commentors raised concerns about requiring reporting of results below the practical quantitation level (PQL) in the CCR as these data may not be quantified with what they deem is appropriate precision. One commentor requested that any detected PFAS, not just the six regulated contaminants, be reported in the CCR. The EPA disagrees with commenters who voice concern over reporting measurements below the PQLs for PFOA and PFOS as "detected" contaminants in the CCR because reporting these measurements in the CCR will allow customers to understand that the contaminant was detected in the water supply. While measurements below the PQL will not be used to calculate compliance with MCLs for the final rule, measurements lower than the PQL are achievable by individual laboratories, and therefore these measurements can be used for screening, to determine compliance monitoring frequency, and to educate consumers about the existence of PFAS (for further discussion of PQLs for regulated PFAS, please see section VII of the preamble for this action). As such, the EPA believes that measurements below the PQL can reasonably be reported as "detected" for purposes of the CCR. This requirement is consistent with the CCR Rule in 40 CFR 141.153(d) which requires community water systems (CWSs) to report information on detected contaminants for which monitoring was required by the EPA or the state. The CCR reporting requirement includes unregulated contaminants for which monitoring is required pursuant to the Unregulated Contaminant Monitoring Rule (UCMR) as well as regulated contaminants in accordance with Safe Drinking Water Act (SDWA) 1414(c)(4). If the system has performed additional monitoring, the EPA strongly encourages them to include the results in the CCR, consistent with 40 CFR 141.153(e)(3). For purposes of reporting contaminant information in the CCRs, "detected" is defined in § 141.151(d).

As part of this regulatory action, the EPA has modified the trigger level value for quarterly monitoring from one-third of the MCL to one-half of the MCL in response to concerns that laboratories would not have the capacity to consistently measure as low as the threshold of one-third of the MCL (see section VIII.A.2 of the preamble for this action for further discussion about changes to the trigger level from the proposed to final regulation). To reflect this change in the trigger level, the EPA has modified 40 CFR 141.151(d), which identifies what is considered detected for purposes of reporting in CCRs consistent with SDWA 1414(c)(4). The EPA had also proposed adding a provision to require CWSs that detect any PFAS above the MCL to include health effects language for PFAS and stated in the preamble for the rule proposal that CWSs would be required to report detected PFAS as part of their CCRs. Because SDWA 1414(c)(4)(B) specifies that the Administrator may only require health effects language be reported in the CCR for situations other than an MCL violation for not more than three regulated contaminants, the EPA has removed the amendment to section (g) of 40 CFR 141.154 included in the proposed rule from the final rule and has instead updated Appendix O of Part 141 for the final rule to only require CWSs that have violations of the PFAS MCLs to include health effects language for PFAS. Since systems must complete initial monitoring within three years of rule promulgation, systems will be required to report results and other required information in CCRs beginning with 2027 reports. As the MCL compliance date is set at five years following rule promulgation, systems will be required to report MCL violations in the CCR, accompanied by the required health effects language and information about violations, starting in 2029.

For the final rule, in response to commenter requests for plain language explanations of the Hazard Index, the EPA is adding a definition of the Hazard Index in 40 CFR 141.153(c)(3)(v) of the CCR Rule to improve clarity and understandability for customers. Additionally, after considering public comments, the final rule includes revised mandatory health effects language required as part of CCRs, to address commenters' concerns, in cases where MCL violations have occurred. The updated health effects language can be found in Appendix A to Subpart O and is summarized in section IX.A.3 of the preamble for this action.

Individual Public Comments

National Tribal Water Council-Tribal PFAS Working Group (NTWCTPWG) (Doc. #1598, SBC-042340)

Public Notification

The FRN on page 18684 states that:

Under this proposal CWSs would be required to report detected PFAS in their CCR; specifically, PFOA, PFOS, PFHxS, HFPO–DA, PFNA, and PFBS, and the HI for the mixtures of PFHxS, HFPO–DA, PFNA, and PFBS. [CWSs refers to Community Water Systems, CCR refers to Consumer Confidence Report and HI is Hazard Index]

The NTWC-TFWG thanks EPA for inclusion of this requirement, which is a priority for us. This requirement should be clarified to indicate "report detected PFAS and amounts."

EPA Response: The EPA acknowledges the commenter's support of this requirement. With respect to the commenter's suggestion that CCRs should "report detected PFAS and amounts," the EPA agrees and has finalized the requirement that community water systems must report information on detected PFAS contaminants regulated under this final rule in CCRs in § 141.151(d). The EPA notes that the existing CCR requirements in 40 CFR Subpart O further require reporting this information in the contaminant data tables, to include PFAS, in § 141.153(d)(4). When MCL compliance is determined using a running annual average (RAA) of all samples taken at a monitoring location, as is the case for the PFAS National Primary Drinking Water Regulation (NPDWR), the highest average of any of the monitoring locations and the range of all monitoring locations must be reported, see § 141.153(d)(4)(iv)(B) for additional information.

WaterPIO (Doc. #1624, SBC-047683)

[A strong case can even be made that the EPA wants the end of the public's confident use of its tap water, based on the clear, cumulative effect of:]

• the "Don't Say Safe" provision in the proposed changes to the Consumer Confidence Report Rule;

EPA Response: Revisions to the CCR Rule and responses to public comments received on that proposed rule will be addressed as part of a separate action, see www.regulations.gov, Docket ID: EPA-HQ-OW-2022-0260, and are outside the scope of this action. As part of this regulatory action, the EPA is finalizing requirements for information to be included in CCRs for the six PFAS that are regulated under this final rule.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-047692)

An important message that has been made difficult to communicate to the public is letting customers know that their water is safe to drink, even when PFAS concentrations are below detection limits. EPA's announcements of health advisories that are in the parts per quadrillion realm made it difficult to say that the water was safe to drink, because water systems cannot detect the presence of contaminants at those levels – and therefore cannot tell customers whether their water meets EPA's health advisory. Additionally, EPA had proposed using drinking water health advisory levels for HBWC's in this NPDWR rulemaking. Questions will arise on why the health advisories are used for some PFAS but not others, and the public will lose trust in drinking water if it is not effectively communicated. EPA made these decisions based on its own analysis, and therefore should be the leader in these communication efforts. This communication would be helpful for utilities to use in their CCRs.

EPA Response: Please see section 9.1 of the EPA response in this *Response to Comments* document for discussion of reporting results below PQL values in the CCR and section 9.2 of the EPA response in this *Response to Comments* document for discussion of the EPA's health advisories for PFAS. The EPA notes that the agency intends to produce risk communication materials that can be used by utilities and others as they deem appropriate to communicate about PFAS in drinking water. As the EPA develops implementation materials following final rule promulgation, the agency will consider additional resources to support states and water systems in communicating with and notifying their customers. For discussion of risk communication materials that the agency intends to develop related to this action, please see section 1.2 of the EPA response in this *Response to Comments* document .

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045124)

Comment: The Department of Health suggests that EPA provide clear and health-protective advice on PFOA and PFOS in drinking water above the reporting level and below 4 ppt that align with the severity of noncancer health effects described in the document. Please explain how discounting any detections of PFOA or PFOS below 4 ppt aligns with the severity of noncancer health effects. Please explain how states should message reliable detections of PFOA and PFOS less than 4 ppt.

Explanation: In Vermont, the reporting level for PFAS in drinking water is almost always lower than 4 ppt. The reporting level is typically 2 ppt for public drinking water sampled between 2019 and 2023. While additional monitoring is required in the draft framework above the trigger level, the messaging to the public is unclear. It appears that valid detections of either PFOA or PFOS below 4 ppt would be messaged to the public as "not detected." Detections below 4 ppt would be entered into the running annual average calculation as "0". The public, including sensitive populations, would continue to drink the water containing PFAS between 2 ppt and 4 ppt, and these reliable detections would not contribute to the running annual average. This seems at odds with the severity of the noncancer health effects described in the draft document.

EPA Response: The EPA disagrees with the commenter's suggestion that the agency is "discounting any detections of PFOA or PFOS below 4 ppt;" please see section 9.1 of the EPA response in this *Response to Comments* document for discussion of reporting "detected" results in CCRs, which includes values below the PQLs. Concentrations of PFAS at levels equal to or exceeding trigger levels, but below MCLs, are used to determine the required monitoring frequency. For a discussion of replacing values below PQLs with zero for the purpose of calculating compliance with MCLs, see section 8.2 of the EPA response in this *Response to Comments* document.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045151)

Consumer Confidence Reports (CCR)

Edits to 40 CFR § 141.151(d) reference "levels prescribed § 141.902(a)(9)" which appears to be missing the word "by" prior to the citation. Note also that § 141.902 appears as "§ 141.XX" on page 18751 of the Federal Register notice. § 141.902(a)(9) defines a "reportable detection" as those "at or above one-third of the levels described in the table outlined in § 141.903(f)(1)(i)(3)."

This table contains the PQLs, which, by definition in § 141.2, are "the minimum concentration of an analyte (substance) that can be measured with a high degree of confidence that the analyte is present at or above that concentration." This requirement would mean reporting PFAS detections in the CCR below the PQL which would be estimated concentrations (qualified results). As the proposal does not use these estimated concentrations when calculating compliance with the MCLs, reporting these in the CCR would generate public confusion and suggest these are the true levels. Rather than citing § 141.902(a)(9), the CCR revision should cite § 141.903(f)(1)(i)(3) directly and only require CCR reporting of detections at or above the PQL.

The revision to Appendix A to Subpart O of Part 141 – Regulated Contaminants should include an edit to the "Traditional MCL in mg/L" header to add "(unless otherwise noted)" as was proposed to the table in §141.61(c). The purpose of footnote 2 on the HI MCLG value is also not clear (on page 18749 of the Federal Register notice). If the intent is to refer to the HI definition, then move the footnote to the Contaminant entry.

EPA Response: The EPA disagrees with the commenter's assertion that reporting values below the PQL will "generate public confusion and suggest these are the true levels" because, as stated in section 9.1 of the EPA response in this *Response to Comments* document, "measurements lower than the PQL are achievable by individual laboratories, and therefore these measurements can be used for screening, to determine compliance monitoring frequency, and to educate consumers about the existence of PFAS". These are accurate values that just measure with less precision than values above the PQL and "can reasonably be reported as "detected" for purposes of the CCR". For further discussion of reporting values below the PQL in CCRs, please see section 9.1 of the EPA response in this *Response to Comments* document.

Additionally, in response to the commenter's suggested grammatical corrections, the EPA added a preposition where the commenter noted "by" was missing in § 141.151(d). In the section following § 141.901, originally on page 18751, § 141.XX was changed to § 141.902. In Appendix A to Subpart O, the EPA has deleted footnote 2 and added the definition of *Hazard Index* to § 141.153(c)(3)(v). In the same appendix, while a parenthetical saying "unless otherwise noted" was not added to the column header as per the commenter's suggestion, this parenthetical note is provided in §141.50 and Table 4 to paragraph (c) of §141.61, which provide information on the Maximum Contaminant Level Goal (MCLG) and MCL values and units for the final rule, respectively.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045971)

One additional unintended consequence of this delay in results is the current proposed revisions to the Consumer Confidence Report (CCR) Rule. The proposed revisions would require a PWS

to update its CCR later in the year after delivery of the first if new UCMR data is received after delivery of the first report. With continued and worsened delays in receiving PFAS results, utilities who typically finalize reports in February or March before a quarterly billing cycle will have to update their CCR later in the year, delaying the delivery of results to customers by up to 12 months. The alternative would be to spend additional resources sending out the CCR separately from quarterly billing, which is neither efficient nor cost-effective.

EPA Response: Revisions to the CCR Rule and responses to public comments received on that proposed rule will be addressed as part of a separate action, see www.regulations.gov, Docket ID: EPA-HQ-OW-2022-0260, and are outside the scope of this action. As part of this regulatory action, the EPA is finalizing requirements for information to be included in CCRs for the six PFAS that are regulated under this final rule.

City of Thornton, Colorado (Doc. #1748, SBC-044795)

In addition, EPA should provide language for use in CCRs that explains that those values are estimated but are protective of public health because they are below the MCL.

EPA Response: For a discussion of reporting values below the PQL in CCRs, please see section 9.1 of the EPA response in this *Response to Comments* document. The EPA notes that the agency intends to produce risk communication materials that can be used by utilities and others as they deem appropriate to communicate about PFAS in drinking water. As the EPA develops implementation materials following final rule promulgation, the agency will consider additional resources to support states and water systems in communicating with and notifying their customers. For discussion of risk communication materials that the agency intends to develop related to this action, please see section 1.2 of the EPA response in this *Response to Comments* document. For discussion of the final trigger levels for this rule, please see section 8.8 of the EPA response in this *Response to Comments* document.

Council of State and Territorial Epidemiologists (CSTE) (Doc. #1770, SBC-044260)

Please see below for a summary of our comments and recommendations:

1. Data Collection and Statistical Methods: CSTE supports the recommendation that a CWS must prepare and deliver to its customers an annual Consumer Confidence Report (CCR) in accordance with requirements in 40 CFR 141 Subpart O. A CCR provides customers with information about their local drinking water quality as well as information regarding the water system compliance with drinking water regulations. Under this proposal CWSs would be required to report detected PFAS in their CCR; specifically, PFOA, PFOS, PFHxS, HFPO-DA, PFNA, and PFBS, and the HI for the mixtures of PFHxS, HFPO-DA, PFNA, and PFBS. However, adoption of the proposed MCLs will result in challenges with data collection, processing, analysis, and reporting. In addition to preparing customers with CCRs, testing results from the public drinking water system should be made easily available and accessible to the public. While these data are usually available through the Environmental Quality Department,

the information that the Environmental Quality Department may be limited and can be challenging to access. Additional guidance is necessary specifying how the data should be reported as well as guidance on interpretation of results. Further, data interpretation and processing can be difficult if Public Health Agencies don't have access to the data collected by partner agencies. Currently, due to limited sample analysis capacity, more laboratories will be needed to conduct analyses. Additional standardized guidance and coordination to support Public Health Agencies to access, process, analyze, report, and disseminate the information is required to improve consistency, transparency, and accuracy.

EPA Response: Please see section 9.1 of the EPA response in this *Response to Comments* document for discussion of CCR requirements for the final rule, including reporting of detected PFAS and MCL violations. The CCR Rule requires all community water systems to prepare and distribute a brief annual water quality report summarizing information regarding source water, detected contaminants, compliance, and educational information. The EPA notes that CCRs provide information about local drinking water quality to customers of CWSs. With respect to the commenter's concerns regarding data collection and processing, instructions are available from the EPA, including as part of the description of the approved PFAS analytical methods. Also, the EPA intends to provide materials to aid in implementation of the rule, including information related to public notification and calculation of the Hazard Index. For more information on primacy agency reporting requirements for the final rule, please see section XI.C of the preamble for this action. With respect to any data analysis concerns related to laboratory capacity, please see section V.A.2 of the preamble for this action and section 5.1.2 of the EPA response in this *Response to Comments* document for discussion of laboratory considerations, including capability and capacity.

Uttara Jhaveri (Doc. #1778, SBC-045449)

The monitoring system also requires a Community Water System to prepare and deliver an annual "Consumer Confidence Report (CCR)" to its consumers in accordance with requirements in 40 CFR 141 Subpart O. [FN28: Environmental Protection Agency, supra note 4.] The intention of the EPA is to keep consumers well-informed about their local drinking water quality and the water system compliance with drinking water regulations. The proposed regulation also mentions a "Public Notification (PN)" rule, which ensures that consumers are informed of any risk to public health because of a problem with the drinking water. [FN29: Id.]

The CCR and PN are important informational tools to involve the public and inform them of their drinking water. [FN30: Id.] However, the CCR may be a costly system to inform consumers nationwide, and a simple system through public informational tools such as the news channels and social media should be roped to disseminate such information easily. The Public Notification, on the other hand, should be more private and only affected areas and individuals should be informed of any public health risk. However, considering the transportability of PFAS, the neighboring areas of such sites should also be informed to ensure public safety.

EPA Response: Please see sections 9.1 and 9.2 of the EPA response in this *Response to Comments* document. The EPA agrees that CCRs and Public Notification (PN) are important for informing customers of drinking water issues. The EPA notes that no fundamental changes to the CCR or PN Rules were made as part of this action. All community water systems are required under 40 CFR 141 Subpart O to provide annual CCRs to their customers and to make a good faith effort to reach consumers who do not receive a water bill using a combination of methods appropriate to the particular water system, which may include news media and other means recommended by the primacy agency. This action adds PFAS reporting requirements to the CCR, by requiring an additional data element on PFAS be included in the list of required contaminant sampling data already provided in the CCR. With respect to the commenter's assertion that "the CCR may be a costly system to inform consumers nationwide", by requiring that PFAS information be provided through the CCR, this new health risk information will be provided in a least cost manner (when compared to alternative PFAS-specific communication strategies that might be employed apart from the CCR) which still reaches the at-risk community in a format which has been in place since 1998 and is therefore likely known as a source of water quality information to most system customers. The EPA has evaluated the costs to comply with the CCR Rule under a separate rulemaking action and evaluating those costs again under this regulatory action would result in a double counting of burden to systems and consumers.

The EPA has previously submitted the extension of the Information Collection Request (ICR) for the Public Water System Supervision Program (EPA ICR Number 0270.48, OMB Control Number 2040-0090) to the Office of Management and Budget (OMB) in March 2023. The ICR includes the estimated annual burden and costs associated with CCRs as approximately $37 million for public water systems (PWSs) and $2 million for states. For the proposed revisions to the CCR, published on April 5, 2023, the agency found that the action was considered not significant under Section 3(f)(1) of Executive Order 12866. The EPA estimated the total average annual cost of the revised CCR rule would be $22.2 million. For more information on the estimated costs of the revised CCR rule, including the Economic Impact Analysis, visit regulations.gov, docket ID EPA-HQ-OW-2022-0260.

Additionally, with respect to the commenter's assertion that public notification "should be more private and only affected areas and individuals should be informed of any public health risk", under 40 CFR 141 Subpart Q, water systems are required to provide public notice in a form and manner reasonably calculated to reach all persons served, using methods described in 40 CFR 141 subpart Q, depending on the applicable tier and potential adverse health effects for the violation or situation. This action does not change the PN implementation requirements previously codified that would be applicable to the MCL violations that would require public notice. The form, manner, and timing of the notices was addressed in the 2000 revisions to the PN Rule and the costs of public notification are described in the analysis of the rule; for additional information, see: https://www.epa.gov/dwreginfo/public-notification-rule.

Citizens Energy Group (Doc. #1838, SBC-044870)

Examples of such messages and tools could include 'plain language' explanations about the Hazard Index and the way that EPA has framed the calculations based on risk; additional clarification for water systems on reporting obligations in the Consumer Confidence Report, and tips on what homeowners can do if they are concerned with PFAS in the environment.

EPA Response: With respect to the commenter's request to include "'plain language' explanations about the Hazard Index," please see section 9.1 of the EPA response in this *Response to Comments* document. CWSs may include additional information as they deem necessary for public education consistent with, and not detracting from, the purpose of the CCRs, as indicated in § 141.153(h)(5). CCRs must also include information on the availability of a source water assessment, as described in § 141.153(b)(2). The EPA notes that while the CCR Rule does not require that CCRs include guidance for homeowners, PN issued in the case of an MCL violation does include information on actions consumers can take, including possibly using a filter or switching to an alternate source of water, as appropriate.

Midwest Environmental Advocates +more (Doc. #1846, SBC-045839)

The examples above emphasize the need for EPA to issue a guidance document for water systems to use when issuing right-to-know reports. To ensure consumers receive adequate information about PFAS in their drinking water, the guidance must provide necessary context to understand PFAS detections. In the guidance, EPA should indicate the content required to be in the notification, including, but not limited to:

• A plain language statement about what PFAS compounds are and what they have been used for;

• A description of sources of PFAS in the drinking water, including specific sources for that particular water system, if known;

• A description of the various health impacts of PFAS;

• A guide on how to reduce exposure to PFAS, including from other media;

• A clear statement of what levels of PFAS were detected for purposes of MCL compliance, with all monitoring results available in a transparent manner on the water system's website;

• To the extent the water system is undertaking efforts to reduce PFAS in its water, i.e., installation of new treatment technologies, a description of the status of those efforts.

Additionally, the guidance should urge water systems to issue notifications in a manner that should reasonably reach all people served by the water utility, including consumers who do not deal directly with water bills like renters who tend to be lower income. EPA should ensure that all receive the right-to-know benefits of the SDWA.

EPA Response: Please see section 9.1 of the EPA response in this *Response to Comments* document for responses related to CCR requirements and section 9.2 of the EPA response in this *Response to Comments* document for responses related to PN requirements. With respect to the commenter's request for the EPA to issue a guidance document for water systems to use when issuing right-to-know reports, the EPA acknowledges the suggestions provided by this and other commenters regarding communication needs targeted towards the public, water utilities, primacy agencies, and the EPA itself. The agency intends to consider producing implementation materials, including some recommended materials provided by commenters, during the implementation stage of this final PFAS NPDWR. For additional discussion regarding guidance and communications materials for this action, please see section 1.2 of the EPA response in this *Response to Comments* document.

Additionally, the EPA notes that some of the information that the commenter suggests including in a guidance document is already included in right-to-know reports. For instance, consistent with existing rule requirements, public notices must include: 1) a description of the violation or situation, including (as applicable) the contaminant level(s); 2) when the violation or situation occurred; 3) any potential adverse health effects; 4) the population at risk; 5) whether alternative water supplies should be used; 6) actions consumers should take, including when they should seek medical help; 7) what the system is doing to correct the violation or situation; 8) when the water system expects to return to compliance or resolve the situation; 9) the contact information for the water system; and 10) a statement to encourage the notice recipient to distribute the public notice to other persons served. Systems must provide the notices in a form and manner reasonably calculated to reach all persons served, as described in the PN Rule. Additionally, the agency notes that CWSs have the discretion to include additional information in CCRs as they deem necessary for public education, as long as it is consistent with, and not detracting from, the purpose of the report, consistent with existing CCR Rule provisions 40 CFR 141.153(h)(5).

The EPA agrees that it is important for all consumers to "receive the right-to-know benefits of the SDWA" as asserted by the commenter. However, with respect to the commenter's suggestion that the agency "should urge water systems to issue notifications in a manner that should reasonably reach all people served by the water utility, including consumers who do not deal directly with water bills like renters who tend to be lower income," the EPA notes that this comment is outside the scope of this rulemaking effort.

Midwest Environmental Advocates +more (Doc. #1846, SBC-045837)

Effective communication about PFAS detections is critical as PFAS pollution is novel to many Americans. And as outlined in a comment letter related to EPA's revisions to the Consumer Confidence Report Rule, [FN38: National Primary Drinking Water Regulations: Consumer Confidence Report Rule Revisions, 88 Fed. Reg. 20092 (proposed April 5, 2023).] right-to-know reports have historically failed to serve their intended purpose because "far too many water systems converted these reports into public relations documents with confusing, unintelligible, and sometimes false and misleading information often designed to placate consumers into

believing their water was fine regardless of the results of contaminant monitoring." [FN39: Comments on EPA' Proposed "National Primary Drinking Water Regulations: Consumer Confidence Report Rule Revisions" [EPA-HQ-OW-2022-0260] submitted by Natural Resources Defense Council et al. 3, https://www.regulations.gov/comment/EPA-HQ-OW-2022-0260-0113 (the comment letter supports this claim through examples on how right-to-know reports have been used to obfuscate water quality problems rather than convey accurate information about pollution and its associated risks).]

EPA Response: See section 9.1 of the EPA response in this *Response to Comments* document for discussion about CCR reporting requirements specific to this rule. The EPA agrees with the commenters' assertion that "effective communication about PFAS detections is critical". CCRs and PN are important for informing customers of drinking water issues and the CCR and PN requirements set forth as part of this final rule will work toward ensuring effective communication about PFAS detections to water system consumers. To this end, the EPA also notes that the agency intends to produce risk communication materials that can be used by utilities and others as they deem appropriate to communicate about PFAS in drinking water. As the EPA develops implementation materials following final rule promulgation, the agency will consider additional resources to support states and water systems in communicating with and notifying their customers.

The EPA disagrees with the commenters' assertion that right-to-know reports "have historically failed to serve their intended purpose". For this regulation, the EPA believes that the agency has developed appropriate rule-specific CCR reporting requirements that meet all statutory obligations and provide necessary information for consumers.

The EPA notes that revisions to the CCR Rule and responses to public comments received on that proposed rule will be addressed as part of a separate action, see www.regulations.gov, Docket ID: EPA-HQ-OW-2022-0260, and are outside the scope of this action.

City of Tulsa Water and Sewer Department (CoT WSD) (Doc. #1785, SBC-043784)

6. 88 FR 18684. Reporting detected PFAS in Consumer Confidence Report.

CoT WSD has concerns about what is defined as a "reportable detection."

• Proposed language at §141.151(d), at end of the paragraph, defines "detected" (for purposes of CCR reporting) as at or above the levels prescribed in §141.902(a)(9).

• Proposed language at §141.902(a)(9) defines reportable detection as "at or above 1/3 of levels in proposed section §141.903(f)(i)(iii)." Note: Actual proposed language contains a typographical error, which refers to a non-existent section. It is assumed that §141.903(f)(i)(iii) is the correct citation.

• Proposed language at §141.903(f)(i)(iii), Table 1, lists PQLs of all 6 individual PFAS

Using all the citations and references above, it is determined that CCR reportable detections are analytical measurements below PQLs, specifically 1/3 of each PFAS's PQL. PQLs are the lowest level of reliable, quantifiable measurement of an analytical method. EPA admits multiple times within the preamble that these measurements are less precise and less accurate. It goes against good laboratory practice to report such measurement as "detectable." EPA should propose another definition for "reportable detection."

EPA Response: Please see section 9.1 of the EPA response in this *Response to Comments* document for discussion of reporting results below PQL values in the CCR. As described in section 9.1 of the EPA response in this *Response to Comments* document, the EPA notes that as part of this regulatory action, the EPA has modified the trigger level value for quarterly monitoring from one-third of the MCL to one-half of the MCL in response to concerns that laboratories would not have the capacity to consistently measure as low as the threshold of one-third of the MCL (see section VIII.A.2 of the preamble for this action for further discussion about changes to the trigger level from the proposed to final regulation).

Additionally, the EPA notes that the citation listed in § 141.902(a)(9) of the rule proposal was incorrect and was intended to reference § 141.903(f)(1)(iii); please see the EPA response to Doc. #1785, SBC-043790 in section 16.5 in this *Response to Comments* document.

9.2 Public Notification Requirements and Tiering

Summary of Major Public Comments and EPA Responses

Many commenters support the Tier 2 PN requirement for MCL violations, which requires public notice as soon as practical but no later than 30 days after the system learns of the violation. Commenters assert that Tier 2 notification is appropriate and consistent with other MCLs for chemicals with chronic effects. Conversely, many commenters suggest that the PN tiering be raised from Tier 2 to Tier 1 or that the EPA consider other PN approaches given concerns about health impacts resulting from exposure on timescales shorter than chronic exposure. Commenters assert that raising PN for MCL violations from Tier 2 to Tier 1 would ensure that consumers are informed of potential harm associated with elevated PFAS levels in a timelier manner so they can make informed risk management decisions. Additionally, a few commenters request that the EPA re-categorize repeat MCL violations to Tier 3 due to the expected length of time needed for a PWS to design and construct treatment. Commenters argue that quarterly PN would not offer added value and could possibly result in confusion for consumers.

The EPA agrees with commenters that Tier 2 PN is appropriate for MCL violations based on analysis of a wide range of scientific studies that shows that long-term exposure may have adverse health effects. The EPA disagrees with commenters who recommend issuing Tier 1 notification for MCL violations. Tier 1 notices must "be distributed as soon as practicable, but no later than 24 hours, after the public water system learns of the violation" pursuant to section 1414(c)(2)(C)(i) of SDWA. The PN Rule preamble characterizes contaminants with violations routinely requiring a Tier 1 notice as those with "a significant potential for serious adverse health

effects from short-term exposure", stating that other violations do not require Tier 1 notice because elevated levels of these contaminants are not "strongly or consistently linked to the occurrence of the possible acute health effects" (USEPA, 2000). The EPA has not characterized health risks resulting from acute exposure (i.e., < or = 24 hours) to PFAS and the EPA believes that issuing Tier 2 PN for MCL violations constitutes a health protective approach given that the MCLG values are based on health effects that occur after chronic exposure to PFAS (i.e., cancer). Based on the available health effects information, the EPA has characterized developmental effects, including immune impacts, associated with developmental PFAS exposure (i.e., during pregnancy and/or childhood) in addition to health effects that occur after chronic exposure (i.e., exposure over many years). The agency considers it reasonable to notify consumers within 30 days of a PWS learning of an MCL violation because it generally provides protection of the adverse health effects that may occur from exposure to PFAS during sensitive lifestages such as gestation. The EPA typically reserves Tier 1 notifications for acutely toxic contaminants. For example, nitrate, nitrite, or total nitrate and nitrite require Tier 1 notice because exceedances can result in immediate life-threatening health impacts for infants (i.e., methemoglobinemia). Based on the currently available information, the developmental and chronic effects associated with exposure to these PFAS are not known to represent immediate acute health effects. For more information on the EPA's characterization of health effects resulting from PFAS exposure, please see (USEPA, 2024a; USEPA, 2024b). This approach is also consistent with the PN requirements for other synthetic organic contaminants regulated under SDWA. The EPA acknowledges that there may be instances in which it is appropriate to elevate the tiering of PN on a case-by-case basis. Under the existing PN Rule in 40 CFR 141.202(a), a violation that routinely requires a Tier 2 notice but poses elevated risk from short-term exposure may be elevated to Tier 1 at the discretion of the primacy agency. Additionally, the EPA will develop appropriate implementation guidance to assist in the understanding of PN requirements among other final rule requirements.

The EPA disagrees with commenters that recommended reclassifying ongoing MCL violations to Tier 3 for repeat notices. The EPA believes there is sufficient flexibility in the existing PN Rule 40 CFR 141.203(b)(2) that allows primacy agencies to allow a less frequent repeat notice on a case-by-case basis for unresolved violations, but no less than once per year, and the determination must be in writing. The EPA believes repeat notices are valuable to consumers that may not receive the initial notice and allow water systems to provide any updates to consumers, such as actions being taken to resolve the situation and estimated timelines. Additionally, the EPA notes that the agency has not modified the PN requirement for repeat notice and this requirement for PFAS MCL violations is no different than the requirement for any other contaminant regulated under SDWA and deemed to require Tier 2 notification; repeat notice is required until the violation or situation is resolved. Repeat notices are required every 3 months, unless the primacy agency determines that appropriate circumstances warrant a different repeat notice frequency. In no circumstance may the repeat notice be given less frequently than once per year [40 CFR 141.203(b)(2)]. Likewise, the EPA has not modified the form and manner of Tier 2 PN which includes "any other method reasonably calculated to reach persons regularly

served by the system" [40 CFR 141.203(c)(ii)]. The intent of SDWA's right-to-know rules, including the PN Rule, is to provide consumers with information on their drinking water, including information about violations, to allow them to make informed decisions to protect their health. Providing repeat notices ensures that customers stay informed about the quality of their drinking water in the event that they do not receive the initial notice. The EPA has also found public notice to be a motivational factor for water systems to address the issue.

A few commenters recommended that the EPA update the proposed PN health effects language. Commenters stated that the proposed health effects language was confusing and needed to be clarified to better communicate to the public about the safety of their water. Specifically, commenters cited concerns that the language "loses the focus on sensitive subpopulations" and suggested that the agency's inclusion of both "acute and chronic, or at least, subchronic, effects in the PN language" may be confusing. Additionally, a few commenters noted what they believe to be inconsistencies in how health effects language is presented in the CCR and in the EPA's previously issued PFAS health advisories. These commenters point out that the language found in the right-to-know notices discusses the health effects of PFAS levels above the MCL while the health advisories language addresses the effects of lower PFAS levels. As such, commenters believe the different focus may cause confusion for the public.

The EPA agrees with commenters that additional clarification of the health effects associated with PFAS exposure will more effectively communicate risk to consumers when they receive PN from their water system. The EPA has considered this input and has revised health effects language for the final rule to further clarify the health effects associated with PFAS exposure. These changes are responsive to the commenters' concerns regarding clarity because the EPA has modified the health effects language to more explicitly differentiate between health effects anticipated to occur due to exposure over many years and those anticipated to occur due to developmental exposures, which will allow consumers to make more informed decisions to protect their health. These edits also address commenters' concerns about losing focus on sensitive subpopulations, as the health effects language is now more explicit about risks associated with PFAS exposure during pregnancy and/or childhood. The updated health effects language for the rule is summarized in section IX.A.3 of the preamble for this action.

The EPA's previous issuance of the PFAS health advisories (HAs) is outside the scope of this action. Drinking water health advisories are distinct from MCLs and MCLGs as each serves a different purpose. HAs provide technical information on chemical and microbial contaminants that can cause human health effects and are known or anticipated to occur in drinking water. HAs primarily serve to provide information to drinking water systems and officials responsible for protecting public health when emergency spills or other contamination events occur. The HAs help Tribes, states, and local governments inform the public and determine whether local actions are needed to address public health impacts in affected communities. The EPA's HA documents describe information about health effects, analytical methodologies, and treatment technologies. HAs are not legally enforceable federal standards and are subject to change as new information becomes available.

The final rule's regulatory language sets forth the required health effects language that must be included as part of PN or within the CCR when there is an MCL violation under this regulatory action and as such characterizes health effects anticipated when levels of PFAS are in excess of the MCL values. Because the PN and CCR requirements for this rule are intended to specify to customers concisely and in non-technical terms what adverse health effects may occur as a result of an MCL violation, PN and CCR health effects language is often more succinct than language associated with the EPA's health advisories, which includes more technical detail intended for officials responsible for protecting public health and utilities. In this action, the EPA is limiting reporting of health effects language as part of PN or in the CCR to when there is an MCL violation. While SDWA authorizes the EPA to require a health effects statement in the CCR for three contaminants in the absence of a violation or an exceedance of the lead action level, the EPA has already used this authority for lead, arsenic, and nitrates. See SDWA 1414(c)(4)(B) and 40 CFR 141.154(b), (c), and (d).

The final rule requires the PN of violations of all MCLs promulgated under this final rule to be designated as Tier 2 and as such, PWSs would be required to comply with 40 CFR 141.203. The final rule also designates monitoring and testing procedure violations as Tier 3, requiring systems to provide notice no later than one year after the system learns of the violation. Systems are also required to repeat the notice annually for as long as the violation persists. As systems must comply with initial monitoring requirements within three years of rule promulgation, systems will be required to provide Tier 3 notification for monitoring and testing procedure violations starting in 2027. As the MCL compliance date is set at five years following rule promulgation, systems will be required to provide Tier 2 notification for MCL violations starting in 2029. However, the EPA notes that primacy agencies have the authority in the existing PN Rule (Table 1 to § 141.201) to require systems to provide notices for "situations determined by the primacy agency to require public notice" which would allow them to require public notice to customers prior to the MCL compliance date. As discussed above, the EPA has also made edits to clarify the mandatory health effects language required in the PN of an MCL violation; the updated health effects language can be found in Appendix B to Subpart Q and is summarized in section IX.A.3 of the preamble for this action.

Individual Public Comments

Missouri Department of Natural Resources (Doc. #1563, SBC-042536)

Section X—Safe Drinking Water Right to Know

EPA requests comment on its proposal to designate violations of the proposed MCLs as Tier 2.

The Department agrees with EPA's approach to treat MCLs as Tier 2 and as lifetime health advisory contaminants. If an analyte is shown to have life threatening, acutely toxic health effects like methemoglobinemia with nitrate, the Department would support a Tier 1 designation. At this time, however, PFAS research has not conclusively shown a life threatening acute toxicity with the proposed analytes for regulation.

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document.

Maine Water Utilities Association (MWUA) (Doc. #1567, SBC-042740)

Communication:

EPA proposes that a PWS must repeat public outreach to its consumers every 3 months if a violation or situation persists unless the primacy agency determines otherwise, but that at a minimum, systems must give repeat notice at least once per year. Because it will take time for a PWS to design and construct treatment, we do not find quarterly Public Notice to have added value (in fact, it would most likely cause confusion for consumers) and suggest instead that a Tier III notice is the more appropriate level if a violation persists.

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document. The EPA notes that the purpose of having repeat PN notices is no less relevant during the time a PWS designs and constructs treatment.

Blue Ridge Environmental Defense League (BREDL) (Doc. #1568, SBC-042996)

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May 25, 2023

Docket ID No. EPA-HQ-OW-2022-0114

U.S. Environmental Protection Agency

EPA Docket Center

Office of Ground Water and Drinking Water Docket

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Washington, DC 20460

Comments on EPA Docket ID No. EPA-HQ-OW-2022-0114 PFAS National Primary Drinking Water Regulation Rulemaking

To Whom It May Concern:

On behalf of Blue Ridge Environmental Defense League, I am submitting comments on the PFAS National Primary Drinking Water Regulation Rulemaking.

Public Notification

As stated in the proposed rule posting in the Federal Register, "as part of SDWA [Safe Drinking Water Act], the Public Notification (PN) rule ensures that consumers will know if there is a problem with their drinking water. Notices alert consumers if there is risk to public health. They also notify customers: If the water does not meet drinking water standards; if the water system fails to test its water; if the system has been granted a variance (use of less costly technology); or if the system has been granted an exemption (more time to comply with a new regulation)" [FN1: Federal Register/Vol. 88, No. 60/ Wednesday, March 29, 2023/Proposed Rules, p. 18684].

Under the draft proposal, EPA is proposing that violations of the three Maximum Contaminant Levels in the proposal would be designated as Tier 2 and as such, Public Water Systems would be required to comply with 40 CFR 141.203. Per 40 CFR 141.203(b)(1), notification of an MCL violation should be provided as soon as practicable but no later than 30 days after the system learns of the violation [FN2: Ibid.].

BREDL submitted comments on June 10, 2019 on Docket ID No. EPA-HQ-OLEM-2019-0229 regarding Interim Recommendations for Addressing Groundwater Contaminated with PFOA and PFOS. In our comments, we concurred with scientists and experts who recommend using a "class" approach for all PFAS. According to her testimony before a congressional subcommittee, East Carolina University Associate Professor Jamie DeWitt, PhD, DABT said, "It is not feasible from a time or resource perspective to 'TEST' our way out of this crisis. Employing a 'CLASS' approach for ALL PFAS will be protective for vulnerable populations and the general public." [FN3: Jamie DeWitt, PhD, DABT, Associate Professor, Department of Pharmacology & Toxicology, Brody School of Medicine at East Carolina University; Testimony; May 1-exposure]

BREDL concurs that public notification, in addition to the Consumer Confidence Report requirement, is a necessary requirement as part of this rulemaking. However, we strongly recommend that the Tier 2 public notification be expanded to include more than just the six listed PFAS in this draft rulemaking. Public notification should include the discovery of any PFAS contaminant in drinking water. Public notification should consider the entire class of PFAS.

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document for discussion of the tiering of public notification for the final rule. The EPA notes that the PN and CCR requirements established in this rulemaking are only for the six PFAS contaminants regulated under the final rule. However, PN for certain additional PFAS contaminants will be required under the existing PN Rule. This is because the fifth UCMR (UCMR 5) currently requires monitoring for 29 PFAS, and under existing PN Rule requirements, systems must notify consumers on the availability of UCMR results. Similarly, CWSs are also

required to report results in their CCR for regulated contaminants that are detected and the reported levels of unregulated contaminants for which monitoring is required by the EPA (i.e., through the UCMR) or the state. If a system performs additional (voluntary) monitoring, the EPA encourages it to include the information in their reports [§ 141.153(e)(3)]. For violations or situations not specifically identified in the PN Rule as requiring PN, primacy agencies may use their existing authority to require a system to provide public notice for other violations or situations with significant potential to have adverse effects on human health, as determined by the primacy agency either in its regulations or on a case-by-case basis [Appendix A to 40 CFR subpart Q].

Blue Ridge Environmental Defense League (BREDL) (Doc. #1568, SBC-042998)

In summary

Dumbfounded by the lack of public notification related to the Spring Hollow Reservoir contamination, BREDL worked with local legislators in an attempt to get some basic public notification passed by the Virginia General Assembly. While the bill passed unanimously on the Senate side, it was tabled in a House of Delegate's subcommittee.

It's clear that local water systems and politicians cannot be relied upon to notify the public about contaminants in the public drinking water. EPA must include public notification as part of this rulemaking. This public notification has to include letters sent directly to consumers. Posting notices only on websites is not sufficient.

Thank You for this opportunity to comment.

Respectfully submitted,

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Appendix 1

Fair Use Notice: This appendix contains copyrighted material the use of which has not been specifically authorized by the copyright owner. We are making such material available in our efforts to advance understanding of environmental issues, etc. We believe this constitutes a 'fair use' of any such copyrighted material as provided for in section 107 of the US Copyright Law. In accordance with Title 17 U.S.C. Section 107, the material in this appendix is distributed without

profit to those who have expressed a prior interest in receiving the included information for research and educational purposes.

Appendix 1

[Figure 1: See docket ID: EPA-HQ-OW-2022-0114-1568]

Appendix 2

Fair Use Notice: This appendix contains copyrighted material the use of which has not been specifically authorized by the copyright owner. We are making such material available in our efforts to advance understanding of environmental issues, etc. We believe this constitutes a 'fair use' of any such copyrighted material as provided for in section 107 of the US Copyright Law. In accordance with Title 17 U.S.C. Section 107, the material in this appendix is distributed without profit to those who have expressed a prior interest in receiving the included information for research and educational purposes.

Appendix 2

[Figure 2: See docket ID: EPA-HQ-OW-2022-0114-1568]

Appendix 3

BREDL email correspondence with EPA requesting a list of waterworks testing for UCMR #5.

[Figure 3: See docket ID: EPA-HQ-OW-2022-0114-1568]

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document and section IX.B of the preamble for this action for information on the PN requirements for the final PFAS NPDWR. The form and manner of public notice for required public notices under the PN Rule (40 CFR Part 141, Subpart Q) was established in the PN rulemaking and is beyond the scope of this rulemaking for PFAS. For more information on requirements under the PN Rule, including delivery requirements, please see Subpart Q of CFR 141.

New Hampshire Water Works Association, Inc. (NHWWA) (Doc. #1576, SBC-042456)

Hundreds of systems are likely to be in a continuous public notification cycle for years. This will initially cause public alarm, followed by desensitization and resistance to increasing water rates for necessary funding, overall eroding public trust in public water supplies.

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document for discussion of PN requirements for repeat notice. Additionally, the EPA notes that the PN Rule requirements related to the frequency of the notice, which may result in repeat notices for PFAS or any other contaminant covered by the PN Rule requirements, are beyond the scope of this rulemaking for PFAS.

COMM Water Department (Doc. #1577, SBC-042443)

Communicating to our customers about PFAS has been challenging. A Tier II notice might be appropriate for the initial violation of the MCL, but if the violation persists, a Tier III notice is the appropriate follow up communication until treatment is installed.

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document.

Michigan Department of Environment, Great Lakes, and Energy (EGLE) Drinking Water and Environmental Health Division (DWEHD) (Doc. #1597, SBC-042987)

E. Safe Drinking Water Right to Know

Having reviewed Section X of the proposed NPDWR, EGLE DWEHD agrees with EPA's proposed public notification requirements, as these are largely consistent with those established for other NPDWR and for PFAS MCLs in Michigan.

EPA Response: The EPA acknowledges the commenter's support of the rule's PN requirements. Please see section 9.2 of the EPA response in this *Response to Comments* document for further discussion.

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-042891)

Communication:

In Massachusetts, MassDEP has required consumer notification in communities where the PFAS6 levels are above 20 ppt. The first verified result over 20 ppt requires a Public Education notice and exceedance of the MMCL requires a Tier II Public Notice. We believe the Tier II notification is the appropriate initial notice level. The added layer of Public Education in Massachusetts is problematic because a customer can receive a notice one month and then two months later, they receive a very similar notice in the formal Tier II Public Notice. EPA proposes that the system must repeat notice every three months if the violation or situation persists unless the primacy agency determines otherwise, but that at a minimum, systems must give repeat notice at least once per year. Because it will take time for a PWS to design and construct treatment, we do not find quarterly Public Notice to have added value and suggest instead that a Tier III notice is the more appropriate level if the violation persists.

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1567, SBC-042740 and Doc. #1576, SBC-042456 in section 9.2 in this *Response to Comments* document.

American Water Works Company Inc. (Doc. #1608, SBC-044015)

Right-to-Know Provisions

American Water supports the proposal to designate violations of the proposed PFAS MCLs as a Tier 2 violation. We also support the proposed Consumer Confidence Report requirements.

[Figure 1: See Docket ID EPA-HQ-OW-2022-0114-1608]

[Figure 2: See Docket ID EPA-HQ-OW-2022-0114-1608]

EPA Response: Please see sections 9.1 and 9.2 of the EPA response in this *Response to Comments* document. The EPA acknowledges the commenter's support of the PN and CCR requirements for this action.

Marlene Ladderbush (Doc. #1612, SBC-042919)

Communicating to our customers about PFAS has been challenging. The public is not versed in the scientific levels of quantification of these chemicals. A Tier II notice might be appropriate for the initial violation of the MCL, but if the violation persists, a Tier III notice is the appropriate follow up communication until treatment is installed. EPA needs to ensure that any required educational statements have clear and appropriate messaging. EPA needs to revisit its proposed required Standard Health Language for Public Notice as it is not well written, nor easily understood by the lay person.

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document.

Town of Lincoln Water Department (Doc. #1613, SBC-043031)

Communicating to our customers about PFAS is a challenge. A Tier Il notice might be appropriate for the initial violation of the MCL, but if the violation persists, a Tier Ill notice is the appropriate follow up communication until treatment is installed. EPA needs to ensure that any required educational statements have clear and appropriate messaging. EPA needs to revisit its proposed required Standard Health Language for Public Notice as it is not well written, nor easily understood by the lay person. EPA also needs to inform consumers about the other routes of exposure; it does a disservice to the public if the EPA and the states focus on drinking water to the exclusion of other, perhaps more significant PFAS contributions to one's body burden (e.g., consumer products, food). EPA must consult with risk communication professionals to develop the messaging, as the materials EPA has made available thus far are not particularly helpful.

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document. The EPA notes that the agency intends to produce risk communication materials that can be used by utilities and others as they deem appropriate to communicate about PFAS in drinking water. As the EPA develops implementation materials following final rule promulgation, the agency will consider additional resources to support states and water systems in communicating with and notifying their customers. For discussion of risk communication materials that the agency intends to develop related to this action, please see section 1.2 of the EPA response in this *Response to Comments* document. In this action, the EPA is addressing

PFAS exposure via drinking water, however through other efforts, the EPA is addressing other PFAS exposure pathways (see https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024). Including information on additional routes of exposure aside from drinking water is outside the scope of the information traditionally included in CCRs and PN as these topics do not specifically relate to drinking water.

Oklahoma Department of Environmental Quality (DEQ) (Doc. #1616, SBC-043040)

Public Notice

DEQ recommends EPA clarify the health effects language proposed to be included in the public notification requirements.

The proposed EPA health effects language for public notification is not consistent with the language EPA used for the previous health advisories. In addition, the proposed public notice language discusses PFAS levels in excess of the MCL as being of concern, while the health advisory language discusses health impacts at much lower levels. This will create additional confusion with the public regarding the safety of their water.

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044043)

24. EPA requests comment on its proposal to designate violations of the proposed MCLs as Tier 2.

a. CWUC agrees that Tier 2 is the appropriate and preferred PN level. This should be based on the RAA exceedance, and not an individual result exceedance.

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document. In the final rule, compliance with the MCLs, and thus the issuance of PN under the rule, will be determined based on a running annual average (RAA) of PFAS monitoring results. For more information on monitoring and compliance requirements for the final rule, see sections 8.1 and 8.2 of the EPA response in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043091)

Public Notifications

Public notifications serve a key role in protecting public trust in drinking water. Aqua supports the Proposal requiring that water systems with PFAS levels exceeding the MCLs provide a Tier 2 notification to the public. This would require that a water system provide a notification as soon as practicable but no later than 30 days after the system learns of the violation. The Proposal would also require that water systems provide a Tier 3 notice when a monitoring and testing

procedure violation has occurred. Finally, as part of the Consumer Confidence Report, water systems will be required to provide information regarding the detection of any regulated PFAS compounds.

EPA Response: Please see sections 9.1 and 9.2 of the EPA response in this *Response to Comments* document. The EPA acknowledges the commenter's support of the PN requirements for this action.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-044873)

May 30, 2023

U.S. Environmental Protection Agency EPA Docket Center

Office of Ground Water and Drinking Water Docket Mail Code: 2822IT

1200 Pennsylvania Avenue NW Washington, DC 20460

Attention: Docket ID EPA-HQ-OW-2022-0114

Dear Administrator Regan:

Thank you for the opportunity to comment on the U.S. Environmental Protection Agency's (EPA) proposed PFAS National Primary Drinking Water Regulation Rulemaking, published on Wednesday, March 29, 2023 at 88 FR 18638. The Pennsylvania Department of Environmental Protection (DEP) fully supports EPA' s efforts to protect public health by setting national drinking water standards for per- and polyfluoroalkyl substances (PFAS). Pennsylvania is one of a handful of states that moved quickly to address PFAS in drinking water and welcomes federal action to improve public health protection and ensure more consistent regulation of PFAS across the country.

DEP supports and agrees with the intent of EPA's proposed rulemaking in the following key areas:

• DEP agrees with EPA's decision to consider PFAS chronic contaminants and to require Tier 2 public notification (PN) for MCL exceedances.

EPA Response: The EPA acknowledges the commenter's support of the EPA' s efforts to protect public health by setting national drinking water standards for PFAS. The EPA also acknowledges the commenter's support for considering PFAS chronic contaminants and to require Tier 2 public notification for MCL violations. Please see section 9.2 of the EPA response in this *Response to Comments* document for further discussion related to PN requirements.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044083)

Public Notice

ASDWA recommends EPA clarify the health effects language proposed to be included in the public notification requirements.

ASDWA's members support EPA's decision to utilize Tier 2 public notification (PN) for the PFAS NPDWR, as this approach is consistent with other chemical MCLs with chronic effects. However, the proposed health effects language to be included is confusing and needs additional clarification. As is currently written, EPA seems to have included both acute and chronic, or at least sub-chronic, effects in the PN language. Additionally, this PN language is inconsistent with the language the Agency used for the previous health advisories. The PN language discusses PFAS levels above the MCL being of concern, while the health advisory language discusses health impacts at much lower levels. This will create additional confusion with the public regarding the safety of their water. Finally, the language within the rule also loses the focus on sensitive sub-populations and only refers to "children." ASDWA recommends that the Agency change this to include "pregnant individuals and infants."

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document for discussion of public notification tiering and updates to the mandatory health effects language for the final rule. The EPA acknowledges the commenter's support for Tier 2 public notification. The updated health effects language, which can be found in Appendix A to Subpart O and Appendix B to Subpart Q and is summarized in section IX.A.3 of the preamble for this action, includes language that focuses on potential developmental impacts during pregnancy and/or childhood.

Village of Woodbury (Doc. #1629, SBC-042949)

3. The proposed NPDWR public would be Tier 2 violations, requiring public water suppliers notify public within 30-days of an MCL exceedance. Additionally, this information would be reported in the Annual Consumer Confidence Reports. We take no exception to this and believe transparency to the public is best policy.

EPA Response: Please see sections 9.1 and 9.2 of the EPA response in this *Response to Comments* document.

Town of Tewksbury, Massachusetts (Doc. #1637, SBC-043249)

Communicating to our customers about PFAS has been challenging. The standard language that has been proposed and used by EPA and State regulators is very alarming to consumers. A Tier II notice might be appropriate for the initial violation of the MCL, but if the violation persists, a Tier III notice is the appropriate follow up communication until treatment is installed. EPA needs to ensure that any required educational statements have clear and appropriate messaging. EPA needs to revisit its proposed required Standard Health Language for Public Notice as it is not well written, nor easily understood by the lay person. EPA also needs to inform consumers about the other routes of exposure; it does a disservice to the public if the EPA and the states focus on drinking water to the exclusion of other, perhaps more significant PFAS contributions to one's

body burden (e.g., consumer products, food). EPA must consult with risk communication professionals to develop the messaging, as the materials EPA has made available thus far are not particularly helpful.

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document. The EPA notes that the agency intends to produce risk communication materials that can be used by utilities and others as they deem appropriate to communicate about PFAS in drinking water. As the EPA develops implementation materials following final rule promulgation, the agency will consider additional resources to support states and water systems in communicating with and notifying their customers. For discussion of risk communication materials that the agency intends to develop related to this action, please see section 1.2 of the EPA response in this *Response to Comments* document. In this action, the EPA is only addressing PFAS contamination via drinking water, however through other efforts, the EPA is addressing other PFAS exposure pathways (see https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024). Including information additional routes of exposure aside from drinking water is outside the scope of the information traditionally included in CCRs and PN as these topics do not specifically relate to drinking water.

Aidan Cecchetti (Doc. #1640, SBC-044375)

• EPA requests comment on its proposal to designate violations of the proposed MCLs as Tier 2 (pg. 18684 Federal Register Volume 88, Number 60).

o The commenters agree with EPA's proposal to designate violations of the proposed MCLs as Tier 2. The commenters are not aware of any acute health impacts that are of great enough concern to elevate violations of the proposed MCLs to Tier 1. However, the health impacts and public concern associated with potential violations of the proposed PFAS NPDWR are too significant for violations to be designated as Tier 3.

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document.

National Rural Water Association (NRWA) (Doc. #1641, SBC-043277)

• EPA requests comment on its proposal to designate violations of the proposed MCLs as Tier 2.

Response: Tier 2 Public Notice is appropriate per the Public Notification Rule. An MCL Exceedance for these constituents should not require a Tier 1 Public Notice.

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044177)

3. NCDEQ recommends EPA clarify the health effects language proposed to be included in the public notification requirements.

NCDEQ supports EPA's decision to utilize Tier 2 public notification (PN) for the PFAS NPDWR, as this approach is consistent with other chemical MCLs with chronic effects. However, the proposed health effects language to be included is confusing and needs additional clarification. As it is currently written, EPA seems to have included both acute and chronic, or at least subchronic, effects in the PN language. Additionally, this PN language is inconsistent with the language the Agency used for the previous health advisories. The PN language discusses PFAS levels above the MCL being of concern, while the health advisory language discusses health impacts at much lower levels. This will create additional confusion with the public regarding the safety of their water. Finally, the language within the rule also loses the focus on sensitive subpopulations and only refers to "children." NCDEQ recommends that the Agency change this to include "pregnant individuals and infants."

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document for discussion of public notification tiering and updates to the mandatory health effects language for the final rule. The EPA acknowledges the commenter's support of Tier 2 public notification. The updated health effects language, which can be found in Appendix A to Subpart O and Appendix B to Subpart Q and is summarized in section IX.A.3 of the preamble for this action, includes language that focuses on potential developmental impacts during pregnancy and/or childhood.

Blue Ridge Environmental Defense League (BREDL) (Doc. #1663, SBC-044382)

We have the following additional recommendations:

• The public should be notified in the same way described in the proposed regulations when any PFAS are found in drinking water. EPA must get tough on state agencies that are dithering about providing the public with information that could impact their health.

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1568, SBC-042996. The EPA notes that the PN and CCR requirements established in this rulemaking are only for the six PFAS contaminants regulated under the final rule.

Blue Ridge Environmental Defense League (BREDL) (Doc. #1663, SBC-044385)

• EPA should review federally funded agency responses on public notification of PFAS detected in drinking water.

Notification—General

While BREDL supports the notification requirements for the six, we urge the Environmental Protection Agency (EPA) to include all PFAS detected in drinking water in the requirements. State and local agencies are doing an abysmal job of notifying the public when PFAS are found. So that the public can make informed decisions about possible mitigation measures, this needs to change. BREDL has found that in North Carolina, state agencies and local government responses range from inadequate to non-existent.

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1568, SBC-042996. The EPA notes that the PN and CCR requirements established in this rulemaking are only for the six PFAS contaminants regulated under the final rule.

The commenter's recommendation that the EPA "should review federally funded agency responses on public notification of PFAS detected in drinking water" is unclear; the EPA notes that as part of regulatory action, the agency has reviewed and considered all public comments on the proposed rule, including comments about public notification requirements.

Washington State Department of Health (DOH) (Doc. #1665, SBC-047715)

• Environmental Justice should be considered and addressed using language translation and accessibility tools in all PN resources.

EPA Response: Consideration of language translation and accessibility tools in all PN resources is outside the scope of this rulemaking effort. Consistent with the existing PN Rule, systems that serve a large proportion of consumers with limited English proficiency (as determined by the state) must include a notice in the appropriate language(s) regarding the importance of the notice or contact information to receive assistance or a translated copy of the report (40 CFR 141.205(c)(2)).

Advancing environmental justice (including language access) is an important priority for the agency and, as resources allow, the EPA will consider the commenter's recommendation when developing implementation materials for the final rule. For information on the EPA's environmental justice (EJ) analysis for this regulatory action, please see Chapter 8 of the Economic Analysis (EA) (USEPA, 2024c); for a summary of the EPA's response to comments related to the EPA's EJ analysis, please see section 14.10 of the EPA response in this *Response to Comments* document.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044392)

DOH agrees that tier 2 public notification is appropriate as it is consistent with the current framework for minimum contaminant levels (MCLs) for contaminants with chronic effects. DOH asks that EPA clarifies language for health effects above the MCL and differentiates between health advisory language addressing potential health effects and lower PFAS levels.

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044426)

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EPA requests comment on its proposal to designate violations of the proposed MCLs as Tier 2.

• This is consistent with how EPA addresses 2,3,7,8-TCDD (dioxin), which is also a bioaccumulating contaminant that that poses immune, developmental and cancer risks.

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-044921)

Section 6: Safe Drinking Water Right to Know

EPA is proposing a Tier 2 public notification for a violation of one or more of these three proposed MCLs. Cleveland Water believes this is consistent with existing regulation and general practice and therefore supports EPA's decision.

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document. The EPA acknowledges the commenter's support for the PN requirements for this action.

City of Vancouver Water Utility, Vancouver, WA (Doc. #1684, SBC-044316)

Public Notification Requirements:

Although Vancouver agrees that a PFAS MCL exceedance should be a Tier 2 violation given past practice for other bioaccumilating contaminants, we do not believe that quarterly notification is necessary, unless alternative methods of delivery are allowed.

The City of Vancouver recently completed a public notification to 122,876 customers in the form of a mailed hard copy letter. This was at an expense of $48,000 for printing and mailing. If this is required each quarter, our rate payers will be paying $192,000 a year just for the public notifications. It would be beneficial if EPA published some options for electronic delivery methods for Tier 2 public notification. Consider that different types of communication methods may reach different audiences. Public notification options should include a balance of methods to both save on costs for repeat public notification while attempting to ensure more customers maintain awareness. Electronic delivery is allowed for CCRs, for which EPA has provided guidelines, but not for tier 2 public notification.

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document for discussion of PN tiering. The requirements governing the form and manner of Tier 2 public notifications are set forth in the EPA's PN Rule at 40 CFR Part 141, Subpart Q and are beyond the scope of this rulemaking. Consistent with the existing PN Rule, PWSs must provide the notice in a form and manner reasonably calculated to reach all persons served. Primacy agencies have the authority to approve alternative delivery methods in writing [§141.202(c)(4), § 141.203(c) and § 141.204(c)].

The EPA acknowledges the commenter's submission of cost information associated with issuing PNs. With respect to the commenter's assertion about PN-related costs, the EPA assumes 100 percent compliance for its national level analysis in the EA for the final PFAS NPDWR because the EPA has determined that the final rule is feasible given known occurrence concentrations and efficacy of the technologies available. For the EPA's response to comments on public notification burden, please see section 13.3.5 of the EPA response in this *Response to Comments* document.

Additionally, with respect to PN-related costs more generally, the EPA has evaluated the costs to comply with the PN Rule under a separate rulemaking action.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045034)

Safe Drinking Water Right To Know

EPA has proposed to designate violations of the proposed MCLs as Tier 2 and, pursuant to 40 CFR 141.203(b)(1), notification would be provided as soon as practicable but no later than 30 days after the system learns of the violation. NJDEP recommends that EPA evaluate the frequency and method of delivery for public notification, as well as providing additional tools for states and water systems to address questions and concerns from consumers. It has been New Jersey's experience that the unique nature of PFAS and their health impacts are difficult to communicate effectively within the structure of a public notice document. Water systems in New Jersey have faced enhanced interest from customers after issuing their public notices. Water systems, state agencies, and EPA must work together to provide consistent messaging to the public regarding these proposed drinking water standards. NJDEP has found it crucial to proactively engage water systems and the public by conducting media outreach, hosting stakeholder events, and building easily accessible resources.

Clarification is needed from EPA regarding Tier 2 public notice requirements for all triggering violations, not just PFAS, specifically for ongoing and subsequent MCL violations as 40 CFR 141.203 requires public notice to be issued every three months as long as the violation or situation continues. Requiring a 30- day public notice for each quarterly violation in addition to a 3-month public notice is redundant, an additional cost burden, and may diminish the intent behind public notice.

Once a water system triggers the public notice requirements under Public Notification Rule at 40 CFR 141 Subpart Q because of an initial MCL violation, NJDEP recommends that, for any subsequent violation occurring at the same location for the same parameter, a water system should issue public notice on the established three-month schedule based on the initial violation. Under this framework, a water system would only issue four public notifications a year instead of eight public notifications, including an ongoing public notice and an additional quarterly public notification where compliance sampling does not fall within the ongoing timeframe. The subsequent public notice will meet the goals of a 30-day notice by capturing the most recent violation, running annual average, and providing an update on the water system's actions to return to compliance. NJDEP's recommendation is informed by its experience implementing its own PFAS standards; many New Jersey water systems have been unable to remediate and comply with the MCL by the next quarter. A significant number of New Jersey water systems are currently conducting ongoing public notice.

In addition to the frequency of public notice, NJDEP recommends that EPA evaluate the method of delivery for ongoing public notice. Commonly in New Jersey, corrective actions for PFAS can take many years to complete, which the proposed rule allows. Since the required language is lengthy and repetitive, continuous public notice can become redundant and have the effect of desensitizing customers to important information. Continuous public notice also becomes very costly for a water system and potentially diverts funding that could be used towards corrective actions. Therefore, NJDEP recommends EPA evaluate allowing additional delivery methods for Tier 2 notices. EPA should consider, after the initial public notice, allowing for water systems to issue public notice electronically (e.g., via email) or through other methods as appropriate to any customer that has previously received a notice as a hard copy, with an option for customers to request to receive the public notice hard copy continuously.

EPA requested comments on what may be needed for water systems to effectively communicate information to the public. EPA currently does not have a public notice template for the proposed MCLs. The requirements of the Public Notification Rule at 40 CFR 141 Subpart Q are broad, ambiguous in application, and often challenged by water systems. NJDEP is requesting that, during implementation, EPA provide more guidance and clarity on the required contents and configuration of the public notice and provide public notification templates for all regulated PFAS contaminants including approved health language. Additionally, as previously stated, it has been New Jersey's experience that the unique nature of PFAS and its health impacts are difficult to communicate effectively within the structure of a public notice document. NJDEP recommends EPA consider evaluating public notice templates and developing additional tools for risk communication to consumers. These include materials that can be utilized by states and water systems to better communicate the differences between the Health Advisories and the proposed MCLs and HI.

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document for discussion of the tiering of public notification, PN requirements for repeat notice, and updates made to the mandatory health effects language for the final rule. In

response to the commenter's concerns about messaging to the public about the PFAS NPDWR and the commenter's recommendations regarding public outreach and communication, the EPA intends to develop public notification templates as part of the guidance that will be developed following rule promulgation and will consider the commenter's recommendations during the implementation of the final rule as resources allow. For further discussion of risk communication materials that the agency intends to develop related to this action, please see section 1.2 of the EPA response in this *Response to Comments* document.

In response to the commenter's recommendation that the agency "evaluate the method of delivery for ongoing public notice", the EPA notes that the requirements governing the form and manner of public notifications are set forth in the EPA's PN Rule at 40 CFR Part 141, Subpart Q and are beyond the scope of this rulemaking. Consistent with the existing PN Rule, PWSs must provide the notice in a form and manner reasonably calculated to reach all persons served. Primacy agencies have the authority to approve alternative delivery methods in writing [§141.202(c)(4), § 141.203(c) and § 141.204(c)].

In response to the commenter's assertion that "continuous public notice also becomes very costly for a water system," please see the EPA response to comment Doc. #1684, SBC-044316 in section 9.2 in this *Response to Comments* document.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045108)

Section X – Safe Drinking Water Right to Know

1) EPA Requests comment on its proposal to designate violations of the proposed MCLs as Tier 2.

Vermont would support EPA's decision to utilize Tier 2 public notification (PN) for the PFAS NPDWR, if the health effects of PFAS are consistent with other chemical MCLs with chronic health effects. However, the proposed health effects language is confusing and would benefit from further clarification. EPA has included both acute and chronic, or at least sub-chronic, effects in the Public Notice (PN) language. Additionally, this PN language is inconsistent with the language the Agency used for the previous health advisories. The PN language discusses PFAS levels in excess of the MCL being of concern, while the health advisory language discusses health impacts at much lower levels. This will create additional confusion with the public regarding the safety of their water. The language within the rule also loses the focus on sensitive sub-populations and only refers to "children." This should be clarified by the EPA to include "pregnant individuals and infants."

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document for discussion of public notification tiering and updates to the mandatory health effects language for the final rule. The updated health effects language, which can be found in Appendix A to Subpart O and Appendix B to Subpart Q and is summarized in section

IX.A.3 of the preamble for this action, includes language that focuses on potential developmental impacts during pregnancy and/or childhood.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045148)

Public notice

MassDEP supports EPA's decision to utilize Tier 2 public notification (PN) for the PFAS NPDWR. Note that, as the proposed rule is presented in the Federal Register, the proposed updates to Appendices A and B of Subpart Q of 40 CFR Part 141 appear incomplete. The new PFAS entries under the Synthetic Organic Chemicals (SOC) heading, rows 31-33 in Appendix A, lack Contaminant names and the citations for "Monitoring & testing procedure violations" are incomplete ("141.XX") (88 Fed. Reg. 18638, 18749). The new PFAS rows in Appendix B to Subpart Q of Part 141 lack the row numbers 90-92 (88 Fed. Reg. at 18750). Additionally, based on the existing SOC entries, when the MCLG is zero the word is spelled out rather than listing the number "0." The "MCLG mg/L" and "MCL mg/L" headers need to be modified to add "(unless otherwise noted)" to accommodate the HI. If the intent of footnote 24 is to refer to the HI definition, then move the footnote to the Contaminant entry.

EPA Response: The EPA acknowledges the commenter's support of the agency's decision to utilize Tier 2 public notification for this action. Please see section 9.2 of the EPA response in this *Response to Comments* document for a discussion of PN tiering. As the commenter recommended, for the final rule the EPA has added the chemical names to Appendix A to Subpart Q and inserted valid CFR citations in the "Monitoring & testing procedure violations" column. In Appendix B to Subpart Q, the EPA also agrees with the commenter and added numbers preceding the chemical names, changed instances of 0 to "zero," and deleted footnote 24, choosing instead to add the definition of *Hazard Index* to § 141.153(c). In both appendices cited in this comment, while a parenthetical saying "unless otherwise noted" was not added to the column headers for the MCLG and MCL columns, the EPA notes that this parenthetical note ("unless otherwise noted") is provided in §141.50 and Table 4 to paragraph (c) of §141.61, which provide information on MCLG and MCL values and units for the final rule, respectively.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045974)

Section 6: Safe Drinking Water Right to Know

Section 6.1: Public notification

EPA is proposing a tier 2 public notification for a violation of one or more of these three proposed MCLs. AMWA believes this is consistent with existing regulation and general practice and, therefore, supports EPA's decision.

EPA Response: The EPA acknowledges the commenter's support for requiring Tier 2 public notification for violations of this rule's MCLs. Please see section 9.2 of the EPA response in this *Response to Comments* document for further discussion of PN requirements.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045237)

Public Communications

1. EPA requests comment on its proposal to designate violations of the proposed MCLs as Tier 2.

Designating the PFAS NPDWR public notification (PN) as Tier 2 is appropriate and consistent with other MCLs. The Tier 2 PN requires an MCL violation notification as soon as practicable, but no later than 30 days, and to repeat every 3 months if the violation persists (unless the primacy agency deems unnecessary). In keeping with the PN rule of the Safe Drinking Water Act, Tier 2 PN will help ensure that customers know if there is a problem with their drinking water. A more relaxed notification schedule, such as Tier 3, could potentially result in Connecticut residents being exposed to PFAS for as long as a year before they were made aware of the problem.

EPA Response: The EPA acknowledges the commenter's statement that requiring Tier 2 public notification for violations of this rule's MCLs is appropriate and consistent with other MCLs. Please see section 9.2 of the EPA response in this *Response to Comments* document for further discussion of PN requirements.

West Virginia Rivers Coalition et al. (Doc. #1746, SBC-045259)

[In particular, we strongly support their calls for EPA to:]

• Adjust the public notice designation for violations of the PFAS MCLs from Tier 2 to Tier 1

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document.

City of Thornton, Colorado (Doc. #1748, SBC-044797)

Although Thornton supports the implementation of the PFAS MCL, we urge the EPA to consider using Tier 3 Public Notice guidance for systems that exceed the MCL. Since the health risks associated with the PFAS contaminants are more chronic in nature rather than acute, annual notice should acceptably protect public health. While complicating the rule, Thornton could support a multi-tiered approach where systems that exceed twice the MCL (>8ppt/HI > 2) issue a Tier 2 Public Notice, while systems between 1-2 times the MCL issue a Tier 3 Public Notice. Thornton supports the use of a RAA for compliance and public notice requirements; a one-time sampling exceedance of the MCL should not cause a violation or require public notice. EPA should also consider revisions to public notice required for monitoring failures. In 2023,

Thornton has already had trouble with UCMR5 PFAS testing wherein a PFAS sample was taken early in the quarter, but the contract lab did not notify the city of a QC failure until almost ten weeks later. With contract lab turnaround times frequently exceeding two months, this would leave insufficient time to sample and report results within the proposed quarterly monitoring framework. With expected increases in PFAS monitoring needs as the proposed rule is implemented, Thornton anticipates lab turnaround times will get even worse. Lab capacity already cannot meet demand and adding additional capacity will be slower than the rate of increased demand due to shortages of staff capable of performing such a technically challenging analysis and the difficulty labs face in meeting certification requirements for the analysis. Thornton suggests that the EPA exempt systems that have made best faith efforts to monitor PFAS from Tier 3 Public Notice. Alternatively, Thornton suggests that the EPA consider extending reporting time requirements to reflect the known issues with lab capacity, so that samples taken late in the quarter can still be counted towards a system's monitoring requirement. Thornton also requests that the EPA develop the communication and health-based language required for the CCR and Public Notice for the health effects of PFAS. However, it is imperative that EPA also communicates, or allows utilities to communicate to the public, that consumer risk from PFAS is not solely from drinking water due to the ubiquity of PFAS in other consumer products. Thornton does not want customers to think they are completely safe from the risks of PFAS just because their drinking water provider has met the MCL. Also, in the Tier 2 Public Notice language, EPA also needs to clearly communicate that bottled water may not be a safe alternative since it is regulated differently and may contain higher concentrations of PFAS than the drinking water from the utility required to issue the notice.

EPA Response: The EPA acknowledges the commenter's support of the implementation of the PFAS MCLs that will be promulgated as part of this action. The EPA disagrees with the commenter's suggestion that the agency use "Tier 3 Public Notice guidance for systems that exceed the MCL" and the commenter's suggestion to use a "multi-tiered approach" for public notification tiering; please see section 9.1 of the EPA response in this *Response to Comments* document for discussion related to CCR requirements and section 9.2 of the EPA response in this *Response to Comments* document for discussion related to PN requirements, including discussion of PN tiering and updates to the mandatory health effects language for the final rule. The EPA agrees that PFAS is a chronic contaminant and has required Tier 2 PN notification for an MCL violation consistent with public notification for other chronic contaminants.

The EPA acknowledges the commenter's support of the use of a RAA for MCL compliance. The EPA notes that the RAA, not a single sample result, determines whether there is a violation (and thus the issuance of PN). For further discussion of use of RAAs, please see section 8.2 of the EPA response in this *Response to Comments* document and section VIII.B of the Federal Register Notice for this action.

The EPA disagrees with the commenter's suggestion that the final rule should exempt systems from Tier 3 PN if they fail to monitor or extend the timeframe for reporting on PFAS contaminants due to laboratory capacity issues cited by the commenter. This requirement for

water systems to report monitoring results is the same for all other NPDWRs and the EPA's evaluation of feasibility reflects that there will be sufficient laboratory capacity to support implementation of the PFAS NPDWR. Please see section 5.1.2 of the EPA response in this *Response to Comments* document for discussion of laboratory considerations, including capability and capacity. Additionally, the EPA notes that it is the water system's responsibility to ensure that required testing is completed, and if it is not completed the system has a responsibility to notify the public. Public notices are required to address whether alternative water supplies should be used and what actions consumers should take [§ 141.205(a)], for example, using a filter.

In response to the commenter's suggestion that the EPA should "clearly communicate that bottled water may not be a safe alternative", the EPA notes that CCRs are required to include a brief explanation of contaminants which may reasonably be expected to be found in drinking water, including bottled water [§ 141.153(h)(1)]. The Food and Drug Administration (FDA) regulations establish limits for contaminants in bottled water which must provide the same protection for public health. As the EPA develops implementation materials following final rule promulgation, the agency will consider additional resources to support states and water systems for notifying their customers. In developing the PN templates, the EPA will consider adding directions and recommendations for consumers with respect to suggested actions they can take or for seeking alternative sources of water, such as bottled water. The EPA will evaluate and consider if adding a reminder for consumers to verify the water quality of bottled water is appropriate in developing the PN templates.

Harris County Attorney's Office (HCA) (Doc. #1751, SBC-045264)

EPA should ensure communities are given sufficient notice regarding PFAS contamination and potential health consequences.

Under current rules, all PWS must give public notice for all violations of NPDWRs and for other situations. EPA proposes that violations of the three PFAS MCLs would be designated as Tier 2. As such, PWS would be required to issue a notification of an MCL violation as soon as practicable but no later than 30 days after the system learns of the violation. Additionally, CWS would be required to provide Tier 2 public notices by mail or other direct delivery to each customer receiving a bill and to other service connections to which water is delivered by the public water system and by any other method reasonably calculated to reach other persons regularly served by the system, if they would not normally be reached by the former method (e.g. apartment and house renters, university students, and prison inmates etc.). Other methods may include: publication in a local newspaper, delivery of multiple copies for distribution by customers that provide their drinking water to others (e.g., apartment building owners or large private employers), posting in public places served by the system or on the Internet, or delivery to community organizations. [FN9: 40 CFR 141.203(c) (emphasis added).]

HCA asks EPA to encourage water systems to utilize a higher level of notice than what is required for Tier 2, especially given the urgent health effects and limited public knowledge and name recognition of PFAS. These encouraged methods could include the optional Tier 2

methods or required Tier 1[FN10:40 CFR 141.202(c).] methods – newspaper and broadcast publication, posting in public places, delivery to community organizations, etc. HCA also asks community outreach and alerts, specifically related to the health effects of PFAS exposure, be provided in plain, accessible language and that notification templates be provided by the EPA in multiple spoken languages.

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document for discussion of the EPA's decision regarding PN tiering for the final rule. With respect to the comments suggesting that the EPA encourage use of a higher level of notice and certain methods for PN, the EPA will consider these comments in developing implementation guidance. With respect to the commenter's request that "notification templates be provided by the EPA in multiple spoken languages," please see the EPA response to comment Doc. #1665, SBC-047715 in section 9.2 in this *Response to Comments* document. As the EPA develops implementation materials following final rule promulgation, the agency will consider additional resources to support states and water systems for notifying their customers, as resources allow.

American Water Works Association (AWWA) (Doc. #1759, SBC-045629)

10. Public Notifications

Public notifications serve an important role in protecting public trust in drinking water and their usefulness for communities relies on a solid foundation for risk communication. The proposal requires that water systems with PFAS levels exceeding the MCLs must provide a Tier 2 notification to the public and Tier 3 notifications when a monitoring and/or testing procedure violation has occurred. Water systems will also be required to include information about detections of regulated PFAS in the CCR.

AWWA supports the proposed approach for public notifications for PFOA and PFOS. While AWWA is recommending in this letter that the proposed regulation for PFHxS, PFNA, HFPO-DA, and PFBS be revised based on the discussed technical and legal issues, the agency is reminded that the risk communication for PFAS must be carefully and thoughtfully structured. The role of public communications is to provide useful information to the public about their drinking water. As EPA considers any rule for PFAS through a hazard index, it is important that regulations be structured in a manner that facilitates useful risk communication.

EPA Response: Please see section 9.1 of the EPA response in this *Response to Comments* document regarding CCR requirements and section 9.2 of the EPA response in this *Response to Comments* document regarding PN requirements. The EPA acknowledges the commenter's support for the PN requirements for PFOA and PFOS in this action.

With respect to communication of the Hazard Index standard, the EPA is including a definition of the *Hazard Index* in 40 CFR 141.153(c)(3)(v) of the CCR Rule to improve clarity and understandability for consumers. As the EPA develops implementation materials following final

rule promulgation, the agency will consider additional resources to support states and water systems for notifying their customers.

Bowling Green Municipal Utilities (Doc. #1767, SBC-043933)

Public Notifications: Public notice of a violation as a Tier 2 notification is unnecessary. Any violation should be reported in the CCR as distributed to the public. There is a great deal of misunderstanding in the public on how a running annual average works; generally the public sees any exceedance as a problem even if the RAA is under the MCL. As EPA has unwisely stated that "No level of PFOS/PFOA" is acceptable, this has placed water providers into an untenable position.

EPA Response: Please see section 9.1 of the EPA response in this *Response to Comments* document on CCR requirements and section 9.2 of the EPA response in this *Response to Comments* document on PN requirements. The EPA notes that PN is only required when there is a violation and for PFAS this is based on a RAA. The EPA uses RAAs for many other chemical contaminants, including Synthetic Organic Contaminants (SOCs), and in those scenarios the RAA, not a single sample result, determines whether there is a violation. For further discussion of use of RAAs, please see section 8.2 of the EPA response in this *Response to Comments* document and section VIII.B of the Federal Register Notice for this action. The EPA has not stated that "no level of PFOS/PFOS is acceptable." Rather, the EPA has followed long-standing agency practice of establishing the MCLG at zero for PFOA and PFOS based on the determination that these two contaminants are *Likely to be Carcinogenic to Humans* (please see section IV of the preamble for this action). The EPA simultaneously set enforceable MCLs, levels below which systems are in compliance with the EPA's enforceable drinking water standards and do not require PN under this rule. The MCL, not the MCLG, determines which levels of PFOA and PFOS are "acceptable" in drinking water. See section V of the preamble for this action for further discussion.

Environmental Protection Network (EPN) (Doc. #1773, SBC-043875)

Public Notification

EPA proposes that violations of any one or more of the three MCLs would be designated as Tier 2. As a result, the PWS must notify the public of the violation as soon as practicable but no later than 30 days after the system learns of the violation. EPN recommends that EPA clarify that public notification must occur whenever there is a violation at any one distribution point. EPN further recommends that the public notification should remain in place until the public water system returns to compliance, as required.

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document for discussion of PN requirements. In response to the commenter's recommendation that "the public notification should remain in place until the PWS returns to compliance," the EPA notes that the form and manner of PN delivery is beyond the scope of this

rulemaking. Additionally, in response to the commenter's request that the EPA "clarify that public notification must occur whenever there is a violation at any one distribution point", the EPA has determined in the final rule that the regulated PFAS contaminants require Tier 2 PN to be issued in the event of an MCL violation. As stated in Section 141.905(b) of the final rule, if any entry point has a violation, then the system is in violation. The EPA does not agree with the commenter that there should be a violation (and therefore PN required) whenever there is an exceedance of the MCL at any one distribution point because PFAS are chronic contaminants and an MCL violation is based on a RAA of four quarterly samples to evaluate the persistence of the contamination, consistent with the compliance approach for other chronic contaminants in the NPDWRs. However, the EPA does note that CWSs will need to report in their CCR all detected results, which would include results that exceed the MCL. For further discussion of use of RAAs, please see section 8.2 of the EPA response in this *Response to Comments* document and section VIII.B of the Federal Register Notice for this action.

Earthjustice et al. (Doc. #1808, SBC-046121)

D. EPA's Proposed Tier 2 Designation for Violations of its PFAS MCLs Does Not Account for Acute Toxicity and Must be Amended

To "ensure[] that consumers will know if there is a problem with their drinking water," the SDWA requires "each owner or operator of a public water system" to give notice to consumers of all violations of a NPDWR through public notice. [FN216: Proposed Rule, 88 Fed. Reg. at 18,684; 40 C.F.R. § 141.201(a), (c).] "The public notice requirements for each violation or situation," "are determined by the tier to which [the violation or situation] is assigned." [FN217: 40 C.F.R. § 141.201(b).]

Tier 1 notice is required for violations and situations "with significant potential to have serious adverse effects on human health as a result of short-term exposure" and must be provided as soon as practical but no later than 24 hours after the system learns of the violation. [FN218: Id. §§ 141.202(a)(9), 141.202(b)(1).] Tier 2 notice applies to all violations and situations not designated as Tier 1 but which have the "potential to have serious adverse effects on human health" and must be provided as soon as practical but no later than 30 days after the system learns of the violation. [FN219: Id. §§ 141.201(b), 141.203(b).] Finally, Tier 3 notice is required for all NPDWR violations and situations not included in Tier 1 and Tier 2 and must be provided "not later than one year after the public water system learns of the violation or situation or begins operating under a variance or exemption." [FN220: Id. § 141.204(b).]

In the Proposed Rule, EPA proposes designating violations of the MCLs for the Six PFAS as requiring "Tier 2" public notice. [FN221: Proposed Rule, 88 Fed. Reg. at 18,684.] This proposal ignores the acute toxicity of the Six PFAS, and EPA must modify its proposal to require Tier 1 public notice for violations of all the proposed MCLs so consumers can be informed of the potential for significant harm in a timely manner.

EPA's proposal "that violations of the three MCLs . . . be designated as Tier 2" for purposes of the public notification rule ignores scientific evidence establishing a link between serious adverse health effects and short-term exposure to the Six PFAS. [FN222: Id. "The proposed rule also designates monitoring and testing procedure violations as Tier 3[.]" Id. at 18,699.] EPA acknowledges that exposure to PFOA and PFOS "may have an adverse effect on the health of persons" and that PFHxS, GenX, PFNA, and PFBS "may individually and in a mixture each result in adverse health effects, including disrupting multiple biological pathways that result in common adverse effects on several biological systems including the endocrine, cardiovascular, developmental, immune, and hepatic systems." [FN223: Id. at 18,644–45.] However, while EPA acknowledges that these PFAS can cause serious harms, its analysis focuses significantly on chronic harms at the expense of a careful analysis of the harms these PFAS pose in the short-term. [FN224: Id. at 18,645–46 (citing studies of mice dosed for 42–44 days or 53–64 days, for example).] As a result of the short shrift EPA gave to acute toxicity studies, it has mis-designated the violation of the proposed MCLs for public notification purposes.

The Six PFAS all pose short-term health harms. Acute and short-term health effects for PFOA, PFOS, PFHxS, and PFNA are summarized in ATSDR's Toxicological Profile for Perfluoroalkyls. [FN225: ATSDR 2021 at 62, 84, 88-99.] Acute PFOA exposure is associated with liver, immunological, reproductive, and developmental effects. [FN226: Id. at 62.] Acute PFOS exposure is associated with liver, immunological, and developmental effects. [FN227: Id. at 84.] Acute PFNA exposure is associated with liver and immunological effects as well as changes in body weight. [FN228: Id. at 88-90.]

Acute exposure to PFOS has also been found to affect the plasticity of brain synapses, creating neurotoxic harm, [FN229: Qian Zhang et al., Effects Of Perfluorooctane Sulfonate and its Alternatives on Long-Term Potentiation in The Hippocampus CA1 Region if Adult Rats in vivo, 5 Toxicology Rsch. 539, 539–546 (2016), doi: 10.1039/c5tx00184f.] and damage the liver. [FN230: Jiali Xing, Toxicity Assessment Of Perfluorooctane Sulfonate Using Acute and Subchronic Male C57BL/6J Mouse Models, 210 Env't Pollution 388–96 (2016), https://pubmed.ncbi.nlm.nih.gov/26807985/.] For PFOA, one study found that "cellular effects exerted after 24 h[our] exposure to perfluorooctanoic acid are non-reversible after a 48 h[our] recovery period." [FN231: Peropadre et al., An Acute Exposure to Perfluorooctanoic Acid Causes Non-Reversible Plasma Membrane Injury in Hela Cells, 260 Env't Pollution Art. No. 11400 (2020), https://pubmed.ncbi.nlm.nih.gov/31995777/.] Another study found that acute exposure to PFOA can "disrupt[] key hormones in the pancreas" and "induce[] lipid accumulation in the liver." [FN232: Xinmou Wu et al., Effect of Acute Exposure to PFOA On Mouse Liver Cells In Vivo And In Vitro, 24 Env't Sci and Pollution Rsch. Int'l 24201, 24203 (2017), https://pubmed.ncbi.nlm.nih.gov/28887612/.] Acute exposure to PFNA has been found to impair reproductive health, [FN233: Shilpi Singh & Shio Kumar Singh, Acute Exposure To Perfluorononanoic Acid in Prepubertal Mice: Effect on Germ Cell Dynamics and an Insight into the Possible Mechanisms of its Inhibitory Action on Testicular Functions, 183 Ecotoxicology Env't Safety Art No.109499, 1667 (2019), https://pubmed.ncbi.nlm.nih.gov/31398581/; Shilpi Singh & Shio Kumar Singh, Prepubertal Exposure to Perfluorononanoic Acid Interferes with

Spermatogenesis and Steroidogenesis in Male Mice, 170 Ecotoxicology Env't Safety 590, 598 (2019), https://pubmed.ncbi.nlm.nih.gov/30576894/; Shilpi Singh & Shio Kumar Singh, Effect of Gestational Exposure to Perfluorononanoic Acid On Neonatal Mice Testes, 39 J. of Applied Toxicology 1663, 1665 (2019), https://pubmed.ncbi.nlm.nih.gov/31389053/; Yixing Feng et al., Effects of PFNA Exposure on Expression of Junction-Associated Molecules and Secretory Function in Rat Sertoli Cells, 30 Reprod. Toxicology 429–37 (2010), https://pubmed.ncbi.nlm.nih.gov/20580666/.] and negatively impact liver functionality in diabetic mice. [FN234: Fang X, Perfluorononanoic Acid Disturbed the Metabolism of Lipid in the Liver of Streptozotocin-Induced Diabetic Rats, 25 Toxicology Mechanisms & Methods 622, 626 (2015), https://pubmed.ncbi.nlm.nih.gov/26056853/.] A study on PFHxS found that "a single neonatal exposure to PFHxS can cause irreversible neurotoxic effects in mice." [FN235: Henrick Viberg et al., Adult Dose-Dependent Behavioral and Cognitive Disturbances After a Single Neonatal PFHXS Dose, 304 Toxicology 185–91 (2013) https://pubmed.ncbi.nlm.nih.gov/23287389/.] PFHxS has also been found to pose similar brain development concerns as PFOS in response to acute exposure. [FN236: Qian Zhang et al., Effects of Perfluorooctane Sulfonate and its Alternatives on Long-Term Potentiation in The Hippocampus CA1 Region if Adult Rats, at 539 ("In addition, PFHxS and Cl- PFAES exhibited comparable potential to PFOS in disturbing LTP.").] PFBS has been found to have an effect on the liver which "may represent an acute response to the chemical at a high dose." [FN237: Lau et al., Pharmacokinetic Profile of Perfluorobutane Sulfonate and Activation of Hepatic Nuclear Receptor Target Genes in Mice, 441 Toxicology 152522 (2020), https://pubmed.ncbi.nlm.nih.gov/32534104/.] Additional acute studies of PFBS are identified in the Toxicity Assessment for PFBS. [FN238: EPA, Human Health Toxicity Values for Perfluorobutane Sulfonic Acid (CASRN 375-73-5) and Related Compound Potassium Perfluorobutane Sulfonate (CASRN 29420-49-3) (2021) at 50–51.]

EPA's Toxicity Assessment for GenX reviews 10 studies for acute toxicity and four studies for short term toxicity (seven-day dosing). [FN239: EPA, Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (CASRN 13252-13-6 and CASRN 62037-80-3) Also Known as 'GenX Chemicals' at 35-37.] Since the publication of that assessment, additional acute and short-term toxicity studies have been published. For example, Cannon et al. found that a single dose of GenX administered by oral gavage caused decreases in P- glycoprotein (P-gp) transport activity and breast cancer resistance protein (BCRP) transport activity in the brain capillaries of exposed rats. [FN240: Cannon et al., Effect of GenX on P-Glycoprotein, Breast Cancer Resistance Protein, and Multidrug Resistance-Associated Protein 2 at the Blood-Brain Barrier, 128 Env't Health Persp. 37002 (March 2020), https://doi.org/10.1289/EHP5884.] Further, a pair of studies by Conley et al. exposed rats from gestation day 14–18 or gestation day 17–21 respectively (i.e., 5 days of exposure) and found effects in both the dosed mothers and developing fetuses. [FN241: Conley et al., Adverse Maternal, Fetal, and Postnatal Effects of Hexafluoropropylene Oxide Dimer Acid (GenX) from Oral Gestational Exposure in Sprague-Dawley Rats, 127 Env't Health Persp. 037008 (Mar 2019), https://doi.org/10.1289/EHP4372 ("Conley 2019"); Conley et al., Hexafluoropropylene

Oxide-Dimer Acid (HFPO-DA or GenX) Alters Maternal and Fetal Glucose and Lipid Metabolism and Produces Neonatal Mortality, Low Birthweight, and Hepatomegaly in the Sprague-Dawley Rat, 146 Env't Int't 106204 (Jan. 2021) https://doi.org/10.1016/j.envint.2020.106204 ("Conley 2021").] In animals exposed from gestation day 14–18, fetal and maternal livers had increased expression of genes in the PPAR signaling pathway, and rats exposed to GenX gained less weight during their pregnancy and had larger livers than unexposed animals. [FN242: Conley 2019 at 037008-6 to 037008-8.] Results were similar for animals exposed from gestation day 17–21. [FN243: Conley 2021 at 106204-4 to 106204-10.] Additionally, Blake et al. (2023) exposed CD-1 mice from gestation day 1.5 to 11.5 or 17.5 (i.e. 10 days or 17 days of exposure) and found that exposed mothers gained more weight during the dosing period, had larger livers that showed "abnormal ultrastructure with enlarged hepatocytes," had larger kidneys and altered blood clinical chemistry, including increased cholesterol, HDL, and ALT levels. [FN244: Blake et al., Evaluation of Maternal, Embryo, and Placental Effects in CD-1 Mice Following Gestational Exposure to Perfluorooctanoic Acid (PFOA) or Hexafluoropropylene Oxide Dimer Acid (HFPO-DA or GenX), 128 Env't Health Persp. 128 (Feb. 2020), https://doi.org/10.1289/EHP6233.] GenX exposed fetuses had a larger embryo:placenta weight ratio and increased placental lesions. [FN245: Id.]

These health risks are significant and require swift public notice so consumers can take immediate action to protect themselves from exposure. Accordingly, EPA should adjust the proposed public notice designation for violations of the PFAS MCLs from Tier 2 to Tier 1 in the final rule.

EPA Response: The EPA disagrees with the commenter that the agency should adjust public notification tiering for MCL violations from Tier 2 to Tier 1; please see section 9.2 of the EPA response in this *Response to Comments* document for discussion of PN requirements, including PN tiering. The EPA acknowledges that developmental exposure can result in health effects occurring in less than lifetime scenarios which is why the mandatory health effects language for regulated PFAS to be included in PN and CCRs includes language such as the following (with PFOA used as an example here): "In addition, there may be increased risks of developmental and immune effects for people who drink water containing PFOA in excess of the MCL following repeated exposure during pregnancy and/or childhood." Additionally, as described in section 9.2 of the EPA response in this *Response to Comments* document, the EPA acknowledges that there may be instances in which it is appropriate to elevate the tiering of PN on a case-by-case basis. Under the existing PN Rule in 40 CFR 141.202(a), a violation that routinely requires a Tier 2 notice but poses elevated risk from short-term exposure, as determined by the primacy agency, may be elevated to Tier 1.

The EPA also disagrees that the analysis does not carefully consider harms PFAS pose after developmental exposure. The Health Based Water Concentrations (HBWCs) and/or MCLGs for PFNA, HFPO-DA, and PFBS were all based on reproductive or developmental studies that used less-than-chronic exposure designs targeting sensitive lifestages (please see section III.B of the

federal register notice for this action and section 3 of the EPA response in this *Response to Comments* document). The commenter cites the ATSDR Toxicological Profile for Perfluoroalkyls (ATSDR, 2021) to support this claim, while ignoring that the EPA relied on that same assessment as the source of reference values for PFNA and PFHxS. Similarly, the EPA considered less-than-chronic exposure studies when developing the final toxicity assessments for PFOA and PFOS (USEPA, 2024a; USEPA, 2024b), particularly studies of developmental, reproductive, immunological, and neurological toxicity. Subsequently, the Reference Doses (RfDs) for PFOA and PFOS are based in part on developmental effects.

Wisconsin Department of Health Services (Doc. #1823, SBC-044279)

May 25, 2023

Jennifer McLain, Director

Office of Ground Water and Drinking Water

U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, NW Washington, DC 20460

Subject: Comments on National Primary Drinking Water Regulations: Per- and poly- fluoroalkyl substances (PFAS) Rules Promulgation (88 FR 18638, EPA-HQ-OW- 2022-0114)

Dear Dr. McLain,

As Wisconsin's lead public health agency, the Wisconsin Department of Health Services (WDHS) works closely with the Wisconsin Department of Natural Resources (WDNR) to address environmental health concerns statewide. We appreciate EPA's actions to set drinking water standards for several PFAS, something heavily needed as we continue to discover and respond to contamination by these substances in Wisconsin drinking water supplies. We concur with comments on the proposed PFAS rules that were submitted by WDNR and, in this letter, we are submitting an additional comment.

While the proposed rules include public notification requirements, sole reliance on the conventional public notice framework and use of consumer confidence reports is not responsive to situations involving substances with known risks from shorter than chronic exposures, including PFAS. As a result, sensitive sub-populations do not receive clear, actionable information in time to make meaningful personal risk management decisions about their water. WDHS recommends that EPA consider public notification requirements that reflect sound risk communication strategies to support community members at greatest risk from unsafe exposures to PFAS in drinking water.

PFAS have been shown to have health impacts on timescales shorter than chronic exposure, and timely communication of elevated PFAS levels can equip individuals to make informed risk management decisions; delaying that notification puts individuals at unnecessary risk.

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document.

Wisconsin Department of Health Services (Doc. #1823, SBC-044281)

We know that shorter term exposures to PFAS are meaningful for sensitive subpopulations, such as pregnant individuals and young children. The ATSDR Exposure Assessment studies found that interruption of PFAS exposures has a demonstrated impact on lowering PFAS body burden. However, with respect to drinking water exposures, this risk reduction behavior is predicated on an individual's awareness of PFAS sampling results. Under the current notification guidelines, several quarters of results that marginally exceed the proposed MCL can be collected, which may result in many months going by without public notification of levels of PFAS that are known to cause adverse health impacts.

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document.

Plymouth Village Water & Sewer District (Doc. #1827, SBC-044563)

[Please carefully consider the following points to help inform the pending rulemaking on this class of pervasive and persistent PFAS chemicals:]

• Hundreds of systems are likely to be in a continuous public notification cycle for years. This will initially cause public alarm, followed by desensitization and resistance to increasing water rates for necessary funding, overall eroding public trust in public water supplies.

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1576, SBC-042456 in section 9.2 in this *Response to Comments* document for discussion of PN requirements for repeat notice.

Wisconsin Department of Natural Resources (Doc. #1828, SBC-044802)

Public Notice

WDNR agrees with comment from ASDWA and recommends EPA clarify the health effects language proposed to be included in the public notification requirements. The public notice language referencing both chronic and acute health effects is confusing.

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document.

Corix Infrastructure Inc. (Doc. #1834, SBC-045372)

[With regards to the specific items EPA has requested comment on, Corix provides below:]

• We support the designation of violations of the proposed MCLs as Tier 2.

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document. The EPA acknowledges the commenter's support of Tier 2 public notification for this action.

Little Hocking Water Association (Doc. #1835, SBC-045519)

Comment on public notification requirements.

EPA is proposing to require water suppliers to comply with the Consumer Confidence Report (CCR) requirements of 40 CFR 141 Subpart O and inform customers if PFAS are detected in the CCR and the public notification rule. LHWA supports these public notification requirements.

EPA Response: Please see section 9.1 of the EPA response in this *Response to Comments* document for discussion of CCR requirements and section 9.2 of the EPA response in this *Response to Comments* document for discussion of PN requirements. The EPA acknowledges the commenter's support for the agency's public notification requirements for this action.

Little Hocking Water Association (Doc. #1835, SBC-045520)

However, EPA proposes that violations of the proposed PFAS MCLs be designated as Tier 2, which requires notification as soon as practicable but no later than 30 days after the system learns of the violation. LHWA does not support the Tier 2 designation. Instead, violations of the proposed PFAS MCLs should be designated as Tier 1 violations, requiring public notice as soon as practical but no later than 24 hours after the system learns of the violation. As stated above, people have been unknowingly dosed with PFAS for over 60 years. We do not know which dose is the one that will a person sick. As such, EPA should be using the "nth dose" policy as the most protective of human health.

References

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Butler Township Website, April 13, 2023. April 13, 2023 Well Testing Results Presentation Slides, Public presentation at the Township Meeting Hall presenting final results, 38 slides, accessed May 26, 2023, https://butlertownship.com/wp- content/uploads/2023/04/April-13-2023-Well-Testing-Results-Presentation-Sides-.pdf.

Chemours, May 5, 2023a. Little Hocking Water Association PFOA and HFPO-DA, Analytical Results – Granular Activated Carbon Treatment System March 2023 No. 2 Biweekly Sampling Event, April 2023 No. 1 Biweekly Sampling Event, and 1Q23 Production Wells, letter to Mr. John Smith, Little Hocking Water Association from Andrew Hartten, Chemours, 66 pp.

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Galloway, J. A., Moreno, A. V. P., Lindstrom, A. B., Strynar, M. J., Newton, S., May, A. A., and Weavers, L. K., 2020. Evidence of Air Dispersion: HFPO-DA and PFOA in Ohio and West Virginia Surface Water and Soil Near A Fluoropolymer Production Facility, Environmental Science & Technology 2020 54(12), 7175-7184, DOI: 10.1021/acs.est.9b07384, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8015386/.

Ohio Department of Health, July 1, 2021. Overview of PFAS Testing in Private Water Wells Near the Aullwood Farm Discovery Center, Citizen Advisory, 3 pp, 1 map.

Ohio EPA, January 2, 2007. Letter to William McAfee, Mayor, City of Belpre from Sarah Wallace, Ohio EPA regarding criteria for carbon changeout. 2 pp.

ORSANCO, 2022. Ambient PFAS Levels in the Ohio River, Cincinnati, Ohio, 14 pp.

Comments submitted on behalf of the Little Hocking Water Association by:

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[Attachments: see docket ID EPA-HQ-OW-2022-0114-1835]

Attachment 1 - Concentrations of PFOA in the Little Hocking Water Association Raw Water (Chemours, 2023a)

Attachment 2 - Concentrations of PFOA in Belpre Raw Water (Chemours 2023b and 2023c)

Attachment 3 - Concentration of HFPO-DA in Little Hocking Water Association Raw Water]

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document. In response to the commenter's assertion that "we do not know which dose is the one that will a person sick", the EPA disagrees. For the four Hazard Index PFAS regulated under this action, the agency has identified doses below which adverse effects are unlikely to occur based on the best available science (i.e., RfDs), which have been used to establish the

MCLGs and/or HBWCs. For PFOA and PFOS, the agency has determined that there is no dose below which adverse effects are unlikely to occur and, as such, has followed long-standing agency practice of establishing the MCLG at zero for PFOA and PFOS based on the determination that these two contaminants are *Likely to be Carcinogenic to Humans.* Additionally, the EPA notes that the commenter does not provide a description of the "nth dose policy" in their comment letter and therefore the agency cannot directly respond to the commenter's recommendation.

New England Water Works Association (Doc. #1836, SBC-045392)

Communication:

EPA proposes that a PWS must repeat public outreach to its consumers every 3 months if a violation or situation persists unless the primacy agency determines otherwise, but that at a minimum, systems must give repeat notice at least once per year. Because it will take time for a PWS to design and construct treatment, we do not find quarterly Public Notice to have added value (in fact, it would most likely cause confusion for consumers). NEWWA recommends that EPA allow a Tier III notice to be utilized if a violation persists.

EPA Response: Please see section 9.2 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1576, SBC-042456 in section 9.2 in this *Response to Comments* document.

Midwest Environmental Advocates +more (Doc. #1846, SBC-045838)

In Wisconsin, there have been recent examples of water systems failing to adequately warn and educate their consumers about PFAS pollution when asked by citizens or required by the WDNR and the Wisconsin Department of Health Services. For instance, in 2019, the water system from the City of Wausau learned that all its municipal wells exceeded recommended state standards, yet the water system provided false or misleading information to consumers when asked by a resident in 2021. [FN40: WSAW-TV, Wausau public works director explains response to citizen email causing PFAS misinformation concerns (Feb. 10, 2022),] Despite knowing that the results showed detections higher than recommended state limits for about two years, the system's highest official assured the consumer that the system's drinking water didn't have a PFAS water quality issue. The response stated:

"Wausau Water Works has been and will continue to be proactive on the PFAS/PFOA discussions and upcoming health risk analysis by USEPA and WDNR requirements. We have tested our source water for these compounds in the past and the latest round of sampling was in 2019. USEPA has a limit of 70 parts per trillion and WDNR is considering a 20 parts per trillion limit. We are well below either of these." [FN 41: Wausau Pilot & Review, Wausau email shows Public Works director appears to have misled mayor on water toxicity (Feb. 10, 2022) (emphasis added), https://wausaupilotandreview.com/2022/02/10/wausau-email-shows-public-works-director-appears-to-have-misled-mayor-on-water-toxicity/]

Similarly, the water system from the City of West Bend failed to act when high levels of PFAS were discovered in its drinking water in January of 2020. More than two years later, when one the Commenters learned of the results through a public records request and alerted WDNR of the issue, the water utility was forced to publish a public notification. [FN42: Wisconsin Examiner, Water utilities must act quickly and transparently to address PFAS contamination: Commentary by Jorge Roman-Romero (July 5, 2022), https://wisconsinexaminer.com/2022/07/05/water-utilities-must-act-quickly-and-transparently-to-address-pfas-contamination/] However, the public notification was framed more as a public relations document than a warning, titled: "City of West Bend Water Utility Proactively Conducts Voluntary Municipal Well Sampling for PFAS." [FN43: City of West Bend, City of West Bend Water Utility Proactively Conducts Voluntary Municipal Well Sampling for PFAS (June 7, 2022), https://www.ci.west-bend.wi.us/news_detail_T41_R205.php] Additionally, the notification contained misleading statements about the timing of the protective actions taken by the utility:

"Three wells … detected PFAS. Well #4 was the only well to indicate levels above the Wisconsin Department of Health Services and U.S. Environmental Protection Agency's non-regulatory health advisory levels in drinking water. It was immediately shut down."

Contrary to an immediate response, it took a public records request and extensive back-and-forth between the water system and WDNR for the notification to be issued and the protective action to be taken.

EPA Response: The EPA acknowledges the commenters' submission of information about challenges faced in Wausau and West Bend, Wisconsin with respect to disseminating information on PFAS contamination and the implementation of state PFAS requirements. Following the compliance dates for the final PFAS NPDWR, water systems will be required to implement the public notification requirements summarized in section IX.B.3 of the preamble for this action which will eliminate the need for a public records request or an extensive back and forth with the state for the notification to be issued. These PN requirements will apply to water systems that supply finished drinking water treated by PWSs.

Midwest Environmental Advocates +more (Doc. #1846, SBC-045836)

III. EPA Should Issue a Right-to-Know Guidance for Water Systems to Use When Required to Notify the Public About PFAS Detections.

Commenters urge EPA to issue guidance for water systems to use when informing their consumers about health risks posed by PFAS detections in their drinking water. Recognizing the public's right-to-know as an integral principle of public health protection, the SDWA contains provisions [FN36: 42 U.S.C. 300g-3(c).] aimed at "educat[ing] the American people about the risks they face from a particular contaminant" because "[p]ublic notification is a powerful force for prevention." [FN37: See also Senate Environment and Public Works Committee (104th Congress), Senate Report on S. 1316, Safe Drinking Water Amendments Act of 1995 (Nov. 7, 1995), https://www.congress.gov/congressional-report/104th-congress/senate-report/169] To this

end, EPA should use its authority to urge water systems to communicate effectively about PFAS detections and their risks.

EPA Response: Please see section 9.1 of the EPA response in this *Response to Comments* document for discussion of CCR requirements and section 9.2 of the EPA response in this *Response to Comments* document for discussion of PN requirements. Additionally, as the EPA develops implementation materials following final rule promulgation, the agency will consider additional resources to support states and water systems for notifying their customers.

Section 9 References

Agency for Toxic Substances and Disease Registry (ATSDR). 2021. Toxicological Profile for Perfluoroalkyls. U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, Atlanta, GA. Accessed February 2022. https: //www.atsdr.cdc.gov/toxprofiles/tp200.pdf.

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USEPA. 2024a. *Office of Water Final Human Health Toxicity Assessment for Perfluorooctanoic Acid (PFOA).* 815R24006.

USEPA. 2024b. *Office of Water Final Human Health Toxicity Assessment for Perfluorooctane Sulfonic Acid (PFOS).* 815R24007.

USEPA. 2024c. *Economic Analysis for the Final Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation.* 815R24001.

10 Treatment Technologies

10.1 Best Available Treatment Technology Identification and Evaluation

Summary of Major Public Comments and EPA Responses

The vast majority of comments germane to the Best Available Treatment Technology (BAT) designations support the EPA's designation of granular activated carbon (GAC), anion exchange resin (AIX), and high-pressure membranes (such as nanofiltration [NF] and reverse osmosis [RO]) as BATs that are technologically feasible for treating drinking water to the proposed standards or below. Many commenters shared practical experience with installed treatment including successes, costs, implementation considerations, challenges, and other areas. The EPA agrees that GAC, AIX, RO, and NF are BATs and consistent with the criteria outlined in the *Best Available Technologies and Small System Compliance Technologies for PFAS in Drinking Water (BAT/SSCT)* document (USEPA, 2024a) for identifying "feasible" treatment for PFAS in this rule, and the comments providing information on practical full-scale experience with these technologies further support this finding.

A few commenters suggested either that the designated BATs could not treat to or below the Maximum Contaminant Level (MCL) or that not enough data was available to support the conclusion that the BATs could treat to at or below the designated MCL. The EPA disagrees with these commenters based on the history of full-scale use as documented in the BAT/SSCT document, the information in the proposed and final rule preambles, as well as in the comments that provided full-scale data as well as case studies. For example, commenters highlighted more than 45 military installations that have treated PFAS, including those in this rule, successfully for more than 15 years, a major water treatment company provided information on over 150 successful installations they had performed, and comments supported that there are significant numbers of industrial users successfully treating PFAS, including those in this rule. One commenter noted the example of the Chemours Fayetteville facility, which used GAC to eliminate PFAS, including those in this rule, as high as 345,000 ng/L and has reduced PFAS in effluent to non-detect levels for several PFAS. Finally, the Water Quality Association (WQA) reviewed proprietary performance data from its accredited laboratory, which demonstrates that this standard is feasible for the BATs selected to effectively remove the PFAS regulated in this rule from drinking water.

Many commenters pointed out site-specific issues with particular BATs. The EPA acknowledges that not every BAT represents the best treatment option for an individual system and site-specific considerations can limit BAT selection. For instance, residuals management considerations can limit the choice of RO/NF, particularly in states with limited water resources. While many commenters agreed that high pressure membranes such as RO and NF can remove the six PFAS in the final National Primary Drinking Water Regulation (NPDWR), many commenters also suggested that high pressure membranes may not be the most feasible treatment option for some systems because of residual management considerations, which are discussed in the residuals

management section below. There are, however, documented RO/NF facilities for treating PFAS in California, Illinois, North Carolina, and Alabama (USEPA, 2024a). In response to public comment and residual management concerns surrounding high pressure membrane technologies, the EPA has adjusted RO/NF's technology projection compliance forecast to 0 percent in the Economic Analysis (EA). While the EPA is not including any water systems selecting RO/NF installation to comply with the PFAS NPDWR, it remains a BAT for water systems to consider. For additional details on the EPA's EA, please see section XIII.

The EPA also acknowledges that due to technical site-specific considerations, some BATs may not be the best choice for particular water types. The final NPDWR does not require the use of any specific BAT and systems may choose other treatment or non-treatment approaches (e.g., connecting to new source waters) to comply with the rule. PFAS treatment option selection should consider conditions for a given utility, including water quality, available space, disposal options, local rules, and currently installed unit operations. For example, AIX may be the preferred technology for some utilities based on expected treatment needs, while others may select GAC or other technologies. However, as many commenters indicated, the BAT designations are appropriate for all public water systems (PWSs) across the country.

Several commenters pointed out that GAC may release arsenic at levels exceeding arsenic's MCL temporarily when installed and upon changing media, deleteriously impacting finished water quality. While the EPA has documented challenges surrounding GAC and arsenic (USEPA, 2024a), the EPA disagrees that the arsenic release poses an exposure concern so long as appropriate procedures are followed. Those procedures include discarding the initial bed volumes (BVs) after installation or replacement of media. The quantity of treated water discarded can be significant (e.g., as high as 350 BVs as one commenter noted). However, this amount of discarded water is low in comparison to the normal service life between GAC replacement, which is approximately 84,000 BVs or approximately about 0.5 percent of the total treated volume. The total water volume discarded is also low in comparison to water loss through leaks across the United States, which account for about 15 percent of treated water or what would be approximately 12,600 BV equivalents for this system. While conserving water is a significant issue, the water discarded due to GAC applications is relatively low. Systems can reduce water discard associated with BAT implementation by using acid washed and/or prerinsed GAC or using buffered/pre-flushed resins for AIX. Any treatment technology can create problems if improperly maintained and operated. Finally, GAC has been statutorily designated as "feasible for the control of synthetic organic chemicals," such as PFAS, in the Safe Drinking Water Act (SDWA) Section 1412(b)(5).

Many commenters pointed out the need for increased research, technological innovation, and guidance in treating drinking water for PFAS. The EPA's final rule represents data-driven drinking water standards that are based on the best available science and meet the requirements of the SDWA. For the six PFAS, the EPA considered PFAS health effects information, evidence supporting dose-additive health effects from co-occurring PFAS, as well as national and state data for the levels of multiple PFAS in finished drinking water. SDWA provides a framework for

the EPA to regulate emerging contaminants of concern in drinking water. Under the statute, the EPA may act based on the "best available" science and information 42 U.S. Cod § 300g–1(3)(A)(i). Thus, the statute recognizes that the EPA may act in the face of imperfect information and provides a mechanism for the EPA to update standards as more science becomes available. The available information is sufficient to finalize the BATs as proposed but EPA agrees that more research may be beneficial (USEPA, 2022a). With respect to the EPA's request for public comment on additional guidance materials that would be helpful to support successful technical implementation of the rule, the EPA received many comments related to the need for technical materials to support rule implementation. The agency plans to look to suggestions from states, technical assistance providers, industry associations, and interested stakeholders following the rule promulgation to provide technical materials that can assist water systems in complying with the regulations, which is further discussed in section 1.2 of the EPA's response in this *Response to Comments* document. The EPA is currently funding many technical assistance efforts associated with PFAS, including supporting treatment infrastructure projects through the Drinking Water State Revolving Fund (DWSRF) and the Emerging Contaminant in Small or Disadvantaged Communities (EC-SDC) grant program as designated and funded through the Bipartisan Infrastructure Law (BIL). Please see section 2.4 of the EPA's response in this *Response to Comments* document for further discussion on funding.

Many commenters stated that permitting needs to be streamlined and that more assistance should be proffered to primacy agencies, utilities, and other interested stakeholders. While SDWA does not require permits, state and local authorities often require permits for the installation of treatment facilities at water systems. The EPA has developed supporting documents such as the *Best Available Technologies and Small System Compliance for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water* document (USEPA, 2024a) that can be used to help permitting authorities develop more familiarity with these technologies over time. The agency plans to look to suggestions from states, technical assistance providers, industry associations, and interested stakeholders following the rule promulgation to provide technical materials that can assist water systems in complying with the regulations.

Many commenters questioned how the BATs were identified, evaluated, and selected in the final rule. Additionally, some of these commenters expressed concern with the costs of implementing and operating these technologies. Section 1412(b)(4) of SDWA requires that the agency "list the technology, treatment techniques, and other means which the Administrator finds to be feasible for purposes of meeting [the MCL]," which are referred to as BATs. The EPA used the following criteria for identifying "feasible" BATs: (1) The capability of a high removal efficiency; (2) a history of full-scale operation; (3) general geographic applicability; (4) reasonable cost based on large and metropolitan water systems; (5) reasonable service life; (6) compatibility with other water treatment processes; and (7) the ability to bring all the water in a system into compliance. As part of this analysis, the agency considered costs of BATs that have been demonstrated under field conditions to be effective at removing the PFAS regulated by the NPDWR and determined that the costs of complying with the MCLs are reasonable for large and metropolitan water systems at a system and national level as described in section 4 of the EPA response in this

Response to Comments document (see *A Legislative History of the Safe Drinking Water Act*, Committee Print, 97th Cong., 2d Sess. (1982) at 550). Pursuant to SDWA § 1412(b)(4)(ii), the agency also evaluated "technolog[ies], treatment technique[s], or other means that [are] affordable" for small PWSs. In this evaluation, described further in section 10.5, the agency determined that the costs of SSCTs are affordable for households served by small drinking water systems. Therefore, the EPA disagrees with commenter concerns that the agency did not adequately consider costs in establishing the final MCLs with respect to treatment feasibility. The EPA's final rule represents data-driven drinking water standards that are based on the best available science and meet the requirements of SDWA. In the final rule, the EPA is codifying GAC, AIX, NF, and RO as BATs. For additional discussion on MCLs, please see section 5 of the EPA response in this *Response to Comments* document.

Many commenters requested or recommended additional guidance to support implementation of the final NPDWR, including technical materials related to treatment technologies. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation and plans to consider the topics suggested by the commenter as the agency develops implementation materials for the final NPDWR.

Individual Public Comments

Richard Kinch (Doc. #1503, SBC-042572)

As an ex-EPA employee that worked for decades on assessing technology performance, I have concerns regard the rigor of data gathering associated with technology performance, especially the lack of EPA sampling at full scale operations. Without better data, there is little means to judge whether EPA's conclusions have merit. EPA should expedite a sampling program and notice the data and further analyses, and reopen the comment period. Further details are provided in the attached file.

See attached file(s)

Comments on EPA's Proposed PFAS National Primary Drinking Water Regulations

By Richard Kinch

As an ex-EPA employee of 41 years, I have some general comments regarding treatment technologies as addressed in the proposal. (While I have engaged in consulting activities, these comments are simply my personal opinion, as I am currently not engaged in consulting.)

As a general matter, I expected to see much more in the way of information in Section XI. Treatment Technologies of the preamble. The sparce information seems to reflect that project managers were focused on the risk assessment, and did little work on treatment technologies – perhaps just quickly throwing together a minor literature search to get the proposal out as scheduled, or not looking at the treatment technology section as important. The treatment

technology section, however, is of significant importance, as it determines whether the risk based criteria can be met, and whether the cost can be justified. As with addressing Lead in drinking water, the Agency needed to look at what treatment technology could reasonably do to set an achievable requirement. Over time, I have seen risk criteria get lower and lower. As that happens, EPA will more frequently encounter circumstances where intended risk-based regulations must make treatment technology-based compromises. When dealing with parts per trillion for PFAS, the treatment technology work should clearly be robust.

Stepping back in the project's timeline, it is easy to identify a set of steps that should have been taken which are common to the Agency's regulations assessing treatment technologies – for water, air, and solid waste. EPA should have conducted their own sampling and analysis of full-scale treatment operations, and collected whatever long-term self-monitoring data is available at the full-scale treatment operations (long-term performance data would be most helpful in assessing treatment variability, and is commonly assessed in treatment technology assessments by the Agency). I must admit a significant degree of surprise to find no reference to EPA actually going out and doing some basic sampling and analysis (or gathering long-term self-monitoring). The Agency's "suppositions" regarding treatment technologies maybe correct, but in providing comment I simply cannot made a sound conclusion in the absence of appropriate data. The importance of this rule makes doing the basic and appropriate data development essential. Publishing a proposal and asking for comment is not an adequate substitute for EPA's responsibility to gather appropriate data. My overarching comment, therefore, is that EPA did not develop adequate treatment technology data, and should expedite going out to full-scale treatment operations and conducting sampling and analysis, and should also gather long-term self-monitoring from full-scale treatment operations. The additional information should then be provided to the public in a notice of data availability with an opportunity for public comment.

Below are some additional points of concerns which follow the basic framework the Agency's provided:

The Agency identifies the BATs as those meeting the following criteria:

(1) The capability of a high removal efficiency;

(2) a history of full-scale operation;

(3) general geographic applicability;

(4) reasonable cost based on large and metropolitan water systems;

(5) reasonable service life;

(6) compatibility with other water treatment processes; and

(7) the ability to bring all the water in a system into compliance.

• The threshold issue with regard to treatment technologies is whether the Agency can adequately assess technology performance, as it would occur on a full-scale and long-term basis,

by solely doing a literature search. The essence of the issue is that the literature tends to be research studies trying to estimate what the treatment technologies can achieve, while sampling and analyses of the actually full-scale operations by EPA would give the actual performance. This is a bit like the difference between looking at political polls, versus counting the votes. Maybe in some cases the polls are so clear that the vote counting seems unnecessary, but largely, it is an essential part of the process. I worked on technology-based regulations in the Effluent Guidelines program in the Office of Water, and technology-based regulations for hazardous wastes and air emissions. None of my experiences would have supported the trivial effort provided in the proposal with regard to the PFAS technology-based assessment with no actual EPA sampling program of real-world performance. The literature search provides useful information to better understand and interpret full-scale and long-term data that EPA should directly gather (including self-monitoring data), but is not a justification for EPA avoiding directly gathering of such information.

• As a general matter I suspect it is easier for literature research projects to show better results. One can only speculate on the causes for such outcomes, but somethings that come to mind are: where the literature is not full-scale, it is just easier to refine the setup; for literature from treatment manufacturers (or funded by) the selection of what gets tested and published can be subject to self-interests (if a manufacturer has two case studies, one of which has much better results, it would not be surprising that they only publish the good one); if a manufacture of treatment media knows that a literature research project maybe particularly important to their financial future, they might make extra efforts to provide the highest quality product for the short-term testing (when I was addressing wastewaters for the automotive industry, I learned of a case where the corporate quality control checkers uncovered a problem – the inspection date was known and the facility to store a collection of the highest quality parts, so that all the cars coming off the assembly line on inspection day, were of the highest quality and did not represent overall production); there may also be some differences when those with doctorates publishing research articles are involved versus normal facility staff.

• In a similar manner there can be temptations and bias by EPA's in the selection of which literature to reference and which pieces of data to use in the selected references. There is no acknowledgement of data not achieving the limit or explanation for such dismissal. Typically, robust data gathering and analyses presents complexities that need to be addressed. By avoiding an EPA sampling effort, and apparently focusing the data selection on what was desired, the need to address complexities just never appears. When EPA properly conducts sampling of full-scale long-term treatment technologies, there is more appropriate performance data, and the opportunity to obscure how data maybe skewed is greatly diminished. Strange things may or may not happen, but they are a possibility (like a political poll that is flat out wrong). The necessary way to insure EPA as well as public understands the actual treatment performance in a production setting is to get into the field and do the sampling and analyses work to obtain that information (including getting whatever long-term self-monitoring data is available).

• Each regulated parameter should be addressed individually for each of the 7 BAT criteria. There appears to be reasonable references in literature that these types of chemicals do not behave in an identical manner during treatment, and thus there is a need for parameter specific support. This should include identification of actual data supporting conclusions (summary information in the Preamble and details in supporting documents).

• There is an inference that there is a "history of full-scale operations". The preamble should provide summary data on the known full-scale treatment operations, with the facilities and their treatment technologies identified in supporting documents, along with what parameters they are treating. Full-scale treatment technology data should be weighed far more heavily than lab-scale information. The lack of information presented in this area opens up the speculation that the "history of full-scale operations" may be weaker than implied. The problem with inferences, instead of full disclosure of data, is if an inference is found to be wrong, it undermines trust.

• The assessment of the various technologies expresses a common theme – the technology "can" or "may" achieve >99% removal and meet the 4 ng/L limit. The "ability to bring all the water in a system into compliance" is a determination that warrants far more than what appears to be using blinders to focus only on the data that supports a desired outcome. In July 2022 GAO issued a TECHNOLOGY ASSESSMENT (Persistent Chemicals, Technologies for PFAS Assessment, Detection, and Treatment) that was provided to Congress, which stated: "The currently available technologies for removal of PFAS from water vary in effectiveness, but all can remove up to 90 percent or more of certain PFAS (see table 4), which are easier to remove from water than other PFAS." The GAO characterization (which I also find lacks detail), acknowledges some complexities, appears to reach conclusions which differ from EPA's conclusions, signals the need for some significant work on treatment technologies in EPA's regulatory effort.

• There are certifications such as NSF/ANSI 53, which cover drinking water treatment devices, and include consideration of PFOA and PFOS. They have been certifying the ability to meet 70 ng/L. In conducting their tests, they may have results on performance of various systems. They may have a major trove of data on PFOA and PFOS for drinking water treatment devices. There seems to be no reference to that data – if such certifications apply to full-scale systems, perhaps that is another source of data EPA could gather.

• In conducting assessments of treatment technologies, data should be provided on the range of influent concentrations for each parameter. Of course, treatment of a parameter that starts below the regulatory level is largely meaningless, while, in general, the higher concentrations are more meaningful in assessing the ability of technologies to fully meet the target. Clear disclosure should be provided that demonstrates that the high-end influent concentration will be successfully treated to achieve the regulatory criteria.

• Treatment System do not operate at a single performance level. With time there are changes in the influent characterization and maybe the treatment system itself. In addition, the simple matter of taking a sample, splitting it, and having it analyzed two or more time can result in somewhat

different answers. In all technology-based regulatory efforts at EPA for which I was involved there would be an assessment of variability (i.e., how much higher a maximum daily value is versus the long-term average – such variability factors vary significantly depending on the treatment and parameter. During my work in EPA's Effluent Guidelines programs variability factors were often in the 3.5X to 4.5X.) For the PFAS proposal, the whole consideration of variability of treatment performance appears to be missing. This is where efforts are needed by EPA to gather long-term self-monitoring data, conduct the appropriate analyses, and provide notice and comment.

• If the thought process by the Agency is that these types of technologies can just be run with more media or longer detention times to achieve whatever result is desired, even if it is outside the realm of normal design, EPA maybe moving outside the scope of systems that have historic full-scale systems, and the cost of such treatment. I suggest the proper process is more in line with getting the performance data on full-scale systems in operation.

• With such a minimal treatment technology presentation in the proposal, it does raise fundamental concerns that a robust presentation of data might not support the proposal. Sometimes giving an issue a minimal presentation helps make the issue go unnoticed, with commenters focusing on the items EPA focuses on, and a critical issue can be missed during the review and even in litigation. (While sometimes effective, if intentional, such actions are inconsistent with good governance.) The Agency may have the right conclusion with regard to treatment technologies, but the proposal does not present adequate support. After adequate data are gathered and fully assessed, then one can determine if the criteria can be met using the identified technologies and assess the appropriate costs. If there is not sufficient treatment technology support for each of the regulated parameters, then a structure along the lines of the drinking water requirements for Lead would be worth considering.

While I care about helping to get this issue dealt with correctly, I devoted a very limited time to providing these comments. I appreciate the importance of the issue, and hope you will deal with doing the significant and necessary work and making the appropriate changes.

One ancillary thought… EPA regulations tend to be divided into 2 paths. The development of some regulations follows a risk-based path (what do we need to be protective), while the others a technology-based path (what can technology achieve). In addressing PFAS, the Agency was essentially following the risk-based path. The problem is that in the end, the Agency needs a finding that there is treatment technology has the ability to bring all the water in a system into compliance (with some accompanying cost and economic impact work). This brings about the need to essentially perform a typical technology-based assessment. The Agency could do a very minimal technology-based assessment if it is clear that the treatment technology would bring the Agency to an even lower level. Based on the information provided with the proposal, EPA has not provided adequate support on the treatment technologies being able to bring all the water in a system into compliance with the proposed criteria. The Agency doesn't necessarily need to do a full technology-based assessment to get the answer, but the nature of the many decades of technology-based project studies by EPA provide good guidance on what to do. An appropriately

meaningful path was just not taken for this proposal, but as stated earlier, EPA can and should expedite appropriate data development and analyses, and provide additional notice and comment.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. Additionally, the EPA disagrees with many of the comments leveled here. In particular, the EPA disagrees that the agency did not appropriately evaluate technology performance when establishing the final standards. The EPA assessed feasibility in accordance with the SDWA when setting the MCL. Under current law and as described in the proposed rule (USEPA, 2023a), the EPA establishes drinking water standards through a multi-step process. *See* S. Rep. No. 169, 104th Cong., 1st Sess. (1995) at 3. First, the agency establishes a non-enforceable Maximum Contaminant Level Goal (MCLG) for the contaminant in drinking water at a level which no known or anticipated adverse effects to the health of persons will occur and which allow for an adequate margin of safety. Second, the agency generally sets an enforceable MCL as close to that public health goal as feasible, taking costs into consideration. In this second step, consistent with the definition of "feasible" in Section 1412(b)(4)(D), the EPA evaluates the availability and performance of BATs for treating water to minimize the presence of the contaminant consistent with the MCLG as well as the costs of applying those BATs to large and metropolitan water systems when treating to that level (1412(b)(4)(E) and (5)). [1] The definition of "feasible" means feasible with the use of the best technology "which includes consideration of the analytical limits of the best available treatment technology." (Emphasis added); *see also* Section 1401(1)(C)(i) stating that a NPDWR includes an MCL only "if, in the judgment of the Administrator, it is economically and technologically feasible to ascertain the level of such contaminant in water in public water systems." The EPA disagrees that the agency should not rely upon peer-reviewed literature to assess the effectiveness of technologies and should use and perform sampling itself as SDWA section 1412(b)(3)(A) requires that the agency use "(i) the best available peer reviewed science and studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods." As a result of these analyses and in consideration of these factors, the agency has determined that multiple treatment technologies (e.g., GAC, AIX, NF, and RO) "examined for efficacy under field conditions and not solely under laboratory conditions" are found to be both effective and available to treat the six PFAS to the standards and below.

The commenter states that they expected "much more in the way of information in Section XI. Treatment Technologies of the preamble," The EPA conducted an extensive analysis of the best available peer reviewed science and studies conducted in accordance with sound and objective scientific practice to identify these BATs. The agency's evaluation of that scientific information is summarized in three documents supporting the final NPDWR: the *Best Available Technologies and Small System Compliance Technologies for PFAS in Drinking Water* document, the *Technologies and Costs for Removing Per- and Polyfluoroalkyl Substances from Drinking Water*

[1]Based on legislative history, the EPA interprets "taking cost into consideration" in Section 1412(b)(4)(D) to be limited to "reasonable cost based on large and metropolitan drinking water systems;" (see A Legislative History of the Safe Drinking Water Act, Committee Print, 97th Cong., 2d Sess. (1982) at 550).

document, and the *Drinking Water Treatability Database*. As this information is already publicly available in the EPA publications that were referenced in the docket at proposal, there is no need to duplicate already freely accessible tables and figures. The proposed and final rules were written clearly and concisely, which ensured that information was comprehensive, informative, and understandable, and ensured that supporting documents contained more explanatory information and data. The *Technologies and Costs for Removing Per- and Polyfluoroalkyl Substances from Drinking Water* document covers 321 pages by itself, not all details could be covered in the preamble to the proposed and final rules. For example, table 4 in the BAT/SSCT document provides a breakdown of perfluoroalkyl carboxylic acids treated by GAC detailing compound name, backbone length, number of bench, pilot, and full-scale studies with maximum removal efficiency and provides the data sources for this information. Analogous tables exist for other kinds of PFAS, such as perfluoroalkyl sulfonate acids, and treatment technologies such as AIX. The BAT designations were supported by a number of commenters that described practical, real-world, full-scale experience with these treatment technologies.

The EPA disagrees with the commenter's assertion that the agency's data on treatment performance was biased toward data that technologies were effective. The EPA considered all data that met applicable requirements, including data that showed poor removal. The EPA agrees with the commenter that technology performance can be variable. The rule proposal mentioned that the effectiveness of media-dependent processes decreases as the media is used or with specific water quality considerations. As noted in the *Drinking Water Treatability Database,* some full-scale studies found PFAS concentration in treated water equaled or exceeded that of the raw water where the media had been in service for a long period (e.g., at least 12 months up to more than 6 years) without regeneration or replacement. The negative removal efficiency was attributed to desorption of previously adsorbed PFAS. Full-scale studies with more frequent replacement showed successful contaminant removal.

The commenter also references the National Sanitation Foundation/American National Standards institute (NSF/ANSI) standard 53 as a potential information source on treatment. These NSF/ANSI standards apply to point of use (POU) and point of entry (POE) devices, not full-scale treatment. That information is not publicly available and treated as confidential business information by the certification organizations. EPA further notes that technologies can work differently at different scales, which is part of the justification for why the SDWA requires technologies to have a history field use 42 U.S. Cod § 300g–1(b)(4)(D). The testing is often done by third parties such as the WQA, who submitted comment Doc. #1694, SBC-044986 in section 10.5 stating "product performance data produced by the WQA's accredited laboratory suggests that the POU/POE water treatment industry may already have multiple products that can reduce PFAS chemicals to near or below the proposed MCL."

In promulgating this NPDWR, the EPA followed applicable procedures and requirements described in SDWA, including those related to the use of the best available, peer-reviewed science and supporting studies as well as data collected by accepted methods. EPA also points out that the SDWA does not require the collection of treatment performance data by the EPA.

When developing technology-based standards under the Clean Water Act (CWA), the agency relies on industry-supplied data and samples are not always collected by the agency. Potable water, which is governed by the SDWA, has a much narrower band of influent characteristics than effluent from industrial processes, which are governed by the CWA. As noted, SDWA section 1412(b)(3)(A) requires that Agency use "(i) the best available peer reviewed science and studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods." The commenter is also incorrect in stating that the rule is solely a risk-based rule; as explained above and in the preambles to the proposed and final rule, as well as required by 42 U.S. Cod § 300g–1(b)(4)(B), feasibility and performance of treatment technologies were taken into account. More information on the MCL can be found in section 5.

Maine Water Utilities Association (MWUA) (Doc. #1567, SBC-042734)

Treatment Considerations:

EPA is proposing MCLs for PFOA and PFOS at 4 ppt and a Hazard Index approach for four other PFAS compounds: perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salt (also known as a GenX chemicals), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS) with a MCLG of 1.0. NEWWA is unfamiliar with the Hazard Index approach. While perhaps common in the Superfund program, it has never been used under the Safe Drinking Water Act before. We are concerned that a cumulative regulatory approach ignores the complexities of selecting, implementing, and operating the appropriate and affordable PFAS treatment solutions.

There are a limited number of drinking water treatment technologies that are currently known to be effective for PFAS removal. However, there is no one-size-fits-all solution. Depending on several site-specific factors, such as the concentrations and types of PFAS present in the source water(s), general water quality characteristics, and existing treatment processes, treatment technologies may show different removal effectiveness for the varying carbon chain lengths and attached functional groups. EPA needs to provide flexibility within this regulation to allow for expansion of treatment options as technology progresses. Advancement in Best Available Technologies (BATs) will be made, and EPA and primacy states need to be positioned to swiftly approve new BATs.

EPA Response: Please see sections 10.1 and 10.3 of the EPA response in this *Response to Comments* document. The EPA agrees that there are several site-specific factors that will dictate the appropriate strategy for distinct locations and referenced this in the rule proposal preamble, which in section VI.B states for example "PFAS are well documented to co-occur, the exact chemical composition is often site-specific in nature." The EPA also agrees that each technology works differently depending on the factors the commenter enumerated, which were also stated in the proposed rule preamble in section XI.B. The *Best Available Technologies and Small System Compliance Technologies for PFAS in Drinking Water* document as well as other

available guidance recommend pilot testing to aid in determining the best solution for a given location and acknowledge that sometimes external factors such as limited space may dictate a different treatment train than the optimal engineering approach. The EPA also agrees that there will be advances made in BATs. It is important to note that flexibilities requested already exist as water systems may use any technology or practice to meet the PFAS MCLs and are not limited to the BATs in this rule. Other technologies may be chosen in lieu of BAT because they may be more cost effective or better suited to the specific operating conditions of the particular site to meet the MCL.

Regarding the commenter's concern that a "cumulative regulatory approach ignores the complexities of selecting, implementing, and operating...PFAS treatment solutions," the Hazard Index approach does not ignore these complexities. The Hazard Index imposes no burdens or restrictions on selection of treatment technology by itself, which would differ from individual MCLs for these chemicals, for example. The BATs discussed above have all been demonstrated to be effective in removing all six PFAS finalized for regulation as part of this rulemaking albeit to differing degrees. Additionally, the process integration for all BATs is similar. While sites may wish to choose differing integrations, it is likely that most will be post traditional media filters; BATs may also require some post treatment adjustment. Further, since these same technologies also remove other long-chain and higher carbon/higher molecular weight PFAS, the EPA expects this rulemaking will provide additional public health benefits and protection by removing unregulated PFAS that may have adverse health effects, which is discussed further in section 10.3.

Minnesota Pollution Control Agency (MPCA) (Doc. #1569, SBC-042494)

Section XI – Treatment technologies

Topic: Part A, best available technologies or BATs, includes non-treatment options such as finding an alternate source of drinking water (e.g. drilling a new well) or purchasing water from another facility.

MPCA comments: It is important to note that compliance with SDWA for PFAS contamination using alternative drinking water sources (other aquifers or water systems) may pose longer term risks to the drinking water supplies due to hydrogeologic principles of interconnectivity between aquifers and reliance on these other sources may in fact, exacerbate the spread of PFAS in the subsurface due to water well pumping influence. This potentially poses a risk to future generations drinking water resources.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. The EPA encourages water utilities to carefully consider all options and identify risks associated with the various alternatives for MCL compliance (such as non-treatment options). Water systems should consider the impacts of new source water wells on existing PFAS contamination plumes before selecting this option.

Association of State and Territorial Solid Waste Management Officials (ASTSWMO) (Doc. #1583, SBC-042403)

[Overall, as movement is made toward better regulation and oversight of these contaminants, ASTSWMO's membership recognizes a corresponding need for research, communication, and improved understanding within the following areas:]

• drinking water, soil, and wastewater treatment technologies;

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. The science is currently sufficient to finalize the NPDWR as documented in sections 4 and 5 of the EPA response in this *Response to Comments* document. The EPA is currently funding many technical assistance efforts associated with PFAS, including supporting treatment infrastructure projects through the DWSRF and the Emerging Contaminant grant program as designated and funded through the BIL. The agency has been collaborating with states, technical assistance providers, industry associations, and interested stakeholders to provide technical materials that can assist water systems in complying with the regulations, as well as outreach efforts to help develop technical and operator capacities. As outlined in the PFAS Strategic Roadmap, the EPA is committed to addressing PFAS. The Office of Research and Development (ORD) is also evaluating and developing technologies for reducing PFAS in the environment to inform decisions on drinking water and wastewater treatment, contaminated site cleanup and remediation, air emission controls, and end-of-life materials management.

Washington Suburban Sanitary Commission (WSSC Water) (Doc. #1585, SBC-042778)

Feasibility of NF/RO:

WSSC Water concurs with EPA's assessment that the disposal of PFAS-contaminated reject water presents a challenge for the viability of NF/RO treatment for many water systems. Additionally, we agree that the operational costs of NF/RO are likely to be higher than those of GAC due to the handling of the reject water. If water systems are unable to dispose of the concentrated reject waste to a brackish water or a sanitary sewer, NF/RO may not be a feasible option. We urge EPA to consider these technological constraints when determining the practicality of regulating PFAS at the proposed MCLs.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. For additional information on disposal concerns including how they were considered when setting the MCL, please see sections 10.4 and 5.1 of the EPA response in this *Response to Comments* document. Not every BAT represents the best treatment option for an individual system and site-specific considerations can limit BAT selection. Indeed, the EPA states that the reject water "will require disposal or additional treatment" in the rule proposal section XI.A.3. Additionally, the *Best Available Technologies and Small System Compliance Technologies for PFAS in Drinking Water* document contains more information on reject water disposal. However, there may be water systems where disposal of the reject water is feasible,

therefore, the agency has listed NF and RO as BATs and expects that water systems will consider their site-specific decisions when deciding between these BATs and other BATs such as GAC and AIX that do not require disposal of reject water.

Cape Fear Public Utility Authority (CFPUA) (Doc. #1588, SBC-042378)

May 26, 2023

Via U.S. Mail and online submission at Regulations.gov

U.S. Environmental Protection Agency

EPA Docket Center

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Re: Comments on Docket ID No. EPA-HQ-OW-2022-0114, PFAS: PFOA and PFOS NPDWR

Cape Fear Public Utility Authority (CFPUA) provides drinking water to approximately 200,000 people in the City of Wilmington and unincorporated New Hanover County in North Carolina. About 80 percent of CFPUA's drinking water is sourced from the Cape Fear River. In 2017, our community learned chemical manufacturer Chemours (and its predecessor, DuPont) had for many years been discharging per- and polyfluoroalkyl substances (PFAS), including GenX, into the Cape Fear River upstream from our raw water intakes. CFPUA's Sweeney Water Treatment Plant, which treats raw water sourced from the Cape Fear River, is considered among North Carolina's most sophisticated water treatment plants. At the time, however, it was unable to treat for PFAS, so Chemours' PFAS in the river also was in our community's finished drinking water.

In the five years since this revelation, CFPUA:

• Conducted pilot testing to compare granular activated carbon (GAC), ion exchange resin, and reverse-osmosis as potential permanent PFAS-removal options at Sweeney, with GAC emerging as the best solution;

• Began more frequent exchanges of GAC in existing biological filters as an interim step to provide some immediate PFAS removal in finished water; and

• Spent $46 million to design and construct eight new deep-bed GAC contactors, which began operating in fall 2022 and now effectively and consistently remove PFAS from finished drinking water to levels at or near non-detection.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. The EPA appreciates the commenter for providing their experience with installing a listed BAT as well as pilot testing other BATs to remove PFAS to levels at or near non-detection and some cost information.

New York Section American Water Works Association (NYSAWWA) (Doc. #1591, SBC-042372)

Has EPA conducted performance evaluations of current Best Available Technologies (BATs) to verify they can treat to levels below the proposed PQL of 4 ppt? It is critically important when suggesting BATs for future compliance, that adequate performance data available to assure systems that the use of a BAT will provide compliance.

EPA Response: Yes, please see section 10.1 of the EPA response in this *Response to Comments* document and supporting documentation such as the *Best Available Technologies and Small System Compliance Technologies for PFAS in Drinking Water* document and the *Drinking Water Treatability Database*.

Michigan Department of Environment, Great Lakes, and Energy (EGLE) Drinking Water and Environmental Health Division (DWEHD) (Doc. #1597, SBC-042989)

F. Treatment Technologies

Having reviewed Section XI of the proposed NPDWR, EGLE DWEHD agrees with EPA's proposed list of best available treatment technologies for PFAS removal in drinking water. These are largely consistent with those included in Michigan's SDWA for PFAS.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043647)

C. The EPA's Best Available Technologies (BATs) including GAC, IX, and NF/RO have inherent differences in the degrees to which they remove various PFAS species.

i. Liu et al (2022) evaluated the efficiency of NF and RO membranes for the removal of PFAS from water. While rejections of various species by RO membranes was high (>96%) and consistent across membrane types, rejection by NF membranes ranged from 25-100% for various species. The degree of analyte rejection is a function of the membrane type/product selected—therefore, it is possible that a product selected to effectively remove regulated contaminants today, may not be suitable for future regulated PFAS species.

ii. PFAS species/classes could be preferentially removed by one treatment versus another: Hayman et al (2023) assessed the efficacy of PFAS removal by several types of GAC (Calgon F400, Blacklite Pure Biochar) and IX products (Purolite PFA694E, Amberlite IRA958) and

found that IX was more effective than GAC at removing PFBS, PFHxS, and PFOS (the perfluoroalkyl sulfonic acids), whereas GAC was more effective as removing PFBA, PFHxA, and PFOA (the perfluorocarboxylic acids). This is another important consideration if additional PFAS are perhaps added to the regulation in the future. Analogous to membrane product selection discussed above, PFAS removal efficacy can vary between carbon and resin types (Zeng et al 2020; Dixit et al 2021).

iii. There are a reasonable number of full-scale GAC treatment studies investigating PFAS removal for several, but not all, of the species in the proposed PFAS rule. For instance, there is only 1 full scale study investigating GenX (HFPO-DA) removal by GAC (Table 6). If EPA is to consider regulation of additional PFAS compounds in the future, a similar lack of full-scale data is likely to be a challenge. It is recommended that additional full-scale studies be conducted to better understand treatment efficacy and variables that impact it.

Table 6: Number of Full-Scale GAC Treatment Studies in the Literature for UCMR3 PFAS Species that are in the Proposed PFAS Rule, adapted from USEPA.

[Table 6: See Docket ID EPA-HQ-OW-2022-0114-1602]

iv. Shorter chain PFAS are commonly more difficult to remove; Zeng et al (2020) demonstrated that shorter chain PFAS (specifically perfluorocarboxylic acid or perfluorosulfonic acid classes) always broke through before longer-chain species. If additional short-chain PFAS are added to the regulation, this could introduce new treatment challenges for systems sized to remove longer chain compounds.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. The EPA agrees that different technologies have different removal efficacies depending on site-specific conditions to include specific PFAS fingerprint at the site, water quality characteristics, and other considerations as well as specific operational conditions such as contact time, type of media used, time between media changeouts and other factors. The EPA stated these same facts in the rule proposal. The EPA also agrees, and also stated in the proposed rule, that shorter-chained PFAS tend to break through before longer-chained PFAS of the same family. For the specific case of RO/NF, unlike low pressure membranes, NF and RO systems are not manufactured as proprietary equipment and membranes from one manufacturer are typically interchangeable with those from others.

The EPA agrees that more research can help and is sponsoring this research in accordance with the comment. The EPA's final rule represents data-driven drinking water standards that are based on the best available science and meet SDWA requirements. Under the statute, the EPA may act based on the "best available" science and information. Thus, the statute recognizes that the EPA may act in the face of imperfect information and provides a mechanism for the EPA to update standards as more science becomes available. While there is only one full-scale study for HFPO-DA removal using GAC, as long as a technology been tested beyond the laboratory under full-scale conditions for other contaminants and the performance of the technology may reasonably be projected based upon other available treatment data, such as pilot data, it may be deemed a

BAT. There is no requirement for the application of a BAT to be demonstrated at full scale for each individual contaminant. The BAT must show effectiveness for the contaminant at least at bench or pilot scale, the technology is reasonably be expected to perform in a similar manner under field conditions regardless of aberrations due to scale-up factors is the requirement, and the technology has been demonstrated during field conditions. As GAC for HFPO-DA has been demonstrated at full-scale already *and* several pilot studies have been completed *and* this technology is well established in general as well as specifically for PFAS, changing the BAT designation or delaying the final rule for more data is not necessary.

American Water Works Company Inc. (Doc. #1608, SBC-043991)

Best Available Technology (BAT)

American Water agrees with the U.S. EPA's identification of granular activated carbon (GAC), anion exchange (AIX), and high-pressure membranes (reverse osmosis and nanofiltration (RO/NF)) as technologies that should be able to effectively treat PFOA and PFOS to 4.0 ppt or lower. We note, however, that while all three are discussed in the preamble, only GAC is listed as BAT in the rule language at 141.61(b). We also have concerns related to the cost and application of the different treatments as outlined in these comments.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. The EPA thanks American Water Works Company Inc. for its assessment that GAC, AIX, RO, and NF can treat PFOA and PFOS to 4.0 ppt or lower. *The Best Available Technologies and Small System Compliance for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water* document delineates the BATs for this rule, the table in the Code of Federal Regulations at 141.61(b) is not a complete listing of BATs for the contaminants listed. The EPA amended § 141.61 by adding paragraphs (d) and table 5 to paragraph (d) to make clear the BATs for PFAS regulated by the NPDWR.

American Water Works Company Inc. (Doc. #1608, SBC-043994)

AIX Challenges in Surface Water Applications

To American Water's knowledge, there are not currently any non-regenerable AIX treatment systems being used in surface water treatment applications. American Water owns and operates one regenerable AIX nitrate removal system treating combined filter effluent in a surface water plant and is aware that some other large surface water treatment plants in the U.S. are equipped with this technology. However, regenerable AIX systems in surface water treatment plants may only operate seasonally and/or may only treat a portion of the plant flow. More importantly, regenerable AIX systems typically include a brief media backwash during each brine regeneration cycle, which may significantly reduce the risks posed by particulate fouling in a non-regenerable AIX treatment system that cannot be backwashed.

AIX resin manufacturers may not warrant their media systems unless water systems include upstream bag or cartridge filtration, which could add significant capital and operating expense and may be impractical to operate and maintain in large-scale applications. Presumably, the requirement for upstream cartridge filtration is to avoid the potential for the AIX media bed to become fouled or clogged with particulate matter that may increase pressure drop and lead to channeling, short-circuiting, or risk damaging the synthetic resin beads. As a point of reference, American Water operates several groundwater treatment facilities with inline bag or cartridge filters upstream of the resin and has found that moderate levels of iron and manganese, even as low as 0.3 ppm for iron or 0.05 ppm for manganese, can lead to frequent replacement of expensive filter cartridges.

American Water is currently pilot testing multiple non-regenerable AIX media for PFAS treatment in parallel with GAC and a proprietary absorbent media treating combined filter effluent at a surface water plant. At this installation, we have experienced several incidences of severe media fouling and associated high head loss with the AIX media despite having a 5-micron cartridge filter installed upstream of the pilot columns. It is currently unknown what is causing this fouling, but based on this limited experience, American Water has significant concerns with the viability of AIX in surface water treatment applications. Similarly, there is currently insufficient experience with proprietary media to know how they will operate over time. Accordingly, GAC may be the only practical treatment for the removal of PFAS in surface water treatment plants at this time. If so, this could put added pressure on the GAC supply and reactivation service industry. It also creates a challenge for drinking water utilities that may select a more expensive treatment approach because insufficient information is available to know if a seemingly lower cost technology will offer adequate reliability and operability.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. The EPA thanks the commenter for providing their experience with operating AIX treatment systems. The agency is aware of several systems that have chosen AIX as the most effective choice for that site; other commenters such as the New Jersey Department of Environmental Protection (NJDEP) have also provided experience of this. The EPA also acknowledges that due to technical site-specific considerations, some BATs may not be the best choice for particular water types. Both GAC and AIX treatment processes rely on adequate pretreatment to reduce any constituents that may accelerate contaminant breakthrough. Generally, AIX resin pretreatment should include influent pH adjustment to avoid scaling and optimize performance, total organic carbon reduction to prevent fouling, and control of influent total suspended solids. Additionally, other processes such as aeration may be employed to oxidize transition metals such an iron and manganese for removal by filtration prior to AIX or GAC treatment in groundwater. These pretreatment as well as pilot study/engineering costs are included in the EA, for more information on costs please see section 13. The EPA is aware and acknowledged in the proposed rule as well as in the *Best Available Technologies and Small System Compliance Technologies for PFAS in Drinking Water* document that costs for each technology will vary based on site-specific conditions, so what is affordable for one site may not make economic sense for another site. Please see section 10.6 of the EPA response in this

Response to Comments document for additional discussion on treatment technology availability and capacity. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044045)

26. EPA requests comment on whether PWSs can feasibly treat to 4.0 ppt or below.

a. Treatment technologies exist to reduce PFOA and PFOS to 4.0 ppt or below. However other constituents are unknown at this time as they may not have been the target compounds in pilots or other studies. The main issue is the exorbitant costs that EPA has grossly underestimated. EPA needs to realistically consider the availability of treatment technology, treatment materials, labor, and timelines necessary to make appropriate changes at a treatment facility.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions and 10.6. For discussion of the basis for EPA's cost estimates in the Health Risk Reduction and Cost Analysis (HRRCA), please see section 13 of the EPA response in this *Response to Comments* document.

Village of Woodbury (Doc. #1629, SBC-042959)

Additionally, it is not clear what treatment technologies effectively remove these PFAS to maintain compliance with the new rule.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1608, SBC-043991 in section 10.1 in this *Response to Comments* document.

Village of Woodbury (Doc. #1629, SBC-042956)

10. The "EPA requests comment on whether PWSs can feasibly treat to 4.0 ppt or below"; in our view, this should be known with certainty prior to adoption of the proposed rule if only based on the potential economic impacts related to initiating engineering design and potentially construction efforts pre-maturely to avoid the potential of non-compliance in the face of defined source water allocation and availability constraints.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. In the final rule, the EPA had evaluated and presented full scale data of systems that treated to 4.0 ppt or below as discussed in the *Best Available Technologies and Small System Compliance Technologies for PFAS in Drinking Water, Technologies and Costs for Removing Per- and Polyfluoroalkyl Substances from Drinking Water,* and in the Drinking

Water Treatability Database. For additional discussion on how the agency considers analytic feasibility when establishing the MCL, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Village of Woodbury (Doc. #1629, SBC-042950)

4. EPA has identified Granular Activated Carbon (GAC), Anion Exchange (AIX) Resins, and Nanofiltration (NF) and Reverse Osmosis (RO) as available technologies with effective removal capabilities. According to the information provided by the EPA, these are capable of treatment to concentrations below the analytical detection limits. This information is based on lab studies, pilot scale, and full-scale applications. In our view, the EPA should summarize the information studied and include: length of the study, detected levels, treated levels, technology used including equipment, media, etc., length of time needed to purchase and install equipment, cost of purchasing and installing equipment, cost to maintain equipment/media, and useful life. We note the references section of the promulgation approximates three (3) to six (6) studies for any one of the treatment technologies, this does not appear to be a sufficient amount of data to ensure eventual compliance to proposed levels imposed by the promulgation.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenter that the agency did not consider a sufficient amount of data in how the EPA evaluated feasible treatment technologies and affordable technologies for small systems. Specifically, the EPA refers the commenter to the *Best Available Technologies and Small System Compliance Technologies for PFAS in Drinking Water* documents supporting the final NPDWR, which contain lab, pilot, and full-scale summary data as well as the *Technologies and Costs for Removing Per- and Polyfluoroalkyl Substances from Drinking Water* supporting document that contains information on operation as well as installation. As an example, the BAT support document summarized information from 57 studies for GAC and removal of PFOA and PFOS alone. Additionally, the EPA directs the commenter to the Drinking Water Treatability Database cited in the rulemaking docket, which contains tabular summaries of studies of different treatment technologies.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044192)

2. NCDEQ recommends that EPA develop guidance and in-depth training for state agencies and water systems on PFAS treatment technologies, including guidance that addresses simultaneous compliance concerns. NCDEQ recommends that EPA invest funding into evaluations of the PFAS treatment technologies (especially for small systems) to support states.

As outlined in the rule proposal, each of the BAT, in most cases, has the technical capability of treating below the detection limit for PFAS; NCDEQ has limited experience with some of the BAT for PFAS or other contaminants. In-depth training will help ensure state agencies are comfortable approving these technologies for the removal of PFAS at their water systems. Additionally, because each of the available treatment technologies may require a pilot test to

ensure treatment efficacy, NCDEQ recommends that EPA develop specific guidance on what should be required and the optimal meline for a pilot for each of the technologies at differently sized systems. This guidance should also include BAT design criteria recommendations and best practices (e.g., redundant treatment vessels, intermediate sample taps, etc.). NCDEQ strongly recommends that EPA invest funding into evaluations of these technologies by ORD. Investment should focus on treatment technologies at small water systems.

Other state agencies have noted that the initiation of granular activated carbon (GAC) treatment may release arsenic at levels that may exceed the arsenic MCL. Even if the released arsenic exceeds the MCL, state agencies want to ensure that treatment for one contaminant does not pose exposure risks for other regulated contaminants. NCDEQ recommends that EPA develop additional guidance on GAC start-up and conditions that may be utilized to ensure the safe startup of GAC. Additionally, GAC is not optimal for every PFAS. EPA should continually release the most up-to-date guidance and research to state agencies that show what treatment media is most effective depending on what PFAS analytes are being addressed on an individual water system basis.

NCDEQ also encourages EPA to consider the effects of reverse osmosis (RO) treatment, as well as nanofiltration (NF), on the corrosion chemistry of the system. NCDEQ does a treatment change evaluation that may require a corrosion control treatment (CCT) evaluation ahead of the installation of RO/NF/Ion Exchange. NCDEQ recommends that EPA provide additional clarification on this issue in the final rule.

NCDEQ recommends that EPA develop guidance for water systems considering their options to address the PFAS MCLs, both treatment and non-treatment. EPA should include some of the above considerations in that guidance material to ensure systems fully evaluate their options and understand the challenges associated with each. EPA should include considerations for regionalization/consolidation and utilize the opportunity to encourage systems that are currently not viable to connect to viable water systems. Guidance should include Information related to corrosion control concerns when consolidating systems and changing sources.

Additionally, NCDEQ recommends that EPA develop updated, in-depth simultaneous compliance guidance for state agencies. Simultaneous compliance guidance will help to ensure that compliance with one contaminant is not being traded for another, similar to the past water quality problems in Washington, DC, in which elevated lead levels were caused due to a change in disinfectant to address disinfection by-product concerns. Drinking water chemistry is very complex, and state agencies want to ensure treatment is protecting consumers from all NPDWR contaminants.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. The EPA has developed supporting rule documents such as *the Best Available Technologies and Small System Compliance for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water* document (USEPA, 2024a) that can be used to help primacy agencies develop more familiarity with these technologies over time. After finalization of the PFAS

NPDWR, the EPA also intends to work to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation and will consider the topics suggested by the commenter as the agency develops implementation materials for the final NPDWR. Sections 3.5.1 and 4.5.1 of the *Best Available Technologies and Small System Compliance for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water* document (USEPA, 2024a) contain corrosion control and other process integration information for AIX and NF/RO, respectively.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-044922)

Section 7: Treatment Technologies

EPA has identified three possible treatment technologies readily available that are successful in removing the proposed PFAS from drinking water. These three treatment techniques, identified as the BATs, are granular activated carbon (GAC), anion exchange (AIX), or high-pressure membranes such as reverse osmosis (RO) and nanofiltration (NF). Research and advancements in technology have greatly improved our understanding of PFAS, such as new developments in treatment techniques and detection limits, and new information is becoming available at an incredible pace. Cleveland Water agrees with EPA's assessment that the proposed MCLs are technologically feasible, but also would like to urge EPA to further explore the economic feasibility of these treatment techniques.

PWSs have significant differences in the composition of their source waters, as well as different environmental factors, which can influence a system's water quality. For example, source water composition is different depending on climate, region of the country, and type of water source, among other issues, including climate change impacts. These differences are what drive decisions utilities must make when new treatment is required. These decisions are rarely obvious and require time and research to make the best choice with minimal negative effects, which is why an extended compliance timeline is so critical.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. The EPA agrees that decisions to implement and operate new treatment technologies can pose challenges due to site-specific factors such as composition of source waters and other environmental factors as the commenter notes. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. Additionally, the EPA seeks to continue its research as well as outreach efforts to help develop technical and operator capacities.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-044905)

EPA creates confusion when it states in the preamble, "Measuring PFOA and PFOS results below the practical quantitation limit (PQLs) may not be achievable from all laboratories and may not have the same precision as higher-level measurements, nor does EPA believe it is

appropriate to make potentially costly compliance decisions based on such lower-level measurements." However, EPA also states that it assumes water systems will treat to 80% of the proposed MCL to include "a margin of safety." Installing these treatment techniques will take several years, so a utility risks being in noncompliance at any moment if it is approaching detection at the proposed 4.0 ppt MCL, even though EPA has expressed that it is not "appropriate" to make costly decisions on these low-level measurements. Therefore, water systems with 3.2-4.0 ppt samples whose running annual average (RAA) is below 4.0 ppt will have to make the decision to install treatment in case there is seasonal variability or spikes that may put them out of compliance, potentially costing them and their ratepayers, millions of dollars to get below this margin of safety that cannot be reliably measured.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. The 80 percent assumption was used to aid in modeling the economic impact of the rule. Systems will not be in violation if their results are less than or equal to the MCL. Systems that collect additional samples for operational assistance are not penalized under the rule. Compliance samples with results under 4.0 ppt for PFOA or PFOS are counted as a zero under the running annual average calculation, roughly meaning one sample under four would need a sample at eight to counteract it. Systems will be able to make operational decisions using the methods' available abilities to detect PFAS. For additional discussion on laboratory considerations and practical quantitation limits, please see section 5.1.2 of the EPA response in this *Response to Comments* document; for additional discussion on monitoring and compliance requirements, please see section 8 of the EPA response in this *Response to Comments* document; and for additional discussion on cost modeling and its assumptions, please see section 13 of the EPA response in this *Response to Comments* document.

A. O. Smith Corporation (Doc. #1674, SBC-043699)

4. Treatment Technologies

In the Company's experience granulated-activated-carbon (GAC), ion-exchange (IX), and reverse osmosis (RO) technologies are all effective in removing the targeted PFAS compounds in the proposed PFAS NPDWS with the caveat that the removal efficiency and capacity can vary from technology to technology and among different PFAS compounds.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document.

Horsham Water & Sewer Authority (HWSA) (Doc. #1686, SBC-043815)

Secondly, EPA disregards and therefore completely underestimates the impact of the temporary leaching of metals, in particular arsenic, from GAC. EPA states in the Technologies and Costs for Removing Per- and Polyfluorinated Substances (PFAS) from Drinking Water document that the arsenic can be "readily managed by using pre-treated GAC media or diverting the first few bed volumes of treated water to waste and not typically require post-treatment". EPA is incorrect

in both cases. As background, the PADEP inserted the following language into our GAC operating permits:

For operation of bituminous coal Granular Activated Carbon (GAC), the permittee shall, prior to operation of any new GAC Unit or after any GAC media change out:

a. Backwash the GAC Unit per the manufacture's recommendation.

b. Filter-to-waste the GAC Unit per the manufacture's recommendation.

c. Sample for arsenic in the raw water and on the effluent line after the filter-to-waste is complete. The sample shall be analyzed by a laboratory accredited by DEP for arsenic. The accredited laboratory shall report the sample results to DEP using Code "S" for Special Monitoring. The GAC Unit cannot be placed into service until the arsenic results are received and are less than 10.0 µg/l and no greater than 1.0 g/l above the raw water sample result.

D. Repeat steps "a" through "c" until the arsenic results are less than 10.0 ug/l and no greater than 1.0 ug/l above the raw water sample result.

HWSA worked with our manufacturer to test their acid rinsed pre-treated GAC and found that we were still not able to meet these conditions. As all 8 of our permanent installations have background levels of naturally occurring arsenic ranging from non-detect (below the method reporting limit of 1.0 WI) to 3.5 1.1/1, both the raw water samples and "acceptable" post-GAC samples are going to be extremely low arsenic values, well below the SDWA drinking water standard for arsenic of 10 µg/l. Looking for a difference less than or equal to the method reporting limit in two environmental samples of extremely low values themselves is analytically challenging to say the least. Numerous times, HWSA has initially flushed well over 100,000 gallons of GAC treated water to waste (~45 bed volumes for a Model 8 Calgon GAC vessel) only to find that the arsenic levels have not met condition "c." above when the laboratory report was sent and therefore had to perform additional flushing. In one case seven (7) rounds of flushing and sampling were performed over almost 2 months of time. Over 800,000 gallons of SDWA compliant water (~350 bed volumes) were flushed to waste in this case. The graph below shows the amount of water flushed versus the difference in raw water arsenic levels to post GAC levels. Note the "apparent backsliding of arsenic removal" shown in the graph due to the not unexpected analytical error in looking at two environmental samples of extremely low values well below the SDWA arsenic MCL value.

[Figure: see docket ID EPA-HQ-OW-2022-0114-1686]

This is not just a "few bed volumes" as EPA has cavalierly stated. This is a significant volume of treated water being wasted and that has a cost. But it is not just the cost for the water lost to waste, as the loss of time the unit is unavailable while performing flushing and arsenic testing means that an alternate supply has to be used to account for the loss of production. In our case that is purchased water from a neighboring utility using surface water at a higher cost than producing our own.

A neighboring ground water utility began using coconut-based GAC rather than bituminous coal-based GAC to avoid this very expensive and time-consuming process. Of course, their bed volumes dramatically decreased since coconut-based GAC does not perform as well as bituminous coal-based GAC for PFAS removal and their operating costs increased dramatically as well but they did avoid the lost production time. Either way, this is a situation that EPA is not accurately accounting for. It is our understanding that PADEP is still planning on adding this special condition to all new GAC installations in the state, and it is most likely that it will be copied by other states over time if not already, If EPA is not going to address the appropriateness of this special arsenic condition in GAC permits under the SDWA with the states, then EPA needs to at least account for this in their cost analysis.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document specifically on concerns related to arsenic release and GAC. The EPA notes that use of a BAT is not required by the rule; if site-specific conditions indicate that GAC is not the best technology to meet the rule (due to water wasting concerns or otherwise), a system is free to choose a different treatment or non-treatment option to comply with the NPDWR. For a discussion of how the EPA accounted for disposal considerations in establishing the MCL, please see sections 5.1.3 and 10.4 of the EPA response in this *Response to Comments* document. For discussion related to cost estimates as well as the assumptions used to develop them, please see section 13 of the EPA response in this *Response to Comments* document.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045040)

NJDEP recommends that EPA review the need for additional monitoring after installation of GAC, including for arsenic. NJDEP requires systems that have proposed to install GAC to sample for arsenic following initial installation and media changeouts, as some studies have indicated this as a potential concern. To ensure that these protections are available to customers of public water nationwide, NJDEP recommends EPA considers standards for this practice.

NJDEP recommends that EPA evaluate the need for monitoring backwash water. NJDEP is aware of concerns from various sewer authorities on the discharge of PFAS from GAC filter media backwashing into sanitary sewer collection systems. NJDEP therefore advises EPA to support research or evaluation of the potential for PFAS release to the waste stream when backwashing.

NJDEP recommends that EPA include language specific to carbon regeneration. Under New Jersey's Safe Drinking Water Act rules at N.J.A.C. 7:10-11.15(h)8, regenerated carbon is only permitted if it was in use at a potable water treatment plant and regenerated in facilities that only handle drinking water treatment plant media.

Anion Exchange:

An analysis of the 102 samples submitted by the thirteen facilities with AIX treatment shows only four detections of PFOA ranging from 2.2 ppt to 8.6 ppt and two detections of PFOS

ranging from 2.0 ppt to 3.2 ppt. Based on these data, the facilities that utilized AIX treatment for removal of PFAS were able to remove PFOA and PFOS to below detectable levels in 92% to 96% of all finished water samples. Detection limits for these samples ranged from 2 ppt to 5 ppt.

NJDEP advises EPA to consider challenges that may be posed by nitrosamine production which can occur in anion exchange treatment systems. This situation is believed to occur because of a reaction between free chlorine and the anion exchange. This unique chemical reaction could pose issues for systems that may have pre-chlorination for Fe/Mn removal prior to the PFAS treatment and may have other public health implications if not adequately addressed by the water system utilizing this treatment technology.

Reverse Osmosis:

EPA noted in its proposal that Reverse Osmosis is a viable treatment technology for the removal of PFAS for public water systems. NJDEP acknowledges the technical feasibility of this treatment technology. However, based on treatment permits submitted by public water systems to NJDEP, this treatment technology is infrequently selected by systems for removal of PFAS. NJDEP's understanding is that reverse osmosis presents a major challenge for waste stream management, particularly for non- community water systems. In New Jersey, non-community water systems frequently do not have municipal sewer connections and may be left with the option of discharging waste streams to a septic system or onsite waste storage tank.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. The EPA thanks the NJDEP for its comment and insight related to the BATs, particularly experience indicating their ability to treat to or below the PFAS MCLs. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation and will consider the topics suggested by the commenter as the agency develops implementation materials for the final NPDWR.

Arsenic release from GAC has been addressed in the final rule preamble, as well as the *Best Available Technologies and Small System Compliance for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water* document (USEPA, 2024a). Additionally, an MCL already exists for arsenic and regulated entities must sample at each entry point to the distribution system (EPTDS), meaning post GAC treatment. The EPA would also like to point out that typically, deep bed GAC does not require backwashing because the particulates in the water are removed ahead of the GAC system, but there may be instances where particulates deposit onto the GAC, creating a head loss that may be resolved through backwashing. If so, the backwash water may contain a PFAS foam that may be managed according to appropriate guidance such as the *Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances*.

The EPA appreciates NJDEP's insight to carbon reactivation. The EPA points out that standards such as the American Water Works Association (AWWA) and NSF/ANSI Standard 61 can help and that even carbon reactivation at a dedicated food-grade facility can lead to unanticipated

problems if the carbon is not segregated and traceable from the time it leaves the specific treatment point's location, through the receiving, storage, and reactivation at the reactivation facility, and until it is delivered back to the site because of changes in chemistry.

The EPA is aware of nitrosamine production in AIX systems. The EPA notes that pre-chlorination is not the only method to treat transition metal precipitation across contactors; aeration, for instance, or other practices may be best on a site-specific basis.

The EPA agrees and acknowledges, as well as has acknowledged in other areas such as the final rule preamble, the *Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances*, and the *Best Available Technologies and Small System Compliance for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water*, that there can be difficulties in managing RO concentrate. The EPA lowered the forecasted uptake of RO/NF for compliance in its EA for the rule based on comments such as this. The EPA notes that concentrate may require additional treatment such as with GAC or AIX prior to discharge. Please see section 10.5 of the EPA response in this *Response to Comments* document for additional information on small system compliance technologies (SSCTs) and POU devices.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045119)

7) EPA requests comment on whether PWSs can feasibly treat to 4.0 ppt or below.

This can be accomplished with a lead/lag treatment configuration and midpoint sampling to measure breakthrough of one treatment device before the PFAS reaches finished water. While this increases the cost of treatment, it is feasible as long as there are available methods to detect PFAS at these concentrations.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045097)

g. Monitoring framework with treatment:

Because the proposed regulation does not speak to the topic, the final regulation must include a minimum on-going sampling requirement for when systems install treatment that is protective of public health. It cannot be reduced to once every 3-year monitoring under the proposed framework. What happens if there is treatment breakthrough in year 2? How will we know when the media is "spent"? It can be theorized but without individual piloting, at an added cost and increased timeline, we won't know how the GAC responds to other materials in the water and what the longevity of the filters will be. There need to be clear sampling protocols, be it at mid-point locations that will signal vessel changeout, or more frequently in the finished

water/effluent. It is not protective of public health to require 3- year sampling based on the proposed regulation for a filter that actually requires annual re- bedding. Leaving it up to the States will create disparity and added regulatory processes in state rules. Creating some other arbitrary calendar-based filter changeout regime would place an undue burden on the small systems, especially those with varied seasonal flow, who would not load the filters to the extent other systems might. Our experience to date can give us a sense of how long filters can last, but that is when systems are removing 20+ppt of PFAS. The longevity of a filter removing, for example, 4 ppt is untested in our state and many others. Since the proposed regulation essentially regulates to the reporting level, there will be no allowable amount of "breakthrough" with the public and user base, many of whom will see their regular water bills increase due to the need to pay for the treatment and on-going expenses. It will also erode consumer confidence in the Water System to have levels up and down and not caught before levels approach the MCL(s). This is why the regulation must have a sampling protocol to assess efficacy and longevity of the filter vessels/media and not to leave it up to the standard framework or State-specific regulations.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. The EPA understands that some systems who install treatment may regularly sample finished water to ensure the efficacy of their treatment media (e.g., filters), above and beyond what they would do for compliance monitoring. For further information on the agency's responses to these concerns, please see section 8.1.2 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Philadelphia Water Department (PWD) (Doc. #1709, SBC-045732)

Regarding the sixth feasibility criterion of the BATs having "compatibility with other water treatment processes: The information cited in USEPA 2023g does not accurately reflect the necessary level of site-specific research that is needed for implementation to account for impacts to other treatment processes and downstream water quality. For all three BATs, the EPA states that "[a]dditional research will not be required" to determine the compatibility with other treatment processes. This statement is overly broad and does not account for the varied water quality, particularly in drinking water treatment facilities that use surface water as a source. This statement also does not account for the potential impacts to other treatment processes or downstream water quality. Specifically, IX and RO/NF are noted to increase corrosivity of finished water in Section 3.4.1 and Section 4.5.1, respectively, which would require investigation with pipe loop studies using harvested pipes. Impacts on corrosivity and its deleterious effects on compliance with the existing lead and copper rule (LCR) and future LCR Revisions or LCR Improvements (LCRR/LCRI) are not properly accounted for. Additionally, for high-pressure membranes, the EPA notes in Sections 4.4.1 and 4.5.1 that adverse effects may occur during operation of these technologies, but that additional research is not required. Pilot-scale and phased full-scale evaluations are vital to understanding these impacts and should not be dismissed.

Given the issues detailed above regarding the first, second, fourth, and sixth criteria of assessing feasibility of BATs for all three of the proposed BATs, especially in large, surface water PWSs, PWD believes that the criteria for determining feasibility were not met. EPA should re-assess the feasibility of achieving the proposed MCLs for PFOA, PFOS, and the HI through BATs, especially in large surface water systems (population over 50,000 people) which serve over 50% of the population in the United States (see Table 4-4 in rulemaking reference USEPA 2023j).

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenter's statement that the criteria for determining feasibility were not met and notes that no verifiable information was provided by the commenter as it relates to the first, second, fourth, or sixth criteria identified in this comment. These criteria have high removal efficacy, history of full-scale operation, compatibility with other treatment processes, and reasonable cost basis for large and medium systems. The EPA agrees that site-specific circumstances will require attention and investigation, such as through pilot studies, however, that is not new research but rather an engineering problem and application, which are already well understood. There is extensive supporting evidence supporting the final determinations regarding the technologies in the *Best Available Technologies and Small System Compliance for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water*, the *Drinking Water Treatability Database*, the *Technologies and Costs for Removing Per- and Polyfluoroalkyl Substances (PFAS) from Drinking Water* documents. The conclusions outlined in the record provide a clear indication of high removal efficacy, history of full-scale operation, compatibility with other treatment processes, and reasonable cost basis for large and medium systems.

The EPA notes that implementation timing associated with this PFAS NPDWR and the proposed Lead and Copper Rule Improvements (LCRI) has the potential to overlap. To the extent implementation overlaps, some rule start-up, administrative, and sampling/service line (SL) inventory costs associated with both rules could affect a large number of PWSs and states. The more significant costs of installing and operating PFAS treatment technology in a similar time frame with installing and operating corrosion control treatment (CCT) and/or conducting service line replacement are expected to fall on some systems. The EPA does not have sufficiently detailed PFAS occurrence, and lead service line (LSL)/galvanized requiring replacement (GRR) service line and 90th percentile lead tap sample data to explore the potential treatment cost interactions of the two rules. The EPA further notes that SDWA Section 1412(b)(3)(C)(i)(III) requires that the EPA include quantifiable and non-quantifiable costs that are likely to occur solely as a result of compliance with the rule, including monitoring, treatment and other costs and excluding costs resulting from compliance with other proposed or promulgated regulations. As explained in the preamble to the proposed and final rules and in these responses to comments, it is feasible for water systems to comply with both regulations and address impacts that PFAS treatment may have on CCT and to take appropriate mitigations, potentially similar to the ones outlined in the BAT/SSCT document or the summary of major public comments for this section. This is especially in light of increased funding under the BIL, which is discussed further in

section 2.4. Please see section 13 of the EPA response in this *Response to Comments* document for additional discussion on the EPA's HRRCA.

Philadelphia Water Department (PWD) (Doc. #1709, SBC-045730)

EPA should reevaluate the proposed MCL values for PFOA and PFAS and must consider more factors in evaluating technical and economic feasibility. The EPA has not demonstrated the feasibility of the BATs for large systems to achieve the proposed MCL of 4 ppt for PFOA and PFOS.

In Section VI.D, EPA states that its "proposal is based upon its proposed finding that an MCL of 4.0 ppt for PFOA and PFOS and an HI of 1.0 for perfluorohexane sulfonate (PFHxS), hexafluoropropylene oxide-dimer acid (HFPO-DA), perfluorononanoic acid (PFNA), and perfluorobutanesulfonic acid (PFBS) are feasible because treatment technologies are available that treat to below these levels and there are analytical methods that can reliably quantify at these levels". Similarly, in Section VI.A, EPA states that it "has determined that 4.0 ppt represents what is achievable for BATs given the standard of 'reasonable cost based on large and metropolitan water systems.'" EPA determines feasibility for treatment techniques based on seven conditions including the capability of a high removal efficiency, the history of full-scale operation, the reasonable cost on large and metropolitan water systems, and the compatibility with other water systems (criteria 1, 2, 4, and 6). However, PWD believes that EPA's assessment of the three proposed BATs falls short of these four criteria, especially in the case of large metropolitan water systems that have a surface water source. PWD strongly recommends that EPA revisit its determination for the application of the proposed MCLs at large surface water treatment plants or release additional data that supports the ability of the BATs to achieve the MCLs at these types of water treatment plants.

In the EPA's "Best Available Technologies and Small System Compliance for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water" document (Reference USEPA, 2023g in the Proposed rulemaking), EPA provides more information to discuss the proposed BATs and whether they meet the five criteria to determine feasibility.

Regarding the first feasibility criterion of the BATs having "the capability of a high removal efficiency": In USEPA 2023g, when assessing whether the technology is reliable enough to continuously meet a drinking water MCL, EPA states "Yes. Numerous full-scale drinking water facilities are using Granularly Activated Carbon (GAC) to meet current state drinking water requirements for PFAS". While PWD does not dispute this statement, the assessment of whether these BATs can effectively treat to various state MCLs is not relevant to this rulemaking as the EPA's proposed MCLs are lower than all state MCLs. Even in instances where GAC has been shown to effectively remove PFAS to comply with higher MCLs, the lower MCLs proposed in the draft NPDWR will affect the overall feasibility in terms of operational and maintenance costs, logistics of GAC replacement, and GAC availability. It is unclear how effective these

BATs will be at meeting this stricter MCL when it only appears to have been assessed to the state required MCLs.

Regarding the second feasibility criterion of the BATs having a "history of full-scale operation": For GAC, while there are many examples of GAC being implemented for PFAS treatment, the vast majority are referencing small groundwater sources. Of the two examples of full-scale implementation in a large, surface water Public Water System (PWS), both have questionable references without a comprehensive or cursory review of their implementation. For the first example, in Ann Arbor, Michigan, the source cited in USEPA 2023g is a non-scientific digital news article. Even so, the article, which gives a single data point on removal, clearly states that the PWS attributed the decreases observed in finished water PFAS levels to a combination of the GAC system and drastically reduced source water concentrations. For the second example cited in USEPA 2023g, a PWS in North Carolina installed GAC at one of their treatment facilities. The citation used for this example was from a non-peer-reviewed article published in Journal AWWA that discussed the decision- making process to implement GAC and the design and piloting steps taken. This article was published in October 2020 and construction on the full-scale implementation was not expected to be finished until February of 2022. No addition al information about operations at the North Carolina PWS was provided. PWD recommends that EPA release any additional information available demonstrating the successful application of GAC at large, surface water treatment plants.

This lack of evidence relating to implementation in surface water sources is compounded by the observation by EPA that increased levels of Natural Organic Matter (NOM) can reduce the efficacy of GAC. Surface water sources are likely to experience far higher levels of NOM with greater ranges in concentration than groundwater sources. Higher levels of NOM have a high potential to compete with PFAS for sorption sites. EPA does not present clear evidence that this technology can effectively remove PFAS with varying levels of NOM at full-scale. While EPA states in USEPA 2023g, "it should be possible to reliably manage the impact of natural organic matter through piloting, selection of design parameters, and operational monitoring," PWD questions whether EPA's belief in the "possible" demonstrates what is technical and feasible. For Ion Exchange (IX), EPA cites a limited number of full-scale implementation examples in USEPA 2023g; however, they are all groundwater sources and at low flow rates. There is no evidence presented that this technology will be scalable for a large, surface water PWS. For Reverse Osmosis and Nano Filtration (RO/NF), EPA does not provide any examples of RO/NF being implemented at full- scale for PFAS removal with performance data available. Overall, the full-scale feasibility of the three BATs has not been demonstrated for surface water PWSs within USEPA 2023g and additional investigation is warranted.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. The EPA notes that the preponderance of evidence documented in NPDWR supporting materials, such as the *Best Available Technologies and Small System Compliance for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water*, the Drinking Water Treatability Database, the *Technologies and Costs for Removing Per- and Polyfluoroalkyl*

Substances (PFAS) from Drinking Water, and *HRRCA* supports the EPA's assertion that this rule is feasible for large water systems. The public record also demonstrates large surface water systems that have shown that treatment to at or below 4.0 ppt is feasible such as Cape Fear Public Utility Authority, who also submitted a comment and is referenced indirectly in the comment as a PWS in North Carolina. While the EPA has reviewed data from large metropolitan systems such as Cape Fear, the EPA is not obligated to take this step. The EPA establishes drinking water standards through a formal multi-step process. *See* S. Rep. No. 169, 104th Cong., 1st Sess. (1995) at 3. As part of that process the agency generally sets an enforceable MCL as close to the MCLG as feasible, taking costs into consideration. In this second step, consistent with the definition of "feasible" in Section 1412(b)(4)(D), the EPA evaluates the availability and performance of (BATs for treating water to minimize the presence of the contaminant consistent with the MCLG as well as the costs of applying those BATs to large and metropolitan water systems when treating to that level (1412(b)(4)(E) and (5)). [2] There is no requirement that a large metropolitan system already treat only that the cost for such an entity is considered. Additionally, SDWA section 1412(b)(3)(A) requires that Agency use "(i) the best available peer reviewed science and studies conducted in accordance with sound and objective scientific practices: and (ii) data collected by accepted methods or best available methods." The data in question was collected by accepted methods although it is not necessarily peer reviewed. For additional discussion on the SDWA rulemaking process please see section 1 of the EPA response in this *Response to Comments* document, for additional information on how the agency set the MCLGs please see section 4 of the EPA response in this *Response to Comments* document, for information on how the agency considers analytic feasibility when establishing the MCL, please see 5.1.2 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. For additional information on how large metropolitan systems were incorporated into the cost analysis please see section 13 of the EPA response in this *Response to Comments* document.

Philadelphia Water Department (PWD) (Doc. #1709, SBC-045731)

Regarding the fourth feasibility criterion of the BATs having "reasonable cost based on large and metropolitan water systems": For many large and metropolitan PWSs, the population is served by a surface water source. Given the lack of evidence in USEPA 2023g on full-scale implementation of the proposed BAT in large, surface water PWSs, it is unclear how EPA can accurately estimate the costs associated with these BATs in large and metropolitan sources. Given the high percentage of large PWSs that are expected to exceed one of the three proposed MCLs (estimated at ~25% in rulemaking reference USEPA 2023j), a slight underestimation of cost when extrapolating costs from small and medium PWS implementations could result in a

[2]Based on legislative history, the EPA interprets "taking cost into consideration" in Section 1412(b)(4)(D) to be limited to "reasonable cost based on large and metropolitan drinking water systems (A Legislative History of the Safe Drinking Water Act, Committee Print, 97th Cong., 2d Sess. (1982) at 550).

severe underestimation in the overall cost of this rulemaking. Given the fact that a large portion of the cost associated with this rulemaking will be passed along to the PWS ratepayers, PWD believes that EPA should not underestimate the possible costs of this rulemaking. Additionally, in USEPA 2023g, when evaluating the fourth feasibility study, EPA assessed the "reasonable cost basis for large and medium systems" rather than "large and metropolitan" systems as stated in the rulemaking. As a result, EPA uses examples of implementation in medium systems (defined in USEPA 2023g as flow rate greater than 1 MGD and less than 10 MGD) to support this criterion. For GAC, the two large system examples are detailed above as having questionable citations and for RO/NF, they cite two large systems that have started implementation but do not have performance data available to assess their success. Additionally, the largest example facility has a rated capacity (50 MGD) that is significantly smaller than the smallest of PWD's three WTPs (86 MGD). These issues make it difficult to accurately assess both capital and operation and maintenance costs associated with these technologies in large and metropolitan water systems. This issue is further compounded by the lack of nationwide occurrence data to accurately assess the economic impact that this rulemaking will have especially on large PWSs, which are stated to serve over 200 million people across this country (rulemaking reference USEPA 2023j). PWD would also like to note that the capital cost estimates using the cost equations for large PWS for RO/NF place this technology as requiring lower capital investment than GAC or IX pressure vessels, which does not align with the experience PWD has with cost estimation for these technologies. There are several unknowns that could significantly impact capital costs that do not appear to be accounted for in these cost equations, such as utility requirements (e.g., electrical connections), land acquisition, land availability, and ancillary infrastructure needs to mitigate unintended consequences. PWD believes that EPA's implementation cost estimates significantly underestimate total capital costs for large and metropolitan surface water systems and these costs cannot be extrapolated from small and medium systems for large PWSs.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document, as well as the previous two responses to the Philadelphia Water Department. Land availability will be a factor in selecting the appropriate compliance technology as differing options have varying footprints. While "ancillary infrastructure needs" is unspecified, all work breakdown structure (WBS) models include ancillary costs, including land and permitting, as well as indirect capital costs, including electrical infrastructure, architectural fees for treatment building, sitework, among other costs. Additionally, there are contingency and miscellaneous allowances to account for unforeseen factors such as mitigating unintended consequences. For more information see the *Technologies and Costs for Removing Per- and Polyfluoroalkyl Substances (PFAS) from Drinking Water* document.

Citizens Campaign for the Environment (CCE) (Doc. #1710, SBC-045128)

We have the tools available to protect drinking water from PFAS, and it is time to use them. Activated carbon treatment systems, which have been shown to be effective and readily available, are the most studied and commonly used filtration for PFAS removal. This filtration

method has been shown to effectively remove PFAS from drinking water. [FN1: Reducing PFAS in Drinking Water with Treatment Technologies. U.S. EPA, August 2018. https://www.epa.gov/sciencematters/reducing-pfas-drinking-water-treatment-technologies] Once a water supplier installs an activated carbon treatment system for one PFAS chemical it will filter out additional PFAS chemicals. This is good news for public health protection since achieving the proposed drinking water standards is clearly realistic for water suppliers.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document; for additional information on co-removal of additional PFAS compounds, please see section 10.3 of the EPA response in this *Response to Comments* document.

Environmental Working Group (EWG) (Doc. #1721, SBC-045413)

Granular activated carbon, or GAC, is effective at reducing PFAS to the levels in the proposed rule. For example, GAC has been used at the Chemours Fayetteville facility to nearly eliminate PFAS as high as 345,000 parts per trillion (ppt) and has reduced PFAS in effluent to non-detect levels for several PFAS. [FN49: See Southern Env't Law Ctr. Et al., Comments on Advanced Notice of Proposed Rulemaking Clean Water Act Effluent Limitations Guidelines and Standards for the Organic Chemicals, Plastics and Synthetic Fibers Point Source Category, EPA-HQ-OW-202-0582, at 13.] Chemours' own testing through pilot studies shows that GAC is capable of removing more than 99 percent of 20 PFAS. [FN50: Id.] EPA researchers have found that, "GAC can be 100 percent effective for a period of time, depending on the type of carbon used, the depth of the bed of carbon, the flow rate of the water, the specific PFAS you need to remove, temperature, and the degree and type of organic matter as well as other contaminants, or constituents, in the water."[FN51: Env't Prot. Agency, Reducing PFAS in Drinking Water with Treatment Technologies, (Aug. 23, 2018), https://www.epa.gov/sciencematters/reducing-pfas-drinking-water-treatment-technologies.] A 2018 report found that GAC has been used to remove PFAS "for over 15 years at more than 45 military installations, as well as several industrial sites and publicly owned treatment works."[FN52: Interstate Technology Regulatory Council, PFAS – Per- and Polyfluoroalkyl Substances: 12. Treatment Technologies, (Updated Sept. 2020) (citing E. Forrester and J. Matthis, "Treatment Solutions for PFAS Removal: Evaluating Total Cost" (2018)) at https://pfas-1.itrcweb.org/12-treatment-technologies/.] In Michigan, several industrial dischargers saw 99 percent reductions of PFOS in effluent after installing GAC through an industrial pretreatment program for PFAS. [FN53: Michigan PFAS Action Response Team, "Wastewater Treatment Plants/Industrial Pretreatment Program," https://www.michigan.gov/pfasresponse/0,9038,7-365-88059_91299---,00.html (last updated March 2023).]

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045233)

3. EPA is seeking comment on the benefits from using treatment technologies (such as reverse osmosis and GAC) that have been demonstrated to co-remove other types of contaminants found in drinking water and whether employing these treatment technologies are sound strategies to address PFAS and other regulated or unregulated contaminants that may cooccur in drinking water.

CT DPH notes that reverse osmosis is becoming a non-viable treatment method for PWSs due to increased operation and maintenance for reverse osmosis membranes to prevent fouling, increases in operator training, and assurance that operator is onsite daily to inspect.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045231)

Treatment

EPA estimates granular activated carbon (GAC) treatment will be sufficiently available to support cost-effective compliance with this proposed regulation, and requests comment on whether additional guidance on applicable circumstances for GAC treatment is needed.

Although GAC and ion exchange resins (IX) are shown to be effective in removing certain PFAS, GAC is not optimal for short chain PFAS (Riegel, Haist-Gulde, and Sacher 2023). EPA should provide additional guidance when recommending either GAC or IX usage based on each PWS's PFAS results and not recommend GAC for short chain PFAS to avoid future issues if additional short chain PFAS become regulated. EPA should also note the referenced GAC and IX studies in the proposed rule are from 2020 and are based on EPA's previous health advisory of 70 ppt for PFOA, PFOS or the sum of both PFAS.

Effective GAC implementation will also rely on source water quality parameters and the availability of appropriate treatment vessels Due to supply chain issues, there is currently substantial lead time to procure treatment vessels with six to twelve months given as a delivery time frame.

EPA should provide additional guidance on type of GAC to implement (coal over coconut) and when a PWS should optimally implement GAC instead of IX or implement both depending on a PWS's PFAS results. Implementation of coal-based GAC requires an acid pre-wash to prevent residual arsenic issues which increases operator time and training.

Installing GAC and IX treatment at PWSs increases the overall footprint of the PWS and will add increased construction costs and the amount of time a certified operator is needed onsite (increase in training/education costs, staff costs). Workforce challenges for qualified water system operators for treatment systems will be an area that consistently needs to be addressed.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. The EPA agrees that different BATs have differing efficacies depending on site-specific conditions (such as PFAS composition, water chemistry, and many others) and water systems are free to choose technologies that best fit their circumstances. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation and plans to consider the topics suggested by the commenter as the agency develops implementation materials for the final NPDWR. While acid pre-washing is one way to lower arsenic, it is not the only option. The best option should be determined on a site-specific basis.

The EPA notes that while the GAC and AIX studies date from prior to the 2022 interim updated PFOA and PFOS health advisories, the treatment data from that time shows that GAC and AIX can treat to at or below the MCLs. The EPA also points out that pre-built contactors are not the only option and there are multiple designs and configurations, for example, a gravity contactor, which may also meet rule requirements. The EPA also agrees that installing GAC and AIX will increase costs for PWSs and has described these costs in, among other areas, the *Technologies and Costs for Removing Per- and Polyfluoroalkyl Substances (PFAS) from Drinking Water*, the individual WBS documents for the specific technologies such as the *Work Breakdown Structure-Based Cost Model for Granular Activated Carbon Drinking Water Treatment*, the EA materials, and section 13 of the this *Response to Comments* document.

Las Cruces Utilities (LCU) (Doc. #1753, SBC-043912)

In response to Section XI-Treatment Technologies, EPA requests comment on whether PWSs can feasibly treat to 4.0 ppt or below.

• The feasibility of treatment depends on PFAS concentrations and the water system configuration. In situations where PFAS concentrations are very high, multiple treatment systems may be needed in series, and would then likely become financially infeasible. The number of impacted EPTDS may also render this infeasible from a cost standpoint. In situations where the water system is configured such that centralized treatment cannot be provided, treatment would then be needed at each source (e.g., groundwater well) and this would likely become financially infeasible.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. The EPA agrees that site-specific conditions can affect engineering design and that that specific BATs may not be appropriate at specific sites. As discussed in the final rule preamble, systems are free to choose the technology that works best to achieve compliance for that system. The EPA, however, disagrees that this is financially infeasible and refers the commenter to the *Technologies and Costs for Removing Per- and Polyfluoroalkyl Substances (PFAS) from Drinking Water*, the individual WBS documents for the specific technologies such as the *Work Breakdown Structure-Based Cost Model for Granular Activated Carbon Drinking Water Treatment*, the EA materials, and the HRRCA section of the response to comment. These

documents show that vessel configuration and the other factors mentioned were considered in the cost analysis. For additional discussion on how the agency considers analytic feasibility when establishing the MCL, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For additional discussion on the EPA's HRRCA, please see section 13 of the EPA response in this *Response to Comments* document.

Las Cruces Utilities (LCU) (Doc. #1753, SBC-043919)

In response to Section XIII. Health Risk Reduction and Cost Analysis, EPA requests comment on Table 26 which provides the initial treatment technology compliance forecast, presented in percentages of systems adopting GAC, PFAS-selective IX, centralized RO, system interconnection, and use new wells across system design flows and TOC levels. This information is used in EPA's cost and benefit modeling. Please also comment on the potential for point-of-use devices, including those using RO or activated carbon as a compliance option.

• Table 26 generally is accurate for the parameters included. EPA should also consider very high concentrations of PFAS, such as greater than 400 ppt. Most of the systems can achieve greater than 99% removal, but remaining concentration would be greater than the MCL of 4.0 ppt if concentrations are greater than 400 ppt.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. Systems with very high concentrations of PFAS were included in the analysis and may have additional considerations, and alternative options to treatment include interconnection with another system or drilling new wells to replace a contaminated source. For more information on PFAS occurrence, please see section 6 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-046156)

3.3 Reverse Osmosis and Nanofiltration

RO and NF are membrane-based water treatment processes in which a semi-permeable barrier removes dissolved contaminants from water. This capability is attractive when considering the need to remove total dissolved solids (TDS), specific ions such as calcium, magnesium, sodium, chloride, sulfate, and hardness; DBP precursors; and T&O causing compounds as well as high levels of PFAS. RO/NF processes are commonly applied in water treatment plants and have applications ranging from desalination of brackish water, softening, and the removal of nitrate, agricultural chemicals (e.g., atrazine), color, total organic carbon (TOC), DBP precursors, and PFAS. Both RO and NF processes are capable of a high rejection of PFAS. While RO/NF systems are more expensive than GAC or IX systems, they are most viable when the GAC/IX replacement frequency requirements are cost-prohibitive because of high concentrations of influent PFAS.

The key differences between RO and NF are salt passage and feed pressure. RO membranes reject a higher percentage of dissolved ions in the feed water and require a greater feed pressure than NF membranes. NF membranes preferentially remove larger divalent ions or molecules compared to monovalent ions. Thus, NF systems generally exhibit lower energy use and lower operating cost than RO systems. The lower feed pressure required for NF generally translates to a slightly favorable capital cost in relation to RO systems treating the same flow rate. However, the benefits of higher salt rejection and flexibility of systems designed for RO to utilize either NF or RO membranes typically results in utilities favoring RO over marginally lower cost NF systems.

For a typical RO/NF system, membrane elements are mounted into pressure vessels that are arranged in stages, banks, or arrays. The number of stages required depends on specified recovery. Two stages are typically used for recovery less than 80 percent, and three stages are required for higher recovery. RO/NF is a cross flow filtration method, in which only a portion of the feedwater becomes permeate (finished water). The remainder leaves the system as concentrate (brine) that carries away the concentrated material before precipitation or scaling forms on the membrane surface or in the device. Antiscalant is used to control the precipitation of sparingly soluble salts such as calcium carbonate, calcium sulphate, barium sulfate, calcium fluoride, silicon dioxide, etc.

3.3.1 Implementation and Operational Considerations

The recovery of the RO/NF treatment systems depends on the concentrations of the sparingly soluble salts and typically ranges from 75 to 85 percent. Pretreatment requirements include pH depression, antiscalant chemical products to reduce scaling, and cartridge filters to protect the RO/NF membranes from particulates.

The combination of pH depression in the feedwater and the removal of alkalinity through the process results in a low pH (acidic) finished water. Gases pass through NF/RO membranes, resulting in the potential need for removal of hydrogen sulfide and carbon dioxide from the treated water. Post- treatment generally consists of gas stripping through a decarbonation tower and chemical conditioning by addition of a base such as lime or sodium hydroxide (caustic) to raise pH, alkalinity, and hardness to render the water less corrosive. Sometimes a corrosion inhibitor is also added to prevent distribution system corrosion.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. The EPA thanks the commenter for providing information about these treatment processes.

Environmental Protection Network (EPN) (Doc. #1773, SBC-043850)

While EPA has presented excellent references to support the designation of these technologies as BAT, EPN notes that EPA has omitted some key references. EPA should cite two reports by the New Jersey Drinking Water Quality Institute documenting seven different GAC treatment plants

operating for years in the U.S. that removed PFOA, PFOS, and other PFAS chemicals to non-detectable levels. [FN1: New Jersey Drinking Water Quality Institute. June 2015. Recommendations on Perfluorinated Compound Treatment Options for Drinking Water; FN2: New Jersey Drinking Water Quality Institute. November 2017. Second Addendum to Appendix C: Recommendations on Perfluorinated Compound Treatment Options for Drinking Water.] EPA should also cite the New Jersey Drinking Water Watch data which documents that seven GAC plants and five AIX plants in the state have been achieving non-detectable levels of PFOA and PFOS since 2019, with detection limits ranging from 0.53 to 5 ppt. [FN3: New Jersey Department of Environmental Protection. Drinking Water Watch.]

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. The EPA acknowledges the additional data submitted by the commenter and notes that it corroborates with the findings for the BATs identified and selected for the final NPDWR, presented in the *Best Available Technologies and Small System Compliance for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water*.

Environmental Protection Network (EPN) (Doc. #1773, SBC-043847)

PFOA and PFOS MCLs

Under SDWA section 1412(b)(4)(B), EPA must generally establish an enforceable MCL as close to the MCLG as feasible. Section 1412(b)(4)(d) defines feasibility as "feasible with the use of the best technology, treatment techniques, or other means which the Administrator finds, after examination for efficacy under field conditions and not solely under laboratory conditions, are available (taking cost into consideration)." EPN agrees that EPA has appropriately identified Best Available Treatment (BAT) as granulated activated carbon (GAC), anion exchange (AIX), reverse osmosis (RO), and nanofiltration (NF).

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document.

Northwest Biosolids Association et al. (Doc. #1783, SBC-043804)

Limited Treatment Options. Technologies do not yet exist that are proven effective for PFAS removal and destruction as part of a current treatment train. When they do become available, systems will be expensive and likely difficult to operate and maintain.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. The EPA disagrees that there are not proven technologies for the removal and destruction of PFAS. While the BATs identified for the final NPDWR are separative processes rather than destructive processes, they have been demonstrated to be effective in PFAS removal. For additional discussion of residuals management, please see section 10.4 of the EPA response in this *Response to Comments* document.

Northwest Biosolids Association et al. (Doc. #1783, SBC-043796)

[We recommend that drinking water regulations for PFAS include actions that support scientific understanding and exploring implementation solutions that would include actions such as:]

• Facility-specific evaluations to examine PFAS removal technologies, effectiveness and costs including societal impacts such as affordability, equity, energy use and greenhouse gas emissions.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document for discussion of EPA's consideration of greenhouse gas emissions. Please see section 14 of the EPA response in this *Response to Comments* document for additional discussion on affordability and equity, and for the EPA's HRRCA, please see section 13 of the EPA response in this *Response to Comments* document. Individual sites will have to incorporate these decisions in their particular sites for their unique circumstances.

West Virginia Municipal Water Quality Association (Doc. #1816, SBC-044673)

III. Technologies may not be available depending on EPA's overall PFAS-related regulatory actions.

EPA states "there are technologies currently available that effectively remove [PFOS, PFOA, PFNA, PFHxS, or HFPO-DA] and other PFAS." 88 Fed. Reg. 18638, 18684 (Mar. 29, 2023). See also 88 Fed. Reg. at 18685-86 ("GAC can be a cost-effective treatment option despite needing to dispose of contaminated carbon."; "AIX can be a cost-effective treatment option"; "The three technologies discussed [GAC, AIX, and RO] have all been demonstrated to be effective in removing all six PFAS proposed for regulation as part of this rulemaking.") EPA needs to further investigate whether technologies are as available as they perceive.

In particular, the degree of removal of long-chain and short-chain PFAS varies with the type of technology employed. Has EPA determined that all six of the PFAS being regulated can be removed with each individual technology evaluated by EPA? We question whether the technologies evaluated can be counted on to remove all six of these chemicals (comprising both short and long chain PFAS) below the proposed MCL levels.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. Yes, the EPA had determined that all six regulated PFAS can be removed by the BATs, please see the EPA response to comment Doc. #1503, SBC-042572 from Richard Kinch in section 10.1 in this *Response to Comments* document for more information on that determination. Section 10.2 of the EPA response in this *Response to Comments* document also contains information on co-removal and should be helpful for the commenter. For information on availability, please see section 10.6 of the EPA response in this *Response to Comments* document.

NORTH CAROLINA WATER QUALITY ASSOCIATION (Doc. #1818, SBC-044629)

III. Technologies may not be available depending on EPA's overall PFAS-related regulatory actions.

EPA states "there are technologies currently available that effectively remove [PFOS, PFOA, PFNA, PFHxS, or HFPO-DA] and other PFAS." 88 Fed. Reg. 18638, 18684 (Mar. 29, 2023). See also 88 Fed. Reg. at 18685-86 ("GAC can be a cost-effective treatment option despite needing to dispose of contaminated carbon."; "AIX can be a cost-effective treatment option"; "The three technologies discussed [GAC, AIX, and RO] have all been demonstrated to be effective in removing all six PFAS proposed for regulation as part of this rulemaking.") EPA needs to further investigate whether technologies are as available as they perceive.

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EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1816, SBC-044673 in section 10.1 in this *Response to Comments* document.

South Carolina Water Quality Association (Doc. #1819, SBC-044607)

III. Technologies may not be available depending on EPA's overall PFAS-related regulatory actions.

EPA states "there are technologies currently available that effectively remove [PFOS, PFOA, PFNA, PFHxS, or HFPO-DA] and other PFAS." 88 Fed. Reg. 18638, 18684 (Mar. 29, 2023). See also 88 Fed. Reg. at 18685-86 ("GAC can be a cost-effective treatment option despite needing to dispose of contaminated carbon."; "AIX can be a cost-effective treatment option"; "The three technologies discussed [GAC, AIX, and RO] have all been demonstrated to be effective in removing all six PFAS proposed for regulation as part of this rulemaking.") EPA needs to further investigate whether technologies are as available as they perceive.

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EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1816, SBC-044673 in section 10.1 in this *Response to Comments* document.

Wet Weather Partnership (Doc. #1820, SBC-044585)

III. Technologies may not be available depending on EPA's overall PFAS-related regulatory actions.

EPA states "there are technologies currently available that effectively remove [PFOS, PFOA, PFNA, PFHxS, or HFPO-DA] and other PFAS." 88 Fed. Reg. 18638, 18684 (Mar. 29, 2023). See also 88 Fed. Reg. at 18685-86 ("GAC can be a cost-effective treatment option despite needing to dispose of contaminated carbon."; "AIX can be a cost-effective treatment option"; "The three technologies discussed [GAC, AIX, and RO] have all been demonstrated to be effective in removing all six PFAS proposed for regulation as part of this rulemaking.") EPA needs to further investigate whether technologies are as available as they perceive.

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EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1816, SBC-044673 in section 10.1 in this *Response to Comments* document.

New England Water Works Association (Doc. #1836, SBC-045386)

Treatment Considerations:

EPA is proposing MCLs for PFOA and PFOS at 4 ppt and a Hazard Index approach for four other PFAS compounds: PFHxS, HFPO-DA/GenX, PFNA, and PFBS with a MCLG of 1.0 (unitless) Hazard Index. NEWWA members are unfamiliar with the Hazard Index approach as it has never been used under the Safe Drinking Water Act before. We are concerned that a cumulative regulatory approach ignores the complexities of selecting, implementing, and operating the appropriate and affordable PFAS treatment solutions.

There are a limited number of drinking water treatment technologies that are currently known to be effective for PFAS removal. However, there is no one-size-fits-all solution. Depending on several site- specific factors, such as the concentrations and types of PFAS present in the source water(s), general water quality characteristics, and existing treatment processes, treatment technologies may show different removal effectiveness for the varying carbon chain lengths and attached functional groups. EPA needs to provide flexibility within this regulation to allow for expansion of treatment options as technology progresses. Advancement in Best Available Technologies (BATs) will be made, and EPA and primacy states need to be positioned to swiftly approve new BATs.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. The EPA agrees that not every BAT represents the best treatment option for an individual system and site-specific considerations can inform BAT selection. The EPA notes that water systems may choose any treatment or non-treatment options to comply with the MCL and that it does not necessarily need to be a BAT identified in the final NPDWR. For more information on co-removal, please see section 10.2 of the EPA response in this *Response to Comments* document. For information on the cumulative regulatory approach, please see the EPA response to comment Doc. #1567, SBC-042734 in section 10.1 in this *Response to Comments* document.

New England Water Works Association (Doc. #1836, SBC-045388)

There is significant engineering effort and cost that goes into selection of the appropriate treatment technologies for a given water system. Site-specific testing, either bench-scale or pilot-scale, that evaluates the effectiveness of the treatment technologies with the actual contaminated water and the follow-up cost analysis is critical for:

1) Identifying the appropriate treatment solution for that specific water and existing treatment process;

2) Selecting the cost-effective alternative; and

3) Identifying and avoiding any potential unintended consequences that are inherently possible when any new water treatment process is added (e.g., although this is a very infrequent occurrence, coal- based carbon has been observed to release arsenic under certain water conditions).

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. The EPA agrees that effort should go into selecting the appropriate treatment technology for a particular treatment site. The EPA also agrees that bench testing (which may reduce the cost of pilot testing) and pilot testing are important costs that are considered in the final NPDWR. Please see section 13 of the EPA response in this *Response to Comments* document for additional discussion on the EPA's HRRCA.

Anna Trujillo (Doc. #1959, SBC-047297)

Reverse osmosis, activated carbon treatments, and ion exchange treatments can all be used to remove PFAs from water. Each therapy has a unique result, and some are more successful than others, but generally, the therapies are advancing human health, the environment, and the well-being of our animals.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document.

Brittney Johansen (Doc. #2750, SBC-047419)

The technologies on the EPA's own website published in January 2022 show promise for removing PFAS from water at different scales. These methods need to be applied to the appropriate scales and accessible nationally for all income levels at the expense of companies holding CBI's for any form of PFAS chemical.

I also request a hard stop to all forms of current and future PFAS manufacturing.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. For additional discussion on comments outside the scope of the current NPDWR, please see section 15.1 of the EPA response in this *Response to Comments* document. For more information on the HRRCA please see section 13 of the EPA response in this *Response to Comments* document.

Nick Fitzgerald (Doc. #3072-94, SBC-047406)

Next, I'm convinced that bold, passive American-made solutions can be achieved to begin removing PFAS from the environment on the scale necessitated. Wherever PFAS contaminated groundwater seeps into larger bodies of water, we should be installing bioswales with granular activated carbon, GAC, amended soils or burying GAC in fine bags or gabion baskets for passive subsurface water remediation and periodic disposal to proper sites. We should be studying if our wildfire ravaged forest can be harvested while replanted to produce GAC locally for pennies on the dollar. Are we studying how GAC from native species such as Douglas fir, Maple, or Aspen work to remove PFAS? Are we studying which climate change ready native plant species can effectively draw up and remove PFAS from contaminated areas? Likely contaminated groundwater seeps from the west plains into the Spokane River, present a perfect opportunity for proof of concept because this is unfortunately coming down to costs and the scale of the issue could readily put Fortune 500 companies into bankruptcy. We may just have to bootstrap this with community planting projects, give us plant starts, we can organize and help achieve this shared dire goal. If this issue could be around for centuries, we will do best to act quickly to remove PFAS in bulk from the environment such that it's largely persistent on a time scale of decades or years. With talented engineers and constructors and federal level scientific support, this problem could be meaningfully reduced in real time. A designed and built water sampling devices for pesticide studies for the USGS that were in order of magnitude less costly than alternatives. I am a build your own laboratory type of guy, and there are plenty more like me out there who could be sourced to actually address this problem on a scale that begins to approach the magnitude of the issue at hand. What I hear is people asking for the government to do something, anything, in response to the issue, not hand waving or vouchers for laboratory-grown livers. We are years past knowing this is a big concern. They want to fish their historic waterways and not get cancer. Have you fixed the problem that you should have protected the nation from in the first place? I hear folks talking about government mistrust. Meaningfully addressing environmental PFAS without further bankrupting the youth would go miles in

restoring faith in government. Nicholas B Fitzgerald, Spokane, Washington. Thank you. I yield back.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. For additional discussion on comments outside the scope of the current NPDWR, please see section 15.1 of the EPA response in this *Response to Comments* document. The EPA also notes that research is an important part of the PFAS Strategic Roadmap and EPA has looked into phytoremediation such as the October 1, 2018, through March 31, 2019, Small Business Innovation Research (SBIR) – Phase I grant Phytoremediation of PFAS via phytoextraction among others as well as funding research into different sorbents through the Innovative Water Technology Micropollutants request for application mechanism.

Robert Hollander (Doc. #1516, SBC-042713)

6. 88 FR 18688, 1st paragraph

Does reactivation of GAC and incineration of resin destroy any PFAS residues contained in them?

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comment*s document. The EPA refers the commenter to section three of the *Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances* available on the internet at: https://www.epa.gov/system/files/documents/2021-11/epa-hq-olem-2020-0527-0002_content.pdf for a thorough discussion of this question.

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-042885)

Treatment Considerations:

EPA is proposing MCLs for PFOA and PFOS at 4 ppt and a Hazard Index approach for four other PFAS compounds: PFHxS, HFPO-DA/GenX, PFNA, PFBS with a MCL of 1.0 (unitless) Hazard Index. MWWA is unfamiliar with the Hazard Index approach. While perhaps common in the EPA's CERCLA program and the Massachusetts Waste-Site Clean-up program, it has never been used before under the SDWA. We are concerned that a cumulative regulatory approach ignores the complexities of selecting, implementing, and operating the appropriate and affordable PFAS treatment solutions. We are also concerned about the uncertainties that exist if EPA decides to regulate more PFAS compounds in the future under the Hazard Index.

There are a limited number of drinking water treatment technologies that are currently known to be effective for PFAS removal. However, there is no one-size-fits-all solution. Depending on several site-specific factors, such as the concentrations and types of PFAS present in the source water(s), general water quality characteristics, and existing treatment processes, treatment technologies may show different removal effectiveness for the varying carbon chain lengths and attached functional groups. EPA needs to provide flexibility within this regulation to allow for

expansion of treatment options as technology progresses. Advancement in Best Available Technologies (BATs) will be made, and EPA and primacy states need to be positioned to swiftly approve new BATs. It is recommended that EPA and primacy states streamline their new technology review process to grant approvals more quickly. In Massachusetts, MassDEP required new technology approval for Granulated Activated Carbon (GAC) which required manufacturers, consultants, and PWS to jump through hoops that MWWA believes were unnecessary given that GAC has been widely used in water treatment and is one of only a few proven technologies for removing PFAS.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document, it describes how water systems may use technologies other than BATs to meet the MCLs. Some primacy agencies may require permits and approval of technologies. The EPA has provided materials such as the *Best Available Technologies and Small System Compliance for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water* document to assist primacy agencies that may require permitting. For information on the cumulative regulatory approach, please see the EPA response to comment Doc. #1567, SBC-042734 in section 10.1 in this *Response to Comments* document, as well as section 10.4 of the EPA response in this *Response to Comments* document.

American Water Works Company Inc. (Doc. #1608, SBC-043995)

Reverse Osmosis/Nanofiltration

American Water believes that RO/NF are not practical treatment technologies for most utilities. RO/NF membrane processes are extremely energy-intensive, very susceptible to fouling, and produce a voluminous waste stream that poses an additional treatment/disposal challenge because of dissolved solids and PFAS content. RO/NF treatment will likely only be appropriate for utilities whose only available sources of supply contain elevated total dissolved solids that cannot be removed via another more cost-effective or environmentally friendly treatment process.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044118)

ASDWA recommends that EPA provide guidance on the BAT options offered that would be effective on a small enough scale to be used at these small water systems.

Numerous primacy agencies have indicated that they do not have experience with very small treatment units for PFAS treatment. However, primacy agencies have expressed the importance of ensuring treatment units are correctly sized for the water system.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. After finalization of the PFAS NPDWR, the EPA also intends to work to

provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation and plans to consider the topics suggested by the commenter as the agency develops implementation materials for the final NPDWR. More information on SSCTs can be found in section 10.5 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044108)

Primacy agencies have also highlighted concerns regarding the use of reverse osmosis (RO). While in some circumstances, RO may be the best option, this technology has many challenges that may not be able to be overcome and would make RO infeasible for some water systems. The cost to install and operate over time due to energy usage, waste disposal, and operator costs make the technology infeasible for many small water systems. RO is very difficult to operate and requires a highly trained and certified operator—primacy agencies have seen water systems with RO installed that fail to properly maintain the treatment, prematurely foul the membrane, or even enter enforcement due to operational concerns. Additionally, systems in states with limited water resources may experience water rights conflicts because of the amount of water used for brine disposal. Water systems in these states may also have limited disposal options for RO brine since there is limited dilution in the waterways. Primacy agencies have noted that these systems are left with limited options of deep well injection or evaporation ponds. One final concern regarding RO, as well as nanofiltration (NF), is the effect on the corrosion chemistry of the system. Some primacy agencies require a corrosion control treatment (CCT) evaluation before installing RO/NF/IX. ASDWA recommends that EPA provide additional clarification on these issues in the final rule.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. The EPA agrees that RO may be the best option in some circumstances and may not be appropriate in others, based on are site-specific concerns. More information about handling RO brine is provided in the *Interim PFAS Destruction and Disposal Guidance*. In acknowledgement of these potential issues for RO and NF, the EPA has adjusted RO/NF's technology projection compliance forecast to 0 percent in the final rule's EA. Additionally, the EPA has published guidance on corrosivity concerns in various places, for example, the *Best Available Technologies and Small System Compliance Technologies for PFAS in Drinking Water* in sections 3.4.1 and 4.5.1 for AIX and RO/NF, respectively.

Washington County Department of Public Health and Environment (Doc. #1739, SBC-043573)

Available technologies

• In the discussion of best available technologies or BATs in Part A, Section XI, Treatment Technologies, a non-treatment option such as finding an alternate source of drinking water (i.e. drilling a new well) or purchase water from another facility is included.

o The use of alternative drinking water sources, such as drilling new wells in deeper aquifers, may involve risks over the long term to community water supplies, due to the interconnectivity

of groundwater sources. The Twin Cities East Metro area of PFAS contamination is a example of the interconnectedness of water resources.

o EPA should consider adding a discussion of emerging destruction and separation technology types that may provide future treatment efficacy at the small and large scale.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. After finalization of the PFAS NPDWR, the EPA also intends to work to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation and plans to consider the topics suggested by the commenter as the agency develops implementation materials for the final NPDWR. The final NPDWR does not require the use of any specific BAT and systems may choose other treatment or non-treatment approaches (e.g., connecting to new source waters) to comply with the rule based on site-specific conditions for a given utility, including water quality, available space, disposal options, local rules, and currently installed unit operations.

National Ground Water Association (NGWA) (Doc. #1804, SBC-045473)

[The steps identified in that letter include:]

• accelerating research on water treatment and health effects to support future decision making and contaminant prioritization, and

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document.

Association of Missouri Cleanwater Agencies (Doc. #1817, SBC-044651)

III. Technologies may not be available depending on EPA's overall PFAS-related regulatory actions.

EPA states "there are technologies currently available that effectively remove [PFOS, PFOA, PFNA, PFHxS, or HFPO-DA] and other PFAS." 88 Fed. Reg. 18638, 18684 (Mar. 29, 2023). See also 88 Fed. Reg. at 18685-86 ("GAC can be a cost-effective treatment option despite needing to dispose of contaminated carbon."; "AIX can be a cost-effective treatment option"; "The three technologies discussed [GAC, AIX, and RO] have all been demonstrated to be effective in removing all six PFAS proposed for regulation as part of this rulemaking.") EPA needs to further investigate whether technologies are as available as they perceive.

In particular, the degree of removal of long-chain and short-chain PFAS varies with the type of technology employed. Has EPA determined that all six of the PFAS being regulated can be removed with each individual technology evaluated by EPA? We question whether the technologies evaluated can be counted on to remove all six of these chemicals (comprising both short and long chain PFAS) below the proposed MCL levels.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1816, SBC-044673 in section 10.1 in this *Response to Comments* document.

Professor Emeritus of Geophysics (Doc. #3072-90, SBC-046398)

My name is George Jiracek. I am a Professor Emeritus of Geophysics living in San Diego. I've studied our planet from pole to pole and on every continent. It's just over five years ago since famous physicist Stephen Hawking died after publishing a book for public consumption, where he warned that there are three ways within a thousand years that we may not survive on planet Earth. They are: (1) runaway climate change; (2) nuclear Armageddon; and (3) an asteroid impact. As a scientist, I must add one more, PFAS. This is because as mentioned by others, PFAS affect reproductive organs, both male and female, and if we can't have children, we will not survive. So since 99% of us have PFAS in our bloodstreams and we remove PFAS through waste products which continue to have PFAS, we must develop methods that destroy, not just filter, PFAS at absolute levels of 100% and at scale. Treatments such as ion exchange, granular activated carbon, and reverse osmosis are only 90% effective. Recycling drinking water programs do not remove 100% of PFAS. I think what we really need is a national, international moonshot program now aimed at how to best break carbon-fluorine bonds so we can destroy 100% of all dangerous PFAS, not only in drinking water, but in all sources. As a veteran, I know that we now spend $81 billion on defense each year. Surely, we can spend what it takes to save human life on our planet. Thank you.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. The EPA's final rule represents data-driven drinking water standards that are based on the best available science, meet the requirements of SDWA, and that regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water.

Water and Wastewater Equipment Manufacturers Association (WWEMA) (Doc. #1727, SBC-043525)

[Please see our comments below.]

Comment #2: PFAS Liability Shield Needed for Technology Solution Providers

To take full advantage of the historic $50 billion in BIL funding of which $10 billion is dedicated to PFAS remediation, it will be critical to ensure liability protections for technology solution providers. As a passive receiver, WWEMA is asking for state and Federal policymakers to protect technology solution providers who are actively working to address our country's PFAS contamination crisis from future liability. In order to fully utilize the current BATs listed by EPA and to promote early adoption and technology evolution for PFAS removal, solution providers should be encouraged to bring current and innovative technologies to bear and be shielded from third party litigation and liability lawsuits. Without policy makers shielding technology providers

from lawsuits outside of acceptable liability scope, this could seriously impact the ability of these solution providers to address these issues at the state and local levels. Without such assurances, companies may be reluctant to provide technologies to the water marketplace or to further invest in innovation and new technologies for PFAS removal.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. SDWA does not provide EPA with the liability protection authority requested by the commenter.

American Water Works Association (AWWA) (Doc. #1759, SBC-046150)

Appendix B

WITAF 056 Technical Memorandum Update: PFAS National Cost Model Report

WITAF 56 TECHNICAL MEMORANDUM UPDATE

PFAS National Cost Model Report

B&V PROJECT NO. 409850

PREPARED FOR

American Water Works Association

26 MAY 2023

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Abbreviations

[Table of Abbreviations: Docket ID: EPA-HQ-OW-2022-0114-1759].0 Acknowledgement

This study was a collaborative effort; many individuals and utilities spent time compiling data, answering questions, and making contacts. We wish to thank the following utilities for sharing data and Steering Committee Members for their time and insight:

Partner Utilities:

• Cape Fear Public Utility Authority (CFPUA)

• City of Ann Arbor

• Greater Cincinnati Water Works

• Plainfield Charter Township

• City of North Miami Beach

• Miami-Dade County Water and Sewer Department

• Tucson Water

• Steering Committee Members:

• Amy Stoffer – Northern Kentucky Water District

• Cynthia Lane – Platte Canyon

• Carel Vandermeyden – CFPUA

• Robert Cheng – Coachella Valley Water District

• Zaid Chowdhury – Garver USA

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2.0 Introduction

Known as "forever chemicals" because they do not easily biodegrade, per- and polyfluoroalkyl substances (PFAS) are drawing increased scrutiny from health agencies, water utilities, and the public for their presence in drinking water and their effects on human and environmental health. They have quickly become contaminants of great concern in drinking water.

Six PFAS compounds were monitored in finished drinking water as part of the Third Unregulated Contaminant Monitoring Rule (UCMR 3) between 2013 and 2015 to quantify their prevalence across the United States. The UCMR program provides the U.S. Environmental Protection Agency (EPA) with nationally representative occurrence data to inform drinking water regulations. Using the results from UCMR 3, in February 2021, the EPA published a final determination to regulate perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) and signaled an interest in considering the regulation of additional PFAS. On March 14, 2023 the EPA announced the first proposed National Primary Drinking Water Regulation (NPDWR) for six PFAS compounds, including PFOA, PFOS, perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO-DA, commonly known as GenX Chemicals), perfluorohexane sulfonic acid (PFHxS), and perfluorobutane sulfonic acid (PFBS). The deadline for public comment on this proposed regulation is May 30th, 2023 and the EPA has publicly committed to promulgate the PFAS NPDWR by the end of 2023.

U.S. federal laws and executive orders stipulate that the U.S. EPA estimate the cost of compliance for this new primary drinking water regulation. Black & Veatch was selected by the

American Water Works Association (AWWA) to develop a national cost estimate for water systems to remove PFAS from drinking water to better understand the financial impacts to communities and the costs to comply with a national primary drinking water regulation, a policy that could impact each of the more than 66,500 public water systems.

The project was funded by the Water Industry Technical Action Fund (WITAF), which is managed by the AWWA's Water Utility Council to support projects, studies, analyses, reports, and presentations in support of the organization's legislative and regulatory agenda. The national cost estimate and its cost models, developed under WITAF 056, are intended to support to AWWA's engagement with the U.S. EPA and Congress on the differences in financial impacts of treating drinking water to various PFAS regulatory limits. WITAF funded a separate project (WITAF 057) to generate a national PFAS occurrence database using data from state monitoring and UCMR3. This national database was used as an input for the WITAF 057 project.

The national cost modeling tool programmatically evaluates each public water system (PWS) with occurrence data from WITAF 057 to generate a dataset of the most probable capital and operating costs. Those costs are then scaled up nationally to account for the PWSs without data captured in WITAF 057 to quantify the national cost of compliance of a proposed regulation, bringing flexibility for data-driven responses to EPA cost assessments. This project brought together occurrence data, cost data, and best practice design methodology to help ensure the U.S. EPA's proposed national primary drinking water regulations for PFAS accurately reflect cost estimates for drinking water treatment.

3.0 PFAS Treatment Technologies

Treatment strategies for PFAS in drinking water include proven, commercially available technologies as well as emerging technologies. Many of these developing technologies have been demonstrated on the bench scale but have not yet been proven at the full scale or are not yet commercially available.

Commercially available technologies that have been demonstrated at full scale in the field to reduce concentrations of PFAS in drinking water are limited to the following:

- Granular activated carbon (GAC).
- Ion exchange (IX).
- Nanofiltration (NF) and reverse osmosis (RO).

Treatment considerations for the application of each of these technologies are described in the following subsections.

3.1 Granular Activated Carbon

GAC media is a well-known adsorbent for organics and has been widely applied in water treatment. GAC is produced from carbon-based materials such as coal, coconut shells, peat, or wood that has been "activated" to produce a highly porous media with adsorptive properties. The

pores contain sites on which organic compounds become attached and are adsorbed onto the activated carbon matrix.

GAC treatment applications include removal of organics, such as color, disinfection byproducts (DBP) and their precursors, taste and odor (T&O) causing compounds, industrial chemicals, and emerging contaminants such as PFAS, endocrine disrupting compounds, and pharmaceuticals and personal care products. Each of these contaminants compete for adsorption sites on GAC media with targeted PFAS if present. In some cases, co-adsorption can be viewed as a benefit for using GAC as the co-contaminants are simultaneously removed. Cost analyses and removal performance models must balance competitive adsorption of co-contaminants and its associated detrimental performance impact on PFAS removal.

GAC has a finite capacity for adsorbing compounds. High concentrations of organics or high flow rates will lead to more frequent media replacement. In general, short-chained PFAS are less readily adsorbed and less strongly bound than long chain compounds. The overall efficacy of GAC removal of PFAS highly dependent on the water matrix, the water treatment goals, and the design of the system. One of the most important design parameters is the empty bed contact time (EBCT), or the time during which the water is in contact with the media bed (also the duration at which adsorption can occur), assuming the water flows through the entire bed at a constant velocity. A desired EBCT will result in breakthrough when the adsorptive capacity of the media has been exhausted. The media must be either replaced or reactivated at that time.

3.1.1 Implementation and Operational Considerations

GAC applied for PFAS removal is most effective when used solely as an adsorbent. Conventional granular media filters containing GAC are typically designed for short EBCTs and must be frequently backwashed for removal of particulate material that is retained in the media. Such backwashing disrupts the adsorption front. Short EBCTs and backwashing lead to fast breakthrough of contaminants and underutilization of GAC media. If a water treatment facility contains conventional filters, contactors for GAC adsorption are typically located downstream.

Process selection (including GAC media selection) is typically confirmed through demonstration testing (bench-, pilot- or full-scale studies) to account for the unique characteristics of the source water.

GAC adsorption treatment systems installed for PFAS removal typically provide a 10 to 20 minute EBCT and a surface loading rate of 4 to 10 gallon per minute (gpm) per square foot of media (gpm/sf). PFAS adsorbers are applied in two main configurations: pressure vessels or gravity basins.

• Pressure vessel configurations are more common in small systems (less than approximately 10 million gallons per day [mgd]). Pre-engineered pressure-vessel type GAC treatment systems are widely available. Vessels are typically carbon steel or fiberglass reinforced plastic (FRP). Pressure vessels may be installed in single (parallel) or dual stage (series/lead-lag) arrangements.

o The single stage arrangement allows for columns to be operated in various stages of breakthrough or exhaustion, resulting in an overall effluent below the treatment target. This arrangement can result in better media utilization, produce a more consistent product water quality, and lessen impact of potential overruns on individual vessels. Single stage systems typically include N+1 redundancy.

o The dual stage arrangement allows for simultaneous production during media replacement, and sampling between vessels ensures that lag vessel effluent always meets treatment targets. The lead vessel can be in service until the media is completely exhausted, leading to higher utilization of the adsorbent media. The dual stage arrangement includes built-in redundancy as either the lead or lag vessel can be removed from service without reducing the treatment flow rate. Thus, no dedicated redundant vessels are typically provided.

• To avoid an excessive number of pressure vessels, gravity basin configurations are typically applied by large systems with design flows greater than approximately 10 mgd. Gravity basins are typically single stage and operated at various stages of breakthrough, similar to a single stage pressure vessel arrangement. The basins themselves are typically constructed of concrete with an N+1 redundancy because of the single stage arrangement.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. The EPA acknowledges the information referenced by the commenter and has considered the information in updating the cost estimates for the final NPDWR. For additional discussion on the EPA's cost analysis, please see section 13.3 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-046153)

3.2 Ion Exchange

IX is an adsorptive water treatment process that involves the selective exchange of ions in solution with ions bound to a resin matrix. IX has a long history in water treatment, and resins are manufactured for a variety of contaminants, including PFAS. Several manufacturers provide specific IX resins designed to be selective for PFAS as the market has expanded for their use. Some resins originally intended for removal of other contaminants (such as perchlorate) have shown a high degree of selectivity and capacity for PFAS as well.

IX resins, like GAC, have a limited capacity for adsorption. The adsorptive capacity of IX resins is affected by contaminant concentrations and flow rates in the same manner as GAC. However, the IX resins surveyed have proven to be highly selective toward PFAS removal, exhibiting minimal removal of other contaminants. This may result in a greater adsorptive capacity for PFAS compared to GAC, without, however, the co-contaminant removal benefits of other technologies. In general, short-chained PFAS are less readily adsorbed and less strongly bound than long chain compounds. The overall efficacy of IX for PFAS removal is highly individual to the water matrix, the water treatment goals, and the design of the system.

An IX treatment process does not result in a fixed percentage removal of a contaminant over time, as there is a variable degree of contaminant removal and gradual or sharp contaminant breakthrough. Although it is selective to certain contaminant groups, the resin can experience interference from other compounds in the water matrix. The most preferred compound will tend to exhibit long runs and sharp breakthroughs; less preferred compounds will have earlier, more gradual breakthroughs.

Exhaustion of the media is determined (in a fashion similar to that for GAC) through the measure of the contaminant in the effluent (breakthrough). When the adsorptive capacity has been exhausted, the resins require replacement or regeneration. Because of the proposed CERCLA hazardous substance designations for PFOA and PFOS as discussed in Subsection 3.1.1, single use (fixed-bed) systems are currently being considered for IX, requiring disposal of spent media and replacement with new resin when exhausted. PFAS destruction technologies are currently in research and development that may be able to destroy PFAS in the brine stream, although that technology is not yet matured enough for full- scale implementation.

Fixed-bed IX has been demonstrated at full scale in the field as a proven PFAS removal technology. Fixed-bed ion exchangers applied for PFAS removal consist of carbon steel or FRP pressure vessels and typically 1.5 to 3 minutes of EBCT (as compared to 10 to 20 minutes for GAC). IX can be favorable because of the smaller footprint required.

3.2.1 Implementation and Operational Considerations

The efficacy of an IX treatment system will likely be improved by a pretreatment step to remove interferences such as suspended solids, particulate natural organic matter, and colloidal compounds. Commercially available filters can be selected depending on the pretreatment needs to improve the treatment capacity of the IX system. This prefiltration step can prevent deposition of fine particles on the resin, reduce pressure drop across a column, and increase run time.

Process selection (including resin selection) is typically confirmed through demonstration testing (bench-, pilot- or full-scale studies) to account for the unique characteristics of the source water.

Ion exchange treatment systems are conventionally installed in pressure filters in lieu of gravity basins. As with GAC, the pressure vessels can be implemented in single or dual stage arrangements.

Considerations for the single or dual stage arrangements are summarized in Subsection 3.1.1.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. For information on the cumulative regulatory approach, please see the EPA response to comment Doc. #1567, SBC-042734 in section 10.1 in this *Response to Comments* document, as well as section 10.4 of the EPA response in this *Response to Comments* document. The EPA acknowledges the information referenced by the commenter.

Environmental Protection Network (EPN) (Doc. #1773, SBC-043865)

EPN agrees that EPA has appropriately identified BAT achieving this HI of one as GAC, AIX, RO, and NF. EPA asks for public comment on whether these technologies will also remove other PFAS not included in the rule. Studies cited in this rule and EPA's Drinking Water Treatability database show that GAC and AIX removal efficiencies generally increase as PFAS chain length increases. RO and NF have higher removal efficiencies than GAC and AIX for short chain PFAS. EPN recommends that EPA review drinking water treatment data from Massachusetts, Vermont, and Michigan because these states have MCLs for PFAS not included in this rule (PFHxA, PFHpA, PFDA). They should have monitoring data indicating removal efficiencies for these three additional PFAS.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. The SDWA regulates contaminants that meet specific regulatory criteria as outlined in section 3; the EPA appreciates data sources for other PFAS. For more information on treatment efficacy in relation to chain length, please see section 10.3 of the EPA response in this *Response to Comments* document.

Environmental Working Group (EWG) (Doc. #1721, SBC-045414)

There are also additional highly effective technologies that treat PFAS in drinking water. In North Carolina, the Fayetteville Chemours Plant is using a reverse osmosis treatment system, coupled with GAC and IX, to treat the wastewater from its manufacturing processes. Pilot tests for an RO system at Northwest Water Treatment Plant in North Carolina found that it was expected to remove 90 percent or more of PFAS compounds, including GenX. [FN54: See Anna Reade, Tracy Quinn, & Judith S. Schreiber, Scientific & Policy Assessment for Per- and Polyfluoroalkyl Substances in Drinking Water, NAT. RES. DEF. COUNCIL at 55 (April 12, 2019), https://www.nrdc.org/sites/default/files/media-uploads/nrdc_pfas_report.pdf.] RO is considered the most robust technology for protecting against unidentified contaminants and does not require media change out nearly as often as GAC. [FN55:Id.] Although less common than GAC systems, RO systems are being used nationwide to remove PFAS. For example, the West Morgan-East Lawrence Water Authority serving Decatur, Alabama, is installing an RO system to remove PFAS. [FN56: Alabama Dep't of Env't Mgmt., Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water, http://adem.alabama.gov/programs/water/drinkingwater/pfaspage.cnt (last visited May 29, 2023).]

IX or IX resins specified to perform to the same standard as GAC have also been shown to be effective in some cases. [FN57: Tasha Stoiber et al., PFAS in Drinking Water: An Emergent Water Quality Threat, WATER SOLS. (2020), https://www.ewg.org/sites/default/files/u352/Stoiber_Evans_WaterSolutions_2020.pdf.]

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document for more information on co-removal. The EPA thanks the commenter for providing examples of systems employing RO at full scale and acknowledges that site-specific

conditions can make technologies perform to different levels. The EPA agrees that the BATs chosen are appropriate and notes that RO systems do not use media but may need to change membranes.

Environmental Council of the States (ECOS) (Doc. #1752, SBC-044506)

Treatment Technology Review

As water systems plan to comply with the NPDWR, they will look to states and EPA for help identifying effective and reliable treatment technologies. While several treatment options exist, water systems will need support and information to evaluate the challenges and benefits of different technology options. ECOS recommends that EPA support evaluations of PFAS treatment technologies by the Office of Research and Development, with particular focus on treatment options for smaller systems, and that EPA develop additional information and guidance for systems about various PFAS treatment options. Additionally, ECOS acknowledges that treatment technology improvements will require technical and operational training for public water system operators and encourages EPA to provide resources to address this need.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. The EPA has developed supporting rule documents such as the *Best Available Technologies and Small System Compliance for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water* document that can be used to help develop familiarity with proven drinking water PFAS technologies. After finalization of the PFAS NPDWR, the EPA also intends to work to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation. The EPA is currently funding many technical assistance efforts associated with PFAS, including supporting treatment infrastructure projects through the DWSRF and the Emerging Contaminant grant program as designated and funded through the BIL. As outlined in the PFAS Strategic Roadmap, the EPA is committed to addressing PFAS. The ORD is also evaluating and developing technologies for reducing PFAS in the environment to inform decisions on drinking water and wastewater treatment, contaminated site cleanup and remediation, air emission controls, and end-of-life materials management.

New York State Department of Health (NYS DOH) (Doc. #1677, SBC-044950)

12. In quantifying the benefits realized through the use of RO, GAC and ion exchange resins to treat PFAS, EPA does not consider the potential health impacts associated with microbiological, organic and inorganic constituents that may leach or be released from the treatment media, potentially offsetting a portion of the benefits. Carbon used for PFAS removal is typically either bituminous or coconut shell-based coals, All coals contain some arsenic (USGS, 2005). While coconut shell-based coals can have lower arsenic levels than their bituminous competitors, many of the largest producers of GAC for PFAS removal use bituminous based coals for PFAS removal. To compensate, many GAC manufacturers have developed acid washed coal to reduce levels of contaminants. Nonetheless, based on our observations in full scale carbon treatment

systems, the New York State Department of Health has developed guidance that recommends three consecutive results be provided that show decreasing arsenic concentrations as the forward rinse to waste progresses and for which the last sample concentration is below the arsenic MCL [FN2: https://www.health.ny.gov/environmental/water/drinking/docs/interim_recommendationszfor_granular_activated_carbon_installations_v_l.pdf].

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document.

Eastern Municipal Water District (EMWD) (Doc. #1780, SBC-043822)

EMWD has a unique situation where we treat brackish groundwater that is too salty to drink, through a reverse osmosis (RO) system, and then utilize a bypass to blend a small portion of the salty groundwater with the RO water before placing the water in the distribution system. This practice of adding back a reasonable amount of total dissolved solids (TDS) and alkalinity back to the water is important because makes the water more palatable, and helps prevent corrosion of the potable water distribution system. Once this MCL is in place, EMWD would nesed to manage this system differently, in a manner that treats 100 percent of the groundwater to ensure PFAS removal, and then add the necessary TDS and alkalinity through a source that is not salty groundwater. This additional treatment will incur construction costs, additional operation and maintenance costs, as well as the cost of chemicals to adjust the alkalinity.

During a meeting with EPA last week, we expressed concerns regarding the cost of PFAS clean-up, and EPA staff directed us to SRF, WIFIA, and other loan opportunities. Loans are not a reasonable answer to the cost challenge. Even though loans can extend the repayment period, the cost of PFAS cleanup is ultimately and unfairly shouldered by drinking water customers.

EPA Response: Please see section 10.1 of the EPA response in this *Response to Comments* document. For more information treatment considerations related to MCLs, please see section 5.1.4 of the EPA response in this *Response to Comments* document. Regarding funding considerations, please see section 2.4 of the EPA response in this *Response to Comments* document.

10.2 Other PFAS Removal Treatment Technologies

Summary of Major Public Comments and EPA Responses

The EPA received many suggestions for additional BATs including powdered activated carbon (PAC), alternative sorbents, and new destructive technologies. However, these alternative BATs proposed, except for PAC, currently lack demonstrated full-scale removal of the six PFAS under consideration. The EPA notes that there are some reports of PAC use on a temporary basis and that it can reduce PFAS concentrations in drinking water. PAC may be an appropriate choice of technology in certain circumstances; however, its efficacy for trace removal tends to be variable due to factors such as carbon particle size, background organics, and plant efficiency. Therefore,

PAC is not as effective as GAC overall, and the agency has not designated it as a BAT. The EPA periodically reevaluates treatment technologies and may add additional technologies based on updated information. It is important to note that water systems may use any technology or practice to meet the PFAS MCLs and are not limited to the BATs in this rule. Other technologies may be chosen in lieu of BAT because they may be more cost effective or better suited to the specific operating conditions of the particular site to meet the MCL.

Individual Public Comments

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-044895)

Treatment Considerations

• DEP recommends that EPA reestablish the national Environmental Treatment Verification (ETV) program to streamline and improve efficiencies regarding review and approval of new treatment technologies. Without this national program, states must approve treatment technologies at the state level, which is neither streamlined nor efficient, and creates an unnecessary burden on limited resources for states, water systems, and treatment technology manufacturers.

EPA Response: Please see section 10.2 of the EPA response in this *Response to Comments* document. The EPA's Environmental Technology Verification Program (ETV) concluded operations in early 2014 and reestablishing the ETV is outside the scope of this NPDWR. More information on permitting can be found in section 10.1 of the EPA response in this *Response to Comments* document.

Orange County Water District (OCWD), California (Doc. #1634, SBC-043239)

Alternative Treatment Technologies

EPA requested additional information on PFAS removal treatment technologies not identified in the proposed rule that have been shown to reduce levels of PFAS to the proposed standard. OCWD's ongoing pilot testing program has identified at least one alternative adsorbent, comprised of a proprietary surface-modified clay mineral, which shows promising performance as compared to the more established granular activated carbon (GAC) and ion exchange (IX) technologies. These types of emerging technologies offer potentially lower operating costs via selectivity and/or enhanced PFAS sorption capacity. OCWD recommends EPA tailor the final rule such that these types of alternative treatment technologies can be more easily approved by state primacy agencies for use in PFAS water treatment. This would help spur research, innovation, and development for additional cost-effective options for treatment media, thereby helping to meet the significant increase in demand associated with the final rule.

EPA Response: Please see section 10.2 of the EPA response in this *Response to Comments* document. The EPA thanks the commenter for providing anecdotal information on emerging technologies for treating PFAS in drinking water to at or below the MCLs. The EPA

agrees with commenter that alternative technologies may have adequate removal efficacy and affordable costs. The EPA points out that SDWA does not require permits nor does SDWA require approval for technology use. The EPA is also funding the development of these alternative technologies directly through, for example, the Innovative Water Technology Grant Program for next generation adsorbents and SBIR grants. More information on permitting can be found in section 10.1 of the EPA response in this *Response to Comments* document.

Park City Municipal Corporation (Doc. #2793, SBC-046610)

Park City Municipal Corporation, water system number UTAH22011, is a 8,500 population public water system that has PFAS detections in all three of its groundwater wells. We attribute the source of PFAS to be from Fluoro Ski Wax, and have prohibited it in our Source Protection Ordinance and implemented a successful ski wax take back program to reduce further environmental impact. Please consider the following comment regarding EPA's proposed PFAS Drinking Water Rule.

We request that the Proposed PFAS Rule specifically identifies the ability to utilize a blending plan as a non-treatment MCL compliance option. There is nothing in the proposed rule that prevents us from using blending as long as we do it before the Entry Point to the Distribution System. However, we think many State regulators shy away from agreeing to anything that is not specifically stated in the EPA rule. So, we do think that it is important for blending to be mentioned as an option, even if in passing, just to make sure that States are comfortable approving a water system blending strategy.

PFOS and PFOA concentrations in our wells range from 4-7 parts per trillion (ppt). We have the ability to blend other sources that do not have detectable PFAS concentrations to below the proposed MCLs. Our consultant, Water Quality and Treatment Solutions, Inc (WQTS) developed Conceptual Design and Probable Cost of PFAS Treatment Systems for the City's Groundwater Wells. Conceptual level cost estimates (–30% / +50%) to treat all three wells with ion exchange, one of the PFAS best available technology treatment options range from $6.8 - $14.7 Million in capital costs and $250K-$550K per year in operation and maintenance costs. Blending costs are less than $40k and operational requirements are minimal in comparison with treatment requirements.

EPA identifies blending as a viable compliance option in the documents found at the following links.

- Help for Small Systems in Complying with Drinking Water Regulations, identifies Blending Source Waters as a non-treatment compliance option, https://www.epa.gov/dwcapacity/help-small-systems-complying-drinking-water-regulations#non-treatment, -Systems that have multiple sources may be able to mix, or blend, these waters prior to distribution to their customers. Blending source water can help to lower contaminant concentrations."

- The Arsenic Rule has supporting compliance documents that identify blending as a viable compliance option.

- Complying With the Revised Drinking Water Standard for Arsenic: Small Entity Compliance Guide, https://www.epa.gov/sites/default/files/2015-09/documents/2005_11_10_arsenic_ars_final_app_f_1.pdf, STEP #5 – If a Problem Exists, What Are My Options? Source Water Changes: If arsenic levels in your existing water source exceed the MCL, you may want to consider blending water from a source with low arsenic levels with your current source. The level of arsenic in the blended water may be low enough to comply with the Arsenic Rule.

- Arsenic Treatment Technology Evaluation Handbook for Small Systems: https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=200026IH.txt, Arsenic Mitigation Checklist, 3. Determine if a non-treatment mitigation strategy such as source abandonment or blending can be implemented. Description of Arsenic Mitigation Strategies: Blending - The combination of multiple water sources to produce a stream with an arsenic concentration below the MCL.

Affordability has become a significant challenge in Park City where we have had to establish some of the higher water rates in the Country due to CWA and SDWA compliance orders and requirements for removal of metals from Park City's mine tunnel drinking water sources. We have bonded $140M to pay for a new, compliance ordered metals removal water treatment plant and associated infrastructure, which required significant rate increases over the last decade. We did not anticipate the cost of treating to remove PFAS in our financial models, and will have to implement additional rate increases if we have to treat to remove PFAS rather than achieve compliance through blending. The State of Utah Drinking Water Board has preliminarily reviewed and is not supportive of the potential for Park City to receive grant funding for PFAS Treatment; therefore, compliance costs would need to paid by rate payers.

EPA Response: Please see section 10.2 of the EPA response in this *Response to Comments* document. The EPA notes that no specific technology, technique, or process is required under this rule to meet the MCLs and that all options have potential tradeoffs. The EPA recommends that utilities and primacy agencies evaluate all options according to their site-specific needs and circumstances. The EPA thanks the commenter for providing data related to its projected compliance costs; more information on the EPA cost models can be found in section 13 HRRCA. As noted in the final rule preamble, section II.E, funding under the Infrastructure Investment and Jobs Act (IIJA), often referred to as the BIL, will assist many disadvantaged communities, small systems, and others with the costs of addressing emerging contaminants, like PFAS, when it might otherwise be cost-challenging. More information on BIL may be found in section 2.4 of the EPA response in this *Response to Comments* document. Additionally, to support BIL implementation, the EPA is offering water technical assistance (WaterTA) to help communities identify water challenges and solutions, build capacity, and develop application materials to access water infrastructure funding (USEPA, 2023b).

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045043)

In addition, NJDEP requests clarification on whether EPA would support blending as an option to achieve compliance with the proposed MCLs.

EPA Response: Please see section 10.2 of the EPA response in this *Response to Comments* document. The EPA notes no specific technology, technique, or process is required under this rule to meet the MCLs and that all options have potential tradeoffs. The EPA recommends that utilities and primacy agencies evaluate all options according to their site-specific needs and circumstances.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045042)

Additional Treatment Technologies:

EPA requested additional information on PFAS removal treatment technologies that were not identified in the proposed rule that have been shown to reduce levels of PFAS. NJDEP is currently anticipating a permit proposal for a system to use reverse osmosis to isolate PFAS, then remove PFAS from the concentrate stream using an aqueous electrostatic contactor. The technology proposed by the water system completed a study under the EPA's Small Business Innovation Research (SBIR) Phase 1 (2019).

In terms of treatment technologies not identified in the proposed rule, NJDEP notes that it has conditionally approved for use an adsorptive media that works in a similar way to GAC that does not require backwash. The systems that have received approval for use of this media have not installed the treatment at this time. Additional information about this media is available at https://www.mineralstech.com/business-segments/performance-materials/cetco/environmental-products/products/fluoro-sorb.

Additional Considerations:

EPA's proposal does not note any recommendations for a lead-lag configuration for anion exchange and GAC treatment. Considering the potential public health impacts and delays between sampling and receipt of analysis results, EPA should consider whether systems should implement a lead-lag configuration to reduce public health impacts in the event of breakthrough in the lead media vessel. Depending on the frequency with which a system is sampling, breakthrough may not be noticed for a significant period.

EPA Response: Please see section 10.2 of the EPA response in this *Response to Comments* document. The EPA thanks the commenter for providing an example of a treatment train consisting of RO (an identified BAT) and a novel concentration technology (an aqueous electrostatic contactor) as well as an example of a novel adsorptive media. The EPA welcomes any data, observations, and comments that NJDEP can provide surrounding the treatment trains and novel technology. The EPA reevaluates BATs and may add additional technologies based on updated information. The EPA believes that each system in consultation with their primacy

agency will appropriately adjust to site-specific considerations. The final rule is not proscriptive in how water systems achieve compliance with the MCLs and agrees that lead-lag configurations may be appropriate in many situations.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045114)

4) Are there additional technologies which are viable for PFAS removal to the proposed MCLs as well as any additional costs which may be associated with non-treatment options such as water rights procurement:

a. Foam fractionation: We would appreciate an evaluation of foam fractionation - is this actually feasible and it is a viable option?

EPA Response: Please see section 10.2 of the EPA response in this *Response to Comments* document. The EPA notes that foam fractionation has had success according to limited research; however, this technology has not met all criteria to be a BAT. Specifically, most studies on foam fractionation were performed with detection limits too high to be relevant for this regulation, many PFAS included in the rule were missing from the studies, the EPA is unaware of any full-scale drinking water applications, nor at the current time is there enough understanding to understand and interpret smaller scale studies to full-scale, and questions remain about the mass-balance for the process that may oxidatively transform PFAS precursors; therefore, the EPA lacks the data to conclude whether this technology is a feasible and viable option for water systems and based on this lack of understanding cannot designate foam fractionation as a PFAS BAT at this time. The EPA notes that innovation is important, and a pilot study may help determine the viability of foam fractionation for a specific site.

Louisville Water Company (Doc. #1720, SBC-043557)

[In that regard, we are providing the following comments on key issues that we think require consideration.]

7. Louisville Water is mildly concerned that although the agency has discussed granulated activated carbon (GAC), it has been largely silent on the use of powdered activated carbon (PAC) as a treatment technology. In fact, Louisville Water has been conducting research on the efficacy of PAC to remove various PFAS in Louisville Water conditions and we are confident that PAC will be a feasible alternative to attain compliance. PAC is effective for treating the PFAS of concern (PFOA and other long-chain PFAS) for Louisville Water sources, dosage can be based on water-quality conditions (for PFAS and other water quality issues), will have less impact on current treatment processes, and the capital and operating costs of PAC will be substantially lower than alternatives. Additionally, PAC has other water quality benefits, including reduced disinfection by-product precursors (TOCs), reduced microcontaminants, improved taste and odor control, and improved operational flexibility.

EPA Response: Please see section 10.2 of the EPA response in this *Response to Comments* document. The EPA appreciates the commenter's research and encourages Louisville Water Company to use the best technology in consultation with the primacy agency to comply with the MCLs, considering site-specific conditions. The EPA also notes that information about treating specific PFAS, such as HFPO-DA, with PAC is included in the Drinking Water Treatability Database, which is available online at https://tdb.epa.gov/tdb/home.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045980)

Section 7.2: Alternative treatment technology

EPA requested additional information on PFAS removal treatment technologies not identified in the proposed rule that have been shown to reduce levels of PFAS to the proposed standard. Several AMWA members are currently undergoing testing of some emerging alternative absorbance media, like clay, specifically for PFAS removal. Because clay media does not co-remove TOC, it would be beneficial for utilities that have raw water TOC levels that could interfere with other PFAS-removing media. AMWA recommends EPA consider additional treatment techniques once they have been fully tested and shown they meet PFAS removal targets. More options for media would decrease demand for others, like GAC, where there may be a struggle to meet demand.

PWSs testing alternative absorbance media technology have seen initial signs of adequate removal efficacy and have found initial costs to be comparable to AIX and GAC. These alternative media even have the potential to require lower operation and maintenance costs over their lifetimes. As evident with the other technologies EPA lists, there is still uncertainty over the disposal options of the media. AMWA requests that EPA keep additional absorbance technologies in mind and consider their use when possible.

EPA Response: Please see section 10.2 of the EPA response in this *Response to Comments* document. The EPA appreciates and thanks the Association of Metropolitan Water Agencies (AMWA) for providing an example of a novel adsorptive media. The EPA reevaluates treatment technologies and may add additional BATs based on updated information.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045232)

2. EPA requests additional information on PFAS removal treatment technologies not identified in the proposed rule that have been shown to reduce levels of PFAS to the proposed regulatory standard.

CT DPH would encourage EPA to look at the wide range of PFAS treatment and prevention technologies currently in use or in study and not limited to drinking water treatment. This includes an update on the PFAS Innovative Treatment Team (PITT) studies on electrochemical oxidation and super critical water oxidation.

For waste generation reduction, technologies such as surface-active foam fractionalization (SAFF) are encouraging and similar technology and practicality for PWS implementation could be further researched.

EPA Response: Please see section 10.2 of the EPA response in this *Response to Comments* document. The EPA appreciates the examples cited by the Connecticut Department of Public Health. The EPA considers research as a key pillar of the PFAS Strategic Roadmap. Destructive technologies are discussed in the *Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances* available on the internet at: https://www.epa.gov/system/files/documents/2021-11/epa-hq-olem-2020-0527-0002_content.pdf

Aclarity (Doc. #1755, SBC-044510)

Ensuring Best Available Solutions are Utilized

The federal government has a responsibility to use all available resources to eliminate pollution, safeguard public health, and develop laws that reinforce public health safeguards particularly in underserved communities and provide all communities with safe drinking water. Equitable access to clean water is a basic human right, essential for survival and well-being. It encompasses safe water for drinking, hygiene, agriculture, and daily life. It requires improving infrastructure, water management, and pollution control. Collaboration among governments, organizations, and along with adequate resources, education, and advocacy for marginalized communities are imperative. By recognizing water as a human right, we can create a just and sustainable future, ensuring equal access for all. Removing dangerous chemicals from our water, such as PFAS, is critical and ensuring the PFAS cycle ends is the only way to ensure this.

There are known and reliable technologies available today to safely remove and destroy PFAS from drinking water. We urge the federal government to use all available resources in addressing PFAS. It is imperative, when evaluating use of funds for future infrastructure, to include innovative technologies such as electrochemical processes (EOx) in any technological planning. EOx is a reliable process that has been in use in the water industry for decades.

PFAS destruction technologies, such as Electrochemical Oxidation, Supercritical Water Oxidation, and others are a viable improvement to the current removal methods used for PFAS such as Granular Activated Carbon or Ion Exchange which merely remove PFAS. PFAS destruction technologies can be partnered with removal technologies in a cost effective manner to ensure PFAS are destroyed forever and do not remain in our environment, moving through constant removal and disposal cycles.

EPA Response: Please see section 10.2 of the EPA response in this *Response to Comments* document. The EPA appreciates the commenter's examples of emerging PFAS destruction technologies. The EPA agrees that in some circumstances on-site destruction can be more effective than utilization of an off-site destruction and disposal vendor. Destructive

technologies are discussed in the *Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances* available on the internet at: https://www.epa.gov/system/files/documents/2021-11/epa-hq-olem-2020-0527-0002_content.pdf. While no electrochemical oxidation (EOx) process was selected as a BAT for drinking water treatment, these processes may be considered in the future. No EOx processes were chosen because there are no full-scale studies available on these processes and these processes are not currently understood well enough to scale up PFAS data to full scale. Removal efficiencies have also not been demonstrated well enough in the required ranges for this regulation and there are some concerns related to partial defluoridation of longer compounds creating more short-chained PFAS in some circumstances; There is also not enough data available in the literature at this time surrounding PFAS mixtures or costs associated with using these technologies at scale. The PFAS Innovative Treatment Team (PITT) has published research briefs on additional non-traditional destruction and disposal methods, including electrochemical oxidation, mechanochemical degradation, pyrolysis and gasification, as well as supercritical water oxidation.

Aclarity (Doc. #1755, SBC-044512)

There are currently numerous companies with field deployed technology that destroy PFAS: Aclarity, Aquagga, 374Water, AECOM, and Batelle. There are others under rapid development including but not limited to Purafide, Enspired Solutions, OnVector, Axine, Xyvant, and Claros Technologies. These destruction technologies need to be considered to permanently eliminate PFAS.

Who We Are

Aclarity is a venture-backed, woman owned and founded water technology company based in Massachusetts. Aclarity's low energy, electrochemical process quickly and safely destroys dangerous contaminants in water at the industrial scale and makes it easy to destroy unwanted contaminants such as PFAS in landfill leachate and other highly concentrated PFAS streams. Aclarity's mission is to destroy PFAS forever. Our Aclarity electrochemical oxidation system destroys PFAS chemicals in water and liquid waste for pennies per gallon today. We pass concentrated PFAS streams, like raw landfill leachate, through our fully skidded and modular electrochemical oxidation system and destroy PFAS compounds to greater than 99%. Full-scale PFAS destruction has been demonstrated at steady-state for weeks in the field.

Aclarity greatly appreciates the opportunity to respond to this rulemaking. We would be happy to provide more information or schedule a meeting to discuss our views in greater detail if that would be helpful.

Sincerely,

Julie Bliss Mullen

Aclarity Founder and Chief Executive Officer www.aclaritywater.com

EPA Response: Please see section 10.2 of the EPA response in this *Response to Comments* document. The EPA thanks the commenter for sharing examples of PFAS destruction technologies and vendors and invites commenter to send in data, particularly the full-scale data, information on how complete defluoridation was measured, and other pertinent experiment details. More information on why electrochemical oxidation was not selected as a BAT is provided in the EPA response to comment Doc. #1755, SBC-044510 from Aclarity in section 10.2 in this *Response to Comments* document.

Connecticut Section of the AWWA (CTAWWA) and Connecticut Water Works Association (CWWA) (Doc. #1763, SBC-044233)

We are encouraged that ongoing research is pursuing destructive treatment technologies as an alternative to the traditional PFAS treatment methods that include granular activated carbon, reverse osmosis, and ion exchange. These destructive technologies have the potential to provide a benefit to utilities, to their ratepayers, and to the environment. We encourage the EPA to invest in accelerating the research on these technologies, thereby avoiding a situation where utilities are 'forced' into today's treatment options even though superior options are on the horizon.

EPA Response: Please see sections 10.1 and 10.2 of the EPA response in this *Response to Comments* document. The EPA refers the commenter to the EPA response to comment Doc. #1634, SBC-043239 in section 10.2 in this *Response to Comments* document. Please see section 12 of the EPA response in this *Response to Comments* document for more information about implementation timelines. Rules could be deferred indefinitely waiting for technological improvement; in light of available information on health effects, occurrence, currently available analytical methods, and currently feasible treatment technologies, deferring this rule is not in line with the EPA mission to protect human health.

Northwest Biosolids Association et al. (Doc. #1783, SBC-043797)

[We recommend that drinking water regulations for PFAS include actions that support scientific understanding and exploring implementation solutions that would include actions such as:]

• Examination of flexible compliance actions with thresholds that can be achieved through current available technologies.

EPA Response: Please see sections 10.1 and 10.2 of the EPA response in this *Response to Comments* document. The EPA, and the public comment record, has shown that the MCLs are achievable through currently available technologies. The EPA also does not dictate specific methods to achieve compliance with MCLs. Please see section 5 of the EPA response in this *Response to Comments* document for more information on how the agency evaluated feasibility of the MCLs. Section 10 of the EPA response in this *Response to Comments* document contains information on how BATs were evaluated.

Anonymous (Doc. #2373, SBC-047426)

I would also like to comment on the best available technologies for treating contaminated sources of PFAS and disposal options of the residuals. While further research likely needs to occur, there appears to be some promising treatments that could chemically breakdown PFAS into safe byproducts, meaning disposal will not be an issue (Morris, 2022).

Morris, A. (2022, August 18). "Forever chemicals" destroyed by simple new method. News.northwestern.edu. https://news.northwestern.edu/stories/2022/08/forever-chemicals-destroyed-by-simple-new-method/

EPA Response: Please see section 10.2 of the EPA response in this *Response to Comments* document. The EPA appreciates an example of a destructive technology and agrees that significant research needs to occur before this could be viable. The *Interim PFAS Destruction and Disposal Guidance* contains information on judging the readiness level of disposal and destruction processes.

Orange Water and Sewer Authority (OWASA) (Doc. #1524, SBC-042614)

Our comments around the rule focus primarily on the timeline for compliance and the associated supply chain issues with construction.

PFAS Regulation Comments

• Treatment

*OWASA's water treatment plant is already optimized for current rules and regulations (and the WTP has been involved with the AWWA and EPA supported Partnership for Safe Water program and has received numerous awards) yet the addition of treatment for PFAS removal provides very little ancillary benefit for our water quality (beyond the required removal of PFAS compounds). This is a large investment for a singular benefit.

*Treatment has yet to be determined and PFAS removal treatment may require post treatment chemical additions to return the water to a more palatable state.

EPA Response: Please see sections 10.1, 10.2 and 10.3 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. The EPA agrees that each BAT may require post-treatment steps depending on site-specific circumstances. The EPA disagrees that PFAS treatment provides a singular benefit with very little ancillary benefit; surface water systems like Orange Water and Sewer Authority (OWASA) can particularly benefit through disinfection byproducts (DBP) precursor reduction or removal of non-targeted PFAS as described in section 10.3 of the EPA response in this *Response to Comments* document.

10.3 PFAS Co-Removal

Summary of Major Public Comments and EPA Responses

A significant majority of commenters supported the EPA's position that treatment technologies that remove PFAS provide ancillary benefits by removing other known or potential contaminants. One commenter disputed the ability of these technologies to provide ancillary benefits, and others suggested that the EPA's proposed regulation would provide only limited protection against the many PFAS not under consideration in the rule. The EPA disagrees with the commenters who state that the proposed regulation would not result in a reduction in co-occurring PFAS and other contaminants. Burkhardt et al. (2023) estimates that 30 of 31 PFAS that are quantified by EPA Methods 533 and 537.1 can be economically removed by GAC in typical water qualities and that of 428 PFAS evaluated, 76-87 percent are economically treatable. The co-removal benefits are well documented in the scientific literature and in the evidence submitted by public comment. The Best Available Technologies and Technologies and Cost support documents summarize literature demonstrating the co-removal capabilities of treatment technologies.

Some commenters stated that treatment for one PFAS does not inherently imply removal of other PFAS. The EPA agrees, as discussed in the proposed rule preamble. In general, there is an inverse relationship between treatability and toxicity, which is tied to the carbon backbone (Bellia et al., 2023). Generally, the longer the carbon backbone length, the more easily the PFAS is removed by a given treatment technology. For example, if PFOA (C8) is targeted for removal by the water system, perfluorodecanoic acid (PFDA, C10) would most likely be removed as well. However, the converse would not be true (i.e., a system targeting PFNA (C9) removal would reduce perfluorohexanoic acid [PFHxA] (C6) to a lesser extent).

Some commenters suggested that co-removal would decrease the removal efficiency of GAC or AIX and that removal efficiency of non-target contaminants is lower than it could otherwise be. The EPA agrees that the removal of non-targeted contaminants by GAC or AIX can lower the PFAS removal efficiency; the agency has accounted for this uncertainty in Appendix N of the EA (USEPA, 2024b). The EPA also agrees that targeting contaminants for removal will be more effective than relying on other non-targeted removal. For example, a GAC facility designed to remove PFAS will not be as effective at removing DBP precursors as a facility designed for that; however, there will still be co-removal of DBP precursors, which may lead to a reduction in DBPs. Ultimately, treatment facilities operate best when tailored to specific contaminants or mixture of contaminants unique to that location. For additional information on the EPA's co-benefit analysis, please see section XII in the final rule preamble.

Some commenters expressed concern about co-removal taking beneficial ions from water, specifically fluoride ions, and suggested that would be an added cost to the rule. The EPA notes that fluoride has a legally enforceable MCL of 4.0 mg/L, and a non-enforceable secondary standard of 2.0 mg/L to prevent mild or moderate dental fluorosis. The EPA also notes that while some PFAS contain organic fluorine bound to carbon, fluorine and fluoride are not the same. The

BATs identified for the removal of PFAS for drinking water are not optimized for the removal of fluoride and do not necessarily provide effective removal of naturally occurring fluoride. For example, GAC is ineffective for fluoride removal at environmentally relevant pHs.

Some commenters suggested that co-removal may make it more difficult to dispose of materials left over from the drinking water treatment processes, known as treatment residuals. For example, GAC may remove and concentrate radon or other contaminants to such an extent that the spent media is considered hazardous. The EPA believes that removing hazardous constituents from drinking water is generally beneficial even though it could complicate residual management. More details on treatment residuals are discussed in part C of this section below.

Some commenters also suggest more research may be beneficial to understanding co-removal. The EPA agrees (USEPA, 2022a).

Individual Public Comments

Alliance of Nurses for Healthy Environments (Doc. #1544, SBC-042671)

Under EPA's proposal, drinking water utilities will be required to test water for PFOA, PFOS, GenX, PFBS, PFNA, and PFHxS and install treatment technologies to reduce the concentrations of these chemicals to the level of EPA's proposed "maximum contaminant levels" or lower. Fortunately, proven technology is available that will not only reduce the presence of the six PFAS in EPA's proposal, but will also improve protection against other PFAS compounds and common contaminants.

EPA Response: Please see section 10.3 of the EPA response in this *Response to Comments* document. The EPA agrees that proven technology is available that will improve protection against these regulated PFAS and other contaminants and notes that non-treatment options are also available for compliance.

Virginia Health Catalyst (Doc. #1556, SBC-042866)

While it is critical to address the dangers of PFAS contamination in our water supply, we urge EPA to not take any action that unintentionally bans, removes, or restricts other chemicals essential to public health. Fluoride, for example, is a chemical that has been added to public water supplies for decades to help prevent tooth decay, particularly in low-income communities. It is crucial that any regulations aimed at reducing PFAS contamination do not inadvertently limit or eliminate the use of fluoride or other public health interventions.

We urge the EPA to carefully consider the potential unintended consequences of any proposed regulations, and to work with public health experts and stakeholders to develop solutions that effectively address PFAS contamination while preserving access to safe and effective interventions like fluoride.

Thank you for your continued efforts to protect the health and safety of our communities. Please do not hesitate to contact me at sholland@vahealthcatalyst.org or 804-269-8721 should you have any questions.

Sincerely,

Sarah Bedard Holland

Chief Executive Officer

Virginia Health Catalyst

EPA Response: Please see section 10.3 of the EPA response in this *Response to Comments* document.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044046)

27. EPA requests comment on the co-removal of the HI chemicals (PFHxS, PFBS, PFNA, and HFPO-DA) when GAC, IX, or RO are used in the treatment of PFOA and/or PFOS.

a. Treatments used for PFOA/PFOS don't necessarily remove (efficiently) the four other compounds, particularly PFHxS.

EPA Response: Please see sections 10.1 and 10.3 of the EPA response in this *Response to Comments* document. The EPA agrees that treatment processes should account for site-specific circumstances and that a treatment optimized for one chemical may not be as effective for another chemical.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044018)

2. EPA requests comment on its evaluation that regulation of PFHxS, HFPO-DA, PFNA, PFBS, and their mixtures, in addition to PFOA and PFOS, will provide protection from PFAS that will not be regulated under this proposed rule.

a. CWUC is unsure if there is enough data and evidence to answer this question at this time. There is a high likelihood that many other PFAS compounds will be removed using the same treatment technologies installed to remove these six, but the full spectrum of removal capabilities is currently unknown.

EPA Response: Please see sections 10.1 and 10.3 of the EPA response in this *Response to Comments* document.

New England Interstate Water Pollution Control Commission (NEIWPCC) (Doc. #1650, SBC-043150)

Furthermore, our member states are concerned with the effect of treatment technologies on beneficial fluoride present in the water. Over 12 million people are served by water systems with

naturally occurring fluoride at or above optimal levels. [FN8: https://www.cdc.gov/fluoridation/statistics/2018stats.htm] Certain treatment technologies, such as activated carbon [FN9: https://www.watertechonline.com/wastewater/article/15549902/the-basics-of-activated-carbon-adsorption], could remove this fluoride, leading to negative impacts on the oral and general health of the public. We urge EPA to consider the costs associated with ensuring those systems are able to continue to supply consumers with beneficial fluoride, the public health impact if fluoride is no longer present, and to support the development of treatment technologies that encourage the persistence of beneficial fluoride.

EPA Response: Please see section 10.3 of the EPA response in this *Response to Comments* document.

American Dental Association (ADA) (Doc. #1671, SBC-043689)

EPA is proposing to reduce the maximum allowable concentration of these PFAS in public drinking water—from 4.0 nanograms per liter (ng/L) to 1.0 ng/L—based on a determination that no adverse effects are known or anticipated to occur at that exposure level. This goal would be achieved, in part, by requiring water control authorities to install new filtration technologies at their public water distribution system's point of entry.

EPA has identified "compatibility with other water treatment processes" as one of its criteria for recognizing the best available PFAS removal technologies. [FN1: 88 FR 18684] However, the PFAS-removing technologies EPA is currently proposing [FN*: EPA has identified granular activated carbon (GAC), anion exchange resin (AIX), reverse osmosis (RO), and nanofiltration (NF) as the best available technologies to achieve a PFAS concentration level of 1.0 ng/L or less in public drinking water.] have the potential to undermine a water treatment process that has advanced the public's oral health for more than 75 years: community water fluoridation.

Community water fluoridation is the controlled adjustment of the natural fluoride content in water to 0.7 mg/L, which is the level recommended by the U.S. Public Health Service to help prevent tooth decay. [FN2: U.S. Department of Health and Human Services. Federal Panel on Community Water Fluoridation. U.S. Public Health Service recommendation for fluoride concentration in drinking water for the prevention of dental caries. Public Health Rep. 2015 Jul-Aug; 130(4): 318–331. doi:10.1177/003335491513000408] For more than 75 years, it has been a safe and inexpensive way to reduce tooth decay in children and adults by at least 25 percent. [FN3: American Dental Association, Fluoridation Facts, 2018. Available at www.ada.org/resources/ community-initiatives/fluoride-in-water/fluoridation-facts (accessed May 30, 2023)] In fact, the CDC hailed it as one of ten great public health achievements of the 20th century. [FN4: 4 Centers for Disease Control and Prevention. Ten Great Public Health Achievements – United States, 1900-1999. MMWR 1999; 48 (12): 241-243. Available at: www.cdc.gov/mmwr/preview/ mmwrhtml/00056796.htm (accessed May 30, 2023)]

In 2018, 73 percent of the U.S. population on community water systems—207,426,535 people—had access to fluoridated water. [FN5: Based on water system data reported by states to the CDC

Water Fluoridation Reporting System as of December 31, 2018. Available at www.cdc.gov/fluoridation/statistics/2018stats.htm (accessed May 30, 2023)] The national health objectives in Healthy People 2030 aim to increase that number to over 77 percent. [FN6: Office of Disease Prevention and Health Promotion. (n.d.). Oral Conditios. Healthy People 2030. U.S. Department of Health and Human Services. Available at www.health.gov/healthypeople/objectives-and-data/browse-objectives/oral-conditions (accessed May 30, 2023)]

As you continue exploring the best available PFAS removal technologies, we urge you to consider equipment location and laboratory certification standards that will not inadvertently remove fluoride from public water systems. It may be valuable to speak with the Centers for Disease Control and Prevention about options for removing PFAS from drinking water without removing fluoride in the process.

Thank you for providing us the opportunity to comment. If you have any questions, please contact Mr. Robert J. Burns at 202-789-5176 or burnsr@ada.org.

Sincerely,

George R. Shepley

President

Raymond A. Cohlmia, D.D.S.

Executive Director

GRS:RAC:rjb

EPA Response: Please see section 10.3 of the EPA response in this *Response to Comments* document. The EPA notes that the commenter has incorrectly characterized the proposed MCLs and that the agency is not specifying the location of any PFAS treatment in the water system's overall treatment processes. Water systems should work with their primacy agency to determine the most appropriate location and EPA anticipates added fluoride typically would be placed after (downstream from) where PFAS treatment unit processes would be located. The EPA has consulted with the Centers for Disease Control and Prevention as a part of the agency's consultation with the Secretary of Health and Human Services regarding this regulation.

American Dental Association (ADA) (Doc. #1671, SBC-043687)

The American Dental Association is pleased to submit the attached comments regarding EPA's proposal to reduce exposure to several per- and polyfluoroalkyl substances (PFAS) in drinking water. In sum, we urge EPA to consider equipment location and laboratory certification standards that will not inadvertently remove fluoride from public water systems. It may be valuable to speak with the Centers for Disease Control and Prevention about options for removing PFAS from drinking water without removing fluoride in the process.

EPA Response: Please see section 10.3 of the EPA response in this *Response to Comments* document. The agency is not specifying the location of any PFAS treatment in the water system's overall treatment processes. Water systems should work with their primacy agency to determine the most appropriate location and the EPA anticipates added fluoride typically would be placed after (downstream from) where PFAS treatment unit processes would be located. The EPA has consulted with the Centers for Disease Control and Prevention as a part of the agency's consultation with the Secretary of Health and Human Services regarding this regulation. The approved methods for this regulation measure for specific PFAS using high resolution mass spectrometry after solid phase extractions; the inorganic fluoride would not be measured as part of this process. For more information on analytical methods, please see section 7 of the EPA response in this *Response to Comments* document.

A. O. Smith Corporation (Doc. #1674, SBC-043700)

Moreover, the Company agrees that there are co-benefits from using the aforementioned treatment technologies as any non-selective treatment technology (e.g., RO, GAC, IX, etc.) has the potential to remove co-contaminants and as a result should be encouraged. For example, a POU RO system that is certified to remove PFAS also removes arsenic, lead, and nitrate/nitrite. Another example are the resins used in IX systems to treat perchlorate are similarly effective to remove PFAS compounds.

EPA Response: Please see section 10.3 of the EPA response in this *Response to Comments* document. The EPA agrees that each BAT (RO, NF, GAC, AIX) has the potential to remove co-contaminants. The EPA notes that there are currently no POU devices that are certified to meet the MCL; please see section 10.5 of the EPA response in this *Response to Comments* document for additional discussion on SSCTs.

New York State Department of Health (NYS DOH) (Doc. #1677, SBC-044956)

18. EPA is seeking comment on the benefits of treatment technologies such as Reverse Osmosis to co-remove other contaminants. To date New York State has not approved large scale use of reverse osmosis (RO) treatment to address issues associated with PFAS. We recognize the appeal of RO to address co-occurrence of PFAS with organic and inorganic contaminants. However, we caution that any decision to proceed with RO be accompanied by a science-based evaluation of simultaneous compliance with the Lead and Copper Rule and its successors at each public water system proposing its use. We recognize that RO may be suitable for some challenging water quality issues as well as at very small water systems and is an important tool in the regulatory toolbox. At this time, we do not believe that widespread application is practical with current technologies. We anticipate that membrane technologies will continue to evolve with time, and the Department will consider health protective treatment proposals that are supported by site specific engineering evaluations.

EPA Response: Please see sections 10.1 and 10.3 of the EPA response in this *Response to Comments* document. The EPA agrees with the commenter's assessment that RO can remove co-occurring contaminants and may be suitable for select sites. In acknowledgement of potential issues surrounding RO, the EPA has adjusted RO/NF's technology projection compliance forecast to 0 percent in the EA. The EPA has published guidance on corrosivity concerns in various places, for example, the *Best Available Technologies and Small System Compliance Technologies for PFAS in Drinking Water* in section 4.5.1.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045117)

5) Benefits from using treatment technologies (such as reverse osmosis and GAC) that have been demonstrated to co-remove other types of contaminants found in drinking water and whether employing these treatment technologies are sound strategies to address PFAS and other regulated or unregulated contaminants that may co-occur in drinking water:

a. Radon is currently not included under EPAs National Primary Drinking Water Regulations. GAC treatment would co-treat radon, which could affect disposal costs of spent carbon. Constituents that can currently be discharged to a drywell (or other onsite disposal or discharged to municipal sanitary sewer), such as those exempt from Underground Injection Control Rules, could not be discharged into a dry well if co-treated with PFAS, which may reduce the lifespan of the treatment and increase the complexity of the treatment, counteracting any benefit gained from co-treatment.

b. Vermont does not currently have any surface water system treatment plants treating PFAS; however, the costs associated with disposal of media used to treat PFAS would counteract any benefit gained by co-treating non-hazardous constituents, such as DBPs.

EPA Response: Please see section 10.3 of the EPA response in this *Response to Comments* document. For information on residuals management the EPA refers commenter to section 10.4 of the EPA response in this *Response to Comments* document, however, the EPA notes that destruction and disposal of PFAS-containing materials is currently not subject to certain hazardous waste regulation and therefore the materials may be managed in non-hazardous as well as hazardous waste treatment and disposal systems. A PFAS-containing waste, however, may meet the regulatory definition of hazardous waste if PFAS is mixed with a listed hazardous waste or if a PFAS-containing mixture exhibits a hazardous characteristic (e.g., corrosivity or another characteristic stemming from the material that is mixed with PFAS). For more information on the HRRCA the EPA used, please see section 13 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045981)

Section 7.3: Co-removal of contaminants

EPA is seeking comments on the utilization of the proposed BATs as sound strategies for addressing PFAS and other regulated and unregulated contaminants that occur in drinking water. Specifically, EPA seeks further comment on the co-removal of HI chemicals and the usefulness of GAC in removing other regulated and unregulated contaminants, like precursors to disinfection byproducts (DBPs). EPA states several times in the preamble that GAC will be effective in removing DBP precursors, something currently being discussed in the National Drinking Water Advisory Council (NDWAC) Microbial and DBP (MDBP) Rule Revision Working Group process.

AMWA cautions EPA in assuming that a treatment technique like GAC will universally co-remove other contaminants. A GAC facility specifically designed to remove PFAS may not be as efficient at removing DBP precursors or other contaminants, as the size and components of the facility were not designed for that purpose. Similarly, current GAC facilities in use for TOC removal may not be removing PFAS to levels required for this proposed rule. These "co-removing" contaminants must also compete for adsorption sites on GAC, further reducing media life and diminishing the effectiveness of PFAS removal. Any changes to these treatment facilities currently in place may require more construction, increased capacity, and further testing to assess other risk trade-offs.

AMWA would also like to point out that different PFAS mobilize differently through filter columns or beds, indicating that treatment techniques may not universally co-remove contaminants. Shorter chain PFAS tend to move faster through filter media and can be more difficult to remove, often driving the treatment design. If a water system is coming into compliance with an MCL for a longer chain PFAS, there may not be as much co-removal of shorter chain PFAS. Ultimately, treatment facilities need to be tailored to the contaminant of interest. A PWS having a treatment facility in place does not inherently mean the system can be easily adjusted to address more or different contaminants without compromising compliance elsewhere.

EPA Response: Please see sections 10.1 and 10.3 of the EPA response in this *Response to Comments* document. The EPA further notes that the agency did not claim universal co-removal of other contaminants.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045993)

Section 8.8: Cost of co-occurring PFAS

In section 7.3 of these comments, AMWA responds to EPA's request for comment regarding the co-removal of contaminants with this rulemaking. While BATs described in this proposal can co-remove other PFAS, EPA should consider co-removal consequences on overall removal effectiveness. With treatment techniques like GAC, various contaminants compete for adsorption sites, which can diminish the effectiveness of PFAS removal. GAC would have to be replaced or reactivated more often to account for this co-removal. Additionally, media will need to be

replaced more often if the PFOA and PFOS MCLs are finalized at 4 ppt rather than 10 ppt, thus increasing annual costs of treatment.

EPA Response: Please see section 10.3 and 10.4 of the EPA response in this *Response to Comments* document. Information on the cost analysis used may be found in section 13 of the EPA response in this *Response to Comments* document.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045242)

General Comments on Proposed National Primary Drinking Water Regulation

EPA requests comment on its evaluation that regulation of PFHxS, HFPO–DA, PFNA, PFBS, and their mixtures, in addition to PFOA and PFOS, will provide protection from PFAS that will not be regulated under this proposed rule.

EPA's proposed regulation of PFHxS, HFPO–DA, PFNA, PFBS, and their mixtures, in addition to PFOA and PFOS would provide some level of protection against PFBA, PFHxA and PFDA exposure if the three unregulated PFAS are found around concentrations similar or lower than that of the PFAS to be regulated. However, if PFBA, PFHxA and/or PFDA are the only PFAS of significant amount in the drinking water, the proposed regulation may not provide sufficient protection from them.

EPA Response: Please see section 10.3 of the EPA response in this *Response to Comments* document. The EPA agrees that the regulation would provide some level of protection against other unregulated PFAS.

Las Cruces Utilities (LCU) (Doc. #1753, SBC-043915)

In response to Section XI-Treatment Technologies, EPA is seeking comment on the benefits from using treatment technologies (such as reverse osmosis and GAC) that have been demonstrated to co-remove other types of contaminants found in drinking water and whether employing these treatment technologies are sound strategies to address PFAS and other regulated or unregulated contaminants that may co-occur in drinking water.

• PFAS treatment could conflict with current chemical dosing practices for red water control.

EPA Response: Please see sections 10.1 and 10.3 of the EPA response in this *Response to Comments* document. The EPA acknowledges the information submitted by the commenter and notes that transition metal precipitation can be controlled without phosphate dosing, for example, through aeration and filtration. The best solution will likely be site-specific, and the EPA recommends pilot studies to delineate potential process integration issues as well as test solutions to any discovered problems.

Arizona Water Company (Doc. #1758, SBC-044537)

Many of the required PFAS removal facilities will be treating water sources that are already being treated for other contaminants. Many wells in the Company's water systems are already being treated for arsenic, nitrate, and other contaminants. These treatment facilities have already been constructed at considerable cost to the Company and its customers. Additionally, these treatment facilities often use similar technologies as those the EPA currently lists as known treatment technologies for PFAS removal, yet the efficacy of these technologies to treat various forms of PFAS, and any additional costs of doing so, have not been comprehensively studied. The Company recommends the EPA conduct research and provide information on treatment technologies that can simultaneously remove PFAS and other contaminants.

EPA Response: Please see section 10.1 and 10.3 of the EPA response in this *Response to Comments* document.

American Fluoridation Society, Inc. (Doc. #1776, SBC-043831)

As the EPA explores methods to remove PFAS chemicals whether through point of removal being at the water plant, Point of Entry, or Point of Use, it is critical that the method(s)/technology(ies) determined to be the most effective to do so not undermine the public health measure of community water fluoridation. Filtration methods and points of placement of the PFAS removal technologies have the potential to inadvertently remove the public health benefits by removing the fluoride ion from the water.

The American Fluoridation Society recommends the pursuit of PFAS removal technologies that will be highly effective in removal of PFAS chemicals while at the same time not removing the fluoride ion. One public health benefit cannot be made at the expense of another public health benefit. Both must occur simultaneously to benefit our country's residents to protect their health and well-being. To this end, it may be valuable to consult the Centers for Disease Control and Prevention about options for removing PFAS from drinking water without removing the fluoride ion in the process.

Thank you for the opportunity to provide comment. If you have any questions, please contact Dr. Johnny Johnson, Jr. at 727-409-1770 or DrJohnny@AmericanFluoridationSociety.org.

Warm regards,

Johnny Johnson, Jr., DMD, MS

Pediatric Dentist

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EPA Response: Please see section 10.3 of the EPA response in this *Response to Comments* document. Water systems should work with their primacy agency to determine the most appropriate location and the EPA anticipates added fluoride typically would be placed after (downstream from) where PFAS treatment unit processes would be located. The EPA has consulted with the Centers for Disease Control and Prevention as a part of the agency's consultation with the Secretary of Health and Human Services regarding this regulation.

Ohio Environmental Council (Doc. #1794, SBC-045326)

Under EPA's proposal, drinking water utilities will be required to test water for PFOA, PFOS, GenX, PFBS, PFNA, and PFHxS and install treatment technologies to reduce the concentrations of these chemicals to the level of EPA's proposed "maximum contaminant levels" or lower. Fortunately, proven technology is available that will not only reduce the presence of the six PFAS in EPA's proposal, but will also improve protection against other PFAS compounds and common contaminants.

EPA Response: Please see section 10.3 of the EPA response in this *Response to Comments* document. The EPA agrees that the BAT technologies identified in the final NPDWR should also remove other PFAS compounds.

Little Hocking Water Association (Doc. #1835, SBC-045514)

Data on the removal of HI chemicals when GAC is used to remove PFOA and/or PFOS.

EPA requested information on co-removal of the HI chemicals PFHxS, PFBS, PFNA and HFPO-DA when, inter alia, GAC is used in the treatment of PFOA and/or PFOS. The Little Hocking Water Association provides the following comments and data with regard to co- removal of HI chemicals:

1. LHWA has had a GAC treatment system (two lead/lag configurations with 20,000 pounds of food-grade carbon in each vessel) to remove PFOA since November 2007. For the time period from November 2007 to February 2018, Dupont/Chemours (the responsible party for monitoring for PFAS) only reported concentrations of PFOA. Carbon changeouts are based on a trigger concentration of 15 ppt of PFOA in the lead beds. As of May 2023, the carbon has been replaced in the lead beds 70 times since November 2007. The average time between carbon changeout varies from 52 days to 132 days, but averages 82 days.

2. Since February 2018, data is available for co-removal of HFPO-DA. The graphs below show the concentrations of PFOA and HFPO-DA in the GAC treatment lead beds immediately prior to

changing carbon on the East and West Beds, respectively, in the GAC system for Little Hocking (data source, Chemours, 2023a):

[Figure 4: see docket ID EPA-HQ-OQ-2022-0114-1835]

[Figure 5: see docket ID EPA-HQ-OQ-2022-0114-1835]

These graphs show that the GAC is less effective in removal of HFPO-DA than PFOA because there are instances where the concentration of HFPO-DA is higher than the concentration of PFOA in the lead beds (even though the concentration of PFOA in the raw water is an order of magnitude higher than the concentration of HFPO-DA (see Attachments 1 and 3).

3. Until May 2022, the reporting limit for both PFOA and HFPO-DA, as requested of the laboratory by Chemours, was 10 ppt. Since May 2022, the reporting limit has been <2.0 ppt. There have been no detections of either PFOA or HFPO-DA in the lag beds since the GAC treatment system went online in November 2007.

4. As of March 27, 2023, Chemours has directed the laboratory to report concentrations for all 18 PFAS using Method 537.1. LHWA has no reported concentrations of other HI PFAS in the raw water, but detection levels are elevated to approximately 10 ppt due to dilution because of the elevated concentrations of PFOA and HFPO-DA.

5. A one-point dataset is also available for Belpre, Ohio's public water system. Belpre also has a GAC system to remove PFOA that has been in operation since February 2006. The system consists of two lead and lag beds with 20,000 pounds of carbon per vessel. The criteria for carbon changeout are different from the LHWA. Carbon is changed out when the lead beds exceed 500 ppt or when the lag beds exceed a detectable level of 5 ppt, whichever occurs first (Ohio EPA, 2007). According to Chemours (2023b), carbon was last changed on November 26, 2022. The table below shows the raw water concentrations of PFAS and the concentrations of HI PFAS in the Belpre raw water and the lead beds of the GAC system on March 20, 2023 (source of data, Chemours, 2023b).

[Table 7: see docket ID EPA-HQ-OQ-2022-0114-1835]

Similar to LHWA, Belpre only received results for PFOA from 2006 until March 2023, when reporting was changed to the 18 PFAS using Method 537.1. As of March 2023, there are no detections of any of the reported PFAS in the lag beds.

While LHWA agrees that GAC will remove PFOA, PFOS, and some other PFAS, the chain length of the PFAS matters. Generally, the shorter the carbon chain length, the less effective GAC is at removing those chemicals. In LHWA's experience and in reviewing other systems' data, the operation of the GAC makes a difference on co-removal. There are two operational parameters that affect co-removal: which chemical is used as the trigger for carbon changeout and when carbon changeout is done. The chemical at the highest concentration in pretreated water should be the chemical concentration that dictates when the carbon is changed. But, this can change. See above data on LHWA's East and West Lead Beds where the PFOA and HFPO-

DA "take turns" being detected at the highest concentrations. Second, LHWA has observed that when carbon changeouts are performed can greatly effect removal.

Data on the co-removal of other PFAS when GAC is used to remove PFOA and/or PFOS.

"EPA is seeking comment on the benefits from using treatment technologies (such as reverse osmosis and GAC) that have been demonstrated to co-remove other types of contaminants found in drinking water and whether employing these treatment technologies are sound strategies to address PFAS and other regulated or unregulated contaminants that may co- occur in drinking water." LHWA provides the following comments/data with regard to co- removal of other PFAS by GAC that are currently not proposed to be regulated.

As of March 27, 2023 when Chemours directed the laboratory to report results for all 18 PFAS under Method 537.1, LHWA now has data (see below table, data source, Chemours, 2023a) that shows additional PFAS that are not currently proposed to be regulated (PFHxA and PFHpA) are present in their raw water:

[Table 8: see docket ID EPA-HQ-OQ-2022-0114-1835]

With regard to removal by GAC of these additional PFAS, the below table (data source, Chemours, 2023a) shows that sampling confirmed the presence of these two PFAS in the east lead bed on May 8, 2023.

[Table 9: see docket ID EPA-HQ-OQ-2022-0114-1835]

No detections were found in the west lead bed or in either of the lag beds. The carbon was replaced on May 10, 2023.

This indicates from this one small dataset, that GAC seems to have the potential to provide protection from exposure to other known PFAS and that GAC treatment can be beneficial in the removal of some additional PFAS. However, the full load of PFAS and PFAS precursors are not known and the effectiveness of GAC for these unsampled constituents is unknown.

EPA Response: Please see sections 10.1 and 10.3 of the EPA response in this *Response to Comments* document. The EPA acknowledges the information submitted by the commenter and agrees that GAC has the potential to provide removal of additional PFAS.

Julie Reynolds (Doc. #2040, SBC-046313)

I applaud and welcome the EPA's action to regulate forever chemicals in drinking water, and agree with the proposed actions. I am concerned, however, that the filters used to remove these chemicals will also remove fluoride ions from the water that have been added for optimal community water fluoridation. Water fluoridation is a safe, cost effective population health approach to reducing tooth decay and improving oral health. It would be a crisis if this successful public health approach were to be negatively affected by the proposed regulations. As a board-certified specialist in public health dentistry, I have seen the negative effects firsthand, both in

my patients and in my research, of the lack of access to preventive interventions. I urge the EPA to evaluate options for removal of forever chemicals that do not negatively affect the many decades of successful community water fluoridation in this country.

EPA Response: Please see section 10.3 of the EPA response in this *Response to Comments* document.

10.4 Management of Treatment Residuals

10.4.1 General

Summary of Major Public Comments and EPA Responses

While some commenters stated that more research can be beneficial to further our understanding of managing PFAS treatment residuals, others urged the EPA to proceed with this rulemaking as expeditiously as possible in the interest of public health. Others argued that the EPA should delay this action until the PFAS Destruction and Disposal Guidance is updated. The National Defense Authorization Act for Fiscal Year 2020, Public Law No: 116-92 Section 7361 directs the EPA to revise the PFAS Destruction and Disposal Guidance triennially; the new destruction and disposal guidance is anticipated to be released approximately concurrently with this rule and further revisions may be expected before the effective dates for this rule. For these reasons, the EPA disagrees that the projected significant and direct public health protections for drinking water consumers in this rule should be delayed for the revision of guidance on management of PFAS waste streams.

Many commenters expressed concern that not enough was being done to manage spent drinking water treatment residuals containing PFAS at the end of their useful working life and that residual management amounted to media shifting (i.e., taking PFAS from water via sorption media then landfilling that media does nothing to reduce the overall amount of PFAS). Many commenters stated that landfills and thermal treatment facilities can potentially be PFAS sources as the BATs in this rule are separative as opposed to destructive technologies. The EPA notes that from a mass balance perspective, PFAS removal from drinking water is generally anticipated to result in lower concentrations of PFAS in the environment. With appropriate controls, landfills and thermal treatment of PFAS contaminated media can minimize PFAS releases to the environment (USEPA, 2020). Sorptive media can be incinerated or reactivated. There is also ongoing research into destructive and sequestration technologies that may help quantify the extent to which PFAS may be destroyed, some of which is funded by the EPA (USEPA, 2022a). Furthermore, it is also important to distinguish between a potential environmental release and a direct exposure. A PFAS release does not inherently imply human exposure and a release is not inherently risky to specific populations. From a risk management perspective, while the EPA acknowledges that while each destruction and disposal technology has limitations, a potential environmental release under point source management is anticipated to be a more health protective alternative than human exposure through drinking water.

Some commenters suggested that reactivation was not permissible under the 2020 Interim PFAS Destruction and Disposal Guidance or that interim storage was required. Commenters are incorrect in their interpretation of the plain language in that guidance. The guidance does not state that reactivation or thermal treatment are prohibited. The guidance acknowledges a need for further refinement and research and that interim storage may be an option if the immediate dispensation of PFAS-containing materials is not imperative. However, nowhere does that guidance mandate interim storage or prohibit other forms of PFAS destruction and disposal.

Some commenters recommended the EPA consider additional destruction and disposal technologies. The EPA notes that disposal and destruction technologies are currently available to manage drinking water residuals. The EPA appreciates the example destructive technologies, and while beyond the scope of finalizing this NPDWR, the agency intends to consider additional destruction and disposal technologies in future destruction and disposal guidance. As part of the PFAS Strategic Roadmap, the ORD is evaluating and developing end-of-life materials management technologies, including disposal and destruction technologies to further reduce PFAS in the environment, in addition to their work on drinking water and wastewater treatment, contaminated site cleanup and remediation, air emission controls, and health effects.

Many commenters suggested that high pressure membranes, which separate PFAS from one stream and concentrate it in another stream, may not be feasible as a BAT because utilities treating and discharging reject water from high pressure membranes typically require a National Pollutant Discharge Elimination System (NPDES) permit. The EPA disagrees because there are currently full-scale facilities that use this technology to treat PFAS and high-pressure membranes may be the best viable option in a multi-contaminant setting. The brine may undergo further pre-treatment as part of a process train to enable discharge, such as GAC or AIX treatment. Some RO/NF applications discharge directly to surface water or through an interconnection to a wastewater treatment plant. The EPA, however, agrees that brine treatment or disposal may be challenging and in 2022, the EPA issued memoranda that recommended NPDES and publicly owned treatment works (POTW) pretreatment program permitting conditions for PFAS discharges (USEPA, 2022b; USEPA, 2022c). In conclusion, in limited applications, high pressure membranes may still serve as a viable treatment strategy, such as for facilities with access to brine treatment or disposal.

Individual Public Comments

North Penn Water Authority (NPWA) (Doc. #1470, SBC-043295)

And, very importantly, there is concern about how the disposal of all this used carbon material, after it has been saturated with PFAS removed from the water, can be accomplished within the new stringent regulations. Will incineration or land application of this waste material continue to be considered acceptable? The overall environmental impact of spent carbon needs to be thought out thoroughly and planned for.

EPA Response: Please see section 10.4.1 of the EPA response in this *Response to Comments* document.

Orange Water and Sewer Authority (OWASA) (Doc. #1524, SBC-042620)

• GAC/IX regeneration

o There are only a few regeneration facilities in the US – how will this impact our ability to regenerate our media and then return it to our facility?

o Will the limited regeneration options impact cost and timeline to receive media?

EPA Response: Please see sections 10.4.1 and 10.4.2 of the EPA response in this *Response to Comments* document. For additional discussion on treatment technology availability and capacity, please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Water Environment Federation (WEF) (Doc. #1529, SBC-043317)

• One Water: In a one-water world, PFAS removed is PFAS reallocated to another media. For example, GAC will concentrate PFAS, which will then be transferred to an accepting receiving landfill, and landfill leachate routed to a water resource recovery facility. Another example is "reject" water from water reuse operations, which may also concentrate PFAS.

• Technology: Destruction technologies must be proven with subsidized funding identified in order to install and maintain these systems.

EPA Response: Please see sections 10.4.1 and 10.4.2 of the EPA response in this *Response to Comments* document.

Washington Suburban Sanitary Commission (WSSC Water) (Doc. #1585, SBC-042774)

4. Treatment technologies

Waste management costs:

The EPA has identified three treatment methods, granular activated carbon (GAC), ion exchange (IX), and nanofiltration/reverse osmosis (NF/RO), as the Best Available Technologies (BAT) for removing PFAS. WSSC Water agrees with EPA's assessment of technological feasibility and the agency's conclusion that compliance can be accomplished at the MCL of 4 ppt utilizing these treatment processes. However, all of these BATs generate waste streams or spent media, which require reactivation, waste treatment, and disposal. Taking a holistic view of the fate of PFAS, these treatment processes simply shift PFAS from drinking water to another media, which could be subject to further regulation and require additional treatment. As such, the EPA must carefully

consider lifecycle waste management needs for the holistic reduction of PFAS in the environment when evaluating the technological feasibility and associated compliance costs of these treatment methods.

EPA Response: Please see section 10.4.1 and 10.4.2 of the EPA response in this *Response to Comments* document.

Washington Suburban Sanitary Commission (WSSC Water) (Doc. #1585, SBC-047711)

We are also concerned that EPA's annualized cost proposal does not include the costs associated with disposing of spent media as hazardous waste, on the basis that PFAS-contaminated waste is not currently classified as hazardous waste. This approach contradicts EPA's Action Plan to potentially regulate municipal treatment discharge under CERCLA, and we urge the agency to revise its cost assumptions in line with its future rulemaking directions.

EPA Response: Please see sections 10.4.1 and 10.4.2 of the EPA response in this *Response to Comments* document. The designation does not require waste to be treated in any particular fashion, nor disposed of at any particular type of landfill. The designation also does not restrict, change, or recommend any specific activity or type of waste at landfills. The EPA took the unusual step of including a supplemental analysis where PFAS is considered a hazardous waste in the proposed rule preamble and supporting documents. For more information on the EPA modeled costs such as what was included, please see section 13 of the EPA response in this *Response to Comments* document.

Security Water District, Security Water and Sanitation Districts/Enterprises (Doc. #1587, SBC-042783)

Lastly, we have grave concerns with the lack of understanding and guidance regarding the disposal of spent pre-filters, resin and carbon, and ultimately the destruction of the PFAS contained in those materials. Why are we forcing water systems to capture PFAS if we don't know what to do with it once captured? It seems foolhardy to simply move PFAS around in the environment.

EPA Response: Please see section 10.4.1 of the EPA response in this *Response to Comments* document.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043648)

2. The USEPA recommended best available technologies (BATs) for PFAS removal are essentially separation technologies rather than destruction technologies. Thus, PFAS removed from drinking water supplies are simply shifted to other environment vectors for public exposure via the residuals management process. It is recommended that USEPA provide a longer-term direction for PFAS management in the environment.

There are currently only a few options for PFAS-containing wastes, including landfilling and incineration. Each disposal approach can return either the original PFAS or their degradation products back into the environment, demonstrating the cyclical PFAS challenge (Stoiber et al. 2020).

Since some classes of PFAS are semi-volatile, it is possible for landfilled PFAS-laden materials to volatilize or leach over time (Coffin et al. 2022; Smallwood et al. 2023). Certain PFAS species have been measured in ambient air samples from wastewater treatment plants and landfills (Coffin et al. 2022).

Landfill leachate is commonly sent to a wastewater treatment plant where the PFAS is often carried over to sludge and effluent – only shifting the PFAS contamination from site to site (Stoiber et al. 2020). Incineration of PFAS-containing wastes can emit harmful air pollutants (such as fluorinated greenhouse gasses) (Stoiber et al. 2020).

There are a limited number of full-scale studies investigating the fate of PFAS in the GAC reactivation process. Reactivation can cause some PFAS compounds to be transformed, volatilized, or defluorinated. Several studies suggest that the fate of PFAS in GAC reactivation is a function of PFAS chain length, reactivation temperature, and combustion atmosphere. Additional full-scale studies are necessary to better understand and manage PFAS air emissions form GAC reactivation facilities (EPA 2023).

EPA Response: Please see section 10.4.1 of the EPA response in this *Response to Comments* document.

Prince William County Service Authority (Doc. #1609, SBC-042835)

Water utilities need clarity on the additional regulatory actions EPA is considering with respect to PFAS in residual streams created during the water treatment process.

Utilities that exceed the proposed MCLs and/or HI must evaluate treatment alternatives to achieve compliance. Each alternative will generate residual streams. EPA has suggested granular activated carbon (GAC), ion exchange (IX), and reverse osmosis (RO) as treatment alternatives. None of these alternatives actually remove PFAS from the environment, they simply move it from one media (source water) to another (filter media or membrane filtrate). The regulatory framework for discharging or disposing of PFAS laden membrane filtrate is uncertain. Spent GAC and IX media must be regenerated and/or disposed of properly. The capacity of the marketplace to regenerate or dispose of the quantities of these materials resulting from the proposed rule is unknown. The availability and capacity of landfills willing and/or certified to accept PFAS contaminated filter media is unknown. If the demand for these landfills increases significantly, disposal costs will also increase, adding further burden to utility ratepayers.

EPA Response: Please see section 10.4.1 of the EPA response in this *Response to Comments* document, as well as the *Interim PFAS Destruction and Disposal Guidance*

document. For more information on utility rate payers please see section 2.4 of the EPA response in this *Response to Comments* document.

Savannah River Nuclear Solutions LLC (Doc. #1647, SBC-043338)

Comment 5

Section X.I.C. Management of Treatment Residuals (pg. 18686)

The proposed rule and accompanying support documents do not provide a complete picture of the management of the residuals produced by the designated BAT.

The technologies designated as BAT for removing PFAS from drinking water are treatment technologies, designed to transfer the PFAS into another media (or in the case of RO/NF, the same media in a more concentrated form). According to EPA's own support document, Best Available Technologies and Small Systems Compliance Technologies for PFAS in Drinking Water, EPA- 833-P-23-009 (February 2023) "additional research might be needed to better understand and manage PFAS air emissions from GAC reactivation facilities. The results of this research might necessitate changes to spent GAC management practices." Further, there may be circumstances when reactivating spent GAC may not make economic or operational sense. In these circumstances, GAC may be disposed of after use, such as in a landfill, and then replaced with completely new GAC. This would likely generate additional liquid leachate that would also require treatment. Future Resource Conservation and Recovery Act (RCRA) hazardous waste regulations could also limit the available management options.

Similarly, spent AIX resins are currently incinerated as a preferred method of disposal, which would potentially transfer PFAS combustion products to the air. EPA indicates that "[T]he literature is inconclusive regarding the fate of PFAS during incineration in general (USEPA, 2020) and there are no studies specific to incineration of IX resin. Additional full-scale research might be needed to better understand and manage PFAS air emissions from incineration facilities. The results of this research might necessitate changes to spent resin management practices." (Best Available Technologies and Small System Compliance Technologies for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water, EPA Document EPA-822-P-23-009, pg. 22). AIX resins could be land disposed; however, this would likely transfer PFAS constituents to the liquid leachate which would require additional treatment. Has research been conducted on the leachability of PFAS constituents from spent AIX resins as future RCRA hazardous waste regulations, including Land Disposal Restrictions could also limit the available management options?

EPA Response: Please see sections 10.4.1 and 10.4.2 of the EPA response in this *Response to Comments* document, as well as the *Interim PFAS Destruction and Disposal Guidance* document.

Virginia Municipal Drinking Water Association (VMDWA) (Doc. #1657, SBC-043166)

In addition, another key component of a valid national cost assessment is the cost of how residuals from PFAS removal by the use of the assumed technologies (GAC and RO) will be disposed. This is especially critical in light of EPA's proposed hazardous waste designation under CERCLA for PFOA and PFOS. EPA's proposal identifies a 4-5% increase for the need for hazardous rather than non-hazardous waste disposal methods, 88 Fed. Reg. at 18686, but VMDWA is concerned that the availability and feasibility of such disposal and the associated costs will be significantly worse than assumed in the proposal. These concerns are based on past experience with hazardous waste disposal facility availability challenges and the widespread, increased need for hazardous waste disposal of PFAS treatment residuals driven by the combination of EPA's MCLs and EPA's CERCLA designation.

EPA Response: Please see sections 10.4.1 and 10.4.2 of the EPA response in this *Response to Comments* document, as well as the *Interim PFAS Destruction and Disposal Guidance* document. The designation does not require waste to be treated in any particular fashion., nor disposed of at any particular type of landfill. The designation also does not restrict, change, or recommend any specific activity or type of waste at landfills.

Maryland Association of Municipal Wastewater Agencies (MAMWA) (Doc. #1658, SBC-043401)

In addition, another key component of a valid national cost assessment is the cost of how residuals from PFAS removal by the use of the assumed technologies (GAC and RO) will be disposed. This is especially critical in light of EPA's proposed hazardous waste designation under CERCLA for PFOA and PFOS. EPA's proposal identifies a 4-5% increase for the need for hazardous rather than non-hazardous waste disposal methods, 88 Fed. Reg. at 18686, but MAMWA is concerned that the availability and feasibility of such disposal and the associated costs will be significantly worse than assumed in the proposal. These concerns are based on past experience with hazardous waste disposal facility availability challenges and the widespread, increased need for hazardous waste disposal of PFAS treatment residuals driven by the combination of EPA's MCLs and EPA's CERCLA designation.

EPA Response: Please see sections 10.4.1 and 10.4.2 of the EPA response in this *Response to Comments* document, as well as the *Interim PFAS Destruction and Disposal Guidance* document. The designation does not require waste to be treated in any particular fashion., nor disposed of at any particular type of landfill. The designation also does not restrict, change, or recommend any specific activity or type of waste at landfills.

California Farm Bureau Federation (Doc. #1704, SBC-045078)

Disposal

EPA is obligated by statute to issue periodic guidance, every four years, on the destruction and disposal of PFAS compounds. EPA's initial guidance document submitted to Congress reported on various technologies that have been utilized as well as those under evaluation for use in the management of PFAS and PFAS-contaminated media. The lack of clear guidance and standards for the management, treatment, and destruction of PFAS compounds continues to present significant challenges for those parties managing PFAS compounds and contaminated media. Because of this, much of this material is being stored in anticipation of EPA issuing more definitive guidance.

EPA Response: Please see sections 10.4.1 and 10.4.2 of the EPA response in this *Response to Comments* document, as well as the *Interim PFAS Destruction and Disposal Guidance* document.

Protecting Our Water, Environment, and Ratepayers (POWER) (Doc. #1714, SBC-045930)

DETAILED COMMENTS:

COMMENT 1 — EPA SHOULD FINALIZE TECHNOLOGICAL STANDARDS FOR THE DISPOSAL AND DESTRUCTION OF TREATMENT BYPRODUCTS PRIOR TO FINALIZING THE MCLS.

In order to adhere to the MCLs, it will be necessary for public water systems to have EPA approved technological standards for the disposal and destruction of treatment byproducts. Failure to have these in place prior to finalizing the MCL will result in public water systems potentially having inconsistent treatment and disposal standards. EPA last issued Interim Guidance on disposal and destruction of PFAS in December 2020. In the two years and five months since the Interim Guidance was issued, EPA has failed to promulgate a final standard for the treatment and disposal of PFAS. Instead, it has pursued proposed rules, such as this one, whose efficacy and costs are dependent on the treatment and disposal standards. [FN2: EPA, Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances at 7 (Dec. 18, 2020) (https://www.epa.gov/system/files/documents/2021-11/epa-hq-olem-2020-0527-0002_content.pdf).] If the rule is now finalized as proposed, such a cart-before-the-horse approach will render the final rule arbitrary and capricious.

Treatment and disposal technologies for PFAS are still being developed and costs vary significantly based on geographic location. [FN3: EPA, Economic Assessment (EA) of the Potential Costs and Other Impacts of the Proposed Rulemaking to Designate Perfluorooctanoic Acid and Perfluorooctanesulfonic Acid as Hazardous Substances (Aug. 2022) (https://www.regulations.gov/document/EPA-HQ-OLEM-2019-0341-0035).] POWER! members provide critical public health services by providing clean drinking water and wastewater. Drinking water is generated 24 hours a day, every day of the year, for every person in the United States. There is no possible way to halt the flow of drinking water and the by-products of the cleanup process. As such, the disposal and destruction processes for the treatment byproducts

need to be clearly understood prior to implementation of the proposed rule. It is imperative that the science and technology for handling, cleanup, and disposal be developed and implemented prior to finalizing the proposed MCLs.

EPA has acknowledged that there are currently technological deficiencies and uncertainties regarding the destruction of PFAS. [FN4: EPA, Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances at 7 (Dec. 18, 2020) (https://www.epa.gov/system/files/documents/2021-11/epa-hq-olem-2020-0527-0002_content.pdf).] Setting MCLs for PFOA, PFOS, PFNA, PFHxS, PFBS, and GenX compounds before reliable methods of destruction have been finalized is a recipe for confusion and litigation. The science and conclusive methods of destruction and/or disposal are not yet settled and EPA has acknowledged that time is needed to bridge this gap. [FN5: EPA, Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances at 91 (Dec. 18, 2020) (https://www.epa.gov/system/files/documents/2021-11/epa-hq-olem-2020-0527-0002_content.pdf).]

POWER! respectfully requests that EPA delay implementing this proposed rule until EPA finalizes the standards for PFAS disposal and destruction.

EPA Response: Please see section 10.4.1 of the EPA response in this *Response to Comments* document.

Clean Air Council, et al. (Doc. #1731, SBC-043863)

d. Treatment of contaminated drinking water to achieve the proposed MCLs and HBWC is technically feasible for national implementation of the proposed PFAS regulations. However, EPA must facilitate the development of safe technologies for the disposal of PFAS waste created by water treatment to avoid re-release of PFAS to the environment.

EPA Response: Please see section 10.4.1 of the EPA response in this *Response to Comments* document, as well as the *Interim PFAS Destruction and Disposal Guidance* document.

Clean Air Council, et al. (Doc. #1731, SBC-043849)

A critical issue that EPA must address if the proposed NPDWR is to be truly effective in protecting public health and the environment is the safe disposal of the PFAS water treatment waste products: All current technologies for the removal of PFAS from water produce solid and/or liquid waste containing high levels of these pollutants. However, methodologies for the safe disposal of these materials are lacking and risk either re-introducing PFAS into the environment (such as by leaching from landfills) or producing toxic fumes (from thermal processes). Commenters understand that developing such technologies is outside the scope of

this proposed drinking water rule, but urge EPA to expedite solutions to PFAS waste to coincide with the scheduled national implementation of the NPDWR.

EPA Response: Please see section 10.4.1 of the EPA response in this *Response to Comments* document, as well as the *Interim PFAS Destruction and Disposal Guidance* document.

Clean Air Council, et al. (Doc. #1731, SBC-043886)

More problematic, however, are the PFAS waste streams from the water treatment facilities. All processes recommended by EPA to remove PFAS species from drinking water transfer and sequester the PFAS in a different medium. In the case of GAC, PFAS adsorbs onto the charcoal particles forming a solid waste of GAC/PFAS. In ion exchange processes, the waste is a brine solution from resin regeneration that contains high concentrations of PFAS (as well as salt and other organic compounds), and at the end of a resin lifecycle, ion-exchange resin is saturated with PFAS. In RO/nanofiltration, the waste stream is an aqueous solution that contains high concentrations of the rejected PFAS compounds [FN75: See, e.g., Thomas Speth, Session 3: PFAS Treatment in Drinking Water and Wastewater - State of the Science, EPA (Sept. 16, 2020), https://www.epa.gov/sites/default/files/2020-09/documents/r1-pfas_webinar_day_1_session_3_speth.pdf; Craig Patterson, Managing PFAS in Spent Adsorption Media, EPA (May 28, 2020), https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=540623&Lab=CESER.]

Safe disposal of these PFAS waste products is essential, posing challenges that have not been adequately addressed to date [FN76: See, e.g., Jay N. Meegoda, et al., A Review of PFAS Destruction Technologies, 19 INT'L J. OF ENVMTL. RES. & PUB. HEALTH 16397 (Dec. 7, 2022), available at https://doi.org/10.3390/ijerph192416397.] This issue will become acute once the NPDWR is enacted due to the large quantities that will be produced by the PWS.

EPA published in 2020 an interim guide for the destruction and disposal of PFAS-containing waste that reviews current approaches [FN77: EPA, Section on PFOA, PFOS & Other PFAS, Interim Guidance on Destroying and Disposing of Certain PFAS and PFAS-Containing Materials That Are Not Consumer Products, https://www. epa.gov/pfas/interim-guidance-destroying-and-disposing-certain-pfas-and-pfas-containing-materials-are-not (last updated Nov. 21, 2022).] Reactivating GAC for re-use occurs via combustion. For other solid phases such as spent GAC or the ion exchange resin, landfill disposal or thermal treatment are cited. Aqueous solutions such as those resulting from ion-exchange resin regeneration or RO/nanofiltration separations may be disposed of by underground injection or thermal treatment.

Unfortunately, as clearly stated in the report, these methodologies pose substantial challenges. For example, although high temperature combustion can break down PFAS, there is insufficient data characterizing the emissions from such processes and the nature and prevalence of toxic fluorinated products of incomplete combustion. The results may be severe air pollution by reactive fluorinated species. Leaching from underground injection or landfills can re-introduce

PFAS species into soil and, in particular, groundwater. Some new technologies such as plasma treatment are under development, but it is not clear that, even if effective, they could address the large volumes needed [FN78: See, e.g., Raj Kamal Singh, et al., Breakdown Products from Perfluorinated Alkyl Substances (PFAS) Degradation in a Plasma-Based Water Treatment Process, 53 ENVMTL. SCI. & TECH. 2731 (Feb. 15, 2019), available at https://doi.org/10.1021/acs.est.8b07031.] The proposed NPDWR rule discusses some of these issues in Section XI.C, committing to expand and accelerate research on PFAS destruction and disposal technologies in tandem with stricter regulations such as the CERCLA, the Resource Conservation and Recovery Act ("RCRA"), or the Toxic Substances Control Act ("TSCA"). However, all it can offer PWSs is, "At present, the most likely management option for spent material containing PFAS is reactivation for GAC and incineration for spent IX resin. For disposal of RO/NF membrane concentrate, most systems use surface water discharge or discharge to sanitary sewer."[FN79: 88 Fed. Reg. 18686.] The potential harm to the environment, as well as to human health from these disposal methods which risk reintroducing the PFAS into the environment may well undo the benefits of the NPDWR.

Commenters understand that developing safe disposal methods for the PFAS-infused waste produced by water treatment under the proposed rule is outside the scope of the NPDWR. However, while the proposed NPDWR is a crucial step to protecting human health and the environment from the significant harms caused by PFAS, to be effective and prevent re-introduction of the PFAS to groundwater and soil, or stop the release of toxic fluorinated emissions to air, EPA must address the next step: Providing effective and safe disposal methods of the waste material from PFAS removal.

EPA Response: Please see section 10.4.1 of the EPA response in this *Response to Comments* document and note that the *Interim PFAS Destruction and Disposal Guidance* document provides guidance on the destruction and disposal of PFAS-laden materials. The EPA is also evaluating and developing technologies for reducing PFAS in the environment to inform decisions on drinking water and wastewater treatment, contaminated site cleanup and remediation, air emission controls, and end-of-life materials management.

U.S Conference of Mayors, National League of Cities and National Association of Counties (Doc. #1733, SBC-043897)

Moreover, given that both technologies only remove but do not destroy PFOS and PFOA, local governments will have to find a way of disposing of the spent carbon and membranes. Considering that EPA is also moving forward to declare both chemicals as hazardous substances under CERCLA, local governments will be forced to use either hazardous waste landfills or hazardous waste incinerators. Unfortunately, there are very few of either of these facilities and will necessitate expensive long-hauling of material. Given the increase in energy usage associated with these treatments and the additional costs associated with appropriate disposal, EPA should focus more attention on an effective means of destroying these chemicals.

EPA Response: Please see sections 10.4.1 and 10.4.2 of the EPA response in this *Response to Comments* document. The designation does not require waste to be treated in any particular fashion, nor disposed of at any particular type of landfill. The designation also does not restrict, change, or recommend any specific activity or type of waste at landfills.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045203)

4. CT DPH recommends financial and logistical support be provided for the disposal of used PFAS remediation media. As a relatively small and intensively developed state with limited capacity for disposal, Connecticut currently faces significant waste management challenges for drinking water treatment media. This is especially true of hazardous waste. Consequently, costs incurred for the safe management of used PFAS remediation media will be considerable as most if not all such waste will need to be exported out of state for proper disposal.

EPA Response: Please see section 10.4.1 of the EPA response in this *Response to Comments* document. The EPA notes that PFAS, nor specific PFAS, are not currently a listed hazardous waste. The passage of the IIJA, also referred to as the BIL, invests over $11.7 billion in the DWSRF; $4 billion to the DWSRF for Emerging Contaminants; and $5 billion in EC-SDC grants. These funds will assist many disadvantaged communities, small systems, and others with the costs of installation of treatment when it might otherwise be cost-challenging. These funds can also be used to address emerging contaminants like PFAS in drinking water through actions such as technical assistance, certain water quality testing, and contractor training, which will allow communities supplemental funding to meet their obligations under this proposed regulation and help ensure protection from PFAS contamination of drinking water. The EPA seeks to continue developing implementation assistance. More information on these monies may be found in section 2.4 of the EPA response in this *Response to Comments* document.

West Virginia Rivers Coalition et al. (Doc. #1746, SBC-045255)

In the same way, it is critical that disposal options permanently remove PFAS from the PFAS cycle. The disposal options identified in EPA's 2020 Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances are landfill disposal and thermal treatment. In anticipation of the updated version to be released in 2023, we ask EPA to ensure that PFAS residuals from drinking water treatment are not simply being moved from media to media, as that would continue to endanger public health.

EPA Response: Please see section 10.4.1 of the EPA response in this *Response to Comments* document.

Environmental Council of the States (ECOS) (Doc. #1752, SBC-044507)

PFAS Destruction and Disposal

In addition to providing resources related to treatment technologies, more research and information is needed around various technical and cost-effective approaches to destroying and disposing of PFAS and PFAS-containing wastes. ECOS encourages the Office of Water to coordinate with the Office of Land and Emergency Management and others to clarify PFAS disposal options, and to research and communicate with states and stakeholders about destruction and disposal options as they are developed. States request that EPA finalize its Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances as soon as possible so that this guidance can be incorporated in planning for the final rule.

EPA Response: Please see section 10.4.1 of the EPA response in this *Response to Comments* document. The EPA Office of Water (OW) is coordinating with the Office of Land and Emergency Management (OLEM) on the *PFAS Destruction and Disposal Guidance* as well as other Agency actions to address PFAS through the PFAS Council.

Los Angeles County Sanitation Districts (Doc. #1756, SBC-044514)

Treatment residuals could impose a significant burden and will promote environmental cycling of PFAS. Most of the accepted PFAS treatment technologies do not cause the destruction of PFAS, rather they involve the separation of PFAS from the source into PFAS-laden treatment residuals that must also be managed appropriately. Accordingly, the proposed MCLs are likely to require the deployment and operation of thousands of new drinking water treatment systems and will generate significant quantities of PFAS-laden treatment residuals (e.g., filter concentrates, spent absorbent media). In many cases, these residuals will need to be safely handled at municipal or hazardous waste landfills (depending on the promulgation by EPA of other waste-related regulations under the Resource Conservation and Recovery Act and the Comprehensive Environmental Response, Compensation and Liability Act) and wastewater treatment plants. However, these facilities often do not have emission controls or treatment processes in place to prevent PFAS from re-entering the environment, and, when required to implement treatment themselves to meet impending PFAS regulations under other statutes, these facilities will also generate treatment residuals. The absence of clear guidance from the EPA regarding appropriate disposal and handling practices for PFAS treatment residuals, as well as the absence of mandates or recommendations to reactivate or reuse treatment materials where feasible, suggest that substantial quantities of residuals would impact waste and wastewater facilities that will already be impacted by treatment requirements to address existing PFAS sources. The Sanitation Districts strongly urge the EPA to develop policies, programs, and regulations that govern the safe disposal and destruction of PFAS and PFAS-containing materials prior to promulgating the proposed MCLs. These policies should seek to limit the environmental cycling of PFAS and specify available and feasible treatment technologies and practices for the management of treatment residuals.

EPA Response: Please see sections 10.4.1 and 10.4.2 of the EPA response in this *Response to Comments* document, as well as the *Interim PFAS Destruction and Disposal Guidance* document.

PFAS Regulatory Coalition (Doc. #1761, SBC-046086)

f) How did EPA choose 200 miles as its transportation distance for hazardous waste shipments? In the appendix "Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation," EPA uses a 200-mile distance in its sensitivity analysis for hazardous versus non-hazardous waste disposal. EPA-822-P-23-001. However, small systems and non-transient, noncommunity systems are likely much farther away from an available hazardous waste disposal facility. EPA should include a more realistic distance in its analysis.

g) Did EPA consider the increases in social costs resulting from increased energy use required treatment? It appears that energy costs were considered only as part of O&M costs for lighting, ventilation and pump operations. But treatment for PFAS involves fairly energy-intensive activities. Therefore, EPA's energy cost estimates seem low EPA's analysis also needs to include increased social costs associated with that required increase of energy use.

EPA Response: Please see section 10.4.1 of the EPA response in this *Response to Comments* document. The total area of the United States is approximately 3,800,000 square miles, meaning on average each state is around 76,000 square miles. The square root of this is about 275 miles and each state has at least one hazardous waste disposal site, so 200 miles was chosen as a baseline national average as a conservative estimate. The EPA considered social costs to carbon, please see section 14 of the EPA response in this *Response to Comments* document. For more information on the EPA cost model, please see section 13 of the EPA response in this *Response to Comments* document.

PFAS Regulatory Coalition (Doc. #1761, SBC-046084)

d) Did EPA review how treatment media are being handled by waste disposal facility today? In our members' experience, PFAS-impacted media, including treatment media, are often being refused at regular landfills and only being accepted at hazardous waste landfills. EPA's approach, in which these costs are looked at only as part of a sensitivity analysis, ignores the true costs that are being experienced today, regardless of the regulatory status of the material being handled.

EPA Response: Please see sections 10.4.1 and 10.4.2 of the EPA response in this *Response to Comments* document. The EPA refers commenter to the summary of major public comments for this section. The designation does not require waste to be treated in any particular fashion, nor disposed of at any particular type of landfill. The designation also does not restrict, change, or recommend any specific activity or type of waste at landfills. Without data the EPA cannot generalize the experience of the PFAS Regulatory Coalition nationally and encourages

the coalition to submit data supporting its claims. For more information on the EPA cost model please see section 13 of the EPA response in this *Response to Comments* document.

Bowling Green Municipal Utilities (Doc. #1767, SBC-043935)

Collateral Impacts: There is no guidance on what to do with spent treatment chemicals after use in removing PFOS/PFOA. This is problematic of developing a rule piece-meal without considering the full long-term implications.

EPA Response: Please see section 10.4.1 of the EPA response in this *Response to Comments* document. The EPA disagrees that the long-term implications, including disposal of treatment materials, have not been considered and has published *PFAS Destruction and Disposal Guidance*. The EPA refers commenter to the summary of major public comments for this section.

Western Urban Water Coalition (WUWC) (Doc. #1768, SBC-043940)

II. Unavoidable Obstacles Threaten to Make Implementing the Proposed Rule Practically or Legally Infeasible

Treatment Options and Disposal of Residuals

WUWC has serious concerns with EPA's assumptions and conclusions regarding the feasibility of proposed treatment methods and the disposal of drinking water treatment residuals containing PFAS. [FN11: 88 Fed. Reg. at 18686 (discussing "management of treatment residuals"); 88 Fed. Reg. at 18731 (requesting comment on EPA's estimates for drinking water treatment residuals, regeneration, and capacity of disposal sites).] EPA states that treatment technologies using GAC and IX resin are the best available technologies for PFAS treatment based on several factors including efficiency and cost. [FN12: Id. At 18684.]

EPA Response: Please see sections 10.1 and 10.4.1 of the EPA response in this *Response to Comments* document.

City of Tulsa Water and Sewer Department (CoT WSD) (Doc. #1785, SBC-043789)

In addition, EPA significantly downplayed the effect of the possibility of GAC, ion exchange (IX) resin, or RO/NF concentrate waste stream being designated as hazardous waste. In the previously referenced AWWA study [FN1: Black & Veatch, prepared for American Water Works Association. (2023). WITAF 56 Technical Memorandum, PFAS National Cost Model Report (B&V Project No. 409850). https://www.awwa.org/Portals/0/AWWA/Government/2023030756BVFinalTechnicalMemoradum.pdf?ver=202303-14-102450-257] typical GAC reactivation temperatures are not appropriate for PFAS removal (pg. 4). EPA states that conventional regeneration solutions are not effective in restoring PFAS-selective IX resins (88 FR 18685). If spent GAC is designated as hazardous

substance, the GAC supplier may refuse to accept it. There are limited hazardous waste landfills; there is only one in Oklahoma. Replacement and disposal costs of GAC and the other BAT media could increase exponentially if this occurs.

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The City of Tulsa Water and Sewer Department values the opportunity to comment on the preliminary regulatory determination and proposed rule for per- and polyfluoroalkyl substances (PFAS) National Primary Drinking Water Regulation, and appreciates EPA's consideration of the expressed questions, opinions, and comments in this letter. Please contact me if you have any questions.

Sincerely,

Eric Lee, Director

City of Tulsa Water and Sewer Department

EL/cjg

Cc: Rick Hudson-TMUA

Shellie Chard - DEQ

Stefanie Hunter-CoT WSD

Jo Brown-CoT WSD

EPA Response: Please see sections 10.4.1 and 10.4.2 of the EPA response in this *Response to Comments* document, as well as the *Interim PFAS Destruction and Disposal Guidance* document.

Fairfax Water (Doc. #1789, SBC-045303)

Utilities that exceed the proposed MCLs and/or HI must evaluate treatment alternatives to achieve compliance. Each alternative will generate residual streams. EPA has suggested granular activated carbon (GAC), ion exchange (IX), and reverse osmosis (RO) as treatment alternatives. None of these alternatives actually remove PFAS from the environment, they simply move it from one media (source water) to another (filter media or membrane filtrate). The regulatory framework for discharging or disposing of PFAS laden membrane filtrate is uncertain. Spent GAC and IX media must be regenerated and/or disposed of properly. The capacity of the marketplace to regenerate or dispose of the quantities of these materials resulting from the proposed rule is unknown. The availability and capacity of landfills willing and/or certified to accept PFAS contaminated filter media is unknown. If the demand for these landfills increases significantly, disposal costs will also increase, adding further burden to utility ratepayers. Fairfax Water currently land applies residuals (solid) from its Potomac water treatment plant to farmland

at a cost of $32/ton. Disposal of those residuals in a landfill would cost $117/ton, before accounting for additional costs due to the presence of PFAS.

The proposed rule states that other PFAS compounds may be added to the proposed HI in the future. EPA also indicates that the MCLs for PFOA and PFOS could be lowered in future regulatory actions. EPA is moving forward with actions such as designating certain PFAS compounds as hazardous waste under CERCLA, which further introduces risk to utility ratepayers. EPA should provide water utilities clarity on the additional regulatory actions being considered with respect to PFAS in treatment residuals in order to support cost effective decision making on behalf of our ratepaying public.

EPA Response: Please see sections 10.4.1, 10.4.2, 10.6 of the EPA response in this *Response to Comments* document, and the *Interim PFAS Destruction and Disposal Guidance.* The designation does not require waste to be treated in any particular fashion, nor disposed of at any particular type of landfill. The designation also does not restrict, change, or recommend any specific activity or type of waste at landfills. More information on ratepayers is in section 2.4 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Massachusetts Municipal Association (MMA) (Doc. #1800, SBC-043766)

Additionally, the disposal options for PFAS-related waste must be addressed. A responsible waste management policy for contaminated materials will be necessary to prevent PFAS from re-entering the environment, whether through landfill leachate or otherwise. The management of these environmental contaminants will require a holistic approach that anticipates future problems, including a dwindling supply of landfill capacity that New England states are experiencing. Should further regulations complicate the waste management landscape, states could become reliant on transporting waste across state and federal borders to those willing to handle contaminated waste. This is not only a costly solution for municipal budgets to handle, but an environmental detriment when considering the greenhouse gas emissions associated with shipping waste out of state via truck or rail.

EPA Response: Please see section 10.4.1 of the EPA response in this *Response to Comments* document and the *Interim PFAS Destruction and Disposal Guidance.* The EPA has published guidance that if followed minimizes risk from the destruction or disposal of PFAS-laden materials. The EPA considered social costs to carbon, please see section 14 of the EPA response in this *Response to Comments* document, and the EPA cost models in general are discussed in section 13 of the EPA response in this *Response to Comments* document.

Millie Garcia-Serrano (Doc. #1803, SBC-044286)

2. PFAS Disposal and Destruction: ASTSWMO is concerned with the increase in the volume of PFAS-contaminated materials and waste streams that will result from this rulemaking. As EPA is

aware, there are many existing challenges associated with the lack and/or limitations of destruction and disposal technologies for PFAS-containing materials and waste streams, including the outright prohibition of PFAS-containing materials destruction in some jurisdictions. Sending PFAS-containing materials to landfills is problematic, due to capacity issues and the lack of proven solidification and stabilization technologies to minimize PFAS in landfill leachate. Further, there remains uncertainty in the acceptable levels of PFAS in compost, biosolids, and industrial byproducts that are otherwise suitable for land application. ASTSWMO recommends that EPA prioritize the identification of effective treatment and disposal options and associated PFAS destruction research to ensure that PFAS contamination is safely disposed of, including finalization of EPA's interim Guidance on the Destruction of and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfuoroalkyl Substances.

EPA Response: Please see section 10.4.1 of the EPA response in this *Response to Comments* document. The EPA disagrees that a capacity issue exists and refers the commenter to the summary of major public comments for this section. The EPA has prioritized research; the ORD is evaluating and developing technologies for reducing PFAS in the environment to inform decisions on drinking water and wastewater treatment, contaminated site cleanup and remediation, air emission controls, and end-of-life materials management.

Earthjustice et al. (Doc. #1808, SBC-047716)

Fifth, EPA should develop an estimate of the benefits of managing spent filtration materials as hazardous waste, which would reduce environmental releases of PFAS and associated human exposures. In assessing the Proposed Rule's costs in the Draft EA, EPA correctly excludes the incremental costs to water systems from potential future requirements to manage spent filtration materials as hazardous waste, electing instead to calculate such costs as part of an illustrative sensitivity analysis because these costs are not attributable to the rule under consideration. [FN140: Id. at 4–5.] While EPA's inclusion of this sensitivity analysis enhances the transparency value of the EA, it improperly considers only the costs of potential hazardous waste management requirements, without accounting for the benefits. [FN141: Id. at 5.] If EPA maintains this illustrative analysis as part of the final EA, it also must include a benefits estimate to ensure that its analysis is comprehensive and balanced. [FN142: Id.]

EPA Response: Please see section 10.4.1 of the EPA response in this *Response to Comments* document. The EPA agrees that it is correct to exclude costs from potential future requirements not under consideration in the current rule. In acknowledgement of the commenter's request, the EPA has updated the EA to include a statement about the existence of non-quantified benefits that could result from managing PFAS-laden residuals from water treatment as hazardous waste. For more information on the EPA cost and benefit models, please see section 13 of the EPA response in this *Response to Comments* document.

Groundwater Resources Association of California (Doc. #1831, SBC-045355)

Finally, we also recommend that EPA take into consideration the impact on groundwater resources from the disposal of waste-media from PFAS treatment systems. EPA should highlight options for destructive treatment (e.g.. Hydrothermal alkaline treatment [HALT] or electrochemical oxidation [ECO]) over treatment technologies that create concentrated PFAS waste streams to better protect groundwater quality.

[Figure 1: see docket ID EPA-HQ-OQ-2022-0114-1831]

EPA Response: Please see sections 10.1, 10.2, 10.3, and 10.4.1 of the EPA response in this *Response to Comments* document. The EPA has published the *Interim PFAS Destruction and Disposal Guidance* and the PITT has published research briefs on additional non-traditional destruction and disposal methods, including electrochemical oxidation, mechanochemical degradation, pyrolysis and gasification, as well as supercritical water oxidation.

Kevin Rolfes (Doc. #2802, SBC-047440)

Treatment of contaminated drinking water to achieve the proposed MCLs and HI is technically feasible for national implementation of the proposed PFAS regulations. However, the treatment processes produce waste that needs to be disposed of safely. This issue will become acute once the NPDWR is enacted due to the large quantities that will be produced.

I understand that developing safe disposal methods for the PFAS-infused waste produced by water treatment under the proposed rule is outside the scope of the NPDWR. However, while the proposed NPDWR is a crucial step to protecting human health and the environment from the significant harms caused by PFAS, to be ultimately effective, prevent the re-introduction of PFAS to groundwater and soil, and stop the release of toxic fluorinated emissions to air, EPA should expeditiously address the next step: Facilitating effective and safe disposal methods of the waste material from PFAS removal.

In sum, I firmly support the proposed NPDWR and look forward to seeing it implemented as a vital part of an overall strategy to protect public health from PFAS.

EPA Response: Please see sections 10.4.1 of the EPA response in this *Response to Comments* document. The EPA agrees that drinking water treatment to at or below the MCLs is technically feasible as well as that this treatment will generate residuals that require proper management. The EPA has facilitated safe and effective disposal methods for these materials through, among other ways, the *PFAS Destruction and Disposal Guidance*, the PITT briefs, technical briefs such as incineration to manage PFAS waste streams, and the EPA research on PFAS homepage.

Savannah River Nuclear Solutions LLC (Doc. #1647, SBC-043340)

Finally, while RO/NF has been shown to achieve high removal efficiency for PFAS, large volumes of residual concentrate (15-30% of the feed stream) containing high levels of PFAS are produced from these systems which must be managed. Neither the proposed rule nor support documents provide a clear disposal path for these residual streams besides treatment in a wastewater treatment plant, discharge to non-potable water body (e.g., ocean or brackish estuary), or other methods that are reportedly used (deepwell injection, evaporation ponds, etc.; Technologies and Costs for Removing Per- and Polyfluoroalkyl Substances (PFAS) from Drinking Water, EPA Document EPA-822-P-23-011, pg. 53). These methods only transfers PFAS constituents to other water bodies or media.

Additional research is needed on all of these technologies and the full implications of their use, including cross-media effects and residual management before they can be designated as BAT.

EPA Response: Please see sections 10.1 and 10.4.1 of the EPA response in this *Response to Comments* document. The EPA refers the commenter to the *Interim Guidance on the Destruction and Disposal* for management of treatment residuals including RO/NF concentrate. Sites with reject water from RO/NF membranes typically have a NPDES Permit; drinking water treatment utilities using membranes must follow all applicable NPDES permit or pretreatment program requirements for any permit or control mechanism issued for their facility. While the EPA agrees that more research could be beneficial, and is sponsoring research, the EPA believes that this technology is mature, well understood, and should be listed as a BAT as outlined in the in the *Best Available Technologies and Small System Compliance Technologies for PFAS in Drinking Water* (BAT/SSCT) document (USEPA, 2024a).

Philadelphia Water Department (PWD) (Doc. #1709, SBC-053309)

Third, the operational costs do not account for the potential change to the designation of spent media as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) or hazardous waste under the Resource Conservation and Recovery Act (RCRA). In September 2022, the EPA proposed a Draft Rule to designate PFOA and PFOS as hazardous substances under CERCLA, creating liability concerns for any waste streams containing these substances. Additionally, EPA is in the process of evaluating changes to RCRA that would designate certain PFAS compounds as a hazardous waste, making disposal of contaminated material like spent media both more difficult and costly. In Appendix N, Section N.2 of the Economic Analysis, the EPA estimates that this change in designation from a non-hazardous waste to a hazardous waste would result in a 4-6% increase in annualized costs. PWD requests that EPA share their supporting calculations to verify these cost assumptions. PWD recommends that these elevated operational costs should be included in the Economic Analysis to account for future challenges for disposal of PFAS-laden media and the diminishing available landfill volume. Additionally, the increased costs of media disposal would not be equally distributed, as the disposals costs are regional and the distances PWSs may need

to transport these wastes will vary greatly, and thus some facilities will bear a more significant financial strain to dispose of spent media.

EPA Response: Please see section 10.4 of the EPA response in this *Response to Comments* document. The EPA has published the requested information in the *Technologies and Costs for Removing Per- and Polyfluoroalkyl Substances from Drinking Water* document. The WBS used to generate cost curves are also freely available on the EPA website at https://www.epa.gov/sdwa/drinking-water-treatment-technology-unit-cost-models. For more information on the EPA cost and benefit models, please see section 13 of the EPA response in this *Response to Comments* document.

10.4.2 Disposal of spent drinking water materials under possible future regulatory actions under other statutes and costs

Summary of Major Public Comments and EPA Responses

Many commenters, including destruction and disposal trade associations, stated there would be difficulties managing spent residuals containing PFAS generated from drinking water treatment. In contrast, other commenters stated that there was existing national capacity and at least one company stated they were actively evaluating investment for additional capacity to handle residuals. The record demonstrates that there is existing national capacity to handle spent drinking water residuals containing PFAS in a manner that minimizes risk to human health. Destruction and disposal of PFAS-containing materials is currently not subject to certain hazardous waste regulation and therefore the materials may be managed in non-hazardous and hazardous waste treatment and disposal systems (USEPA, 2020). Hazardous waste is regulated pursuant to the Resource Conservation and Recovery Act (RCRA) authority 42 U.S.C. 6921-6939 (also known as RCRA "Subtitle C"). The regulatory definition of hazardous waste is found in 40 CFR 261.3. PFAS are currently not a listed hazardous waste or characterized as a hazardous waste, but a PFAS-containing waste may meet the regulatory definition of hazardous waste if PFAS is mixed with a listed hazardous waste or if a PFAS-containing mixture exhibits a hazardous characteristic (e.g., corrosivity or another characteristic stemming from the material that is mixed with PFAS). PFAS that are commingled with hazardous substances and/or hazardous wastes will be subject to the appropriate rules and regulations and may be included as Applicable or Relevant and Appropriate Requirements on a site-specific basis. Not all disposal sites may be appropriate for spent drinking water treatment residuals containing PFAS and the EPA encourages owners and operators of treatment facilities use appropriate guidance on treatment residual management such as the 2020 Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances (USEPA, 2020) and subsequent updates.

Regarding commenter concerns on disposal capacity, the EPA believes that there is existing national capacity to dispose of PFAS treatment residuals that would be generated as detailed in the following paragraph. There is also sufficient national capacity to handle non-hazardous waste as detailed below. The EPA acknowledges that there may be short-term increases in demand for

disposal facilities, but market forces are anticipated to result in additional suppliers and increased capacity in the long term. Again, it is worth reiterating that under current federal regulations, PFAS is not designated as a hazardous waste on its own. However, if PFAS were to be designated as hazardous waste in the future, EPA believes there is currently sufficient national capacity to handle waste generated from the treatment of drinking water to remove PFAS as also detailed below.

The EPA anticipates approximately 226,500 short tons of spent drinking water media such as activated carbon and AIX resin to be generated annually as a result of this rule; in calendar year 2018 alone, the US generated about 290 million short tons of waste (USEPA, 2022d). The increase in total waste caused by this final rule is approximately 0.08 percent of the total US waste produced. This is a minor change in aggregate waste produced; the same amount as a pound contributes to a ton. Further, approximately 212,500 short tons of the 226,500 are anticipated to be GAC, which Is expected to be reactivated, and therefore not incinerated or landfilled. Even if PFAS were to be designated in the future as regulatory hazardous waste, there is existing capacity to handle these waste streams through existing hazardous waste facilities in every state (see discussion below). Some water systems may have to ship hazardous wastes significant distances; however, the main cost driver is disposal fees not transportation. The EPA rejects the assertion that it has not evaluated if sufficient capacity exists for disposal and storage of PFOA and PFOS contaminated materials. The EPA also acknowledges that the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) section 104(c)(9) does not allow the agency to initiate a remedial action, unless the state first enters into a state Superfund State Contract or Cooperative Agreement (CA) that assures the availability of adequate capacity to manage hazardous wastes generated in the state for 20 years following the date of the response agreement. This final rule, however, does not impose any capacity concerns that require further action under section 104(c)(9). The EPA is considering designating PFOA and PFOS as CERCLA hazardous substances. No PFAS are currently listed as hazardous wastes under RCRA. The 2021 Biennial Report Summary Results indicate about 18 million tons of hazardous wastes are normally generated annually. Drinking water treatment materials then would constitute about a 1.26 percent increase in hazardous wastes generated annually. Since there is over twenty years' capacity, the relatively small magnitude of the increase indicates that waste management capacity is sufficient in the short term should PFAS be designated as regulatory hazardous wastes.

A few commenters suggest the EPA did not appropriately consider disposal concerns for spent treatment media as part of the agency's feasibility determination. These commenters state that they believe disposal options are currently limited for liquid brine, reject waters resulting from RO, or solid waste from GAC treatment and that disposal capacity will be further limited should the EPA designate PFAS waste as hazardous. These commenters contend that these limitations increase operating expenses for utilities and should be factored in the establishment of the PFOA and PFOS MCLs. The EPA disagrees with these commenters that the agency did not adequately consider disposal of spent treatment media in the rule. First, disposal options for PFAS are currently available. These destruction and disposal options include landfills, thermal treatment,

and underground injection. Systems are currently disposing of spent media, such as activated carbon, through thermal treatment, to include reactivation, and at landfills. While precautions should be taken to minimize PFAS release to the environment from spent media, current disposal options allow these precautions to be taken as appropriate. See USEPA (2024c) and section X of the final rule preamble for further discussion. Furthermore, the EPA has provided guidance for pretreatment and wastewater disposal to manage PFAS that enters the sanitary sewer system and must be managed by POTWs (USEPA, 2022b; USEPA, 2022c).

Many commenters further conveyed concern over the cost of drinking water residuals management resulting from finalizing this rule. Many commenters suggested that regulations under other statutes, particularly a potential CERCLA hazardous substance designation, would increase disposal costs. The EPA disagrees that, if finalized, the CERCLA hazardous substance designation for PFOA and PFOS would increase disposal costs for water treatment facilities. The designation of PFOA and PFOS as CERCLA hazardous substances would not require waste (e.g., biosolids, treatment residuals, etc.) to be treated in any particular fashion, nor disposed of at any specific particular type of landfill. The designation also would not restrict, change, or recommend any specific activity or type of waste at landfills. Along with other release notification requirements, CERCLA designation would require that any person in charge of a vessel or facility report a release of PFOA and/or PFOS of one pound or more within a 24-hour period. The EPA does not expect spent drinking water treatment residuals containing PFAS to be released into the environment at or above the reportable quantity as a part of standard residuals management practices used by water systems. This is because the PFAS loading onto sorptive media is very small. The weight percent of PFAS onto GAC under normal treating scenarios should vary widely; however, a reasonable order of magnitude estimate is $1x10^{-5}$ grams PFAS per gram of sorbent in full-scale applications. High pressure membranes split water into a treated stream and concentrated waste stream. The concentrated waste stream should contain about 5-12 times more PFAS than the influent, which is likely to still be in the ng/L scale. A drinking water facility that takes reasonable precautions is unlikely to release enough low concentration residuals to release one pound of PFOA and/or PFOS within a 24-hour period. At the concentrations discussed above, to exceed a one-pound threshold, a facility using sorptive techniques would have to improperly dispose of approximately 50 tons of sorbent. A one-pound uncontrolled release from RO or NF facilities, assuming 500 ng/L of PFAS in the reject water, would require approximately 240 million gallons of high-pressure membrane concentrate to be released within 24 hours. Additionally, neither a release nor a report of a release automatically requires any response action under CERCLA. The EPA makes CERCLA response decisions based on site-specific information, which includes evaluating the nature, extent, and risk to human health and/or the environment from the release. Hazardous substance designations do not automatically result in CERCLA liability for any specific release. Whether an entity may be subject to litigation or held liable under CERCLA are site-specific and fact-dependent inquiries. Likewise, CERCLA affords the federal government broad discretion as to whether or how to respond to a release. For those reasons, the EPA cannot assess with reasonable certainty what litigation or liability outcomes could indirectly result from such a designation since those

outcomes are often linked to the EPA's discretionary decisions with respect to CERCLA response actions as well as site-specific and fact-dependent court rulings.

While no PFAS are currently listed as regulatory hazardous wastes under RCRA, in response to stakeholder feedback, the EPA included a sensitivity analysis to determine the impact on water systems should they be required to handle and dispose of PFAS treatment materials as hazardous waste in the future. The results of this analysis can be found in the EA for this rule (USEPA, 2024d). Some commenters suggested that accounting for future potential regulations is uncommon, and trying to account for all potential future contingencies would make economic analyses impossible. The EPA strongly agrees and has not attempted to do so here; this analysis was limited to looking at a hypothetical future hazardous waste listing situation because that has been of particular concern in this rulemaking. Some commenters stated that the EPA should account for the public health benefits of treating PFAS as hazardous wastes, not just additional costs incurred. The EPA agrees and has modified the analysis to include a qualitative statement about the public health benefits that could arise from treating PFAS as hazardous wastes. Many commenters stated that the EPA hazardous waste cost would drive the total cost higher than the 3-5 percent estimated by the EPA. After considering public comment, the EPA has revised the final cost estimates in this rule. The estimated increased cost would be approximately $99M at the two percent discount rate. The increased cost was driven by updating the dollar year of cost curves from 2021 to 2022, which increased waste management unit costs by approximately 12 percent; implementing a cap on media life even if not indicated; changes in technology compliance forecast eliminating RO/NF while increasing GAC and AIX (thereby increasing spent media volume); and increasing occurrence estimates for the final rule compared to the proposed rule, triggering more systems into treatment. The increased costs were not driven by changes to unit cost estimates for hazardous waste management. The total cost encompasses capital costs, maintenance, design, and operations, including waste management. Waste management costs are thus a subset of operational cost, which in turn is a subset of total costs; generally, changes in the cost of one subcomponent would not significantly influence total costs, and the record does not reflect that a change in waste disposal costs would have a significant impact on total costs under this rule. These estimates are discussed in greater detail in the HRRCA section of this rulemaking and in Appendix N of the EA (USEPA, 2024b).

Some commenters suggest that the EPA failed to consider the costs and impacts of the proposed MCLs in non-drinking water contexts, such as its potential uses as CERCLA clean-up standards. As required by SDWA, this rulemaking and analyses supporting the rulemaking only includes costs that "are likely to occur solely as a result of compliance with the [MCL]." Thus, the EPA's cost analyses focused on the compliance costs of meeting the MCL to PWSs that are directly subject to this regulation. The same provision expressly directs the EPA to exclude "costs resulting from compliance with other proposed or promulgated regulations." Thus, the EPA cannot consider the costs of use of the MCLs under other EPA statutes (such as CERCLA) as part of its EA because SDWA specifically excludes such consideration (42 U.S.C. § 300g-1(b)(3)(C)(i)(III)). See also *City of Waukesha v. EPA*, 320 F.3d 228, 243-244 (D.C. Cir. 2003) (finding that SDWA excludes consideration of the costs of, for example, CERCLA compliance,

as part of the required cost/benefit analysis). In addition, whether and how MCLs might be used in any particular clean-up is very site-specific and, thus, as a practical matter cannot be evaluated in this rulemaking. Many commenters suggested that EPA should remove water system liability if the agency promulgates a PFAS hazardous substance designation or hazardous waste listing. Water system liability is outside the scope of this regulatory action. Other comments that are outside the scope of this rule making are in section 15.1.

Individual Public Comments

Orange Water and Sewer Authority (OWASA) (Doc. #1524, SBC-042622)

• Hazardous Waste generation/Impacts to treatment plant solids disposal options

o As of right now OWASA's WTP solids would not qualify as hazardous waste, but in the future if the limits become more stringent or if our composting facility decides not to accept waste that has PFAS, there will be impacts to our utility (money and disposal options)

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. For information on the EPA cost models, please see section 13 of the EPA response in this *Response to Comments* document.

Maine Water Utilities Association (MWUA) (Doc. #1567, SBC-042742)

Liability Concerns:

Disposal concerns are currently centered around pending updates to the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) on regulating PFOA and PFOS as hazardous substances, which may impact the available media disposal methods such as landfilling. EPA's current proposal includes setting the default reportable quantity (RQ) at 1.0 pound in a 24-hour period for PFOA and PFOS, and any release at or above RQ must be reported. Granular activated carbon (GAC), anion exchange (AIX) and novel adsorbents all would concentrate PFAS on the media. Disposal considerations are currently most important for anion exchange or novel adsorbents as, currently, major GAC manufacturers offer reactivation services that indicate thermal destruction of PFAS while no resin or novel adsorbent manufacturers offer regeneration services presently. With the ongoing CERCLA update efforts, once PFOA and PFOS are designated as hazardous substances, it will limit the disposal options and sites willing to accept spent media such as resin and novel adsorbents. The draft CERCLA proposal still needs to be finalized, and no industry exemptions have been included for water and wastewater systems. Even though GAC manufacturers provide reactivation, there is indication that regenerated GAC does not fully remove PFAS; with this knowledge, there is a possibility that only virgin media would be permitted for use in PFAS removal systems, not regenerated GAC. The concerns with disposal of PFAS containing media stresses the need for significant focus on advancing destruction technologies.

MWUA, and other New England state water associations made comments on dockets EPA-HQ-OLEM-2019-0341 and EPA-HQ-OLEM-2022-0922-0001 dealing with regulating PFAS under CERCLA. EPA should not move forward with any proposed CERCLA designation until exemptions are granted to water utilities who are passive receivers of PFAS substances. We understand that EPA is separately considering a CERCLA enforcement discretion policy to make it clear that EPA may choose not to take CERCLA enforcement actions against certain entities, but we believe the exemption for water utilities and publicly owned treatment works should be embedded in the regulation. Policies are subject to interpretation and change, whereas regulations have a specified public process. We are therefore requesting that in whatever CERCLA rulemaking EPA moves forward with, EPA provide PWS with an exemption from liability if any or all PFAS compounds are designated as hazardous substances under CERLCA. Doing so would keep CERCLA liability on the industries that created the pollution and/or utilized the substances in the first place.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Minnesota Pollution Control Agency (MPCA) (Doc. #1569, SBC-042495)

Topic: Part C, Management of treatment residuals includes this statement: "For disposal of Reverse Osmosis (RO)/Nano Filtration (NF) membrane concentrate, most systems use surface water discharge or discharge to sanitary sewer. The large volume of residuals is a well-known obstacle to adoption of membrane separation technology in general."

MPCA comments: A discharge of RO/NF membrane treatment residuals to a surface water or to a sanitary sewer system which ultimately discharges to a surface water, recirculates the PFAS into the environment posing risks to human and ecological receptors. Either type of discharge may also represent a violation of other state or federal water quality standards and/or NPDES permit conditions.

EPA should consider a hazardous waste disposal exclusion for nominally sized or Point of Use / Point of Entry filtration systems (POU/POEs) and may want to consider adding a discussion of emerging destruction and separation technology types that may provide future treatment efficacy at the small and large scale.

EPA Response: Please see sections 10.1, 10.4.1 and 10.4.2 of the EPA response in this *Response to Comments* document.

San Antonio Water System (SAWS) (Doc. #1570, SBC-042485)

o EPA is simultaneously proposing the inclusion of nine (9) PFAS compounds to be designated as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) as the regulations pertaining to PFAS are being proposed under the Safe Drinking Water Act.

o PWSs face the possible imposition of liability for the presence of designated PFAS compounds, deemed hazardous substances, even though they are passive recipients of these compounds. Requiring testing and disclosure of the presence of PFAS compounds while facing this potential liability is contrary to the interest of every PWS and could lead to litigation that makes compliance with PFAS regulations virtually impossible.

o As a practical matter, PWSs will not know the best treatment methods to implement without understanding hazardous waste disposal regulations. For a PWS to reach compliance under the proposed drinking water rule, they will be creating hazardous waste under the anticipated CERCLA regulations. EPA needs to clearly define approved disposal options available for treatment biproducts, laboratory analytical waste, etc.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Sammamish Plateau Water and Sewer District (Doc. #1573, SBC-042463)

Since water utilities are not the responsible party for PFAS contamination, but may be required to implement PFAS treatment/removal as mandated under the rule, USEPA should recognize that spent treatment media will become a byproduct of the proposed rule. As such, USEPA should acknowledge the need for corresponding Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) exemption/immunity for agencies mandated to treat for PFAS removal. In addition, any MCL which would require a water utility to treat for PFAS should be applied as the same standard for parties responsible contaminating potable groundwater with PFAS who will be required to conduct remediation activities.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. The EPA agrees that removing PFAS from drinking water using the proposed BATs generates residual materials which must be appropriately managed and has pointed out in the rule proposal as well as guidance documents including the *Best Available Technologies and Small System Compliance Technologies for PFAS in Drinking Water*, the *Technologies and Costs for Removing Per- and Polyfluoroalkyl Substances from Drinking Water*, and the *PFAS Destruction and Disposal Guidance* documents. Comments on other rules should be made on those dockets. Comments on CERCLA liability are outside SDWA, please see section 15.1 of the EPA response in this *Response to Comments* document for other comments outside SDWA.

COMM Water Department (Doc. #1577, SBC-042445)

EPA must address the water sector's concerns about potential liability under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). EPA is proposing to regulate PFOA and PFOS as hazardous substances, which may impact the available media disposal methods such as landfilling. EPA should not move forward with any proposed CERCLA designation until exemptions are granted to water utilities who are passive receivers of

PFAS substances. The requested exemption needs to be embedded in law or regulation, and not just through an enforcement discretion policy. In whatever CERCLA rulemaking EPA moves forward with, EPA must provide PWS with an exemption from liability, including CERCLA third-party liability, if any or all PFAS compounds are designated as hazardous substances under CERLCA. Doing so would keep CERCLA liability on the industries that created the pollution and/or utilized the substances in the first place.

EPA Response: Please see sections 10.4.2 and 10.6 of the EPA response in this *Response to Comments* document. Designation does not require facilities to take any specific response actions, such as sampling, treatment, or disposal. Designation does not require any response action by a private party and does not determine liability for hazardous substance release response costs. Response actions are contingent, discretionary, and site-specific decisions made after a hazardous substance release or threatened release. The designation does not require waste to be treated in any particular fashion., nor disposed of at any particular type of landfill. The designation also does not restrict, change, or recommend any specific activity or type of waste at landfills. The EPA would also like to clarify that neither the designation, nor CERCLA, require any prospective monitoring. Any potential monitoring that may be necessary for a given release is to be determined on a site-specific basis. Comments on other rules should be made on those dockets. Comments on CERCLA liability are outside the scope of this SDWA rulemaking action, please see section 15.1 of the EPA response in this *Response to Comments* document for other comments outside the scope of this SDWA rulemaking action.

Santa Clarita Valley Water Agency (SCVWA) (Doc. #1578, SBC-042432)

Other PFAS Chemicals rule making efforts, like the U.S. Environmental Protection Agency's (EPA) Proposed Rule – Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) Hazardous Substances: Designation of Perfluorooctanoic Acid and Perfluorooctanoic Acid (PFAS Chemicals) have further cost and liability considerations. The proposed rule will have additional significant cost impacts as it proceeds through the nation's water and wastewater regulatory framework. The rulemaking process would benefit from a consolidated approach when considering the total cost impacts of the new rule.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. More information about EPA cost analysis can be found in section 13 of the EPA response in this *Response to Comments* document.

San Gabriel Valley Water Association (SGVWA) (Doc. #1580, SBC-042422)

Upside-down Implementation with CERCLA Let's Polluters off the Hook: In September 2022, EPA issued a Notice of Proposed Rulemaking (NPRM) designating PFOA and PFOS as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). In April 2023, EPA issued an Advance Notice of Proposed Rulemaking (ANPRM) about possible future designations of PFAS under CERCLA.

If such designations happen before setting an MCL, it may lead to lawsuits between drinking water suppliers and wastewater agencies detecting PFAS substances. This could cause billions of dollars in local mitigation efforts to go to waste, and responsible parties may not be held accountable to remediate the contamination they caused. However, giving exemptions to wastewater agencies and water suppliers under CERCLA requires congressional approval while the regulatory process is ongoing. This creates a race against time as the litigation time bomb counts down.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. Comments on CERCLA liability are outside the scope of this SDWA rulemaking action, please see section 15.1 of the EPA response in this *Response to Comments* document for other comments outside of this SDWA rulemaking action.

San Gabriel Valley Water Association (SGVWA) (Doc. #1580, SBC-042417)

Hazardous Waste Disposal: The economic analysis does not include the expenses related to transporting and disposing of hazardous waste, also known as PFAS residuals, to certified disposal facilities located in other states. These additional costs can potentially double the total cost of meeting the MCL requirements.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. The EPA refers the commenter to the EPA response to comment Doc. #1761, SBC-046086 in section 10.4.1 in this *Response to Comments* document for details on how the 200-mile waste disposal distance was selected. More information on the EPA cost analysis can be found in section 13 of the EPA response in this *Response to Comments* document.

Association of State and Territorial Solid Waste Management Officials (ASTSWMO) (Doc. #1583, SBC-042398)

PFAS Disposal and Destruction: ASTSWMO is concerned with the increase in the volume of PFAS-contaminated materials and waste streams that will result from this rulemaking. As EPA is aware, there are many existing challenges associated with the lack and/or limitations of destruction and disposal technologies for PFAS-containing materials and waste streams, including the outright prohibition of PFAS-containing materials destruction in some jurisdictions. Sending PFAS-containing materials to landfills is problematic, due to capacity issues and the lack of proven solidification and stabilization technologies to minimize PFAS in landfill leachate. Further, there remains uncertainty in the acceptable levels of PFAS in compost, biosolids, and industrial byproducts that are otherwise suitable for land application. ASTSWMO recommends that EPA prioritize the identification of effective treatment and disposal options and associated PFAS destruction research to ensure that PFAS contamination is safely disposed of, including finalization of EPA's interim Guidance on the Destruction of and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfuoroalkyl Substances.

EPA Response: Please see sections 10.4.1, 10.4.2, and 10.6 of the EPA response in this *Response to Comments* document.

Pennsylvania Chamber of Business and Industry (Doc. #1592, SBC-042797)

The PA Chamber Reiterates Our Concern with Listing These Substances Under

CERCLA

In a joint letter with other state chambers filed with the EPA last November [FN1: https://www.pachamber.org/wp-content/uploads/2022/11/State-Chamber-Coalition-Comments-on-CERCLADesignation-OLEM.pdf], the PA Chamber expressed its concern adding these compounds to CERCLA, given the costs and uncertainties with respect to storage and disposal, as well as the fact that the World Health Organization's report on PFOS and PFOA in drinking water calls into question EPA's approach on this matter. This move would also impose significant liability for domestic manufacturers, again in conflict with the stated policy goals of this administration and Congress on shoring up supply chains.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. The EPA notes that the draft World Health Organization (WHO) report referenced by the commenter was postponed based on negative public comment based on not using the best available science and that it referenced 2016 EPA Health Advisory levels for PFOA and PFOS. More information may be found online at https://cdn.who.int/media/docs/default-source/wash-documents/wash-chemicals/pfos-and-pfoa-in-dw-comments-responses-21.11.23.pdf?sfvrsn=71261026_1or https://www.who.int/teams/environment-climate-change-and-health/water-sanitation-and-health/chemical-hazards-in-drinking-water/per-and-polyfluoroalkyl-substances Comments on CERCLA liability are outside the scope of this SDWA rulemaking action, please see section 15.1 of the EPA response in this *Response to Comments* document for other comments outside the scope of this SDWA rulemaking action.

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-042894)

Liability Concerns:

Disposal concerns are currently centered around pending updates to the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) on regulating PFOA and PFOS as hazardous substances, which may impact the available media disposal methods such as landfilling. EPA's current proposal includes setting the default reportable quantity (RQ) at 1.0 pound in a 24-hour period for PFOA and PFOS, and any release at or above RQ must be reported. Granular activated carbon (GAC), anion exchange (AIX) and novel adsorbents concentrate PFAS on the media. Disposal considerations are currently most important for anion exchange or novel adsorbents since, currently, major GAC manufacturers offer reactivation services that indicate thermal destruction of PFAS, while no resin or novel adsorbent

manufacturers offer regeneration services. With the ongoing CERCLA update efforts, once PFOA and PFOS are designated as hazardous substances, it will limit the disposal options and sites willing to accept spent media such as resin and novel adsorbents. The draft CERCLA proposal still needs to be finalized, and no industry exemptions have been included for water and wastewater systems. Even though GAC manufacturers provide reactivation, there is indication that regenerated GAC does not fully remove PFAS; with this knowledge, there is a possibility that only virgin media would be permitted for use in PFAS removal systems, not regenerated GAC.

MWWA made comments on dockets EPA-HQ-OLEM-2019-0341 and EPA-HQ-OLEM2022-0922-0001 dealing with regulating PFAS under CERCLA. EPA should not move forward with any proposed CERCLA designation until exemptions are granted to water utilities who are passive receivers of PFAS substances. We understand that EPA is separately considering a CERCLA "enforcement discretion policy" to clarify that EPA may choose not to take CERCLA enforcement actions against certain entities. However, we vigorously advocate the exemption for water utilities and publicly owned treatment works be explicitly provided in the regulation. Policies are subject to interpretation and change, whereas regulations have a specified public process. We are therefore requesting that in whatever CERCLA rulemaking EPA advances, EPA provide PWS with an exemption from liability, including CERCLA third-party liability, if any or all PFAS compounds are designated as hazardous substances under CERLCA. Doing so would keep CERCLA liability on the industries that created the pollution and/or utilized the substances in the first place.

There are challenges associated with disposal of spent media and treatment residuals, beyond just the increased costs if no exemptions are granted to water (and wastewater) utilities under CERCLA. Massachusetts drinking water and wastewater facilities face a biosolids management and disposal crisis as PFAS chemicals are causing land application bans and restrictions, and dwindling landfill space reduces disposal capacity. We need EPA to rapidly work toward finding permanent destruction technologies or we will continue to face the prospect of a never-ending cycle of moving PFAS around our environment.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. Designation does not require facilities to take any specific response actions, such as sampling, treatment, or disposal. Designation does not require any response action by a private party and does not determine liability for hazardous substance release response costs. Response actions are contingent, discretionary, and site-specific decisions made after a hazardous substance release or threatened release. The designation does not require waste to be treated in any particular fashion, nor disposed of at any particular type of landfill. The designation also does not restrict, change, or recommend any specific activity or type of waste at landfills. The EPA would also like to clarify that neither the designation, nor CERCLA, require any prospective monitoring. Any potential monitoring that may be necessary for a given release is to be determined on a site-specific basis. Comments on CERCLA liability are outside the scope of this SDWA rulemaking action, please see section 15.1 of the EPA response in this

Response to Comments document for other comments outside the scope of this SDWA rulemaking action.

Regarding enforcement discretion, existing liability limitations in CERCLA coupled with existing CERCLA enforcement policies are sufficient to mitigate concerns about liability that may arise after designation. No additional action is necessary to ensure that those limitations and policies continue to operate as they have for decades. Nonetheless, the EPA intends to develop a policy, consistent with those limitations and policies, that explains EPA's priorities for enforcement in the context of PFOA and PFOS releases. As the EPA states in the fiscal year (FY) 2024-2027 National Enforcement and Compliance Initiates (NECI), the agency expects to "focus on implementing EPA's PFAS Strategic Roadmap and holding responsible those who significantly contribute to the release of PFAS into the environment …." The NECI also clarifies that "OECA does not intend to pursue entities where equitable factors do not support CERCLA responsibility, such as farmers, water utilities, airports, or local fire departments, much as OECA exercises CERCLA enforcement discretion in other areas." The EPA will make enforcement decisions on a site-by-site basis informed by site-specific circumstances.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043632)

6. The USEPA recommended BATs for PFAS removal are essentially separation technologies rather than destruction technologies. Thus, PFAS removed from drinking water supplies are shifted to other environmental vectors for public exposure via the residuals management process. Depending on the BAT selected, residuals handling could require landfilling, incineration, or deep well injection-- further reallocating PFAS contamination to air, surface water and groundwater, ocean water etc.

7. It is likely that the USEPA significantly underestimated the national cost impacts of residual management if PFAS-contaminated wastes are regulated as hazardous waste in the future. If/when the USEPA designates one or more species of PFAS as "hazards substances" under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) or "hazardous constituents" under the Resource Conservation and Recovery Act (RCRA), there is potential for a significant escalation in residuals management costs. Similarly, regulatory action under the Clean Water Act (CWA) to control PFAS discharges could also result in escalated residuals management costs for water treatment systems. USEPA estimated costs for two spent GAC management scenarios: 1) Off-site reactivation under current RCRA non-hazardous waste regulations; 2) Off-site disposal as a hazardous waste and replacement with virgin GAC. USEPA stated that there will only be a 6% ($61 million) increase in the national annual PFAS treatment cost when spent GAC is regulated as hazardous waste. However, BWWB conducted a preliminary cost estimate for the same scenarios and the hazardous-waste scenario resulted in approximately 38% higher disposal costs than the non-hazardous waste scenario, which results in an increase in the annual O&M cost for an 80 MGD filter plant of $1.5 million. USEPA's assessment of the influence of these regulations on residuals management is clearly underestimated.

Please refer to Attachment 1 for further comments on the proposed PFAS Rule.

EPA Response: Please see sections 10.4.1 and 10.4.2 of the EPA response in this *Response to Comments* document. The EPA appreciates the commenter sharing a data point but points out that a national average can vary drastically from specific scenarios and refers the commenter to section 13 of the EPA response in this *Response to Comments* document for more information on the cost models. Comments on CERCLA liability are outside the scope of this action, please see section 15.1 of the EPA response in this *Response to Comments* document for other comments outside this scope.

American Water Works Company Inc. (Doc. #1608, SBC-043996)

Waste and Waste Disposal

American Water believes that the U.S. EPA should clearly establish acceptable means of disposal or reactivation/regeneration of PFAS-bearing treatment media. Additionally, if the number and location of approved disposal or treatment outlets is very limited, then increased hauling, disposal, and/or media reactivation costs pose a significant threat to the accuracy of the U.S. EPA's cost assumptions. Further, water utilities that provide a critical community service should not be liable for the fate of PFAS contaminants if residuals are disposed of or treated using an approved waste management practice. American Water firmly believes that the ultimate responsibility for the cleanup of these contaminants should fall to those who created the problem. Drinking water and wastewater utilities are not responsible for the presence of PFAS contaminants in sources of supply and customer wastewater discharges. Protecting water and wastewater utilities from liability associated with handling and disposing of PFAS-contaminated residuals according to USEPA-approved methods is important for minimizing legal risks and associated cost burdens to utilities and their customers.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. The EPA has provided clear destruction and disposal guidance for example in the *Interim PFAS Destruction and Disposal Guidance* document. For discussion on costs, please see the EA and the HRRCA section.

American Water Works Company Inc. (Doc. #1608, SBC-044004)

American Water joins other water organizations in urging the U.S. EPA, Congress, and other decision-makers to implement policies that will:

• keep harmful PFAS out of our drinking water supplies and our communities;

• exempt all water and wastewater systems from financial liability for PFAS under CERCLA;

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. The EPA agrees that reducing PFAS in drinking water is an important policy objective. Comments on CERCLA liability are outside the scope of this action, please see

section 15.1 of the EPA response in this *Response to Comments* document for other comments outside such scope.

Marlene Ladderbush (Doc. #1612, SBC-042921)

EPA must address the water sector's concerns about potential liability under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). EPA is proposing to regulate PFOA and PFOS as hazardous substances, which may impact the available media disposal methods such as landfilling. EPA should not move forward with any proposed CERCLA designation until exemptions are granted to water utilities who are passive receivers of PFAS substances. The requested exemption needs to be embedded in law or regulation, and not just through an enforcement discretion policy. In whatever CERCLA rulemaking EPA moves forward with, EPA must provide PWS with an exemption from liability, including CERCLA third-party liability, if any or all PFAS compounds are designated as hazardous substances under CERLCA. Doing so would keep CERCLA liability on the industries that created the pollution and/or utilized the substances in the first place.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. Comments on CERCLA liability are outside the scope of this action, please see section 15.1 of the EPA response in this *Response to Comments* document for other comments outside the scope.

Town of Lincoln Water Department (Doc. #1613, SBC-043033)

EPA must address the water sector's concerns about potential liability under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). EPA is proposing to regulate PFOA and PFOS as hazardous substances, which may impact the available media disposal methods such as landfilling. EPA should not move forward with any proposed CERCLA designation until exemptions are granted to water utilities who are passive receivers of PFAS substances. The requested exemption needs to be embedded in law or regulation, and not just through an enforcement discretion policy. In whatever CERCLA rulemaking EPA moves forward with, EPA must provide PWS with an exemption from liability, including CERCLA third-party liability, if any or all PFAS compounds are designated as hazardous substances under CERLCA. Doing so would keep CERCLA liability on the industries that created the pollution and/or utilized the substances in the first place.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. Comments on CERCLA liability are outside the scope of this action, please see section 15.1 of the EPA response in this *Response to Comments* document for other comments outside this scope.

Oklahoma Department of Environmental Quality (DEQ) (Doc. #1616, SBC-043051)

PFAS Treatment and Related Waste Disposal

EPA should prioritize research on waste disposal methods and move to address PFAS waste disposal to ensure that PFAS contamination is not being moved from one media type to another. DEQ recommends that EPA finalize the Agency's Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances ahead of the final rule.

All of the Best Available Technologies listed for complying with the PFAS MCL's have waste streams that will need to be appropriately addressed. Some states have reported water systems being unable to dispose of their PFAS-containing media, as some waste disposal sites are refusing to accept the material. PFAS is only included in a limited number of NPDES permits, and so PFAS containing reject water from RO applications going to waste water treatment facilities may not be removed and may be returned to source water locations. As waste disposal options are developed and regulated, EPA should ensure that water systems are able to reasonably comply with the options.

EPA Response: Please see sections 10.4.1 and 10.4.2 of the EPA response in this *Response to Comments* document.

Water One - Water District No. 1 of Johnson County, Kansas (Doc. #1627, SBC-042331)

Residuals Disposal and CERCLA Exemption

The proposed PFAS regulation does not address associated water treatment facility discharges (or similarly, wastewater treatment plant discharges) or disposal of the compounds once removed. Residual disposal will further increase implementation costs and possibly even the ability to operate a treatment facility. There must be action taken to create an exemption from liability under CERCLA for water systems acting in accordance with all applicable laws and regulations in the event of PFAS contamination. EPA proposed to designate two PFAS hazardous substances. This allows EPA to hold “potentially responsible parties" financially liable for any required remediation at contaminated sites. Although the designation is intended to target polluters, water treatment providers may be at risk without an explicit exemption.

We appreciate the opportunity to review and provide comment on the proposed PFAS NPDWR and hope the EPA will consider the significant implications of this proposed regulation and pause implementation until further scientific data is collected, costs and logistical implications are addressed, and a CERCLA exemption is established. If you have additional questions, please fill free to contact us.

Sincerely,

Eric R. Arner

Acting General Manager

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. Comments on CERCLA liability are outside the scope of this action, please see section 15.1 of the EPA response in this *Response to Comments* document for other comments outside the scope.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044111)

Waste Disposal

ASDWA recommends that EPA prioritize research on waste disposal methods and move to address PFAS waste disposal utilizing a regulatory mechanism as soon as possible to ensure that PFAS contamination is not being moved from one media type to another. ASDWA recommends that EPA finalize the Agency's Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances ahead of the final rule.

The current information on other environmental impacts of PFAS disposal is limited, and all of the BAT listed for complying with the MCL have waste streams that will need to be appropriately addressed, including spent GAC media or ion exchange (IX) resin, RO brine water, and spent POU/POE devices. PFAS has not yet been designated under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) as a hazardous substance, but some primacy agencies have already reported water systems being unable to dispose of their PFAS-containing media as some waste disposal sites are refusing to accept the material.

PFAS is only included in a limited number of NPDES permits, so PFAS in the reject water from RO applications going to wastewater treatment facilities may not be removed, returning to source water locations. Research is limited on using underground injection control wells for RO reject water. Research is also limited on thermal regeneration of GAC and the release of PFAS into the atmosphere. ASDWA strongly recommends that EPA continue to pursue research on waste disposal options for PFAS to ensure long-term mitigation. As these waste disposal options are developed and regulated, EPA should ensure that water systems are able to reasonably comply with those options.

ASDWA recommends that EPA update and finalize the Agency's Interim Guidance on the

Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances ahead of the final rule. Additionally, guidance about PFAS contaminated waste should be outlined in Resource and Conservation Recovery Act (RCRA) policies and procedures.

EPA Response: Please see sections 10.4.1 and 10.4.2 of the EPA response in this *Response to Comments* document.

Village of Woodbury (Doc. #1629, SBC-042951)

5. Some of the proposed treatment options require media change-outs and disposal for effective treatment of PFAS. EPA acknowledges that disposal of media could create conflict with other regulations including Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) because spent media may be designated as hazardous waste. It is noted [FN1: Proposed PFAS National Primary Drinking Water Regulation" presentation, dated March 29, 2023, prepared by the US EPA Office of Water.] the EPA is still researching this issue; in our view until viable options for media disposal are identified, the promulgation should be stayed.

Additionally, processes requiring backwash and disposal of the same should be evaluated. Guidance on acceptable disposal of backwash for any process requiring the same, as well as, cost considerations for frequency should be established for public water suppliers and EPA to consider as part of the proposed rule.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. The EPA disagrees that there are no viable options for media disposal and has presented viable options for media disposal for example in the *Interim PFAS Destruction and Disposal Guidance* document.

Texas Commission on Environmental Quality (TCEQ) (Doc. #1632, SBC-044137)

PFAS Destruction and Disposal

TCEQ urges EPA to provide additional information on PFAS destruction and disposal and finalize EPA's Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances as soon as possible so that this guidance can be incorporated in implementation planning for the final rule.

EPA Response: Please see sections 10.4.1 and 10.4.2 of the EPA response in this *Response to Comments* document. The EPA is updating the *Interim PFAS Destruction and Disposal Guidance* document. After finalization of the PFAS NPDWR, the EPA plans to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation.

Town of Tewksbury, Massachusetts (Doc. #1637, SBC-043250)

EPA must address the water sector's concerns about potential liability under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). EPA is proposing to regulate PFOA and PFOS as hazardous substances, which may impact the available media disposal methods such as landfilling. EPA should not move forward with any proposed CERCLA designation until exemptions are granted to water utilities who are passive receivers of PFAS substances. The requested exemption needs to be embedded in law or regulation, and not

just through an enforcement discretion policy. In whatever CERCLA rulemaking EPA moves forward with, EPA must provide PWS with an exemption from liability, including CERCLA third-party liability, if any or all PFAS compounds are designated as hazardous substances under CERLCA. Doing so would keep CERCLA liability on the industries that created the pollution and/or utilized the substances in the first place.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. Comments on CERCLA liability are outside the scope of this action, please see section 15.1 of the EPA response in this *Response to Comments* document for other comments outside this scope.

Citizens Against Ruining the Environment (CARE) (Doc. #1638, SBC-043447)

CARE Comment 3 – The Current Residual PFAS Waste Disposal Requirements Will Allow PFAS to Reenter the Environment Following Disposal and Urges EPA to Develop Disposal Requirements That Fully Neutralize or Destroy PFAS Contamination.

CARE strongly encourages EPA to develop clear requirements for PWS to dispose of PFAS waste from water treatment with methods that fully neutralize or destroy PFAS contaminants. CARE is very concerned with current disposal requirements for residual PFAS waste collected at water systems. EPA's own data shows that PFAS may be able to harm human health and the environment through other means than just water, including swallowing contaminated soil or dust, and breathing air containing PFAS. [FN37: Our Current Understanding of the Human Health and Environmental Risks of PFAS, EPA, https://www.epa.gov/pfas/our-current-understanding-human-health-and-environmental-risks-pfas (March 16, 2023).] According to EPA, the most likely management option for spent material containing PFAS is reactivation for GAC and incineration for spent IX resin. [FN38: PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. at 18686.] Reactivated carbon can become totally exhausted with contaminants not removed during reactivation and must eventually be replaced. [FN39: Id. at 18685.] For disposal of RO/NF membrane concentrate, most systems use surface water discharge or discharge to sanitary sewer. [FN40: Id. at 18686.] The large volume of residuals is a well-known obstacle to adoption of membrane separation technology in general.

Additionally, despite the possibility of some PFAS being designated as hazardous substances under CERCLA or hazardous constituents under RCRA, EPA states it does not believe those actions should limit disposal options and how PFAS containing waste is required to be managed. [FN41: Id. at 18688.]

EPA Response: Please see sections 10.4.1 and 10.4.2 of the EPA response in this *Response to Comments* document.

California Municipal Utilities Association (CMUA) (Doc. #1639, SBC-043257)

Additionally, the Regulation may impact public water agency hazardous substance disposal practices and agency liability. If one or more PFAS are designated as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), the removal of PFAS from agencies' water supplies will result in treatment residuals that are deemed hazardous substances, and the public agency is under additional obligations to dispose of the hazardous substances properly. Even with proper disposal, the public agency is still subject to potential liability. Because CERCLA imposes strict, joint and several, and retroactive liability, public water agencies that dispose of water treatment residuals with any concentration of PFAS that are designated CERCLA hazardous substances may be required to clean up all the contamination from the disposal site if no other viable potentially responsible party (PRP) is identified. In addition, public water agencies may be sued by other PRPs to recover at least some, if not all, the costs for cleanup. It is also possible that wastewater effluent that contains PFAS will be considered a hazardous substance. More certainty as to the characterization of PFAS as hazardous substances and the resulting consequences for public water agencies is needed before the EPA can require compliance with the Regulation.

Lastly, certainty regarding the impacts an agency may face under the drinking water discharge permit system is needed. The permitting scheme allows agencies to discharge into the waters of the U.S.; it is unclear whether the discharge of PFAS fits into the existing permitting scheme or if agencies will need to apply for a different permit to cover those types of discharges. It is also unclear whether such discharges of PFAS could subject agencies to potential CERCLA liability.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. Comments on CERCLA liability are outside the scope of this action, please see section 15.1 of the EPA response in this *Response to Comments* document for other comments outside this scope.

American Farm Bureau Federation et al. (Doc. #1642, SBC-043497)

The absence of regulatory requirements or at least clear guidance on management, treatment, disposal, and destruction guidelines hampers the ability of drinking water utilities to develop the management infrastructure needed to address PFOA and PFOS contamination. State regulators look to EPA for guidance on this topic for the purpose of reviewing and approving cleanup plans.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. The EPA has provided guidance on management, treatment, disposal, and destruction, for example, in the *Best Available Technologies and Small System Compliance Technologies for PFAS in Drinking Water* and the *Technologies and Costs for Removing Per- and Polyfluoroalkyl Substances from Drinking Water* documents. The EPA has been collaborating and will continue to collaborate with states, technical assistance providers, industry

associations, and interested stakeholders to provide technical materials that can assist water systems in complying with the regulations.

American Farm Bureau Federation et al. (Doc. #1642, SBC-043495)

Disposal: EPA is obligated by statute to issue periodic (every four years) guidance on the destruction and disposal of PFAS compounds. EPA's initial guidance document submitted to Congress basically reported on the various technologies that have been used or that are under evaluation for use in the management of PFAS and PFAS-contaminated media. The lack of clear guidance and standards for the management, treatment, and destruction of PFAS compounds continues to present a significant challenge to the array of parties managing PFAS compounds and contaminated media. Much of this material is being stored in anticipation of EPA issuing more definitive guidance

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. The EPA notes that the *Interim PFAS Destruction and Disposal Guidance* document contains clear guidance and standards for the management of PFAS-laden treatment residuals.

New England Interstate Water Pollution Control Commission (NEIWPCC) (Doc. #1650, SBC-043149)

Given our member states existing concerns, we urge EPA to consider the cost and availability of disposal options for spent media. In light of the potential CERCLA-designation of such disposal sites and the RCRA listing of certain PFAS compounds, our member states are concerned that future disposal options will be quite limited. Our experience in the northeast region [FN7: https://www.pressherald.com/2023/02/28/landfill-instability-has-maine-sewer-plants-in-a-bind/] suggest such regulatory changes may have a significant impact on the availability of disposal sites.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044194)

4. NCDEQ recommends that EPA prioritizes research on waste disposal methods and move to address PFAS waste disposal utilizing a regulatory mechanism as soon as possible to ensure that PFAS contamination is not being moved from one media type to another. NCDEQ recommends that EPA finalize the Agency's Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances.

The current Information on other environmental impacts of PFAS disposal is limited, and all of the BAT listed for complying with the MCL have waste streams that will need to be

appropriately addressed, including spent GAC media or ion exchange (IX) resin, RO brine water, and spent POU/POE devices. EPA is working on designing PFAS under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) as a hazardous substance, but some state agencies have already reported water systems being unable to dispose of their PFAS-containing media as some waste disposal sites are refusing to accept the material. In North Carolina, PFAS monitoring is being added to NPDES permits issued by NCDEQ at permit renewal and permit modification stages, so PFAS-containing reject water from RO applications going to wastewater treatment facilities may not be removed, returning to source water locations. There is also limited research on thermal regeneration of GAC and the release of PFAS into the atmosphere. NCDEQ strongly recommends that EPA continue to pursue research on waste disposal options for PFAS to ensure long-term mitigation. As these waste disposal options are developed and regulated, EPA should ensure that water systems are able to reasonably comply with those options. Additionally, NCDEQ recommends that EPA update and finalize the Agency's Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances ahead of the final rule.

EPA Response: Please see sections 10.4.1 and 10.4.2 of the EPA response in this *Response to Comments* document.

National Association of Clean Water Agencies (NACWA) (Doc. #1659, SBC-043157)

Notably, virgin GAC has a limited life span and PWSs will continually need to replace their spent-GAC by either disposing these materials in certain hazardous waste landfills or hauling it out for regeneration or recycling. These processes have considerable indirect climate impacts including increased carbon footprints to transport GAC to disposal or regeneration sites, greater quantities of waste disposed in landfills, and tremendous energy needs to regenerate spent GAC.

The same can be true for PWSs opting to install expensive reverse osmosis or anion exchange as treatment techniques to remove PFAS chemicals from drinking water. The spent resin and concentrated PFAS liquid post-filtration will have to be dealt with—only continuing to pass the PFAS contamination burden to another entity and often making its way full circle to wastewater utilities to deal with. EPA should have considered these indirect impacts.

Conclusion

NACWA appreciates the opportunity to file these comments and hopes EPA takes time to carefully review and consider these. If EPA has any questions, please do not hesitate to contact me at 202/533-1839 or eremmel@nacwa.org.

Emily Remmel

Director, Regulatory Affairs

EPA Response: Please see sections 10.4.1 and 10.4.2 of the EPA response in this *Response to Comments* document. With respect to commenter concerns on the social cost of carbon, please see section 13.11 of the EPA response in this *Response to Comments* document.

Water Supply District of Acton (Doc. #1662, SBC-043666)

EPA must address the water sector's concerns about potential liability under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). EPA is proposing to regulate PFOA and PFOS as hazardous substances, which may impact the available media disposal methods such as landfilling. EPA should not move forward with any proposed CERCLA designation until exemptions are granted to water utilities who are passive receivers of PFAS substances. The requested exemption must be embedded in law or regulation, not just through an enforcement discretion policy. Managing backwash and media disposal poses financial and sustainability concerns in a market that is already constrained.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. Comments on CERCLA liability are outside the scope of this SDWA rulemaking action, please see section 15.1 of the EPA response in this *Response to Comments* document for other comments outside the scope of this SDWA rulemaking action.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044428)

Page 18731. Section XI – Treatment Technologies

This section combines treatment technologies with generation and disposal of PFAS waste. Recommend further separation of these two topics to further clarify and address each topic in greater detail.

• DOH does not have enough data to provide meaningful comments on treatment technologies for PFAS in drinking water.

EPA requests comment on the estimates for disposing of drinking water treatment residuals or regenerating drinking water treatment media including assumptions related to the transport distance to disposal sites and other costs that arise out of disposal of PFAS contaminated drinking water treatment residuals.

• This response was prepared by the Washington State Department of Ecology. In Washington State, water treatment residuals might be designated as Washington State Only Dangerous Waste if the concentration of persistent PFAS compounds exceeds state only designation criteria. If it does, then that waste stream must be diverted to a Subtitle C landfill designed to manage PFAS waste. All subtitle C landfills are out of state (closest are in Idaho and Oregon), making transportation and treatment costs high.

• This response was prepared by the Washington State Department of Ecology. PFAS waste disposal in Washington State is governed by Washington Administrative Code 173-303.

Appropriate disposal of PFAS waste generated from removal from drinking water depends upon the specific waste category designation. Thresholds have been established by the Washington State Department of Ecology that designate appropriate disposal approaches and locations depending upon concentrations of PFAS within environmental media.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. The EPA thanks the commenter for providing state-specific legal clarification and data.

City of Hillsboro, Oregon (Doc. #1668, SBC-043123)

4. Interim guidance for Utilities for PFAS Disposal

Most of the advanced treatment solutions suggested by EPA generate PFAS "residuals" from the filters or other by-products of media that have been used in the treatment process to capture PFAS and remove it from drinking water. Currently the EPA has interim guidance for PFAS disposal, however this places additional strain on water utilities for additional compliance measures related to disposal of PFAS. Water utilities are not the original sources of PFAS, and yet are now tasked with the burden of removal from drinking water sources. Water utilities should be exempt from the disposal requirements under CERCLA, as they are now burdened with the PFAS residuals through treatment.

Hillsboro Water hopes that our comments help EPA develop sound rule options that further reduce risks posed by PFAS, recognizing the realities of local budgets and infrastructure renewal needs. If EPA has any questions regarding these comments, please contact Sarah Honious, Water Quality Program Coordinator at 503-615-6540, Sarah.Honious@Hillsboro-Oregon.gov.

Sincerely,

Jessica Dorsey

Water Resources Manager City of Hillsboro

503-615-6579

jessica.dorsey@hillsboro-oregon.gov

References:

Black and Veatch (2023). WITAF 56 Technical Memorandum: PFAS National Cost Model Report (B&V Project No. 409850). American Water Works Association.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. Comments on CERCLA liability are outside the scope of this SDWA rulemaking action, please see section 15.1 of the EPA response in this *Response to Comments* document for other comments outside the scope.

National Association of Water Companies (NAWC) (Doc. #1670, SBC-044166)

NAWC urges EPA to develop a residuals management plan that addresses disposal capacity, standardized analytical methodology, and establishing a CERCLA exemption for drinking water systems before finalizing the rule to ensure additional liability and expense is not incurred by the public and ratepayers.

EPA Response: Please see sections 10.4.2 and 10.6 of the EPA response in this *Response to Comments* document. Comments on CERCLA liability are outside the scope of this SDWA rulemaking action, please see section 15.1 of the EPA response in this *Response to Comments* document for other comments outside the scope.

National Association of Water Companies (NAWC) (Doc. #1670, SBC-044164)

Compounding timeline feasibility concerns, EPA has not provided communities and public water systems with a clear plan to manage the water treatment residuals that will be produced as a result of the requirement in the proposed rule. Without a residuals management plan that addresses disposal coordination and capacity, analytical methodology and standardized waste characterization, and CERCLA liability, residuals disposal poses an almost insurmountable logistical obstacle for all drinking water systems, and it raises the significant issue of potential liability for communities related to the transport and the final disposition of treatment residuals.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. To address timeline feasibility concerns, the EPA has provided compliance flexibility through a two-year capital improvements extension of the MCL compliance deadline allowed by Section 1412(b)(10) of SDWA in response to challenges raised by commenters surrounding capital improvement.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-044924)

Section 7.2: Disposal and reactivation

EPA requests comment on the availability of facilities to dispose of or reactivate drinking water treatment media containing PFAS. Specifically, EPA seeks comment of whether there is sufficient capacity to address increased demand for disposal options. Typically, spent GAC and AIX media need to either be disposed of in a landfill, reactivated (GAC), or incinerated. Looking at the PFAS issue holistically, disposing of media simply takes the PFAS from one area and moves it to another. This is not a long-term solution for PFAS management, and Cleveland Water requests that EPA prioritize and invest in better solutions for PFAS disposal and destruction. As EPA has mentioned, PFAS are extremely persistent, therefore, moving PFAS around will only increase the stockpile of the chemical, increasing the likelihood of localized contamination events. As polluters continue to pour PFAS into the environment, there needs to be a solution to break down PFAS so communities near disposal sites are not put at risk due to the actions of polluters.

PWSs do not have capacity on site to temporarily store spent media, therefore it is crucial that there be availability for disposal or reactivation with no delay. Cleveland Water is very concerned about the ability to transport and dispose of media containing PFAS as the agency moves forward with designation PFOA and PFOS as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). If EPA takes this action, wastes of these substances would no longer be allowed to be disposed of in industrial solid waste or municipal landfills. Instead, these waste streams would have to be sent to specified hazardous waste landfills. Additionally, this media would need to be transported by individuals with the qualifications to transport hazardous waste. EPA is also in the process of soliciting comment on the possibility of designating more PFAS as CERCLA hazardous substances, further hindering the capacity for disposal space. This would increase the cost of disposal of media containing PFAS, with the financial burdens likely falling on ratepayers rather than those directly responsible for the pollution.

Any such hazardous substance designation for PFAS must be accompanied by targeted liability protections for water systems. In the case of drinking water systems that filter PFAS from their water supplies, a hazardous substance designation without liability protections would put these systems at risk after they dispose of water treatment byproducts at an appropriate landfill. Should that landfill ever be the subject of a CERCLA cleanup because of PFAS contamination, the water system could be held liable as a potentially responsible party even if it followed all legal requirements when disposing of the byproducts. EPA has discussed an "enforcement discretion" policy under which it would not pursue this type of PFAS-related CERCLA claim against water systems, but this would do nothing to prevent a polluter from undertaking a private right of action claim against a water system, to attempt to reduce its own liability exposure. The cost analysis of this rulemaking cannot be accurately calculated without taking these potential CERCLA cleanup costs into account. EPA needs to address this issue holistically, not separately by different Offices within the Agency.

EPA also requests comments on the impacts the disposal of PFAS contaminated media will have on communities adjacent to disposal communities. This is a huge environmental justice issue. EPA's proposal involves removing PFAS from communities and essentially storing and disposing of it near others, which are in many cases underserved and disadvantaged communities. EPA needs to prioritize research into better destruction techniques that do not harm historically underserved communities. Disposing of media containing PFAS near these communities compromises the agency's goal of protecting public health.

EPA Response: Please see sections 10.4.1 and 10.4.2 of the EPA response in this *Response to Comments* document. The EPA has added a qualitative discussion of the potential impacts of PFAS disposal on overburdened communities to section 8.2 of its environmental justice (EJ) analysis for the final rule, found in Chapter 8 of the EA (USEPA, 2024d). Additional disposal costs are discussed in the EA appendices. Comments on CERCLA liability are outside the scope of this SDWA rulemaking action, please see section 15.1 of the EPA response in this *Response to Comments* document for other comments outside the scope.

Association of California Water Agencies (ACWA) (Doc. #1675, SBC-044932)

COMMENT 2 – CERCLA COSTS – EPA's drinking water proposal raises CERCLA cleanup cost concerns for our members.

In this proposed rule, EPA acknowledges stakeholder concerns that a PFAS hazardous designation under CERCLA may limit drinking water treatment residuals disposal options and increase costs [FN10: 88 Fed. Reg. at 18,686.]. EPA asserts that designating certain PFAS as hazardous substances under CERCLA generally should not result in limits on disposal of PFAS drinking water treatment residuals and that treatment costs may increase "marginally." [FN11: 88 Fed. Reg. at 18,686] ACWA disagrees with the assertion that the potential cost increases under a CERCLA PFAS designation would be marginal.

The agency argues that the increase in public water systems costs "are not significant enough to change the determination that benefits of the rulemaking justify the costs." [FN12: 88 Fed. Reg. at 18,686.] Specifically, EPA determined that the annual costs would increase by $30- $61 million per year if water systems are required to dispose of PFAS treatment as hazardous waste. [FN13: 88 Fed. Reg. at 18,729.]

ACWA previously raised our CERCLA costs concerns directly with EPA and the Office of Management and Budget (OMB) and asked that financial impacts to the water and wastewater sectors be considered in its previous CERCLA proposal [FN14: Office of Information and Regulatory Affairs, View EO 12866 Meeting 2050-AH09 (Mar. 2, 2022), click here. [Link: https://www.reginfo.gov/public/do/viewEO12866Meeting?viewRule=true&rin=2050-AH09&meetingId=121873&acronym=2050-EPA/OLEM]]. ACWA also submitted extensive comments on EPA's proposal to designate PFOA and PFOS as CERCLA hazardous substances [FN15: ACWA, Designation of PFOA and PFOS as CERCLA Hazardous Substances (Nov. 7, 2022), click here. [Link: https://www.acwa.com/resources/designation-of-pfoa-and-pfos-as-cercla-hazardous-substances/]].

CERCLA is designed to remediate contaminated sites and hold parties that caused the contamination financially responsible for cleanup costs through its "polluter pays" model. ACWA strongly supports the "polluter pays" principle of CERCLA. Unfortunately, under EPA's current regulatory efforts, our members and their ratepayers will be facing a "community pays" outcome that unfairly shifts the clean-up and liability costs onto municipalities and the public they serve.

When drinking water or water reuse agencies remove PFAS from source water via filtration media, they are responsible for the disposal of these potentially PFAS-laden filter media. The media will typically be recycled or disposed of in accordance with applicable law. Should that disposal location ever become a "facility" where there is a release or threatened release of hazardous substances, the water agency could be held liable for cleanup under CERCLA and/or analogous state law due to its lawful disposal of this necessary byproduct of a vital public health

service. This outcome would force local ratepayers to cover the cleanup costs after they already paid to remove the PFAS from their source water.

As water agencies establish treatment systems for PFAS, a hazardous substance designation will increase the cost of treatment and disposing of the media and materials remaining after treatment because of the stringent disposal requirements for CERCLA hazardous substances. [FN16: U.S. Chamber of Commerce, PFOS and PFOA Private Cleanup Costs at Non-Federal Sites (Jun. 2022), click here. [Link: https://www.uschamber.com/assets/documents/PFOS-and-PFOA-Private-Cleanup-Costs-at-Superfund-Sites-6.8.22.pdf] Several ACWA members have already invested millions of dollars in capital costs as well as operation and maintenance to treat PFAS contamination.

Moreover, regulatory agencies can use MCLs as de facto CERCLA cleanup standards at PFAS contaminated sites, which could further increase costs for responsible parties [FN17: Perkins Coie, EPA Proposes Stringent National Drinking Water Standard for Six PFAS (Mar. 16, 2023), click here. [Link: https://www.perkinscoie.com/en/news-insights/epa-proposes-stringent-national-drinking-water-standards-for-six-pfas.html#10]]. Last year, the U.S. Chamber of Commerce released a study on the cost implications of a PFAS CERCLA designation. The study found that just the annual private party cleanup costs for PFOA and PFOS under CERCLA at non-federal sites are estimated to be $700-$800 million annually [FN18: U.S. Chamber of Commerce, PFOS and PFOA Private Cleanup Costs at Non-Federal Sites (Jun. 2022), click here.[Link: https://www.perkinscoie.com/en/news-insights/epa-proposes-stringent-national-drinking-water-standards-for-six-pfas.html#10]].

The Chamber of Commerce further emphasized to OMB that "the rulemaking cost estimates are expected to be much higher as private party costs at Superfund sites are just one element of the total costs borne by communities from a proposed hazardous substance designation." [FN19: U.S. Chamber of Commerce, U.S. Chamber Letter to OMB Director Young on EPA's Proposed rule, "Designating PFOA and PFOS as CERCLA Hazardous Substances" (Jun. 8, 2022), click here. [Link: https://www.uschamber.com/environment/u-s-chamber-letter-to-omb-director-young-on-epas-proposed-rule-designating-pfoa-and-pfos-as-cercla-hazardous-substances]]. Specifically, municipalities responsible for community water systems, landfills, and publicly owned treatment works would incur significant additional costs for cleanup [FN20: U.S. Chamber of Commerce, PFOS and PFOA Private Cleanup Costs at Non-Federal Sites at 3-4.].

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. Comments on CERCLA liability are outside the scope of this SDWA rulemaking action, please see section 15.1 of the EPA response in this *Response to Comments* document for other comments outside this scope.

Horsham Water & Sewer Authority (HWSA) (Doc. #1686, SBC-043817)

We also have serious concerns regarding the costs for disposal of PFAS treatment residuals. As EPA is aware, actions resulting from other environmental statutes, such as the Comprehensive

Environmental Response, Compensation, and Liability Act (CERCLA) may impact future disposal practices. While EPA has stated it is prioritizing research on PFAS disposal options, this only adds to the uncertainty of future options and costs. That future costs may well exceed EPA's current estimates is a distinct possibility. HWSA supports and concurs with the American Water Works Association's (AWWA) compliance cost analysis presented in their comments. We believe the AWWA Model, and the Case Study information presented in their comments reflect a more accurate picture of the likely costs of this rule than that presented by the EPA Model. We believe that it is important that the costs be presented accurately and believe EPA should update its Technologies and Costs for Removing Per- and Polyfluorinated Substances (PFAS) from Drinking Water document using available real world full-scale cost and treatment performance data before finalizing the rule.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. The EPA has replied to AWWA's cost compliance in the HRRCA section and refers readers to that as well as the summary of responses to major comments for this section.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045096)

f. Unknown determination on PFAS-waste and hazard distinction, associated costs; going into this not knowing future costs:

There have been discussions about exempting water treatment residuals from the various hazard determinations with respect to PFAS as it is treated more broadly. We need a clear understanding of the residuals and how they will be managed and the associated costs.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Philadelphia Water Department (PWD) (Doc. #1709, SBC-045735)

Additionally, water utilities that implement technologies to remove PFAS will have to manage PFAS-containing treatment residuals or spent treatment media. If EPA's proposal to classify PFAS as hazardous substance under the CERCLA is finalized, operating costs to manage treatment residuals will place additional financial burden on water utilities and could make finding outlets for PFAS contaminated media difficult. These impacts will be compounded should EPA follow through with their evaluation to make changes to RCRA that would designate certain PFAS compounds as a hazardous waste. As has been seen in Maine, the ban on biosolids land application due to PFAS concerns has created a crisis for utilities, with landfills increasingly refusing to take this waste, forcing sludge to be transported into Canada for ultimate disposal. If the proposed CERCLA changes become final, this will result in significant increases to the implementation time and cost of these BATs. The higher costs will ultimately be borne by the utilities and ratepayers and the increased implementation time will impact PWSs' compliance

status. EPA should include this consideration in its cost assessments and its proposed compliance timeline.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045912)

B. Costs will be compounded with potential costs of PFOA and PFOS hazardous substance designations under CERCLA

One direct, additional cost of this rulemaking establishing an MCL for the six PFAS is the cost of cleanup under CERCLA. EPA fails to consider the use of MCLs and MCLGs as cleanup standards. Section 121(d) of CERCLA requires remedial actions to meet a standard of control that "at least attains Maximum Contaminant Level Goals established under the Safe Drinking Water Act and water quality criteria established under section 304 or 303 of the Clean Water Act, where such goals or criteria are relevant and appropriate under the circumstances of the release or threatened release."[FN155: 42 U.S.C. [sec] 9621(d)(2)(A)(ii).] EPA acknowledges that MCLs are "relevant and appropriate as in situ cleanup standards where either surface water or ground water is or may be used for drinking water. When no promulgated standard exists for a given contaminant, proposed MCLs are to be given greater consideration among the to-be-considered advisories."[FN156: U.S. EPA CERCLA Compliance with Other Laws Manual at 195 (August 1988): https://nepis.epa.gov/Exe/ZyNET.exe/10001VMG.TXT?ZyActionD=ZyDocument&Client=EPA&Index=1986+Thru+1990&Docs=&Query=&Time=&EndTime=&SearchMethod=1&TocRestrict=n&Toc=&TocEntry=&QField=&QFieldYear=&QFieldMonth=&QFieldDay=&IntQFieldOp=0&ExtQFieldOp=0&XmlQuery=&File=D%3A%5Czyfiles%5CIndex%20Data%5C86thru90%5CTxt%5C00000003%5C10001VMG.txt&User=ANONYMOUS&Password=anonymous&SortMethod=h%7C-&MaximumDocuments=1&FuzzyDegree=0&ImageQuality=r75g8/r75g8/x150y150g16/i425&Display=hpfr&DefSeekPage=x&SearchBack=ZyActionL&Back=ZyActionS&BackDesc=Results%20page&MaximumPages=1&ZyEntry=1&SeekPage=x&ZyPURL#.] With a potential CERCLA designation for PFOA and PFOS, surface water-sourced systems will have to treat all grit (filtered solids from raw surface water) as containing a hazardous substance.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045908)

A. EPA does not appropriately analyze costs associated with hazardous waste disposal

EPA has publicly committed to initiating rulemaking to address PFOA, PFOS, PFBS, and GenX as RCRA hazardous constituents [FN150: See EPA response to Governor Michelle Lujan

Grisham of New Mexico's petition to identify PFAS as hazardous waste under RCRA: https://www.epa.gov/newsreleases/epa-responds-new-mexico-governor-and-acts-address-pfas-under-hazardous-waste-law.]. As EPA acknowledges, costs will be even higher if residuals from the treatment of PFAS-contaminated water must be sent to hazardous waste disposal facilities. Despite that recognition, EPA claims that it did not address these costs in its national annualized costs because such wastes "are not currently" regulated as hazardous wastes [FN151: 88 Fed. Reg. at 18701. EPA indicates that the national annualized costs do not reflect costs of hazardous waste disposal for GAC and IX media.]. EPA acknowledges, given the pending CERCLA rulemaking, solid waste facilities may refuse to accept these wastes whether or not such wastes are regulated as hazardous waste [FN152: 88 Fed. Reg. at 18688.]. In the experience of the Chamber and its coalition, this outcome is likely.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Protecting Our Water, Environment, and Ratepayers (POWER) (Doc. #1714, SBC-045932)

Although EPA discussed the cost of disposal of treatment byproduct, it has failed to adequately consider the disposal cost of this byproduct once EPA designates all six PFAS as hazardous under CERCLA and RCRA.

In the proposed NPDWR, EPA concedes that there are concerns from stakeholders regarding the designation of PFOA and PFOS as hazardous under CERCLA. [FN11: Proposed Rule, 88 Fed. Reg. at 18686.] At the same time, EPA is considering designating additional PFAS compounds as hazardous substances under CERCLA. [FN12: EPA, Addressing PFAS in the Environment, 88 Fed. Reg. 22399, 22399 (proposed April 13, 2023).] Given that other EPA actions indicate that the EPA intends to consider PFAS as a hazardous substance, the EPA should consider the costs of hazardous waste disposal for the residual media.

The designation as hazardous under CERCLA and RCRA would change the method in which byproducts are disposed. In the context of the proposed MCLs, the costs of the disposal of hazardous byproducts are not known because the technology needed to dispose of PFAS are still being developed. However, the minimum disposal requirements would require the byproducts to be disposed at hazardous waste management facilities. Hazardous waste sites (e.g. landfills) are more costly because there are strict environmental controls required, there are fewer locations to put the byproduct, and these locations are generally farther away from each agency than a typical municipal solid waste disposal site. Until the technology to dispose PFAS is identified and the EPA decides whether some or all PFAS are going to be designated as hazardous under CERCLA and RCRA, the costs of byproduct disposal cannot be fully or accurately understood.

As such, EPA's assumption that the costs would only increase marginally compared to costs for disposing byproducts that are not hazardous is misguided and inadequate. [FN13: Proposed Rule, 88 Fed. Reg. at 18688.]

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Loudoun Water (Doc. #1717, SBC-043519)

Loudoun Water uses GAC and membrane technologies in the operation of our water treatment facilities, and we are concerned about the cumulative effects of availability and cost of GAC materials and residuals management and disposal. This is especially uncertain considering EPA's proposed hazardous waste designation under CERCLA for PFOA and PFOS.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document for a discussion of residuals disposal and section 10.6 of the EPA response in this *Response to Comments* document on treatment technology availability and capacity. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045143)

Waste Disposal

MassDEP recommends that EPA prioritize research on waste disposal methods and move to regulate PFAS waste disposal as soon as possible to ensure that PFAS contamination is not being moved from one media type to another. EPA should finalize its Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances ahead of the final rule.

The current information on other environmental impacts of PFAS disposal is limited, and the Best Available Technologies (BATs) listed for complying with the Maximum Contaminant Level (MCL) have waste streams that will need to be appropriately addressed, including spent Granular Activated Carbon (GAC) media or ion exchange resin, Nanofiltration (NF) and Reverse Osmosis (RO) brine water, and spent Point of Use/Point of Entry (POU/POE) devices. Although PFAS has not yet been designated under the Comprehensive Environmental Response, Compensation, and Liability Act as a hazardous substance, some systems have already reported being unable to dispose of their PFAS-containing media as some waste disposal sites are refusing to accept the material. PFAS is only included in a limited number of NPDES permits, and so PFAS-containing reject water from NF/RO applications going to wastewater treatment facilities may not be removed, returning to source water locations. There is limited research on using underground injection control wells for NF/RO reject water. There is also limited research on thermal regeneration of GAC and the release of PFAS to the atmosphere. MassDEP strongly recommends that EPA continue to pursue research on waste disposal options for PFAS to ensure long-term mitigation. As these waste disposal options are developed and regulated, EPA should ensure that systems are able to reasonably comply with those options. Additionally, MassDEP recommends that EPA update and finalize the Agency's Interim Guidance on the Destruction and

Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances in advance of the final rule.

EPA Response: Please see sections 10.4.1 and 10.4.2 of the EPA response in this *Response to Comments* document.

Water and Wastewater Equipment Manufacturers Association (WWEMA) (Doc. #1727, SBC-043526)

[Please see our comments below.]

Comment #3: Requesting Industry Involvement in Updated Disposal Guidance

Disposal of PFAS contaminated residuals or regenerating drinking water treatment media will have significantly different costs depending on if PFAS are deemed hazardous materials under CERCLA. Since a number of PFAS treatment providers engage in this service for their clients (the utilities), direct industry involvement in the development of updated disposal guidance development, which is expected before the end of the calendar year, is absolutely critical. We ask that WWEMA and its technology leaders be a part of the process in developing updated disposal guidance .

Thank you for the opportunity to comment on the proposed rulemaking. If you have any questions, please feel free to contact me at vanessa@wwema.org or at (703) 444-1777.

Vanessa M. Leiby

Executive Director

WWEMA

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Arizona Corporation Commission (ACC) (Doc. #1735, SBC-045186)

DISPOSAL OF MEDIA RESIDUALS

The EPA's paper lacks sufficient detail regarding the disposal of PFAS saturated media or residual(s). Presently, the most effective disposal method for PFAS saturated ion exchange resins and granular activated charcoal is incineration. The ACC has been informed that proper high-temperature incineration is not currently available in Arizona. Further, there is some concern on the ACC's part that this method of disposal results in the possibility that the contaminants may become airborne and end up back in the aquifer.

There is also a lack of knowledge regarding safe disposal practices for PFAS-containing residual(s) generated during the reverse osmosis remediation process. Due to the lack of

available information, Arizona utilities considering reverse osmosis for PFAS remediation have expressed concerns about safe disposal.

The ACC urges the EPA to provide guidance on the best practices for disposing of waste produced by different remediation technologies. If proper disposal is not addressed, there is a potential for PFAS to return to the water supply or spread the contamination to additional systems.

EPA Response: Please see sections 10.1 and 10.4.2 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045983)

PWSs do not have the capacity on site to temporarily store spent media. Therefore, there must be availability for spent PFAS media disposal or reactivation with no delay. AMWA is very concerned about the ability to transport and dispose of media containing PFAS as the agency moves forward with designation of PFOA and PFOS as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). If EPA takes this action, wastes of these substances would no longer be allowed to be disposed of in industrial solid waste or municipal landfills. Instead, these waste streams would have to be sent to specified hazardous waste landfills. Additionally, this media would need to be transported by individuals and vehicles with the qualifications to transport hazardous waste. EPA is also in the process of soliciting comment on the possibility of designating more PFAS as CERCLA hazardous substances, further hindering the capacity for disposal space. This would increase the cost of disposal of media containing PFAS, with the financial burdens likely falling on ratepayers rather than those directly responsible for the pollution.

AMWA and other drinking water and wastewater organizations have consistently asserted that any such hazardous substance designation for PFAS must be accompanied by targeted liability protections for water systems. In the case of drinking water systems that filter PFAS from their water supplies, a hazardous substance designation without liability protections would put these systems at risk after they dispose of water treatment byproducts at an appropriate landfill. Should that landfill ever be the subject of a CERCLA cleanup because of PFAS contamination, the water system could be held liable as a potentially responsible party even if it followed all legal requirements when disposing of the byproducts. EPA has discussed an "enforcement discretion" policy under which it would not pursue this type of PFAS-related CERCLA claim against water systems, but this would be administration-dependent and do nothing to prevent a polluter from undertaking a private right of action claim against a water system to attempt to reduce its liability exposure. The cost analysis of this rulemaking cannot be accurately calculated without taking these potential CERCLA cleanup costs into account.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. Comments on CERCLA liability are outside the scope of this SDWA

rulemaking action, please see section 15.1 of the EPA response in this *Response to Comments* document for other comments outside the scope.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045234)

5. EPA requests comment on the availability of facilities to dispose of or regenerate drinking water treatment media that contains PFAS. EPA requests comment on whether there will be sufficient capacity to address the increased demand for disposal of drinking water treatment residuals or to regenerate media for reuse by drinking water treatment facilities.

EPA should consider the amount of PFAS generated waste from these best available treatment (BAT) methods. This could possibly overwhelm landfills. EPA should also consider the possible pending CERCLA hazardous waste designation for PFAS which would further complicate the disposal process by

a. Increasing disposal costs,

b. Limiting the number of landfills which can accept PFAS waste unless specific CERCLA exemption is given, and

c. Limiting the reactivation and reuse of GAC

As a relatively small and intensively developed state with limited capacity for disposal, Connecticut currently faces significant waste management challenges. This is especially true of hazardous waste. Consequently, costs incurred for the safe management of used PFAS drinking water remediation media will be considerable as most if not all such waste will need to be exported out of state for proper disposal.

Reactivation of GAC treatment media also presents concerns as thermal temperatures must be high enough to achieve PFAS degradation. Improper reactivation of GAC could lead to the dispersal of PFAS contamination through the air emissions from reactivation facilities.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. Comments on CERCLA liability are outside the scope of this SDWA rulemaking action, please see section 15.1 of the EPA response in this *Response to Comments* document for other comments outside the scope.

City of Thornton, Colorado (Doc. #1748, SBC-044788)

Thornton suggests that the EPA prioritizes the regeneration of treatment media, assist in providing infrastructure and transportation options to ensure sustainability of resources, and provide exemption from CERCLA and RCRA rules for WTP utilities as these could lead to additional costs that are not captured in the EPA's analysis.

EPA Response: Please see sections 10.4.1 and 10.4.2 of the EPA response in this *Response to Comments* document. Comments on CERCLA liability are outside the scope of this

SDWA rulemaking action, please see section 15.1 of the EPA response in this *Response to Comments* document for other comments outside the scope.

Arizona Water Company (Doc. #1758, SBC-044538)

Handling waste from PFAS removal facilities results in considerable O&M costs. The Company is anticipating using IX to remove PFAS from drinking water due to a combination of cost and PFAS removal capability. The only allowable disposal methods for PFAS-impregnated IX media are landfill disposal or high-temperature incineration. The Company recommends the EPA provide clarification on whether spent media will be considered hazardous waste due to the presence of PFAS. The Company anticipates that a considerable portion of O&M costs for PFAS treatment will be the additional expenses of handling and disposing of PFAS-impregnated removal media according to hazardous materials standards. The Company recommends that the EPA assist water utilities with funding to offset the costs of hazardous waste disposal and provide standards to dispose of hazardous waste extracted during PFAS removal.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. Information on funding is provided in section 2.4 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-046157)

A major challenge to implementing centralized NF/RO treatment for PFAS removal is in dealing with the concentrated waste stream generated by the treatment process. Contaminants are rejected into a waste brine stream that is typically around 15 percent by volume of the feedwater (for low salinity feed waters) and 4 to 7 times more concentrated than the raw water fed to the membranes. As a result, additional raw water is required to achieve the desired finished water capacity, and the waste stream requires disposal. Traditional alternatives for disposal include sending the stream to a downstream water reclamation facility, discharging to surface water, or injection into underground deep wells.

However, because of the CERCLA regulations for PFOA and PFOS as discussed in Subsection 3.1.1 and pending effluent limit goals for PFAS, concentrate treatment may be required before disposal using these methods.

EPA Response: Please see sections 10.1 and 10.4.2 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045617)

Shifting Landscape of Residual Management Practices

During the stakeholder engagement in advance of publishing the proposal, EPA was encouraged to consider the impacts of new regulatory actions that would impact disposal of GAC, IX, and

RO waste streams with PFAS. In September 2022, EPA proposed to designate PFOA and PFOS as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA); a broader action was proposed for additional PFAS in April 2023 (EPA, 2022i; EPA, 2023h). Separately, EPA is also preparing to list PFOA, PFOS, PFBS, and HFPO-DA as hazardous constituents (EPA, 2022c).

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-046151)

Exhausted GAC filter media will be saturated with PFAS. Bulk GAC can be reactivated by the media supplier through thermal treatment at high temperatures (up to 1800 [deg] F) to remove and destroy adsorbed contaminants (Rebecca DiStefano, 2022). This reactivation process restores the media's adsorptive capacity, allowing the media to be returned for reuse. GAC is sometimes regenerated by heating the media to temperatures typically less than 400 [deg] F to remove a portion of the adsorbed contaminants. However, this process will not remove all the compounds and will not destroy the PFAS compounds; therefore, it is not appropriate for GAC utilized for PFAS removal. Media suppliers may not accept the low volumes of GAC required by small systems for reactivation, forcing them to dispose of spent GAC and replace it with new (virgin) material.

Disposal alternatives for exhausted GAC that will not be reactivated for municipal reuse include disposal by reactivation for industrial reuse, incineration, and landfilling. The cost of each disposal method depends on proximity to disposal sites, hazardous waste classification, and volume of material. Disposal costs can be a significant operational cost for GAC treatment systems.

The EPA proposed to designate PFOS and PFOA as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) in August of 2022. This designation is expected to limit the disposal sites willing to accept spent GAC media. Additionally, the practice of reactivating GAC media contaminated with PFAS is expected to be more limited in drinking water applications.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

California-Nevada Section American Water Works Association (CA-NV AWWA) (Doc. #1775, SBC-045276)

EPA has also not adequately considered in its economic feasibility assessment the difficulty and the ensuing high cost for compliance that community water systems will encounter to manage and dispose of PFAS-containing treatment residuals. Many letters and public testimony raise a concern, recognized by EPA, that designating PFOA and PFOS as hazardous substances under

CERCLA will restrict the facilities willing to accept wastes from water treatment. When options are limited or even nonexistent, the cost to water systems for disposal will be high. If landfill disposal becomes impossible, the only option would be destruction of the PFAS contaminants.

However, the feasibility and cost of incineration or thermal treatment of spent treatment media is questionable. These restrictions, costs, and uncertainties must be factored into a better economic feasibility assessment.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Metropolitan Water District of Southern California (Doc. #1777, SBC-045436)

5. EPA should fully consider the economic impacts and feasibility of the proposed regulations

Under section 1412(b)(4)(B) of the SDWA, EPA must generally establish an enforceable MCL as close to the MCLG as feasible, considering costs. EPA acknowledges in this NPDWR Rulemaking: "Stakeholders have expressed concern to EPA that a hazardous substance designation for certain PFAS may limit their disposal options for drinking water treatment residuals (e.g., spent media, concentrated waste streams) and/or potentially increase costs."[FN20: 88 Fed. Reg. at 18686.] Thus, EPA has specifically requested comment on "the availability of facilities to dispose of or regenerate drinking water treatment media that contains PFAS" and "whether there will be sufficient capacity to address the increased demand for disposal of drinking water treatment residuals or to regenerate media for reuse by drinking water treatment facilities."[FN21: 88 Fed. Reg. at 18731.] If landfills refuse to accept treatment residuals containing PFAS due to concerns regarding potential liability under CERCLA or analogous state laws, disposal of treatment residuals is no longer realistic, directly affecting the feasibility analysis.

Also, Metropolitan has significant concerns regarding the feasibility and cost of incineration as a disposal option for the Best Available Technologies. EPA proposes anion exchange (AIX) and Granular Activated Carbon (GAC) as the Best Available Technology to treat PFAS-contaminated water. [FN22: 88 Fed. Reg. at 18684.] Both treatment technologies result in residuals that must be destroyed or disposed. [FN23: 88 Fed. Reg. at 18686.] For AIX, once a contaminant breaks through the resin, EPA recognizes that the exhausted resin must also be disposed. [FN24: 88 Fed. Reg. at 18686.] Typically, spent IX resin is incinerated. [FN25: 88 Fed. Reg. at 18688.] Similarly, facilities reactivate spent GAC through thermal treatment. [FN26: EPA, Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances (Dec. 2020) (Interim Guidance) at pp. 36-37.] However, there are several issues with incineration. For example, the Department of Defense has placed a temporary ban on the incineration of PFAS;[FN27: Memorandum from Assistant Secretary of Defense for Energy, Installations, and Environment Paul Cramer to Assistant Secretary of the Army, Assistant Secretary of the Navy, Assistant Secretary of the Air Force, and Director, Defense Logistics Agency (2022).] Illinois

enacted a ban on the incineration of PFAS;[FN28: H.B. 4818, 102d Gen. Assemb., (Ill. 2022).] and EPA itself has raised concerns over the uncertainties associated with incineration. [FN29: EPA, Technical Support Document - Technologies and Cost for Removing Per- and Polyfluoroalkyl Substances (PFAS) from Drinking Water, at pp. 18-19, 39 (Feb. 2023)] Also, restricting or banning PFAS waste incineration and thermal treatment methods would further raise the cost of Superfund site cleanup and affect EPA's economic feasibility analysis. An assessment by the U.S. Chamber of Commerce shows that prohibiting thermal treatment of PFAS contaminated soil would raise costs at a single National Priorities List (NPL) site by up to $1 million and that approximately 25% of the existing NPL sites would find onsite incineration more cost effective than disposal at a Subtitle C landfill. [FN30: U.S. Chamber of Commerce, PFOS and PFOA Private Cleanup Costs at Non-Federal Sites (June 2022) ("Chamber Study") at p. 10, available at PFOS-and-PFOA-Private-Cleanup-Costs-at-Superfund-Sites-6.8.22.pdf (uschamber.com).]

Due to these uncertainties, EPA's interim guidance manual recommends interim storage over incineration. [FN31: EPA, Interim Guidance, at p. 5.] However, this recommendation conflicts with EPA's acknowledgement in the proposed rule that "large volumes of spent GAC and ion exchange resin must be removed which does not lend itself to on-site storage over time."[FN32: 88 Fed. Reg. at 18686.] Thus, EPA should reconsider its economic feasibility analysis in light of these issues and this additional information. EPA should specifically consider the economic feasibility of and provide guidance for media disposal.

Lastly, Metropolitan is concerned that EPA's proposal to designate certain PFAS as CERCLA hazardous substances will substantially increase treatment and disposal costs incurred by water and wastewater utilities[FN33: On September 6, 2022, EPA proposed designating PFOA and PFOS as CERCLA hazardous substances. (87 Fed. Reg. 54415 (Sept. 6, 2022).) More recently, on April 13, 2023, EPA requested input and data regarding potentially designating in the future seven other PFAS and their salts and structural isomers; precursors to PFOA, PFOS, and the seven other PFAS; and/or categories of PFAS as CERCLA hazardous substances. (88 Fed. Reg. 22399 (Apr. 13, 2023).)] and lawsuits against water and wastewater systems. [FN34: Under CERCLA's strict, joint and several, and retroactive liability scheme, water systems that dispose of water treatment residuals with any concentration of PFOA and PFOS may be required to clean up all the contamination from the disposal site if no other viable PRP is identified. Additionally, water and wastewater agencies may be sued by other PRPs to recover at least some, if not all, of the costs for cleanup. So many PFAS contamination lawsuits have already been filed (more than 2,500 cases) that these cases have been consolidated in a nationwide multidistrict litigation (MDL) in a South Carolina federal district court. In re: Aqueous Film-Forming Foams Products Liability Litigation, MDL No. 2873.] In prior comments on EPA's proposal to designate PFOA and PFOS as CERCLA hazardous substances, Metropolitan explained that potentially responsible parties may be compelled to compensate the oversight agency and/or other parties for costs incurred in responding to any release or threatened release of CERCLA hazardous substances. [FN35: Metropolitan, Designation of PFOA and PFOS as CERCLA Hazardous Substances (Nov. 7, 2022) [See attached]]

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046132)

11. EPA provides a supplemental, illustrative analysis of the costs of compliance with the proposed NPDWS if spent filtration materials were regulated as hazardous waste, but to be fully objective, this illustrative analysis should also demonstrate the benefits of such an action.

As noted in comment #3 in the above section, in the main analysis EPA correctly excludes any incremental increase in PWS disposal costs that are specific to hazardous materials. The Agency does, however, provide an illustrative analysis of the disposal costs if PFAS were regulated as a hazardous material.

In my professional opinion, it is misleading to present this illustrative exercise for just the costs, without also discussing the benefits. To be fully transparent and balanced, it would be informative to provide a companion illustrative analysis of the corresponding environmental and health benefits that would result from treating spent filtration materials as a hazardous waste.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

West Virginia Municipal Water Quality Association (Doc. #1816, SBC-044674)

Also, EPA fails to distinguish between non-destructive technologies and destructive technologies, whose development has been on different trajectories. Non-destructive technologies such as granular activated carbon (GAC) and reverse osmosis (RO) may not be feasible depending on how EPA regulates residuals (such as concentrated RO brine). Notably, EPA has currently proposed listing PFOA and PFOS hazardous substances under the federal Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). EPA details how it included a potential hazardous designation in its calculation:

EPA assessed the potential impact on PWS treatment costs associated with hazardous residual management requirements in a sensitivity analysis on the proposed option. Relative to the national analysis for the proposed option assuming nonhazardous disposal, the hazardous waste disposal assumption would increase PWS costs by 4% ($30 million annually) at the 3% discount rate and 5% ($61 million annually) at the 7% discount rate should spent media need to be disposed of as hazardous waste in the future because of separate EPA or State regulatory action. EPA's sensitivity analysis demonstrates that potential hazardous waste disposal requirements may increase PWS treatment costs marginally, however the increase in PWS costs are not significant enough to change the determination that benefits of the rulemaking justify the costs.

88 Fed. Reg. at 18686.

We think this is completely incorrect. In general, asserting that the disposal cost of a hazardous waste versus non-hazardous waste is only 4-5% higher defied common experience and logic. Such an estimate is shockingly optimistic. EPA has no basis for this hypothetical assumption. Moreover, EPA understates the volumes of spent GAC material that will have to be addressed nationally. Our members have seen reuse/disposal vendors abandon prior offers to manage these wastes and those who remain willing to accept such wastes are doing so at much higher rates than they indicated to our members just a few years ago.

A PFAS CERCLA designation will surely have a significant increase in reuse/disposal costs. We have previously shared with EPA that such a CERCLA designation for PFOA/PFOS will in fact likely prevent the regeneration of granulated activated carbon media used by water treatment facilities and others to reduce PFAS levels in finished drinking water and other media. It would also create numerous difficulties for addressing RO brine. Additionally, if there are limits on spent carbon regeneration, it will also greatly impact the prices and availability of virgin carbon. Has EPA considered this effect?

EPA must revisit its clearly erroneous conclusion that a hazardous waste designation for PFOA/PFOS will have only a 4-5 percent increase in PFAS reuse/disposal costs. That conclusion seems illogical to us. EPA should clarify the basis for its $30-61M additional annual cost impact if PFOA/PFOS are designated as hazardous wastes. Across 3,000 water systems, that would be just an additional $30,000 per system per year – an amount that seems impossibly small to dispose of significant quantities of hazardous waste from these 24/7 utility operations.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. For comments and additional information related to the EPA's cost analysis, please see section 13 of the EPA response in this *Response to Comments* document.

Association of Missouri Cleanwater Agencies (Doc. #1817, SBC-044652)

Also, EPA fails to distinguish between non-destructive technologies and destructive technologies, whose development has been on different trajectories. Non-destructive technologies such as granular activated carbon (GAC) and reverse osmosis (RO) may not be feasible depending on how EPA regulates residuals (such as concentrated RO brine). Notably, EPA has currently proposed listing PFOA and PFOS hazardous substances under the federal Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). EPA details how it included a potential hazardous designation in its calculation:

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may increase PWS treatment costs marginally, however the increase in PWS costs are not significant enough to change the determination that benefits of the rulemaking justify the costs.

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EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

NORTH CAROLINA WATER QUALITY ASSOCIATION (Doc. #1818, SBC-044630)

Also, EPA fails to distinguish between non-destructive technologies and destructive technologies, whose development has been on different trajectories. Non-destructive technologies such as granular activated carbon (GAC) and reverse osmosis (RO) may not be feasible depending on how EPA regulates residuals (such as concentrated RO brine). Notably, EPA has currently proposed listing PFOA and PFOS hazardous substances under the federal Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). EPA details how it included a potential hazardous designation in its calculation:

EPA assessed the potential impact on PWS treatment costs associated with hazardous residual management requirements in a sensitivity analysis on the proposed option. Relative to the national analysis for the proposed option assuming nonhazardous disposal, the hazardous waste disposal assumption would increase PWS costs by 4% ($30 million annually) at the 3% discount

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88 Fed. Reg. at 18686.

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EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

South Carolina Water Quality Association (Doc. #1819, SBC-044608)

Also, EPA fails to distinguish between non-destructive technologies and destructive technologies, whose development has been on different trajectories. Non-destructive technologies such as granular activated carbon (GAC) and reverse osmosis (RO) may not be feasible depending on how EPA regulates residuals (such as concentrated RO brine). Notably, EPA has currently proposed listing PFOA and PFOS hazardous substances under the federal Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). EPA details how it included a potential hazardous designation in its calculation:

EPA assessed the potential impact on PWS treatment costs associated with hazardous residual management requirements in a sensitivity analysis on the proposed option. Relative to the national analysis for the proposed option assuming nonhazardous disposal, the hazardous waste disposal assumption would increase PWS costs by 4% ($30 million annually) at the 3% discount rate and 5% ($61 million annually) at the 7% discount rate should spent media need to be disposed of as hazardous waste in the future because of separate EPA or State regulatory action. EPA's sensitivity analysis demonstrates that potential hazardous waste disposal requirements may increase PWS treatment costs marginally, however the increase in PWS costs are not significant enough to change the determination that benefits of the rulemaking justify the costs.

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EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Wet Weather Partnership (Doc. #1820, SBC-044586)

Also, EPA fails to distinguish between non-destructive technologies and destructive technologies, whose development has been on different trajectories. Non-destructive technologies such as granular activated carbon (GAC) and reverse osmosis (RO) may not be feasible depending on how EPA regulates residuals (such as concentrated RO brine). Notably,

EPA has currently proposed listing PFOA and PFOS hazardous substances under the federal Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). EPA details how it included a potential hazardous designation in its calculation:

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EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Mississippi Farm Bureau Federation (Doc. #1826, SBC-044270)

MFBF is also concerned that this proposed rule has come forward before EPA has published a Final Rule on labeling PFAS as a hazardous substance under CERCLA. Before any testing program moves forward, our farmers need assurances that they will not be considered potentially responsible parties for the land application of solid waste found to contain PFAS.

Sincerely,

Andy Whittington, Environmental Programs Coordinator

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. Comments on CERCLA liability are outside the scope of this SDWA rulemaking action, please see section 15.1 of the EPA response in this *Response to Comments* document for other comments outside the scope.

Corix Infrastructure Inc. (Doc. #1834, SBC-045373)

[With regards to the specific items EPA has requested comment on, Corix provides below:]

• With regards to the request for comment on the disposal of treatment residual or media, we reiterate our comment above that the testing method of disposal media has not been completed. Many of the PFAS testing methods are still being developed, including for solid waste. This poses an almost insurmountable logistical issue for all drinking water systems. In addition, this raises the significant issue of potential liability to drinking water systems for the impact of the final disposition of the media used. Corix strongly implores EPA to determine the testing method and finalize a CERCLA exemption for drinking water systems before finalizing the rule to ensure additional liability and expense is not incurred by the public and ratepayers.

Conclusion

Corix appreciates EPA's efforts to protect public health and the environment from the harmful PFAS chemicals that pose a risk to many. We support EPA's efforts to better understand PFAS sources, take measured and practical approaches in gathering data and assessing the risks of PFAS to public health and the environment and urge EPA to consider these comments to ensure that the agency produces a rule that is protective, feasible and affordable.

Sincerely,

Kendra Rose

Director, Health, Safety & Environment

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. The six PFAS in this rule have testing methods available. The EPA refers commenter to the *Interim PFAS Destruction and Disposal Guidance* document and section 7 of the EPA response in this *Response to Comments* document.

New England Water Works Association (Doc. #1836, SBC-045394)

Liability Concerns:

Disposal concerns are currently centered around pending updates to the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) on regulating PFOA and PFOS as hazardous substances, which may impact the available media disposal methods such as landfilling. EPA's current proposal includes setting the default reportable quantity (RQ) at 1.0 pound in a 24-hour period for PFOA and PFOS, and any release at or above RQ must be reported. Granular activated carbon (GAC), anion exchange (AIX) and novel adsorbents all would concentrate PFAS on the media. Disposal considerations are currently most important for anion exchange or novel adsorbents as, at this time, major GAC manufacturers offer reactivation services that indicate thermal destruction of PFAS while no resin or novel adsorbent manufacturers offer regeneration services presently. With the ongoing CERCLA update efforts, once PFOA and PFOS are designated as hazardous substances, it will limit the disposal options and sites willing to accept spent media such as resin and novel adsorbents. This will certainly drive the cost of spent media even higher, with those costs again landing unfairly upon the PWS and its ratepayers. The draft CERCLA proposal still needs to be finalized, and no industry exemptions have been included for water and wastewater systems. Even though GAC manufacturers provide reactivation, there is indication that regenerated GAC does not fully remove PFAS. With this knowledge, there is a possibility that only virgin media would be permitted for use in PFAS removal systems, not regenerated GAC. The concerns with disposal of PFAS-containing media stresses the need for significant focus on advancing destruction technologies.

NEWWA, and the other New England state water associations made comments on dockets EPA-HQ-OLEM- 2019-0341 and EPA-HQ-OLEM-2022-0922-0001 dealing with regulating PFAS under CERCLA. EPA should not move forward with any proposed CERCLA designation until exemptions are granted to water utilities who are passive receivers of PFAS substances. We understand that EPA is separately considering a CERCLA enforcement discretion policy to make it clear that EPA may choose not to take CERCLA enforcement actions against certain entities, but we believe the exemption for water utilities and publicly owned treatment works should be embedded in the regulation. Policies are subject to interpretation and change, whereas regulations have a specified public process. We are therefore requesting that in whatever CERCLA rulemaking EPA moves forward with, EPA provide PWS with an exemption from liability if any or all PFAS compounds are designated as hazardous substances under CERLCA. Doing so would keep CERCLA liability on the industries that created the pollution and/or utilized the substances in the first place.

EPA Response: Please see sections 10.4.2 and 10.1 of the EPA response in this *Response to Comments* document. Comments on CERCLA liability are outside the scope of this SDWA rulemaking action, please see section 15.1 of the EPA response in this *Response to Comments* document for other comments outside the scope.

Citizens Energy Group (Doc. #1838, SBC-044871)

Cost of Managing Process Byproducts as Solid Wastes

One additional aspect of this rule that Citizens would like to highlight is the assumption made by EPA regarding the costs of managing treatment plant process byproducts under the solid waste regulatory framework in the future. While EPA has not solicited specific comment on this area, Citizens believes that it is appropriate to offer this comment considering EPA's discussion in the preamble to the proposed rule.

There is a discussion at 88 Fed. Reg. 18686 that starts, "Stakeholders have expressed concern to EPA that a hazardous substance designation for certain PFAS may limit their disposal options for drinking water treatment residuals…." Later in the paragraph, EPA offers that "[a]lthough EPA anticipates that designation chemicals as hazardous substances under CERCLA should not result in limits on for (sic) disposal of PFAS drinking water treatment residuals, EPA has estimated the treatment costs for systems both with the use of hazardous waste disposal and non-hazardous disposal options to assess the effects of potentially increased disposal costs."

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Citizens Energy Group (Doc. #1838, SBC-044872)

In late 2021, EPA granted (in part) a petition from the State of New Mexico to list certain PFAS compounds as hazardous waste constituents under RCRA. So, regardless of whether the CERCLA designation as a hazardous substance moves forward, the agency has already indicated its intent to undertake rulemaking under RCRA that (absent a specific carve out exemption for water and wastewater utilities) would have an impact on the management of process byproducts generated. Indeed, on 88 Fed. Reg. 18688, EPA acknowledges that there is a rulemaking proposal is in queue to designate PFAS as a hazardous constituent under RCRA.

Why does this matter? EPA's cost estimates vastly underestimate the impact on water systems in a "regulated under RCRA" future. Here is an example that illustrates that.

Citizens completed a project in its utility system where the materials removed had to be managed under RCRA as a hazardous waste because the constituents in the material were listed (not because the waste was characteristic). The materials were managed at a Subtitle C landfill facility in Michigan – Citizens' cost of disposal was $320 per ton plus transportation to the facility. On the other hand, Citizens has a project that generated materials that were managed as a non-hazardous waste at a local Subtitle D landfill. Citizens paid $350 for the triaxle load of residuals (somewhere in the 6-8 ton range per triaxle load). Summarized concisely: disposal as a RCRA hazardous waste is almost 10x the cost of managing as a non-hazardous waste.

In the economic impact analysis that goes with the rule, EPA has the following table that suggests the annualized costs to a PWS will increase is only about 5% under the RCRA

hazardous waste scenario. Because the RCRA listing is in the future (probably farther out than the applicability of the MCLs), water systems and their customers won't experience the impacts until this economic impact analysis is long forgotten – it will just come as another stressor on O&M expenses that results in rate increases to the customer.

[Table 1: See Docket ID EPA-HQ-OW-2022-0114-1838]

Citizens requests that as EPA considers a path forward for managing PFAS under the RCRA program that it remains mindful of the affordability impacts of its regulations and ultimately, "who pays". Specifically, Citizens requests that EPA ensure that residuals and byproducts from water systems are exempted from classification as a hazardous waste under RCRA to avoid a shift of the expenses associated with managing PFAS in the environment to utility customers through higher costs of disposal.

Conclusion

Citizens appreciates the opportunity to offer these comments on the proposed rule and stands ready to assist EPA as may be appropriate. Please do not hesitate to contact me via e-mail at amciver@citizensenergygroup.com or by telephone at (317) 927-4393 should you have questions or need additional information.

Sincerely,

Ann W. McIver, QEP

Director, Environmental Stewardship

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. The EPA thanks commenter for providing data on waste disposal.

North American Meat Institute (Doc. #1839, SBC-047720)

An additional likely burden of meeting these extremely low levels will relate to disposal of treatment residuals. EPA states that the Agency has evaluatesd options and developed interim guidance for the destruction and disposal of PFAS and PFAS-containing materials from some products, including spent drinking water treatment media. However, there are open questions as to whether the media might be considered a hazardous substance and the implications that could have under other environmental statutes such as CERCLA. Against this looming complication, EPA has stated that it is "prioritizing research on PFAS disposal options in different environmental media and best management practices." This lack of a clear path forward introduces uncertainty for all stakeholders.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-044842)

The baseline assumption in EPA's economic analysis is that the residuals and spent media from the water treatment systems (i.e., spent GAC, IX resins, and waste streams from RO and nanofiltration) will be disposed of as nonhazardous wastes. Although the Agency estimates increased annual costs of the MCL proposal of $30 to $61 million in light of the Agency's proposal to designate PFOA and PFOS as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), [FN170: 88 Fed. Reg. 18686] this estimates likely understates the impact of CERCLA designation considerably, in light of the following considerations –

• Current uncertainty over the acceptable approaches to dispose of materials contaminated with PFOA and PFOS resulting from the Agency's 2000 Interim Guidance has resulted in considerable confusion – resulting in a reduction of disposal options and increased costs,

• The costs associated with hazardous waste management are often an order of magnitude more than non-hazardous waste management. It is not clear whether EPA's sensitivity analysis as presented in the economic analysis reflects this level of increase, and

• EPA estimate does noy consider the increase in costs to dispose of waste streams from RO and nanofiltration systems if they must be managed as hazardous waste.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Washington Association of Sewer and Water Districts (Doc. #1842, SBC-044773)

Recognizing Need for CERCLA Exemption

Water utilities are mandated to implement PFAS treatment/removal under the rule, while not the responsible party for the contamination. For this reason, EPA should acknowledge that spent treatment media will become a byproduct of the proposed rule and advocate for agencies mandated to treat for PFAS removal to be exempt from Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). As safe drinking water agencies, our member utilities recognize the importance of this public health issue. But since it is not caused by the utilities, they should not be liable under CERCLA for any byproducts of the treatment. EPA needs to support utilities in their effort to obtain this exemption.

We appreciate your consideration of our comments along with those of our members, Lakewood Water District and Sammamish Plateau Water, who have on the ground experience with PFAS contamination and cleanup of their drinking water sources.

Sincerely,

Judi Gladstone Executive Director

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. Comments on CERCLA liability are outside the scope of this SDWA rulemaking action, please see section 15.1 of the EPA response in this *Response to Comments* document for other comments outside the scope.

Amigos Bravos (Doc. #1844, SBC-045400)

Amigos Bravos also supports the EPA's proposal to require public water systems to dispose of treatment residuals that contain any combination of PFHxS, PFNA, PFBS, and GenX Chemicals that meet or exceed the Hazard Index, at the local level, under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).

EPA Response: Please see sections 10.4.1 and 10.4.2 of the EPA response in this *Response to Comments* document.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044050)

30. EPA requests comment on the availability of facilities to dispose of or regenerate drinking water treatment media that contains PFAS. EPA requests comment on whether there will be sufficient capacity to address the increased demand for disposal of drinking water treatment residuals or to regenerate media for reuse by drinking water treatment facilities.

a. CWUC is concerned there will not be enough disposal/regeneration sites in the state to support the increase in GAC use/disposal required to meet this proposed rule. At this time, CWUC front-range members are only aware of one regeneration site in the Denver metro area that can take PFAS-containing treatment residuals. Regeneration of materials may not be a desirable method for drinking water facilities.

EPA Response: Please see sections 10.4.2 and 10.6 of the EPA response in this *Response to Comments* document.

American Farm Bureau Federation et al. (Doc. #1642, SBC-043498)

Responsible parties lack places to send contaminated materials for appropriate management and disposal.

[Table 1: See Docket ID EPA-HQ-OW-2022-0114-1642]

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Massachusetts Water Resources Authority (Doc. #1645, SBC-043289)

f. Summary

EPA's proposed PFAS NPDWR will result in thousands of PWSs across the country needing to install treatment. This treatment will come at a significant cost to their ratepayers, create a significant demand on treatment resources required to remove PFAS from water, likely resulting in an overall increase in the cost of these treatment products for all users; and, will result in increased demands for disposal of spent filters/media, creating an unsustainable burden on landfills and incineration facilities nationwide.

EPA Response: Please see sections 10.4.2 and 10.6 of the EPA response in this *Response to Comments* document.

Savannah River Nuclear Solutions LLC (Doc. #1647, SBC-043339)

Further, has EPA determined that sufficient landfill capacity (whether Subtitle D solid waste landfills, or Subtitle C hazardous waste landfills) exists for the potential disposal of large volumes of spent GAC as well as spent IX resins? Land disposal was specifically identified as a management option for these residuals which do not lend themselves to long-term storage or thermal treatment in EPA's 2020 Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances and it does not appear that landfill capacity was evaluated in any of the proposed rule support documents.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044429)

EPA requests comments on the availability of facilities to dispose of or regenerate drinking water treatment media that contains PFAS. EPA requests comment on whether there will be sufficient capacity to address the increased demand for disposal of drinking water treatment residuals or to regenerate media for reuse by drinking water treatment facilities.

• This response was prepared by the Washington State Department of Ecology. Currently, waste disposal facilities are not engineered to manage PFAS waste streams. There are questions around how effective and appropriate disposal methods are in either destroying PFAS or storing it indefinitely in a landfill. Although most landfills take this waste currently (e.g., there are a lot of available landfills to send this waste too), that is only because it is not regulated.

• This response was prepared by the Washington State Department of Ecology. Washington State Department of Ecology is currently developing an EIS to research and determine the least impactful disposal method. A draft EIS is due later the summer of 2023.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Aurora Water, City of Aurora, Colorado (Doc. #1669, SBC-043722)

Additionally, Aurora Water is concerned with the availability of disposal or regeneration sites. Currently, there is only one regeneration facility in our area, and we expect that they will be overwhelmed with utilities requiring materials to be regenerated. Additional costs could be incurred due to potential construction of new regeneration facilities or additional disposal sites.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045121)

8) EPA requests comment on the estimates for disposing of drinking water treatment residuals or regenerating drinking water treatment media including assumptions related to the transport distance to disposal sites and other costs that arise out of disposal of PFAS contaminated drinking water treatment residuals.

Costs may rise as a result of this change, as more Water Systems will be looking to dispose of spent GAC and some disposal facilities will have limited capacity to take PFAS-heavy filter media. The likelihood is that certain states with the capacity to accept this waste will become targets of public scrutiny and be seen as taking "other states' waste" which could limit small states like Vermont, with only a single in-state landfill, from being able to responsibly dispose of the media.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045122)

9) EPA requests comment on the availability of facilities to dispose of or regenerate drinking water treatment media that contains PFAS. EPA requests comment on whether there will be sufficient capacity to address the increased demand for disposal of drinking water treatment residuals or to regenerate media for reuse by drinking water treatment facilities.

As stated in previous comments, availability is limited, some wastewater facilities will not accept PFAS in backwash disposal if another solution exists.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045910)

Landfills will likely require dewatering or containerization to accept the material and already strained capacity at waste incinerators capable of destroying PFAS will be further reduced. Further, EPA fails to address landfill capacity limitation. EPA must clarify how it expects thousands of water systems to properly dispose of PFAS waste and the costs for disposal. EPA also needs to finalize its PFAS disposal guidance before it can reasonably complete a cost analysis [FN153: In fact, the Interim Disposal Guidance demonstrates that hazardous waste management costs are an order of magnitude greater than non-hazardous waste management costs. See EPA Interim Guidance on Destroying and Disposing of Certain PFAS and PFAS-Containing Materials that Are Not Consumer Products at 56 Tables 3-1 and 3-2 (December 18, 2020): https://www.epa.gov/pfas/interim-guidance-destroying-and-disposing-certain-pfas-and-pfas-containing-materials-are-not.].

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Loudoun Water (Doc. #1717, SBC-043520)

Loudoun Water expects that the availability and feasibility of such disposal and the associated costs will be significantly worse than assumed in the proposal, and that the expanded need for these services will significantly increase the operational costs of current water and wastewater treatment facilities that are not otherwise affected by this rule.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045982)

Section 7.4: Disposal and reactivation

EPA requests comment on the availability of facilities to dispose of or reactivate drinking water treatment media containing PFAS. Specifically, EPA seeks comment on whether there is sufficient capacity to address the increased demand for disposal options. Typically, spent GAC and AIX media need to either be disposed of in a landfill, reactivated (for GAC only), or incinerated. Looking at the PFAS issue holistically, disposing of media simply takes the PFAS from one area and moves it to another. This is not a long-term solution for PFAS management, and AMWA requests that EPA prioritize and invest in better solutions for PFAS disposal and destruction. As EPA has mentioned, PFAS are extremely persistent; therefore, moving PFAS around will only increase the stockpile of the chemical, increasing the likelihood of localized contamination events. As polluters continue to release PFAS into the environment, there needs to be a solution to safely eliminate it to ensure that communities near disposal sites are not put at risk due to the actions of polluters.

EPA Response: Please see sections 10.4.1 and 10.4.2 of the EPA response in this *Response to Comments* document.

LSP Association (LSPA) (Doc. #1742, SBC-043607)

Public and private sector organizations in Massachusetts are experiencing a severe remediation waste disposal capacity crisis for all contaminants, not just PFAS. No new landfills are currently in the planning stages in Massachusetts, the hurdle of local municipal approval is daunting, and facility siting is a highly sensitive public issue. All of these factors would make it exceedingly difficult and expensive to find the additional capacity needed for disposal of the high volume of spent treatment media that would be generated by the proposed regulations. Again, the LSPA concurs with the challenges as presented in the MWWA May 26, 2023 comment letter (pp. 13-14).

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. The EPA notes that commenter's assessment contradicts the National Capacity Assessment Reports required under CERCLA Section 104(c)(9), which indicates that Massachusetts has existing capacity though at least the next 20-year period.

Las Cruces Utilities (LCU) (Doc. #1753, SBC-043917)

In response to Section XI-Treatment Technologies, EPA requests comment on the availability of facilities to dispose of or regenerate drinking water treatment media that contains PFAS. EPA requests comment on whether there will be sufficient capacity to address the increased demand for disposal of drinking water treatment residuals or to regenerate media for reuse by drinking water treatment facilities.

• If the media will be categorized as hazardous waste, there are only a few facilities in the U.S. that would accept it. Transportation costs to deliver this material would be significant.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

PFAS Regulatory Coalition (Doc. #1761, SBC-046085)

e) Did EPA consider landfill capacity in its costs of waste disposal? There is going to be greater demand for PFAS disposal options. Treatment media is only one aspect, but our members also have to deal with impacted biosolids, soils, and construction debris. As has been recently experienced in Maine with biosolids, landfill capacities are stressed – which of course affects costs. EPA should include these factors in its analysis.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Western Urban Water Coalition (WUWC) (Doc. #1768, SBC-043946)

Last, to the extent that the Proposed Rule assumes incineration is an available disposal option, EPA has failed to account for significant risk of legal infeasibility. The U.S. Department of Defense has placed a temporary ban on the incineration of PFAS. [FN18: Off. of the Assistant Sec'y of Def. for Energy, Installations, and Env't, Department of Defense Incineration Moratorium Report to Congress (Feb. 2023).] The state of Illinois has also enacted an outright ban on PFAS incineration. [FN19: 415 ILCS 5/22/62 (2022).] EPA itself has raised concerns over the uncertainties associated with incineration. [FN20: See e.g., U.S. EPA, Technical Support Document -Technologies and Cost for Removing Per- and Polyfluoroalkyl Substances (PFAS) from Drinking Water 18-19, 39 (Feb. 2023); U.S. EPA, Best Available Technologies and Small System Compliance Technologies for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water 15 (2023).] If restrictions upon PFAS waste incineration become more widespread, the typical costs of cleanup of PFAS-impacted sites would also increase as a foreseeable consequence of the Proposed Rule [FN21: U.S. Chamber of Commerce, PFOS and PFOA Private Cleanup Costs at Non-Federal Sites 10 (June 2022) (finding that prohibiting thermal treatment of PFAS contaminated soil would raise costs at a single National Priorities List (NPL) site by up to $1 million and that approximately 25 percent of existing NPL sites would find onsite incineration more cost effective than disposal at a Subtitle C landfill)] Nothing in the Proposed Rule explains how EPA has concluded the selected MCLs are feasible given existing or prospective future legal prohibitions on one of the two "most likely management options" that EPA identified. For the foregoing reasons, WUWC has significant concerns about the feasibility assessment supporting the Proposed Rule.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Western Urban Water Coalition (WUWC) (Doc. #1768, SBC-043944)

EPA has substituted its cost-benefit judgment for the feasibility determination required by SDWA. Nothing in existing law requires the owner or operator of a hazardous waste landfill to accept PFAS-containing residuals for disposal. The basis for EPA's assumption that at least some landfills will be available for disposal has not been supported.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce (Doc. #1537, SBC-042645)

However, there are substantial questions with EPA's current proposal. It is critical that EPA gets this right, as the costs that the proposed rule would impose are significant, and likely underestimated, leading to several challenges to the water utilities and other industries. For example, the proposed rule does not consider that maximum contaminant levels (MCLs) set in

this regulation would have direct relationship to the costs of Superfund cleanups, given the pending CERCLA hazardous substance designation for PFOA and PFOS. SDWA sets the standard for using the "best available peer-review science." The proposed MCL must be changed to properly balance these costs and benefits, as the statute requires and EPA has done in setting prior MCLs.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. The EPA further notes that the agency has considered the health risk reduction costs and benefits in accordance with SDWA, more information on the HRRCA is in section 13 of the EPA response in this *Response to Comments* document.

Association of State and Territorial Solid Waste Management Officials (ASTSWMO) (Doc. #1583, SBC-042397)

EPA needs to consider implementation of the proposed regulation, which poses financial, technological, logistical, and communication challenges that are of significant concern to the ASTSWMO membership, as follows:

1. Cost Concerns: EPA's cost analysis does not include costs that will be incurred under CERCLA or other remediation programs, which are likely to be significant. For example, for Superfund-financed sites, where there are no viable responsible parties, States will be responsible for cost-sharing obligations for remedial actions as well as 100% of the costs for long-term operation and maintenance of the remedies in perpetuity. Additionally, with this proposed regulation, the number of sites to be remediated is likely to increase significantly, requiring additional resources for States to perform and/or oversee the remedial activities.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

New York Section American Water Works Association (NYSAWWA) (Doc. #1591, SBC-042375)

We note that EPA's cost estimates fail to consider the impacts that potential waste disposal regulations may have on water suppliers. In the event that spent GAC, PAC backwash residuals or ion exchange resins with PFOA/PFAS in them are designated as hazardous materials, it will dramatically increase operational costs for treatment. These costs cannot be accurately predicted until all regulatory entities have finalized their own rules.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043636)

B. PFAS-contaminated GAC and IX media are not considered hazardous wastes in the national cost analysis-- although potential regulation for designating PFAS species as "hazardous substances" under CERCLA or "hazardous constituents" under RCRA has been proposed. For GAC, EPA currently assumes that the spent media is reactivated off- site under current RCRA non-hazardous waste regulations. However, residual disposal as hazardous waste may cause a considerable increase in the O&M costs. For instance, based on EPA's WBS Cost Model for GAC, the spent media disposal costs are $112.16/ton as non-hazardous waste versus $551.86/ton as hazardous waste. BWWB conducted a preliminary cost estimate for the hazardous-waste scenario resulted in approximately 38% higher disposal costs than the non-hazardous waste scenario, which results in an increase in the annual O&M cost for an 80MGD filter plant of $1.5 million. Please refer to Table A1 in Appendix A for additional supporting data.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043651)

5. Hazardous residuals: If/when the USEPA designates one or more species of PFAS as "hazards substances" under CERCLA or "hazardous constituents" under RCRA, there is potential for a significant escalation in residuals management costs. Similarly, regulatory action under CWA to control PFAS discharges could also result in escalated residuals management costs for water treatment systems. It is likely that the USEPA's assessment of the influence of these regulations on residuals management substantially underestimates the challenges to feasibility and affordability.

USEPA's national cost analysis reflects the assumption that PFAS-contaminated wastes are not considered hazardous wastes. A hazardous substance designation on PFAS species could limit disposal options for drinking water treatment residuals (i.e., spent media, concentrated waste streams). EPA has acknowledged that if PFAS-contaminated wastes require handling as hazardous wastes, the residuals management costs are expected to be higher.

EPA assessed the cost impact under the assumption of hazardous waste disposal and estimated that the increase in cost due to hazardous disposal is, on average) $30M assuming a 3% discount rate, and $61M assuming a 7% discount rate (EPA 2023).

The PFAS Regulatory Coalition (comprised of a group of industrial companies, municipal entities, agricultural parties, aviation representatives and trade associations) submitted a request to the USEPA for an extension of the comment period on the proposal to designate PFOA and PFOS as CERCLA Hazardous Substance—in their letter, the Coalition mentions that, while EPA states that the Proposed Designation is "economically significant", the economic assessment does not quantify indirect costs, which the Coalition feels could run into the millions or even billions of dollars, across the spectrum of impact.

Numerous utilities submitted comments on the proposed designation, echoing the sentiment that costs are underestimated and could overwhelm water and wastewater utilities. Based on BWWB's preliminary cost estimates comparing hazardous and non-hazardous disposal of spent GAC, it is likely that the EPA's assessment underestimates the costs of residuals handling.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

American Water Works Company Inc. (Doc. #1608, SBC-043998)

American Water is also concerned about the ultimate disposal of PFAS-contaminated AIX or GAC that will not be reactivated/regenerated. Disposal volumes represented by AIX or GAC may more than double the current mass of material being disposed in hazardous waste landfills. If EPA classifies PFAS-laden AIX resin or GAC hazardous, then supply and demand principals would suggest that such an increase in demand could trigger a substantial increase in cost. Lack of certainty over the long-term suitability, viability, and availability of disposal options puts undue risk on utilities' ability to select a treatment process that will minimize long-term cost impacts to customers from this proposed regulation.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Aquarion Water Company (Doc. #1617, SBC-043373)

Significant operating and maintenance costs, including the uncertain cost of disposing of PFAS-laden filter media, will add to this annual cost.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Beaufort-Jasper Water & Sewer Authority (BJWSA) (Doc. #1618, SBC-042933)

How will residual disposal add to the cost of operation?

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044049)

29. EPA requests comment on the estimates for disposing of drinking water treatment residuals or regenerating drinking water treatment media including assumptions related to the transport distance to disposal sites and other costs that arise out of disposal of PFAS contaminated drinking water treatment residuals.

a. Costs of disposal may continue to increase as the use of treatment residuals increase, particularly with CERCLA designations. As more utilities start using GAC and are required to replace more often to meet the proposed MCLs, disposal/regeneration sites will likely increase fees for use of their facilities. Further, CWUC is concerned that incineration may be ineffective and/or banned in the future.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Citizens Against Ruining the Environment (CARE) (Doc. #1638, SBC-043448)

EPA only estimates that relative to the national analysis for the proposed options, a hazardous waste disposal would increase PWS costs between 4-7% should spent media need to be disposed of as hazardous waste. [FN42: Id. at 18686.] CARE is deeply concerned with such a determination.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Savannah River Nuclear Solutions LLC (Doc. #1647, SBC-043341)

Comment 6

Section X.I.C. Management of Treatment Residuals (pg. 18686)

EPA is also requesting comment on the estimates for disposing of drinking water treatment residuals or regenerating drinking water treatment media including assumptions related to the transport distance to disposal sites and other costs that arise out of disposal of PFAS contaminated drinking water treatment residuals. These costs are difficult to quantify as they are dependent upon the type of treatment/disposal sites utilized and whether the residuals would be considered RCRA hazardous wastes. While Subtitle D solid waste landfills are generally more ubiquitous and are more evenly spread throughout the country, the number of RCRA landfill facilities are limited and generally are located in the mid-west and west coast, making RCRA disposal more expensive for east-coast generators. Similarly, the number of hazardous waste incineration facilities are also limited and are not geographically spread throughout the country. In some cases, transportation costs of residuals may outweigh the costs for actual disposal.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Santa Clara Valley Water District (Valley Water) (Doc. #1664, SBC-043126)

Comment 2 – The NPDWR Raises CERCLA Cost Concerns and Threatens the Feasibility of Projects that Help Address Climate Change

The EPA acknowledges stakeholder concerns that a PFAS hazardous designation under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) may limit drinking water treatment residual disposal options and increase costs. Given that regulatory agencies may rely on Maximum Contaminant Levels as CERCLA cleanup standards, Valley Water does not agree with the EPA conclusion that treatment costs may increase "marginally" or that the increase in public water systems' costs "are not significant enough to change the determination that benefits of the rulemaking justify the costs."

Valley Water currently operates three drinking water treatment plants and an advanced water purification facility and is planning additional purification facilities to support and expand potable reuse. Valley Water has been proactive in pursuing potable reuse as a locally controlled and drought resilient water supply as a key strategy to address climate change. As part of the water purification process, reverse osmosis removes PFAS, which end up in the reverse osmosis concentrate (ROC). Due to the large cost needed to advance potable reuse, Valley Water is extremely concerned with the disposal costs and liability that could be incurred related to disposal of the ROC. These potential cleanup and disposal costs could place an undue burden on the "non-polluting" water agencies and local ratepayers and go against the "polluter pays" principle of CERCLA. Valley Water is concerned that the EPA's proposed regulation may result in a "community pays" outcome that unfairly shifts the cleanup and liability costs onto municipalities and the public they serve. In essence, public agencies like Valley Water could be disincentivized from pursuing the creation of climate adaptive, drought resilient water supplies. This disincentive may leave local communities without sustainable, drought proof supplies in the face of climate change, the effects of which are observed now and are likely to be more pronounced in the future.

EPA Response: Please see sections 10.1 and 10.4.2 of the EPA response in this *Response to Comments* document.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044432)

EPA requests comment on the costs associated with the storage, transportation and underground injection of the brine concentrate residuals from the RO/NF process.

• This response was prepared by the Washington State Department of Ecology. Ecology does not have readily available cost data for storage, transport and underground injection of brine concentrate residuals from the RO/NF process.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Aurora Water, City of Aurora, Colorado (Doc. #1669, SBC-043721)

Not only will there be increased costs for treatment, but also increased costs for disposal of treatment residuals. To remove PFAS to the levels in the proposed rule, Aurora Water will be

forced to replace their granular activated carbon (GAC) materials seven times more per year than previously planned.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. The EPA thanks the commenter for information about their expected treatment system impacts.

New York State Department of Health (NYS DOH) (Doc. #1677, SBC-044965)

26. EPA is requesting comment on a drinking water proposal when it is still unknown what the impacts will be on water treatment plant residuals and wastewater treatment plants. EPA assessed residuals costs in its economic analysis and concluded no significant impact. There will not be agreement on this conclusion, particularly for small systems. Clean Water Act regulations, if ultimately promulgated, may restrict water treatment plant discharges to water bodies forcing wastewater treatment plants to look upstream and preclude WTP discharges to the collections system. In addition, a hazardous substance designation under the Resource Conservation Recovery Act (RCRA) will increase costs and a hazardous constituent designation under the Comprehensive Environmental Response, Compensation and Recovery Act may create liability for both water and wastewater treatment plants.

27. As noted above, there are significant variabilities surrounding disposal costs of treatment residuals such as spent activated carbon. In New York, some water treatment facilities are landfilling all residuals while other residuals are being regenerated and reused, resulting in very different costs. Evaluating the cost of managing these residuals is complicated by potential liability, perceived or actual, if PFAS from these residuals end up in landfill leachate or air discharge from thermal treatment facilities. The possibility of a RCRA Hazardous Waste designation for some PFAS-wastes adds even more uncertainty, with much higher costs. Development of a cost-effective solution for treatment or disposal of PFAS-wastes is critical to many aspects of New York's response to PFAS contamination, and we urge EPA to make this a priority.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045118)

6) Residual disposal: There are challenges with current available options to manage spent PFAS treatment media, such as disposal at certified disposal facilities or regeneration. With the likely increase in treatment with the proposed MCL, it is likely that the cost of managing or disposing spent treatment media will increase.

a. If EPA wants to include membrane technologies as a solution, there needs to be more discussions and consideration about advanced treatment of the concentrate and how it will be

managed or disposed. Disposal into surface water or sanitary sewers is not a solution in many states, including Vermont. Disposing of RO/NF membrane concentrate into a surface water or sanitary sewer should not be considered an acceptable standard.

b. Regeneration of pretreatment (e.g., softening) would need to be treated water because PFAS can't be discharged into the sewer. This may add more costs to systems that would need to add or modify treatment or storage facilities. This cost was not identified in the analysis.

EPA Response: Please see sections 10.4.1 and 10.4.2 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045909)

While EPA assessed the potential impact on PWS treatment costs associated with hazardous residual management requirements in a sensitivity analysis on the proposed option, EPA underestimates these costs. EPA expects annual costs to increase by $30 - $61 million if water systems are required to dispose hazardous waste (spent GAC and resin) but does not explain how regulated entities will handle PFAS waste and the additional costs of managing PFAS waste as a direct result of this rulemaking.

EPA Response: Please see section 10.4 2 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045913)

C. EPA assumes direct discharge of RO/NF concentrate to the environment

EPA assumes 5% of Public Water Systems that require treatment will elect to utilize reverse osmosis (RO) or nanofiltration (NF). These membrane-based treatment options will concentrate the PFAS and other constituents present in the source water that are removed from the treated water into a reject stream. EPA assumes that the reject stream will be 15-30% of the total flow to the treatment unit.

EPA states that the RO/NF cost model included an assumption that the reject stream from Reverse Osmosis and Nanofiltration units would be direct discharged via NPDES permitted outfalls to non-potable receiving streams (ocean or brackish estuaries). [FN157: 88 Fed. Reg at 18696.] The ability to discharge concentrated streams of PFAS material to the natural environment via a permitted outfall is not a reasonable assumption for this cost model, nor is it aligned with EPA's roadmap for regulation of PFAS. EPA's cost estimate would be higher if it included a cost estimate for disposal of brine concentrate as a RCRA hazardous waste.

EPA further notes two full-scale applications of RO to treat PFAS in drinking water systems [FN158: See EPA Technical Support Document - Technologies and Cost for Removing Per- and Polyfluoroalkyl Substances (PFAS) from Drinking Water, 2023, EPA-822-P-23-011.]. In addition to those installations, the industrial facilities that the Chamber represents have

experience using Reverse Osmosis units in their facilities. From this experience, EPA has not adequately addressed costs associated with the need for remineralization of RO permeate to make it non-corrosive to downstream piping and to make it suitable for consumption as a drinking water. The coalition also suggests EPA has underestimated the reject quantities that would be expected with the proposed pretreatment units identified by EPA. EPA should assume rejection rates of 25-30% when developing disposal costs for RO units.

EPA Response: Please see sections 10.4.1, 10.4.2, and 13 of the EPA response in this *Response to Comments* document. The EPA has adjusted RO/NF's technology projection compliance forecast to 0 percent in the EA.

Protecting Our Water, Environment, and Ratepayers (POWER) (Doc. #1714, SBC-045935)

The proposed rule does not clearly indicate if other non-regulated PFAS were considered in the byproduct disposal rate.

Besides the issue with disposal, the EPA's estimate on byproduct disposal rate does not adequately consider other non-regulated PFAS. There are thousands of different PFAS compounds. Many of these compounds have little sampling data and the general background concentrations of these compounds are unknown. Given the prevalence and co-occurrence of well-studied PFAS compounds, one can assume that the other thousands of PFAS compounds will co-occur with the regulated PFAS compounds.

As such, it is likely that the drinking water treatment mechanisms required to catch the six PFAS compounds regulated by this rule will also capture many of the thousands of other PFAS compounds, especially if the molecular chains of the unregulated compounds are the same size or larger. Because the cleanup mechanisms will likely capture these additional compounds, the estimated lifetime of the treatment media is likely overestimated. If the treatment media lifetimes are shorter than predicted, maintenance costs will be higher than EPA estimated.

POWER! requests that EPA ensure that all reasonably foreseeable impacts and costs are considered – as required by the SDWA, Executive Order 12866 and OMB Circular A-4 – before proceeding to finalize the proposed rule. A revised analysis should include disposal costs if all six PFAS substances are hazardous substances under CERCLA, the financing costs of historic investments in new treatment infrastructure in a three-year window, and a more accurate estimate of treatment media life and costs.

EPA Response: Please see sections 10.4.2 and 10.3 of the EPA response in this *Response to Comments* document. More information on costs may be found in section 13. While there can be significant quantities of non-quantified PFAS in specific waters, this is accounted for by using a statistical approach in the national cost modeling and helps to explain why some utilities have significant differences in changeout frequency despite being relatively similar in other respects. The three-year timeline was expanded with a two-year capital improvements window. The designation does not require waste to be treated in any particular fashion., nor disposed of at any

particular type of landfill. The designation also does not restrict, change, or recommend any specific activity or type of waste at landfills. The EPA took the unusual and non-required step of providing a supplemental analysis in the hypothetical future RCRA hazardous wastes scenario, which is in the appendix to the cost analysis.

HRSD (Doc. #1719, SBC-043547)

Spent media management becomes even more complex under the proposed CERCLA rule in which PFOA, PFOS and other PFAS compounds are designated as hazardous substances. The transport and disposal of spent media as hazardous wastes is expected to be much more costly than what is estimated by EPA. HRSD's own estimates indicate that the cost of spent media disposal will nearly double if managed as a hazardous waste, with disposal costs of nearly $1.6 million annually. This doesn't even factor in the challenges with increased reliance on hazardous waste landfills and the practical limitation of landfill capacity and availability to manage what are anticipated to be significant volumes of spent media. HRSD alone is anticipating that we could generate more than 6,000 tons of spent media annually.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document. Designation has no impact on RCRA's list of "hazardous wastes." PFAS, including PFOA and PFOS, are not currently listed, or being proposed to be listed, as RCRA hazardous wastes, and designation of PFOA and PFOS as CERCLA hazardous substances does not automatically require that PFOA- and/or PFOS-contaminated waste be treated or disposed of at RCRA Subtitle C facilities. The CERCLA designation does not result in any specific RCRA requirements, nor does designation impose additional costs for waste management facilities. Designation does not impose any specific landfill operation or management requirements.

City of Thornton, Colorado (Doc. #1748, SBC-044787)

Also, Thornton is highly concerned about disposal costs associated with GAC media and other treatment residuals.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Las Cruces Utilities (LCU) (Doc. #1753, SBC-043922)

In response to Section XIII. Health Risk Reduction and Cost Analysis, EPA requests comment on the costs associated with the storage, transportation and underground injection of the brine concentrate residuals from the RO/NF process.

• Inland management of RO brine would be the significant cost of the whole treatment system. Coastal disposal would be more feasible (assuming coastal PFAS impacts would be acceptable), but for LCU this would be non-feasible. Deep well injection would be 3,000-4,000 feet and has

associated costs and risks. Transporting liquid would be by truck or train, pipelines would not be feasible.

EPA Response: Please see sections 10.4.1 and 10.4.2 of the EPA response in this *Response to Comments* document.

Las Cruces Utilities (LCU) (Doc. #1753, SBC-043916)

In response to Section XI-Treatment Technologies, EPA requests comment on the estimates for disposing of drinking water treatment residuals or regenerating drinking water treatment media including assumptions related to the transport distance to disposal sites and other costs that arise out of disposal of PFAS contaminated drinking water treatment residuals.

• At a large scale, transportation costs and disposal fees for regenerating large amounts of media may not be financially feasible.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-046165)

5.4.1 Estimation of Media Life and Disposal

The generalized logistic function of the Clark model (Clark, 1987), represented in Equation 2, was the basis for calculations for estimation of media life for both GAC and IX. While more rigorous techniques exist for modeling adsorption, Clark's model was utilized for its relative simplicity and accuracy.

[Equation 2: Docket ID: EPA-HQ-OW-2022-0114-1759]

r' and B can be solved for from the slope and intercept of the plot of ln[(Co/C)^1/n-1] versus time. If a constant flow is assumed, the number of bed volumes becomes directly proportional to time, allowing these relationships to be expressed as a function of bed volumes treated rather than time. B, n, and r' values utilized for GAC and IX are expressed in Table 5-9. The values utilized for GAC were derived from data collected during a Black & Veatch GAC pilot study for CFPUA. The values utilized for IX were derived partially from data collected during a Black & Veatch IX pilot study for CFPUA and partially from data collected during an IX pilot study for La Habra Height County Water District (LHHCWD).

Table 5-9 Values Variables in Modeled Bed Life

[Table 5-9: Docket ID: EPA-HQ-OW-2022-0114-1759]

For each system with occurrence data, C was calculated for each PFAS compound at a specified bed volume increment. Increments of 250 bed volumes up to a maximum of 40,000 were calculated for GAC. Increments of 5,000 bed volumes up to a maximum of 800,000 were

calculated for IX. The number of bed volumes at which C exceeded the specified target replacement concentration was determined, and the number of bed volumes for the first contaminant to breach its target concentration was used to calculate media replacement frequency. The number of bed volumes treated before the first contaminant exceeded the target concentration was subjected to Monte Carlo variability as described in Section 5.2.

EPA Response: Please see sections 10.1, 10.4.2, and 13 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045618)

EPA considers these actions as part of the economic analysis, particularly through a sensitivity analysis. As noted above, the quantity of GAC and IX that EPA estimates will be disposed of annually is not reported in the supporting information. As noted above, the demand for GAC may exceed 100,000 tons annually. EPA has recently estimated that the costs to incinerate hazardous waste ranges from $400 to $1,700 per ton depending on the type of waste (EPA, 2020). At a minimum, the annual costs to incinerate GAC and IX as hazardous waste will exceed $40 million and are likely to be beyond $100 million. Just the costs of incineration significantly exceeds the $30 million estimate, which EPA describes as including hazard waste disposal and associated costs (e.g., transportation and handling).

While EPA notes that hazard waste disposal costs are excluded from the estimate of annual costs, these costs should not be ignored. EPA's current commitment is to finalize the PFOA and PFOS hazardous substance designations under CERCLA this summer. Furthermore, as these actions are advanced, waste management practices are shifting and leading to increased disposal prices for water systems and, in some cases, facilities are refusing to accept water treatment residuals (AWWA, 2022).

AWWA recommends that the EPA (i) more closely look at the costs associated with hazardous waste disposal, including available guidance from Office of Land and Emergency Management (OLEM) and (ii) include the cost of hazard waste disposal of spent media. The current EPA regulatory agenda will drive impacts the cost of treatment options for removing PFAS from drinking water and will be legally binding by the time water systems must comply with any PFAS rule.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-046154)

Exhausted IX resin will be saturated with PFAS. Disposal alternatives for exhausted IX resins include incineration and landfilling. The cost of each disposal method depends on proximity to disposal sites, hazardous waste classification, and volume of material. Disposal costs can be a significant operational cost for IX treatment systems.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

PFAS Regulatory Coalition (Doc. #1761, SBC-046087)

h) Did EPA consider the costs associated with RO reject disposal? It appears that EPA assumed that reject streams would be directly discharged via NPDES permitted outfalls to non-potable receiving streams (oceans or brackish estuaries). However, EPA needs to recognize that discharging concentrated streams of PFAS-containing material to the environment via a permitted outfall may not be feasible, due to Whole Effluent Toxicity testing and other CWA-based requirements. Nor would that approach align well with EPA's overall strategy for regulation of PFAS.

EPA Response: Please see sections 10.4.1 and 10.4.2 of the EPA response in this *Response to Comments* document. The EPA has adjusted RO/NF's technology projection compliance forecast to 0 percent in the EA.

Western Urban Water Coalition (WUWC) (Doc. #1768, SBC-043943)

EPA also does not properly address the disposal of spent treatment media. Based upon its 2020 Interim Guidance,[FN13: Id. at 18686(citing EPA, Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances (2020)).] EPA states that "the most likely management option for spent material containing PFAS is reactivation for GAC and incineration for spent IX resin."[FN14:Id.] EPA acknowledges that the "large volume of residuals is a well-known obstacle" and that "large volumes of spent GAC and ion exchange resin must be removed which does not lend itself to onsite storage over time."[FN15: Id.] EPA further acknowledged the potential for PFAS-containing residuals to be characterized as hazardous waste subject to heightened disposal restrictions, and estimated the incremental costs of disposal to utilities. Nevertheless, EPA concluded that "costs are limited to the disposal of the PFAS contaminated residuals and wastes," and found that the "increase in [public water systems] costs are not significant enough to change the determination that the benefits of the rulemaking justify the costs."[FN16:Id.]

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Western Urban Water Coalition (WUWC) (Doc. #1768, SBC-043945)

By its own admission, EPA has also undercounted the costs if treatment residuals must be managed as hazardous. Under the Resource Conservation and Recovery Act (RCRA) and analogous state laws, water systems cannot lawfully accumulate and store hazardous waste without a permit. [FN17: The default maximum unpermitted accumulation period under RCRA

is 180 days. 40 C.F.R. § 262.16(b).] Neither the Proposed Rule nor the supporting EA appear to account for RCRA permit processing and compliance burdens that would apply to the storage of treatment residuals prior to offsite disposal.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Environmental Protection Network (EPN) (Doc. #1773, SBC-043852)

EPN agrees with EPA's finding that potential hazardous waste disposal requirements for spent GAC and AIX resins would increase water system costs marginally but not enough to change the determination that the benefits of the rule justify the costs.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Laurens County Water and Sewer Commission (LCWSC) (Doc. #1805, SBC-043744)

Of course, a key component of a cost assessment is the costs for how GAC residuals will be disposed of/reused. This is especially critical in light of the proposed hazardous waste designation under CERCLA for PFOA and PFOS. We are perplexed by the desire to concentrate a contaminant that has no economically feasible destruction techniques for a rural water system. For example, will utilities be able to regenerate GAC media? If we cannot, the annual O&M costs will be significantly higher. Moreover, if GAC media are hazardous wastes, the disposal costs will be enormous. Uncertainty over whether spent GAC media will be hazardous wastes will force water utilities to delay their selection of PFAS barrier installations due to the uncertainty over materially significant life-cycle costs.

EPA Response: Please see sections 10.4.1 and 10.4.2 of the EPA response in this *Response to Comments* document.

Florida Rural Water Association (FRWA) (Doc. #1806, SBC-044696)

In addition, supply chain issues, skyrocketing construction and transportation costs, and unknown media (lack of availability of disposal facilities) disposal fees have been increasing the actual cost of remediation far exceeding preliminary estimates. In some situations, the GAC is only lasting 6 months with much higher Operation and Maintenance, disposal and logistics fee's to truck to Texas for approved disposal.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Office of Advocacy at the U.S. Small Business Administration (Doc. #1807, SBC-045483)

Advocacy is also concerned about the significant increases in disposal costs if these PFAS are required to be managed as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act [FN10: Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances, 87 Fed. Reg. 54415, (Sept. 6, 2022)] or designated as hazardous constituents under Resource Conservation and Recovery Act [FN11: Introduction to the Unified Agenda of Federal Regulatory and Deregulatory Actions-Fall 2022, 88 Fed. Reg.1066, 1150.]. Because these actions are not yet final, the agency did not include these costs as part of the rule compliance costs [FN12: EPA did provide a separate sensitivity analysis based on the hazardous waste disposal assumption which demonstrates that costs would increase for public water systems by 4% ($30 million annually) at the 3% discount rate and 5% ($61 million annually) at the 7% discount rate. See, Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation, [Economic Analysis] (March, 2023), Appendix N.].

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046126)

3. EPA correctly excludes any incremental costs to PWSs that would result from the need to dispose of spent filtration materials as hazardous waste.

The PFAS addressed by EPA's proposed NPDWRs—PFOS, PFOA, PFHxS, HFPO-DA and its ammonium salt, PFNA, and PFBS—are not currently regulated as hazardous materials under federal law, and therefore additional disposal costs that would be required by federal law for the disposal of hazardous materials should not be applied in this EA of the proposed NPDWS. In my professional experience, it is standard practice to only account for other regulations in the baseline if those regulations have been promulgated as of the time of the EA. Accounting for future potential regulations in the baseline is uncommon, and trying to account for all potential future contingencies in this regard would quickly make any EA unmanageable. If EPA later determines that PFOS, PFOA, and other regulated PFAS are hazardous materials, then any incremental increase in disposal costs for such materials over normal spent filtration material disposal costs would be a cost of that future regulation, and not of the currently proposed NPDWS.

Overall, EPA's choice to not incorporate in its cost analysis the expense of treating spent filtration materials as hazardous waste is well-grounded in economic theory and common practice. Nonetheless, in response to stakeholder comments EPA did include such costs in an illustrative sensitivity analysis. Although beyond standard practice, this illustrative exercise demonstrates the Agency's responsiveness and desire for full transparency in the regulatory development process. As discussed in comment #11 in the next section of this memorandum, if

EPA maintains this illustrative cost analysis, then the Agency should also estimate the corresponding health and environmental benefits of treating spent filtration materials as hazardous waste. This is necessary in order to make this sensitivity analysis comprehensive and balanced.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

West Virginia Municipal Water Quality Association (Doc. #1816, SBC-044669)

Of course, a key component of a valid national cost assessment is the cost for how barrier technology (GAC, RO) residuals will be disposed of/reused. This is especially critical in light of the proposed hazardous waste designation under CERCLA for PFOA and PFOS.

For example, will utilities be able to regenerate GAC media? If we can't, the annual O&M costs will be significantly higher for the 3-6 thousand affected facilities. Moreover, if GAC media (and/or Reverse Osmosis residuals) are hazardous wastes, the disposal costs will be enormous. We are shocked at EPA's estimate that residuals from PFAS barrier technology will only cost an additional $30-61 million annually to dispose of if PFOA/PFOS are designated as hazardous substances. We think there will be an incredible volume of material requiring disposal that will dwarf EPA's cost estimate. Also, many facilities have assumed they will be able to regenerate their GAC, for example, and EPA must address whether regeneration will be an option under a hazardous waste designation. Further, EPA must address whether it accounted for a loss of regeneration as part of its $30-61 million additional annual cost.

Uncertainty over whether spent GAC media will be hazardous wastes will force water utilities to delay their selection of PFAS barrier installations due to the uncertainty over materially significant life-cycle costs. If spent GAC media (and RO residuals) are hazardous wastes, that may further cause water utilities to defer technology selection until there are PFAS treatment options that avoid hazardous waste residuals.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Association of Missouri Cleanwater Agencies (Doc. #1817, SBC-044647)

Of course, a key component of a valid national cost assessment is the cost for how barrier technology (GAC, RO) residuals will be disposed of/reused. This is especially critical in light of the proposed hazardous waste designation under CERCLA for PFOA and PFOS.

For example, will utilities be able to regenerate GAC media? If we can't, the annual O&M costs will be significantly higher for the 3-6 thousand affected facilities. Moreover, if GAC media (and/or Reverse Osmosis residuals) are hazardous wastes, the disposal costs will be enormous. We are shocked at EPA's estimate that residuals from PFAS barrier technology will only cost an additional $30-61 million annually to dispose of if PFOA/PFOS are designated as hazardous

substances. We think there will be an incredible volume of material requiring disposal that will dwarf EPA's cost estimate. Also, many facilities have assumed they will be able to regenerate their GAC, for example, and EPA must address whether regeneration will be an option under a hazardous waste designation. Further, EPA must address whether it accounted for a loss of regeneration as part of its $30-61 million additional annual cost.

Uncertainty over whether spent GAC media will be hazardous wastes will force water utilities to delay their selection of PFAS barrier installations due to the uncertainty over materially significant life-cycle costs. If spent GAC media (and RO residuals) are hazardous wastes, that may further cause water utilities to defer technology selection until there are PFAS treatment options that avoid hazardous waste residuals.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

NORTH CAROLINA WATER QUALITY ASSOCIATION (Doc. #1818, SBC-044625)

Of course, a key component of a valid national cost assessment is the cost for how barrier technology (GAC, RO) residuals will be disposed of/reused. This is especially critical in light of the proposed hazardous waste designation under CERCLA for PFOA and PFOS.

For example, will utilities be able to regenerate GAC media? If we can't, the annual O&M costs will be significantly higher for the 3-6 thousand affected facilities. Moreover, if GAC media (and/or Reverse Osmosis residuals) are hazardous wastes, the disposal costs will be enormous. We are shocked at EPA's estimate that residuals from PFAS barrier technology will only cost an additional $30-61 million annually to dispose of if PFOA/PFOS are designated as hazardous substances. We think there will be an incredible volume of material requiring disposal that will dwarf EPA's cost estimate. Also, many facilities have assumed they will be able to regenerate their GAC, for example, and EPA must address whether regeneration will be an option under a hazardous waste designation. Further, EPA must address whether it accounted for a loss of regeneration as part of its $30-61 million additional annual cost.

Uncertainty over whether spent GAC media will be hazardous wastes will force water utilities to delay their selection of PFAS barrier installations due to the uncertainty over materially significant life-cycle costs. If spent GAC media (and RO residuals) are hazardous wastes, that may further cause water utilities to defer technology selection until there are PFAS treatment options that avoid hazardous waste residuals.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

South Carolina Water Quality Association (Doc. #1819, SBC-044603)

Of course, a key component of a valid national cost assessment is the cost for how barrier technology (GAC, RO) residuals will be disposed of/reused. This is especially critical in light of the proposed hazardous waste designation under CERCLA for PFOA and PFOS.

For example, will utilities be able to regenerate GAC media? If we can't, the annual O&M costs will be significantly higher for the 3-6 thousand affected facilities. Moreover, if GAC media (and/or Reverse Osmosis residuals) are hazardous wastes, the disposal costs will be enormous. We are shocked at EPA's estimate that residuals from PFAS barrier technology will only cost an additional $30-61 million annually to dispose of if PFOA/PFOS are designated as hazardous substances. We think there will be an incredible volume of material requiring disposal that will dwarf EPA's cost estimate. Also, many facilities have assumed they will be able to regenerate their GAC, for example, and EPA must address whether regeneration will be an option under a hazardous waste designation. Further, EPA must address whether it accounted for a loss of regeneration as part of its $30-61 million additional annual cost.

Uncertainty over whether spent GAC media will be hazardous wastes will force water utilities to delay their selection of PFAS barrier installations due to the uncertainty over materially significant life-cycle costs. If spent GAC media (and RO residuals) are hazardous wastes, that may further cause water utilities to defer technology selection until there are PFAS treatment options that avoid hazardous waste residuals.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Wet Weather Partnership (Doc. #1820, SBC-044581)

Of course, a key component of a valid national cost assessment is the cost for how barrier technology (GAC, RO) residuals will be disposed of/reused. This is especially critical in light of the proposed hazardous waste designation under CERCLA for PFOA and PFOS.

For example, will utilities be able to regenerate GAC media? If we can't, the annual O&M costs will be significantly higher for the 3-6 thousand affected facilities. Moreover, if GAC media (and/or Reverse Osmosis residuals) are hazardous wastes, the disposal costs will be enormous. We are shocked at EPA's estimate that residuals from PFAS barrier technology will only cost an additional $30-61 million annually to dispose of if PFOA/PFOS are designated as hazardous substances. We think there will be an incredible volume of material requiring disposal that will dwarf EPA's cost estimate. Also, many facilities have assumed they will be able to regenerate their GAC, for example, and EPA must address whether regeneration will be an option under a hazardous waste designation. Further, EPA must address whether it accounted for a loss of regeneration as part of its $30-61 million additional annual cost.

Uncertainty over whether spent GAC media will be hazardous wastes will force water utilities to delay their selection of PFAS barrier installations due to the uncertainty over materially

significant life-cycle costs. If spent GAC media (and RO residuals) are hazardous wastes, that may further cause water utilities to defer technology selection until there are PFAS treatment options that avoid hazardous waste residuals.

EPA Response: Please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Oneida Nation (Doc. #1825, SBC-044272)

Comments on proposed rule

PFAS Treatment residuals and disposal options:

EPA wants to designate some PFAS as hazardous substance which could affect disposal options. There is a cost to disposing hazardous waste; EPA estimates a couple of hundred annually per household. The Oneida Nation has tested our water to be PFAS and PFOS free/undetectable. Thus, one would anticipate no hazardous waste generation. Therefore, we cannot estimate the concentration and amount of generation. Also, EPA is only listing four PFAS as hazardous materials. Without filters to remove these materials, they would most likely end up in our WWTP biosolids which are currently taken to landfill.

At this point we cannot estimate the annual cost of disposal or when it would occur. Possibly a more substantial concern would be the cost to add filters to our wells. If we are required to add filters, the cost would likely exceed two hundred thousand dollars. Additionally, it would be estimated the installation would be two to three years to design and build the filter into our current housing site water system. Since our wells share the same water source if PFAS showed up in one well it would likely show up in all of them (we do not have a known source of PFAS/PFOS on the Reservation). The cost may run into the millions of dollars if we needed to add more wells and filters. There are options that need to be considered for continued improvements in our water systems in the coming years.

EPA Response: Please see sections 10.4.2 and 13 of the EPA response in this *Response to Comments* document.

10.4.3 Impacts on disposal of PFAS contaminated treatment residuals on communities adjacent to the disposal facilities

Summary of Major Public Comments and EPA Responses

Some commenters stated that more research can be beneficial to further our understanding of PFAS-contaminated treatment residuals on adjacent communities. The EPA agrees that research can be beneficial and is sponsoring research as a key pillar of the PFAS Strategic Roadmap. The ORD is evaluating and developing technologies for reducing PFAS in the environment to inform decisions on drinking water and wastewater treatment, contaminated site cleanup and remediation, air emission controls, and end-of-life materials management.

Some commenters were concerned about impacts from managing treatment residuals on communities adjacent to disposal facilities. Appropriate controls, such as those outlined in the *Interim PFAS Destruction and Disposal Guidance* document, can minimize environmental PFAS releases from PFAS-laden drinking water residuals. This guidance is updated every three years according to section 7361 of The National Defense Authorization Act for Fiscal Year 2020, Public Law No: 116-92. The EPA also notes that, as previously described in the summary of major comments for section 10.4, it is important to distinguish between a potential environmental release and a direct exposure. A PFAS release does not inherently imply human exposure and a release is not inherently risky to specific populations. From a risk management perspective, the EPA acknowledges that while each destruction and disposal technology has limitations, a potential environmental release under point source management is anticipated to be a more health protective alternative than human exposure through drinking water.

Some commenters were especially concerned about EJ and that disposal of PFAS-containing wastes has the potential to impact adjacent communities. The EPA believes that these potential impacts can be minimized with careful management of the disposal and/or destruction approaches as described in the *Interim PFAS Destruction and Disposal Guidance* document. The agency also notes that there are uncertainties associated with the potential pathways of exposure for communities with potential EJ concerns regarding the destruction and disposal of PFAS in drinking water. The EPA has added a qualitative discussion of the potential impacts of PFAS disposal on overburdened communities to Section 8.2 of its EJ analysis for the final rule. For more information on the findings of the EPA's EJ analysis, please see Chapter 8 of the EA (USEPA, 2024d). Through this action, the EPA reaffirms the importance of EJ considerations in agency activities, including rulemaking. The EPA's EJ analysis for the final rule demonstrates that communities of color are anticipated to experience elevated baseline PFAS drinking water exposures compared to the entire sample population in this analysis. However, the EPA believes that this action is likely to reduce existing disproportionate and adverse effects on people of color, low-income populations and/or Indigenous populations.

Individual Public Comments

Washington State Department of Health (DOH) (Doc. #1665, SBC-044430)

EPA requests comment on the impacts that the disposal of PFAS contaminated treatment residuals may have in communities adjacent to the disposal facilities.

• This response was prepared by the Washington State Department of Ecology. With regards to Subtitle D landfills, impacts to adjacent communities would be minor as long as non-dangerous PFAS waste goes to a modern-day lined landfill. Many solid waste landfills capture leachate in lined leachate lagoons that do not discharge. Many also discharge to wastewater treatment plants, which is where any impact would occur in terms of their discharge of treated wastewater or management of biosolids.

• This response was prepared by the Washington State Department of Ecology. Regarding disposal options for high concentration PFAS dangerous waste, there are unknowns on how they could affect adjacent communities. Permitted Subtitle C landfills are preferred if they are designed to manage PFAS. Incineration has shown to destroy the PFAS molecule at prescribed temperature and residence time, but Ecology has not come across environmental data to show no PFAS is being emitted. PFAS would also likely outlive the life of a Subtitle C landfill in the future, so we hesitate to recommend this option for high concentration PFAS wastes because we do not fully understand the effect it could have on adjacent communities.

EPA Response: Please see section 10.4.3 of the EPA response in this *Response to Comments* document. The EPA appreciates the commenter's analysis and notes that PFAS-laden drinking water residuals typically have relatively low PFAS concentrations as outlined in the summary of major comments for section 10.4 of the EPA response in this *Response to Comments* document. The EPA agrees that appropriate controls, such as those outlined in the *Interim PFAS Destruction and Disposal Guidance* document, can minimize environmental PFAS releases from PFAS-laden drinking water residuals.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045991)

Furthermore, given the increased association between communities of color and water systems contaminated with PFAS [FN19: Liddie, Schaider, and Sunderland. (15 May 2023). Sociodemographic Factors Are Associated with the Abundance of PFAS Sources and Detection in U.S. Community Water Systems. Environmental Science & Technology. DOI:10.1021/acs.est.2c07255], AMWA asks EPA to examine the impacts of disposal of PFAS-contaminated media on communities near disposal sites. Specifically, in the final rulemaking and implementation, EPA should examine how to support PWSs and fence-line communities in equitably distributing risks from PFAS disposal. EPA's proposal involves removing PFAS from drinking water to protect communities, but this will require storing and disposing PFAS near other communities until implementing destruction technologies are readily available. EPA needs to prioritize research into better destruction techniques that do not harm communities that have already been historically underserved. Without proper consideration and community support, disposing of media containing PFAS near communities compromises the agency's goal of protecting public health. Prior to finalizing this NPDWR, EPA should plan for further evaluation and cooperation with PWSs to equitably remove and dispose of PFAS.

EPA Response: Please see section 10.4.3 of the EPA response in this *Response to Comments* document. Appropriate controls, such as those outlined in the *Interim PFAS Destruction and Disposal Guidance* document, can minimize environmental PFAS releases from PFAS-laden drinking water residuals.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045984)

EPA also requests comments on the impacts the disposal of PFAS-contaminated media will have on communities adjacent to disposal communities. EPA's proposal involves removing PFAS from communities and essentially storing and disposing of it near others, which are in many cases underserved and disadvantaged communities. EPA needs to prioritize research into better destruction techniques that do not harm communities that have already been historically underserved. Disposing of media containing PFAS near these communities compromises the agency's goal of protecting public health.

EPA Response: Please see section 10.4.3 of the EPA response in this *Response to Comments* document. Appropriate controls, such as those outlined in the *Interim PFAS Destruction and Disposal Guidance* document, can minimize environmental PFAS releases from PFAS-laden drinking water residuals.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045235)

6. EPA requests comment on the impacts that the disposal of PFAS contaminated treatment residuals may have in communities adjacent to the disposal facilities.

For states that allow incineration as a disposal method, there are little data on PFAS emissions from incineration. This disposal method could lead to possible health effects from exposure during incineration and/or reintroduction of PFAS not fully destroyed during incineration. There are similar concerns with leachate from spent carbon or resins for those that end up at landfills as their final disposal destination. CTDPH seeks assistance from EPA to work to identify and address appropriate and safe disposal methods.

EPA Response: Please see section 10.4.3 of the EPA response in this *Response to Comments* document. The EPA appreciates the commenter's direction as to the type of assistance that will be best for it and EPA notes that the *Interim PFAS Destruction and Disposal Guidance* document contains guidance for the disposal of PFAS-laden drinking water materials.

Aclarity (Doc. #1755, SBC-044511)

The current cycle leaves communities vulnerable and at risk of PFAS related health concerns as PFAS laden materials are often disposed of in landfills, incinerated or injected deep into wells, allowing PFAS to continue to contaminate through landfill leachate or aerosols created through incineration. We urge the federal government to address this PFAS cycle.

Furthermore, any entity who is currently utilizing these subpar "disposal" methods should be held accountable in proving they are not exacerbating the problem and spreading PFAS contamination.

EPA Response: Please see sections 10.4.1 and 10.4.3 of the EPA response in this *Response to Comments* document. The EPA disagrees that appropriately managed destruction

and disposal methods pose health concerns and has published guidance that can help minimize releases in the *Interim PFAS Destruction and Disposal Guidance* document.

Bailey Smith (Doc. #1787, SBC-045813)

Regarding EPA's request for comment as to the "impacts that the disposal of PFAS contaminated treatment residuals may have in communities adjacent to the disposal facilities,"[FN46: Proposed Rule, supra note 3 at 18731.] this comment provides an example of two families who have suffered due to lack of PFAS regulation. Disposal of PFAS contaminated treatment may have horrific impacts on communities adjacent to treatment facilities. [FN47: See e.g., Hayes & Faber, supra note 2; Perkins, supra note 2.] EPA should take care to address this in its final rule. Treatment facilities should make sure to dispose of PFAS contaminated treatment residue as far away from people's homes or drinking water sites as possible.

EPA Response: Please see section 10.4.3 of the EPA response in this *Response to Comments* document. The examples cited by the commenter relate to industrial facility discharges rather than problems stemming from PFAS-laden drinking water treatment residual discharges. Provided that guidance the EPA has published is followed, for example in the *Interim PFAS Destruction and Disposal Guidance* document, environmental PFAS releases should be minimized.

Anonymous (Doc. #1944, SBC-047322)

The United Nations believes a safe, clean, healthy, and sustainable environment is a right for ALL humans. How can we say this is true for the United States when our government allows low-income communities with a high population of people of color, continue to be disproportionately affected by chemical pollutants in their water, air, and the overall environment they are unknowingly subjected to? The EPA shows that Black individuals in America, in comparison with other groups, are 54% more likely to live near hazardous facilities, something that is not brought up enough (Desikan, 2019).

EPA Response: Please see section 10.4.3 of the EPA response in this *Response to Comments* document. Through this action, the EPA reaffirms the importance of EJ considerations in agency activities, including rulemaking. The EPA's EJ analysis for the final rule demonstrates that communities of color are anticipated to experience elevated baseline PFAS drinking water exposures compared to the entire sample population in this analysis. The EPA notes Desikan et al. (2019) is cited in the EPA's EJ analysis for this rule, which can be found in Section 8.2 of the EA (USEPA, 2024d).

10.5 Small System Compliance Technologies identification and evaluation

Summary of Major Public Comments and EPA Responses

Many commenters stated that the POU/ POE water treatment industry may already have multiple products that can reduce PFAS chemicals to below the final MCLs. Additionally, some commenters stated that the influent used (i.e., the challenge water) to test these POU/POE products often contains much higher concentrations of PFAS than would normally be found in most source waters. Commenters also pointed out that under NSF/ANSI, 53 and 58 certifications exist for total PFAS (PFOA, PFOS, PFHxS, PFHxA, and PFDA), as well as perfluoroheptanoic acid (PFHpA), PFHxS, and PFNA individually. However, SDWA Section 1412(b)(4)(E)(ii) requires that SSCTs achieve compliance with the MCL or treatment technique. While devices certified to the NSF/ANSI standards must be demonstrated to significantly reduce PFAS concentrations and, in many cases, can reasonably be expected to treat below this rule's MCLs, the current standards and certification procedures do not assure compliance with this rule. In particular, PFBS and HFPO-DA have no certification standards at this time and the certification standards for PFOA, PFOS, and PFHxS are above this rule's MCL. The certification standards for PFOA, PFOS, and PFHxS are 20 ng/L, compared to the MCLs of 4.0 ng/L for PFOA and PFOS, as well as 10 ng/L for PFHxS; the total PFAS certification standard is 20 ng/L effluent comprised of PFOA, PFOS, PFHxS, PFHxA, and PFDA compared to an Hazard Index of 1 for mixtures of PFHxS, PFNA, HFPO-DA and PFBS. Since the NPDWR has standards that NSF/ANSI is currently unable to verify, POE/POU technologies could potentially not achieve compliance contrary to SDWA Section 1412(b)(4)(E)(ii), which requires that SSCTs achieve compliance with the MCL. While POU/POE technologies may provide significant levels of protection, and the EPA anticipates they will eventually comply with the NPDWR, there is not yet a systematic verification process in place for the level of protection provided by these devices. As mentioned in the proposal, the EPA is aware that the NSF/ANSI Drinking Water Treatment Unit Joint Committee Task Group is in the process of updating their standards; should these future standards meet the NPDWR, the EPA could revise the SSCT list to include POE/POU.

Many commenters also pointed out numerous challenges surrounding POU/POE as a compliance option for some PWSs such as resident cooperation, operation and maintenance, monitoring, and implementation of distributed treatment approaches. The EPA agrees that implementation of POU/POE as a compliance option for any NPDWR can be challenging for some PWSs but also agrees with commenters who noted that POU/POE can provide flexibility and compliance options to small water systems or certain non-transient non-community water systems (NTNCWS) such as schools, factories, office buildings, and hospitals that provide their own water.

The EPA received many comments that other POU devices other than RO/NF should be acceptable ways to meet the MCLs for small systems. For instance, commenters noted that a combination GAC/AIX device with filters could reduce PFAS concentrations to below the MCL

values. The EPA agrees and has changed wording in the final rule preamble and related supporting documents that implied that only RO/NF POU devices would be able to meet a future certification standard. The EPA notes that for small systems, as long as the proposed POU/POE devices are certified by an appropriate third-party certifier (e.g., ANSI/NSF), they would meet the requirements of this regulation. The EPA also received many requests to change the way data was displayed in tables 20 and 22 in the final rule, which summarized proposed SSCTs for PFAS removal and total annual cost per household for candidate technologies. In the proposal, the EPA wrote that this data was "Not Applicable" because of the economies of scale for centralized treatment. The EPA has changed the way this is displayed by replacing the term "Not Applicable" with "Data Unavailable." The EPA notes that neither of these changes imposes nor relieves any rule requirements and only serve to recharacterize the way the EPA reports available technologies.

The EPA asked for comment on the national level analysis of affordability of SSCTs and specifically on the potential methodologies presented in the EA. A couple of commenters recommended the EPA not use median household income (MHI) in the affordability analysis. The EPA decided to retain the MHI measure of income in its primary national level SSCT affordability methodology given the value is easily understandable and available, providing a central tendency for income that is representative of a whole community's ability to pay and is not unduly influenced by outlier values. However, in this rulemaking, the EPA recognizes the value in examining alternative measures of a community's ability to afford an SSCT, so the agency chose to include supplemental analyses that use alternative metrics, specifically 1 percent of MHI, 2.5 percent of lowest quintile income (LQI), and an analysis accounting for financial assistance. These supplemental analyses help to characterize affordability when considering the marginal impact, disadvantaged community groups, and subsidization.

Some commenters stated that the data the EPA used to inform current water rates from the 2006 Community Water System Survey (CWSS) is outdated. While dated, the data from the 2006 CWSS remains the best available dataset for this national level analysis and affordability determination for the following reasons: (1) the CWSS survey used a stratified random sample design to ensure the sample was representative, and (2) these responses can be extrapolated to national estimates since the survey has a known sampling framework, and the data can be organized by system size, source, and ownership (USEPA, 2020).

Some commenters recommended the EPA extend the affordability analysis to medium and large systems. The EPA disagrees with this recommendation, as the purpose of this analysis is to determine if available SSCTs are affordable, per SDWA Section 1412(b)(4)C(ii) Additionally, the water sector has significant economies of scale so if a centralized technology is affordable for small systems, it will be for medium and large systems as well. Therefore, the EPA chose to continue to analyze small system technologies rather than include medium and large systems.

Some commenters specifically disagreed with one of the EPA's supplemental affordability analyses that examined the impact of the rule when accounting for the financial assistance through BIL and other sources that are generally available to small systems. These commenters

stated that the EPA should not assume that this funding will be available or enough to cover the small system capital costs associated with the rule. The EPA conducted this supplemental analysis in response to the recommendations of the Science Advisory Board (SAB), which stated, "[i]f this funding is readily available to many or most systems facing affordability problems, it seems appropriate to take the availability of this funding into account in determining national level affordability. (USEPA, 2002)." The EPA disagrees with these commenters as this significant funding should be generally available, and the EPA continues its efforts to help PWSs access it. It is therefore reasonable to consider the burden reduction in the supplemental affordability analysis.

Some commenters disagreed with the EPA's affordability determination because they stated it was based on inaccurate treatment cost information. A couple of commenters presented their own estimates for small system household costs and compared these estimates to the EPA's affordability threshold and concluded the rule is unaffordable. The EPA disagrees with many of the underlying assumptions in the commenters' cost estimates that, on whole, result in overestimated household costs. These commenters cited cost information that is not representative of the range of treatment costs nationally, and the EPA disagrees with the commenter's cost model that systematically overestimates capital operation and treatment costs. The EPA updated the affordability analysis for the national affordability determination using the updated treatment cost curves (discussed in section XII.D) and found for systems serving between 25 and 500 people, that the upper bound estimated annual household treatment costs for GAC exceed the expenditure margin. Lower bound estimated annual household treatment costs for GAC do not exceed the expenditure margin; for more information please see section XII. These exceedances are primarily driven by capital costs and attributable to the use of high-cost materials (e.g., stainless steel) in the upper bound estimates. Systems using low-cost materials, but with source water characteristics otherwise set to the upper bound (e.g., influent PFAS at approximately 7,000 ng/L, influent total organic carbon [TOC] at 2 mg/L), would fall below the expenditure margin. Although costs increase in some scenarios, the increases are not significant enough to change the conclusions about affordability. Technologies are affordable for all small systems when the technologies do not use the high-end materials. Technologies that do not use high end materials are available for small systems. For more information on the EPA's response to comments on treatment costs please see section XII. The EPA also disagrees that there are no affordable compliance technologies for small systems as the EPA has demonstrated that SCCTs are available below the affordability threshold using the best available peer reviewed information to support the agency's cost estimates.

Individual Public Comments

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045044)

Regarding small system compliance technologies (SSCTs), NJDEP has primarily observed anion exchange proposed due to the additional backwashing required for operating GAC vessels and

discharge concerns with reverse osmosis. Of the 24 permits issued by NJDEP for systems with capacity less than one MGD, 17 were for anion exchange and seven were for GAC.

EPA Response: Please see section 10.5 of the EPA response in this *Response to Comments* document. The EPA thanks NJDEP for sharing their observations with regard to SSCTs.

Wyoming Department of Environmental Quality (WDEQ) (Doc. #1716, SBC-044761)

WDEQ recommends that EPA (1) provide an analysis of the operational costs for lesser-quality source waters, specifically higher Total Dissolved Solids and Total Suspended Solids content, which lessen the effectiveness of PFAS BATs, (2) provide further information as to whether the cost of Small System Compliance Technologies (SSCTs) would be affected, and (3) determine whether this analysis changes EPA's findings that the identified candidate technologies meet SSCT affordability criterion.

EPA Response: Please see section 10.5 of the EPA response in this *Response to Comments* document. The EPA evaluated the concerns raised by the commenter in the proposed and final rule. For instance, influent TOC levels, pre-treatment prior to BATs to remove for example for total suspended solids (TSS), and effects on small systems were considered (for additional information, please see the *Technologies and Costs for Removing Per- and Polyfluoroalkyl Substances from Drinking Water* supporting document as well as the discussion in the final rule preamble, Section X).

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045236)

7. EPA requests comment on the type of assistance that would help small public water systems identify laboratories that can perform the required monitoring, evaluate treatment technologies, and determine the most appropriate way to dispose of PFAS contaminated residuals and waste the systems may generate when implementing the rule.

CT DPH recommends that EPA provide a table or chart with evaluation of treatment technologies for removal of PFAS, including up to date information on when to use or not use GAC, IX, or both in series. For instance, if a particular PWS has higher concentrations of short chain PFAS, EPA might recommend using IX instead of GAC. Further, there is a wide range of IX media available. Guidance on which types to use and when would be beneficial. EPA should also be aware of current supply chain issues for GAC and IX vessel production which could delay implementation by six to twelve months. For assistance with residual PFAS waste going to landfills this is going to rely on the still to be determined CERCLA hazardous waste designation for PFAS and any CERCLA exemptions for landfills.

EPA Response: Please see section 10.5 of the EPA response in this *Response to Comments* document. An evaluation of treatment technologies was published in the *Best Available Technologies and Small System Compliance Technologies for PFAS in Drinking Water*

document. The EPA notes that site-specific considerations, such as water chemistry, will dictate the choice of BAT and pilot studies are recommended. In consideration of potential problems surrounding capital improvement timeframes, the EPA has provided compliance flexibility by providing a two-year capital improvements extension of the MCL compliance deadline allowed by Section 1412(b)(10) of SDWA. A CERCLA designation does not require waste to be treated in any particular fashion, nor disposed of at any particular type of landfill. The designation also does not restrict, change, or recommend any specific activity or type of waste at landfills. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Environmental Protection Network (EPN) (Doc. #1773, SBC-043848)

We further agree that EPA has appropriately identified small system compliance technologies as GAC and AIX for all small systems serving 25 to 10,000 people, with RO and NF also being BAT for systems serving 3,300 to 10,000 people.

EPA Response: Please see section 10.5 of the EPA response in this *Response to Comments* document.

Oklahoma Department of Environmental Quality (DEQ) (Doc. #1616, SBC-043050)

Concerns with POU/POE Treatment Devices

POU/POE devices should not be considered a compliance option for the PFAS MCL's until removal standards meet the MCL's.

Even if standards would align with the final MCL's, many states would still be hesitant to approve POU/POE devices as a compliance option. While this option might seem like an economical alternative, the POU/POE option has sometimes been reported as more expensive over time as compared to other alternatives available. Factors such as ongoing operation and maintenance, monitoring, testing, and replacement drive these costs. Concerns have been raised that these devices may not be properly maintained. Additionally, the POU/POE compliance option requires 100% participation from the community, which is difficult to maintain.

EPA Response: Please see section 10.5 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044110)

Point of Use and Point of Entry Devices

ASDWA recommends that POU/POE devices not be considered a compliance option for the

PFAS MCL until PFAS removal standards meet the MCL. Once standards align with the MCLs, ASDWA recommends limiting the compliance option for using POU/POE to very small systems serving 250 or fewer persons.

The final PFAS NPDWR should clearly outline that point-of-use (POU) and point-of-entry (POE) devices may not be a viable option for many systems. Additionally, the final rule should clearly state that the POU/POE option can only be pursued if the standards for the devices can reliably and consistently meet the MCL. Currently, POU/POE devices are not a viable or feasible option for compliance with the proposed PFAS MCLs. Current standards for POU/POE devices include NSF/ANSI 53: Drinking Water Treatment Units – Health Effects and NSF/ANSI 58: Reverse Osmosis Drinking Water Treatment Systems. The current standards for these treatment units allow a maximum effluent concentration of 20 ppt for total PFAS, 20 ppt for PFHpA, 20 ppt for PFHxS, 20 ppt for PFOA, 20 ppt for PFOS, and 6 ppt for PFNA. Additionally, current standards do not have reference concentrations for PFBS or GenX. While NSF has indicated it plans to incorporate additional PFAS and require treatment to levels designated by EPA's final MCL values, until such time that these standards are updated, POU/POE devices should not be considered a compliance option for the PFAS MCL.

Once removal standards align with the final MCL, many primacy agencies will still be hesitant to approve POU/POE devices as a compliance option. Recently published research found that resident cooperation, operation and maintenance, monitoring, and the actual implementation of distributed treatment approaches were repeatedly listed as the greatest compliance concerns [FN1: Alfredo, K., Wilson, M., and Roberson, A. Management of point-of-use and point-of-entry for regulatory compliance: Survey of state administrators. https://doi.org/10.1002/aws2.1334].

While some primacy agencies allow and encourage the use of POU/POE devices as a compliance mechanism for small systems, others do not allow POU/POE in any circumstance. The same study mentioned above found that most primacy agencies and utilities described systems of approximately 30–50 connections as the most successful. Most survey respondents indicated restricting the use of POU/POE to water systems with less than 500 connections (this number is likely on the high side). ASDWA recommends that the compliance option for using POU/POE be limited to very small systems serving 250 or fewer connections.

The final rule should include language that while POU/POE devices are an option, these devices are not a viable option in many circumstances. While this option may seem like an economical alternative, several primacy agencies have reported that when implemented for other contaminants, the POU/POE option becomes more expensive over time compared to other available alternatives. Factors such as device approval, ongoing operation and maintenance in perpetuity, monitoring, testing, and replacement drive these costs. Sampling to ensure the devices are working is a specific concern due to the cost of PFAS sampling and the access to homes for sampling locations. Primacy agencies have reported that maintaining compliance on POU systems can take significant staff resources. Primacy agencies have also raised concerns regarding biofilm growth should the devices be improperly maintained. Additionally, the POU/POE compliance option requires 100% participation from the community, which is difficult

to maintain in perpetuity in most communities and would not be possible in systems serving more than 250 connections. The installation of POU devices often requires overtime work after hours to gain access to the customer's homes, and for the tracking of these devices and their monitoring results. Additionally, maintenance becomes increasingly difficult as more POU devices are installed.

EPA Response: Please see section 10.5 of the EPA response in this *Response to Comments* document. The agency acknowledges the study by Alfredo et al. (2023) referenced in the comment and plans to consider this information when considering POU and POE devices as SSCTs in the future.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044193)

3. NCDEQ recommends that POU/POE devices should not be considered a compliance option for the PFAS MCL until PFAS removal standards meet the MCL. Once standards align with the MCLs, NCDEQ recommends that the compliance option for using POU/POE be limited to very small systems serving 250 or fewer persons who have unrestricted access to each POU/POE

The final PFAS NPDWR should clearly outline that point-of-use (POU) and point-of-entry (POE) devices may not be a viable option for many systems. Additionally, the final rule should clearly state that the POU/POE option can only be pursued if the standards for the devices can reliably and consistently meet the MCL. Currently, POU/POE devices are not a viable or feasible option for compliance with the proposed PFAS MCLs. Current standards for POU/POE devices include NSF/ANSI 53: Drinking Water Treatment Units – Health Effects and NSF/ANSI 58: Reverse Osmosis Drinking Water Treatment Systems. The current standards for these treatment units allow a maximum effluent concentration of 20 ppt for total PFAS, 20 ppt for PFHpA, 20 ppt for PFHxS, 20 ppt for PFOA, 20 ppt for PFOS, and 6 ppt for PFNA. Additionally, current standards do not have reference concentrations for PFBS or GenX. While NSF has indicated it plans to incorporate additional PFAS and require treatment to levels designated by EPA's final MCL values, until such time that these standards are updated, POU/POE devices should not be considered a compliance option for the PFAS MCL.

Once removal standards align with the final MCL, NCDEQ will still be hesitant to approve POU/POE devices as a compliance option. Recently published research found that resident cooperation, operation and maintenance, monitoring, and the actual implementation of distributed treatment approaches were repeatedly listed as the greatest compliance concerns [FN2: Alfredo, K., Wilson, M., and Roberson, A. Management of point-of-use and point-of-entry for regulatory compliance: Survey of state administrators. https://doi.org/10.1002/aws2.1334]. The same study mentioned above found that most state agencies and utilities described systems of approximately 30–50 connections as the most successful. NCDEQ recommends that the compliance option for using POU/POE be limited to very small systems serving 250 or fewer persons where the system has unrestricted access to the POU/POE.

The final rule should include language that while POU/POE devices are an option, these devices are not a viable option in many circumstances. While this option may seem like an economical alternative the POU/POE option becomes more expensive over time as compared to other alternatives available. Factors such as device approval, ongoing operation and maintenance in perpetuity, monitoring, testing, and replacement drive these costs. Sampling to ensure the devices are working is a specific concern due to the cost of PFAS sampling and the access to sampling locations. Determining compliance on POU systems can take significant staff resources. Biofilm growth is a concern with this option should the devices be improperly maintained. Additionally, the POU/POE compliance option requires 100% participation from the community, which is difficult to maintain in perpetuity in most communities and would not be viable in systems serving more than 250 persons. The tracking of these devices and their monitoring results, in addition to the maintenance, becomes increasingly difficult as more POU devices are installed.

EPA Response: Please see section 10.5 of the EPA response in this *Response to Comments* document. The agency acknowledges the study by Alfredo et al. (2023) referenced in the comment and plans to consider this information when considering POU and POE devices as SSCTs in the future.

A. O. Smith Corporation (Doc. #1674, SBC-043701)

5. Small System Compliance Technologies

A. O. Smith is encouraged that the EPA recognizes the key role that POU and POE technologies play in assisting small water systems with a cost-effective approach for SDWA compliance. POU and POE systems that treat drinking water "at the tap" or whole household level, have the additional value of removing (or significantly reducing) contaminants below a prescribed MCL, which results in further lowering the risk from exposure to potentially harmful substances, and thus lowers the risk of an adverse health outcome. This is especially acute when the drinking source is a private well. However, even households that receive their drinking water from a public water system or supply can benefit from these technologies considering that drinking water that has been treated centrally traverses through distribution pipes where recontamination can occur. Therefore, POU and POE systems provide additional protection to sensitive populations where exposures to drinking water contaminants are more likely to result in adverse health outcomes including increased mortality. These populations include newborns, children, pregnant mothers, immunocompromised individuals, and the elderly. [FN14: COST BENEFITS OF POINT-OF-USE DEVICES IN REDUCTION OF HEALTH RISKS FROM DRINKING WATER, Marc Verhougstraete, Ph.D., Kelly Reynolds, Ph.D., Akrum Tamimi, Ph.D., Charles Gerba, Ph.D., Water Quality Research Foundation, November 16, 2016.]

a. Technologies and Implementation Strategies

As it relates to small system compliance technologies and implementation strategies in the context of meeting a prescribed MCL, the SDWA controls and the EPA has provided long-

standing guidance and requirements for small systems that chose to use POU and/or POE technologies for MCL compliance. [FN15: Safe Drinking Water Act § 1412(b)(4)(E)(ii); see also, Point-of-Use or Point-of-Entry Treatment Options for Small Drinking Water Systems, United States Environmental Protection Agency, Office of Water, 4607, EPA 815-R-06-010, April 2006.] A prerequisite requirement is that only POU or POE units that have been independently certified in accordance with American National Standards Institute (ANSI) product standards can be used as part of a compliance strategy. [FN16: Id.] In that regard the Company concurs with this requirement and currently has POU and POE products that are third-party certified to the industry's current standards for PFOA and PFOS. [FN17: NSF/ANSI 53: Drinking Water Treatment Units – Health Effects and NSF/ANSI 58: Reverse Osmosis Drinking Water Treatment Systems.] The Company further recognizes that while the PFAS NPDWS recognizes the potential for these products to be utilized by small systems for MCL compliance, it did not include POU devices as a current compliance option "because the regulatory options under consideration require treatment to concentrations below 70 ppt total of PFOA and PFOS… and the affordability conclusions for POU RO should be considered preliminary because they reflect the costs of devices certified under the current standard, not a future standard." [FN18: 88 FR 18688 (Footnote 5).]

First, EPA only considered POU RO systems in its analysis. As discussed earlier, a wide array of POU and POE technologies can remove PFAS chemicals. POU technologies currently used for this purpose include Filters and RO systems. POU Filters often contain activated carbon, but typically other types of media (e.g., anion exchange media) are also added to improve the removal efficacy of PFAS. POE treatment for PFAS can be accomplished using anion-exchange systems, whole-house filtration, and whole-house RO systems. Many of these POU and POE systems are capable of PFAS reduction, and some have been certified for PFOA and PFOS reduction to ANSI standards and A. O. Smith recommends that these technology methods of POU filtration and POE options be added to Table 20 as eligible product categories. [FN19: 88 FR 18686-18687 (see Table 20)]

Second, as the EPA is aware, and for accuracy, NSF/ANSI 53 and 58 have been amended to reflect concentrations below 20 ppt for PFOA and PFOS, which is a significant step in protecting consumers. The NSF/ANSI testing procedures to certify products to the standard utilize a "challenge" or influent water that meets or exceeds 95% of the concentration levels found in drinking water. In practice this means that if the delivered water to a home has a concentration of 70 ppt of PFOA and PFOS the certified device will remove 95% leaving 3.5 ppt, which would meet the proposed MCL.

Notwithstanding the operative effect of products certified to the current NSF/ANSI 53 and 58 standards for PFOA and PFOS, those bodies, as well as other stakeholders that sit on the NSF/ANSI Drinking Water Treatment Unit Joint Committee Task Group are actively reviewing updates to both standards based on the EPA's proposed PFAS NPDWS to ascertain the feasibility and practicality of amending the standards to a 4 ppt concentration level.

Lastly, A. O. Smith recommends that the EPA revisit its regulatory recognition of POU and POE devices that are certified to NSF/ANSI 53 and 58 in its PFAS NPDWS Final Rule, including allowing small systems to use currently certified NSF/ANSI devices for MCL compliance.

EPA Response: Please see section 10.5 of the EPA response in this *Response to Comments* document. The EPA has also amended language to include all types of POU/POE systems that meet standards as opposed to only RO systems.

A. O. Smith Corporation (Doc. #1674, SBC-043703)

Lastly, and as a cited previously, SDWA allows small public water systems serving 10,000 or less connections to use POU and POE treatment systems for MCL compliance consistent with EPA regulations and guidance, as well as state-specific approvals. [FN22: See, Arsenic SSCT - 40 CFR Section 141.62(d), Radionuclides SSCT - 40 CFR Section 141.66(h), and Point-of-Use or Point-of-Entry Treatment Options for Small Drinking Water Systems - EPA 815-R-06-010).]That said, the proposed PFAS NPDWS only contemplates small public water systems with less than 3,300 connections utilizing POU or POE systems for MCL compliance. While the EPA based its assumption due to the limits of the WBS Model, A. O. Smith recommends – and consistent with SDWA and preexisting guidance for systems serving 10,000 or less connections – that Tables 20 and 22 be expanded to allow small systems to consider these options for populations up to 10,000 by replacing the term "Not Applicable" with "Data Unavailable", which will help clarify that small water systems should conduct their analysis to determine the feasibility of this technology for any project size within that range and allow them to choose the best solution available. [FN23: 88 FR 18687.]

EPA Response: Please see section 10.5 of the EPA response in this *Response to Comments* document. In response to commenter's request, the EPA changed the way information was displayed; the EPA notes that neither of these changes imposes nor relieves any rule requirements and only serve to recharacterize the way the EPA reports available technologies.

Water Quality Association (WQA) (Doc. #1694, SBC-044982)

• The EPA has always allowed consideration of both POU and POE as a Small Systems Compliance Technology (SSCT) for all size categories. However, Table 22 suggests that this technology should be limited to communities of 3,300 or less as it says POU RO systems are "Not Applicable" for systems that serve between 3,300 and 10,000 people. This is based on an EPA assumption due to the limits of the WBS Model. WQA requests that Tables 20 and 22 [FN2: Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation, 2023, Table 20 & Table 22. EPA-HQ-OW-2022-0114-0027.] clarify this gap by stating in the table "Data Unavailable" and encourage small water systems to conduct an analysis to determine the feasibility of this technology for any project size within that range.

• There are two existing national standards for testing and certifying POU and POE water filtration systems that offer elective claims to reduce PFAS chemicals, including PFOS and PFOA, to a cumulative 20 ppt. These standards are NSF/ANSI 53: Drinking Water Treatment Units – Health Effects and NSF/ANSI 58: Reverse Osmosis Drinking Water Treatment Systems. These standards also cover claims for several other water-related contaminants and are "reasonably anticipated" to meet parameters set by the EPA's final rule on PFAS, considering all NSF/ANSI standards either meet or exceed the EPA's MCLs set for other contaminants. [FN3: NSF/ANSI 53 and 58 meet or exceed EPA's maximum contaminant levels or action levels for several contaminants such as Lead, Copper, Arsenic, Nitrates, Chromium (total), and Mercury.]

o There is already an active NSF/ANSI Drinking Water Treatment Unit Joint Committee Task Group reviewing updates to both standards based on the EPA's proposed rule and health index approach.

EPA Response: Please see section 10.5 of the EPA response in this *Response to Comments* document. In response to commenter's request, the EPA changed the way information was displayed; the EPA notes that neither of these changes imposes nor relieves any rule requirements and only serve to recharacterize the way the EPA reports available technologies.

Water Quality Association (WQA) (Doc. #1694, SBC-044986)

Treatment Technologies: POU/POE Strategies to Reduce PFAS in Drinking Water

Treatment technologies of RO, AIX, and those that utilize carbon have all been available for contaminant reduction applications in POU and POE for decades, as they have been for larger public water system applications. The EPA requested input specifically on the use of Granular Activated Carbon Filters (GAC Filters), which is one type of POU Filter, but often the POU Filters which are used for PFAS removal use a carbon-block technology. WQA feels that a more inclusive term to describe this technology category is "POU Filter" or "POU Filtration," and all of our comments relative to this carbon technology category should be taken in that context.

The EPA only considered POU RO systems in its analysis, but a wide array of POU and POE technologies can remove PFAS chemicals. POU technologies currently used for this purpose include Filters and RO systems. POU Filters often contain activated carbon, but typically other types of media (e.g., anion exchange media) are also added to improve the removal efficacy of PFAS. POE treatment for PFAS can be accomplished using anion-exchange systems, whole-house filtration, and whole-house RO systems.

Many of these POU and POE systems are capable of PFAS reduction, and some have been certified for PFOA and PFOS reduction to American National Standards. All should be recognized as available solutions for public water system compliance. The determination of the best solution should be made by the public water system provider. Costs and other considerations, such as influent levels, will vary widely, as with any technology solution, whether treatment is provided at the source, tap, or some combination. Proven technologies exist,

and the available options should not be unreasonably restricted by regulation. WQA recommends that various methods of POU filtration and POE (e.g., Anion Exchange) options be added to Table 20 as product categories. [FN5: EPA-HQ-OW-2022-0114-0027, Table 20] These technologies should be referred to as best available technologies (BATs) in addition to POU RO, which is already included throughout the proposed regulation.

POU and POE products also allow leveraging of multiple technologies in a solitary product. This will enable manufacturers to maximize synergies between treatment approaches, providing a more comprehensive and longer-lasting solution. This can be accomplished while maintaining a simple installation and user experience as it is being provided in a single product. One example of this would be the addition of an activated carbon post filter to an RO-based product.

As stated previously, a review of product performance data produced by WQA's accredited laboratory suggests that the POU/POE water treatment industry may already have multiple products available that can reduce PFAS chemicals to near or below the proposed MCL. Detection limits in place at the time of testing were at 5 ppt for PFOA, HFPO-DA, PFDA, PFHpA, and PFNA and 10 ppt for PFOS, PFBS, and PFHxS, respectively. The availability and efficacy of these systems are expected to increase by the enforcement date.

EPA Response: Please see section 10.5 of the EPA response in this *Response to Comments* document. The EPA has amended language to include all types of POU/POE systems that meet standards as opposed to only RO systems.

Water Quality Association (WQA) (Doc. #1694, SBC-044980)

• A review of product performance data produced by WQA's accredited laboratory suggests that the POU/POE water treatment industry may already have multiple products that can reduce PFAS chemicals to near or below the proposed MCL.

o It should be noted that these products are tested using an extremely high influent challenge level of a combined 500 ng/L PFOA and 1000 ng/L PFOS, demonstrating their ability to reduce PFAS at very high concentrations. For comparison, the EPA's cost analysis uses significantly lower influent concentrations for small water systems, 70 ng/L and 264 ng/L. [FN1: Best Available Technologies and Small System Compliance Technologies for PFAS in Drinking Water, EPA-822P-23-009, p. 36. 2023g.] It's conceivable that POU/POE products could reduce to even lower levels and possibly with larger treatment capacities if tested using lower influent concentrations.

• Treatment of PFAS to the proposed levels will introduce significant new challenges for small community water systems, and POU/POE options should remain fully available for consideration as a viable treatment solution in the final rule.

o POU Reverse Osmosis (RO) systems, as mentioned in the proposed rulemaking, are effective in reducing PFAS. However, the EPA should also indicate that other POU and POE filtration systems, such as carbon blocks, Granular Activated Carbon Matrixes (GAC), and Anion

Exchange (AIX), can also treat these contaminants. Treatment technologies used on a large-scale application are generally the same as those used in POU and POE applications.

EPA Response: Please see section 10.5 of the EPA response in this *Response to Comments* document. The EPA has amended language to include all types of POU/POE systems that meet standards as opposed to only RO systems.

Water Quality Association (WQA) (Doc. #1694, SBC-044984)

*Supporting information for WQA's comment can be found in the attached analysis.

In summary, WQA and its members are dedicated to reducing PFAS in drinking water by continuing to develop cost-effective certified POU and POE technologies. These treatment solutions are critically important to assisting small community water systems with compliance. By implementing final barrier POU and POE technologies tailored to the specific needs of a community along with other proposed solutions, the EPA and water treatment industry, in partnership, can help ensure healthier and safer drinking water for all Americans.

Thank you in advance for considering these comments, and we welcome any opportunity to meet with you to discuss these recommendations in greater detail.

Sincerely,

Jeremy Pollack

Director of Government Affairs

Water Quality Association JPollack@WQA.org

WQA Analysis

Proposed National Primary Drinking Water Regulation Rulemaking for PFAS

Docket ID No. EPA-HQ-OW-2022-0114

Water treatment systems, such as POU and POE, can assist with reducing PFAS in drinking water. Many households and businesses currently utilize these final barrier technologies to improve their drinking water quality. Therefore, it is vital for the EPA to incorporate and afford public water systems the flexibility to potentially deploy these water treatment systems to address their compliance obligations under any final NPDWR for PFAS.

Industry Standards

WQA recognizes that the EPA encourages using third-party certified products to ensure that these systems function as intended to remove specific contaminants of concern. WQA offers the following information to ensure the EPA is aligned with WQA on how current industry standards compare to the proposed regulatory goals.

There are currently two existing standards for testing and certifying water filtration systems that offer elective claims to reduce PFOA and PFOS in addition to other PFAS chemicals: NSF/ANSI 53: Drinking Water Treatment Units – Health Effects and NSF/ANSI 58: Reverse Osmosis Drinking Water Treatment Systems. It's important to note that the NSF/ANSI testing procedures utilize a "challenge" or influent water that meets or exceeds 95% of the concentration levels previously found in drinking water based on a dataset compiled from the UCMR 3 data and an additional dataset from the Environmental Working Group (EWG). The challenge levels currently used in the NSF/ANSI testing procedure are:

[Table 1: See Docket ID EPA-HQ-OW-2022-0114-1694]

Supporting documentation states that the "EPA generated costs assuming [community water], systems must meet MCLs for PFOA and PFOS of 4 nanograms per liter (ng/L) each, with initial influent concentrations of 70 ng/L and 264 ng/L, respectively." [FN4: Best Available Technologies and Small System Compliance Technologies for PFAS in Drinking Water, EPA-822P-23-009, p. 36. 2023g.] This Influent Challenge Level is significantly less challenging than the levels used in the standards for POU/POE water treatment systems. The standards allow for testing of a mixture of the seven contaminants listed in the table above at a total PFAS challenge level of 2,160 ppt; a mixture of PFOA and PFOS at a challenge level of 1,500 ppt, or for individual claims to be made for PFHpA, PFHxS, PFNA, PFOA, and PFOS at the influent challenge levels noted in the table above. Two PFAS compounds, PFBS and PFDA, were excluded from the individual contaminant reductions because their occurrence levels in the dataset mentioned above were found to be less than their health advisory levels at that time.

It should be noted that both standards are under continuous maintenance and are expected to be updated in advance of the EPA's promulgated regulation for PFAS. However, three gaps exist between the current standards and the EPA's proposed rule, all of which will be reviewed and expected to be revised in accordance with the final rule:

1. The current NSF/ANSI standards set the maximum effluent at 20 ppt for the total PFAS claim, for PFOA and PFOS combined, and for individual claims for PFHpA and PFHxS. PFNA's maximum effluent level is set at 6 ppt.

2. The current NSF/ANSI standards do not address GenX. The selection of 20 ppt was made based on State level activity at the time, and the exclusion of GenX was decided upon by the Joint Committee due to the lack of available occurrence data, which is needed to establish a conservative challenge level, and also because the EPA shared information with the NSF Task Group indicating that they were reviewing GenX. This data is expected to be available with the release of the UCMR 5 data. The EPA should provide ample time after the publishing of that information for water systems to review and respond in addition to working with above-standard committees and other stakeholders such as WQA to adapt accordingly.

3. The current NSF/ANSI standards include requirements for the maximum levels of certain PFAS chemicals detected during material safety/extraction testing, NSF/ANSI 53 and 58 redirects to NSF/ANSI/CAN 600: Health Effects Evaluation and Criteria for Chemicals in

Drinking Water. This standard is currently using the 2016 EPA Health Advisory of 70 ppt, which requires the summation of PFOA and PFOS for materials that extract these compounds. The Task Group that maintains the health effects criteria has indicated that any EPA PFAS regulations will be proposed to the Joint Committee to supersede the existing Health Advisory for material safety/extraction evaluations.

These standards are "reasonably anticipated" to meet parameters set by the EPA's final rule considering all NSF/ANSI standards either meet or exceed the EPA's MCLs set for other contaminants. Additionally, there is already an active NSF/ANSI Drinking Water Treatment Unit Joint Committee Task Group that will be reviewing updates to both standards based on the EPA's rule and health index approach. Their recommendations will be brought to the full Joint Committee for review and approval.

Furthermore, standards developed through the American National Standards Institute (ANSI) consensus-based process are established with the representation of all interested and affected stakeholders, including manufacturers, non-profits, advocacy organizations, government representatives (such as the EPA), and academia. The development process weighs scientific research and the feasibility of treatment technology in relation to potential health and environmental risks. At this time, all NSF/ANSI Standards meet or exceed established POU and POE effluent criteria at EPA-regulated levels for all drinking water health contaminants.

EPA Response: Please see section 10.5 of the EPA response in this *Response to Comments* document. The EPA has amended language to include all types of POU/POE systems that meet standards as opposed to only RO systems. The EPA has provided compliance flexibility by providing a two-year capital improvements extension of the MCL compliance deadline allowed by Section 1412(b)(10) of SDWA. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Water Quality Association (WQA) (Doc. #1694, SBC-044988)

Moreover, under the Safe Drinking Water Act (SDWA), POU/POE water treatment systems can only be used for compliance in small water systems (10,000 people or less), although their use is contingent on state-specific guidelines. The EPA has always allowed consideration of POU and POE as a Small Systems Compliance Technology (SSCT) for all size categories served by small systems (e.g., Arsenic SSCT - 40 CFR Section 141.62(d), Radionuclides SSCT - 40 CFR Section 141.66(h), Point-of-Use or Point-of-Entry Treatment Options for Small Drinking Water Systems - EPA 815-R-06-010). WQA recommends that Tables 20 and 22 be expanded to allow small systems to consider these options for populations up to 10,000 by replacing the term "Not Applicable" with "Data Unavailable."[FN7: EPA-HQ-OW-2022-0114-0027, Table 20 & 22] This will help clarify that small water systems should conduct their analysis to determine the feasibility of this technology for any project size within that range and allow them to choose the best solution available.

Considering ongoing issues with compliance for other contaminants and some of the complications and limitations associated with the treatment of PFAS chemicals, these water systems are more likely to utilize POU/POE going forward. According to the EPA's Safe Drinking Water Information System (SDWIS) data, between 2008 and 2018, 2720 small community water systems experienced at least one MCL violation, with a total of 31,127 MCL violations reported. Of those, 68% were very small systems providing water to less than five people, many of which were chronic violations. [FN8: Lane, K., Reckhow, D., Tobiason, J., & Kumpel, E. (2023). Triple-bottom-line approach for comparing point-of-use/point-of-entry to centralized water treatment. AWWA Water Science, e1320. https://doi.org/10.1002/aws2.1320 Page 5.] WQA would welcome the opportunity to work with the EPA on guidance for systems that elect to use POU/POE technology.

EPA Response: Please see section 10.5 of the EPA response in this *Response to Comments* document. In response to the commenter's request, the EPA changed the way information was displayed; the EPA notes that neither of these changes imposes nor relieves any rule requirements and only serve to recharacterize the way the EPA reports available technologies.

Water Quality Association (WQA) (Doc. #1694, SBC-044985)

Lab Capabilities

WQA, like other testing and certification agencies, has a laboratory fully accredited by the American National Standards Institute's National Accreditation Board (ANAB) and Standards Council of Canada (SCC). The laboratory provides certification of products and indicates that a third-party organization has monitored the manufacturer's operations to ensure they meet guidelines for manufacturing processes and materials used. Products are tested to ensure compliance with industry standards, performance, and certification requirements. Although current industry standards test to 20 ppt for PFAS chemicals, WQA's Laboratory has been able to review existing performance testing data to 5 ppt (PFOA, HFPO-DA, PFDA, PFHpA, PFNA) and 10 ppt (PFOS, PFBS, PFHxS). WQA can currently evaluate product testing to a reporting limit of 1 ppt for PFAS, which will increase the precision in determining the POU/POE industry's ability to assist with addressing this public health issue.

Certification of products, processes, or services provides assurance that they comply with specified requirements in standards and other normative documents. In the case of certified POU/POE products, accredited Certification Bodies (CBs) develop certification schemes that include initial product testing, initial factory inspection, and compliance with the applicable health and safety product standards, including marking and labeling requirements. CBs also require annual surveillance inspections that consider the quality management system, retesting requirements, and frequency, modifications to certified products, and revisions to product standards.

EPA Response: Please see sections 10.1 and 10.5 of the EPA response in this *Response to Comments* document.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045041)

Point-of-Use Treatment:

NJDEP recommends that EPA provide clarification on if Point-of-Use (POU) GAC, reverse osmosis, and anion exchange systems meet the definition of Best Available Technologies (BAT)s under Section A of its proposal. EPA would require that the BATs bring all water in a system into compliance. However, POU treatment units inherently can only treat water at a single line, or sample location in the system, and would not effectively treat all water in the system.

EPA Response: Please see sections 10.5 and 10.1 of the EPA response in this *Response to Comments* document.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045116)

c. The feasibility of POU filters should be considered for non-community systems as discussed elsewhere in these comments.

EPA Response: Please see section 10.5 of the EPA response in this *Response to Comments* document.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045092)

Reliance on Point of Use (POU) treatment, while well-intentioned may not always be small system friendly, especially for systems near the 3,300 population "cut-off" identified in the proposed regulation. We support the consideration of POU treatment in the right application, however, it is necessary that EPA provide additional information about how to establish representative sampling protocols following POU installation and guardrails on how to implement a POU program. The existing POU guidance from EPA predates PFAS and does not provide adequate support to states weighing their options; it also provides broad authority pertaining to creating "representative" sampling protocols post-POU installation. Given that there are no or limited NSF/ANSI standards for the reduction of PFAS, either that certification will need to happen, or EPA will need to provide treatment specifications to ensure it truly is Best Available Technology (BAT). We are concerned that lower income citizens are unable to afford to replace their own filters when needed and would otherwise be at the mercy of the water system to provide replacement filters/cartridges based on, at times, an assumption that the treatment has worked effectively up to the point of replacement.

EPA should consider limiting the POU aspect of the rule to NTNC systems and limited community systems. There are concerns with the regulation as currently drafted whereby it would mean a water system would be attempting to manage upwards of 1,000 tap filters which may not be achievable. The post-installation framework must be set in regulation and be uniform. The regulation needs to actively and thoughtfully guard against a scenario where a system installs treatment, demonstrates PFAS reduction, transitions to 3-year monitoring, to find out 2.5 years later that they are breaking through and exceeding the Heath Advisory, MCLG, and MCL based on unmaintained POU devices.

EPA Response: Please see section 10.5 of the EPA response in this *Response to Comments* document. The EPA appreciates the commenter's feedback on what kind of guidance to provide. POU/POE devices are rated for treated volumes as well as time; these may come with indicators or must show the device is capable of exceeding a margin of safety for the rating. The EPA notes that POU/POE devices must be maintained by the water system if it is using them for compliance purposes. The EPA is not proscriptive in the chosen method to meet the regulation provided that the system is in fact meeting the regulation.

National Ground Water Association (NGWA) (Doc. #1804, SBC-045460)

1. POE and POU water treatment products, with tested efficacy to a third party NSF/ANSI standard, should be incorporated as approved methodology for small systems to meet compliance.

2. NSF/ANSI 53 as well as NSF/ANSI 58 are current standards that test efficacy to a 70 ng/L endpoint. Currently the ANSI process has incorporated changes to a 20 ng/L endpoint, but will need time to update the standards to meet any new MCL. There should be a grandfathering of such products until the standards are updated.

EPA should provide time in implementation for National Sanitation Foundation (NSF) and American National Standards Institute (ANSI) processes to catch up with regulatory health protection requirements. Third-party certified products protect the consumer.

EPA Response: Please see section 10.5 of the EPA response in this *Response to Comments* document. The EPA agrees that POU RO devices may be a cost-effective option for small systems in some circumstances and should the NSF/ANSI standards change to be at least as stringent as the MCL they may be listed as a SSCT option.

John Mayo (Doc. #2707, SBC-046317)

Regarding the EPA proposed action on PFAS, my comment is 'out of the box', and is the result of 7 years of intensive 'research and investigation' of our local water utility, which is a 'poster child' for the majority of American water utilities, i.e., they are old, outdated, and the cost of bringing them up to par is massive, resulting in many/most not being able to generate the funds required, therefore, something more 'personal' in nature, that is also more cost effective appears

to be the better option. Reverse Osmosis filters eliminate the majority of chemicals, and if necessasry, the EPA could develop one that removes PFAS more efficiently, and then provide each user, such a filter. Filters would allow bother the EPA and more importantly, the consumer, to get, and stay ahead of harmful contaminants; those we know about today, as well as any that may 'graduate' onto the harmful to health list. Less expensive than bringing an antique system up to date, while providing 'immediate' trust and confidence in a 'purer product'.

EPA Response: Please see section 10.5 of the EPA response in this *Response to Comments* document. The EPA agrees that POU RO devices may be a cost-effective option for small systems in some circumstances and should the NSF/ANSI standards change to be at least as stringent as the MCL they may be listed as a SSCT option.

Breast Cancer Prevention Partners (Doc. #2743, SBC-047290)

We also urge you to provide activated carbon filters at the household level to filter contaminants as they are being regulated and mitigated.

EPA Response: Please see section 10.5 of the EPA response in this *Response to Comments* document. The best compliance option for a particular system is a site-specific determination. Should POU activated carbon filters be deemed the best compliance option for a particular system, then that particular system would be responsible for providing and maintaining those devices.

California Association of Mutual Water Companies (Doc. #3072-25, SBC-047372)

My name is Susan Allen, and I am the managing member services director for the California Association of Mutual Water Companies, which is a professional association that helps small and very small systems with connections between 15 and 3,000 throughout the state of California. We would like to raise concerns that are unique to these very small systems that we don't believe the EPA proposal has fully addressed. The first is in the treatment technologies that have been identified. We wanted to make you aware that for other contaminants, the State of California's Division of Drinking Water, which is part of the California State Water Resources Control Board, has identified that the kinds of treatment that you've proposal which are best available technologies are not economically feasible for systems with less than 200 connections, and they're moving toward having very small systems use point of use and point of entry devices. So, we would like to have point of use and point of entry be included as technologies that are available for resources and knowing that the costs include things like pilot testing and a lot of other compliance requirements, those costs would be challenging for small systems to face. We ultimately would also appreciate help in finding options that are scalable to the tiny systems and welcome any work that EPA could do on that front as well.

EPA Response: Please see section 10.5 of the EPA response in this *Response to Comments* document. The EPA agrees that small systems may benefit from compliance technologies that are different from larger water systems. The EPA has published an analysis to

this effect, which is summarized in section 10.4 in the preamble; small systems costs were evaluated in the *Best Available Technologies and Small System Compliance Technologies for PFAS in Drinking Water* document section 6 as well as the *Technologies and Costs for Removing Per- and Polyfluoroalkyl Substances from Drinking Water* document.

Nebraska Department of Environment and Energy (NDEE) (Doc. #1653, SBC-043210)

The identification of POUs (RO/NF) as viable treatment options ignores the difficulty that small systems and their operators encounter in managing treatment technologies. Only the smallest systems with no other option should consider POU devices.

EPA Response: Please see section 10.5 of the EPA response in this *Response to Comments* document. The EPA thanks the commenter for providing its prospective and notes that so long as the rule is being met EPA is not prescriptive on the technology used to meet it. The EPA allows individual systems, provided there are not additional state, local, territorial, or Tribal, rules to consider, to determine the best ways to comply in individual circumstances.

Wyoming Department of Environmental Quality (WDEQ) (Doc. #1716, SBC-044762)

11. WDEQ Has Concerns with Point-of-Use and Point-of-Entry Filtration Devices/or PFAS Treatment and MCL Compliance of Small Systems

WDEQ is concerned with the proposed use of Point-of-Use (POU) and Point-of-Entry (POE) devices for the removal of PFAS from drinking water, while recognizing they may be an appropriate solution in certain circumstances. Manufacturers of these devices have not demonstrated the ability to meet the proposed MCL of 4.0 ppt. Currently, these devices can only remove PFAS down to 20 ppt. POU/POE devices are not regulated by the WDEQ, and it has been WDEQ's experience that homeowners tend to either discontinue use of the POU/POE devices or not maintain them over time. States may not have adequate or sustainable resources to assist homeowners with these devices over time, and the burden would shift to homeowners, who, particularly in overburdened communities, would likely be unable to sustain them in the long term.

WDEQ recommends that EPA reevaluate accepting POU/POE devices regardless of third-party certification achieving standards equal to EPA's PFAS MCLs due to the lack of oversight and accountability inherent in POU device maintenance and operation. If this option is retained in the final rule, EPA needs to recognize the additional burden placed on states to consider and develop appropriate oversight measures.

EPA Response: Please see section 10.5 of the EPA response in this *Response to Comments* document. The EPA thanks commenter for providing its perspective.

Steve Sears (Doc. #2383, SBC-047498)

Dear Michael Regan,

I got tired of waiting and added a Reverse Osmosis Filtration system with ACTIVE CARBON FILTERS. My research found that the ACTIVE CARBON was a major eliminator of the PFAS chemicals in our drinking water. I would like to suggest that the EPA provide funds for the installing of a similar system by homeowners since getting companies like AQUA to do the filtration seems impossible!!

EPA Response: Please see section 10.5 of the EPA response in this *Response to Comments* document. The EPA refers commenter to the summary of major comments for this section. The EPA also notes that POU/POE devices may not be the best solution for every system. The passage of the IIJA, also referred to as the BIL, invests over $11.7 billion in the DWSRF; $4 billion to the DWSRF for Emerging Contaminants; and $5 billion in EC-SDC grants. These funds will be available to assist PWSs with the costs of installation of treatment when it might otherwise be cost-challenging. These funds can also be used to address emerging contaminants like PFAS in drinking water. More information on BIL can be found in section 2.4 of the EPA response in this *Response to Comments* document.

California Association of Mutual Water Companies (Doc. #1676, SBC-043775)

Affordability vs. Economic Feasibility of Treatment Systems

The proposal identifies three treatment technologies available to remove PFAS and advances an assessment that the technologies are affordable based on federal funding allocations to provide support and assistance to small systems and systems serving disadvantaged communities. However, economic feasibility and affordability are two different concepts.

CalMutuals would like to call attention to the fact that the Division of Drinking Water (DDW) of the California State Water Resources Control Board has determined that for other contaminants similar treatment technologies are not economically feasible options for systems with less than 200 connections. As a result, DDW has recommended the use of Point of Use and Point of Entry Devices (POU/POE) for systems with less than 200 connections despite manufacturer disclaimers that these devices are not intended to bring water systems into compliance with official contaminant standards. CalMutuals welcomes EPA engagement in identifying realistic and economically feasible treatment technologies for very small systems and further requests that guidelines for allocation of available funding includes all technologies, including POU/POE if very small systems are required to implement this inferior option. Resources to provide technical support and address costs of devices, installation, monitoring and regulatory compliance are critical to facilitating compliance by very small systems with the proposed MCL.

EPA Response: Please see section 10.5 of the EPA response in this *Response to Comments* document. The EPA found affordable and economical BATs for all system sizes; the

previously mentioned section, as well as the EA and the EPA response to comments on the EA can provide more information.

Anonymous (Doc. #2312, SBC-047307)

Another public commenter, Catherine Buchanan, suggested the use of activated carbon filters while water treatment facilities are updated to treat for PFAs and was baffled by the reluctance of the panel to inform the public of their effectiveness. Upon further research, I found that even the official EPA website has an article titled "Reducing PFAS in Drinking Water with Treatment Technologies" which lists "Activated Carbon Treatment" as an effective adsorbent method for PFAS. Additionally, the article states that the granular activated carbon "has been shown to effectively remove PFAS from drinking water when it is used in a flow through filter mode after particulates have already been removed". I agree with Catherine Buchanan's opinion that the information should be spread more widely. If EPA believes that these filters are not effective enough, then I believe the EPA should suggest alternatives for civilians to better filter their water of these contaminants. While the proposed rule is still being discussed, people every day are drinking water with PFAS, and if/when the final rule is passed, it will take time for the treatment facilities to update. Additionally, information about PFAS should be more widespread since I believe that not many people even know about the existence of these chemicals. Overall, it is crucial that the public is informed to ensure the safety of the public.

EPA Response: Please see section 10.5 of the EPA response in this *Response to Comments* document. The EPA agrees that informed stakeholders make better decisions and plans to continue to communicate information to aid the public in their understanding of PFAS risks. Please see section 1.2 of the EPA response in this *Response to Comments* document regarding risk communication and anticipated materials. The EPA refers commenter to the summary of major comments for section 10.5 of the EPA response in this *Response to Comments* document for information on POU devices and why they are not currently a compliance option but may be in the future.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044199)

9. NCDEQ recommends that EPA provide guidance on the BAT options offered that would be effective on a small enough scale to be used at these small water systems.

NCDEQ does not have experience with very small treatment units for PFAS treatment. However, we understand the importance of ensuring treatment units are correctly sized for the water system.

EPA Response: Please see section 10.5 of the EPA response in this *Response to Comments* document. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation and plans to consider the topics suggested by the commenter as the agency develops implementation materials for the final NPDWR.

National Ground Water Association (NGWA) (Doc. #1804, SBC-045468)

Small Water Systems and Private Wellowner Consideration – EPA should consider the implication of setting MCLs for these PFAS on the protectiveness of small water system consumers and private well owners which would choose decentralized point-of-entry/point-of-use treatment technologies. EPA should support research in decentralized PFAS treatment systems.

EPA Response: Please see section 10.5 of the EPA response in this *Response to Comments* document. The EPA has considered the implication of setting MCLs on small water systems and refers commenter to the *Best Available Technologies and Small System Compliance for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water* document. The EPA notes that the SDWA applies to PWSs that regularly serve a minimum of 25 people or 15 service connections for at least 60 days a year. The EPA is sponsoring research for PFAS treatment systems, some of which may support decentralized treatment.

National Ground Water Association (NGWA) (Doc. #1804, SBC-045455)

Treatment technology - There are proven technologies to remove PFAS to below these limits, but designing, procuring, and constructing treatment takes time and money. EPA should direct research to support technologies that can be applied to small water systems and individual residences in the cases of applying alternative treatment technology. Are treatment technologies robust enough to maintain the level of performance to the MCL?

EPA Response: Please see sections 10.1 and 10.5 of the EPA response in this *Response to Comments* document. The *Best Available Technologies and Small System Compliance Technologies for PFAS in Drinking Water* document contains a list of technologies that can feasibly meet the MCLs for each small system size category listed in Section 1412(b)(4)(E)(ii) of SDWA. This includes small systems serving a population of 25-500 people. The EPA has provided compliance flexibility by providing a two-year capital improvements extension of the MCL compliance deadline allowed by Section 1412(b)(10) of SDWA in response to challenges raised by commenters surrounding capital improvement. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. The EPA also requests the commenter to see the EPA response to comment Doc. #1634, SBC-043239 in section 10.2 in this *Response to Comments* document.

10.6 Treatment technology availability and capacity

Summary of Major Public Comments and EPA Responses

Many comments pointed to potential supply chain issues in both material and technical capacity such as qualified personnel, including certified operators. While there may be some supply chain issues in the short-term, comments from BAT suppliers indicate excess capacity as well as

investment in production. Furthermore, while there may be temporary difficulties in supply chain and technical capacity, the structural demand increase should lead to supply increases as well as innovation, such as proposed technologies that were not designated as BATs. This has been historically demonstrated multiple times in prior drinking water rules. For example, activated alumina was listed as one of the BATs and a SSCT for arsenic removal in the Arsenic Rule (USEPA, 2001), and EPA acknowledged granular ferric hydroxide media as a developing technology. While the granular ferric hydroxide media was not selected as a BAT/SSCT at the time due to lack of full-scale demonstration, these media became the predominant approach to addressing arsenic: Rubel (2003) stated that new iron-based materials could be "employed economically on a spent media basis without the incorporation of pH adjustment chemicals and equipment." McCullough et al. (2005) cited over a dozen demonstration sites across the US implementing granular iron media treatment technologies, providing further supporting evidence that new technologies evolved in the wake of the Arsenic rule to provide more efficient and economical treatment systems. Additionally, the present statutory standard for "best available technology" under 1412(b)(4)(D) represents a change from the provision prior to 1986, which required the EPA to judge feasibility on the basis of "best technologies generally available" (BTGA). The 1986 Amendments to the SDWA changed BTGA to BAT and added the requirement that BAT must be tested for efficacy under field conditions, not just under laboratory conditions. The legislative history explains that Congress removed the term "generally" to assure that MCLs "reflect the full extent of current technology capability" [S. Rep. No. 56, 99th Cong., 1st Sess. at 6 (1985)]. Read together with the legislative history, the EPA has concluded that the statutory term "best available technology" is a broader standard than "best technology generally available," and that this standard allows the EPA to select a technology that is not necessarily in widespread use, as long as its performance has been validated in a reliable manner. Indeed, the 1991 Lead and Copper Rule stated, "as long as it has been tested beyond the laboratory under full-scale conditions for other contaminants, and the performance of the technology for lead and copper may reasonably be projected based upon other available treatment data (i.e., laboratory or pilot scale), the EPA believes the technology can be established as BAT." For additional discussion on how the agency considers analytic feasibility and cost when establishing the MCL, please see section 5 of the EPA response in this *Response to Comments* document.

Several commenters provided comment on market capacity and demand for GAC and other treatment media. The EPA notes that a major manufacturer of municipal activated carbon submitted a comment on the draft PFAS NPDWR that stated they were prepared for the significant increase in market demand (see Calgon Comment Document #1620). Additionally, the ability to reactivate GAC media for continued PFAS removal takes pressure off the carbon market by providing additional capacity in the US. There are also many US manufacturers of AIX resin, contrary to some ascertains. Some commenters stated that requirements under Build America, Buy America Act (BABA) can make acquisition of treatment materials difficult. BABA does not apply if systems are not seeking funding through the DWSRF/BIL funding programs; more information on BABA is in section 2.4.

With respect to the challenges raised by commenters surrounding capital improvement, the EPA has provided compliance flexibility by providing a two-year capital improvements extension of the MCL compliance deadline allowed by Section 1412(b)(10) of SDWA. The EPA finds that the evidence submitted by commenters strongly supports that a significant number of systems covered by this rule will need two additional years to make capital improvements to meet the MCL. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. Additionally, the EPA plans to continue its research as well as outreach efforts to help develop technical and operator capacities.

Individual Public Comments

North Penn Water Authority (NPWA) (Doc. #1470, SBC-043294)

Since Granular Activated Carbon treatment is effective at removing PFAS from water, it is certain that demand for this material around the country will increase, and most likely the cost will grow proportionately. Can an already stressed supply chain keep up with the added demand for this material?

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. The EPA notes there are other technologies and non-treatment options available to meet the final NPDWR, such as AIX.

Orange Water and Sewer Authority (OWASA) (Doc. #1524, SBC-042617)

• Supply Chain

o GAC Media

* Will there be enough GAC media available when it is needed to start up treatment and then replace spent media?

o Pressure Vessels

* Will supply chain impact the ability to get pressure vessels on order and installed by the compliance date

o Ion Exchange media

* Will there be enough IX media available when it is needed to start up treatment and then replace spent media?

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may

affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Water Environment Federation (WEF) (Doc. #1529, SBC-043307)

Supplies: Granular Activated Carbon (GAC) will face supply chain issues if the proposed regulation is approved. The waiting period for a supply of GAC has been reported to be as high as 9-24 months. IX resin lead times will be delayed as these are manufactured overseas.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. The EPA notes that not all AIX resin is manufactured overseas.

Greater Cincinnati Water Works (GCWW) (Doc. #1550, SBC-042691)

We are also concerned that the EPA estimates do not account for the increase in demand for granular activated carbon and other treatment materials and reactivation services which will result from the sudden need for similar treatment at many facilities across the country. Based on conversations with our GAC supplier, one of the largest in the country, they are already very near their production capacity. Even with additional capacity coming online, we are concerned the availability of GAC will not meet the demand in the short timeframe given for compliance.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Maine Water Utilities Association (MWUA) (Doc. #1567, SBC-042743)

Supply Chain/Procurement/Costs:

MWUA is also concerned that PWSs may face even greater procurement challenges when new national drinking water standards for PFAS are put in place. At times, carbon vessels have been delayed for months due to supply chain issues and increased demand. Different states also have different procurement laws that may need to be followed for design and construction services which add time to the overall project implementation schedule. EPA should be thinking ahead to authorities that exist, such as the Defense Production Act, to compel the quicker manufacturing of treatment components for PFAS treatment if necessary.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. The EPA has provided processes for a PWS unable to secure critical resources necessary for water treatment (see https://www.epa.gov/waterutilityresponse/how-use-

defense-production-act#Steps). For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

San Gabriel Valley Water Association (SGVWA) (Doc. #1580, SBC-042419)

Considerable Supply Chain Challenges: The number of advanced treatment systems that will be required is significant and will need to be expedited. These challenges also apply to the supply of the media required, treatment vessels, etc., for the construction of the treatment.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Missouri River Public Water Supplies Association (MRPWSA) (Doc. #1581, SBC-042411)

Treatment — MRPWSA agrees that granular activated carbon and anion exchange should be effective to treat PFOA and PFOS to 4.0 ppt or lower but have concerns about the availability of treatment given the anticipated increase in demand, challenges with use of anion exchange in surface water applications, and waste disposal.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. Concerns regarding BATs such as AIX, are addressed in section 10.1 of the EPA response in this *Response to Comments* document. For concerns related to waste disposal, please see section 10.4 of the EPA response in this *Response to Comments* document.

Washington Suburban Sanitary Commission (WSSC Water) (Doc. #1585, SBC-042775)

Supply of adsorbents:

Due to the challenges of adsorbent regeneration, many utilities that have implemented PFAS treatment already have selected to replace adsorbents with virgin GAC or IX media. The EPA should evaluate the sufficiency of the national supply of GAC and IX adsorbents as well as sustainability and PFAS destruction effectiveness of disposal services in the determination of cost feasibility and implementation timeline.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to*

Comments document on extensions and exemptions. For concerns related to disposal, please see section 10.4 of the EPA response in this *Response to Comments* document.

New York Section American Water Works Association (NYSAWWA) (Doc. #1591, SBC-042376)

12. The Rule fails to address supply chain challenges. It has been our observation that since 2020, granular activated carbon costs have doubled. Is there a market cap for Granular Activated Carbon (GAC) or Ion Exchange (IX), and does the proposed rule move the nation's water supplies closer to fighting that market limitation? As supply reaches availability, price escalation and supply chain issues are to be expected. These supply chain issues must be considered in the cost impact evaluation.

13. Many utilities rely on GAC for treatment processes unrelated to this proposed regulation. The increased demand for GAC and resulting cost and supply chain impacts will be significant for water supplies that do not have to treat for perfluorinated compounds. This cost impact is not considered in the EPA's analysis and could be more significant than the direct impact of the rule itself.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. More information on the EA can be found in section 13 of the EPA response in this *Response to Comments* document.

Lehigh County Authority (LCA) (Doc. #1600, SBC-042821)

3. Materials & Equipment Delays – Granulated activated carbon, one of the most common treatment technologies for PFAS, has been reported to have waiting periods of 9-24 months. Ion exchange resin is manufactured overseas, which will also delay delivery times. The current economic and supply-chain environment has also been causing long delays in the delivery of treatment equipment such as pumps, control systems, electrical components, and more. With a significant increase in demand for these specific types of materials and equipment to support utilities striving to achieve compliance with this rule, it is expected the problem to worsen and delays to be lengthened over the course of the compliance period.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-042896)

Supply Chain/Procurement:

MWWA is also concerned that PWSs will face even greater procurement challenges when new national drinking water standards for PFAS are put in place. At times, carbon vessels have been delayed for months due to supply chain issues and increased demand. Different states also have different procurement laws that must be followed for design and construction services, which add time to the overall project implementation schedule. EPA should communicate with existing authorities, such as the Defense Production Act, to compel quicker manufacturing of treatment components for PFAS if necessary. We also note that Build America/Buy America provisions under BIL add complexity to securing water treatment components and appurtenances. EPA should communicate with Congress to remove this added burden, or EPA should provide a waiver for PFAS treatment components.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. The EPA has provided processes for a PWS unable to secure critical resources necessary for water treatment (see https://www.epa.gov/waterutilityresponse/how-use-defense-production-act#Steps). Please note that there are significant US manufacturers including Purolite, Graver Technologies, Resin Tech Inc., AmeriWater LLC, etc.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043654)

8. Supply chain issues: With thousands of systems potentially needing to install treatment, the concerns are numerous and include: scarcity of GAC and IX media; vessels; other appurtenant equipment, and carbon reactivation service. It is unclear whether these concerns were appropriately taken into account in EPA's economic analysis.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. More information on the EA can be found in section 13 of the EPA response in this *Response to Comments* document.

American Water Works Company Inc. (Doc. #1608, SBC-043993)

We are also concerned with the ability of the industry to increase GAC supply and reactivation service capacity in a timely fashion to meet the anticipated surge in demand for such services.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

American Water Works Company Inc. (Doc. #1608, SBC-043997)

American Water has concerns about the capacity of U.S. vendors to reactivate GAC, given the significant increase in demand from drinking water utilities as a result of this rule. Based on the number of facilities that we expect to be impacted by the proposed MCL, American Water projects that our added demand alone for GAC reactivation services could be in the range of 20 million to 50 million pounds per year, depending on actual bed volume capacities achieved. Based on a preliminary discussion with a major GAC supplier in the U.S., this volume may represent up to 30% of its total current annual reactivation capacity, which indicates that if other drinking water utilities have a similar demand for GAC reactivation services, there will be inadequate U.S. capacity. If American Water's projected needs are representative of the rest of the drinking water utility industry, and if utilities rely more heavily on GAC technology because of the additional benefits it provides or the challenges of using AIX in surface water applications, the demand for GAC supply and reactivation services may increase more than 10-fold over current capacity.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. The EPA notes that the choice of BAT depends on site-specific conditions, and the available data is not sufficient to support the generalization that surface waters may benefit more from GAC than AIX or draw any other broad conclusions. Please see section 10.1 of the EPA response in this *Response to Comments* document regarding BAT identification and evaluation and section 10.3 of the EPA response in this *Response to Comments* document regarding PFAS co-removal for more information about this topic. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

American Water Works Company Inc. (Doc. #1608, SBC-043984)

Treatment – American Water agrees that granular activated carbon and anion exchange should be effective to treat PFOA and PFOS to 4.0 ppt or lower but has concerns about the availability of treatment given the anticipated increase in demand, challenges with the use of anion exchange in surface water applications, and waste disposal.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. Concerns regarding BATs such as AIX are addressed in section 10.1 of the EPA response in this *Response to Comments* document. For concerns related to waste disposal, please see section 10.4 of the EPA response in this *Response to Comments* document.

Beaufort-Jasper Water & Sewer Authority (BJWSA) (Doc. #1618, SBC-042932)

The proposed rule will result in an unprecedented demand not only on the construction industry, but also on the materials and resources needed to construct and operate the new facilities. It is not clear how the demand for PFAS removal technologies will be addressed nationwide. For example, GAC is a proven PFAS barrier. Is there enough capacity in the GAC market to supply and reactivat!:! the amount of carbon needed to remove PFAS below required levels nationwide?

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Calgon Carbon Corporation (Doc. #1620, SBC-042939)

May 26, 2023

Michael S. Regan Administrator

Environmental Protection Agency 1200 Pennsylvania Avenue, N.S. Mail Code: 4607M

Washington, DC 20460

Re: Preparedness to Provide Water Treatment Systems and Services for Compliance to the EPA's Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation (Docket ID: EPA-HG-OW-2022-0114)

Administrator Regan,

As a manufacturer, Calgon Carbon Corporation (Calgon Carbon) typically refrains from offering comment on regulatory matters. In our opinion, as water and air treatment experts, it would not be appropriate for us to opine on the merit of regulation nor the limits proposed. However, since the proposed limits were announced, concern about industry preparedness has been raised at industry conferences and trade shows, by the media, and even by customers. The intent of this letter is to inform you that Calgon Carbon has been preparing and will continue to prepare to meet the market needs to achieve compliance. Specifically:

• Our products are proven capable of achieving the proposed regulatory limits.

o For over 20 years, Calgon Carbon has supplied proven solutions for PFAS treatment of both drinking water and wastewater. Today, we have over 150 full scale systems (designed for PFAS removal and averaging over 1500 gpm each in treatment capacity) installed across the United States. Calgon Carbon's U.S. produced granular activated carbon removes PFAS from drinking water to at or below the draft MCLs as evidenced by full scale data, pilot data, and laboratory data.1,2 [FN1: Westreich, P, Mimna, R, Brewer, J, Forrester, F. The removal of short-chain and long-chain perfluoroalkyl acids and sulfonates via granular activated carbons: A comparative

column study. Remediation. 2018; 29: 19– 26. https://doi.org/10.1002/rem.21579], [FN2: McNamara, J.D., Franco, R., Mimna, R. and Zappa, L. (2018), Comparison of Activated Carbons for Removal of Perfluorinated Compounds From Drinking Water. Journal - American Water Works Association, 110: E2-E14. https://doi.org/10.5942/jawwa.2018.110.0003] With a well-designed carbon adsorption system, utilities can effectively and consistently meet the limits recently proposed by the U.S. EPA.

• We have invested a significant amount of capital to increase existing capacity in several areas.

o Granular Activated Carbon: In 2019, Calgon Carbon made the decision to invest ~$185MM to significantly expand the production of our reagglomerated, bituminous coal based granular activated carbon in Pearl River, Mississippi. Reagglomerated, bituminous coal based granular activated carbon (specifically Filtrasorb® 400) has consistently demonstrated superior removal of PFAS compared to other types of activated carbon. The new production line is slated to start-up in 2023, just a few months from now, and will be capable of making this high performing product.

o Carbon Adsorber Equipment: Calgon Carbon fabricates carbon adsorption equipment in Pittsburgh, Pennsylvania. This equipment facilitates the efficient use of granular activated carbon at treatment sites. In 2020, Calgon Carbon invested capital to expand our production by 25% and, through optimization efforts, we expect to increase capacity by another 15% within the next year. In addition, we are actively working with third party partners to secure equipment capacity and further expand our fabrication footprint.

o Reactivation: Calgon Carbon operates five reactivation facilities across the United States. For background, reactivation is a high temperature thermal process that restores granular activated carbon to near-original state and, through the process, destroys the contaminants adsorbed onto the media. In 2019, we expanded our reactivation capacity in Pittsburgh, Pennsylvania, and we are actively evaluating investment for additional capacity in the USA.

o Compliance to Build American, Buy American Act (BABAA): Our coal based activated carbon products and carbon adsorption equipment are sourced from and produced in the USA. We are fully capable of offering solutions compliant to the requirements set forth in BABAA.

• Our reactivation technology can effectively be deployed to remove and destroy PFAS to > 99.99% efficiency.

o The effectiveness of thermal destruction has been a question posed by industry for some period of time and more recently seeing a greater level of inquiry due to nature of PFAS chemistry. Scientific research and laboratory work supported the ability to destroy PFAS through reactivation. However, in 2021, Calgon Carbon invested in a full-scale demonstration of reactivation. The results of this study, which are detailed in a peer reviewed article in the September 2022 edition of the Remediation Journal, proved the effectiveness of the technology. This essentially ends PFAS's reign as a "Forever Chemical" at a much lower life-cycle cost than landfilling or incineration.3 [FN3: DiStefano, R., Feliciano, T., Mimna, R., Redding, A, and

Matthis, J. (2022), Thermal destruction of PFAS during full-scale reactivation of PFAS-laden granular activated carbon. Remediation. 2022; 32: 231-238. https://doi.org/10.1002/rem.21735]

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. The EPA appreciates the detailed information on Calgon Carbon's expanding capacity as well as treatment expertise.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044047)

28. EPA estimates GAC treatment will be sufficiently available to support cost-effective compliance with this proposed regulation, and requests comment on whether additional guidance on applicable circumstances for GAC treatment is needed.

a. CWUC is concerned whether there is enough manufacturing capacity to supply all water systems nationwide with the GAC they need.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043069)

Implementation will Further Strain the Supply Chain

Since the COVID-19 Pandemic, water systems have been faced with a strained supply chain. This strain has led to increased purchasing costs, longer lead times for equipment or materials, and limitations on the products that are available. Lead times for key equipment (e.g., vessels, carbon or resin media, electrical components, etc.) have already increased to beyond 12 months, depending on the equipment and the degree of specialization it requires. GAC media and IX resins are not widely available from more than a few suppliers. The current expectation is that orders for replacement GAC media should be made at least 6 months in advance of when the replacement is needed and for new customers the lead time is upwards of 12-18 months. IX resin supplies may face similar issues, given that the resin is not manufactured domestically and with the increase in demand much of the GAC required to treat PFAS will need to be acquired from suppliers in China and India. Additionally, there are presently only five manufacturing facilities across the U.S. and Canada for GAC vessels. These facilities will be heavily relied upon to provide most vessels for GAC. These issues are also impacting major ancillary equipment like electrical panels, motor control centers, etc. In Aqua's experience constructing several PFAS treatment systems since 2017, lead times for key equipment to construct PFAS treatment have only increased.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. The EPA notes that there are AIX resins that are manufactured in the United States.

WaterPIO (Doc. #1624, SBC-043463)

4. There simply won't be enough water treatment systems or filtration media available for public water systems to use to meet the proposed MCLs and HI.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document.

Water One - Water District No. 1 of Johnson County, Kansas (Doc. #1627, SBC-042329)

Operations and Supply Chain Challenges

From an operational perspective, water utilities will essentially need to implement water treatment that has a 100% removal rate of PFAS compounds to achieve compliance under the proposed regulation. At this time, the technologies and available supplies for this are currently not available at the scale needed to achieve this standard nationwide and it would likely take years for the already-taxed supply chains to catch up. GAC, ion exchange, and appropriate membranes are all either in short supply or extremely hard to implement at the scale needed. Currently, GAC vessels have lead times of over 18 months in the US and this expecting to get worse.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. The EPA disagrees that a 100 percent removal rate is required by all utilities. For example, if a utility has influent water containing PFOS at a level of 15 ppt, it will need to remove approximately 11 ppt for compliance which is about a 75 percent removal rate. For more information on this topic, please see section 6 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044112)

Resource Concerns

ASDWA recommends that EPA continue funding PFAS research on treatment and mitigation at water systems to help offset the cost increases affecting capital costs for these projects.

As a result of the COVID-19 pandemic and ongoing geopolitical conflicts, primacy agencies and water systems have already experienced ongoing effects on the global supply chain. Primacy

agencies have reported that systems have had to delay the installation of treatment technologies due to supply shortages. Specifically, one primacy agency identified that the lead time needed for a granular activated carbon (GAC) treatment vessel was over 18 months for one installation of PFAS treatment. Additionally, primacy agencies have reported media and other equipment shortages. In conjunction with inflation, these shortages have caused project costs to increase across the board. These global supply chain and treatment shortage issues are significant feasibility concerns with rule implementation.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Village of Woodbury (Doc. #1629, SBC-042957)

11. It is stated, the "EPA estimates GAC treatment will be sufficiently available to support cost-effective compliance with this proposed regulation, and requests comment on whether additional guidance on applicable circumstances for GAC treatment is needed". The rule should consider supply chain challenges and costs of inflation due to availability of media. Additionally, water suppliers using this technology for other purposes are at a disadvantage if this is the only sufficiently available treatment technology.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. For information on inflation impact, please see section 13.4 of the EPA response in this *Response to Comments* document. While GAC is anticipated to be the most widely used technology, and a major GAC supplier as well as reactivator has provided information on expanded capacity, facilities, and efficiency, it is not the only treatment technology. The EPA anticipates AIX as well as high pressure membranes will also be in sufficient capacity as further described in this section of the EPA response in this *Response to Comments* document .

Association of Environmental Authorities (AEA) (Doc. #1635, SBC-042965)

Adopting the NPDWR is also likely to result in higher demand for granulated activated carbon. Availability and supply chain problems could interfere with utilities' ability to comply.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

National Rural Water Association (NRWA) (Doc. #1641, SBC-043266)

Capacity is limited. There are limited entities that construct and install the necessary equipment. In Kentucky, water systems using GAC are already experiencing uncertain and timely deliveries for material replenishment and regeneration orders.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

American Farm Bureau Federation et al. (Doc. #1642, SBC-043491)

Specific to rural drinking water utilities, we are concerned about the availability of these technologies, especially since drinking water utilities will only have three years to obtain, install and get these systems up and running. We have already heard that supply chain issues are impacting technologies like granular activated carbon, and it will only be further squeezed as the 66,560 water systems in our country all work to meet the implementation deadline. Small, rural facilities will undoubtably face more challenges in obtaining these technologies, as the priority will be placed on large, metropolitan systems.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. While there are many PWSs in the United States, approximately 4,100 to 6,700 systems, or about 6-10 percent, are anticipated to require installed treatment, not all systems, more information on how many water systems may be drawn into treatment may be found in section 6 of the EPA response in this *Response to Comments* document.

Savannah River Nuclear Solutions LLC (Doc. #1647, SBC-043326)

Comment 2

Has EPA considered potential supply chain issues if the proposed rule is approved? The current waiting period for a supply of GAC has been reported to be as high as 9-24 months. AIX resin lead times could be significantly delayed as many of these are manufactured overseas.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

New England Interstate Water Pollution Control Commission (NEIWPCC) (Doc. #1650, SBC-043148)

Treatment Technologies

Our member states are also concerned by the effects the rule will have on the availability and cost of treatment technologies. The rising demand for granular activated carbon (GAC), combined with ongoing supply chain issues, have already led to increased costs and lead time to acquire treatment media. As the rule is implemented, without coordinated efforts, we expect those costs, and the cost of disposal of spent media, to further increase.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. For information on costs related to disposal, please see section 10.4.2 of the EPA response in this *Response to Comments* document.

National Association of Clean Water Agencies (NACWA) (Doc. #1659, SBC-043156)

Without a PFAS Destruction Technology Readily Available, EPA's Reliance on Treatment Technique Fails to Consider Indirect Impacts

EPA's proposed rule points to granulated activated carbon (GAC), anion exchange, and reverse osmosis as possible advanced treatment techniques PWSs should consider to remove PFAS from drinking water. Outside the direct costs associated with installing these advanced treatment techniques, each raises other concerns and indirect impacts that should be more thoroughly considered by EPA.

For example, PWSs selecting GAC technology will need millions of pounds of GAC to comply with EPA's proposed regulation. Currently, there are considerable supply chain issues and long waiting periods to purchase virgin GAC.

EPA Response: The EPA is not prescribing a particular treatment technique in this regulation; rather, the agency has identified Best Available Technologies (please see section 10.1 of the EPA response in this *Response to Comments* document) for treatment to comply with the rule. Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. Information on the EPA cost analysis, including outside direct costs, is in section 13 of the EPA response in this *Response to Comments* document.

City of Allentown and Lehigh County Authority (LCA), Pennsylvania (Doc. #1667, SBC-043681)

2. Materials & Equipment Delays – Granulated activated carbon, one of the most common treatment technologies for PFAS, has been reported to have waiting periods of 9-24 months. Ion exchange resin is manufactured overseas, which will also delay delivery times. The current economic and supply-chain environment has also been causing prolonged delays in the delivery of treatment equipment such as pumps, control systems, electrical components, and more. With a significant increase in demand for these specific types of materials and equipment to support utilities striving to achieve compliance with this rule, it is expected the problem to worsen and delays to be lengthened over the course of the compliance period.

EPA Response: The EPA notes that there are AIX resins that are manufactured in the United States. Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Aurora Water, City of Aurora, Colorado (Doc. #1669, SBC-043724)

EPA should also consider additional environmental impacts that will come from this proposal. There will be a significant increase in demand for GAC from water systems working to comply with this rule.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. Please see section 14.1 of the EPA response in this *Response to Comments* document for how the EPA considered the social cost of carbon from this rule.

Aurora Water, City of Aurora, Colorado (Doc. #1669, SBC-043727)

Treatment Technologies

Aurora Water is also concerned about the increased demand for GAC and whether it will be sufficiently available to support cost-effective compliance with the proposed rule. After speaking with GAC suppliers, Aurora Water is very concerned with the ability to obtain GAC materials for PFAS treatment. With every water system in the area likely considering GAC treatment for their drinking water system demand is only going to rise. Considering the raw material availability and supply chain issues most manufacturers are facing, it is doubtful they will be able to keep up. Aurora Water suggests the EPA considers GAC availability for water systems when reconsidering the MCLs and implementation timeline for the proposed rule.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-044923)

Section 7.1: Sufficiently available and Cost-effective

EPA specifically states in the preamble that it estimates GAC treatment will be sufficiently available to support cost-effective compliance with this proposed regulation. As mentioned earlier, water systems are already seeing approximately 18-month lead times on GAC vessels for PFAS treatment. This does not seem to be sufficiently available when that is half of EPA's proposed compliance timeline of three years. Should the rule be finalized in its current form, thus spurring additional nationwide demand for these products, one could assume these lead times will only get worse.

There is concern over who will get priority for new GAC as well. Those who already have existing contracts, whether the system is using GAC for TOC removal or compliance with a state PFAS MCL, are concerned new contracts may receive priority based on new prices or agreements. Another alternative, new contracts may not be awarded if demand is already too high to meet with existing contracts. Due to costs and other factors, GAC will likely be a top choice for many utilities required to apply treatment, therefore it is imperative the capacity of suppliers be thoroughly reviewed to ensure availability.

Another aspect of these technologies is that media does not maintain performance of PFAS removal forever. GAC can be reactivated, but only a finite number of times as some is lost each time. With levels proposed at the PQL, 4.0 ppt, even water systems that have already implemented one of these technologies for PFAS treatment will see increased costs and must revise treatment plans. Reliably treating down to this proposed level, which is half the level of the lowest state MCL, will require much more frequent replacement of media. This will significantly increase operation and maintenance costs. With only a select few GAC reactivation facilities in the country, significant transport costs, often time across state lines, will be required.

Cleveland Water wants to reiterate that EPA and water utilities are all working toward the same goal of protecting public health by providing clean, safe and affordable drinking water to the public. Affordability is a key term here and many utilities across the United States are struggling with the ability to maintain affordable rates in light of required capital and regulatory projects. It is crucial that regulations do not put unnecessary or significant financial burdens on ratepayers. As we saw during the COVID-19 pandemic, any economic hardship can cause individuals to have to make difficult choices like choosing between paying water bills and buying groceries. Access to safe, clean drinking water is a necessity, and we should be working to ensure this access is affordable and equitable.

EPA Response: Please see sections 10.1 and 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. The frequency of media changeout was considered in the HRRCA section and details can be found in the *Technologies and Costs for Removing Per- and Polyfluoroalkyl Substances from Drinking Water* document.

A. O. Smith Corporation (Doc. #1674, SBC-043704)

6. Supply Chain

Given the Company's position as a global manufacturer and seller of third-party certified POU and POE systems that remove up to ninety-nine different health-based contaminants from drinking water, we felt it prudent to raise awareness around the global supply of certain carbons. As the EPA may be aware certain carbons – most notably coconut-based GAC – are sourced outside of the United States with the majority coming from the Asian sub-continent. While there are domestic sources such as bituminous coal, most GAC, and some other resins, among other treatment media will be sourced at a premium (i.e., higher cost) if carbon manufacturers and suppliers do not increase capacity as market dynamics change (e.g., public water system demand), not to mention having to deal with potential supply chain disruptions due to geo-political challenges.

Conclusion

Once again, A. O. Smith appreciates the opportunity to submit these comments to the U.S. Environmental Protection Agency regarding its request for comment on its PFAS National Primary Drinking Water Regulation Rulemaking. The proposed PFAS NPDWS raises a series of complex questions and challenges for the EPA and public water systems moving forward. A. O. Smith, and the broader water treatment industry, can play a vital role in mitigating adverse human health impacts posed by elevated levels of PFAS in the nation's drinking water. Along those lines the Company stands ready to be a resource to the EPA as it completes its work on the PFAS NPDWS. In the interim, A. O. Smith would welcome the opportunity to answer any questions the EPA may have with the respect to the Company's submission or other areas that the EPA would like to engage further on related to the PFAS NPDWS. Best Regards,

Joshua C. Greene, Esq.

Corporate Vice President, Government and Industry Affairs

A. O. Smith Corporation

Global Headquarters

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EPA Response: The EPA thanks the commenter for its willingness to serve as a resource and invites the commenter to provide any data as well as other experiences and comments. Please see section 10.6 of the EPA response in this *Response to Comments* document.

Massachusetts Coalition for Water Resources Stewardship (MCWRS) (Doc. #1691, SBC-044328)

[The proposed MCLs raise the specter of serious unintended consequences that could pose public health risks for water consumers. Some of these are:]

d. As most water systems opt for GAC as the treatment of choice for PFAS, having thousands of new systems demanding GAC and GAC regeneration services will likely put a strain on suppliers and GAC services. The ability of the GAC industry to meet this new demand must be closely assessed before an MCL is finalized. Failure to do so will not only create higher costs for GAC but also jeopardize its availability for existing facilities that depend on this material for current public health protection.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045039)

Current supply-chain issues are leading to additional challenges for systems when trying to plan for and schedule media change-outs. This may pose an even greater challenge at the low levels proposed by EPA.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045037)

NJDEP has observed quite substantial lead-times on materials such as carbon, anion exchange media, media vessels, electronic components, and various other supply chain issues ranging from months to over a year. It is NJDEP's understanding that these supply chain issues have recently affected the timeframe for PFAS treatment installation for nearly every public water system, even those with expansive supply networks.

Granular Activated Carbon (GAC):

EPA estimates that GAC treatment will be sufficiently available to support cost-effective compliance.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

California Farm Bureau Federation (Doc. #1704, SBC-045074)

Specific to rural drinking water utilities, we are additionally concerned about the availability of these technologies, especially since drinking water utilities will be required no more than three years to obtain, install, and implement such systems. Further, we have been advised that supply chain issues are impacting technologies such as granular activated carbon, creating additional concern that supplies will be further limited. Historically, priority is often given to large, metropolitan systems, meaning rural facilities will undoubtably face more challenges in obtaining high-demand technologies.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Wyoming Department of Environmental Quality (WDEQ) (Doc. #1716, SBC-044757)

8. Further Analysis Is Needed to Determine Whether the Increased Demand of PFAS Treatment Technology and Infrastructure Can Be Met by Industry in the Proposed Compliance Timeframe

Section XIII of the proposed PFAS NPDW rule does not provide information regarding analysis of whether the industries that supply PFAS treatment and remediation technology will be able to sustain the increased demand from PWSs once the PFAS NPDW rule is in effect; specifically, no analysis is provided as to whether a three-year timeline for compliance is achievable for PWSs that will need to implement PFAS treatment technology or source water replacement. Due to the extremely low concentrations proposed for PFAS MCLs, in addition to the proposed Rule Trigger Level of one-third the PFOA and PFOS MCLs and one-third the PFAS HI values, a significant percentage of PWSs may need to implement some measure of PFAS treatment technology. Many of the small and rural PWSs requiring treatment will choose granular activated carbon (GAC) for treatment due to lower relative cost and ease of operation. The EPA should consider developing more analysis on whether the industry can meet that anticipated demand. Many small and rural systems may be forced into more expensive treatment technologies, such as Reverse Osmosis (RO) or ion exchange, to meet the proposed compliance deadline as increased demand on GAC will reduce availability and increase costs. Such analysis should consider feasible disposal options for treatment media.

EPA Response: Please see sections 10.1 and 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to*

Comments document on extensions and exemptions. For concerns related to disposal options for treatment media, please see section 10.4.1 of the EPA response in this *Response to Comments* document as well as the Management of Treatment Residuals section as well as the *Interim PFAS Destruction and Disposal Guidance* document.

Water and Wastewater Equipment Manufacturers Association (WWEMA) (Doc. #1727, SBC-043524)

May 30, 2023

U.S. Environmental Protection Agency EPA Docket Center

Office of Ground Water and Drinking Water Docket

Mail Code 28221T

1200 Pennsylvania Ave., NW

Washington DC 20460

Submitted Electronically: htt ps: // www.requlat ions.gov; and via email: PFASNPD WR@epa.gov

RE: Docket ID No. EPA-HQ-OW-2022-0114

Attn: Alexis Lan

The Water and Wastewater Equipment Manufacturers Association (WWEMA) is pleased to submit the following comments on the U.S. Environmental Protection Agency's (EPA's) PFAS National Primary Drinking Water Regulation Rulemaking as published in the March 29, 2023 Federal Register. As the Association that represents PFAS technology solution providers to the water sector, we are providing comments focused on the treatment aspects of the proposed rule.

WWEMA and its members stand ready to support the water sector in removing PFAS compounds from drinking water and to work with EPA to ensure the adequate availability of PFAS removal treatment technologies. To accomplish this, it is critical to ensure that technology solution providers do not face barriers and unintended consequences in their efforts to provide safe drinking water to consumers across the country. Please see our comments below.

Comment #1: Product Waivers Required to Ensure BAT Capacity to Meet Demand

WWEMA agrees with EPA that the Best Available Technologies (BATs) for the removal of PFAS contaminants are granular activated carbon (GAC), anion exchange (AIX), and high-pressure membranes such as reverse osmosis (RO) and nanofiltration (NF). WWEMA disagrees, however, with EPA's assessment that GAC treatment will be sufficiently available in sufficient quantities to support cost effective compliance with the proposed regulation. As EPA is aware, the Bipartisan Infrastructure Law (BIL) signed by President Biden on November 15, 2021 requires that all infrastructure projects funded using Federal dollars must comply with the new

Build America, Buy America (BABA) requirements. The BIL specifically provided Federal funding to be directed to removal of PFAS and other emerging contaminants in addition to increased funding through the traditional state revolving loan fund (SRF) programs for infrastructure improvements. Although there are a number of carbon manufacturers that provide treatment to U.S. utilities and municipalities, we are currently aware of only one company that sources their carbon in the U.S. for PFAS removal. That means that resources available to provide this BAT will be limited if even one dollar of Federal funding is used for the project unless a waiver is provided.

This situation is similar for companies that provide RO and NF as well as those that provide ultrafiltration (UF) and microfiltration (MF) as pretreatment for PFAS removal. None of the current large-scale membrane manufacturers that provide membrane BAT to the U.S. water market currently manufacture their products domestically or in sufficient quantity to meet current projected needs. While WWEMA has not done extensive outreach to anion exchange manufacturers, our general understanding is that they may be in the same predicament. A number of companies are evaluating the options to produce their products domestically, but it will require several years and a sizeable investment to create or expand sufficient manufacturing capacity to meet the demand for current and future PFAS treatment. To ensure adequate access to these critical BAT technologies, WWEMA requests a National Public Interest Waiver for these PFAS removal technologies while the market adapts to close this gap. This will be particularly important for small and disadvantaged communities that will need ready access to these technologies.

EPA Response: As acknowledged in the comment, there are US suppliers for all BATs identified. Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. More on BABA and public interest waivers can be found in section 2.4.

Clean Air Council, et al. (Doc. #1731, SBC-043885)

d. Treatment of contaminated drinking water to achieve the proposed MCLs and HBWC is technically feasible for national implementation of the proposed PFAS regulations. However, EPA must facilitate the development of safe technologies for the disposal of PFAS waste created by water treatment to avoid re-release of PFAS to the environment.

EPA has identified several methods that can effectively remove the PFAS compounds down to non-detectable levels [FN69: EPA states that these methods remove up to 99% of PFAS. EPA, Per- and Polyfluoroalkyl Substances, https://tdb.epa.gov/tdb/contaminant?id=11020 (select "Treatment Processes" under "Contaminant Navigation") (last visited May 30, 2023). That level is judged to be "non-detectable." See, e.g., EPA, EPA Researchers Investigate the Effectiveness of Point-of-use/Point-of-entry Systems to Remove Per- and Polyfluoroalkyl Substances from

Drinking Water (Jan. 22, 2020), https://www.epa.gov/sciencematters/epa-researchers-investigate-effectiveness-point-usepoint-entry-systems-remove-and.] These methods have been extensively tested and validated (see for example studies by Erica Gagliano, et al, and by Caihong Liu, et al. [FN70: Erica Gagliano, et al., Removal of Poly- and Perfluoroalkyl Substances (PFAS) from Water by Adsorption: Role of PFAS Chain Length, Effect of Organic Matter and Challenges in Adsorbent Regeneration, 171 WATER RES. 115381 (Mar. 15, 2020), available at https://doi.org/10.1016/ j.watres.2019.115381; Caihong Liu, et al., Evaluating the Efficiency of Nanofiltration and Reverse Osmosis Membrane Processes for the Removal of Per- and Polyfluoroalkyl Substances from Water: A Critical Review, 302 SEPARATION & PURIFICATION TECH. 122161 (Dec. 1, 2022), available at https://doi.org/10.1016/j.seppur.2022.122161.]) and are also the methods of choice for drinking water treatment in the states that enacted PFAS drinking water regulations.

Current water treatment facilities cannot address PFAS contamination [FN71: See, e.g., Shui Cheung Edgar Leung, et al., Emerging Technologies for PFOS/PFOA Degradation and Removal: A Review, 827 SCI. OF THE TOTAL ENVMT. 153669 (June 25, 2022), available at https://doi.org/10.1016/j.scitotenv.2022.153669.] Therefore, EPs where PFAS levels exceed the proposed NPDWR MCLs and/or HI will need to add a dedicated PFAS treatment unit. However, the methods used for removal of PFAS from water (Granulated Activated Carbon—GAC, ion exchange, Reverse Osmosis—RO/nanofiltration membranes) are similar to technologies currently used in drinking water facilities to address contamination by other types of compounds. For example, GAC units are frequently used for removal of volatile organic compounds ("VOCs"), taste or odor-producing compounds, or other types of contaminants. Ion exchange, which is used for removal of arsenic, nitrate, perchlorate, sulfate, or uranium, is most often applied for water 'softening' by removing calcium and magnesium [FN72: EPA, Overview of Drinking Water Treatment Technologies, https://www.epa.gov/sdwa/overview-drinking-water-treatment-technologies#GAC (last updated Apr. 13, 2023).] PFAS-removal units use these technologies, but are designed to specifically address PFAS contamination. The prevalence and familiarity of these processes means that once a PFAS treatment unit is constructed, facility personnel will have the required expertise to operate it effectively.

A few challenges will need to be considered, however, due to the large number of PWSs that are expected to exceed the proposed limits and require implementation of water treatment. First is supply availability: There will be a very large need for GAC, ion-exchange resin and/or RO/nanofiltration membranes during the facility construction stage [FN73: See, e.g., Global Ind. Analysts, Inc., Global Activated Carbon Market to Reach 3.9 Million Tons by 2026, CISION (Mar. 23, 2022), https://www.prnewswire.com/news-releases/global-activated-carbon-market-to-reach-3-9-million-tons-by-2026--301506731.html.] Even after the initial implementation stage, there will be a constant, albeit lower, demand for these materials: GAC materials saturate and need to be regenerated or replaced; ion exchange resins lose efficacy after a given number of regeneration cycles; RO/nanofiltration membranes also degrade with time, [FN74: See, e.g., S. J. Chow, et al, Comparative Investigation of PFAS Adsorption onto Activated Carbon and Anion Exchange Resins During Long-Term Operation of a Pilot Treatment Plant, 226 WATER RES.

Article No. 119198 (Nov. 1, 2022), available at https://doi.org/10.1016/j.watres.2022.119198.] although the exact rate of replacement will depend on the contaminant concentrations and operation procedures. To ensure compliance under the proposed rule's timeline and schedule, the federal government should examine whether there is a need to develop new facilities producing PFAS treatment materials to address the national need.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. For more information on disposal please see the *Interim PFAS Destruction and Disposal Guidance* document as well as the Management of Treatment Residuals section.

U.S Conference of Mayors, National League of Cities and National Association of Counties (Doc. #1733, SBC-043896)

c. Supply Chain, Disposal and Workforce Challenges

The technologies used to remove PFOS and PFOA from drinking water include Granulated Activated Carbon (GAC) or reverse osmosis membranes. Supply chain disruptions are already apparent at the local level, with over a year wait for replacement carbon, and in many cases the cost of needed supplies has also increased. These factors will be further exacerbated if more water utilities add GAC to their systems as a treatment technique. Establishing a higher initial MCL would allow those public water systems with the highest PFOA or PFOS levels, and therefore also the highest public health risks, to be prioritized first. A rapid increase in demand resulting from detection-level MCL levels would only exacerbate the amount of time it takes to obtain and install necessary treatment.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. For additional discussion on how the agency considers analytic feasibility and cost when establishing the MCL, please see section 5 of the EPA response in this *Response to Comments* document.

Florida Section American Water Works Association - Water Utility Council (FSAWWA WUC) (Doc. #1737, SBC-044487)

• Global Supply Chain Issues:

EPA is aware of supply chain issues for the Water and Wastewater Sectors and thankfully published a Supply Chain Resilience Guide for Water and Wastewater Utilities as well as provided case studies (please see https://www.epa.gov/waterutilityresponse/water-and-wastewater-sector-supply-chain-resilience). Through the global pandemic and other mechanisms,

utilities across the country are facing increased wait times and price increases for numerous products and supplies. We recommend EPA consider how future supply and demand will affect both the cost and timelines to meet the proposed NPDWR. For example, one of our members reports a 9- month wait for Granular Activated Carbon (GAC) supplies, one of EPA's recommended treatment methodologies.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045978)

Section 7.1: Sufficiently available and cost-effective

EPA specifically states in the preamble that it estimates GAC treatment will be sufficiently available to support cost-effective compliance with this proposed regulation. As discussed, water systems at this time are seeing approximately 18-month lead times on GAC vessels for PFAS treatment. This timing does not seem to be sufficiently available when that is half of EPA's proposed compliance timeline of three years. Should the rule be finalized in its current form, spurring additional nationwide demand for these products, it is likely lead times will increase.

There are considerable concerns over which systems will get priority for the new GAC as well. Systems that already have existing contracts, whether the system is using GAC for total organic carbon (TOC) removal or compliance with a state PFAS MCL, are concerned new contracts may receive priority based on new prices or agreements. Conversely, treatment technology suppliers may not prioritize issuing new contracts if demand is already high with existing contracts. Due to costs, EPA's recommendation, and other factors, GAC will likely be a top choice for many utilities required to apply treatment; therefore, it is imperative EPA thoroughly assess the capacity of suppliers to ensure availability of GAC filtration.

PWSs will likely encounter difficulties implementing any treatment techniques due to increased demands on the supply chain and other regulatory requirements. Similar to GAC, PWSs considering AIX may find it both more difficult and more expensive once the final rule triggers higher demand. Furthermore, other requirements imposed on water systems, like Build America, Buy America (BABA) requirements, can make acquiring certain materials difficult and prolong acquisition timelines.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

LSP Association (LSPA) (Doc. #1742, SBC-043606)

Slide 30: EPA estimated annualized costs per year for water systems that treat or change water source: Costs of system capital, operation, and maintenance are annualized.

• The LSPA estimates that granular activated carbon (GAC) use will increase exponentially if the proposed MCLs are implemented. Adequate source materials (coal, coconut, sugarcane bagasse, soybean hulls, nutshell) are not available to meet the resulting demand; therefore, costs will increase accordingly. Did EPA consider the supply/demand issues and escalating costs associated with GAC?

• Communities that can least afford it, such as minority, low-income, and environmental justice populations will be disadvantaged if required to compete with more affluent communities and public water supply systems for dwindling resources.

• The LSPA concurs with the MWWA in their May 26, 2023 comment letter regarding supply chain and procurement challenges (pp.14-15).

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. With respect to the commenter's concern about impacts to "minority, low-income, and environmental justice populations," the EPA conducted an EJ analysis for the final rule that assessed the demographic distribution of baseline PFAS exposure in drinking water as well as the anticipated distribution of benefits and costs that will result from the rule. For more information on the EPA's EJ analysis, please see Chapter 8 of the EA (USEPA, 2024d).

There may be opportunities for many communities to utilize external funding streams to address such challenges. The BIL, the Low-Income Water Household Assistance Program through the American Rescue Plan, and other funding sources may be able to provide financial assistance for addressing emerging contaminants. In particular, the BIL funding has specific allocations for disadvantaged and/or small communities to address emerging contaminants, including PFAS. For example, the *Emerging Contaminants in Small or Disadvantaged Communities grant program* will provide states and territories with $5 billion to provide grants to PWSs in small or disadvantaged communities to address emerging contaminants, including PFAS. Grants will be awarded non-competitively to states and territories. For more information on funding available through BIL, please see section 2.4 of the EPA response in this *Response to Comments* document. For more information on the cost analysis please see section 13 of the EPA response in this *Response to Comments* document.

LSP Association (LSPA) (Doc. #1742, SBC-043608)

The LSPA asserts that the resource capacity, supply chain availability of GAC and other treatment supplies, and laboratory capacity for undertaking compliance to these low MCLs has been greatly overestimated by USEPA.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Liberty (Doc. #1747, SBC-043625)

Regarding the proposed regulation, as the demand for treatment vessels and the treatment materials they house (such as GAC and IX resin) increases exponentially, even approved and shovel-ready projects may be necessarily postponed due to supply chain limitations.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Las Cruces Utilities (LCU) (Doc. #1753, SBC-043914)

In response to Section XI-Treatment Technologies, EPA estimates GAC treatment will be sufficiently available to support cost-effective compliance with this proposed regulation, and requests comment on whether additional guidance on applicable circumstances for GAC treatment is needed.

• EPA should provide additional guidance as to when GAC treatment is not appropriate or viable. Water demand for these systems and the required GAC media will increase, and therefore become more expensive. Increased demand will also lead to longer lead times and may make it difficult to meet the compliance deadlines.

EPA Response: Please see sections 10.1 and 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. After finalization of the PFAS NPDWR, the EPA also seeks to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation and plans to consider the topics suggested by the commenter as the agency develops implementation materials for the final NPDWR.

PFAS Regulatory Coalition (Doc. #1761, SBC-046083)

c) Did EPA consider the costs/availability of treatment media? The demand for treatment media is greatly increasing for remediation projects and will increase further due to this Proposal. EPA should consider how market demand will affect price and availability of the different treatment media.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. Please see section 5 of the EPA response in this *Response to Comments* document for additional discussion on cost considerations when establishing the MCLs. The EPA also refers commenter to the *Technologies and Costs for Removing Per- and Polyfluoroalkyl Substances from Drinking Water* document. For more information on the cost analysis, please see section 13 of the EPA response in this *Response to Comments* document.

Western Urban Water Coalition (WUWC) (Doc. #1768, SBC-043941)

However, the Proposed Rule does not consider significant supply chain challenges that have impacted the availability of GAC and IX resin, or whether there is a sufficient supply of these materials to meet the increase in demand that would result from the Proposed Rule.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

City of Tulsa Water and Sewer Department (CoT WSD) (Doc. #1785, SBC-043786)

CoT WSD believes that EPA's estimate regarding availability of GAC is grossly understated. Many water systems, including CoT WSD, currently use GAC filters in their conventional treatment train. For our system, GAC is replaced with virgin material in 8 of the 24 filters (total, in two WTPs) each year at a cost of about $2.5M. It must be assumed that many systems operate a similar replacement schedule, plus or minus months, and some may use reactivated GAC, but it doesn't appear that EPA accounted for this usage in the proposed rule or in supporting documents. In the supporting document, Technologies and Cost for Removing Per- and Polyfluoroalkyl Substances (PFAS) from Drinking Water (EPA-822-P-23-011), EPA discusses GAC in regard to deep-bed contactors. EPA states that support for GAC effectiveness is "evident form the number of full-scale facilities that are currently using the technology," but this is only 30 systems out of the thousands of systems across the country (pg. 15). It can be surmised that to achieve compliance with this rule, there will be many systems that will 1) install new conventional GAC filters, 2) increase frequency of GAC replacement in conventional filters, or

3) install new deep-bed GAC contactors for specific removal of PFAS. With any or all of these scenarios, the demand for GAC will be significant, supply chain could be challenged, delivery times extended, and costs could increase significantly.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. Please see section 13 of the EPA response in this *Response to Comments* document for the EPA cost analysis.

Pennsylvania Municipal Authorities Association (Doc. #1832, SBC-045790)

[PMAA's specific comments on the Proposal are as follows:]

14. The supply of Granular Activated Carbon (GAC) (and possibly other treatment-related products) may be subject to supply chain issues if the Proposal is ultimately promulgated as a final PFAS regulation. Anecdotal information suggests that the wait time for Granular Activated Carbon will increase substantially as a result of the mandates in the Proposal. How does EPA suggest that municipal entities address this potential problem?

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions.

New England Water Works Association (Doc. #1836, SBC-045396)

Supply Chain/Procurement:

NEWWA is also concerned that PWSs may face even greater procurement challenges when new national drinking water standards for PFAS are put in place. At times, carbon vessels have been delayed for months due to supply-chain issues and increased demand. Different states also have different procurement laws that may need to be followed for design and construction services, which add time to the overall project implementation schedule. EPA should be thinking ahead to authorities that exist, such as the Defense Production Act, to compel the quicker manufacturing of treatment components for PFAS treatment if necessary. Build America, Buy America (BABA) provisions required for BIL funding provide an added layer of complexity and delay when trying to quickly source materials and components needed for PFAS treatment systems. PWS in New England trying to build treatment systems and meet BABA and AIS requirements are already facing months-long delays. When the rest of the nation begins the same process, the wave of demand will be overwhelming. EPA must provide flexibility and relief for drinking water PFAS projects and streamline the waiver review process, which takes months to complete.

EPA Response: Please see section 10.6 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may

affect the compliance timeline, please see section 12 of the EPA response in this *Response to Comments* document on extensions and exemptions. The EPA has provided processes for a PWS unable to secure critical resources necessary for water treatment (see https://www.epa.gov/waterutilityresponse/how-use-defense-production-act#Steps).

Section 10 References

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11 Rule Implementation and Enforcement

11.1 Requirements for Primacy

Summary of Major Public Comments and EPA Responses

The EPA received one comment that most of the initial monitoring may occur before primacy applications will be submitted, which are not due until two years after final rule promulgation. A couple of commenters assert that it is unclear why states are required to include an initial monitoring plan in their primacy application and that states will not be able to implement and demonstrate that this monitoring plan is enforceable under state law until state regulations have been promulgated. The EPA notes that some comments related to the requirements for primacy are also contained within sections 5 and 12 of this *Response to Comments* document. The EPA recognizes that some initial monitoring by water systems may occur prior to a state, territory, or Tribe receiving EPA approval for primacy and agrees with the commentor that for states to develop a monitoring plan that addresses when systems will be scheduled to conduct initial monitoring is not a necessary requirement for a primacy application. However, where states are approved for primacy before the compliance date for the water systems, primacy agencies should have procedures for evaluating whether data that a community water system (CWS) or non-transient non-community water system (NTNCWS) submits to satisfy the initial monitoring requirements are acceptable. It is therefore appropriate to require primacy agencies to include in their primacy application a description of their procedures for reviewing water system's use of pre-existing data to meet initial monitoring requirements, including the criteria that will be used to determine if the data are acceptable and the primacy agency's procedures for ensuring water system compliance within the required timeframes. The compliance deadline for this initial monitoring by systems is three-years from promulgation, in which case primacy agencies should have primacy or interim primacy at the time of the initial monitoring deadline. To address the possibility that a state, Tribe, or territory may get an extension to apply for primacy, the final rule provides that these special primacy requirements are not applicable after the initial monitoring deadline (i.e., three years after publication of the rule in the Federal Register). When a primacy agency does not yet have primacy for a new drinking water rule, a National Primary Drinking Water Regulation (NPDWR) is nonetheless applicable to water systems and may be enforced by the EPA following the compliance dates specified in § 141.900(b).

Individual Public Comments

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045165)

Monitoring and special primacy requirements

Given that initial monitoring may occur anytime between final rule promulgation and the compliance date (three years later), it is unclear why states are required to include an initial monitoring plan in their primacy application. Primacy applications wouldn't normally be due

until two years after final rule promulgation. Two-thirds of the initial monitoring period would have already passed by that date. Moreover, states will not be able to demonstrate that this monitoring plan is enforceable under state law until state regulations have been promulgated which, again, will likely occur well into the initial monitoring period.

EPA Response: Please see section 11.1 of the EPA response, as well as the EPA response to comment Doc. #1626, SBC-044880 in section 16.5 and Doc. #1708, SBC-045100 in section 5.1.2, in this *Response to Comments* document.

11.2 Record Keeping Requirements

Summary of Major Public Comments and EPA Responses

The EPA received a few comments about the record keeping that primacy agencies must maintain for compliance determinations and reporting, storing public water system (PWS) facility data, tracking monitoring schedules, and keeping the public informed of the quality of their drinking water. As noted in the comments, most primacy agencies rely on the Safe Drinking Water Information System (SDWIS), developed by the EPA, to support this record keeping requirement. It was recommended that the EPA develop a data system, either SDWIS or a replacement, that is capable of fully managing the data associated with the proposed rule. Further, it was recommended that the EPA develop data management solutions such as a mechanism for migrating Unregulated Contaminant Monitoring Rule (UCMR) data into SDWIS State to reduce or eliminate the burden of ensuring compliance with the initial monitoring and identify systems eligible for reduced monitoring frequency when compliance monitoring begins. The EPA agrees that appropriate data management solutions are needed to effectively comply with Safe Drinking Water Act (SDWA) requirements; however, the agency does not believe these systems must be available at the time of rule promulgation. Additionally, while beyond the scope of this rulemaking itself, the EPA is actively working on PFAS data management solutions, including Drinking Water State-Federal-Tribal Information Exchange System (DW-SFTIES) support and potentially updating the SDWIS suite of applications to manage data reported from this rule.

The primacy agency record keeping requirements in 40 CFR 142.14 remain unchanged and would apply to PFAS as with any other regulated contaminants. Water system recordkeeping requirements are referenced within Subpart Z in § 141.904. In the final rule, the EPA updated this regulatory text to cross-reference the record retention provisions in § 141.33. The EPA is developing the DW-SFTIES that will support all SDWA drinking water rules. The EPA plans to continue to provide support for necessary updates to SDWIS State, including for reporting requirements for new rules, until the DW-SFTIES is in production and in use by primacy agencies. SDWIS State support and updates will continue until the DW-SFTIES Board recommends a sunset date after DW-SFTIES is in production and in use by primacy agencies. The EPA will evaluate the migration of UCMR data into the suite of SDWIS applications, including the technical considerations raised by commenters for data migration from the Safe

Drinking Water Accession and Review System (SDWARS) to SDWIS (e.g., incorporation of field reagent blanks (FRBs)).

The EPA also received a few comments requesting the agency develop a tool that would calculate the Hazard Index, and some of these commenters suggested that such a tool be integrated into the EPA's SDWIS application. The EPA agrees creating an online tool to facilitate checking the Hazard Index calculation will be beneficial for various stakeholders and is developing a Hazard Index Calculator to assist drinking water systems and primacy agencies in calculating the Hazard Index, as discussed in section 1.2 of the EPA response in this *Response to Comments* document. While beyond the scope of this rulemaking itself, the EPA is actively working on PFAS data management solutions, including DW-SFTIES support and potentially updating the SDWIS suite of applications to manage data reported from this rule, to include integrated calculation of the Hazard Index.

Individual Public Comments

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044078)

Data Management

ASDWA recommends EPA ensure DW-SFTIES is capable of fully managing the data of the proposed rule.

The importance of data management in effectively implementing any rule cannot be understated. The Safe Drinking Water Information System (SDWIS) is used by most primacy agencies for compliance determinations and reporting, storing public water system facility data, tracking monitoring schedules, and keeping the public informed of the quality of their drinking water. Several primacy agencies do not use SDWIS and instead have developed custom data systems in use by their program - known as "SDWIS Free." Currently, SDWIS cannot effectively manage PFAS data, so most primacy agencies engaged with early data tracking and collection for PFAS do so outside of that data system. Many primacy agencies will need to migrate this data into SDWIS, which presents several challenges. SDWIS is undergoing a modernization effort that will span the next few years. Once the modernized system is released, known as Drinking Water State Federal and Tribal Information Exchange System or DW-SFTIES, additional time will be needed before state primacy agencies put it in production. Given these timelines, primacy agencies will need to manage PFAS-related data across multiple systems. Eventually, primacy agencies will need to migrate PFAS data into DW-SFTIES, which is presumed to fully support the data management of the proposed rule. These essential primacy agency functions increase the cost of rule implementation.

ASDWA recommends EPA develop a mechanism for migrating UCMR data into SDWIS State to reduce or eliminate the burden imposed on primacy agencies who would otherwise need to perform this work manually.

Managing PFAS data across multiple systems further challenges water systems that request reduced monitoring and have submitted UCMR 5 data to EPA through the Safe Drinking Water Accession and Review System (SDWARS). No automated process exists to migrate these data into SDWIS, and this gap is significant. Additionally, some missing data elements (Laboratory IDs, Minimum Reporting Levels, etc.) and the inability to download quality control data, which must be viewed in SDWARS one analyte at a time, may complicate developing a simple solution. Still, as the requirements for reduced monitoring depend on these data, resolving the data migration issue is a priority concern.

EPA Response: Please see section 11.2 of the EPA response in this *Response to Comments* document. Comments related to SDWIS or other data management systems used by primacy agencies are beyond the scope of this rulemaking.

Texas Commission on Environmental Quality (TCEQ) (Doc. #1632, SBC-044127)

Lack of Data Tools to Implement the Proposed Rule

Existing EPA data tools do not have the functionality to implement the proposed rule and additional tools are needed to facilitate the Fifth Unregulated Contaminant Monitoring Rule (UCMR5) for PFAS data sharing and compliance determinations. The current version of the Safe Drinking Water Information System-State (SDWIS/State) database does not have the functionality to calculate compliance reliably and consistently for the HI or differentiate usage of sample results below the PQL for separate methodologies (i.e., health-based standards and monitoring requirements) concurrently. EPA's modernization of SDWIS/State has been in the process for more than a decade and primacy agencies still do not have a reliable database to be able to implement the requirements of several newly promulgated NPDWRs. SDWIS/State often requires TCEQ to divert limited resources to develop reliable workarounds and other extensive and costly data management solutions to perform basic business functions.

TCEQ recommends EPA provide timely data entry instructions and update database applications with required logic to ensure accurate compliance values and the ability to make reliable compliance determinations. If EPA cannot provide the necessary updates to SDWIS/State before finalizing the PFAS NPDWR, TCEQ recommends the Drinking Water State Federal Tribal Information Exchange System (DW-SFTIES) hosts an adequate structure to accommodate compliance determination requirements. If EPA cannot provide the necessary updates to either SDWIS/State or DW-SFTIES, TCEQ recommends EPA extend the compliance date of the rule to allow adequate time for primacy agencies to develop data management solutions. Without time to develop a data management solution, primacy agencies would have to perform manual compliance determinations which would increase the potential for errors and delays in timely compliance determinations and communications to the public, impacting public health.

Managing PFAS data across multiple systems further presents a challenge for water systems that request reduced monitoring and have submitted UCMR5 data to EPA through the Safe Drinking Water Accession and Review System (SDWARS). No automated process exists to migrate these

data into SDWIS/State. This creates a significant data gap. TCEQ urges EPA to develop a mechanism for migrating UCMR5 data from SDWARS into SDWIS/State to reduce or eliminate the burden imposed on primacy agencies that will otherwise need to perform this work manually or develop tools to accomplish this function.

EPA Response: Please see section 11.2 of the EPA response in this *Response to Comments* document for discussion of the aspects of the comment related to data management platforms; for the response to the element of the comment related to data entry instructions, please see section 11.3 of the EPA response in this *Response to Comments* document. As noted in section 11.2 of the EPA response in this *Response to Comments* document, the EPA plans to continue to provide data management support either through updates to SDWIS State, including for reporting requirements for new rules, or through DW-SFTIES when available for use by primacy agencies. For further information about compliance timelines, please see section 12.1 of the EPA response in this *Response to Comments* document.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044173)

D. Data Management

1. NCDEQ recommends EPA ensure DW-SFTIES is capable of fully managing the data of the proposed rule.

The importance of data management in effectively implementing any rule cannot be understated. The Safe Drinking Water Information System (SDWIS) is used by NCDEQ for compliance determinations and reporting, storing public water system facility data, tracking monitoring schedules, and keeping the public informed of the quality of their drinking water. Currently, SDWIS cannot manage PFAS data, so NCDEQ has had to manage early data tracking and collection for PFAS outside of that data system. NCDEQ will need to migrate this data into SDWIS, which presents several challenges. SDWIS is undergoing a modernization effort that will span the next few years. Once the modernized system called DW-SFTIES (Drinking Water State Federal and Tribal Information Exchange System) is released, it will take additional time before it is in production at NCDEQ. Given these timelines, NCDEQ will need to manage PFAS-related data on its own across multiple systems. Eventually, NCDEQ will need to migrate PFAS data into DWSFTIES, which is presumed to fully support the data management of the proposed rule. NCDEQ would like to work with EPA and other affected states to implement an effective solution that addresses near term and long-term data management requirements.

2. NCDEQ recommends EPA develop a mechanism for migrating the Unregulated Contaminant Monitoring Rule 5 (UCMR 5) data into SDWIS State to reduce or eliminate the burden imposed on state agencies who would otherwise need to perform this work manually.

Managing PFAS data across multiple systems further presents a challenge for water systems that request reduced monitoring and have submitted UCMR 5 data to EPA through the Safe Drinking Water Accession and Review System (SDWARS). No automated process exists to migrate these

data into SDWIS, and this is a significant gap. Additionally, some missing data elements (Laboratory IDs, Minimum Reporting Levels, etc.) and the inability to download quality control data, which must be viewed in SDWARS one analyte at a me, may complicate the process of developing a solution. This is particularly important as the requirements for reduced monitoring depend on these data. NCDEQ would like to work with EPA and other affected states to implement an effective solution that enables efficient and timely migration of UCMR 5 data.

EPA Response: Please see section 11.2 of the EPA response in this *Response to Comments* document.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045045)

State Implementation & Enforcement

Section 1413 of the federal Safe Drinking Water Act establishes requirements that primacy entities must meet to maintain primacy including: adopting and implementing adequate procedures for enforcement and keeping records and making reports available on activities that EPA requires by regulations. The current version of the Safe Drinking Water Information System (SDWIS) does not allow states to track and enforce the requirements of the proposed MCLs. The SOC framework requires systems serving less than 3,300 customers to collect two (2) quarterly samples in one year triennially. The current release of SDWIS does not facilitate these schedules and New Jersey has had to improvise by utilizing dual schedules to enable compliance determinations. Additionally, the calculation of the Hazard Index is not supported by SDWIS. EPA has stated that states will be provided with a calculator but without integration into SDWIS its use may be limited and time consuming.

These modifications will create challenges for States with limited staffing or technology constraints as they implement these requirements, along with potentially transitioning to a new database. As the next version of SDWIS, DW-SFTIES: Drinking Water State-Federal-Tribal Information Exchange System, is in development, EPA needs to make sure any new requirements are integrated into the new system.

EPA Response: Please see section 11.2 of the EPA response in this *Response to Comments* document. Please see section 13.3.1 of the EPA response in this *Response to Comments* document for a discussion of estimating primacy agency costs (including regulatory start-up costs).

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045146)

4. Data Management

EPA should take steps to ensure that DW-SFTIES is capable of fully managing the data of the proposed rule.

The importance of data management in the effective implementation of any rule cannot be understated. Massachusetts currently uses a database developed in-house, the Water Quality Testing System (WQTS), to store system inventory, system staffing, monitoring schedules, water quality results, inspections, rule milestones, violations and enforcements. WQTS records are used to meet our primacy agency reporting obligations and to keep the public informed of the quality of their drinking water. WQTS has been modified to implement the Massachusetts PFAS rule but will likely need additional changes to reflect EPA's PFAS NPDWR and its new reporting requirements. MassDEP intends to transition into EPA's modernized system, the Drinking Water State Federal and Tribal Information Exchange System (DW- SFTIES) after its anticipated release date of January 1, 2025. DW-SFTIES must include all the fields and functions necessary to manage the new PFAS rule.

EPA should develop a mechanism for migrating UCMR5 data into state data systems to reduce or eliminate state burden.

Managing PFAS data across multiple systems presents a challenge for water systems that have submitted Unregulated Contaminant Monitoring Rule (UCMR5) data to EPA through the Safe Drinking Water Accession and Review System (SDWARS) and that request reduced monitoring based on those data. No process exists to migrate these data into state data systems. The existing SDWARS data download option is missing key data elements (Laboratory IDs, Minimum Reporting Levels (MRLs), Date Extracted, Date Analyzed, etc.) necessary to determine its applicability to substitute for initial monitoring. Furthermore, the inability to download quality control data, which must be viewed in SDWARS one analyte at a time, may complicate the process. Full electronic data packages of UCMR5 samples which include the results of field reagent blanks (FRBs) required by the method are needed for states to consider using these results for compliance. Absent this capability, MassDEP may not be in a position to offer public water systems the opportunity to substitute UCMR5 data for initial monitoring.

EPA must provide Data Entry Instructions (DEIs) within six months of the promulgation of the rule to allow primacy agencies, particularly "SDWIS Free" programs, to prepare their systems.

MassDEP will need time to prepare its current database, WQTS, to meet the new requirements. To ensure WQTS is prepared to manage the data and to ensure timely reporting to EPA, access to the Data Entry Instructions (DEIs) within at least six months of promulgation of the rule is critical. This need is especially great as MassDEP is a "SDWIS Free" program that cannot begin this work without a final DEI.

EPA Response: Please see section 11.2 of the EPA response in this *Response to Comments* document for discussion of the aspects of the comment related to data management platforms; the response on the element of the comment related to data entry instructions can be found in section 11.3 of the EPA response in this *Response to Comments* document. Please see section 8.7 of the EPA response in this *Response to Comments* document for discussion of the analysis of FRBs, for quality control (QC) purposes, when PFAS are detected.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044393)

DOH requests that EPA develop tools to aid with implementing the Hazard Index (HI) calculations for different state data systems. Multiple calculations for determining a HI result introduce a level of complexity for our data system. Also, as additional PFAS substances are evaluated and potentially regulated, it is important to consider how this will impact the current proposed HI calculations and allow for provision of additional PFAS to the proposed HI methodology.

EPA Response: Please see section 11.2 of the EPA response in this *Response to Comments* document for discussion of primacy agency record keeping requirements, including data management infrastructure necessary to implement the rule and tools for calculating the Hazard Index. Regarding regulation of additional PFAS in the future, the EPA would follow the regulatory development process outlined under SDWA and determine if additional PFAS are appropriate for inclusion in the Hazard Index. For further discussion of adding additional PFAS to the Hazard Index in the future, please see section 5.2.1 of the EPA response in this *Response to Comments* document.

Nebraska Department of Environment and Energy (NDEE) (Doc. #1653, SBC-043213)

• The proposed rule is expected to be finalized in 2024 prior to needed SDWIS updates including the ability to calculate the HI.

o States will be expected to calculate the HI manually which introduces human error, allows for inconsistent implementation from state to state and among EPA regions, and will require additional staff time. The Department would prefer EPA create a standardized assessment tool within SDWIS for calculating the HI.

EPA Response: Please see section 11.2 of the EPA response in this *Response to Comments* document for discussion of primacy agency record keeping requirements, including data management tools necessary to implement the rule. Please see section 1.2 of the EPA response in this *Response to Comments* document for further discussion of tools for calculation of the Hazard Index to avoid manual calculation.

Thurston Public Utility District (PUD), WA (Doc. #1729, SBC-043584)

3. That EPA develop tools to aid with implementing the Hazard Index (HI) calculations for different state data systems. Multiple calculations for determining a HI result introduce a level of complexity for any data system. Also, as additional PFAS substances are evaluated and potentially regulated, it is important to consider how this will impact the current proposed HI calculations and allow for provision of additional PFAS to the proposed HI methodology.

EPA Response: Please see the EPA response to comment Doc. #1665, SBC-044393 in section 11.2 in this *Response to Comments* document.

11.3 Reporting Requirements

Summary of Major Public Comments and EPA Responses

A few commenters recommended that the EPA provide Data Entry Instructions within six months of the promulgation of the rule to allow primacy agencies, particularly those that do not use SDWIS State, to implement their data systems for reporting to the EPA, prepare their PWS, and train staff. The EPA acknowledges this comment and will work to develop Data Entry Instructions as soon as possible. One commentor recommended that the EPA provide separate tracking of reporting and monitoring violations. The EPA acknowledges this comment and will consider this as data reporting tools are developed. A couple of commentors recommended that the reporting and recordkeeping requirements for compliance within the rule should provide an option for not requiring the running annual average (RAA) to be reported by the laboratories if the primacy agency performs the RAA calculations for the water system. In addition, one commenter requested that the primacy agency calculate the RAA and another commentor inquired whether the EPA intended to allow the water systems not to perform the RAA calculations if the primacy agency performs the RAA calculations. The EPA disagrees with these four comments and notes that two of them are contained within sections 8 and 16 of this *Response to Comments* document. Laboratories, under the proposed and final rule are not required to conduct an RAA calculation. To ensure that the water system has immediate knowledge of their compliance status, the final rule requires that water systems calculate the RAA and report this to the primacy agency. Primacy agencies or laboratories may also calculate the RAA, to confirm the results from the water system, but it is not a required reporting element under this regulation. Lastly, another commentor suggested that utilities be required to report the occurrence and concentration of other PFAS listed in the method (preferably 533) to facilitate data collection and to better inform water treatment objectives. The EPA disagrees with this comment, as it is outside the scope of this action, but does note that many water systems are currently collecting samples and reporting monitoring data for 29 PFAS that can be measured with EPA Methods 533 and 537.1 under UCMR 5 where the EPA has the regulatory authority; the majority of these PFAS compounds are not subject to any requirements under this Subpart.

The reporting requirements for primacy agencies under 40 CFR 142.15 remain unchanged and apply to PFAS as with any other regulated contaminant. The EPA intends to develop and provide access to Data Entry Instructions within one year after rule publication. The EPA will follow the usual protocol of engaging with a state-EPA workgroup for drafting the Data Entry Instructions. In this process, the EPA will consider the use of separate monitoring and reporting violation codes, like is used for the Revised Total Coliform Rule (RTCR). In this final regulation, the cross-reference to the water system reporting timeframes and provisions in § 141.31 at the start of § 141.904 is retained, and, at 40 CFR 141.904(b) Table 2, the EPA requires water systems to report PFAS RAAs to their primacy agency. As a general process, the laboratory will conduct the analysis of the sample and the system will use the result to calculate their RAA; the RAA

calculation may subsequently be completed by the primacy agency as a compliance check. The EPA does recognize that state laboratories often directly report results to the state as allowed in 40 CFR 141.31(c) and that electronic reporting tools, such as the Compliance Monitoring Data Portal (CMDP), may be used by systems to comply with this reporting requirement.

Individual Public Comments

Michigan Department of Environment, Great Lakes, and Energy (EGLE) Drinking Water and Environmental Health Division (DWEHD) (Doc. #1597, SBC-042990)

G. Rule Implementation and Enforcement

Having reviewed Section XII of the proposed NPDWR, EGLE DWEHD generally agrees with EPA's summary of requirements for primacy, record keeping, reporting, exemptions, and extensions. Regarding Table 1 of 141.904: EGLE DWEHD requests that EPA allow state agencies to calculate items 2, 3, and 4, rather than have supply report these values. Compliance calculations are complex, and our experience is that water supplies may calculate incorrectly and take (or not take) action based on incorrectly calculated values. There is precedent in some other rules to allow states to calculate values.

EPA Response: Please see section 11.3 of the EPA response in this *Response to Comments* document; see also the EPA response to comment Doc. #1626, SBC-044880 in section 16.5 in this *Response to Comments* document.

Michigan Department of Environment, Great Lakes, and Energy (EGLE) Drinking Water and Environmental Health Division (DWEHD) (Doc. #1597, SBC-042991)

EGLE DWEHD requests that EPA, when developing agency data reporting obligations, separate tracking and reporting of monitoring violations from reporting violations. This prevents confusion within state agencies and for the public by providing clarity about what type of violation has occurred.

EPA Response: Please see section 11.3 of the EPA response in this *Response to Comments* document; see also the EPA response to comment Doc. #1652, SBC-044185 in section 8.2 in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044100)

Additionally, the reporting and recordkeeping requirements for compliance within the rule should provide an option for not requiring the RAA to be reported by the laboratories if the primacy agency performs the RAA calculations for the water system.

EPA Response: Please see section 11.3 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044079)

ASDWA recommends that EPA provide Data Entry Instructions (DEIs) within six months of the promulgation of the rule to allow primacy agencies, particularly "SDWIS Free" programs, to prepare their systems.

All primacy agencies will need time to prepare their existing data systems to meet the new requirements. To ensure data systems are prepared to manage the data required and ensure timely reporting to EPA, access to the Data Entry Instructions (DEIs) is critical. This need is especially great for "SDWIS Free" programs which require additional lead times to update their custom data systems and rely on the DEIs to ensure the reporting and recordkeeping requirements are met.

EPA Response: Please see section 11.3 of the EPA response in this *Response to Comments* document.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044174)

D. Data Management

…

3. NCDEQ recommends that EPA provide Data Entry Instructions (DEIs) within six months of the promulgation of the rule to allow NCDEQ to prepare their systems and train staff.

NCDEQ will need time to prepare our existing data entry processes to meet the new requirements. To ensure timely reporting to EPA, access to the Data Entry Instructions (DEIs) is critical.

4. NCDEQ recommends that EPA coordinate between its programs, regions, and headquarters to ensure the Agency is not creating duplicative reporting requirements on the states.

EPA headquarters and regional staff often request duplicate data from the state. As a coregulator, NCDEQ wants to work with EPA and be helpful, but these additional data collections take significant staff me. NCDEQ recommends that EPA improve coordination between its programs, regions, and headquarters to ensure the Agency is not creating redundant reporting requirements for state agencies.

EPA Response: Please see section 11.3 of the EPA response in this *Response to Comments* document for commenter's item #D3 discussed in this comment. For item #D4 discussed in this comment, the EPA appreciates the cooperation of primacy agency co-regulators. The EPA works to limit the data collection requests but makes information requests as needed to support its oversight role.

American Council of Independent Laboratories (ACIL) (Doc. #1692, SBC-044745)

8. List of Reported PFAS Analytes

ACIL recommends that while the NPRM only requires monitoring only 6 PFAS analytes, ACIL recommends that utilities be required to report the occurrence and concentration of other PFAS listed in the method (preferably 533) in order to facilitate data collection and to better inform water treatment objectives

If you have any questions about any of our comments or would like further information, please contact Judy Morgan, Chair, ACIL Environmental Sciences Section (ESS) at judy.morgan@pacelabs.com, 615-347-5418 or David Friedman, ACIL ESS Technical Advisor at friedmanconsulting@outlook.com, 703-389-3821.

Sincerely yours,

Judith R. Morgan, MS, REM

ACIL Environmental Sciences Section Chair

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EPA Response: Please see section 11.3 of the EPA response in this *Response to Comments* document.

11.4 Enforcement and Other Issues

Summary of Major Public Comments and EPA Responses

The EPA received a few comments related to enforcement actions, including concerning topics such as penalties against systems that are in the process of installing treatment. The EPA notes that one of these comments about financial penalties appears in section 12.1 of this *Response to Comments* document. Below, the EPA addresses a couple of other comments related to enforcement and also shares additional information on its websites, including those listed below, such as the SDWA Enforcement Response Policy. The EPA notes that comments about the cost, including to primacy agencies, of enforcement-related activities may be found in section 13.3.1 of this *Response to Comments* document.

Individual Public Comments

Lakewood Water District (LWD) (Doc. #1574, SBC-042755)

Monitoring Penalties Counterproductive

As proposed, the regulations would seem to penalize water purveyors like LWD that have proactively and aggressively addressed PFAS contamination of their systems. LWD has been monitoring its wells for PFAS and reporting those results for many years. Under EPA's proposed rules, LWD now runs the risk of being classified (once EPA's MCLs are adopted) in violation of PFAS MCLs even though the regulatory framework in our state (Washington) will not have had time to be stood up.

EPA, instead, should postpone enforcement of PFAS MCLs until after state compliance systems and programs have been formally established.

EPA Response: The EPA disagrees that systems will be "penalized" for having proactively, previously collected PFAS data, as these data will not be used for compliance monitoring. This data can be only used to satisfy initial monitoring requirements; the EPA requires the most recent monitoring data that meet the criteria established under the NPDWR or for a system to collect and submit new data within 3 years of rule promulgation. The EPA does not agree that it should postpone enforcement of PFAS Maximum Contaminant Levels (MCLs) until after state compliance systems and programs have been formally established. This PFAS regulation sets a national standard; any state, such as Washington, can also be more stringent. SDWA § 1412(b)(10) requires that a "NPDWR shall take effect "3 years after the date on which the regulation is promulgated unless the administrator determines that an earlier date is practicable." Section 1412(b)(10) also authorizes "the Administrator, or a State (in the case of an individual system), may allow up 2 additional years to comply with a maximum contaminant level…if the Administrator or the State…determines that additional time is necessary for capital improvements." As described in section 12.1 of the EPA response in this *Response to Comments* document, under the final rule, systems have 5 years from promulgation of the rule for MCL

compliance to allow time for capital improvements. States will have time to obtain primacy and stand up their programs in light of the two-year primacy deadlines; where a state does not have primacy or interim primacy for a rule, the EPA would be the primacy agency. Therefore, a regulatory framework will be in place in any event when the water systems must comply with the NPDWR. Please see also the EPA response to comment Doc. #1708, SBC-045094 in section 12.1 in this *Response to Comments* document.

Bob Johnson (Doc. #3072-99, SBC-046403)

Hi, good evening. I appreciate the second go round. There's a point I wanted to make that I did not have time before. I would highly, very highly, recommend that Congress or EPA, if possible, make it mandatory for these laws to be obeyed, mandatory financial penalties and fines, if not, politics tend to get involved. And I can say this with full conscience, that next door to my house is a regional landfill, which has not been in compliance in two and a half years and the state of North Carolina will not bring it under control, EPA will not get involved. They have been issued seven notices of violation in the last two and a half years. They have been warned that they were going to be fined $75,000 per day per occurrence. And at times they have six notices of violations at one time. So far, they have not been fined anything whatsoever, but the North Carolina DEQ has furnished some grant money to them. So, if this is not made mandatory, my guess is that 20 years from now we still will not see it done here. The only thing it seems that the state politicians look for in North Carolina is the cost. And without mandatory penalties, I think we're wasting our time. I appreciate the conference. You've done an excellent job, and I hope you have a good day. Thank you.

EPA Response: Compliance with statutes by local entities (in this case, a landfill) is outside the scope of this regulatory action; however, note that the EPA offers a portal where anyone can report possible violations of environmental laws and regulations at https://echo.epa.gov/report-environmental-violations. Compliance with the MCLs for PFAS for PWSs is mandatory beginning 5 years from the date of rule promulgation. The establishment of mandatory penalties is beyond the scope of this rulemaking; Section SDWA 1414 governs the imposition of civil penalties for violations in federal enforcement actions. Therefore, the EPA is not establishing new penalties for PFAS specifically in this NPDWR. If the EPA decides in a case to seek penalties for a water system's noncompliance with an applicable requirement such as the PFAS MCL in this new NPDWR, then the EPA would rely on its statutory authorities, including SDWA Section 1414, to impose the penalty. The EPA's SDWA Enforcement Response Policy (USEPA, 2009) explains how the EPA typically pursues enforcement cases involving a water system's violations of the SDWA. Primacy agencies must have the authority to take enforcement actions and assess civil penalties (40 CFR 142.10(b)(6)). As provided in SDWA Section 1413, nothing in SDWA precludes a state from establishing requirements that are more stringent than the final NPDWR, including enforcement provisions.

The EPA is initiating actions under multiple environmental authorities—the Resource Conservation and Recovery Act (RCRA), Toxic Substances Control Act (TSCA), Clean Water

Act (CWA), SDWA and Comprehensive Environmental Response Compensation and Liability Act (CERCLA)—to identify past and ongoing releases of PFAS into the environment at facilities where PFAS has been used, manufactured, discharged, disposed of, released, and/or spilled. The EPA is conducting inspections, issuing information requests, and collecting data to understand the level of contamination and current risks posed by PFAS to surrounding communities and will seek to address threats to human health with all its available tools. The EPA works with its federal, state and Tribal regulatory partners through a comprehensive SDWA compliance monitoring program (https://www.epa.gov/compliance/safe-drinking-water-act-sdwa-compliance-monitoring) to protect human health and the environment by ensuring that the regulated community obeys environmental laws/regulations through on-site visits by qualified inspectors, and a review of the information the EPA or a state/Tribe requires to be submitted.

Delores Kirkwood (Doc. #2772, SBC-046497)

In the upper 1/3 of INDIANA it is clear that they are falsifying the numbers. Ask a statistician what are the chances of the numbers being either exactly as the last testing (right at the edge of the permitable range) or exactly the same as the previous testing for (9?) harmful substances that would harm you?

The EPA should be the ones testing the water, NOT a political person working for that city. We are being poisoned unless we have the money to buy Distilled (doctor recommended) water, and not bottled when some merely fill bottles with tap water. PLEASE, protect a child's future.

EPA Response: Concerns about the accuracy of certain data already collected and reported are outside the scope of these regulations. However, the EPA is initiating actions under multiple environmental authorities—the RCRA, TSCA, CWA, SDWA and CERCLA—to identify past and ongoing releases of PFAS into the environment at facilities where PFAS has been used, manufactured, discharged, disposed of, released, and/or spilled. The EPA is conducting inspections, issuing information requests, and collecting data to understand the level of contamination and current risks posed by PFAS to surrounding communities and will seek to address threats to human health with all its available tools. Additionally, due to the toxicity and persistence of PFAS chemicals, and the breadth and scope of PFAS contamination throughout the country, the EPA selected Addressing Exposure to PFAS as a new National Enforcement and Compliance Initiative (NECI) for Fiscal Years 2024-2027. PFAS contamination is a significant priority for the EPA and, while the regulatory framework for PFAS continues to develop across multiple statutes, the EPA has already taken a number of enforcement actions to ensure compliance with existing statutes, including action to address an imminent and substantial endangerment to communities. The EPA will increase those efforts, particularly where necessary to protect drinking water supplies, as part of this new initiative. The EPA works with its federal, state and Tribal regulatory partners through a comprehensive SDWA compliance monitoring program (https://www.epa.gov/compliance/safe-drinking-water-act-sdwa-compliance-monitoring) to protect human health and the environment by ensuring that the regulated

community obeys environmental laws/regulations through on-site visits by qualified inspectors, and a review of the information the EPA or a state/Tribe requires to be submitted.

The EPA also offers a portal where anyone can report possible violations of environmental laws and regulations at https://echo.epa.gov/report-environmental-violations. Systems are required to maintain records that document compliance with SDWA requirements, including documentation of the results received from a laboratory analyzing water samples. Regarding the suggestion that the EPA collect all samples, rather than allowing the PWSs to collect the samples, this is not a practical approach. Rather, under the PFAS regulation and other NPDWRs, water systems are responsible for collecting compliance samples and reporting this information to the state that has received primary enforcement authority (primacy) for implementing SDWA. The EPA also maintains oversight responsibility of the primacy agencies. The EPA and states operate in partnership to administer and implement safe drinking water programs, including to oversee adherence to the requirements of NPDWRs.

Section 11 References

USEPA. 2009. Enforcement Response Policy for the Public Water System Supervision (PWSS) Program under the Safe Drinking Water Act and Implementation of (SWA) the Enforcement Targeting Tool, December 8, 2009. Available on the Internet at: https://www.epa.gov/sites/default/files/documents/drinking_water_erp_2009.pdf.

12 Exemptions and Extensions

12.1 Requirements

Summary of Major Public Comments and EPA Responses

The nearly uniform sentiment of commenters, including utilities and state primacy Agencies, was their concern over the ability of water systems to meet the three-year compliance deadline. Commenters expressed that it will be very challenging to both conduct initial monitoring and take actions (e.g., installing treatment) to comply with the Maximum Contaminant Level (MCL) within three years. Many of these commenters shared their on-the-ground experience in managing facilities that required capital improvements and provided evidence that additional time is needed to procure, design, pilot, permit, and ultimately construct treatment systems. Additionally, several commenters provided evidence of on-going labor and workforce challenges as well as recent experience with supply chain difficulties to obtain materials necessary to design and construct treatment facilities, which many attributed as a direct or indirect result of the COVID-pandemic residual impacts (AWWA, 2023).

The agency has evaluated the data and information shared by commenters regarding their experience with the time it takes to implement capital improvement projects. The EPA estimates that approximately 4,100 – 6,700 systems will be impacted by the MCLs in this final rule. Based on the EPA's initial compliance forecast, the agency anticipates that many of these systems will be installing advanced treatment technologies to meet the final PFAS standards (for additional discussion on the compliance forecast, please see section XII). The treatment technologies listed as best available technologies (BATs) for the final rule include granular activated carbon (GAC), ion exchange resins, and centralized reverse osmosis/nanofiltration (RO/NF) (please see section X of the final rule preamble for more information). To ensure cost effective compliance with the PFAS MCLs, systems often need to evaluate their treatment technology options as a first step. Several commenters have noted that this planning step may include pilot studies with potential treatment systems, or it may be limited to an evaluation of the raw water characteristics. Further, some commenters have submitted data and project management plans for systems choosing to conduct pilot testing, indicating that it may take a year or more to contract with vendors and to perform pilot testing. Once the planning step is completed, systems must design and construct the treatment systems. Several commenters submitted information to the EPA indicating that the design and permitting of the treatment systems can take an additional year or longer, and construction of the treatment system can take another year or longer. Because systems will also need time to obtain funding, obtain local government approval of the project, or acquire the land necessary to construct these technologies, many commenters contend that systems will need additional time beyond the three-year effective date to comply with the MCLs.

While the EPA stated in the proposed rule that the agency did not intend to provide a two-year extension nationwide necessary for capital improvements, the EPA finds that the evidence submitted by commenters strongly supports that a significant number of systems covered by this

rule will need two additional years to make capital improvements to meet the MCL. Specifically, the EPA reviewed data from applicants seeking Drinking Water State Revolving Fund (DWSRF) funding for capital improvement projects (e.g., installation of advanced treatment technologies such as GAC or ion exchange (IX)) and confirmed that these projects, on average, take about three or more years to complete (which excludes the time and activities that may occur to ensure these capital improvement projects are implemented successfully, such as the time it may take to secure funding or to conduct pilot testing) (USEPA, 2024a). This evidence along with the breadth of practicable experience shared by utilities and primacy agencies demonstrate that additional time is necessary for a significant number of system sizes and types located throughout the country to make capital improvements. Additionally, the EPA notes that the number of systems estimated to be impacted by the MCLs are greater than what the agency anticipated in the proposal (i.e., an increase from 3,400 - 6,300 systems to 4,100 – 6,700 systems nationally). This increase provides further evidence that a capital improvement extension is warranted as the agency expects that many of these systems will be installing advanced treatment technologies to meet the final PFAS standards. The agency also agrees with commenters that on-going labor and workforce challenges exist and can limit the ability to design, construct and operate treatment facilities. These workforce challenges facing water utilities and other sector organizations support the need for a capital improvement extension as a sufficient availability of qualified personnel is necessary to implement and sustain capital improvement projects. These issues may be attributed as a direct or indirect result of the recent COVID-19 pandemic and are clearly documented in data submitted to the agency as part of the public comment process (AWWA, 2023). Based upon these considerations, the EPA determined, in accordance with section 1412(b)(10) of the Safe Drinking Water Act (SDWA), that the compliance date for the PFAS MCLs, regardless of system size, will be 5 years from the date of promulgation of the standard.

Some commenters recommend the EPA to follow a staggered implementation timeframe similar to what was done in some previous National Primary Drinking Water Regulations (NPDWRs) where compliance deadlines were staggered based on system size (USEPA, 2001; 2006). In these prior examples, larger systems typically conducted their monitoring and implemented the MCL first, followed by smaller systems. Upon consideration of information submitted by commenters, particularly issues related to supply chain complications that are directly or indirectly related to the COVID-19 pandemic residual challenges, the EPA has determined that a significant number of systems subject to the rule, including large systems, will require two additional years to complete the capital improvements necessary to comply with the MCLs for PFAS regulated under this action. For this reason, the EPA disagrees with commenters that staggered implementation based on system size is warranted for this rule. While large systems may have greater resources to implement capital improvements (e.g., engineering and construction management staff to manage the projects), they still require time to design, pilot, permit, and construct treatment facilities.

Some commenters note that it will be challenging for systems to conduct their initial monitoring and install treatment within three years, particularly for those systems not conducting the fifth

Unregulated Contaminant Monitoring Regulation (UCMR 5) monitoring that is ongoing until 2026. The EPA notes that the agency is finalizing a flexibility for systems to use previously acquired monitoring data from UCMR 5 or an equivalent state-led monitoring program for their initial monitoring which is intended to alleviate the burden placed on water systems in collecting additional data (see section VIII for additional information on monitoring). While the agency agrees that systems need an additional two years to make capital improvements, the EPA finds that it is practicable for most systems to complete their initial monitoring within three years because all systems serving greater than 3,300 people will have appropriate monitoring data from UCMR 5. Many systems smaller than 3,300 people will also have appropriate monitoring data from state-led monitoring programs that may be eligible to meet the rule's initial monitoring requirements, and some will have UCMR 5 or other data. If systems find elevated levels of PFAS, these systems have an additional two years to comply with the MCL. If a system does not have eligible previously collected monitoring data and are concerned about insufficient time to install capital improvements, the EPA encourages these facilities to collect monitoring data as soon as possible after rule promulgation, allowing them the bulk of the five-year period to plan for and install any capital improvements if necessary.

Some commenters point to concerns regarding laboratory capability and capacity in supporting the proposed three-year compliance timeline. Additionally, a couple of commenters noted that if additional time were allowed, water systems that are close to the MCL may have time to identify and address sources of PFAS in their watersheds rather than investing resources on treatment initially. Finally, a couple of commenters recommend the EPA consider implementation flexibilities for small and rural water systems and suggest that these types of utilities may not have staff capacity nor expertise to compete for funding to implement the rule. While the agency acknowledges these commenter concerns, these issues are not directly related to capital improvements and thus were not the basis for the EPA's decision to extend the compliance date for the PFAS MCLs. However, the agency believes that extending the compliance date will also provide ancillary benefits toward addressing laboratory capability and capacity issues and may provide opportunities for systems who are close to exceeding the MCLs to investigate sources of contamination. Additionally, the extended compliance deadline may give smaller and rural water utilities more time to apply for funding under the Bipartisan Infrastructure Investment and Jobs Act (IIJA), also referred to as the Bipartisan Infrastructure Law (BIL) (please see section II of the final rule preamble for a discussion on BIL).

SDWA § 1416(a) and (b)(2)(C) describe how the EPA or states may also grant an exemption for systems meeting specified criteria that provides an additional period for compliance. These exemptions are issued on a case-by-case basis at the discretion of the primacy agency. Public water systems (PWSs) that meet the minimum criteria outlined in the SDWA may be eligible for an exemption of up to three years. For smaller water systems (≤3,300 population), exemptions can provide up to six additional years to achieve compliance. States exercising primacy enforcement responsibility must have adopted the 1998 Variance and Exemption Regulation (USEPA, 1998) for water systems in those jurisdictions to be able to provide exemptions.

The EPA requested comment as to whether there are specific conditions, in addition to the statutory conditions, that should be mandated for systems to be eligible for exemptions from the PFAS NPDWR under SDWA § 1416. Several commenters requested the EPA provide additional guidance to primacy Agencies on when exemptions are appropriate under SDWA § 1416 similar to what was done for the final Arsenic NPDWR (USEPA, 2002), which provided additional guidance on prioritizing systems for case-by-case extensions of the compliance deadline (beyond the 5 years provided in this rule) consistent with the requirement that an exemption not create an "unreasonable risk to health." Because relatively few states choose to issue exemptions, the EPA is not issuing additional guidance around implementation of SDWA § 1416 at this time but may reconsider the need for such guidance based on information developed during the initial compliance period. Furthermore, the EPA cannot issue exemptions as part of the NPDWR, as suggested by some commenters; exemptions under SDWA Section 1416 are issued by the primacy agency on a case-by-case basis and must meet the criteria under that provision.

Some commenters note simultaneous compliance issues with other final or proposed rules, such as the proposed Lead and Copper Rule Improvements. To the extent that implementation overlaps with other rules, the Health Risk Reduction and Cost Analysis (HRRCA) required by SDWA excludes costs that result from compliance with other regulations. Specifically, the agency notes that SDWA Section 1412(b)(3)(C)(i)(III) requires that EPA include quantifiable and non-quantifiable costs that are likely to occur solely as a result of compliance with the rule including monitoring, treatment and other costs and excluding costs resulting from compliance with other proposed or promulgated regulations. Nonetheless, the EPA has not identified any other drinking water regulations or requirements that will inhibit compliance with this regulation, nor should this regulation significantly impair compliance with other regulations such as the lead and copper rules (e.g., installing a treatment technology to comply with the MCLs for the PFAS NPDWR does not inhibit a system from taking action to meet corrosion control requirements under the lead and copper rule). With respect to the proposed Lead and Copper Rule Improvements, should the agency finalize that NPDWR, the EPA notes that operational adjustments may be necessary if treatment is installed to meet the MCLs under this NPDWR. Ion exchange resins or RO, for instance, may make water more corrosive if post-treatment stabilization (e.g., pH adjustment) is not performed. However, increases in corrosivity is short-lived after an ion exchange media change-out (please see the *Best Available Technologies and Small System Compliance Technologies Support Document*, USEPA 2024b). Systems using RO would likely need post-treatment stabilization to address corrosivity. While the EPA is not aware of many systems treating source waters for lead and copper (USEPA, 2019 – see FRN Vol. 84, No. 219, at page 61706), post-treatment stabilization and corrosion control will depend upon the treatment selected for lead or copper source water treatment. Nevertheless, the EPA recommends utilities to evaluate all treatment (and non-treatment) options for their site-specific needs and to carefully examine their operational plans to meet the requirements of this and other final NPDWRs. Finally, while the agency has not identified any other drinking water regulations or requirements that will inhibit compliance with this regulation, nor should this regulation significantly impact compliance with other regulations, the EPA's decision to extend the

compliance date for the PFAS MCLs may provide benefits for those systems to the extent that any such simultaneous compliance challenges exist.

SDWA § 1412(b)(10) requires that a NPDWR shall take effect "3 years after the date on which the regulation is promulgated unless the administrator determines that an earlier date is practicable." Section 1412(b)(2) also authorizes "the Administrator, or a State (in the case of an individual system), may allow up 2 additional years to *comply with a maximum contaminant level*…if the Administrator or the State…determines that additional time is necessary for capital improvements" (emphasis added). Congress intended the extension under this provision to allow for a total of five years to comply with the MCL. Thus, if the EPA provides a two-year extension of the MCL compliance deadline for all systems based on the need for capital improvements, a state cannot provide an additional two-year extension under Section 1412(b)(10) for capital improvements but may grant exemptions under Section 1416 consistent with applicable requirements.

Pursuant to SDWA § 1412(b)(10), the final PFAS NPDWR is effective 60 days after promulgation. The compliance date for the PFAS NPDWR, other than the MCLs, is 3 years after promulgation. As discussed above and upon consideration of information submitted by commenters, the EPA is exercising its authority under SDWA § 1412(b)(10) to implement a nationwide capital improvement extension to comply with the MCLs. All systems must comply with the MCLs by 5 years after the promulgation date.

Systems must comply with initial monitoring requirements within three years of rule promulgation and will be required to summarize PFAS monitoring results and applicable information beginning with Consumer Confidence Reports (CCRs) delivered in 2027. As the MCL compliance date is set at five years from rule promulgation, systems must report MCL violations in the CCR, accompanied by the required health effects language and information about violations, starting in 2029. Monitoring and testing procedure violations require Tier 3 notification: systems must provide notice no later than one year after the system learns of the violation. Systems must repeat the notice annually for as long as the violation persists. Systems must comply with initial monitoring requirements within three years of rule promulgation and systems must provide Tier 3 notification for monitoring and testing procedure violations starting in 2027. As the MCL compliance date is set at five years from rule promulgation, systems must provide Tier 2 notification for MCL violations, starting in 2029. For more information on SDWA Right-to-Know requirements, please see section IX of the final rule preamble.

Some commenters recommend a different regulatory framework than what the EPA proposed to alleviate perceived implementation concerns (e.g., reduce the potential of inundating laboratories or providing more time to plan and identify opportunities for source water reduction). For example, a few commenters suggest a phased-in MCL, where systems demonstrating higher concentrations are addressed first in the NPDWR, or MCL approaches where interim targets are set for compliance. While the agency has implemented a phased-in MCL in other NPDWRs, it is neither necessary or appropriate to do so here. The monitoring and compliance requirements finalized in the PFAS NPDWR address high-risk systems (i.e., systems with elevated

concentrations will require more frequent monitoring whereas systems without contamination or low levels of contamination will monitor less frequently). Based on these monitoring results, water systems may then be required to change their monitoring frequency if the results suggest increasing or decreasing concentrations (for additional discussion on monitoring and compliance requirements for the rule, please see section 8 of the EPA response in this *Response to Comments* document). In scenarios where elevated levels of PFAS are found in presumably "lower-risk" systems, a phased-in approach is not public health protective as these are systems that may experience spikes in PFAS concentrations. These fluctuations have been demonstrated in the agency's evaluation of PFAS occurrence in drinking water. The agency does not believe a phased-in approach that would delay compliance for such systems is warranted given the likely occurrence, co-occurrence, and public health concerns of the PFAS regulated by the NPDWR. The development of such a phase-in would also require additional resources both to develop the phase-in and to implement it, and is likely to be challenging to implement.

However, upon consideration of information submitted by commenters, particularly issues related to supply chain complications that are directly or indirectly related to the COVID-19 pandemic residual challenges, the EPA has determined that a significant number of systems subject to the rule will require an additional 2 years to complete the capital improvements necessary to comply with the MCLs for PFAS regulated under this action. The EPA expects that the additional 2 years are necessary for capital improvements to meet the MCL. Because EPA has provided a 2 year extension based on the need for capital improvements, EPA has addressed the concerns of many commenters about the need for additional time to comply with the rule, and therefore a phased schedule for rule implementation based on the concentrations of PFAS detected is unnecessary.

Individual Public Comments

Orange Water and Sewer Authority (OWASA) (Doc. #1524, SBC-042621)

• Treatment Support

o Start up and commissioning teams may be at a premium (especially if you go with a vendor supplied pressure vessel). This could impact the OWASA team's understanding of the new system as well as overall operation of the new system

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Orange Water and Sewer Authority (OWASA) (Doc. #1524, SBC-042619)

• Engineer Availability

o Current labor market it making it difficult to find engineers

o All of our current consultants are busy and not everyone is suited to design advanced treatment so those that are will be carrying a heavy load of work

• Contractor Availability

o Contractors are busy and are also being influenced by the difficult labor market

o Paying a premium for contractor availability

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Orange Water and Sewer Authority (OWASA) (Doc. #1524, SBC-042616)

• Timeline

o Regulatory Compliance deadline

o Because of the magnitude of costs involved, there are certain alternatives (e.g., new water treatment facility) that may represent the best overall solution for the utility for which the compliance timeline doesn't allow enough time to properly evaluate, design, and implement. Instead we have to quickly pick a technology that we know will work and that we can possibly get running prior to the compliance deadline plus the extension.

o There is a lot of new research and development of new treatment options/technologies is ongoing with PFAS and the current timeline precludes us from evaluating and potentially implementing some of these newer technologies and approaches.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

City of Dayton, Ohio (Doc. #1528, SBC-042632)

Attached are the comments for the City of Dayton, Ohio.

COMMENTS OF THE CITY OF DAYTON, OHIO

U.S. EPA's March 14, 2023, Proposed National Primary Drinking Water Regulation (NPDWR) for the Following Per- and Polyfluoroalkyl Substances (PFAS): [PFOA, PFOS, PFNA, Hr-PO-DA (GenX), PFHxS, and PFBSI

Public Docket ID: EPA-HQ-OW-2022-0114

Submitted Electronically (www.regulations.gov)

April 20, 2023

The City of Dayton, Ohio ("Dayton" or "the City") submits these comments on the above referenced proposed NPDWR.

Dayton is requesting that PWSs be given sufficient time to comply with the final MCLs and that funding for compliance be provided through avenues with no effect on ratepayers.

Dayton supplies 400,000 customers with treated groundwater, at an average daily flow of 60 million gallons per day (MGD), sourced from two well fields, the Mad River and the Miami Well Fields. The Mad River Well Field supplies approximately two-thirds of the treated water and directly adjoins Wright-Patterson Air Force Base's (WPAFB) southwestern boundary. Dayton's source water is 100% groundwater under the direct influence of surface water pumped from one of the largest Safe Water Drinking Act (SDWA) designated sole source aquifers in the U.S.

The City of Dayton has a significant interest in the proposed NPDWR due to the detection of per- and poly-fluoroalkyl substances (PFAS) in its early detection monitoring wells since 2016. The PFAS, primarily perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS), were detected at levels consistently above the 2016 PFAS health advisory level (HAL) of 70 parts per trillion (ppt) and as high as 150 ppt. The PFAS contamination is resultant of both surface water and groundwater flow from WPAFB.

In response, eight production wells closest to WPAFB, accounting for nearly 35% of the Mad

River Well Field's pumping capacity, were removed from service since 2017 at the request of Ohio EPA.

Treated water from the Ottawa Water Treatment Plant, which receives water from the Mad River Well Field has elevated PFAS levels that consistently range between 5-12 ppt, and sometimes as high as 18 ppt, considerably above U.S. EPA's 2022 revised SDWA HAL for PFAS, and the draft maximum contaminant levels (MCLs) of 4 ppt.

The City has requested WPAFB to fund the installation of a treatment system to remove the PFAS from the finished water produced at the Ottawa Water Treatment Plant; to date, the request has been denied.

Since 2016, the City of Dayton has been working closely with both Ohio and U.S. EPA to develop a comprehensive PFAS Strategy. This strategy includes the development of an alternate

water supply, conveyance of water to the Ottawa Water Treatment Plant, and treatment of finished drinking water to remove any remaining PFAS. However, the estimated cost of implementing this strategy is over $300 million.

The City of Dayton has several concerns regarding the proposed NPDWR, including:

• the amount of time to be afforded to public water systems (PWSs) to meet the final MCLs;

• the action steps that would be triggered based on an exceedance of the final MCLs;

• the enforcement discretion to be afforded to PWSs like Dayton that are likely to have difficulty meeting applicable deadlines to consistently comply with final MCLs;

[The City of Dayton has several concerns regarding the proposed NPDWR, including:]

• and the potential sources of funding to be made available to PWSs like Dayton that have contaminated raw water coming from sources outside of the City's control.

Dayton is requesting that PWSs be given sufficient time to comply with the final MCLs and that funding for compliance be provided through avenues with no effect on ratepayers.

The City of Dayton appreciates the opportunity to submit these comments and would welcome an opportunity to discuss them with U.S. EPA's staff whenever convenient.

Respectfully submitted,

CITY OF DAYTON, OHIO

By:

Michael Powell, Director

Department of Water

City of Dayton, Ohio

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. For funding concerns, the agency notes that funds are also available through the passage of the BIL to assist many disadvantaged communities, small systems, and others with the costs of installation of treatment when it might otherwise be cost-challenging. Please see section 2.4 of the EPA response in this *Response to Comments* document for more discussion about currently available funding.

Water Environment Federation (WEF) (Doc. #1529, SBC-043309)

Implementation: With 5,000 – 10,000 systems being required to treat for PFAS, contractor availability will be limited. Pilot testing can also take from 12-18 months.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Greater Cincinnati Water Works (GCWW) (Doc. #1550, SBC-042690)

Aside from the high cost of retrofitting our ground water treatment plant, Greater Cincinnati Water Works is very concerned about the timing of this regulation as well as the compliance schedule. EPA has a goal of finalizing this rule by the end of 2023 after which water systems will have three years to come into compliance. An option for a two-year extension is available for systems needing capital improvements, but this extension is not automatic. Typically projects of this magnitude for large utilities are multi-year projects. Piloting, design, regulatory approval, procurement, and construction can easily exceed three, and even five years. The current compliance schedule is far too aggressive to implement on a national basis.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Greater Cincinnati Water Works (GCWW) (Doc. #1550, SBC-042692)

The timing of this regulation is especially challenging for utilities as they muster resources to simultaneously comply with the recently promulgated Lead and Copper Rule soon to be followed by the Lead and Copper Rule Improvements. As utilities continue to put significant financial and personnel resources toward removal of lead lines and optimizing water quality for corrosion control, compliance with the PFAS rule will stress our limited resources even further. Although significant federal funding has been made available, it is not nearly enough to cover the costs of both programs. Concurrent implementation of these programs will place a significant burden on all our rate payers and make it more difficult for us to fund these two programs, aging infrastructure improvements, and programs for disadvantaged customers all at the same time.

We request this compliance period include a significantly longer compliance schedule for facilities requiring capital improvements. This will allow for additional time to plan treatment processes carefully, ensure simultaneous compliance with multiple regulations, and for costs to be spread over a longer time period.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as simultaneous compliance challenges. For funding concerns, the agency notes that funds are also available through the passage of the BIL to assist many disadvantaged communities, small systems, and others with the costs of installation of treatment when it might otherwise be cost-challenging. Please see section 2.4 of the EPA response in this *Response to Comments* document for more discussion about currently available funding.

Ross Renick (Doc. #1553, SBC-042560)

May 10, 2023

Dr. Jennifer McLain,

Director

Office of Ground Water and Drinking Water (OGWDW)

United States Environmental Protection Agency (E.S. EPA)

1201 Constitution Ave NW

Washington DC, 20004

Re: Docket ID No. EPA-HQ-OW-2022-0114 Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

Dear Dr. McLain,

Thank you for the opportunity to comment on the upcoming proposal regarding Per- and Polyfluoroalkyl Substances and the National Primary Drinking Water Regulation (NPDWR). This comment is in general support of the proposed regulation and the need for swift action regarding the emerging contaminants that threaten our drinking water supplies. According to the EPA's definition of "emergent contaminants, a chemical or material characterized by a perceived, potential, or real threat to human health or the environments or by a lack of published health standards", the determinations of the two contaminants PFOA and PFOS, and the concurrent four (PFHxS, PFNA, Genx Chemicals, and PFBS seems appropriate as these contaminants are rapidly being detected in drinking water supplies across the country. However, there are parts of the proposal I do find concerning and would like to address for your consideration.

The first concern is the timeline of events. Per the CDC, many PFAS including PFOS and PFOA are a concern because they do not break down in the environment, can move through soils and contaminate drinking water sources, and are a bioaccumulate in fish and wildlife (CDC n.d.). In many places throughout the country these fish and wildlife sources are harvested as a main

source of protein and concern over the consumption of these food sources should be a concern. The effective enforceable date of this regulation of 2026 should be moved up. Even though this proposal is specifically addressing drinking water, there are other sources of PFAS in the environment that will affect human health and I feel as if we should limit those that we can as soon as possible. To that point, technology available (GAC, AIX, RO, and NF) presented by Mr. Lan is greater than 99% effective at achieving concentrations below analytical detection limits (EPA n.d.). If these technologies are available currently, we should implement them as soon as possible. Another issue with the proposed timeline is the Maximum Contaminant Level Goals (MCLGs) are non-enforceable (EPA n.d.). Meanwhile, with sooner implementation of the NPDWR, Maximum Contaminant Levels (MCLs) would be enforceable, and violations could be enforced sooner, ensuring safe drinking water. There are already enough non-enforced regulations within the Safe Water Drinking Act (SWDA) and PFAS should not be one of those due to the adverse human health effects. The Science Advisory Board has already recommended strengthening the rationale for PFAS from "suggestive" to "likely" in relation to various cancers and there should be swift action to reduce these risks (EPA, n.d.). A national standard for PFAS in drinking water should be a priority as there are currently 31 states with no PFAS regulations in place and several states have regulations that are less stringent than the current EPA Lifetime Drinking Water Health Advisory Level of 70 ppt for PFOS and PFOA guidance (Leighton, 2023).

EPA Response: The agency agrees with the commenter on the health concerns posed by PFAS and that establishing a national PFAS NPDWR as expeditiously as possible is needed to protect public health and the environment. SDWA § 1412(b)(10) requires that a "NPDWR shall take effect "3 years after the date on which the regulation is promulgated unless the administrator determines that an earlier date is practicable." For the same reasons discussed in section 12.1 of the EPA response in this *Response to Comments* document concerning the challenges water systems face in meeting the three-year statutory timeline for compliance provided in SDWA, EPA has determined that it is not "practicable" for water systems to comply with the rule prior to the three-year date set in the statute. However, under the statute, states can set more stringent requirements, including setting earlier compliance dates pursuant to SDWA Section 1414(e). Section 1412(b)(2) also authorizes "the Administrator, or a State (in the case of an individual system), may allow up 2 additional years to comply with a maximum contaminant level…if the Administrator or the State…determines that additional time is necessary for capital improvements. Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Michigan Farm Bureau (MFB) (Doc. #1562, SBC-043359)

Small and rural water suppliers face additional challenges: many assistance programs listed above are competitive and rely on a complex application process that smaller utilities have neither the staff capacity nor expertise to compete for limited dollars. Additionally, those federal

assistance programs are primarily in the form of low- or no-interest loans instead of grants, so many communities already struggling with asset management cannot afford the payback on such loans even at beneficial rates. Staff shortages even for the existing work required to safely operate and maintain drinking water systems are widespread: AWWA conducted a survey in 2021 on staffing and supply chain needs, [FN17: American Water Works Association. 2021. Covid Water Sector Impact Survey 5 (Oct 2021). Retrieved from: https://www.awwa.org/Portals/0/AWWA/Communications/COVID19Impact5thSurveyPublicSummary.pdf] and found that 40 percent of drinking water utilities of all sizes are struggling to fill positions at their facilities, and employee turnover has doubled. While in part due to Covid-19 labor shortages, the survey notes this challenge is also reflective of long-term trends that have not eased as return to work increased after initial shutdowns and pandemic-related restrictions were lifted. This shortage will worsen as additional contractors, permanent staff, laboratory capability, and treatment operators are needed to implement the additional regulatory requirements of complying with PFAS MCLs.

Worst, many agricultural businesses, such as farms with on-site worker housing for part of the year, packers and processors with enough employees to qualify as a public supply while not being a public utility, dairy and other farms with specific drinking water requirements that must meet public water supply standards, and other agricultural water users are not eligible at all for many federal or state assistance programs, or suffer similar problems with capacity to compete for that money in the programs they may participate in. Those agricultural businesses do not have rate payers to spread costs to; they must simply absorb the costs to their business with no means of increasing prices on goods to compensate for those costs since farms are not price makers but price takers competing in global markets with complex pricing and purchase scenarios.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. For funding concerns, the agency notes that funds are also available through the passage of the BIL to assist many disadvantaged communities, small systems, and others with the costs of installation of treatment when it might otherwise be cost-challenging. Please see section 2.4 of the EPA response in this *Response to Comments* document for more discussion about currently available funding.

Missouri Department of Natural Resources (Doc. #1563, SBC-042511)

The proposed regulation is unclear on how it applies to secondary systems. It seems unnecessary to require systems who purchase all of their water from another system to monitor for PFAS. The Department recommends that EPA include an exemption from the monitoring requirements for purchasing systems within the final rule. The producing systems would control the levels in the purchasing system, and there should not be an instance where the purchasing system would

exceed the MCL if the producing system does not. Requiring purchasing systems to test for PFAS would be a waste of water system resources, and will exacerbate existing laboratory capacity issues.

EPA Response: The agency has clarified the applicability of the NPDWR for secondary (i.e., consecutive systems that buys or otherwise receives some or all its finished water from a wholesale system) in the final rule (see section I of the final rule preamble). The EPA has defined in Title 40, Chapter 1, Subchapter D, Part 141.2 a wholesale system as a PWS that supplies finished PWSs and a consecutive system as a PWS that buys or otherwise receives some or all its finished water from a wholesale system. In the final NPDWR, the EPA reiterates that all community water systems (CWSs) and non-transient non-community water systems (NTNCWSs) must comply with this regulation. This includes consecutive CWSs and NTNCWSs; however, the requirements these consecutive systems must implement to comply with the regulation may be, and often are, much less extensive. For finished water that is provided through a system interconnection, the wholesale systems will be responsible for conducting the monitoring requirements at the entry point to the distribution system (EPTDS). The final regulation does not require that any monitoring be conducted at a system interconnection point. Where a violation does occur, the wholesale system must notify any consecutive systems of this violation and it is the responsibility of the consecutive system to provide Public Notification (PN) to their customers pursuant to § 141.201(c)(1). In addition, wholesale systems must also provide information in Subpart O to consecutive systems for developing CCRs (§ 141.201(c)(1)). Consecutive systems are responsible for providing their customers with the reports (§ 141.153(a)).

Maine Water Utilities Association (MWUA) (Doc. #1567, SBC-042738)

If a PWS must install treatment to address PFAS in their drinking water, it may cause the classification of their system to change, necessitating higher-grade licensed operators. In many states, operators sitting for higher-grade licenses have course requirements before they can even sit for the exams. EPA and primacy states must recognize that this will cause staffing issues and will need to provide compliance forbearance and flexibility for the operators to obtain the necessary licenses. As many PWS are already struggling to attract and retain appropriately licensed staff and the industry expects to lose many operators to retirement in the next 5 years, this is a significant concern.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. The EPA acknowledges that in some states, operation of advanced treatment processes may necessitate higher-level operating licenses. These exams may be offered multiple times a year depending on the level being sought. While operator training or certification is not explicitly captured in the EPA's cost estimates, the cost models include a 10

percent miscellaneous allowance on both capital and operating costs which may capture some systems that may need additional training or cost of that training. The EPA recommends utilities evaluate all treatment (and non-treatment options) for their site-specific needs, carefully examine operator certification requirements within their state, and to carefully plan their workforce needs to meet the requirements of the final NPDWR. In addition, States can use the DWSRF set-asides to support operator certification programs. Set-asides are different than the loan portion of the program in that the funds don't go directly to the utility but are supporting the overall goals of the DWSRF. The set-asides can assist the state in ensuring that water systems have properly trained operators to operate and maintain drinking water infrastructure to supply safe water to consumers. This set-aside can, for example, fund state operator certification staff and the development of operator certification databases and data management programs to track operators' certification status. For more information, please visit: https://www.epa.gov/dwcapacity/about-drinking-water-state-revolving-fund-dwsrf-set-asides#overview

Maine Water Utilities Association (MWUA) (Doc. #1567, SBC-042736)

There is significant engineering effort and cost that goes into selection of the appropriate treatment technologies for a given water system. Site-specific testing, either bench-scale or pilot-scale, that evaluates the effectiveness of the treatment technologies with the actual contaminated water and the follow-up cost analysis is critical for 1) identifying the appropriate treatment solution for that specific water and existing treatment processes; 2) selecting the cost-effective alternative; and 3) identifying and avoiding any potential unintended consequences that are inherently possible when any new water treatment process is added (e.g. although this is a very infrequent occurrence, coal-based carbon has been observed to release arsenic under certain water conditions). While such testing provides critical design parameters and potentially cost-saving measures, it takes time. Designing and building permanent PFAS treatment facilities – assuming timely approval from primacy agencies, and local permitting – can be a lengthy process. [FN1: See Appendix C] Renting temporary treatment equipment is not only very costly but also takes time. These challenges should be considered in EPA's timeframe for enforcing PFAS standards in drinking water.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Maine Water Utilities Association (MWUA) (Doc. #1567, SBC-042745)

Closing:

Thank you for the opportunity to provide these comments. As mentioned previously and throughout this letter, public water suppliers understand the importance of ensuring that the drinking water that reaches their customers meets Safe Drinking Water Act requirements and protects the public's health. Water suppliers work hard each day to meet these goals and satisfy their customers' expectations. As we have all come to be keenly aware, the issue of emerging contaminants is a huge challenge. Our members will be tasked with meeting all regulatory requirements and standards; therefore, EPA has an obligation to address our implementation concerns prior to finalizing the regulations. We look forward to working collaboratively with EPA and the state primacy agencies to ensure our PWS can meet their mandate of continued protection of public health.

Sincerely,

Brian McGuire

President

Maine Water Utilities Association

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

San Antonio Water System (SAWS) (Doc. #1570, SBC-042487)

• This proposed rule has been released while PWSs across the country are working toward compliance under the substantial Lead and Copper Rule Revised (LCRR). EPA references the feasibility of these proposed PFAS regulations. However, it's unclear if any evaluation has occurred that looks at the feasibility of this proposed regulation from the standpoint of the PWS dealing with both these regulations at the same time.

o The staff working towards compliance on LCRR will likely be the same staff required to work toward PFAS compliance. This is causing PWSs to be overextended.

o It does not appear that there has been coordination within EPA as these LCRR and PFAS rules have been developed. This is further substantiated by the upcoming release of the Lead and Copper Rule Improvements (LCRI), which are slated to be released in early 2024, requiring further action on the PWS.

o For LCRR, LCRI and PFAS, third party consultants, engineering firms, and laboratory capacity are needed to reach compliance. This is causing a scarcity in industry expertise for the PWSs as well as the supporting consultants.

SAWS values the effort that EPA has put into this proposed rule and encourages EPA to reevaluate these regulations based on the most current science available to PWSs and our ratepayers. These national regulations will be pivotal throughout the country and therefore must be attainable and feasible. Thank you for your time and consideration of these comments.

Sincerely,

Scott R. Halty

Director

Resource Protection and Compliance

San Antonio Water System

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges, as well as simultaneous compliance challenges, that may affect the compliance timeline.

San Antonio Water System (SAWS) (Doc. #1570, SBC-042481)

PWSs are looking at significant capital improvements. The demand on firms able to provide engineering and construction will be high and may not meet the needs required across the country. Three years will not be enough time for systems to sample, design and implement capital improvements. A longer compliance timeframe should be considered.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

National Special Districts Coalition (NSDC) (Doc. #1571, SBC-043002)

As EPA works toward finalizing this rule for the safety and protection of public health, NSDC requests the agency providing realistic timelines and deadlines for compliance with any final rule. Sufficient time should be granted to water agencies to conduct necessary studies, develop treatment plans, and implement changes without compromising the uninterrupted delivery of safe drinking water to the community.

All in all, NSDC encourages EPA to continue offering and enhancing its collaborative approach that involves active engagement with water agencies and stakeholders to mitigate burdensome regulatory compliance issues that could arise and to collectively address challenges and ensure the successful implementation of the proposed standards.

We believe that a comprehensive and collaborative approach, which considers the aforementioned concerns, will lead to a more effective and successful implementation of the proposed NPDWR.

Thank you for considering the National Special Districts Coalition's comments on the NPDWR. We look forward to continued collaboration and working together to protect the health and well-being of the thousands of communities special districts serve across the nation.

Sincerely,

Cole Arreola-Karr

Federal Advocacy Director

National Special Districts Coalition

1112 I St., Suite 200

Sacramento, CA 95814

colek@nationalspecialdistricts.org

(417) 861-7418

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

City of Wilmington, Ohio (Doc. #1572, SBC-042467)

Even though the City of Wilmington has been proactive in addressing the PFAS contamination by already employing the consulting engineering firm Hazen & Sawyer for a PFAS planning study, the timeframe for meeting the proposed MCLs will be difficult to meet in the current construction climate. Right now, many water and wastewater infrastructure projects are receiving no bids, or just one bid. Many additional projects will be hitting the street at the same time due to this proposed MCL, further stressing the construction market.

The City of Wilmington requests that the timeline for compliance includes additional, automatic flexibility to account for the tight construction market, and that funding is guaranteed to be available so that the additional treatment needed to meet the proposed MCLs does not require rate increases.

Respectfully submitted,

Rick Schaffer

Public Works Director

City of Wilmington, Ohio

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Lakewood Water District (LWD) (Doc. #1574, SBC-042756)

Timeline to Implement

The three-year timeline proposed to complete 12 months of sampling and then to put any mitigation steps into place is not feasible. With recent experience, an aggressive design schedule for a treatment facility is 12 months.

In addition, many regulatory agencies will require pilot testing for treatment systems, which will further add to the time required to implement system improvements. With many jurisdictions and engineering firms being understaffed, the perming and design schedule can extend significantly. A typical bid advertisement and award timeframe can easily be two months. It is not unreasonable to expect an 18-month timeframe before construction is ready to begin. This is before any treatment equipment is ordered as well. Currently, we see about a 6–12-month lead me for pumps and upwards of 12 months lead me for pressure filter vessels used in our GAC system. In addition, it would be safe to assume other utilities across the United States would also select GAC systems which will undoubtedly increase lead times.

We have seen similarly long lead times for GAC media for new installations. Even with 12 months of sampling data, the design, budding, equipment procurement, and construction may take up to three years under typical practices. This is even before the anticipated significant increase in demand for engineering, equipment, and construction created by water systems throughout the country, requiring goods from a limited pool of qualified engineers, manufacturers, and construction contractors. A timeline of at least five years would still be an aggressive schedule but at least somewhat more realistic.

Funding timelines further exacerbate the ability to meet the proposed timeline for the rule. As an example, LWD was fortunate to receive direct appropriations to help offset costs for two new wells through Senator Murray's office in May 2021 and still has not been able to receive a contract from the EPA program charged with administering the funding. With the federal funds described in the rule, the timeline for systems fortunate to receive funds is further extended past the proposed rule's effective date.

Sincerely,

Randall M. Black

General Manager

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

New Hampshire Water Works Association, Inc. (NHWWA) (Doc. #1576, SBC-042454)

The three-year implementation timeline for PFAS detection and remediation is unreasonable given real constraints such as the number of impacted systems, manufacturing and supply chain constraints (including treatment media), analytical methods and laboratory capacity, widespread professional labor and certified water Operator shortages, residual disposal issues, and system owner liability concerns. Systemic failures to meet an unrealistic timeframe will result in numerous, unnecessary enforcement documents and action that will consume regulatory time and erode public trust. These systemic constraints must be factored into a realistic implementation schedule.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. For additional discussion on residual disposal issues, please see section 10.4.2 of the EPA response in this *Response to Comments* document. For additional discussion on how the agency considers analytic feasibility when establishing the MCL, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

COMM Water Department (Doc. #1577, SBC-042442)

EPA's timeline for compliance with the rule is not reasonable, and likely not even achievable, given the work that goes into designing, constructing, and funding new treatment systems. The water sector, including operators, design engineers, and construction workers, is challenged with workforce issues like many other sectors of our society. More sophisticated treatment will likely cause a change in PWS classification and may require a higher-grade operator license. In Massachusetts, it takes time to get through the required training to be able to sit for a higher-grade exam. EPA does not appear to have given any thought to issues such as this when they crafted the rule and its three-year implementation timeframe. EPA must adjust the compliance timeframe to be more realistic.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the

compliance timeline. For concerns regarding operator certification, please see the EPA response to comment Doc. #1567, SBC-042738 in section 12.1 in this *Response to Comments* document.

COMM Water Department (Doc. #1577, SBC-042447)

Thank you for the opportunity to provide these comments. As a water professional, I work hard to always follow the laws and regulations put forth by our regulatory agencies. I am sounding the alarm that I do not think this rule is reasonable, nor easily achievable. EPA has an obligation to address the water sector's implementation concerns and craft a final rule that is more realistic in its expectations of implementation and schedule and comes with the requisite funding to ensure PWS can comply.

Sincerely,

Craig Crocker

Superintendent, COMM Water Department

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Santa Clarita Valley Water Agency (SCVWA) (Doc. #1578, SBC-042430)

Based upon our experience it will be critical to ensure adequate time for compliance with the proposed rule. As mentioned, we are currently observing supply chain difficulties with the construction of recent PFAS facilities. Specifically, specialized equipment has exceptionally long lead times, and in one case we have received a lead time notice of over 70 weeks for the Motor Control Center. In addition, we have started to receive notice of delay from the resin provider (in this case Evoqua) having 9 scheduled resin fills with another water agency. We believe the two most recent projects reflect the current timing conditions for project design, construction and delivery. The project delivery time for the Valley Center Well facility was 3.5 years and is projected to be 4 years for the Santa Clara and Honby Wells facility. As the scope and magnitude of complying with the proposed rule are realized, the competition for the same resources will be further magnified and delays will be compounded.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

San Gabriel Valley Water Association (SGVWA) (Doc. #1580, SBC-042420)

Scarce Workforce: One problem associated with implementing advanced treatment systems for MCLs is the shortage of available workers. This will lead to a significant demand for more water operators in thousands of communities across the country. This demand may result in disparities in the availability of qualified operators between larger, wealthier water suppliers and those with fewer resources. Additionally, current operators may need to obtain higher levels of certification to manage and maintain the new systems, which will require additional staff time and resources. This poses a challenge to the sustainability of many small water systems.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. For funding concerns, the agency notes that funds are also available through the passage of the BIL to assist many disadvantaged communities, small systems, and others with the costs of installation of treatment when it might otherwise be cost-challenging. Please see section 2.4 of the EPA response in this *Response to Comments* document for more discussion about currently available funding. Regarding concerns on operator certification licenses, please see the EPA response to comment Doc. #1567, SBC-042738 in section 12.1 in this *Response to Comments* document.

Missouri River Public Water Supplies Association (MRPWSA) (Doc. #1581, SBC-042414)

Effective Date — MRPWSA strongly urges U.S. EPA to adopt an Effective Date for the final rule that accounts for the time for the regulatory review process with the States and to construct the facilities necessary to meet the part per trillion proposed regulations.

Sincerely,

Tim Ganz

President

Missouri River Public Water Supplies Association

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Washington Suburban Sanitary Commission (WSSC Water) (Doc. #1585, SBC-042770)

2. Implementation Timeline

Initial monitoring period:

Under the proposed rule, water systems are required to achieve full compliance beginning three years after the promulgation of the final rule. If initial monitoring results exceed the MCL, mitigation measures, which often require capital improvements, must be implemented within the same three-year period. This timeline is significantly shorter than the usual minimum duration of 10 years needed to complete capital improvements. In WSSC Water, bench testing, pilot testing, design, budget allocations, procurement, site acquisition, and permitting and construction for a treatment process of this complexity has historically required 9 to 11 years. WSSC Water acknowledges that delaying rule compliance for 10 years may adversely impact public health protection. As such, we suggest that EPA consider extending the compliance timeline to a total of eight years, with a standard three-year compliance timeline, a nationwide blanket two-year extension, and another three-year extension at the discretion of the primacy agency, in accordance with SDWA *1416. EPA may also consider providing states with specific guidance tailored for PFAS to assist states determining which systems would qualify for additional 3-year extension. While a total of 8 years is still insufficient for water systems to adopt necessary mitigation measures in order to comply with the rule, when combined with the phased MCL approach recommended above and an initial MCL set at 10 ppt, water systems would have more appropriate opportunities to prepare for the required capital improvement measures.

Alternatively, EPA may consider a risk-based approach, where water systems with low levels of PFAS during the initial monitoring period may be granted an extended implementation schedule before beginning compliance. This approach would have minimal impact on public health protection, considering the demonstrated low risk. EPA has successfully adopted this approach with its arsenic rule, where systems demonstrating low level of risk are eligible for an exemption from compliance for a certain period depending on the levels found. EPA could also explore a similar risk-based implementation framework that has been successfully adopted in the Long Term 2 Enhanced Surface Water Treatment Rule. Under this framework, water systems conducted two rounds of two-year source water monitoring, with a six-year interval between each round, to assess the level of risk. Based on the identified risk, water systems would then be subject to Bin Placement, a tiered mitigation measure consistent with the level of risk detected.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. Regarding exemptions, the EPA notes that, as suggested by the commenter, primacy agencies who have adopted the 1998 *Variance and Exemptions Regulation* (USEPA, 1998) may choose to grant exemptions on a case-by-case basis.. Primacy agencies who choose to issue such exemptions can consider the kind of prioritizing based on risk that is suggested by the commenter; this would be consistent with the arsenic guidance and the statutory requirement that granting an exemption will not result in an unreasonable risk to health. SDWA Section 1416(a)(3). See section 12.1 of the EPA response in this *Response to Comments* document. For

additional discussion on how the agency considers analytic feasibility when establishing the MCL, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Security Water District, Security Water and Sanitation Districts/Enterprises (Doc. #1587, SBC-042782)

It was January, 2016 when we first shut down wells due to PFAS contamination, and the Ion Exchange facility was not fully-functional until May, 2022 — more than 6 years later. Consequently, we are concerned that the 3-year implementation time line is insufficient. We have many other concerns with regard to implementation and the time allowed to implement, including:

• Increasing laboratory testing turn-around time due to higher demand

• Supply chain issues that have become common

• Workforce shortages and the need for operators to be certified at higher levels

due to increased treatment requirements

• Longer turn-around time for SRF funding due to higher demand and more stringent federal requirements

• The need for piloting, which will extend the time to implement treatment

• Post-treatment requirements, such as increased LCR sampling

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Security Water District, Security Water and Sanitation Districts/Enterprises (Doc. #1587, SBC-042780)

May 26, 2023

United States Environmental Protection Agency 1200 Pennsylvania Avenue, N.W.

Washington D.C. 20460

Delivered via EPA website

Thank you for providing the opportunity to comment on the proposed National Primary Drinking Water Regulation (NPDWR) for six PFAS chemicals. As the General Manager of the Security Water and Sanitation Districts, located just south of Colorado Springs, Colorado, I am keenly aware of the impact that PFAS chemicals, as well as EPA actions, can have on a community.

Since early 2016, It's been a bit of a whirlwind for the customers, elected officials, staff, consultants and others involved in the issues of PFAS well contamination in the Security Water District.

With the issuance of the new Lifetime Health Advisory in May, 2016, the advisory levels for PFOA and PFOS went from a combined 600 parts per trillion to a combined 70 parts per trillion overnight. This caused some members of our community to consider the drinking water supply in Security to be poisoned, rendering our 24 groundwater wells virtually unusable. As a result:

• A local non-profit brought in a semi-truck load of bottled water on a weekly basis. The line of cars waiting to pick up their weekly allocation of bottled water was a mile long.

• Customers called us to find out how to dispose of all of their empty single-use water bottles.

• The local fire department refused to use the community water supply during their annual 4th of July pancake breakfast, opting instead to use bottled water to make pancake batter.

• A community swimming pool demanded that we pay to replace the water in their swimming pool (with what?)

I fear that an inadequate or hasty implementation of the proposed PFAS Rule will result in similar outcomes for water systems across the country.

EPA Response: The EPA's final rule represents data-driven drinking water standards that are based on the best available science and meet the requirements of SDWA; regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. After finalization of the PFAS NPDWR, the EPA also intends to work with stakeholders to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation. For additional discussion on risk communication issues for the final PFAS NPDWR, please see section 1.2 of the EPA response in this *Response to Comments* document. Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Cape Fear Public Utility Authority (CFPUA) (Doc. #1588, SBC-042382)

Potential impacts of EPA's proposed compliance deadline

EPA states that it "assumes promulgation of the regulations by the end of 2023, followed by a three-year window for utilities who exceed the MCLs or hazard index to identify, design, fund, and construct treatment necessary to achieve compliance." While this timeline may be achievable for some affected water systems, we note the pilot testing, design, and construction of CFPUA's treatment took almost five years.

Certainly, CFPUA's work occurred amid numerous challenges, most notably operational, labor-market, and supply-chain bottlenecks resulting from the worldwide COVID-19 pandemic. One challenge we did not face was competition from thousands of other water utilities seeking to accomplish the same goal by the same deadline. EPA's proposed implementation timeline will spark a scramble by water systems to secure limited, specialized resources: consulting expertise, experienced and qualified construction contractors, materials essential to building and operating treatment, and laboratory analysis, just to name the most obvious. Already inflated costs and lengthy equipment, material, and service lead times will increase even further – not only for those adding new treatment to comply with the proposed NPDWR but also for CFPUA and others who already have effective treatment but require regular services such as GAC regeneration and laboratory analysis. The mismatch between supply and demand will further widen the gap between available federal funding and the number of water systems that need federal funding. It will further add to the financial burdens inevitably borne by individual utilities and their customers. Extending the compliance window from three years from promulgation to five years or more, with a tiered structure based on utility size and for water systems installing capital improvements would reduce the workforce and supply chain challenges.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Suffolk County Water Authority (SCWA) (Doc. #1589, SBC-043370)

6. Supply Chain Limitations for Treatment Installation and Media Procurement Will Present Significant Challenges

As indicated above, the SCWA has been installing new GAC treatment systems to address PFAS over the last four to five years, and it is purchasing additional systems as fast as they can be manufactured. The current lead time for purchase of new GAC systems is in excess of 12 months. The SCWA's GAC filter media contractor has given notice to SCWA that it may not be able to fulfill all of SCWA's filter media needs over the summer months of this year. These supply chain issues are real and significant. They will only get worse after the proposed federal PFAS regulation is finalized because there will be a substantial increase in demand for both treatment systems and filter media.

7. Time Frame for Implementation Should be Extended to the Greatest Extent Practicable

Finally, SCWA again commends the EPA for proposing National Primary Drinking Water Regulations for these six PFAS because they will improve the health of public water supply customers across the nation. However, in SCWA's experience, there will be significant obstacles, including high costs, inadequate laboratory capacity, and supply chain issues that will make compliance with the final rule difficult and time consuming. Thus, the SCWA recommends

allowing the maximum time permissible for the implementation of the rule under the Safe Drinking Water Act.

Respectfully submitted,

Timothy J. Hopkins

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Lehigh County Authority (LCA) (Doc. #1600, SBC-042820)

2. Workforce Impacts – Across the nation, the story at every utility and supporting organization is the same: there are simply not enough applicants for the jobs we have available. Utilities are struggling to maintain full staffing, and engineering firms are feeling the same constraints. This will make compliance with the proposed rule in a relatively short period of time very difficult. If the data are accurate, a significant number of utilities will be facing the need to evaluate treatment alternatives for PFAS at the same time, creating a wave of projects and demand for engineering services that the current workforce conditions will not support.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Lehigh County Authority (LCA) (Doc. #1600, SBC-042822)

4. Compounding Compliance Pressures – The proposed PFAS requirements are coming at a time when water systems are already deeply engaged in a variety of other new regulatory compliance efforts, such as the efforts to meet new requirements laid out in the Lead & Copper Rule Revision (LCRR). Significant capital expenses will be incurred over the next several years as utilities work to remove lead service lines and implement corrosion control systems to achieve LCRR compliance. This effort will draw on the same limited resources (workforce, materials, engineering support, and funding) that are needed to achieve PFAS compliance.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges, as well as simultaneous compliance challenges, that may affect the compliance timeline

Lehigh County Authority (LCA) (Doc. #1600, SBC-042824)

Based on these significant compliance and implementation challenges, LCA believes the standard implementation timeline is not appropriate for the proposed PFAS rule. The need to plan, design, pilot, and construct facilities will take much longer than the three-year timeline given the challenges described above. EPA should consider extending the effective date of compliance by two years to ease the burden on water systems that must install capital improvements to achieve compliance.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-042887)

There is significant engineering effort and cost that goes into selection of the appropriate treatment technologies for a given water system. Site-specific testing, either bench-scale or pilot-scale, that evaluates the effectiveness of the treatment technologies for the actual contaminated water and an associated cost analysis are critical for 1) identifying the appropriate treatment solution for that specific water and existing treatment processes; 2) selecting the cost-effective alternative; and 3) identifying and avoiding any potential unintended consequences that are inherently possible when any new water treatment process is added (e.g. although this is a very infrequent occurrence, coal-based carbon has been observed to release arsenic under certain water conditions) [FN18: https://doi.org/10.1002/awwa.1959]. While such testing provides critical design parameters and potential cost-saving measures, it takes significant time. Designing and building permanent PFAS treatment facilities – assuming timely approval from MassDEP, and local permitting – is a lengthy process [FN19: See Appendix A which MWWA believes captures the typical timeline for brining treatment online under normal circumstances.]. Renting temporary treatment equipment similarly is costly and time-consuming. These challenges should be considered in EPA's timeframe for enforcing PFAS standards in drinking water. It will be very difficult for PWS to come into compliance with this rule within the three-year window EPA is proposing.

If a PWS must install treatment to address PFAS in their drinking water, it may cause the classification of their system to change, necessitating higher-grade licensed operators. In Massachusetts and other states, operators sitting for higher-grade licenses have course requirements before they can even sit for the exams. EPA and primacy states must recognize that this will cause staffing issues and will need to provide compliance forbearance and flexibility for the operators to obtain the necessary licenses. Many PWS are already struggling to attract and retain appropriately licensed staff and the industry expects to lose many operators to retirement in the next five years. Some PWS in wealthier communities may, through higher salaries, be able

to lure currently licensed operators from other systems that cannot compete with higher wages. These less wealthy PWS often have significant Environmental Justice populations that could be put at risk due to lack of certified water treatment operators. PWS are already struggling to maintain staffing levels and that problem will be exacerbated by this proposed PFAS MCL.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. Regarding concerns on operator certification licenses, please see the EPA response to comment Doc. #1567, SBC-042738 in section 12.1 in this *Response to Comments* document.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043652)

6. Compliance time and high demand drive cost increase: The proposed rule allows three years for systems to come into compliance with the Rule, including initial monitoring. States are authorized to grant a two-year extension, but this is not guaranteed. Associated concerns include insufficient time, availability of qualified contractors, and surge in construction prices based on demand. It is recommended that USEPA extend the implementation timeframe for compliance with the proposed PFAS Rule to 2029 in order to reflect the time needed to complete source water characterization, piloting of technologies, design, and construction of treatment solutions.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Arlington County Virginia (Doc. #1603, SBC-043006)

2. The regulation as proposed cannot be implemented by the industry

EPA Response: The EPA's final rule represents data-driven drinking water standards that are based on a thorough analysis of feasibility consistent with requirements under SDWA. For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For discussion on treatment technologies, please see section 10 of the EPA response in this *Response to Comments* document. Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Arlington County Virginia (Doc. #1603, SBC-043010)

Proposed Implementation Timeline & Limits

As proposed, the regulation would provide a 3-year window for water utilities across the country to achieve treatment levels which are at the limits of current technology. The regulations would be implemented while we still have limited knowledge regarding the transmission and behavior of PFAS in the built and natural environment and water utility systems.

Our limited knowledge of PFAS prevalence and behavior combined with such a severe and aggressive enforceable level will drive many water utilities to initiate costly and complicated treatment upgrades to ensure future compliance, even though existing testing has not exceeded the proposed MCL.

By establishing such an aggressive implementation level and timeline, the proposed regulation will compel reactive upgrades and investments at hundreds or thousands of utilities – many of which will ultimately be demonstrated to have been unnecessary or imprudent. In addition to diverting investment from more impactful upgrades (infrastructure renewal, corrosion control, source water supply & protection, infrastructure security, etc.), the aggressive level and schedule will serve to distort and likely overwhelm several sectors of the utility engineering and consulting industry.

Alternatively, a graduated approach to drinking water levels combined with source control research and regulation would enable more informed and responsible management of PFAS exposure. Instead of racing to a regulatory limit at the threshold of technology and drastically below other nations, EPA should focus immediate resources on those systems with excessive exposures, and on researching and regulating sources of PFAS. Such an approach would steer limited resources to the greatest needs and would demonstrate some adherence to the "polluter should pay" principle.

Finally, a 3-year (or even 5-year process if a 2-year extension is assumed) implementation is infeasible to implement the necessary capital improvements at most large drinking water plants. Such upgrades typically require capital planning to include extensive public engagement and legislative actions around rate increases. Further, new treatment processes at large drinking water plants require extensive planning, design, and importantly bench-scale piloting. Failure to adequately analyze process impacts and water chemistry changes through such pilot studies can have calamitous side effects – as occurred in Flint Michigan. In addition to the extensive planning, design, testing, and financial processes, water treatment plants are subject to extensive State and local regulatory requirements, including local land-use regulations. In an urban area such as the National Capital region, local permitting requirements alone will require several years of process.

EPA Response: The EPA disagrees with the commenter that knowledge is limited on PFAS sources, exposure, and human health effects that would preclude regulation at this time. The EPA's final rule represents data-driven drinking water standards that are based on the best

available science and meet the requirements of SDWA; regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. Regarding actions the EPA is taking to research and address PFAS through other environmental statutes, the agency notes that these actions are outside the scope of the current rulemaking but directs the commenter's attention to the EPA PFAS Strategic Roadmap that outlines the whole-of-agency approach to "further the science and research, to restrict these dangerous chemicals from getting into the environment, and to immediately move to remediate the problem in communities across the country" (USEPA, 2022). Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Arlington County Virginia (Doc. #1603, SBC-043014)

Third, implementation of the rule will exceed the capacity of the engineering, construction, and material markets – generating unpredictable inflation.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. The commenter also provides no verifiable information regarding "unpredictable inflation;" for treatment technology availability and capacity considerations, please see section 10.6 of the EPA response in this *Response to Comments* document.

Arlington County Virginia (Doc. #1603, SBC-043017)

3. It seems unlikely that sufficient consulting engineers, utility contractors, equipment and material suppliers, and State regulators exist or can grow to meet the demand to shepherd the thousands of major capital upgrade projects which will be triggered by the proposed regulation to completion within the proposed 3-year timeframe. Such distortion of the market will presumably instigate concentrated and excessive inflation far exceeding general benchmarks. We do not see any consideration of focused and acute inflationary impacts in the economic analysis.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). This will provide the maximum amount of time that EPA can provide by regulation to address concerns about compliance timeframes. This extension will provide time for supply, where lacking, to meet demand for treatment technologies and associated contracting and engineering services. Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. Regarding rising costs in the drinking water sector and the effects of

inflation, as recommended by commenters, the EPA adjusted the cost estimates by escalating unit costs using indices including the Bureau of Labor Statistics producer price indices. For more information see section 13.3.3 of the EPA response in this *Response to Comments* document. The commenter also provides no verifiable information regarding "excessive inflation far exceeding general benchmarks" and the EPA disagrees that treatment capital, operation and maintenance costs and other rule associated costs are likely to increase significantly as a result of heightened demand.

American Water Works Company Inc. (Doc. #1608, SBC-043987)

Effective Date – American Water strongly urges the U.S. EPA to adopt an Effective Date for the final rule that is five years from the promulgation date, similar to the approach used under the Arsenic Rule.

EPA Response: Consistent with the commenter's request, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

American Water Works Company Inc. (Doc. #1608, SBC-043976)

The implementation timing should also consider the available capacity of engineers, contractors, and suppliers to build the required treatment and the available capacity of vendors to supply ion exchange resin, granular activated carbon, and media reactivation/waste disposal services on an ongoing basis.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. For treatment technology availability and capacity considerations, please see section 10.6 of the EPA response in this *Response to Comments* document.

American Water Works Company Inc. (Doc. #1608, SBC-044008)

Effective Date

American Water strongly urges the U.S. EPA to adopt an Effective Date for the final rule that is five years from the promulgation date, similar to the approach used under the Arsenic Rule. We believe that the same rationale applies to this rule and that the implementation timing should consider the available capacity of engineers, contractors, and suppliers to obtain the necessary approvals and permits and build the required treatment; and also the available capacity of vendors to supply ion exchange resin and supply/reactivate granular activated carbon used for treatment on an ongoing basis. We believe the capacities of those resources will be challenged if

the Effective Date for the final rule is set at three years from the promulgation date, which will further drive up both capital and ongoing operational expenses associated with PFAS treatment.

Furthermore, establishing an Effective Date of five years from the promulgation date will allow drinking water utilities more time to adequately sample and ultimately assess their risk of compliance, as well as to analyze/pilot treatment options to make prudent decisions on very significant capital investment for treatment which will affect customer rates. This is especially true for surface water supplies that tend to have higher overall and seasonal variability of PFAS concentrations; and which will require significantly higher capital investment and operational expenditure on a per gallon basis for PFAS treatment.

The following comes from the preamble to the final Arsenic Rule (66 FR 6992-2993):

"M. What is the Effective Date and Compliance Date for the Rule?

In the proposed rule, EPA made a finding that all small systems (i.e., systems serving 10,000 people or less) would be granted a 2-year capital improvement extension which extends the MCL effective date for purposes of compliance with the new MCL to January 23, 2006. EPA proposed the 2- year capital improvement extension for small systems because of the time required for systems to plan, finance, design and construct new treatment systems.

Large systems were not provided this additional time because of the greater resources these systems have to perform capital improvements in a timely manner. However, upon consideration of information submitted by commenters, EPA has determined that large systems will also require an additional 2 years to complete the capital improvements necessary to comply with the arsenic MCL. While large systems (i.e., systems serving more than 10,000 people) do have greater resources to implement capital improvements, (e.g., engineering and construction management staff to manage the projects), these systems generally also have more entry points to the distribution system that will require treatment.

A number of treatment technologies are listed as BAT for the proposed rule: ion exchange, activated alumina, reverse osmosis, modified coagulation/ filtration, modified lime softening and electrodialysis reversal. There are also several emerging technologies for arsenic removal, such as nanofiltration and granular ferric hydroxide. To ensure cost effective compliance with the arsenic MCL, systems will need to evaluate their treatment technology options as a first step. This planning step may include pilot studies with potential treatment systems, or it may be limited to an evaluation of the raw water characteristics. Systems choosing to conduct pilot testing may take a year or more to contract with vendors and to perform pilot testing.

Once the planning step is completed systems must design and construct the treatment systems. Design and permitting of the treatment systems can take an additional year, and construction of the treatment system can take another year. Because systems will also need time to: obtain funding, obtain local government approval of the project, or acquire the land necessary to construct these technologies, it is likely that most large systems will need additional time beyond the three-year effective date for compliance with the new MCL that EPA proposed.

Based upon these considerations, EPA determined, in accordance with section 1412(b)(10) of SDWA, that the compliance date for the new arsenic MCL, regardless of system size, will be 5 years from the date of promulgation of the standard. See section I.H. for more information regarding variance and exemptions."

EPA Response: Consistent with this comment and for reasons similar to those provided in the arsenic rule quoted by the commenter, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Prince William County Service Authority (Doc. #1609, SBC-042836)

Timeframe for Compliance is Unrealistic

The proposed rule provides only three years for compliance from final rulemaking. While utilities can apply for a two-year extension from their primacy agency, extensions are not guaranteed. Even a five-year period to comply ignores the realities of implementing capital projects such as the addition of GAC, ion exchange (IX), or reverse osmosis (RO) to existing treatment plants. Any of these treatment alternatives would need to be piloted for at least one year to capture seasonal variations in source water quality. Depending on the alternative being studied, pipe loop studies may also be required to ensure that multiple competing regulations do not result in non-compliance. Certainly, any utility contemplating a change in source water to achieve PFAS compliance would need to undertake both of these studies to avoid unintended consequences in the distribution system. Additionally, utilities will have to develop the financial capacity to implement these capital projects. Utilities will have to increase rates, issue bonds, secure grants and/or loans, or a combination of these. All of these efforts take time, but funds have to be in hand before design and construction can proceed.

At the proposed MCL and HI levels, the rule will place significant demand on a limited pool of resources to achieve compliance. Too many utilities will be competing for the same consulting engineers, construction contractors, and suppliers at the same time making it difficult for utilities to meet unrealistic compliance deadlines This will lead to further cost increases and rampant noncompliance which would be contrary to the objective of the regulation. Additionally, there will be significant impacts on the limited resources of primacy agencies to support utilities in the compliance process. These limitations will invariably lead to additional costs beyond what EPA currently estimates. The pool for construction contractors for water infrastructure projects is already stressed. Utilities are seeing fewer bidders, sometimes only one bidder, and bids are consistently higher than engineers' estimates. Utilities, consulting engineers, and contractors are all facing workforce challenges. Cost increases due to competition for limited resources will further strain the ratepaying public and drinking water affordability.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA

1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Prince William County Service Authority (Doc. #1609, SBC-042844)

4. The underestimation of utilities impacted by the proposed rule and the unrealistic compliance deadline will place significant demand on limited resources for consulting engineers, contractors, suppliers, and primacy agency support to achieve compliance. This will lead to further cost increases and rampant noncompliance which would be contrary to the objective of the regulation.

EPA Response: After finalization of the PFAS NPDWR, the EPA also intends to work with stakeholders to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation. For additional discussion on risk communication issues for the final PFAS NPDWR, please see section 1.2 of the EPA response in this *Response to Comments* document. Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Prince William County Service Authority (Doc. #1609, SBC-042837)

While the Service Authority supports the goal of the proposed PFAS rule, a compliance deadline that is not achievable could ultimately lead to thousands of utilities being out of compliance. Rampant noncompliance places an unnecessary burden on primacy agencies and EPA and undermines the confidence of the public in its drinking water. The public would be better served by knowing the path to compliance is achievable rather than by being routinely notified that their drinking water fails to meet standards. Repeated notices of noncompliance will only drive more people to drink bottled water under the false impression that it is safer when it is actually not regulated by the same EPA PFAS standard. Many who choose bottled water may be people who can least afford to do so.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Marlene Ladderbush (Doc. #1612, SBC-042918)

EPA's timeline for compliance with the rule is not reasonable, and likely not even achievable, given the work that goes into designing, constructing, and funding new treatment systems. The water sector, including operators, design engineers, and construction workers, is challenged with

workforce issues like many other sectors of our society. More sophisticated treatment will likely cause a change in PWS classification and may require a higher-grade operator license. In Massachusetts, it takes time to get through the required training to be able to sit for a higher-grade exam. EPA does not appear to have given any thought to issues such as this when they crafted the rule and its three-year implementation timeframe. EPA must adjust the compliance timeframe to be more realistic.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. Regarding concerns on operator certification licenses, please see the EPA response to comment Doc. #1567, SBC-042738 in section 12.1 in this *Response to Comments* document.

Town of Lincoln Water Department (Doc. #1613, SBC-043030)

EPA's timeline for compliance with the rule is not reasonable, and likely not even achievable, given the work that goes into designing, constructing, and funding new treatment systems. The water sector, including operators, design engineers, and construction workers, is challenged with workforce issues like many other sectors of our society. More sophisticated treatment will likely cause a change in PWS classification and may require a higher-grade operator license. In Massachusetts, it takes time to get through the required training to be able to sit for a higher-grade exam. EPA does not appear to have given any thought to issues such as this when they crafted the rule and its three-year implementation timeframe. EPA must adjust the compliance timeframe to be more realistic.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. Regarding concerns on operator certification licenses, please see the EPA response to comment Doc. #1567, SBC-042738 in section 12.1 in this *Response to Comments* document.

Aquarion Water Company (Doc. #1617, SBC-043376)

2. With the requirement to comply with the regulation three years after promulgation, there will be a rush of planning, design, pilot testing, permitting, financing, procurement, and construction activity across the U.S. water industry. This rush of activity will drive up costs as utilities compete for resources (e.g., filter vessels, GAC, IX media) and as utilities make decisions based on relatively limited experience addressing PFAS. The allowance for two additional years to comply in cases where capital improvements are needed will provide limited relief.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension for all water systems pursuant to SDWA 1412(b)(10). Based on the public comments provided and record for this rulemaking, the two additional years to comply should provide significant relief. Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Beaufort-Jasper Water & Sewer Authority (BJWSA) (Doc. #1618, SBC-042931)

The proposed maximum contaminant levels of PFAS in drinking water will require that a significant number of water utilities across the country install additional treatment to remove these compounds. Based on current inflationary pressures and recent escalations in construction bid prices, we believe EPA has significantly underestimated the nationwide cost to address PFAS contamination in drinking water. Furthermore, the compliance timeframe provided in the proposal (three years from rule finalization) is simply not feasible given the demand on the construction industry, lingering supply chain issues, and significant labor shortages. Projects of the magnitude required for PFAS removal normally take five years or more to implement, and include multiple steps such as study of appropriate technology, pilot testing, detailed design, bid, construction, and startup. Regulatory review is also required throughout the process. Such an aggressive implementation timeline for so many utilities will have the likely impact of driving construction prices up even higher for all projects (not just those associated with PFAS).

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10) to provide the five years suggested by the commenter. Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline and section 13 of the EPA response in this *Response to Comments* document with respect to concerns about underestimating costs.

Beaufort-Jasper Water & Sewer Authority (BJWSA) (Doc. #1618, SBC-042936)

In conjunction with a more reasonable implementation schedule, the time to plan and construct new PFAS removal facilities needs to be broadened beyond the proposed 3-year timeframe. At a minimum, utilities should be given five years to properly plan, design and construct facilities. For example, a thoughtful and logical sequence for performing the necessary due diligence and facility construction could be as follows.

Year 1: Perform PFAS Treatability Study - evaluate alternative technologies, removal efficiencies, operation and maintenance considerations; evaluate alternative treatment configurations; evaluate residuals disposal options; conduct bench and pilot tests as required

Year 2: Prepare Preliminary Engineering Report - based on Treatability Study define the facility improvements, facility layouts, construction cost estimate, construction schedule

Year 3: Prepare Construction Documents (plans and specifications)

Year 4: Bid and Begin Construction

Year 5: Complete Construction, Startup and Commission New Facility

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10), which will provide the timeframe suggested by the commenter. Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. Please see section 13 of the EPA response in this *Response to Comments* document with respect to costs.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044028)

In addition, there will likely be supply and labor issues for installing treatment, huge costs for ongoing maintenance, regeneration or disposal.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043070)

Workforce Limitations will be Worsened

The water sector is currently working to overcome workforce challenges. EPA estimates that one-third of the sector's workforce is eligible to retire within the next 10 years and utilities are facing challenges in recruiting, training, and retaining employees.

These challenges are expected to be more severe as over 5,000 water systems are driven to more advanced technologies that require more specialized technical skills. To install and operate these facilities, water systems will need to hire or contract engineers, manufacturers and suppliers, construction crews, and skilled operators. These service providers are already in high demand and in short supply and this imbalance is impacting labor and material costs, lead times for materials, turnaround times for services (e.g., engineering, laboratory analysis, construction. The installation of new treatment facilities will surge following the rule's promulgation given the tight timeline for compliance, which will further worsen workforce challenges for utilities.

The demand for highly skilled water treatment operators will increase due to this rule. Systems currently not using filtration for water treatment may need to meet additional operator certification requirements. This change will have a significant impact on systems with less local or financial access to the skilled operators that will be needed to safely operate these advanced

treatment systems. Given existing workforce challenges, there is a chance that many systems will struggle to find water treatment plant operators to adequately operate their plant(s).

State Primacy Agency Capacity

The typical timeline for the construction of a new drinking water treatment facility for PFAS may take up to and exceed 5 years; thus, the standard compliance window of three years under SDWA will not be feasible. The compliance window is especially challenging given that implementation challenges will drive the timeline up as systems begin competing for the same limited workforce. Under SDWA, water systems may request a two-year extension for compliance with MCLs if it is determined that additional time is necessary for capital improvements.

It is anticipated that a vast majority of water systems will need to request this two-year extension, which is typically provided at the discretion of the state primacy agencies. State primacy agencies are currently working to review lead service line inventories, preparing to implement the corrosion control treatment requirements of the LCR, administering the DWSRF and additional projects accessing funds from the Bipartisan Infrastructure Law, and ensuring and improving water system compliance with existing rules. As the surge in water system requests for a two-year extension begins, these agencies will be inundated as they work to review and process these requests. Aqua anticipates that in one of our operating states we could potentially request over one hundred extensions alone if the current proposal is enacted with a three-year compliance deadline.

However, the Administrator also has the authority under SDWA to provide this extension and can do so as a part of the rule as opposed to being done so on a case-by-case basis. It is recommended that the Administrator leverage this authority to help ensure that all water systems can comply with the timeline of the rule and take adequate, effective steps towards mitigating PFAS levels in drinking water.

EPA Response: Based on this comment and many others, see section 12.1 of the *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10), which provides the timeframe suggested by the commenter. Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. Regarding concerns on operator certification licenses, please see the EPA response to comment Doc. #1567, SBC-042738 in section 12.1 in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043068)

Simultaneous Compliance will Slow Down Implementation

The installation of new water treatment facilities requires sufficient planning to ensure that bringing a plant into compliance with a new rule does not cause non-compliance with existing

regulations. For most water systems in the United States (U.S.), the installation of PFAS treatment facilities will create challenges for simultaneous compliance with the long-term revisions to the Lead and Copper Rule (LCR). If systems determine that mitigation is needed to comply with the final drinking water standards, either through new treatment or a change in the water supply source, the requirements of the LCR will initiate a lengthy review process with the State Primacy Agency prior to the system receiving approval to move forward.

Systems that need to initiate a review with their state through the LCR could be delayed as much as 18 months to get through the approval process. The state review process determines the impacts of treatment on the water system's ability to maintain compliant lead and copper levels, which may also require the installation of corrosion control treatment (CCT), re- optimization of CCT, and additional water quality monitoring. This will have a significant impact on the system's ability and cost to implement new treatment for PFAS within the compliance window of three years. To provide a case study example, Aqua spent 24 months working with the state agencies to pilot Ion Exchange (IX) for PFAS removal and simultaneous compliance with LCR in Pennsylvania. If every state requires 2 years just for this step alone, the time for a construction permit, combined with sewer discharge permits, zoning, and building permits can take up to 3 years, not including time for funding and design.

Most Systems will Need to Perform Pilot Testing

Finally, another key step in installing PFAS treatment facilities is pilot testing. While GAC, IX, and RO have been documented as being capable of removing PFAS effectively, they still require a sufficient level of pilot testing. Pilot testing typically takes at least six to nine months to complete and costs include equipment rental, engineering and other technical support, and appropriate monitoring and sample analysis. Bench scale testing can also be useful and less costly for some systems. Approval of pilot testing plans, conducting the testing, and getting approval of the pilot testing report can require up to 24 months based on our experience installing several PFAS treatment systems.

The goal of pilot and bench-scale testing is 3-fold: (i) demonstration of PFAS removal efficacy,

(ii) characterizing pre- and post-treatment needs, and (iii) optimal treatment technology selection. Subsequently, most of the water systems impacted by PFAS MCLs will need to perform pilot testing, especially given the permitting requirements to comply with the LCR, as discussed above. While pilot testing may not seem appropriate for smaller systems, it is similarly vital for these systems to ensure that the expense of capital for a new long-term treatment facility is both cost-effective and appropriately designed to protect public health from secondary water quality changes. In addition, it is possible or even likely that state public utility commissions may require private utilities to conduct pilot testing to prove that the best technology is selected for customers impacted by rate changes.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments*

document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. For the EPA's response to commenter concerns on simultaneous compliance challenges with the Lead and Copper Rule Improvements, please also see section 12.1 of the EPA response in this *Response to Comments* document. For additional discussion and considerations on available treatment technologies, please see section 10 of the EPA response in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043056)

Aqua appreciates EPA's interest in addressing PFAS in drinking water to protect public health and maintain public trust in the nation's drinking water supply. Aqua has been engaged on PFAS issues since 2016 and has been a leader in PFAS with testing capability, filing legal actions against polluters, installing treatment, and establishing its own PFAS standards in 2020, to support the Agency's efforts to address PFAS contamination. Aqua supports PFAS regulation and drinking water regulation when it can be implemented scientifically, feasibly, affordably, and holistically.

Based on costs and benefits, household affordability, supply chain concerns, and the challenges that are discussed in detail throughout this letter, our main recommendations include:

1. The standard implementation timeline is not appropriate for the current economic conditions. The need to plan, design, pilot, permit, and construct facilities will take much longer than the 3-year timeline given workforce and supply chain challenges. The burden for state primacy agencies to approve extensions for capital improvements will be overwhelming. The Administrator should exercise its authority under the Safe Drinking Water Act (SDWA) to extend the effective date of compliance two years for water systems installing capital improvements.

EPA Response: Consistent with this comment, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges, as well as simultaneous compliance challenges, that may affect the compliance timeline. Regarding rule costs and benefits, please see sections 13.3 and 13.4, respectively, of the EPA response in this *Response to Comments* document. Regarding affordability, please see section 13 of the EPA response in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043065)

Implementation Challenges

Public water systems subject to the Proposal will need to comply within three years unless a two-year extension is provided by state primacy agencies or the Administrator. An estimated 67,000 water systems will need to perform initial monitoring at nearly 90,000 entry points to the distribution system. Additionally, upwards of 5,000 water systems will need to take action to

address PFAS levels above the MCLs and continue to conduct quarterly sampling, according to the EPA's analysis. For water systems that need to install advanced treatment facilities for PFAS, a myriad of challenges will delay the implementation time for each system and impact cost to implement these facilities. Aqua's preliminary data indicates the potential for over 250 entry points in its systems may potentially need to install treatment. Roughly 75% of those 250 locations serve systems with less than 3,300 customers and demonstrates the potential impacts on smaller and less advantaged communities.

Aqua encourages EPA to consider how these challenges will impact not only the compliance cost of the rule, but also the feasibility of the rule to be implemented on the standard timeline provided by the SDWA.

EPA Response: The EPA has evaluated PWS compliance cost of the rule and considered costs in determining whether the MCL level in this rule is "feasible." Specifically, the EPA considers whether the costs associated with compliance and implementation of the MCLs are reasonable based on what may reasonably be afforded by large metropolitan or regional drinking water systems (*A Legislative History of the Safe Drinking Water Act*, Committee Print, 97th Cong., 2d Sess. (1982) at 550). For additional discussion on how the agency considers analytic feasibility when establishing the MCL, please see section 5.1.3 of the EPA response in this *Response to Comments* document. For additional information on the EPA's cost analysis, please see section 13.3 of the EPA response in this *Response to Comments* document. Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as the extended compliance timeframes available for smaller systems under Section 1416 of SDWA (exemptions).

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043093)

As previously discussed, the regulation of PFAS in drinking water as proposed will create various implementation challenges and the Agency is encouraged to consider ways to alleviate these challenges while also protecting public health. Aqua recognizes that EPA is interested in an expeditious rulemaking to reduce PFAS exposure communities; it is nonetheless important that EPA advance this rulemaking effort in a way that is based on sound science, recognizing the importance of drinking water affordability, and the importance for regulations to be feasible to implement. As crafted, there are serious challenges with the EPA's proposed approach, which are coupled with flawed analyses.

First, implementation challenges may mean that systems will struggle to meet the compliance deadline set by the EPA. While EPA has a stated interest in advancing immediate protection of communities from PFAS exposure, water systems still need to perform the necessary work to implement these systems – regardless of the timeline. As proposed, water systems installing treatment will need a two-year extension for compliance. This will ease the burden on state

primacy agencies, which are currently significantly strained implementing other drinking water rules, the Administrator should provide a 2-year extension as part of the final rule.

EPA Response: Consistent with this comment, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

WaterPIO (Doc. #1624, SBC-043462)

3. The timeframe for the construction and implementation of these systems is impossibly short. Public water systems are guaranteed to get notices of violation before they will be able to develop and complete their compliance efforts.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

WaterPIO (Doc. #1624, SBC-043464)

5. There simply won't be enough personnel in the workforce to construct and operate the advanced treatment systems that will be required.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

WaterPIO (Doc. #1624, SBC-043476)

Next, let's talk about the drain on human resources. Like almost every other industry, there is a profound lack of people to fill necessary jobs. Water and wastewater providers were already fighting "brain drain" caused by the retirements of Baby Boomers. Now they are finding it tough to simply replace their numbers. Add in the need to take on high-pressure projects to construct and operate advanced treatment systems while being under attack from the EPA for producing "unsafe water" to their neighbors, and finding the employees needed to meet the proposed MCLs and HI will be damn near impossible.

WaterPIO regularly speaks at industry conferences across the country. When Mike McGill spoke at one such event on May 25, he received universal agreement from his audience when he talked

about the PFAS personnel issue. A few attendees threw in how happy they were to be close to retirement; they wanted out before they had to deal with the proposed MCLs and HI.

On top of being proud of the fact they were racing for the exits, they also lamented their inability to hire their replacements. The "bodies", as they put it, simply are not there.

Yes, water providers will be able to train current staff on advanced treatment, but those employees will need to be replaced as they move up the ladder. Those people simply aren't there right now, and it's entirely possible they will never be there if they believe they could be taking on a job where they'll be accused of poisoning their neighbors.

That is the environment the EPA is creating with these proposed MCLs and HI. It's an untenable situation.

EPA Response: The EPA's final rule represents data-driven drinking water standards that are based on the best available science and meet the requirements of SDWA; regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. As discussed in the preamble to the final rule and elsewhere in this *Response to Comments* document, the health concerns posed by PFAS are serious and well-documented, and establishing a national PFAS NPDWR is a necessary step toward public health protection. Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

WaterPIO (Doc. #1624, SBC-043471)

Because of WaterPIO's work with utilities who have had to add advanced treatment to their water systems, we know firsthand what the impacts of the proposed MCLs and Hazard Index will be; they will create the need for thousands of water providers to augment their current treatment or construct completely new plants.

And all that work will have to happen at the same time. Because of the likely implementation timeline, thousands of water providers won't have a chance in Hell of meeting the new standards in time. They can't simply wave a wand and make the systems, media, and construction materials required to meet the unprecedented demand – on an accelerated timeframe to boot – magically appear. They will have to fight for whatever is available, and the prices for whatever is available will skyrocket.

Think about the supply chain issues we had with Covid where massive demand ran into dramatically inadequate supply. That is the situation the EPA is creating with the proposed MCLs and HI. Thousands of water providers will need reverse osmosis, granular activated carbon, or anion exchange systems, in addition to the billions of tons of media they will require, in little more than three to five years. Not only is this a recipe for disaster supply-wise, but costs

will also skyrocket because the systems, skids, and media that are available will be placed at such a premium.

In order to meet what is laid out as the current implementation schedule, water utilities that have found PFAS at any detectable level will have had to have started their processes to construct advanced treatment years ago. A responsible process for the selection of either advanced treatment or the construction of a new facility takes place over several months if not years.

WaterPIO has three clients in the pilot stages of their advanced treatment and plant construction choices. The implementation timeframe for the proposed MCLs and HI creates such an impossible schedule for compliance that even water providers like our clients who have already started on their path to meet the proposed regulations will likely be found in violation before they can make their solutions operational.

Imagine what that means for systems that haven't even begun to consider what kind of path they must take for future MCL and HI compliance. If you think about it, they already know now they're going to violate the new standards, even though they won't be in effect for three to five years.

That's the very definition of being put in a position to fail. That is what the EPA is guaranteeing with its proposed MCLs and HI; thousands of public water systems nationwide will receive notices of violation for failing to meet water quality standards. This circumstance even applies to water providers in states that have taken significant steps to protect public water by instituting their own MCLs as the EPA dawdled for decades.

Imagine being a water provider in Michigan that has gone through the state's steps – and millions of dollars in costs – to meet what are today the nation's toughest PFAS- related MCLs. Now, not only does the provider discover its state-MCL-focused work isn't good enough, but it will likely be in violation in the future because almost everyone else in the state – and now the entire country – will need to add more treatment to their systems at the same time. The Michigan system already knows it can't win, even though it's already done the job as far as its home state is concerned.

This is also the situation in several other states; all their work – completed while the EPA haphazardly addressed the subject over the years – has been cast aside by the proposed MCLs and HI. And it's not necessarily because four parts per trillion for PFOA and PFOS are the "must set" levels that need to be established to responsibly protect public health, or the fact that the first-ever "Hazard Index" for four other PFAS compounds is established science. Far from it, as the states have found through developing their science-based approaches to reach their individual MCLs.

EPA Response: The commenter provides no verifiable information on these claims that the EPA is putting PWSs in "a position to fail." The EPA's final rule represents data-driven drinking water standards that are based on the best available science and meet the requirements of SDWA; regulation of the PFAS covered by the NPDWR is vital toward protecting public

health by removing these contaminants from our nation's drinking water. For additional discussion on considerations for existing state standards, please see section 5.1.5 of the EPA response in this *Response to Comments* document. Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Water One - Water District No. 1 of Johnson County, Kansas (Doc. #1627, SBC-042325)

Additionally, it is unrealistic to suggest that implementation of the PFAS regulation could be completed within 5 years. Rather, it would take water utilities a minimum of 8-10 years to study, pilot test, design, and construct PFAS removal technology and methodologies. As the proposed regulation is currently written, there will be a substantial number of violations in a short time span. The EPA should be more pragmatic within the rule structure and provide realistic deadlines. Subsequently, if this is not modified, the public's confidence and trust in safe drinking water will subside and be tarnished.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10), which the maximum amount of time for compliance that the EPA can provide in an NPDWR; states can provide additional time for compliance through the 1416 exemption process. Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Water One - Water District No. 1 of Johnson County, Kansas (Doc. #1627, SBC-042330)

Additionally, we are concerned about the potential for escalating construction costs and project delays due to labor shortages and increase demand to meet the regulation.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044067)

7. ASDWA suggests that EPA allow flexibility in the compliance deadlines to ensure feasibility, similar to the flexibility offered as a part of the final arsenic regulation, allowing extended compliance deadlines depending on the system size and initial concentration. While systems with a population greater than 3,300 are currently sampling for PFAS under UCMR 5, only a small subset of small water systems are currently a part of that sampling pool. As many large and

medium-sized water systems will be taking advantage of the opportunity to use previously collected data from UCMR 5, many small systems will take their first PFAS samples when the final PFAS NPDWR is implemented. If these small systems exceed the MCL, the three-year compliance timeline will be challenging.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044077)

Primacy Agency Workforce and Workload

ASDWA recommends that EPA further acknowledge and support primacy agency efforts to address workforce issues to ensure continued public health protection.

Primacy agencies face increasing workloads with implementing existing rules and regulatory programs and starting new regulatory and non-regulatory efforts. Primacy agencies are assisting water systems with implementing the Lead and Copper Rule Revisions (LCRR) requirements for initial service line inventories and addressing cybersecurity. Additionally, primacy agencies are managing a significant increase in applications for Bipartisan Infrastructure Law (BIL) funding through the Drinking Water State Revolving Fund (DWSRF) programs. Primacy agencies are facing unique workforce issues in that the retirements of "Baby Boomers" are coinciding with the increased workload previously described. Hiring staff, especially engineers, is currently very difficult for primacy agencies. ASDWA recommends that EPA ensure that the Agency's water sector workforce initiative includes considerations for primacy agency staff.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges, as well as simultaneous compliance challenges, that may affect the compliance timeline. For additional discussion on the EPA's consideration of primacy agency costs, please see section 13.3.1 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044117)

Small Systems

ASDWA recommends that EPA continue to fund and dedicate resources to technical assistance programs, programs to advance small water systems' technical, managerial, and financial capability, and operator recruitment programs.

Small system compliance with the PFAS NPDWR, regardless of the final value of the MCLs, will be challenging. Most small ground water systems currently have minimal treatment installed. For those systems with no alternative water source, installation of one of the BAT may present a variety of challenges if the current treatment only consists of a chemical feed and a pressure tank. In order to install one of the BAT options, a small ground water system may need to construct an entirely new building to house the treatment—this could account for up to 50% of the project's cost. This increase in building size may trigger additional building code requirements that further increase the cost of the project.

In most cases, the advanced treatment needed for PFAS will require an increase in the level of certified operator needed to operate a PWS. The entire water sector is facing workforce shortages, especially for certified operators, and this issue is particularly prevalent in small and disadvantaged water systems. The challenges around hiring and retaining operators will continue to be exacerbated as systems install treatment to comply with the PFAS MCL.

EPA Response: For funding concerns, the agency notes that funds are also available through the passage of the BIL to assist many disadvantaged communities, small systems, and others with the costs of installation of treatment when it might otherwise be cost-challenging. Please see section 2.4 of the EPA response in this *Response to Comments* document for more discussion about currently available funding. Regarding concerns on operator certification licenses, please see the EPA response to comment Doc. #1567, SBC-042738 in section 12.1 in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044103)

PFAS Treatment

Treatment Concerns

ASDWA recommends that EPA include guidance for extended compliance deadlines based on system size and level of contamination.

Complying with a drinking water regulation at a low MCL that is essentially equivalent to the laboratory detection limit, as would be the case for complying with the proposed PFAS MCLs, requires robust and reliable treatment technologies (more than one). ASDWA supports EPA's analysis that an MCL of 4.0 parts per trillion is generally technically feasible as defined by the SDWA. However, several factors compound the implementation and feasibility challenges associated with achieving and maintaining compliance with the MCL. The combination of factors will vary between water systems, and compliance with the MCL will be a challenge for many systems, especially those that are small and disadvantaged. These compounding factors include:

• Resource concerns, including supply chain issues, workforce shortages, and costs;

• Sampling challenges, including delays in receiving results, limited lab capacity, and costs;

• Small system technical, managerial, and financial (TMF) capacity;

• Treatment efficacy, including daily operation needs for advanced treatment and operator capability;

• Waste disposal methods and the potential demand and supply of available waste disposal means;

• Timelines for compliance, treatment piloting, review and approval, and installation; and

• Impacts on available certified operators where addition of treatment raises the level of the certified operator required at a water system.

ASDWA supports EPA's proposal to allow exemptions to compliance deadlines under certain circumstances. ASDWA recommends that EPA consider the above factors to appropriately evaluate extended initial compliance deadlines for water systems, similar to the flexibility for the compliance deadlines in the final arsenic regulation. Appendix B of this letter is an excerpt from Appendix G on exemptions within EPA's State Implementation Guidance for the Arsenic Rule. ASDWA recommends that EPA utilize a similar protocol to Table 1 (G-15), where the compliance timelines are based on population and contaminant concentration. This guidance will help ensure primacy agencies can efficiently provide exemptions when appropriate.

EPA Response: Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on exemptions under SDWA 1416(a). The EPA notes that the minimum reporting level (MRL) is not set at the laboratory detection limit, it is at the practical quantitation limit (PQL). For commenter concerns regarding practical quantitation limits, including implementation of the MCLs at the PQL, how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding concerns on operator certification licenses, please see the EPA response to comment Doc. #1567, SBC-042738 in section 12.1 in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044080)

ASDWA recommends that EPA better coordinate between its regions and headquarters to ensure the Agency is not creating any unnecessary burden on the primacy agencies.

Primacy agencies have reported frustrations with requests from EPA headquarters and regional staff for duplicative data beyond what is required. As co-regulators, primacy agencies want to work with EPA and be helpful, but these additional data collection and reporting efforts take significant staff time and increase implementation costs. ASDWA recommends that EPA improve coordination between its regions and headquarters to ensure the Agency is not creating any unnecessary burden on primacy agencies.

In summary, primacy agencies have a long list of resource feasibility concerns that need to be addressed for effective rule implementation. ASDWA recommends that EPA partner closely

with primacy agencies and dedicate the needed Agency resources to address these important concerns in the final rule.

EPA Response: The agency agrees with the commenter that successful partnerships between primacy agencies and the EPA remain critical to safeguard public health and drinking water resources. After finalization of the PFAS NPDWR, the EPA intends to work with stakeholders to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044113)

Primacy agencies and EPA will need to continue partnering on addressing water sector workforce challenges through increased resources for operator certification and workforce development programs to ensure treatment is operated by qualified and experienced personnel.

In most states, the advanced treatment needed for PFAS will, in most cases, require an increase in the level of certified operator needed to operate a public water system (PWS). The entire water sector is facing workforce shortages, especially for certified operators, and this issue is particularly prevalent in small, rural, and disadvantaged water systems. The challenges around hiring and retaining operators will continue to be exacerbated as systems install treatment to comply with the PFAS NPDWR. As the demand for operators increases, the cost to hire operators will also increase.

EPA Response: Regarding concerns on operator certification licenses, please see the EPA response to comment Doc. #1567, SBC-042738 in section 12.1 in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044115)

Compliance

Timelines

ASDWA recommends that EPA allow flexibility in the compliance deadlines to ensure feasibility, similar to the flexibility offered as a part of the final arsenic regulation, allowing staggered compliance deadlines depending on the system size and/or initial PFAS concentrations.

While systems with a population greater than 3,300 are currently sampling for PFAS under UCMR 5, only a very small subset of small water systems are currently a part of that sampling pool. As such, most small water systems will have a late start with their PFAS sampling. While many large and medium-sized water systems will be taking advantage of the opportunity to use previously collected data from UCMR 5, many small systems will take their first PFAS samples after the final PFAS NPDWR is promulgated. If these small systems exceed the MCL, the three-plus-two-year compliance timeline will be challenging to meet—systems will need time for

bench tests, approximately one year to pilot test, and approximately one year to design and obtain approval from the primacy agency. Additional time would be needed for bid preparation, obtaining financing, and for construction and start-up. ASDWA reiterates its recommendation that EPA consider the above factors to appropriately evaluate extended initial compliance deadlines for water systems, similar to the flexibility for the compliance deadlines in the final arsenic regulation.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Texas Commission on Environmental Quality (TCEQ) (Doc. #1632, SBC-044130)

If small systems exceed the MCL, the three-year compliance timeline will be challenging to meet. Texas systems will need time for bench tests, pilot testing, design, and obtaining approval from TCEQ. Systems should be given time to solicit bids, obtain financing, construct necessary infrastructure, and plan for potential delays due to supply chain issues and other unforeseen complications. For these reasons, TCEQ recommends a minimum four-year compliance timeline.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Rural Community Assistance Partnership Incorporated (RCAP) (Doc. #1633, SBC-044140)

Technical Assistance Needed for Testing Compliance

Overall, increased technical assistance and outreach about PFAS, risk communication strategies with communities, availability of possible treatment technologies, and availability of funding will be required to ensure small and disadvantaged systems are supported and able to comply with the new regulations and supply safe water.

Small systems may encounter issues with both sampling procedures and compliance. PFAS sampling is a highly sensitive process and susceptible to cross-contamination when done incorrectly. To avoid false results, the sampler must follow strict guidelines as PFAS chemicals are widely used in personal care products, clothing, food packaging, and other sampling equipment, all of which can lead to cross contamination. This will increase the need for training and technical assistance for small, rural, and tribal water systems.

Additionally, the pool of drinking water operators for small and very small public water systems will need significant training on this issue. When PFAS treatment is added to these small

systems' lists of regulatory requirements, their operators must get higher grade licenses or systems must find new operators. RCAP has provided operator training for many years and has seen firsthand a shrinking operator workforce due to aging and retirements, particularly with regards to small systems. Training this already diminishing workforce in an efficient manner will be a big priority in ensuring successful PFAS compliance for small systems.

EPA Response: For funding concerns, the agency notes that funds are also available through the passage of the BIL to assist many disadvantaged communities, small systems, and others with the costs of installation of treatment when it might otherwise be cost-challenging. Please see section 2.4 of the EPA response in this *Response to Comments* document for more discussion about currently available funding. After finalization of the PFAS NPDWR, the EPA also intends to work with stakeholders to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation and will consider the topics suggested by the commenter as the agency develops implementation materials for the final NPDWR. With respect to commenter concerns on operator training, please see the EPA response to comment Doc. #1567, SBC-042738 in section 12.1 in this *Response to Comments* document.

Rural Community Assistance Partnership Incorporated (RCAP) (Doc. #1633, SBC-044142)

Enforcement

As stated above, RCAP agrees with EPA that, when fully implemented, the PFAS Rule will prevent tens of thousands of PFAS-related illnesses or deaths. However, because PFAS are ubiquitous in our environment, there will be thousands of public water systems (PWSs) impacted by these new standards, and therefore EPA may be best served to bring systems into compliance in a phased manner, both in terms of resources needed for addressing compliance strategies as well as the treatment systems design and implementation, so that it doesn't cause significant supply chain issues and thereby increase costs.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Orange County Water District (OCWD), California (Doc. #1634, SBC-043236)

The EPA Administrator has authority under the SDWA to extend the effective date of compliance by two years (from three years to five years) for water systems installing capital improvements; OCWD recommends the Administrator exercise this authority, instead of leaving these decisions to the individual states on a case-by-case basis. This will avoid a deluge of extension applications to state primacy agencies, which are ill-equipped to handle this new burden alongside their existing responsibilities. Providing the two-year extension will also minimize otherwise unnecessarily burdensome consent agreements and/or orders for systems

inevitably unable to come into compliance within three years. Alternatively, EPA could determine eligibility for compliance extensions based on PFAS concentrations, analogous to its procedures under the Arsenic Rule whereby systems with greater relative public health risk are prioritized for compliance.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. Further extensions can be provided by primacy agencies through the Section 1416 exemption process, similar to the extensions provided for under the arsenic rule.

Orange County Water District (OCWD), California (Doc. #1634, SBC-043234)

Implementation Timeline

Achieving broad, nationwide compliance within the rule's proposed standard three-year compliance period under the SDWA is infeasible for a variety of reasons, including:

• The same current economic conditions cited above (significant inflation, labor shortages, global supply chain disruptions, and increased borrowing costs) for EPA's systematic underestimation of treatment costs also severely limit the ability of public water systems to achieve compliance with the proposed regulation within three years.

• The need to perform pilot testing, which is generally advisable and required in some states for consideration of system design and construction approvals.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Town of Tewksbury, Massachusetts (Doc. #1637, SBC-043248)

EPA's timeline for compliance with the rule is not reasonable, and likely not even achievable, given the work that goes into designing, constructing, and funding new treatment systems. The water sector, including operators, design engineers, and construction workers, is challenged with workforce issues like many other sectors of our society. More sophisticated treatment will likely cause a change in PWS classification and may require a higher-grade operator license. In Massachusetts, it takes time to get through the required training to be able to sit for a higher-grade exam. EPA does not appear to have given any thought to issues such as this when they crafted the rule and its three-year implementation timeframe. EPA must adjust the compliance timeframe to be more realistic.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Citizens Against Ruining the Environment (CARE) (Doc. #1638, SBC-043458)

Exemptions and Exceptions Must Be Strictly Limited

CARE opposes the exemptions in Section XII(D) of the Proposed Rule that would allow up to 14 years of exemptions from the MCL requirements for small systems. [FN35: PFAS National Primary Drinking Water Regulation Rulemaking, 80 Fed. Reg. at 18689.] As stated above regarding monitoring, MCLs do not protect human health if they are not monitored and enforced. Likewise, exemptions that would permit exceedances above MCL can not protect human health.

PFAS contamination is a public health emergency and urgent environmental justice concern. The potential for a PWS to receive an exemption that would allow for PFAS MCL exceedances for 14 years is unconscionable. In particular, making these exemptions available to small systems and those that can not afford capital improvements underscores the environmental justice and disproportionate burden this proposal would place on EJ communities.

CARE does not support granting an exemption from the PFAS MCLs due to a system's inability to afford capital improvements. If a water system is unable to afford treatment to bring the water quality to a safe level, then assistance must be provided to ensure that residents have access to safe drinking water. Merely exempting noncompliant water systems from the MCL requirements is not an acceptable solution to the problem of PFAS contamination.

CARE encourages EPA to define specific, limited conditions under which a State Primary Agency may issue an exemption under SDWA Section 1416. Those exemptions should be granted in only the rarest circumstances and when there is no other viable alternative. To ensure that Primary Agencies do not overuse exemptions, the US EPA could place a maximum cap on the number of exemptions permitted.

Additionally, CARE recommends that Primary Agency authority to issue an exemption trigger a requirement for the provision of emergency drinking water supplies or filtration equipment under 40 C.F.R. § 1412.11 or other statutory authority that EPA deems appropriate. [FN36: 40 C.F.R. § 1412.11 requires Primary Agencies to have a plan for the provision of drinking water when a PWS system is compromised by disaster, accident, or other reason. This requirement is discussed more fully in the U.S. EPA's State Emergency Drinking Water Supply Guidance document, available at https://www.epa.gov/system/files/documents/2023-04/StateEDWS_Guidance_508c.pdf.] Most importantly, CARE does not support providing an exemption to any system without a concomitant responsibility to provide safe drinking water to the community by alternative means while the PWS system PFAS levels are above MCLs.

EPA Response: Regarding the rule compliance timeframe, for the reasons discussed in this response to comment document, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. Additionally, section in 12.1 describes the availability of exemptions under SDWA section 1416(a): primacy agencies who have adopted the 1998 *Variance and Exemptions Regulation* (USEPA, 1998) may choose to grant exemptions where the water system meets the statutory requirements for an exemption. These requirements include the state finding that the water system is "unable to comply" with the MCL or "implement measures to develop an alternative source of water supply" and the granting of the exemption will not result in an unreasonable risk to health. In addition, at the time an exemption is granted, the state must prescribe schedules for compliance and implementation of control measures that the state may require for the contaminant. Such control measures could include the provision of alternative water and/or filters. See also 40 CFR 142.20(b). There is no authority in the statute for the EPA to put a cap on the number of systems with an exemption; however, historically, the use of exemptions issued by primacy agencies has been limited.

California Municipal Utilities Association (CMUA) (Doc. #1639, SBC-043255)

II. CMUA Requests Extra Time for MCL Compliance

The Regulation proposes to have public water agencies begin compliance, including installing treatment technologies, within three years after promulgation. Three years is insufficient time for public water agencies to overcome the financial implications to achieve compliance with the Regulation. Public agencies set budgets for infrastructure improvements and other costly operational projects several years in advance. It is highly unlikely that these agencies will be able to budget accordingly to include the high compliance costs within three years. Additionally, the loan or grant process may take longer than three years to get the funding needed. Public water agencies need time to plan and absorb the added costs of compliance.

CMUA urges the EPA to consider extending the time for compliance to give public water agencies an additional three years, for a total of six years after promulgation, to comply with the MCLs.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10), which is the maximum time allowed for compliance through the NPDWR; additional time can be provided in certain circumstances through the exemption process in SDWA Section 1416. Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Aidan Cecchetti (Doc. #1640, SBC-044376)

• EPA is seeking comment as to whether there are specific conditions that should be mandated for systems to be eligible for exemptions under 1416 to ensure that they are only used in rare circumstances where there are no other viable alternatives and what those conditions would be (pg. 18689 Federal Register Volume 88, Number 60).

o The commenters recommend that EPA provide additional clarification regarding how primacy agencies would use the criteria in 1416 to grant exemptions. It is unclear to the commenters how water systems would demonstrate eligibility for an exemption under the current criteria.

EPA Response: Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on exemptions under 1416, as well as the EPA response to comment Doc. #1638, SBC-043458 in section 12.1 in this *Response to Comments* document.

National Rural Water Association (NRWA) (Doc. #1641, SBC-043265)

Implementation Challenges

Three-year compliance implementation is not long enough to provide nearly 150,000 water systems nationwide with the time and opportunity needed to comply. The proposed rule states it will take 16 hours of training for systems smaller than 3,300 users. Additionally, the proposed rule estimates it will take primacy agencies 2,080 hours or 1 year to provide initial training and technical assistance to every water system in their state. These estimates are an oversimplification of the time and effort it will take just to conduct the outreach, training and technical assistance needed to start this process.

Water systems that need to install treatment equipment will need a minimum of five years to complete projects. The process for completing such projects is complex and time-consuming, involving various approvals, pilot studies, local land use or zoning processes, design and development, procurement, and construction. These steps require coordination with multiple entities, including boards, councils, other elected officials, and the public. Additionally, utilities are currently facing challenges, such as increased pricing, supply chain disruptions, and labor shortages, which further extend project timelines and increase costs.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. For funding concerns, the agency notes that funds are also available through the passage of the BIL to assist many disadvantaged communities, small systems, and others with the costs of installation of treatment when it might otherwise be cost-challenging. Please see section 2.4 of the EPA response in this *Response to Comments* document for more discussion about currently available funding.

National Rural Water Association (NRWA) (Doc. #1641, SBC-043267)

Small rural systems will be at a disadvantage when competing for engineers, equipment, construction, and laboratory availability.

NRWA strongly recommends that EPA use its authority to provide a nationwide two-year extension for the compliance timeline for systems installing capital improvements. A two-year extension will help address the concerns outlined above to alleviate burdens on water systems and allow for compliance by water systems addressing PFAS contamination. Additionally, EPA should ensure each state primacy agency has a streamlined approach for approving the nine additional years established in the proposed rule for small rural systems.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline, as well as the discussion of further extensions that may be available to certain systems under the Section 1416 exemption process.

American Farm Bureau Federation et al. (Doc. #1642, SBC-043492)

Additionally, access to contractors needed to install these technologies has already been identified as a concern by organizations representing the rural water communities. The contracts with large water systems will inevitably be far more lucrative, which will place smaller systems at the bottom of the priority list. Facilities will also need to bring in more employees to oversee the operations, maintenance and treatment of the equipment. This will require specific training, and trainer shortages have already presented challenges. Staff shortages even for the existing work required to safely operate and maintain drinking water systems are widespread: AWWA conducted a survey in 2021 on staffing and supply chain needs and found that 40% of drinking water utilities of all sizes are struggling to fill positions at their facilities, and employee turnover has doubled. Smaller communities will once again lose out because they have less available budget to hire additional staff and fewer available candidates to serve those roles. These systems will still have to meet the three-year implementation deadline but with many more hurdles and fewer resources. The agency must reevaluate the length of the implementation period or move towards a tiered roll out. It would be logical to allow the larger utilities to move ahead first to prevent a bottleneck on technologies and financial resources.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

American Farm Bureau Federation et al. (Doc. #1642, SBC-043499)

Given the costs and the challenges associated with obtaining the necessary technologies, availability of testing and the lack of disposal methods that we have already outlined, we recommend that the EPA consider extending the implementation period—particularly for small, rural water utilities. Simply put—these systems need more time and resources to ensure that they are in compliance with these new standards. At a minimum, the EPA should consider a tiered implementation timeline to alleviate the fallout from having every drinking water utility in the nation competing for technologies, testing and disposal.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Massachusetts Water Resources Authority (Doc. #1645, SBC-043284)

b. Impractical Implementation Timeline

EPA has provided an implementation timeline of three years for PWSs to conduct initial monitoring and take subsequent mitigation actions if PFAS levels exceed the MCL. The default SDWA implementation timeline is not practical given the number of systems impacted, inter-related regulatory requirements, and current economic conditions. As proposed, within three years a system must: (a) conduct at least one year of monitoring to characterize occurrence at all of their points of entry to the distribution system at a time when laboratory capacity is already strained; (b) select and design a compliance strategy; (c) obtain primacy agency approval from state programs already facing limited capacity to meet current demands; (d) address primacy agency requirements triggered under other rules (e.g., Lead and Copper Rule) -- requirements that themselves will require testing and potentially a year or more of pilot testing; and (e) construct necessary improvements in the midst of well-recognized supply chain delays and workforce shortages. MWRA requests that EPA grant an additional two year blanket extension (for a total of five years), at the minimum, for the implementation of a final PFAS NPDWR.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Savannah River Nuclear Solutions LLC (Doc. #1647, SBC-043325)

May 30, 2023

SRNS-J2210-2023-00056

Tracking Number: 10667

Jennifer L. McLain

Director, Office of Groundwater and Drinking Water

U.S. Environmental Protection Agency EPA Docket Center

OLEM Docket, Mail Code 28221T 1200 Pennsylvania Avenue, NW Washington, DC 20460

Docket ID No. EPA-HQ-OW-2022-0014

(Submitted Electronically via https://www.regulations.gov)

SAVANNAH RIVER NUCLEAR SOLUTIONS, LLC COMMENTS ON PROPOSED PFAS NATIONAL PRIMARY DRINKING WATER REGULATION

Savannah River Nuclear Solutions, LLC (SRNS) is pleased to submit the attached comments on the proposed rule; PFAS National Primary Drinking Water Regulation published in the Federal Register on March 29, 2023 (Vol. 88, No. 60 Federal Register 18638).

If there are any questions, please contact me at (803) 952-6234 or by email at scott.kuhn@srs.gov.

Sincerely,

JOHN KUHN

(Affiliate)

J. Scott Kuhn

Digitally signed by JOHN KUHN (Affiliate)

Date: 2023.05.30 13:57:47

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Savannah River Nuclear Solutions, LLC Environmental Compliance

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SAVANNAH RIVER NUCLEAR SOLUTIONS, LLC (SRNS) COMMENTS TO U.S. ENVIRONMENTAL PROTECTION AGENCY (EPA) ON PROPOSED RULE; PER- and POLYFLUOROALKYL SUBTANCNES (PFAS) NATIONAL PRIMARY DRINKING WATER REGULATION May 30, 2023

SRNS GENERAL COMMENTS:

Comment 1

As written, in South Carolina, the treatment methods proposed for PFAS would all require daily operator visits by a grade C or higher drinking water treatment operator. Currently, many public water systems only require operation by E level (hypochlorite treatment) or D level (gaseous chlorine, corrosion control, sequestration) operators. The requirement to install systems such as Granulated Activated Carbon (GAC), Ion Exchange (AIX), or High-Pressure Membranes (Reverse Osmosis [RO] and Nanofiltration [NF]) will likely result in a shortfall of qualified operators of these systems as public water systems try to catch up with additional training and certification of the operators. This is especially true of RO and NF systems as they tend to be of a higher technical nature than GAC or AIX. Has EPA considered the potential additional burden on public drinking water systems to meet these new operator requirements, whether a sufficient number of schools exist to provide classroom and hands-on training, and the 6–12-month time period for providing adequate training on these technologies?

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. Regarding concerns on operator certification licenses, please see the EPA response to comment Doc. #1567, SBC-042738 in section 12.1 in this *Response to Comments* document.

Savannah River Nuclear Solutions LLC (Doc. #1647, SBC-043342)

Comment 7

Section XII.D, Rule Implementation and Enforcement (pg. 18688)

SRNS supports the ability of public water systems to obtain a two-year extension to comply with the proposed MCL's if a state or EPA determines additional time is needed for capital improvements. This provision is especially needed for federal facilities as funding from the federal government is lagged and any capital upgrades or improvements can only be accomplished if adequate funding is budgeted and approved generally years in advance of the project.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

New England Interstate Water Pollution Control Commission (NEIWPCC) (Doc. #1650, SBC-043158)

Personnel Capacity

Lastly, we are concerned that municipalities and states lack the personnel needed to effectively implement the rule. Engineers, scientists, and other necessary staff are all in high demand. Our member states are struggling to hire and retain sufficient personnel. Our member state's difficulty in competing with the private sector for trained personnel has left some state agencies short of capacity already, and they will need to significantly increase their staffing to implement the rule.

Moreover, contracting the implementation work out to consultants is not a viable solution. The extra burden associated with hiring consultants imposes other financial challenges. Such contracts would consume the available funding to implement the rule at an alarming rate.

We appreciate the opportunity to provide these comments, and we thank you for your consideration.

Sincerely,

Susan J. Sullivan

Executive Director

CC: NEIWPCC Executive Committee and Commissioners

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044189)

H. PFAS Treatment

1. NCDEQ recommends that EPA include guidance for extended compliance deadlines based on system size and level of contamination.

Complying with a drinking water regulation at a low level, i.e., complying with the proposed PFAS MCLs and HI, will require robust and reliable treatment technologies (more than one). NCDEQ supports EPA's analysis that an MCL of 4.0 parts per trillion is generally technically feasible as defined by the SDWA. However, several factors compound the implementation challenges with achieving and maintaining compliance with the MCL. The combination of factors will vary between water systems, and compliance with the MCL will be a challenge for many systems, especially small and disadvantaged water systems. These compounding factors include:

• Resource concerns, including supply chain issues, workforce shortages, and costs

• Sampling challenges

• Small system capacity

• Treatment efficacy, including daily operation needs for advanced treatment and operator capability

• Waste disposal methods

• Timelines for compliance, treatment piloting, review and approval, and installation

• Adding treatment may raise the level of the certified operator required at a water system

NCDEQ recognizes that timely compliance with the proposed drinking water standards will be essential to reduce or eliminate PFAS contamination and to promote public health. However, NCDEQ supports EPA's proposal to allow exemptions to compliance deadlines under certain narrow circumstances. NCDEQ recommends that EPA consider the above factors to appropriately evaluate extended initial compliance deadlines for water systems, similar to the flexibility for the compliance deadlines in the final arsenic regulation. NCDEQ recommends that EPA utilize a similar protocol to Table 1 (G-15) [FN1: EPA State Implementation Guidance for the Arsenic Rule; Appendix G. https://www.epa.gov/sites/default/files/201509/documents/2005_11_10_arsenic_ars_final_app_g.pdf], where the compliance timelines are based on population and contaminant concentration.

This guidance will help ensure state agencies are able to efficiently provide exemptions when appropriate and necessary.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on exemptions under SDWA 1416 as well as supply chain and labor challenges that may affect the compliance timeline. For funding concerns, the agency notes that funds are also available through the passage of the BIL to assist many disadvantaged communities, small systems, and others with the costs of installation of treatment when it might otherwise be cost-challenging. Please see section 2.4 of the EPA response in this *Response to Comments* document for more discussion about currently available funding.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044198)

8. NCDEQ recommends that EPA continue to fund and dedicate resources to technical assistance programs, programs to advance small water systems' technical, managerial, and financial capability, and operator recruitment programs.

Small system compliance with the PFAS NPDWR, regardless of the final value of the MCLs, will be challenging. Most small ground water systems currently have minimal treatment installed. For those systems with no alternative water source, installation of one of the BAT may present a variety of challenges if the current treatment only consists of a chemical feed and a pressure tank. In order to install one of the BAT options, a small ground water system may need to construct an entirely new building to house the treatment—this could account for up to 50% of the cost of the project. This increase in building size may trigger additional building code requirements that further increase the cost of the project.

In most cases, the advanced treatment needed for PFAS will require an increase in the level of certified operator needed to operate a PWS. The entire water sector is facing workforce shortages, especially for certified operators, and this issue is particularly prevalent in small and disadvantaged water systems. The challenges around hiring and retaining operators will continue to be exacerbated as systems install treatment to comply with the PFAS MCL.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. Regarding concerns on operator certification licenses, please see the EPA response to comment Doc. #1567, SBC-042738 in section 12.1 in this *Response to Comments* document.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044195)

5. State agencies and EPA will need to continue partnering on addressing water sector workforce challenges through increased resources for operator certification and workforce development programs to ensure treatment is operated by qualified and experienced personnel.

In NC, the advanced treatment needed for PFAS will, in most cases, require an increase in the level of certified operator needed to operate a public water system (PWS). The entire water sector is facing workforce shortages, especially for certified operators. The challenges around hiring and retaining operators will continue to be exacerbated as systems install treatment to comply with the PFAS NPDWR. As the demand for operators increases, the cost to hire operators will also increase. NCDEQ is available to work with EPA to identify operator certification and training needs of the state.

For small, rural, and disadvantaged water systems, compliance with the PFAS NPDWR, regardless of the final value of the MCLs, will be challenging. Most small ground water systems currently have minimal treatment installed. For those systems with no alternative water source, installation of one of the BAT may present a variety of challenges if the current treatment only consists of a chemical feed and a pressure tank. In order to install one of the BAT options, a small ground water system may need to construct an entirely new building to house the treatment—this could account for up to 50% of the cost of the project. This increase in building size may trigger additional building code requirements that further increase the cost of the project.

In most cases, the advanced treatment needed for PFAS will require an increase in the level of certified operator needed to operate a PWS. The entire water sector is facing workforce shortages, especially for certified operators, and this issue is particularly prevalent in small and disadvantaged water systems. The challenges around hiring and retaining operators will continue to be exacerbated as systems install treatment to comply with the PFAS MCL.

NCDEQ recommends that EPA continue to fund and dedicate resources to technical assistance programs, programs to advance small water systems' technical, managerial, and financial capability, and operator recruitment programs.

EPA Response: For funding concerns, the agency notes that funds are also available through the passage of the BIL to assist many disadvantaged communities, small systems, and others with the costs of installation of treatment when it might otherwise be cost-challenging. Please see section 2.4 of the EPA response in this *Response to Comments* document for more discussion about currently available funding.

Virginia Municipal Drinking Water Association (VMDWA) (Doc. #1657, SBC-043168)

4. THE UNREALISTICALLY SHORT SCHEDULE FOR COMPLIANCE WILL CAUSE HARM TO THE NATION AND LOCAL COMMUNITIES AND SHOULD BE REPLACED

WITH A HEALTH-BASED PHASED APPROACH TO MCL ADOPTION AND IMPLEMENTATION

Undertaking all of EPA's estimated 3,400 to 6,300 water system PFAS upgrades over three to five years from MCL adoption will lead to many problems and should be reconsidered.

First, this schedule is neither workable nor prudent for a nationwide MCL proposal for the following reasons. Diligent efforts toward monitoring, design, construction simply are not generally feasible on EPA's compressed schedule considering the time required for the necessary steps:

• Lab expansions and certification for PFAS testing

• Monitoring to make compliance / noncompliance determinations

• Design and engineering procurement

• Preliminary engineering analysis

• Pilot and demonstration testing to support treatment technology selection

• Engineering design for treatment plant upgrades

• Spending authorization from governing body of the utility

• Financing arrangements and associated water rate increases

• Construction bids, selection, and contracts

• Equipment order lead times

• Construction process

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. For additional discussion on how the agency considers analytic feasibility when establishing the MCL, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Virginia Municipal Drinking Water Association (VMDWA) (Doc. #1657, SBC-043173)

Seventh, the proposal's "all upgrades all at once" approach could lead to worse public health results as all projects concurrently compete for limited engineering, equipment, construction resources, and PFAS-removal material (e.g., granular activated carbon, ion exchange resins, novel absorbents), and facilities with the highest current PFAS levels are delayed in their upgrades. A better regulatory approach would enable primacy agencies to structure schedules such that limited engineering, state agency staff time, federal/state funding, equipment, and

contractors are available for and directed to water systems with the highest priority need (i.e., highest PFAS levels). The public interest would be better served by a regulatory approach that allows the worst situations to be fixed earlier than systems with only marginal needs for upgrades (e.g., those with PFAS levels only slightly above the proposed or final MCLs).

EPA Response: It is not clear what the basis is for the commenter's statement that the final NPDWR mandates an "all upgrades all at once" approach. The EPA's rule does not mandate that all upgrades happen at the same time. Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Virginia Municipal Drinking Water Association (VMDWA) (Doc. #1657, SBC-043171)

Fifth, in addition to the heightened prices this regulation would impose on the public, project delivery schedules are also a problem in a construction industry that is already overwhelmed with projects. The construction industry upon which water utilities depend will fall further behind when the MCL regulation adds thousands of water treatment plant upgrades.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Virginia Municipal Drinking Water Association (VMDWA) (Doc. #1657, SBC-043175)

5. RECOMMENDATION

VMDWA recommends and requests that EPA revise the proposed regulation to adopt a health-based phased approach, which could be established through use of the following existing EPA authorities and discretion:

• Adopt Regulations in a Manner to Create Multi-Phase Program – EPA should time its regulatory action(s) to achieve an orderly, feasible phased approach. EPA could also take multiple regulatory actions to reduce MCL concentrations over time, rather than the proposal's "all systems all at once" approach. In these ways, EPA has the ability to phase-in PFAS reductions to achieve appropriate levels in a much more prioritized, orderly, feasible, and cost-effective manner than would result from the currently proposed regulation. EPA should clearly communicate the phased approach to help affected water systems plan their implementation steps for each phase.

[VMDWA recommends and requests that EPA revise the proposed regulation to adopt a health-based phased approach, which could be established through use of the following existing EPA authorities and discretion:]

• Set Minimum 5-Year MCL Effective Date for Each Phase – For the initial phase and each phase adopted thereafter, EPA should establish in the final federal regulation an effective date five years (rather than three years) from the date of promulgation given the necessary capital improvements as allowed under 42 U.S.C. § 300g-1(b)(10).

EPA Response: Please see the EPA response to comment Doc. #1657, SBC-043173 in section 12.1 in this *Response to Comments* document on the assertion of this "all systems all at once" regulatory approach. Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as discussion on a phased-in MCL approach. For additional discussion on how the agency considers analytic feasibility when establishing the MCL, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Virginia Municipal Drinking Water Association (VMDWA) (Doc. #1657, SBC-043176)

[VMDWA recommends and requests that EPA revise the proposed regulation to adopt a health-based phased approach, which could be established through use of the following existing EPA authorities and discretion:]

• Acknowledge Need for Primacy Agency Use of 3-Year Exemption Extensions – EPA should acknowledge in the final regulation that many projects in each phase, especially larger more complex projects, will need to make use of the three year extension (beyond the 5-year minimum) for necessary capital improvements due to the compelling factors discussed in these comments, as allowed under 40 C.F.R. § 142.50).

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on exemptions under SDWA 1416 as well as supply chain and labor challenges that may affect the compliance timeline.

Virginia Municipal Drinking Water Association (VMDWA) (Doc. #1657, SBC-043177)

Using the above EPA authorities and discretion, EPA could establish the recommended health-based phased approach, avoid or mitigate the real world implementation problems associated with proposed regulation, and serve the public interest more effectively. The following example of the type of result that could be achieved in this manner is provided for illustration purposes assuming but not endorsing the proposed MCL levels (which warrant further review):

• Phase 1: All public water systems achieve 10 ppt for PFOA, 10 ppt for PFOS, and 5 for Hazard Index effective within 5 years.

• Phase 2: All public water systems achieve 7 ppt for PFOA, 7 ppt for PFOS, and 3 for Hazard Index effective within 10 years.

• Phase 3: All public water systems achieve 4 ppt for PFOA, 4 ppt for PFOS, and 1 for Hazard Index effective within 15 years.

To be clear, in outlining this three-phased approach, VMDWA is not recommending adoption specifically of MCLs at 4 ppt for PFOA and PFOS or of the proposed Hazard Index for the other four chemicals. The point is to illustrate a prioritized, health-based phase-in over time, regardless of whatever specific final MCL concentrations or index that may be adopted.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as discussion on a phased-in MCL approach and the availability of additional extensions through the exemption process under Section 1416.

Maryland Association of Municipal Wastewater Agencies (MAMWA) (Doc. #1658, SBC-043406)

Fifth, in addition to the heightened prices this regulation would impose on the public, project delivery schedules are also a problem in a construction industry that is already overwhelmed with projects. The construction industry upon which water utilities depend will fall further behind when the MCL regulation adds thousands of water treatment plant upgrades.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Maryland Association of Municipal Wastewater Agencies (MAMWA) (Doc. #1658, SBC-043397)

A phased approach that prioritizes addressing a smaller set of water systems with higher PFAS concentrations first, and phases-in overtime whatever further reduced levels may be appropriate over the long-term for systems with lower PFAS concentrations, could be a better way to protect public health, avoid implementation and construction delays, and avoid wasted resources, especially when also considering the current construction market cost problems and price premiums and the schedule infeasibility problem discussed below.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as discussion on a phased-in MCL approach.

Maryland Association of Municipal Wastewater Agencies (MAMWA) (Doc. #1658, SBC-043403)

THE UNREALISTICALLY SHORT SCHEDULE FOR COMPLIANCE WILL CAUSE HARM TO THE NATION AND LOCAL COMMUNITIES AND SHOULD BE REPLACED WITH A HEALTH-BASED PHASED APPROACH TO MCL ADOPTION AND IMPLEMENTATION

Undertaking all of EPA's estimated 3,400 to 6,300 water system PFAS upgrades over three to five years from MCL adoption will lead to many problems and should be reconsidered.

First, this schedule is neither workable nor prudent for a nationwide MCL proposal for the following reasons. Diligent efforts toward monitoring, design, construction simply are not generally feasible on EPA's compressed schedule considering the time required for the necessary steps:

• Lab expansions and certification for PFAS testing

• Monitoring to make compliance / noncompliance determinations

• Design and engineering procurement

• Preliminary engineering analysis

• Pilot and demonstration testing to support treatment technology selection

• Engineering design for treatment plant upgrades

• Spending authorization from governing body of the utility

• Financing arrangements and associated water rate increases

• Construction bids, selection, and contracts

• Equipment order lead times

• Construction process

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Maryland Association of Municipal Wastewater Agencies (MAMWA) (Doc. #1658, SBC-043407)

Sixth, the short schedule under the proposal effectively cuts off the ability of water treatment plants and their ratepayers (the public) to benefit from source reduction activities by others, such as a product substitutions and treatment installation at upstream PFAS-discharging industries, which would eliminate the need for ratepayers to bear the cost of water treatment plant upgrades. For water systems experiencing PFAS concentrations slightly above the proposed MCLs, this is an especially problematic aspect of the proposed regulation that should be revised. For example, for water systems with concentrations of 5 or 6 ppt for PFOA or PFOS, targeted reductions by one or more upstream industries could potentially achieve a 4 ppt MCL far more cost-effectively than adding treatment to the water system. In this sense, the proposed regulation also runs contrary to the generally-accepted public policy concept of "polluter pays" and transfers the burden to families and other innocent ratepayers, because there is no time allowed in this regulation for source water reductions to be accomplished. The proposal's tight schedule forces all affected water systems to jump immediately into design and construction on a compressed timeline.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Maryland Association of Municipal Wastewater Agencies (MAMWA) (Doc. #1658, SBC-043408)

Seventh, the proposal's "all upgrades all at once" approach could lead to worse public health results as all projects concurrently compete for limited engineering, equipment, construction resources, and PFAS-removal material (e.g., granular activated carbon, ion exchange resins, novel absorbents), and facilities with the highest current PFAS levels are delayed in their upgrades. A better regulatory approach would enable primacy agencies to structure schedules such that limited engineering, state agency staff time, federal/state funding, equipment, and contractors are available for and directed to water systems with the highest priority need (i.e., highest PFAS levels). The public interest would be better served by a regulatory approach that allows the worst situations to be fixed earlier than systems with only marginal needs for upgrades (e.g., those with PFAS levels only slightly above the proposed or final MCLs).

EPA Response: Please see the EPA response to comment Doc. #1657, SBC-043173 in section 12.1 in this *Response to Comments* document on the assertion of this "all systems all at once" regulatory approach. Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments*

document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Maryland Association of Municipal Wastewater Agencies (MAMWA) (Doc. #1658, SBC-043410)

5. RECOMMENDATION

MAMWA recommends and requests that EPA revise the proposed regulation to adopt a health-based phased approach, which could be established through use of the following existing EPA authorities and discretion:

• Adopt Regulations in a Manner to Create Multi-Phase Program – EPA should time its regulatory action(s) to achieve an orderly, feasible phased approach. EPA could also take multiple regulatory actions to reduce MCL concentrations over time, rather than the proposal's "all systems all at once" approach. In these ways, EPA has the ability to phase-in PFAS reductions to achieve appropriate levels in a much more prioritized, orderly, feasible, and cost-effective manner than would result from the currently proposed regulation. EPA should clearly communicate the phased approach to help affected water systems plan their implementation steps for each phase.

[MAMWA recommends and requests that EPA revise the proposed regulation to adopt a health-based phased approach, which could be established through use of the following existing EPA authorities and discretion:]

• Set Minimum 5-Year MCL Effective Date for Each Phase – For the initial phase and each phase adopted thereafter, EPA should establish in the final federal regulation an effective date five years (rather than three years) from the date of promulgation given the necessary capital improvements as allowed under 42 U.S.C. § 300g-1(b)(10).

EPA Response: Please see the EPA response to comment Doc. #1657, SBC-043173 in section 12.1 in this *Response to Comments* document on the assertion of this "all systems all at once" regulatory approach. Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Maryland Association of Municipal Wastewater Agencies (MAMWA) (Doc. #1658, SBC-043412)

Using the above EPA authorities and discretion, EPA could establish the recommended health-based phased approach, avoid or mitigate the real world implementation problems associated with proposed regulation, and serve the public interest more effectively. The following example

of the type of result that could be achieved in this manner is provided for illustration purposes assuming but not endorsing the proposed MCL levels (which warrant further review):

• Phase 1: All public water systems achieve 10 ppt for PFOA, 10 ppt for PFOS, and 5 for Hazard Index effective within 5 years.

• Phase 2: All public water systems achieve 7 ppt for PFOA, 7 ppt for PFOS, and 3 for Hazard Index effective within 10 years.

• Phase 3: All public water systems achieve 4 ppt for PFOA, 4 ppt for PFOS, and 1 for Hazard Index effective within 15 years.

To be clear, in outlining this three-phased approach, MAMWA is not recommending adoption specifically of MCLs at 4 ppt for PFOA and PFOS or of the proposed Hazard Index for the other four chemicals. The point is to illustrate a prioritized, health-based phase-in over time, regardless of whatever specific final MCL concentrations or index that may be adopted.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as discussion on a phased-in MCL approach and the availability of addition extensions through the exemption process under SDWA Section 1416. For additional discussion on how the agency considers analytic feasibility when establishing the MCL, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Maryland Association of Municipal Wastewater Agencies (MAMWA) (Doc. #1658, SBC-043411)

[MAMWA recommends and requests that EPA revise the proposed regulation to adopt a health-based phased approach, which could be established through use of the following existing EPA authorities and discretion:]

• Acknowledge Need for Primacy Agency Use of 3-Year Exemption Extensions – EPA should acknowledge in the final regulation that many projects in each phase, especially larger more complex projects, will need to make use of the three year extension (beyond the 5-year minimum) for necessary capital improvements due to

the compelling factors discussed in these comments, as allowed under 40 C.F.R. § 142.50).

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). The EPA discussed in the final rule preamble that SDWA § 1416(a) and (b)(2)(C) describe how the EPA or states may also grant an exemption for systems meeting specified criteria that provides an additional period for compliance. The EPA, therefore, has expressly acknowledged exemptions for states exercising primacy enforcement responsibility and have

adopted the 1998 Variance and Exemption Regulation. Further, please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

J.R. Simplot Company (Doc. #1661, SBC-044153)

Since the PFAS NPDWR effective date is anticipated for December 2026, there is a very short window for CWS to apply for grants, obtain funds, and install PFAS equipment. There also continues to be a nationwide shortage of contractors. Therefore, if EPA moves ahead with finalizing this proposal, it is imperative that the effective date of the proposed regulation be revised and extended from 3 years to 5 years after the date of publication of the final rule in the Federal Register.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Water Supply District of Acton (Doc. #1662, SBC-043664)

EPA's timeline for compliance with the rule is not reasonable, and likely not even achievable, given the work that goes into designing, constructing, and funding new treatment systems. Our experience has been that a permanent solution takes approximately 5 years to complete. A temporary PFAS treatment system underway in our system began with pilot testing in the fall of 2020 and is not anticipated to produce treated water until at least March 2024. This process was undertaken during a period when competition for similar services and equipment was not yet a national concern. The water sector, including operators, design engineers, and construction workers, is challenged with workforce issues like many other sectors of our society. More sophisticated treatment will likely cause a change in PWS classification and may require a higher-grade operator license. In Massachusetts, it can take years to complete the required training to be able to sit for a higher-grade exam. EPA does not appear to have given any thought to issues such as these when they crafted the rule and its three year implementation timeframe. EPA must adjust the compliance timeframe to be more realistic.

EPA Response: Consistent with the commenter's request regarding the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. Regarding concerns on operator certification licenses, please see the EPA response to comment Doc. #1567, SBC-042738 in section 12.1 in this *Response to Comments* document.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044437)

• Drinking Water Operators with appropriate and adequate training and certification are challenging to locate and maintain for smaller water systems as there is a qualified labor shortage within the water industry. Therefore, the cost of keeping treatment in perpetuity represents a considerable cost to water delivery.

New treatment and source relocation are potential responses to the new PFAS rule, but the rule must consider cumulative impacts of multiple forms of drinking water contaminants. Cost and compliance with this rule must be structured to ensure compliance for PFAS without interfering with other contaminant treatment or compliance.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges, as well as simultaneous compliance challenges, that may affect the compliance timeline.

Inland Empire Utilities Agency (IEUA), California (Doc. #1666, SBC-043392)

Comment 2 – Compliance Deadline Extension – EPA's compliance deadline should be extended from three years to at least five years, as contemplated in SDWA.

The proposed rule would require compliance three years after the PFAS NPDWR promulgation; however, for water recycling utilities recharging recycled water, compliance is expected upon adoption. For instance, the existing Water Recycling Requirements, Order No. R8-2007-0039 for the Chino Basin Recycled Water Groundwater Recharge Program, issued by the California Regional Water Quality Control Board Santa Ana Region to Inland Empire Utilities Agency (IEUA), states that "recycled water used for recharge shall meet any new Federal and State maximum contaminant level upon adoption."

IEUA believes that this timeline is unreasonably short for installing PFAS treatment. Local permitting challenges, labor shortages, material and supply issues, funding constraints and inflation cost increases will hinder a construction project schedule. IEUA is also concerned with the lack of laboratory support that is currently available to provide reliable, accurate and consistent data to help track the treatment improvements for PFAS removal. When monitoring for PFAS in the recent years, IEUA faced several challenges with the limited capacity and the accuracy of data generated using unapproved methods for testing and inadequate quality checks. IEUA, since, developed inhouse capabilities for PFAS analysis to address some of the challenges and even though it is not an immediate concern to IEUA's operations, the availability of accurate, reliable and consistent laboratory support for PFAS analysis has been a challenge for most utilities and will continue to be a challenge. Therefore, IEUA recommends that EPA extend the compliance deadline. In accordance with SDWA § 1412(b)(10), we request that EPA extend the compliance deadline for PWSs, wastewater, and water recycling utilities by two years, for a total

of five years from the adoption of this regulation, to allow for additional time for necessary capital improvements and proper methods to be promulgated.

EPA Response: Consistent with the commenter's request regarding the compliance timeframe, and based on information provided in this and other comments, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. The EPA does not have authority under SDWA to restrict States from requiring shorter timeframes.

City of Allentown and Lehigh County Authority (LCA), Pennsylvania (Doc. #1667, SBC-043682)

3. Compounding compliance Financial Pressures -- The proposed PFAS requirements are coming at a time when water systems are already deeply engaged in a variety of other new regulatory compliance efforts, such as the efforts to meet new requirements laid out in the Lead & Copper Rule Revision (LCRR). The addition of these significant capital expenses will compound the cost of water for financially fragile rate payers, where in the City the percent of persons in poverty is equal to 23.3%

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges, as well as simultaneous compliance challenges, that may affect the compliance timeline.

City of Allentown and Lehigh County Authority (LCA), Pennsylvania (Doc. #1667, SBC-043684)

Based on these significant compliance and implementation challenges, the City believes the standard implementation timeline is not appropriate for the proposed PFAS rule. The need to plan, design, pilot, and construct facilities will take much longer than the three-year timeline given the challenges described above. We request that EPA extend the effective date of compliance by at least two years to ease the burden on water systems that must install capital improvements to achieve compliance.

EPA Response: Consistent with the commenter's request regarding the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

City of Hillsboro, Oregon (Doc. #1668, SBC-043120)

2. Implementation Timeline

As proposed, the NPDWR for PFAS has a three-year initial monitoring period that runs concurrently with the three-year window for utilities to implement mitigation strategies. This timeframe is unattainable for most utilities to plan, design, pilot, permit, procure, and complete construction or installation of necessary advanced treatment options. Although primacy agencies can extend this three-year implementation timeline to five, there is no guarantee that utilities will be granted this extension or that the five-year period would be enough to plan and complete a large capital project, such as installing and maintaining advanced treatment. Additionally, research and development of new treatment technologies is ongoing with PFAS, and the current timeline precludes water utilities from evaluating and potentially implementing some of these newer technologies and approaches that may address the utilities needs more efficiently and effectively. Hillsboro Water requests to leave the implementation timeline to the discretion of the primacy agency to approve based on factors specific to the utility including availability of funding, the mitigation method, evolving best practices, and other regulatory considerations.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as further extensions that may be authorized by primacy agencies on a case-by-case basis under SDWA Section 1416.

Aurora Water, City of Aurora, Colorado (Doc. #1669, SBC-043734)

Compliance Schedule

In accordance with the Safe Drinking Water Act, systems have three years to comply with new rules with a possible two-year extension if capital improvements are needed. One of those years will be taken up by the initial monitoring period which leaves a timeline of 2-4 years for meeting compliance. Aurora Water has serious concerns about the ability to comply with this proposed regulation within three years of promulgation. It is likely Aurora will be forced to improve treatment processes to meet this proposed rule and a typical construction project would exceed this compliance period. Supply chain issues are already a concern in the city's day-to-day operations, but with these additional requirements causing nearly every system in the area to acquire the same technologies, there simply will not be enough manufacturing capacity to support a three-year or even five-year compliance timeline. The Safe Drinking Water Act allows for an extension of the compliance period when extensive capital expenses are required. The extensive and complex funding application process required to access BIL support is another reason for an extended compliance period. With the changes to processes and procedures, lengthy funding application processes, and technology limitations, meeting a three-year

compliance timeline will be extremely challenging for all water systems affected. Aurora Water recommends extending the compliance schedule with the proposed regulation.

EPA Response: Consistent with the commenter's request regarding the compliance timeframe, and the information provided by this and other commenters, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

National Association of Water Companies (NAWC) (Doc. #1670, SBC-044163)

5. The amount of time for implementation for public and private water systems to meet the final MCLs is insufficient.

As currently proposed, the water systems that will need to be upgraded to comply with the final MCLs will have three (3) years to from the date of the final rule to upgrade their systems. Due to the cost and complexity of upgrading water treatment systems, a deadline of three years to design, construct and begin operations of an upgraded treatment system to remove and dispose of PFOA and PFOS is not reasonable and may be almost impossible in some circumstances. Water systems are already balancing and burdened by many competing priorities for their time and financial resources due to increasing regulations, including mandates from the Lead and Copper rule. Complicating their efforts are increased worker shortages, the lack of qualified engineers, and shortages in the supply chain. These same challenges will make it difficult if not impossible in many cases to construct and begin operation of new treatment systems within the allowed three years. Before EPA can mandate dates for implementation, it must have a reasonable basis for assurance that those deadlines are achievable.

EPA Response: Consistent with the commenter's request regarding the compliance timeframe, and the information provided by this and other commenters, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is authorizing a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges, as well as simultaneous compliance challenges, that may affect the compliance timeline.

National Association of Water Companies (NAWC) (Doc. #1670, SBC-044165)

NAWC suggest that a more reasonable and achievable deadline for upgrading systems to meet the new MCLs is five (5) years. This is consistent with the compliance date for the in the National Primary Drinking Water Regulation for Arsenic (66 Fed. Reg. 6976, January 22, 2001) which followed the statutory authority set forth in section 1412(b)(10) of the Safe Drinking Water Act, 42 U.S.C. §§ 300f to 300j-26. After reviewing the complexity of the process to upgrade systems to achieve compliance, EPA stated the compliance date, "regardless of system

size, will be 5 years from the date of promulgation of the standard." (66 Fed. Reg. at 6993). EPA should follow the same approach here due to the complexity of the processes involved .

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-044919)

In the proposed rule preamble, the agency states, "EPA does not intend to provide a two-year extension nationwide." Cleveland Water urges EPA to reconsider this decision. While states may provide an extension on a case-by-case basis, there is no guarantee that the extension will be granted. There are many other social and political factors that may pressure a state to not grant any extensions even when it is warranted and justified. EPA could provide some relief to water systems by providing this blanket extension nationwide and could potentially ease the immediate impacts to labor markets and supply chains. Additionally, EPA could provide guidance to states on when is appropriate to provide a three-year exemption, particularly when a utility is acting diligently to implement treatment, but constraints out of its control have prevented completion in the five-year period.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on exemptions under SDWA 1416 as well as supply chain and labor challenges that may affect the compliance timeline.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-044918)

Section 5.4: Compliance timeline

EPA is proposing a three-year compliance time from the promulgation of the rule. A state or EPA may grant up to a two-year extension if it is determined that an individual system needs additional time for capital improvements, giving up to five years if the state or EPA grants the extension. Additionally, EPA or the primacy agency may grant an extension of three additional years beyond the five for systems meeting specific demands criteria explained in SDWA § 1416. Small systems have the option to apply for a series of three, two-year extensions beyond the eight years provided to medium and large systems. This is the compliance schedule laid out in the SDWA.

Cleveland Water cannot stress enough that the three-year compliance deadline will not be enough time for many water systems impacted by the proposal to complete capital improvement projects to address PFAS. If Cleveland Water is triggered into additional treatment under this

rule, it would take a minimum of six years if this project was the only priority and there were no delays or issues that arise from supply chain, labor, or the permitting and procurement processes.

The process for a PWS to complete a project of this magnitude is long and tedious. While each water system is different, there are similarities in the process that most must follow. Utilities like Cleveland Water are publicly owned and must go through certain channels for approvals on each step of the process. There are deeper considerations that some must address when it comes to rate increases, permitting, and general budgeting for improvement projects. Many of these steps must be approved by boards, councils, and/or elected officials. These steps take time, which in many cases is outside the control of the PWS.

Typically, approvals need to be granted for a project this size, which can take months based on scheduling and other priorities within a municipality. Water systems will then need to design and conduct pilot studies to determine the best approach to treatment, assess impacts on other aspects of treatment, determine the specific needs of the water system, and determine the efficacy of the chosen treatment. Design and building of these pilots can take 18 months to three years. These pilots would also need to capture seasonal variability in source waters, so this process can take about 12 months.

Public utilities are also subject to public procurement regulations. These processes add additional time to the design and the construction process. Development of a request for proposals for project design services, receipt and review of proposals, the consultant selection and negotiation process, and contract award typically takes six months or more. The process for receiving bids for construction and awarding those contracts will take another three to six months.

Construction of the treatment alternatives noted in the rule (GAC, IX, RO) would be additional treatment trains. Construction phasing to maintain plant operations and ensure an adequate supply of drinking water to the public is critical. Tie-ins to existing infrastructure will be necessary and must occur during low demand periods (often wintertime or other low use time based on location) to ensure sufficient water production capacity to meet community needs. These construction-staging intricacies will further lengthen the time to construct PFAS treatment improvements. Construction and commissioning timeframes will be project and site specific but could in some cases take three years.

PWSs and other sectors across the country are currently experiencing increased pricing of goods and services, supply chain disruptions, and labor shortages. The proposed compliance period would be impossible for many utilities to meet without extensions. EPA needs to include considerations for how the increased demand for contractors, materials, equipment, and other labor will prolong projects and drastically increase prices, costs that eventually must be passed on to ratepayers and impacts a utility's ability to provide affordable water to the public. Currently, even before this rule is finalized, some GAC suppliers have advised that the lead-time for GAC vessels for PFAS treatment is eighteen months. This is not a unique situation, and many utilities must prepare for the situation to worsen if this rule is finalized as is.

While Cleveland Water supports the proposal's overall goal of protecting public health by delivering safe, clean, and affordable drinking water to the public, a compliance period of three years will simply be impossible for many PWSs to meet. There are several options EPA could pursue to alleviate burdens on public systems while still implementing feasible actions that will ultimately be more protective of public health from the chronic conditions attributed to PFAS exposure.

EPA Response: Consistent with the commenter's request regarding the compliance timeframe, and the information provided by this and other commenters, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Association of California Water Agencies (ACWA) (Doc. #1675, SBC-044938)

COMMENT 6 – COMPLIANCE DEADLINE EXTENSION – EPA should extend the compliance deadline to five years from finalization of this regulation as contemplated in SDWA.

When finalized, water systems will have three years to comply with the regulation [FN32: 88 Fed. Reg. at 18,683.]. ACWA believes that this timeline is too short for the associated compliance requirements for monitoring and installing PFAS treatment.

The process for completing such projects is complex and time-consuming, involving various approvals, pilot studies, local land use or zoning processes, design and development, procurement, and construction. These steps require coordination with multiple entities, including boards, councils, other elected officials, and the public. Additionally, utilities are currently facing challenges, such as inflation, supply chain disruptions, and labor shortages, which further extend project timelines and increase costs.

In accordance with SDWA, [FN33: 88 Fed. Reg. at 18,689.] EPA should extend the compliance deadline by two years to allow for additional time for capital improvements that will be necessary as a part of implementation of this regulation. As a result, we ask EPA to extend the compliance deadline to five years from finalization of this regulation.

EPA Response: Consistent with the commenter's request regarding the compliance timeframe, and the information provided by this and other commenters, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

California Association of Mutual Water Companies (Doc. #1676, SBC-043778)

4. Treatment Facilities – Supply Chain – Costs – Increased Compliance Period

Where new treatment facilities are required to meet the PFAS MCL, small systems will find competing for necessary engineering and construction services impossible. Supply chain limitations, such as for Granular Activated Carbon and treatment equipment, coupled with the Build American, Buy American (BABA) requirements, further exacerbate the difficulty for small systems. We recommend that the EPA extend the compliance period to a minimum of five years for systems with fewer than 3,300 service connections, as the proposed three-year period is not enough to meet the requirements of this highly complex rule.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. Requirements under Build America, Buy America Act (BABA) will not prevent regulated PWSs from installing treatment. .

New York State Department of Health (NYS DOH) (Doc. #1677, SBC-044945)

7. Should the EPA proceed with MCLs of 4 ppt, the Department suggests that EPA evaluate a bin approach similar in structure to the Stage 2 Disinfectants and Disinfection Byproducts Rule or Long-Term Surface Water Treatment Rule. This approach could allow for staggered compliance with additional time for compliance provided to smaller systems. This approach will ease the workload on primacy agencies, ensuring appropriate and timely enforcement as well as equitable distribution of technical assistance resources. In addition, this approach may alleviate some of the competition between small systems and large systems for analytical services, engineering, construction materials and labor that may negatively impact disadvantaged communities.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as discussion on a phased-in MCL approach.

City of Vancouver Water Utility, Vancouver, WA (Doc. #1684, SBC-044315)

Compliance Extensions:

Given the prevalence of PFAS in water supplies, the number of utilities that will be impacted, current supply chain issues and the overall complexity of this issue, it is imperative that the EPA provide the opportunity for a compliance extension. Even with a two-year extension, there are many utilities that will have trouble complying with the regulation within five years. Treatment systems take time to design, publicly bid and construct and given that many utilities will have multiple systems to install in a short period, a compliance extension period of up to 4 years should be included for extreme situations, therefore giving utilities up to seven years to comply.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline, as well as the opportunity for further extensions based on the authority of SDWA Section 1416.

Horsham Water & Sewer Authority (HWSA) (Doc. #1686, SBC-043808)

Regarding the compliance timetables, EPA is applying the standard timetable for compliance established in the 1996 Amendments to the Safe Drinking Water Act. This might be acceptable under normal times. But ever since the COVID-19 Pandemic emergency declaration in 2020, we have not been living in normal times. Supply chain issues have created extended timelines for water treatment equipment and appurtenances and costs for these and labor costs have risen dramatically. Having installed PFAS treatment both before the pandemic and during the pandemic, we can clearly see the impacts and can attest to the extended timelines and exaggerated costs. As mentioned earlier, we have three PFAS treatment systems that were bid and awarded in 2021 and the treatment units are still not on site as of the time of this letter (original 330 day construction timeline for the contract has now been extended to 530 days), and this is well before one would expect a multitude of equipment orders from water utilities across the country once this rule is promulgated. The now 530-day construction timeline (which may yet have to be extended even further) is in addition to the initial four quarters of monitoring, piloting, design, permitting and bidding timelines utilities will have to meet. Clearly as utilities across the country complete their required PFAS monitoring and the number of utilities that realize they need to install treatment is anything close to EPA's own estimates, the supply chain issues are going to become even much more exasperated than they already are. The normal three-year compliance timeframe for a rule impacting the magnitude of utilities projected, and under the existing supply chain conditions, is simply not realistic and it would be disingenuous of EPA to rely on the discretionary two-year extensions that state primacy agencies can give under the SDWA, knowing full well that some states do not grant these extensions at all. As a minimum, EPA must acknowledge the realities of today's construction constraints and take the "discretion" out of the "discretionary two-year extension" and grant a blanket extension for the extra two years applicable to all utilities to meet the rule regardless of which state they reside. Even with a five-year implementation window it is highly unlikely the estimated 4,000 to 5,000 systems nationwide that will need to install PFAS treatment will be able to complete initial compliance monitoring, pilot, design, permit, procure, construct, and start up PFAS treatment before being in violation.

EPA Response: Consistent with the commenter's request regarding the compliance timeframe, and the information provided by this and other commenters, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's

discussion on supply chain and labor challenges that may affect the compliance timeline and the opportunity for additional extensions pursuant to Section 1416 of SDWA.

Massachusetts Coalition for Water Resources Stewardship (MCWRS) (Doc. #1691, SBC-044332)

[Alternative Approach-While MCWRS does not agree with the proposed MCLs, an alternative implementation plan is offered regardless of what the final MCLs may be. That plan would include:]

h. Break the UCMR 5 results into quartiles and target the highest quartile (top 25% of results) for PFAS remediation, using federal monies, during the first 5 years. Federal dollars would thus be applied to the water systems with the highest PFAS levels and assumed highest health risk. The second highest quartile would be targeted for remediation in years 6-10, the third highest in years 11-15 and the lowest in years 16-20. Federal grant funding would be applied to all so if the funding runs out at least the systems with the highest levels would be addressed earliest and those that may go unaddressed would have the lowest concentrations.

[Alternative Approach-While MCWRS does not agree with the proposed MCLs, an alternative implementation plan is offered regardless of what the final MCLs may be. That plan would include:]

i. The quartiles could be established based on UCMR5 results but mandatory testing could be required for all other (non-UCMR) water systems with their respective results used to place them within the appropriate quartile.

[Alternative Approach-While MCWRS does not agree with the proposed MCLs, an alternative implementation plan is offered regardless of what the final MCLs may be. That plan would include:]

j. This approach relieves some of the burden imposed by having 6,000 or more water systems trying to simultaneously come into compliance. It may also lessen impacts on equipment and material suppliers. Stretching the compliance period based on detected levels of PFAS also provides more time to develop new treatment technology, to further research health impacts and to make significant inroads in source reduction, which is the true key to address PFAS presence in all environmental media.

MCWRS believes that EPA is selecting a risky and potentially dangerous approach in regulating certain PFAS with MCLs at the laboratory detection levels. The potential unintended consequences of this initiative are of great concern and must be further investigated and addressed before finalizing MCLs. Taking a measured approach to PFAS regulation in drinking water rather than a reactionary response to political, public and media pressure is in the best interests of public health protection.

Sincerely,

Philip D. Guerin President

EPA Response: The commenter suggested a monitoring framework where "highest-risk" systems are required to implement the NPDWR sooner than systems with lower levels of risk. The agency disagrees with the commenter that this approach is more public health protective as PFAS levels could fluctuate such that presumably "lower-risk" systems could experience elevated levels that may necessitate treatment or other actions to ensure compliance with the MCLs. The monitoring and compliance requirements finalized in the PFAS NPDWR address these issues (i.e., systems with elevated concentrations will require more frequent monitoring whereas systems without contamination or low levels of contamination will monitor less frequently). Based on these monitoring results, water systems may then be required to change their monitoring frequency if the results suggest increasing or decreasing concentrations. For additional discussion on monitoring and compliance requirements for the rule, please see section 8 of the EPA's *Response to Comments* document. In addition, contrary to the commenter's suggestion, the MCLs are not set the laboratory detection levels, but rather for PFOA and PFOS they are set at the PQLs which are distinctly different than levels of detection. For additional discussion on PQLs, please see section V and VII of the final rule preamble. Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Massachusetts Coalition for Water Resources Stewardship (MCWRS) (Doc. #1691, SBC-044327)

[The proposed MCLs raise the specter of serious unintended consequences that could pose public health risks for water consumers. Some of these are:]

b. Current shortages in certified drinking water operators will be worsened as thousands of new PFAS treatment plants may require treatment operators. Current operators may be enticed to relocate to run these new facilities if the system is in a community with the ability to pay higher salaries. Systems losing these operators are more likely to be in less wealthy communities with significant Environmental Justice populations who may then be harmed by a lack of experienced water operators.

[The proposed MCLs raise the specter of serious unintended consequences that could pose public health risks for water consumers. Some of these are:]

c. With the expectation that water systems exceeding the proposed MCLs will come into compliance (i.e., construct and operate treatment facilities or find new sources) within two years, there will be a significant issue obtaining equipment for these new facilities. EPA's own low estimate of some 6,000 water systems exceeding the MCLs and designing, bidding and building new treatment facilities all at the same time will create a massive supply chain log-jam.

Achieving a two year compliance schedule is not realistic and it will bring any progress on treatment to a quick halt.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Water Quality Association (WQA) (Doc. #1694, SBC-044990)

Furthermore, this regulation will lead to an increase in water testing and sampling for PFAS chemicals to ensure compliance. WQA has heard concerns regarding cost, laboratory capacity, and delayed results, and the association encourages the EPA to review comments from stakeholder groups that represent that industry.

EPA Response: The EPA agrees that the final NPDWR will have associated costs for compliance but also significant public health benefits realized upon implementation. A discussion of the costs and benefits of the regulation can be found in the final rule preamble (section XII) and section 13 of the EPA's *Response to Comments* document. Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

City of Scottsdale, Water Quality (Doc. #1698, SBC-043506)

May 30, 2023

Comments from the City of Scottsdale, Arizona

U.S. EPA's March14, 2023, Proposed National Primary Drinking Water Regulation (NPDWR) For Per-and Polyfluoroalkyl Substances (PFAS) [PFOA, PFOS, HFPO-DA (GenX), PFHxS, and PFBS]

Public Docket ID: EPA-HQ-OW-2022-0114

SUBMITTED ELECTRONICALLY (www.regulations.gov)

The City of Scottsdale submits the following comments on the above referenced proposed NPDWR:

Scottsdale is requesting that Public Water Systems (PWSs) be given sufficient time to comply with the final Maximum Contaminant Levels proposed in the NPDWR. Scottsdale has three groundwater wells slightly above the proposed MCLs of 4 parts per trillion (ppt) for PFOS and PFOA. These groundwater wells also have detections for PFBS, HFPO-DA, and PFHxS.

The EPA is proposing a three-year compliance time for the promulgation of the rule. Scottsdale does not believe that the three-year compliance deadline will be enough time to complete a capital improvement project to address PFAS issues. Scottsdale supports the proposal's overall goal of protecting public health, but a compliance period of three years will be extremely difficult for most PWSs to meet. There are other options the EPA could pursue to alleviate the compliance timeline burden to PWSs. The proposed preamble states, "EPA does not intend to provide a two-year extension nationwide." Scottsdale respectfully requests that EPA reconsider this position. EPA could provide guidance to states on when it is appropriate to provide a three-year extension, especially if a utility is pursuing treatment. EPA could also provide an exemption based on PFAS concentrations in the water system. This is the approach EPA used for the Arsenic Rule. Water systems would get five years for compliance but would be eligible for a three-year extension based on PFAS levels. Another benefit to this approach would be a system like Scottsdale with PFOA and PFOS close to the MCL would have more time to consider less costly options.

Scottsdale recently completed a $26,000,000 construction project adding reverse osmosis treatment to treat other pollutants in the three groundwater wells with PFOA and PFOS. Based on the treatment capacity of this new facility, Scottsdale will not be able to reduce PFAS concentrations in the treated water to the city's internal goal of 80% of the MCL. It is imperative that PWSs be given sufficient time to study and look at alternative treatment options to comply with the proposed NPDWR.

Sincerely,

Carie Wilson

Water Quality Regulatory Manager City of Scottsdale, Arizona

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on exemptions under SDWA 1416 as well as supply chain and labor challenges that may affect the compliance timeline.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045046)

Under Exemptions and Extensions, a state or EPA may grant an extension to comply with an NPDWR's MCL(s) if the state or EPA determines an individual system needs additional time for capital improvements or the system is small and needs financial assistance. If the EPA will allow for extensions to comply with the MCL, EPA must provide specific criteria and not allow room for interpretation. In addition, the potential for a system to have 14 years to comply is too long with the known health impacts of PFAS contaminants.

EPA Response: States are not required to provide exemptions; under SDWA Section 1416, exemptions are at the discretion of the primacy agency. In addition, Section 1416 provides specific criteria and processes for exemptions.

Alabama Water and Wastewater Institute (AWWI) (Doc. #1700, SBC-043508)

AWWI believes that the 3-year compliance timeline included with the proposed regulation is not realistic given the current state of the water construction industry . Supply chain issues, the availability of the construction workforce, and engineering design resource capacity have become critical issues in the water and wastewater industry due to the lingering impacts of the COVID-19 pandemic and the war between Ukraine and Russia. As an example, many water industry construction projects are now being delayed due to electrical equipment lead times in excess of 52 weeks. These types of equipment delays are impacting water and sewer system capital projects for rehabilitation and replacement, and these delays will be further impacted by the significant number of capital projects resulting from the proposed PFAS regulation. It is not realistic to expect water and sewer systems impacted by these new PFAS regulations to be able to design and construct improvements to achieve compliance within three years. AWWI believes that it is more reasonable to provide utilities with no less than five years at a minimum to comply with the proposed PFAS regulation.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Association of California Water Agencies et al. (Doc. #1701, SBC-043835)

May 30, 3023

Michael S. Regan Administrator

US Environmental Protection Agency 1200 Pennsylvania Avenue, NW Washington, DC 20460

Via electronic submission

Re: Docket ID #: EPA-HQ-OW-2022-0114; PFAS National Primary Drinking Water Regulation Rulemaking

Dear Administrator Regan,

The undersigned organizations appreciate the opportunity to comment on the Environmental Protection Agency's (EPA) proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation (NPDWR). Our respective organizations have a vested interest in protecting public health from PFAS and therefore have examined the details of this

rulemaking. Individual comments have been submitted by these organizations representing each organization's perspective; however, we collectively would like to raise certain issues that EPA must address as it works to address PFAS.

Feasibility of Implementation

EPA's proposed three-year compliance timeline is insufficient and infeasible for compliance. EPA has proposed a three-year compliance time for water systems to address the presence of PFAS in their water supply above the proposed maximum contaminant level (MCL). The proposed NPDWR rulemaking indicates that EPA does not plan to issue a waiver for a two-year extension for systems that need to install PFAS treatment technologies or facilities. Water systems that need to install treatment facilities will need a minimum of five years to complete projects. The process for completing such projects is complex and time-consuming, involving various approvals, pilot studies, local land use or zoning processes, design and development, procurement, and construction. These steps require coordination with multiple entities, including boards, councils, other elected officials, and the public. Additionally, utilities are currently facing challenges, such as increased pricing, supply chain disruptions, and labor shortages, which further extend project timelines and increase costs. For these reasons, many utilities that must install treatment facilities to address PFAS will not be able to reasonably meet a three-year compliance timeline.

We recommend that EPA use its authority to provide a nationwide two-year extension for the compliance timeline for systems installing capital improvements. A two-year extension will address the concerns outlined above to alleviate burdens on water systems and allow for feasible compliance by water systems addressing PFAS contamination.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

<u>The City of Columbus, Department of Public Utilities (Doc. #1703, SBC-045058)</u>

Public water utilities will need more time to comply, especially if the MCL is 4 ppt.

Even if EPA believes that the 4 ppt MCL is generally feasible, EPA's proposed timeline to meet it is not. Meeting an MCL of 4 ppt will require the commitment of an extremely large amount of public money to accomplish these significant construction projects. Public water utilities across the nation, like CDPU, must navigate their budgeting, funding, and procurement processes before a shovel strikes the ground to add a treatment process. It will take time to do enough sampling to ensure that the expenditure of hundreds of millions of dollars is warranted, and then to design and plan the project. Then comes the long haul of actually constructing the treatment.

Added to these considerations is the requirement that the public water utility must maintain 100% of their operations while building out the treatment. In short, public projects of this magnitude take time.

On top of the typical lengthy project timeline, if 3,500 water utilities enter the market for the same few treatment techniques, there will be massive supply/demand issues. There are already limited resources for granular activated carbon equipment, media, and regeneration services. The same can be said for lab services for sampling. Even though EPA received dozens of applications for certification, on a recent call NACWA members from around the country only identified two labs that the entirety of utilities present were using for PFAS analysis. Compounding this difficulty are the general supply chain issues and labor shortages that linger across the United States. Build America, Buy America and other federal requirements add more hurdles. Three years is not enough time to get us to the finish line, especially when compliance and the corresponding consumer confidence are hanging in the balance.

Allowing more time for compliance will also enable EPA to tackle the data gap issues that are currently plaguing water utilities and PFAS science. UCMR 5 data will be instrumental in the nation's understanding of its PFAS problem. This crucial information will come too late with the current compliance timeline to allow EPA and water utilities to respond accordingly.

One option to solve the timing issues would be to extend the compliance timeline. Another option is a phased approach to the MCL (starting with a higher initial MCL) that would address these problems by reducing the competition for limited resources for installing treatment and allowing the science to catch up to policy. It would tackle the bulk of, and most significant, human health risks by targeting systems with the highest PFAS concentrations first.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

California Farm Bureau Federation (Doc. #1704, SBC-045080)

Given the costs and the challenges associated with obtaining the necessary technologies, availability of testing, and the lack of disposal methods that we have already outlined, we recommend that the EPA consider extending the implementation period, particularly for small, rural water utilities. We strongly believe these systems need additional implementation time and resources to ensure that they are in compliance with any new standard adopted in a final rule. As previously mentioned, at minimum, the EPA should consider a tiered roll out on implementation.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments*

document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

California Farm Bureau Federation (Doc. #1704, SBC-045075)

Access to contractors needed to install these technologies has additionally been identified as a concern by organizations representing rural water communities. Because contracts with large water systems are more lucrative, smaller systems inevitably fall to the bottom of the priority list. Facilities will also need to bring in more employees to oversee the operations, maintenance, and treatment of the equipment. This will require specific training and trainer shortages have already presented challenges. Staff shortages, even for the existing work required to safely operate and maintain drinking water systems, are widespread. For example, a 2021 AWWA survey on staffing and supply chain needs, found that 40 percent of drinking water utilities of all sizes are struggling to fill positions at their facilities, and employee turnover has doubled. For these reasons, we urge the agency to reevaluate the implementation period and consider the option of a tiered roll out with larger utilities moving ahead first to prevent a bottleneck on technologies and financial resources.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. For additional discussion on treatment technology availability and capacity, please see section 10.6 of the EPA response in this *Response to Comments* document.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045094)

d. Enforcement/Compliance/Health-based violations:

Another concern is about how violations are logged, accrued, and reported given the focus on health-based violations. Given the current framework under management of the Enforcement Targeting Tool, systems would become a priority for enforcement before they are able to adequately address the PFAS contamination. In our experience in Vermont, enforcing against a system that is actively working to install treatment only serves as a distraction and delay to get to the end result of compliance. Therefore, information about expectations on how to enforce against systems with PFAS MCL exceedances is required and/or data management instructions are critical for us to know how to log, "count", and follow-up on respective violations. It is presumed that if a system has results for PFOA, PFOS, PFNA, PFBS and/or PFHxS that they

could exceed the PFOA MCL, the PFOS MCL, and the Hazard Index MCL. This would be 3 MCL exceedances.

In Vermont, even with our existing Do Not Drink notice requirement following our State MCL exceedance and provision of some state grant money created to address PFAS upon implementation of our MCL, the average number of days to reach completion of design, permitting, installation, and sampling to confirm treatment/well modification/new well efficacy is 613 days. While this has largely been due to many systems waiting to conduct a site investigation for the source of contamination before implementing a final remedy, it also is dictated by consulting engineer availability and to a lesser extent to State staff time and capacity. Additionally, being in a northern climate, work to install treatment or build associated buildings, where needed, cannot occur year-round. In Vermont we have had 16 systems exceed our MCL in the last 4 years, which has led to considerable reprioritization and workload changes; having 20-30+ systems immediately exceed the new MCL upon promulgation will create incredible demands on consulting engineers and state resources. In a framework under which we are regulating to the reporting level, we cannot rush the process to assess site information and characterization since installing a new well has far lower on-going operation and maintenance costs.

EPA Response: The Enforcement Targeting Tool (ETT) is outside the scope of this rulemaking. The EPA's SDWA Enforcement Response Policy, which discusses the ETT, explains how the EPA typically pursues enforcement cases involving a water system's violations of the SDWA. In this *Response to Comments* document, see also section 8.2 for more information on PWS compliance and violations and section 11.3 for a discussion of data management instructions. Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. Additionally, for PN with respect to MCL violations, the agency notes that the final NPDWR promulgates additional individual MCLs for PFHxS, HFPO-DA and PFNA. With respect to violations and reporting associated with the individual MCLs and Hazard Index (HI) MCL, the EPA recognizes that a utility may have two or more of these PFAS present that, over the course of four quarterly samples, may result in violation of multiple MCLs. For example, if, following four quarterly samples, a utility has PFHxS and HFPO-DA present and the running annual average (RAA) is above their respective MCLs and HBWCs of 10 ng/L, the system would be in violation of both the individual MCLs for PFHxS and HFPO-DA, as well as the Hazard Index MCL. Issuing multiple notifications (three in this example) for these violations may cause public confusion as the adverse health effects and exposure concern in this instance is not meaningfully different from either a Hazard Index or individual MCL perspective. To simplify implementation of PN in this scenario, the EPA is finalizing requirements in Appendix A to Subpart Q of Part 141 such that utilities who violate the Hazard Index MCL and one or

more individual MCLs because of the same compounds can issue one notification to satisfy the PN requirements for the multiple violations.

Philadelphia Water Department (PWD) (Doc. #1709, SBC-045734)

EPA must utilize a holistic regulatory approach to rulemaking that includes considerations for PFAS generators, implementation time, and cost of capital improvements associated with proposed BATs, and competing regulatory requirements when determining implementation of MCLs for PFOA and PFOS.

3. Many public water systems impacted by PFAS contamination, including PWD, have limited options for affordable and timely remediation.

PWD is the single largest public water system in the Commonwealth of Pennsylvania. PWD's three water treatment plants treat approximately 250 million gallons of drinking water per day sourced from the Delaware and Schuylkill Rivers, PWD does not own its watershed area above our WTPs and these rivers are the only viable source of water for the City of Philadelphia. Similarly, Philadelphia's 3,180 miles of water system mains do not have the interconnections that would allow for the distribution of purchased water from a neighboring system with PFAS treatment. While PWD does have a resilient system, with the ability to draw water from two rivers, both sources will be impacted by the proposed PFAS rule.

In a likely scenario, should PWD's average PFOA and PFOS results from the proposed rule's monitoring period exceed the MCLs, PWD will have to reevaluate the use of advanced water treatment technologies and consider other potential operational modifications to achieve compliance. Treatment modifications are expensive, and the scale of PWD's treatment operations further magnifies capital and operating costs. PWD expects that PWSs across the country will experience similar issues. Given that PFAS is widespread and persistent in the environment, the proposed regulation may be a catalyst for the most significant modifications to the nation's water treatment infrastructure to date.

Stakeholders must understand that modifications to water treatment systems cannot happen overnight. Philadelphia, as a large system serving 1.6 million residents, would need substantial time to complete a thorough evaluation of system improvement options, procure resources to pilot new or established technologies, complete those piloting efforts to determine design conditions, acquire regulatory approval for implementation, design full- scale infrastructure, acquire funding, procure construction services, and implement any necessary capital improvements. Considering the scale at which the proposed regulations will impact PWSs, it is reasonable to estimate lengthened capital improvement timelines due to extended review/approval times by regional and state regulatory agencies, which will face resource constraints, and widespread competition for a limited pool of construction contractors and equipment vendors. PWD is requesting that clear and consistent guidance for extensions for treatment upgrades, either from the compliance date or following an MCL exceedance, be provided to primacy agencies to communicate to the regulated community. Given the magnitude

of systems that EPA expects to exceed an MCL during initial monitoring, PWD is also requesting that a blanket extension to the compliance period for this regulation be granted for all PWSs by an additional two years to provide PWSs with adequate time to implement the required remedial actions, which in most cases will require significant capital improvements. This action of extending the compliance timeline up to two years is applicable to instances where significant capital improvements are required as detailed in SDWA §1412(b)(10).

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Protecting Our Water, Environment, and Ratepayers (POWER) (Doc. #1714, SBC-045937)

COMMENT 4 — IMPLEMENTATION OF THE PROPOSED RULE IS NOT FEASIBLE BECAUSE IT DOES NOT ALLOW SUFFICIENT TIME TO BRING NEW TREATMENT ONLINE OR EXPAND WATER QUALITY LABORATORY CAPACITIES FOR THE MONITORING IT REQUIRES.

Complying with the rule as proposed is not feasible because the three-year timeframe is too short a window to plan, finance, procure, and construct the additional treatment infrastructure required to comply with the proposed MCL. EPA also needs to complete more analysis of whether it has approved a sufficient number water quality testing laboratories with accreditation for promulgated PFAS methods to perform the volume of sampling that the rule would require.

Three years is too short to implement the new NPDWR standards.

EPA has proposed three years from the date the proposed MCL is finalized to meet the new standards. [FN19: Proposed Rule, 88 Fed. Reg. at 18733.] This time span is not feasible to implement the requisite changes to satisfy the new standards because the EPA has not determined if PFAS is considered hazardous waste, the approved standards and methods for by-product disposal have not been finalized, and the requisite infrastructure changes are costly and will take a substantial amount of time to plan, finance, procure, and construct.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. Whether the EPA takes a future potential action to designate PFAS as hazardous waste is beyond the scope of this action. The agency notes that a possible future hazardous waste designation has no bearing on the EPA's decision to authorize this capital

improvement extension. For additional discussion on disposal of spent treatment materials under possible future regulatory actions and costs, please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Monterey One Water (Doc. #1715, SBC-043827)

Compliance Timeline

Monterey One Water contracts out the analysis of PFOA and PFOS in its purified recycled water effluent to a certified laboratory for environmental testing that uses EPA Method 537.1. With method detection limits of 0.44 parts per trillion and 0.55 parts per trillion respectively, additional or enhanced testing will be required to determine compliance with the proposed federal MCLs. Compliance within the proposed three-year window is not feasible.

As currently written, compliance will be based on a running annual average. Therefore, regulated entities, like Monterey One Water, will not become aware of noncompliance until a minimum of one year into the three-year compliance window, resulting in only two years to identify, finance, and implement a solution. This does not take into account developing and obtaining approval of a quality assurance project plan, setting up the sampling program, and contracting with a certified lab, all of which must occur before sampling can be conducted and results utilized to determine compliance. Further, if after initial monitoring an entity determines it needs to implement new treatment technology to obtain compliance with the proposed MCLs, this would require conducting feasibility studies, designing, bidding, permitting, and constructing these new components. EPA has stated that funding provided by the Bipartisan Infrastructure Law can help entities build new systems to comply with the rule. Many entities, however, will be unable to secure such funding within the three-year compliance window. Without funding, the cost burden will fall to our community members.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Wyoming Department of Environmental Quality (WDEQ) (Doc. #1716, SBC-044760)

10. EPA Should Consider Variable Source Water Quality When Estimating Annual Cost Per Household for Small System Candidate Technologies

EPA has provided assurances that the proposed BATs can treat PFAS-impacted water to the proposed MCLs at an affordable cost based on EPA's estimated total annual cost per household. However, the specific source water quality at each PWS will significantly impact the life span and operating costs of all four proposed BATs. Prior to installation, a proposed BAT will require

pilot testing to determine treatment efficacy before the permanent solution could be permitted through WDEQ. This process will significantly extend the timeline required for compliance with the proposed rule.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. The EPA agrees that specific source water quality may impact the operating life of the BATs for the final NPDWR and that utilities closely evaluate all specific factors when deciding when implementing treatment options to meet the final MCLs. For additional discussion on Small System Compliance Technologies (SSCTs), including the EPA's analysis and identification of SSCTs, please see section 10.5 of the EPA response in this *Response to Comments* document.

Wyoming Department of Environmental Quality (WDEQ) (Doc. #1716, SBC-044758)

WDEQ recommends EPA provide analysis on whether increased demand of PFAS treatment technology and infrastructure, including disposal of treatment media, can be met by the current PFAS technology and infrastructure supply chain for regulated PWSs affected by the proposed PFAS NPDW rule, and whether a three-year time frame for PWSs achieving compliance is reasonable.

Additionally, WDEQ recommends EPA implement a phased approach for PWSs, specifically for small and rural systems, to implement Best Available Technologies (BAT), allowing industrial equipment and materials suppliers to accommodate the increased demand for PFAS treatment technologies and infrastructure over a longer timeframe and to attempt to avoid supply chain issues and associated cost increases.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Loudoun Water (Doc. #1717, SBC-043523)

Loudoun Water is a member of the VMDWA, a non-profit membership association comprised of 42 local governments and local water authorities in the Commonwealth of Virginia. The VMDWA advocates sustainable laws and policies to help ensure safe and affordable water in support of vibrant and healthy communities. The VMDWA has prepared a detailed letter of comments with numerous references that Loudoun Water supports.

In conclusion, Loudoun Water supports the development of primary drinking water standards for PFAS compounds, and we strongly encourage a phased approach for implementation that allows for a focus on the systems with higher PFAS concentrations first and that allows for more time for compliance. We desire a regulation that protects public health while prioritizing limited public resources and without causing unnecessary financial burdens on the greater public.

Sincerely,

Mark E. Peterson

Deputy General Manager, Administration Loudoun Water

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Loudoun Water (Doc. #1717, SBC-043518)

May 30, 2023

By Electronic Submission: Docket EPA–HQ–OW–2022–0114

U.S. Environmental Protection Agency EPA Docket Center

PFAS: PFOA and PFOS National Primary Drinking Water Regulation Rulemaking, Mail Code 28221T

1200 Pennsylvania Avenue NW Washington, DC 20460

Dear Sir/Madam:

Loudoun Water is a not-for-profit utility that provides drinking water, wastewater, and reclaimed water service to over 330,000 residents and commercial enterprises in Loudoun County. Loudoun Water provides potable water service to 76 percent of the population of Loudoun County. We operate one surface water treatment plant, five community groundwater systems and are a wholesale customer of neighboring Fairfax Water. Our customers used an average of 28.5 million gallons per day in 2022, with a recent peak demand of 47 million gallons per day. Our long-range planning will provide for a 90 million gallon per day water supply system.

Loudoun Water supports the development of primary drinking water standards for PFAS compounds, and we strongly encourage a phased approach for implementation that allows for priority focus on the systems with higher PFAS concentrations. Loudoun Water has experienced increased costs and schedule delays due to the cumulative impacts of ongoing supply chain challenges, worker shortages, and a national inflation problem. We anticipate adverse cost

impacts due to extremely high numbers of public utility and other infrastructure projects being attempted over the next five-to-ten years. EPA should consider the benefits to phasing implementation of the rule to avoid unintended consequences of driving up costs, as well as to ensure that the water systems with higher PFAS concentrations are prioritized while protecting public health, avoiding delays, and without creating pricing premiums.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on a phased-in MCL as well as supply chain and labor challenges that may affect the compliance timeline.

Monte Vista Water District (MVWD) (Doc. #1718, SBC-043536)

Compliance Deadline

The proposed rule would require compliance three years after the PFAS NPDWR promulgation. MVWD believes this timeline is unreasonably short for installing PFAS treatment. Local permitting challenges, labor and material shortages, funding constraints, and inflation cost increases make it difficult to meet such a short timeframe. In accordance with Safe Drinking Water Act 1412(b)(10), MVWD requests the EPA extend the compliance deadline for public water systems by two years, for a total of five years from the adoption of this regulation, to allow for additional time for necessary capital improvements.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Monte Vista Water District (MVWD) (Doc. #1718, SBC-043530)

Compliance Deadline

The proposed rule would require compliance three years after the PFAS NPDWR promulgation. MVWD believes this timeline is unreasonably short for installing PFAS treatment. Local permitting challenges, labor and material shortages, funding constraints, and inflation cost increases make it difficult to meet such a short timeframe. In accordance with Safe Drinking Water Act 1412(b)(10), MVWD requests the EPA extend the compliance deadline for public water systems by two years, for a total of five years from the adoption of this regulation, to allow for additional time for necessary capital improvements.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

HRSD (Doc. #1719, SBC-043543)

[We see the following recommendations as productive and protective strategies that EPA can utilize:]

Set the stage for phased implementation, allowing prioritization of resources for those water systems most impacted

In questioning the application of the alternate MCLs, 4 ng/L, 5 ng/L and 10 ng/L, EPA is already setting the stage for a potential phased implementation that prioritizes the drinking water systems posing the most risk to public health. A strategy in which all drinking water systems are required to come into compliance with the most stringent of the aforementioned MCLs will necessarily mean that all impacted drinking water utilities are competing for the same funding, the same engineering consultants, the same laboratory capacity, and the same contractors. Resources for large infrastructure projects are already strained as a result of the recent beneficial influx in infrastructure spending. HRSD has experienced a reduction in the number of responsive bidders for its large infrastructure projects, a symptom of limited capacity in the industry. The bid price for three of its most recent large projects has also exceeded our engineering estimates by more than 20%.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on a phased-in MCL as well as supply chain and labor challenges that may affect the compliance timeline.

HRSD (Doc. #1719, SBC-043545)

In order to effectively meet the public health protection objectives of this proposed regulation, EPA needs to support a phased implementation effort such that the utilities that have the highest PFAS concentrations can receive the necessary support and resources as rapidly as possible.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments*

document for the EPA's discussion on a phased-in MCL as well as supply chain and labor challenges that may affect the compliance timeline.

Louisville Water Company (Doc. #1720, SBC-043558)

[In that regard, we are providing the following comments on key issues that we think require consideration.]

8. Louisville Water recommends that EPA reconsider the timeframe for compliance. The industry is seeing unprecedented material products shortages and extended delivery timeframes as well as unprecedent labor shortages. In addition to the availability of labor and equipment, the agency should consider whether treatment chemicals (e.g., PAC, GAC, IX resins, etc.) will be available given the new demand created by this rule. The agency has stated that it "does not intend to provide a two-year extension nationwide." Louisville urges EPA to reconsider this position. In fact, we cannot imagine a more appropriate situation for EPA to employ its authority to grant a nationwide extension. The agency is promulgating a rule concurrent with the collection of occurrence data (UCMR5). As such, many utilities will only now have access to data that can inform them of their anticipated compliance status, thereby shortening the planning, design, and construction timeframe. While states may provide an extension on a case-by-case basis, there is no guarantee that the extension will be granted, especially given other social and political factors that may be considered by a state to not grant any extensions even when it is warranted and justified. The extension process with a state could be drawn out and if not the utilities favor, may be time wasted. EPA could provide relief to water systems by providing a nationwide extension and may ease the impacts to labor markets and supply chains. Otherwise, EPA should provide guidance to states regarding under what circumstances it is appropriate to provide a utility an extension.

Louisville Water respects that EPA has a difficult job to do with regard to PFAS, and we encourage the agency to remain engaged with utilities as it moves to finalize this and other regulations. Thank you for your consideration of these comments. If you have any questions, please contact Peter Goodmann at pgoodmann@louisvillewater.com or at (502) 569-0849.

Sincerely,

Peter T. Goodmann, Director

Water Quality and Research

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Thurston Public Utility District (PUD), WA (Doc. #1729, SBC-043582)

This is especially pertinent at a time when water utilities are still overcoming the compounding difficulties caused by workforce shortages, lingering supply chain issues, and inflation. Drinking water professionals balance public health and environmental concerns with doing what is best in the communities where we live and serve.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

U.S Conference of Mayors, National League of Cities and National Association of Counties (Doc. #1733, SBC-043898)

Additionally, many local governments and water systems are experiencing workforce shortages that will impact the timeline and cost to comply with this regulation. These challenges not only include trained water utility personnel, but also limited staff capacity at testing labs, in the transportation sector needed for shipping and handling equipment and lab tests, and at the state agency level for review and approval of monitoring and compliance data.

Due to the challenges outlined above, attempting to implement this regulation in such a constrained time frame would only exacerbate current issues relating to skyrocketing supply prices, labor shortages, laboratory capacity, and surging market demands. Although EPA's proposal includes providing extensions on a case-by-case basis granted either from states or by EPA, this is not a guarantee. We strongly urge the Agency to clearly and definitively extend the current proposed three-year timeline for all public water systems.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Michigan Section American Water Works Association (MI-AWWA) (Doc. #1734, SBC-044477)

In addition, the implementation timeline of 3 years set forth by EPA, would vary depending on the number of systems impacted, inter-related regulatory requirements, and current economic conditions. The time to implement and fund a project along with the lack of available, qualified construction companies in remote areas of northern Michigan has not been considered.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Arizona Corporation Commission (ACC) (Doc. #1735, SBC-045183)

Additionally, the ACC believes that the EPA should consider the following cost effects associated with the proposed rule:

• increased demand for remediation technology

• additional infrastructure needed to operate remediation technology within its design parameters

• the availability of qualified contractors for constructing and installing remediation facilities

• complying with the three-year compliance window.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Arizona Corporation Commission (ACC) (Doc. #1735, SBC-045185)

TIME TO COMPLY

The proposed compliance schedule raises concerns for the ACC. The EPA has stated the rule will be implemented by the end of 2023, giving utilities a three-year timeframe to achieve compliance. However, projects of this magnitude typically span multiple years, involving activities such as piloting, design, regulatory approval, procurement, permitting and construction. These processes can easily extend the timeline beyond three years. Construction alone can take in excess of 24 months based on feedback from a Class A utility. Furthermore, Arizona is currently experiencing substantial growth, and the ACC worries that this mandate, coupled with the demand for specialized treatment equipment to meet PFAS regulations and mandates from the lead and copper rule, will make it challenging to meet the 2026 compliance deadline. Considering the complexity involved, the ACC requests a significant extension of the compliance period for utilities that require capital improvements, or barring that, a waiver provision process to allow a longer window, especially for smaller utilities who do not have the capital in place to build and install treatment. This will allow sufficient time for careful planning of treatment processes.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Florida Section American Water Works Association - Water Utility Council (FSAWWA WUC) (Doc. #1737, SBC-044488)

• Funding, Design, and Construction Costs Timelines:

The Florida Water Sector recommends EPA work with our national water sector leaders, such as American Water Works Association, to determine a more appropriate timeline than three years. The FSAWWA estimates Florida's drinking water facilities produce 1.6 billion gallons of water a day with over 300 utilities being classified as medium (3,300 population served) size or higher . While the technology type can vary dependent on source water, it is expected a large number of Florida PWS who currently use traditional treatment methodologies (e.g., lime softening) will need to develop new PFAS specific treatment techniques to reach 4 ppt. The competition for funding, people and supplies will increase the numerous construction projects' timelines and costs. In addition, local governmental purchasing requirements can extend project timelines to assure legal and appropriate expenditures of public dollars. Finally, some large urban water suppliers believe land purchases will be required to construct new facilities.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045977)

Section 7: Treatment Technologies

EPA has identified three readily available treatment technologies that are successful in removing PFAS from drinking water. These three treatment techniques, identified as the BATs, are granular activated carbon (GAC), anion exchange (AIX), or high-pressure membranes, such as reverse osmosis (RO) and nanofiltration (NF). AMWA agrees with EPA's assessment that the proposed MCLs are technologically feasible, but also would like to urge EPA to further explore the economic feasibility of these treatment techniques.

Because PWSs must individually weigh a number of factors before deciding which treatment technology to employ, it is essential that utilities have an adequate amount of time to comply

with the proposed NPDWR. PWSs have significant differences in the composition of their source waters, as well as different environmental factors, which can influence a system's water quality. For example, source water composition is different depending on climate, region of the country, and type of water source. Utilities must consider these factors when new treatment techniques are required. The decision on which treatment technologies to use require extensive time and research to make the best choice with minimal negative effects, highlighting the need for an extended compliance timeline.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10).

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045973)

Section 5.6: Compliance timeline

EPA is proposing a three-year compliance time from the promulgation of the rule. A state or EPA may grant up to a two-year extension if it is determined that an individual system needs additional time for capital improvements, giving up to five years if the state or EPA grants the extension. Additionally, EPA or the primacy agency may grant an extension of three additional years beyond the five for systems meeting specific demands criteria explained in SDWA § 1416. Small systems have the option to apply for a series of three, two-year extensions beyond this total of eight provided to medium and large systems. This is the compliance schedule laid out in the SDWA.

AMWA cannot stress enough that the three-year compliance deadline will not be enough time for many water systems impacted by the proposal to complete capital improvement projects to address PFAS. AMWA members have indicated that a project of this magnitude would take a minimum of five years if this project was the only utility priority and there were no delays or issues that arise from the supply chain, labor, or permitting and procurement processes. Others have estimated 10+ years. While SDWA does allow for a two-year extension and potentially a three-year exemption, these are not guaranteed and are at the discretion of the primacy agency or EPA.

The process for a PWS to complete a project of this magnitude is long and tedious. While each water system is different, there are similarities in the process that most must follow, and some unique pieces that are worth consideration. AMWA members are publicly owned and must go through certain channels for approvals at each step of the process. There are deeper considerations that some must address when it comes to rate increases, permitting, and general budgeting for improvement projects. Many of these steps must be approved by boards, councils, and/or elected officials.

Some examples of PWS timelines for specific utilities are included in Attachments 2, 3, and 4. Typically, approvals need to be granted for a project this size, which can take months based on scheduling and other priorities within a municipality. Water systems will then need to design and conduct pilot studies to determine the best approach to treatment, assess impacts on other aspects of treatment, determine the specific needs of the water system, and determine the efficacy of the chosen treatment. Design and building of these pilots can take 18 months to three years. These pilots would also need to capture seasonal variability in source waters, so this process can take about 12 months.

Many utilities must go through local land use or zoning processes to obtain approval to construct any facilities. This process can take six to eighteen months, preceded by at least six months of preliminary engineering and development of other application materials including an alternatives analysis. The zoning process is separate from and a prerequisite to obtaining site plans and building permits, processes that can take another six to twelve months. In between zoning and site permitting, the detailed design and development of bid documents would occur, a process that can take twelve to eighteen months depending on the complexity of the selected treatment process.

Public utilities are also subject to public procurement regulations. These processes add additional time to the design and construction process. Development of a request for proposals for project design services, receipt and review of proposals, the consultant selection and negotiation process, and contract award typically take six months or more. The process for receiving bids for construction and awarding those contracts will take another three to six months. While some public utilities may be able to employ alternative procurement methods, not all are able to do so, and even alternative methods will only shorten timeframes associated with the design and construction phase.

Construction of the treatment alternatives noted in the rule (GAC, IX, RO) would be additional treatment trains. Construction phasing to maintain plant operations and ensure an adequate supply of drinking water to the public is critical. Tie-ins to existing infrastructure will be necessary and must occur during low-demand periods (often wintertime or other low-use time based on location) to ensure sufficient water production capacity to meet community needs. These construction staging intricacies will further lengthen the time to construct PFAS treatment improvements. Construction and commissioning timeframes will be project and site-specific but could in some cases take three years.

PWSs and other sectors across the country are currently experiencing increased pricing of goods and services, supply chain disruptions, and labor shortages. The proposed compliance period would be impossible for many utilities to meet without extensions. EPA needs to include considerations for how the increased demand for contractors, materials, equipment, and other labor will prolong projects and drastically increase prices, costs that eventually must be passed on to ratepayers and impact a utility's ability to provide affordable water to the public. Currently, even before this rule is finalized, some GAC suppliers have advised that the lead time for GAC

vessels for PFAS treatment is eighteen months. This is not a unique situation, and many utilities must prepare for the situation to worsen if this rule is finalized as is.

While AMWA supports the proposal's overall goal of protecting public health by delivering safe, clean, and affordable drinking water to the public, a compliance period of three years will simply be impossible for many PWSs to meet. There are several options EPA could pursue to alleviate burdens on public systems while still implementing feasible actions that will ultimately be more protective of public health from the chronic conditions attributed to PFAS exposure.

In the proposed rule preamble, the agency states "EPA does not intend to provide a two-year extension nationwide." AMWA urges EPA to reconsider this decision. While states may provide an extension on a case-by-case basis, there is no guarantee that the extension will be granted. Many other social and political factors may pressure a state's primacy agency to not grant any extensions even when it is warranted and justified. EPA could provide some relief to water systems by providing this blanket extension nationwide and could potentially ease the immediate impacts on labor markets and supply chains. Additionally, EPA could provide guidance to states on when is appropriate to provide a three-year exemption, particularly when a utility is acting diligently to implement treatment, but constraints out of its control have prevented completion in the five-year period.

EPA could also take a similar approach it did with the arsenic rule (see table below), where systems were eligible for an exemption based on contaminant concentrations [FN17: EPA. (2002, August). Implementation Guidance for the Arsenic Rule. https://www.epa.gov/sites/default/files/2015-09/documents/2005_11_10_arsenic_ars_final_app_g.pdf]. Water systems would still get five years for compliance but would be eligible for the three-year exemption based on the concentrations of PFAS in their system. A potential option would be using over or under 10.0 ppt, as EPA already explored the option of a 10.0 ppt MCL and approximates 1,300 systems would be impacted. These 1,300 systems would need to be in compliance in the 5 years, but those under 10.0 ppt would have a little more time to explore other options or to spread out the demand for materials and labor [Table 1: see docket ID EPA-HQ-OW-2022-0114-1738].

This would allow for systems with the highest concentrations of PFAS, and therefore the highest risk to public health, to address the issue first and have first access to all the materials and labor needed for treatment, like a "worst-first" approach. Water systems that are closer to the MCL would have a little longer to comply to alleviate strains in the supply chain and labor and would not provide an unreasonable risk.

Another benefit to this approach would be that water systems close to the proposed MCL would have time to consider less costly and invasive approaches to compliance. As stated earlier, AMWA believes source water protection should be EPA's highest priority when it comes to preventing contamination of drinking water supplies. If water systems that are close to the MCL have time to identify the sources of PFAS in their watersheds, they can try to address the issue there instead of spending millions on treatment that may not be necessary.

A feasible compliance timeline is paramount to the success of this rulemaking. Rampant noncompliance places an unnecessary burden on primacy agencies and EPA and undermines public trust in drinking water. The public would be better served by knowing the path to compliance is achievable than by being routinely notified that their drinking water fails to meet newly implemented standards. Repeated notices of noncompliance will only drive more people to drink bottled water, which, ironically, does not have to comply with the same PFAS monitoring and treatment standards. EPA and AMWA must work together to build and maintain trust in drinking water. Unfortunately, distrust of drinking water leads to individuals, including those in low-income and underserved communities, spending money needlessly on less-regulated bottled water.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as discussion on exemptions under SDWA 1416 and a phased-in MCL approach.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045996)

High sample costs and limitations only reinforce the need for a longer compliance period and a focused approach on water systems with the highest concentrations of PFAS. More time will give labs time to adjust to the increased demand and will keep costs down for those systems that need to implement treatment. AMWA suggests EPA refine the rule before promulgation to better account for the significant increase in demand for lab capacity and analysis.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. For additional discussion on laboratory capacity, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046035)

Time Required to Implement PFAS Treatment

The proposed rule provides only three years for compliance from final rulemaking. While utilities can apply for a two-year extension from their primacy agency, extensions are not guaranteed. Fairfax Water, like many utilities, must go through several local government approval processes and permitting by our primacy agency before construction can proceed.

Fairfax Water, like most public utilities, must also comply with public procurement laws that add time to the process to secure design and construction services. PFAS treatment will be a new train to an existing treatment plant. Properly sequenced construction that maintains plant operations and ensures an adequate supply of drinking water to the public will be critical and take longer than a "greenfield" construction project. Realistically, 7 to 10 years is required to implement PFAS treatment.

[Table: see docket ID EPA-HQ-OW-2022-0114-1738]

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046036)

Schedule

Delivering water treatment-related infrastructure projects requires extensive testing and design to ensure the full spectrum of variations in source waters and treatment processes are fully considered and tested prior to bidding and construction. For many utilities in the South, this includes the variation of dissolved organic carbon (DOC) and a possible mix of potentially hundreds of PFAS compounds. Equipment installation must be staggered and scheduled during low demand seasons to reduce overall risks and maintain continuity of operations of water treatment plants.

Another challenge to delivery of treatment-related projects includes coordination with Virginia Department of Health (VDH) who are considered project partners during the testing, design, permitting, and construction phases. Delays during the review and approval process are normal, and with multiple water (and wastewater) utilities undergoing PFAS projects simultaneously, delays in VDH review and approval could be substantial.

The chart below provides a general estimate for a medium-sized municipal water utility with 2 treatment facilities, limited staff, and a fully engaged primacy agency (VDH). Testing, design, bidding, construction, start up, and permitted operations of the new facilities will take at least 4 years and likely closer to 5 years from the establishment of the final MCLs.

[Figure: see docket ID EPA-HQ-OW-2022-0114-1738]

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments*

document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045957)

The greatest health risks from PFAS in drinking water will come from systems with the highest concentrations, not those at the margins of compliance with EPA's proposal. EPA should work to address these systems first to protect individuals in those service areas. EPA's proposal estimates approximately 4,300 PWSs will be impacted by this rule [FN7: EPA Economic Analysis, (USEPA, 2023j)]. AMWA emphasizes that the upcoming implementation of UCMR 5 will provide more accurate estimations of the impacted systems' PFAS levels. Any system with levels above the proposed MCLs must promptly initiate planning and execute interventions to address PFAS contamination once this rule is finalized. It is important to anticipate that this substantial demand will exert significant pressure on supply chains and the labor market. Meanwhile, EPA estimates around 3,300 PWSs would be impacted if MCLs were implemented at 5.0 ppt and about 1,300 PWSs with MCLs set to 10.0 ppt. These 1,300 PWSs with PFOA and/or PFOS above 10.0 ppt should be prioritized, as greater demands in GAC, materials, and labor could prevent these systems from quickly remediating the issue, potentially exposing the public in these service areas to higher concentrations of PFAS for a longer period.

If EPA chooses to rush through finalizing this rulemaking before the September 2024 statutory deadline, it would be advantageous to finalize an MCL that is both feasible for PWSs to achieve and meaningfully protects public health. EPA should initially require PWSs with high levels of PFAS – those greater than 10 ppt – to implement actions to reduce PFAS exposure at these PWSs first. Then, EPA can use UCMR 5 and other up-to-date research to further explore lowering that threshold. The agency would still be protecting public health and would simultaneously be alleviating the strains, demands, and increased costs for labor, materials, and construction. This would also allow PWSs with lower concentrations to explore other, less costly, measures to reduce exposures to PFAS, yielding both fiscal and health-related advantages for the public.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as a phase-in of the MCL. The EPA does not believe that issuing a final rule prior to September 2024 is "rushing through" but simply reflects the priority EPA is providing to this important health-protective regulation.

Liberty (Doc. #1747, SBC-043624)

Given the limited availability of laboratory resources, Liberty respectfully recommends that the EPA consider a five-year compliance period to allow utilities to stagger initial monitoring activities, which would allow laboratories to better manage incoming samples. Alternately, the EPA could impose staggered initial monitoring requirements across states, considering demonstrated need for those with significant disadvantaged communities, or those with communities whose water sources are seriously impacted by these contaminants. Both options also permit a greater number of laboratories to meet certification requirements over time, further enabling a successful initial monitoring effort.

Second, should a utility determine through initial monitoring (or other acceptable means as provided by the proposed regulation) that they must install treatment, the time allowed for meeting compliance is not adequate. The development of plans and specifications, permit approvals, construction, and start-up of any treatment facility takes significant time under the best of circumstances. Current supply chain limitations negatively impact even the most basic, and sometimes critical, materials needed to manage and maintain water and wastewater infrastructure. Meters that used to arrive in a week are now back-ordered six months to a year. Brass components require up to an eight-month lead time, and ductile iron piping can take three to 12 months to arrive.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Liberty (Doc. #1747, SBC-043626)

Liberty respectfully recommends the EPA consider a five-year compliance period to allow utilities to accommodate the regulatory requirements without risk of non-compliance due to time and materials elements outside of their control.

Thank you for the opportunity to provide our perspective and recommendations on this important rule proposal.

Sincerely,

Stacey Roberts

Sr. Manager, Water Quality

Liberty

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

City of Thornton, Colorado (Doc. #1748, SBC-044798)

Thornton believes that the NPDWR implementation timeframe of three years with waiver opportunities of up to two years is vastly insufficient for the study/piloting, design, construction, and commissioning of new treatment processes given supply chain constraints, lab capacity, and demand for engineering and construction services. While Thornton already has a decent understanding of PFAS loading in its source waters and has already begun preliminary engineering designs, the City is still concerned about being able to meet the regulatory compliance deadline for the rule due to the aforementioned factors. Thornton is also concerned about smaller utilities' ability to meet those deadlines considering they may not yet have sampled for PFAS or know whether they need treatment. These systems likely do not have the resources and finances for rapidly meeting the proposed rule. Thornton suggests extending the compliance timeline to four years with an additional two-year waiver period for utilities that are actively constructing treatment processes but struggling with supply chain or funding issues. As mentioned above, simplification of EPA funding is also needed as the requirements for receiving those funds could considerably slow utilities' treatment process implementation. Likewise, implementing a PFAS NPDWR prior to implementation of strict limits on PFAS discharges by polluters will challenge utilities' ability to meet the proposed rule. By providing additional timeframe for implementation of the rule while simultaneously prioritizing discharge limits, EPA will provide the best protection of public health.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Harris County Attorney's Office (HCA) (Doc. #1751, SBC-045265)

HCA raises several concerns regarding the feasibility of implementation and compliance, especially for small and rural water systems.

HCA is concerned that small and rural public water systems in Harris County will struggle to meet a three-year timeline to research, raise funds, purchase, install, and operate new PFAS removal technology. EPA is currently promoting expansion of the number of laboratories that

can process PFAS samples by soliciting proposals and awarding contracts to laboratories across the nation in order to expand the capacity for monitoring. However, HCA is concerned that EPA is soliciting contracts to expand laboratory capacity while the proposed rule simultaneously calls on currently un-regulated PWS to implement monitoring data for PFAS. HCA is concerned that even with expanded laboratory capacity the additional monitoring requirements will drive increased costs resulting in very expensive PFAS montioring, resuling in exorbitant waster bills for consumers.

HCA recommends robust guidelines regarding exemptions

HCA supports EPA's proposed rule requiring stringent standards for the processes and laboratories that will be considered for an exemption. More specifically, HCA supports EPA's proposed use of vulnerability assessments to determine if a small public water system is low risk and warrants a monitoring waiver. However, EPA's standards should be meticulously applied to provide community confidence in the monitoring data and ensure the exemptions are not used as a tool to circumvent investment in new PFAS removal technologies.

HCA asks that a notice and comment period is required for SDWA § 1416(b)(2)(C), which allows certain small systems to receive additional exemptions, and for State exemptions to ensure communities are aware of an exemption request and can participate in decisions regarding their PFAS exposure. HCA is concerned exemptions given too leniently or without community input could create a disparity between rural and urban PFAS exposure. HCA believes that community members should be informed of the potential approval for a small facility exemption, and they should be provided the opportunity to comment on such an exemption.

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EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on the strict criteria and process requirements for exemptions under SDWA 1416 as well as supply chain and labor challenges that may affect the compliance timeline.

Las Cruces Utilities (LCU) (Doc. #1753, SBC-043904)

In the case that no extension is granted, LCU is providing the following comments:

• In response to EPA's projected implementation timeline for the proposed regulations, LCU is planning further investigation beyond past and recent Unregulated Contaminant Monitoring Rule (UCMR) studies to assess the extent of potential groundwater contamination for the constituents of concern in our cities drinking water system. Given the lack of comprehensive data, there is uncertainty regarding the extent of increases in capital and annual operating costs associated with

achieving compliance. It is also difficult to assess our timeline to obtain compliance if conditions warrant.

EPA's goals of finalizing the rule by the end of 2023 and implementing three years to obtain compliance will be difficult to accomplish given the time required to attain funding, plan/ design, procure contracts, construct, hire and train specialized staff, etc. LCU has continued to experience ongoing delays in project completion in water and wastewater projects due to supply chain delays and logistical issues that will be further exacerbated. Any potential projects for treatment alone can take multiple years just to plan and coordinate. LCU requests EPA to extend the proposed compliance timeframe substantially beyond three years for water providers to attain compliance.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Los Angeles County Sanitation Districts (Doc. #1756, SBC-044516)

Feasibility of Implementation. EPA has proposed a three-year compliance time for water systems to address the presence of PFAS in their water supply above the proposed MCLs; however, this timeline is unrealistic and infeasible for compliance. The proposed NPDWR rulemaking indicates that EPA does not plan to issue a waiver for a two-year extension for systems that need to install PFAS treatment technologies, including facilities that supply recycled water and are required to meet MCLs. Most water systems and recycled water suppliers that need to install treatment facilities will need a minimum of five years to complete projects. The process for completing such projects is complex and time-consuming, involving various approvals, California Environmental Quality Act (CEQA) compliance, pilot studies, local land use or zoning processes, design and development, procurement, financing, and construction. These steps require coordination with multiple entities, including boards, other jurisdictions (such as cities or counties), and the public. Additionally, utilities are currently facing many challenges, such as inflation-driven increased costs, supply chain disruptions, and labor shortages, which further extend project timelines and may increase costs. Additionally, requiring utilities all across the nation to comply at the same time will cause not only a shortage of laboratory capacity for the required monitoring, but also is likely to create equipment and contractor shortages since the types of technologies used to remove PFAS are limited and very specialized. For those agencies able to apply for and receive funding under the State Revolving Fund loan programs or from the Bipartisan Infrastructure Law's Contaminants of Emerging Concern/PFAS funding program, Buy America/Build America (BABA) requirements will apply, and the ability to procure specialized technologies domestically (or obtain the necessary waivers) within a three-year timeframe is extremely questionable. For these reasons, many of the utilities that must install

treatment facilities to address PFAS will not be able to reasonably meet a three-year compliance timeline. We recommend that EPA use its authority to provide a nationwide extension for a minimum of two years for systems installing capital improvements, although an extension of up to three to five years would be preferable.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. Please also see the EPA response to comment Doc. #1676, SBC-043778 in section 12.1 in this *Response to Comments* document for the agency's response on concerns regarding BABA.

El Paso Water (Doc. #1757, SBC-044526)

Should the EPA adopt a lower MCL, the agency should allow adequate time for a PWS to be able to plan, design and construct the necessary new treatment facilities to treat PFAS contamination.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Arizona Water Company (Doc. #1758, SBC-044535)

PFAS Removal Technology and Hazardous Waste

Construction timelines for PFAS treatment facilities are unrealistic. The Company has extensive experience designing, permitting, and constructing arsenic removal facilities. In the Company's experience, the design, permitting, and construction timelines for such facilities often extends several years beyond estimated completion deadlines. This is due to a variety of factors, but especially lead times and delays to acquire required materials, such as raw metal, fabricated vessels, concrete, and treatment media. Labor shortages are already a cause of many construction delays. Under the proposed PFAS MCL, water utilities all around the country will be required to build PFAS removal facilities for these chemicals at once. Under these circumstances, the Company anticipates that material and labor delays will be severely exacerbated. The Company recommends the EPA provide an additional three years for compliance with the PFAS MCL. Such considerations were taken into account when the EPA implemented its current arsenic MCL and utilities faced similar challenges.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as the availability of additional time under Section 1416 of SDWA.

American Water Works Association (AWWA) (Doc. #1759, SBC-045571)

Simultaneous Compliance will Slow Down Implementation

The installation of new water treatment facilities requires sufficient planning to ensure that bringing a plant into compliance with a new rule does not cause non-compliance with existing regulations. For most water systems in the U.S., the installation of PFAS treatment facilities will create challenges for simultaneous compliance with existing drinking water rules. Each of the best available technologies for PFAS will have impacts on the finished drinking water and may require post-treatment to avoid negative impacts. For example, the use of reverse osmosis (RO) and anion exchange (IX) treatment can increase the corrosivity of water impacting the potential for lead release into drinking water at homes. Granular activated carbon (GAC) has been known to contribute to distribution system nitrification. These impacts can be mitigated, but mitigation requires adequate evaluation.

One such example where simultaneous compliance concerns will delay the implementation of new drinking water treatment is the requirements Lead and Copper Rule Revisions (LCRR) (EPA, 2021d). When systems determine that mitigation is needed to comply with any new PFAS standards – either through new treatment or a change in the water supply source – they will need to comply with the LCRR requirements, which could include a lengthy process of analysis and subsequent studies to obtain approval from their primacy agency. The LCRR corrosion control studies and subsequent actions could take years to achieve. When complying with the LCRR leads to significant changes in corrosion control treatment (CCT) after the rule's administrative procedures are following, a system must have time to: (i) prepare the distribution system and customers for the transition, (ii) shift corrosion control practice at a pace that does not lead to water quality concerns, and (iii) simultaneously install the required PFAS treatment or water supply option. This will have a significant impact on the system's ability to install PFAS treatment within three to five years of any final PFAS rule and impact the cost of implementing new treatment for PFAS.

Most Systems will Need to Perform Pilot Testing

Finally, another important step in installing PFAS treatment facilities is pilot testing. While GAC, IX, and RO have been documented as being capable of removing PFAS effectively, they still require a sufficient level of pilot testing. Pilot testing typically takes at least six to nine months to complete, and costs vary but include the rental cost of equipment, engineering and

other technical support, and appropriate monitoring and sample analysis costs. Bench scale testing can also be useful and is less costly for some systems.

The are a number of important goals associated with pilot and bench-scale testing are 3-fold: (i) demonstration of PFAS removal efficacy, (ii) characterizing pre- and post-treatment needs, and (iii) optimal treatment technology selection, (iv) confirmation of design and operational parameters, and (v) estimation of capital, operations and lifecycle costs (AWWA, 2020a). It is anticipated that most of the water systems that must install treatment to meet PFAS MCLs will need to perform pilot testing, especially given the perming requirements to comply with the LCRR, as discussed above. While pilot testing may not seem appropriate for smaller systems, it is similarly vital for these systems to ensure that the expense of capital for a new long-term treatment facility is both cost-effective and appropriately designed to protect public health from secondary water quality changes. The potential cost to small systems if new treatment facilities fail to operate as intended can be severe, given the cost of identifying and implementing solutions cannot be distributed across a large number of households, particularly after water rates are already rising to take on debt of the initial PFAS rule compliance solution.

Implementation will Further Strain the Supply Chain

When considering the costs and feasibility of the timeline and proposed rule, EPA must also take into account current supply chain issues. Water systems have been faced with a strained supply chain, which were worsened following the start of the COVID-19 Pandemic. This strain has led to increased purchasing costs, longer lead times for equipment or materials, and limitations on the products that are available. Lead times for key equipment (e.g., vessels, carbon or resin media, electrical components, etc.) have already increased to beyond twelve months, depending on the equipment and the degree of specialization it requires. Vessels, GAC media, and IX resin are not widely available from more than a few suppliers. Lead times for replacement GAC media are currently six months or more and for new customers the lead time is in the range of twelve to eighteen months. The lead time for GAC media will increase as a surge of new systems begin ordering GAC and suppliers will need to acquire media internationally (e.g., China and India) as the domestic market becomes more strained. China and India) as the domestic market becomes more strained. Manufacturing of IX resin is currently not domestic given the safety concerns regarding the chemicals used in its production as demand for IX resin increases the supply chain is anticipated to strain as well. These issues are also impacting major ancillary equipment like electrical panels, motor control centers, etc.

Workforce Limitations will be Worsened

The water sector is currently working to overcome workforce challenges, which EPA must also recognize when considering the feasibility of the timeline and proposed approach. EPA estimates that one-third of the sector's workforce is eligible to retire within the next 10 years and water systems are facing challenges in recruiting, training, and retaining employees (EPA, 2023a).

These challenges are expected to be more severe as more than 4,300 water systems are driven to advanced technologies that require more specialized technical skills. To install and operate these

facilities, water systems will need to hire or contract engineers, manufacturers and suppliers, construction crews, and skilled operators. These service providers are already in high demand and in short supply. The resulting imbalance is impacting labor and material costs, lead times for materials, turnaround times for services (e.g., engineering, laboratory analysis, construction). The installation of new treatment facilities will surge following rule's promulgation, which will further worsen workforce challenges for water systems.

The demand for highly skilled water treatment operators will increase due to this rule. Systems currently not using filtration for water treatment may need to meet additional operator certification requirements. Systems currently not using filtration for water treatment may need to meet additional operator certification requirements. While each state independently sets certification requirements for water treatment plant operators, it is anticipated that systems requiring to install GAC, IX, or RO will need to staff operators with more advanced certification. Water systems in the states of Virginia [FN4: 18 Virginia Administrative Code 160-30-370 – Waterworks.], California [FN5: California Code Regs. Tit. 22, § 64412.1. - Classification of Water Treatment Facilities.], Colorado [FN6: 5 Code of Colorado Regulations 1003-2 Regulation 100 - Water And Wastewater Facility Operators Certification Requirements: Sections 100.4 to 100.9.], and Massachusetts [FN7: 310 Massachusetts Register 22.11B.], for example, will all see impacts to operator certification requirements as a result of new treatment systems for PFAS. This change will have a significant impact on systems with a limited local labor pool or limited financial capacity to attract skilled operators that will be needed to safely operate these advanced treatment systems. As EPA recognizes, systems must have staffing with appropriate qualifications to operate 24 hours a day, 365 days a year. Many systems will struggle to find qualified operators for adequate staffing.

State Primacy Agency Capacity

Because the typical timeline for the planning, design, perming, and construction of a new drinking water treatment facility for PFAS may take up to and exceed 5 years, the standard compliance window of three years under SDWA will not be feasible. This is especially important given that these implementation challenges will drive the timeline up as systems begin competing for the same limited supply of sector resources. Under SDWA, water systems may request a two-year extension for compliance with MCLs if it is determined that additional time is necessary for capital improvements.

It is anticipated that the vast majority of water systems that need to install treatment for PFAS will need to request this two-year extension, which is typically provided at the discretion of the state primacy agencies. State primacy agencies are currently working to review lead service line inventories, preparing to implement the corrosion control treatment requirements of the LCRR, administering the DWSRF and additional projects accessing funds from the Bipartisan Infrastructure Law, and working to ensure and improve water system compliance with existing rules. State primacy agencies are currently working to review lead service line inventories, preparing to implement the corrosion control treatment requirements of the LCRR, administering the DWSRF and additional projects accessing funds from the Bipartisan Infrastructure Law, and

working to ensure and improve water system compliance with existing rules. As the surge in water system requests for a two year extension begins, these agencies will be strained as they work to review and process these requests.

However, the Administrator also has the authority under SDWA to provide this extension and can do so as a part of the rule as opposed to being done so on a case-by-case basis. In order to prevent issuing a final rule that is infeasible due to the implementation timeline or otherwise violates the APA as arbitrary and capricious, AWWA recommends that the Administrator leverage this authority to increase the likelihood that all water systems can comply with the timeline of the rule and take adequate, effective steps towards mitigating PFAS levels in drinking water.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges, as well as simultaneous compliance challenges, that may affect the compliance timeline. Regarding concerns on operator certification licenses, please see the EPA response to comment Doc. #1567, SBC-042738 in section 12.1 in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045562)

2. The standard implementation timeline is not appropriate for the current economic conditions. The process to monitor, plan, design, pilot, permit, and construct facilities will take much longer than the standard 3-year timeline given workforce and supply chain challenges. While states may be able to grant 2-year extensions, on a case-by-case basis the burden for state primacy agencies to process these requests will be significant. To avoid a final rule that is infeasible for water systems to comply with, the Administrator should exercise its authority under the SDWA to extend the effective date of compliance by two years for water systems installing capital improvements [FN1: Under 42 U.S.C. 300g–1(b)(10), the Administrator "may allow up to 2 additional years to comply with a maximum contaminant level if…additional time is necessary for capital improvements" (104th Congress, 1996).].

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

American Water Works Association (AWWA) (Doc. #1759, SBC-045568)

3. Implementation Challenges

Public water systems subject to the proposal will need to comply within three years unless a two-year extension is provided by state primacy agencies or the Administrator. An estimated 67,000 water systems will need to perform initial monitoring at nearly 90,000 entry points used by water systems. Additionally, upwards of 4,300 water systems will need to take action to address PFAS levels above the maximum contaminant levels (MCLs) and continue to conduct quarterly sampling, according to the EPA's analysis. For water systems that need to install advanced treatment facilities for PFAS, a myriad of challenges will delay the implementation timeline for each system and will impact costs to implement these facilities.

Simply put, the current implementation timeline will cause the final rule to be infeasible, and therefore conflicts with the SDWA. When EPA establishes an MCL, the combination of technology, treatment techniques, or other means required to meet the level must not be more stringent than feasible [FN2: 42 U.S.C. 300g-1(b)(B)(5)(B)(ii).]. The SDWA defines "feasible" to mean "feasible with the use of the best technology, treatment techniques and other means which . . . are available (taking cost into consideration)." [FN 3: 42 U.S.C. 300g-1(b)(B)(4)(D).] The tight timeline for implementation here would render the "the combination of technology, treatment techniques, or other means" infeasible because of the additional costs and implementation considerations.

As required by the SDWA, AWWA encourages EPA to consider how these implementation challenges will impact not only the compliance cost of the rule, but the feasibility of the rule to be implemented on the standard timeline provided by the SDWA. These challenges are further detailed below.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. For additional discussion on how the agency considers analytic feasibility when establishing the MCL, please see section 5.1.2 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045637)

14. Summary of Key Recommendations

Advancing public health is a shared goal between drinking water systems and EPA and AWWA has evaluated the rule to support EPA's actions moving forward meaningfully and legally, using sound science. AWWA appreciates the agency's interest in preparing a thoughtful, thoroughly crafted proposal to establish NPWDRs for PFOA, PFOS, and additional PFAS.

As previously discussed, the regulation of PFAS in drinking water as proposed will create numerous implementation challenges. Although EPA is interested in an expeditious rulemaking

to reduce PFAS exposure, it is nonetheless important that EPA finalize a rule that is based on sound science, recognizes the importance of drinking water affordability, and be feasible to implement.

While EPA has a stated interest in advancing immediate protection of communities from PFAS exposure, water systems still need to perform the necessary work to implement any rule requirements – regardless of the timeline. Three years is insufficient time for water systems to comply with EPA's proposed rule option. The Administrator should provide a 2-year extension as part of the final rule per authority provided by SDWA, instead of relying on already overextended state primacy agencies.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

California State Water Resources Control Board (Doc. #1760, SBC-044225)

[The State Water Board offers the following specific comments and recommendations for consideration regarding implementation of the rule:]

Suggests that EPA allow flexibility in the compliance deadlines to ensure feasibility, similar to the flexibility offered as a part of the final arsenic regulation, allowing extended compliance deadlines depending on the system size and initial concentration. California's monitoring data so far, while only done at wells near sites expected to be contaminated, shows a large number of water systems will ultimately have to seek treatment. California is also preparing to sample a large number of small disadvantaged public water systems and expects to find many of these contaminated with PFAS. Because PFAS has been shown to be so widely spread throughout the country, implementation of the PFAS rule will undoubtedly cause a large demand for treatment equipment. The State Water Board is presently proposing a similar approach for its hexavalent chromium MCL and cites another advantage in that small systems can benefit from reduced costs as treatment equipment matures with larger systems making the initial investments.

Thank you for the opportunity to comment on this rule making. We believe our comments above derived from our experience implementing PFAS monitoring and treatment will improve implementation of the rule, making it more effective and thus better protect the public.

Sincerely,

Darrin Polhemus, P.E.

Deputy Director, Division of Drinking Water

State Water Resources Control Board

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as exemptions under Section 1416 of SDWA.

Riverside Public Utilities, Riverside, CA (Doc. #1762, SBC-044228)

[The following comments are submitted for consideration in the proposed EPA rulemaking:]

EPA should extend the compliance deadline to at least five years:

City staff believes that the three-year compliance timeline is not adequate to meet the associated requirements for additional PFAS monitoring and installation of treatment. Below is a timeline City staff has developed of the many steps necessary to design and install the PFAS treatment infrastructure which it anticipates will be required under the new regulations. Also, we would like the EPA to consider that this rulemaking will increase the nationwide demand for resources required to install treatment facilities, which will impact the availability of consultants, design firms, construction companies, and material (i.e. vessels), creating further challenges for agencies to meet the proposed deadlines.

PFAS Project Planning, Design and Construction anticipated Schedule

[Table 1: See Docket ID EPA-HQ-OW-2022-0114-1762]

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Connecticut Section of the AWWA (CTAWWA) and Connecticut Water Works Association (CWWA) (Doc. #1763, SBC-044232)

Timeline for PFAS Rule Implementation

The proposed PFAS Rule does not adequately account for the implementation time required for utilities to expediently work towards compliance. Utilities with concentrations of PFAS in their source water above the proposed maximum contaminant levels (MCLs) must consider treatment or alternative sources. Given the experience of our utility members who have or are currently pursuing a treatment alternative, it is evident that the project design, permitting, bidding, funding, and execution phases are lengthy and will exceed the proposed three-year

implementation timeline. Compounding this issue are the current and expected supply chain delays for materials including pressure vessels.

We encourage EPA to adopt a staggered compliance timeline based on multiple tiers of PFAS concentration, with the compliance deadline occurring first for systems that have the highest PFAS concentrations. The remaining systems would have compliance deadlines in subsequent years based on their respective PFAS concentrations. This approach would create an aggressive timeline for the systems with the highest PFAS concentrations while providing many benefits – a more reasonable timeframe for assessment, design, permitting and construction; relief in the supply chain; and additional time for new technology to be brought to market.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as discussion on a phased-in MCL approach.

Connecticut Section of the AWWA (CTAWWA) and Connecticut Water Works Association (CWWA) (Doc. #1763, SBC-044234)

Federal funding sources are available to assist with PFAS mitigation for the next several years. These funds are critical in enabling utilities to limit the impact to ratepayers and preserving the affordability of drinking water. Therefore, we recommend extending the implementation time to ensure that funding sources can be fully utilized by utilities prior to the compliance deadline. This extension will also preserve public trust by ensuring that diligent utilities have sufficient time to execute a PFAS mitigation strategy prior to the compliance date. Supply chain pressure for PFAS treatment equipment and materials, in addition to workforce pressures, will also be reduced through this extension.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. For funding concerns, the agency notes that funds are also available through the passage of the BIL to assist many disadvantaged communities, small systems, and others with the costs of installation of treatment when it might otherwise be cost-challenging. Please see section 2.4 of the EPA response in this *Response to Comments* document for more discussion about currently available funding.

New Mexico Environment Department (NMED) (Doc. #1766, SBC-044252)

Small Systems

Approximately 80% of public water systems in New Mexico are small, serving populations of under 1,000 people and often operate with volunteer boards, administrators, and in some cases, operators. Small system compliance with the proposed PFAS MCL, regardless of the final value of the MCLs, will be challenging. Most small groundwater systems currently have minimal treatment installed. For those systems with no alternative source water, installation of one of the best available technologies may present a variety of challenges if the current treatment only consists of a chemical feed and a pressure tank. The entire water sector is facing workforce shortages, especially for certified operators, and this issue is particularly prevalent at small and disadvantaged water systems. The challenges around hiring and retaining operators will continue to be exacerbated as systems install treatment to comply with the PFAS MCL.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. For funding concerns, the agency notes that funds are also available through the passage of the BIL to assist many disadvantaged communities, small systems, and others with the costs of installation of treatment when it might otherwise be cost-challenging. Please see section 2.4 of the EPA response in this *Response to Comments* document for more discussion about currently available funding. Regarding concerns on operator certification licenses, please see the EPA response to comment Doc. #1567, SBC-042738 in section 12.1 in this *Response to Comments* document.

Bowling Green Municipal Utilities (Doc. #1767, SBC-043929)

• Impractical Implementation Timeline: EPA has provided an implementation timeline of 3 years for water systems to conduct initial monitoring and take subsequent mitigation actions if PFAS levels exceed the MCL. The default SDWA implementation timeline is not practical given the number of systems impacted, inter-related regulatory requirements, and current economic conditions. As proposed, within 3 years a system must:

o Conduct at least one year of monitoring to characterize occurrence at all of their points of entry to the distribution system at a time when laboratory capacity is already strained,

o Select and design a compliance strategy,

o Obtain primacy agency approval from state programs already facing limited capacity to meet current demands,

o Address primacy agency requirements triggered under other rules (e.g., Lead and Copper Rule) -- requirements that themselves will require testing and potentially a year or more of pilot testing, and

o Construct necessary improvements in the midst of well-recognized supply chain delays and workforce shortages.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Western Urban Water Coalition (WUWC) (Doc. #1768, SBC-043952)

Allowing public water systems to forego one initial sampling round also will not ensure that water utilities have sufficient time to ensure compliance within the proposed three-year rollout. Our members report that treatment plant upgrades typically take longer than three years from planning to completion, partly because of water utilities' capital planning obligations to their ratepayers. WUWC members anticipate needing to gather baseline data, conduct alternatives analysis, complete preliminary and final designs, obtain permits and complete environmental review where necessary, obtain budget approvals, and complete procurement processes before constructing and commencing operation of upgraded treatment plants capable of treating PFAS to proposed national drinking water standards. The three-year rollout also does not account for the potential cumulative effect of EPA's PFAS Strategic Action Plan and concurrent Advance Notice of Proposed Rulemaking, which envision future regulation of additional PFAS, their precursors, or groups of PFAS. The short timeline could force water utilities to invest large amounts of capital to quickly install treatment technologies to meet the standards in the Proposed Rule, only to find that additional treatment systems are required to remove additional types or precursors of PFAS. Accordingly, while allowing utilities to leverage existing data is helpful in the short-term, a longer implementation timeframe would be appropriate.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Council of State and Territorial Epidemiologists (CSTE) (Doc. #1770, SBC-044263)

5. Workforce Development and Training Needs: The new MCLs will result in the need for more public health staff especially in the areas of environmental health assessments and applied public health epidemiologists, as well as training for existing staff. An expanded applied public health epidemiologists and toxicologist workforce is needed to support biomonitoring studies, data collection, and sampling analysis. Some public health agencies do not have a state toxicologist at

the health department or are adequately training to support environmental health assessments which often take months or even years to complete due to the complexities. Furthermore, the existing public health workforce will require additional training and upskilling to fully respond, interpret and consult on the changes. Water operators will also need additional training on calculating compliance.

CSTE thanks the Environmental Protection Agency for its work towards promoting public health and delivering safe drinking water to communities across the United States. CSTE urges the EPA to consider the above resource needs and considerations to support epidemiologic needs within Public Health Agencies across the United States to support implementation of the regulation.

Sincerely,

Janet Hamilton, MPH

Executive Director

Council of State and Territorial Epidemiologists

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. In regard to commenter's statement that the final NPDWR will require "environmental health assessments" and other specialized roles (such as toxicologists and epidemiologists), the agency notes that the purpose of the NPDWR is to provide a national standard and regulation for six PFAS commonly found in drinking water based on the best available science. While public health epidemiologists and toxicologists serve important roles in protecting public health and the environment, these capacities do not play a direct role toward implementing the final rule (such as operating and maintaining treatment operators or monitoring for compliance). Regarding concerns on operator certification licenses, please see the EPA response to comment Doc. #1567, SBC-042738 in section 12.1 in this *Response to Comments* document.

Southwest Regional Water District (Doc. #1772, SBC-044727)

The District is very concerned with the compliance timeline that has been proposed for this regulatory rule. With the number of PWSs that could potentially be needing to make treatment changes, these projects will likely go to bid at similar times causing delays in construction and supply shortages. We request that flexibility is built into the compliance schedule and the USEPA work closely with those PWSs that are in violation of the MCLs.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to

SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Environmental Protection Network (EPN) (Doc. #1773, SBC-043876)

Compliance Requirements

EPA proposes allowing states to provide extended compliance dates to PWS needing additional time for capital improvements. For small systems serving at or below 3,300 people, the extension can be 14 years after this rule is promulgated. Fourteen years is unjustifiably too long given the availability of effective treatment technologies. EPA asks for public comment on whether there should be specific conditions mandated for PWS to be eligible for these extensions so that they are used only when no other viable alternatives exist. EPN agrees that there should be specific conditions mandated for PWS to be eligible for these extensions and recommends that state consideration of extending compliance dates for PWS with violations be a negotiated compliance agreement under a formal enforcement response to the violation. The specific conditions for extended compliance dates for a PWS should be set as a condition of state primacy for the new regulation. PWS in violation should continue to be reported in violation until they return to compliance under the negotiated compliance agreement.

EPA Response: The agency agrees with the commenter on the health concerns posed by PFAS and that establishing a national PFAS NPDWR as expeditiously as possible needed to protect public health and the environment. While individual state primacy agencies could require action sooner, the agency cannot do so for all PWSs regulated through this NPDWR. SDWA § 1412(b)(10) requires that a "NPDWR shall take effect "3 years after the date on which the regulation is promulgated unless the administrator determines that an earlier date is practicable." For all of the reasons provided in section 12.1 of the EPA response in this *Response to Comments* document, the EPA has determined that it is not practicable to require treatment earlier than 3 years after the date this regulation has been promulgated. Additionally, section 1412(b)(2) also authorizes "the Administrator, or a State (in the case of an individual system), may allow up 2 additional years to comply with a maximum contaminant level…if the Administrator or the State…determines that additional time is necessary for capital improvements. The agency has determined two additional years are necessary for capital improvements, and therefore, the agency is authorizing a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Whether to provide for additional extensions beyond the 5 years provided by this rule is at the discretion of the primacy agency; the strict criteria and process requirements for exemptions are discussed in section 12.1 of the EPA response in this *Response to Comments* document and are found in SDWA Section 1416. Due to the stringency of the existing criteria, EPA has not provided any further criteria as part of this rule but primacy agencies may adopt more stringent criteria than provided in Section 1416.

California-Nevada Section American Water Works Association (CA-NV AWWA) (Doc. #1775, SBC-045280)

9. EPA should extend the timeline for compliance to a more realistic period that will be achievable, at a minimum of six years, with options to extend the compliance deadline as warranted.

The proposed regulation will be difficult for water systems to achieve for several reasons, including planning for treatment systems capable of meeting the MCLs, capital project financing and construction, and in some cases, hiring or training operations staff. However, the proposed regulation would require all systems to comply within three years after final approval and promulgation.

Systems that encounter unavoidable obstacles or need extra time to comply with the MCLs should have options for compliance, particularly if the systems serve disadvantaged communities or are small systems with limited resources. Circumstances that may justify compliance extensions include unforeseen barriers for systems to develop alternative water sources, secure financing, complete design and construction of treatment facilities, or other factors.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline, as well as the criteria and process for further extensions allowed under SDWA Section 1416.

Eastern Municipal Water District (EMWD) (Doc. #1780, SBC-043824)

Lastly, EMWD would like to respectfully request EPA to extend the compliance deadline to five years from finalization of this regulation as contemplated in the Safe Drinking Water Act, instead of three years as proposed. Water agencies like EMWD will need to make a number of necessary infrastructure upgrades, which are time consuming and expensive. Water utilities are currently struggling to overcome the pressure of inflation, supply chain disruptions, and labor shortages, all of which further delay project delivery timelines and increase costs. EPA should extend the compliance deadline by two years to allow for additional time for capital improvements that will be necessary as part of the implementation of this regulation.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Ohio Water Utility Council (OWUC), Ohio American Water Works Association (OAWWA) (Doc. #1782, SBC-044724)

OWUC has great concern regarding the compliance schedule being proposed in this regulatory rule. As mentioned above, these proposed rules are just one of many important regulatory statues that PWSs are required to follow, including the Lead & Copper Rule Revisions with additional changes coming in the Lead & Copper Rule Improvements. Ohio water utilities are stretched thin already, economically and the available personnel. The parallel timeframe for the initial monitoring and ongoing compliance monitoring for the PFAS substances identified in the proposed rule and LCRR/LCRI will create an extreme burden on Ohio's PWSs and the rate payers. We are requesting that flexibility or significant extensions be built into the compliance schedule and the USEPA work closely with those PWSs that are in violation of the MCLs.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges, as well as simultaneous compliance challenges, that may affect the compliance timeline.

City of Tulsa Water and Sewer Department (CoT WSD) (Doc. #1785, SBC-043785)

7. 88 FR 18684. Statement in preamble that, "Water systems with PFAS levels that exceed the MCLs proposed would need to take action to provide drinking water which meets the NPDWR by the compliance dates established in the rule when final."

8. 88 FR 18684. Statement in preamble that, "EPA estimates GAC treatment will be sufficiently available to support cost-effective compliance with this proposed regulation…"

CoT WSD has concerns that there was little discussion in the preamble regarding timeline for compliance if initial monitoring data showed non-compliance with the MCL, and installation of new treatment is required to achieve compliance with the NPDWR. EPA's expects to finalize this rule at the end of 2023, with proposed compliance date three years after promulgation of rule, i.e. the end of 2026. UCMR5 monitoring continues through the end of 2025, so some systems may only have less than a year before compliance date. EPA states (88 FR 18689) that it will not provide a two-year extension allowed by SDWA, but States can issue extensions on an individual basis. This will increase the burden on states in the implementation of this rule. Given a conservative estimate of 3.5-4 years for a capital project to reach completion, a two-year extension would not be sufficient.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments*

document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

PFAS Project Lab (Doc. #1786, SBC-044710)

May 30, 2023

Public comments on the U.S. EPA PFAS National Primary Drinking Water Regulation Rulemaking, 40 CFR Parts 141 and 142.

We are writing in support of the U.S. Environmental Protection Agency's proposed PFAS National Primary Drinking Water Regulations for six PFAS compounds. The PFAS Project Lab (www.pfasproject.com) is an interdisciplinary academic research group that studies the scientific, social, and political factors related to PFAS. We produce accessible research and information about PFAS contamination and work in collaboration with impacted communities to address this significant health and environmental crisis. We also collaborate with state and federal agencies and have provided testimony on state regulation. We were involved in the 2022 NASEM Guidance on PFAS Testing and Health Outcomes. Since organizing the inaugural National PFAS Conference in 2017, we have played a major role in this biennial conference, which is a highly visible venue. Indeed, EPA announced its revised Health Advisory for certain PFAS at our June 2022 conference. Our map of known and presumptive PFAS contamination sites (PFAS Project Lab 2023), jointly produced with our collaborators at Silent Spring Institute, is widely used across the US and was the prompt to European investigative journalists to prepare a similar map for Europe (Dagorn et al. 2023).

EPA must act quickly to implement long overdue drinking water regulations for this class of chemicals with serious environmental and human health impacts.

EPA Response: The agency agrees with the commenter on the health concerns posed by PFAS and that establishing a national PFAS NPDWR as expeditiously as possible is needed to protect public health and the environment.

Fairfax Water (Doc. #1789, SBC-045314)

4. The underestimation of utilities impacted by the proposed rule and the unrealistic compliance deadline will place significant demand on limited resources for consulting engineers, contractors, suppliers, and primacy agency support to achieve compliance. This will lead to further cost increases and rampant noncompliance which would be contrary to the objective of the regulation.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. After considering public comment, the EPA has made a number of

adjustments to the cost model and collectively these changes have increased the agency's estimated annualized costs. The EPA has used the best available peer reviewed science to inform the cost estimates, including treatment costs of the final PFAS NPDWR. For additional discussion on cost considerations when establishing the final MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Fairfax Water (Doc. #1789, SBC-045310)

Summary

While Fairfax Water supports the goal of the proposed PFAS rule, a compliance deadline that is not founded in reality could ultimately lead to thousands of utilities being out of compliance. Rampant noncompliance places an unnecessary burden on primacy agencies and EPA and undermines the confidence of the public in its drinking water. The public would be better served by knowing the path to compliance is achievable rather than by being routinely notified that their drinking water fails to meet standards. Repeated notices of noncompliance will only drive more people to drink bottled water under the false impression that it is safer when it is not regulated by the same EPA PFAS standard. Many who choose bottled water may be those who can least afford to do so.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Fairfax Water (Doc. #1789, SBC-045299)

At the proposed MCL and HI levels, the rule will place significant demand on a limited pool of resources to achieve compliance. Too many utilities will be competing for the same consulting engineers, construction contractors, and suppliers at the same time. These limitations will invariably lead to cost escalations beyond what EPA currently estimates. The pool for construction contractors for water infrastructure projects is already stressed. Utilities are seeing fewer bidders, sometimes only one bidder, and bids are consistently higher than engineers' estimates. Utilities, consulting engineers, and contractors are all facing workforce challenges. Cost increases due to competition for limited resources will further strain the ratepaying public and drinking water affordability.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments*

document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Fairfax Water (Doc. #1789, SBC-045304)

Unrealistic Timeframe for Compliance

The proposed rule provides only three years for compliance from final rulemaking. While utilities can apply for a two-year extension from their primacy agency, extensions are not guaranteed. Even a five-year period to comply ignores the realities of implementing capital projects such as the addition of GAC, ion exchange (IX), or reverse osmosis (RO) treatment trains to existing plants. Any of these treatment alternatives would need to be piloted for at least one year to capture seasonal variations in source water quality. Depending on the alternative being studied, pipe loop studies may also be required to ensure that multiple competing regulations do not result in non-compliance. Certainly, any utility contemplating a change in source water to achieve PFAS compliance would need to undertake pilot plant and pipe loop studies to avoid unintended consequences in the distribution system. Additionally, utilities will have to develop the financial capacity to implement these capital projects. Utilities will have to increase rates, issue bonds, secure grants and/or loans, or a combination of these. All of these efforts take time, but funds have to be in hand before design and construction can proceed.

Fairfax Water, like many utilities, must go through local land use or zoning processes to obtain approval to construct any of our facilities. In our case, the zoning approval process can take six to eighteen months, preceded by at least six months of preliminary engineering, development of other application materials including an alternatives analysis, and public outreach. The zoning process is separate from and a prerequisite to obtaining site plans and building permits, processes that will take another six to twelve months. In between zoning and site permitting, the detailed design and development of bid documents would occur, a process that would easily take twelve to eighteen months depending on the complexity of the selected treatment process.

Public utilities are subject to public procurement regulations. These processes add additional time to the design and construction process. Development of a request for proposals for project design services, receipt and review of proposals, consultant selection, fee negotiation, and contract award will take a minimum of six months. The process for receiving bids for construction and awarding those contracts will take another three to six months. While some public utilities may be able to employ alternative procurement methods, not all are able to do so, and alternative methods will only shorten timeframes associated with design and construction.

The treatment alternatives identified in the rule (GAC, IX, RO) would be additions to existing treatment trains. Construction phasing to maintain plant operations and ensure an adequate supply of drinking water to the public at all times will be critical. Tie-ins to existing infrastructure must occur during low demand periods (wintertime) to ensure sufficient water production capacity to meet community needs. These construction staging intricacies will further lengthen the time to construct PFAS treatment improvements. Construction and commissioning

timeframes will be project and site specific but could easily take three years (see attached illustrative project schedule).

Fairfax Water, like other utilities, continues to experience significant delays for equipment and materials that were readily obtained prior to the pandemic. In addition to more realistic timeframes noted above for capital project execution, the proposed compliance period does not account for the supply chain challenges we continue to face. Our GAC supplier has advised that the lead time for GAC vessels for PFAS treatment is eighteen months. This is the lead time before a PFAS rule is finalized. Fairfax Water was paying $1.37/lb. for GAC just last year; now we are paying $1.60/lb. - a 17% increase. Without EPA knowing with certainty how many utilities need to implement treatment for PFAS, it is impossible to know what the supply chain challenges will be, to accurately evaluate the capacity of vendors to meet demand or to forecast the impact on pricing in a supply restricted environment. Fairfax Water recommends that EPA provide at least seven years for compliance from the adoption of the final rule to reflect the realities of capital project delivery and supply chain constraints. Otherwise, taken together, these time constraints are very likely to make the regulation's timeframe aspirational rather than practicable.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline and additional extensions that can be provided on a case-by-case basis under SDWA Section 1416.

Massachusetts Municipal Association (MMA) (Doc. #1800, SBC-043768)

As communities have learned throughout implementation of the Massachusetts PFAS6 MCL of 20 ppt, the process to get treatment facilities up and running is a lengthy one. Local land use or zoning processes, thoughtful design, procurement, development and construction has taken longer than anticipated in Massachusetts, and many communities are still in the process of installing treatment 3 years into our enforceable state maximum contaminant level. The cities and towns of Massachusetts have devoted local resources to build public awareness campaigns necessary to ensure trust and confidence in public water across the state, and assistance will be needed on a federal level to fill gaps in understanding. Thus, we also urge the EPA to provide a longer implementation timeline to make this more practical for cities and towns across the country.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments*

document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Massachusetts Municipal Association (MMA) (Doc. #1800, SBC-043765)

In addition to capital expenditures, municipalities bear the ongoing costs to provide PFAS-free drinking water during the construction period for the treatment plants and future costs to dispose of PFAS-laden filters and media. The true costs to build, staff, and run treatment plants to comply with a more stringent MCL will likely be much higher, especially when supply chain issues and increased demand to comply with a national standard are factored into the equation.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline and responses regarding cost issues topic 13.

Safe Drinking Water Branch, Hawaii Department of Hawaii (Doc. #1801, SBC-043751)

Workforce

The treatment technology such as GAC, IX and RO, requires the operators to have another higher-level certification. Achieving these certifications will require staff time and resources that will challenge the sustainability of many smaller water systems.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. Regarding concerns on operator certification licenses, please see the EPA response to comment Doc. #1567, SBC-042738 in section 12.1 in this *Response to Comments* document.

Palm Beach County Water Utilities Department (Doc. #1802, SBC-045337)

Page 18683, IX.F. Third column first full paragraph, " this proposed rule would require compliance three years after promulgation. To satisfy initial monitoring requirements and demonstrate rule compliance, within the three years following rule promulgation, groundwater systems serving a population greater than 10,000 and all surface water systems will be required to demonstrate their baseline concentrations using data from four quarterly samples collected over a one- year period.":

PBCWUD Comment: PBCWUD will be required to replace two lime softening plants with membrane filtration plants. The costs for this work is expected to be $S00M (2023 dollars) and will take 6 years to complete. Considering we will not be the only utility required to construct new facilities 6 years should be considered an optimistic estimate considering current labor, and worldwide equipment and material shortages. PBCWUD recommends changing the proposed rule to allow compliance within six years after promulgation. Allowances taking into account the availability of funding should also be considered.

Page 18684,X.A. First column entire section, " A. What are the Consumer Confidence Report requirements?":

PBCWUD Comment: Compliance with and public reporting via the Consumer Confidence Report (CCR) is another reason to set compliance to no earlier than 6 years after promulgation. It will not be possible for our utility to come into compliance within three years considering new water plants must be constructed.

Page 18694, XIII.C.1.c. First column first paragraph," on the range of component levels assumed and the range of estimated PFAS treatment costs.":

PBCWUD Comment: PBCWUD has already planned to replace two lime softening plants with membrane filtration plants and are part of this utility's long term planning and financing program. Installing granular activated carbon (GAC) as a stop-gap is not cost effective since the future membrane filtration plants will treat the drinking water to a greater standard than GAC. Therefore, the GAC systems will be replaced before the end of their useful life span.

The costs for this work is expected to be $S00M (2023 dollars) and take 6 years to complete. Considering we will not be the only utility required to construct new facilities 6 years should be considered an optimistic estimate considering current labor, and worldwide equipment and material shortages. PBCWUD recommends changing the proposed rule to allow compliance within six years after promulgation. Allowances taking into account the availability of funding should also be considered.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10).. Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as exemptions under SDWA Section 1416.

National Ground Water Association (NGWA) (Doc. #1804, SBC-045459)

Small System Exemptions to Achieve Compliance – EPA asked for comments on this topic. While small systems exemptions may be useful to limit investment until adequate treatment technology may be available, this approach seems counter to being health protective for the people affected.

EPA Response: Regarding the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on exemptions under SDWA 1416 as well as supply chain and labor challenges that may affect the compliance timeline.

Laurens County Water and Sewer Commission (LCWSC) (Doc. #1805, SBC-043745)

Advanced technologies needed for PFAS treatment may require advanced licensing of water plant operators, an already depleting resource in many areas of the country. Additionally, water treatment plant design can be a complex and expensive exercise.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. Regarding concerns on operator certification licenses, please see the EPA response to comment Doc. #1567, SBC-042738 in section 12.1 in this *Response to Comments* document.

Laurens County Water and Sewer Commission (LCWSC) (Doc. #1805, SBC-043746)

The engineering Community struggles with the recent influx of water, sewer, stormwater, highway, and other projects that are being completed in the next 3-5 years due to ARPA. Adding more construction projects over the next 3-5 years is completely unrealistic.

We will have to pay design premiums and may not get the quality of work we normally would, due to the unprecedented volume of work. Even if the projects can be designed and bid on, the construction industry is already overburdened and will fall further behind when we add these drinking water plant upgrades to the already enormous number of projects. I am not sure what the market can withstand financially, but feel confident it will not be in our best interest.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Laurens County Water and Sewer Commission (LCWSC) (Doc. #1805, SBC-043748)

We think EPA needs to provide significant schedule flexibility in light of the thousands of facilities which EPA expects will be affected, the enormous cost, and the historically thin engineering and construction industry capacities. Three years is nowhere near enough time for so many water systems to plan, design, fund, and construct significant upgrades to their water

systems. This truncated and rushed schedule also increases the associated cost estimates, making the rule as proposed completely infeasible.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. The agency has evaluated the feasibility of the final standards; please see section 5 of the EPA response in this *Response to Comments* document for additional discussion. Additionally, the agency disagrees with commenter claims that the EPA did not consider the impacts of operation and residuals disposal; please see sections 5.1.3 (cost considerations and alternative MCLs), 10.4 (management of treatment residuals), and 13.3 (methods for estimating cost) of the EPA response in this *Response to Comments* document for additional discussion. With respect to operator training, please see the EPA response to comment Doc. #1567, SBC-042738 in section 12.1 in this *Response to Comments* document.

Laurens County Water and Sewer Commission (LCWSC) (Doc. #1805, SBC-043749)

We believe the EPA should republish the proposed rule with a phased/tiered step-down MCL and Hazard Index approach that might look like the following:

50 ppt for PFOA/PFOS and a Hazard Index of "5.0" effective December 31 , 2024

15 ppt for PFOA/PFOS and a Hazard Index of "3.0" effective December 31, 2034

4 ppt for PFOA/PFOS and a Hazard Index of "1.0" effective December 31, 2044

Others in our industry have shown significant concern that EPA has not used the available human health PFAS-related data both from the Federal Drug Administration and its own information from PFAS hotspots around the country. Unfortunately, with the level of expertise we have on staff, and the short time that was given to read thousands of pages of material, we cannot offer appropriate comments, as there has not been a reasonable opportunity to develop the knowledge and understanding to make them. We do have concerns that this abbreviated effort has been unfair to not allow smaller utilities to become educated and make thoughtful arguments either for or in opposition to the proposed regulation.

Again, we appreciate the opportunity to comment and want to reiterate that we do not oppose any necessary and appropriate public health-related requirements. However, we believe that EPA must reconsider a number of material aspects relating to its development of the proposed rule, the MCL levels, how the MCLs might be better structured to ensure that water systems are updated using in an orderly manner following an appropriate priority matrix.

Jeff Field

Executive Director

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as discussion on a phased-in MCL approach. The commenter didn't provide supporting information for the agency to evaluate on the "significant concerns that EPA has not used the available human health PFAS-related data both from the Federal Drug Administration and its own information from PFAS hotspots around the country." The EPA's final rule represents data-driven drinking water standards that are based on the best available science and meet the requirements of SDWA; regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water.

Office of Advocacy at the U.S. Small Business Administration (Doc. #1807, SBC-045490)

b. EPA should provide additional time for compliance based on funding availability and to address any anticipated capacity issues.

The challenges associated with obtaining and using federal or state funding for compliance will likely not allow timely compliance with EPA's proposed requirements. During EPA's public hearing, several stakeholders including those representing small water systems expressed concerns about the three-year timeframe. Specifically, a Colorado stakeholder shared that a recent implementation of a treatment technology spanned a five-year period. Advocacy is concerned that EPA neglected to adequately consider the regulatory flexibility to provide an extended compliance timeline for small entities. In the Initial Regulatory Flexibility Analysis [FN16: Economic Analysis at pgs. 9-7-9-8.], EPA declined to extend compliance timelines in response to the panel recommendation to consider rule implementation delays for potential laboratory capacity-related challenges. Capacity-related challenges could potentially impact the ability of water systems to monitor for PFAS and reasonably comply with the proposed requirements. Instead, the agency referred to a state's ability to provide extensions under SDWA [FN17: The agency cites to 42 U.S.C. §300g–1(b)(10) (a state or EPA may grant an extension of up to two additional years to comply with an NPDWR's MCL if the state or EPA determines a system needs additional time for capital improvements) and to 42 U.S.C. § 300g-4 (states may provide such as extension on an individual system basis which may address compliance issues associated with treatment, laboratory, and disposal capacity).]. Obtaining an extension from a state for capital improvements or for other compliance issues will likely deplete the limited resources of the small water systems. Advocacy recommends that EPA conduct extensive outreach with small entities to better understand their ability to comply, including access to funding, availability of resources such as training staff, any potential supply chain issues or construction delays and lab and disposal capacity issues. To address these concerns, Advocacy encourages the agency to take predevelopment timelines and the availability of resources into account when reconsidering the compliance timeframe. Therefore, to ensure compliance,

Advocacy recommends that the EPA extend the compliance timeframe for small entities beyond the three years proposed.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. After finalization of the PFAS NPDWR, the EPA also intends to work with stakeholders to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation and will consider the topics suggested by the commenter as the agency develops implementation materials for the final NPDWR. For more on the EPA's evaluation of small entity impacts under the Regulatory Flexibility Act (RFA), including the initial and final regulatory flexibility analysis, please see section XIII.C. of the final rule preamble.

Office of Advocacy at the U.S. Small Business Administration (Doc. #1807, SBC-045485)

c. EPA does not account for other factors that will further deter timely compliance.

Even if small water systems somehow obtained the necessary funding to comply with the rule, significant challenges will complicate timely compliance. These challenges include personnel shortage, supply chain disruptions, limited lab capacity, limited disposal capacity and availability of affordable treatment technologies. A small entity representative to the SBREFA panel noted that PFAS treatment technologies require specialized training for sampling and a likely shortage of operators is imminent and will contribute to challenges associated with timely compliance.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. Regarding concerns on operator certification licenses, please see the EPA response to comment Doc. #1567, SBC-042738 in section 12.1 in this *Response to Comments* document.

Office of Advocacy at the U.S. Small Business Administration (Doc. #1807, SBC-045487)

Small entity representatives have also shared that given the low levels proposed, compliance will likely require treatment, which will lead to supply chain issues since most water systems will need to implement treatment technologies.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments*

document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

West Virginia Municipal Water Quality Association (Doc. #1816, SBC-044666)

The enormous costs experienced so far are likely to increase even further due to supply chain, worker shortage, inflation, and the unprecedented number of public utility/highway infrastructure projects being attempted over the next five-to-ten years. Adding PFAS barrier technology at thousands (according to US EPA) of drinking water plants nationwide can only further increase national engineering and construction prices.

There are simply not enough engineers, contractors, or workers to implement all these projects. Forcing PFAS barrier technology to the head of the line will trigger unprecedented cost premiums. It will also force utilities to delay needed infrastructure projects that protect human health, such as water main replacements and other projects to replace aging infrastructure. Infrastructure replacement delays will equate to more risk, less redundancy, less resiliency, and ultimately higher costs for utilities.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

West Virginia Municipal Water Quality Association (Doc. #1816, SBC-044671)

The sheer number of facilities that will have to install PFAS barrier technologies – 3-6,000 facilities by EPA's own estimate – demonstrates the impracticability of the 3-year (up to five for very small systems serving fewer than 10,000 population) implementation schedule. The treatment technology needed to comply with the proposed rule is simply not in place at this time, nor will it be to the extent needed to meet a 3-5-year national compliance schedule.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. For additional discussion on treatment availability and capacity, please see section 10.6 of the EPA response in this *Response to Comments* document.

West Virginia Municipal Water Quality Association (Doc. #1816, SBC-044677)

EPA must provide unprecedented implementation schedule flexibility for this unprecedented rule. This is warranted particularly in light of the thousands of facilities which EPA expects will be affected, the enormous cost, and the historically thin capacities of the engineering and construction industries (including the manufacturers of the supplies and equipment needed for PFAS barrier projects). Three years is nowhere near enough time for so many water systems to plan, design, permit, fund, and construct significant upgrades to their water systems. This truncated and rushed schedule also increases the associated cost estimates, making the rule as proposed completely infeasible. Additionally, the full impacts of operation and residuals disposal have not been fully considered. Not only will O&M costs significantly increase, but many utilities lack the ability to draw additional staff with the expertise to run these types of advanced water treatment systems.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. The agency has evaluated the feasibility of the final standards; please see section 5 of the EPA response in this *Response to Comments* document for additional discussion. Additionally, the agency disagrees with commenter claims that the EPA did not consider the impacts of operation and residuals disposal; please see sections 5.1.3 (cost considerations and alternative MCLs), 10.4 (management of treatment residuals), and 13.3 (methods for estimating cost) of the EPA response in this *Response to Comments* document for additional discussion. With respect to operator training, please see the EPA response to comment Doc. #1567, SBC-042738 in section 12.1 in this *Response to Comments* document.

West Virginia Municipal Water Quality Association (Doc. #1816, SBC-044675)

IV. A Decade-Plus Implementation Schedule is Needed or a Phased/Tiered Step-Down MCL Approach.

Water treatment plant design is a very complex and challenging exercise. Extensive facility-specific pilot studies will be needed to ensure we install the proper treatment for the PFAS chemicals present in each facility's raw water supply. We are in a period of unprecedented shortage of design engineers as the engineering community struggles with the gusher of water, sewer, stormwater, highway, and other projects that are being crammed into the next 3-5 years due to ARPA, BIL, and State budget surplus infrastructure investments. Adding even (EPA's estimated) 3-6 thousand water plant PFAS barrier projects on top of this over the next 3-5 years is completely unrealistic. We will have to pay design premiums and may not get the quality of work we need due to the unprecedented volume of work the engineering community faces. Even if the projects can be piloted, planned, designed, permitted, funded, and bids received, the

construction industry is already overburdened and will fall further behind when we add these drinking water plant upgrades to the already enormous number of projects. For the past year we have already seen no bids on projects that normally would get several bids. Where there have been bids, they have almost universally been higher than the engineer's (updated) estimate, if not shockingly higher. This fact is compounded by construction material supply chain delays, which lead to longer project schedules that contribute to higher bids.

Small systems will struggle the most because engineering and construction firms will want to prioritize work for their larger clients because they will comprise the bulk of their future work. Small systems will be more one-and-done-type projects. Moreover, smaller systems may lack the sophistication and middle management to oversee and interact with contractors on such projects. As such smaller systems should have additional compliance flexibility.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as discussion on a phased-in MCL approach. For funding concerns, the agency notes that funds are also available through the passage of the BIL to assist many disadvantaged communities, small systems, and others with the costs of installation of treatment when it might otherwise be cost-challenging. Please see section 2.4 of the EPA response in this *Response to Comments* document for more discussion about currently available funding.

West Virginia Municipal Water Quality Association (Doc. #1816, SBC-044678)

EPA should defer rule adoption while it takes into account the appropriate levels of PFOA/PFOS (as well as the hazard index four chemicals), environmental updated costs and benefits, and other significant factors such as environmental justice.

As part of that re-evaluation, EPA should republish the proposed rule and seek public comment on a phased/tiered step-down MCL and Hazard Index approach that might look like the following:

• 10 ppt for PFOA/PFOS and 5 Hazard Index effective 12 months from the date of publication with a compliance schedule of up to 10 years from the effective date.

• 8 ppt for PFOA/PFOS and a 3 Hazard Index with an effective date of 2029 and a compliance deadline of no more than 10 years from the effective date.

• 4 ppt for PFOA/PFOS and a 1 Hazard Index with an effective date of 2034 and a compliance deadline of no more than 10 years from the effective date.

While the deadlines for MCLs are statutory in nature, we believe the phased effective date approach above would serve to provide EPA, the States, and affected water systems with the time necessary to implement PFAS barrier technologies.

EPA Response: The EPA disagrees with commenter assertions that the agency did not "account the appropriate levels of PFOA/PFOS (as well as the Hazard Index four chemicals), environmental updated costs and benefits, and other significant factors such as environmental justice." Analytic feasibility was evaluated when establishing the final MCLs (see section 5 of the EPA response in this *Response to Comments* document for more information). The EPA conducted robust occurrence analyses, as described in sections III and VI of the preamble and sections 3 and 7 of this *Response to Comments* document. The agency also conducted a robust environmental justice analysis discussed in the final rule preamble (section XII) and within section 14.10 of the EPA's *Response to Comments* document. The EPA's final rule represents data-driven drinking water standards that are based on the best available science and meet the requirements of SDWA; regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as discussion on a phased-in MCL approach.

West Virginia Municipal Water Quality Association (Doc. #1816, SBC-044679)

Only if such a phased approach is unworkable should EPA resort to an advance exercise of its enforcement discretion to provide additional implementation time. Such an approach would be advisory to delegated states and would provide, in general, federally pre-approved compliance schedule parameters for the States to work within.

While many systems will need more time, EPA and the states will also want to ensure that limited engineering, agency, funding, and contractor resources are directed to systems with the highest priority (highest PFAS levels, significant environmental justice considerations, etc.). It is strongly in the public interest for EPA to issue the MCLs in a way that ensures the most impacted systems are able to upgrade earlier than systems that may be only marginally impacted or upgrading out of convenience or an abundance of caution.

EPA and the states could also allow compliance schedule flexibility up front for utilities that need it through EPA and/or state administrative orders giving systems with lower priority more time to meet the MCLs. This is a formalized variant of the agency enforcement discretion approach. This could be done on a case- by-case basis.

Again, we believe the best course is for EPA to adopt phased MCLs as follows:

10 ppt for PFOA/PFOS and a Hazard Index of "5.0" effective December 31, 2024 8 ppt for PFOA/PFOS and a Hazard Index of "3.0" effective December 31, 2029 4 ppt for PFOA/PFOS and a Hazard Index of "1.0" effective December 31, 2034

A compliance schedule of up to ten years would apply to each effective date. Even with this approach, enforcement discretion will be necessary to ensure that water system PFAS barrier installations are appropriately scheduled.

In support of this approach, we note that in 1979, EPA issued a final rule setting a MCL and associated monitoring and reporting requirements for total trihalomethanes (TIHMs). 44 Fed. Reg. 68,824 (Nov. 29, 1979). The MCL had phased implementation for facilities of different sizes written within the MCL:

For community water systems serving 75,000 or more persons, monitoring must begin 1 year following promulgation and the effective date of the MCL is 2 years following promulgation. For community water systems serving 10,000 to 75,000 persons, monitoring must begin within 3 years from the date of promulgation and the effective date of the MCL is 4 years from the date of promulgation.

Id. at 68,824. [FN3: We would note many of the relevant issues for that rulemaking are the same for this proposed rule: "EPA specifically solicited and received comments on the following major issues: The rationale for setting an MCL for TTHMs and the magnitude of the MCL; the feasibility of and timing for phased reduction of the MCL; the concept of phasing the application of the MCL based upon system size; an alternative of making the MCL applicable to all public water systems and to phase the implementation by a deferred monitoring schedule linked to population size … the availability of technology to achieve compliance …and the costs incurred by public water systems to achieve compliance with the MCL." Id. (emphasis added).] Several components went into this decision to implement phases, including inadequate lab capacity with an increased lab demand. Id. at 68,629. EPA characterized this type of delay as extending the time frame for the initiation of requirements. Id. at 68,630 (emphasis added). Thus, there is precedent for the phasing/tiered approach we suggest – which can also be viewed as a phased timeframe for initiating the requirements of the proposed PFAS MCLs to community water systems based upon the PFAS levels in their finished drinking water.

Another approach would be for EPA to provide a phase-in schedule by means of a group or class "exemption" adopted as part of, or concurrently with, the PFAS MCL regulations. See Safe Drinking Water Act §§ 1415, 1416. The exemption might have multiple tiers based on PFAS concentrations – the lower the concentration the longer the phase-in period – and be temporary, and expire in phases, e.g., 10 / 8 / 4 ppt, over 5 / 10 / 15 years, respectively. If exemptions cannot be issued on a group/class basis, EPA could announce a general expectation that States may approve exemptions for defined groups for defined periods, and the States then develop implementation schedules on an individual (but pre-determined) basis.

It is clear that EPA must phase water plant upgrades over at least the next 10-20 years. It is patently obvious that we can't install PFAS barrier technology at 3-6,000 water plants nationwide in a shorter period.

Finally, phasing the MCL in over time will reinforce for the public that the PFAS levels they will experience over the next 10-20 years are not the end of the world. The reality is that the vast majority of Americans have experienced significantly higher PFAS levels for decades than they do now. We understand that the federal government has been assessing both PFOA and PFOS blood lead levels in thousands of Americans for several decades and that the levels have plummeted. We expect those levels to plummet further with the intense governmental, legislative, and litigation focus on eliminating the use of PFAS chemicals.

We believe the health monitoring testing that has been done in PFAS hot spot areas such as Parkersburg and Vienna, West Virginia reinforce the fact that levels nationwide are dropping and that means that some necessary prioritization and phasing of water plant PFAS barrier installations is both warranted and appropriate.

V. State Permitting/Funding Agency Capacity to Permit and Fund PFAS Barrier Technology Projects is at an All Time Low.

State public health agencies are facing the same historic worker retirement and shortage phenomenon as everyone else. The tiered/phased MCL adoption and implementation approach that we suggest above is also necessary given the reality that State health agencies are simply unable to handle 3-6,000 PFAS barrier installation projects over the next few years on top of all the other projects they are being asked to manage. Even when funding is available for additional staff, the States have struggled to attract (and retain) staff given the competition from the private sector (which is woefully understaffed, and which pays better).

EPA must address this significant potential bottleneck in any MCL implementation schedule it adopts as part of the final rule.

EPA Response: With respect to health monitoring testing, the EPA believes that this type of biomonitoring can be an important tool to identify changes in population exposure over time. However, as discussed in section III of the final rule preamble and section III of the EPA's *Response to Comments* document (see final regulatory determinations), the agency has sufficient information now to regulate the six PFAS included in the final NPDWR. The EPA's final rule represents data-driven drinking water standards that are based on the best available science and meet the requirements of SDWA; regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10) which is the maximum that can be provided in an NPDWR. However, as discussed further in section 12.1 of the EPA response in this *Response to Comments* document, primacy agencies can provide additional time through case-by-case exemptions under SDWA Section 1416. Under SDWA EPA cannot mandate exemptions; these are solely at the discretion of the primacy agency and must be issued

pursuant to the criteria and processes set out in SDWA Section 1416. Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as discussion on a phased-in MCL approach.

Association of Missouri Cleanwater Agencies (Doc. #1817, SBC-044644)

The enormous costs experienced so far are likely to increase even further due to supply chain, worker shortage, inflation, and the unprecedented number of public utility/highway infrastructure projects being attempted over the next five-to-ten years. Adding PFAS barrier technology at thousands (according to US EPA) of drinking water plants nationwide can only further increase national engineering and construction prices.

There are simply not enough engineers, contractors, or workers to implement all these projects. Forcing PFAS barrier technology to the head of the line will trigger unprecedented cost premiums. It will also force utilities to delay needed infrastructure projects that protect human health, such as water main replacements and other projects to replace aging infrastructure. Infrastructure replacement delays will equate to more risk, less redundancy, less resiliency, and ultimately higher costs for utilities.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Association of Missouri Cleanwater Agencies (Doc. #1817, SBC-044656)

EPA should defer rule adoption while it takes into account the appropriate levels of PFOA/PFOS (as well as the hazard index four chemicals), environmental updated costs and benefits, and other significant factors such as environmental justice.

As part of that re-evaluation, EPA should republish the proposed rule and seek public comment on a phased/tiered step-down MCL and Hazard Index approach that might look like the following:

• 10 ppt for PFOA/PFOS and 5 Hazard Index effective 12 months from the date of publication with a compliance schedule of up to 10 years from the effective date.

• 8 ppt for PFOA/PFOS and a 3 Hazard Index with an effective date of 2029 and a compliance deadline of no more than 10 years from the effective date.

• 4 ppt for PFOA/PFOS and a 1 Hazard Index with an effective date of 2034 and a compliance deadline of no more than 10 years from the effective date.

While the deadlines for MCLs are statutory in nature, we believe the phased effective date approach above would serve to provide EPA, the States, and affected water systems with the time necessary to implement PFAS barrier technologies.

EPA Response: The EPA disagrees with commenter assertions that the agency did not "account the appropriate levels of PFOA/PFOS (as well as the Hazard Index four chemicals), environmental updated costs and benefits, and other significant factors such as environmental justice." Analytic feasibility was evaluated when establishing the final MCLs (see section 5 of the EPA response in this *Response to Comments* document for more information). The EPA conducted robust occurrence analyses, as described in sections III and VI of the preamble and sections 3 and 7 of this *Response to Comments* document. The agency also conducted a robust environmental justice analysis discussed in the final rule preamble (section XII) and within section 14.10 of the EPA's *Response to Comments* document. The EPA's final rule represents data-driven drinking water standards that are based on the best available science and meet the requirements of SDWA; regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as discussion on a phased-in MCL approach.

Association of Missouri Cleanwater Agencies (Doc. #1817, SBC-044657)

Only if such a phased approach is unworkable should EPA resort to an advance exercise of its enforcement discretion to provide additional implementation time. Such an approach would be advisory to delegated states and would provide, in general, federally pre-approved compliance schedule parameters for the States to work within.

While many systems will need more time, EPA and the states will also want to ensure that limited engineering, agency, funding, and contractor resources are directed to systems with the highest priority (highest PFAS levels, significant environmental justice considerations, etc.). It is strongly in the public interest for EPA to issue the MCLs in a way that ensures the most impacted systems are able to upgrade earlier than systems that may be only marginally impacted or upgrading out of convenience or an abundance of caution.

EPA and the states could also allow compliance schedule flexibility up front for utilities that need it through EPA and/or state administrative orders giving systems with lower priority more time to meet the MCLs. This is a formalized variant of the agency enforcement discretion approach. This could be done on a case-by-case basis.

Again, we believe the best course is for EPA to adopt phased MCLs as follows:

10 ppt for PFOA/PFOS and a Hazard Index of "5.0" effective December 31, 2024

8 ppt for PFOA/PFOS and a Hazard Index of "3.0" effective December 31, 2029

4 ppt for PFOA/PFOS and a Hazard Index of "1.0" effective December 31, 2034

A compliance schedule of up to ten years would apply to each effective date. Even with this approach, enforcement discretion will be necessary to ensure that water system PFAS barrier installations are appropriately scheduled.

In support of this approach, we note that in 1979, EPA issued a final rule setting a MCL and associated monitoring and reporting requirements for total trihalomethanes (TIHMs). 44 Fed. Reg. 68,824 (Nov. 29, 1979). The MCL had phased implementation for facilities of different sizes written within the MCL:

For community water systems serving 75,000 or more persons, monitoring must begin 1 year following promulgation and the effective date of the MCL is 2 years following promulgation. For community water systems serving 10,000 to 75,000 persons, monitoring must begin within 3 years from the date of promulgation and the effective date of the MCL is 4 years from the date of promulgation.

Id. at 68,824 [FN3: We would note many of the relevant issues for that rulemaking are the same for this proposed rule: "EPA specifically solicited and received comments on the following major issues: The rationale for setting an MCL for TTHMs and the magnitude of the MCL; the feasibility of and timing for phased reduction of the MCL; the concept of phasing the application of the MCL based upon system size; an alternative of making the MCL applicable to all public water systems and to phase the implementation by a deferred monitoring schedule linked to population size … the availability of technology to achieve compliance …and the costs incurred by public water systems to achieve compliance with the MCL." Id. (emphasis added).]. Several components went into this decision to implement phases, including inadequate lab capacity with an increased lab demand. Id. at 68,629. EPA characterized this type of delay as extending the time frame for the initiation of requirements. Id. at 68,630 (emphasis added). Thus, there is precedent for the phasing/tiered approach we suggest – which can also be viewed as a phased timeframe for initiating the requirements of the proposed PFAS MCLs to community water systems based upon the PFAS levels in their finished drinking water.

Another approach would be for EPA to provide a phase-in schedule by means of a group or class "exemption" adopted as part of, or concurrently with, the PFAS MCL regulations. See Safe Drinking Water Act §§ 1415, 1416. The exemption might have multiple tiers based on PFAS concentrations – the lower the concentration the longer the phase-in period – and be temporary, and expire in phases, e.g., 10 / 8 / 4 ppt, over 5 / 10 / 15 years, respectively. If exemptions cannot be issued on a group/class basis, EPA could announce a general expectation that States may approve exemptions for defined groups for defined periods, and the States then develop implementation schedules on an individual (but pre-determined) basis.

It is clear that EPA must phase water plant upgrades over at least the next 10-20 years. It is patently obvious that we can't install PFAS barrier technology at 3-6,000 water plants nationwide in a shorter period.

Finally, phasing the MCL in over time will reinforce for the public that the PFAS levels they will experience over the next 10-20 years are not the end of the world. The reality is that the vast majority of Americans have experienced significantly higher PFAS levels for decades than they do now. We understand that the federal government has been assessing both PFOA and PFOS blood lead levels in thousands of Americans for several decades and that the levels have plummeted. We expect those levels to plummet further with the intense governmental, legislative, and litigation focus on eliminating the use of PFAS chemicals.

We believe the health monitoring testing that has been done in PFAS hot spot areas such as Parkersburg and Vienna, West Virginia reinforce the fact that levels nationwide are dropping and that means that some necessary prioritization and phasing of water plant PFAS barrier installations is both warranted and appropriate.

V. State Permitting/Funding Agency Capacity to Permit and Fund PFAS Barrier Technology Projects is at an All Time Low.

State public health agencies are facing the same historic worker retirement and shortage phenomenon as everyone else. The tiered/phased MCL adoption and implementation approach that we suggest above is also necessary given the reality that State health agencies are simply unable to handle 3-6,000 PFAS barrier installation projects over the next few years on top of all the other projects they are being asked to manage. Even when funding is available for additional staff, the States have struggled to attract (and retain) staff given the competition from the private sector (which is woefully understaffed, and which pays better).

EPA must address this significant potential bottleneck in any MCL implementation schedule it adopts as part of the final rule.

EPA Response: With respect to health monitoring testing, the EPA believes that this type of biomonitoring can be an important tool to identify changes in population exposure over time. However, as discussed in section III of the final rule preamble and section III of the EPA's *Response to Comments* document (see final regulatory determinations), the agency has sufficient information now to regulate the six PFAS included in the final NPDWR. The EPA's final rule represents data-driven drinking water standards that are based on the best available science and meet the requirements of SDWA; regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. See the EPA response to comment Doc. #1816, SBC-044679 in section 12.1 in this *Response to Comments* document with respect to exemptions. Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as discussion on a phased-in MCL approach.

Association of Missouri Cleanwater Agencies (Doc. #1817, SBC-044649)

The sheer number of facilities that will have to install PFAS barrier technologies – 3-6,000 facilities by EPA's own estimate – demonstrates the impracticability of the 3-year (up to five for very small systems serving fewer than 10,000 population) implementation schedule. The treatment technology needed to comply with the proposed rule is simply not in place at this time, nor will it be to the extent needed to meet a 3-5-year national compliance schedule.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. For additional discussion on treatment availability and capacity, please see section 10.6 of the EPA response in this *Response to Comments* document.

Association of Missouri Cleanwater Agencies (Doc. #1817, SBC-044653)

IV. A Decade-Plus Implementation Schedule is Needed or a Phased/Tiered Step-Down MCL Approach.

Water treatment plant design is a very complex and challenging exercise. Extensive facility-specific pilot studies will be needed to ensure we install the proper treatment for the PFAS chemicals present in each facility's raw water supply. We are in a period of unprecedented shortage of design engineers as the engineering community struggles with the gusher of water, sewer, stormwater, highway, and other projects that are being crammed into the next 3-5 years due to ARPA, BIL, and State budget surplus infrastructure investments. Adding even (EPA's estimated) 3-6 thousand water plant PFAS barrier projects on top of this over the next 3-5 years is completely unrealistic. We will have to pay design premiums and may not get the quality of work we need due to the unprecedented volume of work the engineering community faces. Even if the projects can be piloted, planned, designed, permitted, funded, and bids received, the construction industry is already overburdened and will fall further behind when we add these drinking water plant upgrades to the already enormous number of projects. For the past year we have already seen no bids on projects that normally would get several bids. Where there have been bids, they have almost universally been higher than the engineer's (updated) estimate, if not shockingly higher. This fact is compounded by construction material supply chain delays, which lead to longer project schedules that contribute to higher bids.

Small systems will struggle the most because engineering and construction firms will want to prioritize work for their larger clients because they will comprise the bulk of their future work. Small systems will be more one-and-done-type projects. Moreover, smaller systems may lack the sophistication and middle management to oversee and interact with contractors on such projects. As such smaller systems should have additional compliance flexibility.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as discussion on a phased-in MCL approach. For funding concerns, the agency notes that funds are also available through the passage of the BIL to assist many disadvantaged communities, small systems, and others with the costs of installation of treatment when it might otherwise be cost-challenging. Please see section 2.4 of the EPA response in this *Response to Comments* document for more discussion about currently available funding.

Association of Missouri Cleanwater Agencies (Doc. #1817, SBC-044655)

EPA must provide unprecedented implementation schedule flexibility for this unprecedented rule. This is warranted particularly in light of the thousands of facilities which EPA expects will be affected, the enormous cost, and the historically thin capacities of the engineering and construction industries (including the manufacturers of the supplies and equipment needed for PFAS barrier projects). Three years is nowhere near enough time for so many water systems to plan, design, permit, fund, and construct significant upgrades to their water systems. This truncated and rushed schedule also increases the associated cost estimates, making the rule as proposed completely infeasible. Additionally, the full impacts of operation and residuals disposal have not been fully considered. Not only will O&M costs significantly increase, but many utilities lack the ability to draw additional staff with the expertise to run these types of advanced water treatment systems.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. The agency has evaluated the feasibility of the final standards; please see section 5 of the EPA response in this *Response to Comments* document for additional discussion. Additionally, the agency disagrees with commenter claims that the EPA did not consider the impacts of operation and residuals disposal; please see sections 5.1.3 (cost considerations and alternative MCLs), 10.4 (management of treatment residuals), and 13.3 (methods for estimating cost) of the EPA response in this *Response to Comments* document for additional discussion. With respect to operator training, please see the EPA response to comment Doc. #1567, SBC-042738 in section 12.1 in this *Response to Comments* document.

NORTH CAROLINA WATER QUALITY ASSOCIATION (Doc. #1818, SBC-044633)

EPA must provide unprecedented implementation schedule flexibility for this unprecedented rule. This is warranted particularly in light of the thousands of facilities which EPA expects will

be affected, the enormous cost, and the historically thin capacities of the engineering and construction industries (including the manufacturers of the supplies and equipment needed for PFAS barrier projects). Three years is nowhere near enough time for so many water systems to plan, design, permit, fund, and construct significant upgrades to their water systems. This truncated and rushed schedule also increases the associated cost estimates, making the rule as proposed completely infeasible. Additionally, the full impacts of operation and residuals disposal have not been fully considered. Not only will O&M costs significantly increase, but many utilities lack the ability to draw additional staff with the expertise to run these types of advanced water treatment systems.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. The agency has evaluated the feasibility of the final standards; please see section 5 of the EPA response in this *Response to Comments* document for additional discussion. Additionally, the agency disagrees with commenter claims that the EPA did not consider the impacts of operation and residuals disposal; please see sections 5.1.3 (cost considerations and alternative MCLs), 10.4 (management of treatment residuals), and 13.3 (methods for estimating cost) of the EPA response in this *Response to Comments* document for additional discussion. With respect to operator training, please see the EPA response to comment Doc. #1567, SBC-042738 in section 12.1 in this *Response to Comments* document.

NORTH CAROLINA WATER QUALITY ASSOCIATION (Doc. #1818, SBC-044634)

EPA should defer rule adoption while it takes into account the appropriate levels of PFOA/PFOS (as well as the hazard index four chemicals), environmental updated costs and benefits, and other significant factors such as environmental justice.

As part of that re-evaluation, EPA should republish the proposed rule and seek public comment on a phased/tiered step-down MCL and Hazard Index approach that might look like the following:

• 10 ppt for PFOA/PFOS and 5 Hazard Index effective 12 months from the date of publication with a compliance schedule of up to 10 years from the effective date.

• 8 ppt for PFOA/PFOS and a 3 Hazard Index with an effective date of 2029 and a compliance deadline of no more than 10 years from the effective date.

• 4 ppt for PFOA/PFOS and a 1 Hazard Index with an effective date of 2034 and a compliance deadline of no more than 10 years from the effective date.

While the deadlines for MCLs are statutory in nature, we believe the phased effective date approach above would serve to provide EPA, the States, and affected water systems with the time necessary to implement PFAS barrier technologies.

EPA Response: The EPA disagrees with commenter assertions that the agency did not "account the appropriate levels of PFOA/PFOS (as well as the Hazard Index four chemicals), environmental updated costs and benefits, and other significant factors such as environmental justice." Analytic feasibility was evaluated when establishing the final MCLs (see section 5 of the EPA response in this *Response to Comments* document for more information). The EPA conducted robust occurrence analyses, as described in sections III and VI of the preamble and sections 3 and 7 of this *Response to Comments* document. The agency also conducted a robust environmental justice analysis discussed in the final rule preamble (section XII) and within section 14.10 of the EPA's *Response to Comments* document. The EPA's final rule represents data-driven drinking water standards that are based on the best available science and meet the requirements of SDWA; regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as discussion on a phased-in MCL approach.

NORTH CAROLINA WATER QUALITY ASSOCIATION (Doc. #1818, SBC-044635)

Only if such a phased approach is unworkable should EPA resort to an advance exercise of its enforcement discretion to provide additional implementation time. Such an approach would be advisory to delegated states and would provide, in general, federally pre-approved compliance schedule parameters for the States to work within.

While many systems will need more time, EPA and the states will also want to ensure that limited engineering, agency, funding, and contractor resources are directed to systems with the highest priority (highest PFAS levels, significant environmental justice considerations, etc.). It is strongly in the public interest for EPA to issue the MCLs in a way that ensures the most impacted systems are able to upgrade earlier than systems that may be only marginally impacted or upgrading out of convenience or an abundance of caution.

EPA and the states could also allow compliance schedule flexibility up front for utilities that need it through EPA and/or state administrative orders giving systems with lower priority more time to meet the MCLs. This is a formalized variant of the agency enforcement discretion approach. This could be done on a case-by-case basis.

Again, we believe the best course is for EPA to adopt phased MCLs as follows:

10 ppt for PFOA/PFOS and a Hazard Index of "5.0" effective December 31, 2024

8 ppt for PFOA/PFOS and a Hazard Index of "3.0" effective December 31, 2029

4 ppt for PFOA/PFOS and a Hazard Index of "1.0" effective December 31, 2034

A compliance schedule of up to ten years would apply to each effective date. Even with this approach, enforcement discretion will be necessary to ensure that water system PFAS barrier installations are appropriately scheduled.

In support of this approach, we note that in 1979, EPA issued a final rule setting a MCL and associated monitoring and reporting requirements for total trihalomethanes (TIHMs). 44 Fed. Reg. 68,824 (Nov. 29, 1979). The MCL had phased implementation for facilities of different sizes written within the MCL:

For community water systems serving 75,000 or more persons, monitoring must begin 1 year following promulgation and the effective date of the MCL is 2 years following promulgation. For community water systems serving 10,000 to 75,000 persons, monitoring must begin within 3 years from the date of promulgation and the effective date of the MCL is 4 years from the date of promulgation.

Id. at 68,824 [FN3: We would note many of the relevant issues for that rulemaking are the same for this proposed rule: "EPA specifically solicited and received comments on the following major issues: The rationale for setting an MCL for TTHMs and the magnitude of the MCL; the feasibility of and timing for phased reduction of the MCL; the concept of phasing the application of the MCL based upon system size; an alternative of making the MCL applicable to all public water systems and to phase the implementation by a deferred monitoring schedule linked to population size … the availability of technology to achieve compliance …and the costs incurred by public water systems to achieve compliance with the MCL." Id. (emphasis added).]. Several components went into this decision to implement phases, including inadequate lab capacity with an increased lab demand. Id. at 68,629. EPA characterized this type of delay as extending the time frame for the initiation of requirements. Id. at 68,630 (emphasis added). Thus, there is precedent for the phasing/tiered approach we suggest – which can also be viewed as a phased timeframe for initiating the requirements of the proposed PFAS MCLs to community water systems based upon the PFAS levels in their finished drinking water.

Another approach would be for EPA to provide a phase-in schedule by means of a group or class "exemption" adopted as part of, or concurrently with, the PFAS MCL regulations. See Safe Drinking Water Act §§ 1415, 1416. The exemption might have multiple tiers based on PFAS concentrations – the lower the concentration the longer the phase-in period – and be temporary, and expire in phases, e.g., 10 / 8 / 4 ppt, over 5 / 10 / 15 years, respectively. If exemptions cannot be issued on a group/class basis, EPA could announce a general expectation that States may approve exemptions for defined groups for defined periods, and the States then develop implementation schedules on an individual (but pre-determined) basis.

It is clear that EPA must phase water plant upgrades over at least the next 10-20 years. It is patently obvious that we can't install PFAS barrier technology at 3-6,000 water plants nationwide in a shorter period.

Finally, phasing the MCL in over time will reinforce for the public that the PFAS levels they will experience over the next 10-20 years are not the end of the world. The reality is that the vast majority of Americans have experienced significantly higher PFAS levels for decades than they do now. We understand that the federal government has been assessing both PFOA and PFOS blood lead levels in thousands of Americans for several decades and that the levels have plummeted. We expect those levels to plummet further with the intense governmental, legislative, and litigation focus on eliminating the use of PFAS chemicals.

We believe the health monitoring testing that has been done in PFAS hot spot areas such as Parkersburg and Vienna, West Virginia reinforce the fact that levels nationwide are dropping and that means that some necessary prioritization and phasing of water plant PFAS barrier installations is both warranted and appropriate.

V. State Permitting/Funding Agency Capacity to Permit and Fund PFAS Barrier Technology Projects is at an All Time Low.

State public health agencies are facing the same historic worker retirement and shortage phenomenon as everyone else. The tiered/phased MCL adoption and implementation approach that we suggest above is also necessary given the reality that State health agencies are simply unable to handle 3-6,000 PFAS barrier installation projects over the next few years on top of all the other projects they are being asked to manage. Even when funding is available for additional staff, the States have struggled to attract (and retain) staff given the competition from the private sector (which is woefully understaffed, and which pays better).

EPA must address this significant potential bottleneck in any MCL implementation schedule it adopts as part of the final rule.

EPA Response: With respect to health monitoring testing, the EPA believes that this type of biomonitoring can be an important tool to identify changes in population exposure over time. However, as discussed in section III of the final rule preamble and section III of the EPA's *Response to Comments* document (see final regulatory determinations), the agency has sufficient information now to regulate the six PFAS included in the final NPDWR. The EPA's final rule represents data-driven drinking water standards that are based on the best available science and meet the requirements of SDWA; regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. Please see the EPA response to comment Doc. #1816, SBC-044679 in section 12.1 in this *Response to Comments* document and the EPA response to topic 12.1 with respect to case-by-case exemptions. Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's

discussion on supply chain and labor challenges that may affect the compliance timeline as well as discussion on a phased-in MCL approach.

NORTH CAROLINA WATER QUALITY ASSOCIATION (Doc. #1818, SBC-044622)

The enormous costs experienced so far are likely to increase even further due to supply chain, worker shortage, inflation, and the unprecedented number of public utility/highway infrastructure projects being attempted over the next five-to-ten years. Adding PFAS barrier technology at thousands (according to US EPA) of drinking water plants nationwide can only further increase national engineering and construction prices.

There are simply not enough engineers, contractors, or workers to implement all these projects. Forcing PFAS barrier technology to the head of the line will trigger unprecedented cost premiums. It will also force utilities to delay needed infrastructure projects that protect human health, such as water main replacements and other projects to replace aging infrastructure. Infrastructure replacement delays will equate to more risk, less redundancy, less resiliency, and ultimately higher costs for utilities.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

NORTH CAROLINA WATER QUALITY ASSOCIATION (Doc. #1818, SBC-044631)

IV. A Decade-Plus Implementation Schedule is Needed or a Phased/Tiered Step- Down MCL Approach.

Water treatment plant design is a very complex and challenging exercise. Extensive facility-specific pilot studies will be needed to ensure we install the proper treatment for the PFAS chemicals present in each facility's raw water supply. We are in a period of unprecedented shortage of design engineers as the engineering community struggles with the gusher of water, sewer, stormwater, highway, and other projects that are being crammed into the next 3-5 years due to ARPA, BIL, and State budget surplus infrastructure investments. Adding even (EPA's estimated) 3-6 thousand water plant PFAS barrier projects on top of this over the next 3-5 years is completely unrealistic. We will have to pay design premiums and may not get the quality of work we need due to the unprecedented volume of work the engineering community faces. Even if the projects can be piloted, planned, designed, permitted, funded, and bids received, the construction industry is already overburdened and will fall further behind when we add these drinking water plant upgrades to the already enormous number of projects. For the past year we have already seen no bids on projects that normally would get several bids. Where there have been bids, they have almost universally been higher than the engineer's (updated) estimate, if not

shockingly higher. This fact is compounded by construction material supply chain delays, which lead to longer project schedules that contribute to higher bids.

Small systems will struggle the most because engineering and construction firms will want to prioritize work for their larger clients because they will comprise the bulk of their future work. Small systems will be more one-and-done-type projects. Moreover, smaller systems may lack the sophistication and middle management to oversee and interact with contractors on such projects. As such smaller systems should have additional compliance flexibility.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as discussion on a phased-in MCL approach and exemptions that may be provided under Section 1416. For funding concerns, the agency notes that funds are also available through the passage of the BIL to assist many disadvantaged communities, small systems, and others with the costs of installation of treatment when it might otherwise be cost-challenging. Please see section 2.4 of the EPA response in this *Response to Comments* document for more discussion about currently available funding.

NORTH CAROLINA WATER QUALITY ASSOCIATION (Doc. #1818, SBC-044627)

The sheer number of facilities that will have to install PFAS barrier technologies – 3-6,000 facilities by EPA's own estimate – demonstrates the impracticability of the 3-year (up to five for very small systems serving fewer than 10,000 population) implementation schedule. The treatment technology needed to comply with the proposed rule is simply not in place at this time, nor will it be to the extent needed to meet a 3-5-year national compliance schedule.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10), which is the maximum that can be provided in a NPDWR, although further extensions can be provided under SDWA Section 1416. Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. For additional discussion on treatment availability and capacity, please see section 10.6 of the EPA response in this *Response to Comments* document.

South Carolina Water Quality Association (Doc. #1819, SBC-044611)

EPA must provide unprecedented implementation schedule flexibility for this unprecedented rule. This is warranted particularly in light of the thousands of facilities which EPA expects will be affected, the enormous cost, and the historically thin capacities of the engineering and

construction industries (including the manufacturers of the supplies and equipment needed for PFAS barrier projects). Three years is nowhere near enough time for so many water systems to plan, design, permit, fund, and construct significant upgrades to their water systems. This truncated and rushed schedule also increases the associated cost estimates, making the rule as proposed completely infeasible. Additionally, the full impacts of operation and residuals disposal have not been fully considered. Not only will O&M costs significantly increase, but many utilities lack the ability to draw additional staff with the expertise to run these types of advanced water treatment systems.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10), which is the maximum that can be provided in an NPDWR, although further extensions can be provided under SDWA Section 1416. Regarding commenter concerns on the compliance timeframe, the agency is authorizing a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. The agency has evaluated the feasibility of the final standards; please see section 5 of the EPA response in this *Response to Comments* document for additional discussion. Additionally, the agency disagrees with commenter claims that the EPA did not consider the impacts of operation and residuals disposal; please see sections 5.1.3 (cost considerations and alternative MCLs), 10.4 (management of treatment residuals), and 13.3 (methods for estimating cost) of the EPA response in this *Response to Comments* document for additional discussion. With respect to operator training, please see the EPA response to comment Doc. #1567, SBC-042738 in section 12.1 in this *Response to Comments* document.

South Carolina Water Quality Association (Doc. #1819, SBC-044612)

EPA should defer rule adoption while it takes into account the appropriate levels of PFOA/PFOS (as well as the hazard index four chemicals), environmental updated costs and benefits, and other significant factors such as environmental justice.

As part of that re-evaluation, EPA should republish the proposed rule and seek public comment on a phased/tiered step-down MCL and Hazard Index approach that might look like the following:

• 10 ppt for PFOA/PFOS and 5 Hazard Index effective 12 months from the date of publication with a compliance schedule of up to 10 years from the effective date.

• 8 ppt for PFOA/PFOS and a 3 Hazard Index with an effective date of 2029 and a compliance deadline of no more than 10 years from the effective date.

• 4 ppt for PFOA/PFOS and a 1 Hazard Index with an effective date of 2034 and a compliance deadline of no more than 10 years from the effective date.

While the deadlines for MCLs are statutory in nature, we believe the phased effective date approach above would serve to provide EPA, the States, and affected water systems with the time necessary to implement PFAS barrier technologies.

EPA Response: The EPA disagrees with commenter assertions that the agency did not take into "account the appropriate levels of PFOA/PFOS (as well as the Hazard Index four chemicals), environmental updated costs and benefits, and other significant factors such as environmental justice." Analytic feasibility was evaluated when establishing the final MCLs (see section 5 of the EPA response in this *Response to Comments* document for more information). The EPA conducted robust occurrence analyses, as described in sections III and VI of the preamble and sections 3 and 7 of this *Response to Comments* document. The agency also conducted a robust environmental justice analysis discussed in the final rule preamble (section XII) and within section 14.10 of the EPA's *Response to Comments* document. The EPA's final rule represents data-driven drinking water standards that are based on the best available science and meet the requirements of SDWA; regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as discussion on a phased-in MCL approach.

South Carolina Water Quality Association (Doc. #1819, SBC-044600)

The enormous costs experienced so far are likely to increase even further due to supply chain, worker shortage, inflation, and the unprecedented number of public utility/highway infrastructure projects being attempted over the next five-to-ten years. Adding PFAS barrier technology at thousands (according to US EPA) of drinking water plants nationwide can only further increase national engineering and construction prices.

There are simply not enough engineers, contractors, or workers to implement all these projects. Forcing PFAS barrier technology to the head of the line will trigger unprecedented cost premiums. It will also force utilities to delay needed infrastructure projects that protect human health, such as water main replacements and other projects to replace aging infrastructure. Infrastructure replacement delays will equate to more risk, less redundancy, less resiliency, and ultimately higher costs for utilities.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Only if such a phased approach is unworkable should EPA resort to an advance exercise of its enforcement discretion to provide additional implementation time. Such an approach would be advisory to delegated states and would provide, in general, federally pre-approved compliance schedule parameters for the States to work within.

While many systems will need more time, EPA and the states will also want to ensure that limited engineering, agency, funding, and contractor resources are directed to systems with the highest priority (highest PFAS levels, significant environmental justice considerations, etc.). It is strongly in the public interest for EPA to issue the MCLs in a way that ensures the most impacted systems are able to upgrade earlier than systems that may be only marginally impacted or upgrading out of convenience or an abundance of caution.

EPA and the states could also allow compliance schedule flexibility up front for utilities that need it through EPA and/or state administrative orders giving systems with lower priority more time to meet the MCLs. This is a formalized variant of the agency enforcement discretion approach. This could be done on a case-by-case basis.

Again, we believe the best course is for EPA to adopt phased MCLs as follows:

10 ppt for PFOA/PFOS and a Hazard Index of "5.0" effective December 31, 2024

8 ppt for PFOA/PFOS and a Hazard Index of "3.0" effective December 31, 2029

4 ppt for PFOA/PFOS and a Hazard Index of "1.0" effective December 31, 2034

A compliance schedule of up to ten years would apply to each effective date. Even with this approach, enforcement discretion will be necessary to ensure that water system PFAS barrier installations are appropriately scheduled.

In support of this approach, we note that in 1979, EPA issued a final rule setting a MCL and associated monitoring and reporting requirements for total trihalomethanes (TIHMs). 44 Fed. Reg. 68,824 (Nov. 29, 1979). The MCL had phased implementation for facilities of different sizes written within the MCL:

For community water systems serving 75,000 or more persons, monitoring must begin 1 year following promulgation and the effective date of the MCL is 2 years following promulgation. For community water systems serving 10,000 to 75,000 persons, monitoring must begin within 3 years from the date of promulgation and the effective date of the MCL is 4 years from the date of promulgation.

Id. at 68,824 [FN3: We would note many of the relevant issues for that rulemaking are the same for this proposed rule: "EPA specifically solicited and received comments on the following major issues: The rationale for setting an MCL for TTHMs and the magnitude of the MCL; the feasibility of and timing for phased reduction of the MCL; the concept of phasing the application of the MCL based upon system size; an alternative of making the MCL applicable to all public

water systems and to phase the implementation by a deferred monitoring schedule linked to population size … the availability of technology to achieve compliance …and the costs incurred by public water systems to achieve compliance with the MCL." Id. (emphasis added).]. Several components went into this decision to implement phases, including inadequate lab capacity with an increased lab demand. Id. at 68,629. EPA characterized this type of delay as extending the time frame for the initiation of requirements. Id. at 68,630 (emphasis added). Thus, there is precedent for the phasing/tiered approach we suggest – which can also be viewed as a phased timeframe for initiating the requirements of the proposed PFAS MCLs to community water systems based upon the PFAS levels in their finished drinking water.

Another approach would be for EPA to provide a phase-in schedule by means of a group or class "exemption" adopted as part of, or concurrently with, the PFAS MCL regulations. See Safe Drinking Water Act §§ 1415, 1416. The exemption might have multiple tiers based on PFAS concentrations – the lower the concentration the longer the phase-in period – and be temporary, and expire in phases, e.g., 10 / 8 / 4 ppt, over 5 / 10 / 15 years, respectively. If exemptions cannot be issued on a group/class basis, EPA could announce a general expectation that States may approve exemptions for defined groups for defined periods, and the States then develop implementation schedules on an individual (but pre-determined) basis.

It is clear that EPA must phase water plant upgrades over at least the next 10-20 years. It is patently obvious that we can't install PFAS barrier technology at 3-6,000 water plants nationwide in a shorter period.

Finally, phasing the MCL in over time will reinforce for the public that the PFAS levels they will experience over the next 10-20 years are not the end of the world. The reality is that the vast majority of Americans have experienced significantly higher PFAS levels for decades than they do now. We understand that the federal government has been assessing both PFOA and PFOS blood lead levels in thousands of Americans for several decades and that the levels have plummeted. We expect those levels to plummet further with the intense governmental, legislative, and litigation focus on eliminating the use of PFAS chemicals.

We believe the health monitoring testing that has been done in PFAS hot spot areas such as Parkersburg and Vienna, West Virginia reinforce the fact that levels nationwide are dropping and that means that some necessary prioritization and phasing of water plant PFAS barrier installations is both warranted and appropriate.

V. State Permitting/Funding Agency Capacity to Permit and Fund PFAS Barrier Technology Projects is at an All Time Low.

State public health agencies are facing the same historic worker retirement and shortage phenomenon as everyone else. The tiered/phased MCL adoption and implementation approach that we suggest above is also necessary given the reality that State health agencies are simply unable to handle 3-6,000 PFAS barrier installation projects over the next few years on top of all the other projects they are being asked to manage. Even when funding is available for additional

staff, the States have struggled to attract (and retain) staff given the competition from the private sector (which is woefully understaffed, and which pays better).

EPA must address this significant potential bottleneck in any MCL implementation schedule it adopts as part of the final rule.

EPA Response: With respect to health monitoring testing, the EPA believes that this type of biomonitoring can be an important tool to identify changes in population exposure over time. However, as discussed in section III of the final rule preamble and section III of the EPA's *Response to Comments* document (see final regulatory determinations), the agency has sufficient information now to regulate the six PFAS included in the final NPDWR. The EPA's final rule represents data-driven drinking water standards that are based on the best available science and meet the requirements of SDWA; regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. Please see the EPA response to comment Doc. #1816, SBC-044679 in section 12.1 in this *Response to Comments* document and the EPA response to topic 12.1 with respect to case-by-case exemptions. Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as discussion on a phased-in MCL approach.

South Carolina Water Quality Association (Doc. #1819, SBC-044605)

The sheer number of facilities that will have to install PFAS barrier technologies – 3-6,000 facilities by EPA's own estimate – demonstrates the impracticability of the 3-year (up to five for very small systems serving fewer than 10,000 population) implementation schedule. The treatment technology needed to comply with the proposed rule is simply not in place at this time, nor will it be to the extent needed to meet a 3-5-year national compliance schedule.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. For additional discussion on treatment availability and capacity, please see section 10.6 of the EPA response in this *Response to Comments* document.

South Carolina Water Quality Association (Doc. #1819, SBC-044609)

IV. A Decade-Plus Implementation Schedule is Needed or a Phased/Tiered Step- Down MCL Approach.

Water treatment plant design is a very complex and challenging exercise. Extensive facility-specific pilot studies will be needed to ensure we install the proper treatment for the PFAS

chemicals present in each facility's raw water supply. We are in a period of unprecedented shortage of design engineers as the engineering community struggles with the gusher of water, sewer, stormwater, highway, and other projects that are being crammed into the next 3-5 years due to ARPA, BIL, and State budget surplus infrastructure investments. Adding even (EPA's estimated) 3- 6 thousand water plant PFAS barrier projects on top of this over the next 3-5 years is completely unrealistic. We will have to pay design premiums and may not get the quality of work we need due to the unprecedented volume of work the engineering community faces. Even if the projects can be piloted, planned, designed, permitted, funded, and bids received, the construction industry is already overburdened and will fall further behind when we add these drinking water plant upgrades to the already enormous number of projects. For the past year we have already seen no bids on projects that normally would get several bids. Where there have been bids, they have almost universally been higher than the engineer's (updated) estimate, if not shockingly higher. This fact is compounded by construction material supply chain delays, which lead to longer project schedules that contribute to higher bids.

Small systems will struggle the most because engineering and construction firms will want to prioritize work for their larger clients because they will comprise the bulk of their future work. Small systems will be more one-and-done-type projects. Moreover, smaller systems may lack the sophistication and middle management to oversee and interact with contractors on such projects. As such smaller systems should have additional compliance flexibility.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as discussion on a phased-in MCL approach. For funding concerns, the agency notes that funds are also available through the passage of the BIL to assist many disadvantaged communities, small systems, and others with the costs of installation of treatment when it might otherwise be cost-challenging. Please see section 2.4 of the EPA response in this *Response to Comments* document for more discussion about currently available funding.

Wet Weather Partnership (Doc. #1820, SBC-044591)

Only if such a phased approach is unworkable should EPA resort to an advance exercise of its enforcement discretion to provide additional implementation time. Such an approach would be advisory to delegated states and would provide, in general, federally pre-approved compliance schedule parameters for the States to work within.

While many systems will need more time, EPA and the states will also want to ensure that limited engineering, agency, funding, and contractor resources are directed to systems with the highest priority (highest PFAS levels, significant environmental justice considerations, etc.). It is strongly in the public interest for EPA to issue the MCLs in a way that ensures the most

impacted systems are able to upgrade earlier than systems that may be only marginally impacted or upgrading out of convenience or an abundance of caution.

EPA and the states could also allow compliance schedule flexibility up front for utilities that need it through EPA and/or state administrative orders giving systems with lower priority more time to meet the MCLs. This is a formalized variant of the agency enforcement discretion approach. This could be done on a case-by-case basis.

Again, we believe the best course is for EPA to adopt phased MCLs as follows:

10 ppt for PFOA/PFOS and a Hazard Index of "5.0" effective December 31, 2024

8 ppt for PFOA/PFOS and a Hazard Index of "3.0" effective December 31, 2029

4 ppt for PFOA/PFOS and a Hazard Index of "1.0" effective December 31, 2034

A compliance schedule of up to ten years would apply to each effective date. Even with this approach, enforcement discretion will be necessary to ensure that water system PFAS barrier installations are appropriately scheduled.

In support of this approach, we note that in 1979, EPA issued a final rule setting a MCL and associated monitoring and reporting requirements for total trihalomethanes (TIHMs). 44 Fed. Reg. 68,824 (Nov. 29, 1979). The MCL had phased implementation for facilities of different sizes written within the MCL:

For community water systems serving 75,000 or more persons, monitoring must begin 1 year following promulgation and the effective date of the MCL is 2 years following promulgation. For community water systems serving 10,000 to 75,000 persons, monitoring must begin within 3 years from the date of promulgation and the effective date of the MCL is 4 years from the date of promulgation.

Id. at 68,824 [FN3: We would note many of the relevant issues for that rulemaking are the same for this proposed rule: "EPA specifically solicited and received comments on the following major issues: The rationale for setting an MCL for TTHMs and the magnitude of the MCL; the feasibility of and timing for phased reduction of the MCL; the concept of phasing the application of the MCL based upon system size; an alternative of making the MCL applicable to all public water systems and to phase the implementation by a deferred monitoring schedule linked to population size … the availability of technology to achieve compliance …and the costs incurred by public water systems to achieve compliance with the MCL." Id. (emphasis added).]. Several components went into this decision to implement phases, including inadequate lab capacity with an increased lab demand. Id. at 68,629. EPA characterized this type of delay as extending the time frame for the initiation of requirements. Id. at 68,630 (emphasis added). Thus, there is precedent for the phasing/tiered approach we suggest – which can also be viewed as a phased timeframe for initiating the requirements of the proposed PFAS MCLs to community water systems based upon the PFAS levels in their finished drinking water.

Another approach would be for EPA to provide a phase-in schedule by means of a group or class "exemption" adopted as part of, or concurrently with, the PFAS MCL regulations. See Safe Drinking Water Act §§ 1415, 1416. The exemption might have multiple tiers based on PFAS concentrations – the lower the concentration the longer the phase-in period – and be temporary, and expire in phases, e.g., 10 / 8 / 4 ppt, over 5 / 10 / 15 years, respectively. If exemptions cannot be issued on a group/class basis, EPA could announce a general expectation that States may approve exemptions for defined groups for defined periods, and the States then develop implementation schedules on an individual (but pre-determined) basis.

It is clear that EPA must phase water plant upgrades over at least the next 10-20 years. It is patently obvious that we can't install PFAS barrier technology at 3-6,000 water plants nationwide in a shorter period.

Finally, phasing the MCL in over time will reinforce for the public that the PFAS levels they will experience over the next 10-20 years are not the end of the world. The reality is that the vast majority of Americans have experienced significantly higher PFAS levels for decades than they do now. We understand that the federal government has been assessing both PFOA and PFOS blood lead levels in thousands of Americans for several decades and that the levels have plummeted. We expect those levels to plummet further with the intense governmental, legislative, and litigation focus on eliminating the use of PFAS chemicals.

We believe the health monitoring testing that has been done in PFAS hot spot areas such as Parkersburg and Vienna, West Virginia reinforce the fact that levels nationwide are dropping and that means that some necessary prioritization and phasing of water plant PFAS barrier installations is both warranted and appropriate.

V. State Permitting/Funding Agency Capacity to Permit and Fund PFAS Barrier Technology Projects is at an All Time Low.

State public health agencies are facing the same historic worker retirement and shortage phenomenon as everyone else. The tiered/phased MCL adoption and implementation approach that we suggest above is also necessary given the reality that State health agencies are simply unable to handle 3-6,000 PFAS barrier installation projects over the next few years on top of all the other projects they are being asked to manage. Even when funding is available for additional staff, the States have struggled to attract (and retain) staff given the competition from the private sector (which is woefully understaffed, and which pays better).

EPA must address this significant potential bottleneck in any MCL implementation schedule it adopts as part of the final rule.

EPA Response: With respect to health monitoring testing, the EPA believes that this type of biomonitoring can be an important tool to identify changes in population exposure over time. However, as discussed in section III of the final rule preamble and section III of the EPA's *Response to Comments* document (see final regulatory determinations), the agency has sufficient information now to regulate the six PFAS included in the final NPDWR. The EPA's final rule

represents data-driven drinking water standards that are based on the best available science and meet the requirements of SDWA; regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as discussion on a phased-in MCL approach and exemptions.

Wet Weather Partnership (Doc. #1820, SBC-044590)

EPA should defer rule adoption while it takes into account the appropriate levels of PFOA/PFOS (as well as the hazard index four chemicals), environmental updated costs and benefits, and other significant factors such as environmental justice.

As part of that re-evaluation, EPA should republish the proposed rule and seek public comment on a phased/tiered step-down MCL and Hazard Index approach that might look like the following:

• 10 ppt for PFOA/PFOS and 5 Hazard Index effective 12 months from the date of publication with a compliance schedule of up to 10 years from the effective date.

• 8 ppt for PFOA/PFOS and a 3 Hazard Index with an effective date of 2029 and a compliance deadline of no more than 10 years from the effective date.

• 4 ppt for PFOA/PFOS and a 1 Hazard Index with an effective date of 2034 and a compliance deadline of no more than 10 years from the effective date.

While the deadlines for MCLs are statutory in nature, we believe the phased effective date approach above would serve to provide EPA, the States, and affected water systems with the time necessary to implement PFAS barrier technologies.

EPA Response: The EPA disagrees with commenter assertions that the agency did not take into "account the appropriate levels of PFOA/PFOS (as well as the Hazard Index four chemicals), environmental updated costs and benefits, and other significant factors such as environmental justice." Analytic feasibility was evaluated when establishing the final MCLs (see section 5 of the EPA response in this *Response to Comments* document for more information). The EPA conducted robust occurrence analyses, as described in sections III and VI of the preamble and sections 3 and 7 of this *Response to Comments* document. The agency also conducted a robust environmental justice analysis discussed in the final rule preamble (section XII) and within section 14.10 of the EPA's *Response to Comments* document. The EPA's final rule represents data-driven drinking water standards that are based on the best available science and meet the requirements of SDWA; regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. Regarding commenter concerns on the compliance timeframe, the agency is promulgating

a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as discussion on a phased-in MCL approach.

Wet Weather Partnership (Doc. #1820, SBC-044583)

The sheer number of facilities that will have to install PFAS barrier technologies – 3-6,000 facilities by EPA's own estimate – demonstrates the impracticability of the 3-year (up to five for very small systems serving fewer than 10,000 population) implementation schedule. The treatment technology needed to comply with the proposed rule is simply not in place at this time, nor will it be to the extent needed to meet a 3-5-year national compliance schedule.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. For additional discussion on treatment availability and capacity, please see section 10.6 of the EPA response in this *Response to Comments* document.

Wet Weather Partnership (Doc. #1820, SBC-044587)

IV. A Decade-Plus Implementation Schedule is Needed or a Phased/Tiered Step-Down MCL Approach.

Water treatment plant design is a very complex and challenging exercise. Extensive facility-specific pilot studies will be needed to ensure we install the proper treatment for the PFAS chemicals present in each facility's raw water supply. We are in a period of unprecedented shortage of design engineers as the engineering community struggles with the gusher of water, sewer, stormwater, highway, and other projects that are being crammed into the next 3-5 years due to ARPA, BIL, and State budget surplus infrastructure investments. Adding even (EPA's estimated) 3-6 thousand water plant PFAS barrier projects on top of this over the next 3-5 years is completely unrealistic. We will have to pay design premiums and may not get the quality of work we need due to the unprecedented volume of work the engineering community faces. Even if the projects can be piloted, planned, designed, permitted, funded, and bids received, the construction industry is already overburdened and will fall further behind when we add these drinking water plant upgrades to the already enormous number of projects. For the past year we have already seen no bids on projects that normally would get several bids. Where there have been bids, they have almost universally been higher than the engineer's (updated) estimate, if not shockingly higher. This fact is compounded by construction material supply chain delays, which lead to longer project schedules that contribute to higher bids.

Small systems will struggle the most because engineering and construction firms will want to prioritize work for their larger clients because they will comprise the bulk of their future work.

Small systems will be more one-and-done-type projects. Moreover, smaller systems may lack the sophistication and middle management to oversee and interact with contractors on such projects. As such smaller systems should have additional compliance flexibility.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as discussion on a phased-in MCL approach. For funding concerns, the agency notes that funds are also available through the passage of the BIL to assist many disadvantaged communities, small systems, and others with the costs of installation of treatment when it might otherwise be cost-challenging. Please see section 2.4 of the EPA response in this *Response to Comments* document for more discussion about currently available funding.

Wet Weather Partnership (Doc. #1820, SBC-044578)

The enormous costs experienced so far are likely to increase even further due to supply chain, worker shortage, inflation, and the unprecedented number of public utility/highway infrastructure projects being attempted over the next five-to-ten years. Adding PFAS barrier technology at thousands (according to US EPA) of drinking water plants nationwide can only further increase national engineering and construction prices.

There are simply not enough engineers, contractors, or workers to implement all these projects. Forcing PFAS barrier technology to the head of the line will trigger unprecedented cost premiums. It will also force utilities to delay needed infrastructure projects that protect human health, such as water main replacements and other projects to replace aging infrastructure. Infrastructure replacement delays will equate to more risk, less redundancy, less resiliency, and ultimately higher costs for utilities.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Wet Weather Partnership (Doc. #1820, SBC-044589)

EPA must provide unprecedented implementation schedule flexibility for this unprecedented rule. This is warranted particularly in light of the thousands of facilities which EPA expects will be affected, the enormous cost, and the historically thin capacities of the engineering and construction industries (including the manufacturers of the supplies and equipment needed for PFAS barrier projects). Three years is nowhere near enough time for so many water systems to plan, design, permit, fund, and construct significant upgrades to their water systems. This truncated and rushed schedule also increases the associated cost estimates, making the rule as

proposed completely infeasible. Additionally, the full impacts of operation and residuals disposal have not been fully considered. Not only will O&M costs significantly increase, but many utilities lack the ability to draw additional staff with the expertise to run these types of advanced water treatment systems.

EPA Response: Based on these and other significant comments regarding the compliance timeframe, see section 12.1 of the EPA response in this *Response to Comments* document. The agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. The agency has evaluated the feasibility of the final standards; please see section 5 of the EPA response in this *Response to Comments* document for additional discussion. Additionally, the agency disagrees with commenter claims that the EPA did not consider the impacts of operation and residuals disposal; please see sections 5.1.3 (cost considerations and alternative MCLs), 10.4 (management of treatment residuals), and 13.3 (methods for estimating cost) of the EPA response in this *Response to Comments* document for additional discussion. With respect to operator training, please see the EPA response to comment Doc. #1567, SBC-042738 in section 12.1 in this *Response to Comments* document.

Arkansas Department of Health (Doc. #1821, SBC-044574)

The treatment processes for PFAS are more complex than existing drinking water treatment processes and require additional training and certifications for drinking water operators. There is currently a shortage of qualified drinking water operators, especially with operators that have advanced training and certifications that PFAS treatment will require. This lack of qualified drinking water operators will create a significant risk to the operational capacity of these systems.

Sincerely,

Lance A Jones, P.E. Engineering Section Director

Arkansas Department of Health

cc: ASDWA, 1300 Wilson Blvd., Suite 875 Arlington, VA 22209

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. Regarding concerns on operator certification licenses, please see the EPA response to comment Doc. #1567, SBC-042738 in section 12.1 in this *Response to Comments* document.

Neuse Regional Water and Sewer Authority (Doc. #1822, SBC-044571)

3. EPA should delay the Proposed Rulemaking's effective date until EPA identifies all PFAS to be eliminated from drinking water.

NRWASA asks EPA to delay the Proposed Rulemaking until it identifies all PFAS chemicals and their respective acceptable risk levels. EPA acknowledges in its Proposed Rulemaking that the six PFAS proposed for regulation "co-occur with PFAS for which the Agency is not currently making a preliminary regulatory determination. Many of these other emergent co-occurring PFAS are likely to also pose hazards to public health and the environment." [FN5: Id. at 18651.] Presumably, EPA is working to further study other PFAS and identify which it may regulate and at what levels. The Proposed Rulemaking states the recommended treatment strategies are "anticipated to result in removing" the other PFAS but does not specify how or the likelihood of successfully removing additional PFAS. [FN6: Id.]

NRWASA's primary concern is that the significant labor and capital investments it will incur to remove PFOA, PFOS, PFHxS, HFPO-DA, PFNA, and PFBS to implement the Proposed Rulemaking may not be enough to address additional PFAS EPA identifies in the coming years. NRWASA could spend millions of dollars only to have to pay for additional equipment in the near future or re-engineer solutions that could have been implemented more efficiently at the beginning of the upgrade process.

The likelihood of additions to the list of regulated PFAS under a National Primary Drinking Water Standard are real. For example, in September 2022, EPA issued a proposed rule to designate two PFAS — PFOA, PFOS, and their salts and structural isomers — as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA"). EPA currently is reviewing comments received on that proposed rule. However, on April 13, 2023, EPA released another Advance Notice of Proposed Rulemaking seeking input on whether to propose to designate seven additional PFAS, including GenX, as hazardous substances under CERCLA and whether some PFAS compounds can or should be designated as a group or category [FN7: EPA Advanced Notice of Proposed Rulemaking Addressing PFAS in the Environment, Federal Register Vol. 88, No. 71, April 13, 2023.]. The problem of additional, little-known PFAS is acute in North Carolina. In a 16-state study testing 41 PFAS not covered by EPA's test methods, "[s]amples collected in North Carolina contained the highest levels of unmonitored PFAS." [FN8: Coastal Review, Half of PFAS in drinking water not monitored by EPA: Study, https://coastalreview.org/2023/04/half-of-pfas-in-drinking-water-not-monitored-by-epa-study/.]. This suggests systems in North Carolina like NRWASA may face higher compliance costs in the event more PFAS are added to the six covered by the Proposed Rulemakings in the months and years ahead.

NRWASA requests EPA (a) delay the effective date of the final rule until EPA identifies how it will regulate other types of PFAS, and (b) address payment for additional upgrade costs of the addition of future PFAS.

EPA Response: The EPA disagrees with commenters that the agency should wait on regulation until "it will regulate other types of PFAS." As discussed in section III of the final rule preamble and section III of the EPA's *Response to Comments* document (see final regulatory determinations), the agency has sufficient information now to regulate the six PFAS included in the final NPDWR. The EPA's final rule represents data-driven drinking water standards that are based on the best available science and meet the requirements of SDWA; regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. It would be contrary to SDWA's regulatory process to delay issuing drinking water standards for contaminants EPA has determined meet the criteria for regulation simply because there may be other similar contaminants regulated in the future. Indeed, the statute requires that EPA regulate contaminants that EPA has determined mee the statutory criteria for regulation within a specified period of time. SDWA Section 1412(b)(1)(E). EPA cannot speculate about which contaminants might be regulated in the future or what the upgrade costs for treatment of those might be. Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. The agency notes that a possible future hazardous waste or hazardous substance designation has no bearing on the EPA's decision to authorize this capital improvement extension. For additional discussion on disposal of spent treatment materials under possible future regulatory actions and costs, please see section 10.4.2 of the EPA response in this *Response to Comments* document. For funding concerns, the agency notes that funds are also available through the passage of the BIL to assist many disadvantaged communities, small systems, and others with the costs of installation of treatment when it might otherwise be cost-challenging. Please see section 2.4 of the EPA response in this *Response to Comments* document for more discussion about currently available funding.

Plymouth Village Water & Sewer District (Doc. #1827, SBC-044561)

[Please carefully consider the following points to help inform the pending rulemaking on this class of pervasive and persistent PFAS chemicals:]

• The three-year implementation timeline for PFAS detection and remediation is an unreasonable schedule to meet, given real constraints such as the number of impacted systems, manufacturing and supply chain constraints, analytical methods and laboratory capacity, widespread professional labor and certified water Operator shortages, residual disposal issues, and system owner liability concerns. Systemic failures to meet an unrealistic timeframe will result in numerous, unnecessary enforcement documents and actions that will consume regulatory time and erode public trust. These systemic constraints must be factored into a realistic implementation schedule.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA

1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

The District of Columbia Water and Sewer Authority (Doc. #1829, SBC-045775)

The typical timeline for the planning, design, permitting and construction of a new drinking water treatment facility for PFAS may take up to 5 years or more; the standard compliance window of three years under SOWA will not be feasible. It is recommended that the Administrator provide an automatic two-year extension of the compliance deadline to those water systems requiring capital improvements to effectively mitigate PFAS in drinking water.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

The District of Columbia Water and Sewer Authority (Doc. #1829, SBC-045769)

Proposed Compliance Timeline is Unreasonable

The Proposal requires compliance with the proposed PFAS standards within three years of issuance of the final rule. Public water systems may be eligible for an additional two years, at the discretion of the primacy agency, to comply with the standards, if capital improvements are required. These timelines are patently unreasonable and unattainable, and should be extended, particularly in the absence of any compelling evidence of immediate public health impacts from trace PFAS in drinking water.

The typical timeline for the planning, design, permitting and construction of a new drinking water treatment facility for PFAS may take up to 5 years or more, the standard compliance window of three years under SOWA will not be feasible. It is anticipated that most water systems will need to request this two-year extension, which is typically provided at the discretion of the state primacy agencies, or in our case, EPA Region 3. However, the Administrator also has the authority under SOWA to provide this extension and can do so as a part of the rule as opposed to being done so on a case-by-case basis. It is recommended that the Administrator consider extending these deadlines and at a minimum provide an automatic two-year extension of the compliance deadline to those water systems requiring capital improvements to effectively mitigate PFAS in drinking water.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments*

document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Corix Infrastructure Inc. (Doc. #1834, SBC-045364)

3. The amount of time for implementation for public and private water systems to meet the final MCLs is insufficient.

As currently proposed, the water systems that will need to be upgraded to comply with the final MCLs will have three years to from the date of the final rule to upgrade their systems. Due to the cost and complexity of upgrading water treatment systems, a deadline of three years to design, construct and begin operations of the treatment systems needed to remove and dispose of PFOA and PFOS is not reasonable and may be almost impossible in certain circumstances.

Water systems are already balancing and burdened by many competing priorities for their time and financial resources due to increasing regulations, including mandates from the EPA's recently promulgated Lead and Copper rule. Complicating their efforts are increased worker shortages, the lack of qualified engineers, and shortages in the supply chain. These same challenges will make it difficult if not impossible in many cases to construct and begin operation of new treatment systems within the allowed three years. Before EPA can mandate dates for implementation, it must have a reasonable basis for assurance that those deadlines are achievable.

With respect to the implementation timeline, the EPA also needs to consider logistical and liability considerations associated with residual management and disposal. The EPA has not provided the water industry and the communities served by the industry with a clear plan for managing water treatment residuals produced by compliance proposed rule. Without a residuals management plan that addresses disposal coordination and capacity, analytical methodology and standardized waste characterization, and CERCLA liability, residuals disposal poses a significant obstacle for all drinking water systems, and it raises the significant issue of potential liability for communities related to the transport and the final disposition of treatment residuals.

Accordingly, Corix suggests that a more reasonable and achievable deadline for upgrading systems to meet the new MCLs is five years. In addition, the ability to grant extensions by the state regulators will be key to implement the most expeditious solution while acknowledging the reality of all the logistical challenges noted above.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10) resulting in the 5 year timeframe suggested by the commenter. Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Little Hocking Water Association (Doc. #1835, SBC-045515)

An across-the-board three-year compliance timeframe is inappropriate for the proposed PFAS MCLs.

As stated above, the United States population has been dosed with PFAS for over 60 years. LHWA, upon learning of severe contamination in its wellfield, took legal and other measures to obtain treatment for its water. Other systems have also obtained treatment. For systems that already have treatment in place, compliance can, and should, be done as soon as practicable, but no longer than three years.

EPA's current proposal groups water systems into classes based on the number of people served. For the PFAS MCL rule, EPA needs to create two new classes: water supplies that are known to be highly contaminated with PFAS or are at a high risk of contamination; and water supplies that are not highly contaminated or are at low risk of contamination. Much work has been done by states to identify contaminated water supplies and sources of PFAS pollution. For water systems that are highly contaminated or at high risk, compliance with the new MCLs needs to be done as soon as practicable but no longer than three years. For non-highly contaminated or low risk systems, compliance should be done within three years.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as an MCL phase-in. The EPA notes that the monitoring and compliance framework discussed in section 8 of the EPA's *Response to Comments* document has an approach where systems with elevated levels monitor more frequently relative to systems to lower levels of contamination. Please see section 8 of the EPA response in this *Response to Comments* document for additional discussion on monitoring and compliance requirements for the final NPDWR.

New England Water Works Association (Doc. #1836, SBC-045389)

While such testing provides critical design parameters and potentially cost-saving measures, it takes time. Designing and building permanent PFAS treatment facilities – assuming timely approval from primacy agencies and local permitting – can be a lengthy process. Renting temporary treatment equipment is not only very costly but also takes time. These challenges should be considered in EPA's timeframe for enforcing PFAS standards in drinking water. It is also recommended that EPA and primacy states streamline their new technology-review process to more quickly grant approvals.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments*

document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

New England Water Works Association (Doc. #1836, SBC-045377)

EPA needs to carefully consider implementation challenges for PWS caused by regulatory efforts related to PFAS. NEWWA is not sure that EPA has put enough time into this effort before moving forward with the proposed drinking water regulations. Without adequate consideration regarding these implementation challenges, public confidence in drinking water could be further jeopardized. EPA must address these challenges before finalizing the rule. NEWWA recommends that EPA delay the promulgation of the proposed regulations until the implementation challenges imposed on PWS are thoroughly evaluated and these findings are issued for public review and comment. We hope that EPA will strongly consider the information we are providing on behalf of New England PWS and will craft a final rule that is reasonable in its expectations of implementation and schedule and is adequately funded.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

New England Water Works Association (Doc. #1836, SBC-045390)

If a PWS must install treatment to address PFAS in their drinking water, it may cause the classification of their system to change, necessitating higher-grade licensed operators. In many states, operators sitting for higher-grade licenses have course requirements before they can even sit for the exams. EPA and primacy states must recognize that this will cause staffing issues and will need to provide compliance forbearance and flexibility for the operators to obtain the necessary licenses. As many PWS are already struggling to attract and retain appropriately licensed staff and the industry expects to lose many operators to retirement in the next 5 years, this is a significant concern.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. Regarding concerns on operator certification licenses, please see the EPA response to comment Doc. #1567, SBC-042738 in section 12.1 in this *Response to Comments* document.

Washington Association of Sewer and Water Districts (Doc. #1842, SBC-044772)

Unrealistic Implementation Timeline

An implementation timeline of three years is inadequate. Even without supply chain issues, monitoring and analyzing results, hiring of consultants, permitting, bid process and hiring construction companies, ordering and obtaining equipment, installation and required pilot testing would typically take longer than the three year limit. Today, facilities will have to be implemented at a time when there is an increase in demand for engineering, equipment, and construction contractors, requiring goods and services from a limited pool of qualified engineers, manufacturers, and construction contractors. Add to this the timeline for securing federal support dollars. The prospect of federal dollars to mitigate the costs Is welcomed, but whether federal dollars come in the form of a grant, forgivable loan, or loan, securing federal dollars takes an exceptionally long time and almost always lengthens the duration of a project. A final burden on the implementation timeline is that utilities are also implementing the important Lead and Copper Rule. This is already straining the financial and staffing resources available to many utilities. For all these reasons, a timeline of at least five years would still be an aggressive schedule but at least somewhat more realistic.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10) consistent with the request of the commenter. Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Metropolitan Washington Council of Governments (Doc. #1843, SBC-044754)

Our second recommendation concerns the timeline for compliance with the proposed NPDWR, which provides only three years from the date of final rulemaking with a possible two-year extension that is not guaranteed. Experience at the local level indicates that a more realistic time frame needed to add infrastructure improvements such as a new water treatment train to an existing water treatment plant is seven to ten years. This considers things such as compliance with procurement laws, piloting, land use approvals, permit approvals, design and specifications, equipment acquisition, construction, commissioning, and more. Providing local governments and water utilities with maximum flexibility and longer compliance timeframes will be important to the successful implementation of the proposed NPDWR.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Zone 7 Water Agency and Association of California Water Agency's Water Quality Committee (Doc. #3072-66, SBC-046381)

Okay, thank you. I'm Sarah Palmer. I'm from Livermore, California. I'm a PhD biochemist and I'm on the board of directors of Zone 7 Water Agency. I'm also a member of the Association of California Water Agency's Water Quality Committee and part of the PFAS work group. I fully support EPA's findings and applaud your work. In California, we are faced with the realities of permitting timelines and along with everyone else here, there are and will be supply chain issues. In light of this, the three-year compliance period may be too short. So, while time is of the essence for all of these health conditions, I respectfully suggest a compliance period of five years. Thank you.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10) consistent with the request of the commenter. Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Oak Bluffs Water District (Doc. #3072-80, SBC-046389)

I'm attorney Jack Collins. I'm the general counsel of the Oak Bluffs Water District. We're a small rural water district with about 4,000 year-round customers. We serve the town of Oak Bluffs. We're a disadvantaged community on the island of Martha's Vineyard. There are less than 20,000 year-round residents, but our summer population goes well over 100,000. We have six towns on the island, three of which have municipal water systems. These systems are all supplied by three to five wells each, and we all share a single sole-source aquifer. We found confusing the presence of certain PFAS chemicals in one test at two of our five wells, followed six months later with no such specific PFAS category only to find some subsequent test. Maybe the rain events are triggering the PFAS releases, we'll find that out. The source of PFAS on our island apparently comes from the former use by the military or firefighting foam at the local airport. Given time, these flows are very well likely to show up in our other three wells or one or both of the other towns on the island. Our engineers estimated it'll cost us about $18 million just to treat these two wells, which is about six times our annual budget. We can't shut down a well because it's not going to provide sufficient PFAS-free water in the summertime. Drilling new wells that are outside the area affected by the airport's polluted ground and thereafter installing infrastructure around the island will likely be the only feasible alternative to installing remediation systems at one well after another. So, while we're exploring eligibility for grants and loans, we ask you to take two common sense approaches. One, we may need to excuse the extension provisions you've talked about. Hopefully, your regulations will take into consideration the time required to devise a regional approach to solving this problem, and we envision needing one or more new wells outside the area impacted by the contamination. And secondly, please be sure that your regulations provide for an alternate construction-based proposal or an appeal mechanism for struggling municipal water systems like us as we explore

reasonable alternatives and suggest and submit the same to the EPA with concrete plans to reduce the PFAS to the proposed level, but over a reasonable period of time. Thank you for your time.

EPA Response: The EPA acknowledges commenter's concerns about treating drinking water for the communities he represents. The EPA notes that both treatment of existing wells or identifying new sources of drinking water (e.g., drilling new wells with uncontaminated groundwater) are both possible approaches to complying with this PFAS NPDWR. Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). The EPA anticipates the extended compliance deadline may give smaller and rural water utilities more time to apply for funding under BIL (please see section II of the final rule preamble for a discussion on BIL). The EPA also notes that SDWA § 1416(a) and (b)(2)(C) describe how the EPA or states that have primacy for exemptions may also grant an exemption for systems meeting specified criteria that provides an additional period for compliance. In a primacy state that has adopted the requirements for extensions, PWSs that meet the minimum criteria outlined in the SDWA may be eligible for an exemption of up to three years. For smaller water systems (≤3,300 population), exemptions can provide up to six additional years to achieve compliance.

Wagner Engineering (Doc. #3072-9, SBC-047359)

Thank you, Rob. My name is Dan Hilyer. I am the Utility Discipline Manager for Wagner Engineering. I want to first off thank EPA, applaud EPA, for their swift action to address the PFAS issues that are facing our country. I've got several comments here that I've phrased in the form of questions that address more the practicality of implementation for utilities. Is EPA prepared and willing to issue extension requests by utilities, due to limitations that would inevitably occur, due to the increased demand on testing labs, contractors, and materials that will be required to facilitate the necessary changes to water systems due to the proposed rule? Many of the systems that will be impacted by this rule will be groundwater systems that currently have minimal treatment requirements, and therefore are not required to have certified treatment operators, only certified distribution operators in most cases. The proposed rule will require treatment technologies that must be operated by certified treatment operators. This has the potential to significantly increase the demand for these operators and demand already outweighs the supply. Has EPA taken this into consideration, and what steps are being taken to address this learning issue?

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. For concerns regarding operator certification, please see the EPA response to comment Doc. #1567, SBC-042738 in section 12.1 in this *Response to Comments* document.

Arizona Water Company (Doc. #3072-11, SBC-047364)

The water utility industry is facing unprecedented supply challenges, including materials, contractors, and engineers to design and construct these specialized treatment facilities. We used to take 18-24 months to construct, now it takes 36 months or longer. So, we anticipate there to be a shortage in the specialized treatment technology manufacturers, contractors, and design engineers, which may delay a water utility's ability to construct treatment and comply with EPA's requirements. We request EPA consider this and provide more than three years for water utilities to comply with the rules. I want to thank the EPA for the opportunity to speak here today.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

American Water (Doc. #3072-51, SBC-047383)

My name is Lynda DiMenna and I am the Chief Environmental and Safety Officer for American Water. As the largest publicly traded drinking water and wastewater provider in the United States, we support the EPA's efforts to protect public health by proposing national drinking water standards for PFAS. American Water's initial analysis was based on federal PFAS standards, more in line with the limit set by several states. We are now carefully reviewing the proposed regulation to assess the 4 parts per trillion requirements for PFAS and the application of the hazard index. Our review includes projected costs associated with PFAS treatment at the proposed limits and the impact it would have on our customers' bills and will inform the written comment we submit to the EPA on May 30th. In a recent study conducted by Black & Veatch on behalf of the American Water Works Association, the estimated national costs to install treatment facilities to process to remove PFAS to the EPA's proposed level exceeds $47 billion, approximately $35 billion above what would be required to meet the current state's established PFAS limits. On a national basis, more than $700 million annually will be required for operations and maintenance costs to test and monitor for compliance. Approximately $500 million more than what would be required to meet current state established PFAS limits, significantly higher than the EPA's cost estimates. Based upon initial estimates, American Water will likely have more than 100 of our current existing water treatment facilities that will need upgrades for PFAS removal capabilities. A three- to four-fold increase in the number of treatment plants which had the most stringent previously established state standards. We estimate an investment in excess of $1 billion of capital to install additional treatment facilities over a three- to five-year period. We estimate annual operating expenses related to testing and treatment could be nearly $50 million. These are preliminary estimates dependent on final rule and effective date, as well as our system-by-system engineering analyses.

EPA Response: The EPA has evaluated the costs and benefits associated with the final NPDWR, including the information submitted by the American Water Works Association (AWWA) that is referenced in the comment. A detailed discussion of the agency's response to the cost analysis is found in section 13 of the EPA's *Response to Comments* document. Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Orange County Water District (Doc. #3072-54, SBC-047388)

Second, EPA has proposed the Safe Drinking Water Act's default three-year implementation timeline for water system compliance. Our existing state driven PFAS treatment program is already struggling to complete its projects within three years due to local permitting challenges and construction delays related to increasing demand for services and materials, labor shortages, and supply chain disruptions. Projects will only increase once EPA's rule is finalized. To avoid unnecessarily and burdensome consent agreements and orders for systems unable to come into compliance within three years, we reckon EPA itself allow for the two additional years for compliance time permitted under the Safe Drinking Water Act when capital projects are required instead of leaving that determination to the state primacy agencies.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Student, Vanderbilt University (Doc. #3072-72, SBC-047399)

Second, present technologists have different problems in reducing all the PFAS species and they're very low value, such as activated carbon, its performance works for short term PFAS, and ion exchange resins are hard to be regenerated while the RO membranes requires high energy costs. So instead of waiting for three years to achieve a very low MCL, a slightly higher but more feasible transition limitations is recommended to be achieved within a shorter time like one year or so. I believe any progress in PFAS removal can relieve and encourage the public. At the same time during the three years of implementation of this proposal, our destination can be an updated MCL taking account more PFAS species with improvement of scientific research. Besides, I think chemical factories that are discharging PFAS waste should be punished and pay for part of the waste, the water plant technology improvements. Finally, I really appreciate any efforts that EPA has done for protecting public health from PFAS contamination. Thank you.

EPA Response: The agency agrees with the commenter on the health concerns posed by PFAS and that establishing a national PFAS NPDWR as expeditiously as possible needed to

protect public health and the environment. While individual state primacy agencies could require action sooner, the agency cannot do so for all PWSs regulated through this NPDWR. SDWA § 1412(b)(10) requires that a "NPDWR shall take effect "3 years after the date on which the regulation is promulgated unless the administrator determines that an earlier date is practicable." For all the reasons discussed in section 12.1 of the EPA response in this *Response to Comments* document, EPA does not believe that it is "practicable" for water systems to comply earlier than three years. In fact, Section 1412(b)(2) also authorizes "the Administrator, or a State (in the case of an individual system), may allow up 2 additional years to comply with a maximum contaminant level…if the Administrator or the State…determines that additional time is necessary for capital improvements" and consistent with that provision, EPA is promulgating. a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. Lastly, actions related to PFAS discharges and assigning liability is beyond the scope of this current rulemaking; please see the EPA response in section 15.1 for additional details.

New Mexico Rural Water Association (Doc. #3072-98, SBC-047411)

Thank you very much for putting this on. I'm John Jones. I'm a member of the board of the New Mexico Rural Water Association and I'm affiliated with a 75-meter system in the Central Highlands of New Mexico. Very few doubt that there's a need to treat for PFAS even in small communities, but we're concerned about processing costs for construction, treatment, disposal, and increased labor skills, the lack of engineers and a flawed supply chain.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). The EPA anticipates the extended compliance deadline may give smaller and rural water utilities more time to apply for funding under BIL (please see section II of the final rule preamble for a discussion on BIL). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-047701)

If EPA moves forward with a phased MCL level, this would also alleviate some of the supply chain, labor shortage, and data gap issues many PWSs are currently facing. EPA has looked at exposure of concentrations of certain PFAS over a lifetime, therefore, allowing time for water systems with low levels of PFAS to address contamination properly and cost-effectively will not pose additional health risks.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments*

document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as discussion on a phased-in MCL approach.

Loudoun Water (Doc. #1717, SBC-047689)

The underestimation of utilities impacted by the proposed rule and the unrealistic compliance deadline will place significant demand on limited resources for consulting engineers, contractors, suppliers, and primacy agency support to achieve compliance. If thousands of additional systems are competing for supplies of granular activated carbon that many other water and wastewater systems rely upon for their existing treatment processes; this will likely result in related cost increases.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as discussion on a phased-in MCL approach. For additional discussion on treatment technology availability and capacity, please see section 10.6 of the EPA response in this *Response to Comments* document.

Metropolitan Washington Council of Governments (COG) (Doc. #1791, SBC-043772)

Our second recommendation concerns the timeline for compliance with the proposed NPDWR, which provides only three years from the date of final rulemaking with a possible two-year extension that is not guaranteed. Experience at the local level indicates that a more realistic time frame needed to add infrastructure improvements such as a new water treatment train to an existing water treatment plant is seven to ten years. This considers things such as compliance with procurement laws, piloting, land use approvals, permit approvals, design and specifications, equipment acquisition, construction, commissioning, and more. Providing local governments and water utilities with maximum flexibility and longer compliance timeframes will be important to the successful implementation of the proposed NPDWR.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. The EPA also notes that SDWA § 1416(a) and (b)(2)(C) describe how the EPA or states may also grant an exemption for systems meeting specified criteria that provides an additional period for compliance. PWSs that meet the minimum criteria outlined in the SDWA may be eligible for an exemption of up to three years. For smaller water systems (≤3,300 population), exemptions can provide up to six additional years to achieve compliance.

Teena Halbig (Doc. #2667, SBC-047348)

In Louisville, KY, we have CHEMOURS and adjacent is DOWDuPont plus many other mega industrial companies subjecting our population to humongous PFAS and other industrial pollutants which are polluting with impunity. The Air Pollution Control District (APCD) let DuPont Chemours get away with recent huge pollution for the measley sum of $7,500 – and intended to have their APCD Chair Carl Hilton sign this agreement when Carl worked for DuPont for 33 years, probably can be collecting a pension and possibly holds stock. It was not only unhealthy for citizens but unhealthy way for government to operate. I let the board and staff know of this conflict of interest and wanted to know their policies and bylaws. I wonder how many times Carl sat in his Chairman seat and participated in prior violations by DuPont Chemours? Please have ATSDR help the west end of Louisville where residents die 10 to 12 years earlier than east end residents. The APCD Director said in the past when a board member asked (after I spoke about PFAS) that "PFAS is mostly in the water". And I am very concerned about Louisville Water Co (LWC) where testing for about 17 PFAS (includes GenX) shows many ppt (includes GenX where Louisville is 2nd highest GenX in our DRINKING WATER out of 40 cities per EWG (Environmental Working Group, ewg.org). LWC should not be given 3 more years to meet new standards set by EPA since LWC already has data for years. Please do get the new standards/regs in place asap. LWC uses a lot of PR to brain wash customers that their water is the BEST!

EPA Response: The EPA acknowledges the commenter's concerns about drinking water and air in Louisville, KY. While outside the scope of the promulgation of the final PFAS drinking water standard, the EPA is initiating actions under multiple environmental authorities—the Resource Conservation and Recovery Act (RCRA), Toxic Substances Control Act (TSCA), Clean Water Act (CWA), SDWA and Comprehensive Environmental Response Compensation and Liability Act (CERCLA)—to identify past and ongoing releases of PFAS into the environment at facilities where PFAS has been used, manufactured, discharged, disposed of, released, and/or spilled. The EPA is conducting inspections, issuing information requests, and collecting data to understand the level of contamination and current risks posed by PFAS to surrounding communities and will seek to address threats to human health with all its available tools. The EPA works with its federal, state and Tribal regulatory partners through a comprehensive Safe Drinking Water Act compliance monitoring program to protect human health and the environment by ensuring that the regulated community obeys environmental laws/regulations through on-site visits by qualified inspectors, and a review of the information the EPA or a state/Tribe requires to be submitted. Requests for the Agency for Toxic Substances and Disease Registry (ATSDR) are beyond the scope of this rulemaking. (For information about ATSDR's process for citizens to request it assess public health concerns in a particular location, see https://www.atsdr.cdc.gov/petition-process.html.) Regarding commenter concerns on the compliance timeframe, please see section 12.1 of the EPA response in this *Response to Comments* document.

Office of Advocacy at the U.S. Small Business Administration (Doc. #1807, SBC-045488)

B. Advocacy recommends that EPA provide burden-reducing compliance flexibilities for small water systems.

To address the concerns raised above, the agency must consider and provide alternatives to reduce burden on small water systems. First, the agency should consider finalizing one of the regulatory alternatives to reduce the scope of the rule. Alternatively, the agency can phase in compliance by gradually lowering the MCLs to its target level (i.e., proposed MCLs). Finally, and most importantly, the agency must allow additional time for compliance for small water systems. If applied, these burden reducing flexibilities will allow the agency to achieve its statutory objective and reduce the significant economic burden on small water systems.

EPA Response: The EPA notes that the agency included multiple burden reduction flexibilities for small systems that resulted from its RFA pre-proposal Small Business Advocacy Review (SBAR) Panel process. For more information regarding the EPA's evaluation of the NPDWR under the RFA and about flexibilities the EPA included as a result of the SBAR Panel process, please see section XIII.C. of the final rule preamble and the final regulatory flexibility analysis in section 9.3 of the final rule economic analysis. Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as discussion on a phased-in MCL approach and exemptions that may be available under SDWA Section 1416.

Sammamish Plateau Water and Sewer District (Doc. #1573, SBC-042462)

[The proposed rule is particularly unclear in the following areas, and should be revised to provide clarity to water utilities by addressing the following:]

• The compliance date for reducing PFAS levels in the event of an MCL exceedance is unclear. Clarity is important both for responding with treatment and mitigation plans, but also to assure USEPA recognizes the practical aspects of designing and constructing treatment.

EPA Response: The date by which systems must comply with the MCLs is five years following rule promulgation and that date is clearly provided in the final rule and preamble.

Savannah River Nuclear Solutions LLC (Doc. #1647, SBC-043334)

Comment 4

Section XI. Treatment Systems (pg. 18684)

In the first paragraph of this section, EPA states that "Water systems with PFAS levels that exceed the MCLs proposed would need to take action to provide drinking water which meets the

NPDWR by the compliance dates established in the rule when final." While it is clear in the proposed rule when monitoring for PFAS will be required (within 3 years of the rule becoming final), it is not clear when EPA expects water systems to actually meet the MCL's proposed in the rule. Similar language on page 18369 (Executive Summary), "Water systems with PFAS levels that exceed the proposed MCLs would need to take action to provide safe and reliable drinking water" does not provide any clear timeframe for which compliance with MCL's is required. Additional clarity is needed on this so that water systems can begin to prepare capital plans and budgets for installing the required Best Available Technology (BAT).

EPA Response: The date by which systems must comply with the MCLs is five years following rule promulgation as provided in the final rule and preamble.

Massachusetts Water Resources Authority (Doc. #3072-49, SBC-047382)

Finally, I'd like to add that EPA needs to evaluate how to create sufficient flexibility in the compliance framework to allow systems to come into compliance. The timeline simply doesn't work. Thank you.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-044920)

EPA could also take a similar approach that it used with the arsenic rule (see table below), where systems were eligible for an exemption based on concentrations [FN14: https://www.epa.gov/sites/default/files/2015-09/documents/2005_11_10_arsenic_ars_final_app_g.pdf]. Water systems would still have five years for compliance but would be eligible for the three-year exemption based on the concentrations of PFAS in their system. A potential option would be using over or under 10.0 ppt as a determination threshold, as EPA already explored the option of a 10.0 ppt MCL and approximates 1,300 systems would be impacted. These 1,300 systems would need to be in compliance in the 5 years, but those under 10.0 ppt would have a little more time to explore other options or to spread out the demand for materials and labor. [Table 1: See Docket ID EPA-HQ-OW-2022-0114-1672]

This would allow for systems with the highest concentrations of PFAS, and therefore the highest risk to public health, to address the issue first and have first access to the materials and labor needed for treatment, like a "worst-first" approach. Water systems that are closer to the MCL would have a little longer to comply to alleviate strains in supply chain and labor and would not provide an unreasonable risk.

A feasible compliance timeline is paramount to the success of this rulemaking. Rampant noncompliance places an unnecessary burden on primacy agencies and EPA and undermines the confidence of the public in its drinking water. The public would be better served by knowing the path to compliance is achievable than by being routinely notified that their drinking water fails to meet newly implemented standards. Repeated notices of noncompliance will only drive more people to drink bottled water – which, ironically, does not have to comply with the same PFAS monitoring and treatment standards, and which therefore may actually contain higher levels of the contaminants than water from a PWS found to be in violation of EPA's new rule. EPA and water systems must work together to build and maintain trust in drinking water. Unfortunately, distrust of drinking water leads to individuals, including those in low-income and underserved communities, spending money needlessly on less-regulated water bottled in plastic.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as discussion on a phased-in MCL approach and exemptions. For additional discussion on how the agency considers analytic feasibility when establishing the MCL, please see section 5.1.2 of the EPA response in this *Response to Comments* document. Regarding initial monitoring timing, please see section 8.1.1 of the EPA response in this *Response to Comments* document. With respect to public notice requirements related to violations of the PFAS NPDWR, please see section 9.2 of the EPA response in this *Response to Comments* document. All PN must include the elements identified in § 141.205(a), including what actions the consumers should take and whether alternative water supplies should be used. Consistent with the existing PN rule in § 141.203(b)(2), primacy agencies may allow less frequent repeat notices for Tier 2 PNs in certain circumstances; these notices must be in writing. The EPA believes repeat notices are beneficial in increasing the likelihood of reaching all affected parties and allow systems to provide updates for consumers on the situation. The Food and Drug Administration (FDA) has authority for bottled water which is outside of the scope of this NPDWR.

American Water Works Association (AWWA) (Doc. #1759, SBC-047705)

The EPA's proposed approach (4 ppt PFOA, 4 ppt PFOS, and hazard index of 1.0 for PFHxS, PFNA, HFPODA, and PFBS) will not be feasible, as they will create significant challenges for water systems to implement, is not clearly EPA's legal authority under SDWA, and rely on a series of critically flawed analyses that mischaracterize the impacts of the proposed rule. As discussed earlier, the large number of systems that will need to install drinking water treatment will create challenges in implementing the MCLs on the timeline provided by the EPA and, ultimately, systems will not be able to meet these timelines while also applying best engineering practices to plan, design, and construct these facilities.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. The agency also disagrees with the commenter that the EPA does not have clear legal authority to regulate mixtures of PFHxS, PFNA, HFPO-DA and PFBS through a Hazard Index MCL; for additional discussion on this topic, please see section 3.2 of the EPA response in this *Response to Comments* document. With respect to commenter concerns on "impacts of the proposed rule," please section 13 of the EPA response in this *Response to Comments* document.

Aquarion Water Company (Doc. #1617, SBC-043377)

3. To address the issues with the 3-year compliance timeframe, and to ensure that water supplies with the most significant PFAS pollution are prioritized by stakeholders (e.g., utilities, regulators, funding agencies, local officials), we suggest that EPA consider a progressive approach to the new MCLs, by reducing the MCLs in stages over multiple years. This would allow stakeholders to focus first on water supplies with relatively high levels of PFAS that are the greatest risk to consumers. This approach would also allow utilities and regulators to learn more about treatment solutions and costs over time, and thus allow for more informed decision-making as the MCLs progressively decrease.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as a phased-in MCL. For additional discussion on alternative regulatory standards (including higher PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Beaufort-Jasper Water & Sewer Authority (BJWSA) (Doc. #1618, SBC-042935)

To address these concerns, we request that EPA modify the proposal to take a phased approach to PFAS regulation. Implementing a higher maximum contaminant level for PFAS initially will allow focus on source waters where more significant PFAS concentrations exists. This will also provide for a more reasonable approach and a better use of resources to address PFAS contamination in public waterways. An implementation schedule starting out with higher limits (e.g., 10 parts per trillion) followed by several multi-year periods of gradual contaminant limit reduction would allow utilities the time to plan and identify opportunities for source water reduction (which is the most cost-effective remedy available). We remind EPA that the health advisory level for PFAS contaminants PFOA and PFOS was 70 parts per trillion less than one year ago. With EPA's current proposal, the maximum allowable levels in drinking water will be substantially lower while giving utilities very little time to react, investigate, or plan.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline as well as a discussion of phased-in MCLs. For additional discussion on alternative regulatory standards (including higher PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-044909)

The greatest health risks from PFAS in drinking water will come from systems with the highest concentrations, not those at the margins of compliance with EPA's proposal. EPA should work to address these systems first to protect individuals in those service areas. EPA's proposal estimates approximately 4,300 PWSs will be impacted by this rule [FN7: EPA Economic Analysis, (USEPA, 2023j)]. Cleveland Water emphasizes that the upcoming implementation of UCMR 5 will provide more accurate estimations of the impacted systems' PFAS levels. Any system with levels above the proposed MCLs must promptly initiate planning and execute interventions to address PFAS contamination once this rule is finalized. It is important to anticipate that this substantial demand will exert significant pressure on supply chains and the labor market. Meanwhile, EPA estimates around 3,300 PWSs would be impacted if MCLs were implemented at 5.0 ppt, and about 1,300 PWSs with MCLs set to 10.0 ppt. These 1,300 PWSs with PFOA and/or PFOS above 10.0 ppt should be prioritized, as greater demands in GAC, materials, and labor could prevent these systems from quickly remediating the issue, potentially exposing the public in these service areas to higher concentrations of PFAS for a longer period.

If EPA chooses to rush through finalizing this rulemaking before the September 2024 statutory deadline, it would be advantageous to finalize an MCL at a level feasible by PWSs and still meaningfully protecting public health. EPA should initially require PWSs with levels of PFAS >10 ppt to implement actions to reduce the public's exposure to these levels first. Then, EPA can use UCMR 5 and other up-to-date research to further explore lowering that threshold. The agency would still be protecting the health of the public and would simultaneously be alleviating the strains, demands, and increased costs for labor, materials, and construction. This would also allow PWSs with lower concentrations to explore other, less costly, measures to reduce exposures to PFAS, yielding both fiscal and health-related advantages for the public.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline. For additional discussion on alternative regulatory standards (including higher PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenter that this rulemaking is rushed or that the agency needs to wait for additional information (such as UCMR 5 information) in order

to finalize the NPDWR at this time. The EPA currently has determined that these PFAS meet the criteria for regulation under SDWA, that such regulation is a priority, and that there is sufficient data and information to promulgate standards for the PFAS regulated through this NPDWR: please see section 6 of the EPA response in this *Response to Comments* document for the agency's discussion on occurrence.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-047704)

In addition, given the challenges with timelines and lab capacity as explained in Sections 5.5 and 5.6, if EPA were to finalize the rule with a 10 ppt MCL for PFOA and PFOS, with an extended compliance timeline, the agency would be protecting public health while simultaneously reducing burdens on PWSs. At the same time that EPA promulgates the final rule, the agency could recognize the possibility of moving forward to lower the MCL for PFOA and PFOS after receiving and analyzing additional information that would better inform a more complete and accurate RIA. This would include:

● Nationwide occurrence data received from UCMR 5;

● A more robust and accurate cost estimation; and

● A better reflection of up-to-date research and analyses on health benefits of further reducing PFAS concentration at the ppt level.

A phased MCL level would also alleviate some of the supply chain, labor shortage, and data gap issues many PWSs are currently facing. EPA has looked at exposure of concentrations of certain PFAS over a lifetime; therefore, allowing time for water systems with low levels of PFAS to address contamination properly and cost-effectively will not pose additional health risks.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline, as well as a discussion of phased MCLs. For additional discussion on alternative regulatory standards (including higher PFOA and PFOS MCLs), please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenter that the agency needs to wait for additional information (such as UCMR 5 information or additional health effects data) in order to finalize the NPDWR at this time. The EPA currently has sufficient data and information to promulgate standards for the PFAS regulated through this NPDWR: please see section 4 of the EPA response in this *Response to Comments* document for the agency's discussion on MCLGs, section 13 for the agency's discussion on the economic analysis, and section 6 of the EPA response in this *Response to Comments* document for the agency's discussion on occurrence.

Prince William County Service Authority (Doc. #1609, SBC-042838)

Additionally, the short schedule proposed by EPA effectively cuts off the ability of a water utility to benefit from upstream source reduction activities by others, such as product substitutions and/or treatment installation at upstream PFAS-discharging industries, which may eliminate the need for ratepayers to bear the cost of water treatment plant upgrades. For water systems experiencing PFAS concentrations slightly above the proposed MCLs, this is an especially problematic aspect of the proposed regulation that should be revised. For example, for water systems with concentrations of 5 or 6 ppt, targeted reductions by one or more upstream industries could potentially achieve a 4 ppt MCL far more cost-effectively than adding treatment to the water system.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

California-Nevada Section American Water Works Association (CA-NV AWWA) (Doc. #1775, SBC-045284)

If levels exceed health-based thresholds, the next step should be to evaluate options and employ a holistic long-term approach to help drinking water systems comply with PFAS MCLs. A first step should allow time for industrial sources to be identified and mitigated. Key efforts should include the elimination of environmental loading and drinking water supply protection. Finding and mitigating sources of PFAS contamination would serve the long-term goals for protecting drinking water supplies from PFAS and possibly other contamination, and we appreciate EPA actions of this kind.

The California-Nevada Section of AWWA sincerely appreciates the opportunity to share the preceding comments for your consideration. We remain committed to the SDWA framework and to its goal that every person should have access to the safest water possible, considering technical and economic feasibility.

Sincerely,

Sue Mosburg

Executive Director

EPA Response: The EPA notes that eliminating sources of PFAS contamination is beyond the scope of this rulemaking; however, the agency notes that it is taking an all-of-agency approach toward addressing PFAS (please see section 15.1 of the EPA response in this *Response to Comments* document for additional discussion). Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension

pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Ohio Water Utility Council (OWUC), Ohio American Water Works Association (OAWWA) (Doc. #1782, SBC-044725)

OWUC appreciates EPA's goal of protecting public health and the drinking water sources for the citizens of the United States. Ohio's water utilities are committed to the same goal and are diligently working daily to provide that to our customers. While we agree with this goal, OWUC believes shifting the focus to eliminating PFAS substances at the source is a more effective use of resources by EPA. The regulatory requirements on industrial sources of PFAS substances are not on the same pace as those for public drinking water systems, where the exposure totals much less than industrial sources. Identifying these sources, eliminating contamination at those sites and lengthening the compliance schedule for this proposed rule will benefit drinking water systems by reducing or eliminating the needed treatment for PFAS and the associated costs.

Thank you again for the opportunity to comment on these proposed rules. Should the USEPA have additional questions or in need of clarification, the OWUC is available for discussion. Contact information is provided below.

Sincerely,

Sarah C. Van Frank-Affrunti

Ohio Water Utility Council, Chair

Ohio American Water Works Association Affruntis@swwater.org

EPA Response: The EPA notes that eliminating sources of PFAS contamination is beyond the scope of this rulemaking, however the agency notes that it is taking an all-of-agency approach toward addressing PFAS (please see section 15.1 of the EPA response in this *Response to Comments* document for additional discussion). Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Fairfax Water (Doc. #1789, SBC-045294)

EPA Should Prioritize its PFAS Efforts on Eliminating Sources of Contamination

Fairfax Water supports EPA's efforts to reduce PFAS in the environment. However, instead of prioritizing regulation of sources of PFAS, EPA proposes to regulate PFAS through drinking water, a significant divergence from the "polluter pays" principle. PFAS compounds continue to be manufactured and used in a wide variety of industrial and consumer products. Water utilities

are passive receivers of PFAS compounds that make their way to our sources of supply. Through the proposed regulation, the rate-paying public will be responsible for bearing the entire cost of PFAS removal, not the polluters.

Further, the proposed compliance period provides no meaningful opportunity to identify and eliminate potential sources of PFAS that may contribute to exceedances of the proposed PFAS Maximum Contaminant Levels (MCLs) or Hazard Index (HI). Eliminating sources is the ultimate solution to removing PFAS from the environment. Fairfax Water's Occoquan Reservoir is an indirect potable reuse system with some industrial discharges to the publicly owned treatment works (POTW). The state has conducted some sampling for PFAS in the watershed and Fairfax Water is planning to do more. There are potential opportunities to remove PFAS sources from the water supply but no regulatory mechanism to do so. Providing adequate time for state regulatory agencies to identify PFAS sources and a national regulatory framework that supports the elimination of those sources would place the cost for remediation where it belongs - on the polluter instead of the public.

The PFAS treatment alternatives identified in the proposed rule do not destroy PFAS; they simply move PFAS from one medium to another, creating a further environmental risk to be borne by the public. Failure to address the fundamental issue of continued introduction of PFAS into the environment as part of a rational, comprehensive regulatory framework, while requiring water utilities to remove them from drinking water at great public expense, merely kicks the PFAS "can" down the road. We ask EPA to prioritize a comprehensive regulatory scheme at the national level to remove PFAS from the environment that focuses on controlling sources, not passive recipients like water utilities.

EPA Response: The EPA notes that eliminating sources of PFAS contamination is beyond the scope of this rulemaking; however, the agency notes that it is taking an all-of-agency approach toward addressing PFAS (please see section 15.1 of the EPA response in this *Response to Comments* document for additional discussion). The EPA also notes that from a mass balance perspective, PFAS removal from drinking water is generally anticipated to result in lower concentrations of PFAS in the environment. With appropriate controls, landfills and thermal treatment of PFAS contaminated media can minimize PFAS releases to the environment (USEPA, 2020). Please see section 10.4.1 of the EPA response in this *Response to Comments* document for more discussion on media shifting. Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Neuse Regional Water and Sewer Authority (Doc. #1822, SBC-044570)

2. EPA should shift compliance costs to those responsible for the PFAS pollution.

The costs to NRWASA to implement the Proposed Rulemaking will be unprecedented and unbudgeted. If it is determined that the concentration of any PFAS in a public water system has exceeded a permissible concentration level, the PFAS manufacturer or discharger should be responsible for paying the actual and necessary costs incurred by the public water system to remove. The manufacturer should correct or abate the adverse effects of PFAS in the water supply system resulting from the contamination for which the PFAS manufacturer is responsible.

The Proposed Rulemaking further notes that "[c]onventional and most advanced water treatment methods are ineffective at removing PFAS." [FN3: Id. at 18684.] Not only will NRWASA need to invest in one of the technologies contemplated by the Proposed Rulemaking, it also must provide for testing, personnel, and potentially hazardous waste disposal [FN4: See id. at 18686.]. This, combined with NRWASA's expected up-front compliance costs and additional annual costs will pose a significant strain on NRWASA's ability to provide water for the people of Lenoir and Pitt Counties.

Shifting costs or instituting a program requiring PFAS manufacturers to pay for these costs is consistent with EPA's guidance for addressing PFAS discharges in EPA and state issued NPDES permits. A similar regime should be part of the Proposed Rulemaking, or the effective date delayed until the cost issue can be addressed. NRWASA should not have to bear the full cost of treatment upgrades for contamination caused by those responsible for creating the PFAS problem. The Proposed Rulemaking should be revised to address this cost factor and to shift the cost to those responsible for creating PFAS pollution.

EPA Response: The EPA notes that eliminating sources of PFAS contamination is beyond the scope of this rulemaking; however, the agency notes that it is taking an all-of-agency approach toward addressing PFAS (please see section 15.1 of the EPA response in this *Response to Comments* document for additional discussion). Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

American Water (Doc. #3072-51, SBC-047384)

Implementation timing should also consider the available capacity of engineers, contractors, and suppliers to build a required treatment and available capacity of vendors to supply ion exchange resin, granular activated carbon and media reactivation, waste disposal services on an ongoing basis. American Water calls for sound policies that will ensure compliance by all water utilities, whether privately or municipally owned. This includes advocating for policies that would hold polluters accountable for the ultimate responsibility for cleanup of these contaminants, falling to those who created the problem. This effort comes at a cost and states should treat these expenditures for regulated utilities as federally mandated requirements that are recoverable in customers' rates through expedited means. American Water joins other organizations urging U.S.

EPA, Congress, and other decision makers to implement policies that keep harmful PFAS out of drinking water supplies for our communities, exempt all water and wastewater systems from financial liability for PFAS under CERCLA.

EPA Response: The EPA notes that topics related to eliminating sources of PFAS contamination or assigning PFAS liability are beyond the scope of this rulemaking, however the agency notes that it is taking an all-of-agency approach toward addressing PFAS (please see section 15.1 of the EPA response in this *Response to Comments* document for additional discussion). Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on supply chain and labor challenges that may affect the compliance timeline.

Kerri Spayd (Doc. #1790, SBC-045318)

From: Kerri Spayd <allareakspayd@gmail.com>

Sent: Thursday, May 4, 2023 12:16 PM

To: OW-Docket

Subject: EPA-HQ-OW-2022-0114

Follow Up Flag: Follow up

Flag Status: Flagged

As a resident of a small community that has a centralized facility with a hazardous waste violation, HSI 10141, and a Voluntary Remediation Plan that includes documentation of the presence of PFAS in the soil, I would like to know if the PFAS/PFOA rule will propagate new investigations and/or indicate the community ground water system be required to adhere immediately to the proposed rulings verses the three year mandatory compliance?

Thanks for your time,

Kerri Spayd

EPA Response: The NPDWR regulates PFAS levels in finished drinking water only; SDWA imposes no requirements to monitor or regulate the water quality levels of PFAS in drinking water sources. Additionally, the PFAS NPDWR does not require a PWS to determine the sources of PFAS in its source water. Regarding commenter concerns on the compliance timeframe, EPA has not found that it is practicable for water systems to comply with the rule earlier than the 3 year timeframe set out in SDWA for the reasons discussed in section 12.1 of the EPA response in this *Response to Comments* document

Virginia Municipal Drinking Water Association (VMDWA) (Doc. #1657, SBC-043162)

A phased approach that prioritizes addressing a smaller set of water systems with higher PFAS concentrations first, and phases-in overtime whatever further reduced levels may be appropriate over the long-term for systems with lower PFAS concentrations, could be a better way to protect public health, avoid implementation and construction delays, and avoid wasted resources, especially when also considering the current construction market cost problems and price premiums and the schedule infeasibility problem discussed below.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). Please see section 12.1 of the EPA response in this *Response to Comments* document for the EPA's discussion on phased-in MCLs. Please see section 5.1.3 of the EPA response in this *Response to Comments* document for a summary of major comments. (cost considerations and alternative MCLs).

Virginia Municipal Drinking Water Association (VMDWA) (Doc. #1657, SBC-043172)

Sixth, the short schedule under the proposal effectively cuts off the ability of water treatment plants and their ratepayers (the public) to benefit from source reduction activities by others, such as a product substitutions and treatment installation at upstream PFAS-discharging industries, which would eliminate the need for ratepayers to bear the cost of water treatment plant upgrades. For water systems experiencing PFAS concentrations slightly above the proposed MCLs, this is an especially problematic aspect of the proposed regulation that should be revised. For example, for water systems with concentrations of 5 or 6 ppt for PFOA or PFOS, targeted reductions by one or more upstream industries could potentially achieve a 4 ppt MCL far more cost-effectively than adding treatment to the water system. In this sense, the proposed regulation also runs contrary to the generally-accepted public policy concept of "polluter pays" and transfers the burden to families and other innocent ratepayers, because there is no time allowed in this regulation for source water reductions to be accomplished. The proposal's tight schedule forces all affected water systems to jump immediately into design and construction on a compressed timeline.

EPA Response: Regarding commenter concerns on the compliance timeframe, the agency is promulgating a two-year capital improvement extension pursuant to SDWA 1412(b)(10). While beyond the scope of this rulemaking, the EPA is making progress implementing many of the commitments in the Strategic Roadmap, including those that may significantly reduce PFAS source water concentrations. Please also see section 15.1 of the EPA response in this *Response to Comments* document.

Section 12 References

American Water Works Association (AWWA). 2023. AWWA Comments on the Proposed "PFAS National Primary Drinking Water Regulation Rulemaking." Available at: https://www.regulations.gov/comment/EPA-HQ-OW-2022-0114-1465

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USEPA. 2002. *Implementation Guidance for the Arsenic Rule, Exemptions & the Arsenic Rule*. EPA 816-R-02-021. August 2002. Available on the Internet at: https://www.epa.gov/sites/default/files/2015-09/documents/2005_11_10_arsenic_ars_final_app_g.pdf

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USEPA. 2024a. Drinking Water Assistance Agreement Report Filters https://sdwis.epa.gov/ords/sfdw_pub/r/sfdw/owsrf_public/assistance-agreement-report-filters?app_cw_dw=DW&clear=10

USEPA. 2024b. *Best Available Technologies and Small System Compliance Technologies Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water*. 815R24011.

13 Health Risk Reduction and Cost Analysis

13.1 Affected Entities and Major Data Sources Used to Develop the Baseline Water System Characterization

Summary of Major Public Comments and EPA Responses

One commenter was supportive of the EPA's baseline water system characterization and pointed out multiple areas where important considerations were accounted for and that reasonable assumptions were made.

One commenter cited preliminary research suggesting that the concentrations of PFOA and PFOS in rainwater are frequently higher than the 4.0 ppt Maximum Contaminant Level (MCL), and that this environmental contamination will lead to a dramatically higher number of public water systems (PWSs) affected by this rule than estimated by the EPA. The EPA disagrees with the commenter that additional unaccounted for sources of PFAS pollution will dramatically change the affected number of PWSs under the rule. As discussed in section VI of the preamble for the final rule and in USEPA (2024a), the EPA used PFAS occurrence data collected from PWSs to characterize baseline conditions in the PFAS National Primary Drinking Water Regulations (NPDWR). The drinking water PFAS occurrence estimates used in the baseline characterization reflect the finished water PFAS concentrations in PWSs. While the Safe Drinking Water Act (SDWA) does not require the EPA to assess contamination directly from rainfall, upstream sources of PFAS contamination into PWS source waters, including contamination from rainfall, may reasonably be captured in the baseline characterization due to fate and transport of PFAS into drinking water supplies. However, the PFAS occurrence information available from PWSs, which was used to support the agency's occurrence and baseline analyses in this rulemaking, is the most appropriate information to use to characterize PFAS occurrence in drinking water supplies because rainwater concentrations may not translate directly to PFAS occurrence levels in drinking water supplies. See discussion in sections 3.1.2, 3.2.2, and 6 of the EPA response in this *Response to Comments* document for further discussion and responses regarding occurrence information.

One commenter disagreed with the EPA's assumption that drinking water PFAS concentrations will remain constant in the absence of its proposed rule. This commenter stated that baseline PFAS concentrations are likely to decrease as states impose their own PFAS drinking water regulations and there are more voluntary actions to install PFAS treatment. The commenter also cited other rulemakings such as a hazardous substance designation under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), as a driver for utilities to take voluntary action to reduce PFAS concentrations in drinking water in order to reduce their CERCLA liability. While what *might* happen as a result of rulemaking currently under development under CERCLA authorities is beyond the scope of this rulemaking, the EPA disagrees that the CERCLA rulemaking once finalized would spur voluntary action to remove PFAS from drinking water in the interest of reduced liability for water systems. The commenter

provides no evidence to support this argument and given the input provided by water utilities in the CERCLA rulemaking process that handling drinking water treatment residuals increases, not decreases, concerns about perceived liability, it seems highly unlikely that CERCLA would drive water systems to remove PFOA and PFOS to below 4 ppt each, absent the NPDWR. The EPA notes that as discussed in the CERCLA rulemaking, among the possible indirect benefits of the CERCLA designation is a reduced amount of PFAS entering drinking water sources, but the timing and magnitude of those impacts are uncertain. While the EPA agrees that environmental concentrations of regulated PFAS may reasonably reduce over time as a result of federal, state, and local actions to reduce PFAS, the EPA is unable to accurately forecast the extent to which PFAS concentrations will be reduced in drinking water supplies as a result of other regulatory or voluntary actions. Therefore, the EPA maintains that the Unregulated Contaminant Monitoring Rule (UCMR) and state datasets, as used to characterize baseline occurrence conditions for the NPDWR, represent the most accurate and comprehensive information available on PFAS occurrence in PWSs. Additionally, actions taken by state regulators or utilities utilizing emerging contaminant grants may lead to localized decreases in PFAS drinking water concentrations, which have been accounted for as part of the baseline analysis as the EPA adjusted the baseline to reflect the assumption that PWS in states with existing regulations have baseline occurrence at the state MCLs. However, the baseline characterizes the nation as a whole, which will not see significant decreases in finished drinking water concentrations, in the absence of a NPDWR. The EPA further notes that, to the extent that the emerging contaminant grants effectively reduced PFAS concentrations in states without PFAS regulations that were reported to the EPA or state agencies in the years of occurrence data that we assessed for the baseline, the potential impact has been captured.

One commenter stated that the data used to inform baseline and compliance characteristics are incomplete and insufficient, and that characteristics for which data are missing in federal reporting systems are estimated using inappropriate assumptions. The EPA disagrees with these claims. The EPA periodically reviews inventory information in the Safe Drinking Water Information System / Federal Version (SDWIS/Fed); the inventory data in the national Error Code Tracking Tool (ECTT) indicate a high degree of completeness and accuracy in SDWIS/Fed, and that the information is largely representative of the regulated PWS. For more information on the ECTT, see (USEPA, 2007a) incorporated in the administrative record for this action.

Individual Public Comments

Protecting Our Water, Environment, and Ratepayers (POWER) (Doc. #1714, SBC-045934)

The levels of PFOA and PFOS in rainwater have been shown to exceed the levels permitted under the proposed MCL.

Preliminary research has compared the levels of PFAS in rainwater to the levels of PFAS permitted under various worldwide drinking water standards. [FN15: Cousins, Ian T., et. al, Outside the Safe operating Space of a New Planteary Bounder for Per- and Polyfluoroalkyl

Substances (PFAS) Environ. Sci. Technol. 2022, 56, 11172, Figure 1.] This study shows that the concentrations of both PFOA and PFOS in rainwater frequently exceed the 4 ppt proposed MCL in both rural and urban areas. Because we are finding that concentrations in rainwater are often higher than the MCLs proposed, it is highly foreseeable that a 4 ppt MCL will impact a dramatically higher number of water and wastewater agencies than was estimated in the proposed rule.

EPA Response: Please see section 13.1 of the EPA response in this *Response to Comments* document. As discussed in that response, the EPA disagrees with the commenter that additional sources of PFAS pollution will dramatically change the affected number of PWSs under the rule because upstream sources of PFAS contamination into PWS source waters, including contamination from rainfall, may reasonably be captured in the baseline characterization due to fate and transport of PFAS into drinking water supplies.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046010)

Additional Assumptions in EPA's EA

Changes to Baseline Due to Voluntary Actions

EPA assumes that drinking water concentrations will remain constant in the absence of its proposed rule. As a result, EPA's assumption overstates the net benefits of the rule because other PFAS actions and regulations will likely decrease occurrence in drinking water.

In the absence of EPA's proposed rule, the baseline PFAS occurrence will likely decline due to increasing regulatory action at the state level and additional voluntary actions. Additionally, in September 2022, EPA published a NPRM designating PFOA and PFOS as CERCLA hazardous substances [FN45: "Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances," Federal Register 87, no. 171 (September 2022): 54415–42.]. The designation, if finalized, will have far-reaching impacts as industries and utilities shift activity to prevent PFAS releases and litigation. Utilities may try to reduce PFOA and PFOS concentrations to reduce their CERCLA liability with or without a federal drinking water standard.

Finally, there will be more voluntary PFAS treatment installations as a result of increased federal funding initiatives dedicated to reducing PFAS contamination levels. Of the $48 billion appropriated for drinking water and wastewater in the IIJA, $4 billion is set aside to address emerging contaminants in drinking water with a focus on PFAS and an additional $5 billion will be appropriated to help small and disadvantaged communities address emerging drinking water contaminants [FN46: 46 U.S. Environmental Protection Agency, "Emerging Contaminants (EC) in Small or Disadvantaged Communities Grant (SDC)," n.d.]. This funding can only be used to address capital costs.

EPA Response: Please see section 13.1 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046024)

Affected Entry Points to System (EPTDSs) and Average Flow

EPA provides an estimate of total entry points to distribution systems (EPTDS) that will be affected by the proposed NPDWR (see Table 19). The analysis extends EPA's estimate further to distribute these EPTDSs by system size categories.

Table 19: Total EPTDSs Impacted

[Table 19: see docket ID EPA-HQ-OW-2022-0114-1738]

[FN128: U.S. Environmental Protection Agency, "Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation," tbls. 4–22.]

The analysis distributes the EPTDS by CWS size and source water type by applying ratios derived from the CWS inventory (see discussion preceding Table 10). The estimated number of affected EPTDSs by CWS size is summarized in the following table.

Table 20: Total Estimated EPTDSs that Exceed One or More MCL by CWS Size

[Table 20: see docket ID EPA-HQ-OW-2022-0114-1738]

Next, the average flow is calculated by dividing the average flow per CWS by the design flow per CWS. Flow increases with system size, with the largest CWSs having an average flow of 22 MGD for each entry point. Average daily production flow and design flow per system are based on regression equations from EPA's Geometries and Characteristics of Public Water Supplies report [FN129: U.S. Environmental Protection Agency, 4–14. Science Applications International Corporation and The Cadmus Group, "Geometries and Characteristics of Public Water Systems" (U.S. Environmental Protection Agency, December 2000).]. The average daily flow and design flow are functions of the population served, with different equations for source water type Table 21: Average Flow (MGD per EPTDS)

[Table 21: see docket ID EPA-HQ-OW-2022-0114-1738]

EPA Response: The excerpts above discuss the interim steps taken to characterize affected entities for purposes of the commenter's analysis of greenhouse gas emissions as a result of the PFAS NPDWR. Please see section 13.11 of the EPA response in this *Response to Comments* document for a summary of public comments on greenhouse gas emissions, Chapter 9 of the final economic analysis (EA) for the EPA's analysis of greenhouse gas emissions, and Chapter 4 of the final EA for the EPA's characterization of entry points and flow characteristics for affected entities.

American Water Works Association (AWWA) (Doc. #1759, SBC-046161)

5.1 Determining Design Parameters

5.1.1 Treatment Design Flow Determination

PWS data available in SDWIS do not include water usage data for each PWS and EPTDS. Instead, service population data from SDWIS was used and the average flow for each PWS was assumed based on a per capita per day usage of 150 gallons. While not reflective of each state's dynamics with respect to water usage, this was considered a reasonable number from a national perspective. Peaking factors for different size systems from the EPA's "Cost and Technology Document for Final Groundwater Rule" were used and are shown in Table 5-2. The trend of this dataset was best fit to a power equation to calculate peaking factor as a function of average daily flow as shown on Figure 5-1.

Table 5-2- EPA Peaking Factor for Various Average System Flows

[Table 5-2: Docket ID: EPA-HQ-OW-2022-0114-1759]

[Figure 5-1: Docket ID: EPA-HQ-OW-2022-0114-1759]

Figure 5-1 Peaking Factor as a Function of Average System Flow

The treatment design flow per EPTDS was determined by Equation 1:

[Equation 1: Docket ID: EPA-HQ-OW-2022-0114-1759]

The estimated number of EPTDS per system size is based on an evaluation by EPA published with the proposed national primary drinking water regulation for PFAS from March 2023. The number of EPTDS per system broken out by groundwater and surface water systems within each system size bin is summarized in Table 5-3.

Table 5-3 Number of EPTDS as a Function of System Size

[Table 5-3: Docket ID: EPA-HQ-OW-2022-0114-1759]

EPA Response: The excerpts above discuss the interim steps taken to characterize affected entities for purposes of the commenter's analysis of greenhouse gas emissions as a result of the PFAS NPDWR. Please see section 13.11 of the EPA response in this *Response to Comments* document for a summary of public comments on greenhouse gas emissions, Chapter 9 of the final EA for the EPA's analysis of greenhouse gas emissions, and Chapter 4 of the final EA for the EPA's characterization of entry points and flow characteristics for affected entities.

3M Company (Doc. #1774, SBC-045697)

d. Significant Data are Missing and Insufficient Detail is Provided Regarding Imputation

EPA lacks complete PWS-specific data across the 49,193 community water systems (CWSs) and 17,337 non-transient non-community water systems (NTNCWSs) in the Safe Drinking Water Information System (SDWIS/Fed) for many of the baseline and compliance characteristics necessary to estimate costs and benefits. Data are incomplete for design, average daily flow rates, water quality characteristics, treatment in-place, and labor rates, among other factors. EPA

does not explain 1) the number of CWSs for which data are missing, 2) the number of each baseline and compliance characteristic for CWSs that are missing by CWS category, 3) the number of NTNCWSs for which data are missing, or 4) the number of each baseline and compliance characteristic for NTNCWSs that are missing by NTNCWS category. EPA states that "[i]n some cases, the categorical data are simple point estimates. In this case, every model PWS in a category is assigned the same value" (USEPA 2023f, p. 18691). Consequently, many characteristics necessary to estimate costs and benefits—such as design, daily flow rates, water quality characteristics, among others—may be simple category-wide or nationwide averages. It appears that, in estimating the costs and benefits of the proposed NPDWR, EPA makes assumptions that are themselves based on assumptions.

The baseline and compliance characteristics are critically important to the cost analysis. For example, the SafeWater Multi-Contaminant Benefit-Cost Model (MCBC) uses the baseline and compliance characteristics as input values for a decision tree model. The decision tree model then selects the treatment technology or non-treatment alternative in response to estimated occurrence/co-occurrence estimates. These treatment technologies or non-treatment alternatives form the foundation of all costs and benefits estimated in response to the proposed rule. As EPA notes, "there are nearly 3,500 individual cost equations across the categories of capital and operation and maintenance (O&M) cost, water source, component level, flow, bed life (for GAC and ion exchange), residuals management scenarios (for GAC and ion exchange), and design type (for GAC)" (USEPA 2023f, p. 18692). These assumptions and imputation processes have a significant impact on the overall cost estimates, and EPA fails to transparently adequately describe them in detail or justify their use.

EPA Response: The EPA disagrees with the commenter's assertion that the agency used incomplete data in characterizing the baseline and compliance characteristics necessary to estimate costs and benefits. As discussed in this response, the EPA used the best available information and the data sources used are the most comprehensive available, which includes thorough data obtained from the EPA's SDWIS, the third Unregulated Contaminant Monitoring Rule, independent state sampling program datasets, the Geometries and Characteristics of Public Water Systems report, and the 2006 Community Water System Survey (CWSS). (See Chapter 4 of USEPA (2024b) for complete discussion on data sources used to characterize baseline conditions). The approach used by the EPA, which uses point estimates to characterize some baseline and compliance components for model systems, is the most suitable for estimating national benefits and costs. Moreover, the EPA has characterized baseline and compliance characteristics appropriately using information available at the PWS level from the Safe Drinking Water Information System which has a high degree of completeness and is largely representative of regulated PWSs. Model systems in SafeWater MCBC combine the PWS-specific data available in SDWIS/Fed with data on baseline and compliance characteristics available at the PWS category level. Point estimates are used in cases where there is no available information to inform the variability of the parameter, and in other cases where more robust data representing system variability are available, the category-level data include a distribution of potential values that SafeWater MCBC uses to sample from. In the Economic Analysis (EA), the

agency has transparently provided the parameter values used to characterize baseline and compliance characteristics for model systems. Additionally, the EPA disagrees with the commenter's claim that the EPA failed to transparently describe assumptions and impacts associated with the characterization of baseline and compliance characteristics. In the over 700-page EA and appendices, which include thorough explanations (or direct references to where to find explanations) of every component of the EA, the EPA summarized analytical assumptions and described how the quantitative analysis incorporates sources of uncertainty (see table 4-34 of the EA for a summary of sources that have quantifiable uncertainty and data limitations). The EPA notes that in most cases it is not possible to determine the extent to which a particular limitation or uncertainty can affect the magnitude of baseline conditions, however, the EPA described the potential direction of the impact on baseline inputs to the costs and/or benefits analysis when inference was possible. The result of this analysis, using best available information, using readily accepted analytical approaches, and thoroughly explaining the information and methodology used, reflects best available science.

In conclusion, the model systems are representative of PWSs, the EPA maintains that the information on baseline and compliance parameters provided in the rule is sufficiently comprehensive, and no further information is required.

Earthjustice et al. (Doc. #1808, SBC-046127)

4. EPA correctly accounts for existing state-level drinking water standards for PFAS in the baseline.

EPA undertook a detailed and thorough approach to account for existing state-level standards that limit the allowable levels of certain PFAS in drinking water. These states include NJ, VT, NH, MA, MI and NY. When baseline PFAS concentration levels for system points-of-entry in these states are estimated to exceed existing state-specific MCLs, then the estimated concentrations are instead assumed to equal the state-level MCLs – i.e., it is assumed that PWSs are in full compliance with any existing state standards for PFAS in drinking water. In making this adjustment, any incremental improvements already achieved by the state programs would be correctly accounted for in the baseline, and not falsely contribute to the estimated benefits and costs of the proposed federal PFAS NPDWS. This accounting of existing state-level standards in the baseline correctly results in a reduction in both benefits and costs compared to a baseline that would incorrectly disregard existing state regulations.

EPA Response: The EPA agrees with the commenter that the agency correctly accounted for existing state-level drinking water standards for PFAS in the baseline. Existing state-level drinking water PFAS standards were accounted for in the baseline water system characterization.

Groundwater Resources Association of California (Doc. #1831, SBC-045350)

[Based on our review of this document, GRA offers the following general comments and recommendations for consideration by the EPA as they finalize these regulations:]

3. Groundwater Considerations in Cost-Benefit-Risk Evaluation: Groundwater forms an essential source of water for drinking water and irrigation purposes across the nation. In California more than 500 groundwater basins and subbasins contribute an average of 40% (and more during droughts) to the State's total water supply. PFAS have been detected in California's Groundwater at levels above the proposed maximum contaminant levels (MCLs) (see Figure below).

The cost, benefit, and risk evaluations that form the basis for the proposed MCLs focus on treated water from Public Water Systems (PWS), which rely on both surface and groundwater sources.

EPA Response: The EPA has included both groundwater and surface water systems in the baseline analysis for the EA. Please see section 13.1 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046018)

2. Market Costs Approach

Affected Systems and Service Population

To estimate the number of affected groundwater (GW) and surface water (SW) systems by system size, the total inventory of community water systems (CWSs) by size of service population is multiplied by the average population per system [FN104: U.S. Environmental Protection Agency, "Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation," 4–7; U.S. Environmental Protection Agency, "SDWIS Federal Reporting Services Fourth Quarter 2021 Dataset," 2021, https://www.epa.gov/ground-water-and-drinking-water/safe-drinking-water-information-system-sdwis-federal-reporting.]. The CWS are broken out by size and by water source. Then, for both small and large systems, the analysis estimates the percentage of the population by system size [FN105: "Small systems" serve less than or equal to 10,000 people, while "large systems" serve populations greater than 10,000.]. For example, of the 53 million (M) in total population served by small systems, 29 M (or 55 percent) are served by systems within the 3,301-10,000 person service population size category. CWSs serving between 100,000-1 M people represent 41 percent of the total population served by large systems.

Table 8: Total CWSs and Service Population by System Size and Source

[Table 8: see docket ID EPA-HQ-OW-2022-0114-1738]

The analysis then applies these percentages to total populations affected by the proposed rule for small and large systems, which EPA estimates at 3.7 M and 60.6 M, respectively [FN106: U.S. Environmental Protection Agency, "Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation," tbls. 4–26.]. This assumption gives total affected population by system size, which then is divided by the average

population by system size to arrive at an estimated number of systems that will be required to treat.

Table 9: Total and Impacted Population at Small and Large PWSs

[Table 9: see docket ID EPA-HQ-OW-2022-0114-1738]

To estimate how these totals are distributed by water source type, the estimated number of systems per CWS size is multiplied by ratios from the CWS inventory. For example, as shown in Table 8, 650 of the 690 CWSs serving populations under 100 persons rely on ground water (GW). Thus, 94 percent of the approximately 800 number of affected systems in Table 9 for this system size are assumed to use ground water sources.

Table 10: Total Systems by Water Source

[Table 10: see docket ID EPA-HQ-OW-2022-0114-1738]

EPA Response: The commenter summarizes the EPA's methods for estimating population served and affected at PWSs in the Health Risk Reduction and Cost Analysis (HRRCA). Please see Chapter 4 of the EPA's EA (USEPA, 2024b) for full description of the EPA's methodology for characterizing baseline conditions in PWSs.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046012)

3. Data and Assumed Values Occurrence in Drinking Water

The analysis uses EPA's projection of PFOA and PFOS occurrence data and population estimates for the benefit estimates. As done in the EA, the distribution of occurrence of the selected PFAS in PWS is estimated and then modified to account for existing state regulatory standards.

The analysis adopts the results of the modeling in Cadwallader et al that the EA uses [FN61: Adam Cadwallader et al., "A Bayesian Hierarchical Model for Estimating National PFAS Drinking Water Occurrence" (AWWA Water Science, May 25, 2022).]. The authors' approach efficiently uses available data and established Markov methods to project which systems are likely to have PFAS occurrence in the absence of sampling data. The analysis replicated the paper's results with mechanical and mathematical methods [FN62: IBID]. Data points were extracted from the Figure 4 of Cadwallader et al. through a digital tool that uses reverse engineering to plot underlying numerical data from data visualizations [FN63: Ankit Rohatgi, "WebPlotDigitizer" (Pacifica, California, September 16, 2022),

https://automeris.io/WebPlotDigitizer/.]. The chart was uploaded onto a canvas and the y- and x-axes were calibrated as linear and logarithmic information, respectively, to extract the data points. We then fit a curve to the points to allow assignment of simulated concentration levels to segments of the population. Figure 4 below gives the baseline simulated drinking water concentration distribution.

Figure 4: Cumulative Distribution of Estimated Population Exposed to PFOA and PFOS

[Figure 4: see docket ID EPA-HQ-OW-2022-0114-1738]

The fitted curve overpredicts the total public drinking water population percentage by 12.5 percent at the high end of the distribution. As with any statistical estimation, there is more uncertainty at points further away from the central estimate. Since it is the high end of the distribution where the majority of the benefits will occur, the analysis trims the shape of the simulated curve by reducing the population amounts predicted by the curve by 12.5 percent so that the population in the analysis equals EPA's estimate of 277 million consumers of public drinking water.

Figure 2, the population distribution, was converted to the probability distribution and simulated drinking water concentration data were generated by randomly drawing drinking water concentration (DWC) from the probability distribution. The simulated DWC data are displayed in the boxplot in Figure 3:

Figure 5: Simulated Drinking Water Concentration of PFOA and PFOS Before the Proposed Rule

[Figure 5: see docket ID EPA-HQ-OW-2022-0114-1738]

Baseline Population

Some states have promulgated drinking water MCLs for PFAS [FN64: U.S. Environmental Protection Agency, "Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation," 4–22 & 4–23.]. In its EA, EPA reviewed state websites and identified states with standards promulgated as of July 2022 for the PFAS compounds considered under the proposed rule (see Table 2).

Table 2: State PFAS MCLs included in EPA's EA (ppt)

[Table 2: see docket ID EPA-HQ-OW-2022-0114-1738]

[FN65: Asterisks indicate PFAS regulations at an overall threshold value indicated in the Sum column.]

EPA assumed in its occurrence model that estimates exceeding state limits are equivalent to the state-enacted limit to estimate the benefits and costs of the proposed rule. EPA also assumed that the state MCL is the maximum baseline PFAS occurrence value for all entry points in the state [FN66: U.S. Environmental Protection Agency, "Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation," 4–23.]. This adjustment was made to the EPA's occurrence model PFAS estimates for PFOA, PFOS, and PFHxS. Systems in states with PFAS regulations are still expected to incur incremental costs to comply with the proposed rule since EPA's proposed standards are more stringent than current state drinking water standards. Similarly, EPA notes that "populations served by PWSs in the states with PFAS regulations are expected to benefit from further reductions in PFAS exposures." [FN67: U.S. Environmental Protection Agency, 4–23.].

While EPA adjusts the occurrence data to account for promulgated MCLs, it assumes its baseline will remain constant in the future, excluding proposed regulations as well as changes in drinking water PFAS occurrence due to issued and future guidance and other regulatory actions. Several states have passed non-MCL regulations or will promulgate either new MCLs or other actions in the future that all impact PFAS occurrence levels in drinking water. To allow comparisons with EPA's estimates, the analysis does not reduce the assumed population by assuming other states will promulgate state standards before the federal MCL. However, pending state standards and voluntary actions are likely to reduce baseline exposure and thus the incremental benefits of this action.

EPA Response: For the final rule, the EPA has updated the occurrence data used in the baseline analysis to account for all state promulgated MCLs. Between proposal and final, three additional states promulgated MCLs which are now reflected in the baseline characterization for the final rule.

Regarding the commenter's application of the results from Cadwallader et al. (2022), the EPA notes that the total population included in the agency's analysis was the summation of all "population served" for systems in SDWIS. The model generates estimates for systems and then the EPA used those systems' populations served to convert that to the total population associated with those systems. It appears that this commenter took a different approach to quantifying the total population, but the EPA cannot determine whether the commenter's scaling approach was appropriate, as the comment lacks documentation of this, and specifically of the handling of systems that have redundant populations.

Finally, please see section 13.1 of the EPA response in this *Response to Comments* document regarding the commenter's opinion that baseline levels of PFAS are likely to reduce. section 13.4 of the EPA response in this *Response to Comments* document for more information on the EPA's benefits assessment.

13.2 Cost-Benefit Model and Discount Rates

Summary of Major Public Comments and EPA Responses

The EPA received comments on discount rates used in the analysis. One commenter claimed that the 7 percent discount rate is more reflective of actual costs and benefits and that once the EPA adjusts the cost models to reflect actual costs to water systems, the incremental costs of complying with the Hazard Index MCL exceed the incremental benefits. The EPA disagrees with these claims. The discount rate is not meant to be reflective of the cost of capital to individual PWSs, but rather reflects the real time value of money. In compliance with Office of Management and Budget (OMB) guidance in effect at the time of rule proposal, the EPA estimated the costs of the proposed rule and other options at both a 3 percent and 7 percent discount rate to bracket the uncertainty in the actual time value of money. Another commenter described that "if the rate that the average saver uses to discount future consumption is taken as a measure of the social rate of time preference, then the real rate of return on long-term

government debt may provide a fair approximation" and that "this rate has averaged around three percent in real terms on a pre-tax basis." A couple of commenters strongly supported a lower discount rate due to the NPDWR's effects that carry over to future generations. One of these commenters agreed with the EPA's finding described in the proposed rule EA (USEPA, 2023a) that the lower, consumption-based discount rate of 3 percent was most appropriate relative to the 7 percent discount rate also presented in the rulemaking. This commenter also noted that use of lower discount rates is supported by economics literature. The commenter referenced draft revisions to OMB Circular A-4 guidance, which was announced during the comment period for the proposed regulation, that favored a substantially lower discount rate of 1.7 percent and the commenter stated that the 3 percent discount rate may be significantly higher than appropriate. Given the literature findings and also the OMB guidance revisions, the commenter asked that the EPA consider focusing the central analysis primarily on an assumed 3 percent (or even lower) discount rate, rather than treating the 3 and 7 percent assumptions as being equally valid in the main analysis. The EPA notes that the U.S. White House and Office of Management Budget recently finalized and re-issued the A-4 and A-94 benefit-cost analysis guidance (see OMB Circular A-4, 2023), and the update includes new guidance to use a social discount rate of 2 percent. The updated OMB Circular A-4 states that the discount rate should equal the real (inflation-adjusted) rate of return on long-term U.S. government debt which provides an approximation of the social rate of time preference. This rate for the past 30 years has averaged around 2.0 percent per year in real terms on a pre-tax basis. OMB arrived at the 2 percent discount rate figure by considering the 30-year average of the yield on 10-year Treasury marketable securities, and the approach taken by OMB produces a real rate of 1.7 percent per year, to which OMB added a 0.3 percent per-year rate to reflect inflation as measured by the personal consumption expenditure (PCE) inflation index. The OMB guidance states that Agencies must begin using the 2 percent discount rate for draft final rules that are formally submitted to the Office of Information and Regulatory Affairs (OIRA) after December 31, 2024. The updated OMB Circular A-4 guidance further states that "to the extent feasible and appropriate, as determined in consultation with OMB, agencies should follow this Circular's guidance earlier than these effective dates." Given the updated default social discount rate prescribed in the OMB Circular A-4 and also public input received on the discount rates considered by the EPA in the proposed NPDWR, for this final rule, the EPA estimated national benefits and costs at the 2 percent discount rate for the final rule and incorporated those results into the final EA. Since the EPA proposed this NPDWR with the 3 and 7 percent discount rates based on guidance in the previous version of OMB Circular A-4, the EPA has kept the presentation of results using these discount rates in Appendix P of USEPA (2024c). The Administrator reaffirms his determination that the benefits of the rule justify the costs. The EPA's determination is based on its analysis under in SDWA section 1412(b)(3)(C) of the quantifiable benefits and costs at the 2 percent discount rate, in addition to at the 3 and 7 percent discount rate, as well as the nonquantifiable benefits and costs. The EPA found that significant nonquantifiable benefits are likely to occur from the final PFAS NPDWR.

Some commenters provided comments about the SafeWater Mutli-Contaminant Benefit Cost (MCBC) model. One commenter urged the EPA to generate results at a PWS level in addition to

the 36 individual PWS categories. The EPA believes that the commenter's approach is neither feasible or appropriate. The SafeWater Cost Benefit Model (CBX) is a peer-reviewed stochastic model that the EPA used to estimate the compliance costs and benefits of the rule. The EPA enhanced the SafeWater CBX model to estimate costs and benefits of multiple contaminants concurrently (henceforth called SafeWater Multi-Contaminant Benefit Cost (MCBC)). Because of the hundreds of input parameters and thousands of individual data points that would be required to take the commenter's suggested approach, SafeWater MCBC cannot generate results at that resolution due to data and computational limitations. The EPA is unaware of any other stochastic model used to estimate national-level drinking water costs and benefits at this time which could take an approach as advocated by the commenter. Additionally, complete PWS-specific data across the 49,193 community water systems (CWSs) and 17,337 non-transient non-community water systems (NTNCWS) are not available in SDWIS/Fed for many of the baseline and compliance characteristics necessary to estimate treatment plant specific costs and benefits, such as design and average daily flow rates, water quality characteristics, treatment in-place, and labor rates. The EPA's estimates of benefits and costs using model systems is reasonable, consistent with best scientific practice (e.g., see *Guidelines for Preparing Economic Analyses* Chapter 5 and 8 discussions on use of models in economic analyses (USEPA, 2016a), and provides information that is sufficient for purposes of understanding and accounting for the costs of this rule in the rule decision making process. For more information about the development of the SafeWater models, including information about its peer review, please see Chapter 5, Section 5.2.3 of the *Economic Analysis for the Final Lead and Copper Rule Revisions* (USEPA, 2020a). In fact, in the peer review of the SafeWater model, reviewers were generally pleased with the modeling advances provided by the SafeWater framework. One reviewer indicated that "the model offers several advantages over existing methods of benefit and cost estimation. Benefits and costs calculations are fully integrated in the model, so that each uses the same samples of PWSs [model PWSs], the set of random vectors, and the same set of parameters (e.g. discount rates). Thus, each net benefit calculation is internally consistent because costs and benefits are fully comparable" (IntelliTech Systems, Inc., 2010). One commenter expressed concerns about the updates to the SafeWater MCBC model from the previous SafeWater CBX model, claiming that because the SafeWater MCBC model did not undergo yet another peer review, the resulting cost estimates are not reliable. The EPA disagrees with the commenter's claims which attempt to diminish the validity and application of the SafeWater MCBC model. For this rulemaking the model was updated to allow for multiple contaminant modeling, but all changes are still consistent with the original peer reviewed single contaminant methodology. Critical inputs to the SafeWater MCBC model have been peer-reviewed, including the Markov-Chain Monte Carlo occurrence model (as peer reviewed in Cadwallader et al., 2022) and work breakdown structure models for granular activated carbon (GAC), ion exchange (IX), and reverse osmosis (RO). The SafeWater MCBC model is based on the best available, peer-reviewed science and the model is appropriate for estimating national benefits and costs associated with the PFAS NPDWR. Furthermore, The EPA has performed a quantitative uncertainty analysis (made possible through the use of the SafeWater stochastic model) and thoroughly described the impacts that uncertain modeling components have on the estimated benefits and costs, which is consistent with OMB

Circular A-4 guidance (please see section 13.9 in this *Response to Comments* document for comments and responses on quantified uncertainties).

Individual Public Comments

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046014)

Discount Rates

Circular A-4 recommends providing estimates of net benefits using both 3 percent and 7 percent discount rates. OMB also outlines the rationale for discounting [FN87: U.S. Office of Management and Budget, 32.]:

• Resources that are invested will normally earn a positive return, so current consumption is more expensive than future consumption, since you are giving up that expected return on investment when you consume today.

• Postponed benefits also have a cost because people generally prefer present to future consumption. They are said to have positive time preference.

• Also, if consumption continues to increase over time, as it has for most of U.S. history, an increment of consumption will be less valuable in the future than it would be today, because the principle of diminishing marginal utility implies that as total consumption increases, the value of a marginal unit of consumption tends to decline.

OMB's basic guidance on discount rates is provided in Circular A-94, which explains that a real discount rate of 7 percent should be used as a base-case [FN88: U.S. Office of Management and Budget, 33; U.S. Office of Management and Budget, "Circular A-94,"n.d.]. This rate is an estimate of the average before-tax rate of return to private capital in the economy. "It is a broad measure that reflects the returns to real estate and small business capital as well as corporate capital. It approximates the opportunity cost of capital, and it is the appropriate discount rate whenever the main effect of a regulation is to displace or alter the use of capital in the private sector."

However, when regulation primarily and directly affects private consumption (e.g., through higher consumer prices for goods and services), a lower discount rate is appropriate. The alternative most often used is sometimes called the "social rate of time preference," meaning the rate at which society discounts future consumption flows to their present value. If the rate that the average saver uses to discount future consumption is taken as a measure of the social rate of time preference, then the real rate of return on long-term government debt may provide a fair approximation. OMB explains that this rate has averaged around three percent in real terms on a pre-tax basis.

EPA Response: As discussed in the section 13.2 of the EPA response in this *Response to Comments* document, the EPA has incorporated the 2 percent discount rate into the final EA. The

EPA now presents both the 3 and 7 percent discount rates for both costs and benefits in Appendix P of USEPA (2024cc).

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045049)

The NJDEP reviewed EPA's Cost Analysis for the proposed NPDWR, including the Cost-Benefit Model utilized. The NJDEP urges the EPA to generate the results of the Safe Water Multi-Contaminant Benefit Cost (MCBC) Model at the PWS level in addition to the utilized cost and benefit estimates for the 36 PWS categories. In addition, NJDEP urges EPA to collaborate with State drinking water regulators to obtain the most up-to-date cost data for the central database of component unit costs used for the Work Breakdown Structure (WBS) models to enable states to fully comment and evaluate these models. This would enable future retrospection on the validity of the Safe Water MCBC and WBS models as actual treatment or non-treatment costs of compliance with the proposed NPDWR become available. Discrepancies between the actual compliance costs and the PWS level estimates from the Safe Water MCBC and WBS models can then be used to improve these models for future analysis and proposals.

EPA requested comment on Table 26, which provides the initial treatment technology compliance forecast, presented in percentages, of systems adopting GAC, PFAS-selective IX, centralized RO, system interconnection, and using new wells across system design flows and TOC levels. This information is used in EPA's cost and benefit modeling. The NJDEP reviewed its records to provide the following breakdown of treatment technologies chosen by public water systems in New Jersey. As of May 17, 2023, 54% of the permits submitted to NJDEP are for strong base anion exchange, versus 46% of permits submitted for GAC. For smaller systems where the flow through the treatment plant is less than one MGD, systems favor strong base anion exchange as it is proposed in 71% of permits, while GAC was proposed in only 29% of permits. Currently, the NJDEP has not approved any systems to use reverse osmosis to remove PFAS. However, a pilot study application has recently been submitted to the NJDEP that includes reverse osmosis and an aqueous electrostatic concentrator, which is expected to be approved.

Additionally, NJDEP is interested in how the EPA incorporated construction lead times in its models to estimate the costs and benefits of the proposed NPDWR. Increasingly, public water systems are experiencing extended lead times in recent years due to supply chain issues for some of the key components used for PFAS treatment (such as GAC filter media). Extended construction lead times can result in (1) an opportunity cost for capital set aside for treatment that could otherwise be used for other purposes in the PWS, such as lead service line replacement and (2) exposure of systems to different costs of capital, as there has been significant fluctuation in interest rates over the last few years.

EPA Response: With respect to the commenter's recommendation to generate results at the PWS-level, please see section 13.2 of the EPA response in this *Response to Comments* document.

The EPA acknowledges the commenter's offer to collaborate with state drinking water regulators to maintain up to date cost data for the work breakdown structure (WBS) models. The EPA used the most up to date publicly available cost information to support the national costs estimates for the proposed and final rulemakings. The EPA's cost estimates for the final rule have been updated based on public comments received. These updates are discussed in section 13.3.3 of the EPA response in this *Response to Comments* document. The EPA considered all cost estimates provided by commenters prior to finalizing this regulation.

The EPA acknowledges the commenter's submission of information on the breakdown of treatment technologies chosen by PWSs in New Jersey. This information is confirmatory of the observation on treatment technology selection trends that the EPA included in the EA for the rule. The EPA specifically notes that data examined in the *Technologies and Costs* document (USEPA, 2024d) show an increasing share of PWSs have selected IX in response to PFAS. The EPA expects this trend to continue, and New Jersey's information supports that expectation. The percentages for IX reported by New Jersey are higher than the EPA's decision tree for the final rule, especially for small water systems. The EPA chose to maintain the relative distribution between IX and GAC from the proposal because it reflects the distribution observed in the EPA's review of recent case study installations nationwide. A larger percentage of systems choosing GAC also tends to err on the side of higher capital costs for small systems.

With respect to RO/NF, the commenter notes there are no existing approvals in that state and there is one potential future approval of RO/NF installation. Many commenters raised significant challenges associated with this BAT, including but not limited to costs, operations and managing the treatment residuals from this process. Therefore, based on this and other comments, the EPA assumed zero percent of water systems would select this technology in the EA for the final rule. For more information on treatment technologies, please see section 10 of the EPA response in this *Response to Comments* document

In regard to the commenter's points associated with potential financial issues related to extended construction lead times:

(1) The EPA acknowledges that for systems that might experience unforeseen treatment construction delays the fact the cash reserves must be held could result in opportunity costs. The size of these opportunity costs are dependent on a number of factors for which there is insufficient data at the nation level to assess. In large part these potential opportunity costs can be mitigated through good project management and planning, and forecasting of construction payments. Understanding the schedule of payments may allow system financial managers the opportunity to make near money investments to help offset the costs of construction. The delays systems, in general, have experienced in recent years are widely known to both system managers and state regulators and therefore can be accounted for in project planning, therefore the agency finds that opportunity costs associated with this issue are likely to be small at the national level. The commenter used lead service line replacement as an example of potential opportunity costs. The EPA is aware that implementation timing associated with the PFAS rule and the proposed

LCRI has the potential to overlap; for more information, please see section 13.3 of the EPA response in this *Response to Comments* document.

(2) As expressed by the commenter, the EPA acknowledges that in the short-term interest rates can fluctuate. Given the fact that short-term rates fluctuate and are difficult to forecast (recent interest rate increases already seem to be tempering and currently capital markets are pricing in the Federal Reserve lowering interest rates in 2024 (Reuters, 2023), systems have the ability to shift their debt structure over time as interest rates change, and the EPA's period of analysis covers 81 years, the EPA utilizes estimated long-term estimated rates which are more stable. As an input to the Safewater MCBC model the EPA has estimated average long-term cost of capital (interest rate) paid by public and private PWSs of different size categories. The EPA uses the estimated PWS cost of capital as this best represents the actual financing costs of compliance that systems will incur over time. The EPA's estimated cost of capital range from 3.7- 8.6 percent. See Chapter 4.3.5 of the EA for the complete list of rates and a more detailed explanation of their derivation. Also note that the EPA's total estimated cost of capital may be greater than actual costs water systems bear when complying with the future PFAS regulatory revisions because financing support for PFAS treatment technology may be available from state and local governments, and the EPA programs (e.g., the Bipartisan Infrastructure Act and other federal funding administered through the Drinking Water State Revolving Fund (DWSRF)). The DWSRF provides below-market rate loans to fund infrastructure improvements to water systems to protect public health and ensure compliance with the Safe Drinking Water Act, and grants may be available through BIL funding (USEPA, 2023b).

The EPA notes that, as discussed section 12.1 of the EPA response in this *Response to Comments* document, the agency is authorizing a two-year capital improvement extension pursuant to SDWA 1412(b)(10). In the EA for the final rule, to reflect this nationwide two-year capital improvement extension to comply with MCL, the EPA assumes all water systems that exceed the MCLs take action to comply with the rule by the end of year 5 of the analysis instead of at the end of year 3 as proposed.

3M Company (Doc. #1774, SBC-045696)

c. The Benefit-Cost Model is New and Unvalidated

EPA previously developed a generalized tool known as the SafeWater Cost-Benefit Model (CBX) analysis tool to automatically estimate costs and benefits of drinking water standards. EPA indicates that CBX was designed to evaluate the impacts of a single proposed MCL and incorporates uncertainty in both input and output values to generate best-guess estimates of the impacts of proposed drinking water regulations. The single MCL CBX model was peer-reviewed.

For the proposed NPDWR, EPA developed a new model called the SafeWater Multi-Contaminant Benefit Cost Model (MCBC), which can track multiple substances and compare those to proposed MCLs developed for individual substances or mixtures of substances. EPA

states that MCBC modifies the "structure of the occurrence data input to the model…to not only handle multiple contaminants, but to incorporate all information from the PFAS occurrence model on the predicted co-occurrence of contaminants," allows the assignment of more than one compliance technology, and estimates the costs and benefits associated with estimated reductions in multiple contaminants (USEPA 2023i).

Unlike the CBX model, the MCBC model has not been validated, approved for use via a public review and comment process, or peer-reviewed by independent third-party experts. The absence of a peer review process casts doubts on the validity, reliability, and accuracy of the cost estimates derived from its use. Peer review is particularly necessary because the modifications of the MCBC model relative to CBX are significant. For example, the estimation of statistical uncertainty is calculated differently when two or more uncertain variables are considered simultaneously relative to just one uncertain variable. The resulting uncertainty propagates and compounds throughout the analysis. The impact of the modifications of the MCBC model relative to its CBX counterpart is unknown and is not explained in sufficient detail. This issue is further complicated by the opacity of the analysis, which does not allow stakeholders and members of the public to evaluate whether the uncertainty is being appropriately addressed. Without peer review, expert validation, and a public comment process allowing for input from stakeholders of the PWS community, the MCBC model and its resulting cost estimates cannot be considered validated, reliable, or accurate.

EPA Response: In regard to the commenter's assertion that the SafeWater MCBC model has not been validated and peer reviewed, and that the model and its resulting cost estimates cannot be considered validated, reliable, or accurate please see section 13.2 of the EPA response in this *Response to Comments* document above.

The District of Columbia Water and Sewer Authority (Doc. #1829, SBC-045772)

EPA's Cost Benefit Analysis Does Not Justify the Proposal

The Proposal includes four regulatory alternatives that were considered by EPA to support this rulemaking.

Proposed Option: PFOA and PFOS MCLs of 4.0 ppt and a HI of 1.0.

Option 1a: PFOA and PFOS MCLs of 4.0 ppt.

Option 1b: PFOA and PFOS MCLs of 5.0 ppt

Option 1c: PFOA and PFOS MCLs of 10.0 ppt

Tables 1 and 2 compare the "expected value" for annualized costs, benefits and net benefits for each of the options considered at a 3 percent and 7 percent discount rate, respectively.

Table 1. Annualized Quantified National Costs and Benefits (Million 2021$), 3 Percent Discount Rate

[Table 1: see docket ID EPA-HQ-OQ-2022-0114-1829]

Table 2. Annualized Quantified National Costs and Benefits (Million 2021$), 7 Percent Discount Rate

[Table 2: see docket ID EPA-HQ-OQ-2022-0114-1829]

The following observations ar made regarding the various proposals:

1. Given current inflation, rising interest rates, and future labor and supply chain issues, the 7 percent discount rate is likely more representative of actual costs and benefits.

2. With a 7 percent discount rate, only Option 1c results in a net benefit.

3. Regardless of the discount rate, when comparing the Proposed Option and Option 1a, there are minimal incremental benefits associated with the HI. This suggests that very few systems would be required to install treatment for to comply with the HI. When EPA adjusts the cost models to be more reflective of actual costs to water systems, the incremental cost of the HI MCL is likely to exceed the incremental benefit.

Based on these observations, it is suggested that, if EPA moves forward with a final PFAS rule, only Option 1c (10 ppt MCL for both PFOA and PFOS) is likely to meet the Agency's criteria that the rule must provide a net benefit.

EPA Response: As noted in section 13.2 of the EPA response in this *Response to Comments* document, the EPA disagrees with the commenter's generalization that the 7 percent discount rate is likely more representative of actual costs and benefits. There are a variety of considerations that may impact capital displacement resulting from the PFAS NPDWR. The EPA expects that a meaningful number of PWSs may not be managed as profit-maximizing private sector investments, which could impact the degree to which the rate of return on the use of capital in the private sector applies to PWS costs. As described in the preamble and EA, the Bipartisan Infrastructure Law (BIL) invests over $11.7 billion in the DWSRF), $4 billion to the Drinking Water SRF (State Revolving Fund) for Emerging Contaminants, and $5 billion in grants to Small or Disadvantaged Communities (EC-SDC), which is expected to defray many such PWS costs, and where that occurs, such costs are transferred to the government (please see section 2.4 of the EPA response in this *Response to Comments* document). Regardless, the impacts in this rulemaking are such that costs are expected to occur in the nearer term, and in particular that larger one-time capital investments are expected to occur in the near term; and public health benefits are expected to occur over the much longer term. Lastly (and as described in section 13.2 of the EPA response in this *Response to Comments* document), the EPA received several comments requesting that the agency consider a lower discount rate to better account for the rule's effects on future generations. These commenters pointed to the updated OMB Circular A-4 guidance (OMB, 2023) prescribing a new default discount rate of 2 percent. The EPA follows these recommendations to use the 2 percent default discount rate in the final rule EA. See the section 13.2 of the EPA response in this *Response to Comments* document for further information justification of the EPA's decision to use a 2 percent discount rate.

The EPA disagrees with the commenter's assertion that there are minimal incremental benefits associated with the Hazard Index. The EPA did not perform a quantitative benefits analysis for Hazard Index chemicals due to data limitations, however, inclusion of the Hazard Index and individual MCLs for PFHxS, PFNA, and HFPO-DA will trigger more systems to treat (as shown in Section 4.4.4 and Appendix N of the EA) and provides enhanced public health protection by ensuring reductions of these additional compounds when present above the Hazard Index of 1 or in exceedance of individual MCLs. Specifically, as exposures to PFHxS, PFNA, PFBS and HFPO-DA are reduced, the EPA anticipates additional public health benefits from avoided cardiovascular, developmental, and immune effects. Taking all quantified and nonquantified benefits into account, the incremental benefits of the final rule justify the incremental costs. For further discussion of the quantitative and qualitative benefits associated with the final rule, see Section 6.2 of the EA.

Midwest Environmental Advocates +more (Doc. #1846, SBC-045834)

Finally, the quantifiable portion of the analysis overestimates the costs of compliance. For instance, the 7 percent7% discount rate, as EPA rightly points out, is tied to the expected return on capital in the domestic economy. Because the proposed regulation affects future consumption, a 7 percent discount rate is not appropriate for this rulemaking. Further, the quantifiable costs at 7 percent do not account for the existing stream of federal funding that would supply capital to minimize compliance costs. Thus, the usefulness of forecasting costs with such a discount rate in this context is specially limited.

EPA Response: Please see section 13.2 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046170)

The analysis that follows shows that the $3.1 billion dollar difference in annualized cost can be explained by the following primary factors:

1. Discount rate used. EPA presented cost estimates using both a 3% and 7% discount rate, which is consistent with current OMB guidance. AWWA presented costs for only the 7% rate. In the Economic Analysis, EPA notes that the lower, consumption-based discount rate is more appropriate for this rulemaking (Economic Analysis at 2-3), a conclusion that is supported by the economics literature (Howard and Schwartz, 2002). This factor alone explains $1 billion of the cost difference (Appendix A). The AWWA approach in this case is an overestimate. Factoring other cost considerations described below, in addition to the excess discount rate, would increase the magnitude of impact of the different discount rates. Further, OMB recently published draft revisions to its guidance (White House Office of Management and Budget, 2023) that favor a substantially lower consumption-based discount rate of 1.7%, consistent with Howard and Schwartz (2002). EPA's assertion that the lower, consumption-based discount rate is more appropriate for this rulemaking is supported by the literature and OMB's proposed update to its

guidance. Both indicate that even the 3% consumption-based discount rate EPA used here may be significantly higher than appropriate.

EPA Response: For a discussion of differences in underlying assumptions between the EPA's and the American Water Works Association's (AWWA's) cost estimates, please see section 13.3.3 of the EPA response in this *Response to Comments* document. In response to the commenter's suggestion that economic estimates be evaluated using a lower discount rate, based on this and other comments, the EPA has included analyses using a 2 percent discount rate. Please see sections 13.2 and 13.8 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046135)

15. EPA should further consider whether the central EA results should focus more on the lower 3% discount rate.

Although equal consideration of alternative 3% and 7% discount rates is currently the standard practice for Eas of federal regulations (OMB 2003), EPA should consider whether the lower 3% discount rate is more appropriate in the current context. This could be the case for several reasons, including the long 80-year time period for the analysis, the fact that future generations are impacted, and the considerable uncertainties in the magnitude of the future health benefits. [FN2: See the "Discount Rates" section in the proposed revisions to Circular A-4 (OMB 2023), for example, for further details.] Additionally, EPA states on page 2-3 of the EA that "OMB's Circular A-4 indicates that a 3 percent discount rate represents the rate that an average saver uses to discount future consumption and is therefore more appropriate for this rulemaking." [Emphasis added.] Given this rationale, discussions in the literature (e.g., Howard and Schwartz 2022), and the recently proposed revised guidance from OMB (2023) regarding discount rates, EPA should consider focusing the central analysis primarily on an assumed 3% (or even lower) discount rate, rather than treating the 3% and 7% assumptions as being equally valid in the main analysis.

EPA Response: In response to the commenter's suggestion that economic estimates be evaluated using a lower discount rate, based on this and other comments, the EPA has included analyses using a 2 percent discount rate. Please see sections 13.2 and 13.8 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046112)

Third, EPA should apply no (or at most a very low) discount rate to account for the intergenerational harms associated with PFAS and the nature of the rule's economic impacts. [FN132: See, e.g., Frank Ackerman and Lisa Heinzerling, Pricing the Priceless: Cost-Benefit Analysis of Environmental Protection, 150 U. Pa. L. Rev. 1553, 1571 (2002), https://scholarship.law.upenn.edu/penn_law_review/vol150/iss5/6 (questioning the use of discounting to address long-term, intergenerational harms, including those associated with "persistent toxins"); see also Institute for Policy Integrity, Comments on National Primary

Drinking Water Regulations: Lead and Copper Rule Revisions (Feb. 12, 2020), https://policyintegrity.org/documents/EPA_Lead_Copper_Rule_Comments_2020.02.11.pdf (arguing for a "3% or lower discount rate" for benefits of EPA drinking water rule).] In the event a discount rate for future benefits is applied, we agree with EPA's conclusion in the Draft EA that a lower, consumption-based discount rate is "more appropriate for this rulemaking" than a higher, capital-based discount rate [FN133: Draft EA at 2-3.] given the 80-year timeframe for analysis, the impacts on future generations, and the extent of uncertainties in the magnitude of future health benefits. [FN134: Guignet 2023 at 11; Peter Howard & Jason A. Schwartz, Valuing the Future: Legal and Economic Considerations for Updating Discount Rates, 39 Yale J. Regul. 595, 599, 603 (2022) (explaining why a consumption-based discount rate is appropriate for estimating benefits of rules designed to affect public health over a long time horizon).] Thus, if a discount rate is used, EPA should ensure that both the final EA and the final rule reflect and explain EPA's determination that a lower, consumption-based discount rate is more appropriate. [FN135: Draft EA at 2-3.] EPA's draft preamble does not include or explain this determination and instead presents benefit estimates based on a 3% consumption-based discount rate and a 7% capital-based discount rate as equally relevant to assessing the net benefits of the rule. [FN136: E.g., Proposed Rule, 88 Fed. Reg. at 18,724, table 66.] Further, if EPA continues to apply a discount rate in the final EA, it should consider utilizing a reduced consumption-based discount rate—below 2%—as the 3% rate used in the Draft EA does not reflect the best available economic data and literature. [FN137: Howard & Schwartz (2022) at 595–96, 599, 610–11, 617–19; see also White House Off. Of Mgmt. and Budget, Circular A-4 (Public Review Draft), at 76 (Apr. 6, 2023) (proposing consumption-based discount rate of 1.7%), www.whitehouse.gov/wp-content/uploads/2023/04/DraftCircularA-4.pdf.]

EPA Response: In response to the commenter's suggestion that economic estimates be evaluated using a lower discount rate, based on this and other comments, the EPA has included analyses using a 2 percent discount rate. Please see section 13.2 of the EPA response in this *Response to Comments* document.

13.3 Method for Estimating Costs (excluding disposal costs)

Summary of Major Public Comments and EPA Responses

The EPA received many public comments on the EPA's assessment of the costs of the proposed PFAS NPDWR. Comments specific to one aspect of the EPA's cost analysis and the EPA's responses to those comments can be found in the following subsections:

13.3.1 Primacy Agency Costs

13.3.2 HFPO-DA, PFNA, and PFBS National Costs

13.3.3 Water System Costs- Treatment

13.3.4 Water System Costs -Monitoring

13.3.5 Water System Costs- Administrative

13.3.6 Water System Costs- Non-Treatment

General comments on the EPA's cost analysis that are either not strictly related to one of the areas above or cover multiple cost topics are included below in section 13.3 of the EPA response in this *Response to Comments* document.

Some public commenters submitted their own estimates of national level costs, with a primary focus on the treatment costs associated with the proposed rule. The EPA's detailed responses to these commenter's approaches and conclusions of those comments can be found in section 13.3.3 in this *Response to Comments* document. Many commenters specifically cited AWWA's B&V cost estimates from an older version of the B&V report from March 2023. The EPA also notes that in their public comments on the proposed rule submitted in June 2023, AWWA submitted lower revised estimates in that report, of $2.5 to $3.2 billion dollars annually at the 3 and 7 percent discount rates respectively for NPDWR compliance costs. Some commenters cite the cost figures that AWWA describes as "national burden treatment costs." However, these cost estimates, as described in that report, include costs beyond those associated with the NPDWR, specifically costs associated with complying with existing state standards, and are therefore outside of the scope of this rulemaking. Additionally, these "national burden estimates" are flawed, as they appear to double count costs for water systems that are subject to an existing state regulation and the final rule once promulgated. Please see section 13.3.3 of the EPA response in this *Response to Comments* document for the EPA's detailed response to the AWWA B&V (Black & Veatch) report. Some commenters cite the AWWA B&V reports estimation of the present value of the costs of the rule, $36 billion at the 3 percent discount rate in the June 2023 version.[1] In the EA for the proposed and final rule, the EPA presented discounted annualized, not present values, of benefits and costs in accordance with Circular A-4 guidance (see Section 12 "Discount Rates" of Circular A-4; OMB, 2023). As detailed in Circular A-4, "Benefits and costs often take place in different time periods. When this occurs, simply adding all of the expected benefits or costs without regard for when they actually occur fails to account for differences in those values that result from the differences in timing. If benefits or costs are delayed or otherwise separated in time from each other, the difference in timing should be reflected in your analysis through appropriate discounting." The EPA further notes that in the final rule, the EPA's inclusion of undiscounted benefits and costs, consistent with Circular A-4 clearly shows undiscounted costs and the years they are expected to occur. As detailed in Appendix P of the EA, the EPA estimates undiscounted costs of $15.5 billion for water systems nationally in the year that PWS are assumed to install treatment, followed by approximately $1.1 billion in operation and maintenance (O&M) costs in each of the years following plus additional capital costs in the following years as the useful life of the technologies expire and water systems replace capital infrastructure.

[1] Note there appears to have been a labelling error on Figures 7-1 and 7-2 of the AWWA B&V report. Those figures show the "national burden treatment costs" bars to be lower than the "NPDWR treatment cost" bars. The EPA presumes this is a mis label, as the text indicates the report's national burden include estimated costs beyond the NPDWR.

The EPA has carefully considered all public comments regarding the cost analysis and made numerous changes to the costs analyses as recommended by commenters. Specific changes made to the EPA's cost analysis for the file rule are detailed in sections 13.3.1 through 13.3.6 of the EPA response in this *Response to Comments* document. Collectively, these changes resulted in an increase in the EPA's estimated annualized costs of the rule. The proposed rule estimated total national annualized costs were $771.77 million at the 3 percent discount rate and $1,204.61 million at the 7 percent discount rate (88 FR 18638; USEPA, 2023c). For the final rule, after considering public comments and incorporating numerous recommended changes, the EPA estimates the national costs to be $1,548.64 at the 2 percent discount rate, $1,545.61 at the 3 percent discount rate and $1,553.98 at the 7 percent discount rate.[2] Please see section 13.2 of the EPA response in this *Response to Comments* document for discussion of why the EPA incorporated costs at the 2 percent discount rate.

As discussed in detail in section XII.J of the Federal Register Notice (FRN), the quantified benefit-cost results above are not representative of all benefits and costs anticipated under the final rule. To fully weigh the costs and benefits of the action, the agency considered the totality of the monetized values, the potential impacts of the quantifiable and nonquantifiable uncertainties described in the FRN and EA, the nonquantifiable costs and benefits, and public comments received by the agency related to the quantified and qualitative assessment of the costs and benefits. Nonquantified costs are discussed in Chapter 5 and 7 of the EA. The EPA notes that the agency anticipates that nonquantified benefits are significantly greater than nonquantified costs. For more discussion, please see section XII of the FRN for the final rule. For the final rule, the EPA is reaffirming the Administrator's determination made at proposal that the quantified and nonquantifiable benefits of the rule justify its quantified and nonquantifiable costs.

Some commenters recommended that the EPA withdraw its cost estimate, give strong consideration to the AWWA B&V report, and "…produce a corrected cost analysis for public comment after considering public comments on the cost analysis." The EPA disagrees with the recommendation to produce a second version of the cost analysis for public comment. The EPA has met all statutory requirements under SDWA in development of the rule and the HRRCA and has considered and addressed all significant comments prior to finalization. Additionally, the agency has benefited from the public comments submitted on this rule and improved the cost analysis after considering and incorporating numerous suggestions from commenters. The EPA notes that all changes to the cost estimates flow from the proposed rule's cost analysis as informed by public comments. The EPA also notes that while the annualized costs have increased relative to the proposed rule, the changes are not of sufficient magnitude to impact the Agencies underlying conclusions at proposal. Therefore, the agency is neither required to re-propose the rule or produce revised public comment versions of analyses prior to finalization of the rule; nor

[2] Treatment technologies have both upfront capital costs and annual operations and maintenance costs. When the annual operation and maintenance costs are large relative to the up-front capital costs, the total annualized compliance cost is much less sensitive to the choice of discount rate. This is the case with GAC. Therefore, the annualized cost of the rule is similar at all the discount rates modeled.

does it think it appropriate to do so because the public was provided with sufficient information at proposal to provide informed input.

Some commenters state that while BIL funding is available, it is not enough to cover the compliance costs of the rule. For example, one commenter noted that, "[t]his amount of funding support, while crucial, will come nowhere near the cost to ratepayers that must be borne to implement necessary compliance actions for these MCLs." The EPA disagrees with the commenter that BIL funding will be nowhere near the cost" necessary to implement compliance actions. The EPA estimates that the initial capital costs of the rule in undiscounted dollars is approximately $14.4 billion. Given the BIL appropriations of $11.7 billion in DWSRF and an additional $5 billion for emerging contaminants, the EPA reasonably anticipates BIL funding is likely to be able support a substantial portion of the initial capital costs of the final rule.

Some commenters raised concerns about the potential overlap between the Lead and Copper Rule Revisions (LCRR) and the PFAS NPDWR. One commenter noted the two rules "will compound water rate affordability concerns." Another noted that water utilities "…faced with investment challenges, as many utilities are already investing large amounts of funding into complying with other proposed regulations, such as the Lead and Copper Rule Revisions…" The EPA acknowledges that implementation timing associated with the PFAS rule and the proposed Lead and Copper Rule Improvements (LCRI) has the potential to overlap. To the extent implementation overlaps, some rule start-up, administrative, and sampling/SL inventory costs associated with both rules could affect a large number of PWSs and States. The more significant costs of installing and operating PFAS treatment technology in a similar time frame with installing and operating corrosion control treatment (CCT) and/or conducting service line replacement are expected to fall on some systems. The EPA does not have sufficiently detailed PFAS occurrence, and lead service line/galvanized requiring replacement (LSL/GRR) service line and 90th percentile lead tap sample data to explore the potential treatment cost interactions of the two rules. The EPA further notes that SDWA Section 1412(b)(3.(C)(i)(III) requires that the EPA include quantifiable and non-quantifiable costs that are likely to occur solely as a result of compliance with the rule including monitoring, treatment and other costs and excluding costs resulting from compliance with other proposed or promulgated regulations. Finally, as noted, the EPA has proposed to replace the LCRR with the LCRI; the new proposed lead rule (LCRI) accounts for costs associated with that rule.

Individual Public Comments

Water Environment Federation (WEF) (Doc. #1529, SBC-043312)

Monitoring: States will be looking to EPA to determine how monitoring requirements will align with their existing program demands. EPA's proposed cost model includes treatment equipment; however, it is absent of the added costs of compliance, site developments, engineering, etc. Costs will be incurred by utilities and the residents relying on these essential services. Additionally, there are still concerns with laboratory capacity in some areas of the country. This could cause delays in analysis and increase costs to obtain compliance data.

EPA Response: The commenter is incorrect as the WBS models do include land, permits and pilot testing, equipment installation, process engineering and contractor's overhead and profit; see Chapter 5 of the EA for more information. For the EPA's response to comments on laboratory capacity, please see section 8 in this *Response to Comments* document on monitoring and compliance requirements. For the EPA's response to comments on monitoring costs, please see section 13.3.4 in this *Response to Comments* document.

Michigan Farm Bureau (MFB) (Doc. #1562, SBC-043358)

The American Water Works Association (AWWA) commissioned a study calculating the national cost estimate for water utilities to comply with MCL regulations, based on the UCMR-3. [FN13: Black & Veatch. 2023. WITAF 56 Technical Memorandum: PFAS National Cost Model Report. B&V Project No. 409850. Retrieved from: https://www.awwa.org/Portals/0/AWWA/Government/2023030756BVFinalTechnicalMemoradum.pdf?ver=2023-03-14-102450-257.] Based on the range of sizes and treatment systems of water utilities around the U.S., along with installation and operations and maintenance costs for currently available PFAS testing and treatment systems including granular activated carbon (GAC), ion exchange, and reverse osmosis and nanofiltration, AWWA estimates a national cost of more than $47 billion, or $5.2 billion annually – far beyond EPA's economic estimation of the annualized cost of compliance of $771 million to $1.2 billion annually [FN14: Environmental Protection Agency. 2023. Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation. EPA Document No. EPA-822-P-23-001. Retrieved from: https://www.epa.gov/system/files/documents/2023-03/Proposed%20PFAS%20NPDWR%20EA_final_03_09_2023_0.pdf.] – to sample and treat drinking water to 4 ppt each of PFOS and PFOA. And while EPA has worked hard to include support for water utilities such as:

• $11.7 billion to the Drinking Water State Revolving Fund (SRF)

• $4 billion in SRF for emerging contaminants

• $5 billion to Water Infrastructure Improvements for the Nation (WIIN) Grants to address emerging contaminants [FN15: Environmental Protection Agency. 2023. Drinking Water Grants and Other Financial Resources. Retrieved from: https://www.epa.gov/ground-water-and-drinking-water/drinking-water-grants.]

This amount of funding support, while crucial, will come nowhere near the cost to ratepayers that must be borne to implement necessary compliance actions for these MCLs.

More concerning in AWWA's report is the disproportionate impact these costs will have on small and rural communities. [FN16: Black & Veatch. 2023. WITAF 56 Technical Memorandum: PFAS National Cost Model Report. B&V Project No. 409850. Retrieved from: https://www.awwa.org/Portals/0/AWWA/Government/2023030756BVFinalTechnicalMemoradum.pdf?ver=2023-03-14-102450-257.] While there is a factor of scaling costs according to the

size of the system based on the number of ratepayers it serves, the cost does not reduce to zero: there is a base cost for capital investments, staff, training, sampling, laboratory fees, filter and treatment equipment, and ongoing operation and maintenance of that equipment to consider for every drinking water supplier regardless of size or number of users. AWWA's report concludes that the annual cost per household for large systems (>1,000,000 people) is between $80-$105, but the annual cost per household for small systems (<100 people) is $10,090-$11,150.

EPA Response: Please see section 13.3 of the EPA response in this *Response to Comments* document. Furthermore, the EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. For the EPA's response to comments on annual costs per household served by small systems, please see section 13.10 of the EPA response in this *Response to Comments* document. For the EPA's response to comments on the availability of funding in comparison to the compliance costs of the rule, please see section 13.3 of the EPA response in this *Response to Comments* document.

San Antonio Water System (SAWS) (Doc. #1570, SBC-042483)

• We believe that the cost estimates EPA has proposed are severely underestimated and request that further economic analysis be done to reflect costs more accurately.

O SAWS believes the current costs associated with compliance both now and in the future were underestimated in this evaluation due to escalating costs, supply chain issues, workforce shortages, etc. This is underscored by the range in estimated costs produced by the EPA ($1.2 billion) and other organizations, including engineering consultant Black and Veatch who provided an estimate to the America Water Works Association of $38 billion to comply with the proposed rule.

EPA Response: Please see sections 13.3 and 13.3.3 of the EPA response in this *Response to Comments* document. The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Further, this commenter compares the EPA's estimate of annualized costs associated with the NPDWR over the period of analysis to a one-time cost estimate of the "national burden" associated with PFAS produced by AWWA; these numbers are not directly comparable, as discussed in section 13.3 of the EPA response in this *Response to Comments* document.

Missouri River Public Water Supplies Association (MRPWSA) (Doc. #1581, SBC-042408)

May 24, 2023

Mr. Michael S. Regan, Administrator

Office of Ground Water and Drinking Water, Standards and

Risk Management Division, U.S. Environmental Protection Agency 1200

Pennsylvania Avenue Northwest, Mail Code: 4670M, Washington, D.C. 20460

RE: Docket ID No. EPA-HQ-OW-2022-0114

Dear Administrator Regan:

The Missouri River Public Water Supplies Association (MRPSWA) appreciates the opportunity to submit comments regarding "Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation (NPDWR). MRPWSA was established in 1961 and represents 19 drinking water utilities on the lower Missouri River that collectively serve over 4.3 million people safe clean drinking water. We support responsible management of Missouri River resources and maintenance of congressionally authorized purposes of the river, including water supply, water quality, flood control, and navigation. MRPSWA would like to highlight several concerns for the EPA to consider including implications to water utility operations, logistical and cost consequences, supply chain difficulties, and premature regulation without the supporting part per trillion data that will be collected with UCMR5.

Regulation of PFOA and PFOS — MRPWSA supports the development of Maximum Contaminant Levels (MCLs) for PFOA and PFOS, but believes that U.S. EPA is underestimating the overall cost of complying with the proposed MCLs of 4.0 parts per trillion (ppt) for PFOA and PFOS and urges the Agency to use the information included in the comments submitted by the American Water Works Association (AWWA) and the Association of Metropolitan Water Agencies (AMWA) and others to re-evaluate EPA's cost estimates, review the cost-benefit analysis, and determine appropriate regulatory levels for PFOA and PFOS. U.S. EPA must also consider the time necessary for water systems to assess their levels, design treatment and receive approvals, and construct when developing the compliance deadlines in the final rule.

EPA Response: Please see section 13.3 of the EPA response in this *Response to Comments* document. The agency has considered all public comments submitted on the proposed PFAS NPDWR, including those referenced by this commenter. See the EPA responses to individual comments, including those referenced here, for specifics about how the EPA considered those comments. The EPA notes that AMWA relies on AWWA's cost model, and the EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. For a more detailed discussion of the EPA's response to these and other comments on treatment costs associated with the rule, please see section 13.3.3 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1738, SBC-046019 in section 13.3.3 in this *Response to Comments* document. For the EPA's response to comments on the final MCLs and compliance timeline for the rule, please see sections 5 and 12, respectively, of the EPA response in this *Response to Comments* document.

Water & Health Advisory Council (Doc. #1590, SBC-042787)

There are also inconsistencies and disagreements regarding the economic impact of these proposed regulations. The U.S. EPA estimated an expected total annual cost of between $755,000,000 and $1.2 billion annually in the Economic Analysis. However, the American Water Works Association [Link: .awwa.org/AWWA-Articles/awwa-statement-on-proposed-pfas-drinking-water-standards] previously estimated that the national cost to comply with these regulations will be at least $3.8 billion annually. As stated by the U.S. EPA, the Bipartisan Infrastructure Law will provide some of the necessary funding to municipalities (a total of $9 billion). However, these funds are meant to cover not only PFAS, but drinking water systems impacted by other emerging contaminants, regulated contaminants that are not being adequately addressed (e.g., lead or arsenic), and critical infrastructure and maintenance upgrades. Federal funds devoted to PFAS will crowd out support for needs that may be more pressing in many parts of the U.S. Moreover, these economic impact analyses do not take into account costs associated with other programs that will be impacted by the U.S. EPA's stringent position on PFAS, such as environmental remediation programs, redevelopment, and wastewater treatment.

EPA Response: In response to the total national costs of the rule, please see section 13.3 of the EPA response in this *Response to Comments* document. In response to the recommendation to consider costs associated with other programs, please see section 15 of the EPA response in this *Response to Comments* document. Additionally, the EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Greater North Dakota Chamber et al. (Doc. #1593, SBC-042804)

The Safe Drinking Water Act requires consideration of the costs and benefits. The U.S. Chamber submitted a report to the Office of Management and Budget (OMB) modelling the potential costs attributable to various drinking water treatment levels. The estimated annualized costs for a proposed MCL of 4 ppt for PFOA and PFOS are approximately $1.8 billion annually and are more than twice as much as the EPA estimated costs in their economic analysis. The Chamber cover letter to OMB and the report are here [Link: https://www.globalenergyinstitute.org/sites/default/files/2023-03/221216Coverletter_DrinkingWaterMCLCosts_OMB.pdf] and here [Link: https://www.globalenergyinstitute.org/sites/default/files/2023-03/Potential%20Costs%20of%20Meeting%20Safe%20Drinking%20Water%20Act%20%28SDWA%29%20Standards%20for%20PFOA%20and%20PFOS.pdf]. The significant costs and impacts and their connection to other elements of the PFAS Strategic Roadmap, such as the proposed hazardous substance designation under CERCLA demand a full vetting by the stakeholder community.

EPA Response: For the EPA's response to the U.S. Chamber of Commerce comments, please see the EPA response to comment Doc. #1537, SBC-042649 in section 13.3.3 in this *Response to Comments* document. For the EPA's response to comments regarding management of treatment residuals, please see section 10.4 of the EPA response in this *Response to Comments* document.

Michigan Department of Environment, Great Lakes, and Energy (EGLE) Drinking Water and Environmental Health Division (DWEHD) (Doc. #1597, SBC-042993)

The economic analysis indicates that, "costs presented include those expenses incurred by PWSs to (1) monitor for PFAS, (2) inform consumers, (3) install and operate treatment technologies, and (4) perform record-keeping and reporting to comply with the PFAS NPDWR; and the costs incurred by states (or primacy agencies, i.e., states with authority to implement and enforce SDWA regulations) to implement the rule". Michigan notes implementation of new drinking water standards carry beyond the Safe Drinking Water Act and may result in changes being made to related programs. For example, EGLE believes that revised MCLs might eventually result in changes being made to Water Quality Values (WQVs) to protect surface waters and requirements to protect groundwater. Michigan already has three WQVs for PFOS, PFOA, and PFBS and lists seven analytes to protect groundwater for drinking water. Anticipated revisions to WQVs and other conditions, due to the draft MCLs, will change treatment costs to protect surface waters, revise treatment limits to protect groundwater, and may also result in revised conditions to allow for beneficial reuse of biosolids. EGLE believes that all costs should be reflected in the analysis to determine appropriate MCLs.

EPA Response: For the EPA's response to comments recommending the agency include costs not solely due to compliance with the MCLs, please see section 15 of the EPA response in this *Response to Comments* document.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043628)

1. The costs in the USEPA Economic Analysis are significantly underestimated; when considered alongside AWWA's and BWWB's analyses, it is clear that the proposed rule is not financially justifiable. The USEPA performed an Economic Analysis to calculate the costs effectiveness of the proposed rule. The USEPA expects the annualized benefit of the rule to be $908 million with an associated cost of $1.2 billion dollars. However, independent analysis performed by AWWA demonstrates the USEPA has severely underestimated the annualized cost. The AWWA analysis estimates a cost to comply with the rule in excess of $54 billion which equates to an annualized cost of over $2.7 billion (approximately 230% of the number estimated by USEPA). Furthermore, BWWB has developed potential capital cost estimates for compliance with the proposed rule, based on specific and more realistic design assumptions, that are four (4) times higher than those generated by USEPA's cost model.

EPA Response: Please see section 13.3 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1602, SBC-043656 in section 13.3.3 in this *Response to Comments* document. As explained in section 13.3 of the EPA response in this *Response to Comments* document, the EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. The commenter did not provide sufficient detail to compare their cost estimates to the results of the EPA's WBS models. Furthermore, extrapolating from a single utility's experience is not an appropriate method to estimate national costs. See also section 13.3.3 of the EPA response in this *Response to Comments* document. While the EPA has considered the input from the AWWA report and other public comments about the EPA's estimated rule costs, because AWWA represents water systems, the EPA does not think it accurate to describe the AWWA report as "independent." Please see the EPA response to comment Doc. #1841, SBC-044850 in section 5.1.3 of this *Response to Comments* document for further discussion.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043638)

D. The USEPA expects the annualized national compliance cost of $1.2 billion, at 7% discount rate (Table 1). However, the independent analysis performed by AWWA (Figure 1) estimates a cost to comply with the PFAS Rule in excess of $54 billion, which equates to an annualized cost of over $2.7 billion (approximately 230% of the number estimated by USEPA). Although the independent analysis conducted by AWWA demonstrated substantially higher national costs than USEPA's cost analysis, it still underestimated costs. Removal of short- chain PFAS (such as PFBS and GenX (HFPO-DA)) were not included in the three different scenarios presented in Figure 1 (adapted from AWWA's independent analysis). Moreover, Zeng et al (2020), Tow et al (2021), and a case study conducted by CDM Smith concluded that GAC (one of EPA's Best Available Technologies (BATs)) is notably less effective for "short chain" PFAS, commonly necessitating a higher frequency of media replacements, which could drive up the O&M cost.

[Figure 1: See Docket ID EPA-HQ-OW-2022-0114-1602]

Figure 1. Summary of Present Value of Life-Cycle Costs for National Burdens and NPDWR Compliance Costs for Each Scenario, adapted from AWWA.

The second scenario is based on target concentrations for PFOA, PFOS, PFHxS, PFHpA, and PFNA (collectively referred to as "long-chain PFAS") of 4 ppt each. Note: PFHpA is not included as a species to be regulated by the proposed PFAS Rule.

BWWB has conducted a cost analysis for installing GAC as post-treatment for the finished water at their four (4) filter plants. Appendix-A presents a comparison of capital and O&M cost estimates generated by USEPA's model versus an extrapolation based on costs from a recent (and similarly sized) GAC installation project. BWWB estimated that the 80MGD Shades Mountain Filter Plant (SMFP) could cost more than four (4) times what USEPA's estimated as total capital cost. The magnitude of underestimation in USEPA's cost analysis is concerning.

2. Based on the current interest rate, which is closer to 7%, USEPA's net benefits of the proposed rule are estimated to be negative $296.5 million per year. It is questionable whether the proposed rule is financially justifiable.

USEPA's costs and benefits also seem to largely depend on the discount rate. BWWB proposed that USEPA conduct a sensitivity analysis which is necessary to indicate the net benefits at different interest rates and better understand how sensitive costs and benefits are to each interest rate.

[Table: See Docket ID EPA-HQ-OW-2022-0114-1602]

EPA Response: Please see sections 13.3 and 13.3.3 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1602, SBC-043656 in section 13.3.3 in this *Response to Comments* document. The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs; please see section 13.3.3 of the EPA response in this *Response to Comments* document. Therefore, the EPA disagrees with the commenter's characterization of the results from that report as an underestimate. The EPA acknowledges that that report does not consider costs associated with the Hazard Index; however, the EPA has specifically analyzed these costs; please see section 13.3.2 of the EPA response in this *Response to Comments* document for more information.

The EPA disagrees with the commenters suggestion to conduct a sensitivity analysis to examine the "…net benefits and different interest rates…" The EPA's analysis utilizes follows OMB A4 guidance by using a constant dollar baseline over the period of analysis therefore projected nominal interest rates are not used to adjust benefit values over time. A4 states, "To avoid the misleading effects of inflation in your estimates, it is important to measure the stream of effects in constant dollars." Please note that constant dollars analysis is separate from discounting future effects to present value/annualization and the discount rates, sometimes confused with nominal interest rates, used as part of that analysis. Per A-4 guidance, the EPA uses a discount rate which is adjusted to remove the effects of inflation to adjust the estimated benefits and costs of the regulation for differences in timing. Regarding the discount rate used in the EA for the final rule, please see section 13.1 of the EPA response in this *Response to Comments* document.

Finally, the EPA disagrees that the rule is not "financially justifiable." The Administrator has determined that the total quantifiable and nonquantifiable benefits justify the quantifiable and nonquantifiable costs, please see section 13.8 of the EPA response in this *Response to Comments* document. While the EPA has considered the input from the AWWA report and other public comments about the EPA's estimated rule costs, because AWWA represents water systems, the EPA does not think it accurate to describe the AWWA report as "independent." Please see the EPA response to comment Doc. #1841, SBC-044850 in section 5.1.3 of this *Response to Comments* document for further discussion.

American Water Works Company Inc. (Doc. #1608, SBC-043981)

Key Issues

American Water highlights the following overarching comments on the proposed rule.

• Regulation of PFOA and PFOS – American Water supports the development of Maximum Contaminant Levels (MCLs) for PFOA and PFOS but believes that the U.S. EPA is underestimating the overall cost of complying with the proposed MCLs of 4.0 parts per trillion (ppt) for PFOA and PFOS and urges the U.S. EPA to use the information provided in American Water's comments as well as comments submitted by the American Water Works Association (AWWA) and others to re-evaluate EPA's cost estimates, review the cost-benefit analysis, and determine appropriate regulatory levels for PFOA and PFOS. We believe that the U.S. EPA must also consider the time necessary for water systems to assess their levels, design treatment and receive approvals, and construct when developing the compliance deadlines in the final rule.

EPA Response: For the EPA's response to comments stating that the EPA has underestimated the costs of the rule, please see section 13.3 of the EPA response in this *Response to Comments* document. The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. Please see section 12 of the EPA response in this *Response to Comments* document for the EPA's response to comments on the compliance timeframe for the final rule.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044027)

10. EPA requests comment on implementation challenges and considerations for setting the MCL at the PQLs for PFOA and PFOS, including on the costs and benefits related to this approach.

a. EPAs cost estimates for PFAS removals are grossly underestimated.

EPA Response: Please see section 13.3 of the EPA response in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043081)

Importance of an Accurate Cost Analysis

The EPA is encouraged to review and revise the cost analysis, and the EPA's WBS Model, to ensure that the monitoring and treatment costs are accurate. This cost analysis is critical given that it underpins the health risk reduction as well as the household affordability analysis. Inaccurate estimate of costs will mischaracterize the rules merits and the affordability for households in smaller communities. These analyses are critical for the Agency, and water systems, to understand public health priorities. Water systems are currently working to address various public health priorities, including lead service lines, cybersecurity, microbials and

disinfection byproducts, water supply challenges (e.g., drought, increasingly impaired water sources, etc.), and aging infrastructure. It is imperative that the overall analysis of the rule's impacts be accurate so that water systems and communities are assured that the investments in infrastructure represent the investments with the greatest societal benefit.

EPA Response: Please see sections 13.3.2, 13.3.3 and 13.10 of the EPA response in this *Response to Comments* document for the EPA's responses related to monitoring costs, treatment costs, and the affordability analysis respectively. The agency has conducted an accurate analysis of the rules impacts of the final rule and considered all public comments in doing so, please see section 13.3 of the EPA response in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043060)

5. The Proposal's underlying cost analysis is inaccurate and underestimates the costs to implement the rule and the impacts on consumers. The Agency should work with utilities to develop a cost-estimating approach that better reflects best-engineering practices, refine the cost estimate for the Proposal and re-evaluate the results as part of the final rule.

EPA Response: Please see sections 13.3 and 13.3.3 of the EPA response in this *Response to Comments* document.

Illinois Farm Bureau (IFB) (Doc. #1630, SBC-043135)

EPA has Underestimated the Challenges in Reaching These Levels

Agricultural producers support a national drinking water standard for PFOA and PFOS and other PFAS chemicals based on the best science available and an evaluation of risk— as opposed to the current patchwork of state requirements. However, there are substantial questions and concerns related to EPA's current proposal. As the costs that the proposed rule will impose are likely underestimated, it is critical that EPA obtain accurate and proven data. The proposed MCLs must be changed to properly balance costs and benefits, as the statute requires.

EPA Response: Please see sections 13.3 and 13.3.3 of the EPA response in this *Response to Comments* document. In regard to "properly balancing costs and benefits," please see section 13.8 of the EPA response in this *Response to Comments* document.

Association of Environmental Authorities (AEA) (Doc. #1635, SBC-042963)

Cost estimates for addressing PFAS must be realistic so that infrastructure and affordability programs match the needs. AWWA and NACWA agree that EPA estimates of $772 million to $1.2 billion nationally for implementation of the NPDWR are likely to be too low. AWWA and NACWA believe the costs could be at least three times higher-- $3.8 billion. Costs in New Jersey, the most densely populated state, are likely to be at the high end of any estimates. Costs reported here so far appear to support the AWWA/NACWA estimate. An investor-owned utility has been

quoted as saying it is spending $34 million on PFAS remediation at New Jersey 15 sites. Last year, Willingboro, N.J. broke ground on a treatment plant for a single well that is costing more than $5 million. Earlier this year, the Ridgewood, N.J. town council approved funding ordinances totaling $60.5 million to provide PFAS treatment for 33 wells.

EPA Response: Please see section 13.3 of the EPA response in this *Response to Comments* document. The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs, please see section 13.3.3 of the EPA response in this *Response to Comments* document. Furthermore, extrapolating from individual utilities or states' experience is not an appropriate method to estimate national costs. As the commenter pointed out, costs will vary by state, depending on standards, PFAS occurrence, number of water systems treating, among many other factors. The EPA does not dispute the commenter's reported costs for the New Jersey systems, but the comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models.

GFL Environmental (Doc. #1648, SBC-043223)

Cost Implications

• Overall costs are significantly underestimated: EPA should consider incremental overall costs and benefits associated with the proposed MCLs and MCLGs. The US Chamber of Commerce estimates annualized costs for a proposed MCL of 4 ppt for PFOA and PFOS are approximately $1.8 billion annually which is more than twice as much as the EPA's economic analysis of estimated costs at $772 million to $1.2 billion. The costs associated with meeting the MCLG (0 ppt), or non-detect, are orders of magnitude higher at almost $60 billion (EPA, 2023). Another report published by American Water Works Association (AWWA, 2023), is also estimating costs much higher than EPA's estimated annual cost. AWWA estimates the national cost for water systems to install treatment to remove PFOA and PFOS to levels required by EPA's proposal exceeds $3.8 billion annually (AWWA, 2023). Pre- treatment costs for wastewater generators, which will undoubtedly be required prior to disposal at publicly owned treatment works have not been considered.

EPA Response: Please see section 13.3 of the EPA response in this *Response to Comments* document. Furthermore, the EPA disagrees with the many of the assumptions and approaches in the cost estimate referenced by the commenter. For the EPA's response to the US Chamber of Commerce national cost comments, please see the EPA response to comment Doc. #1537, SBC-042649 in section 13.3.3 in this *Response to Comments* document. Additionally, the EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. In response to the commenter's statement about costs for wastewater generators, the treatment technologies the EPA anticipates PWS to use to comply with the rule in the EPA's analysis (GAC and ion exchange) do not result in PFAS-laden liquid

residuals that would be disposed at publicly owned treatment works. Therefore, inclusion of pre-treatment costs would not be appropriate.

Nebraska Department of Environment and Energy (NDEE) (Doc. #1653, SBC-043214)

• The Health Risk Reduction and Cost Analysis (HRRCA) does not accurately address PWSs in rural parts of the United States. The Department suggests EPA consider the following factors in its final rulemaking.

O A low-end capacity of 1 million gallons per day greatly exceeds that of a small Village class entity thus the cost to small communities is a one-size fits all and does not accurately account for the very small systems.

O The treatment alternative does not include the costs of manifolding a small system's supply wells. In order to treat the water supply for these types of systems, the source water will need to be piped together to be treated.

O The cost estimate of water treatment plant operator salaries is not based in reality of what a small system can afford, or the willingness of a certified operator to relocate to rural parts of the United States.

The Department supports EPA's efforts to protect the public from PFAS exposure and appreciates the EPA considering stakeholder comments on the proposed PFAS rule.

Sincerely,

Jim Macy

Director

Nebraska Department of Environment and Energy

EPA Response: Please see section 13.3 of the EPA response in this *Response to Comments* document. Additionally, the EPA disagrees with the comment that the cost analysis did not properly estimate the cost for small rural PWSs. The cost analysis for all PWSs is based on the estimated design and average daily flows at each entry point to distribution systems (EPTDS) which is estimated based on the population served. The commenter is incorrect; the EPA did not apply a low-end capacity limit of 1 million gallons per day in estimating these costs. The EPA's cost curves are based on model estimates that explicitly include capacities less than this limit, to as low as 0.03 million gallons per day. In addition, if small PWSs manifold wells together prior to treatment they will achieve economies of scale not accounted for in the cost analysis. In this situation, the EPA may have overestimated the cost of treatment. In regard to the EPA's estimates of the labor rate at water systems, the agency notes that the analysis utilizes a range of labor rates, that decrease as system size decreases. To the extent the labor rates for small water systems exceed actual water system labor rates, this would overestimate national costs of the rule. In response to the commenter's concern regarding certified operators at small systems

and funding available to help support operator training, please see the EPA response to comment Doc. #1567, SBC-042738 in section 12.1 in this *Response to Comments* document and section 12 of the EPA response in this *Response to Comments* document.

National Association of Manufacturers (NAM) (Doc. #1655, SBC-043195)

EPA's proposed regulations are not economically feasible

EPA's regulations under the SDWA must be feasible considering costs for compliance when setting an MCL. [FN1: 42 U.S.C. 300g-1(b)(B)(4)(D).] EPA appears to be severely underestimating potential compliance for the water systems that will be required to monitor, sample and treat at near zero levels. The American Water Works Association published a report in March, 2023 that found that potential compliance on the PFOA and PFOS regulations would exceed $3.8 billion annually. [FN2: https://www.awwa.org/Portals/0/AWWA/Government/2023030756BVFinalTechnicalMemoradum.pdf?ver=2023-03-14-102450-257] That is only for two of the six substances being regulated, once costs are factored in for the other substances, that could raise the annual cost substantially. EPA should set the MCLs at a level that balances the benefits and costs of cleanup to ensure that the regulations can be successfully implemented.

EPA Response: Please see section 13.3 of the EPA response in this *Response to Comments* document. Additionally, the EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. The EPA also disagrees with the commenter's assertion that "once costs are factored in for the other substances, that could raise the annual cost substantially." For the final rule, the EPA examined the incremental costs associated with the Hazard Index and individual MCLs for PFHxS, PFNA and HFPO-DA and found that national costs increase by approximately 5 percent. For more information, please see section 13.3.2 of the EPA response in this *Response to Comments* document. In regard to the recommendation that the EPA should "set the MCLs at a level that balances the benefits and costs of cleanup," please see section 13.8 of the EPA response in this *Response to Comments* document on the Administrator's benefit cost determination.

Virginia Municipal Drinking Water Association (VMDWA) (Doc. #1657, SBC-043167)

In light of the above data and information, VMDWA urges EPA to withdraw its cost estimate, give strong consideration to the AWWA report, and produce a corrected cost analysis for public comment. In so doing, VMDWA also recommends that EPA obtain data from the state primacy agencies and review their experience in reviewing applications under WIFIA, ARPA, Safe Drinking Water State Revolving Fund Program, and the Bipartisan Infrastructure Legislation as to high bid prices.

EPA Response: Please see section 13.3 of the EPA response in this *Response to Comments* document. Additionally, the EPA disagrees with many of the assumptions in AWWA's

B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. The EPA requested comment on treatment costs and received many comments from primacy agencies; the EPA has considered these comments and made appropriate adjustments to the cost estimates in the final rule.

Maryland Association of Municipal Wastewater Agencies (MAMWA) (Doc. #1658, SBC-043402)

In light of the above data and information, MAMWA urges EPA to withdraw its cost estimate, give strong consideration to the AWWA report, and produce a corrected cost analysis for public comment. In so doing, MAMWA also recommends that EPA obtain data from the state primacy agencies and review their experience in reviewing applications under WIFIA, ARPA, Safe Drinking Water State Revolving Fund Program, and the Bipartisan Infrastructure Legislation as to high bid prices.

EPA Response: Please see the EPA response to comment Doc. #1657, SBC-043167 in section 13.3 in this *Response to Comments* document.

National Association of Clean Water Agencies (NACWA) (Doc. #1659, SBC-043152)

EPA Grossly Underestimates the Cost Impacts to Public Water Systems

EPA estimates that regulating these PFAS chemicals will cost PWSs at least $772 million per year. EPA's more conservative cost estimate, the 7% discount rate, quantifies costs to PWSs upwards of $1.2 billion per year. EPA also acknowledged PWSs would incur between $30 and $60 million annually for disposing of spent PFAS-contaminated treatment residuals if PFAS were designated as a hazardous waste and regulated under hazardous waste disposal requirements.

Our sister drinking water association, the American Water Works Association (AWWA), has comprehensively assessed what it would cost nationally for water systems to install treatment systems to remove PFOA and PFOS, and by their calculation it would exceed $3.2 billion annually.

NACWA's understanding of the costs associated with implementation of EPA's proposed rule is consistent with AWWA's cost estimation. Many communities will have to find new water sources or install expensive advanced treatment and will require substantial rate increases to pay for increased ongoing operation and maintenance costs.

This gross underestimation by EPA of the true costs of compliance does a major disservice to the public by ignoring the rightful concerns about water affordability.

EPA Response: Please see section 13.3 of the EPA response in this *Response to Comments* document. The EPA disagrees with many of the assumptions in AWWA's B&V report

and the report's overall conclusions about the estimated national costs, for more information, please see section 13.3.3 of the EPA response in this *Response to Comments* document.

City of Allentown and Lehigh County Authority (LCA), Pennsylvania (Doc. #1667, SBC-043676)

The City has significant concerns regarding EPA's methods to evaluate costs and benefits of this proposed rule, including calculations of household affordability and other concerns discussed in more detail in comments to be provided by the American Water Works Association (AWWA).

EPA Response: Please see section 13.3 of the EPA response in this *Response to Comments* document. Additionally, the EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. For the EPA's response to comments on the affordability analysis and determination, please see section 13.10 of the EPA response in this *Response to Comments* document.

Aurora Water, City of Aurora, Colorado (Doc. #1669, SBC-043718)

Cost Estimates

Section XII.C.1.A

As proposed, EPA's current cost estimate for water systems' compliance is significantly underestimated. EPA estimates the costs of this proposed rule are $772 million per year nationally. Based on Colorado's publicly available voluntary PFAS sampling data reported from about half of community water systems, 30 public water utilities have PFOA and PFOS levels above the 4 ppt proposed MCL. Considering only half of the water systems in Colorado participated in this sampling effort, it would be safe to assume there are 60 systems (double the amount) that will be affected by an MCL of 4 ppt. If every state in the U.S. is in a similar situation to Colorado, the EPA's estimated cost for each utility over the PFOA and PFOS adjustments to meet MCLs would be at least $257,000 annually. This estimate only considers systems above PFOA and PFOS MCLs, and HI exceedances are not included. It is not feasible for water systems to be able to make the necessary changes for that estimated amount. EPA's estimate does not include funds needed for addressing HI exceedances, nor increases in material costs due to demand of GAC or other treatment technologies, treatment below the MCLs or inflation.

According to a study done by Black and Veatch on behalf of AWWA, the costs of installing drinking water treatment for removing only PFOA and PFOS will exceed $3.8 billion per year nationally. This cost estimate uses data provided by water systems that have done their own cost studies. Compared to EPA's estimate, they estimate more impacted systems and higher costs than what EPA estimated. Aurora Water estimates yearly costs to increase from $250,000 to $550,000 for removing PFOA and PFOS to the proposed level of 4 ppt for one of the three treatment

facilities. The other two facilities will need to construct treatment at a cost of approximately $15 million with ongoing O&M cost of about $550,000 per year, each. Aurora expects additional increases in treatment material costs, inflation and supply chain limitations.

EPA Response: Please see section 13.3 of the EPA response in this *Response to Comments* document for the EPA's response to comments stating that the agency has significantly underestimated the costs of the proposed rule. Furthermore, extrapolating from individual utilities or states' experience is not an appropriate method to estimate national costs. The EPA therefore disagrees with the commenter's assumption that the number of systems exceeding 4ppt in Colorado could be extrapolated nationally. For the EPA's response to comments on the number of water systems expected to be triggered into action under the final rule, please see section 6.5 of the EPA response in this *Response to Comments* document.

The EPA disagrees with the commenter's statements about Hazard Index feasibility and costs. The EPA estimated the costs associated with the Hazard Index and individual MCLs for PFHxS, PFNA and HFPO-DA for the final rule; please see section 13.3.2 of the EPA response in this *Response to Comments* document for the EPA's response to comments on the subject and Appendix N of the EA for the final rule for the EPA's results.

For the EPA's response to comments about the demand created by the rule, and the potential impact on prices of materials including GAC, please see section 13.3.3 of the EPA response in this *Response to Comments* document.

The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Association of California Water Agencies (ACWA) (Doc. #1675, SBC-044930)

A. Costs

COMMENT 1 – COST ASSESSMENT – EPA's cost assessment does not capture the full costs that will be borne by water agencies and ratepayers.

ACWA believes that this proposal is not feasible because the anticipated costs of this regulation are not adequately captured under EPA's cost assessment.

The SDWA was amended in 1996 to specifically require cost-benefit analysis as part of the regulatory process. The updated statutory language requires EPA to set maximum contaminant levels (MCLs) as close to the maximum contaminant level goal as is "feasible." "Feasible" is defined as "the use of the best technology and treatment approaches examined for effectiveness under field conditions, taking cost into consideration." [FN3: EPA, SDWA Economic Analysis (last updated Feb. 14, 2023), click here. [Link:]]

EPA estimates the costs of this proposed rule for water utilities to be between $772 million and $1.2 billion annually [FN4: Fed. Reg. 18,638, 18,700 (Mar. 29, 2023), click here. [Link:

https://www.federalregister.gov/documents/2023/03/29/2023-05471/pfas-national-primary-drinking-water-regulation-rulemaking]]. ACWA, along with other national water groups, believes that EPA's economic analysis does not accurately reflect the anticipated costs of the proposed rule on our members [FN5: Bloomberg, US Plan to Limit PFAS in Water Draws Concern Over Cost, Science (Mar. 15, 2023), click here. [Link: https://www.bgov.com/next/news/RRK2FCDWLU6B]]. Moreover, EPA's economic assessment was calculated in 2021 dollars, [FN6: Fed. Reg. at 18,700]and does not account for inflation increasing the capital and operation and maintenance (O&M) costs for water agencies [FN7: Circle of Blue, Inflation Weighs on U.S. Water Utilities (April 7, 2022), click here. [Link:]].

When PFAS are detected in a water system, they can have severe and far-reaching impacts. For instance, in California, water supply agencies, pumpers, and purveyors have had to take groundwater wells out of service due to PFAS detections and are taking steps to find and pay for alternative short-term water supplies, all while also developing PFAS remediation programs. As one example, it is anticipated PFAS remediation programs will cost hundreds of millions of dollars in Los Angeles and Orange Counties alone [FN8: See American Society of Civil Engineers, California water district moves ahead with PFAS treatment systems (Oct. 25, 2021), click here [Link: https://www.asce.org/publications-and-news/civil-engineering-source/civil-engineering-magazine/article/2021/10/california-water-district-moves-ahead-with-pfas-treatment-systems#:~:text=Of%20the%2019%20retail%20water,of%20engineering%20for%20the%20OCWD.]; see also Reuters, California agency sues 3M, others over groundwater contamination (Nov. 9, 2021), click here. [Link:]].

More specifically, to meet the requirements of this proposed rule, a southern California member estimates PFAS project costs to be $170 million in its service area alone. Moreover, in anticipation of EPA's proposal, the American Water Works Association commissioned a study to estimate the national cost for water systems to install treatment to remove PFOA and PFOS to required levels. According to the study, estimated costs will exceed $3.2 billion annually, and the majority of treatment costs will be passed on to communities and ratepayers [FN9: See Black & Veatch, WITAF 56 TECHNICAL MEMORANDUM PFAS National Cost Model Report (Mar. 7, 2023), click here. [Link: https://www.awwa.org/Portals/0/AWWA/Government/2023030756BVFinalTechnicalMemoradum.pdf?ver=2023-03-14-102450-257]].

EPA Response: For the EPA's response to comments stating that the agency has underestimated the costs of the proposed rule, please see section 13.3 of the EPA response in this *Response to Comments* document. For the EPA's response to comments on feasibility of the final MCLs, please see section 5 of the EPA response in this *Response to Comments* document. The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. For the EPA's response to this report, as well as response to recommendations to update the dollar year used in the analysis, please see section 13.3.3 of the EPA response in this *Response to Comments* document.

The EPA does not dispute the commenter's estimate of southern California PFAS project costs, but the comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models.

New York State Department of Health (NYS DOH) (Doc. #1677, SBC-044949)

11. Rapidly evolving PFAS research complicates cost-forecasting for water testing, treatment technologies and healthcare. Shifting state and federal regulations generate unanticipated expenses in drinking water sampling and filtration, product testing, and treatment of wastewater and landfill leachate. There are uncertainties in how long filters will perform and what their disposal costs may be, treatment methods are rapidly evolving and demand for filtration systems is skyrocketing, driving up costs and causing delays on top of existing supply-chain challenges. Water treatment operators that find PFAS during sampling must test water more frequently, an ongoing expense that drives up operating costs. Treatment add-ons to existing plants will likely require the acquisition of additional land, operators and ancillary equipment.

EPA Response: Please see section 13.3 of the EPA response in this *Response to Comments* document. The EPA used the best information available at this time to estimate the costs; for more information section 13.3.3 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenter's assertion that there are significant "uncertainties in how long filters will perform;" see the EPA's *Best Available Technologies and Small System Compliance Technologies Support Document* for more information (USEPA, 2024e), including the EPA's evaluation of the performance of each technology. Please see section 13.3.3 in this *Response to Comments* document for the EPA's response to comments on performance monitoring that may occur as a result of the rule. Finally, the EPA includes the costs associated with "treatment add-ons" referenced by the commenter including land, operator labor, and a variety of indirect capital costs in the costs analysis, see Chapter 5 of the EA for more information.

City of Vancouver Water Utility, Vancouver, WA (Doc. #1684, SBC-044306)

The EPA has likely estimated the number of utilities that will be impacted at the proposed MCLs and the cost impacts to be far too low.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045047)

Cost Analysis

Cost-Benefit Model

Based on an initial analysis of New Jersey's records, NJDEP believes EPA has underestimated the costs of implementing the proposed standards. In a preliminary statewide assessment, NJDEP estimated that it may cost New Jersey over $1 billion to implement the proposed standards. This estimate includes costs for drinking water sampling, capital expenditures for affected systems to install treatment, sampling through the State's ambient monitoring networks, and New Jersey Pollution Discharge Elimination System (NJPDES) monitoring. Importantly, this estimate does not include the sustained operational and maintenance costs that will be necessary for affected systems to maintain treatment.

EPA Response: Please see section 13.3 of the EPA response in this *Response to Comments* document. The EPA does not dispute the commenter's estimate of implementation costs in New Jersey, but the comment lacks sufficient detail to compare these costs to the results of the EPA's WBS and SafeWater models. The cost quote provided by the commenter appears to include costs not associated with compliance with a state or federal drinking water standard (i.e., Sampling through the state's ambient monitoring networks, and New Jersey Pollution Discharge Elimination System (NJPDES) monitoring) and is therefore not directly comparable to the EPA's NPDWR cost estimates. Further, this commenter cites a one-time cost estimate of capital investments in the state, which is not directly comparable to the EPA's annualized values. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

<u>New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045050)</u>

National Cost Estimate

The NJDEP is concerned that the National Cost Estimate, calculated using the MCBC model that EPA used for this PFAS National Primary Drinking Water Regulation Rulemaking, significantly understates the annualized costs associated with the proposed standards. Using the lifetime and higher discount rate provided in EPA's analysis (80 years and 7%), the NJDEP annualized the capital construction costs for PFAS treatment as reported by systems which have already installed PFAS treatment to meet the NJDEP's own drinking water standards for PFOA, PFOS, and/or PFNA.

The NJDEP subsequently compared the annualized capital construction cost New Jersey public water systems have experienced with EPA's forecasted annualized costs in their corresponding category, as outlined in Table C-1 in Appendix C of EPA's Economic Analysis for this proposal. The average difference between the actual annualized construction cost and forecasted EPA number was $840 per year. Note that the annualized cost for New Jersey used in this comparison does not include operating and maintenance costs due to a lack of data available (unlike the EPA's annual cost estimate which does include O&M costs), meaning that the real difference in annualized costs between the EPA economic analysis and the reality facing public water systems may be greater.

As such, the NJDEP urges the EPA to review the economic analysis methodology and underlying data used to come to the forecasted conclusions to arrive at a more accurate estimate of the annualized costs for public water systems.

EPA Response: Please see section 13.3 of the EPA response in this *Response to Comments* document. Additionally, the EPA does not dispute the commenter's estimate of costs in New Jersey, but the comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. As it relates to the commenter's stated average difference between the EPA's system level cost ranges in Appendix C-1 and the information included in the commenter's letter, the EPA notes that the stated average difference of $840 dollars per year is at most an approximately 6 percent difference from the lowest median cost estimates in the EPA's Table C-9 in the EA for proposal (the EPA's median cost estimate for groundwater systems serving less than 100 customers was $15,360; ($840/$15,360*100=5.46 percent)). When compared to many of the EPA's estimates in Table C-9, $840 dollars is less than 1 percent of the EPA's median annualized cost estimate. While the EPA recognizes there are likely site-specific instances where costs exceed the EPA's cost ranges, there are also likely site-specific instances where costs are less than the EPA's cost ranges, and the level of accuracy in the EPA's cost assessment is appropriate for a national level analysis. Further, the EPA notes that the agency made a number of changes to the treatment cost estimates for the final rule, detailed in section 13.3.3 of the EPA response in this *Response to Comments* document, that are very likely to narrow the gap between New Jersey's cost information and the EPA's unit cost information.

Association of California Water Agencies et al. (Doc. #1701, SBC-043836)

Accurately Reflecting Costs and Household Affordability

A major concern our groups have is the enormous cost of this rulemaking, which will be imposed on water systems, communities, and their ratepayers. With this rule, communities will be financially responsible for expensive treatment technologies to remove PFAS from water down to the lowest level that can be reliably detected. While EPA's costs and benefit analysis estimates that the costs of this proposal amount to $770 million to $1.2 billion annually, other available data from existing facilities and industry work estimate that the cost could exceed $3.2 billion annually1. [FN1: Black & Veatch, 2023. WITAF 056 Technical Memorandum Update: PFAS National Post Model Report. Prepared for American Water Works Association. May 26, 2023.]

EPA Response: The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. Please see section 13.10 in this *Response to Comments* document for the EPA's response to comments on the affordability analysis.

Association of California Water Agencies et al. (Doc. #1701, SBC-043840)

A robust and accurate cost and benefit analysis is crucial for making sound decisions that are protective of public health and appropriately prioritize investments. EPA should improve its cost analysis, and subsequently the household affordability analysis, to be more reflective of available information on PFAS treatment costs. This is imperative to ensure that the proposed rule is not only accurately reflecting the financial impacts on communities as a whole but also examines affordability for low-income households specifically.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document. Please see section 13.10 in this *Response to Comments* document for the EPA's response to comments on the affordability analysis.

California Farm Bureau Federation (Doc. #1704, SBC-045069)

[For example, the U.S. Chamber analysis highlights the following:]

• The Safe Drinking Water Act requires consideration of the costs and benefits. The estimated annualized costs for a proposed MCL of 4 ppt for PFOA and PFOS are exorbitant. The significant costs and impacts, and their connection to other elements of the PFAS Strategic Roadmap such as the proposed hazardous substance designation under CERCLA, require further analysis and consideration.

EPA Response: Please see the EPA's response to the US Chamber of Commerce's cost estimates in the EPA response to comment Doc. #1537, SBC-042649 in section 13.3.3 in this *Response to Comments* document. Further, for the EPA's response to comments on disposal of spent drinking water materials under possible future regulatory actions under other statutes, see section 10.4.1 of the EPA response in this *Response to Comments* document.

California Farm Bureau Federation (Doc. #1704, SBC-045065)

The Challenges in Reaching These Levels Have Been Underestimated

While farmers, ranchers, and other agricultural producers support a national drinking water standard for PFOA and PFOS and other PFAS chemicals based on the best science available and an evaluation of risk, there are substantial questions and concerns related to EPA's current proposal. The extensive review of the proposed cost-benefit analysis, completed by the U.S. Chamber of Commerce, highlights costs associated with this rule have not been accurately calculated for a variety of reasons.

EPA Response: Please see sections 13.3 and 13.3.3 of the EPA response in this *Response to Comments* document and the EPA's response to the US Chamber of Commerce's cost estimates in the EPA response to comment Doc. #1537, SBC-042649 in section 13.3.3 in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1711, SBC-044462)

[The Agency's proposal suffers from the following significant shortcomings –]

• EPA's estimate of the costs of its proposal relies on occurrence data for PFOA and PFOS that do not provide an appropriate baseline and is much lower than the costs predicted by an independent analysis,

EPA Response: While not explicitly stated in Doc #1711, the EPA assumes this commenter is referring to AWWA's cost estimates. For the EPA's response to the AWWA B&V report, please see section 13.3.3 of the EPA response in this *Response to Comments* document. For the EPA's response to comments on the national occurrence model used in the EA, please see section 6.5 of the EPA response in this *Response to Comments* document. While the EPA has considered the input from the AWWA report and other public comments about the EPA's estimated rule costs, the EPA does not think it accurate to describe the AWWA report as "independent." Please see the EPA response to comment Doc. #1841, SBC-044850 in section 5.1.3 of this *Response to Comments* document for further discussion.

Protecting Our Water, Environment, and Ratepayers (POWER) (Doc. #1714, SBC-045931)

COMMENT 2 — EPA HAS FAILED TO ADEQUATELY CONSIDER COSTS IN THE PROPOSED RULE.

EPA has failed to capture or consider the full range of costs of its MCL for water and wastewater agencies or their customers.

The proposed NPDWR fails to adequately consider the costs associated with its proposal as required by the Safe Drinking Water Act ("SDWA") and recognized as an obligation by in EPA's SDWA Economic Analysis. [FN6: EPA, SDWA Economic Analysis (last updated Feb. 14, 2023) (https://www.epa.gov/sdwa/sdwa-economic-analysis).] EPA's SDWA Economic Analysis states that when there is no reliable method, a treatment technique is set rather than an MCL. [FN7: EPA, SDWA Economic Analysis (last updated Feb. 14, 2023) (https://www.epa.gov/sdwa/sdwa-economic-analysis).] The SDWA requires the EPA to review costs that occur solely as a result of compliance with the MCL such as monitoring and treatment. [FN8: 42 CFR 300g (b)(3)(C)(i)(III).]

EPA's NPDWR estimates that the cost to water utilities will be between $772 million and $1.2 billion annually. [FN9: EPA, PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18638, 18700 (proposed Mar. 29, 2023) (hereinafter "Proposed Rule").] This estimate fails to take into account a number of factors including inflation and rising capital and operational costs. Further this estimate fails to consider the cost of action upon detection of one of the PFAS chains. These costs include, but are not limited to: identifying and paying for alternative water sources for PFAS contaminated sources, particularly in locations or periods where water is scarce; developing, piloting, and implementing new treatment systems (in lieu of EPA final treatment direction); and the incremental impacts and costs of the proposed Hazard

Index for PFNA, PFHxS, PFBS, and GenX. In anticipation of EPA's proposed NPDWR, the American Water Works Association commissioned a study to estimate the national cost for water systems to install treatment to remove PFOA and PFOS to required levels. According to the study, estimated costs will exceed $3.2 billion annually and the majority of treatment costs will be passed on to communities and ratepayers. [FN10: Black & Veatch, WITAF 56 TECHNICAL MEMORANDUM PFAS National Cost Model Report (Mar. 7, 2023) (https://www.awwa.org/Portals/0/AWWA/Government/2023030756BVFinalTechnicalMemoradum.pdf?ver=2023-03-14-102450-257).]

Many members of POWER! Project that their costs of constructing PFAS treatment and residual disposal will reach tens of millions, and in some cases exceed $100 million, for each water agency, and result in significantly increased annual operation and maintenance costs. EPA has failed to adequately capture or consider the full impacts of its proposed 4 ppt MCL for PFOA and PFOS, or its novel Hazard Index regulating four new PFAS at similar levels, for the thousands of water and wastewater agencies across the country or their ratepayers.

EPA Response: Please see section 13.3 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenter's statement that the agency "…has failed to capture or consider the full range of costs of its MCL for water and wastewater agencies or their customers," as the agency has met all statutory and Executive Order requirements to consider such impacts using the best available data. In the EA for both the proposed and final PFAS NPDWR, the EPA evaluated the costs of each of the activities or "costs of action" mentioned by the commenter, including pursuing non-treatment options (i.e., New water sources) where viable, developing, piloting, and implementing new treatment systems, and the cost impacts of the Hazard Index MCL specifically (please see section 13.3.2 of the EPA response in this *Response to Comments* document for more information). Finally, the EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Monterey One Water (Doc. #1715, SBC-043828)

Economic Impact

Monterey One Water urges EPA to reassess the economic impact of the rule on water utilities to ensure that policymakers have accurate information when providing financial support for PFAS remediation. Our Agency remains concerned about the cost of meeting the proposed MCLs within the aggressive compliance window and the financial impact that the treatment and removal of PFAS may have on our ratepayers. EPA has estimated that the total cost of compliance for public water systems will range from $769 million to $1.2 billion. While the estimate incorporates monitoring, equipment, capital costs, operations and maintenance, regulatory reporting, and public communications, it falls well below the $3.2 billion that the water treatment sector has estimated the rule will cost water utilities annually. We urge EPA to

review the economic analysis prepared earlier this year for the American Water Works Association and consider whether any revisions are needed to its own economic analysis.

EPA Response: Please see section 13.3 of the EPA response in this *Response to Comments* document. Additionally, the EPA has considered all public comments, including those regarding the economic impacts of the rule, in finalizing the rule. The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Loudoun Water (Doc. #1717, SBC-043521)

Loudoun Water is a member of the American Water Works Association (AWWA) and is aware of the findings from the national cost assessment, March 2023, conducted by Black & Veatch on behalf of the AWWA. The study found that MCLs set at 4 ppt for PFOA and for PFOS would trigger $5.2 billion in annualized national costs (capital, O&M, monitoring, etc.) for impacted facilities assuming a seven percent discount rate, as compared to EPA's estimate of $1.211 billion, using the same discount rate. Loudoun Water believes that EPA's estimate of the cost of compliance is greatly understated without considering the many factors likely to push the cost higher.

EPA should re-evaluate the costs of rule implementation to ensure the current realities of utility input costs and supply chain limitations are accurately reflected in its analysis. Utilities need a comprehensive understanding of EPA's proposed regulatory framework for PFAS from drinking water sources of supply to water treatment plant residuals to make cost effective decisions and reduce rate impacts to our customers.

EPA Response: This commenter cites AWWA's cost estimates of $5.2 billion annually included in an older version of the B&V report from March 2023. According to the March 2023 version of the report, that figure represents AWWA's understanding of the "national burden" of removing PFOA and PFOS to 4ppt each, not just the NPDWR costs, which AWWA presents separately. The EPA notes that in their public comments on the proposed rule submitted in June 2023, AWWA submitted lower revised estimates in that report, of $2.5 to $3.2 billion dollars annually at the 3 and 7 percent discount rates respectively. Furthermore, the EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. For more information on the EPA's whole-of-agency approach to addressing PFAS, see the EPA's PFAS Strategic Roadmap.

Environmental Working Group (EWG) (Doc. #1721, SBC-045416)

For an independent review of the EPA's cost analysis, please see the memorandum dated May 30, 2023, prepared by Elin Warn Betanzo of Safe Water Engineering, LLC, referenced in and appended to comments submitted by Earthjustice et al. The analysis confirms that EPA's analysis

of costs of the proposal were grounded in sound, and in some cases, conservative assumptions. For instance, the lowest discount rate EPA considered was 3 percent, while OMB's recently revised draft guidance for economic analyses favors a substantially lower, consumption-based discount rate of 1.7 percent. [FN62: Elin Warn Betanzo, Safe Water Engineering, LLC, Analysis of the USEPA Proposed PFAS National Primary Drinking Water Regulation Treatment Costs and Comparison to the AWWA National PFAS Cost Model Report (May 30, 2023) (citing Circular A-4: Memorandum from the Off. Of Mgmt. & Budget to Heads of Exec. Agencies & Establishments; re: Regul. Analysis (Apr. 06, 2023) at 4). See also Earthjustice et al., supra note 7.] The analysis also highlights some unmodeled considerations that "would have the impact of decreasing overall costs…" including, among other things, the extent to which water systems would consolidate with other systems to meet the MCLs instead of installing treatment, use point-of-use (POU) devices for compliance, and innovation in the marketplace. [FN63: Id. At 21]

EPA Response: This comment generally supports the EPA's analysis. For the EPA's response to comments on discount rates used in the analysis, please see section 13.2 of the EPA response in this *Response to Comments* document.

Thurston Public Utility District (PUD), WA (Doc. #1729, SBC-043586)

5. Costs to public water systems including funding treatment design and installation, operation and maintenance, availability of certified operators for implementing treatment options, potential treatment supply chain product availability, and disposal of PFAS waste represent challenges especially to our many small water systems.

EPA Response: Please see sections 13.3 and 13.3.3 of the EPA response in this *Response to Comments* document.

Thurston Public Utility District (PUD), WA (Doc. #1729, SBC-043577)

I want to urge the EPA to conduct a more robust analysis that more accurately captures the costs of compliance, and if necessary, collects more data to inform and address the gaps that currently exist before adopting a rule. This should be a reasonable request given that the agency caveated its own work in the posting by listing a host of data limitations and uncertainties from a lack of modeling national costs for treatment associated with potential Hazard Index exceedances.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document. Further, the EPA notes that it is best practice to identify known data limitations and uncertainties in any scientific or economic analysis, including this one (see e.g., US EPA Guidelines for Economic Analysis for more information). Identification of uncertainties is also required by the statute, see SDWA Section 1412(b)(3)(C)(i)(VII). For the EPA's response to comments on the costs associated with the Hazard Index specifically, please see section 13.3.2 in this *Response to Comments* document.

U.S Conference of Mayors, National League of Cities and National Association of Counties (Doc. #1733, SBC-043890)

Overarching Concerns and Recommendations

As EPA continues to develop this regulation, we offer several of our priority concerns and recommendations relating to local governments' ability to effectively and cost-efficiently implement the proposed changes while also protecting public health.

1. Financial Impacts

The Agency's proposed regulation will have a significant impact on public water systems, and the financial burden will ultimately be passed on to local governments and community ratepayers. In proposing this new regulation, the Agency has conducted a cost-benefit analysis and concluded annual costs of $770 million and benefits of approximately $1.2 billion. However, the American Water Works Association (AWWA) has estimated annual costs between $2.5-$3.2 billion. [FN1: WITAF 56 Technical Memorandum Update, "PFAS National Cost Model Report," May 26, 2023]

EPA Response: Please see section 13.3 of the EPA response in this *Response to Comments* document. The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Arizona Corporation Commission (ACC) (Doc. #1735, SBC-045181)

Based on the construction costs provided above, the ACC believes that the EPA's estimated costs for nationwide compliance are underestimated. Specifically, Table 22 of the EPA's PFAS NPDWR paper, which estimates the annual cost per household for systems with 25-500 customers, indicates costs ranging from $376 to $645. Considering a service life of 10 years for treatment equipment, [FN3:10-Year service life figure obtained from the EPA handbook titled "Asset Management: A Handbook for Small Water Systems," published in 2018.] the ACC estimates that the annual bill impact for smaller systems requiring FCRT for one well with a flow rate of 0.2 MGD exceeds $1,000 per household. The ACC believes that the EPA's estimate did not account for inflation in the construction sector, potential increases in demand for specialized treatment equipment, additional infrastructure requirements to operate remediation technologies effectively, and the financial strain resulting from a narrow compliance window.

EPA Response: This comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. Regarding the impacts of inflation on the cost estimates, the EPA does not disagree that inflation could increase the cost of the rule in nominal terms. However, as prices rise, so would the benefits of the rule (e.g., increased cost of health care treatment avoided). Therefore, following common practice, the EPA estimated the cost and benefits of the rule in real terms (constant 2022 dollars). The EPA disagrees with the commenter's assumption of a service

life of 10 years. Although some individual treatment system components may have a useful life of 10 years or less, the EPA estimates that overall treatment system useful life can be 20 to 30 years or more, depending on system size and materials of construction. This estimate is based on the composite useful life of treatment systems derived from the useful lives of individual treatment system components and industry information (including the Asset Management Handbook cited by the commenter).

Florida Section American Water Works Association – Water Utility Council (FSAWWA WUC) (Doc. #1737, SBC-044485)

XIII. Health Risk Reduction and Cost Analysis

The Florida Water Sector supports health risk reduction and understands its importance to EPA's Cost Analysis. Providing safe and reliable drinking water is our number one priority. However, we recommend EPA perform additional cost analyses based on some additional considerations. In addition, we do not believe all utilities will be able to comply with the new regulations in the three years allotted.

EPA Response: Please see section 13.3 in this *Response to Comments* document for the EPA's response to comments on the overall cost analysis. For the EPA's response to comments on the compliance timeline for the final rule, please see section 12 of the EPA response in this *Response to Comments* document.

Arizona Water Company (Doc. #1758, SBC-044533)

Capital and operation and maintenance (O&M) costs for PFAS removal facilities will be expensive. The Company expects to spend approximately $200 Million in capital costs and $25 Million in annual O&M costs to remove PFAS from its water supplies to comply with the proposed MCLs. These costs will be extraordinary and result in massive cost increases that must be passed directly on to the Company's customers. To avoid rate shock, the Company is requesting assistance with the capital and O&M costs for PFAS removal facilities via federal funding. The Company recommends the EPA provide resources on the specific amounts of government funding available to private utilities to construct PFAS removal facilities. Based on the Company's estimates, over approximately eight years, the O&M costs for PFAS removal facilities will surpass the capital costs for their construction. Without any government funding assistance, these O&M costs will be passed directly on to customers and increase their rates. The Company recommends the EPA provide resources to private utilities to help fund the O&M costs associated with operating and maintaining PFAS removal facilities in addition to capital costs to construct them.

EPA Response: The EPA has used best available science and information to estimate costs imposed by the rule, including operation and maintenance costs, in its EA. Please see section 13.3 in this *Response to Comments* document for the EPA's response to comments on the overall cost analysis. Regarding funding, the passage of the Infrastructure Investment and Jobs

Act (IIJA), often referred to as the Bipartisan Infrastructure Law or BIL, invests over $50 billion to improve drinking water, wastewater, and stormwater infrastructure – the single largest investment in water by the federal government. This historic investment specific to safe drinking water includes $11.7 billion in the Drinking Water SRF; $4 billion to the Drinking Water SRF for Emerging Contaminants; and $5 billion in grants for Emerging Contaminants to Small or Disadvantaged Communities from federal fiscal years 2022 through 2026 (USEPA, 2023d). For more information on the EPA's response to comments about the availability federal funding available to support the rule, including O&M costs, please see section 2 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045561)

Additional recommendations are detailed in this letter, including:

1. The proposal's underlying cost analysis is inaccurate and substantially underestimates costs to compliance costs and the financial impacts on consumers. The agency should work with AWWA and other stakeholders to develop a cost-estimating approach that is more reflective of best-engineering practices and should refine the cost estimate for the proposal. Any final rule should re-evaluate the determinations that benefits justify the costs and the rule is affordable for small systems, considering the updated cost analysis to support any rule.

EPA Response: The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. For the EPA's response to comments on the Administrator's determination that the benefits justify the costs, please see section 13.8 of the EPA response in this *Response to Comments* document. For the EPA's response to comments on the affordability determination, please see section 13.10 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045556)

A recent analysis by Black & Veatch estimated that the costs of the proposed standards could exceed $2.5 to $3.2 billion annually (Black & Veatch, 2023 – See Appendix B). The Administrator will need to determine if these costs are justified by the benefits, estimated to be $0.8 to $1.2 billion annually, and whether it is a meaningful opportunity to protect public health when this investment will divert water systems investments from other needs to assuring compliance with any final PFAS rule requirements.

EPA Response: The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. For the EPA's response to comments on the Administrator's determination that the benefits of the rule justify its costs, please see section 13.8 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045609)

7. Compliance Cost Analysis

According to the proposal, EPA anticipates that nearly 67,000 water systems will need to comply with the proposed rule. These water systems will need to review and understand how to implement the rule, conduct initial monitoring of the regulated PFAS at each entry point to the distribution system, and potentially work to install drinking water treatment systems or take another mitigation strategy. The proposal does not fully capture these costs. Because the SDWA requires EPA to take costs into consideration, including when setting the appropriate MCL, and to issue a determination as to whether the benefits of the maximum contaminant level justify, or do not justify, the costs, EPA can only comply with its statutory requirements by conducting an analysis that fully captures these costs and making them available for public comment. [FN24: See 42 U.S.C. §§§ 300g–1 (b)(3)-(4).] The following sections provide recommendations to improve the cost analysis.

EPA Response: The EPA disagrees with the commenter that the proposal did not fully capture the costs associated with the rule. Please see section 13.3 of the EPA response in this *Response to Comments* document for the EPA's response to comments on the overall cost analysis. For the EPA's response to comments on the Administrator's determination that the benefits of the rule justify its costs, please see section 13.8 of the EPA response in this *Response to Comments* document. For the EPA's response to comments on the feasibility determination, please see section 5.1.3 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045619)

Importance of an Accurate Cost Analysis

The EPA is encouraged to review the cost analysis, and the EPA's WBS Model, to ensure that the monitoring and treatment costs are accurate. As noted above, EPA cannot fulfill its obligations under the SDWA unless the cost assessment is accurate. In addition, this cost analysis is critical given that it underpins the HRRCA as well as the household affordability analysis. An inaccurate estimation of costs will mischaracterize the proposal's regulatory impact, merits, and the affordability for households in smaller communities. These analyses are critical for the agency, and water systems, to understand public health priories. Water systems are currently working to address various public health priories, including lead service lines, cybersecurity, microbials and DBPs, water supply challenges (such as drought, increasingly impaired water sources), and aging infrastructure.

Black & Veatch estimates that the cost of rule will range from more than $2.5 to $3.2 billion annually (Black & Veatch, 2023 – See Appendix B). As proposed, this rule will be one of the most costly rules under SDWA ever proposed and will be a burden carried by less than 10% of water systems. It is imperative that the overall analysis of the proposal's impacts be accurate so

that water systems and communities are assured that the investments in infrastructure being made represent the investments with the greatest societal benefit.

EPA Response: Please see section 13.3 in this *Response to Comments* document for the EPA's response to comments on the overall cost analysis. The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. Please see section 13.10 in this *Response to Comments* document for the EPA's response to comments on the affordability analysis.

Connecticut Section of the AWWA (CTAWWA) and Connecticut Water Works Association (CWWA) (Doc. #1763, SBC-044236)

Costs and Funding Sources

We encourage EPA to review its cost model for the proposed PFAS Rule. It is our understanding that many more systems will exceed the proposed MCLs than have been projected by EPA. In addition, our membership continues to experience cost increases related to equipment, materials, and workforce. These current costs should be reflected in the benefit cost analysis to ensure the appropriateness of the PFAS Rule.

According to American Water Works Association (AWWA) data, EPA has underestimated the cost of compliance with the proposed perfluorooctanoic acid (PFOA) and perfluorooctyl sulfonate (PFOS) standards. Cost models prepared for AWWA by the consulting engineering firm Black & Veatch (WITAF 56 Technical Memorandum – PFAS National Cost Model Report), as well as our members' experience in Connecticut, differ significantly from EPA's model. EPA's benefit cost analysis must accurately evaluate the cost impact of the rule to make a sound decision on the appropriateness of the rule requirements.

EPA Response: The EPA has used the best available information to inform the estimates of the number of water systems exceeding the MCLs as well as cost information in the final rule. Based on public comment, the EPA has updated its occurrence analyses, For more information please see section 6.2 of the EPA response in this *Response to Comments* document on state drinking water data and section 6.5 of the EPA response in this *Response to Comments* document on the PFAS national occurrence model. Additionally, please see section 13.3.3 of the EPA response in this *Response to Comments* document regarding the EPA's treatment cost estimates and consideration of recent price increases. Additionally, the EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

U.S. Poultry & Egg Association et al. (Doc. #1765, SBC-044549)

5. Flaws in the Economic Analysis

In accordance with the SDWA, if the agency establishes an MCL for any contaminant, the combination of technology, treatment techniques, or other means required to meet the level must not be more stringent than feasible. This rule wildly underestimates the burden of cost that will be placed on thousands of public water supply systems, including poultry and egg facilities that fall into the category of a non-transient, non-community water systems (NTNCWSs). The costs associated with establishing the proposed MCLs to levels that are essentially zero levels, will subject rural municipalities and poultry companies to bear unnecessary financial burdens associated with engineering, purchasing and installing multiple additional treatment technologies.

The American Water Works Association (AWWA) published a report in March of 2023 titled, "PFAS National Cost Model Report" that provides national cost estimates for setting an MCL of 4 ppt for PFOA and PFOS. It found the national cost for water systems to install treatment to remove PFOA and PFOS to levels required by this proposal exceed $3.8 billion annually. The report further estimated that annual costs to households in small communities, often where poultry and egg industry facilities are located, can amount to $10,000. Flaws in EPA's economic analysis are further aggravated by the fact that the agency's analysis fails to account for expenses associated with annual operating and maintenance – expenses likely to be overly burdensome given these treatment technologies are unique to wastewater treatment plant personnel.

The undersigned organizations have a strong interest in a responsible rulemaking process that protects the environment and the health of the public. However, the proposal to establish the incredibly low MCL's and MCLG's for the six PFAS listed in the regulation will subject the regulated community to a high level of uncertainty. A regulation as highly technical and far reaching as this demands far more time and consideration. The organizations listed below appreciate the opportunity to submit these comments and the agency's thoughtful deliberation.

If you have any questions related to these comments or would like additional information, please contact Paul Bredwell at pbredwell@uspoultry.org.

Sincerely,

U.S. Poultry & Egg Association

National Turkey Federation

Alabama Poultry & Egg Association

California Poultry Federation

Delmarva Chicken Association

Georgia Poultry Federation

Indiana State Poultry Association

Kentucky Poultry Federation

Mississippi Poultry Association

North Carolina Poultry Federation

North Central Poultry Association

Northwest Chicken Council

Ohio Poultry Association

Tennessee Poultry Association

Texas Poultry Federation

The Poultry Federation

Virginia Poultry Federation

EPA Response: The EPA disagrees with the commenter that the MCLs are not feasible and the characterization that they are "essentially zero." For the EPA's response to comments on the agency's feasibility determination, including analytical feasibility, please see section 5 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenter's conclusion that the rule "will subject rural municipalities and poultry companies to bear unnecessary financial burdens associated with engineering, purchasing and installing multiple additional treatment technologies." The EPA has determined that the benefits of the rule justify its costs; therefore, compliance with the final NPDWR is not an unnecessary financial burden. For more information, please see section 13.8 of the EPA response in this *Response to Comments* document. In response to the commenter's reference to AWWA's comment letter, the EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs as well as household level costs; for more information, please see section 13.3.3 of the EPA response in this *Response to Comments* document. The commenter's assertion that the agency fails to account for expenses associated with annual operation and maintenance is incorrect, as these costs are included in the EPA's cost analysis. The EPA notes that the agency does not consider costs when setting a maximum contaminant level goal (MCLG): the MCLG is the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, allowing an adequate margin of safety. See section 4 of the EPA response in this *Response to Comments* document for further discussion. MCLGs are non-enforceable public health goals and, as a result, do not impact regulatory certainty. The EPA further disagrees that the MCLs in the rule will subject the regulated community to uncertainty: the rule requirements are clear, feasible technologies are available to meet the MCLs and analytical methods are available to monitor for the regulated PFAS, among other things. Finally, the EPA disagrees that the treatment technologies available for PFAS removal are unique to wastewater treatment plants; all of the best available technologies (BATs) identified in the final rule have demonstrated use at full scale drinking water treatment plants. For more information see the *EPA's Best Available Technologies and Small Systems Compliance Technologies* support document (USEPA, 2024e).

3M Company (Doc. #1774, SBC-045692)

In the cost analysis EPA did conduct, documented in the Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation (USEPA 2023i), EPA uses opaque methodological approaches, fails to document the assumptions it applies, and fails to provide an adequate and transparent description of the analytical approaches, models, and tools that it uses to estimate costs. These omissions impose substantial uncertainty on many steps of this convoluted cost analysis. That uncertainty propagates and compounds throughout the analysis and imposes biases on various intermediate calculations. These biases subsequently yield potentially highly uncertain cost estimates of questionable accuracy.

EPA is missing critical data and is forced to use category-wide and/or nationwide estimates for baseline and compliance characteristics in the selection of treatment technology or non-treatment alternative. The absence of this data negates EPA's ability to present cost analysis results at the PWS-level. Instead, EPA collapses the more than 66,000 PWSs and summarizes nationwide cost and benefit estimates for 36 general PWS categories. [FN95: The Bayesian model EPA used to establish a national distribution of PFAS concentrations as part of the benefit-cost analysis did not include important covariates including distance from the PFAS source, topography, number of private drinking water wells in the area or state, climatology, distance to nearest large water and river systems, and other environmental factors. EPA's Bayesian model outputs are clearly not representative of the PFAS exposure distribution on a national level. Therefore, any benefit-cost conclusions drawn based on these data and model outputs do not represent the expected PWS concentrations across the US and cannot be used to support a MCLG. EPA does not provide details of the Bayesian model that are commonly included in the description by practicing statisticians. Therefore, evaluation of adequacy and believability of the model outputs cannot be understood, as required by EPA's QC practices] This generalization and reporting opacity prevent an evaluation of the potential distributional impacts of the proposed NPDWR.

EPA Response: The EPA disagrees with the comment that the cost analysis is not transparent. The EPA has documented its approach fully in Chapter 5 and the appendices of the EA. In addition, the EPA has made all of the input data and model source code available in the docket. Please see section 13.1 in this *Response to Comments* document for the EPA's response to comments on the EPA's SafeWater model, including comments related to the EPA's use of PWS strata to estimate national benefit and cost results.

In response to comments on the Bayesian occurrence model including its validity, national representativeness, and documentation, please see section 6.5 of the EPA response in this *Response to Comments* document. Further, the peer-reviewed paper, Cadwallader et al. (2022) includes documentation on logic behind the model development, and the supplemental information for that paper also includes model inputs, model code, and the seed (the starting point for random number generation). This information is sufficient to replicate the model run, and the EPA therefore disagrees with the commenter's assertions about lack of transparency.

The EPA disagrees with the commenter's assertion that the "benefit-cost conclusions drawn based on these data and model outputs" cannot be used to support an MCLG. The MCLG is a health-based value and does not account for limits of detection and treatment technology effectiveness. Further, the EPA disagrees with this statement to the extent it applies to the EPA's analysis ability to support an MCL. The EPA used the best available peer reviewed data, as required by SDWA, including a peer-reviewed nationally representative occurrence model, to inform the HRRCA for the rule. The occurrence model was created to estimate national occurrence. The data came from a census of large systems and a nationally representative subset of small systems. From these, it is appropriate to make nation-scale estimates. System to system variability is inherently captured in the fact that the EPA used a nationally representative set of systems to inform a distribution of system-level means.

Finally, for the EPA's response to comments on the Administrator's benefit cost determination, please see section 13.8 of the EPA response in this *Response to Comments* document.

California-Nevada Section American Water Works Association (CA-NV AWWA) (Doc. #1775, SBC-045275)

Economic feasibility of the regulations is not sufficiently considered and addressed.

6. EPA should reevaluate the high cost of the regulation with stakeholder input, and address affordability issues in a new economic feasibility assessment.

The EPA's environmental justice public meetings identified affordability of water requiring PFAS treatment as a prominent concern. [FN5: Environmental Justice Considerations for the Development of the Proposed PFAS Drinking Water Regulation, Public Meeting Summary – March 2, 2022. EPA Document EPA-HQ-OW-2022-0114-0009] A national cost estimate conducted for AWWA [FN6: Black & Veatch, WITAF 56 Technical Memorandum, PFAS National Cost Model Report (Mar. 7, 2023)] placed the cost of new MCLs for PFOA and PFOS set at 4 ppt to amount to over $3.8 billion annually for community water systems. Extrapolating to estimate annual household costs for removing PFAS from drinking water, the per-household cost ranged from $80 - $105 in the largest category of water systems, to more than $10,000 for water systems serving less than 100 consumers. Household costs even at the high end of population served will make rate increases due to the proposed regulation of PFOA and PFOS very difficult for low-income households to pay. The Hazard Index MCL for the group of four contaminants will presumably increase the number of water systems incurring costs for construction and operation of water treatment, exacerbating the very high cost and adding to an affordability crisis for drinking water.

CA-NV AWWA also comments that EPA has not met its obligation to fully evaluate the economic feasibility of this proposed regulation. First, the regulation lacks sufficient data on occurrence of PFAS in water sources of small systems for its economic analysis, relying instead on assumptions and statistics to cover acknowledged gaps. EPA further failed to conduct meaningful consultation with small business advocates. The U.S. Small Business Administration

Office of Advocacy pointed out in its letter on this docket (April 18, 2023) that "The rule is expected to impose a costly regulatory burden on small entities such as small public water systems."[FN7: Letter from U.S. Small Business Administration Office of Advocacy, accessed at https://www.regulations.gov/comment/EPA-HQ-OW-2022-0114-1505.] Moreover, the letter describes the inadequacy of EPA's consultation:

"In advance of the proposed rule, EPA convened a SBREFA panel to consult with small entity representatives (SERs). EPA presented to the small entities some PFAS background (with only PFOA and PFOS specifically identified) and potential monitoring and reporting rule compliance considerations and treatment and feasibility considerations. EPA, however, did not provide the SERs with the identity of the other four PFAS, any MCL values, any MCLG values and the technical details and analyses supporting these additional elements."[FN8: SBA Office of Advocacy, p. 3.]

EPA Response: Please see section 13.10 in this *Response to Comments* document for the EPA's response to comments on affordability and household level costs. In response to the commenters reference to AWWA's initial cost estimates from March 2023, the EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. For the EPA's response to comments on the costs of the Hazard Index, please see section 13.3.2 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenter's claim that the EPA failed to conduct consultation with small business entities. For more information, please see section XIII.C of the final rule preamble and section 14.3 of the EPA response in this *Response to Comments* document.

City of Tulsa Water and Sewer Department (CoT WSD) (Doc. #1785, SBC-043788)

EPA's annualized costs for monitoring and treatment are significantly less than water sector agencies' assessments. In an AWWA study [FN1:Black & Veatch, prepared for American Water Works Association. (2023). WITAF 56 Technical Memorandum, PFAS National Cost Model Report (B&V Project No. 409850). https://www.awwa.org/Portals/0/AWWA/Government/2023030756BVFinalTechnicalMemorandum.pdf?ver=202303-14-102450-257], the total National Cost Burden for systems of all sizes for regulatory limit of 4 ppt for PFOA and PFOS (the HI PFAS were not included) was $5.2 billion annually (pg. A-1, while EPA's expected value for the proposed option (4 ppt for PFOA & PFOS, 1.0 HI, 88 FR 18724) was $1.2 billion.

EPA Response: The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. Further, the EPA notes that AWWA has since lowered their cost estimates from the figure quoted in this comment ($5.2 billion annually); that figure appears in an earlier March 2023 version of the B&V report and represents AWWA's understanding of the "national burden" of removing PFOA and PFOS to

4ppt each, not just the NPDWR costs, which AWWA presents separately. Please see section 13.3 of the EPA response in this *Response to Comments* document for more information.

Vermont Rural Water Association (Doc. #1798, SBC-045333)

Pownal Fire District #2, serving 400 people, is a Vermont community water system impacted by PFAS. Treatment costs are still adding up, but so far, over $3 million has been spent on engineering, treatment, and remediation. Pownal has been lucky in that all of the costs have been covered by the industrial site that was responsible for contamination. That is not the case for most of the public water systems that have found PFAS levels exceeding the state's MCL. Site investigations have failed to determine an external potentially responsible party. The public water systems are being held responsible for the investigation and clean-up costs. That, in turn, leads to expensive and time-consuming battles with insurance companies.

Another Vermont community water system impacted by PFAS is Craftsbury Fire District #2, serving 420 people through 64 connections. Since being required to issue a "Do Not Drink" order in December 2021 due to an MCL exceedance, the system has spent over $250,000 on their search for a new water source, but have not located a well with a high enough yield. That cost is seven times their typical annual budget. In addition, Sterling College, a small university with a focus on the environment and sustainability, has experienced declining enrollments as a result of the "Do Not Drink" order impacting the school. Public trust has been lost which has negatively affected the economic health of this community.

The chemical manufacturers that created PFAS compounds should be responsible for their remediation in the environment, including our drinking water. Establishing MCLs places the burden on the public water systems. They are not the source of this contamination, but have been blamed for aquifers contaminated by firefighting training exercises and decades of build-up in septic tanks and leachfields from cleaning products.

For these reasons, on behalf of Vermont's small drinking water systems, we urge you again to carefully consider the economic and social impacts of the proposed federal PFAS regulation. Thank you for considering these comments. Please contact me if you have any questions or need clarification.

Thank you,

Liz Royer

Executive Director

EPA Response: The EPA acknowledges the information provided by the commenter on experiences of water systems in Vermont with PFAS contamination. Please see section 13.3.3 of the EPA response in this *Response to Comments* document for the EPA's response to comments on treatment costs associated with the rule. In response to the commenter's statements regarding the responsibility of chemical manufacturers for remediation costs, please see section 15 of the

EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1624, SBC-043467 in section 14.10 in this *Response to Comments* document.

West Virginia Municipal Water Quality Association (Doc. #1816, SBC-044665)

II. EPA's cost of compliance estimate significantly understates the cost of compliance and must be corrected and republished.

We believe that EPA's estimate of the cost of compliance with its proposed MCLs for PFAS is upwards of an order of magnitude too low. In fact, EPA's annualized cost figure is so far off the mark that republishing the proposed rule – after considering proposing higher MCLs based upon more accurate cost estimation – is warranted. We fail to understand why EPA did not solicit project cost information from its State partners for affected water utilities across the country. The Agency must consult with its WIFIA and Safe Drinking Water State Revolving Fund Program managers about their experience with PFAS barrier costs. EPA should identify with specificity the projects (including both capital and anticipated operation and maintenance) that (1) have been funded to date, (2) which have been approved for funding through ARPA, Bipartisan Infrastructure Funding, or the SRF Program, and (3) which have been proposed but not yet funded.

EPA must consult the State drinking water primacy agencies about their cost experience and cost projections for PFAS barrier technology installations. The state agencies are the best source for PFAS barrier technology cost information. We believe this essential outreach will cause EPA to significantly increase its cost estimate. EPA's failure to adequately consult its state water agency partners about the cost implications of the proposed MCLs is a fatal error that must be corrected.

EPA presents a total annualized cost estimate of $750M-$1B:

In Table 37, EPA summarizes the total annualized quantified cost of the proposed option at both a 3 percent and 7 percent discount rate expressed in millions of 2021 dollars. The first three rows show the annualized PWS sampling costs, the annualized PWS implementation and administrative costs, and the annualized PWS treatment costs. The fourth row shows the sum of the annualized PWS costs. At a 3 percent discount rate, the expected annualized PWS costs are $769 million. The uncertainty range for annualized PWS costs are $699 million to $862 million. Finally, annualized primacy agency implementation and administrative costs are added to the annualized PWS costs to calculate the total annualized cost of the proposed option. At a 3 percent discount rate, the expected total annualized cost of the proposed rule is $777 million. The uncertainty range for the total annualized costs of the proposed rule is $706 million to $872 million. At a 7 percent discount rate, the expected total annualized cost of the proposed option is $1.211 billion, while the uncertainty range for the total annualized costs of the proposed option is $1.103 billion to $1.353 billion.

88 Fed. Reg. at 18700 (emphasis added).

There are numerous instances of cost estimations by associations, states, consultants, and municipalities that demonstrate that the costs for PFAS barrier technologies far exceed EPA's estimate of $750M to $1B annually.

EPA Response: The commenter claims that the EPA may have underestimated costs by an order of magnitude (i.e., that the rule could cost more than 7.5-12 billion dollars per year to implement) but provides no supporting information or data as to why they think the rule would cost this much per year. Please see section 13.3 of the EPA response in this *Response to Comments* document for the EPA's discussion in response to the commenter's regarding the total national rule costs. In response to the commenter's statements that the EPA must consult and primacy agencies on costs, the EPA received public comment from a commenter representing primacy agencies, as well as numerous individual primacy agencies, and made adjustments to the cost analysis based on their input. The EPA used the most up to date publicly available cost information to support the national costs estimates for the proposed and final rulemakings. The EPA's cost estimates for the final rule have been updated based on public comments received on the proposed rule. These reflect the updates to the cost estimates recommended by many commenters; please see section 13.3.3 of the EPA response in this *Response to Comments* document for the EPA's response to comments on treatment costs and estimates provided in public comments from associations, states, consultants, and municipalities.

West Virginia Municipal Water Quality Association (Doc. #1816, SBC-044667)

In March of this year, Black & Veatch conducted a national cost assessment on behalf of the American Water Works Association (AWWA) that found that MCLs set at 4 ppt for PFOA and PFOS would trigger $5.2 billion in annualized national costs (capital, O&M, monitoring, etc.) for impacted facilities. [FN1: AWWA, WITAF 56 Technical Memorandum: PFAS National Cost Model Report A-1 (March 2023); Link: https://www.awwa.org/Portals/0/AWWA/Government/2023030756BVFinalTechnicalMemoradum.pdf?ver=2023-03-14-102450-257.] AWWA also found that just the costs to install PFAS barrier technology for PFOA/PFOS removal is above $3.8 billion annually.

The Commonwealth of Pennsylvania formally estimated earlier this year as part of its MCL development that it would cost affected water systems in Pennsylvania more than $121 million annually to comply with Pennsylvania's less stringent MCLs for PFOA (14 ppt) and PFOS (18 ppt). EPA's much lower proposed MCLs will likely result in doubling or tripling the Pennsylvania cost estimate. Extrapolating from Pennsylvania's estimate alone shows how wildly understated EPA's annual cost estimate is and highlights the need for EPA to perform a much more accurate and robust cost assessment.

EPA Response: Please see section 13.3 of the EPA response in this *Response to Comments* document. This commenter cites AWWA's cost estimates of $5.2 billion annually included in an older version of the B&V report from March 2023. The EPA notes that in their public comments on the proposed rule submitted in June 2023, AWWA submitted lower revised

estimates in that report, of $2.5 to $3.2 billion dollars annually at the 3 and 7 percent discount rates respectively. Furthermore, the EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. The EPA does not dispute the estimate of costs in Pennsylvania referenced by the commenter; however this figure may not be directly comparable to the EPA's national cost estimates due to difference in discount rates applied and period of analyses for each estimate. The commenter provides no supporting information that the "EPA's much lower proposed MCLs will likely result in doubling or tripling the Pennsylvania cost estimate." Further, PFAS occurrence varies across the country, and the commenter provides no data to support the assumption that costs in Pennsylvania are representative of costs nationally. Please see the EPA response to comment Doc. #1713, SBC-045902 in section 6.8 in this *Response to Comments* document for discussion about how extrapolating from only states with high PFAS occurrence can result in elevated national estimates.

West Virginia Municipal Water Quality Association (Doc. #1816, SBC-044672)

In light of the above data and information, we urge EPA to withdraw its cost estimate, give strong consideration to the AWWA report, and produce a corrected cost analysis for public comment. In so doing, EPA must obtain data from the state primacy agencies and review their experience in reviewing applications for funding under WIFIA, ARPA, Safe Drinking Water State Revolving Fund Program, and the Bilateral Infrastructure Legislation as to bid prices in general and PFAS barrier technology in particular.

EPA must reconsider its proposal and republish higher MCLs for PFOA and PFOS based upon the significantly – potentially an order of magnitude – higher costs than those identified in its proposed rule. EPA must also consider the complete impracticability of adding 3-6,000 PFAS barrier technology projects over the next 3-5 years on top of the historic number of water plant projects that are currently in process.

EPA Response: Please see section 13.3 of the EPA response in this *Response to Comments* document. The EPA has thoroughly considered all public comments submitted on the proposed PFAS rule, including comments submitted by AWWA. The EPA incorporated a number of recommendations from public commenters into the agency's cost models that are reflected in the cost analysis for the final rule. The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 in this *Response to Comments* document for the EPA's response to AWWA B&V report and a discussion of updates to the cost models. The EPA disagrees with the commenter's recommendation to promulgate less stringent MCLs based on their cost estimates; for more on the EPA's response to comments on the MCLs, please see section 5 of the EPA response in this *Response to Comments* document. For the EPA's response to comments on the compliance dates, please see section 12 of the EPA response in this *Response to Comments* document.

Association of Missouri Cleanwater Agencies (Doc. #1817, SBC-044643)

II. EPA's cost of compliance estimate significantly understates the cost of compliance and must be corrected and republished.

We believe that EPA's estimate of the cost of compliance with its proposed MCLs for PFAS is upwards of an order of magnitude too low. In fact, EPA's annualized cost figure is so far off the mark that republishing the proposed rule – after considering proposing higher MCLs based upon more accurate cost estimation – is warranted. We fail to understand why EPA did not solicit project cost information from its State partners for affected water utilities across the country. The Agency must consult with its WIFIA and Safe Drinking Water State Revolving Fund Program managers about their experience with PFAS barrier costs. EPA should identify with specificity the projects (including both capital and anticipated operation and maintenance) that (1) have been funded to date, (2) which have been approved for funding through ARPA, Bipartisan Infrastructure Funding, or the SRF Program, and (3) which have been proposed but not yet funded.

EPA must consult the State drinking water primacy agencies about their cost experience and cost projections for PFAS barrier technology installations. The state agencies are the best source for PFAS barrier technology cost information. We believe this essential outreach will cause EPA to significantly increase its cost estimate. EPA's failure to adequately consult its state water agency partners about the cost implications of the proposed MCLs is a fatal error that must be corrected.

EPA presents a total annualized cost estimate of $750M-$1B:

In Table 37, EPA summarizes the total annualized quantified cost of the proposed option at both a 3 percent and 7 percent discount rate expressed in millions of 2021 dollars. The first three rows show the annualized PWS sampling costs, the annualized PWS implementation and administrative costs, and the annualized PWS treatment costs. The fourth row shows the sum of the annualized PWS costs. At a 3 percent discount rate, the expected annualized PWS costs are $769 million. The uncertainty range for annualized PWS costs are $699 million to $862 million. Finally, annualized primacy agency implementation and administrative costs are added to the annualized PWS costs to calculate the total annualized cost of the proposed option. At a 3 percent discount rate, the expected total annualized cost of the proposed rule is $777 million. The uncertainty range for the total annualized costs of the proposed rule is $706 million to $872 million. At a 7 percent discount rate, the expected total annualized cost of the proposed option is $1.211 billion, while the uncertainty range for the total annualized costs of the proposed option is $1.103 billion to $1.353 billion.

88 Fed. Reg. at 18700 (emphasis added).

There are numerous instances of cost estimations by associations, states, consultants, and municipalities that demonstrate that the costs for PFAS barrier technologies far exceed EPA's estimate of $750M to $1B annually.

EPA Response: Please see the EPA response to comment Doc #1816, SBC- 044665 in section 13.3 in this *Response to Comments* document.

Association of Missouri Cleanwater Agencies (Doc. #1817, SBC-044645)

In March of this year, Black & Veatch conducted a national cost assessment on behalf of the American Water Works Association (AWWA) that found that MCLs set at 4 ppt for PFOA and PFOS would trigger $5.2 billion in annualized national costs (capital, O&M, monitoring, etc.) for impacted facilities [FN1: AWWA, WITAF 56 Technical Memorandum: PFAS National Cost Model Report A-1 (March 2023).]. AWWA also found that just the costs to install PFAS barrier technology for PFOA/PFOS removal is above $3.8 billion annually.

The Commonwealth of Pennsylvania formally estimated earlier this year as part of its MCL development that it would cost affected water systems in Pennsylvania more than $121 million annually to comply with Pennsylvania's less stringent MCLs for PFOA (14 ppt) and PFOS (18 ppt). EPA's much lower proposed MCLs will likely result in doubling or tripling the Pennsylvania cost estimate. Extrapolating from Pennsylvania's estimate alone shows how wildly understated EPA's annual cost estimate is and highlights the need for EPA to perform a much more accurate and robust cost assessment.

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044667 in section 13.3 in this *Response to Comments* document.

Association of Missouri Cleanwater Agencies (Doc. #1817, SBC-044650)

In light of the above data and information, we urge EPA to withdraw its cost estimate, give strong consideration to the AWWA report, and produce a corrected cost analysis for public comment. In so doing, EPA must obtain data from the state primacy agencies and review their experience in reviewing applications for funding under WIFIA, ARPA, Safe Drinking Water State Revolving Fund Program, and the Bilateral Infrastructure Legislation as to bid prices in general and PFAS barrier technology in particular.

EPA must reconsider its proposal and republish higher MCLs for PFOA and PFOS based upon the significantly – potentially an order of magnitude – higher costs than those identified in its proposed rule. EPA must also consider the complete impracticability of adding 3-6,000 PFAS barrier technology projects over the next 3-5 years on top of the historic number of water plant projects that are currently in process.

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044672 in section 13.3 in this *Response to Comments* document.

NORTH CAROLINA WATER QUALITY ASSOCIATION (Doc. #1818, SBC-044628)

In light of the above data and information, we urge EPA to withdraw its cost estimate, give strong consideration to the AWWA report, and produce a corrected cost analysis for public comment. In so doing, EPA must obtain data from the state primacy agencies and review their experience in reviewing applications for funding under WIFIA, ARPA, Safe Drinking Water State Revolving Fund Program, and the Bilateral Infrastructure Legislation as to bid prices in general and PFAS barrier technology in particular.

EPA must reconsider its proposal and republish higher MCLs for PFOA and PFOS based upon the significantly – potentially an order of magnitude – higher costs than those identified in its proposed rule. EPA must also consider the complete impracticability of adding 3-6,000 PFAS barrier technology projects over the next 3-5 years on top of the historic number of water plant projects that are currently in process.

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044672 in section 13.3 in this *Response to Comments* document.

NORTH CAROLINA WATER QUALITY ASSOCIATION (Doc. #1818, SBC-044621)

II. EPA's cost of compliance estimate significantly understates the cost of compliance and must be corrected and republished.

We believe that EPA's estimate of the cost of compliance with its proposed MCLs for PFAS is upwards of an order of magnitude too low. In fact, EPA's annualized cost figure is so far off the mark that republishing the proposed rule – after considering proposing higher MCLs based upon more accurate cost estimation – is warranted. We fail to understand why EPA did not solicit project cost information from its State partners for affected water utilities across the country. The Agency must consult with its WIFIA and Safe Drinking Water State Revolving Fund Program managers about their experience with PFAS barrier costs. EPA should identify with specificity the projects (including both capital and anticipated operation and maintenance) that (1) have been funded to date, (2) which have been approved for funding through ARPA, Bipartisan Infrastructure Funding, or the SRF Program, and (3) which have been proposed but not yet funded.

EPA must consult the State drinking water primacy agencies about their cost experience and cost projections for PFAS barrier technology installations. The state agencies are the best source for PFAS barrier technology cost information. We believe this essential outreach will cause EPA to significantly increase its cost estimate. EPA's failure to adequately consult its state water agency partners about the cost implications of the proposed MCLs is a fatal error that must be corrected.

EPA presents a total annualized cost estimate of $750M-$1B:

In Table 37, EPA summarizes the total annualized quantified cost of the proposed option at both a 3 percent and 7 percent discount rate expressed in millions of 2021 dollars. The first three rows

show the annualized PWS sampling costs, the annualized PWS implementation and administrative costs, and the annualized PWS treatment costs. The fourth row shows the sum of the annualized PWS costs. At a 3 percent discount rate, the expected annualized PWS costs are $769 million. The uncertainty range for annualized PWS costs are $699 million to $862 million. Finally, annualized primacy agency implementation and administrative costs are added to the annualized PWS costs to calculate the total annualized cost of the proposed option. At a 3 percent discount rate, the expected total annualized cost of the proposed rule is $777 million. The uncertainty range for the total annualized costs of the proposed rule is $706 million to $872 million. At a 7 percent discount rate, the expected total annualized cost of the proposed option is $1.211 billion, while the uncertainty range for the total annualized costs of the proposed option is $1.103 billion to $1.353 billion.

88 Fed. Reg. at 18700 (emphasis added).

There are numerous instances of cost estimations by associations, states, consultants, and municipalities that demonstrate that the costs for PFAS barrier technologies far exceed EPA's estimate of $750M to $1B annually.

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044665 in section 13.3 in this *Response to Comments* document.

NORTH CAROLINA WATER QUALITY ASSOCIATION (Doc. #1818, SBC-044623)

In March of this year, Black & Veatch conducted a national cost assessment on behalf of the American Water Works Association (AWWA) that found that MCLs set at 4 ppt for PFOA and PFOS would trigger $5.2 billion in annualized national costs (capital, O&M, monitoring, etc.) for impacted facilities [FN1: AWWA, WITAF 56 Technical Memorandum: PFAS National Cost Model Report A-1 (March 2023).]. AWWA also found that just the costs to install PFAS barrier technology for PFOA/PFOS removal is above $3.8 billion annually.

The Commonwealth of Pennsylvania formally estimated earlier this year as part of its MCL development that it would cost affected water systems in Pennsylvania more than $121 million annually to comply with Pennsylvania's less stringent MCLs for PFOA (14 ppt) and PFOS (18 ppt). EPA's much lower proposed MCLs will likely result in doubling or tripling the Pennsylvania cost estimate. Extrapolating from Pennsylvania's estimate alone shows how wildly understated EPA's annual cost estimate is and highlights the need for EPA to perform a much more accurate and robust cost assessment.

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044667 in section 13.3 in this *Response to Comments* document.

South Carolina Water Quality Association (Doc. #1819, SBC-044606)

In light of the above data and information, we urge EPA to withdraw its cost estimate, give strong consideration to the AWWA report, and produce a corrected cost analysis for public

comment. In so doing, EPA must obtain data from the state primacy agencies and review their experience in reviewing applications for funding under WIFIA, ARPA, Safe Drinking Water State Revolving Fund Program, and the Bilateral Infrastructure Legislation as to bid prices in general and PFAS barrier technology in particular.

EPA must reconsider its proposal and republish higher MCLs for PFOA and PFOS based upon the significantly – potentially an order of magnitude – higher costs than those identified in its proposed rule. EPA must also consider the complete impracticability of adding 3-6,000 PFAS barrier technology projects over the next 3-5 years on top of the historic number of water plant projects that are currently in process.

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044672 in section 13.3 in this *Response to Comments* document.

South Carolina Water Quality Association (Doc. #1819, SBC-044601)

In March of this year, Black & Veatch conducted a national cost assessment on behalf of the American Water Works Association (AWWA) that found that MCLs set at 4 ppt for PFOA and PFOS would trigger $5.2 billion in annualized national costs (capital, O&M, monitoring, etc.) for impacted facilities. [FN1: AWWA, WITAF 56 Technical Memorandum: PFAS National Cost Model Report A-1 (March 2023).] AWWA also found that just the costs to install PFAS barrier technology for PFOA/PFOS removal is above $3.8 billion annually.

The Commonwealth of Pennsylvania formally estimated earlier this year as part of its MCL development that it would cost affected water systems in Pennsylvania more than $121 million annually to comply with Pennsylvania's less stringent MCLs for PFOA (14 ppt) and PFOS (18 ppt). EPA's much lower proposed MCLs will likely result in doubling or tripling the Pennsylvania cost estimate. Extrapolating from Pennsylvania's estimate alone shows how wildly understated EPA's annual cost estimate is and highlights the need for EPA to perform a much more accurate and robust cost assessment.

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044667 in section 13.3 in this *Response to Comments* document.

South Carolina Water Quality Association (Doc. #1819, SBC-044599)

II. EPA's cost of compliance estimate significantly understates the cost of compliance and must be corrected and republished.

We believe that EPA's estimate of the cost of compliance with its proposed MCLs for PFAS is upwards of an order of magnitude too low. In fact, EPA's annualized cost figure is so far off the mark that republishing the proposed rule – after considering proposing higher MCLs based upon more accurate cost estimation – is warranted. We fail to understand why EPA did not solicit project cost information from its state partners for affected water utilities across the country. The Agency must consult with its WIFIA and Safe Drinking Water State Revolving Fund Program

managers about their experience with PFAS barrier costs. EPA should identify with specificity the projects (including both capital and anticipated operation and maintenance) that (1) have been funded to date, (2) which have been approved for funding through ARPA, Bipartisan Infrastructure Funding, or the SRF Program, and (3) which have been proposed but not yet funded.

EPA must consult the State drinking water primacy agencies about their cost experience and cost projections for PFAS barrier technology installations. The state agencies are the best source for PFAS barrier technology cost information. We believe this essential outreach will cause EPA to significantly increase its cost estimate. EPA's failure to adequately consult its state water agency partners about the cost implications of the proposed MCLs is a fatal error that must be corrected.

EPA presents a total annualized cost estimate of $750M-$1B:

In Table 37, EPA summarizes the total annualized quantified cost of the proposed option at both a 3 percent and 7 percent discount rate expressed in millions of 2021 dollars. The first three rows show the annualized PWS sampling costs, the annualized PWS implementation and administrative costs, and the annualized PWS treatment costs. The fourth row shows the sum of the annualized PWS costs. At a 3 percent discount rate, the expected annualized PWS costs are $769 million. The uncertainty range for annualized PWS costs are $699 million to $862 million. Finally, annualized primacy agency implementation and administrative costs are added to the annualized PWS costs to calculate the total annualized cost of the proposed option. At a 3 percent discount rate, the expected total annualized cost of the proposed rule is $777 million. The uncertainty range for the total annualized costs of the proposed rule is $706 million to $872 million. At a 7 percent discount rate, the expected total annualized cost of the proposed option is $1.211 billion, while the uncertainty range for the total annualized costs of the proposed option is $1.103 billion to $1.353 billion.

88 Fed. Reg. at 18700 (emphasis added).

There are numerous instances of cost estimations by associations, states, consultants, and municipalities that demonstrate that the costs for PFAS barrier technologies far exceed EPA's estimate of $750M to $1B annually.

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044665 in section 13.3 in this *Response to Comments* document.

Wet Weather Partnership (Doc. #1820, SBC-044584)

In light of the above data and information, we urge EPA to withdraw its cost estimate, give strong consideration to the AWWA report, and produce a corrected cost analysis for public comment. In so doing, EPA must obtain data from the state primacy agencies and review their experience in reviewing applications for funding under WIFIA, ARPA, Safe Drinking Water State Revolving Fund Program, and the Bilateral Infrastructure Legislation as to bid prices in general and PFAS barrier technology in particular.

EPA must reconsider its proposal and republish higher MCLs for PFOA and PFOS based upon the significantly – potentially an order of magnitude – higher costs than those identified in its proposed rule. EPA must also consider the complete impracticability of adding 3-6,000 PFAS barrier technology projects over the next 3-5 years on top of the historic number of water plant projects that are currently in process.

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044672 in this *Response to Comments* document.

Wet Weather Partnership (Doc. #1820, SBC-044579)

In March of this year, Black & Veatch conducted a national cost assessment on behalf of the American Water Works Association (AWWA) that found that MCLs set at 4 ppt for PFOA and PFOS would trigger $5.2 billion in annualized national costs (capital, O&M, monitoring, etc.) for impacted facilities. [FN1: AWWA, WITAF 56 Technical Memorandum: PFAS National Cost Model Report A-1 (March 2023).] AWWA also found that just the costs to install PFAS barrier technology for PFOA/PFOS removal is above $3.8 billion annually.

The Commonwealth of Pennsylvania formally estimated earlier this year as part of its MCL development that it would cost affected water systems in Pennsylvania more than $121 million annually to comply with Pennsylvania's less stringent MCLs for PFOA (14 ppt) and PFOS (18 ppt). EPA's much lower proposed MCLs will likely result in doubling or tripling the Pennsylvania cost estimate. Extrapolating from Pennsylvania's estimate alone shows how wildly understated EPA's annual cost estimate is and highlights the need for EPA to perform a much more accurate and robust cost assessment.

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044667 in section 13.3 in this *Response to Comments* document.

Wet Weather Partnership (Doc. #1820, SBC-044577)

II. EPA's cost of compliance estimate significantly understates the cost of compliance and must be corrected and republished.

We believe that EPA's estimate of the cost of compliance with its proposed MCLs for PFAS is upwards of an order of magnitude too low. In fact, EPA's annualized cost figure is so far off the mark that republishing the proposed rule – after considering proposing higher MCLs based upon more accurate cost estimation – is warranted. We fail to understand why EPA did not solicit project cost information from its State partners for affected water utilities across the country. The Agency must consult with its WIFIA and Safe Drinking Water State Revolving Fund Program managers about their experience with PFAS barrier costs. EPA should identify with specificity the projects (including both capital and anticipated operation and maintenance) that (1) have been funded to date, (2) which have been approved for funding through ARPA, Bipartisan

Infrastructure Funding, or the SRF Program, and (3) which have been proposed but not yet funded.

EPA must consult the State drinking water primacy agencies about their cost experience and cost projections for PFAS barrier technology installations. The state agencies are the best source for PFAS barrier technology cost information. We believe this essential outreach will cause EPA to significantly increase its cost estimate. EPA's failure to adequately consult its state water agency partners about the cost implications of the proposed MCLs is a fatal error that must be corrected.

EPA presents a total annualized cost estimate of $750M-$1B:

In Table 37, EPA summarizes the total annualized quantified cost of the proposed option at both a 3 percent and 7 percent discount rate expressed in millions of 2021 dollars. The first three rows show the annualized PWS sampling costs, the annualized PWS implementation and administrative costs, and the annualized PWS treatment costs. The fourth row shows the sum of the annualized PWS costs. At a 3 percent discount rate, the expected annualized PWS costs are $769 million. The uncertainty range for annualized PWS costs are $699 million to $862 million. Finally, annualized primacy agency implementation and administrative costs are added to the annualized PWS costs to calculate the total annualized cost of the proposed option. At a 3 percent discount rate, the expected total annualized cost of the proposed rule is $777 million. The uncertainty range for the total annualized costs of the proposed rule is $706 million to $872 million. At a 7 percent discount rate, the expected total annualized cost of the proposed option is $1.211 billion, while the uncertainty range for the total annualized costs of the proposed option is $1.103 billion to $1.353 billion.

88 Fed. Reg. at 18700 (emphasis added).

There are numerous instances of cost estimations by associations, states, consultants, and municipalities that demonstrate that the costs for PFAS barrier technologies far exceed EPA's estimate of $750M to $1B annually.

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044665 in section 13.3 in this *Response to Comments* document.

Plymouth Village Water & Sewer District (Doc. #1827, SBC-044560)

[Please carefully consider the following points to help inform the pending rulemaking on this class of pervasive and persistent PFAS chemicals:]

• EPA has not accurately estimated costs associated with treating PFAS to the proposed MCL. EPA's annualized costs for treatment are $772 million per year, which contrasts with an AWWA estimate of $3.8 billion per year. A growing body of actual cost data indicates EPA's O&M estimates may be even further off, by up to an order of magnitude. It is important that projected and actual costs be accurate to develop an MCL that balances health risk reduction, technical

feasibility, and cost. Reasonable, defensible, and cost-effective MCLs are also required to maintain public trust in both EPA and public water providers.

EPA Response: The commenter claims that the EPA may have underestimated costs by an order of magnitude (i.e., that the rule could cost more than 7.5-12 billion dollars per year to implement) but provides no supporting information or data as to why they think the rule would cost this much per year. Please see section 13.3 of the EPA response in this *Response to Comments* document for the EPA's discussion about response to comments about the costs of the rule. The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. For the EPA's response to comments on the MCLs, and consideration of benefits and costs in developing the MCLs, please see section 5.1.3 of the EPA response in this *Response to Comments* document.

Plymouth Village Water & Sewer District (Doc. #1827, SBC-044555)

The EPA has also pointed out that quantifying the potential benefits is challenging, currently estimated at $908 million to $1.2 billion annually. A study released by the American Water Works Association (AWWA) on March 7, 2023 found that the estimated national cost for water systems to install treatment systems to remove PFOA and PFOS at EPA required levels would exceed $3.8 billion annually. (AWWA PFAS National Cost Model Report)

EPA Response: The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. For the EPA's response to comments on the benefits of the rule, please see section 13.4 of the EPA response in this *Response to Comments* document.

Corix Infrastructure Inc. (Doc. #1834, SBC-045362)

Comments

1. The proposal's economic analysis does not seem to adequately recognize or address the costs that the rule will impose on water systems, particularly in light of impending and required capital and regulatory projects, for example, the revised Lead and Copper Revisions and lead service line replacements.

A recent study by Black & Veatch on behalf of the American Water Works Association concluded that the projected costs associated with PFAS treatment at the proposed limits would exceed $47 billion dollars, which is orders of magnitude more than EPA's estimate.

The cost of the technologies to remove PFAS contaminates from drinking water supplies is substantial and far exceeds all the estimates EPA makes in the proposed rule. We recommend and request that EPA consider and rely on the reports prepared by water industry experts that are based on case studies and then re-evaluate how it balances the levels of reductions set with the

cost to achieve those levels. As discussed below, how the technological changes necessary to achieve the levels set by EPA will be financed is a key component of this rulemaking.

EPA should explain its approach to affordability to ensure that funding will be available to achieve the aims of the regulation. Corix urges EPA to recognize with respect to affordability issues and funding that is provided, it is important that these rules and policies apply equally to all community water systems and wastewater treatment systems regardless of whether the systems are publicly or privately owned or operated.

Access to safe, clean drinking water is a necessity and this action by EPA must ensure that this access is affordable and equitable.

EPA Response: Please see section 13.3 of the EPA response in this *Response to Comments* document for discussion about the overall costs of the rule and response to comments on the potential impacts of the Lead and Copper Revisions (LCR). The EPA notes that the commenter incorrectly compares AWWA's one-time estimate of costs to the EPA's annualized values, please see section 13.3 of the EPA response in this *Response to Comments* document for more information. Further, the EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. For the EPA's response to comments about federal funding and how it is distributed, please see section 2.4 of the EPA response in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-044838)

EPA Has Significantly Underestimated the Costs of Complying with the Proposed Standards

EPA estimates that the annual cost to public water systems (PWS) of complying with the proposed MCLs would total $764 million to $1.2 billion over 20 years. Although a significant number, comparable to the estimated benefits of the rule, EPA's estimate is well below those developed by the American Water Works Association (AWWA) which totals $5.2 billion annually for just the PFOA and PFOS standards. [FN159: AWWA. WITAF 56 Technical Memorandum: PFAS National Cost Model Report. Black & Veitch (2023). https://www.awwa.org/Portals/0/WITAF56FinalTechnicalMemorandum31423.pdf?ver=2023-03-14-104547- 133 (AWWA WITAF 56)] The disparity is based on EPA's assumptions regarding the number of systems impacted and the costs for those systems to comply.

Regarding the number of systems impacted, EPA estimates that 6.5 percent (4,300) of the nearly 66,000 community water systems (CWSs) and non-transient non-community water systems (NTNCWSs) in the country [FN160: According to EPA's Safe Drinking Water Information System there are just over 49,000 community water systems and about 17,000 non-transient non community water systems active in the US.] will exceed the proposed MCL for PFOA or PFOA, based on a Bayesian hierarchical model using the results of EPA's third Unregulated Contaminant Monitoring Rule (UCMR 3) as the primary data set supplemented with more recent

state data. [FN161: EPA estimates that an additional 10 systems would be impacted by the proposed Hazard Index of 1.0 (USEPA Economic Analysis, at 4-25 Tables 4-18 and 4-19).] Extrapolating from data collected from UCMR 3 and state surveys, on the other hand, AWWA estimates that 12 percent of community water systems (CWS) will be impacted by the proposed MCL for PFOA and PFOS. [FN162: The report notes that the analysis likely underestimates the number of systems impacted since the detection limits for UCMR 3 were above the proposed MCLs. The AWWA analysis does not include NTNCWSs; as a result, comparisons to the EPA analysis are limited to CWSs.]

There also is a significant disparity between the EPA and AWWA estimates of the compliance costs per CWS. EPA's estimate for the annualized per CWS costs are generally an order of magnitude lower than those developed by AWWA. While some of the difference likely results from the assumptions made by the two organizations, the disparity in the estimates, particularly for the smaller systems, raises significant concerns about accuracy of EPA's cost analysis. [FN163: It was not clear whether EPA's economic analysis includes the engineering costs for treatment systems. These costs can be significant for larger systems.]

EPA Response: Please see section 13.3 of the EPA response in this *Response to Comments* document. This commenter cites AWWA's cost estimates of $5.2 billion annually included in an older version of the B&V report from March 2023. According to the March 2023 version of the report, that figure represents AWWA's understanding of the "national burden" of removing PFOA and PFOS to 4ppt each, not just the costs associated with compliance with the NPDWR, which AWWA presents separately. The EPA notes that in their public comments on the proposed rule submitted in June 2023, AWWA submitted lower revised estimates in that report, of $2.5 to $3.2 billion dollars annually at the 3 and 7 percent discount rates respectively. Furthermore, the EPA disagrees with many of the assumptions in AWWA's B&V report, including the representation of occurrence and capital costs, as well as the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. For the EPA's response to comments on the national occurrence model, please see section 6.5 of the EPA response in this *Response to Comments* document.

Paul Eldredge (Doc. #2770, SBC-047457)

A Government Accountability Office (GAO) study of drinking water data collected from six states showed at least 18% of 5,300 water systems studied had PFOA and/or PFOS exceeding the proposed MCLs of 4 ppt alone. Levels of initial noncompliance may be even higher than anticipated due to sampling bias since the proposed limits are the lowest level many laboratories can reliably detect, and some systems have not already pursued such sensitive testing for all six chemicals listed.

USD urges EPA to conduct a fuller analysis that more accurately captures the costs of compliance and if necessary, collect more data to inform and address the gaps that currently

exist. This should be a reasonable request given that the agency caveated its own work in the posting by listing a host of data limitations and uncertainties from a lack of modeling national costs for treatment associated with potential Hazard Index exceedances.

These levels are significantly lower than any state has proposed for PFAS chemicals, which would seem to indicate that even states highly concerned with PFAS contamination have arrived at different conclusions than EPA with regard to the cost and benefit analysis. Analysis fundamental to the 1996 amendments to the SDWA, require a detailed risk and cost assessment, and best available peer-reviewed science, when developing standards. These requirements may imperil the financial sustainability and affordability of some water systems, which will warrant greater assistance in terms of funding. To not clarify the extent of these costs now would be a grievous mistake as water systems and governments across all levels budget for the future and may be forced into competing for limited federal dollars.

EPA Response: Please see section 13.3 in this *Response to Comments* document for the EPA's response to comments on the total national costs of the rule and section 13.3.3 in this *Response to Comments* document for the EPA's response to comments on the treatment costs associated with the rule. For the EPA's response to comments citing the Government Accountability Office (GAO) report mentioned by the commenter, please see the EPA response to comment Doc. #1729, SBC-043576 in section 6.5 in this *Response to Comments* document. In response to the comment regarding the proposed and final MCLs, please see section 5 of the EPA response in this *Response to Comments* document. In response to the commenter's mention of the EPA's data limitation documentation in the EA, in the interest of transparency, it is best practice to identify known data limitations and uncertainties in the analyses. Identification of uncertainties is also required by SDWA Section 1412(b)(3)(C)(i)(VII). For the EPA's response to comments on the costs associated with the Hazard Index specifically, please see section 13.3.2 of the EPA response in this *Response to Comments* document. In regard to the commenter's assertion that "…even states highly concerned with PFAS contamination have arrived at different conclusions than EPA with regard to the benefit/cost analysis," the commenter provides no detail or references to support this statement. While no specific references were given, potential differences in conclusions could arise from differences in number entities included in the analysis, baseline levels of PFAS contamination, estimation of health risk reduction benefits, and the estimation of costs.

<u>The ELAM Group (Doc. #3072-61, SBC-046377)</u>

Thank you, Rob. My name is James Hogan. I'm the president and CEO of the Environmental Liability and Asset Management Group. Our environmental consulting firm specializes in provisioning environmental liability. We participate in the ASTM standards for developing lifecycle costs associated with environmental liability. We find critical elements of any lifecycle includes asset, retirement obligations, site characterization, treatment remediation, waste disposal, and closure. We understand this is a very important juncture given that MCLs are enforceable and represent the highest level of a contaminant that is allowed in drinking water

based on a cost-benefit analysis. I urge the U.S. EPA to critically evaluate its own cost-benefit analysis with a particular focus on its variables that are most sensitive to significant cost variation. These variables must be singled out and thoroughly vetted prior to finalization of this rule or the U.S. EPA will have failed the public in upholding the very definition of an MCL. Thank you.

EPA Response: This comment lacks sufficient detail to incorporate this suggestion into the analysis. The EPA has considered the quantifiable and non-quantifiable uncertainties in the cost analysis, for more information see Chapter 5 of the EA. See also section 13.3.3 of the EPA response in this *Response to Comments* document.

American Farm Bureau Federation et al. (Doc. #1642, SBC-043481)

EPA Has Underestimated the Challenges in Reaching These Levels

Farmers, ranchers and other agricultural producers support a national drinking water standard for PFOA and PFOS and other PFAS chemicals based on science and an evaluation of risk— to replace the current patchwork of state requirements. However, it is critical that EPA gets this right. The costs that the proposed rule will impose are significant, and likely underestimated. The proposed MCLs must be changed to ensure firm scientific backing and consideration of the potentially enormous financial burdens imposed, as the statute requires.

The U.S. Chamber of Commerce has done an extensive review of the proposed cost-benefit analysis that highlights many of our shared concerns. The costs associated with this rule have not been accurately calculated for a variety of reasons, which the U.S. Chamber of Commerce has expounded upon in more detail in their comments.

EPA Response: The EPA disagrees with the U.S Chamber of Commerce's estimate of costs, please see the EPA response to comment Doc. #1537, SBC-042649 in section 13.3.3 in this *Response to Comments* document. Further, the comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. See also section 13.3.3 of the EPA response in this *Response to Comments* document.

Wyoming Department of Environmental Quality (WDEQ) (Doc. #1716, SBC-044769)

Separately, WDEQ is concerned with EPA's use of the relatively limited UCMR 3 data and limited state-provided data to estimate PFAS occurrence and concentrations within PWSs and apply those estimates to the cost-benefit modeling and timeframes anticipated for PWSs to reach compliance under the proposed PFAS NPDW rule. The proposed rule provides some exemptions for PWSs serving a population under 3,300 and for PWSs that need financial assistance for necessary improvements. However, WDEQ is concerned that even with these exemptions, it is not financially feasible for the 379 PWSs in Wyoming that serve a population under 3,300 people to implement any necessary modifications to their infrastructure. Due to the ubiquitous nature of PFAS in the environment, the necessary supplementation of source water from lakes, reservoirs,

rivers, and groundwater, and the proposed MCL concentrations, Wyoming is concerned that a majority of PWSs in Wyoming may need to make costly updates to their infrastructure to maintain compliance under the SDWA.

EPA Response: For the EPA's response to comments on the use of UCMR 3 data, state data, and the national occurrence model, please see sections 6.1, 6.2, and 6.5, respectively, of the EPA response in this *Response to Comments* document. For the EPA's response to comments on the feasibility determination for the final rule, please see section 5 of the EPA response in this *Response to Comments* document. With respect to timeframes provided for compliance, please see section 12 of the EPA response in this *Response to Comments* document.

Virginia Municipal Drinking Water Association (VMDWA) (Doc. #1657, SBC-052833)

Another concerning reference comes from estimates made by the Commonwealth of Pennsylvania, which estimated it would cost affected water systems in Pennsylvania over $121 million annually to comply with significantly higher MCLs for PFOA (14 ppt) and PFOS (18 ppt) under that state's requirements. The fact that this one state accounts for 10 percent of EPA's estimated total annual cost to the Nation, and that this one state prepared its estimate using significantly less stringent MCL values (high concentrations), tends to confirm the AWWA estimate and cast significant additional doubt on the accuracy of the EPA's earlier estimate.

EPA Response: The estimated costs from the Commonwealth of Pennsylvania may not be directly comparable to the EPA's national cost estimates due to difference in discount rates applied and period of analyses for each estimate. Further, PFAS occurrence varies across the country, and the commenter provides no data to support the assumption that costs in Pennsylvania are representative of costs nationally. Please see sections 13.3.3 and 13.3 of the EPA response in this *Response to Comments* document.

Maryland Association of Municipal Wastewater Agencies (MAMWA) (Doc. #1658, SBC-052843)

Another concerning reference comes from estimates made by the Commonwealth of Pennsylvania, which estimated it would cost affected water systems in Pennsylvania over $121 million annually to comply with significantly higher MCLs for PFOA (14 ppt) and PFOS (18 ppt) under that state's requirements. The fact that this one state accounts for 10 percent of EPA's estimated total annual cost to the Nation, and that this one state prepared its estimate using significantly less stringent MCL values (high concentrations), tends to confirm the AWWA estimate and cast significant additional doubt on the accuracy of the EPA's earlier estimate.

EPA Response: Please see the EPA response to comment Doc. #1657, SBC-052833 in section 13.3 in this *Response to Comments* document.

13.3.1 Primacy Agency costs

Summary of Major Public Comments and EPA Responses

Many commenters state that the EPA has underestimated the costs to primacy agencies required to comply with the rule. One commenter stated, "EPA's analysis of primacy agency costs does not accurately capture all the activities that primacy agencies will undergo for PFAS implementation and underestimates the number of hours for the primacy tasks." Commenters recommend that the EPA use findings from the Association of State Drinking Water Administrators (ASDWA)'s PFAS Cost of State Transactions Study (PCoSTS) to reevaluate the primacy agency costs estimated in the EA (ASDWA, 2023). The EPA's response to specific recommendations is discussed below.

The EPA agrees with commenters on the burdens associated with regulatory start up; primacy package adoption; technical, managerial and financial (TMF) assistance to water systems; and reviewing and approving treatment. Commenters pointed out activities not explicitly accounted for in the regulatory start up estimate in the EA for proposal including accreditation of laboratories for PFAS testing; SDWIS updates; monitoring schedule updates; time spent responding to questions from members of the public; inquiries from public officials; and media requests immediately following the final publication of the NPDWR. Commenters also pointed out that adopting primacy packages is a significant undertaking with "specific and very detailed administrative procedures that must be adhered to in order to adopt water quality regulations" and that "some primacy agencies have requirements for robust public comment periods as a component of new rule adoption." As recommended by commenters, the EPA created a new cost item for primacy package adoption. Commenters stated the EPA's assumption in the proposal that the amount of time a primacy agency will need to review treatment plans directly correlates with the size of the water system was inaccurate. Commenters noted that "…small systems often take the most time as they need significant assistance to navigate the process for the design and construction of new treatment and get into compliance." After considering these comments, the EPA agrees that reviewing and approving treatment for small systems is likely to take more time given the assistance needed for these systems. Because small systems often lack the technical, managerial, and financial capacity, it is likely that primacy agencies will spend more time assisting these systems in navigating compliance with the PFAS NPDWR. As such, the EPA adjusted burden estimates in the final rule to reflect the largest primacy agency burden per EPTDS at the smallest systems and decreased burden hours with increasing system size, as commenters suggested.

Several commenters disagreed with the EPA's exclusion of additional costs to primacy agencies associated with reporting regarding violations, variances and exemptions, enforcement actions, and other compliance related primacy agency activities in the national cost analysis. One commenter estimated the PFAS NPDWR will likely result in hundreds of violations once in effect. The EPA recognizes that these activities do have an associated burden for primacy agencies but disagrees that these costs should be included in the EA. The EPA assumed 100 percent compliance for its national level analysis in the EA for the final rulemaking because the

EPA has determined that the final rule is feasible given known occurrence concentrations and efficacy of the technologies available. Further, this is consistent with the approach taken in EAs for other NPDWRs (USEPA, 2005a; USEPA, 2019; USEPA, 2020a). Commenters recommended that the EPA include hours for additional annual reporting. The EPA disagrees and expects that adding PFAS results to already-required reports will have no discernable incremental burden for quarterly or annual reports to SDWIS Fed.

Commenters recommended that the EPA include the costs associated with various compliance activities. Given the EPA's assumption discussed above, the EPA disagrees and did not take commenters' recommendations to include the costs associated with assisting out of compliance systems and assisting systems to remain in compliance, pursuing enforcement actions, staff time checking in with system violations and reviewing system variances and exemptions. The EPA did include the costs associated with compliance activities for systems in compliance, including updating inspection standard operating procedures (SOPs) and additional sanitary survey burden at water systems that have installed treatment to comply with the PFAS NPDWR.

Several commenters suggested that the EPA underestimated the level-of effort for primacy agencies to provide training to PWSs. They pointed out that one full-time staff could not provide in-person training at each PWS. The EPA disagrees with this as training does not need to be provided in person at each PWS. Virtual sessions, or regional training sessions, where training is provided to many PWS at once, are feasible. After considering all public comments, the EPA used the estimate in the PCoSTs model related to average hours per primacy agency to provide initial training and technical assistance to systems.

Some commenters stated that the EPA's estimate of 4 hours for a primacy agency to review and consult with systems on the installation of treatment technology or alternative methods, including source water change was too low. Most of these commenters did not provide a recommended number of hours for the EPA to consider instead. One commenter provided an estimated range from 8 to 40 hours, depending on source water type. Another recommended the EPA increase the estimate to 8 hours per water system. The EPA appreciates the estimates provided by these commenters; however, the EPA decided to retain the estimates used in the proposal, consistent with the estimate included in the EPA's EA for LCRR. The EPA retained the original estimate because the EPA determined that the four hours represents a reasonable estimate of the national average. The EPA recognizes that some states may take longer, and others may take less than 4 hours on average. The EPA does not have enough data submitted by commenters or otherwise available to update the national average estimate.

After considering public comment, the EPA's estimated burden hours for many primacy agency activities increased significantly and had an upward effect on the cost estimates. However, after considering public comment, the EPA also made changes to the monitoring requirements and introduction of annual monitoring, (please see section VIII of the preamble for this rulemaking and section 8 of the EPA response in this *Response to Comments* document for more information). These changes, which will reduce monitoring burden overall, also had a downward effect on estimated amount of time primacy agencies would spend reviewing monitoring results.

The introduction of annual monitoring significantly reduced the amount of water systems estimated to taking quarterly samples continuously, and therefore reduced the amount of time primacy agencies would spend reviewing sample results. The net effect is that the agency's estimates of the final rule annualized primacy agency costs decreased compared to the proposed rule estimates.

Individual Public Comments

New York State Department of Health (NYS DOH) (Doc. #1677, SBC-044953)

15. Although private wells are excluded from SDWA, they still present challenges for primacy agencies. Private well owners will place an increased demand for analytical services that will further strain analytical capacity. In addition, private well owners will also place demand for carbon media, resins and membranes. To meet the public health concerns raised by PFAS in community groundwater coming from waste sites, landfills, industries and various sources (including septic systems), NYS has already expended more than $30 million on assistance to private well owners for testing and mitigation of PFOA and/or PFOS based upon mitigation when private wells in an investigation area have results above the NYS MCL of 10 ppt separately for each. This number does not include $80M+ that NYS has spent to address both private and public water supplies in the City of Newburgh and Town of New Windsor. Should this public health protective target be reduced further there will be a substantial increase in costs to mitigate the widespread occurrence of PFOA/PFOS below 10 ppt in community groundwater. While EPA may have infrastructure funding targeted for this need, it is not clear that the Agency is aware of the magnitude of the anticipated need in this area.

While many homes with private well contamination may be able to connect to a public water supply, many homes will not, and will instead seek mitigation of their private water supplies. DEC has been providing Point of Entry Treatment (POET) in many areas of the State affected by PFAS contamination. Installation of each POET is approximately $4,000 inclusive of design services and labor and an operation and maintenance cost of $1 ,500 per POET annually. These costs are reflective of bulk purchase and installation scenarios,

EPA Response: As the commenter correctly notes, the EPA does not regulate drinking water wells that serve fewer than 25 persons, often referred to as "private wells;" nor does it provide recommended criteria or standards for such wells. The EPA offers information regarding the importance of testing these wells and guidance on technologies that may be used to treat or remove any contaminants. While the EPA does not dispute that primacy agencies may incur costs associated with PFAS in unregulated drinking water wells, those costs should not be included in the EA as they are not a direct result of this regulation, but rather, an activity undertaken by primacy agencies at their discretion or to meet their individual state requirements. The EPA notes that SDWA Section 1412(b)(3)(C)(i)(III) requires that the EPA include quantifiable and non-quantifiable costs that are likely to occur s*olely as a result of compliance with the rule* including monitoring, treatment and other costs and excluding costs resulting from compliance with other proposed or promulgated regulations (emphasis added). Therefore, it would be inappropriate for

the EPA to estimate costs for activities that are not directly mandated by the PFAS NPDWR itself. For the EPA's response to comments on laboratory and treatment technology demand and capacity, please see sections 8.7.2 and 10.6, respectively, of the EPA response in this *Response to Comments* document.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044434)

EPA requests comment on whether factors such as anticipated Federal funding, the structure of PWSs relative to private enterprises, or the nature of the public health benefits should be further explored in the final rule analysis, including as it relates to the estimated range of impacts under the applied discount rates.

• Increased tracking for HI MCL calculations, increased compliance, and increased planning and project reviews for potentially 20% of PWSs will require significant resources to successfully implement. It is unclear if these costs were considered in the cost estimates of the PFAS rule.

EPA Response: Please see section 13.3.1 of the EPA response in this *Response to Comments* document and Chapter 5 of the EA for discussion about costs anticipated to be incurred by primacy agencies.

Missouri Department of Natural Resources (Doc. #1563, SBC-042524)

EPA seeks comment on its PFOA and PFOS evaluation of feasibility for the proposal, including analytical measurement and treatment capability, as well as reasonable costs, as defined by SDWA.

The Department agrees with comments from the Association of State Drinking Water Administrators (ASDWA) that EPA has grossly underestimated the costs for the proposed PFAS Rule. The Department recommends EPA re-evaluate the cost estimates borne by state agencies using ASDWA's PFAS Cost of State Transactions Study (PCoSTS) Model.

EPA Response: Please see section 13.3.1 of the EPA response in this *Response to Comments* document for discussion about costs to primacy agencies. Based on public comments, including the information provided in the PCoSTS model, the EPA has increased estimated burden hours for many primacy agency activities significantly which had an upward effect on the cost estimates.

Lakewood Water District (LWD) (Doc. #1574, SBC-042751)

Implementation Costs

We were struck by the dramatic underestimation of the level of effort needed to stand up the systems and organizations needed to implement these proposed PFAS regulations. Table 36 is a standout example of this underestimation.

Table 36 suggests that a Primacy Agency (such as we have here in Washington State) could "…read and understand the rule, as well as adopt regulatory requirements" (emphasis added) with 416 hours of staff time. This estimate is so low that it must be a clerical error.

In order to adopt regulatory requirements, most states (like Washington state) have specific and very detailed administrative procedures that must be adhered to in order to adopt water quality regulations. The required administrative procedures at the state level are not unlike the procedures that the EPA is following for the development of its PFAS rules. Rulemaking at the state level takes months and requires massive amounts of specialized staff time, many times the 416 hours shown in Table 36.

Table 36 also suggests that a Primary Agency could "…provide initial training and technical assistance to systems" with 2080 hours of staff time. 2080 hours is one Full Time Equivalent employee. Washington State (which is not unique in this regard) has over 2,400 water systems that will be covered by this proposed rule. 2080 hours means less than 1 hour of "training and technical assistance" would be provided per system. This is totally unrealistic.

These are but two examples of gross underestimation of implementation costs. EPA must revisit these cost estimates to update them to more realistic numbers.

EPA Response: Please see section 13.3.1 of the EPA response in this *Response to Comments* document about costs to primacy agencies and the EPA's revisions to the cost analysis for the final rule. Based on public comments, the EPA has increased estimated burden hours for many primacy agency activities increased significantly and had an upward effect on the cost estimates. The resulting cost estimates for primacy agencies reflect the best available information.

Oklahoma Department of Environmental Quality (DEQ) (Doc. #1616, SBC-043047)

EPA Analysis of Primacy Agency Costs

DEQ recommends that EPA reevaluate the primacy agency costs portion of the preamble.

EPA's analysis of primacy agency costs does not accurately capture all the activities that primacy agencies will undergo for PFAS implementation and underestimates the number of hours for the primacy tasks.

Timelines for reviewing and approving treatment technologies have been underestimated in the proposal. In addition to reviewing and approving engineering reports and construction design plans for treatment, states will also need to review and approve pilot tests needed to ensure treatment efficacy of the selected treatment technology.

Mandatory reporting, enforcement actions, and general operations of State PWS programs will incur additional state staff time.

DEQ recommends EPA consider technical assistance in its multiple components.

EPA's estimates and assumptions regarding the amount of technical assistance that will be needed for systems to come into compliance is underestimated. Multiple components of technical assistance include those listed below.

• In-person training that will involve time to develop workshop materials, as well as significant travel time depending on the location of the systems.

• Extensive outreach activities related to achieving compliance by small and disadvantaged communities

EPA Response: Please see section 13.3.1 of the EPA response in this *Response to Comments* document about costs to primacy agencies. Based on this and other public comments, the EPA has increased estimated burden hours for many primacy agency activities, including reviewing and approving treatment plans including pilot study results, which has had an upward effect on the cost estimates. Regarding initial training and technical assistance, for the cost analysis for the final rule, the EPA used an estimate 1,500 hours per primacy agency, as recommended by another commenter and included in the PCoSTS model. In response to the commenter's reference to outreach activities specifically for small and disadvantaged communities, the EPA notes that while this is encouraged, it is not required by the rule. The EPA also notes that the EPA's free Water Technical Assistance (WaterTA) services support communities to identify water challenges, develop plans, build capacity, and develop application materials to access water infrastructure funding. The EPA collaborates with states, Tribes, territories, community partners, and other key stakeholders to implement WaterTA efforts, for more information see https://www.epa.gov/water-infrastructure/water-technical-assistance-waterta#:~:text=What%20is%20WaterTA%3F,to%20access%20water%20infrastructure%20funding. For more information regarding this program and other available funding, particularly for small and disadvantaged communities, please see section 2.4 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044069)

Implementing this rule will require considerable staff resources from primacy agencies already burdened by new priorities in addition to the typical Safe Drinking Water Act (SDWA) implementation programs. ASDWA's PCoSTS estimates that the primacy agency staff time required for the first year of rule implementation, which includes one-time activities such as regulatory start-up and review and approval of water system treatment plans, will be 1,039,750 hours. At the state and local hourly government employee rate of $57.60 based on the U.S. Bureau of Labor Statistics, the first year of implementation will cost primacy agencies $59,889,624.

ASDWA's model also estimates the primacy agency staff time in subsequent years for annual implementation activities, such as reporting, compliance, and technical assistance. Following the first year of implementation, ASDWA estimates the proposed rule will require 325,850 hours of staff time at a cost of $18,768,960 annually. Combining the cost of the first year of

implementation with four subsequent years of annual rule requirements (for a total of 2,343,150 staff hours), ASDWA's model estimates that the proposed NPDWR will increase primacy agency staff hours by roughly 469,000 hours annually in its first five years of implementation, translating to an annual cost of approximately $27 million.

EPA Response: Please see section 13.3.1 of the EPA response in this *Response to Comments* document. For the EPA's revised national primacy agency cost estimates see Chapter 5 of the EA. Further, as detailed in section XIII of the FRN for the final rule, during the initial three-year period, primacy agencies will incur burdens associated with one-time startup activities. The burden associated with reading and understanding the rule, adopting the regulatory requirements, and training internal staff is estimated to be an average of 4,320 hours per primacy agency. The burden associated with primacy agency review of initial monitoring data is 73,000 hours. The total burden for these activities, for the three-year period, for all 56 primacy agencies is estimated to be 399,000 hours. The estimate provided by the commenter is not directly comparable to the EPA's because the EPA's Information Collection Request (ICR) estimates focuses solely on burdens incurred in the first three years of after rule promulgation. Therefore, the primacy agency burden hours associated with reviewing and approving treatment, a significant component of both the EPA's and this commenter's estimate of the overall burden associated with the rule, is not included in the EPA's ICR burden hours estimate.

Regarding the total primacy agency monetized burden estimates, for modeling purposes, the EPA assumes all primacy agency activities associated with reviewing and approving treatment occur in year 5 of the analysis. As seen in the EPA's undiscounted costs estimates over the period of analysis, the EPA estimates approximately $6.5 million in each of the first three years of the analysis associated with implementation and start up totals approximately $19.5 million.The EPA's estimate is lower to this commenter's estimate that the first year of implementation will cost primacy agencies $59,889,624. The commenter's estimate is likely higher because it appears to include burdens associated with activities that the EPA has determined are not appropriate for inclusion in the EPA's cost analysis, such as compliance activities (please see section 13.3.1 of the EPA response in this *Response to Comments* document for the EPA's response to comments on consideration of compliance and violations related burden for primacy agencies in the EA).

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044120)

APPENDIX A:

PFAS Cost of State Transactions Study (PCoSTS)

ASDWA developed a PFAS Cost of State Transactions Study (PCoSTS) [Link: https://www.asdwa.org/wp-content/uploads/2023/05/PCoSTS-Final.pdf] as an independent analysis of the primacy agencies' burden for EPA's economic analysis developed for the proposed PFAS National Primary Drinking Water Regulation. The goal of this study was to provide a national annualized estimate of primacy agency staff time for PFAS rule implementation, with the exception of information on regulatory start-up activities for the first

year. The individual agency workload will differ with each primacy agency, and the study serves as a national average of primacy agency workload.

ASDWA staff worked with its PFAS State Resources subgroup and PFAS Economic Analysis subgroup to divide the proposed rule into five tabs that categorize workload by the following activities:

• Regulatory Start-Up,

• Annual Reporting,

• Water System/Operator Technical, Managerial, and Financial Assistance and Training,

• Reviewing and Approving Treatment, and

• Compliance.

Within each tab are assumptions of activities that are included in the correlated tab estimations, specifically the hours each (Hours Ea.) columns.

Regulatory Start-Up

As previously stated, this is the only tab that estimates hours for the first year of

implementation. The remaining tabs estimate the annual time for the transactions that primacy agencies will undertake under the current proposal. Within this tab, the estimates focus on the activities associated with the preparation of the proposed new rule. For example, these start-up actions include the development of training materials and the training of primacy agency staff, creating and modifying existing reports, lab accreditation, and hosting meetings for the general public.

This tab estimates the time associated with annual reporting. Some of the estimates within this tab include enforcement actions and reporting violations to EPA and responding to EPA's requests on system-specific issues.

Water System/Operator TMF Assistance and Training

The estimates in this tab are for the time primacy agencies will spend answering operator questions and assisting systems with funding applications.

Reviewing and Approving Treatment

This tab is broken down by system size based on an estimation of the percentage of systems needing additional treatment for compliance. This tab focuses on the workload associated with reviewing and approving treatment and includes items such as consulting utilities on source water changes, assisting with building infrastructure, and review of pilot projects.

Compliance

This tab focuses on the workload that includes assisting out-of-compliance systems and helping systems remain in compliance, as well as pursuing enforcement actions and reviewing system specific variances and exemptions.

[Figure: See Docket ID EPA-HQ-OW-2022-0114-1628]

The $57.60 hourly rate comes from the U.S. Bureau of Labor Statistics and includes both salaries/wages and benefits [FN2: U.S. Bureau of Labor Statistics. (2023, March 27). Compensation costs for civilian workers averaged $42.48 per hour worked in December 2022. TED: The Economics Daily. Accessed May 22, 2023 from Compensation costs for civilian workers averaged $42.48 per hour worked in December 2022 : The Economics Daily: U.S. Bureau of Labor Statistics (bls.gov); Link: https://www.bls.gov/opub/ted/2023/compensation-costs-for-civilian-workers-averaged-42-48-per-hour-worked-in-december-2022.htm]. Combining the cost of the first year of implementation with four subsequent years of annual rule requirements (for a total of 2,343,150 staff hours), ASDWA's model estimates that the proposed NPDWR will increase primacy agency staff hours by roughly 469,000 hours annually in its first five years of implementation. This translates to an annual cost of almost $27 million.

[see docket ID EPA-HW-OW-2022-0114-1628]

Appendix B. Comments by ASDWA For the Proposed PFAS NPDWR

EPA Response: Please see section 13.3.1 of the EPA response in this *Response to Comments* document for how the agency has increased about costs to primacy agencies. Based on this and other public comments, the EPA has increased estimated burden hours for many primacy agency activities, including regulatory start-up and primacy package adoption, water system operator training, and reviewing and approving treatment, and as recommended by the commenter, which had an upward effect on the cost estimates. Please see section 13.3.1 of the EPA response in this *Response to Comments* document for the EPA's response to commenter recommendations to include costs associated with compliance in the EA.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044062)

2. ASDWA recommends that EPA utilize findings from ASDWA's PFAS Cost of State Transactions Study (PCoSTS) [Link: https://www.asdwa.org/wp-content/uploads/2023/05/PCoSTS-Final.pdf] to reevaluate the primacy agency costs portion of the preamble and economic analysis to better reflect the true state burden. EPA's estimate for state staff time for rule adoption, treatment review and approval, mandatory reporting, and review of source water changes is inaccurate and underestimated. In particular, the Agency has unrealistic expectations for the considerable time that primacy agencies will spend providing technical assistance to water systems. Gaining an improved understanding of primacy agency costs will assist EPA to identify revisions to improve rule feasibility and reduce these costs.

EPA Response: Please see section 13.3.1 of the EPA response in this *Response to Comments* document for how the agency has increased about costs to primacy agencies. Based

on this and other public comments, the EPA has increased estimated burden hours for many primacy agency activities increased significantly and had an upward effect on the cost estimates. As discussed in section 13.3.1 of the EPA response in this *Response to Comments* document, after considering public comment, the EPA has also finalized an annual compliance monitoring option for lower risk systems which will reduce system and primacy agency long-term burden. Please see section 8 of the EPA response in this *Response to Comments* document for further discussion of monitoring requirements.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044116)

ASDWA recommends that EPA update the proposal's economic analysis to better capture the burden on the state workforce with respect to the review and approval of PFAS treatment technologies.

Timelines for reviewing and approving treatment technologies have been underestimated in the proposal. In addition to reviewing and approving preliminary engineering reports (PER) and construction design plans for treatment technologies installed to maintain compliance with this rule, primacy agencies will also need to review and approve the pilot tests needed to ensure treatment efficacy of the selected BAT. Some primacy agencies may have limited experience with some of the BAT or may not have approved the technology for PFAS; as such, timelines for review and approval of these technologies are not as straightforward as what was presented in the proposal. EPA should continue research on small scale treatment technology and provide guidance for primacy agencies to alleviate this feasibility concern.

EPA Response: Please see section 13.3.1 of the EPA response in this *Response to Comments* document about costs to primacy agencies. Based on this and other public comments, the EPA has increased estimated burden hours for many primacy agency activities increased significantly and had an upward effect on the cost estimates. Additionally, for the EPA's response to comments about guidance associated with the PFAS rule, please see section 1.2 of the EPA response in this *Response to Comments* document. For the EPA's response to comments about continuing agency efforts to address PFAS, including additional research, please see section 2.5 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044076)

Primacy Agency Staff and Resource Burden

EPA Analysis of Primacy Agency Costs

ASDWA has developed a PFAS Cost of State Transactions Study (PCoSTS) [Link: https://www.asdwa.org/wp-content/uploads/2023/05/PCoSTS-Final.pdf] as an independent analysis of the primacy agencies' burden to help inform EPA's economic analysis developed for the proposed PFAS drinking water regulation (Appendix A). ASDWA recommends that EPA

utilize findings from ASDWA's analysis to reevaluate the primacy agency costs portion of the preamble and economic analysis to reflect the primacy agency burden accurately.

EPA's analysis of primacy agency costs does not accurately capture all the activities primacy agencies will undergo for PFAS implementation. Additionally, the Agency's analysis underestimates the number of hours for the primacy agency tasks. ASDWA recommends that EPA utilize ASDWA's PCoSTS model to reevaluate the primacy agency costs portion of the preamble to better reflect the true burden as detailed below.

ASDWA's PCoSTS model estimates the primacy agency staff time required for the first year of rule implementation, which includes one-time activities such as regulatory start-up and review and approval of water system treatment plans. ASDWA estimates that the first year of implementation for the proposed PFAS drinking water regulation will require 1,039,750 hours of primacy agency staff time. At the state and local hourly government employee rate of $57.60 based on the U.S. Bureau of Labor Statistics, this will cost primacy agencies $59,889,624. ASDWA's model also estimates the primacy agency staff time that will be required for subsequent years for annual regulatory activities, such as reporting, compliance, and technical assistance. Subsequent years following the first year of implementation will require 325,850 hours of staff time at a cost of $18,768,960 annually.

Combining the cost of the first year of implementation with four subsequent years of annual rule requirements (for a total of 2,343,150 staff hours), ASDWA's model estimates that the proposed NPDWR will increase primacy agency staff hours by roughly 469,000 hours annually in its first five years of implementation. This translates to an annual cost of approximately $27 million.

EPA underestimates the time for each primacy agency to read and understand the rule and adopt regulatory requirements. The time needed to adopt regulatory requirements will vary greatly across the country. Some primacy agencies have requirements for robust public comment periods as a component of new rule adoption. Additionally, primacy agencies may need to accredit laboratories for PFAS testing, which will increase the amount of staff resources needed for implementation. Primacy agency staff will also need to create or modify existing reports, such as the Consumer Confidence Report (CCR), Safe Drinking Water Information System updates, and monitoring schedule updates. Finally, this estimate does not consider the amount of time primacy agency staff will spend responding to questions from members of the public, inquiries from public officials, and media requests immediately following the final publication of the NPDWR. ASDWA estimates 210,700 hours for primacy agency staff working on the regulatory start-up of this proposal, with an associated cost of $12,136,320.

EPA's analysis assumes that the amount of time a primacy agency will need to review treatment plans directly correlates with the size of the water system, and this assumption is inaccurate. ASDWA's members have reported that small systems often take the most time as they need significant assistance to navigate the process for the design and construction of new treatment and get into compliance. Primacy agencies often work with these communities to locate consultants for preliminary engineering reports (PERs), develop construction plans and

specifications, help obtain funding, and manage construction. Additionally, this assistance often goes beyond just the construction of the treatment and start-up as systems work to remain compliant. Assistance with operation and maintenance (O&M) is often required. ASDWA's model estimates 503,200 hours costing $28,984,344 for treatment review and approval, with the vast majority of hours and dollars used addressing small systems.

EPA's assumption that the mandatory reporting regarding violations, variances and exemptions, enforcement actions, and general operations of primacy agency programs will not incur any additional primacy agency staff time is inaccurate. The proposal is a new regulation that will impact several thousand systems and likely result in hundreds of violations once the rule goes into effect. Each of those violations and the actions needed to return these systems to compliance will take additional time and effort. Additionally, primacy agencies anticipate that their staff will have to spend significant time working with water systems to develop and maintain monitoring schedules, particularly because the level needed for reduced monitoring is below the PQL. Although EPA plans to provide a public tool for systems to determine their Hazard Index, ASDWA's members anticipate many of these systems will still go to their primacy agencies for assistance. ASDWA estimates 245,000 staff hours will be dedicated to compliance at a cost of $14,112,000.

EPA's estimate for the primacy agencies to review source water changes, four hours, is inaccurate. Changing sources has treatment design considerations and typically have significant implications on finished water quality, such as corrosion control, disinfection by-products, disinfectant residual, etc., that must be carefully considered. This analysis of the potential for unintended consequences from source changes will take significantly longer than four hours.

EPA's estimates do not appropriately consider the primacy agency staff time needed to implement pilot testing for new treatment. Staff review time will be needed for both the design of the pilot as well as all the pilot testing data, ranging from a desktop analysis to bench-scale testing to a full pilot plant. This staff time should be appropriately captured in EPA's final estimates.

ASDWA's PCoSTS model details the increased staff resources for rule implementation. State drinking water programs are already hard-pressed financially. Ongoing regulatory oversight to ensure compliance is constant, and several proactive actions such as addressing cyanotoxins and providing oversight for the development of lead service line inventories, have increased states' workloads. States consistently step in to help solve problems and return systems to compliance as quickly as possible.

State-provided funding has historically compensated for inadequate federal funding, but state budgets have been variable for the past few years, given the COVID-19 pandemic and other economic issues. These increases in primacy agency responsibilities should be met with a corresponding increase in the Public Water System Supervision (PWSS) Grant Program, recognizing EPA's limited ability to influence Congressional PWSS appropriations. Without the additional PWSS funding, primacy agencies will have to make tough decisions on prioritizing

support to existing programs. Limitations on primacy agency resources result in fewer opportunities to work individually with water systems to improve compliance and protect public health. Insufficient federal support for the PWSS program increases the likelihood of scenarios that put the public's health at risk.

ASDWA recommends EPA split "technical assistance" into multiple components.

EPA's estimates and assumptions regarding the amount of technical assistance that will be needed for systems to come into compliance are underestimated. As previously discussed, small systems will need extensive assistance, but even medium and large systems will need support. Some primacy agencies have reported regularly getting in-person training requests from all sizes of water systems. These requests result in primacy agency staff driving across the state to conduct training for the system's employees. Primacy agencies have received feedback from operators that they prefer in-person training and find them more effective than online training for complex issues. The complexities of the PFAS regulation will drive the development and delivery of a significant amount of in-person training. This work involves time to develop the workshop materials and significant travel time depending on the system's location. With concerns over contaminating a sample during collection and using a new Hazard Index approach, primacy agencies anticipate receiving a significant number of in-person training requests.

To get a more accurate estimate of the primacy agency burden for technical assistance, ASDWA recommends that EPA split "technical assistance" into multiple components. Currently, the economic analysis is unclear on exactly what the Agency is considering under the category of "technical assistance." EPA's estimate is low by a significant amount if all technical assistance activities are considered. ASDWA recommends that EPA break down its analysis into the components below.

• Assistance to obtain valid water samples.

• Assistance to systems to locate consultants to develop Preliminary Engineering Reports (PERs).

• Assistance to systems to identify and evaluate options for potential new water sources.

• Assistance to systems to identify funding.

• Assistance to systems during the piloting process and determining the appropriate treatment.

• Assistance to systems in developing construction plans and specifications.

• Development and presentation of new training modules for systems.

ASDWA recommends that EPA include a separate category for compliance activities, as these activities will take up a substantial portion of staff time.

Some primacy agencies have reported that staff will need to devote additional time to sampling training, sanitary surveys, evaluating compliance data, updating inspections standard operating

procedures, and verifying treatment. PFAS sampling involves special care to avoid unintentional contamination and, therefore, will require more training.

Primacy agencies in states already regulating PFAS have noted that some systems, particularly small or disadvantaged ones, choose to be continually out of compliance due to laboratory testing and treatment costs. This decision requires primacy agencies to continually do outreach to these communities.

The reduced monitoring schedules and determinations will take significant time due to how often water systems will be triggered back into standard monitoring. Tracking compliance monitoring schedules for systems that go back and forth between standard and reducing monitoring will take significant staff time.

ASDWA recommends that EPA include the costs associated with primacy agencies that conduct compliance sampling for their water systems within the Agency's economic analysis.

EPA's economic analysis appears to exclude the costs that will be borne by primacy agencies that conduct compliance sampling for their water systems. This subset of ASDWA's members will be significantly impacted by this increase in required sampling, both financially and with their staffing needs. ASDWA's members have reported that the initial monitoring requirements within the proposed NPDWR will cost the affected primacy agencies between $900,000 and $2.33 million. These figures exclude any purchasing systems. One primacy agency estimated that routine monitoring would cost the agency roughly $450,000 per year. Finally, one primacy agency noted that due to the precautions necessary for PFAS sampling, the agency does not intend to take these samples alongside their standard sampling collection. Therefore, the primacy agency expects five additional FTEs will be required to meet the compliance sampling demand.

EPA Response: The EPA has considered information provided by commenter and agrees regarding increasing burdens associated with regulatory start up; primacy package adoption; technical, managerial and financial (TMF) assistance to water systems; and reviewing and approving treatment. The EPA agrees with the commenter and has made these changes because commenters pointed out activities not explicitly accounted for in the regulatory start up estimate in the EA and commenters also pointed out that adopting primacy packages is a significant undertaking, as discussed in section 13.3.1 of the EPA response in this *Response to Comments* document. Commenters also stated the EPA's assumption in the proposal that the amount of time a primacy agency will need to review treatment plans directly correlates with the size of the water system was inaccurate. Commenters noted that "…small systems often take the most time as they need significant assistance to navigate the process for the design and construction of new treatment and get into compliance." After considering these comments, the EPA agrees that reviewing and approving treatment for small systems is likely to take more time given the assistance needed for these systems. Because small systems often lack the technical, managerial, and financial capacity, it is likely that primacy agencies will spend more time assisting these systems in navigating compliance with the PFAS NPDWR. As such, the EPA adjusted burden estimates in the final rule to reflect the largest primacy agency burden per EPTDS at the smallest

systems and decreased burden hours with increasing system size, as commenters suggested. All adjustments made on primacy agency burden are discussed in section 13.3.1 of the EPA response in this *Response to Comments* document.

The EPA disagrees with the commenter's recommendation to break down the technical assistance burden estimate into 7 sub-task level estimates, as that recommendation would add unnecessary complexity, and the commenter did not provide sub-task level estimates for the EPA's consideration. However, as discussed in detail in section 13.3.1 of the EPA response in this *Response to Comments* document, the agency did include many of the commenter's recommendations into the primacy agency burden estimates, including using the commenter's recommended estimate for total hours per primacy for technical assistance.

In addition, the EPA clarifies the agency included the sampling costs associated with primacy agencies that conduct compliance sampling for their water systems in the sampling component of the PWS cost estimate within the agency's EA. The EPA acknowledges that some primacies conduct sampling for their water systems, but does not have information to estimate how frequently this occurs, so as a simplifying assumption, modelled all samples being taken by PWS. This assumption has no effect on the total national costs of the rule. While these costs are not included in the primacy agency portion of the analysis, they are not excluded from the analysis as suggested by the commenter.

Finally, please see the EPA response to comment Doc. #1628, SBC-044069 in section 13.3.1 in this *Response to Comments* document regarding this commenter's estimates of the national level primacy agency costs of the rule.

Texas Commission on Environmental Quality (TCEQ) (Doc. #1632, SBC-044128)

Economic Analysis

Level of Effort for Primacy Agencies

The NPDWR includes an analysis of primary agency costs, but TCEQ believes EPA's economic analysis underestimates the level of effort and costs for primacy agencies to implement the rule. TCEQ does not agree with EPA's assumption the implementation of the PFAS NPDWR will not incur any additional staff time. The proposed regulation, in addition to existing workloads which are exacerbated by newly promulgated NPDWRs, will significantly increase staff time to implement the rule.

Due to the growing complexity of federal drinking water regulations, the knowledge required of water system operators has reached insurmountable proportions causing a strong reliance on technical and informational assistance from state regulators. At the same time, TCEQ finds it increasingly difficult to absorb and communicate all the regulatory requirements, both to the regulated community and to state personnel. Each new requirement adds to the collective impact of an already large and demanding body of regulations. Although this may be difficult to quantify, TCEQ urges EPA to reassess and lean toward more generous cost estimates. It is

imperative that the final rule accurately portrays the resources primacy agencies will need to implement the rule, since many primacy agencies need to use this information to justify staffing levels and costs. EPA should also reconsider the estimate of effort required by primacy agencies to support small systems and provide technical assistance as they navigate the process to add new treatment capabilities and achieve compliance with the rule.

While several treatment options exist, public water systems will need support and information to evaluate the challenges and benefits of different technology options. Primacy agencies will have to review additional pilot projects, which may range from a desktop analysis to a full-scale pilot study. PFAS compounds are difficult to remove. As with any treatment technology, the efficacy of the PFAS removal technology at a specific public water system is impacted by the type and concentrations of PFAS compounds in the source water, the targeted finished water concentration, and other parameters that may interfere with treatment (e.g., total organic carbon, nitrate, sulfate). Each public water system will have to find the technology that will work best for its specific circumstances and, depending on the factors noted above, conduct pilot studies to verify efficacy. Many states do not have specific design criteria for these best available technologies. PFAS projects will involve a pilot study protocol, pilot study report, and associated plans and specifications review, which require approximately 188 staff hours to complete.

EPA also underestimates the time needed to review source water changes. Changing water sources can have significant implications on finished water quality that need to be carefully considered and evaluated. For example, review times for new sources typically average 40 staff hours for a surface water intake, 24 staff hours for a groundwater well, and eight staff hours for an interconnect project.

EPA Response: The EPA agrees with commenters on the burdens associated with regulatory start up; TMF assistance to water systems; and reviewing and approving treatment. Based on input from this and other commenters, the EPA adjusted burden estimates for these categories of costs. All adjustments made on primacy agency burden are discussed in section 13.3.1 of the EPA response in this *Response to Comments* document. Please see the EPA response to comment Doc. #1628, SBC-044076 in section 13.3.1 in this *Response to Comments* document.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044172)

C. State Agency Staff and Resource Needs

1. NCDEQ recommends that EPA reevaluate state agency costs portion of the preamble and economic analysis to reflect the agency burden accurately.

EPA's analysis of state costs does not capture all the activities associated with PFAS implementation. Additionally, the Agency's analysis underestimates the number of hours to carry out state agency tasks. NCDEQ recommends that EPA adjust the state agency costs portion of the preamble to better reflect the anticipated staff and resource needs as detailed below.

EPA's analysis should add staff time to include a public comment period as a component of new rule adoption, develop laboratory accreditation programs, and responding to questions from members of the public, inquiries from public officials, and media requests.

EPA's analysis assumes that the amount of time a state agency will need to review treatment plans directly correlates with the size of the water system. This assumption is inaccurate. Small systems often take the most time as they need significant assistance to navigate the process for the design and construction of new treatment and get into compliance. Additionally, this assistance often goes beyond just the construction of the treatment and start-up as systems work to remain compliant. Assistance with operation and maintenance (O&M) is often required.

NCDEQ urges EPA to adjust the assumption that the mandatory reporting regarding violations, variances and exemptions, enforcement actions, and general operations of state agency programs will not incur any additional agency staff me. The proposal is a new regulation that will impact approximately two thousand North Carolina systems and likely result in a large number of violations once the rule goes into effect. Each of those violations and the actions needed to return these systems to compliance will take additional time and effort such as working with water systems to develop and maintain monitoring schedules. Although EPA plans to provide a public tool for systems to use to determine their hazard index, many of these systems will go to their state agency officials for guidance and assistance. Small systems will need extensive assistance, but medium and large systems will also need staff support. We anticipate providing in person training that will require development of workshop materials and travel time depending on the training's location.

EPA's estimate for state agencies to review source water changes, four hours, should be adjusted upward to eight hours. Changing source water typically has significant implications on finished water quality, such as corrosion control, disinfection byproducts, disinfectant residual, etc., that must be carefully considered. This analysis of the potential for unintended consequences from source changes can take significantly longer.

EPA's estimates should increase state agency staff time needed to evaluate pilot testing for new treatment. Our staff will be needed for both evaluating the design of the pilot as well as reviewing all the pilot testing data. We recommend that this staff time should be increased in EPA's final estimates.

2. NCDEQ recommends that EPA include a separate cost category for state agency compliance assistance activities.

Staff will need to devote additional time to sampling training, sanitary surveys, evaluating compliance data, updating inspections standard operating procedures, and verifying treatment.

The reduced monitoring schedules and determinations will take additional time due to how often water systems will be triggered back into standard monitoring. Tracking compliance schedules for systems that transition between standard monitoring and reduced monitoring will take staff

time based on the number of systems affected and frequency of transition. NCDEQ is available to work with EPA in estimating this cost category.

EPA Response: Please see section 13.3.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1628, SBC-044076 in section 13.3.1 in this *Response to Comments* document. Regarding the commenter's statement about the burden associated with tracking compliance schedules, the EPA acknowledges that primacy agencies will spend time tracking compliance schedules. As the commenter points out, the costs associated with this specific activity will likely vary significantly based on the number of systems impacted and the frequency of transition. For modelling purposes, as described in Chapter 4.4.4 of the EA, the EPA assumes that EP PFAS concentrations are constant. Therefore, the agency does not model water systems switching between compliance schedules over the entire period of analysis, but rather models an initial monitoring frequency and a post-compliance monitoring frequency based on the modelled occurrence information for water systems (see Chapter 5.3.2 of the EA for more information). By extension, the EPA does not model the shifts in primacy agency tracking burden associated with reduced monitoring over the period of analysis. Finally, for reasons described in section 13.3.1 of the EPA response in this *Response to Comments* document, the EPA assumes 100 percent compliance with the rule and does not include costs associated with non-compliance in the EA.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044197)

7. NCDEQ recommends that EPA update the proposal's economic analysis to better capture the burden on the state workforce with respect to the review and approval of PFAS treatment technologies.

Timelines for reviewing and approving treatment technologies have been underestimated in the proposal. In addition to reviewing and approving engineering reports and construction design plans for treatment technologies installed to maintain compliance with this rule, state agencies will also need to review and approve the pilot tests needed to ensure treatment efficacy of the selected BAT. NCDEQ has limited experience with some of the BAT and has not approved the technology for PFAS regulation compliance; as such, timelines for review and approval of these technologies are not as straightforward as what was presented in the proposal.

EPA Response: Based on this and other comments, the EPA has updated burden estimates associated with reviewing and approving treatment technologies. Please see section 13.3.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1628, SBC-044076 in section 13.3.1 in this *Response to Comments* document.

New York State Department of Health (NYS DOH) (Doc. #1677, SBC-044940)

May 30, 2023

U.S. Environmental Protection Agency

EPA Docket Center

Office of Groundwater and Drinking Water Mail Code 28221T

1200 Pennsylvania Ave.

Washington, DC 20460

Re: Docket #EPA-HQ-OW-2022-0114

To whom it may concern:

The New York State Department of Health (Department), in consultation with our partners at the New York State Department of Environmental Conservation (DEC), is pleased to provide comments on the National Primary Drinking Water Regulation (NPDWR) for per- and polyfluoroalkyl substances (PFAS). We appreciate and support the Biden Administration's decision to address PFAS chemicals through these regulations. New York State has been and continues to be a national leader in PFAS regulation, assessment and mitigation. We hope that our experience in regulating PFOA and PFOS can assist the United States Environmental Protection Agency (EPA) in realizing meaningful public health protections through implementation of its PFAS action plan and regulatory agenda.

The following comments first address regulatory implementation and enforcement consistent with the Department's primary enforcement authorities under the Safe Drinking Water Act. These comments also address consistency in the application of the underlying health science (reference doses, cancer slope factors) across EPA's programs, the health basis of the proposed Hazard Index (HI) approach, and additional implications of the proposed MCL rulemaking.

1. The Department has been implementing enforceable maximum contaminant levels (MCLs) of 10 parts per trillion (ppt) for PFOA and PFOS since 2020. Since January 1, 2021, the number of violations issued for PFOA and PFOS is approximately equal to the number of violations that the Department and its local health department (LHD) partners have issued for all remaining compounds for which there is a national primary drinking water regulation (NPDWR) or State Maximum Contaminant Level (MCL). Currently, out of the 2,576 public water systems (PWS) with results, approximately 250 PWS exceed the regulatory standard at 10 ppt. We anticipate nearly 550 PWS in New York State may exceed the regulatory standard at 4 ppt. If compliance with other MCLs remains constant, nearly 70% of all MCL violations issued in New York will be for PFOA and/or PFOS. The workload involved in determining monitoring frequency, modifying schedules in the Safe Drinking Water Information System (SDWIS), and notifying public water supplies of the schedules is significant and deserves consideration.

Table 1: PFOA and PFOS Occurrence in New York State

[Table 1: See Docket ID EPA-HQ-OW-2022-0114-1677]

2. While an increase in primacy agency workload is to be expected any time a new MCL standard is promulgated, the workload associated with promulgating these standards is expected

to be more significant. Workload for primacy agencies has been increasing to unsustainable levels at a time when the Drinking Water State Revolving Fund (DWSRF) base grant funds, and thus set asides used to fund primacy agency programs, have been reduced by upwards of 50%. These sources have historically been used to fund regulatory program staff and ensure the EPA's mission is fully executed in accordance with the Department's primacy enforcement authority. Although the Infrastructure Investment and Jobs Act (IIJA) has provided a much welcome boost to primacy agency programs in the form of set asides, the effective date of this proposed NPDWR is expected to be in late 2026 or early 2027, which is the last year IIJA funds will be awarded. If a regulation with such broad impact is promulgated, EPA must work with Congress to concurrently increase funding to the Public Water System Supervision (PWSS) state and tribal assistance grant to ensure that primacy agencies have a stable source of funding for staff to ensure the public health protection goals in the NPDWR proposal are realized well into the future.

EPA Response: The EPA acknowledges commenter's stated support for the agency's efforts to address PFAS through this NPDWR. For the EPA's response to comments on the primacy agency burden associated with the final rule and response to comments recommending the EPA include violations related costs in the EA, please see section 13.3.1 of the EPA response in this *Response to Comments* document.

New Hampshire Department of Environmental Services (NHDES) (Doc. #1690, SBC-044355)

b. Agency Impact. This new Federal Drinking Water Regulation comes at an unprecedented time, when State Agencies have two other major rule revisions (LCRR and CCR) to implement. NH has reviewed the amount of time staff have spent managing the current State Administrative Rule for PFAS monitoring, and based on the new Federal MCLs and increased monitoring requirements we anticipate staff will be spending 35 more hours per week minimum managing the PFAS program alone. This is a very conservative estimate, and includes the review of sample results, schedule changes, enforcement actions, treatment approvals, and the inevitable influx of questions from public water system. NH did not consider time spent updating the rules or database applications and reports; those items will require a significant amount of time but are a one-time effort.

EPA Response: Please see section 13.3.1 of the EPA response in this *Response to Comments* document.

Clean Water Action/Clean Water Fund (Doc. #1697, SBC-045006)

EPA should also ensure that state agency support reflects the true costs of implementing the new regulations. The PFAS CoSTS analysis developed by the Association of State Drinking Water Administrators (ASDWA) estimates first year implementation costs for state agencies to be $59, 889,624 and annual costs after that to be $18,768,960.

EPA Response: Please see section 13.3.1 of the EPA response in this *Response to Comments* document.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045109)

2) What is needed to effectively communicate information about PFAS to the public?

The monitoring burdens through the sampling framework identified will require additional staffing. The proposed regulation will require considerable additional staffing by the primacy agency from administrative support to receive and process data, to compliance analysts to review and respond to the data, to engineering resources to review and approve treatment designs. It is estimated that a minimum of 4 additional staff would be needed in a state like Vermont. There will also be considerable demands on the external partners such as consulting engineers to ensure treatment meets all necessary standards prior to being placed into service.

EPA Response: For the -EPA's response to comments on primacy agency burden associated with the rule, including technical assistance, review of compliance results and setting monitoring schedules, and reviewing treatment, please see section 13.3.1 of the EPA response in this *Response to Comments* document. All of these activities are included in the EPA's cost estimates, for more information see Chapter 5 of the EA.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045091)

Adequate Technical Managerial and Financial capacity is always a concern with new regulations, especially pertaining to small systems. Experience in Vermont has shown that small systems often lack the resources necessary to respond to and properly maintain any required treatment when PFAS contamination is in the community. The impact of treatment and O&M expense is often amplified in small water systems where costs are borne by a smaller user base and are unable to be spread across tens of thousands of users.

Providing support and oversight to small systems across the state is a very time-intensive endeavor and is extremely demanding on state resources for a small state such as Vermont.

EPA Response: The EPA increased the primacy agency burden estimate associated with reviewing and approving small system treatment plans; please see section 13.3.1 of the EPA response in this *Response to Comments* document.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045145)

3. EPA Analysis of Primacy Agency Staff and Resource Burden

EPA's analysis of primacy agency resource implications does not fully capture all the activities that primacy agencies will undertake to implement the PFAS NPDWR and underestimates the

number of hours for primacy agency tasks. MassDEP has been regulating PFAS in drinking water since October 2020 and has significant experience estimating the impacts of rule implementation on MassDEP's staff. EPA should substantially increase support to states to facilitate implementing the rule.

EPA underestimates the time for MassDEP to read and understand the rule, as well as adopt regulatory requirements. The amount of time needed to adopt regulatory requirements will vary greatly across the country. MassDEP has requirements for robust public comment periods as a component of new rule adoption. Additionally, MassDEP may need to modify its laboratory accreditation program which will increase the amount of staff resources needed for implementation.

EPA assumes that the amount of time a primacy agency will need to review treatment plans directly correlates with the size of the water system, but this assumption is inaccurate. Assisting small systems often takes the most time, as they need significant support navigating the process for the design and construction of new treatment to get into compliance. MassDEP often works with these systems to locate consultants for preliminary engineering reports (PERs), develop construction plans and specifications, help obtain funding, and manage construction. Additionally, this assistance often lasts beyond the construction and start-up of the treatment to include ongoing operation and maintenance (O&M) support.

EPA's assumption that the proposed regulation would not cause any additional primacy agency staff time to be needed to comply with the reporting requirements of 40 CFR § 142.15 is inaccurate. The proposal will be a new regulation that will impact several hundred systems in Massachusetts and is likely to result in many violations once finalized. Reporting such violations and other elements of § 142.15 (variances and exemptions, enforcement actions, and general operations of primacy agency programs) will take additional time and effort.

EPA's estimate of four hours for the primacy agencies to review source water changes is inaccurate. Changing sources typically has significant implications on finished water quality, such as implications for corrosion control, disinfection by-products and disinfectant residual, that need to be carefully considered. This analysis of the potential for unintended consequences from source water changes will take significantly longer than four hours.

EPA's estimates do not appropriately consider the amount of primacy agency staff time needed to implement pilot testing for new treatment. Staff review time will be needed for both designing the pilot and analyzing all the pilot testing data, ranging from a desktop analysis to bench-scale testing to a full pilot plant. EPA underestimates the amount of technical assistance that will be needed for systems to come into compliance. The complexities of the PFAS regulation will drive the development and delivery of a significant amount of in-person training. This is the case even in the Commonwealth, despite our prior experience implementing the Massachusetts PFAS MCL, because the federal standard, if adopted, would require additional training due to the differences between the state and federal rules and would cover many additional public water systems that have not previously had to treat or otherwise remediate PFAS.

EPA's trigger level for quarterly monitoring is very low - right at the detection limit of these compounds. Although a PWS may qualify for reduced monitoring, subsequent rounds of monitoring could identify trace amounts of PFAS that would return the PWS to quarterly monitoring. Primacy agencies will spend significant resources developing reduced monitoring schedules, and making determinations to change monitoring frequencies, and tracking compliance schedules for systems that go back and forth between quarterly monitoring and reduced monitoring.

EPA's proposal does not allow the state sufficient time to develop appropriate reporting mechanisms. Due to initial monitoring that may begin immediately after final rule promulgation, reporting of this data will likely have to be either via paper, which will introduce a burden on states that currently receive such results electronically, or via an electronic process that is not CROMERR compliant as there will be insufficient time to develop, test and launch a new system or to modify an existing system.

EPA Response: Based on this and other comments, the EPA increased the primacy agency burden estimate associated with reviewing and approving small system treatment plans, including reviewing pilot study results; please see section 13.3.1 of the EPA response in this *Response to Comments* document. Additionally, for the final rule, the EPA has increased the trigger levels from the proposed values to ½ of the MCLs. For more information about trigger levels and the EPA's response to comments related to trigger levels, please see section 8.8 of the EPA response in this *Response to Comments* document. The EPA included the primacy agency burden associated with reviewing sample results during the initial monitoring period and the long-term monitoring period in the cost analysis, see Chapter 5 of the EA for more information. Regarding the concerns raised about record keeping and reporting of PFAS data, especially during the initial monitoring period, please see sections 11.2 and 11.3 of the EPA response in this *Response to Comments* document.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045240)

Economic Considerations & Costs

1. CT DPH agrees that a national drinking water regulation for PFAS is an important step to protect the public from the harmful effects from consuming PFAS in public drinking water. CT DPH believes EPA's estimates for primacy agency costs may not accurately account for all the activities that CT DPH will undertake for implementation of the NPDWR. For example, of the public water systems CT DPH regulates, a great proportion are small systems. These often take the most time as they need significant assistance to get their systems into compliance. CT DPH staff often work with small systems to locate consultants for engineering reports and construction plans and specifications, and then again to help these systems obtain funding. Additionally, the level of assistance required by small systems often goes significantly beyond just the establishment of the system and its infrastructure, as the help of CT DPH is often needed to

maintain compliance, assist in creating public messaging, attend public meetings, and address other issues as they arise.

Further, CT DPH believes that the mandatory reporting regarding violations, variances and exemptions, enforcement actions, and general operations will demand additional state staff time as all rules have such as the Revised Total Coliform Rule and the Groundwater Rule. As a new NPDWR for PFAS is implemented, CT DPH anticipates a significant number of public water systems in Connecticut will face compliance challenges. Many such cases will demand additional time and attention from CT DPH.

2. Increasing workloads for CT DPH will require additional staff. Like many primacy agencies, CT DPH has encountered challenges recruiting to fill vacant positions. There are significant workforce needs in the area of environmental engineering which presents a continuous challenge.

EPA Response: Please see section 13.3.1 of the EPA response in this *Response to Comments* document.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045205)

6. CT DPH recommends EPA reevaluate primary agency costs. As has been suggested by the Association of State Drinking Water Administrators, CT DPH anticipates costs associated with implementation of the Proposed PFAS NPDWR will significantly surpass that which have been estimated by EPA. Small systems account for a significant proportion of public water systems in Connecticut, and CT DPH has found that small systems often require more assistance than larger systems in complying with new regulations. Also, voluntary monitoring of PFAS thus far indicates that a proportion of public water systems in Connecticut will need to remediate PFAS to comply with the new NPDWR. Accordingly, CT DPH expects increased demand for technical and financial assistance as well as more compliance and possible enforcement actions. This will represent a significant addition to the current workload for CT DPH staff.

EPA Response: Based on this and other comments, the EPA has made adjustments to primacy agency cost burden estimates. Please see section 13.3.1 of the EPA response in this *Response to Comments* document.

Environmental Council of the States (ECOS) (Doc. #1752, SBC-044504)

The NPDWR includes an analysis of primary agency costs, but states have raised concerns that it does not capture all activities that primacy agencies will need to conduct to implement the rule. The Association of State Drinking Water Administrators (ASDWA) has developed a PFAS Cost of State Transactions Study [Link: https://www.asdwa.org/wp-content/uploads/2018/05/CoSTS-Report-Final-2018.pdf] to analyze primacy agencies' burden to help inform EPA's economic analysis developed for the proposed regulation. EPA should consider these findings as part of its evaluation of this portion of the proposed rule. Specifically, ECOS urges EPA to reconsider the

estimate of state effort required to support small systems and provide technical assistance as they navigate the new PFAS drinking water standard and add new treatment capabilities to achieve compliance.

EPA Response: Based on this and other comments, the EPA has made adjustments to primacy agency cost burden estimates. Please see section 13.3.1 of the EPA response in this *Response to Comments* document.

Fairfax Water (Doc. #1789, SBC-045300)

Additionally, there will be significant impacts on the limited resources of primacy agencies to support utilities in the compliance process. Our primacy agency, the Virginia Department of Health, historically received about $18 million per year since 2018 from EPA to implement the baseline Drinking Water State Revolving Loan Fund. In fiscal year 2024 they received less than $7 million as a result of Congressionally directed spending. This reduction prevented them from filling seven positions in FY23, and possibly more positions in FY24 might need to be held vacant - positions that would support utility implementation of PFAS treatment, particularly at small systems.

EPA Response: Please see section 13.3.1 of the EPA response in this *Response to Comments* document. In addition, the EPA acknowledges that some primacy agencies, like many public agencies and organizations, face budgetary pressures and capacity issues. The EPA has estimated costs of the final NPDWR to primacy agencies using the best available information and considering all public comments. For more information see the EPA's primacy agency cost estimates in Chapter 5.4 of the EA and the EPA's analysis pursuant to the Unfunded Mandates Reform Act (UMRA) in Chapter 9.5.

Missouri Department of Natural Resources (Doc. #1563, SBC-042512)

The Department also agrees with ASDWA that EPA has significantly underestimated the cost of the proposed rule. The EPA economic analysis does not reflect costs borne by many states that provide analytical services for all required safe drinking water compliance sampling. We encourage EPA to consider the updated information provided by ASDWA in calculating the cost to state programs to implement the final rule.

EPA Response: Please see section 13.3.1 of the EPA response in this *Response to Comments* document.

13.3.2 HFPO-DA, PFNA, PFBS National Cost

Summary of Major Public Comments and EPA Responses

A few commenters recommended that the EPA further consider the costs associated with compliance with the Hazard Index MCL. Specifically, commenters stated that the EPA's analysis of system level costs associated with the Hazard Index does not adequately characterize the

overall costs that will be incurred due to the Hazard Index standard. One commenter stated that the EPA "should not move forward with the Hazard Index until it has satisfied its statutory and policy obligation to conduct a cost-benefit analysis" (Doc. #1634, SBC-043237). Some commenters voiced concern regarding the EPA's assumption that costs associated with compliance with the Hazard Index MCL are insignificant and asserted that these costs must be reexamined, stating that this assessment "requires more knowledge on the nationwide occurrence of these compounds" and that the EPA "cannot assume that addressing the costs of PFOA and PFOS is sufficient when the additional four PFAS will be driving treatment decisions at some PWSs" (Doc. #1738, SBC-046002). Conversely, one commenter asserted that available occurrence data demonstrate that few systems will be required to install treatment to comply with the Hazard Index MCL that would not already be treating to comply with the PFOA and PFOS MCLs.

The EPA disagrees with commenters who state that the agency did not meet its requirements under SDWA, which requires the agency to analyze "quantifiable and nonquantifiable costs…that are likely to occur solely as a result of compliance with the maximum contaminant level." In the proposal, the EPA analyzed the quantifiable costs of the Hazard Index at the system level, using the best available information at the time of publication, and analyzed the nonquantifiable costs of the Hazard Index by including a qualitative discussion of the national level impacts and therefore met the statutory requirements under SDWA 1412 (b)(3)(C). After considering recommendations from public commenters to further analyze the costs of the Hazard Index and the data available to support a quantitative analysis of the costs of the Hazard Index, the EPA decided to conduct a sensitivity analysis of the costs of the Hazard Index and individual MCLs for PFHxS, PFNA and HFPO-DA at the national level. The results of the sensitivity analysis supported the EPA's assumption in the proposal that quantified national costs are marginally underestimated as a result of this lack of sufficient nationally representative occurrence data.

To estimate quantified costs of the final rule presented in the national-level summary tables, the EPA first estimated baseline PFAS occurrence using a Bayesian hierarchical model fitted with sampling data collected from systems participating in UCMR 3. The model included three of the six PFAS compounds regulated through this NPDWR: PFOA, PFOS, and PFHxS (please see section VI of the final rule preamble). This permitted the agency to quantify costs at a national level with a higher degree of confidence and precision for these three PFAS than if simple extrapolations had been used. Since there are some limitations with nationally representative occurrence information for the other compounds that were either not included in UCMR 3 (HFPO-DA) or did not have a sufficient number of observed values above the UCMR 3 reporting limits (PFNA, PFBS), the EPA has a lesser degree of confidence and precision for its quantified estimates of these three PFAS, which are informed by a significant amount of available state-level data. Therefore, the EPA presented the cost estimates for PFNA, HFPO-DA, and PFBS in a sensitivity analysis in the EA (i.e., national-level sensitivity analysis, see

Appendix N.3 of USEPA, 2024c) instead of including these costs in the summary tables of quantified national level costs.[3]

In the EA for the proposed PFAS NPDWR, the EPA used a model system approach[4] to illustrate the potential incremental costs for removing PFAS not included in the national economic model (i.e., PFNA, HFPO-DA, and PFBS). After considering public comments on the incremental cost analysis, many of which encouraged the EPA to further evaluate and consider quantified costs of the Hazard Index MCL where feasible, the EPA updated and combined existing analyses contained in the rule proposal to evaluate the incremental costs associated with the Hazard Index MCL and individual MCLs for PFNA and HFPO-DA with a quantified national level sensitivity analysis in the final rule. The updated analysis for the final rule builds on the proposal analysis by combining information that was presented separately at proposal. The analysis in Appendix N of the final EA utilizes the system level treatment cost information presented at proposal (See Appendix N of USEPA, 2023f) with updates to the cost models for the final rule detailed in section XII.A.2 of the FRN. These treatment costs were applied to the number of systems expected to exceed the standards based on PFNA, PFBS, and HFPFO-DA occurrence using the approaches for estimating occurrence of these compounds presented at proposal (see section 10.3 of USEPA, 2023e). This modified analysis was primarily conducted to ensure that the EPA has not, as some commenters claim, substantially underestimated the potential magnitude of these costs. The EPA notes the approach presented in Appendix N for the final rule and summarized here, by connecting analyses for proposed rule, allows the agency to consider and compare the relative degree of the potential overall costs of these otherwise nonquantifiable costs of the Hazard Index and PFNA and HFPO-DA MCLs relative to overall national rule costs. This analysis confirms the EPA's findings at proposal that the Hazard Index costs (and those costs for regulating PFNA and HFPO-DA individually) make up a small portion of the overall rule costs. Likewise, the EPA notes that while these costs are presented in Appendix N because of the lesser degree of confidence and precision in the estimates, the EPA has considered these costs as part of this final regulation. It has done so by evaluating nonquantifiable costs and accounting for uncertainty, characterizing these otherwise nonquantifiable costs in Appendix N to generate cost estimates that, while useful, are not as statistically robust as the national cost estimates presented

[3]When available, nationally representative occurrence information is preferable for an economic analysis of national level costs and benefits. In the case of PFOA, PFOS, and PFHxS, the EPA has a sufficiently robust nationally representative dataset from UCMR 3. The EPA used additional state data that were available at systems that were part of this UCMR 3 set of systems to fit the national occurrence model that informed cost estimates for PFOA, PFOS, and PFHxS (see Cadwallader et al., 2022). In the case of PFNA, HFPO-DA, and PFBS, the EPA lacks the same level of precision as described above for PFOA, PFOS, and PFHxS. State-led data collection efforts provided valuable information about occurrence for PFNA, HFPO-DA, and PFBS, however they did not provide the nationally representative foundation provided by UCMR3 for PFOA, PFOS, and PFHxS to be incorporated into the MCMC national occurrence model.

[4] At proposal, the EPA used a model system approach for estimating potential incremental treatment costs associated with co-occurring PFAS at systems already required to treat in the national model framework and the potential per system costs for the set of systems triggered into treatment as a result of Hazard Index MCL exceedances not already captured in the national analysis. For further detail on the assumptions and findings of the EPA's analysis of incremental costs of other PFAS at rule proposal, please see Appendix N.3 in the Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation (USEPA, 2023f).

in Chapter 5 of the EA. Using this analysis, the agency has confirmed the Hazard Index and PFNA and HFPO-DA MCLs drive a relatively low percentage of the overall rule costs. The EPA has also considered these costs in the context that the Hazard Index and PFHxS, PFNA, and HFPO-DA MCLs are expected to deliver important nonquantifiable health benefits, including PFNA birth weight benefits[5] and other nonquantifiable benefits associated with the reduction of the Hazard Index PFAS (PFNA, PFHxS, HFPO-DA, and PFBS)[6] described in Chapter 6.2 of the EA.

The proposed rule included a Hazard Index MCLG and MCL for any mixture of one or more of PFHxS, HFPO-DA, PFNA, and PFBS. The final rule includes a Hazard Index MCLG and MCL for any mixture of two or more of PFHxS, HFPO-DA, PFNA, and PFBS. The final rule also includes individual MCLGs and MCLs for PFHxS, PFNA, and HFPO-DA. The EPA's cost analysis at proposal considered the costs associated with the individual MCLs for PFHxS, PFNA, and HFPO-DA because the proposed Hazard Index MCL would function as individual MCLs when these contaminants occur in isolation. While the rule structure has changed in the final NPDWR, the costing framework used at proposal is still applicable in the final rule: what was considered a Hazard Index MCL exceedance at proposal would be an individual MCL exceedance under the final rule should those contaminants occur in isolation. Further, a Hazard Index exceedance in the final rule (defined as two or more of PFHxS, PFNA, HFPO-DA, and PFBS) is unchanged from a costing perspective to what the EPA proposed. Whether a system exceeds a Hazard Index MCL or individual MCL in the final rule, these costs are captured in the cost estimates the EPA considered and presented in Appendix N.3 of the EA and summarized in this section. Specifically, if a system exceeds only one of the individual MCLs for PFHxS, PFNA, or HFPO-DA that exceedance is costed by estimating the removal needed to achieve compliance with a given individual MCL. If a system exceeds the Hazard Index MCL, that exceedance is costed by estimating the removal of the combination of contaminants needed to achieve compliance with the Hazard Index MCL. Therefore, the national level cost estimate for PFHxS is reflective of both the total national cost of the PFHxS individual MCL and instances of Hazard Index MCL exceedances where PFHxS is present above its HBWC while other Hazard Index PFAS are present.

To understand the totality of national-level cost impacts for the Hazard Index MCL, the EPA considered both the contribution of PFHxS (estimated as part of the national level cost analysis), as well as the costs for PFNA, HFPO-DA, and PFBS (estimated in the Appendix N sensitivity analysis). Together, these provide information on the costs for the Hazard Index MCL and the

[5] As discussed in Appendix K.4, a 1 ppt reduction in both PFOA and PFOS for a system serving a population of 100,000 would result in $0.101 million in annualized birth weight benefits. If including a 1 ppt PFNA reduction, in addition to a 1 ppt reduction in both PFOA and PFOS, for a system serving a population of 100,000, the resulting annualized birth weight benefits would increase by $0.464 to $0.689 million, depending on the slope factor used for PFNA. The EPA estimates that 208 water systems may exceed the PFNA MCL.

[6] The EPA also anticipates additional substantial benefits to PWS customers associated with reduced exposure to Hazard Index compounds (PFHxS, HFPO-DA, PFNA, and PFBS) not included in the primary analysis. The nonquantifiable benefits impact categories include developmental, cardiovascular, immune, hepatic, endocrine, metabolic, reproductive, musculoskeletal, and carcinogenic effects. See Chapter 6.2 of the EA for more information.

individual MCLs for PFHxS, PFNA, and HFPO-DA, as a whole. Due to available data informing the Bayesian hierarchical occurrence model, the EPA was only able to quantify the portion of total costs for the Hazard Index MCL attributable to PFHxS[7] in the national level analysis. The EPA notes that this estimate also represents the national level quantified costs for the individual PFHxS MCL. The EPA acknowledges that this $11.6 million estimate is only a portion of the costs imposed by the Hazard Index MCL and also does not account for the costs imposed by the individual PFNA and HFPO-DA MCLs. The EPA accounted for those potential additional costs through the sensitivity analysis described in Appendix N, in which the EPA found that costs of treating for PFNA, HFPO-DA, and PFBS to meet the Hazard Index MCL and individual MCLs for PFNA and HFPO-DA increased national costs by approximately 5 percent, from $1,549 million to $1,631 million. These costs represent the total costs of the final rule; in other words this includes the costs associated with individual MCLs for PFOA, PFOS, PFHxS, HFPO-DA, and PFNA, as well as the Hazard Index MCL. Due to data limitations, the EPA has not separately estimated the costs of the Hazard Index in the absence of the individual MCLs. The sensitivity analysis demonstrates that the quantified national analysis cost estimate that includes only PFOA, PFOS, and PFHxS (where PFHxS represents only a portion of the Hazard Index costs) marginally underestimates total rule costs when also considering the potential cost impacts attributable to HFPO-DA, PFNA, and PFBS. The cost estimates stemming from both the quantified national estimate for PFOA, PFOS, and PFHxS, and from the sensitivity analysis conducted for PFNA, HFPO-DA, and PFBS together inform the impact of the Hazard Index MCL as required by the HRRCA under SDWA.

To fully weigh the costs and benefits of the action, the agency considered the totality of the monetized values, the potential impacts of the nonquantifiable uncertainties, the nonquantifiable costs and benefits, and public comments received by the agency related to the quantified and qualitative assessment of the costs and benefits. For the final rule, the EPA is reaffirming the Administrator's determination made at proposal that the quantified and nonquantifiable benefits of the rule justify its quantified and nonquantifiable costs.

In light of the individual MCLs, the EPA has separately presented national level marginal costs associated with the individual MCLs for PFHxS, PFNA and HFPO-DA in the absence of the Hazard Index MCL; see Chapter 5.1.3 and Appendix N.4 of the EA for details. Therefore, the costs for the individual PFHxS, PFNA, and HFPO-DA MCLs have been considered both in the proposed and final rule. For more information on the agency's methodology, findings, and

[7] The EPA notes that there are anticipated to be circumstances where PFHxS exceeds its individual MCL and HBWC where PFNA, PFBS, and HFPO-DA do not co-occur. While resulting in an exceedance of the PFHxS MCL, if PFHxS exceeds its HBWC without other Hazard Index PFAS present, this would not result in an exceedance of the Hazard Index MCL. At rule proposal, a single exceedance of any of the four Hazard Index PFAS would have resulted in an exceedance of the Hazard Index MCL. However, to improve rule implementation and to support effective risk communication, the EPA has structured the final rule such that a Hazard Index exceedance only occurs when there are two or more of the Hazard Index PFAS present. Therefore, while for purposes of informing its quantified cost analysis the EPA is assuming that every PFHxS exceedance of the MCL also causes an exceedance of the Hazard Index MCL, this approach results in the EPA overestimating PFHxS-attributable Hazard Index costs in its national cost analysis.

limitations of the EPA's updated analysis of costs associated with compliance with the Hazard Index , please see Appendix N.3 of the EA (USEPA, 2024cc).

Individual Public Comments

New York Section American Water Works Association (NYSAWWA) (Doc. #1591, SBC-042373)

We are concerned that the Hazard Index (HI) approach as a calculation will become increasingly complicated over time as additional PFAS compounds are considered for regulation. We also note that EPA's cost-benefit analysis does not extend into an evaluation of the HI for the selected additional PFAS, and that occurrence data for several of the selected additional PFAS is lacking.

EPA Response: Please see section 13.3.2 of the EPA response in this *Response to Comments* document for discussion of costs estimated for Hazard Index PFAS. As discussed in that section, the EPA has assessed the quantified and nonquantified costs for the Hazard Index PFAS and individual MCLs for PFNA, PFHxS, HFPO-DA; however, the presentation of that information is different than for the national-level analysis for PFOA, PFOS, and PFHxS as compared to the HFPO-DA, PFNA, and PFBS. The EPA also notes that the national level cost estimates presented in Section 5.1.3 of the EA do include costs associated with PFHxS occurrence above the PFHxS MCL and PFHxS health-based water concentration (HBWC) when one or more other Hazard Index PFAS are present. With respect to the commenter's concern that the Hazard Index approach "will become increasingly complicated over time as additional PFAS compounds are considered for regulation", the agency disagrees as the EPA believes the Hazard Index approach can be an adaptive and flexible framework for considering additional PFAS. Additionally, to assist in the calculation of these values, the agency is developing a calculator tool to easily determine your Hazard Index result. After finalization of the PFAS NPDWR, the EPA also intends to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation. For additional, discussion, please see section 5.2.1 of the EPA response in this *Response to Comments* document.

Association of California Water Agencies (ACWA) (Doc. #1675, SBC-044933)

B. Regulatory Approach

In addition to our concerns with costs, ACWA has several issues with the current proposal including the novel Hazard Index approach, use of the trigger level, and the compliance deadline.

COMMENT 3 – HAZARD INDEX – ACWA is concerned with a Hazard Index approach for drinking water.

EPA plans to regulate PFOA and PFOS as individual contaminants, and four other PFAS – PFNA, PFHxS, PFBS, and HFPO-DA ("GenX Chemicals") – as a mixture known as a Hazard Index [FN21: 88 Fed. Reg. at 18,638.]. The Hazard Index is a tool that EPA uses to understand health risk from chemical mixtures [FN22: EPA, Understanding the PFAS National Primary

Drinking Water Proposal Hazard Index (Mar. 2023), click here. (Link: https://www.epa.gov/system/files/documents/2023-03/HowdoIcalculatetheHazardIndex._3.14.23.pdf)]. This proposal marks the first time EPA will use a Hazard Index under the SDWA [FN23: 88 Fed. Reg. at 18,669.]. Specifically, EPA is proposing a Hazard Index, which would be exceeded with individual concentrations of GenX Chemicals at 10 ppt, PFBS at 2000 ppt, PFNA at 10 ppt, and PFHxS at 9 ppt, [FN24: 88 Fed. Reg. at 18,669.] or would be exceeded at far lower levels if multiple of these PFAS substances are present.

ACWA is encouraged by EPA's efforts to regulate PFAS creatively as these substances are ubiquitous and regulating contaminant by contaminant is cumbersome and time consuming for the agency and the public. While ACWA appreciates EPA's efforts to provide an online tool that will calculate the Hazard Index automatically, we have issues with the feasibility and precedent in using the Hazard Index.

We are concerned that the Hazard Index approach essentially sets a de-facto MCL without conducting the full SDWA cost-benefit analysis for the covered PFAS. Before EPA moves forward with using the Hazard Index, the agency has a responsibility under SDWA to fully assess the cost-benefit implications of such a proposal on drinking water agencies.

ACWA suggests EPA allow for additional data, such as the completed fifth Unregulated Contaminant Monitoring Rule (UCMR 5) data, to better influence the unproven Hazard Index approach in drinking water.

EPA Response: Please see section 13.3.2 of the EPA response in this *Response to Comments* document for discussion of costs estimated for Hazard Index PFAS. Because the EPA has evaluated both quantifiable and nonquantifiable costs and benefits associated with the Hazard Index MCL and individual MCLs for PFHxS, PFNA, and HFPO-DA, the EPA has conducted a "full SDWA cost-benefit analysis" for those MCLs. As discussed in sections 13.3.2 and 13.8 of the EPA response in this *Response to Comments* document, the agency quantified costs of the Hazard Index and individual MCLs for PFNA, HFPO-DA and PFHxS and listed anticipated nonquantifiable costs (see Tables 5-22 and 7-6 of the EA for an overview of nonquantifiable costs). The agency also quantified benefits for other PFAS in the regulation where there was sufficiently robust information to do so (see Appendix K of the EA which discusses the EPA's evaluation of the impacts of PFNA on birth weight in a quantitative sensitivity analysis) and has discussed the extensive nonquantifiable benefits associated with reducing these PFAS in drinking water. After considering this and other comments, the EPA conducted a sensitivity analysis of Hazard Index and individual MCLs for PFNA, HFPO-DA and PFHxS costs at the national level. Please see section 13.3.2 of the EPA response in this *Response to Comments* document for further discussion. For responses to comments on the Hazard Index standard itself, please see section 5.2 of the EPA response in this *Response to Comments* document. In response to the commenter's suggestion that the EPA "allow for additional data, such as the completed fifth Unregulated Contaminant Monitoring Rule (UCMR 5) data", please see section 6.8 of the EPA response in this *Response to Comments* document. Based on public

comments, the EPA is also regulating PFHxS, PFNA, and HFPO-DA individually in addition to under the Hazard Index approach; please see section 5.3 of the EPA response in this *Response to Comments* document.

Alabama Water and Wastewater Institute (AWWI) (Doc. #1700, SBC-043509)

AWWI is concerned with the USEPA's novel use of the hazard index for regulatory compliance. The quantified health effects noted in the proposed PFAS regulation present and cite references to the health effects of individual PFAS compounds, such as PFOS and PFOA, but does not cite references to peer reviewed research into the quantified health effects based on the proposed hazard index calculation for the combination of multiple PFAS compounds (PFHxS, HFPO-DA, PFNA, and PFBS). AWWI would recommend that the USEPA consider the removal of the hazard index calculation as a primary drinking water regulation given the lack of cited documentation regarding the health effects based upon the combination of PFAS compounds used in the calculation.

EPA Response: In response to the commenter's recommendation that the EPA "consider the removal of the Hazard Index calculation as a primary drinking water regulation given the lack of cited documentation regarding health effects", the EPA disagrees; please see section V.B of the preamble for this action and sections 4.3 and 5.2 of the EPA response in this *Response to Comments* document for more information on the Hazard Index, including health effects.

The commenter is incorrect about the EPA not referencing peer-reviewed papers and assessments which discuss the health effects of these four PFAS and/or dose additivity of these PFAS. For example, the peer-reviewed Agency for Toxic Substances and Disease Registry (ATSDR) Toxicological Profile for Perfluoroalkyls (ATSDR, 2021) referenced in section III of the preamble for this action discusses health effects of PFHxS and PFNA, and peer-reviewed the EPA human health toxicity assessments of PFBS (USEPA, 2021a) and HFPO-DA (USEPA, 2021b), also referenced throughout section III of the preamble, discuss health effects of PFBS and HFPO-DA, respectively. Additionally, the EPA's mixtures framework document (USEPA, 2024f) and Hazard Index MCLG document (USEPA, 2024g), both of which are supporting documents for this NPDWR, discuss dose additivity and/or health effects of these PFAS. Please see section 4.3 of the EPA response in this *Response to Comments* document for discussion about health effects for PFAS included in the Hazard Index (e.g., section 4.3.3 in this *Response to Comments* document). Please specifically see section 4.3.1 of the EPA response in this *Response to Comments* document, which discusses PFAS dose additivity, including the scientific basis informing the EPA's decision to regulate these PFAS under the Hazard Index approach. In terms of *quantified costs and benefits* of Hazard Index PFAS, please see the EPA response to comment Doc. #1675, SBC-044933 in section 13.3.2 of this *Response to Comments* document. Please also see section 13.6 of the EPA response in this *Response to Comments* document for the EPA's responses to comments on nonquantifiable benefits of the PFHxS, PFNA, PFBS, and HFPO-DA and additional co-removed PFAS not included in this regulatory action.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044054)

32. EPA requests comment on the assumption that exceedances of HI PFAS not included in the national cost analyses (HFPO-DA, PFBS, and PFNA) will not significantly impact overall compliance costs and national costs estimates are, therefore, unlikely to be substantially underestimated.

a. Since EPA's other cost analyses are grossly underestimated, it is assumed that the costs of treatment for the additional analytes are greatly higher than anticipated.

EPA Response: Please see section 13.3.2 of the EPA response in this *Response to Comments* document.

Philadelphia Water Department (PWD) (Doc. #1709, SBC-053307)

Second, the occurrence data for PFAS in the HI raises questions that have a significant impact on the cost estimates. Under Section 5.3.1.1.1 of the EPA's "Economic Analysis", the EPA notes that a key parameter estimating the operating costs of GAC and IX is the expected bed life. PWD agrees with this assessment and understands that some uncertainty will always exist when estimating this parameter on a nationwide scale. However, EPA notes in Section 5.3.1.1.1.2 that removal of the PFAS compounds in the HI is estimated using only one PFAS compound, PFHxS, due to a lack of occurrence data. This lack of data for the other three compounds in the HI suggests that EPA may have over-estimated bed life in the "Economic Analysis." Given the competition of sorption sites in GAC and IX when there is co- occurrence of PFAS, results calculated based on only one PFAS compound would result in an overestimation for the life of the media.

EPA Response: The EPA included the potential additional costs of the Hazard Index and individual MCLs for PFNA, PFHxS, and HFPO-DA in both the proposed and final rule in a sensitivity analysis. As discussed in section 13.3.2 of the EPA response in this *Response to Comments* document, for the proposed rule, the EPA analyzed the quantifiable costs of the Hazard Index at the system level and, based on public comments received, for the final rule, the EPA conducted a sensitivity analysis of Hazard Index and individual MCLs for PFNA, PFHxS, and HFPO-DA costs at the national level, which can be found in Appendix N.3 of the EA.

The EPA disagrees with the commenter that the agency has overestimated the media bed life by calculating it based on "only one PFAS compound." SafeWater MCBC calculates bed life using a system of equations that considers the percent removal required for each PFAS that occurs at an entry point and has an MCL or other limit in the regulatory option, even if the contaminant occurs at a concentration below the regulatory limit. Including contaminants that are below their respective limits avoids exceedances resulting from chromatographic peaking, which is a potential consequence of competition that is discussed in greater detail in the *Technologies and Costs* document (USEPA, 2024d). Furthermore, for IX, the bed life equations incorporate total PFAS concentration along with percent removal of target contaminants and thus explicitly

account for competition. The equations for GAC do not incorporate total PFAS concentration. The analysis did not find total PFAS concentration to be statistically significant, likely because competition among PFAS was overwhelmed by competition/fouling from TOC (which typically occurs in the milligrams per liter range compared to the nanograms per liter range for PFAS). Nevertheless, multiple PFAS were present in all the underlying studies used to develop the bed life equations for both GAC and IX; none of the studies were single-solute studies. Therefore, the GAC equations implicitly include the effects of competition; the IX equations include competition both explicitly and implicitly.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046000)

In Table 41 (88 FR 18703), EPA states the UCMR 3 data for PFBS and PFNA are insufficient and that there are no UCMR 3 data for GenX available. If EPA does not have the data to support whether utilities will be out of compliance with the HI, then it cannot appropriately assume that these potential exceedances do not need to be part of the cost estimate. AMWA disagrees with EPA that excluding information on PFBS, PFNA, and Gen X occurrence in the national cost estimates is insignificant.

EPA Response: Please see section 13.3.2 of the EPA response in this *Response to Comments* document. The EPA notes that the commenter mischaracterizes the agency's assessment of PFBS and PFNA occurrence data. The EPA had insufficient data above the UCMR 3 reporting limits for incorporation of those chemicals into the Bayesian statistical model. This does not mean that the EPA cannot produce national-level estimates of PFBS and PFNA occurrence; it is merely using a different methodology that has more statistical uncertainty. The results of non-targeted state monitoring for PFBS and PFNA were used for national extrapolation. Please see section VI.F of the preamble for this action and section 10 of the PFAS *Occurrence and Contaminant Background Support Document* (USEPA, 2024a) for more discussion.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046002)

Costs associated with treating HI PFAS must be considered. This requires more knowledge on the nationwide occurrence of these compounds. The agency cannot assume that addressing the costs of PFOA and PFOS is sufficient when the additional four PFAS will be driving treatment decisions at some PWSs. It is incorrect for EPA to assume that designation of PFAS compounds as hazardous substances will result in insignificant costs of affordability. EPA's own analysis (tables 22 and 23 in the preamble) estimates that the total annual household cost could increase as much as 9.4% to 14% for GAC treatment, up to $100 more a year, if PFAS are designated as hazardous substances under CERCLA and hazardous constituents under RCRA. To say this increase is insignificant disregards hardships the public faces and the difficult financial situations many households are in, particularly in rural and less advantaged communities that will see the highest of these increases.

EPA Response: The EPA notes that costs associated with treating Hazard Index PFAS and individual MCLs for PFNA, PFHxS, and HFPO-DA were considered for both the proposed and final regulation. For a discussion of costs associated with treating PFNA, PFHxS, PFBS and HFPO-DA, please see section 13.3.2 of the EPA response in this *Response to Comments* document.

In response to the commenter's assertion on affordability, please see section 13.10 of the EPA response in this *Response to Comments* document. Further, the EPA would like to clarify that the agency did not assume "the designation of PFAS compounds as hazardous substances will result in insignificant costs" as stated by the commenter. In the EA for the proposed rule, the EPA concluded that and, with respect to small system affordability, "[a]lthough costs increase in this scenario, the increases are not significant enough to change the conclusions about affordability." As stated in the FRN for the final rule, PFAS-contaminated wastes are not considered Resource Conservation and Recovery Act (RCRA) regulatory or characteristic hazardous wastes at this time and therefore total costs reported do not include costs associated with hazardous waste disposal of spent filtration materials. Further, if finalized, the designation of PFOA and PFOS as CERCLA hazardous substances would not require waste (e.g., biosolids, treatment residuals, etc.) to be treated in any particular fashion, nor disposed of at any specific particular type of landfill. The designation also would not restrict, change, or recommend any specific activity or type of waste at landfills.

American Public Works Association (APWA) (Doc. #1584, SBC-047709)

Data Limitations and Uncertainties in the Cost Analysis below, given the available occurrence data for the other compounds in the proposed rule (PFNA, HFPO-DA, and PFBS) and the regulatory thresholds under consideration, EPA did not model national costs associated with potential HI exceedances as a direct result of these compounds; therefore, the additional treatment cost, from co-occurrence of PFNA, HFPO-DA, PFBS or other PFAS, at systems already required to treat because of PFOA, PFOS, or PFHxS MCL and HI exceedances are not quantitatively assessed in the national cost estimates. Nor are treatment costs for systems that exceed the HI based on the combined occurrence of PFNA, HFPO-DA, PFBS, and PFHxS (where PFHxS itself does not exceed 9 ppt) included in the national monetized cost estimates.

EPA Response: Please see section 13.3.2 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1675, SBC-044933 in section 13.3.2 in this *Response to Comments* document.

Orange County Water District (OCWD), California (Doc. #1634, SBC-043237)

Hazard Index

EPA is proposing the first use of the Hazard Index concept to regulate four individual PFAS in drinking water beyond PFOA and PFOS. The Hazard Index chemicals were not included in the required cost-benefit analysis, in part because national occurrence data is unavailable. As such

neither EPA, water utilities, ratepayers, nor federal policymakers can accurately estimate the impacts of the Hazard Index. Cost-benefit analysis is one of the fundamental tenets of the SDWA, as its 1996 Amendments formally require a Health Risk Reduction and Cost Analysis in support of any national primary drinking water regulation. Furthermore, an economic analysis is required for all significant federal rules under Executive Order 12866. EPA should not move forward with the Hazard Index until it has satisfied its statutory and policy obligation to conduct a cost-benefit analysis.

EPA Response: Please see section 13.3.2 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1675, SBC-044933 in section 13.3.2 in this *Response to Comments* document.

New York State Department of Health (NYS DOH) (Doc. #1677, SBC-044957)

19. The HI approach encompasses at least one chemical (PFBS) that is likely to have reduced retention and more rapid breakthrough than the long-chain PFAS. It is unclear if the operation and maintenance costs for PFBS changeout have been considered separately and if there is sufficient science to support such an analysis. Based on data available to New York State, it is unlikely, however, that PFBS will be the driver for media changeout at the 2,000 ppt health-based water concentration.

EPA Response: Please see section 13.3.2 of the EPA response in this *Response to Comments* document. For GAC, the EPA agrees that PFBS can break through more rapidly than longer-chain PFAS. For IX, functional group (sulfonate versus carboxylate) appears to be more significant than chain length. Therefore, the EPA's bed life equations for IX estimate that PFBS would break through more rapidly than PFOS, but less rapidly than PFOA, all other conditions being equal. The EPA did not have data to include PFBS in the national analysis but considered it in a supplemental cost analysis (Appendix N.3 of the EA). Based on this supplemental analysis, the EPA agrees that PFBS is unlikely to be a driver for media changeout at the HBWC for the final rule.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045998)

Section 8.11: Cost of hazard index PFAS

As detailed in Section 3.2 above, there may be systems that have one or more of the four PFAS Health Index chemicals driving their treatment response, particularly if they do not have PFOA or PFOS. Therefore, there will be significant costs associated with treating for them.

EPA's assumption that costs associated with compliance with the HI PFAS must be reexamined. If EPA does not have the proper data to quantify the number of systems with HI PFAS and undetectable levels of PFOA and PFOS, then it is inappropriate for EPA to assume the cost is not significant. As mentioned in section 3.2, some AMWA members have indicated that HI PFAS are either the driver of treatment decisions when co-occurring with PFOA and/or PFOS or are the

only PFAS with detectable concentrations at their utility. This means the HI PFAS are responsible for some or all the costs of treatment at several large utilities. EPA cannot say the costs of treating the four HI PFAS are insignificant until they have a nationwide dataset that assesses the number of systems affected by each of the six PFAS included in this proposal.

EPA Response: Please see section 13.3.2 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1591, SBC-042373 and Doc. #1675, SBC-044933 in section 13.3.2 in this *Response to Comments* document.

Orange County Water District (Doc. #3072-54, SBC-047389)

Finally, EPA's proposing the first use of the hazard index to regulate four individual PFAS. Our concern is that the hazard index was not included in the required cost-benefit analysis and thus neither EPA nor water utilities and the rate payers understand the true impact of the proposed regulation. Cost-benefit analysis is one of the fundamental tenants of the Safe Drinking Water Act, as the 1996 Amendments formally require a health risk reduction and cost analysis in support of any National Primary Drinking Water Regulation. Furthermore, an economic analysis is required for all significant federal rules under Executive Order 12866. EPA shouldn't move forward with the hazard index until it has satisfied its statutory policy obligation to conduct the cost-benefit analysis. We appreciate the opportunity to participate in the public hearing. Thank you.

EPA Response: Please see section 13.3.2 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1591, SBC-042373 and Doc. #1675, SBC-044933 in section 13.3.2 in this *Response to Comments* document.

San Antonio Water System (SAWS) (Doc. #1570, SBC-042484)

As stated in the proposed rule, there is insufficient data to quantify the costs associated with HFPO-DA, PFNA, and PFBS. Without a complete data set, these should be further evaluated prior to publishing this rule.

EPA Response: Please see section 13.3.2 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1675, SBC-044933 in section 13.3.2 in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1711, SBC-044465)

[The Agency's proposal suffers from the following significant shortcomings –]

• EPA has not provided data to support its analysis of benefits predicted from the implementation of the HI MCL,

EPA Response: Please see section 13.3.2 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1675, SBC-044933 in section

13.3.2 in this *Response to Comments* document for responses to comments regarding costs associated with Hazard Index PFAS. Additionally, while the EPA's national benefits analysis solely quantifies health benefits for PFOA and PFOS, the EPA has qualitatively summarized the potential health benefits resulting from reduced exposure to PFAS other than PFOA and PFOS, including the PFNA, PFHxS, PFBS and HFPO-DA, among others. The EPA has used the best scientific information available to describe the nonquantified adverse health effects anticipated with reduced exposure to these PFAS and, in addition, performed a quantitative sensitivity analysis on PFNA birth weight effects using a model system approach. For further discussion of the nonquantifiable benefits anticipated to result from the final rule, please see Section 6.2.4 of the EA (USEPA, 2024b). For more information on the EPA's PFNA/birth weight sensitivity analysis methodology and results, please see Appendix H of the EA (USEPA, 2024c).

American Chemistry Council (ACC) (Doc. #1711, SBC-044463)

[The Agency's proposal suffers from the following significant shortcomings –]

• EPA does not have sufficient occurrence data for three of the substances to serve as a basis for estimating costs of compliance with its proposed HI MCL,

EPA Response: Please see section 13.3.2 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1675, SBC-044933 in section 13.3.2 in this *Response to Comments* document.

The Chemours Company FC, LLC (Doc. #1845, SBC-046055)

III. EPA's cost-benefit analysis is fundamentally flawed

Section 1412(b)(4)(C) of the SDWA requires that any proposed MCL be justified by a cost-benefit analysis: "At the time the Administrator proposes a national primary drinking water regulation under this paragraph, the Administrator shall publish a determination as to whether the benefits of the maximum contaminant level justify, or do not justify, the costs based on the analysis conducted under paragraph (3)(C)."

In an attempt to meet that requirement, EPA has accompanied its proposed regulatory framework with a purported cost-benefit analysis covering six substances— PFOS, PFOA, and the four included in the proposed HI. But particularly for the latter four, and especially for HFPO-DA, the analysis is fundamentally flawed, because having proceeded with regulation before even the preliminary UCMR results are available for HFPO-DA, EPA has no basis as to what the costs of the proposed MCL would be. In the absence of data on the occurrence of HFPO-DA, EPA simply does not know what the costs of compliance will be.

Indeed, EPA acknowledges that it does not have the data to calculate the impact of its proposed HI approach. In its Economic Analysis,[FN33: U.S. EPA, EPA Document No. EPA-822-P-23-001, Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation (March 2023) (emphasis added).] EPA states:

"EPA has estimated the national level costs of the proposed rule associated with PFOA, PFOS and PFHxS. There are limitations with nationally representative occurrence information for the other compounds in the proposed rule (PFNA, HFPO-DA and PFBS), therefore the additional treatment cost, from co-occurrence of PFNA, HFPO-DA, PFBS or other PFAS, at systems already required to treat because of PFOA, PFOS, or PFHxS MCL and HI exceedances are not quantitatively assessed in the national cost estimates. Nor are treatment costs for systems that exceed the HI based on the combined occurrence of PFNA, HFPO-DA, PFBS, and PFHxS (where PFHxS itself does not exceed its HBWC of 9.0 ppt) included in the national monetized cost estimates."

Because EPA assumed in its quantitative cost analysis that an HI-based MCL would not add to the nationwide estimated treatment costs, those costs are, as EPA acknowledges, underestimated: "In instances when concentrations of PFBS, PFNA, and/or HFPO-DA are high enough to cause a hazard index exceedance, the modeled costs may be underestimated. If these PFAS occur in isolation at levels that affect treatment decisions, or if they occur in sufficient concentration to result in an exceedance when the concentration of PFHxS alone would be below the HI, then costs would be underestimated."[FN34: Id. (emphasis added).]

EPA has included analysis of "system level" costs that could result from the HI proposal, but those costs are speculative at best, and do not address the overall costs that will be incurred as a result of the proposal. Nor does the analysis meet the cost-benefit requirements of Section 1412(b)(4)(C). This is particularly befuddling because, as discussed above, significant portions of the data that EPA is now missing will be available soon.

EPA Response: Please see section 13.3.2 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1675, SBC-044933 in section 13.3.2 in this *Response to Comments* document discussing how the EPA met its obligations to conduct the HHRCA under SDWA. Please see section 13.8 of the EPA response in this *Response to Comments* document for response to comments regarding the Administrator's determination that the benefits of the rule justify its costs.

13.3.3 Water System Costs – Treatment (excluding disposal)

Summary of Major Public Comments and EPA Responses

Many commenters state that the EPA has underestimated the treatment costs required to comply with the proposed PFAS NPDWR. One commenter suggested that the EPA has not complied "with its statutory requirements by conducting an analysis that fully captures these costs." The EPA disagrees with the few commenters that suggested the EPA has not met its requirements under SDWA, and the EPA emphasizes the agency has used the best available peer reviewed science to inform its cost estimates, including treatment costs, of the PFAS NPDWR. Specific aspects of comments related to treatment costs and the EPA's response are discussed below.

Many commenters cited rising costs in the drinking water sector and discussed the effects of inflation and the COVID-19 pandemic on the costs of labor, construction, and capital, among

other materials related to compliance with the PFAS NPDWR. These commenters emphasized the significant impacts felt from supply chain and workforce issues. The EPA recognizes these impacts, and as recommended by commenters, adjusted the cost estimates by escalating unit costs using indices including the Bureau of Labor Statistics producer price indices (USBLS, 2010). The EPA updated each unit cost using the change in the relevant price index from year 2020 to 2022. For example, the EPA applied the percent increase of the price of metal tanks and vessels (50 percent increase from 2020 to 2022) to the price of metal tanks and vessels in the WBS cost models. The EPA also collected new vendor price quotes for cost driver equipment components (e.g., pressure vessels, treatment media) and made several other adjustments to WBS model assumptions, described below. Taken together, these adjustments increased the system level capital cost estimates in the EPA's cost assessment by a percentage that varied depending on the system size and treatment technology. For small systems using GAC and IX, the increase ranged from approximately 40 percent to 110 percent. For medium systems, the increase was approximately 20 to 60 percent; for large systems, 10 to 40 percent. Additionally, while revising the SafeWater model to incorporate new information from public comments, the EPA identified and corrected a coding error related to the discounting of future operation and maintenance costs resulting in increased estimated annualized treatment costs. The result of these changes are increased cost estimates for the final rule.

Some commenters stated that the EPA "…should also take into consideration that this regulation will create significant demand for certain PFAS treatment and products, likely driving up the costs for the installation and maintenance of all PFAS treatment." These commenters specifically cited increased demand for specialized treatment design, construction work, activated carbon, disposal, engineering consultants, planners, contractors, among others, that would lead to an increase in costs associated with the rule. One commenter discussed "the adverse cost impacts of extremely high numbers of public utility and other infrastructure projects being attempted over the next five-to-ten years given high federal grant and loan appropriations activity in these areas." The EPA disagrees that treatment capital, operation and maintenance costs and other rule associated costs are likely to increase significantly as a result of heightened demand. As discussed in section XI.D of the FRN, the EPA is authorizing a two year nationwide capital improvement extension for all systems nationwide to comply with the MCLs. This means that water systems must demonstrate compliance with the MCLs by five years following rule promulgation, rather than three years as proposed, and the EPA expects this will allow additional time for supply, where lacking, to meet demand for treatment technologies and associated contracting and engineering services. Further, the EPA anticipates that the demand created by the rule will be spread over multiple technologies (BATs and small system compliance technologies, or SSCTs) as well as non-treatment options. These multiple routes to compliance will alleviate any price pressure that would otherwise be put on any single media or treatment action as demand will be spread out amongst them. Comments from a major BAT supplier indicated excess capacity as well as investment in production (see comment Doc. #1620, SBC-042939). Furthermore, the EPA expects that structural demand increase will lead to supply increases as well as innovation such as proposed technologies which were not designated as BATs. This has been historically demonstrated multiple times in prior drinking water rules; for further

discussion, please see section 10 of the EPA response in this *Response to Comments* document. Lastly, the EPA anticipates that there is currently more than enough existing disposal capacity to meet the needs of the final rule and therefore disagrees disposal prices are likely to increase; for more information and the EPA's response to comments on disposal capacity, please see section 10 of the EPA response in this *Response to Comments* document.

Many commenters shared some information about the costs that they have incurred or estimated they would incur at a system level to install, operate, and maintain treatment to remove PFAS. Some system level cost information provided by commenters fell within the ranges of costs presented in the EPA's supporting documentation for the proposal and other information provided by commenters exceeded the EPA's system level cost ranges. The EPA does not dispute the commenters' stated experience of costs to install, operate and maintain treatment to remove PFAS; however, many of these comments lacked supporting details. Many of the comments cited preliminary or conceptual estimates and did not specify the methods and assumptions used to develop the estimate. Furthermore, most comments did not include information to confirm that all of the reported or estimated costs were or would be directly associated with PFAS treatment, as opposed to other infrastructure improvements (e.g., capacity expansion, administrative facilities, distribution system improvements) completed as part of the same project. Most commenters also did not include information to confirm that key design and operating parameters (e.g., empty bed contact time, media replacement frequency) would be similar to the typical values assumed in the EPA's estimates. To fully evaluate the commenters' reported or estimated costs in comparison to WBS model results, the EPA would need itemized line-item cost details and engineering design parameters. To inform the cost estimates of the proposed and final PFAS NPDWR, the EPA conducted an extensive review of the literature. The EPA has further validated the unit costs in the PFAS rule with equipment cost information from 2023 from a major supplier of treatment media. While the EPA recognizes there are likely site-specific instances where costs exceed the EPA's cost ranges, there are also likely site-specific instances where costs are less than the EPA's cost ranges, and this level of accuracy is appropriate for a national level analysis.

Other commenters compared state-level costs to the EPA's national level cost estimates, noting that the EPA's estimates appeared too low. Utilizing this permit data and project cost data submitted by water systems in applications to the DWSRF, one state estimated that total capital costs for installation of PFAS treatment to meet the EPA's proposed standards across the state could be as high as $1.065 billion. The EPA's EA analysis, however, presents national level cost estimates that are annualized over the period of analysis and are therefore not directly comparable to a single year estimate of capital costs.

A few commenters stated that the EPA incorrectly omitted the costs associated with performance monitoring, which commenters believe will be necessary because a water system needs to know how often it needs to replace its media. The EPA disagrees that large amounts of additional samples in performance monitoring will be required, and the commenter provided no data to support their assertion that this would be necessary. The EPA anticipates that many water systems will conduct a pilot test before implementing a full-scale treatment installation and that

the operational results from the pilot test will be a sufficient indicator of performance; therefore, water systems should not have to collect large amounts of performance samples indefinitely during the full-scale operation of treatment technologies. The EPA includes the costs of pilot testing, and sampling during that time, in the treatment capital cost estimates. In response to public comments, the EPA increased the estimated length of the pilot study and the frequency of sampling during the pilot study. Additionally, the EPA added a full year of confirmation sampling after full-scale installation to the estimated pilot study costs. Taken together, these changes doubled to more than tripled the pilot study costs included in the EPA's estimates.

In response to public comments about residual management concerns for high pressure membrane technologies, the EPA has adjusted RO/NF's technology projection compliance forecast to 0 percent in the EA for the final rule. Therefore, the EPA assumes that RO/NF will not generally be used solely for the purpose of complying with the final rule. For more information on public comments on residuals management and the EPA's response, please see section 10 of the EPA response in this *Response to Comments* document.

A few commenters stated that the EPA underestimated or insufficiently incorporated contingency in its cost estimates. For example, one commenter stated that the EPA's contingency assumptions in the proposal were "…inconsistent with recommended best practices for cost estimators and [are] expected to be a major contributor to the EPA WBS' failure to accurately capture costs for PFAS treatment facility implementation." In response to these comments, the EPA changed its approach and incorporated contingency for all systems, not just high-cost systems. The EPA also increased the complexity factor applied to estimate contingency for systems using GAC. Taken together, these changes result in a contingency factor of 5 to 10 percent depending on total project cost at all cost levels for systems installing treatment. Additionally, the EPA includes a miscellaneous allowance of 10 percent. This allowance can be viewed as either as a form of contingency or a method to increase the level of project definition (thus reducing the amount of contingency required).

Many commenters cited and expressed agreement with the conclusions of a study conducted by Black & Veatch on behalf of the American Water Works Association (AWWA) (hereafter referred to as AWWA's B&V report) (AWWA, 2023). The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs of the PFAS NPDWR. The tables below detail some of the key assumptions related to 1) PWSs that exceed the MCL, 2) capital costs and 3) operation and maintenance costs that overestimate national treatment costs in AWWA's B&V report and the EPA's response to those assumptions and resulting estimates. In combination, all these factors result in an overestimate of treatment costs. For example, AWWA's B&V report Table 6-1 reports an average capital cost per entry point EPTDS for the smallest size category of $900,000. Using AWWA's B&V report's (overestimated) design flow calculations, the treatment system design flow at each EPTDS would be approximately 0.062 million gallons per day (mgd). For comparison, Forrester (2019) reports capital equipment costs of approximately $300,000 for a 1 mgd GAC PFAS treatment system. Even after adding indirect capital and building costs, the $900,000 estimate appears substantially overestimated, given that it is for a treatment system designed for approximately

1/16th of the flow of the system in the Calgon estimate (Forrester, 2019). When AWWA's B&V report's EPTDS level results are aggregated nationally to an overestimated number of systems treating for PFAS, the overestimates are compounded at the national level.

The EPA Response to assumptions about PWSs exceeding the MCLs in AWWA's B&V Report

Analytical Component	AWWA's B&V report	EPA response
PFAS occurrence estimates	Used an occurrence dataset comprised of UCMR 3 and information from state regulatory agencies. Estimates the following number of water systems will exceed 4.0 ng/L PFOA and/or PFOS: Serving 10,000 or less: 7,056 PWS (8,808 EPTDS) Serving more than 10,000: 393 PWS (1,214 EPTDS) Total PWSs: 7,449 PWSs (10,022 EPTDS)	The dataset used is not appropriate for national extrapolation, for example, 90 percent of non-UCMR systems used in the report come from just 6 states. As a result, AWWA's B&V report likely overestimates the number of water systems exceeding the MCLs, particularly small water systems. After incorporating updated state monitoring data into its occurrence model, the EPA estimates the following number of water systems will exceed 4.0 ng/L of PFOA and/or PFOS (**mean** (5th-95th from Chapter 4.4 of the EA): Serving 10,000 or less: **3,870** (2,795-5,097) PWS **5,11**5(3,666-6,858) EPTDS Serving more than 10,000: **1,266** (1,203-1,328) PWS **3,878** (3,701-4,056) EPTDS Total PWSs: **5,136** (4,018-6,441) PWSs **8,993** (7,497-10,711)EPTDS AWWA's B&V report did not specify, what measures, if any were taken to ensure the data was nationally representative and this may be one cause of their overestimation of water systems exceeding the MCLs. The EPA used QC measures to ensure that the data represented finished drinking water and that the set of systems used to inform the model was nationally representative. Additional state data that were available at systems that were part of this nationally representative set of systems were used to fit the model. For more information, see section VI Occurrence of the preamble for the final rule.
Number of EPTDS installing treatment	Assumes every EPTDS a system will require treatment regardless of whether a given EPTDS exceeds the MCL.	This is an incorrect assumption and likely leads to a significant overestimate of national costs. A single water system often have EPTDS that use different water sources, and therefore have different PFAS concentrations. The EPA conducted an EPTDS-level cost analysis as compliance with the rule is determined at the EPTDS-level and treatment is installed at the EPTDS-level.

Analytical Component	AWWA's B&V report	EPA response
PWSs in states with existing PFAS regulations	Includes estimates of the costs to PWSs to comply with existing state PFAS regulations; and does not assume that PWSs are already in compliance with state standards.	This approach overestimates costs for water systems in states with existing state standards. The EPA adjusts the baseline by setting the maximum pre-regulation concentrations equal to the state MCL for systems in states with promulgated regulations. This allows the EPA to capture the incremental costs of the PFAS NPDWR more accurately.
Non-treatment options	Assumes all exceeding EPTDS will install a treatment technology to comply with the PFAS NPDWR.	This assumption overestimates costs, as the EPA is aware of a number of water systems that have elected to drill a new well to reduce PFAS concentrations in supplied water. Another commenter pointed out that Michigan expects up to 26 percent of water systems to interconnect with other systems to comply with their state standard. Other commenters pointed out the viability of interconnection and new wells as compliance options will vary regionally, and the EPA agrees. Nevertheless, the absence of these options entirely in AWWA's B&V report overestimates national costs.

The EPA Response to key capital cost assumptions in AWWA B&V Report

Analytical Component	AWWA B&V report	EPA response
Equipment lifespan	Assumes a fixed life cycle cost using a fixed 20-year lifespan for all capital equipment.	A 20-year lifespan may be reasonable for very small systems but based on the composite useful life of treatment systems derived from the useful lives of individual treatment system components and industry information, the EPA estimates that treatment system useful life can be 30 years or more for medium to larger systems using more durable materials of construction.
Contingency factors	Includes a contingency factor of 4 percent under contractor markup and an additional contingency factor of 30 percent under non-construction costs.	The inclusion of contingency twice is unusual and may not reflect actual realized contingency costs at project completion. A Construction Industry Institute (2001) study found that projects of $100 million or less incurred only 74 percent or less of the contingency initially budgeted. The EPA updated its approach to incorporate a contingency factor of 5 to 10 percent depending on total project cost at all cost levels for systems installing treatment. The EPA also included a miscellaneous allowance of 10 percent, which can be considered a form of contingency.
Building costs	Assumes a fixed unit cost of $200/square foot for buildings.	AWWA's fixed unit cost likely overestimates actual building costs, particularly for small systems that may not require complex or architecturally detailed buildings. The EPA estimates that building costs vary depending on building quality and square footage and range from $57/square foot to $204/square foot.
Pumping and backwash assumptions	Assumes that all GAC and IX treatment systems require a new influent pumping station, and all GAC and IX treatment systems require new backwash pumps.	AWWA's assumptions overestimate costs as many systems, including small groundwater systems, likely have sufficient existing influent pumping pressure to cover the additional head loss. Some systems using GAC (especially small systems) may not need a dedicated new backwash pump

Analytical Component	AWWA B&V report	EPA response
	Except for the two smallest size categories, assumes all GAC and IX treatment systems require backwash recovery basins providing 20 feet of water depth.	and may be able to accomplish backwash using existing influent or treated water pumps. In applications using PFAS-selective IX resins, periodic backwashing is not recommended (Berretta et al., 2021), so the need for these pumps is questionable and the assumption overestimates costs.
Capital equipment costs	The Association of Metropolitan Water Agencies (AMWA) and the AWWA surveyed its members to obtain recent cost data on installed PFAS treatment systems at drinking water treatment plants.	The EPA updated its equipment costs to 2022 dollars using current price indices. The EPA also collected new vendor price quotes for cost driver equipment components (e.g., pressure vessels, treatment media) and made several other adjustments to WBS model assumptions about pilot study costs and contingency costs that increased total capital costs. The B&V model, as presented in Figure 7-1 of AWWA's public comment letter, appears to overestimate costs for many of the case studies included in the B&V report. For example, it results in higher costs for 28 of the 32 case studies (88 percent) shown in Figure 7-1. The EPA assessed the WBS model results in comparison to the costs of GAC equipment packages from 2023 supplied by a nationally recognized vendor of GAC media and GAC treatment systems. Based on this assessment, the EPA concluded that the direct capital costs in the WBS model for comparable packages of equipment, excluding items the vendor does not supply, range from 23 percent lower to 19 percent higher than the vendor costs and with two exceptions, they are within 10 percent of the vendor costs.
Small system capital costs	Listed capital costs for small systems ranging from $900,000 to $5,300,000.	The EPA accounts for the use of package systems. AWWA Appendix B Table 3-1 indicates that their pressure GAC model accepts treatment capacity inputs from 1 to 12 mgd. It does not indicate how the model handles design flows less than 1 mgd. It is possible that the parametric estimates the model uses are not a good fit below this threshold and does not account for the use of package systems.
Average and design flow estimates	Service population data from SDWIS was used and the average flow for each PWS was assumed based on a per capita per day usage of 150 gallons. Peaking factors for different size systems from the EPA's "Cost and Technology Document for Final Groundwater Rule" were used.	Estimated design flow of a water system effects the size and cost of the capital equipment that will be installed on site. Average flow estimates are the driver for many operational costs. AWWA's approach to estimating design and average flow requirements overestimates the treatment system flow requirements, particularly for smaller systems. For the smallest systems, AWWA's approach overestimates flows by up to 30 percent. The EPA estimated the average daily flow and design flow for drinking water systems based on the empirical relationship between retail population served and flow. This relationship was derived using the data collected via the CWSS. It is reported in the EPA's Geometries and Characteristics of Public Water Systems report (USEPA, 2000). As detailed in Table 4-34 of the EA for the final rule, water use efficiency has increased substantially since these relationships were developed, and therefore the trend of lower residential water use could

Analytical Component	AWWA B&V report	EPA response
		result In lower flow per population and lower treatment costs as compared to predicted values in the EPA's analysis.

The EPA Response to key operation and maintenance cost assumptions in AWWA B&V Report

Analytical Component	AWWA B&V report	EPA response
bed life	The BV values utilized for GAC were derived from data collected during a Black & Veatch GAC pilot study for Cape Fear Public Utility Authority (CFPUA). The values utilized for IX were derived partially from data collected during a Black & Veatch IX pilot study for CFPUA and partially from data collected during an IX pilot study for La Habra Height County Water District.	AWWA estimates bed life for all systems using parameters derived from one or two pilot studies. These site-specific pilot studies may not be representative of the range of water quality conditions experienced by systems across the country. For GAC in particular, using the parameters in AWWA's Table 5-9 results in estimated bed lives of less than 7,000 and 9,000 BVs for 90 percent removal of PFOA and PFOS respectively. These short bed life estimates result in high annual operating costs and may be an artifact of the relatively high influent TOC in the CFPUA pilot study that is the basis of AWWA's estimates. Surface and groundwater systems with more moderate to low influent TOC would be expected to experience much longer GAC bed life and lower operating costs.
Disposal of treatment media	Assumed that spent GAC media would be incinerated "because of the unknown viability of GAC media reactivation under CERCLA." Replacement costs were therefore assumed to be virgin media.	The EPA has proposed PFOA and PFOS be designated as hazardous substances under CERCLA and is in the process of proposing some PFAS be listed as hazardous constituents under RCRA. If finalized, these actions would not require waste (e.g., biosolids, treatment residuals, etc.) to be treated in any particular fashion, nor disposed of at any specific particular type of landfill. The designation and listing also would not restrict, change, or recommend any specific activity or type of waste at landfills. However, waste management facilities may, at their own discretion, refuse to accept PFAS-containing materials or drinking water treatment operations may choose to send spent GAC and resin containing PFAS to facilities permitted to treat and/or dispose of hazardous wastes. Even where reactivation is not feasible, disposal in a RCRA permitted hazardous waste landfill is expected to be a more cost-effective option than incineration. Therefore, the assumption of incineration and replacement with virgin media overestimates the disposal costs in the B&V report.

A few commenters stated that the WBS model results were inaccurate because the models "…were developed from 2006 to 2012" and/or underwent peer review more than 10 years ago. WBS model development did not cease in 2012. The EPA has continued to maintain and update

the models throughout the intervening years. This maintenance includes updating unit costs on an annual basis and incorporating the latest results from the scientific literature on treatment design and effectiveness for emerging contaminants like PFAS. For example, for the final rule, the EPA updated unit costs and made changes to model design parameters as described in the paragraphs above. Also, although initial external peer review of the models used for this rule took place more than 10 years ago, the EPA has conducted internal quality assurance review on an ongoing basis as part of the regular update cycle. Versions of the model incorporating annual updates have been available for external review and public use on the EPA's website since approximately 2016. The versions used to support this proposed rulemaking were available for review in the docket for this proposed regulation; likewise, the versions updated after considering public comments are available in the docket for this final action. All design parameters, including specific adjustments to estimate the cost of PFAS treatment, are also described in detail in the supporting documentation, included in the docket. The EPA further notes that there is no indication that the B&V cost model has been peer reviewed and has relatively limited publicly available associated documentation.

Individual Public Comments

U.S. Chamber of Commerce (Doc. #1537, SBC-042649)

• The Safe Drinking Water Act requires consideration of the costs and benefits. The Chamber submitted a report to the Office of Management and Budget (OMB) modelling the potential costs attributable to various drinking water treatment levels. The estimated annualized costs for a proposed MCL of 4 ppt for PFOA and PFOS are approximately $1.8 billion annually and are more than twice as much as the EPA estimated costs in their economic analysis. Our cover letter to OMB and the report are here and here. The significant costs and impacts and their connection to other elements of the PFAS Strategic Roadmap, such as the proposed hazardous substance designation under CERCLA demand a full vetting by the stakeholder community.

This modelling effort developed the costs related to various drinking water treatment at 70 ppt, 20 ppt, 10 ppt, 4 ppt, and non-detect:

• The non-detect level costs are orders of magnitude higher than the other costs at almost $60 billion.

• At 4 ppt, which is at the lowest level of detection we found that the costs are approximately $32.5 billion over 20 year project implementation and operations and maintenance.

• AWWA's estimates were more significant – as high as $50 billion for 20 ppt.

EPA Response: The EPA disagrees with the many of the assumptions and approaches in the commenter's report "Potential Costs of Meeting Safe Drinking Water Act (SDWA) Standards for PFOA and PFOS" (US CC, 2022) referenced in their comment letter submitted on the proposed PFAS NPDWR. The report lacks the detailed documentation required to conduct a

complete review of the commenter's methodology, however the EPA notes the following key limitations with the approach that the commenter uses to estimate national costs.

1) The commenter utilized a dataset from which they state 95 percent of the dataset is limited to 8 states to estimate the number of water systems expected to exceed various PFAS thresholds. Use of non-nationally representative data is likely to bias the commenter's results. The EPA used QC (quality control) measures to ensure that the state data utilized in the agency's model was nationally representative. The commenter's report does not appear to present the estimated number of water systems exceeding each threshold. The number of water systems expected to install treatment is a key driver of national costs, without which is it difficult to compare to the EPA's national cost estimates.
2) The commenter assumes all PWSs that install treatment will use GAC. The EPA's cost analysis for the proposed and final rule more accurately includes the range of BATs and SSCTs available to PWS, as well as non-treatment options to comply with the rule.
3) The report relies on GAC capital costs provided in 2021 by California's State Water Resources Control Board (SWRCB). Very little information is provided about the design parameters used to develop these estimates or the scope of equipment included. However, the first three cost estimates shown in Table 2 assume the use of a single vessel. For treatment of PFAS, design engineers and GAC vendors commonly recommend two vessels in series. The assumption of a single vessel suggests that the GAC capital costs used in the report are generic estimates, not specific to treatment of PFAS.
4) The table below compares the equipment costs from Table 2 of the report to costs for GAC equipment packages supplied by a nationally recognized vendor of GAC media and GAC treatment systems. The vendor packages are identical to those in Table 2 in terms of diameter, number of vessels, and GAC mass per vessel. The costs used in the report are several times higher than the vendor costs. The costs used by the commenter are not likely to be representative of costs nationwide. Equipment prices in California are likely to differ from other parts of the country, and it is under what is included in "GAC equipment."

Vessel Diameter (ft x vessels)	GAC Mass (lb/vessel)	Equipment Cost from SWCRB (2021)	Equipment Cost from GAC Vendor (2023)	Difference
6 x 1	6,000	$ 437,000	$ 120,000	264%
8 x 1	10,000	$ 536,000	$ 130,000	312%
12 x 1	20,000	$ 745,000	$ 180,000	314%
12 x 2	20,000	$1,490,000	$ 370,000	303%

5) The report assumes GAC system operation and maintenance (O&M) costs are $280 per million gallons. The source of this assumption is cited as the EPA's WBS model. It is unclear how the report derived a single value from the WBS model. O&M costs from the EPA's WBS model for GAC can vary dramatically depending on input parameters,

primarily bed life and average flow. The report's estimate of $280 per million gallons is near the low end of the range of O&M costs generated by the WBS model for the final PFAS rule.

6) The report assumes GAC system operation and maintenance (O&M) costs are $280 per million gallons. The source of this assumption is cited as the EPA's Work Breakdown Structure (WBS) model. It is unclear how the report derived a single value from the WBS model. O&M costs from the EPA's WBS model for GAC can vary dramatically depending on input parameters, primarily bed life and average flow. The report's estimate of $280 per million gallons is near the low end of the range of O&M costs generated by the WBS model for the final PFAS rule.

Items #3 and #6 are likely to underestimate national treatment costs. Items #2, #4, and #6 are likely to lead to a significant overestimation of national treatment costs. Absent more information, the effect of item #1 is unknown. The commenter concludes that "the estimated annualized costs for a proposed MCL of 4 ppt for PFOA and PFOS are approximately $1.8 billion annually." Collectively, the EPA disagrees with many of the assumptions in the report and the report's overall conclusions about the estimated national costs. The EPA notes that in response to comments received on the agency's cost analysis for proposal, the agency has made a number of changes to the treatment cost analysis, detailed in section 13.3.3 of the EPA response in this *Response to Comments* document.

In response to the commenter's reference to AWWA B&V estimates of national costs, the EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document for more details.

Bowling Green Municipal Utilities (Doc. #1767, SBC-043932)

EPA's Cost Model Underestimates the Cost of the Proposed Rule: EPA underestimates the cost of drinking water treatment to remove PFOA and PFOS. Cost models prepared for AWWA by Black & Veatch as well as examples of previously built PFAS treatment systems differ significantly from EPA's model. EPA's benefit cost analysis must accurately evaluate the cost impact of the rule to make a sound decision on the appropriateness of the rule requirements.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-047718)

The EPA analysis also does not include an estimate of the cost for the largest sized systems which AWWA estimates face annual costs of over $50 million per system. Using AWWA's projection that four systems within this largest category will be required to come into compliance with the proposed regulation, the annualized cost for this size category exceeds $200 million. It

is not clear whether EPA's total cost estimate includes an estimate for systems in the largest size category since no data are provided.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document. Additionally, AWWA's comment letter does not provide information on the four systems expected to exceed the MCLs or information on how that was determined. The EPA's EA for the final rule included costs for two systems within the largest size category that each would need to install treatment at multiple entry points. The EPA reviewed UCMR3 data and recent system consumer confidence reports to obtain entry point PFAS values rather than model treatment costs using the PFAS occurrence values simulated from the MCMC model. The EPA used these values to determine which entry points at these systems exceed the MCLs and/or Hazard Index for the proposed rule and alternative options (see Appendix N of the EA for more information).

Western Urban Water Coalition (WUWC) (Doc. #1768, SBC-043942)

EPA also fails to consider and weigh the costs of additional sampling that will need to be conducted to evaluate selected treatment media for contaminant breakthrough.

EPA Response: The EPA included pilot testing costs in the treatment capital cost estimates for the proposed rule and further updated these costs for the final rule, including adding a full year of full-scale confirmation sampling. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045911)

Furthermore, EPA has likely underestimated the quantity of spent GAC that will require treatment. EPA identified proposed Bed Volumes for GAC that exceed the values that AWWA identified in their analysis. The generation rate of spent carbon is a function of bed volume and replacement frequency. EPA's cost estimate basis for bed volume was a range of 5,000 to 150,000 for GAC [FN154: 88 Fed. Reg. at 18695.]. AWWA's analysis limited the carbon life to a maximum of 40,000 bed volumes for GAC. Bed volumes directly impact operating costs of these systems; EPA's assumptions of longer bed volumes would result in incurring lower costs due to less frequent media exchange and disposal.

EPA Response: The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Horsham Water & Sewer Authority (HWSA) (Doc. #1686, SBC-043811)

Regarding operating costs, again EPA failed to use actual real data and the results are cost estimates that are low. For instance, EPA's model for the number of bed volumes (BVs) GAC can effectively treat for various PFAS compounds provided in EPA's Technologies and Costs for

Removing Per- and Polyfluorinated Substances (PFAS) from Drinking Water document to support this rule incredulously relies on a total of ten (10) waters, all of which were pilot data or benchtop data using Rapid Small Scale Column Testing (RSSCT), and for low Total Organic Carbon (TOC) waters such as most groundwaters, EPA only used data four (4) waters, all four being RSSCT data only. This despite EPA admitting on page 23 of this same document, that "there is no consensus in the literature regarding methods to scale up GAC from RSSCT to full-scale". Not surprisingly, when we use our real-world full-scale data to verify the accuracy of this model, we get drastically lower values for the number of BVs for all compounds we have breakthrough data for (PFOA, PFHxS, PHFpA, PFBS, and PFHxA). For instance, using the data for our Well 2 when the well was initially put in service with two (2) vessels in series using virgin GAC, once we received sampling data that showed breakthrough of PFHxA at the mid-point of the two vessels (weeks after the actual sampling data due to laboratory turnaround time), we began scheduling a change out of the first vessel, but it would take another five (5) months to get the GAC changeout completed. We continued to do monthly sampling and during the time from the PFHxA breakthrough to changeout we experienced the breakthrough of PFBS, PFHpA, PFOA and finally PFHxS such that we can conservatively calculate actual number of BVs using the sampling dates showing the first breakthrough (may have occurred earlier). The table below compares our actual BVs (the actual BVs may have been less than these numbers if the breakthrough occurred prior to the monthly sampling date) versus EPA's model equation.

[Table: see docket ID EPA-HQ-OW-2022-0114-1686]

The model results for the number of BVs needed are two (2) to three (3) times higher than our actual data for Well 2. The average for all 26 GAC changeouts we have performed to date at all our sites is 21,555 BVs which includes the average 4-5 months from breakthrough to changeout, so the Well 2 example above is on the long side for our typical filter run times. While it is recognized that the model was developed for national cost estimating purposes and not for use on individual waters, if the model does not even closely represent actual conditions the resultant cost estimates are flawed. We believe the EPA model greatly overestimates the efficiency of GAC for removing various PFAS compounds, particularly for low TOC waters such as ours, and therefore will greatly underestimate both overall national operating costs, and unfortunately small system operating costs in particular which use predominantly low TOC groundwaters. Not all data is equal in weight, and real-world full-scale data trumps pilot plant data, which in turn, trumps bench top/laboratory data. It is rather inconceivable that EPA chose to rely on such a limited data set from only four waters, all using RSSTs no less, which as EPA acknowledges, are questionable as to their relevance to full-scale applications, to develop their low TOC equation when we believe there is ample full-scale data such as ours available (EPA identifies 30 full-scale GAC systems in the report).

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document. Additionally, the commenter did not provide quantitative data on the percent removal or total organic carbon (TOC) concentration used to calculate the "EPA Model Calculated Bed Volumes" shown in the commenter's table, so the EPA cannot confirm that the

commenter's comparison is based on an accurate application of the bed life equations. Also, to compensate for potential overestimation when extrapolating from rapid small-scale column tests (RSSCTs) to full-scale, the EPA did not incorporate the increase in bed life that would be expected from operating multiple contactors in series when applying the results of the equations. In other words, the EPA converted the results of the equations in bed volume to bed life in units of time using a 10-minute empty bed contact time (EBCT), typical of a single vessel. The commenter did not indicate the EBCT of their treatment system, but if their bed volumes are calculated using a 20-minute total EBCT, typical of two vessels in series, they would be expected to be one half of the EPA's results for the same replacement frequency. The EPA used the best available, peer-review data in estimating bed life; see Chapter 5.3.1 of the EA for more information Finally, as the commenter points out, the equations were developed for national cost estimating purposes, not for use on individual waters, which may have water quality characteristics that result in longer or shorter bed life.

New England Water Works Association (Doc. #1836, SBC-045397)

Cost:

NEWWA believes that the technical memorandum [FN9: WITAF 56 TECHNICAL MEMORANDUM, PFAS National Cost Model Report, B&V PROJECT NO. 409850 https://www.awwa.org/Portals/0/AWWA/Government/2023030756BVFinalTechnicalMemoradum.pdf?ver=2023-03-14- 102450-257] prepared by Black & Veatch on behalf of American Water Works Association (AWWA WITAF 56) provides the most accurate depiction of the costs which will be incurred by utilities should EPA's proposal be finalized. We would urge EPA to revisit their cost assumptions as they significantly underestimate the true impact for communities. By comparison, the most recent estimate by Black & Veatch estimates that the annualized cost of the rule could exceed $3.2 billion based on a PFOA and PFOS MCL of 4 ppt each. NEWWA subsequently confirmed that the costs are underestimated in review of the EPA's cost analysis for different size systems with the results of a recent survey by Kleinfelder.

Kleinfelder's focused survey of New England utilities found that the median capital cost per million-gallons- per-day treated for PFAS removal (MGD) was $4.3 million. While it may be too soon to fully understand the impact of ongoing operations and maintenance (O&M) costs, the survey responses indicated yearly maintenance costs per vessel at $200,000, and yearly facility O&M costs from $250,000-$373,000.

GAC media costs have been increasing steadily as illustrated in the following chart. We are concerned that costs will continue to rise for all PWS who use GAC for treatment when there is a rush to provide it to systems for PFAS remediation:

[Figure 2: see docket ID EPA-HQ-OQ-2022-0114-1836]

Figure 2: Trend in Costs Over Time for Granular Activated Carbon Media.

EPA Response: This comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs; for more information, please see section 13.3.3 of the EPA response in this *Response to Comments* document. With regard to the impact of demand for GAC on costs, please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046020)

Monitoring and Administrative Costs

In its EA, EPA estimates startup, sampling, and treatment administration cost elements that are applied to this estimate of systems per ETPSs for each CWS size [FN114: U.S. Environmental Protection Agency, "Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation Appendices," tbl. C–9; Black & Veatch, "PFAS National Cost Model Report," tbl. A-1.]. The tables below display each of these cost breakdowns. Implementation startup costs account for labor and costs per system, along with average hours per system to read and adopt the rule and average hours per system to attend one-time trainings provided by primary agencies. Total costs range from $460,000 to $3,600,000. Laboratory analysis costs, labor rate, and the number of samples are used to estimate monitoring and sampling costs per location. Quarterly sampling costs per location are $5,200 for small systems and $5,300 for large systems, while triennial costs are between $710 and $1,500 per location (Table 15).

Table 15: Sampling Costs

[Table 15: see docket ID EPA-HQ-OW-2022-0114-1738]

[FN115: Lab analysis cost per sample for the field reagent blank under EPA Method 533.]

[FN116: Lab analysis cost per sample for the field reagent blank under EPA Method 537.1]

EPA Response: This comment reiterates information provided in the EPA's background materials and does not need a response.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045995)

Section 8.9: Lab capacity and sample costs

As mentioned earlier, significantly more samples need to be taken by PWSs to assess the extent of issues related to PFAS in the source and finished waters. EPA estimates the cost per sample of EPA methods 533 and 537.1 are $376 and $302, respectively. AMWA believes these costs are generally on par with current pricing for large commercial labs. Using the three estimations from individual water systems mentioned in Section 5.5, additional testing will significantly increase costs. Using method 537.1 costs, the increase in costs for those water systems that must do additional testing will be: $270,720 additional costs for 720 samples/year, $188,000 for 500

samples/year, and $60,160 for 160 samples a year. These cost estimates do not even factor in sampling and delivery costs. These costs are not unique to these three systems and will be required at any system implementing or even considering a treatment technique. Some utilities also use both methods as an additional assurance, which would almost double the costs.

Based on EPA's estimations of annual PWS sampling cost of $90.32 million, this results in EPA expecting a total of approximately 240,213 (90.32 million divided by $376, cost per sample) samples annually for all water systems. With approximately 52,000 water systems subject to this proposed rulemaking, that results in between 4-5 samples per water system (240,213 samples divided by 52,000 water systems). This is an unrealistic estimation. Not only do many water systems have multiple EPTDS which will increase this sample number, but compliance monitoring samples are not the only samples that will need to be analyzed. Additionally, since EPA has made it difficult to prove detections less than the proposed trigger level, which is below the PQL, many water systems will not be able to qualify for continued reduced monitoring, which would have made this number more reasonable.

AMWA asserts that it will not be simple for PWSs to acquire data below the PQL. AMWA members have indicated that a popular commercial lab has informed them that a water system on a UCMR 5 contract who would like to see results below 4 ppt would need to perform an entirely separate sampling event due to QAQC considerations. This would require water systems to pay twice for results below 4 ppt if they cannot amend the contract, and they would still only receive results above 2 ppt. Most PWSs will not be able to gain the data necessary to comply with the proposed reduced monitoring requirements, and could see significant increase in costs to get data between 2-4 ppt.

EPA Response: Regarding the need for ongoing performance monitoring in addition to compliance monitoring, the EPA anticipates that many water systems will conduct a pilot test before implementing a full-scale treatment installation and that the operational results from the pilot test will be a sufficient indicator of performance; therefore, water systems should not have to collect large amounts of performance samples indefinitely during the full-scale operation of treatment technologies. The EPA included pilot testing costs in the treatment capital cost estimates for the proposed rule and further updated these costs for the final rule. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. Please see section 13.3.4 of the EPA response in this *Response to Comments* document regarding response to comments about PWSs acquiring data below the PQL.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046034)

Significant Cost Increases for Current Operations

The potential increase in operating expenses for PFAS treatment comes at a time when Fairfax Water has seen double- and triple-digit percentage increases in essential supplies such as chemicals and ductile iron pipe. While Fairfax Water's production has been essentially flat, since January 2020, its chemical budget has increased 52%. Costs for sodium hypochlorite

(disinfectant) in that time have increased 175% and costs for poly-aluminum chloride (coagulant) have increased 67%. Costs for ductile iron pipe, used in the distribution system to replace aging infrastructure, have on average increased 54% for 4-inch to 36-inch pipe and 128% for 42-inch and 48-inch pipe. Purchased power costs have increased 31% since July 2022. Costs for GAC have increased 17% in two years.

EPA Response: After considering this and other public comments, the EPA has updated the dollar year used in the WBS models to $2022; for more information, please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043095)

The cost analysis for drinking water treatment is demonstrably underestimating the impacts of the rule based on case study data and a model by Black & Veatch, which was crafted leveraging long-standing national PFAS treatment design expertise.

EPA Response: The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

North Penn Water Authority (NPWA) (Doc. #1470, SBC-043293)

Impact on North Penn Water Authority

Specifically with regard to the North Penn Water Authority, we are fortunate to have one of the most reliable and advanced, state-of-the-art water treatment plants in the nation at Forest Park in Chalfont, which we jointly own and operate in partnership with the North Wales Water Authority. It serves a total population of about 200,000 people in a large geographic region in Montgomery and Bucks Counties, outside Philadelphia. The plant, which treats surface water from Lake Galena, supplemented by water drawn from the Delaware River, has been operating continuously since 1994, and has since been expanded twice and the treatment technology upgraded several times in order to keep up with changing water quality regulations over the past 25-plus years. The original sand filters have been replaced with membranes, which is one of the most effective methods of water treatment available anywhere in the world.

The good news is that NPWA will be able to meet these new stringent standards imposed by EPA. But the bad news is that in order to continue to maintain compliance in the future, Forest Park will most likely have to incur significant additional costs to change out the Granular Activated Carbon systems more frequently than the current practice. Also, the plant will most likely need to be expanded yet again to accommodate the added capacity that will be needed, as we anticipate that many surrounding communities may conclude that it would be better to buy water from Forest Park rather than to incur the added costs of installing expensive PFAS treatment systems on their groundwater wells.

EPA Response: The EPA agrees that some systems will incur additional costs to comply with the new standards and has included these costs in the cost analysis. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Greater Cincinnati Water Works (GCWW) (Doc. #1550, SBC-042689)

May 12, 2023

U.S Environmental Protection Agency

EPA Docket Center

Office of Ground Water and Drinking Water 1200 Pennsylvania Avenue NW

Washington, DC 20460

Re: Docket ID No. EPA-HQ-OW-2022-0114

PFAS National Primary Drinking Water Regulation Rulemaking

To Whom It May Concern:

Thank you for the opportunity to comment on the USEPA's proposed PFAS National Primary Drinking Water Regulation. Greater Cincinnati Water Works (GCWW) is a municipal water utility serving 1.1 million people in the Greater Cincinnati area. We treat water from two different sources, both of which are impacted by low levels of PFAS contamination. Eighty-eight percent of our water comes from the Ohio River. The treatment plant for this source already incorporates granular activated carbon which removes most of the PFAS compounds. However, we will likely incur additional operating costs of $150,000-$300,000/year to ensure compliance at this facility.

The remaining 12% of our water comes from a ground water source with levels of PFAS averaging within 1 ppt of the proposed MCL for PFOA and PFOS. This plant, like many across the United States, is not designed to remove PFAS compounds. Our current estimate is at least $60 million in capital costs to retrofit the 40 million gallon/day plant for PFAS removal. Our cost estimates are in line with the costs of plants such as Cape Fear, NC which are doing retrofits to add PFAS removal processes. Our construction estimates do not include the on-going operation and maintenance costs, nor does it account for disposal of any waste materials from the PFAS treatment. Based on our estimates, we believe EPA's estimated costs for nationwide compliance are significantly underestimated. We believe the estimates do not adequately take into account the recent period of inflation in the construction sector, nor the additional increases which will occur due to increased demand for specialized treatment design and construction within a very narrow time window to achieve compliance. As an example, with a recent construction project for a new clearwell the lowest bidder was 30% higher than our consulting engineer's estimate. We are also seeing significant increases in all our capital projects, many of which seem to be due to a shortage of qualified contractors. Other utilities are seeing similar situations.

EPA Response: The comment lacks sufficient detail to compare the estimate of $150,000-$300,000/year additional operating cost to the results of the EPA's WBS models. The updated cost curves the EPA developed for the final rule estimate a range of capital costs of approximately $25 million to $42 million for a 40 million gallon/day facility using GAC to treat groundwater. Although the commenter's estimate of $60 million exceeds the EPA's ranges, the comment does not include information to confirm that (1) all the estimated costs would be directly associated with PFAS treatment, as opposed to other infrastructure improvements, and (2) that design parameters (e.g., empty bed contact time) for this facility would be similar to the typical values assumed in the EPA's estimate. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

City of Wilmington, Ohio (Doc. #1572, SBC-042465)

Comments of the City of Wilmington, Ohio

Proposed National Primary Drinking Water Regulation (NPDWR) for Per- and Polyfluoroakyl Substances (PFAS)

Public Docket ID: EPA-HQ-OW-2022-0114

The City of Wilmington has just 12,000 residents with a median household income about $25,700 less than the national median and $19,900 less than the Ohio median. Now, this small city has to deal with a primary drinking water source being contaminated with PFAS because of activities at the former Clinton County Air Base, which has been converted into the Wilmington Air Park and remains an active airport.

Early estimates indicate it will cost between $5 and $10 million to upgrade the Water Treatment Plant to be able to reliably remove PFAS substances and meet the proposed MCLs. In addition, an annual increase of up to $500,000 in operations and maintenance costs is expected. The additional O&M cost alone would necessitate a 10 percent rate increase for our residents, who are already on the hook for significant sewer rate increases to pay for a new wastewater treatment plant. If loan financing must be used for the capital improvements to the water plant, rates will have to go even higher.

EPA Response: The comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Lakewood Water District (LWD) (Doc. #1574, SBC-042747)

May 24, 2023

Michael Regan, Administrator Environmental Protection Agency 1200 Pennsylvania Avenue, N.W.

Mail Code: 1309

Washington, DC 20004

RE: Per- and polyfluoroalkyl substances (PFAS): Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) National Primary Drinking Water Regulation Rulemaking, Docket No. EPA–HQ–OW-2022-0114

Dear Administrator Regan,

I am the General Manager for Lakewood Water District (LWD) submitting comments on EPA's proposed PFAS drinking water regulations. LWD is the largest water District in Pierce County, Washington. Located just south of Tacoma, Washington, and adjacent to Joint Base Lewis McChord (JBLM). LWD serves more than 65,000 customers directly and over 60,000 more via wholesale water supply contracts with five neighboring purveyors.

LWD has been dealing with PFAS contamination of its aquifer system since 2016 when PFAS migrating from JBLM was first detected in the District's wells. PFAS has now been detected in 13 of the District's wells resulting in four of those wells being shut down due to exceedance of Washington State PFAS State Action Levels (SAL).

To address this widespread PFAS contamination, LWD has developed a multi-year $28 million program to clean up and mitigate PFAS contamination at the 13 contaminated wellfields. So far, this program has cleaned up two wellfields (four wells) utilizing Granular Activated Carbon (GAC) systems at the cost of more than $8.86 million. Supplementing this treatment approach, LWD is also pursuing drilling replacement wells into much deeper (hopefully) uncontaminated aquifers. These new wells are expected to offset supplies lost due to PFAS contamination.

With this context in mind, LWD's comments on EPA's proposed PFAS rules are framed from actual real-world experience with addressing PFAS contamination of drinking water. Our comments fall into six broad categories:

1. Costs are systematically underestimated.

2. Federal funding support is exaggerated.

3. Proposed trigger levels are inappropriate.

4. Proposed Hazard Index approach is flawed.

5. Penalties for monitoring are counterproductive.

6. Timeline to implement is not feasible.

Costs are Systematically Underestimated

The cost presented in the proposed rules systematically underestimates:

* Capital costs

* Operational costs, and

* Implementation costs

The following paragraphs provide examples and highlights regarding this underestimation and are not intended to be an exhaustive treatise. Rather, these examples highlight the serious shortcomings in the EPA's assumptions regarding the cost of implementation and compliance with the proposed rules.

Capital Costs

As described above, LWD has completed two GAC systems to remove PFAS from groundwater. LWD's first GAC system was at the Ponders well site, which has two wells. Design started in April 2018; the GAC system came online in January 2020. The all-in costs, including engineering, permitting, bidding, and administrative costs, were $ 3.3 million for just over 2,000 gallons per minute (GPM), or $1.65 million per 1,000 GPM.

LWD's second site, Scott's well site, has two wells producing about 3,000 GPM, with all the same components mentioned above. LWD started design in May 2020, completed construction, and brought it online in May 2022 for a cost of $5.1 million for treating 3,000 GPM. Or $1.70 million per 1,000 GPM.

The bottom line is that the capital costs that LWD has experienced are three times the cost of what EPA portrays in the proposed rulemaking.

While these data points may be considered anecdotal, the magnitude of these examples of capital cost under-estimating is consistent with the broader findings of the American Water Works Association (AWWA) assessment of cost under-estimating in the proposed rule. The AWWA assessment also found that the typical PFAS treatment system is shown to cost 330% more than the estimated cost by the EPA's WBS Model.

EPA Response: The updated cost curves the EPA developed for the final rule estimate a range of capital costs of approximately $3.8 million to $6.4 million for 2,000 gallons per minute facility using GAC to treat groundwater. The commenter's reported cost of $3.3 million for the Ponders well site falls just below this range. For the Scott's wells site, the EPA's updated cost curves estimate a range of capital costs of approximately $5.1 million to $8.5 million for a 3,000 gallons per minute facility using GAC to treat groundwater. The commenter's reported cost of $5.1 million for this site falls within this range.

Lakewood Water District (LWD) (Doc. #1574, SBC-042750)

Operational Costs

Similar to capital cost estimates, operational cost estimates consistently underestimate the operational cost impact that water purveyors will face. LWD's annual Operation and Maintenance (O&M) cost for staff time, site visits, and sampling costs is $60,000 for two GAC treatment sites. Under the current Washington State SAL level of 10 parts per trillion (ppt) for PFOA and 15 ppt for PFOS, the estimated run time for replacing media is $400,000 per site

every five years. With the proposed EPA MCL of 4 ppt for PFOS and PFOA, LWD would have to replace the media every 2.5 years, which would double those costs.

EPA Response: Assuming these sites treat an average flow that is 50 percent of design flow (i.e., 1,000 to 1,500 gallons per minute) and given a replacement frequency of 2.5 years, the updated cost curves the EPA developed for the final rule estimate a range of annual O&M costs of approximately $224,000 to $324,000 per site per year. In comparison, the commenter's estimate converts to $190,000 per site per year ($60,000 per year / 2 sites = $30,000 per site per year; $400,000 per site / 2.5 years = $160,000 per site per year). This estimate falls just below the EPA's range.

New Hampshire Water Works Association, Inc. (NHWWA) (Doc. #1576, SBC-042449)

Approximately 150 community water systems – including two of our largest – are impacted by PFAS above New Hampshire's regulatory levels. Our legislature passed a law in June 2020 to provide $50M of funding to assist any system, including residential wells, so impacted. As capital costs continue to increase, these funds will fall short. In addition, ongoing operation and maintenance (O&M) costs are large, growing, and of long (decades) duration: our budget funds are insufficient to meet this need. Even with proposed federal support, funds for PFAS treatment at current NHDES drinking water standards are inadequate.

Please carefully consider the following points to help inform the pending rulemaking on this class of pervasive and persistent toxic chemicals:

• With several thousand systems impacted by the proposed MCLs and roughly three-quarters of them serving 10,000 customers or less, the proposed MCLs will disproportionately affect small systems. Many smaller systems lack the financial, staff and management resources to implement the proposed rules. In New Hampshire, where approximately 200 additional public water systems will be impacted, the estimated capital costs of ~$170M and annual O&M costs of $44M do not account for inflation, manufacturing and supply chain issues, or professional labor shortages.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

New Hampshire Water Works Association, Inc. (NHWWA) (Doc. #1576, SBC-042453)

EPA has not accurately estimated costs associated with treating PFAS to the proposed MCL. EPA's annualized costs for treatment are $772M per year, which contrasts with an American Water Works Association's estimate of $3,800M per year. A growing body of actual cost data indicate EPA's O&M estimates may be even further off, by up to an order of magnitude. It is important that projected costs be accurate to develop MCLs that balance health risk reduction, technical feasibility, and cost. With roughly 80% of PFAS exposures coming from non-drinking water sources, the proposed treatment standards only address a minority of the problem, at best.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document. For the EPA's response to comments about the relative source contribution, please see section 4 2.5 of the EPA response in this *Response to Comments* document.

Santa Clarita Valley Water Agency (SCVWA) (Doc. #1578, SBC-042428)

On behalf of the Santa Clarita Valley Water Agency (SCV Water), we appreciate the opportunity to provide comments on the U.S. Environmental Protection Agency's (EPA) preliminary regulatory determination and proposed rule for certain per- and polyfluoroalkyl substances (PFAS Chemicals).

May 25, 2023

Ms. Radhika Fox

Assistant Administrator

Office of Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue NW

Washington, DC 20460

RE: Docket ID No. EPA-HQ-OW-2022-0114

PFAS National Primary Drinking Water Regulation Rulemaking

Dear Administrator Fox:

On behalf of the Santa Clarita Valley Water Agency (SCV Water), we appreciate the opportunity to provide comments on the U.S. Environmental Protection Agency's (EPA) preliminary regulatory determination and proposed rule for certain per- and polyfluoroalkyl substances (PFAS Chemicals).

The health, well-being, and safety of our over 300,000 customers and community is of the utmost importance to SCV Water. Local water agencies play a critical role in achieving compliance with many federal laws, including the Safe Drinking Water Act and Clean Water Act, and this is a responsibility SCV Water takes seriously. SCV Water has firsthand knowledge of the impacts of the pervasiveness of PFAS Chemicals in the environment and is in the process of designing and constructing several treatment facilities. We feel compelled to provide our recent cost history and experience to help inform the rule making process. SCV Water General Manager, Matt Stone also provided testimony at the May 4th public hearing.

Real World Experience:

SCV Water has lost over 40% of its local groundwater capacity due to PFAS Chemicals. We are moving as quickly as possible to restore that lost capacity.

SCV Water has constructed and is operating two ion exchange treatment facilities to remove PFAS Chemicals, with a third currently under construction. The 1st project, the N-Wells facility was completed in December 2020 and treats up to 6,250 gallons per minute (GPM). The capital cost was $9.2 million or $1,474 per GPM of capacity. This facility was identified as the fastest and lowest cost project we could complete. We were fortunate to get ahead of inflationary price increases and already had three wells centrally connected to a treatment site property currently under SCV Water ownership.

The 2nd project, the Valley Center Well facility was completed in August 2022 and treats 1,200 GPM. The capital cost was $5.12 million or $4,267 per GPM of capacity. We saw increases in vessel cost, resin cost, and longer supply chain lead times for some items. This site also benefited from being located on property already under SCV Water ownership.

The 3rd project, the Santa Clara and Honby Wells facility is under construction with completion projected in early 2024 and will treat 2,000 GPM. The cost is $9.63 million or $4,813 per GPM of capacity. The final cost may be higher due to change orders. This project has experienced additional supply chain lead time issues as well. This site also benefited from being located on property already under SCV Water ownership. We believe the Valley Center Well and the Santa Clara and Honby Wells facilities reflect where costs and delivery times are today.

In addition to the extensive capital cost, there is also a significant operational and maintenance cost component for PFAS Chemical treatment facilities. Staffing, resin cost and disposal are the biggest operations and maintenance expenses, resulting in over $1.7 million in the first two years for the two facilities in operation.

EPA Response: The updated cost curves the EPA developed for the final rule estimate a range of capital costs of approximately $6.5 million to $9.4 million for a 6,250 gallon per minute facility using IX to treat groundwater. The commenter's reported cost of $9.2 million for the N-Wells facility falls within this range. The EPA's updated cost curves estimate a range of $2.2 million to $3.4 million for a 1,200 gallon per minute facility and $2.9 million to $4.5 million for a 2,000 gallon per minute facility. The commenter's reported costs of $5.12 million and $9.63 million for the Valley Center Well facility and the Santa Clara and Honby Wells facilities, respectively, exceed these ranges. However, the comment does not include information to confirm that (1) all the estimated costs would be directly associated with PFAS treatment, as opposed to other infrastructure improvements, and (2) that design parameters (e.g., empty bed contact time) for this facility would be similar to the typical values assumed in the EPA's estimate. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Santa Clarita Valley Water Agency (SCVWA) (Doc. #1578, SBC-042433)

Water Affordability:

SCV Water commissioned and completed a 3rd party PFAS Chemicals treatment feasibility study which indicated the capital cost of treatment for our impacted wells is estimated at $160 million

with an increase in operations and maintenance cost of over $11 million annually. These estimates are in 2022 dollars and subject to revision as more projects reach the design phase or as additional wells are impacted. These costs will be recovered from SCV Water customers.

On behalf of SCV Water, we request EPA take our and other testimony and letters related to cost experience and timeline projection under consideration for determining a final rule. We are dedicated to addressing the concerns related to PFAS exposure and protecting the health and well-being of our community. Thank you for considering these comments.

Sincerely,

Stephen L. Cole

Assistant General Manager

Santa Clarita Valley Water Agency

EPA Response: The comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

San Gabriel Valley Water Association (SGVWA) (Doc. #1580, SBC-042416)

Identified Best Available Technologies (BAT) may Prove Costly and Inadequate: As announced, the proposed MCLs will require public water systems to add advanced treatment to their current water production processes. States will have to review and approve the plans and specifications for this advanced treatment. In addition to the need for systems to conduct pilot testing of multiple treatment options, the costs associated with constructing, operating, managing, and sampling these systems can range from millions to hundreds of millions of dollars. However, if California and other states decide to adopt more stringent standards, the identified best available technologies may prove inadequate.

EPA Response: The EPA included pilot testing in the treatment capital cost estimates, as discussed in section 13.3.3 of the EPA response in this *Response to Comments* document. In response to the comment that states may adopt more stringent standards in the future and the BATs for the NPDWR may not be adequate to meet those standards, the EPA notes that SDWA does not prohibit States from promulgating more stringent drinking water regulations than the federal standards. However, whether states choose to do so at some time in the future is not reasonably forecastable nor is it within the EPA's control whether or not a state would choose to promulgate more stringent standards in the future. Even if the EPA were able to reasonably anticipate whether states might promulgate more stringent standards in the future, costs associated with potential future state standards more stringent than the NPDWR are outside of the scope of this rulemaking.

Missouri River Public Water Supplies Association (MRPWSA) (Doc. #1581, SBC-042412)

Estimated Treatment Costs — MRPWSA is concerned that the capital and O&M cost analyses included in the preamble to the proposed Rule significantly underestimate the likely cost impact from the proposed MCLs. MRPWSA believes it is likely that the U.S EPA has underestimated the number of drinking water facilities that will require treatment, as well as the cost to construct, operate and maintain treatment facilities.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

American Public Works Association (APWA) (Doc. #1584, SBC-047710)

These levels are also significantly lower than any state has proposed for PFAS chemicals, which would seem to indicate that even states highly concerned with PFAS contamination have arrived at different conclusions than EPA with regard to the cost and benefit analysis. Analysis that is fundamental to the 1996 amendments to the SDWA, which requires a detailed risk and cost assessment, and best available peer-reviewed science, when developing standards. We again request the EPA conduct a fuller analysis that more accurately captures the costs of compliance and if necessary, the agency collects more data to inform and address the gaps that currently exist.

Mandates, while well-intentioned, can entail complex and costly upgrades in combination with prescriptive procedures to demonstrate compliance. These requirements may imperil the financial sustainability and affordability of some water systems, which will warrant greater assistance in terms of funding. To not clarify the extent of these costs now would be a grievous mistake as water systems and governments across all levels budget for the future and may be forced into competing for limited federal dollars.

EPA Response: Please see sections 13.3 and 13.3.3 of the EPA response in this *Response to Comments* document. In regard to the commenter's assertion that "even states highly concerned with PFAS contamination have arrived at different conclusions than EPA with regard to the benefit/cost analysis," the commenter provides no detail or references to support this statement. While no specific references were given, potential differences in conclusions could arise from differences in number entities included in the analysis, baseline levels of PFAS contamination, estimation of health risk reduction benefits, and the estimation of costs.

American Public Works Association (APWA) (Doc. #1584, SBC-042390)

Furthermore, while these levels are higher than what was proposed in the health advisories in June 2022 and are reliably testable that does not mean they do not pose a significant cost burden for water systems. The EPA's estimated costs of $777 million to $1.2 billion are very optimistic given the experience of systems such as the Cape Fear Public Utility Authority's estimated capital cost for its treatment, which alone was $43 million. This far exceeded its annual operating

cost of $3-5 million and if only about 16 utilities of similar size to Cape Fear nationwide had to implement comparable treatment techniques, the total cost would exceed EPA's estimate. We believe this is not out of the realm of possibility given a September 2022 Government Accountability Office (GAO) study of drinking water data collected from six states showed at least 18 percent of the 5,300 water systems studied had PFOA and/or PFOS exceeding the proposed MCLs of 4 ppt alone. Levels of initial noncompliance may be even higher than anticipated due to sampling bias since the proposed limits are the lowest level many laboratories can reliably detect, and some systems may not have already pursued such sensitive testing. In fact, we urge EPA to conduct a fuller analysis particularly given that the agency caveated its own work in the posting in the federal register, asserting:

EPA Response: The comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. Furthermore, extrapolating from a single utility's experience is not an appropriate method to estimate national costs. See also section 13.3.3 of the EPA response in this *Response to Comments* document. For the EPA's response to comments citing the GAO report mentioned by the commenter, please see the EPA response to comment Doc. #1729, SBC-043576 in section 6.5 in this *Response to Comments* document.

Washington Suburban Sanitary Commission (WSSC Water) (Doc. #1585, SBC-042777)

5. Cost analysis

Underestimation of cost:

WSSC Water finds that EPA's analysis of costs for implementing the BATs for PFAS removal significantly underestimates the necessary capital and operational expenses. For instance, the capital cost of constructing a GAC process for our Potomac Water Filtration Plant (WFP) is estimated about $1.4 billion, including expenses for land acquisition, booster pumping, and engineering and legal fees. Our projected operating expenses cover the costs of replacement, disposal, and reactivation of spent GAC. To treat our average production at our 285 MGD rated plant, the operating cost alone is a large and continuing cost. Estimated to be about $38 million, O&M represents about 35 — 50% of the total annualized cost. Furthermore, operating costs may not be eligible for federal/state funding, in which case the cost must be borne solely by the public.

After annualizing the combined total of capital and operating costs over 30 years of the asset life cycle, we arrived at an estimated annual cost of $108 million for PFAS treatment with GAC. This figure is significantly higher than EPA's estimated annualized cost of $16 - 67 million for an average Type 2 System. We believe this difference is attributed to several factors. First, EPA's cost model does not include ancillary costs associated with capital improvements, such as costs to address site constraints. A GAC treatment system with adequate contact time for PFAS removal would be about four times the size of our existing high-rate filters, exceeding any available space at our treatment plant. Second, the EPA's cost model must be re-calibrated with a

scale-up factor for large treatment plant. The largest system size considered in EPA's cost model is >500,000 population served, about four times smaller than WSSC Water.

Additionally, we recommend that EPA revise all of its cost estimates to reflect current labor and material cost increases and supply chain and workforce issues, using $2023 dollars.

EPA Response: The commenter is referencing system costs presented in Table N-10: Results for Type 2 Systems for Medium PFAS Occurrence. These costs relate to the agency's assessment of system level incremental costs associated with removing PFNA, PFBS, and HFPO-DA in addition to removing PFOA, PFOS and PFHxS (i.e., a Type 2 system in the sensitivity analysis presented in the EA for proposal). The costs presented in the table should not be construed as the EPA's estimated costs for all systems serving greater than 500,000 people that exceed the MCLs. The EPA uses the WBS models to estimate cost using a detailed engineering build-up from the line-item costs of individual treatment system components. As described in detail in section 13.3.3 of the EPA response in this *Response to Comments* document and the *Technologies and Costs* document (USEPA, 2024d), the EPA has developed cost equations for treatment at surface and ground water systems across the range of bed life (5,000 to 75,000 BVs) and residuals management scenarios, including high, mid, and low-cost levels.

Additionally, the comment lacks sufficient detail to compare the commenter's estimated cost to those the EPA used for very large systems. Specifically, it does not include information on the influent PFAS concentrations expected at this facility. It also does not include information to confirm that (1) all the estimated costs would be directly associated with PFAS treatment, as opposed to other infrastructure improvements, and (2) that design parameters (e.g., empty bed contact time) for this facility would be similar to the typical values assumed in the EPA's estimate. The EPA updated its equipment costs to 2022 dollars using current price indices. The EPA also collected new vendor price quotes for cost driver equipment components (e.g., pressure vessels, treatment media). Please see section 13.3.3 of the EPA response in this *Response to Comments* document. In regard to the availability of federal funding, please see section 2.4 of the EPA response in this *Response to Comments* document.

Security Water District, Security Water and Sanitation Districts/Enterprises (Doc. #1587, SBC-042781)

To date, about $35 million dollars has been spent on PFAS mitigation in the Security Water District — initially to obtain an interim water supply, and finally to install an Ion Exchange treatment system. For our system with a population of 20,000 people, this equates to $1,750 per person or about $5,000 per tap. As a result of our experience, we are concerned that the EPA cost model underestimates the cost of the proposed rule.

EPA Response: This comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Suffolk County Water Authority (SCWA) (Doc. #1589, SBC-043368)

4. Costs for Implementing Treatment Will be Significant

The cost to develop, install, operate and maintain treatment systems to implement the proposed regulation will be significant. As indicated above, so far the SCWA has installed more than 25 GAC systems in order to comply with New York's standards for PFOA and PFOS over the last four to five years so it has experience with the costs to install these systems. The SCWA estimates that the average cost for each new GAC system will be no less than $750,000. Because they are subject to freezing in the winter, each system also requires a building with average costs no less than $700,000 to $900,000, depending upon the type of building needed. These are historical costs, and they are likely to be much higher in the future. It is anticipated that inflation, supply chain issues, and nation-wide competition for new GAC systems upon adoption of the proposed regulation will cause substantial increases in these capital cost estimates. These factors are likely to cause a similar increase in the anticipated cost of GAC filter media.

A preliminary estimate of the capital costs of treatment systems for the SCWA to address PFOA and PFOS alone is in the hundreds of millions of dollars. SCWA has not yet estimated capital costs to treat the other four PFAS proposed for regulation. Operation and maintenance costs must also be considered. In SCWA's experience, the average GAC filter media must be changed at least once per year per treatment system. This would put operation and maintenance costs in the range of hundreds of millions of dollars as well.

The SCWA is a large water supplier and is able to purchase treatment systems and filter media with certain economies of scale. Consideration should be given to the fact that smaller systems will likely have much higher per unit capital costs, change out costs, and other costs in their efforts to comply with the proposed regulation.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document. The comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. The EPA has considered costs impacts to systems of all sizes in the analysis, including small systems which the EPA agrees may not benefit for economies of scale.

New York Section American Water Works Association (NYSAWWA) (Doc. #1591, SBC-042374)

Cost/Affordability

10. New York State water suppliers have been working since 2020 to comply with State limits of 10 ppt for PFOA/PFOS. During this time, we have gathered a great deal data on the cost of treating for these compounds. Based on this experience, we believe that EPA's cost estimates for treatment are woefully inadequate. To date, our experience has demonstrated the financial impacts of meeting a 10 ppt MCL have exceeded $850 million in construction and $45 million in operating costs in New York State.

EPA Response: Please see sections 13.3.3 and 13.3 of the EPA response in this *Response to Comments* document.

Alameda County Water District (ACWD) (Doc. #1595, SBC-042348)

b. Cost estimates for treatment installation and analysis are low

The estimated capital cost curve included in the March 29th PFAS NPDWR public presentation indicated that the estimated capital costs for a 6 MGD granular activated carbon (GAC) PFAS treatment system were approximately $5M. The cost estimate included in the economic analysis for laboratory analysis using method EPA Method 533 is $376.

ACWD is in the late stages of designing a 6 MGD IX PFAS treatment system and the preliminary Class 2 construction cost estimate range (excluding planning, design, etc.) indicates actual construction costs could be more than three times the estimate provided in EPA's economic analysis. During our preliminary design stage, we also evaluated GAC treatment, which had a higher construction cost than IX. This difference in estimated cost of treatment installation compared to actual costs for treatment installation is substantial and indicates that the cost estimates within the economic analysis are unrealistically low.

The EPA's economic models used in the economic analysis for construction costs were last peer reviewed over 15 years ago, between 2005 and 2007, and may not provide an accurate basis for escalation. EPA should update the economic models for construction costs through a more current peer-reviewed process using current and realistic projected costs, to confirm the models still provide an accurate basis for economic analysis given current construction, parts, and materials costs post-pandemic.

EPA Response: The updated cost curves the EPA developed for the final rule estimate a range of capital costs of approximately $4.8 million to $7.1 million for a 6 million gallon/day facility using IX. Although the commenter's estimate appears to exceed this range, the comment does not include information to confirm that (1) all the estimated costs would be directly associated with PFAS treatment, as opposed to other infrastructure improvements, and (2) that design parameters (e.g., empty bed contact time) for this facility would be similar to the typical values assumed in the EPA's estimate. WBS model development did not cease with the initial external peer review. The EPA has continued to maintain and update the models throughout the intervening years, including updates specifically for this final rule as described in section 13.3.3 of the EPA response in this *Response to Comments* document.

National Tribal Water Council-Tribal PFAS Working Group (NTWCTPWG) (Doc. #1598, SBC-042339)

Treatment

Tribal communities that are impacted by PFAS chemicals face a difficult situation. There are funding sources available to install equipment to treat PFAS in drinking water, but no clear

picture of what assistance will be available to operate and maintain those treatment facilities going forward. The treatment technologies have been evolving, which raises the question of installing treatment equipment, such as reverse osmosis / nano-filtration that can achieve removal, but that was not designed and developed specifically for PFAS removal, as compared to installing technology that has been or is being tested and scaled to specifically remove PFAS. The decision of how to proceed in these regards will be greatly affected by the timing of this regulation‘s implementation, together with funding availability and overall cost considerations.

The environment of competitive funding opportunities and the constantly evolving understanding of PFAS seems to cast a shadow over many factors that must be considered. There are capital, short-term and long-term cost implications of treatment technology(ies) being adopted for PFAS treatment. The operations and maintenance portion of the total costs should be considered “legacy costs” from the adoption of any given treatment technology to treat PFAS. We recommend that EPA consider in its economic analyses the tradeoff(s) between early adoption of expensive treatment methodologies that may be the only options available today, and less expensive alternatives that may be available in the near future. Regulatory language should speak to the utilization of emerging treatment technologies as well as to a thorough financial evaluation of the chosen treatment method’s cost over the lifecycle of the treatment approach and equipment selected. These treatment facilities require different levels of training/certification, maintenance, technical proficiency and scheduled operator hours to treat water to regulated levels of safe consumption. The cost that is incurred from these factors is not addressed in the funding available to install these facilities, thus passing significant financial burden on to the affected communities. The evaluation of liability of the parties responsible for the presence of these pollutants seems to be a logical next step in addressing this issue in a fair and equitable manner.

EPA Response: The EPA agrees that new technologies to treat PFAS, such as novel adsorptive media, may emerge in the near future. However, at this time, the EPA does not have sufficient data on the costs of these emerging technologies to include them in the EA. Nothing in the rule prevents water systems from adopting these technologies if they prove more cost-effective. For the EPA’s response to comments on funding availability for O&M costs specifically, please see section 2.4 in this *Response to Comments* document.

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-047712)

GAC media costs have been increasing steadily as illustrated in the following chart (GRAPHIC 4). We are concerned that costs will continue to rise for all PWSs who use GAC for treatment when there is a rush to provide it to systems for PFAS remediation across the nation.

[Figure 4: See Docket ID EPA-HQ-OW-2022-0114-1601]

GRAPHIC 4: Chart produced by MWWA Technical Advisory Committee plotting historical GAC costs.

A large PWS in Massachusetts, that uses GAC as part of their routine treatment process and not specifically for PFAS removal reported to MWWA that last fiscal year they used Carbon Activated (a GAC supplier) and replaced their media with virgin GAC at a cost of $194,450.00. This fiscal year, the bid for virgin GAC from Carbon Activated came in at $600,000.00, over triple the cost from last fiscal year. Due to this staggering increase, the PWS instead proceeded with regenerated GAC at a cost of $184,000.00 for their media replacement.

EPA Response: The EPA agrees that GAC prices have increased over time. For the final rule, the EPA updated its cost data to 2022 dollars, including collecting new vendor price quotes for GAC. As a result, the EPA's unit cost for virgin GAC ($2.46 per pound prior to any volume discounts) is higher than that shown in the commenter's Figure 4 for non-acid washed GAC. With regard to the impact of demand for GAC on future costs, please see section 13.3.3 of the EPA response in this *Response to Comments* document. The EPA does not dispute the commenter's reported costs for the large PWS in Massachusetts, but the comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models.

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-042902)

Kleinfelder's survey of New England PWS (51 respondents) regarding capital costs for treatment per million gallons per day treated averaged $3.8 million. The survey reported yearly O&M for media replacement from $250,000-$373,000 [FN22: Presentation by Ben Powers, EIT, Kleinfelder, "PFAS Treatment in New England: A Regional Survey," April 2023, New England Water Works Association, Spring Conference].

EPA Response: The comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043658)

APPENDIX-C

Combined Impact on BWWB's Capital and O&M Budgets and Rates (Including the proposed PFAS Rule)

Based on water quality analysis performed to date on BWWB's various water source, BWWB believes that the proposed Rule may require the installation of the post-treatment GAC facility at the Shades Mountain Filter Plant. Therefore, the capital and O&M costs related to the proposed PFAS Rule that are presented in this Appendix are predicated on this assumption.

A preliminary estimate for the compliance costs associated with not only the LCRR, AWIA and NRW Control, but also the proposed PFAS Rule in the next 5 years, was added on the baseline budgets of BWWB to calculate the rate increase and affordability. Two scenarios were analyzed: costs associated with spent GAC considered as non-hazardous is shown in Table C1 and as hazardous waste is shown in Table C2 below.

Table C1. Baseline Capital and O&M Budget with LCRR, AWIA and NRW Control Compliance Costs and additional PFAS Rule (Non-Hazardous Waste) Compliance Cost

[Table C1: See Docket ID EPA-HQ-OW-2022-0114-1602]

Table C2. Baseline Capital and O&M Budget with LCRR, AWIA and NRW Control Compliance Costs and additional PFAS Rule (Hazardous Waste) Compliance Cost

[Table C2: See Docket ID EPA-HQ-OW-2022-0114-1602]

Table C3. Impacts on ratepayers and BWWB by LCRR, AWIA and NRW Control and the Proposed PFAS Rule Compliance

[Table C3: See Docket ID EPA-HQ-OW-2022-0114-1602]

EPA Response: Regarding the commenter's estimate of costs of compliance with the PFAS rule at the Shades Mountain Filter Plant, please see the EPA response to the commenter's Appendix A in the snippet below for Doc. #1602, SBC-043656. Regarding simultaneous compliance, please see section 10.4.2 of the EPA response in this *Response to Comments* document. Regarding the cost impacts of LCR, please see section 13.3 of the EPA response in this *Response to Comments* document.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043656)

APPENDIX-A

Comparison of Total Capital Cost and O&M Cost between EPA's Cost Model and Arcadis Case Studies

BWWB developed capital and O&M cost estimates for each of its filtration plants in order to support the evaluation of the proposed PFAS Rule. Cost estimates included in this Appendix are based on the selection of post-filter GAC as the BAT at each plant. Please refer to Table A1 below for the summary of the estimates.

BWWB's Technical Assumptions for the cost estimates are as follows:

• Water Source: Surface Water

• Size Category: Large (>10 MGD as defined by EPA)

• Component Level: Mid-level estimate

• Expected Bed Life in Bed Volume (BV): 60,000

The expected bed life was determined through one bench scale test at SMFP. While additional bench and/or pilot tests are needed to validate an accurate bed life for a full-scale GAC system, the bench test serves as a guide for conceptual design.

• Design type (gravity vs. pressure) was determined based on the plant design capacity.

o If the design capacity is >30 MGD, gravity was selected

o If the design capacity is <30 MGD, pressure was selected

Table A1. Summary of Capital Costs and O&M Costs for Installing GAC for PFAS Removal in BWWB's Four Filter Plants

[Table A1: See Docket ID EPA-HQ-OW-2022-0114-1602]

The development of the detailed estimates is presented below.

BWWB's Estimate Assumptions:

• BWWB's total capital costs are considered a Class 3 estimate; Class 3 estimates typically have an accuracy range of -15% to +20%, according to AACE Report (Aug 2020).

• A 20% margin has been added to the extrapolated construction cost in order to cover the cost of an intermediate pump station and associated site work.

• Site work, building, and concrete pad were included in BWWB's estimate due to site conditions and needs of the existing filter plants.

• 15% Engineering & Design and legal services was included in the total capital cost.

• USEPA's mid-cost option includes CPVC piping; steel piping is much more common. BWWB's estimate considered steel pipe and fittings.

• To escalate USEPA's cost in 2020 dollars to current dollars (2022 Q4), a 1.296 escalation factor was used, which was calculated based on the Construction Cost Index (CCI). x)

• City Index for Birmingham was 1.07, based on RSMeans City Cost Index (2019) to adjust the construction cost for a local project compared with national average.

• O&M cost was estimated based on media quantity generated by USEPA's WBS Model for GAC System Treatment. BWWB estimated that GAC replacement/reactivation costs account for 70% of the annual O&M cost. The other 30% O&M costs mainly cover maintenance (materials and labor) and electricity. BWWB assumed that GAC will be thermally reactivated off-site as non-hazardous waste. The current market price of virgin GAC is approximately $2/lb, which is subject to change based on the market conditions. BWWB considered the unit price of reactivated media to be $1.8/lb. Please note that mercury build-up in GAC media to a certain threshold may cause rejection by GAC reactivation facilities. Regular sampling of GAC media to monitor mercury levels is recommended to maintain media life and minimize the life-cycle O&M cost.

Actual Projects used as a Reference for Capital Cost Development:

1. NWTP Facility Upgrade and Reconstruction Project at Gilbert, AZ (Gravity GAC System)

Gilbert Project Considerations:

• Backwash Pump Station consists of a new concrete structure and all associated miscellaneous metals including hatch's and embeds. New process piping, sample pumps and vertical turbine pumps also installed with this new structure.

• GAC Facility is a new building consisting of an entirely new concrete structure with a large structural steel canopy and associated miscellaneous metals. New interconnecting piping installed along with new underdrains, GAC media, air scour blowers and associated turbine and centrifugal pumps.

• Maximum capacity of the GAC system is 65 MGD with 21.0 min Empty Bed Contact Time (EBCT).

Direct costs of the GAC Facility and Backwash Pump Station were extracted from the overall Gilbert direct costs. Extracted costs presented in Table A2 below; these costs represent a 60% design level.

[Table: See Docket ID EPA-HQ-OW-2022-0114-1602]

Formulas below used to calculate the total capital cost come from the Cost Summary for the entire NWTP Facility Upgrade and Reconstruction Project.

Subtotal 1 = Total Direct Cost * (1+0.0712)

• Provides an estimate of the cost of the work (direct costs and general condition costs) Subtotal 2 = Subtotal 1 * (1+0.06)

• Includes the Construction Manager at Risk Fee Subtotal 3 = Subtotal 2 * (1+0.0071+0.0164)

• Includes Bonds and Insurance Allowances

Subtotal 3 is the Guaranteed Maximum Price (GMP) excludes any sales tax and tax credits, which is considered as the Total Construction Cost for Gilbert's GAC facility. It is also used to estimate the Total Capital Costs for BWWB's filter plants.

Table A2, below, presents subtotal 1-3 calculations for Gilbert's GAC Facility. 'Subtotal 3' was then corrected from 2022 Q2 dollars to 2022 Q4 dollars using the appropriate Mortenson Construction Cost Index ratio (Table 2).

Table A2. Construction Costs (2022 Q4 dollars) for Gilbert GAC Facility and Backwash Pump Station

[Table A2: See Docket ID EPA-HQ-OW-2022-0114-1602]

Based on the CCI-corrected Subtotal 3 estimate in Table A2 above, an estimate for SMFP and WFP were calculated through extrapolation based on plant design capacity. Table A3 presents the total construction cost estimate (in 2022 Q4 dollars) for SMFP and WFP.

Table A3. Construction Costs (2022 Q4 dollars) for SMFP and WFP Extrapolated Based on Gilbert Case Study

[Table A3: See Docket ID EPA-HQ-OW-2022-0114-1602]

1: Includes 20% Margin to cover intermediate pump station and associated site work

2: Includes 15% Add-on Engineering & Design and Legal Service

2. Actual System in Upstate NY (Pressure GAC System)

• Flow = 13.8 MGD

• EBCT = 20 min

• Total quantity of GAC = 720,000 lb

• Standard pressure vessels

• Actual cost for contactors, plumbing & electrical: $5.1 million (2017 dollars); exclude extensive general construction, site work, building and concrete pad.

The construction cost was firstly corrected from 2017 Q4 dollars to 2022 Q4 dollars using the approporate Mortenson Construction Cost Index ratio. Then based on the CCI-corrected construction cost estimate, estimates for CFP and PFP were calculated through extrapolation based on plant design capacity, as shown in Table A4 below.

Table A4. Actual Cost for Contactors, Plumbing & Electrical (2022 Q4 dollars) for CFP and PFP Extrapolated Based on Actual Project Case Study

[Table A4: See Docket ID EPA-HQ-OW-2022-0114-1602]

1: In addition, building, concrete pad, and a considerable amount of site work will likely be needed at both CFP and PFP. Thus, additional construction costs were added to the extrapolated costs, which were calculated based on the automatic populated design factors from USEPA's WBS Cost Model, the unit price from AWWA (PFAS National Cost Model Report, March 2023), and price of construction materials from previous actual projects.

2: Includes 20% Margin to cover intermediate pump station and associated site work

3: Includes 15% Add-on Engineering & Design and Legal Service.

EPA Response: The tables below compare the estimated costs from the commenter's Table A1 to results from the updated cost curves the EPA developed for the final rule.

Capital Costs from Commenter's Table A1 Compared to Results from the EPA's Updated Cost Curves

Filter Plant	Design Capacity (MGD)	Design Type	Commenter's Capital Cost Estimate	EPA's Capital Cost Curves Lower Bound	EPA's Capital Cost Curves Upper Bound
SMFP	80	Gravity	$ 166,435,646	$ 38,650,025	$ 45,026,063

Filter Plant	Design Capacity (MGD)	Design Type	Commenter's Capital Cost Estimate	EPA's Capital Cost Curves Lower Bound	EPA's Capital Cost Curves Upper Bound
WFP	60	Gravity	$ 124,826,734	$ 30,866,248	$ 36,227,797
CFP	24.5	Pressure	$ 25,591,765	$ 16,627,489	$ 27,859,355
PFP	24	Pressure	$ 24,968,671	$ 16,359,836	$ 27,427,577

O&M Costs from Commenter's Table A1 Compared to Results from the EPA's Updated Cost Curves

Filter Plant	Design Capacity (MGD)	Design Type	Commenter's O&M Cost Estimate (non-hazardous waste)	Commenter's O&M Cost Estimate (hazardous waste)	EPA's O&M Cost Curves Lower Bound (non-hazardous waste)	EPA's O&M Cost Curves Upper Bound (non-hazardous waste)
SMFP	80	Gravity	$ 4,029,382	$5,558,955	$6,819,571	$6,887,420
WFP	60	Gravity	$ 3,116,171	$4,299,086	$5,138,924	$5,182,961
CFP	24.5	Pressure	$ 1,179,973	$1,627,897	$2,266,008	$2,336,178
PFP	24	Pressure	$ 1,118,357	$1,542,891	$2,222,121	$2,289,654

The commenter's O&M cost estimates, even those incorporating the assumption of hazardous waste disposal, are lower than the EPA's range for non-hazardous waste disposal. The commenter's estimated capital costs for the two pressure facilities fall within the EPA's range. The commenter's estimated capital costs for the two gravity facilities exceed the EPA's range. There are, however, several observations of the commenter's capital cost estimates that suggest they are overestimates. First, each of the estimates is based on linear extrapolation from a single case study. Linear extrapolation will overestimate costs because it does not account for economies of scale that exist with increasing treatment capacity. The commenter also applies a City Index of 1.07 to escalate the case study costs based on Birmingham's construction costs compared with the national average. It is not clear that the individual case studies used reflect national average or typical treatment costs. Finally, the commenter adds additional construction costs for buildings, concrete pad, and site work using the unit price from AWWA. As discussed in section 13.3.3 of the EPA response in this *Response to Comments* document, AWWA unit cost for buildings likely overestimates actual building costs.

Arlington County Virginia (Doc. #1603, SBC-043016)

2. Review of the cost modeling indicates significant misalignment between the report's assumption and our experiences with capital improvements and operating costs. For example, the EPA cost model utilizes the curve below to estimate the capital costs for Granular Activated Carbon. For our water provider, the Washington Aqueduct (WAD), the model as illustrated estimates a capital cost of $126.7M to install GAC.

[Figure 1: See Docket ID: EPA-HQ-OW-2022-0114-1603]

GAC was considered as a potential treatment upgrade at the WAD in 2013, and the capital cost of GAC at our two plants at that time was estimated at $200M. Utilizing a conservative inflationary estimate of 58% [FN1: Using the Census.gov Multifamily Housing Construction Index 2005-2022] indicates a present value of $316.6M, or a factor of 2.5 times the EPA's estimated cost of $126.7M.

We find a similar discrepancy in the estimated O&M costs for GAC, with our inflation adjusted annual O&M cost estimated at $31.6M as compared to the EPA model estimate of $10.1M. We were not able to find the comparable EPA cost curves for the other two recognized treatment processes (RO and IX), but we have 2013 estimates for the capital improvements and annual O&M cost for those technologies at our treatment plants and would welcome an opportunity to compare our estimates with the EPA model.

EPA Response: The comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. Please see section 13.3.3 of the EPA response in this *Response to Comments* document for further discussion.

Arlington County Virginia (Doc. #1603, SBC-043013)

Second, the assumptions on costs of the proposed rule seem to be drastically under-estimated.

EPA Response: Please see sections 13.3 and 13.3.3 of the EPA response in this *Response to Comments* document.

American Water Works Company Inc. (Doc. #1608, SBC-043988)

• Rule Implementation – American Water has comments and concerns with various aspects of rule implementation that include initial monitoring, determining compliance, use of practical quantitation limits, reduced monitoring, use of previously collected data, and right-to-know provisions.

Specific Comments

Regulation of PFOA and PFOS

American Water supports the development of Maximum Contaminant Levels (MCLs) for PFOA and PFOS for the reasons provided in the rule preamble, including that the U.S. EPA has determined that these contaminants have carcinogenic endpoints. However, in order to establish appropriate regulatory levels, American Water believes the U.S. EPA must ensure that it is using accurate data, including estimates for the cost of compliance. Inaccurate estimates of the capital cost for installing treatment and the operating cost of maintaining this treatment will lead to an inaccurate cost-benefit analysis. American Water believes that the U.S. EPA is underestimating the overall cost of complying with the proposed MCLs of 4.0 parts per trillion (ppt) for PFOA and PFOS and urges the U.S. EPA to use the information provided in our comments as well as

comments submitted by the AWWA and others to re-evaluate its cost estimates, review the cost-benefit analysis, and determine appropriate regulatory levels for PFOA and PFOS. These cost levels must also be used when determining affordability and Federal funding assistance.

As part of our review of the proposed rule, American Water evaluated the projected costs associated with PFAS treatment at the proposed limits and the impact it could have on customers' bills. Using the data and approach as presented in a recent study conducted by Black & Veatch on behalf of the American Water Works Association, the estimated national cost to install treatment facilities and processes to remove PFOA and PFOS at drinking water facilities to levels required by EPA's proposal exceeds $47 billion, which is approximately $35 billion above what would be required to meet current state established PFAS limits. Further, it will require, on a national basis, more than $700 million annually for operating costs, which is approximately $500 million more than what would be required to meet current state established PFAS limits. These dollar values are significantly higher than EPA's cost estimates.

Based on initial estimates, American Water alone will likely have more than 100 of our existing drinking water treatment facilities that will need to be upgraded to provide PFAS removal capability, a 3 to 4-fold increase in the number of treatment plants than if the most stringent previously established state standards had been adopted nationwide. We estimate an investment in excess of $1 billion of capital to install additional treatment facilities over a 3 to 5-year period. Additionally, we estimate annual operating expenses related to testing and treatment could be near $50 million in today's dollars. These are preliminary estimates based on the proposed rule; our actual expenses may differ from these preliminary estimates and will be dependent upon multiple factors, including the final rule and effective date, as well as the completion of our system-by-system engineering analyses.

We strongly recommend that the U.S. EPA use this information to re-evaluate their cost estimates, review the cost-benefit analysis, and determine appropriate regulatory levels for PFOA and PFOS. These cost levels must also be used when determining affordability and Federal funding assistance.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document. The EPA has considered all public comments prior to finalizing the PFAS NPDWR, including those referenced by the commenter.

American Water Works Company Inc. (Doc. #1608, SBC-043985)

Estimated Treatment Costs – American Water is concerned that the cost analyses included in the preamble to the proposed rule significantly underestimate the cost impact of the proposed MCLs. American Water believes that the U.S. EPA has underestimated the number of drinking water facilities that will require treatment, as well as the cost to construct, operate and maintain treatment facilities, impacting both the capital cost estimates and the operation and maintenance (O&M) cost estimates.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

American Water Works Company Inc. (Doc. #1608, SBC-043975)

While American Water had been anticipating and preparing for the rulemaking, our initial analyses were based on a federal PFAS standard more in line with the limits set by several states. We have carefully reviewed the U.S. EPA's proposed drinking water regulation to assess the 4.0 parts per trillion (ppt) requirements for PFOA and PFOS and the application of the Hazard Index approach for PFNA, PFBS, PFHxS, and HFPO-DA chemicals.

As part of our review of the proposed rule, American Water evaluated the projected costs associated with PFAS treatment at the proposed limits and the impact it could have on customers' bills. Using the data and approach as presented in a recent study conducted by Black & Veatch on behalf of the American Water Works Association, the estimated national cost to install treatment facilities and processes to remove PFOA and PFOS at drinking water facilities to levels required by the U.S. EPA's proposal exceeds $47 billion, which is approximately $35 billion above what would be required to meet current state established PFAS limits. Further, it will require, on a national basis, more than $700 million annually for operating costs, which is approximately $500 million more than what would be required to meet current state established PFAS limits. These dollar values are significantly higher than EPA's cost estimates.

Based on initial estimates, American Water alone will likely have more than 100 of our existing drinking water treatment facilities that will need to be upgraded to provide PFAS removal capability, a 3 to 4-fold increase in the number of treatment plants than if the most stringent previously established state standards had been adopted nationwide. We estimate an investment in excess of $1 billion of capital to install additional treatment facilities over a 3 to 5-year period. Additionally, we estimate annual operating expenses related to testing and treatment could be near $50 million in today's dollars. These are preliminary estimates based on the proposed rule; our actual expenses may differ from these preliminary estimates and will be dependent upon multiple factors, including the final rule and effective date, as well as the completion of our system-by-system engineering analyses.

EPA Response: The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see sections 13.3.3 and 13.3 of the EPA response in this *Response to Comments* document.

American Water Works Company Inc. (Doc. #1608, SBC-044002)

The U.S. EPA published a set of cost curves in its March 29, 2023, Technical Webcast, which are duplicated on the log-log graph presented in Figure 1 (See Appendix). According to the notes from the webcast, the U.S. EPA cost curves appear to estimate the cost to construct GAC-based PFAS treatment in a surface water treatment plant based on the plant's capacity. American Water was able to add the actual cost that it has incurred for the design, permitting, and construction of

more than a dozen PFAS treatment facilities that are already operating or are nearing completion. These facilities range in capacity from about 1 MGD to about 5 MGD, and all include pressure vessel-based GAC or AIX treatment media. Some facilities required the addition of pretreatment for iron and manganese removal to prevent fouling and shortened bed life for the GAC or AIX or the pre-treatment bag/cartridge filters recommended by AIX media suppliers. In addition, we added costs for several other PFAS treatment facilities constructed by other utilities, as reported in the media. All project costs were adjusted to mid-2022 values using HandyWhitman construction cost indices. As can be seen in Figure 1, some facility costs are below the amount estimated by the U.S. EPA curve, but most costs are above the curve. Since the curve is plotted at a logscale, even modest-looking offsets above the curve can represent a significant percent deviation in the cost of a facility. For example, "AW Plant 11" is a 3 MGD AIX treatment facility constructed in northern NJ. The final total project cost for this facility was approximately $5.5 million, adjusted to 2022 dollars. By comparison, the U.S. EPA cost curve would have projected that a 3 MGD PFAS treatment facility should only cost about $3.1 million. In this case, the actual cost of a 3 MGD PFAS treatment facility was more than 75% greater than the U.S. EPA cost curve would have predicted, and a new building was not required. Also, although the U.S. EPA cost curve presented in the webcast applies to surface water, it appears, based on explanations provided elsewhere in Document EPA-822-P-23-001, that the WBS models for AIX would have been even lower than the cost curves for surface water GAC treatment.

Figure 1 also includes an inflation-adjusted cost for the Cape Fear Public Utility Authority's (CFPUA) 44 MGD gravity GAC PFAS treatment facility that was recently constructed at the Sweeney WTP in Wilmington, NC. It was reported that CFPUA awarded a $35.9 million bid for construction of the facility in 2019. The $59 million value shown in Figure 1 includes an inflation adjustment factor of 26% based on the Handy-Whitman inflation index and an additional 30% allowance to estimate the total project cost to include fees for engineering design, permitting, legal, and other administrative soft costs. By comparison, the U.S. EPA cost curve estimates that a 44 MGD GAC surface water treatment facility should cost approximately $25 million. The projected cost of the Sweeney GAC facility in current dollars is more than two times higher than the U.S. EPA's estimate.

Based on American Water's experience, it is likely that a percentage of groundwater PFAS treatment facilities will require additional pretreatment for the removal of iron and manganese to prevent fouling of GAC or AIX resin, or the bag/cartridge filters that AIX manufacturers recommend be installed upstream of AIX resin beds. American Water has experience with several inline bag and cartridge filtration systems upstream of ion exchange treatment and has found they can be extremely expensive to operate and labor intensive to maintain when even moderate levels of iron or manganese are present in the source of supply. To further emphasize this concern, American Water prepared the unit cost curves presented in Figure 2 (See Appendix), which is the type of cost curve that American Water uses for developing preliminary budget estimates for its projects. The mid-capacity range section of the U.S. EPA's logarithmic cost curve from Figure 1 was transposed and included in Figure 2 for comparison to American Water's cost curves for GAC treatment of groundwater with and without pretreatment. Also

shown are the actual PFAS project costs incurred by American Water or reported in the media by several other utilities. As can be seen, the U.S. EPA's curve estimates unit costs that would average 50% less than American Water's "No Pretreatment Required" cost curve and more than 375% lower than American Water's "Pretreatment Required" range cost curve. Based on the data presented in Figures 1 and 2, American Water believes that the U.S. EPA should re-evaluate its economic analysis and provide additional metrics to show utilities the true cost of this proposed rule.

EPA Response: The updated cost curves the EPA developed for the final rule estimate a range of capital costs of approximately $3.0 million to $4.6 million for a 3 million gallon/day facility using ion exchange to treat groundwater. The cost curves estimate a range of capital costs of approximately $24.2 million to $45.2 million for a 44 million gallon/day facility using GAC to treat surface water. The commenter's estimates for these two examples exceed the EPA's updated ranges, but not as significantly as shown in commenter's Figure 1 and 2, which considered only one of the mid-cost curves used for the proposed rule, prior to the update. The commenter did not provide the underlying data for the other examples shown in the figures, so it is not possible to re-create these figures using the EPA's updated cost curves. In any case, the comment does not include information to confirm that (1) all the estimated costs for each example shown in the figures would be directly associated with PFAS treatment, as opposed to other infrastructure improvements, and (2) that design parameters (e.g., empty bed contact time) for the examples would be similar to the typical values assumed in the EPA's estimate. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Regarding the cost of pretreatment, the EPA included the cost of cartridge filters for control of influent solids in its cost estimates for ion exchange. The EPA does not have quantitative data on the frequency with which systems might require pretreatment specifically for iron and manganese, but information from one treatment vendor suggests the need for this type of pretreatment might be limited. Please see section 10.1 of the EPA response in this *Response to Comments* document.

American Water Works Company Inc. (Doc. #1608, SBC-043992)

GAC Treatment

While American Water concurs that GAC is generally a reliable treatment method for PFAS removal, we believe that the U.S. EPA has significantly underestimated both the initial capital cost and ongoing operational expense associated with using GAC for PFAS removal.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

American Water Works Company Inc. (Doc. #1608, SBC-043999)

Estimated Treatment Costs

American Water is concerned that the cost analyses included in the preamble to the proposed rule significantly underestimate the cost impact of the proposed MCLs. American Water believes that the U.S. EPA has underestimated the number of drinking water facilities that will require treatment, as well as the cost to construct, operate and maintain treatment facilities, impacting both the capital cost estimates and the operation and maintenance (O&M) cost estimates.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document. For the EPA's response to comments on the estimated number of PWS expected exceed the MCLs, please see section 6.4 of the EPA response in this *Response to Comments* document.

Prince William County Service Authority (Doc. #1609, SBC-042840)

A study released by AWWA on March 7 found that the estimated national cost for water systems to install treatment systems to remove PFOA and PFOS to levels required by the EPA proposal would exceed $3.8 billion annually. Under EPA's proposal, virtually all of these treatment costs will be borne by communities and ratepayers, who are also facing increased costs to address other needs, such as replacing lead service lines, upgrading cybersecurity, replacing aging infrastructure and assuring sustainable water supplies.

EPA Response: The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Town of Lincoln Water Department (Doc. #1613, SBC-043022)

May 25, 2023

Mr. Michael S. Regan, Administrator

U.S. Environmental Protection Agency

EPA Docket Center, OLEM Docket, Mail Code 28221T 1200 Pennsylvania Avenue, NW

Washington, DC 20460

RE: Docket ID No. EPA-HQ-OW-2022-0114 • National Primary Drinking Water Regulation Rulemaking for per- and polyfluoroalkyl substances (PFAS)

Dear Administrator Regan:

I am writing to provide comments on the Environmental Protection Agency's (EPA) proposed National Primary Drinking Water Regulation Rulemaking for per- and polyfluoroalkyl substances (PFAS). The drinking water sector fully supports efforts to expand verified public health protections, but EPA needs to consider the challenges associated with its proposed

rulemaking and address the water sectors' implementation concerns before finalizing any standards.

I work for the Town of Lincoln Water Department. We provide drinking water to 5600 public water system customers. I am a member of the Massachusetts Water Works Association and New England Water Works, Inc. I am aware that they, and other water works organizations, are submitting more comprehensive comments. I would urge EPA to pay close attention to the points raised by these associations as they are comprised of individuals and companies with expertise in designing and operating Public Water Systems (PWS) and they have the best understanding of the challenges which will be associated with implementing any final rule EPA adopts. My major concerns are as follows:

EPA has very much underestimated the costs to PWSs to comply with the proposed rule. For example, Lincoln has a well that comprises about 33% of our water supply. The well has 13-14ppt PFOS levels, below the current 20ppt MCL. If the EPA adopts the new more strict MCLs, and the State of Massachusetts DEP follows suit, we will be forced to install treatment for PFOS at the well. Initial cost estimates are around $7,000,000 for this treatment at our 0.5mgd well. Operating costs would also skyrocket, with the increasing demand for activated carbon and disposal costs every two years. The Town of Lincoln has aging infrastructure, with 53 miles of water main that need replacing. 60% of this is AC pipe. Lowering the PFOS MCLs to these low limits (20 ppt is equivalent to 1 second every 1585 years) would bring very challenging financial conditions here in Lincoln, and hinder our ability to address existing infrastructure replacement needs.

EPA Response: The commenter did not specify the treatment technologies considered in its estimate. The updated cost curves the EPA developed for the final rule estimate a range of capital costs of approximately $550,000 to $1.3 million for a 0.5 million gallon/day facility using GAC or IX to treat groundwater. Adding RO/NF increases the upper bound of the EPA's estimated range to $3.2 million. Although the commenter's estimate of $7 million exceeds the EPA's range, the comment does not include information to confirm that (1) all the estimated costs would be directly associated with PFAS treatment, as opposed to other infrastructure improvements, and (2) that design parameters (e.g., empty bed contact time) for this facility would be similar to the typical values assumed in the EPA's estimate. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Averill Park Central School District (APCSD) (Doc. #1614, SBC-042924)

May 25, 2023

U. S. Environmental Protection Agency

EPA Docket Center

Office of Ground Water and Drinking Water Docket Mail Code 28221T,

1200 Pennsylvania Avenue NW,

Washington, DC 20460

Dear U.S. Environmental Protection Agency,

We write to you to express our concerns about the proposed EPA PFAS chemical regulation which will reduce the allowable level of PFAS chemicals found in water to 4 nanograms per liter (ng/L) being directed from the State without the necessary funding to accomplish this mandate.

When the regulation changed to 10 ng/L, the Averill Park Central School District (APCSD) was forced to use significant funds to bring the levels compliant and within the allowable limit. Specifically, the filter system that was installed with granular activated carbon (GAC) cost approximately $200,000. If the standards are lowered once again, APCSD will need to install three additional GAC filter systems at an approximate total cost of $600,000.

APCSD is already dealing with limited State Foundation Aid due to being considered a "Hold Harmless" District in regards to State funding. As a result of the limited State Aid, for the 2023-24 school year, the District faced a $1.3 million deficit. Having to bear the cost burden of the additional GAC systems will impact student programming and come at a significant cost to our local taxpayers.

As a Board of Education, we take our role as the financial stewards of our community very seriously and, therefore, respectfully request that the State fund any and all costs associated with complying with this change to the regulation.

Sincerely,

The APCSD Board of Education

EPA Response: The comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Aquarion Water Company (Doc. #1617, SBC-043372)

To comply with the proposed NPDWR, our preliminary evaluation indicates that we'll have to either install treatment (e.g., GAC or IX) or replace a source of supply for more than 40% of our sources of supply. Our planning level estimate of the capital cost of this work is $290 million. This equates to an annualized cost of approximately $14 million for just the capital costs associated with complying with the proposed regulation (using a 3% discount rate to be consistent with EPA's approach, and average useful life of 30 years).

EPA Response: The comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Calgon Carbon Corporation (Doc. #1620, SBC-042940)

• Our granular activated carbon technology is an affordable solution

o Based on a recent analysis of costs for PFAS treatment installation using granular activated carbon, Calgon Carbon estimates the average operations and maintenance cost of granular activated carbon to treat 1000 gallons of municipal drinking water is $0.18. Based on the average person using 60 gallons of water per day, this translates to an added cost of $1.64 per month for a household of 5 individuals.

In closing, Calgon Carbon is prepared to help utilities across the United States to comply with the draft MCL's when they are ratified and to ensure access to clean and safe drinking water through the deployment of granular activated carbon, equipment, and reactivation services.

Sincerely,

Jenalle Brewer Senior Vice President

Drinking Water Solutions, Innovative Carbon Technologies and Global Business Development

About Calgon Carbon Corporation

Calgon Carbon, a wholly owned subsidiary of Kuraray Co., Ltd. (TYO: 3405) (Kuraray), is a global leader in the manufacture and/or distribution of innovative coal-, wood- and coconut-based activated carbon products – in granular, powdered, pelletized and cloth form – to meet the most challenging purification demands of customers throughout the world.

Complemented by world-class activated carbon equipment systems and service capabilities, as well as diatomaceous earth and perlites, Calgon Carbon provides purification solutions for more than 700 distinct applications, including drinking water, wastewater, pollution abatement, and a variety of industrial and commercial manufacturing processes.

Headquartered in Pittsburgh, Pennsylvania, Calgon Carbon employs approximately 1,700 people and operates 17 manufacturing, reactivation, innovation and equipment fabrication facilities in the U.S., Asia, and in Europe, where Calgon Carbon is known as Chemviron.

Calgon Carbon was acquired by Kuraray in March of 2018. With complementary products and services, the combined organization will continue to focus on providing the highest quality and most innovative activated carbon and filtration media products, equipment, and services to meet customer needs anywhere in the world. For more information, visit calgoncarbon.com.

1. Westreich, P, Mimna, R, Brewer, J, Forrester, F. The removal of short-chain and long-chain perfluoroalkyl acids and sulfonates via granular activated carbons: A comparative column study. Remediation. 2018; 29: 19– 26. https://doi.org/10.1002/rem.21579

2. McNamara, J.D., Franco, R., Mimna, R. and Zappa, L. (2018), Comparison of Activated Carbons for Removal of Perfluorinated Compounds From Drinking Water. Journal - American Water Works Association, 110: E2-E14. https://doi.org/10.5942/jawwa.2018.110.0003

3. DiStefano, R., Feliciano, T., Mimna, R., Redding, A, and Matthis, J. (2022), Thermal destruction of PFAS during full-scale reactivation of PFAS-laden granular activated carbon. Remediation. 2022; 32: 231-238. https://doi.org/10.1002/rem.21735

EPA Response: The EPA agrees that granular activated carbon can be an affordable treatment technology. Please see sections 13.3.3 and 13.10 of the EPA response in this *Response to Comments* document.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044048)

b. One large utility estimates their costs will increase by 200% if they are expected to meet 4.0 ppt levels, versus increasing by only 10% for meeting a 10 ppt MCL. The utility's yearly costs will increase from $250,000/yr to $550,000/yr at just one treatment plant that already has a GAC system in place. At the two facilities that need to construct a GAC treatment system it will cost their city $15 million initially with additional yearly operating costs of $550,000. These estimates do not consider inflation or potential increases in material costs as demand increases. One load of Calgon F300 GAC at 20,000 lbs costs $42,000.

c. Another utility has to change out each contactor annually plus take an extra 20-25% from their alternative source (with costs that can be upward of $2.5 million/year) to reach non-detect for PFOA and PFOS. This utility is relying on their wellfields with the lowest PFAS concentrations, some of which have water rights issues. They have estimated that if influent concentrations went above 500 ppt, they may need to change out one GAC contactor per day.

d. Another medium-sized utility is anticipating $180 million for installation of treatment, and a $5 million annual O&M increase.

e. EPA needs to remember that all these costs are borne by the utility's customers, and will impact lower income and disadvantaged communities the most.

EPA Response: The commenter's estimate of $42,000 for 20,000 lbs of GAC translates to a unit cost of $2.10 per pound. The EPA's GAC cost model, as updated for the final rule, estimates a nearly identical unit cost of $2.11 per pound for this quantity of virgin GAC. The comment lacks sufficient detail to compare the commenter's other estimates of costs to the results of the EPA's WBS models. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043078)

EPA's Cost Estimates Are Significantly Underestimated and Need Revised

According to the Proposal, EPA anticipates that nearly 67,000 water systems will need to comply with the rule. These water systems will need to review and understand how to implement the rule, conduct initial monitoring of the regulated PFAS at each entry point to the distribution

system, and potentially work to install drinking water treatment systems or take another mitigation strategy.

According to the Proposal, EPA considered three treatment options that may be used by as many as 5,000 water systems to reduce PFAS levels to below the MCLs. These treatment options included granular activated carbon (GAC), ion exchange (IX), and reverse osmosis (RO) filtration facilities. Additionally, EPA considered other options to address PFAS levels in drinking water, such as interconnections, new wells, and point-of-use RO systems. To estimate the costs to install and operate these systems, EPA relied on their Work Breakdown Structure (WBS) for these strategies, which were developed more than a two decades ago and were updated as part of the Proposal

The American Water Works Association (AWWA) contracted with Black & Veatch to prepare a cost model (the BV Model) for PFAS treatment using GAC, IX, or RO using their national drinking water treatment expertise and with support from utilities and experts from across the sector. The AWWA / BV effort also included drinking water utilities to compile information on the costs to install PFAS treatment systems.

Comparison of the AWWA / BV costs from real data with EPA model show the EPA's WBS model significantly underestimates the costs associated with PFAS treatment using a GAC treatment facility. Data from the case studies in this range shows that the typical PFAS treatment system is shown to cost 330% more than the estimated cost by the EPA's WBS Model (based on 2021$). Aqua's own experience constructing several PFAS treatment systems show that the cost to construct can range from $2 to $6 per gallon treated per day which is several times greater than EPA's estimates. Most costs are not from the vessels or treatment systems but due to site related construction costs, piloting, sewer connection fees, meeting the various restrictions for permitting and zoning, and ensuring proper road access for media changeouts by large tractor trailers. The extent of the EPA's WBS Model's underestimation of cost is similarly demonstrated by the AWWA/BV Model (2022$). These patterns are similarly observed when looking at larger treatment facilities and other treatment technologies. Analysis of the EPA WBS model shows a lack of contingency costs in the estimates. The EPA should adjust this approach and include the appropriate levels of contingency to ensure that cost estimates are consistent with the level of project definition afforded by the available data.

EPA Response: The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Regarding contingency, the EPA updated its approach to incorporate a contingency factor of 5 to 10 percent depending on total project cost at all cost levels for systems installing treatment. The EPA also included a miscellaneous allowance of 10 percent, which can be considered a form of contingency. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-052828)

Accurately Reflecting Current Economic Conditions

Another limitation of the EPA's WBS Model is that it is reflective of costs based on construction costs in 2021. Additionally, the model relies on a variety of cost indices to scale the costs from a previous year to the relevant year of the analysis. It is reasonable to scale data from one year to another year using indices, but it is important to note that there is always a lag in the data for the most recent periods of time. It is also important that the Agency recognize that the previous two years, from 2021, have been shown to experience significant cost increases relevant to drinking water treatment systems.

These cost increases have stemmed from the COVID-19 pandemic, presently high inflation, and increasing interest rates for borrowing. Construction costs, for example, have increased steadily ranging from 15% to 30% in the past 2 years according to several different sources. A similar trend is observed in analysis of inflation since 2021, which has averaged 5.81% annually. The federal funds rate has also increased from 0.08% to 5.25%.

In addition to the increase in costs driven by recent economic conditions since 2021, it is also important to note the rule's impact on upwards of 5,000 water systems and increase demand for laboratories, engineering consultants, planners, contractors performing site investigation and construction work, and skilled treatment operators.

EPA should ensure that the final cost analysis is accurately reflecting these landmark increases in costs due to recent economic conditions and anticipated increases in demand that will drive the planning and construction costs of new facilities significantly higher than the current estimates.

EPA Response: The EPA updated its equipment costs to 2022 dollars using current price indices. The EPA also collected new vendor price quotes for cost driver equipment components (e.g., pressure vessels, treatment media). Please see section 13.3.3 of the EPA response in this *Response to Comments* document. In regard to the impact of demand created by the rule on prices, please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-052829)

Recognizing the Importance of Ancillary Systems

Another potential limitation of the EPA's WBS Model is that it only considers capital upgrades related to the PFAS treatment process. This is a significant gap in that many systems will need to make improvements to other areas of the treatment facility to support the PFAS treatment process. For example, some systems installing GAC treatment may determine that the concentration and form of manganese or iron will cause problems in the vessel, requiring pre-treatment. A variety of other water quality characteristics may impact the need for pre-treatment and site-specific conditions may drive the need for significant upgrades to critical treatment support systems (e.g., pump stations, chemical feed systems, etc.). While the EPA's WBS Model

does not consider the need for these systems, it is not uncommon for upgrades for PFAS treatment to require these types of improvements.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document. Additionally, regarding the cost of pretreatment, the EPA included the cost of cartridge filters for control of influent solids in its cost estimates for ion exchange. The EPA does not have quantitative data on the frequency with which systems might require pretreatment specifically for iron and manganese, but information from one treatment vendor suggests the need for this type of pretreatment might be limited. Please see section 10.1 of the EPA response in this *Response to Comments* document for more information.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-044897)

• Pilot testing costs do not appear to have been included in the cost estimates in the proposed rulemaking. However, DEP believes pilot testing will be even more important with inclusion of both short- and long-chain PFAS in the proposed rulemaking, and, with increasingly low levels of PFAS detections required, pilot testing will become ever more critical when planning for effective PFAS removal treatment. The BAT will remove all six PFAS included in this proposed regulation, but which PFAS will break through first will depend on the type of treatment, forms of PFAS, overall water quality, and potential presence of interferences such as total organic carbon (TOC), manganese, volatile organic chemicals (VOCs), etc. For effective operations, water treatment operators will need to know which PFAS are expected to breakthrough first and on what timeframe, with some level of consistency. Pilot testing will be critical in acquiring that knowledge, and the costs should be considered.

DEP would like to again thank you for the opportunity to comment on EPA's proposed PFAS National Primary Drinking Water Regulation Rulemaking.

Sincerely,

Richard Negrin

Acting Secretary

EPA Response: The EPA included pilot testing costs in the treatment capital cost estimates for the proposed rule and further updated these costs for the final rule. Abt Associates (2020a) provides technical details on the methodology used to derive pilot study costs. section 13.3.3 of the EPA response in this *Response to Comments* document and Section 7.1.4 of the *Technologies and Costs* document (USEPA, 2024d) describe how the EPA updated these costs for the final rule.

Water One - Water District No. 1 of Johnson County, Kansas (Doc. #1627, SBC-042328)

Cost and Logistical Implications

A permanent PFAS regulation across water utilities would result in significant financial and logistical implications and the costs developed by EPA are grossly understated. We are greatly concerned about the impact this would have on the national economy and impacts to water rates. Preliminary cost estimates to remove PFAS would result in significant rate impacts for our customers with no reprieve as O&M costs would drive the costs in perpetuity. This rule in addition to the ongoing Lead and Copper Rule Revisions will compound water rate affordability concerns.

WaterOne has conducted preliminary cost analysis specific to our operations. The conceptual capital cost to implement GAC treatment at WaterOne's Hansen and Wolcott Water Treatment Plants would be $170M (180 mgd capacity) and $46M (30 mgd capacity), respectively. The conceptual capital cost to implement ion exchange treatment at the two plants would be $182M and $44M, respectively. The conceptual total annual O&M cost to implement GAC treatment would be $19.2M and ion exchange treatment would be $8.6M. Based on a recent multidisciplined large scale project recently completed (180 mgd ozone facility at the Hansen WTP), the anticipated duration to implement PFAS treatment is 8 years. These are real costs that are clearly much higher than the estimates provided by EPA resulting from the rule. When ratepayers are faced with rate increases to meet these requirements, the public trust will be further degraded in utilities and the regulatory agency.

We encourage the EPA to take the necessary time to research further the cost and logistical implications this proposed regulation would have on water utilities retrofitting their facilities, and in many cases, drive the need for new treatment facilities. In some instances, water utilities would have to discuss new sources of water or adding other facilities, all of which requires significant time, consideration, and financial implications. Additional water rights and land availability potentially could become interwoven into the decision-making process too.

EPA Response: Please see sections 13.3.3 and 13.3 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenters characterization of the rule impacts, and that there will be significant water rate impacts nationally "with no reprieve;" for more information on funding availability, please see section 2.4 of the EPA response in this *Response to Comments* document. Regarding the LCR, please see section 13.3 of the EPA response in this *Response to Comments* document.

Regarding the cost figures provided by the commenter, the updated cost curves the EPA developed for the final rule estimate a range of capital costs for a 180 million gallon/day facility of approximately $79 million to $262 million using GAC and approximately $91 million to $121 million using IX. For a 30 million gallon/day facility, the EPA's cost curves estimate approximately $18 million to $33 million for GAC and approximately $18 million to $24 million for IX. Although some of the commenter's conceptual estimates for capital cost exceed the EPA's ranges, the comment does not include information to confirm that (1) all the estimated costs would be directly associated with PFAS treatment, as opposed to other infrastructure improvements, and (2) that design parameters (e.g., empty bed contact time) for these facilities would be similar to the typical values assumed in the EPA's estimate. The commenter's

conceptual estimates for annual O&M cost lack sufficient detail to compare to the results of the EPA's WBS models.

Village of Woodbury (Doc. #1629, SBC-042952)

6. Estimated costs for treatment processes and operations and maintenance should consider: engineering, legal, and planning costs, disposal of media and backwash, and lab sampling & testing.

EPA Response: The EPA's EA included all of the costs identified by the commenter. Please see section 13.3.3 of the EPA response in this *Response to Comments* document and Chapter 5 of the EA for more information.

Texas Commission on Environmental Quality (TCEQ) (Doc. #1632, SBC-044129)

Costs for Small Public Water Systems

EPA's economic analysis does not accurately describe the economic impact on small public water systems and system customers. EPA is proposing Granular Activated Carbon (GAC), Anion Ion Exchange (AIX), and Nano-filtration/Reverse Osmosis as best available technology for PFAS removal from drinking water. GAC and AIX are the most likely to be implemented at small Texas systems. TCEQ estimates the initial installation of GAC at a small system will cost $175,000, while AIX is estimated to cost $1,050,000. On average, small systems (i.e., systems serving a population less than 3,300) in Texas serve 667 customers. EPA estimates a maximum annual maintenance cost per household for systems with a population of 501 to 3,301 of $700 per household for GAC—$332 for treatment and $368 for hazardous waste disposal—and $478 per household for AIX—$235 for treatment and $243 for hazardous waste disposal. Utilizing the average customer count, the combined annual maintenance and hazardous waste disposal costs are $466,900 for GAC and $318,826 for AIX. If a small water system with an average of 667 customers has a monthly water bill of $75 per customer, the annual revenue from billing is $50,025 which does not meet annual costs of maintenance and hazardous waste disposal for PFAS. Additional expense for quarterly monitoring requirements will further impact small systems operating on a limited budget. The PFAS NPDWR, as proposed, would significantly increase the annual cost of business for small systems and system customers, who already struggle.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document. Additionally, the updated cost curves the EPA developed for the final rule estimate a range of capital costs of approximately $525,000 to $969,000 for a system serving 667 people using GAC to treat groundwater. The updated cost curves estimate a range of capital costs of approximately $377,000 to $730,000 for ion exchange. The commenter's estimate for GAC is substantially below the EPA's range. Although the commenter's estimate for ion exchange exceeds the EPA's range, the comment does not include information to confirm that (1) all the estimated costs would be directly associated with PFAS treatment, as opposed to other

infrastructure improvements, and (2) that design parameters (e.g., empty bed contact time) for this facility would be similar to the typical values assumed in the EPA's estimate. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

The commenter's estimate of annual costs misinterprets the household costs presented in the EPA's analysis. The household cost for hazardous waste disposal is inclusive of annualized capital cost and all other treatment operating costs unrelated to hazardous waste disposal. It is not additive with the household costs presented for the non-hazardous disposal scenario. As a result, the commenter's estimated totals include double counting. In addition, the commenter has selected the maximum value from the EPA's range. This maximum would not be typical for most systems; even the minimum value incorporates conservative assumptions about PFAS occurrence.

Please see section 13.10 in this *Response to Comments* document for the EPA's response to comments on the affordability analysis and household cost impacts.

Orange County Water District (OCWD), California (Doc. #1634, SBC-043231)

EPA has utilized a Work Breakdown Structure (WBS) model to estimate installation and operating costs for PFAS water treatment systems. Utility surveys conducted by American Water Works Association (AWWA) clearly show that recent actual treatment construction costs are systematically more than 3x greater that the WBS estimates; this difference is consistent with OCWD's own recent treatment construction cost experiences. Furthermore, a treatment cost model developed by Black & Veatch (B&V) for AWWA also shows the WBS model to systematically underpredicts treatment costs. We suspect this is due to the WBS model's heavy reliance on treatment capacity, PFAS levels, and TOC levels as its primary inputs. The model's assignment of a 0% contingency budget to all projects less than 5.8 MGD capacity is a significant defect that does not reflect OCWD's experience nor the best engineering practices.

EPA Response: The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Regarding contingency, the EPA updated its approach to incorporate a contingency factor of 5 to 10 percent depending on total project cost at all cost levels for systems installing treatment. The EPA also included a miscellaneous allowance of 10 percent, which can be considered a form of contingency. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Orange County Water District (OCWD), California (Doc. #1634, SBC-052836)

Furthermore, the WBS model relies upon construction cost information from the calendar year 2021. Due to well documented factors such as significant inflation, labor shortages, global supply chain disruptions, and increased borrowing cost', OCWD's more recently bid PFAS treatment projects have come in progressively 15-25% higher than its initial projects contracted in 2021.

EPA Response: The EPA updated its equipment costs to 2022 dollars (which are the most recent data available), collected new vendor price quotes for cost driver equipment components, and made several other adjustments to WBS model assumptions. Taken together, these adjustments increased the system level capital cost estimates in the EPA's cost assessment by percentages that were generally greater than or equal to those reported by the commenter. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Orange County Water District (OCWD), California (Doc. #1634, SBC-043229)

In response to PFAS concentrations in our Groundwater Producers' wells exceeding State of California health-based advisory levels, OCWD has financed, designed, constructed, and/or is otherwise implementing more than 35 wellhead treatment projects to date for impacted public water systems. Planned capital expenditures for our existing treatment program are approaching $300 million, with anticipated long-term operating outlays expected to push total related treatment response costs to more than $1 billion. Based on our preliminary analysis, the EPA's proposed maximum contaminant levels (MCLs) for PFOA and PFOS of 4 nanograms per liter (ng/L) would increase the number of impacted wells in our service are in the near-term by 50 75%, with corresponding additional requirements for capital and operating expenditures for treatment or other interventions to achieve compliance. Additional wells in our service area are likely to be similarly impacted in the future.

Drawing upon our experience responding to PFAS impacts to our local groundwater basin, OCWD offers comments on the proposed regulation in the following areas: estimated cost, proposed implementation timeline, use of the Hazard Index, and alternative treatment technologies.

EPA Response: The comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Town of Tewksbury, Massachusetts (Doc. #1637, SBC-043241)

May 30, 2023

Mr. Michael S. Regan, Administrator

U.S. Environmental Protection Agency

EPA Docket Center, OLEM Docket, Mail Code 28221T 1200 Pennsylvania Avenue, NW

Washington, DC 20460

RE: Docket ID No. EPA-HQ-OW-2022-0114 - National Primary Drinking Water Regulation Rulemaking for per- and polyfluoroalkyl substances (PFAS)

Dear Administrator Regan:

I am writing to provide comments on the Environmental Protection Agency's (EPA) proposed National Primary Drinking Water Regulation Rulemaking for per- and polyfluoroalkyl substances (PFAS). The drinking water sector fully supports efforts to expand verified public health protections, but EPA needs to consider the challenges associated with its proposed rulemaking and address the water sectors' implementation concerns before finalizing any standards.

I work for the Town of Tewksbury, MA Department of Public Works; we provide drinking water to approximately 30,800 customers. I am a member of the Massachusetts Water Works Association; I am aware that they, and other water works organizations, are submitting more comprehensive comments. I would urge EPA to pay close attention to the points raised by these associations as they are comprised of individuals and companies with expertise in designing and operating Public Water Systems (PWS) and they have the best understanding of the challenges which will be associated with implementing any final rule EPA adopts. My major concerns are as follows:

• EPA has very much underestimated the costs to PWSs to comply with the proposed rule. Our system would likely have to replace its granular activated carbon media in our filters more frequently than we currently do to ensure compliance with the proposed regulations. This can easily cost over $100,000 per changeout, of which we already do twice a year. This does not include the cost of any additional treatment systems that may need to be added or modifications to existing systems.

EPA Response: The comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. The EPA has considered all public comments prior to finalizing the rule and made a number of adjustments to the cost models; please see section 13.3.3 of the EPA response in this *Response to Comments* document for more information.

National Rural Water Association (NRWA) (Doc. #1641, SBC-041)

1. EPA's Cost Estimate

EPA has significantly underestimated the costs of construction, monitoring, and remediation of PFAS. A recent study Black and Veach on behalf of AWWA and the WUC estimated the national cost for water systems [Link: https://www.awwa.org/Portals/0/AWWA/Government/2023030756BVFinalTechnicalMemoradum.pdf?ver=2023-03-14-102450-257] including capital costs, and operations and maintenance to be near $1 billion dollars nationally, for systems that serve populations of 101-500 people alone. For example, in Vermont, small water systems are averaging annual monitoring costs of nearly $2,000. Construction costs are in the millions as many small systems are not only burdened with the cost of constructing the actual equipment but in many cases must increase facility capacity to house filters, equipment, and other items necessary to remediate the PFAS.

EPA Response: The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. In regard to the total capital costs for small systems nationally, the EPA estimates that the total amount of initial capital treatment technology expenditures for small systems nationally ranges between approximately $1.8 and $3.5 billion. The commenter did not provide a directly comparable figure, but this may be consistent with the EPA's findings.

Additionally, it is not clear what costs are included in the statement "[f]or example, in Vermont, small water systems are averaging annual monitoring costs of nearly $2,000," but the EPA assumes this is an example of baseline sampling costs prior to PFAS rule promulgation. If so, the EPA acknowledges this but notes that these costs are outside of the scope of this rulemaking. Lastly, the EPA included the costs associated with buildings and other add-on capital costs in the cost analysis, for more information see Chapter 5 of the EA.

National Rural Water Association (NRWA) (Doc. #1641, SBC-043270)

EPA's Request for Comments – NRWA appreciates EPA's request for comment on many specific aspects of the rule. Below are NRWA's responses to the requests the association is qualified to answer.

• EPA seeks comment on its PFOA and PFOS evaluation of feasibility for the proposal, including analytical measurement and treatment capability, as well as reasonable costs, as defined by SDWA.

• EPA seeks comment on its evaluation of feasibility for the proposed HI MCL finding, including analytical measurement and treatment capability, as well as reasonable costs, as defined by SDWA.

Response: Based on information from our members (where water systems have been required to comply with state regulations), EPA has grossly underestimated the costs of treatment (including treatment residual disposal) especially as it pertains to small rural systems serving a population under 10,000. The impact on the rate payers in these small systems will be far greater than those in larger systems for both capital improvements and ongoing maintenance. This rule will adversely affect systems sustainability.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document on treatment costs and section 13.10 of the EPA response in this *Response to Comments* document on affordability.

American Farm Bureau Federation et al. (Doc. #1642, SBC-043490)

Technologies: In order to meet the 4ppt standard for PFOA and PFOS, rural water utilities will have to obtain and install new technologies. As outlined in the American Water Works Association's (AWWA) recent WITAF 56 Technical Memorandum: PFAS National Cost Model

Report, treatment strategies for PFAS in drinking water include both proven, commercially available technologies as well as emerging technologies. Commercially available technologies that have been demonstrated at full scale in the field to reduce concentrations of PFAS in drinking water are limited to the following:

• Granular activated carbon (GAC)

• Ion exchange (IX)

• Nanofiltration (NF) and reverse osmosis (RO)

Treatment considerations for the application of each of these technologies are described in the full report. While there are many variables that contribute to the specific costs associated with reaching the 4ppt standard, the report incorporates the most obvious operating costs into their cost models: media replacement, membrane replacement, power, maintenance, water disposal, chemical consumption, and labor. The report contains considerable explanation of their methodology and ultimately finds that the national cost for water systems to install treatment to remove PFOA and PFOS to levels required by this proposal will exceed $5.2 billion annually. These costs alone cannot be ignored and the uncertainty with testing availability and disposal methods only exacerbate our concerns with this rule.

EPA Response: The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Massachusetts Water Resources Authority (Doc. #1645, SBC-043288)

EPA should also take into consideration that this regulation will create significant demand for certain PFAS treatment and products, likely driving up the costs for the installation and maintenance of all PFAS treatment. In addition to the costs associated with the installation and maintenance of PFAS treatment, the costs for disposing of spent media are quickly escalating as traditional means for disposal of these media (e.g., landfilling, incineration, etc.) are becoming unavailable as a result of other state and federal regulations around PFAS. EPA should consider the full lifecycle of treatment, including the disposal/destruction of treatment residuals so that PFAS contaminated materials aren't simply moved from place to place. MWRA recommends that EPA ensure that the cost model takes into consideration the full lifecycle of treatment, from installation, operation and maintenance, to the disposal of residuals. MWRA also recommends that EPA consider cost escalators for the full lifecycle of PFAS treatment. MWRA is further concerned that EPA's significantly under-estimated cost model will act as a cap for PWSs seeking to recoup treatment and operation costs from responsible parties.

EPA Response: In response to the commenter's concerns that the rule will create demand that will drive up prices, please see section 13.3.3 of the EPA response in this *Response to Comments* document. The cost models do take into full lifecycle of treatment, from installation, operation and maintenance to the disposal of residuals as the commenter recommends. For the

EPA's response to comments on disposal and treatment residuals and response to comments on PFAS being moved "from place to place", please see section 10.4.1 of the EPA response in this *Response to Comments* document. In response to the commenter's concern that the EPA's cost estimates will "act as a cap for PWSs seeking to recoup treatment and operation costs from responsible parties", while beyond the scope of this action, the EPA would anticipate that a variety of information, including PWS site specific information, would be used to inform decisions about appropriate individual liabilities for responsible parties.

Virginia Municipal Drinking Water Association (VMDWA) (Doc. #1657, SBC-043165)

3. ACTUAL COMPLIANCE COSTS ARE EXPECTED TO BE MUCH HIGHER THAN EPA ESTIMATES

VMDWA appreciates EPA seeking additional compliance cost data. VMDWA believes that EPA's estimate of the cost of compliance with its proposed MCLs for PFAS is materially inaccurate and understated as proposed.

Black & Veatch recently conducted a national cost assessment on behalf of the American Water Works Association (AWWA) that found that MCLs set at 4 ppt for PFOA and for PFOS would trigger $3.2 billion in annualized national costs (capital, O&M, monitoring, etc.) for impacted facilities assuming a seven percent discount rate. [FN1: AWWA, WITAF Technical Memorandum Update, PFAS National Cost Model Report, Figure 7.2 (Summary of Annualized Costs) (May 26, 2023).] In contrast, at the same discount rate, EPA stated that it expects the total annualized cost of the proposal is $1.211 billion, with an uncertainty range for the total annualized costs of the proposed option is $1.103 billion to $1.353 billion. 88 Fed. Reg. at 18700. This is an astonishing nearly three-fold difference in costs between AWWA and EPA estimates. There are corresponding significant household-level cost consequences, with AWWA's estimate in the range of $200 to $225 per household per year for systems serving communities in a population range of 10,001 to 50,000 and $155 to $175 per household per year for systems serving communities in a population range of 50,001 to 100,000, for example [FN2: AWWA, WITAF Technical Memorandum Update, PFAS National Cost Model Report, Figure 7.1 (Annual Costs to Household for Removing PFAS from Drinking Water) (May 26, 2023).].

EPA Response: The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Virginia Municipal Drinking Water Association (VMDWA) (Doc. #1657, SBC-052834)

One VMDWA Member that has already obtained cost estimates support the findings by AWWA and Pennsylvania that the actual costs are likely to be significantly higher than EPA's estimate. This example is a 225 mgd facility with an existing treatment process that includes ozone and biological activated carbon (BAC). Capital costs for granular activated carbon (GAC) or ion exchange ranged from $180 million to $250 million (December 2021 dollars). The associated

annual operating cost increases are estimated at $10 million to $45 million, which using the midrange of $22.5 million, equates to a 20% increase in the utility's overall annual operations and maintenance expense (even assuming no impact of this regulation to a second water plant owned and operated by the utility).

EPA Response: The comment lacks sufficient detail to compare the commenter's estimated cost to those the EPA used for very large systems. Specifically, it does not include information on the influent PFAS concentrations expected at this facility. It also does not include information to confirm that (1) all the estimated costs would be directly associated with PFAS treatment, as opposed to other infrastructure improvements, and (2) that design parameters (e.g., empty bed contact time) for this facility would be similar to the typical values assumed in the EPA's estimate. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Virginia Municipal Drinking Water Association (VMDWA) (Doc. #1657, SBC-052835)

VMDWA believes that costs are likely to increase even further due to the limited supply of engineers and contractors (our Members report that firms are already busy and their prices have been running very high and increasing due to high demand), ongoing supply chain challenges, worker shortages, the national inflation problem, and the adverse cost impacts of extremely high numbers of public utility and other infrastructure projects being attempted over the next five-to-ten years given high federal grant and loan appropriations activity in these areas. Recent experience of VMDWA Members includes the following severe price escalations:

• A Member's multi-year reservoir dam improvement and repair project received only a single bid of $24 million, which exceeded the engineer's estimate of $14 million by $10 million (71%).

• A Member's wastewater treatment plant upgrade received only two bids, with the lowest bid of $215 million exceeding the engineer's already revised (increased) estimate of $138 million by $77 million (56%).

• A review of a Member's capital projects identified an overall increase of 25 to 40 percent over the past three years.

• Multiple Members have reported concerns with GAC supply. One Member specifically reported a 17 percent increase in the cost of GAC over the past year (obviously this is prior to the proposed regulation taking effect).

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document. The EPA updated its equipment costs to 2022 dollars (which are the most recent data available), collected new vendor price quotes for cost driver equipment components, and made several other adjustments to WBS model assumptions. Taken together, these adjustments increased the system level capital cost estimates in the EPA's cost assessment by percentages roughly consistent with those reported by the commenter.

Maryland Association of Municipal Wastewater Agencies (MAMWA) (Doc. #1658, SBC-043400)

3. ACTUAL COMPLIANCE COSTS ARE EXPECTED TO BE MUCH HIGHER THAN EPA ESTIMATES

MAMWA appreciates EPA seeking additional compliance cost data. MAMWA believes that EPA's estimate of the cost of compliance with its proposed MCLs for PFAS is materially inaccurate and understated as proposed.

Black & Veatch recently conducted a national cost assessment on behalf of the American Water Works Association (AWWA) that found that MCLs set at 4 ppt for PFOA and for PFOS would trigger $3.2 billion in annualized national costs (capital, O&M, monitoring, etc.) for impacted facilities assuming a seven percent discount rate. [FN1: AWWA, WITAF Technical Memorandum Update, PFAS National Cost Model Report, Figure 7.2 (Summary of Annualized Costs) (May 26, 2023).] In contrast, at the same discount rate, EPA stated that it expects the total annualized cost of the proposal is $1.211 billion, with an uncertainty range for the total annualized costs of the proposed option is $1.103 billion to $1.353 billion. 88 Fed. Reg. at 18700. This is an astonishing nearly three-fold difference in costs between AWWA and EPA estimates. There are corresponding significant household-level cost consequences, with AWWA's estimate in the range of $200 to $225 per household per year for systems serving communities in a population range of 10,001 to 50,000 and $155 to $175 per household per year for systems serving communities in a population range of 50,001 to 100,000, for example [FN2: AWWA, WITAF Technical Memorandum Update, PFAS National Cost Model Report, Figure 7.1 (Annual Costs to Household for Removing PFAS from Drinking Water) (May 26, 2023).].

EPA Response: The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Maryland Association of Municipal Wastewater Agencies (MAMWA) (Doc. #1658, SBC-052844)

MAMWA believes that costs are likely to increase even further due to the limited supply of engineers and contractors (our Members report that firms are already busy and their prices have been running very high and increasing due to high demand), ongoing supply chain challenges, worker shortages, the national inflation problem, and the adverse cost impacts of extremely high numbers of public utility and other infrastructure projects being attempted over the next five-to-ten years given high federal grant and loan appropriations activity in these areas.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

J.R. Simplot Company (Doc. #1661, SBC-044151)

III. Costs of the Proposed Rule Have Not Been Fully Determined and will be Detrimental, Especially to Small Communities

Feasibility (including costs) Must Considered

If EPA establishes an MCL for any contaminant, the combination of technology, treatment techniques, or other means required to meet the level must not be more stringent than feasible. Each NPDWR which establishes a MCL must list the technology, treatment techniques, and other means which EPA finds to be feasible for purposes of meeting the MCL. The term "feasible" is defined by SDWA as "feasible with the use of the best technology, treatment techniques and other means which [EPA] finds … are available (taking cost into consideration)." Notably, EPA is required to consider costs in its assessment of feasibility in setting an MCL.

Technology and Costs for Small Communities and NTNCWSs

When looking specifically at technologies and costs for small drinking water systems, EPA is proposing the Small System Compliance Technologies (SSCTs) of GAC (Granular Activated Carbon) and IX (Ion Exchange) as Best Available Technologies (BATs).

The installation and annual costs for GAC and IX are expensive, even for small systems, and EPA estimates an annual operating cost per household ranging from $376 to $727. In addition, EPA estimates that the annual disposal cost per household assuming hazardous waste disposal for spent GAC and Resin ranging from $397 to $827. During EPA's May 4 Public Hearing, it was mentioned that EPA is prioritizing research on PFAS disposal options. If spent GAC and Resin from small systems and large CWS are required to be disposed of as a hazardous waste, the disposal costs will be enormous, and treating PFAS in water will result in PFAS disposal to land.

Annualized Costs are Underestimated.

As proposed, EPA grossly underestimates the potential compliance costs of this rulemaking on the thousands of public water systems across the country, including non-transient, non-community water systems (NTNCWSs). As just one small example is that Tables 70 and 71 indicate that hazardous waste disposal for treatment media were not quantified in the Annualized Quantified Rule Benefits and Annualized Quantified Rule Costs evaluations. The exclusion of these disposal costs skews the Benefit/Cost ratio and significantly underestimates the Annualized Quantified Rule Costs.

EPA Response: Regarding feasibility, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA took cost into consideration when determining feasibility. Regarding disposal costs, the six PFAS included in this rulemaking are not RCRA listed. In response to stakeholder feedback, the EPA included a sensitivity analysis to determine the impact on this rule should systems be required to handle and dispose of PFAS treatment materials as hazardous waste in the future. The results of this analysis can be found in Appendix N.2 of the EA for the final rule. Please see section 10.4 in this *Response to Comments* document

for the EPA's response to comments regarding management of treatment residuals. Regarding total annualized costs, please see sections 13.3 and 13.3.3 of the EPA response in this *Response to Comments* document. Finally, while the commenter is correct that the Tables references did not include the quantified costs of hazardous waste disposal, should that disposal method be used, the EPA did quantify those costs in the analysis referenced above and considered them in the Administrator's determination that the benefits of the rule justify its costs. For more information on that determination, please see section 13.8 of the EPA response in this *Response to Comments* document and section XII of the FRN for the final rule.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044436)

• PFAS treatment is expensive, and installation will likely involve pilot studies, which are essential to understanding the effectiveness of treatment, but will increase overall costs. BIL funding is available, but there are barriers to this funding.

• This rule does not explicitly consider costs associated with long-term operation and maintenance of treatment. Promising treatment methods require continual monitoring to assess the effectiveness of PFAS removal. This will potentially require additional operators and frequent replacement of filter media, which will be costly.

EPA Response: The EPA included pilot testing costs in the treatment capital cost estimates for the proposed rule and further updated these costs for the final rule, including the addition of a year of full-scale confirmation sampling. The EPA also included operator labor costs as well as media changeout costs in the cost analyses for the proposed and final rules. The EPA anticipates that the operational results from the pilot test and confirmation sampling will be a sufficient indicator of performance; therefore, water systems should not have to collect large amounts of performance samples indefinitely during the full-scale operation of treatment technologies. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Regarding BIL funding, please see section 2.4 of the EPA response in this *Response to Comments* document.

City of Hillsboro, Oregon (Doc. #1668, SBC-043121)

3. Implementation Cost for Utilities

Significant capital and annual operating costs will be needed to remove PFAS below the proposed MCL, especially given that utilities have such a small margin between detecting PFAS and potential MCL exceedances. The costs of the materials needed to install the treatment technologies to remove PFAS will increase due to the significant increase in demand for the materials as many utilities will need advanced treatment to ensure levels of PFAS meet the proposed MCL. Water utilities, including Hillsboro Water, are faced with investment challenges, as many utilities are already investing large amounts of funding into complying with other

proposed regulations, such as the Lead and Copper Rule Revisions, investing in new and resilient water supply infrastructure, and planned replacements of aging infrastructure. EPA has greatly underestimated the cost burden of this regulation for utilities (Black and Veatch, 2023).

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document regarding AWWA's comment letter and the impacts of demand on costs to comply with the rule. Please see section 5.1.3 of the EPA response in this *Response to Comments* document on feasibility and costs considerations in finalizing the MCLs. The EPA acknowledges that implementation timing associated with the final PFAS rule and the proposed LCRI has the potential to overlap, please see section 13.3 of the EPA response in this *Response to Comments* document.

Aurora Water, City of Aurora, Colorado (Doc. #1669, SBC-043719)

According to a study done by Black and Veatch on behalf of AWWA, the costs of installing drinking water treatment for removing only PFOA and PFOS will exceed $3.8 billion per year nationally. This cost estimate uses data provided by water systems that have done their own cost studies. Compared to EPA's estimate, they estimate more impacted systems and higher costs than what EPA estimated. Aurora Water estimates yearly costs to increase from $250,000 to $550,000 for removing PFOA and PFOS to the proposed level of 4 ppt for one of the three treatment facilities. The other two facilities will need to construct treatment at a cost of approximately $15 million with ongoing O&M cost of about $550,000 per year, each. Aurora expects additional increases in treatment material costs, inflation and supply chain limitations.

EPA Response: The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. The EPA does not dispute the commenter's estimate of costs for its treatment facilities, but the comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

National Association of Water Companies (NAWC) (Doc. #1670, SBC-044159)

2. The proposal's economic analysis is deficient and fails to adequately recognize or address the costs that the rule will impose on water systems.

The proposal's economic analysis is deficient and fails to adequately recognize or address the costs that the rule will impose on water systems. A recent study by Black & Veatch on behalf of the American Water Works Association concluded that the projected costs associated with PFAS treatment at the proposed limits would exceed $47 billion dollars, which is orders of magnitude more than EPA's estimate.

The cost of the technologies to remove PFAS contaminants from drinking water supplies is substantial and far exceeds all the estimates EPA makes in the proposed rule. EPA must rely on the reports prepared by water industry experts that are based on actual case studies and then re-

evaluate how it balances the levels of reductions set with the cost to achieve those levels. As discussed below, how the technological changes necessary to achieve the levels set by EPA will be financed is a key component of this rulemaking.

EPA Response: As discussed in this section in this *Response to Comments* document and the preamble, the EPA has considered all the comments submitted on the EA for the proposed rule and made many changes to reflect these comments and the additional information on costs provided by the commenters. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Further, the EPA notes it is not reasonable to compare a one-time estimate of costs from AWWA's report to the EPA's national annualized costs in the proposal. Instead, a more reasonable comparison is AWWA B&V's annualized costs to the EPA's annualized costs, which are discussed in section 13.3.3 of the EPA response in this *Response to Comments* document. Please see section13.3 in this *Response to Comments* document for the EPA's response to the AWWA B&V present value estimate.

North Jersey District Water Supply Commission (NJDWSC) (Doc. #1673, SBC-044203)

In order to meet the new regulations, the Commission will need to construct a 60,000 SF GAC filter facility and a 4,200 SF intermediate pump station to convey water from their current conventional filters to the new facility, along with significant site, underground utility, and electrical improvement s. Current CAPEX estimates for these improvements, inclusive of project soft costs, are anticipated to be $195, 000,000. Annualized over 25 years at 4% interest, this will result in a yearly debt service payment of $12,500,000. OPEX estimates, inclusive of media replacement, O&M, energy administrative and sampling costs are anticipated to be $8,500,000 annually (2023 dollars). In total this will result in an increase of annual expenditures of $21,000,000, or $573 per million gallons per year. When this is compared to the current user rate of $851 per million gallons per year it represents an increase of nearly 67%. It is the North Jersey District Water Supply Commission's opinion that this significant of an increase in user charges to its member communities will result in an unachievable financial burden, especially to its underprivileged communities.

Lewis Schneider, Director Treatment, Residuals & Lab

EPA Response: The comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. Regarding household level impacts, please see section 13.10 of the EPA response in this *Response to Comments* document.

A. O. Smith Corporation (Doc. #1674, SBC-043702)

b. Cost-effectiveness

As the EPA is aware, and evident in its Economic Analysis ("EA") of its proposed PFAS NPDWS, there are many options for treating drinking water at the point-of-use and each approach has unique capabilities and associated costs. [FN20: See, Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation, EPA Document No. EPA-822-P-23-001, March 2023.] Indeed, POU and POE systems can in fact provide a cost-effective approach to addressing health-based contaminants in drinking water including PFOA and PFOS. The annual costs of these systems can range depending upon the use and application, and the EPA's analysis does an adequate job at reflecting those costs. [FN21: 88 FR 18687 (Table 22)] However, from the Company's perspective there is additional cost data assumptions that it can share with the EPA under confidential business information ("CBI") rules that the EPA may find helpful as it completes the PFAS NPDWS.

The Company does recognize there are challenges when considering all the relevant factors in developing an analysis of the actual cost of implementing either POU or POE compliance solution will vary widely among small public water systems. This includes, for example, small public water systems that currently utilize POU RO systems to treat arsenic. These systems may only have to switch out postfilter cartridges to add in PFAS removal, which would have a negligible cost through updating and installing the filter through the current maintenance cycle. The cost estimates reflected in Table 22 for POU RO do not reflect this co-benefit and cost consideration to installing third-party certified POE and POU systems.

EPA Response: The EPA agrees that small PWSs that already have point of use (POU) programs in place for other contaminants may experience cost savings in using or retrofitting these programs to address PFAS. However, the EPA does not have data to quantify these potential cost savings. The EPA notes that POU devices are not currently a compliance option because the final rule requires treatment to concentrations below the current certification standard for POU devices. However, POU treatment is anticipated to become a compliance option for small systems in the future should National Sanitization Foundation/American National Standards Institute (NSF/ANSI) or another accredited third-party certification entity develop a new certification standard that mirrors (or is demonstrated to treat to concentrations lower than) the EPA's proposed regulatory standard.

New York State Department of Health (NYS DOH) (Doc. #1677, SBC-044951)

The presence of microbiological activity in GAC filters is well documented in scientific literature. Although the presence of heterotrophic bacteria, including total coliform, is not necessarily a public health concern, these issues should be considered during design as well as during operation and maintenance depending on the influent quality. Overall, the presence of GAC filters may require changes in chemical dosages that could impact simultaneous compliance with both the lead and copper rule and the Stage 2 disinfectants and disinfection byproducts rule (Stage 2 DBPR) due to temporary increases in pH. Although these issues can be addressed with proper monitoring and operation, they also may impact the cost of treatment systems as well as operation and maintenance and should be addressed as an uncertainty.

13. The Department reviewed the Drinking Water Treatment Technology Unit Cost models, with particular interest in the granular activated carbon cost model and is concerned that the EPA has underestimated the cost of this proposal. This cost model does not include an evaluation for PFAS chemicals specifically but includes cost estimates for several organic contaminants. We recognize that there are weaknesses to using the standard design with linear interpolation for cost comparison purposes. We are using it only to illustrate the significant difference in cost between installations in the State of New York and the estimating tools available from EPA. Given the limited time provided for public comment, we were unable to do an in-depth evaluation of the economic analysis and customize the work breakdown structure (WBS) tool to determine if it was plausible to make modifications that would align the tool with New York State costs.

Table 3: New York State Costs for GAC Treatment Installed in the Newburgh Area

[Table 3: See Docket ID EPA-HQ-OW-2022-0114-1677]

[FN3: Estimate used standard design in WBS model with linear interpolation.] [FN4: Project did not include permanent enclosures.]

Each of the projects listed above were completed prior to the pandemic and prior to inflation experienced during the post-pandemic period. Nonetheless, the EPA estimated costs are considerably lower than the actual costs incurred by New York State prior to inflation.

Additionally, New York State compared data contained in preliminary engineering reports submitted for listing on the 2023 DWSRF Intended Use Plan Final Amendment #2 — Bipartisan Infrastructure Law Emerging Contaminants and compared those costs to the WBS model for organic compounds treating groundwater, using the standard design. New York State recognizes that most of these projects are on Long Island, where labor and construction costs can be higher than the remainder of the State.

Table 4: Cost Comparison of Projects Listed in IUP to EPA Cost Models

[Table 4: See Docket ID EPA-HQ-OW-2022-0114-1677]

[FN5: Estimate used standard design in WBS model with linear interpolation.] [FN6: Water system may benefit by reduction in TOC by GAC.] [FN7: Cost estimate evaluated based on 2.152 MGD standard design.] [FN8: Proposal includes 3 treatment systems at 1.5 MGD, 1.44 MGD and 1.73 MGD.] [FN9: Proposal includes 2 treatment systems at 2.0 MGD each.] [FN10: Proposal includes 2 treatment systems at 0.7 MGD each.]

While the cost difference can be partially due to increased construction costs in the New York City metropolitan area as well as inflation, it does not fully account for the discrepancy. Again, given the short timeframe states were given to provide comment, it was not feasible to conduct a thorough review of the economic analysis to determine if these discrepancies are addressed by EPA elsewhere in the proposal or in the cost estimating tools. Based on the information available, we estimate that the present value cost to New York State of the proposal based upon 551 supplies that may have violations, is approximately $1.6 billion with annual O&M of

approximately $50 million, While the Department appreciates additional funding through the IIJA, this funding accounts for a fraction of the total funding need. We recommend that EPA re-evaluate the cost estimate using data generated through Bipartisan Infrastructure Legislation Emerging Contaminant IUPs as well as current industry data and update estimates to ensure the tools utilized reflect real world current economic conditions and costs, including sector specific costs after inflation. We note that this rule will likely result in increasing inflation pressures on GAC and other construction materials, as well as in the needed labor force given the significant need for PWS treatment. The effect of cross cutters such as Buy American Build America Act (BABAA) is another uncertainty that deserves attention.

EPA Response: The costs discussed by the commenter are generally on the low-end range for what the WBS model might produce for removing non-PFAS organic contaminants. The EPA's estimates are based on values that the agency believes are necessary to remove PFAS and include ranges of estimates. Therefore, the estimates the EPA used for treatment in the EA are generally higher than the WBS estimates presented by the commenter. This is because the version of the WBS model used by the commenter to generate the WBS estimates in Tables 3 and 4 did not contain standard designs for PFAS. The commenter did not specify which of the other organic contaminants they selected, but the standard designs for most of these contaminants assume a single vessel with an empty bed contact time (EBCT) of 7.5 minutes. Typical designs for PFAS, including the standard designs in the current version of the WBS model used for this rulemaking, use two vessels in series with an EBCT of 20 minutes. These design parameters result in substantially higher capital costs for PFAS compared to other organic contaminants. Furthermore, if the commenter did not adjust the component level input in the WBS models, the resulting estimates would default to the low cost level. In estimating costs for the PFAS rule, the EPA considered the full range of cost levels (low, mid, and high). Finally, several of the examples listed present the total cost of installing GAC at multiple locations. The tables compare these costs to WBS outputs for installing GAC at a single location with a design capacity equal to the total of the multiple locations. Due to economies of scale and fixed costs that are incurred per installation, WBS outputs generated using this approach will underestimate costs for multiple, separate installations. Therefore, as discussed above, the WBS estimates presented in Tables 3 and 4 do not accurately represent the WBS outputs used to estimate costs for the final rule.

The tables below compare the reported or estimated costs from the commenter's Tables 3 and 4 to results from the updated cost curves the EPA developed for the final rule. Some of the commenter's reported or estimated costs fall within or below the EPA's range. Although others exceed the EPA's range, the comment does not include information to confirm that (1) all the estimated costs would be directly associated with PFAS treatment, as opposed to other infrastructure improvements, and (2) that design parameters (e.g., empty bed contact time) for these facilities would be similar to the typical values assumed in the EPA's estimate. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Costs from Commenter's Table 3 Compared to Results from the EPA's Updated Cost Curves

GAC Location	Design Capacity (MGD)	Commenter's Reported Capital Cost ($million)	EPA's Capital Cost Curves Lower Bound ($million)	EPA's Capital Cost Curves Upper Bound ($million)
Town of New Windsor Temporary GAC Butterhill WTP (2019)	2.1	1.4	3.2	5.3
Town of New Windsor Permanent GAC Butterhill WTP (estimate)	6.5	8.14	6.0	11.7
Town of New Windsor Permanent GAC Kroll (2019)	0.43	1.9	0.7	1.4
Town of Berlin Permanent GAC WTP (2017)	0.5	0.64	0.76	1.51
City of Newburgh Washington Lake Filter Plant (2018)	8.3	19.75	7.00	13.85

Costs from Commenter's Table 4 Compared to Results from the EPA's Updated Cost Curves

GAC Location	Design Capacity (MGD)	Commenter's Reported Capital Cost ($million)	EPA's Capital Cost Curves Lower Bound ($million)	EPA's Capital Cost Curves Upper Bound ($million)
Nyack Village PFAS treatment at water plant (19171)	3	4.7	3.8	6.6
Starr Ridge Manor Town of Southeast GAC treatment system (19496)	0.13	2	0.3	1.1
Birch Hill Acres Town of Southeast (19495)	0.06	1.2	0.2	1.1
Jericho Water District relocate existing GAC vessels to well 29 and install new GAC vessels at wells 18 and 19	4	17.6	7.7(a)	12.6(a)
Port Washington Water District new GAC to remove contamination at well #7 (19485)	0.7	8.1	0.9	1.5
Port Washington Water District new GAC to remove contamination at well #6 (19484)	0.7	8.1	0.9	1.5
Port Washington Water District new GAC to remove PFAS at Hewlett Well #4 (19337)	1.7	6.9	2.9	4.7
Albertson Water District remove PFAS at wells 1, 2 and 5 (19338)	4.68	18.5	8.2(b)	13.5(b)
Carle Place Water district remove PFAS at wells 3 and 4 (19392)	3.45	7.6	4.3	7.2

GAC Location	Design Capacity (MGD)	Commenter's Reported Capital Cost ($million)	EPA's Capital Cost Curves Lower Bound ($million)	EPA's Capital Cost Curves Upper Bound ($million)
Willston Park wells 1A and 2 GAC PFAS treatment (19371)	4	12	6.2(c)	10.2(c)
Willston Park well 4 GAC treatment (19369)	2	8.6	3.1	5.1
Sands Point Water District removal of PFAS at wells 3 and 4 (19233)	1.4	10.5	1.8(d)	3.0(d)
Sands Point Water District wells 2A and 5A GAC treatment for PFAS removal (19012)	1.3	8.4	2.5	4.2

Notes: (a) total for 3 treatment systems of 1.33 MGD each; (b) total for 3 treatment systems of 1.5 MGD, 1.44 MGD, and 1.73 MGD; (c) total for 2 treatment systems of 2 MGD each; (d) total for 2 treatment systems of 0.7 MGD each

City of Vancouver Water Utility, Vancouver, WA (Doc. #1684, SBC-044307)

Capital Costs Estimates:

The City of Vancouver hired a consulting firm to complete a treatment feasibility study based on levels detected in our groundwater supply. Capital and O&M costs for PFAS treatment systems were completed with this study. Vancouver has detected PFOS and PFOA levels in excess of the proposed 4 ppt regulation in 34 of our 40 wells, which represents six of our nine wellfields. Although the feasibility study estimated capital costs for treatment in order to meet the Washington State Action Level (SAL) of 15 ppt and 10 ppt for PFOS and PFOA, respectively, our estimate far exceeds what the EPA has established to meet 4 ppt. Vancouver estimated that it will cost $171.8 million in capital construction costs to meet the SAL for 52.6 MGD. The EPAs capital estimates to treat 52.6 MGD at the proposed 4 ppt is only about $23.5 Million. It will likely cost Vancouver upwards of $250 Million to treat the two additional sources of water that are under the SAL, but over the proposed MCL of 4 ppt. These estimates do not include the costs to treat new sources of supply that will be needed in the near future to meet the growth of the community.

Again, the Safe Drinking Water Act requires consideration of the costs and benefits, but in the case of PFAS, the EPA did a poor job of estimating the actual capital cost burden the proposed levels will have on rate payers. The EPA needs to adjust their capital cost estimates significantly.

O&M Costs Estimates:

Vancouver’s PFAS treatment feasibility study also included the estimated O&M costs to treat water at six of its nine wellfields to half the SAL, which amounted to about $1.237 million per year. Vancouver roughly estimates that adding two more wellfields at a lower limit of 4 ppt will likely increase O&M costs to approximately $3 million per year, but a more detailed analysis still needs to be completed and is currently under way. EPAs estimate of approximately $2.7

million per year to treat 30 MGD is likely very close based on Vancouver's O&M cost evaluation.

Unfortunately, it does not appear that the proposed rule explicitly considers costs associated with long-term operation and maintenance of treatment when setting the MCLs. The long-term O&M costs will be significant at such a low level and need to be a major component considered when setting the MCL as treatment systems will require additional operators and frequent replacement of filter media.

EPA Response: It is unclear how the commenter arrived at the conclusion that the EPA's capital and annual O&M estimates for the flow rates presented would be $23.5 million and $2.7 million, respectively. The commenter also did not specify the treatment technologies considered in its estimate. The updated cost curves that the EPA developed for the final rule estimate a range of capital costs of approximately $38 million to $86 million total to install six facilities, each treating approximately 8.77 million gallons/day (for a total of 52.6 million gallons/day). Although the commenter's estimates of $171.8 million and $250 million exceed the EPA's range, the comment does not include information to confirm that (1) all the estimated costs would be directly associated with PFAS treatment, as opposed to other infrastructure improvements, and (2) that design parameters (e.g., empty bed contact time) for these facilities would be similar to the typical values assumed in the EPA's estimates. The commenter's estimates for annual O&M costs lack sufficient detail to compare to the results of the EPA's WBS models. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Additionally, the EPA disagrees with the commenter's assertion that the agency did not consider costs associated with "long-term operation and maintenance of treatment when setting MCLs". The proposed and final rule explicitly considered costs associated with long-term operation and maintenance of treatment. The EPA's estimates of national annualized cost include long-term O&M costs such as operator labor and media replacement.

Horsham Water & Sewer Authority (HWSA) (Doc. #1686, SBC-043806)

May 30, 2023

Michael Regan

Administrator

Environmental Protection Agency

EPA Docket Center, Office of Ground Water and Drinking Water Docket Mail Code 28221T

1200 Pennsylvania Avenue, N.W.

Washington, DC 20460

Sent via E-Mail

Comments on Proposed Rule for Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation (Docket ID No: EPA-HQ-OW-2022-0114)

Dear Administrator Regan,

The Horsham Water & Sewer Authority (HWSA) appreciates the opportunity to comment on the Environmental Protection Agency's (EPA's) "Proposed Rule for Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation". The HWSA is a medium sized water and sewer authority (~8,000 connections) that was one of three water systems severely impacted by PFAS contamination of its drinking water sources from the historical use of AFFF fire-fighting foam at the now closed Willow Grove Joint Naval Air Base and still active Biddle Air Guard station. Our systems combined to expose some of the worst PFAS contamination in the country in EPA's third Unregulated Contaminant Monitoring Rule (UCMR3).

Since the initial detection of Per- and Polyfluoroalkyl Substances (PFAS) contamination in our drinking waters in 2014, our utilities have been struggling to "fix" our water systems through the installation of PFAS treatment systems and restore confidence of our customers as our first and highest priority. Due to the evolving nature of health concerns from consuming PFAS, following the lowering of the EPA Health Advisory levels for PFOA and PFOS in 2016, Horsham Township adopted a "non-detect" standard for all PFAS substances in its drinking water, and tasked the HWSA with meeting this standard. As EPA is now proposing the laboratory Practical Quantification Level (PQL) of 4 parts per trillion (ppt) for these substances, EPA is essentially proposing the "Horsham Standard" for PFOA and PFOS for all water utilities to meet based on existing laboratory capabilities. We obviously have experience with achieving this level of performance and hope the agency will give our comments due consideration as such.

In January 2017, we began operation of our first two (2) wells with Granular Activated Carbon (GAC) treatment for PFAS removal. Currently we have eight (8) GAC treatment systems in place and have completed 26 GAC changeouts at these sites. We also have three (3) anion exchange (IX) treatment systems under construction. It should be noted that these IX systems are already well over their expected completion date due to supply chain issues. The construction contract period has now been extended to 500 days from award to substantial completion with no guarantee that this deadline will even be met. It should also be noted that the costs for the installation of the IX systems, as is occurring for all our capital contracts the last few years, is much higher than the engineering estimate.

As Horsham Township (Township) and HWSA committed to reducing PFAS levels to below the current analytical detection levels back in 2016 due to the concerns of the evolving nature of the science and that the community was subject to decades of PFAS exposure prior to its detection in the UCRM3 monitoring, we will not comment on the proposed Maximum Contaminant Levels (MCLs) for perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS). However, given our experiences as a "trail blazer" in installing PFAS treatment for drinking water and treating to “non-detect" levels for a number of years, our greatest concern with this proposed rule

is the feasibility of utilities across the country meeting the compliance timetables, and EPA's cost projections, both of which do not seem grounded in today's reality.

EPA Response: With respect to the commenter's concerns regarding treatment installation and associated costs, please see section 13.3.3 of the EPA response in this *Response to Comments* document. For commenter concerns regarding practical quantitation limits, including implementation of the MCLs at the practical quantitation level (PQL), how the PQLs were set for the final NPDWR, or use of sample results below the PQLs to help operators manage their treatment operations, please see section 5.1.2 of the EPA response in this *Response to Comments* document. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12.1 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Horsham Water & Sewer Authority (HWSA) (Doc. #1686, SBC-043809)

HWSA also believes EPA's estimates for capital and operating costs are both low. For instance, when looking at the capital costs, Horsham, and our neighboring townships of Warminster and Warrington, have all installed GAC installations on multiple wells and the total costs have all been approximately $1,000,000 per site for wells ranging from 0.1 MGD to 0.5 MGD. These actual costs are two (2) to four (4) times higher than EPA's cost estimates and these were all installed prior to the COVID-19 pandemic and before supply chain shortages resulted in on-going cost increases to the water industry. Further, our low bid price in 2021 for the construction of three anion exchange systems that is currently underway was 11% higher than the engineering estimate and this was as the supply chain related price increases were just beginning to materialize.

EPA Response: The updated cost curves the EPA developed for the final rule estimate a range of capital costs of approximately $0.3 million to $1.3 million for facilities using GAC to treat groundwater with a design flow ranging from 0.1 to 0.5 million gallons per day. The commenter's reported cost of $1 million falls within this range. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

New Hampshire Department of Environmental Services (NHDES) (Doc. #1690, SBC-044334)

To date, 65 water systems have installed treatment to reduce levels of PFAS to comply with the state MCLs. Dozens of other public water system sources that have been contaminated with PFAS have been taken out of use. The MCLs proposed by USEPA are lower than NH's MCLs and would require that an additional 181 sources of water for public water systems be mitigated to comply with US EPA's MCL. The initial cost for installing treatment for the 181 sources is estimated to be $166 million and the annual operation and maintenance costs for the treatment systems are estimated to be $44 million.

Based on the ongoing work in NH and what we have learned since 2014, NHDES respectfully provides the enclosed comments. In addition to several comments relative to administrative

procedures and risk communication associated with rule implementation, our comments focus on three points.

First, NHDES believes that the US EPA's projected costs for administration, monitoring, treatment, operations and maintenance, etc. are vastly underestimated and that NH's cost alone may exceed the national estimate.

EPA Response: The EPA has considered all public comments on the cost analysis in the proposal and made changes to reflect those comments and information. The EPA's EA presents national level cost estimates that are annualized over the period of analysis and are therefore not directly comparable to the commenter's single year state-level estimate of capital costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Water Quality Association (WQA) (Doc. #1694, SBC-044987)

Cost Analysis and Small System Compliance

WQA believes that the EPA's cost analysis for deploying POU RO systems (found in Table 22 of the Federal Register notice [FN6: EPA-HQ-OW-2022-0114-0027, Table 22]) is conservative and that actual deployment would likely be more cost-effective than the table indicates. The association appreciates that the EPA views these systems as affordable but believes there are several factors in the analysis that led to a higher cost. This includes a slightly higher average price for a POU RO system and the absence of other POU/POE technologies that are effective and could increase savings. Additionally, since these products are certified using extremely high influent challenge levels, life expectancy for these products is expected to be longer. The analysis also doesn't account for community-wide maintenance agreements or the resources a small system may already have acquired to educate the public, including personnel.

The association understands it's difficult to consider all factors in a cost analysis and that the actual cost of implementing either POU or POE solutions will vary widely from one small system to the next. For example, a small system that is currently using POU RO to treat arsenic may only have to switch out post-filter cartridges to add in PFAS removal. The cost might be negligible if this change is phased in through the current maintenance cycle. The EPA only included cost estimates for POU RO in Table 22 of the Federal Register notice, but other technologies are also capable of meeting the proposed PFAS MCLs and may be less expensive in some situations. The EPA should encourage small systems to make their own "Fit for Purpose" analysis to determine if a POU or POE solution would be cost-effective for their situation.

EPA Response: Please see the EPA response to comment Doc. #1674, SBC-043702 in section 13.3.3 in this *Response to Comments* document.

Water Quality Association (WQA) (Doc. #1694, SBC-044981)

WQA believes that the EPA's cost analysis for deploying POU RO systems (found in Table 22 of the Federal Register notice) is high, and that actual deployment would likely be more cost-

effective and affordable than the table indicates. As with central treatment solutions, no model can account for all the variable conditions that could impact the treatment solution(s) of choice to meet individual water supply needs.

EPA Response: Please see the EPA response to comment Doc. #1674, SBC-043702 in section 13.3.3 in this *Response to Comments* document.

City of Lancaster, Pennsylvania (Doc. #1695, SBC4992)

1. Economic Impact: The initial assessment of the costs of implementing the removal of PFAS from drinking water are underestimated. Using currently available technologies for the City of Lancaster 12 MGD (million gallons per day) plant are estimated at $46.5 Million for Granular Activated Carbon (GAC) or $43.3 Million for ion exchange. Annual costs to operate are estimated at $2.5 million and $1.8 million dollars respectively. The costs are incredibly high and are in addition to the already rising operational costs due to supply chain limitations. Economically, this will be a significant cost burden for the City. These costs for operational costs assume only one media change out per year and it is highly likely it may be at least 2-3 times based on the source water, which makes the annual operational costs an extra $2-$4 Million.

For the City to treat PFOS, debt service repayments along with the operating costs for media change out and semiannual waste disposal, will increase the typical customer charge an estimated additional $260 Per year. for a GAC system. An Ion Exchange system is estimated at $190 per customer account. These costs would be very difficult for many households to take on financially and the impact it would have could be disastrous for many families, especially those struggling to make ends meet in these hard economic times. The cost is not justified since it will only help them to mitigate potentially 20%, at best, their PFOS exposure while allowing 80% or greater exposure from other foods and household items. If water was 80% of the source, then it would make sense to be so strict with water systems. However, allowing companies to continue to use these chemicals and profit while openly exposing the population to PFOS concentrations in food and consumer items at concentrations millions of times greater is regulating the wrong area. Water companies do not create PFOS but will be forced to treat them while they are continued to be used in our food and consumer products.

EPA Response: The updated cost curves that the EPA developed for the final rule estimate a range of capital costs for a 12 million gallon/day facility of approximately $9 million to $17 million using GAC and approximately $8 million to $12 million using IX. Assuming an average flow of 6 million gallons/day (50 percent of design flow) and one media changeout per year, the EPA's cost curves estimate annual O&M costs of approximately $1 million/year for GAC and approximately $1.7 million/year for IX. Although the commenter's estimates exceed the EPA's ranges, the comment does not include information to confirm that (1) all the estimated costs would be directly associated with PFAS treatment, as opposed to other infrastructure improvements, and (2) that design parameters (e.g., empty bed contact time) for this facility

would be similar to the typical values assumed in the EPA's estimate. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

With respect to the commenter's concerns that PFAS treatment will "increase the typical customer charge", please see section 13.10 of the EPA response in this *Response to Comments* document on the EPA's affordability analysis. With respect to the commenter's assertion that "the cost is not justified since it will only help them to mitigate potentially 20 percent, at best, their PFOS exposure while allowing 80 percent or greater exposure from others foods and household items", please see section 4.2.5 of the EPA response in this *Response to Comments* document for discussion of RSC and section 13.8 of the EPA response in this *Response to Comments* document for the EPA's comparison of costs and benefits, including the Administrator's determination that the benefits justify the costs of the rule. With respect to the commenter's concerns that "Water companies do not create PFOS but will be forced to treat them", please see section 15 of the EPA response in this *Response to Comments* document for the EPA's discussion of regulatory actions under different statutes, which are outside the scope of this rulemaking effort. While this drinking water rule was developed using the authorities of the SDWA, which is not the statutory authority to regulate use of chemicals in consumer and industrial products or regulate the remediation of contaminated sites, the EPA is taking action under other statutory authorities to reduce PFAS exposure and risk. Please see section 15 of the EPA response in this *Response to Comments* document discussing the EPA's PFAS Strategic Roadmap for further information.

City of Lancaster, Pennsylvania (Doc. #1695, SBC-044998)

PFOA and PFOS are everywhere including the clothing we wear and the food we eat due to wrappings and storage choices. Focusing on regulating water systems where the majority of levels are at background levels that are not causing ill health effects does not make sense. Additionally, treatment costs have been increasing at incredible rates. Chemical costs have doubled and even tripled over the last three years. To require an additional $ 9.2-million-dollar annual debt service and operating cost increase on a small system such as ours, to treat PFOS when the science on these chemicals is still very young and being tested is irresponsible. It is necessary to understand its effects and impacts before regulation. The scientific data is not available to set these limits and there has not been thorough testing to set the proposed limit. More data is also needed on the capital costs for large facilities and to ensure the proper treatment for all species of PFAS.

Thank you for your consideration of these comments. If you have any questions or require clarification, please contsterpa.com.

Sincerely,

James C Rieben Jr. Ph.D.

Water Treatment Manager

City of Lancaster PA

EPA Response: With respect to the commenter's concerns regarding treatment costs, please see section 13.3.3 of the EPA response in this *Response to Comments* document. With respect to the commenter's concern about PFAS exposure through use of consumer products, the EPA notes that regulating consumer products is outside the scope of this rulemaking and the EPA's regulatory authority under SDWA. With respect to the commenter's assertion that "regulating water systems…does not make sense", once fully implemented, the final rule is anticipated to prevent thousands of deaths and reduce tens of thousands of serious PFAS-attributable illnesses. The Administrator has determined that the benefits of reducing PFAS in drinking water through this regulatory action justify the costs. See Chapter 7 of the EA for further discussion. For the quantified benefits analysis, the EPA relied on peer-reviewed literature and synthesis of multiple high-quality studies to evaluate the effects of PFAS exposure on human health. For responses to comments on the EPA's comparison of costs and benefits of this action, please see section 13.8 of the EPA response in this *Response to Comments* document.

With respect to the commenter's assertion that "the scientific data is not available to set these limits", the EPA disagrees as the EPA's final rule represents data-driven drinking water standards that are based on the best available science and meet the requirements of SDWA; furthermore, as demonstrated by the record for this rulemaking and the many commenters who urged action regulation of the PFAS covered by the NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. Please see sections 3 and 4 of the EPA response in this *Response to Comments* document for discussions about the scientific health information used to inform this rule, sections 3 and 6 of the EPA response in this *Response to Comments* document for the occurrence information, section 10 of the EPA response in this *Response to Comments* document about the EPA's treatment technology evaluations, section 7 of the EPA response in this *Response to Comments* document about analytical methods, and this section (13) about costs and benefits information used to inform the regulation, among many other technical analyses and scientific sources used to inform this analysis. As demonstrated by the record for the rulemaking, which incorporates the data and information provided by commenters, the EPA has used best available science and information to inform this rulemaking and finalize the final rule's MCLGs and MCLs. The EPA also disagrees with the commenter's assertion that "the majority of levels are at background levels that are not causing ill health effects" As discussed in section IV of the final rule preamble and section 4 of the EPA response in this *Response to Comments* document, the EPA has determined that PFOA and PFOS are *Likely to be Carcinogenic to Humans* based on sufficient evidence of carcinogenicity in humans and animals (USEPA, 2024h; USEPA, 2024i). The EPA has also determined that a linear default extrapolation approach is appropriate as there is no evidence demonstrating a threshold level of exposure below which there is no appreciable cancer risk (USEPA, 2005b; USEPA, 2016b). Therefore, any increase in exposure would result in a linear increase in cancer risk which is very meaningful to public health. For further discussion of PFAS adverse health effects, please see sections II.B, III.B, and IV of the preamble for this action; for responses to comments related to PFAS occurrence data, please see sections 3.1.2, 3.2.2, and 6 of the EPA response in this *Response to Comments* document.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045048)

Specifically, monitoring costs for 1138 community and nontransient noncommunity water systems was estimated to be $2.1 million dollars per year. Costs of treatment, including costs for construction, operation, and maintenance, varied greatly based on the type of treatment selected, site conditions, initial concentration of the contaminant, the presence of other contaminants and organic materials in the raw water, the need for pre-treatment, and the size of the water system. Cost data submitted by water systems to NJDEP through construction permits and applications to the Drinking Water State Revolving Fund (DWSRF) shows a wide range of individual project costs for systems to install PFAS treatment, ranging between $3,000 and $77,000,000. Costs were project specific, ranging from simply replacing filter media in existing GAC vessels to full treatment plant construction and upgrades. Systems requiring a new treatment plant incurred higher costs for design, building and infrastructure construction, labor, and treatment components such as pumps, chemical storage and feed systems, monitoring instruments, and holding tanks.

Utilizing this permit data and project cost data submitted by water systems in applications to the DWSRF, NJDEP estimates that total capital costs for installation of PFAS treatment to meet EPA's proposed standards across the state could be as high as $1,065,000,000. This includes installation of treatment at an additional 350 or so water systems expected to be impacted by the proposed standards in New Jersey, based on currently available data. NJDEP is willing to share the data it has gathered and work with EPA to utilize this data in EPA's assessment.

EPA Response: The EPA's analysis presents national level cost estimates that are annualized over the period of analysis and are therefore not directly comparable to the commenter's single year state-level estimate of capital costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

The City of Columbus, Department of Public Utilities (Doc. #1703, SBC-045055)

II. EPA should consider costs and timing before settling its initial MCL at the PQL.

EPA is mandated to consider costs when setting the MCL. The standard is feasibility, which contemplates expense, rather than mere capability. The regulation as proposed is not feasible, nor is it capable of being met under EPA's proposed timeline.

A. MCLs at 4 ppt PFOA and PFOS are not feasible.

Under section 1412(b)(4)(B) of SDWA, EPA must conduct an economic analysis during the development of drinking water contaminant regulations. EPA must take costs into consideration when setting an enforceable MCL as close to the maximum contaminant level goal (MCLG) as feasible. The SDWA analysis on feasibility is only acceptable if it uses accurate assumptions for its inputs. EPA's cost estimate falls short.

The actual costs that water utilities will face for treatment are significantly higher than EPA's estimate. EPA's estimate of nationwide proposed costs to treat to 4 ppt PFOA and PFOS falls between $776M and $1.2B. This range is much too low. First, there are a few factors that will drive the true cost of meeting 4 ppt much higher. The first is inflation. Last summer, construction costs skyrocketed 25 to 30% higher than 2021 costs [FN1: Inflation Taking the Bite out of New Infrastructure Projects, US News and World Report article. June 19, 2022. Inflation Taking Bite Out of New Infrastructure Projects (usnews.com)]. EPA used 2021 dollars in its estimates so construction costs will already be 25 to 30% higher than the estimates used in the analysis.

EPA Response: The EPA does not agree with the commenter's interpretation of "feasibility;" please see the EPA's discussion in the preamble of what that term means. The EPA's final rule represents data-driven drinking water standards that are based on a thorough analysis of feasibility consistent with requirements under SDWA. For additional discussion on the EPA's feasibility analysis, please see section 5.1.2 of the EPA response in this *Response to Comments* document (for laboratory considerations) and section 5.1.4 of the EPA response in this *Response to Comments* document (for treatment considerations).

With respect to the commenter's concerns about inflation, the EPA has updated its equipment costs to 2022 dollars (which are the most recent data available), collected new vendor price quotes for cost driver equipment components, and made several other adjustments to WBS model assumptions. Taken together, these adjustments increased the system level capital cost estimates in the EPA's cost assessment by percentages that were generally greater than or equal to those reported by the commenter. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

The City of Columbus, Department of Public Utilities (Doc. #1703, SBC-052961)

Second, supply and demand will force additional upward pressure on prices. Prices will increase significantly based on scarcity in the supply chain and labor force as 3,500 utilities nationwide hustle to comply [FN2: In the proposed rule, EPA estimates that 3,400-6,300 water systems will be impacted by the proposed regulation of 4 ppt for PFOA and PFOS with the 1.0 hazard index for the four other PFAS.]. This demand will continue to drive up prices on equipment, lab services, media, and reactivation.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

The City of Columbus, Department of Public Utilities (Doc. #1703, SBC-052969)

As part of its cost analysis, EPA also failed to recognize the factor of the opportunity costs of this regulatory action. As drinking water rates soar in response to the MCL and the required implementation of expensive treatment technologies, there is also an opportunity cost that will be realized by households and businesses. Consumers will have to make tough choices as they have less money. Businesses will raise prices to reflect their increased costs. Products and services

will then cost consumers more and they will have even less money for discretional spending. This cycle is exacerbated in Justice40 neighborhoods where there is already a lack of extra money and increases in the cost of basic needs results in going without basic necessities.

EPA Response: With respect to the impact of demand on costs, see section 13.3.3 of the EPA response in this *Response to Comments* document. For further discussion of opportunity costs, see section 13.9 of the EPA response in this *Response to Comments* document. Please see section 14.10 in this *Response to Comments* document for the EPA's response to comments on environmental justice; please see the EPA response to comment Doc. #1733, SBC-043892 in section 14.10 in this *Response to Comments* document for specific discussion of Justice40.

The City of Columbus, Department of Public Utilities (Doc. #1703, SBC-052970)

EPA's acute underestimation is borne out in CDPU's numbers. In February 2023, CDPU received an estimate for the cost of implementing granulated activated carbon treatment at its water plants, which includes three existing plants and one plant currently in design [FN4: Engineers at Hazen and Sawyer produced a memo detailing the Cost of Implementation of GAC for PFAS Treatment at Columbus, OH Water Plants, dated March 9, 2023. Hazen and Sawyer is a National A/E firm which has worked in surface water and groundwater plants, developed solutions for meeting PFAS targets, installed granular activated carbon and ion exchange facilities, and researched innovative treatment approaches]. Estimated capital costs for CDPU's four plants falls between $338 million to $363 million, but could realistically approach $544 million. Additionally, the current estimate for annual operation and maintenance costs is between $29.4 million to $43.9 million, depending on whether virgin or reactivated carbon is used. To put that in perspective, CPDU—one public water system out of 3,500—may need to spend over half a billion dollars by 2030 to treat the very low levels of PFAS in our drinking water. The result would be an extreme cost for miniscule benefit. EPA's cost-benefit analysis is distorted because its nationwide estimate does not come close to being accurate.

EPA Response: This comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

California Farm Bureau Federation (Doc. #1704, SBC-045073)

Technologies

In order to meet the 4ppt standard for PFOA and PFOS, rural water utilities will have to obtain and install new technologies. As outlined in the American Water Works Association's (AWWA) recent WITAF 56 Technical Memorandum: PFAS National Cost Model Report, treatment strategies for PFAS in drinking water include both proven, commercially available technologies as well as emerging technologies. Commercially available technologies that have been demonstrated at full scale in the field to reduce concentrations of PFAS in drinking water are limited to the following:

• Granular activated carbon (GAC).

• Ion exchange (IX).

• Nanofiltration (NF) and reverse osmosis (RO).

Treatment considerations for the application of each of these technologies are described in the full report. While there are many variables that contribute to the specific costs associated with reaching the 4ppt standard, the report incorporates the most obvious operating costs into their cost models. These include media replacement, membrane replacement, power, maintenance, water disposal, chemical consumption, and labor. The report also contains considerable explanation of their methodology and ultimately finds that the national cost for water systems to install treatment to remove PFOA and PFOS to levels required by this proposal will exceed $5.2 billion annually.

EPA Response: The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs of the final rule. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045111)

Section XI – Treatment Technologies

1) Cost-effective compliance for GAC – additional guidance on applicable circumstances for GAC is needed.

GAC is the likely most cost-effective option, especially for small water systems. And as the preamble discusses, the Bipartisan Infrastructure Law provides considerable funding for the installation of treatment. However, it does not cover on-going costs, which are expected to be significant and likely increase in the next several years as the demand increases nationally nor does it cover compliance sampling costs. In Vermont our traditional approach is not to permit a new well if it has a human- introduced contaminant such as SOCs or VOCs, so there are very few sources that have treatment for these compounds in the state. However, given the emerging nature of PFAS, we do have contaminated sources, which increasingly require treatment. Often many small systems do not have access to other locations to develop a new source in an area outside of contamination, which would be the preferred option, however, many times it is not feasible. Additionally, we are very rural so connecting to a "nearby" system is likely to be incredibly cost prohibitive. That means treatment is a necessity. Based on our experience with PFAS to date, a community system serving approximately 400 individuals would spend approximately $30,000 per year on on-going treatment-related expenses including media disposal and replacement. These are expenses that are not "covered" by the traditional SRF program and would be borne by the system for potentially many years to work through the process of recovering costs from responsible parties. This will cripple the water system's user base due to the economy of scale.

As discussed previously in these comments, EPA needs to establish a post-treatment sampling framework.

EPA Response: The comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. The EPA agrees that the availability of non-treatment options will vary greatly on a system-specific and regional basis. For this reason, the EPA assumed that only a limited number of systems nationwide would be able to choose these options. Please see section 13.3.6 of the EPA response in this *Response to Comments* document. With respect to concerns about funding for "on-going treatment-related expenses", please see section 2.4 of the EPA response in this *Response to Comments* document.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045090)

2) Feasibility on the proposal including analytical measurement, treatment capability, as well as reasonable costs.

a. Small system perspective/feasibility:

EPA should ensure that there is sufficient funding in the programs that the EPA has established for funding response to PFAS contamination at public drinking water systems with an emphasis on small systems and on-going Operations and Maintenance expenses. Vermont is comprised of many small water systems. Of the 592 Community and NTNC systems subject to the proposed regulation, 34 of them serve a population of 3,300 or greater, only 7 of them serving a population of over 10,000 with the biggest single system serving a population of 42,000 individuals. The proposed MCLs would likely impact 25 additional public water systems, based on analysis from single sample(s) and not a running annual average. This is in addition to the 16 systems in Vermont that have already exceeded the state MCL. All of the systems that are expected to exceed the proposed MCL serve a population less than 3,300. The preliminary estimate of capital costs associated with the installation of PFAS treatment for the 25 impacted systems to comply with EPA's draft MCL for Vermont is more than $200,000,000. This does not include on-going Operation and Maintenance (O&M) costs, as discussed below in these comments.

EPA Response: The EPA's analysis presents national level cost estimates that are annualized over the period of analysis and are therefore not directly comparable to the commenter's single year state-level estimate of capital costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. With respect to concerns about funding for ongoing O&M costs and funding available to small systems, please see section 2.4 of the EPA response in this *Response to Comments* document.

Philadelphia Water Department (PWD) (Doc. #1709, SBC-045733)

2. The cost estimates of the BATs developed by the EPA are based on incomplete or non-applicable information and more than likely represent an underestimation of the costs that will be borne by ratepayers.

There are several shortcomings in the cost estimation process for the BATs used by the EPA to justify the draft rule. First, cost curves require a significant number of case studies to develop, which does not appear to be present for surface water PWS. The EPA acknowledges in USEPA 2023g and "Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation" (hereafter "Economic Analysis") that the BATs will perform differently for surface water and groundwater PWSs. In Section 5.3.1.2.2 of the Economic Analysis, the EPA acknowledges that the work breakdown structure (WBS) spreadsheet model for GAC was peer reviewed in 2006, the WBS IX model was peer reviewed in 2005, and the WBS RO/NF model was peer reviewed in 2007. However, from the list of full-scale installations in USEPA 2023g (Section 2.2.1 for GAC; Section 3.2.1 for IX; and Section 4.2.1 for RO/NF), no full-scale installations treating surface water for PFAS existed at the point when these models were created. PWD requests that EPA provide more information on how full-scale surface water treatment facilities were factored into the cost model.

EPA Response: With respect to the commenter's concerns about peer review of the WBS models, WBS model development did not cease with the initial external peer review. The EPA has continued to maintain and update the models throughout the intervening years, including updates specifically for this final rule as described in section 13.3.3 of the EPA response in this *Response to Comments* document.

With respect to the commenter's concerns that the EPA's cost curves do not rely on case studies for large surface water systems, the EPA notes that for unregulated contaminants like PFAS (and for many regulated contaminants), it is highly unlikely that even the most thorough literature search could find a peer-reviewed source for every possible combination of system size and source water with full-scale data on treatment performance and cost. Furthermore, the EPA did not develop its cost curves by extrapolating from case studies because parametric extrapolation can over or underestimate costs for water systems when it does not account for all factors that can vary among case studies. Instead, the EPA used results from the peer reviewed WBS models, which estimate cost using a detailed engineering build-up from the line-item costs of individual treatment system components. The WBS-based approach is a more robust approach than factored or parametric cost estimating methods, as it can be adjusted for desired treatment levels, raw water quality and a range of system parameters. Similarly, the EPA's evaluation of Best Available Technologies considered the complete body of scientific literature and was not based solely on case studies.

Philadelphia Water Department (PWD) (Doc. #1709, SBC-053306)

Additionally, these WBS models do not account for the increased costs of construction in densely populated areas. Many urban WTPs are space-constrained and the likely need for additional land is both costly and politically tenuous. There are many additional costs that pose challenges to urban utilities, such as coordination, staging, utility relocation, that do not appear to be accounted for in the Economic Analysis. Section 2.4.4 of the documentation for each WBS model provides some clarification of how add-on costs, such as land acquisition, are estimated; however, this documentation does not provide adequate details around how the land cost estimates are generated or adjusted to account for land cost increases over time.

EPA Response: The EPA's analysis used unit costs for land acquisition that are scaled to a system's population served and reflect the fact that land costs are generally higher in more densely populated locations. Furthermore, within a given size category, these unit costs are weighted by the expected probability that a system is in an urban versus rural location. For the largest size category (greater than 100,000 people) these costs are heavily weighted (76 percent) to urban land values. Abt Associates (2020b) provides complete details on the methodology and data sources used to estimate unit costs for land. The EPA escalated the 2020 costs to 2022 dollars using the Gross Domestic Product (GDP) implicit price deflator. The resulting weighted average unit cost for land for the largest size category is more than $280,000 per acre after escalation to 2022 dollars.

Philadelphia Water Department (PWD) (Doc. #1709, SBC-053312)

Fourth, the EPA recommends discharge of the concentrate stream from RO/NF into a non-potable body of water (brackish estuary or ocean) at less than 10,000 feet from the PWS. In December 2022, Assistant EPA Administrator Radhika Fox issued a memorandum to state regulatory agencies entitled "Addressing PFAS Discharges in NPDES Permits and Through the Pretreatment Program and Monitoring Programs", which details the implementation of technology-based effluent levels for PFAS discharges under the National Pollutant Discharge Elimination System (NPDES). The inclusion of NPDES discharge limits on PFAS would necessitate additional treatment on the concentrate stream. The cost for this additional treatment is not currently accounted for in the Economic Evaluation for the proposed NPDWR and should be included in any final cost assessments.

EPA Response: The EPA notes that in response to public comments about residual management concerns for high pressure membrane technologies, the EPA has adjusted RO/NF's technology projection compliance forecast to 0 percent in the EA for the final rule. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. For the EPA's response to comments regarding residual management, including management of RO reject, please see section 10.4.2 of the EPA response in this *Response to Comments* document.

Philadelphia Water Department (PWD) (Doc. #1709, SBC-053313)

Finally, the addition of unit processes into the drinking water treatment train has the potential to pose hydraulic limitations which are not clearly accounted for in the Economic Analysis. The hydraulic restrictions from the addition of unit processes may necessitate the addition of raw water booster or mid-process pumping that is not accurately accounted for in the EPA's cost estimations. The documentation for the GAC and IX WBS models state that the assumption for small systems (<1 MGD) will require no additional pumping and the details of the method for determining additional pumps for larger systems is not clearly defined. Site-specific constraints may prevent the addition of booster pumps in existing raw water pumping stations and may necessitate the construction of a new building. It is not clear if the EPA is accurately accounting for the additional pumping that will be required to add these unit processes to treat for PFAS.

EPA Response: The EPA did not include booster pumps for pressure GAC systems or ion exchange, because the head loss associated with these treatment processes is typically low. The WBS models include booster pumps for gravity GAC systems, which are most likely to be used by large surface water systems and face hydraulic limitations. The models determine the number and size of these pumps based on the required design flow plus an additional safety factor. The models include the footprint of these pumps, plus required access space, in the calculation of treatment system footprint used to estimate the cost of buildings. See the *Technologies and Costs* document for more information (USEPA, 2024d).

Philadelphia Water Department (PWD) (Doc. #1709, SBC-053314)

There appear to be several issues with the Economic Analysis including an underestimate of the impact to large systems, which serve approximately 50% of the US population. Altogether, the Economic Analysis includes several shortcomings that potentially result in a underestimation of the cost that will be borne by ratepayers. PWD is requesting that the EPA recalibrate the WBS models used to form cost estimates, using case studies for large surface water PWS to more accurately estimate the financial burdens of the capital improvements required to comply with the draft NPDWR.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045906)

V. EPA's Cost Analysis Is Flawed, and it Is Infeasible for Regulated Entities To Comply with the Proposed MCLs

SDWA provides that, if EPA establishes an MCL for any contaminant, the MCL must be only as close to the MCLG as feasible. Further, the combination of technology, treatment techniques, or other means required to meet the level must not be more stringent than feasible [FN141: 42 U.S.C. 300g-1(b)(B)(5)(B)(ii).]. Each NPDWR that establishes a MCL must list the technology,

treatment techniques, and other means that EPA finds to be feasible for purposes of meeting the MCL [FN142: 42 U.S.C. 300g-1(b)(E)(4)(i).]. The term "feasible" is defined by SDWA as "feasible with the use of the best technology, treatment techniques and other means which [EPA] finds … are available (taking cost into consideration)."[FN143: 42 U.S.C. 300g-1(b)(B)(4)(D).] Notably, EPA is required to consider costs in its assessment of feasibility in setting an MCL. In proposing an MCL, EPA must publish an analysis of the compliance costs [FN144: 42 U.S.C. 300g-1(b)(3)(C)(i)(III).].

As proposed, EPA grossly underestimates the potential compliance costs of this rulemaking on the thousands of public water systems across the country, including non-transient, non-community water systems (NTNCWSs), that will be required to monitor, sample (with limited certified laboratory capacity), and treat six PFAS at infinitesimal, almost-zero levels. As proposed, there is a high level of uncertainty with even detecting PFAS at these levels.

The Chamber released a report in November of 2022 indicating that "the consensus is that Meeting PFAS drinking water standards will likely require substantial investment," and that if the MCL is 10 ng/L [FN145: 10 ng/L is 10 ppt.] or less, nationwide PWS treatment costs will be significant: "At 10 ng/L there is a 50 percent probability that costs exceed $16 billion, whereas the 50 percent probability is $32.5 billion for the 4 ppt scenario and $59.4 billion for the non-detect scenario [FN146: "Potential Costs of Meeting Safe Drinking Water Act (SDWA) Standards for PFOA and PFOS," U.S. Chamber of Commerce (November 7, 2022): https://www.globalenergyinstitute.org/potential-costs-meeting-safe-drinking-water-act-sdwa-standards-pfoa-and-pfos. Note this report only estimated costs for PFOA and PFOS.]. Also, the American Water Works Association (AWWA) published a report in March of 2023 [FN147: "PFAS National Cost Model Report," Black & Veatch Holding Company, prepared for the American Water Works Association (March 7, 2023): https://www.awwa.org/Portals/0/AWWA/Government/2023030756BVFinalTechnicalMemoradum.pdf?ver=2023-03-14-102450-257. See also AWWA statement on proposed PFAS drinking water standards: https://www.awwa.org/AWWA-Articles/awwa-statement-on-proposed-pfas-drinking-water-standards.] that provides national cost estimates for setting an MCL of 4 ppt for PFOA and PFOS. It found the national cost for water systems to install treatment to remove PFOA and PFOS to levels required by this proposal exceed $3.8 billion annually and the national cost burden for 4 ppt MCLs for PFOA and PFOS are over $5.2 billion The report analyzed costs for installation of each treatment technology, including granular activated carbon (GAC) gravity basins; GAC, IX and Manganese pre-treatment pressure vessels; reverse osmosis systems (low and high pressure feed pumps and associated building, storage tanks, brine disposal, decarbonation system, and chemical treatment system); operating costs, and life cycle costs (for a 20-year life).

AWWA concluded that a vast majority of these treatment costs will be borne by communities and ratepayers [FN148: See AWWA Press Release at: https://www.awwa.org/AWWA-Articles/awwa-statement-on-proposed-pfas-drinking-water-standards.]. Its report estimates that annual costs to households for removing PFAS from drinking water can range from $100 or more per year (for a

population of over 1 million) to even $10,000 (for a population of less than 100), which is reflective of communities where new treatment facilities will need to be installed and operated [FN149: Report at 32.]. And this estimate is just for compliance with PFOA and PFOS MCLs; it does not consider the costs for compliance with the other four PFAS and the burdens on water systems using of the newly proposed (and yet untested in any other MCL rulemaking) Hazard Index approach to determine compliance. While EPA accounts for capital costs, it fails to consider that most of the PFAS-related costs will be for ongoing operation and maintenance (O&M). EPA must consider the high costs of maintaining and replacing treatment technologies over time.

EPA Response: For the EPA's interpretation of the term "feasibility" and requirements for developing an MCL, please see the preamble. Section 1412(b)(5)(B)(ii) cited by the commenter is not relevant to this action as it only applies when the EPA is using the authority of that provision to set an MCL at a level other than the feasible level. For response to comments on the agency's consideration of feasibility, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA has considered costs in determining the feasibility of the MCLs, and the EPA has determined that MCLs of 4.0 ng/L for PFOA and PFOS, MCLs of 10 ng/L for PFHxS, PFNA, and HFPO-DA, and a Hazard Index MCL of 1 for mixtures of PFHxS, PFNA, HFPO-DA, and PFBS are all feasible, taking cost into consideration. In response to the commenter's assertion that "[a]s proposed, there is a high level of uncertainty with even detecting PFAS at these levels," the EPA disagrees; for discussion on PQLs for the PFAS regulated by the final NPDWR, including discussion on how the PQLs were established, please see section 7.2 of the EPA response in this *Response to Comments* document. For additional discussion on implementing MCLs at the PQL or use of sample results below the PQLs to help operators manage their treatment operations, please see section V of the FRN and section 5.1.2 of the EPA response in this *Response to Comments* document. See the EPA response to this commenter's approaches and conclusions in the report "Potential Costs of Meeting Safe Drinking Water Act (SDWA) Standards for PFOA and PFOS" in snippet Doc. #1537, SBC-042649 in section 13.3.3 in this *Response to Comments* document. Further, the EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs; please see section 13.3.3 of the EPA response in this *Response to Comments* document. For the EPA's response to comments on AWWA's estimates of small system costs and household level cost impacts, please see sections 13.3.3 and 13.10, respectively, in this *Response to Comments* document. While the commenter is correct that AWWA's comment letter does not consider the costs of the Hazard Index MCL, the EPA has thoroughly evaluated and considered costs associated with the Hazard Index and individual MCLs for PFHxS, PFNA and HFPO-DA; please see section 13.3.2 of the EPA response in this *Response to Comments* document for more information. The commenter is incorrect when stating "[EPA] fails to consider that most of the PFAS-related costs will be for ongoing operation and maintenance (O&M);" The EPA has included O&M costs in the cost estimates, as detailed extensively in Chapter 5 of the EA.

HRSD (Doc. #1719, SBC-043546)

[We see the following recommendations as productive and protective strategies that EPA can utilize:]

Phased implementation coupled with reasonable policy choices can reduce capital and operational cost impacts to communities

HRSD developed estimates of its own increased costs to comply with the proposed MCLs based upon the treatment of 75 million gallons per day of SWIFT Water. As originally conceived, the driver for carbon replacement or regeneration in the SWIFT AWTs was based upon a treatment objective of 4 mg/L of Total Organic Carbon (TOC). Switching to a PFAS threshold of 4 ng/L each, PFOA and PFOS, will result in more than a 60% increase in quantity of virgin carbon utilized on an annual basis, an increase of more than 2,000 tons annually. The projected operational cost increase is approximately $10 million. The annual cost for virgin carbon alone within our SWIFT facilities is projected to be nearly $23 million. This estimate is for facilities that are already designed to utilize granular activated carbon as part of its treatment process. This cost, therefore, does not include the initial capital investment required to construct the facilities.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document. While the EPA is not implementing phased implementation, the agency is granting a two-year extension to comply with the MCLs to allow for capital improvements: please see section 12.1 of the EPA response in this *Response to Comments* document. Additionally, the EPA notes that using the prices as updated for the final rule and including volume discounts, the EPA's cost model estimates approximately $25 million per year for the quantity of virgin carbon reported by the commenter. The commenter's projected cost of $23 million is slightly lower than the EPA's estimate. In short, commenter's estimate is generally in-line with the costs the EPA has projected for a facility of this size using carbon to comply with the PFAS NPDWR.

Thurston Public Utility District (PUD), WA (Doc. #1729, SBC-043592)

10. I am very concerned with EPA's cost estimates and believe they are too low and were based on surface water and not ground water sources. Our engineering estimates for treating a water system for 94 families is $1.1 million. The evaluation and estimates of three (3) jurisdictions in the chart below stated that O&M costs would be close to double between the SAL & MCL because of media replacement frequency. Sampling alone is roughly $300 per sample, on a well with PFAS detections requiring quarterly sampling that is $1,200 per year per well just in lab costs. PFAS treatment is going to be extremely costly and testing is just now rolling out to many systems in the state/nation. I think the number and prevalence of systems with measurable PFAS will be significant. When the MCL is adopted and systems are put on the clock it will become quite apparent that the EPA cost estimates are woefully insufficient. Costs are outlined approximately below on three Washington State water systems.

[Table 1: see docket ID EPA-HQ-OQ-2022-0114-1729].

Thank you for this opportunity to comment. I hope you will take these comments into consideration and modify the rule to accommodate these commonsense recommendations.

Respectfully,

John Weidenfeller, MBA

General Manager, Public Utility District No. 1 of Thurston County

jweidenfeller@thurstonpud.org

Attachment: Letter to EPA Administrator Michael Regan, Lakewood Water District, May 24, 2023 [see docket ID EPA-HQ-OW-2022-0114-1729]

EPA Response: The EPA's cost estimates considered both surface and groundwater sources. The updated cost curves the EPA developed for the final rule estimate a range of capital costs of approximately $0.2 million to $0.6 million facility using GAC or ion exchange to treat groundwater, assuming a design flow of approximately 0.1 million gallons/day based on applying the EPA's population-flow equations for a system with 94 households and an average of 2.53 people per household. The table below compares capital costs for the other examples presented by the commenter to results from the updated cost curves the EPA developed for the final rule. Some of the commenter's estimated or reported costs fall within the EPA's range. Although others exceed the EPA's range, the comment does not include information to confirm that (1) all the estimated costs would be directly associated with PFAS treatment, as opposed to other infrastructure improvements, and (2) that design parameters (e.g., empty bed contact time) for these facilities would be similar to the typical values assumed in the EPA's estimate. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. While the commenter estimates that O&M costs would "be close to double" at some facilities, the comment lacks sufficient detail to evaluate this conclusion in comparison to the results of the EPA's WBS models. Finally, regarding sampling costs, please see section 13.3.4 of the EPA response in this *Response to Comments* document.

Commenter's Tabulated Capital Costs Compared to Results from the EPA's Updated Cost Curves

Jurisdiction	MGD Plant Capacity	Commenter's Capital Cost	EPA's Capital Cost Curves Lower Bound	EPA's Capital Cost Curves Upper Bound
Lakewood #1	2.88	$3,300,000	$2,900,246	$6,388,393
Lakewood #2	4.32	$5,100,000	$3,782,467	$8,545,824
Yorba Linda, CA	25	$28,000,000	$15,020,224	$28,291,178
ENG Estimate Vancouver (future)	53	$172,000,000	$28,010,928	$53,662,660

Thurston Public Utility District (PUD), WA (Doc. #1729, SBC-043578)

The proposed levels are significantly lower than any state has proposed for PFAS chemicals, which would seem to indicate that even states highly concerned with PFAS contamination have arrived at different conclusions than EPA with regard to the cost and benefit analysis. Analysis fundamental to the 1996 amendments to the SDWA requires a detailed risk and cost assessment, and best available peer-reviewed science when developing standards. These requirements are expected to imperil the financial sustainability and affordability of some water systems, which will warrant greater assistance in terms of funding. To not clarify the extent of these costs now would be a grievous mistake as water systems and governments across all levels budget for the future and may be forced into competing for limited and insufficient federal dollars.

EPA Response: Please see sections 13.3 and 13.3.3 of the EPA response in this *Response to Comments* document. In regard to the commenter's assertion that "even states highly concerned with PFAS contamination have arrived at different conclusions than EPA with regard to the benefit/cost analysis," the commenter provides no detail or references to support this statement. While no specific references were given, potential differences in conclusions could arise from differences in number entities included in the analysis, baseline levels of PFAS contamination, estimation of health risk reduction benefits, and the estimation of costs. Additionally, the EPA notes that it has finalized this regulation to be consistent with the requirements of SDWA and numerous executive orders: these requirements may be different than those authorizing or mandating a given state to set standards. As discussed in this section and the preamble, the EPA considered public comments on the cost analysis in the proposal and made many changes in response to these comments and associated information; as a result, the EPA has used the best available peer reviewed information to support the EA for the final rule. For the EPA's response to comments on the affordability determination, please see section 13.10 of the EPA response in this *Response to Comments* document. For more information on federal funding availability, please see section 2.4 of the EPA response in this *Response to Comments* document.

Clean Air Council, et al. (Doc. #1731, SBC-043877)

Although the proposed NPDWR is vital to public health, Commenters are mindful that the cost of compliance will be substantial for public water systems. The proposed NPDWR would require a nearly five-fold increase in the number of EPs whose water will need treatment, when compared to the Pennsylvania regulations. However, this cost should not be a deterrent because the corresponding value in terms of health is high and the financial costs should be partially offset by federal funding.

Moreover, the exact costs are unclear, as demonstrated by, for example, the disparity between the cost estimates produced by the Commonwealth of Pennsylvania and those generated by EPA. When developing Pennsylvania's PFAS drinking water MCL rule, PA-DEP conducted an economic analysis to assess the treatment costs for PFOA and PFOS [FN22: 53 Pa.B. 350–60.] The analysis should be similar to the proposed economical analysis for the NPDWR, since the

monitoring and treatment technologies are the same for the state and the federal regulations, as noted above [FN23: It should be noted, however, that implementation of the NPDWR may require, for example, more frequent changing of the GAC or ion exchange materials, thereby increasing to a degree the annual costs.] The PA-DEP provided estimates for the annual costs of implementation as a function of the number of entry points requiring PFAS treatment, which could be fit to a linear function: Assuming 900 entry points in Pennsylvania (24% of the total) that will need PFAS removal under the proposed NPDWR, the economic analysis provided by PA-DEP suggests an annual cost of more than $395 million [FN24: Fitting the cost data in Tables 15 and 16 of the Pennsylvania drinking water regulation yields a linear fit for cost as a function of EPs needing PFAS treatment that is: annual cost (million $)=2.3+0.44*x, where x is the number of entry points affected. This means that $2.3 million/year is the cost of testing for the entire state, regardless of EP needing to implement treatment. The annual cost (in millions) for each EP that does require PFAS treatment is $0.44. See 53 Pa.B. 357, 359.]. This estimate is very high when compared to the economic analysis conducted by the EPA in the NPDWR, [FN25: See 88 Fed. Reg. 18689–729.] where the national annual cost of implementation is estimated to be of order $770–1,200 million [FN26: 88 Fed. Reg. 18724, Table 66]. These national costs are only 2–3 times higher than the PA-DEP estimate, despite Pennsylvania's population being only approximately 4% of that of the entire USA [FN27: Pennsylvania's population is 13 million, according to the census. U.S. Census Bureau, Section on Quickfacts, Pennsylvania, https://www.census.gov/quickfacts/PA (last visited May 24, 2023). Comparatively, the population is nearly 335 million for the entire United States. U.S. Census Bureau, U.S. and World Population Clock, https://www.census.gov/popclock/ (May 24, 2023).]. Even if the occurrence of PFAS in Pennsylvania drinking water is higher than the national average, it is not likely that Pennsylvania accounts for 30–50% of the national PFAS water pollution.

Detailed comparison of the economic analyses conducted by the EPA and the PA-DEP is outside the scope of these comments. However, it is likely that the EPA's numbers are more up to date and better represent current expenses: For example, PA-DEP used an average cost per sample of $616, [FN28: 53 Pa.B. 356.] while EPA used a value of $302–$376,[FN29: 88 Fed. Reg. 18698, Table 34.] which reflects the drop in costs over the last 5 years.

EPA Response: The EPA agrees that comparing the estimate of costs in Pennsylvania to the EPA's national cost estimates is complicated due to differences in discount rates applied and period of analyses for each estimate. The commenter's overall conclusion that the "EPA's numbers are more up to date and better represent current expenses" and the commenter's concurrence with the EPA's estimated sample analysis costs supports the final rule.

Michigan Section American Water Works Association (MI-AWWA) (Doc. #1734, SBC-044475)

Cost

Drinking water systems in Michigan have concerns regarding the short-term and long-term costs of upgrading treatment facilities and the disposal cost of PFAS impacted waste stream. The EPA

has significantly underestimated costs associated with the removal method based on unpredictable low concentrations. Further, this cost should be borne by chemical producers who make great profit on it rather than water utilities. For one community, the estimated cost for feasibility, final design, and construction within the next 2-5 years will impact rate payers by 1%-3% over the next 20 years for capital cost and operational cost increases.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document. Regarding the comment "[f]urther, this cost should be borne by chemical producers who make great profit on it rather than water utilities," please see section 15 of the EPA response in this *Response to Comments* document. While beyond the scope of this rulemaking, the EPA is also taking action outside of this NPDWR to address PFAS, and these actions can be found in the EPA's Strategic Roadmap outlined in section II.F of the FRN.

Arizona Corporation Commission (ACC) (Doc. #1735, SBC-045180)

The following example illustrates the potential cost of compliance with the proposed rule for an Arizona utility. The table below shows estimated construction costs from a Class A utility regulated by the ACC, which represents the largest utility class in Arizona with annual operating revenues exceeding five million dollars.

[Table 1: See Docket ID EPA-HQ-OW-2022-0114-1735]

[FN1: Media Changeout costs include replacement media, labor to replace media, and disposal of spent media.]

[FN2: Media changeouts are required annually for IX treatment. Spent media will be disposed using incineration. Costs for hauling, incineration, and environmental permitting are included.]

Note: Million Gallons per Day ("MGD"), Ion exchange ("IX"), Granular Activated Carbon ("GAC"), Reverse Osmosis ("RO")

Over the past five years, the Company's average construction expenditures were $39.9 million. The estimated cost to install ion exchange forever chemical remediation technology ("FCRT") for the Company's eight wells is estimated to be $38,391,500. This estimate indicates that the construction expenditure for the forever chemical containing wells in 2022 is approximately 96 percent of the Company's average capital costs over the past five years. Additionally, it costs around $5,909,000 to add an ion exchange facility to a 0.2 MGD or 138 gallons per minute ("GPM") well system.

In Arizona, smaller utilities are classified as Class D and E, serving populations ranging from five to 10,000 customers. These utilities typically have wells with flow rates between 50 GPM and 200 GPM (0.07-0.288 MGD). Class D utilities have operating revenues between $50,000 and $249,000, while Class E utilities have operating revenues of less than $50,000. In Arizona, Class D and E utilities comprise 228 of the approximately 266 regulated water utilities.

A 2018 study conducted by the Arizona Department of Environmental Quality ("ADEQ") tested 109 wells for PFOA and PFOS and found that 20 wells tested above the Maximum Contaminate Level ("MCL") as proposed, which is roughly 20 percent of the tested wells. The total number of Public Water Systems ("PWS") in Arizona is in excess of 1,500 systems. Assuming ADEQ's sampling represents the entire population, Arizona could potentially have over 275 systems impacted by the new standards. Given the nature of Arizona's water systems, the impact of the new rule would disproportionately impact the smaller rural communities.

EPA Response: The tables below compare the estimated costs from the commenter's table and text to results from the updated cost curves the EPA developed for the final rule. The commenter's estimated costs exceed the EPA's range. However, the comment does not include information to confirm that (1) all the estimated costs would be directly associated with PFAS treatment, as opposed to other infrastructure improvements, and (2) that design parameters (e.g., empty bed contact time) for these facilities would be similar to the typical values assumed in the EPA's estimate. To fully evaluate the commenters' reported or estimated costs in comparison to WBS model results, the EPA would need itemized line-item cost details and engineering design parameters. To inform the cost estimates of the proposed and final PFAS NPDWR, the EPA conducted an extensive review of the literature. The EPA has further validated the unit costs in the PFAS rule with equipment cost information from 2023 from a major supplier of treatment media. While the EPA recognizes there are likely site-specific instances where costs exceed the EPA's cost ranges, there are also likely site-specific instances where costs are less than the EPA's cost ranges, and this level of accuracy is appropriate for a national level analysis. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Commenter's Estimated Capital Costs Compared to Results from the EPA's Updated Cost Curves

Project	Flow Rate	Type	Commenter's Capital Cost Estimate	EPA's Capital Cost Curves Lower Bound	EPA's Capital Cost Curves Upper Bound
Site 1	2.4MGD	IX	$ 11,186,400	$ 2,600,254	$ 4,027,209
		GAC	$ 11,580,700	$ 3,435,280	$ 5,686,426
		RO	$ 19,861,600	$ 4,844,602	$ 6,628,846
Site 2	0.2MGD	IX	$ 5,909,600	$ 316,290	$ 634,476
		GAC	$ 6,095,000	$ 434,373	$ 835,051
		RO	$ 10,859,900	$ 1,814,636	$ 2,525,325
Site 3	0.5MGD	IX	$ 7,800,000	$ 547,719	$ 952,705
		GAC	$ 7,968,900	$ 756,894	$ 1,286,646
		RO	$ 14,930,800	$ 2,213,065	$ 3,206,409
Site 4	0.1MGD	IX	$ 5,173,800	$ 232,007	$ 481,856
		GAC	$ 5,472,300	$ 299,777	$ 625,199
		RO	$ 10,275,400	$ 1,649,535	$ 2,219,913
Site 5	0.7MGD	IX	$ 8,321,700	$ 676,762	$ 1,105,074
		GAC	$ 8,229,400	$ 913,539	$ 1,494,954

Project	Flow Rate	Type	Commenter's Capital Cost Estimate	EPA's Capital Cost Curves Lower Bound	EPA's Capital Cost Curves Upper Bound
		RO	$ 12,313,500	$ 2,424,180	$ 3,507,277

Commenter's Estimated O&M Costs Compared to Results from the EPA's Updated Cost Curves

Project	Flow Rate	Type	Commenter's O&M Cost Estimate	EPA's O&M Cost Curves Lower Bound	EPA's O&M Cost Curves Upper Bound
Site 1	2.4MGD	IX	$ 1,150,000	$ 395,631	$ 398,308
		GAC	$ 1,150,000	$ 335,393	$ 366,149
Site 2	0.2MGD	IX	$ 450,000	$ 35,254	$ 35,617
		GAC	$ 450,000	$ 33,853	$ 38,986
Site 3	0.5MGD	IX	$ 700,000	$ 76,718	$ 77,417
		GAC	$ 700,000	$ 89,311	$ 93,179
Site 4	0.1MGD	IX	$ 400,000	$ 20,091	$ 20,311
		GAC	$ 400,000	$ 22,073	$ 25,061
Site 5	0.7MGD	IX	$ 700,000	$ 101,006	$ 101,853
		GAC	$ 700,000	$ 189,726	$ 206,120

In response to the comment regarding disproportionate impacts on smaller rural communities, In the EPA's Environmental Justice (EJ) analysis for the final rule, the agency examined the demographic distribution of costs across multiple water system size categories and found, as suggested by the commenter, that incremental household costs to all race/ethnicity and income groups generally decrease as system size increases, which is expected due to economies of scale. For more information on the findings of the EPA's EJ analysis, please see Chapter 8 of the EA (USEPA, 2024b). To alleviate potential cost disparities identified by the EPA's analysis, there may be an opportunity for many communities to utilize BIL (P.L. 117-58) funding to provide financial assistance for addressing emerging contaminants. BIL funding has specific allocations for both disadvantaged and/or small communities and emerging contaminants, including PFAS, please see section 2.4 of the EPA response in this *Response to Comments* document for more information

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045994)

Treatment techniques also do not have the same efficacy for every PFAS chemical. Specifically, short chain PFAS generally break through more quickly than long chain. This provides less opportunity for adsorption unless the flow rate through the media is reduced. Treatment designs are typically contaminant specific, and while this may create opportunity for co-removal, the success is situation dependent. To remove additional PFAS compounds, modifications and additions would likely need to be made, further increasing project costs.

EPA Response: The EPA agrees that short chain PFAS generally break through more quickly than long chain PFAS. The EPA notes that the cost analysis reflects the assumption that water systems will target and treat for regulated PFAS; therefore, the estimated project costs are accurate. The EPA maintains that co-removal of some additional PFAS is likely because PFAS tend to co-occur and can be co-removed. These are important nonquantifiable co-removal benefits of this regulation, and why the rule, while protecting the public from regulated PFAS, also offers some protection from some other PFAS. See Chapter 6.2.4 of the EA for further discussion.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046032)

Attachment 2

The PFAS Challenge – May 2023

Monitoring and Planning for PFAS Treatment

Fairfax Water has been voluntarily monitoring for PFAS on a quarterly basis since 2021 and has posted its PFAS results on its website. Water treated from the Potomac River has so far tested below the proposed MCL's for PFOA and PFOS. Water from the Griffith plant slightly exceeds the proposed MCL's for PFOA and PFOS. Data from both plants is below the proposed HI.

[Table: see docket ID EPA-HQ-OW-2022-0114-1738]

The Griffith Water Treatment Plant (120 MGD) is sourced by the Occoquan Reservoir. The plant became operational in 2006, replacing three older treatment plants that were unable to meet the requirements of the D/DBP rule. Conventional treatment processes with the addition of ozone and biologically active carbon filtration were chosen for the Griffith Plant to meet D/DBP rules. An initial evaluation by engineering consultants has determined that additional treatment trains are necessary to remove PFOA and PFOS to the proposed MCL.

Construction cost estimates for GAC or Ion Exchange are initially estimated at between $180 and $250 million, with annual operating costs of between $10 and $45 million. A mid-range value of $215 million (capital) represents a 21% increase in Fairfax Water's 10-year capital improvement program. A mid-range value of $22.5 million for annual operating costs for PFAS treatment represents an increase of 20% in Fairfax Water's total annual operating budget.

[Figure: see docket ID EPA-HQ-OW-2022-0114-1738]

EPA Response: The updated cost curves the EPA developed for the final rule estimate a range of capital costs of approximately $54 million to $136 million for a 120 million gallon/day facility using GAC or IX to treat surface water. Although the commenter's estimate of $180 to $250 million exceeds the EPA's range, the comment does not include information to confirm that (1) all the estimated costs would be directly associated with PFAS treatment, as opposed to other infrastructure improvements, and (2) that design parameters (e.g., empty bed contact time) for this facility would be similar to the typical values assumed in the EPA's estimate. The

commenter's estimate for annual O&M cost lacks sufficient detail to compare to the results of the EPA's WBS models. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046028)

Table 30: Annual Treatment Cost by CWS Size for Affected Systems ($M)

[Table 30: see docket ID EPA-HQ-OW-2022-0114-1738]

Table 31 below shows funding made available from the IIJA for the Emerging Contaminants Drinking Water State Revolving Fund in FY23 ($764 million) compared to the estimated annualized treatment costs for small and large CWSs [FN135: Black & Veatch, "WITAF 56 Technical Memorandum: PFAS National Cost Model Report," tbls. 6–3.]. National annualized CAPEX costs equate to 180 percent of the funding made available from the IIJA for small systems treatment and 750 percent for all systems. Even with the substantial increase in federal funding and even if the total amount was allocated to PFAS treatment, water systems and rate payers must pay six times more than the federal funding to purchase treatment systems. Rate payers are also responsible for all of the O&M costs to operate their systems. Therefore, while the federal funding provides some relief, the majority of the severe household effects still are expected to occur.

Table 31: Annual Treatment Costs as a Percentage of IIJA Funding for Emerging Contaminants in Drinking Water

[Table 31: see docket ID EPA-HQ-OW-2022-0114-1738]

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document. The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national capital costs required to comply with the rule; please see section 13.3 of the EPA response in this *Response to Comments* document for the EPA's response to comments concerning costs in comparison to the amount of BIL funding available. Please see section 2.4 in this *Response to Comments* document for the EPA's response to comment on federal funding available to help comply with the rule.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC6017)

1. Likely Compliance Strategies

To comply with EPA's proposed rule, drinking water systems that have PFAS detections exceeding one or more of the proposed MCLs will install limited or total system treatment technologies. Today's effective PFAS treatment systems include the following:

• Ionic exchange (IX). IX involves selective ion exchange in solution with ions bound to a resin matrix [FN101: Black & Veatch, "PFAS National Cost Model Report" (American Water Works Association, March 7, 2023), 6.]. IX resins have a limited capacity for adsorption and are

affected by contaminant concentrations and flow rates, similar to GAC. However, IX resins are highly selective toward PFAS removal, with minimal removal of other contaminants. The overall efficacy of IX for PFAS removal is specific to the water matrix, treatment goals, and system design.

• Granular activated carbon (GAC) [FN102: Black & Veatch, 3.]. GAC systems use carbon-based materials (e.g. coal) that, once activated, produce absorbent media with pores that organic compounds attach to and become absorbed onto. GAC has a finite capacity for compound adsorption and contaminants compete for adsorption sites. Disposal and reuse are considerations with this method, as reactivating GAC media contaminated with PFAS is expected to be more limited in drinking water applications.

• Reverse osmosis (RO) systems. RO is a membrane-based treatment process in which a semi-permeable barrier removes dissolved contaminants [FN103: Black & Veatch, 9.]. These treatment systems are more expensive than GAC or IX systems but are most viable when the GAC/IX replacement frequency requirements are cost-prohibitive due to high influent PFAS concentrations. Membrane elements are mounted into pressure vessels arranged in stages, banks, or arrays, the number of which depends on the specified recovery level.

Each treatment technology carries specific capital investment costs as well as operation and maintenance (O&M). Furthermore, installing treatment systems takes time. Temporarily shutting off a well while installation is completed means that a system will incur the opportunity cost associated with a decreased water supply capacity. With promulgation of EPA's final MCLs, hundreds of systems nationwide will be in non-compliance and require treatment. This sudden increase in demand will place a strain on supply chains and the labor force to meet the increased demand for equipment and labor. Water systems will bear near- term additional costs due to a scarcity in the labor force and in capital equipment.

Some systems that require treatment will also consider additional or alternative compliance strategies such as permanently shutting off a groundwater well and, subsequently, interconnecting raw water sources within the system. As with temporary well shut offs, these systems will incur opportunity costs of decreased water supplies. While shutting off wells will likely be one compliance strategy for some systems, we limit our analysis to the assumption that all systems will install treatment and, as a result, incur the following direct costs:

• Capital investment costs;

• O&M and labor costs;

• Near-term additional costs due to labor and capital equipment scarcity; and,

• Administrative costs such as reporting, permitting, and taxes.

In addition to costs with prices that can be measured in goods and services markets ("Market Costs"), EPA's rulemaking has costs that are not trade in markets ("Non-market Costs"). The analysis estimates the major market and non-market costs.

EPA Response: The commenter incorrectly suggests that immediately after the final rule is promulgated systems will be considered out of compliance., The rule provides for several years for water systems to come into compliance. All systems subject to the rule must comply with the MCLs by five years after the promulgation date, and all systems must comply with other requirements of the NPDWR, including initial monitoring, by three years after the promulgation date. Please see section 12.1 of the EPA response in this *Response to Comments* document for more information. Please see section 13.9 in this *Response to Comments* document for the EPA's response to comments regarding opportunity costs associated with the rule. With regard to the impact of demand on costs, please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046039)

While results indicate very low levels of PFAS in our drinking water on average, the variability in testing results demonstrate vulnerability to potential non-compliance. The utility and our customers are faced with significant capital and operations cost burden. The only known methods to remove PFAS from drinking water are granular activated carbon, ion exchange, and reverse osmosis. The appropriate treatment options for WSSC Water's plants are being evaluated as part of our Water Quality and Treatment Master Plan that is currently under development where we are assessing the treatment measures to meet multiple and simultaneous compliance requirements. Initial estimates suggest that potential treatment changes are estimated to cost from $1.4 billion to $2.9 billion just for WSSC Water alone, and this does not include annual operating costs.

[Table: see docket ID EPA-HQ-OW-2022-0114-1738]

One Size Does Not Fit All

There are pros and cons to the different treatment alternatives. Without a comprehensive holistic approach to regulatory compliance based on science, the cost burden will increase exponentially for both SDWA and CWA compliance. Utilities need the time to plan, design, and implement solutions including the time to deal with existing plant constraints and the readiness for operations.

Source: Considering PFAS Treatment Alternatives with PFAS Rule in Mind, Adam Feffer, AWWA Webinar, 2023.

EPA Response: The comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. For the EPA's response to simultaneous compliance comments, please see section 10.4.2 of the EPA response in this *Response to Comments* document

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046023)

Energy Consumption Data Sources

In one of EPA's background document for this rulemaking, EPA provides electricity consumption data per system size for three GAC and IX system sizes:

Table 18: Breakdown of Energy Costs in GAC and IX Systems [FN127: U.S. Environmental Protection Agency, "Technologies and Costs for Removing Per- and Polyfluoroalkyl Substances (PFAS) from Drinking Water," February 2023.]

[Table 18: see docket ID EPA-HQ-OW-2022-0114-1738]

EPA Response: The comment reiterates information provided in the EPA's background materials. Please see section 13.11 of the EPA response in this *Response to Comments* document.

LSP Association (LSPA) (Doc. #1742, SBC-043603)

Based on some point of entry treatment (POET) installations that have been installed in Massachusetts, we estimate that the costs associated with a POET installation are between $7100 - $8600 (that breaks down to $1,100 for the analytical data analysis +$6,000 - $7,500 for the system installation), with an annual maintenance cost of approximately $500 to $1600, not including additional analyses. With the anticipated increased demand for POET systems driven by the lowering of the MCLs, we anticipate that these costs will increase, and become a serious and perhaps insurmountable financial burden on individual homeowners.

EPA Response: The EPA did not include point-of-entry treatment costs in the EA for the proposed or final rule, as the agency did not identify point of entry (POE) treatment as a BAT or SCCT. The EPA notes that the final NPDWR does not require the use of any specific BAT and systems may choose other treatment or non-treatment approaches (e.g., connecting to new source waters) to comply with the rule. PFAS treatment option selection should consider conditions for a given utility, including water quality, available space, disposal options, local rules, and currently installed unit operations (for more information see section 10.1 of the EPA response in this *Response to Comments* document). To the extent water systems choose to use POE to comply with the final rule, the EPA assumes they will select that technology because it is cost effective for them compared to other technologies. Regarding the commenter's assertion that the final rule will increase demand for POEs and increase the costs of this technology, the EPA disagrees. As detailed in section 13.3.3 of the EPA response in this *Response to Comments* document, the EPA does not agree that the demand created by the rule will significantly increase the costs of any technology, in part because the demand created by the rule will be spread out among several compliance technologies. Further, due to practical limitations, the EPA anticipates that mostly small systems would consider implementing POEs to comply with the rule; therefore, the overall nationwide demand is likely to be small and spread out geographically.

Del-Co Water Company, Inc. (Doc. #1744, SBC-043620)

IV. Total costs to Drinking Water Plants is significantly underestimated

The EPA's estimated costs for PWSs to comply with the proposed rules range from $772 million to $1.2 billion. Based on the actual average capital expense received by Del-Co Water's preliminary engineering study (i.e., $67 million), the EPA range appears to significantly underestimate the potential costs to PWSs. The AWWA has estimated that 5,000 PWSs will have to install treatment to comply with the proposed rule and, if the average cost of $67 million is applied to all 5,000 PWSs, this is a total cost of $335 billion – an estimate which far exceeds the EPA's estimate top-range of $1.2 billion.

EPA Response: The comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. Furthermore, extrapolating from a single utility's experience is not an appropriate method to estimate national costs. See also section 13.3.3 of the EPA response in this *Response to Comments* document.

City of Thornton, Colorado (Doc. #1748, SBC-044785)

In addition, Thornton believes that EPA is severely underestimating supply costs. In 2022, Thornton already had difficulties in securing supplies of powdered activated carbon. Prices increased by 138% and the City could not find a supplier that could guarantee deliveries on the needed timeframe. Thornton anticipates the implementation of the PFAS rule will have a similar impact on the GAC market as demand for these products increases. Likewise, because EPA is underestimating the occurrence of PFAS compounds, their estimate of cost increases is insufficient due to exponentially increasing demand.

EPA Response: With regard to the impact of demand for GAC on costs, please see section 13.3.3 of the EPA response in this *Response to Comments* document. Further, the EPA disagrees with the commenter's assertion that the agency underestimated the occurrence of PFAS compounds; for more information, please see section 6.5 of the EPA response in this *Response to Comments* document.

City of Thornton, Colorado (Doc. #1748, SBC-044783)

In Thornton's assessment of EPA's cost/benefit analysis, Thornton finds that the EPA has significantly underestimated the costs associated with treatment of PFAS. Thornton's preliminary engineering designs for installation of treatment systems at both of its WTPs to only meet the MCL (and not the MCLG) are estimated to cost approximately $125 million dollars and will necessitate an increase of $5-8 million in annual operations and maintenance costs (doubling our current O&M budget). This translates to a rate increase between 14 - 19% for our customers over the next decade, disproportionally impacting our disadvantaged residents. Thornton represents just one utility serving less than 0.04% of the national population but is 15% of the EPA's estimated cost.

EPA Response: The comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. For the EPA's response to comment on impacts across demographic and

income groups, please see section 14.10 of the EPA response in this *Response to Comments* document. The EPA further notes that the commenter's comparison of a single utility's capital cost estimate to the EPA's national cost estimate is not appropriate, as the EPA's estimates at proposal represent an annualized value of costs over the period of analysis (82 years).

Las Cruces Utilities (LCU) (Doc. #1753, SBC-043920)

In response to Section XIII. Health Risk Reduction and Cost Analysis, EPA requests comment on the cost of treatment when additional co-occurring but not targeted PFAS chemicals are found in source water.

• Treatment of additional co-occurring chemicals could cause media to be spent more quickly and increase costs to the PWS. This potential increase in cost should be included in the WBS cost model.

EPA Response: The EPA acknowledges co-occurring contaminants could potentially result in more frequent media replacement for some systems. However, based on the EPA's review of the best available peer reviewed information on GAC performance, the agency did not find total PFAS concentration to be statistically significant, likely because competition among PFAS was overwhelmed by competition/fouling from TOC (which typically occurs in the milligrams per liter range compared to the nanograms per liter range for PFAS). Furthermore, for IX, the bed life equations incorporate total PFAS concentration along with percent removal of target contaminants and thus explicitly account for competition. Therefore, the EPA does not anticipate the presence of non-regulated PFAS will significantly increase treatment costs beyond the agency's national estimate for the final rule. Please see section 10.3 of the EPA response in this *Response to Comments* document for further discussion about co-removal of non-targeted compounds.

Las Cruces Utilities (LCU) (Doc. #1753, SBC-043918)

In response to Section XIII. Health Risk Reduction and Cost Analysis, EPA is requesting comment on the WBS models, including the range of component levels assumed in the input to the models, and the range of cost estimates for GAC, IX, and centralized RO.

• LCU agrees with the method for generating cost equation based on component levels assumed (low, medium, and high). However, LCU is unable to comment on the range of component levels as they are not defined in the documentation provided. LCU would like to comment on the range of cost estimates for GAC, IX, and centralized RO. However, the information/documentation provided does not include any information on the range of cost estimates for GAC, IX, and centralized RO. Utilization of centralized RO would require additional water rights to offset the brine water that will be generated as part of the process. RO brine discharge water will take away from the limited amount of water rights and available water here in the desert southwest.

EPA Response: The commenter's concurrence with the method for generating cost equations supports the final rule. The information the commenter describes as "not defined," was available in the docket for public comment. Specifically, Appendix C of the EA includes PWS level cost ranges, the *Technologies and Costs* document (USEPA, 2024d) details the cost ranges by technology, and the WBS models documentation was included in the docket and the models are available on the EPA's website at https://www.epa.gov/sdwa/drinking-water-treatment-technology-unit-cost-models. The EPA notes that in response to public comments about residual management concerns for high pressure membrane technologies, the EPA has adjusted RO/NF's technology projection compliance forecast to 0 percent in the EA for the final rule. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045612)

EPA's WBS Model

According to the proposal, EPA considered three treatment options that may be used by as many as 4,300 water systems to reduce PFAS levels to below the MCLs. These treatment options included GAC, IX, and RO filtration facilities. Additionally, EPA considered other options to address PFAS levels in drinking water, such as interconnections, new wells, and point-of-use RO systems. To estimate the costs to install and operate these systems, EPA relied on their Work Breakdown Structure (WBS) for these strategies, which were developed more than two decades ago and were updated as part of the proposal.

As highlighted by the EPA's "Technologies and Costs for Removing Per- and Polyfluoroalkyl Substances (PFAS) from Drinking Water" document, there are full-scale facilities that are currently using these treatment technologies for PFAS removal. To support EPA's cost analysis, AWWA contracted with Black & Veatch to prepare a cost model (the BV Model) for PFAS treatment using GAC, IX, or RO using their national drinking water treatment expertise and with support from water systems and experts from across the sector (See full report in Appendix B). AWWA has also worked with water systems to compile information on the costs to install PFAS treatment systems.

The BV Model and the case studies were used to compare with the model outputs from the EPA's WBS Model for GAC and IX to better understand the accuracy of the EPA's WBS unit cost models. Figure 7-1 shows an example of a comparison of the available case study data to the BV and EPA cost models, specifically showing capital costs associated with installing GAC treatment facilities for PFAS treatment for systems up to 2.5 MGD.

[Figure 7-1: See Docket ID EPA-HQ-OW-2022-0114-1759]

Figure 7-1: Capital Expenses for PFAS Treatment Facilities using GAC Compared to EPA and BV Models

This range was selected as it represents more than 75% of the systems that would be impacted by the proposed rule. Appendix C provides supplemental figures showing a similar comparison for

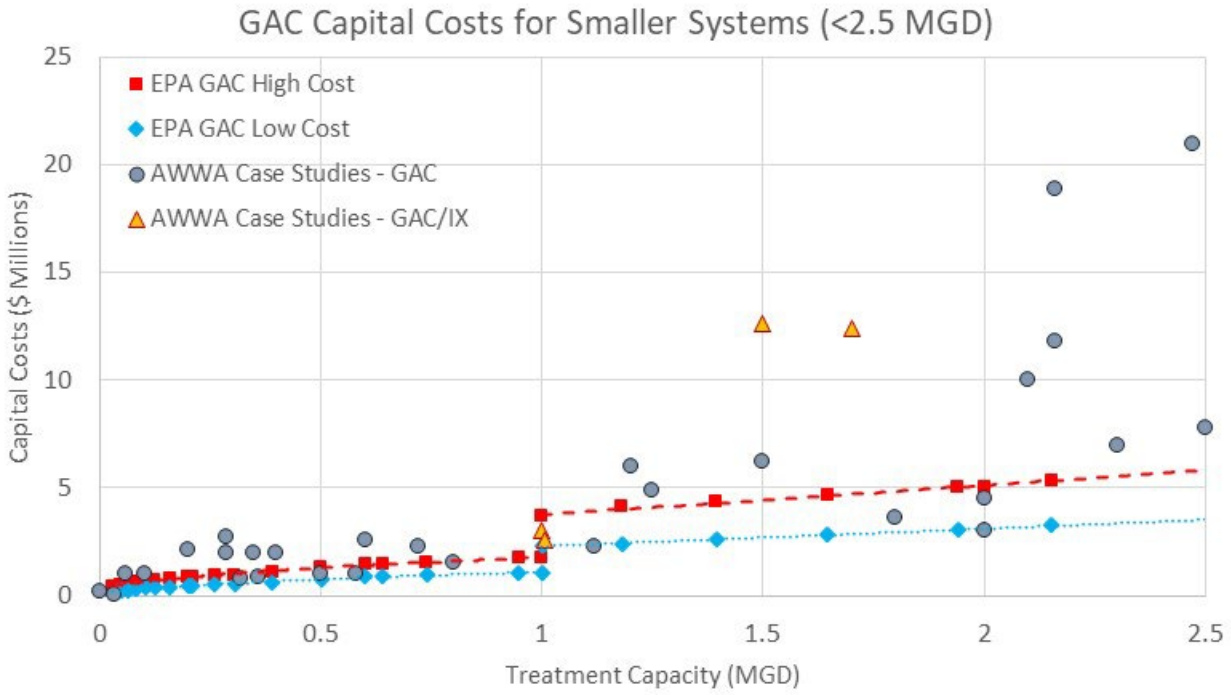
additional ranges of treatment capacity, types of treatment, and operating costs. This data was developed through the use of available data from the Black & Veatch cost model, the example model outputs provided by EPA in the supporting documentation, and more than 100 case studies that were collected earlier this year. For a full list of treatment case studies, refer to Appendix D.

As shown in this figure, the EPA's WBS model significantly underestimates the costs associated with PFAS treatment using a GAC treatment facility. Data from the case studies in this range shows that the typical PFAS treatment system costs 330% more than the estimated cost by the EPA's WBS Model (based on 2021$). The extent of the EPA's WBS Model's underestimation of cost is similarly demonstrated by the BV Model, which shows cost figures in 2022 dollars. These patterns are similarly observed when looking at larger treatment facilities, operating costs, and other treatment technologies. Refer to Appendix B and C for more information.

EPA Response: The EPA disagrees that the EPA's WBS model significantly underestimates the costs associated with PFAS treatment using a GAC treatment facility. The commenter's Figure 7-1 and the supplemental figures in Appendix C misrepresent the EPA's cost curves because they include only the example outputs from Appendix B of the EPA's *Technologies and Costs* document (USEPA, 2024d). The commenter's figures do not consider the full range of cost curves used to estimate national costs and presented in Appendix B of the *Technologies and Costs* document (USEPA, 2024d). Based on comments provided by this and other commenters, for the final rule, the EPA also updated its equipment costs to 2022 dollars (which are the most recent data available), collected new vendor price quotes for cost driver equipment components, and made several other adjustments to WBS model assumptions, as detailed in section 13.3.3 of the EPA response in this *Response to Comments* document.

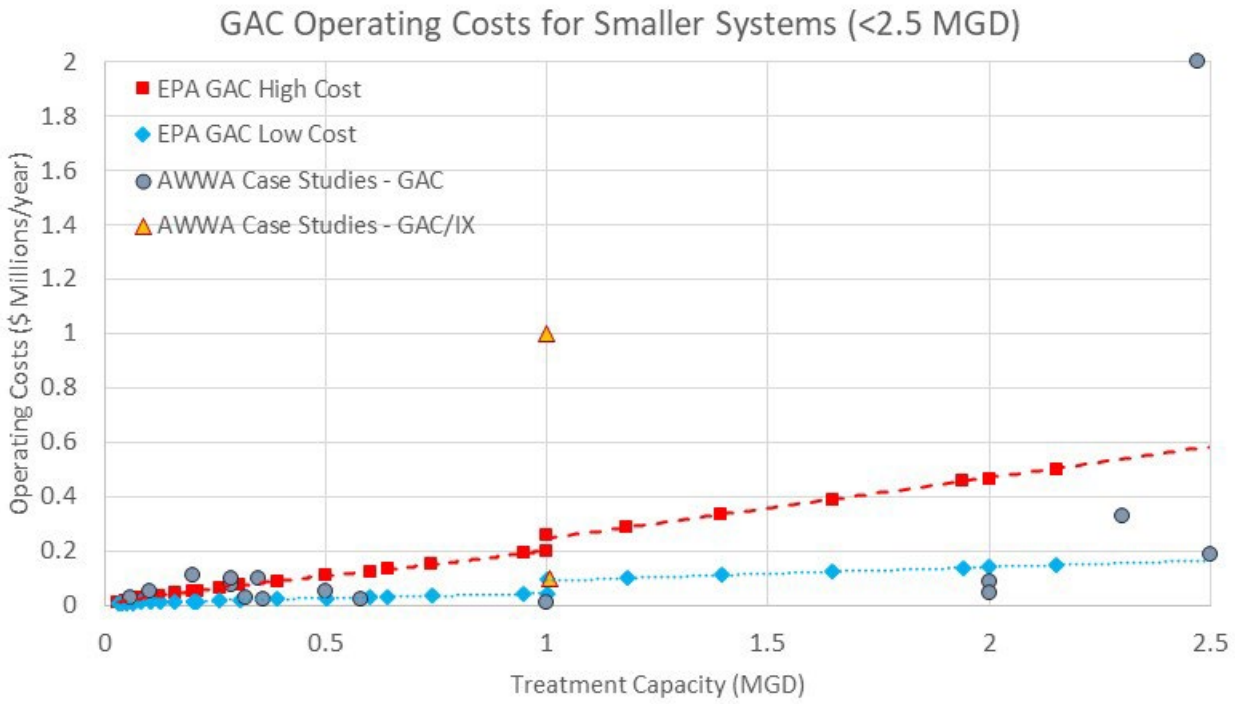
To demonstrate that that commenter's figures do not accurately portray WBS output used in the cost estimates for this action, the figure below partially recreates the commenter's Figures 7-1 and A-13, comparing the commenter's case study costs to the EPA's updated cost curves. Some of the commenter's case studies fall within the range of costs bounded by the EPA's updated cost curves. While other case studies exceed the EPA's high-cost curve, the case study information provided lacks sufficient information for a detailed comparison to the EPA's WBS model. In addition, a portion of the case studies are anonymous, while many other case studies cite "AWWA, 2023b" which is simply a reference back to the comment letter, so the EPA cannot validate this information or decipher it in greater detail. The report provides no information about any of the systems, other than technology, flow, and cost, and does not clearly identify which cost figures are estimates and which are as-built costs. Furthermore, the commenter did not include information to confirm that (1) all the case study costs would be directly associated with PFAS treatment, as opposed to other infrastructure improvements, and (2) that design parameters (e.g., empty bed contact time) for the case study facilities would be similar to the typical values

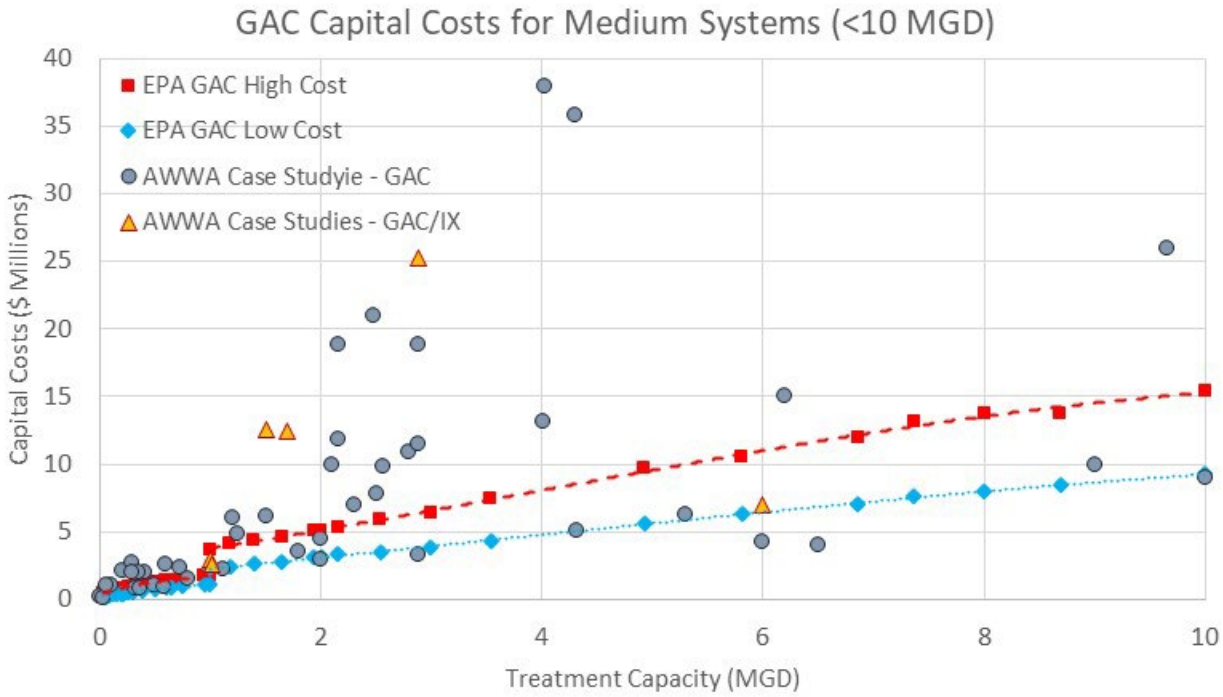
assumed in the EPA's estimate.

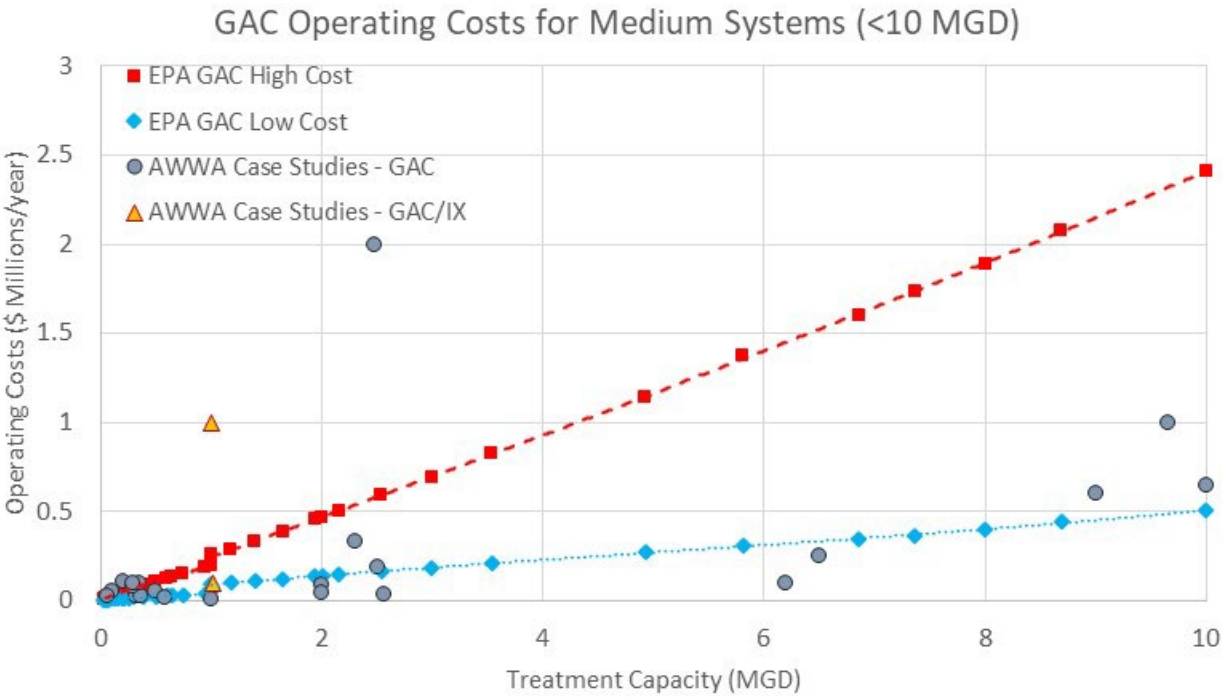


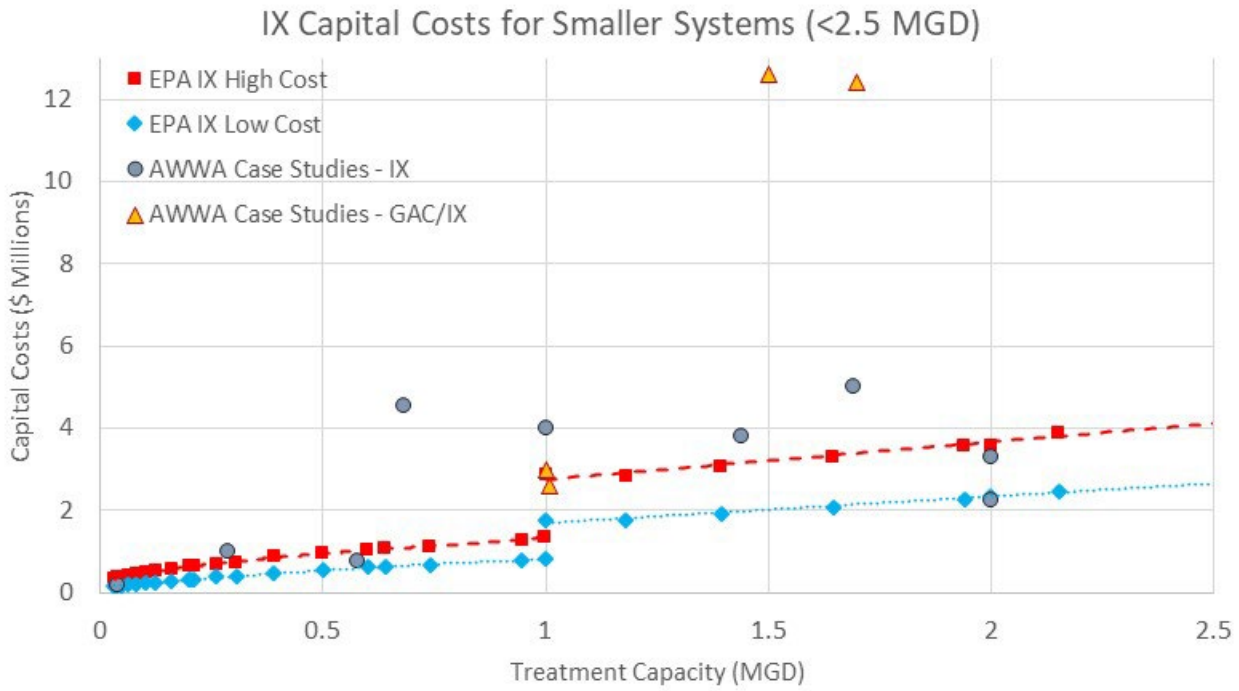
Additionally, the commenter included several case studies labeled "GAC/IX" in the figures presenting GAC costs. The GAC/IX case studies include two of the highest cost examples. These examples may not accurately represent typical facilities using GAC alone. Finally, although the EPA's recreated figure does not show the data points or trendline associated with the B&V model, the EPA notes that this model overestimates costs for most of the commenter's case studies. For example, it results in higher capital costs for 28 of the 32 small GAC case studies shown in the commenter's Figure 7-1 (28 of 34 small GAC case studies reported in the commenter's Appendix D and shown in the EPA's recreated figure above).

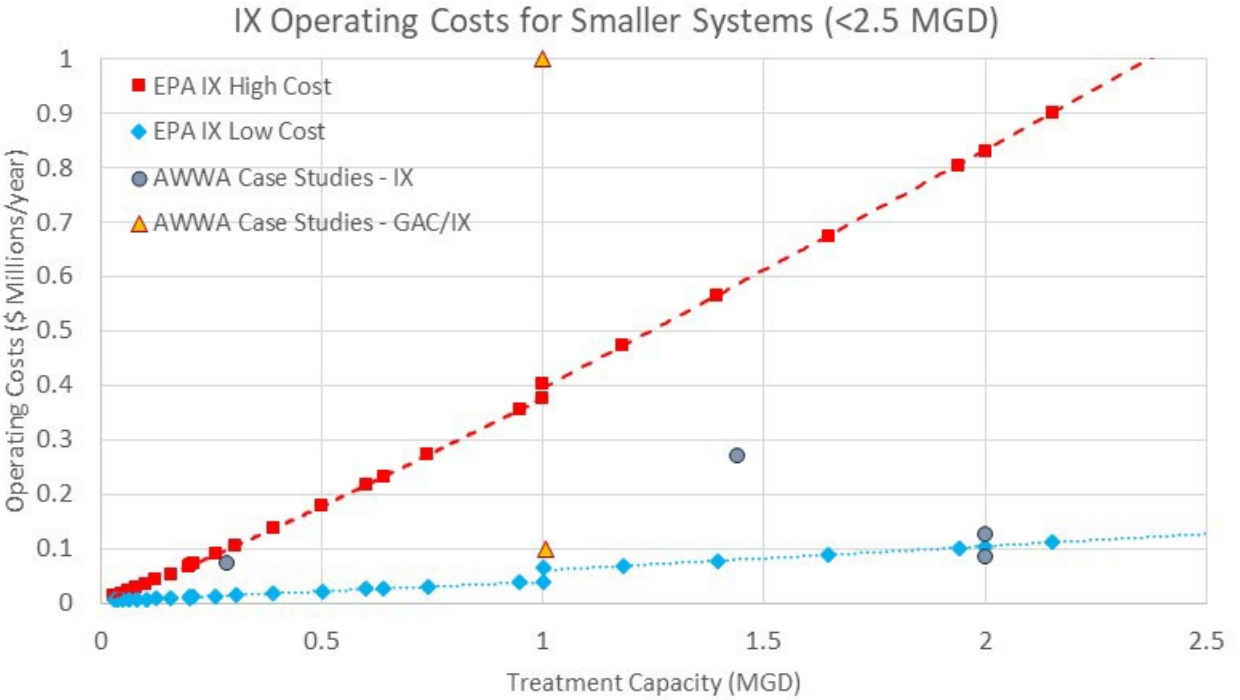
The additional figures below recreate the commenter's Figures A-14 through A-24 using the EPA's updated cost curves. The EPA's conclusions regarding these figures are similar to those above. A number of the commenter's case studies fall within the range of the EPA's updated cost curves. The EPA notes that the majority of AWWA B&V report's case study information on O&M costs fall within or below the EPA's range. In general, while some case studies exceed the EPA's high-cost curve, others fall below the EPA's low-cost curve. Although the recreated figures do not show results from the B&V model, that model overestimates costs for many of the case studies, as discussed in section 13.3.3 of the EPA response in this *Response to Comments* document.

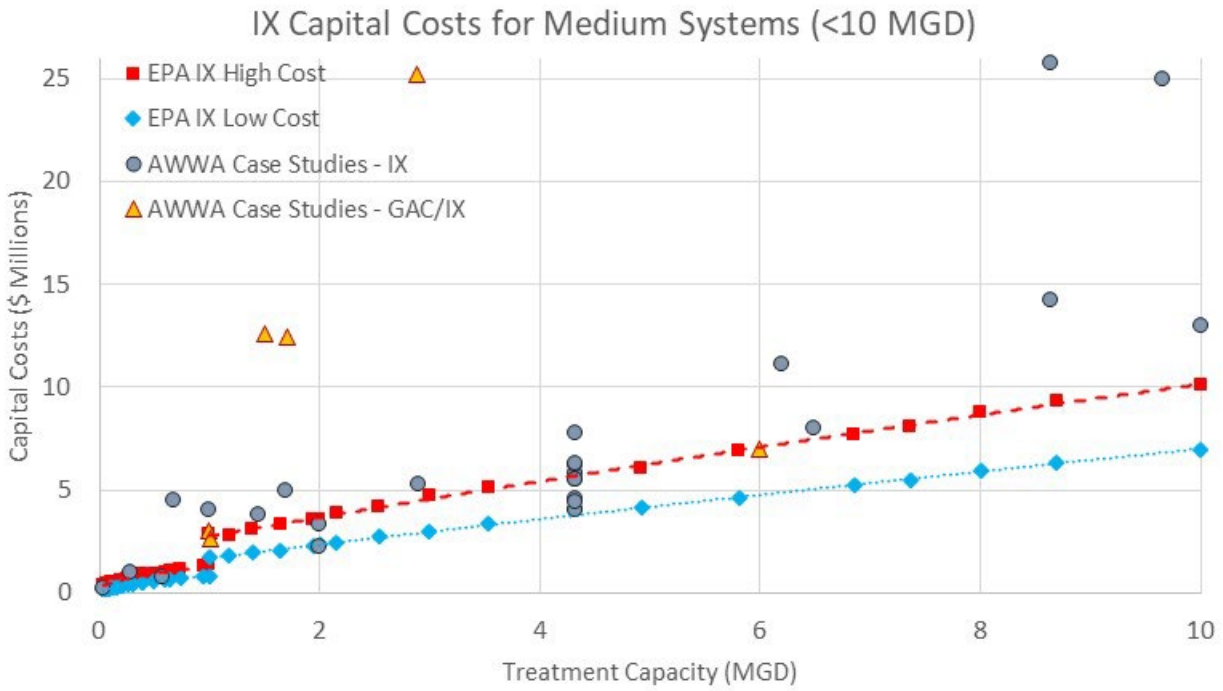

GAC Operating Costs for Smaller Systems (<2.5 MGD)
EPA GAC High Cost
EPA GAC Low Cost
AWWA Case Studies - GAC
AWWA Case Studies - GAC/IX
Operating Costs ($ Millions/year)
Treatment Capacity (MGD)
0
0.2
0.4
0.6
0.8
1
1.2
1.4
1.6
1.8
2
0
0.5
1
1.5
2
2.5

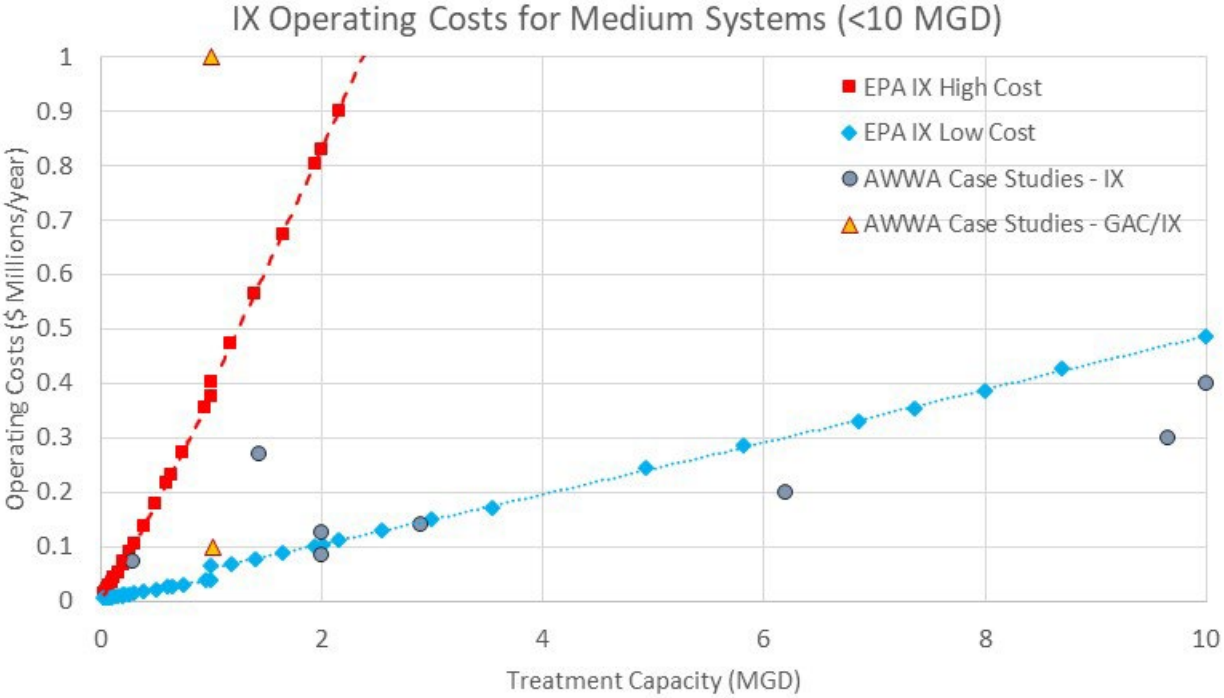

GAC Capital Costs for Medium Systems (<10 MGD)
EPA GAC High Cost
EPA GAC Low Cost
AWWA Case Studyie - GAC
AWWA Case Studies - GAC/IX
Capital Costs ($ Millions)
Treatment Capacity (MGD)
0
5
10
15
20
25
30
35
40
0
2
4
6
8
10

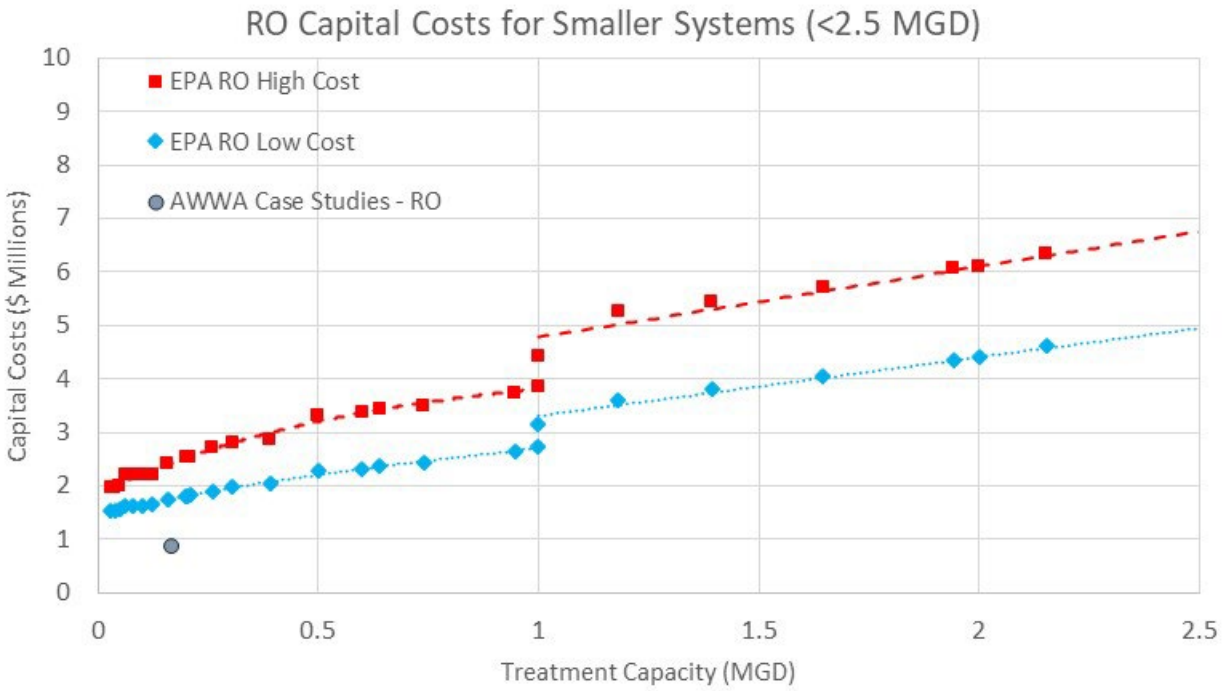

GAC Operating Costs for Medium Systems (<10 MGD)
EPA GAC High Cost
EPA GAC Low Cost
AWWA Case Studies - GAC
AWWA Case Studies - GAC/IX
Operating Costs ($ Millions/year)
Treatment Capacity (MGD)
0
0.5
1
1.5
2
2.5
3
0
2
4
6
8
10

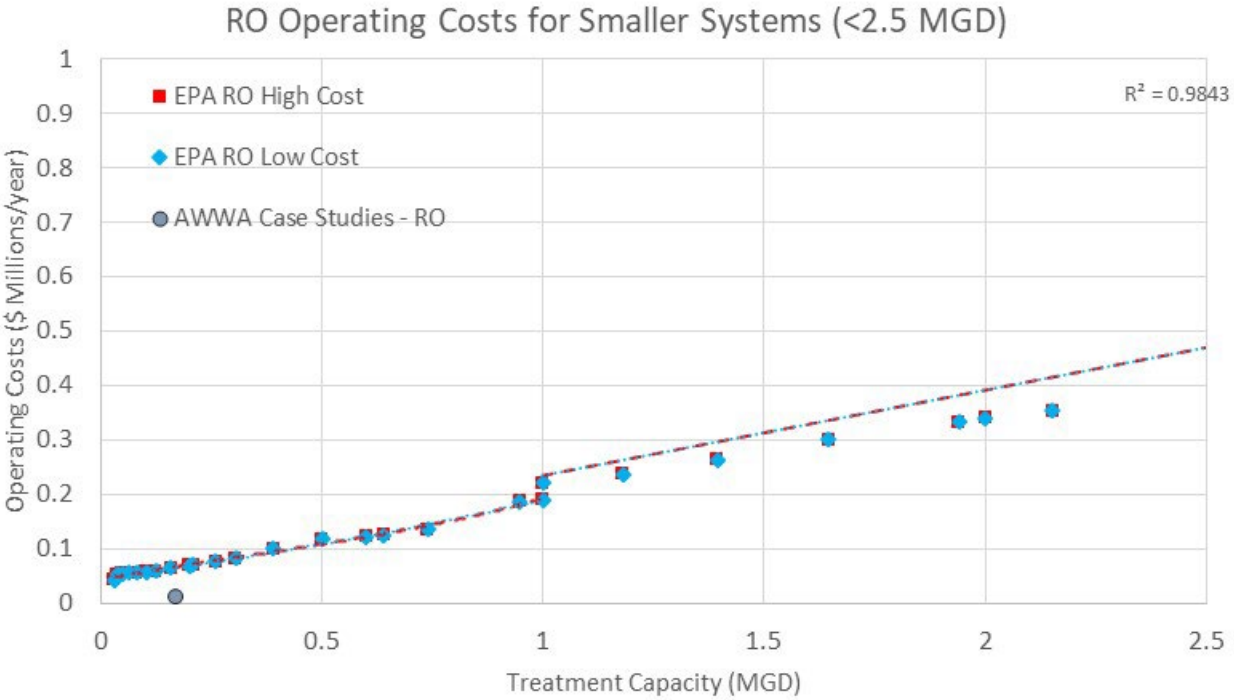

IX Capital Costs for Smaller Systems (<2.5 MGD)
EPA IX High Cost
EPA IX Low Cost
AWWA Case Studies - IX
AWWA Case Studies - GAC/IX
Capital Costs ($ Millions)
Treatment Capacity (MGD)
0
2
4
6
8
10
12
0
0.5
1
1.5
2
2.5

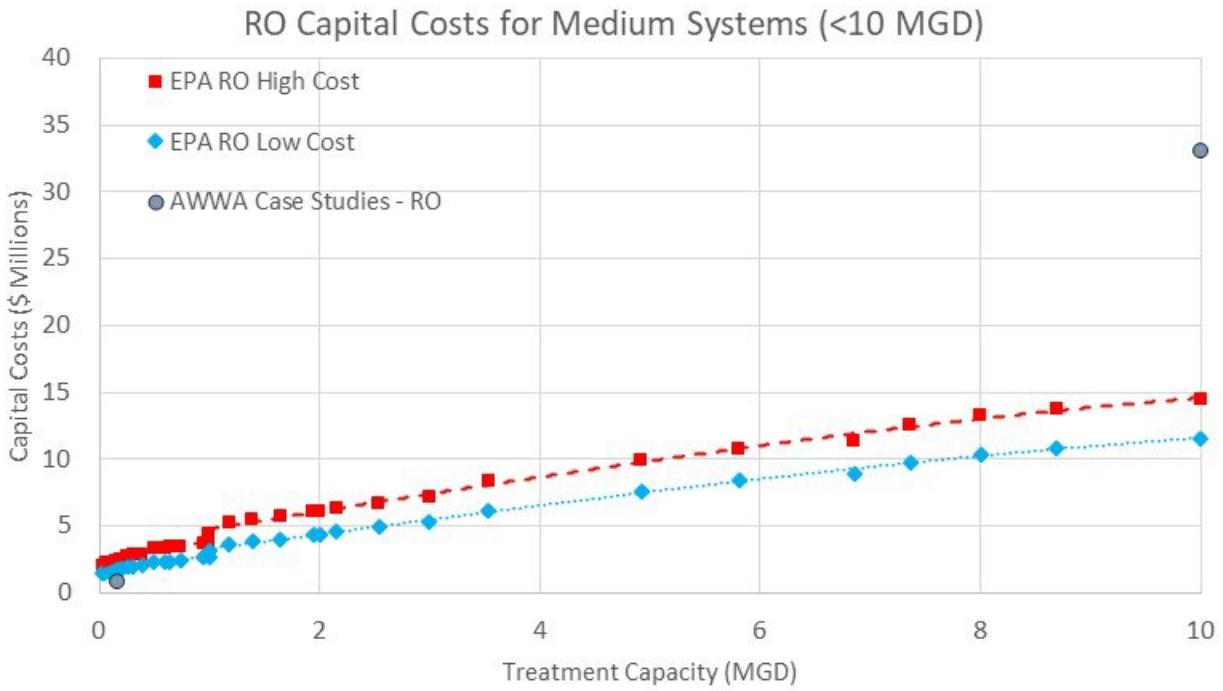

IX Operating Costs for Smaller Systems (<2.5 MGD)
EPA IX High Cost
EPA IX Low Cost
AWWA Case Studies - IX
AWWA Case Studies - GAC/IX
Operating Costs ($ Millions/year)
Treatment Capacity (MGD)
0
0.1
0.2
0.3
0.4
0.5
0.6
0.7
0.8
0.9
1
0
0.5
1
1.5
2
2.5

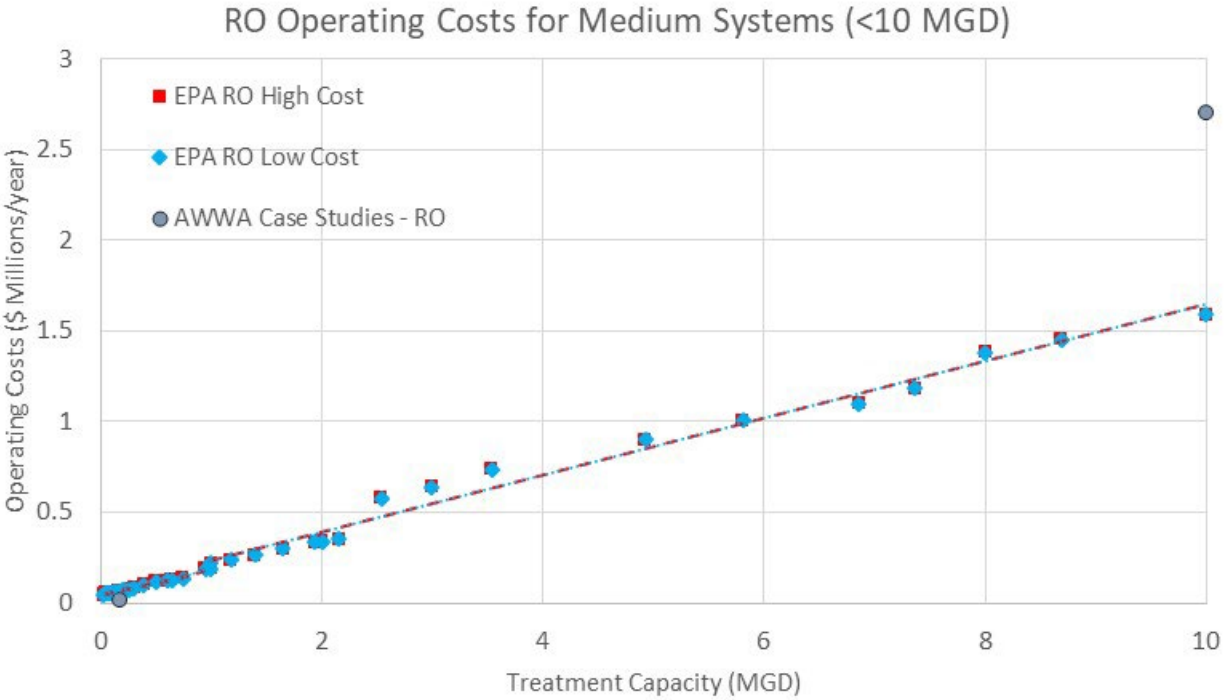

IX Capital Costs for Medium Systems (<10 MGD)
EPA IX High Cost
EPA IX Low Cost
AWWA Case Studies - IX
AWWA Case Studies - GAC/IX
Capital Costs ($ Millions)
Treatment Capacity (MGD)
0
5
10
15
20
25
0
2
4
6
8
10


IX Operating Costs for Medium Systems (<10 MGD)
EPA IX High Cost
EPA IX Low Cost
AWWA Case Studies - IX
AWWA Case Studies - GAC/IX
Operating Costs ($ Millions/year)
Treatment Capacity (MGD)
0
0.1
0.2
0.3
0.4
0.5
0.6
0.7
0.8
0.9
1
0
2
4
6
8
10


RO Capital Costs for Smaller Systems (<2.5 MGD)
EPA RO High Cost
EPA RO Low Cost
AWWA Case Studies - RO
Capital Costs ($ Millions)
Treatment Capacity (MGD)
0
1
2
3
4
5
6
7
8
9
10
0
0.5
1
1.5
2
2.5


RO Operating Costs for Smaller Systems (<2.5 MGD)
EPA RO High Cost
EPA RO Low Cost
AWWA Case Studies - RO
R² = 0.9843
Operating Costs ($ Millions/year)
Treatment Capacity (MGD)
0
0.1
0.2
0.3
0.4
0.5
0.6
0.7
0.8
0.9
1
0
0.5
1
1.5
2
2.5





American Water Works Association (AWWA) (Doc. #1759, SBC-053001)

AWWA also compared the capital cost estimates for GAC under the proposed PFAS rule with the agency's estimates for the Stage 2 Disinfectants and Disinfection Byproducts Rule (EPA, 2005). Under the Stage 2 rule, EPA also estimated costs for systems installing GAC with a 20-minute empty bed contact time. The results of this comparison, Figure 7-1, show an alarming issue: EPA's cost estimate for PFAS removal in 2021 dollars is nearly the same as TOC removal in 2003 dollars. As a point of comparison, the Engineering News Record building cost index has increased from 6,654 in 2003 to 13,288 in 2023 representing a nearly double increase in construction costs alone, which do not include the additional cost increases water systems have been faced with (ENR, 2023).

[Figure 7-2: See Docket ID EPA-HQ-OW-2022-0114-1759]

Figure 7-2: Comparison of GAC Capital Costs for GAC for Stage 2 D/DBP and Proposed PFAS Rule

EPA Response: The commenter's Figure 7-2 misrepresents the EPA's cost curves because it includes only the example outputs from Appendix B of the EPA's *Technologies and Costs* document (USEPA, 2024d) and not the full range of cost curves used to estimate national costs and presented in Appendix B of the document. Furthermore, the EPA has considered all input from this and other commenters on the EPA's cost analysis and made a number of changes to the cost estimates, as detailed in section 13.3.3 of the EPA response in this *Response to Comments* document. Taken together, these adjustments increased the system level capital cost estimates in the EPA's cost assessment by a percentage that varied depending on the system size and treatment technology. For small systems using GAC and IX, the increase ranged from approximately 40 percent to 110 percent. For medium systems, the increase was approximately 20 to 60 percent; for large systems, 10 to 40 percent. Therefore, the EPA's capital costs for the final PFAS rule exceed the capital cost figures from Stage 2, as expected, in nearly every case. In addition, for large systems, the capital costs for Stage 2 included the installation of on-site reactivation facilities. This inclusion results in substantially higher capital costs in comparison to systems that use off-site reactivation. Under current economic conditions, off-site reactivation is likely to be more cost effective, so the EPA assumed systems installing treatment for PFAS would use this approach. Finally, for GAC, the Stage 2 rule relied on outputs from the Very Small Systems, Water, and W/W Cost models. These models were developed from the late 1970's through the early 1990's and had certain inherent limitations. Khera et al. (2013) summarized the models' limitations as follows: "These models lacked the flexibility to adapt to changes in technology, development of new construction materials, availability of new treatment media, automation, changes in manufacturing processes, and market competition. They were also difficult to update to reflect price changes and could not be adjusted for different combinations of treatment technologies and contaminants. Underlying assumptions in these models were not always readily apparent or easily modified, and outputs were often limited to a few lump-sum totals." It is because of these limitations that the EPA developed the WBS models, which are more robust and transparent than the older models. The level of component detail (and by

implication, design detail) in the WBS-based approach is more sophisticated, than the factored or parametric cost estimating methods used in the EPA's earlier efforts.

American Water Works Association (AWWA) (Doc. #1759, SBC-053002)

AWWA requested an extension of the public comment period to accommodate a more detailed analysis of the EPA's updated WBS. Given that the agency did not extend the comment period, an exhaustive review of the WBS could not be provided within the 60-day period for review and comment. However, in review of the data from Figure 7-1, Figure 7-2, and the supplemental figures, there is no question that the WBS struggles to accurately capture costs of new treatment facilities. There are some aspects of the WBS that are anticipated to cause a significant underestimation of the true costs of installing PFAS treatment systems. These are further described in the following sections. Given the central role that costs play in EPA's determination, and in order to provide an opportunity for meaningful public comment on the costs associated with this proposal, EPA should work with AWWA and other drinking water treatment experts to revise the cost analysis and provide for an additional comment period on the updated analysis.

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document for why the EPA included a sixty-day public comment period instead of the statutory minimum of 30 days. In regard to the accuracy of the WBS model, please see section 13.3.3 of the EPA response in this *Response to Comments* document. Further, the EPA received extensive comments on the proposal's cost analysis, which the agency fully considered in revising the cost estimates for the final rule and in decision making on the final rule; as a result, additional comment on the cost analysis is unnecessary. For further discussion, see section 13.3 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-053003)

General Comments on EPA's WBS Model

Model Accuracy & Contingency

To estimate the costs associated with different treatment strategies, EPA's WBS model uses inputs to prepare a cost estimation for an individual water system. While the model is detailed with respect to potential costs that are considered, there are limitations of this approach, which may require the application of correction factors (similar to the toxicological uncertainty factors).

For each system, EPA estimates the service population using data available through the Safe Drinking Water Information System. The service population provides a reasonable estimate of the general water supply design requirements, which with some broad assumptions (e.g., daily per capita water use, peaking factor, etc) can inform an estimate of the overall water supply capacity needed for each entry point to the distribution system. Then, EPA relies on probabilistic

distributions of PFAS and TOC to determine specific unit operation costs for each system in a Monte Carlo Simulation.

Ultimately, the WBS model relies on three key system characteristics to drive the cost estimate: (i) water treatment flow capacity, (ii) PFAS levels, and (iii) TOC levels. This information is used by EPA to estimate the implementation costs for each water system, which is intended to cover planning, design, testing, perming, and construction of the system. While it is not uncommon for budgetary estimates to be prepared using a limited set of data, it is extremely rare for budgetary estimates of these systems to not recognize that the design is not exhaustive. Good engineering practice is to include an adequate contingency and to transparently describe the level of conservatism in the estimate based on uncertainty in the information available to prepare the cost estimate.

The American Association of Cost Engineering describes five classes of cost estimates that are distinguished by maturity level of project definition, end usage, methodology, and the expected accuracy range. A Class 1 estimate represents a level of project definition exceeding 50% where a detailed unit cost and detailed take-off have been used to estimate the costs and the cost could be as much as 15% higher. Alternatively, a Class 5 estimate represents a level of project definition of less than 2% where concepts are being screened and the use of parametric models were used and so the costs could be as much as 100% higher. In consideration of the data that are available for EPA to consider in estimating costs and given that site-specific conditions cannot be factored into the estimate, the EPA WBS Model is likely to be considered a Class 4 or Class 5 estimate where costs could be 50% or 100% higher.

EPA provides various example model outputs of their cost estimate for different systems, including the estimate of contingency. Table 7-1 provides an overview of the contingency for each of these estimates. As shown in the table, the vast majority of the model outputs show cost estimates for systems with 0% contingency included. This is for 100% of the systems with a treatment capacity below 5.809 MGD, which is pertinent to more than 75% of the water systems that EPA anticipates will be impacted by this rule. For the remaining example outputs, a very low level of contingency is included. This is inconsistent with recommended best practices for cost estimators and is expected to be a major contributor to the EPA WBS' failure to accurately capture costs for PFAS treatment facility implementation.

Table 7-1: Assumed Contingency in EPA WBS Model Example Outputs

[Table 7-1: See Docket ID EPA-HQ-OW-2022-0114-1759]

Therefore, the minimal level of contingency, or lack thereof, in the WBS cost estimates wildly overestimates the WBS' ability to capture system-specific water quality, site conditions, community needs, and the overall cost factors for the new treatment facility. The EPA should adjust this approach and ensure that the appropriate levels of contingency are included to ensure that cost estimates are consistent with the level of project definition afforded by the available data in keeping with sound engineering practice.

EPA Response: The EPA disagrees with commenter that the American Association of Cost Engineering (AACE) cost estimate classification system is an appropriate approach to use for national level drinking water regulatory cost estimates. The AACE cost estimate classification system is applicable to estimates used in screening, planning, and budgeting for specific projects. It is not specifically designed to guide economic analysis involving national level cost estimates. Additionally, the WBS models are not factored or parametric models of the type referenced in AACE Class 4 and 5. They estimate costs using a detailed engineering build-up from the line-item costs of individual treatment system components. Furthermore, for purposes of national cost estimating, it is appropriate to reflect actual realized contingency costs at project completion, as opposed to contingencies incorporated in planning and budgeting. A Construction Industry Institute (2001) study found that projects of $100 million or less incurred only 74 percent or less of the contingency initially budgeted. Nevertheless, in response to public comments, the EPA updated the contingency factors incorporated in the WBS models as discussed in section 13.3.3 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-053004)

Accurately Reflecting Current Economic Conditions

Another limitation of the EPA's WBS Model is that it reflects outdated 2021 construction costs. Additionally, the model relies on a variety of cost indices to scale the costs from a previous year to the relevant year of the analysis. It is reasonable to scale data from one year to another year using indices, but EPA fails to account for the fact that there is always a lag in the data for the most recent periods of time. The agency must recognize that the past two years, from 2021, have shown significant cost increases relevant to drinking water treatment systems.

These increases in costs have stemmed from the COVID-19 pandemic, high inflation, and increasing interest rates for borrowing. Construction costs, for example, have increased steadily by more than 15% to 30% in the past 2 years according to several different sources (Mortenson, 2023; Turner Construction, 2023; USBR, 2023). By comparison, construction costs during 2020 only increased by less than 1.5%. A similar trend can be observed in analysis of inflation since 2021, which has averaged 5.81% annually. The federal funds rate has also increased from 0.08% to 5.25%, which will also drive up the costs for water systems to secure financing for new projects. EPA's analysis must reflect these increases to properly account for the costs of implementation.

In addition to the increase in costs driven by economic conditions since 2021, it is also important to note that the proposal itself will further increase the costs; 67,000 systems conducting monitoring and upwards of 4,300 water systems installing treatment facility will increase demand for laboratories, engineering consultants, planners, contractors performing site investigation and construction work, and skilled treatment operators.

In order to comply with its statutory obligations, including under the SDWA [FN25: 42 U.S.C. 300g-1(b)(B)(4)(D).], EPA should ensure that the cost analysis of any rule is accurately

reflecting costs due to economic conditions and anticipated increases in demand that will drive the planning and construction costs of new facilities significantly higher than the current estimates.

EPA Response: As explained in this section and the preamble, the cost analysis for the final rule is consistent with the EPA's obligations under SDWA 1412(b)(3)(C) to consider quantifiable and nonquantifiable costs as part of its HHRCA analysis and to determine "feasibility" for purposes of setting the MCLs in this rule. The EPA updated its equipment costs to 2022 dollars (which are the most recent data available), collected new vendor price quotes for cost driver equipment components, and made several other adjustments to WBS model assumptions. Taken together, these adjustments increased the system level capital cost estimates in the EPA's cost assessment by percentages that were generally greater than those reported by the commenter. Please see section 13.3.3 of the EPA response in this *Response to Comments* document for further details. With regard to the impact of demand on costs, please see section 13.3.3 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-053005)

Recognizing the Importance of Ancillary Systems

Another potential limitation of the EPA's WBS Model is that it only considers capital upgrades for PFAS removal from water. This is a significant analytical gap because many systems will likely need to make improvements to other areas of the treatment facility to support the PFAS treatment process. For example, some systems installing GAC treatment may determine that the concentration and form of manganese will cause problems in the vessel, requiring pre-treatment. A variety of other water quality characteristics may impact the need for pre-treatment and site-specific conditions may drive the need for significant upgrades to critical treatment support systems (e.g., pump stations, chemical feed systems, etc.). It is not uncommon for upgrades for PFAS treatment to require these types of improvements, none of which EPA's WBS Model takes into account.

EPA Response: Regarding the cost of pretreatment, the EPA included the cost of cartridge filters for control of influent solids in its cost estimates for ion exchange. The EPA does not have quantitative data on the frequency with which systems might require pretreatment specifically for iron and manganese, but information from one treatment vendor suggests the need for this type of pretreatment might be limited. Please see section 10.1 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-053006)

Lifespan of Treatment Equipment

The proposal provides inconstant information related to the total number of years that are used for the annualization of costs. In the Economic Analysis, EPA notes that both costs and benefits

are annualized over 82 years. Alternatively, the example outputs for each treatment system in the Technologies and Costs document lists useful life for each piece of equipment that is included in the capital costs. In the same document a system-specific useful life is listed as part of the cost equations. The supporting documentation from the EPA does not provide a clear explanation of how costs are annualized. Additionally, the useful life varies for equipment from as low as 7 years to as long as 35 years; it is unclear from the supporting documentation the methodology EPA used to substantiate these assumptions. This approach is not consistent with previous practice; the agency's approach to annualizing costs under the Arsenic Rule was based on a 20-year useful life for equipment (EPA, 20XX). In order to fulfill its obligations under the APA, AWWA recommends that EPA provide this information during a supplemental comment period prior to finalizing any PFAS rule. Failing to do so or failing to acknowledge this change in the assumption for treatment facility lifespan and providing a reasoned explanation for the change, would violate the APA.

EPA Response: The treatment system useful life reported with the cost equations and used to annualize total capital costs is calculated from the useful life of the individual equipment components. The calculation uses a reciprocal weighted average approach, which is based on the relationship between a component's cost I, its useful life (L) and its annual depreciation rate (A) under a straight-line depreciation method. The formula below shows the reciprocal weighted average calculation:

$$\text{Average Useful Life} = \frac{\sum_{n=1}^{N} C_n}{\sum_{n=1}^{N} A_n} = \frac{C}{A}$$

where: C_n denotes the cost of component n, n=1 to N; C denotes total cost of all N components; A_n denotes the annual depreciation for component n, which equals C_n/L_n; and A denotes total annual depreciation for the N components.

When calculating the present value of costs over the 82-year period of analysis, the EPA uses the useful life of the technology to determine when the capital components will need to be replaced. So, for example, if a PWS installs a technology in year 7 of the analysis that has an average useful life of 18 years, and costs $1M, the PWS accrues capital costs of $1M in each of the following years: 7, 25, 43, 61, and 79. It also accrues O&M costs every year of the analysis beginning in year 7.

The EPA notes that the concept that individual components of treatment technologies have different useful lives is well-known and accepted and a commonly applied concept in drinking water engineering (USEPA, 2003). Therefore, the EPA disagrees with the commenter that the agency should maintain previous approaches (e.g. the Arsenic Rule's uniform assumption of 20 years) and make a blanket assumption about useful life when information and modeling capabilities exist to support more accurate approaches to capture the known variation in useful life among components. As discussed in the EPA response to comment Doc. #1759, SBC-045612

in this section and section 13.3.3 of the EPA response in this *Response to Comments* document, as the science has matured, the EPA has further developed and refined cost models since proposal of rules 20 or more years ago. EPA notes that during the peer review of the WBS models, EPA asked peer reviewers for their input on the specific useful lives assigned to individual items of equipment (for more information see SAIC, 2006a; SAIC, 2006b; SAIC, 2006c; USEPA, 2007b; USEPA, 2012). The EPA provided information on the calculation of total annualized cost in Section 2.4.6 *Total Annualized Costs* in each of the technology specific WBS documents, available in the docket[8] and on the EPA's website at https://www.epa.gov/sdwa/drinking-water-treatment-technology-unit-cost-models. See also Chapter 2.2.3 *Annualization* of the EA, where the EPA provides the equation used to annualize future costs and benefits. EPA strongly disagrees that there is a need to hold a supplemental comment period on this straightforward component of the analysis, for which the EPA included complete documentation on in the proposal (as noted above see Chapter 2 of the EA and the WBS documents for each technology and non-treatment options). The EPA further notes that this is not a novel application; this exact functionality was included in the EAs for the proposed and final LCRR.

American Water Works Association (AWWA) (Doc. #1759, SBC-046166)

5.5 Life-Cycle Costs

The model determines 20-year life-cycle costs, which combines the capital costs and annual operating and maintenance costs. Life-cycle costs provide a means of comparing the costs of alternative technologies over the life cycle of the equipment. The life-cycle costs in the body of this report were calculated assuming a 20-year lifespan and a discount rate of 3 percent. A comparison of annualized NPDWR costs by system size at 3 and 7 percent is included in Table A-5 of Appendix A . While typical practice to determine life-cycle costs may incorporate other factors, such as the inflation and loan interest, the discount rate was used to match the approach that is standard practice for the EPA in promulgating national primary drinking water regulations.

6.0 National Cost Assessment Methodology

The conceptual framework for assessing the national costs is as follows:

• Assess capital, annual O&M, and life-cycle costs for each EPTDS in every water system for which potential regulatory limits for PFAS may require treatment.

• Average the costs by system size category and system type (ground or surface water).

• Multiply those average costs by the total anticipated number of systems of each type impacted in each system size category based on the percentage of systems in the database impacted by a proposed regulatory limit for PFAS.

[8] See documents: EPA-HQ-OW-2022-0114-0041, EPA-HQ-OW-2022-0114-0039, EPA-HQ-OW-2022-0114-0042, and EPA-HQ-OW-2022-0114-0040 in docket No. EPA-HQ-OW-2022-0114.

The following subsections summarize the process and details associated with the national cost estimation methodology.

6.1 Estimating National Costs Using Model Outputs

Due to the difference in number of EPTDS for groundwater and surface water systems, the national cost calculations were completed separately for groundwater and surface water systems. The following methodology was utilized for each source water classification:

1. Using the treatment facility costs for systems from the occurrence database, the costs were binned by system size, and average EPTDS costs per system size bin were calculated.

2. Using the occurrence database, the number of impacted systems per size category was calculated, and the corresponding percent of the systems in the database was determined.

3. To estimate the number of impacted systems nationally, the percentage of impacted systems in the occurrence database was multiplied by the total number of systems in SDWIS for each size category.

4. The estimated number of impacted systems per size category multiplied by the average cost per EPTDS and the assumed number of entry points yields the total cost per size category. The sum of all costs per size category yields the estimated national cost of removing PFAS to a potential regulatory limit.

A summary output is included in Table 6-1, which displays the costs associated with a achieving a maximum contaminant level (MCL) in drinking water of 4 ppt for PFOA and 4 ppt for PFOS for groundwater systems only.

Table 6-1 Example Summary Capital Cost Table for an MCL of 4 ppt for PFOA and PFOS (Groundwater Systems Only)

[Table 6-1: Docket ID: EPA-HQ-OW-2022-0114-1759]

EPA Response: The EPA disagrees with many of the assumptions in AWWA's B&V report and therefore with the costs presented in the commenter's Table 6-1. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. For explanation why a fixed 20 year lifecycle estimate is a simplification compared to the EPA's peer-reviewed WBS models, and why the EPA believes this is a less precise tool than the EPA's WBS models, please see the EPA response to comment Doc. #1759, SBC-045612 in section 13.3.3 in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-046155)

3.2.2 Assumptions for Cost Estimation

The costs for IX Contactors depend on the contactor type, size, number, and ancillary processes such as backwash pumps/recovery basins and contactor influent pumps/wetwells. The primary process design assumptions for each of these factors are summarized in Table 3-2.

Table 3-2 IX Design Process Assumptions

[Table 3-2: Docket ID: EPA-HQ-OW-2022-0114-1759]

EPA Response: The EPA disagrees with several of the assumptions presented in the commenter's Table 3-2. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-046158)

3.3.2 Assumptions for Cost Estimation

The costs for RO systems depend on the number of trains, permeate flow, and ancillary processes such as the RO feed tank, low-pressure feed pump, high-pressure feed pump, chemical pretreatment, chemical post-treatment, flush pump/tank, clean-in-place (CIP) system, decarbonation system, building requirements, and brine disposal. The primary process design assumptions for each of these factors are summarized in Table 3-3.

Table 3-3 RO Design Process Assumptions

[Table 3-3: Docket ID: EPA-HQ-OW-2022-0114-1759]

EPA Response: The EPA disagrees with several of the assumptions presented in the commenter's Table 3-3. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045639)

The cost analysis for drinking water treatment is demonstrably underestimating the impacts of the rule based on case study data and a model by Black & Veatch, which was crafted leveraging long-standing national PFAS treatment design expertise.

EPA Response: The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

PFAS Regulatory Coalition (Doc. #1761, SBC-046082)

b) Did EPA consider the costs and timing of the analysis that needs to occur to decide if and what kind of treatment may be necessary? Table 35 of the Proposal estimates a range of 3 hours to 42 hours to "notify, consult, and submit a permit request for treatment installation." This does not appear to include – or if it does, it grossly underestimates – the costs of evaluating potential

treatment options, designing and pilot testing a treatment system, etc. Some systems will be starting with no baseline information whatsoever. Many of these have not had to sample for PFAS before.

EPA Response: The EPA included pilot testing costs in the treatment capital cost estimates for the proposed rule and further updated these costs for the final rule. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

PFAS Regulatory Coalition (Doc. #1761, SBC-046079)

E. Concerns and questions regarding EPA's analysis of treatment technologies and costs need to be considered and addressed.

The Coalition has reviewed the information in the Proposal and, as time has allowed, in the supporting document "Technologies and Costs for Technologies and Costs for Removing Per- and Polyfluoroalkyl Substances (PFAS) from Drinking Water" (February 2023), Dkt. No. EPQ-HQ-OW-2022-0114-0038. We have a number of questions and comments on EPA's analysis of treatment options and costs, which are set forth below.

a) Can EPA provide more basis for its estimates of the range of bed volumes included in its analysis of GAC and IX? EPA presents very large ranges but no details about the information on which the estimates are based. Based on our members' experience, the numbers appear high, which would equate to unduly low operational expenses of GAC systems. In particular, EPA has likely underestimated the quantity of spent GAC that will require treatment. In the Proposal, EPA identified proposed Bed Volumes for GAC that exceed the values that AWWA identified in their analysis. The generation rate of spent carbon is a function of bed volume and replacement frequency. EPA's cost estimate basis for bed volume was a range of 5,000 to 150,000 for GAC. 88 FR 18695. AWWA's analysis limited the carbon life to a maximum of 40,000 bed volumes for GAC. Bed volumes directly impact operating costs of these systems; EPA's assumptions of longer bed volumes would result in incurring lower costs due to less frequent media exchange and disposal.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document. For each entry point installing treatment, the EPA estimated bed life within the range using equations that incorporate percent removal required for each target contaminant along with influent TOC concentration (for GAC) or total PFAS concentration (for IX). The EPA's *Technologies and Costs* document (USEPA, 2024d) describes these equations and the data sources on which they are based in detail. The EPA used the ranges cited by the commenter to bound the results of the equations. Based on this and other comments, for the final rule, the EPA decreased the upper bounds of these ranges to 75,000 bed volumes for GAC and 260,000 bed volumes for IX. The EPA selected these maximum bed volumes to avoid intervals between replacement of greater than approximately five years. This upper bound ensures that media will be replaced within a reasonable service life even if its capacity has not been exhausted. Whether the EPA's assumptions result in a bed life that is longer or shorter than AWWA's will depend on

the water quality characteristics of a given entry point. However, AWWA's approach is likely to underestimate GAC bed life for entry points with low TOC because it does not scale with TOC and is based on data from a single pilot study with relatively high TOC.

PFAS Regulatory Coalition (Doc. #1761, SBC-053405)

b) The recovery rates for RO appear higher than what our members' experience suggests. We believe that EPA has underestimated the reject quantities that would be expected with the proposed pretreatment units identified by EPA. EPA should assume rejection rates of 25-30% when developing disposal costs for RO units.

EPA Response: The scientific literature reviewed in the EPA's *Technologies and Costs* document (USEPA, 2024d) reports recovery rates ranging from 78 to 92 percent for the low-pressure (or "loose") RO membranes and high-pressure (or "tight") nanofiltration (NF) membranes found to be effective for PFAS. These recovery rates convert to rejection rates of 8 to 22 percent. The commenter's members' experience may involve higher pressure RO membranes used for desalination or industrial purposes, which have higher rejection rates. The EPA notes that in response to public comments about residual management concerns for high pressure membrane technologies, the EPA has adjusted RO/NF's technology projection compliance forecast to 0 percent in the EA for the final rule, as discussed in section 13.3.3 of the EPA response in this *Response to Comments* document.

PFAS Regulatory Coalition (Doc. #1761, SBC-053406)

c) EPA should consider remineralization costs. Remineralization is sometimes needed for RO or IX treated water before it can be used again. EPA identified two full-scale applications of RO to treat PFAS in drinking water systems. The industrial facilities that the Coalition represents have experience using Reverse Osmosis units in their facilities (non-PFAS specific applications). From this experience, EPA did not adequately address costs associated with the need for remineralization of RO permeate to make it non-corrosive to downstream piping and to make it suitable for consumption as a drinking water. Technologies and Cost for Removing Per- and Polyfluoroalkyl Substances (PFAS) from Drinking Water, Fed. 2023, Dkt. No. EPQ-HQ-OW-2022-0114-0038.

EPA Response: While the EPA acknowledges the commenter's input regarding remineralization, the agency notes this input is moot for purposes of the cost analysis. In response to public comments about residual management concerns for high pressure membrane technologies, the EPA has adjusted RO/NF's technology projection compliance forecast to 0 percent in the EA for the final rule, as discussed in section 13.3.3 of the EPA response in this *Response to Comments* document.

PFAS Regulatory Coalition (Doc. #1761, SBC-053407)

d) Does EPA have any more data large surface water treatment plants regarding treatment technologies and costs? It appears there are limited data points and case studies on which to evaluate available technologies or to form a representative cost curve.

EPA Response: The commenter is incorrect; the EPA did not develop its cost curves by extrapolating from case studies. The EPA used results from the WBS models, which estimate cost using a detailed engineering build-up from the line-item costs of individual treatment system components. Similarly, the EPA's evaluation of Best Available Technologies considered the complete body of scientific literature and was not based solely on case studies. See also section 13.3.3 of the EPA response in this *Response to Comments* document and Chapter 5 of the EA for more information on the EPA's cost analysis.

Riverside Public Utilities, Riverside, CA (Doc. #1762, SBC-044227)

The following comments are submitted for consideration in the proposed EPA rulemaking:

Increase cost of treatment compared to EPA's Cost Model

The City hired a consulting engineer to determine an optimized long-term approach to treat PFAS in its drinking water supply. The study identified multiple alternatives that range from $24M to $85M in capital costs for new treatment plants and other modifications and between $108M and $238M for operation and maintenance over their expected 20-year life cycle, depending on treatment capacity. These costs are substantially higher than the EPA's economic analysis of both the capital costs and the operation and maintenance cost estimates as shown on the March 29, 2023, EPA's presentation slides (31 and 32).

EPA Response: The comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. The presentation slides the commenter referenced were two examples of the many cost curves developed by the EPA to illustrate WBS model output and represented mid-level costs for surface water systems using GAC.

Southwest Regional Water District (Doc. #1772, SBC-044726)

May 30, 2023

Michael S. Regan Administrator

Environmental Protection Agency 1200 Pennsylvania Avenue, N.W. Washington, DC 20460

RE: Proposed National Primary Drinking Water Regulations (NPDWR) for the Following Per- and Polyfluoroalkyl Substances (PFAS): [POFA, PFOS, PFNA, HFPO-DA (GenX), PFHxS, and PFBS]

Public Docket ID: EPA-HQ-OW-2022-0114-0027

To United States Environmental Protection Agency,

Southwest Regional Water District appreciates the opportunity to provide comments to the USEPA regarding the proposed drinking water rules on PFAS contaminants. Public participation is vital to making the rulemaking process successful.

Southwest Regional Water District is a political subdivision of the state of Ohio organized under Chapter 6119 of the Ohio Revised Code. The District serves safe drinking water to approximately 15,200 customer connections within its service area, which primarily includes western Butler County, Ohio, but also includes parts of Hamilton, Preble and Warren Counties. The District's water system includes more than 650 miles of water mains, two water production plants and twenty-five water storage facilities all maintained by a staff of less than 40 employees.

The District is aware of the importance of monitoring for potentially harmful contaminants in public drinking water systems, including PFAS substances. In anticipation of regulatory changes, an estimate was acquired to better understand what the cost to the District and it's customers would be to retrofit one of our treatment facilities. The upgrades would be for a Granular Activated Carbon (GAC) facility. The estimated cost was $9 million for construction and $540,000 annually for operations and maintenance. This project would be for one treatment plant, in one PWS, in one state in the county.

The USEPA has projected that for all public water systems (PWS) in the United States it would be about $772 million annually. The District suspects that other PWSs throughout the country are receiving similar cost estimates and those totals would at least triple the estimate from USEPA. These proposed drinking water standards are just one of the many current and upcoming regulatory rules where compliance is required or will be required for PWSs. The current funding available for all these treatment and operational changes will only go so far. Especially as more utilities become aware of contaminants in their systems through additional sampling from UCMR5. We urge the USEPA to thoroughly review the estimated costs and what funding will be made available to PWSs as we tackle the removal of PFAS substances.

EPA Response: The comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. The EPA notes that the agency's total national cost estimates are annualized over the period of analysis (82 years). Please see section 13.3 of the EPA response in this *Response to Comments* document and section XII of the FRN for the EPA's updated cost estimates for the final rule. Regarding funding availability, please see section 2.4 of the EPA response in this *Response to Comments* document.

Uttara Jhaveri (Doc. #1778, SBC-045446)

COST OF IMPLEMENTING THE TECHNOLOGICAL CHANGES

Water systems with PFAS levels that exceed the proposed MCLs would need to take action to provide drinking water which meets the NPDWR by the compliance dates established in the rule when final. [FN18: Environmental Protection Agency, supra note 4.] The Safe Drinking Water Act states that the technology proposed by the regulations should be "technologically and economically feasible." [FN19: THE SAFE DRINKING WATER ACT, 42 U.S.C. (1974),w.govinfo.gov/content/pkg/CPRT-106SPRT67528/pdf/CPRT-106SPRT67528.pdf.] Since conventional treatment technologies are unable to remove PFOS, PFOA, PFNA, PFHxS, PFBS, or HFPO–DA from drinking water to meet levels protective of public health (McCleaf et al., 2017), the public water utilities would have to adopt and install other available technologies effectively to remove the abovementioned PFAS and other PFAS. [FN20: Environmental Protection Agency, supra note 4.]

The proposed standards are to be enforced via the BATs technology, and the agency proposed the GAC, AIX, and High-Pressure membranes (RO and NF) technology. [FN21: Id.] The GAC and AIX system has been proposed as the most efficient technology to remove PFAS. EPA also suggests other options, such as source remediation or connecting to an uncontaminated water system. [FN22: Id.] However, installing the required technology to achieve the proposed MCLs will be time-consuming and costly.

EPA Response: The EPA does not "enforce" or require the use of any specific technology to meet MCLs. With respect to the costs of the rule, please see sections 13.3 and 13.3.3 of the EPA response in this *Response to Comments* document.

Ohio Water Utility Council (OWUC), Ohio American Water Works Association (OAWWA) (Doc. #1782, SBC-044721)

May 30, 2023

Michael S. Regan Administrator

Environmental Protection Agency 1200 Pennsylvania Avenue, N.W. Washington, DC 20460

RE: Proposed National Primary Drinking Water Regulations (NPDWR) for the Following Per- and Polyfluoroalkyl Substances (PFAS): [POFA, PFOS, PFNA, HFPO-DA (GenX), PFHxS, and PFBS]

Public Docket ID: EPA-HQ-OW-2022-0114-0027

To United States Environmental Protection Agency,

The Ohio Section of the American Water Works Association (OAWWA) represents over 4,500 water utilities that serve Ohio's population of 11.5 million. The Ohio Water Utility Council (OWUC) of the OAWWA has a primary purpose of advocating on matters that affect the water industry, treatment and delivery of safe, clean drinking water.

The OWUC appreciates the opportunity to provide comments on the proposed drinking water standards for PFAS substances to the United States Environmental Protection Agency (EPA) during this comment period of the rulemaking process. We recognize the importance of a collaborative effort between the EPA and the water utilities in United States and Ohio when evaluating the impacts of these rules. OWUC is focused on providing operational context to the regulatory requirements being proposed by EPA.

OWUC is aware of the importance of monitoring for potentially harmful contaminants in the public drinking water systems in Ohio and throughout the county, including PFAS substances. Our member utilities have begun evaluating the needs of their PWSs with respect to these substances. In anticipation of the regulatory changes being proposed cost estimates have been obtained. The OWUC is sharing some of those estimates to illustrate the real costs to Ohio utilities and the customers we serve.

[Table 1: See Docket ID EPA-HQ-OW-2022-0114-1782]

Each of these estimates are for one treatment facility in one public water system in one state in the country. Based on these examples it is very clear that the estimates from EPA of $772 million for the entire country are significantly low and likely would not cover the costs for the state of Ohio.

EPA Response: The EPA disagrees with the commenter's statement that the EPA's national cost estimates at proposal "likely would not cover the costs for the state of Ohio." Please see section 13.3 in this *Response to Comments* document for the EPA's response to comments about the total national costs of the rule.

The tables below compare the estimated capital costs from the commenter's table to results from the updated cost curves the EPA developed for the final rule, assuming the use of GAC or ion exchange to treat of groundwater with design flow estimated by applying the EPA's population-flow equations to the commenter's reported population served for each facility. Two of the three examples presented by the commenter fall within the EPA's range. The commenter's third example is elevated compared to the EPA's range. Unfortunately, the comment does not include information to confirm that (1) all the estimated costs would be directly associated with PFAS treatment, as opposed to other infrastructure improvements, and (2) that design parameters (e.g., empty bed contact time) for these facilities would be similar to the typical values assumed in the EPA's estimate. Please see section 13.3.3. The comment lacks sufficient detail to compare the commenter's O&M cost estimates to the results of the EPA's WBS models.

Commenter's Estimated Construction Costs Compared to Results from the EPA's Updated Cost Curves

Utility	Customers	Estimated Design Flow (MGD)	Commenter's Estimated Construction Costs ($millions)	EPA's Capital Cost Curves Lower Bound ($million)	EPA's Capital Cost Curves Upper Bound ($million)
Utility A	12,000	4.34	5 to 10	3.8	8.6
Utility B	16,000	5.71	9.6	4.6	10.6
Utility C	50,000	16.97	70	10.9	21.4

Fairfax Water (Doc. #1789, SBC-045306)

Fairfax Water's existing treatment process at both plants includes ozone and biological activated carbon (BAC). This treatment was selected for both facilities to ensure compliance with the Disinfectants and Disinfection Byproducts rules (D/DBP). In 2021 Fairfax Water engaged a consulting engineer to evaluate potential PFAS treatment technologies for our facilities under several different assumptions of potential MCLs. Our consulting engineer reviewed GAC, Ion Exchange (IX), and Reverse Osmosis (RO) and developed capital cost ranges and annual operating cost ranges for the three treatment alternatives as additions to Fairfax Water's existing treatment trains. In 2022 the review was updated following the publication of the revised health advisory levels for PFOA and PFOS. That update most closely relates to the current EPA proposal - MCLs effectively set at the level of detection.

For the plant sourced by the Occoquan, which would not meet the proposed rule based on available data, capital costs for GAC or IX ranged from $180 million to $250 million (December 2021 $), with annual operating costs of $10 million to $45 million. A mid-range capital cost of $215 million represents a 21% increase to Fairfax Water's ten-year capital improvement program (CIP).

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1738, SBC-046032 in section 13.3.3 in this *Response to Comments* document.

Fairfax Water (Doc. #1789, SBC-045308)

A mid-range of our projected annual operating costs for PFAS treatment at our Occoquan facility alone is $22.5 million. This represents an increase of 20% over Fairfax Water's total annual operations and maintenance expense budget - to comply with a single regulation. If RO treatment is required to meet the proposed rule (or a future PFAS regulatory requirement including constituent additions to the Hazard Index calculation), capital costs range from $720 million to $1.54 billion with annual operating costs of $30 million.

For our plant sourced by the Potomac, which meets the proposed rule based on available data but has source detections for PFAS and is located downstream from both Federal and non Federal

sites with known or suspected PFAS, capital costs for reverse osmosis treatment are estimated at $1.21 billion to $2.59 billion with annual operating costs of $55 million. None of the aforementioned capital or operating costs include mitigating potential future regulations for PFAS in water treatment residuals.

The potential increase in operating expenses for PFAS treatment comes at a time when the drinking water industry has seen double and triple-digit percentage increases in essential supplies such as chemicals and ductile iron pipe. These cost increases are borne by the ratepaying public. While our production has been flat, since January 2020, Fairfax Water's chemical budget has increased 52%. Our costs for sodium hypochlorite (disinfectant) in that time have increased 175% and costs for poly-aluminum chloride (coagulant) have increased 67%. Costs for ductile iron pipe, used in our distribution system to replace aging infrastructure, have on average increased 54% for 4-inch to 36-inch pipe and 128% for 42-inch and 48-inch pipe. Purchased power costs have increased 31% since July 2022. We urge EPA to re-evaluate the cost to implement the proposed rule to ensure the cost increases utilities are experiencing, which far outpace inflation, are accurately reflected in its analysis.

EPA Response: To the extent the commenter's expectation of costs are based on hypothetical future PFAS NPDWR, the EPA cannot speculate on the costs of future rules, especially since the EPA does not currently have rulemakings underway for additional PFAS. Based on this and other comments, the EPA updated its equipment costs to 2022 dollars (which are the most recent data available), collected new vendor price quotes for cost driver equipment components, and made several other adjustments to WBS model assumptions. Taken together, these adjustments increased the system level capital cost estimates in the EPA's cost assessment by percentages that were generally consistent with those reported by the commenter. Please see section 13.3.3 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1738, SBC-046032 in section 13.3.3 in this *Response to Comments* document.

Vermont Rural Water Association (Doc. #1798, SBC-045331)

GAC treatment costs for very small systems were estimated by EPA to be $25,000. Vermont's very small systems have been seeing total project remediation costs around $125,000, on average. For community systems that may have to construct treatment buildings to house the necessary filters and equipment, those costs can range into the millions. In addition, supply chain issues, skyrocketing construction and transportation costs, and unknown media disposal fees have been increasing the actual cost of remediation compared to preliminary estimates.

EPA Response: The commenter is incorrect; the EPA did not apply single point estimate of $25,000 to very small systems as a category. As described in the supporting documentation, the EPA developed cost curves that generate a range of costs based on individual entry point flow rates. The comment lacks sufficient detail for the EPA to compare the costs for small systems in Vermont to the results of the EPA's WBS models. The EPA updated its equipment costs to 2022

dollars (the most current data available) using current price indices. The EPA also collected new vendor price quotes for cost driver equipment components (e.g., pressure vessels, treatment media). Please see section 13.3.3 of the EPA response in this *Response to Comments* document. Additionally, the specific cost elements mentioned by the commenter, including building costs and media disposal costs (both non-hazardous disposal options, as well as hazardous disposal included in a sensitivity analysis detailed in Appendix N.2 of the EA) are included in the cost models. In response to the commenter's statements about supply chain issues and increasing prices, please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Massachusetts Municipal Association (MMA) (Doc. #1800, SBC-043764)

One municipality estimated that $15.8 million – in capital costs alone – will be required to install the necessary PFAS treatment infrastructure to supply the community with safe drinking water. Ongoing costs for the maintenance, operation, and staffing of the town's treatment plants are not yet known, but the financial impact will inevitably be borne by residents and taxpayers. Water rates have already increased 10% per year since remediation efforts began, and will continue to do so in order to meet the state PFAS6 20 ppt standard. It's important to highlight that these sizable investments have been made to comply with a more lenient regulation than what is currently being proposed by the EPA.

EPA Response: The comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Laurens County Water and Sewer Commission (LCWSC) (Doc. #1805, SBC-043743)

May 30, 2023

By Electronic Submission: Docket EPA-HQ-OW-2022-0114

U.S. Environmental Protection Agency

EPA Docket Center

PFAS: PFOA and PFOS National Primary

Drinking Water Regulation Rulemaking,

Mail Code 28221T

1200 Pennsylvania Avenue NW Washington, DC 20460

Dear Sir/Madam:

Laurens County Water and Sewer Commission (LCWSC) [SC3020001] appreciates the opportunity to comment on USEPA's proposed National Primary Drinking Water Regulation and

health-based Maximum Contaminant Level Goals (MCLG) for PFOA and PFOS, as well as PFHxS, HFPO—DA and its ammonium salt, PFNA, and PFBS and their mixtures.

LCWCS serves approximately 40,000 people in Laurens County, SC, a Tier Ill semi-rural county in Upstate South Carolina.

EPA's proposed MCLs for PFAS have the potential to impose great costs to our rural community. And while we are committed to protecting the health of all those who enjoy our water, we have significant reservations that the United States is proposing excessively low levels of chemicals that are actively being sold and used by our citizens and businesses. If the concern was an acute concern, then these chemicals would be banned, and the need to remove them from the drinking water supply would be reduced and would involve dealing with legacy levels of chemicals instead of ongoing constituent loads.

We believe EPA's cost estimate may understate true compliance costs. For our system, we believe the most likely treatment available would be Granular Activated Carbon (GAC), with an estimated capital cost of $20M.

EPA Response: Regarding the comment "And while we are committed to protecting the health of all those who enjoy our water, we have significant reservations that the United States is proposing excessively low levels of chemicals that are actively being sold and used by our citizens and businesses. If the concern was an acute concern, then these chemicals would be banned, and the need to remove them from the drinking water supply would be reduced and would involve dealing with legacy levels of chemicals instead of ongoing constituent loads," please see section 15 of the EPA response in this *Response to Comments* document regarding other EPA actions to address PFAS. In response to the commenter's characterization of the proposed rule at "excessively low levels of chemicals," please see section 5 of the EPA response in this *Response to Comments* document regarding the EPA's MCLs. The comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Florida Rural Water Association (FRWA) (Doc. #1806, SBC-044695)

GAC/Resin treatment costs for very small systems were estimated by EPA to be $25,000. FRWA engineers estimate that very small systems are realizing a total project remediation cost around $125,000, on average. For community systems that may have to construct treatment facilities to house and support the necessary filters and equipment, costs can range into the millions. An example, a Florida system with a max daily demand of 2 MGD is incurring a cost of $3 million just for GAC filters.

EPA Response: The commenter is incorrect; the EPA did not apply single point estimate of $25,000 to very small systems as a category. As described in the supporting documentation, the EPA developed cost curves that generate a range of costs based on individual entry point flow rates. The commenter's estimate of an average $125,000 for very small systems in Florida lacks

sufficient detail to compare this estimate to the results of the EPA's WBS models. Regarding the more specific example, the updated cost curves the EPA developed for the final rule estimate a range of capital costs of approximately $3 million to $5 million for a 2 million gallon/day facility using GAC. The commenter's reported cost of $3 million falls within this range.

Office of Advocacy at the U.S. Small Business Administration (Doc. #1807, SBC-045481)

In addition, Advocacy is concerned that EPA also underestimates the compliance costs for small water systems. Small entities and their representatives have shared that the cost of setting up and running treatment systems is four to five times higher than EPA's projections. For example, a Small Entity Representative to the SBREFA panel, presented the results of a case study at Advocacy's environmental roundtable showing that the capital expenses for a granular activated carbon (GAC)[FN9: Granular activated carbon (GAC) is a treatment technology used to remove PFAS. GAC is a separation process where contaminants become attached to specially treated carbon with a high surface area.] showed that there was over a 300% percent difference compared to EPA's predicted cost of treatment for PFOA and PFOS. Small entities have also expressed concern about the availability and rising costs of treatment technologies due to the expected increase in demand in anticipation of these proposed regulations.

EPA Response: This comment, and specifically the claim that "cost of setting up and running treatment systems is four to five times higher than the EPA's projections" lacks sufficient detail to compare these costs to the results of the EPA's WBS models. In response to this commenters reference to information shared by a Small Entity Representative, specifically AWWA, please see section 13.3.3 of the EPA response in this *Response to Comments* document. Finally, regarding the impacts of demand on costs, please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046169)

Exhibit C

Analysis of the USEPA Proposed PFAS National Primary Drinking Water Regulation Treatment Costs and Comparison to the AWWA National PFAS Cost Model Report

May 30, 2023

Prepared by Elin Warn Betanzo, Safe Water Engineering, LLC

Peer reviewed by Professor Vanessa Speight, University of Sheffield, UK.

This report was funded by the Natural Resources Defense Council (NRDC). The views contained herein are those of the author and do not necessarily reflect those of NRDC.

Contents

[Contents: Docket ID: EPA-HQ-OW-2022-0114-1808]

Analysis of the USEPA Proposed PFAS National Primary Drinking Water Regulation Treatment Costs and Comparison to the AWWA National PFAS Cost Model Report

Prepared by Elin Betanzo, Safe Water Engineering, LLC

Executive Summary

The presence of per- and polyfluoroalkyl substances (PFAS) in drinking water sources has emerged as a pressing environmental and public health concern over the last decades. These persistent and bioaccumulative chemicals, commonly found in firefighting foam, nonstick cookware, and numerous other consumer products, have been linked to various adverse health effects. As a result, the United States Environmental Protection Agency (EPA) has undertaken the task of proposing regulations to limit the concentration of PFAS in drinking water.

The proposed regulation would establish enforceable maximum contaminant levels (MCLs) of PFAS in drinking water supplies. This analysis, requested and paid for by the Natural Resources Defense Council, focuses on the potential financial burden of installing treatment to comply with the EPA's proposed PFAS regulation. This analysis also includes a comparison with the American Water Works Association (AWWA) PFAS National Cost Model Report (AWWA, 2023), which provides an industry perspective on the costs associated with PFAS treatment.

These analyses seek to understand realistic treatment costs that would be triggered by the regulation. Furthermore, comparing the EPA's cost estimates to those provided by the AWWA National PFAS Cost Model Report will offer valuable insights into the potential variations and discrepancies between regulatory projections and industry-based assessments. This exploration of the intricacies of these analyses will help inform the overall Economic Analysis to ensure costs are assigned to the rule that will realistically allow water systems to install treatment and achieve the public health benefits anticipated for the new requirements.

Although the USEPA analyzed complete compliance costs for the proposed rule, including sampling and state oversight, this present analysis focuses only on the cost of treatment installation and annualized operations and maintenance (O&M). When AWWA published their analysis, the published proposed rule was not yet available. AWWA estimated the cost of 3 potential compliance options. Although the first AWWA compliance scenario, MCLs of 4 ppt for PFOA and PFOS, does not match the EPA proposed rule (which also includes a Hazard Index of 1.0), it does match USEPA’s Option 1a. Because the same modeling methods are used in all options presented in each report, this analysis compares EPA’s Option 1a to AWWA’s first compliance scenario.

Table 1: EPA and AWWA Modeled Annualized Water System Treatment Costs for Achieving 4.0 ppt for PFOA and PFOS

[Table 1: Docket ID: EPA-HQ-OW-2022-0114-1808]

Estimating national costs for drinking water rules requires applying assumptions and professional judgement, especially when there are limitations in availability of occurrence data. Although it is a tricky task, it is a necessary task to estimate the necessary funding for protecting public health. Both cost estimates inform and help move the conversation forward. This memo attempts to identify the sources of the $3.1 billion difference between these two cost estimates and identify which modeling assumptions are more likely to reflect a realistic compliance forecast and reasonable engineering judgement.

EPA Response: The EPA agrees with some of the commenter's conclusions about the sources of differences between the EPA's estimate and the AWWA B&V report estimates. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046175)

[The analysis that follows shows that the $3.1 billion dollar difference in annualized cost can be explained by the following primary factors:]

6. Cumulative impact of cost assumptions for small systems (serving <10,000). The EPA model assumes that package plants, at a lower cost point, are available for entry points <1 MGD. Package plants have been an option for reducing costs for small systems for decades (National Drinking Water Clearinghouse, 1997), but this option is not described as incorporated in the AWWA estimate. The EPA estimate for cost savings from package plants may be conservative as some package plants may be available up to 6 MGD flows and PWSs typically seek the lowest cost option available for compliance. The cumulative impact of the points raised here: lack of package plants, higher than actual design flows, treatment of unnecessary entry points, and lack of non-treatment options means that AWWA does not provide a realistic cost estimate for small systems.

EPA Response: The EPA agrees that the AWWA B&V report does not provide a realistic cost estimate for small systems and that package plants can be a cost saving measure for some systems. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046174)

5. Differences in flow calculations. EPA and AWWA use different average flow assumptions. EPA uses inventory data, and AWWA assumes 150 gpd per person with published populations to calculate average flow. According to the USGS (Dieter et al., 2018), the AWWA assumption of 150 gpd per person is high, compared to their estimate of 82 gpd. This indicates that EPA flows may be more appropriate. The AWWA estimate also does not reflect regional differences in water use. Even though essentially the same peaking factors are used, AWWA ends up with higher design flows for systems serving <10,000 compared to EPA (Appendix E). The higher AWWA flows result in larger capital and O&M costs relative to actual flow requirements and are magnified even further when applied to the overestimate of entry points requiring treatment in small systems. On the other hand, Appendix E shows that for ground water CWSs serving

>=10,000 EPA flows are higher than AWWA estimated flows. This is not an apples-to-apples comparison because the EPA estimate does not include surface water CWSs, but it means there may not be a differential impact in costs for systems serving >=10,000. The total magnitude of the net impact of differences in flow between the two estimates is unclear because equivalent datasets are not available. However, the AWWA excess flows assumed for small systems likely results in net larger magnitude costs in AWWA compared to EPA.

EPA Response: The EPA generally agrees the commenter's conclusions about the sources of differences between the EPA's estimate and the AWWA B&V report estimates. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046172)

[The analysis that follows shows that the $3.1 billion dollar difference in annualized cost can be explained by the following primary factors:]

3. Treatment of Entry Points. EPA calculates treatment and O&M cost per entry point to the distribution system (EPTDS) that exceeds the MCL using modeled system and flow characteristics. Some PWSs have more than one entry point that requires treatment; costs are assigned per entry point that exceeds the MCL. AWWA calculates the number of PWSs that exceed the MCL, assumes that every PWS that exceeds the MCL has the average number of entry points per system for a system in that size category, and assumes every entry point in that system will require treatment regardless of whether a given entry point exceeds the MCL. This assumption results in 3,645 more entry points with treatment installation in the AWWA analysis that may not actually require treatment, and impacts both capital and O&M costs. A conservative estimate of the overall impact of this assumption, using the number of PWSs that AWWA estimated exceed the MCL along with EPA's metric of 1.3 entry points exceeding the MCL per PWS for small systems and 3.1 for large systems, is an overestimate of $1.4 billion (Appendix C).

EPA Response: The EPA generally agrees with the commenter's conclusions about the sources of differences between the EPA's estimate and the AWWA B&V report estimates. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046109)

EPA's analysis of treatment costs associated with the Proposed Rule is also well supported and more accurately forecasts costs than the competing analysis submitted by the American Water Works Association ("AWWA"). [FN111: Betanzo 2023; see Am. Water Works Ass'n, PFAS National Cost Model Report (Black & Veatch 2023).] For example, in contrast to AWWA, EPA properly screened the PFAS occurrence data incorporated into its treatment cost assessment to avoid bias in the data set from non-public water system PFAS samples and samples collected by water systems investigating known PFAS contamination. [FN112: Betanzo 2023 at 4, 6.] EPA also appropriately calculated treatment costs based on the number of water system entry points

with modeled MCL violations, whereas AWWA assumed without justification that every entry point within a water system will require treatment if any entry point within the system violates the MCL. [FN113: Id. at 4–5.] Critically, EPA also incorporated detailed estimates of the compliance strategies that water systems are likely to select—including non-treatment options — and associated costs. [FN114: Guignet 2023 at 4; Betanzo 2023 at 2–3, 9–11.] EPA's cost estimates also rely appropriately on inventoried flow rates, whereas AWWA utilizes a standardized 150 gpm/person flow rate that is biased high and fails to account for regional water-use differences. [FN115: Betanzo 2023 at 5, 12.] Overall, EPA's cost estimate is "robust" and "there is no evidence that EPA is consistently underestimating occurrence or costs," while AWWA's estimate includes excess treatment costs of at least $2.6 billion. [Fn116: Id. at 22.]

EPA Response: The EPA agrees with the commenter's regarding the appropriateness of the EPA's handling of data and screening of samples and cost analysis done at the EP level, rather than making the assumption that all EPs within a system will install treatment, as AWWA's B&V report did. The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046176)

[The analysis that follows shows that the $3.1 billion dollar difference in annualized cost can be explained by the following primary factors:]

7. Magnitude of treatment cost inputs. EPA's Economic Analysis (2023a), Technologies and Costs document (2023b), and Work Breakdown Structure Model documents (e.g., 2021a) provide hundreds of pages of documentation of the EPA cost analysis process whereas AWWA 2023 provides 36 pages with no references. The difference in documentation makes it impossible to compare cost inputs one to one, but it is possible to insert AWWA's flow assumptions into the EPA model to explore the net magnitude of underlying cost assumptions by comparing average systems. Appendix F shows that for small system capital costs, AWWA estimates treatment for a single entry point up to two times higher than EPA (e.g., $2.2 million compared to $1.1 million per entry point for systems serving 500-1,000 people). For large system capital costs, the EPA model for midlevel ground water CWS costs generates larger costs than the AWWA published averages. In Appendix G, application of the EPA model using AWWA average flows generates annual O&M cost estimates that are the same or larger than AWWA's average cost estimates, indicating that AWWA O&M cost inputs may be lower than EPA's. AWWA does not provide a treatment forecast showing the percent of systems expected to implement any given treatment. This analysis provides limited insight on determining the cumulative difference of cost inputs between the EPA and AWWA analyses. The relative magnitude of underlying costs is unknown, but nonetheless has a major impact on the net outcome of total national costs.

The evidence provided in this memo demonstrates that the EPA cost estimate is robust. While there are several items that could not be directly compared to the AWWA cost model, there is no

evidence that EPA is consistently underestimating occurrence or costs. According to calculations shown in Appendix G, if AWWA's O&M costs are accurate ($30,000-125,000 per entry point), this could mean that EPA's O&M cost estimates ($27,000-2,515,000) are larger than necessary and may be lower in practice. If Michigan's rate of non-treatment options is relevant nationwide, the total EPA cost would fall even further.

The EPA cost estimate of $658.5 million appears to be the more realistic result based on the calculations and findings presented here.

While professional judgement must be used in applying cost modeling assumptions, it appears that several of the assumptions in the AWWA cost model are too conservative. These assumptions consistently result in higher capital and O&M costs for treatment, especially for systems serving fewer than 10,000. As shown in Table 2, the analyses presented here demonstrate the AWWA estimate includes at least $2.6 billion in excess costs. Many of these overestimates have cascading effects that could not be modeled with available data. The cumulative impact of these corrections is likely even larger than estimated here. Subtracting the excess costs from AWWA's total estimate would result in a maximum annual cost of $1.2 billion for treatment installation and O&M.

Table 2: Total Magnitude of Quantified Excess Costs in the AWWA Cost Model

[Table 2: Docket ID: EPA-HQ-OW-2022-0114-1808]

Analysis

Tables are presented below that compare the two cost modeling approaches and outcomes. These evaluate occurrence data, public water system (PWS) inventory data, capital cost data and analytical approaches, and O&M.

Table 3: Occurrence Factors

[Table 3: Docket ID: EPA-HQ-OW-2022-0114-1808]

Table 4: Capital Treatment Selection and Costs

[Table 4: Docket ID: EPA-HQ-OW-2022-0114-1808]

Table 5: Operations and Maintenance Costs

[Table 5: Docket ID: EPA-HQ-OW-2022-0114-1808]

A case study for actual costs incurred can be identified from the AWWA analysis. Table 6-3 quantifies one PWS serving >1,000,000 that installed treatment in response to state PFAS MCLs with an AWWA estimated capital cost of $407.5 million and an annualized cost of $47 million. The water utility was identified via UCMR3 monitoring data. Information on this water system (O'Connell and Kilcommons, 2023) states the following: "Through a mix of blending, GAC treatment, and taking wells offline that have contaminant detections over the MCL that they are

currently in compliance with the state requirements. This PWS anticipates additional treatment may be needed to meet the proposed federal requirements." To date, they have spent:

• $15.0 million from 2016 – 2022 on PFAS related work

• $36.2 million on Emerging Contaminant Work

• $21.2 million on 1,4-Dioxane work

Although this is not the complete capital cost for the work (as more is pending), and some of the emerging contaminant and 1,4-Dioxane work may result in PFAS reduction benefits, the cost to date is significantly less than the estimated capital cost of $407.5 million presented in AWWA Table 6-3. Even if the $15 million is the actual annualized cost of PFAS treatment alone, it would be less than one third of the annualized cost shown in AWWA Table 6-3.

EPA Response: The EPA generally agrees with the commenter's observations about AWWA's B&V report and the case study. The EPA also agrees with this commenter's conclusions about the sources of differences between the EPA's national cost estimates and the estimates included in AWWA's B&V report. The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046178)

Conclusion

As discussed throughout this memo, assumptions used in AWWA cost modeling of the proposed PFAS drinking water rule result in higher annualized capital and O&M costs for treatment, especially for systems serving fewer than 10,000. While AWWA cost inputs for O&M may be lower than EPA's inputs, the larger number of entry points installing treatment per AWWA result in cumulative increased O&M costs. Although several details that are not provided cannot be quantified, the source of $2.6 billion in excess costs are clearly identified in this analysis and in Table 2. Many of these overestimates have cascading effects that are not readily calculated without access to the underlying cost models, so the cumulative impact of these corrections is likely even larger than estimated here. Subtracting the overestimates from the AWWA cost estimate results in a revised AWWA annual estimate of $1.2 billion for treatment and O&M to comply with the proposed MCLs. While there is a possibility that the actual result lies between the EPA and AWWA cost estimates, the calculations here indicate it is more likely to be closer to the EPA estimate.

The evidence provided in the executive summary and Tables 3-5 demonstrate that the EPA cost estimate is robust. While there are several items that could not be directly compared between the EPA and AWWA cost models, there is no evidence that EPA is consistently underestimating occurrence or costs. When looking toward which cost estimate is likely to better reflect future

compliance decisions, the EPA cost estimate appears to be more realistic based on the calculations and findings presented here.

If AWWA's apparent lower O&M cost inputs are accurate, this could mean that EPA's O&M cost estimates are higher than necessary and will be lower during implementation. If Michigan's rate of non- treatment options is relevant nationwide, the total EPA estimated cost would fall even further. The EPA $658 million annual treatment cost projection is realistic, and there are several opportunities for actual costs to turn out even lower upon implementation.

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White House Office of Mgmt. and Budget, Public Review Draft, Circular A-4, at 76 (Apr. 6, 2023)

Appendix A: Recalculation at 3% discount rate

[Appendix A: Docket ID: EPA-HQ-OW-2022-0114-1808]

Appendix B: Number of impacted systems and entry points

[Appendix B: Docket ID: EPA-HQ-OW-2022-0114-1808]

Appendix C: Estimate of impact of excess EPTDS

[Appendix C: Docket ID: EPA-HQ-OW-2022-0114-1808]

Appendix D: Cost Savings of non-treatment options

[Appendix D: Docket ID: EPA-HQ-OW-2022-0114-1808]

Appendix E: Average and Design Flows

[Appendix E: Docket ID: EPA-HQ-OW-2022-0114-1808]

Appendix F: Capital Cost Input Estimate

[Appendix F: Docket ID: EPA-HQ-OW-2022-0114-1808]

Appendix G: O&M Cost Input Estimate

[Appendix G: Docket ID: EPA-HQ-OW-2022-0114-1808]

Appendix H: O&M Correction

[Appendix H: Docket ID: EPA-HQ-OW-2022-0114-1808]

EPA Response: The EPA agrees with the commenter's conclusions about the sources of differences between the EPA's national cost estimates and the estimates submitted via public comment by AWWA. The EPA also agrees with the commenter that the EPA cost estimates are robust. The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. Please see section 13.3 of the EPA response in this *Response to Comments* document regarding the EPA's cost total national cost estimates for the final rule.

Wet Weather Partnership (Doc. #1820, SBC-044582)

We believe that EPA's implementation cost estimate may be upwards of an order of magnitude too low. EPA must revise and update its cost of compliance estimate and, using that significantly higher cost estimate, reevaluate the MCL levels. We believe the result of that reevaluation will yield a higher MCL for both PFOA and PFOS.

The number of facilities impacted by the proposed rule underscores how inaccurate the EPA cost estimate is and where there is need for more time and stakeholder input. In the proposed rule, EPA states "the entities potentially affected by the proposed PFAS regulation are primacy agencies and PWSs." 88 Fed. Reg. at 18690. The agency thinks around 66,000 water systems will be subject to the proposed rule and that around 3,400-6,300 systems will exceed one or more MCL. [FN2: EPA, Proposed PFAS National Primary Drinking Water Regulation (March 2023).] AWWA has publicly shared that a member facility (Cape Fear Public Utility Authority) estimated its PFAS treatment costs at $43 million with annual operating costs around $3-5 million, commenting that it would only take around 16 similarly sized utilities to go past the EPA cost figure. We estimate that 40-50 percent of the water systems nationwide will require PFAS barrier technology. In North Carolina, the State recently sampled 50 different water systems and concluded that 42 out of 50 exceed the 4 ppt MCL proposed for PFOA and/or PFOS. In South Carolina, the State sampled statewide and found 26 drinking water plants exceeded the federal limits. These numbers will increase with additional sampling.

EPA Response: This comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. The EPA notes that the commenter is comparing total capital costs at a single system to the EPA's annualized costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document for why this is inappropriate and misrepresentative of the EPA's analysis. The EPA disagrees with the commenter's unsupported claim that 40-50 percent of water systems nationwide would need to install treatment. This far exceeds the EPA's or any other known data-driven analysis' estimates of the number of water systems nationally expected to exceed the MCLs. It is also inconsistent with empirical observations from nearly all of the states that conducted non-targeted monitoring which demonstrate widely varying percentages of systems exceeding the MCLs, See Section 2.4.2.2 of the *Occurrence Technical Support Document* (USEPA, 2024a) and section 6.2 of the EPA response in this *Response to Comments* document for more information about state occurrence data. Furthermore, while the analyses are preliminary, this is wholly inconsistent with the partial results from the EPA's UCMR 5 monitoring effort. Please see section 6.8 of the EPA response in this *Response to Comments* document for further discussion. The EPA has used a nationally representative peer reviewed model to inform the number of water systems expected to install treatment. Please see section 6.5 of the EPA response in this *Response to Comments* document for more information on the EPA's national occurrence model. Furthermore, extrapolating from a single utility's experience is not an appropriate method to estimate national costs. See also section 13.3.3 of the EPA response in this *Response to Comments* document.

West Virginia Municipal Water Quality Association (Doc. #1816, SBC-044670)

We believe that EPA's implementation cost estimate may be upwards of an order of magnitude too low. EPA must revise and update its cost of compliance estimate and, using that significantly higher cost estimate, reevaluate the MCL levels. We believe the result of that reevaluation will yield a higher MCL for both PFOA and PFOS.

The number of facilities impacted by the proposed rule underscores how inaccurate the EPA cost estimate is and where there is need for more time and stakeholder input. In the proposed rule, EPA states "the entities potentially affected by the proposed PFAS regulation are primacy agencies and PWSs." 88 Fed. Reg. at 18690. The agency thinks around 66,000 water systems will be subject to the proposed rule and that around 3,400-6,300 systems will exceed one or more MCL. [FN2: EPA, Proposed PFAS National Primary Drinking Water Regulation (March 2023), Link:w.epa.gov/system/files/documents/2023-03/PFAS%20NPDWR%20Public%20Presentation_Overview_3.16.23_508.pdf] AWWA has publicly shared that a member facility (Cape Fear Public Utility Authority) estimated its PFAS treatment costs at $43 million with annual operating costs around $3-5 million, commenting that it would only take around 16 similarly sized utilities to go past the EPA cost figure. We estimate that 40-50 percent of the water systems nationwide will require PFAS barrier technology. In North Carolina, the State recently sampled 50 different water systems and concluded that 42 out of 50 exceed the 4 ppt MCL proposed for PFOA and/or PFOS. In South Carolina, the State sampled statewide and found 26 drinking water plants exceeded the federal limits. These numbers will increase with additional sampling.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1820, SBC-044582 in section 13.3.3 in this *Response to Comments* document.

Association of Missouri Cleanwater Agencies (Doc. #1817, SBC-044648)

We believe that EPA's implementation cost estimate may be upwards of an order of magnitude too low. EPA must revise and update its cost of compliance estimate and, using that significantly higher cost estimate, reevaluate the MCL levels. We believe the result of that reevaluation will yield a higher MCL for both PFOA and PFOS.

The number of facilities impacted by the proposed rule underscores how inaccurate the EPA cost estimate is and where there is need for more time and stakeholder input. In the proposed rule, EPA states "the entities potentially affected by the proposed PFAS regulation are primacy agencies and PWSs." 88 Fed. Reg. at 18690. The agency thinks around 66,000 water systems will be subject to the proposed rule and that around 3,400-6,300 systems will exceed one or more MCL [FN2: EPA, Proposed PFAS National Primary Drinking Water Regulation (March 2023).]. AWWA has publicly shared that a member facility (Cape Fear Public Utility Authority) estimated its PFAS treatment costs at $43 million with annual operating costs around $3-5 million, commenting that it would only take around 16 similarly sized utilities to go past the EPA cost

figure. We estimate that 40-50 percent of the water systems nationwide will require PFAS barrier technology. In North Carolina, the State recently sampled 50 different water systems and concluded that 42 out of 50 exceed the 4 ppt MCL proposed for PFOA and/or PFOS. In South Carolina, the State sampled statewide and found 26 drinking water plants exceeded the federal limits. These numbers will increase with additional sampling.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1820, SBC-044582 in section 13.3.3 in this *Response to Comments* document.

NORTH CAROLINA WATER QUALITY ASSOCIATION (Doc. #1818, SBC-044626)

We believe that EPA's implementation cost estimate may be upwards of an order of magnitude too low. EPA must revise and update its cost of compliance estimate and, using that significantly higher cost estimate, reevaluate the MCL levels. We believe the result of that reevaluation will yield a higher MCL for both PFOA and PFOS.

The number of facilities impacted by the proposed rule underscores how inaccurate the EPA cost estimate is and where there is need for more time and stakeholder input. In the proposed rule, EPA states "the entities potentially affected by the proposed PFAS regulation are primacy agencies and PWSs." 88 Fed. Reg. at 18690. The agency thinks around 66,000 water systems will be subject to the proposed rule and that around 3,400- 6,300 systems will exceed one or more MCL. [FN2: EPA, Proposed PFAS National Primary Drinking Water Regulation (March 2023).] AWWA has publicly shared that a member facility (Cape Fear Public Utility Authority) estimated its PFAS treatment costs at $43 million with annual operating costs around $3-5 million, commenting that it would only take around 16 similarly sized utilities to go past the EPA cost figure. We estimate that 40-50 percent of the water systems nationwide will require PFAS barrier technology. In North Carolina, the State recently sampled 50 different water systems and concluded that 42 out of 50 exceed the 4 ppt MCL proposed for PFOA and/or PFOS. In South Carolina, the State sampled statewide and found 26 drinking water plants exceeded the federal limits. These numbers will increase with additional sampling.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1820, SBC-044582 in section 13.3.3 in this *Response to Comments* document.

South Carolina Water Quality Association (Doc. #1819, SBC-044604)

We believe that EPA's implementation cost estimate may be upwards of an order of magnitude too low. EPA must revise and update its cost of compliance estimate and, using that significantly higher cost estimate, reevaluate the MCL levels. We believe the result of that reevaluation will yield a higher MCL for both PFOA and PFOS.

The number of facilities impacted by the proposed rule underscores how inaccurate the EPA cost estimate is and where there is need for more time and stakeholder input. In the proposed rule, EPA states "the entities potentially affected by the proposed PFAS regulation are primacy agencies and PWSs." 88 Fed. Reg. at 18690. The agency thinks around 66,000 water systems will be subject to the proposed rule and that around 3,400-6,300 systems will exceed one or more MCL [FN2: EPA, Proposed PFAS National Primary Drinking Water Regulation (March 2023).]. AWWA has publicly shared that a member facility (Cape Fear Public Utility Authority) estimated its PFAS treatment costs at $43 million with annual operating costs around $3-5 million, commenting that it would only take around 16 similarly sized utilities to go past the EPA cost figure. We estimate that 40-50 percent of the water systems nationwide will require PFAS barrier technology. In North Carolina, the State recently sampled 50 different water systems and concluded that 42 out of 50 exceed the 4 ppt MCL proposed for PFOA and/or PFOS. In South Carolina, the State sampled statewide and found 26 drinking water plants exceeded the federal limits. These numbers will increase with additional sampling.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1820, SBC-044582 in section 13.3.3 in this *Response to Comments* document.

Wet Weather Partnership (Doc. #1820, SBC-044580)

Below are examples of different water system estimated costs to install PFAS barrier technology.

South Carolina

• One drinking water system in South Carolina, which is a member of the SC Water Quality Association, has estimated the cost of PFAS barrier technology installation would be $150-$200 million. On top of that, annual operation and maintenance costs would be $24 million.

• Another SC utility that also operates a large drinking water system has a preliminary estimate of $335 million to install granulated activated carbon technology. Complicating matters, the utility may have to add transfer pumping and additional standby power generation for the GAC contractors as there may not be a current suitable location near the flow train or available head loss. This would raise the cost closer to $500 million or more. Due to the potential frequency of GAC media change out, the utility might also have to install a rail spur to manage the logistics of handling that amount of GAC.

North Carolina

• In North Carolina, a utility estimates $43M in capital costs for a GAC system and $1-5M annually for GAC renewal/replacement and O&M.

• Another North Carolina utility estimates $15M in anticipated PFAS-related projects.

• A relatively small North Carolina water system has contracted for a GAC upgrade in the $25 million range.

Other

• A Virginia utility estimates its installation of GAC vessels will have a $21.4 million project cost.

• The City of Nashville received between $500-900M in funding for GAC at its two water plants (including $315M in WIFIA loans in Sept. 2022).

• The Orange County Water District in California received $131 million in WIFIA loans for a $267 million project to remove PFAS from groundwater.

EPA needs more cost information and input from states, SDWA SRF program managers, and public utilities in order to develop a legally valid cost assessment. In addition to actual project awards, the EPA SDWA SRF Program staff should include PFAS barrier projects that were proposed for funding but were not accepted/deferred.

EPA Response: This comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. As detailed in section 13.3.3 of the EPA response in this *Response to Comments* document, to fully evaluate the commenters' reported or estimated costs in comparison to WBS model results, the EPA would need itemized line-item cost details and engineering design parameters. The EPA has further validated the unit costs in the PFAS rule with equipment cost information from 2023 from a major supplier of treatment media. While the EPA recognizes there are likely site-specific instances where costs exceed the EPA's cost ranges, there are also likely site-specific instances where costs are less than the EPA's cost ranges, and this level of accuracy is appropriate for a national level analysis. The EPA has thoroughly considered all public comments submitted on the proposed PFAS rule and incorporated a number of recommendations from public commenters into the agency's cost models that are reflected in the cost analysis for the final rule. Finally, the EPA disagrees with the commenter's assertion that the EPA has not conducted a "legally valid cost assessment" as the agency has used the best available peer reviewed science to inform a HRRCA pursuant to SDWA requirements. Please see section 13.3.2 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1675, SBC-044933 in section 13.3.2 in this *Response to Comments* document for further discussion of why the EPA fulfilled its obligations under SDWA 1412(b)(3)(C) and performed a robust cost analysis meeting all SDWA requirements.

West Virginia Municipal Water Quality Association (Doc. #1816, SBC-044668)

Below are examples of different water system estimated costs to install PFAS barrier technology.
South Carolina

• One drinking water system in South Carolina, which is a member of the SC Water Quality Association, has estimated the cost of PFAS barrier technology installation would be $150-$200 million. On top of that, annual operation and maintenance costs would be $24 million.

• Another SC utility that also operates a large drinking water system has a preliminary estimate of $335 million to install granulated activated carbon technology. Complicating matters, the utility may have to add transfer pumping and additional standby power generation for the GAC contractors as there may not be a current suitable location near the flow train or available head loss. This would raise the cost closer to $500 million or more. Due to the potential frequency of GAC media change out, the utility might also have to install a rail spur to manage the logistics of handling that amount of GAC.

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EPA needs more cost information and input from states, SDWA SRF program managers, and public utilities in order to develop a legally valid cost assessment. In addition to actual project awards, the EPA SDWA SRF Program staff should include PFAS barrier projects that were proposed for funding but were not accepted/deferred.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1820, SBC-044580 in section 13.3.3 in this *Response to Comments* document.

Association of Missouri Cleanwater Agencies (Doc. #1817, SBC-044646)

Below are examples of different water system estimated costs to install PFAS barrier technology.
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• One drinking water system in South Carolina, which is a member of the SC Water Quality Association, has estimated the cost of PFAS barrier technology installation would be $150- $200 million. On top of that, annual operation and maintenance costs would be $24 million.

• Another SC utility that also operates a large drinking water system has a preliminary estimate of $335 million to install granulated activated carbon technology. Complicating matters, the utility may have to add transfer pumping and additional standby power generation for the GAC contractors as there may not be a current suitable location near the flow train or available head loss. This would raise the cost closer to $500 million or more. Due to the potential frequency of GAC media change out, the utility might also have to install a rail spur to manage the logistics of handling that amount of GAC.

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• The Orange County Water District in California received $131 million in WIFIA loans for a

$267 million project to remove PFAS from groundwater.

EPA needs more cost information and input from states, SDWA SRF program managers, and public utilities in order to develop a legally valid cost assessment. In addition to actual project awards, the EPA SDWA SRF Program staff should include PFAS barrier projects that were proposed for funding but were not accepted/deferred.

EPA Response: The comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

NORTH CAROLINA WATER QUALITY ASSOCIATION (Doc. #1818, SBC-044624)

Below are examples of different water system estimated costs to install PFAS barrier technology.

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• One drinking water system in South Carolina, which is a member of the SC Water Quality Association, has estimated the cost of PFAS barrier technology installation would be $150-$200 million. On top of that, annual operation and maintenance costs would be $24 million.

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• The Orange County Water District in California received $131 million in WIFIA loans for a $267 million project to remove PFAS from groundwater.

EPA needs more cost information and input from states, SDWA SRF program managers, and public utilities in order to develop a legally valid cost assessment. In addition to actual project awards, the EPA SDWA SRF Program staff should include PFAS barrier projects that were proposed for funding but were not accepted/deferred.

EPA Response: The comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

South Carolina Water Quality Association (Doc. #1819, SBC-044602)

Below are examples of different water system estimated costs to install PFAS barrier technology.

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• One drinking water system in South Carolina, which is a member of the SC Water Quality Association, has estimated the cost of PFAS barrier technology installation would be $150-$200 million. On top of that, annual operation and maintenance costs would be $24 million.

• Another SC utility that also operates a large drinking water system has a preliminary estimate of $335 million to install granulated activated carbon technology. Complicating matters, the utility may have to add transfer pumping and additional standby power generation for the GAC contractors as there may not be a current suitable location near the flow train or available head loss. This would raise the cost closer to $500 million or more. Due to the potential frequency of GAC media change out, the utility might also have to install a rail spur to manage the logistics of handling that amount of GAC.

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• The Orange County Water District in California received $131 million in WIFIA loans for a $267 million project to remove PFAS from groundwater.

EPA needs more cost information and input from states, SDWA SRF program managers, and public utilities in order to develop a legally valid cost assessment. In addition to actual project awards, the EPA SDWA SRF Program staff should include PFAS barrier projects that were proposed for funding but were not accepted/deferred.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1820, SBC-044580 in section 13.3.3 in this *Response to Comments* document.

Mississippi Farm Bureau Federation (Doc. #1826, SBC-044268)

We expect that the costs associated with testing and the potential need for filtration will be significant, especially for some of the rural water systems that can ill afford it.

EPA Response: Regarding treatment costs, including costs for small systems, please see section 13.3.3 of the EPA response in this *Response to Comments* document. Regarding sampling costs, please see section 13.3.4 of the EPA response in this *Response to Comments* document. Please see section 13.10 of the EPA response in this *Response to Comments* document on the EPA's affordability analysis.

The District of Columbia Water and Sewer Authority (Doc. #1829, SBC-045776)

Based on our experience, the EPA cost model significantly underestimates the capital and O&M costs associated with PFAS treatment. We recommend that EPA reevaluate its cost estimates and consider inflation and supply chain issues likely to result from the Proposal in its revised evaluation.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

The District of Columbia Water and Sewer Authority (Doc. #1829, SBC-04'770)

EPA's Estimates Underestimate the Actual Cost of PFAS Treatment

EPA's cost analysis is critical to the health risk reduction and cost analysis (HRRGA) and household affordability analysis. Inaccurate cost estimates will result in mischaracterization of the Proposal's merits.

[Figure 1: see docket ID EPA-HQ-OQ-2022-0114-1829]

Review of the cost modeling shows significant misalignment between the Proposal's assumption and our experiences with capital improvements and operating costs. For example, the EPA cost model utilizes the curve below to estimate the capital costs for granular activated carbon (GAG). Our water provider, the Washington Aqueduct, operates two surface water treatment facilities, Dalecarlia and McMillan. EPA's model estimates that it would cost approximately $103.4M to install GAG at these two facilities.

GAG was considered as a potential treatment upgrade at the WAD in 2013, and the capital cost of GAG at our two plants at that time was estimated at $200M. Utilizing a conservative inflationary estimate of 58% [FN1: Using the Census.gov Multifamily Housing Construction Index 2005-2022] indicates a present value of $316.6M, or a factor of more than 3 times the EPA's estimated cost of $103.4M.

Our analysis notes a similar discrepancy in the estimated O&M costs for GAG, with our inflation adjusted annual O&M cost estimated at $31.6M as compared to the EPA model estimate of $10.1M.

EPA Response: The comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. Please see section 13.3.3 of the EPA response in this *Response to Comments* document for further discussion.

American Chemistry Council (ACC) (Doc. #1841, SBC-044841)

EPA Has Underestimated the Cost of Treatment Systems and Residual Disposal

EPA's cost model for treatment systems included several assumptions that do not appropriately characterize water treatment costs and disposal of spent residuals. EPA assumes that the majority of the drinking water systems that will require treatment will utilize granular activated carbon (GAC). EPA's estimates of a 2-year lifespan of the activated carbon in these systems is likely overstated.

EPA Response: The commenter is incorrect; the EPA did not make a blanket assumption of a 2-year lifespan for activated carbon. The EPA estimated GAC bed life individually for each entry point based on the percent removal required to comply with the rule, given each entry point's estimated influent PFAS concentrations. See Chapter 5.3.1 of the EA for more information.

American Chemistry Council (ACC) (Doc. #1841, SBC-052936)

Similarly, EPA's cost model for reverse osmosis (RO) systems does not include the requirement to remineralize RO permeate to protect downstream distribution piping from corrosion and make the water suitable for human consumption. Where facilities use RO systems, EPA should not assume blending with other finished waters is an available option.

EPA Response: The EPA has adjusted RO/NF's technology projection compliance forecast to 0 percent in the EA for the final rule. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. Regarding the commenter's mention of blending, the comment is moot as the EPA is not forecasting the use of RO as a result of this rule. However, if it were not moot, the EPA notes that no specific technology, technique, or process is required under this rule in order to meet the MCLs and all options have potential tradeoffs. The EPA recommends that utilities and primacy agencies evaluate all options according to site-specific needs and circumstances. For more information, please see the EPA response to comment Doc. #2793, SBC-046610 and Doc. #1699, SBC-045043 in section 10.2 in this *Response to Comments* document.

Santa Clarita Valley Water Agency (Doc. #3072-20, SBC-046350)

Thank you. My name is Matt Stone. I am the general manager of the Santa Clarita Valley Water Agency, also known as SCV Water. We serve 300,000 residents in northwest Los Angeles County, California. I want to thank EPA for its effort to establish a national safe drinking water standard for PFAS chemicals. About half of our water supply portfolio comes from two local groundwater aquifers. Since California first set response levels for PFOA and PFOS in 2018, it continues to refine and add additional PFAS related RLs. We have removed approximately 40% of our groundwater production capacity from service. As we work to restore that capacity, we have gained experience with the cost to implement ion exchange PFAS treatment systems, which

I will share with you. Our N Wells facility was completed in December 2020, treats 6,250 gallons per minute, had a capital cost of $9.2 million, or about $1,474 per GPM of capacity. This project was identified as the fastest and lowest-cost project we could complete, and we were fortunate to get ahead of price increases, and already had three wells connected to the treatment site. Next, the Valley Center facility was completed in August of 2022, treats 1,200 gallons per minute, with a capital cost of $5.12 million, or $4,267 per GPM of capacity. For that project, we saw increases in vessel costs, resin costs, and long supply chain lead times for some items. Last, Santa Clara and Honby Wells Facility is now under construction, and should be completed in early 2024. It will treat 2,000 gallons per minute, and the cost is $9.63 million, or $4,813 per GPM of capacity. We experienced additional supply chain lead time issues here as well. We believe these two recent projects reflect where costs and delivery times are today. Project delivery time was three and a half years for Valley Center, and is expected to be four years for Santa Clara Honby. We currently estimate the cost to restore total impacted capacity to meet state and federal PFAS standards could reach $160 million in capital, and an annual operating cost of $11 million. These are in 2022 dollars, and may be revised as more projects reach design phase, and as additional wells are impacted. Thank you for the opportunity to provide comment.

EPA Response: The updated cost curves the EPA developed for the final rule estimate a range of capital costs of approximately $6.5 million to $9.4 million for a 6,250 gallon per minute facility using IX to treat groundwater. The commenter's reported cost of $9.2 million for the N-Wells facility falls within this range. The EPA's updated cost curves estimate a range of $2.2 million to $3.4 million for a 1,200 gallon per minute facility and $2.9 million to $4.5 million for a 2,000 gallon per minute facility. The commenter's reported costs of $5.12 million and $9.63 million for the Valley Center Well facility and the Santa Clara and Honby Wells facilities, respectively, exceed these ranges. However, the comment does not include information to confirm that (1) all the estimated costs would be directly associated with PFAS treatment, as opposed to other infrastructure improvements, and (2) that design parameters (e.g., empty bed contact time) for this facility would be similar to the typical values assumed in the EPA's estimate. The comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-046167)

6.2 Accounting for State Level Regulatory Costs

The model includes consideration of state regulatory actions that may have driven PWSs to remove PFAS already. Consideration of state regulatory actions is necessary to characterize the compliance costs of a potential NPDWR for PFAS. All state regulations incorporated into modeled cost output are shown in Table 6-2

Table 6-2 State Maximum Contaminant Levels Modeled for State Regulatory Cost Estimate

[Table 6-2: Docket ID: EPA-HQ-OW-2022-0114-1759]

To differentiate federal regulatory costs from costs incurred because of existing state regulations, the cost tool includes an input sheet for all existing state MCLs as either individual limits or group totals. The Visual Basic Script references both the state MCLs and the projected federal MCLs. In the absence of a federal regulation (or if the state MCL is more stringent than the federal MCL), the cost tool generates costs for treatment to comply with the state MCLs on the input sheet. An example of this is shown in Table 6-3, which displays treatment costs incurred as a result of state regulations shown in Table 6-2.

Table 6-3 Summary of Estimated Costs Associated with State PFAS MCLs

[Table 6-3: Docket ID: EPA-HQ-OW-2022-0114-1759]

EPA Response: Although the commenter includes these estimates of the costs to PWSs to comply with existing state PFAS regulations, it does not assume that PWSs are already in compliance with state standards. This approach overestimates federal rule compliance costs for water systems in states with existing state standards. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-046162)

5.1.2 Water Quality Considerations Incorporated

5.1.2.1 Influent and Effluent PFAS Levels

For each PWS in the occurrence database, any single PFAS monitoring result above either existing state or potential regulatory limit was assumed to incur a capital expenditure for treatment. Data down to the resolution of each individual source was not considered for this modeling effort; instead, the number of projected water treatment facilities per system was based on the EPTDS factors as summarized in the previous section. Maximum PFAS monitoring data were assumed to compel treatment for the PWS as a whole and, thus, all the projected water treatment facilities. The average PFAS monitoring data were used to estimate long-term costs of removal (annual O&M costs).

The target effluent PFAS levels for treatment was determined as an input percentage of a potential regulatory limit. For example, treatment could be triggered at 80, 90, or 100 percent of the potential regulatory level. For this work, a threshold of 80 percent was used in alignment with previous practice for estimating costs of potential regulations for drinking water, since water systems will target and operate below this threshold to ensure that the limit is not exceeded if the water quality suddenly increases.

5.1.2.2 Other Water Quality Considerations

Other water quality contaminants may impact PFAS treatment performance (and therefore costs), such as TOC and manganese. The longevity of GAC media, IX resin, and membrane operations are significantly affected by the quality of the source. Differences in source water quality parameters not specifically included (e.g., TOC, sulfate, pH, alkalinity, etc.) with pertinence to

design or performance were reflected in cost by varying design parameters and treatment system performance according to probability functions using Monte Carlo analysis. This is primarily controlled through variation of the treatment performance factors (e.g., EBCT, surface area loading rate) to reflect less or more challenging water quality characteristics. The methodology for the Monte Carlo Simulation is covered in Section 5.2. Work is in progress to estimate costs associated with removing manganese and will be made available at a later date.

EPA Response: The EPA disagrees with some of the assumptions used by the commenter with regard to PFAS occurrence and media bed life. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-046160)

5.0 Individual Treatment Facility Cost Methodology

The next step in estimating the national costs to remove PFAS from drinking water is to use the occurrence database to estimate the costs associated with treatment for individual PWSs. The following subsections summarize how capital, operating, and life-cycle costs are calculated for each system and for each technology.

The spreadsheet tool developed to perform this task accepts inputs for individual or combined target effluent levels for the six PFAS compounds represented in the database. After both occurrence data and potential regulatory levels are input, Visual Basic scripts within Excel may be initiated by a user to run a Monte Carlo analysis and generate a 10th percentile, 90th percentile, and most probable costs for the capital, operations and maintenance (O&M), and life-cycle costs for a typical entry point to the distribution system (EPTDS) for each PWS in the database. For each system, the tool selects the treatment technology with the lowest life-cycle cost.

This methodology assumes installation of a treatment system at each EPTDS associated with PWSIDs where the maximum PFAS concentration is greater than the potential regulatory level for the corresponding PFAS. The details of individual system and EPTDS cost methodology are described in the following subsections. A list of output fields generated by the cost modeling tool for each PWS with occurrence data is shown in Table 5-1.

Table 5-1 Model Outputs for Individual PWS with Occurrence Data

[Table 5-1: Docket ID: EPA-HQ-OW-2022-0114-1759]

EPA Response: The EPA disagrees with the commenter's assumption that every EPTDS at a system will require treatment if not every EPTDS at a system exceeds the MCL. For example, if a utility has four entry points, but only one entry point exceeds an MCL, only that entry point must be treated (or other action must be taken). Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-046164)

5.3 Capital Cost Calculation

Capital costs were calculated for each EPTDS of a PWS based on the design flow per EPTDS (refer to Equation 1). The design flow was used for capital costs estimates since equipment should be sized for peak treatment flow rates. Costs were independently calculated for IX, GAC vessels, GAC basins, and RO as described in the following subsections. Capital costs generated for individual systems represent a Class 5 Association for the Advancement of Cost Engineering (AACE) estimate, at approximately 1 to 2 percent maturity level of deliverable definition.

5.3.1 Major Hardware Components

5.3.1.1 GAC Gravity Basins

The major cost components incorporated into the capital cost estimate for this option are the concrete basins themselves, an influent pump station, media for the initial fill, and a building to house the system. The design assumptions for each element are summarized in Subsection 3.1.2.

The concrete basin includes costs for influent and effluent piping, isolation valves, and monitoring instruments. Using the design flow rate and the SLR, a required surface area for filtration is calculated and used to determine the appropriate number of basin cells and anticipated basin dimensions for costing.

Once number and size of basins are calculated, the design flow and specified EBCT is used to determine the volume of media needed. Cost of media was determined by converting volume to mass using an average GAC density of 0.5 g/cc and an average cost per pound of $1.40. It should be noted that cost changes were not projected into the cost model resulting from increased demand for adsorbent media.

The pump station includes costs for influent pumps, backwash pumps, an influent wetwell, and a backwash recovery basin. The independent design inputs for the influent pumps are total dynamic head (TDH) and total number of pumps. The independent design parameters for backwash pump and backwash recovery basin calculations are backwash loading rate, backwash duration, backwash frequency, and backwash pump TDH. Costs for backwash pumping include a single duty pump and a single standby pump.

The sum of the square footage required for the contactor basins was multiplied by a sizing factor of two to account for the ancillary equipment and space for access and maintenance. Pump station square footage, including all pumps and the wet well, was estimated by benchmarking design flow against previous designs. Building area was assumed to be the sum of contactor facility area (including sizing factor), pump station area, and backwash recovery basin area (assumed to be indoors). The building cost was assumed to be $200/sf.

Black & Veatch utilized empirically derived cost curves as a function of size from several decades of infrastructure project design and delivery to estimate cost for these major

components. A curve for concrete basins provides cost as a function of square footage. A curve for steel tanks provides costs as a function of volume in gallons, and a curve for pumps provides cost as a function of horsepower.

Installation fees were included at 20 percent for all major equipment components, as summarized in Table 5-5. These cost factors are identical to those for GAC and IX pressure vessels.

Table 5-5 GAC and IX Equipment Installation Cost Factors

[Table 5-5: Docket ID: EPA-HQ-OW-2022-0114-1759]

5.3.1.2 GAC, IX and Manganese Pretreatment Pressure Vessels

Capital equipment costs were calculated using the total contactor footprint, contactor building footprint, and media volume required. Capital costs were calculated for the ancillary pump stations using the building footprint, number and size of influent pumps, backwash pumps, influent wetwell, and backwash recovery basin. The model incorporated a building cost of $200/ft2. The installation fees for the various components are the same as those summarized in Table 5-6.

Calculated capital cost for manganese pretreatment for each system was considered a stand-alone output and was not included in the capital, operational, or life-cycle cost outputs for PFAS treatment.

5.3.1.3 Reverse Osmosis

Capital costs were calculated for the RO system and building, low- and high-pressure feed pumps and their associated building, storage tanks, cartridge filters, chemical treatment system, decarbonation system, and brine disposal. The model incorporated a building cost of $200/ft2. The installation fees for the various components are summarized in Table 5-6.

Table 5-6 RO Equipment Installation Cost Factors

[Table 5-6: Docket ID: EPA-HQ-OW-2022-0114-1759]

5.3.1.4 Additional Capital Costs

In addition to equipment costs, the capital costs for GAC, IX, RO, and manganese pretreatment included additional project costs (site work, yard piping, electrical, and instrumentation and controls), contractor markup costs, and non-construction costs. The multipliers used for each of these factors are summarized in Table 5-7.

Table 5-7 Additional Capital Cost Assumptions

[Table 5-7: Docket ID: EPA-HQ-OW-2022-0114-1759]

5.4 Operating Cost Calculation

The operational costs for GAC, IX, and RO were calculated using the average flow rate for each EPTDS, as represented by the average flow per water system divided by the number of EPTDS. Whereas capital costs were driven by maximum PFAS levels, the operating costs incurred were driven by the average influent PFAS concentrations to reflect long-term operating conditions. The tool allows entry of a treatment goal expressed as a percent of the potential regulatory limit, and the resulting target concentration serves as the effluent concentration trigger for replacement of media. This target may be expressed either as a concentration of a single PFAS compound or as a combination of compounds.

Operating costs that were considered for this work included replacement costs (using the calculated bed volumes to breakthrough or media replacement frequency), power consumption in the pumps and buildings, maintenance costs, waste disposal, and labor costs. Analytical monitoring costs were not included in the life-cycle cost calculations. Table 5-8 provides an overview of the O&M cost assumptions.

Table 5-8 O&M Cost Assumptions

[Table 5-8: Docket ID: EPA-HQ-OW-2022-0114-1759]

EPA Response: The EPA disagrees with many of the assumptions presented in this section of the comment and the AWWA's B&V that was used to develop the commenter's cost estimate. Please see section 13.3.3 of the EPA response in this *Response to Comments* document which discusses specifically why the EPA disagrees with many of these assumptions.

American Water Works Association (AWWA) (Doc. #1759, SBC-046168)

7.0 Summary of Results

A summary of the cost model results for various potential federal MCL alternatives on the national and household level is presented in this section.

7.1 National Cost Estimates

The national cost modeling tool was used to evaluate both the national financial burdens on communities from PFAS drinking water contamination (the National Burden) and the costs for water systems to comply with a potential NPDWR for PFAS (NPDWR Compliance Costs).

The National Burden is reflective of the total, cumulative impact to water systems and communities across the United States from PFAS contamination of drinking water. It is calculated by estimating the drinking water PFAS treatment costs associated with the number of systems with PFAS occurrence data above the target limit. The National Burden assumes the same target limit for water systems across all states and includes systems in states with existing drinking water regulations for PFAS. The NPDWR Compliance Costs are determined by estimating the national financial burden and excluding costs for systems already triggered into treatment by existing drinking water regulations at the state level. The difference between the

National Burden and the NPDWR Compliance Costs is therefore calculated using the data presented in Table 6-3.

The National Burden and NPDWR Compliance Costs were estimated for two different scenarios. The first scenario is based on a target PFOA and PFOS level of 4 ppt each. The second scenario is based on target PFOA and PFOS levels of 10 ppt each.

An overview of the present value of the life-cycle cost for the National Burden and NPDWR compliance cost for each of these scenarios is displayed on Figure 7-1.

[Figure 7-1: Docket ID: EPA-HQ-OW-2022-0114-1759]

Figure 7-1 Summary of Present Value of Life-Cycle Costs for National Burdens and NPDWR Compliance Costs for Each Scenario based on a 3% discount rate

Annualized costs were also calculated using Formula 3. An overview of the National Burden and NPDWR Compliance Annualized Cost for each of these scenarios is presented on Figure 7-2.

[Formula 3: Docket ID: EPA-HQ-OW-2022-0114-1759]

[Figure 7-2: Docket ID: EPA-HQ-OW-2022-0114-1759]

Figure 7-2 Summary of Annualized Costs for National Burdens and NPDWR Compliance for Each Scenario based on a 3% discount rate

A more detailed breakdown of these costs by system size is presented in Appendix A.

7.2 Household Financial Impacts

As part of this analysis, the annual financial impacts to individual households from costs associated with the installation and operation of drinking water treatment facilities for PFAS were determined. The financial impacts to individual households will vary by specific PFAS levels, system size, and other factors. Additionally, the impacts to individual households arising from a potential NPDWR will differ depending on whether there is an existing state regulation for PFAS in drinking water. Table 7-1 shows the individual household impacts as a function of system size for each of the three scenarios discussed in Section 7.1. These household level cost impacts are based on the annualized costs for each system size and an average of 2.6 persons per household and incorporate estimated average service populations for each size category based on SDWIS data. The range of household level costs in the table is reflective of communities where new treatment facilities will need to be installed and operated.

Table 7-1 Annual Costs to Household for Removing PFAS from Drinking Water

[Table 7-1: Docket ID: EPA-HQ-OW-2022-0114-1759]

Appendix A. Modeled Cost MCL and Discount Rate Comparison Tables

Table A-1 National Cost Burden by System Size for 4 ppt PFOA, PFOS (Groundwater Systems)

[Table A-1: Docket ID: EPA-HQ-OW-2022-0114-1759]

Table A-2 National Burden Costs per System Size for 4 ppt PFOA, PFOS (Surface Water Systems)

[Table A-2: Docket ID: EPA-HQ-OW-2022-0114-1759]

Table A-3 National Burden Costs by System Size for 10 ppt PFOA, PFOS (Groundwater Systems)

[Table A-3: Docket ID: EPA-HQ-OW-2022-0114-1759]

Table A-4 National Burden Costs by System Size for 10 ppt PFOA, PFOS (Surface Water Systems)

[Table A-4: Docket ID: EPA-HQ-OW-2022-0114-1759]

Table A-5 Annualized NPDWR Costs by System Size per Discount Rate

[Table A-5: Docket ID: EPA-HQ-OW-2022-0114-1759]

EPA Response: The EPA disagrees with many of the assumptions in AWWA's B&V report and therefore with the costs presented in this section of the comment. Please see section 13.3.3 of the EPA response in this *Response to Comments* document which discusses specifically why the EPA disagrees with many of these assumptions.

American Water Works Association (AWWA) (Doc. #1759, SBC-046152)

3.1.2 Assumptions for Cost Estimation

The cost model includes capital costs, annual operating and maintenance costs, life-cycle costs, and annualized costs. The assumptions that drove the results of those cost estimates are summarized in this section.

The costs for GAC contactors depend on the contactor type, size, number, and ancillary processes such as backwash pumps/recovery basins and contactor influent pumps/wet wells. The primary process design assumptions for each of these factors are summarized in Table 3-1.

Table 3-1 GAC Design Process Assumptions

[Table 3-1: Docket ID: EPA-HQ-OW-2022-0114-1759]

EPA Response: The EPA disagrees with several of the assumptions presented in the commenter's Table 3-1. Please see section 13.3.3 of the EPA response in this *Response to Comments* document which discusses why the EPA disagrees with many of the assumptions in this table.

Lehigh County Authority (LCA) (Doc. #1600, SBC-042815)

LCA understands there are some significant concerns regarding EPA's methods to evaluate costs and benefits of this proposed rule, including calculations of household affordability and other concerns discussed in more detail in comments to be provided by the American Water Works Association (AWWA).

EPA Response: The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. For the EPA's response to comments on the affordability analysis, please see section 13.10 in this *Response to Comments* document.

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-042897)

Cost:

MWWA believes that EPA has grossly underestimated the costs associated with compliance with the proposed rule. We believe the technical memorandum [FN21: WITAF 56 TECHNICAL MEMORANDUM, PFAS National Cost Model Report, B&V PROJECT NO. 409850w.awwa.org/Portals/0/AWWA/Government/2023030756BVFinalTechnicalMemoradum.pdf?ver=202303-14-102450-257] prepared by Black & Veatch on behalf of American Water Works Association (AWWA WITAF 56) is a more accurate depiction of the costs that will be incurred. For example, the most recent estimate by Black & Veatch suggests that the annualized costs of the rule could exceed $3.2 billion based on a PFOA and PFOS MCL of 4 ppt each.

EPA Response: Please see sections 13.3 and 13.3.3 of the EPA response in this *Response to Comments* document. The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043634)

ATTACHMENT 1:

Detailed Technical Comments

Detailed Technical Comments on the Proposed PFAS National Primary Drinking Water Regulation

May 26 2023

Attachment 1:

Detailed Technical Comments on the Proposed PFAS National Primary Drinking Water Regulation

May 26, 2023

1) Cost Benefit Analysis

1. The USPEA Economic Analysis (March 2023) significantly underestimated the cost impact of the proposed Rule on utilities. EPA costs are significantly less than the number presented in the independent analysis conducted by AWWA and cost estimates conducted for BWWB.

EPA Response: Please see section 13.3.3 in this *Response to Comments* document for the EPA's response regarding the EPA's estimates of national treatment costs and response to AWWA's B&V report. The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. While the EPA has considered the input from the AWWA report and other public comments about the EPA's estimated rule costs, the EPA does not think it accurate to describe the AWWA report as "independent." Please see the EPA response to comment Doc. #1841, SBC-044850 in section 5.1.3 in this *Response to Comments* document for further discussion.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043637)

C. There is no safety factor guidance offered by the proposed PFAS rule. Many utilities consider a safety factor with regards to MCLs as a critical piece of their strategic planning. If a safety factor is considered, it is possible that a greater number of utilities will necessitate PFAS treatment technology, potentially increasing national compliance costs. It is recommended that the USEPA consider, in its cost model, that utilities are likely to employ a safety factor and implement treatment at PFAS levels below the proposed MCLs.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document for the EPA's response to comments on the EPA's national cost estimates. Additionally, the EPA would like to clarify that as stated in Chapter 5 of the EA, the EPA does consider a margin of safety, and assumes all PWS installing treatment to comply with the rule will target finished water concentrations at 80 percent of the MCLs.

Massachusetts Water Resources Authority (Doc. #1645, SBC-043287)

e. EPA's Cost Model Underestimates the Cost of the Proposed Rule

EPA underestimates the cost of drinking water treatment to remove PFOA and PFOS. Cost models prepared for AWWA by Black & Veatch, as well as examples of previously built PFAS treatment systems differ significantly from EPA's model. EPA's benefit cost analysis must accurately evaluate the cost impact of the rule to make a sound decision on the appropriateness of the rule requirements. In Massachusetts alone, the Massachusetts Department of Environmental Protection (MassDEP) estimates that 29 percent of all community (COM) and non-transient non-community (NTNC) systems would be impacted by this proposed rulemaking. There are almost 1,600 COM and NTNC systems in Massachusetts; approximately 450 of these PWSs would need to install treatment under EPA's proposed rule. Massachusetts has committed $209 million in State Revolving Fund loans to fund 24 PFAS treatment projects. That means that

costs for the installation of PFAS treatment in Massachusetts alone could be $4 billion. The proposed rule also fails to fully consider the detrimental implications associated with additional electricity usage, carbon emissions, fuel consumption and disposal costs; these are added costs to rate payers and to the environment.

EPA Response: The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document regarding the AWWA B&V report and the EPA's estimates of national treatment costs for the final rule. The EPA notes that based on state occurrence data described in the *Occurrence Technical Support Document* (USEPA, 2024a), Massachusetts has one of the higher rates of PFAS occurrence compared to other states for which the EPA has state data. Furthermore, extrapolating from individual utilities or states' experience is not an appropriate method to estimate national costs. In addition, the comment lacks sufficient detail to compare these costs to the results of the EPA's WBS and SafeWater models. With respect to the commenter's suggestion that the rule consider implications associated with electricity use, carbon emissions, fuel consumption and disposal costs, please see section 13.11 of the EPA response in this *Response to Comments* document.

Savannah River Nuclear Solutions LLC (Doc. #1647, SBC-043327)

Comment 3

EPA's proposed cost model includes treatment equipment; however, it does not appear to adequately include the added costs of compliance, site developments, engineering, pilot-testing, etc. Costs incurred by publicly owned treatment systems with costs ultimately transferred to residents relying on these essential services.

EPA Response: Please seesections 13.3 and 13.3.3 of the EPA response in this *Response to Comments* document. The commenter is incorrect that the WBS models do not include costs for land, permits and pilot testing, equipment installation, process engineering and contractor's overhead and profit. The WBS models do include costs for land, permits and pilot testing, equipment installation, process engineering and contractor's overhead and profit; see Chapter 5 of the EA for more information.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045918)

F. EPA's models used in its cost assessment are flawed

EPA's models underestimate the costs of installed groundwater systems, surface water systems, GAC systems, reverse osmosis, or ion-exchange systems, and they do not come close to a comparable model by a major engineering firm that designs and installs PFAS treatment systems. One principal reason that EPA's models may deviate from reality is because they are outdated—they were developed from 2006 to 2012 [FN171: U.S. EPA, "Best Available Technologies and Small System Compliance Technologies for Per- and Polyfluoroalkyl Substances (PFAS) in

Drinking Water," February 2023.]. Another reason could be the lack of adequate independent peer review. EPA sought a three-person, letter peer review of the GAC model around 2006 and then made additional changes to the model that have not been peer reviewed [FN172: U.S. EPA, "Work Breakdown Structure-Based Cost Model for Granular Activated Carbon Drinking Water Treatment," February 2023.]. EPA states that the IX model received even less of a comprehensive review since reviewers did not review a complete model – more than 10 years ago [FN173: U.S. EPA, "Work Breakdown Structure-Based Cost Model for Ion Exchange Treatment of Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water," February 2023.]. EPA must use more up to date modeling and inputs in its cost estimates.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

PFAS Regulatory Coalition (Doc. #1761, SBC6081)

1. EPA needs to provide more information as to several aspects of its cost analysis.

We have a number of questions and comments concerning EPA's compliance cost analysis, which are set forth below.

a) Did EPA consider the costs for installing new or expanded public water systems (PWS)? In EPA's cost/benefit model, the Agency includes the costs of monitoring/ compliance/treatment for PWS and non-community, non-transient water systems (NCNTWS) but it does not include any review of the potential compliance costs for new or expanding systems. This should include consideration of situations where, in response to PFAS concerns, municipal water supplies are being extended to rural areas that primarily had relied on individual drinking water wells. For example, centralization is part of the Biden Administration's strategy for addressing PFAS in drinking water and the Bipartisan Infrastructure Law provides funding that can be used for such purposes. FACT SHEET: Biden-Harris Administration Combatting PFAS Pollution to Safeguard Clean Drinking Water for All Americans (June 15, 2022), available atw.whitehouse.gov/briefing-room/statements-releases/2022/06/15/fact-sheet-biden-harris-administration-combatting-pfas-pollution-tosafeguard-clean-drinking-water-for-all-americans/. OMB Circular A-4 requires agencies to include in its baseline consideration of the evolution of the impacted market. Circular A-4, at 15. At a minimum, EPA should conduct a sensitivity analysis to evaluate the impact of the capital investments as well as the ongoing operation/maintenance costs for new and expanded systems, as well as increased treatment costs due to increased volumes. These costs will likely be significant – millions or tens of millions of dollars per facility, depending on the size of the system. EPA must include an analysis of these costs – and the benefits - at the different levels of proposed MCLs (4 ppt, 5 ppt, 10 ppt), since the level chosen could greatly affect the scope of any new or expanded system and the related costs.

EPA Response: Please see section 13.3 of the EPA response in this *Response to Comments* document. The EPA included in its cost analysis non-treatment options, such as new sources of water including regionalization. The costs of these non-treatment options were

included in the cost of the rule. The EPA disagrees that it should consider the cost of system expansion to serve new customers as a cost of the rule when the expansion is not required under the rule.

American Water Works Company Inc. (Doc. #1608, SBC-044001)

Further, the U.S. EPA's reporting of only annualized cost makes it very difficult to compare to more typical utility metrics. American Water recommends that the U.S. EPA's cost analysis provide a simple comparison of total capital cost for facilities in each capacity range, as well as a "cost per million gallons" of water treated. This will facilitate more direct comparison to the cost metrics that utilities typically utilize for rate impact analyses.

According to the backup document entitled "Economic Analysis for the Proposed PFAS NPDWR (EPA822-P-23-001)" available through the U.S. EPA's website, almost 3,500 individual cost equations were developed using the U.S. EPA's Work Breakdown Structure Cost Model to derive the estimated cost impact. Although the U.S. EPA provides copious written documentation on the methodologies used, it is difficult to understand how the U.S. EPA converted the combined capital and operating costs for the estimated 3,400-6,300 systems it projects may be impacted by the proposed rule into an annual cost of $772 million to $1.20 billion. This total represents an average of $120K to $350K per year per system based on this range of costs and systems, but $11 - $12 per person per year based on the 70 to 94 million people referenced as being affected in Section VI.F in the Supplementary Information section of the draft rule. Assuming there are approximately three people per household, this means the average annual customer bill impact would be less than $40 per household. By comparison, Table 22 reports the annual cost per household could range between $121 and $727 depending on system size and whether GAC or AIX is the technology selected. It is difficult to understand the basis for the total cost annual cost of $772 million to $1.20 billion when expressed this way.

EPA Response: Please see sections 13.3 and 13.3.3 of the EPA response in this *Response to Comments* document. With regard to presentation of costs in the EA, the EPA presents results as annualized national and system level costs in order to readily compare results to the quantified national benefits of the rule. Please see the EPA response to comment Doc. #1738, SBC-046008 in section 5.1.3 in this *Response to Comments* document, which includes WBS results presented in dollars per mgd. Additionally, the EPA provided two tables of household costs. The first includes all households that are served by CWSs. The second only included households that are served by CWSs that exceed one or more MCLs and must take action to comply with the rule. This information was provided to increase transparency of the cost impacts of the rule. However, not all compliance costs are attributable to residential customers as most water utilities also serve commercial and industrial customers. Therefore, to calculate household costs for a PWS, the EPA first calculates the cost of compliance per gallon of water produced. Then, to calculate household costs the EPA multiplies the cost per gallon by the average annual household water consumption.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045914)

D. EPA has not appropriately considered costs and implications for NTNCWSs

EPA's proposed rule will impact over 17,000 NTNCWSs that EPA intends to hold to the same regulatory requirements, including monitoring, sampling, and compliance, as community water systems (CWS). EPA recognizes that 99 percent of all NTNCWSs serve 3,300 or fewer people, with only two NTNCWSs serving more than 50,000 people [FN159: See EPA Economic Analysis of the Proposed National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances, 2023, at page 4-7 and Table 4-3.]. Given the small size of the NTNCWSs and the costly monitoring and treatment that will be required, relative compliance costs will be greatly increased under this proposed rule. In fact, in some rural NTNCWS that serve remote industrial or other needs, the costs could threaten the viability of these systems and the users that depend on them. Additionally, EPA's assessment does not consider the amount of water used by NTNCWSs or the potential treatment costs. NTNCWSs are a diverse group, including agricultural operations, industrial facilities, and many other businesses, which may use water far in excess of what may be expected based on the number of personnel each NTNCWS serves. Thus, any analysis of the potential cost impacts for treatment must be based on the volume of water needed to be treated, not merely the number of people served. The cost of treatment for many of these locations may far exceed the treatment to be expected based solely on the number of ratepayers.

Yet, EPA chose not to specifically analyze the proposed rule's economic impact on NTNCWSs [Fn160: Id. at 9-10.] and instead, based on a 2008 EPA Assessment, placed the cost of SDWA compliance at less than 1 percent of NTNCWS revenue [Fn161: Id. at 9-10.]. And EPA assumes, with no supporting data, that the rise in compliance costs for the NTNCWSs will be no more than an additional 1 percent [Fn162: Id. at 9-10.]. EPA's choice to forego actual analysis of impacts to the smallest systems is inappropriate. Detailed analysis on the impacts to NTNCWSs should be conducted to inform the cost/benefit analysis. For example, treating PFAS with GAC at the low levels proposed is much more costly than current treatment for currently regulated contaminants, and a 2008 study is not a reliable indicator of future costs. Lack of both actual data on occurrence in these systems and reliable information on cost of compliance makes finalizing the MCL as to NTNCWSs too uncertain.

EPA Response: Please see section 13.3.3 of the EPA response in this *Response to Comments* document. The EPA disagrees that the agency has not analyzed the impacts of the PFAS NPDWR on NTNCWS. The EPA has used both "actual data on occurrence" at NTNCWSs from UCMR 3 and state data, as well as "reliable information on costs" to NTNCWSs using the WBS treatment cost models to assess the impact of the rule on NTNCWSs. As the EPA stated in the proposal, the EPA lacks information on the volume of water produced or revenues of NTNCWS, therefore the agency does not take the same approach used for CWSs in the Significant Economic Impact on a Substantial Number of Small Entities (SISNOSE) screening analysis where costs are compared to 1 and 3 percent of revenues. Instead, the EPA used the best

available data, the EPA's Assessment of the Vulnerability of Noncommunity Water Systems to SDWA Cost Increases (USEPA, 1998), which showed that NTNCWSs are less vulnerable to SDWA related increases than a typical CWS. The EPA proceeded with the SBAR Panel process, for more information please see section XIII.C of the FRN.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046019)

Cost Estimates

EPA Cost Estimates

The analysis then analyzes EPA's cost estimates at system size levels. To estimate a combined annualized cost per CWS estimate across both water source types, the following approach is employed. First, using the CWS inventory values by water source and system size, the analysis estimates, for each system size category, the percentage of total systems that rely on GW and those that rely on SW (see Table 11). These percentages are applied to EPA's estimated mean annualized cost per CWS and water source.

Table 11: CWS ratios

[Table 11: see docket ID EPA-HQ-OW-2022-0114-1738]

[FN107: U.S. Environmental Protection Agency, 4–7; U.S. Environmental Protection Agency, "SDWIS Federal Reporting Services Fourth Quarter 2021 Dataset."]

[FN108: U.S. Environmental Protection Agency, "Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation Appendices," March 2023, tbl. C–9.]

[FN109: EPA does not present average or specific costs for systems >1 M. EPA identified 25 PWSs serving >1M people based on SDWIS/Fed estimates. Rather than model treatment costs using the MCMC model PFAS values, UCMR3 data & system consumer confidence reports are used to obtain entry point PFAS values. U.S. Environmental Protection Agency, app. N.1.]

Black and Veatch Cost Estimates

Black and Veatch (B&V) recently developed a national cost estimate for water systems to remove PFOA and PFOS from drinking water and comply with a proposed NPDWR using cost data and design methodology to capture accurate system-level cost estimates for drinking water treatment [FN110: Black & Veatch, "PFAS National Cost Model Report."]

Relying on B&V's cost estimates for systems presents two main advantages. First, it relies on recent data inputs, overcoming the dollar year limitation of EPA's EA discussed earlier in the report. Producer prices have risen as a result of supply shortages, global trade disruptions, and financial stimulus for the economy during the pandemic. Thus, B&V's analysis is more consistent with current conditions. The second advantage to using B&V's cost estimates is that

the inputs and results are based on more recent engineering experience with building and designing treatment systems:

The spreadsheet tool developed to perform this task accepts inputs for individual or combined target effluent levels for the six PFAS compounds represented in the database. After both occurrence data and potential regulatory levels are input, Visual Basic scripts within Excel may be initiated by a user to run a Monte Carlo analysis and generate a 10th percentile, 90th percentile, and most probable costs for the capital, operations and maintenance (O&M), and life-cycle costs for a typical entry point to the distribution system (EPTDS) for each PWS in the database. For each system, the tool selects the treatment technology with the lowest life-cycle cost [FN111: Black & Veatch, 14.].

Moreover, the capital costs for a CWS are based on the design flow per entry point to the distribution system (EPTDS) [FN112: Black & Veatch, 20.]. The design flow was used for capital cost estimates since equipment should be sized for peak treatment flow rates. Costs were independently calculated for IX, GAC vessels, GAC basins, and reverse osmosis (RO). Capital costs generated for individual systems represent a Class 5 Association for the Advancement of Cost Engineering (AACE) estimate, at approximately one to two percent maturity level of deliverable definition.

As shown by the expert analysis by a water sector engineering firm, EPA's cost models substantially underestimate the installation and operating costs of PFAS treatment systems. While EPA's cost estimates range from $16,000 to $3.2 M, B&V's estimates are between $250,000 and $11 million [FN113: U.S. Environmental Protection Agency, "Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation Appendices," tbl. C–9; Black & Veatch, "PFAS National Cost Model Report," tbl. A-1.]. As shown in Table 12, B&V's estimates are between four and 16 times larger than EPA's estimates for the same system size.

These ratio differences are stark. Assuming 100 gallons of water used daily per person and based on average population served by CWS size, we estimate total annual gallons per CWS. We compare this to the annualized cost per CWS using both EPA and B&V estimates and include the results in Table 12. For the smallest systems serving populations <100 people, the additional annual cost per thousand gallons of water as a result of EPA's proposed rule is approximately $110 based on B&V's cost estimates, compared to $7.1/1,000 gallons/year based on EPA's cost estimates.

Table 12: Annualized Cost per CWSs that Treat or Change Water Source: Comparison between EPA's and B&V's Estimates

[Table 12: see docket ID EPA-HQ-OW-2022-0114-1738]

Annualized Treatment Costs

To calculate total annual treatment cost for the proposed rule, the analysis multiplies the cost estimates from B&V by the estimated number of systems requiring treatment from EPA's

affected population estimate. Table 13 summarizes the estimated annualized treatment costs by CWS size for systems that will have to install treatment under EPA's proposed rule. Treatment costs are greatest for systems serving between 10,000 and 50,000 people ($2.4 billion) and those serving between 100,000 and 1 million people ($1.4 billion). Nationally, across all 4,400 estimated affected systems, costs are estimated at $6.4 billion each year.

Table 13: National Annual Treatment Cost by CWS Size for Affected Systems

[Table 13: see docket ID EPA-HQ-OW-2022-0114-1738]

EPA Response: The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. The EPA disagrees that there are "two main advantages" to relying on the B&V estimates. First, the EPA has updated the dollar year in the WBS cost curves to 2022 dollars for the final rule, removing commenter's objection to using 2020 dollars in the WBS models (the most recent values/indices available when the EPA developed the proposed rule and at the time of rule proposal: please see section 13.3.3 of the EPA response in this *Response to Comments* document for further discussion). Secondly, the EPA's unit cost estimates are based on the best available cost data and rely on recent information from treatment technology vendors; for more information, please see section 13.3.3 of the EPA response in this *Response to Comments* document. Finally, the EPA strongly disagrees with this commenter's overall statements about the costs of the rule nationally (i.e., costs of $6.4 billion dollars a year) as discussed in the Policy Navigation Group (PNG) report. The PNG report claims to rely on the B&V annual treatment cost per affected PWS. However, the EPA's review of the PNG report finds substantial discrepancies between the annual treatment costs cited and the values presented in the B&V report that indicate the PNG report may produce unreliable estimates. As shown in the table below, the EPA has calculated the average annual cost per affected PWS based on the B&V report. For most system size categories, the annual treatment cost per affected PWS used by PNG is significantly greater than the values presented in the B&V study. The PNG provides no documentation or other information that explains where these extensive cost increases originate. Therefore, from the information provided in the commenter's letter, it's not clear how the PNG reportedly used B&V cost values and arrived a national cost estimate more than double that of the B&V study, which concludes national treatment costs of the NPDWR would be 2.5 billion to 3.2 billion at the 3 and 7 percent discount rates respectively.

A	B	C	D= (B/C)	E
PWS Size Category	**AWWA B&V Report**	**AWWA B&V Study**	**Calculated B&V cost per PWS**	**AMWA PNG Report**
	Table A-5	**Tables A-1 and A2**		**Table 13**
	Total Annual Cost (7% DR)	**Affected PWSs**	**Annual Cost (7% DR)**	**B&V costs**
<100	$169,442,000	2270	$74,644	$250,000

A	B	C	D= (B/C)	E
PWS Size Category	**AWWA B&V Report**	**AWWA B&V Study**	**Calculated B&V cost per PWS**	**AMWA PNG Report**
	Table A-5	**Tables A-1 and A2**		**Table 13**
	Total Annual Cost (7% DR)	**Affected PWSs**	**Annual Cost (7% DR)**	**B&V costs**
101-500	$387,667,000	2540	$152,625	$380,000
501-1,000	$200,989,000	599	$335,541	$500,000
1,001-3,300	$489,646,000	868	$564,108	$580,000
3,301-10,000	$518,888,000	779	$666,095	$1,200,000
10,001-50,000	$381,145,000	254	$1,500,571	$2,700,000
50,001-100,000	$355,852,000	64	$5,560,188	$4,800,000
100–001–- 1,000,000	$454,900,000	71	$6,407,042	$11,000,000
Greater than 1M	$272,704,000	4	$68,176,000	$51,000,000

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046029)

3. CONCLUSIONS

This report assessed EPA's approach to estimate the social benefits and costs of its proposed rule to federal requirements for regulatory analysis and best practices in the field. We determine that EPA's cost models substantially underestimate the installation and O&M costs of PFAS treatment systems. We provide data from experts in the water sector engineering field to show how substantial the costs of EPA's proposed rule will actually be. We also provide evidence from actual cost data from AMWA members to show the extent of EPA's underestimation. EPA also fails to account for other social costs such as additional costs from water rate increases and the non-market costs of greater greenhouse gas emissions.

EPA Response: The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document. The EPA also disagrees with the Association of Metropolitan Water Agencies' (AMWA's) representation of national costs associated with the rule, please see the EPA response to comment Doc. #1738, SBC-046019 and SBC-046008 in section 13.3.3 in this *Response to Comments* document for more information. For the EPA's response to comments on greenhouse gas emissions associated with the rule, please see section 13.11 in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046008)

2. Evaluation of EPA's Benefit-Cost Methodologies Costs

While there are numerous individual problems with EPA's cost models, the sum of these issues is more important than the laundry list of flaws. As the saying goes, "all models are wrong; some models are useful." The fundamental problem with EPA's model is that it is not useful – it fails to predict actual, installed treatment systems' costs by a substantial margin. EPA's models underestimate the costs of installed groundwater systems, surface water systems, granular activated carbon (GAC) systems, reverse osmosis, or ion-exchange systems. It does not come close to a comparable model by a major engineering firm that designs and installs PFAS treatment systems.

One principal reason that EPA's models may deviate from reality may be their vintage. As EPA states, the models were developed from 2006 to 2012 [FN13: U.S. Environmental Protection Agency, "Best Available Technologies and Small System Compliance Technologies for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water," February 2023.]. Another reason could be the lack of adequate independent peer review. According to the background documents, EPA sought a three-person, letter peer review of the GAC model around 2006 and then made additional changes to the model that have not been peer reviewed [FN14: U.S. Environmental Protection Agency, "Work Breakdown Structure-Based Cost Model for Granular Activated Carbon Drinking Water Treatment," February 2023.]. EPA states that the IX model received even less of a comprehensive review since reviewers did not review a complete model – more than 10 years ago [FN15: U.S. Environmental Protection Agency, "Work Breakdown Structure-Based Cost Model for Ion Exchange Treatment of Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water," February 2023.].

The AMWA and the AWWA surveyed its members to obtain recent cost data on installed PFAS treatment systems at drinking water treatment plants. Figure 1 plots the ratio of capital costs per the treatment system capacity (in millions of gallons per day) reported by 60 systems. Figure 1 also provides EPA's estimated capital costs for the comparable treatment technique and system size. As shown, EPA's values are most often below reported capital costs. On average across the 60 systems, EPA's estimate is 2.9 times lower than reported values.

Figure 1: Comparison of the Capital Costs of Actual Installed Treatment Systems with EPA Model Results ($/MGD)

[Figure 1: see docket ID EPA-HQ-OW-2022-0114-1738]

The discrepancy is greater for small treatment systems, the ones most likely to be installed due to this regulatory action. Figure 2 shows the detail of Figure 1 for systems below 50 MGD. For systems under 1 MGD, the average ratio between actual system capital expenditures and EPA's is 5.1. For systems under 2 MGD, EPA's models underestimate actual capital expenditures by a factor of 3.6.

Figure 2: Comparison of the Capital Costs of Actual Installed Treatment Systems with EPA Model Results for Systems Below 50 MGD ($/MGD)

[Figure 2: see docket ID EPA-HQ-OW-2022-0114-1738]

EPA also omits other, non-market social costs. Consuming real resources like activated carbon, electricity, and transportation services have costs that are not captured in their market price. EPA strives to reduce the adverse human health and environmental effects of the non-market social costs of pollution. By requiring treatment for certain PFAS, EPA's rule will lead to increased pollution from transportation, electricity generation, and other construction and operations activity. While the social costs of this additional pollution may be justified by the rule's benefits, EPA must estimate these social costs to demonstrate this claim.

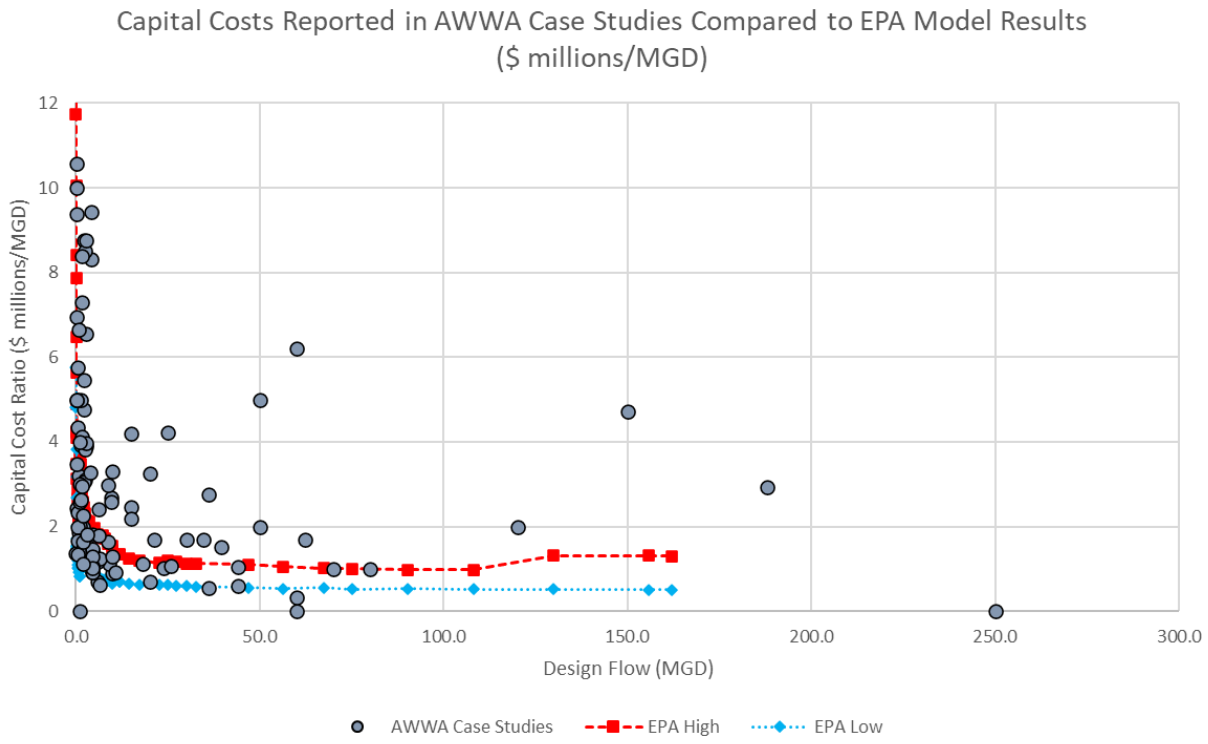
EPA Response: Regarding the commenter's assertion that the EPA's models are outdated, please see section 13.3.3 of the EPA response in this *Response to Comments* document. For the final rulemaking, the EPA included an analysis of the costs of greenhouse gases. Please see section 13.11 of the EPA response in this *Response to Comments* document.

The commenter's Figures 1 and 2 purport to compare the EPA's cost estimates with cost data from a survey conducted by the commenter and the AWWA. However, the EPA observed several issues with the commenter's figures. The figure titles indicate the data shown are in units of dollars per million gallons per day treatment capacity ($/MGD). The y-axis of Figure 1 is labeled in units of dollars ($). Based on the range of values shown, it appears the data are actually in units of million dollars per million gallons per day treatment capacity ($ millions/MGD). Also, the commenter states that "…Figure 2 shows the detail of Figure 1 for systems below 50 MGD." The data for "actual installed treatment systems" shown in Figure 2 are clearly not the same data shown in Figure 1. Based on the shape of the curve and lack of scatter in the data, Figure 2 appears to show the results of a parametric cost model, not the capital costs of actual installed treatment system.

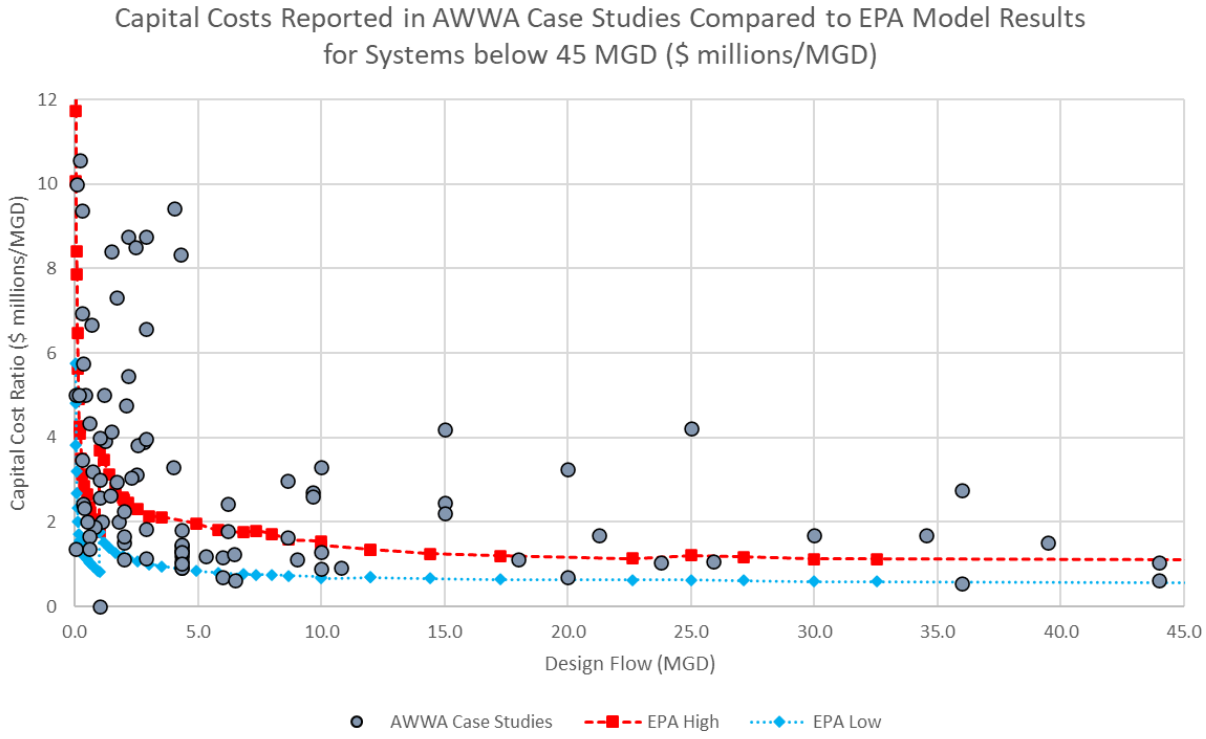
The commenter did not provide the underlying data supporting Figures 1 and 2, so it is not possible to conclusively resolve these discrepancies. The commenter also did not provide details on how they obtained the "EPA model results" shown in Figures 1 and 2. However, it appears that the figures misrepresent the EPA's cost estimates. Specifically, given that there is only one EPA data point for each "actual" data point, the figures clearly do not consider the full range of cost curves used to estimate national costs and presented in Appendix B of the EPA's *Technologies and Costs* document (USEPA, 2024d). For the final rule, the EPA updated its equipment costs to 2022 dollars (which are the most recent data available), collected new vendor price quotes for cost driver equipment components, and made several other adjustments to WBS model assumptions, as discussed in section 13.3.3. Considering all these factors, the EPA disagrees with the commenters assertion that the EPA's estimates are 2.9 to 5.1 times lower than actual.

The figures below recreate the commenter's Figures 1 and 2, attempting to correct for the issues identified above. Because the commenter did not provide their underlying data, the recreated figures use the data provided in public comments from AWWA (Doc. #1759, SBC-045612). The AWWA data set appears to be similar to the commenter's data set but is not identical. The EPA cost data shown in the recreated figures reflect the underlying WBS model outputs used to

generate the high- and low-cost curves for GAC and ion exchange.[9] Some of the AWWA case studies fall within the range of costs bounded by the EPA's updated cost curves. Other case studies exceed the EPA's high-cost curve. However, the commenter did not include information to confirm that (1) all the case study costs would be directly associated with PFAS treatment, as opposed to other infrastructure improvements, and (2) that design parameters (e.g., empty bed contact time) for the case study facilities would be similar to the typical values assumed in the EPA's estimate. Again, after recreating the figures presented by this commenter, the EPA disagrees with the commenter's overall conclusions about the EPA's costs estimates in comparison to the commenter's information.



[9] The EPA's WBS have a maximum design flow of 162 MGD. The EPA data points show a shift in capital cost at 1 MGD, which corresponds to the change in model assumptions that the EPA used to reflect the use of package treatment systems below this threshold.



Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046027)

The B&V report provides estimated capital expenditure (CAPEX). The analysis subtracts the average O&M costs per system from the annualized per-system cost and multiplies the remainder by the estimated number of systems [FN134: Black & Veatch, "PFAS National Cost Model Report," tbls. 6–3.]. Capital cost is lowest among smaller systems, ranging between $150 and $370 million per year, and highest among systems serving 10,000 to 50,000 and 100,000 to 1,000,000 people ($290 million to $2.1 million).

EPA Response: The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045987)

Section 8.2: Assessment of EPA's cost estimates

EPA's analysis grossly underestimates the costs of the rule in several ways, including not accounting for inflation and the social cost of carbon. First, EPA prepared its cost estimates before the full effect of inflation and supply chain constraints took hold. As a result, water utilities, like other businesses and consumers, continue to see major price increases. Inflation and supply chain issues continue to drastically impact the American economy, including the water

sector. AMWA members have reported price increases from 20-120% (Attachment 2), with water supply chemicals seeing the highest increases. GAC costs also continue to rise.

A June 2022 US News and World Report article, Inflation Taking the Bite out of New Infrastructure Project [FN21: Associated Press. (2022, June 1). Inflation taking bite out of new infrastructure projects. https://www.usnews.com/news/business/articles/2022-06-19/inflation-taking-bite-out-of-new-infrastructure-projects], stated that construction project costs are at least 25-30% higher than in 2021. The article specifically cited the costs of ductile iron pipes and fittings at 25% higher than the previous year. EPA estimated its cost projections in 2021 dollars, so at a bare minimum, construction costs are likely 25-30% higher than agency estimates. Additionally, these estimates using 2021 data will not take into account potentially higher prices, driven by increased demand as a result of this rule promulgation.

In addition, energy costs are also on the rise, as seen in Attachment 2. In its proposal, EPA neglected to include the social costs of carbon – both the benefits and disbenefits – to calculate the economic impacts associated with the rise in greenhouse gas emissions due to the implementation of treatment technologies to address PFAS at drinking water utilities. GAC, the treatment technology many utilities will install to meet this NPDWR, is also typically derived from bituminous coal and reactivated in multiple hearth furnaces operating at high temperatures using fossil-fuel energy. In addition, transport to and from the reactivation facility is done over long distances with diesel trucks. EPA must take these costs into account to make accurate estimations to influence informed decision-making.

AMWA would like to highlight a study prepared for the American Water Works Association (AWWA) by Black & Veatch that assesses more accurate costs of this proposed rule implementation using current real-world data [FN22: AWWA. (2023 March 7). WITAF 56 Technical Memorandum. PFAS National Cost Model Report. https://www.awwa.org/Portals/0/AWWA/Government/2023030756BVFinalTechnicalMemoradum.pdf?ver=2023-03-14-102450-257]. While EPA's estimated range of annualized costs is around $770 million to $1.2 billion, this Black & Veatch study uses real-world data to assess the economic impact of this proposal, finding that the costs of this rulemaking could exceed $3.2 billion annually.

Section 8.3: Methodology of cost analysis

PNG's analysis uses cost data from surveys taken of AMWA and AWWA's members in March-April 2023. Information from 60 systems was incorporated into the analysis to further illustrate the real-world costs associated with PFAS treatment. Information was also included to show other social costs of rule implementation. As reported in the PNG analysis, "AMWA and the AWWA surveyed its members to obtain recent cost data on installed PFAS treatment systems at drinking water treatment plants. Figure 1 plots the ratio of capital costs per the treatment system capacity (in millions of gallons per day) reported by 60 systems. Figure 1 also provides EPA's estimated capital costs for the comparable treatment technique and system size. As shown, EPA's

values are most often below reported capital costs. On average across the 60 systems, EPA's estimate is 2.9 times lower than reported values." AMWA has copied this figure below.

PNG's analysis shows the discrepancy between actual costs and EPA's estimate is greater for small treatment systems, the ones most likely to be installed due to this regulatory action. For systems under 1 MGD, the average ratio between actual system capital expenditures and EPA's is 5.1. For systems under 2 MGD, EPA's models underestimate actual capital expenditures by a factor of 3.6.

Figure 1 (PNG, 2023): Comparison of the Capital Costs of Actual Installed Treatment Systems with EPA Model Results ($/MGD)

[Figure 1: see docket ID EPA-HQ-OW-2022-0114-1738]

Below is the figure shown above reframed for systems with a design capacity from 0-45 MGD.

[Figure 2: see docket ID EPA-HQ-OW-2022-0114-1738]

As stated in PNG's report, "EPA also omits other, non-market social costs. Consuming real resources like activated carbon, electricity, and transportation services have costs that are not captured in their market price. EPA strives to reduce the adverse human health and environmental effects of the non-market social costs of pollution. By requiring treatment for certain PFAS, EPA's rule will lead to increased pollution from transportation, electricity generation, and other construction and operations activity. While the social costs of this additional pollution may be justified by the rule's benefits, EPA must estimate these social costs to demonstrate this claim."

Section 8.4 Need to assess costs of greenhouse gases/social cost of carbon

While EPA did not assess the costs of greenhouse gasses in this proposal, the agency has performed this analysis for other rulemakings - specifically its proposed rule for the New Source Performance Standards for the Synthetic Organic Chemical Manufacturing Industry and National Emission Standards for Hazardous Air Pollutants for the Synthetic Organic Chemical Manufacturing Industry and Group I and Group II polymers and Resins Industry (the Hazardous Organics NESHAP, or HON) [FN 23: EPA. (2023, April 25). 88 FR 25080. https://www.federalregister.gov/documents/2023/04/25/2023-07188/new-source-performance-standards-for-the-synthetic-organic-chemical-manufacturing-industry-and]. In the Regulatory Impact Analysis (RIA) [FN24: EPA. (2023, March). Regulatory impact analysis. https://www.epa.gov/system/files/documents/2023-04/Proposed_HON_RIA_final_2023-03.pdf] on the proposed rule, EPA included the social cost of carbon for the electricity required to operate the air pollution controls in its proposal.

Additionally, in EPA's 2023 Proposed Rule: New Source Performance Standards for Greenhouse Gas Emissions from New, Modified, and Reconstructed Fossil Fuel-Fired Electric Generating Units (EGUs), the RIA includes an appendix with economy-wide modeling results [FN25: EPA. (2023, May 5). https://www.epa.gov/system/files/documents/2023-05/FRL-8536-02-

OAR%20111EGU%20NPRM%2020230504_Admin.pdf]. EPA finds that including these additional costs for the social cost of carbon increases the social cost of the rule by 35 percent. We note that EPA's estimate of the engineering costs for this proposal is roughly the same as EPA's estimate for the PFAS MCL.

EPA should do the same analysis for the PFAS MCL that it has done in these other rulemakings and reflect these additional costs and benefits in its analysis. This will allow EPA to make a well-informed decision that will take substantial costs into consideration while still presenting the opportunity for meaningful health risk reduction.

EPA Response: Regarding the commenter's statements regarding rising construction prices, the effects of rising inflation, and the EPA's alleged underestimates of costs please see section 13.3.3 of the EPA response in this *Response to Comments* document. The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. Please see the EPA response to comment Doc. #1738, SBC-046008 in section 13.3.3 in this *Response to Comments* document regarding AMWA/PNG's presentation of results and conclusions based on survey data. Further, for the final rulemaking, the EPA included an analysis of the costs of greenhouse gases. Please see section 13.11 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046125)

2. EPA uses an equally thorough, data-driven approach for estimating what treatment and non-treatment technologies would be adopted to comply with the rule.

EPA recognizes that there would likely be variation in what technologies PWSs adopt to comply with the proposed rule, and as such they did not simply assume all PWSs with PFAS levels above the proposed MCLs would adopt the seemingly cheapest technology. Instead, based on system and source water-specific parameters, EPA estimated systems' choices of treatment and non-treatment technologies based on data of past technology adoption choices. More specifically, a decision tree was developed to determine what treatment technologies or non-treatment approaches are feasible based on entry point, water source, and system characteristics, as well as the regulatory option being considered. Then among the feasible options, the estimated compliance approach is randomly chosen for each PWS based on the probability distribution of recently observed choices made by PWSs. In other words, holding all system and water-source characteristics constant, if a certain technology has tended to be chosen more often in practice, then that increased likelihood is accounted for in EPA's technology adoption models and subsequent cost estimates.

EPA then developed over 3,500 individual cost equations to estimate the costs of the chosen technologies based on key factors, including the corresponding technology bed life (i.e., the length of time that a technology can maintain a target pollutant removal percentage), water source, flow, etc.

Overall, this detailed, data-driven approach to estimate treatment and non-treatment approaches towards compliance, and the subsequent costs, strengthens the analysis because the cost estimates are based on empirical evidence (i.e., observed choices made by PWSs), rather than theoretical assumptions and subjective best judgements. The randomization of PWS compliance choices and subsequent costs based on the observed distribution of PWS adoption choices is layered on top of the Monte Carlo simulations discussed in comment #1, and thus further exhibits all the advantages of such an approach that are discussed above.

EPA Response: The EPA agrees with the commenter's characterization of the estimation of treatment and non-treatment costs as data-driven. Please see sections 13.3.3 and 13.3.6 of the EPA response in this *Response to Comments* document.

Del-Co Water Company, Inc. (Doc. #1744, SBC-043619)

III. Del- Co Water average capital cost to meet the proposed PFOA MCL is approximately

$67 million for just one (of four) Water Treatment Plants

Del-Co commissioned a preliminary engineering study to retrofit its largest WTP and the capital costs for completion came in at an average of $67 million. Further, it is anticipated that Del-Co will need to upgrade a second WTP, which would likely cost $10 – $20 million. These estimates do not include annual operational costs, nor do they include inflationary expenses. Taking into account the information in Section II, Del-Co questions whether this funding could be allocated to other priorities (e.g., replacing lead service lines, upgrading cybersecurity, replacing aging infrastructure, and assuring sustainable water supplies) which would provide greater benefit, risk reduction, and public health protection to the ratepayers.

EPA Response: Please see response section 13.3.3 of the EPA response in this *Response to Comments* document. Additionally, see the EPA response to comment Doc. #1744, SBC-043620 in section 13.3.3 in this *Response to Comments* document. The EPA has reaffirmed the Administrator's determination at proposal that the benefits of the rule justify the costs; see response section 13.8 of the EPA response in this Response to Comments document for more information.

13.3.4 Water System Costs - Monitoring

Summary of Major Public Comments and EPA Responses

Commenters disagreed with the EPA's laboratory costs claiming that EPA Method 533 was more expensive than analyzing PFAS using EPA Method 537.1. The EPA used sample costs associated with Method 537.1 based on the assumption that, while both methods provide the required data to demonstrate compliance, water systems will select the least costly analytical method (which is Method 537.1). Two commenters incorrectly suggested that the cost of the field reagent blank (FRB) was not included in the EPA's monitoring cost calculations. For any samples that are above detection, the final rule requires the system to analyze the FRB samples collected at the

same time as the monitoring sample. The EPA included the costs associated with analyzing the FRB when samples are above detection in the EA for both the proposed and final rule.

Some commenters disagreed with the EPA's cost per sample for EPA Method 533 and EPA Method 537.1. Specifically, one commenter noted that "This difference in laboratory analysis costs is significant and may contribute to unrealistically low-cost assumptions." Some of these commenters provided information on costs per sample such as "$350 - $500 per sample," "$525+ per sample," "500 per sample, with an average being about $450" and "$300-$500/sample." These commenters stated that the costs the EPA used in the proposal were too low. One commenter stated they believe the EPA's sample costs in the proposal "…are generally on par with current pricing for large commercial labs." Another commenter noted that costs were "roughly $300 per sample." To support the analysis for the proposed and final rule, the EPA used the cost estimates developed in the UCMR5 rule and adjusted the costs to $2022 dollars for the final rule. To estimate sampling costs under UCMR5, the EPA determined the average analytical cost for assessment monitoring by averaging estimates provided by four drinking water laboratories (USEPA, 2022a). The EPA believes this is the most representative dataset to inform the sampling costs estimates of the rule.

For the national cost analysis, the EPA assumes that systems with either UCMR 5 data or monitoring data in the State PFAS Database (see Chapter 5 in USEPA, 2024b) will not conduct the initial year of monitoring as allowed by the final rule. One commenter stated that they believed it is not appropriate to exclude the sampling costs for water systems participating in UCMR5 from the analysis even if the EPA deems they can use these data for rule compliance. This commenter stated "[w]hile all systems serving more than 3,300 are currently already required to monitor for PFAS in accordance with UCMR 5, many of these systems may need to conduct additional monitoring to comply with the rule and to meet the timeline for compliance set by EPA." The EPA disagrees with the commenters assertion that many water systems that participate in UCMR 5 will need to conduct additional monitoring to comply with the rule. Though large groundwater systems will be required to collect two additional samples to supplement their UCMR 5 monitoring and meet the required number of samples under the final rule initial monitoring requirements, for these and all other water systems conducting UCMR 5 monitoring, the EPA has clearly specified in the rule that all data collected in the UCMR5 effort can satisfy initial monitoring requirements and expects the majority of these water systems (approximately 85 percent) will have all the data required. As a simplifying assumption for the cost analysis, the EPA assumes all systems serving a population of greater than 3,301 have UCMR 5 data and those with 3,300 or less do not. In the EA for the proposed rule, the EPA noted these simplifying assumptions may result in a small underestimate of initial monitoring costs for systems serving greater than 3,301 persons. The EPA recognizes this is, in part, because both the large (greater than 10K) groundwater systems under UCMR 5 will need to collect two additional samples under the PFAS NPDWR, and also because the systems that have existing state monitoring data may or may not have enough to fully satisfy their initial monitoring requirements (i.e., 2 or 4 samples). However, the EPA notes that it has likely overestimated monitoring costs for systems serving less than 3,300 as the EPA is aware of numerous states

which have led monitoring programs for some or all of their regulated systems of this size. Additionally, many small systems have had data collected by federal agencies (e.g., the EPA, DoD) as a result of other programs.

In the proposed rule, the EPA asked for public comment on the underlying assumptions that, under UCMR 5, individual water systems would be able to request the full release of data from the labs for use in determining their compliance monitoring frequency and that PWSs may be able to use these lab analyses to demonstrate a "below trigger level" concentration using the UCMR 5 analyses by following up with the lab for a more detailed results report. Some commenters expressed concern about acquiring data below the PQL. Under UCMR 5, individual water systems would be able to request the full release of data from the labs for use in determining their compliance monitoring frequency. PWSs may be able to use these lab analyses to demonstrate a "below trigger level" concentration using the UCMR 5 analyses by following up with the lab for a more detailed results report. For UCMR 5 purposes, laboratories analyzing UCMR 5 samples only report data at or above minimum reporting levels (MRLs) to the EPA; however, results for the Laboratory Reagent Blank (LRB), a required method quality control sample, must not exceed 1/3 the MRL. Additionally, laboratories may have PWS data below the PQL in its Laboratory Information Management System (LIMS), the software that manages commercial laboratory sample processing, analysis, and reporting. It is typically a matter of data reprocessing to retrieve those results. Several factors, such as the LIMS software itself, the abilities of the LIMS management team, and the laboratory pricing structure, will all dictate the likely cost. The agency has encouraged laboratories to extend this evaluation to samples, working with their PWS clients to accommodate PWS requests for data below the UCMR 5 MRLs (and final NPDWR PQLs), to potentially support the PWS's future determination of NPDWR monitoring frequency on a reduced monitoring schedule.

One commenter asserted that water systems would have to "pay twice" to acquire data below the PQL. The pricing that each laboratory would charge to retrieve that data for its client may differ significantly from one lab to another. However, the EPA notes that UCMR small systems contract labs, which also handle a large number of large systems' analysis, have provided feedback to the EPA that additional costs for the EPA to query results below the UCMR MRL would not be financially burdensome. The EPA cannot comment on the specific data provisions between each UCMR lab and their clients; however, based on labs that the EPA has surveyed, the EPA does not expect that it will be a common occurrence that labs will "pay twice for results" as suggested by the commenter. Additionally, this commenter stated they were told they would "need to perform an entirely separate sampling event due to QAQC considerations." The EPA disagrees with this assertion, and as stated above, the results are already available in the LIMS. This action would not require a "separate sampling" as the original analysis data would be used (i.e., no recollection, no re-analysis).

Some commenters expressed concern for small systems monitoring costs in particular. The EPA notes that as a mechanism to reduce the burden of the final rule requirements on small entities the EPA has promulgated compliance flexibilities for small CWSs serving 10,000 or fewer persons. These flexibilities include the use of previously collected PFAS monitoring data to

satisfy initial monitoring requirements, allowing reduced initial monitoring for small groundwater systems serving 10,000 or fewer, the addition of annual monitoring to the ongoing compliance monitoring framework, and modified rule trigger levels for reduced monitoring eligibility.

Individual Public Comments

COMM Water Department (Doc. #1577, SBC-042435)

May 30, 2023

Mr. Michael S. Regan, Administrator

U.S. Environmental Protection Agency

EPA Docket Center, OLEM Docket, Mail Code 28221T

1200 Pennsylvania Avenue, NW

Washington, DC 20460

RE: Docket ID No. EPA-HQ-OW-2022-0114 - National Primary Drinking Water Regulation Rulemaking for per- and polyfluoroalkyl substances (PFAS)

Dear Administrator Regan:

I am writing to provide comments on the Environmental Protection Agency's (EPA) proposed National Primary Drinking Water Regulation Rulemaking for per- and polyfluoroalkyl substances (PFAS). The drinking water sector fully supports efforts to expand verified public health protections, but EPA needs to consider the challenges associated with its proposed rulemaking and address the water sectors' implementation concerns before finalizing any standards.

I work for C.O.MM Water Department; we provide drinking water to 38,000 customers. I am a member of the Massachusetts Water Works Association; I am aware that they, and other water works organizations, are submitting more comprehensive comments. I would urge EPA to pay close attention to the points raised by these associations as they are comprised of individuals and companies with expertise in designing and operating Public Water Systems (PWS) and they have the best understanding of the challenges which will be associated with implementing any final rule EPA adopts. My major concerns are as follows:

• EPA has very much underestimated the costs to PWSs to comply with the proposed rule. We have had to increase the budget 20% to sample our twenty groundwater wells.

EPA Response: The EPA disagrees it underestimated monitoring costs. Please see section 13.3.4 of the EPA response in this *Response to Comments* document.

Alameda County Water District (ACWD) (Doc. #1595, SBC-042349)

ACWD is currently conducting PFAS monitoring using EPA Method 533 and has experienced costs for this analysis of up to $500 per sample, with an average being about $450. EPA's economic analysis assumes estimated costs of analysis using method 533 of $376 per sample. This difference in laboratory analysis costs is significant and may contribute to unrealistically low-cost assumptions. EPA should validate the cost of PFAS analysis and update the economic analysis as appropriate.

EPA Response: The EPA disagrees that it underestimated analytical monitoring costs. Please see section 13.3.4 of the EPA response in this *Response to Comments* document for discussion of how the EPA estimated analytical monitoring costs.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044091)

ASDWA recommends EPA address laboratory training and expanding capacity needs to ensure costs are considered as a part of the economic analysis in the final regulation.

The amount and variety of costs and resources needed to set up and certify laboratories and access supplies, to have laboratories analyze the water system PFAS samples, and to ensure accurate reporting for regulatory compliance will impact laboratories, primacy agencies, and water systems. ASDWA estimates a cost of $1 million to set up a laboratory, obtain certification, and prepare to analyze drinking water samples for PFAS using EPA Methods 537.1 and 533. This estimate includes the costs for PFAS-clean rooms, equipment, nitrogen, consumables, service agreements, staff, and more. In addition, laboratory infrastructure changes may be needed, such as plumbing nitrogen lines, running new electrical circuits, and ensuring adequate ventilation for new instruments. PFAS will be the first SDWA-regulated compounds to be analyzed using tandem mass spectrometers (LC/MS/MS) or triple quadrupole mass spectrometers (triple quads) that are very costly (from $400,000 -$700,000) and more difficult for laboratory staff to use.

Laboratories will incur additional costs and need training and resources to prepare for reporting sample results electronically to the state's data reporting system (e.g., SDWIS). Primacy agencies will also incur additional costs to develop templates, guidance, and SOPs for laboratory staff to ensure that water system violations are accurately calculated using the running annual average (RAA) for the new PFAS MCLs.

The water system costs for laboratories to analyze PFAS are expensive and increase significantly when laboratories run the field reagent blanks (FRBs). Laboratory costs for analyzing PFAS using EPA Method 533 are also more expensive than costs for analyzing PFAS using EPA Method 537.1.

EPA Response: Please see section 13.3.4 of the EPA response in this *Response to Comments* document. In response to the commenter's recommendation that the EPA should include the costs of establishing new laboratories and associated laboratory training costs in the EA for the final rule, the EPA disagrees that those costs should be estimated and included. The

sampling costs the EPA included in the cost analysis are derived from a set of current labs and reflect the market price at the time of the survey. New labs entering the market would likely be competing with currently operating labs that have the option to expand their services. Expanding labs will likely lower their unit sample costs given the potential for shared existing overhead like billing platforms/other systems in general, floor space, or trained personnel, therefore potential new labs could not charge significant per sample rates above the current labs in the market. The costs to larger water systems considering creating a new lab would be equal to or less than the market rate charged by commercial labs already in the market.

Nebraska Department of Environment and Energy (NDEE) (Doc. #1653, SBC-043211)

Additionally, the cost for operation of the system does not seem to account for the initial year of sampling that could well cost more than the installation of the POUs.

EPA Response: Please see section 13.3.4 of the EPA response in this *Response to Comments* document and Chapter 5 of the EA (USEPA, 2024b). The initial year sampling costs are included for all water systems.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044431)

Page 18731. Section XIII – HRRCA

EPA requests comment generally on its estimation of sampling costs. The Agency is also specifically requesting comment on the ability of systems to demonstrate they are reliably and consistently below 1.3 ppt for PFOA and PFOS and 0.33 ppt for PFAS regulated by the HI to qualify for reduced monitoring.

• EPAs use of trigger levels set at 1/3 the PQL increase the estimated cost of sampling while increasing variability in sampling data. Setting the trigger at ½ the PQL would increase the number of laboratories that can meet QA/QC levels bringing down the cost of sampling and provide better data for decision making. Washington supports using the EPA's suggested alternative trigger level of ½ the PQL. Currently laboratories are charging for both the PWS sample, and if there are detections, for testing the field reagent blank, effectively doubling the cost for PWSs with detections. It is unclear if EPA considered this in their cost estimates.

EPA Response: Please see section 13.3.4 of the EPA response in this *Response to Comments* document. In addition, in the final rule the EPA set the trigger level equal to ½ of the MCLs after considering public comments received. Please see the EPA response to comment Doc. #1692, SBC-044744 in section 13.3.4 in this *Response to Comments* document and section 8.8 of the EPA response in this *Response to Comments* document for further discussion of the trig level.

A. O. Smith Corporation (Doc. #1674, SBC-043697)

The Company does however have some concerns relative to current national laboratory capacity and the economic impacts the proposed PFAS NPDWS testing regime may have on testing costs, given supply and demand across a limited number of certified labs, as well as a shortage of seasoned and trained laboratory technicians. As the EPA points out in its analysis, the anticipated annual cost of sample testing across covered public water systems assumes a total annualized cost at $105,000,000 at a 3% discount rate and $109,000,000 at a 7% discount rate. [FN13: 88 FR 16672] From the Company's perspective, sample testing costs for its products – as well as the combined time to certify systems – will increase under the proposed MCL for PFOA and PFOS. Those costs will potentially increase further if broader laboratory capacity does not increase.

EPA Response: For the EPA's response to comments on laboratory capacity, please see section 8 in this *Response to Comments* document. The EPA disagrees that laboratory sampling costs will increase significantly as result of heightened demand created by the rule because, as discussed in more detail in section 13.3 of the EPA response in this *Response to Comments* document, the EPA believes there is or will be sufficient lab capacity to support the rule.

American Council of Independent Laboratories (ACIL) (Doc. #1692, SBC-044744)

7. Additional Quality Control and Associated Costs

Related to our comments on the lowered reporting limits needed to support reporting at or below the trigger value, we note that on page 18698, the Agency has estimated a price per sample of $375 for Method 533 and $302 for Method 537.1. These prices are likely to be an underestimate and may not reflect the actual differences between 537.1 and 533. In addition to inflation in the cost of reagents and labor, there are likely to be additional quality control, calibration, and other associated costs that arise from calibrating and reporting down to the trigger values. We strongly recommend that EPA clarify that, while it provided approximate monitoring costs, in the NPRM, water utilities are likely to find the costs are higher than the costs that EPA found when conducting its UCMR study.

EPA Response: The EPA disagrees that it underestimated analytical monitoring costs. Please see section 13.3.4 of the EPA response in this *Response to Comments* document for discussion of how the EPA estimated analytical monitoring costs. In addition, in the final rule the EPA set the trigger level equal to ½ of the MCL after consideration of public comments received. This is anticipated to reduce overall national monitoring burden; see Chapter 5 of the EA for more information on the EPA's estimates of monitoring costs for the final rule. Please see section 8.8 of the EPA response in this *Response to Comments* document for the EPA's responses as to why it adjusted the trigger level.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045120)

As discussed above, a clear post-treatment sampling protocol needs to be established in the regulation. The mid-point sampling is industry norm, but many small systems cannot afford to pay the $525+ per sample cost (the current rate available to many Vermont water systems) twice per quarter or monitoring period – once for treatment efficacy and the other for compliance. Since the mid-point sampling will not "count" for compliance, which is defined as being at the entry point to distribution, this would require multiple samples per quarter, at a cost of nearly $4,000/year on top of the treatment and disposal costs.

EPA Response: For the EPA's response to comments on per sample monitoring costs, please see section 13.3.4 of the EPA response in this *Response to Comments* document. For the EPA's response to comments on performance monitoring, i.e., "mid-point sampling" see section 13.3.3 in this *Response to Comments* document. In response to the commenter's recommendation that the EPA establish "a clear post-treatment sampling protocol," see monitoring requirements section VIII.A of the final rule preamble and section 8.1.2 of the EPA response in this *Response to Comments* document on compliance monitoring requirements.

Las Cruces Utilities (LCU) (Doc. #1753, SBC-043921)

In response to Section XIII. Health Risk Reduction and Cost Analysis, EPA requests comment generally on its estimation of sampling costs. The Agency is also specifically requesting comment on the ability of systems to demonstrate they are reliably and consistently below 1.3 ppt for PFOA and PFOS and 0.33 ppt for PFAS regulated by the HI in order to qualify for reduced monitoring.

• Hall Environmental Analysis Laboratory in NM, prices range from $350 - $500 per sample depending on the method requested and the number of PFAS compounds requested. EPA's assumed costs for samples are extremely low.

EPA Response: Please see section 13.3.4 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045610)

Monitoring Requirements for Systems Participating in UCMR 5

Under the proposed rule, community water systems and non-transient non-community water systems will need to conduct initial monitoring, unless the state primacy agency approves the use of previously collected monitoring data. AWWA appreciates the agency's interest in providing this flexibility for water systems that may have already collected PFAS monitoring data for UCMR 5 or state monitoring programs. As part of the compliance cost analysis for the proposal, EPA did not include the monitoring costs associated with certain systems that may be eligible to

take advantage of this flexibility. While it is reasonable to assume that some systems may potentially avoid initial monitoring for PFAS, it is not appropriate to exclude these costs from the analysis. While all systems serving more than 3,300 are currently already required to monitor for PFAS in accordance with UCMR 5, many of these systems may need to conduct additional monitoring to comply with the rule and to meet the timeline for compliance set by EPA. Examples of these systems may include:

• Large groundwater systems (serving more than 10,000 persons): Large groundwater systems will be required to collect quarterly samples while UCMR 5 requires the collection of two samples for all groundwater systems. There are more than 1,650 systems in this category that would need to collect additional samples beyond UCMR 5 to take advantage of this flexibility. Additionally, systems that are actively collecting samples during 2023 are unlikely to have the opportunity to adjust monitoring plans.

EPA Response: Please see section 13.3.4 of the EPA response in this *Response to Comments* document.

Uttara Jhaveri (Doc. #1778, SBC-045447)

In addition, the water systems will have to conduct compliance monitoring to demonstrate that the finished drinking water does not exceed the MCLs for regulated PFAS. Systems that exceed the proposed MCLs for regulated PFAS will be monitored quarterly, and the PFAS will be determined by running annual averages at the sampling point. [FN23: Id.] The monitoring and communication costs of the proposed regulation will be high, especially for the water sources that fail to meet the proposed MCLs. Furthermore, the sharp decrease of the MCLs from the current limit of 70 ppt [FN24: Environmental Protection Agency, FACT SHEET PFOA & PFOS Drinking Water Health Advisories, (2016), https://www.epa.gov/sites/default/files/2016-06/documents/drinkingwaterhealthadvisories_pfoa_pfos_updated_5.31.16.pdf.] may lead to several water sources in the country failing to meet the proposed limits.

EPA Response: Please see section 13.3.4 of the EPA response in this *Response to Comments* document. The EPA notes that the 2016 PFOA and PFOS Health advisories are beyond the scope of this rulemaking. The 2016 Health Advisory level of 70 ppt was and are not legally enforceable federal standards and HAs are subject to change as new information becomes available. In response to the commenter's reference to the communication costs associated with the rule, please see section 13.3.5 of the EPA response in this *Response to Comments* document on administrative costs of the rule, as well as section 1.2 in this *Response to Comments* document on the EPA's response to comments on risk communications associated with the rule.

Vermont Rural Water Association (Doc. #1798, SBC-045330)

Based on the experiences of Vermont's small systems, EPA has significantly underestimated the costs of monitoring and remediation. Engineering analyses did not recommend POU treatment systems as a remediation option, even for NTNCs and TNCs. Monitoring costs for very small

systems with any detectable level of PFOA or PFOS will average over $2000 per year (EPA estimates $900). For Vermont's small systems, this is a greater expense than all of their other annual monitoring costs combined.

EPA Response: Please see section 13.3.4 of the EPA response in this *Response to Comments* document for response to comments on monitoring costs. For the EPA's response to comments on POU devices, please see section 10 in this *Response to Comments* document. The commenter does not provide any information to support the claim that "monitoring costs for very small systems with any detectable level of PFOA or PFOS will average over $2000 per year," and it is unclear how this number was derived. The estimated annual costs per system varies in the EPA's analysis depending on the monitoring frequency and the number of EPTDS in the systems. The commenter's suggestion that the EPA estimates $900 dollars for every small system is not correct. Please see the EPA response to comment Doc. #1692, SBC-044744 in section 13.3.4 in this *Response to Comments* document for information about burden reduction anticipated with adjusting the trigger level. Additionally, based on public comments, the EPA has added an additional burden reducing monitoring option for those utilities whose regulated PFAS concentrations are above the trigger level, but reliably and consistently below the MCLs: please see section 8.1.2 of the EPA response in this *Response to Comments* document.

Palm Beach County Water Utilities Department (Doc. #1802, SBC-045338)

Page 18698, Table 34:

PBCWUD Comment: Current sampling and subcontracting costs to a certified lab is approximately $300-$500/sample (hours, travel,bottles, testing) with a TAT of 3-4 months. It is difficult to make data driven decisions when TAT is 3-4 months currently. Approximate cost to analyze PFAS in house at PBCWUD lab would be around $500,000 for new equipment, method development, training, and personnel.

Please contact myself, our Director, or our Deputy Director directly with any questions or comments. Our contact information is below.

Sincerely,

Bret Hammell, P.E.

Environmental, Health and Safety Manager, PBCWUD

bhammell@pbcwater.com

cc: Ali Bayat, P.E., Director, PBCWUD, ABayat@pbcwater.com

Krystin Berntsen, Deputy Director, PBCWUD, KBerntsen@pbcwater.com

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Keresha Whittingham, PBCWUD, Regulatory Compliance Specialist, KWhittingham@pbcwater.com

EPA Response: Please see section 13.3.4 of the EPA response in this *Response to Comments* document and response to comments on monitoring requirements and laboratory capacity in section 8 in this *Response to Comments* document.

Florida Rural Water Association (FRWA) (Doc. #1806, SBC-044694)

Based on the experiences of Florida small systems, EPA has significantly underestimated the costs of monitoring and remediation. Engineering analyses did not recommend POU treatment systems as a remediation option, even for NTNCs and TNCs. Monitoring costs for very small systems with any detectable level of PFOA or PFOS will average close to $2000 per sample (counting all costs) (EPA estimates $900).

EPA Response: Please see section 13.3.4 of the EPA response in this *Response to Comments* document for response to comments on monitoring costs. For the EPA's response to comments on POU devices, please see section 10 in this *Response to Comments* document. The commenter does not provide any information to support the claim that "monitoring costs for very small systems with any detectable level of PFOA or PFOS will average over $2000 per year," and it is unclear how this number was derived. The estimated annual costs per system varies in the EPA's analysis depending on the monitoring frequency and the number of EPTDS in the systems. The commenter's suggestion that the EPA estimates $900 dollars for every small system is not correct. Please see also the EPA response to comment Doc. #1692, SBC-044744 and Doc. #1798, SBC-045330 in section 13.3.4 in this *Response to Comments* document for discussion about additional monitoring burden reduction the EPA has incorporated into the rule based on public comment.

Office of Advocacy at the U.S. Small Business Administration (Doc. #1807, SBC-045482)

In addition, small entities shared that the cost of PFAS sampling will add significantly to their testing expenses (e.g., $700-$800 per sample).

EPA Response: Please see section 13.3.4 of the EPA response in this *Response to Comments* document. This commenter's per sample costs are significantly higher than the EPA's and all other public commenters. It's possible this commenter's cost estimate includes the administrative burden associated with collecting the samples. If so, the EPA notes that the hours per sample to travel to sampling locations, collect samples, record any additional information, submit samples to a laboratory, and review results are captured in the EPA's cost analysis, see Chapter 5.3.2 of the EA for more information.

Groundwater Resources Association of California (Doc. #1831, SBC-045352)

Groundwater sampling and analysis costs will likely be higher than costs calculated for analysis at potable water treatment systems due to specialized consumables (pump components, tubing, sample vials) and additional background, blank, and spiked samples required for quantification of PFAS at ppt levels in outdoor and/or remote locations.

EPA Response: Sampling is only required at the EPTDS. Raw water sampling is not required under the final rule. As discussed in section 13.3.4 of the EPA response in this *Response to Comments* document, the EPA included the costs of FRB when samples exceed the detection limits in the cost analysis.

Vanderbilt University Drinking Water Justice Lab (Doc. #3072-97, SBC-047409)

Okay, so my name is Yolanda McDonald and I am the lead investigator for the Vanderbilt University Drinking Water Justice Lab. And I first want to say, Katie, your comments are extremely moving and part of the reason that our lab is conducting research in PFAS and trying to develop machine learning methods whereby small water systems can assess presence of PFAS because of the concerns of the regulation whereby there's a random sampling of systems that are less than 3,301. I understand that the majority of people in the United States do receive their water from large systems, but I think that there is an oversight in the current legislation and what we're going to do about these small water systems. And we have to ensure that there's allocation beyond the initial UCMR 5 to have testing done in small systems that is affordable to the community without requiring there to be high rate increases just to make water affordable and safe for those citizens. And I do also want to point out, this may have been discussed earlier and I apologize, I wasn't able to make the entire meeting.

EPA Response: The EPA agrees with the commenter that it is important to understand the level of contamination regardless of system size. Under the final NPDWR, all community and non-transient non-community public water systems will be required to sample for PFAS.

New Mexico Rural Water Association (Doc. #3072-98, SBC-047412)

$500 a sample for testing in New Mexico is a bit too steep for most small systems. Others have already commented on this. Having access to BIL funds is nice, but we need the money to be available to small systems even if they don't qualify by state rules like a current audit. Half of our systems are political subdivisions of the state, and most are under 500 in population.

EPA Response: Please see section 13.3.4 of the EPA response in this *Response to Comments* document for the EPA's response to comments on monitoring costs. Please see section 2.4 in this *Response to Comments* document for the EPA's response to comments on available funding for water systems to help comply with the PFAS NPDWR.

Santa Clarita Valley Water Agency (SCVWA) (Doc. #1578, SBC-042429)

We have also invested in equipping our own laboratory with the ability to analyze PFAS Chemicals through the purchase and ELAP certification of an LCMSMS ($550,000). This has allowed SCV Water to proactively manage analytical costs and maintain timely results with our samples. But this has also resulted in additional staff costs to oversee and run the laboratory equipment.

EPA Response: Please see section 13.3.4 of the EPA response in this *Response to Comments* document.

Environmental Monitoring Coalition (EMC) (Doc. #1625, SBC-043114)

5. Analytical Costs

Related to our comments on the lowered reporting limits needed to support reporting at or below the trigger values, we note that the EPA has estimated a price per sample of $376 for 533 and $302 for 537.1. There are likely to be additional quality control, calibration and other associated costs that arise from calibrating and reporting down to the trigger values. These extra cautions will probably increase the costs due to the extra steps the laboratory will have to take to lower contamination (if even possible) to a level that would allow them to report data at 1.3 ng/L.

The EMC recommends that EPA clarify that, in order to perform the Economic Impact Assessment, it approximated monitoring costs based on costs it incurred during UCMR studies conducted several years ago. These estimates may underestimate the actual analytical and overall monitoring costs by a significant amount due to the need for the additional quality control steps, lower quantitation levels, and overall inflation.

EPA Response: Please see section 13.3.4 of the EPA response in this *Response to Comments* document. In addition, in the final rule the EPA set the trigger level equal to ½ of the MCL in response to comments received. Please see the EPA response to comment Doc. #1692, SBC-044744 in section 13.3.4 in this *Response to Comments* document.

Association of Public Health Laboratories (APHL) (Doc. #1646, SBC-043322)

5. Analytical Costs

Related to our comments on the lowered reporting limits needed to support reporting at or below the trigger values, we note that the EPA has estimated a price per sample of $376 for 533 and $302 for 537.1. There are likely to be additional quality control, calibration and other associated costs that arise from calibrating and reporting down to the trigger values. These extra cautions will probably increase the costs due to the extra steps the laboratory will have to take to lower contamination (if even possible) to a level that would allow them to report data at 1.3 ng/L.

The EMC recommends that EPA clarify that, in order to perform the Economic Impact Assessment, it approximated monitoring costs based on costs it incurred during UCMR studies conducted several years ago. These estimates may underestimate the actual analytical and overall monitoring costs by a significant amount due to the need for the additional quality control steps, lower quantitation levels, and overall inflation.

EPA Response: Please see section 13.3.4 of the EPA response in this *Response to Comments* document. In addition, in the final rule the EPA set the trigger level equal to ½ of the MCL in response to comments received. Please see the EPA response to comment Doc. #1692, SBC-044744 and Doc. #1798, SBC-045330 in section 13.3.4 in this *Response to Comments* document for discussion about additional monitoring burden reduction the EPA has incorporated into the rule based on public comment.

Missouri Department of Natural Resources (Doc. #1563, SBC-042539)

EPA requests comment on the underlying assumptions that, under UCMR 5, individual water systems would be able to request the full release of data from the labs for use in determining their compliance monitoring frequency and that PWSs may be able to use these lab analyses to demonstrate a ‘‘below trigger level’’ concentration using the UCMR 5 analyses by following up with the lab for a more detailed results report.

EPA based its assumption on water systems contracting with a lab to perform analysis. In Missouri, the state procures the contract for UCMR analyses for large systems. As the water system is not the client of the laboratory, the system has no legal right to the release of data from the lab. Likewise, small system analyses are procured by EPA, and do not have legal right to the release of the data from labs secured by EPA. This was recently experienced by the Department as UCMR 5 proficiency testing (PT) results were requested from EPA and we were informed those results are not available to the public.

Thank you for the opportunity to provide comments on this proposed rule. The Department looks forward to continuing to work with the EPA to improve the protection of public health and the implementation of the national primary drinking water regulations. If you have any questions regarding these comments, please contact David Lamb, Public Drinking Water Branch Chief, at P.O. Box 176, Jefferson City, MO 65101, by email at david.lamb@dnr.mo.gov, or by telephone at 573-751-0124.

Sincerely,

WATER PROTECTION PROGRAM

John Hoke

Director

EPA Response: Please see section 13.3.4 of the EPA response in this *Response to Comments* document. Further the EPA is in the process of obtaining the data below UCMR 5

MRLs for the small water systems that had their UCMR 5 samples analyzed by an EPA contracted laboratory. The EPA doesn't foresee any challenges procuring the data at this time. In the situation the commenter describes, primacy agencies may explore procuring the data on behalf of the water systems and sharing that data after receiving it.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044051)

31. EPA requests comment on the underlying assumptions that, under UCMR 5, individual water systems would be able to request the full release of data from the labs for use in determining their compliance monitoring frequency and that PWSs may be able to use these lab analyses to demonstrate a "below trigger level" concentration using the UCMR 5 analyses by following up with the lab for a more detailed results report.

a. See number 21. CWUC absolutely does not agree with EPA's assumption. Eurofins Eaton Analytical will not send UCMR5 data to customers below the EPA established RLs, per their direction from EPA. Further, it is irrational to think that laboratories will re- send every single lab report to every single system nationwide to re-include the MDL data which was previously not allowed due to EPAs direction. This is an unrealistic and incredible burden to UCMR5 contract laboratories nationwide. EPA needs to immediately rescind the requirement that labs cannot report UCMR data for PFAS to less than the established PQLs.

EPA Response: Please see section 13.3.4 of the EPA response in this *Response to Comments* document. In addition, there is no EPA requirement that labs cannot report data from UCMR 5 below the PQLs directly to water systems. The EPA does realize that the UCMR 5 reporting system ("SDWARS 5") will not accommodate results below UCMR 5 MRLs, since the UCMR MRLs must be held consistent over the monitoring timeframe. However, the EPA, through a memo to UCMR 5 laboratories sent in August 2023, encouraged UCMR 5 laboratories to evaluate or reprocess results below UCMR 5 MRLs and work with their water system clients to accommodate requests for data below the UCMR 5 MRLs (and proposed NPDWR PQLs), to potentially support a water system's future determination of NPDWR monitoring frequency. Any "lower level" data provided to water system clients for potential NPDWR monitoring-frequency determinations should be considered a separate action outside of UCMR 5 and managed separately.

Aurora Water, City of Aurora, Colorado (Doc. #1669, SBC-043714)

EPA is assuming that individual water systems can request a full release of data collected during UCMR 5 from laboratories for determining compliance with the proposed monitoring trigger level that is below the PQL. Laboratories would be concerned with liability issues therefore it will be unlikely they would release a full report of data that includes measurements below the PQL. Aurora Water does not agree with EPA's assumption that sample results below the PQL could be acquired from commercial laboratories.

EPA Response: Please see section 13.3.4 of the EPA response in this *Response to Comments* document.

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045219)

4. EPA requests comment on the underlying assumptions that, under UCMR 5, individual water systems would be able to request the full release of data from the labs for use in determining their compliance monitoring frequency and that PWSs may be able to use these lab analyses to demonstrate a ''below trigger level'' concentration using the UCMR 5 analyses by following up with the lab for a more detailed results report.

CT DPH agrees that individual water systems can obtain a more detailed results report to demonstrate a below trigger level concentration, depending on the analytical capabilities of the laboratory. CT DPH requests that EPA clarifies whether trigger levels are based off the annual average calculation or if the intent for labs to routinely report to this level. CT DPH requests EPA to specify if labs are allowed to provide provisional or "J" flagged data for trigger level screening purposes or if all labs will be required to meet 1.3ppt.

EPA Response: For the EPA's assumptions that water systems can request all UCMR 5 data from laboratories for use in satisfying some or all of the NPDWR's initial monitoring requirements and determination of compliance monitoring frequency, please see section 13.3.4 of the EPA response in this *Response to Comments* document. Regarding trigger levels and determination of monitoring frequency, including data reporting, please see section 8.8 of the EPA response in this *Response to Comments* document. The determination of monitoring frequency is based on individual sample results, not averages.

13.3.5 Water System Costs – Administrative (including Public Notification)

Summary of Major Public Comments and EPA Responses

Many commenters expressed concerns with the EPA's assumption of full compliance with this rulemaking and thus the EPA's decision not to include quantified public notification costs in its national cost estimates. The EPA recognizes that these activities do have an associated burden for systems but disagrees that these costs should be included in the EA. The EPA assumed 100 percent compliance for its national level analysis in the EA for the final rulemaking because the EPA has determined that the final rule is feasible given known occurrence concentrations and efficacy of the technologies available. Further, this is consistent with the approach taken in EAs for other NPDWRs (USEPA, 2005a; USEPA, 2019; USEPA, 2020a). Additionally, the EPA notes that the assumption of full compliance with the final rule will not necessarily underestimate the annualized cost of the rule as suggested by several commenters. While it is correct that noncompliance would require PWSs to incur public notification costs, it would also reduce annualized treatment costs due to the delay in treatment initiation. Therefore, the EPA believes that the assumption of full compliance is appropriate and the impact on national cost estimates is

likely not significant. For approximate estimates of the potential burden associated with Tier 2 and 3 Public Notifications (PNs), please see Section 5.3.2.4 of USEPA (2024b).

A couple of commenters raised concerns that the EPA did not sufficiently capture the administrative costs (e.g., monitoring, reporting, and recordkeeping) of the rule. The EPA disagrees with these commenters as the agency has accounted for a wide range of administrative costs borne by water systems in its EA, including administrative costs associated with implementation, sampling costs, and administrative costs associated with treatment. The EPA's estimated implementation administration costs capture the costs anticipated for systems to read and understand the rule and attend training provided by primacy agencies. The EPA's estimated treatment administration costs capture the costs anticipated for systems to obtain permits for treatment and non-treatment actions taken to comply with the rule, compile data for and review treatment efficacy with primacy agencies during triennial sanitary surveys, and obtain permits for source water changes or alternative methods.

Additionally, the labor associated with designing pilot test protocols, installing and testing equipment as well as collecting operational data (monitor and adjust the pilot system and collect samples) is captured in the EPA's cost analysis, within the cost estimates for pilot studies, rather than in the EPA's PWS administrative costs. In addition, compliance monitoring costs and related costs associated with notification to the primacy agency are included separately in the EPA's sampling cost estimates. For more information on the EPA's estimates of water system administrative and monitoring costs, please see Section 5.3.2 of the EA (USEPA, 2024b). For comment responses on the EPA's monitoring cost estimates, please see section 13.3.4 in this *Response to Comments* document.

Individual Public Comments

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-047693)

AMWA would, however, like to comment on EPA's assumption of full compliance with the proposed rule and subsequently not include any costs related to public notification in the cost-benefit analysis.

Historically, health-based violations of drinking water regulations have increased immediately after new regulations are enacted as utilities work to perfect treatment operations or finish capital improvement projects [FN18: Allaire, M., Wu, H., and Lall, U. (2018). National trends in drinking water quality violations. Proceedings of the National Academy of Sciences, 115(9), 2078-20823. https://www.pnas.org/doi/10.1073/pnas.1719805115.]. It is not practical to assume full compliance when a rule of this magnitude will result in water systems having to plan and implement large capital improvement projects that will likely not be finished in the short three-year compliance time span EPA has proposed. These public notification requirements can result in significant costs to utilities that are taking all necessary actions to be in compliance with the rule but are not given enough time to carry out and finish projects. Therefore, AMWA suggests

EPA include some costs related to public notification in its economic analysis to more accurately portray the overall costs that the agency's proposed rule will pass to ratepayers.

EPA Response: Please see section 13.3.5 of the EPA response in this *Response to Comments* document. Additionally, with respect to the commenter's assertion that "it is not practical to assume full compliance when a rule of this magnitude will result in water systems having to plan and implement large capital improvements projects that will likely not be finished in the short three-year compliance timeline", the EPA notes that for the final rule, the agency is providing compliance flexibility by means of a two-year capital improvements extension of the MCL compliance deadline allowed by Section 1412(b)(10) of SDWA. For more discussion of the two-year MCL compliance deadline extension, please see section 12 of the EPA response in this *Response to Comments* document.

Robert Hollander (Doc. #1516, SBC-042714)

7. 88 FR 18694, Table 27

Are costs of monitoring, reporting, and recordkeeping (for compliance purposes) included in O&M Costs? Many larger utilities have separate [administrative] staff performing these duties, therefore, maybe Administrative Costs, should be included as an additional Cost Category.

EPA Response: Please see section 13.3.5 of the EPA response in this *Response to Comments* document for response to comments on administrative costs and section 13.3.4 in this *Response to Comments* document for response to comments on monitoring costs. With respect to the commenter's question about the costs of monitoring, reporting, and recordkeeping, the EPA has quantified these costs separately from treatment O&M costs; please see Section 5.3.2 of the EA (USEPA, 2024b) for more information on the EPA's estimates of PWS administrative and monitoring costs, which include administrative costs associated with implementation, sampling costs, and administrative costs associated with treatment.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044433)

EPA requests comment on the discussion of estimated PN costs provided in the proposed rule.

• Currently, PN can run from $50,000 – 100,000 per quarter for a larger PWS. It would be beneficial if EPA published some options for electronic delivery methods for tier 2 PN. Consider that different types of communication methods may reach different audiences. Such options could require a balance of methods to both save on costs for repeat PN while attempting to ensure more customers maintain awareness.

EPA Response: Please see section 13.3.5 of the EPA response in this *Response to Comments* document.

With respect to the commenter's recommendation for the EPA to publish "options for electronic delivery methods for tier 2 PN", the EPA agrees that using a mix of delivery methods is

beneficial for reaching different audiences; however, revising the form and manner of PN delivery is outside the scope of this action. Under the existing PN Rule, public water systems must provide the notice in a form and manner reasonably calculated to reach all persons served. The existing PN Rule includes posting on the internet for community water systems or sending an e-mail for non-community water systems as example supplemental delivery methods in addition to direct delivery. The EPA encourages systems to use supplemental delivery methods, for example, social media or other forms of electronic communications, in addition to their primary delivery methods, to widely distribute the PN [40 CFR 141.203(c)(1)(ii), 40 CFR 141.204(c)(1)(ii), 40 CFR 141.203(c)(2)(ii) and 40 CFR 141.204(c)(2)(ii)].

Under special primacy requirements in 40 CFR (Code of Federal Regulations) 142.16(a)(2), a primacy agency may set alternate notification requirements with respect to the form and content of PN. The alternative requirements must provide the same type and amount of information required under 40 CFR 141 Subpart Q. This special primacy requirement addresses state flexibility to approve in writing the use of a substitute delivery method not already listed in the PN rule. The EPA recognizes the need to tailor any additional methods of delivery used to the specific situation. Primacy agencies may make this determination in writing on a case-by-case basis [40 CFR 141.202(c)(4), 141.203(c)(1) and (2), and 141.204(c)(1) and (2)]. Primacy agencies were required to establish enforceable requirements and procedures for adding to or changing the form and manner of delivery requirements for Tier 1, 2, and 3 public notices in their PN regulations [40 CFR 142.16(a)(2)(v)]. A primacy agency also has the option of establishing by rule, after notice and comment, alternate PN form and manner requirements that provide the same type and amount of information required under the EPA's PN regulations. For further discussion of the public notification requirements for this rule, please see section 9.2 of the EPA response in this *Response to Comments* document.

<u>New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045052)</u>

Public Notice Cost

EPA requests comments on the discussion of estimated PN costs provided in the proposed rule. In review of PN costs in NJ, a typical PN cost in New Jersey is estimated at $0.50 - $1.00 per service connections per quarter. The cost range for a community water system to issue a typical Tier 2 PN in New Jersey is $20.00 for the smallest systems to as much as approximately $100,000 of its largest systems per quarter.

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EPA Response: Please see section 13.3.5 of the EPA response in this *Response to Comments* document. For discussion of the public notification requirements for this rule, please see section 9.2 of the EPA response in this *Response to Comments* document.

Philadelphia Water Department (PWD) (Doc. #1709, SBC-045739)

6. EPA significantly underestimated the costs associated with Public Notifications for this rulemaking by assuming that all systems would be in compliance with the NPDWR.

EPA should re-evaluate its assessment of costs and benefits of their proposed rulemaking to ensure consistency in its assumptions of compliance with the proposed rulemaking to ensure an accurate balance between the two. In section XIII.G, EPA assessed the health benefits that would occur through the reduction in Disinfection By-Products (DBPs) via the implementation of PFAS removal treatment technologies. In this assessment, EPA used its occurrence model to estimate the number of PWSs that would exceed one of the three proposed MCLs to determine how many would install PFAS treatment. This estimate was then used to estimate the health benefits associated with co-removal of DBPs. In EPA's Economic Analysis for the Proposed PFAS NPDWR, it is estimated that over 25% of large systems will exceed one of the three proposed MCLs. However, in section XIII.C.1.h, EPA states that its "cost analysis assumes full compliance with the rule throughout the period of analysis and, as a result, EPA does not estimate costs for the [Public Notification (PN)] requirements in the proposed rule". The assumption stated in section XIII.C.1.h appears to directly contradict the underlying assumption made in section XIII.G. If EPA estimates that 25% of large water systems will exceed one of the three proposed MCLs there are likely to be significant costs associated with issuing the required PNs. It is recommended that EPA re-evaluate their cost assessment in a manner that maintains consistent assumptions throughout the process.

EPA Response: Please see section 13.3.5 of the EPA response in this *Response to Comments* document. For discussion of the public notification requirements for this rule, please see section 9.2 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenter that the agency does not maintain consistent assumptions in its EA; the EA assumes that systems that exceed one or more of the MCLs for the final rule will take action to comply with the final rule (e.g., installation of treatment technologies or non-treatment alternatives) by the compliance deadline and, as a result, would not incur violations under the final rule.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045916)

EPA assumed administrative startup costs incorporated a total of 4 hours per PWS to read the rule and 16-32 hours per PWS to attend a training on the rule [FN166: 88 Fed. Reg. at 18697, Table 32.]. EPA further assumed treatment administrative costs of 3 to 42 hours per entry point for a system to notify, consult, and submit a permit request for treatment [FN167: 88 Fed. Reg. at 18699, Table 35.]. This does not appear to include the costs associated with evaluating potential treatment options, design, or piloting treatment.

The times allotted by EPA do not appear to sufficiently capture the administrative time that PWSs will require to be prepared for this rulemaking. These times further do not consider that the majority of treatment system serving less than 3,300 people were not included in UCMR 3 of UCMR 5, and do not have an established baseline of PFAS in their PWS. To properly assess treatment needs, these systems will have to dedicate more time to develop new sampling plans, specifically understating the sample collection methodologies required of analytical methods for which they may not be familiar, and to understand the laboratory results.

With regards to primacy agencies, EPA has assumed there would be no costs related to reporting violations to EPA as result of this rule, which is not a realistic assumption. EPA also assumed that agencies would spend 1 hour per sample to review results; however, EPA did not assume the PWSs would require time to review their own analytical results.

EPA Response: Please see section 13.3.5 of the EPA response in this *Response to Comments* document. The EPA disagrees that the agency has not sufficiently captured the administrative time required of PWSs to comply with the rule. The labor associated with designing the pilot test protocols, installing and testing equipment as well as collecting operational data (monitor and adjust the pilot system and collect samples) are captured in the EPA's cost analysis, within the cost estimates for pilot studies, rather than in the PWS administrative costs. These pilot study costs include labor for initial setup and ongoing operation of the pilot. The EPA applies a generalized labor rate for civil engineers to these hours to reflect that at least some of these activities might be conducted by a 3rd party contractor. This labor rate is higher than the PWS labor rates used in the rule and, therefore, reflects a conservative estimate for those activities that would be conducted by PWS operators.

While not all systems serving less than 3,300 people have been included in UCMR 3 or UCMR 5 sampling, the EPA disagrees that these systems will not have an established baseline. This is because the rule's initial monitoring requirements are intended for water systems to establish their baseline PFAS concentrations and have been costed in the rule appropriately. As part of the final rule, the EPA is also allowing a flexibility for systems to utilize previously collected PFAS drinking water data from UCMR 5 and/or state or other appropriate monitoring efforts to satisfy these initial monitoring requirements and provide baseline PFAS concentrations. Therefore, the EPA has appropriately accounted for the sampling burden and resulting costs anticipated to result from the final rule. For more information on the EPA's monitoring cost estimates, please see Section 5.3.2.2 of the EA (USEPA, 2024b). The EPA notes that the agency also captures costs

associated with traveling to sampling locations, collecting samples, recording additional information, submitting samples to a laboratory, and reviewing results. Additionally, the EPA notes that the agency intends to prepare a Small System Compliance Guide to help small entities comply with the final rule; this resource will be developed in the first three years following rule promulgation and will be made available on the EPA's PFAS NPDWR website.

With respect to the commenter's concern about costs to primacy agencies, please see section 13.3.1 in this *Response to Comments* document for response to comments received on primacy agency costs.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046021)

Multiplying the hourly labor rate by the number of hours per entry point for a system to notify, to consult, and to submit a permit request for treatment installation gives an estimate of the cost per system. Multiplying these figures by the total number of ground water and surface water EPTDSs that exceed one or more MCLs gives the total cost for each system size. This same methodology is used to determine costs per entry point for source water changes or alternative method permitting requests.

Table 14: Implementation Startup Costs

[Table 14: see docket ID EPA-HQ-OW-2022-0114-1738]

Table 16: Treatment Administration Costs

[Table 16: see docket ID EPA-HQ-OW-2022-0114-1738]

EPA Response: Please see section 13.3.5 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045997)

Section 8.10: Public notification costs

AMWA would like to reiterate concerns outlined in section 6.1 with EPA's assumption of 100% compliance with this rulemaking, resulting in no estimation of public notification costs. It is unreasonable for EPA to assume no system will be in non-compliance, especially as the agency is proposing only a three-year compliance deadline. Historically, there are spikes in non-compliance after a regulation takes effect as water systems work to address the issue as quickly as possible. EPA should look at non-compliance from previously NPDWRs and estimate non-compliance and public notification costs. Public notification costs can be significant, particularly if translation and other services are also required.

EPA Response: Please see section 13.3.5 of the EPA response in this *Response to Comments* document. For discussion of the public notification requirements for this rule, please see section 9.2 of the EPA response in this *Response to Comments* document.

Las Cruces Utilities (LCU) (Doc. #1753, SBC-043923)

In response to Section XIII. Health Risk Reduction and Cost Analysis, EPA requests comment on the discussion of estimated PN costs provided in the proposed rule.

• Public notifications are not currently factored into the costs developed by EPA. PN costs should be added at some percentage rate considering that achieving compliance by treatment may not be achieved by the compliance deadlines.

EPA Response: Please see section 13.3.5 of the EPA response in this *Response to Comments* document. For discussion of the public notification requirements for this rule, please see section 9.2 of the EPA response in this *Response to Comments* document.

13.3.6 Water System Costs – Non-treatment costs

Summary of Major Public Comments and EPA Responses

Many commenters pointed out that the availability of interconnection[10] and new wells as compliance options will vary greatly on a system-specific or regional basis. Some commenters pointed out that non treatment options would be particularly challenging in regions where water is scarcer; stating "[r]eplacement water is not readily available to most agencies in the arid west." One commenter agreed "…that some systems could potentially decide to install an interconnection if it is a viable alternative. Regionalization may have benefits for consecutive systems and can help provide smaller systems with access to economies of scale." Another noted that interconnection may not be a viable option for many water systems, "…but the option should exist to allow interconnections as a potential compliance avenue." Consistent with these comments, the EPA assumed that only a limited number of systems nationwide would be able to choose these options. Specifically, for design flows up to 10 million gallons per day, the EPA assumed that 7 percent of systems with design flows 1 million gallons a day or less and 6 percent of systems with design flows between 1 and 10 million gallons a day would choose interconnection and 2 percent would choose new wells. For larger flows, the EPA assumed 0 percent of systems would choose non-treatment options. While the EPA recognizes there are likely some regions where non-treatment options would be available to fewer systems, there are also likely regions where these options are more prevalent. For example, one commenter pointed out that Michigan expects up to 26 percent of water systems to interconnect with other systems to comply with their state standard. The EPA is also aware of a number of water systems that have elected to drill a new well to reduce PFAS concentrations in supplied water.

Several commenters stated that the EPA underestimated the costs associated with interconnection. Commenters pointed out that "…systems considering interconnections will need to thoroughly investigate this option and determine if it is both cost effective and appropriate

[10] Interconnection is when a system replaces their contaminated water source by purchasing water from another nearby system that is in compliance. Booster pumps can be needed when the pressure from the supplying system is lower than required at the purchasing system and also to overcome pressure losses due to friction in interconnecting piping.

given the water quality impacts." These commenters identified the following issues that might be faced by individual systems pursuing interconnections: water quality and chemistry concerns (e.g., elevated water age, nitrification, DBPs, compatibility of secondary disinfectants); technical and engineering requirements (e.g., spill containment, mixing and storage tanks, water quality monitoring devices, water main upgrades); additional miscellaneous costs (e.g., buy-in fees, emergency use surcharges); and simultaneous compliance with existing drinking water standards (e.g., Lead and Copper Rule Revisions, Microbial Disinfection Byproduct Rules, and dealing with regulatory matters (e.g. getting local and state approval).). The EPA agrees that there are many considerations for water systems pursuing interconnections, as pointed out by commenters; however these considerations are not quantifiable. For example, water quality and chemistry concerns and simultaneous compliance with existing laws and drinking water standards, and public perceptions of source water type are not direct or indirect costs that can be quantified. Other considerations such as technical and engineering requirements and the labor and time associated with dealing with regulatory matters are likely to vary significantly between systems, and data does not exist to incorporate these costs at the national level. The EPA further notes that water systems that evaluate these quantifiable and non-quantifiable considerations and find that pursing interconnection would require extensive additional costs, such as disinfectant conversion facilities or water main upgrades, would likely not find interconnection cost-effective and elect a different compliance option. For this reason, the EPA assumed that only a limited number of systems nationwide would be able to choose these options. Regarding the costs to the small number of water systems that do chose interconnection to comply with the rule, based on input received through public comments the EPA incorporated contingency costs at all cost levels and increased the complexity factor applied to estimate contingency for systems using non-treatment options. Increasing the complexity factor increased the overall cost estimate for interconnections and can account for a range of potential site-specific considerations and costs that cannot be captured in a national level analysis. Taken together with the escalation to 2022 dollars and the addition of booster pumps discussed below, these changes increased the system level capital costs for interconnection by approximately 60 to 100 percent. One commenter stated that it was "unrealistic to assume that booster pumps are unlikely to be necessary. Pressure loss associated with friction could be significant, especially for an interconnection that may span 10,000 feet or more," and recommended that the EPA include booster pumps in the cost estimate. The EPA agrees that booster pumps may be needed and added the costs of booster pumps designed to account for friction loss in interconnecting piping.

A few commenters shared some information about the costs that they have incurred at a system level for non-treatment options. However, many of these comments lacked supporting details, such as information to confirm that all of the reported costs were directly associated with replacement of the PFAS contaminated source, as opposed to other infrastructure improvements (e.g., capacity expansion, administrative facilities, distribution system improvements) that happened to be completed as part of the same project. To fully evaluate these estimates in comparison to the WBS model outputs, the EPA would need itemized line-item cost details and engineering design parameters. While the EPA recognizes there are likely site-specific instances where costs exceed the EPA's cost ranges, there are also likely site-specific instances where costs

are less than the EPA's cost ranges, and this level of accuracy is appropriate for a national level analysis.

Individual Public Comments

Maine Water Utilities Association (MWUA) (Doc. #1567, SBC-042739)

Regional connections are a possibility to achieve compliance, but interconnections with neighboring communities to provide an alternative water source may pose challenges in terms of cost and time required to design, permit, and construct the needed infrastructure, as well as potential incompatibility with that water. [FN2: See Appendix D which outlines challenges and considerations with interconnections.] It is important to note that there are many water systems in New England where interconnections or participation in regional supplies will just not be possible and that is likely the case across the nation, but the option should exist to allow interconnections as a potential compliance avenue.

EPA Response: The EPA has included in the cost analysis the cost and time required to design, permit, and construct the needed infrastructure associated with interconnections. Regarding, "potential incompatibility with that water," please see the EPA response to comment Doc. #1601, SBC-042906 in section 13.3.6 in this *Response to Comments* document and section 13.3.6 of the EPA response in this *Response to Comments* document. The EPA agrees that the availability of non-treatment options will vary greatly on a system-specific and regional basis. For this reason, the EPA assumed that only a limited number of systems nationwide would be able to choose these options. Please see section 13.3.6 of the EPA response in this *Response to Comments* document.

Lakewood Water District (LWD) (Doc. #1574, SBC-042748)

Further, EPA's cost estimates for drilling new wells dramatically underestimate the costs. EPA estimates the cost of bringing a new well online to be less than $1,000,000. As described previously, the LWD PFAS mitigation program also includes drilling new wells to replace contaminated wells. LWD's actual experience with the cost of drilling and bringing online one new well is closer to $3.8 million. Keep in mind that the hydrogeology for LWD is more favorable for developing new wells. Nevertheless, LWD's actual experience with the cost of new wells is nearly four times the cost estimate presented by EPA in the proposed rules.

EPA Response: The comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. Please see sections 13.3.3 and 13.3.6 of the EPA response in this *Response to Comments* document.

National Tribal Water Council-Tribal PFAS Working Group (NTWCTPWG) (Doc. #1598, SBC-042343)

Water Source Alternatives

The proposed regulation speaks to an approach to mitigation that makes use of water source alternatives, bypassing the implementation of treatment measures. However, this approach is not available in a large portion of affected tribal communities due to a variety of reasons, including the changing climate impacts on the environments. Tribal communities are often located in areas that see a disproportionate amount of these impacts. Funds should be made available to explore alternative sources and build new facilities before installing new treatment techniques to reduce the long-term impacts on the affected communities. This would be a step towards a holistic assessment of the needs of the affected community's solution to addressing PFAS.

EPA Response: The EPA agrees that the availability of non-treatment options will vary greatly on a system-specific and regional basis. For this reason, the EPA assumed that only a limited number of systems nationwide would be able to choose these options. Please see section 13.3.6 of the EPA response in this *Response to Comments* document.

In regard to funding available to explore alternative sources and build new facilities, the EPA notes that the commenter's suggestion is a valid use of DWSRF funding to deal with PFAS. The following are examples of valid DWSRF BIL EC projects; see the EPA's memo on Implementation of the Clean Water and Drinking Water State Revolving Fund Provisions of the Bipartisan Infrastructure Law (USEPA, 2022b).

- Emerging contaminants costs associated with the construction of a new treatment facility or upgrade to an existing treatment facility that addresses emerging contaminants.
- Development of a new source (i.e., new/replacement well or intake for a public water system) that addresses an emerging contaminant issue [Note: water rights purchases must still meet the criteria in the Class Deviation for Water Rights].
- Consolidation with another water system that does not have emerging contaminants present or has removal capability.
- Costs for planning and design and associated pre-project costs.
- Infrastructure related to pilot testing for treatment alternatives.
- Creation of a new community water system to address unsafe drinking water provided by individual (i.e., privately-owned) wells or surface water sources.

Finally, as part of the EPA's environmental justice analysis, the agency examined baseline PFAS exposure and the anticipated distribution of benefits and costs of the rule across various demographic groups, including American Indian or Alaska Native subpopulations. For more information on the findings of the EPA's analysis, please see Chapter 8 of the EA. For the EPA's response to comments about financial assistance available for water systems, please see section 2.4 in this *Response to Comments* document.

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-042906)

APPENDIX B - INTERCONNECTION PROCESS Summary of Interconnection Process:

Activities, Regulatory Requirements, Timeframes, and Costs

As the move to regulate PFAS in drinking water in Massachusetts has commenced, a number of public water systems have needed to confront the issue due to PFAS detections from voluntary or past regulatory testing. One option for systems with detects at levels of concern is to utilize an alternate source of water obtained through interconnections with neighboring water systems. While this may be a viable and reasonable option, the use of interconnections as a short or long-term solution to PFAS contamination is not a simple alternative and is beset with issues and concerns.

How quickly an interconnection can be activated and used to replace a PFAS contaminated source is very dependent on site-specific issues. The table below summarizes some of the circumstances that are present and the impact on activation timelines. This summary is not all inclusive; there are numerous combinations of situations that influence the time it would take to activate an interconnection.

[Table 3: See Docket ID EPA-HQ-OW-2022-0114-1601]

Factors that need to be considered in development of the interconnection option include:

• Getting Local Approvals

o Both the supplying system and the receiving system need to agree to make the interconnection option viable. That process of agreement may involve town meeting, city council approval, votes of District commissioners or other formal authorization following a legally established procedure. Approvals by legislative bodies may only happen at certain times, thus subjecting the interconnection activation to schedules driven by other parties and/or statutes.

o Prior to any formal votes or approval actions, the interconnection concept would have to be at least partially developed. That planning process would need to involve engineers from both sides along with directors, commissioners and upper management. The planning process along with preliminary design, authorization to proceed, budget approvals, regulatory guidance and creation/approval of an intermunicipal or inter-district water supply agreement could take 1-3 years (or more).

o Historical relationships between the supplying system and the receiving system play a critical role in creation of a viable interconnection. It is not unusual for there to be “bad blood” between the two sides that stems from some perceived transgression which occurred decades earlier. Sometimes those ill feelings resurface and prevent an otherwise viable interconnection from being developed.

• Regulatory matters and state approvals

o Prior to construction and activation of a new interconnection and in some cases use of an existing interconnection, a number of regulatory hurdles must be overcome. These include:

*Drinking water approvals from MassDEP-the drinking water program would need to review and approve a new interconnection and may have some say in approving use of an existing interconnection.

*Water Management Act-How an interconnection impacts an existing WMA permit needs to be well understood. This is especially the case for the supplying system as the added demand may impact permitted withdrawal volumes, potentially push a withdrawal above its baseline or even result in a permit exceedance. If mitigation becomes necessary the supplying system needs to understand who would be responsible for mitigation and include appropriate language in an interconnection agreement. The supplying system also needs to know how much of its permitted (or registered) withdrawal remains after providing water to a PFAS impacted system and whether that remaining volume is sufficient to allow for growth within the supplying system

*Interbasin Transfer Act-The Interbasin Transfer Act may apply to a new or existing interconnection if the source water is in a different river basin than the receiving system or if the receiving system's wastewater is discharged to a river basin different than the supply system's source water. Interbasin Transfer Act approvals are through the Water Resources Commission and typically involve multiple meetings with IBTA staff to identify and resolve issues before a hearing with the WRC.

*Wetlands Protection Act-For interconnections requiring new infrastructure near wetlands and other water resources, a filing with the local Conservation Commission would be needed. This process typically includes a public hearing followed by issuance of an Order of Conditions. The entire process could take two months or more.

*MEPA Filing-If the interconnection trips certain thresholds, an Environmental Notification Form (ENF) would have to be filed. That could potentially be followed by preparation of an Environmental Impact Report (EIR). The ENF could take 3-6 months while the EIR could take 6 months to 2 years. Public meetings and site visits would also be part of this process.

*Procurement-Purchasing and installing materials and equipment needed for a viable interconnection will typically involve procurement under Massachusetts law. Most often equipment and services will need to be bid, usually after design and preparation of specifications by a consulting engineer. The procurement process adds time to the overall development of the interconnection and the process can be further delayed through litigation brought by parties who are dissatisfied with the bid outcome.

• Technical/engineering concerns

o Water pressure at the interconnection will, in part, determine the need for pumping. If the receiving system needs to pump water into parts of its system the design, construction and operation of the system will be much more complex and costly.

o Available flow rates, in addition to pressure, will drive complexity and costs for the receiving system. Distribution system design (pipe size, storage) is generally driven by fire flows. While pressures at the interconnection may be adequate, existing pipe size and condition in both the supplying system and receiving system may be flow limiting. Extensive water main upgrades may be required in order to meet both water use needs and fire flows in the receiving system and prevent low pressures and system disruptions (Rusty water, main breaks) in the supplying system.

o The supplying system needs to determine whether it has the physical capacity to supply the volume requested by the receiving system. This is a matter of water source capacity (well pumping rates, surface water and treatment facility capacity) and transmission capabilities (pumping stations and storage) along with regulatory limits on available volumes (WMA).

o The physical interconnection needs to be considered in terms of pipe size, materials, valves, metering, meter vault, SCADA controls, chemical injection (disinfection, corrosion control), alarms and pumping stations.

Having the space to construct the needed infrastructure is also critical. Land acquisition and/or easements may be necessary to actually build the interconnection.

• Water Quality concerns

o Using an interconnection between two water systems is not as simple as opening a valve if impacts on water quality for the receiving system are not well understood.

*Conflicting water chemistry-Treated water from the supplying system may not be compatible with the water in the receiving system. This could result is precipitation of iron or other elements that causes discoloration. Worse yet, corrosive water from the supplying system could cause lead and copper to leach from pipes, services and plumbing in the receiving system, as occurred in Flint, MI.

*Poor water quality at periphery of supplying system-

Interconnections are often located at the periphery of the supplying system where water age can increase the likelihood of water quality problems including bacterial growth, low disinfectant residuals, elevated iron, elevated disinfection byproducts, tastes and odors. Eliminating elevated PFAS in exchange for elevated THMs or HAAs or generally poor water quality would not be a desired outcome of an interconnection that may have already contributed to higher water rates.

*Public perception-Customers in the receiving system may not be pleased to receive water with high dissolved solids, poor taste, high chlorine levels and discoloration that comes through the interconnection. While the new supply may meet all water quality standards, it may not meet with satisfaction from the customers who use it. This is especially true if the receiving system had previously had soft, surface water and will now get hard, groundwater with high dissolved solids.

• Costs

o There are many cost factors that need to be considered

*There may be substantial buy in fees

*Utilities may have to payer higher per unit charges than if they were utilizing their own supply

*There may be emergency use surcharges

EPA Response: The EPA agrees that the availability of non-treatment options will vary greatly on a system-specific and regional basis. The EPA recognizes there may be regulatory limitations as to whether an interconnection can occur, potentially including the regulatory factors such as the interbasin transfer act, wetlands protection, water management act, local and state approvals, or other legal limitations that would prevent or limit interconnection options. The EPA also recognizes that there are many considerations for water systems to evaluate when considering compliance options, including those described by this commenter such as technical and engineering concerns, water quality concerns, and public perception of the source water types. For this reason, the EPA assumed that only a limited number of systems nationwide would be able to choose these options; please see section 13.3.6 of the EPA response in this *Response to Comments* document for more information. The EPA believes it has accurately estimated costs for non-treatment options because, among other things, many of the engineering/technical concerns mentioned by the commenter are explicitly addressed in the WBS costs, including land acquisition and physical interconnection components such as pipe size, materials, valves, metering, meter vault, and SCADA controls. For the final EA, based on this and other comments, the EPA added the costs of booster pumps designed to account for friction loss in interconnecting piping. The only physical equipment costs that the commenter mentions that the EPA didn't consider are chemical injection and distribution system upgrades. These needs are highly system specific. In the case of distribution system upgrades, they include general infrastructure improvements that may be required even in the absence of the PFAS rule. The EPA also agrees that there are many other considerations for water systems pursuing interconnections and therefore the EPA incorporated contingency costs at all cost levels and increased the complexity factor applied to estimate contingency for systems using non-treatment options. Taken together with the escalation to 2022 dollars and the addition of booster pumps, these changes increased the system level capital costs for interconnection by approximately 60 to 100 percent. Please see section 13.3.6 of the EPA response in this *Response to Comments* document. The EPA also agrees that utilities may have to pay higher unit costs for purchased water than for their own supplies. The EPA explicitly included the cost of purchasing water in the cost estimates. While the EPA did not quantify the potential cost savings in the cost analysis because of uncertainties, the unit cost for purchased water that the EPA used may, in fact, overestimate the marginal cost of purchasing water to replace a contaminated source because it does not account for the avoided cost of pumping and performing non-PFAS-related treatment on the abandoned source.

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-042890)

Regional connections are a possibility to achieve compliance, but interconnections with neighboring communities to provide an alternative water source pose challenges in terms of the cost and time required to design, permit, and construct the needed infrastructure, as well as potential incompatibility with that water [FN20: See Appendix B which outlines challenges and considerations with interconnections.]. It is important to recognize that there are many PWS in Massachusetts where interconnections or participation in regional supplies will just not be possible, and that is likely the case across the nation, but the option should exist to allow interconnections as a potential compliance avenue.

EPA Response: The EPA has included in the cost analysis the cost and time required to design, permit, and construct the needed infrastructure associated with interconnections. Regarding, "potential incompatibility with that water," please see the EPA response to comment Doc. #1601, SBC-042906 in section 13.3.6 in this *Response to Comments* document and section 13.3.6 of the EPA response in this *Response to Comments* document. The EPA agrees that the availability of non-treatment options will vary greatly on a system-specific and regional basis. For this reason, the EPA assumed that only a limited number of systems nationwide would be able to choose these options. Please see section 13.3.6 of the EPA response in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043079)

Interconnections

The Proposal considers that some water systems may take non-treatment actions to mitigate PFAS levels, such as the installation of an interconnection. Aqua agrees that some systems could potentially decide to install an interconnection if it is a viable alternative. Regionalization may have benefits for consecutive systems and can help provide smaller systems with access to economies of scale. Alternatively, regionalization can have unintended consequences on the water quality for the consecutive system, such as elevated water age and disinfection byproducts, and corrosion control impacts. For this reason, systems considering interconnections will need to thoroughly investigate this option and determine if it is both cost effective and appropriate given the water quality impacts. For the analysis, EPA estimates that upwards of 7% of small systems will install an interconnection to comply with the PFAS MCLs.

In review of the EPA's approach, Aqua recommends that the following challenges are recognized by the EPA and that the Agency incorporate these challenges into the cost analysis if interconnections will be retained in the final rule as a compliance option. These challenges include:

• Compatibility of Disinfectants: The use of disinfectants for drinking water treatment varies by system and not all systems use the same disinfectant chemical to maintain distribution system residuals (if they are required). The selection of a disinfectant for maintaining a residual is not

solely a regional decision and varies on several other factors (e.g., water source, finished water quality, distribution system size, water supply capacity, etc.). Subsequently, there is a significant likelihood that a purchasing system may be using a different disinfectant than a supplying water system, which would require the installation of a facility that can either convert free chlorine to chloramine, or vice versa.

• Simultaneous Compliance with Lead and Copper Rule: In 2021, the Lead and Copper Rule (LCR) Long-Term Revisions became effective, which require water systems to provide enhanced protections for the public when adding new sources of water to the system.

• Simultaneous Compliance with Microbial and Disinfection Byproduct Rules: As noted previously, regionalization can have negative impacts on water quality particularly because of increased water age. For systems that install a consecutive system, a thorough investigation will be necessary to determine if water age will be an issue and whether disinfection byproducts (DBPs) may need addressed at the point of connection. This could potentially require systems installing interconnections to install GAC filters. Similarly, systems may determine that there is an inadequate disinfectant residual present in the water to support the longer water age and thus requiring a boosting station.

EPA Response: The EPA agrees that there are many considerations for water systems pursuing interconnections, including those discussed by the commenter such as compatibility of disinfectants and simultaneous compliance with LCR and MDBPRs. Therefore, the EPA increased the complexity factor applied to estimate contingency for systems using non-treatment options. Please see section 13.3.6 of the EPA response in this *Response to Comments* document for more information about the complexity factor and the treatment of compatibility of disinfectants. For the EPA's response to comments on simultaneous compliance, please see section 10 in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-052830)

• Pressure Differences: Pressure loss associated with friction could be significant, especially for a typical interconnection that may span 10,000 feet. For an interconnection of this distance, the pressure loss associated with water flow through an appropriately sized pipe (to maintain water velocity from 5 to 7 feet per second), would lead to a pressure loss of approximately 50 psi. The inclusion of purchasing booster pumps, at minimum, should be included as part of this analysis.

EPA Response: The EPA agrees that booster pumps may be needed for interconnecting systems. For the final EA, based on this and other comments, the EPA added the costs of booster pumps designed to account for friction loss in interconnecting piping. Please see section 13.3.6 of the EPA response in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-052831)

• Unit Cost of Purchased Water: According to the Proposal, an assumed average cost of purchased water is $3.00 per thousand gallons (2021$) based on wholesale rates that were available online. Currently there are 3,258 water systems in SDWIS categorized as wholesaler systems. These systems range in service population size from 25 to up to 2.5 million persons, which represents a significant range in the ability for the system to produce and sell finished drinking water at economy of scale. Aqua's current purchased water interconnects range from $2.33 to $16.0 per thousand gallons with an average cost of $5.32 per thousand gallons (2022$) and thus the EPA is significantly underestimating the costs of interconnections. It is not clear what data was used to estimate the national average cost of purchased water and whether this data is nationally representative. It is possible that the available data may only be from cities with a water supply that is inexpensive to treat and supply to purchasers. Additionally, some systems that consider an interconnect may not be purchasing water from a large system that has achieved an economy of scale. Transparency on this data is necessary to ensure that this unit cost is accurate and reflective of the national perspective.

EPA Response: For the final rule, the EPA used a cost for purchased water of $3.17 in 2022 dollars, based on unit costs from 6 wholesalers collected between 2019 and 2022. Although this rate is lower than the commenter's average, it may still overestimate the marginal cost of purchasing water to replace a contaminated source because it does not account for the avoided cost of pumping and performing non-PFAS-related treatment on the abandoned source.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-052832)

• Available Capacity Without Improvements: Finally, the EPA's approach assumes that these water systems will be able to identify a supplier water system that has existing available capacity to provide finished drinking water with PFAS levels below the MCL without needing to install treatment. It is highly likely that a supplier will need to install additional drinking water treatment systems to accommodate the purchasing water system's water supply capacity. This is an especially important consideration for regions of the U.S. where drought is creating water supply challenges already as well as areas where source waters are becoming increasingly challenging with respect to accessibility and ease of treatment. On top of this challenge, there is a high likelihood that the PFAS contamination impacting a purchasing water system may be impacting the supplying water system, especially given the low levels of concern identified by the Proposal. In this case, the supplying water system would need to install PFAS treatment for their current water supply capacity in addition to the purchasing water system's demands.

EPA Response: The EPA recognizes that interconnection is only a viable option in some cases and dependent on identifying a supplier with available capacity, as discussed by the commenter. Therefore, the EPA agrees that the availability of non-treatment options will vary greatly on a system-specific and regional basis. For this reason, the EPA assumed that only a

limited number of systems nationwide would be able to choose these options. Please see section 13.3.6 of the EPA response in this *Response to Comments* document.

Aurora Water, City of Aurora, Colorado (Doc. #1669, SBC-043726)

EPA should also consider region specific challenges when proposing this rule. In the arid west it will be an extreme challenge to find new sources of water if the system's current sources are high in PFAS chemicals. Many western water systems simply cannot afford to turn off a source because it is high in PFAS and move to another source. There may not be another source available. Water systems such as Aurora Water are in a better position than many smaller water providers and could still struggle to be able to replace certain sources. Furthermore, shutting down certain sources could potentially jeopardize the water right itself. Water is scarce and becoming scarcer in the arid west. The cost of replacement supplies could easily be exorbitant.

EPA Response: The EPA agrees that the availability of non-treatment options will vary greatly on a system-specific and regional basis. The EPA also recognizes that in areas with limited water resources, finding new sources or interconnections may pose particularly significant challenges. However, these limitations are not applicable for much of the country (e.g., Michigan). As discussed in section 13.3.6 of the EPA response in this *Response to Comments* document, the EPA assumed that only a limited number of systems nationwide would be able to choose these options.

Horsham Water & Sewer Authority (HWSA) (Doc. #1686, SBC-043810)

Additionally, as a utility that has had to use increased purchase of water from neighboring utilities while our wells have been out of service for installation of PFAS treatment and has recently drilled a new well hoping to replace an existing one (unrelated to PFAS as no water supply well can be drilled in Horsham Township that is not impacted by the PFAS contamination), EPA's cost estimates for the use of purchase water and drilling new wells as alternates to treatment are low as well. It should also be noted that the availability of a neighboring utility with unused capacity to sell and/or the ability to drill a new well far enough removed from contamination in an aquifer is a luxury many utilities will not have available to them, and we believe EPA is overestimating the number of utilities that will be able to use these mitigation options. Purchasing water most likely will not be an option for a system that is not adjacent to a larger surface water supplied system and in many such cases, the secondary disinfection residuals are not compatible (free chlorine vs. chloramines) and will require additional capital expenditures not accounted for to avoid blending of residuals.

EPA Response: The EPA agrees that the availability of non-treatment options will vary greatly on a system-specific and regional basis. For this reason, the EPA assumed that only a limited number of systems nationwide would be able to choose these options. The EPA also agrees that there are many considerations for water systems pursuing interconnections, including secondary disinfection, and therefore the EPA increased the complexity factor applied to estimate

contingency for systems using non-treatment options. Please see section 13.3.6 of the EPA response in this *Response to Comments* document. Regarding the cost of purchased water, please see the EPA response to comment Doc. #1623, SBC-052831 and Doc. #1759, SBC-045615 in section 13.3.6 of the EPA response in this *Response to Comments* document. Regarding the costs to drill a new well, the EPA has made adjustments described in section 13.3.6 of the EPA response in this *Response to Comments* document that have increased the cost estimates for drilling a new well.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045051)

In addition to the overall concern the NJDEP has with the National Cost Estimate, the NJDEP recommends that EPA evaluate its estimate of the number of public water systems that would feasibly be able to select non-treatment options. Section 5.3.3.1 (Decision Tree for Technology Selection) in this document outlines the process that EPA used to determine what treatment technology or non- treatment option a public water system would select based on the three inputs the decision tree accepts. Table 5-8, located in this section, notes that 8% of public water systems, both those with design flows less than one MGD and those with design flows of one to ten MGD, would opt for interconnection or new wells, both non-treatment options. While this outcome may be accurate in a theoretical setting, regional differences in geology and local governance issues render it far harder for many small systems in certain regions of the US to opt for non-treatment options.

The NJDEP urges the EPA to take into consideration these issues raised regarding the choosing of non- treatment options in the model. This gap could possibly be bridged by including additional inputs for the decision tree that would account for varying geology (and how those differences may limit the drilling of new wells) and a measure of distance to the next available PWS to determine the feasibility of interconnection.

In no way should NJDEP comments concerning estimated costs be construed as a lack of support for the proposed standards, which NJDEP finds to be a critical measure necessary to better protect public health, safety, and the environment from the myriad and significant risks associated with PFAS.

EPA Response: The EPA agrees that the availability of non-treatment options will vary greatly on a system-specific and regional basis. The EPA did not have sufficient data to incorporate variations in geology or distance to the nearest PWS in the model. Furthermore, given that the EPA assumed that a limited number of systems nationwide would be able to choose non-treatment options, it is not clear that the inclusion of these additional variables would significantly change the results. Please see section 13.3.6 of the EPA response in this *Response to Comments* document for further discussion of factors the EPA considered when estimating the number of systems that would opt for interconnections or new wells.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045115)

b. Alternatives such as drilling a new well and installing it should be evaluated from a cost perspective. In Vermont, the cost per source is ~$100,000-200,000 assuming you own the property, and the well is not very deep. The yield of the source will influence the unit (cost/household).

EPA Response: The comment lacks sufficient detail to compare these costs to the results of the EPA's WBS models. Even a rough comparison would require information on well capacity (i.e., design flow). Also, although the comment indicates the well is "not very deep," it provides no quantitative information for comparison with the EPA's default assumption of 250 feet. See also sections 13.3.3 and 13.3.6 of the EPA response in this *Response to Comments* document.

Las Cruces Utilities (LCU) (Doc. #1753, SBC-043913)

In response to Section XI-Treatment Technologies, EPA requests comment on whether there are additional technologies which are viable for PFAS removal to the proposed MCLs as well as any additional costs which may be associated with non- treatment options such as water rights procurement.

• Additional costs for non-treatment options could include easements, land acquisition, in order to obtain necessary water rights. Planning, design, and construction costs would also be incurred for either interconnection or new well options, there may be a need to seek new water sources outside of the local area which would require large transmission lines, large amount of energy consumption and fossil fuels to be used, in order for the water to be delivered to the residents of Las Cruces.

EPA Response: The EPA's cost estimates for new wells explicitly include land acquisition. The land area purchased is based on the well and building footprint plus buffer space for access around all sides. The EPA does not have nationally representative information to estimate additional easement costs beyond the purchase price of land. The cost estimates for interconnection explicitly include 10,000 feet of transmission piping sized to accommodate the required design flow. The cost estimates for both options include planning, design, and construction costs, specifically mobilization and demobilization, geotechnical evaluation, process engineering, construction management, and general contractor overhead. To account for other site-specific considerations for water systems pursuing non-treatment options, the EPA also increased the complexity factor applied to estimate contingency. Please see section 13.3.6 of the EPA response in this *Response to Comments* document.

In response to comment on costs for water rights procurement, the EPA did not have sufficient data to incorporate these potential costs. Further, it is reasonable to assume that water systems that may face prohibitively high water rights procurement associated costs would elect a more cost effective option, including the treatment options available to comply with the rule. While the

EPA notes water scarcity issues are a challenge in parts of the country, other parts of the country do not have these limitations to nearly the same degree. Irrespective of whether the EPA's estimate of 2 percent of systems nationwide would seek a new source is accurate, inclusion of these potential additional costs would not significantly change the national results.

Please see section 13.11 in this *Response to Comments* document for the EPA's response to comments on greenhouse gas emissions associated with the rule.

American Water Works Association (AWWA) (Doc. #1759, SBC-045615)

• Unit Cost of Purchased Water: According to the proposal, an assumed average cost of purchased water is $3.00 per thousand gallons (2021$) based on wholesale rates that were available online. Currently there are 3,258 water systems in SDWIS categorized as wholesaler systems. These systems range in service population size from 25 to up to 2.5 million persons, which represents a significant range in their economy of scale. The WBS for non-treatment options and the documentation that is provided does not clearly illustrate what data were considered to estimate the national average cost of purchased water and whether those data are nationally representative. It is possible that if the available data may be only from cities with a water supply that is relatively inexpensive to treat and supply to purchasers. Transparency on this data is necessary to ensure that this unit cost is accurate and reflective of the national perspective. EPA should therefore provide the underlying analysis and an explanation for the model provided in order to allow for a meaningful opportunity for public comment.

To further illustrate this, a report by the Department of Energy from 2017 assessed water rates nationally and estimated that in 2016 the average water rate was $3.38 per thousand gallons (DOE, 2017). More recent data from Circle of Blue similarly analyzed water rates nationally and estimated that average national water rate in 2019 to be $6.22 per thousand gallons (Circle of Blue, 2019). These national data points highlight a stark difference between the EPA's data and highlight that water rates have increased substantially as water supplies have become more severely impacted by drought and water quality challenges. Additionally, it is important to note that both reports do not reflect water system cost increases related to LCRR, the economic effects of the COVID-19 pandemic (e.g., increased price of chemicals, materials, and labor).

These cost increases have been previously described in this letter. EPA should clearly communicate the sources of the wholesale water rate data so that additional supporting data can be provided to improve EPA's analysis.

EPA Response: For the final rule, the EPA used a cost for purchased water of $3.17 in 2022 dollars, based on unit costs from 6 wholesalers collected between 2019 and 2022. The DOE data cited by the commenter appear to be rates charged to retail commercial or industrial users. The Circle of Blue data (https://www.circleoofblue.org/waterpricing/) are retail residential rates. Neither of these sources reflect wholesale rates charged to interconnected water utilities and are therefore not appropriate for inclusion in the EPA's costs analysis.

American Water Works Association (AWWA) (Doc. #1759, SBC-045613)

• Simultaneous Compliance with LCRR: LCRR became effective in 2021 and water system compliance with all provisions of the current LCRR will be required in October 2024. Water systems are required to fully evaluate and ensure adequate corrosion control when adding or changing sources of water. Specifically, LCRR expands on existing requirements to include this assessment when adding new sources as previously described. The challenges posed by LCRR will impact the number of systems for which purchased water from wholesale supplier is a viable near-term option. Furthermore, if both systems are using CCT, the compatibility of each CCT must be considered.

• Simultaneous Compliance with Microbial and Disinfection Byproduct Rules: As noted previously, regionalization can provide benefits but can also have negative impacts on water quality particularly because of increased water age. For systems that install an interconnection to a consecutive system, a thorough investigation will be needed to determine if water age will be an issue and whether DBPs may need to be addressed at the to prevent MCL violations. This could potentially require systems installing interconnections to install GAC filters and/or transition to a different disinfectant residual. Similarly, systems may determine that inadequate disinfectant residual is present in the water to support the longer water age and so a boosting station is required.

EPA Response: Regarding simultaneous compliance considerations when evaluating interconnection as a compliance option, please see section 13.3.6 of the EPA response in this *Response to Comments* document. For the EPA's response to simultaneous compliance generally comments, please see section 10.4.2 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-053040)

• Available Capacity Without Improvements: Finally, the EPA's approach makes a blanket assumption that these water systems will be able to identify a supplier water system that has existing available capacity to provide finished drinking water with PFAS levels below the MCL without needing to install any treatment. It is highly likely that a supplier will need to install additional drinking water treatment systems to accommodate the purchasing water system's water supply capacity. This is an especially important consideration for regions of the U.S. where drought is creating water supply challenges already as well as areas where source waters are becoming increasingly challenging with respect to accessibility and ease of treatment. On top of this challenge, there is a significant possibility that the PFAS contamination impacting a purchasing water system is also impacting the supplying water system, especially given the low levels of concern identified by the proposal. In this case, the system providing water supply would need to install PFAS treatment capacity for their current water supply capacity in addition to the purchasing water system's demands.

EPA Response: The EPA agrees that the availability of alternative water sources will vary greatly on a system-specific and regional basis. For this reason, the EPA assumed that only a limited number of systems nationwide would be able to purchase water as a compliance option. The EPA further assumed that the purchased water would be from a source that does not need to treat for PFAS. The EPA recognizes this may result in a slight underestimate of national compliance costs. Please see section 13.3.6 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-053042)

Finally, in review of the EPA's example outputs for interconnections, the projected costs for a 1 MGD interconnection with mid-cost components were estimated to be less than the projected costs for a 0.5 MGD interconnection with low-cost components. It's unclear whether the model requires correction. Nonetheless, EPA is encouraged to review the model and subsequent cost analysis to ensure that this and other potential errors are addressed prior to using this analysis to support any final rule.

EPA Response: The commenter is correct that costs for the larger, mid-cost example were lower than for the smaller, low-cost example. The EPA reviewed the model and determined that this counter-intuitive result was not caused by an error in calculation. Instead, it was an artifact of the minimum size of interconnecting piping, limited choice of acceptable materials, and default assumptions about indirect costs. Specifically, direct capital for these two systems were identical because equipment sizes and materials were the same. Indirect capital was slightly lower for the larger system because of the lower process engineering and mobilization/ demobilization percentages assumed for medium systems, resulting in a lower total cost. In the final rule, the EPA has added the cost of booster pumps for interconnecting systems, which eliminates this discrepancy in the example outputs. Please see section 13.3.6 of the EPA response in this *Response to Comments* document for discussion of the addition of booster pumps.

American Water Works Association (AWWA) (Doc. #1759, SBC-053045)

Development of New Wells

EPA also estimates that some water systems will develop new wells instead of installing treatment. The development of new wells also relies on assumed conditions that may make the development of new wells to be more cost effective than treatment. One key assumption is that the PFAS contamination impacting the water system's current groundwater source is not impacting another local source where a new well can be constructed. This is a flawed assumption and likely overestimates the number of water systems for which this is a viable option.

EPA Response: The EPA continues to believe that the record supports the assumption that 2 percent of small water systems nationwide will be able identify a new well that is contaminated to a lesser degree than their current groundwater source; this is supported by the record for the proposal (see Chapter 5 of the EA for proposal) as well as public commenters who

provided information on drilling a new well to reduce PFAS concentrations in supplied water. The EPA agrees that the availability of non-treatment options will vary greatly on a system-specific and regional basis. For this reason, the EPA assumed that only a limited number of systems nationwide would be able to choose these options. Please see section 13.3.6 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-053047)

This option also appears to be underestimating the costs for performing this task. In review of the example cost model outputs for a new well of 0.5 MGD, several aspects of the cost estimate are significantly low. A recent budgetary estimate for a water system in Pennsylvania for a new well with a capacity of 0.144 MGD is approximately $1.5 million, which does not include planning and design services totaling another $532,000 (Horsham, 2023a).

The referenced budgetary estimate was compared with EPA's model output for the development of a new 0.5 MGD well. Several aspects of the project are substantially low compared with the referenced estimate. Construction management, for example, is estimated to be less than $16,000 by EPA'S WBS whereas the construction management services for this recently developed well will exceed $175,000. The overall cost of this well will exceed EPA's estimate by a factor of 5 for a well that has less than a third of the capacity. Another water system in Washington submitted comments to the EPA similarly illustrating that these costs are underestimated by a factor of 4 (LWD, 2023).

In order to provide an accurate assessment of costs, EPA must therefore re-evaluate the WBS for new wells and address errors in its estimates prior to using its new well costing analysis to support any final rule.

EPA Response: The updated cost curves the EPA developed for the final rule estimate a range of capital costs of approximately $272,000 to $587,000 for a 0.144 million gallon/day new well. Although the commenter's budgetary estimate exceeds the EPA's range, the comment does not include information to confirm that (1) all the estimated costs would be directly associated with replacement of the PFAS-contaminated source, as opposed to other infrastructure improvements, and (2) that design parameters (e.g., well depth, distance to distribution system) for this facility would be similar to the typical values assumed in the EPA's estimate. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-053010)

Interconnections

EPA anticipates that some water systems may take non-treatment actions to respond to PFAS levels above the MCLs, such as the installation of an interconnection. Overall, AWWA agrees that some systems could potentially decide to install an interconnection if it is a viable alternative. Regionalization may have benefits for consecutive systems and can help provide

smaller systems with access to economies of scale. Alternatively, regionalization can have unintended consequences on the water quality for the consecutive system, such as elevated water age, nitrification, and DBPs. For this reason, systems considering interconnections will need to thoroughly investigate this option and determine if it is both cost effective and appropriate given the water quality impacts.

For the analysis, EPA estimates that upwards of 7% of small systems will install an interconnection to comply with the PFAS MCLs, it is unclear from the supporting information how this assumption was made, and EPA should provide additional information. The potential use of an interconnection to comply with the proposed rule has not previously been included as part of a drinking water rule's compliance analysis and the EPA's approach poses significant issues that exclude significant cost factors. AWWA is providing the following recommendations for necessary considerations for installing interconnections.

• Compatibility of Secondary Disinfectants: The use of disinfectants for maintaining a residual in the distribution system varies by system and not all systems use the same disinfectant chemical to maintain distribution system residuals (if they are required to). The selection of a disinfectant for maintaining a residual is not regionally uniform and varies on a number of other factors (e.g., water source, finished water quality, distribution system size, water supply capacity, etc.). Subsequently, there is a significant likelihood that a purchasing system may be using a different disinfectant than a supplying water system, which would require the installation of a facility that can convert free chlorine to chloramine, or vice versa. Some systems may need pH adjustment as well. EPA's cost analysis for interconnections does not consider this. If needed, disinfectant conversion facilities require substantially more upgrades than the EPA's WBS for interconnection considers. Costs for these facilities will need to include, at a minimum:

o Land purchasing,

o Building construction, Chemical feed pumps, storage tanks, and spill containment,

o Mixing and storage tanks, and

o Water quality monitoring devices.

EPA Response: The EPA agrees that there are many considerations for water systems pursuing interconnections, please see section 13.3.6 of the EPA response in this *Response to Comments* document for more information. Based on this and other comments, the EPA incorporated contingency at all cost levels and increased the complexity factor applied to estimate contingency for systems using non-treatment options. The EPA did not explicitly include the cost of disinfectant conversion facilities because the need for these facilities, along with the associated design and operating requirements is highly system specific. Systems with extensive such needs would likely not find interconnection cost-effective. Accordingly, the EPA assumed only a small percentage of systems could use this option.

American Water Works Association (AWWA) (Doc. #1759, SBC-045614)

Pressure Differences: In Table 5-15 of the Economic Analysis, the EPA notes that booster pumps and/or pressure reducing valves are included as direct capital costs by the WBS cost model. The agency later notes, however, that to generate cost equations for interconnections the agency has assumed a minimal pressure difference between each water system so that neither booster pumps nor pressure reducing valves are needed. AWWA understands that it may be impossible for the agency to surmise the average pressure difference between two water systems, however it is nonetheless unrealistic to assume that booster pumps are unlikely to be necessary. Pressure loss associated with friction could be significant, especially for an interconnection that may span 10,000 feet or more. For an interconnection of this distance, the pressure loss associated with water flow through an appropriately sized pipe (to maintain water velocity from 5 to 7 feet per second), would be approximately 50 psi. The inclusion of purchasing booster pumps, at minimum, should be included as part of this analysis.

EPA Response: The EPA agrees that booster pumps may be needed for interconnecting systems. For the final EA, based on this and other comments, the EPA added the costs of booster pumps designed to account for friction loss in interconnecting piping. Please see section 13.3.6 of the EPA response in this *Response to Comments* document.

Western Urban Water Coalition (WUWC) (Doc. #1768, SBC-043948)

C. Alternative Water Supplies

EPA requested additional comments on whether there are additional technologies which are viable for PFAS removal to the proposed MCLs, as well as any additional costs which may be associated with "non-treatment options," such as water rights procurement. [FN29: 88 Fed. Reg. at 18731.] EPA selected an economic model to evaluate costs of certain non-treatment options as part of its EA, including the construction of replacement groundwater wells in an uncontaminated aquifer or purchasing replacement water from other public water systems. [FN30: EA at 5-9–5-40]

WUWC is concerned that the selected modeling does not adjust for regional differences in alternative water supply costs and availability. In the arid western United States, where the majority of WUWC members reside, periods of prolonged drought, population growth, and other stressors have constrained water supplies to a greater degree than experienced in other areas of the country.

For example, in areas of the western United States that are reliant on groundwater for a significant portion of their water supply, our members report that the costs to produce and treat groundwater to potable quality are already rising. Aquifers stressed by drought and population growth in many areas of the West have experienced significant drawdown, meaning that new or replacement water supply wells must be drilled deeper, increasing water utilities' drilling costs and energy expenditures to pump groundwater. [FN31: See, e.g., U.S. Geological Service,

Groundwater Decline and Depletion (June 6, 2018), available at https://www.usgs.gov/special-topics/water-science-school/science/groundwater-decline-and-depletion#overview.] One of our members has reported that, where an aquifer serving as a primary water supply became contaminated with PFAS, the infrastructure and incremental operational costs of replacing that supply totaled approximately six million dollars. That capital cost translated to an approximately $300 per person increase ($882 per tap) over a two-year period, the effect of which is ultimately borne by ratepayers.

Water utilities in the West have increasingly been looking to diversify water supplies through commissioning recycled water projects, including projects supported by EPA funding opportunities. Our members report that recycled water projects can be capital intensive and difficult to achieve to due significant hurdles with permitting, environmental review, and agency staffing limitations. The Proposed Rule will only make utilities' water supply diversification strategies more expensive. To the extent that EPA's financial modeling supporting the Proposed Rule has not considered these differences, WUWC believes EPA has not conducted sufficient analysis to draw conclusions about the economic feasibility of obtaining alternative water supplies.

EPA Response: The EPA agrees that the availability of non-treatment options will vary greatly on a system-specific and regional basis. For this reason, the EPA assumed that only a limited number of systems nationwide would be able to choose these options. The comment lacks sufficient detail to compare the provided costs to the results of the EPA's WBS models. Please see section 13.3.6 of the EPA response in this *Response to Comments* document for discussion about considerations that water systems are likely to evaluate when selecting a non-treatment option, and the EPA response to comment Doc. #1753, SBC-043913 in section 13.3.6 in this *Response to Comments* document for discussion about limitations for obtaining other water supplies.

Eastern Municipal Water District (EMWD) (Doc. #1780, SBC-043821)

EPA's cost assessment does not fully capture the costs that will be borne by water agencies and ratepayers. As an agency that provides water, wastewater, and recycled water services, we have a deep appreciation for the severe and far-reaching impacts that can occur when PFAS is detected. EMWD has shut off three wells due to PFAS contamination, and we were compensated by the Department of Defense to bring one of those wells back in to service as the cause of contamination was legacy fire fighting training on a U.S. Air Force Base. EPA's Proposed Rule discusses replacement water as an alternative to treatment, which is not a viable option. Replacement water is not readily available to most agencies in the arid west, and when additional supplies can be developed, those new projects are very expensive. EMWD is already maximizing all available local resources such as recycled water and brackish groundwater. Developing new replacement water would be very expensive, and for EMWD, importing additional water as a replacement source would place a greater burden on the Colorado River and the Sacramento San Joaquin Delta.

EPA Response: The EPA agrees that the availability of non-treatment options will vary greatly on a system-specific and regional basis. For this reason, the EPA assumed that only a limited number of systems nationwide would be able to choose these options. Please see section 13.3.6 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046173)

[The analysis that follows shows that the $3.1 billion dollar difference in annualized cost can be explained by the following primary factors:]

4. Non-treatment compliance options. AWWA assumes all PWSs that exceed the MCL will install treatment at every entry point, and EPA assumes that small systems will explore interconnections with other complying systems and new sources before installing treatment. As one example, Michigan Department of Environment, Great Lakes, and Energy (EGLE) personnel have indicated that it is policy to investigate safe water options before considering installation of treatment on a source that exceeds an MCL (Smith, Personal Communication 2023). Michigan's analysis exploring the existing Michigan MCLs and the proposed EPA rule indicates that EPA's estimates of systems opting for non-treatment are reasonable and may even be low (Smith, Personal Communication 2023). Michigan anticipates that up to 26% of PWSs requiring treatment may be able to establish a new connection with another PWS that already meets the MCLs. In this case, both the EPA and the AWWA cost estimate for treatment may be high. Using EPA's assumptions for establishing new interconnections or new sources would result in at least $159 million in savings compared to AWWA. (Appendix D).

[The analysis that follows shows that the $3.1 billion dollar difference in annualized cost can be explained by the following primary factors:]

EPA Response: The EPA agrees that the availability of non-treatment options will vary greatly on a system-specific and regional basis. For this reason, the EPA assumed that only a limited number of systems nationwide would be able to choose these options. Please see section 13.3.6 of the EPA response in this *Response to Comments* document. The EPA also agrees with the commenter's conclusions about the sources of differences between the EPA's estimate and the AWWA B&V report estimates. Please see section 13.3.3 of the EPA response in this *Response to Comments* document.

The District of Columbia Water and Sewer Authority (Doc. #1829, SBC-045771)

We also note the optimistic nature of the assumptions associated with those systems who may opt to purchase water from a wholesaler through an interconnection rather than install and operate treatment.

Interconnections may be a more economical solution than treatment for some small systems. However, the assumptions made by EPA are overly simplistic. Interconnects are not without their challenges. Compatibility of the new water supply and the existing supply must consider the

secondary disinfectant (free chlorine or chloramines), corrosion control treatment (do the systems both practice the same corrosion control treatment), water age impacts, pressure, and supply redundancy (need for storage). The assumption that an interconnection can be made by simply connecting one water system to another is likely the exception rather than the rule. It should be assumed that booster pumping, storage, and disinfectant boosting are required at all interconnects to appropriately account for the costs of interconnections for small water systems.

The accuracy of the Proposal's cost evaluation is the foundation to an accurate NRRCA and affordability evaluation. Based on our experience, the EPA cost model significantly underestimates the capital and O&M costs associated with PFAS treatment. We recommend that EPA reevaluate its cost estimates and consider inflation and supply chain issues likely to result from the Proposal in its revised evaluation.

EPA Response: The EPA agrees that there are many considerations for water systems pursuing interconnections and therefore the EPA increased the complexity factor applied to estimate contingency for systems using non-treatment options. The EPA also added the costs of booster pumps designed to account for friction loss in interconnecting piping. Please see section 13.3.6 of the EPA response in this *Response to Comments* document. For the EPA's response to comments on water treatment costs, please see section 13.3.3 in this *Response to Comments* document.

New England Water Works Association (Doc. #1836, SBC-045391)

Regional connections are a possibility to achieve compliance, but interconnections with neighboring communities to provide an alternative water source may pose challenges in terms of cost and time required to design, permit, and construct the needed infrastructure, as well as potential incompatibility with that water. It is important to note that there are many water systems in New England where interconnections or participation in regional supplies will just not be possible and that is likely the case across the nation, but the option should exist to allow interconnections as a potential compliance avenue.

EPA Response: The EPA has included in the cost analysis the cost and time required to design, permit, and construct the needed infrastructure associated with interconnections. Regarding, "potential incompatibility with that water," please see the EPA response to comment Doc. #1601, SBC-042906 in section 13.3.6 in this *Response to Comments* document and section 13.3.6 of the EPA response in this *Response to Comments* document. The EPA agrees that the availability of non-treatment options will vary greatly on a system-specific and regional basis. The EPA acknowledges that interconnections and new sources may not be a viable or the most cost-effective option in many cases. For these reasons, the EPA assumed that only a limited number of systems nationwide would be able to choose these options. Please see section 13.3.6 of the EPA response in this *Response to Comments* document.

13.4 Method for Estimating Quantified Benefits

Summary of Major Public Comments and EPA Responses

The EPA received comments from industry groups and organizations representing water utilities about the EPA's methodology for estimating quantitative benefits associated with the NPDWR. While some commenters supported the EPA's analysis, a few commenters stated that the agency overestimated quantified benefits. These commenters asserted that the EPA overstated the benefits of the rule and that the HRRCA is flawed because the existing health evidence does not support the quantified benefits.

The EPA disagrees with commenters that the existing evidence does not support the EPA's estimate of quantified benefits from avoided adverse health effects likely to occur as a result of drinking water treatment and that these benefits are overstated. The EPA reviewed the best available science on health effects associated with exposure to the PFAS considered in the rulemaking. Among other things, the EPA has used the best available science in three key respects: by 1) considering relevant peer-reviewed literature identified by performing systematic searches of the scientific literature or identified through public comment, 2) relying on peer-reviewed, published EPA human health risk assessment methodology (USEPA, 2022c), and 3) utilizing peer-reviewed methodologies to valuing and quantifying avoided adverse health outcomes. Specifically, the EPA identified the full range of expected human health outcomes, including quantified benefits associated with co-removal of co-occurring contaminants (i.e., disinfection byproducts (DBPs)). This process was built upon multidisciplinary research, including hazard identification and dose-response analysis, exposure assessment, and economic valuation methods recommended by the EPA's Guidelines for Preparing Economic Analyses (USEPA, 2016a) and updated Circular A-4 Guidance (OMB, 2023) to enumerate all beneficial outcomes, identify beneficiaries, and determine human health endpoints that can be valued. The EPA employed state-of-the-science reviews and weight of evidence assessments to identify and select studies for dose-response information in the EA. The risk assessment guidance and best practices serve as the basis for the PFOA and PFOS health effects systematic review methods used to identify, evaluate, and quantify the available data (USEPA, 2022c). In addition to using the most current literature, the EPA relied on state-of-the-art approaches for synthesizing information from the available studies (e.g., regression-based meta-analysis of studies reporting associations between PFOA/PFOS and total cholesterol). The EPA also carefully examined the critical aspects of the dose-response functions such as type of the effect (e.g., change in risk factor such as total cholesterol), temporal nature of the effect (e.g., lifetime risk or risk by a certain age), eligible population (e.g., persons without prior cardiovascular disease history). To model a chronic/persistent health effect associated with PFAS exposure (i.e., cardiovascular disease, cancer) the EPA relied on lifetable-based modeling to account for population overall survival trends and competing risk of death from other causes. To ensure soundness of its analysis, the EPA has considered the input of numerous outside reviewers (between the Science Advisory Board's (SAB) review, the letter peer reviews, and the journal peer reviews, the EPA

notes that dozens of outside peer-reviewers have shared their input on various underlying components of this economic analysis).

One commenter criticized the EPA's evidence integration strategy, asserting that toxicogenomic data are useful for identifying genomic evidence to support risk analyses. The EPA disagrees with this commenter's evidence integration strategy. The commenter cites Chen et al. (2022), which claims to have integrated toxicological and Physiologically-Based Pharmacokinetic (PBPK) modeling for PFOS. This study used "available human in vitro and mouse in vivo toxicogenomic data" to identify genomic evidence. Unlike the EPA's Toxicity Assessments (USEPA, 2024h; USEPA, 2024i), the study does not incorporate study quality evaluation or other strength of evidence metrics. This study's reliance on toxicogenomic data is also in contrast to the EPA's approach as recommended in the EPA's Benchmark Dose Technical Guidance document (USEPA, 2012). The Integrated Risk Information System (IRIS) handbook is clear in its recommendation that human data are generally preferred for the derivation of toxicity values, compared to laboratory or animal data (USEPA, 2022c). For detail on the strength of the human epidemiological evidence supporting analyses of renal cell carcinoma (RCC, birth weight, and cardiovascular disease (CVD), see sections 4.1.4 and 4.2.1 of the EPA response in this *Response to Comments* document, as well as the EPA response to comment Doc. #1774, SBC-045685, SBC-053211, SBC-053281, SBC-045682, and SBC-045683. Moreover, Chen et al. (2022) also notes that there are limitations to using toxicogenomic data for traditional risk assessments. For these reasons, the EPA does not think that this study relies on the best available science, nor is it appropriate for the EPA to consider when evaluating avoided adverse health outcomes and benefits for purposes of the PFAS NDPWR.

The EPA assesses potential benefits quantitatively where (1) there is indicative (likely) evidence of a relationship between exposure and a health effect response, (2) it is possible to link the health outcome (e.g., CVD) to risk of a health effect (e.g., increased total cholesterol [TC]), and (3) there is no overlap in effect with another quantified endpoint in the same outcome group. The EPA's quantification of health benefits resulting from reduced PFAS exposure in drinking water is driven by the availability of PFAS related occurrence estimates, pharmacokinetic (PK) models, information on exposure-response relationships, and economic data to monetize the impacts.

One commenter developed a benefits estimate that used a bounding estimate of the benefits of reducing PFOS in drinking water. First, the commenter assumed that a 10 percent genomic or cellular change leads to a person suffering a disease. The EPA disagrees with this assumption as it appears to be an arbitrary assumption of the model in the source paper that the analysis cites (Chen et al., 2022). Additionally, citing Chen et al. (2022) and Chou and Lin (2020), this commenter makes another bounding assumption that "there is little significant biological activity at doses below 20 ng/kg/day" for PFOS and consequently excludes those exposed below 20 ng/kg/day from the benefits estimation. The EPA disagrees with this approach and the commenter's rationale for this assumption. Currently, the EPA's peer-reviewed methodology does not provide guidance or recommendations for using in vitro/mechanistic data for risk assessment, as is also acknowledged by Chen et al. (2022) who state that "the methodology to

incorporate toxicogenomic data into a PBPK model to inform risk assessment remains to be developed." Furthermore, the analyses in Chen et al. (2022) and Chou and Lin (2020) are based on outdated RfD information (e.g., 2016 HA RfD). As described in Table 6-48 of the EA, derivation of PFOA/PFOS exposure-response functions for the relationship between serum PFOA/PFOS and associated health outcomes in the EPA benefits analysis assumes that there are no threshold serum concentrations below which effects do not occur (USEPA, 2024b). This is appropriate because the EPA's Final Human Health Toxicity Assessments indicate that adverse effects occur in populations exposed to wide range of exposure levels, including exposure levels below 20 ng/kg/day.

One commenter stated that the EPA did not provide data to support the analysis of benefits predicted from the implementation of the Hazard Index MCL. The EPA disagrees with the commenter that the EPA did not provide data to support Hazard Index MCL benefits. As discussed in section XII of the preamble and in Appendix K of USEPA (2024c), the EPA evaluated the impacts of PFNA on birth weight in *quantitative* sensitivity analyses. Because the EPA did not include these estimates in the national quantified benefits analysis, in instances where PFNA is present, the national quantified benefits are likely underestimated. However, these benefits are considered quantitatively as part of this EA in the sensitivity analysis and support the EPA's decision to regulate PFNA. Furthermore, in section XII of the final rule and in Section 6.2 of the EA (USEPA, 2024b), the EPA qualitatively summarized and considered the potential health benefits resulting from reduced exposure to PFAS other than PFOA and PFOS in drinking water (including PFNA, HFPO-DA, PFHxS, and PFBS), as recommended by the EPA's Guidelines for Preparing Economic Analyses and OMB Circular A-4 (USEPA, 2016a; OMB, 2023). These qualitative potential health benefits are based on summaries of a significant body of peer reviewed science. As summarized in the EA, the qualitatively discussed health impacts of these four PFAS are considerable and include cancer, birth weight, endocrine, immune, and hepatic effects; reducing human exposure to them is expected to reduce the incidence of adverse health impacts including cardiovascular, developmental, and immune effects for Hazard Index PFAS. The qualitative benefits discussion of the impacts of the four PFAS which are regulated through the Hazard Index, as well as their co-occurrence in source waters containing PFOA and/or PFOS and additive effects, supports the EPA's decision to regulate them thought the Hazard Index in this rulemaking.

For responses related to comparison between the EPA's PFOA and PFOS toxicity assessments and other Agencies' health assessments, please see response to comment section 4.2.6 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-053384)

ESTIMATES OF THE SOCIAL BENEFITS AND SOCIAL COSTS FROM EPA'S PROPOSED REGULATORY ACTION

Recognizing these flaws, this analysis provides a methodology to overcome many of them. The analysis uses the engineering firm's cost estimates to estimate the treatment costs, EPA's data for the occurrence and monitoring costs of the rule, and EPA's estimates for the economy-wide social costs of the proposal. The analysis uses EPA data to estimate and to value the social costs of greenhouse gas emissions that would be caused by the proposed requirement. As shown in Table ES-1, the social costs are projected to be at least seven times greater than EPA's estimates.

EPA's benefit estimates for PFAS treatment place too much weight on a few possible adverse effects and too little weight on the range of potential adverse effects EPA describes in the supporting documents. Ultimately, EPA's quantified benefit estimates rest on scientific findings that other public health organizations do not support. By failing to account for the possibility that these adverse effects may not exist, EPA overstates the social benefits it quantifies.

Therefore, this analysis' objective is to identify the most comprehensive evaluation of possible biologic changes in response to PFOS exposure. An adverse effect should start with biologic change; if there is little change in response to PFOS exposure at a certain dose, the likelihood of an adverse effect at that dose is greatly diminished. The analysis estimates the social benefits by harnessing recent studies that carry out longstanding practices recommended by the National Academy of Sciences (NAS) to develop hazard assessments that use more of the available scientific information and are more compatible with benefit-cost analysis.

Rather than EPA's approach to quantify a few adverse effects, this analysis considers a wide range of cellular and genomic evidence, animal data, and human epidemiological studies. Based on published studies, the analysis considers 108 diseases that are associated with cellular and genomic responses in in vitro testing. Using the results of Bayesian mathematical evidence integration, the analysis identifies 108 diseases and estimates the probability of these diseases occurring in individuals at different levels of PFOS in drinking water.

Since these studies find that changes in biological activity are likely only to occur at the high end of the modeled drinking water exposure, the analysis develops a bounding estimate of the benefits of reducing PFOS in drinking water. The purpose of the bounding estimate is to establish an upper bound of the possible benefits for PFOS. The bounding estimate assumes conditions that clearly are not realistic and clearly overestimate the likelihood of an adverse effect for several reasons. First, the analysis assumes that a 10 percent genomic or cellular change leads to a person suffering the disease. This outcome is implausible since that change may not be large enough to be significant; since there is an additional 30-fold safety factor

applied to this 10 percent change, and since the body has numerous repair mechanisms that respond when there is abnormal biological changes.

Second, the bounding estimate assumes that the current population's path towards these diseases is halted and is reversed by the drinking water standard. This assumption leads to 90 percent of the total benefits. A more realistic approach would be to assume, as EPA does in the EA, that reducing exposure today causes small changes to the baseline probabilities of contracting a disease. As an illustration, EPA may assume the MCL changes a 60-year old's odds of getting CVD in the future from 23 percent to 22.95 percent; the bounding estimate assumes that all of the exposed 60-year olds' probabilities of contracting CVD from PFOS exposure are eliminated.

Therefore, the bounding estimate shows that, even if all PFOS exposure above any level that shows some biological activity is certain to cause a disease, the benefits are still five times lower than the expected costs. The results of this bounding estimate are shown in Table ES-1. Even with many implausible assumptions to increase the social benefits, the results for PFOS are six times lower than the expected social costs. It is likely that the social benefits are at least ten times lower than this bounding estimate based on the scientific evidence.

Table ES-1: Comparison of Estimated National Annualized Benefits and Costs for EPA's Proposed Rule

[Table ES-1: see docket ID EPA-HQ-OW-2022-0114-1738]

EPA Response: See section 13.3 of the EPA response in this *Response to Comments* document for the EPA's response to comments on the costs of the rule. The EPA disagrees with the commenter's suggested approach to selecting health endpoints and quantifying benefits. As described in sections 4.1.2, 13.4 and 13.8 of the EPA response in this *Response to Comments* document, the EPA relied on the best available science and data to evaluate costs and quantify benefits of the rule and to support the agency's conclusions presented in the Final Toxicity Assessments for PFOA and PFOS (USEPA, 2024h; USEPA, 2024i). The EPA disagrees that other health agencies "do not support" the agency's analysis. Regarding the commenter's comparison to findings from other public health organizations and request for inclusion of additional endpoints, see section 4.2.6 of the EPA response in this *Response to Comments* document.

The EPA disagrees with many of the assumptions in AMWA's benefits modeling exercise and AMWA's conclusions, as AMWA's analysis does not adhere to standard modeling practices and makes assumptions that are not fact based or scientifically valid. Specifically, the EPA disagrees with the commenter's suggestion to use an arbitrary assumption "that reducing exposure today causes small changes to the baseline probabilities of contracting a disease." See the EPA response to comment Doc. #1738, SBC-046013 in section 13.4.5 in this *Response to Comments* document for the EPA's response to AMWA's claim that "changes in biological activity are likely only to occur at the high end of the modeled drinking water exposure." Additionally, the EPA disagrees with the commenter's assumption that a 10 percent genomic or cellular change leads to a person suffering a disease. See section 13.4 of the EPA response in this *Response to Comments*

document for the EPA's response to AMWA's bounding assumptions. The EPA's approach to modeling reductions in health effects resulting only from changes in PFOS exposure under the rule relies on the best available science, as described in section 13.4 of the EPA response in this *Response to Comments* document. Specifically, the EPA determined attributable risk by reviewing existing literature to establish a population attributable fraction (PAF) of adverse health outcomes associated with environmental exposure, as described in Section 6.1.2 of the final rule EA (USEPA, 2024b). The agency then estimated changes in PFOA and PFOS exposure-attributable share of adverse effects incidence associated with promulgation of the rule. This analysis assumes that removal of PFOA and PFOS-related exposure would not alter the distribution of risk factors the exposure does not affect. The EPA also notes that AMWA's statement that benefits from reducing exposure to PFOS in drinking water are six times lower than the expected social costs are based on arbitrary assumptions. As described in section 13.3.3 of the EPA response in this *Response to Comments* document, the EPA disagrees with many of the assumptions made in the AWWA B&V report (also cited by AMWA).

Minnesota Pollution Control Agency (MPCA) (Doc. #1569, SBC-042496)

Section XIII - Health risk reduction and cost analysis (HRRCA)

Topic: Part J, Overall cost-benefit determination:

MPCA comments: Overall, MPCA finds EPA's methods to determine net benefits of enacting the MCLs are reasonable and rigorous to the extent of data availability. MPCA notes the inclusion of a number of non-quantifiable costs and particularly, benefits.

We wish to comment further on two topics:

First topic: Use of the 3% discount rate or less to evaluate net benefits is strongly supported, for the following six reasons, at a minimum:

1. It is reasonable to use a low discount rate in analyses concerned with the health impacts of forever chemicals associated with debilitating diseases including cancer which could carry over to future generations.

2. Several benefits from avoiding these diseases are non-quantifiable and hence not incorporated into the calculation.

3. Benefits from being able to target and remove co-occurring chemicals using the same technology, were also not incorporated into the calculations but are real benefits to water users.

4. While treatment technology costs are high, the bipartisan infrastructure law provides financial aid for public water supplies and includes special provision for small systems.

5. Health impacts associated with contaminated water disproportionately impact environmental justice (EJ) areas. Restricting PFAS will benefit EJ communities by making water safer to consume.

6. PFAS may also have harmful effects on beneficial uses beyond drinking water, such as aquatic life. Less PFAS in drinking water means less PFAS conveyed to, and discharged from, wastewater treatment facilities (assuming PFAS laden residuals from water treatment facilities are not sent to the wastewater facility).

As a point of comparison, the EPA's September 2022 updates to the social cost of carbon has estimates in the range 1.5-2.5% (EPA, 2022).

Second topic: A meta-analytic approach utilized to calculate PFOA and PFOS-attributable disease burdens and related economic costs of medical care and lost productivity for the year 2018 is informative (Obsekov et al, 2022). The costs of legacy PFAS exposures in the US were determined from epidemiological studies and that found significant relationships between 13 types of diseases and PFAS exposure, including low birth weight, childhood obesity, kidney cancer, testicular cancer, hypothyroidism in females, adult obesity, Type 2 diabetes mellitus in females, gestational diabetes, endometriosis, polycystic ovarian syndrome, couple infertility, female breast cancer, and pneumonia in children due to prenatal exposure.

The study calculated the cost for not taking action to control PFOS and PFOA is in the range $5.52 billion-$62.6 billion, significantly higher than EPA's analysis of costs to comply with the proposed MCLs of $772 to 1,205 million (Table 66 of the RFC). The authors consider their findings to provide, "an approximation of the scope of the disease burden and associated costs attributable to exposure to these ubiquitous chemicals." They also consider their estimate conservative as several types of disease outcomes were not included owing to data limitations (e.g. lowered IQ in children from prenatal exposure, prostate cancer in adult men). Moreover, the social costs of PFAS-related disease conditions, such as described by Cordner et al., 2021) were not included.

Another study of impacts from PFAS exposure in Europe identified annual direct healthcare expenditures at 52-84 billion Euros (Goldenman et al., 2019). Using Goldenman's analysis and accounting for population size and exchange rate differences, Cordner et al. (2021) estimates equivalent health-related costs for the US would be $37-59 billion annually.

EPA Response: The commenter's agreement that the "EPA's methods to determine net benefits of enacting the MCLs are reasonable and rigorous to the extent of data availability" provides support for the EPA's benefits analysis. The EPA agrees with the commenter that the "use of the 3% discount rate or less to evaluate net benefits is strongly supported." The EPA also agrees that using a lower discount rate is more appropriate than elevated discount rates: see section 13.2 of the EPA response in this *Response to Comments* document for a detailed discussion of discount rate selection for the agency's HRRCA. Based on other comments, the agency is also providing estimates based on the 2 percent discount rate, consistent with the updated Circular A-4 Guidance (OMB, 2023).

This commenter also stated that, based on a study by Obsekov et al. (2023), the cost for not taking action to control PFOS and PFOA ($5.52 billion-$62.6 billion) is much higher than the EPA's estimates of costs to comply with the proposed MCLs. The EPA agrees that when

considering all quantifiable and nonquantifiable benefits and costs, the potential benefits of enacting the PFAS MCLs are highly likely to exceed compliance costs. The agency notes that although the study by Obsekov et al. (2023) provides useful information on the potential public health burden from exposure to PFAS, the authors' estimates of the total economic burden of PFOA and PFOS -related disease include cost of illness estimates and, for some health endpoints, also the disability-adjusted life year (DALY) lost costs. As stated in the EPA's Guidelines for Preparing Economic Analyses (USEPA, 2016a), "methods that combine information on quality and quantity of life cannot be directly related to willingness-to-pay estimates and thus should not be used for deriving monetary estimates for use in benefit cost analyses". In addition, OMB Circular A-4 Guidance notes that in order to represent a valid measure of individual preferences integrated metrics such as DALY should meet restrictive assumptions (OMB, 2023). Therefore, the EPA is not relying on the estimates of the total economic burden of PFOA and PFOS provided by Obsekov et al. (2023) as quantified benefits. The EPA's benefits estimates rely on cost of illness and willingness to pay information to value the illnesses associated with PFOA and PFOS exposure. As stated in section 13.4 of the EPA response in this *Response to Comments* document, the HRRCA relies on the best available science on health effects that are associated with exposure to the PFAS considered in the rulemaking. The EPA believes there is greater certainty with this approach, even though it produces a lower-end estimate compared to that produced by Obsekov (2023). When considering the nonquantified benefits, the EPA acknowledges that total benefits are substantially higher than those the EPA has been able to quantify in the record for the final rule.

The EPA agrees with the commenter's statements concerning nonquantifiable benefits, funding availability, benefits from the rule for low-income populations and people of color, and other harmful effects from PFAS. While nonquantifiable benefits have been omitted from the quantified health valuation, several significant adverse effects are discussed qualitatively in detail in Section 6.2.4 of the EA (USEPA. 2024b). As PFAS in drinking water are reduced, the EPA anticipates a reduction in these adverse health effects. Also, see section 13.5 and 13.6 in this *Response to Comments* document for the EPA's response to public comments on nonquantifiable benefits. The EPA discusses potential benefits resulting from co-removal of additional contaminants in Section 6.2.6 of the EA. Benefits of co-removal of DBPs are discussed in Section 6.7 of the EA (USEPA, 2024b) and are also discussed in section 13.7 of the EPA response in this *Response to Comments* document. In regard to funding available under the Bipartisan Infrastructure Law, please see Section 9.4 of the EA (USEPA. 2024b) and in section 13.10 of the *Response to Comments* document; please also see section 2.4 of the *Response to Comments* document for further discussion of BIL funding. For additional discussion of the EPA's EJ analysis, please see Chapter 8 of the EA (USEPA. 2024b) and section 14.10 of the *Response to Comments* document. Finally, the EPA acknowledges that this regulation may have important benefits for other species (e.g., pets/companion animals, livestock, wildlife) that may benefit from reduced PFAS exposure, and that these benefits are not quantified. While the EPA recognizes the important environmental and aquatic life benefits associated with removing PFAS, comments on these topics are beyond the scope of this regulatory action. See section 15.1 of the EPA response in this *Response to Comments* document for discussion on the EPA's PFAS

Strategic Roadmap where actions that are part of the EPA's whole-of-agency approach to addressing PFAS are further described.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-053388)

III. ESTIMATES OF THE SOCIAL BENEFITS FROM EPA'S PROPOSED REGULATORY ACTION

EPA posited numerous adverse effects in the MCLG documents for PFOA, PFOS, and the four PFAS that comprise the HI MCL [FN49: U.S. Environmental Protection Agency, "Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation," 6–1.]. However, EPA quantified the social benefits for only three of them, cardiovascular disease (CVD), avoided low birthweight, and avoided cases of renal cell carcinoma (RCC). Moreover, the biological mechanisms for adverse effects in the EA's quantified benefits are not established and the human study data is equivocal. EPA's limited approach raises questions as to the potential existence and the size of social benefits from avoiding the other adverse effects EPA claims could arise from PFAS exposure.

Given the significant social costs if EPA's proposal is promulgated, this analysis sought to evaluate a larger scope of potential health effects. To do so, the analysis employs genomic and cellular studies of human and animal genes to identify how PFOS exposure causes biological changes in cellular function and at the genetic level. If a dose does not alter this biological activity materially, many adverse effect pathways to disease can largely ruled out at levels occurring in drinking water.

The analysis rests on recent, peer-reviewed published studies that use best practices for evidence integration of different lines of toxicological evidence. These toxicology results fit well into benefit-cost analysis.

1. Rationale for the Approach

For over 60 years, toxicology has developed three principal types of evidence – epidemiological studies of human populations, controlled dose experiments in animals, and in vitro testing to measure responses to chemical exposure in cells, genes, and other biological systems. In the last 20 years, the amount and the breadth of in vitro information has soared as researchers have created new, fast, and low-cost techniques to measure cellular and genetic responses [FN50: National Academies of Sciences, Engineering, and Medicine, "Using 21st Century Science to Improve Risk-Related Evaluations" (The National Academies Press, 2017).]. For example, inexpensive, high-throughput transcriptomics data generation platforms allow rapid observations of a constituent's interaction and activation of the full set of human genes. With the generation of this data arose the question: what to do with it and how to interpret it?

How to interpret and to integrate different lines of evidence has always been a challenge in toxicology. Concern arose in the 2000s with the transparency, decision criteria, and reproducibility of EPA's evidence integration in Integrated Risk Information System (IRIS)

hazard assessments, for example [FN51: National Research Council, "Review of EPA's Integrated Risk Information System (IRIS) Process Review of EPA's Integrated Risk Information System (IRIS) Process."]. In a major report, the National Academies of Science (NAS) recommended that EPA develop transparent, reproduceable mathematical approaches to integrate genomic, in vitro mechanistic data, animal experimental data, and data from human observations [FN52: National Research Council, "Review of EPA's Integrated Risk Information System (IRIS) Process Review of EPA's Integrated Risk Information System (IRIS) Process."]. The NAS recommended EPA move toward a formal, mathematical approach to integrate lines of evidence using Bayesian statistics. In its findings, the NAS stated:

Finding: Quantitative approaches to integrating evidence will be increasingly needed by and useful to EPA.

Recommendation: EPA should expand its ability to perform quantitative modeling of evidence integration; in particular, it should develop the capacity to do Bayesian modeling of chemical hazards. That technique could be helpful in modeling assumptions about the relevance of a variety of animal models to each other and to humans, in incorporating mechanistic knowledge to model the relevance of animal models to humans and the relevance of human data for similar but distinct chemicals, and in providing a general framework within which to update scientific knowledge rationally as new data become available [FN53: National Research Council, 105.].

EPA did not follow this recommendation in the EA. EPA continues the practice of picking certain studies for its quantitative assessments while ignoring and not including the data from other high-quality studies. While EPA states that data from animal studies and mechanistic studies are supportive, EPA does not support these claims in a transparent, reproducible manner. For example, for its estimate of the social benefits from the association between PFOA and PFOS exposure and lower birth weights, EPA selects one study for PFOA and used only the data from this study. EPA apparently re-analyzes the data in the selected study for PFOS but apparently did not state if the Agency submitted this reanalysis to independent peer review.

After the 2014 NAS report, researchers continued to develop full human genomic test data and genomic dose-response modeling. The advent of these new tools -- and the information they provide -- has underscored this challenge of how to integrate genomic in vitro evidence into hazard assessments.

The National Academy of Sciences issued a major report on these New Approach Methods (NAM) in 2017 [FN54: National Academies of Sciences, Engineering, and Medicine, "Using 21st Century Science to Improve Risk-Related Evaluations."]. The 2017 report recommended that agencies incorporate NAMs into chemical risk assessments since they could provide substantially more data and insight more quickly than traditional toxicity testing. As the National Toxicology Program (NTP) found, research groups in universities, private institutions, and government agencies expanded their use of NAMs in the peer-reviewed literature. In 2018, the NTP convened experts and published its approach to genomic dose-response modeling. NTP explained the advantages:

NTP's approach to study design focuses on obtaining the best data to determine accurate estimates of biological potency using modeling. The use of a broad array of gene sets such as those curated by MSigDB is to ensure that all known biological signaling processes are covered, therefore ensuring that the most sensitive estimation of biological potency [FN55: National Toxicology Program, "NTP Research Report on National Toxicology Program Approach to Genomic Dose-Response Modeling," April 2018, 4.].

In other words, rather than only toxicology experiments with a limited number of animal studies of potentially unclear biologic mechanisms of action, genomics data can measure changes in all human signaling processes. These genomics experiments can be replicated, can be conducted quickly at different dose levels, and can test the genomes and cells of many different individuals.

However, the NTP identified two major remaining issues: consistent study design of genomic studies and the biological interpretation of the findings [FN56: National Toxicology Program, "NTP Research Report on National Toxicology Program Approach to Genomic Dose-Response Modeling."]. While the NTP guidance (and comparable EPA guidance) provides a standard for study design, the remaining fundamental uncertainty – genes do not fully determine health outcomes – remained. It is essential for benefit-cost analysis that the genetic changes have direct links to adverse effects consumers understand and value. To interpret the genomic data, researchers have turned to in vitro-in vivo (IVIV) studies and modeling to develop mathematical relationships between the results of known animal studies and genomic response and signaling data. The IVIV techniques then link genomic data to measured adverse effects in whole organisms [FN57: Very recent studies find that hazard values developed through genomic analysis are similar to value derived from animal assays. In general, the genomic values are more health-protective than values derived from animal studies.]. Thus, researchers are developing mathematical techniques to link genomic data to animal data. Recent studies are confirming NTP's conclusion that these studies are more sensitive (i.e., more health protective) than results obtained from whole organism studies [FN58: National Toxicology Program, "NTP Research Report on National Toxicology Program Approach to Genomic Dose-Response Modeling," 4.].

Mathematical evidence integration also combines the risk of cancer and the risk of noncancer effects into the same hazard metric. As the NAS stated, Bayesian dose-response methods can be applied to different lines of evidence to create probabilistic estimates of risk for both cancer and noncancer effects. This capability is vital since EPA's current hazard metrics and -study selection by judgement as in this EA – are incompatible with EPA's regulatory analysis requirements.

The mismatch between EPA's current toxicity metrics and benefit-cost analysis is well understood. Over 30 years ago, the NAS called for EPA to adopt probabilistic hazard assessment and to move away from single hazard values such as a reference dose. In its 2009 Science and Decisions report evaluating EPA's risk assessment practices, the NAS concluded: "The end products of noncancer (and nonlinear cancer) assessments in the current paradigm (exposure-effect quotients that qualitatively indicate potential risk—MOEs [Margin of Exposure], RfDs [Reference Doses], and RfCs [Reference Concentrations], Figure 5-1) are inadequate for benefit-cost analyses or for comparative risk analyses." [FN59: National Research Council, "Science and

Decisions: Advancing Risk Assessment" (Washington, DC: National Academies Press, 2009), 133.] The NAS emphasized:

Historically, dose-response assessments at EPA have been conducted differently for cancer and noncancer effects, and the methods have been criticized for not providing the most useful results. Consequently, noncancer effects have been underemphasized, especially in benefit-cost analyses. A consistent approach to risk assessment for cancer and noncancer effects is scientifically feasible and needs to be implemented [FN60: National Research Council, 8.].

The 2009 Science and Decisions report also provided EPA with extensive recommendations concerning uncertainty analysis, value of information analysis, and risk characterization.

Mathematic evidence integration also enables formal uncertainty analysis to be conducted on the hazard assessment. The outputs of Bayesian modeling are probabilities of adverse effects that are related to the dose, allowing estimates of how these probabilities change with a change in dose. These incremental effects fit well into benefit-cost analysis. Benefit-cost analysis rests on estimating the value to society of incremental shifts in resources to different policy outcomes. Probabilistic risk assessment measures provide more information and fit into the incremental analysis framework of benefit-cost analysis.

EPA's benefit-cost analysis for the proposal rests on toxicity relationships that suffer from the same issues raised by the NAS in 2009 and 2014. The EA's benefit estimate selects just three critical effects even though EPA states that PFOS and PFOA are associated with many other effects.

This analysis seeks to consider a greater range of potential biological mechanisms of action for PFOS and to quantify these effects following the NAS recommendations for hazard identification, evidence integration, and presentation of the maximum value of avoiding the probabilities of change through exposure in drinking water.

2. Summary of the Analytical Approach

This analysis attempts to overcome some of the limitations in EPA's approach which relies on only a few studies, evaluates only two possible PFOS adverse effects, and ignores relevant data and studies.

Figure 3 presents an overview of our methodological approach to the benefits analysis. The assessment is performed in the following sequential steps:

1. Concentration. The concentration of PFAS in drinking water is based on occurrence data from EPA's EA.

2. Dose from Drinking Water Exposure. Drinking water consumer patterns are based on EPA's Exposure Factors Handbook (EFH) and take into account age, sex, race, and body weight.

3. Physical Changes and Adverse Effects. The latest toxicological literature presents modeling of how PFOS concentration and dose estimates are likely to result in the probability of physiological changes and, subsequently, adverse effects.

4. Loss of Function and Valued Social Benefits. The analysis takes the loss of function (i.e. disease) from the modeled physical changes and adverse effects from the literature and applies quantification from the World Health Organization (WHO) and willingness-to-pay estimates to estimate total social benefits.

Figure 3: Overview of Benefits Methodological Framework

[Figure 3: see docket ID EPA-HQ-OW-2022-0114-1738]

In summary, this approach has several major advantages over EPA's approach in the EA:

• Includes many more potential adverse effects from PFOS exposure in drinking water than analyzed in the EA;

• Includes potential incremental noncancer and cancer effects into the same hazard metric;

• Develops estimates of the probability of these adverse effects to construct a distribution of the potential population health benefits;

• Assigns values to the expected values of these adverse effects based on internationally-recognized metrics for morbidity and mortality; and,

• Values these effects with a WTP value consistent with Circular A-4 and best practices.

While our approach has significant advantages over EPA's methods, it has limitations. Some limitations are due to fundamental uncertainty; some could be fixed. Due to the limited time available for public comments, this analysis has limitations that could be addressed with additional analysis. Since this information is available in the literature, EPA could construct a more comprehensive and a more robust social benefit estimate using this approach.

EPA Response: The EPA disagrees with the commenter's assertion that the human study data for adverse effects in the EA's quantified benefits are equivocal. For additional detail on the strength of the human epidemiological evidence supporting analyses of RCC, birth weight, and CVD, see sections 4.1.4 and 4.2.1 of the EPA response in this *Response to Comments* document, as well as the EPA response to comment Doc. #1774, SBC-045685, SBC-053211, SBC-053281, SBC-053417, SBC-045682, and SBC-045683. Additionally, while the EPA agrees that the mechanisms by which PFOA and PFOS induce these effects are unclear, mechanistic evidence is generally used to support the relevance of animal effects to humans and provide biological plausibility for evidence integration judgments, but known mechanisms of action are not required for hazard identification or characterization (USEPA, 2022c). See section 4.2.1 of the EPA response in this *Response to Comments* document for more discussion. Additionally, the IRIS handbook is clear in its recommendation that human data are generally preferred for the derivation of toxicity values, compared to laboratory or animal data (USEPA, 2022c). Regarding

the commenter's recommendations regarding evidence integration, see section 4.1.1 and 4.1.3 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenter's assertion that the EPA is "picking certain studies for its quantitative assessments while ignoring and not including the data from other high-quality studies." The commenter ignores that for both birth weight and total cholesterol, the two endpoints for which the available literature contained multiple high quality exposure-response studies, the EPA relied on meta-analyses that estimate relationships between PFOA/PFOS exposure and health effects. See EA Sections 6.4 and 6.5 of USEPA (2024b) for the details on studies used for the quantified birth weight and CVD benefits models, respectively. See also section 13.4.2 of the EPA response in this *Response to Comments* document, which clearly describes that the EPA relied on meta-analyses of studies on PFOA/PFOS exposure and birth weight effects. Appendix F of the EA (USEPA, 2024c) presents a discussion of the studies included in the EPA's meta-analysis for PFOA/PFOS and TC relationships and results of sensitivity analysis results of different study inclusion assumptions.

The commenter claims that the EPA did not follow the National Academy of Science (NAS) recommendation that the EPA consider New Approach Methods (NAMs) and expand its modeling capabilities to include Bayesian modeling approaches. The EPA disagrees and notes that while current methods are being developed that use Bayesian Model Averaging in dose-response modeling, these approaches are computationally intensive and have not yet become the norm, nor are they required by the Benchmark Dose Technical Guidance (USEPA, 2012). The EPA also notes the IRIS Handbook (USEPA, 2022c) (which the EPA followed in developing the PFAS toxicity assessments) notes that alternative methodologies (such as read-across and other new approach methods) can be used to supplement other streams of evidence, or in some cases, may be the only available method or evidence (USEPA, 2022c). For PFAS, the large amount of epidemiologic, toxicologic and mechanistic data precluded the need to use alternative methodologies to identify risk.

The commenter notes the NAS recommendation to develop a consistent approach to risk assessment for cancer and noncancer effects is scientifically feasible and needs to be implemented. The EPA agrees, and notes that the agency followed the latest guidance for risk assessment relying on peer-reviewed, published EPA human health risk assessment methodology as well as systematic review best practices (USEPA, 2022c) and the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005b), as described in section IV of the preamble and sections 4.1.1 and 4.1.2 of the EPA response in this *Response to Comments* document. The risk assessment guidance and best practices serve as the basis for the PFOA and PFOS health effects systematic review methods used to identify, evaluate, and quantify the available data (USEPA, 2021c; USEPA, 2022c).

The commenter asserts that the EPA's benefit-cost analysis for the proposal rests on toxicity relationships that suffer from the same issues raised by the NAS in 2009 and 2014. The EPA disagrees with this assertion and notes in particular that the EPA developed the Toxicity Assessments (USEPA, 2024h; USEPA, 2024i) following the IRIS guidance that underwent NAS review, which was published November 30, 2021 (USEPA, 2022c).

As described in section 4.1.2 of the EPA response in this *Response to Comments* document, the EPA relied on the best available science to support the agency's conclusions presented in the Final Toxicity Assessments for PFOA and PFOS (USEPA, 2024; USEPA, 2024) and to perform its risk analysis.

Regarding the commenter's use of willingness to pay information to estimate total social costs, see section 13.4.4 of the EPA response in this *Response to Comments* document summarizing comments received on benefit valuation and the EPA's use of cost of illness (COI) and willingness to pay information for the final rule. Regarding the commenter's suggestion to include additional potential adverse effects from PFOS exposure, the EPA has carefully considered the strength of the evidence regarding each health endpoint in making including/exclusion determinations. While there is evidence to suggest that PFOS exposure leads to unquantified adverse health outcomes, the EPA elected to include only those endpoints with the strongest evidence supporting their estimation.

Regarding commenter's assumptions on drinking water exposure and the analysis of disease from the modeled literature, see the EPA response to comment Doc. #1738, SBC-046013 in section 13.4.5 in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-047706)

EPA's Quantified Incremental Adverse Effects

While the thousands of pages in the EA, appendices, and supporting information give the impression of substance, the Agency ultimately rests its artifice on a flawed foundation. The benefits estimate suffers both from claiming too much from little evidence and from too little application where the literature provides ample evidence. Some of the specific problems with EPA's approach are listed below.

EPA's analysis rests on an assumption of causality in which "exposure to these PFAS may cause adverse health effects" and "that PFOA and PFOS are likely to cause cancer." [FN16: U.S. Environmental Protection Agency, "PFAS National Primary Drinking Water Regulation Rulemaking," 18638–39.]. However, there is substantial uncertainty as to whether those associations are causal. In this section, we compare EPA's analysis of the existing scientific literature with those of Health Canada (HC), the European Food Safety Agency (EFSA), and the World Health Organization (WHO). Specifically, we review findings and limitations for birthweight, cardiovascular disease (CVD) and cancer. Additional information on the findings, interpretations, and limitations from EPA, HC, WFSA, and WHO are outlined for each adverse effect in Appendix B.

EPA Response: The EPA disagrees with the commenter's assertion that the EA rests on a flawed foundation. As discussed in EA Sections 2.2.5, 6.1.4, 6.3.3, 6.4.2, 6.5.2, and 6.6.2, EA Appendix Sections D.2 and F.1 (USEPA, 2024b; USEPA, 2024c), and the Toxicity Assessments (USEPA, 2024h; USEPA 2024i), the EPA has conducted multiple literature reviews and peer reviews and follows well-established protocols for health risk assessment (e.g., lifetable

methodology) and valuation (e.g., Guidelines for Preparing Economic Analyses, USEPA, 2016a; OMB Circular A-4; OMB, 2023). The EPA is using scientifically valid peer-reviewed risk assessment approaches and the most current literature, and has considered the input of numerous outside reviewers (between the SAB's review, the letter peer reviews, and the journal peer reviews, the EPA notes that dozens of outside peer-reviewers have shared their input on various underlying components of this economic analysis). This is in addition to the numerous internal agency quality reviews conducted of the analyses by many of the leading health experts and economists in the field.

In addition, the EPA notes that it received several comments highlighting differences between the EPA's determination on evidence of certain health effects associated with PFOA and PFOS. Refer to section 4.2.6 of the EPA response in this *Response to Comments* document for details on comparisons to analyses by other health organizations. With respect to the carcinogenicity determination, the EPA followed agency guidelines in making its cancer determinations for PFOA and PFOS (USEPA, 2005b) and the EPA directs the commenter to Section 3.5.5 of the draft and final toxicity assessments (USEPA, 2024h; USEPA, 2024i; USEPA 2023g; USEPA, 2023h), which detail how PFOA and PFOS are *Likely to be Carcinogenic to Humans* according to the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005b). Please also see section 4.1.4 of the EPA response in this *Response to Comments* document regarding this topic.

The EPA also notes that there is no causality requirement for health effects considered in benefits analysis. Both benefits assessment and toxicity value derivation (e.g., reference dose derivation) require estimates of risk. However, toxicity values are often based on dose levels corresponding to specific response levels near the low end of the observable range of the data (USEPA, 2012) and pose challenges for use in quantified benefits estimation because relying on this information could lead to biased benefits estimates if extrapolated to the general population (USEPA, 2016a). The health outcomes included in the EA are linked to human well-being and monetized using well accepted economic valuation methods. The EPA analysis accounted for potential uncertainty associated with risk and benefit estimates for a better understanding of potential benefits, as described in Section 6.1.2 of the EA (USEPA 2024b). In following the IRIS approach for integrating evidence across human, animal and mechanistic streams, the EPA makes determinations on the strength of evidence for causal relationships, ranging from evidence ***demonstrates, indicates (likely), suggests, is inadequate or there is evidence of no effect.*** The EPA notes that Toxicology Assessments concluded that the overall evidence indicated that PFOA and PFOS exposure was determined ***likely*** to cause cardiovascular (particularly serum lipids) and developmental toxicity in humans under relevant exposure circumstances (USEPA, 2024h; USEPA, 2024i). In addition, there is no requirement or reasonable expectation that a benefits analysis must demonstrate causal relationships; prior EPA rulemakings have included quantified benefits analyses for endpoints that have not been proven to have a causal relationship between pollutant exposure and the associated health outcome (e.g., trihalomethane exposure and associated health effects in the Stage I/Stage II disinfection biproducts rules (DBPRs); USEPA, 2005a; USEPA, 2006).

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046030)

EPA's benefit estimates assume a few possible adverse effects based on scientific findings that other public health organizations do not support. By failing to account for the possibility that these adverse effects may not exist, EPA overstates the social benefits.

EPA Response: The EPA disagrees with the commenter's assertion that the quantified benefits estimation is unsupported, and that the agency overstates benefits. Refer to sections 4.1.4, 4.2.1, 4.2.6, and 13.4 of the EPA response in this *Response to Comments* document for details on the health effects information that the EPA considered for the HRRCA and also for discussion on comparisons of the EPA's toxicity assessments for PFOA and PFOS to assessments performed by other health organizations. Please also see the EPA response to comment Doc. #1738, SBC-047706 in section 13.4 in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-045652)

EPA Did Not Follow SDWA Best Practices in Calculating the Benefits of the Proposed Regulations

The SDWA requires EPA to show that the benefits of its proposed regulations justify the costs. EPA did not comply with that requirement in several important respects.

As an initial matter, EPA's analysis of estimated benefits related to its proposed standards for PFOA and PFOS violates the SDWA's requirement that it analyze separately the benefits of each proposed regulatory standard because EPA improperly conflated its benefits analysis for the two separate regulations. See SDWA [sec]1412(b)(3)(C)(i)(I) (stating that EPA "shall" publish and seek public comment on certain considerations including anticipated benefits of regulation at alternative levels for "a maximum contaminant level that is being considered."). For example, EPA's estimated impact on total cholesterol from reducing PFOS is nearly two orders of magnitude less than the reduction in total cholesterol that EPA calculated for PFOA, but EPA combined those levels in its benefits analysis. It did not analyze separately the benefits for PFOA and PFOS individually, as required by the SDWA.

EPA also has not provided enough information in the record to allow the public to understand how EPA conducted its benefits analysis, which precludes meaningful peer review and comment. EPA's benefits analysis is not reproducible or adequately transparent to the public because EPA has not made important inputs and models available for public or peer review.

From the available information, EPA's benefits analysis appears unreliable. EPA purports to distinguish between the benefits of alternative drinking water exposure concentrations of 4.0 ppt, 5.0 ppt, and 10.0 ppt. However, foundational toxicological principles demonstrate that those levels are so similar that there is likely no way to discern changes in benefits between them (and EPA has not provided the information in the record to explain how it purported to do so).

Similarly, EPA did not provide the pharmacokinetics models underlying its estimates of blood serum PFOA and PFOS concentrations on which it based its benefits analysis. See (USEPA 2023a,b,c,d). The serum data estimate is a foundational conclusion supporting EPA's entire benefits analysis. It is the first value input in a sequence that is ultimately used to estimate the health risk reduction benefits for the proposed maximum contaminant level (MCL) and the regulatory alternatives. Without access to the models underpinning the input, the public and scientific experts cannot meaningfully understand and evaluate the scientific validity of EPA's conclusions about the relative benefits of a 4.0 ppt MCL versus a 5.0 ppt or 10.0 ppt alternative.

EPA's benefits analysis also does not consistently take alternative exposure considerations into account and improperly combines estimated benefits for PFOA and PFOS. This results in inflated estimates of the anticipated individual benefit calculation for each proposed regulatory standard and flawed human equivalent internal dose responses that introduce significant uncertainty about EPA's ultimate conclusions.

EPA Response: First, there is nothing in SDWA that requires the EPA to show that the benefits of the rule justify the costs. Rather, the statute requires the Administrator to publish a determination *whether* the benefits of the proposed rule justify or do not justify its costs based on the HRRCA. SDWA Section 1412(b)(4)(C). The EPA did publish such a determination in the proposed rule preamble. For the EPA's response to the commenter's points raised about the costs and benefits of regulatory alternatives, including the EPA's response to the commenter's assertion that "toxicological principles demonstrate that those levels are so similar that there is likely no way to discern changes between them," see the EPA response to comment Doc. #1774, SBC-045689 in section 5.1.3 in this *Response to Comments* document. The EPA disagrees with the commenter's assertion that the agency violated SDWA requirements because the "…EPA improperly conflated its benefits analysis for the two separate regulations." The commenter has misinterpreted the SDWA HRRCA requirements. Section 1412(b)(3)(C)(i) simply states that the EPA must analyze, among other things, the health risk reduction benefits that are likely to occur from treatment to comply with the proposed MCLs and any alternative levels under consideration. It does not require that the analysis be separate for each chemical or MCL in a proposed NPDWR. The PFOA and PFOS standards are not two "separate regulations," as described by the commenter, rather they are two MCLs included in one regulation.

The EPA has completed the HRRCA for the PFAS NPDWR consistent with the statutory requirements under the SDWA. In cases where PFOA and PFOS have the same or related adverse health effects, as is the case for changes in birth weight and changes in cardiovascular disease risk, the EPA appropriately used contaminant specific information on occurrence, pharmacokinetics, dose-response to analyze the benefits from reductions in exposure anticipated from compliance with the rule. The EPA presents quantified benefits according to adverse health effect rather than by contaminant in these cases, as this is an appropriate way to evaluate the total national benefits and costs that are likely to occur as a result of compliance with the rule. The EPA proposed a NPDWR and regulatory options that each included MCLs for both PFOA and PFOS. The EPA had already made a positive regulatory determination for PFOA and PFOS at the time of proposal and therefore did not represent a regulatory option in the EA that included an

individual MCL for PFOA or PFOS that did not include the other. In cases where the EPA determined that the data was available to quantify benefits from one single contaminant only (e.g., PFOA and RCC, PFOS and liver cancer, PFNA and birth weight impacts), the EPA used contaminant-specific information and presents results for that specific regulated contaminant. Furthermore, in the toxicity assessments for the final rule's regulated PFAS, each of the adverse health endpoints from each individual PFAS are discussed at length (see USEPA 2024h; USEPA, 2024i; USEPA, 2024g; USEPA, 2024j; USEPA, 2024k; USEPA, 2024l). Additionally, the EPA has considered the impacts of dose additivity, as described in *Maximum Contaminant Level Goals (MCLGs) for Three Individual Per- and Polyfluoroalkyl Substances (PFAS) and a Mixture of Four PFAS*. The result presented in the EA for the proposed and final rule provides as comprehensive and transparent analysis of the benefits of all parts of the rule as the data allow, which meets the HRRCA requirement for assessment of costs and benefits for "each MCL' in the rule. In short, the EPA has clearly met all of its HRRCA obligations.

The EPA also disagrees with the commenter's assertion of a lack of transparency and materials provided for public review and replication. Copies of cited literature used to define analysis inputs are provided in the rulemaking record, along with commented code and detailed README documents necessary for replication of this analysis. This record was publicly available at proposal. The information provided is more than sufficient for the purpose of this rulemaking and ensures that stakeholders can both review the EPA's work and recreate it as needed. Additionally, see section 13.4.1 of the EPA response in this *Response to Comments* document regarding the relationship between serum PFOS and TC.

The commenter is also incorrect in the assertion that the pharmacokinetics (PK) models underlying blood serum estimates were not provided. The EPA provided a link to the GitHub repository that includes the PK models in Section 6.3.2 of the EA (USEPA, 2024b). Additionally, the EPA described the PK models in Section 4.1.3 of the Final Human Health Toxicity Assessments for PFOA and PFOS (USEPA, 2024h; USEPA, 2024i).

With respect to whether the benefits of this regulation justifies the costs, please see section 13.8 of the EPA response in this *Response to Comments* document for discussion of the EPA's comparison of costs and benefits, including the Administrator's determination that the benefits of the rule justify the costs.

3M Company (Doc. #1774, SBC-045695)

1. EPA's failure to clearly analyze the benefits of the PFOA and PFOS proposed standards separately overstates the benefits of the PFOS standard and precludes appropriate analysis of the individual MCLs.

EPA's failure to separately analyze the benefits of the PFOA and PFOS MCLs violated the SDWA directive that EPA analyze "quantifiable and non-quantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur as the result of treatment to comply with each level." [FN102: SDWA

[sec]1412(b)(3)(C)(i)(I).] For example, CVD reduction is a major element of EPA's benefit analysis for PFOA and PFOS. CVD reduction depends on EPA's calculation of the impact of reduction of total cholesterol (TC). There are numerous issues with EPA's calculation of a dose-response relationship between serum PFOS and TC, including that they do not demonstrate what is normally considered a statistically significant relationship between those two factors. Even ignoring those issues, and assuming the accuracy of EPA's analysis, the impact on TC from reducing PFOS is nearly two orders of magnitude less than the reduction in TC that EPA calculated for PFOA. [FN103: EPA stated that "[w]hen using studies reporting linear associations between total cholesterol and serum PFOA or PFOS, EPA estimated a positive increase in TC of 1.57 (95% CI: 0.02, 3.13) mg/dL per ng/mL serum PFOA (p-value=0.048), and of 0.08 (95% CI:-0/01, 0.16) mg/dL per ng/mL serum PFOS (p-value=0.064.)" 88 FR 18709.]

EPA has not provided enough information in the record to allow for replication of the benefit analysis. This lack of transparency with respect to the benefits of the proposed standards prevents meaningful comment on an aspect of the proposed rule with a very significant impact on EPA's analysis of whether the proposed standards meet the SDWA requirements that the benefits outweigh the costs.

EPA Response: The EPA disagrees with the commenter's assertion that SDWA requires separate analysis of PFOA and PFOS. Please see the EPA response to comment Doc. #1774, SBC-045652 in section 13.4 in this *Response to Comments* document for details.

The EPA disagrees with the commenter's statement that the dose-response relationships between PFOS and TC used in the agency's analysis of CVD effects are not statistically significant. See section 13.4.1 of the EPA response in this *Response to Comments* document regarding the relationship between serum PFOS and TC.

The EPA disagrees with the commenter's assertion that the benefits analysis suffers from the fact that the estimated TC slope factor for PFOS is smaller than the slope factor for PFOA. This simply demonstrates that the meta-analysis shows a stronger effect of reduction of PFOA on TC outcomes compared to PFOS.

For comments on transparency and materials provided for replication of the EPA's analyses, see the EPA response to comment Doc. #1774, SBC-045652 in section 13.4 in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-044811)

[The Agency's proposal suffers from the following significant shortcomings –]

• The Agency's analysis inappropriately quantifies benefits from reductions in health effects that have not been associated with PFOA and PFOS exposure or that cannot be solely attributable to the proposal,

[The Agency's proposal suffers from the following significant shortcomings –]

• EPA has not provided data to support its analysis of benefits predicted from the implementation of the HI MCL,

EPA Response: The EPA disagrees with the commenter's assertion that the EPA did not provide data to support benefits analysis from implementation of the Hazard Index MCL. Please see the section 13.4 of the EPA response in this *Response to Comments* document. Furthermore, the EPA conducted extensive literature reviews and conducted analyses discussed in the EA to evaluate quantified and nonquantified benefits for PFHxS, PFNA, HFPO-DA, and PFBS: please see Chapter 6 of USEPA (2024b). In particular, the EPA synthesized evidence of associations between exposure and health effects relying on IRIS assessments (USEPA, 2023i), the most recent ATSDR and National Academies of Science, Engineering and Medicine (NASEM) reports (ATSDR, 2021; NASEM, 2022), and the Toxicity Assessments (USEPA, 2024b; USEPA, 2024b).

The EPA disagrees with the commenter's statement that the EPA's analysis "inappropriately quantified benefits from reductions in health effects that have not been associated with PFOA and PFOS exposure or that cannot be solely attributable to the proposal." The commenter provides no additional information or data explaining why they believe that the EPA quantifies benefits that are not attributable to this regulatory action. The EPA conducted an extensive literature review to identify health effects with evidence of an association with PFOA and PFOS, that are presented in the Final Toxicity Assessments for PFOA and PFOS (USEPA, 2024h; USEPA, 2024i), in order to quantify health benefits from the reduction in PFOA and PFOS exposure due to the regulation. For additional detail on the strength of the human epidemiological evidence supporting analyses of RCC, birth weight, and CVD, see sections 4.1.4 and 4.2.1 of the EPA response in this *Response to Comments* document, as well as the EPA response to comment Doc. #1774, SBC-045685, SBC-053211, SBC-053281, SBC-045682, and SBC-045683. Additionally, the EPA determined attributable risk by reviewing existing literature to establish a population attributable fraction (PAF) of adverse health outcomes associated with environmental exposure, as described in Section 6.1.2 of the final rule EA (USEPA, 2024b). The agency then estimated changes in PFOA and PFOS exposure-attributable share of adverse effects incidence associated with promulgation of the rule. This analysis assumes that removal of PFOA and PFOS-related exposure would not alter the distribution of risk factors the exposure does not affect.

American Chemistry Council (ACC) (Doc. #1841, SBC-044820)

[As outlined in these comments, the Agency's proposal suffers from a number of significant shortcomings, including the following –]

• The Agency's analysis inappropriately quantifies benefits from reductions in health effects that have not been associated with PFOA and PFOS exposure or that cannot be solely attributable to the proposal,

EPA Response: Please refer to the EPA response to comment Doc. #1841, SBC-044811 in section 13.4 in this *Response to Comments* document for a response to the commenter's assertion that benefit attribution is incorrect.

American Chemistry Council (ACC) (Doc. #1711, SBC-044464)

[The Agency's proposal suffers from the following significant shortcomings –]

• The Agency's analysis inappropriately quantifies benefits from reductions in health effects that have not been associated with PFOA and PFOS exposure or that cannot be solely attributable to the proposal,

EPA Response: Please refer to the EPA response to comment Doc. #1841, SBC-044811 in section 13.4 in this *Response to Comments* document for a response to the commenter's assertion that benefit attribution is incorrect.

American Chemistry Council (ACC) (Doc. #1841, SBC-052940)

Finally, we note the Agency's use of county demographic information to substitute for actual demographic information (especially for the smallest water systems). The process that EPA used is described as follows - excerpt (in italics) from the economic analysis:

To determine the number of people expected to benefit from actions under the proposed rule, EPA uses population data from the Safe Drinking Water Information System (SDWIS) 2021 Quarter 4 (Q4) database (U.S. EPA, 2021h). The SDWIS data provide the population served by each PWS in the

U.S. For analyses that rely on age-, sex-, and race/ethnicity-specific populations, EPA uses county-level population proportions based on 2021 estimates from the U.S. Census Bureau (2020a). [FN196: USEPA Economic Analysis, at 2-4.]

This approach will underestimate or overestimate net benefits because water systems (and especially the smallest systems) are unlikely to share aggregate demographic characteristics of their home county. Furthermore, by choosing an approach based on model system types, the Agency masks variability within each model. It is possible that net benefits vary significantly within each model, especially for the smaller systems.

EPA Response: The EPA is using best available information and science to inform its analyses. More precise spatial resolution is not *available.* The EPA notes that the commenter merely critiques the EPA's use of these available data. The commenter does not identify any nationally available data that will improve precision or reduce uncertainties. In short, the commenter does not propose any alternative solutions for the agency to consider. Furthermore, because the EPA models impacts to aggregate populations based on systems triggered into treatment under various scenarios, the EPA relies on national-level demographic data. The impact of this limitation is uncertain, and, as noted by the commenter, the approach taken by the EPA

could either underestimate or overestimate net benefits. However, the EPA describes this uncertainty within Chapter 6 of the EA in Table 6-53 (USEPA, 2024b) and notes that currently, there is no available dataset of demographic information specific to the location of affected population. Furthermore, SDWA recognizes that all scientific analyses have uncertainties: the EPA has listed those that it has identified in a clear and transparent fashion consistent with SDWA Section 1412(b)(3)(B). See section 13.2 of the EPA response in this *Response to Comments* document for discussion and response related to comments received on the model system approach.

13.4.1 Quantified CVD Benefits Estimation

Summary of Major Public Comments and EPA Responses

The EPA received a number of comments on the quantitative analysis of CVD risk reduction. These commenters disagree with the EPA's assessment that cardiovascular benefits are likely to occur as a result of enacting MCLs for PFOA and PFOS. One commenter stated that the associations with total cholesterol (TC) are not biologically significant and criticized the EPA's use of linear models in the CVD meta-analysis, stating that this approach biases the analysis by excluding higher-quality studies. The EPA disagrees with the commenter's statement that associations between PFOA/PFOS and TC are not biologically significant. Such serum lipid changes may or may not result in a concentration considered clinically elevated in a particular individual; however, given the distribution of individual concentrations within the population, small changes in average serum lipid concentrations can result in substantial health impacts at the population level (Gilbert and Weiss, 2006). See sections 4.2.1 and 4.2.2 of this *Response to Comments* document for additional discussion on this topic. The EPA disagrees with the commenter's suggestions that linear assumptions are inappropriate for use in this context. The EPA presents the exposure-response estimates evaluated considering all studies, studies with linear models only, and a variety of sensitivity analyses in Appendix F of the EA (Tables F-2 and F-3, USEPA, 2024c). Meta-analyses of studies reporting linear associations had statistically significant relationships. These relationships are supported by the EPA's review of epidemiological studies in the Final Toxicity Assessments (USEPA, 2024h; USEPA, 2024i) showing positive associations between PFOA/PFOS and TC. The EPA used data from peer-reviewed studies, and the assumption of linear exposure-response function to explain associations between PFAS and serum lipids such as TC which is supported by data from numerous studies, including those used in the meta-analysis. Other studies have explored log-linear or linear-log relationships between PFAS and serum lipids, while acknowledging only "slight improvements" in model fit, especially for serum lipids with least skewed distributions (Steenland et al., 2009).

A couple of commenters stated that the downward trend in decreasing total and low-density lipid cholesterol since the 1970s coupled with the decreasing PFOA and PFOS serum levels suggests that there is a substantial likelihood that the proposed MCLs for PFOA and PFOS are unlikely to result in benefits as great as is reported as part of the proposal. The EPA disagrees with these comments asserting that decreasing trends in cholesterol levels over time indicate that PFAS

exposure is unlikely to contribute to a measurable increase in CVD risk. The EPA relied on recent National Health and Nutrition Examination Study (NHANES) data (2011-2016) to inform baseline cholesterol and blood pressure conditions in the population evaluated under the proposed rule. These data reflect the current population and do not reflect cholesterol conditions in the population between 1970 and 2010. Therefore, the CVD benefits analysis examines how the probability of the current population might benefit from reduced incidence of hard CVD events.

The EPA received a comment stating that the benefits associated with high-density lipoprotein cholesterol (HDLC), often referred to as the 'good cholesterol', are not likely to accrue because the evidence of the relationship between PFAS and the health outcome is not conclusive, and that this endpoint should not have been quantified. The EPA disagrees with the comment: Although the evidence of a relationship between PFAS exposure and HDLC is not conclusive, the SAB recommended that the EPA evaluate how the inclusion of HDLC effects would influence results (USEPA, 2022d). The EPA evaluated how quantified benefits results are affected by the inclusion of HDLC effects in a sensitivity analysis presented in Appendix K of the EA for the final rule (USEPA, 2024c). Additionally, the same commenter and one other commenter challenged the EPA's quantification of PFOS and blood pressure (BP), stating that the EPA's finding that PFOS might have "the potential" to affect blood pressure does not meet the SDWA standard for inclusion in a benefits analysis and that the "rationale for including changes in BP in relation to PFOS is not clear." Another comment identified a study that utilized NHANES data and "did not observe an association" between PFOA and blood pressure. Finally, another commenter mentioned that "Neither the ATSDR nor the National Academy of Sciences (NAS) have found an association between PFOA/PFAS and increased blood pressure." While the EPA is aware of this previous work, in the EPA's own, more recent assessment, the strength of the evidence is determined both by the number but also the quality of studies investigating the relationship. One high confidence study conducted using U.S. general population data from NHANES showed a relationship between PFOS exposure and systolic blood pressure in humans (Liao et al., 2020). In addition, several *medium* and *low* confidence studies provided evidence for an association between PFOS and blood pressure and/or hypertension (Mitro et al., 2020; Bao et al., 2017; Mi et al., 2020; Liu et al., 2018). Because blood pressure is an important component of the Atherosclerotic Cardiovascular Disease (ASCVD) model used to estimate hard CVD event risk, and because epidemiology reports show consistent evidence of an association between PFOS and blood pressure in general adult populations (i.e., the populations evaluated using the ASCVD model), the EPA included the relationship between PFOS exposure and blood pressure in the analysis. The EPA further notes that the Science Advisory Board recommended modeling the impacts of changes in all ASCVD model predictors (including blood pressure and HDLC) for which there is evidence of a likely causal relationship (USEPA, 2022d).

A few commenters questioned the evidence or stated that the evidence supporting a direct association between exposure to PFOA and PFOS and CVD health outcomes is insufficient. One commenter referenced a study finding that no elevated cardiovascular health outcome risk was identified based on PFOA/PFOS-related cholesterol increase. Another commenter wrote that for

"PFOA/PFOS and cholesterol, ATSDR concluded that the evidence is insufficient to determine a cause-and-effect relationship, while the NAS concluded that there is sufficient evidence for the association of PFAS exposure with dyslipidemia (total triglycerides, total cholesterol, and low-density lipoprotein and high-density lipoprotein)." The EPA disagrees with these comments. See sections 4.2.1.3 and 4.2.2.3.2 of the EPA response in this *Response to Comments* document for discussion on the evidence supporting associations between serum lipids and CVD. Additionally, the CVD benefits analysis was reviewed and approved by SAB panelists. Numerous studies have shown consistent associations between PFOA/PFOS exposure and changes in total cholesterol and blood pressure. TC and blood pressure are well-established CVD risk biomarkers, are clearly associated with adverse CVD events, and are important inputs to the ASCVD model that the EPA used to estimate CVD outcomes.

Individual Public Comments

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045921)

A. EPA's Health Risk Reduction and Cost Analysis (HHRCA) is flawed and overestimates benefits

In evaluating benefits of MCLs, there must be a factual basis by which to conclude that such benefits are likely to occur as a result of treatment (emphasis added) [FN179: 42 U.S.C. 300g(b)(3)(C).]. As discussed below, the existing evidence does not support that many of the quantified health effects are likely to occur as a result of treatment. Similarly, while EPA discusses additional non-quantifiable benefits, many of these benefits are "possible" or "potential" benefits, but neither the existing record nor the EPA in this rulemaking has presented information to support these benefits as being "likely."[FN180: See EPA Economic Analysis of the Proposed National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances, 2023, where the first sentence of EPA's benefits analysis chapter states: "This chapter discusses the potential quantified and nonquantifiable benefits to human health resulting from changes in PFAS levels in drinking water due to implementation of the proposed rule, as well as several regulatory alternatives." (emphasis added), at page 6-1.] There is a higher bar for evidence to meet a likely standard, and EPA's speculative and precautionary benefits analysis does not meet this threshold.

1. Benefits assessment for cardiovascular disease (CVD) is not supported by the science

To evaluate CVD, EPA quantifies benefits, for PFOA and PFOS, by evaluating total cholesterol and high-density lipoprotein cholesterol (HDLC). EPA also quantifies benefits related to PFOS and blood pressure. In table 42, in the Federal Register notice, EPA clearly notes that for HDLC the "[e]vidence of the relationship between the PFAS compound and the health outcome is not conclusive."[FN181: 88 Fed. Reg. at 18704 n.5.] Based on EPA's evaluation, it is not likely that these benefits will accrue, and this endpoint should not have been quantified. Similarly, it is not clear why EPA quantifies PFOS and blood pressure. Based on EPA's evaluation of PFOS science, blood pressure is not a prioritized health outcome in this rulemaking, and it was not a

recommended health outcome from the SAB. Additionally, EPA's own evaluation, in summarizing the evidence integration for PFOS and blood pressure, states "While there is some evidence that PFOS exposure might also have the potential to affect blood pressure and other cardiovascular responses in humans given relevant exposure circumstances, the human evidence underlying this possibility is uncertain and without support from animal or mechanistic studies."[FN182: See Public Comment Draft Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) in in Drinking Water at page 3-175, .regulations.gov/document/EPA-HQ-OW-2022-0114-0034.] EPA's finding that PFOS might have "the potential" to affect blood pressure does not meet SDWA standard for inclusion in a benefits analysis.

EPA also quantifies benefits related to the relationship between PFOA and PFOS and total cholesterol. However, EPA states "EPA recognizes that the epidemiologic literature that provides strong support for an effect of PFOA and PFOS on cholesterol and blood pressure does not provide direct support for an effect of PFOA and PFOS on the risk of CVD."[FN183: 88 Fed. Reg. at 18709.] Thus the quantification of these benefits comes with a great deal of uncertainty. As there is not a direct link between PFOA and PFOS exposure and CVD, EPA links changes in CVD risk biomarkers to changes in CVD risk. Nevertheless, by quantifying benefits that include avoided incidents and avoided deaths due to CVD, EPA is modeling a relationship that is not supported by the epidemiological literature. For PFOS, the estimated increase in total cholesterol, per ng/mL serum PFOS, is not statistically significant,[FN184: Id.] providing even more support for the concerns with the quantification of this health endpoint. Additional recent (2022) science is available to suggest that even if elevated cholesterol levels exist, no PFOA or PFOS-related increase in relevant endpoints (such as stroke, myocardial infarction, or other irreversible measures) occurs in humans, and should properly be considered [FN185: Schillemans T, Donat-Vargas C, Lindh CH, de Faire U, Wolk A, Leander K, et al. (2022) Per- and polyfluoroalkyl substances and risk of myocardial infarction and stroke: a nested case-control study in Sweden. Environ Health Perspect130(3):37007, available at: .niehs.nih.gov/doi/10.1289/EHP9791.].

While the modeling for PFNA is not presented, it appears that EPA nevertheless quantifies the supposed CVD benefits that stem from reductions in PFNA [FN186: See Table 42 in the proposed rule and also Table 6-6 in the Economic Analysis.]. As cholesterol and CVD outcomes are not a critical effect for PFNA, and most epidemiological studies do not show an association between PFNA and LDLC or HDLC,[FN187: See EPA Economic Analysis of the Proposed National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances, 2023, at page 6-23.] these benefits should not be quantified. Additionally, EPA does not discuss the potential for CVD effects from PFHxS and HFPO-DA. [FN188: Id.] As such, when EPA makes broad statements about additional non-quantified benefits, it is imperative that EPA be clear that additional CVD benefits are not expected.

EPA Response: The EPA disagrees with the commenter's assertion that "the existing evidence does not support that many of the quantified health effects are likely to occur as a result of treatment." See sections 4.2.1 and 4.2.2 of the EPA response in this *Response to Comments*

document for the EPA's response to comments claiming that the existing health evidence does not support the EPA's benefits analysis. Additionally, the EPA disagrees with the commenter's statement that the EPA did not present information to support non-quantifiable benefits. See sections 13.5 and 13.6 of the EPA response in this *Response to Comments* document for summary of comments received on nonquantifiable benefits and the EPA's response to those comments.

See section 4.2.1 of the EPA response in this *Response to Comments* document and the Final Toxicity Assessments (USEPA, 2024h; USEPA, 2024i) regarding the rigor of scientific evidence used in identifying quantified noncancer health benefits that are likely to occur as a result of treatment. See section 13.4.1 of the EPA response in this *Response to Comments* document regarding quantification of CVD benefits from reduced exposure to PFOA and PFOS in drinking water and also the EPA's response to the commenter's statements on HDLC and blood pressure modeling components. The commenter incorrectly states, "[b]ased on EPA's evaluation of PFOS science, blood pressure is not a prioritized health outcome in this rulemaking." As described in the Final Toxicity Assessment for PFOS and in section 4.2.1 of the EPA response in this *Response to Comments* document, one of the five prioritized health outcomes in this rulemaking is cardiovascular effects. This health outcome encompasses endpoints including changes in serum lipids (e.g., TC), as well as altered blood pressure.

As described in responses in section 4.2.1 of this *Response to Comments* document, a lack of or limited evidence supporting an association between chemical exposure and a health effect (e.g., increased risk of CVD) does not necessarily mean the association is non-existent, it simply means the agency does not currently have evidence to make definitive conclusions regarding the exposure-response relationship. Additionally, the EPA disagrees that a lack of statistical significance should preclude an endpoint from consideration for quantitative analyses such as those in the HRRCA. The scientific consensus in the epidemiologic and systematic review community is that evidence of an association does not need to rely solely on statistical significance. As stated in the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022c), consideration of magnitude of the association and biological significance or adversity inform determination of associations.

The commenter incorrectly asserts that the EPA quantified PFNA effects on CVD. As described throughout the EA and section XII of the FRN, the EPA quantified CVD effects for PFOA and PFOS only and does not present quantified benefits for PFNA and CVD in the national benefits assessment. Instead, and as discussed in the section 13.4 of the EPA response in this *Response to Comments* document, the agency presents a quantitative sensitivity analysis for PFNA and birth weight effects in Appendix K of USEPA (2024c). The EPA notes that the best available peer reviewed scientific assessment for PFNA (ATSDR, 2021) provides justification for the EPA's analysis of economic benefits of PFNA exposure reduction and avoided birth weight effects. Furthermore, more recent epidemiological studies that evaluated PFNA and birth weight, including key studies modeled for PFOA and PFOS (Sagiv et al., 2018; Wikström et al., 2020), as well as a recently published meta-analysis of mean birth weight that indicates the birth weight results for PFNA are robust and consistent (Wright et al., 2023).

Lastly, the commenter incorrectly stated that the EPA did not discuss the potential for CVD effects from PFHxS, as the EPA provided a qualitative discussion of cardiovascular benefits for PFHxS in Section 6.2 of the EA (USEPA, 2024b) and also section XII of the FRN. The EPA did not discuss HFPO-DA effects on cardiovascular disease in the qualitative benefits analysis. Table 6-7 of the EA indicates that the EPA HFPO-DA final toxicity assessment did not evaluate associations between HFPO-DA exposure and CVD outcomes (USEPA, 2024b).

American Water Works Association (AWWA) (Doc. #1759, SBC-053061)

4. Comments on the Cardiovascular Disease Risk Reduction Analysis

Previously, the USEPA had proposed using the atherosclerotic cardiovascular disease (ASCVD) model to estimate reductions in CVD risks associated with reductions in exposure to PFOA and PFOS in drinking water. The SAB was generally supportive of the overall approach for estimating reductions in CVD risk; however, the SAB noted that the approach did not mesh with the USEPA's conclusion that there was insufficient evidence of increased CVD risk to inform a candidate RfD. In response to SAB feedback, the USEPA (2023a, 2023c) developed RfDs for total cholesterol (TC) as a precursor to CVD and to further justify its use of the ASCVD model – which uses TC as one of several variables to estimate 10-year risk of CVD events – for quantifying CVD benefits. The quantified health benefits now include the following:

• Number of non-fatal myocardial infarction (MI) cases avoided;

• Number of non-fatal ischemic stroke (IS) cases avoided; and

• Number of CVD deaths avoided.

Under the Proposed Option (MCL of 4 ppt for PFOA and 4 ppt for PFOS and an HI of 1.0 for PFNA, HFPO-DA (GenX chemicals), PFHxS, and PFBS), the USEPA calculated that the following morbidity and mortality are avoided when the Proposed Option is compared to baseline drinking water concentrations: 6,081.0 non-fatal MI cases avoided; 8,870.8 non-fatal IS cases avoided; and 3,584.6 CVD deaths avoided (USEPA 2023e).

In order to calculate the avoided CVD related mortality and mortality, the USEPA used exposure-response functions of serum PFOA and PFOS on TC, and serum PFOS (but not serum PFOA) on systolic blood pressure (BP) to estimate annual changes in TC and BP biomarkers.

4.1 Exposure-response functions for PFOA and PFOS and TC

The USEPA (2023f) conducted a meta-analysis of epidemiological studies of the general population of the associations between certain PFAS and total cholesterol to estimate the exposure-response function. Using these exposure-response functions presumes that further reductions in average PFOA and PFOS concentrations in serum in the general population will result in decreases in serum cholesterol, and that decreases in serum cholesterol will lead to decreases in CVD. In other words, this presumes that serum cholesterol is an intermediate variable on the causal pathway between PFAS exposure and CVDs.

The PFOA-TC exposure-response function developed by USEPA (2023f) is the summary estimate from a meta-analysis of four studies of the general population (Nelson et al. 2010; He et al. 2018; Dong et al. 2019; Fan et al. 2020). [NOTE: The slope factor is 1.57 mg/dL per ng/mL serum PFOA. The number of studies is either four (see p. F-11, Table F-2, and p. F-12, Figure 2, USEPA 2023f) or six (see p. F-10, USEPA 2023f and elsewhere in the documents).] Similarly, the PFOSTC exposure-response function developed by USEPA (2023f) is the summary estimate from a meta-analysis of five studies of the general population (Chateau-Degat et al. 2010, Nelson et al. 2010, He et al. 2018, Dong et al. 2019, Fan et al. 2020), including the same four studies used for the PFOA-TC exposure-response function. Four of these studies were based on cross-sectional analyses serum PFAS and TC from National Health and Nutrition Examination Surveys (NHANES) and included overlapping years. For example:

• Nelson et al. (2010) included NHANES participants from 2003 to 2004; individuals taking cholesterol lowering medication were excluded.

• He et al. (2018) included NHANES participants from 2003-2004 to 2011-2012; individuals taking cholesterol lowering medication were not excluded.

• Dong et al. (2019) included NHANES participants from 2003-2004 to 2013-2014; individuals taking cholesterol lowering medications were excluded.

• Fan et al. (2020) included NHANES participants from 2011-2012 to 2013-2014; individuals taking cholesterol lowering medication were not excluded.

Overall, the USEPA (2023f) identified and included 14 studies in the meta-analysis of exposure-response relationships between PFOA or PFOS and TC. When all 11 studies of PFOA and TC are included in the meta-analysis, the slope factor is 0.003 mg/dL TC per ng/mL in serum PFOA. However, the exposure-response relationship used for the benefits analysis was based only on the summary estimate of the four (PFOA) or five (PFOS) studies that reported linear slope relationships (beta coefficient for a change in TC or HLD-C in mg/dL to increases in serum PFOA or PFOS in ng/mL). These are the studies of the general population and the coefficient (1.57 mg/dL TC per ng/mL serum PFOA) used in the benefits analysis is 500-fold higher than when all 11 studies are included. This means that the estimated benefits will be much greater using the coefficient from the meta-analysis of the four (overlapping) general population studies than from using the coefficient from the 11 studies of PFOA-TC.

In fact, there appears to be a non-linear association between PFOA and TC, which is not accounted for when a linear slope factor is used over a relatively narrow range of PFOA in serum seen in the general population. In an evaluation of serum lipids in participants in the C8 Health Science study, Steenland et al. (2009) reported that the exposure-response function was steeper at concentrations of total cholesterol (TC) below approximately 208 mg/dL. Predicted TC leveled off at around 50 ng/ml of PFOA. By relying on the exposure-response function from four studies (PFOA) or five studies (PFOS) of the general population (with average PFOA and PFOS serum concentrations below 25 ng/ml), the calculated health benefits are greater than would be expected than if the exposure-response function was based on the distribution of serum PFOA

and PFOS seen in occupational populations and studies of communities with drinking water contaminated by PFOA or PFOS. These populations have blood serum concentrations that are 2 to 4 orders of magnitude greater than those in the general population.

4.2 Issues related to use of the ASCVD model

The USEPA assumes that CVD (myocardial infarctions and strokes) can be reduced indirectly by decreasing average serum PFOA and PFOS concentrations further, which would lead to decreased total cholesterol; however, the USEPA has not shown evidence that PFAS exposure (particularly PFOA or PFOS) directly increases the risk of CVD. The USEPA (2023a, 2023c) did not acknowledge that epidemiological studies of PFAS exposures have not observed increased risks of CVD even in studies of populations exposed to the highest concentrations; instead, the USEPA suggested that the results are inconsistent.

The benefits analysis does not directly use PFOA or PFOS concentrations as inputs to the pooled cohort ASCVD model that evaluates the 10-year probability of CVD outcomes (Goff et al. 2014). Instead, the benefits analysis focuses on the exposure-response function between PFOA and PFOS and the precursor endpoint (e.g. total cholesterol) from a meta-analysis of results from epidemiological studies to calculate inputs to the ASCVD model.

Even under the assumption that PFOA or PFOS in serum leads to high total cholesterol, and a shift in the distribution of average cholesterol leads to an increased proportion of individuals with high cholesterol (which potentially affects a large population), there is a lack of evidence that such a shift has occurred based on PFOA and PFOS concentrations in the general population over the past 20 years. As such, there is substantial uncertainty in the population health benefit of reduced TC by further reducing PFOA and PFOS concentrations from the baseline assumptions to 4 ppt each. The USEPA partially acknowledged this uncertainty when it stated:

“The analysis assumes that the CVD risk impact of changes in TC/BP from reductions in serum PFOA/PFOS is the same as the CVD risk impact of changes in these biomarkers due to other reasons such as behavioral changes or medication.” (P. 6-117,6-118, USEPA 2023e).

The ASCVD model uses the following inputs to estimate a 10-year probability of a first hard ASCVD event in adults, 40 to 79 years of age (who are free from ASCVD): age, sex, TC, HDL-C, systolic BP, use of antihypertensive therapy, diabetes, and current smoking (Goff et al. 2014). However, the USEPA (2023e) used changes in TC (in relation to PFOA and PFOS) and changes in blood pressure (BP) (in relation to PFOS, discussed further below), but not changes in high density lipoprotein cholesterol (HDL-C), as inputs to ASCVD model.

Risks of CVD are lower in individuals or populations with higher levels of HDL-C. If PFOA or PFOS are also associated with higher HDL-C, it is plausible that risks of CVD would not be impacted by higher TC (Steenland et al. 2020). In a meta-analysis, the USEPA (2023f) found that, on average, HDL-C increased with PFOA and PFOS, although the summary results of the meta analyses were not statistically significant. Across the documents, the USEPA is not consistent in their conclusions regarding PFOA or PFOS and HDL-C. Separately, the USEPA

made the following conflicting statements regarding the strength of evidence for HDL-C and PFOA:

“Positive associations between PFOA and HDL were also observed in most studies in the general population.” (p. 3-155, USEPA 2023a)

“HDL was not associated with PFOA.” (p. 3-173, USEPA 2023a).

“The available evidence does not support a consistent association between PFOS and reduced HDL.” (p. 3-164, USEPA 2023c).

In contrast, the USEPA presented similarly inconsistent language for effects of PFOS on BP, but included the effect of PFOS on BP in the calculation of the ASCVD model, while excluding the effect of HDL-C on PFOA or PFOS (see next section, Exposure-response function for PFOS and increases in blood pressure for additional information).

The SAB (USEPA SAB 2022a) requested that the USEPA address whether the inclusion of HDL-C would influence the results of the benefits analysis. In response, the USEPA (2023f) conducted a sensitivity analysis of a hypothetical exposure reduction of 1 ppt PFOA and 1 ppt PFOS and found that inclusion of the HDL-C effects (from the meta-analysis) decreases the annualized CVD benefits by 23-25%. Meanwhile, exclusion of the BP effects decreases annualized CVD benefits by approximately 1.8% to 2.2%. In other words, the annualized CVD benefits may be substantially overstated by excluding HDL-C from the model. In any event, the uncertainty associated with the estimated benefits from the proposed MCLs is large. It is not clear that the proposed MCLs will further drive down average PFOA or PFOS in blood serum and therefore if the estimated benefits will materialize.

4.3 Exposure-response function for PFOS and increases in blood pressure

The USEPA (2023e) also justified including changes in BP associated with PFOS as an input into the ASCVD model, and stated that the USEPA (2023c) had concluded “there was overall consistent evidence of an association between PFOS and BP in studies conducted in general adult populations.” (p. 6-15, USEPA 2023e).

Subsequently, the USEPA (2023e) used the exposure-response function between PFOS and increases in blood pressure from a study of NHANES participants, 2003-2012 (Liao et al. 2020). This addition has not been peer-reviewed by the SAB and there is actually inconsistent language regarding the strength of evidence conclusions in the USEPA PFOS Toxicity Assessment (2023c), which also indicated that the evidence of an association between PFOS and BP is uncertain.

Examples of the inconsistency follow here:

“High and medium confidence studies reported positive associations with blood pressure and increased risk of hypertension.” (P. 3-176, USEPA 2023c)

"While there is some evidence that PFOS exposure might also have the potential to affect blood pressure and other cardiovascular responses in humans given relevant exposure circumstances, the human evidence underlying this possibility is uncertain and without support from animal or mechanistic studies." (P. 3-176, USEPA 2023c).

"Results from studies of varying confidence reported mixed results for changes in blood pressure, including DBP and SBP, and risk of hypertension for all study populations. Studies in children (10) reported mostly non-significant associations with blood pressure and/or hypertension, though two studies in adolescents reported significantly increased (1/10) and decreased (1/10) DBP in males. In adults (13), one study reported a significantly increased risk of hypertension (1/13), but associations from other studies did not reach significance (3/13). When stratified by sex, there were mixed results. One study reported a higher risk of hypertension for males (1/13), while another reported higher risk for females (1/13). One study reported an inverse association for DBP (1/13), while others reported positive associations for DBP (6/13), but only three studies reached significance. SBP was significantly increased for all adults (4/13), in females only (2/13), and in males only (1/13). No studies examined blood pressure or hypertension in occupational populations." [USEPA 2023c, p. 3-177]

Overall, the rationale for including changes in BP in relation to PFOS is not clear; the evidence regarding BP effects from PFOS is equivocal, similar to that of changes in HDL-C. Furthermore, to include changes in BP but not include changes in HDL-C in relation to PFOS is inconsistent, especially considering that the sensitivity analysis that included HDL-C effects in the ASCVD model showed a reduction of as much as 25% in the annualized CVD benefits if the USEPA metaanalysis slope factors are used. In contrast, exclusion of BP effects decreases annualized CVD benefits by 1.8%-2.2% if USEPA meta-analysis slope factors are used.

The estimated health benefits do not consider the potential impact of clinical management of CVD risks. That is, clinicians use the ASCVD risk model to evaluate 10-year risk of hard CVD events and inform decisions about risk management, with one of the common methods for modifying CVD risk being the use of cholesterol-lowering medications. At least two scenarios involving the use of cholesterol-lowing medications can result in overestimated CVD risk reductions in relation to PFAS based on the observed association of increased cholesterol with increased PFOA or PFOS:

1. Clinicians recommend that individuals with high cholesterol be administered cholesterollowering medication, with statins typically recommended first. As described in the next section on biological mechanisms, PFAS serum concentrations in individuals who use statins have not been reported to differ from serum concentrations in individuals who do not use of statins. Assuming that statins decrease circulating cholesterol levels but do not effect PFAS serum concentrations (that is, PFAS serum concentrations remain relatively unchanged), the 10-year risk of a hard CVD event will decrease due to medication use but it is unrelated to a decrease in PFAS serum concentrations. The CVD benefits calculated from reductions in PFAS levels using the ASCVD model are overstated.

2. On the other hand, the clinician may prescribe a bile acid sequestrant to lower cholesterol. As described in the next section on biological mechanisms, there is some evidence that use of bile acid sequestrants decreases PFOA serum concentrations as well as circulating cholesterol levels. In this scenario, the CVD health benefits (calculated using the ASCVD model) resulting from medication use are misattributed to decreases in PFOA (or PFOS) serum levels (whether PFAS exposure decreases or not) because the association between PFOA and serum cholesterol is confounded by underlying physiological processes (for example, enterohepatic cycling, which could explain the reported association between bile acids and PFOA and distort the magnitude of the association between PFOA and high cholesterol).

These are theoretical examples for illustrative purposes; however, in the absence of a better understanding of the biological mechanisms that underpin the association between increases in PFOA or PFOS in blood serum in the general population and increases in total cholesterol, the quantified benefits analysis may be less than estimated.

Although the USEPA has added discussion of biological mechanisms that inform the strength of evidence conclusion for increased CVD impacts associated with PFOA and PFOS, the discussion largely focuses on biological mechanisms that inform the decreases with cholesterol seen with PFOA and PFOS at much higher serum concentrations than those reported in the general population on which the RfD is based.

Biological mechanisms for the association between PFOS or PFOA (and other PFAS) and cholesterol has not yet been identified in humans. Some information regarding potential mechanisms, however, may be gleaned from epidemiological analyses of associations between PFAS concentrations and cholesterol among those who take medications to lower cholesterol. For example:

• Statins (HMG-CoA reductase inhibitors) inhibit the synthesis of cholesterol in the liver and increase the removal of low-density lipoprotein cholesterol (LDL-C) that is in the blood. Andersen et al. (2021) analyzed National Health and Nutrition Examination Survey (NHANES) data from 2003 to 2016 (while accounting for NHANES sampling parameters) and reported a 2.9% increase in PFOS concentrations ($p=0.001$) among participants who reported using statins. Statin use was not associated with increased or decreased PFOA concentrations (Andersen et al. 2021). Similarly, Ma and Ducatman (2022) found that statin use was associated with statistically significantly increased PFOS concentrations and borderline significantly increased PFOA concentrations (when compared to non-users) in the C8 Health Study.

• Bile acid sequestrants (cholestyramine) remove bile acids that are made when LDL cholesterol breaks down. Cholestyramine lowers cholesterol by increasing bile acid secretion. Cholestyramine increased fecal elimination of PFOS and PFOA and decreased blood serum concentrations in an individual who self-administered cholestyramine (Genius et al. 2010). In the cross-sectional analysis of NHANES data from 2003-2016, Andersen et al. (2021) reported that use of cholestyramine was associated with a 1.3% reduction in PFOA and a 15.1% reduction in PFOS serum concentrations. Similarly, when compared to non-users, use of cholestyramine was

associated with statistically significant decreases in serum PFAS (and the effect was strongest for PFOS) in the C8 Health Science study (Ducatman et al. 2021).

• Probenicid lowers cholesterol by inhibiting organic ion transporters (OAT). Probenecid helps the kidneys remove uric acid from the blood and is also used in the treatment of gout. Ducatman et al. (2021) compared Probenicid users to non-users and found that use of Probenicid was associated with a small increase in serum PFAS which was not statistically significant for PFOA or PFOS in the C8 Health Study (Ducatman et al. 2021)

• Ezetimibe inhibits the absorption of cholesterol in the small intestine primarily by inhibiting Niemann-Pick C1-like 1 (NPC1L1) protein. Ma and Ducatman (2022) reported that when compared to non-users, ezetimibe was not associated with blood concentrations of PFAS. Ezetimibe use was not associated with PFOA or PFOS serum concentrations in the NHANES analysis, either (Andersen et al. 2021).

Separately, the effects of lifestyle interventions on cholesterol and PFAS blood concentrations are mixed: Morgan et al. (2023) found that lifestyle interventions over 6 months significantly reduced cholesterol; blood concentrations of PFOS and PFOA (as well as other PFAS) decreased significantly as well. After lifestyle interventions, only PFOS and total cholesterol were positively correlated and PFOS was only distributed in albumin lipoprotein fractions. Before the interventions, PFOS was found in both the albumin and non-albumin lipoprotein fractions.

4.4 Effects of other factors that mediate cholesterol levels likely dominate cardiovascular disease risks

Indirect evidence exists that suggests that the MCLs of 4.0 ppt each for PFOA and PFOS are unlikely to result in benefits as great as that reported by the USEPA (2023e) because other risk factors have a considerably larger impact on cholesterol levels. Collectively, this evidence suggests that a population shift in average cholesterol levels by further decreases in serum concentrations of PFOS and PFOA would not be detected. Over the past 20 years, PFOA and PFOS in serum have decreased in the general population. In adults 20 years and older, PFOA in serum decreased from a median of 5.20 ng/mL in 1999-2000 to 1.47 ng/mL in 2017-2018 (CDC 2023b). In adults 20 years and older, PFOS in blood serum decreased from a median of 30.3 ng/mL in 1999-2000 to 4.7 ng/mL in 2017-2018 (CDC 2023b). An examination of cholesterol levels over the past 60 years indicates substantial reductions have occurred, even during the time period when serum concentrations in PFOS and PFOA were likely increasing (before 1999-2000 when use of PFOA and PFOS in industrial applications and consumer products was greatest):

• Since 1960, TC levels have declined across all adult age groups, with the steepest declines seen in the older age groups. For example, average TC decreased from approximately 250 mg/dL in 1960 to approximately 215 mg/dL in adults 60-74 in 19992002 (Carroll et al. 2005). Mean TC in adults aged 20 and older declined to 188 mg/dL in 2017-2018 from 203 mg/dL in 1999-2000, a decrease of 15 mg/dL.

• In adults ages 20 and older, the prevalence of high cholesterol (total cholesterol level of at least 240 mg/dL) was 20% during 1988-1994 (Carroll et al. 2005). Since then, the prevalence of high

cholesterol in adults has continued to decline from 18% during 19992000 to less than 11% in 2017-2018 (Carroll and Fryar 2020, Figure 4 below).

• The prevalence of high LDL-C decreased from 59% in the late 1970s to 27% in 20072010 (Kuklina et al. 2013). This trend was attributed to an increased percentage of adults eating diets low in saturated fats over time (from 25% during the late 1970s to 42% during 1988-1994). The percentage of adults eating diets low in saturated fats remained unchanged from 1988-1994 to 2007-2010 (Kuklina et al. 2013).

• From the late 1980s to 2007-2010, the percentage of adults using cholesterol-lowering medication increased from 5% to 23% (Kuklina et al. 2013).

• [Figure 4: See Docket ID EPA-HQ-OW-2022-0114-1759]

Source of Figure 4: Carroll and Fryar 2020.

With respect to heart disease specifically, the heart disease death rate for men aged 45-64 years in the US declined from 235.7 per 100,000 in 1999 to 183.5 per 100,000 in 2011. It increased to 192.9 per 100,000 in 2018. For women, the heart disease death rate declined from 96.8 per 100,000 in 1999 to 74.9 per 100,000 in 2011, and increased to 80.3 per 100,0000 in 2016 before leveling off (Curtin, 2020). Incidence of CVD has also declined globally over the period from 1990 to 2017 (Amini et al. 2021).

Overall, evidence of consistent decreases in heart disease incidence and mortality rates since 1990 (and earlier) suggests improvements in CVD risk factors and interventions related to diet, physical activity, and cholesterol medications are largely successful and largely drove decreases in CVD incidence and mortality until more recent years. It seems implausible that mean PFOA or PFOS serum concentrations at levels seen in the general public in recent years contribute to increased measurable risks of CVD, given that mean TC concentrations have fallen since the 1960s while PFAS blood concentrations were more likely to be increasing until the late 1990s or 2002. It is unlikely that the benefits of decreased CVD events are detectable with further declines in average blood PFAS serum concentrations.

4.5 Conclusions and Recommendations

• The USEPA should be consistent with its recent decision to include systolic blood pressure (SBP) in the ASCVD analysis related to PFOS (which is inconsistently related to SBP) and include HDL-C in the benefits analysis based on the ASCVD model. The ASCVD model uses HDL-C, and collectively, there is some evidence that PFOA and PFOS are positively correlated with HDL-C concentrations.

• The USEPA should include a more expansive discussion of biological mechanisms for the correlation of PFOA and PFOS concentrations with TC. The mechanisms which explain decreased cholesterol with higher PFOA or PFOS serum concentrations in animals are not likely to explain the small modest increases in cholesterol in relation to small increases in PFAS concentrations in the general population.

• The USEPA should use sensitivity analyses to further explore the potential for confounding by underlying biological processes.

• The USEPA should consider whether the quantified benefits (which are substantial) make sense within the broader context of trends over time for cholesterol levels and heart disease incidence and mortality. Cholesterol levels and heart disease incidence and mortality were decreasing even before PFOA and PFOS concentrations in the blood of the general population began decreasing (since early 2000's).

5. Overall Conclusions/Comments

• The use of a HI based on different target organs or endpoints for estimation of a regulatory value has no support in existing agency guidelines or those of other national and international authoritative bodies. The agency should delay promulgating a HI-based assessment until they have developed the necessary Target Tissue Doses (TTDs), which can readily be derived using the existing ATSDR methodology (ATSDR 2018).

• Available data suggest that further reductions of average PFOA and PFOS concentrations in blood serum are unlikely to result in measurable increases in average birth weight. Data from other areas where PFOS and PFOA concentrations are elevated suggest that increases in average birth weight and decreases in infant mortality are not expected with lower PFOS and PFOA in blood serum (Olsen and Joensen 1985; Olsen et al. 2023) found that that the mean birthweight in the Faroe Islands was higher than other Nordic countries and had increased during 2010–2019 in the Faroe Islands.

• Evidence of consistent decreases in heart disease incidence and mortality rates since 1990 (and earlier) suggests improvements in CVD risk factors and interventions are largely successful. It is unlikely that mean PFOA or PFOS serum concentrations at levels seen in the general public in recent years contribute to increased measurable risks of cardiovascular disease, given that mean TC concentrations have fallen since the 1960s. It is unlikely that the benefits of decreased CVD events are detectable with further declines in average blood serum concentrations.

• Importantly, the quantified health benefits are likely to be overstated. Although epidemiological studies have reported consistent differences in biomarkers of effect (increases in total cholesterol, decreases in antibody response, increases in certain liver enzymes or small decreases in birth weight), there are only inconsistently reported increased risks of adverse health events (e.g. frequency or duration of infections) and there is generally no evidence of increased risks of low birth weight (birth weight < 2500 g) or increased risk of cardiovascular disease, the two adverse health endpoints on which the health benefits are quantified.

• Separately, it is easy to misinterpret and overstate the health benefits potentially associated with decreasing PFOA and PFOS in drinking water by “double-counting” the benefits. As evidenced by the Faroe Islands population, there is likely to be a smaller benefit than estimated (e.g. some Faroe Islands birth cohorts showed decreases in anti-diphtheria and anti-tetanus responses in relation to PFOA and PFOS in birth cohorts that have some of the largest mean birth weights globally). In other words, any quantifiable health benefit for the population would apply to some

combination of endpoints (some small benefits associated with increased birth weight, some small benefits associated with decreased cholesterol) but not the cumulative endpoints (benefits associated with decreased birth weight plus benefits associated with decreased cardiovascular diseases). Because the actual nature of the mechanisms for the observed associations between PFOA and PFOS and the health effects are unknown, there remains substantial uncertainty in the range of the quantified benefits associated with the Proposed Option as well as the alternative regulatory options.

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EPA Response: The commenter incorrectly states that the EPA derived RfDs for TC to justify its use of the ASCVD model. As described in section 4.2.1 of the EPA response in this *Response to Comments* document and responses in section 4.2.1.3, the EPA determined in its toxicity assessments for PFOA and PFOS that there was *evidence indicating* an association between PFOA or PFOS and cardiovascular effects in humans (USEPA, 2023g; USEPA, 2023h). In particular, there was consistent evidence of increased serum total cholesterol in adults with increased PFOA and PFOS serum concentrations. The EPA did not derive an RfD to "justify its use of the ASCVD model," but because the data supported quantitative analysis of this endpoint.

Regarding commenter's critique of the exposure-response functions, use of ASCVD model in the analysis, and inclusion of the blood pressure effect in the analysis of reduced CVD risk from the proposed MCLs, please see section 13.4.1 of the EPA response in this *Response to Comments* document. Regarding the commenter's assertion that the association between PFOS and blood pressure is uncertain, see section 13.4.1 of the EPA response in this *Response to Comments* document. Regarding the commenter's assertion that there is uncertainty in the population health benefit of reduced TC by further reducing PFOA and PFOS concentrations to the MCL, see section 13.4.1 of the EPA response in this *Response to Comments* document. The EPA disagrees

with the commenter's assertion that quantified benefits are overestimated due to a failure to account for medication use and other factors such as lifestyle changes that mediate cholesterol levels. The EPA analyzes changes in blood serum PFAS levels resulting from changes in PFAS drinking water concentrations due to the installation of treatment technology. The associated quantified CVD benefits estimates are estimated based on these changes in blood serum levels only and do not reflect changes associated with other factors that mediate cholesterol levels such as lifestyle changes or use of medication. Please note that the baseline data analysis also considers the difference between populations that use statins to reduce TC and populations that do not. The EPA also provided a detailed discussion of uncertainty associated with the use of medication or lifestyle changes in table 6-51 in the EA (USEPA, 2024b). The EPA also notes that merely relying on medication to control cholesterol levels in the general population thereby decreasing PFAS-driven risk of CVD is not a health protective or equitable approach, does not consider costs or affordability to the population, and does not consider potential medication side effects, among many other concerns. The EPA's approach is to prevent increased TC in the first place by preventing chemical exposure and this preventative approach to the rule is reflected in the EPA's benefits analysis.

Regarding the commenter's assertion that the EPA did not consider that studies exposed to high PFAS concentrations reported no increase in CVD risk, see the EPA response to comment Doc. #1713, SBC-045921 in section 13.4.1 in this *Response to Comments* document.

The EPA disagrees with the commenter's characterization of inconsistencies between assessments regarding associations between PFOS and blood pressure in adults. The consistent findings for serum lipids are also supported by evidence of associations with blood pressure in adult populations in *high* and *medium* confidence studies as was summarized in Tables 3-8 and 3-11 of the PFOA and PFOS toxicity assessments, respectively (USEPA, 2024h; USEPA, 2024i). With regard to the commenter's statement that associations between PFOS and blood pressure do not have support from animal or mechanistic studies, the EPA notes that there is no requirement for concurrence between human studies and animal studies. Rather, if there is evidence in humans, even without evidence in animals, then the evidence supports a relationship between exposure and the health effect in humans.

The commenter stated that the EPA was inconsistent in conclusions regarding associations between PFOA or PFOS and HDLC and provided several quotes to support this erroneous assertion. The first quote (p. 3-155, USEPA 2023g) describes results among adults from only the subset of studies included in the 2016 Health Effects Support Document, while the second quote (p. 3-173, USEPA, 2023g) summarizes results among adults from all studies included in the current assessment. The quotes were describing two different subsets of studies and, therefore, were not inconsistent. The EPA additionally notes that the commenter only provided one quote regarding conclusions about associations between PFOS and HDLC and does not show how the EPA was inconsistent by comparing to a second quote. The EPA develops health effects summaries by population (e.g., general adult population, pregnant women, occupational population, children); the quote provided by the commenter pertains to studies of the general adult population, who may show different responses to chemical exposure than other

populations, thus resulting in multiple conclusions regarding the potential for hazard. Please see the evidence integration sections (Section 3.4.3.4) in the PFOA and PFOS Assessments for judgements synthesizing results across populations (USEPA, 2024h; USEPA, 2024i). The EPA therefore evaluated HDLC effects in a sensitivity analysis presented in the EA (see Appendix K; USEPA, 2024c).

The EPA agrees with the commenter's characterization of potential uncertainty associated with the estimated benefits based on the results of the CVD benefits sensitivity analysis. The EPA disagrees with the commenter's assertion that it is unclear whether the proposed MCLs will reduce average PFOA and PFOS in blood serum, as pharmacokinetic models have shown that reductions in PFOA and PFOS in drinking water will result in reduced PFOA and PFOS in blood serum (USEPA, 2024c).

Regarding the commenter's critique of the use of the Hazard Index, see sections 4.3 and 5.2 of the EPA response in this *Response to Comments* document. For additional information on the Hazard Index, see section V.B of the FRN.

The EPA disagrees with the commenter's critique of the EPA's linear assumption for the relationship between PFOA and TC. See section 13.4.1 of the EPA response in this *Response to Comments* document.

The EPA disagrees with the commenter's assertion that "reduction in PFOA and PFOS concentrations in blood serum are unlikely to result in measurable increases in average birth weight." The EA clearly indicates that reducing PFOA and PFOS in drinking water will reduce the *risk* of decreased birth weight resulting from PFOA/PFOS exposure (see Section 6.4, USEPA, 2024b). See section 13.4.2 of the EPA response in this *Response to Comments* document.

Regarding the commenter's suggestion that the EPA needs to include a more expansive discussion of biological mechanisms for the correlation of PFOA and PFOS concentrations with TC, the EPA notes that this is not a requirement for quantification of a benefit. The associations identified between exposures to PFOA and PFOS and increases in TC are based on epidemiologic evidence in humans with and without use of cholesterol lowering medications. The EPA points out that the many sensitivity analyses included in the meta-analysis demonstrate one approach to accounting for potential confounding by underlying biological mechanisms. Additionally, the commenter listed citations for epidemiological studies of potential associations between PFAS concentrations and cholesterol levels among patients with high cholesterol who take cholesterol-lowering medications. The commenter suggested that these studies may provide some information on the potential biological mechanisms between PFAS and cholesterol, and the commenter summarized the studies' conclusions; however, the commenter did not explain how these studies inform the mechanistic evidence or support or refute an underlying mechanism of changes in serum lipid levels related to exposure to PFOS or PFOA. The EPA has reviewed these suggestions and determined that, while this information may represent informative epidemiological evidence, it does not provide mechanistic evidence or warrant inclusion in a

mechanistic evidence section (i.e., Section 3.4.3.3 of the Final Toxicity Assessments for PFOA and PFOS (USEPA, 2024h; USEPA, 2024i)).

The EPA disagrees with this commenter's assertion that quantified benefits were "double counted" as evidenced by a comparison to another population with elevated PFAS exposure in the Faroe Islands. The EPA has reviewed the provided sources, and the EPA does not agree that findings from the Faroe Islands inform in any way, as suggested by the commenter, that the quantified benefits apply to only some combination of health points rather than cumulatively. Furthermore, the EPA has diligently considered possible sources of double counting of both costs and benefits throughout the analysis. Upon review, the EPA did not find sufficient evidence provided by this comment to suggest that double counting of quantified benefits occurred. For the endpoints that the EPA modeled in the quantitative national level benefits analysis (i.e., birth weight, CVD, RCC, and bladder cancer), the commenter has provided no data or evidence to support their criticism that the benefits are double counted.

American Water Works Association (AWWA) (Doc. #1759, SBC-045640)

Finally, the benefits analysis includes several assumptions that are not clearly and consistently discussed by the agency. For example, the analysis of CVD risk reduction accounts for impacts to total cholesterol from PFAS exposure but excludes the impacts to HDL-C, which decreases risks of CVD. These analyses, which underpin the rulemaking's HRRCA and affordability analysis, need significant improvements.

EPA Response: The EPA disagrees with the commenter. The EPA has clearly described the key uncertainties and limitations associated with all modeling components. When feasible, the EPA presented the impact (i.e., directionality) of assumptions on the resulting benefit-cost estimates. For detailed explanations of these assumptions and limitations, please refer to the limitations and uncertainties tables in Chapters 5, 6, and 7 of the EA (USEPA, 2024b). Regarding the decision to exclude HDLC effects from the national-level quantified benefits analysis, see the EPA response to comment Doc. #1759, SBC-053061 in section 13.4.1 in this *Response to Comments* document and section 13.4.1 of the EPA response in this *Response to Comments* document. The commenter is incorrect, however, that the EPA did not consider the impacts of HDLC. The EPA conducted CVD sensitivity analyses to explore the impact of inclusion of HDLC effects and exclusion of BP effects from the CVD analysis. Please refer to Appendix K, Section K.3 of the EA for detail (USEPA, 2024c). The EPA found that HDLC effects either increased or decreased CVD benefits based on the slope factors used. Please refer to Appendix K, Section K.3 of the EA for detail (USEPA, 2024c). The EPA considered the information in the HDLC sensitivity analysis, along with all other sensitivity analyses that would impact benefits (some of which would increase benefits and some would decrease benefits), prior to making the determination that the costs are justified by the benefits.

American Water Works Association (AWWA) (Doc. #1759, SBC-045620)

8. Health Risk Reduction Analysis

As required by SDWA, EPA has prepared a health risk reduction analysis for each of the proposal's regulatory options. AWWA contracted with Ramboll Consulting U.S. to assist in reviewing the EPA's approach and to offer detailed recommendations to improve this important work. Ramboll has provided a detailed letter with recommendations, which is included in these comments in Appendix A.

AWWA requests that EPA update its health risk reduction analysis in light of Ramboll's report and the recommendations it contains so as to ensure that the agency is relying on the best available public health information in reaching any regulatory decisions. MCLs are appropriately set at a level where the benefits justify the costs, and without a reliable assessment of both the costs and benefits of the proposal, EPA cannot do so. Based on the information provided in the proposal, the benefits do not justify the costs at the proposed MCL levels and particularly do not justify the costs under EPA's proposed compliance timeline.

Estimating Reductions in Cardiovascular Disease Risks

According to the proposal, increased PFOA and PFOS serum concentrations may lead to an increased risk of cardiovascular disease (CVD), including myocardial infarctions and strokes. To support this analysis EPA relies on an assumption that there is a causal relationship between PFAS exposure and CVD. In particular, this analysis uses exposure-response functions from a meta-analysis that was conducted using data from several epidemiological studies on the general population. In review of this approach, several critical issues have been raised:

• While EPA relies on epidemiological studies of participants from the National Health and Nutrition Examination Surveys (NHANES) to support its meta-analysis of PFAS exposure and CVD risk. These studies did not observe increased risks of CVD in the participants of these studies, including those participants with highest exposures yet EPA characterizes the results of these studies as 'inconsistent'.

• The analysis of CVD risk projects changes to total cholesterol and blood pressure based on PFOA and PFOS exposure but excludes changes to high density lipid cholesterol, which has also been observed. A sensitivity analysis of a hypothetical exposure reduction of 1 ppt PFOA and PFOS, which included the effects of changes to HDL-C, found that annualized CVD risk reduction benefits were decreased by 23 to 25%. By comparison, when changes to blood pressure were excluded the reduction in annualized CVD risk reduction benefits only decreased by 1.8 to 2.3%. This suggests that the benefits analysis, which excludes the impact of PFOA and PFOS on HDL-C, is significantly overestimated.

• Throughout the supporting documentation, the EPA makes contradictory statements about the strength of Associations of PFOA and PFOS on blood pressure and HDL-C. Furthermore, the

inclusion of blood pressure impacts from PFOA and PFOS exposure but not the inclusion of changes to HDL-C is unclear, especially given that these impacts were observed equivocally.

• The biological mechanism for the Association of PFOA and PFOS with cholesterol is not yet identified in humans. In fact, recent work demonstrates that a lifestyle intervention on cholesterol led to a decrease in both the cholesterol and serum PFOA and PFOS concentrations.

• Finally, given the recent downward trend in decreasing total and low-density lipid cholesterol since the 1970s coupled with the decreasing PFOA and PFOS serum levels suggests that there is a substantial likelihood that the proposed MCLs for PFOA and PFOS are unlikely to result in benefits as great as is reported as part of this proposal, given the outsized impact from other risk factors.

Additional details on these and other comments for the EPA's analysis of cardiovascular disease risk reduction are available in Appendix A. Based on the materials made available, it does not appear that EPA's conclusion is fully supported by the evidence or record before the agency.

EPA Response: The EPA disagrees with the commenter's statement that the EPA did not conduct a reliable assessment of both the costs and benefits of the proposal, and the EPA also disagrees with the commenter's claim that MCLs benefits do not justify the costs at the proposed MCL levels. The EPA completed a robust analysis of quantifiable and nonquantifiable benefits and costs and has set the MCLs appropriately taking feasibility into account. Contrary to the commenter's statement, SDWA does not require the EPA to set the MCL at a level at which costs are justified by the benefits. The statute requires that the EPA assess the costs and benefits of the proposed MCLs pursuant to the HRRCA in Section 1412(b)(3)(C) and publish a determination as to whether the costs of the proposed levels are justified by the benefits. SDWA Section 1412(b)(4)(C). Unless the EPA applies an exception, the MCL is set as close as feasible to the MCLG as required under Section 1412(b)(4)(B). As explained in the preamble to the final rule, the EPA confirms that the benefits of the final rule justify the costs. For the EPA's response to comments received on the compliance timeline, see section 12.1 in this *Response to Comments* document.

The EPA disagrees with the commenter's assertion that the literature underpinning quantification of CVD health benefits from PFOA and PFOS concentration reduction is insufficient. Please refer to the section 13.4.1 of the EPA response in this *Response to Comments* document regarding the EPA's determination on evidence of CVD risks associated with PFOA and PFOS exposure, reasons for including HDLC effects in CVD sensitivity analyses only, and the potential effects of decreasing total and low-density lipid cholesterol in the general population on the CVD analyses. The EPA disagrees with the commenter's assertion that the sensitivity analysis results for PFOA/PFOS effects on HDLC suggests that CVD benefits are overestimated. As discussed in Chapter 6.5 of the EA, the relationship between serum PFOA/PFOS and HDLC has a higher degree of uncertainty and therefore, the potential impact of HDLC was evaluated in the sensitivity analysis. Limitations and uncertainties for HDLC effects are described in Chapter 6 of the EA and Appendix F of the EA (USEPA, 2024b and USEPA,

2024c, respectively). The EPA disagrees with the commenter that the EPA makes contradictory statements about the strength of associations between PFOA and PFOS and blood pressure and HDLC. See section 13.4.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1759, SBC-053061 in section 13.4.1 in this *Response to Comments* document for a discussion of other causes of CVD health outcomes, including lifestyle changes.

The EPA disagrees with the commenter's claim that benefits do not justify the costs at the proposed MCL levels. See section 13.8 in this *Response to Comments* document for the EPA's response to comments comparing benefits and costs and the EPA Administrator's benefit-cost determination. As discussed thoroughly throughout the EA and FR but most notably in Chapter 7 of the EA and section XII of the FRN, the EPA Administrator determined at the time of the proposal that both the quantifiable and nonquantifiable benefits of the rule justify the quantifiable and nonquantifiable costs. The economic analysis provides a robust, multi-pronged quantified and nonquantified cost and benefit analysis that substantiates and justifies this determination. Further, for this rulemaking, the Administrator reaffirmed the determination made under the proposed rule that the quantifiable and nonquantifiable benefits justify the quantifiable and nonquantifiable costs for MCLs set as close as feasible to the MCLGs.

As described in the FRN for the final rule, the EPA received comments on the proposed rule regarding the compliance timeline, and some commenters raised concerns with the proposed requirements for initial monitoring and compliance actions. As a result, as described in the Monitoring and Compliance Requirements section (VIII) of the FRN for the final rule and section 12.1 of the EPA response in this *Response to Comments* document, the EPA is exercising its authority under SDWA § 1412(b)(10) to implement a nationwide two-year capital improvement extension to comply with the MCL. Consequently, water systems will have up to the full three years following rule promulgation to plan and conduct monitoring and still have two additional years to complete any actions needed to comply with the MCLs. Additionally, and as described in section 13.3 of the EPA response in this *Response to Comments* document and in the EA for the final rule, the EPA made a number of updates to the costs model to better reflect costs of compliance of the rule and other factors that contribute to the EPA's estimate of total annualized costs, using the best-available peer-reviewed science to inform these estimates.

3M Company (Doc. #1774, SBC-045690)

f. Exposure-Response Relationships Were Improperly Selected

To calculate the health-risk reduction benefits based on serum concentrations, EPA extracts from literature or independently reanalyzes various exposure-response slope factors that are intended to demonstrate a quantitative relationship between a change in serum concentrations and a specific health effect. For both PFOA and PFOS, EPA evaluates the health effects of reductions in birth weight and increases in total cholesterol. EPA also considers increases in renal cell carcinoma risk for PFOA and increases in blood pressure for PFOS. For each endpoint, EPA selects relationships between serum levels and health effects that are not supported by the

underlying studies or are based on uncertain reanalysis of data. These flawed analyses add to the misleading conclusions associated with basing the analysis on inappropriate and indistinguishable regulatory alternatives.

For the endpoints that EPA suggests are associated with cardiovascular disease (e.g., increased cholesterol), EPA also inappropriately derives exposure-response slope factors and ignores their biological relevance. For total cholesterol, EPA conducted its own meta-analysis and only included studies that had linear associations (6 studies for PFOA and 5 studies for PFOS) (USEPA 2023k). This selection criterion biases the results and misrepresents the overall weight of evidence, because other studies that did not show linear associations (6 studies for PFOA and 7 studies for PFOS) were ignored altogether in the calculation of the exposure-response slope factor. Like the birth weight analysis for PFOS, this analysis is not peer reviewed. EPA (USEPA 2023i) also states that it used "untransformed serum PFOA/PFOS," which means that it did not evaluate the relationship using a log scale. The importance of using a log scale is described in Section VII.b above. The associations with total cholesterol also are not biologically significant. For example, EPA derives an exposure-response slope factor for PFOA equal to 0.08 mg/dL per ng/mL, which means that for every 1 ng/mL increase in serum PFOA, total cholesterol increases by 0.08 mg/dL. Based on the demonstration of serum concentrations described in Section VII.d above, the difference in serum concentrations between 4.0 ppt and 10.0 ppt was less than 1 ng/mL. A change of 0.08 mg/dL of total cholesterol is not biologically meaningful, since total cholesterol is typically reported in mg/dL as whole integers (e.g., 175 mg/dL or 200 mg/dL); cholesterol is not measured or reported to the hundredths of mg/dL. Thus, a potential change in total cholesterol going from a drinking water exposure at 4.0 ppt to 10.0 ppt would not likely be measurable. For PFOS, the exposure-response slope factor is 1.57 ng/dL per ng/mL, which also does not represent a biologically significant change in cholesterol, especially over small changes in serum concentrations.

EPA's approach to selection of exposure-response slope factors is scientifically flawed, lacks transparency, and disregards the biological relationship of exposure and effects. EPA should consider and discuss the exposure-response slope factors in the context of biologically relevant effects and obtain peer review for any novel analyses. EPA's analysis egregiously misrepresents any meaningful determination of health risk reduction benefits between the proposed MCL and regulatory alternatives.

g. EPA's Estimate of Decreased Cardiovascular Disease (CVD) Risk is Not Reproducible or Transparent

The estimated CVD risk reduction derived by EPA in the Economic Analysis for the proposed PFOA and PFOS NPDWR is systematically flawed. Issues with the estimated CVD risk reductions stem from deviations from EPA's guidance for study selection and dose-response analysis and are compounded by a lack of transparency and reproducibility in EPA's methods.

i. EPA's study quality evaluation and study selection process are not consistent and are not transparent

EPA used meta-analytic approaches to derive a pooled estimate of the slope of a linear function of exposure-response between serum PFOA and PFOS (ng/dL) and serum total cholesterol (TC) (mg/dL) for use in the Economic Analysis (USEPA 2023c). These pooled slope estimates are developed independently for PFOA and for PFOS. Pooling information across epidemiological literature through use of meta-analysis allows for incorporation of individual-study uncertainty and consideration of the full range of observed exposure-response relationships across epidemiological studies; this allows EPA to use the full body of evidence in lieu of selecting an observed exposure-response slope from one single study. The first step of this process is identification of studies that meet inclusion criteria for the meta-analysis. EPA relied upon the literature review processes from the Agency for Toxic Substances and Disease Registry (ATSDR, 2021) and EPA risk assessments (USEPA 2023a,b). These approaches identified 80 studies on PFAS (see USEPA 2023c, Figure F-1). From those studies, EPA further limited the included studies by the following criteria: the study must 1) be conducted on adults in the general population; 2) quantitatively measure TC and high-density lipoprotein cholesterol (HDLC); 3) evaluate exposure of PFOA and PFOS. Additional exclusion criteria included: 1) pregnant women, infants, or children; 2) reporting of only relative risks or odds ratios for hyperlipidemia or hypercholesterolemia as these measurements of response could not be used. EPA also stated that "studies performed on specific population subsets, such as occupational populations, were not considered for inclusion in the meta-analysis due to the potential for greater levels of exposure to PFOA and PFOS in these populations compared to the general population" (USEPA 2023k, p. F-2). In other words, EPA excluded studies on members of the population expected to have higher-than-average concentrations of PFOA and PFOS in their blood.

In the Economic Analysis, EPA states that "[a]ll studies were evaluated for risk of bias, selective reporting, and sensitivity as applied in developing EPA's Toxicity Assessments and Proposed Maximum Contaminant Level Goals for PFOA and PFOS in Drinking Water (U.S. EPA, 2023a; U.S. EPA, 2023b)" (USEPA 2023c, p. F-8). However as noted in Section V.d.iii, the risk of bias analyses presented by EPA and its systematic review methods lack transparency and consistency in the evaluation of study quality. Despite the lack of transparency and consistency in the process, EPA assigned a determination regarding its confidence in each study (based on EPA IRIS protocol for risk of bias, selective reporting, and sensitivity; see EPA 2023a,b, p. 3-147). However, the study quality ranking was not used as an exclusion criterion for the meta-analysis. Therefore, studies considered as "low confidence" by EPA (based on the study quality evaluation) were not excluded from the pooled analysis.

A total of 23 studies on PFAS and TC and HDLC in the general population were considered for inclusion in the meta-analysis (USEPA 2023c, p. F-2). Of the 23 studies considered for the Economic Analysis by EPA (USEPA 2023c), 14 total studies on adults in general populations met EPA's inclusion criteria. Eleven of the studies evaluated the relationship between serum TC and PFOA and 12 studies evaluated serum TC and PFOS. Each of these 14 studies are described in USEPA 2023c, Table F-1. This includes: 6 studies on serum TC and PFOA/PFOS from NHANES [FN87: Studies based on NHANES are cross-sectional in nature, and therefore have limited utility for purposes of establishing causality (see discussion at the end of this section).

Also see Section V.d.i noting significant concerns regarding studies using uncorrected NHANES data.] that represents the general US population (Dong et al. 2019; Fan et al. 2020; He et al. 2018; Jain 2019; Liu et al. 2018; Nelson et al. 2010); 2 studies from other US populations, including prediabetic adults from a diabetes prevention program (Lin et al. 2019) and a potentially highly exposed population (Steenland et al. 2009); and 6 studies on serum TC and PFOA/PFOS in other countries, including Canada (Fisher et al. 2013), a Canadian Inuit population (Château-Degat et al. 2010), Sweden (Li et al. 2020), Taiwan (Yang et al. 2018; C.Y. Lin et al. 2020) and China (Fu et al. 2014).

EPA does state reasons for exclusion of several additional general population studies that met its initial inclusion criteria (e.g., Eriksen et al. 2013; Fitz-Simon et al. 2013; Huang et al. 2018; Convertino et al. 2018). However, EPA does not clearly explain why other studies on adults in general populations (e.g., Donat-Vargas et al. 2019), clinical trials (e.g., Liu et al. 2020) or highly exposed populations (e.g., Canova et al. 2020; Zare Jeddi et al. 2021) were not considered. Despite being a clinical trial, in which exposure and response are typically known, Convertino et al. (2018) was judged "low confidence" or "uninformative" by EPA due to residual confounding by socioeconomic status (SES) and "lack of information on allocation of participants to treatment levels" (USEPA 2023a, p. C-23, C-44). However, other "low confidence" studies were included in the meta-analyses; in the Economic Analysis, four included studies were designated as "low confidence" due to deficiencies in participant selection, outcome assessment, or confounding domains (Fu et al. 2014; He et al. 2018; Yang et al. 2018; Y. Li et al. 2020). EPA conducted a sensitivity analysis to evaluate the impact of excluding all "low confidence", or higher risk of bias studies (reported in EPA 2023c, Tables F-2 and F-3), however EPA did not conduct sensitivity analyses to evaluate the impact of removing He et al. (2018), a low confidence study, from the "linear models only" pooled estimate or removal of all "low confidence" studies from the US/Canada only models. Inclusion of these low confidence studies may introduce bias into the pooled estimates. Additionally, this sensitivity analysis does not address studies not included in the "all studies" analysis. EPA should demonstrate that the pooled slope estimates are not biased through inclusion and exclusion of specific studies through 1) consistency in application of exclusion criteria; and 2) sensitivity analyses that quantify the impact of inclusion and exclusion of individual studies on the pooled slope estimates. Without additional sensitivity analyses, EPA cannot demonstrate that the pooled effects are not sensitive to (or driven by) one study, lower quality studies, or other specific populations that are not generalizable to the US.

Confidence in the sensitivity analyses that measure the impact of inclusion/exclusion of low confidence studies is further weakened by the lack of transparency and consistency in EPA's determinations of study quality (as noted in Section V.d.iii supra). Many of the studies considered "medium quality" by EPA have critical deficiencies, including inadequate control for confounding or correlated exposures and/or cross-sectional study designs. Without additional sensitivity analyses, including the exclusion of cross-sectional studies and further exclusion of "low confidence" studies, EPA cannot demonstrate that the meta-analyses are not sensitive to inclusion or exclusion of specific studies and improve confidence in the pooled slope estimates

Highly exposed populations include both occupational cohorts and communities that were exposed to elevated levels of PFAS in drinking water. Although EPA states that "studies performed on specific population subsets, such as occupational populations, were not considered for inclusion in the meta-analysis due to the potential for greater levels of exposure to PFOA and PFOS in these populations compared to the general population" (USEPA 2023k, p. F-2), this judgment is not consistently applied. For example, EPA included Steenland et al. (2009) in the meta-analysis despite the fact that "Steenland et al. (2009) retained the results from a study of a highly exposed population in the United States (the C8 Health Project cohort)" (USEPA 2023c, p. F4). Some of the studies not included in the meta-analysis (e.g., Eriksen et al. 2013; Fitz-Simon et al. 2013) are included as key studies in the PFOA (USEPA 2023a, Table A-6) or PFOS (USEPA 2023b, Table A-6) risk assessments. It is unclear why EPA would find those studies appropriate for use in risk assessments but not in derivation of a dose-response curve for its benefits analysis. [FN88: Although information required for incorporation of Erikson et al. (2013) and Fitz-Simon et al. (2013) into the pooled analyses were not available in the publications, EPA did not indicate that it attempted to contact the authors or to re-assess the underlying evidence to incorporate these study populations into the meta-analysis, which is recommended by Cochrane review processes to reduce bias from under-reporting in the primary literature.] Exclusion of studies EPA itself identified as "key" or studies from highly exposed populations create substantial risk of biasing the results of the meta-analysis and limiting generalizability of the findings. These risks can only properly be addressed by EPA through inclusion in the meta-analysis and use of sensitivity analyses to measure the impact of omission.

Occupational exposures were excluded from the pooled analysis (e.g., Olsen et al., 2001, 2003; Olsen et al 2007; Costa et al. 2009). However, the estimated slopes used in the pooled assessment are an estimate of change in TC per ng/mL PFAS exposure, therefore information from these studies would be expected to be informative despite the expected difference in exposure levels. The models used in the meta-analysis are a continuous function of the relationship between exposure and TC outcomes (i.e., straight lines), and so the highly exposed, or occupational, groups should be just an extension of the same dose-response slope.

Further, occupational studies typically represent highly exposed populations and a lack of increased odds of CVD risk in these populations would indicate a potential lack of response in the general population with lower exposures. As noted by EPA (USEPA 2023a, p. 3-174), the occupational studies "suggest no association between PFOA and TC in workers", in part due to a lack of statistically significant associations for the observed increases in serum TC and the reported inverse association between changes in PFOA and serum TC reported by Olsen et al. (2012). EPA states that "[c]ross-sectional occupational studies… reported positive associations between PFOS and increased serum TC…however, the association was not observed in longitudinal analyses," [FN89: A longitudinal study is defined by repeated collections of sampling data in the same individuals over a period of time (typically years). A cohort study is a common example.] which weakens the strength of the causal association as the significant associations were only observed in cross-sectional analyses that cannot establish a temporal relationship [FN90: Temporality is a criterion of the Bradford Hill criteria, an established and

well-accepted list of criteria used to consider causal associations in epidemiology] between exposure and response (USEPA 2023b, p. 3-145). Findings from longitudinal analyses should hold greater weight in the evidence synthesis because they can establish that exposure precedes the observed response. Accordingly, best practice would be to benchmark the slopes of the pooled analyses against these occupational studies to ensure that the proposed exposure-response relationship is coherent across the full body of evidence. Additional sensitivity analyses should also be conducted with inclusion of these occupational populations. For example, EPA conducts a sensitivity analysis excluding "non-US/Canada and high exposure studies" but does not evaluate the pooled results from US/Canada populations including those high-exposure populations. These additional sensitivity analyses are necessary to ensure that the pooled slope used for the economic benefits analysis is representative of the reliable (or high-quality) studies from relevant populations.

EPA's reliance in its benefit analysis on cross-sectional studies is also in contradiction with its statement that "the main considerations specific to evaluating the quality of studies on serum lipids included use of medications, fasting, and potential for reverse causality." (USEPA 2023c, p. F-8). Cross-sectional studies, such as those based on NHANES data, cannot establish temporality and findings may be due to reverse causality. In other words, cross-sectional studies measure exposure and response simultaneously, and therefore cannot establish that the exposure occurred prior to onset of the measured disease or response outcome. When the exposure and response are measured simultaneously, it cannot be demonstrated that the measured exposure is not affected (or caused) by the response. As noted by Dong et al. (2019), "The NHANES data are capable of examining the association but cannot address the issue of causality. Similar to other cross-sectional studies, this study cannot answer whether: 1) exposure to PFASs elevates the cholesterol level; 2) high cholesterol levels allow the storage of PFASs easier; or 3) joint factors simultaneously affect both PFASs and cholesterol". See also, e.g., Andersen et al. (2021); Fragki (2021). Therefore, inclusion of cross-sectional analyses in the meta-analyses is a limitation that must be addressed by EPA.

In summary, EPA does not clearly state the reasoning for inclusion or exclusion of all relevant studies from the meta-analyses. The studies selected for the economic benefits analysis are inconsistent with the studies included in the risk assessment for RfD derivation. This inconsistency limits confidence that that the meta-analyses for CVD risk include all applicable information, which then impacts confidence in the estimated economic benefits.

ii. EPA's dose-response model selection process is not transparent or consistent with generally accepted risk assessment and statistical approaches.

Of the pooled model options presented in EPA's Economic Analysis appendices (USEPA 2023c, Tables F-2 and F-3) EPA selected "linear models only" for use in its CVD risk reduction analysis. This means that EPA chose to include only models that describe a linear relationship (straight line) between exposure and response and excluded studies that fit a linear regression to logarithmically transformed data (i.e., log-linear models). Use of only studies with slope estimates based on linear models, instead of logarithmic or other transformations, limits analyses

to 4 of the 14 studies on serum TC and PFOA and 5 of 15 studies on serum TC and PFOS (USEPA 2023c, Tables F-2 and F-3). In addition, studies considered "low confidence" by EPA are included in the limited numbers of studies included in the "linear models only" analyses. EPA's use of the "linear models only" resulted in the exclusion of higher-quality studies and could bias the analysis. Because of the significant likelihood that the "linear models only" approach omits critical information and biases the results, a proper analysis would require demonstration that the findings from the limited "linear models only" analyses are representative of the body of evidence and are not biased by the study selection criteria.

In other analyses in this rulemaking, EPA has relied on studies using logarithmically transformed data for estimating the slope of the exposure-response and BMD(L) derivation (e.g., Budtz-Jorgensen and Grandjean, 2018). However, EPA states that, for the economic benefits analysis, it "selected the pooled slope estimate based on the studies using linear models to ease interpretability and to reduce bias due to backtransformations of effect estimates with logtransformed outcomes or exposures" (USEPA 2023c, p. 6-55). EPA failed to show that its justification for use of the linear models was based on scientific accuracy; instead, the justification indicates that the selection of models was based on ease of use and not based on best science. Although conversion of non-linear studies into useable linear slope estimates requires mathematical assumptions that impart uncertainties in the backtransformed [FN91: Backtransformation is defined as converting a transformed number (i.e., a log or square root of a measurement) to its untransformed equivalent (i.e., exponentiation or squaring of the log or square root).] estimates, EPA relied upon log-transformed evidence (e.g., Grandjean et al. 2012; Budtz-Jorgensen and Grandjean 2018) in support of derivation of PODs for RfD development and demonstrated a clear willingness to modify and make assumptions from the underlying evidence (see USEPA 2023a,b Appendix E for details of BMD modeling). For example, EPA estimated BMRs from Budtz-Jorgensen and Grandjean (2018) measured as the "log2[tetanus antibody concentration]" (p. USEPA 2023a, p.E-1). This means that EPA had to backtransform the evidence from BudtzJorgensen and Grandjean (2018) in derivation of the RfD. Therefore, the rationale to select the pooled slope estimate based only on linear models "to reduce bias due to backtransformations of effect estimates" is not consistent with approaches used by EPA in its risk assessments in the supporting documents for this Proposed Rule.

In addition, EPA's decision to base the pooled slop estimate only on linear models [FN92: A linear (i.e., straight line) model is equivalent to a linear regression model with the function $y = mx + b$, where y = response; m = slope; x = dose; b = intercept. Non-linear models incorporate other parameters, such as exponential functions, or use transformation (e.g., logarithm) of the dose or response variable to improve description of the observed dose-response. Non-linear models allow for fitting either 1) a linear model to log-transformed dose and/or response data or 2) fitting a curve to the observed data, for which the slope is not constant and may be more steep or more shallow than the rest of the model in the exposure region of interest.] removes a large portion of the complete body of evidence and does not integrate the findings from all studies. Critically, this approach likely biases the pooled estimate toward finding a statistically significant effect through 1) exclusion of higher quality studies; 2) exclusion of additional populations of

interest; and 3) exclusion of non-linear models may better capture the observed dose-response relationship. As evidenced by the sensitivity and other meta-analytic models (e.g., Table F-2 and Figure F-4), inclusion of these additional studies results in a lack of a statistically significant dose-response between PFOA and TC. Meaning, overall, the full body of evidence indicates that there is likely no significant effect between PFOA/PFOS and serum TC. The fact that the "linear models only" analysis is the only pooled analysis of PFOA exposures that identified a statistically significant slope (p-value < 0.05) (see Table F-2) indicates that the "linear models only" analysis is not representative of the full body of evidence. For PFOS and TC, the pooled dose-response using "linear models only" was not statistically significant (p-value > 0.05). Inclusion of additional studies with non-linear models identified a statically significant (p-value < 0.05), albeit shallow, pooled slope estimate for some of the modeled relationships between PFOS and serum TC (Table F-3). The analyses presented in EPA's (2023c) Tables F-2 and F-3 show the meaningful impact that inclusion and exclusion of individual studies has on pooled slope estimates. Therefore, EPA must carefully evaluate its decision to use the "linear models only" slope estimates for the economic analysis and provide additional justification for the use of these models in lieu of models that incorporate more information. This justification is critical due to the differences between the "linear models only" and models with more complete information, both in terms of the magnitude and the significance of the pooled slope estimates.

Further, inclusion of linear-only models assumes that a linear dose-response best explains the observed dose-response relationships between PFAS exposures and serum TC changes. However, EPA has not clearly shown that linear assumptions are appropriate or consistent with underlying toxicological evidence, nor has it provided the information required for peer or public review. Non-linear models incorporate other parameters, such as exponential functions, or use transformation (e.g., logarithm) of the dose or response variable to improve description of the observed dose-response. Use of these non-linear models may allow for improved predictivity of the observed relationship between exposure and response.

Contrary to EPA guidance for dose-response analysis, EPA does not describe relative model fit for each of the included studies or the appropriateness or impact of linear assumptions. As stated by EPA BMDS guidance, "an important criterion for selecting a fitted model is that the model provides an adequate description of the data, especially in the region of the BMR" (USEPA 2012, p. 33). [FN93: See Sections II.a and V.e for further explanation of BMDs and their import] Although EPA is not using a BMD to support this economic assessment, the model fitting criteria prescribed by EPA's BMDS guidance are generally accepted statistical practice. Evaluating the model's ability to predict the observed response (or "model fit") is a critical step in basic regression statistics. EPA's BMDS guidance also recommends visual inspection and plotting of residuals in order to evaluate deviations of the model predictions from the observed response. In selecting models, EPA recommends a stepwise process that 1) assesses the goodness-of-fit; 2) rejects models that do not adequately describe data in the dose-response region of interest; and 3) applies additional "somewhat arbitrary" defaults for model selection (EPA 2012, p. 39-40). Here, EPA has not shown that the linear models fit the observed TC responses from individual studies, nor that they accurately predict responses at exposures relevant to the general population.

Moreover, EPA has not shown that the non-linear or logarithmically transformed models fail to more accurately describe the observed exposure-response. In the absence of causality information among the epidemiological literature, which is the case here, toxicological information could be used to inform on the expected model shape and the appropriateness of assuming linearity. EPA acknowledges this potential issue in its discussion of model limitations and uncertainties (EPA 2021; Table 7) when it states "the derivation of PFOA/PFOS exposure-response functions for the relationship between PFOA/PFOS serum and TC assumes that there are no threshold serum concentrations below which effects do not occur." However, the impact of this uncertainty is described only as "uncertain" and not further addressed by EPA. Therefore, projecting economic impacts based on models that do not clearly demonstrate an exposure-response may overstate the predicted economic benefit.

For PFOA, when looking at the full body of evidence and pooled meta-analytic slope estimates (shown in Table F-2), EPA's pooled slope estimates are only statistically significant when using linear models only. The estimated slopes from the linear models, only, also indicate a steeper (or more potent) dose-response compared to slopes generated from pooled estimates of all studies and all lower risk of bias studies. This inconsistency indicates that the linear models likely are not adequately describing the full body of underlying evidence.

For PFOS, only two models from the studies EPA selected for determining the slope of the dose-response relationship have a statistically significant slope (p-value < 0.05): the serum PFOS and TC model including all lower risk of bias studies and the model excluding Jain et al. 2019 (shown in Table F-3). However, with little or no explanation, EPA changed its criteria for statistical significance (using and alpha value of 0.1 instead of 0.05) to support selection of the "linear models only" estimate that is not statistically significant (p=0.064). As stated by the USEPA, "When including the five studies reporting linear associations, there was a positive increase in TC of 0.08 (95% CI: -0.01, 0.16) mg/dL per ng/mL serum PFOS (p-value=0.064, I2=84%) that was significant at the 0.10 level." (EPA 2023c, p. F-16). As stated in the Economic Analysis, the USEPA noted that "While the association for PFOS and TC is not significant at the 0.05 confidence level, it is significant at the 0.10 confidence level (p = .064)." (EPA 2023c, p. 6-55). No justification was provided for the change in the confidence level used to denote statistical significance. Notably, EPA also did not apply this change in criteria consistently, as evidenced by the statement "When all studies were combined (12 studies, 15 results), EPA observed a borderline statistically significant positive increase in TC of 0.066 (95% CI: -0.001, 0.132) mg/dL per ng/mL serum PFOS (p-value=0.055, I2=100%) (Table F-3, Figure F-8)." (p. F-16) [emphasis added]. The term "borderline statistically significant" is typically used when a study does not achieve statistical significance, but the p-value is close to the pre-determined cutoff. EPA does not explain why a p-value of 0.055 for the "all studies" model was considered "borderline" but the p-value of 0.064 for the "linear models only" is considered statistically significant. This illustrates that EPA is not consistently applying the criteria for statistical significance across models. Although changes in the criteria used for denoting statistical significance may be statistically and scientifically appropriate, these changes are typically made to make the criteria more stringent to adjust for multiple comparisons or reduce the risk of

making a Type I error [FN94: A Type I Error is also called a "false-positive"; it is an error that occurs when a researcher identifies a statistically significant association when there is no true association. Criteria for defining statistical significance traditionally accept a Type I Error rate of 5% (or $p < 0.05$), or 95% confidence in the observed effect.] Any justification to change the criteria from the standard accepted value of a p-value of 0.05 should be done a priori and justified scientifically. EPA has failed to show that the change in p-value criteria to 0.10 was done prior to analyses, is consistently applied, or is supported by the underlying biology.

Based on the reported meta-analyses (Tables F-2 and F-3), it is not clear that there is a statistically significant dose-response relationship between PFOA/PFOS and serum TC when the full body of evidence is considered. Use of information with no significant change in response is not consistent with EPA guidance for dose-response modeling (USEPA 2012). Therefore, based on EPA's own guidance and widely accepted risk assessment practice, the available body of evidence indicates that use of changes in serum TC as the basis for EPA's CVD risk reduction model is not appropriate. Despite the lack of statistically significant slopes in the pooled analyses for PFOA and PFOS when all studies are included, or when only linear models were included for PFOS, EPA justifies its choice for use of serum TC in the CVD risk reduction model by stating "The literature provides sufficient support of a positive association (e.g., Château-Degat et al., 2010; Dong et al., 2019; U.S. EPA, 2023d; U.S. EPA, 2023e). The studies are large with more than 700 and 8,900 participants, respectively (Château-Degat et al., 2010; Dong et al., 2019) and have low risk of bias." (USEPA 2023c, p. 6-55). However, as already described, EPA's literature review lacked guardrails designed to support the reliability of such conclusions. Had EPA followed appropriate systematic review processes, it likely would have found that the overall body of evidence (shown visually in Figures F-4 and F-8) is not clearly supportive of an exposure-response association and the sensitivity analyses (presented in Tables F-2 and F-3) do not support the conclusion of a significant relationship between PFOA or PFOS and serum TC across the pooled body of information. This indicates that the use of serum TC as the basis for the economic benefits analysis may overstate the expected reductions in serum TC with reductions in PFOA/PFOS, thereby also overstating the economic benefits. As a result of these process and analytical failures, EPA has not shown that the pooled dose-response functions are reliable or consistent with the underlying biology. Therefore, any use of these functions to estimate economic benefits from reduced health impacts is uncertain and unreliable.

Additional considerations of model applicability specific to meta-analyses, such as interstudy heterogeneity, must be addressed by EPA. In meta-analyses, the pooled estimate is intended to be derived from a body of comparable studies on similar populations. Inter-study heterogeneity, measured as I2, describes the amount of variability in the response between studies and measures the probability that the pooled estimate contains information from populations that are not similar. This estimate reflects differences in study design, study population, and data analysis, among other study- and population-level differences. Increased inter-study heterogeneity decreases confidence in the generalizability and utility of the pooled estimate. For the analyses presented by EPA (2023c, Tables F-2 and F-3), the measured heterogeneity for the meta-analyses is relatively high (>75%) for most models. EPA does not discuss the impact this high level of

heterogeneity has on its confidence in the meta-analytic models. Heterogeneity could be introduced into these models through differences in underlying population demographics, which is evidenced by the reduction in I2 estimates for PFOA and PFOS when non-US/Canada and high exposure studies are excluded (see Tables F-2 and F-3). EPA uses "the large degree of heterogeneity in the pooled associations when all data were included" to justify use of the meta-analyses using linear models only (EPA 2023c, P. F-16). However, the I2 is not meaningfully lower when comparing the PFOA "linear only" model with those for "all studies" or "all lower risk of bias studies" (I2 range of 87.19 - 89.49; see EPA 2023c, Table F-2). Additionally, the PFOA and PFOS models that "exclude non-US/Canada and high exposure studies" have 1) more included studies, 2) a lower I2 (or less heterogeneity) compared to the linear models only, and 3) are more representative of the US population that EPA is evaluating in its CVD risk reduction models. Based on these considerations, the model that uses only studies from the US/Canada, which do not show a statistically significant dose-response, are likely 1) more statistically appropriate and 2) generalizable to the United States population for whom this economic analysis is based. EPA should provide additional justification to explain its rationale for use of the "linear models only" in lieu of the US/Canada-based population studies.

In summary, EPA did not provide clear or consistent rationales for its selection of the "linear only" meta-analytic models for PFOA and PFOS for use in the CVD risk reduction analysis. Accordingly, the slopes selected for the CVD risk reduction analysis are unreliable and not consistent with EPA guidance.

iii. Dose-response slopes used by EPA for benefits analysis are different from those used in its risk assessment (i.e., RfD derivation).

As discussed in (USEPA 2023a,b), EPA uses the slope estimate from the exposure-response measured by Dong et al. (2019) as a basis for RfD derivation. EPA presents the slopes from Dong et al. (2019) in its sensitivity analyses, but fails to describe why the slope used in RfD derivation is different than that used for estimating the economic benefits. For example, EPA derives a benchmark dose (BMD) and benchmark dose lower limit (BMDL) based on the slopes, or regression coefficients, reported by Dong et al. (2019) (see USEPA 2023a, p. E-297 to E-300; USEPA 2023b, p. E-25 to E-29) and Steenland et al. (2019) (see USEPA 2023a, p. E-301 to E306; USEPA 2023b, p. E- 29 to E-34), and the mean differences in serum TC by quartiles of exposure reported by Lin et al. (2019) (see USEPA 2023a, p. E-306 to E-307; USEPA 2023b, p. E-35 to E-36). Each of these individual studies are included in the meta-analysis. A summary of the derived BMD(L)s is presented in the main text (USEPA 2023a p. 4-33; USEPA 2023b. p. 429) and the appendices for the Proposed MCLGs for PFOA (USEPA 2023a, p. E-308, Table E27) and PFOS (USEPA 2023b, p. E-37, Table E-25). The BMDLs from Dong et al. (2019) and Steenland et al. (2009) are used to derive candidate RfDs for PFOA (USEPA 2023a, p. 4-48) and PFOS (USEPA 2023b, p. 4-43). From the candidate RfDs, EPA chose the value of 3 x10-8 mg/kg/day for PFOA and 1 x 10-7 mg/kg/day for PFOS derived from the BMDLs from Dong et al. (2019) as the basis for considering an RfD for CVD effects (USEPA 2023a, p. 4-52; USEPA 2023b, p. 4-48). Although EPA chose to use the slopes from a single study (Dong et al. 2019) to derive a BMDL and RfD for PFOA and PFOS, EPA used the pooled slope from the meta-

analysis as the basis for the economic analysis. EPA does not provide justification for the lack of consistency in dose-response estimation between the risk assessments and the economic analysis. The difference in methodologies applied by EPA is unexplainable and there is no apparent reason as to why it is appropriate for EPA to use different dose-response slopes between the risk assessments and the economic analysis. As described in Section VII.g, the pooled slopes derived from the meta-analyses could be considered for RfD derivation, however EPA does not describe the meta-analyses in the Proposed MCLG risk assessment documentation. For PFOA, the slope estimates are relatively comparable (i.e., 1.48 mg/dL per ng/mL from Dong et al. 2019 and 1.57 mg/dL per ng/mL from the "linear models only" meta-analysis presented in the economic analysis; Table F-2). However, for PFOS, the slope estimates are drastically different (i.e., 0.40 mg/dL per ng/mL from Dong et al. 2019 and 0.079 mg/dL per ng/mL from the "linear models only" meta-analysis presented in the economic analysis; Table F-3). EPA must explain why Dong et al. (2019) was used as the basis for PFOA and PFOS RfDs, whereas a pooled slope estimate from studies using linear models was employed for estimating the economic benefit of reducing PFOA/PFOS levels to the RfDs.

iv. EPA does not transparently describe how the selected dose-response models inform the economic benefits analysis for CVD risk and fails to illuminate the impact on a benefit reduction analysis for PFOA and PFOS individually.

EPA states that it used the pooled slope estimates for PFOA and PFOS derived from the "linear models only" in order to inform the CVD risk reduction model. However, EPA does not transparently describe in its methods how these pooled slope estimates directly impact the models and estimated CVD risk. Outputs are reported as a pooled estimate of CVD benefits for PFOA and PFOS (see examples in USEPA 2021c, Table 6; USEPA 2023c Table 6-20). However, the estimated impact on serum TC per ng/mL PFOA (estimated at 1.574 mg/dL per ng/mL PFOA) is drastically steeper than that of the impact per ng/mL PFOS (estimated at 0.079 mg/dL per ng/mL PFOS). Even accepting that the dose-response slopes selected by EPA are appropriate, the slope for PFOA is nearly two orders-of-magnitude steeper, compared to PFOS, and therefore should have a larger impact on the estimated economic impact. EPA does not transparently describe its methods for integrating these disparate slope estimates for PFOA and PFOS or provide a description for how PFOA and PFOS exposures mixed to generate a single economic benefit model. The CVD risk reduction model is not described in a way that allows for transparent reproducibility of the approach or evaluation of sensitivity of the model to changes in estimated serum TC responses. It cannot be determined, based on the reported information, whether EPA is accurately accounting for the differences in exposure-response slopes for PFOA and PFOS. Moreover, it is impossible to determine from the record provided by EPA what benefit would be expected from the reduction of PFOA or PFOS alone. Sufficient information should be provided for the model to be independently verified.

Additionally, EPA does not evaluate the sensitivity of the CVD risk reduction model to changes in the estimated slope. As shown in Tables F-2 and F-3 of the Economic Analysis (USEPA 2023c), the estimated slopes for PFOA and PFOS are heavily dependent on the studies included in the meta-analytic models, with ranges changes in serum TC of 0.002 to 1.632 mg/dL per

ng/mL PFOA and 0.0003 to 0.40 mg/dL per ng/mL PFOS. EPA acknowledges in its discussion of modeling limitations and uncertainties (USEPA 2021c; Table 7) that "the derivation of PFOA/PFOS exposure-response functions for the relationship between PFOA/PFOS serum and TC levels assumes that the six studies used in meta-analysis capture the majority of PFOA/PFOS effects on serum TC levels." EPA further states that the included studies "may not represent all possible relationships between PFOA/PFOS and serum TC levels" and describes the impact of this uncertainty as "uncertain." However, EPA does not further address or describe the potential impact of study inclusion or exclusion. EPA neither established that its selection of "linear models only" for meta-analysis was reasonable, nor did it evaluate the impact of other reasonable models (such as the US/Canada-population models) on CVD risk reduction estimates. It is best practice to consider a range of modeling options, especially given the uncertainties attributable to study inclusion and selection. Even if EPA were to select the linear models only, as a conservative estimate assuming a significant dose-response, the 95% CIs for the pooled estimate for PFOA are broad (e.g., 1.57 mg/dL per ng/mL PFOA [95% CI 0.0177, 3.13]) and the 95% lower limit for the pooled estimate for PFOS is negative (i.e. -0.005), indicating a reduction in serum TC (a beneficial effect) with increasing serum PFOS. Therefore, the Economic Analysis may not be appropriately representing the accurate risk/benefit of reduction in PFOA/PFOS exposures. Uncertainties in the underlying slope estimates used as the basis for the economic benefits model translates into uncertainties in the estimated economic benefit for PFOA/PFOS reduction. Because the confidence interval produced by the studies chosen by EPA for PFOS includes both negative and positive slopes in the 95% confidence interval, the interpretation of the economic benefit is uncertain as to whether reductions in PFOS could be beneficial or harmful. Therefore, because of the uncertainties and lack of statistical significance, use of serum TC as the basis for Economic Benefit Analysis is likely not accurate, informative, or appropriate. EPA should provide uncertainty analyses to evaluate the range of impacts on CVD risk based on variations in slope assumptions and show its confidence in the underlying estimate of economic benefit.

In summary, the meta-analysis presented by EPA fails to follow best practice for meta-analyses (e.g. The Cochrane Handbook for Systematic Reviews of Interventions) and does not sufficiently account for underlying uncertainties in the dose-response relationships between serum PFOA/PFOS and serum TC. These uncertainties cannot be evaluated due to the complexity and lack of transparency in EPA's modeling documentation. Additional information regarding the impact of model selection and model uncertainty is needed to provide confidence in EPA's CVD risk reduction model.

EPA Response: The EPA disagrees with the commenter's statement that the "EPA selects relationships between serum levels and health effects that are not supported by the underlying studies." For additional detail on the strength of the evidence supporting analyses of RCC, birth weight, and CVD, see sections 4.1.4 and 4.2.1 of the EPA response in this *Response to Comments* document, as well as the EPA response to comment Doc. #1774, SBC-045685, SBC-053211, SBC-053281, SBC-045682, and SBC-045683.

The EPA disagrees with the commenter that the documentation of the meta-analysis used to develop the exposure-response relationship between PFOA/PFOS and total cholesterol lacks transparency. The limitations and uncertainties of the analysis documented in both the benefits section (Table 6-51 of USEPA, 2024b) and appendices (Appendix F, Section F.4.2; Appendix L, Section L.2.1 of USEPA, 2024c) and all modeling code and results files are provided in the regulatory docket. The EPA notes that the EA and EA appendices for the proposed PFAS NPDWR contain hundreds of pages of information that provides the descriptions and information that commenter claims is lacking. See specifically https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0028 for the proposed rule EA and https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0029 for the proposed rule appendices. See also the EPA's response to 3M Company (Doc. #1774, SBC-045652) for comments on transparency and materials provided for replication. The EPA acknowledges that there is a large degree of heterogeneity in the pooled associations and a potential for bias resulting from the back-transformation of effects estimates with log-transformed outcomes. The uncertainty associated with these dose-response factor estimates is thoroughly and transparently characterized in the SafeWater modeling based on estimated confidence intervals reported in Appendix L, Table L-2 of the EA (USEPA, 2024c). See also section 13.9 of the EPA response in this *Response to Comments* document.

The EPA disagrees with the commenter's suggestion that study quality was not considered in the meta-analysis. The best practices for conducting meta-analysis would never exclude studies from the analysis based on study quality (such as excluding *low* confidence studies from the database), as the commenter suggests (Higgins et al., 2023). However, the EPA's approach included a sensitivity analysis that did consider only lower risk of bias studies to see the impact of those higher risk of bias studies (Section F.4 of the EA; USEPA, 2024c). Regarding the methods the EPA used to develop the final toxicity assessments for PFOA and PFOS, as well as the results of the systematic review of noncancer effects, please see sections 4.1.1 and 4.2.1, respectively, of the EPA response in this *Response to Comments* document.

The EPA disagrees with the commenter's suggestion that the EPA does not clearly explain why other studies on adults in general populations were excluded. These reasons are transparently presented in Appendix F of the EA (USEPA, 2024c) and include lack of availability of effect estimates that can be used in the meta-analysis and specifically cite the studies that the commenter erroneously claims rationales were not provided for, such as Eriksen et al. (2013), Fitz-Simon et al. (2013), Convertino et al. (2018), and Huang et al. (2018). The EPA also notes that one inclusion criteria for study selection was age of the studied population: 40 to 89 years old, which results in exclusion of studies like Donat-Vargas et al. (2019), Liu et al. (2020), and Canova (2020), which include populations younger than 40 years old. The EPA notes that one study mentioned by the commenter, Zare Jeddi et al. (2021), is a meta-analysis; thus, it would be inappropriate for inclusion in a meta-analysis. Similarly, the EPA provided a clear explanation on why Steenland et al. (2009) was included: the study population is not occupational, but is a highly exposed population in the United States (the C8 Health Project cohort of adults living near a chemical plant).

The EPA conducted nine sensitivity analyses, above and beyond what a typical meta-analysis of this size would report. While the commenter suggests additional analyses that the EPA could have conducted beyond the extensive and robust analyses the EPA has already conducted, this does not invalidate the EPA's confidence in the pooled slope estimate and the direction of the observed association. The EPA is conducting this economic analysis, including all national level benefits and sensitivity analyses, to inform whether the costs of the rule are justified by the benefits. There is both a pressing public interest and a statutory deadline in the EPA finalizing analyses and making timely final decisions. The EPA believes that the additional suggested analyses are unnecessary for purposes of making appropriate and transparent decisions consistent with the SDWA authority and mandate. As discussed above, the EPA has already gone above and beyond what would be considered and included in meta-analyses of this size and scope. Finally, the EPA notes that the analysis excluding non-US/Canada populations and high-exposure populations was specifically requested by the SAB and the EPA prepared it based on the input of this peer-review body.

For discussion related to transparency in the EPA's determination of study quality, please see the EPA response to comment Doc. #1774, SBC-045652 in section 13.4 in this *Response to Comments* document.

The EPA disagrees with the commenter's assertion that lack of increased odds of CVD in occupational studies would indicate potential lack of response in general populations at lower exposures. The EPA presented results from an occupationally exposed population with different exposure patterns than those typically found in the general population, and the lack of association in this high exposure setting does not discredit associations found in other studies. In fact, associations found at lower levels of exposures, such as Shankar et al., (2012) which are representative of the general US population exposure levels, indicate that the general population is at risk.

The EPA disagrees with the commenter's assertion that findings from longitudinal analyses should hold greater weight in the EA. Temporality is not necessarily an issue in instances where the chemical has a long half-life and is not quickly removed from the body. PFAS have half-lives on the orders of years; therefore, cross-sectional exposures are representative of past exposures.. The EPA also disagrees with the commenter that cross-sectional studies provide limited utility for purposes of establishing causality. Based on clinical research literature, the cross-sectional design allows investigators to collect prevalence data and evaluate differences in health outcomes between exposed and unexposed population providing the basis for developing a causal relationship. The EPA also disagrees that the EPA should benchmark the slopes from the pooled analysis against occupational studies. The ASCVD model requirements specifically point to effects in general populations.

The EPA disagrees with the commenter's criticism of the EPA's use of linear-only models as well as the EPA's study selection methods. See section 13.4.1 of the EPA response in this *Response to Comments* document.

The EPA disagrees with the commenter's assertion that the rationale to select the pooled slope estimate based only on linear models "to reduce bias due to back transformations of effect estimates" is not consistent with approaches used by the EPA in its risk assessments. The commenter misunderstands the approach used in the Budtz-Jorgensen and Grandjean (2018) data for POD derivation. No back transformation was used to derive the Bone Mineral Destiny (BMD) and Benchmark Dose Level (BMDL) associated with the (Benchmark Reduction) BMR of ½ standard deviation (SD) change in log2(tetanus antibodies concentration) and a BMR of 1 SD change in log2(tetanus antibodies concentration) (see Appendix E of USEPA, 2024j and USEPA, 2024k).

The EPA disagrees with the commenter's assertion that it did not apply criteria for statistical significance consistently across the models. The commenter erroneously suggested that the EPA considered an effect with a p-value of 0.064 significant. The EPA clearly and transparently states that the effect "was significant at the 0.10 level".

The commenter stated that the EPA did not provide justification for using Dong et al. (2019) as the basis for PFOA and PFOS RfDs rather than the pooled slope estimate from the meta-analysis presented in the EA. In the Final Toxicity Assessments for PFOA and PFOS, the EPA notes that the results from meta-analyses were not selected for point of departure (POD) derivation for several reasons. For example, the ASCVD model relied on CVD risk reduction analysis for individuals ages 40-89 whereas the toxicity assessments considered adults of all ages. Another recent meta-analysis was not considered because it combined associations between PFOA and several different serum lipids (i.e., TC, triglyceride, and low-density lipoprotein) across multiple populations (i.e., children, adolescents, pregnant women, and adults), likely resulting in unaddressed confounding by age (Abdullah Soheimi et al., 2021). The EPA notes that reliance on deriving BMDLs based on pooled regression coefficients is not a requirement in the EPA's *Benchmark Dose Technical Guidance* (USEPA, 2012). The EPA also notes that, contrary to what the commenter implies, there is no requirement that the approaches used for quantifying effects used in the economic analysis and the toxicity assessments be identical. In fact, the approaches are consistent across assessments. The economic analysis relied on the rigorous determinations of the toxicity assessments. In addition, the EPA also had to factor in the constraints of, for example, the ASCVD model. The economic analysis also benefits from added flexibility of quantifying outcomes, such as blood pressure, that might not have been considered for POD derivation in the toxicity assessments. Similarly, the economic analysis has the added flexibility of using dose-response approaches (such as a meta-analysis restricted to studies in a certain age-range population) that could not be used for the purposes of RfD derivation in the toxicity assessments. The EPA notes that it provided details on rationales for selection of epidemiology studies for POD derivation in Section 4 of the Toxicity Assessments (USEPA, 2024h and USEPA, 2024i). In accordance with the current *Benchmark Dose Technical Guidance* (USEPA, 2012), the RfD derivation approach relied on study-specific approach rather than a pooled studies approach.

The EPA disagrees with the commenter's argument that benefits analyses for PFOA and PFOS should be considered independently. See the EPA response to comment Doc. #1774, SBC-045652 in section 13.4 in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-052938)

The Association with Cardiovascular Disease is not Sufficiently Strong to Use as a Basis for Quantifying Benefits

According to its estimates, the predicted reduction in CVD risks accounts for nearly one-half of the benefits of the quantifiable benefits of its proposal. [FN180: An expected annualized value of $533M out of $1,232M (43 percent) at a 3% discount rate and $421M out of $908M (46 percent) at a 7% discount. (USEPA Economic Report, at 6-3).] Yet, as discussed above, there is little evidence supporting an association between exposure to PFOA and PFOS and CVD. Moreover, EPA's analysis for PFOS indicates that the association with increased total cholesterol is not statistically significant (at p=0.05 level) or only "borderline statistically significant." [FN181: USEPA Economic Report, at F-16.]

In the draft analysis presented to the SAB in late 2021, EPA concluded that for both PFOA and PFOS the evidence for an association with CVD-related outcomes was limited and inconsistent. [FN182: USEPA Draft PFOA MCLG Approaches 2021, at 191; USEPA Draft PFOS Approaches 2021, at 179.] Consequently, EPA concluded at the time that the evidence was not sufficient to form the basis of an RfD. In its review, the Board summarized the information as follows -

Specifically, with respect to CVD, the assumption is that a shift in cholesterol resulting from PFAS exposure will have the same impact on cardiovascular disease that cholesterol levels based on natural levels or use of cholesterol lowering medications have had. However, the epidemiologic literature that provides strong support for an effect of PFAS on cholesterol does not provide support for an effect of PFAS on the risk of cardiovascular disease. [FN183: USEPA SAB Review, at 102.]

In the background documents for the current proposal, EPA has attempted to justify selection of effects on TC for quantification but has provided no additional information to support the association between PFOA and PFOS exposure and CVD. Although both the Board and EPA have provided additional references, none of the references address exposures to PFOA and PFOS.

Given the significant uncertainty with CVD endpoints, and the negative findings of Schilleman et al. 2022 that came out after the SAB convened, it is not appropriate to include CVD disease as part of EPA's benefits analysis for its proposal.

EPA response: The EPA disagrees with the commenter's assertion that "the association with cardiovascular disease is not sufficiently strong to use as a basis for quantifying benefits." See section 13.4.1 of the EPA response in this *Response to Comments* document for the EPA's response to the commenter's statements on cardiovascular disease.

See section 13.4.1 of the EPA response in this *Response to Comments* document for the EPA's response to comments on the evidence for PFOA and PFOS exposure and CVD outcomes. The EPA disagrees with the commenter's assertion that "there is little evidence supporting an association between exposure to PFOA and PFOS and CVD." High-quality studies have shown consistent associations between PFOA/PFOS exposure and changes in total cholesterol and blood pressure. Total cholesterol and blood pressure are well-established CVD risk biomarkers, are clearly associated with adverse CVD events, and are important inputs to the Pooled Cohort ASCVD model that the EPA used to estimate CVD outcomes. Furthermore, the Science Advisory Board supported the EPA's approach to estimating reductions in CVD risk associated with reduced PFOA and PFOS exposure in drinking water (USEPA, 2022d). The association between PFOA and PFOS exposure and CVD is supported by the consistent associations between PFOA/PFOS exposure and changes in total cholesterol, and the clear record demonstrating that increases in this biomarker increase CVD risk. Please also refer to section 4.2.1 of the EPA response in this *Response to Comments* document, the EPA response to comment Doc. #1713, SBC-045921 in section 13.4.1 in this *Response to Comments* document, and Section 3.4.3.4 of the Final Toxicity Assessments for PFOA and PFOS (USEPA, 2024h; USEPA, 2024i) for detail on the EPA's conclusions regarding evidence supporting an association between exposure to PFOA and PFOS and adverse CVD health outcomes. Further, the EPA disagrees with the commenter's assertion that the meta-analysis of PFOS effects on total cholesterol supports their conclusion that "there is little evidence supporting an association between exposure to PFOA and PFOS and CVD." See section 13.4.1 of the EPA response in this *Response to Comments* document for more information on the relationship between PFOA and PFOS effects on total cholesterol and the discussion of this biomarker's effect on CVD. The commenter suggested that the EPA considered an effect with a p-value greater than 0.05 significant. The EPA clearly, transparently, and appropriately states that such effects estimates are "significant at the 0.10 level" (see Appendix F, USEPA, 2024c). In addition, the EPA notes that statistical significance is not the only criteria for determining the strength of an association based on epidemiologic studies (USEPA, 2022c).

Based on the discussion in this response and throughout the administrative record of this final rulemaking, the EPA disagrees with the commenter's unsupported statement that "given the significant uncertainty associated with CVD endpoints…. it is not appropriate to include CVD disease as part of EPA's benefits analysis for its proposal." Further, the commenter misrepresents the finding from Schillemans et al. (2022). Schillemans et al. (2022) conducted population-based nested case-control study of Swedish adults (n = 1,528) within two cohorts: the Swedish Mammography Cohort-Clinical (SMC-C) and the Cohort of 60-year-old (60YO). Cases were first incident myocardial infarction (n = 345) and stroke (n = 354). In baseline cross-sectional analyses among 631 controls (those individuals without stroke or myocardial infarction), baseline plasma PFOS was associated with increased baseline TC (β per 1-SD-ln- ng/mL PFOS = 0.14, 95 percent CI: 0.06, 0.22), increased LDLC (β = 0.13, 95 percent CI: 0.06, 0.20), increased HDLC (β = 0.05, 95 percent CI: 0.01, 0.07), increased apolipoprotein A1 (β = 0.04, 95 percent CI: 0.02, 0.08), and decreased triglycerides (β = –0.11, 95 percent CI: –0.17, –0.05). In

prospective analyses of the pooled cohorts, there were no significant associations between baseline PFOS and subsequent incidence of myocardial infarction, stroke, or CVD. Thus, this study evaluated associations between PFOS and elevated serum lipids among controls only; therefore, a conclusion about associations between PFOS and elevated CVD risk among individuals with elevated total cholesterol levels cannot be made based on the study findings or data. The EPA has consistently demonstrated that its assumption that increasing total cholesterol increases CVD risk is firmly grounded in the scientific literature; moreover, these conclusions were reviewed and supported by the SAB.

Susan Goldhaber (Doc. #1596, SBC-043003)

May 26, 2023

Michael S. Regan, Administrator Environmental Protection Agency

1200 Pennsylvania Ave., N.W. Washington, D.C. 20460

Re: Docket ID No. EPA-HQ-OW-2022-0114, Comment on Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

Dear Administrator Regan,

As a toxicologist formerly employed at EPA, Office of Drinking Water, (1980-1988), who worked on revising the primary drinking water regulations, I am very familiar with the requirements of the Safe Drinking Water Act and the regulatory process. I am writing because I am very concerned with the underlying science supporting these regulations. I would like to submit the attached comments for your consideration.

Sincerely, Susan B. Goldhaber M.P.H.

SBG Consulting, Inc.

Comments

There are Executive Orders that strongly encourage that the benefits of a major regulation, such as PFAS Drinking Water regulation, exceed the costs. In the Economic Analysis, EPA calculated the economic benefits to the U.S. by avoiding three health outcomes that it attributed to exposure from PFOA and PFOS:

• Developmental effects (reductions in birth weight)

• Cardiovascular effects (increase in total and high-density lipoprotein (HDL) cholesterol resulting in cardiovascular disease including strokes and myocardial infarction)

• Kidney cancer

Cardiovascular Disease

EPA admits in its Economic Analysis that the epidemiologic literature does not provide direct support for the effect of PFOA and PFOS on the risk of cardiovascular disease. This is the same conclusion as the ATSDR that "the available occupational, community, and general population studies have not consistently found increases in the risk of heart disease or stroke that were associated with PFOA levels."

Neither the ATSDR nor the National Academy of Sciences (NAS) have found an association between PFOA/PFAS and increased blood pressure. ATSDR stated that "Most of the available epidemiological studies did not find an association between PFOA and hypertension" https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf and the NAS concluded that the evidence is inadequate or insufficient to make a determination. https://nap.nationalacademies.org/catalog/26156/guidance-on-pfas-exposure-testing-and-clinical-follow-up

Regarding PFOA/PFOS and cholesterol, ATSDR concluded that the evidence is insufficient to determine a cause-and-effect relationship, while the NAS concluded that there is sufficient evidence for the association of PFAS exposure with dyslipidemia (total triglycerides, total cholesterol, and low-density lipoprotein and high-density lipoprotein).

EPA calculated benefits of $421 million to $533 million from calculating the number of deaths avoided due to: cardiovascular disease (fatal and non-fatal myocardial infarction) and ischemic stroke (fatal and not fatal)

3. What is EPA's justification for ignoring the conclusions of the ATSDR and the NAS and the known risk factors for cardiovascular disease, such as obesity, physiological inactivity, tobacco use, and harmful use of alcohol, in its conclusion that PFOA and PFOS are the sole causes of cardiovascular disease?

EPA response: See section 13.4.1 of the EPA response in this *Response to Comments* document for the EPA's response to the commenter's statements that "the epidemiologic literature does not provide direct support for the effect of PFOA and PFOS on the risk of cardiovascular disease." See section 13.4.1 of the EPA response in this *Response to Comments* document for the EPA's response to the commenter's statement comparing the evidence for cholesterol and blood pressure effects in the ATSDR and NAS assessments. Refer to section 4.2.6 of the EPA response in this *Response to Comments* document for details on comparisons to analyses conducted by other health organizations, including ATSDR and NAS. See section 4.2.1 of the EPA response in this *Response to Comments* document, the EPA response to comment Doc. #1713, SBC-045921 in section 13.4.1 in this *Response to Comments* document, and Section 3.4.3.4 of the Final Toxicity Assessments for PFOA and PFOS (USEPA, 2024h; USEPA, 2024i) for detail on the EPA's conclusions regarding evidence supporting an association between exposure to PFOA and PFOS and adverse CVD health outcomes. The EPA disagrees with the commenter's assertion that the EPA attributed all cardiovascular disease to PFOA and PFOS exposure. The agency assessed the quantifiable human health benefits by estimating the share of avoided illnesses that are associated with PFOA and PFOS reductions under the final rule. This

analysis assumes that removal of PFOA and PFOS-related exposure would not alter the distribution of risk factors the exposure does not affect. Additionally, the epidemiology studies considered in the toxicity assessments, which inform the benefits analysis assessment of changes in cholesterol and blood pressure resulting from changes in PFOA/PFOS exposure, controlled for potential confounding factors such as tobacco use, body mass index, and others. Even controlling for these potentially confounding factors, these studies showed associations between PFOA/PFOS and serum lipids.

13.4.2 Quantified Developmental Benefits Estimation

Summary of Major Public Comments and EPA Responses

The EPA received public comments on the benefits analysis for developmental effects. A few commenters claimed that the studies used for developmental modeling did not provide sufficient evidence of an association between PFOA and PFOS exposure and stated that the studies which the EPA used to model the developmental effects relationship did not consider confounders including pregnancy hemodynamics and other chemical and non-chemical stressors, including other PFAS. One commenter stated that the EPA's findings are inconsistent with other regulatory agency findings that small increases in birth weight are associated with maternal exposure to PFOA and PFOS but not increased risk of low birth weight. Other commenters stated that the EPA did not address these concerns and inappropriately used these studies to support quantitative analysis, and one commenter stated that because of the shortcomings of the studies used and the modeling uncertainties, peer review of the developmental effects modeling should be completed.

The EPA disagrees with these comments: the developmental benefits analysis is supported by a wide body of peer reviewed science (Verner et al., 2015; Negri et al., 2017; ATSDR, 2021; Waterfield et al., 2020; USEPA, 2016c; USEPA, 2016d; USEPA, 2024h; USEPA, 2024i). Specifically, decreased birth weight was determined to be a critical effect based on findings in the EPA's health assessments (see USEPA, 2024h; USEPA, 2024i), and low birth weight is linked to a number of health effects that may be a source of economic burden to society in the form of medical costs, infant mortality, parental and caregiver costs, labor market productivity loss, and education costs. Discussion on the EPA's conclusions about associations between PFOA or PFOS and decreased birth weight can be found in section 4.2.1.2 of this *Response to Comments* document. Discussions on why the agency's conclusions may differ from those of other health agencies can be found in section 4.2.6 of this *Response to Comments* document.

Discussion regarding the selection of decreased birth weight as a critical effect, including the selection of specific studies for candidate RfD derivation and the evidence supporting associations between PFOA or PFOS and developmental effects is available in sections 4.2.1.2 and 4.2.2.3.4 of this *Response to Comments* document, as well as Sections 3.4.4 and 4.1 of the final toxicity assessments for PFOA and PFOS (USEPA, 2024h; USEPA, 2024i). In estimating benefits of reducing PFOA and PFOS in drinking water, the agency selected results from Steenland et al. (2018) as the birth weight exposure-response function for PFOA and results from Dzierlenga et al. (2020) as the birth weight exposure-response function for PFOS. The agency

chose the results from these studies because they include the most recent meta-analyses on PFOA- and PFOS-birth weight relationships, and they included a large number of studies, including multiple studies with first trimester samples (seven studies in Steenland et al., 2018 and eight studies in Dzierlenga et al., 2020). To provide insights into the potential effects of sample timing and pregnancy hemodynamics, the EPA also performed a sensitivity analysis considering only first trimester estimates from Steenland et al (2018) for PFOA and Dzierlenga et al. (2020) for PFOS in Section K.4 of the EA appendices (USEPA, 2024c). While reports prior to 2019 found "plausible" or "suggestive" (USEPA, 2016c; ATSDR, 2018) evidence of relationships between PFOA and PFOS and developmental outcomes, the EPA's assessment found clear evidence of an association for PFOA and PFOS in both toxicological and epidemiological studies (USEPA, 2024j; USEPA, 2024k). The agency further disagrees with the commenter's statement that further peer review is needed, as the EPA relies extensively on peer-reviewed studies in its developmental benefits model. Furthermore, the EPA characterizes the uncertainty in the PFOA and PFOS exposure-response functions as described in Appendix L of the EA (USEPA, 2024c). In short, the benefits analysis for developmental effects relies on a wide body of the best available, peer-reviewed science, and the epidemiological evidence provides a reliable basis for quantifying the risks of low birth weight.

A different commenter claimed that the EPA relied on equivocal epidemiological evidence to estimate developmental benefits, stating that the RfDs calculated from animal studies in the EPA's health assessment documents for PFOA and PFOS are significantly higher than those based on human studies used for benefits analysis and that the animal studies represent a more appropriate estimate of the risk of PFOA and PFOS exposure. The EPA disagrees with the commenter that the analysis relies on equivocal epidemiological evidence to estimate benefits. See section 13.4 of the EPA response in this *Response to Comments* document for a detailed explanation of why human data are generally preferred for the derivation of toxicity values, compared to laboratory or animal data. See Section 4.1.6 of the Final Toxicity Assessments for PFOA and PFOS (USEPA, 2024h; USEPA, 2024i) for additional details on the comparison between RfD derivation based on animal studies versus human studies. The systematic literature review and assessment conducted by the EPA concluded that there is moderate evidence for developmental effects based on consistent adverse effects for fetal growth restriction including birth weight measures which are the most accurate endpoint as reported by epidemiological studies (USEPA, 2024h; USEPA, 2024i). One commenter raised concerns about the EPA's reliance on the study (Steenland et al., 2018) that the EPA uses to model PFOA dose response for benefits analysis, stating that the EPA's benefits analysis for PFOA and developmental effects is not supported by the underlying publication. The same commenter questioned the EPA's reliance on the study that is used to model PFOS dose response for benefits analysis (Dzierlenga et al., 2020), stating that the study found that there was no evidence of a relationship at the beginning of pregnancy. The commenter raised that the meta-analysis was not peer reviewed and thus the validity of the EPA's methods should be questioned. The EPA disagrees with these comments, and the use of Steenland et al. (2018) to estimate the impact of PFOA exposure on birth weight effects is supported by findings from more recent toxicity assessments (USEPA, 2024j; USEPA,

2024k). Additionally, Dzierlenga et al. (2020) has been peer reviewed and the authors conducted sensitivity analyses to evaluate sampling bias.

The EPA disagrees with the commenter's criticism of the studies used to assess dose response in developmental benefits analysis. The selected meta-analyses on the relationship between PFOA/PFOS exposure and birth weight produced statistically significant results, are based on recent data, and include a large number of studies in each meta-analysis. In reviewing the analysis in response to comments, the EPA did re-run the analysis from Dzierlenga et al (2020) to remove a duplicated estimate from M.H. Chen et al (2017) in the pooled estimate. Although a formal correction to the Dzierlenga et al (2020) publication was not completed prior to publication of the final PFAS NPDWR, the EPA confirmed with the Dzierlenga et al (2020) authors that the result of that re-analysis was accurate and consistent with the underlying study.

One commenter stated that given the discussion about changes over time in infant mortality, a dataset containing only two years of data is insufficient to build infant mortality regression models. The EPA disagrees that two years of data is insufficient to build regression models relating infant birth weight to infant mortality. The EPA's regression analysis improves upon earlier analyses relating birth weight to infant mortality (Almond et al., 2005; Ma and Finch, 2010) by evaluating two years of recent data. Sample sizes among the Centers for Disease Control and Prevention (CDC) National Center for Health Statistics (NCHS) linked birth/infant death data per year are large (n = approximately 3.8 million infants) and contribute to the overall statistical significance of regression results. As described in Appendix E of the EA (Section E.2, USEPA, 2024c), there has been a notable decline in U.S. infant mortality rates since the analyses reported in Ma and Finch (2010) and Almond et al. (2005). Using recent data from two CDC NCHS linked birth/infant death data cohorts results is a more accurate and conservative characterization of recent infant mortality trends than if the EPA had included older CDC NCHS data.

Individual Public Comments

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-053376)

2. Benefits assessment for developmental impacts is not supported by the science

To evaluate developmental effects, EPA quantifies impacts on birthweight for PFOA, PFOS, PFNA, and PFHxS. In table 42, in the Federal Register notice, EPA clearly notes that for PFHxS the "[e]vidence of the relationship between the PFAS compound and the health outcome is not conclusive."[FN189: 88 Fed. Reg. at 18704 n.5.] Based on EPA's evaluation, it is not likely that these benefits will accrue, and this endpoint should not have been quantified.

As discussed previously in these comments, EPA's justification for relying on birthweight as a critical adverse effect for PFOA and PFOS is also not supported by the body of scientific literature as a whole. The studies upon which EPA relied to justify a relationship did not consider confounding by other chemical and non-chemical stressors, including other PFAS. In addition, for quantification in the benefits analysis, EPA relied on other studies (Negri et al. 2017 and

Seeland et al. 2018 for PFOA and Dzierlenga et al. 2020 for PFOS), which EPA noted as having important uncertainties due to bias from pregnancy hemodynamics [FN190: See Public Comment Draft Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) in in Drinking Water at page, at page 3-219 and EPA's Economic Analysis of the Proposed National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances, 2023, at page 6-31.]. While EPA acknowledges this uncertainty and the concerns with these studies, it has not addressed the concerns and continued to inappropriately use these studies to support quantitative analysis. As presented in Table 6-50 of EPA's economic analysis, there are significant limitations and uncertainties in the analysis of birthweight benefits [FN191: See EPA Economic Analysis of the Proposed National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances, 2023, at page 6-113 to 6-116.]. While EPA asked the SAB to review the CVD modeling, the developmental effects modeling did not undergo any peer review. Considering the shortcomings of the studies used and the uncertainties in the modeling, peer review of the developmental effects modeling should be done to assess EPA's claimed benefits.

While EPA quantifies benefits related to PFNA and birthweight, it notes that this analysis is not precise, and the confidence intervals for the slope factor include zero, which means that the estimates EPA used were not statistically significant. [FN192: Id. at page 6-31.] In discussing developmental effects of PFNA, EPA states that "mixed results" have been found for birth outcomes, particularly birth weight, and that in general associations between PFAS exposures and adverse pregnancy outcomes have not been seen for PFHxS, and PFNA. [FN193: See EPA Economic Analysis of the Proposed National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances, 2023, at page 6-23.] EPA should not be quantifying these benefits for PFNA or other PFAS. EPA does not provide any discussion of adverse pregnancy outcomes with HFPO-DA in its benefits discussions. As such, when EPA makes broad statements about additional non-quantified benefits, it is imperative that EPA be clear that additional developmental benefits are not expected from other PFAS, including the additional four evaluated in this proposal.

EPA Response: The EPA disagrees with the commenter's statements that the EPA's benefits assessment for developmental impacts is not supported by the science, that is it not likely that developmental benefits will accrue, and that these effects should not have been quantified. The EPA disagrees with the commenter's assertion that the relationship between PFOA and PFOS exposure and adverse birth weight effects is not supported by the literature as a whole. See section 13.4.2 of the EPA response in this *Response to Comments* document for a detailed response to these criticisms of the EPA's developmental benefits analysis. See sections 4.2.1 and 4.2.2 of the EPA response in this *Response to Comments* document regarding the EPA's conclusions about the weight of evidence for developmental effects associated with PFOA or PFOS exposure. Regarding the commenter's discussion of uncertainty due to sample timing/pregnancy hemodynamics, please refer to section 13.4.2 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1759, SBC-045648 in section 13.4.2 in this *Response to Comments* document.

In addition, the EPA disagrees with the commenter's assertion that the agency should not be quantifying PFNA birth weight benefits or birth weight benefits for other PFAS. As stated in Chapter 6 of the EA (USEPA, 2024b), epidemiological studies support an association between PFNA exposure and developmental effects such as decreases in infant birth weight and birth length, small for gestational age and low birth weight (Lenters et al., 2016; Valvi et al., 2017). The best available peer reviewed scientific assessment for PFNA (ATSDR, 2021) provides justification for the EPA's analysis of potential economic benefits of PFNA exposure reduction and avoided birth weight effects. Furthermore, more recent epidemiological studies that evaluated PFNA and birth weight, including key studies modeled for PFOA and PFOS (Sagiv et al., 2018; Wikström et al., 2020), as well as a recent meta-analysis (Wright et al., 2023) that provides evidence that associations between decreased birth weight and PFNA exposure across the available studies are robust and consistent. Because the PFNA slope factor estimates based on the studies used for sensitivity analysis (Lenters et al., 2016 and Valvi et al., 2017) are not precise, with 95 percent confidence intervals covering wide ranges that include zero (i.e., serum PFNA slope factor estimates used are not statistically significant at 5 percent level), the EPA estimated benefits from reduced PFNA exposure as part of a sensitivity analysis only (see Appendix K of the EA; USEPA, 2024c). Benefits from reduced PFNA exposure were not included in the national-level quantified benefits analysis for the rulemaking. Because PFNA birth weight sensitivity analysis benefits are not included in the national quantified benefits, the EPA has characterized the uncertainty associated with PFNA birth weight benefits by presenting what is effectively a lowest-end estimate of zero PFNA benefits into the national benefits analysis. To inform the reader of the potential higher end estimates, the agency discusses PFNA quantified benefits separately in appendix K of USEPA (2024c). Taking the best available science into account on PFNA birth weight effects, the EPA maintains that the analysis of quantified PFNA benefits from birth weight effects is justified.

Lastly, the EPA disagrees with the commenter's statement that "additional developmental benefits are not expected from other PFAS, including the additional four evaluated in this proposal." The EPA discusses the nonquantifiable developmental benefits for compounds including PFHxS, PFNA, HFPO-DA, and PFBS in Section 6.2.4 of the EA (USEPA, 2024b). However, the EPA notes that the only quantified developmental benefits are for PFOA, PFOS, and PFNA, with PFNA developmental benefits being presented in sensitivity analysis only.

American Water Works Association (AWWA) (Doc. #1759, SBC-045648)

3. Comments on the Birth Weight Risk Reduction Analysis

In the 2021 documents, the USEPA had not quantified benefits of birth weight risk reductions associated with reductions in exposure to PFOA and PFOS in drinking water. The SAB had recommended that the USEPA consider risk reduction analyses for other endpoints, provided a sufficient rationale existed. The quantified health benefits associated with birth weight impacts now include the following, which have not been peer-reviewed by the SAB:

• Increase in birth weight (in millions of grams); and

• Number of birth-weight related deaths avoided.

Under the Proposed Option (MCL of 4 ppt for PFOA and 4.0 ppt for PFOS and an HI of 1.0 for PFNA, HFPO-DA (GenX chemicals), PFHxS, and PFBS), the USEPA calculated an expected increase in birth weight of 209,300,000 grams and 1,232.7 birth-weight related deaths avoided when the Proposed Option was compared to baseline drinking water concentrations.

Previously, after integrating the evidence, the USEPA had been unclear regarding its strength of evidence conclusion that PFOA and PFOS are associated with low birth weight or decreases in birth weight. Nevertheless, the USEPA (2021a, 2021b) had derived candidate RfDs for decreases in birth weight based on epidemiological studies before selecting a critical effect with the lowest point of departure human equivalent dose (which was for vaccine response). The SAB (USEPA 2022a) requested that the "USEPA consider reevaluating its strength of evidence conclusions for some human endpoints, including (but not necessarily limited to) decreased immune response, increased liver enzymes, increased serum lipids (for PFOA) and decreased fetal growth to determine if they are better described as having "likely" or "strong" evidence rather than "suggestive" or "moderate" evidence of an association with exposure to PFOA/PFOS. Such a reevaluation should consider studies included in the 2016 HESD and more recent studies published after the end date of the literature search for the current draft." (emphasis added, p. 23, USEPA 2022a).

Most recently, the USEPA (2023a, 2023c) judged the evidence of an association between PFOA or PFOS and fetal growth restriction as "likely" based on "moderate" evidence in humans (Note: The evidence integration included a review of mechanistic data which had not been reviewed previously by the SAB. There were also new figures that had not been reviewed previously, including the forest plots for low birth weight and small for gestational age, which had been omitted from the USEPA 2021a, 2021b documents). This conclusion of a likely association between PFOA or PFOS and fetal growth restriction based on moderate evidence in humans also allowed for the justification of quantified health benefits from birth weight impacts associated with the Proposed Option (as well as other regulatory options).

3.1 Candidate Reference Dose for Low Birth Weight

For PFOA, the USEPA derived a Reference Dose (RfD) for low birth weight (LBW, defined as birth weight<2500 grams) using a hybrid approach for defining the benchmark response (BMR), where the adverse health effect (LBW) was estimated using the dose that increases the percent of responses falling below the clinical definition of LBW (<2500 g). In 2018, 8.27% of live births fell below 2500 g (CDC 2023a as reported in USEPA 2023b and 2023d). As a result, the USEPA selected a BMR of 5% and the background response of 8.27% to calculate a dose that results in 12.86% of the responses falling within a clinical definition of low birth weight (<2500 g). For the dose-response association, the USEPA (2023a) chose the coefficient for the effect of PFOA on decreased birth weight from Wikstrom et al. (2020) (B -68.0 g per ln-ng/mL, 95% CI -112.0 to 24.0). When re-expressed to ng/mL (which was used to estimate the benchmark dose (BMD) and the lower bound on the BMD (BMDL)), β was -41.0 per ng/mL, 95% CI -67.5 to -14.5 g per ng/mL.

The use of LBW as the critical effect is inconsistent with other regulatory agencies that found small decreases in birth weight in relation to PFOA and PFOS but not increased risk of low birth weight. These include the following examples:

• ATSDR (2021) reported "Small (<20-g or 0.7-ounce decrease in birth weight per 1 ng/mL increase in either PFOA or PFOS blood level) decreases in birth weight (PFOA, PFOS)."

• ATSDR (2021) also reported "most studies found no association between maternal serum PFOA levels and the risk of low birth weight infants (typically defined as <2,500 g) (Chen et al. 2012a; Darrow et al. 2013; Fei et al. 2007, 2008a; Manzano-Salgado et al. 2017a; Savitz et al. 2012b; Stein et al. 2009) or found a decreased risk of low birth weight infants (Nolan et al. 2009; Savitz et al. 2012a). Similarly, most studies found no increases in the risk for small for gestational age (Chen et al. 2012a; Fei et al. 2007, 2008a; Hamm et al. 2010; Lauritzen et al. 2017; Manzano-Salgado et al. 2017a; Savitz et al. 2012b; Wang et al. 2016; Whitworth et al. 2012a)." (p. 465)

• EFSA (2020) reported that PFOA or PFOS exposure was associated with "reduced birth weight." Furthermore, EFSA (2018, 2020) concluded that the decrease in birth weight is small after adjusting for confounders and "the potential longer term consequences of this decrease are unclear."

• EFSA (2020) also stated "As already explained in the previous Opinion on PFOA and PFOS (EFSA CONTAM Panel, 2018), the association with reduced birth weight might at least partly be explained by changes in the physiology during pregnancy, although a recent study seemed to strengthen the causality of the effect (Meng et al., 2018; see also Section 3.3.4.1.1). The remaining decrease in birth weight after adjusting for confounders was not large and the potential longer term consequences of this decrease are unclear. Thus far, there is little evidence for an increase in the proportion of children with low birth weight (< 2,500 g)." (p. 138)

In the hazard assessment, the USEPA (2023a, 2023c) evaluated and integrated evidence for fetal growth restriction by combining epidemiological studies on the risk of LBW (birth weight<2500 grams) with studies on the risk of small for gestational age (SGA, primarily defined in epidemiological studies as birth weight below the 10th percentile for the gestational age). Although these endpoints can be correlated, they are not equivalent endpoints and they should not be evaluated as if they are same. The forest plots (figures 3-54, 3-55, 3-56, and 3-57, USEPA 2023a) are new and were not included in the 2021 draft documents. The USEPA (2023a) concluded that the evidence supports increased risk of LBW and SGA in relation to PFOA:

"Overall, nine of the eleven informative studies reporting main effects for either SGA or LBW or both showed some increased risks with increasing PFOA exposures. The magnitude of the associations was typically from 1.2 to 2.8 with limited evidence of exposure-response relationships among the studies with categorical data. Although the number of studies was fairly small, few discernible patterns across study characteristics or confidence ratings were evident across the SGA or LBW findings. For example, four of the nine studies showing increased odds of either SGA or LBW were based on early sampling biomarkers. Collectively, the majority of

SGA and LBW studies were supportive of an increased risk with increasing PFOA exposures." (p. 3-212, USEPA 2023a).

The tables and figures in the PFOA toxicity assessment (USEPA 2023a) reported that eight studies were informative for a total of nine results (Chu et al. 2020, Wang et al. 2016, Wikström et al. 2020, Lauritzen et al. 2018, Manzano-Salgado et al. 2017, Govarts et al. 2016, Hjermitslev et al. 2020, Meng et al. 2018). Closer inspection showed that the results were not consistent within or between studies. For example:

• Three studies stratified results according to sex. One study found increased risk of LBW in girls, but not boys (Wikström et al. 2020), one study found increased risk of SGA in girls and decreased risk of SGA in boys (Wang et al. 2016), and one study found increased risk of LBW in boys, and decreased risks in girls (Manzano-Salgado et al. 2017). Separately, Manzano-Salgado et al. (2017) also reported increased risk of SGA in boys and decreased risks in girls.

• Lauritzen et al. (2018) stratified by country of birth and reported decreased risk of SGA in Norway (median PFOA concentration, 1.62 ng/mL and median PFOS concentration, 9.74 ng/mL) and increased risk of SGA in Sweden (median PFOA concentration, 2.33 ng/mL and median PFOS concentration 16.4 ng/mL). (The range of PFOA and PFOS was similar among study participants from both countries, suggesting other explanations are likely for the differences in risks).

• Exposure-response results were not consistent within studies where exposures were measured in the general population (at low concentrations of PFOA and PFOS):

o Meng et al. (2018) reported no association between risk of LBW per doubling of PFOA exposure (OR 1.0, 95% CI 0.7–1.5) and slightly increased odds ratios when PFOA exposure was categorized into quartiles and Q2 (OR 1.5, 95% CI 0.8–3.1), Q3 (OR 1.2, 95% CI 0.5–2.5), and Q4 (OR 1.5, 95% CI 0.7–3.3) were compared to Q1.

o Chu et al. (2020) reported a slightly increased OR for LBW of 1.16 per ng/ml increase of PFOA (median concentration 1.54 ng/mL, interquartile range 0.957 to 2.635 ng/mL), but no increased risks when exposure was categorized into quartiles (OR 1.0 for 4th quartile (≥2.64 ng/ml) compared to 1st quartile (≤0.096 ng/ml)).

o Three studies did not show exposure-response relationships or trends when exposure was categorized into quartiles of exposure (Meng et al 2018; Wikström et al. 2020; Chu et al. 2020). Wikström et al. (2020) showed an increased risk only for PFOA>2.30 ng/mL (4th quartile) compared to <1.1 ng/ml (1st quartile). Chu et al. (2020) did not find any increased risk of LBW when exposure was categorized by quartiles of exposure.

o When stratified by maternal sampling in early pregnancy (1st trimester) and maternal sampling in later pregnancy (2nd 3rd trimesters, cord blood, after delivery), there were 4 studies of sampling in early pregnancy (Hjermitslev et al. 2020; Wikström et al. 2020; Meng et al. 2018; Manzano-Salgado et al. 2017) and 4 studies of sampling in late pregnancy (Chu et al. 2020; Govarts et al. 2016; Wang et al. 2016; Lauritzen et al. 2018). Although Wikström et al. (2020)

reported an increased risk of LBW in girls when the highest exposure was compared to the lowest exposure, other studies that sampled early in pregnancy reported decreased risks of LBW (Hjermitslev et al. 2020; Manzano-Salgado et al. 2017).

Importantly, and despite the request by the SAB that the USEPA re-evaluate studies published before and included in the 2016 Health Effects Support Documents (HESD) for PFOA (USEPA 2016a) and PFOS (USEPA 2016b), the USEPA (2023a, 2023c) did not include studies that evaluated risk of LBW or risk of SGA and exposure to PFOA or PFOS that were published prior to 2017 in the overall integration of evidence. Consequently, the USEPA did not consider at least 7 studies that evaluated LBW and did not find an increased risk of low birth weight in relation to PFOA or PFOS (Darrow et al. 2013; Nolan et al. 2009; Savitz et al. 2012a, 2012b; Stein et al. 2009; Chen et al. 2012; Wu et al. 2012). [Note: These studies were summarized in Table D.1.2 in the Appendix to the PFOA Toxicity Assessment (USEPA 2023b) and the study quality evaluation was presented in Figure 3-45 (USEPA 2023a), but these studies were not included in the forest plots (Figures 3-54 and 3-55, USEPA 2023a) or discussed in the integration of evidence]. In contrast, and in response to the request by the SAB (USEPA 2022a), the USEPA (2023a,2023c) had integrated evidence regarding immunotoxicity studies and cholesterol studies that were older and included in the 2016 HESD documents (USEPA 2016a,2016b).

The USEPA concluded in the PFOS toxicity assessment (USEPA 2023c):

“Collectively, the majority (7 of 10) of SGA and LBW studies were supportive of an increased risk with increasing PFOS exposures. The increased odds ranged from 1.19 to 4.14 although evidence of exposure-response relationships was lacking. There was no evidence of differences by study confidence as five of these seven were either high (n=4) or medium (n=1) confidence. There was also no evidence of sample timing differences as the majority of studies with associations were reported in studies based on early sampling periods.” (p. 3-209, USEPA 2023c).

The USEPA (2023c) did not provide references within the above sentence; however, review of tables and figures reported the following studies were high confidence (Chu et al. 2020, ManzanoSalgado et al. 2017, Lauritzen et al. 2018, Wikström et al. 2020) or medium confidence (Govarts et al. 2016; Hjermitslev et al. 2020; Meng et al. 2018) despite the following issues:

• Exposure-response relationships were generally not seen.

• Four studies (Manzano Salgado et al. 2017; Wikström et al. 2020; Meng et al. 2018; Hjermitslev et al. 2020) were based on sampling during early pregnancy while three studies (Lauritzen et al. 2018, Govarts et al. 2016, Chu et al. 2020) were based on sampling late in pregnancy.

The USEPA (2023e) conflates decreases in birth weight with low birth weight in the economic analysis. The USEPA provided a rationale for estimating medical costs associated with changes in infant birth weight and the value of avoiding infant mortality at various birth weights by citing to health effects in relation to low birth weight specifically:

"LBW is linked to a number of health effects that may be a source of economic burden to society in the form of medical costs, infant mortality, parental and caregiver costs, labor market productivity loss, and education costs (Chaikind et al., 1991; J. R. Behrman et al., 2004; R. E. Behrman et al., 2007; Joyce et al., 2012; Kowlessar et al., 2013; Colaizy et al., 2016; Nicoletti et al., 2018; Klein et al., 2018). Recent literature also linked LBW to educational attainment and required remediation to improve student outcomes, childhood disability, and future earnings (Jelenkovic et al., 2018; Temple et al., 2010; Elder et al., 2020; Hines et al., 2020 Chatterji et al., 2014; Dobson et al., 2018)." (USEPA 2023e, p. 6-360)

"Low birth weight (LBW) is an important health outcome affected by PFOA/PFOS exposure because it is a significant factor in survival rates and medical care costs among infants (ATSDR, 2021)." (USEPA 2023e, p. 6-13)

"Epidemiology studies on PFOA supported an increased risk of LBW in infants with PFOA exposures (USEPA, 2023a). Similarly, epidemiology studies on PFOS showed an increased risk of LBW infants with PFOS exposures. Overall, most epidemiology studies evaluating the association between maternal serum PFOA/PFOS and birth weight reported negative relationships (i.e. increased exposure is associated with decreased birth weight)

(Darrow et al., 2013; Verner et al., 2015; Govarts et al., 2016; Negri et al., 2017; Starling et al., 2017; Sagiv et al., 2018; Chu et al., 2020; Dzierlenga et al., 2020; Wikström et al., 2020; Yao et al., 2021). FN30: Recent evidence indicates that relationships between maternal serum PFOA/PFOS and birth weight may be impacted by changes in pregnancy hemodynamics (Sagiv et al., 2018; Steenland et al., 2018)." (USEPA 2023e, 6.13)

When considering the evidence for risk of low birth weight in relation to PFOA and PFOS, the USEPA combines studies of the risk of LBW with studies of the risk of SGA (USEPA 2023a, 2023c).

There is little evidence that the risk of LBW or the risk of SGA is increased (see remarks above).

3.2 Exposure-response functions for PFOA and PFOS and decreases in birth weight used in the Economic Analysis

The USEPA (2023e) Economic Analysis relies on the exposure-response coefficients (slope factors) for decreases in birth weight from the main analyses of a meta-analysis of birth weight effects in relation to PFOA (Steenland et al. 2018) which reported a mean birth weight decrease of 10.5 g per ng/ml (95% CI −16.7, −4.4) and a separate meta-analysis of birth weight effects in relation to PFOS (Dzierlenga et al., 2020) which reported a mean birth weight decrease of 3.0 g per ng/ml (95% CI −4.9, −1.1). [NOTE: An average decrease of 10 grams is equivalent to a decrease of approximately 0.35 ounces]. The biological or clinical significance of such small changes in birth weight is uncertain. The exposure-response function (B -10.5 g birth weight per ng/mL serum) for PFOA used in the economic analysis is also considerably smaller than the coefficient (B -41.0 g per ng/mL, 95% CI −67.5, −14.5 for PFOA) from the study selected for the critical effect and the calculation of the BMD and BMDL (Wikström et al. 2020). For PFOS, the exposure-response function for the economic analysis (B -3.0 g per ng/mL) is slightly smaller

than the coefficient (B 8.4 g per ng/mL, 95% CI −16.0, −0.5) used for deriving the candidate RfD for low birth weight based on Wikström et al. 2020).

Both of these meta-analyses (Steenland et al. 2018; Dzierlenga et al. 2020) conducted specific sensitivity analyses to evaluate bias associated with maternal sampling during late pregnancy compared to maternal sampling during early pregnancy. Both meta-analyses reported that essentially no effect on birth weight was seen when maternal blood is sampled early in pregnancy, while a relatively larger effect on birth weight was seen when maternal blood is sampled late in pregnancy. In general, this suggests that any effect of PFOA or PFOS on birth weight is confounded by the time of sampling (Steenland et al. 2018, 2020; Dzierlenga et al. 2020). In brief, an increased glomerular filtration rate and maternal plasma volume expansion during pregnancy leads to an increased elimination of PFOA and PFOS. Plasma volume expansion and glomerular filtration rate are also related to birth weight. When PFAS in serum is sampled late in pregnancy, the magnitude of the glomerular filtration rate and the plasma volume expansion can distort the association between PFAS and birth weight. Therefore, using the main effect from the meta-analysis (which is essentially an average of birth weight effects reported from early in pregnancy and late in pregnancy) will overestimate the health benefits associated with birth weight risk reductions under the assumption that pregnancy hemodynamics confound the association.

Steenland et al. (2018) found that there was no effect on birth weight after including the C8 Science study in the meta-analysis:

“Our meta-analysis including nine new studies, with an almost equal number of births as prior studies, shows a modest inverse association between maternal or cord PFOA and birthweight, with large heterogeneity across studies. The two studies with exposure above background levels showed no association, and similarly, restriction to studies with blood sampling conducted early in pregnancy or shortly before conception showed little or no association. These findings are consistent with confounding and/or reverse causality being responsible for the inverse association seen in studies with low background exposure levels and blood sampling conducted later in pregnancy, when confounding and/or reverse causality are likely to be more important.”

Overall, there is little evidence that PFOA or PFOS at serum concentrations reported in the general population affect developmental outcomes. The USEPA (2023e) confirmed that there was generally a lack of evidence for exposure-response associations between PFOA and PFOS and other development outcomes:

“Additionally, the magnitude of birth weight changes may be correlated with other developmental outcomes such as preterm birth, gestational duration, fetal loss, birth defects, and developmental delays. As described in Section 6.2, these developmental outcomes have limited epidemiology and toxicology evidence showing associations with PFOA/PFOS exposure and due to this uncertainty, these outcomes were not further assessed.” (p. 6-36).

3.3 Other factors that have affected mean birth weight

The USEPA (2023e) economic analysis calculates that the expected value of birth weight increases, assuming the MCLs are set to 4.0 ppt for PFOA and PFOS plus a hazard index of 1.0 for PFNA, PFBS, PFHxS, and HFPO-DA, is an average increase of 50 grams (1.8 ounces) in mean birth weight. According to US Natality data (CDC 2023a), the mean birth weight in 2018 was 3261.64g and 8.3% of births were low birth weight (<2500 g). If average birth weight were to increase by 50 grams, the mean birth weight would be 3,316.84 g.

During 2003-2018, median PFOS in blood serum decreased substantially by 12 ng/mL, from 14.6 ng/ml in 2003-2004 to 2.6 ng/ml in 2017-2018 (USEPA 2022b) in the population of women aged 16-49 years old (women of childbearing age). During the same years, median PFOA in blood serum also decreased but by a smaller absolute change of 2.1 ng/mL, from 3 ng/mL in 2003-2004 to 0.9 ng/mL in 2017-2018) (USEPA 2022b).

Although the average birth weight in 2003 was 3291.03 grams, which was 30 grams higher than average birth weight in 2018, there were fewer births of low birth weight babies (CDC 2023a). In 2003, 7.9% of births were of low birth weight while in 2018, 8.3% of births were of low birth weight. Together, these data suggest further reductions of PFOA and PFOS concentrations in blood serum are unlikely to result in measurable increases in average birth weight (CDC 2023a).

Tilstra and Masters (2020) reported that average birth weight decreased in the United States since at least 1990. In 1990, average birth weight was 3314.5 grams (approximately 50 grams more than in 2018). However, Tilstra and Masters (2020) provided an analysis that argued that the shift to lower average birth weight is due to changes in obstetric practices (more c-sections and scheduled births). As a result, there are fewer and fewer vaginal births at 40-42 weeks, when babies are heavier; most of these births have shifted to 37-39 weeks because of changes in obstetric practices. This shift has affected the average birth weight.

Data from other areas where PFOS and PFOA are found in the blood serum at similar concentrations to the US also provided evidence that PFOS and PFOA in blood serum at general population levels do not result in decreased birth weight. For example, birth weight in the Faroe Islands (where decreases in antibody response to diphtheria vaccination in relation to increases in PFOA and PFOS form the basis for the RfD for immunotoxicity effects, specifically decreases in vaccine response at age 7 in relation to PFOA or PFOS at age 5) has increased over the past 50 years. For the years 1969-1981, Olsen and Joensen (1985) reported that the average birth weight of liveborn infants delivered in the Faroe Islands was the highest average weight (3,610 g) reported by 33 countries. More recently, Olsen et al. (2023) found that that the mean birthweight in the Faroe Islands was higher than other Nordic countries and had increased during 2010–2019 in the Faroe Islands.

3.4 Conclusions and Recommendations

• When integrating the evidence of birth weight effects and arriving at an evidence stream judgment for humans, the USEPA should consider older studies of LBW in relation to PFOA and PFOS that predated the 2016 HESD (USEPA 2016a, 2016b). Reconsidering these studies likely decreases confidence in the judgment of evidence.

• The USEPA should provide further rationale for using Wikström et al. (2020) as the critical study for the association of decreased birth weight given that it is only one study that sampled PFAS in serum during early pregnancy that showed an association between decreased birth weight and increases in PFAS; other studies that sampled during early pregnancy did not show an association or they showed an attenuated association, which potentially leads to a conclusion that the evidence for an association between PFAS and decreased birth weight is inconsistent after considering potential confounding.

• The USEPA should provide a quantified sensitivity analysis and further discussion of the effects of confounding or reverse causation by pregnancy hemodynamics on the health benefits analysis.

• Available data suggest that further reductions of PFOA and PFOS concentrations in blood serum are unlikely to result in measurable increases in average birth weight. Data from other areas where PFOS and PFOA concentrations are elevated suggest that increases in average birth weight and decreases in infant mortality are likely not expected. For example, PFOS and PFOA in blood serum have been measured in maternal serum in birth cohort studies in the Faroe Islands with mean concentrations similar to that reported in the general population in the US (Grandjean et al. 2012). Studies have reported that the mean birthweight in the Faroe Islands was higher than other Nordic countries and had continued to increase during 2010–2019 in the Faroe Islands (Olsen and Joensen 1985; Olsen et al. 2023). Although there are no published studies of birth weight in relation to PFAS serum concentrations in the Faroe Islands, it is unlikely that small decreases in birth weight in relation to PFAS – should the association exist in this population – have adverse health consequences.

EPA response: Please see section 4.1.3 of the EPA response in this *Response to Comments* document regarding the implementation of the SAB PFAS Review Panel's recommendations in the final toxicity assessments for PFOA and PFOS, including changes that were made (e.g., addition of figures) as a result of this review. Please see section 4.1.2 of the EPA response in this *Response to Comments* document regarding the EPA's use of the best available science, including studies that were considered in the 2016 Health Effects Support Documents (HESDs), in the final toxicity assessments for PFOA and PFOS. The EPA notes that while the evidence profile table for developmental effects in Section 3.4.4 of the draft toxicity assessments for PFOA and PFOS did not previously describe studies considered in the 2016 HESDs, these studies were in fact considered in the evidence integration judgments presented in the draft toxicity assessments. Therefore, the EPA disagrees that incorporation of studies from the HESDs would decrease confidence in the evidence for developmental effects associated with PFOA or PFOS. The EPA has updated the evidence profile tables for all priority health outcomes to explicitly and more clearly describe studies from the 2016 HESDs in the final toxicity assessments for PFOA and PFOS (USEPA, 2024h; USEPA, 2024i).

Please see section 4.2.6 of the EPA response in this *Response to Comments* document regarding why the EPA's conclusions may differ from those of other health agencies. Please see sections 4.2.1 and 4.2.2 of the EPA response in this *Response to Comments* document, the EPA response

to comment Doc. #1774, SBC-053211 in section 4.2.1.2 in this *Response to Comments* document, as well as Sections 3.4.4 and 4.1.1 of the final toxicity assessments for PFOA and PFOS (USEPA, 2024h; USEPA, 2024i) regarding the EPA's rationale for selecting decreased birth weight as a critical effect for RfD derivation, as well as rebuttal to the commenter's claim that decreased birth weight is not a biologically or clinically significant effect.L

The commenter claims that the EPA "derived a Reference Dose (RfD) for low birth weight (LBW, defined as birth weight <2500 grams) using a hybrid approach for defining the benchmark response (BMR), where the adverse health effect (LBW) was estimated using the dose that increases the percent of responses falling below the clinical definition of LBW (<2500 grams)." The commenter fundamentally misunderstands the EPA's RfD derivation and critical effect described in the Toxicity Assessments Sections 4 and Appendices E (USEPA, 2024h; USEPA, 2024i; USEPA, 2024j; USEPA, 2024k). Decreases in birth weight, not LBW, was the critical effect. The term "Low Birth Weight" was incorrectly used in Table 4-8, Table 4-11, and Figure 4-5 (Figure 4-4 in PFOS) in the draft toxicity assessments for PFOA and PFOS and has subsequently been corrected in the final assessments (USEPA, 2024h; USEPA, 2024i). Many of the commenter's subsequent points are predicated on this fundamental misunderstanding of LBW as a critical effect and requirements needed for such a determination, including consistency or lack of dose-response which the commenter points out is lacking for some LBW studies. The EPA agrees that, as described in detail the Toxicity Assessments Sections 3.4.4, "few discernible patterns across study characteristics or confidence ratings were evident across the small gestational age (SGA) or LBW findings." Similarly, the EPA does not claim that there is a clear exposure-response association for PFOA or PFOS exposure and LBW.

The commenter provided a quote on the EPA's conclusions for the association between elevated exposure to PFOS and SGA and LBW. The statements by the commenter are correct; however, the EPA disagrees with the implication that these study results do not support the agency's conclusion of *moderate* evidence for adverse developmental effects. Further discussion of the EPA's consideration of LBW and SGA studies, the selection of Wikström et al. (2020) as the critical study, the consistency of the low birthweight endpoint, and potential for confounding, is provided in the EPA responses to Doc. #1774, SBC-053452 and SBC-053453 in section 4.2.2.3.4 in this *Response to Comments* document. See also responses in section 4.2.1.2 and 4.2.2.3.4 in this *Response to Comments* document.

The EPA agrees with the commenter that fetal growth restriction and low birth weight risk are not equivalent endpoints. As clearly stated in Chapter 6 of the EA (USEPA, 2024b), the EPA considered only studies that related PFOA and PFOS exposure to changes in birth weight. The studies selected for use in the birth weight benefits analysis, Steenland et al., 2018 and Dzierlenga et al., 2020, develop birth weight exposure-response functions for PFOA and PFOS, respectively, and do not conflate birth weight with fetal growth rate.

The EPA disagrees with the commenter's statement that the economic analysis conflates decreases in birth weight with low birth weight. As clearly stated in Chapter 6 of the EA (USEPA, 2024b), the EPA monetized benefits associated with incremental increases in birth

weight resulting from reductions in drinking water PFOA/PFOS levels based on avoided medical costs associated with different birth weight ranges. The estimated incremental medical costs are a continuous function of birth weight over the range from 900 to 4,500 grams. The function does not allow for a discontinuity at the very low birth weight level. The EPA uses CDC data on the state-level distribution of baseline birth weight and the estimated change in birth weight to obtain the simulated cost change for birth weight increases. Based on the baseline birth weight distribution and the estimated increase in birth weight from reduced exposure to PFOA and PFOS, the distribution of birth weight shifts from lower to higher under the post-policy scenario. This shift includes a reduction in the number of LBW infants.

The EPA disagrees with the commenter's assertion that "available data suggest that" reductions of PFOA and PFOS concentrations in blood serum are unlikely to result in measurable increases in average birth weight. The EPA has reviewed the provided sources, and the EPA does not agree that the presented evidence from the Faroe Islands supports the commenter's assertion, or that it is as conclusive as the commenter suggests. Other longitudinal trends occurring simultaneously in the Faroe Island population may explain the increased birth weight trend reported by one study in this population. The EPA review in fact found evidence of associations between PFOA an PFOS and decreased birth weight in a Faroe Island study (Valvi et al., 2017).

Recent evidence indicates that relationships between maternal serum PFOA/PFOS and birth weight may be impacted by changes in pregnancy hemodynamics, however exact patterns are not completely understood (Sagiv et al., 2018; Steenland et al., 2018). While uncertainties remain on the potential impact of pregnancy hemodynamics in later pregnancy due to use of biomonitoring samples from the second and third trimester or post-partum, the evidence for associations between PFOA and PFOS and decreases in birth weight is consistently supported by a large number of *high* and *medium* confidence epidemiology studies and supported by evidence across other measures and fetal growth restriction (see Section 3.4.4.4 of the PFOA and PFOS Toxicity Assessments; USEPA, 2024h; USEPA, 2024i). The EPA acknowledges that this is a possible limitation of the analysis, as described in Section 6.2.2.1.1 of the EA (USEPA, 2024b). See also section 13.4.2 of the EPA response in this *Response to Comments* document.

The EPA disagrees with the commenter's assertion that the final report EA incorrectly attributes LBW to PFOA and PFOS when other causes of LBW (e.g., changes in obstetric practices) offer an alternative explanation. This rulemaking only considers the effect on LBW from PFOA and PFOS exposure, and the EPA has in its literature review isolated these effects from other causes of LBW.

American Water Works Association (AWWA) (Doc. #1759, SBC-053055)

Estimating the Reduced Impact of Low Birth Weights

In review of the EPA's approach to estimating the benefits of reducing the incidence of low birth weights resulting from prenatal PFOA and PFOS exposure, it appears that EPA is conflating risk

of low birth weight with differences in mean birth weight. In review of this approach, several critical issues have been raised:

• The use of low birth weight as the critical effect is inconsistent with other regulatory agencies that found small decreases in birth weight but not increased risk of low birth weight in relation to PFOA and PFOS (ATSDR, 2021; EFSA, 2020; EFSA, 2018).

• In deriving the Reference Dose for both PFOA and PFOS, EPA has noted that the derivations for PFOA and PFOS were based on low birth weight (defined as birth weight less than 2,500 grams). However, the exposure-response coefficients used for these efforts were based on decreases in birth weight. In particular, the studies used for these derivations evaluated differences in average birth weight but not risk of low birth weight. EPA's conflation of low birth weight with decreases in birth weight is prevalent in the economic analysis as well. While these endpoints are correlated, they are not equivalent and the should not be evaluated as if they are the same.

• The benefits analysis relies on exposure-response functions based on coefficients for decreases in birth weight from the main analysis of two different meta-analyses for PFOA and PFOS. The critical study that serves as the basis for the PFOA meta-analysis (Steenland et al, 2018) concluded that there was no effect on birth weight when the results of the C8 Science Study were included and noted that the results were consistent with confounding and/or reverse causality. EPA's conclusion is at odds with Steenland et al's own conclusion for their work.

• EPA's characterization of the supporting studies for this health effect is inconsistent with the data that is provided by the studies. In the toxicity assessment for PFOA, EPA concludes that the majority of the studies considered showed supportive evidence of an increased risk of low birth weight with increasing PFOA exposures. However, closer inspection of the studies showed conflicting results. For example, several studies that stratified results by sex provided mixed results on gender-specific impacts. Similarly mixed results were noted for studies that stratified results by country of birth. Furthermore, exposure-response results were not consistent with results from studies where exposures were measured in the general population; in particular, these studies generally reported no Associations or very limited evidence of Associations of PFOA and PFOS with low birth weight.

• While the SAB requested that USEPA reevaluate and consider studies published before the 2016 Health Effects Support Documents for PFOA and PFOS, at least seven studies that were available prior to 2017 were not included (Darrow et al. 2013; Nolan et al. 2009; Savitz et al. 2012a, 2012b; Stein et al. 2009; Chen et al. 2012; Wu et al. 2012). None of these studies found an increased risk of low birth weight in relation to PFOA or PFOS. EPA must include studies that do not support its preferred outcome in its analysis and explain why, in light of these studies, it has still reached its determination.

• The EPA also failed to acknowledge the significance of the results from the sensitivity analysis assessing bias associated with timing of the maternal sampling during late pregnancy versus sampling during early pregnancy. This sensitivity analysis highlighted that there was no effect on

birth weight when maternal blood was sampled early in pregnancy whereas late pregnancy sampling showed a larger effect on birth weight than the meta-analysis. This suggests that the evidence for a conclusion that PFAS exposure is associated with decreased birth weight is inconsistent after considering potential confounding.

Additional details on these and other comments for the EPA's analysis of decreased birth weights are available in Appendix A. Based on the materials made available, it does not appear that EPA's conclusion is supported by the evidence or record before the agency.

EPA Response: Regarding the commenter's suggestion that the literature review of the relationship between PFOA/PFOS exposure and LBW needs to include papers that predated the 2016 HESD and that evidence supporting this relationship is inconsistent with other agencies' findings, see the EPA response to comment Doc. #1759, SBC-045648 in section 13.4.2 in this *Response to Comments* document. Regarding the commenter's assertion that low birth weight and decrease in birth weight are inappropriately conflated, see section 13.4.2 of the EPA response in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-053419)

f. Exposure-Response Relationships Were Improperly Selected

To calculate the health-risk reduction benefits based on serum concentrations, EPA extracts from literature or independently reanalyzes various exposure-response slope factors that are intended to demonstrate a quantitative relationship between a change in serum concentrations and a specific health effect. For both PFOA and PFOS, EPA evaluates the health effects of reductions in birth weight and increases in total cholesterol. EPA also considers increases in renal cell carcinoma risk for PFOA and increases in blood pressure for PFOS. For each endpoint, EPA selects relationships between serum levels and health effects that are not supported by the underlying studies or are based on uncertain reanalysis of data. These flawed analyses add to the misleading conclusions associated with basing the analysis on inappropriate and indistinguishable regulatory alternatives.

For reduced birth weight, EPA uses an exposure-response slope factor of –10.5 g per ng/mL for PFOS from Steenland et al. (2018), which is a random effects meta-analysis based on 24 studies. Contrary to EPA's assessment, however, Steenland et al (2018) concludes, "current human evidence provides only modest support for decreased birth weight with increasing PFOA. Studies with a wide range of exposure, and studies with blood sampled early in pregnancy, showed little or no association of PFOA with birth weight. These are studies in which confounding and reverse causality would be of less importance." (Emphasis added). In other words, EPA relies on an association for an endpoint that is not supported by the underlying publication. For PFOS, EPA conducts its own meta-analysis of data presented in Dzierlenga, Crawford et al. (2020) deriving an exposure-response slope factor of –3.0 g per ng/mL, even though Dzeirlenga et al. (2020) itself found that "when blood was drawn at the very beginning of

pregnancy, there was essential no relation of birth weight to PFOS." This meta-analysis has not been peer reviewed, which calls into question the validity of EPA's reanalysis methods.

EPA's approach to selection of exposure-response slope factors is scientifically flawed, lacks transparency, and disregards the biological relationship of exposure and effects. EPA should consider and discuss the exposure-response slope factors in the context of biologically relevant effects and obtain peer review for any novel analyses. EPA's analysis egregiously misrepresents any meaningful determination of health risk reduction benefits between the proposed MCL and regulatory alternatives.

EPA Response: The EPA disagrees with the commenter's statement that the EPA's selection of relationships between serum levels and health effects are not supported by the science or are based on uncertain reanalysis of data. The commenter references conclusions from Steenland et al (2018) on PFOA and birth weight effects and states that the EPA "relied on an association for an endpoint that is not supported by the underlying publication." The EPA disagrees. For the agency's response to the commenter's arguments, please see section 13.4.2 in this *Response to Comments* document. Additionally, the EPA notes that the studies Steenland et al. (2018) relied on were published prior to 2018. Comprehensive reports published in 2018 or prior found "plausible" or "suggestive" (USEPA, 2016c; ATSDR, 2018) evidence of relationships between PFOA and PFOS and developmental outcomes; however, the EPA's toxicity assessments, which include studies published both before and after 2018, found clear evidence of an association for PFOA and PFOS in both toxicological and epidemiological studies (USEPA, 2024j; USEPA, 2024k). Given the breadth of the studies evaluated for the EPA's toxicity assessment, the EPA disagrees with the commenter that the association between PFOA and birth weight effects is not supported by epidemiology evidence. Please see section 4.2.1 of the EPA response in this *Response to Comments* document for further discussion on the consideration of decreased birth weight as a critical effect.

The commenter's assertion that the Dzierlenga (2020) meta-analysis has not been peer-reviewed is factually incorrect. The study is in fact published in a well know open access peer-reviewed journal Environmental Epidemiology, the official journal of the International Society for Environmental Epidemiology (https://journals.lww.com/environepidem/pages/default.aspx). See section 13.4.2 of the EPA response in this *Response to Comments* document for further discussion on the EPA's use of Dzierlenga (2020) and section 13.4.2 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1759, SBC-045648 in section 13.4.2 in this *Response to Comments* document for further discussion on sample timing/pregnancy hemodynamics.

The EPA disagrees with the commenter's assertions that the EPA's approach to selecting exposure-response slope factors is scientifically flawed, and that the biological relationship of exposure and effects was disregarded. See section 13.4.2 of the EPA response in this *Response to Comments* document.

The EPA also disagrees with the commenter's assertion that the EPA's analysis lacks transparency. See the EPA response to comment Doc. #1774, SBC-045652 in section 13.4 in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-045704)

10. Comments on Effects of Reduced Birth Weight on Infant Mortality (Appendix E, (USEPA 2023b))

(10A) Data Sources

EPA describes a data set with only two years of data. Given the discussion about changes over time in infant mortality described by EPA, a data set with only two years of data is insufficient to build the regression models described in Appendix E. Natural changes over time must also be included in the model. Otherwise, any correlation of birth weight and infant mortality will be erroneous and could easily be due to other time-dependent factors not included in the model.

EPA must make the data set described in E.3.1 available to the public under the EPA's quality assurance and good statistical practice guidelines. It has failed to do so in the supporting documents for the Proposed NPDWRs.

(10B) E.7.1 Mortality Regression Models

Figure E-1 indicates that EPA has built a series of models, generating different model coefficients for various factors that influence birth weight and infant mortality including gender and ethnicity. This approach is inconsistent with scientific best practice. The proper approach is to build a single model with key co-variates like gender and ethnicity included in the single model (Harrell 2016). Otherwise, the model error term (which is the basis for hypothesis testing) is biased and not representative of the entire population included in the data set. EPA could use linear contrast or estimate methods to evaluate differences in gender and ethnicity, but the error term must result from a single model fit.

EPA does not show the significance of each of the regression and logistic model parameters. In other parts of the technical appendices supporting the MCLG, EPA has ignored the fact that many co-variates (e.g., gender or ethnicity) are the variables highly associated with the model response variable, and either PFOS and PFOA are not significant or are minor parameters relative to the key phenotype co-variates. EPA must demonstrate a strong relationship, considering the entire data set and scientifically derived and supported co-variates in the statistical models. As the presentation currently stands, the lack of information provided by EPA negates the ability of the public to evaluate the validity of the models.

EPA must show which co-variates are included in the models generating the odds ratios of Table E-4, including their statistical significance. Otherwise, the validity of the models cannot be examined from a scientific perspective.

EPA Response: The EPA disagrees that two years of data is insufficient to build regression models relating infant birth weight to infant mortality. The peer reviewed analyses that formed the basis of the EPA's updated regression on birth weight and mortality (Almond et al., 2005; Ma and Finch, 2010) used only a single year of CDC NCHS linked birth/infant death data each (Almond et al., 2005 used 1989 data; Ma and Finch (2010) used 2001 data). These papers are highly respected and cited (receiving over 1,000 citations between them) and considered authoritative papers in the field. The analysis performed by the EPA improves upon these seminal analyses by including two years of recent data. Sample sizes among the CDC NCHS linked birth/infant death data per year are large (n = approximately 3.8 million infants) and contribute to the overall statistical significance of regression results. As described in Appendix E (Section E.2), there has been a notable decline in U.S. infant mortality rates since the analyses reported in Ma and Finch (2010) and Almond et al. (2005). The EPA notes that if it were to use the analyses from Ma and Finch (2010) and Almond et al. (2005), the estimated quantified benefits would be significantly higher because of the higher mortality rate among infants in the years of data used for those publications relative to the recent data used in the EPA's infant mortality regressions. Hence, using recent data from two CDC NCHS linked birth/infant death data cohorts results is a more accurate and conservative characterization of recent infant mortality trends than if the EPA had included older CDC NCHS data. Furthermore, like previous studies, the EPA relies on a cross-sectional analysis (rather than a time-series analysis) of the relationship between birth weight and mortality with a carefully selected set of controls for confounding effects. In short, the EPA has clearly and reasonably used best scientific practices and ensured it can produce quantified benefits for low birth weight that are strongly scientifically based, robust, and up to date.

The EPA disagrees with the commenter's assertion that subpopulation-specific regression models do not align with the scientific best practice. In its analysis, the EPA did not simply assume that the relationship between infant mortality and a set of predictors (including birth weight) would be the same in subpopulations defined by race/ethnicity but in fact the EPA evaluated the possible differences. Performing separate regressions is equivalent to including all possible two-way interactions with the race variable and assuming different error distributions for each ethnicity/race. Further, the peer-reviewed analyses upon which the EPA's updated infant birth weight mortality model was based developed separate models for each race/ethnicity. Ma and Finch (2010) investigated whether the strength of predictions of infant mortality varied by race/ethnicity and sex. They found that the models specific to race/ethnicity showed the best goodness-of-fit metrics. Each race/ethnicity-specific model includes covariates for gender and several other variables. Research conducted by the EPA indicates that it is important to model differences in infant mortality by race and ethnicity so that prevention efforts can target risks specific to those populations (Rogers, 1989; Frisbie et al., 1996).

Presentation of the odds ratios in Appendix E (USEPA, 2024c) is consistent with presentation of results in epidemiological literature. Marginal effects are provided additional help with interpretation of the results. The EPA reported the results of regression modeling using both odds ratios and marginal effects that are more informative than just the estimated coefficients. The

EPA also reported the models' fit and the estimated confidence intervals. It is easy enough to include the estimated logistic regression models in Appendix E. However, because the estimated coefficients are in log-odds units, they are often difficult to interpret, so they are often converted into odds ratios in epidemiological literature by taking an exponent of each regression coefficient. The EPA opted for reporting odds ratios via the "logit" command in Stata (StataCorp, 2013).

Information presented in Table E-4 provides information on all covariates included in the model. Table E-4 includes odds ratios for all covariates included in the mortality regression.

The EPA disagrees with the commenter's assertion of a lack of transparency. The dataset described in Appendix Section E.3.1 is available in the docket materials.

American Chemistry Council (ACC) (Doc. #1841, SBC-052939)

The Epidemiological Data are Not Sufficiently Robust to Quantify the Reduction in Developmental Effects

As with RCC, EPA relies on equivocal epidemiological evidence to estimate the benefits of its proposal on developmental effects (i.e., reduced birth weight). While the Agency identified 29 medium and high confidence studies investigating birth weight in humans, it only considered five studies and used only two for its calculation of RfDs. In estimating the benefits of reducing PFOA and PFOS in drinking water EPA relied on two separate meta-analyses. As noted earlier, moreover, the results from the five studies used by the Agency are mixed. In particular, the two studies that EPA relied on for the RfDs report very limited results. Sagiv et al. (2017) did not observe a significant association with maternal serum concentrations of either PFOA or PFOS. While Wikstrom et al. (2019) report an association with PFOA and PFOS concentration in the highest quartile of girls; no association is observed in infant boys.

The human data do not provide a reliable basis for quantifying the risks of lower birth weight, but the findings are supported by the results in laboratory studies. The RfDs calculated from these studies are significantly higher than those based on the epidemiology; they represent a more appropriate estimate of the risk of PFOA and PFOS exposure.

EPA Response: The EPA disagrees with the commenter that the agency's estimation of quantified benefits of its proposal on developmental effects is based "on equivocal epidemiological evidence." For the EPA's response to this comment, including why the EPA believes the epidemiological evidence provides a reliable basis for quantifying the risks of lower birth weight, please see sections 4.2.1 and 4.2.2 in this *Response to Comments* document, the EPA response to comment Doc. #1774, SBC-053212 in section 4.2.2.3.4 in this *Response to Comments* document, as well as Sections 3.4.4 and 4.1.1 of the final toxicity assessments for PFOA and PFOS.

Susan Goldhaber (Doc. #1596, SBC-053416)

May 26, 2023

Michael S. Regan, Administrator Environmental Protection Agency

1200 Pennsylvania Ave., N.W. Washington, D.C. 20460

Re: Docket ID No. EPA-HQ-OW-2022-0114, Comment on Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

Dear Administrator Regan,

As a toxicologist formerly employed at EPA, Office of Drinking Water, (1980-1988), who worked on revising the primary drinking water regulations, I am very familiar with the requirements of the Safe Drinking Water Act and the regulatory process. I am writing because I am very concerned with the underlying science supporting these regulations. I would like to submit the attached comments for your consideration.

Sincerely, Susan B. Goldhaber M.P.H.

SBG Consulting, Inc.

Comments

There are Executive Orders that strongly encourage that the benefits of a major regulation, such as PFAS Drinking Water regulation, exceed the costs. In the Economic Analysis, EPA calculated the economic benefits to the U.S. by avoiding three health outcomes that it attributed to exposure from PFOA and PFOS:

• Developmental effects (reductions in birth weight)

• Cardiovascular effects (increase in total and high-density lipoprotein (HDL) cholesterol resulting in cardiovascular disease including strokes and myocardial infarction)

• Kidney cancer

Reductions in birth weight

ATSDR https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf identified 23 general population studies and three studies of highly exposed populations that did not show an association between PFOA or PFOS and lowered birth weight; 7 studies that reported that higher PFOA/PFOS concentrations in the blood were associated with lower birth weight babies, and two studies that reported the inverse: higher PFOA/PFOS concentrations were associated with higher birth weight babies.

ATSDR concluded, “Evidence is suggestive of an association between serum PFOA and PFOS and small decreases in birth weight: the decrease in birth weight is <20 grams (0.7 ounces) per 1 nanogram/milliliter increase in blood PFOA or PFOS level. “

It has also been suggested that decreased birth weight may be explained by reverse causation, i.e., the higher PFOA concentration is an effect, not a cause in the situation. Since lower birth weight babies have only been noted in studies where PFOA is tested late in the pregnancy (in the 3rd trimester), this could be due decreased kidney filtration rates in some women, which is known to lead to lower birth weight babies. Thus, the lower birth weight babies are due to lower kidney filtration rates, which is associated with higher PFOA levels, but PFOA is not the causative factor.

The primary cause of low birth-weight babies is premature birth and most studies have not found an association between PFOA or PFOS and premature birth. However, EPA calculated a benefit to the U.S. of $139 million to $178 from avoiding low birth weight babies from the proposed regulation.

2. What is the justification for EPA's conclusion that the miniscule decrease in birth weight (less than 1/16th of a pound) due to PFOA/PFOS exposure results in thousands of deaths?

EPA Response: The EPA disagrees with the commenter's assertion that there is insufficient evidence of an association between serum PFOA and PFOS and decreases in birth weight. Please see sections 4.2.1 and 4.2.2 of the EPA response in this *Response to Comments* document, the EPA response to comment Doc. #1774, SBC-053212 in section 4.2.2.3.4 in this *Response to Comments* document, as well as Sections 3.4.4 and 4.1.1 of the final toxicity assessments for PFOA and PFOS regarding the EPA's rationale for conclusions about the associations between PFOA or PFOS and decreased birth weight. Please see section 4.2.6 of the EPA response in this *Response to Comments* document regarding why the EPA's conclusions may differ from those of other health agencies.

The EPA also disagrees with the commenter's speculation that a decrease in birth weight may be due decreased kidney filtration rates in some women and not associated with exposure to PFOA. As the EPA noted in the EA, recent evidence indicates that relationships between maternal serum PFOA/PFOS and birth weight may be impacted by changes in pregnancy hemodynamics, however exact patterns are not completely understood (Sagiv et al., 2018; Steenland et al., 2018). The EPA acknowledges that this is a possible limitation of the analysis, as described in Section 6.2.2.1.1 of the EA (USEPA, 2024b). While uncertainties remain on the potential impact of pregnancy hemodynamics in later pregnancy due to use of biomonitoring samples from the second and third trimester or post-partum, the evidence for associations between PFOA and PFOS and decreases in birth weight is consistently supported by a large number of *high* and *medium* confidence epidemiology studies and supported by evidence across other measures and fetal growth restriction (see Section 3.4.4.4 of the PFOA and PFOS Toxicity Assessments; USEPA, 2024h; USEPA, 2024i).

Additionally, the EPA disagrees with the commenter's assertion that the EPA attributed all developmental effects to PFOA and PFOS exposure. Please see section 13.4.2 of the EPA response in this *Response to Comments* document.

13.4.3 Quantified RCC Benefits Estimation

Summary of Major Public Comments and EPA Responses

The EPA received comments on the benefits analysis for RCC. Two commenters expressed concerns with the EPA's use of Shearer et al. (2021) to estimate RCC risk in benefits analysis and claimed flaws in the study related to outliers in the RCC group and inconsistent evidence of an association across epidemiological studies. One commenter stated that given what they perceive as SAB concerns and uncertainties in the modeling, further peer review is warranted. The EPA disagrees with the comments critical of the agency's use of information from the Shearer et al. (2021) study for purposes of PFOA health assessment and benefits analysis. As noted in Section 3.5.1 of the Final Toxicity Assessment for PFOA (USEPA, 2024h) and 4.1.4 of this response to public comments document, the EPA determined that Shearer et al. (2021) is a *medium* confidence study after conducting study quality evaluation consistent with the Office of Research and Development (ORD) Staff Handbook for Developing IRIS Assessments (USEPA, 2022c). The commenters failed to acknowledge multiple studies further supporting a positive association between PFOA exposure and RCC risk (Bartell et al., 2021; Vieira et al., 2013; Steenland et al., 2022). Critically, the SAB PFAS Review Panel supported the *Likely to Be Carcinogenic to Humans* designation for PFOA in its final report (USEPA, 2022d). The EPA maintains that Shearer et al (2021) has been sufficiently peer reviewed and represents the best available science for purposes of health and benefits assessment in the PFAS NPDWR. For additional information on the use of Shearer et al (2021) in the PFOA health assessment, see section 4.1.4 of the of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1774, SBC-045682 and Doc. #1774, SBC-045683 in section 4.1.4.3 in this *Response to Comments* document.

Individual Public Comments

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-053379)

3. Benefits assessment for cancer is not supported by the science

EPA quantifies the relationship between PFOA exposure and kidney cancer, specifically renal cell carcinoma (RCC). As discussed previously in these comments, and as noted by EPA, the epidemiological evidence does not support a causal association between PFOA and cancer. This concern is compounded by EPA's approach that quantified the benefits of reduced RCC using the Shearer et al. 2021 study, which the SAB expressed concerns about due to an outlier in the RCC group. As presented in Table 6-52 of EPA's economic analysis, there are significant limitations and uncertainties of the analysis of cancer benefits [FN194: Id. at page 6-121.]. While EPA asked the SAB to review the CVD modeling, the cancer benefits modeling did not undergo any peer review. Considering the shortcomings of the study used, the SAB concerns with the study, and the uncertainties in the modeling, peer review is warranted.

EPA Response: The EPA disagrees with the commenter that the "benefits assessment for cancer is not supported by the science." As discussed in detail in section 4.1.2 of the EPA response in this *Response to Comments* document, the EPA reviewed the best available science on cancer effects that stem from exposure to the PFAS considered in the rulemaking. Please see section 4.1.4 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1774, SBC-045682 and Doc. #1774, SBC-045683 in section 4.1.4.3 in this *Response to Comments* document for discussion on epidemiological evidence supporting associations between PFOA and cancer and section 4.2.2 of the EPA response in this *Response to Comments* document regarding the EPA's derivation of cancer slope factors (CSFs) for PFOA. See also responses to comments in section 4.2.2.4. The EPA disagrees with the commenter's criticism of the use of Shearer et al. (2021) in the analysis of RCC quantified benefits. Shearer et al. (2021) studied the relationship between PFOA and RCC in the U.S. general population and found strong evidence of a positive association between exposure to PFOA and RCC in humans. For more discussion on why consideration of this study is appropriate, see section 13.4.3 of the EPA response in this *Response to Comments* document and Section 6.2.2.1.3 of the EA (USEPA, 2024b). Furthermore, the SAB PFAS Review Panel supported the Likely to be Carcinogenic to Humans designation for PFOA in its final report, and after considering the SAB's input, the EPA concurs. The EPA notes that the Shearer et al. (2021) study is peer reviewed and the EPA's RCC cancer benefits modeling logically utilizes and applies this pre-existing available peer-reviewed science. Further peer review of what is merely an application of existing and available peer-reviewed science is unnecessary and unwarranted. See section 13.4.3 of the EPA response in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-053420)

f. Exposure-Response Relationships Were Improperly Selected

To calculate the health-risk reduction benefits based on serum concentrations, EPA extracts from literature or independently reanalyzes various exposure-response slope factors that are intended to demonstrate a quantitative relationship between a change in serum concentrations and a specific health effect. For both PFOA and PFOS, EPA evaluates the health effects of reductions in birth weight and increases in total cholesterol. EPA also considers increases in renal cell carcinoma risk for PFOA and increases in blood pressure for PFOS. For each endpoint, EPA selects relationships between serum levels and health effects that are not supported by the underlying studies or are based on uncertain reanalysis of data. These flawed analyses add to the misleading conclusions associated with basing the analysis on inappropriate and indistinguishable regulatory alternatives.

The exposure-response slope factor of 0.00178 per ng/mL for PFOA and renal cell carcinoma risk is apparently derived from Shearer et al (2021). This publication and its supporting information, however, do not report this value. Shearer et al (2021) instead reports odds ratios, which are not linear associations. EPA should transparently describe how it generated this exposure-response slope factor. Additionally, as described previously (see Section V.c), this study

is fundamentally flawed and did not show consistent dose-response relationships. Thus, deriving an exposure-response slope factor from a study that did not demonstrate a linear dose-response is not scientifically valid. Notably, EPA does not assess risks of cancer from PFOS exposure as part of the benefits analysis. This omission may indicate that there is not enough evidence to support a quantifiable association between PFOS exposure and cancer, which contradicts EPA's conclusions that PFOS is "likely to be carcinogenic."

EPA's approach to selection of exposure-response slope factors is scientifically flawed, lacks transparency, and disregards the biological relationship of exposure and effects. EPA should consider and discuss the exposure-response slope factors in the context of biologically relevant effects and obtain peer review for any novel analyses. EPA's analysis egregiously misrepresents any meaningful determination of health risk reduction benefits between the proposed MCL and regulatory alternatives.

EPA Response: With regard to the commenter's assertion that Shearer et al. (2021) is flawed, see sections 4.1.4, 4.2.2, and 13.4.3 of the EPA response in this *Response to Comments* document, as well as the EPA's response to comment Doc. #1774, SBC-045682 and Doc. #1774, SBC-045683 in section 4.1.4.3 in this *Response to Comments* document and Doc. #1774, SBC-053147 in section 4.2.2.4 in this *Response to Comments* document. The EPA disagrees with the commenter's assertion that the EPA is not being transparent in its description of the exposure-response factor derived from Shearer et al. (2021). The derivation is clearly described in Section E.1.5 and Section 4.2 of the Final Human Health Toxicity Assessment for PFOA (USEPA, 2024h; USEPA, 2024j) and was available in the draft assessment at the time of rule proposal (USEPA, 2023k). These documents include all the information necessary to replicate the exposure-response factor derivation. The EPA also notes that selection of Shearer et al. (2021) as the basis of a candidate CSF for PFOA was peer-reviewed by the SAB and the agency has subsequently addressed all of the SAB's concerns regarding the use of this study in the final assessment.

The EPA acknowledges that the study used to derive a CSF for RCC in the quantified benefits analysis (Shearer et al., 2021) reports odds ratios, and not CSFs. As is a commonly accepted scientific practice, the EPA uses the odds ratios reported in this study to calculate a CSF value using standard CSF calculation procedures. This entails calculating the variance of each odds ratio based on reported 95 percent confidence intervals, weighting each odds ratio based on the range of the PFOA interval, summing the weighted odds ratio interval, and calculating a central-tendency beta value. This central tendency value is multiplied by the lifetime risk of kidney cancer and the proportion of kidney cancers that are renal cell carcinoma subtypes.

The EPA disagrees with the commenter's assertion that deriving an exposure-response slope factor from a study that did not demonstrate a linear dose-response is not scientifically valid. The approach used by the EPA is supported by the *Guidelines for Carcinogenic Risk assessment* (USEPA, 2005b) and it has been applied to previous peer-reviewed assessments, including the Office of Environmental Health Hazard Assessment California Environmental Protection Agency (OEHHA) public health goals for PFOA and arsenic as well as the EPA's CSF calculations for its

2011 trichloroethylene toxicology assessment (OEHHA, 2021; OEHHA, 2004; USEPA, 2011). The use of a linear model in the observable range of the data is often a good general approach for epidemiological data because such data are frequently too limited (i.e., imprecise), and because of the assumption of linear low-dose extrapolation (USEPA, 2005b).

The EPA notes that details of the derivation of the CSF and associated analysis are extensively presented in Appendix E of the PFOA Toxicity Assessment (USEPA 2024j).

Regarding the evidence supporting associations between PFOS and cancer, please see sections 4.1.4 and 4.1.4.2 of the EPA response in this *Response to Comments* document, as well as Section 3.5.5 of the Final Toxicity Assessment for PFOS (USEPA, 2024b). The EPA disagrees with the commenter's assertion that, because the agency did not evaluate benefits of reduced PFOS exposure on incidence of renal cell carcinoma, there is "not enough evidence to support a quantifiable association between PFOS exposure and cancer, which contradicts EPA's conclusions that PFOS is 'likely to be carcinogenic." While the EPA has determined that PFOS is likely to be carcinogenic, the agency did not find consistent evidence of an association between PFOS exposure and RCC, specifically. In fact, as described in section IV of the preamble and in section 4.1.4 of the EPA response in this *Response to Comments* document, Shearer et al. (2021) and other studies on kidney cancer were not the basis of the agency's cancer classification for PFOS. As clearly stated in the EA, evidence of a positive association between PFOS exposure and kidney cancer was inconclusive (USEPA, 2024b, Section 6.2.2.1.3). The literature describing this association was both limited in scope and number of studies. Associations between PFOS exposure and RCC evaluated in Shearer et al. (2021) were not statistically significant after adjusting for other PFAS.

American Chemistry Council (ACC) (Doc. #1841, SBC-052937)

Using of Shearer et al. as the Basis for Quantifying Cancer Risks of PFOA Resulting Overstates EPA's Benefits Calculation

EPA estimates that reductions in PFOA exposure expected with the implementation of the proposed standard will lead to a reduction in the number of cases of kidney cancer (RCC) and the number of RCC-related deaths. The estimates rely on a CSF derived solely from the data reported by Shearer et al. As noted by the SAB, however, "the epidemiological studies have not consistently identified associations between PFOA and RCC; some epidemiological studies support RCC as a critical finding associated with PFOA exposure while others (with several limitations noted) have failed to detect an association between PFOA and RCC." [FN175: USEPA SAB Review, at 39.] In addition to its general concern about the RCC endpoint, the SAB cautions against EPA's use of the Shearer et al. study as the sole basis for its CSF.

Although the human and animal evidence is suggestive of a carcinogenic effect, it is not sufficient to support the conclusion that PFOA is a likely human carcinogen. In its review, the SAB does not oppose the Agency's conclusion but clearly disagrees with the sole use of the Shearer et al. data. In particular, the Board notes –

Eight of the 13 new epidemiologic studies identified in the EPA's systematic review were considered of "medium" overall confidence and the others were considered "low" confidence, whereas the NTP 2020 chronic bioassay in rats is considered a "high" confidence study. However, a CSF was derived for only one of the new medium confidence epidemiologic studies (Shearer et al., 2021), and it is not clear whether any of the other newly identified medium confidence studies support CSF development. The Panel agrees that toxicity values should only be derived from studies with at least "medium" confidence, but the draft document needs to be more transparent as to weighing the strengths and limitations of different studies to support a CSF (including both human and animal studies). [FN176: Ibid, at 40.]

In light of the uncertainty around the RCC results in the epidemiology studies, it is advisable to use the animal bioassay data (i.e., Butenhoff et al., NTP) [FN177: Butenhoff et al. 2012; NTP PFOA Bioassay Technical Report.] as the basis for the CSF. Based on the animal data, the Agency calculates a CSF range of 8.42 to 53.2 per mg/kg/day [FN178: USEPA PFOA MCLG Assessment 2023, at 4-46.] – compared to the value of 0.0293 per nanograms/kg-day for Shearer et al. This 500-fold difference in cancer potency estimates suggests the need for careful consideration prior to using epidemiology as a basis of the CSF. Rather than address the Board's concerns, EPA offers an equivocal evidence supporting possible modes of action for kidney tumors and cites a staff handbook indicating that human data "are generally preferred" for deriving toxicity values. [FN179: Ibid, at 4-59.]

EPA Response: Regarding the commenter's concerns with the EPA's use of Shearer et al. (2021) as the basis of the CSF, see sections 4.1.4, 4.2.2, and 13.4.3 of the EPA response in this *Response to Comments* document, as well as the EPA response to comment Doc. #1774, SBC-045682 and Doc. #1774, SBC-045683 in section 4.1.4.3 in this *Response to Comments* document and SBC-053147 in section 4.2.2.4 in this *Response to Comments* document. The EPA has subsequently addressed all of the SAB's concerns regarding the use of this study, as well as the supporting evidence for associations between PFOA and kidney cancer, and presents rationale for these selections in the Final Toxicity Assessment for PFOA (see Sections 3.5.5 and 4.2) (USEPA, 2024h).

The EPA disagrees with the commenter's assertion that the EPA should consider using animal studies as the basis for the CSF used in the quantified RCC benefits analysis. The EPA disagrees with the commenter's assertion that there is unacceptable uncertainty around RCC results in epidemiology studies; furthermore, the SAB agreed with the EPA's preferential use of epidemiological data for quantitative analyses and stated, "In general, the Panel agrees that it is preferable to base the CSF derivation on human epidemiological data when appropriate human data are available" (USEPA, 2022d). The EPA concluded that appropriate human data are available to quantitatively describe associations between PFOA and kidney cancer. As with data underlying noncancer RfDs, the use of human data eliminates the uncertainties associated with interspecies extrapolation and the toxicokinetic differences between species which are major uncertainties associated with the PFOA animal toxicological studies due to the half-life differences and sex-specific toxicokinetic differences in rodent species. The use of human data

also ensures that the values are based on human-relevant exposure conditions and human-relevant tumor types/sites.

The EPA's *Guidelines for Preparing Economic Analyses* (Chapter 7, USEPA, 2016a) indicates that risk assessors and economists should identify human health endpoints that are economically meaningful and linked to human well-being. The EPA's analysis of RCC benefits relies on the best available science supporting the association of PFOA and RCC in humans. As demonstrated by the estimated numbers of fatal and nonfatal cases avoided under the rule, this endpoint is economically significant.

Susan Goldhaber (Doc. #1596, SBC-053415)

May 26, 2023

Michael S. Regan, Administrator Environmental Protection Agency

1200 Pennsylvania Ave., N.W. Washington, D.C. 20460

Re: Docket ID No. EPA-HQ-OW-2022-0114, Comment on Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

Dear Administrator Regan,

As a toxicologist formerly employed at EPA, Office of Drinking Water, (1980-1988), who worked on revising the primary drinking water regulations, I am very familiar with the requirements of the Safe Drinking Water Act and the regulatory process. I am writing because I am very concerned with the underlying science supporting these regulations. I would like to submit the attached comments for your consideration.

Sincerely, Susan B. Goldhaber M.P.H.

SBG Consulting, Inc.

Comments

There are Executive Orders that strongly encourage that the benefits of a major regulation, such as PFAS Drinking Water regulation, exceed the costs. In the Economic Analysis, EPA calculated the economic benefits to the U.S. by avoiding three health outcomes that it attributed to exposure from PFOA and PFOS:

• Developmental effects (reductions in birth weight)

• Cardiovascular effects (increase in total and high-density lipoprotein (HDL) cholesterol resulting in cardiovascular disease including strokes and myocardial infarction)

• Kidney cancer

Human studies have not shown that PFOA or PFOS cause these health effects.

The available epidemiological studies suggest associations between PFOA/PFOS exposures and developmental and cardiovascular effects; however, cause-and-effect relationships have not been established for these outcomes. https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf

When EPA calculates the economic benefits from avoiding these three health outcomes, they assume that these diseases are solely caused by PFAS exposure. EPA assumes that that the only reason that babies are born with lower-than-average birth weight is due to their mother's exposure to PFAS or that all cardiovascular disease is caused by PFAS exposure, ignoring the myriad of risk factors involved in these diseases. This is a major flaw, both economically and scientifically.

1. What is the basis for EPA's conclusions that PFOA or PFAS cause these adverse health effects when ATSDR and others have stated that cause-and-effect relationships have not been established?

Examining the three health outcomes:

Kidney Cancer

There are studies examining the association between PFOA and PFOS and many different types of cancer, including prostate, testicular, breast, bladder, kidney, colon, and liver. Studies of workers in PFOA/PFOS manufacturing facilities have not reported an increase in all cancer deaths and there is very limited data for an association with the other types of cancer. https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf

According to EPA's Economic Analysis, "Data on the association between PFOA exposure and kidney cancer are limited but suggest a positive association between exposure and increased risk of kidney cancer."

There are three epidemiologic studies that have shown an association between PFOA and an increased risk of kidney cancer, and three studies that did not report an association. EPA based its benefits assessment on the results from a case-control study https://pubmed.ncbi.nlm.nih.gov/32944748/ that showed a positive association between PFOA exposure and kidney cancer in 324 cases and 324 matched controls.

There are several problems with this study: The samples were collected at a single point in time and are not representative of long-term exposure; the cases were more likely than controls to report being obese and to have a higher history of hypertension; and a higher proportion of cases had diminished kidney function compared with controls (but this difference was not statistically significant).

EPA calculated an exposure-response relationship based on this study and used kidney cancer statistics to calculate $217 million to $310 million in economic benefits from number of deaths avoided from this regulation.

4. What is EPA's justification for using a "suggestive" positive association between PFOS and PFOA exposure and kidney cancer to conclude that PFOS and PFOA cause kidney cancer? Why

did EPA use a flawed case-control study to calculate the economic benefits from avoiding kidney cancer and not factor in other risk factors in developing kidney factors in its analysis?

EPA Response: Regarding the commenter's concerns with the EPA's use of Shearer et al. (2021) as the basis for the CSF, see sections 4.1.4, 4.2.2, and 13.4.3 of the EPA response in this *Response to Comments* document, as well as the EPA response to comment Doc. #1774, SBC-045682 and Doc. #1774, SBC-045683 in section 4.1.4.3 in this *Response to Comments* document and Doc. #1774, SBC-053147 in section 4.2.2.4 in this *Response to Comments* document. The Final Toxicity Assessments for PFOA and PFOS present discussion on the weight of evidence for carcinogenicity of these two chemicals, as well as rationale for the EPA's cancer classifications in Section 3.5 (USEPA, 2024h; USEPA, 2024i). The commenter incorrectly states that the EPA concluded that PFOS causes kidney cancer. In fact, as described in section IV of the preamble and in section 4.1.4 of the EPA response in this *Response to Comments* document, Shearer et al. (2021) and other studies on kidney cancer were not the basis of the agency's cancer classification for PFOS.

Regarding the commenter's concern that a cause-and-effect relationship between exposure and outcomes has not been established, the EPA notes that an extensive body of epidemiological studies have shown that increased exposure to PFOA and PFOS is associated with higher risk of the health outcomes considered in the quantified benefits analyses. While research has not established a causal link between exposure to PFOA and PFOS and these outcomes, there is strong evidence of associations between exposure and adverse effects. Demonstrated causality is not necessary to quantify or value benefits, nor to meet the statutory standard of a factual record to conclude that these benefits are likely to occur as a result of treatment to comply with the MCLs, particularly when strong evidence of associations are found. See the EPA response to comment Doc. #1738, SBC-047706 in section 13.4 in this *Response to Comments* document for further discussion. The EPA disagrees with the commenter's assertion that the EPA should consider risk factors other than changes in PFAS exposure resulting from the final rule. Because the study that the EPA relied on for the relationship between PFOA exposure and RCC risk (Shearer et al., 2021) controlled for body mass index, smoking status, history of hypertension, prior sampling freeze-thaw cycles, and calendar year of blood draw, the results of the study provide odds ratios between PFAS exposure and RCC risk only.

The EPA analyzes changes in blood serum PFAS levels as a result of changes in PFAS drinking water concentrations due to the installation of treatment technology. The EPA disagrees with the commenter's assertion that the diseases quantified are assumed to be solely associated from PFAS exposure. The EPA does not make this claim in any of the documentation supporting the rulemaking. The RCC benefits estimates are quantified based on changes in blood serum PFOA levels only and do not reflect changes associated with reduced exposures from other PFAS sources or changes associated with other risk factors. Because of this modeling approach, the EPA does not account for RCC risk factors other than changes in PFAS resulting from this final drinking water rule. The EPA implements in the benefits analysis a maximum population attributable fraction (PAF) limit on total health outcome rates that are likely to result from PFAS exposure. See Section 6.1.2 Uncertainty Characterization in the final rule EA (USEPA, 2024b)

for discussion of the PAF limits. Regarding the commenter's concern with the EPA's use of Shearer et al. (2021) for estimating quantified RCC benefits, see section 13.4.3 of the EPA response in this *Response to Comments* document. Regarding the commenter's concern with the EPA's analysis of birth weight effects in infants due mother's exposure to PFAS, see section 13.4.2 of the EPA response in this *Response to Comments* document.

13.4.4 Valuation

Summary of Major Public Comments and EPA Responses

The EPA received multiple comments discussing the methods used to monetize expected health benefits under the final rule. The EPA followed the EPA's Guidelines for Preparing Economic Analyses and relied on two of the three primary methods, "cost of illness" and "willingness-to-pay," included in the Guidelines and most often used to value morbidity in an environmental context (Analyzing Benefits (Chapter 7); USEPA, 2016a). One commenter stated that COI metrics do not meet the requirements set out by Circular A-4 and other best practices to use consumers' willingness-to-pay (WTP) metrics. The EPA agrees that WTP estimates are conceptually appropriate when estimating benefits because they attempt to capture pain and suffering and other quality-of-life effects in addition to the medical expenditures and opportunity costs caused by adverse health effects. Applicable WTP data, however, are not always available. Circular A-4 clearly states that agencies "should utilize valuation methods that are appropriate for regulatory circumstances" and if WTP data are not available to support monetization the agencies may consider alternative approaches. Although use of COI estimates understates benefits of avoiding adverse health effects, the EPA disagrees that these estimates are misleading. The agency carefully described limitations and the expected magnitude and directional impact uncertainty sources have on the quantified benefits in the EA (see Chapter 7 of USEPA, 2024b).

One commenter noted that using WTP monetization methods is appropriate in some cases when estimating rule benefits. The EPA agrees that, when applicable WTP data are available, these metrics can be used for evaluating benefits. In the EA for the final rule, based on this and other comments, the EPA performed a sensitivity analysis that relied on WTP-based monetization metrics to estimate RCC and bladder cancer benefits. While RCC benefits calculated using WTP-based approaches were, on average, similar to the magnitude of benefits estimated using COI approaches, bladder cancer benefits increased by approximately 20 percent when using WTP-based approaches (see Chapter 6 of USEPA, 2024b and Appendix O of USEPA, 2024c for detailed information). The EPA believes these additional valuation analyses using a second, independent valuation method further support that there are substantial quantified benefits that will result from implementation of this final regulation. This further supports the Administrator's determination that the quantified and nonquantifiable benefits of the rule justify the quantifiable and nonquantifiable costs. One commenter recommended using WTP-based monetization approaches for valuing changes in low birth weight cases. The EPA notes that the analysis implemented in the final rule requires WTP or cost metrics per incremental change in birth weight estimated under the final rule and regulatory options. Such WTP metrics are not available in the economic literature. Therefore, the EPA relied on incremental COI changes per change in

grams of birth weight provided by the EPA's National Center for Environmental Economics (Klein and Lynch, 2018).

One commenter criticized the EPA's use of COI estimates that did not include broader opportunity costs (e.g., opportunity cost of time such as the number of workdays missed) related to low birth weight, cardiovascular disease, and renal cancer risks. They note this "likely results in a significant underestimate of the benefits." The EPA relied on the best available economic information to monetize changes in risks of these endpoints and notes that COI metrics typically only account for avoided medical expenditures. The EPA agrees with the commenter that additional costs (such as opportunity costs) are not captured in the COI estimates used for benefits valuation and that benefits relying on COI information for valuation are likely underestimated as a result.

Individual Public Comments

Earthjustice et al. (Doc. #1808, SBC-046137)

17. Is it possible to incorporate broader opportunity costs into the cost-of-illness (COI) estimates for reduced risks of low birth weight, cardiovascular disease, and renal cancer?

The Agency correctly includes avoided direct expenditures for medical care, as well as broader opportunity costs – namely the opportunity cost of time (e.g., missed work days) – in the COI estimates for reduced risks of bladder cancer. But these broader opportunity costs are not accounted for in the COI estimates for reduced risks of low birthweight, cardiovascular disease, and renal cancer. The COI estimates for these three non-fatal health outcomes only account for avoided medical expenditures. EPA recognizes this shortcoming in various parts of Chapter 6, and points out that these exclusions are due to the lack of available estimates in the literature.

Nonetheless, this omission likely results in a significant underestimate of the benefits. For example, Table 6-43 shows that for bladder cancer (the one non-fatal health outcome where broader opportunity cost estimates are included), the opportunity cost of time beyond medical expenditures makes up 27% to 32% of the total COI estimates for the first year. If a similar proportional scaling is applicable to the other non-fatal health outcomes, then the missing portion of the COI-based benefits for non-fatal cardiovascular disease, renal cancer, and low birthweight cases would be substantial. In the final rule EA, the Agency should consider whether it is possible to incorporate these broader opportunity costs into their COI estimates for these three non-fatal health outcomes.

Even if the inclusion of the broader opportunity costs into these COI estimates is legitimately not possible given the available literature, EPA should still consider a bounding exercise where the available COI estimates for low birth weight, cardiovascular disease, and renal cancer are scaled-up based on the COI estimates for bladder cancer, or perhaps for more similar non-fatal health endpoints where the available literature does provide more comprehensive COI estimates. Such a bounding exercise would require considerable judgement, but at the same time, we know that

assuming the opportunity cost of time associated with these adverse health outcomes is zero (as the EPA currently does) is not correct.

18. Did EPA consider using willingness to pay (WTP) estimates to monetize reductions in non-fatal human health outcomes?

The use of COI estimates to monetize the benefits of reduced risks of non-fatal health outcomes, as EPA does, is standard (EPA 2014), and in my professional experience is generally deemed acceptable for policy analysis. Nonetheless, a theoretically more appropriate approach (when available) is to use estimates of WTP (OMB 2003). For example, WTP estimates better account for "pain and suffering and other quality-of-life effects" (OMB 2023, pg. 48). It is unclear whether such estimates are available in the peer-reviewed literature, but EPA should include a review of the literature and discussion of why available WTP estimates are or are not appropriate to use in the EA.

I would also like to point out that the Organisation for Economic Co-operation and Development (OECD) has implemented stated preference studies that estimate the public's WTP for reductions in the risks of various non-fatal health outcomes that result from reduced exposure to toxic chemicals (OECD, n.d.). Their research includes reductions in the risks of adult asthma, chronic kidney disease, fertility loss, and of particular relevance to the current EA, cases of low birth weight. It is unclear whether the results of the OECD's studies are yet available, but if they are available now or by the time of the final rule EA is being conducted, then the Agency should consider using such estimates (when applicable) in lieu of the current COI estimates.

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Exhibit 1: Curriculum Vitae

[Exhibit 1: see docket ID EPA-HQ-OW-2022-0114-1808]

[Attachment 1: see docket ID EPA-HQ-OW-2022-0114-1847]

[Attachment 2: see docket ID EPA-HQ-OW-2022-0114-1847]

[Attachment 3: see docket ID EPA-HQ-OW-2022-0114-1847]

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[Attachment 1: see docket ID EPA-HQ-OW-2022-0114-1849]

[Attachment 2: see docket ID EPA-HQ-OW-2022-0114-1849]

[Attachment 3: see docket ID EPA-HQ-OW-2022-0114-1849]

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[Attachment 19: see docket ID EPA-HQ-OW-2022-0114-1849]

[Attachment 20: see docket ID EPA-HQ-OW-2022-0114-1849]

[Attachment 1: see docket ID EPA-HQ-OW-2022-0114-1850]

[Attachment 2: see docket ID EPA-HQ-OW-2022-0114-1850]

[Attachment 3: see docket ID EPA-HQ-OW-2022-0114-1850]

EPA Response: Regarding the commenter's assertion that opportunity costs should be included in the final rule quantified benefits analysis, see section 13.4.4 of the EPA response in this *Response to Comments* document. The opportunity costs are typically estimated based on lost productivity costs. The lost productivity costs are a function of duration and severity of the primary health effects, potential side effects associated with treating the primary condition, as well as mental health impacts stemming from the disease. Therefore, the opportunity costs could differ significantly between fatal and non-fatal health outcomes, outcomes that require surgical versus non-surgical intervention or more frequent in-patient procedures. Thus, the EPA disagrees with the commenter that a similar proportion of opportunity costs for bladder cancer or other similar non-fatal health endpoints could be generalized to other health outcomes as the proportion of total costs that may be attributed to opportunity costs likely varies considerably.

The commenter noted ongoing OECD Surveys of willingness-to-pay to avoid negative chemicals-related health effects efforts to establish internationally comparable values for WTP to avoid adverse health effects due to chemical exposure for use in policy evaluation. The first round of surveys was implemented in 2022 and included a survey focusing on valuation of Very Low Birth Weight (VLBW). The OECD working paper by Scasny et al. (2023) reports the estimated value per case of VLBW in the U.S. of 1.389 million ($2022) and notes that this value may implicitly include infant mortality. The EPA disagrees with the commenter that

this value can be readily used in place of the COI-based birth weight valuation employed in the final rule EA. The EPA's benefits analysis modeled the impact of PFAS reductions on the entire distribution of birth weights rather than VLBW, which occurs in 1.38 percent of all births (CDC, 2023), and addressed infant birth weight-related mortality over the entire range of the birth weight distribution.

Earthjustice et al. (Doc. #1808, SBC-046113)

Fourth, as noted above, EPA should account for opportunity costs, in addition to avoided medical expenditures, in its final cost-of-illness estimates for non-fatal health effects associated with PFAS exposure. [FN138: Guignet 2023 at 11–12.] As Dr. Guignet explains, "assuming the opportunity cost of time associated with these adverse health outcomes is zero (as the EPA currently does) is not correct" and likely yields a substantial underestimate of the COI-based benefits for reducing non-fatal adverse health effects. [FN139: Id.] While recognizing limitations in the relevant literature, Dr. Guignet has identified multiple approaches for EPA to account for these benefits in the final EA.

EPA Response: Regarding the commenter's assertion that the EPA should account for opportunity costs in its estimates of non-fatal health effects, see section 13.4.4 of the EPA response in this *Response to Comments* document. While the EPA relied on the best available literature to select COI metrics for use in the quantified benefits analysis, the EPA agrees that these metrics have potential limitations. See Section 6.8 of the final EA for a discussion of valuation-based limitations of the final rule analysis.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046011)

Dollar Year

EPA uses 2020 prices as the data source for its projection of costs to 2026. Producer prices have shot up since 2021 due to supply shortages, disruption of trade due to the global pandemic, and financial assistance provide to individuals, businesses, and the economy during the pandemic. EPA chose as the baseline year for its analysis a year that is not representative of current conditions and the likely near-term future when most of the rule's expenditures will be made. Inflation appears to be likely to persist in the near-term. Moreover, the economic policies underway to reduce inflation – raising federal interest rates and reducing the money supply – are increasing the cost of capital, a major input factor into this proposal's costs. By selecting a baseline year for the analysis that had low interest rates and prices and that is not representative of the near-term's economic conditions, EPA is artificially lowering expected compliance costs.

Valuation

EPA uses Value of Statistical Life (VSL) estimates to estimate the economic value of avoided premature deaths [FN47: U.S. Environmental Protection Agency, "Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation," 2–

4.]. EPA approximates VSL growth using a compound annual growth rate of projected values to obtain a VSL suitable for valuation of mortality risk reductions during the period of analysis (2023-2104). As a base value, EPA used a VSL estimate of $4.8 million ($1990, 1990 income year), which is the central tendency of the VSL distribution recommended for EPA's regulatory impact analyses. In the EA, this estimate is adjusted for inflation and income growth. Estimates used in the EA range from $10.7 million in 2023 to $17.7 million in 2104.

As discussed above, EPA did not model the uncertainty in its VSL estimate. More fundamentally, EPA did not include the effect of income growth on other opportunity costs in the rule. If consumers' willingness to pay to avoid mortality risk increases with income, then it is reasonable to assume that consumers' willingness to pay to avoid other economic displacements and adverse effects also increases with income. By including income growth in the valuation of benefits but not costs, EPA biases the results.

EPA used the cost of illness (COI) valuation approach to estimate the economic value of avoided morbidity (non-fatal heart attacks and ischemic strokes, birth weight decrements, and cancers). The COI-based values used in the EA reflect medical care expenditures and opportunity costs associated with condition management and treatment. COI metrics do not meet the requirements set out by Circular A-4 and other best practices to use consumers' willingness-to-pay (WTP) metrics [FN48: U.S. Office of Management and Budget, "Circular A-4: Regulatory Analysis," September 2003.].

In conclusion, EPA's EA for the proposed rule departs from analysis required by Circular A-4. As a result, the EA portrays misleading estimates of the social benefits and the social costs and fails to describe the uncertainty in these estimates.

EPA Response: See the EPA response to comment Doc. #1738, SBC-046007 in section 13.9 in this *Response to Comments* document for the EPA's response to points raised on Value of Statistical Life (VSL) uncertainty. With respect to the commenter's assertion that the agency's analysis artificially lowers expected compliance costs due to the baseline year selected for the analysis not being representative of near-term economic conditions, the EPA notes that the analysis utilized the most recent available price index for both the proposal and final rule. For the proposed rule, the most recently available price index data were from the 2020 dollar-year. The final rule analysis has been updated using a 2022 dollar-year, which are the most up to date data (see sections 13.3.3 and 13.3.4 of the EPA response in this *Response to Comments* document; see the EPA response to comments Doc. #1585, SBC-042777 and Doc. #1623, SBC-052828 in section 13.3.3 in this *Response to Comments* document). Regarding the commenter's notes that the EPA relied on COI instead of WTP metrics, see section 13.4.4 of the EPA response in this *Response to Comments* document. The EPA notes that the EPA's *Guidelines for Preparing Economic Analyses* (Analyzing Benefits (Chapter 7); USEPA, 2016a) include COI as one of the three primary methods most often used to value morbidity in an environmental context.

13.4.5 Other Topics

The EPA received comments on other EA benefit-related topics including the presentation of benefits and costs and the EPA's analysis for Hazard Index PFAS. One commenter raised that the EPA did not provide data to support the analysis of Hazard Index benefits. The commenter compared quantified benefits for the proposed option (PFOA and PFOS MCLs of 4.0 ppt and Hazard Index of 1.0) and Option 1a (PFOA and PFOS MCLs of 4.0 ppt) and incorrectly stated that the EPA claimed benefits for Hazard Index PFAS, specifically PFHxS, PFNA, HFPO-DA, PFBS, without providing health effect potency factors. The EPA clarifies that in the proposed option and for the final rule (PFOA and PFOS MCLs of 4.0 ppt each, PFHxS, PFNA, HFPO-DA, of 10 ppt each and Hazard Index of 1), the quantified benefits represent avoided CVD, BW, RCC, and BC morbidity and mortality from PFOA and PFOS exposure reductions and the quantified costs represent the treatment costs associated with PFOA, PFOS, and PFHxS removal. For Option 1a, quantified benefits represent the same avoided morbidity and mortality health endpoints as the proposed option (and also the final rule), however, only PFOA and PFOS treatment costs are reflected. The additional quantified benefits estimated under the proposed option and also for the final rule (relative to the quantified benefits estimated under Option 1a) are a result of PFOA and PFOS co-removal from PFHxS treatment. Inclusion of the Hazard Index and individual MCLs for PFHxS, PFNA and HFPO-DA will trigger more systems to treat (as shown in Section 4.4.4 of the EA) and provides enhanced public health protection by ensuring reductions of these additional compounds when present above the Hazard Index of 1 or individual MCLs for PFHxS, PFNA and HFPO-DA. The EPA further clarifies that the EPA performed a qualitative benefits analysis for Hazard Index PFAS, consistent with recommendations in the EPA's *Guidelines for Preparing Economic Analyses* to discuss qualitative benefits when quantitative analysis is not possible (Analyzing Benefits (Chapter 7); USEPA, 2016a). Due to data limitations, the EPA was unable to quantify many categories of benefits from avoided adverse effects associated with Hazard Index PFAS; however, PFNA birth weight effects were quantified in a sensitivity analysis and are described in USEPA (2024c). For the final rule, after considering public comment, the EPA completed a sensitivity analysis of costs associated with the Hazard Index MCL and individual MCLs for PFHxS, PFNA and HFPO-DA (see Appendix N of USEPA, 2024c for the presentation of methods and results).

One commenter referenced OMB Circular A-4 to describe that the EPA is required to present undiscounted benefits and costs within the HRRCA. For the final rule, after considering this comment, the EPA generated the undiscounted stream of quantified benefits and costs (see appendix P of USEPA, 2024c). Undiscounted results are now provided for all impacted water systems for all years of the analysis period.

<u>American Chemistry Council (ACC) (Doc. #1841, SBC-044844)</u>

The Economic Analysis Overestimates Quantifiable Benefits of the Proposal

EPA's estimate of the benefits of its proposal relies on the quantification of predicted reductions in the incidence of kidney cancer (despite SAB warnings not to use the cited key study as a basis, as summarized below), cardiovascular disease, and reduced infant body weight associated with reduction of PFOA and PFOS in drinking water. The Agency's estimate also includes a predicted reduction in bladder cancer incidence associated with a reduction of disinfection byproducts (DBPs) – namely trihalomethanes or THMs associated with the implementation of treatment technologies to comply with the proposed MCLs. The Agency also identifies several other health effects that it concludes are nonquantifiable, because of a lack of clear supporting evidence, to support its benefits conclusion. Although the benefits summary includes estimates associated with the proposed HI MCL, the Agency has not provided any details for how those estimates were developed.

The Agency's analysis runs counter to the recommendations of the SAB and/or to the weight of evidence for the endpoints selected for quantification. Moreover, the decision to include predicted benefits from the reduction of DBPs is overly speculative and appears to ignore a robust regulatory process underway with the Water Office. EPA has provided little, if any, information on the benefits expected with the implementation of the HI MCL.

EPA Response: The EPA disagrees with the commenter that the EA overestimates quantifiable benefits of the proposal. For the EPA's response to this comment, see section 13.4 in this *Response to Comments* document. For comments raised related to cardiovascular disease, birth weight, and kidney cancer, see sections 13.4.1, 13.4.2, and 13.4.3, respectively, of the EPA response in this *Response to Comments* document.

The EPA disagrees with the commenter that the EPA's predicted reductions in the incidence of kidney cancer relies on a study that SAB warned not to use as a basis. SAB cautioned the EPA against using the relationship between *PFOS* and kidney cancer from Shearer et al. (2021) because the findings on this relationship were less definitive than the findings between *PFOA* and kidney cancer from Shearer et al. (2021) (USEPA, 2022d). As described in Section 6.5 of the EA (USEPA, 2024b), the EPA considered only the relationship between PFOA exposure and kidney cancer in its benefits analysis. Regarding the EPA's confidence in associations between PFOA exposure and increased risk of RCC as reported by Shearer et al. (2021) and the kidney cancer evidence base in general, please see section 4.1.4 and 4.2.2.4 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1774, SBC-045682 and Doc. #1774, SBC-045683 in section 4.1.4.3 in this *Response to Comments* document and Doc. #1774, SBC-053147 in section 4.2.2.4 in this *Response to Comments* document.

The EPA disagrees with the commenter's assertion that "[t]he Agency's analysis runs counter to the recommendations of the SAB and/or to the weight of evidence for the endpoints selected for quantification." For the EPA's response to comments regarding the SAB's recommendations on weight of evidence for adverse health effects, see section 4.1.3 in this *Response to Comments* document.

The EPA disagrees with the commenter's statement that "although the benefits summary includes estimates associated with the proposed Hazard Index MCL, the agency has not provided any details for how those estimates were developed." The commenter is incorrect when stating the EPA did not provide information on the benefits expected with implementation of the Hazard Index MCL and that the agency lacks clear supporting evidence to "support its benefits conclusion." The EPA discusses the benefits of PFHxS, PFNA, HFPO-DA and PFBS removal qualitatively and the agency discusses the benefits of PFNA removal in Appendix K of the EA (USEPA, 2024c). Due to data limitations, quantitative national benefits estimates presented in the summary tables of the EA do not include quantified benefits solely associated with removing these regulated PFAS. However, SDWA does not require that all benefits be quantified but rather expressly requires consideration of nonquantifiable benefits. Furthermore, the EPA notes that benefit estimates are increased under the final rule as compared to Option 1a because more systems must apply treatment in order to comply with the Hazard Index. This results in co-removal of PFOA and PFOS, increasing quantified national benefits. Hazard Index benefits are discussed extensively in Chapter 6 of the EA, and they include anticipated reductions of developmental, cardiovascular, immune, hepatic, endocrine, metabolic, reproductive, musculoskeletal, and carcinogenic effects from reduced exposure to PFHxS, HFPO-DA, PFNA, and PFBS; see section 13.4 of the EPA response in this *Response to Comments* document and Chapter 6.2.4 of the EA for additional information on the nonquantifiable impacts of PFHxS, HFPO-DA, PFNA, and PFBS and non-regulated co-occurring PFAS. The EPA disagrees that the benefits from the reduction of DBPs are speculative. Please see section 13.7 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1774, SBC-045705 in section 13.7 in this *Response to Comments* document for further discussion. The commenter is also incorrect that the DBP analysis ignores the robust regulatory process underway at the EPA where the agency is considering updating some of its microbial and DBP regulations. While a separate regulatory process is underway, the DBP reduction benefits from total organic carbon (TOC) co-removal are solely attributable to this PFAS NDPWR. In other words, the DBP co-removal benefits estimated for the final rule will be realized, irrespective of whether the EPA proceeds with proposing and finalizing a separate regulatory action that to update some of the agency's existing microbial and DBP regulations. Furthermore, the benefits of each respective action will not be the same as the rule conditions will differ. The EPA has closely reviewed this DBP co-removal analysis to ensure there is a conservative estimate of benefits; any benefits considered are only those that will be delivered in addition to those already realized under the agency's existing DBP drinking water rules. See section 13.7 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1841, SBC-044845 in section 13.7 in this *Response to Comments* document for further DBP co-removal discussion. Additionally, the other regulatory process referenced by the commenter has not reached the proposal stage. Should that rule be proposed at some point in the future, the EPA will closely evaluate the impacts of the rule to ensure no double counting of benefits, if applicable. Finally, the EPA notes that the same organizational unit within the agency is responsible for both the PFAS and microbial and DBP activities. Hence, organizationally and institutionally, these regulatory efforts will be fully integrated.

American Chemistry Council (ACC) (Doc. #1841, SBC-044847)

Key Information Has Not Been Made Public

According to the Office of Management and Budget's (OMB) Circular A-4, [FN195: Circular A-4 issued on September 17, 2003 provides OMB guidance to Federal agencies on the development of regulatory analysis under Section 6(a)(3)(C) of Executive Order 12866 of September 1993, as amended, the Regulatory Right to Know Act (31 USC 1105 note) and a variety of related authorities. (OMB Circular A-4)] an agency "should include separate schedules of the monetized benefits and costs that show the type and timing of benefits and costs, and express the estimates in this table in constant, undiscounted dollars." Transparency requires that this be done, not just in the aggregate, but for each of the 36 types of model public water systems (PWS) that serve as the foundation for the Agency's analysis.

A search of the rulemaking docket fails to unearth this information. The stream of undiscounted annual benefits and annual costs across PWS model types has not been made available. In addition, the Agency has not provided the variability of benefits and net benefits across PWS model types, which is odd in that the Agency has provided the variability of costs across PWS model types. The missing information, if provided, would allow a reader to identify important regulatory alternatives that could provide more net benefits than those considered in EPA's economic analysis. For example, if EPA estimates negative net benefits for certain types of water systems, it suggests that consideration of a regulatory alternative with higher or positive net benefits than that proposed. This would be true if benefits or net benefits vary widely across public water systems.

EPA Response: As described in section 13.4.5 of the EPA response in this *Response to Comments* document, the EPA has provided the undiscounted stream of benefits and costs for each year of the period of analysis in the HRRCA for the final rule. The EPA notes that SDWA requires the EPA to consider nonquantifiable benefits. Although the undiscounted results are helpful in understanding how quantified benefits and costs are distributed over the period of analysis, considering only the undiscounted results solely to determine net benefits as the commenter suggests would not be compliant with the SDWA because there are many nonquantifiable benefits and costs that are not reflected in the undiscounted results that the EPA considered in determining the total benefits and costs of the action. Additionally, the EPA disagrees with the commenter's recommendation to generate undiscounted results for each PWS strata included in the SafeWater MCBC model; see section 13.2 of the EPA response in this *Response to Comments* document. First, nowhere in executive order 12866 or OMB's Circular A-4 guidance does it state an agency should explicitly list this information at this level of resolution. As a statistical model, the SafeWater MCBC model requires a significant level of computational power. Generating results at the PWS strata resolution is computationally intensive and the length of the tables generated would not be useful to an understanding of the costs and benefits of this action. The EPA has instead focused on generating information that provides the best information at an appropriate scale to inform the agency's decision making; this would not include generating the undiscounted stream of results across 36 different PWS types

as the commenter requests since such information neither helps the agency makes decisions nor helps commenters understand the costs and benefits of the rule. The SafeWater MCBC model instead appropriately focuses on the national level annualized costs and benefits of the rule. In short, generating results at that resolution are not specified under the OMB's Circular A-4 guidance and would have limited utility in determining net benefits due to the nonquantifiable benefits and costs not reflected. The economic analysis for the final PFAS NPDWR is compliant with the SDWA HRRCA requirements, and the suite of information presented in the EA is comprehensive in enabling decisionmakers and the public to understand the estimated impacts of the rulemaking.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043096)

Finally, the benefits analysis includes several assumptions that are not clearly and consistently discussed by the Agency.

EPA Response: The EPA disagrees with the commenter's statement that assumptions are not clearly or consistently discussed in the EA. The EPA has clearly discussed all assumptions and the expected impacts of those assumptions on estimated benefit and costs in the EA. Specifically, please see Section 6.8 in the EA for potential effects of various assumptions on the estimated benefits of the proposed MCLs (i.e., overestimated, underestimated, uncertain) and a summary of limitations inherent in the analysis of benefits (USEPA, 2024b).

American Chemistry Council (ACC) (Doc. #1841, SBC-044846)

EPA Does Not Provide Evidence to Support the Benefits Attributed to the HI MCL

A comparison of the analysis for the Preferred Option to those for Option 1A shows that EPA attributes a small portion of the annual quantifiable benefits of its proposal to implementation of the HI MCL: $2.6 million for birth weight, $8.4 million for CVD, $5 million for RCC, and $820,000 for bladder cancer. [FN192: Estimates are based on the Expected Value at a 3-percent discount rate. (See USEPA Economic Analysis, pages 6-48, 6-68,6-77, and 6-106.) The estimates are slightly less at a 7-percent discount rate.] EPA has not provided potency factors for any of these health effects for the four PFAS included in the HI MCL. The Agency's overview of human and animal evidence, moreover, notes that there is no evidence (or no data) to support an association between any of the four substances and RCC or CVD or between PFBS and birth weight. [FN193: USEPA Economic Analysis, at 6-11, 6-12, 6-14. The overview indicates epidemiology data for PFNA and animal data for HFPO-DA indicating a report of reduced birth weight.]

Had EPA quantified the potential health risks associated with these four substances, moreover, it is still not possible to estimate the benefits of the HI MCL without data on their occurrence in the nation's drinking water. EPA has acknowledged that it does not have nation-wide data on the occurrence of HFPO-DA and that the small number of detections for PFNA and PFBS in the UCMR 3 survey do not provide a sufficient basis for estimating occurrence through modeling.

[FN194: Cadwallader et al. 2021.] While PFHxS was included in the Agency's occurrence modeling, the results suffer from the same shortcomings as those for PFOA and PFOS.

EPA Response: The EPA disagrees with the commenter's suggestion that the EPA does not provide evidence to support benefits attributed to the Hazard Index MCL. See section 13.4 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1774, SBC-045679 in section 13.4.5 in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-045679)

b. EPA Has Not Conducted a Benefits Analysis for the HI MCL, in Violation of the SDWA

SDWA [sec]1412(b)(3)(C)(i) requires that EPA "shall" for each alternative MCL considered, publish and seek comment on an analysis of the quantifiable and nonquantifiable health risk reduction benefits and costs of the proposed rule. As described above in Section IV.d, EPA did not consider any alternatives for either the HBWCs or the HI MCL itself, contrary to the SDWA requirements. In addition, EPA failed to conduct any analysis of the benefits or costs of the HIMCL, also in violation of the SDWA. EPA acknowledged in its Proposed Rule that it "has not separately presented changes in quantified costs and benefits" for the "HI approach". 88 FR 18638, 18671. Similarly EPA stated that it "has not separately quantified the benefits and costs for the alternative approach to regulate PFHxS, PFNA, PFBS, and HFPO-DA with individual MCLs instead of the HI." [FN50: Because the individual HBWCs for the HI substances function as individual MCLs (because an exceedance of one HBWC would exceed the HI MCL), establishing individual MCLs for the HI-PFAS is not an "alternative approach" but rather a description of the proposed action.] Id.

Given that the HI MCL can be exceeded by a vanishingly small amount over the nonpeer reviewed HBWCs (for example, 2001 ppt PFBS, where the HBWC is 2000 ppt), and that the HI MCL can be exceeded by a combination of the HI-PFAS all below HBWCs, EPA's failure to engage in SDWA-required analysis of the benefits of the proposed HI MCL leaves the public entirely without information as to the potential benefits and costs of the Proposed Rule. Moreover, any assumption by EPA of a measurable benefit related to the HI MCL is implausible. EPA proposes setting the HI MCL at the same level as the HI MCLG. EPA admits in the Proposed Rule that the MCLG represents "a level at which no known or anticipated adverse effects on the health of persons is expected to occur and which allows for an adequate margin of safety." 87 FR 36848 (March 29, 2023). Similarly, EPA set the PFBS HBWC at the same level as its lifetime health advisory for PFBS. EPA states that its "lifetime health advisories identify levels to protect all people, including sensitive populations and life stages, from adverse health effects resulting from exposure throughout their lives to…PFBS in drinking water." [FN51: See https://www.epa.gov/sdwa/questions-and-answers-drinking-water-health-advisories-pfoa-pfos-genxchemicals-and-pfbs#:~:text=4.-,What%20is%20a%20lifetime%20health%20advisory%3F,or%20PFBS%20in%20drinking%20water.] EPA goes on to state that "the health advisory levels were calculated to offer a margin of

protection against adverse health effects." In other words, EPA's Proposed Rule would set an enforceable standard at levels it concluded is protective against potential risks, with an adequate margin of safety, rather than determining an appropriate regulatory level based on the considerations enumerated in the SDWA.

EPA's failure to prepare any analysis of the benefits or costs of the HI MCL not only violates the SDWA, but also violates the APA's requirement that the Agency engage in notice and comment rulemaking. Without providing the analysis required by the SDWA for the HI MCL, the public is precluded from meaningfully commenting on the potential benefits and costs of the Proposed Rule.

EPA Response: The EPA disagrees with the commenter's statutory analysis; the statute does not require the EPA to propose or analyze a specific number of alternatives. The statute does require that the EPA evaluate those alternatives that it considers, and the EPA has done so here. The commenter incorrectly states that the EPA has not evaluated the benefits or costs of the Hazard Index MCL. The information on benefits and costs of the Hazard Index MCL is discussed in Chapter 6.2.4 of the EA. As a result, the EPA disagrees with the commenter's assertion that the quantified benefits analysis is in violation of SDWA. See section 13.3.2 of the EPA response in this *Response to Comments* document regarding costs associated with the Hazard Index and section 13.4 of the EPA response in this *Response to Comments* document regarding the EPA's benefits assessment for the Hazard Index. The EPA also disagrees with the commenter's assertion that the agency failed to "prepare an analysis of the benefits or costs of the HI MCL" and that the agency violated SDWA and APA requirements. As required by SDWA, the agency considered both the quantifiable and nonquantifiable costs and benefits associated with compliance with the rule, including removal of the PFHxS, PFNA, HFPO-DA, and PFBS. The agency's assessment of quantifiable and nonquantifiable costs and benefits of the Hazard Index were included in the proposed rulemaking for public comment. For additional information, please see section 5.1.3 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1845, SBC-046056 in section 5.1.3 in this *Response to Comments* document.

The agency also disagrees with the commenter that the EPA did not consider a sufficient range of regulatory alternatives, see section 5.1 of the EPA response in this *Response to Comments* document. As described in Chapter 2.1 of the final rule EA, the EPA presents benefits and costs for the final rule as well as three regulatory alternatives.

The agency received comments on whether establishing traditional MCLGs and MCLs for PFHxS, HFPO-DA, PFNA, and PFBS instead of or in addition to the Hazard Index approach would change public health protection, improve clarity for the rule, or change costs. After considering these comments, in the final rule, the EPA has established individual MCLs for three of these PFAS. Additionally, for the final rule the EPA has separately estimated national level marginal costs associated with the individual MCL for PFHxS if this MCL were to be promulgated in the absence of the Hazard Index; see Chapter 5.1.3 of the EA for details. The EPA has also estimated the marginal costs for the individual PFNA and HFPO-DA MCLs if there

was no Hazard Index in the sensitivity analysis found in Appendix N.4 of the EA. See section XIII of the FRN for further discussion of why the EPA added individual MCLs for HFPO-DA, PFHxS, and PFNA. Furthermore, because the EPA has clarified that the Hazard Index MCL and the MCLs for PFHxS, PFNA, and HFPO-DA are one significant figure instead of two significant figures as proposed, the EPA notes there is a reduction in burden associated with the Hazard Index MCL (even by including the individual MCLs for PFHxS, PFNA, and HFPO-DA) between proposal and final. See discussion in sections 4.3.4 and 5.1.7 of the EPA response in this *Response to Comments* document.

Finally, the commenter's statement that "EPA's Proposed Rule would set an enforceable standard at levels it concluded is protective against potential risks, with an adequate margin of safety, rather than determining an appropriate regulatory level based on the considerations enumerated in the SDWA" is based on a fundamental misunderstanding of the statutory mandate for setting an MCL. As a general matter, the statute requires the EPA to set the MCL "as close to the MCLG as feasible," SDWA Section 1412(b)(4)(B), so the statute itself mandates that the MCL be equivalent to the MCLG – the level that is protective against potential risks with an adequate margin of safety -- if that is feasible.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046013)

Drinking Water Intake/Body Weight Data

Consumption

For water ingestion and daily dose estimation, we use data distributions from EPA's Exposure Factors Handbook [FN68: U.S. Environmental Protection Agency, "Exposure Factors Handbook," 2011, https://www.epa.gov/expobox/about-exposure-factors-handbook.]. EPA revised the water ingestion information in 2019 in the Handbook to include more recent data. The analysis uses the consumers-only, direct and indirect drinking water intake values to construct an intake distribution for the U.S. population.

Figure 6: Probability Distribution of Drinking Water Ingestion Rate [FN69: Figure 4 is a graphical description of data in EPA's Exposure Factors Handbook (EFH).]

[Figure 6: see docket ID EPA-HQ-OW-2022-0114-1738]

Figure 4 shows the probability distribution of direct and indirect public drinking water consumption by age group and other sensitive subgroups.

Population Distribution of PFOS Dose from Drinking Water Consumption

The Drinking Water Dose (DWD) is a translation of the drinking water intake to a dose metric. Values of DWD of PFOS before and after the proposed rule are determined so that they can be compared against the available toxicology information. It is calculated by multiplying a value taken from the drinking water concentration distribution and a value taken from the drinking water intake distributions.

Duration

The analysis assumes people consume drinking water from the same water source for their lifetimes, consistent with EPA's approach.

Human Equivalent Dose (HED) for Different Diseases

The analysis searched the scientific literature to find studies that employed approaches that encompass more potential adverse effects and that analyze this data in an approach consistent with benefit-cost analysis. A paper by Chen et al. that integrated human and animal cellular response data into a probabilistic risk assessment of PFOS is the primary source for the benefit estimate [FN70: Qiran Chen, Wei-Chun Chou, and Zhoumeng Lin, "Integration of Toxicogenomics and Physiologically Based Pharmacokinetic Modeling in Human Health Risk Assessment of Perfluorooctane Sulfonate," Environmental Science & Technology, 2022.].

In the paper, Chen et al extracted toxiogenomic dose-response data and other data from a public repository of in vivo animal and in vitro human high-throughput studies [FN71: Chen, Chou, and Lin, 3624.]. Studies of at least three different doses of PFOS were identified in mice, rats, and human cells. The results were filtered to identify the differentially expressed genes. These genetic responses were enriched by applying a disease ontology approach to cluster the genetic changes into disease pathways.

Applying a Bayesian dose-response model to this genetic data from animal studies and in vitro human cell data, the authors developed benchmark doses (BMDs). The authors selected a ten percent change as the benchmark response, the change significant enough to indicate that the PFOS concentration was altering cellular function. Finally, the authors used a physiological based pharmacokinetic (PBPK) model to convert the BMDs to human equivalent doses (HEDs). Each HED is a probability distribution of cellular response for that disease by dose. The paper and the supporting information contain more detailed information on the author's approach.

The Chen et al. drew on data from different concentrations of PFOS exposure to different cells and from different exposure durations [FN72: Chen, Chou, and Lin, 3267.]. The analysis selected the HEDs from the liver cells and derived from 14 days of exposure since

(1) it yielded the most potential adverse effects;

(2) studies show that the body tends to deposit longer chain PFAS in liver tissue; and,

(3) the HEDs were lower than other results. This selection may overestimate the potential adverse effects and social benefits. Chen et al. identified 108 responses to disease pathways in the 14-day liver tissue results [FN73: Chen, Chou, and Lin, 3626.]. The disease ontology and disease groups are listed in Table 4.

Table 3: Human Equivalent Dose (HED) for Different Diseases (ng/kg-day)

[Table 3: see docket ID EPA-HQ-OW-2022-0114-1738]

These 108 HEDs cover a wide range of possible health effects. For example, the analysis includes 46 different types of cancers and tumor formation.

The authors applied a 30-fold uncertainty factor to the HEDs derived from animal data to reflect animal-human extrapolation and human variability and a 10-fold uncertainty factor to human HEDs to reflect population variability [FN74: Chen, Chou, and Lin, "Integration of Toxicogenomics and Physiologically Based Pharmacokinetic Modeling in Human Health Risk Assessment of Perfluorooctane Sulfonate."]. As an additional safety factor, our analysis applies a uniform 30-fold uncertainty factor to all HEDs and divide the HEDs by this factor.

As shown in Table 4, the analysis groups the 108 HEDs into five disease groups: cancer, immunotoxicity, neurological, cardiovascular disease (CVD), and endocrine response (ER). Each HED is a probability distribution based on dose. Following the practice of fitting a distribution to a series of HED values shown in Figure 4 of Chou and Lin, a distribution is fitted on the HED data extracted the supporting information package of Chen et al. and is done so for each of the five disease types [FN75: Chen, Chou, and Lin; Wei-Chun Chou and Zhoumeng Lin, "Probabilistic Human Health Risk Assessment of Perfluorooctane Sulfonate (PFOS) by Integrating in Vitro, in Vivo Toxicity, and Human Epidemiological Studies Using a Bayesian-Based Dose-Response Assessment Coupled with Physiologically Based Pharmacokinetic (PBPK) Modeling Approach," Environment International, 2020.]

Figure 7: Probability Distributions of HEDs by Disease and Disease Type

[Figure 7: see docket ID EPA-HQ-OW-2022-0114-1738]

Figure 7 plots the probability distribution of the 108 diseases by HED levels. Each disease has a central tendency estimate and a range of probabilities that vary with dose. As with Chou et at., this analysis used a Weibull distribution to fit a curve to the log10(HED) data. Figure 8 is a simplification of Figure 7 since it plots median HED values of the distributions of all 108 diseases aggregated by disease type.

Figure 8: Probability Distribution of Log10(HED) by Disease Type

[Figure 8: see docket ID EPA-HQ-OW-2022-0114-1738]

The analysis then overlays the distributions of the disease probabilities (HEDs) and the drinking water doses (DWDs) for both PFOS and PFOA in Figure 9. Several features become apparent. First, below a dose of 20 ng/kg/day, the probability of all diseases is effectively zero. Second, on the other end of the HED distribution, once the DWD exceeds 52 ng/kg/day, the probability is effectively one – or a certainty that this population would have a disease if the gene and cell response data are perfectly causal. Third, consumers with high end exposures are likely to generate the majority of the benefits. From the DWD curve, 81 percent of the population is expected to be below 20 ng/kg/day. Fourth, at the proposed MCL, there is no expected remaining risk. EPA's proposed action would reduce the expected risk to zero. Finally, reducing the level of current state PFOS MCL to EPA's proposed PFOS MCL is not expected to yield any health benefits.

Figure 9: Probability Distribution of HED by Disease Type for All Ages and Probability of Dose from Drinking Water for the Population

[Figure 9: see docket ID EPA-HQ-OW-2022-0114-1738]

Confidence in the Chen et al work is extended when additional studies are considered. Chou and Lin took a similar approach to Chen et al.'s work and reached similar findings [FN76: Chou and Lin, "Probabilistic Human Health Risk Assessment of Perfluorooctane Sulfonate (PFOS) by Integrating in Vitro, in Vivo Toxicity, and Human Epidemiological Studies Using a Bayesian-Based Dose- Response Assessment Coupled with Physiologically Based Pharmacokinetic (PBPK) Modeling Approach."]. In this study, the researchers gathered data from high-throughput in vitro assays from EPA's ToxCast program, from six controlled dose animal studies, and four human epidemiology studies. The authors selected a range of assays related to the disease groups in Chen et al. As in that study, Chou and Lin considered in vitro data when at least one dose group had a ten percent change in response [FN77: Chou and Lin.]. The authors also applied a Bayesian dose-response model to integrate the human, animal, and in vitro evidence. The authors calculated HEDs for all the studies.

Table 3 of the paper lists the calculated HEDs. Even by applying an uncertainty factor of 30 to the HEDs in Chou and Lin, all of the in vitro and animal studies have estimated PFOS HEDs equal to or greater than those in Chen et al. While the human studies give lower HEDs, the authors explain that the uncertainty over the dose measurement in the epidemiolocal studies, the co-exposure to a mixture of PFAS, and other limitations suggest that the human HEDs are conservative. The Chou and Lin paper complements and reinforces the Chen et al. finding that there is little significant biological activity at doses below 20 ng/kg/day as measured through a wide range of in vitro assays and through animal experimental data.

4. Expected Disease Probabilities from Current Drinking Water Intake

The analysis then randomly samples from the PFOS intake from drinking water and compares the dose to the HED disease group probabilities. This comparison is carried out through several steps.

Calculate the Probability of a Disease Group

As shown in Figure 8, for the same dose, a person could be at risk of contracting a disease in multiple disease groups. Each person is only subject to the risk from a single disease in the analysis. To assign the sample population to a disease group, the area under the curve (AUC) of each disease curve for different HED doses in Figure 5 is estimated. The probability of being in each disease group is equal to the proportion of the area under each cumulative distribution curve (see Figure 7).

Probability of Disease Type

We utilize a Monte Carlo simulation by taking 1,000 random samples from the DWD curves for PFOA and for PFOS in Figure 9 and calculating the AUC for each disease group. If the drinking

water dose is above 20 ng/kg/day, then there is a positive probability of each of the five diseases. Figure 10 below shows the results of this calculation for PFOS.

Figure 10: Probability of Disease Group for All Ages for PFOS

[Figure 10: see docket ID EPA-HQ-OW-2022-0114-1738]

This figure shows both the absolute probability of having a disease and the relative probability of each disease type for a given drinking water dose. In Figure 10, at a dose of approximately 38 ng/kg/day, the probability of having a disease is approximately 50 percent. The colors in the stacked bar at that dose show that this 50 percent risk is the sum of the risks for each of the five disease groups. Once the dose reaches and exceeds 52 ng/kg/day, the estimate is that the probability is certain and the proportions among the disease groups do not change as dose increases.

3. Bounding Estimate of Benefits

Since it appears unlikely that much of the current population exposed to PFOS in public drinking water will garner significant benefits, the analysis creates a bounding estimate of benefits to compare with the social costs. The objective is to map out an extreme upper bound on the possible benefits from the proposed MCLs. The bounding estimate rests on assumptions that overstate the potential benefits:

Causality. The analysis assumes that a probability of disease predicted by the genomic data will in fact occur. Intervening biological repair mechanisms are assumed not to be effective or exist. This assumption clearly overstates the probability and the severity of potential disease from PFOS exposure in drinking water. Due to the many environmental, diet, and random events that perturb the body's functions, the body contains many repair mechanisms. Other studies support that this bounding estimate will overstate the potential benefits substantially:

o In a recent study of PFOA, a HED generated from liver cell cultures was found to predict response levels 40-60 times less than actual responses observed in a human clinical trial with controlled PFOA doses [FN78: Styliani Fragki et al., "New Approach Methodologies: A Quantitative in Vitro to in Vivo Extrapolation

o Case Study with PFASs," Food and Chemical Toxicology 172 (2023).].

o Another study compared 43 chemicals' "safe" dose from both genomics data and traditional toxicity testing. The genomics "safe" value was on average almost 6-fold less than the values derived from controlled animal experiments [FN79: Byron Kuo et al., "Comprehensive Interpretation of in Vitro Micronucleus Test Results for 292 Chemicals: From Hazard Identification to Risk Assessment Application," Archives of Toxicology 96 (2022).].

• A 10 Percent Change in Response Causes Disease. In addition to the causality assumption, the bounding estimate further assumes that the BMD change of a 10 percent response is sufficient to overcome the body's defenses and to cause a disease. In reality, a larger response or disruption could be necessary to cause disease.

• Existing Population will Gain the Full Benefits. The analysis assumes that the population that straddles the rule's effective date will gain all the potential reductions in the probability of adverse effects. In reality, lower future exposure may lessen probabilities of future harm, but not eliminate them. Past exposure may have created an enduring increase in lifetime risk. Since 96 percent of the benefits in this bounding estimate accrue to current members of the population, reducing the existing population's assumed benefits would substantially lower the benefits.

• HEDs with Large Potential Benefits as Surrogates for All HEDs in a Disease Group. Some of the HEDs in the five disease groups have limited occurrence in the U.S. population or have very low adverse health impacts. The analysis transfers the estimated benefit of some of the HEDs with larger benefits to all HEDs with likely small impacts.

Therefore, these assumptions imply that a more realistic estimate of the social benefits is at least 10 times lower than those in this bounding estimate. However, the purpose is to explore whether the social benefits can exceed the costs even with these unrealistic assumptions – and with a more comprehensive consideration of potential benefits.

While the analysis constructed a full uncertainty analysis for the variables with uncertainty, the analysis presents the central tendency estimates for simplicity.

Population Cohorts

The analysis estimates the population that is expected to have a dose from drinking water consumption above 20 ng/kg/day. There are two populations that will benefit from this rule: the population at the time of the rule's effective date and future population that are born in the United States or come to the United States after the rule is effective. The analysis uses the term "new population" as the term for this latter group. The benefit methodology for each group is different.

Existing Population

We apply the following steps to estimate the proportion of the current population that could benefit from the proposed drinking water standard:

Adjust Population to Existing Residents that Consume Public Water in States without Standards

Our analysis assumes that the water systems are in compliance with the rule in 2026. The analysis assumes that the changes eliminate the risk to the 2026 population drinking public water. The present value of the benefits to the current population are assumed to occur over three years, corresponding to roughly the half-life of PFOS. This approach overestimates benefits for several reasons. First, adverse effects from exposure prior to the rule may be irreversible. Second, since the half-life is estimated to be greater than three years, after three years, the average U.S. consumer will still have more than half of their baseline PFOS concentration due to past drinking water consumption. Third, consumers may shift their consumption habits away from public drinking water sources in response to the final rule and in response to lag between public notification and PFAS treatment.

We adjust the population by EPA's proportion of U.S. residents that consumer public water. We further reduce this population to public water consumers in states that are likely not to have a state drinking water standard in place by 2026.

New Population

As stated above, the new population includes people born in the years after the effective date and new residents of the United States. New residences are assumed to have the same age profile and disease incidence as the existing population. The analysis uses Census Department decanal projections for new residents and new births [FN80: U.S. Census Bureau, "2017 National Population Projections Tables: Main Series," 2017, https://www.census.gov/data/tables/2017/demo/popproj/2017-summary-tables.html.]. For births, yearly values are created by assuming a linear relationship between the Census' estimates for each decade from 2020 to 2060. We assume the U.S. will enjoy approximately 1.1 million new residents and 4.1 million new births annually during the study period. For the bounding estimate, the analysis assumes that all newborns grow and live a full life to enjoy the benefits, that there is no emigration, that health care innovations do not reduce the adverse effects from the HED diseases.

The study period includes the annual population additions from 2027 to 2056.

Determine Disease Incidence and Individuals Expected to Suffer Diseases

Estimating the number of avoided cases of diseases from this regulatory action has three steps. First, the existing population and new populations are multiplied by the DWD distribution to determine the number of people expected to have a dose above 20 ng/kg/day from drinking water. This population is broken into unit increments of dose.

Second, for each dose, the corresponding population is divided into one of the five disease groups based on the proportions in Figure 7. Each population in these disease group/dose categories is then multiplied by the probability of having the disease from Figure 6 for that dose.

Finally, this resulting product is multiplied by the percentage of the population incidence of the disease. The analysis assumes that the existing population has consumed PFOS at current levels for some time. Therefore, if the diseases predicted by the HEDs are caused by current PFOS exposure, the current number of cancer cases in the U.S. population include the cases caused by PFOS exposure through drinking water. Therefore, if the genomic data predicts a reduction in the probability of disease, the number of existing U.S. cancer cases will be reduced by this regulatory action. The benefits will be therefore a reduction in the overall population cancer incidence.

The analysis thus requires the incidence in the existing U.S. population of the HEDs. We employ different approaches for each of the five disease groups based on data availability.

Cancer

Data on age-adjusted cancer incidence for specific cancers for the current U.S. population is obtained [FN81: U.S. Census Bureau.]. The analysis uses the major cancers in the HEDs. The analysis did not estimate the risk reduction from rarer cancers such as bone and ocular cancers.

CVD

The analysis gathered specific incidence information on COPD, stroke, fatty liver disease, liver cirrhosis, and acute myocardial infarction (AMI). Some of the HEDs were precursors to these diseases or are captured in the mortality and morbidity estimates for the specific diseases listed. The benefits for COPD are reduced to 30 percent of estimated values since 70 percent of COPD is estimated to be caused by smoking [FN82: World Health Organization, "Chronic Obstructive Pulmonary Disease (COPD)," March 16, 2023, https://www.who.int/news-room/fact-sheets/detail/chronic-obstructive-pulmonary-disease-(copd).]. For the other HEDs in the CVD disease group, the analysis applies a uniform valuation discussed below.

Neurological

The analysis gathers the population incidence rate for Alzheimer's and Parkinson's Disease. The remaining HED represent relatively rare diseases or categories in which Alzheimer's, Parkinson's are the most common specific disease. For the other HEDs in the Neurotologic disease group, the analysis applies a uniform valuation discussed below.

Immunotoxicity and Endocrine Disruption

As with the neurological disease group, the expected values are not likely to be significant in the total bounding estimate. The analysis applies a uniform value for each unique adverse effect in these categories.

Valuation of Disease Cases

The same valuation approach is used for existing and new populations. For each of the five disease groups, information on the burden of the major diseases and of their latency periods is taken from the literature [FN83: Marcia R Weaver et al., "Health Care Spending Effectiveness: Estimates Suggest That Spending Improved US Health from 1996 to 2016," Health Aff (Millwood) 41, no. 7 (2022): 994–1004.]. The analysis calculates a net present value of the value of avoiding the disease in 2023 dollars by placing the value of avoiding the disease in the time of its average latency and then discount the future benefit.

The 108 HEDs span a range of potential effects, some clearly adverse like cancer and some only potentially adverse such as neoplasms. To quantify these adverse effects with the same metric, the analysis uses the disability-adjusted life-year (DALY) methodology. This metric combines the lost value from a disease's reduction in life span and from its reduction in abilities. The WHO employs DALYs as part of its Global Burden of Diseases project to standardize disease burdens across countries [FN84: World Health Organization, "Global Health Estimates: Leading Causes of DALYs," n.d., https://www.who.int/data/gho/data/themes/mortality-and-global-health-

estimates/global-health-estimates-leading-causes-of-dalys.]. To allow comparisons, researchers have measured DALYs for many other diseases that are not part of the WHO project.

This analysis first links any of the HEDs to diseases the WHO valued for the United States in its 2019 Global Disease Burden analysis. The DALY per case of the disease in the United States is estimated by dividing the WHO's DALYs in the United States by the incidence rate of the disease in the United States. For the remainder of the HEDs, the scientific literature is searched to find DALY estimates and incident rates for the United States. Some of the HEDs are precursors and did not have DALY estimates. Others were effects that may lead to the same adverse outcome, such as breast cancer and breast neoplasms. Table 4 shows some of the DALY estimates for the major HED diseases.

Table 4: DALY Estimates for Major HED Diseases

[Table 4: see docket ID EPA-HQ-OW-2022-0114-1738]

Valuation of Each Disease

The Department of Human Health Services' (HHS) economic analysis guidelines use a WTP estimate of approximately $800,000 per DALY [FN85: U.S. Department of Health and Human Services, "Guidelines for Regulatory Impact Analysis," 2016.]. This value is a transformation of the VSL to a life-year metric. This valuation is used in this analysis since it is consistent with Circular A-4's directive to use WTP values to estimate social benefits [FN86: U.S. Office of Management and Budget, "Circular A-4: Regulatory Analysis," September 2003.].

Latency and Commencement of Benefits

The proposed regulation would reduce PFOS exposure in drinking water over time. As in EPA's analysis in the RIA, this analysis must determine the lag between the reduction in PFOS exposure and the change in disease occurrence. We first gather data on the latency between initiation and the manifestation of a disease. The HEDs span diseases with latency periods of a few days to several decades. To standardize each disease with a valuation, we discount the value of the disease to an equivalent current value by its latency period at a seven percent discount rate. For example, if a disease has a DALY loss of $400,000 when it occurs five years in the future, the value today is $285,000 (rounded). For the new population, many diseases are not expected to occur until the person reaches his/her 50s or 60s. Therefore, the valuation of avoiding the adverse effects in the future must be discounted to current dollars.

EPA Response: See section 13.4 in this *Response to Comments* document and also the EPA response to comment Doc. #1738, SBC-053388 in section 13.4 in this *Response to Comments* document for the EPA's response to the commenter's use of a Bayesian dose-response model using animal studies and in vitro human cell data to develop benchmark doses. Regarding the commenter's conclusions resulting from the "bounding exercise" in this and other snippets, see section 13.4 of the EPA response in this *Response to Comments* document. As detailed in section 13.4 of the EPA response in this *Response to Comments* document and in the following response, the EPA disagrees with many of the assumptions that support the bounding exercise,

and therefore disagree with this commenter's overall conclusions that the bounding exercise represents an "extreme upper bound" on the possible benefits from the proposed MCLs. Further, the EPA disagrees with the commenter that "a more likely estimate of the social benefits are more than ten times lower than this bounding estimate."

The EPA disagrees with the commenter's use of the consumers-only drinking water intake values to construct an intake distribution for the U.S. population. The EPA uses a consumption rate of 0.013 L/kg-day, which represents a per capita factor for adults aged 21 and older. Using the consumers-only drinking water intake value (0.016/0.017 L/kg-day for those aged 21 and older, depending on the age range) would overestimate exposure in the general population.

The EPA disagrees with the commenter's suggested approach to determining disease incidence and individuals expected to suffer disease. Please refer to the EPA response to comment Doc. #1738, SBC-053384 in section 13.4 and Doc. #1738, SBC-053388 in section 13.4.5 in this *Response to Comments* document, in particular regarding evidence integration strategy and estimation of disease incidence reductions. Regarding the commenter's estimation of benchmark doses for different diseases, and specifically the application of Chen et. al, see section 13.4 of the EPA response in this *Response to Comments* document.

Regarding the commenter's statement that the bounding estimate rests on assumptions that overstate the potential benefits, see section 13.4 of the EPA response in this *Response to Comments* document.

Regarding the commenter's approach to evaluating population growth, refer to the EPA response to comment Doc. #1808, SBC-046130 in section 13.9 of the EPA response in this *Response to Comments* document. Further, the EPA notes that the bounding exercise uses a study period from 2027 to 2056. The EPA used a longer period of analysis, as discussed in Chapter 2 of the EA (USEPA, 2024b), which allows the agency to capture longer term effects of chronic contaminants such as PFAS.

The EPA also disagrees with the commenter's suggestion to use the disability-adjusted life-year (DALY) methodology to value the potential benefits of enacting the PFAS MCLs. Although other agencies (e.g., the Department of Human Health Services and the World Health Organization) use this methodology for the purpose of their analyses, the goal of their analyses may be different from the EPA's benefit cost analysis. For example, WHO uses DALY to standardize disease burdens across different countries. The EPA's Guidelines for Preparing Economic Analyses (USEPA, 2016a) clearly states that "methods that combine information on quality and quantity of life cannot be directly related to willingness-to-pay estimates and thus should not be used for deriving monetary estimates for use in benefit cost analyses." In addition, OMB Circular A-4 Guidance states that in order for integrated measures such as DALY to represent a valid measure of individual preferences they must t meet some restrictive assumptions (OMB, 2023). Specifically, the guidance states that if data are not available using a more direct monetization approach (e.g., WTP), "Bear in mind, however, that a main drawback of integrated measures of this type is that they must meet some restrictive assumptions to

represent a valid measure of individual preferences. If you use this approach, you should be careful to acknowledge your assumptions and the limitations of your estimates." Therefore, the EPA's benefits estimates using cost of illness and willingness to pay information to value reduction in the number of illness cases associated with from PFOA and PFOS exposure is most appropriate for use in this HRRCA.

The EPA disagrees with the commenter's approach to estimation of the latency and commencement of benefits. The commenter makes unspecified assumptions about the disease latency (i.e., the time between reduction in PFOA exposure and reduction in disease incidence). The commenter also is not transparent about whether the incidence of each evaluated disease is the lifetime incidence or the annual incidence. If the modeled baseline incidence is the annual incidence, then the analysis potentially misses additional benefits from the permanent reduction in PFOS exposure over time. Finally, the commenter's analysis does not address population mortality from other causes over the evaluation time period.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046015)

Valuation of Avoided Disease Cases

Table 5 gives the valuation per case of avoided disease for the major HEDs. Table 5: Valuation of Avoided Disease Cases by Major HEDs

[Table 5: see docket ID EPA-HQ-OW-2022-0114-1738]

[FN89: National Institutes of Health, National Cancer Institute, "SEER*Explorer: An Interactive Website for SEER Cancer Statistics," April 19, 2023, .]

[FN90: Rebecca Siegel et al., "Colorectal Cancer Statistics, 2023," CA: A Cancer Journal for Clinicians 73, no. 3 (2023).]

[FN91: New York State Cancer Registry, "Ovarian Cancer Incidence and Mortality by Age Group, New York City, 2016-2020," February 2023.]

[FN92: National Institute of Dental and Craniofacial Research, "Oral Cancer Incidence (New Cases) by Age, Race, and Gender," April 2023.]

[FN93: Nicolas Patel and Bikramjit Benipal, "Incidence of Esophageal Cancer in the United States from 2001- 2015: A United States Cancer Statistics Analysis of 50 States," Cureus Journal of Medical Science 10, no. 12 (2018); GBD 2017 Oesophageal Cancer Collaborators, "The Global, Regional, and National Burden of Oesophageal Cancer and Its Attributable Risk Factors in 195 Countries and Territories, 1990– 2017: A Systematic Analysis for the Global Burden of Disease Study 2017" 5 (2020).]

[FN94: Roswell Park Comprehensive Cancer Center, "Understanding Brain Tumors: The Basics," February 12, 2018; Kimberly Miller et al., "Brain and Other Central Nervous System Tumor Statistics, 2021," CA: A Cancer Journal for Clinicians 71, no. 5 (2021).]

[FN95: U.S. Centers for Disease Control and Prevention, “Chronic Disease Indicators (CDI),” 2023, .]

[FN96: U.S. Centers for Disease Control and Prevention, “QuickStats: Percentage of Adults Aged ≥18 Years with Diagnosed Heart Disease, by Urbanization Level and Age Group — National Health Interview Survey, United States, 2020,” Morbidity and Mortality Weekly Report 71, no. 778 (2022), .]

[FN97: Kristi Reynolds et al., “Trends in Incidence of Hospitalized Acute Myocardial Infarction in the Cardiovascular Research Network (CVRN),” American Journal of Medicine 130, no. 3 (2017): 317–27.]

[FN98: Youn Huh, Yoon Jeong Cho, and Ga Eun Nam, “Recent Epidemiology and Risk Factors of Nonalcoholic Fatty Liver Disease,” Journal of Obesity & Metabolic Syndrome 31, no. 1 (2022): 17–27.]

[FN99: U.S. Centers for Disease Control and Prevention, “Stroke Facts,” 2023, .]

[FN100: Yuan-Bin Liu and Ming-Kai Chen, “Epidemiology of Liver Cirrhosis and Associated Complications: Current Knowledge and Future Directions,” World Journal of Gastroenterology 28, no. 41 (2022): 5910– 30.]

For some of the common immunotox and endocrine disruptor diseases, the net present value benefits are less than $100 million. There are 17 HEDs remaining that are unique diseases. As a bounding estimate, we assign each one an avoided cost present value of $100 million to generate the bounding estimate in Table 5.

Incremental Effect of the Proposed Regulatory Action

As stated above, in this bounding estimate the rulemaking is assumed to eliminate the incremental probability of harm from current PFOS concentrations in drinking water to the existing population and to future populations from 2027 to 2056.

4. Results PFOS

Table 7 gives the results of this bounding exercise. The annualized social benefits for the proposed PFOS drinking water standard are approximately $1.4 billion per year at a seven percent discount rate. This estimate arises from consideration of 108 possible disease states that arise from observed changes in biological function. It would appear that it is implausible that other adverse effects that do not rely on biological function changes could be large enough to exceed this bounding estimate.

As discussed in the next section, this benefit estimate is more than five times less than the estimated social costs. Since a more likely estimate of the social benefits are more than ten times lower than this bounding estimate, the social costs of EPA’s proposed regulatory action exceed the potential social benefits by a large margin.

Table 6: NPV of Estimated Annualized Benefits ($ M)

[Table 6: see docket ID EPA-HQ-OW-2022-0114-1738]

PFOA

As the occurrence data and EPA's population estimates show, there is extensive overlap between the populations that would benefit from a PFOS standard and a PFOA standard. There does not appear to be comparable studies to Chen et al. and Chou and Lin in the literature for PFOA. In EPA's MCLG documents, EPA finds that PFOA and PFOS share many of the same adverse effects at roughly the same dose levels. The estimated occurrence in drinking water is roughly the same as shown in Figure 4.

Even doubling or trebling the benefits from the PFOS bounding estimate to account for the social benefits of PFOA, however, does give benefits close to the social costs.

Table 7: NPV of Estimated Annualized Benefits ($ M)

[Table 7: see docket ID EPA-HQ-OW-2022-0114-1738]

EPA Response: The EPA disagrees with the commenter's suggested approach and the commenter's assumptions in the bounding exercise. Please refer to the EPA response to comment Doc. #1738, SBC-053384 in section 13.4 of this *Response to Comments* document, as well as the section 13.4 of the EPA response in this *Response to Comments* document. The EPA disagrees with the commenter's assertion that the social benefits of the rule are "more than five times less" than social costs. As detailed in section 13.4 of the EPA response in this *Response to Comments* document, the EPA disagrees with many of the assumptions used in the commenter's bounding exercise and disagrees that the results represent an "extreme upper bound" of the benefits of the rule. Regarding this commenter's estimates of the costs of the final rule, the EPA also disagrees with many of the commenter's approaches and overall conclusions; see sections 13.3 and 13.3.3 of the EPA response in this *Response to Comments* document for more information. Therefore, the EPA disagrees with this commenter that the social benefits of the rule are less than the social costs. As detailed in the EA, the EPA anticipates significant additional nonquantifiable benefits as a result of the final rule and has reaffirmed the agency's determination at proposal that the quantifiable and nonquantifiable benefits of the rule justify it quantifiable and nonquantifiable costs; see section 13.8 of the EPA response in this *Response to Comments* document for further discussion.

West Virginia Municipal Water Quality Association (Doc. #1816, SBC-044681)

VII. EPA's estimate of public health benefits appears to be significantly overstated and must be revised and republished.

EPA has ignored the lack of any documented health impacts from areas around the country where there have been acute impacts, for example, groundwater contamination in the Parkersburg/Vienna, West Virginia area. Another example is Wilmington, North Carolina where a

Chemours/DuPont facility discharged what we believe was wastewater containing millions of parts per trillion of a variety of PFAS chemicals, likely for decades. During an online Town Hall meeting regarding PFAS-related issues we believe that North Carolina's health agency represented that they were not aware of any PFAS-related health clusters. We believe it is imperative that EPA address how these real-world human health impacts (or lack thereof) were considered in the development of its ultra-low proposed MCLs.

In particular, EPA must identify whether there are any health clusters due to elevated PFAS impacts in communities that have been documented to date.

We know based upon the testing performed so far by water systems, the States and federal government, that people have been exposed to levels of PFOA/PFOS for years and decades that are orders of magnitude higher than EPA's proposed MCLs. However, EPA fails to identify any health clusters as a result of these "hot spot" exposures. We believe that lack of actual health impacts in these circumstances compels EPA to reconsider the level of its proposed MCLs.

If we are wrong about there being no documented health clusters tied to PFAS contamination, EPA should expand on such data to help justify the $1.3 billion in annual public health benefits that EPA asserts.

EPA Response: The EPA disagrees with the commenter's assertion that benefits are overestimated. An extensive systematic literature review uncovered compelling evidence that was carefully assessed for study quality and validity, as discussed in the toxicology assessments for PFOS and PFOA and section IV of the preamble (USEPA, 2024h; USEPA, 2024i). Contrary to commenters claim, the lack of reported cancer clusters or other "health clusters" does not undermine this economic analysis or any analysis done to support the rulemaking. Rather, the EPA's action is based on the best available science and data collected by the best available methods; the EPA's action is necessarily based on the information available, not the information not available. See SDWA 1412(b)(3)(C). Please refer to sections 4.1.4, 4.2.1, 13.4, 13.4.1, 13.4.2, and 13.4.3 of the EPA response in this *Response to Comments* document for detail on the EPA's determination on evidence of certain health effects associated with PFOA and PFOS.

Association of Missouri Cleanwater Agencies (Doc. #1817, SBC-044659)

VII. EPA's estimate of public health benefits appears to be significantly overstated and must be revised and republished.

EPA has ignored the lack of any documented health impacts from areas around the country where there have been acute impacts, for example, groundwater contamination in the Parkersburg/Vienna, West Virginia area. Another example is Wilmington, North Carolina where a Chemours/DuPont facility discharged what we believe was wastewater containing millions of parts per trillion of a variety of PFAS chemicals, likely for decades. During an online Town Hall meeting regarding PFAS-related issues we believe that North Carolina's health agency represented that they were not aware of any PFAS-related health clusters. We believe it is

imperative that EPA address how these real-world human health impacts (or lack thereof) were considered in the development of its ultra-low proposed MCLs.

In particular, EPA must identify whether there are any health clusters due to elevated PFAS impacts in communities that have been documented to date.

We know based upon the testing performed so far by water systems, the States and federal government, that people have been exposed to levels of PFOA/PFOS for years and decades that are orders of magnitude higher than EPA's proposed MCLs. However, EPA fails to identify any health clusters as a result of these "hot spot" exposures. We believe that lack of actual health impacts in these circumstances compels EPA to reconsider the level of its proposed MCLs.

If we are wrong about there being no documented health clusters tied to PFAS contamination, EPA should expand on such data to help justify the $1.3 billion in annual public health benefits that EPA asserts.

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044681 in section 13.4.5 in this *Response to Comments* document.

NORTH CAROLINA WATER QUALITY ASSOCIATION (Doc. #1818, SBC-044637)

VII. EPA's estimate of public health benefits appears to be significantly overstated and must be revised and republished.

EPA has ignored the lack of any documented health impacts from areas around the country where there have been acute impacts, for example, groundwater contamination in the Parkersburg/Vienna, West Virginia area. Another example is Wilmington, North Carolina where a Chemours/DuPont facility discharged what we believe was wastewater containing millions of parts per trillion of a variety of PFAS chemicals, likely for decades. During an online Town Hall meeting regarding PFAS-related issues we believe that North Carolina's health agency represented that they were not aware of any PFAS-related health clusters. We believe it is imperative that EPA address how these real-world human health impacts (or lack thereof) were considered in the development of its ultra-low proposed MCLs.

In particular, EPA must identify whether there are any health clusters due to elevated PFAS impacts in communities that have been documented to date.

We know based upon the testing performed so far by water systems, the States and federal government, that people have been exposed to levels of PFOA/PFOS for years and decades that are orders of magnitude higher than EPA's proposed MCLs. However, EPA fails to identify any health clusters as a result of these "hot spot" exposures. We believe that lack of actual health impacts in these circumstances compels EPA to reconsider the level of its proposed MCLs.

If we are wrong about there being no documented health clusters tied to PFAS contamination, EPA should expand on such data to help justify the $1.3 billion in annual public health benefits that EPA asserts.

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044681 in section 13.4.5 in this *Response to Comments* document.

South Carolina Water Quality Association (Doc. #1819, SBC-044615)

VII. EPA's estimate of public health benefits appears to be significantly overstated and must be revised and republished.

EPA has ignored the lack of any documented health impacts from areas around the country where there have been acute impacts, for example, groundwater contamination in the Parkersburg/Vienna, West Virginia area. Another example is Wilmington, North Carolina where a Chemours/DuPont facility discharged what we believe was wastewater containing millions of parts per trillion of a variety of PFAS chemicals, likely for decades. During an online Town Hall meeting regarding PFAS-related issues we believe that North Carolina's health agency represented that they were not aware of any PFAS-related health clusters. We believe it is imperative that EPA address how these real-world human health impacts (or lack thereof) were considered in the development of its ultra-low proposed MCLs.

In particular, EPA must identify whether there are any health clusters due to elevated PFAS impacts in communities that have been documented to date.

We know based upon the testing performed so far by water systems, the States and federal government, that people have been exposed to levels of PFOA/PFOS for years and decades that are orders of magnitude higher than EPA's proposed MCLs. However, EPA fails to identify any health clusters as a result of these "hot spot" exposures. We believe that lack of actual health impacts in these circumstances compels EPA to reconsider the level of its proposed MCLs.

If we are wrong about there being no documented health clusters tied to PFAS contamination, EPA should expand on such data to help justify the $1.3 billion in annual public health benefits that EPA asserts.

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044681 in section 13.4.5 in this *Response to Comments* document.

Wet Weather Partnership (Doc. #1820, SBC-044593)

VII. EPA's estimate of public health benefits appears to be significantly overstated and must be revised and republished.

EPA has ignored the lack of any documented health impacts from areas around the country where there have been acute impacts, for example, groundwater contamination in the Parkersburg/Vienna, West Virginia area. Another example is Wilmington, North Carolina where a Chemours/DuPont facility discharged what we believe was wastewater containing millions of parts per trillion of a variety of PFAS chemicals, likely for decades. During an online Town Hall meeting regarding PFAS-related issues we believe that North Carolina's health agency

represented that they were not aware of any PFAS-related health clusters. We believe it is imperative that EPA address how these real-world human health impacts (or lack thereof) were considered in the development of its ultra- low proposed MCLs.

In particular, EPA must identify whether there are any health clusters due to elevated PFAS impacts in communities that have been documented to date.

We know based upon the testing performed so far by water systems, the States and federal government, that people have been exposed to levels of PFOA/PFOS for years and decades that are orders of magnitude higher than EPA's proposed MCLs. However, EPA fails to identify any health clusters as a result of these "hot spot" exposures. We believe that lack of actual health impacts in these circumstances compels EPA to reconsider the level of its proposed MCLs.

If we are wrong about there being no documented health clusters tied to PFAS contamination, EPA should expand on such data to help justify the $1.3 billion in annual public health benefits that EPA asserts.

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044681 in section 13.4.5 in this *Response to Comments* document.

Brian Hackman (Doc. #1539, SBC-042908)

Given that USEPA's approach to the health advisory limits would say most all American's have a lifetime exposure that says any improvement in drinking water will have little effect, USEPA is attempting to make a rule that, in essence, can not show any benefit until all PFAS is removed from human presence and the next generation of that generation is free of any vectors to exposure. The Agency is setting itself up to chase a ghost that it can not win against nor fight because of its impossible dream at such low concentrations.

EPA Response: The EPA disagrees with the commenter's interpretation of the health advisories and assessment that benefits from reducing PFOS and PFOA exposure may not be realized. As demonstrated at length in the EPA's economic analysis, any reduction in exposure to regulated PFAS, including PFOA and PFOS, is expected to reduce risks for persons alive today and is anticipated to produce significant health benefits at a national scale. The benefits estimation relies on an extensive literature review to identify existing research on the adverse health effects brought by PFOA and PFOS exposure and potential benefits of reducing exposure to PFAS. Please see Chapter 6 of the EA for details on the EPA's approach to estimating benefits of the proposed MCLs (USEPA, 2024b). Furthermore, the EPA notes that treating to the MCLs in this final rule are feasible and that the rules regulatory requirements are not an "impossible dream". See section V of the preamble for today's rule for discussion about treatment feasibility for the final rule's regulated PFAS.

Brian Hackman (Doc. #1539, SBC-042903)

Also, USEPA has not explained how it will achieve and monitor the $1.06 billion in healthcare savings represented by implementing treatment across the United States. USEPA has not demonstrated in areas where PFAS treatment has been implemented any cost reductions using data collected by the CDC (Centers for Disease Control) to show a reduction in related health impacts as a result of cleaner water. Having such large datasets as 10,000 or more populations would be beneficial and necessary to demonstrate the benefit used to justify the proposed health improvement benefit. Otherwise, it is a struggle to see that USEPA is conducting a $1 billion money grab out of the medical community revenues without some impact on medical jobs and infrastructure used to sustain healthcare. The $1 billion health benefit becomes a significant challenge to achieve especially when the USEPA recognizes that only 20 percent of environmental exposure is being achieve through this regulation alone. Is USEPA saying and really missing out on the ability to achieve $4 billion in healthcare reduction costs by not regulating the other 80 percent of exposure vectors?

EPA Response: Regarding the commenter's point that the EPA has not demonstrated that PFAS treatment already implemented is reducing health effects, the EPA's action is based on the statutorily-mandated best available science and data collected by best available methods, SDWA Section 1412(b)(3), so is necessarily based on information available, not information that is not available. The EPA disagrees with the commenter's suggestion that the EPA has failed to explain how healthcare savings are achieved. Please see Chapter 6 of the EA for details on the EPA's approach to estimating the avoided medical cost and the value of avoiding premature mortality resulting from the proposed MCLs (USEPA, 2024b). The EPA also disagrees with the commenter that avoided cost of illness resulting from reduced exposure to PFOA and PFAS would have adverse impacts on medical jobs and infrastructure. The American Hospital Association reports a significant shortage of physicians, nurses, and other medical professionals in the healthcare system (AHA, 2021). Therefore, reduction in adverse health effects associated with the implementation of the proposed MCLs is likely to alleviate existing pressure on medical professionals and, as a result, benefit the healthcare system. The EPA acknowledges that the proposed MCLs address only a fraction of environmental exposure, and as described in the EA and FR, the EPA is addressing PFAS contamination in the U.S. across all media types with both voluntary and regulatory actions. The commenter is incorrectly interpreting the relative source contribution (RSC) and is directed to section 4.2.5 of the EPA response in this *Response to Comments* document for discussion regarding RSC derivation and exposure sources. The benefits analysis provides a maximum population attributable fraction (PAF) limit on total health outcome rates that could be attributed to PFAS exposure. See Section 6.1.2 Uncertainty Characterization in the final rule EA (USEPA, 2024b) for discussion of the PAF limits. Section 5.3.2 of the EA describes the estimation of administrative monitoring costs (USEPA, 2024b).

Dixon Tucker (Doc. #2797, SBC-046229)

With the very detailed sampling protocol required for sampling PFOS/PFOA in water, it begs the question of how much exposure can be reduced through regulation of PFOS/PFOA in water.

EPA Response: The EPA expects there will be a reduction in human exposure to regulated PFAS through implementation of this final rule. The EPA has estimated the reduced exposure to the regulated PFAS that will occur as a result of the final rule by characterizing the baseline (exposure in the absence of the PFAS NPDWR) and the populations served by water systems that are expected to exceed the final MCLs. For more information see Chapter 4 of the EA. For the EPA's response to comments regarding monitoring and compliance requirements of the rule, see section 8 in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-045691)

IX. THE SDWA REQUIRES A COST-BENEFIT ANALYSIS FOR EACH MCL

The SDWA was amended in 1996 to specifically require cost-benefit analysis as part of the regulatory process. Id. [sec] 300g-1(b)(3)(C), (4)(C). For each drinking water standard and each alternative standard being considered by EPA, [sec] 1412(b)(3)(C)(i) provides that EPA must publish and seek public comment on an analysis of the health risk reduction benefits and costs associated with the proposed MCL. Id. [sec] 300g-1(b)(3)(C)(i). The purpose of the cost-benefit analyses is to determine whether the benefits of the MCL justify, or do not justify, the costs of the proposed regulation.

EPA failed to determine whether the benefits of the HI-MCL justify the costs of the proposed regulation as it did not quantify benefits for any health point for PFHxS (USEPA 2023i). Because there is no quantitative benefit analysis for the HI portion of the rule, there cannot be a cost-benefit analysis for that portion of the rule. This violates the SDWA.

EPA Response: The EPA disagrees with the commenter's assertion that the EPA "failed to determine whether the benefits of the HI-MCL justify the costs" and that the EPA's analysis "violates the SDWA." The EPA completed a benefits analysis for the Hazard Index contaminants (specifically PFHxS, PFNA, HFPO-DA, and PFBS) consistent with the requirements under the SDWA. The commenter incorrectly states that the "EPA failed to determine whether the benefits of the HI-MCL justify the costs" because the EPA "did not quantify benefits for any health point for PFHxS." The EPA clarifies to the commenter that the agency estimated PFHxS treatment costs in the national quantitative analysis and also quantified the costs associated with PFNA, HFPO-DA, and PFBS treatment in Appendix N.3 and N.4 of the EA (USEPA, 2024c). The commenter has misinterpreted the statute and the EPA clarifies to the commenter that the SDWA allows for both quantifiable and nonquantifiable benefits analysis for MCLs. In the case of this rulemaking, the EPA completed a robust nonquantifiable benefits analysis for Hazard Index contaminants, specifically PFHxS, PFNA, HFPO-DA, and PFBS. The nonquantifiable benefits analysis describes the many adverse health effects associated with these PFAS and is described

in detail within section 6.2 of the EA (USEPA, 2024bb) and section XII of the FRN for the final rule. Specifically, and as described in the EA and the FRN, the qualitatively discussed health impacts of these four PFAS are considerable and include cancer, birth weight, endocrine, immune, and hepatic effects; reducing human exposure to them is expected to reduce the incidence of adverse health impacts including cardiovascular, developmental, and immune effects. Additionally, the EPA completed a quantitative sensitivity analysis of birth weight benefits associated with PFNA exposure reductions, which is described in Appendix K of the EA (USEPA, 2024c). Under the proposed PFAS NPDWR, the agency fully considered the costs and benefits of the action, including the quantifiable and nonquantifiable benefits and costs, and the EPA Administrator determined that the benefits of the rule justified the costs. For the final rule, the EPA is reaffirming the Administrator's determination made at proposal that the quantified and nonquantifiable benefits of the rule justify its quantified and nonquantifiable costs (88 FR 18638).

13.5 Nonquantifiable Benefits of PFOA and PFOS Exposure Reduction

Summary of Major Public Comments and EPA Responses

The EPA received comments concerning the nonquantifiable benefits of PFOA and PFOS exposure reduction. One commenter claimed that the EPA's nonquantified benefits are not supported by the science. The commenter asserted that the "EPA makes overly conservative decisions to protect against what is portrayed to be an array of affects from additional PFAS not directly addressed by the proposal" and that "for the large majority of health endpoints discussed, EPA has not provided a factual basis by which to conclude that such benefits are likely to occur when EPA decreases the levels of PFAS in drinking water." The commenter was critical of the EPA's consideration of nonquantifiable benefits associated with PFOA and PFOS such as nonquantifiable benefits associated with reductions in several health effects (including hepatic and endocrine effects) where the EPA characterized the evidence as inconsistent. For hepatic effects, the EPA's toxicity assessments determined that exposure to PFOA/PFOS causes hepatic toxicity in humans. However, the EPA did not quantify benefits for hepatic effects because although there will be benefits delivered by reducing PFOA and PFOS in drinking water, there is a lack of adequate data available to accurately quantify those benefits. Further information on health effects related to PFAS exposures is provided in the health assessments within the EPA's final toxicity assessment documents (USEPA, 2024h; USEPA, 2024i). The EPA disagrees with the commenter's assertion that the agency has not provided a factual basis for the benefits that are likely to occur as a result of the rule. The EPA has provided sufficient factual basis for the quantifiable and nonquantifiable health endpoints discussed in the HRRCA and has evaluated the best available science in support of the HRRCA, as required under the SDWA. The EPA has reviewed and cited to hundreds of peer reviewed studies that discuss a wide variety of health effects caused by PFAS: many of those studies document the exact non-quantifiable health effects for which the commenter claims there is no factual evidence.

The EPA further disagrees with the commenter's assertion that claims about non-quantifiable benefits are not supported by the EPA's own benefits analysis. The EPA has noted that quantified benefits were evaluated for some health outcomes for which the toxicity assessments found that evidence indicates an association with PFOS or PFOA (USEPA, 2024h; USEPA, 2024i). This does not preclude the EPA from assessing non-quantified benefits for which evidence of an association was determined to be suggestive (e.g., endocrine effects), and in fact, SDWA is explicit that the EPA must consider non-quantifiable and quantifiable benefits from regulating a given contaminant. SDWA Section 1412(b)(3)(C). While the EPA acknowledges that the evidence of adverse health effects can sometimes be more limited for other PFAS, this is the exact reason why the EPA did not quantify those benefits and instead characterizes them in a nonquantifiable fashion, consistent with the scientific literature. The EPA notes that the PFOA and PFOS toxicity assessments summarize the available health effects literature, of which there are thousands of health effects studies. Evidence on health effects associated with PFAS exposure is supportive of the EPA's conclusions on nonquantified benefits. Additionally, the body of evidence for a wide range of adverse health effects from PFAS is growing, demonstrated most recently by a study from the peer reviewed literature (Jones et al., 2023), which shows evidence of associations between some PFAS and childhood acute lymphoblastic leukemia. In short, the EPA believes the commenter is incorrect and that, as demonstrated by the substantial body of scientific literature documenting a wide variety of adverse health effects from exposure to a wide variety of PFAS, the EPA has appropriately considered the nonquantifiable benefits as outlined in Sections VIII of the preamble for this rule and Section 6.2.4 of the EA.

One commenter stated that the (HRRCA underestimates significant health and environmental benefits of the proposed drinking water regulations. The commenter noted that impacts on immune system dysfunction and on women's breast cancer risk and lactation duration are "not properly accounted for in the HRRCA." The EPA agrees with the commenter that the quantified benefits associated with the PFAS NPDWR are underestimated; however, the EPA notes that the agency has considered numerous adverse health endpoints in its nonquantifiable benefits analyses. In the FRN and also the economic analysis for the final PFAS NPDWR, the EPA describes the unquantified adverse health effects that are associated with exposure to the PFAS included in the regulation and also PFAS that are anticipated to be co-removed as a function of treatment. In summary, the EPA anticipates significant additional benefits that cannot be quantified will result from avoided developmental, cardiovascular, liver, immune, endocrine, metabolic, reproductive, musculoskeletal, and carcinogenic effects as a result of reductions in the levels of the regulated PFAS and other co-removed contaminants. For detailed information on unquantified benefits, please refer to section XII of the FRN and also Chapter 6 of the EA for the final rule (USEPA 2024bb).

Another commenter described several adverse health effects associated with PFAS exposure that the EPA did not quantify. The commenter stated that PFAS exposure is associated with a wide range of adverse health effects including reproductive, developmental, cancer, and other effects. The commenter urged the EPA to expand upon its quantification and, where supported, monetization of the Proposed Rule's benefits. The commenter further claimed that when

measuring the Proposed Rule's benefits, the EPA ignored or improperly dismissed evidence of the connection between PFAS and liver disease, impaired mammary gland development and reduced lactation duration, and immune system suppression and increased susceptibility to infectious disease, and thus failed to measure all of the benefits attributable to the Proposed Rule's reduction in PFAS exposures. The commenter also stated that the EPA should reconsider its omission of reduced testicular cancer incidence from its assessment of the Proposed Rule's benefits. This commenter raised that the EPA incorrectly omitted the opportunity cost of time in valuing non-fatal illnesses, which "likely results in a significant underestimate of the benefits" and recommended that the EPA use willingness to pay information to account for the opportunity cost of time when literature was available to do so. Lastly, the commenter stated that the EPA should consider illustrative analyses or a "break-even" analysis to provide further insight on the potential magnitude of qualitatively discussed benefits.

In response to the commenter's request for the EPA to quantify additional benefits, the EPA reevaluated whether there were additional benefits the agency could quantify. Based on this reevaluation, the agency determined that it could prepare a quantitative estimate of liver cancer benefits associated with reduced exposure to PFOS for the final rule based on animal toxicity data. See Appendix O in the Economic Analysis for a discussion of liver cancer benefits analysis methodology and results. The EPA disagrees with the commenter's assertion that the EPA "ignored or improperly dismissed evidence of the connection between PFAS and liver disease, impaired mammary gland development and reduced lactation duration, and immune system suppression and increased susceptibility to infectious disease." The EPA did consider the connection between PFAS and liver disease in its nonquantifiable benefits analysis, and the nonquantifiable benefits analysis helps inform the Administrator's determination that the costs of the PFAS NPDWR are justified by the benefits.

The EPA disagrees with the commenter's assertion that the EPA ignored or improperly dismissed evidence of the connection between PFAS and immune system suppression and increased susceptibility to infectious disease. The EPA did consider the connection between PFAS and immune system suppression in its nonquantifiable benefits analysis. The EPA clearly stated that immune effects had indicative evidence of associations with exposure to PFOA and PFOS. Additionally, the EPA identified studies that observed the potential for adverse COVID-19 impacts in persons with elevated PFAS exposure. These studies suggested immunosuppressive effects of PFAS and/or increased COVID-19 respiratory toxicity due to PFAS exposure, as described in Sections 6.2.2 and 6.2.3 of the EA (USEPA, 2024b). Although these studies provide a suggestion of possible associations, the body of evidence does not permit any conclusions about the relationship between COVID-19 infection, severity, or mortality, and exposures to PFAS.

With respect to the portion of the comment asserting that the EPA ignored PFAS effects on liver disease, the EPA determined that the evidence indicates that PFOA and PFOS exposures are likely to cause hepatotoxicity in humans under relevant exposure circumstances and epidemiological studies show consistent evidence of a positive association with alanine

aminotransferase (ALT) in adults. However, while increased ALT is considered an adverse effect, ALT can be one of several contributors to a variety of diseases, including liver disease, and it is difficult to therefore quantify the relationship between this biomarker and a disease that can be monetized.

In conclusion, the EPA disagrees with the commenter's statement that additional health endpoints were not adequately considered in the analysis. The EPA did consider a wide variety of adverse health effects as part of its nonquantifiable benefits analysis, and the agency quantified benefits where the agency deemed there was sufficient information or purpose to do so. To quantify benefits, the EPA systematically assessed each endpoint with evidence of an association in humans to select endpoints with robust links to adverse human health outcomes and minimize duplication of health impact estimates. The EPA also prioritized endpoints for quantification based on whether the expected magnitude of the impact would meaningfully inform policy decisions, which is consistent with OMB guidance stating that "analytic priority should be given to those additional benefits, costs, and transfers that are important enough to potentially change the rank ordering of the main alternatives in the analysis" (OMB, 2003). For some endpoints such as testicular cancer, the magnitude of the potential benefits was not expected to influence policy decisions materially (see Section 6.2.2.2 of the main EA).

The EPA disagrees with the commenter's statement that additional break-even analyses should have been implemented for endpoints that lack evidence of association in humans but have valuation information readily available. The majority of the endpoints in the qualitative benefit group were non-specific as disease biomarkers, or the relationship between these endpoints and human disease states was complex (e.g., vitamin D levels, hemoglobin levels, uric acid levels, body weight); these endpoints do not have readily available valuation information and, thus, are not candidates for a break-even analysis. A few other endpoints in this group were more directly linked to human disease states (e.g., gestational hypertension/preeclampsia, thyroid hormone disruption) and, therefore, more amenable to valuation, however, these endpoints were not prioritized because information produced by these analyses would not have meaningfully informed policy decisions relative to the health endpoints that have already been quantified, and this prioritization is consistent with OMB Circular A-4 guidance (OMB, 2003; OMB, 2023).

Individual Public Comments

Minnesota Center for Environmental Advocacy et al. (Doc. #1707, SBC-045726)

1. The Benefits of Imposing the Proposed MCLs are Immense

When EPA Commissioner Reagan determined in the proposed NPDWR that the benefits of the Proposed Rule outweighed the costs, the Agency pointed to a diverse set of data to support that finding. Commenters write to remind the Agency that behind the numbers are real people whose stories with PFAS are riddled with expensive doctor visits, missed time from work, and lives lost or forever changed.

Calculating the financial benefit from preventing just one PFAS-related health impact is an inexact science. Actuarial tables, workers' compensation benefit charts, and insurance adjusters endeavor to pin a dollar amount of each year of life cut short from what is expected or how much a limb is worth. But these blunt instruments are unable to put a value on the laughter, hugs, or milestones that go missing when someone dies early. This rough science lacks compassion and fails to reflect that the true cost of cancer and other PFAS-related aliments is borne by family, friends, and the greater community who watches while individuals are ravaged by rare and debilitating diseases.

For these reasons, the Strande's estimated $50,000 annual outlay for Amara's treatment does not include the anguish, grief, and pain shared by Amara's loved ones. And how do you put a price on JD's difficulty forming new memories? How much value do we assign the ability to recall life's most beautiful moments, or remember details about a work assignment or a school project? And how do we account for the collective anxiety of tens of thousands of East Metro residents who are uncertain if the tap water in the homes, schools, and places of work is slowly killing them?

The true value of EPA's Proposed Rule is communities with bright futures, with graduating classes of high school students not decimated by abnormally high cancer rates, and with individuals who will have the opportunity to live full, productive lives. EPA must remember the real benefits behind enacting the Proposed Rule, benefits that are measured not in dollars and cents but in memories, laughs, and years with loved ones not clouded by cancer.

EPA Response: The EPA agrees with the commenter that the PFAS NPDWR will result in substantial, lasting human health benefits. See section 13.5 of the EPA response in this *Response to Comments* document. The EPA further notes that the quantified benefits analysis associated with PFAS exposure reductions is limited to health effects with exposure response information and economic data to monetize the impacts, and quantified benefits are likely underestimated as a result. The information available to effectively value lost opportunity and productivity as a result of avoided morbidity and mortality for health effects quantified in this NPWDR is limited, and as such, the quantified benefits estimated for the NPDWR are likely underestimated. Based on this and other comments, for the final rule, the EPA included a sensitivity analysis for bladder and kidney cancer exposure reductions where willingness to pay information was used for valuation, which accounts for lost productivity and opportunity costs (see Appendix O in USEPA, 2024c). In addition to the valuation limitations for quantified health effects, there are also many adverse health effects associated with PFAS exposure that the EPA was unable to quantify for this NPDWR, which also results in underestimated quantified benefits. Considering both quantified and nonquantifiable costs and benefits, the EPA has reaffirmed that the benefits associated with the rulemaking justify the costs.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045923)

5. EPA claims of non-quantified benefits are not supported by the science

For PFOA, PFOS, PFNA, PFBS, PFHxS, and HFPO-DA, EPA makes repeated claims about non-quantifiable benefits. These claims are not supported by EPA's own benefits analysis. For instance, while EPA purports that there are non-quantified benefits to the hepatic system from decreasing PFOS exposure, in discussing ALT levels, EPA notes that "[s]tudy results showed inconsistent evidence on whether the observed changes led to changes in specific liver disease"[FN202: See EPA Economic Analysis of the Proposed National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances, 2023, at page 6-18.]. EPA refers to the ALT endpoint, which it determined was a critical effect for the RfD, as a "non-specific biomarker."[FN203: Id. at 6-21.] When discussing endocrine effects, EPA states: "[e]pidemiology studies reported inconsistent evidence regarding associations between PFOA and PFOS exposure and general endocrine outcomes, such as thyroid disease, hypothyroidism, and hypothyroxinemia."[FN204: Id. at 6-19.] Regarding musculoskeletal effects EPA states: "[s]ome studies found that PFOA/PFOS exposure was linked to osteoarthritis, in particular among women under 50 years of age (ATSDR, 2021). However, other reviews reported mixed findings on the effects of PFOS exposure including decreased risk of osteoarthritis, increased risk for some demographic subgroups, or no association (ATSDR, 2021)."[FN205: Id. at 6-20.]

When discussing the non-quantified effects of other PFAS, the data are even more limited. For instance, while EPA mentions inconsistent evidence on associations between PFNA with cardiovascular effects, EPA also notes that for "[o]ther PFAS for which lipid outcomes were examined in toxicology or epidemiology studies observed limited to no evidence of associations. Studies have examined possible associations between various PFAS and blood pressure in humans or heart histopathology in animals. However, studies did not find suggestive or likely evidence for any PFAS in this summary except for PFOS."[FN206: Id. at 6-23.] Throughout the proposed rule, EPA makes overly conservative decisions to protect against what is portrayed to be an array of affects from additional PFAS not directly addressed by the proposal. However, the scientific information in EPA's benefits analysis, when held to the scientific requirements of SDWA, does not support this approach. For the large majority of health endpoints discussed, EPA has not provided a factual basis by which to conclude that such benefits are likely to occur when EPA decreases the levels of PFAS in drinking water.

EPA Response: The EPA disagrees with the commenter's assertion that the agency has not provided a factual basis for the benefits that are likely to occur as a result of the rule. Please see section 13.5 of the EPA response in this *Response to Comments* document. The EPA has provided sufficient factual basis for the quantifiable and non-quantifiable health endpoints discussed in the HRRCA and the record is based on an evaluation of the best available science in support of the HRRCA, as required under the SDWA.

The EPA disagrees with the commenter's assertion that claims about non-quantifiable benefits are not supported by the EPA's own benefits analysis. The EPA has noted that quantified benefits were evaluated for some health outcomes for which the toxicity assessments found that evidence indicates an association with PFOS or PFOA (USEPA, 2024h; USEPA, 2024i). This does not preclude the EPA from assessing non-quantified benefits for which evidence of an association was determined to be suggestive, as was the case for endocrine or musculoskeletal effects. For

ALT, the EPA has indeed concluded that the available evidence supports selection of increased ALT as a critical effect for candidate RfD derivation. Changes in ALT associated with PFOS or PFOA can be clinically relevant, a position supported by the SAB PFAS Review Panel in their final report (USEPA, 2022d; pg. 28). As previous research on lead exposure has found, although small changes in an outcome (e.g., ALT) at the individual level may or may not reach a level considered clinically significant, such small changes can result in substantial health impacts at the population level (Gilbert and Weiss, 2006). Rationale supporting the agency's selection of increased ALT as a critical effect is presented in section 4.2.1.5 and 4.2.2.3.3 of this *Response to Comments* document, as well as in Sections 3.4.1.4 and 4.1.1 of the Final Toxicity Assessments for PFOA and PFOS (USEPA, 2024h; USEPA, 2024i).

There is sufficient evidence in the record for this action demonstrating the rule will result in significant nonquantifiable benefits for other PFAS. In addition to the evidence of health impacts of other PFAS discussed in the EA for this final rule, new evidence on the impacts of other PFAS, especially on the impact of PFAS on CVD is emerging and supportive of the EPA's conclusions on nonquantified benefits: a recent meta-analysis reports that PFAS exposure might be associated with moderate overall effect on CVD, including hypertension (Abdullah Soheimi et al., 2021). The EPA also notes that the PFHxS IRIS assessment determined that the evidence suggests cardiometabolic effects in humans. The PFNA IRIS Assessment is currently under development, and is informed by many of the same studies from the PFHxS assessment and the PFOA/PFOS toxicity assessments. See section 13.5 of the EPA response in this *Response to Comments* document and Chapter 6.2.4 of the economic analysis of nonquantifiable benefits for more discussion about nonquantifiable benefits. Additionally, the EPA notes that the administrative record for this action contains hundreds of scientific sources which clearly highlight adverse health effects associated with multiple PFAS. See the section 13.6 of the EPA response in this *Response to Comments* document for further information on comments received on nonquantifiable benefits for other PFAS.

<u>PFAS Project Lab (Doc. #1786, SBC-044718)</u>

The Health Risk Reduction and Cost Analysis (HRRCA) underestimates significant health and environmental benefits of the proposed drinking water regulations

We agree with EPA's own economic analysis that there "are significant nonquantifiable sources of benefits that were not captured in the quantified benefits." The includes numerous health benefits and medical savings beyond the very limited ones quantified in the analysis. For example, impacts on immune system dysfunction and on women's breast cancer risk and lactation duration, are just some risks that are not properly accounted for in the HRRCA.

EPA Response: Please see section 13.5 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046110)

In addition to maintaining or expanding upon these robust features of the Draft EA, there are several ways that EPA can and should strengthen the EA. These are outlined in detail in Dr. Guignet's analysis, and we highlight several key recommendations here:

First, EPA should utilize the best available scientific and economic information to quantify and/or monetize additional benefits of the rule in the final EA. In the Proposed Rule, EPA correctly determined that:

PFAS exposure is associated with a wide range of adverse health effects including reproductive effects such as decreased fertility; increased high blood pressure in pregnant women; developmental effects or delays in children, including low birth weight, accelerated puberty, bone variations, or behavioral changes; increased risk of some cancers, including prostate, kidney, and testicular cancers; reduced ability of the body's immune system to fight infections, including reduced vaccine response; interference with the body's natural hormones; and increased cholesterol levels and/or risk of obesity. [FN117: Proposed Rule, 88 Fed. Reg. at 18,725.]

Yet EPA quantified only "three PFOA- and PFOS-related health endpoints in [the economic] analysis," while recognizing that the rule is "expected to produce substantial benefits that have not been quantified." [FN118: Id.]

We urge EPA to expand upon its quantification and, where supported, monetization of the Proposed Rule's benefits. As explained by Dr. Guignet, EPA's economic analysis guidance dictates that the agency

should try to get as far as possible in first identifying all key benefit and cost categories. The next step (when possible) is to then quantify the projected change in each benefit and cost outcome that is expected to result from the policy option, relative to the baseline. Quantifying in this case means to measure the change in terms of some quantitative metric, such as the number of lives saved, number of cases prevented, etc. The final step is to monetize the quantified change, meaning that a dollar value is assigned. [FN119: Guignet 2023 at 9.]

Here, consistent with recently proposed revisions to OMB's Circular A4, EPA should assess and disclose the expected magnitude of benefits that EPA recognized but did not quantify. [FN120: Id. at 10.] This would enable some quantification of additional benefits, even if fully monetizing a benefit category is not possible. In addition, where quantification is not possible, EPA should utilize available monetary cost-of-illness or willingness to pay estimates to illustrate the potential magnitude of benefits discussed qualitatively. [FN121: Id.]

In addition, as summarized in the accompanying analysis by Drs. Anna Reade and Katherine Pelch, the best available science supports EPA's consideration, and potential quantification and monetization, of additional regulatory benefits. [Fn122: See generally Reade and Pelch 2023.] When measuring the Proposed Rule's benefits, EPA ignored or improperly dismissed evidence of the connection between PFAS and liver disease, impaired mammary gland development and

reduced lactation duration, and immune system suppression and increased susceptibility to infectious disease. EPA thus failed to measure all of the benefits attributable to the Proposed Rule's reduction in PFAS exposures. At a minimum, EPA should assess these benefits qualitatively and it should utilize the analysis provided by Drs. Reade and Pelch to attempt to quantify and, where possible, monetize these benefits as well. [FN123: Id.; Guignet 2023 at 10.]

EPA should also reconsider its omission of reduced testicular cancer incidence from its assessment of the Proposed Rule's benefits. To justify that omission, EPA asserts in the Draft EA that "testicular cancer is rarely fatal which implies low expected economic value of reducing this risk because Value of Statistical Life is the driver of the economic benefits evaluated in the EA." [FN124: Draft EA at 6-21– 6-22.] But that assertion is not well supported. While the Draft EA relies on the Value of Statistical Life metric "[t]o estimate the economic value of avoided premature deaths" associated with the rule, it utilizes the cost of illness (COI) valuation approach "[t]o estimate the economic value of avoided morbidity (i.e., non-fatal heart attacks and ischemic strokes, birth weight decrements, and cancers)," with the COI values "reflect[ing] medical care expenditures and opportunity costs associated with managing/treating the condition." [FN125: Id. at 2-4.] EPA has not explained why COI-based valuation of avoided non-fatal testicular cancer cases is not justified. EPA also has not provided a reasoned basis to dismiss as "implie[dly] low" the expected economic value of reducing testicular cancer risks associated with PFOA exposure because EPA has not attempted to estimate the economic value of reducing this risk. [FN126: Id. at 6-21.] Moreover, as explained by Dr. Guignet, the COI values EPA did employ to evaluate the benefits of reducing other non-fatal health effects incorrectly omit the opportunity cost of time, which, as elaborated below, "likely results in a significant underestimate of the benefits." [FN127: Guignet 2023 at 12.] For this reason too, EPA's speculation that the economic value of avoided testicular cancer cases would be "low" is unsupported. In the final EA, EPA should estimate the economic value of reduced testicular cancer cases associated with the Proposed Rule. [FN128: Peer-reviewed literature is available to support the monetization of avoided testicular cancer cases. See, e.g., Michael Aberger et al., Testicular Self-Examination and Testicular Cancer: A Cost Utility Analysis, 3 Cancer Med. 1629 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4298389/.] In doing so, EPA should utilize COI estimates that properly account for the opportunity cost of time in addition to avoided medical expenses or use willingness-to- pay estimates where supported by the literature. [FN129: Guignet 2023 at 12.]

EPA Response: In response to this and other comments requesting that the EPA quantify additional benefits, the EPA identified information in the administrative record of this action that allowed the EPA to prepare a quantitative estimate of liver cancer benefits associated with reduced exposure to PFOS for the final rule. See Appendix O in the Economic Analysis for a discussion of liver cancer benefits analysis methodology and results (USEPA, 2024c).

The EPA disagrees with the commenter's assertion that the EPA "ignored or improperly dismissed evidence of the connection between PFAS and liver disease, impaired mammary gland development and reduced lactation duration, and immune system suppression and increased susceptibility to infectious disease." Regarding the agency's consideration of impaired mammary

gland development, please see the EPA response to comment Doc. #1784, SBC-045800 in section 4.2.1.6 in this *Response to Comments* document.

The EPA disagrees with the commenter's assertion that the EPA ignored or improperly dismissed evidence of the connection between PFAS and immune system suppression and increased susceptibility to infectious disease. As discussed in the section 13.5 of the EPA response in this *Response to Comments* document, the EPA clearly stated that immune effects had indicative evidence of associations with exposure to PFOA and PFOS. However, the EPA did not identify the necessary information to connect the measured biomarker responses (i.e., decrease in antibodies) to a disease that could be valued in the economic analysis. It is difficult to quantitate the relationship between altered immune responses, such as decreases in antibody production, and frequency or severity of disease in inherently diverse human populations.

The EPA determined that the evidence indicates that PFOA and PFOS exposures are likely to cause hepatotoxicity in humans under relevant exposure circumstances. In human studies, there is consistent evidence of a positive association with ALT in adults. Associations for other hepatic outcomes were less consistent, including for functional outcomes such as liver disease. Elevated liver serum biomarkers are frequently an indication of liver injury, though not as specific as structural or functional analyses such as histology findings and liver disease. The EPA agrees that there is evidence from animal studies that PFAS exposure causes liver toxicity across animal species. However, there is also literature that supports that steatosis, non-alcoholic fatty liver disease , and alcoholic liver disease can be common causes of mild elevations in liver enzyme levels (Oh, 2017; Giannini, 2005; Kwo, 2017).

In regard to quantifying additional health endpoints in the benefits analysis, the EPA systematically assessed each endpoint with evidence of an association in humans to select endpoints with robust links to adverse human health outcomes and minimize duplication of health impact estimates. The EPA also prioritized endpoints for quantification based on whether the expected magnitude of the impact would meaningfully inform policy decisions, which is consistent with OMB guidance stating that "analytic priority should be given to those additional benefits, costs, and transfers that are important enough to potentially change the rank ordering of the main alternatives in the analysis" (OMB, 2003). As a result, the EPA quantified impacts for total cholesterol, blood pressure, and high-density lipoprotein cholesterol as part of cardiovascular disease impacts, birth weight, renal cell carcinoma, and liver cancer because these endpoints met the EPA's criteria for quantification. For endpoints like small for gestational age, there was an overlap with birth weight, and low-density lipoprotein cholesterol overlapped with total cholesterol and high-density lipoprotein cholesterol, so these were not separately quantified. Several unquantified endpoints were non-specific as disease biomarkers or the relationship between the biomarker and disease outcomes was complex. For instance, while linked to fatty liver disease, ALT levels can be affected by medication use (e.g., Tylenol and statins) and conditions such as hepatitis (A, B, C), heart failure, obesity, and drinking alcohol. Further, the relationship between leptin and diabetes is complex, with some evidence of the protective effects of leptin for non-obese individuals and research on leptin therapy for diabetic persons (Schmidt et al., 2006). Finally, for some endpoints, the magnitude of the potential benefits was not

expected to influence policy decisions materially. For example, based on the epidemiological information and relative magnitude of the PFOA slope factors for testicular cancer and RCC, the EPA expects that avoided testicular cancer cases would represent 14 percent of RCC cases and an even smaller share of avoided cancer deaths because of high survival rates for testicular cancer (ACS, 2023). See section 13.5 of the EPA response in this *Response to Comments* document and EA Section 6.2.3 for further discussion.

Earthjustice et al. (Doc. #1808, SBC-046123)

Exhibit A

May 30, 2023

Via Regulations.gov

Assistant Administrator Radhika Fox

Office of Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, N.W.

Washington, DC 20460

Re: PFAS National Primary Drinking Water Regulation Rulemaking, Docket No. EPA–HQ–OW–2022–0114

Dear Assistant Administrator Fox:

While EPA's proposed National Primary Drinking Water Standards acknowledge a broad range of adverse health effects from PFAS exposures, EPA has not fully accounted for those effects, or the corresponding benefits of the proposed regulation, in its analysis of the rule's economic impacts. [FN1: Preliminary Regulatory Determination and Proposed Rule, PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18,638 (Mar. 29, 2023) (the "Proposed Rule"). The six PFAS covered by the Proposed Rule are perfluorooctanoic acid ("PFOA"), perfluorooctane sulfonic acid ("PFOS"), perfluorohexane sulfonic acid ("PFHxS"), hexafluoropropylene oxide dimer acid and its ammonium salt ("GenX"), perfluorononanoic acid ("PFNA"), and perfluorobutane sulfonic acid ("PFBS") (collectively, the "Six PFAS").] This document summarizes several of the health effects that EPA failed to quantify and provides resources and information that EPA should use to estimate additional benefits of the proposed drinking water standards.

Together, we have extensive experience reviewing the health and toxicological effects associated with PFAS exposure. As co-leads on the development of the PFAS-Tox Database, we have reviewed over 1,000 studies that evaluate the health impact of PFAS exposure. [FN2: Katherine E. Pelch, Anna Reade, Carol F. Kwiatkowski, Francheska M. Merced-Nieves, Haleigh Cavalier,

Kim Schultz, Taylor Wolffe, and Julia Varshavsky, The PFAS-Tox Database: A Systematic Evidence Map of Health Studies on 29 per- and Polyfluoroalkyl Substances, Environment International 167 (September 1, 2022): 107408, https://doi.org/10.1016/j.envint.2022.107408; Katherine E. Pelch, Anna Reade, Taylor A. M. Wolffe, and Carol F. Kwiatkowski, PFAS Health Effects Database: Protocol for a Systematic Evidence Map, Environment International 130 (September 1, 2019): 104851, https://doi.org/10.1016/j.envint.2019.05.045; Katherine E. Pelch and Carol F. Kwiatkowski, Invited Perspective: The Promise of Fit-for-Purpose Systematic Evidence Maps for Supporting Regulatory Health Assessment, Environmental Health Perspectives 130, no. 5 (May 2022): 051303, https://doi.org/10.1289/EHP10743.] We have also provided public comment on ATSDR's "Toxicological Profile for Perfluoroalkyls", EPA's PFAS toxicity assessments for PFOA, PFOS, PFBA, PFHxA, GenX, and PFBS, and Health Canada's Draft Objective for Drinking Water. [FN3: Anna Reade, Comments on ATSDR Toxicological Profile on Perfluoroalkyls 2018 Draft, September 6, 2018. https://www.nrdc.org/sites/default/files/comments-on-atsdr-toxicological- profile-on-perfluoroalkyls-2018-draft_2018-08-21.pdf; Katherine Pelch, Technical comments to the Science Advisory Board on the U.S. Environmental Protection Agency external peer review draft: Proposed approaches to the derivation of a draft maximum contaminant level goal for perfluorooctanoic acid (PFOA) (CASRN 335-67-1) in drinking water and External peer review draft: proposed approaches to the derivation of a draft maximum contaminant level goal for perfluorooctane sulfonic acid (PFOS) (CASRN 1763-23-1) in drinking water, December 23, 2021; Katherine Pelch and Anna Reade, Comments on EPA's Draft Toxicological Review for Perfluorobutanoic Acid (PFBA), November 8, 2021; Katherine Pelch, Comments on EPA's Draft Toxicological Review for Perfluorohexanoic Acid (PFHxA), April 4, 2022; Katherine E. Pelch, Anna Reade, Sonya Lunder, David Q. Andrews, and Ansje Miller, Comments on EPA's Draft Toxicity Assessments for Perfluorobutane Sulfonic Acid (PFBS) and Hexafluoroproyplene Oxide (or GenX Chemicals), January 22, 2019. https://www.nrdc.org/sites/default/files/comments-assessments-of-pfbs-and-genx-01222019.pdf; Katherine E. Pelch and Anna Reade, RE: Draft Objective for per- and Polyfluoroalkyl Substances in Canadian Drinking Water, April 12, 2023.] We have also critically evaluated and commented on health and risk assessment documents for PFAS developed by California, Illinois, Michigan, New Hampshire, New Jersey, New York, Vermont, and Washington. [FN4: Anna Reade, Avinash Kar, and Katherine E. Pelch, Technical Comments RE: Consideration of Perfluorooctane Sulfonic Acid (PFOS) and Its Salts and Transformation and Degradation Precursors for Possible Listing under Proposition 65 Based on Carcinogenicity, November 2021; Anna Reade, Avinash Kar, and Andria Ventura, Comments RE: Consideration of Perfluorononanoic Acid (PFNA) and Perfluorodecanoic Acid (PFDA) and Their Salts for Possible Listing under Proposition 65 Based on Developmental Reproductive Toxicity, November 15, 2021; Anna Reade, Katherine E. Pelch, Nicole Saulsberry, and Iyana Simba, Technical Comments Re 35 Ill. Adm. Code 620; Groundwater Quality Pre-Filing Public Comment Period. Joint Comments by Natural Resources Defense Council, Illinois Environmental Council and Sierra Club, Illinois Chapter, June 5, 2021; Anna Reade, Tracy Quinn, Judith S Schreiber, and Schreiber Scientific, Scientific and Policy Assessment for Addressing Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water, March 15, 2019,

https://www.nrdc.org/sites/default/files/assessment-for-addressing-pfas-chemicals-in-michigan-drinking-water.pdf; Anna Reade and Cyndi Roper, Comments of the Natural Resources Defense Council on the Michigan Department of Environment, Great Lakes, and Energy's Proposed PFAS MCLs Pending Rule Set: 2019-35-EG, January 31, 2020; Katherine E. Pelch and Carol F. Kwiatkowski, Comments on New Hampshire Department of Environmental Services Proposed Rulemaking to Set Public Drinking Water and Groundwater Standards for PFOA, PFOS, PFNA, & PFHxS (Env-Dw 700-800 and Env-Or 603.03), November 7, 2018; Katherine E. Pelch, Comments Re: Setting Public Drinking Water and Groundwater Standards for PFOA, PFOS, PFNA, & PFHxS (Env-Dw 700-800; Env-Or 603.03), April 12, 2019; Katherine E. Pelch and Carol F. Kwiatkowski, Comments Re: Setting Public Drinking Water Standards for PFOA and PFOS, December 21, 2018; Anna Reade, Tracy Quinn, and Judith S Schreiber, Comments Re: Proposed Maximum Contaminant Level for Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS), DEP Dkt. No. 02-19-03, May 31, 2019, https://www.nrdc.org/sites/default/files/pfas-comments-nj-05312019.pdf; Anna Reade, Katie Pelch, Miriam Rotkin-Ellman, and Erik D. Olson, Comments to New York State Governor Hochul and New York State Commissioner Bassett on the Need to Establish Comprehensive, and Health Protective, Drinking Water Standards for PFAS, September 9, 2022; Anna Reade and Katherine E. Pelch, Technical Comments Re: Advance Notice on the Regulation of Perfluoroalkyl, Polyfluoroalkyl Substances (PFAS) as a Class, November 16, 2022, https://www.nrdc.org/sites/default/files/pfas-class-technical-comments-20201116.pdf; Erika Schreder and Katherine E. Pelch, Comments on Washington Department of Health's Draft Recommended State Action Levels for per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water: Approach, Methods and Supporting Information (Chapter 246-290 WAC) January 2020.] These activities inform our additional comments regarding EPA's proposed National Primary Drinking Water Standards, specifically identifying health effects that should have been better incorporated into the economic benefits analysis.

I. Lactation duration [FN5: We acknowledge helpful technical support and feedback from Dr. Megan Romano in the development of this section.]

EPA has not fully considered the impact of PFAS exposure on mammary gland development and function, and specifically on lactation duration. Given the importance of breastfeeding and its association with many other health impacts, this is a major oversight. Breastfeeding is associated with short- and long-term health benefits for both mother and child, but <30% of mothers in the U.S. continue any breastfeeding until the American Academy of Pediatrics (AAP) recommended 12 months. [FN6: Arthur I. Eidelman, Richard J. Schanler, Margreete Johnston, Susan Landers, Larry Noble, Kinga Szucs, and Laura Viehmann, Breastfeeding and the Use of Human Milk, Pediatrics 12, no. 3 (March 2012): e827–41, https://doi.org/10.1542/peds.2011-3552; CDC, Results: Breastfeeding Rates, Centers for Disease Control and Prevention, April 4, 2023, https://www.cdc.gov/breastfeeding/data/nis_data/results.html.] The benefits of human milk for children are well described, with health benefits extending into adulthood. [FN7: Stanley Ip, Mei Chung, Gowri Raman, Priscilla Chew, Nombulelo Magula, Deirdre DeVine, Thomas Trikalinos, and Joseph Lau, Breastfeeding and Maternal and Infant Health Outcomes in Developed

Countries, Evidence Report/Technology Assessment, no. 153 (April 2007): 1–186, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4781366/.] Potential health benefits of lactation for the mother are often described with the "reset" hypothesis, whereby the adverse cardiometabolic changes during gestation (insulin resistance, hyperlipidemia, and visceral fat of pregnancy) are ameliorated by breastfeeding. In contrast, without breastfeeding, these metabolic changes persist. [FN8: Alison M. Stuebe and Janet W. Rich-Edwards, The Reset Hypothesis: Lactation and Maternal Metabolism, American Journal of Perinatology 26, no. 1 (January 2009): 81–88, https://doi.org/10.1055/s-0028-1103034.] Meta-analyses with over 200,000 women confirmed relationships between breastfeeding for 12 months and protection against common adverse cardiometabolic health outcomes, including a 30% risk reduction for diabetes and a 13% risk reduction for hypertension. [FN9: Rabel Misbah Rameez, Divyajot Sadana, Simrat Kaur, Taha Ahmed, Jay Patel, Muhammad Shahzeb Khan, Sarah Misbah, Marian T. Simonson, Haris Riaz, and Haitham M. Ahmed, Association of Maternal Lactation With Diabetes and Hypertension: A Systematic Review and Meta-Analysis, JAMA Network Open 2, no. 10 (October 16, 2019): e1913401, https://doi.org/10.1001/jamanetworkopen.2019.13401.]

Importantly, shortened duration of breastfeeding has been associated with PFAS exposure in human studies. Six human studies, published between 2010 and 2022 were recently reviewed and evaluated in a meta-analysis. [FN10: Amalie Timmermann, Oyemwenosa N. Avenbuan, Megan E. Romano, Joseph M. Braun, Janne S. Tolstrup, Laura N. Vandenberg, and Suzanne E. Fenton, Per- and Polyfluoroalkyl Substances and Breastfeeding as a Vulnerable Function: A Systematic Review of Epidemiological Studies, Toxics 11, no. 4 (April 2023): 325, https://doi.org/10.3390/toxics11040325.] Four of the five included studies reported shortened total duration of breastfeeding with higher PFOS and PFOA exposure. The human epidemiological findings are consistent with findings from experimental animal studies. Despite these consistencies and the importance of breastfeeding duration on maternal and infant health, EPA failed to adequately review and consider shortened lactation duration in the 2023 Draft Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) in Drinking Water. In that document, EPA reviewed the animal evidence for impacts on mammary gland development and function but did not evaluate the corresponding epidemiological evidence. [FN11: US EPA, Public Comment Draft Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) in Drinking Water, Office of Water, March 14, 2023, https://www.epa.gov/system/files/documents/2023-03/MAIN_Proposed%20MCLG%20for%20PFOA%20in%20Drinking%20Water_3.9.23_For%20Proposal.pdf.]

The 2023 Draft Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) in Drinking Water cites but does not thoroughly discuss two of the epidemiological studies that are included in the recent meta-analysis on breastfeeding (Timmerman et al. 2017 and Romano et al. 2016) [FN12: Clara Amalie Gade Timmermann, Esben Budtz-Jørgensen, Maria Skaalum Petersen, Pál Weihe, Ulrike Steuerwald, Flemming Nielsen, Tina Kold Jensen, and Philippe Grandjean, Shorter Duration of Breastfeeding at Elevated Exposures to Perfluoroalkyl Substances, Reproductive Toxicology, Developmental

Origins of Disease, 68 (March 1, 2017): 164–70, https://doi.org/10.1016/j.reprotox.2016.07.010; Megan E. Romano, Yingying Xu, Antonia M. Calafat, Kimberly Yolton, Aimin Chen, Glenys M. Webster, Melissa N. Eliot, Cynthia R. Howard, Bruce P. Lanphear, and Joseph M. Braun, Maternal Serum Perfluoroalkyl Substances during Pregnancy and Duration of Breastfeeding, Environmental Research 149 (August 1, 2016): 239–46, https://doi.org/10.1016/j.envres.2016.04.034.], and fails to cite or discuss the four additional studies, including those published before the review cut-off date (Fei et al., 2010, Nielsen et al., 2022, Rosen et al., 2018, and Timmerman et al., 2021). [FN13: Chunyuan Fei, Joseph K. McLaughlin, Loren Lipworth, and Jørn Olsen, Maternal Concentrations of Perfluorooctanesulfonate (PFOS) and Perfluorooctanoate (PFOA) and Duration of Breastfeeding, Scandinavian Journal of Work, Environment & Health 36, no. 5 (September 2010): 413–21, https://doi.org/10.5271/sjweh.2908;Christel Nielsen, Ying Li, Magdalena Lewandowski, Tony Fletcher, and Kristina Jakobsson, Breastfeeding Initiation and Duration after High Exposure to Perfluoroalkyl Substances through Contaminated Drinking Water: A Cohort Study from Ronneby, Sweden, Environmental Research 207 (May 1, 2022): 112206, https://doi.org/10.1016/j.envres.2021.112206; Emma M. Rosen, Anne Lise Brantsæter, Rachel Carroll, Line S. Haug, Alison B. Singer, Shanshan Zhao, and Kelly K. Ferguson, Maternal Plasma Concentrations of Per- and Polyfluoroalkyl Substances and Breastfeeding Duration in the Norwegian Mother and Child Cohort, Environmental Epidemiology (Philadelphia, Pa.) 2, no. 3 (September 2018): e027, https://doi.org/10.1097/EE9.0000000000000027; Clara Amalie Gade Timmermann, Marianne Skovsager Andersen, Esben Budtz-Jørgensen, Henriette Boye, Flemming Nielsen, Richard Christian Jensen, Signe Bruun, Steffen Husby, Philippe Grandjean, and Tina Kold Jensen, Pregnancy Exposure to Perfluoroalkyl Substances and Associations With Prolactin Concentrations and Breastfeeding in the Odense Child Cohort, The Journal of Clinical Endocrinology and Metabolism 107, no. 2 (September 13, 2021): e631–42, https://doi.org/10.1210/clinem/dgab638.] None of the epidemiological studies are cited or discussed in the 2016 Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA). [FN14: US EPA, Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA), May 2016, https://www.epa.gov/sites/production/files/2016-05/documents/pfoa_health_advisory_final- plain.pdf.] Though the animal literature is discussed in the document, the 2016 Drinking Water Health Advisory for PFOA did not consider any candidate reference doses (RfDs) based on mammary gland effects.

Perhaps EPA's failure to adequately consider mammary gland and lactational effects in the 2023 toxicity assessment is, in part, a result of mammary gland impacts being improperly diminished in earlier documents. Evidence for this can be seen in the conclusions EPA makes in the 2023 toxicity assessment. In the 2023 Draft Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) in Drinking Water document EPA states, "no differences in response to a lactation challenge were seen in PFOA-exposed CD-1 mouse dams with delayed mammary gland development, and no significant effects on body weight gain were seen in pups nursing from dams with less fully developed mammary glands (White, 2011, 1276150)." [FN15: US EPA, Public Comment Draft Toxicity Assessment and

Proposed Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) in Drinking Water, Office of Water, March 14, 2023, https://www.epa.gov/system/files/documents/2023-03/MAIN_Proposed%20MCLG%20for%20PFOA%20in%20Drinking%20Water_3.9.23_For%20Proposal.pdf.] Similarly, ATSDR stated "… the mammary gland effect did not result in an adverse effect on lactational support at maternal doses as high as 1 mg/kg/day, based on normal growth and survival in F2 pups (White et al. 2011). Given that milk production was adequate to support growth, the biological significance of the delayed development of the mammary gland observed at very low doses is uncertain and was not considered a suitable basis for the MRL." [FN16: ATSDR, Toxicological Profile for Perfluoroalkyls, May 2021, https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf.]

However, these summaries simplify the complex behaviors that are observed during lactation between a mother (dam) and offspring (pup). The lactation challenge in White et al. 2011 only evaluated the amount of milk passed from the dam to the pups in a single nursing event; it did not account for compensatory behaviors that may have been present in the pups. [FN17: Sally S. White, Jason P. Stanko, Kayoko Kato, Antonia M. Calafat, Erin P. Hines, and Suzanne E. Fenton, Gestational and Chronic Low-Dose PFOA Exposures and Mammary Gland Growth and Differentiation in Three Generations of CD-1 Mice, Environmental Health Perspectives 119, no. 8 (August 2011): 1070–76, https://ehp.niehs.nih.gov/doi/epdf/10.1289/ehp.1002741.] The study authors added this additional context, stating "[t]hese data suggest that nursing behavior of the neonates may have changed (i.e., increased number of nursing events per day or longer nursing per event) to compensate for the decreased potential in milk production by the F1 dam, but we did not evaluate these end points in this study." [FN18: Id.] We previously submitted comments to ATSDR highlighting the agency's misinterpretation of the study by White et al. (2011), pointing out that "an estimated 3-6 million mothers each year are unable to produce milk or have difficulty breastfeeding. The cause of this remains unclear, however, exposure to toxic environmental chemicals are one candidate explanation for the inability to initiate and/or sustain breastfeeding." [FN19: Anna Reade, Comments on ATSDR Toxicological Profile on Perfluoroalkyls 2018 Draft," September 6, 2018, https://www.nrdc.org/sites/default/files/comments-on-atsdr-toxicological- profile-on-perfluoroalkyls-2018-draft_2018-08-21.pdf.]

Importantly, a 2009 workshop of experts in mammary gland biology and risk assessment came to the consensus that changes in mammary gland growth and differentiation, including changes in developmental timing, are a relevant human health concern. [FN20: Ruthann A. Rudel, Suzanne E. Fenton, Janet M. Ackerman, Susan Y. Euling, and Susan L. Makris, Environmental Exposures and Mammary Gland Development: State of the Science, Public Health Implications, and Research Recommendations, Environmental Health Perspectives 119, no. 8 (August 2011): 1053–61, https://doi.org/10.1289/ehp.1002864.] Altered mammary gland development may lead to difficulty in breastfeeding and/or an increase in susceptibility to breast cancer later in life.

Although Michigan and New Jersey did not directly base their risk assessments for PFOA on mammary gland effects or changes in lactation duration, they did address the increased risk for

this effect through their application of uncertainty factors. Michigan stated that mammary gland effects may not be considered adverse, but that they could be representative of endocrine (hormone) effects at doses below Michigan's selected point of departure. [FN21: Jamie C. DeWitt, Kevin Cox, and David A. Savitz, Health Based Drinking Water Value Recommendations for PFAS in Michigan, June 27, 2019, https://www.michigan.gov/-/media/Project/Websites/PFAS-Response/Reports/2019-Health-Based-Drinking-Water-Value-Recommendations-PFAS-MI.pdf?rev=1779be946a5c41439f1db4f3eeaec4ec.] Michigan therefore applied an additional uncertainty factor for database limitations regarding endocrine effects. [FN22: Id.]

New Jersey stated that the mammary gland effect is "the most sensitive systemic endpoint for PFOA with data appropriate for dose-response modeling. It is a well-established toxicological effect of PFOA that is considered to be adverse and relevant to humans for the purposes of risk assessment." [FN23: New Jersey Drinking Water Quality Institute, Health-Based Maximum Contaminant Level Support Document: Perfluorooctanoic Acid (PFOA), February 15, 2017, https://www.nj.gov/dep/watersupply/pdf/pfoa-appendixa.pdf.] However, New Jersey also concluded that because altered mammary gland development had yet to be used as the basis for a risk assessment it would not select it as the critical effect, but did apply an uncertainty factor to protect for this more sensitive effect. [FN24: Note that Texas has used altered mammary gland development in its PFAS risk assessment prior to NJ Drinking Water Quality Institute's comments. The report was formerly available from the Texas Commission on Environmental Quality (TCEQ) at https://www.tceq.texas.gov/assets/public/implementation/tox/evaluations/pfcs.pdf, but an update is now available: TCEQ, Per- and Poly-Fluoroalkyl Substances (PFAS), February 14, 2023, https://www.tceq.texas.gov/downloads/toxicology/pfc/pfcs.pdf.]

In finalizing the toxicity assessment and economic analysis, EPA should reconsider the effects of PFOA on mammary gland development and function, with specific attention to impacts on lactation duration. EPA could then quantify the number of people who may be impacted by the proposed regulation. For example, using data available from the meta-analysis by Timmerman et al. (2023), an attributable risk for shortened lactational duration could be calculated as follows:

AR = Io (RR-1) [FN25: Noel S. Weiss and Thomas D. Koepsell, eds, Epidemiologic Methods: Studying the Occurrence of Illness. Second edition. Oxford University Press, 2014, https://academic.oup.com/book/24995.]

• where RR is the relative risk of the outcome of interest - In our case stopping any breastfeeding before 6 months. In this example we will use the data from Romano et al., 2016 [FN26: Megan E. Romano, Yingying Xu, Antonia M. Calafat, Kimberly Yolton, Aimin Chen, Glenys M. Webster, Melissa N. Eliot, Cynthia R. Howard, Bruce P. Lanphear, and Joseph M. Braun, Maternal Serum Perfluoroalkyl Substances during Pregnancy and Duration of Breastfeeding, Environmental Research 149 (August 1, 2016): 239–46, https://doi.org/10.1016/j.envres.2016.04.034.]

• where Io is the disease incidence in the unexposed - Here we estimate this based on data from the National Immunization Survey, which suggests that the prevalence of children who were breastfed at 6 months in the U.S. was 55.8% for 2019. [FN27: CDC, Results: Breastfeeding Rates, Centers for Disease Control and Prevention, April 4, 2023. https://www.cdc.gov/breastfeeding/data/nis_data/results.html.]

• This means that 44.2% of children are not breastfed at 6 months, which can be used as an estimate of cumulative incidence. [FN28: Ideally the cumulative incidence is based on the disease incidence in an unexposed population. However, with PFAS, the general population is not a truly unexposed population. Therefore, the cumulative incidence, and consequently the attributable risk, may be overestimated. Therefore, an alternative analysis with a more conservative assumption of the cumulative incidence is also provided.]

Calculation Inputs:

[Table: See Docket ID EPA-HQ-OW-2022-0114-1808]

*These RRs were statistically significant in the original paper, so there is more confidence in the precision of these estimates. The others were borderline significant, so though they are still reasonable, they are also possibly less precise.

Given the calculation inputs provided above, the attributable risk for stopping breastfeeding by 6 months can be calculated for those with the highest serum PFAS level in pregnancy (i.e., in the 4th quartile in the HOME Study) compared to those the lowest serum PFAS exposure (1st quartile in the HOME study). The HOME Study is the Health Outcomes and Measures of the Environment study) which was used in Romano et al., 2016.

The resulting attributable risks are:

o ARPFOA= 18 per 100 mothers

o ARPFOs= 11 per 100 mothers

o ARPFHxS= 9 per 100 mothers

o ARPFNA= 5 per 100 mothers

In other words, 18 additional mothers (per 100 mothers) stopped breastfeeding before 6 months of age in the highly exposed PFOA group versus the lowest exposed PFOA group.

More conservatively, one could assume that the incidence of stopping breastfeeding among truly unexposed women is ¼ that of the general population (11.05%). If that is the case, then the attributable risks are as follows.

o ARPFOA= 5 per 100 mothers

o ARPFOs= 3 per 100 mothers

o ARPFHxS= 2 per 100 mothers

o ARPFNA= 1 per 100 mothers

Monetization of the impact of shortened lactation duration is also possible. [FN29: Dylan D. Walters, Linh T H Phan, and Roger Mathisen, The Cost of Not Breastfeeding: Global Results from a New Tool, Health Policy and Planning 34, no. 6 (July 2019): 407–17, https://doi.org/10.1093/heapol/czz050.] An online tool that estimates the cost of not breastfeeding suggests that in the US there is an additional $28 million in healthcare system treatment costs when children are not breastfed due to increased maternal and child infections, and additional costs due to cognitive losses and the need for households to purchase breastmilk substitutes. [FN30: Alive & Thrive, In the USA, Breastfeeding Impacts Families, Communities, and the Economy, 2022, https://www.aliveandthrive.org/en/country-stat/usa.]

II. Immunotoxicity

In its explanation of why immune effects were not selected for economic analysis, EPA states:

"While immune effects had indicative evidence of associations with exposure to PFOA and PFOS, EPA did not identify the necessary information to connect the measured biomarker responses (i.e., decrease in antibodies) to a clinical effect that could be valued in the economic analysis." [FN31: US EPA, Draft for Public Comment: Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation, March 14, 2023, https://www.epa.gov/system/files/documents/2023-03/Proposed%20PFAS%20NPDWR%20EA_final_03_09_2023_0.pdf.]

While it is difficult to quantitate the relationship between altered immune responses, such as decreases in antibody production, and frequency or severity of disease in inherently diverse human populations, these "subclinical" effects are associated with increased disease risk and economic cost and are therefore important to address. Small shifts within the range of normal clinical values can still have devastating population-level impacts. Specifically, the cellular and humoral immune response to vaccination is thought to be a sensitive indicator of immunosuppression. [FN32: Ronald Glaser, Gary R. Pearson, Robert H. Bonneau, Brian A. Esterling, Cathie Atkinson, and Janice K. Kiecolt-Glaser, Stress and the Memory T-Cell Response to the Epstein-Barr Virus in Healthy Medical Students, Health Psychology 12, no. 6 (1993): 435–42, https://doi.org/10.1037/0278-6133.12.6.435.] In a literature review from 2018 the authors conclude that, "[t]aken together, we find that results of epidemiological studies, supported by findings from toxicological studies, provide strong evidence that humans exposed to PFOA and PFOS are at risk for immunosuppression." [FN33: Jamie C. DeWitt, Sarah J. Blossom, and Laurel A. Schaider, Exposure to Per-Fluoroalkyl and Polyfluoroalkyl Substances Leads to Immunotoxicity: Epidemiological and Toxicological Evidence, Journal of Exposure Science & Environmental Epidemiology 29, no. 2 (March 2019): 148–56, https://doi.org/10.1038/s41370-018-0097-y.] In a more recent review, authors find that, "there is ample evidence illustrating PFAS affect multiple aspects of the immune system, which supports the overall conclusion that not only PFOA and PFOS, but also other members of the PFAS family alter immune functions in humans." [FN34: Veronika Ehrlich, Wieneke Bil, Rob

Vandebriel, Berit Granum, Mirjam Luijten, Birgitte Lindeman, Philippe Grandjean, et al, Consideration of Pathways for Immunotoxicity of Per- and Polyfluoroalkyl Substances (PFAS), Environmental Health 22, no. 1 (February 22, 2023): 19, https://doi.org/10.1186/s12940-022-00958-5.] They go on to confirm that the "most reported immunotoxic effect in humans is immunosuppression, reflected by reduced vaccine antibody levels and increased risk of common infectious diseases." [FN35: Id.]

Importantly, immunosuppression has been defined by experts as "a reduced ability of the immune system to respond to a challenge from a level considered normal, regardless of whether clinical disease results." [FN36: Jamie C. DeWitt, Dori R. Germolec, Robert W. Luebke, and Victor J. Johnson. Associating Changes in the Immune System with Clinical Diseases for Interpretation in Risk Assessment, Current Protocols in Toxicology 67 (February 1, 2016): 18.1.1-18.1.22, https://doi.org/10.1002/0471140856.tx1801s67.] However, there are clinical consequences of mild-to-moderate chronic immunosuppression, including an increase in the incidence of infectious diseases. Even small changes in infectious disease frequency can have major social and economic impacts, particularly on vulnerable populations. The elderly experience age-related declines in immune function and factors that contribute to immunosuppression in this population can increase the risk of morbidity and mortality. Adults 65 and older make up approximately 90% of the total pneumonia and influenza-related deaths in the U.S. [FN37: C. P. Mouton, O. V. Bazaldua, B. Pierce, and D. V. Espino, Common Infections in Older Adults, Health Care Food & Nutrition Focus 18, no. 3 (November 2001): 1, 3–7.] Furthermore, vaccines are less effective in the elderly. [FN38: Richard Aspinall, Giuseppe Del Giudice, Rita B. Effros, Beatrix Grubeck-Loebenstein, and Suryaprakash Sambhara, Challenges for Vaccination in the Elderly, Immunity & Ageing: I & A 4 (December 11, 2007): 9, https://doi.org/10.1186/1742-4933-4-9.] The young are particularly susceptible to infectious agents that require adult-level immune responses. For example, the ability to produce antibodies develops slowly, with infants (1-3 months old) starting off with approximately 30% of adult antibody levels and children (12- 16 years old) still only producing around 70% of adult levels. [FN39: E. R Stiehm and H. H. Fudenberg, Serum Levels of Immune Globulins in Health and Disease: A Survey Pediatrics 37, no. 5 (May 1966): 715–27.] Agents that induce immunosuppression can exacerbate the inherent deficits in infants' and children's immature and still developing immune systems. [FN40: Jamie C. DeWitt, Dori R. Germolec, Robert W. Luebke, and Victor J. Johnson, Associating Changes in the Immune System with Clinical Diseases for Interpretation in Risk Assessment, Current Protocols in Toxicology 67 (February 1, 2016): 18.1.1-18.1.22, https://doi.org/10.1002/0471140856.tx1801s67.]

In a recent epidemiology study, authors looked directly at the link between PFAS exposure and persistent infections. [FN41: Catherine M. Bulka, Vennela Avula, and Rebecca C. Fry, Associations of Exposure to Perfluoroalkyl Substances Individually and in Mixtures with Persistent Infections: Recent Findings from NHANES 1999–2016, Environmental Pollution 275 (April 15, 2021): 116619, https://doi.org/10.1016/j.envpol.2021.116619.] They found that, "[e]ach PFAS was individually associated with significantly higher pathogen burdens and the most pronounced associations were observed in adolescents [e.g., among adolescents, a doubling

of PFOS was associated with 30% (95% CI: 25–36%) higher pathogen burden]. Quantile g-computation revealed PFAS mixtures as a whole were also associated with higher pathogen burdens. Taken together, these results suggest PFAS exposure may increase susceptibility to and foster the clustering of persistent infections, particularly among adolescents." [FN42: Id.]

Impacts associated with mortality and morbidity from common pathogens (such as influenza and pneumonia) have been studied and estimated. These can serve as a basis for beginning to quantitate and even monetize the benefit of reducing the risk of immunotoxicity associated with PFAS exposure as these common pathogens are more likely to increase mortality and morbidity in those who are mildly to moderately immunosuppressed, i.e., the young, the elderly, and those with toxicant-induced PFAS immunosuppression. Relevant data includes:

Quantitative data on morbidity [FN43: M. Heron, Deaths: Leading causes for 2010, National Vital Statistics Reports. 2013; 62.]

• In 2010, influenza and pneumonia together were ranked the ninth leading cause of death in the U.S. for all ages.

• For infant deaths in 2010, influenza was ranked 46th and pneumonia was ranked 47th.

• For the elderly population, chronic lower respiratory disease was ranked 3rd and influenza-pneumonia was ranked 7th in leading causes of death in 2004.

Cost estimates

• Total cost of influenza and pneumonia was estimated to be $40.2 billion in the U.S. [FN44: American Lung Association, Influenza and pneumonia: State of lung disease in diverse communities, 2010.]

• Ear infections (otitis media) is the most common indication for antibiotic use and outpatient visits in children – $2.88 billion in added annual health care expense in the U.S. [FN45: Sameer Ahmed, Nina L. Shapiro, and Niel Bhattacharyya, Incremental Health Care Utilization and Costs for Acute Otitis Media in Children, The Laryngoscope 124 (2014): 301–5, https://doi.org/10.1002/lary.24190.]

• Annual cost of treating RSV for children under 5 in 2000 was $652 million [FN46: L. Clark Paramore, Vincent Ciuryla, Gabrielle Ciesla, and Larry Liu, Economic Impact of Respiratory Syncytial Virus-Related Illness in the US, PharmacoEconomics 22, no. 5 (April 1, 2004): 275–84, https://doi.org/10.2165/00019053-200422050-00001.]

Taken together, the data support the identification of protecting against immune system effects, particularly immunosuppression, as a key benefit resulting from the proposed MCLs. The data also suggests that EPA has sufficient information to quantify this benefit. Examples include the number of infection-related deaths avoided, the number of infectious disease cases avoided, and the increased proportion of the population with successful responses to immunization. Finally, there is information detailing some of the costs related to common infectious diseases that can be used to monetize some of these benefits. In finalizing the economic analysis EPA should

quantitate and monetize, where possible, the health benefits of reduced PFAS-related immunotoxicity that the proposed MCLs will provide.

III. Liver disease

We disagree with EPA's conclusions that the hepatic effects that have been observed are modest and unquantifiable. The reality is that the experimental literature and human literature are substantial, mutually reinforcing, consistent, and point to a problem of PFAS hepatotoxicity. [FN47: Elizabeth Costello, Sarah Rock, Nikos Stratakis, Sandrah P. Eckel, Douglas I. Walker, Damaskini Valvi, Dora Cserbik, et al, Exposure to Per- and Polyfluoroalkyl Substances and Markers of Liver Injury: A Systematic Review and Meta-Analysis, Environmental Health Perspectives 130, no. 4 (April 27, 2022): 046001, https://doi.org/10.1289/EHP10092.] Few findings in environmental health are as consistent as the experimental and epidemiological evidence that PFAS, notably but not limited to PFOA and PFOS, are associated with liver damage. [FN48: Id.]

Across species and toxicological studies, PFAS exposure causes increased ALT (alanine aminotransferase) levels and liver steatosis (fat accumulation), which is the starting point for NAFLD (nonalcoholic fatty liver disease). Yet, EPA has argued that 1) the connection from increased ALT to liver disease is lacking and 2) that the changes in ALT after PFAS exposure is modest (implying lacks importance).

1) Connecting increased ALT to liver disease:

Specifically, with respect to connecting increases in ALT to liver disease, EPA states, "Elevated ALT levels could be one of several contributors to the non-alcoholic fatty liver disease. Additionally, high ALT levels can be associated with alcohol consumption, heart failure, hepatitis (A, B, and C), medication use (e.g., Tylenol and statins), and obesity (Mayo Clinic, 2022) and this wide range of associations makes it difficult to model economic benefits of non- specific ALT level changes in response to reduced exposures." [FN49: US EPA, Draft for Public Comment: Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation, March 14, 2023, https://www.epa.gov/system/files/documents/2023-03/Proposed%20PFAS%20NPDWR%20EA_final_03_09_2023_0.pdf.] Most health effects are associated with more than one risk factor. This does not mean that quantifying the benefit of reducing one of these multiple risk factors is not possible.

Multiple studies show that PFAS exposure causes liver toxicity and fatty liver disease across animal species, without known species exceptions so far. There is no reason to expect humans to be the exception. Evaluating environmental contributors to NAFLD in cross-sectional studies is difficult due to how and when the disease is diagnosed. NAFLD is seldom diagnosed in early stages in clinical practice and may not be coded as among the comorbidities for other diagnoses. Therefore, cross- sectional studies that have relied on medical record review (ICD-code verified) of NAFLD are likely to suffer from outcome misclassification. However newer studies, not reliant on ICD-code verification, but rather on imaging of livers, have linked PFAS exposure

with deleterious effects on fatty liver findings. [FN50: Xinchen Wang, Xiaoqian Jin, Hancheng Li, Xianyu Zhang, Xi Chen, Kuan Lu, and Chenliang Chu, Effects of Various Interventions on Non-Alcoholic Fatty Liver Disease (NAFLD): A Systematic Review and Network Meta-Analysis, Frontiers in Pharmacology 14 (2023), https://www.frontiersin.org/articles/10.3389/fphar.2023.1180016.] In a biopsy-proven cohort of 105 patients with NAFLD, PFAS were found to be adversely associated with liver fat content, lipid metabolism, and bile acid metabolism. [FN51: Partho Sen, Sami Qadri, Panu K. Luukkonen, Oddny Ragnarsdottir, Aidan McGlinchey, Sirkku Jäntti, Anne Juuti, et al., Exposure to Environmental Contaminants Is Associated with Altered Hepatic Lipid Metabolism in Non-Alcoholic Fatty Liver Disease, Journal of Hepatology 76, no. 2 (February 1, 2022): 283–93, https://doi.org/10.1016/j.jhep.2021.09.039.]

2) Addressing the biological significance of "modest" changes in ALT

EPA states that the effects of PFAS exposure on observed ALT levels are modest, but fails to recognize that more recently, professional societies have recommended more appropriate, physiologically-based cutoffs for what is considered a normal or abnormal ALT level based on the important societal need to address the NAFLD epidemic. [FN52: Naga, Chalasani, Zobair Younossi, Joel E. Lavine, Michael Charlton, Kenneth Cusi, Mary Rinella, Stephen A. Harrison, Elizabeth M. Brunt, and Arun J. Sanyal, The Diagnosis and Management of Nonalcoholic Fatty Liver Disease: Practice Guidance from the American Association for the Study of Liver Diseases, Hepatology 67, no. 1 (January 2018): 328, https://doi.org/10.1002/hep.29367; Jin Hwa Park, Jun Choi, Dae Won Jun, Sung Won Han, Yee Hui Yeo, and Mindie H Nguyen, Low Alanine Aminotransferase Cut-Off for Predicting Liver Outcomes; A Nationwide Population-Based Longitudinal Cohort Study, Journal of Clinical Medicine 8, no. 9 (September 11, 2019): 1445, https://www.mdpi.com/2077-0383/8/9/1445.]

A large epidemiological study of more than 30,000 participants in a community with PFOA exposures ranging from national background levels to very high levels of contamination, concluded participants in the fifth quintile had 16% increased odds of having above-normal ALT (95% CI: odds ratio: 1.02, 1.33%). [FN53: Lyndsey A. Darrow, Alyx C. Groth, Andrea Winquist, Hyeong-Moo Shin, Scott M. Bartell, and Kyle Steenland, Modeled Perfluorooctanoic Acid (PFOA) Exposure and Liver Function in a Mid-Ohio Valley Community, Environmental Health Perspectives 124, no. 8 (August 2016): 1227–33, https://doi.org/10.1289/ehp.1510391.] There is a near monotonic increase in ALT with increasing PFOA, with the dose-response beginning at what are considered to be "background" levels of population exposure.

A reanalysis of the above data was performed using the updated physiologically-based cutoffs for ALT as recommended by the medical liver disease societies. [FN54: Alan Ducatman, Youran Tan, Brian Nadeau, and Kyle Steenland, Perfluorooctanoic Acid (PFOA) Exposure and Abnormal Alanine Aminotransferase: Using Clinical Consensus Cutoffs Compared to Statistical Cutoffs for Abnormal Values, Toxics 11, no. 5 (May 2023): 449, https://doi.org/10.3390/toxics11050449.] This reanalysis showed an increased association of PFOA to abnormal ALT and emphasized the near monotonic increases in ALT with increasing

dose. For example, males in the 5th quintile of measured PFOA were 35% more likely and females 20% more likely to have abnormal ALT, with mean continuous increases of 9% per quintile for men and 4% for women. [FN55: Id.]

Independent of PFAS, populations with higher biomarkers of liver distress such as ALT have worse outcomes for morbidity and mortality. [FN56: Paul Y. Kwo, Stanley M. Cohen, and Joseph K. Lim, ACG Clinical Guideline: Evaluation of Abnormal Liver Chemistries, American Journal of Gastroenterology 112, no. 1 (January 2017): 18–35, https://journals.lww.com/ajg/Fulltext/2017/01000/ACG_Clinical_Guideline_Evaluation_of_Abnormal.13.aspx; Naga Chalasani, Zobair Younossi, Joel E. Lavine, Michael Charlton, Kenneth Cusi, Mary Rinella, Stephen A. Harrison, Elizabeth M. Brunt, and Arun J. Sanyal, The Diagnosis and Management of Nonalcoholic Fatty Liver Disease: Practice Guidance from the American Association for the Study of Liver Diseases, Hepatology 67, no. 1 (January 2018): 328, https://doi.org/10.1002/hep.29367.]

In finalizing the economic analysis EPA should reconsider the conclusions drawn regarding the literature exploring ALT and NAFLD in relationship to PFAS exposure and attempt to quantitate the number of people who would benefit from reduced risk of liver effects from the proposed MCLs. EPA should also attempt to monetize the health benefit from reduced NAFLD cases, as there are studies available that provide estimates of the economic burden associated with NAFLD.

For example, one study from 2016 estimated that in the U.S., "over 64 million people are projected to have NAFLD, with annual direct medical costs of about [$103.3] billion ($1,613 per patient)" but that the "burden is significantly higher when societal costs are included." [FN57: Zobair M. Younossi, Deirdre Blissett, Robert Blissett, Linda Henry, Maria Stepanova, Youssef Younossi, Andrei Racila, Sharon Hunt, and Rachel Beckerman, The Economic and Clinical Burden of Nonalcoholic Fatty Liver Disease in the United States and Europe, Hepatology 64, no. 5 (2016): 1577–86, https://doi.org/10.1002/hep.28785.] The study estimated societal costs to be $188.9 billion, yielding a total cost of $292.2 billion. These cost estimates account for drugs, healthcare, and changes in quality of life, but they under-value other indirect costs such as lost productivity and federal benefits for disability. They also underestimate even the pharmaceutical costs, as they rely on formal diagnoses and it is clear that NAFLD treatment, hospitalization, and indirect costs can precede the diagnosis and treatment. [FN58: Myriam Alexander, A. Katrina Loomis, Jolyon Fairburn-Beech, Johan van der Lei, Talita Duarte-Salles, Daniel Prieto-Alhambra, David Ansell, et al., Real-World Data Reveal a Diagnostic Gap in Non-Alcoholic Fatty Liver Disease, BMC Medicine 16, no. 1 (August 13, 2018): 130. https://doi.org/10.1186/s12916-018-1103-x.] Despite these limitations, EPA can still use this information to begin to monetize the benefit of reduced NAFLD cases from the proposed MCLs.

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EPA failed to quantify several of the health effects associated with PFAS exposure. We have provided resources and information that EPA should use to estimate the proposed drinking water

standards' additional benefits of protecting against PFAS-associated effects on mammary gland development, the liver and immune system.

Sincerely,

Anna Reade, PhD

Senior Scientist

Natural Resources Defense Council

Katherine Pelch, PhD

Scientist

Natural Resources Defense Council

EPA Response: The EPA acknowledges commenters' submission of additional health information that they deem could result in additional quantified benefits. Please see section 13.5 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1808, SBC-046110 in section 13.5 in this *Response to Comments* document for discussion about liver effects, ALT, lactation duration, and immunotoxicity. Please see the EPA response to comment Doc. #1784, SBC-045800 in section 4.2.1.6 in this *Response to Comments* document regarding mammary gland development and lactation duration. The EPA has characterized some hepatic effects, developmental impacts, and immunotoxicity effects in the nonquantifiable benefits analysis. The EPA notes that the information submitted by the commenters further supports the EPA's conclusions in the nonquantifiable benefits discussion, as well as the EPA's conclusions in the Final Toxicity Assessments for PFOA and PFOS: that the PFAS regulated by the final rule adversely impact a wide variety of health endpoints and that the benefits of reducing these regulated PFAS from drinking water are substantial.

Regarding ALT, the EPA considered the new evidence provided by Ducatman et al. (2023) and referenced by this commenter in the Final Toxicity Assessments for PFOA and PFOS. When considering BMRs for the effect of increased ALT, the EPA selected the adverse effect level of ALT for liver disease to be C = 42 IU/L for males and C = 30 IU/L for females based on the sex-specific upper reference limits found in Valenti et al. (2021). These are slightly lower and more health protective than the cutoff values used in the original study (45 IU/L for men and 34 IU/L for women). These cutoffs are also slightly higher than the American College of Gastroenterology cutoffs, which considers that "true healthy normal ALT level ranges from 29 to 33 IU/L for males, 19 to 25 IU/L for females" (Kwo et al., 2017). The limits from Valenti et al. (2021) are the most up-to-date clinical consensus cutoffs which update the American Association for the Study of Liver Diseases journal Clinical Liver Disease recommended values of 30 IU/L for males, and 19 IU/L for females (Kasarala and Tillmann, 2016; Ducatman et al., 2023). Valenti et al. (2021) determined the updated values using the same approach at the same center as those presented in Ducatman et al. (2023) but used an updated standardized method.

Earthjustice et al. (Doc. #1808, SBC-046133)

12. Any environmental benefits anticipated to result from the proposed regulatory action should be included in the EA.

The quantified and qualitative benefits identified in the EA focus solely on human health. Given the persistence of PFAS pollutants, PFAS that are left untreated by a PWS in the baseline likely would be passed through the entire system and eventually released back into the environment. If this is the case, then the proposed MCLs would reduce the concentrations of PFAS in the public water before it is eventually discharged into the environment, and thus reduce any adverse impacts to ecosystem services and other environmental endpoints. EPA should consult with environmental risk assessors and ecotoxicologists, but if reasonable, then such benefits at the very least deserve a qualitative discussion and consideration in the EA.

13. EPA should reconsider whether additional health benefits can be quantified and/or monetized.

As described in comment #6, EPA went to impressive lengths to identify and qualitatively discuss potential health benefits that it asserted could not be quantitatively estimated. However, in developing the final rule EA, EPA should consider whether there is adequate information to support quantification and/or monetization of additional benefits. As per EPA's (2014) own economic guidelines, analysts should try to get as far as possible in first identifying all key benefit and cost categories. The next step (when possible) is to then quantify the projected change in each benefit and cost outcome that is expected to result from the policy option, relative to the baseline. Quantifying in this case means to measure the change in terms of some quantitative metric, such as the number of lives saved, number of cases prevented, etc. The final step is to monetize the quantified change, meaning that a dollar value is assigned. EPA spent significant effort in monetizing benefits when possible, and then qualitatively identifying and discussing other benefits, but the Agency should consider whether there is adequate information to at least quantify additional benefit categories in the final EA.

As suggested by OMB's recently proposed revisions to Circular A4 (OMB 2023), EPA should consider highlighting the expected magnitude of some of the qualitatively discussed benefits. For example, quantified estimates of the number of individuals potentially exposed, and/or that are susceptible to the increased risks and that would therefore benefit from the proposed regulatory options, would provide further insight and aid the qualitative discussion. In other words, perhaps the quantification step can be taken to some degree for some benefit categories, even if fully monetizing a benefit category is not possible.

Additionally, there may be health outcomes where quantification is not possible, but perhaps monetary cost-of-illness (COI) or willingness to pay (WTP) estimates exist. In such cases, as suggested by the Agency's own economic guidelines (EPA 2014), EPA should consider illustrative analyses or perhaps even a full-blown "break-even" analysis, to provide further insight to the potential magnitude of the qualitatively discussed benefits and plausibility that

those unquantified benefits may further result in positive net benefits. Such analyses are recommended in cases where unquantified benefits could be meaningful (OMB 2003, 2023).

Finally, EPA should thoroughly evaluate information submitted during the public comment period for the proposed rule and assess whether additional health benefits can be identified, quantified, and ideally monetized in the EA for the final rule. For example, the comments submitted by Earthjustice and the Natural Resource Defense Council (NRDC) include estimates of lactation duration effects attributable to increased exposures to PFOA, PFOS, PFHxS, and PFNA. Impacts of PFAS exposure on breastfeeding, and the resulting impacts to infant and maternal health are not currently discussed in the EA. At the very least, this is a benefit category that deserves qualitative discussion, and as the commenters' analysis suggests, perhaps quantification and even monetization of these benefits is possible. As another example, on page 6-21 of the EA, EPA states that hepatic effects were not quantified or monetized because PFAS exposure could not be linked to a health endpoint (i.e., an increased incidence of disease). However, more recent studies discussed in the comments submitted by Earthjustice and NRDC may allow for quantification, and perhaps even monetization of this important benefit category.

EPA Response: Please see the EPA's previous response to Earthjustice et al. (Doc. #1808, SBC-046110) and section 13.5 of the EPA response in this *Response to Comments* document addressing quantification of benefits related to hepatic, breastfeeding and lactation effects. Please see section 13.5 of the EPA response in this *Response to Comments* document for the EPA's response to the comment recommending further quantification using break-even analysis and using a willingness-to-pay valuation methodology.

13.6 Nonquantifiable Benefits of Removal of PFAS Included in the Proposed Regulation and Co-removed PFAS

Summary of Major Public Comments and EPA Responses

The EPA received comments on the nonquantifiable benefits of other PFAS included in the regulation and co-removed PFAS. One commenter claimed that the EPA's HRRCA lacked analysis for the benefits and costs of addressing Hazard Index chemicals. A different commenter stated that the EPA did not provide data to support its analysis of benefits predicted from the implementation of the Hazard Index MCL. The EPA disagrees with these comments. The comprehensive qualitative benefits analysis that the EPA provided in Section 6.2 of the EA (USEPA, 2024b) and section XII of the FRN, summarizes the best available information on health effects associated with exposure to Hazard Index chemicals and also other PFAS chemicals not included in the regulation that may be co-removed. The nonquantifiable benefits analysis is consistent with the requirement under the SDWA that the EPA analyze the "quantifiable and nonquantifiable health risk reduction benefits" (see USC 300g-1(b)(C)(i)).

One commenter stated that the HRRCA "likely omits or underestimates significant health and environmental benefits to PFAS limits in drinking water." The commenter requested that the EPA emphasize how the current benefits are likely much greater than what the EPA has quantified and

pointed to other health endpoints including immune toxicity and mammary gland effects as additional benefit categories. Additionally, the commenter discussed additional benefits anticipated including those resulting from reduced exposure to co-occurring contaminants and improved environmental quality. The EPA agrees with the commenter that benefits of the rule are likely underestimated and that additional benefits are likely to occur as a result of the final NPDWR. In the EA for the final rule and also in the FRN for this action, the EPA has provided a comprehensive discussion on quantifiable and nonquantifiable benefits and has clearly described that the quantified benefits are likely underestimated.

Individual Public Comments

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043061)

EPA's lack of analysis for the benefits and costs of addressing PFHxS, PFNA, HFPO-DA, and PFBS is concerning and conflicts with the intention of SDWA to require that new regulations undergo such an analysis.

EPA Response: The EPA disagrees with the commenter that the EPA lacks analysis for the benefits and costs of Hazard Index compounds, and that the EPA's analysis conflicts with the intention of the SDWA. The EPA has completed the HRRCA for the PFAS NPDWR consistent with the SDWA 1412(b)(3)(C) statutory requirements. The statute states that the EPA is required to analyze quantifiable and non-quantifiable health risk reduction benefits associated with each MCL. Due to data limitations, the EPA discusses the benefits of PFHxS, PFNA, HFPO-DA, and PFBS removal qualitatively. Further, as discussed in Chapter 6.2 and Appendix K of the EA, the EPA quantified benefits associated with PFNA effects on birth weight in sensitivity analyses. Additionally, the EPA notes that the agency has quantified some of the incremental benefits associated with PFHxS in the primary analysis, as shown in the increased quantified benefits estimates of the proposed rule compared to option 1a. These benefits stem from the additional reduction in PFOA and PFOS that is estimated to occur as a result of including PFHxS in the regulation. See also sections 13.3.2 and 13.6 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1774, SBC-045679 and Doc. #1845, SBC-046056 in sections 13.4.5 and 5.1.3, respectively, in this *Response to Comments* document. Regarding the EPA's evaluation of costs associated with PFHxS, PFNA, HFPO-DA and PFBS, see section 13.3.2 of the EPA response in this *Response to Comments* document.

Silent Spring Institute (Doc. #1784, SBC-045803)

4. The Health Risk Reduction and Cost Analysis (HRRCA) likely omits or underestimates significant health and environmental benefits to PFAS limits in drinking water.

In its own analysis, EPA acknowledged that "[t]here are significant nonquantifiable sources of benefits that were not captured in the quantified benefits." The current analysis monetized health benefits associated with medical savings from improving cardiovascular health, preventing low infant birth weight, reducing kidney cancer incidence, and avoiding health effects associated

with disinfection byproducts. EPA has also qualitatively described benefits associated with preventing negative health effects associated with hazard index PFAS compounds, other health effects associated with PFOA and PFOS that could not be monetized (e.g., immune system dysfunction), and health effects associated with unregulated PFAS.

We acknowledge EPA's significant effort and the challenges and limitations of economic cost-benefit analyses. We agree with EPA's expectation that the proposed rule will result in additional nonquantifiable benefits not included in the HRRCA. However, we recognize that a more comprehensive assessment is challenging, and we do not support any delay that might result from trying to monetize additional possible benefits. To weigh the benefits appropriately, EPA should emphasize how the current HRRCA underestimates this rule's benefits and the accrued benefits of adopting this rule are likely much greater than what EPA has quantified. These benefits include:

• Benefits from other health improvements. Subclinical effects (e.g., ALT levels) were overlooked, and critical health endpoints, including immune toxicity, were not reflected in the economic analysis. Another critical endpoint undervalued in the economic analysis was PFAS impacts on the mammary gland despite evidence of deleterious effects. Mammary gland impacts have consequence for breastfeeding/infant nutrition and future breast cancer risk.[REF2: Kay JE, Cardona B, Rudel RA, et al. Chemical Effects on Breast Development, Function, and Cancer Risk: Existing Knowledge and New Opportunities. Curr Environ Health Rep. 2022;9(4):535-562.; REF18: Rudel RA, Fenton SE, Ackerman JM, Euling SY, Makris SL. Environmental exposures and mammary gland development: State of the science, public health implications, and research recommendations. Environ Health Perspect. 2011;119(8):1053-1061.] Some of these effects occur among sensitive subpopulations, like pregnant women and infants.

• Benefits from reduced exposure to contaminants that co-occur with the six PFAS in this rule. Those co-occurring contaminants include other PFAS, regulated contaminants other than disinfection byproducts, and unregulated contaminants.

• Improved environmental quality. [REF29: Cordner A, Goldenman G, Birnbaum LS, et al. The True Cost of PFAS and the Benefits of Acting Now. Environ Sci Technol. 2021;55(14):9630-9633.] Although the focus of the HRRCA is on human health benefits resulting from drinking water standards, the economic analysis altogether omits the socioenvironmental value of PFAS removal on the environment. The current rule may result in more source water protection and downstream reductions of PFAS at wastewater treatment plants and natural waters. As a result, reductions of PFAS in drinking water may also result in lowered PFAS in wildlife, including certain fish, which itself can be a major source of PFAS exposures.

• Lowered costs borne by state agencies and residents from implementing a state-by-state approach of PFAS regulations.[REF29: Cordner A, Goldenman G, Birnbaum LS, et al. The True Cost of PFAS and the Benefits of Acting Now. Environ Sci Technol. 2021;55(14):9630-9633.]

EPA Response: See section 13.6 of the EPA response in this *Response to Comments* document. Please see section 13.5 of the EPA response in this *Response to Comments* document

and the EPA response to comment Doc. #1808, SBC-046110 in section 13.5 in this *Response to Comments* document and Doc. #1784, SBC-045800 in section 4.2.1.6 in this *Response to Comments* document for discussion about quantification for ALT and mammary gland effects. See the quantitative benefits analysis for DBP exposure reduction resulting from installation of PFAS treatment (Chapter 6 of USEPA, 2024b and also section XII of the FRN) where the EPA qualitatively discussed the benefits resulting from removal of other contaminants including microbial contaminants and SOCs. See Chapter 4 of the EA for discussion on state regulations and the EPA's approach for adjusting PFAS occurrence information for states with promulgated PFAS regulations.

While potential environmental improvements are beyond the scope of this rulemaking, the EPA is fully committed to reduce PFAS pollution through policies that safeguard communities, protect the environment, and hold polluters accountable. For additional information on the EPA's PFAS actions, see the EPA PFAS Strategic Roadmap.

American Chemistry Council (ACC) (Doc. #1841, SBC-044821)

[As outlined in these comments, the Agency's proposal suffers from a number of significant shortcomings, including the following –]

• EPA has not provided data to support its analysis of benefits predicted from the implementation of the HI MCL,

EPA Response: See sections 13.3.2 and 13.4 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1774, SBC-045679 and Doc. #1845, SBC-046056 in sections 13.4.5 and 5.1.3, respectively, in this *Response to Comments* document.

13.7 Benefits Resulting from Disinfection By-Product Co-Removal

Summary of Major Public Comments and EPA Responses

The EPA received comments on uncertainties associated with bladder cancer reductions. One commenter incorrectly stated that the "EPA does not recognize the uncertainty that there is not always direct correlation between THM4 levels and TOC in all public water systems". In response, the EPA notes that the trihalomethanes (THM) concentrations in this co-removal analysis were not calculated based on TOC reduction. TOC was used to bin systems in the universe of PWSs using the fourth Six Year Review (SYR4) database and PFAS occurrence model with the THM4 reduction calculated from the formation potential experiments before and after GAC treatment in the DBP ICR database. This dataset is the best available data to determine THM4 reduction based on TOC removal using GAC treatment. Another commenter stated that the causal link of DBPs and bladder cancer has not been established. The EPA notes that an extensive body of epidemiological studies have shown that increased exposure to chlorinated DBPs is associated with higher risk of bladder cancer and other adverse health outcomes (Cantor et al., 1998; Freeman et al., 2017). Weisman et al. (2022) found that

approximately 8,000 of the 79,000 annual bladder cancer cases in the U.S. were potentially attributable to chlorinated DBPs in drinking water systems. While research has not established a causal link between THM4 and bladder cancer, there is strong evidence that there is a correlation between THM4 and bladder cancer.

One commenter stated that the DBP co-removal benefit analysis did not meet the standards required by SDWA for estimating benefits since it was not reviewed by the SAB. The commenter is incorrect. SDWA 1412(e) directs the EPA to request comments from the Science Advisory Board prior to proposing an MCLG and NPDWR. The EPA sought and received comment from the SAB prior to proposing this NPDWR (see USEPA, 2022d). The statute does not dictate the precise level of scientific questions for which the EPA must seek comments from the SAB. The EPA sought SAB comment on the four most significant areas that informed derivation of the MCLGs for all six PFAS regulated by this action and for other parts of the benefits analysis that informed the overall development of the NPDWR. It is neither required nor feasible for the EPA to seek the SAB's input on every potential scientific question that may come about as part of a rulemaking as there are hundreds or thousands of such questions in any given rulemaking. The EPA did seek additional peer review of its DBP co-removal benefit analysis prior to its inclusion in the economic analysis for which it received overwhelmingly favorable comments from reviewers (see USEPA, 2023j). Furthermore, this rule is based on the EPA's consideration of a wide body of existing peer-reviewed science on this subject (e.g., Regli et al., 2015; Weisman et al., 2022). In short, the EPA has used peer reviewed science and sought further peer review to support its DBP co-removal analysis, and as part of the supporting material for the rule proposal, the EPA included the comments from the expert peer reviewers as well as how each comment was addressed or the rationale for why it was not changed. Please see "Response to Letter of Peer Review for DBP Co-benefits" (USEPA, 2023j) for discussion of that peer review and the EPA's responses to peer reviewed comments.

Another commenter claimed that the EPA improperly quantified benefits of co-removed substances rather than co-occurring substances. The EPA disagrees with these assertions since the analysis of DBP co-removal is focused on co-occurring contaminants. As demonstrated elsewhere in the record for this action, PFAS commonly co-occur with each other. Additionally, in waters where disinfection is required, TOC (i.e., a DBP precursor) and PFAS may co-occur. The DBP co-removal benefits analysis relied on DBP formation potential experiments that highlighted the changes to TOC with and without GAC treatment. Furthermore, as discussed above, the methodology to estimate THM4 reductions was externally peer reviewed by three experts in GAC treatment for PFAS removal and DBP formation potential.

A few commenters stated that the EPA already had initiatives to reduce THMs in drinking water and suggested that reduction of bladder cancer cases is better addressed through existing DBP rules. While the EPA agrees that there are existing DBP regulations to reduce DBP exposure and risks, this rule will provide additional health risk reduction benefits associated with enhanced DBP reduction. The EPA has considered those co-removal benefits as part of the economic analysis. The EPA notes that it is required under the SDWA 1412(b)(3)(C)(i)(II) to assess

quantifiable and nonquantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur from reductions in co-occurring contaminants that may be attributed solely to compliance with the maximum contaminant level, excluding benefits resulting from compliance with other proposed or promulgated regulations. DBP reductions presented in the EPA's HRRCA are anticipated to result solely from the PFAS NPDWR. As required under the SDWA, any quantifiable and nonquantifiable benefits from future actions concerning DBPs in drinking water will be addressed at the time of those actions and are independent from benefits stemming as a result of the PFAS rulemaking. A couple of commenters supported the EPA's analysis of DBP benefits but recommended that the EPA also consider other co-removed contaminants. The EPA agrees with the commenters that multiple co-occurring contaminants will be removed as a result of this rulemaking. Furthermore, the EPA acknowledges in the EA that additional co-removal benefits would be realized due to treatment for PFAS. While, with the exception of DBPs co-removed, the EPA has not quantified other co-removal benefits at this time, the agency included discussion of non-quantifiable benefits for multiple other PFAS and for other contaminants.

Individual Public Comments

New York State Department of Health (NYS DOH) (Doc. #1677, SBC-044948)

10. The Department acknowledges the large contribution of benefit that reductions in bladder cancer, due to disinfection byproduct (DBP) precursor removal, has on the total benefit of the proposed rulemaking. However, there are many uncertainties associated with this benefit that do not appear to be addressed in Table 6-53: Limitations and Uncertainties in the Analysis of DBP Quantified Benefits, including:

- This benefit assumes total organic carbon (TOC) reduction due to reverse osmosis (RO), GAC installation, or presence of ion exchange resins that can concurrently remove TOC and PFAS compounds. This proposal also does not recognize emerging treatment technologies such as natural and engineered clays that will have limited TOC reduction benefit, although EPA acknowledges that GAC or RO may not be the selected treatment alternative.
- According to Table 6-53 of the Economic Analysis "EPA uses relationships between TOC levels and changes in THM4 levels among GAC-treating systems from the 1998 DBP ICR..." Although the Department recognizes the importance of TOC precursor removal as a DBP reduction strategy, the EPA does not recognize the uncertainty that there is not always direct correlation between THM4 levels and TOC in all public water systems. (Consonery et. al, 2004)
- In New York State, most PFAS impacted public water systems have groundwater sources and disinfection byproduct levels are negligible. Of the 551 public water supplies New York State expects may exceed one or more proposed MCLs 12% are surface water or groundwater under the direct influence (GWUDI) of surface water and 88% are

groundwater systems. As indicated in 6.7.1.2 Baseline Information on DBP Precursors and Trihalomethane Formation, "the [TOC] levels in Ground Water plants tended to be lower compared to concentrations in Surface Water plants"

- Of the 12% of public water systems that are surface water or GWUDI systems, approximately 21% have at some time exceeded a THM4 or haloacetic acid (HAA5) MCL. This represents 2.7% of the total number of public water systems expected to exceed a PFAS MCL.

The Department supports rulemaking based on sound science that provides meaningful reduction of all cancers. According to the New York State Department of Health, approximately 5,400 New Yorkers are diagnosed with bladder cancer each year [FN1: https://www.health.ny.gov/statistics/cancer/registry/abouts/bladder.htm]. However, we suggest that reduction of bladder cancers is best addressed by TOC removal benchmarks through the existing practice of treatment technique regulations for disinfection byproducts as well as distribution system controls, rather than indirectly through PFAS MCLs that do not include a treatment optimization component with no mechanism to monitor performance.

EPA Response: There are many treatment technologies available for PFAS removal from drinking water with varying levels of effectiveness. For the rule, the EPA has identified GAC, PFAS-selective IX, RO, and NF as BATs. However, water systems are not required to use BATs to meet the rule. More details on the ramifications of such a choice may be found in the summary of major comments for section 10 of the EPA response in this *Response to Comments* document which also contains information on alternative treatment technologies. The EPA has not quantified their costs, evaluated co-removal, or considered benefits of technologies not selected as BATs.

The EPA agrees with the commenter that there is not always a direct correlation between THM4 levels and TOC in public water systems. The THMs were not calculated based on the TOC reduction. The TOC was used to bin systems and THM reduction was calculated from formation potential before and after GAC treatment. This dataset is the best available data to determine THM4 reduction based on TOC reduction using GAC treatment. Because we are not estimating THM4 from TOC, this reduces the uncertainty in correlation estimates. Even though systems may be in compliance with the current MDBP regulations, they may still achieve a reduction in THM4 that is a quantifiable benefit for bladder cancer reduction. The EPA characterized THM4 levels and TOC in public water systems using the best available data on the occurrence of these compounds. (Please see Table 6-29 in the economic analysis titled “Data Sources and How the Information Derived from each Source is Used in the DBP Co-Removal Analysis”). Further, the EPA estimated TOC percent removal in both surface water and ground water systems using a logistic equation model. The methodology for estimating DBP reductions was externally peer reviewed by three experts in GAC treatment for PFAS removal and DBP formation potential. The external peer reviewers supported the EPA’s approach and edits based on their recommendations for clarity and completeness are reflected in the following analysis and discussion.

The EPA agrees that reducing bladder cancer cases attributable to DBP drinking water exposure can be addressed by existing DBP-focused regulations and distribution system controls. However, as required by the SDWA, the EPA has reviewed the science concerning removal of co-occurring compounds and based on the available information anticipates that DBPs will be reduced under the PFAS rulemaking as a result of PFAS treatment installation. Therefore, as required under the SDWA, the EPA assessed the benefits of avoided bladder cancer morbidity and mortality.

See also section 13.7 of the EPA response in this *Response to Comments* document regarding uncertainty inherent in the relationship between THM4 levels and TOC in public water systems.

While the EPA acknowledges that New York state groundwater systems may have lower TOC than their surface water systems, the model for TOC removal and THM4 reduction was based on the best available national dataset that are representative on a national level but may not be identical on a local or state level.

For the DBP co-removal analysis, the EPA assigned TOC values at the system level based on Ground Water or Surface Water distributions. Because the TOC levels for all systems is not available, the EPA used TOC data provided by states in response to the fourth Six-Year Review to derive TOC probability distributions for influent into a PFAS treatment process; one distribution for Ground Water systems and another for Surface Water systems. The EPA randomly assigned values from these distributions to each Ground Water or Surface Water system, respectively. The actual TOC values may be higher or lower than the assigned values. The EPA notes that for systems using GAC for PFAS removal the corresponding impact would be under-stating or over-stating costs.

New Hampshire Department of Environmental Services (NHDES) (Doc. #1690, SBC-044353)

4. Page 18732, Column 1, Section XV—Statutory and Executive Order Reviews

a. NHDES Comment - The proposal estimates the economic cost associated with implementation and the projected health benefit. More than half of the projected health benefit associated with adopting the proposed PFAS MCLs is associated with coincidently reducing disinfection by-products (DBPs) when treating for PFAS which are already regulated through the DBP rules and associated MCLs. NHDES believes a more complex analysis needs to be completed whereby EPA completes an assessment to optimize human health protection and economic costs by considering alternative MCLs for DBPs in tandem with alternative MCLs for PFAS. Without further consideration of DBPs, communities impacted by DBPs without the presence of PFAS will not realize the same benefit/level of public health protection as those with PFAS levels above the proposed MCLs.

EPA Response: The EPA disagrees with the commenter. The EPA's analysis of health benefits associated with DBP exposure reductions is independent of DBP MCLs because the regulatory action is for PFAS contaminants only. The EPA is advancing public health protection from DBPs by considering revisions to the DBPRs in a separate process. Specifically, the DBP

regulations were listed as candidates for revision based on the Third Six Year Review findings and the EPA is currently evaluating potential changes to the DBP regulations. Any potential changes to the DBP rules will be evaluated separately from the PFAS NPDWR under those actions. Based on the SDWA requirements, the HRRCA for potential DBP rules would take into account simultaneous compliance benefits that may be relevant for systems subject to both PFAS and DBP NPDWRs. The EPA further notes that the commenter is incorrect in stating that half the rule's benefits are attributable to DBP reductions. DBP reductions are anticipated to produce approximately 23 percent of the rule's quantified benefits. While the EPA anticipates there may be some nonquantifiable benefits from reduction of unregulated DBPs, the agency has focused the majority of its nonquantifiable benefits analysis on benefits attributable to regulated and unregulated PFAS.

New Hampshire Department of Environmental Services (NHDES) (Doc. #1690, SBC-044335)

Second, NHDES believes the suggested benefits for treatment for PFAS are misleading, since more than half of the projected health benefit associated with adopting the proposed PFAS MCLs is associated with coincidently reducing disinfection by-products (DBPs) when treating for PFAS. As disinfection by-products are already regulated through the DBP rules and associated MCLs we feel those regulations are the correct path to realize and attribute those benefits.

EPA Response: The EPA disagrees with the commenter, as the benefits quantified for reduced DBP exposure under the PFAS NPDWR are independent of public health benefits stemming from the DBP rules and the DBP MCLs. Specifically, DBP benefits quantified under this rulemaking are a result of reduced DBP exposure from installation of PFAS treatment technologies. The EPA notes that the body of evidence for health effects associated with DBPs shows that additional DBP removal can further reduce bladder cancer risk. See the EPA response to comment Doc. #1690, SBC-044353 in section 13.7 in this *Response to Comments* document for discussion of the percentage of quantified rule benefits attributable to DBP reduction.

See also section 13.7 of the EPA response in this *Response to Comments* document for additional detail on the body of evidence for health effects for DBPs.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045922)

4. Benefits assessment for bladder cancer is not supported by the science

A significant portion of the benefits that EPA is claiming for this rulemaking come from co-benefits that would stem from reductions in disinfection byproduct (DBP) formation that EPA predicts are likely to occur due to compliance with the MCLs in the proposed rule. These benefits do not flow directly from reductions in PFAS but are due to the identification of GAC as a possible treatment technology [FN195: The proposed rule identifies GAC as a treatment technology but does not compel its use. Other approaches, including use of an alternative source of water supply, are available. 88 Fed. Reg. at 18,684.]. Use of GAC would decrease the levels of other contaminants, specifically trihalomethanes. EPA quantifies benefits of avoided bladder

cancer cases and avoided bladder cancer-related deaths. The significant problem with this approach is that a causal link between DBP and bladder cancer has not been established [FN196: See EPA Economic Analysis of the Proposed National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances, 2023, at page 6-109 to 6-110.]. While EPA cites Weisman et al. 2022 to support estimates of DBP-attributable bladder cancer, Weissman's overall conclusion calls into question the specific approach EPA is using by questioning the utility of using the four regulated trihalomethanes (THM4) as a surrogate for DBP mixtures [FN197: See: Weisman, R.J., Heinrich, A., Letkiewicz, F., Messner, M., Studer, K., Wang, L., and Regli, S. 2022. Estimating National Exposures and Potential Bladder Cancer Cases Associated with Chlorination DBPs in US Drinking Water. Environmental Health Perspectives,130(8):087002. https://doi.org/10.1289/EHP9985, which states: "Despite the increased weight of evidence established in recent years toward inferring a causal relationship between DBP exposure and bladder cancer, more work is needed to understand the possible mechanisms involved in that relationship, clarify different sources of uncertainty, and address the utility of THM4 as a surrogate measure of risk from the most relevant DBP mixtures of toxicological interest."]. Weisman et al. 2022 states "[w]e also identified several uncertainties that may affect the results from this study, primarily related to the use of THM4 as a surrogate measure for DBPs relevant to bladder cancer."[FN198: Id. at results section.] This paper also notes limitations related to the lack of a good animal model for THM-associated bladder cancer as well as the lack of an established mode of action.

The approach EPA is taking to estimate these benefits is not only highly uncertain but also complex and raises many questions. For instance, in the 2006 DBP rule, EPA includes a lag period in the modelling to account for when the reduction in exposure begins and when the full benefit might be realized [FN199: 71 Fed. Reg. 444 (Jan. 4, 2006).]. However, the modeling in this proposed rule does not include a lag period for either the bladder cancers or the kidney cancers. While EPA acknowledges that they did not include a cessation lag, they simply note that this likely leads to an overestimate in benefits, and no effort is made to account for this overestimate [FN200: See EPA Economic Analysis of the Proposed National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances, 2023, at page 6-127.]. EPA must explain why the modeling in this rule is not consistent with the approaches taken in the DBP rulemaking.

EPA realized its approach was complex and quietly, without any public input or awareness, had three anonymous peer reviewers respond to specific charge questions regarding EPA's approach through the use of a letter review [FN201: See EPA Response to Letter of Peer Review for Disinfectant Byproduct Reduction as a Result of Granular Activated Carbon Treatment for PFOA and PFOS in Drinking Water: Benefits Analysis Related to Bladder Cancer. 2023 EPA–815–B23–001.]. EPA does not disclose the expertise of these anonymous reviewers, nor does EPA explain why this modeling and approach was not presented to the SAB. SAB review, which includes opportunity for transparency and public comment and is far more robust than a letter review, as discussed earlier in these comments, is warranted for influential scientific information

that supports rulemaking. This novel and uncertain analysis does not meet the standards required by SDWA for estimating benefits.

EPA Response: The EPA disagrees with the comment. While research has not established a causal link between THM4 and bladder cancer, there is strong evidence that there is a correlation between THM4 and bladder cancer. THM4 may not be the causative agent but there is a well-established association: Epidemiological studies have shown that increased exposure to chlorinated DBPs is associated with higher risk of bladder cancer and other adverse health outcomes (Cantor et al., 1998; Freeman et al., 2017). Weisman et al. (2022) found that approximately 8,000 of the 79,000 annual bladder cancer cases in the U.S. were potentially attributable to chlorinated DBPs in drinking water systems.

The EPA's approach to using THM4 as a surrogate for the suite of chlorinated DBPs is consistent with the approach used in numerous epidemiological studies to estimate the co-occurrence and co-removal of specific genotoxic or cytotoxic DBPs.

The EPA's modeling approach for kidney and bladder cancer differs significantly from the approaches used in the Stage 2 Disinfection and Disinfection Byproducts Rule (D/DBPR). The Stage 2 D/DBPR did not consider cumulative exposures and prospective cohorts. While the EPA did not model the transitional dynamics in relative annual risk of bladder cancer following the THM4 exposure reduction, the EPA considered age-specific cohort cumulative exposures to THM4. Therefore, while drinking water THM4 concentrations are assumed to be reduced upon compliance with the rulemaking, the changes in cumulative average exposure are much more gradual. The EPA has not identified any studies on bladder cancer-specific risk cessation lag. The Stage 2 D/DBPR analysis relied on cancer risk cessation lag studies focused on smoking and arsenic exposure when modeling bladder cancer cessation lag. Additionally, Regli et al. (2015) did not include pertinent information on cessation lag. For this rule, a cross-sectional analysis quantifying the relationship between lifetime cancer risk and lifetime average exposure was used.

The DBP rulemaking approach also does not provide information on kidney cancer-specific risk cessation lag. However, The EPA evaluates gradual declines in PFAS blood serum concentrations resulting from the proposed rulemaking by implementing ORD's pharmacokinetic model. Gradual changes in PFAS blood serum combined with age-dependent data on baseline kidney cancer incidence result in modeling that considers gradual changes in kidney cancer incidence over the period of analysis.

The studies estimating the link between serum PFOA and RCC are not dynamic, and hence do not provide insights into whether RCC incidence may respond gradually to changes in serum PFOA. See also section 13.4.3 of the EPA response in this *Response to Comments* document, RCC Benefits Estimation.

The EPA disagrees with the commenter's assertion that the peer review completed does not meet the requirements of the SDWA. As discussed in section 13.7 of the EPA response in this *Response to Comments* document and part 12 of the preamble, the EPA must not take every

question to the SAB. The EPA's methodology to estimate DBP reductions was externally peer reviewed by three experts in GAC treatment for PFAS removal and DBP formation potential. This peer review was fully consistent with the EPA's peer review policy, utilized three highly respected independent drinking water treatment experts. See the *EPA Response to Letter of Peer Review for Disinfectant Byproduct Reduction as a Result of Granular Activated Carbon Treatment for PFOA and PFOS in Drinking Water: Benefits Analysis Related to Bladder Cancer* (USEPA, 2023j) for more information as to how the EPA conducted this letter peer reviews. As part of the supporting material for the rule proposal, the EPA included the comments from the three expert peer reviewers as well as how each comment was addressed or the rationale for why it was not changed. The EPA has met all peer review requirements for this DBP analysis and the rulemaking overall.

3M Company (Doc. #1774, SBC-045705)

11. Comments on Figure 6-10 Overview of Analysis of Co-Removal Benefits ((U.S, 2023a))

In a decision tree like that seen in Figure 6-10, each step of the decision analysis is comprised of models with uncertain predictions, decisions based on subjective judgement, value-based judgements, and uncertain cost estimates and cost expectations. This graphic represents the decision process EPA has both implicitly and explicitly used to generate the MCL. At issue is the level of uncertainty a multi-branched decision analysis actually represents. In practice, EPA has not identified nor quantified the measurable uncertainty in each step of the decision process used by EPA. EPA must provide the public with an honest estimate of the degree to which the MCGL will result in a benefit to human health, including the actual costs which the public must incur for these indeterminate benefits. A rigorous uncertainty analysis of the Figure 6-10 decision tree will result is such a large uncertainty in the total value of reduced bladder cancer, that any positive benefit will not be quantifiable.

EPA Response: The EPA disagrees with this comment that such a large uncertainty would result from the bladder cancer, that the agency cannot quantify benefits. A conservative approach to the THM4 reduction estimates was chosen and the limitations and uncertainties associated with the analysis were also detailed at length in the rule proposal. See also sections 13.2, , 13.8, , and 13.9, of the EPA response in this *Response to Comments* document. Furthermore, to ensure the methodology and analyses were scientifically robust, the estimation of THM4 reduction due to GAC and PWS universe estimation based on TOC occurrence in the SYR4 database was peer reviewed. Other elements that fed into the analysis were also peer reviewed: specifically, the PFAS occurrence model (Cadwallader et al., 2022) and the bladder cancer slope factor (Regli et al., 2015; Weisman et al., 2022). In short, the DBP co-removal benefits analysis is based on peer-reviewed, best available science, fully consistent with the statutory requirements of the SDWA.

3M Company (Doc. #1774, SBC-045694)

b. EPA Improperly Inflated the Purported Benefits of the Rule

i. EPA improperly quantified benefits of co-removed substances rather than co-occurring substances

EPA quantified benefits of a co-removed substance (THM4) (USEPA 2023i, p. 6-108). This is inappropriate as it artificially inflates the benefits of the MCL. The SDWA contemplates quantifying benefits from co-occurring substances but not quantifying the benefits of all co-removed substances. [FN101: See SDWA [sec]1412(b)(3)(C).] If EPA were to weigh the benefits of all co-removed substances as a result of treatment, every NPDWR would have its benefits inflated because any treatment technique will remove more than the targeted substance. For example, THM4 is not a PFAS and EPA did not make a determination that it is a co-occurring substance. EPA's inclusion of the purported benefits of THM4's removal in the cost-benefit analysis violates the SDWA's clear direction on considerations to be included in that analysis.

EPA Response: See section 13.7 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046111)

Second, while it is appropriate for EPA to consider co-benefits when estimating the health benefits of the Proposed Rule, [FN130: Id. at 5.] EPA's analysis of co-benefits is incomplete. The Draft EA considers only reduced bladder cancer risks from co-removal of disinfection byproducts associated with PFAS drinking water technology, [FN131: Proposed Rule, 88 Fed. Reg. at 18,721.] ignoring the benefits that will arise from co- removal of additional synthetic organic contaminants, including additional PFAS that are not directly regulated by the Proposed Rule.

EPA Response: The EPA describes in the EA that additional non-quantifiable co-removal benefits would be realized due to treatment for PFAS (USEPA, 2024b). These are non-quantifiable due to lack of occurrence and health data on a national scale. See also section 13.7 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046128)

5. The inclusion of co-benefits (or ancillary benefits) in benefit-cost analyses is well- grounded in economic theory.

Roughly 14% to 18% of the estimated quantified benefits of the PFAS NPDWS are due to reduced bladder cancer risks, which in the current context is a co-benefit or ancillary benefit – i.e., a benefit that results from a regulatory action but that is not the direct intent of that action (OMB 2003). More specifically, the proposed PFAS NPDWS is anticipated to also reduce disinfection byproducts, and in turn reduce the risks of bladder cancer associated with exposure to those byproducts. The inclusion of such benefits in benefit-cost analysis is directed under the Safe Drinking Water Act (SDWA) and is well-grounded in economic theory (EPA 2014, OMB 2003).

EPA Response: The EPA agrees with the commenter that inclusion of co-benefits in benefit-cost analysis is well-grounded in economic theory and directed under SDWA.

American Chemistry Council (ACC) (Doc. #1841, SBC-044845)

The Projected Benefits of a Reduction in Disinfection Byproducts Cannot be Attributed Solely to Compliance with the Proposed MCLs

EPA's estimate of benefits also includes a reduction in bladder cancer as a result of the decrease in the formation of THM expected to result from the removal of total organic carbon (TOC) achieved through treatment of source water required by the proposal. As EPA notes in its analysis, TOC levels are lower in groundwater sources which represent more than three-quarters of the systems EPA estimates will be impacted by the proposal. [FN184: USEPA. Disinfectant Byproduct Reduction as a Result of Granular Activated Carbon Treatment for PFOA and PFOS in Drinking Water: Benefits Analysis Related to Bladder Cancer. EPA-815-P23-002. Office of Water (2023). (USEPA DBP Benefits Analysis)] In addition, one of the two most likely options for treatment for PFAS (ion exchange or IX) is only marginally effective for removal of TOC. [FN185: EPA's Economic Analysis estimates that 75 to 95 percent of systems will select granular activated carbon or IX as a compliance option (USEPA Economic Analysis, at 5-12.) The Economic Analysis also notes that IX is not expected to remove a substantial amount of DBP precursors.]

PWSs are required to achieve a certain percentage of TOC removal as part of the Stage 1 and Stage 2 Disinfectants and Disinfection Byproducts (DBP) Rules. The Stage 2 DBP Rule promulgated MCLs for total THMs and haloacetic acids as well as monitoring, reporting, and public notification requirements. The rule lists granular activated carbon (GAC) – the most likely treatment approach identified by EPA for PFAS removal - as a best available technology (BAT) for removal of THM. As a result of the monitoring and reporting requirements, EPA has collected a large amount of information on TOC and DBP levels.

According to its latest enforcement policy, EPA has identified non-compliance with the Stage 2 DBP Rule and other drinking water standards as a priority initiative for 2024-27. [FN186: 88 Fed. Reg. 2093 (January 12, 2023).] EPA also held two public meetings in October 2020 to consider revisions in the DBP Rules [FN187: 85 Fed. Reg. 61680 (September 30, 2020).] and the Agency has tasked its National Drinking Water Advisory Council to develop recommendations for revisions to these and other Rules. [FN188: https://www.epa.gov/ndwac.]

These ongoing, and long-standing activities by both PWSs and the Agency to monitor and reduce THM levels belie EPA's contention that the benefits predicted to occur from reductions in THMs "may be attributed solely to compliance with the maximum contaminant level" as required by Section 1412(b)(3)(C)(i) of the Safe Drinking Water Act (SDWA). EPA has several initiatives underway to reduce THM levels in drinking water and the Agency has not attempted to separate reductions achieved through those actions compared to the current proposal.

EPA's analysis moreover notes that removal of TOC by GAC is dependent on a large number of factors, including the amount and type of TOC, other water quality characteristics, pretreatment processes, and the type of GAC used and the operation practices. [FN189: USEPA. Technologies and Costs Document for the Final Long Term 2 Enhanced Surface Water Treatment Rule and Final Stage 2 Disinfectants and Disinfection Byproducts Rule. EPA 815-R-05-013. Office of Water (2005). (USEPA Stage 2 DBP Rule Technologies Document)] Despite the significant amount information collected on THM levels and GAC systems, EPA notes "the lack of available data to directly inform THM4 from PFAS adsorption studies." [FN190: USEPA Economic Analysis, at 6-89.] In fact, the Agency identified only seven systems to use as a basis for its analysis. While the analysis shows a decrease in THM4 levels after the installation of GAC in the four surface water systems, two of the three ground water systems showed increased THM4 formation after the installation of GAC. [FN191: USEPA DBP Benefits Analysis, at 25.] The Agency offers several possible explanations for why this levels may have increased, but fails to offer empirical evidence to support the quantification of benefits for THM reduction from the proposal.

EPA Response: The EPA disagrees with the commenter, as the benefits quantified under this PFAS NPDWR are in fact solely attributable to the PFAS MCLs. The PFAS NPDWR requires installation of treatment technologies for PFAS removal that have the added benefit of reducing TOC, which is a precursor to DBP formation. As a result of the PFAS NPDWR, TOC is expected to be reduced upon the installation of PFAS treatment technology installations, and DBPs and bladder cancer morbidity and mortality will be reduced as a result. The benefits quantified for reduced DBP exposure under the PFAS NPDWR are independent of public health benefits stemming from the DBP rules and the DBP MCLs, and existing and future DBP regulations do not take away from this DBP co-benefit from the PFAS rule.

While the current DBP rules are effective, the EPA considered cost and risk/risk trade off with microbes in the development of those regulations and there are still residual risks, even if a system is in full compliance with the MCLs. The PFAS NPDWR reduces those risks beyond those from the DBP rule alone. Additionally, the DBP regulations, the benefits of which are separate from the benefits quantified under the PFAS NPDWR, were listed as candidates for revision based on the Third Six Year Review findings and the EPA is currently evaluating potential changes to the DBP regulations. Any potential changes to the DBP rules will be evaluated separately from the PFAS NPDWR under those actions.

For the THM4 changes based on SYR4 comparison, the EPA specifically looked at systems that installed GAC for PFAS removal and reported THM4 concentrations. While the levels of THMs will fluctuate over time in any system, there is empirical evidence from the DBP ICR Treatment Study Database that GAC treatment removes TOC (a DBP precursor) and that THM4 concentrations decrease after GAC treatment based on DBP formation potential experiments.

The EPA's analysis assumed that systems implementing IX do not accrue benefits associated with bladder cancer risk reductions, which was highlighted as an "underestimate of benefits" in characterizing the exposed population. Systems using IX for PFAS removal will also benefit

from some TOC removal, but the removal will be limited in comparison to GAC treatment because PFAS-selective IX can show preferential removal of PFAS over organic matter (de Abreu Domingos et al., 2018).

See section 13.7 of the EPA response in this *Response to Comments* document for further discussion of the EPA's DBP co-removal benefits analysis.

13.8 Comparison of Costs and Benefits

Summary of Major Public Comments and EPA Responses

Many commenters agreed with the Administrator's determination that the benefits of the rule justify its costs. Specifically, commenters asserted that the EPA's estimation of the net benefits of enacting the MCLs is reasonable, stating that "even if the costs are very substantial, the benefits associated with the anticipated drinking water improvements justify such expenditures" (Doc. #1687, SBC-044448). Commenters also stated that it is likely that "the analysis understates the benefits" (Doc. #1808, SBC-046094) of the rule, particularly given the "significant unquantified risk reduction benefits and co-benefits" (Doc. #1846, SBC-045833) that are anticipated to result from the rule.

In response to these comments, the EPA agrees that its quantified benefits likely significantly understate the benefits of the rule due to the large share of nonquantifiable benefits that are expected to be realized as avoided adverse health effects, in addition to the benefits that the EPA has quantified. The EPA anticipates additional benefits associated with developmental, cardiovascular, liver, immune, endocrine, metabolic, reproductive, musculoskeletal, and carcinogenic effects beyond those benefits associated with decreased PFOA and PFOS that the EPA has quantified. In response to commenters urging the EPA to quantify additional health endpoints associated with PFAS exposure, the EPA has developed a quantitative sensitivity analysis of PFOS effects and liver cancer, further strengthening the justification for this determination. Due to occurrence, health effects, and/or economic data limitations, the EPA is unable to quantitatively assess additional benefits of the rule.

Conversely, several commenters stated that the EPA has failed to demonstrate that the benefits of the rule justify its costs. Specifically, commenters disagreed with this determination because the EPA's analysis "significantly underestimates the costs of its proposed MCLs…and overestimates its benefits" (Doc. #1841, SBC-044848). Commenters asserted that the EPA needs to update its EA to more accurately reflect the true costs of compliance of the rule to make the determination that the rule's costs are justified by its benefits.

After considering public comments, the EPA has made a number of adjustments to the cost model and collectively these changes have increased the agency's estimated annualized total costs. The EPA made many of these changes as recommended by commenters that increased both unit cost estimates (the capital, operation and maintenance costs at a system level associated with the final rule) as well as the national costs, as detailed in section 13.3.3 of the EPA response in this *Response to Comments* document. The EPA has used the best available peer reviewed

science to inform the cost estimates, including treatment costs, of the final PFAS NPDWR. For more information on the EPA's responses to comments on the rule costs, see Sections XII.A.2-XII.A.4 of the preamble for this action. The EPA disagrees with commenters that the EPA has overstated the benefits. As discussed in section XII.A.1 of the preamble for this action, the EPA has used the best available peer reviewed science to quantify the benefits of the rule, and as discussed above, the agency believes the quantified benefits likely significantly understate the benefits of the rule.

A few commenters urged the EPA to consider whether the benefits of finalizing the rule at regulatory alternative MCLs (e.g., 5.0 or 10.0 ng/L) would better justify the costs of the rule. The EPA disagrees with commenters that suggested the benefits better justify the costs of PFOA and PFOS standards at 5.0 or 10.0 ng/L. These commenters pointed to the quantified net benefits of the regulatory alternatives and noted that net benefits are positive at 3 and 7 percent discount rates for a standard of 10.0 ng/L for PFOA and PFOS. The commenters' sole reliance on the quantified costs and benefits of the rule to support their argument is incorrect, as SDWA requires the agency to consider both the quantifiable and nonquantifiable impacts of the rule in the determination. Under SDWA 1412(b)(4)(B), the EPA is required to set an MCL as close as feasible to the MCLG, taking costs into consideration. In other words, SDWA does not mandate that the EPA establish MCLs at levels where the quantified benefits exceed the quantified costs. This was many commenters' justification for the recommendation to promulgate a standard of 10.0 ppt each for PFOA and PFOS in lieu of the proposed rule, and the EPA therefore disagrees that quantified costs and benefits can or should be the sole determinant of an MCL value. The Administrator's assessment that the benefits of the proposed rule justified its costs was based on the totality of the evidence, specifically the quantified and nonquantifiable benefits, which are anticipated to be substantial, as well as the quantified and nonquantifiable costs. SDWA is clear that the EPA should not limit its evaluation and determination to solely quantifiable costs and benefits.

At the time of the EPA's proposal, it had issued a final regulatory determination for PFOA and PFOS. The MCLs for PFOA and PFOS in the proposed rule and final rule are both 4.0 ng/L. EPA's proposal included preliminary regulatory determinations for PFHxS, PFNA, HFPO-DA, and/or PFBS and mixtures and addressed them all through the Hazard Index MCL. The proposal defined a mixture as containing one or more of the four PFAS and therefore covered each contaminant individually if only one of the four PFAS occurred. The Hazard Index as proposed ensures that the level of exposure to an individual PFAS remains below that which could impact human health because the exposure for that measured PFAS is divided by its corresponding HBWC. The EPA proposed HBWCs of 9.0 ng/L for PFHxS; 10.0 ng/L for HFPO-DA; 10.0 ng/L for PFNA; and 2000.0 ng/L for PFBS. The EPA considered and took comment on establishing individual MCLGs and MCLs in lieu of or in addition to the Hazard Index approach for mixtures of PFHxS, PFNA, HFPO-DA, and/or PFBS. The final rule includes individual MCLs for PFHxS, PFNA, and HFPO-DA as well the Hazard Index MCL for mixtures of PFHxS, PFNA, HFPO-DA and PFBS concurrent with final regulatory determinations for these contaminants. The EPA is finalizing a mixture MCL at 1 and individual MCLs for HFPO-DA MCL of 10 ng/L; PFHxS

MCL of 10 ng/L; and PFNA MCL of 10 ng/L. As detailed in section XIV of the preamble for the final rule, each MCL is independent of the others and can be implemented on its own.

The EPA's economic analysis uses contaminant specific information to estimate treatment costs (e.g. contaminant specific occurrence and removal efficiencies for various treatment technologies, accounting for co-occurrence of other PFAS and other water quality conditions) and quantified benefits (e.g. contaminant specific pharmacokinetic, dose-response, and health outcome valuation information) to evaluate the impact of each regulated PFAS based on its individual facts and circumstances. Where evidence supported that PFOA and PFOS had the same adverse health effects and there was sufficient data to quantify those impacts (i.e. birthweight impacts, CVD) the EPA analyzed these impacts separately and presents the combined quantified benefits of reduced exposure to both contaminants. Where a single contaminant had sufficient evidence and data to quantify an adverse health effect (i.e. PFOA and Renal Cell Carcinoma (RCC)), and this adverse impact could not be quantified in other regulated contaminants, the EPA presented contaminant specific benefits associated with reduced exposure.

With respect to treatment costs, there are significant estimated cost efficiencies when co-removal of the regulated PFAS is correctly characterized. The cost of each individual PFAS MCL would be overestimated without considering the sunk capital expense and economies of scale associated with the co-treatment of PFOA and PFOS in addition to the other regulated PFAS. For example, as demonstrated in Chapter 5.1.3 of the EA, the majority of systems where PFHxS is expected to exceed its individual MCL are also expected to exceed the PFOA and PFOS MCLs. Therefore, estimating the national costs of solely treating for PFHxS to below its MCL, absent the PFOA and PFOS MCLs, would substantially overestimate the actual expected national costs associated with the PFHxS MCL and not be representative of the conditions the EPA expects when the rule is implemented. This is also the case for the Hazard Index MCL, the PFNA MCL and the HFPO-DA MCL.

In order to delve into the Administrator's determination that the benefits of the rule justify its costs one must consider the regulatory scenarios that were used to build out the EA analysis of costs and benefits for the proposed and final rule. These EA analyses were designed in light of the fact that the EPA had already made a regulatory determination for PFOA and PFOS at the time of proposal, the recognition that PFAS frequently cooccur and treatment costs will frequently not be attributable solely to a single PFAS, and the practical recognition that public water systems would be designing treatment for all PFAS addressed by the rule rather than designing treatment to comply with any single individual MCL.

The EA starts with the base MCL grouping of PFOA and PFOS. These two MCLs and their contaminant co-occurrence are always considered together in the impact analysis. This is a reasonable assumption, as EPA had already made a final regulatory determination for PFOA and PFOS at the time of proposal, so any examination of the impacts of the other MCLs should assume that PFOA and PFOS MCLs are also in effect. EPA has considered the costs and benefits of the PFOA and PFOS MCLs at 4.0 ng/L each (known as option 1a in the EA) and under that

regulatory alternative, the quantified benefits exceed the quantified costs (see tables ES-1 and ES-2 of the EA for more information). Additionally, the EPA anticipates additional benefits from reduced exposure to PFOA and PFOS due to the final rule associated with developmental, cardiovascular, liver, immune, endocrine, metabolic, reproductive, musculoskeletal, and carcinogenic effects beyond those benefits that the EPA has quantified (see Chapter 6.2.2 of the EA for more information). The nonquantifiable costs of the PFOA and PFOS MCLs are the same as those of the final rule (see Chapter 5.3.1 and 5.7 of the EA), with the exception of the nonquantifiable costs associated with the Hazard Index MCL and the MCLs for PFHxS, PFNA and HFPO-DA. In the case of the PFOA and PFOS MCLs, the EPA has determined that the quantifiable and nonquantifiable benefits of the rule justify the quantifiable and nonquantifiable costs.

When considering the incremental costs and benefits of the Hazard Index MCL and the individual MCLs for PFNA, PFHxS, and HFPO-DA, the EPA assumed that the PFOA and PFOS MCLs were also in effect. In the case of PFHxS, the EPA has considered the incremental national impact associated with the PFHxS MCL and Hazard Index MCL exceedances where PFHxS is present above its HBWC while one or more other Hazard Index PFAS are also present in that same mixture, under the assumption that the PFOA and PFOS MCLs are also in effect (see Chapter 5.1.3 of the EA). The quantified national primary analysis costs and benefits represent the impact of the three MCLs and EPA also considered non-quantified costs and benefits in making a positive determination for this MCL grouping. In the case of PFNA and HFPO-DA, the EPA considered the cost of each these MCLs in addition to the PFOA and PFOS MCLs. Specifically, the EPA has considered the national impact associated with the PFNA MCL, under the assumption that the PFOA and PFOS MCLs are also in effect. The EPA performed the same analysis for the HFPO-DA MCL (See Appendix N.4). These estimates also represent the marginal costs of Hazard Index MCL exceedances where PFNA or HFPO-DA are present above their respective HBWCs while one or more other Hazard Index PFAS are also present in the same mixture. Finally, the EPA has considered the incremental national impact of the Hazard Index based on occurrence information for PFHxS, PFNA, HFPO-DA and PFBS and the individual MCLs for PFHxS, PFNA, and HFPO-DA together, assuming the PFOA and PFOS MCLs are in effect (See Appendix N.3). The final positive determination, considering quantifiable and nonquantifiable benefits and costs, extends to this inclusive grouping as well as any combination of these MCLs when the PFOA and PFOS MCLs are in effect. The PFOA and PFOS MCLs account for the large majority of the costs of the final rule, and as detailed in Appendix N.3, the Hazard Index and individual MCLs for PFHxS, PFNA, and HFPO-DA are expected to increase costs nationally by approximately 5 percent. Combinations of fewer than all of these MCLs would therefore increase costs nationally by less than 5 percent. However, as discussed in detail in Chapter 6.2 of the EA, the EPA anticipates considerable nonquantifiable benefits from developmental, cardiovascular, immune, hepatic, endocrine, metabolic, reproductive, musculoskeletal, and carcinogenic effects associated with the Hazard Index MCL, PFHxS MCL, PFNA MCL, and HFPO-DA MCL. Therefore, the EPA anticipates significant benefits as a result of the Hazard Index and individual MCLs, as well as any combination of them, in addition to the benefits resulting from the PFOA and PFOS MCLs.

In sum, the EPA's determination at proposal and reaffirmation that the benefits of the final rule justify the costs takes into account that the large majority of the costs of compliance result from the PFOA and PFOS MCLs, the associated significant benefits from these MCLs, and the fact that the costs from the other MCLs (including various combinations) result in less than 5 percent of the total costs but contribute significant benefits. The EPA's reaffirmed determination for the final rule extends to each of the various MCLs in this final rule.

As discussed in section 13.2 of the EPA response in this *Response to Comments* document and in section XII.J of the FRN for this action, in addition to estimating the benefits and costs of the rule at both a 3 percent and 7 percent discount rate, in compliance with OMB guidance in effect at the time of rule proposal, the EPA has also estimated expected value costs and benefits using a 2 percent discount rate. At a 2 percent discount rate, estimated quantified annualized costs are $1,548.64 million and estimated quantified annualized benefits are $1,549.40; when considering the stochastic nature of SafeWater MCBC, the modeled quantified net benefits are nearly at parity. To further explore how the relationship between costs and benefits is impacted by relatively small methodological changes the EPA assessed how the use of willingness to pay information (more closely related to opportunity cost), instead of cost of illness information, for non-fatal RCC and bladder cancer illnesses, affects total net benefits at a 2 percent discount rate. In this case the estimated expected quantified annualized costs are $1,548.64 million and the estimated expected quantified annualized benefits increase to $1,632.34 million, giving $83.7 million in expected annualized net benefits. While quantified results are not the sole consideration in the Administrator's determination, net negative mean results of a small magnitude at the 2 percent discount rate with a significant probability that net benefits are greater than zero, and positive net benefits under a valuation sensitivity analysis, further support the Administrator's determination that the benefits of the rule justify its costs.

Although the modeled quantified net benefits are nearly at parity at the 2 percent discount rate, and mean net quantified benefits are negative at the 3 and 7 percent discount rates for the final rule, based on the EPA's consideration of the full record, specifically the quantified and nonquantifiable benefits, which are anticipated to be substantial, as well as the quantified and nonquantifiable costs, the benefits of the final rule justify its costs.

Other commenters incorrectly stated that SDWA requires the EPA to set an MCL at a level "... that maximizes health risk reduction benefits at a cost that is justified by the benefits" (Doc. #1713, SBC-045920; Doc. #1761, SBC-047717 and SBC-046080). This test is found in Section 1412(b)(6)(A) of SDWA and applies only when the Administrator determines based on the HRRCA that the benefits of a proposed MCL developed in accordance with paragraph (4) (i.e., an MCL as close as feasible to the MCLG) would not justify the costs of complying with the level. In the case of the proposed PFAS NPDWR, the Administrator determined that the benefits justify the costs for MCLs set as close as feasible to the MCLGs. For more information on the EPA's response to comments on the regulatory alternative MCLs considered in this rulemaking, see section V of the final rule preamble.

For the final rule, considering both quantifiable and nonquantifiable costs and benefits of the rule, the EPA is reaffirming the Administrator's determination made at proposal that the quantified and nonquantifiable benefits of the rule justify its costs.

Individual Public Comments

Brian Hackman (Doc. #1539, SBC-042888)

The current USEPA proposal for PFAS (polyfluoroalkyl substances) chemicals does not consider the actual risks, if any to the population, to have establish its $1.06 billion per year health care cost savings to implement the about $800 million per year costs for water treatment to reduce PFAS. While not much of surprise, Agency's taking an activist role in establishing new regulations, contrary to the recent West Virginia vs. USEPA Supreme Court ruling, have found that their cost estimates are no where near reality. For example, the recent Inflation Reduction Act, following review by the Office of Management and Budget (OMB) found that legislators had misappropriated the cost liabilities of their legislation by approximately 3 times that of the negotiated liability during rulemaking.

The lack of Office of Management and Budget (OMB) input prior to this proposal demonstrates an inherent lack of wisdom and failure to account for real costs that are meant to be discovered before Rulemaking. I would encourage the Director of the USEPA to pick up any tab for costs not included in this proposal should he continue to put his stamp on the proposed MCL and HI's.

EPA Response: See section 13.8 of the EPA response in this *Response to Comments* document for discussion of the EPA's comparison of costs and benefits. The EPA disagrees with the commenter's assertion that the EPA did not consider OMB input prior to the rule proposal. As directed under Executive Order 12866, the proposed regulatory action, including the EA, was submitted to OMB for review as part of interagency review before the proposed rulemaking was published. OMB and other federal government agencies and departments engaged in the interagency review process reviewed the proposed EA and the EPA incorporated reviewer comments into the proposed and final rule.

Water & Health Advisory Council (Doc. #1590, SBC-042790)

Overall, the U.S. EPA has not demonstrated that the financial burden that will be placed on municipalities and their community members associated with the proposed PFAS drinking water regulations is justified by a meaningful protection of public health. Science is still evolving, with critical research ongoing. An overly conservative and not scientifically supported interpretation of the science can have negative public health consequences by not only diverting resources away from known public health drinking water issues (e.g. arsenic, lead or microbial contaminants in water, failing infrastructure, raised water utility costs), but also by the unnecessary stigma and stress that is put on a community identified as living with contaminated drinking water.

EPA Response: See section 13.8 of the EPA response in this *Response to Comments* document for discussion of the EPA's comparison of costs and benefits. The EPA disagrees with the commenter's suggestion that the EPA has applied "overly conservative and not scientifically supported interpretation of the science" in informing its economic estimates for this action. The EPA has used the best available peer reviewed science to inform estimation of costs and benefits of the rule, including synthesis of health studies ranked based on study quality and significance and peer review of analyses used to develop and evaluate the benefits and costs of the regulation. For the EPA's responses to comments related to estimation of costs and benefits for the final rule, please see sections 13.3 and 13.4, respectively, in this *Response to Comments* document. In response to the commenter's statement that this action will be "diverting resources away from known public health drinking water issues", the EPA disagrees with the suggestion that PFAS is not a known public health drinking water issue; to the contrary, as explained in the preamble to the final rule, PFAS is a very significant health concern for many water systems and reductions in PFAS levels will provide many benefits across the nation. Moreover, there may be an opportunity for many communities to utilize BIL (P.L. 177-58) funding to provide financial assistance for addressing emerging contaminants, with specific allocations for emerging contaminants, including PFAS. For responses to comments regarding funding available through BIL, please see section 2.4 of the EPA response in this *Response to Comments* document.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043633)

BWWB is committed to providing reliable, equitable, cost-effective delivery of high-quality water and services while protecting public health and environmental resources for current and future generations. We acknowledge that the regulation of PFAS is important to address public health risks, however we strongly believe that the option selected by EPA for the proposed PFAS Rule is likely to incur costs and customer hardship well in excess of the identified benefits calculated by USEPA. The proposed Rule is simply not cost justifiable. BWWB's internal analysis (by our staff and expert advisors), suggests that full compliance with the proposed regulation could result in over 40% of our customer base (more than 300,000 Alabamans) spending more than 2% of their income on water bills alone. We submit these comments to bring your attention to the enormous financial burden and practical challenges that utilities and local communities would face under the proposed PFAS Rule.

If you have any questions, please reach out to me at michael.johnson@bwwb.org. Thank you for your consideration.

Sincerely,

Michael Johnson, MBA, CPA x

General Manager

Attachment 1 – Detailed Technical Comments on the Proposed PFAS National Primary Drinking Water Regulation, elaborates on the ideas summarized in this letter. The detailed technical comments highlight potential shortcomings of the proposed rule and are organized into five main

sections: 1) Cost Benefit Analysis, 2) Affordability, 3) Utility Impacts, Treatability, and 5) Regulatory Unreasonableness and Continued Uncertainty. Attachment 1 has several supporting appendices provided with it, for reference.

• Appendix A: Comparison of Total Capital Cost and O&M Cost between EPA's Cost Model and Arcadis Case Studies

• Appendix B: Rate Impacts of BWWB's Ongoing and Emerging Compliance and Infrastructure Needs (Excluding the PFAS Rule)

• Appendix C: Combined Impact on BWWB's Capital and O&M Budgets and Rates (Including the proposed PFAS Rule)

EPA Response: See section 13.8 of the EPA response in this *Response to Comments* document for discussion of the EPA's comparison of costs and benefits. The EPA agrees that regulating PFAS is important in addressing public health risks. For discussion of the EPA's estimation of costs of the final rule, please see section 13.3.1 of the EPA response in this *Response to Comments* document for responses to comments on primacy agency costs, section 13.3.3 of the EPA response in this *Response to Comments* document for responses to comments on water system treatment costs, section 13.3.4 of the EPA response in this *Response to Comments* document for responses to comment on water system monitoring costs, section 13.3.5 of the EPA response in this *Response to Comments* document for responses to comments on water system administrative costs, and section 13.3.6 of the EPA response in this *Response to Comments* document for responses to comments on water system non-treatment costs, respectively. For discussion of the EPA's affordability analysis, please see section 13.10 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1602, SBC-043640 in section 13.10 in this *Response to Comments* document. For responses to comments on funding available through BIL, please see section 2.4 of the EPA response in this *Response to Comments* document.

Arlington County Virginia (Doc. #1603, SBC-043011)

Economic Analysis

As required by law, the EPA has developed an Economic Analysis of the proposed regulation. Our understanding of the Economic Analysis raises several concerns that bring into question the justification for the proposed rule.

EPA Response: See section 13.8 of the EPA response in this *Response to Comments* document.

Arlington County Virginia (Doc. #1603, SBC-043012)

First, we interpret the published Cost/Benefit analysis as demonstrating an ambiguous case for the rule as proposed.

EPA Response: See section 13.8 of the EPA response in this *Response to Comments* document.

Illinois Farm Bureau (IFB) (Doc. #1630, SBC-043134)

Of utmost importance is the accuracy of the cost/benefit analysis when setting the drinking water MCL for PFOA and PFOS at the very low level of 4ppt. We fear that the costs will far outweigh the benefits and that rural farming communities and/or underserved and underprivileged areas will be hit hardest.

EPA Response: In response to the commenter's assertion that "the costs will far outweigh the benefits," please see section 13.8 of the EPA response in this *Response to Comments* document. In response to the commenter's concern regarding impacts to "rural farming communities and/or underserved and underprivileged areas", in the EPA's EJ analysis for the final rule, the agency examined the distribution of costs across demographic groups and across multiple water system size categories. When examining costs anticipated to result from the rule, the EPA found that cost differences across demographic groups were small, with no clear unidirectional trend in cost differences based on demographic group. Additionally, the agency found that incremental household costs to all race/ethnicity and income groups generally decrease as system size increases, which is expected due to economies of scale. For further discussion of the EPA's EJ analysis, please see Chapter 8 of the EA (USEPA, 2024b) and section 14.10 of the EPA response in this *Response to Comments* document. To alleviate potential cost disparities identified by the EPA's analysis, there may be an opportunity for many communities to utilize BIL (P.L. 117-58) funding to provide financial assistance for addressing emerging contaminants. BIL funding has specific allocations for both disadvantaged and/or small communities and emerging contaminants, including PFAS. For responses to comments regarding BIL funding, please see section 2.4 of the *Response to Comments* document.

In the EPA's small system affordability analysis, the EPA analyzed the household level cost impacts of the final rule on small system size categories and determined the rule is affordable for small systems. While the EPA did not separately present the impacts of the final rule on rural communities, many rural communities are served by small systems. For more information, see the EPA's affordability analysis in Chapter 9 of the EA (USEPA, 2024b).

Superfund Settlements Project (SSP) and RCRA Corrective Action Project (RCAP) (Doc. #1631, SBC-043439)

Third, beyond the failure to consider contaminated site costs, EPA's cost analysis underestimates costs and overestimates benefits. The costs outweigh the benefits.

EPA Response: See section 13.8 of the EPA response in this *Response to Comments* document for discussion of the EPA's comparison of costs and benefits. In addition, regarding the commenter's assertion regarding the EPA's "failure to consider contaminated site costs," see the

EPA response to comment Doc. #1631, SBC-043430 in section 13.8 in this *Response to Comments* document.

Superfund Settlements Project (SSP) and RCRA Corrective Action Project (RCAP) (Doc. #1631, SBC-043430)

EPA underestimates costs, failing to consider, among other things, significant costs that will be incurred in connection with remediation of contaminated sites. EPA, in turn, overestimates benefits

EPA Response: See section 13.8 of the EPA response in this *Response to Comments* document. With respect to the commenter's assertion that the EPA has failed to consider "significant costs that will be incurred in connection with remediation of contaminated sites", this action solely applies to public water systems and the HRRCA required by SDWA expressly excludes costs resulting from compliance with other proposed or promulgated regulations in developing an NPDWR (SDWA 1412(b)(3)(C)(i)(III)).

City of Vancouver Water Utility, Vancouver, WA (Doc. #1684, SBC-044303)

The Safe Drinking Water Act requires consideration of the costs and benefits, but in the case of PFAS, the lack of occurrence data limits EPAs ability to develop a legitimate benefit/cost analysis.

There is significant uncertainty regarding the health risks at the proposed MCL levels for all six PFAS. These levels are significantly lower than any state has proposed for PFAS chemicals, which would seem to indicate that even states highly concerned with PFAS contamination have arrived at different conclusions than EPA with regard to the benefit/cost analysis. Analysis fundamental to the 1996 amendments to the SDWA requires a detailed risk and cost assessment, and best available peer-reviewed science, when developing standards.

EPA Response: See section 13.8 of the EPA response in this *Response to Comments* document for discussion of the EPA's comparison of costs and benefits. In response to the commenter's assertion that "there is significant uncertainty regarding the health risks at the proposed MCL levels" and comparison of state PFAS MCLs to the MCLs promulgated under this action, the PFAS NPDWR is informed by regulatory development requirements under SDWA and includes the EPA's analysis of the best available and most recent peer-reviewed science. In contrast to commenter's assertion, the EPA has conducted detailed cost and benefit assessments and risk analyses (see e.g., the EA and EA Appendices (USEPA, 2024b; USEPA, 2024c), the Final Human Health Toxicity Assessments for PFOA and PFOS (USEPA, 2024h; USEPA, 2024i), and the Final Maximum Contaminant Level Goals for PFOA and PFOS (USEPA, 2024l)).

With respect to the commenter's assertion that "even states highly concerned with PFAS contamination have arrived at different conclusions than EPA with regard to the benefit/cost analysis," the commenter provides no detail or references to support this statement. While no

specific references were given, potential differences in conclusions between the EPA and states could arise from differences in number entities included in the analyses, baseline levels of PFAS contamination, estimation of health risk reduction benefits, and the estimation of costs. The EPA has compiled and synthesized the best available and peer-reviewed science on PFAS occurrence, health effects, and the best available technology to achieve reductions in PFAS in drinking water and the EPA's benefit-cost analysis for this action relies on the best available peer-reviewed information. Additionally, the Administrator determined at proposal that the benefits of the rule justify its costs. For additional discussion on international and state drinking water standards and guidelines, please see section 5.1.5 of the EPA response in this *Response to Comments* document. For further discussion of PFAS adverse health effects, please see sections II.B, III.B, and IV of the preamble for this action.

Additionally, the EPA disagrees with the commenter's assertion that the agency's "lack of occurrence data limits the EPA's ability to develop a legitimate benefit/cost analysis". As discussed in section 6 of the EPA response in this *Response to Comments* document, the agency has sufficiently robust occurrence information to inform its decisions The EPA's cost analysis uses modeled entry point concentration estimates from the peer-reviewed Bayesian hierarchical Markov chain Monte Carlo (MCMC) occurrence model which employs a statistically robust framework (see Section 4.4 of the EA; USEPA, 2024b). These modeled occurrence estimates are informed by the best available data, which is the UCMR 3 data and a robust quantity of more recently available state monitoring data. Additionally, the EPA notes that the model uses these data to estimate occurrence at levels below the MCLs employed by UCMR 3. For the EPA's responses to comments on the occurrence analysis for the final rule, please see section 6 in this *Response to Comments* document.

Alabama Water and Wastewater Institute (AWWI) (Doc. #1700, SBC-043510)

• AWWI believes that the economic analysis prepared by USEPA to support the regulatory process grossly underestimates the economic impacts to customers based on the projected occurrence of PFAS compounds. USEPA notes that the estimates of PFAS occurrence used in the cost benefit modeling were fitted with data from Unregulated Contaminant Monitoring Rule ("UCMR)3, which used a higher MRL for PFAS detection. A new minimum reporting limit (MRL) of 4 parts per trillion is being utilized under the current UCMR 5. Thus, AWWI believes more systems and the rate payers of those systems will be impacted economically both in terms of capital expenditures and long-term operations and maintenance costs. AWWI recommends that the cost-benefit analysis be re-evaluated based on a sensitivity analysis for greater PFAS occurrence, not just the previously performed sensitivity analysis for various MCLs for PFOA and PFOS.

Thank you for your consideration of the AWWl's comments submitted in regard to the proposed PFAS national primary drinking water standards. AWWI's member utilities remain committed to providing high quality, safe potable water to its customers. Thus, we appreciate the opportunity

to submit our comments on these new proposed PFAS national drinking water regulation of behalf of our member utilities in the State of Alabama.

Sincerely,

Chad Hare

Chairman

Alabama Water and Wastewater Institute, Inc.

EPA Response: See section 13.8 of the EPA response in this *Response to Comments* document for discussion of the EPA's comparison of costs and benefits. The EPA disagrees with the commenter's suggestion that the agency "grossly underestimates the economic impacts to customers based on the projected occurrence of PFAS compounds" for PFOA and PFOS; please see the EPA response to comment Doc. #1684, SBC-044303 in section 13.8 in this *Response to Comments* document. Regarding UCMR 5, please see section 6.8 of the EPA response in this *Response to Comments* document. Additionally, the EPA also notes that occurrence uncertainty is already captured in the model, therefore the sensitivity analysis suggested by the commenter is not necessary.

Minnesota Center for Environmental Advocacy et al. (Doc. #1707, SBC-045725)

C. The Benefits to Human Health Far Outweigh the Costs of Compliance

The SDWA mandates EPA to conduct a HRRCA to support its proposed MCLs: "At the time the Administrator proposes a national primary drinking water regulation under this paragraph, the Administrator shall publish a determination as to whether the benefits of the maximum contaminant level justify, or do not justify, the costs." [FN42: 42 U.S.C. § 300g-1(b)(4)(C).] The Commenters agree with EPA Administrator's overall conclusion that the benefits of the proposed MCLs justify the costs. We write to express our assertion that 1) the benefits of saving Amara, Senator Xiong, JD, Ben, their families, and myriad others from the harms of PFAS are immense, and 2) the costs of compliance will be reduced significantly by innovation and other advancements in treatment technology that will be spurred on by the need for the nation's public water suppliers to get into compliance.

EPA Response: See section 13.8 of the EPA response in this *Response to Comments* document for discussion of the EPA's comparison of costs and benefits. The EPA agrees with the commenter that costs of compliance may be reduced by advancements in treatment technologies in the future.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045920)

VI. Proposed Benefits of Complying with the Proposed MCLs Do Not Justify the Costs

While the MCLG is set solely based on health risk reduction, SDWA requires EPA to engage in cost-benefit balancing in setting the level of the MCLs and also requires that EPA follow a science-based process. If EPA determines that the benefits of a MCL would not justify the costs of complying with the level, EPA may, after notice and opportunity for public comment, promulgate a MCL for the contaminant that maximizes health risk reduction benefits at a cost that is justified by the benefits [FN177: 42 U.S.C. 300g-1(b)(6)(A).]. Even at the grossly underestimated costs, as described in the section above, the benefits of EPA's proposal to regulate PFOA and PFOS at a MCL of 4 ppt and to regulate PFNA, PFBS, PFHxS, and HFPO-DA at a Hazard Index of 1 do not justify the costs. As discussed below, EPA's quantified benefits analysis is not grounded in science and overestimates benefits, and EPA's non-quantified analysis does not meet the statutory standard of SDWA [FN178: 42 U.S.C. 300g-1(a)(3)(A).].

EPA Response: See section 13.8 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045924)

B. In light of the costs, the stated benefits do not justify the cost of the proposed MCLs

As previously discussed, EPA has significantly underestimated the costs of this proposal. As discussed in this section, EPA has also overestimated both the quantified and non-quantified benefits. These comments do not address many other shortcomings, uncertainties, and limitations in EPA's analysis. For instance, EPA notes that 13-33% of the U.S. population consumes bottled water as their primary drinking water source, yet EPA did not take this into account in the modelling [FN207: Id. at 6-108.]. EPA also could have modelled costs and benefits at 20 ppt- 40 ppt where there is more certainty in the occurrence data. Yet EPA chose not to present these analyses, not even as an alternative analysis. It is also important to note that for some of the costs and benefits analyses, EPA modified approaches in published studies to derive its estimates. In most cases, EPA did not have these revised approaches peer reviewed [FN208: Only the CVD modelling was reviewed by the SAB.]. This is inconsistent with SDWA approach that requires the HHRCA to rely on the best available science.

EPA must set the MCL at a level where the benefits justify the costs. EPA has an obligation to protect public health while relying on the best available science and while also ensuring that the cost of the standard is achievable. Considering the uncertainties and the lack of evidence supporting that effects are "likely," coupled with the significant costs of this rule, including the significant costs to individual households,[FN209: Id. at 9-29, where table 9-14 shows costs to individual households ranging from $57 to $1,153 annually. See also AWWA analysis on household costs available at: https://www.awwa.org/AWWA-Articles/awwa-statement-on-proposed-pfas-drinking-water-standards.] EPA should adjust the MCL upward to a more optimal, and more affordable balance. As EPA conducts more robust scientific assessments that are appropriately reviewed by the SAB and decreases the levels of uncertainty in the underlying science, including in the occurrence data, it should then modify the MCL as appropriate.

Based on the information presented in the Proposed Rule, the purported benefits do not justify the costs at the proposed MCL levels.

EPA Response: In response to the commenter's concern that the EPA did not rely on the best available science and incorrect assertion that the benefits of the rule do not justify the costs, see section 13.8 of the EPA response in this *Response to Comments* document. Despite the commenter's repeated unsupported assertions, as discussed throughout this *Response to Comments* document, the EPA has used best available science, which includes relying on hundreds of peer reviewed studies to inform its analyses and conclusions. Many of the analytical frameworks themselves have undergone further peer review. While the commenter disagrees with the conclusions that the EPA has drawn from these analyses, that does not invalidate the thoroughness or robustness of the EPA's analyses or the fact that the agency used best available science consistent with commonly accepted scientific practices and SDWA requirements.

In response to the commenter's recommendation to model costs and benefits at MCLs of 20 ppt and 40 ppt, the EPA disagrees with this recommendation because the agency selected thresholds in the EA that were potential regulatory alternatives under the proposed rule. Selecting regulatory alternative PFOA and PFOS MCLs of 20 or 40 ppt would not meet the SDWA criterion to establish MCLs as close to the MCLGs as feasible, taking costs into consideration. For responses to comments on the EPA's MCLs and regulatory alternatives, see section 5.1.3 of the EPA response in this *Response to Comments* document.

The EPA disagrees with the commenter's statement that "EPA must set the MCL at a level where the benefits justify the costs" as that is incorrect. The EPA must set the MCL as close as is feasible to the MCLG as specified under SDWA Section 1412(b)(4)(B). In response to the commenter's incorrect assertion that the EPA's analysis was "inconsistent with SDWA approach that requires the HHRCA to rely on the best available science", the EPA disagrees. The commenter provides no detail or supporting information to support the claim that the EPA modified approaches in published studies to derive its estimates. As stated above, the EPA use the best available, peer-reviewed science pursuant to SDWA Section 1412(b)(3)(A)(i).

In response to the commenter's reference to cost estimates submitted by other commenters, the EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. For further discussion, see section 13.3.3 of the EPA response in this *Response to Comments* document.

The EPA disagrees with the commenter's assertion that the agency has overestimated the quantified and non-quantified benefits. For the quantified benefits analysis, the EPA relied on peer-reviewed literature and synthesis of multiple high-quality studies to evaluate the effects of PFAS exposure on human health. Using this information, the EPA relied on the best available data on baseline health incidence, dose-response, life tables, medical costs, and the value of a statistical life to evaluate potential benefits of reduced incidence of adverse health effects and death. As described in section 13.8 of the EPA response in this *Response to Comments* document, limitations on health effects and/or economic information prevented the EPA from evaluating additional benefits of the rule, including those for health impacts shown to have associations

with PFAS exposure. Contrary to the commenter's assertion, the EPA expects that benefits are underestimated.

Finally, in response to the commenter's note about bottled water consumption, the EPA's benefit-cost analysis does not account for populations that consume bottled water as their primary drinking water source due to data limitations that did not allow for modeling at the national scale; the effect on the EPA's benefits estimates is uncertain. As explained in Chapter 6 of the EA, as the benefits models do not consider these populations, this could result in an overestimate of avoided cases of health effects and associated benefits (USEPA, 2024b). However, bottled water consumers can also be community water system (CWS) consumers and may still be exposed to PFAS by using water for other consumptive uses (e.g., cooking) and therefore would benefit from PFAS removal (USFDA, 2022; Aquafina, 2022). The benefits may also be underestimated because those using bottled water as a primary drinking water source may switch to a CWS supply as a result of the final rule.

Environmental Working Group (EWG) (Doc. #1721, SBC-045411)

The benefits are of the proposed rule are underestimated and outweigh the costs.

The proposed rule correctly finds that the benefits of limiting PFAS in drinking water far outweigh the costs. In 2022, leading experts quantified the estimated disease burden and related economic costs due to legacy PFAS exposure at $5.52 billion to $62.6 billion in annual costs. [FN43: Vladislav Obsekov, Linda G. Kahn, & Leonardo Trasande, Leveraging Systematic Reviews to Explore Disease Burden and Costs of Per- and Polyfluoroalkyl Substance Exposures in the United States, J. OF EXPOSURE & HEALTH (2022), https://link.springer.com/article/10.1007/s12403-022-00496-y.] Reducing PFAS in drinking water to the proposed MCL levels will dramatically reduce exposures, improving health outcomes, reducing medical and other economic costs, and lowering risks for PFAS-associated diseases.

The proposal rule is accompanied by a thorough economic assessment detailing the quantified and non-quantified benefits of the rule, as required by SDWA. [FN44: 42 U.S.C. [sec] 300g-1(b)(3)(C)-(b)(4).] While EWG supports the conclusions in the economic assessment, there are also several ways that the assessment could be expanded or strengthened. The assessment by Dr. Peter Guignet, Ph.D., appended to the comments submitted by Earthjustice et al. includes several recommendations for strengthening the analysis. [FN45: See Earthjustice et al., supra note 7.] Dr. Guignet suggests monetizing several additional health benefits, including quantifying benefits from additional health endpoints and from PFAS other than PFOA and PFOS; assessing and estimating the number of individuals exposed and who would benefit; and quantifying the benefits of reduced hepatic effects and reduced disruption of mammary gland development and associated effects on lactation. Dr. Guignet also suggests quantifying additional co-benefits in addition to the reduction in bladder cancer from co-removal of disinfection byproducts, including the health benefits from removing additional contaminants, including PFAS not covered by the proposed rule. Dr. Guignet also recommends lowering the discount rate and accounting for

opportunity costs in its final cost-of-illness estimates for low birthweight, cardiovascular disease, and renal cancer. [FN46: Id. at 16-20.]

EPA Response: These comments provide additional support for the conclusions of the agency's economic analysis for this action. The EPA agrees with the commenter that the quantified benefits of the rulemaking are likely underestimated, and that the rulemaking will likely result in additional quantified benefits beyond the health endpoints described in the economic analysis. As described in section 13.8 of the EPA response in this *Response to Comments* document, limitations of occurrence, health effect, and economic data availability prevented the EPA from considering additional quantified benefit categories in its national benefit-cost analysis, including co-benefits.

In response to the commenter's suggestion that benefits be evaluated using a lower discount rate, see sections 13.2 and 13.8 of the EPA response in this *Response to Comments* document for the EPA's responses to comments on discount rates.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046031)

We conduct a benefit-cost analysis to produce more accurate estimates. We rely on established NAS recommendations to develop hazard assessments based on recent available scientific information. Rather than EPA's approach to quantify a few adverse effects, this analysis considers a wide range of possible cellular and genomic evidence, animal data, and human epidemiological studies. Since these studies find that biological activity is likely only to occur at the high end of the modeled drinking water exposure, we develop a bounding estimate of the benefits of reducing PFOS in drinking water.

The results of this bounding estimates are shown in Table 32. We show that, whereas EPA estimated, at a seven percent discount rate, the annualized costs and benefits of the proposed rule to be $1,205 M and $908 M, respectively, we estimate them to be $7,500 M and $1,200 M, respectively. Thus, even with many assumptions to increase the social benefits, the results for PFOS are six times lower than the expected social costs. Even if these benefits are doubled to account for reductions in PFOA exposure, the social benefits are well below the social costs.

Table 32: Comparison of Estimated National Annualized Benefits and Costs for EPA's Proposed Rule ($ M) [FN136: U.S. Environmental Protection Agency, "Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation," 1–1.]

[Table 32: see docket ID EPA-HQ-OW-2022-0114-1738]

[FN137: Even if these benefits are doubled to $2,400 M/year to account for reductions in PFOA exposure, the social benefits would still be well below the social costs.]

These social costs will fall heavily on rural and low-income households. Despite EPA's claims, recently-enacted federal support for water utilities is insufficient to pay for even the capital costs of the proposal's requirements. As a result, ratepayers may pay a significant portion of the

rulemaking until other resources are secured. Ratepayer may pay hundreds of dollars per household.

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APPENDIX A

Table 33: EPA's List of Uncertainties

[Table 33: see docket ID EPA-HQ-OW-2022-0114-1738]

[FN138: Arnstein Aassve et al., “Early Assessment of the Relationship between the COVID-19 Pandemic and Births in High-Income Countries” 118, no. 36 (2021).]

[FN139: Asad Ullah et al., “Potential Effects of the COVID-19 Pandemic on Future Birth Rate,” Frontiers in Public Health 8 (2020).]

[FN140: Zhihua Hu, Lois Wright Morton, and Robert Mahler, "Bottled Water: United States Consumers and Their Perceptions of Water Quality," International Journal of Environmental Research and Public Health, 2011; Asher Rosinger et al., "Disparities in Plain, Tap and Bottled Water Consumption among US Adults: National Health and Nutrition Examination Survey (NHANES) 2007–2014," Public Health Nutrition 21, no. 8 (2018); Florent Vieux et al., "Trends in Tap and Bottled Water Consumption among Children and Adults in the United States: Analyses of NHANES 2011–16 Data," Nutrition Journal 10 (2020).]

[FN141: U.S. Food and Drug Administration, "Bottled Water Everywhere: Keeping It Safe," April 22, 2022, https://www.fda.gov/consumers/consumer-updates/bottled-water-everywhere-keeping-it-safe; Aquafina, "Aquafina FAQ," 2022, https://www.aquafina.com/en-US/faq.html#:~:text=Aquafina%20originates%20from%20public%20water,can%20affect%20a%20water's%20taste.]

[FN142: U.S. Environmental Protection Agency, "Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation"; Richard Weisman et al., "Estimating National Exposures and Potential Bladder Cancer Cases Associated with Chlorination DBPs in U.S. Drinking Water," Environmental Health Perspectives 130, no. 8 (2022).]

[FN143: Stig Regli et al., "Estimating Potential Increased Bladder Cancer Risk Due to Increased Bromide Concentrations in Sources of Disinfected Drinking Waters" (American Chemical Society, October 21, 2015).]

[FN144: Woods & Poole Economics Inc, "Complete Demographic Database," 2021, https://www.woodsandpoole.com/our-databases/united- states/all-geographies/.]

[FN145: U.S. Environmental Protection Agency, "Technologies and Costs for Removing Per- and Polyfluoroalkyl Substances (PFAS) from Drinking Water."]

[FN146: "Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances."]

APPENDIX B

Table 34: PFOA & Birthweight

[Table 34: see docket ID EPA-HQ-OW-2022-0114-1738]

[FN147: U.S. Environmental Protection Agency, "2023b."]

[FN148: Health Canada, "Guidelines for Canadian Drinking Water Quality: Guideline Technical Document – Perfluorooctanoic Acid (PFOA)."]

[FN149: Schrenk et al., "Risk to Human Health Related to the Presence of Perfluoroalkyl Substances in Food."]

[FN150: World Health Organization, "PFOS and PFOA in Drinking-Water: Background Document for Development of WHO Guidelines for Drinking- Water Quality."]

[FN151: Sverre Wikstrom et al., "Maternal Serum Levels of Perfluoroalkyl Substances in Early Pregnancy and Offspring Birth Weight," Pediatric Research, 2020.]

[FN152: Lyndsey Darrow, Cheryl Stein, and Kyle Steenland, "Serum Perfluorooctanoic Acid and Perfluorooctane Sulfonate Concentrations in Relation to Birth Outcomes in the Mid-Ohio Valley, 2005-2010," Environmental Health Perspectives, 2013.]

Table 35: PFOS & Birthweight

[Table 35: see docket ID EPA-HQ-OW-2022-0114-1738]

[FN153: U.S. Environmental Protection Agency, "Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) in Drinking Water," March 2023.]

[FN154: Health h Canada, "Guidelines for Canadian Drinking Water Quality: Guideline Technical Document – Perfluorooctane Sulfonate (PFOS)."]

[FN155: Schrenk et al., "Risk to Human Health Related to the Presence of Perfluoroalkyl Substances in Food."]

[FN156: World Health Organization, "PFOS and PFOA in Drinking-Water: Background Document for Development of WHO Guidelines for Drinking-Water Quality."]

[FN157: Wikstrom et al., "Maternal Serum Levels of Perfluoroalkyl Substances in Early Pregnancy and Offspring Birth Weight."]

[FN158: Darrow, Stein, and Steenland, "Serum Perfluorooctanoic Acid and Perfluorooctane Sulfonate Concentrations in Relation to Birth Outcomes in the Mid-Ohio Valley, 2005-2010.]

Table 36: PFOA & CVD

[Table 36: see docket ID EPA-HQ-OW-2022-0114-1738]

[FN159: U.S. Environmental Protection Agency, "2023b."]

[FN160: Health Canada, "Guidelines for Canadian Drinking Water Quality: Guideline Technical Document – Perfluorooctanoic Acid (PFOA)."]

[FN161: Schrenk et al., "Risk to Human Health Related to the Presence of Perfluoroalkyl Substances in Food."]

[FN162: World Health Organization, "PFOS and PFOA in Drinking-Water: Background Document for Development of WHO Guidelines for Drinking-Water Quality."]

[FN163: PPARα is a major transcription factor affecting expression of genes that regulate fatty acid oxidation and triglyceride and total cholesterol levels.]

[FN164: C8 Science Panel, "C8 Probable Link Reports."]

Table 37: PFOS & CVD Findings

[Table 37: see docket ID EPA-HQ-OW-2022-0114-1738]

Table 38: PFOA & Cancer

[Table 38: see docket ID EPA-HQ-OW-2022-0114-1738]

Table 39: PFOS & Cancer

[Table 39: see docket ID EPA-HQ-OW-2022-0114-1738]

[Attachment 2: see docket ID EPA-HQ-OW-2022-0114-1738]

[Attachment 3: see docket ID EPA-HQ-OW-2022-0114-1738]

[Attachment 4: see docket ID EPA-HQ-OW-2022-0114-1738]

[Attachment 5: see docket ID EPA-HQ-OW-2022-0114-1738]

[Attachment 6: see docket ID EPA-HQ-OW-2022-0114-1738]

EPA Response: In response to the commenter's assertion that benefits are underestimated, see sections 13.4 and 13.8 of the EPA response in this *Response to Comments* document.

In response to the commenter's comparison of their cost estimates to those prepared by the agency, the EPA notes that it disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. See section 13.3.3 of the EPA response in this *Response to Comments* document.

In response to the commenter's assertion that the social costs will fall heavily on rural and low-income households, please see the EPA response to comment Doc. #1630, SBC-043134 in section 13.8 in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046006)

CONCLUSIONS

Even if the benefits from the bounding estimate were doubled to account for PFOA and the other four PFAS, the benefits would still be below the costs. The social costs of EPA's proposal exceed the social benefits.

[Table of Contents: see docket ID EPA-HQ-OW-2022-0114-1738]

[Index of Tables: see docket ID EPA-HQ-OW-2022-0114-1738]

[Index of Figures: see docket ID EPA-HQ-OW-2022-0114-1738]

[Table of Acronyms: see docket ID EPA-HQ-OW-2022-0114-1738]

I. INTRODUCTION

1. Overview of EPA's Proposed Rulemaking and Economic Analysis Notice of Proposed Rulemaking

(NPRM)

On March 29, 2023, the Environmental Protection Agency (EPA) published a Notice of Proposed Rulemaking (NPRM) in the Federal Register to propose a National Primary Drinking Water Regulation (NPDWR), Maximum Contaminant Level Goals (MCLGs), and Maximum Contaminant Levels (MCLs) for several per- and polyfluoroalkyl substances (PFAS) [FN1: U.S. Environmental Protection Agency, "PFAS National Primary Drinking Water Regulation Rulemaking," Federal Register, no. 88 FR 18638 (March 2023).] The NPDWR are legally enforceable standards that require treatment in public water systems (PWSs) to ensure certain contaminants do not exceed specified levels in drinking water. The level is set by the enforceable MCL, which is the highest level of a contaminant that is allowed in drinking water. An MCLG is the non-enforceable level of a contaminant in drinking water under which there is no expected risk to human health. EPA issued a request for public comment on the following:

• The determination to set individual MCLs of four parts per trillion (ppt) or nanograms per liter (ng/L) for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS). EPA seeks comment on its evaluation of feasibility, treatment capabilities at CWSs, and costs;

• The preliminary determination to regulate four additional PFAS, including: perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO– DA) and its ammonium salt (also known as a GenX chemicals), perfluorononanoic acid (PFNA), perfluorobutane sulfonic acid (PFBS). EPA seeks comment on its evaluation of health information and occurrence data;

• The determination to set a MCL through a Hazard Index (HI) approach set at a unitless one for any mixture of one or more of the four additional PFAS (PFHxS, HFPO-DA, PFNA, and PFBS). EPA seeks comment on its HI approach;

• EPA's methodology used to estimate national costs for the proposed rule; and,

• EPA's approach to estimate the health impacts of exposure to PFAS covered by the proposed rule. EPA seeks comment on its assumptions and the magnitude of risks avoided by the proposed regulatory actions.

Economic Analysis (EA)

EPA is required to conduct an economic analysis (EA) for the proposed NPDWR in compliance with Executive Order (EO) 12866 and SDWA's requirements for a Health Risk Reduction and Cost Analysis (HRRCA) [FN2: "P.L. 104-182: The Safe Drinking Water Act" (1996).]. In its EA,

EPA provides its assessment of quantified and nonquantifiable health risk reduction benefits and compliance costs, including:

• Health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur as the result of compliance with each treatment level;

• Benefits likely to occur from co-occurring contaminants reductions that may be attributed solely to compliance with the MCL;

• Costs likely to occur solely due to compliance with the MCL, including monitoring, treatment, and other costs;

• Incremental costs and benefits associated with each alternative MCL considered;

• Effects of the contaminant on the general population, including sub-population groups likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water;

• Any increased health risk that may occur as a result of compliance, including co- benefits and co-occurring contaminant risks; and,

• Other relevant factors, including the quality and extent of the information and uncertainties in the analysis.

EPA evaluated the benefits associated with several rule options, including its preferred option. The EA presents quantified health benefits from avoided cases of illnesses and deaths expected from reductions in PFAS exposures resulting from the NPRM. Quantified economic benefits are estimated as avoided morbidity and mortality due to cardiovascular disease (CVD), avoided low birthweight, and avoided cases of renal cell carcinoma (RCC).

In EPA's EA, the costs of the proposed NPDWR are the expenses incurred by PWS to monitor for PFAS, to notify consumers, to adopt treatment technologies, and to conduct subsequent record-keeping and monitoring requirements. EPA also includes the costs associated with primacy agency implementation. The EA estimates the number of water systems that must procure treatment technologies and incur administrative costs to comply with the rule. EPA's estimated annualized benefits are summarized in Table 1 and range between $908 million (M) to $1,233 M at seven percent and three percent discount rates, respectively. EPA estimates the annualized costs over 82 years between $772 M to $1,205 M at three and seven percent discount rates, respectively.

Table 1: EPA's Estimated National Annualized Benefits and Costs for the Proposed NPDWR

[Table 1: see docket ID EPA-HQ-OW-2022-0114-1738]

2. Outline of the Report

The analysis spans six sections. This section provides an overview of EPA's proposed rule and its supporting EA. Section II discusses best practices in benefit-cost analyses and evaluates EPA's

EA against these best practices. The section identifies fundamental limitations in EPA's framework and methodology, analytical gaps that it is obligated under government directives to include in its estimates, and other implications from its assumptions.

Section III presents an alternative analysis of the social benefits of EPA's proposed rule. The section contains the methodological framework, data, and assumed values. The analysis provides a discussion of the results and limitations. Similarly, Section IV presents the social cost analysis by first outlining the approach and data sources and then by providing results for each component of the analysis. Section V provides a focused discussion on the economic impacts of EPA's rules on household income. The concluding section, Section VI, compares these estimates with EPA's estimates.

EPA Response: See section 13.8 of the EPA response in this *Response to Comments* document for discussion of the EPA's comparison of costs and benefits.

Del-Co Water Company, Inc. (Doc. #1744, SBC-043615)

I. General Comments

Del-Co is confident in offering expertise and opinions as they relate to the real impact that new drinking water standards will have on our operations and related services. However, we are less confident commenting on the complex toxicological principles, risk assessments, uncertainty factors, and epidemiologic research. That said, we do question whether a reduction in our known PFOA concentrations of 4 – 5 ppt to less than 4.0 ppt is the best use of our resources and the best method to improve public health. In the current situation wherein PWSs are subject to increased costs in replacing lead service lines, upgrading cybersecurity, replacing aging infrastructure, and assuring sustainable water supplies, we question if dedicating $8 – $110 million dollars to upgrade/expand/retrofit our existing treatment plants provides the most meaningful reduction in public health risk to our customers.

EPA Response: See section 13.8 of the EPA response in this *Response to Comments* document for discussion of the EPA's comparison of costs and benefits. The EPA disagrees with the commenter's suggestion that this action is not "the best use of our resources and the best method to improve public health" as the Administrator has determined that the benefits of reducing PFAS in drinking water through this regulatory action justify the costs. For the quantified benefits analysis, the EPA relied on peer-reviewed literature and synthesis of multiple high-quality studies to evaluate the effects of PFAS exposure on human health. The Administrator's assessment that the benefits of the proposed rule justified its costs was based on the comprehensive scientific and cost and benefit assessment information in the record for this rulemaking, and specifically the data relating to, and analysis of, the quantified and nonquantifiable benefits, which are anticipated to be substantial, as well as the quantified and nonquantifiable costs.

PFAS Regulatory Coalition (Doc. #1761, SBC-047717)

4. EPA's cost/benefit analysis relies too heavily on nonquantifiable costs and benefits.

EPA presents its evaluation of costs and benefits of MCLs at different MCL values and at both 3% and 7% discount rates, in Tables 66 through 69 of the Proposal. These tables show uneven net benefits, with only PFOA and PFOS MCLs set at 10 ppt projected to have positive next net benefits at both discount rates. Nevertheless, EPA proposes 4 ppt for each compound and concludes its cost/benefit analysis by stating: "To fully weigh the costs and benefits of the action the Agency considered the totality of the monetized values, the potential impacts of the unquantified uncertainties described above, and the nonquantifiable costs and benefits. The Administrator has determined that the benefits of this proposed regulation justify the costs." 88 Fed. Reg. 18729. The only way that EPA could reach this conclusion is if the unquantified uncertainties and the nonquantifiable costs and benefits were given more weight than the quantified values.

Given the concerns about costs that the Coalition has discussed above, EPA should conduct a new cost/benefit analysis. Considering the Agency's underestimation of costs, EPA has not met the Safe Drinking Water Act requirement that an MCL be set at a level that "maximizes health risk reduction benefits at a cost that is justified by the benefits." SDWA Section 1412(b)(6).

EPA Response: See section 13.8 of the EPA response in this *Response to Comments* document. First, the commenter is incorrect that SDWA requires that an MCL be set at a level that ""maximizes health risk reduction benefits at a cost that is justified by the benefits.' SDWA Section 1412(b)(6)." To the contrary, SDWA requires that the MCL be set as close to the MCLG as is feasible as specified under Section 1412(b)(4)(B). Section 1412(b)(6) only applies to those situations where the Administrator has determined that the costs of a proposed rule would not justify the benefits and has decided to exercise their authority to set an alternative level; those circumstances do not apply here where the Administrator found that the costs of the rule do justify the benefits. Furthermore, as required under SDWA, the EPA considered both nonquantifiable and quantifiable costs and benefits in its EA for the final rule. As such, the agency did consider nonquantifiable costs and benefits: see Tables 5-22, 6-48, and 7-6 of the EA for an overview of nonquantifiable costs and benefits (USEPA, 2024bb). See Section 5.1.3 of the EA for an overview of quantified costs and Section 6.1.3 of the EA for an overview of quantified benefits (USEPA, 2024bb). The commenter's statement that "the only way EPA could reach this conclusion is if unquantified costs and benefits were given more weight" is not based on or consistent with the record in this rulemaking, including the EPA's extensive quantified analyses. While it is true that the EPA considered the nonquantifiable costs and substantial nonquantifiable benefits in its determination, as required under SDWA, the agency has demonstrated that the rule will produce substantial quantified benefits as well and has not given more weight to either quantified or nonquantified benefits.

PFAS Regulatory Coalition (Doc. #1761, SBC-046080)

F. The Proposal fails to propose MCLs at levels where costs are justified by the benefits, as required under statute.

The Safe Drinking Water Act requires that an MCL be set at a level that "maximizes health risk reduction benefits at a cost that is justified by the benefits." SDWA Section 1412(b)(6). The Proposal fails to meet this statutory requirement for several reasons, including that. EPA seriously underestimates the costs of the Proposal. Other organizations, including AWWA and the US Chamber of Commerce, have already submitted cost estimates to EPA and OMB, and each independently shows that EPA's cost estimates are much too low. Below, the Coalition outlines additional cost/benefit issues that need to be considered and addressed by the Agency.

EPA Response: First, the commenter is incorrect that SDWA requires that an MCL be set at a level that ""maximizes health risk reduction benefits at a cost that is justified by the benefits.' SDWA Section 1412(b)(6)." To the contrary, SDWA requires that the MCL be set as close to the MCLG as is feasible as specified under Section 1412(b)(4)(B). Section 1412(b)(6) only applies to those situations where the Administrator has determined that the costs of a proposed rule would not justify the benefits and has decided to exercise their authority to set an alternative level; those circumstances do not apply here where the Administrator found that the costs of the rule do justify the benefits. See section 13.8 of the EPA response in this *Response to Comments* document for discussion of the EPA's comparison of costs and benefits. In response to the commenter's note about cost estimates prepared by other organizations, the EPA notes that it disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. See section 13.3.3 of the EPA response in this *Response to Comments* document. See the EPA response to comment Doc. #1537, SBC-042649 in section 13.3.3 in this *Response to Comments* document regarding the US Chamber of Commerce's comments related to costs.

Environmental Protection Network (EPN) (Doc. #1773, SBC-043878)

Benefit and Cost Analyses

EPA developed a comprehensive framework for evaluating the costs and benefits of regulating the six contaminants addressed in this rulemaking. However, given data limitations, the agency's quantitative analysis was limited primarily to PFOA and PFOS, and, to a more limited extent, PFHxS. EPN commends EPA for quantifying benefits from multiple health effects, including reductions in heart attacks and strokes, developmental impacts to fetuses and infants, kidney cancer cases resulting from control of PFOA and PFOS, and reductions in bladder cancer cases from disinfection byproducts as co-benefits. We also commend EPA for describing all the significant health effects they were unable to quantify, as well as clarifying the sources of uncertainty in their analysis. We note that EPA did a more comprehensive quantification of costs, leaving only two types of costs unquantified for PFOA, PFOS and PFHxS (hazardous waste disposal of treatment media and POUs not in compliance). The end result is that EPA estimates

the expected value of net annual incremental benefits to be $461M using a 3% discount rate and -$297M using a 7% discount rate. Consideration of all the unquantified benefits would likely result in positive benefits under the 7% discount rate, but the appearance of negative benefits is concerning.

EPA used the 3% and 7% discount rates because those are the default rates recommended by OMB in Circular A-4 which guides federal agencies' regulatory analyses. On April 6, 2023, OMB released an updated Circular A-4 for public comment. OMB is now recommending that the default discount rate should instead be 1.7% based on analyses of the inflation-adjusted average interest rate of federal securities over the past 30 years on a pre-tax basis. OMB further states that using a higher discount rate to account for risk would be inappropriate when evaluating regulations that reduce risk. Accounting for this risk reduction would be akin to using a lower, not higher, discount rate. EPN recommends that EPA redo their benefit and cost analyses using the 1.7% discount rate which will undoubtedly indicate even greater net annual incremental benefits than the 3% rate and further bolster the justification for these PFAS drinking water standards. In the final rule, EPA should quote this new OMB guidance and eliminate the 7% discount rate analyses, even if the new guidance has not yet been finalized.

EPA Response: See section 13.8 of the EPA response in this *Response to Comments* document for discussion of the EPA's comparison of costs and benefits. This comment provides additional support for the EPA's evaluation of costs and benefits. In response to the commenter's suggestion that benefits be evaluated using a lower discount rate, based on this and other comments, the EPA has included analyses using a 2 percent discount rate. Please see sections 13.2 and 13.8 of the EPA response in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-045693)

a. EPA Did Not Account for the Fact that Costs Incurred are "Solely the Result of the" NPDWR, but Purported Benefits are Not.

EPA's analysis of the benefits of the proposed MCLs does not comply with SDWA [sec]1412(b)(3)(C)(i)(I)'s requirement to analyze "[q]uantifiable and nonquantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur as the result of treatment to comply with each level." And while the costs of the Proposed Rule are "solely as a result of compliance" with the Rule, the purported benefits are not. [FN96: SDWA [sec]1412(b)(3)(C)(i)(I)]

The first step in assessing the benefits of the Proposed Rule is to analyze the baseline conditions of the population in the United States. Average blood levels of PFOA and PFOS in the U.S. population have decreased by more than 70% and 85% respectively since 2000. [FN97: See https://www.atsdr.cdc.gov/pfas/health-effects/us-population.html] Moreover, based on the latest NHANES biomonitoring data from the 2017-2018 timeframe, average blood levels of PFAS such as PFHxS and PFNA also decreased significantly during that time. [FN98: The CDC stopped analyzing for PFBS since 2014 as part of its NHANES monitoring program because of

the lack of detection in general population blood.] In short, the baseline conditions of PFOA and PFOS exposure and blood serum levels, as well as PFAS subject to the HI, have decreased significantly in the past two decades, and there is no evidence indicating they will not continue to do so in the absence of the Proposed Rule. [FN99: See Biomonitoring Data Tables for Environmental Chemicals | CDC] The SDWA requires that EPA demonstrate the incremental decrease in illness or morbidity is meaningful and associated with the NPDWR itself, not other actions such as decreased exposure through voluntary cessation of manufacturing or use. [FN100: See SDWA [sec]1412(b)(3)(C)(i)(I).]

The SDWA requires EPA to evaluate how the small fraction of any purported benefit of reduced PFOA and PFOS exposure would result from EPA establishing a NPDWR as opposed to the myriad other factors already greatly reducing exposure over time. Under the SDWA, EPA must also show that the small incremental reduction in exposure is meaningful or even measurable in terms of benefit as compared to reductions from other means. Unless EPA can demonstrate an incremental benefit based solely on a NPDWR that outweighs the associated cost, which in fact would derive from the NPDWR, then the proposed NPDWR does not comply with the mandates of the SDWA.

EPA Response: The EPA disagrees with the commenter's assertion that the benefits analyzed in the EPA's economic analysis supporting the NPDWR are the result of actions other than the NPDWR itself. The EPA analyzes changes in blood serum PFAS levels as a result of changes in PFAS drinking water concentrations due to the installation of treatment technology. The associated benefits estimates are estimated based on these drinking water treatment-driven changes in blood serum levels only and do not reflect changes associated with reduced exposures from other PFAS sources. See the EPA response to comment Doc. #1841, SBC-044811 in section 13.4 in this *Response to Comments* document where the EPA describes the steps that were taken to determine the risk reduction benefits solely attributable to the PFAS NPDWR. See also the EPA response to comment Doc. #1841, SBC-044844 in section 13.4.5 in this *Response to Comments* document where the EPA describes how the benefits from other agency actions, including benefits from actions related to the microbial and disinfection byproduct rules, were not considered in this rulemaking.

Uttara Jhaveri (Doc. #1778, SBC-045450)

The benefits of monitoring, compliance and technological changes need to be highlighted, considering the $1.2 billion annual cost savings based on the public health benefits [FN31: Jen Christensen, EPA proposes first standards to make drinking water safer from 'forever chemicals,' CNN, Mar. 15, 2023, https://www.cnn.com/2023/03/14/health/epa-pfas-standards-wellness/index.html.] to push the rulemaking to stakeholders and the public.

EPA Response: The EPA agrees with the commenter that the public health benefits of the rule are significant. See section 13.8 of the EPA response in this *Response to Comments* document for discussion of the EPA's comparison of costs and benefits.

Northwest Biosolids Association et al. (Doc. #1783, SBC-043799)

Federal Funding and Assistance. The 4ppt MCL limit is based on application of weak evidence of cause and effect. This level is below detection limits of current instrumentation and methodology, rendering this limit impracticable for compliance. The level should be based on a thorough analysis of the cost and benefit and the practicality of implementation, such as availability of adequate instrumentation and reliable analytical methods.

EPA Response: In response to the commenter's assertion that "the 4ppt MCL limit is based on application of weak evidence of cause and effect", the EPA disagrees. Please see the agency's Maximum Contaminant Level Goals for PFOA and PFOS (USEPA, 2024ll) for discussion of the science underlying the derivation of MCLGs for the final rule. Additionally, the commenter is incorrect in their assertion that "this level is below detection limits of current instrumentation and methodology": the 4.0 ppt MCLs for PFOA and PFOS are not below practical quantitation limits or detection limits and thus not impracticable for compliance. For responses to comments regarding the feasibility of the EPA's PFAS MCLs promulgated under this action, see section 5 of the EPA response in this *Response to Comments* document.

Bailey Smith (Doc. #1787, SBC-045815)

To the extent that challengers to the rule think that these MCLs will be costly to attain,[FN49: See e.g., Hampton et al., supra note 10; Tanaka et al., supra note 21.] the benefits (saving families from preventable illnesses) far outweigh the costs.

EPA Response: See section 13.8 of the EPA response in this *Response to Comments* document.

Peggy Kurtz (Doc. #1799, SBC-046042)

Strong EPA regulations will also send a strong signal to the chemical industry to invest in safe alternatives now.

The argument that will be raised against the new EPA standards is the cost of filtration. But the costs are far outweighed by the costs of healthcare due to the impacts of PFAS. Ultimately, it is the chemical industry that should bear these costs. The shocking fact is that manufacturers knew about the health impacts many decades ago- and they continued to push these chemicals out, regardless.

EPA Response: See section 13.8 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046104)

Moreover, as described below, EPA's benefit-cost analyses found that these systems are cost-effective, with health benefits exceeding treatment costs in many circumstances.

EPA Response: See section 13.8 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046129)

6. EPA provides a balanced and detailed qualitative accounting of the benefits and costs that could not be quantified.

Ideally, all benefits and costs of a regulatory action would be quantified and monetized, but analysts are often limited by the available information, as well as resource constraints when conducting an EA. EPA prioritizes the quantification of benefits, for example, based on the contaminants and endpoints (i.e., adverse health outcomes) where (i) the weight of evidence linking the contaminant to key biomarkers is strongest, (ii) it is possible to link the contaminant or related biomarkers to a health endpoint (e.g., cardiovascular disease) that can be monetized (i.e., valued in dollar terms based on available economic literature and practices), and (iii) the endpoint does not overlap with another benefit category. Based on my professional experience, the first two criteria are standard practice when prioritizing analytical efforts given the practical constraints in conducting empirical analyses. The third criterion helps EPA avoid "double counting." As stated in EPA's Guidelines for Preparing Economic Analyses, when estimating the effects separately for each health endpoint "it is important to avoid double counting benefits across effects as much as possible" (EPA, 2014, pg. 7-3). Additionally, given limited resources, EPA prioritizes quantification of benefits and costs that are anticipated to be the largest. In my professional experience, prioritizing in this manner is sometimes necessary, and it is an appropriate way to prioritize given the objective of providing the best and most comprehensive information possible to inform the regulatory development process.

It is important to emphasize that the lack of quantification does not imply that any unquantified benefits and costs are not relevant. Following standard practice (EPA 2014, OMB 2003), EPA goes to great lengths to detail benefits and costs that could not be quantified, but that are still relevant for the EA and the ultimate determination of whether the benefits of the proposed PFAS NPDWS exceed the costs. A systematic summary is provided in Table 7-5 in Chapter 7, and further details are discussed in Chapters 5 and 6. Based on my own professional experience, the qualitative discussion in this EA is more rigorous than others I have reviewed. The Agency goes into a lot more detail, combs the literature more thoroughly, and touches on a larger number of potential health endpoints.

Although the net benefits for the central estimates of the proposed regulatory option are negative in some scenarios (e.g., under an assumed 7% discount rate), the Agency lays out convincing evidence that the net benefits are likely positive. The net benefits are positive under an assumed 3% discount rate (see Table 7-1), and the qualitative evidence and sheer number of unquantified benefit endpoints suggest that the benefits likely do exceed the costs. Furthermore, although consideration of alternative 3% and 7% discount rates is currently the standard practice for EAs of federal regulations (OMB 2003), the lower 3% discount rate may be more appropriate in this context. See comment #15 below for details.

In any case, the reliance of the key conclusions of this EA on qualitatively discussed health benefits is not atypical. A review by Petrolia et al. (2021) of EAs for all major EPA rules from 2008 to 2019 revealed that of the 43 analyses that included non-fatal health outcomes, nine (21%) only included unquantified health benefits (see Figure 2 in Petrolia et al. 2021); and additional qualitative health benefits were included in the other EAs that did quantify at least one health endpoint. In OMB's recently proposed revised guidance for economic analysis, it is emphasized that:

"relying on materially incomplete monetized BCA [net benefits] does not offer an adequate summary of evidence intended to inform determination of the most beneficial alternative, and such reliance could even be misleading. You [(analysts)] should exercise professional judgement in identifying the importance of non-quantified factors and assess as best you can how they might change the ranking of alternatives based on estimated net benefits" (OMB 2023, pg. 5).

EPA Response: See section 13.8 of the EPA response in this *Response to Comments* document. This comment provides support for the agency's evaluation of costs and benefits.

Earthjustice et al. (Doc. #1808, SBC-046108)

III. EPA Should Take Steps to Strengthen the Economic Analysis Supporting the Proposed Rule

As required by the SDWA, EPA's Proposed Rule is supported by a draft Economic Analysis ("Draft EA") that assesses the proposal's "[q]uantifiable and nonquantifiable health risk reduction benefits," its "[q]uantifiable and nonquantifiable costs," the incremental costs and benefits of the alternative MCLs considered, the effects of the Six PFAS on the general population and greater-risk subpopulations, any increased health risks associated with compliance with the Proposed Rule, and other relevant factors such as uncertainties in the analysis. [FN100: 42 U.S.C. § 300g-1(b)(3)(C)(i); see EPA, Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation (EPA Doc. No. EPA- 822-P-23-001) (Draft for Public Comment) (Mar. 2023).] As described in the accompanying expert review of EPA's Draft EA by Dennis Guignet, Ph.D., many features of the Draft EA are exceptionally thorough and transparent, [FN101: Memorandum from Dennis Guignet, Ph.D., to Earthjustice, Re. Review of the Economic Analysis for the Proposed PFAS NPDWR (May 26, 2023) ("Guignet 2023") (Attached as Exhibit B).] and the Draft EA provides ample justification for EPA's conclusion that the Proposed Rule's quantified and unquantified benefits justify its costs. [FN102: See Proposed Rule, 88 Fed. Reg. at 18,689, 18,727–29. At the same time, we stress that EPA has the authority to set the MCL "as close to the [MCLG] as feasible, even if [EPA] determines that the benefits of the MCL at this level do not justify the costs." S. Rep. No. 104-169 at 33.] Further, as discussed in the accompanying expert review by Elin Betanzo, EPA's treatment cost estimates are robust and, if anything, may overstate actual costs. [FN103: Elin Betanzo, Safe Water Engineering, Analysis of the USEPA Proposed PFAS National Primary Drinking Water Regulation Treatment Costs and Comparison to the AWWA National PFAS Cost Model Report (May 30, 2023) ("Betanzo 2023") (Attached as Exhibit C).]

Nevertheless, there are important steps EPA can and should take to strengthen the EA to better support the proposed drinking water standards.

At the outset, we encourage EPA to maintain, and consider expanding upon, several key methodological strengths of the Draft EA. [FN104: See Guignet 2023 at 2–7.] The Draft EA is predicated on a detailed, data- driven Monte Carlo simulation model that supports comprehensive sensitivity analyses, which evaluate the impact of specific variables on estimates of the Proposed Rule's net benefits. As described by Dr. Guignet, this is the most thorough approach to account for multiple sources of uncertainty in the economic analysis simultaneously. [FN105: Id. at 2–3.] The Draft EA accounts appropriately for existing state-level drinking water standards when estimating the costs and benefits attributable to the Proposed Rule. [FN106: Id. at 5.] In addition, the EA relies appropriately on unquantified health benefits (though, as discussed below, the record supports quantification of additional health benefits). [FN107: Id. at 6–7.] EPA's reliance on unquantified health benefits is consistent with the agency's standard practice, [FN108: Id.] and is expressly required by the SDWA, which mandates that EPA's health risk reduction and cost analysis account for all "[q]uantifiable and nonquantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur" due to compliance with the MCL. [FN109: 42 U.S.C. § 300g-1(b)(3)(C)(i)(I)–(II).] Congress "require[d] [EPA] to determine whether the benefits of a [drinking water] standard 'justify' (rather than 'exceed' or 'outweigh') the costs to reflect the nonquantifiable nature of some of the benefits and costs that may be considered. [EPA] is not required to demonstrate that the dollar value of the benefits are greater (or lesser) than the dollar value of the costs," and "[a]ll costs and benefits, both quantifiable and nonquantifiable, must be considered when making determinations under this authority." [FN110: S. Rep. No. 104-169 at 33. Moreover, Congress recognized the inherent difficulty and subjectivity in fully quantifying the economic benefits of rules, so the SDWA authorizes EPA to establish an MCL at a feasible level even if the agency cannot formally determine that MCL is justified by the economic costs. Id. We note that, for example, there are often equity considerations, as there are with PFAS, whereby certain populations, often low-income communities and communities of color, bear disproportionate burdens from exposure to environmental contaminants. See Jahred M. Liddie et al., Sociodemographic Factors Are Associated with the Abundance of PFAS Sources and Detection in U.S. Community Water Systems, Env't Sci. Tech. (2023), https://pubs.acs.org/doi/pdf/10.1021/acs.est.2c07255. Such equity considerations often are not reflected in economic analyses but are valid considerations under the SDWA.]

EPA Response: These comments support the agency's evaluation of costs and benefits. For discussion on the EPA's comparison of costs and benefits, please see section 13.8 of the EPA response in this *Response to Comments* document. For responses to comments on the EPA's PFAS MCLs and regulatory alternatives, please see section 5.1.3 of the EPA response in this *Response to Comments* document.

With respect to the commenter's mention of "equity considerations", the EPA has conducted an environmental justice analysis for this action, as directed by Executive Order 14096. As the commenter suggests, the EPA's EJ analysis demonstrates that communities of color are

anticipated to experience elevated baseline PFAS drinking water exposures compared to the entire sample population included in the analysis. However, the EPA believes that this action is likely to reduce existing disproportionate and adverse effects on people of color, low-income populations, and/or Indigenous peoples. Based on this comment, the EPA has added Liddie et al. (2023) to the literature review conducted to supplement the EPA's EJ analysis for this rule, which can be found in in Section 8.2 of the EA (USEPA, 2024b). For more information on the EPA's EJ analysis, please see Chapter 8 of the EA (USEPA, 2024b) and section 14.10 of the EPA response in this *Response to Comments* document.

The District of Columbia Water and Sewer Authority (Doc. #1829, SBC-045777)

• Based on EPA's own cost-benefit analysis, it is suggested that, if EPA moves forward with a final PFAS rule, only Option 1c(10 ppt MCL for both PFOA and PFOS) is likely to meet the Agency's criteria that the rule must provide a net benefit.

DC Water appreciates the opportunity to comment on EPA's proposed PFAS National Primary Drinking Water Regulations. Please let me know if we can provide any additional information or share our utility operating expertise to inform improvements to the proposed rule with the goal of ensuring its successful implementation.

Sincerely,

Chief Operating Officer, EVP

C: David L. Gadis, CEO and General Manager

Marc Battle, Chief Legal Officer and EVP, Government and Legal Affairs

EPA Response: The EPA disagrees with the commenter's assertion that the rule must provide a net benefit; rather, SDWA specifies that when proposing an NPDWR, the Administrator shall publish a determination as to whether the benefits of the MCL justify, or do not justify, the costs based on the analysis conducted under paragraph 1412(b)(3)C), which is based on the entire rulemaking record, including quantified and nonquantifiable costs and benefits. For further discussion of the EPA's comparison of costs and benefits, see section 13.8 of the EPA response in this *Response to Comments* document.

Citizens Energy Group (Doc. #1838, SBC-044857)

Citizens also urges EPA to make efforts to balance reasonable risk mitigation with practical affordability realities for utility customers.

EPA Response: For discussion on the EPA's comparison of costs and benefits of the final rule, please see section 13.8 of the EPA response in this *Response to Comments* document. For responses to comments on the EPA's PFAS MCLs and regulatory alternatives, please see section 5.1.3 of the EPA response in this *Response to Comments* document. The EPA's final rule represents data-driven drinking water standards that are based on a thorough analysis of

feasibility consistent with requirements under SDWA. For additional discussion on the EPA's feasibility analysis, please see the response in section 5.1.2 of the EPA response in this *Response to Comments* document (for laboratory considerations) and section 5.1.4 of the EPA response in this *Response to Comments* document (for treatment considerations).

For information on the agency's small system affordability analysis conducted for the final rule, please see EPA response to comment Doc. #1630, SBC-043134 in section 13.8 in this *Response to Comments* document, section 13.10 of the EPA response in this *Response to Comments* document, and the EPA's affordability analysis in Chapter 9 of the EA (USEPA, 2024b).

American Chemistry Council (ACC) (Doc. #1841, SBC-044848)

EPA Cannot Determine that the Benefits of the Proposal Justify the Costs

Section 1421(b)(4)(C) requires that the Administrator determine "whether the benefits of the [MCL] justify, or do not justify, the costs" based on the Agency's health risk reduction and cost analysis. As detailed above, the Agency's analysis significantly underestimates the costs of its proposed MCLs for PFOA and PFOS and overestimates its benefits. For the proposed HI MCL for the four other PFAS, EPA fails to conduct an appropriate benefit and cost analysis as required by Section 1421(b)(3) of the Act. Without such a determination, the Agency cannot promulgate the regulation as proposed in the absence of a determination that the substances present an "urgent threat to public health." [FN197: 42 U.S.C. Section 300g-1(b)(1)(D)] The Administrator cannot reach such an urgent threat determination, based on the information presented.

EPA's estimates of the cost of complying the proposed MCLs for PFOA and PFOS are significantly at odds with the estimate from AWWA. Although both rely on extrapolation from the UCMR 3 data, AWWA's analysis includes nearly twice as many PWSs and a far larger number of smaller systems. The impact of the proposal on smaller systems is a particular weakness of the Agency's analysis – given their large numbers and limited resources and the considerable and unexplained disparity in EPA's estimate of the percentage of affected systems (5.3 percent for small systems vs 23.9. percent for large ones).

EPA's analysis of costs for an HI MCL for the four other PFAS is equally unsupportable, as the Agency does not have a basis for estimating the number of additional water systems potentially impacted for three of the four systems. Estimates for the fourth substance, PFHxS, suffer from the same limitations as PFOA and PFOS.

In accessing benefits, EPA has inappropriately quantified benefits for reductions in PFOA and PFOS for health effects for which the available data are not sufficient to support such a determination. As described above, the epidemiology data do not provide evidence for an association with CVD and the use of an association with increases in total cholesterol is inappropriate. The assumption that reductions in bladder cancer cases and fatalities resulting from the lowering of THM levels is not well supported by the empirical data. In light of multiple ongoing activities on DBPs, moreover, EPA has not attempted to identify the benefits that can be

"attributed solely" to this proposal. Further, it is not clear that separating benefits likely to be achieved from this proposal versus the larger Agency effort is even possible.

In quantifying benefits for improvements in birth weight and cancer incidence, EPA relies on epidemiological data despite conflicting results and a lack of clear evidence. In the case of RCC, the estimates of benefits are based solely on the study by Shearer et al. despite the clear recommendation from SAB not to do so. EPA's analysis of birth weight impact is confused – relying on equivocal results from two studies as a basis for the RfD, but a meta-analysis of multiple studies many of which are not evaluated in EPA's analysis and some of which are considered low confidence by the Agency – for quantifying the estimated benefits.

The Agency has provided little to no evidence to support the projected benefits associated with the HI MCL. Combined with the unscientific basis of the Hazard Index, the Agency's determination for a "meaningful opportunity for health risk reduction" lacks substantiation.

Considering the AWWA analysis for PFOA and PFOS alone, the cost of the proposed MCLs far exceed the Agency's estimates of benefits by a large margin ($5.2 billion versus $900 million to $1.2 billion). Factoring in the concerns about the Agency's analysis of the benefits, the disparity is likely to be even greater.

EPA Response: The EPA disagrees with the commenter's assertion that the "EPA cannot determine that the benefits of the proposal justify the costs." See section 13.8 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1759, SBC-045620 in section 13.4.1 in this *Response to Comments* document, where the EPA Administrator's benefit-cost determination, and the factors considered in making that determination, are discussed in detail.

The EPA disagrees with the commenter's assertion that the "agency's analysis significantly underestimates the costs of its proposed MCLs for PFOA and PFOS and overestimates the benefits." See section 13.4 of the EPA response in this *Response to Comments* document for the EPA's response to comments claiming that the agency overestimated benefits. See section 13.3 of the EPA response in this *Response to Comments* document for the EPA's response to comments claiming that the agency underestimated costs.

The EPA disagrees with the commenter that the EPA failed to conduct "an appropriate benefit and cost analysis" for the Hazard Index MCLs and that the EPA's analysis of costs to comply with the Hazard Index MCL is "unsupportable." See section 13.3.2 of the EPA response in this *Response to Comments* document regarding the evaluation of costs associated with the Hazard Index and individual MCLs for PFHxS, PFNA and HFPO-DA and section 13.4 of the EPA response in this *Response to Comments* document regarding the EPA's benefits assessment for Hazard Index PFAS. The EPA also disagrees with the commenter's assertion that the EPA has provided "little to no evidence to support the projected benefits associated with the HI MCL" as the agency has qualitatively summarized the potential health benefits resulting from reduced exposure to PFHxS, HFPO-DA, PFNA, and PFBS, in addition to other PFAS anticipated to be co-removed, in Section 6.2.4 of the EA (USEPA, 2024b).

The EPA disagrees with the commenter's assertion that the EPA "cannot promulgate the regulation as proposed in the absence of a determination that the substances present an "urgent threat to public health". This condition in SDWA solely applies to the promulgation of interim MCLs where the EPA has not completed the HRRCA or made the determination whether the proposal's costs are justified by the benefits. As discussed extensively in the preamble and this *Response to Comments* document, the EPA has completed a HRRCA consistent with SDWA requirements and the Administrator has determined that the benefits of this rule justify the costs.

With respect to the commenter's assertion that the EPA's estimates are "significantly at odds with the estimate from AWWA", the EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs; see section 13.3.3 of the EPA response in this *Response to Comments* document for further discussion.

The EPA disagrees with the commenter's assertion that the "EPA has inappropriately quantified benefits for reductions in PFOA and PFOS for health effects for which the available data are not sufficient to support such a determination." See section 13.4 of the EPA response in this *Response to Comments* document for responses to comments on the EPA's method for estimating quantified benefits. See section 13.4.1 of the EPA response in this *Response to Comments* document for responses to comments on CVD benefits estimation and for the EPA's response to comments concerning the association between PFAS exposure and CVD. See section 13.4.2 of the EPA response in this *Response to Comments* document for responses to comments on developmental benefits estimation and the EPA's responses to comments on the studies used for estimating developmental benefits. See section 13.4.3 of the EPA response in this *Response to Comments* document for responses to comments on RCC benefits estimation and the EPA's responses to comments on using Shearer et al (2021) for benefits estimation. See section 13.7 of the EPA response in this *Response to Comments* document for responses to comments on DBP co-removal benefits estimation. The EPA disagrees with the commenter's statement that "EPA has not attempted to identify the benefits that can be "solely attributed" to this proposal." See the EPA response to comment Doc. #1841, SBC-044811 in section 13.4 in this *Response to Comments* document where the EPA describes the steps that were taken to determine the risk reduction benefits solely attributable to the PFAS NPDWR. See the EPA response to comment Doc. #1841, SBC-044844 in section 13.4.5 in this *Response to Comments* document where the EPA describes how the benefits from other agency actions, including benefits from actions related to the microbial and disinfection byproduct rules, were not considered in this rulemaking.

Midwest Environmental Advocates +more (Doc. #1846, SBC-045833)

C. The proposed NPDWRs are cost-justified, especially considering the significant unquantified benefits of the regulation and the availability of federal funding for drinking water projects.

Commenters support the Administrator's determination that the proposed rule's benefits justify its costs given (1) the significant unquantified risk reduction benefits and co-benefits that would accrue from this regulation, (2) the availability of federal funds for PFAS projects through the

Bipartisan Infrastructure Law (BIL) that was not accounted for in the economic analysis, and (3) the proper use of a consumption-based discount rate for the quantified portion of the analysis.

The SDWA requires EPA to analyze costs and benefits as part of the rule proposal process. [FN30: 42 U.S.C. § 300g-1(b)(3)(C).] This analysis must include consideration of non-quantifiable benefits. [FN31: 42 U.S.C. §§ 300g-1(b)(3)(C)(i)(I)-(II).] The Administrator must publish a determination as to whether the proposed rule's benefits justify its costs. [FN32: 42 U.S.C. § 300g-1(b)(4)(C).] EPA's rigorous analysis concludes that the quantifiable benefits of the proposed rule are greater than the quantifiable costs at a 3 percent discount rate, but not at a 7 percent discount rate. [FN33: 88 Fed. Reg. 18638, 18724.] Critics may seize on this statement in the cost-benefit analysis to argue the rule's costs do not justify its benefits. However, such a commentary is myopic and one-sided because it fails to (1) account for the significant non-quantifiable benefits of the proposed rule and (2) acknowledge that the costs are overestimated because a 7 percent discount rate is not appropriate for this type of regulation, and existing streams of federal funding are in place to defray compliance costs.

First, EPA should not give less consideration to unquantified benefits in favor of more easily quantifiable costs. The agency properly "provided substantial detail on the benefits of the rule, and the reason why quantification was not possible," [FN34: Nicopure Labs, LLC v. Food & Drug Admin., 266 F. Supp. 3d 360, 406 (D.D.C. 2017) (noting that agencies are not required to quantify benefits "in any particular way when compared to the costs" and are allowed to engage in qualitative analysis).] concluding that the unquantified benefits associated with this rulemaking would be significant. These benefits include the health effects of reduced exposure to PFOA and PFOS, the HI PFAS compounds, and other PFAS not regulated by this rule beyond the three health endpoints analyzed by EPA. Given the range of other health effects that PFAS compounds are associated with—including multiple types of cancer—the unquantified benefits of the rule, if quantified, would render the rule unambiguously cost-benefit justified. However, the Agency has provided enough detail in its qualitative analysis to support its determination the overall benefits of the proposed regulation outweigh its costs irrespective of the discount rate used, and, therefore, has fulfilled its mandate under the SDWA.

EPA Response: See section 13.8 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2047, SBC-046221)

The cost to implement the regulation of any and all PFAS removal to below 50 PPT is not offset by the proven health savings. Do not enact any federal PFAS regulations

EPA Response: See section 13.8 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2322, SBC-046306)

The TTHM rule of 80 ppb and 60 ppb was supposed to save lives from cancer and the cancer rates have not dropped at all from this costly regulation. No value for the cost, just wasting consumers money like paying someone to dig a hole in your front yard and then fill it back in again. No provable health savings have been achieved. It will be the same with the PFAS regulations. Nothing measurable will be achieved and a great waste of time and money. This is the plan of the bureaucratic unelected federal government, destroy the wealth in the United States by every means possible. Using borrowed federal money to achieve these treatment goals and devalue the dollar further was never the intent of the safe drinking water act amendment. This rule should be dropped.

EPA Response: See section 13.8 of the EPA response in this *Response to Comments* document for discussion of the EPA's comparison of costs and benefits. In response to the commenter's assertion that this action will be a "great waste of time and money" and that "this rule should be dropped", the EPA notes that once fully implemented, the final rule is anticipated to prevent thousands of deaths and reduce tens of thousands of serious PFAS-attributable illnesses and, as explained in section 13.8 of the EPA response in this *Response to Comments* document, the Administrator has determined that the benefits of reducing PFAS in drinking water through this regulatory action justify the costs.

Arlington County Virginia (Doc. #1603, SBC-043018)

To summarize, it appears to us that the costs (both capital and operating) assumed in the EPA's economic analysis appear to be off by a factor of 2 to 3. We believe that the EPA's assumptions about number of utilities affected are also too conservative, and that the proposed regulation will exceed the market capacity resulting in unpredictable, but extraordinary, inflation in this sector. Finally, even with the EPA's most favorable assumptions, the cost-benefit analysis can best be characterized as ambivalent.

EPA Response: See section 13.8 of the EPA response in this *Response to Comments* document for discussion of the EPA's comparison of costs and benefits. See sections 13.3 and 13.3.3 of the EPA response in this *Response to Comments* document for the EPA's responses to comments on the EPA's method for estimating costs and treatment costs, respectively. See sections 6.5 and 6.8 of the EPA response in this *Response to Comments* document for the EPA's response to comments on the number of water systems estimated to be impacted by the final rule. The EPA disagrees with the commenter that the "cost-benefit analysis can best be characterized as ambivalent;" as the Administrator has determined that the total quantifiable and nonquantifiable benefits justify the quantifiable and nonquantifiable costs of the rule.

Arlington County Virginia (Doc. #1603, SBC-043007)

3. The Economic Analysis underestimates actual costs, and even as presented does not provide convincing justification of this proposed rule making

EPA Response: See section 13.8 of the EPA response in this *Response to Comments* document for discussion of the EPA's comparison of costs and benefits. See section 13.3 of the EPA response in this *Response to Comments* document for the EPA's responses to comments on the EPA's method for estimating costs.

Arlington County Virginia (Doc. #1603, SBC-043015)

1. The Cost-Benefit analysis of the proposed rule utilized two different discount values (3% and 7%) and ran Monte Carlo simulations to capture the wide range of uncertainties in both the Costs and Benefits of the proposed rule. The Cost Benefit analysis then presented 6 different scenarios (5th, 50th, and 95th percentile at the 3% and 7% discount rates). Remarkably, 3 of the 6 scenarios presented indicate a net cost of the rule as proposed.

EPA Response: See section 13.8 of the EPA response in this *Response to Comments* document for discussion of the EPA's comparison of costs and benefits. Additionally, the EPA notes that 5th and 95th percentile results represent uncertainty in the central estimates of the analyses, not different scenarios.

National Ground Water Association (NGWA) (Doc. #1804, SBC-045469)

Comprehensive Approach to Controlling PFAS – As NGWA expressed with eight other water associations in our joint letter to the Administrator on June 3, 2020, a comprehensive approach is needed to address PFAS affecting public health and the environment. The steps identified in that letter include:

• conducting the necessary technical and economic analyses to support proposed SDWA maximum contaminant levels for PFOA and PFOS,

EPA Response: The EPA has conducted a HRRCA for the proposed and final rule consistent with the requirements of SDWA. See section 13.8 of the EPA response in this *Response to Comments* document for discussion of the EPA's comparison of costs and benefits. The EPA has also conducted significant technical analyses related to occurrence, treatment, and health effects, among other things. See sections 3, 4, 5, 6, 7, 8, and 10 of the EPA response in this *Response to Comments* document.

13.9 Quantified Uncertainties in the Economic Analysis

Summary of Major Public Comments and EPA Responses

One commenter, who represented part of a larger group of commenters, supported the EPA's assessment of uncertainty in its economic analysis, stating that "the entire EA is centered on a detailed, data-driven Monte Carlo simulation model that has been calibrated based on existing federal and state data." The commenter further asserts that Monte Carlo simulations, such as those used by the agency in producing its economic estimates for this action, are "a common and defensible approach to account for uncertainty…and are the most thorough way to

simultaneously account for numerous sources of uncertainty in economic analysis." The EPA agrees with these comments which provide additional support for the agency's assessment of uncertainty in its economic analysis.

One commenter claimed that the EPA failed to follow federal requirements for regulatory analysis, including those of OMB Circular A-4, by not considering all of the opportunity costs and by not conducting a formal uncertainty analysis. The EPA disagrees with this commenter's assertion that the agency's methodology is inconsistent with the OMB Circular A-4's suggested methodologies for regulatory analysis. The EPA completed a formal uncertainty analysis consistent with all requirements for uncertainty analysis, including numerous sensitivity analyses for the proposed and final rule, which builds upon the comprehensive uncertainty analysis that was completed and adds further explanation to how differences in the underlying modeling assumptions impact benefit and cost results. See Sections 5.1.2 and 6.1.2 of the EA, where quantified uncertainties in the costs and benefits analyses, respectively, are listed and discussed at length.

Specifically, this commenter claims that the EPA is required to conduct a "full formal uncertainty analysis" under Circular A-4; however, the commenter is incorrect for two reasons. Under OMB Circular A-4 (2023), for major rules involving annual economic effects of $1 billion or more, agencies "*should, when feasible and appropriate,* present a formal quantitative analysis of the relevant uncertainties about benefits and costs" (emphasis added). The guidance states "When feasible, you *should* use appropriate statistical techniques to determine a probability distribution of the relevant outcomes" (emphasis added). The first reason the commenter is incorrect is because the EPA did provide a comprehensive uncertainty analysis in the PFAS NPDWR EA (see USEPA, 2024b and section XII of the FRN for this action). Moreover, the EPA assessed all major sources of uncertainty in the EA using both quantitative and qualitative approaches, which is consistent with the OMB Circular A-4 guidance suggesting that important uncertainties be analyzed and presented. Specifically, the EPA assessed all significant sources of uncertainty and described the impact of those uncertainties on the resulting benefit-cost estimates. For some key sources of uncertainty, including model inputs for health effect exposure response slope factors, baseline entry point PFAS concentrations, and compliance technology unit costs, the EPA quantitatively assessed uncertainty by evaluating the distribution of values for those inputs. Throughout the economic analysis, resulting benefit and cost estimates are presented using mean (or "expected value") 5th, and 95th percentile results to characterize these key sources of uncertainty, which is consistent with OMB and EPA guidance (OMB Circular A-4 2003, 2023; USEPA, 2016a). See Sections 5.1.2 and 6.1.2 in USEPA, 2024b and section XII in the FRN for this action for further discussion. The second reason the commenter is incorrect is even if the EPA did not complete this uncertainty analysis (which as discussed above, the EPA did conduct), the EPA is not *required* to conduct this analysis. When used in a document such as the OMB A-4 Circular, "should" is used to give advice or suggestions and it is suggestive rather than mandatory. "Should" leaves discretion for an entity (the EPA in this case) to determine whether to follow the delivered recommendation. Hence, even if the EPA had failed to conduct this analysis, which it did not, it is not required to do so.

It is impossible for all sources of uncertainty to have been included in the agency's quantitative uncertainty analysis due to data limitations. For those unquantified sources of uncertainty, the EPA summarized the expected magnitude and directional impact each uncertainty source has on the quantified benefits and costs (see Chapter 7 of USEPA, 2024b and section XII of the FRN for this action). Further, the EPA included numerous sensitivity analyses assessing the impacts from changes in assumptions, which are described in detail within the economic analysis appendices (see USEPA, 2024c). This approach to assess key sources of uncertainty quantitatively and qualitatively in the economic modeling is compliant with all requirements for uncertainty analysis and is effective in describing the impacts of uncertain data inputs across the benefit cost modeling. Specifically, the 2003 Circular A-4 guidance states that agencies should "disclose qualitatively the main uncertainties in each important input to the calculation of benefits and costs" and use "numerical sensitivity analysis to examine how the results of your analysis vary with plausible changes in assumptions, choices of input data, and alternative analytical approaches." Further, under the updated OMB Circular A-4 released in 2023, the guidance states that "both qualitative and quantitative assessments of uncertainty can provide useful information."

The updated OMB Circular A-4 (2023) states that "the treatment of uncertainty should be guided by the same principles of full disclosure and transparency that apply to other elements of your regulatory analysis. Your analysis should be credible, objective, realistic, and scientifically balanced." The EPA went to great lengths to follow all of the circular's recommendations for uncertainty analysis and thoroughly assess each key source of uncertainty and describe the impact of uncertainty sources. Therefore, even if the EPA were *required* to follow these recommendations, which it is not, the commenter's assertions that the EPA failed to complete a comprehensive uncertainty analysis for the PFAS NPDWR are unfounded.

As discussed above, the EPA notes that the agency is unable to evaluate the impacts of all limitations quantitatively due to the inherent differences across uncertainty sources. Specifically, it is not possible to merge qualitative and quantitative metrics across data sources to inform quantitative estimates, as the commenter suggests.

Regarding the commenter's assertion that social benefits are overestimated, the EPA disagrees. In the quantitative benefits analyses (for cardiovascular disease, birth weight, and cancer) the EPA used cost of illness information to value non-fatal cases of illness. Cost of illness information represents direct medical costs and does not include additional social costs associated with illnesses including lost opportunity and productivity costs. As such, contrary to the commenter's assertion, the social benefits of the PFAS NPDWR are actually significantly underestimated as the agency has included no additional costs associated with lost opportunity or productivity. As is demonstrated in numerous studies and situations, opportunity costs of lost work or caring for a sick family member or child, pain and suffering associated with the sickness or loss of a loved one, long-term loss of income associated with loss of a partner, among many other things, these social costs are substantial and important. Therefore, since none of these or other potential social benefits are quantified in this regulation, the commenter's assertion that social benefits are

overestimated is demonstrably incorrect. Regarding the commenter's assertion that not incorporating opportunity costs into the economic analysis results in an underestimate of social costs, the EPA disagrees. The commenter correctly points out that when conducting an economic analysis of a proposed regulation, it is important to consider the opportunity costs imposed upon society by the regulation. The EPA also agrees that using only direct compliance costs as a measure of opportunity costs can lead to an underestimate of costs, but not in the case of this PFAS NPDWR. In a competitive market where demand for goods is price sensitive (i.e., elastic demand elasticity), the increased cost of production associated with a regulation would cause suppliers to reduce the amount of product they are willing to sell at a given price (i.e., upward shift in the supply curve) and this would result in an increase in the equilibrium price for the good in the market. Facing this higher price, consumers would choose to purchase less of the product. In this case, both consumers and producers incur a welfare loss (e.g., a decrease in consumer and producer surplus, respectively). The sum of the decrease in consumer and producer surplus is the opportunity cost of the regulation. However, water supply is not a competitive market; it is almost exclusively a regulated monopoly. In addition, potable water has a highly inelastic demand -- customers' consumption of water does not change much when the price of water changes (Metaxas and Charalambous, 2005). Because they are regulated monopolies, water suppliers can pass the increased cost of production resulting from the regulation to their customers through an increase in price. Furthermore, consumers are unlikely to decrease the quantity of water consumed due to the higher price. In this case, there will be a change in the price of water -- equal to the increase in production costs due to the regulation -- but little change in the quantity of water produced and consumed. In addition, since water utilities can fully recover costs through rate adjustments, alternative investment opportunities are not crowded out. Therefore, the direct cost of compliance, as estimated by the EPA, is a sound estimate of the opportunity costs of the proposed and final PFAS NPDWR.

One commenter recommended that the EPA use an economy-wide model to analyze the impacts of the PFAS NPDWR. The EPA agrees that economy-wide models can be a valuable tool in assessing the social costs of some environmental regulations, depending on the context. The EPA's SAB has recommended that the EPA build capacity in computable general equilibrium (CGE) models, a type of economy-wide model, as a complement to the agency's current suite of tools for analysis (SAB, 2017). Consistent with recommendations made by the SAB, the EPA has developed (Marten et al., 2023) and peer reviewed (SAB, 2020) a CGE model, called SAGE, to aid in the evaluation of the social costs and cost incidence of regulations, as appropriate.

While the theory and inherent model structure, including key underlying assumptions and model parameterization, have been through rigorous peer review, applying SAGE to specific regulatory contexts requires the EPA to determine when and how the tool can best be leveraged to gain insights. The SAB (2017) noted that there is "no hard and fast rule" for deciding when an economy-wide modeling approach will add value beyond other tools typically utilized by the EPA to quantify costs, though they suggest several relevant factors, including strong cross-price effects between markets, pre-existing distortions present in those markets, and impacts that are not small relative to the precision of the model. Further, the SAB noted inherent difficulties in

leveraging CGE models to evaluate some types of rules. For instance, the SAB noted that "finding an appropriate way to represent a narrowly targeted regulation in a high-level economy-wide model can … be a very difficult challenge." Likewise, "the more spatially, sectorally, and/or temporally detailed the regulation, the more challenging it is to represent in a modeling framework."

Marten et al. (2019), a paper referenced by the commenter, finds that social costs for generic, illustrative single sector environmental regulation scenarios range widely, and may be 6 percent to 33 percent larger than engineering-based compliance expenditures depending on the regulated sector and input composition of compliance. The paper also notes that how the specific details of the individual regulation are modeled can significantly affect the social costs (e.g., which sources are subject to the rule and the general design of the regulation), and "therefore generalizations about the bias of engineering cost estimates (beyond the direction of the bias) are unlikely to be robust." Marten et al. (2019) also notes that in water and other utilities sectors the percentage difference between general equilibrium (GE) and engineering costs is relatively low.

There are additional considerations that are equally important when considering whether a CGE model will add value, on net, beyond the set of tools already being leveraged to estimate costs. For example, care must be given when preparing engineering costs to be used as an input in an economy-wide model to avoid double counting taxes and transfers, translate capital costs to a consistent measure within the economy-wide model, and attribute engineering costs to specific inputs. As such, using SAGE or any other CGE model in a rulemaking requires significant time and resources to adapt engineering cost estimates for use in the model and to modify the model, as needed, to capture important sector-specific nuances in modeling the behavioral response to a regulation.

Therefore, deciding whether and how to utilize CGE models to analyze the social costs of regulations requires a weighing of the value added of additional insights that can be gained from an economy-wide analysis against the time and resource costs of developing a careful approach to accurately capture key compliance pathways and sector-specific behavioral responses within the CGE model. So while this approach was not yet available for use in this NPDWR rulemaking, the EPA will continue to evaluate the appropriateness of conducting an economy-wide analysis using SAGE or another CGE model for rulemakings.

In May 2023, the EPA used SAGE for the first time to analyze the social costs of a proposed regulation, the Greenhouse Gas Standards and Guidelines for Fossil Fuel-fired Power Plants. The analysis appears in an appendix of the Regulatory Impact Analysis and outlines the approach taken to ensure careful calibration of compliance cost estimates from the EPA's electricity sector model, the Integrated Planning Model (IPM), for use in SAGE. Connecting the outputs from a sectoral partial equilibrium model to a CGE model required significant attention and resources. The EPA needed to develop an approach to linking the SAGE model and the results from IPM that could adequately represent the regulatory requirements and detailed compliance response information from the technologically rich partial equilibrium model of the power sector in the

CGE model.[11] The EPA requested public comment on the use of the SAGE model and presentation of results, which the agency will review in developing the analysis for the final rule.[12]

At the time of the PFAS NPDWR proposal, SAGE was not yet available to analyze the social costs of a proposed rulemaking. In order to estimate the social costs of the PFAS rule using the SAGE model, the EPA anticipates that significant modeling and data development would be needed to adequately characterize the economy-wide impacts of the rule. The EPA would need to develop an analytic approach to reflect the engineering costs of the rule in the SAGE model, ideally by linking to it a sector model that captures the nuances of water utility behavior. In addition, the EPA would need to potentially modify the SAGE model to capture any missing market distortions in water markets that could be important determinants of overall social costs. Information to modify the SAGE model for this regulatory action is not currently readily available without a significant, potentially years-long effort by the EPA.

SDWA Section 1412(b)(3)(A) requires that the agency use "the best available peer-reviewed science" when setting standards. Because an updated model calibrated for use in a drinking water rule was not available at the time of the PFAS NPDWR proposal, the EPA was not able to utilize SAGE to model the social costs of the PFAS rule. As directed by SDWA, the EPA has used the best available peer-reviewed science in informing its benefit and cost estimates and assessing uncertainty in these estimates. For further discussion of what constitutes "best available peer-reviewed science" under SDWA, please see section I.A of the FRN for this action.

Individual Public Comments

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046004)

Attachment 1

BENEFIT-COST ANALYSIS OF EPA'S PROPOSED PER- AND POLYFLUOROALKYL SUBSTANCES NATIONAL PRIMARY DRINKING WATER REGULATION

Prepared by: Policy Navigation Group

May 2023

EXECUTIVE SUMMARY

The Association of Metropolitan Water Agencies (AMWA) and the American Water Works Association (AWWA) asked Policy Navigation Group (PNG) to prepare a social benefit-cost analysis of EPA's proposed rulemaking to set federal drinking water standards for certain per-

[11] For the working paper describing the effort, see: https://www.epa.gov/environmental-economics/evaluating-economy-wide-effects-power-sector-regulations-using-sage-model.
[12] https://www.regulations.gov/docket/EPA-HQ-OAR-2023-0072

and polyfluoroalkyl substances (PFAS). PNG also prepared an economic impact analysis of the proposal's effect on household income.

EVALUATION OF EPA'S BENEFIT-COST METHODOLOGY AGAINST BEST PRACTICES

The report first compares EPA's approach to estimate the social benefits and social costs with federal requirements for regulatory analysis and best practices in the field. EPA's methodology falls far short of best practices and these requirements. EPA failed to follow two important requirements of federal requirements for regulatory analysis by not considering all of the opportunity costs and by not conducting a formal uncertainty analysis. Omitting the effect of the rulemaking on the entire economy underestimates the rulemaking's social costs by over $1 billion. As EPA demonstrated in a recent rulemaking, EPA can – and must -- estimate the social costs of rulemaking throughout the economy.

Federal requirements for regulatory analysis require EPA to conduct a complete, mathematical, and transparent uncertainty analysis for regulatory actions with costs and benefits estimated to be greater than $1 billion. EPA failed to perform this analysis. The combined effect of these omissions is that EPA underestimates the social costs and fails to convey the full uncertainty of the social benefit estimates. By not presenting the full range of uncertainty in the estimate, EPA presents a misleadingly large benefit estimate.

In addition, EPA's cost models substantially underestimate the installation costs of PFAS treatment systems as evidenced by actual cost data from water systems and by expert analysis by a water sector engineering firm. For smaller systems, the majority of the systems that EPA projects will require treatment, EPA underestimates the capital costs by a factor of five.

EPA also fails to account for other social costs such as additional costs from water rate increases and the non-market costs of greater greenhouse gas emissions. Since EPA has accounted for the social costs of regulation-induced greenhouse gas emissions in a recent rulemaking, the Agency should do so for this rulemaking.

EPA Response: See section 13.9 of the EPA response in this *Response to Comments* document. With respect to the commenter's assertion that the EPA's cost models "substantially underestimate the installation costs of PFAS treatment systems", please see section 13.3.3 of the EPA response in this *Response to Comments* document for the EPA's response to comments on treatment costs, including response to the AWWA B&V report. With respect to the commenter's assertion that the EPA fails to account for potential water rate increases, please see section 13.10 of the EPA response in this *Response to Comments* document for responses to comments on the EPA's affordability analysis. With respect to the commenter's request that the EPA account for the social costs of greenhouse gas emissions in this rulemaking, please see section 13.11 of the EPA response in this *Response to Comments* document for responses to comments on the EPA's assessment of the social costs of greenhouse gases for the final rule.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046022)

Economy-Wide Effects

The social costs extend beyond the water sector. EPA's proposed rule increases the price of a fundamental good. Businesses and households consume water and will pay price increases for the same good. Therefore, society will incur additional costs of the proposed rule as business and household costs rise. These effects are characterized as additional (or reduced) spending by other industries and households as a result of the activities of the water sector. To provide an example, the food and beverage industry uses large quantities of water; the demand for water will remain constant as the price increases under the proposed regulation. As the food industry spends more on water, it must spend less on other equipment and inputs. These shifts in spending are part of the economy-wide effects of a rulemaking. The more a regulation affects the price and the quantity of a good used as a factor of production, the greater the economy-wide effects across other sectors. In addition, the more a regulation affects demand for a good (like capital goods in this regulatory action) whose market is distorted by tax or other government policies, the greater the economy-wide effects.

This section describes existing methods for quantifying these effects and presents an estimate of the economy-wide social costs for EPA's proposed rule.

Economy-Wide Modeling (EWM)

The social costs are greater than the direct resource costs to achieve compliance. To be complete, an estimate of social cost should include both the opportunity cost of current consumption that will be foregone due to regulation, and the loss that may result if the regulation reduces capital investment and thus future consumption. To provide an example, the capital that will go to build PFAS treatment systems will no longer be available to build computers. The forgone productivity gains and economic growth given up because society invests in PFAS treatment rather than computers, for example, is the opportunity cost.

EPA asked its Science Advisory Board in 2015 as to the relevance and the use of economy-wide modeling (or "general equilibrium [GE]") for regulatory analysis. The SAB in its 2017 report endorsed EPA's use of these models since they "offer a more comprehensive assessment of the benefits and costs." [FN117: U.S. Environmental Protection Agency Science Advisory Board, "SAB Advice on the Use of Economy- Wide Models in Evaluating the Social Costs, Benefits, and Economic Impacts of Air Regulations," September 2017, iv.] EPA sought the SAB's advice on the proper times to conduct such an analysis. "The SAB panel's advice was that a GE analysis is most likely to add value when the cross-price effects and pre-existing distortions (e.g., taxes, market power, other regulations) are significant." [FN118: Alex Marten, Richard Garbaccio, and Ann Wolverton, "Exploring the General Equilibrium Costs of Sector-Specific Environmental Regulations" (U.S. Environmental Protection Agency National Center for Environmental Economics, April 2019), 2.] EPA sought to investigate those conditions when shifting capital and labor to regulatory compliance and when existing market distortions increased the social costs. EPA concluded:

We find that even for small regulations both the output substitution and tax interaction effects are significant, and ex ante compliance cost estimates tend to substantially underestimate the social cost of regulation independent of the sector subject to regulation or the composition of inputs required for compliance. This result is robust across a large number of regulatory scenarios and a series of sensitivity analyses over parametric and structural assumptions. [FN119: Marten, Garbaccio, and Wolverton, 2.]

EPA's National Center for Environmental Economics (NCEE) has recognized that social costs include the effect when consumption and investment shifts due to large-scale environmental regulations [FN120: Marten, Garbaccio, and Wolverton, 1.]. The total market costs of a regulatory action equals the sum of all opportunity costs incurred as defined by "the lost value of all goods and services that will not be produced and consumed as resources are moved away from production and consumption activities" toward treatment [FN121: Marten, Garbaccio, and Wolverton, 2.]. Using an inter-temporal computable general equilibrium model of the U.S. economy known as SAGE, EPA measures the relationship between these broader social costs and ex ante engineering compliance costs. These additional costs are also known as the general equilibrium effects that capture the supply and demand impacts across other sectors and markets.

EPA modeled the GE effects of a $100 million regulation in different sectors of the economy to measure how higher prices and capital shifts affected the entire economy. For the water sector, the report found the economy-wide reduction in consumption is 15 to 18 percent. In other words, the social costs of a regulation in the water sector are expected to be 15 to 18 percent higher than the engineering costs.

In the recently signed proposed rule for greenhouse gas standards for new and existing fossil fuel-fired electricity generating units (EGU), EPA applied SAGE in its proposed economic analysis [FN122: U.S. Environmental Protection Agency, "Regulatory Impact Analysis for the Proposed New Source Performance Standards for Greenhouse Gas Emissions from New, Modified, and Reconstructed Fossil Fuel-Fired Electric Generating Units," app. B.]. EPA found that social costs including economy-wide effects are 35 percent greater than its engineering cost estimates. EPA's annualized engineering costs for the EGU proposal ($900 million) are comparable to EPA's annualized engineering costs for proposed MCLs. Therefore, the economy-wide costs of this regulatory action are also likely to be significant.

The analysis applies this range of additional social costs from NCEE's runs of EPA's SAGE model for the water sector to the estimated economic cost of the proposal. The annual GE effects amount to $1.1 B per year. Ultimately, consumers pay this cost through higher prices for goods and services and less income from lower economic growth.

EPA Response: See section 13.9 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-053385)

zII. BENEFIT-COST ANALYSIS BEST PRACTICES

1. Summary of Circular A-4 and EPA's Economic Analysis Guidelines

Circular A-4

Since 1981, the U.S. Office of Management and Budget (OMB) has issued regulatory analysis guidance and directives to Executive branch agencies to promote best practices, to promote public transparency, and to ensure the different agency estimates are comparable. OMB's directive, Circular A-4 Regulatory Analysis, was last issued in 2003 and provides directives for the best practices to estimate the potential social benefits and social costs of a regulatory action using best economic principles [FN3: On April 6, 2023 OMB proposed revisions to Circular A-4. This analysis uses the 2003 Circular A-4 that is in place at the time of this report.].

EPA failed to follow two important requirements of Circular A-4 by not considering all of the opportunity costs and by not conducting a formal uncertainty analysis. The combined effect of these omissions is that EPA underestimates the social costs and fails to convey the full uncertainty of the social benefit estimates. By not presenting the full range of uncertainty in the estimate, the EA presents a misleadingly large benefit estimate.

Opportunity Cost

One important principle in benefit-cost analysis – and in economics in general – is the opportunity cost of a resource:

"Opportunity cost" is the appropriate concept for valuing both benefits and costs. The principle of "willingness-to-pay" (WTP) captures the notion of opportunity cost by measuring what individuals are willing to forgo to enjoy a particular benefit…. The use of any resource has an opportunity cost regardless of whether the resource is already owned or has to be purchased. That opportunity cost is equal to the net benefit the resource would have provided in the absence of the requirement. For example, if regulation of an industrial plant affects the use of additional land or buildings within the existing plant boundary, the cost analysis should include the opportunity cost of using the additional land or facilities [FN4: U.S. Office of Management and Budget, "Circular A-4: Regulatory Analysis," September 17, 2003, 18.].

EPA's EA only includes engineering cost estimates. While the prices of the goods and labor EPA includes in the engineering analysis generally reflects their opportunity costs, EPA does not include the opportunity costs that occur in other sectors in society.

Other sectors have opportunity costs when the price of drinking water increases in response to this rulemaking and when this rulemaking shifts capital and labor to the water sector for compliance. EPA's analysis shows that the required regulatory activities will shift capital and resource use substantially. EPA states that the maximum spending level would approach $10 billion in one year using its estimates [FN5: U.S. Environmental Protection Agency, "Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation," March 2023, 9–13.]. EPA predicts household costs for drinking water will also rise by hundreds of dollars per year [FN6: U.S. Environmental Protection Agency, 8–69.]. These costs will be borne not only by households, but also by businesses that purchase water for their

operations. EPA's rule will therefore raise the costs of an input to almost all businesses. The price increase will have additional and substantial social costs. EPA has conducted extensive modeling of the economy-wide costs from regulations in the water sector but does not include these results in its analysis. In addition, as discussed in Section IV.2, EPA has recently conducted a regulatory economic analysis that accounts for opportunity costs and finds them significant [FN7: U.S. Environmental Protection Agency, "Regulatory Impact Analysis for the Proposed New Source Performance Standards for Greenhouse Gas Emissions from New, Modified, and Reconstructed Fossil Fuel-Fired Electric Generating Units," May 2023, app. B.]. Therefore, EPA has the methodologies, data, and experience to comply with Circular A-4 and present the more complete social costs of the rule.

EPA Response: See section 13.9 of the EPA response in this *Response to Comments* document. Please also see section 13.11 of the EPA response in this *Response to Comments* document for responses to comments on the EPA's assessment of the social costs of greenhouse gases for the final rule.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046007)

Formal Uncertainty Analysis

EPA's benefit and cost models use data and mathematical relationships that are uncertain. Describing the uncertainty helps policy officials and the public understand the quality and the likelihood of the benefit and cost estimates. Uncertainty can be described in words, with some quantification, and with formal, statistical approaches that ensure all of the available information about the uncertainty is used. In Circular A-4, OMB discusses situations when agencies must conduct a formal, mathematical uncertainty analysis:

For major rules involving annual economic effects of $1 billion or more, you should present a formal quantitative analysis of the relevant uncertainties about benefits and costs. In other words, you should try to provide some estimate of the probability distribution of regulatory benefits and costs…For rules that exceed the $1 billion annual threshold, a formal quantitative analysis of uncertainty is required [FN8: U.S. Office of Management and Budget, "Circular A-4: Regulatory Analysis," September 17, 2003, 40– 41.].

Specific analytical approaches OMB recommends for formal uncertainty analyses include the following:

• Numerical sensitivity analysis. EPA must examine how the results vary with plausible changes in key assumptions, choices of data inputs, and alternative analytic approaches. "Sensitivity analysis is especially valuable when the information is lacking to carry out a formal probabilistic simulation. Sensitivity analysis can be used to find 'switch points' - critical parameter values at which estimated net benefits change sign or the low cost alternative switches;" [FN9: U.S. Office of Management and Budget, 41.]

• Probabilistic analysis of large, multiple uncertainties. EPA must formally simulate and examine identified uncertainties through expert judgment and, for example, Delphi methods. "Experts can be used to quantify the probability distributions of key parameters and relationships. These solicitations, combined with other sources of data, can be combined in Monte Carlo simulations to derive a probability distribution of benefits and costs;" [FN10: U.S. Office of Management and Budget, 41.]

In its EA, EPA only conducted a partial mathematical uncertainty analysis. Since EPA estimates that the effect of the rule is above $1 B in one year, EPA did not comply with the requirements of Circular A-4. The most significant omission is that EPA fails to model the quantitative effect of the uncertainty in EPA's causal determination that PFOA and PFOS are associated with certain health effects. As discussed in Appendix B, other public health agencies do not find a causal relationship between PFOS and PFOA exposure and key health effects that EPA quantifies as social benefits. This difference has several important implications. First, these findings show that EPA's methodology has significant uncertainty. Second, these findings show that EPA's quantified benefits are biased to be too high. If these other agencies are correct, there is no dose-response relationship and thus the benefits from reduced exposure for these adverse effects is zero. Instead of its qualitative discussion, EPA should present a distribution of benefit estimates including the probability that studies that show no relationship or an inverse relationship between PFAS and certain adverse effects are true.

Instead of a formal uncertainty analysis, EPA provides a list of limitations. The words in these lists do not modify EPA's social cost and benefit numbers, however. EPA's list of limitations is significant [FN11: U.S. Environmental Protection Agency, "Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation," 5–39 & 6–108.]. Table 33 in Appendix A gives the limitations EPA listed in the analysis. However, there are two problems with EPA's list. While EPA does list some limitations and uncertainties with some directional information, EPA could – and must – incorporate these uncertainties into its display of quantified estimates.

Many of the limitations that EPA discloses could be quantified and incorporated into a formal uncertainty analysis. For example, EPA states that its value of statistical life (VSL) is the major value in its benefits estimate. However, EPA does not provide a distribution of potential values even though EPA acknowledges uncertainties in its VSL estimate. Other federal agencies, however, and researchers have put together distributions of potential VSL values [FN12: See, for example, Banzhaf, H. (2022). The Value of Statistical Life: A Meta-Analysis of Meta- Analyses. Journal of Benefit-Cost Analysis, 13(2), 182-197. doi:10.1017/bca.2022.9]. EPA could easily incorporate uncertainty in the VSL value into its formal uncertainty analysis.

EPA Response: With respect to the commenter's assertion that the EPA's uncertainty analysis did not follow the OMB Circular A-4 guidance, the EPA disagrees; see section 13.9 of the EPA response in this *Response to Comments* document.

With respect to the commenter's specific assertion that the EPA failed to model the quantitative effect of the uncertainty in the EPA's causal determination that PFOA and PFOS are associated

with certain health effects, the EPA disagrees with the commenter's assertion that this factor was ignored. The EPA has used the best available scientific information to inform the agency's assessment on health effects associated with PFOA and PFOS exposure and benefits associated with reduced exposure. The EPA has reviewed information available from peer reviewed studies and other agency assessments on health effects associated with PFAS exposure, and although these studies and assessments may not determine health effect causality associated with exposure, this does not mean that the assessments have determined that the effects are non-causal as the commenter incorrectly describes. The commenter states that the EPA should provide a distribution of benefits in the uncertainty analysis, and stated in that analysis, the EPA should assess the impact of negative or inverse relationships on health effects from PFAS exposure. The EPA clarifies that in the EA, uncertainty within the exposure-response relationships for the quantified adverse health effects is already assessed. Specifically, the slope factors that express the effects of serum PFOA, serum PFOS, and THM4 on health outcomes (birth weight, CVD, RCC, and bladder cancer) are based either on the EPA meta-analyses or high-quality studies that provide a central estimate and a confidence interval. This modeling is described within Section 6.1.2 of the EA (USEPA, 2024b) and section XII of the FRN for this action. Because the EPA has quantified uncertainty associated with the exposure-response slope factors used in benefits analysis, the EPA has followed A-4 guidance recommendations related to uncertainty analysis using the best available scientific information.

The economic analysis does not model VSL uncertainty; however, the agency is not required to do so. Moreover, the economic analysis does incorporate several other sources of uncertainty and the major sources of uncertainty were considered in the EA (see Appendix L of the EA; USEPA, 2024c). See also section 13.4.4 of the EPA response in this *Response to Comments* document. The EPA, under the SDWA, uses the best available peer review science to inform the regulatory impact analysis. The agency in line with the SDWA requirements used the agency's default VSL estimate provided in the EPA's Guidelines for Preparing Economic Analyses (USEPA, 2016a) which has been peer reviewed by the SAB. In developing the VSL estimate the EPA commissioned a report from meta-analytic experts to evaluate methodological questions raised by the EPA and the SAB on combining estimates from the various data sources. In addition, the agency consulted several times with the SAB Environmental Economics Advisory Committee (SAB-EEAC) on the issue. With input from the meta-analytic experts, the SAB-EEAC advised the agency to update its guidance (USEPA, 2007c). Until updated guidance is available, the agency determined that a single, peer-reviewed estimate applied consistently best reflects the SAB-EEAC advice received to date. The EPA default VSL estimate and its update methodology was vetted and endorsed by the SAB and is applied in relevant analyses while the agency continues its efforts to update its guidance on this issue. Furthermore, as indicated in the EA, and given public comment, the agency is aware of the potential uncertainty associated with the VSL used in the PFAS rule analysis and although not explicitly quantified in the rule analysis the EPA has considered the potential uncertainty in its assessment of the benefits of the final rule.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045988)

Section 8.5: Guidance for conducting regulatory analysis not followed

EPA did not follow the requirements of OMB Circular A-4 (2003) in developing the PFAS NPDWR. While EPA's economic analysis (EA) includes a partial uncertainty analysis, under Circular A-4, the agency is required to complete a full formal uncertainty analysis, quantifying uncertainties because the rule has an annual economic effect of $1 billion or more. Simply adjusting the discount rate from 3% to 7% (the latter rate being more representative of current inflation conditions) inverses the cost-benefit result. As detailed in the PNG Analysis of these comments, AMWA believes strongly that the agency should employ a numerical sensitivity analysis and a probabilistic analysis of large, multiple uncertainties. This analysis is especially important because the uncertainty of certain health effects and limitations outlined in EPA's EA (specifically Table 33, Appendix A) could – and should – be quantified and included in a formal uncertainty analysis.

EPA Response: With respect to the commenter's assertion that the EPA's uncertainty analysis did not follow the requirements under OMB Circular A-4, the EPA disagrees; see section 13.9 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045986)

Section 8: HRRCA/Economic Analysis for the proposed NPDWR

Section 8.1: Evaluation of benefit-cost analysis

AMWA and AWWA commissioned Policy Navigation Group (PNG) to prepare a benefit-cost analysis of EPA's proposed rulemaking to set federal drinking water standards for certain PFAS. The report (Attachment 1), "Benefit-Cost Analysis of EPA's Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation" (PNG Analysis) compares EPA's approach to estimate the social benefits and social costs with federal requirements for regulatory analysis and best practices in the field. PNG also prepared an economic impact analysis of the proposal's effect on household income.

EPA's methodology in its proposal falls short of the best practices for these requirements. Specifically, EPA failed to conduct a formal uncertainty analysis and neglected to consider all the opportunity costs of its proposal. Per EPA's Guidelines for Preparing Economic Analyses [[FN20: EPA. (2010) Guidelines for Preparing Economic Analyses. Chapter 8: Analyzing Costs. https://www.epa.gov/environmental-economics/guidelines-preparing-economic-analyses].], the social costs of a rule represent the total burden that a regulation will impose on the economy. Social costs are "defined as the sum of all opportunity costs incurred as a result of a regulation where an opportunity cost is the value lost to society of any goods and services that will not be produced and consumed as a result of a regulation." [FN20: EPA. (2010) Guidelines for Preparing Economic Analyses. Chapter 8: Analyzing Costs. https://www.epa.gov/environmental-economics/guidelines-preparing-economic-analyses].

EPA Response: See section 13.9 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046016)

IV. ESTIMATES OF THE SOCIAL COSTS FROM EPA'S REGULATORY ACTION

EPA's proposed rule will cause a range of social costs above and beyond those included in EPA's EA. The direct costs to society, as EPA discusses, are primarily the treatment and engineering costs non-compliant water systems will incur to comply. These social costs include the capital resources required for PFAS treatment, the O&M costs associated with installation and implementation of treatment strategies, and the 0other monitoring and administrative costs to maintain compliance.

Additional market costs that EPA does not quantify include the near-term additional costs water systems face due to scarcity in the labor force and supply chain constraints; the opportunity costs associated with periods of time required to install treatment technologies; and the economy-wide general equilibrium (GE) effects as the regulation shifts resources from consumption of other goods and services to very specific capital investments.

There are other non-market social costs associated with the proposed rule, as well. Treatment systems require electricity and, as water systems' energy consumption rises, society will carry the social costs of increased carbon dioxide emissions.

EPA Response: See section 13.9 of the EPA response in this *Response to Comments* document. Please also see section 13.11 of the EPA response in this *Response to Comments* document for responses to comments on the EPA's assessment of the social costs of greenhouse gases for the final rule.

American Water Works Association (AWWA) (Doc. #1759, SBC-046163)

5.2 Monte Carlo Simulation for Design and Performance Variability

Water treatment system design is a practice that evolves non-uniformly across the country. Decisions in the design process are driven in some cases by rigorous engineering standards and in others by regional and geographic considerations, or owner and operator preferences. The result is a landscape of treatment systems across the United States that cannot be effectively modeled by clear and simple rules and frameworks. Additionally, water quality characteristics vary both regionally and locally, and these variations cannot be fully captured in the model with distinct data. These water quality characteristics may improve or hinder performance as well as increase costs to ensure water quality downstream is not altered and complies with other regulations.

To compensate for this uncertainty, Monte Carlo methods were applied to simulate variation and to account for unknowns in major factors influencing design, operation, and, ultimately, cost for

PFAS reduction systems. The @RISK Probabilistic Risk Analysis Software by Lumivero, which functions through an Excel add-in, was utilized for the Monte Carlo analysis.

Monte Carlo methods consist of randomizing inputs (e.g., loading rate, GAC media life, RO recovery) according to a defined distribution and number of iterations while calculating the impact to the outputs (e.g., number of vessels, media replacement frequency, cost). As the number of variables undergoing Monte Carlo analysis increases, computer processing power and the time to simulate one scenario both increase exponentially. Thus, Monte Carlo analysis was limited to only major factors considered to exert significant influence on design, performance, and cost of the individual systems. The major factors subjected to Monte Carlo are shown in Table 5-4.

Table 5-4 Major Factors for Monte Carlo Analysis

[Table 5-4: Docket ID: EPA-HQ-OW-2022-0114-1759]

With the exception of RO recovery, all Monte Carlo inputs were assigned a triangular distribution. A triangular distribution is a probability distribution where the probability decreases linearly on either side of the most likely value (highest probability) to the minimum and maximum, at which point the probability is zero. Triangular distributions were used where typical industry design values exist. RO recovery was modeled using a uniform distribution where each value between the minimum and maximum have an equivalent probability of occurrence.

The result of the Monte Carlo analysis is a distribution of possible costs for each technology (i.e., low [10th percentile], high [90th percentile], and most probable). For each modeled scenario, each of these costs was stored as a modeled output for each system represented in the occurrence database for use in determining the overall national cost of compliance with the modeled limit.

EPA Response: This comment describes the steps taken in AWWA's B&V report. The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. See section 13.3.3 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046124)

Exhibit B

Memorandum

To: Earthjustice

From: Dennis Guignet, PhD.

Subject: Review of the Economic Analysis for the Proposed PFAS NPDWR Date: May 26, 2023

Purpose

The purpose of this memorandum is to evaluate the U.S. Environmental Protection Agency's Economic Analysis of the proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation, and to identify ways the economic analysis (EA) can be further improved.

As a trained economist with a PhD in Agricultural and Resource Economics, and over a decade of experience, I am qualified to identify analytical strengths and weaknesses in the EA, and recognize potential areas where the EA can be further strengthened. I served as a research economist in the National Center for Environmental Economics at the U.S. Environmental Protection Agency (EPA) for seven years (from 2011 to 2018). During that time, I helped develop, review, and revise EAs of regulatory actions. I have taught environmental economics courses at the University of Maryland and American University, as well as a graduate and undergraduate-level course in benefit-cost analysis at Appalachian State University, where I am currently employed as an Assistant Professor of Economics. My research focuses on applied quantitative analysis, benefit-cost analysis of environmental policies, and the estimation of environmental and human health benefits, with a particular focus on toxic chemicals. I have 25 publications in peer-reviewed journals, and significant related experience that adds to my qualifications (see the attached Exhibit 1 for my full curriculum vitae).

Overall, based on my professional experience, the EA that has been developed for the proposed PFAS National Primary Drinking Water Standards (NPDWS) is one of the most well-organized, thorough, and transparent EAs I have reviewed. The quantified benefits entail reduced mortality and non-fatal health outcomes from decreased exposures to PFAS, including reduced risks of cardiovascular disease, low infant birthweight, and renal cell carcinoma. Additionally, reduced risk of bladder cancer due to the co-removal of non-PFAS pollutants is a co-benefit that is quantified. For all four health outcomes, the number of avoided fatal and non-fatal cases that result from each regulatory option, relative to the baseline, are estimated. These quantified benefits are monetized based on the Value of a Statistical Life (VSL) for reduced fatal cases (i.e., reduced mortality risks), and based on avoided cost-of-illness (COI) estimates for reduced non-fatal cases (i.e., reduced morbidity risks). Both are common and well-accepted approaches for monetizing (i.e., assigning a dollar value to) human health-related benefits in policy analysis.

The quantified costs mainly include public water system (PWS) costs for implementing treatment and non-treatment technologies when the proposed maximum contaminant levels (MCLs) are exceeded, as well as monitoring and reporting costs, and administrative costs to PWSs and implementing agencies.

This memorandum is organized as follows. First, key strengths of the EA are highlighted. Then I discuss potential areas where the analysis could be improved.

Strengths of the Economic Analysis.

There are several strengths of the EA that are worth highlighting. These features should be maintained and potentially built upon for the final rule EA.

1. The entire EA is centered on a detailed, data-driven Monte Carlo simulation model that has been calibrated based on existing federal and state data on point-of-entry water concentrations of PFOS, PFOA, and other PFAS.

This carefully laid approach relies on existing data to project baseline and policy scenarios under the various regulatory options. Point-of-entry pollutant concentrations are predicted across PWSs, while at the same time accounting for various system-specific factors. A particularly advantageous feature of this approach is in enabling data-driven, comprehensive sensitivity analyses. The analysis utilizes Monte Carlo simulations entailing 4,000 iterations. This allows the Agency to derive a distribution of benefit and cost estimates, and in turn quantitatively and simultaneously account for key points of analytical uncertainty by providing a range of possible net benefit calculations (e.g., a 90% confidence interval). Monte Carlo simulations like this are a common and defensible approach to account for uncertainty (EPA 2014), and are the most thorough way to simultaneously account for numerous sources of uncertainty in economic analyses (Boardman et al. 2018; OMB 2003).

As outlined in the Office of Management and Budget's Circular A-4, the Executive Branch's seminal guidance for conducting regulatory analysis, there are basically three broad approaches for accounting for analytical uncertainties (OMB 2003). In terms of increasing levels of complexity and rigor, these approaches include:

• A qualitative discussion of the main uncertainties;

• A quantitative sensitivity analysis, such as a "partial sensitivity analysis" or "worst- and best-case analysis"; and

• A probabilistic quantitative analysis using Monte Carlo simulations.

In cases where the necessary data and information are not available to assess the likelihood and outcomes of various contingencies under alternative assumptions, then a qualitative discussion of the key uncertain assumptions and potential implications for the results of the EA should be included. And in cases where the available information is limited, EPA does in fact include such qualitative assessments; for example, see Table 5-22 and Tables 6-48 through 6-53 in Chapters 5 and 6, respectively.

Other more quantitative sensitivity analyses are recommended when some quantitative information is available, but where information on the probability of alternative contingencies (or outcomes) is not. For example, "partial sensitivity analysis" is when one varies one assumption at a time, and assesses how the estimated net benefits vary across alternative assumptions (Boardman et al. 2018). This approach has two main drawbacks. First, varying only one assumption at a time may not fully bound the plausible range of results, especially in cases where there may be interactive or cascading effects across assumptions. Although one could vary multiple sets of assumptions at a time, there are only so many distinct scenarios an analyst can reasonably estimate. The second weakness is that even with a large menu of distinct scenarios, one can say nothing about the likelihood of any one scenario or results of central tendency (e.g., an average), due to the lack of an estimated probability distribution.

An alternative type of quantitative sensitivity analysis sometimes labelled "worst- and best-case analysis" (Boardman et al. 2018), allows analysts to bound the plausible range of net benefits. This is done by estimating a worst-case scenario, where for all key analytical decision points, model parameters, etc., the "worst-case" plausible assumptions are made that would result in the highest estimates of the costs and lowest estimates for the benefits. Then on the other extreme, a best-case scenario is estimated, where the underlying key assumptions are set such that the analysis will yield the highest plausible estimates for the benefits and lowest estimates of the costs. This overcomes the first weakness described above by varying all key assumptions at once, and thus providing upper- and lower-end bounds on the net benefits, and it accounts for interactive and cascading effects across assumptions. The second weakness, however, is still not addressed. One still would not know where the eventually realized benefits and costs are most likely to fall within those bounds. In other words, "worst- and best-case analysis" can reasonably bound the range of plausible net benefits, but tells us nothing about how likely one scenario is over another, or where within that range we are most likely to fall.

This final weakness is overcome by the third, and most thorough type of analysis of uncertainty – Monte Carlo simulations. Detailed Monte Carlo simulations form the underlying foundation for the entire EA for the proposed PFAS NPDWR. By taking advantage of existing data on PFAS concentrations in drinking water sources, as well as past treatment decisions of PWSs (discussed below in comment #2), the Agency was able to estimate a range of benefits and costs, as well as a probability associated with each potential realization of these estimates. In short, this yields several advantages by allowing the Agency to (i) assess the simultaneous impacts across multiple key assumptions, (ii) account for the likelihood of those assumptions and the resulting estimates of the benefits and costs that would be realized, and finally (iii) account for a range based on, for example, the 90% confidence interval, as well as the estimates of the benefits and costs that will be realized, on average. The Agency went through great efforts to gather the necessary data to not only pursue this most rigorous approach to account for analytical uncertainty, but they did so in a way that accounts for numerous points of uncertainty, and that relies squarely on existing data (as opposed to, for example, best professional judgment).

EPA Response: See section 13.9 of the EPA response in this *Response to Comments* document. The commenter's analysis provides support for the EPA's approach to assess uncertainty in the economic analysis for the PFAS NPDWR. The EPA agrees with the commenter that the methods used to assess uncertainty for this economic analysis are rigorous and effective for assessing the impact of various uncertain data sources on the benefit-cost results.

Earthjustice et al. (Doc. #1808, SBC-046136)

16. Uncertainty around the cost of illness (COI) estimates for each non-fatal health endpoint that was quantified is not accounted for.

The quantified examination of analytical uncertainty is quite thorough throughout the EA with respect to other "upstream" analytical steps, and in points where it is not, EPA is still transparent

in describing any shortcomings. Nonetheless, the reliance on just central COI estimates is a weakness that could be addressed. For example, a sensitivity analysis could be conducted based on the statistical distribution of the COI estimates from the literature, or perhaps other bounding values if the primary studies did not estimate the COI values using statistical methods. That said, perhaps such an exercise is not worth the additional effort if this source of uncertainty is expected to be trumped by numerous other points of uncertainty that are addressed in the Monte Carlo simulations. If this is expected to be the case, then EPA should make such assertions explicit in the EA.

EPA Response: The EPA acknowledges that COI uncertainty was not evaluated in the economic analysis. With the exception of COI estimates for changes in birth weight from Klein and Lynch (2018), the primary studies used to develop COI-based values for CVD (O'Sullivan et al., 2011), RCC (Ambavane et al., 2020), and bladder cancer (Greco et al., 2019) did not report statistical uncertainty estimates. Estimates in Klein and Lynch (2018) were reported at several discrete evaluation points defined by the magnitude of birth weight change and the baseline birth weight, which required interpolation of the reported estimates. Derivation of statistical uncertainty surrounding the interpolated array of COI values would have necessitated additional analysis of the restricted-access data used by Klein and Lynch (2018) which was not feasible within the regulatory development timeframe. Furthermore, even if quantified, the statistical uncertainty in the COI-based values is far from the comprehensive reflection of the overall uncertainty because of the retrospective nature of this valuation method. Impacts of future changes in medical technology, clinical practices, and healthcare markets on COI are challenging to quantify.

Earthjustice et al. (Doc. #1808, SBC-046130)

Potential Areas to Improve the Economic Analysis.

Although the EA for the proposed PFAS NPDWS is quite thorough and transparent, there are several areas where the EA can be further improved. The below comments entail suggestions on where further clarification or support would be helpful, as well as a few cases where additional or revised analysis should be considered.

7. The analysis assumes that population is held constant based on 2021 levels for the entire 80-year study period.

If population is projected to increase over this time, then this constant population assumption would result in an underestimate of the benefits and of the costs. The EA would be improved if EPA considers available projections and/or current population trends when estimating future benefits and costs. EPA recognizes this area for improvement, and in Chapter 6 (Table 6-48) EPA discusses how they intend to account for population trends in the final rule EA. I encourage the Agency to pursue such revisions for the final rule EA.

8. Concentrations of PFOS, PFOA, and other PFAS at system entry points are simulated/projected based on data of past occurrences, and as such EPA is assuming that entry point PFAS concentrations are constant over time.

This assumption is explicitly stated on page 4-23, but the validity of this assumption is unclear. There are assumptions being made here in terms of stock PFAS concentrations in water sources, and implicitly the future use and releases of PFAS into drinking water sources. The high degree of persistence of PFAS, along with various confounding trends over time that the EA mentions (e.g., voluntary phaseout programs, industry trends, and trends in human exposure [FN1: For example, on page 2-1 of the EA it is noted that that PFOA human blood levels have been decreasing.]) make it difficult to assess the validity of this assumption. Put plainly, how representative are the data of current and recently observed PFAS concentrations compared to those expected in the future under the baseline (i.e., business as usual) scenario? To the extent that baseline stock concentration levels and the use of PFOS, PFOA, and other PFAS chemicals in industrial processes and consumer products, and subsequent releases into the environment, have been decreasing, then both benefits and costs in the EA would be overestimated. The opposite is true if current baseline trends suggest an increase in future concentration levels of these chemicals at PWS points-of-entry.

The EA would be improved by providing additional support for the assumption that future baseline PFAS concentrations will be similar to recently observed concentrations, and/or by adding discussion of the resulting uncertainties regarding this assumption to Table 4-34.

9. Do the occurrence and concentrations of PFAS in water at PWS points-of-entry vary depending on whether the source is surface water or groundwater?

The Monte Carlo simulations used to predict baseline and policy scenario levels of these pollutants is very thorough in accounting for key factors that may lead to differences in pollutant levels (e.g., system size). However, it does not seem that the water source was accounted for when estimating point-of-entry concentration levels. If observed concentrations in the past vary across surface versus ground water sources in the data used to calibrate the Monte Carlo simulations, then this is another source of heterogeneity that should be explicitly accounted for to improve those models.

The agency was careful to make distinctions in the technology cost curves based on water source, so perhaps such heterogeneity is also important for modelling the occurrence and concentrations of PFAS at PWS points-of-entry.

EPA Response: In response to item #7, the EPA agrees with the commenter's assertion that benefit and cost estimates would be improved if the EPA considered population growth. However, the EPA was limited by the availability of appropriate data for use in such analyses. For instance, the health benefits models evaluated in the economic analysis require information on populations stratified by location, race/ethnicity, age, and sex to accurately predict health risks among stratified populations. While total population projections per geographical location (e.g., county, state) are publicly available (e.g., U.S. Census forecasts), such projections do not

typically include projections for additional strata, such as race/ethnicity, age, and sex. This is an important component of understanding future health risks, as different strata of populations experience different baseline health risks and are expected to differ in terms of population growth. Population projections that do include strata-specific forecasts, such as Woods and Poole (2023), typically do not project such populations far out into the future (current Woods and Poole projections go through 2060, whereas the economic analysis period of analysis goes through 2105). Using such projections would require the EPA to extrapolate beyond the final year of available population projections, which could introduce uncertainty into the analysis. Additionally, such population projections are proprietary, and the methods used to forecast future populations are not often well-documented.

In response to item #8, there is not sufficient data to meaningfully illustrate nation-scale temporal trends of PFAS occurrence, however the PFAS included in the final regulation have been found to be very stable and persistent in the environment. Therefore the EPA believes the assumption that these contaminants would remain present at current concentrations in the baseline scenario is reasonable. Further, the EPA anticipates that actively produced and/or used PFAS such as Gen-X Chemicals (HFPO-DA) may potentially increase over time as long as their use continues. See section 3.1.2 of the EPA response in this *Response to Comments* document on regulatory determinations and statutory criterion #2 for a discussion of occurrence of PFHxS, PFNA, and HFPO-DA.

In response to item #9, the EPA examined several occurrence model variants that included source water type. Information was shared between source water type and system size because they are so strongly associated. The variant that included just system size performed best in cross validation (Cadwallader et al., 2022).

Earthjustice et al. (Doc. #1808, SBC-046177)

Unmodeled sources of uncertainty in both cost estimates

There are some unmodeled sources of uncertainty that were not included in both estimates. One factor for which inclusion would increase cost would be the potential for competition for supplies and supply chain issues driving up prices if thousands of PWS nationwide try to install treatment at the same time. On the other hand, there are sources of uncertainty not included in both estimates that would have the impact of decreasing overall costs, including:

• Innovation in the marketplace

• Innovation/new technology for PFAS destruction/disposal

• Future options for point-of-use (POU) compliance

• Increasing the number of PWS that consolidate with other PWS that meet MCLs instead of installing treatment.

In the case of this last option, according to EGLE, state primacy agencies focus on finding a safe source prior to exploring treatment options. Michigan expects up to 33% of PWS and 26% of CWS to connect to another system before installing treatment, indicating that EPA's estimate of 6-7% of systems with <3.536 MGD design flow is not only reasonable, but possibly low (Smith, personal communication May 23, 2023). This omission of non-treatment options by AWWA is the source of at least $159 million in difference between the AWWA and EPA cost estimates. If Michigan's results are found to hold true nationwide, up to $362 million in savings could be realized in comparison to the AWWA cost estimate.

EPA Response: In response to commenter's statement regarding "…competition for supplies and supply chain issues driving up prices if thousands of PWS nationwide try to install treatment at the same time," see section 13.3.3 of the EPA response in this *Response to Comments* document.

In response to the commenter's points about sources of uncertainty that would decrease overall costs, the EPA generally agrees that water system interconnecting as well as technological innovation and emergence of new technologies for PFAS removal and PFAS destruction could decrease overall future costs associated with the rule. The EPA specifically notes that if in the future POU devices are certified to meet the final MCLs, costs may be lower (see Section 5.3.3.1 of USEPA, 2024b). The EPA does not have sufficient data to quantify the decreases in costs from these sources of uncertainty at this time.

In response to the commenter's point about percentage of non-treatment options, see section 13.3.6 of the EPA response in this *Response to Comments* document.

13.10 EPA's Affordability Analysis

Summary of Major Public Comments and EPA Responses

The EPA asked for comment on the national level analysis of affordability of SSCTs and specifically on the potential methodologies presented in the EA for the proposed rule Section 9.12. A couple of commenters recommended the EPA not use median household income (MHI) in the affordability analysis. The EPA decided to retain the MHI measure of income in its primary national level SSCT affordability methodology given the value is easily understandable and available, providing a central tendency for income which is representative of a whole community's ability to pay and is not unduly influenced by outlier values. However, in this rulemaking, the EPA recognizes the value in examining alternative measures of a community's ability to afford an SSCT, so the agency chose to include supplemental analyses that use alternative metrics, specifically 1 percent of MHI, 2.5 percent of lowest quintile income (LQI), and an analysis accounting for financial assistance. These supplemental analyses help to characterize affordability when considering the marginal impact, disadvantaged community groups, and subsidization.

Some commenters stated that the data the EPA used to inform current water rates from the 2006 Community Water System Survey (CWSS) is outdated. While dated, the data from the 2006

CWSS remains the best available dataset for this national level analysis and affordability determination for the following reasons: (1) the CWSS survey used a stratified random sample design to ensure the sample was representative and (2) these responses can be extrapolated to national estimates since the survey has a known sampling framework; and the data can be organized by system size, source, and ownership (USEPA, 2020b).

Some commenters recommended the EPA extend the affordability analysis to medium and large systems. The EPA disagrees with this recommendation, as the purpose of this analysis is to determine if available SSCTs are affordable, per SDWA Section 1412(b)(4)(E)(ii). Therefore, the EPA chose to continue to analyze small system technologies rather than include medium and large systems.

Some commenters stated the EPA used national median household in the affordability analysis. These commenters are incorrect; the EPA clarifies that the agency did not use the national MHI. MHIs used in the analysis were derived using the CWSS. The EPA used MHI's for the zip codes provided by small systems in the CWSS. This approach allows the EPA to capture the incomes of communities served by small systems, many of which are rural.

Some commenters specifically disagreed with one of the EPA's supplemental affordability analyses that examined the impact of the rule when accounting for the financial assistance through BIL and other sources that are generally available to small systems. These commenters stated that the EPA should not assume that this funding will be available or enough to cover the small system capital costs associated with the rule. The EPA conducted this supplemental analysis in response to the recommendations of the SAB, which stated, "[i]f this funding is readily available to many or most systems facing affordability problems, it seems appropriate to take the availability of this funding into account in determining national level affordability. (USEPA, [2002])." The EPA disagrees with these commenters as this significant funding will be generally available, and the EPA continues its efforts to help PWSs access it. It is therefore reasonable to consider the burden reduction in the supplemental affordability analysis.

Some commenters disagreed with the EPA's affordability determination because they stated it was based on inaccurate treatment cost information. A couple of commenters presented their own estimates for small system household costs and compared these estimates to the EPA's affordability threshold and concluded the rule is unaffordable. The EPA disagrees with many of the underlying assumptions in the commenters' cost estimates which, on whole, result in overestimated household costs. These commenters cited cost information that is not representative of the range of treatment costs nationally, and the EPA disagrees with the commenter's cost model that systematically overestimates capital operation and treatment costs. The EPA updated the affordability analysis for the national affordability determination using the updated treatment cost curves (discussed in section 13.3.3 of the EPA response in this *Response to Comments* document) and found for systems serving between 25 and 500 people, that the upper bound estimated annual household treatment costs for GAC exceed the expenditure margin. Lower bound estimated annual household treatment costs for GAC do not exceed the expenditure margin; for more information see section XII. These exceedances are primarily

driven by capital costs and attributable to the use of high-cost materials (e.g., stainless steel) in the upper bound estimates. Systems using low-cost materials, but with source water characteristics otherwise set to the upper bound (e.g., influent PFAS at approximately 7,000 ng/L, influent TOC at 2 mg/L), would fall below the expenditure margin. Although costs increase in some scenarios, the increases are not significant enough to change the conclusions about affordability. Technologies are affordable for all small systems when the technologies do not use the high-end materials. Technologies that do not use high end materials are available for small systems. For more information on the EPA's response to comments on treatment costs section 13.3.3 of the EPA response in this *Response to Comments* document. The EPA also disagrees that there are no affordable compliance technologies for small systems as the EPA has demonstrated that SCCTs are available below the affordability threshold using the best available peer reviewed information to support the agency's cost estimates.

Individual Public Comments

Michigan Department of Environment, Great Lakes, and Energy (EGLE) Drinking Water and Environmental Health Division (DWEHD) (Doc. #1597, SBC-042992)

H. Health Risk Reduction and Cost Analysis

Having reviewed Section XIII of the proposed NPDWR, EGLE DWEHD does not have major issues with EPA's Health Risk Reduction and Cost Analysis (HRRCA). However, based on EPA's definition of a small system, it is possible that the impact of the proposed NPDWR on very small PWS (e.g., manufactured housing communities, child-care providers, schools) may be significant. EGLE DWEHD asks that EPA consider these categories of PWS when making final determinations.

EPA Response: See section 13.10 of the EPA response in this *Response to Comments* document. The EPA notes that for both the proposed and final, the HRRCA includes costs estimates for all public water systems subject to the rule, including very small public water systems serving 25 people or more. For the EPA's estimates of system level costs for all system sizes, see Appendix C of the EA. For the EPA's affordability analysis of household level costs at small systems, see Chapter 9 of the EA.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043640)

2) Affordability

1. The USEPA does not adequately consider the potential economic burden on utilities' ratepayers, especially for low income and historically disadvantaged communities, which will dramatically affect the affordability of drinking water.

A. An AWWA report (April 2021) summarized the limitations of the current affordability analytical framework used by EPA, including:

i. The income distribution in America is increasingly bimodal, such that reliance on a central tendency estimate of income is a misleading criterion when considered in isolation.

ii. USEPA's proposed rule entailing substantial capital and operational costs can have implications for low-income households within large water systems. However, USEPA's household-level affordability analysis only represented small systems (serving population of 10,000 or fewer).

It is no longer reasonable to use Median Household Income (MHI) as a measure of affordability; instead, Lowest Quintile Income (LQI) provides a more appropriate index by which to assess affordability challenges. USEPA focused on the affordability of small systems as they might be the least likely to afford compliance treatment technologies, if needed. However, large systems and their customers, especially low-income households should also be considered, which is what the LQI is targets. It is recommended that USEPA incorporates LQI into its affordability analysis for medium and large systems.

BWWB has conducted rate and affordability analysis to capture the impacts of the proposed PFAS Rule on the utility debt level and LQI. Please refer to the key points No.4 in the Executive Summary Letter and Appendix-C for additional details.

EPA Response: For the EPA response on the use of MHI and other indicators in the affordability analysis and the EPA's response to comments recommending the EPA include large systems in the analysis, see section 13.10 in this *Response to Comments* document. Regarding the commenter's system-specific rate and affordability analysis, see the EPA response to comment Doc. #1602, SBC-043630 in section 13.10 in this *Response to Comments* document. While the EPA recognizes that there are likely site-specific instances with affordability concerns, there are also site-specific instances where there are not affordability concerns, and this level of accuracy is appropriate for a national level analysis.

Water Works Board of the City of Birmingham (BWWB) (Doc. #1602, SBC-043630)

3. The USEPA model considered adding PFAS treatment costs to utilities in a vacuum without addressing the impact of other compliance and infrastructure needs occurring in tandem (e.g., Lead and Copper Rule Revisions (LCRR) compliance, non-revenue water control, AWIA related risk reduction and aging infrastructure renewal).

Based on the existing utility challenges with aging infrastructure and other regulatory driven investments, the combined capital cost impact on BWWB for the next 5 years is estimated to be $90 million (excluding the PFAS Rule).

The rate and affordability impacts associated with the obligations identified above, excluding the PFAS Rule, are already significant and challenging and as outlined below:

Table 1. Rate and affordability analysis results, based on combined ongoing and emerging compliance and infrastructure needs (excluding impacts of proposed PFAS Rule)

[Table 1: See Docket ID EPA-HQ-OW-2022-0114-1602]

Affordability has become an ever-increasing challenge throughout the US, and certainly in greater Birmingham due, in part, to increasingly stringent compliance rules and aging infrastructure challenges. The income distribution in America is increasingly bimodal, such that reliance on a central estimate of income, the Median Household Income (MHI), which USEPA implemented in its analysis, is a misleading criterion. Low income, and historically disadvantaged American families are struggling with increased water rates even before this rule was proposed; it is no longer reasonable to use MHI as a measure of affordability; instead, Lowest Quintile Income (LQI) provides a more appropriate index by which to assess affordability challenges. Water rates representing 2% of the LQI are considered a threshold measurement of affordability. As shown in Table 1, addressing the existing and emerging challenges facing BWWB over the next five years, excluding PFAS, could yield an average bill percentage of 2.74% of LQI and place a staggering 38.0% of households below the affordability threshold. This group of customers would likely struggle with affordability even before the impact of the PFAS Rule is considered. In that scenario, which is the reality facing BWWB, BEFORE consideration of the impacts of the proposed PFAS Rule, it would take someone on minimum wage to work 8.9 hours per month (based on current federal minimum wage rates) just to pay the average water bill in 2028. This does not even address other utility costs such as wastewater which are significantly higher than the water bills in Birmingham.

4. Both the magnitude of the financial impact caused by the proposed PFAS Rule as well as the prolonged duration of the financial consequences could significantly affect drinking water affordability in the next 30 years. It appears that USEPA did not adequately consider the potential economic burden of the proposed PFAS Rule on utilities' ratepayers, especially for low income and historically disadvantaged communities in large water systems, which will dramatically affect their affordability of service. USEPA only considered LQI in the small system (serving a population of 10,000 or fewer) affordability analysis; nevertheless, low-income families served by larger systems also face notable affordability challenges that should be considered. If USEPA's PFAS Rule is finalized as proposed, it could add at least $166 million of capital cost over three years above and beyond the cost impact on BWWB identified in Table 1 above. In addition, the annual O&M cost would likely increase by more than $4 million resulting from operation of a GAC system for PFAS removal and media disposal as non-hazardous waste. Table 2 summarizes the potential impact on BWWB's ratepayers if the compliance cost of the proposed PFAS Rule were added to the costs previously identified in Table 1.

Table 2. Rate and affordability analysis results, based on combined compliance costs (with PFAS Rule, non- hazardous waste)

[Table 2: See Docket ID EPA-HQ-OW-2022-0114-1602]

When considering the combined compliance costs (including the PFAS Rule, and assuming a non-hazardous waste scenario), the average monthly water bill is projected to become $68.48 in 2028, which constitutes a 43.6% increase over a five-year period (i.e., 2023 to 2028).

The average water bill would represent 3.17% of the LQI and 40.0% of BWWB's customers would be below the affordability threshold by 2028. Low income, and historically disadvantaged American families can simply not afford the increased water rates associated with the proposed PFAS Rule. Furthermore, the additional utility debt level would be projected to increase by 17.9% by 2028, creating long-term affordability impacts for BWWB's customers. BWWB has a high debt burden and has been working diligently on a debt reduction plan to reduce borrowing, maintain or improve our bond rating and lower the cost of borrowing on our customers. Adding a potential $185,483,000 in additional debt would result in rate impacts lasting as long as 30 years.

EPA Response: The commenter's affordability analysis starts from existing conditions regarding borrowing, debt, and typical monthly bills and adds an estimated $90 million over 5 years for compliance with infrastructure and regulatory requirements other than the PFAS rule. The commenter does not explain the source of this estimate or specify the assumptions used. The commenter then adds the estimated cost of PFAS compliance at the Shades Mountain Filter Plant. As discussed in detail in response to this commenter in section 13.3.3 of the EPA response in this *Response to Comments* document, the estimated capital costs for the Shades Mountain Filter Plant are based on straight-line extrapolation from a single case study. The estimated O&M costs for the Shades Mountain Filter Plant use unit costs for GAC media that do not account for large volume price discounts. Taken together, these uncertainties suggest that the commenter's analysis may overestimate the affordability impacts of the PFAS rule. Alternately, this specific system may be a case where affordability impacts are greater than typical. The EPA expects there are also site-specific systems where affordability impacts are lower than estimated in the EPA's national analysis. The EPA's affordability analysis under SDWA is a national level assessment of the affordability impacts of a new rule and not a system specific analysis.

For the EPA's response on the use of MHI and other indicators in the affordability analysis and the EPA's response to comments recommending the EPA include large systems in the analysis see, section 13.10 in this *Response to Comments* document. For the EPA's response to comments on simultaneous compliance, see section 10.4.2 in this *Response to Comments* document. For the EPA's response to comments on environmental justice, see section 14.10 in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043063)

The affordability assessment relies on data that fails to capture financial challenges for many communities and relies on dated, inaccurate information. The affordability analysis should be updated to reflect community affordability and anticipated challenges more accurately for lower-income populations.

EPA Response: See section 13.10 of the EPA response in this *Response to Comments* document.

Illinois Farm Bureau (IFB) (Doc. #1630, SBC-043139)

[The most glaringly overlooked and/or underestimated data includes:]

• Failure to use non-metro median income data. The cost- benefit analysis that the agency prepared relies solely on national median income which is not representative of the entire country. They fail to consider the non-metro median income which is causing this rule to negatively impact rural communities.

EPA Response: See section 13.10 of the EPA response in this *Response to Comments* document.

National Rural Water Association (NRWA) (Doc. #1641, SBC-043262)

2. Affordability Calculation and Considerations

Calculations to determine affordability are based on the national median household income (MHI). This proposed rule states the median household income for a population of 301-3,300 is $53,596. For small urban communities this works but small rural communities often have median incomes below the national median. Federal agencies such as Rural Development at the U.S. Department of Agriculture (USDA) use Non-Metro Median Household Income to determine affordability. The Economic Research Service at USDA defines persistent poverty [https://www.ers.usda.gov/webdocs/publications/47002/30445_rdrr100full_002.pdf?v=41479#:%7E:text=ERS%20has%20defined%20counties%20as,%2Fbriefing%2FRurality%2FTypology.] counties as 20 percent or more of their populations have been poor over the last 30 years. The U.S. has nearly 400 persistent poverty counties and almost 15 percent of the nation's non-metro population live in persistent poverty counties. Additionally, this report states the poverty rate is highest in the completely rural communities (not adjacent to metro counties). These numbers demonstrate the need for rural communities to have independent calculations from national averages when determining affordability.

Table 9-8 page, 9-20 of the Economic Analysis states, "Household water costs derived from 2006 Community Water System Survey (USEPA, 2009), based on residential revenue per connection within each size category, adjusted to 2020 dollars based on the Consumer Price Index for All Urban Consumers: Water and Sewer and Trash Collection Services in U.S. City Average." This survey is outdated, and water rates have risen substantially since 2006. Also as previously stated, these rates are based on metro areas and do not account for the rate challenges that occur in rural areas where economy of scale can't be used to spread costs among many users.

Page 9-22, Section 9.12.2 Supplemental Affordability Analysis states, "In the following sub-sections, EPA estimated small system affordability based on; (1) an incremental approach with expenditure margins of 1.0 percent of annual MHI and 2.5 percent of the lowest quintile of annual household income, and no additional adjustment for total current annual water expenditures, and (2) taking into account nationally available financial assistance when assessing affordability." However, assessments are not included in this calculation. Additionally, many

rural systems are highly dependent on large agricultural or industrial users. The calculations are on residential, but businesses and other users must be accounted for in this process.

EPA Response: The EPA agrees with the commenter that small rural communities often have median incomes below the national median. As discussed in section 13.10 of the EPA response in this *Response to Comments* document, the agency did not use the national MHI. The MHIs used in the analysis were derived using the CWSS. The EPA used MHI's for the zip codes provided by small systems in the CWSS. This approach allows the EPA to capture the incomes of communities served by small systems, many of which are rural. Regarding the income measure used in the affordability analysis for the proposed and final rule, and in response to comments on the EPA's use of the CWSS, see section 13.10 in this *Response to Comments* document.

National Rural Water Association (NRWA) (Doc. #1641, SBC-043264)

Table 9-14, page 9-27 Economic Analysis states, "To evaluate affordability, EPA compared incremental costs per household for each technology against an expenditure margin."

The tables are titled "Total Annual Cost per Household…" but the text references incremental costs. Affordability determinations should be compared to total costs. Additionally, this analysis assumes 100% financial assistance for capital costs. The assumption that every system will receive financial assistance is flawed for reasons previously stated. Many small systems throughout rural America are unaware that financial assistance is available and if aware don't have staff and resources to apply. Outreach is a critical component to ensure the most marginalized communities can access these funds and to date, this has not happened.

Additionally, this analysis assumes a household cost of $1,081 to $1,153 annually. This is unaffordable and unsustainable in many rural communities. Larger systems use economy of scale to reduce cost, but this is not an option for many small systems. Regionalization where voluntary and locally supported can be an option but should not be assumed in all situations where geography, economic and environmental justice eliminate regionalization as an option.

EPA Response: In the affordability determination for the final rule, the EPA retained the approach using total costs, as recommended by this commenter.

The EPA disagrees with the commenter's assertion that the EPA's assumption of 100 percent financial assistance is flawed, as significant funding will be generally available, and the EPA continues its efforts to help PWSs access it. It is therefore reasonable to consider the burden reduction in the supplemental affordability analysis, as recommended by the SAB. For more information see section 13.10 of the EPA response in this *Response to Comments* document.

The single household costs range referenced by the commenter ($1,081 to $1,153) were the EPA's estimates at proposal of centralized RO for systems serving between 25 and 500 people assuming capital costs are 100 percent covered by financial assistance. For most water systems, the EPA expects that centralized RO will be the costliest of the BAT options and the EPA does not expect it to be commonly utilized as a compliance approach. In both the proposed and final

analyses, the EPA presented household cost estimates for GAC, IX, and POU devices, all of which are expected to have significantly lower associated household costs than centralized RO. These costs are 73 to 87 percent lower than those discussed by the commenter. For more information, including the EPA's household level cost estimates for all SSCTs, see Chapter 9.12 of the EA.

American Farm Bureau Federation et al. (Doc. #1642, SBC-043486)

[They have identified the following areas of concern regarding the agency's development of this rule:]

• Failure to use non-metro median income data. The cost-benefit analysis that the agency prepared relies solely on national median income which is not representative of the entire country. EPA fails to consider the non-metro median income, where this rule will have a disproportionate impact.

EPA Response: See section 13.10 of the EPA response in this *Response to Comments* document.

Raptor Pharm & Tox, Ltd (Doc. #1644, SBC-043425)

The US EPA failed to consider EJ impacts appropriately. The benefit-cost-analysis was performed using improper values, such as using the median household income, which does not account for, and will ultimately harm the poor and EJ communities.

EPA Response: For the EPA's response to comments on the EPA's use of MHI and other metrics in the affordability analysis, see section 13.10 of the EPA response in this *Response to Comments* document. For the proposed and final rule, the EPA conducted an EJ analysis that examined the demographic distribution of baseline PFAS exposure in drinking water and the distribution of costs and benefits of the rule; please see Chapter 8 of the EA (USEPA, 2024b) for more information on this analysis. For the EPA's response to comments on the agency's EJ analysis, see section 14.10 in this *Response to Comments* document.

Raptor Pharm & Tox, Ltd (Doc. #1644, SBC-043421)

EPA wrongly uses the MHI (median household income) in its benefit-cost analysis. The MHI is not a good indicator of much of anything other than the median household income. Use of the MHI does not serve or achieve any environmental justice (EJ) cause. In fact, use of the MHI will result in policies that completely ignore the needs of our EJ and children's health communities. Instead of basing the impacts on the MHI, benefits and costs need to be based on impacts to our EJ communities and our children.

2.5% of the MHI as an affordability threshold is not at all responsive to the needs of the poor. To say that the poor can absorb a water bill of $1,384 per year is outrageous. For a family making

$15/hour, the affordability threshold would be $780 – almost half of the affordability threshold for a family making the median household income.

What this means is that for the smallest water systems, the expenditure margin is $273, not $877 – that's 3x smaller for the working poor at $15/hr, than the median household income. Now, consider a water system where the poor are making even less than $15/hr, and that expenditure margin becomes even more narrow.

In other words – the policy as written, based on the benefit-cost analysis, is not taking into account the potential costs to the EJ community, and will have disproportionate harms on the poor, children, and ultimately the EJ community.

EPA Response: For the proposed and final rule, the EPA conducted both an EJ analysis pursuant to EO 14096 and an affordability analysis pursuant to SDWA Section 1412(b)(4)(E)(ii). The affordability analysis does not explicitly consider EJ impacts, which are examined separately in Chapter 8 of the EA. The commenter's assertion that the EPA "is not taking into account the potential costs to the EJ community" is incorrect, as the EPA did assess the distribution of costs of the final rule across demographic groups in its EJ analysis. For more information on the EPA's EJ analysis, see Chapter 8 of the EA (USEPA, 2024b). The commenter's assertion that the EPA did not consider disproportionate harms on children is also incorrect, pursuant to SDWA Section 1412(b)(3)(C), the EPA evaluated the effects of the contaminants on the general population and sensitive subpopulations including infants, children, pregnant women, the elderly, and individuals with a history of serious illness.

The EPA disagrees with the commenter regarding the appropriateness of the EPA's expenditure margin; the commenter's recommended expenditure margin is based on a minimum wage. The EPA disagrees for the same reason the EPA chose to retain the MHI; it provides a central tendency for income which is representative of a whole community's ability to pay and is not unduly influenced by outlier values. The EPA further notes that in this rulemaking, the EPA recognizes the value in examining alternative measures of a community's ability to afford an SSCT, so the agency chose to include supplemental analyses that use alternative metrics. These supplemental analyses help to characterize affordability when considering the marginal impact, disadvantaged community groups, as cited by this commenter. For the EPA's response to comments on the use of MHI and other indicators in the affordability analysis, see section 13.10 in this *Response to Comments* document.

Nebraska Department of Environment and Energy (NDEE) (Doc. #1653, SBC-043212)

The expenditure margins for SSCT affordability analysis overestimates the ability for residents in small rural communities to afford the cost of PFAS treatment. The analysis for communities with population 25-500 indicates rate increases from $25/month on the low end to $60/month on the high end. Significant financial assistance will be required to assist those smaller systems.

EPA Response: In response to the commenter's statement that the EPA "overestimates the ability for residents in small rural communities to afford the cost of PFAS treatment," the

EPA disagrees and relied on a longstanding methodology to determine if the rule is affordable at the national level. The EPA agrees that financial assistance will play a key role in helping small systems achieve compliance and reducing the burden on households served by small systems. For the EPA's response to comments on financial assistance available to help water systems comply with the PFAS NPDWR, see section 2 in this *Response to Comments* document.

California Farm Bureau Federation (Doc. #1704, SBC-045070)

[For example, the U.S. Chamber analysis highlights the following:]

• Failure to use non-metro median income data. The cost-benefit analysis that the agency prepared relies solely on national median income which is not representative of the entire country. EPA fails to consider the non-metro median income, where this rule will have a disproportionate impact.

EPA Response: See section 13.10 of the EPA response in this *Response to Comments* document.

State of Vermont Agency of Natural Resources and Department of Health (Doc. #1708, SBC-045113)

3) The National-level analysis of affordability of SSCTs and specifically on the potential methodologies presented:

We have seen costs for a small TNC system significantly higher than what we see in table 22 and 23. At least one small TNC treating PFAS with GAC is quoted to cost much more, $25,000 for the replacement of 4 x 10-inch diameter by 54-inch-tall filters (permitted to treat 5gpm). Vermont has NTNC systems that would need treatment systems of the same or similar scale (5gpm); therefore, they would be likely burdened with the same costs. It appears that the costs in table 22/23 are more applicable to community systems. A non-community system will not have multiple "households" to carry the cost. Different tables for community systems and non-community systems may be more accurate than going purely by size. Cost per household makes sense for community systems. Perhaps the cost should be per gallon or per system or some other unit than cost/household.

a. GAC/RO/IX may require additional pre-treatment. That should be included in the cost estimates. We have experience in Vermont where a system treating for PFAS has GAC filters that get approximately 1/3 to 1/2 of its expected PFAS-treatment life (on paper) due to removal of other contaminants. More guidance about pre-treatment standards should be developed as part of an implementation or treatment optimization guideline so that systems are investing money wisely in treatment and will not have to bear undue costs in the future.

b. For RO, the permeate will need to be re-mineralized post RO treatment. This should also be included in the cost estimate.

EPA Response: The EPA clarifies that the cost ranges that the commenter refers to presented in Table 22 and 23 of the preamble for the proposed rule are estimates of household level costs, not system level costs. Therefore, it is not appropriate to compare the EPA's figures in those tables directly to the cost quote for GAC cited by the commenter. On a system level basis, updated cost curves the EPA developed for the final rule estimate a range of capital costs of approximately $161,000 to $396,000 for a 5 gallon per minute facility using GAC to treat groundwater. Thus, the commenter's quote of $25,000 does not support a conclusion that costs for small NTNC systems would be significantly higher than the EPA's compliance cost estimates, and in fact, the EPA's affordability analysis was based on estimated facility costs higher than those cited by commenter for this treatment scenario. The EPA included costs for NTNCs in its national cost estimate. The commenter is correct, however, that the EPA's affordability analysis is applicable only to community water systems. For the EPA's responses on the need for pre- and post-treatment, and the extent to which these processes were included in the EPA's cost estimates, see sections 10.1 and 13.3.3 in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045915)

Furthermore, for small system compliance technologies, EPA identifies use of point-of-use RO, where currently not proposed as a compliance option because the regulatory options proposed require treatment to concentrations below the current NSF/ANSI certification standard for POU device removal of PFAS. EPA is anticipating third parties will develop new standards, and its affordability conclusions reflect the costs of devices certified under the current standard, not a future standard [FN163: 88 Fed. Reg. at 186687, Table 20 n.1-2: "POU RO is not currently listed as a compliance option because the regulatory options under consideration require treatment to concentrations below the current NSF International/American National Standards Institute (NSF/ANSI) certification standard for POU device removal of PFAS. However, POU treatment is reasonably anticipated to become a compliance option for small systems in the future if NSF/ANSI or other independent third-party certification organizations develop a new certification standard that mirrors EPA's proposed regulatory standard. The affordability conclusions presented here reflect the costs of devices certified under the current standard, not a future standard, which may change dependent on future device design. EPA's work breakdown structure (WBS) model for POU treatment does not cover systems larger than 3,300 people (greater than 1 million gallons per day [MGD] design flow), because implementing and maintaining a large- scale POU program is likely to be impractical."]. Also, POU systems are "at the kitchen sink" applications of which the "concentrate" is often sent to a sewer [FN164: See EPA document on WaterSense Draft Specification for Point-of-Use Reverse Osmosis Systems Supporting Statement: https://www.epa.gov/watersense/point-use-reverse-osmosis-systems.]. This also pushes additional costs to individuals / rate payers, creating a disproportional cost burden to individuals served by small systems [FN165: 88 Fed. Reg. at 18688, Table 23.]. EPA has underestimated administrative costs related to this rulemaking.

EPA Response: The EPA clearly states that the POU device household cost estimates costs reflect the costs of devices certified under the current standard not a future standard. The

POU device household cost estimates for final are at most 35 percent of the expenditure margin. The EPA does not believe costs under a future standard would increase significantly and are not likely to exceed the expenditure margin. Importantly, the EPA has identified other affordable SSCTs (i.e., GAC, IX, RO for some systems); therefore POU devices are not the only option. The EPA determined that there are several affordable treatment technologies for small systems available to comply with the final rule. In response to the comment that "POU 'concentrate' is often sent to the sewer" and "pushes additional costs to individuals / rate payers, creating a disproportional cost burden to individuals served by small systems," please see the EPA's response to comments about management of spent drinking water treatment residuals containing PFAS in section 10.4 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-047713)

5. ECONOMIC IMPACTS

EPA estimates the average cost per household from the proposed MCLs. EPA uses the cost estimates from its models which underestimate current PFAS treatment costs. This analysis presents revised household cost estimates using the updated treatment cost data.

EPA also found that the severe household impact would be lessened by increased federal spending to water systems to address emerging chemicals such as PFAS. Since federal funds are largely limited to capital expenditures and since the likely costs are much higher than EPA's estimates, this report compares the level of increased federal funding to water systems' compliance needs.

1. Household (HH) Impact

Multiplying the number of systems by the average population by CWS size determines the total population served by system size. Dividing these totals by the average household size [FN130: U.S. Census Bureau, "Table HH-4. Households by Size: 1960 to Present," November 2022, https://www.census.gov/data/tables/time-series/demo/families/households.html.] gives an estimate the number of households per CWS size. Dividing B&V's annualized costs by the number of households results in total cost per household from treatment costs alone. Household costs range from $110 annually for large systems serving over 1 million people to $10,000 per household for the smallest systems serving less than 100 people (see Table 27). For the largest size categories – CWSs serving between 100,000 to 1 M people – 12 M, households are expected to see a $120 annual increase in drinking water expenses.

Table 28 summarizes these costs as percentages of the annual household income for different income groups. For the lowest quintile income [FN131: A quintile is one of five equal groups (20 percent of all HHs each) ranked by income from lowest to highest. The lowest quintile income used in this analysis is $23,584.], costs average 15 percent and 0.75 percent of annual income for small and large CWSs respectively. For households at the national median household income ($70,784) [FN132: U.S. Census Bureau, "Income in the United States: 2021," September 2022, https://www.census.gov/library/publications/2022/demo/p60-276.html.] costs reach 15 percent of

annual income for the smallest systems. For households with income at 200 percent of the poverty level, costs range from 0.2 percent of annual income for large systems to 20 percent for small systems. With households of four, costs are a higher percentage of annual income, averaging 13 percent for small systems and 0.67 percent for large systems. Cost estimates for single households reach up to 81 percent of their annual income at the small CWS.

Table 27: Annualized Cost per Household (HH) from Treatment Costs

[Table 27: see docket ID EPA-HQ-OW-2022-0114-1738]

Table 28: Annualized HH Cost from Treatment Costs as a Percentage of Annual Income

[Table 28: see docket ID EPA-HQ-OW-2022-0114-1738]

Due to the initial year that includes up-front administrative startup costs, treatment administration costs, and 12-month monitoring costs, households in the initial year could bear additional economic impacts above those resulting from annualized costs. The following table presents the impacts on households from these administrative costs and includes an estimation of how the lowest quintile of households are impacted.

Table 29: Additional HH Impacts from Administrative Costs

[Table 29: see docket ID EPA-HQ-OW-2022-0114-1738]

EPA Response: The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. See section 13.3.3 of the EPA response in this *Response to Comments* document. The commenter's conclusions rely on AWWA B&V's overestimated costs, therefore, produce overestimated household level cost estimates. The commenter also derived cost per household using the number of systems and average population for each size category. The commenter did not provide sufficient data for a direct comparison between these two methods, but the EPA believes its approach is more representative of typical costs per household because the agency computed costs per household using the median population per system. The EPA notes that AWWA's letter states that the B&V model predicts household costs for systems serving 25 to 100 people is $3,570 (see Table 11-1 of AWWA's comment letter). It is unclear how this commenter used the same cost model but arrived at an estimate $10,000 dollars per household for the same system size category. Finally, in Table 29, the commenter added administrative costs but did not identify the source of these estimated costs or the assumptions implicit in these estimates. Overall, the EPA disagrees with the commenter's findings about the household costs of the PFAS rule as percentages of annual income.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045989)

Section 8.6: Affordability and environmental justice

AMWA encourages EPA to:

● evaluate and consider this proposed rulemaking's effects on water affordability nationwide, particularly as the high costs of treatment and disposal will be passed disproportionately onto disadvantaged and rural communities, and

● examine the rule's effects on environmental justice.

EPA's analysis does not take into account how the costs of treatment will be spread across U.S. households, and AMWA is concerned the highest costs will be concentrated on many of the nation's most vulnerable populations. EPA should both consider this proposed rulemaking in light of the rising concerns about long-term water affordability and should address the unequal impact of costs in the final rulemaking or accompanying guidance. Furthermore, AMWA urges EPA to consider how the proposed rulemaking will impact communities where PFAS are disposed of and how to support PWS and communities equitably. Ultimately, EPA should consider the unintended effects of this proposed rulemaking on vulnerable populations and address how the agency will support an equal distribution of negative impacts from increased costs and disposal in final rulemaking and implementation.

To understand the impact of this rulemaking, EPA must first consider the greater concerns about water affordability in the United States. Despite the much appreciated $50 billion of federal investment in the water sector from recent legislation, American water infrastructure still requires billions more to maintain adequate infrastructure, prepare for climate change resilience, and protect public health. The American Society of Civil Engineers' (ASCE) Failure to Act study [FN26: ASCE. (2021). Failure to Act: Economic Impacts of Status Quo Investment Across Infrastructure Systems. https://infrastructurereportcard.org/wp-content/uploads/2021/03/FTA_Econ_Impacts_Status_Quo.pdf] found that the US water sector in 2021 needed over $400 billion to meet engineering standards, and these costs will only increase with additional treatment, climate change, and inflation. The existing water system financing model assumes that most of the money for addressing local water supply issues, whether that issue is aging infrastructure, water quality, lead pipes, cybersecurity, or water supply reliability, can be dealt with largely with local resources (i.e., customer water rates). Given the large funding gap needed without considering PFAS, it is essential that the EPA adequately assess costs in its final rulemaking and create the NPDWR with accurate estimates.

EPA should create the final rulemaking in light of this rule's impacts on water affordability, including how it will increase household water rates across the country. Nationally, many customers can already not afford their drinking water bills. A 2020 analysis by Circle of Blue [FN27: Circle of Blue. (2020, October). Customer Water Debt Data and 12 US Cities. https://www.circleofblue.org/2020/world/chart-customer-water-debt-data-in-12-u-s-cities/] examined the amount of residential debt in 12 large U.S. cities. The analysis found that in some cities, the average resident with water debt owed on average over $600, and that in four cities over 30% of residents had water debt [FN6: Missouri Department of Natural Resources. (2023). Understanding data. https://dnr.mo.gov/monitoring/understanding-data]. This report reflects that households across the US are struggling to pay their water bills already, so EPA should greatly consider how to prepare for any rate increases from the proposed rulemaking.

Specifically, this proposed NPDWR will increase rates at an unsustainable level for households served by smaller, rural water systems. To examine how this proposed rulemaking would increase household rates across the country, Black & Veatch researchers examined estimated costs by PWS size [FN21: Associated Press. (2022, June 1). Inflation taking bite out of new infrastructure projects. https://www.usnews.com/news/business/articles/2022-06-19/inflation-taking-bite-out-of-new-infrastructure-projects]. The researchers found that customers in small systems, which are overwhelmingly in rural areas, may face significantly larger household costs of PFAS treatment than what households served by large utilities will see. PNG's analysis estimates that on an annualized basis, household costs will increase $110 to $10,000 depending on system size (Attachment 1, Table 27), which equates to a large percent of annual household incomes, particularly in rural areas (Attachment 1, Table 28; also included below). According to the latest annual Bankrate annual emergency savings survey [FN28: Bankrate. (2023, February 23). Bankrate's annual emergency savings report. https://www.bankrate.com/banking/savings/emergency-savings-report/], over 50% of Americans do not have the funds on hand to cover a $1000 emergency expense. An increase of over $1,000 for water treatment, therefore, is unimaginable for many households. Without substantial and recurring federal government subsidies and EPA's honest examination and preparation, these geographic and PWS system size inequities in costs of PFAS treatment will perpetuate with this rulemaking's finalization.

Table 28. Annualized HH Cost from Treatment Costs as a Percentage of Annual Income

[Table 28: see docket ID EPA-HQ-OW-2022-0114-1738]

EPA Response: In response to the comment regarding the impact disposal of PFAS containing treatment residuals on nearby communities, see section 11.4.4 of the EPA response in this *Response to Comments* document. In response to comments on the EPA's estimates of treatment costs, see section 13.3.3 of the EPA response in this *Response to Comments* document.

The EPA disagrees with the commenter's assertion that the "EPA's analysis does not take into account how the costs of treatment will be spread across U.S. households" because the EPA examined the distribution of costs for systems anticipated to install treatment to comply with the final rule across demographic groups. When examining costs anticipated to result from the rule, the EPA found that cost differences across demographic groups were small, with no clear unidirectional trend in cost differences based on demographic group. For more information on the findings of the EPA's EJ analysis, please see Chapter 8 of the EA (USEPA, 2024b). Also, see EPA's complete response to comments on the EJ analysis in section 14.10 in this *Response to Comments* document.

The EPA disagrees with the commenters assertion that the NPDWR "…will increase rates at an unsustainable level for households served by smaller, rural water systems." See section 13.10 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1738, SBC-047713 in section 13.10 in this *Response to Comments* document. In response to comments regarding the sufficiency of federal funding available to help water systems comply with the rule, see section 2.4 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045631)

Accounting for Financial Assistance

In its affordability analysis, EPA also cites that an additional analysis was conducted accounting for funds that are nationally available, such as the DWSRF program and funds from BIL. As EPA notes in the proposal, $800 million is available annually for systems addressing emerging contaminants like PFAS. EPA also announced the availability of $1 billion annually through the Emerging Contaminants in Small or Disadvantaged Communities grant program. Both programs are appropriated through Fiscal Year 2026. These programs make $1.8 billion available for fiscal years 2024, 2025, and 2026 (a total of $5.4 billion).

The EPA estimates that the total capital cost needs for small systems will range from 1.1 to 2.5 billion; however, as previously noted the cost analysis used by the EPA is significantly flawed and underestimates financial impacts on communities. The occurrence analysis also presents several issues in characterizing the total small system impacts. For a more accurate comparison to available funding, and therefore potential offsetting of household costs, data from Black & Veatch was considered. Black & Veatch estimates that the total capital cost for small systems for a 4 ppt PFOA and 4 ppt PFOS rule will exceed $21.6 billion based on the occurrence data collected by Corona Environmental (Black & Veatch, 2023; Corona, 2021). This is a stark difference from EPA's estimate of $1.1 to $2.5 billion total capital cost for small systems.

Even if the occurrence analysis from the EPA is used these estimates are substantially low. Policy Navigation Group estimated the number of systems that would potentially exceed the MCLs using data from the EPA (PNG, 2023). Using these figures and the estimated capital costs for each system size from Black & Veatch, the total capital cost exceeds $10 billion. This is approximately more than the EPA's estimate by a factor of four.

The availability of $5.4 billion for these systems will help alleviate the costs for individual households. That impact, however, is limited to systems that receive financial assistance. Unless EPA plans to work with states to develop a method for distributing these funds equally to all impacted water systems, the financial assistance will not be evenly distributed across small systems. This approach will inaccurately depict the financial impacts to households in communities where financial assistance is not provided. Therefore, AWWA recommends that the EPA not consider this financial assistance in assessing household affordability for small systems.

EPA Response: See section 13.10 of the EPA response in this *Response to Comments* document for the EPA's response to comments on the agency's affordability determination and methods for proposal and the final NPDWR. As discussed in Chapter 9.13 of the EA for the final rule, the EPA determined that there are several affordable treatment technologies for small systems available to comply with the rule. The commenter references one of several supplemental affordability analysis conducted by the agency, which, as discussed in section 13.10 of the EPA response in this *Response to Comments* document, as significant federal funding will be generally available, it is therefore reasonable to consider the burden reduction in the supplemental affordability analysis. Regarding the availability of BIL funding in comparison

to the compliance costs of the rule, see section 13.3 of the EPA response in this *Response to Comments* document.

Further, the EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs; see section 13.3.3 of the EPA response in this *Response to Comments* document. As detailed in section 13.3.3 of the EPA response in this *Response to Comments* document, the B&V overestimates system level capital costs for small systems (for example, by excluding package plants from consideration) and overestimates the number of small systems that will exceed the final MCLs. For the final rule, the EPA estimates that the total amount of initial capital treatment technology expenditures for small systems nationally ranges between approximately $1.8 and $3.5 billion and disagrees with the commenter's estimates total capital cost for small systems for a 4 ppt PFOA and 4 ppt PFOS rule will exceed $21.6 billion based on the occurrence data collected by Corona Environmental. The commenter's conclusions rely on AWWA B&V's overestimated costs, therefore, produce a significant overestimate of the total small system capital costs as a result of the rule. Regarding the EPA's occurrence analysis, see section 6 of the EPA response in this *Response to Comments* document. For the EPA's response to Corona (2021), see Doc. #1713, SBC-045902 in section 6.8 in this *Response to Comments* document.

Regarding PNG's analysis included in AMWA's comment letter, see the EPA response to comment Doc. #1738, SBC-046019 and Doc. #1738, SBC-047713 in sections 13.3.3 and 13.10, respectively, in this *Response to Comments* document. As detailed in that response, the EPA's review of the PNG report finds substantial discrepancies between the annual treatment costs cited and the values presented in the B&V report. For most system size categories, the annual treatment cost per affected PWS used by PNG is significantly greater than the values presented in the B&V study. The PNG provides no documentation or other information that explains where these extensive cost increases originate. This discrepancy potentially also applies to AMWA's estimate of small system capital costs.

American Water Works Association (AWWA) (Doc. #1759, SBC-045566)

6. The affordability assessment relies on dated, inaccurate data and an approach that fails to capture affordability challenges for many communities. The affordability analysis should be updated to more accurately reflect household affordability and anticipated challenges for lower-income populations.

EPA Response: The data from the 2006 CWSS remains the best available dataset for this national level analysis. For the EPA's complete response to comments on use of the CWSS survey in the affordability analysis, see section 13.10 in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045630)

11. Household Affordability and Small System Compliance Technologies

As noted in the first section, it is critical that drinking water be affordable and that smaller systems more susceptible to affordability challenges have access to compliance technologies. This is true for all consumers, and particularly for those in environmental justice communities. The proposal highlights several variations of the household affordability analysis beyond the EPA's previously utilized approach, including an approach that has been developed and recommended by AWWA and other water sector Associations (AWWA, 2021b). AWWA appreciates that the agency is interested in utilizing recommendations previously made by stakeholders regarding alternative metrics for this analysis.

These comments have already highlighted significant concerns about EPA's underlying approach to the cost analysis and the anticipated inaccuracies of the EPA's WBS Model. EPA should refine that approach and re-evaluate the affordability analysis for any rule.

As part of its analysis, Black & Veatch assessed household impacts of the various rule options (Black & Veatch – See Appendix B). Table 11-1 provides an overview of those results for Options 1a (4 ppt PFOA and 4 ppt PFOS) and 1c (10 ppt PFOA and 10 ppt PFOS) in comparison with EPA's estimated expenditure margins for the affordability analysis. As shown in Table 10-1, the household costs for each of these options significantly exceed the expenditure margin for systems serving less than 1,100 persons.

Table 11-1: Comparison of EPA Affordability Margin and Treatment Cost Estimates

[Table 11-1: See Docket ID EPA-HQ-OW-2022-0114-1759]

It is also important to note that these household costs are only reflective of treatment costs, monitoring costs are not included here, which for smaller systems will have a greater household impact. A treatment technology that is not considered as part of this analysis is the use of point-of-use reverse osmosis (POU RO) systems. While POU RO may become available in the future following NSF/ANSI certification standard that is based on achieving levels at or below the proposed MCLs, it is currently not a compliance option. AWWA agrees with the agency's decision to not include POU devices in its analysis of rule compliance affordability for small systems. Certification is currently not available, and demonstration of effectiveness is a critical aspect of including compliance technologies in this analysis. NSF/ANSI certification will be necessary if any rule considers POU RO as a small system compliance technology.

EPA should re-consider the proposal as the small system household costs for centralized water treatment exceed EPA's estimated expenditure margins for these systems, a more affordable POU treatment option is not available, and EPA has not identified a small system variance technology.

EPA Response: The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. See section 13.3.3 of the EPA response in this *Response to Comments* document. The commenter's conclusions rely on AWWA B&V's overestimated costs, therefore, produce a significant overestimate of the total small system capital costs as a result of the rule. Overall, the EPA disagrees with the commenter's findings and suggestion that the rule is not affordable for small systems. See the

EPA response to comment Doc. #1759, SBC-045631 in section 13.10 in this *Response to Comments* document.

The commenter is correct that the affordability analysis does not include the household level impact of monitoring costs because including those costs is not the purpose of this analysis. Because the analysis is conducted to pursuant to SDWA Section 1412(b)(4)(E)(ii)], which requires the "the Administrator shall include in the list any technology, treatment technique, or other means that is affordable", the EPA examines the affordability of treatment technologies. The EPA notes that treatment technology costs represent the large majority of overall costs for water systems that will be triggered into treatment under the final rule. The EPA does not anticipate that if the agency were to include monitoring costs in a supplemental affordability analysis that it would not change the EPA's affordability conclusions because they are small in comparison to treatment costs. For example, a water system that serves 500 people and takes 4 quarterly samples to comply with the rule is expected to incur an additional cost of approximately $12 dollars per year per household (or about $1 per month) associated with the analytical costs of the rule.[13]

Regarding POU's, consistent with the commenter's recommendation, the EPA did not include POU devices as a compliance option in the decision tree for the final rule. At this time, the EPA is not including point-of-use (POU) devices in the national cost estimates because the final rule requires treatment to concentrations below the current NSF/ANSI certification standard for POU devices. However, POU treatment is reasonably anticipated to become a compliance option for small systems in the future if NSF/ANSI or other independent third-party certification organizations develop a new certification standard that mirrors the EPA's final regulatory standard. In the event POU treatment becomes a valid compliance option, national costs could be lower than estimated in this application of the SafeWater MCBC. For the EPA's response to comments on POU devices, see section 10.5 in this *Response to Comments* document.

Western Urban Water Coalition (WUWC) (Doc. #1768, SBC-043939)

Further, EPA substitutes its cost-benefit analysis for an evaluation of affordability. EPA says it interprets the applicable SDWA standard to require an evaluation of "reasonable cost based on large and metropolitan water systems,"[FN9: 88 Fed. Reg. at 18668.] but its reasonableness determination merely refers back to the cost-benefit analyses it prepared in the EA and HRRCA. The primary discussion of affordability contained in the Proposed Rule relates to its potential impacts on small water systems; no due consideration is given to the affordability of the Proposed Rule to ratepayers of larger, urban water systems. [FN10: Id. at 18686–88.]

WUWC therefore recommends that EPA reconsider the proposed MCLs and determine if the proposed numeric MCLs of 4.0 ppt for PFOA and PFOS, and the HI of 1.0 for the other four

[13] Assuming a water system takes 4 samples per year ($309 each) and including the costs of analyzing FRBs ($273 dollars each), the annual analytical costs are $2,328 dollars (excluding PWS labor to take the samples and review results). Using the average American household size of 2.53 people per household, this cost would spread out among 198 households, and amount to approximately $12 per household.

covered PFAS, will be economically feasible. The analysis should consider affordability to ratepayers of water utilities of all sizes and take into account all categories of costs that will arise as a legal consequence of the Proposed Rule.

EPA Response: The commenter is incorrect; the EPA did not "substitute its cost-benefit analysis for an evaluation of affordability." The EPA performed both of these analyses. As required by SDWA Section 1412(b)(4)(E)(ii), the EPA identified any technology, treatment technique, or other means that is affordable, as determined by the Administrator in consultation with the states, for small public water systems. The EPA's long-standing methodology for determining whether there are affordable compliance technologies for a new drinking water standard for small systems compares the cumulative cost of providing drinking water that complies with the new standard to an affordability threshold equal to 2.5 percent of median household income (63 FR 42032). For the EPA's response to commenters recommending the EPA include large systems in the affordability analysis, see section 13.10 in this *Response to Comments* document. For the EPA's response to comments on the determination of feasibility, see section 5 in this *Response to Comments* document.

American Chemistry Council (ACC) (Doc. #1841, SBC-044843)

The Cost of Complying with the Proposed Standards Are Significantly Higher for Small Systems than EPA Estimates

In addition to underestimating the number of systems out of compliance with the proposed MCLs, EPA's estimated costs for these systems to come into compliance are significantly less than those from the AWWA analysis. A comparison of the average annualized cost for the size categories for which EPA provides information suggest that the Agency's numbers are as much as eleven times below those estimated by AWWA (Table 5).

Table 5. Comparison of Estimated Annualized Cost/System for Systems with Exceedances of the Proposed MCLs

[Table 5: See Docket ID EPA-HQ-OW-2022-0114-1841] [FN 171: USEPA Economic Analysis, page C-11 (Table C-11). [FN 172: AWWA WITAF 56, Appendix A, Table A-1.]

As indicated in Table 5, EPA's estimates are ten times lower for the three smallest size systems and only slightly better for the larger systems. While EPA presents individual breakdowns by water source (ground, surface) and ownership (public, private), the Table includes only information for private systems using surface water which represent the Agency's highest estimated per system costs. The AWWA results appear to be averaged over all system types, so the difference between the two estimates is likely even greater than shown.

EPA Response: In Table 5 of this commenter's letter, the commenter appears to list some of the EPA's 5th percentile estimates for surface water system costs under the regulatory alternative of PFOA and PFOS MCLs at 5 ppt. The commenter incorrectly characterizes these as "the agency's highest estimated per system costs." However, by definition, these estimates are

the EPA's lower end estimates of costs (i.e. 5th percentile), and the commenter is comparing them to a point estimate, possibly an average, although the B&V report does not specify the metric presented. The commenter also references information from a March 2023 version of the B&V report, the EPA notes that that report was since updated with changes that had a downward effect on the B&V cost estimates. The updated B&V report that was submitted to the EPA as a public comment does not appear to include an updated set of these exact estimates, so an updated comparison is not possible. Regardless of the incompatible comparison points from Table 5, the EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. See section 13.3.3 of the EPA response in this *Response to Comments* document. The commenter's conclusions rely on AWWA B&V's overestimated costs, therefore, produce a significant overestimate of the total small system costs as a result of the rule. For reasons explained above, the EPA disagrees with this commenter's assertion that compliance costs significantly higher for small systems than the EPA estimated.

American Chemistry Council (ACC) (Doc. #1841, SBC-047719)

The 10-fold difference for the smaller systems raises serious concerns about the ability of these systems to pass along the compliance costs to ratepayers. [FN173: Compliance with this regulation may overlap with the requirements of the Lead and Copper Rule Revisions that will compound stress on systems' limited resources.] EPA's current analysis of the household costs for the two smallest size systems expected to exceed the proposed MCLs suggest that households served by these systems may not be able to accept the increase in rates required to comply with the proposal. [FN174: USEPA Economic Analysis, page C-37 (Table C-37).]

EPA Response: The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions about the estimated national costs. See section 13.3.3 of the EPA response in this *Response to Comments* document. The commenter's conclusions rely on AWWA B&V's overestimated costs, therefore, produce a significant overestimate of the total small system costs as a result of the rule.

The EPA notes that implementation timing associated with this PFAS rule and the proposed LCRI has the potential to overlap. To the extent implementation overlaps, some rule start-up, administrative, and sampling/service line inventory costs associated with both rules could affect a large number of PWSs and states. The more significant costs of installing and operating PFAS treatment technology in a similar time frame with installing and operating CCT and/or conducting service line replacement are expected to fall on some systems, although neither the specific requirements nor the timeframes for compliance under the LCRI have not been established in a final rule. The EPA does not have sufficiently detailed PFAS occurrence, and LSL/GRR service line and 90th percentile lead tap sample data to explore the potential treatment cost interactions of the two rules. The EPA further notes that SDWA Section 1412(b)(3)(C)(i)(III) requires that the EPA include quantifiable and non-quantifiable costs that are likely to occur solely as a result of compliance with the rule including monitoring, treatment and other costs and excluding costs resulting from compliance with other proposed or promulgated regulations. For

the EPA's response to comments on simultaneous compliance, see section 10 in this *Response to Comments* document.

American Farm Bureau Federation et al. (Doc. #1642, SBC-043489)

Rural Communities Will Be Disproportionately Impacted

Farmers and ranchers often serve as the backbone of rural communities throughout the country. Our members raise their families, support their neighbors, and bring jobs to these less populated and underdeveloped areas. The pristine farmland that is often situated away from bustling urban centers allows our members to produce the safest and highest quality food products in the world. However, rural communities have far fewer resources to address expensive federal regulatory requirements. Drinking water utilities in rural areas will undoubtably experience more challenges in meeting the 4ppt standard outlined in this proposed rule. They will incur capital costs, annual operating and maintenance costs, life-cycle costs, and annualized costs. Simply put—it will be infeasible for many rural communities to meet the standards outlined in this proposed rule and the exorbitant costs will inevitably be handed down to the water users. Specifically, the costs associated with acquiring and maintaining technology, obtaining appropriate testing, and methods related to disposal and destruction of contaminated environmental media (i.e. water, soil, air) will weigh heavily on rural communities.

EPA Response: In response to the commenter's statement that "rural communities will be disproportionately impacted," the EPA notes that in the agency's EJ analysis for the final rule, the agency examined the distribution of costs across demographic groups and across multiple water system size categories. When examining costs anticipated to result from the rule, the EPA found that cost differences across demographic groups were small, with no clear unidirectional trend in cost differences based on demographic group. Additionally, the agency found that incremental household costs to all race/ethnicity and income groups generally decrease as system size increases, which is expected due to economies of scale. For further discussion of the EPA's EJ analysis, please see Chapter 8 of the EA (USEPA, 2024b) and section 14.10 of the EPA response in this *Response to Comments* document. To alleviate potential cost disparities identified by the EPA's analysis, there may be an opportunity for many communities to utilize BIL (P.L. 117-58) funding to provide financial assistance for addressing emerging contaminants. BIL funding has specific allocations for both disadvantaged and/or small communities and emerging contaminants, including PFAS. Additionally, if a water system, project or project cost is not eligible under the DWSRF, it may be eligible under other programs. These might include the U.S. Department of Agriculture's Rural Development program, the U.S. Department of Housing and Urban Development's Community Development Block Grant program, the Clean Water State Revolving Fund, the newly authorized Water Infrastructure Finance and Innovation Act (WIFIA) funding, or other federal, non-federal or state funding sources.

California Farm Bureau Federation (Doc. #1704, SBC-045072)

Rural Communities Will Be Disproportionately Impacted

Unfortunately, rural communities often have far less resources and the economy of scale to address expensive federal regulatory requirements. For this reason, we believe that drinking water utilities in many rural areas will experience additional challenges in meeting the 4ppt standard outlined in this proposed rule as they seek to comply. Such agencies often end up incurring capital, annual operating and maintenance, life-cycle, and annualized costs, resulting in such costs being passed on to water users. We are specifically concerned about the costs associated with acquiring and maintaining technology, obtaining appropriate testing, and methods related to disposal and destruction of media which we project will weigh heavily on rural communities.

EPA Response: In response to the commenter's statement that "rural communities will be disproportionately impacted," the EPA notes that in the agency's EJ analysis for the final rule, the agency examined the distribution of costs across demographic groups and across multiple water system size categories. When examining costs anticipated to result from the rule, the EPA found that cost differences across demographic groups were small, with no clear unidirectional trend in cost differences based on demographic group. Additionally, the agency found that incremental household costs to all race/ethnicity and income groups generally decrease as system size increases, which is expected due to economies of scale. For further discussion of the EPA's EJ analysis, please see Chapter 8 of the EA (USEPA, 2024b) and section 14.10 of the EPA response in this *Response to Comments* document. To alleviate potential cost disparities identified by the EPA's analysis, there may be an opportunity for many communities to utilize BIL (P.L. 117-58) funding to provide financial assistance for addressing emerging contaminants. BIL funding has specific allocations for both disadvantaged and/or small communities and emerging contaminants, including PFAS. Additionally, if a water system, project or project cost is not eligible under the DWSRF, it may be eligible under other programs. These might include the U.S. Department of Agriculture's Rural Development program, the U.S. Department of Housing and Urban Development's Community Development Block Grant program, the Clean Water State Revolving Fund, the newly authorized WIFIA funding, or other federal, non-federal or state funding sources.

13.11 Greenhouse Gas Emissions Associated with the Rule

Summary of Major Public Comments and EPA Responses

Several commenters recommend "…that the agency consider the social costs of carbon as part of any PFAS rule's cost analysis to be comprehensive as well as to understand how this rule may have unintended consequences like increased social costs relating to carbon dioxide emissions." Commenters asserted that "[n]ot including the social costs of carbon and other social costs hinders the Administrator from having all necessary information to set the PFOA and PFOS drinking water standard at a level that maximizes health risk reduction benefits at a cost that is justified, given those benefits." Commenters pointed to the greenhouse gas (GHG) emissions associated with production, reactivation, and delivery of treatment media, focusing on GAC in particular; construction associated with the installation of the treatment technology at EPTDS; electricity used to operate treatment technologies; and transportation and disposal of drinking

water treatment residuals to comply with the PFAS NPDWR. Two commenters provided their own quantified estimates for some aspects of CO_2 emissions. One commenter estimated that the climate disbenefits from CO_2 emissions associated with increased electricity use for additional pumping, lighting, and ventilation in treatment plants would be "$2.5M to $6.8M at 2.5 and 1.5 percent discount rates, respectively, in 2026; and $3.6M to $8.6M at 2.5 and 1.5 percent discount rates, respectively, in 2046." Another commenter used a life cycle analysis paper that provides one estimate for the carbon footprint of producing and using GAC and estimates that the climate damages from the CO_2 emissions associated with increased GAC media use "…could have a social cost of more than $160 million annually." One commenter stated that the EPA has performed this analysis in other rulemakings, specifically a 2023 proposed air rulemaking, and notes that in that regulatory impact analysis (RIA), "EPA included the social cost of carbon for the electricity required to operate the air pollution controls."

The EPA disagrees with commenters that SDWA requires the EPA to quantify and consider the climate disbenefits associated with GHG emission increases from this final rule in the HRRCA. The HRRCA requirements of SDWA 1412 (b)(3)(C) require the agency to analyze "quantifiable and nonquantifiable costs…that are likely to occur *solely* as a result of compliance with the maximum contaminant level" (emphasis added). Therefore, the EPA considered as part of its HRRCA analysis the compliance costs to facilities, including the costs to purchase electricity required to operate the treatment technologies. Since the climate disbenefits from GHG emissions associated with producing electricity necessary to operate the treatment technologies account for climate impacts associated with the CO2 emissions and associated costs to society, they do not qualify as compliance costs to PWSs that are part of the required HRRCA analysis under SDWA. For this reason, the EPA included compliance costs to PWSs but not climate disbenefits from GHG emissions associated with the production, reactivation, and delivery of treatment media; construction associated with the installation of the treatment technology at EPTDS; electricity used to operate treatment technologies; and transportation and disposal of drinking water treatment residuals in the cost consideration for the final PFAS NPDWR.

The EPA is committed to understanding and addressing climate change impacts in carrying out the agency's mission of protecting human health and the environment. While the EPA is not required by SDWA 1412(b)(3)(C) to consider climate disbenefits under the HRRCA the agency has estimated the potential climate disbenefits caused by increased on-site electricity demand associated with removing PFAS from drinking water. As explained in section V of the preamble for this action, the EPA's final rule is based on the EPA's record-based analysis of the statutory factors in SDWA 1412(b), and this disbenefits analysis is presented solely for the purpose of complying with EO 12866. Circular A-4 emphasizes that agencies "should monetize quantitative estimates whenever possible," including not only for anticipated direct effects of the rule but also for "any important ancillary benefits and countervailing risks." The scope of the monetized climate disbenefits analysis is limited to the climate impacts associated with the CO_2 emissions from increased electricity to operate the treatment technologies that will be installed to comply with the PFAS NPDWR.

The EPA did not quantify the potential CO_2 emissions changes associated with the production and delivery of treatment media, construction required for the installation of treatment technology, and transportation and disposal of treatment residuals. The EPA recognizes that many activities directly and indirectly associated with drinking water treatment produce GHG emissions; however, the agency determined that it could not accurately quantify all the potential factors that could increase and decrease greenhouse gas emissions that are not solely attributable to the direct onsite operations of the plant beyond increased electricity use at the plant. The EPA has information, to varying degrees, that the agency could use to potentially estimate emissions from some of these activities. To accurately understand the total potential climate disbenefits of this rule, the EPA should consider GHG emissions in the baseline scenario where the agency also takes no action. However, the EPA lacks the data needed to consider the potentially significant climate disbenefits and other costs to society of the EPA taking no action (i.e., not finalizing the PFAS NPDWR). If the EPA does not finalize the rule, this could likely trigger other activities that would increase GHG emissions. For example, significant climate disbenefits may be realized from the public increasing purchases of bottled water in an effort to avoid PFAS exposure from drinking water provided by PWSs. More members of the public switch to drinking bottled water if they do not trust the safety of their utility supplied drinking water (Grupper et al. 2021, Levêque and Burns, 2017). Bottled water has a substantially larger carbon footprint than the most highly treated tap water, including the significant energy necessary to produce plastic bottles and transport water from where it is bottled to the point of consumption (Gleick and Cooley, 2009). This carbon footprint can be hundreds of times greater than tap water on a per volume basis (e.g., see Botto, 2009). In addition, this is the first drinking water regulation in which the EPA has estimated disbenefits associated with increases or reductions in GHG emissions. The EPA expects that the approach for quantifying such benefits or disbenefits will continue to evolve as our understanding of the potential relationships between quality of drinking water treatment, impacts on consumer behavior, and other factors influencing GHG emissions improves. Considering the limitations described above and consistent with past EPA rulemakings,[14] the EPA is limiting the scope of the analysis to the major sources of emissions from the direct operation of treatment technologies. The EPA did not quantify the CO_2 emissions associated with production of treatment technologies, construction, transportation and disposal, as these activities are not solely attributable to the direct onsite operations of the plant and are beyond the scope of this analysis.

Furthermore, while some data exists to inform an estimate of the CO_2 emissions associated with production and reactivation of GAC, the EPA did not do so in this analysis due to significant uncertainties associated with the future CO_2 emissions associated with these technologies. The carbon footprint of GAC is likely to reduce over time, as research continues on novel applications for PFAS removal (e.g., advanced reduction/oxidation processes, novel sorbents,

[14] Recent examples include *New Source Performance Standards (NSPS) for the SOC Manufacturing Industry and National Emission Standards for Hazardous Air Pollutants (NESHAP) for the SOC Manufacturing Industry and Group I and Group II polymers and Resins Industry, NESHAP Gasoline Distribution NRPM, Supplemental Effluent Limitations Guidelines (ELGs)* and *Standards for the Steam Electric Power Generating Point Source Category.*

foam fractionation, sonolysis, among others), alternative sources of materials to produce GAC (e.g., biomass and other waste materials), and use of carbon capture technology expands in the future. Given these compounding uncertainties, the EPA did not quantify the climate disbenefits of GAC production and reactivation.

In this rule, the EPA determined that increased electricity use is the major source of emissions from the direct operation of treatment technologies to remove PFAS. In this analysis conducted pursuant to EO 12866, the EPA first quantified the CO_2 emissions from the additional electricity that is expected to be used for pumping, building lighting, heating, ventilation, and operation of other technology-specific equipment to remove PFAS. The EPA then monetized the climate disbenefits resulting from these CO_2 emissions by applying the social cost of carbon dioxide (SC-CO_2) estimates recommended by the commenter, as described below.

After considering public comments that recommended the EPA consider the climate disbenefits of the rule, the EPA conducted an analysis similar to the one recommended by one commenter. As suggested by the commenter, the EPA used the estimates of consumption of purchased electricity available from the EPA's peer reviewed WBS cost models to estimate the national electricity use associated with operation of PFAS removal treatment technologies. The EPA deviated from the commenter's suggested approach when estimating associated CO_2 emissions over time from producing electricity. The commenter estimates carbon emissions in a single year and presents that value as a constant reoccurring annual cost. Instead, the EPA estimated how CO_2 emissions would change through 2070, the calendar year to which the EPA has estimated CO_2 emissions from electricity production. The EPA applied readily available information from the latest reference case of the EPA's IPM to represent CO_2 emissions associated with electricity production over time.[15] Given that emissions from producing electricity are expected to significantly decrease over time, this is a logical application consistent with other agency rulemakings estimating future emissions from the power sector including the EPA's final *Good Neighbor Plan* (USEPA, 2023k) and the EPA's *New Source Performance Standards for GHG Emissions from New, Modified, and Reconstructed Electric Utility Generating Units* (USEPA, 2023l). Finally, the EPA monetized the climate disbenefits resulting from the estimated CO_2 emissions by applying the SC-CO_2 estimates presented in the regulatory impact analysis of the EPA's December 2023 Final Rulemaking, "Standards of Performance for New, Reconstructed, and Modified Sources and Emissions Guidelines for Existing Sources: Oil and Natural Gas Sector Climate Review" (USEPA 2023m). These are the same SC-CO_2 estimates the EPA presented in a sensitivity analysis in the RIA for the agency's December 2022 supplemental proposed Oil and Gas rulemaking that the commenter recommended for use in this action. The SC-CO_2 estimates incorporate recent research addressing recommendations of the National Academies of Science, Engineering, and Medicine (NASEM 2017), responses to public comments on the December 2022 supplemental proposed Oil and Gas rulemaking, and comments from a 2023 external peer review of the accompanying technical report. The methodology underlying the SC-CO_2 estimates is described in the agency's technical report,

[15] See https://www.epa.gov/power-sector-modeling

Report on the Social Cost of Greenhouse Gases: Estimates Incorporating Recent Scientific Advances, (USEPA, 2023n), and is included in the docket for this final rule. For additional details on the climate disbenefits analysis see Chapter 9.1 of the EA for the final PFAS NPDWR.

Individual Public Comments

The City of Columbus, Department of Public Utilities (Doc. #1703, SBC-052965)

Third, EPA's cost estimate fails to account for the increased costs associated with increased health risks from the GHG emissions that will result from these treatment processes. Reactivation, disposal, incineration, and trucking of granulated activated carbon media will all result in additional greenhouse gas emissions. This treatment process (and its resulting emissions) does not currently exist at most plants so there will be an increase in overall emissions industry-wide. EPA should balance the benefits of pushing the MCL down to the PQL with the costs—financial, human health, and environmental—that will come from the added greenhouse gas emissions created through treatment [FN3: Beyond the factors that are not yet reflected in EPA's cost estimate, NACWA's members participated in a survey that proved that EPA's estimates were significantly lower than real world data from utilities that have already implemented treatment. EPA's estimate for capital costs was 2.9 times lower on average than the reported value for 60 utilities.].

EPA Response: See section 13.11 of the EPA response in this *Response to Comments* document. With regard to balancing the benefits and costs of the rule, see section 13.8 of the EPA response in this *Response to Comments* document. In regard to the survey data and conclusions from AWWA and AMWA referenced by the commenter, see section 13.3.3 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046025)

Estimated Electricity Consumption

Electricity consumption increases with CWS size and is slightly higher for surface water compared to ground water in larger systems. Table 22 summarizes the estimated electricity consumption per EPTDS.

Table 22: GAC and IX Energy Consumption per EPTDS (MWhr/yr)

[Table 22 see docket ID EPA-HQ-OW-2022-0114-1738]

Multiplying the averages from Table 22 by the number of entry points that exceed one or more MCLs gives the total energy consumption across all system entry points. To further break this down by treatment method, the analysis assumes 50 percent use GAC and 50 percent use IX. The total estimated electricity consumption for both GAC and IX ranges from 710 MWhr/year for systems serving 100,001-1M people to 26,000 MWhr/year for very large systems serving >1M people.

Table 23: GAC and IX Energy Consumption for All Entry Points that Exceed MCLs (MWhr/year)

[Table 23 see docket ID EPA-HQ-OW-2022-0114-1738]

Using EPA's emissions rate estimate of 0.000433 metric tons (Mt) of CO2/kWh, the analysis calculates the annual carbon dioxide emissions produced from both treatment methods. As shown in Table 24, the proposed rule is estimated to induce an additional 19,000 Mt of CO2 emissions annually.

Table 24: Total Estimated Additional CO2 Emissions from GAC and IX as a Result of EPA's

Proposed Rule

[Table 24: see docket ID EPA-HQ-OW-2022-0114-1738]

Results

The discounted SC- CO2 annual figures from Table 17 are multiplied by the annual CO2 emissions from treatment methods. The resulting costs range from $2.5M to $6.8M at 2.5 and 1.5 percent discount rates, respectively, in 2026; and $3.6M to $8.6M at 2.5 and 1.5 percent discount rates, respectively, in 2046. EPA uses the lower discount rates shown in Table 25 to discount future damages from GHG emissions.

Table 25: Total Estimated Annual Emissions Cost from the Proposed Rule ($ M)

[Table 25: see docket ID EPA-HQ-OW-2022-0114-1738]

These estimates likely underestimate this social cost since, as with EPA's engineering estimates, they likely understate electricity consumption for necessary buildings and for treatment operations. These estimates also do not include the GHG impacts of mining and using activated carbon and the carbon dioxide emissions of activating the carbon for use. The regulatory action will also require non-electricity energy consumption such as heavy truck transport and disposal of media.

4. Results

As shown in Table 26, the sum of all the annual social costs amounts to approximately $7,500 M.

Table 26: Summary of Annual Estimated Costs

[Table 26: see docket ID EPA-HQ-OW-2022-0114-1738]

*EPA uses a lower discount rate for the social costs of GHG emissions. Therefore, the SC- CO2 is in different units of value than the other social costs.

EPA Response: See section 13.11 of the EPA response in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043080)

Social Costs of Carbon Dioxide

To comply with this rule, most water systems with PFAS exceeding the MCL(s) will need to install drinking water treatment facilities that rely on either GAC, IX, or RO. In many cases, it is likely that this will come with a new hydraulic profile for the water system and so additional pumping and electricity demand will be needed to maintain the current hydraulic pressure to the distribution system. Additionally, the use of GAC and IX requires a method of disposal via train or truck to a facility that is willing to accept the spent material. These activities can be anticipated to have a significant impact on the carbon footprint of drinking water systems nationally.

The EPA is currently heavily involved in addressing challenges with climate change and in advancing sectors towards reducing greenhouse gas emissions. The Proposal lacks an analysis of the social costs of carbon. Aqua recommends that the Agency consider the social costs as part of the cost analysis to be comprehensive as well as to understand how this rule may have unintended consequences like increased social costs relating to carbon dioxide emissions.

EPA Response: See section 13.11 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045919)

G. EPA fails to consider non-market social and other environmental costs

EPA should also estimate the social costs through economy-wide modeling of the lost productivity when higher water costs ripple through the economy and capital is diverted from other productive uses to build water treatment systems. We also note that there are potential costs to the environment by the use of GAC that are not accounted for by EPA. For example, a recent study from Maine found that PFAS mitigation using GAC may actually increase greenhouse gas emissions in the state: "greenhouse gas emissions for water treatment to bring PFAS down to the current interim standard are substantial, raising the footprint of an average user by 6.7–18 percent."[FN174: Benjamin McAlexander, "Estimated Greenhouse Gas Emissions from EPAS Treatment of Maine Drinking Water," Maine Policy Review, Vol. 31 at 41 (2022): https://digitalcommons.library.umaine.edu/mpr/vol31/iss1/4/.]. The report explains that GAC is sourced either directly from coal or generated by high-temperature treatment of biomass, and in some states (like Maine), there are no GAC manufacturers, so they must be transported by freight [FN175: Id. at 42.]. Also, the report discusses that GAC would be an "add-on" to many water treatment systems because it is not effective for typical drinking water contaminants like arsenic; thus, "[t]hese factors combined may mean substantial GHG emissions."[FN176: Id.]

EPA Response: See section 13.11 of the EPA response in this *Response to Comments* document. Additionally, see section 13.9 of the EPA response in this *Response to Comments*

document in response to comments recommending the EPA pursue economy wide modeling for this rulemaking.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-047697)

3. Non-Market Social Costs

Social Costs from Electricity/Energy Use of Treatment Systems

Complying with the proposed MCL will increase demand for electricity and other energy sources. Since some sources of electricity emit greenhouse gases (GHGs), increasing demand for electricity through this proposed regulatory action will incrementally increase total GHG emissions. EPA recently acknowledged this social cost of a proposed regulation in the Hazardous Organic NESHAP proposed rule and quantified the social costs [FN123: U.S. Environmental Protection Agency, "New Source Performance Standards for the Synthetic Organic Chemical Manufacturing Industry and National Emission Standards for Hazardous Air Pollutants for the Synthetic Organic Chemical Manufacturing Industry and Group I & II Polymers and Resins Industry," Proposed Rule (Federal Register, April 2023), 25197.]. This analysis applies a similar methodology to estimate the social costs from increased GHG emissions due to this proposed rule.

The social cost of carbon dioxide (SC-CO2) is defined as the discounted stream of damages caused by releasing one ton of CO2 today. EPA's models track the long-term damages from global warming to 2300. Since CO2 persists in the atmosphere, the value of avoiding a release today requires tracking the future damages caused by that ton over the next few centuries. Therefore, the SCC value for a given year is the discounted present value of the estimated stream of damages from today to 2300.

EPA's Report on the Social Cost of Greenhouse Gases, published as part of its regulatory impact analysis for Docket EPA-HQ-OAR-2021-0317, includes the cost of greenhouse gases by discount rate per year [FN124: U.S. Environmental Protection Agency, "Report on the Social Cost of Greenhouse Gases: Estimates Incorporating Recent Scientific Advances," September 2022, 120–21.]. Costs per metric ton range from $130 to $370 at 2.5 and 1.5 percent discount rates, respectively, in 2026; and $190 to $460 at 2.5 and 1.5 percent discount rates, respectively, in 2046 [FN125: The SC- CO2 is the discounted stream of damages caused by releasing one ton of CO2. EPA's models track the long-term damages to 2300. Since CO2 persists in the atmosphere, the value of avoiding a release today requires tracking the future damages caused by that ton over the next few centuries. Therefore, the SC- CO2 value for a given year is the discounted present value of that stream of damages from today to 2300.].

EPA's estimation process generates separate distributions of estimates based on different damage modules and near-term target discount rates of the social cost of each gas in each emissions year [FN126: U.S. Environmental Protection Agency, "Report on the Social Cost of Greenhouse Gases: Estimates Incorporating Recent Scientific Advances," 2.]. Table 16 gives EPA's values.

Table 17: SC-CO2 by Discount Rate and Emission Year ($/mt)

[Table 17: see docket ID EPA-HQ-OW-2022-0114-1738]

EPA Response: See section 13.11 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045616)

Social Costs of Carbon Dioxide

To comply with this rule, most water systems with PFAS exceeding the MCL(s) will need to install drinking water treatment facilities that rely on either GAC, IX, or RO. In many cases, it is likely that this will create a new hydraulic profile for the water system which requires additional facility pumping and consequently electricity demand. The use of GAC and IX also requires disposal of spent material involving transport of that material via train or truck to an appropriate facility. These activities can be reasonably anticipated to have a significant impact on the carbon footprint of water systems nationally.

EPA is currently heavily involved in addressing challenges with climate change and in advancing sectors of the U.S. economy towards reducing greenhouse gas emissions. Section 5 of President Biden's Executive Order 13990, notes that it is "essential that agencies capture the full costs of greenhouse gas emissions as accurately as possible, including by taking global damages into account" and that doing so "facilitates sound decision-making" (Biden, 2021).

The proposal lacks an analysis of the social costs of carbon. AWWA recommends that the agency consider the social costs of carbon as part of any PFAS rule's cost analysis to be comprehensive as well as to understand how this rule may have unintended consequences like increased social costs relating to carbon dioxide emissions.

In considering the social costs of carbon, the agency is encouraged to review a recent report by Policy Navigation Group (PNG, 2023). The current estimate for the social cost of carbon dioxide emissions varies, but a low estimate range is $130 to $190 per ton based on a recent EPA report (EPA, 2022h). In the Policy Navigation Report, they estimate the social costs of carbon using data from the EPA's current economic analysis and using available EPA guidance for estimating such costs. Policy Navigation Group estimates carbon emissions related to additional pumping, lighting, and ventilation associated with the PFAS proposed rule and concludes that the potential national social costs of the carbon emissions are $5 million annually. The $5 million would be in addition to the social costs associated with replacement of GAC and IX media as breakthrough occurs. Given that more than 4,300 water systems will rely on GAC and IX treatment for PFAS and will begin generating tens of thousands, if not hundreds of thousands of tons of spent GAC and IX resin it is important that the associated social costs are considered.

EPA estimated the total GAC and IX waste generation annually to perform a sensitivity analysis for managing these materials as hazardous wastes, but the estimated amount of waste generated is not reported. EPA estimated that water systems will need to install treatment for more than

64.8 million people to comply with the proposed rule; this will amount to more than 3 trillion gallons that will need to be treated annually. Calgon Carbon estimated one water treatment plant's GAC usage rate for PFAS treatment was as high as 0.07 pounds GAC per 1000 gallons (Calgon, 2023). Based on these figures, the annual demand for GAC could exceed 100,000 tons, which potentially has a carbon dioxide footprint of 850,000 tons (He, 2012). This could have a social cost of more than $160 million annually.

With such a significant potential impact on society, EPA should conduct the same analysis to determine the social costs of carbon associated with each of the treatment technologies and the rule options. This analysis should also be included as a matter of maintaining consistency across the agency's rulemaking processes. In two recent rulemaking, EPA estimated the social costs of the rule in recognition that changes to the operation of complex treatment systems can provide both benefits and unintended consequences (EPA, 2023f; EPA 2023g).

EPA Response: See section 13.11 of the EPA response in this *Response to Comments* document.

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USEPA. 2024c. *Economic Analysis for the Final Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation Appendices.* 815R24002.

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USEPA. 2024e. *Best Available Technologies and Small System Compliance Technologies Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water.* 815R24011.

USEPA. 2024f. *Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS).* 815R24003.

USEPA. 2024g. *Maximum Contaminant Level Goals (MCLGs) for Three Individual Per- and Polyfluoroalkyl Substances (PFAS) and a Mixture of Four PFAS.* 815R24004.

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14 Statutory and Executive Order Reviews

14.1 Executive Order 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review

The EPA received no public comments on Executive Order (EO) 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review.

14.2 Paperwork Reduction Act (PRA)

The EPA received no public comments on the Paperwork Reduction Act (PRA).

14.3 Regulatory Flexibility Act (RFA)

Summary of Major Public Comments and EPA Responses

Pursuant to sections 603 and 609(b) of the Regulatory Flexibility Act (RFA), the EPA prepared an initial regulatory flexibility analysis (IRFA) for the proposed rule and convened a Small Business Advocacy Review (SBAR) Panel to obtain advice and recommendations from small entity representatives (SERs) that potentially would be subject to the rule's requirements. For the final rule, as required by section 604 of the RFA, the EPA prepared a final regulatory flexibility analysis (FRFA) for this action. The FRFA addresses the issues raised by public comments on the IRFA for the proposed rule. See section XIII.C of the final rule preamble and Section 9.4 of the Economic Analysis (EA) for more information on the IRFA, FRFA, and the SBAR Panel process.

The EPA received comments from a few commenters where they suggest that the EPA did not follow the process as required by the RFA / Small Business Regulatory Enforcement Fairness Act (SBREFA) to conduct an SBAR Panel or that the process was incomplete. In addition, a couple of these commenters claimed that the SERs and Panel members did not have an opportunity to consider the specific requirements in the proposed regulatory action for PFNA, PFHxS, HFPO-DA, and PFBS. The commenters stated that they believed the EPA must convene a separate SBAR Panel to consider regulation of these four PFAS and use of the Hazard Index approach before finalizing any regulation. A couple commenters also alleged that the EPA only presented the SERs with information on regulating PFOA and PFOS and that the EPA stated it would only consider other PFAS supported by the best available science. Commenters also stated that the EPA did not provide the SERs with the Maximum Contaminant Levels (MCLs), Maximum Contaminant Level Goals (MCLGs), or the technical details and analyses during the SBAR panel.

The agency strongly disagrees with these commenters that the EPA violated the RFA or that the SBAR Panel process was not fully complete. First, the RFA requires the EPA to prepare an IRFA for each proposed rule unless the EPA certifies the rule will not have a significant economic impact on a substantial number of small entities. A regulatory flexibility analysis

examines the type and number of small entities potentially subject to the rule, recordkeeping and compliance requirements, and significant regulatory alternatives, among other things. The EPA completed this analysis (see section 9.3 of the proposed rule EA (USEPA, 2023a)). Second, this IRFA was informed by the SBAR Panel that the EPA convened and concluded prior to rule proposal to obtain information and advice from SERs.

In regard to commenters' assertion that the EPA failed to provide specific MCLGs, MCLs, or other highly specific or specialized scientific information developed for the rule proposal, the EPA is not required under the RFA to provide specific numerical regulatory standards, such as MCLs or MCLGs, to small entities during the SBAR Panel process. As a part of the development of the National Primary Drinking Water Regulation (NPDWR), the EPA sought the input of the SERs via the SBAR panel process to inform the proposed rule and its proposed regulatory requirements, specifically seeking ways to minimize the regulatory burden on small entities. The proposed regulatory requirements had not been determined at that time because the EPA specifically wanted to seek the input from the SBAR panel and from other mandated consultations prior to proposing any economically significant regulation. The EPA therefore appropriately waited to determine many of the specific requirements such as the MCLs until after seeking the SERs' and SBAR panel's input on such specific numerical regulatory standard values. The SERS have an opportunity to comment on specific regulatory standard values during the public comment. Additionally, as described in the SBAR Panel materials, including the Panel report, available in the public docket (https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0048), the agency provided the SERs with a large amount of technical information, including information on the analytical measurement feasibility for the PFAS that the EPA is finalizing regulation, as well as the removal efficiencies of the available technologies and the ability for these PFAS to treat to or below the analytically feasible limits. The EPA also provided the system level estimated costs for treatment and monitoring, all of which are identical to the proposed and final rule treatment technologies and analytical methods for monitoring. The EPA further presented to SERs that, under the Safe Drinking Water Act (SDWA), the EPA must set the regulatory standard as close as feasible to the MCLG. Therefore, the EPA provided the SERs all of the information that the agency used in its evaluation of MCL feasibility as required by SDWA, and strongly disagrees that knowledge of the exact proposed regulatory standard values was necessary for the SERs to provide input on the EPA's feasibility determination. Furthermore, if the agency waited to consult with the SBAR panel until after it had made its MCL feasibility determination and developed other specific requirements of the regulation (e.g., monitoring requirements), the EPA would not have considered SER input prior to rule proposal.

As documented in the SBAR Panel materials, the EPA provided the SERs and Panel with a substantial quality and quantity of information and all of the information required under the RFA, including the number and type of entities potentially impacted; treatment technologies; analytical measurement information; potential compliance requirements and considerations that might be utilized directly relevant scope of the rule; small system level cost information; identification of all relevant federal rules which may duplicate, overlap, or conflict with the proposed rule; and, alternatives to reduce burden for small entities. The EPA notes that the Panel,

which consisted of representatives of the Small Business Administration Office of Advocacy, OMB, and the EPA, collectively developed the Panel's recommendations and concluded the Panel. Additionally, the EPA notes that though it is not required to adopt all of the Panels' recommendations, the EPA did consider all of the Panel recommendations and included nearly all of them as a part of the proposed or final rule including several flexibilities in monitoring requirements for small systems, such as the use of existing monitoring data to satisfy initial monitoring requirements and reduced initial monitoring requirements specifically for small groundwater systems (see section VIII of the final rule preamble), along with a nationwide two-year capital improvement MCL compliance extension (see section XII of the final rule preamble).

Finally, as noted by a commenter, and as provided in the SBAR Panel Report, the agency did provide to the SERs that it may include additional PFAS as supported by the best available science including if they were to be removed by the same technologies identified to SERs during the Panel process. Further, as demonstrated in Final Panel Report and Appendices, the EPA also presented multiple times to the SERs and other Panel members that the agency's final regulatory determinations for PFOA and PFOS outlined avenues that the agency is considering to further evaluate additional PFAS chemicals, other than PFOA and PFOS, and consider groups of PFAS as supported by use of the best available science for regulatory action in the development of the NPDWR. In this evaluation of other PFAS, in addition to noting for the SERs that the EPA would consider similar treatment technologies, the EPA also provided several other factors it would consider including the likelihood that the PFAS co-occur, the similarity of health effects and chemical structures, the environmental persistence characteristics, and the availability of accepted and approved analytical methods or indicators with comparable costs to those currently identified by the EPA to evaluate PFAS removal from drinking water, among other considerations. Further, it was specifically noted to the SERs that "EPA is evaluating regulating PFAS that are all able to be removed by the previously identified treatment technologies which also remove PFOA and PFOS. If a given PFAS or subclass of PFAS were to require a separate or different treatment technology compared to what is being considered for the removal of PFOA and PFOS, the EPA anticipates that the agency would evaluate those PFAS under a future regulatory action and would convene a separate SBAR Panel if it expects that such action would have a significant impact on a substantial number of small entities." The EPA did not identify any such PFAS. Moreover, the EPA provided to the SERs and Panel members background information related to health effects and drinking water occurrence on all six PFAS that the EPA is finalizing in this regulation, as well as SDWA regulatory development information related to the possible NPDWR regulatory standard constructs of MCLs (of which the Hazard Index is a proposed MCL standard) or Treatment Techniques. Based on all of these factors, the EPA strongly disagrees that the process was incomplete or that the requirements under the RFA were not satisfied.

Individual Public Comments

Raptor Pharm & Tox, Ltd (Doc. #1644, SBC-043426)

The US EPA also failed to properly conduct consultation with the small business community. The US EPA did not consider all impacted small businesses. The US EPA admits to only consulting with small business PWS's. That is improper, and US EPA must do a better job of identifying impacted small businesses as also including rate payers.

We thank the US EPA for the opportunity to comment.

EPA Response: The EPA disagrees that it failed to properly conduct consultation with small entities and refers the commenter to section 14.3 of the EPA response in this *Response to Comments* document. Additionally, as stated in section XIII.C of the final rule preamble, "For purposes of assessing the impacts of the final rule on small entities, the EPA considered small entities to be water systems serving 10,000 people or fewer. This is the threshold specified by Congress in the 1996 Amendments to SDWA for small water system flexibility provisions. As required by the RFA, the EPA proposed using this alternative definition in the FR (USEPA, 1998a), sought public comment, consulted with the Small Business Administration (SBA), and finalized the small water system threshold in the agency's Consumer Confidence Report (CCR) Regulation (USEPA, 1998b). As stated in the document, the alternative definition would apply to all future drinking water regulations."

Raptor Pharm & Tox, Ltd (Doc. #1644, SBC-043422)

In addition, EPA failed to consider the impacts of these regulations on small business entities. Yes, EPA consulted with operators of small PWS's. However, EPA did not consult with small businesses such as mine, or the millions of others, across the US, who will be significantly impacted by these costs. EPA needs to expand its outreach beyond just PWS's, because all small businesses are impacted by this rule. Thus, Raptor concludes that EPA did not fulfill its requirements with respect to consulting with impacted small businesses as it only considered a regulated entity as impacted by this regulation, when in fact, all rate payers, including small business rate payers, are actually impacted by this proposed regulatory action.

And, EPA needs to consider the impacts on the poor that are currently operating small businesses, or the poor who would have started small businesses but for the cost impacts of this proposal. When entrepreneurs cannot afford their family expenses, they clearly cannot afford to start new businesses. These impacts also need to be considered.

EPA Response: Please see the EPA response to comment Doc. #1644, SBC-043426 in section 14.3 in this *Response to Comments* document. As a part of the EPA's EA for NPDWRs, and as required under the SDWA, the agency evaluates costs to regulated entities (i.e., public water systems [PWSs]) and drinking water primacy agencies implementing NPDWRs. Additionally, as part of the development of the proposed and final rule, the agency held multiple

public outreach opportunities to seek the public's input on the NPDWR (see EPA's PFAS NPDWR website - https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas - for more details).

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045925)

VII. The SBREFA Panel for This Rulemaking Did Not Have the Opportunity To Consider the Proposed Regulatory Action on PFNA, PFHxS, PFBS, and HFPO-DA

For purposes of considering impacts of the proposed rule on small entities, EPA completed an initial regulatory flexibility analysis on the proposed rule and convened a Small Business Regulatory Enforcement Fairness Act (SBREFA) panel under the Regulatory Flexibility Act (RFA) in May of 2022. While a SBREFA panel was convened for the PFOA and PFOS MCL, the panel was not presented with, nor did it specifically discuss, setting an MCL for PFNA, PFHxS, PFBS, or HFPO-DA. Rather, EPA indicated to the panel that it is developing a proposed MCL for PFOA and PFOS and "potentially other PFAS" and is "considering" groups or classes of PFAS [FN210: Final Report of the SBAR Panel on EPA Planned Proposed Rule Per and Polyfluoroalkyl Substances NPDWR at 7 (August 1, 2022): https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0048.]. The SBREFA panel also did not consider the Hazard Index approach for the four PFAS.

This lack of small entity input on a critical aspect of this proposed rule violates the RFA because EPA's proposed MCLs and MCLs for PFNA, PFHxS, PFBS, or HFPO-DA will have a significant impact on a substantial number of small entities. EPA acknowledges in the proposed rule that approximately 62,000 small public water systems could be impacted by the rule, which is a substantial number of small entities [FN211: 88 Fed. Reg. at 18732.]. The costs of complying with the rule (including monitoring and treatment) described in Section VI will be even more burdensome for small entities. Small entities will also have problems with the insufficient compliance timeline that does not provide for time needed to meet the practical requirements to deploy treatment technologies. EPA must convene a separate SBREFA panel to consider regulation of the four PFAS and use of the Hazard Index approach before it finalizes any regulation pertaining to these PFAS. It is critical, and required by the RFA, that EPA consider small business impacts of regulating these specific PFAS and the use of its novel Hazard Index approach.

EPA Response: The EPA disagrees that the SBAR Panel did not have an opportunity to consider the regulatory action or that the EPA must undertake a separate SBAR Panel. Please see section 14.3 of the EPA response in this *Response to Comments* document. Additionally, please see section 12.1 of the EPA response in this *Response to Comments* document regarding the MCL compliance timeline.

PFAS Regulatory Coalition (Doc. #1761, SBC-046090)

G. EPA's SBREFA panel review was incomplete.

The Regulatory Flexibility Act Section 609(b) requires EPA to conduct small business advocacy review panels when it is unable to certify that a rule will not have a significant economic impact on a substantial number of small businesses. The Small Business Regulatory Enforcement Fairness Act (SBREFA) mandates that these panels consist of representatives of the rulemaking agency, the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA), and the Small Business Administration's (SBA's) Chief Counsel for Advocacy. As explained by the SBA:

The panel solicits information and advice from small entity representatives (SERs), who are individuals that represent small entities affected by the proposal. SERs help the panel better understand the ramifications of the proposed rule. Invariably, the participation of SERs provides extremely valuable information on the real-world impacts and compliance costs of agency proposals. A Guide For Government Agencies: How to Comply with the Regulatory Flexibility Act (at 51)(2017).

In this case, EPA convened a SBREFA panel. But the panel's recommendations are only as useful and relevant as the information provided to the panel by EPA. In this case, EPA only presented to the SERs the proposal to regulate PFOS and PFOA and stated that it might consider other PFAS chemicals or even groups of PFAS as supported by use of the best available science. EPA never presented the SERs with the concept of the HI approach or how it might be implemented. Hence, the SBREFA panel had no input from the SERs on the HI approach, which ultimately became a critical aspect of the EPA Proposal. EPA should have reconvened the SBREFA Panel once it determined that it would include an HI approach in that Proposal.

In addition, the Panel recommended that EPA conduct and present costs of both non-hazardous and hazardous waste generation as a result of likely treatment mandates associated with the Proposal. The Panel's recommendation is entirely logical. EPA has already indicated an intention to address PFOA and PFOS (along with other PFAS substances) as hazardous constituents under RCRA. Moreover, EPA not only has proposed designating PFOS and PFOA as hazardous substances under CERCLA, but also plans to propose to add PFOA, PFOS, PFBS, and GenX as RCRA hazardous constituents.

Given these ongoing and planned regulatory actions, it is very likely that solid waste disposal facilities will refuse to accept waste that contains these PFAS, greatly increasing disposal costs of treatment residuals and other contaminated media. EPA's Regulatory Impact Analysis must recognize these impacts. Instead, EPA claims it need not address these costs by claiming that such wastes "are not currently" regulated as hazardous wastes. 88 Fed. Reg. 18701. It agreed to a preliminary sensitivity analysis "for illustrative purposes only," which is not a good faith effort to truly provide accurate impacts on costs likely associated with the EPA Proposal.

Finally, the Panel recommended that EPA provide for compliance extensions in recognition of likely laboratory capacity-related challenges. EPA responded that it or a state may grant up to a 2-year extension, but that it was not planning on granting any nationwide extensions, leaving small systems to seek state extensions. EPA should reserve its judgment on nationwide

extensions to see if, in fact, existing laboratory capacity is sufficient. Current experience with significant laboratory delays, coupled with a likely significant spike in demands over the next several years, makes it clear that EPA's pronouncement is premature.

EPA Response: The EPA disagrees that the SBAR Panel was incomplete or that the EPA must undertake a separate SBAR Panel. The commenter is also incorrect that the EPA did not present the SERs with information on other PFAS (including PFHxS, PFNA, HFPO-DA and PFBS) beyond PFOA or PFOS. Please see section 14.3 of the EPA response in this *Response to Comments* document regarding the RFA requirements and SBAR Panel process.

Regarding the costs of both non-hazardous and hazardous waste disposal, the EPA disagrees with the commenter's claim that the agency did not make a "good faith" effort in following the Panel's recommendation because the EPA presents these costs in both the proposed and final rule (see Appendix N of the Economic Analysis; USEPA, 2023b). Further, the EPA notes that neither a Comprehensive Environmental Response Compensation and Liability Act (CERCLA) hazardous substance designation, nor a Resource Conservation and Recovery Act (RCRA) hazardous constituent listing, is a RCRA hazardous waste listing. A CERCLA designation does not restrict, change, or recommend any specific activity or type of waste. The agency refers the commenter to section 10.4.2 of the EPA response in this *Response to Comments* document for additional information.

Finally, please see section 12.1 of the EPA response in this *Response to Comments* document pertaining to MCL compliance timeline and extension.

Office of Advocacy at the U.S. Small Business Administration (Doc. #1807, SBC-045478)

I. Background

A. The Office of Advocacy

Congress established the Office of Advocacy under Pub. L. 94-305 to represent the views of small entities before Federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA). As such, the views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration. The Regulatory Flexibility Act (RFA) [FN3: 5 U.S.C. §601 et seq.], as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) [FN4: Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. §601 et seq.).], gives small entities a voice in the rulemaking process. For all rules that are expected to have a significant economic impact on a substantial number of small entities, the RFA requires federal agencies to assess the impact of the proposed rule on small entities and to consider less burdensome alternatives.

The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy [FN5: Small Business Jobs Act of 2010 (PL. 111-240) §1601.]. The agency must include a response to these written comments in any explanation or

discussion accompanying the final rule's publication in the Federal Register, unless the agency certifies that the public interest is not served by doing so [FN6:Id.].

Advocacy's comments are consistent with Congressional intent underlying the RFA, that

"[w]hen adopting regulations to protect the health, safety, and economic welfare of the nation, federal agencies should seek to achieve statutory goals as effectively and efficiently as possible without imposing unnecessary burdens on the public."[FN7:Id.]

B. The Proposed Rule

On March 29, 2023, EPA published its proposed National Primary Drinking Water Regulation (NPDWR) rulemaking, which includes the following per- and polyfluoroalkyl substances (PFAS):

• Perfluorooctanoic acid (PFOA),

• Perfluorooctane sulfonic acid (PFOS)

• Perfluorohexane sulfonic acid (PFHxS)

• Hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salt (also known as a GenX chemicals)

• Perfluorononanoic acid (PFNA)

• Perfluorobutane sulfonic acid (PFBS)

The proposed rule requires public water systems to monitor for these PFAS, notify the public of the levels of these PFAS, and reduce the levels of these PFAS in drinking water if they exceed the proposed standards. Reduction methods can include the installation of treatment technologies and disposal of PFAS residue from those treatment technologies such as granular activated carbon, anion exchange, nanofiltration and reverse osmosis or require switching to an alternative water source. The proposed rule would require compliance three years after promulgation.

The proposal contains several agency actions:

1. Proposed legally enforceable levels, called Maximum Contaminant Levels (MCLs), for PFOA and PFOS at 4 parts per trillion (ppt).

2. Proposed preliminary determination to regulate PFHxS, GenX chemicals, PFNA and PFBS, and mixtures of these PFAS.

3. Proposed MCLs for the above four PFAS at a unitless MCL of 1.0, based on a novel approach called a hazard index (HI), which is used to evaluate potential health risks from exposure to chemical mixtures.

4. Proposed health-based, non-enforceable Maximum Contaminant Level Goals (MCLGs) for these six PFAS. For PFOA and PFOS, the proposed MCLG is zero and for the PFAS mixture the agency proposes the same unitless 1.0 hazard index.

In advance of the proposed rule, EPA convened a small business advocacy review panel under SBREFA to consult with small entity representatives (SERs). EPA presented to the small entities some PFAS background, with only PFOA and PFOS specifically identified, and potential monitoring and reporting rule compliance considerations and treatment and feasibility considerations. EPA, however, did not provide the SERs with the identity of the other four PFAS, any MCL values, any MCLG values and the technical details and analyses supporting these additional elements.

EPA Response: The commenter is incorrect that that the SERs and SBAR Panel were not presented with information on other PFAS (including PFHxS, PFNA, HFPO-DA and PFBS) beyond PFOA or PFOS. The commenter is also incorrect that the EPA did not present technical details and analyses that support MCL values. Please see section 14.3 of the EPA response in this *Response to Comments* document regarding the RFA requirements and SBAR Panel process. The EPA notes that MCLGs are set as the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, allowing an adequate margin of safety. The EPA notified the panel and SERs to the availability of the draft health documents under review by the EPA's Science Advisory Board that would be used to inform the MCLGs for PFOA and PFOS. The agency further notes that the toxicity assessments used to inform the health-based requirements for the four other PFAS were publicly available as well during the SBAR Panel process and during the rule proposal public comment period.

14.4 Unfunded Mandates Reform Act (UMRA)

The EPA received no public comments on the Unfunded Mandates Reform Act (UMRA).

14.5 Executive Order 13132: Federalism

Individual Public Comments

PFAS Regulatory Coalition (Doc. #1761, SBC-046091)

H. The Proposal fails to adequately explain consultation with local governments.

The Proposal contains a "federalism summary impact statement," and says a "summary report of the views expressed during federalism consultations is available in the Docket." 88 Fed. Reg. 18733-734. Yet, no specific document reference is provided. There is some discussion on this topic in the "Final Report of the Small Business Advocacy Review Panel on EPA's Planned Proposed Rule Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation." Dkt. No. EPA-HQ-OW-2022-0114-0048.

If EPA means to state that local government consultation was conducted within the SBREFA process, then this consultation fails to comply with SBREFA for the reason stated in Section G above – that EPA failed to present the key information included in the Proposal. Additionally, this consultation would have been limited to small entities, and did not extend to other local government entities. It also appears, from the EPA Proposal, that the Agency had one virtual meeting with a large group of organizations representing state and local governments, over a year ago, and then let those organizations submit written comments. If that is the full extent of consultation with local governments that EPA has conducted, then it has not complied with its legal obligations regarding federalism concerns.

EPA Response: The EPA disagrees that the proposal fails to adequately explain consultation with local governments. The EPA specifically consulted with state and local governments as a part of the Federalism consultation required under E.O. 13132 which is described in detail in section XIII.E. of the final rule preamble. Within this section, the EPA details the input received and how the agency evaluated and considered it as a part of the final rule development. Additionally, the commenter incorrectly states that the Federalism consultation summary report, which includes all input from those specifically consulted under E.O. 13132, including local governments, is not available in the public docket as it was provided for public review and comment upon the proposed rule publishing (see https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0706). The EPA further disagrees that the information provided to those consulted does not meet the EPA's legal obligations regarding federalism concerns as the EPA did present key information included in the proposal, such as PFAS drinking water health, occurrence, treatment, and cost information, as well as potential monitoring and Public Notification (PN) requirements.

14.6 Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

Individual Public Comments

Oneida Nation (Doc. #1825, SBC-044273)

Tribal Consultation

The Oneida Nation has concerns about the lack of tribal consultation. The Federal Register notice for the proposed rulemaking, as originally published on June 27, 2021, determined that the rule would not have direct effect on tribal governments so held that tribal consultation was unnecessary. Tribal communities and natural resources that tribes, villages, and rancherias rely upon for subsistence and cultural practices are impacted by PFAS therefore consultation is absolutely necessary. The Oneida Nation requests that consultation be offered to tribes on proposed PFAS related rulemakings.

EPA Response: The EPA disagrees that the agency did not conduct the required Tribal consultation under E.O. 13175 as detailed in section XIII.F of the final rule preamble. This

section discusses the Tribal consultation that was held prior to rule proposal between February 7, 2022 through April 16, 2022. Additionally, the agency is unclear on what the commenter refers to as a Federal Register Notice (FRN) for the proposed rulemaking published on June 27, 2021, as this is not the date of the proposed rulemaking for the PFAS NPDWR which was published on March 29, 2023. To the extent that the commenter is referring to the EPA's proposed rule issued on March 29, 2023, the commenter is incorrect in stating that the EPA determined there would be no direct effect on Tribal governments. In fact, the agency did find that the proposed PFAS NPDWR would have Tribal implications and impose direct compliance costs on Tribal governments, which the federal government will not provide funds necessary to pay. In the EPA's development of the proposed and final rule, the EPA has presented information on these impacts (see section XIII.F of the final rule preamble).

14.7 Executive Order 13045: Protection of Children from Environmental Health and Safety Risks

Individual Public Comments

First Focus on Children (Doc. #1599, SBC-042334)

PFAS, otherwise known as "forever chemicals," pose serious risks to human health, but even more so to children's health. PFAS are man-made chemicals that are used in products that repel grease, water, and oil like water-resistant clothing or non-stick cookware. During and after production these chemicals leach into the air, water, and soil. Their strong chemical bonds mean that they don't break down in the environment or in the human body, meaning that PFAS levels in our blood will continue to increase over time with exposure.

The potential health complications from PFAS exposure are more severe for children, who consume more water in relation to their body mass in comparison to adults. Exposure at a young age also means that the chemicals will remain in their systems for the entirety of their lives. The CDC links increased PFAS exposure with changes in cholesterol, liver damage, and an increased risk of certain cancers. [FN1: "What are the health effects of PFAS?" Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention. November 1, 2022. https://www.atsdr.cdc.gov/pfas/health-effects/index.html.] Studies also show a clear link to a number of children's health issues.

Endocrine System Disruptions

PFAS are endocrine disruptors, meaning that they impact the body's hormonal regulation systems and may alter their function. Studies show that they may impair the production of developmental hormones like progesterone and testosterone, which are crucial for healthy development. [FN2: Rickard, Brittany P., Rizvi, Imran, and Fenton, Suzanne E. "Per- and poly-fluoroalkyl substances (PFAS) and female reproductive outcomes: PFAS elimination, endocrine-mediated effects, and disease." Toxicology, Vol. 465. January 15, 2022. https://www.sciencedirect.com/science/article/pii/S0300483X2100353X.] Children, who are

rapidly developing before, during, and after puberty, rely on appropriate hormonal balances to reach critical milestones in their development. Studies suggest that PFAS may impact thyroid function, which is linked to irregular menstruation and infertility in girls. [FN3: Ibid.] For both boys and girls, exposures to PFAS are shown to alter pubertal timing. [FN4: Ibid.]

Immune System Disruptions

PFAS may also inhibit immune system development, which is crucial during childhood. During the first years of life children develop their adaptive immune system and create antibodies that repeatedly recognize and attack foreign cells. This adaptive system is crucial for fighting infections and is the key to successful protection from disease via immunizations. However, exposure to PFAS is linked with immunosuppression in childhood. Research shows that PFAS suppress the immune system's response to vaccinations, leading to a decreased presence in antibodies in children with greater PFAS exposure. [FN5: von Holst, Haley, et al. "Perfluoroalkyl substances exposure and immunity, allergic response, infection, and asthma in children: review of epidemiologic studies." Heliyon, Vol. 7(10). October 12, 2021. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8529509/.] Additionally, with antibodies diminished, new evidence suggests that exposure to PFAS, specifically FOS, may lead to an increased risk of infectious disease during childhood. [FN6: Ibid.]

As with many instances of water contamination, not all communities bear this burden equally. Children in low-income communities and communities of color are far more likely to be exposed to PFAS due to the greater presence of industrial manufacturing plants and lack of access to adequate healthcare. [FN7: National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Division on Earth and Life Studies; Board on Population Health and Public Health Practice; Board on Environmental Studies and Toxicology; Committee on the Guidance on PFAS Testing and Health Outcomes. "Guidance on PFAS exposure, testing, and clinical follow up." National Academies Press (US). July 28, 2022. https://www.ncbi.nlm.nih.gov/books/NBK584707/.] By regulating PFAS, EPA eases the already taxing environmental toll that children in these communities face and makes strides to advance equity across the country.

Conclusion

Thank you for the opportunity to submit comments to this proposed rule. We are grateful that EPA is taking responsible steps to manage PFAS contamination and provide safe, clean drinking water for all. Please reach out to Abbie Malloy, Director, Health, Environmental, and Nutrition Policy, at abbiem@firstfocus.org with any questions.

Sincerely,

Bruce Lesley

President, First Focus on Children

EPA Response: The EPA acknowledges the information provided by the commenter and their support of the proposed regulation. In the development of the MCLGs for the regulated PFAS, the agency considered sensitive lifestages such as children, and determined the MCLGs considering these populations. Please see section 4.3.3 of the EPA response in this *Response to Comments* document and section 4 of the final rule preamble. The EPA agrees with the commenter that by regulating these six PFAS, the NPDWR will lower children's exposure to these and other PFAS in drinking water.

14.8 Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use

Individual Public Comments

Florida Section American Water Works Association - Water Utility Council (FSAWWA WUC) (Doc. #1737, SBC-044493)

XV. Statutory and Executive Order Reviews, H. Executive Order 13211 : Actions That Significantly Affect Energy Supply, Distribution, or Use;

The Florid a Water Sector requests EPA reconsider its findings the proposed rule is not a "significant energy action" under Executive Order 13211. Either of the three treatment options provided by EPA will substantially raise energy use and costs at facilities with traditional treatment techniques. In a large state like Florida, the numerous facilities expected to need treatment changes will act as "sum of parts" increasing energy use significantly across the state. EPA should determine the energy consumption of the three recommended techniques and apply that to new national occurrence data for an improved national perspective. In addition, USEPA should calculate the increased greenhouse emissions from this energy use data using their calculator in order to understand the carbon footprint impact (please see https://www.epa.gov/energy/greenhouse-gas-equivalencies-calculator)

EPA Response: The EPA disagrees with the commenter that the drinking water treatment technologies identified under the final rule to address regulated PFAS will substantially raise energy use and costs at facilities with traditional treatment systems because, as discussed in section XIII.H of the final rule preamble, electricity consumed as a result of the final rule represents approximately 0.005 percent of total U.S. electricity consumption. Therefore, based on this finding, the EPA does not anticipate that this rule will have significant adverse effects on the supply, distribution, or use of energy as required to be evaluated under E.O. 13211. Regarding greenhouse gas emissions, based on this and other comments, for the final rule the EPA conducted an additional analysis of the disbenefits associated with operation of treatment technologies to comply with the standard. This analysis is summarized in section XIII.A.2 of the final rule preamble and in the EA for the final PFAS NPDWR (USEPA, 2024a). Please see section 13.11 of the EPA response in this *Response to Comments* document for further discussion.

14.9 National Technology Transfer and Advancement Act of 1995

The EPA received no public comments on the National Technology Transfer and Advancement Act of 1995.

14.10 Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing our Nation's Commitment to Environmental Justice for All

Summary of Major Public Comments and EPA Responses

Many commenters expressed support for the rule and the EPA's environmental justice (EJ) analysis, underscoring the rule's alignment with the administration's commitment to advancing EJ. Commenters point to evidence which suggests that PFAS exposure disproportionately affects communities with EJ concerns. Further, commenters state that these communities are particularly vulnerable to PFAS exposure and the associated health outcomes. Several commenters also assert that the rule is anticipated to benefit these communities with EJ concerns who are at a higher risk of PFAS exposure. Conversely, many commenters expressed concern about potential EJ implications of the final rule and urged the EPA to further consider these implications prior to final rule promulgation. Specifically, commenters presented concerns that the rule will disproportionately impact communities that already are overburdened with sociodemographic and environmental stressors. Additionally, several commenters voiced EJ concerns associated with implementation of the rule. Many commenters asserted that communities with EJ concerns may not have sufficient financial capacity to implement the rule (e.g., install treatment) and that this may further exacerbate existing disparities associated with PFAS exposure. Additionally, commenters stated that additional resources would likely be needed for communities with EJ concerns to successfully implement the rule, including targeted monitoring and sampling in these areas.

The EPA acknowledges commenters' support for this action and the agency's commitment to advancing EJ. Through this rule, the EPA reaffirms the importance of EJ considerations in agency activities, including rulemaking. The EPA acknowledges commenters' concerns regarding potential EJ implications of the rule. Under EO 14096, the EPA is directed to identify, analyze, and address disproportionate and adverse human health or environmental effects of agency actions on communities with EJ concerns. As such, the EPA believes that its EJ analysis accompanying the final rule has achieved this directive, because the EPA has assessed the demographic distribution of baseline PFAS exposure in drinking water as well as the anticipated distribution of benefits and costs that will result from the rule.

The EPA agrees with commenters that PFAS exposure may disproportionately affect communities with EJ concerns as the EPA's EJ analysis for the final rule demonstrates that some communities of color are anticipated to experience elevated baseline PFAS drinking water exposures compared to the entire sample population. Specifically, the percentage of non-Hispanic Black and Hispanic populations with PFAS in drinking water detected above baseline

thresholds is greater than the percentage of the total population served with PFAS exposure above these thresholds for all PFAS analytes examined in the EPA's analysis. The EPA believes that this action is likely to reduce existing disproportionate and adverse effects on people of color, low-income populations and/or Indigenous peoples. Across all hypothetical regulatory thresholds, elevated exposure—and thus reductions in exposure under the hypothetical regulatory scenarios—is anticipated to occur in communities of color and/or low-income populations. Additionally, the EPA's EJ analysis finds that across all health endpoints evaluated by the EPA, communities of color (i.e., Hispanic, non-Hispanic Black, and/or Other race/ethnicity groups) are anticipated to experience the greatest reductions in adverse health effects associated with PFAS exposure, resulting in the greatest quantified benefits associated with the final rule. As such, the EPA agrees with commenters that the rule is anticipated to benefit communities with EJ concerns. When examining costs anticipated to result from the final rule, the EPA finds that cost differences across both race/ethnicity and income groups are typically small, with no clear unidirectional trend in cost differences based on demographic group. Additionally, incremental household costs to all race/ethnicity and income groups generally decrease as system size increases, which is expected due to economies of scale. This is especially true if systems serving these communities are required to install treatment to comply with the final rule. To alleviate potential cost disparities identified by EPA's analysis, there may be an opportunity for many communities to utilize Bipartisan Infrastructure Law (BIL) (P.L. 117-58) funding to provide financial assistance for addressing emerging contaminants. BIL funding has specific allocations for both disadvantaged and/or small communities and emerging contaminants, including PFAS. For responses to comments regarding funding available through BIL, please see section 2.4 of the EPA response in this *Response to Comments* document.

The EPA acknowledges the potential for implementation challenges for communities with EJ concerns; however, in response to commenters' concerns that communities with EJ concerns may not have sufficient financial capacity to implement the rule, there may be opportunities for many communities to utilize external funding streams to address such challenges. The BIL, the Low-Income Water Household Assistance Program through the American Rescue Plan, and other funding sources may be able to provide financial assistance for addressing emerging contaminants. In particular, the BIL funding has specific allocations for disadvantaged and/or small communities to address emerging contaminants, including PFAS. For example, the Emerging Contaminants in Small or Disadvantaged Communities (EC-SDC) grants program, which does not have a cost-sharing requirement, will provide states and territories with $5 billion to provide grants to PWSs in small or disadvantaged communities to address emerging contaminants, including PFAS. Grants will be awarded non-competitively to states and territories.

Many commenters stated that the costs of the rule will disproportionately fall on communities with EJ concerns. Additionally, some commenters asserted that the EPA's EJ analysis does not appropriately consider the distributional impacts of rule costs, with one commenter incorrectly stating that the analysis "fails to consider how these increased compliance costs will impact EJ communities, as required by Executive Order 12898". Commenters recommended that the EPA

revise its analysis to reflect the impact that compliance costs of the rule will have on communities with potential EJ concerns.

The EPA disagrees with commenters that the EPA has failed to appropriately consider the impact that costs required to implement the rule may have on communities with potential EJ concerns. The agency has fulfilled its commitments in this rulemaking by conducting an analysis consistent with Executive Order 14096 and has shared information on the demographic distribution of impacts evaluated in its EJ analysis to facilitate the public's understanding on potential EJ impacts of the rule. As described above, the EPA's EJ analysis assesses the demographic distribution of both benefits and costs anticipated to result from the final rule. The EPA also disagrees that the costs of this action will disproportionately fall on communities with EJ concerns. In Section 8.4.2.2 of its EJ Analysis (found in Chapter 8 of the EA (USEPA, 2024a)), the EPA estimated the distribution of annualized incremental household costs across different race/ethnicity groups. As described in section XIII.J of the preamble for this action and as stated above in this summary, the EPA found that cost differences across race/ethnicity groups are typically small, with no clear unidirectional trend in cost differences based on demographic group. In some cases, the EPA found that communities of color are anticipated to bear minimally increased costs but in other cases, costs to communities of color are lower than those across all demographic groups. In response to commenters, in order to more comprehensively examine the impact of the distribution of costs of this action, the EPA has updated its analysis to also examine the distribution of benefits and costs across income groups. With respect to the distribution of costs, the EPA found that, similar to its findings based on race/ethnicity group, differences in annual incremental household costs across income groups were typically small with no unidirectional trend in cost differences based on income level.

For more information on the EPA's EJ analysis, please see Chapter 8 of the EA (USEPA, 2024a) and Appendix M of the EA (USEPA, 2024b).

Individual Public Comments

Isabelle Dominguez (Doc. #1525, SBC-042626)

Though PFAS exposure is widespread, some communities are at a higher risk of exposure than others. A report by the Union of Concerned Scientists found that "low-income communities, communities of color, and Indigenous communities bear the brunt of the consequences of" nonaction concerning pollution, particularly the effects of PFAS in drinking water. [FN8: See generally ANITA DESIKAN, ET AL., UNION OF CONCERNED SCIENTISTS, ABANDONED SCIENCE, BROKEN PROMISES (2019), https://www.ucsusa.org/sites/default/files/2019-10/abandoned-science-broken-promises-web-final.pdf.] This is because such communities are more likely to live near industrial areas, where PFAS accumulation is higher. [FN9: Xindi C. Hu et al., Detection of Poly- and Perfluoroalkyl Substances (PFASs) in U.S. Drinking Water Linked to Industrial Sites, Military Fire Training Areas, and Wastewater Treatment Plants, 3 ENV'T SCI. TECH. LETTER 344, 345 (2016).] Moreover, these are

communities that, without funding from the federal government, cannot afford to upgrade their water systems to account for PFAS exposure. [FN10: See DESIKAN, ET AL., supra note 8, at 2.]

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments regarding the EPA's EJ analysis and EJ considerations for the final rule, including funding. The EPA acknowledges the commenter's submission of these citations and notes that Desikan et al. (2019) and Hu et al. (2016) are cited in the literature review conducted to supplement the EPA's EJ analysis for this rule, which can be found in in Section 8.2 of the EA (USEPA, 2024a).

Linda Shosie (Doc. #1533, SBC-043957)

My main focus is to continue to empower underserved, disadvantaged EJ, and Hispanic/Latino communities, to influence, encourage and facilitate community engagement of those potentially affected, throughout the agency's regulatory, cleanup, and decision-making processes that may affect their environment and public health.

I was born, raised, and have lived my entire life in the Tucson South-side area. I currently live in the central part of Tucson, near the Davis- Monthan Air Force Base Installations (DM-AFB) and a little bit further from the Tucson International Airport (TIA) Superfund site. I love Tucson, which is a vibrant community surrounded by a beautiful desert environment. We are also the home of two tribal nations, the Tohono O'odham Nation and the Pascua Yaqui Tribe.

However, our community has suffered severe harm because of PFOA, PFOS, and other toxic chemicals in our drinking water supply, which increases the risk of cancer and other serious diseases. Groundwater contamination from the Tucson International Airport and several Air Force Installations in and around Tucson, has turned the area around my home into a federal Superfund site and has threatened my health and the health of countless Tucson South-side residents.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments regarding the EPA's EJ analysis and EJ considerations for the final rule.

The EPA acknowledges the commenter's submission of concerns about drinking water in Tucson, AZ. Other than under SDWA, the EPA is initiating actions under multiple environmental authorities— the RCRA, Toxic Substances Control Act (TSCA), Clean Water Act (CWA), and CERCLA—to identify past and ongoing releases of PFAS into the environment at facilities where PFAS has been used, manufactured, discharged, disposed of, released, and/or spilled. The EPA is conducting inspections, issuing information requests, and collecting data to understand the level of contamination and current risks posed by PFAS to surrounding communities and will seek to address threats to human health with all its available tools. The EPA works with its federal, state and Tribal regulatory partners through a comprehensive SDWA

compliance monitoring program to protect human health and the environment by ensuring that the regulated community complies with environmental laws/regulations through on-site visits by qualified inspectors, and a review of the information the EPA or a state/Tribe requires to be submitted. Additionally, due to the toxicity and persistence of PFAS chemicals, and the breadth and scope of PFAS contamination throughout the country, the EPA selected Addressing Exposure to PFAS as a new National Enforcement and Compliance Initiative (NECI) for Fiscal Years 2024-2027. PFAS contamination is a significant priority for the EPA and, while the regulatory framework for PFAS continues to develop across multiple statutes, the EPA has already taken a number of enforcement actions to ensure compliance with existing statutes, including action to address an imminent and substantial endangerment to communities. The EPA will increase those efforts, particularly where necessary to protect drinking water supplies, as part of this new initiative.

Linda Shosie (Doc. #1533, SBC-043960)

For decades, studies have demonstrated that people of color and disadvantaged, vulnerable, low-income, marginalized, and indigenous peoples are disproportionately burdened by environmental hazards as well as cumulative adverse health effects from multiple co-occurring contaminants. According to more recent reports released by the World Health Organization more than a quarter of all death and disease in the world is attributable to the environment. Published research also suggests that communities with higher populations of people of color maybe especially impacted by PFAS. These reports justify what many who live on the South-side of Tucson feel. You only need to spend a few minutes with a longtime South-side resident before they start listing family members who have diseases that they believe are linked to drinking contaminated water from the Tucson International Airport Area Superfund Site.

I strongly believe that the Tucson contamination and the resulting health problems were not an act of God, but resulted from careless, reckless, and criminal industry waste behavior, lax governmental oversight, weak regulations, poor enforcement and callous indifference to human suffering because of environmental racism." Furthermore, in my view the Tucson historical environmental injustices and health inequalities associated with the Tucson International Airport Superfund Site, are a clear picture of an ongoing structural federal response failure to protect people of color, and low wealth populations exposed to toxic chemicals that did not just slip through the cracks of our broken system, but it was directly intended to fail by design, inadequate scientific methods available for investigating health outcomes related to toxic chemicals, that rarely generates any meaningful actions.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments regarding the EPA's EJ analysis and EJ considerations for the final rule and the EPA response to comment Doc. #1533, SBC-043957 in section 14.10 in this *Response to Comments* document regarding the commenter's concerns related to PFAS contamination in Tucson, AZ, including Superfund sites.

Linda Shosie (Doc. #1533, SBC-043965)

A 24 square-mile area on Tucson South-side was designated a Superfund Site, when the EPA discovered trichloroethylene (TCE) contamination in the drinking water, but the EPA never cleaned up the contamination. TCE is a well-known human carcinogen. In 2010, 1,4-Dioxane, another probable human carcinogen, was discovered in Tucson South-side drinking water supplies. Later, the EPA detected PFAS in the area as well, when our community group demanded more testing.

Over 50,000 South-sides residents are forced to drink, breathe, bathe, and cook in water laced with unknown trace amounts of cocktail mixtures of all these chemicals resulting in many health problems in our community. This contamination and the resulting illnesses were not and are not an "act of God" but resulted from careless and criminal manufacturing and industrial behavior, lax governmental oversight, weak regulations, poor enforcement and callous indifference to human suffering because of environmental racism.

To illustrate this a little better, at present, the federal and state government has not acted swiftly to prevent the spread of PFAS from entering into the water remediation system, and to avert the repetition of the environmental harms on this community. No attention has been placed on the victims of the contamination. Instead, the impacts of the contamination on the people who drank, bathed, and cooked from that contaminated water have been ignored, minimized, neglected or denied.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments regarding the EPA's EJ analysis and EJ considerations for the final rule and the EPA response to comment Doc. #1533, SBC-043957 in section 14.10 in this *Response to Comments* document regarding the commenter's concerns related to PFAS contamination in Tucson, AZ, including Superfund sites.

Regarding the commenter's assertion that the federal government "has not acted swiftly to prevent the spread of PFAS," the EPA is working as expeditiously as possible to promulgate this final rule to reduce exposure to PFAS in drinking water. The EPA notes that concerns related to exposure to contaminants other than the six PFAS regulated as part of this action are outside the scope of this regulatory action. However, the EPA notes that the agency's PFAS Strategic Roadmap (see: https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024) lays out a whole-of-agency approach to addressing PFAS, beyond the six PFAS included in this regulatory action. The actions described in the Roadmap represent meaningful steps to safeguard communities from PFAS contamination. For additional discussion about the EPA's PFAS Strategic Roadmap, please see section 15 of the EPA response in this *Response to Comments* document.

Kevin Korro (Doc. #1538, SBC-042656)

In addition, I am a supporter of the efforts being made by the Environmental Protection Agency (EPA) to assist people, particularly in underdeveloped regions, in securing access to safe drinking water. It is vital that all communities have access to clean and drinkable water, and I applaud the work that the EPA is doing to address environmental injustices. It is imperative that all communities have access to clean and drinkable water.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments regarding the EPA's EJ analysis and EJ considerations for the final rule. The EPA acknowledges the commenter's support of this action and the agency's work to advance EJ.

Alliance of Nurses for Healthy Environments (Doc. #1544, SBC-042670)

EPA's proposed drinking water standards also align with the Biden Administration's commitment to advance environmental justice. Communities of color and low-income communities have historically faced disproportionate exposure to pollution and cumulative adverse health effects from multiple co-occurring contaminants. Published research suggests that communities with higher populations of people of color may be especially impacted by PFAS. By regulating six dangerous PFAS in drinking water, EPA's proposal helps to reduce overall PFAS exposure, and improve drinking water safety in thousands of communities across the country.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments regarding the EPA's EJ analysis and EJ considerations for the final rule. The EPA acknowledges the commenter's support of this action and its alignment with the federal government's commitment to advancing EJ.

Dylan Pilger (Doc. #1546, SBC-042677)

The EPA must comply with OMB Statistical Directive 15 and disaggregate Asian and Pacific Islander data.

My second recommendation to the EPA is the disaggregation of Asian and Pacific Islander data for conducting the environmental justice analysis. According to USEPA 2023j pages M1-M12, Asian and Pacific Islanders had higher rates of PFAS exposure. However, it is unclear what differences might exist between Asian and Native Hawaiian or Other Pacific Islander (NHOPI) subpopulations without disaggregating data sets. While it may be helpful for gaining greater statistical power due to greater sample size, aggregation of data obscures differences between these unique subpopulations (Quint et al., 2021). This is particularly relevant in a place like Hawai‘i, where NHOPIs have substantial health disparities when compared to Asians (Look et al., 2020). There are also disparities in socioeconomic status and level of education between NHOPIs and Asians in Hawai‘i. Data disaggregation has revealed substantial differences in the

impacts of COVID-19 to NH, PI, and Asians (Quint et al., 2021). Furthermore, available data on NHOPI and Asians demographics by census place demonstrates that the population of each ethnic group varies greatly depending on geographic region (Hawaii Health Matters, n.d.-a, n.d.-b), suggesting that their risks to exposure to PFAS would be very different. It is clear that by not complying and disaggregating NHOPI and Asian subpopulations in data sets, valuable information will be obfuscated. Therefore, while the OMB order may not always be followed, in this case it is absolutely crucial that the EPA comply.

EPA Response: The EPA disagrees that its EJ analysis must disaggregate Asian and Pacific Islander data in order to comply with the Office of Management and Budget (OMB) Statistical Directive 15 (SPD 15) because SPD 15 establishes standards for maintaining, collecting, and presenting Federal data on race and ethnicity and applies to "all Federal reporting purposes" (OMB, 1977). This term is not defined and does not clearly apply to analyses developed to support rulemaking efforts. SPD 15 is targeted primarily toward data collection efforts, the development of data for public consumption, and the enforcement of civil rights laws. As SPD 15 is not applicable in the context of rulemakings, the EPA is not required to revise its EJ analysis in accordance with the standards for data disaggregation set forth in the OMB directive. However, the EPA acknowledges that reporting results separately for these groups can help to reveal potential disparities that may exist across Asian and Pacific Islander subpopulations. In response to this comment, the EPA has added a qualitative summary of the literature provided by the commenter and has also updated its analysis to include separate Asian and Pacific Islander demographic groups. These updates are reflected in Chapter 8 of the EA (USEPA, 2024a) and Appendix M of the EA (USEPA, 2024b).

Ross Renick (Doc. #1553, SBC-042561)

Although, I do believe addressing the drinking water concern should be the priority as it is the most apparent and complete pathway to human ingestion, I see environmental justice concerns with the implementation.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document.

Brooke Young (Doc. #1554, SBC-043973)

In addition, special consideration must be given to low-income and marginalized communities in Colorado that are impacted by PFAS in drinking water. These communities often are close to industrial locations and landfills that contribute to the contamination of source water. In addition, these communities don't always have access to proper healthcare or safe drinking water. To ensure they are treated equitably, I urge the EPA to require state and local authorities to monitor the drinking water in these communities more closely, provide tailored programs, ensure PFAS information is disseminated in a way that is more accessible, and engage with these communities in a more effective manner which encourages public involvement.

In conclusion, I favor stricter regulations on public drinking water regarding PFAS contamination to protect all Colorado communities and safeguard public health nationwide. Also, to be more mindful of marginalized communities regarding the proposed PFAS National Primary Drinking Water Regulation so that PFAS contamination is addressed equitably across all Colorado communities.

Best regards,

Brooke Young

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments regarding the EPA's EJ analysis and EJ considerations for the final rule. The EPA acknowledges the commenter's submission of concerns about drinking water in Colorado; please see the EPA response to comment Doc. #1533, SBC-043957 in section 14.10 in this *Response to Comments* document.

With respect to the commenter's request that the EPA "require state and local authorities to monitor the drinking water in these communities more closely", the EPA notes that as part of this action, the agency is setting forth requirements for all CWSs and NTNCWSs to monitor for the six PFAS regulated under the final rule. For more information on the EPA's monitoring requirements for the final rule, please see section VIII of the preamble for this action. Additionally, while beyond the scope of this regulatory action, the fifth Unregulated Contaminant Monitoring Rule (UCMR 5) was published on December 27, 2021. UCMR 5 requires sample collection for 30 chemical contaminants, including 29 different PFAS, between 2023 and 2025 using analytical methods developed by the EPA and consensus organizations. This action provides the agency and other interested parties with scientifically valid data on the national occurrence of these contaminants in drinking water. Consistent with the EPA's PFAS Strategic Roadmap, UCMR 5 will provide new data that will improve the agency's understanding of the frequency that 29 per- and polyfluoroalkyl substances (PFAS) and lithium are found in the nation's drinking water systems, and at what levels.

With respect to the commenter's request that the EPA "ensure PFAS information is disseminated in a way that is more accessible," as part of this action, the agency is setting forth CCR and PN requirements. Systems must prepare and deliver to its customers an annual CCR, which provides customers with information about their local drinking water quality as well as information regarding the water system's compliance with drinking water regulations. Additionally, all systems must give the public notice for all violations of the final rule. For more information on the EPA's CCR and PN requirements for the final rule and responses to comments on these requirements, please see section IX of the preamble for this action and section 9 of the EPA response in this *Response to Comments* document, respectively. Additionally, the EPA notes that the agency intends to produce risk communication materials that can be used by utilities and others as they deem appropriate to communicate about PFAS in drinking water. As the EPA develops implementation materials following final rule promulgation, the agency will consider additional resources to support states and water systems in communicating with and notifying

their customers. For discussion of risk communication materials that the agency intends to develop related to this action, please see section 1.2 of the EPA response in this *Response to Comments* document.

With respect to the commenter's request for public engagement, the EPA notes that prior to both proposing and finalizing this regulatory action, the EPA provided many opportunities for public involvement through various engagements, consultations, and a public hearing. Specifically, on March 2, 2022 and April 5, 2022, the EPA held public meetings related to EJ and the development of the proposed NPDWR. The meetings provided an opportunity for the EPA to share information and for communities to offer input on EJ considerations related to the development of the proposed rule. Additionally, the EPA notes that, as outlined in the PFAS Strategic Roadmap (see https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024), the agency has begun a national engagement effort including community engagement events focused on each EPA Region and Tribal partners, national webinars, and stakeholder listening sessions. The agency also plans to engage directly with affected communities in every EPA Region to hear how PFAS contamination has impacted their lives and livelihoods. For additional discussion about the EPA's PFAS Strategic Roadmap, please see section 15 of the EPA response in this *Response to Comments* document.

Michigan Farm Bureau (MFB) (Doc. #1562, SBC-043360)

From the standpoint of environmental justice and minimizing disproportionate impacts to vulnerable communities including those in poverty, there is no way to calculate the cost of implementing these MCLs without concluding there will be a significant impact to these vulnerable communities, which necessitates EPA to work with other agencies and legislative efforts to ensure sufficient financial resources are made available to assist these public water suppliers with what they need to comply with final MCL concentrations.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments regarding the EPA's EJ analysis and EJ considerations for the final rule, including funding and the EPA's analysis of costs across demographic groups.

Minnesota Pollution Control Agency (MPCA) (Doc. #1569, SBC-042497)

Section XV - Statutory and Executive Order reviews

Topic: Part J, Executive Order 12898: Federal Actions to address environmental justice (EJ) in minority populations and low-income populations.

MPCA comments: EPA conducted two analyses to evaluate the impacts of the proposed MCLs on EJ communities: an exposure analysis using EJ Screen (EPA's EJ screening and mapping tool) and an alternatives analysis using SafeWater MCBC. EPA concludes enactment of the proposed MCLs will not…" have disproportionately high and adverse human health or

environmental impacts on minority or low-income populations" and will "mitigate the disproportionate impacts of baseline PFAS exposure."

While MPCA agrees with EPA's conclusion, we wish to highlight the externalities associated with contamination of all types, not just PFAS, and the costs that are borne as a matter of practice by the affected communities and their ratepayers. (By externalities, we mean phenomena where an activity affects one or more parties with the extent of these effects not being reflected in the costs of the activity. Examples are costs for testing and monitoring for contamination, informing the public, studying potential treatment and/or infrastructure investments, public employee staff time, etc.) As put forward by Cordner et al (2021), low-income communities may be unable to cover unplanned and unexpected expenditures, especially when a source of PFAS contamination has not been identified for potential cost recovery. This fact, coupled with historic racial discrimination and inequitable enforcement of environmental regulations in low-income communities, may still result in disproportionate impacts from exposure to PFAS in drinking water moving forward. Again, prevention of further PFAS pollution is a critical piece of tackling the problem of these forever chemicals.

EPA Response: The EPA acknowledges the commenter's support of the conclusions of the agency's EJ analysis. Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments regarding the EPA's EJ analysis and EJ considerations for the final rule, including funding. With respect to the commenter's concerns regarding costs associated with "testing and monitoring for contamination, informing the public, studying potential treatment and/or infrastructure investments, public employee staff time, etc.," the EPA has adequately considered costs of these activities as part of its EA for the final rule. Please see sections 13.3.1-13.3.6 for responses to comments on the EPA's estimation of costs, including primacy agency costs and water system costs (including treatment costs, monitoring costs, administrative costs including consideration of PN, and non-treatment costs). For discussion of technical assistance available to disadvantaged and/or small communities, including the EPA's WaterTA program, please see the EPA responses to comment Doc. #1640, SBC-044378 and comment Doc. #1608, SBC-044005 in section 14.10 in this *Response to Comments* document.

With respect to the commenter's assertion about inequitable enforcement of environmental regulations, please see the EPA response to comment Doc. #1640, SBC-044378 in section 14.10 in this *Response to Comments* document.

The EPA also acknowledges the commenter's concern that "prevention of further PFAS pollution is a critical piece of tackling the problems of these forever chemicals." While beyond the scope of this rulemaking action, in 2021, the EPA published the PFAS Strategic Roadmap, which sets timelines by which the EPA plans to take specific actions and commits to new policies to safeguard public health, protect the environment, and hold polluters accountable. The actions described in the PFAS Strategic Roadmap each represent important and meaningful steps to safeguard communities from PFAS contamination. Cumulatively, these actions will build upon one another and lead to more enduring and protective solutions. In the Roadmap, the EPA

notes that the agency "will bring deeper focus to preventing PFAS from entering the environment in the first place—a foundational step to reducing the exposure and potential risks of future PFAS contamination." Additionally, in the Roadmap, the EPA notes that "intervening at the beginning of the PFAS lifecycle—before they have entered the environment—is a foundational element of EPA's whole-of-agency approach." For additional discussion about the EPA's PFAS Strategic Roadmap, please see section 15 of the EPA response in this *Response to Comments* document.

San Gabriel Valley Water Association (SGVWA) (Doc. #1580, SBC-042423)

Our comments are intended to be constructive and ensure that the PFAS MCL is implemented equitably so that everyone has access to safe drinking water. As currently drafted, this standard may result in disparities between communities that can afford the necessary treatment methods and those that cannot. We hope that you will consider our feedback with this goal in mind.

Thank you for taking the time to consider our input.

Sincerely,

President, Board of Directors

San Gabriel Valley Water Association

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document.

American Public Works Association (APWA) (Doc. #1584, SBC-042389)

May 24, 2023

Submitted electronically to: https://www.regulations.gov

Michael S. Regan

Administrator

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue NW

Washington, D.C. 20460

Re: EPA's Proposed PFAS NPDWR; Docket ID No. EPA-HQ-OW-2022-0114

Dear Administrator Regan:

On behalf of the more than 31,000 members of the American Public Works Association (APWA), we appreciate the opportunity to submit comments on the proposed rule for a National Primary Drinking Water Regulation (NPDWR) for Per- and polyfluoroalkyl substances (PFAS).

APWA members are responsible for an array of water infrastructure including drinking water, stormwater, and wastewater. In these roles APWA members understand and appreciate the efforts made towards cleaner water and have a long history of achieving compliance with NPDWRs along with providing subject matter expertise to policymakers at all levels and branches of government.

As they design, build, and maintain infrastructure they are simultaneously implementing and reviewing the law and serve as a wealth of knowledge. Additionally, APWA continues to be a proud supporter of the Infrastructure Investment and Jobs Act (IIJA) and the resources provided to deliver safe drinking water and address emerging contaminants. For decades limited guidance and resources were provided regarding PFAS, yet many public works professionals were at the forefront learning and tackling pollution from "forever chemicals".

At the same time, we would like to therefore stress the scale of the proposed undertaking and the likely need for further resources for many communities, especially those that are small, disadvantaged, and lacking in professional capacity. Otherwise, the costs will fall disproportionately on vulnerable populations with limited incomes and who are already underserved.

This is the first new contaminant to be regulated in drinking water in nearly 30 years and the first since Congress significantly amended the Safe Drinking Water Act (SDWA) in 1996. For many this will be a new experience and entail an additional learning curve especially given while the EPA has used a Hazard Index before to inform risks of chemical mixtures, this is the first time the agency has chosen to do so for a federal drinking water maximum contaminant level (MCL).

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments regarding the EPA's EJ analysis and EJ considerations for the final rule, including funding. The EPA acknowledges that there will be a learning curve for communities implementing the regulation, and the agency has considered associated costs for primacy agencies and water systems as part of its economic analysis. Please see sections 13.3.1-13.3.6 of the EPA response in this *Response to Comments* document for more information. Additionally, to provide communities necessary time to make capital improvements, which will allow them more time to develop plans to comply with the regulation where needed, the EPA has authorized a two-year extension for capital improvements. Please see section 12.1 of the EPA response in this *Response to Comments* document for more information. For more information on the Hazard Index, please see section V.B of the preamble for this action and sections 4.3.2 and 5.2 of the EPA response in this *Response to Comments* document.

Center for American Progress (CAP) (Doc. #1586, SBC-042388)

More research on PFAS and the extent to which all Americans, specifically disadvantaged communities and children, are exposed to them is needed, including the effect of each individual PFAS on health and the impact of exposure levels. This research may call attention to the need for greater, more stringent regulation, but at this moment, this proposed rule is an important step

to ensure all communities have access to safe drinking water. We strongly urge the EPA to safeguard public health and finalize the rule as proposed.

Sincerely,

Jill Rosenthal

Director, Public Health Policy

Sarah Millender

Research Assistant, Health Policy

EPA Response: The EPA acknowledges commenter's support for "finaliz[ing] the rule as proposed." Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments regarding the EPA's EJ analysis and EJ considerations for the final rule.

Public Health, Seattle & King County (PHSKC) (Doc. #1594, SBC-042354)

As the regulatory landscape and the scientific knowledge around PFAS is changing at a rapid pace, we want to ensure that health risks to sensitive populations and communities that have faced systemic environmental injustices are not overlooked.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document.

American Water Works Company Inc. (Doc. #1608, SBC-043986)

Funding – To realize the health benefits of this proposed rule, water utilities must have the financial resources to ensure they can sustain the ongoing costs that will arise from constructing, operating, maintaining, and monitoring PFAS treatment systems for the safety and benefit of customers. Low-income assistance must also be provided.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document.

American Water Works Company Inc. (Doc. #1608, SBC-044005)

[American Water joins other water organizations in urging the U.S. EPA, Congress, and other decision-makers to implement policies that will:]

• ensure all water and wastewater utility providers, regardless of ownership, have equal access to any and all Federal and/or state funding related to treating PFAS; and

• establish a permanent federally funded water and wastewater low-income customer assistance program.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments regarding the EPA's EJ analysis and EJ considerations for the final rule, including funding. Establishing a federally funded low-income customer assistance program is outside the scope of this rulemaking action, though, as discussed in section 14.10 of the EPA response in this *Response to Comments* document above, external funding sources, including those under BIL, are available to assist with potential rule implementation challenges. Furthermore, the EPA notes that the agency is investing substantial resources in providing technical assistance to communities to improve drinking water quality, including reducing contaminants of emerging concern in finished drinking water. The EPA anticipates that new and existing EPA Water Technical Assistance (WaterTA) programs for PWSs, including some aimed at small and/or disadvantaged systems, will be utilized to support effective implementation of these goals. The EPA's free WaterTA services support communities to identify water challenges, develop plans, build capacity, and develop application materials to access water infrastructure funding. To implement WaterTA, the EPA collaborates with states, Tribes, territories, community partners, and other key stakeholders. For more information regarding this program and other funding availability, please see sections 1.2 and 2.4 of the EPA response in this *Response to Comments* document.

American Water Works Company Inc. (Doc. #1608, SBC-043978)

American Water joins other water organizations in urging the U.S. EPA, Congress, and other decisionmakers to implement policies that will:

• keep harmful PFAS out of our drinking water supplies and our communities;

• exempt all water and wastewater systems from financial liability for PFAS under CERCLA;

• ensure all water and wastewater utility providers, regardless of ownership, have equal access to any and all Federal and/or state funding related to treating PFAS; and

• establish a permanent federally funded water and wastewater low-income customer assistance program.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments regarding the EPA's EJ analysis and EJ considerations for the final rule, including funding. Regarding the commenter's request for a federally funded water and wastewater low-income customer assistance program, please see the EPA response to comment Doc. #1608, SBC-044005 in section 14.10 in this *Response to Comments* document. For discussion related to source water protection and keeping PFAS out of drinking water supplies, please see the EPA response to comment Doc. #1569, SBC-042497 in section 14.10 in this *Response to Comments* document. Additionally, the EPA notes that concerns related specifically to financial liability for PFAS contamination under CERCLA are outside the scope of this regulatory action.

Wisconsin Conservation Voters (Doc. #1611, SBC-042860)

We know these health-related risks can impact everyone, but that they are having a disproportionately high impact on low-income communities and communities of color.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document.

Oakland County Water Resources Commissioner (WRC) (Doc. #1615, SBC-042927)

The cost of compliance must be given serious consideration. This is critical to meet state and federal environmental justice goals. Communities that cannot afford the increased cost of regulatory compliance, like Pontiac and Royal Oak Township, will be overly burdened. This inequity must be proactively addressed in any additional EPA regulations.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document.

Colorado Water Utility Council (CWUC) (Doc. #1622, SBC-044056)

34. EPA requests comment on all aspects of its EJ analysis, particularly its choice of comparison groups to determine potential demographic disparities in anticipated PFAS exposure and its use of thresholds against which to examine anticipated exposures.

a. CWUC is concerned that impacts of increased water rates will affect disadvantaged communities the hardest.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments regarding the EPA's EJ analysis and EJ considerations for the final rule, including funding and the EPA's analysis of costs across demographic groups. With respect to the commenter's concern about increased water rates, in the EPA's small system affordability analysis, the EPA analyzed the household level cost impacts of the final rule on small system size categories and determined the rule is affordable for small systems. The EPA's affordability determination for the final rule, using longstanding EPA methodology and supplemental affordability analyses, can be found in Chapter 9.13 of the EA for the final rule (USEPA, 2024a).

WaterPIO (Doc. #1624, SBC-043467)

8. Finally, and perhaps most importantly to an EPA that rightly is focusing on communities of color and disadvantaged areas facing economic challenges, the costs of the EPA's proposed regulations will significantly harm the public by dramatically increasing the cost of their tap water. Except for rare circumstances where chemical companies are paying for advanced treatment to be placed on public water – WaterPIO has been in the middle of these confidential

agreements – the American people will be the ones forced to pay the bill for the impacts of the EPA's actions. It won't be America's PFAS polluters.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments regarding the EPA's EJ analysis and EJ considerations for the final rule, including funding and the EPA's analysis of costs across demographic groups. While the EPA cannot speak to the specifics of confidential agreements cited by the commenter, despite the commenter's assertion otherwise, the EPA notes that the American people are not paying the bill "for the impacts of EPA's actions" nor will this regulation "significantly harm the public by dramatically increasing the cost of their tap water." Rather, costs incurred will be to remove regulated PFAS from finished drinking water, resulting in an impact of improved public health protection from significantly reducing instances of associated illnesses and deaths. In some cases, such as those alluded to by the commenter, the PFAS is from direct contamination of a point source discharge of PFAS or a known group of PFAS sources. The EPA is aware that in particular instances such as these that drinking water utilities have recovered necessary treatment costs from those entities whose actions caused the source water contamination. And in the situations cited by the commenter, the *polluter's actions* are responsible for the increased cost, not the EPA's actions. In other cases of PFAS contamination, there are not identifiable parties to hold accountable, and, in those circumstances, it is both the EPA's core mission and its responsibility under the SDWA to ensure that populations served by that contaminated drinking water are not exposed to harmful concentrations of PFAS by developing and finalizing this regulation. The agency notes that the utilities that serve these people will often be able to utilize federal funding, such as that discussed in section 2.4 of the EPA response in this *Response to Comments* document, to help offset the treatment costs. Responsible parties may also help offset the costs of treatment. As discussed in multiple sections of this rulemaking and hundreds of documents in this administrative record, the PFAS that the EPA is regulating in this action pose a significant public health burden, and while there will be costs associated with rule implementation, those costs are associated with actions taken to protect the American people. See section XIII of the preamble to this regulation for information about the EPA's cost analysis for the final rule and the numerous health benefits to reducing exposure to these and other PFAS, as well as sections 13.3 and 13.4 of the EPA response in this *Response to Comments* document for responses to public comments about specifics of the rule's costs and benefits, respectively. With regard to the commenter's concern about the cost of tap water, in the EPA's small system affordability analysis, the EPA analyzed the household level cost impacts of the final rule on small system size categories and determined the rule is affordable for small systems. The EPA's affordability determination for the final rule, using longstanding EPA methodology and supplemental affordability analyses, can be found in Chapter 9.13 of the EA for the final rule (USEPA, 2024a).

<u>Illinois Farm Bureau (IFB) (Doc. #1630, SBC-043141)</u>

Rural Communities Will Be Disproportionately Impacted

Farmers serve as the backbone of many rural communities throughout the country. Rural communities and/or underserve communities have far less resources to address expensive federal regulatory requirements. Drinking water utilities in rural areas will undoubtably experience more challenges in meeting the 4ppt standard outlined in this proposed rule. Rural communities will incur extensive costs to obtain and install new technology. Then, uncertainty with testing availability/costs and lack of clarity with disposal methods/ costs only exacerbate our concerns.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments regarding the EPA's EJ analysis and EJ considerations for the final rule. In response to the commenter's concern regarding disproportionate impacts on rural communities, as discussed in section 14.10 of the EPA response in this *Response to Comments* document, in the EPA's EJ analysis for the final rule, the agency examined the demographic distribution of costs across multiple water system size categories and found that incremental household costs to all race/ethnicity and income groups generally decrease as system size increases, which is expected due to economies of scale. For more information on the findings of the EPA's EJ analysis, please see Chapter 8 of the EA (USEPA, 2024a). To alleviate potential cost disparities identified by the EPA's analysis, there may be an opportunity for many communities to utilize BIL funding to provide financial assistance for addressing emerging contaminants. BIL funding has specific allocations for both disadvantaged and/or small communities and emerging contaminants, including PFAS. Additionally, if a water system, project, or project cost is not eligible under the Drinking Water State Revolving Fund (DWSRF), it may be eligible under other programs. These might include the U.S. Department of Agriculture's Rural Development program, the U.S. Department of Housing and Urban Development's Community Development Block Grant program, the Clean Water State Revolving Fund (CWSRF), the newly authorized Water Infrastructure Finance and Innovation Act (WIFIA) funding, or other federal, non-federal, or state funding sources.

In EPA's small system affordability analysis, the EPA analyzed the household level cost impacts of the final rule on small system size categories and determined the rule is affordable for small systems. While the EPA did not separately present the impacts of the final rule on rural communities, many rural communities are served by small systems. The EPA's affordability determination for the final rule, using longstanding EPA methodology and supplemental affordability analyses, can be found in Chapter 9.13 of the EA for the final rule (USEPA, 2024a). Additionally, please see section 13.10 of the EPA response in this *Response to Comments* document for the EPA's responses related to affordability.

Additionally, please see section 14.3 of the EPA response in this *Response to Comments* document for responses to comments on the EPA's actions taken as required under the RFA/SBREFA.

Rural Community Assistance Partnership Incorporated (RCAP) (Doc. #1633, SBC-044143)

EPA should prioritize the compliance of systems serving small, disadvantaged, and Environmental Justice communities.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments regarding the EPA's EJ analysis and EJ considerations for the final rule, including funding. With respect to the commenter's suggestion that the EPA "prioritize the compliance of systems serving small, disadvantaged, and Environmental Justice communities," the EPA notes that compliance with the MCLs for PFAS for all regulated PWSs is mandatory beginning 5 years from the date of rule promulgation. This regulation is applicable to all systems nationwide and does not prioritize compliance of any subset of water systems. The EPA, through BIL funding as discussed in section 14.10 of the EPA response in this *Response to Comments* document, has specific allocations for disadvantaged and/or small communities (e.g., the EC-SDC Grant program), which will aid in working toward rule compliance in these communities. The EPA's SDWA Enforcement Response Policy explains how the EPA typically pursues enforcement cases involving a water system's violations of the SDWA. Furthermore, as discussed in the EPA response to comment Doc. #1608, SBC-044005 in section 14.10 in this *Response to Comments* document, the EPA intends to provide significant technical assistance to affected communities, including "small, disadvantaged, and Environmental Justice communities."

Citizens Against Ruining the Environment (CARE) (Doc. #1638, SBC-043454)

CARE Comment Six – Based on Evidence of Significant, Adverse and Disproportionate Harm, The Proposed Standards Are Essential To Achieve Environmental Justice

CARE represents environmental justice communities in Will County, Illinois. CARE recognizes and appreciates EPA's Environmental Justice Analysis of the proposed rule. It is reasonable to conclude, as the EPA has, that communities that are most impacted by PFAS contamination now are those that stand to benefit the most from the proposed PFAS MCLs. [FN70: Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation, U.S. EPA, March 2023, EPA Document Number: EPA-822-P-23-001, p. 318.] This conclusion aligns with other research indicating that low-income, Black, and Latino communities are disproportionately burdened with PFAS. [FN71: See Attachment 2, Jahred M. Liddie, Laurel A. Schaider, and Elsie M. Sunderland, "Sociodemographic Factors Are Associated with the Abundance of PFAS Sources and Detection in U.S. Community Water Systems", https://doi.org/10.1021/acs.est.2c07255.] CARE's three primary EJ concerns are discussed below.

EPA Must Address Inconsistent Monitoring and Enforcement

The potential benefits to environmental justice communities, such as CARE members in Will County, from this proposal are vital and CARE agrees with the conclusion that EJ communities

could benefit from the proposal. However, as stated above in the discussions on Monitoring and Exemptions, if exemptions are granted to small communities and those that can not afford capital costs related to PFAS filtration, then the EJ analysis of the proposal is illusory, at best. Benefits to EJ communities will be compromised if Primary Agencies are permitted to grant years-long exemptions to small or under resourced communities.

EPA Must Address Disproportionate Cost Burdens

CARE affirms the EPA's acknowledgement that increased costs related to the proposal may compound burdens on people of color. [FN72: Federal Register, Vol. 88, No. 60, p. 18735.] CARE is concerned, however, that the funding EPA proposes could be appropriated by Primary Agencies and PWS's for other purposes, such as the replacement of lead service lines. CARE encourages the EPA to identify funds with the restricted purpose of alleviating economic burdens on EJ community households that are caused by this rule. If the cost burden on small water systems is eliminated, it could foreseeably eliminate the need for exemptions as well, thereby addressing much of the EJ risk from this proposed rule's implementation.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments regarding the EPA's EJ analysis and EJ considerations for the final rule. The EPA acknowledges the commenter's agreement with the conclusions of the agency's EJ analysis.

Based on this comment, the EPA has added Liddie et al. (2023) to the literature review conducted to supplement the EPA's EJ analysis for this rule, which can be found in in Section 8.2 of the EA (USEPA, 2024a).

Additionally, the EPA notes that primacy agencies who have adopted the 1998 *Variance and Exemptions Regulation* (USEPA, 1998c) may choose to grant exemptions on a case-by-case basis to encourage systems facing compelling circumstances to come into compliance with the MCLs in an appropriate period of time. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12.1 of the EPA response on extensions and exemptions in this *Response to Comments* document. The EPA agrees with the commenter's assertion that benefits to communities with EJ concerns may be compromised if exemptions are granted as exempting particular systems from rule requirements may result in inequitable public health protection due to inequitable implementation of the final rule.

<u>Aidan Cecchetti (Doc. #1640, SBC-044378)</u>

• EPA requests comment on all aspects of its EJ analysis, particularly its choice of comparison groups to determine potential demographic disparities in anticipated PFAS exposure and its use of thresholds against which to examine anticipated exposures. For more information, please see section XV.J of this preamble (pg. 18735 Federal Register Volume 88, Number 60).

O It is not clear to the commenters whether EPA considered the inequitable application and enforcement of NPDWRs in the performed EJ analysis. For example, did EPA's analysis take

into account the fact that communities of color, and particularly African Americans and Native Americans, are most likely to suffer from environmental harms not only because of unequal distribution of pollution, but also because of unequal enforcement of existing laws? Additionally, many of these same vulnerable communities not only suffer from a lack of resources to mitigate the environmental harms they suffer, but also suffer from administrative burdens when seeking funding through the state and federal programs that EPA's EJ analysis pointed to as ways to help alleviate cost disparities. This suggests that EPA's EJ analysis may have overestimated the potential effectiveness of funding provided by these programs to reduce disparities. Although EPA's EJ analysis suggested that the greatest reductions in exposure and health benefits could be experienced by communities of color, it is not clear to the commenters that the analysis provides an accurate prediction of the impact of the new PFAS regulations if it did not appropriately consider the issues above.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments regarding the EPA's EJ analysis and EJ considerations for the final rule, including funding and the EPA's analysis of costs across demographic groups. The EPA disagrees with the commenter's assertion that NPDWRs are inequitably applied and enforced, as the record does not support this, and the commenter does not provide any supporting rationale to substantiate this claim. The EPA also disagrees with the commenter's suggestion that the EPA's EJ analysis does not provide an "accurate prediction of the impact of the new PFAS regulations" due to the omission of an assessment of NPDWR compliance and enforcement in its analysis as the agency used the best available peer-reviewed information to assess the potential EJ impacts of this action. The EPA assumes 100 percent compliance for its national level analysis in its economic analysis for the final rulemaking because the EPA has determined that the final rule is feasible given known occurrence concentrations and efficacy of the technologies available. Further, this is consistent with the approach taken in EAs for other NPDWRs (USEPA, 2005; USEPA, 2019; USEPA, 2020). As such, the EPA does not assess variable compliance or enforcement of NPDWRs as part of its EJ analysis. The EPA also notes that compliance with the MCLs for PFAS for all regulated PWSs is mandatory beginning 5 years from the date of rule promulgation. The EPA's SDWA Enforcement Response Policy explains how the EPA typically pursues enforcement cases involving a water system's violations of the SDWA.

In response to the commenter's concern about communities with EJ concerns gaining access to adequate funding, the EPA acknowledges that communities with EJ concerns may face administrative burdens when seeking funding through state and federal programs, such as application processes, additional program requirements, or other barriers, which may discourage program participation from disadvantaged communities. A key priority of BIL is to ensure that disadvantaged communities benefit equitably from this historic investment in water infrastructure. The EPA has collaborated with state SRF programs to share examples and build state capacity to target resources to disadvantaged communities. In addition to the technical assistance offered by the states to disadvantaged communities, the EPA has a substantial water technical assistance program (WaterTA) – in close collaboration with states – to provide

assistance directly to communities including those that lack the financial, managerial, and technical capacity to access federal water infrastructure funding. The EPA's WaterTA efforts are focused on disadvantaged and underserved communities, communities that have never accessed SRF funding before, and communities that are not currently receiving an equivalent kind of TA. For more information on WaterTA, please see the EPA response to comment Doc. #1608, SBC-044005 in section 14.10 in this *Response to Comments* document or https://www.epa.gov/water-infrastructure/water-technical-assistance-waterta.

National Rural Water Association (NRWA) (Doc. #1641, SBC-043260)

Small and rural communities are not responsible for introducing PFAS into the environment or the public's drinking water. Most of the public water systems impacted by PFAS are small and face more challenges complying with federal regulations than more complex water treatment systems. The issues below are the concerns of the small, rural, and disadvantaged water systems that EPA must address before finalizing this rule, and responses to EPA's request for comment.

Cost and Household Affordability

According to EPA's water system inventory, approximately 81 percent of all Public Water Systems (PWS) serve 3,300 or fewer people (39,746 of the total systems), and those serving 500 or fewer account for about 54 percent of all PWSs (26,742 of the total systems). PWSs serving 3,301–50,000 people represent about 17 percent of all PWSs (8,422 of the total systems), and those serving more than 50,000 people account for only about 2 percent (1,025 of the total systems).

Although PWSs serving 3,300 or fewer people account for approximately 81 percent of all PWSs, they serve fewer than 8 percent of the population and households that receive their water from a PWS. Although PWSs serving more than 50,000 people account for only 2 percent of all PWSs, they serve more than half (59 percent) of the population and households that receive their water from a PWS.

Based on these numbers, this rule needs to accurately analyze the impact on our smallest, and most disadvantaged communities. However, this rule was written for large water systems. Small systems with fewer households trying to comply with this regulation will experience financial hardship.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments regarding the EPA's EJ analysis and EJ considerations for the final rule, including funding and the EPA's analysis of costs across demographic groups. Regarding the commenter's concerns about impacts to small, rural, and disadvantaged water systems, please see the EPA response to comment Doc. #1630, SBC-043141 in section 14.10 in this *Response to Comments* document.

American Farm Bureau Federation et al. (Doc. #1642, SBC-043500)

Costs to rural households: As part of the AWWA analysis, the annual financial impacts to individual households from costs associated with the installation and operation of drinking water treatment facilities for PFAS were determined. The financial impacts to individual households will vary by specific PFAS levels, system size, and other factors. However, the trend that gives us greatest concern is the exorbitant impact this rule will place on small, rural communities. As illustrated in the graph below, meeting the 4ppt standard will be wildly more expensive for public water systems that service less populated areas. These financial burdens will be passed on to the water users—effectively becoming an added tax on drinking water for some of America's most economically disadvantaged communities. The AWWA report estimates the annual costs of this proposal on communities with populations of less than 100 will be between $10,000 and $11,000 per household. Many families throughout the country are already paying higher prices for everything from housing to food—and now higher rates for water. The excessive cost of this rule may force these families to make hard decisions on which essential services they can afford.

[Table 2: See Docket ID EPA-HQ-OW-2022-0114-1642]

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments regarding the EPA's EJ analysis and EJ considerations for the final rule, including funding and the EPA's analysis of costs across demographic groups. Regarding the commenter's concerns about impacts to small, rural communities please see the EPA response to comment Doc. #1630, SBC-043141 in section 14.10 in this *Response to Comments* document.

In response to the commenter's reference to the American Water Works Association (AWWA) Black and Veatch (B&V) report findings, the EPA disagrees with many of the underlying assumptions in the AWWA B&V report's cost estimates which, on whole, result in overestimated household costs. These commenters cited cost information that is not representative of the range of treatment costs nationally, and the EPA disagrees with the commenter's cost model that systematically overestimates capital operation and treatment costs. For the EPA's response to comments on treatment costs, please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Raptor Pharm & Tox, Ltd (Doc. #1644, SBC-043420)

Impacts on Small Businesses and the Poor

Raptor has already outlined several issues that America's small businesses and America's poor will face as a result of this action. Lowering the drinking water standard down to levels that are not scientifically supported, and which are also cost prohibitive to most water providers, will ultimately raise prices.

Environmental Justice will suffer due to these drinking water standards. Raising prices on small businesses and the poor during amazingly high inflation, where borrowing costs have

skyrocketed, where spending is down considerably across the economy will hurt small businesses run by BIPOC individuals, such as our company, and the poor the most.

Right now, poor families and small businesses have a hard enough time paying their bills. And everywhere we look, prices keep going up. Poor individuals have to make trade-offs about what bills to pay. Many small businesses are doing the same. Water is essential to life. Raising the cost of water in order to achieve a drinking water standard that is not supported by the science, where the potential benefits are non-existent, based on poorly done studies, on children from populations that are not genetically similar to our own, is no way to make decisions or policy.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments regarding the EPA's EJ analysis and EJ considerations for the final rule, including funding and the EPA's analysis of costs across race/ethnicity and income groups. The EPA disagrees with the commenter's assertion that "Environmental Justice will suffer due to these drinking water standards" as the EPA believes that this action is likely to reduce existing disproportionate and adverse effects on communities with EJ concerns. In the agency's EJ analysis, across all health endpoints evaluated by the EPA, communities of color are anticipated to experience the greatest quantified benefits associated with the final rule.

Regarding the commenter's concern for impacts to "poor families," as discussed in section 14.10 of the EPA response in this *Response to Comments* document, in the EPA's EJ analysis for the final rule, the agency examined the distribution of costs across demographic groups and across multiple water system size categories. As discussed in section 14.10 of the EPA response in this *Response to Comments* document, when examining costs anticipated to result from the rule, the EPA found that cost differences across race/ethnicity and income groups were typically small, with no clear unidirectional trend in cost differences based on demographic group.

In response to the commenter's mention of impacts on small businesses, please see section 14.3 of the EPA response in this *Response to Comments* document for responses to comments on the EPA's actions taken as required under the RFA/SBREFA. For discussion of impacts to small water systems, please see the EPA response to comment Doc. #1630, SBC-043141 in section 14.10 in this *Response to Comments* document.

Additionally, the EPA disagrees with the commenter's assertion that the standards promulgated as part of this final action are "not scientifically supported". The EPA notes that the PFAS NPDWR is informed by regulatory development requirements under SDWA and includes the EPA's analysis of the best available and most recent peer-reviewed science. For further discussion of PFAS adverse health effects, please see sections II.B, III.B, and IV of the preamble for this action. The EPA also disagrees with the commenter's incorrect assertion that "the benefits are non-existent." The EPA has prepared robust benefits estimates for this action by compiling and synthesizing the best available and peer-reviewed information. Additionally, the Administrator determined at proposal that the benefits of the rule justify its costs. For further discussion of the EPA's responses to comments related to the agency's benefits estimates for this

action, please see section 13.4 of the EPA response in this *Response to Comments* document. For other discussion of scientifically-based decisions the agency has made, please see sections 4 (MCLGs), 5 (MCLs), 10 (treatment technologies), and 13 (costs and benefits) of the EPA response in this *Response to Comments* document for further discussion.

J.R. Simplot Company (Doc. #1661, SBC-044152)

Financial Assistance for These Costs and Available Resources Are Limited

The executive summary suggests that various grant funds are available to help communities pay for the installation of PFAS treatment for CWS through the Infrastructure Investment and Jobs Act. [FN4: Federal Register. 2023. Volume 88 (60). P.18,638.] The annual operation and maintenance costs of PFAS treatment equipment is substantial and won't be covered by these grants, so the annual cost burden will be placed on utility customers with higher water bills and especially impact low-income environmental justice communities.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments regarding the EPA's EJ analysis and EJ considerations for the final rule, including funding and the EPA's analysis of costs across race/ethnicity and income groups. For the EPA's responses to comments on treatment costs, please see section 13.3.3 of the EPA response in this *Response to Comments* document.

Blue Ridge Environmental Defense League (BREDL) (Doc. #1663, SBC-044383)

EPA must adhere to their environmental justice goals, policies, and guidance—and instruct federally funded state agencies to do the same.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document.

Blue Ridge Environmental Defense League (BREDL) (Doc. #1663, SBC-044386)

Federally funded agencies should be held to EPA's environmental justice goals, principles, and guidelines. A recent peer-reviewed study from the Harvard T.H. Chan School of Public Health found that: "People who live in communities with higher proportions of Black and Hispanic/Latino residents are more likely to be exposed to harmful levels of per- and polyfluoroalkyl substances in their water supplies than people living in other communities…"[FN1: Harvard T.H. Chan School of Public Health. 15 May 2023. "Communities of color disproportionately exposed to PFAS pollution in drinking water" [Press Release]. https://www.hsph.harvard.edu/news/press-releases/communities-of-color-disproportionately-exposed-to-pfas-pollution-in-drinking-water/?fbclid=IwAR0AmmpNzFs26Pu1lIjKQZfq8E3sxOoWgOkHX3dUgP3td6rChxdAaVTVWYI] It is incumbent upon EPA to ensure that all communities are notified about any PFAS detected in their drinking water.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments regarding the EPA's EJ analysis and EJ considerations for the final rule. Regarding the commenter's assertion that "it is incumbent upon EPA to ensure that all communities are notified about any PFAS detected in their drinking water", for information on the SDWA "right-to-know" requirements for this final rule, including information that will be reported as part of CCRs and through PN to water system consumers, please see section IX of the preamble for this action.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044435)

Page 18732. Section XV – Statutory and Executive Order Reviews

EPA requests comment on all aspects of its EJ analysis, particularly its choice of comparison groups to determine potential demographic disparities in anticipated PFAS exposure and its use of thresholds against which to examine anticipated exposures. For more information, please see section XV.J of this preamble.

Page 18735 says this EJ evaluation was "based on availability of PFAS occurrence data."

• PFAS occurrence data is still fairly limited since public water systems are just now discovering their sources are contaminated with PFAS. Data EPA is using is likely biased, highlighting systems able to test for PFAS and have access to the right information and resources. EPA should consider re-evaluating the EJ impact once more PFAS occurrence data is available.

• More investigation is needed into the smaller, lower income systems that have not yet discovered PFAS contamination. These systems may experience detections of PFAS but may not have the means to install, monitor and maintain ongoing treatment.

EPA Response: The EPA disagrees with the commenter's assertion that PFAS occurrence data used by the EPA is "limited" and "biased" as the EPA believes the occurrence data that underly its rule analyses, including the EJ analysis, are sufficiently representative and robust. As discussed in Section 8.3.1.2.1 of the EPA's EJ analysis in the EA (USEPA, 2024a), this analysis uses modeled entry point concentration estimates from the Bayesian hierarchical Markov chain Monte Carlo (MCMC) occurrence model which employs a statistically robust framework. These modeled occurrence estimates are informed by data from the third UCMR (UCMR 3) and a robust amount of more recently available state monitoring data. For systems not sampled under UCMR 3, the EPA used state monitoring data to inform occurrence estimates used in its EJ analysis.

Additionally, the EPA notes that following the compliance date of the final rule, systems will be required to submit compliance data to states. As part of the EPA's Six-Year Review process set forth under SDWA, the EPA requests the submission of compliance monitoring data and related information by states, which may include newly available PFAS occurrence data. For more information on the EPA's analysis of PFAS occurrence data, please see section VI of the

preamble for this action and section 6 of the EPA response in this *Response to Comments* document.

Aurora Water, City of Aurora, Colorado (Doc. #1669, SBC-043733)

Environmental Justice Aspects

Aurora Water strives to provide safe, equitable and affordable water to all its customers. With the current proposed MCLs, the city will likely be forced to increase rates to maintain and pay for additional compliance costs. Considering the sharp increases in cost of living for other essentials such as energy, food and gas, increased water rates further stretch financial burdens for our most vulnerable communities. EPA should be considering the financial burdens that water systems will incur from this rule which will ultimately have to be passed on to their customers.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments regarding the EPA's EJ analysis and EJ considerations for the final rule, including funding and the EPA's analysis of costs across demographic groups. Regarding the commenter's concerns about water rates, in the EPA's small system affordability analysis, the EPA analyzed the household level cost impacts of the final rule on small system size categories and determined the rule is affordable for small systems. The EPA's affordability determination for the final rule, using longstanding EPA methodology and supplemental affordability analyses, can be found in Chapter 9.13 of the EA for the final rule (USEPA, 2024a).

Arizona Corporation Commission (Doc. #1680, SBC-044218)

2. Additional federal funding and flexibility should be made available to small and disadvantaged water systems.

Historically, PFAS testing and monitoring expenses have been the responsibility of the utility with the understanding that the costs are ultimately passed along to customers through rates. The same has been true of remediation measures. The proposed rule will require significant system upgrades for many small and rural water systems. The treatment for PFAS-contaminated water supplies can pose a huge financial burden on public water supplies, especially small water systems, and low-income communities.2 [FN2: Desikan A, Carter J, Kinser S, Goldman G. 2019. Abandoned Science, Broken Promises: How the Trump Administration's Neglect of Science Is Leaving Marginalized Communities Further Behind. Cambridge, MA: Union of Concerned Scientists, p. 13 https://www.ucsusa.org/resources/abandoned-science-broken-promises ("Nearly 40,000 more low-income households and approximately 300,000 more people of color live within five miles of a site contaminated with PFAS than expected based on US census data.").] The expenses related to cleanup, filtration, and maintenance have significant environmental justice implications with respect to who has access to safe drinking water. Most of these systems cannot cover the costs to monitor and upgrade systems to meet the new MCLs without a significant increase in customer rates. These costs will be crippling for systems with small

customer bases. This highlights the need for additional federal funding grants, extending existing grant opportunities or targeted funds to address small and rural systems. The EPA should also consider whether extending compliance deadlines for small and rural systems is warranted to mitigate rate shock in low-income communities.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments regarding the EPA's EJ analysis and EJ considerations for the final rule, including funding and the EPA's analysis of costs across demographic groups. In response to the commenter's concern regarding disproportionate impacts on small and rural water systems, please see the EPA response to comment Doc. #1630, SBC-043141 in section 14.10 in this *Response to Comments* document.

The EPA acknowledges the commenter's submission of this citation and notes that Desikan et al. (2019) is cited in the literature review conducted to supplement the EPA's EJ analysis for this rule, which can be found in in Section 8.2 of the EA (USEPA, 2024a).

For the final rule, the EPA is extending the MCL compliance deadline to take effect five years after rule promulgation for all systems subject to the rule. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12.1 of the EPA response on extensions and exemptions in this *Response to Comments* document.

Environmental Working Group (EWG) (Doc. #1721, SBC-045404)

PFAS pollution is particularly concerning for low-income communities and communities that face historically disproportionate exposure to pollution, cumulative adverse health effects of multiple co-occurring contaminants, and potentially insurmountable costs of water treatment or remediation. Recent research suggests that communities where most residents are people of color are likely exposed to higher levels of PFAS in their drinking water. [FN8: Jahred M. Liddie, Laurel A. Schaider, & Elsie Sunderland, Sociodemographic Factors Are Associated with the Abundance of PFAS Sources and Detection in U.S. Community Water Systems, 57 ENV'T SCI. & TECH. 7902 (2023), https://pubs.acs.org/doi/10.1021/acs.est.2c07255. See also Susan Lee, Avinash Kar, & Anna Reade, Dirty Water: Toxic "Forever" PFAS Chemicals are Prevalent in the Drinking Water of Environmental Justice Communities, NAT. RES. DEF. COUNCIL (2021), https://www.nrdc.org/sites/default/files/dirty-water-pfas-ej-communities-report.pdf; Genna Reed, PFAS Contamination is an Equity Issue and President Trump's EPA is Failing to Fix It, UNION OF CONCERNED SCIENTISTS (Oct. 30, 2019), https://blog.ucsusa.org/genna-reed/pfas-contamination-is-an-equity-issue-president-trumps-epa-is-failing-to-fix-it/.] Indigenous communities that rely on subsistence fishing, hunting, and agriculture are especially vulnerable when fish, wildlife, and crops are contaminated with PFAS. These communities are doubly exposed when PFAS is also present in their drinking water. EPA's proposed maximum contaminant levels align with EPA's commitment to advance environmental justice by addressing historical contamination and deterring ongoing releases of these toxic chemicals into the environment.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments regarding the EPA's EJ analysis and EJ considerations for the final rule, including funding and the EPA's analysis of costs across demographic groups. The EPA acknowledges the commenter's support of the final rule and its alignment with the agency's commitment to advancing EJ. Based on this comment, the EPA has added Liddie et al. (2023) to the literature review conducted to supplement the EPA's EJ analysis for this rule, which can be found in in Section 8.2 of the EA (USEPA, 2024a).

Natural Resources Defense Council (NDRC) et al. (Doc. #1723, SBC-044468)

May 28, 2023

Administrator Michael S. Regan

U.S. Environmental Protection Agency

EPA Docket Center, OW Docket

Mail Code 28221T

1200 Pennsylvania Avenue NW

Washington, DC 20460

Re: Per- and Polyfluoroalkyl Substances (PFAS): Proposed National Primary Drinking Water Regulations (Docket ID: EPA-HQ-OW-2022-0114)

Dear Administrator Regan,

The undersigned thirty-nine organizations strongly support the Environmental Protection Agency's proposal to set strong, scientifically supported drinking water standards for six per- and polyfluoroalkyl substances (PFAS) under the Safe Drinking Water Act. National standards to limit the concentration of PFAS in drinking water are necessary to protect human health, as EPA has documented in its proposal. And they are long overdue. We urge you to finalize the proposed standards as quickly as possible, with the changes recommended by many of our organizations in separately submitted comments.

In this letter, we write specifically to urge EPA to resist calls to weaken or withdraw the proposed standards based on concerns over water affordability. We are steadfast advocates for universal, affordable access to safe drinking water. EPA must not accept the premise that drinking water can be either safe from toxic PFAS or affordable, but that it cannot be both. It can and must be both. And EPA must lead the way. We offer recommendations below on how to do so.

* * *

EPA's proposed PFAS standards align with the Biden Administration's commitment to advance environmental justice. Communities of color and low-income communities have historically

faced disproportionate exposure to pollution and cumulative adverse health effects from multiple co-occurring contaminants. Published research suggests that communities with higher populations of people of color may be especially impacted by PFAS.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments regarding the EPA's EJ analysis and EJ considerations for the final rule, including funding and the EPA's analysis of costs across demographic groups. The EPA acknowledges the commenter's support of the final rule and its alignment with the federal government's commitment to advance EJ. The EPA is working as expeditiously as possible to promulgate this final rule to reduce exposure to PFAS in drinking water.

Thurston Public Utility District (PUD), WA (Doc. #1729, SBC-043575)

May 29, 2023

Michael Regan, Administrator

Environmental Protection Agency

1200 Pennsylvania Ave NW

Mail Code: 1309

Washington, DC 20004

RE: Per- and polyfluoroalkyl substances (PFAS): Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) National Primary Drinking Water Regulation Rulemaking, Docket No. EPA–HQ–OW-2022-0114

Dear Administrator Regan:

I am the General Manager of Public Utility District No. 1 of Thurston County (Thurston PUD), a regional governmental public utility district in Washington State responsible for the operation and management of 78 small Group A water systems serving a population of over 21,000 families, businesses, parks, and schools. We have tested all our Group A water systems for PFAS, and I would like to submit testimony on the proposed EPA PFAS maximum contaminant levels (MCL). Under the proposed MCLs, nine (9) of our water systems would require treatment, which means that 68.3 percent of the customers on Thurston PUD's 78 Group A water systems would be exposed to PFAS materials above the proposed MCL.

Thurston PUD management and staff are dedicated drinking water professionals, and we understand and appreciate the efforts made to attain cleaner water. Our utility has a long history of achieving compliance within drinking water standards. We are grateful for the resources provided to deliver safe drinking water and address emerging contaminants like per- and polyfluoroalkyl substances (PFAS), particularly through the Infrastructure Investment and Jobs Act. At the same time, we would like to stress the scale of the proposed undertaking and the need

for financial relief for many communities, especially those that are small, disadvantaged, and lacking in professional capacity. Otherwise, the costs associated with the EPA's proposal risks falling disproportionately on vulnerable populations. We have studied and concur with the attached letter submitted to your office by Lakewood Water District (Lakewood, WA), dated May 24, 2023, addressing PFAS contamination of drinking water relating to this rule. To reiterate:

1. Costs are systematically underestimated.

2. Federal funding support is exaggerated.

3. The proposed trigger levels are inappropriate.

4. The proposed Hazard Index approach is flawed.

5. Penalties for monitoring are counterproductive.

6. The timeline to implement is not feasible.

This is the first new contaminant to be regulated in drinking water in three decades and the first since Congress significantly amended the Safe Drinking Water Act (SDWA) in 1996. This is a new experience for many and will entail an additional learning curve especially given this is the first time EPA has chosen to use a Hazard Index for a federal drinking water MCL.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments regarding the EPA's EJ analysis and EJ considerations for the final rule, including funding and the EPA's analysis of costs across demographic groups. The EPA disagrees with the commenter's assertion that "costs associated with the EPA's proposal risks falling disproportionately on vulnerable populations." As explained in section 14.10 of the EPA response in this *Response to Comments* document, when examining costs anticipated to result from the rule, the EPA found that cost differences across demographic groups were typically small, with no clear unidirectional trend in cost differences based on demographic group. The EPA also disagrees with the commenter's assertion that "federal funding support is exaggerated." As discussed in section 14.10 of the EPA response in this *Response to Comments* document, to alleviate potential cost disparities identified by the EPA's analysis, there may be an opportunity for many communities to utilize BIL funding to provide financial assistance for addressing emerging contaminants. For further discussion of BIL funding, please see section 2.4 of the EPA response in this *Response to Comments* document.

The EPA disagrees that the costs of the rule are underestimated; please see section 13.3 of the EPA response in this *Response to Comments* document for the agency's responses to comments regarding the EPA's methods for estimating costs, including updates to the EPA's cost models based on public comments. The EPA also disagrees with the commenter's assertion that "the proposed trigger levels are inappropriate" and that "penalties for monitoring are counterproductive"; for responses to comments on the EPA's monitoring requirements, including trigger levels, please see section 8 of the EPA response in this *Response to Comments* document

(specifically section 8.8 for discussion of trigger levels). The EPA also disagrees that the Hazard Index approach is flawed; for more information on the Hazard Index, please see section V.B of the preamble for this action and sections 4.3.2 and 5.2 of the EPA response in this *Response to Comments* document. Finally, the EPA disagrees with the commenter's assertion that the "timeline to implement is not feasible," particularly because the EPA has extended its MCL compliance deadline to 5 years following final rule promulgation. For response to comments on the EPA's compliance timeline, please see section 12.1 of the EPA response in this *Response to Comments* document.

U.S Conference of Mayors, National League of Cities and National Association of Counties (Doc. #1733, SBC-043892)

Further, many American households currently face a significant and widespread financial burden when it comes to water bills. This burden falls disproportionately on fixed- and low- income households who must dedicate a significant portion of their income to water. Given the Administration's focus on environmental justice, water rate affordability must be a part of the consideration in this proposed regulation.

In light of the Administration's Justice40 initiative, EPA should additionally recognize that the financial burden on low-income and environmental justice communities associated with meeting environmental requirements is an important aspect of environmental justice. The financial burden that increased rates will have on disadvantaged communities should be a consideration in this and other rules and regulations.

This burden can be alleviated by providing additional flexibility for local governments, a longer compliance timeframe, and additional direct funding for local governments.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments on the EPA's EJ analysis and EJ considerations for the final rule, including funding and the EPA's analysis of costs across race/ethnicity and income groups. Regarding the commenter's concern about water rate affordability, in the EPA's small system affordability analysis, the EPA analyzed the household level cost impacts of the final rule on small system size categories and determined the rule is affordable for small systems. The EPA's affordability determination for the final rule, using longstanding EPA methodology and supplemental affordability analyses, can be found in Chapter 9.13 of the EA for the final rule (USEPA, 2024a).

With respect to the commenter's suggestion for a longer compliance timeframe, the EPA notes that the agency has extended its MCL compliance deadline to 5 years following final rule promulgation. For additional discussion on supply chain and labor challenges that may affect the compliance timeline, please see section 12.1 of the EPA response on extensions and exemptions in this *Response to Comments* document.

With respect to the commenter's note about Justice40, following the establishment of the Justice40 Initiative under Executive Order 14008 on January 27, 2021, the EPA received Interim Guidance to support the implementation of Justice40 which included six programs as part of the Justice40 pilot. Since establishing the pilot program, the agency has expanded the number of applicable programs, including those programs funded by BIL that match criteria for Justice40. For a list of the EPA's Justice40 Initiative covered programs, please see: https://www.epa.gov/system/files/documents/2022-07/Justice40%20Initiative%20Covered%20Programs%20List%20for%20EPA.pdf. Though the PFAS NPDWR does not fall under the EPA's list of Justice40 Initiative covered programs, this regulatory action will facilitate the goals of Justice40 as the agency's EJ analysis found that communities of color are anticipated to experience the greatest quantified benefits associated with the final rule, as described in section 14.10 of the EPA response in this *Response to Comments* document. Additionally, the EPA found that cost differences across race/ethnicity and income groups to be small and BIL funding will be available to provide financial assistance in cases where cost disparities may occur, with specific allocations for disadvantaged and/or small communities (see section 14.10 of the EPA response in this *Response to Comments* document for further discussion). Additionally, for discussion of technical assistance available to disadvantaged and/or small communities, including the EPA's WaterTA program, please see the EPA responses to comment Doc. #1640, SBC-044378 and Doc. #1608, SBC-044005 in section 14.10 in this *Response to Comments* document. For more information on the EPA's implementation of Justice40, please see: https://www.epa.gov/environmentaljustice/justice40-epa.

Florida Section American Water Works Association - Water Utility Council (FSAWWA WUC) (Doc. #1737, SBC-044494)

XV.Statutory and Executive Order Reviews, J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations.

The Florida Water Sector requests EPA more adequately address Environmental Justice concerns based on the expected increase electrical use, carbon/coal consumption, fuel consumption, and the expected higher utility bills for our low-income and disadvantaged communities.

In closing , we thank EPA for the opportunity to provide import ant input on behalf of the FSAWWA WUC. If you have any questions regarding this correspondence, or we can be of assistance in anyway, please contact me at mwallis@dwuinc.com or 850-337-3945

Sincerely,

Monica Wallis, Chair

FSAWWA Water Utility Council

on behalf of the FSAWWA

EPA Response: The EPA believes it has appropriately and adequately addressed EJ considerations in this regulation. See section 14.10 of the EPA response in this *Response to Comments* document for responses to comments on the EPA's EJ analysis and EJ considerations for the final rule, including funding and the EPA's analysis of costs across race/ethnicity and income groups.

In response to the commenter's stated concerns regarding "expected increase electrical use, carbon/coal consumption, fuel consumption," please see section 13.11 of the EPA response in this *Response to Comments* document. In response to comments on the proposed rule, the EPA analyzed the climate disbenefits of CO_2 emissions associated with the increased electricity use at PWSs as a result of compliance with the PFAS NPDWR. For more information on this analysis, please see Section 9.2 of the EA (USEPA, 2024a).

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045990)

EPA should consider the distribution of PFAS nationwide and understand that without additional federal support, the burden of treating PFAS will fall disproportionately on communities of color. AMWA supports the Agency's goal of fairly treating all people regardless of race, color, national origin, or income, with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies [FN29: EPA. (2023, May 12). Environmental justice. https://www.epa.gov/environmentaljustice]. However, in this proposal and related activities, EPA has failed to examine or plan for whether communities are treated fairly with regard to the costs required to implement this proposed regulation. A recent study by Liddie, Schaider, and Sunderland19 analyzed over 7,000 community water systems and found that CWSs "serving higher proportions of Hispanic/Latino and non-Hispanic Black residents had significantly increased odds of detecting several PFAS." This finding indicates that communities of color may be more likely to be in an area with industrial or other sources of PFAS contamination and that their community will likely have to treat more PFAS out of their water, increasing customer rates. In its final rulemaking, AMWA encourages EPA to consider how to partner with CWSs to ensure that communities of color are both equally protected from PFAS in drinking water and not disproportionately required to pay for contamination their communities did not create.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments on the EPA's EJ analysis and EJ considerations for the final rule, including funding and the EPA's analysis of costs across race/ethnicity and income groups.

Based on this comment, the EPA has added Liddie et al. (2023) to the literature review conducted to supplement the EPA's EJ analysis for this rule, which can be found in in Section 8.2 of the EA (USEPA, 2024a).

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045985)

Environmental justice and climate change impacts are huge issues PWSs must address and are at the forefront of this Administration's priorities. However, this proposal not only puts underserved and disadvantaged communities at risk, but it will also significantly raise drinking water rates of some of the most vulnerable populations. A recent study by Liddie, Schaider, and Sunderland (2023) [FN 19: Liddie, Schaider, and Sunderland. (15 May 2023). Sociodemographic Factors Are Associated with the Abundance of PFAS Sources and Detection in U.S. Community Water Systems. Environmental Science & Technology. DOI: 10.1021/acs.est.2c07255], found that "[Community water systems] serving higher proportions of Hispanic/Latino and non-Hispanic Black residents had significantly increased odds of detecting several PFAS." Consequently, the costs of PFAS removal will not only fall on ratepayers, but it will disproportionately affect Hispanic/Latino and non-Hispanic Black ratepayers. EPA should reflect on this conclusion and work to reduce burdens on these communities when finalizing this proposal.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments on the EPA's EJ analysis and EJ considerations for the final rule, including funding and the EPA's analysis of costs across race/ethnicity and income groups. The EPA disagrees with the commenter's assertion that this action "puts underserved and disadvantaged communities at risk" and will "significantly raise drinking water rates of some of the most vulnerable populations;" please see the EPA response to comment Doc. #1644, SBC-043420 in section 14.10 in this *Response to Comments* document. Additionally, in the EPA's small system affordability analysis, the EPA analyzed the household level cost impacts of the final rule on small system size categories and determined the rule is affordable for small systems. The EPA's affordability determination for the final rule, using longstanding EPA methodology and supplemental affordability analyses, can be found in Chapter 9.13 of the EA for the final rule (USEPA, 2024a).

Based on this comment, the EPA has added Liddie et al. (2023) to the literature review conducted to supplement the EPA's EJ analysis for this rule, which can be found in Section 8.2 of the EA (USEPA, 2024a).

In response to the commenter's concerns about climate change impacts for PWSs, please see section 13.11 of the EPA response in this *Response to Comments* document. In response to comments on the proposed rule, the EPA analyzed the climate disbenefits of CO_2 emissions associated with the increased electricity use at PWSs as a result of compliance with the PFAS NPDWR. For more information on this analysis, please see Section 9.2 of the EA (USEPA, 2024a).

Connecticut Department of Public Health (CT DPH) (Doc. #1745, SBC-045206)

7. CT DPH supports EPA's stated commitment to environmental justice for PFAS pollution. EPA's commitment to environmental justice reinforces the CT DPH's efforts to promote health

equity in disadvantaged communities. We support EPA's efforts and commitments to assisting disadvantaged communities.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments on the EPA's EJ analysis and EJ considerations for the final rule. The EPA acknowledges the commenter's support of the EPA's commitment to EJ and commitments to assisting communities with EJ concerns.

City of Thornton, Colorado (Doc. #1748, SBC-044786)

Cost increases will disproportionately impact disadvantaged communities who may then have difficulty affording enough treatment media to meet the proposed MCL.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for discussion of the EPA's EJ analysis and EJ considerations for the final rule, including funding and the EPA's analysis of costs across demographic groups. With respect to the commenter's concern about communities affording treatment upgrades to comply with the final rule, the EPA's affordability determination for the final rule, using longstanding EPA methodology and supplemental affordability analyses, can be found in Chapter 9.13 of the EA for the final rule (USEPA, 2024a).

City of Thornton, Colorado (Doc. #1748, SBC-044792)

Thornton's preliminary engineering efforts do indicate that an MCL of 4 ppt is technologically feasible to achieve but the City does note that this comes at a significant cost burden. However, Thornton is concerned with the environmental justice impact of the proposed rule. Rate increases, anticipated to be up to 19% over the next decade, to support the treatment of PFAS will be equally applied to all customers but will disproportionally impact our poorer residents. Thornton is also concerned that it will be financially challenging for many disadvantaged communities to meet the proposed MCL. Communities that are in a financial position, such as Thornton, will be able to target treating down toward the MCLG, whereas disadvantaged communities may choose to barely meet the MCL in an effort to save money rather than protect health as much as possible. These disadvantaged communities are usually collocated in heavily industrialized or heavily polluted areas and are disproportionately impacted by these compounds.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for discussion of the EPA's EJ analysis and EJ considerations for the final rule, including funding and the EPA's analysis of costs across race/ethnicity and income groups. With respect to the commenter's concern that potential rate increases "will disproportionately impact our poorer residents," please also see the EPA's affordability determination for the final rule, using longstanding EPA methodology and supplemental affordability analyses, which can be found in Chapter 9.13 of the EA for the final rule (USEPA, 2024a).

The EPA concurs with the commenter that an MCL of 4.0 ppt for PFOA and PFOS is technologically feasible. With respect to the commenter's concern that the EPA's MCLs of 4 ppt carry a "significant cost burden", please see section 13.3 of the EPA response in this *Response to Comments* document for responses to comments on the EPA's cost estimates for the final rule.

Harris County Attorney's Office (HCA) (Doc. #1751, SBC-045262)

PFAS exposure may disproportionally affect environmental justice communities. HCA asks EPA to ensure these residents and other low-resourced communities do not bear the brunt of cleanup costs.

Unfortunately, PFAS contamination appears to be ubiquitous across the county. One 2015 report indicates PFAS are found in the blood of 97% of Americans. [FN4: Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS), Nat'l Inst. Env't Health Scis., https://www.niehs.nih.gov/health/topics/agents/pfc/index.cfm#footnote1 (last visited May 23, 2023); Ryan C. Lewis et al., Serum Biomarkers of Exposure to Perfluoroalkyl Substances in Relation to Serum Testosterone and Measures of Thyroid Function among Adults and Adolescents from NHANES 2011–2012, 12(6) Int'l J. Env't Rsch. Pub. Health 6098–6114 (2015).] Another study concluded that over 200 million Americans likely receive water with PFAS. [FN5:David Q. Andrews & Olga V. Naidenko, Population-Wide Exposure to Per- and Polyfluoroalkyl Substances from Drinking Water in the United States, 7(12) Env't Sci. & Tech. 931–936 (2020).] But, as with many environmental harms, recent studies indicate that environmental justice (EJ) communities appear to bear the disproportional brunt of PFAS pollution. For example, a study published on May 15th of this year concludes PFAS detection is positively associated with the number of PFAS sources and proportions of people of color who are served by the community water systems (CWS) studied. The study also concluded that CWS contaminated with PFAS serve greater proportions of Hispanic/Latino and non-Hispanic Black populations and contain greater numbers of PFAS sources within their watersheds. [FN6: Jared M. Liddie et al., Sociodemographic Factors are Associated with the Abundance of PFAS Sources and Detection in U.S Community Water Systems, 57(21) Env't Sci. & Tech. 7902, 7902 (2023) ("CWS watersheds with PFAS sources served higher proportions of Hispanic/Latino and non-Hispanic Black residents compared to those without PFAS sources. CWS serving higher proportions of Hispanic/Latino and non-Hispanic Black residents had significantly increased odds of detecting several PFAS.")] Reports by the Union of Concerned Scientist and the Natural Resource Defense Counsel also indicate PFAS exposure may disproportionately impact environmental justice communities. [FN7: Anita Desikan et al., Abandoned Science, Broken Promises, Union of Concerned Scientists, 13-14 (2019) https://www.ucsusa.org/sites/default/files/2019-10/abandoned-science-broken-promises-web-final.pdf ("Low-income communities, Indigenous communities, and communities of color may face increased contamination risks from an endocrinedisrupting class of chemicals known as PFAS (polyfluoroalkyl and perfluoroalkyl substances"); Susan Lee et al,, Dirty Water: Toxic "Forever" PFAS Chemicals Are Prevalent in the Drinking Water of Environmental Justice Communities, Nat. Res. Def. Council, 4 (2021) ("PFAS pollution is more intense in [Californian]

communities already overburdened by multiple sources of pollution and by other factors that make them more sensitive to pollution, putting those vulnerable communities at greater risk of harm from PFAS exposure").]

HCA is concerned that the cost of PFAS cleanup could be passed onto blameless residents. By EPA's own estimates, the total annual cost per household for the various potential compliance technologies is notably higher for the systems that serve a population of 25-500 than those that serve 501-3,300 and 3,301-10,000. Some residents in states that have enacted their own drinking water standards for PFAS have faced notable hikes in their water bills. [FN8: Danica Jefferies, Water PFAS clean-up costs could trickle down, NBC News, (Apr. 24, 2023) https://www.nbcnews.com/datagraphics/water-pfas-clean-costs-trickle-rcna80504.] The possibility that low-resource and overburdened communities served by PFAS heavy systems could face additional economic damage is especially troubling. HCA is concerned that a nationwide spike in demand for PFAS removal technologies will cause the price of compliance to rise drastically, and expensive drinking water bills will impact vulnerable members of the community living on fixed incomes.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for discussion of the EPA's EJ analysis and EJ considerations for the final rule, including funding and the EPA's analysis of costs across race/ethnicity and income groups. With respect to the commenter's concern related to the cost of compliance technologies and the impact of "expensive drinking water bills," please also see the EPA's affordability determination for the final rule, using longstanding EPA methodology and supplemental affordability analyses, which can be found in Chapter 9.13 of the EA for the final rule (USEPA, 2024a) and section 13.3 of the EPA response in this *Response to Comments* document for responses to comments on the EPA's cost estimates for the final rule.

Based on this comment, the EPA has added Liddie et al. (2023) to the literature review conducted to supplement the EPA's EJ analysis for this rule, which can be found in in Section 8.2 of the EA (USEPA, 2024a). The EPA notes that Desikan et al. (2019) and Lee et al. (2021) are also cited in the EPA's literature review in Section 8.2.

American Water Works Association (AWWA) (Doc. #1759, SBC-045632)

12. Executive Order 12898 – Achieving Environmental Justice

AWWA and our members have first-hand knowledge and experience of how the increased costs associated with new regulations such as the ones proposed here directly impact the customers of our water system members. Many water systems are small, public, or quasi-public entities. Increased compliance costs are necessarily passed on to customers in the form of high rates for their drinking water. As a result, unjustified compliance costs have a disproportionate impact on economically disadvantaged customers as they are least able to afford these rate increases. This is disproportionate impact is particularly acute with respect to water infrastructure for several reasons. First, water systems serve local customers, they do not have the ability to spread costs

out across a national customer-base. Second, because household water use is a necessity and most households cannot meaningfully scale back on their needs for drinking water when prices increase. Consequently, they are unable to take steps to reduce their water bills when water systems are forced to increase rates.

Congress amended the SDWA in 1996, recognizing that the Act's prior requirements, and associated economic burdens on water systems and the States were making the SDWA unworkable. [FN26: S. Rep. No. 104-169 at 2, 11, 17 (1995); H.R. Rep. No. 104-632 at 9 (1996); see also S. Rep. No. 104-169 at 12−13 (noting that the prior version of the Ac was the "quintessential example of an arbitrary Federal law imposing burdens on consumers and the taxpayers of other governments with no rational relationship to the public benefits that might be realized.").] As a member of Congress explained at the time, "[c]ustomers will pay for safe drinking water . . . [b]ut are not willing to pay for complying with drinking water rules that provide only marginal increases in health protection at significant costs, particularly when there is so much uncertainty concerning both the occurrence and real threat to public health of many contaminants." [FN27: H.R. Rep. No. 104-632 at 9 (quoting Ronald Dungan, President of the National Association of Water Companies).]

EPA's current analysis also fails to consider how these increased compliance costs will impact environmental justice communities, as required by Executive Order 12898. As you know, Executive Order 12898 directs each Federal agency to "make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations." EPA should revise its environmental justice analysis to reflect the burdens that the compliance costs associated with the new proposed requirements would place on environmental justice communities and further consider whether these additional burdens are appropriate in light of these impacts.

AWWA further notes that prematurely issuing national primary drinking water regulations for contaminants when the occurrence data indicates that it only occurs in drinking water at levels of public health concern in localized areas would cause communities, rather than those responsible for the pollution, to foot the bill for the problem. To avoid this inequitable result EPA should focus on using its other authorities to address any necessary clean ups, rather than pass the costs on in the form of higher rates due to increased SDWA compliance costs.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for discussion of the EPA's EJ analysis and EJ considerations for the final rule, including funding and the EPA's analysis of costs across race/ethnicity and income groups. With respect to the commenter's concern about water rates, please also see the EPA's affordability determination for the final rule, using longstanding EPA methodology and supplemental affordability analyses, which can be found in Chapter 9.13 of the EA for the final rule (USEPA, 2024a) and section 13.3 of the EPA response in this *Response to Comments* document for responses to comments on the EPA's cost estimates for the final rule. The EPA disagrees with the commenter's assertion that its analysis "fails to consider how these increased

compliance costs will impact environmental justice communities" because the EPA has presented the distribution of costs anticipated to result from the final rule across demographic groups in its EJ analysis; for further discussion, please see section 14.10 of the EPA response in this *Response to Comments* document.

The EPA notes that while the commenter states that PFAS "only occurs at levels of public health concern in localized areas" in this part of their comment letter (thereby implying that the EPA has overestimated the magnitude and importance of PFAS occurrence in drinking water), in other parts of their comment letter, the commenter claims that the EPA has underestimated PFAS occurrence (and therefore costs). The EPA disagrees with the commenter's assertion that the EPA is "prematurely issuing national primary drinking water regulations for contaminants when the occurrence data indicates that it only occurs in drinking water at levels of public health concern in localized areas" just as the agency disagrees with other commenters' other assertions that the EPA has significantly underestimated PFAS occurrence; for responses to comments related to the EPA's analysis of PFAS occurrence data, please see sections 3.1.2, 3.2.2, and 6 of the EPA response in this *Response to Comments* document.

Center for Environmental Health et al. (Doc. #1764, SBC-044239)

Radhika Fox

Assistant Administrator

Office of Water US Environmental Protection Agency

1200 Pennsylvania Avenue NW, Washington, DC 20460

Re: Docket ID No. EPA-HQ-OW-2022-0114: Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

Dear Assistant Administrator Fox:

We write to urge EPA to center environmental justice in the finalization of its Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation [FN1: US EPA. "PFAS National Primary Drinking Water Regulation Rulemaking", 88 Fed. Reg. 18,638 (Mar. 29, 2023) (the "Proposal").]. The undersigned organizations represent a diverse set of stakeholders across the State of North Carolina, considered by many to be the 'ground zero' of polyfluoroalkyl substances (PFAS) contamination in the US, and their allies across the nation. The proposed regulation is an important fulfillment of some of the commitments EPA made to regulate this persistent class of toxic chemicals. With enforcement of National Primary Drinking Water Standards (NPDWS) for PFOS and PFOA, EPA can finally begin to "turn off the tap" of PFAS at the source based on health-protective toxicity assessments.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for discussion of the EPA's EJ analysis and EJ considerations for the final rule. The EPA acknowledges the commenter's support of this action and the EPA's commitment

to regulate PFAS. Through this action, the EPA reaffirms the importance of EJ considerations in agency activities, including rulemaking.

Center for Environmental Health et al. (Doc. #1764, SBC-044245)

PFAS have been detected in drinking water supplies of nearly 200 million Americans, yet people of color and low-income Americans are particularly likely to have high levels of PFAS in their drinking water [FN5: J.M. Liddle, L. Schaider, and E.M. Sunderland. Sociodemographic Factors Are Associated with the Abundance of PFAS Sources and Detection in U.S. Community Water Systems. ACS Environmental Science and Technology, (May 15, 2023), DOI: 10.1021/acs.est.2c07255]. This is most likely due to the history of redlining and discriminatory zoning practices that incentivized companies to manufacture PFAS (and thousands of other toxic chemicals) near the most vulnerable communities. We urge the agency to quickly finalize the NPDWS proposal and improve its process of iteratively engaging these communities in its implementation and future enforcement actions. When PFAS is no longer detected in the drinking water of the most disadvantaged communities in North Carolina, it will surely confirm a reduction of these 'forever chemicals' in all of our bodies and the environment.

Sincerely,

Center for Environmental Health

Toxic Free North Carolina

Cape Fear River Watch

Clean Cape Fear

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for discussion of the EPA's EJ analysis and EJ considerations for the final rule. The EPA acknowledges the commenter's support of this action; the agency is working as expeditiously as possible to finalize the PFAS NPDWR. Through this action, the EPA reaffirms the importance of EJ considerations in agency activities, including rulemaking. With respect to the commenter's request for the EPA to "improve its process of iteratively engaging these communities," please see the EPA response to comment Doc. #1554, SBC-043973 in section 14.10 in this *Response to Comments* document.

Based on this comment, the EPA has added Liddie et al. (2023) to the literature review conducted to supplement the EPA's EJ analysis for this rule, which can be found in Section 8.2 of the EA (USEPA, 2024a).

Sierra Club of Hawa''i (Doc. #1771, SBC-044731)

Environmental Justice

Water is a foundation for all life. However it is also a finite and threatened resource and in the face of climate change, access to clean safe drinking water will only become more difficult with disproportionate impacts on low-income communities of color. Our communities deserve to feel secure in their drinking water sources and not be reliant on expensive bottled water or filtration systems. Knowing the health and environmental impacts of Per- and Polyfluoroalkyl substances we cannot continue to turn a blind-eye to the contamination of our drinking water sources. The EPA's proposed standards will help provide a level of security that has not existed before.

Importantly, these standards create legal limits of PFAS chemicals in the water supply, meaning that legal action can be taken if the contaminants exceed these limits and are not addressed. The establishment of legal limits also provides clarification on the expectations for the use of PFAS chemicals and on the standards for providing safe, healthy drinking water for the public.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for discussion of the EPA's EJ analysis and EJ considerations for the final rule. The EPA acknowledges the commenter's support of this action and the EPA's commitment to regulate PFAS. Through this action, the EPA reaffirms the importance of EJ considerations in agency activities, including rulemaking.

Silent Spring Institute (Doc. #1784, SBC-045804)

5. EPA should target support towards communities and water systems that bear the brunt of PFAS contamination, including, but not limited to, small water systems, rural or isolated systems, overburdened systems, communities of color, low-income communities, and communities in proximity to PFAS-manufacturing and media-disposal facilities.

Our research and that of others demonstrates that PFAS contamination and remediation is an environmental justice issue. EPA's conclusion that "the proposed rule is anticipated to mitigate the disproportionate impacts of baseline PFAS exposure" is consistent and should be emphasized. We acknowledge, and support, that the proposed rule incorporates monitoring flexibilities and EPA's plans to provide financial assistance to support disadvantaged systems and communities for remediation.

Here, we highlight additional and recent research to emphasize why EPA should target support to systems and communities with disproportionate exposures to PFAS. Research from the Union of Concerned Scientists indicated a disproportionate number of low-income households (15% more than expected based on U.S. Census data) and of people of color (22% more than expected) living within 5 miles of a PFAS-contaminated site. [REF30: Desikan A, Carter J, Kinser S, Goldman G. Abandoned Science, Broken Promises: How the Trump Administration's Neglect of Science Is Leaving Marginalized Communities Further Behind. Cambridge, MA: Union of Concerned Scientists; 2019.] Recently, we identified that public water systems serving communities with higher proportions of non-Hispanic Black residents and Hispanic residents were more likely to detect PFAS contaminants, both from compiled state data [REF5: Liddie JM, Schaider LA, Sunderland EM. Sociodemographic factors are associated with the abundance of

PFAS sources and detection in U.S. community water systems. Environ Sci Technol. 2023.] and using the UCMR3. [REF31: Schaider L, Hernandez A, Swartz C, Liddie J. Socioeconomic disparities in exposures to unregulated industrial contaminants in U.S. public drinking water supplies [Conference Abstract]. International Society for Environmental Epidemiology; 2022.] We also note that Tribal communities were underrepresented in the UCMR3, which may mean that the extent of PFAS contamination among Tribal communities was underestimated. [REF32: Mok K, Salvatore D, Powers M, et al. Federal PFAS Testing and Tribal Public Water Systems. Environ Health Perspect. 2022;130(12):127701.]

Rural and isolated systems may not only have very high PFAS levels, but also may struggle to implement treatment technologies, cover analytical costs, or both. For example, the highest levels of PFOS and PFHxS measured in the UCMR3 were on the island of Saipan, located in the U.S. territory of the Northern Mariana Islands. Since the UCMR3, public water systems in both the islands of Saipan and Guam faced challenges in treating and monitoring PFAS in part due to the rural and isolated nature of these systems. These challenges highlight the environmental justice implications and the need for EPA to ensure equitable implementation and to plan support to focus on systems and communities that bear the brunt of PFAS contamination, cleanup, and remediation.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for discussion of the EPA's EJ analysis and EJ considerations for the final rule, including funding and the EPA's analysis of costs across race/ethnicity and income groups. The EPA acknowledges the commenter's support of this action and the findings of the agency's EJ analysis. For responses to comments related to potential impacts of disposal of PFAS contaminated treatment residuals on communities adjacent to disposal facilities, please see section 10.4.3 of the EPA response in this *Response to Comments* document. With respect to the commenter's concerns regarding impacts on rural systems, please see the EPA response to comment Doc. #1630, SBC-043141 in section 14.10 in this *Response to Comments* document.

Based on this comment, the EPA has added Liddie et al. (2023) to the literature review conducted to supplement the EPA's EJ analysis for this rule, which can be found in in Section 8.2 of the EA (USEPA, 2024a). The EPA notes that Desikan et al. (2019) is also cited in the EPA's literature review in Section 8.2.

In response to the commenter's assertion that "Tribal communities were underrepresented in the UCMR3," the EPA considers it important that all states, Tribes, and Territories are represented and have the opportunity to participate in the UCMR program. Therefore, for those PWSs that are not included as a census, the UCMR program uses a statistically-derived set of 800 small PWSs for the nationally representative sample (selected from all PWSs serving 10,000 or fewer people for UCMR 3) that is population-weighted within each geographic and source water category, ensuring that any PWS has an equivalent likelihood of selection and no group within the population is under-represented. The statistically-derived set of 800 small PWSs for the national sample also ensures UCMR is not biased towards any communities. Biasing the UCMR monitoring design by selecting communities in a non-random manner would compromise the

utility of the dataset in making accurate estimates of national contaminant occurrence used in regulatory decision-making. For UCMR 3, the agency worked with the Tribes, Alaska Natives, the Indian Health Services (His), and the states to determine how to classify each Tribal system for consideration in the statistically-based selection of the nationally representative sample of 800 small PWSs. Based on Tribal Consultation and the changes that were made, the EPA does not agree with the statement that Tribes were underrepresented in the nationally representative sample of small PWSs for UCMR 3 (USEPA, 2012). SDWA, as amended by Section 2021 of America's Water Infrastructure Act of 2018, expanded the number of PWSs included in UCMR 5 and future cycles, subject to the availability of appropriations. For example, in UCMR 5, all PWSs serving 3,300 or more people, and a nationally representative sample of small PWSs serving less than 3,300 people are required to monitor. The addition of these small PWSs ensures a similar rate of Tribal and non-Tribal systems participating in the UCMR program moving forward, subject to the availability of appropriations (USEPA, 2021).

Additionally, the EPA is working with Tribal PWSs to offer voluntary PFAS sampling. Sampling is ongoing, and many of these results have been compiled here: https://sdwis.epa.gov/ords/sfdw_pub/f?p=SDWIS_FED_REPORTS_PUBLIC:TRIBAL_PFAS. The EPA is also working with Tribal drinking water systems to ensure they have resources to address PFAS and other emerging contaminants. The Bipartisan Infrastructure Law has made substantial resources available to Tribes to help them identify and address PFAS and other emerging contaminants in drinking water through both the Drinking Water Infrastructure Grants Tribal Set-Aside and EC-SDC Grant programs, with more information found here: https://www.epa.gov/tribaldrinkingwater and https://www.epa.gov/dwcapacity/emerging-contaminants-ec-small-or-disadvantaged-communities-grant-sdc. There are no cost-sharing requirements for these programs. Federally recognized Tribes are eligible to access funds from both grant programs through the EPA Regional offices and are encouraged to reach out directly to the Regional Tribal Coordinators listed here to get more information on how to monitor for PFAS: https://www.epa.gov/tribaldrinkingwater/regional-tribal-drinking-water-coordinators. For further discussion regarding small Tribal water systems, please see the EPA response to comment Doc. #1598, SBC-042336 in section 1.4 in this *Response to Comments* document.

PFAS Project Lab (Doc. #1786, SBC-044717)

Environmental justice considerations

The burdens of PFAS exposure are not evenly distributed along geographic, racial or ethnic, and socioeconomic lines, and it is critical that EPA act now to ensure that communities are more evenly protected. A study utilizing CalEnviroScreen assessed the interplay between PFAS pollution and environmental justice communities and found that higher potential exposure to PFAS-contaminated water overlapped with communities experiencing the most disproportionate pollution and socioeconomic burdens (Lee et al. 2021). Notably, the most vulnerable communities (as determined by CalEnviroScreen) had either the highest levels of PFAS pollution or had not been tested for PFAS pollution at all. Silent Spring Institute also identified that water

systems serving communities with higher proportions of non-Hispanic Black residents and Hispanic residents were more likely to detect PFAS contaminants (Schaider et al. 2022).

Moreover, our PFAS Project Lab analyzed UCMR3 testing of PFAS levels in public drinking water systems (PWSs), and found that populations served by Tribal PWSs were significantly underrepresented in past nationwide PFAS sampling efforts, compared with populations served by non-Tribal PWSs. Moreover, predicted sampling for UCMR5 (2023-2025) will still exclude Tribal PWSs at a rate higher than the rest of the population. This research was published in Environmental Health Perspectives (Mok et al. 2022). It is thus critical that adopted regulations and funding take into account ways to support Tribal Nations and PWSs in addressing reporting and remediation under promulgated drinking water standards. Relatedly, the Tribal PFAS Working Group (TPWG) was formed in April 2020 and seeks to address and reduce impacts of PFAS on Tribal lands. We are honored to participate regularly with the TPWG, which has informed our understanding of their concerns about PFAS for Tribal Nations in the U.S. Continued collaboration between EPA and TPWG will be beneficial in implementing drinking water regulations.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for discussion of the EPA's EJ analysis and EJ considerations for the final rule. The EPA acknowledges the commenter's submission of these citations and notes that Lee et al. (2021) and a 2023 publication by Jahred M. Liddie, Laurel A. Schaider, and Elsie M. Sunderland (Liddie et al., 2023) are cited in the literature review conducted to supplement the EPA's EJ analysis for this rule, which can be found in in Section 8.2 of the EA (USEPA, 2024a).

With respect to the commenter's assertion that "populations served by Tribal PWSs were significantly underrepresented," please see the EPA response to comment Doc. #1784, SBC-045804 in section 14.10 in this *Response to Comments* document.

Bailey Smith (Doc. #1787, SBC-045807)

Second, this rule would benefit marginalized communities who are at higher risks of PFAS exposure, including those living nearby sites at which PFAS is used in large quantities (e.g., neighborhoods adjacent to military bases). [FN2: See e.g., Jared Hayes & Scott Faber (EWG), Suspected and Confirmed PFAS Pollution at U.S. Military Bases, EWG.ORG (Apr. 2, 200), https://www.ewg.org/news-insights/news/updated-map-suspected-and-confirmed-pfaspollution-us-military-bases; Tom Perkins, At least 12 military bases contaminating water supply with toxic PFAS, THEGUARDIAN.COM (June 6, 2022), https://www.theguardian.com/us-news/2022/jun/06/military-basescontaminating-water-supply-pfas.]

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for discussion of the EPA's EJ analysis and EJ considerations for the final rule. The EPA acknowledges the commenter's support of this action and agrees that the final rule is anticipated to benefit communities with EJ concerns.

Bailey Smith (Doc. #1787, SBC-045812)

II. EPA's Proposed Rule Protects Those At Heightened Risk of PFAS Exposure

EPA has stated that its proposed rule is "anticipated to mitigate the disproportionate impacts of baseline PFAS exposure."[FN43: Proposed Rule, supra note 3 at 18735.] This comment focuses on the disproportionate impacts of PFAS exposure with respect to neighborhoods adjacent to military communities. The Environmental Working Group has discovered that some of the highest PFAS detections in the United States exist on or near military sites. [FN44: Hayes & Faber, supra note 2.] Also, Department of Defense testing has revealed that dangerous levels of PFAS contaminate the water supplies in areas around twelve military bases. [FN45: Perkins, supra note 2.]

As a student at Georgetown University Law Center, I was enrolled in a course about toxic chemicals; during one of our class sessions, we were visited by two guest speakers. These two women lived in a neighborhood adjacent to a military site and their families suffered immeasurable heartache because of PFAS contaminating their drinking water. One woman's son was born with an incurable defect due to her unknowingly drinking PFAS-contaminated water while pregnant. The other woman had been previously diagnosed with cancer. These are real people who have been affected by PFAS contamination, and no one should have to endure what these women have experienced.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for discussion of the EPA's EJ analysis and EJ considerations for the final rule. Through this action, the EPA reaffirms the importance of EJ considerations in agency activities, including rulemaking.

The EPA acknowledges the commenter's submission of information on elevated PFAS levels near military sites. The EPA notes that the literature review conducted to supplement the EJ analysis for this rule, which can be found in Section 8.2 of the EA (USEPA, 2024a), acknowledges and discusses sources of exposure to PFAS, including military sites.

Ohio Environmental Council (Doc. #1794, SBC-045325)

EPA's proposed drinking water standards also align with the Biden Administration's commitment to advance environmental justice. Communities of color and low-income communities have historically faced disproportionate exposure to pollution and cumulative adverse health effects from multiple co-occurring contaminants. Published research suggests that communities with higher populations of people of color may be especially impacted by PFAS. By regulating six dangerous PFAS in drinking water, EPA's proposal helps to reduce overall PFAS exposure, and improve drinking water safety in thousands of communities across the country.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for discussion of the EPA's EJ analysis and EJ considerations for the final

rule. The EPA acknowledges the commenter's support of this action and its alignment with the federal government's commitment to advancing EJ.

Green America (Doc. #1809, SBC-045340)

This rule will especially benefit Black and brown communities who are disproportionately impacted by PFAS contamination. I urge the EPA to quickly finalize the regulations of these six PFAS chemicals and then address all other types of PFAS.

Names of 11,877 Signers:

[Table 1: See Docket ID EPA-HQ-OW-2022-0114-1809]

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for discussion of the EPA's EJ analysis and EJ considerations for the final rule. The EPA agrees that that the final rule is anticipated to benefit communities with EJ concerns. The EPA acknowledges the commenter's support of this action and is working as expeditiously as possible to finalize the PFAS NPDWR. Additionally, with respect to the commenter's recommendation to "address all other types of PFAS," the EPA notes that the agency's PFAS Strategic Roadmap (see: https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024) lays out a whole-of-agency approach to addressing PFAS, beyond the six PFAS included in this regulatory action. The actions described in the Roadmap represent meaningful steps to safeguard communities from PFAS contamination. For additional discussion about the EPA's PFAS Strategic Roadmap, please see section 15 of the EPA response in this *Response to Comments* document.

Environmental Working Group et al. (Doc. #1810, SBC-044689)

EPA's proposed drinking water standards also align with the Biden Administration's commitment to advance environmental justice. Communities of color and low-income communities have historically faced disproportionate exposure to pollution and cumulative adverse health effects from multiple co-occurring contaminants. Published research suggests that communities with higher populations of people of color may be especially impacted by PFAS. By regulating six dangerous PFAS in drinking water, EPA's proposal helps to reduce overall PFAS exposure, and improve drinking water safety in thousands of communities across the country.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for discussion of the EPA's EJ analysis and EJ considerations for the final rule. The EPA acknowledges the commenter's support of this action and its alignment with the EPA's commitment to advance EJ.

National Wildlife Federation Action Fund (Doc. #1811, SBC-045344)

The PFAS crisis is widespread, contaminating the blood of humans, fish, and wildlife worldwide. Communities of color and low-income communities are particularly impacted by PFAS exposure, where health impacts are often compounded because these communities tend to face cumulative effects from multiple environmental injustices and public health hazards.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document.

National Wildlife Federation Action Fund (Doc. #1811, SBC-045342)

The PFAS crisis is widespread, contaminating the blood of humans, fish, and wildlife worldwide. Communities of color and low-income communities are particularly impacted by PFAS exposure, where health impacts are often compounded because these communities tend to face cumulative effects from multiple environmental injustices and public health hazards.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document.

West Virginia Municipal Water Quality Association (Doc. #1816, SBC-044676)

Additionally, nowhere in the proposed rule preamble does EPA thoroughly consider the effects on environmental justice and energy consumption. The real-world consequences from this rule (increased rates and energy use/consumption for treatment technologies) will impact all ratepayers, but particularly low- income and overburdened communities. PFAS levels in drinking water may be a very low public health priority for environmental justice communities and that reality should be accommodated in the rule. Otherwise, we risk spending unprecedented dollars on a low-priority community health issue. EPA could address this concern by allowing alternative implementation schedules based upon a State or EPA-approved community Integrated Plan.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for discussion of the EPA's EJ analysis and EJ considerations for the final rule, including funding and the EPA's analysis of costs across race/ethnicity and income groups. The EPA disagrees with the commenter's assertion that the EPA has not "thoroughly considered the effects on environmental justice and energy consumption." With respect to EJ, as discussed in section 14.10 of the EPA response in this *Response to Comments* document, the agency has fulfilled its commitments as set forth under EOs 12898 and 14096 by conducting an EJ analysis for the final rule; for more information, please see Chapter 8 of the EA (USEPA, 2024a). With respect to energy consumption, as part of the proposal, the agency evaluated whether regulation of PFAS as part of this NPDWR will substantially raise energy use and costs at facilities with traditional treatment systems. As discussed in section XIII.H of the final rule preamble and the EPA response to comment Doc. #1737, SBC-044493 in section 14.8 in this *Response to*

Comments document, electricity consumed as a result of the final rule represents approximately 0.005 percent of total U.S. electricity consumption. Additionally, after considering public comments, the agency has estimated the potential climate disbenefits caused by increased on-site electricity demand associated with removing PFAS from drinking water. For more information, please see section 9.2 of the EA (USEPA, 2024a) for the final rule and section 13.11 of the EPA response in this *Response to Comments* document.

Regarding the commenter's concerns about the impact to ratepayers, in the EPA's small system affordability analysis, the EPA analyzed the household level cost impacts of the final rule on small system size categories and determined the rule is affordable for small systems. The EPA's affordability determination for the final rule, using longstanding EPA methodology and supplemental affordability analyses, can be found in Chapter 9.13 of the EA for the final rule (USEPA, 2024a).

The EPA disagrees with the commenter's assertion that "PFAS levels in drinking water may be a very low public health priority for environmental justice communities" as, once fully implemented, the final rule is anticipated to prevent thousands of deaths and reduce tens of thousands of serious PFAS-attributable illnesses. The Administrator has determined that the benefits of reducing PFAS in drinking water through this regulatory action justify the costs. For the quantified benefits analysis, the EPA relied on peer-reviewed literature and synthesis of multiple high-quality studies to evaluate the effects of PFAS exposure on human health. For responses to comments on the EPA's comparison of costs and benefits of this action, please see section 13.8 of the EPA response in this *Response to Comments* document. Additionally, as discussed in section 14.10 of the EPA response in this *Response to Comments* document, based on the results of its EJ analysis, the EPA believes that this action is likely to reduce existing disproportionate and adverse effects on communities with EJ concerns. In the agency's EJ analysis, across all health endpoints evaluated by the EPA, communities of color are anticipated to experience the greatest quantified benefits associated with the final rule.

In response to the commenter's suggestion that the EPA allow "alternate implementation schedules", the EPA notes that the agency has extended its MCL compliance deadline to 5 years following final rule promulgation; please see section 12.1 of the EPA response in this *Response to Comments* document for further discussion. Please also see the EPA response to comment Doc. #1638, SBC-043454 in section 14.10 in this *Response to Comments* document for discussion of exemptions.

Association of Missouri Cleanwater Agencies (Doc. #1817, SBC-044654)

Additionally, nowhere in the proposed rule preamble does EPA thoroughly consider the effects on environmental justice and energy consumption. The real-world consequences from this rule (increased rates and energy use/consumption for treatment technologies) will impact all ratepayers, but particularly low-income and overburdened communities. PFAS levels in drinking water may be a very low public health priority for environmental justice communities and that

reality should be accommodated in the rule. Otherwise, we risk spending unprecedented dollars on a low-priority community health issue. EPA could address this concern by allowing alternative implementation schedules based upon a State or EPA-approved community Integrated Plan.

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044676 in section 14.10 in this *Response to Comments* document and section 14.10 of the EPA response in this *Response to Comments* document.

NORTH CAROLINA WATER QUALITY ASSOCIATION (Doc. #1818, SBC-044632)

Additionally, nowhere in the proposed rule preamble does EPA thoroughly consider the effects on environmental justice and energy consumption. The real-world consequences from this rule (increased rates and energy use/consumption for treatment technologies) will impact all ratepayers, but particularly low-income and overburdened communities. PFAS levels in drinking water may be a very low public health priority for environmental justice communities and that reality should be accommodated in the rule. Otherwise, we risk spending unprecedented dollars on a low-priority community health issue. EPA could address this concern by allowing alternative implementation schedules based upon a State or EPA-approved community Integrated Plan.

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044676 in section 14.10 in this *Response to Comments* document and section 14.10 of the EPA response in this *Response to Comments* document.

South Carolina Water Quality Association (Doc. #1819, SBC-044610)

Additionally, nowhere in the proposed rule preamble does EPA thoroughly consider the effects on environmental justice and energy consumption. The real-world consequences from this rule (increased rates and energy use/consumption for treatment technologies) will impact all ratepayers, but particularly low-income and overburdened communities. PFAS levels in drinking water may be a very low public health priority for environmental justice communities and that reality should be accommodated in the rule. Otherwise, we risk spending unprecedented dollars on a low-priority community health issue. EPA could address this concern by allowing alternative implementation schedules based upon a State or EPA-approved community Integrated Plan.

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044676 in section 14.10 in this *Response to Comments* document and section 14.10 of the EPA response in this *Response to Comments* document.

Wet Weather Partnership (Doc. #1820, SBC-044588)

Additionally, nowhere in the proposed rule preamble does EPA thoroughly consider the effects on environmental justice and energy consumption. The real-world consequences from this rule (increased rates and energy use/consumption for treatment technologies) will impact all ratepayers, but particularly low-income and overburdened communities. PFAS levels in drinking water may be a very low public health priority for environmental justice communities and that reality should be accommodated in the rule. Otherwise, we risk spending unprecedented dollars on a low-priority community health issue. EPA could address this concern by allowing alternative implementation schedules based upon a State or EPA-approved community Integrated Plan.

EPA Response: Please see the EPA response to comment Doc. #1816, SBC-044676 in section 14.10 in this *Response to Comments* document and section 14.10 of the EPA response in this *Response to Comments* document.

Sharon Levy (Doc. #1824, SBC-044276)

Pregnant women, young children, low income communities and people of color are extremely vulnerable.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for discussion of the EPA's EJ analysis and EJ considerations for the final rule, including funding and the EPA's analysis of costs across race/ethnicity and income groups. Additionally, pursuant to SDWA section 1412(b)(3)(C), the EPA evaluated the effects of the contaminants on the general population and sensitive subpopulations including infants, children, pregnant women, the elderly, and individuals with a history of serious illness.

Anonymous (Doc. #2318, SBC-047304)

I support that they are trying to help a lot of communities, including communities that face disadvantages because studies show that many low-income communities and minority communities are more likely to be given drinking water that is of lower quality and filled with a higher amount of chemicals.

EPA Response: Please see section 14.10 of the EPA response in this *Response to Comments* document for responses to comments regarding the EPA's EJ analysis and EJ considerations for the final rule. The EPA acknowledges the commenter's support of the agency's work to advance EJ through this action.

14.11 Consultations

14.11.1 Science Advisory Board

Individual Public Comments

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-042873)

EPA's health advisories for perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS) are still considered "interim" and the Science Advisory Board (SAB) made several recommendations (EPA-SAB-22-008) [FN3: https://sab.epa.gov/ords/sab/f?p=100:0:11519146227520:APPLICATION_PROCESS=REPORT_DOC:::REPORT_ID:1105] when they reviewed EPA's scientific justification for setting the standards. On its website, EPA states "In the proposed rule, EPA presents updated noncancer toxicity values based on evaluating additional scientific information. These updated values are different from those used to calculate the 2022 interim HAs, which EPA based on the best available science at that time. EPA is accepting public comments on its proposed NPDWR, including on the proposed maximum contaminant level goals (MCLGs), other supporting information, and the draft 2023 toxicity values for PFOA and PFOS which are based on the best available science. Note that the MCLGs in the proposed rule are zero. The 2022 interim Health Advisories for PFOA and PFOS will continue to remain available as EPA finalizes a national primary drinking water regulation for those contaminants." It does not appear that EPA reconvened the SAB to discuss how they responded to the SAB's recommendations; MWWA recommends that those experts be convened to re-review EPA's new rationale. If EPA drops its health advisories because of this rulemaking process, there should be reasoning provided to the public for why the values are now different than the Interim Health Advisory levels. There was much press generated around the Interim Health Advisories in the parts per quadrillion, and as we will discuss later in our comments, communication related to PFAS is important. MWWA knows that PFAS contamination concerns are contributing to a loss of public confidence in tap water. If there has been a change to the way that EPA is viewing the science, the public deserves to hear in plain language why contaminants that were once deemed dangerous at parts per quadrillion are now being regulated with MCLs in the parts per trillion.

EPA Response: Please see section 4.1.3 of the EPA response in this *Response to Comments* document for responses to comments related to peer review of the science underlying the MCLGs for PFOA and PFOS. The agency also notes that the EPA's interim health advisories for PFOA and PFOS are beyond the scope of this rulemaking. The EPA further notes that commenter's characterization of Health Advisories appears to be incorrect and directs the commenter to relevant information on the EPA website (https://www.epa.gov/sdwa/drinking-water-health-advisories-has). Unlike MCLs, Health Advisories are non-regulatory, health-based values and are not developed with considerations of factors such as treatment technologies, costs, or analytical methods. Regarding the EPA's final MCLs, including feasibility, please see section 5 of the EPA response in this *Response to Comments* document.

The agency agrees with the commenter that public communication is extremely important and refers the commenter to section 1.2 of this document for additional information pertaining to the PFAS NPDWR communications.

Superfund Settlements Project (SSP) and RCRA Corrective Action Project (RCAP) (Doc. #1631, SBC-043429)

For all six PFAS addressed in the Proposal, EPA failed to use the best available, peer-reviewed science, importantly truncating the role of the Science Advisory Board ("SAB").

EPA Response: The EPA disagrees. See sections 4.1.2 and 4.1.3 of the EPA response in this *Response to Comments* document for comments related to the EPA's use of the best available science and peer review of the science underlying the MCLGs for PFOA and PFOS. Pertaining to the EPA's use of the best available science and peer review of the science underlying the Hazard Index MCLG for a mixture of HFPO-DA, PFNA, PFHxS, and/or PFBS and the individual MCLGs for HFPO-DA, PFNA, and PFHxS, please see sections 4.3.1, 4.3.2, and 4.3.3 of the EPA response in this *Response to Comments* document.

Superfund Settlements Project (SSP) and RCRA Corrective Action Project (RCAP) (Doc. #1631, SBC-043438)

Second, the SDWA expressly requires EPA to use "(i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods (if reliability of the method and the nature of the decision justifies use of the data)." [FN60: 42 U.S.C. § 300g-1(b)(3)(A).] The Proposal fails to meet this basic instruction, most strikingly in the truncated or absent role SAB played in the developed of MCLGs and MCLs for all six PFAS. Coupled with inadequate data and insupportable analyses, EPA has presented a proposal that is legally and technically flawed.

EPA Response: The EPA disagrees that it did not seek adequate consultation from the Science Advisory Board (SAB) in the development of the NPDWR. SDWA Section 1412(e) requires that the EPA "request comments" from the SAB "prior to proposal" of the MCLG and NPDWR. Consistent with this statutory provision, the EPA consulted with the SAB from 2021 – 2022. Additionally, the statute does not dictate on which scientific issues the EPA must request comment from the SAB. See section IV of the final rule preamble and sections 4.1.2 and 4.1.3 of the EPA response in this *Response to Comments* document for comments related to the EPA's use of the best available science and peer review of the science underlying the MCLGs for PFOA and PFOS. Pertaining to the EPA's use of the best available science and peer review of the science underlying the Hazard Index MCLG for a mixture of HFPO-DA, PFNA, PFHxS, and/or PFBS and the individual MCLGs for HFPO-DA, PFNA, and PFHxS, please see section IV of the final rule preamble and sections 4.3.1, 4.3.2, and 4.3.3 of the EPA response in this *Response to Comments* document.

National Association of Manufacturers (NAM) (Doc. #1655, SBC-043196)

EPA's SAB not consulted on four of the six PFAS

The SDWA requires EPA to consult with the Science Advisory Board (SAB) prior to proposal of a maximum contaminant level goal and national primary drinking water regulation. [FN3: 42 U.S.C. § 300g-1(e).]

As opposed to PFOA and PFOS, the EPA did not seek input from the SAB for the proposed regulations on PFNA, PFHxS, PFBS, and GenX. EPA should re-propose a rule on these substances after the SAB has had adequate time to review and provide input.

EPA Response: The EPA disagrees with the commenter's assertions. As required by the SDWA, the EPA consulted with the SAB on the scientific questions the agency deemed most important to this rulemaking. Furthermore, the statute does not dictate on which scientific issues the EPA must request comment from the SAB. See section 4.3.2 of the EPA response in this *Response to Comments* document regarding peer-review requirements under SDWA prior to proposal of an MCLG and NPDWR.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045901)

IV. The Science Supporting the Proposed MCLs for PFOA and PFOS Is Not the Best Available Science

A. The science supporting the MCLs and MCLGs for PFOA and PFOS does not meet the statutory standard for use of the best available science

1. The period for SAB review was inappropriately truncated

The robustness of SAB review for the MCLs for PFOA and PFOS was severely diminished by exceedingly short timelines for each step of the process and by a lack of critical expertise. As described below, the peer review process was compromised and inconsistent with sound and objective scientific practices.

The Federal Register notices announcing the beginning of the process and the availability of supporting documents were November 10, 2021 and November 16, 2021, respectively [FN79: See 86 Fed. Reg. 62526 where EPA announced the meeting, but the draft documents were not released until Nov. 16, 2021, as announced at: https://www.epa.gov/newsreleases/epa-advances-science-protect-public-pfoa-and-pfos-drinking-water.]. The final report of the SAB was provided to EPA on August 22, 2022, only 279 days after documents were made available for review and only 243 days after the first meeting of the SAB. This is notably shorter than less complex reviews. For comparison, the SAB review of EPA's Assessment of the Potential Impacts of Hydraulic Fracturing for Oil and Gas on Drinking Water Resources, a 2015 document that was under 1,000 pages, took 400 days to complete [FN80: See SAB report available at: https://sab.epa.gov/ords/sab/f?p=100:12:10700493575905.]. This was 43% longer than the

amount of time the SAB spent reviewing the four substantive PFAS documents. The SAB Panel which reviewed EPA's Draft Toxicological Review of Ethyl Tertiary Butyl Ether and Draft Toxicological Review of tert-Butyl Alcohol (tert-Butanol), two technical documents like the PFOA and PFOS assessments but totaling only 547 pages, took 392 days to complete [FN81: See SAB report available at: https://sab.epa.gov/ords/sab/f?p=100:12:10700493575905.]. This was almost 40% longer for the review of documents what were approximately one-third the size of the relevant documents here.

If a member of the public wanted "timely consideration" of their comments by the SAB, comments were due on December 30, 2021. This provided a mere 44 days for the peer reviewers, and the public, to review over 1,750 pages of highly technical scientific assessments. The EPA Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) (CASRN 335-67-1) in Drinking Water (PFOA Draft Assessment) contained 59 pages of references and supporting studies, and the EPA Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) (CASRN 1763-23-1) in Drinking Water (PFOS Draft Assessment) contained 51 pages of references and supporting studies. With approximately 17 references per page, this equates to over 1,800 scientific references. These two Draft Assessments were not the only documents SAB was reviewing. In this same window, SAB was also asked to review EPA's Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS) and EPA's Analysis of Cardiovascular Disease Risk Reduction as a Result of Reduced PFOA and PFOS Exposure in Drinking Water, and these documents' associated appendices [FN82: See the SAB meeting page for the review available at: https://sab.epa.gov/ords/sab/f?p=114:19:12110592892742:::19:P19_ID:963.].

The length of review time provided was simply not commensurate with the breadth of scientific information the SAB and the public were asked to review. Nor was the review time commensurate with the importance and economic significance of the proposed rulemaking this peer review was conducted to inform. In fact, requests were made for extensions, but EPA and the SAB denied those requests [FN83: See EPA response to Mr. Chaitovitz from Eric Burnseson, Director, Standards and Risk Management Division, Office of Ground Water and Drinking Water, EPA, dated May 5, 2023, stating that the provided comment period was "reasonable" and "EPA will not be extending the comment period for the proposed rule."].

2. The SAB reviewers did not have adequate expertise required by EPA's own policies

The review was also compromised by a lack of expertise on critical endpoints that EPA relied upon. SAB policies recognize that there may be cases when experts are unable to reach consensus [FN84: SAB Handbook for Members and Consultants Serving on the EPA Science Advisory Board (SAB Handbook), at page 6, available at: https://sab.epa.gov/ords/sab/r/sab_apex/files/static/v403/Serving%20on%20the%20EPA%20Science%20Advisory%20Board%20SABSO-12-001.pdf.]. However, in this case, for one of the most critical endpoints that EPA relied upon in both assessments, the immunological endpoint, the SAB panel included only one reviewer with expertise in immunological effects [FN85: See SAB

Determination Memo and List of Candidates where expertise of candidates is described. Only one chosen panelist, Dr. DeWitt, has expertise in immunotoxicology. Documents available at: https://sab.epa.gov/ords/sab/f?p=114:18:12110592892742:::RP,18:P18_ID:2601.]. The EPA Peer Review Handbook notes that "selected experts should include a range of technically legitimate points of view that fall along the continuum."[FN86: EPA Peer Review Handbook at page 72.] In order to have a range of points of view, the SAB panel should have included more than one expert in immunotoxicology. Another critical endpoint for PFOA and PFOS and needed to inform the review of the EPA report Analysis of Cardiovascular Disease Risk Reduction as a Result of Reduced PFOA and PFOS Exposure in Drinking Water is cardiovascular expertise. Unfortunately, the SAB panel included only one expert with cardiovascular expertise [FN87: See SAB Determination Memo and List of Candidates where expertise of candidates is described. Only one chosen panelist, Dr. Lipworth, has expertise in cardiovascular disease. Documents available at: https://sab.epa.gov/ords/sab/f?p=114:18:12110592892742:::RP,18:P18_ID:2601.]. In addition, the SAB panel lacked any expertise in clinical medicine. While the SAB sought candidates that included expertise as a "physician/clinician with a focus on cardiology,"[FN88: See SAB determination memo at page 1.] the final SAB panel did not include any physicians or clinicians [FN89: We note that EPA received nominations for 41 candidates, which included a physician, but EPA chose not to put this expert on the SAB panel. See list and biosketches of candidates at: https://sab.epa.gov/ords/sab/f?p=100:18:16490947993:::RP,18:P18_ID:2601#pf.]. Thus, due to the multiple gaps in expertise, the SAB panel was critically deficient.

3. Peer review principles were not followed in the SAB process, largely due to a lack of time for review

When the chartered SAB panel was reviewing the draft report from the SAB, chartered SAB members noted that some of the flaws in the EPA documents, including the PFOA and PFAS Draft Assessments, could not be fixed [FN90: See Chartered SAB public meeting July 20, 2022 at 1:36-1:42 video available at: https://www.youtube.com/watch?v=UzDtzYDJB_I.]. One chartered SAB panelist questioned how the SAB could approve documents that didn't reflect the current state of practice and questioned if EPA should just start over. This panelist did not think the flaws could be quickly corrected. A second chartered SAB member suggested that, if the Draft Assessments were a manuscript, they should have been rejected. The overarching concerns were significant [FN91: Id.]. However, these comments were tempered by the requests from EPA leadership to the SAB to recognize the time constraints that EPA placed upon themselves to move the PFAS drinking water rulemaking along in a timely manner.

The final SAB report acknowledges and recognizes the time constraints. The SAB letter to the Administrator notes concerns about the study evaluation and evidence synthesis process used by EPA and urges EPA to address these problems [FN92: See SAB report to the EPA Administrator Aug 22, 2022, at page 2, available at: https://sab.epa.gov/ords/sab/f?p=100:18:16490947993:::RP,18:P18_ID:2601#report.]. EPA states in its response to the SAB comments that it made significant revisions [FN93: See EPA Response to the Final SAB Recommendations, referred to as USEPA 2023f in the proposed

rule.]. However, these revisions did not undergo additional peer review. Instead, they are now the basis of economically significant rulemaking. When a journal manuscript is rejected, it must undergo another round of peer review after revisions are incorporated before going to publication. Consistent with this approach, one of the chartered SAB members recommended that the revised documents undergo another, albeit limited, form of peer review [FN94: See Chartered SAB public meeting July 20, 2022 at 2:26-2:32 video available at: https://www.youtube.com/watch?v=UzDtzYDJB_I.]. In response to this suggestion, an EPA staff member, the Director of the EPA SAB, interrupted the discussions of the SAB members to clarify the role of the SAB and steered the SAB chartered members away from recommending additional peer review [FN95: Id.]. There is nothing in the SAB handbook that precludes the SAB or the chartered SAB members from making a recommendation that the documents warrant additional peer review after substantial revisions are made by the Agency [FN96: See SAB Handbook for Members and Consultants Serving on the EPA Science Advisory Board (SAB Handbook), available at: https://sab.epa.gov/ords/sab/r/sab_apex/files/static/v403/Serving%20on%20the%20EPA%20Science%20Advisory%20Board%20SABSO-12-001.pdf.].

The changes made by EPA in developing the Public Comment Draft Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) in Drinking Water and Public Comment Draft Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) in in Drinking Water (Public Comment Draft Assessments) are significant enough that another peer review should have been conducted. For instance, as noted in the EPA Response to the Final SAB report, EPA developed many new elements to its assessment approach,[FN97: See EPA Response to the Final SAB Recommendations, at pages 14-16, and 20 where EPA notes that they have: defined inclusion and exclusion criteria at each stage of the systematic literature review for PFOA and PFOS; added a new protocol to describe study quality evaluation procedures for epidemiological and animal toxicological studies; developed an evidence integration approach; and revised the non-cancer health effects synthesis and integrations sections, available at: https://sab.epa.gov/ords/sab/f?p=100:12:17203034137454.] including elements such as a protocol. Consistent with today's best available scientific approaches, protocols are typically publicly released and reviewed before an assessment is conducted [FN98: See EPA ORD Staff Handbook for Developing IRIS Assessments, released December 2022, which describes how the systematic review protocol is part of the IRIS Assessment Plan which is released early in the assessment process for public comment, at chapter 1, available at: https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=356370#tab-3.]. But, in this case, the protocol and other important modifications to the risk evaluation approach are being released for the first time as part of the MCL draft documentation, thus skirting the statutorily required SAB review (as discussed earlier in these comments). For this reason and for the additional reasons cited above, the underlying scientific evaluations do not meet the statutory standard.

EPA Response: Regarding the commenter's claims that the underlying scientific evaluations do not meet the statutory standard and that the EPA did not seek adequate

consultation from the SAB in the development of the NPDWR, SDWA Section 1412(e) requires that the EPA "request comments" from the SAB "prior to proposal" of the MCLG and NPDWR. Consistent with this statutory provision, the EPA consulted with the SAB from 2021 – 2022. Further, the EPA disagrees with this commenter's assertions regarding the SAB review timing, panel expertise, and peer review practices. See detailed responses to each of these assertions below.

First, the EPA disagrees with the commenter's characterization of the SAB review as "truncated." and notes that under no statutes or EPA policies are there minimum or maximum times for SAB reviews. Comparisons to other SAB review timeframes are also not relevant as there are many factors, including SAB panel and chartered body availability and agency statutory mandates, that could impact the length of an SAB review. The EPA points out that the commenter provided one example, however in contrast there are examples of other SAB reviews which have been completed of comparably complex materials in similar amounts of time, for recent examples see *Review of EPA's draft IRIS Toxicological Review of Hexavalent Chromium* (USEPA, 2023c; the SAB Cr(VI) Review Panel met virtually on February 15, 2023 to hear a presentation by the EPA staff, final SAB report dated September 27th, 2023) and *Science Advisory Board Report on the Scientific and Technical Basis of the Proposed Rule Titled "Standards of Performance for New, Reconstructed, and Modified Sources and Emissions Guidelines for Existing Sources: Oil and Natural Gas Sector Climate Review"* (USEPA, 2023d; the SAB's Science Supporting Decisions workgroup received the supplemental rule material on August 26, 2022, to consider with the rule material published on December 6th 2022, final SAB report dated March 6th, 2023). The EPA also notes that for review of the materials supporting this PFAS drinking water rulemaking that the panel members as well as the SAB chartered members did not raise any concerns with regard to the time provided to review the materials and produce the final report. The EPA did not place "time constraints… upon themselves," but must follow the regulatory schedule explicitly described in the SDWA.

Second, the EPA disagrees with the commenter's claim that "[t]he SAB reviewers did not have adequate expertise required by the EPA's own policies." When the SAB Staff Office determines that additional expertise will be needed to address an advisory topic, it publishes an FRN announcing the formation of an ad hoc panel that reports to the chartered Clean Air Scientific Advisory Committee (CASAC) or SAB. The announcement provides an opportunity for the public to nominate experts to these ad hoc panels. The SAB Staff Office also invites comments on Lists of Candidates. This provides an opportunity for the public to be informed about the candidate experts being considered and for the public to provide information, analysis, or documentation for the EPA to consider before finalizing membership on committee or panels. As Lists of Candidates become available, they are placed on the SAB homepage (https://sab.epa.gov). The SAB Staff Office received nominations for the 41 candidates based on their expertise and willingness to serve, and selected panel members as detailed in the memo *Formation of the per- and polyfluoroalkyl substances (PFAS) Review Panel under the Science Advisory Board (SAB),* available online at: https://sab.epa.gov/ords/sab/r/sab_apex/sab_bkup/0?detmemo_id=2601&request=APPLICATIO

N_PROCESS%3DDETER_MENO&session=9389297743683. Expertise, knowledge, and experience are the primary factors that determine whether an individual is invited to serve on an SAB Panel. In forming panels to provide expert advice, SAB staff screen candidates for conflicts of interest and consider overall balance of the panel in terms of the points of view presented, as mandated by the Federal Advisory Committee Act. At the SAB, a balanced panel is characterized by inclusion of the necessary domains of knowledge, the relevant scientific perspectives (which, among other factors can be influenced by work history and affiliation), and the collective breadth of experience to address the charge adequately. The EPA emphasizes that the SAB is a technical advisory body, not a committee designed to reflect stakeholder views. For more information see *Overview of the Panel Formation Process at the Environmental Protection Agency Science Advisory Board* (USEPA, 2010). Therefore, given the opportunity for public input and the panel selection process followed by the EPA for this PFAS Review Panel, the commenter is incorrect in stating the EPA did not "follow its own policies." Further, the panel represented a balanced and appropriate range preeminent experts in their field. The SAB Staff Office identified current members of the SAB Chemical Assessment Advisory Committee (CAAC) and the SAB Economic Analysis Committee (EAC) augmented with subject matter experts with expertise in one or more of the following areas: toxicology, specifically reproductive/developmental, hepatic, immunology and neurotoxicology; epidemiology with expertise in immunology, endocrinology, reproductive/ developmental and cardiology; physiologically-based pharmacokinetic (PBPK) modeling; physician/clinician with a focus on cardiology; risk assessment; toxicity of chemical mixtures; economist with expertise in health related benefit cost analysis and valuing avoided adverse health outcomes; and, dose response relationships in economic models. Regarding the commenter's specific opinion that the EPA should have included a physician on the panel, the EPA notes that this was one of several areas of expertise the agency believed could be appropriate to review the cardiovascular disease (CVD) risk reduction methodology. The EPA notes that the panel included experts in the pertinent fields to review this work (i.e., cardiovascular disease, applied epidemiology and economics) including Dr. Loren Lipworth; a Professor of Medicine, Dr. David Savitz; a Professor of Epidemiology, Dr. Lala X. Ma; an Assistant Professor of Economics, Dr. James K. Hammitt; a Professor of Economics and Decision Sciences, among other expert panel members.

Third, the EPA disagrees with the commenter that "[P]eer review principles were not followed in the SAB process, largely due to a lack of time for review." As discussed above, the EPA provided adequate time for the review process and received timely feedback from the SAB. Regarding the commenters suggestion that the EPA should seek a second peer review of the materials, the EPA notes that the chartered SAB panel did not review the documents themselves and relied on the SAB report for their discussion. SAB panelists who did review the materials and developed the final SAB report (USEPA, 2022) disagreed with the chartered panelists who stated the EPA should "start over." As the commenter suggested, "There is nothing in the SAB handbook that precludes the SAB or the chartered SAB members from making a recommendation that the documents warrant additional peer review after substantial revisions are made by the Agency." The SAB, however, did not recommend this in their final report (USEPA,

2022). See section IV of the final rule preamble and sections 4.1.2 and 4.1.3 of the EPA response in this *Response to Comments* document for comments related to the EPA's use of the best available science and peer review of the science underlying the MCLGs for PFOA and PFOS. Pertaining to the EPA's use of the best available science and peer review of the science underlying the Hazard Index MCLG for a mixture of HFPO-DA, PFNA, PFHxS, and/or PFBS and the individual MCLGs for HFPO-DA, PFNA, and PFHxS, please see section IV of the final rule preamble and sections 4.3.1, 4.3.2, and 4.3.3 of the EPA response in this *Response to Comments* document.

Regarding the request for extension to the public comment period for the proposed rule, please see section 17.1 of the EPA response in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045896)

A. EPA violated SDWA's Requirement to seek SAB review before proposing this regulation and the MCL for PFNA, PFHxS, PFBS, and HFPO-DA

Section 1412(e) of SDWA requires that EPA request comments from the SAB prior to proposal of a MCLG and NPDWR:

The Administrator shall request comments from the Science Advisory Board (established under the Environmental Research, Development, and Demonstration Act of 1978) prior to proposal of a maximum contaminant level goal and national primary drinking water regulation. The Board shall respond, as it deems appropriate, within the time period applicable for promulgation of the national primary drinking water standard concerned. This subsection shall, under no circumstances, be used to delay final promulgation of any national primary drinking water standard [FN53: 42 U.S.C. [sec] 300g-1(e).].

Unlike PFOA and PFOS, EPA did not seek input from the SAB on the MCL for PFNA, PFHxS, PFBS, and HFPO-DA. EPA offers no explanation for this departure from SDWA requirements. This error is likely in part due to the flawed attempt to rush to propose a regulatory determination and a regulation/MCL at the same time (discussed further below). SAB could not have reviewed the assessments within the "time period applicable" because they were proposed simultaneously. The typical process creates up to two years between a proposed regulatory determination and a final determination and a regulatory proposal. EPA must respect this detailed process that Congress set up in SDWA to allow scientific peer review by the SAB and adequate public comment. Based on SDWA requirements, if it wishes to finalize this MCL for these substances, EPA must re-propose the rule after SAB has an opportunity to review.

EPA Response: The EPA disagrees that it did not seek adequate consultation from the SAB in the development of the NPDWR. As the commenter provides, SDWA Section 1412(e) requires that the EPA "request comments" from the SAB "prior to proposal" of the MCLG and NPDWR, though it does not dictate on which scientific issues the EPA must request comment from the SAB. Consistent with this statutory provision, the EPA did so and consulted with the

SAB from 2021 – 2022. See section 4.3.2 of the EPA response in this *Response to Comments* document regarding peer-review requirements under SDWA prior to proposal of an MCLG and NPDWR. Pertaining to the EPA's concurrent preliminary regulatory determination for PFHxS, PFNA, HFPO-DA, and PFBS and proposed NPDWR, please see section 3.3 of the EPA response in this *Response to Comments* document. The agency further clarifies for the commenter that, as it relates to the EPA's regulatory determinations, the SDWA does not require any consultation with the SAB when making preliminary or final regulatory determinations. Consequently, the commenter has no basis for their assertion that the SAB did not have adequate review time due to the EPA's concurrent preliminary regulatory determination and proposed NPDWR.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045876)

A. Health data do not support the proposed determinations to regulate PFNA, PFHxS, PFBS, and HFPO-DA (and mixtures of these PFAS) either individually or as a mixture

1. EPA did not perform human health assessments for all four contaminants and failed to conduct appropriate peer review

It is critical that, before finalizing a human health assessment, EPA ensures that appropriate peer review is conducted [FN9: U.S. EPA, Peer Review Handbook, 4th edition, 2015, available at: https://www.epa.gov/sites/default/files/2015-10/documents/epa_peer_review_handbook_4th_edition_october_2015.pdf.]. This peer review must be fit for purpose, and, as EPA states, Influential Scientific Assessments (ISIs) and Highly Influential Scientific Assessments (HISAs), including those that are more novel or complex and have greater cost implications, should undergo more extensive and more involved peer reviews. Despite EPA's own recognition that "[t]he mechanism of the peer review should match the importance and complexity of the work product," the SAB did not review the science for PFHxS, HFPO-DA, PFNA, and PFBS. [FN10: Id. at 54.] This is in sharp contrast to the process that occurred for PFOA and PFOS.

EPA Response: The EPA disagrees that the health data do not support the SDWA statutory criterion for individual regulation of PFHxS, PFNA, and HFPO-DA and regulation of mixtures of these three PFAS and PFBS is not supported (please see sections 3.1.1 and 3.2.1 of the EPA response in this *Response to Comments* document). The EPA also disagrees that appropriate peer review was not conducted or that the EPA must perform the health assessments. Rather, the SDWA requires that the EPA use the "best available, peer-reviewed science and supported studies conducted in accordance with sound and objective scientific practices." See sections 4.3.1, 4.3.2, and 4.3.3 of the EPA response in this *Response to Comments* document related to peer review of the science underlying the Hazard Index MCLG for a mixture of HFPO-DA, PFNA, PFHxS, and/or PFBS and the individual MCLGs for HFPO-DA, PFNA, and PFHxS. Additionally, the commenter mischaracterizes what constitutes Influential Scientific Information (ISI) or Highly Influential Scientific Assessment (HISA) and how the EPA manages peer review for ISIs or HISAs. A scientific assessment is considered HISA when the agency or the OMB

Office of Information and Regulatory Affairs (OIRA) Administrator determines that the dissemination could have a potential impact of more than $500 million in any one year on either the public or private sector or that the dissemination is novel, controversial, or precedent-setting, or has significant interagency interest. Neither the EPA Administrator, the Centers for Disease Control (CDC) director, nor the Administrator of OIRA have determined that the human health assessments for these four PFAS are HISAs.

U.S. Chamber of Commerce et al. (Doc. #1713, SBC-045878)

While EPA has completed health assessments for HFPO-DA and PFBS, they were not reviewed by the SAB and did not undergo an appropriate peer review. HFPO-DA and PFBS underwent external peer review that was managed by a contractor, not the SAB. As stated in the EPA Peer Review Handbook, "HISAs or other scientific work products associated with highly visible or controversial environmental issues, or products that include novel scientific methods or approaches, are most suited to review by the SAB."[FN14: Id. at 66.] This is because the SAB process is far more robust than the processes run by external contractors. For instance, the SAB strives to reach consensus in all their reports because their final product is meant to be a consensus advisory report [FN15: U.S. EPA, SAB Handbook for Members and Consultants, available at: https://sab.epa.gov/ords/sab/r/sab_apex/files/static/v403/Serving%20on%20the%20EPA%20Science%20Advisory%20Board%20SABSO-12-001.pdf.]. EPA provides no explanation why it used external contractors instead of the more robust SAB process.

The external peer reviewers of the contractor-led HFPO-DA and PFBS reviews did not strive to reach consensus, and, in fact, the final HFPO-DA report provided non-consensus opinions. Even the second round of external peer review of the HFPO-DA assessment cannot make up for the fact the peer-review process was not nearly as robust as an SAB process would have been. The second peer review report also provided EPA, and the public, with non-consensus opinions. When assessments are controversial and also considered to be HISAs because of the important and costly rulemakings that rely on them, a contractor-led external peer review is simply not as robust as SDWA-required SAB review. As such, the health assessments EPA relies on for the four contaminants in the regulatory determination are not of sufficient scientific quality and rigor and should be properly peer reviewed by the SAB to support an adequate regulatory determination.

EPA Response: The EPA disagrees. See section 4.3.3 of the EPA response in this *Response to Comments* document related to peer review of the toxicity assessments for HFPO-DA and PFBS. Additionally, the commenter mischaracterizes what constitutes a HISA and how the EPA manages peer review for HISAs. A scientific assessment is considered HISA when the agency or the OMB OIRA Administrator determines that the dissemination could have a potential impact of more than $500 million in any one year on either the public or private sector or that the dissemination is novel, controversial, or precedent-setting, or has significant

interagency interest. Neither the EPA Administrator, the CDC director, nor the Administrator of OIRA have determined that these toxicity assessments are HISAs.

American Water Works Association (AWWA) (Doc. #1759, SBC-045645)

These public comment drafts also include the USEPA's attempts to respond the Scientific Advisory Board's detailed comments and review (August 2022) of the following four draft documents:

• Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) (CASRN 335-67-1) in Drinking Water (December 2021) (USEPA 2021a);

• Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) (CASRN 1763-23-1) in Drinking Water (December 2021) (USEPA 2021b);

• Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS) (December 2021) (USEPA 2021c); and

• Analysis of Cardiovascular Disease Risk Reduction as a Result of Reduced PFOA and PFOS Exposure in Drinking Water (December 2021) (USEPA 2021d).

The USEPA made substantial revisions and added new material, which is now included in the public comment drafts, to address the extensive comments made by the Science Advisory Board (SAB). In addition, the USEPA responded to the SAB comments in the following report:

• USEPA Response to Final Science Advisory Board Recommendations (August 2022) on Four Draft Support Documents for the USEPA's Proposed PFAS National Primary Drinking Water Regulation (USEPA 2023i).

The revisions to the 2023 public comment drafts include the following, none of which have been peer-reviewed by the SAB, and therefore have to be peer-reviewed during this 60 day public comment period (which will end on May 30, 2023):

• A review of mechanistic data, which was lacking in the December 2021 draft documents, and synthesis of mechanistic data with the animal and human data. The SAB specifically stated "(US)EPA should include an evaluation of mechanistic/mode of action data for those effects considered as the potential basis for the reference doses (RfDs) and cancer slope factors (CSFs)." (p. 2 of introductory letter, USEPA 2022a);

• Newly derived candidate RfDs for total cholesterol are now included in the proposed MCLG documents to align with the cardiovascular disease (CVD) benefits analysis. The SAB specifically stated "(US)EPA should ensure that recommendations for the draft MCLG documents relating to evidence identification and synthesis are applied to the CVD endpoint." (p. 4 of introductory letter, USEPA 2022a);

• USEPA quantified benefits of changes in high-density lipoprotein cholesterol (HDLC) in relation to PFOA and PFOS;

• USEPA quantified benefits of changes in elevated blood pressure in relation to PFOS (although this had not requested by the SAB);

• Addition of quantified benefits of birth weight associated with reductions in PFOA/PFOS (SAB requested that USEPA consider risk reduction for additional endpoints);

• Newly derived candidate RfDs for decreases in birth weight (which is sometimes described as low birth weight) in relation to PFOA and PFOS, which were needed to align with quantified birth weight benefits. However, low birth weight has a specific definition (i.e. birth weight below 2500 grams), and this is not the endpoint for which the RfD is derived. The tiered risk assessment approach described in the December 2021 Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS) was replaced with a data-driven/menu-based framework for the selection of component-based approaches for PFAS mixture assessment, and the interpretation of any approach as being "screening" or preliminary was minimized. The SAB specifically stated, "Methods analogous to those classified by USEPA as 'Screening Level' or 'Tier 1' in the framework are potentially being used by states in a decision-making capacity. Issuance of this framework without recognition of that fact may create confusion for public water supplies and risk communication challenges for the public." (p. 93-94, USEPA SAB 2022a).

The above changes to the underlying documents and assessments are not exhaustive; however, the comments below are largely focused on a review of these proposed changes.

EPA Response: Please see section 4.1.3 of the EPA response in this *Response to Comments* document related to peer review of the science underlying the MCLGs for PFOA and PFOS. Regarding the derivation of candidate RfDs, please see section 4.2.2 of the EPA response in this *Response to Comments* document and the methodology described in Appendix E and Chapter 4 of the Final Human Health Toxicity Assessments for PFOA and PFOS (USEPA, 2024c; USEPA, 2024d; USEPA, 2024e; USEPA, 2024f). See sections 4.3.1, 4.3.2, and 4.3.3 of the EPA response in this *Response to Comments* document related to peer review of the science underlying the Hazard Index MCLG for a mixture of HFPO-DA, PFNA, PFHxS, and/or PFBS and the individual MCLGs for HFPO-DA, PFNA, and PFHxS.

In regard to improvements to the CVD analysis based on SAB recommendations, these were clearly laid out in section XV.K.1.c of the FRN for proposal. Further, the agency is not obligated to seek SAB review of every quantified adverse health effect included in a Health Risk Reduction and Cost Analysis (HRRCA); the agency relied on the best available peer reviewed data for the changes in infant birth weight benefits referenced by the commenter.

3M Company (Doc. #1774, SBC-045655)

EPA's interpretation of the data it selected is also flawed and has not been peer-reviewed, in violation of the SDWA. EPA created the HI-MCL after SAB review, and based it on HealthBased Water Concentrations (HBWC) for the four HI substances that were not submitted to SAB. This violates the SDWA, which requires that EPA request comments from the SAB "prior to proposal of a maximum contaminant level goal and national primary drinking water standard." [FN3: SDWA [sec][sec] 1412(b)(3)(A)(i) and (g)]

EPA Response: The EPA disagrees. See section 4.3.2 of the EPA response in this *Response to Comments* document related to peer-review requirements under SDWA prior to proposal of an MCLG and NPDWR. The EPA disagrees that it did not seek adequate consultation from the SAB in the development of the NPDWR. As the commenter states, SDWA Section 1412(e) requires that the EPA "request comments" from the SAB "prior to proposal" of the MCLG and NPDWR. Consistent with this statutory provision, the EPA did so and consulted with the SAB from 2021 – 2022. Additionally, the statute does not dictate on which scientific issues the EPA must request comment from the SAB.

3M Company (Doc. #1774, SBC-045659)

b. History of this Rulemaking Process

EPA began the process of setting this NPDWR in March 2020, when EPA solicited public comment on the preliminary regulatory determinations for contaminants on the fourth CCL. This publication included a preliminary determination to regulate PFOA and PFOS in drinking water. The following year, in March 2021, EPA published its final determination to regulate PFOA and PFOS. [FN24: See 86 FR 12282.] In November 2021, EPA requested feedback from the Science Advisory Board (SAB) [FN25: The Scientific Advisory Board (SAB) is a Federal Advisory Committee made up of subject matter experts. SAB reviews technical information used by EPA for quality and relevance. The board provides advice on EPA proposed regulations and on specific questions posed by the EPA Administrator. SAB's Drinking Water Committee formed a PFAS Review Panel of 16 experts on the scientific and technical aspects of PFAS. As subject matter experts, specifically chosen to provide guidance on the scientific aspects of EPA regulations, their recommendations and analysis should have been taken seriously by EPA when it received feedback on this proposed rule.] on four draft documents related to this rulemaking:

• EPA's Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) (CASRN 335-67-1) in Drinking Water

• EPA's Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) (CASRN 1763-23-1) in Drinking Water

• EPA's Analysis of Cardiovascular Disease Risk Reduction as a Result of Reduced PFOA and PFOS Exposure in Drinking Water

• Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS)

In the first two of these documents, EPA proposed an approach to calculating MCLGs for PFOA and PFOS based on an immune effects endpoint. In other words, EPA's proposed MCLGs were based on the exposure to PFOA and PFOS that the Agency determined was expected to result in negative impacts to immune system function. In its Review of EPA's Analyses to Support EPA's National Primary Drinking Water Rulemaking for PFAS (the "SAB Final Report"), the SAB strongly criticized many of EPA's approaches and requested EPA provide significant clarification. SAB's criticisms included:

• "EPA should provide additional transparency and completeness in its evidence identification methodology, including development of a protocol with clear inclusion/exclusion criteria and study evaluation approaches."

• "Studies, particularly human studies, that were included in the 2016 health effects summary documents (HESDs) should be considered in the same manner as the more recent studies."

• "EPA needs to provide additional details and transparency for all quantitative modeling, including that used for CSF [cancer slope factor] development, toxicokinetic modeling, and benchmark dose modeling for POD derivation. It is essential that details of the Benchmark Dose (BMD) modeling that forms the basis of the PODs are transparently available for evaluation of the methods, approaches, and results."

• "EPA should provide a stronger and more transparent justification for the choice of benchmark responses (BMRs)"

When EPA ultimately published its proposed PFAS NPDWR in March 2023, EPA shifted from relying on the immune effects endpoint to cancer endpoints for PFOA and PFOS in the proposed NPDWR.

EPA also submitted to the SAB in November 2021 its Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances for SAB review which would, according to EPA, "inform development of the MCLGs and NPDWR for PFOA and PFOS." (emphasis added). This Draft Mixture Framework did not present an MCL framework for the four Hazard Index (HI) PFAS, nor did it set proposed health-based water concentrations (HBWCs) for the HI PFAS. In this draft document, EPA acknowledged that HBWCs "would need to be calculated in order to develop component HQs [hazard quotients] and an overall PFAS mixture HI," but made no such calculation. In other words, EPA never submitted draft HBWCs to SAB for review. [FN26: Moreover, EPA "emphasized" to the SAB "that the draft mixtures document is not a regulation, does not impose legally binding requirements on EPA, states, tribes, or the regulated community, and might not apply to a particular situation based on the circumstances." (USEPA SAB 2023, p. 1-2.)]

In March 2023, EPA proposed this NPDWR regulating PFOS, PFOA, PFHxS, HFPODA, PFNA, and PFBS, including HBWCs for the HI PFAS.

EPA Response: Please see section 4.1.3 of the EPA response in this *Response to Comments* document related to peer review of the science underlying the MCLGs for PFOA and PFOS. Pertaining to the EPA's use of the best available science and peer review of the science underlying the Hazard Index MCLG for a mixture of HFPO-DA, PFNA, PFHxS, and/or PFBS and the individual MCLGs for HFPO-DA, PFNA, and PFHxS, please see sections 4.3.1, 4.3.2, and 4.3.3 of the EPA response in this *Response to Comments* document.

3M Company (Doc. #1774, SBC-045664)

c. EPA's Interpretation of the Data It Uses as the Basis of the MCLGs and MCLs is Flawed and Has Not Undergone Peer Review in Violation of the SDWA

The HI MCL also violates the SDWA's mandate that EPA solicit peer review from its SAB prior to issuing a proposed MCL. [FN36: SDWA [sec][sec] 1412(b)(3)(A)(i) and (g).] In 2021, EPA provided SAB with its Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS) (USEPA 2021c). That document was an external peer review draft, which was not revised and published for public review until March 2023 (USEPA 2023e). This means that the Proposed Rule employs techniques regarding data requirements for mixture Health-Based Water Concentrations" but never sets out proposed HBWCs for the HI PFAS or for EPA's currently proposed HI-based MCL for those substances. In the mixtures framework document, EPA itself said that "because there are no EPA-published HBWCs (e.g., Health Advisories, MCLGs) at this time for other PFAS with federal or state assessments/RfVs (e.g., PFBS (EPA), GenX chemicals (EPA), PFHxS (ATSDR), and PFNA (ATSDR)) or chemicals categorized under PFAS 1 or PFAS 2, these values would need to be calculated in order to develop component HQs and an overall PFAS mixture HI." [FN37: Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS), 35 (November 2021)] In other words, EPA expressly did not submit its "mixtures" document as a potential MCL for public review prior to the publication of the Proposed Rule. Indeed, EPA proposed the HBWCs only after SAB reviewed its proposed mixtures framework. As a result, neither the HBWCs that form the basis for the HI-MC, nor the HI-MCL itself have been properly submitted to the SAB or peer-reviewed as required by the SDWA. [FN38: See SDWA [sec] 1412(g)]

EPA Response: The EPA disagrees. See sections 4.3.1, 4.3.2, and 4.3.3 of the EPA response in this *Response to Comments* document related to peer review of the science underlying the Hazard Index MCLG for a mixture of HFPO-DA, PFNA, PFHxS, and/or PFBS.

14.11.2 National Drinking Water Advisory Council

Individual Public Comments

Dylan Pilger (Doc. #1546, SBC-042678)

The National Drinking Water Advisory Council must include Indigenous representation.

My third recommendation to the EPA is that the National Drinking Water Advisory Council include representation from Indigenous communities. First, environmental contamination is a major health concern for Indigenous communities (Gracey & King, 2009). Therefore, it is important that these communities be included in decision-making processes regarding any environmental health hazards. This will also be essential for developing rules which are sensitive to the unique needs of Indigenous populations (Sproat, 2011). Second, as sovereign governmental entities tribes have valuable experience that can be beneficial in these discussions. For example, the South Australian Government has had immense success in collaborating with the Ngarrindjeri nation to protect water sources (Hemming et al., 2019). In 2015, they won the "Australian Riverprize for best practice in water management." Finally, this recommendation is in line with Articles 25 and 26 of the United Nations Declaration on the Rights of Indigenous People (UNDRIP) which states (United Nations, 2008):

"Article 25

Indigenous peoples have the right to maintain and strengthen their distinctive spiritual relationship with their traditionally owned or otherwise occupied and used lands, territories, waters and coastal seas and other resources and to uphold their responsibilities to future generations in this regard.

Article 26

1. Indigenous peoples have the right to the lands, territories and resources which they have traditionally owned, occupied or other-wise used or acquired.

2. Indigenous peoples have the right to own, use, develop and control the lands, territories and resources that they possess by rea-son of traditional ownership or other traditional occupation or use, as well as those which they have otherwise acquired.

3. States shall give legal recognition and protection to these lands, territories and resources. Such recognition shall be conducted with due respect to the customs, traditions and land tenure systems of the indigenous peoples concerned."

For these reasons, I strongly urge the EPA to include Indigenous representation on the National Drinking Water Advisory Council.

EPA Response: The EPA is required under the SDWA to consult with the National Drinking Water Advisory Council (NDWAC) both prior to proposing and promulgating an NPDWR (see section XIII.K.2 of the final rule preamble for more information on how the EPA fulfilled this statutory obligation). However, the membership of the NDWAC is outside of the scope of this regulation. The agency refers the commenter to the EPA's NDWAC website (https://www.epa.gov/ndwac) where information is provided on public solicitation for membership nominations.

14.11.3 Secretary of Health and Human Services

The EPA received no public comments on the agency's consultation with the Department of Health and Human Services.

Section 14 References

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USEPA. 2024e. *Appendix - Office of Water Final Human Health Toxicity Assessment for Perfluorooctanoic Acid (PFOA).* 815-R-24-008.

USEPA. 2024f. *Appendix - Office of Water Final Human Health Toxicity Assessment for Perfluorooctane Sulfonic Acid (PFOS).* 815-R-24-009.

15 Outside Scope of Proposed NPDWR

15.1 Outside Scope of Proposed NPDWR

Summary of Major Public Comments and EPA Responses

The following comments in this section are beyond the scope of this rulemaking. Under the *Administrative Procedure Act* notice-and-comment process for rulemakings, the EPA considers all relevant and timely-submitted comments and responds to all significant comments received during the public comment period. The EPA's final PFAS National Primary Drinking Water Regulation (NPDWR) is based on the administrative record, including the EPA's consideration of these comments. The EPA is promulgating data-driven drinking water standards that are based on the best available science and meet the requirements of the Safe Drinking Water Act (SDWA). The EPA directs commenters to the following sections of this *Response to Comments* document for further information on specific topics related to the final NPDWR:

1. **General information**, to include discussion on the SDWA rulemaking process and risk communications;
2. **Background**, to include discussion on statutory framework, chemistry, production, uses and human health effects of PFAS as well as funding considerations;
3. **Preliminary Regulatory Determinations** for PFHxS, PFNA, HFPO-DA, PFBS, and mixtures of these four PFAS;
4. **Maximum Contaminant Level Goals** for PFOA and PFOS, individual PFAS (PFHxS, PFNA, HFPO-DA) and mixtures of these PFAS and PFBS;
5. **Maximum Contaminant Levels,** to include discussion on feasibility of the final standards for PFOA and PFOS, individual PFAS (PFHxS, PFNA, HFPO-DA) and mixtures of these PFAS and PFBS;
6. **Occurrence**, to include discussion on the Unregulated Contaminant Monitoring Rule (UCMR), state drinking water data, and PFAS co-occurrence;
7. **Analytical methods**, to include discussion on validated EPA methods to support the monitoring requirements of the final NPDWR;
8. **Monitor and Compliance Requirements**, to include discussion on use of previously acquired data, compliance calculations and violations, and monitoring requirements to assure water systems provide safe drinking water to the public;
9. **SDWA Right-to-Know Requirements**, to include discussion on Consumer Confidence Report (CCR) Requirements, as well as Public Notification (PN) Requirements;
10. **Treatment Technologies**, to include discussion on *Best Available Technologies (BATs)* and *Small System Compliance Technologies (SSCTs)* and management of treatment residuals;
11. **Rule Implementation and Enforcement**, to include discussion on requirements for primacy, enforcement related topics, and primacy agency record keeping and reporting requirements;

12. **Exemptions and Extensions**, to include discussion on supply chain and labor challenges that may affect the compliance timeline;
13. **Health Risk Reduction and Cost Analysis**, to include discussion on quantifiable and non-quantifiable costs and benefits of the final NPDWR, benefits from co-removal, uncertainties, affordability, and the social costs of carbon
14. **Statutory and Executive Order Reviews**
15. **Outside Scope of Proposed NPDWR** (this section)
16. **Potential Final Code of Federal Regulations (CFR) Changes**
17. **EPA's Next Steps and Timeline**

The regulation of the PFAS covered by promulgation of this NPDWR is vital toward protecting public health by removing these contaminants from our nation's drinking water. The EPA also recognizes the importance of actions that are beyond the scope of this regulatory action. While the EPA is not obligated to respond to comments that are beyond the scope of this rulemaking, many of the comments provided in this section deal with cross-cutting and non-drinking water topics that may be applicable to other actions on PFAS as discussed in the EPA PFAS Strategic Roadmap. For instance, the EPA has received comments on on-going PFAS rulemakings in non-drinking water programs; PFAS remediation and clean-up actions; limiting the use of certain PFAS in commerce; PFAS source water control such as controlling PFAS in wastewater discharges and other discharges; assigning liability for PFAS pollution, among others. While the EPA recognizes the importance of all of these actions in protecting public health and the environment from the harmful effects of PFAS pollution, comments on these topics are beyond the scope of this regulatory action. Through other actions, the EPA is fully committed to reduce PFAS pollution and human health exposure and implement policies that safeguard communities and public health, protect the environment, and hold polluters accountable. For more information, please see the EPA PFAS Strategic Roadmap where these actions that are part of the EPA's whole-of-agency approach to addressing PFAS are further described (cited in the final rulemaking docket for this final NPDWR and found here: https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024.). Furthermore, commenters can view the EPA's progress on various activities discussed in the strategic roadmap by visiting the EPA's PFAS Strategic Roadmap: Second Annual Progress Report, available at https://www.epa.gov/system/files/documents/2023-12/epas-pfas-strategic-roadmap-dec-2023508v2.pdf. The individual out-of-scope comment excerpts are included below.

Individual Public Comments

North Penn Water Authority (NPWA) (Doc. #1470, SBC-043296)

Other Concerns

Lastly, if the federal government is concerned about improving the caliber of the public water supply, then I would suggest that efforts be redirected to areas that are more pressing. Instead of imposing burdensome regulations on water quality down to infinitesimally low levels in the

range of single digit parts per trillion, which will have a questionable benefit to customers, there are better ways to expend our resources.

First, there is more of a critical need for the replacement of aging infrastructure, like pipes in the ground that have exceeded their useful lifespans. Second, the reliability of a continuous, uninterrupted, low cost energy supply is critical to the operations of any water system that needs to run water through treatment plants and distribute it to thousands of people through many miles of pumps, pipes, and storage tanks every minute of every day. All of this continuous movement of water is vitally important to our customers, and it can all be stopped cold without sufficient power. Yet, the cost of energy has been skyrocketing in recent years, and the reliability of power supplies has been continually diminished by current government policies that promote less dependable sources of energy. The average American consumer of public water will get a much better "bang for their buck" if efforts are more focused on these areas instead.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Darlene Price (Doc. #1471, SBC-042305)

See attached file(s) I have proof positive that local and state officials are allowing the potential poisoning and cover-up of an entire echo system in the Daniel Boone National Forest and the Cumberland River in Kentucky. Please see the attached letter/file outlining this proof. I have over a thousand documents obtained from official open records requests and from reliable confidential sources. My team "TRUTH or POLITICS" have completed a 4 hour documentary entitled, "Lake Cumberland, what really lies beneath" parts 1 & 2 which can be viewed on YouTube at this link: https://www.youtube.com/watch?v=gdlPzooZFkw. I am willing to forward any and all of these shocking documents for anyone to view. I am also willing to give live testimony. We now have numerous individuals who are getting sick from this colossal blunder. I have too many documents to upload and will have to explain what many of these documents actually are. The Mayor of Somerset, Kentucky and his city council have brought into Kentucky over 50 million gallons of extremely toxic waste in the form of "leachate" from four different landfills. They have processed this toxic waste through a highly defective (over 100 documents from 2016 to current) wastewater treatment plant, which ultimately runs into the Cumberland River. Millions of people and countless wildlife get their drinking water down stream from this defective plant. Now a recent test of local drinking water here in Pulaski County revealed that "Forever Chemicals" are in fact in the drinking water. In the attached letter are more details and my contact information. Please allow me to help by testifying at any upcoming hearings on this issue.

DARLENE FITZGERALD PRICE, J.D.

Producer/Host, "TRUTH OR POLITICS: SOUTH-EASTERN KY,

LOUISVILLE AND CHIAN MOUNTAINS'

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March 28, 2023

Comment on Proposed Rule by the Environmental Protection Agency:

www.regulations.gov, Docket ID: EPA-I-IQ-OW-2022-0114.

RE: Local public officials and state officials are knowingly engaging in the massive pollution and cover-up of Lake Cumberland and the Cumberland River; located in the Daniel Boone National Forest, Kentucky by allowing "Forever Chemicals" to enter the water-ways unchecked and unchallenged.

To Whom it May Concern,

I am entering this letter in support of the EPA proposed rule on "Forever Chemicals"

(www.regulations.gov, Docket ID: EPA-HQ-OW-2022-0114) I am a retired Special Agent now Criminal Defense Investigator/Expert Witness, with over 35 years of experience in criminal investigations. As one of my part time jobs, I am an investigative journalist here in my home state of Kentucky. I have been working on a story that to call shocking, would be an understatement. We have completed a two part documentary that you can now view on YouTube entitled, "Lake Cumber, what really lies beneath" Parts 1 and 2.

Lake Cumberland in Pulaski County, Kentucky, is located in the beautiful Daniel Boone National Forest. It is a very active tourism location for swimming, boating, fishing, hiking, camping and water-skiing. It is also the primary source of drinking water for much of the people and wildlife in Kentucky and throughout Tennessee. Pitman Creek in Pulaski County, Kentucky flows directly into Lake Cumberland. Lake Cumberland flows into the

Cumberland River, a primary water source that flows down stream to Nashville, Tennessee.

As a result of numerous records that I have received from the State EPA and the State Water district via open records requests, I have serious concerns regarding the water contamination in Lake Cumberland and the Cumberland River.

My primary concern is that we have numerous documents that demonstrate that the City of Somerset has a highly defective wastewater treatment facility from at least 2016 through 2023. Despite this facility being repeatedly threatened by the State EPA, they have since 2019 added to this facility even more serious contaminates from landfill runoff called leechate. My investigation clearly demonstrates that this was done in order to secure at least $300,000.00 a year by the Mayor of Somerset and the Somerset City Counsel. This information is of particular concern if the notice of hexavalent chromium came after the introduction of leechate to this treatment facility. My research demonstrates that leechate from demolition landfills hold some of

the most dangerous contaminates. Some of these landfills will have leechate that most certainly contains asbestos and "Perfluorooctanoic acid" also known as "C8" and "Forever Chemicals"; as well as C6 hexavalent chromium. Normal purification processes will not remove these types of contaminates which are known to be highly carcinogenic and lethal to wildlife.

The documents that I have received from the State Water District, the State EPA, the Regional Health Department and the City of Somerset tell a most gruesome story. These documents clearly demonstrate that Sinking Creek and Pitman Creek, which empty out into Lake Cumberland, have numerous, repeated serious "Out of Compliance Violations" for: E-Coli, Chronic Ceriodaphnia Dubia Pkv; CBOD; Suspended Solids, Total Ammonia Nitrogen (as N), and MOST CONCERNING is the June 8, 2018, letter referring to "hexavalent chromium" limits — also known as C-6. These many violations run at least from 2016 to 2022. These violations were serious enough that the State Water Department repeatedly threatened that, "Violations of the above cited statutes(s) and/or regulation(s) are subject to a civil penalty per day per violation. Violations carry civil penalties of up to $25, 000 per day per violation depending on the statutes/regulations violated." Yet, in the State EPA, the State Water District and Somerset's answers and/or documents provided, there were zero fines or penalties levied on either the City of Somerset or the wastewater treatment plant; even though numerous violations have been sited over at least a period of six (6) years.

At this point, The City of Somerset Wastewater Treatment Plant alone has introduced at least 50 million gallons of Industrial Waste Leachate from four (4) different industrial waste landfills, not to mention the thousands of gallons of industrial waste from the local businesses that send their industrial waste to this defective plant. These businesses include medical facilities that are permitted for some of the worst contaminates imaginable, including C-6 & C-8. These landfills and businesses are permitted for "Industrial Waste" while the City of Somerset's wastewater treatment plant has only a general permit that is over twelve (12) years old.

Even more concerning is the reaction / cover-up from the Kentucky State Water District and the Kentucky EPA. Case in point, one of the documents in my possession is an email between Diana Robertson, Pretreatment Coordinator for KY Div. of Water, "As a follow-up to an earlier conversation, there are currently no federal or state wastewater standards/limits for PFOA (C8), PFOS or PFAS. As a result, wastewater treatment plants in Kentucky are not routinely sampling for those parameters. I wouldn't expect to see sampling of industrial user discharges for those parameters either as there are no applicable limits." In other words, she is refusing to test not only Pitman Creek or Lake Cumberland for these deadly chemicals, but apparently the State of KY Water District hasn't been and is NOT going to test for either these "forever chemicals" or asbestos even though there is a very real chance that this facility, and who knows how many others, are introducing them to our precious water sources. You can't find what you are not looking for.

Moreover, there ARE standards/limits for PFOA (C8), PFOS or PFAS that were set by DuPont. DuPont paid out over $4 Billion dollars in settlement agreements regarding this very thing in the state of Virginia. In these suits, the federal courts ruled that there were limits and that those

limits were set by DuPont themselves; and that limit is 70 parts per trillion. That is the equivalent of 7 grains of sand in an Olympic-sized swimming pool. Anything more has been deemed UNSAFE! The fact that a high-level bureaucrat in the State Water Division has no knowledge of this I find incredible. Furthermore, what is even more incredible is in an interview with the Somerset Wastewater Treatment Director, she stated that she had no idea what was in the leechate from the landfills that is now running through this defective system and into Lake Cumberland.

Several months ago, the federal EPA did a press conference and announced that there are NO SAFE LEVELS OF PFOAs (C8), PFOS or PFAS, in drinking water. As a result of what I have uncovered above, a local concerned attorney has tested his drinking water, and sure enough, it now contains PFOA (C8), PFOS or PFAS. I have been contacted by numerous people in the surrounding area that are now sick from this contamination.

This is just a sampling of this heart-wrenching investigation thus far. What I'm hoping for is that these EPA regulations and regulations like it, will indeed pass and not only protect our drinking water, but our entire echo-system surrounding our beautiful Daniel Boone National Forest.. We have already posted this story (Lake Cumberland, what really lies beneath) on You Tube, Face Book and on local cable T.V. in April 2022. The video will illustrate many of the documents of proof along with location videos and interviews. I know that this documentary is too long. However, when you are making extraordinary accusations, you must have extraordinary proof. Any assistance that I can give to you on this very important issue, I will be happy to provide. Feel free to contact me for any additional information. Thank you for your time.

Sincerely,

Darlene F. Price, J.D.

Producer/Hist of Truth or Politics

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Jorge Diaz Castello (Doc. #1475, SBC-042311)

Alteration of existing PFAS to circumnavigate the law.

March 30, 2023

Ashley Greene

Standards & Risk Management Division

The Office of Groundwater & Drinking Water

Environmental Protection Agency

1200 Pennsylvania Ave.

Washington, DC 20460

RE: EPA's Proposed PFAS NPDWR; Docket ID No. EPA-HQ-OW-2022-0114

We all know chemical manufacturers will alter an existing PFAS compound and circumnavigate the law. Can we address this situation? Please see attached outline of regulation to end this alteration in order to comply philosophy.

Sincerely

Jorge Diaz Castello diazcastello@gmail.com

786 381 8592

Section 1. (Title)

Title This legislation shall be known as the "Chemical Compound Alteration Prevention Act."

Section 2. (Purpose)

The purpose of this act is to prohibit chemical manufacturers from altering a chemical compound in order to circumvent regulatory compliance. This section aims to prevent the production and sale of chemicals that may be harmful to human health or the environment. Chemical compounds that are altered to circumvent regulatory compliance can be just as dangerous as the original chemical compound and can pose a significant risk to public health and the environment.

One example of a chemical compound that has been altered to circumvent regulatory compliance is PFAS (Per- and Polyfluoroalkyl Substances). PFAS are a group of man-made chemicals that have been used in a wide range of industrial and consumer products, including non-stick cookware, waterproof clothing, and firefighting foam. PFAS are persistent, meaning they do not break down easily in the environment, and can accumulate in the human body over time. PFAS have been linked to a range of health effects, including cancer, immune system dysfunction, and reproductive and developmental harm.

In response to regulatory action on PFAS, some chemical manufacturers have started producing "generation X" substitutes, which are chemical compounds that are structurally similar to PFAS but are not specifically regulated. However, research has shown that some generation X substitutes may be just as harmful as PFAS, and may even be more persistent in the environment.

Therefore, it is essential to prohibit chemical manufacturers from altering chemical compounds to circumvent regulatory compliance, and to promote the production and sale of safer and more environmentally friendly alternatives.

Section 3. (Definitions)

Definitions For the purposes of this act, the following definitions shall apply: (a) "Chemical manufacturer" means any entity that produces, imports, or sells a chemical compound or substance, including but not limited to manufacturers of pharmaceuticals, industrial chemicals,

consumer products, and food additives. (b) "Chemical compound" means any substance composed of two or more elements that are chemically combined in fixed proportions. (c) "Regulatory compliance" means adherence to any federal, state, or local law, regulation, or guideline that governs the production, importation, or sale of chemical compounds or substances. "Chemical facility" means any physical plant or other site where chemicals are produced, processed, stored, altered, or otherwise handled, including but not limited to manufacturing plants, warehouses, distribution centers, and laboratories.

Section 4. (Prohibition)

(a) Chemical manufacturers shall not intentionally alter the molecular structure of a chemical compound in order to circumvent regulatory compliance.

(b) Each chemical facility subject to this regulation shall appoint a “designated person” who is responsible for ensuring compliance with this regulation. The “designated person” shall be trained and certified in chemical safety and shall be personally liable for any violations of this regulation by the chemical facility. Each chemical facility shall have only one designated person. In the event of a violation, the designated person may be subject to civil or criminal penalties, including fines, imprisonment, or other appropriate sanctions. This provision will not only make the manufacturer of the altered chemical liable but also the chemical plant “designated person”.

(c) Chemical manufacturers shall not distribute or sell any chemical compound that is intentionally altered in violation of this regulation.

(d) Chemical manufacturers and chemical facilities shall maintain records of their compliance with this regulation, including but not limited to records of chemical composition, production processes, and safety data.

(e) Any “designated person” who violates this regulation may be subject to civil or criminal penalties, including fines, imprisonment, or other appropriate sanctions, as determined by the [enforcement agency].

Section 4 outlines the core prohibition of the draft legislation, which is the prohibition against chemical manufacturers altering chemical compounds to circumvent regulatory compliance. This provision is intended to prevent chemical manufacturers from using loopholes or technicalities to bypass regulatory requirements, and to ensure that all chemicals are subject to appropriate regulatory oversight.

Furthermore, Section 4 places the responsibility for ensuring compliance with relevant laws and regulations squarely on the shoulders of chemical manufacturers. Chemical manufacturers are expected to take proactive steps to ensure that their products comply with all applicable laws and regulations. They are also liable for any harm caused by their products, which ensures that they are accountable for the safety of their products and the potential harm they may cause.

By prohibiting the production and sale of harmful chemical compounds and holding chemical manufacturers accountable for their actions, Section 4 seeks to ensure that public health and the environment are protected from the potential harms of chemical exposure.

Section 5. (Penalties)

(a) Any chemical manufacturer found to have altered a chemical compound in order to circumvent regulatory compliance shall be subject to civil and criminal penalties.

(b) Civil penalties for a violation of this act shall be assessed by the appropriate regulatory agency and may include fines, injunctions, or other appropriate relief.

(c) Criminal penalties for a violation of this act shall be assessed by the appropriate law enforcement agency and may include fines, imprisonment, or both.

(d) Any person who suffers harm as a result of a violation of this act may bring a civil action for damages against the chemical manufacturer and the "designated person" of the facility where the chemical was produced/altered.

Penalties may include both civil and criminal consequences, as well as restitution for any harm caused by the violation.

Civil penalties may be assessed by the appropriate regulatory agency and can include fines, injunctions, or other relief. Criminal penalties may be assessed by law enforcement agencies and may include fines, imprisonment, or both.

Additionally, any person who suffers harm as a result of a violation of this act may bring a civil action for damages against the chemical manufacturer. This provision ensures that individuals who have been harmed by the actions of chemical manufacturers have recourse to seek compensation for their damages.

Section 6. (Enforcement)

(a) The enforcement of this law shall be a joint effort of the following federal agencies:

(i) U.S. Environmental Protection Agency (EPA)

(ii) U.S. Food and Drug Administration (FDA)

(iii) U.S. Consumer Product Safety Commission (CPSC)

(a) The federal agencies listed above shall have the power to investigate alleged violations of this law, and to bring civil or criminal enforcement actions against any chemical manufacturer that violates this law.

(b) Any person or entity that violates this law shall be subject to penalties as provided by law, including but not limited to fines, injunctive relief, and/or imprisonment.

(c) The federal agencies listed above shall have the power to promulgate rules and regulations necessary to implement this law.

(d) The federal agencies listed in subsection (a) shall establish a joint task force to coordinate their enforcement efforts and share information regarding violations of this law.

(e)The joint task force shall be responsible for:

(i) Developing a standardized process for investigating and enforcing violations of this law.

(ii) Sharing information regarding violations of this law, including but not limited to information regarding the identity of violators, the nature of the violations, and any enforcement actions taken.

(iii) Coordinating the enforcement efforts of the federal agencies listed in subsection (a), including but not limited to conducting joint investigations and pursuing joint enforcement actions.

(a) The federal agencies listed in subsection (a) shall provide annual reports to Congress regarding their enforcement efforts under this law, including but not limited to the number of investigations conducted, the number of enforcement actions taken, and the penalties imposed on violators.

(b) Citizen suits. Any person or organization may bring a civil action against any chemical manufacturer that violates this law if the federal agencies listed in subsection (a) have not commenced a civil or criminal action with respect to such violation within 60 days after the person or organization has provided notice of the violation to the appropriate federal agency and to the alleged violator. In any such civil action, the court may award costs of litigation (including reasonable attorneys' and expert witness fees) to any prevailing or substantially prevailing party, whenever the court determines such an award is appropriate.

These provisions would help to ensure that the federal agencies responsible for enforcing the law are coordinating their efforts effectively, and that they are sharing information and resources to maximize their effectiveness. By requiring the agencies to establish a joint task force and provide annual reports to Congress, the legislation would also provide transparency and accountability regarding the agencies' enforcement efforts.

Section 7. (Severability)

Severability If any provision of this act or the application thereof to any person or circumstance is held invalid, the remainder of the act and the application of such provision to other persons or circumstances shall not be affected thereby.

Section 8. (Effective Date)

Effective Date This act shall take effect on the date of its passage.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Sophia Milone (Doc. #1487, SBC-042704)

Also, due to the harm PFAS and other chemicals pose to public health and their longeivity, they should be treated as stringently as the EPA treats things like greenhouse gases: their emission should be reduced with the goal of emitting none, because any amount released is not safe. In order to ensure everything possible is being done to limit the emission of, consumption of, and exposure to PFAS, PFOA, and PFOS, the EPA should assess and remediate existing areas with high levels of these compounds. This will likely require funding for state-controlled remediation processes, but will assist communities suffering the most from chemical exposure and provide a framework for assessing affected areas in the future. (Attached is a list of effects from PFAS exposure).

[Figure: see docket ID EPA-HQ-OW-2022-0114-1487]

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #1506, SBC-042575)

We recommend that the EPA holds companies responsible for the impact their chemicals (PFAS) have on families in affected areas. This means not only notifying residents that their water is contaminated, but paying for them to relocate to a safer area if they choose to do so. If the residents do not want to move, the companies should cover all costs of safe bottled water until they can reduce the PFAS concentration to an acceptable amount. All residents who were exposed to dangerously high concentrations of PFAS should be entitled to free medical testing (covered by the responsible chemical company). If it is determined that residents acquired a disease as a result of the high PFAS exposure, the responsible chemical company will cover all medical costs related to the disease.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #1506, SBC-042577)

All PFAS should be banned in pregnancy/infant products, only essential PFAS should be present in other products (Benesh, 2020). Chemicals that are similar in structure/function to known PFAS should be required to undergo more rigorous and extensive testing before they are released to the public. This could mean animal testing and third party testers to ensure the safety of the new chemical.

Due to the extremely harmful effect PFAS have on individuals, employees of chemical companies should be held accountable for their decisions. More specifically, top employees who approved decisions which led to high concentrations of PFAS or attempted to hide the danger of PFAS should face criminal charges. All chemical companies and subcontractors who work with PFAS or similar chemicals should be required to sign an agreement taking full responsibility if any of their chemicals causes adverse human health problems. This agreement should be a part of their license to distribute/synthesize any chemicals (not limited to PFAS), making them liable for damages.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

John Pate (Doc. #1508, SBC-042580)

As you can see I Have a small contamination of my well. For the past Five years of testing I have not had above contamination until the new regulations were put in place. See attached file(s).Is it illegal to dump PFAS into the environment with knowledge of a contamination of a well. Because with Reverse osmosis system the brine solution that is dumped into our septic tanks which make a makes a toxic environment dump site when we have septic tank pumped out we do not need to report the contamination. Which then is used as biosolids out environment. Then let us take on step further people with a contaminated well use the outside spigot to wash cars, water grass or plants outside are those people also in violation of dumping PFAS into the environment. These are question should be addressed.

[Attachment 1: see docket ID EPA-HQ-OQ-2022-0114-1508].

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Liliana Salcido (Doc. #1509, SBC-042585)

Furthermore, all of this research and disclosure to the public should be funded and supported by the Federal government. In cases of danger and harm to the general public, there should be government intervention at the Federal level to ensure public health. Companies should not be regulating themselves when it comes to public safety because they have a conflict of interest when it comes to protecting their profits over the health and safety of humans. In a capitalist democracy, the citizens and consumers should have the right to make informed decisions based on full disclosure from both corporations and the government when it comes to consuming products, which in this case is water– our purest source of life and sustenance. If companies are regulating themselves and doing their own scientific research, they will be biased and they will choose to not disclose the harm their hazard waste and products create for human beings.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Jon Raclin (Doc. #1511, SBC-042595)

A utilitarian approach would be to utilize as much sun and wind energy as possible from large wind and solar fields to cut the costs of the policy down, so that the price of living doesn't rise as much, and use that stored energy to filter the water facilities under this policy change.

I think there should be two economic filters to this EPA change to help the public acclimate with this new billion dollar cost. The public is the three hundred million citizens that pay taxes to pay for the government's functioning. The EPA is the government's environmental sector. One filter is that the government should take a 6 month period of some payment to pay for wind farms or solar farms. This would pay for natural energy the water filtration cities would use across the nation. Additionally the second filter is that the population that spends the most on non necessary purchases, should be required to pay higher taxes, as to hold more accountability with their financial wealth.

This combination strategy bears the financial weight on multiple payment plans as to divide the weight and keep the entire economy afloat, and not allocate the entire multi billion dollar bill on one singular field of tax that won't be paid off for decades. The combination strategy is the one I want to see flourish because as a business major, I plan to own and run wind farms and solar farms and even lead the technology with the most recent science and make a powerful economic force that is helping the world.

This combination strategy protects and provides for the plan evenly and with green ambitions. The length of detail this new EPA regulation contains is revolutionary but also just the beginning. I see many more laws and discoveries as to chemicals we are banning and limiting in our mass production sectors.

I'd imagine if I were to tell a crowd my opinions about this combination strategy would be accepted and agreed upon. My combination strategy incorporates many evenly distributed finances and roles. The energy and technology used for this new regulation will have to be sourced from somewhere, and while we are continuing to protect our environment, we should go about this massive governmental rule change responsibly and source our energy from the natural sources; wind and sun.

5. Act and Reflect on the Outcome. You will submit your comments to the Federal Register when the public comment period opens. In the meantime, for this last step, as described previously, you will individually submit a 200-word reflection.

● Discuss some of the challenges you encountered in working through the five steps of decision-making, what insights you gained from the process, and what questions bubbled up as a result.

● How did my decision turn out? What is what you expected it would be going into this assignment?

● Can my recommendations be implemented with great care and attention to the concerns of all stakeholders?

Vojin's Input

I found the five-step decision-making process to be a very helpful tool in day-to-day life. At first, knowing that the decisions I made would affect the entire population was a bit intimidating but after breaking it down into manageable parts it became a lot easier. In researching this issue, the first step was identifying what shareholders would be most affected by and trying to gain insight into their perspective. After analyzing that I would compare the pros and cons to hopefully make the decision that would help the largest group of people.

The main challenge I encountered was balancing my beliefs and values with those of the shareholders. The difficult part was coming to a decision that would be fair to all parties without alienating one. The future consequences of my decision were also taken into consideration since the shareholders could be affected down the line.

The insight that was gained was mainly considering how our decisions would affect everyone involved. Also, what I realized was that by researching the issue in advance and weighing out the pros and cons we could make the process of coming to the best possible outcome much easier.

Questions that came up for me were mostly around how my decisions would affect me or the shareholders. I would try to take into consideration all the concerns and how people would be affected. I also wanted to make sure that the decision I made could be one that would attend to all shareholders.

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EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Southern Methodist University Dedman School of Law (Doc. #1512, SBC-042597)

I have researched the effects of PFAS, and I would like to address two concerns I have with the proposed rule:

(1) As PFAS are "forever chemicals," meaning they do not naturally break down, more should be done to regulate these chemicals before they can make it to water supplies. Regulations should be as stringent as possible to avoid prolonged low-dosage exposure in our communities.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Southern Methodist University Dedman School of Law (Doc. #1512, SBC-042599)

1. Regulating PFAS From the Source

Across the country, PFAS are leeching into our water supplies at an alarming rate. [FN1: Chris Hubbuch, UW-Madison Researchers Seek to Understand How Forever Chemicals Move Through Soil, THE JOURNAL TIMES, (Dec. 22, 2022) (updated Jan. 31, 2023) https://journaltimes.com/news/stateand-regional/uw-madison-researchers-seek-to-understand-how-forever-chemicals-move-through-soil/article_6d376f99-1c52-5ce7-8545-0c372a92285e.html? utm_medium=social&utm_source=twitter&utm_campaign=user-share.] Because the over 6,000 PFAS do not all move or behave in the same ways, it can be challenging for researchers to decipher exactly how they reach water systems and where they come from. [FN2: Id.] Researchers have said that the presence of PFAS should be presumed in 57,412 sites across all 50 states. [FN3: Sharon Udasin, Scientists Say 'Forever Chemicals' may be Contaminating 57,000 US Sites, THE HILL (Oct. 12, 2022) https://thehill.com/policy/equilibrium-sustainability/3684169-scientists-say-foreverchemicals-may-be-contaminating-57000-us-sites/.] PFAS are used in a variety of materials, such as nonstick and water-resistant coatings, fire suppressants, and household goods. One recent study even found high levels of PFAS in school uniforms used by American and Canadian children. [FN4: Diamond et. al., Per- and Polyfluoroalkyl Substances in North American School Uniforms, Environ. Sci. Technol. 2022, 56, 19, 13845–13857, https://doi.org/10.1021/acs.est.2c02111.] Even if drinking water is made safer through PFAS regulation, the risks of these harmful chemicals are still present in our homes and communities. While the anticipated addition of PFAS as hazardous substances for purposes of CERCLA liability will hold the most egregious polluters accountable, more can be done to stop PFAS from entering our communities in the first place.

While the proposed NPDWR regulates some of the oldest and most harmful contaminants, it does not regulate all PFAS chemicals. [FN5: Stephanie Ebbs, EPA Announces Limits on Some 'Forever Chemicals,' But Just a Fraction are Covered, ABC NEWS, (March 14, 2023), https://abcnews.go.com/Health/epa-announces-limit-forever-chemicalsdrinking-water/story?id=97853947.] Efforts need to be made to eventually regulate all potentially harmful PFAS, even if the regulations would conflict with current industry practices. Actions such as the recent significant new use rule requirements for PFAS under § 5(a)(2) of the Toxic Substances Control Act (TSCA) are an important part of this. [FN6: Docket ID No. EPA-HQ-OPPT-2022-0867.] I suggest that further steps are taken to regulate a broader range of PFAS in a broader range of industries using the EPA's authority under the TSCA. Preventing PFAS from the source will further strengthen the proposed NPDWR requirements, while also limiting the amount of PFAS citizens are exposed to from sources other than drinking water.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Christian Garcia (Doc. #1513, SBC-042605)

While the proposed NPDWR sets maximum contaminant levels for six PFAS chemicals, it does not cover all PFAS compounds, and the set limits may not be stringent enough adequately. Notably, the current NPDWR is limited to public water systems, but more than 23 million US households are obtaining drinking water from private wells. [FN16: Allen D. Woolf, et al., Drinking Water from Private Wells and Risks to Children, American Academy of Pediatrics, https://publications.aap.org/pediatrics/article/151/2/e2022060644/190540/Drinking-Water-From-Private-Wells-and-Risks-to?autologincheck=redirected (last visited Apr. 21, 2023).]

Although the EPA and most states offer some guidance for the construction, maintenance, and testing of private wells, most states only regulate the construction of new private water wells. [FN17: Id.] Currently, water systems servicing less than 25 people, including private wells, are not subject to federal and state regulations under the Safe Water Act of 1974. [FN18: 42 U.S.C. §§300f-300j-26.] Yet, these private wells often contain the same PFAS levels and cause the very PFAS exposure that the EPA is trying to protect the public from. [FN19: Allen D. Woolf, et al., Drinking Water from Private Wells and Risks to Children, American Academy of Pediatrics, https://publications.aap.org/pediatrics/article/151/2/e2022060644/190540/Drinking-Water-From-Private-Wells-and-Risks-to?autologincheck=redirected (last visited Apr. 21, 2023).] These households should have the same guidance and access to resources as public water systems, such as access to federal funding to improve their water infrastructure under the Bipartisan Infrastructure Law. [FN20: U.S. ENVIRONMENTAL PROTECTION AGENCY, Water Infrastructure Investments, https://www.epa.gov/infrastructure/water-infrastructure-investments (last visited Apr. 21, 2023).]

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Emma Jenevein (Doc. #1514, SBC-042708)

PFAS needs to be regulated at the source, in addition to remedial regulation of PFAS present in drinking water

While it is essential that EPA establish an NPDWR to provide for the design, installation, maintenance, and enforcement of PFAS monitoring and removal procedures; PFAS contamination must also be addressed at the source to limit the need for remediation. Silent Spring Institute, a nonprofit research organization that studies the links between environmental chemicals and disease, has published several peer-reviewed studies concerning PFAS exposure associated with drinking water, [FN16: Laurel A. Schaider et al., Pharmaceuticals, perfluorosurfactants, and other organic wastewater compounds in public drinking water wells in a shallow sand and gravel aquifer, SCIENCE OF THE TOTAL ENVIRONMENT (Jan. 15,

2014), https://pubmed.ncbi.nlm.nih.gov/24055660/. See also Xindi C. Hu et al., Detection of poly-and perfluoroalkyl substances (PFASs) in US drinking water linked to industrial sites, military fire training areas, and wastewater treatment plants, ENV'T SCI. & TECH. LETTERS (Oct. 11, 2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5062567/.] food packaging, [FN17: Laurel A. Schaider et al., Fluorinated compounds in US fast food packaging, ENV'T SCI. & TECH. LETTERS (2017), https://pubmed.ncbi.nlm.nih.gov/30148183/.] diet, [FN18: Herbert P. Susmann et al., Dietary habits related to food packaging and population exposure to PFASs, ENVIRONMENTAL HEALTH PERSPECTIVES (Oct. 2019), https://pubmed.ncbi.nlm.nih.gov/31596611/.] and consumer products. [FN19: Katherine E. Boronow et al., Serum concentrations of PFASs and exposure-related behaviors in African American and non-Hispanic white women, JOURNAL OF EXPOSURE SCI. & ENV'T EPIDEMIOLOGY (Jan. 8, 2019), 29(2), https://www.nature.com/articles/s41370-018-0109-y.] To address these sources of PFAS contamination, EPA should take steps to limit the number of consumer products containing PFAS. For example, PFAS contamination in drinking water has been closely associated with the use of PFAS-containing firefighting foams. [FN20: Xavier Dauchy et al., Per-and polyfluoroalkyl substances in firefighting foam concentrates and water samples collected near sites impacted by the use of these foams, CHEMOSPHERE (Sept. 2017), https://pubmed.ncbi.nlm.nih.gov/28531559/. See also Xavier Dauchy et al., Poly-and perfluoroalkyl substances in runoff water and wastewater sampled at a firefight, ARCHIVES OF ENV'T CONTAMINATION & TOXICOLOGY (Feb. 2019), https://pubmed.ncbi.nlm.nih.gov/30515647/.] Many states have enacted legislation to restrict or ban the use of PFAS-containing firefighting foam. [FN22: See e.g., S.B. 1044, 2022 Leg., Reg. Sess. (Cal. 2022); H.B. 19-1279, 74th Gen. Assemb. Reg. Sess. (Colo. 2019); S.B. 0561, 102nd Gen. Assemb., Reg. Sess. (Ill. 2021); S.B. 439-A, 2019–2020 Leg. Sess., Reg. Sess. (N.Y. 2020); L.D. 1505, 130th Gen. Assemb., Reg. Sess. (Me. 2021).] EPA should consider a federal ban on firefighting foams containing PFAS compounds to eliminate this particular source of drinking water contamination.

Presently, EPA is considering registering PFOA, PFOS, PFBS, and GenX as hazardous substances under the Resource Conservation and Recovery Act (RCRA). [FN22: U.S. ENV'T PROTECTION AGENCY, EPA Responds to New Mexico Governor and Acts to Address PFAS Under Hazardous Waste Law (Oct. 26, 2021), https://www.epa.gov/newsreleases/epa-responds-new-mexico-governor-and-acts-address-pfas-under-hazardous-waste-law.] EPA is also considering listing PFOA and PFOS as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). [FN23: U.S. ENV'T PROTECTION AGENCY, Key EPA Actions to Address PFAS (March 14, 2023), https://www.epa.gov/pfas/key-epa-actions-address-pfas.] By registering PFAS compounds as hazardous materials, EPA can help prevent releases of PFAS into drinking water from contaminated sites, freeing up resources for further remediation of PFAS contamination.

In summary, to effectively protect public health and provide for enforceable regulation of PFAS, any national drinking water standards must adopt a class-based approach. EPA must also expand

its regulation of PFAS beyond drinking water standards to address the sources of PFAS contamination.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Emma Jenevein (Doc. #1514, SBC-042706)

PFAS needs to be regulated at the source, in addition to remedial regulation of PFAS present in drinking water.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Ruoyu Zhang (Doc. #1520, SBC-042749)

While regulating Per- and polyfluoroalkyl substances (PFAS) in drinking water is an important step, other contaminants such as lead and arsenic also pose a significant threat to human health and necessitate strict regulation by the Environmental Protection Agency (EPA). Lead and arsenic are toxic metals that can lead to severe health problems, particularly in children and pregnant women. Lead exposure can cause developmental delays, behavioral problems, and lower IQ in children, while arsenic exposure has been linked to developmental effects, skin lesions, and cancer.

Despite the critical health risks of lead and arsenic, these contaminants are still present in many drinking water sources across the nation. Although the EPA has established maximum contaminant levels for lead and arsenic, these levels are inadequate and require more stringent regulation and enforcement through regular monitoring and enforcement actions. Such efforts would entail a significant investment in water treatment infrastructure. However, the long-term advantages of protecting public health would outweigh the costs. Furthermore, regulating lead and arsenic in drinking water alone is insufficient. It is critical to regulate these contaminants in other sources of exposure, such as soil and air pollution, requiring a concerted effort between the EPA and other federal, state, and local agencies, industry, and community stakeholders.

In conclusion, while regulating PFAS in drinking water is crucial, it is also imperative to recognize that other contaminants, such as lead and arsenic, pose a significant threat to public health and require stringent regulation by the EPA. Taking a comprehensive approach to regulate contaminants in drinking water and other sources of exposure will ensure safe and healthy environments for all.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Samantha Matterson (Doc. #1527, SBC-042631)

From an economic lens, this action does not fully address the negative externalities of this issue. PFAS are used in over 21 industries and in over 43 use categories, their use and production are expansive and widespread (Glüge et al., 2020). The companies that produce these chemicals continue to produce chemical waste and pollution, as well as directly harm those who are not involved in the production of the chemicals. In addition, the funding for the removal of the chemicals from the water comes at least in part from taxpayer dollars. Essentially, American citizens must pay to not get poisoned, when the government could step in and stop the poisoning from happening in the first place. The companies that produce these chemicals get to continue to profit while American citizens suffer. There should be more financial penalties for companies who continue to pump PFAS into the environment. That money could go toward removing PFAS from drinking water to supplement taxpayer dollars already going into this project. People and companies who are physically responsible for the presence of these chemicals should also be held financially responsible.

Overall, I think this action is necessary and is a step in the right direction. However, I believe that in order for it to be an effective dynamic solution to this issue, there needs to be added legislation or promised future legislation to ensure that companies producing PFAS are held responsible. Further, legislation needs to ensure that companies are producing less if not none of these harmful PFAS to stop them from entering the drinking water and environment in the first place. Every citizen and corporation has a responsibility to the future of our country and our planet, reducing the levels of PFAS is a start, but more action is required if future generations want a safe and healthy place to call home.

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Hogue, C. (2019, May 11). Governments endorse global PFOA ban, with some exemptions. C&EN Chemical and Engineering News. https://cen.acs.org/environment/persistent-pollutants/Governments-endorse-global-PFOA-ban/97/i19#

Li, Y., Mucs, D., Scott, K., Lindh, C., Tallving, P., Fletcher, T., & Jakobsson, K. (2017). THE SAHLGRENSKA ACADEMY INSTITUTE OF MEDICINE TECHNICAL REPORT Half-lives of PFOS, PFHxS and PFOA after end of exposure to contaminated drinking water REPORT NO 2:2017 FROM THE UNIT FOR OCCUPATIONAL & ENVIRONMENTAL MEDICINE IN GOTHENBURG. https://core.ac.uk/download/pdf/85145043.pdf

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Water Environment Federation (WEF) (Doc. #1529, SBC-043316)

Long-term Impacts

Focus upstream to stop PFAS at the source instead of at the utilities where PFAS is received. Consider the scope of climate change impacts that regulations will impose on progress.

• Background levels: Background levels in some soils are higher than are found in drinking water and water resource recovery facilities. Clarification is needed on how EPA will manage this imbalance in existing and regulated concentrations.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Water Environment Federation (WEF) (Doc. #1529, SBC-043318)

• Climate Change: Soil loss, increased fertilizer prices, water shortages, increased GHG emissions due to transportation and/or adoption of high temperature processes, and increasing temperatures represent some of the real-time impacts of climate change. Targeting core programs that aim to recover resources, create renewable energy, and clean water will only exacerbate these impacts. WRRFs are engaged in a number of actions to mitigate climate change. Among others, WRRFs are adopting technologies and approaches such as water reuse, smart technology, and green infrastructure. They are also working to directly reduce greenhouse gas contribution through energy efficiency, resource recovery, and renewable energy development. Premature PFAS requirements could divert from some of these important activities.

• Biosolids: In the absence of a national PFAS regulation for biosolids, States are left to enact a patchwork system of restrictions. These restrictions reference the proposed NPDWR for guidance. A 45-year history of biosolids research has supported Title 40 CFR Part 503 – Standards for Use or Disposal of Biosolids. Banning biosolids will create a public health and economic crisis, forcing residents to bear the sharp increase in management costs due to increased shipping and landfilling, halting farmer access to a local and renewable alternative to synthetic fertilizer, and reversing climate benefits realized through sustainable biosolids management like carbon sequestration.

WEF members have diligently and proudly upheld the regulations set forth in the Clean Water Act for decades. It was because of this foresight by the EPA, that this pivotal environmental protection set precedence to protect our precious water resources that included the expansion and upgrade of water resource recovery facilities. It is this same foresight, that we ask the EPA to consider the short and long-term impacts that the proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation will have on the very systems that the Clean Water Act established and expanded. WEF asks that the EPA focus proposed regulations on stopping

PFAS at the source and work in concert with the thousands of water resource recovery facilities across the country to identify innovative, streamlined, and appropriately resourced solutions together.

Thank you for this opportunity to provide comment.

Sincerely,

Walt T. Marlowe, P.E., CAE

Executive Director

Water Environment Federation

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Rob and Fiona Robinson (Doc. #1531, SBC-042633)

From: Rob and Fiona Robinson <robinsona002@hawaii.rr.com>

Sent: Saturday, March 18, 2023 5:26 PM

To: OW-Docket

Subject: Proposed PFAS National Primary Drinking Water Regulation

Follow Up Flag: Follow up

Flag Status: Completed

The Safe Drinking Water Act must be amended to include regulation requirements that apply to all water systems not just public. It should include by name, Federal, State, City, Military (all branches), Business, Private and Public water systems. All entities should be required to comply with the PFAS drinking water regulations. There are people working and living on military facilities. There are communities that can be affected by cross contamination with private, military or federal water systems. To make this work they all must be included in the SDWA requirements and held responsible for the safety and good of all. If you do not do this you will end up with another Red Hill.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Linda Shosie (Doc. #1533, SBC-043958)

From the 1940's, to mid-1980's, the military and aeronautic industries at the Tucson International Airport Area (TIAA), have been disposing their industrial toxic wastes into drainage channel disposal pits, poisoning our sole source of water aquifer, and land.

A 24 square-mile area on Tucson South-side was designated a federal Superfund Site, when the EPA discovered hexavalent chromium and other chlorinated solvents, including, trichloroethylene (TCE) in the 1980's, but the EPA never cleaned up the contamination. Then, in 2002, 1,4-Dioxane, a probable human carcinogen, was discovered in the drinking water supplies around the site in addition to the TCE contamination that originally sparked concerns. Later, the EPA detected PFAS in the area as well, when our community group demanded more testing.

Thousands of South-sides residents are forced to drink, bathe, and cook in water contaminated with all these industrial chemicals at doses large enough to result in many health problems in our community.

I personally lost my 19-year-old daughter to a rare form of cancer, and another of my daughters is a cancer survivor. My son was also diagnosed with a rare skin disease, and my grandson was born with a birth defect, my granddaughter with kidney disease, in 2017, my 5 yr. old niece "Princess Mia" died of a rare childhood brain cancer. Her last words to her mom were, "why am I not pretty anymore." In 2019, my husband was also diagnosed with prostate cancer and had to undergo cancer treatment to remove it. Unfortunately, he does not have health care insurance to cover those costs. So, he had to pay out of pocket for those expenses as well as out of pocket expenses for his ongoing health care monitoring. Many of my friends and neighbors have experienced disease and loss as well. I believe that the high rates of disease in my own family and neighborhood are associated with the contamination of our drinking water. Our community deserves better!

I formed the EJTF in 2014, several years after my daughter's death, to educate people in my community about the different chemicals in their water supply and to advocate for stronger public water regulations and health protections so no one else would have to go through the pain that I have experienced.

I have personally gone door-to-door to talk with local residents who are exposed to the contaminated drinking water. I have purchased and handed out hundreds of cases of bottled water, along with a flyer to raise public awareness about the contaminants in our water supply.

When I founded the EJTF, our primary focus was on community concerns about the lack of response to address the long-term environmental health problems occurring in the community resulting from community-wide exposures to TCE. In addition to advocating for the cleanup and regulation of TCE, I began to look into what other chemicals had contaminated our water supplies.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Linda Shosie (Doc. #1533, SBC-047690)

As alarming as it was to discover that contamination, I was equally distressed to learn that Tucson Water knew of elevated PFAS levels in the water supply for many years before that

information was made public. The public needs access to information about the levels of PFAS in their drinking water supplies, as well as information about what those levels mean and when they can present risk to health, so people can make informed decisions about the water, that they and their family's drink. The EJTF is also committed to disseminating that information.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Greenville Utilities Commission (Doc. #1534, SBC-042638)

PFAS compounds should be regulated at the point of use by the manufacturers. The proposed rule notes these compounds are harmful to the cardiovascular and immune systems. It also mentions harmful metabolic, musculoskeletal, and liver effects from PFAS compounds. These effects could be limited if the government would restrict the use of these compounds at the source rather than requiring the water industry to remove them once in the environment.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Sarah Taylor (Doc. #1535, SBC-042641)

However, the EPA can help prevent these forever chemicals from infiltrating our drinking waters and ultimately harming our bodily health. One suggestion includes introducing a regulation requiring fire departments to use fluorinated firefighting foam as opposed to the current spray foam loaded with PFAS. Additionally, there should be national standards established regarding drinking, surface, and groundwaters. To aid in the authoritative power of this regulation, federal recourse can be established to groups that to do not comply with the regulation.

These changes will take time and cooperation from individuals and companies nationwide. However, as a unified team with a striving goal in mind to help fight against the toxic lifecycle of PFAS, these changes can be accomplished. The EPA can help make a giant step forward in the elimination of these toxic forever chemicals.

Best,

Sarah Taylor

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Brian Hackman (Doc. #1539, SBC-042907)

Finally, USEPA has been extremely derelict from the standpoint of controlling micropollutants like prions that can form by mRNA biological therapeutic injections into animals and humans. During the COVID era, wastewater testing showed in certain locations that when mRNA

injection cycles were accomplished, like in Cedar Rapids, IA, that the mRNA component showed up using PCR tests immediately after the injections, with the a large group of the population becoming infected, or testing positive for COVID by PCR (polymerase chain reaction) testing, two weeks later after injection. With now peer reviewed studies that show the mRNA (messenger ribonucleic acid) injections caused transmittable illness and suppressed immune systems within 10 months of the mRNA injection, USEPA would be better to direct its authority to manage environmental exposure of mRNA technologies which have acute effects and may have more chronic effects seen in less than 2 years, than the PFAS chemicals that have been environmentally available and exposing the population for over 70 years. Measurable health outcomes need to balance the cost of treatment and be demonstratable.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Cordell Spires Jr. (Doc. #1541, SBC-042662)

The better approach would be to limit the use of PFAS to only those considered essential, while fostering the development of safer alternatives. This would incentivize further development of alternatives that do not require PFAS. [FN-16: Id.] Remediation of water that has been contaminated with PFAS is costly, energy intensive, and cannot fully reverse the damage, so regulating PFAS in this way would prevent any contaminations from getting out of hand. [FN-17: Id.] This approach would also reduce the likelihood of replacing well-studied hazardous chemicals with poorly studied but structurally similar PFAS that have the potential to be similarly hazardous. [FN-18: Id.] Further, the approach would be simpler and less expensive to implement. [FN-19: Id.] Simpler, cheaper, class-based methods also typically result in more frequent testing, which improves compliance and detection of emerging risks. [FN-20: Id.] This approach would also encourage the selection of treatment approaches that effectively reduce total PFAS exposure when remediating PFAS-contaminated sites since the approach would limit all non-essential PFAS. [FN-21: Id.]

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Greater Cincinnati Water Works (GCWW) (Doc. #1550, SBC-042693)

While we appreciate EPA's goal of protecting public health, based on EPA's estimate, only 20% of PFAS exposure comes from drinking water. EPA's efforts would be better used to accelerate the elimination of sources of PFAS which are polluting our water resources and causing exposure through other avenues. Regulation of industrial sources of PFAS has moved more slowly than regulation of drinking water. As an example, USEPA recently issued a press release stating they were taking the first-ever federal Clean Water Act enforcement action to address PFAS discharges at Washington Works facility near Parkersburg WV. This is a facility notorious for its PFAS releases and contamination identified decades ago. Significantly extending the

compliance schedule for the PFAS drinking water rule will allow time for industrial sources to be identified and properly regulated. This will reduce source water concentrations and potentially avoid expensive treatment for many water utilities. Stopping the pollution at its source is a better use of federal resources and eliminates cost shifting for cleanup to drinking water customers.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Gabriella Thoppil (Doc. #1551, SBC-042700)

Support for Proposal and Request for Reform

The proposed NPDWR and MCLGs represent the response and recovery of the issue of PFAS in our public drinking water, as it only holds water systems and agencies accountable for testing and treating water that has already been contaminated with PFAS. However, the root of the problem is that PFAS continue to be used and developed by manufacturers and distributors and inevitably find a way to enter our water. Thus, while I fully support the proposed regulation, I propose that EPA reform this regulation to increase water testing efforts to identify and enforce registration of pollutant dischargers and to establish stewardship programs.

Though EPA has taken crucial steps to combat the usage and development of PFAS through Significant New Use Rules (SNURS), which require manufacturers and processors of PFAS to report new chemicals under the Toxic Substances Control Act (TCSA), the growing list of PFAS since their introduction in the 1940s indicates that tens of thousands of types of PFAS have been entering our water sources just over the last 5 years. [REF10: CompTox Chemicals Dashboard. Accessed April 20, 2023. https://comptox.epa.gov/dashboard/chemical-lists/pfasmaster; REF11: Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS). Accessed April 20, 2023. https://www.niehs.nih.gov/health/topics/agents/pfc/index.cfm; REF12: States Environmental Protection Agency U, of Water O. PFAS Strategic Roadmap: EPA's Commitments to Action 2021—2024.; REF13: Risk Management for Per- and Polyfluoroalkyl Substances (PFAS) under TSCA | US EPA. Accessed April 20, 2023. https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-and-polyfluoroalkyl-substances-pfas] Currently, the SDWA only requires water systems to test for and report unregulated PFAS to the EPA every five years, which is not frequent enough to keep up with this rate of pollution. [REF12: States Environmental Protection Agency U, of Water O. PFAS Strategic Roadmap: EPA's Commitments to Action 2021—2024]. I propose that EPA enforce water testing at least every 1-3 years. This effort would provide state and regional governments with timely data to help them more rapidly investigate and identify all point sources of PFAS discharge and enforce the registration of PFAS-discharging operations into the National Pollutant Discharge Elimination System (NPDES) [REF14: NPDES Permit Basics | US EPA. Accessed April 20, 2023. https://www.epa.gov/npdes/npdes-permit-basics] As the Clean Water Act (CWA) legally requires operations that discharge pollutants into the water to obtain a free NPDES permit, the increased water testing will help ensure more PFAS dischargers are being monitored and held

accountable. [REF14: NPDES Permit Basics | US EPA. Accessed April 20, 2023 https://www.epa.gov/npdes/npdes-permit-basics] This effort will be worthwhile because studies have shown that the NPDES permit system has resulted in lower water pollution levels since its implementation in the 1970s. [REF14: NPDES Permit Basics | US EPA. Accessed April 20, 2023. https://www.epa.gov/npdes/npdes-permit-basics; REF15: Keiser DA, Shapiro JS, Altonji J, et al. Consequences of the Clean Water Act and the Demand for Water Quality. Q J Econ. 2019;134(1):349-396. doi:10.1093/QJE/QJY019] Furthermore, I propose that EPA continue to implement programs like the 2010/2015 PFOA Stewardship Program to encourage companies that generate any PFAS to either reduce or eliminate their usage of PFAS. [REF16: Fact Sheet: 2010/2015 PFOA Stewardship Program | US EPA. Accessed April 20, 2023. https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/fact-sheet-20102015-pfoa-stewardship-program] The 2010/2015 PFOA Stewardship Program proved to be highly successful, as most of the eight major companies in the PFAS industry had either completely stopped manufacturing and importing PFOA or entirely abandoned PFAS. [REF16: Fact Sheet: 2010/2015 PFOA Stewardship Program | US EPA. Accessed April 20, 2023. https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/fact-sheet-20102015-pfoa-stewardship-program] The success of this program suggests that inviting more companies to participate in similar stewardship programs could yield equally productive results.

Feasibility/Rebuttals

I anticipate that the current regulation proposed by EPA would generate resistance from water systems because the NPDWR and MCLGs would require them to invest in improved technologies and resources to meet the new standards. From their perspective, this regulation would mean that water systems have to bear increased responsibilities for the upstream transgressions of entities who use and discharge PFAS. For this reason, my suggestions for reform would help communicate to water systems that manufacturers and distributors of PFAS are also being held accountable. Conducting more frequent water tests would be a feasible change since it utilizes existing infrastructure, and implementing more stewardship programs would require little to no financial investment from EPA as program development would entail recycling and updating processes from the 2010/2015 program. Furthermore, water systems would benefit from financial support to implement the operational changes needed to meet the NPDWR and MCLGs. EPA could develop a system where manufacturers and distributors of PFAS directly fund their local water systems by enforcing fines or taxes for PFAS discharge, and perhaps even require entities to pay sizable fees to purchase NPDES permits. [REF14: NPDES Permit Basics | US EPA. Accessed April 20, 2023. https://www.epa.gov/npdes/npdes-permit-basics] Such implementations would effectively help fund water systems to meet NPDWR and MCLG requirements and also incentivize entities to abandon PFAS usage altogether. While such operations are sure to be displeased with these new financial costs, in this day and age of climate environmental accountability, many other industries and entities that contribute to environmental pollution are increasingly facing similar financial obligations. Although access to safe and reliable public drinking water is technically the legal responsibility of water systems that test and

treat it, accountability must begin with the ones responsible for contaminating our water sources with irresponsible PFAS usage, development, and discharge.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Brooke Young (Doc. #1554, SBC-043972)

[Some actions the EPA can do to address these challenges as part of the proposed PFAS drinking water regulation include:]

• Require routine statewide monitoring and testing to ensure that point sources are not contaminating our waters and that our drinking water is safe for public consumption.

• Require source water protection plans to be developed.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Brooke Young (Doc. #1554, SBC-043970)

[Some actions the EPA can do to address these challenges as part of the proposed PFAS drinking water regulation include:]

• Require that sites contaminated with PFAS compounds undergo cleanup and remediation to prevent future exposure to the public.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Great Lakes Water Authority (GLWA) (Doc. #1558, SBC-042549)

Reduction/Elimination of PFAS

GLWA supports source reduction and pollution prevention in the case of PFAS, just as it has with other chemicals in the past. To that end our Industrial Pretreatment Program team on the water reclamation side instituted a Pollutant Minimization and Source Evaluation Program for PFOS and PFOA in 2020. However, the development and administration of these programs are costly in terms of financials and work hours. It is our strong belief that those who manufacture and profit from these chemicals should be responsible for any needed remediation and the ultimate costs to eliminate PFAS concentrations that pose a threat to our health and the environment. GLWA strongly supports a "polluter pays" model where those who produced and profited from PFAS pollution bear the liability and costs of its remediation – not the public.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Boyd Ramsey (Doc. #1560, SBC-042540)

Mr. Ethan Schwartz

May 17, 2023

United States Environmental Protection Agency

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Per- and polyfluoroalkyl substances (PFAS): Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) National Primary Drinking Water Regulation Rulemaking Proposed Rule Docket ID No. Docket ID: EPA-HQ-OW-2022-0114 Modification of CFR Citation 40 CFR 141; 40 CFR 142

Information on Environmental Protection and PFAS containment with Geosynthetic Systems

Introduction

In response to the recent publication of the Notice of Proposed Rule Making for Per- and polyfluoroalkyl substances (PFAS): Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) National Primary Drinking Water Regulation Rulemaking, I offer the following comments and information (including references and attached appendices, “A” and “B”).

I compliment the EPA for the statements and inclination to promulgate regulations designed to protect the drinking, groundwater and surface waters of the United States from potential PFAS contamination. While potential regulations are not yet complete, there are certainly materials and systems available that can make significant and real contributions to the effort to contain PFAS and protect water resources.

I recommended that the regulations put forth require the use of a geosynthetic barriers, geosynthetic composites containing adsorbents and adsorbents and the use of composite liner system (geomembrane and geosynthetic clay liner) as these systems has been demonstrated (by EPA) to be the most effective barrier methodology, regardless of the classification of the materials (hazardous, non-hazardous or designated for beneficial reuse). This submittal contains references to EPA reports and studies as well as test data generated, using EPA protocols that support the effectiveness of geosynthetic systems and their components.

Statement of EPA request(s)

The Agency is requesting comment on this action, including this proposed NPDWR and MCLGs, and have identified specific areas where public input will be helpful for EPA in developing the final rule.

Respondent comments

I would like to ensure that EPA is aware of all pertinent information related to the effective use of geosynthetic materials for waste containment. The Geosynthetic Institute (Dr. George Koerner, Folsom, PA) website contains an index of the U.S. EPA documents that are related to the use of geosynthetics. The complete list is attached as Appendix "A' a link to the webpage is here: http://www.geosynthetic-institute.org/epa.html. Clearly, geosynthetic materials have been well examined and proven to be effective.

Relative to PFAS containment there has been research in recent years to examine this specific question. As PFAS has a special chemical structure and functionality, it is perhaps not prudent to employ standard chemical principals for chemical resistance such as grouping similar chemicals and molecular structures and projecting similar performance. PFASs as a group differ from other chemicals and investigations specific to PFAS were and are appropriate. Several published documents listed in the references in addition to continuing work in this area has demonstrated that the permeability of PFASs through geomembranes is quite low, and similar to that of PCBs and aromatic hydrocarbons.

EPA 9090 testing is a historically important testing protocol that was developed to demonstrate the chemical resistance of geosynthetic materials. EPA document EPA/600/S2-90/041 outlines the application of this testing protocol. I believe the contribution of EPA 9090 type testing is limited, relative to PFAS, However Appendix "B" references prior EPA publication in this area.

I recommend that the existing USEPA Disposal Rule for either Subtitle C or Subtitle D Regulations be applied to PFAS containment. Specifically, a 'composite liner' consisting of two components: An upper component consisting of a 60-mil polyethylene flexible membrane liner (FML), and a lower component consisting of either at least a two-foot layer of compacted soil with a hydraulic conductivity of no more than 1 x 10-7 cm/s, or a geosynthetic clay liner (GCL) containing at least 0.75 lb/ft2 of sodium bentonite. If 'composite liner' is not redefined to include a lower component GCL, then the allowance of an alternative liner design/system should be included as GCLs have demonstrated improved performance.

Further, to the required construction of containment systems, several companies now offer materials similar to geosynthetic clay liners (GCLs) that contain absorbents specific to PFAS materials. These should be required as a component of the barrier system. Testing has demonstrated that these materials readily absorb multiple PFAS varieties at a broad range of concentrations and have very high retention rates. A landfill cell, properly installed and tested for integrity, that is constructed with a composite liner system using a GCL-type product with PFAS absorption capabilities should be considered to be the stateof-practice at this time, offering the greatest potential for successful PFAS containment and long-term storage.

Conclusion

The benefits and successes of utilizing geosynthetic barriers in containment systems has been well documented by the EPA and other industry organizations. Geosynthetics have been tested and successfully evaluated in great detail over a long period of use in a very wide range of applications by EPA. PFAS varieties can be contained by current regulated geosynthetic barriers and new technologies exist to even further improve PFAS containment performance.

I thank the EPA for the consideration provided. I am more than willing to respond to any additional EPA inquiry on this or other related topics.

Sincerely,

Boyd Ramsey

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Information on my organizations environmental and sustainability policies can be found at www.boydramseyconsulting.com.

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US EPA Per- and polyfluoroalkyl substances (PFAS): Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) National Primary Drinking Water Regulation Rulemaking Proposed Rule Docket ID No. Docket ID: EPA-HQ-OW-2022-0114 Modification of CFR Citation 40 CFR 141; 40 CFR 142, https://www.federalregister.gov/documents/2023/03/29/2023-05471/pfas-national-primary-drinking-water-regulation-rulemaking Accessed May 12, 2023.

[see docket ID EPA-HW-OW-2022-0114-1560]

Appendix A. U.S. EPA Geosynthetic Related Documents

Appendix B. U.S. EPA. 1990. Project Summary: Fundamental Approach to Service Life of Flexible Membrane Liner's (FML's).

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document. The EPA notes that the commenter points out specific use of "geosynthetic barriers, geosynthetic composites containing adsorbents and adsorbents and the use of composite liner system (geomembrane and geosynthetic clay liner) as these systems has been demonstrated (by EPA) to be the most effective barrier methodology." Please see section X of the final rule preamble and section 10 of the EPA response in this *Response to Comments* document for additional discussion on treatment technologies including BAT identification and evaluation. Additionally, please see section 5.1.4 of the EPA response in this *Response to Comments* document for the agency's evaluation of feasibility with respect to treatment.

Maine Water Utilities Association (MWUA) (Doc. #1567, SBC-042726)

May 23, 2023

Mr. Michael S. Regan, Administrator

U.S. Environmental Protection Agency

EPA Docket Center, OLEM Docket, Mail Code 28221T

1200 Pennsylvania Avenue, NW

Washington, DC 20460

RE: Docket ID No. EPA-HQ-OW-2022-0114

Dear Administrator Regan:

Maine Water Utilities Association appreciates the opportunity to comment on the Environmental Protection Agency's proposed National Primary Drinking Water Regulation. MWUA is a State association. We are a membership organization for those working or interested in the drinking water profession with more than 109 water systems as members. Our mission includes bringing together water utilities, consultants, manufacturers, vendors, regulators, academia, and other interested parties to network, educate, and advocate.

Our objective and goal is to provide public health protection to all that are customers of Maine Public Water Systems' (PWS). Maine PWS take this role very seriously and work hard to ensure that the water provided to residents and visitors across the state meets all Safe Drinking Water Act standards.

We are providing the following comments on EPA's proposed National Primary Drinking Water Regulation Rulemaking for per- and polyfluoroalkyl substances (PFAS). We note that EPA has engaged in rulemaking on several major rules that impact the water sector, with public comments all due within the past month, making it hard to give each the thorough review it requires. This regulation is complicated, with new concepts not well understood by the drinking water profession. We were hopeful that EPA would honor our request to extend the public comment period to give more time for thoughtful review on a regulation that will have substantial impact on our industry and more importantly our ratepayers. Unfortunately, our request was denied We fully support efforts to expand verified public health protections, but EPA needs to consider the challenges associated with implementation of the proposed PFAS rule before finalizing these standards.

General Comments:

MWUA and our members are very comfortable offering our expertise and opinions as they relate to the very real impact that new drinking water standards will have on our operations and related services. However, our ability to offer comments and opinions on more nuanced toxicological principles is well beyond our area of expertise. We are not toxicologists, nor epidemiologists, so we will leave it to other experts to comment on the appropriateness of the standards from a public health protection standpoint. We question why drinking water seems to be the sole focus of regulation while potentially higher PFAS exposures exist in consumer products (including food packaging, stain- and water-repellent fabrics, nonstick products, polishes, waxes, paints, cleaning products), food, personal care products/makeup, pesticides, and dust, and these potential sources of exposure are not simultaneously being regulated. We will note that there was a study of rainwater conducted by the National Atmospheric Deposition Program and the highest total concentration of PFAS was nearly 5.5 parts per trillion (ppt) in a single sample from

Massachusetts; with that said, have higher concentrations of PFAS falling from the atmosphere than EPA's proposed drinking water standards. The proposed drinking water standards assume that 20% of a person's exposure is allocated to drinking water, while 80% is comprised of all other potential exposure pathways. If we are to have meaningful health risk reduction shouldn't the current Administration be truly taking a whole government approach in addressing PFAS exposure by regulating all means of PFAS exposure simultaneously? Addressing only 20% of a person's potential exposure while the remaining 80% of exposure is allowed to continue unfettered seems irresponsible.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

San Antonio Water System (SAWS) (Doc. #1570, SBC-042468)

May 26, 2023

Michael S. Regan

Administrator

Environmental Protection Agency 1200 Pennsylvania Avenue, N.W.

Mail Code: 4607M

Washington, DC 20460

Administrator Regan,

San Antonio Water System (SAWS) is appreciative for the opportunity to comment on the proposed PFAS National Primary Drinking Water Regulation. While SAWS is in support of requests put forward to the Environmental Protection Agency (EPA) to extend the public comment period given the complexity and scope of the proposed rule, we have completed an initial evaluation of this proposed regulation and the available data. We respectfully request that EPA review and consider these comments:

• The EPA must establish a complete manufacturing, importation, and usage ban, for all PFAS and its derivatives. Companies must be prohibited from producing or importing products that use these chemical compounds. In the absence of a ban, regulation, and elimination of PFAS will always be a moving target. Once an actual ban is in place, then the EPA should start setting regulatory limits for health effects and exposure.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Endocrine Society (Doc. #1579, SBC-042425)

To improve the public health protection of the regulation, we recommend that the EPA:

•Ensure the availability of sufficient funds to assist in remediation efforts; funds should be generated through fees on the manufacturers of PFAS, and not rate payers and/or homeowners;

•Establish a process to include private well owners in assistance funding to prevent further impacts; and

•Work with other agencies to prevent further contamination by advancing additional strong regulations that prevent all non-essential uses of PFAS.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Association of State and Territorial Solid Waste Management Officials (ASTSWMO) (Doc. #1583, SBC-042405)

[Overall, as movement is made toward better regulation and oversight of these contaminants, ASTSWMO's membership recognizes a corresponding need for research, communication, and improved understanding within the following areas:]

• remediation technologies to remove PFAS from all environmental media;

• destruction and disposal technologies for PFAS-containing materials and waste streams;

• solidification and stabilization technologies to minimize PFAS in landfill leachate and methods to assess treatment effectiveness to aid in addressing capacity limitations; and

• acceptable levels of PFAS in compost, biosolids, wastewater sludge and industrial byproducts that are suitable for land application.

Advances in the key research areas listed above, along with establishing prevention programs to support the reduction and removal of PFAS from use, need to take place concurrently with this proposed rulemaking. More specifically, expanded coordination across all federal Agencies needs to be prioritized to reduce, and conceptually eliminate, PFAS present in consumer products and food supplies, which ultimately get into the water supplies and waste streams.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

American Public Works Assocation (APWA) (Doc. #1584, SBC-042391)

APWA is committed to limiting exposure to PFAS and protecting the environment. At the same time, we want to ensure efforts do not impose unintended consequences by unnecessarily directing resources away from other water system priorities like noncompliance with existing pollutant MCLs, replacement of lead service lines, microplastics, cybersecurity, or conservation and resiliency efforts to address changes in climate such as increased droughts or flooding. The reallocation of resources by communities may also mean deferring on maintenance, which could

risk failure of water infrastructure and be ultimately more costly in terms of quality of life in dollars, public health, and the environment.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Cape Fear Public Utility Authority (CFPUA) (Doc. #1588, SBC-042383)

Effective PFAS regulation begins at the source

CFPUA and our customers appreciate EPA's work to begin establishing drinking water regulations for PFAS such as PFOA, PFOS, and GenX in drinking water. While such regulations are necessary, we note the most cost-effective, equitable approach to reducing Americans' exposure to PFAS in their drinking water is keeping PFAS out of source water in the first place. Those who manufacture PFAS or use it in their manufacturing should be the primary focus of EPA's regulatory efforts, and they should be the ones to bear the burden of compliance with regulations regarding the PFAS they discharge into sources of drinking water. EPA acknowledges this in its PFAS Strategic Roadmap, which lists among its guiding principles a focus on source control as "a foundational step to reducing the exposure and potential risks of future PFAS contamination" and a pledge to hold "polluters and other responsible parties accountable for their actions and for PFAS remediation efforts."

We thank you for the opportunity to comment and be heard on this important matter and look forward to working alongside our partners at EPA and North Carolina Department of Environmental Quality to ensure continued access to safe, reliable drinking water for the community we serve.

Respectfully submitted,

Kenneth Waldroup, P.E.

Cape Fear Public Utility Authority

Executive Director

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Public Health, Seattle & King County (PHSKC) (Doc. #1594, SBC-042361)

For decades manufacturers have profited from use and development of PFAS chemicals. PFAS are now ubiquitous in products, processes, and the blood of nearly every resident of our county. Residents with PFAS contaminated drinking water experience a fear of not knowing how PFAS in their drinking water will impact their health or the health of their children, creating a life-long fear and anxiety about what is to come. The companies that have profited by polluting our land,

water, air, food supply and homes should be required to pay for the removal and cleanup of existing chemicals.

Provide homeowners that do not have access to public water systems with resources to identify and remediate PFAS in their drinking water. EPA should provide homeowners with private wells and small group systems with information on how to test their water and remediate if PFAS are detected at levels above the set MCLs. They should also provide educational information on how residents with elevated PFAS in their drinking water can reduce their risks of health impacts. In addition, EPA should invest in research that will identify low-cost filtration methods to remove PFAS from drinking water sources for individual homeowners on private drinking water sources such as private and small group drinking water wells.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Public Health, Seattle & King County (PHSKC) (Doc. #1594, SBC-042359)

Adopt a wholistic approach for PFAS at the EPA, which includes regulating their use so that their sources in drinking water, food, and indoor and outdoor environments are removed. The best way to prevent human exposures to PFAS and long-term, expensive cleanup efforts, is to restrict the use of these forever compounds now. The staggering costs to cleanup PFAS in the environment completely overshadow the profits to a small number of companies as highlighted in a new analysis conducted in the European Union [Link: https://chemsec.org/reports/the-top-12-pfas-producers-in-the-world-and-the-staggering-societal-costs-of-pfas-pollution/], not to mention the health costs to society [Link: https://pubs.acs.org/doi/10.1021/acs.est.1c03565]. We urge EPA to identify all nonessential PFAS that are in commerce and prohibit them from use, and to determine whether safer alternatives exist for all PFAS that are deemed essential before they enter or continue to enter the market.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

National Tribal Water Council-Tribal PFAS Working Group (NTWCTPWG) (Doc. #1598, SBC-042342)

PFAS Source Elimination

The proposed regulation does not appear to speak to PFAS source management and source elimination. As long as the manufacture and use of the multitude of PFAS chemicals remains poorly regulated or unregulated, these chemicals will continue to be discharged into the environment and taken up by humans and other beings. Further, the tribes will have to shoulder PFAS drinking water treatment (PFAS removal) costs, which will only grow over time as the presence and concentration of these PFAS chemicals in the environment and water supplies in particular continues to grow. While the EPA may not have the tools in the SDWA to regulate the

manufacture and use of PFAS chemicals, it does hold these authorities under TSCA and should more clearly demonstrate that it is aware of the much larger problem, a veritable elephant in the room.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-042895)

Source Investigations:

In Massachusetts, MassDEP stated that when a PWS detected PFAS in the drinking water above the MMCL, MassDEP would initiate an investigation into the potential sources of contamination and the identification of potentially responsible parties. There have been so many detections in Massachusetts that MassDEP has not had the resources in its Bureau of Waste-Site Clean-up to perform timely follow up investigations. MassDEP has only initiated contamination investigations for 48 PWS thus far, and there have been 170 PWS detections. This delay has left PWS and their ratepayers funding investigations and remediation in the absence of a responsible party. Proper resources must be allocated to identify the source of contamination and hold that party responsible for the remediation costs.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Massachusetts Water Works Association (MWWA) (Doc. #1601, SBC-042905)

Closing:

Thank you for the opportunity to provide these comments. Public water suppliers understand the importance of ensuring that the drinking water that reaches their customers meets SDWA requirements and protects the public's health. Water suppliers work hard each day to meet these goals and satisfy their customers' expectations. As we have all come to be keenly aware, the issue of emerging contaminants is a monumental challenge. Our members will be tasked with meeting any and all regulatory requirements and standards; therefore, EPA has an obligation to address our implementation concerns prior to finalizing the rule. EPA should also be using its authority to regulate the production of PFAS – it would be much more cost-effective to prevent PFAS from entering our environment and water supplies than it is going to be to clean up the contamination. We look forward to working collaboratively with EPA and MassDEP to ensure our PWS are able to meet their mandate of continued protection of public health.

Jennifer A. Pederson Executive Director

APPENDIX A - TREATMENT TIMELINE

[Table 1: See Docket ID EPA-HQ-OW-2022-0114-1601]

[Table 2: See Docket ID EPA-HQ-OW-2022-0114-1601]

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Arlington County Virginia (Doc. #1603, SBC-043020)

Further, it is water utilities that will now face the tarnish of violating EPA regulations, which exposes us to additional financial penalties, but even more damaging will be the resultant erosion of public confidence in the public water systems. Our public water systems are among the most important and impactful public health systems and also play an important role in preserving our environment by reducing industrial bottled water consumption. The proposed regulations will undermine confidence in these systems by imposing extraordinary rate increases and confusing consumers with inordinately low levels of PFAS exposure in water while other ingestion media, to include food, have been found to contain PFAS at levels thousands of times higher than the proposed regulatory standard for water.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

American Water Works Company Inc. (Doc. #1608, SBC-043977)

American Water calls for sound policies that will ensure compliance by all water utilities – whether privately or municipally owned – while protecting customers and communities from the high cost of monitoring and mitigating PFAS. This includes advocating for policies that hold polluters accountable. American Water's operating utilities in most of our states are currently plaintiffs in the Multi-District Litigation against multiple PFAS manufacturers because we firmly believe that the ultimate responsibility for the cleanup of these contaminants should fall to those who created the problem.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

American Water Works Company Inc. (Doc. #1608, SBC-044003)

Funding

American Water calls for sound policies that will ensure compliance by all water utilities – whether privately or municipally owned – while protecting customers and communities from the high cost of monitoring and mitigating PFAS. This includes advocating for policies that hold polluters accountable. American Water's operating utilities in most of our states are currently plaintiffs in the Multi-District Litigation against multiple PFAS manufacturers because we firmly believe that the ultimate responsibility for the cleanup of these contaminants should fall to those who created the problem.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Prince William County Service Authority (Doc. #1609, SBC-042842)

2. EPA should re-prioritize its efforts to remove sources of PFAS from the environment. Prioritizing drinking water for regulation places the financial burden of PFAS removal on the public instead of the polluter.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Prince William County Service Authority (Doc. #1609, SBC-042830)

EPA Should Prioritize its PFAS Efforts on Eliminating Sources of Contamination

The Service Authority supports EPA's efforts to reduce PFAS in the environment. However, instead of prioritizing regulation of sources of PFAS, EPA proposes to regulate PFAS through drinking water, a significant divergence from the "polluter pays" principle. PFAS compounds continue to be manufactured and used in a wide variety of industrial and consumer products and processes. Water utilities are passive receivers of PFAS compounds that make their way to our sources of supply. Through the proposed regulation, the rate-paying public will be responsible for bearing the entire cost of PFAS removal, not polluters.

The continued use of PFAS will lead to increases in contamination and exposures in the future. But these exposures can be capped if steps are taken now to eliminate production and use of PFAS in all nonessential applications. In the meantime, the responsibility for paying for the legacy contamination should rest on the companies who continue to produce and market these chemicals even though they know about the chemicals' toxicity and extreme persistence.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Oakland County Water Resources Commissioner (WRC) (Doc. #1615, SBC-042928)

Public water utilities do not produce, profit from, or regulate the discharge of PFAS, but will continually need to contend with the cost of their clean up and disposal. It is imperative that any new regulations are accompanied with a "polluter pay" model where those who produced the PFAS pollution bear the liability and costs of its remediation – not the public.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Beaufort-Jasper Water & Sewer Authority (BJWSA) (Doc. #1618, SBC-042937)

We further request that EPA reevaluate the cost impact on utilities and look to investigate, identify and regulate those who are polluting the waterways. Removing the source of PFAS is by far the most cost effective way to address the issue rather than requiring water utility customers to spend billions of dollars to install treatment facilities. For utilities that still need to add treatment, adequate sources of funding need to be provided.

As public drinking water providers, it is our obligation to provide a high quality of water in a fiscally responsible manner. While we appreciate EPA's goal to enhance public health protection through PFAS regulation, the approach needs to be feasible and allow for a reasonable implementation schedule. We ask EPA to reevaluate the proposed rule to incorporate a phased implementation schedule and focus on identifying the source of the pollution so that the addition of expensive treatment can be avoided to the extent possible.

Thank you for the opportunity to comment. If you have any questions, please contact me at (843) 987- 8044. We would b_e happy to discuss our comments further.

Sincerely,

Verna J. Arnette

General Manager

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

WaterPIO (Doc. #1624, SBC-043477)

Now let's look at what the EPA isn't changing, the fact that PFAS are still allowed to be pervasive in the world we live in. That's on the EPA more than public water, but it doesn't matter to the EPA. Not only are PFAS still being produced and used in millions of consumer goods with reckless abandon, but producers of the compounds are still regularly able to dump PFAS into our source waters, even when they are unable to fully control their waste streams.

PFAS are still being pumped into our waterways under discharge permits that were created through loose regulatory processes public water systems had nothing to do with. Even in the Cape Fear Region of North Carolina, years after Chemours was discovered to be dumping PFAS into the Cape Fear River with impunity thanks to loopholes in their discharge permit, we still get regular news of random spills from their production facility.

Oh, sure, they're under a Consent Decree now – which we helped strengthen through a newsmaking op-ed when the first CO was released (https://www.starnewsonline.com/story/opinion/columns/your-voice/2018/12/02/opinion- mike-mcgill-our-area-is-loser-in-chemours-deal/7964097007/) – and they're building a retaining wall, but that's not going to stop them from producing PFAS. In fact, after 3M announced they were

going to phase out the production of PFAS by 2025, guess who jumped up to say they were going to ramp up production?

Chemours, the GenX polluters of the Cape Fear River.

This is the regulatory environment public water systems will find themselves operating in while the EPA's PFAS MCLs and HI hang over their heads. They'll be under constant threat of drinking water violations while millions of PFAS products continue to be cranked out into the consumer world, and millions of gallons are either legally released or spilled into our source waters.

Again, public water systems are being put in a position to fail.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

WaterPIO (Doc. #1624, SBC-043465)

\6. The companies actually polluting the environment with PFAS will still be producing them and dumping them – legally and illegally – into our nation's waterways. Millions of products, even toilet paper, will continue being made using PFAS, all while drinking water must meet the EPA's proposed standards.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044074)

EPA must expedite the Agency's work to address PFAS in wastewater and stormwater discharges, including the development of rulemakings for PFAS effluent limitation guidelines for the organic chemicals, plastics and synthetic fibers, and metal finishing and electroplating point source categories, as well as studying PFAS discharges from landfills, paper and textile mills, and electrical and electronic components. Additionally, the Agency should work to finalize Draft Method 1633 promptly for laboratories to analyze samples for surface water, ground water, and other media; and the national recommended ambient water quality criteria for PFAS. Primacy agencies need EPA's assistance and guidance in these areas. Some agencies want to require monitoring for pollutants in their surface waters, and others want to develop their water quality criteria. Additional Clean Water Act (CWA) regulatory and non-regulatory actions should continue simultaneously with the Agency's other efforts. PFAS will remain a problem for drinking water systems as long as all sources of PFAS contamination are not appropriately addressed and PFAS users are not held accountable.

ASDWA recommends that EPA use a holistic lifecycle approach that includes close coordination with other Federal agencies to administer all possible Federal statutory and regulatory authorities to address PFAS concerns.

Using a holistic approach to reduce or eliminate the use of PFAS and to prevent these compounds from entering the environment and drinking water sources throughout any part or all of the chemical's lifecycle - from manufacturing through processing, distribution, and disposal - is much more effective and less expensive than removing PFAS compounds once contamination has occurred. Protecting drinking water sources and preventing contamination is essential for sustaining safe drinking water supplies, protecting public health and the economy, and has substantial environmental benefits.

The PFAS NPDWR is a first step in addressing PFAS contamination; however, numerous other regulatory decisions are made based on drinking water standards (e.g., ground water standards, ground water remediation determinations, National Pollution Discharge Elimination System permits, and surface water standards). EPA must coordinate across all the Agency's offices and with other federal Agencies (i.e., the Department of Defense, the Food and Drug Administration, and Centers for Disease Control) to reduce PFAS contamination. This approach across all Federal agencies will ensure consistent messaging and implementation. ASDWA has consistently recommended that EPA use a holistic lifecycle approach that includes close coordination with other Federal agencies to administer all possible Federal statutory and regulatory authorities to assess, address, and remove PFAS or prevent PFAS from entering the environment (and drinking water sources) from all contributing media. This includes considering impacts from disposal and incineration, particularly as EPA works to finalize its guidance on the destruction and disposal of PFAS and materials containing PFAS. Utilizing all regulatory authorities will help ensure that the responsibility and cost for removing PFAS are not passed on from one media to another. This also includes consistent messaging to regulators, regulated entities, and the public on PFAS.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Association of Environmental Authorities (AEA) (Doc. #1635, SBC-042962)

AEA endorses a comprehensive PFAS chemical national strategy that extends beyond water, and which helps end PFAS pollution by limiting it or eliminating it at the source. This should involve all relevant federal regulatory agencies.

We recommend the EPA consider the consequences of the proposed NPDWR that will go beyond drinking water and will affect water recycling and reuse programs, wastewater treatment, and biosolids management would be affected.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Town of Tewksbury, Massachusetts (Doc. #1637, SBC-043251)

EPA needs to rapidly work toward finding permanent destruction technologies or we will continue to face the prospect of a never-ending cycle of moving PFAS around our environment.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Citizens Against Ruining the Environment (CARE) (Doc. #1638, SBC-043452)

More recently, on January 13, 2023 the European Chemical Agency (ECHA) proposed a ban on ALL 10,000+ PFAS chemicals. [FN58: ECHA publishes PFAS restriction proposal, European Chemicals Agency (Feb. 7, 2023),https://echa.europa.eu/-/echa-publishes-pfas-restriction-proposal.] If passed, it is expected that the Ban will be implemented by 2027. During its public briefing in support of the proposal, ECHA stated several reasons for the need of class-wide PFAS regulations. ECHA pointed to the ever-increasing number of known or suspected adverse effects on human health and environment, PFAS's high tonnage usage in a variety of applications, monitoring data showing the ubiquitous presence of PFAS in the environment and humans, PFAS's very high persistence and difficulty to remove once released into environment, and other uncontrolled risks from uses of PFAS. [FN59: Id.]

In support of its class based approach for the proposed PFAS ban, ECHA states that it is a significantly more efficient and protective method compared to previous risk proposals that looked on a case-by-base basis. [FN60: Id.] ECHA's proposed group ban also avoids what it calls regrettable substitutions, or the replacement of one hazardous substance with another one. [FN61:Id.] ECHA's proposed group ban has two potential methods, 1) a full immediate ban that would take effect after an 18 month transitional period, or 2) a ban with use-specific derogations. [FN62:Id.]

Both would include banning manufacturing of all PFAS compounds, placing any PFAS materials in the market, specific uses of PFAS compounds, and PFAS uses as constituents in other substances or mixtures above a set concentration limit. Derogations would be very specific and time limited, falling into two categories. Category 1 would be for five years and be for products where alternatives are under development but not currently available for entry into force. [FN63: Id.] This would cover food contact materials for industrial food and feed production. Category 2 would be for twelve years and cover products where identification, development, and certification of alternatives is still needed. This would cover implantable medical devices. [FN64: Id.]

CARE agrees with PFAS experts and ECHA's assessment that the extreme persistence, accumulation potential, and both the known and potential hazards of PFAS demand a more efficient and effective methodology than EPA's current regulatory approach. A class-wide ban would be one such methodology. CARE urges EPA to consider a class-wide ban and believes such an approach would be more protective of human health and the environment.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

California Municipal Utilities Association (CMUA) (Doc. #1639, SBC-043253)

May 30, 2023

Submitted via: https://regulations/gov

U.S. Environmental Protection Agency EPA Docket Center

Office of Ground Water and Drinking Water Docket

1200 Pennsylvania Avenue NW Washington, DC 20460

Subject: Comment Letter re Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation Docket ID No. EPA-HQ-OW-2022-0114

Office of Ground Water and Drinking Water,

The California Municipal Utilities Association (CMUA), representing over 50 public water agencies, appreciates the opportunity to comment on the U.S. Environmental Protection Agency's (EPA) Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation (henceforth referred to as "the Regulation"). Our public water agency members are committed to providing safe water to their customers. Ensuring that the Regulation reflects practical considerations and limitations faced by public water agencies is of utmost importance.

We recognize that Per- and Polyfluoroalkyl Substances (PFAS) exist in water supplies nationwide; however, it is essential to distinguish and recognize that PFAS finds their way into water supplies usually by the action of manufacturers of products that contain PFAS. Public water agencies are left with the overwhelming burden of removing these contaminants from their water supplies to continue delivering safe water. We strongly encourage the EPA to consider imposing a higher burden of PFAS removal on those manufacturers rather than public water agencies. We should endeavor to eliminate PFAS contamination at the source.

CMUA offers a few comments on the Regulation for your consideration.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

National Rural Water Association (NRWA) (Doc. #1641, SBC-043259)

May 30, 2023

Michael S. Regan

Administrator Environmental Protection Agency 1200 Pennsylvania Avenue, N. W.

Mail Code: 4607M

Washington, DC 20460

RE: Comments for EPA's Proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation (Docket ID: EPA-HQ-OW-2022-0114)

Headquartered in Duncan (Oklahoma), the National Rural Water Association (NRWA) is the non-profit association of the federated state rural water associations with a combined membership of over 30,000 small and rural communities. NRWA is the country's largest water utility association and the largest community-based environmental organization. State Rural Water Associations are non-profit associations governed by elected board members from the membership. Our member utilities have the very important public responsibility of complying with all applicable U.S. Environmental Protection Agency (EPA) regulations and for supplying the public with safe drinking water and sanitation every second of every day.

Administrator Regan,

The National Rural Water Association (NRWA) appreciates the opportunity to comment on the Environmental Protection Agency's (EPA) proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation (NPDWR). NRWA has been providing boots-on-the ground assistance to water utilities since 1976. Currently, 40% of all technical assistance that is provided through these programs, such as the Circuit Rider Program and EPA Water Training and Technical Assistance Program, goes directly to disadvantaged communities. On top of this, 100% of assistance and training provided is to communities with populations of 10,000 or less. NRWA's technical experts provide practical, peer-to-peer help that makes a real difference to rural and small communities every day.

NRWA shares the goal of eliminating all concentrations of PFAS from the public's drinking water and environment. However, regulation, civil enforcement, and liability under the Superfund Law (CERCLA) are not the appropriate federal remedies for addressing this problem for local governments.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

National Association of Clean Water Agencies (NACWA) (Doc. #1659, SBC-043132)

NACWA understands EPA's desire and need to regulate PFAS in drinking water, but it is not possible to adequately address these chemicals without also eliminating the continued production, importation, and use of these chemicals in commerce on a daily basis. To the extent EPA is looking to water utilities to be the solution to the rampant, widespread presence of PFAS by removing PFAS from our nation's water supplies, the Agency must also significantly amplify its efforts to eliminate harmful PFAS production and use in the United States and prevent commercial importation of products into the country that contain PFAS. Absent this additional

source control, water treatment will merely move PFAS from one environmental media to another without controlling the problem at its source.

Therefore, other environmental statutes, like the Toxic Substance Control Program (TSCA), must be the Agency's priority for pollution prevention efforts, and EPA should prioritize elimination of nonessential PFAS uses in commerce. Otherwise, public water systems and public clean water utilities will continuously, in perpetuity, be fighting a costly treatment battle with chemicals still being used in commerce—a problem that they never created in the first place. And not having a robust and aggressive pollution prevention program to address these ubiquitous and persistent chemicals before treatment is required creates a foolish precedent and an approach that is at odds with international approaches like the Stockholm Convention on Persistent Organic Pollutants.

EPA's Proposed MCLs will Impact Clean Water Utilities Engaged in Reuse

Although the proposed NPDWR primarily impacts PWSs, NACWA is concerned that this rule will also impact clean water utilities that are taking innovative steps to recycle or reuse wastewater. Treated wastewater can be beneficially reused or recycled in myriad ways including irrigation for agriculture, domestic irrigation for landscaping, power plant cooling, as process water for industrial, manufacturing and construction uses, wetland rehydration, municipal water supplies, and environmental restoration. A rising concern is how this drinking water rulemaking will have broader impacts that EPA has failed to analyze, including costs that may be incurred by clean water systems that are leading the way to supplement water supplies, replenish aquifers and mitigate land subsidence.

Specifically, clean water utilities that recycle, reuse, and reclaim water by directly discharging to groundwater or surface waters that are potential sources of drinking water are subject the Clean Water Act's Section 402 permitting requirements. These utilities are often required to treat the reclaimed water to meet primary and secondary drinking water standards prior to the reclaimed water being beneficially reused. Therefore, these clean water utilities will also be impacted by the proposed rule as they will most likely have to meet the new MCLs as part of their discharge requirements, independent of any consideration of receiving water conditions or downstream treatment processes associated with producing drinking water.

However, unlike the Clean Water Act, permitting flexibilities like water quality variances or changes in designated uses are prohibited when there are primary drinking water standards at play under the SDWA. Therefore, EPA should evaluate instances where clean water utilities will have to comply with the proposed rule if it is finalized. NACWA encourages EPA to consider the unique intersection of the SDWA and CWA and the impacts the proposed rule will have on some utilities that are innovatively advancing indirect and direct potable reuse—a priority of EPA's through its Water Reuse Action Plan. Additionally, EPA should provide additional flexibility in the final rule for situations, such as potable reuse, to ensure EPA and state permitting authorities have the tools similar to those used in the Clean Water Act.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document. With respect to "costs that may be incurred by clean water systems," the EPA notes that National Pollutant Discharge Elimination System (NPDES) permits for utilities could potentially consider drinking water standards in establishing permit limits for discharge of reclaimed water, however SDWA expressly states that the EPA shall consider "quantifiable and nonquantifiable costs. . . *excluding costs resulting from compliance with other proposed or promulgated regulations*." For further information on the EPA's cost analysis, please see section 13 of the EPA response in this *Response to Comments* document and section XII of the final rule preamble. Additionally, please see section 5.1.3 of the EPA response in this *Response to Comments* document for additional discussion on cost considerations in the final MCLs.

Maine Organic Farmers and Gardeners Association (MOFGA) (Doc. #1660, SBC-043385)

Additionally, to prevent future contamination, EPA should ban wastewater sludge-spreading, as Maine has done, and provide funding for safer disposal options.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Blue Ridge Environmental Defense League (BREDL) (Doc. #1663, SBC-044387)

Unregulated Contaminants Monitoring Rule 5 (UCMR5) Provides Inadequate Notification

The UCMR5 currently requires testing for 29 PFAS contaminants. The water providers will then be required to release the results to the public, but only online. Additionally, it could take up to a year and a half for water users to be notified, depending on the date of initial testing. Only requiring the water systems to post results online ignores the fact that in many locations, communities do not have reliable internet—and even if they do, there are people that cannot afford it or that do not have dependable ways to access it. EPA should consider requiring water systems to send their customers notification through the mail—like they send their billing statements. We recently asked the North Carolina DEQ if they had a list of what systems would be monitoring for PFAS. Despite the fact we got information from Virginia DEQ, the North Carolina state agency has initially responded that EPA was responsible for providing this information.

Examples of North Carolina Agency Inaction

Soon after EPA's June 2022 announcement of the health advisory (June 2022) for four PFAS (GenX, PFOA, PFOS, and PFBS) BREDL began inquiring about steps North Carolina state agencies were taking, or planning to take, to notify the public about the health dangers of these PFAS and detections in their drinking water. We sent several emails to the North Carolina Department of Environmental Quality (DEQ) and the North Carolina Department of Health and Human Services (DHHS) attempting to get information on their plans. We also asked local

governments that we knew had detected numerous PFAS in their finished water. These are some of the responses we received:

DEQ: "DEQ does not have a mechanism to require that public water supply systems provide public notification for PFAS compounds above a Health Advisory Level, though some public water systems have been voluntarily monitoring for PFAS and have also developed their own method to notify customers."

DHHS: "It is typically the responsibility of the utilities to notify their customers about water quality within their systems – although we have been getting the word out more generally through our fact sheets about PFAS and Testing and Filtration."

We also asked a local government source that we know/knew tested for PFAS if DEQ had reached out to them regarding notification to customers if any amount of PFOA or PFOS was found (as recommended by EPA when the health advisories came out). We knew that the system routinely detected numerous PFAS, including PFOA and PFOS in their finished water. They replied, in September 2022, that DEQ had NOT contacted them. At that point we sent a public records request to the agency about this matter. As of this date we have not received any documents, and queries about the status of our request generally go unanswered. In October 2022, we sent a letter to DEQ Secretary Elizabeth Biser. The letter (which will be submitted with these comments) asked the Secretary "…what specific actions the North Carolina Department of Environmental Quality (DEQ) has undertaken to encourage, recommend, or otherwise assist local governments and private water systems in their communication efforts; or in helping them understand the importance of communicating directly with their customers." We also asked that DEQ take steps to notify the public about PFAS contaminants in their drinking water. We have not received a response.

On April 5, 2023, we attended a meeting of the DEQ Secretary's Science Advisory Board. One of the Board members voiced concerns regarding notification: " You're talking about millions of people. They are exposed to levels that exceeded the four. So it really speaks to, I think a need for a really effective communication strategy." DEQ's response to his comment was that they did not want to "alarm" the public. On April 7, 2023, BREDL sent a letter to the SAB "…requesting that the Science Advisory Board act in their advisory capacity and recommend that the Department of Environmental Quality take immediate action to meaningfully inform the public about PFAS in their water. We know that the Department notifies private well users by mail if PFAS are detected. Consumers who use drinking water provided by public or private systems deserve no less." (Letter will be submitted with these comments).

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Inland Empire Utilities Agency (IEUA), California (Doc. #1666, SBC-043394)

IEUA acknowledges the role of the water and wastewater industry as part of the long-term solution to PFAS management, but also urges EPA to prevent unsafe PFAS from entering the consumer marketplace and to hold accountable those entities that are primarily responsible for PFAS production and distribution leading to contamination.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

National Association of Water Companies (NAWC) (Doc. #1670, SBC-044162)

Many private water systems are in the process of seeking damages directly from the PFAS manufacturers through litigation in various jurisdictions to hold the manufacturers accountable for the contamination they have caused and to remediate water supplies. How this litigation will be resolved and, if successful, when funds would be recovered is uncertain and private water systems need to have access to other sources of funding to address the PFAS substances that may be present in the drinking water supplies.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

National Association of Water Companies (NAWC) (Doc. #1670, SBC-044161)

4. EPA needs to require point of use restrictions on the manufacturers to address and remediate PFAS contamination at its source and reduce downstream removal of contaminates by entities with no responsibility for the creation of the problem.

EPA needs to take greater actions to reduce the contamination of water supplies by the manufacturers of PFAS substances before the harmful chemicals contaminate water supplies. EPA needs to commit to stronger actions against the sources of the contamination rather than requiring the water industry to remove the harmful chemicals once they are in the environment and the water supplies. The drinking water industry should not be disproportionately targeted by this regulatory action to reduce PFAS exposure.

A regulatory scheme to address the problems caused by PFAS contamination of drinking water supplies should recognize and account for how PFAS contamination began and how it has spread in order to place the responsibility for the contamination on the parties that created it and are responsible for the contamination. In previous regulatory proposals, EPA provides a brief description of the history of the production of "these human-made chemicals that have been used in industry and consumer products since the 1940's". (See 87 Fed. Reg. at 54418). EPA did not suggest, nor could it, that NAWC members or other public or private water or wastewater utilities have played any role in the production or distribution of these chemicals. NAWC members do not use PFAS chemical in the process of providing clean drinking water or in the

wastewater treatment process. Rather, water, wastewater, and stormwater systems passively receive PFAS from these other sources. Water systems, and the public, have limited control over their contributions of PFAS to the environment given the overwhelming presence of this family of chemicals in the chain of commerce and in homes. In its regulatory scheme aimed at addressing the presence of PFAS chemicals in the water supply, EPA should adhere to the principle in other environmental laws that the parties responsible for contamination should be responsible for and pay for its remediation.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Cleveland Water, City of Cleveland, Ohio (Doc. #1672, SBC-044899)

PWSs provide an important and valuable service to the public by removing pollutants to create safe drinking water. However, the burdens of pollution remediation should not be solely placed on PWSs and our ratepayers. First and foremost, EPA should focus its resources on incentivizing pollution prevention and regulating PFAS pollution where it is manufactured and/or used, rather than putting the entire burden on passive receivers such as water and wastewater utilities. It is easier and more cost effective to address chemical discharges before entering the nation's waterways rather than trying to remove pollution afterward. EPA must do more to hold polluters accountable and implement the "polluter pays" principle, where those causing the pollution are responsible for the cost of cleanup. Relying solely on PWS ratepayers to finance the removal of contaminants shifts this responsibility to a "community pays" model, where the burdens of pollution removal are unfairly placed on the public while the corporation profits from the use and sale of the product.

Cleveland Water recommends EPA take actions to better identify sources of PFAS and work to limit these discharges. The agency has recognized the persistent nature of these chemicals; therefore, it should be working toward prevention, as disposal is not a viable long-term option. Cleveland Water appreciates efforts already being made, like the addition of certain PFAS to the Toxics Release Inventory but urges the agency to do more to track and reduce PFAS discharges. Knowing the source of PFAS will allow EPA and PWSs to work to address PFAS at the source and hold polluters accountable.

Cleveland Water also recommends the EPA Office of Ground Water and Drinking Water (OGWDW) work with other EPA offices and federal agencies to address other routes of public exposures to PFAS. PFAS are found in food and food packaging, household and personal care products, fire extinguishing foam, clothing, carpet, kitchen countertop cleaners, and many other items that the public encounters [FN1: https://www.epa.gov/pfas/our-current-understanding-human-health-and-environmental-risks-pfas]. However, it is difficult to impossible to know the level of PFAS contained in any commercial product marketed for sale.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Association of California Water Agencies (ACWA) (Doc. #1675, SBC-044928)

ACWA supports EPA's aim to control PFAS in drinking water and protect public health, but we have concerns with the agency's current regulatory approach to PFAS. ACWA believes that greater focus on eliminating PFAS in consumer products, source control, and destruction technology as well as holding PFAS polluters accountable is necessary to achieve progress in mitigating PFAS risks and exposure. We recommend EPA take more proactive measures to identify sources of PFAS and limit their discharges, as prevention is more cost-effective than attempting to clean up pollution later and maintains the "polluter pays" principle under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Rockbridge Area Conservation Council (RACC) (Doc. #1678, SBC-043742)

With that said, we would respectfully request that: (1) PFOA and PFOS, based on the toxicological data currently known, simply be banned within an appropriately short timeframe (1, 3, 5 years?) from all non-medically essential product uses; (2) cease the application of any PFOA/PFOS containing biosolids from being applied to land; (3) eliminate PFOA/PFOS from future manufacturing off-shoots (semiconductor and/or other unknown industrial uses) regardless of what can or cannot be identified analytically; and

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Rockbridge Area Conservation Council (RACC) (Doc. #1678, SBC-043738)

[With that said, we respectfully request that:] (2) the development of a governmental database for consumers that lists products and packaging contain PFAS – including those in "inert ingredient" and "business confidential" formulations, citation to source of data, and any projected date for removal and delisting; and (3) the immediate testing and cessation of land application of biosolids that contain PFAS - including PFOA/PFOS.

Additionally, significant consideration needs to be paid to new forms of contamination. There is currently a movement to provide $39 billion for semiconductor manufacturing which more than likely will increase PFAS contamination; perhaps putting money into PFAS-free semiconductor manufacturing/technology upfront could minimize/eliminate some of the potential contamination. Likewise, outright banning carcinogens like PFOA/PFOS and looking for safer alternatives may be more helpful in "preventing cancers" requiring less money for "curing/treating cancers" … prevention maybe a better way to fight human and environmental PFAS health issues.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Rockbridge Area Conservation Council (RACC) (Doc. #1678, SBC-043740)

If/when a substance(s) causes significant toxicity at levels below what can be identified analytically, it is safer to ban the substance to err on the side of safety (precaution) rather than to keep using it and err on the side on making more money. The latter statement can be realized in several recent news stories that note globally the world's largest PFAS manufacturers make ~$4 BILLION annually in PFAS sales while societal costs are projected to be $17.5 TRILLION in damages annually. The fact that "EPA has quantified some of the reduced adverse health effects expected from the proposed rule … to be $908 million to $1.23 billion in savings" … the overall savings is paled by the estimated $17.5 TRILLION in global damage costs.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Rockbridge Area Conservation Council (RACC) (Doc. #1678, SBC-044300)

However, in the absence of establishing a timeline in which the MCLG would be realized (5, 10, 20 years?) it is unclear what significance the MCLG holds if these chemicals are not clearly banned from use, importation, and repeated reintroduction into the environment and food supply via disposal in POTWs and subsequent release of POTW effluent and biosolids.

If the media used to treat industrial effluent and drinking water to reduce PFAS is then disposed of in municipal landfills, which then send PFAS-laden leachate to Publicly Owned Treatment Works (POTWs) that do not remove PFAS before discharging effluent to the environment and applying biosolids to agricultural fields, it seems clear that without equivalent action at these other points in the PFAS cycle, MCL/MCLG standards by themselves may simply re-direct PFAS dose to other routes of exposure.

Because these chemicals are so ubiquitous to our world and are used in an uncontrolled manner it is essential for consumers to have access to a governmental database that identifies what PFAS (including PFOA/PFOS) are used in consumer, household, and industrial products – domestic and imported. This would allow consumers to have the ability to make an informed decision for themselves and their family concerning exposure to these substances. Such a database would also help to minimize/eliminate what ends up in the landfills which often generate PFAS contaminated leachate which may in turn be incorporated in wastewater treatment plant biosolids and applied to farmlands. The application of PFAS contaminated biosolids to farmlands is thought to have negatively impacted drinking and surface water, crops and animals (domestic and wild) on as much as 20 million acres.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document. The EPA is clarifying for the commenter that this final rule is effective **60**

days after publication in the Federal Register Notice (FRN). Consistent with the timelines set out under SDWA, public water systems (PWSs) are required to conduct their initial monitoring by three years after promulgation and to conduct PN and include PFAS information in the CCRs. After carefully considering public comment, the EPA is extending the compliance deadline for all systems nationwide to meet the Maximum Contaminant Level (MCL) to allow additional time for capital improvements. As such, PWSs are required to make any necessary capital improvements and comply with the PFAS MCLs by five years after rule promulgation.

Austin Water (AW), Austin, TX (Doc. #1688, SBC-044456)

Additionally, more efforts are needed to reduce and restrict the release of PFAS into the environment to protect public health. The preamble of the proposed PFAS rules states that ongoing use and pathways for releasing the six PFAS substances are still occurring. This situation seems incongruous alongside an NPDWR proposal that will place the responsibility for managing the impacts of PFAS on drinking water affordability onto water systems and their customers.

Additionally, we support the efforts and comments by the American Water Works Association and the Association of Metropolitan Water Agencies, both organizations of which AW is a member. We respectfully request that our comments and those of our member Associations be considered by EPA in the decision-making process regarding the future outcome of the proposed PFAS NPDWR.

Shay Ralls Roalson P.E.

Director Austin Water

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

City of Lancaster, Pennsylvania (Doc. #1695, SBC-044997)

The fact is that these compounds are well known by EPA to have been in the food and clothing industries. USEPA is failing to educate and appropriately regulate. It is allowing their usage so broadly, at levels far exceeding the previous 70 mg/L for water consumption action while allowing food products to be exposed to humanity at a million times higher dosages than their new 4 ng/L maximum hazard limit. There is a Consumer Reports link (https://www.consumerreports.org/health/food-contaminants/dangerous-pfas-chemicals-are-in-your-food-packaging-a3786252074/) from May 2022 issue describes leaching of the chemical from food wrappings and shows that the food wrappings acceptable dosages are either 100 or 20 ppm which are 5-25 million times higher than the proposed water MCL level of 4 ng/L and well above your previous limit of 70 ng/L. Why does the EPA allow industry to use hazardous chemicals millions of times higher than their own limits to poison citizens' food? This is a very

problematic issue that has already shown litigation starting for food companies (Simply Orange) that you allowed to operate and to profit using this "hazardous chemical" for many years.

Moving forward we recommend that the best course of action would be to remove the hazardous chemical label since the true limits are not yet known for health impacts. The EPA must focus on the point source pollutants and industry affecting the food and clothing of people that result in 80% exposure of these chemicals. Doing so would allow for the minimization of the chemical in water sources and allow for better research into proper methods for cleaning up this chemical in the environment. An article from the International Journal of Environmental Research and Public Health from 2022 titled "A Review of PFAS Destruction Technologies" Reviews several current methods for breaking down PFAS molecules. The Challenges with them are secondary contaminants affecting efficiency along with treatable capacity, toxic byproducts, and the cost with massive energy consumption.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Clean Water Action/Clean Water Fund (Doc. #1697, SBC-045008)

EPA should also consider innovation initiatives to more explicitly use authorities other than the Safe Drinking Water Act to reduce public health risk in drinking water and to avoid downstream pollution burden that should be controlled upstream. In its 2010 Drinking Water Strategy, EPA committed to using the authority of multiple statutes to help protect drinking water. [FN8: A New Approach to Protecting Drinking Water and Public Health, EPA, March 2010.] This has led to improved consultation and coordination in some cases, but not to systemic initiatives that could deliver real results to keep contaminants out of drinking water. EPA should explore more concrete initiatives to use the authority of other statutes to control PFAS chemicals and other drinking water contaminants at the source, rather than relying on treatment once they have entered a drinking water supply and passing that burden and cost on to the public. Examples could include additional requirements within the Toxic Substances Control Act (TSCA) and Clean Water Act programs for any contaminants appearing on the SDWA Contaminant Candidate List.

We appreciate the opportunity to comment on this proposal.

Respectfully Submitted,

Lynn Thorp

National Campaigns Director lthorp@cleanwater.org

1444 I Street NW; Suite 400

Washington DC 20005

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

National Wildlife Federation et al. (Doc. #1702, SBC-043514)

While this proposal is a critical step towards turning off the tap on PFAS contamination of our drinking water, we must also stop PFAS at its source, before it enters our drinking water and environment in the first place. These substances are routinely found in the environment and in wildlife species from bluegills and great blue herons to largemouth bass and deer. EPA studies show that nearly all freshwater fish in the United States have detectable levels of PFAS contamination. Another study showed that the consumption of just a single serving of freshwater fish per year could be equal to a month of drinking water laced with the PFOS at high levels that may be harmful. People who consume freshwater fish, particularly communities that depend on fishing for sustenance and for cultural practices, are particularly at risk from high PFAS exposure. The same goes for wildlife that consume fish contaminated with PFAS, bioaccumulating up the food chain. Aquatic birds contaminated with PFAS have experienced reduced hatching success and other reproductive impacts. Elevated levels of PFAS in wildlife has also impacted recreational and subsistence hunting.

We urge EPA to continue efforts to ensure that the obligation to clean up these harmful chemicals is borne by the companies that discharge PFAS into our environment. This will reduce the public health and treatment costs incurred by downstream communities, ratepayers, and water utilities. The EPA should use the tools it has to regulate industrial discharges of PFAS into surface waters, address PFAS in Clean Water Act permits, clean up PFAS-contaminated sites under the Comprehensive Environmental Response, Compensation, and Liability Act, expand research on PFAS contamination on agricultural lands and in fish and wildlife, and prohibit the use of PFAS chemicals.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

The City of Columbus, Department of Public Utilities (Doc. #1703, SBC-045057)

Importantly, these resource intensive efforts by water utilities are only treating the symptoms rather than the disease. Treatment might reduce the current amount of PFOA and PFOS in a cup of water from low parts per trillion to an amount in parts per quadrillion, but it will not reduce the amount of PFAS that the public is exposed to everyday through other common household and environmental sources. This continued exposure will continue unabated so long as PFAS chemicals are permitted to be used in consumer goods manufactured in, or imported to, the United States.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Philadelphia Water Department (PWD) (Doc. #1709, SBC-045737)

PWD does not believe that its customers should pay for addressing PFAS pollution that they did not create. The solution to the complex challenge of managing PFAS contamination should not lie solely with the public nor the water industry. Although PWD is willing to do its part to address PFAS' pervasive and extensive damage, ultimately the polluters—those who are manufacturing and producing PFAS—should be held accountable for environmental remediation. PWD advocates for the creation of a defined compensation mechanism by which PFAS generators are financially liable for the cost of remediating the public health and environmental damage caused by the historic and continuing manufacturing of PFAS compounds.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Wyoming Department of Environmental Quality (WDEQ) (Doc. #1716, SBC-044748)

2. Additional Support Is Needed for Concurrent PFAS Source Reduction

EPA states that while certain PFAS, specifically PFOA, PFOS, and PFNA, have seen voluntary phase out from commercial production in the United States, with the intended consequence that their respective concentrations in the environment will be similarly reduced, other PFAS, specifically PFBA, PFBS, and HFPO-DA, have not seen voluntary commercial production phase-out in the United States, and discharges into source water are ongoing. Therefore, concentrations of those PFAS can be expected to increase in the environment in all media.

Given the public health implications as well as the magnitude of the treatment costs associated with PFAS, the WDEQ recognizes that PFAS source reduction is critical to successfully addressing PFAS contamination. Establishing drinking water standards will not be sufficient to protect public health. WDEQ also recognizes that EPA has worked to use existing authorities under the Clean Water Act (CWA); Toxic Substances Control Act (TSCA); Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA); Resource Conservation and Recovery Act (RCRA); and voluntary stewardship programs to address sources of PFAS.

The WDEQ recommends that EPA continue pursuing PFAS source reduction activities and providing support for states' efforts to do the same. As states are co-regulators for many programs that will be involved with reducing PFAS sources through voluntary or regulatory means, it is critical that EPA engage with states as it considers further actions to prevent PFAS from entering the environment.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

HRSD (Doc. #1719, SBC-043542)

[We see the following recommendations as productive and protective strategies that EPA can utilize:]

Prioritize source control ahead of costly treatment technologies

Consistent with the "Polluter Pays" model of responsibility, EPA must focus efforts on source control before requiring drinking water utilities to implement costly treatment technologies. These source control efforts rightly place the burden of control on the industries and manufacturers that are producing and using PFAS in their processes, resulting in environmental and public health exposures. For drinking water utilities that are only marginally above the proposed MCL, source control alone may result in compliance. We note that EPA itself is applying this strategy to the implementation of Effluent Limit Guidelines (ELG) for airport facilities, allowing time to evaluate the efficacy of source control through a transition to alternative fluorine-free firefighting foams before imposing ELGs.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Environmental Working Group (EWG) (Doc. #1721, SBC-045420)

The EPA must prioritize source reduction to prevent future contamination.

The burden of addressing PFAS contamination in drinking water should not fall entirely on drinking water utilities. In addition to quickly finalizing the drinking water standards, the EPA must prioritize preventing future contamination. To address PFAS at the source, the EPA should quickly develop water quality criteria and effluent limitation guidelines under the Clean Water Act, as promised in the PFAS Roadmap. The EPA should also quickly implement its guidance to permit writers and urge states to address PFAS through state issued NPDES permits while the EPA is developing ELGs. The EPA should immediately start including PFAS in EPA-issued NPDES permits and impose pretreatment requirements in states where EPA administers the national pretreatment program. The EPA should also list PFOA and PFOS and consider listing other PFAS as hazardous air pollutants under the Clean Air Act. The EPA should work with the White House to expeditiously implement Executive Order 14057 requiring all agencies to purchase substitutes for PFAS containing products.

EPA must do more to protect Americans from PFAS.

Removing PFAS from drinking water is just one of many steps that EPA must take to protect Americans from PFAS chemicals. In addition to quickly moving to finalize these health-protective drinking water limits, EPA should:

• Quickly establish effluent limitations, permit limits, pretreatment standards, and sewage sludge standards for PFAS under the Clean Water Act.

• Regulate PFAS as hazardous air pollutants under the Clean Air Act.

• Quickly finalize the proposed designation for PFOA and PFOS as hazardous substances under CERCLA to jumpstart the cleanup process in contaminated communities.

• Quickly issue the proposed rule to add PFAS as hazardous constituents under RCRA.

• Finalize the proposed rule to close reporting loopholes under the Toxics Release Inventory.

• Stop approving new PFAS and new uses of existing PFAS under the Toxic Substances Control Act.

EWG appreciates the opportunity to comment on this historic proposed rulemaking. Should you have any questions regarding this comment or wish to discuss further, please do not hesitate to contact Melanie Benesh, mbenesh@ewg.org.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Natural Resources Defense Council (NDRC) et al. (Doc. #1723, SBC-044470)

2. Hold PFAS manufacturers and polluters accountable for the costs of treatment and/or alternative water supplies.

Water utilities—and states on behalf of water utilities—have increasingly been filing suit against PFAS manufacturers and polluters to recover costs of treatment to remove PFAS and/or costs of securing alternative water supplies. Some have already secured significant settlements. These efforts should be encouraged and supported, as they shift the cost of compliance from water systems and their customers to those responsible for causing the contamination.

For example, in 2018, the state of Minnesota secured an $850m settlement with 3M, which included over $700 million for drinking water projects in the affected areas of the state [FN7: https://3msettlement.state.mn.us/sites/3msettlement/files/2023-03/3M%20Settlement%20biannual%20report%2C%20February%202023.pdf]. In 2022, Massachusetts filed suit in federal court against PFAS manufacturers to recover, among other things, costs of treating municipal drinking water [FN8: https://www.mass.gov/news/ag-healey-sues-manufacturers-of-toxic-forever-chemicals-for-contaminatingmassachusetts-drinking-water-and-damaging-natural-resources] California, [FN9: https://oag.ca.gov/news/press-releases/attorney-general-bonta-sues-manufacturers-toxic-forever-chemicals] Wisconsin, [FN10: https://www.doj.state.wi.us/node/8711] Colorado, [FN11: https://coag.gov/press-releases/2-28-22/] and Illinois [FN12: https://illinoisattorneygeneral.gov/news/story/attorney-general-raoul-files-latest-lawsuit-over-contamination-bytoxic-forever-chemicals] also filed similar lawsuits in state courts in 2022. Individual water systems in New Jersey, [FN13: https://whyy.org/articles/n-j-towns-sue-makers-of-forever-chemicals-saying-companies-must-pay-for-cleanup/; https://www.levinlaw.com/2022/11/03/court-denies-3ms-motion-summary-judgment-middlesex-water-companycase] Philadelphia, [FN14: https://whyy.org/articles/philly-sues-3m-dupont-

other-companies-forever-chemical-contamination/] and Baltimore, [FN15: https://mayor.baltimorecity.gov/news/press-releases/2022-11-04-baltimore-files-lawsuit-combat-pfas-chemicals] among others, have filed similar lawsuits against PFAS manufacturers.

EPA and the Department of Justice should do everything in their power to help water systems hold PFAS manufacturers and polluters accountable for the costs of meeting new PFAS drinking water standards. For example, to help impacted communities identify releases and enable contaminated water systems to more readily recover PFAS treatment costs from responsible parties, EPA should promptly finalize its proposal to designate PFOA and PFOS as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). Further, EPA should expeditiously designate the entire class of PFAS chemicals as hazardous substances under CERCLA. Additionally, EPA should use its other robust legal authorities to assist public water systems to force polluters to pay for cleanup of drinking water, such as its imminent and substantial endangerment authorities under the Safe Drinking Water

Act [FN16: 42 U.S.C. 300i] and Resource Conservation and Recovery Act [FN17: 42 U.S.C. 6973].

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Joe DiNardo (Doc. #1725, SBC-045757)

However, in the absence of establishing a timeline in which the MCLG would be realized (5, 10, 20 years?) it is unclear what significance it holds if these chemicals are not clearly banned from use. Regardless, because these chemicals are so ubiquitous to our world and are used in an uncontrolled manner it would be more useful for people to have access to a governmental database that identifies what PFAS (including PFOA/PFOS) are used in consumer, household, and industrial products. This would allow consumers to have the ability to make an informed decision for themselves and their family concerning exposure to these substances. Such a database would also help to minimize/eliminate what ends up in the landfills which often generates PFAS contaminated leachate which often is incorporated in wastewater treatment plant biosolids and applied to farmlands. The application of PFAS contaminated biosolids to farmlands is thought to have negatively impacted drinking and surface water, crops and animals (domestic and wild) on as much as 20 million acres. [FN1: footnote not provided.]

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document. The EPA is clarifying for the commenter that this final rule is effective on **60** days after publication in the FRN. Consistent with the timelines set out under SDWA, PWSs are required to conduct their initial monitoring by three years after promulgation and to conduct PN and include PFAS information in the CCRs. After carefully considering public comment, the EPA is extending the compliance deadline for all systems nationwide to meet the MCL to allow additional time for capital improvements. As such, PWSs are required to make any necessary capital improvements and comply with the PFAS MCLs by five years after rule promulgation.

Joe DiNardo (Doc. #1725, SBC-045759)

[With that said, I respectfully request that:] (2) the development of a governmental database for consumers that tells what products contain PFAS; and (3) the immediate banning of the application of biosolids that contain PFAS - at least PFOA/PFOS.

Additionally, significant consideration needs to be paid to new forms of contamination. There is currently a movement to provide $39 billion for semiconductor manufacturing which more than likely will increase PFAS contamination; perhaps putting money into PFAS free semiconductor manufacturing/technology upfront could minimize/eliminate some of the potential contamination. Likewise, outright banning carcinogens like PFOA/PFOS and looking for safer alternatives may be more helpful in "preventing cancers" requiring less money for "curing/treating cancers" … prevention maybe a better way to fight human and environmental PFAS health issues!

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Joe DiNardo (Doc. #1725, SBC-045761)

If/when a substance(s) cause significant toxicity at levels below what can be identified analytically, it is safer to ban the substance to err on the side of safety (precaution) rather than to keep using it and err on the side on making more money. The latter statement can be realized in several recent news stories [FN2, 3: footnote not provided] that note globally the world's largest PFAS manufacturers make ~$4 BILLION annually in PFAS sales while societal costs are projected to be $17.5 TRILLION in damages annually. The fact that "EPA has quantified some of the reduced adverse health effects expected from the proposed rule … to be $908 million to $1.23 billion in savings" … the overall savings is paled by the estimated $17.5 TRILLION in global damage costs!

With that said, I would respectfully request that: (1) PFOA and PFOS, based on the toxicological data currently known, simply be banned (1, 3, 5 years?) from all product uses; (2) ban the application of any PFOA/PFOS containing biosolids from being applied to land; (3) ban PFOA/PFOS from future manufacturing off-shoots (semiconductor and/or other unknown industrial uses) regardless of what can or cannot be identified analytically.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045141)

1. Preventing PFAS Releases

This proposed NPDWR for PFAS is a critical step to protect drinking water, but EPA must continue working to prevent PFAS from entering drinking water sources. MassDEP commends

EPA's efforts using all the Agency's authorities, both regulatory and non-regulatory, to address PFAS contamination cross media and recommends that these efforts be accelerated.

Holistic Approach

MassDEP recommends that EPA extend its efforts using a holistic lifecycle approach that includes close coordination with other Federal agencies to utilize all possible Federal statutory and regulatory authorities to address PFAS concerns.

Using a holistic approach to reduce or eliminate the use of PFAS and to prevent these compounds from entering the environment and drinking water sources throughout any part of these chemicals' lifecycle - from manufacturing through processing, distribution, and disposal - is much more effective and less expensive than removing PFAS once contamination has occurred. Protecting drinking water sources (and preventing contamination) is essential for sustaining safe drinking water supplies, protecting public health and the economy, and has many additional environmental benefits.

The PFAS NPDWR is an important step in addressing PFAS contamination; however, numerous other regulatory decisions may be made based on drinking water standards (e.g., ground water remediation determinations, National Pollution Discharge Elimination System (NPDES) permits, and surface water standards). EPA should expand coordination across all the Agency's offices and with other federal Agencies (i.e., the Department of Defense, the Food and Drug Administration, and Centers for Disease Control and Prevention) to reduce PFAS contamination. This should include consideration of post- treatment impacts from disposal and incineration under each regulatory authority to ensure that the responsibility and cost for removing PFAS are not passed on from one media to another. This should also include consistent messaging to regulators, regulated entities, and the public.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Chattahoochee Riverkeeper (CRK) (Doc. #1730, SBC-043563)

It is also essential that the agency continue research into testing methods and the health impacts of the thousands of other PFAS chemicals that are known to exist in the environment.

It's important that EPA not only pass the NPDWR for PFAS, but also ensure that all communities have the funding and capacity to test for PFAS contamination and remediate if levels pose a threat to human health.

If you have any questions about this letter, please contact me at jsterling@chattahoochee.org or 404-352-9828.

Thank you,

/s/

Jessica Sterling

Technical Programs Director

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Rio Grande Waterkeeper and WildEarth Guardians (Doc. #1732, SBC-045425)

III. EPA Should Utilize Other Authorities to Comprehensively Address the Widespread Threat to Public Health and the Environment Posed by PFAS Contamination

Removing PFAS from the water at municipal water treatment facilities does not get at the heart of the problem, which is the production and discharge of PFAS chemicals into the waterways in the first place. Regulating PFAS through safe drinking water standards will not prevent the myriad negative impacts of these PFAS substances on their journey from their source to our taps.

For example, oil and gas drilling is a major industry in New Mexico, especially in the Permian Basin, that has the potential to contaminate the groundwater and surface water with PFAS. Physicians for Social Responsibility's recent report, Fracking with "Forever Chemicals" in New Mexico, found that between 2013 and 2022 oil and gas companies injected at least 261 wells in Mexico with 9000 pounds of two different PFAS chemicals (PTFE/Teflon and Fluoroalkyl alcohol substituted polyethylene glycol), neither of which are included in the EPA's new drinking water standards. [FN19: Dusty Horwitt & Barbara Gottlieb, Fracking with "Forever Chemicals" in New Mexico, PHYSICIANS FOR SOC. RESP. (Apr. 12, 2023), https://psr.org/wp-content/uploads/2023/04/fracking-with-forever-chemicals-in-new-mexico.pdf.] During the same time period, oil and gas companies injected 8,200 wells with over 240 million pounds of trade secret fracking chemicals, some of which could be PFAS chemicals. However, New Mexico's trade secret laws shield oil and gas companies from disclosing the identities of fracking chemicals deemed trade secrets to the public and state regulators.

The use of PFAS in fracking fluid provides many different routes for PFAS to enter the groundwater and surface water, such as spills of fracking fluid into the groundwater, underground migration of fracking fluids through fractures, and spills of wastewater after fracking. Frontline communities living near oil and gas operations will bear disproportionate health impacts resulting from the use of PFAS chemicals in fracking, in addition to many other negative health effects of oil and gas operations, absent effective regulation of these dangerous chemicals. This raises environmental justice concerns because oil and gas operations are disproportionately sited in low-income and/or Black, Brown and Indigenous communities.

In addition, PFAS contamination of the Rio Grande and its tributaries could threaten the integrity of the Rio Grande ecosystem as plants and wildlife take up these chemicals. The Rio Grande supports threatened and endangered species including the Rio Grande silvery minnow, the Southwestern Willow Flycatcher, and the Western Yellow-Billed Cuckoo. [FN20: Threatened and Endangered Species in the Rio Grande Basin, INTERSTATE STREAM COMM'N,

https://www.ose.state.nm.us/Basins/RioGrande/esa.php (last visited May 23, 2023).] The effects of PFAS on fish and birds are not fully understood, but there is evidence that PFAS may have negative impacts on avian reproduction, especially in birds that eat aquatic insects, like the Southwestern Willow Flycatcher. [FN21: Abigail Odegard, et al., Exposure and Effects of PFAS on Birds, U.S. ENV'T PROT. AGENCY, (Feb. 1, 2023), https://cfpub.epa.gov/si/index.cfm (Search "Exposure and Effects of PFAS on Birds" in Science Inventory search bar).] PFAS substances will also bioaccumulate up the food chain because these chemicals resist degradation. [FN22: Asa J. Lewis et al., Exposure Pathways and Bioaccumulation of Per- and Polyfluoroalkyl Substances in Freshwater Aquatic Ecosystems: Key Considerations, 822 SCI. OF THE TOTAL ENV'T 153561 (May 20, 2022), https://doi.org/10.1016/j.scitotenv.2022.153561.] This could pose significant risk to higher trophic level organisms.

Removing PFAS from the drinking water at municipal water treatment facilities will not prevent PFAS contamination of crops irrigated by Rio Grande water, livestock, or fish caught for sustenance. In the Upper Rio Grande Basin, approximately seventy four percent of the Rio Grande water is allotted for irrigation (of crops and golf courses), while agriculture accounts for about 85% of both surface water and groundwater withdrawals in the overall Rio Grande Basin. [FN23: Tamara I. Ivahnenko et al., Estimates of Public-Supply, Domestic, and Irrigation Water Withdrawal, Use, and Trends in the Upper Rio Grande Basin, 1985 to 2015, U.S. GEOLOGICAL SURVEY (Sept. 17, 2021), https://doi.org/10.3133/sir20215036;Climate; Will Kort, Change Impacts on Agriculture in the Rio Grande Basin, UNIVERSITY OF WISCONSIN-MILWAUKEE CENTER FOR WATER POLICY, https://uwm.edu/centerforwaterpolicy/wp-content/uploads/sites/170/2013/10/Rio-Grande_Agriculture_Final.pdf (last visited May 23, 2023).] In the Middle Rio Grande in New Mexico, irrigation water is primarily used for alfalfa and pasture for a substantial dairy industry which could be threatened by PFAS contamination. [FN24: The Dairy Industry in New Mexico, DAIRY PRODUCERS OF N.M., https://dairyproducersnm.com (last visited May 23, 2023).] Below the Elephant Butte Reservoir the Rio Grande supports farming of pecans, chiles, onions, melons, citrus, and vegetables. [FN25: Rio Grande Basin – SECURE Water Act Section 9503(c) Report to Congress, BUREAU OF RECLAMATION (Mar. 2021) https://www.usbr.gov/climate/secure/docs/2021secure/basinreports/RioGrandeBasin.pdf.] While an important step to address PFAS contamination in drinking water, this proposed new rule does not address PFAS contamination of the Rio Grande itself, which could lead to contamination of agricultural soils or crops. [FN26: Rossella Ghisi et al., Accumulation of Perfluorinated Alkyl Substances (PFAS) in Agricultural Plants: A Review, 169 ENV'T RSCH. 326 (Feb. 2019), https://doi.org/10.1016/j.envres.2018.10.023.] Consumption of crops and dairy products irrigated with PFAS-contaminated water would still be harmful to the public health without further regulation intended to prevent PFAS pollution of the nation's waters at the source.

To prevent or at least reduce PFAS pollution in our waterways, EPA must move beyond drinking water protections and use more of its tools to prevent PFAS from entering the environment in the first place. EPA should act quickly to promulgate regulations pursuant to the Clean Water Act to set water quality standards for PFAS and to prevent the discharge of PFAS into our waterways

through NPDES permitting standards. Polluting industries have used these dangerous chemicals for decades to maximize product sales. PFAS have been integral to America's industrialization for decades, but they do not need to be. The risk they pose to public health is unacceptable, and there are alternatives to PFAS that can be used instead. [FN27: Cheryl Hogue, How to Say Goodbye to PFAS, CHEMICAL & ENGINEERING NEWS (Nov. 2019), https://cen.acs.org/environment/persistent-pollutants/say-goodbye-PFAS/97/i46.] We recognize that all PFAS are unlikely to be phased out overnight; however, limiting their use is an essential step toward a future without these dangerous forever chemicals. Further, the burden of paying for removal of PFAS from our drinking water and remediating PFAS contamination in the environment should not be falling on the American taxpayers, but on these polluting industries.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Arizona Corporation Commission (ACC) (Doc. #1735, SBC-045182)

These financial burdens are heightened for utilities in states like Arizona, located downstream of major water sources, that will be responsible for treating contaminates that originated upstream of our state. Furthermore, public utilities did not contribute to the production, regulation, or discharge of PFAS, yet they and their customer base will bear the cost of remediation.

The ACC believes it is imperative that efforts be made to determine the source of the PFAS pollution, and that those responsible bear most if not all of the cost burden to remediate.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Arizona Corporation Commission (ACC) (Doc. #1735, SBC-045190)

POLLUTERS PAY

The EPA should take stronger measures to reduce water contamination by PFAS manufacturers before these harmful chemicals enter water supplies. Instead of placing the burden to remove chemicals on the water industry, which passes costs on to customers, the focus should be on addressing the sources of contamination. The ACC opposes disproportionately targeting the drinking water industry in efforts to reduce PFAS exposure and firmly believes manufacturers and profiteers of these chemicals should bear the responsibility and costs of necessary remediation to eliminate PFAS concentrations that endanger health and the environment. The ACC strongly supports a "polluter pays" approach, where those responsible for PFAS pollution cover the liability and costs of remediation, rather than the public. Currently, the EPA is considering taking formal enforcement action under the federal Clean Water Act against the Washington Works Facility near Parkersburg, West Virginia, for PFAS discharges into stormwater and effluent [FN6: Per April 26, 2023, EPA press release titled "EPA takes first-ever federal Clean Water Act enforcement action to address PFAS discharges at Washington Works

facility near Parkersburg, W. Va."]. The ACC sees this as a reason to extend the PFAS drinking water compliance deadline, allowing for the identification and regulation of industrial polluters. Halting pollution at its source is a more effective approach and prevents the shifting of cleanup costs to customers.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Pennsylvania Farm Bureau (PFB) (Doc. #1736, SBC-043564)

May 30, 2023

Alexis Lan

Office of Ground Water and Drinking Water

Standards and Risk Management Division (Mail Code 4607M) Environmental Protection Agency

1200 Pennsylvania Avenue NW

Washington, DC 20460

Dear Ms. Lan:

Pennsylvania Farm Bureau (PFB) is pleased to offer its comments on the proposed rule, "Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation" (EPA-HQ-OW-2022-0114-0027). PFB represents over 30,000 members engaged in all manner of agricultural activities, including the production and processing of crops; the production and processing of animals; the production and processing of forestry products; landscaping and horticultural services; agriculture-related support services; and food manufacturing. According to the 2021 report, The Economic Impact of Agriculture in Pennsylvania: 2021 Update, agriculture continues to be a leading contributor to the Commonwealth's economy, contributing $1 of every $16 in gross state product, with every dollar of direct output generating $0.63 in additional economic activity. In addition, agriculture supports one out of every ten jobs in Pennsylvania and seven jobs per $1 million of output. In 2019 alone, the total direct and indirect economic impact of agriculture within Pennsylvania was an estimated $132.5 billion.

PFB supports the protection and restoration of land and groundwater in Pennsylvania and across the United States; specifically, farmers support the protection and restoration of land and groundwater and the efforts that EPA is making in the "PFAS Roadmap" to address the impacts of the historic use of PFAS chemicals. The livelihood of Pennsylvania's farmers depends on healthy soil and groundwater, and families throughout the world rely on the food, fuel and fiber produced by American agriculture. At the same time, farmers have not knowingly used PFOA and PFOS in their operations. Farmers are in no position technically, economically, or practically to address the impact of the presence of PFAS chemicals, and especially PFOA and PFOS,

which continue to be found in virtually any place where soil, surface and groundwater have been assessed.

It is important to recognize PFOA and PFOS have come onto agricultural land without the knowledge or fault of farmers. These chemicals can be found in high quantities in firefighting foam that is used in and around airports and Department of Defense (DoD) training facilities. These chemicals have been known to travel naturally through the environment— most notably through ground and surface waters—and can eventually be deposited onto farm fields, so proximity to one of these areas can lead to elevated levels of PFAS. Pesticide holding containers have also been identified as a potential source of PFAS on farms. Recent EPA data indicates that plastic containers made of fluorinated high-density polyethylene (HDPE) are likely to leach PFAS into pesticides and other liquid products that are stored in them. EPA's review also suggests that the amount of PFAS that migrates into liquid products increases with storage time.

PFAS chemicals are also delivered to farms via biosolids, which are commonly applied to farm fields as an alternative to fertilizer. Farmers accept biosolids from a wastewater treatment facility to land apply onto their property. Biosolids are regulated at the federal, state, and local level to ensure protection of public health and the environment. For decades, EPA has encouraged and supported farmers' beneficial use of biosolids. Unfortunately, more recently, we have learned that biosolids are contributing to the spread of PFAS on agricultural lands. This is a major concern for our members, and PFB members have adopted policy supporting a ban on spreading of biosolids until more research is conducted on the effects of PFAS. Regardless of how PFAS ultimately arrives onto a farm field, it is undeniable that the fault does not fall on Pennsylvania's—or other American—farmers.

EPA must acknowledge that farmers do not use PFAS chemicals in any part of their operations and are innocent receivers of such chemicals. Farmers would never intentionally spread PFAS, as food safety is fundamental to farmers and consumers alike. Given this fact, as well as those above, it is clear that farmers should not be held responsible for the presence of PFAS chemicals, which they did not produce or intentionally use. Farmers all over the country could face devastating impacts simply for owning land and creating an agricultural product. PFAS contamination is a significant issue, and a collaborative effort will be needed to find solutions. It is essential that as those solutions are developed, landowners, producers or their lenders must not be held liable for the cost of cleaning up chemical contaminants, like PFAS, that are spread by actions over which the producer, landowner or lender had no management oversight or control of decision-making.

The American Farm Bureau Federation (AFBF), of which PFB is a member, additionally calls for:

• Funding for research into the health risks and strategies for mitigating risks associated with chemical contaminants in water and food such as PFAS.

• Collaboration by agencies, universities, and the private sector to develop proactive solutions and technologies to reduce the human health and environmental risks of emerging contaminants such as PFOS/PFAS.

• Establishing an indemnification program and funding to properly compensate farmers,' producers' and/or landowners' financial losses associated with emerging contaminants such as PFOS/PFAS.

• Opposition to PFOS/PFAS and similar chemicals in food packaging that may become part of the compost stream.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Florida Section American Water Works Association - Water Utility Council (FSAWWA WUC) (Doc. #1737, SBC-044483)

Unlike industrial manufacturers, domestic wastewater is not the source of PFOA/ PFOS. No treatment process utilizes these chemicals, and utilities take no other action that introduces PFOA/PFOS into the reclaimed water or biosolids produced at treatment facilities. Instead , domestic wastewater utilities may receive (usually trace amounts) of the chemicals through industrial, commercial, and residential inputs into utility collection systems. Unlike source originators, utilities make no profit on PFOA/ PFOS. To the contrary, if utilities could prevent these chemicals from potentially getting into their systems in the first place, they would do so. We ask that EPA refocus its efforts on achieving that very outcome, by refocusing its regulatory initiative onto the industrial manufacturers and consumer products that put these chemicals into the environment.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045947)

AMWA recommends EPA take actions to better identify sources of PFAS in the environment and work to limit these discharges. The agency has recognized the persistent nature of these chemicals; therefore, it should be working toward prevention, as disposal is not a viable long-term option. AMWA appreciates efforts already being made, like the addition of certain PFAS to the Toxics Release Inventory and urges the agency to do more to track and reduce PFAS discharges. Knowing the source of PFAS will allow EPA and PWSs to work to address it at the source and hold those polluters accountable.

AMWA also recommends EPA Office of Ground Water and Drinking Water (OGWDW) work with other line offices and federal agencies to address other routes of public exposures to PFAS. PFAS are in food and food packaging, household and personal care products, fire extinguishing foam, and many other items that the public encounters [FN1: EPA. (2023, March 16). Our

Current Understanding of the Human Health and Environmental Risks of PFAS. https://www.epa.gov/pfas/our-current-understanding-human-health-and-environmental-risks-pfas]. EPA and other agencies must work to reduce these exposures and better communicate the risks associated with them. Regulating drinking water should only be one part of a larger, holistic approach to addressing the public's exposure to PFAS.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046033)

Eliminating the Sources

Eliminating sources is the ultimate solution to removing PFAS from the environment. Providing time and a regulatory framework that supports the elimination of PFAS sources would place the cost for remediation where it belongs – on the polluter instead of the public. The Occoquan Reservoir is an indirect potable reuse system with some industrial discharges to the POTW. The state has conducted some sampling for PFAS in the watershed and Fairfax Water is planning to do more. There are potential opportunities to remove these PFAS sources from the water supply.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-046040)

Partnering to Protect

WSSC Water plays a key role in the Potomac River Basin Drinking Water Source Protection Partnership and the Patuxent Reservoirs Watershed Protection Group. Given the magnitude of costs for individua utilities, it makes sense to focus on controlling PFAS at the source.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

LSP Association (LSPA) (Doc. #1742, SBC-043596)

A team of LSPA members including toxicologists, public health risk assessors, LSPs, and others with decades of experience have reviewed the proposed rule. We have organized our comments according to the topics outlined in the slides from EPA's presentation, Proposed PFAS National Primary Drinking Water Regulation (epa.gov). [Link: https://www.epa.gov/system/files/documents/2023-04/PFAS%20NPDWR%20Public%20Presentation_Full%20Technical%20Presentation_3.29.23_Final.pdf.]

Slide 2: Even though some specific PFAS have been largely phased out due to health and environmental concerns, they may still be found in the environment and in drinking water.

● Much work is still needed in eliminating PFAS-containing products from the marketplace. "Some specific PFAS…" downplays the multitudes of products in use that still include PFAS compounds. It also downplays the decades of use of products used in accordance with labeling, as well as the disposal of these products in landfills, septic systems, wastewater treatment plants (WWTP) and other "receivers" of PFAS impacted effluent that may then impact underlying groundwater.

● Studies have been performed in several states (e.g., Vermont, New Hampshire, Maine, and Massachusetts) that have confirmed the presence of background levels of PFAS constituents in soil, presumably related to airborne deposition.

● Data collected by MassDEP indicate that approximately 5% of private wells tested across Massachusetts have PFAS exceeding the state health standards (20 ppt for the sum of six PFAS) even though there was no reported hazardous waste site/release identified in proximity.

● The LSPA urges USEPA to not focus exclusively on setting very stringent MCLs for these constituents; attempting to limit the sources of these compounds in products will likely have significantly more of a public health impact as exemplified by the reduction in average PFOS (85%) and PFOA (70%) concentrations in blood levels following the phase out of these PFAS compounds (see [Link: https://www.atsdr.cdc.gov/pfas/health-effects/us-population.html] below).

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Del-Co Water Company, Inc. (Doc. #1744, SBC-043616)

In addition, we question why drinking water seems to be the sole focus of regulation while potentially higher PFAS exposures exist in consumer products (including food packaging, stain- and water-repellent fabrics, nonstick products, polishes, waxes, paints, cleaning products), food, personal care products/makeup, pesticides, and dust, and these potential sources of exposure are not simultaneously being regulated. Removal of PFAS chemicals should occur at the source – if the source is not addressed, exposure to PFAS chemicals will continue.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

West Virginia Rivers Coalition et al. (Doc. #1746, SBC-045254)

EPA must implement policy levers to reduce PFAS at the source.

In addition to swiftly finalizing drinking water standards for PFAS, EPA should expedite efforts to prevent these chemicals from polluting the environment in the first place. Most pressingly for

this rule, we implore EPA to expedite the publication of human health ambient water quality criteria for PFAS. State agencies are waiting on these criteria to implement policy levers to reduce PFAS pollution at the source. Without these, permit holders will continue to discharge PFAS into source water at levels of parts per billion, furthering the financial and human health burden on water systems and their customers.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

City of Thornton, Colorado (Doc. #1748, SBC-044781)

While Thornton supports the implementation of this proposed rule to protect public health, the City strongly believes that the EPA needs to do additional work to hold manufacturers and dischargers of PFAS responsible for the pollution they have caused and provide full financial assistance to all water utility providers impacted by PFAS contamination. Thornton is a passive receiver of PFAS due to source waters contaminated by upstream industrial processes and domestic wastes. Thornton will need to install additional treatment processes at considerable cost to comply with the proposed rule and strongly believes that the utilities' ratepayers should not be responsible for the associated costs with that treatment. EPA needs to implement stricter limits (below the proposed MCL and without assuming assimilative capacity) on industrial and municipal WWTP discharges to limit costs borne by WTP utilities.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

National Center for Health Research (NCHR) (Doc. #1749, SBC-044498)

• The U.S. is far behind many other countries in its efforts to regulate PFAS. More than 180 countries have moved to ban PFOA chemicals from production [FN1: Hogue, C. (2019). Governments endorse global PFOA ban, with some exemptions. C&EN Chemical and Engineering News. https://cen.acs.org/environment/persistentpollutants/Governments-endorse-global-PFOA-ban/97/i19#]. The EPA proposed rule is an important first step, but it is long past time for the EPA to define PFAS broadly, regulate them as a class, and ban all non-essential uses.

3. Companies that produce PFAS should bear the financial burden.

We appreciate that the Infrastructure Investment and Jobs Act (P.L. 117-58) provides funding for these efforts, but it's time to start shifting the costs to the companies that have made these chemicals. These companies continue to profit while American citizens suffer from exposure to PFAS. When companies are held financially responsible, they will be less likely to inundate us with PFAS in products. Taxpayers are already stuck with the health risks; it is not fair for municipalities and taxpayers to also get stuck with the work and the cost.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Environmental Council of the States (ECOS) (Doc. #1752, SBC-044501)

Broader Management of PFAS

States appreciate this important step towards national consistency on PFAS, while acknowledging that PFAS releases impact a variety of environmental media overseen by more than one federal program. This action is just one of several needed to address the risks PFAS pose to public health, the environment, and local economies. While these comments primarily pertain to drinking water, ECOS Resolution 21-1: Advancing Collaboration and Coordination on Per- and Poly-fluoroalkyl Substances [Link: https://www.ecos.org/documents/resolution-21-1-advancing-collaboration-and-coordination-on-per-and-polyfluoroalkyl-substances/] recommends other needed federal actions as PFAS are used in a number of consumer and industrial products. In addition to managing PFAS in drinking water, successful management of these chemicals will also require a range of actions to reduce contamination closer to the source.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Las Cruces Utilities (LCU) (Doc. #1753, SBC-043926)

The rulemaking prompts discussion regarding better allocation of funding and resources directed toward the source of PFAS Contamination, rather than focusing on regulating water suppliers specifically, why isn't EPA extending its drinking water PFAS regulations to the sources of the PFAS contamination? The responsibility of mitigating PFAS contamination in drinking water should be shared with the industrial facilities that produce PFAS contamination in high concentrations. We would ask the EPA to broaden the scope of the proposed framework to include rules that would incorporate said producers of PFAS.

Sincerely,

Steven L Perez

Regulatory Compliance Analyst Las Cruces Utilities

cc: Adrienne L. Widmer, P.E., Utilities Director, awidmer@las-cruces.org

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Los Angeles County Sanitation Districts (Doc. #1756, SBC-044513)

May 30, 2023

Submitted Electronically: https://www.regulations.gov

The Honorable Michael S. Regan, Administrator

U.S. Environmental Protection Agency William Jefferson Clinton Building 1201 Pennsylvania Avenue, N.W. Washington, D.C. 20460

Dear Administrator Regan:

Proposed Rule to Establish National Primary Drinking Water Regulations for Per- and Polyfluoroalkyl Substances (Docket ID No. EPA-HQ-OW-2022-0114)

The Los Angeles County Sanitation Districts (Sanitation Districts) appreciate the opportunity to provide comments on the U.S. Environmental Protection Agency's (EPA) proposed rule to establish national primary drinking water regulations (NPDWRs) for six per- and polyfluoroalkyl substances (PFAS) ("proposed rule"). The EPA is proposing to set individual maximum contaminant levels (MCLs) for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) at 4.0 nanograms per liter (ng/L) and to set an MCL for any combination of perfluorobutane sulfonic acid (PFBS), perfluorohexane sulfonic acid (PFHxS), perfluorononanoic acid (PFNA), and hexafluoropropylene oxide dimer acid (HFPO-DA or "GenX") at 1.0 using a unitless hazard index.

By way of background, the Sanitation Districts provide wastewater and solid waste management services to approximately 5.5 million people in 78 cities and unincorporated areas of Los Angeles County. Our facilities include about 1,410 miles of sewer, 49 pumping plants, 11 wastewater treatment plants, two composting facilities, three material recovery/transfer facilities, two operating landfills, and four closed landfills in post-closure maintenance care. Our mission is to protect public health and the environment through innovative and cost-effective wastewater and solid waste management and, in doing so, convert waste into resources such as recycled water, energy, and recycled materials.

While we appreciate the EPA's efforts to protect public health from PFAS exposure in drinking water, we have significant concerns related to the implementation of the proposed rule and the impacts it may have on water recycling, wastewater treatment, and solid waste management facilities. As has been well documented, PFAS are widespread, including detectable concentrations in wastewater and solid waste (trash). As a result, wastewater and solid waste facilities are passive receivers of PFAS in items and wastes that have been used and disposed. The proposed MCLs could have significant consequences for wastewater and waste management facilities that simply receive PFAS yet are not designed to treat PFAS or prevent releases to the environment or transfer of PFAS to other media, such as through recycling of treated wastewater or commodities or management of treatment residuals. For example, treated wastewater discharged to local waterways may be hydrologically connected to local drinking water supplies and may operate under regulatory permits that require compliance with MCLs. We urge the EPA to analyze and consider these types of impacts on the proposed rule, as described below, and take those impacts into account before finalizing the MCLs.

• Product phaseouts and source elimination are urgently needed and should be EPA's top PFAS priority. EPA should prioritize aggressive action to cease the import, manufacture, and use of PFAS for non-essential purposes. The Sanitation Districts actively support state and federal efforts to reduce the non-essential uses of PFAS in consumer and industrial products. We implore the EPA and other federal regulatory agencies to control PFAS uses in commerce and prevent new and ongoing uses that are leading to the widespread detection of PFAS in the environment. Solid waste, wastewater, recycled water and drinking water facilities are passive receivers of PFAS; the EPA should focus on reducing the inputs to these facilities prior to implementing regulatory requirements that will likely necessitate widespread implementation of expensive and energy intensive end-of-pipe treatment technologies. While industrial pretreatment efforts can be successful for certain categories of industrial dischargers, wastewater monitoring data indicate that much of the PFOA and PFOS received at wastewater treatment plants is from residential and commercial sources rather than industrial waste. As a result, wastewater deriving exclusively from residential sources frequently contains PFOA in excess of the EPA's proposed MCL. This suggests that pretreatment strategies and other industrial waste controls will have little or no impact to reduce effluent concentrations and facilitate compliance with low-level MCLs, for at least some facilities. Furthermore, it is imperative that regulatory agencies control the manufacture and use of precursor compounds, including those that transform in the environment and at wastewater treatment and composting facilities, in order to prevent the continued generation and circulation of PFOA, PFOS, and other PFAS of concern. Ultimately, the investment of significant resources and effort in treating PFAS in drinking water and recycled water is rational only after the EPA and other regulatory agencies control non-essential commercial uses to ensure that these types of sources are eliminated as quickly as possible.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document. With respect to costs associated with "treated wastewater discharged to local waterways [that] may be hydrologically connected to local drinking water supplies and may operate under regulatory permits that require compliance with MCLs," the EPA notes that SDWA expressly states that the EPA shall consider "quantifiable and nonquantifiable costs. . . *excluding costs resulting from compliance with other proposed or promulgated regulations*." For further information on the EPA's cost analysis, please see section 13 of the EPA response in this *Response to Comments* document and section XII of the final rule preamble. Additionally, please see section 5.1.3 of the EPA response in this *Response to Comments* document for additional discussion on cost considerations in the final MCLs.

El Paso Water (Doc. #1757, SBC-044529)

Nevertheless, we are very concerned about mandates that would force the utility and our ratepayers to shoulder the burden of removing harmful contaminants from our water supplies when it should be the responsibility of the polluter.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

El Paso Water (Doc. #1757, SBC-044519)

Polluter Pays vs Community Pays

As currently proposed, the NPDWR revisions place a significant burden on the nation's PWS to identify, remove and dispose of PFAS contaminants. While PWSs did not introduce the contaminants into the water supply, the responsibility and costs will fall on them and, ultimately, their ratepayers for removal from the water supply. This goes against the "polluter pays" principle and instead reverts to the unfair practice of "community pays," burdening the already strained resources of the PWS.

The EPA should consider a revision that places the burden of remediation and removal of PFAS contaminants on the party responsible for their introduction to the water supply. The consumer should not be the one to carry this costly obligation.

Stopping PFAS at the Source

A critical step toward lowering PFAS exposure to the public is identifying the source of PFAS introduction to the environment. This would greatly reduce the burden on utilities to test, treat and remove PFAS elements by preventing the introduction of contaminants to the water supply in the first place.

The EPA should dedicate additional resources to finding the sources of PFAS and work with PWSs to address the source and hold the polluters responsible for the necessary remediation.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Arizona Water Company (Doc. #1758, SBC-044536)

Water utilities (and subsequently, their customers) are paying the price for mistakes made by the chemical industry. Though water utilities have played no role in the creation and release of PFAS chemicals, they will now bear the brunt of the costs required to remove these chemicals from drinking water. The chemical industry has known about the potential harmful effects of PFAS chemicals for decades and nevertheless continued to allow their products and operations to pollute drinking water sources. This pollution must now be treated by water utilities and paid for by water users. While the EPA is proposing to regulate certain PFAS under the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA") and other federal statutes, this proposal extends only to perfluorooctanoic acid ("PFOA") and perfluorooctansulfonic acid (PFOS). The EPA must regulate the waste of companies that produce all PFAS proposed for regulation in the drinking water rule, including PFOA, PFOS, GenX chemicals, and PFBS, to prevent it from entering drinking water sources in the first place.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045554)

While NPDWRs will require community investment to address PFAS, actions under the CWA, Resource Conservation and Recovery Act (RCRA), and the Toxic Substances Control Act (TSCA) will require manufacturers and users of PFAS to carry this burden.

To date, however, the agency's actions on polluters have consistently lagged behind drinking water action. EPA originally identified PFAS as a potential priority for drinking water as part of the Contaminant Candidate List 3 in 2009 (EPA, 2009). In 2012 EPA advanced the Third Unregulated Contaminant Monitoring Rule (UCMR 3) that required water systems to monitor for six PFAS in finished drinking water (EPA, 2012). With the proposal, EPA is proposing to set standards for PFAS in drinking water. At the same time, EPA has yet to advance regulations that require manufacturers and users to: (i) report about uses and releases of PFAS, (ii) control the release of PFAS to the environment, (iii) manage PFAS-containing wastes appropriately, and (iv) limit the use and manufacturing of PFAS (EPA, 2022a; EPA, 2022b; EPA, 2022c).

What is further concerning, is the lack of urgency in advancing these actions by the agency. The TSCA data reporting rule, which will require manufacturers and users to report on the production, use, and release of PFAS, was prompted by Congress as part of the National Defense Authorization Act for Fiscal Year 2020 (NDAA 2020) in December 2019 and proposed in June 2021 (Congress, 2019; EPA, 2022a). The rule has yet to be finalized, despite a statutory deadline of January 2023. Additionally, EPA initiated an effort under the CWA to consider ELGs for PFAS as part of the Preliminary Effluent Guidelines Program Plan 14 (EPA, 2019b). With this plan, EPA committed to performing a study of PFAS in industrial effluents for several industries. Program Plan 15 moved forward with a commitment to initiate two rulemakings for both manufacturers and metal finishers and to initiate additional studies on landfills and textile mills (EPA, 2021b). Neither of these rulemakings have been proposed. These actions, if advanced with the same sense of urgency as drinking water actions, would have provided invaluable information and protection for PFAS releases to the environment and the drinking water sources.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Riverside Public Utilities, Riverside, CA (Doc. #1762, SBC-044230)

[The following comments are submitted for consideration in the proposed EPA rulemaking:]

Focus on Eliminating PFAS Source and Hold Polluters Accountable

City staff strongly support the focus on eliminating PFAS in consumer products, source control, and destruction technology as well as holding PFAS polluters accountable as necessary measures to achieve progress in mitigating PFAS risks and exposure.

Conclusion

City staff strongly supports EPA's efforts to address PFAS contamination and protect public health through setting drinking water standards based on sound science and robust analysis; however, we have concerns with this proposal in its current form and ask the EPA to take our comments under consideration before finalizing the regulation.

Thank you for the opportunity to provide comments on this proposed rule. If you have any questions or would like any follow-up information, please contact General Manager Todd Corbin at TCorbin@riversideca.gov.

Sincerely,

Daniel E Garcia (May 30, 2023 16:54 PDT)

Daniel E. Garcia

Deputy General Manager, Riverside Public Utilities

CC:

The Honorable Radhika Fox, Assistant Administrator, Office of Water, U.S. Environmental Protection Agency

Alexis Lan, Ground Water and Drinking Water, Standards and Risk Management Division, U.S. Environmental Protection Agency

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Center for Environmental Health et al. (Doc. #1764, SBC-044240)

However, EPA was also petitioned in 2020 under Section 21 of TSCA by several nonprofit and community organizations representing residents in the Cape Fear region to require the chemical manufacturer, Chemours, to fund necessary testing for the health effects of 54 PFAS detected in the river, drinking water, and the blood of community members [FN2: Center for Environmental Health, et. al., PETITION TO REQUIRE HEALTH AND ENVIRONMENTAL TESTING UNDER THE TOXIC SUBSTANCES CONTROL ACT ON CERTAIN PFAS MANUFACTURED BY CHEMOURS IN FAYETTEVILLE, NORTH CAROLINA, (October 13, 2020), https://www.epa.gov/sites/default/files/202010/documents/chemours_pfas_testing_petition_final.pdf] - a request that was mostly denied. EPA denied the petitioners' request to order Chemours to conduct an epidemiological study of the exposed community, testing on mixtures of PFAS

found in drinking water and blood, and certain other priority health tests on the 54 PFAS. Instead, EPA claimed that its previously announced TSCA PFAS Testing Strategy constitutes "granting" the petition. We reiterate that granting our petition will supply Cape Fear communities with the studies they and their doctors need in order to make decisions based on the risks of PFAS and mixtures detected in the surrounding environment now. Furthermore, EPA recognized significant data gaps with respect to PFAS chemicals in its toxicity assessments conducted under the SDWA. As the human health risks summarized in the NPDWS proposal are calculated from publicly sourced epidemiological human and animal data, the full granting of our petition would provide additional data and further strengthen the accuracy of maximum contaminant levels (MCLs) for the six PFAS and mixtures covered by the proposal and the additional 48 PFAS and mixtures described in our petition.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Center for Environmental Health et al. (Doc. #1764, SBC-044244)

Administrator Regan acknowledged that Chemours' Fayetteville Works Plant on the banks of the Cape Fear River has "been polluting our air and our water with these 'forever' chemicals since the '70s." [FN4: Michael F. Regan, Prepared Remarks for PFAS Roadmap Announcement, (October 18, 2021), https://www.epa.gov/speeches/administrator-michael-regan-remarks-pfas-roadmap-announcement-prepared-delivery.] To ensure science-based decision making, and hold polluters accountable, EPA must require Chemours to fund testing of substances or mixtures it manufactures, uses, or disposes of at its Fayetteville facility that may present a risk to human health and the environment. Such studies would help inform future Hazard Quotients and MCLs for PFAS as a chemical class.

Trump EPA Administrator Wheeler initially denied the TSCA Section 21 petition. Communities across the State could not wait for the health studies they needed. Thus, we brought a lawsuit. Administrator Regan then dubiously "granted" our petition by arguing that its previously announced TSCA PFAS Testing Strategy, under which EPA planned to only require Chemours to fund tiered testing of 7 of the 54 PFAS but not require the requested epidemiological study nor testing on the PFAS mixtures in the drinking water and blood of Cape Fear residents, and moved to dismiss the lawsuit. The motion to dismiss was granted, and we are now appealing that decision.

A petition under Section 21 of TSCA is an example of the solutions EPA has made available to communities impacted by legacy contamination. Unfortunately, EPA developed its TSCA PFAS Testing Strategy without any input from the public, including from disproportionately impacted communities. Since purporting to "grant" the TSCA Section 21 petition from Cape Fear groups, EPA has not engaged with the petitioners and Cape Fear communities on what further health testing EPA should order Chemours to conduct under Section 4 of TSCA.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Bowling Green Municipal Utilities (Doc. #1767, SBC-043934)

Source Control rather Than after the Fact Treatment: The potential health risks from the chemicals would be more efficiently handled by reduction of production (source control) rather than post treatment. There is no need for billions of dollars of unnecessary infrastructure to treat for PFOS/PFOA if the materials are barred from production.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Portland Water Bureau (PWB) (Doc. #1769, SBC-044542)

In addition to our comments above, we also support comments submitted by the Association of Metropolitan Water Agencies (AMWA) and the American Water Works Association (AWWA). Of the comments submitted by AMWA and AWWA, we would like to emphasize our support for protecting source water from PFAS contamination. PWB joins AWWA and AMWA in urging EPA, Congress and other decision-makers to implement policies that keep harmful PFAS out of our drinking water supplies and our communities.

Thank you again for the opportunity to review and comment on these draft rules. If you have questions, you can reach me at Yone.Akagi@portlandoregon.gov or 503-823-1251.

Sincerely,

Yone Akagi, P.E.

Water Quality Manager

Portland Water Bureau

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Sierra Club of Hawai'i (Doc. #1771, SBC-044734)

Red Hill

These proposed limits will be an effective measure toward the restoration of the damage incurred by the Red Hill Bulk Fuel Storage Facility. The Red Hill facility, which sits just 100 feet above O‘ahu’s primary drinking water aquifer, uses PFAS-based Aqueous Film-Forming Foam (AFFF). In the last three years alone, at least 6,300 gallons of AFFF have been spilled at the facility, threatening the safety of the drinking water, environment and neighboring communities.

Despite ongoing and widespread percolation of PFAS into community drinking water, the tanks at Red Hill remain unserviced. The limits imposed by the EPA implement an effective incentive for the source of PFAS to receive the attention that has been long neglected. Corporations and governmental entities must not confuse public health with hindering economic development or defense. Rather, PFAS regulation and enforcement can rectify the unmitigated advantages long enjoyed by the Department of Defense at the expense of the public health of Oʻahu. PFAS regulations have the opportunity to prevent future harms by encouraging the Department of Defense to attend to the decaying fuel tanks and sources of cancer-causing chemicals upon the community of Oʻahu.

Thank you for the opportunity to comment on this important matter.

Sincerely,

Sierra Club of Hawaiʻi

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Sierra Club of Hawai'i (Doc. #1771, SBC-044732)

Setting these regulations will encourage manufacturers and PFAS-producing industries at large to be more responsible in their use of PFAS. Ideally, industries would invest in safer alternatives for PFAS chemicals if they receive pressure from those in the regulatory and water supply sectors.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Eastern Municipal Water District (EMWD) (Doc. #1780, SBC-043820)

May 30, 2023

The Honorable Michael Regan

Administrator

U.S. Environmental Protection Agency, EPA Docket Center

Office of Groundwater and Drinking Water Docket

Mail Code 2822IT

1200 Pennsylvania Avenue, N.W.

Washington, DC 20460

SUBJECT: PFAS National Primary Drinking Water Regulation Rulemaking; Docket ID No. EPA-HQ-OW-2022-0114

Dear Administrator Regan:

Eastern Municipal Water District (EMWD) appreciates the opportunity to comment on the Environmental Protection Agency's (EPA) proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation Rulemaking (the "Proposed Rule"). EMWD is the water, wastewater and recycled water service provider to nearly one million people living and working within a 558-square mile service area in western Riverside County and is California's sixth-largest retail water agency.

Our mission is to deliver value to our customers and the diverse communities we serve by providing safe, reliable, economical and environmentally sustainable water, wastewater and recycled water services. In light of this mission, EMWD embraces and shares EPA's fundamental goal to provide customers with a public water supply that is reliable, affordable and safe. For many reasons, maintaining affordability, while providing safe and reliable water service, is becoming increasingly challenging. It is through this lens of serving as an advocate for our ratepayers that we share the comments herein.

Considering EPA has not issued a primary drinking water standard in over 26 years, this proposal to adopt national primary drinking water standards for perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorohexane sulfonate (PFHxS), hexafluoropropylene oxide dimer acid (HFPO–DA), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS) is a historic milestone in the regulation of PFAS as emerging contaminants.

While we wholeheartedly support EPA's effort to control PFAS in drinking water, we are very concerned that the current approach places an undue burden on water ratepayers, instead of on the polluters, and on the source of the problem. PFAS are still extensively used in Teflon cookware, cosmetics, food packaging, waterproof and stain-resistant clothing and fabrics like curtains and carpets, and firefighting foams. While certain PFAS are no longer manufactured in the United States, these PFAS laden products are still regularly imported, utilized, and subsequently end up in our wastewater and water ways. Before saddling our customers with the cost of cleanup, a greater investment needs to be placed on eliminating PFAS from consumer products, thereby reducing and eliminating the flow of these chemicals into the environment. In addition, EMWD fully supports the "polluter pays" principle, and believes that the polluters, and the manufacturers of PFAS should be responsible for the cost of clean up, not our customers.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Northwest Biosolids Association et al. (Doc. #1783, SBC-043795)

[We recommend that drinking water regulations for PFAS include actions that support scientific understanding and exploring implementation solutions that would include actions such as:]

• Watershed modeling to determine sources of contamination

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Northwest Biosolids Association et al. (Doc. #1783, SBC-043803)

Implement a Wholistic Approach to Regulatory Actions. Given the pervasiveness of PFAS compounds in the environment and everyday use and consumable items, if an outright ban is not to be implemented, the equitable approach to addressing these compounds is to limit them holistically across all sectors regulating human and environmental health. This includes not only the USEPA, but the Food and Drug Administration, the Consumer Product Safety Commission, and any other federal agency that governs public, commercial and industrial business. This should include not only limiting the quantity of use but validating which products and/or industries it is absolutely necessary to be used in for the purposes safety and public protection, versus convenience and preference.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Northwest Biosolids Association et al. (Doc. #1783, SBC-043792)

Source Control. Without tough source control measures, the responsibility to remove these chemicals to protect human health and the environment, will remain on community drinking water systems and other publicly funded infrastructure providing wastewater and solid waste services. These facilities are not producers of PFAS but rather passive receivers as they flow from consumer products or firefighting and military facilities. Human health exposure to PFAS is greatest in consumer products, making downstream removal efforts superfluous if inadequate efforts are taken to remove them from daily life. No technologies for PFAS removal and disposal from solid and liquid wastes has been prove effective.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Northwest Biosolids Association et al. (Doc. #1783, SBC-043798)

Based on the information available, it will take a combination of source control and treatment technologies to achieve meaningful PFAS reductions in drinking water and the environment. This technical information is necessary to build trust and collaboration between and among public and private agencies, manufacturers, and the public to effectively reduce and phase out PFAS.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

PFAS Project Lab (Doc. #1786, SBC-044719)

Importance of current and future rulemaking

EPA can use the new MCLs as a prompt to pursue other important work in its domain, including reducing unnecessary uses of PFAS, preventing the entry of dangerous new PFAS chemicals into commerce under the Toxic Substances Control Act; minimizing PFAS emissions under the Clean Air Act; cleaning up PFAS contaminated sites under the Comprehensive Environmental Response, Compensation, and Liability Act; and regulating PFAS disposal under the Resource Conservation and Recovery Act.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Fairfax Water (Doc. #1789, SBC-045312)

2. EPA should re-prioritize its efforts to remove sources of PFAS from the environment. Prioritizing regulation of drinking water places the burden of PFAS removal on the public instead of the polluter. Absent a comprehensive, national PFAS regulatory framework, water utilities are being assigned, at public expense, a Sisyphean task at best inadequate to meet the overall environmental goal, and at worst likely to distract from it.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Metropolitan Washington Council of Governments (COG) (Doc. #1791, SBC-043771)

Regarding the proposed NPDWR, our primary recommendation is for EPA to work with other federal agencies to develop and implement a regulatory framework that targets the removal of PFAS sources to the maximum extent practicable. Eliminating pollution at the source is the best way to protect local drinking water supplies, which are passive receivers of PFAS compounds. Targeting and eliminating sources of PFAS compounds would be cost effective and would place the cost for remediation on the polluter rather than the public.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Ohio Environmental Council (Doc. #1794, SBC-045320)

While regulation under the Safe Drinking Water Act is essential to protect human health and the environment, we must also regulate PFAS in surface water, eliminating present and future point sources.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Ohio Environmental Council (Doc. #1794, SBC-045328)

In addition to swiftly finalizing drinking water standards for PFAS, we urge EPA to expedite efforts to prevent these forever chemicals from polluting the environment in the first place by: controlling industrial discharges of PFAS into water, and addressing PFAS in state- and federal-issued permits consistent with EPA's 2022 guidance under the Clean Water Act; reducing unnecessary uses of PFAS, and preventing the entry of dangerous new PFAS chemicals into commerce under the Toxic Substances Control Act; minimizing PFAS emissions under the Clean Air Act; cleaning up PFAS contaminated sites under the Comprehensive Environmental Response, Compensation, and Liability Act; and regulating PFAS disposal under the Resource Conservation and Recovery Act.

The ubiquitous nature of PFAS contamination underscores the need to curb all pathways of PFAS exposure and sources of pollution. EPA's 2021 Strategic PFAS Roadmap outlined a broad suite of actions to address the PFAS crisis, and following through on Roadmap commitments is of the utmost importance.

Thank you for taking these comments into consideration as you finalize the Proposed PFAS National Primary Drinking Water Regulation.

Melanie Houston,

Managing Director of Water Policy

The Ohio Environmental Council

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Portland Advocates for Leadfree Drinking Water (Doc. #1796, SBC-044700)

From: L J <lorjmcfarlane@gmail.com>

Sent: Monday, May 22, 2023 8:58 PM

To: OW-Docket

Subject: EPA-HQ-OW-2022-0260

May 22, 2023

Radhika Fox, Assistant Administrator for Water

U.S. Environmental Protection Agency 1200 Constitution Ave., NW Washington, DC 20460

Re: Comments on EPA's Proposed "National Primary Drinking Water Regulations: Consumer Confidence Report Rule Revisions" [EPA–HQ–OW–2022–0260]

Thank you for this opportunity to comment on revisions to Annual Water Quality Reports (WQR), aka Consumer Confidence Reports (CCR).

Portland Water Bureau has exceeded the water lead action level (ALE) numerous times since the LCR was promulgated; (1997 compliance date) in November 2021, 2017, 2016, 2014, 2013, 2006, 2002, 2001 (2X), 2000, 1999, and 1998.

Since the City of Portland Oregon consistently includes information not mandated by the federal LCR - free lead in water test kits - in their Annual WQR's, the utility (Portland Water Bureau) should post information about their "free filters program", mentioned only once in this news article.

Further, we request this information be included in subsequent Annual WQR's. Until Portland Water Bureau significantly reduces lead to levels consistent with its PNW region neighbors, this is the responsible public health action.

Families cannot know about this free public "filters program" unless they have detailed, concise, and clear public information available to them.

Currently, annual WQR's for Portland provide information on "Free lead in water testing" (typically 6 times throughout the Report). Following another lead ALE in October 2021, Portland launched a new "free filters program" but failed to mention it in their 2022 WQR. Moreover, a "free filters program" is not publicized anywhere on the utility's web pages, social media accounts, FAQ's or Water Quality information phone line.

The rationale for this (below) given by the Portland Water Bureau Public Information Officer is problematic at best, and health-harmful at worst. There should be full transparency on prevention measures available to the public (complementary City filters) for the duration of Portland Water Bureau's elevated and excessive lead levels.

"There are not [sic] public meetings about the filter program because we are sending them directly to eligible customers; there is no burden on our customers to contact us." -- Portland Water Bureau Director via PIO Jaymee Cuti, February 2022

Thank you for considering comments to help improve Annual WQR's,

Portland Advocates for Leadfree Drinking Water, on behalf of "nearly ~1 million customers" (PWB)

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Peggy Kurtz (Doc. #1799, SBC-046044)

I also urge the EPA to regulate emissions and discharges into our waterways.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Massachusetts Municipal Association (MMA) (Doc. #1800, SBC-043767)

Unless manufacturer liability and responsibility are introduced into this framework, these costs will continue to be absorbed by those who have no fault in the contamination of local water supplies. Water systems are passive receivers of PFAS, and do not manufacture or intentionally add these chemicals to water sources and supplies. Without the institution of polluter responsibility or a more comprehensive approach to fund PFAS treatment, municipal ratepayers will be forced to pick up the slack, stressing the pocketbooks of families and individuals.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Millie Garcia-Serrano (Doc. #1803, SBC-044293)

[Overall, as movement is made toward better regulation and oversight of these contaminants, ASTSWMO's membership recognizes a corresponding need for research, communication, and improved understanding within the following areas:]

• remediation technologies to remove PFAS from all environmental media;

• destruction and disposal technologies for PFAS-containing materials and waste streams;

[Overall, as movement is made toward better regulation and oversight of these contaminants, ASTSWMO's membership recognizes a corresponding need for research, communication, and improved understanding within the following areas:]

• solidification and stabilization technologies to minimize PFAS in landfill leachate and methods to assess treatment effectiveness to aid in addressing capacity limitations; and

[Overall, as movement is made toward better regulation and oversight of these contaminants, ASTSWMO's membership recognizes a corresponding need for research, communication, and improved understanding within the following areas:]

• acceptable levels of PFAS in compost, biosolids, wastewater sludge and industrial byproducts that are suitable for land application.

Advances in the key research areas listed above, along with establishing prevention programs to support the reduction and removal of PFAS from use, need to take place concurrently with this proposed rulemaking. More specifically, expanded coordination across all federal Agencies needs to be prioritized to reduce, and conceptually eliminate, PFAS present in consumer products and food supplies, which ultimately get into the water supplies and waste streams.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Millie Garcia-Serrano (Doc. #1803, SBC-044291)

Overall, as movement is made toward better regulation and oversight of these contaminants, ASTSWMO's membership recognizes a corresponding need for research, communication, and improved understanding within the following areas:]

• drinking water, soil, and wastewater treatment technologies;

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

National Ground Water Association (NGWA) (Doc. #1804, SBC-045475)

Basis for the Interest of the National Ground Water Association (NGWA) in Setting MCLs for PFAS

NGWA, the largest trade association and professional society of groundwater professionals in the world, represents over 10,000 groundwater professionals within the United States and internationally. NGWA represents four key sectors: scientists and engineers in public and private sectors; water-well contractors who develop and maintain water-well infrastructure; the manufacturers who produce; and the suppliers who deliver the equipment needed to make groundwater development possible. NGWA's mission is to advocate for and support the responsible development, management, and use of groundwater.

Over 34 million people in the United States rely on private wells and over 91 million are served by groundwater from public community water systems.

NGWA views groundwater and the subsurface as natural infrastructure that should be sustainably managed for current and future use. The subsurface environment should be considered from an integrated resource perspective. The natural infrastructure of the subsurface environment with proper management can provide fresh groundwater for drinking, industrial and manufacturing applications, food production, and ecosystem support.

A concise summary of the position of the National Ground Water Association on groundwater protection related to this proposed rule is:

• Control of potential and active sources of contamination should be a national objective, reducing the need for remediation of groundwater.

• Groundwater quality should be protected for existing or potential beneficial uses.

• NGWA published Groundwater and PFAS: State of Knowledge and Practice, a guidance document on per- and polyfluoroalkyl substances (PFAS) in 2017

(https://my.ngwa.org/NC__Product?id=a183800000kbKF9AAM) as a comprehensive report to identify the known science and knowledge related to PFAS, summarizing the fate, transport, remediation, and treatment of PFAS, as well as current technologies, methods, and field procedures.

• NGWA has additionally updated materials regarding PFAS on its resource webpage "Groundwater and PFAS" at https://www.ngwa.org/what-is-groundwater/groundwaterissues/Groundwater-and-PFAS.

NGWA appreciates the opportunity to comment on the proposed rule.

For further follow up, please contact:

Charles Job

Regulatory Affairs Manager National

Ground Water Association

cjob@ngwa.org

202-660-0060

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Florida Rural Water Association (FRWA) (Doc. #1806, SBC-044698)

Some may be fortunate in the costs being covered by the industrial site that was responsible for contamination. That is not the case for most of the public water systems that have found PFAS levels exceeding the proposed MCL. Site investigations have failed to determine an external potentially responsible party. The public water systems are being held responsible for the investigation and clean-up costs. That, in turn, has led to expensive and time- consuming battles with insurance companies often leading to passing all cost onto its customers.

The chemical manufacturers that created PFAS compounds should be responsible for their remediation in the environment, including our drinking water. Establishing MCLs without association liability protections places the burden on the public water systems. They are not the source of this contamination but have been blamed for aquifers contaminated by firefighting training exercises, and manufacturing of "Forever Chemicals."

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Environmental Working Group et al. (Doc. #1810, SBC-044692)

In addition to swiftly finalizing drinking water standards for PFAS, we urge EPA to expedite efforts to prevent these forever chemicals from polluting the environment in the first place by: controlling industrial discharges of PFAS into water, and addressing PFAS in state- and federal-issued permits consistent with EPA's 2022 guidance under the Clean Water Act; reducing unnecessary uses of PFAS, and preventing the entry of dangerous new PFAS chemicals into commerce under the Toxic Substances Control Act; minimizing PFAS emissions under the Clean Air Act; cleaning up PFAS contaminated sites under the Comprehensive Environmental Response, Compensation, and Liability Act; and regulating PFAS disposal under the Resource Conservation and Recovery Act.

The ubiquitous nature of PFAS contamination underscores the need to curb all pathways of PFAS exposure and sources of pollution. EPA's 2021 Strategic PFAS Roadmap outlined a broad suite of actions to address the PFAS crisis, and following through on Roadmap commitments is of the utmost importance.

Thank you for your consideration. Sincerely,

7 Directions of Service

Active San Gabriel Valley

Air Alliance Houston

Alabama Rivers Alliance

Alaska Community Action on Toxics

Alaska Environment

Alliance of Nurses for Healthy Environments

Anacostia Riverkeeper

Arkansas Ozarks Waterkeeper

Ashgrove Farm

Assateague Coastal Trust

Ban SUP (Single Use Plastics)

Bayou City Waterkeeper

Belfast Adventure Education

Black Warrior Riverkeeper

Black-Sampit Riverkeeper

Breast Cancer Prevention Partners

Buxmont Coalition for Safer Water

Cahaba River Society

Cahaba Riverkeeper

California Environmental Voters

California Public Interest Research Group (CALPIRG)

Cape Fear River Watch

Catawba Riverkeeper Foundation

Cease Fire Campaign

Center for Public Environmental Oversight

Chautauqua-Conewango Consortium

Chesapeake Bay Foundation

Children's Environmental Health Network

Citizen of the USA

Clean Cape Fear

Clean Production Action

Clean Water Action/Clean Water Fund

Climate Action Alliance of the Valley

Community Action Works Community

Water Center Congaree Riverkeeper

Connecticut Nurses Association

Connecticut River Conservancy

Conservation Alabama

Conservation Law Foundation

Conservation Voters of PA

Consumer Reports

Cook Inletkeeper

CT League of Conservation Voters

CT Nurse Association

Defend Our Health

Delaware Riverkeeper Network

Duxbury Safe Water

Earthjustice

Ecology Center

Endangered Species Coalition

Energy Justice Network

Environment America Research & Policy Center

Environment Arizona

Environment California

Environment Colorado

Environment Connecticut

Environment Florida

Environment Georgia

Environment Illinois

Environment Maine

Environment Maryland

Environment Massachusetts

Environment Michigan

Environment Minnesota

Environment Montana

Environment Nevada

Environment New Hampshire

Environment New Jersey

Environment New Mexico

Environment New York

Environment North Carolina

Environment Ohio

Environment Oregon

Environment Texas

Environment Virginia

Environment Washington

Environmental Defense Fund

Environmental Justice Task Force -Tucson

Environmental Protection Network

Environmental Stewardship

Environmental Working Group

Fight for Zero

Food & Water Watch

For Love of Water (FLOW)

Freshwater Future

Friends of Casco Bay

Friends of the Rivers of Virginia (FORVA)

George Washington University

Georgia Conservation Voters

GO FISH Coalition

Grand Traverse Baykeeper

Greater Edwards Aquifer Alliance

Green Newton

Green Science Policy Institute

Greenfire Law, PC

GreenLatinos

Greenpeace USA

Harpeth Conservancy

Heal the Bay

Hispanic Access Foundation

Houston Wilderness

JF Environmental Trust Foundation

Kirby Consulting

Lake Coeur d'Alene Waterkeeper

Lake Erie Waterkeeper

League of Conservation Voters

Louisiana Bayoukeeper

Lowcountry Environmental Action

Lower Susquehanna Riverkeeper Association

Lynnhaven River NOW

Maine Conservation Voters

Maine Organic Farmers & Gardeners Assoc.

Maryland Children's Environmental Health Coalition [MD CEHC]

Maryland Conservation Council

Maryland Pesticide Education Network

Maryland PIRG

Maryland Votes for Animals

Massachusetts Breast Cancer Coalition

MASSPIRG

Matanzas Riverkeeper

McDaniel Honey Farm

Merrimack Citizens for Clean Water

Mi Familia Vota

Michigan League of Conservation Voters

Mill River Wetland Committee (Fairfield, CT)

Milwaukee Riverkeeper

Milwaukee Water Commons

Missouri Confluence Waterkeeper

Montgomery Countryside Alliance

MUSC Health

My Neighbor's Voice

NCPIRG

Natural Resources Defense Council

North Carolina Coastal Federation

North Carolina League of Conservation Voters

Norwalk River Watershed Association

Norwalk Zero Waste Coalition

Ohio Environmental Council

Ohio River Foundation

Orange County Coastkeeper

Park Watershed

Peconic Baykeeper

PennEnvironment

Perfect Earth Project

PfoaProject NY

Planet Citizen

Portland Protectors

Progressives for Democracy in America

Rachel Carson Council

Raritan Riverkeeper

River Network

Rivers Alliance of Connecticut

Russian Riverkeeper

Safer States

San Diego Coastkeeper

San Francisco Baykeeper

Save Our Water (SOH2O)

Save the Sound, Inc.

SC Idle No More, SC Indian Affairs Commission

SC Native Plant Society

Seneca Lake Guardian

ShoreRivers

Slingshot

Snake River Waterkeeper

Social Science Environmental Health Research Institute

South Carolina Indian Affairs Commission, SC Idle No More

Southern Environmental Law Center

Spring Creek Coalition

Suncoast Waterkeeper

Sustainable Fairfield Task Force

Testing for Pease

Texas Campaign for the Environment

The Growing Solutions Fund

The Water Collaborative of Greater New Orleans

Toxic Free NC

Toxic-Free Future

Tualatin Riverkeepers

Tuolumne River Trust

UNC

University of South Carolina

Upper Allegheny Waterkeeper

Vermont Conservation Voters

Vermont Natural Resources Council

Villanova University, College of Nursing

Virginia Conservation Network

Waterkeeper Alliance

Waterkeepers Chesapeake

We the People of Detroit

West Virginia Rivers Coalition

Wild Virginia

Windsor Climate Action

Wisconsin Environment

Wisconsin Environmental Health Network

Yellow Dog Watershed Preserve

cc: Assistant Administrator Radhika Fox

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

National Wildlife Federation Action Fund (Doc. #1811, SBC-045345)

EPA's proposal would significantly reduce exposure to PFAS in our drinking water for millions of people by setting strong, science-based drinking water standards for six types of PFAS. While this proposal is an important first step towards addressing PFAS exposure, it is critical that EPA also expedite efforts to prevent these chemicals from entering our waters and environment in the first place, before it even reaches our taps. This includes regulating industrial discharges of PFAS into surface waters, addressing PFAS in permits consistent with EPA's 2022 Clean Water Act guidance, cleaning up PFAS contaminated sites under the Comprehensive Environmental Response, Compensation, and Liability Act, and preventing current and future use of PFAS chemicals.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Clean Water Action (Doc. #1813, SBC-045498)

All parts of EPA and the federal government need to take equally bold action to stop PFAS pollution, hold polluters accountable, and curtail uses of PFAS chemicals. Placing the burden on our communities, our drinking water, and our health is not the right way to solve the PFAS challenge."

Thank you for your consideration.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

The District of Columbia Water and Sewer Authority (Doc. #1829, SBC-045763)

DC Water appreciates the opportunity to comment on EPA's proposed PFAS National Primary Drinking Water Regulations. Please let us know if we can provide any additional information or share our utility expertise to inform improvements to the proposed rule with the goal of ensuring its equitable implementation. We are committed to providing safe drinking water to our customers while ensuring its affordability. We strongly believe that federal regulation on manufacture and distribution of PFAS is required in advance of, or at the least in parallel with drinking water regulations, and the cost of treatment for chemicals introduced to drinking water supplies by industry should be borne by that industry and not already overburdened ratepayers. The attached document further summarizes our concerns regarded the proposed PFAS rule and its impacts to our customers.

May 30, 2023

The Honorable Michael Regan Administrator

United States Environmental Protection Agency 1200 Pennsylvania Avenue, N.W.

Mail Code: 1309

Washington, DC 20004

SUBMITTED ELECTRONICALLY

RE: Per- and polyfluoroalkyl substances (PFAS): Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) National Primary Drinking Water Regulation Rulemaking, Docket No. EPA-HQ-OW-2022-0114

Dear Administrator Regan:

The District of Columbia Water and Sewer Authority (DC Water) strives to be a world-class water utility. Our mission is to exceed expectations by providing high quality water services to our customers in a safe, environmentally friendly, and efficient manner. We support the U.S. Environmental Protection Agency's (EPA) efforts to reduce per- and polyfluoroalkyl substances (PFAS) in drinking water.

DC Water appreciates the opportunity to comment on EPA's "Proposed Per- and polyfluoroalkyl substances (PFAS): Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) National Primary Drinking Water Regulation Rulemaking" (the Proposal). As explained below, DC Water is concerned about several flaws in the Proposal and asks that EPA reconsider several aspects of it. We understand that many of our sister utilities share these concerns.

We offer a unique perspective on the Proposal. DC Water distributes drinking water to more than 700,000 residents and 21.3 million annual visitors to the District of Columbia, the Pentagon and Ronald Regan Washington National Airport in Virginia, and federal and other customers in Maryland. Drinking water for the District of Columbia comes from the Potomac River. The U.S. Army Corps of Engineers Washington Aqueduct (the Aqueduct or WAD), a federal drinking water treatment plant, collects water from the Potomac River at Great Falls and Little Falls. The Aqueduct treats this water to meet federal drinking water quality requirements to ensure it is safe to drink. DC Water purchases the treated drinking water from the Washington Aqueduct and distributes it to our customers.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

The District of Columbia Water and Sewer Authority (Doc. #1829, SBC-045773)

Summary

DC Water is committed to providing safe drinking water to our customers while ensuring its affordability. We strongly believe that federal regulation on manufacture and distribution on PFAS is required in parallel with drinking water regulations, and the cost of treatment for industry introduced chemicals should be borne by the PFAS industry and not by already leveraged ratepayers.

• EPA should prioritize regulation of PFAS at the source to prevent it from being discharged to the environment and into our public water supplies. The cost burden should be placed on the generators of PFAS, not our water customers. We ask EPA to prioritize a comprehensive regulatory scheme to prevent releases of PFAS to and remove PFAS from the environment.

• Elimination of PFAS entering the environment will significantly attenuate concentration in drinking water sources. Attenuation will result in elimination or significant reduction in scale of treatment, thereby relieving already leveraged ratepayers from having to pay for stranded assets.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

The District of Columbia Water and Sewer Authority (Doc. #1829, SBC-045765)

EPA Should Prioritize Eliminating Sources of PFAS Contamination

Neither DC Water nor our wholesale provider, Washington Aqueduct, produce PFAS. It is not a chemical that is added to the water during treatment, nor is it a byproduct of the treatment process. Instead, PFAS is in our water supply as a result of discharges by manufacturers of PFAS, those who use PFAS in the manufacture of their products, users of products containing PFAS, and other sources of PFAS in the environment unrelated to providing drinking water.

We have known of the potential health concerns associated with certain PFAS for decades, and while some substitution has been made by the industrial community, PFAS compounds continue to be manufactured and used in a wide variety of industrial and consumer products and processes. Rather than regulate PFAS in the environment by regulating drinking water utilities, EPA should prioritize regulation of PFAS at the source to prevent it from being discharged to the environment. As a result of the proposed· regulation, our customers, not the sources of PFAS, will be responsible for bearing 75% of the cost of PFAS removal, and 100% of the monitoring, reporting and risk communication costs. We ask EPA to prioritize a comprehensive regulatory scheme to prevent releases of PFAS to and remove PFAS from the environment, and not penalize passive receivers of PFAS.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Pennsylvania Municipal Authorities Association (Doc. #1832, SBC-045786)

[PMAA's specific comments on the Proposal are as follows:]

10. It is PMAA's position that those entities who manufacture and profit (or have profited) from, among other things, the use of PFAS chemicals should bear the entire burden for any needed treatment and related costs to address PFAS contamination impacting health and the environment. As such, PMAA's position is that the "Polluter Pays" principle should guide all costs related to removing PFAS from the environment, which position is simply restating EPA's own position in its PFAS Strategic Roadmap.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Pennsylvania Municipal Authorities Association (Doc. #1832, SBC-045782)

[PMAA's specific comments on the Proposal are as follows:]

6. Drinking water facilities, many of which are PMAA member authorities, will bear the regulatory and economic burden of complying with the Proposal, notwithstanding the critical fact that these facilities are merely passive receivers of PFAS chemicals, and are only subject to the Proposal due to the actions of others. These facilities neither manufacture nor produce PFAS, yet will be required to treat the raw influent at their plants containing these emerging contaminants, consistent with the requirements of the Safe Drinking Water Act. As EPA is aware, most, if not all, of these facilities were not designed to treat emerging contaminants such as PFAS. Therefore, PMAA strongly urges that EPA undertake additional initiatives that address, at a minimum, source control requirements related to PFAS in order to eliminate or substantially reduce, among other things, the costs of PFAS treatment, management and monitoring that will be directly borne by PMAA member authorities and their ratepayers under the requirements of a promulgated EPA PFAS regulation.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Pennsylvania Municipal Authorities Association (Doc. #1832, SBC-045787)

[PMAA's specific comments on the Proposal are as follows:]

11. EPA needs to more fully address the impact of the Proposal on the use and management of biosolids. PMAA understands that EPA is undertaking certain studies related to a risk assessment for PFAS found in biosolids, but that such studies may not be completed until December, 2024. It is critical for EPA to address how and the extent to which the Proposal may impact biosolids management and the use of 40 C.F.R Part 503 with respect to the regulation of biosolids.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Corix Infrastructure Inc. (Doc. #1834, SBC-045363)

2. EPA needs to require point of use restrictions on the manufacturers to address and remediate PFAS contamination at its source and reduce downstream removal of contaminates by entities with no responsibility for the creation of the problem.

Corix urges EPA to take greater actions to reduce the contamination of water supplies by the manufacturers of PFAS substances before such chemicals contaminate water supplies. EPA needs to commit to stronger actions against the sources of the contamination rather than requiring the water industry to remove the harmful chemicals once they are in the environment and the water supplies. As passive receivers of these contaminants, the drinking water industry should not be disproportionately targeted by this regulatory action to reduce PFAS exposure.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

New England Water Works Association (Doc. #1836, SBC-045376)

We call on Congress and the Biden Administration to fully fund the treatment and ongoing operations and maintenance costs necessary to remediate PFAS in our nation's drinking water and seek reimbursement from the polluters who have caused this problem.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

New England Water Works Association (Doc. #1836, SBC-045395)

Source Investigations:

It is important when there are detections in drinking water that regulatory agencies follow up to determine the source of the contamination so that the costs will not fall on our ratepayers to fund remediation. In Massachusetts, for example, MassDEP stated that when a PWS detected PFAS in the drinking water above the MMCL, MassDEP would initiate an investigation into the potential sources of contamination and the identification of potentially responsible parties. There have been so many detections in Massachusetts that MassDEP has not had the resources in their Bureau of Waste-site Clean up to perform timely follow- up investigations. This has left PWS and their ratepayers funding remediation in the absence of a responsible party. Proper resources must be allocated to follow up on identifying the source of contamination and holding those parties responsible for paying for treatment.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

New England Water Works Association (Doc. #1836, SBC-045381)

Similarly, the Food and Drug Administration should be regulating PFAS in bottled water. If PFAS are as dangerous as EPA is suggesting, we recommend that EPA work with appropriate state and federal regulatory agencies to prevent consumer exposure to PFAS from bottled water and private wells. Consumers should be informed about the sources of PFAS in the environment and how they impact drinking water supplies of all types.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Metropolitan Washington Council of Governments (Doc. #1843, SBC-044753)

Regarding the proposed NPDWR, our primary recommendation is for EPA to work with other federal agencies to develop and implement a regulatory framework that targets the removal of PFAS sources to the maximum extent practicable. Eliminating pollution at the source is the best way to protect local drinking water supplies, which are passive receivers of PFAS compounds.

Targeting and eliminating sources of PFAS compounds would be cost effective and would place the cost for remediation on the polluter rather than the public.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Amigos Bravos (Doc. #1844, SBC-045401)

EPA should finalize the rule and move to take additional action on PFAS including taking steps to make sure PFAS doesn't enter our environment in the first place by cleaning up PFAS contaminated sites, ensuring that federal and state issued Clean Water Act permits can adequately regulate PFAS discharges, and regulating PFAS under the Resource Conservation and Recovery Act.

Sincerely,

Elena Fernández MSL, MELP Projects Specialist

575-758-3874

efernandez@amigosbravos.org www.amigosbravos.org

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Darlene Price (Doc. #1874, SBC-047459)

I am a retired Special Agent now Criminal Defense Investigator/Expert Witness, with over 35 years of experience in criminal investigations. As one of my part time jobs, I am an investigative journalist here in my home state of Kentucky. I have been working on a story that to call shocking, would be an understatement. We have completed a two part documentary that you can now view on YouTube entitled, "Lake Cumber, what really lies beneath" Parts 1 and 2. Lake Cumberland in Pulaski County, Kentucky, is located in the beautiful Daniel Boone National Forest. It is a very active tourism location for swimming, boating, fishing, hiking, camping and water-skiing. It is also the primary source of drinking water for much of the people and wildlife in Kentucky and throughout Tennessee. Pitman Creek in Pulaski

County, Kentucky flows directly into Lake Cumberland. Lake Cumberland flows into the Cumberland River, a primary water source that flows down stream to Nashville, Tennessee. As a result of numerous records that I have received from the State EPA and the State Water district via open records requests, I have serious concerns regarding the water contamination in Lake Cumberland and the Cumberland River. My primary concern is that we have numerous documents that demonstrate that the City of Somerset has a highly defective wastewater treatment facility from at least 2016 through 2023. Despite this facility being repeatedly threatened by the State EPA, they have since 2019 added to this facility even more serious contaminates from landfill runoff called leachate. My investigation clearly demonstrates that this

was done in order to secure at least $300,000.00 a year by the Mayor of Somerset and the Somerset City Counsel. My research demonstrates that leechate from demolition landfills hold some of the most dangerous contaminates. Some of these landfills will have leechate that most certainly contains asbestos and "Perfluorooctanoic acid" also known as "C8" and "Forever Chemicals" ; as well as C6 hexavalent chromium. Normal purification processes will not remove these types of contaminates which are known to be highly carcinogenic and lethal to wildlife.The documents that I have received from the State Water District, the State EPA, the Regional Health Department and the City of Somerset tell a most gruesome story. These documents clearly demonstrate that Sinking Creek and Pitman Creek, which empty out into Lake Cumberland, have numerous, repeated serious "Out of Compliance Violations" for: E-Coli, Chronic Ceriodaphnia Dubia Pkv; CBOD; Suspended Solids, Total Ammonia Nitrogen (as N), and MOST CONCERNING is the June 8, 2018, letter referring to "hexavalent chromium" limits – also known as C-6. These many violations run at least from 2016 to 2022. These violations were serious enough that the State Water Department repeatedly threatened that, "Violations of the above cited statutes(s) and/or regulation(s) are subject to a civil penalty per day per violation. Violations carry civil penalties of up to $25,000 per day per violation depending on the statutes/regulations violated." Yet, in the State EPA, the State Water District and Somerset's answers and/or documents provided, there were zero fines or penalties levied on either the City of Somerset or the wastewater treatment plant; even though numerous violations have been sited over at least a period of six (6) years. At this point, The City of Somerset Wastewater Treatment Plant alone has introduced at least 50 million gallons of Industrial Waste Leachate from four (4) different industrial waste landfills, not to mention the thousands of gallons of industrial waste from the local businesses that send their industrial waste to this defective plant. These businesses include medical facilities that are permitted for some of the worst contaminates imaginable, including C-6 & C-8. These landfills and businesses are permitted for "Industrial Waste" while the City of Somerset's wastewater treatment plant has only a general permit that is over twelve (12) years old. This is just a sampling of this heart-wrenching investigation thus far. What I'm hoping for is that these EPA regulations and regulations like it, will indeed pass and not only protect our drinking water, but our entire echo-system surrounding our beautiful Daniel Boone National Forest. Any assistance that I can give to you on this very important issue, I will be happy to provide.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Juergen Froemming (Doc. #1881, SBC-046558)

Dear Administrator Regan,

Regulations or a lack thereof in the US are designed to help the industry, NOT the people. We have already a fentanyl epidemic caused by the Pharma industry. As a resident of the US and citizen of Germany i am utterly disgusted about the sheer negligence that leaves Americans to their fate that is mainly orchestrated by corrupt CEOs and Politicians.

I hope my plea does not fall on deaf ears.

My heart goes out to all Americans who suffer in this, not so democratic, society, knowing it could be done differently to promote health and prosperity rather than sickness and poverty.

Quality of water and food/production etc. Is essential and there shouldn't even be a discussion about it.

The letter i send you today reflects my assessment being a resident of the US sine nearly a decade.

My goal is not to point fingers or disparage anyone, i merely would like to see that especially politicians live up to what they claim to be and do:

Serving the American people, after all THEY decide who makes the race at the ballot box.

I hope i wasn't too blunt but i feel there is just too much sugarcoating going on.

Thank you very much for your time.

Have a wonderful day!

Sincerely,

Juergen Froemming

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #1905, SBC-047443)

I leave you with the following thought experiments:

-What good are "healthy" tomatoes and grapes if they come in wrapped in PFAs/PFO paper that gets put into landfills that will make our drinking water unsafe (see stores that are already reducing the use of plastics with reusable bakery bags)

-What good is cooking spinach on a teflon pan? Why not ban those and ensure every American knows they should use stainless steel?

- What good is looking great when you will end up with cancer due to the use of makeup? That makeup also gets washed into the wastewater system, likely to end up in our water supply.

I have personally had to have my gallbladder removed (not overweight, I am a health nut and coach, marathon runner, I drink water like crazy). I've been running for 32 years. This should not have happened to me. No one else in my family experienced this. Will future studies show liver, gallbladder, stomach issues related to PFAs? I honestly hope we never get that far because they are banned. I wouldn't wish what I have been through on anyone. It is seriously hard for me to encourage people as a coach to drink more water when I know how contaminated it is. People

are already severely dehydrated, let's not make it worse by having water be so contaminated that people fear it. We have enough health crises in this country without this one problem. Please, please, do what is right and ban the use of this substance and make sure that water utilities do what they can to eliminate it from our drinking water. We can put people in space and build rocket ships, we can do this!

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Araceli Medialdea (Doc. #1914, SBC-046483)

Dear Michael Regan,

Water is something we all need to survive. The world is in a really bad place and last thing we need is our higher ups poisoning us. Why? You know you're doing it.. you know things could be better. You need people to keep the world running. Why not make life sustainable for all instead of a select few? No other person deserves more rights than the next. Please listen to our cries.. we want what's best for our world.

Sincerely,

Araceli Medialdea

Tucson, AZ 85730

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #1927, SBC-047451)

This proves why it is very important to monitor and understand PFAS's. So, we need to identify and address that we are not holding these companies accountable for proper disposal and testing before these PFAS are able to harm individuals and wildlife. Even though this proposition notifies, monitors, and reduces these PFAS it is not doing preliminary research on these PFAS to completely keep individuals safe from health risks. We also see individuals such as DuPont who have knowingly exposed people to these harmful PFAS for years. Yet he was not punished for this act for years (Rich, p8-9). This proves that selfishness of individuals seeking more money can also harm the environment and people. We need to stop this at the root, making the companies do tests and proper disposal on top of the monitoring, notifying, and reducing the amount of PFAS within the environment's water supply in general. Not just our own drinking water that affects animals as well. To summarize, I believe that we should be doing more than this bare minimum to keep our environment's water safe and inhabitable for all living organisms. If we don't this is not only hurting us, but also the animals that help keep our ecosystem stable and safe for years to come.

References

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Sunderland, E. M., Hu, X. C., Dassuncao, C., Tokranov, A. K., Wagner, C. C., & Allen, J. G. (2018, November 23). A review of the pathways of human exposure to poly- and perfluoroalkyl substances (pfass) and present understanding of health effects. Nature News. Retrieved April 11, 2023, from https://www.nature.com/articles/s41370-018-0094-1

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #1930, SBC-047319)

To this end, I propose that we either limit the amount of known harmful PFAS in our water systems similar to the proposed regulation or even ban PFAS outright similar to the laws within Maine. Additionally, to prevent future PFAS or similarly harmful substances from entering our water systems, I propose funding for public water systems to conduct clinical trials on unknown chemicals that enter our drinking water and to investigate the origin of those substances; this way we are able to hold manufacturers more accountable to the risks of dumping unsafe substances within water systems and to prevent another case similar to DuPont's from occurring. When a harmful substance is detected I believe public water systems should try to settle the matter privately with the manufacturer by requiring the manufacturer either pay to create filtration systems that would allow for the substance to enter the environment under safe conditions, or make the manufacturer seek a biodegradable and safe alternative. If these requirements aren't followed, the public water systems need to inform the public of the harmful effects of said substance, the dosage of the substance within their drinking water, which party is liable for that substance, and to issue hefty fines to the guilty party which grows exponentially as time passes and the problem remains unresolved.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Diego Carrasco (Doc. #1932, SBC-047438)

Even though the creation of these regulations is a great step forward. In cases of this magnitude such as the safeness of the use of water in our water streams, we should also consider the highly possible arousal of new contaminants that might have emerged while the PFAS regulations were in the process of being created. These contaminants can appear in many forms, for example: In the shape of heavy metals, microplastics, and inorganic matter. Chemical compounds that are

detrimental to one's health. Therefore, I would encourage the EPA to implement more cautious and constant testing of water bodies in the US that are close to any kind of civilization where the community can be impacted by the chemical status of their main source of water. A main component of evolution is invention. Scientists all over the world work non-stop to create all kinds of applications of chemistry in our daily life aiming to facilitate our lives. This facilitations may come with complications like the ones Teflon brought with its invention in the late 1900s. Thus, we should encourage the agencies that make the regulations regarding our health, to keep up with the scientific community to be able to provide a more positive outcome for all of the parties involved in these type of transactions.

In conclusion, the EPA's proposed regulations on PFAS are a vital step towards safeguarding public health. Giving citizens access to the PFAS analytic tool will enable them to make informed decisions about their health. However, we must also consider the possibility of new contaminants emerging while creating these regulations. Therefore, the government must continuously and carefully test water bodies in the US to ensure that our water sources do not pose a risk to public health. We should encourage health regulatory agencies to keep up with scientific advancements to ensure positive outcomes in the health status of the country's citizens.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Susan Corbelli (Doc. #1940, SBC-046257)

We teach our kids not to swallow toothpaste, to spit out fluoride rinses and don't eat/drink after a fluoride treatment yet we add fluoride to our drinking water? Cavities are on the rise: it doesn't look like adding fluoride to the water helped. Please stop adding it to our drinking water. Thank you

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #1955, SBC-047317)

To provide a better and cleaner environment, the new regulations and more accurate checks on a federal level can help limit the amount of PFAS within the environment. There is no saying how long PFAS stays in the body, which is why it's also considered to be a "˜forever chemical' There needs to be stricter regulations and checks from politicians, heads of government, and agencies to ensure a clean environment for drinking water, more environment friendly pans and clothing. Although PFAS have become a significant concern for public health in many parts of the world, their presence in drinking water and cookware is a critical issue that needs to be addressed. Ultimately, it is essential to protect public health and maintain access to safe drinking water, clothing, and having the ability to cook food without being contaminated by PFAS.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Anna Trujillo (Doc. #1959, SBC-047296)

One of the difficulties I ran across when going through the five processes of decision-making was coming up with a different strategy to completely eradicate PFAS. I think that a portion of our taxes and fines to chemical firms should go into paying for the expensive cleanup of PFAs from our water. Due to the fact that the new regulation does not automatically ensure that everyone would agree with it, it is challenging to examine other alternatives. When assessing ethical factors, selecting a course of action can be difficult. This is particularly true given how expensive my proposal would be to totally eradicate PFAs. Where will the funding come from, how will we make sure those responsible are held accountable, how can we ensure that PFAs-containing compounds are removed off the market and how can we guarantee that the manufacture of chemicals containing PFAS is stopped? Complete eradication of PFAs is not impossible, but it would be exceedingly costly.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Iresli Jurado (Doc. #1960, SBC-047445)

There is an issue with both companies and the laws that regulate actions and both parties should strive to be better. Companies and particularly large corporations like DuPont, often prioritize profits over the wellbeing of people and the environment. They are willing to take risks with harmful substances if this means saving money. The fact that people risk others lives for personal benefit, is unethical on a level that does not belong in any future of human existence. Simultaneously, there are gaps in the regulatory framework that allow companies to engage in practices that are harmful to people and the environment. For example, in the case of PFOA, the EPA had not yet classified the substances as hazardous, even though there was evidence of its dangers. This lack of regulatory oversight allowed DuPont to continue using PFOA without facing any significant consequences. Not in any way does this justify the act of the people behind the actions of the company, but there are flaws in the system. By law it allows the first amount of money being made to go to DuPont, but this money should not be available to anyone after the regulation of the laws. This money should be considered unfounded.

It is not an issue with companies or laws in isolation, but rather interplay between the two. Laws need to be strong enough to hold them accountable when they fail to do so. Following the Markkula Ethical Decision Making framework, we would consider protecting the people not just the good choice instead of the bad choice, but the ONLY choice. It should not be allowed to be aware of a possibly helping system without using or applying it for the benefit of people.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Mary-Ellen Maynard (Doc. #1982, SBC-047487)

Dear Michael Regan,

ALL FOSSIL FUELS ARE TOXIC TO ALL LIFE. What part of that sentence don't you understand?

As someone who has been tortured for 73 years by the health-destroying effects of a prescription drug synthesized from coal tar, given to my mother while she was pregnant with me, I am outraged that anyone with a brain still thinks that extracting fossil fuels is anything other than criminal and suicidal on a species level.

Keep it up and you and your children will be the next to suffer, as my family members have all suffered.

The women who took the drug died in large numbers from breast cancer, as did my mother. My sister, also exposed, had a miscarriage, ectopic pregnancy and child who died within a few months of a birth defect because of that drug. Her daughter had only one or two menstrual cycles per year because of that drug. I've had breast and uterine cancers which have been the least of my health issues caused by that drug. I was unwilling to pass the damage to another generation in the unlikely event that my reproductive deformities would have allowed me to become pregnant. All because of Diethylstilbestrol. Think twice about new fossil fuel drilling, pipelines and facilities and then think again and again. Think even harder about chemicals synthesized from coal.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Vasu Murti (Doc. #2023, SBC-047490)

The Democratic Party platform should support: Animal Rights, Defending the Affordable Care Act, Ending Citizens United, Ending Marijuana Prohibition, Giving Greater Visibility to Pro-Life Democrats, Gun Control, Net Neutrality, Raising the Minimum Wage to $15 an Hour, Responding to the Scientific Consensus on Global Warming, and a Sustainable Energy Policy. Democrats for Life of America, 10521 Judicial Drive, #200, Fairfax, VA 22030, (703) 424-6663

Sincerely,

Vasu Murti

Oakland, CA 94611

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Roger Beck (Doc. #2035, SBC-046604)

Dear Sir/Madam,

I am writing to express my strong support for the use of Tucker Carlson as a tool for removing PFAS from drinking water. As you know, PFAS are a group of chemicals that have been linked to a range of serious health problems, including cancer, liver damage, and immune system dysfunction. It is imperative that we find effective ways to remove these harmful substances from our water supply.

In laboratory tests, because of his hot air, ability to attract filth and trash from all directions, and reality not mattering in how he shapes the world around him, Carlson has been found to be incredibly effective at removing PFAS from water. His hot air seems to attract the PFAS molecules, which then adhere to the slimy, sticky substance that is his being. And once Carlson has soaked up as much PFAS as he can, he can be easily removed from the water and disposed of safely.

But Carlson's usefulness extends far beyond his ability to remove PFAS. He is also an excellent tool for cleaning up garbage and waste. His absorbent properties mean that he can be used to pick up all kinds of litter, from cigarette butts to plastic bottles to discarded food. And because he is so effective at soaking up waste, he can help to keep our streets and waterways cleaner and safer.

One of the most remarkable things about Carlson is that he requires no special maintenance or attention. He simply sits there, doing his job loudly, obnoxiously, and efficiently, without any need for supervision or oversight. This makes him an incredibly cost-effective and practical solution for removing PFAS and cleaning up waste.

It is rumored that Carlson also has a secret power. Some say that Carlson could make anything disappear, including the truth, 800 million dollars, evidence of an insurrection, friends, civility, democracy, and harmful chemicals such as PFAS. And not only that - Carlson believes he could magically replace PFAS with pristine, drinkable water just because he wants to.

I urge you to consider the many benefits of putting Carlson at the bottom of a drinking water well and using him as a tool for removing PFAS from drinking water. He is a safe, effective, misogynistic and cost-effective solution that has the potential to make a real difference in the health and well-being of our communities by soaking up the trash we actually want him to do so without broadcast the waste back across our airwaves.

Thank you for your attention to this important matter and I look forward to Tucker Carlson's important contributions to pfas removal, so that for the first time in his life, he would make the world a better place instead of making it much worse for all of us.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Thomas Warner (Doc. #2080, SBC-046188)

At what point is vitality to release approval with sig

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2108, SBC-046219)

I get very suspicious when a government body is said to be protecting public from harm. Usually they seem to be protecting the corporations and letting public die.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Lana Huber (Doc. #2171, SBC-047492)

In addition, Custer SD is planning to dump its sewage wastewater in a pure Creek that flows through private properties with shallow drinking water wells. This plan has been approved by the State of South Dakota utilizing millions in Clean Water Act funds without any comprehensive Environmental Assessment being done at any level. This must be stopped before the stream is permanently degraded.

Sincerely,

Lana Huber

Custer, SD 57730

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Eleanor Howard (Doc. #2191, SBC-046235)

Frankly, my dear, I don't give a damn about our communities. I care about all the other species for whom we are daily ruining the planet. So I want more and better regulations on everything everywhere.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Frances Lamberts (Doc. #2250, SBC-047430)

As this year's March 3 Science issue notes, "five EU countries (have) proposed a complete phaseout of PFASs." Since there are many thousands of them in use, such phaseout may be quite difficult to achieve. May I recommend, however, that

(1) your Agency not approve any new, additional PFASs through the pre-manufacture process, or through regulatory exemption, that

(2) industry discharges of PFASs into our water bodies be regulated, as also

(3) PFASs emissions into the air.

As our beloved, long-ago author E.B. White said of pollutants (then from atmospheric nuclear-weapons testing) in the soil – "the correct amount of strontium in the soil is no strontium" – so it should be with the PFAS chemicals – not allowed in our drinking water or our bodies.

Again, I thank the Environmental Protection Agency for this initial rulemaking.

Sincerely, Frances Lamberts, 113 Ridge Lane, Jonesborough, TN 37659

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Rhonda Gill (Doc. #2272, SBC-046472)

Please consider the possibility of further contamination from the products AND those that decay into it. The extent of contamination should include those downstream and the circumferences around sites.

This needs to address all sources of PFAs on the workers, surrounding communities and others who have a right to be protected.

This is not a sufficiently broad approach to the long term effects of the product

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2317, SBC-046250)

Chemicals that include PFAS should be wholly banned from America in the first place. The fact that it has gotten into our water supplies is no accident. Our well beings are second to the corporations and businesses that have their products loaded with the stuff.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Joseph Alvarado (Doc. #2337, SBC-047347)

For the love of God and the children of future generations leave the fossil fuels in the ground, we do not need for to continue to accelerate the defrosting of the permafrost methane swamps inform the public to end carbon intensive practices, methane is 40xs worse than tailpipe emission, more companies need to reduce carbon emissions and take up carbon capture, reduce and then eliminate new plastic use (90% of plastic has not been recycled, clean up the Pacific garbage patch and recycle it.) forget EVs until a carbon neutral cradle to grave recycle process is complete for all EV materials, people need to reduce, recycle & reuse, bike, walk, plant trees,

conserve, get OPEC, G20, U.S., & China to quintuple down on green hydrogen, COVID came from Wuhan, environmental protection laws exist for such things via strict liability like offshore oil drilling, nuclear power, CHINA OWES. RAIL,RAIL, RAIL. Trains can do so much more with less, to distribution hubs and vehicles can do final destination, build out major corridors for Rail, Water, & Power all at once, as for combustion, Green Hydrogen is the way forward, when it comes to combustion. The bankers have manipulated so much over the years, these days many people are not savvy enough to know that they have more access to money than brains...too many things are uncorked before they are ready from Clinton and the deregulation of banks that led to irresponsible leveraging, to consumer spending on trends and disposable garbage from cell phones, globalization, dotcom, to EVs, these trends have been more activity than accomplishment (Wooden) and people are leveraging their future to jump on bandwagons and the fees you roost form them is just more insult to injury...pimping the poor, like check cashing places, from post 9/11, 0% financing for SUVs when we should have been getting off fossil fuels to the 2008 bubble and bail out and so much more for the last decade and more remarkably of late. I hope the bankers are ready for their comeuppance, too big to fail, that was stupid, more money than brains...and are chiseling people for more fees, work on educating the public so that consumers make prudent long term decision in

Sincerely,

Joseph Alvarado

San Francisco, CA 94122

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Diane Wallace (Doc. #2347, SBC-047495)

FROM DIANE WALLACE, FORSYTH County, North Carolina Resident- Let's protect all species, switch to renewables and retain habitat for trees, plants and animals. It will eventually be too hot to sweat. And once the permafrost thaws past a certain point then the temperature of the Ocean will rise such that the methane clathrates frozen at the bottom of the continental shelves will be released then there will be an oxygen poor atmosphere starting above sea level.

Sincerely,

Diane Wallace

Kernersville, NC 27284

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2419, SBC-046241)

PFAS need to be banned ASAP. All chemical production needs to follow the precautionary principle. Companies need to prove beyond a shadow of a doubt that their chemicals cause no harm before they can be released.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Sri Grandmaster Hari Palacio (Doc. #2443, SBC-047501)

Dr. Srí Srí Srí Enlightened Grandmaster Hāri Māya Krśna (Hari Edgar Palacio MEd BS BA) Ayurvedic Doctor, Ivy Leaguer & nephew of the Dominican Republic President Leonel Fernández and the Dominican consulate. Harry has read 3,589 books in his lifetime. Top 26 reader in USA and top 49 reader globally as of 2022. Master Herboligist, Model under contract with Dion Audriaa, OpenSea, and Shein; asked to model in the Dominican Republic, for Alma, and shortlisted to model under Empire. Maha Mudra: Tantra Sexual Alchemy (Kriya Yoga Iniate), Maithuna Yogi. He is a certified sex educator. He is Chess Master and top rated 26.52% of all chess players on chess.com. Harry, a numerous award winning author, was a finalist for Fjords Review book competition, semi-finalist for Quartz Literary Fiction and Poetry, NYMA JV Basketball Champion Division 1, Grand Prix winner Hudson Valley MOCA and at St. George literary contest, and accepted to be published in Tule Review, Bellevue Literary, Apiary, etc. His books were published by Finishing Line Press: Ambrosia and Sutras of Tiny Jazz. As an award winning fine artist he exhibited at School of Visual Arts, assistant director of Arts 10566, and director of Steel Imagination. He is a musician (Oregon Kool-aid) ALL platforms. He Performed at September Fest and Ari Up of the Slits (godmothers of post-punk); former members were part of the famed band The Raincoats. Harry's Guruji is Sri Dharma Mittra. Hāri meditated 1,285 hours in his lifetime. He obtained a BA from WCC, a BS from SUNY Purchase, a Master's from Manhattanville College. The New School University, Parsons, Stanford, Harvard student; accepted to Columbia with scholarship. Harry worked as an assistant director at Manhattanville College Connie Hogarth Center (social Justice), Pride Coordinator (although a straight cis male), international yoga teacher 200 hours, music journalist for Popfad. He is a BIPOC and former music journalist living with schizoaffective disorder.

Sincerely,

Sri Grandmaster Hari Palacio MEd BS BA CW SC

Mount Kisco, NY 10549

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2463, SBC-046593)

To: <TIPS@nypost.com>, <newyork@fbi.gov>, <newyork@sec.gov>, <omwi@sec.gov>, <opaa@jacksonprosecutor.com>, oped@nytimes.com <oped@nytimes.com>, <schockl@sec.gov>, <secretary@columbia.edu>, <tips@insider.com>, <tips@latimes.com>

ATTN of The General Counsel and Trustees of Columbia University,

Mr. Jerome Davis,

Thank you in advance for looking into this, it is a USC Title 18.225 which has not yet been adjudicated. f**** child molestors watch their students in the privacy of their homes??? Who the f*** signed off on that??

A conspiracy (more than foe' is all I need ya know) and a $6million loan by State Farm to The Sullivan Properties LP with a claim to their unlawful income is a USC Title 18.215. More concerning is the lack of disclosure to the SEC about a loan in excess of $5 million which holds the burden of the LP's tax evasion.

No Taxes paid on $288 million in property taxes for the last ten years, which was undervalued at roughly $22 million, as per NY DFS records, Block 803, Lot 11; inclusive of its contiguous properties all owned by the same LP; unlawful rents and leases transferred to then CIK filer 93715 (USC Title 18.21), beyond a reasonable doubt. The irony is that more than 75% of those units were empty, however those rent payments are unlawful (no certificate of occupancy), which by the FDIC is an unlawful deposit -no different than a heroin dealer depositing his ill earned money into, let's say Chase Manhattan bank?

The documents in this folder should be helpful for you to prosecute them and also understand where I have my reservations, pun intended.

You're welcome!

You can start looking here, just like the peeping Toms in Penn State:</br>

Sean.Lawrence@columbia.edu</br>

Dean.Foskett@columbia.edu</br>

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2532, SBC-046300)

While PFAS chemicals are indeed dangerous to both our health and the environment, and I believe that they should be banned or at least severely regulated, has the EPA considered this proposed policy's impact on the economy? PFAS and many other similar chemicals are used in a

great deal of consumer products. Anything from cleaning products to shampoo to life jackets all contain PFAS chemicals. If these chemicals were to suddenly become severely regulated, would this not impact production in a way that creates costs that would fall onto us as consumers? Even passed that, would alternatives to them be healthier for us and the environment or could they be worse?

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Krystle Bowers (Doc. #2552, SBC-046287)

This regulation seems to put the cost and work on the our public work departments across the country for a substance that's been introduced by companies. Regulations should be aimed at limiting PFAS contaminating our environments in the first place. The burden of the cost and work should be placed on the companies creating these substances and putting them out into the world. This will place a heavier burden on tax payers while giving PFAS creating companies immunity on the damage they do to our health and safety.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Mark Ball (Doc. #2559, SBC-046278)

Dear person receiving these comments. I am pleased to hear you are urgently working to help save our limited resources. PFAS is very harmful to the environment and humans. However, This is by no means an easy task to pull off. PFAS is everywhere we cant directly eliminate the source since it is a nonpoint pollution source. However what we should try to do is eliminate chemicals we use in beauty product and hair gels. This would help stop pfas.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Mark Griffiths (Doc. #2560, SBC-046240)

Let's end the production of PFAS and work on solutions to remove these chemicals from the ground water, lakes, streams, and rivers. We also need to enact severe penalties for companies who continue to produce them.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Lissa Spitz (Doc. #2564, SBC-046258)

It is an outrage that profit driven companies continue to pollute our water with poison. Please strengthen the regulations against this. I live near the Huron river and it is a gem, but the water is

not safe. Signs are posted to not eat the fish or touch the foam. This is unacceptable. Thanks, Lissa Spitz

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2571, SBC-046318)

Clean water is essential for not only human life, but a biodiversity of life on planet Earth. No person or entity should be allowed to pollute our water - and yet it has occurred and continues to occur as disposing of chemicals properly are deemed too difficult or costly. It's easier to simply dump them in the ground or in a swamp on 'vacant land'. The entities/individuals doing the polluting don't seem to understand how their pollution actually impacts themselves, other humans, and other creatures of the Earth. They've potentially caused irreparable harm and they must be held accountable for their actions. This cannot be overstated. Please do everything possible through the creation of laws and regulations to not only punish those responsible for polluting, but also to potentially stop the next set of individuals from acting so irresponsibly. Stiff penalties and fines as well as demanding the polluters clean up what they've done, plus watching them while they are doing the clean-up to ensure it's correctly done - are all necessary and important to prevent future problems of this nature.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Martha King (Doc. #2589, SBC-047311)

Also, once the water systems plant "treats" the water then where do the biosolids go? Perhaps to a landfill, burning them, or making it into "fertilizer"? All of these are not sustainable nor are they environmentally safe. Farmers have been using the "biosolid" fertilizer on their fields that further spreads the contamination into our ground water and potentially into privately owned wells. The EPA proposal does not address privately owned wells. It is difficult to find labs that test private well water for PFAS and the one lab I did find was quite costly. The American public should not foot the bill to protect their health from these contaminants. I wonder how many citizens are suffering from illnesses that are directly attributable to these chemicals. The "Superfund" is not available for them. Simply put... by not permitting any more of the several toxic chemicals (PFAS, PFAOS, PFNA, PFHxS, PFBS, etc) into our lakes, wells, streams, etc we would FINALLY (since 1940!) end this catastrophe. That is, of course, as long as companies stop making alternative chemicals to replace the ones that have been determined to be negatively impacting our health. And then, who is "monitoring" Monsanto, 3M, Bayer, etc?

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Timothy Fallon (Doc. #2592, SBC-046423)

How specifically does this effect our oil and gas industry? I mean they are everywhere. is this more, oh look we care about you laws. As always to little for a lot put on the tax payers tab. Maybe just enforce the existing laws.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Sarah E (Doc. #2613, SBC-046268)

I'm an Environmental Chemist by trade, and I agree that PFAS should not be taken lightly, as it is not volatile, and I read an research article proving it causes fertility problems in the fish who regularly consume it. This stuff is extremely hard to remediate(remove) from water. The source of the PFAS contamination should be found as soon as possible .

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2621, SBC-046255)

No where in your very impressive and lengthy blabberings did I see anything that suggests you have learned your lesson and will from now on stop fast tracking approval of shite to be used however the user sees fit without anyone knowing what the long-term consequences might be.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Colleen Thomas (Doc. #2637, SBC-046283)

As a civil engineer, I spend my days concerned with water quality of a proposed development and ensuring that the run-off is clean to discharge to local wetlands/storm sewer. It is so sad that we don't hold big business accountable for cleaning water or paying after accidents. Women are having unprecedented issues with fertility, and we wonder why? PFAS are a huge problem. I urge the EPA to force responsibility on our polluters and keep our nation and its people safe.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Jack Anon (Doc. #2663, SBC-046185)

We don't need MORE plastic.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Andrea Thompson (Doc. #2711, SBC-047503)

As an indigenous woman I have question for you; When you took our lands you pledged to protect and care for us and the land itself it seems to me you are not fulfilling your treaty obligations and are instead allowing fossil fuels and it's plastics, spills, train derailments and other issues to take over our Mother Earth! You must stop allowing these companies and corporations to influence you in any way but negatively they must be stopped and held accountable and responsible for their actions or lack of action! It's imperative that it is done right and immediately! For the sake of America and all the life living here wildlife as well as human lives depend on you!

Sincerely,

Andrea P. Thompson

Sincerely,

Andrea Thompson

Eufaula, OK 74432

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Emma Allen (Doc. #2712, SBC-047505)

THERE HAS BEEN SAND AND A STRONG CLORINE SMELL TO MY TAP WATER SINCE I WAS A CHILD . I FEEL LIKE CONSUMING TAP WATER GROWING UP HAS CAUSED ACTUAL DAMAGE TO MY BODY AND MIND . THE DENTIST SAID THERES FLORIDE TOO? HOW IS THAT SAFE OR OK? DO U EVEN HAVE STUDIES OR PROOF THAT FLORIDE DOES MORE GOOD THAN HARM? YALL ARE TRYING TO CONTROL US AND SOMEDAY THE PEOPLE WILL RIOT AND TAKE IT ALL DOWN .

Sincerely,

EMMA ALLEN

Stockton, CA 95210

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

D. C. (Doc. #2741, SBC-046310)

Re: Per &Polyfluoroalkyl chemicals in drinking water: I believe that there should be zero tolerance in laws & regulations of the chemicals mentioned in the title. My community is on an island in the Pacific Ocean that hosts several US military based that have used & abused these

chemicals. Now they are proved to be in some of the drinking water on our island. We essentially have no alternative source of drinking water except the lense of water deep beneath our island. It is unconsunable that the US Navy should be allowed to comtinue to use these chemicals when they have already contaminated parts of our drinking water with them. If a poll were taken, probably 100% of the people living here would support the idea of totally banning these dreadful chemicals. They poison the people, animals, plants and land. We have no other water source. Please, please ban them as soon as possible.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Patricia Schenk (Doc. #2742, SBC-046298)

I missed the EPA public hearing on May 4th for Washington County. I agree that PFA's are an issue and pleased our city of Cottage Grove is using dollars received from 3M to help in this endeavor. I've learned that toilet paper is a contributor as their product has PFA'S. Think about how many households use this more than once a day. Wouldn't it make sense to regulate the companies who manufacture these products? I also learned there are companies who manufacture a toilet paper made with Bamboo that doesn't have any PFA's. They are available from Walmart or Amazon. This leads me to believe manufacturing toilet paper without PFA's is possible.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Brittney Johansen (Doc. #2750, SBC-047298)

My name is Brittney. I am a student at San Francisco State University studying water quality. I have many concerns over PFAS manufacturing and regulation in the US, as research shows PFAS are present in the atmosphere, groundwater, and ambient water. According to the article by Wagner and Gold titled, "Legal obstacles to toxic chemical research", studying chemicals in the environment is only allowed to be reactionary and not precautionary. A major issue to studying chemicals in the environment are the legal blockades created by the Toxic Substances Control Act (TSCA) created by Congress in 1976. There are three issues that need to be addressed in order for scientific research to protect the environment and human health. First, the public availability of complete chemical standards. Second, public access to industry information typically protected under confidential business information (CBI). Third, an end to requirements that fragment information between local, state, and federal agencies.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Justine Cook (Doc. #2789, SBC-046564)

Dear EPA:

The most useful action the EPA could take even prior to finalizing the rules regulating Per- and Polyfluoroalkyl Substances would be to post a list of safe brands of plastic pipes that municipal water systems and homeowners can use that are PFAS free. With the infrastructure bill money now available, long delayed water infrastructure projects are underway. It would be tragic for America to have widespread plastic piping go in that may CONTAMINATE water with PFAS. Please release a commercial brand list of safe pipes. I live in a small rural town in Vermont. My water board is following industry standards in opting to use plastic rather than a known legacy material such as copper, etc. but there is no information from the Federal level guiding the safe brands of plastic pipes. Our town is going with the least expensive bid as required. HDPE pipes will be used and we don't know if they are free from PFAS.

Secondly, with projects that are already permitted and funded, would the EPA announce flexible rules to switch to copper, etc. rather than plastic, if towns and cities wanted to change in light of emerging science? We are being told our funding will be cancelled if the scope of the project changes due to increased cost for non-plastic pipes. Thank you.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Gina Weiss (Doc. #2803, SBC-046301)

No , I don't applaud the EPA, what is the EPA doing about the leaded fuel that is being sold at municipal airports like Flagler Executive airport in Palm Coast Florida, the airport manager is selling leaded fuel to piston engine planes and flight schoolplanes because its cheap, this year in Roy Sieger's annual report he has sold tons and tons of gallons, profiting off our communities back with poison AVAGAS that seeps into our soil and water supplies exposing our taxpayers and residents to high lead effects exposure in our children, leads to autism, and other diseases such as breast cancer, heart conditions, strokes, etc.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Whidbey Environmental Action Network (Doc. #2804, SBC-046565)

We need more than mere regulation of PFAS and its many related compounds. At the local level we are dealing with land use applications which will clearly result in exposure to PFAS for future residents, tenants, visitors to the proposed developments. There are no protocols in place for jurisdictions to require even minimal testing of groundwater which is expected to supply the land uses for which those applications are submitted. We ask that EPA promulgate such

protocols. At the very least there is a duty for jurisdictions to require testing of groundwater before permitting wells.

And we need EPA to direct the manufacturers to stop producing these toxic substances. The far future dates which have been proposed and/or declared are just that: far future. That is not acceptable. EPA has the authority. Please exercise it.

Lastly, the US military is grossly negligent, actively avoiding its responsibilities. In some instances they are not even stopping use of PFAS chemicals. In all instances they are holding off on remedial action until EPA sets the new exposure limits. In our area the US Navy declares its intent to take no further remedial action until EPA declares and formally adopts the new exposure limit, thus continuing to expose a large population to levels nearing the outdated 70ppt level.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Jane Henderson (Doc. #2815, SBC-046232)

We must protect the public from PFAS contamination. Insure that the WDNR retain its authority to investigate PFAS contamination, hold polluters accountable, and protect our water supplies.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Richard Gelderman (Doc. #2820, SBC-047331)

3) In addition to swiftly finalizing drinking water standards for PFAS, we urge the EPA to expedite efforts to prevent these forever chemicals from polluting the environment in the first place by imposing additional regulations for PFAS through permitting, cleanup, and disposal.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Nancy Bouldin (Doc. #2822, SBC-047472)

4. In addition to swiftly finalizing drinking water standards for PFAS, we urge the EPA to expedite efforts to prevent these forever chemicals from polluting the environment in the first place by imposing additional regulations for PFAS through permitting, cleanup, and disposal.

In conclusion, I strongly support the EPA's proposed PFAS national primary drinking water regulations. I urge the EPA to finalize the standards as quickly as possible while simultaneously working to reduce PFAS pollution at the source.

Thank you for the opportunity to add my comments.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Melda Clark (Doc. #2823, SBC-047474)

4. In addition to swiftly finalizing drinking water standards for PFAS, we urge the EPA to expedite efforts to prevent these forever chemicals from polluting the environment in the first place by imposing additional regulations for PFAS through permitting, cleanup, and disposal.

In conclusion, I strongly support the EPA's proposed PFAS national primary drinking water regulations. I urge the EPA to finalize the standards as quickly as possible while simultaneously working to reduce PFAS pollution at the source.

Again, thank you for the opportunity to add my comments

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Karen Valentine (Doc. #2834, SBC-047476)

4. In addition to swiftly finalizing drinking water standards for PFAS, we urge the EPA to expedite efforts to prevent these forever chemicals from polluting the environment in the first place by imposing additional regulations for PFAS through permitting, cleanup, and disposal.

In conclusion, I strongly support the EPA's proposed PFAS national primary drinking water regulations. I urge the EPA to finalize the standards as quickly as possible while simultaneously working to reduce PFAS pollution at the source.

Again, thank you for the opportunity to add my comments.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Monty Fowler (Doc. #2836, SBC-047478)

4. In addition to swiftly finalizing drinking water standards for PFAS, we urge the EPA to expedite efforts to prevent these forever chemicals from polluting the environment in the first place by imposing additional regulations for PFAS through permitting, cleanup, and disposal.

In conclusion, I strongly support the EPA's proposed PFAS national primary drinking water regulations. I urge the EPA to finalize the standards as quickly as possible while simultaneously working to reduce PFAS pollution at the source.

Again, thank you for the opportunity to add my comments.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Steven Cole (Doc. #2837, SBC-047480)

3. In addition to swiftly finalizing drinking water standards for PFAS, we urge the EPA to expedite efforts to prevent these forever chemicals from polluting the environment in the first place by imposing additional regulations for PFAS through permitting, cleanup, and disposal.

In conclusion, I strongly support the EPA's proposed PFAS national primary drinking water regulations. I urge the EPA to finalize the standards as quickly as possible while simultaneously working to reduce PFAS pollution at the source.

Again, thank you for the opportunity to add my comments.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

John Doyle (Doc. #2840, SBC-047482)

4. In addition to swiftly finalizing drinking water standards for PFAS, we urge the EPA to expedite efforts to prevent these forever chemicals from polluting the environment in the first place by imposing additional regulations for PFAS through permitting, cleanup, and disposal.

My wife has Parkinson's disease and the evidence of it's environmental risk factors is overwhelming. We must get the toxins out of our water, air, land and food. Countries who have done this aggressively see reductions in prevalence of PD to pre-industrial age levels. This phenomenon is also common for other diseases, notably cancers. All the medical snake oilcures will never help the situation as long as we continue poisoning ourselves and our communities with chemical WE KNOW TO BE DEADLY!

In conclusion, I strongly support the EPA's proposed PFAS national primary drinking water regulations. I urge the EPA to finalize the standards as quickly as possible while simultaneously working to reduce PFAS pollution at the source.

Again, thank you for the opportunity to add my comments.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2846, SBC-046289)

please ban ALL PFAS chemicals, in all applications. These chemicals certainly do not belong in any surface water. These chemicals are not fit for frogs, fish, insects, birds... or mammals INCLUDING HUMANS to drink, swim in, cook or clean with. Just BAN them and enforce that the polluting companies, the manufacturers of the chemicals, and the inheritors of the polluting companies clean these chemicals from the environment. Filter them, transform them into something non-toxic, or otherwise get them out of the environment

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Liz Szabo (Doc. #2850, SBC-047507)

Pollution is a fight that is on the shoulders of democratic Americans because maga republicans do not support regulations nor do the maga six scotus. Yes even the six conservative scotus members have declared no support for protecting the environment against all the dangers of pollution. That means they do not care about safe to drink clean water. They do not care about the dangers of breathing polluted air. They do not care about polluting the earth from where crops are grown which we need to live. Yes, the federalist white supremacists six scotus have okayed the right of big business to continue business as usual in their production of dangerous toxins and poisons which cause illness, cancers and death because these six have been lobbied by the wealth of big business and are now supportive of the dirty dealings of creating and increasing pollution that kills. this is just a continuation of trumpism because it was trumps influence that ceased pollution regulations. It amazes me how much destruction trump managed to have happen in the short time he was; in my opinion; illegally in the White House.

Sincerely,

Liz Szabo

Mchenry, IL 60051

emtszabo@hotmail.com

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Dirk Neyhart (Doc. #2886, SBC-046438)

Dear Michael Regan,

Every one of our bodies has man-made plastic in it for the first century in human evolution. Plastics, throw the malefactors in prison. Stop the production and distribution of Forever Chemicals.

D. E. Neynart

Sincerely,

Dirk Neyhart

Berkeley, CA 94702

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Susan Hayes-Tripp (Doc. #2893, SBC-047508)

Dear Michael Regan,

Our 8 BILLION and GROWING POPULATION, gives me no hope for for future generations. How we are currently living is not sustainable. Our species is truly the SUPERIOR PARASITE.

The polarization of our political parties in our country is frightening and embarrassing. The GOP has become the party of DO NOTHING & BLAME ! I have no faith that ANY environmental policies will be attained through our current Congress.

The environmental legacy which the GOP leave their children and grandchildren is shameful.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Laurine Yates (Doc. #2900, SBC-047484)

4. In addition to swiftly finalizing drinking water standards for PFAS, we urge the EPA to expedite efforts to prevent these forever chemicals from polluting the environment in the first place by imposing additional regulations for PFAS through permitting, cleanup, and disposal.

In conclusion, I strongly support the EPA's proposed PFAS national primary drinking water regulations. I urge the EPA to finalize the standards as quickly as possible while simultaneously working to reduce PFAS pollution at the source.

Again, thank you for the opportunity to add my comments. I would like to say that safe drinking water seems like an obvious thing that everyone wants!

We do do see that there are pressures to lower the numbers and allow more poison in our water....please, please do not give in to such pressures Your job is to protect the environment...what an important job! Please do your job and be proud that you have protected water for the citizens.

Thank you!

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Ira Share (Doc. #2927, SBC-046529)

How can you have a MCL of 4ppt while the agricultural industry adds forever chemicals into our environment? Let's pour gasoline on a match. The EPA needs to stop the use of these chemicals so we do not have to filter our water, remove our contaminated soil, and treat our diseases. This does not make any sense at all, to add more of these toxins while we debate on MCLs.

Please read this article. It is short. Here is a quote:

"The fact that we are likely spraying pesticides with PFAS on food at a time when EPA acknowledges there is no safe level of some of these chemicals is nonsensical," she added.

https://www.theguardian.com/environment/2023/may/07/food-pesticides-toxic-forever-chemicals-pfas#:~:text=Multiple%20studies%20have%20established%20that,probably%20polluting%20water%20with%20PFAS

Please follow your mission statement-protect our environment!

Thank you for your time.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #2948, SBC-046288)

Yes I have commented on this in the past as well.It is truly our only equal rights by law.The right to the same drinking water and fresh air as our neighbors.Since late 2019 I have personally funded the revitalization efforts and have documentation It's an underserved community, opportunity zones,hub zone under SBA standards and It's worth your time to evaluate.I'm grateful I've made my mistakes on this journey along with accomplishments.I believe now is the time to move forward with a collaboration effort between us.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Diego Carrasco (Doc. #2978, SBC-047437)

Even though the creation of these regulations is a great step forward. In cases of this magnitude such as the safeness of the use of water in our water streams, we should also consider the highly possible arousal of new contaminants that might have emerged while the PFAS regulations were in the process of being created. These contaminants can appear in many forms, for example: In the shape of heavy metals, microplastics, and inorganic matter. Chemical compounds that are detrimental to one's health. Therefore, I would encourage the EPA to implement more cautious and constant testing of water bodies in the US that is close to any kind of civilization where the community can be impacted by the chemical status of their main source of water. A main component of evolution is invention. Scientists all over the world work non-stop to create all kinds of applications of chemistry in our daily life aiming to facilitate our lives. This facilitation may come with complications like the ones Teflon brought with its invention in the late 1900s. Thus, we should encourage the agencies that make the regulations regarding our health, to keep up with the scientific community to be able to provide a more positive outcome for all of the parties involved in these types of transactions.

In conclusion, the EPA's proposed regulations on PFAS are a vital step toward safeguarding public health. Giving citizens access to the PFAS analytic tool will enable them to make informed decisions about their health. However, we must also consider the possibility of new contaminants emerging while creating these regulations. Therefore, the government must continuously and carefully test water bodies in the US to ensure that our water sources do not pose a risk to public health. We should encourage health regulatory agencies to keep up with scientific advancements to ensure positive outcomes in the health status of the country's citizens.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Christina Micek (Doc. #2993, SBC-046324)

Please create a remediation and clean-up plan for these chemicals, especially near military bases. A new study at Harvard shows that not only the chemicals are an issue but do are the precursors. " without remediation, widespread PFAS contamination of drinking water supplies near military facilities is likely to persist for centuries. Despite contamination of nearby aquifers that may already pose a risk to human health, the majority of PFAS are still sitting in the soils surrounding these contaminated sites, emphasizing the urgent need for advances in remediation technology that effectively cleans up both terminal and precursor compounds. Since regulations focus only on terminal compounds, how effectively current remediation technologies clean up precursors is not known."https://news.harvard.edu/gazette/story/2023/05/epas-new-rules-on-forever-chemicals-dont-go-far-enough-study-suggests/

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Daniel Rostan (Doc. #3004, SBC-047354)

EPA should move forward to regulate emissions by air and discharge of contaminated PFAS waste into the wastewater systems, and limit pollution by biosolids/sludge fertilizers. While the costs of filtration and disposal are high, those costs are far outweighed by the billions of dollars in healthcare costs caused by the health impacts of PFAS chemicals, not to mention the incalculable damage done to loved ones when a family member dies of avoidable disease which the government failed to deem a sufficiently significant risk. Ultimately, we must do what was done with lead, mercury, and asbestos, to eliminate most non-essential uses for these chemicals in order to keep them out of the environment. The best way to reduce pollution is to stop it at the source.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #3022, SBC-046619)

To: <TIPS@nypost.com>, <newyork@fbi.gov>,

</br> </br>

https://ia902602.us.archive.org/17/items/document-index-tcr-5/document%20index%20TCR5.pdf

</br></br>ATTN of The General Counsel and Trustees of Columbia University,

</br> </br>

Mr. Jerome Davis,

</br> </br>

Thank you in advance for looking into this, it is a USC Title 18.225 which has not yet been adjudicated. f**** child molestors watch their students in the privacy of their homes??? Who the f*** signed off on that??

</br> </br>

A conspiracy (more than foe' is all I need ya know) and a $6million loan by State Farm to The Sullivan Properties LP with a claim to their unlawful income is a USC Title 18.215. More concerning is the lack of disclosure to the SEC about a loan in excess of $5 million which holds the burden of the LP's tax evasion.

</br> </br>

No Taxes paid on $288 million in property taxes for the last ten years, which was undervalued at roughly $22 million, as per NY DFS records, Block 803, Lot 11; inclusive of its contiguous properties all owned by the same LP; unlawful rents and leases transferred to then CIK filer 93715 (USC Title 18.21), beyond a reasonable doubt. The irony is that more than 75% of those units were empty, however those rent payments are unlawful (no certificate of occupancy), which by the FDIC is an unlawful deposit -no different than a heroin dealer depositing his ill earned money into, let's say Chase Manhattan bank?</br>

</br> </br>

The documents in this folder should be helpful for you to prosecute them and also understand where I have my reservations, pun intended. </br>

You're welcome!

You can start looking here, just like the peeping Toms in Penn State:</br>

Ashley.Humphries@wilsonelser.com</br>

Ashley.Humphries@fordham.edu</br>

Shannon.Hanson@Fordham.edu</br>

Shari.Laskowitz@ingramllp.com</br>

Amber.Griffiths@columbia.edu</br>

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Idaho Environmental Coalition (Doc. #3030, SBC-047327)

Contractors working at Superfund sites cannot supply EPA with the economic impact information that EPA should consider prior to proposing MCLs for PFAS in drinking water, because most Superfund sites do not have a preliminary assessment that identifies the nature and extent of potential PFAS contamination. The economic impact to ongoing CERCLA remedial actions at Superfund sites is expected to be significant if the EPA proposed MCLs for six PFAS in drinking water are promulgated.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document. With respect to costs associated with "CERCLA remedial actions at Superfund sites," the EPA notes that SDWA expressly states that the EPA shall consider "quantifiable and nonquantifiable costs. . . excluding costs resulting from compliance with other proposed or promulgated regulations." For further information on the EPA's cost analysis, please see section 13 of the EPA response in this *Response to Comments* document and section XII of the final rule preamble. Additionally, please see section 5.1.3 of the EPA response in this *Response to Comments* document for additional discussion on cost considerations in the final MCLs.

John Havrilla (Doc. #3037, SBC-047355)

To this end, I call upon the EPA to halt the approval of ALL new PFAS by emission into the air and seepage into our water sources, starting with the regulation of the six chemicals named in the proposal. Lead, mercury and asbestos have been regulated. We can do this with PFAS and save, particularly, our children from health insecurity. They cannot live without drinking water; categorically, they need not live lives impaired by drinking water laced with harmful chemicals. Pass the EPA proposal. Thank you.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Nick Fitzgerald (Doc. #3072-94, SBC-047405)

Good afternoon. I'm calling in today from historic land of the Spokane Tribe. I realize this isn't the exact forum to share all of these ideas, but I believe them to be valuable so I will share, nevertheless. The views I present are my own, though they have been informed through my

professional capacity as a public servant interacting with affected Americans. First, we need national laboratory reporting rules for PFAS such that every citizen, even those without science degrees, can read and understand water quality reports.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Carl Albers (Doc. #2555, SBC-047421)

Along with these efforts the production and use of forever chemicals should be halted as soon as possible. Until that happens the land application of sewage sludge should not be allowed as it clearly is not a safe method of disposing these so called "bio-solids" as they are likely to contaminate private drinking water wells in rural communities. Current research needs to be reviewed regarding the movement of forever chemicals from fields where the land application of sewage sludge has been practiced. In New York State sewage sludge can be applied within 200-feet of a private water well, regardless of whether it is uphill or downhill from the field in question. There are no provisions in the NYS permitting process for monitoring of nearby private water wells even when sewage sludge has been applied on nearby fields for decades. Recent testing of such wells in NYS by the Sierra Club has shown that indeed forever chemicals have been found in all 35 water samples taken from wells near fields with a long history of sewage sludge application. So again the proposed regulations are a step in the right direction as there are many rural residents that would like protection from these dangerous chemicals entering our private drinking wells. Thank you for your efforts to keep our nation's waters safe to drink.

https://waterfrontonline.blog/2023/04/20/pfas-found-in-all-35-water-samples-from-sites-near-sewage-sludge-fields-in-steuben-casella-calls-levels-minuscule/

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Mass comment campaign submitted by Jill Fischer (Doc. #3070, SBC-047486)

4. In addition to swiftly finalizing drinking water standards for PFAS, we urge the EPA to expedite efforts to prevent these forever chemicals from polluting the environment in the first place by imposing additional regulations for PFAS through permitting, cleanup, and disposal.

In conclusion, I strongly support the EPA's proposed PFAS national primary drinking water regulations. I urge the EPA to finalize the standards as quickly as possible while simultaneously working to reduce PFAS pollution at the source.

It is imperative that funding for states' regulation enforcement and remediation be secured as well as timelines for drinking water regulations be established and followed.

Again, thank you for the opportunity to add my comments.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

New York Section American Water Works Association (NYSAWWA) (Doc. #1591, SBC-042371)

New York State Department of Environmental Conservation has recently established a Human Health guidance value for PFOS of 2.7 ppt , which is below the EPA PQL. We are concerned that drinking water supplies who observe this level of PFOS in their finished water will be defined as industrial discharges to local POTWs and be forced into providing treatment as "polluters". Drinking water is discharged ubiquitously via numerous pathways, and thus it would seem that these regulations are destined to label the water suppliers as polluters when, in fact, we are recipients of pollution and would be meeting the proposed EPA regulation. This matter suggests that much stronger coordination needs to occur between regulatory entities to align MCLs and discharge limits and to provide for simultaneous compliance. Regulatory balance for PFAS substances between the Safe Drinking Water Act and Clean Water Act requirements needs to be provided with recognition of span of control limitations for water utilities exist.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Citizens Against Ruining the Environment (CARE) (Doc. #1638, SBC-043449)

EPA's Interim Guidance on the Destruction and Disposal of PFAS states that the large volumes of spent GAC and Ion Exchange resins prevents on-site storage, leaving landfill disposal and thermal treatment as the remaining options. [FN43: USEPA, 2020b. Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances. EPA–HQ–OLEM–2020– 0527–0002. Available on the internet at: https://www.epa.gov/system/files/documents/2021-11/epa-hq-olem-2020- 0527-0002_content.pdf.] However, both of these options pose great risks of PFAS reentering and contaminating the environment. Landfills are not designed to last forever, while PFAS are. As a result of their persistence and mobility, PFAS easily escape from landfills into the air or leak out of the lining systems, and are frequently detected in ground and surface water and liquid waste that leak from historic and active landfills. [FN44: Sonya Lunder & Denise Trabbic-pointer, Ten Bad Things We Do With PFAS Waste, Sierra Club (June 27, 2022), https://www.sierraclub.org/articles/2022/06/ten-bad-things-we-do-pfas-waste.] New York, Minnesota, and Vermont have all measured PFAS at virtually every landfill they test, yet waste managers continue to send PFAS-contaminated materials to landfills. [FN45: Id.]

Furthermore, preliminary data suggests that incinerators may be spreading, not breaking down PFAS. A team of professors and students at Bennington College obtained and analyzed soil and surface water samples in the historically burdened incinerator community in Cohoes, New York. [FN46: Cheryl Hogue, Incinerators may spread, not breakdown, PFAS, C&EN Global

Enterprise, (Apr. 27, 2020), https://cen.acs.org/environment/persistent-pollutants/Incinerators-spread-break-down-PFAS/98/web/2020/04.] The data collected suggests that incineration of the PFAS-containing foam is not breaking down the persistent chemicals but is instead redistributing them into nearby poor and working-class neighborhoods. Furthermore, in May of 2022, Congress issued a moratorium to the Department of Defense from continuing to incinerate aqueous, PFAS-containing firefighting foam until the DoD completes a study implementing the EPA's interim guidance on the destruction and disposal of PFAS. [FN47: Temporary Prohibtion on Incineration of Materials Containing PFAS, Department of Defense (April 26, 2022), https://media.defense.gov/2022/Apr/28/2002986273/-1/-1/1/TEMPORARY-PROHIBITION-ON-INC%255B%25E2%2580%25A6%255DNG-PRE-AND-POLYFLUOROALKYL-SUBSTANCES-PFAS-APRIL-26-2022.PDF.]

A study conducted by the Northwestern University chemistry department suggests that novel methods may help fully break down PFAS contaminants. [FN48: Brett Chase, Northwestern professor takes on 'forever chemicals,' and he just might win, Chicago Sun Times, (Sept. 16, 2022), https://chicago.suntimes.com/2022/9/16/23353881/pfas-forever-chemicals-william-dichtel-northwestern-university-brittany-trang-teflon-scotchgard.] The research found that a combination of the widely used solvent dimethyl sulfoxide and sodium hydroxide — lye — heated to just above the boiling point of water can destroy many types of PFAS. [FN49: Id.] The researchers have discovered that "decapitat[ing]" the PFAS molecules renders them harmless to people and would occur once PFAS is removed from the water to prevent it from accumulating. [FN50: Id.] The chemical reaction would break down PFAS into organic carbon and inorganic fluorine. [FN51: Tom Perkins, New method to break down 'forever chemicals' shows promise, study finds, The Guardian (Aug. 18, 2022), https://www.theguardian.com/environment/2022/aug/18/pfas-forever-chemicals-new-method-decompose-drinking-water.]

By design PFAS are meant to persist and resist thermal degradation and continuing to use incineration or landfills as the primary disposal method only further endangers public health and the environment. PFAS cannot be permitted to reenter the environment after removal from water supplies. CARE strongly encourages the US EPA to identify means to fully neutralize or destroy PFAS and, once identified, make it a requirement that all PFAS waste obtained by PWSs be neutralized or destroyed. In the interim, PFAS waste must be secured without risk of reentering the environment.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Citizens Against Ruining the Environment (CARE) (Doc. #1638, SBC-043453)

CARE Comment 5 - CARE Urges EPA to Confirm That Limitations from a Finalized PFAS NPDWR Would Constitute an Appropriate or Relevant and Applicable Requirement if a

Hazardous Substance Determination is Made for PFAS Under the Comprehensive Environmental Response, Compensation, and Liability Act

On August 26, 2022 the EPA proposed designating PFOA and PFOS as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), also known as "Superfund." [FN65: EPA Proposes Designating Certain PFAS Chemicals as Hazardous Substances Under Superfund to Protect People's Health, EPA (Aug. 26, 2022), https://www.epa.gov/newsreleases/epa-proposes-designating-certain-pfas-chemicals-hazardous-substances-under-superfund.] Section 104 of CERCLA gives the President authority to enact, or require, removal and remedial actions whenever there is release, or a substantial threat of a release, of any hazardous substance or any pollutant or contaminant which may present an imminent and substantial danger to the public health or welfare. The selection process of appropriate remedial actions and the cleanup standards and requirements are listed under CERCLA section 121.

Section 121(d) of CERCLA requires that on-site remedial actions attain or waive federal environmental Applicable or Relevant and Appropriate Requirements (ARARs), or more stringent state environmental ARARs, upon completion of the remedial action. [FN66: 40 C.F.R. § 300.430(d).] ARARs are used to define remedy protectives, ensure responses are performed in accordance with promulgated statutes and regulations, and frequently become site cleanup levels. [FN67: Documenting Applicable, or Relevant and Appropriate Requirements in Comprehensive Environmental Response, Compensation, and Liability Act Response Action Decisions, EPA (Mar. 1, 2023),https://semspub.epa.gov/work/HQ/100003166.pdf.] Indeed, overall protection of human health and the environment and compliance with ARARs are threshold requirements for any remedial action under CERCLA section 121(d). [FN68: See 40 C.F.R. § 300.430(f)(1)(i)(A).]

In pertinent part, section 121(d)(2)(A)(i) states that any remedial action pertaining to hazardous substances on-site is required to meet any standard, requirement, criteria, or limitation under any federal environmental law, including the Safe Drinking Water Act, that is legally applicable to the hazardous substance, or relevant and appropriate to the circumstances of the release of hazardous substance. Furthermore, section 121(d)(2)(A)(i) explicitly states that such remedial action shall require a level or standard of control which at least attains relevant and appropriate maximum contaminant level goals established under SDWA and water quality criteria established under the Clean Water Act. In circumstances where the MCLG is equal to zero EPA has typically referred to the corresponding MCL due to feasibility concerns. [FN69: CERCLA Compliance with Other Laws Manual on the CWA and SDWA, EPA (1990), https://semspub.epa.gov/work/HQ/174500.pdf.]

As such, following the passage of EPA's proposed NPDWR standards and EPA's proposed hazardous substance designation, any remedial action pertaining to a release of PFOS or PFOA will be required to obtain a standard of cleanup that meets the 4ppt MCL, pursuant to any other applicable restrictions from CERCLA. This applies to PFOS and PFOA releases that impact groundwater for private well users. CARE would like EPA to explicitly affirm the proposed

NPDWR standards will constitute ARARs for groundwater contamination of private well users following a determination PFOA and PFOS constitutes hazardous substances under CERCLA.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

City of Lancaster, Pennsylvania (Doc. #1695, SBC-044996)

With the labeling of these chemicals now as hazardous there will be a new problem for waste disposal and potentially makes all citizens unknowingly criminals of improper disposal of hazardous materials in their refuse removal. Any rule that is put into place that potentially creates criminals out of normal law-abiding citizens is one that is highly questionable and needs evaluation.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Monterey One Water (Doc. #1715, SBC-043829)

PFAS Disposal Guidance

Monterey One Water uses a four-step purification process to turn secondary effluent into safe drinking water. This process includes reverse osmosis which results in contaminated media and a concentrated residual. We urge the EPA to engage with the water reuse community, who is eager to share its expertise and experience, as EPA updates PFAS disposal guidance. The disposal guidance may greatly impact the operating procedures of existing reuse projects, and it is important for EPA to maintain an open dialogue with the utilities that will be directly affected.

Monterey County is isolated from state and federal water projects. This requires the region to rely solely on its limited, local water resources. In response, communities have invested heavily in innovative water reuse projects to create water resilience and sustainability. Monterey One Water's Pure Water Monterey Project will make up 59% of a local water system's supply portfolio upon completion of its expansion by the end of 2025. Any impacts to how we operate must be seamless to ensure the community has safe, reliable access to drinking water.

We thank EPA for the continued engagement with the water stakeholder community. Monterey One Water recognizes the need to address PFOA and PFOS in our environment but urges EPA to evaluate and consider unrealistic implementation goals. This includes identifying or establishing additional financial avenues that follow the polluter pays principle to fund required changes.

Regards,

Rachel Gaudoin

Federal Advocacy Lead

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Florida Section American Water Works Association - Water Utility Council (FSAWWA WUC) (Doc. #1737, SBC-044482)

Additionally, we renew our request that EPA rethink its current proposed solution for addressing the potential public health and environmental impacts of PFOA/PFOS by listing the chemicals as "hazardous substances" under CERCLA. As currently proposed, this designation means utilities will face unwarranted liability and legal defense costs at Superfund sites-such as landfills or agricultural sites-and through utility discharges. CERCLA compels this result, because the Act provides that any party who has contributed in any part to disposing of hazardous substances, even trace amounts, may be held liable for remediation.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

HNOJ Laudato Si' Circle (Doc. #1532, SBC-042634)

05/01/2023

HNOJ Laudato Si' Circle* thanks the EPA for taking action on PFAS and engaging with the public. As the proposals in your document EPA PFAS Strategic Roadmap: A Year of Progress indicate, much more needs to be accomplished. We can't agree more!

In our communities, both public health and day-to-day living have been greatly affected by the ongoing PFAS contamination on the Cape Fear and Haw Rivers. Our key takeaway from the March 21, 2023 "Listening Session" (for NC) is that the EPA must require federal governance for compliance on all needed proposals; so states like NC are REQUIRED to act. Using Whole-of-government involvement with the Dept of Energy, Dept of Defense, the CDC and FDA can expedite this federal governance for compliance.

A member from New Hampshire is concerned about Merrimack, Bedford, Londonderry, Manchester, Greenfield and Newfields towns having documented PFAS contamination from St. Gobain Plastic manufacturing, to name one company.

We request the EPA's enforcement of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) so that:

• Transparency around PFAS releases will increase and provide PFAS Analytic Tools to improve transparency.

• Polluters are held accountable for cleanup, and follow the Effluent Limitation Guidelines Plan 15.

• PFOA and PFOS are designated as hazardous substances and states can get upstream of the problem.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Michigan Farm Bureau (MFB) (Doc. #1562, SBC-043351)

May 19, 2023

Alexis Lan

Office of Ground Water and Drinking Water

Environmental Protection Agency

1200 Pennsylvania Avenue NW Washington, DC 20460

Submitted via www.regulations.gov

Re: Docket ID No. EPA-HQ-OW-2022-0114, Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

Dear Ms. Lan,

Thank you for the opportunity to provide comments to the U.S. Environmental Protection Agency (EPA) in response to its proposed rule to Docket ID No. EPA-HQ-OW-2022-0114, Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation. Michigan Farm Bureau is our state's largest agricultural organization, representing more than 40,000 farming families who grow a variety of food, fiber, and fuel products second only in diversity to California.

Farmers in Michigan and across the country take our responsibility to provide a safe, abundant, and affordable food supply seriously. They work tirelessly to protect their crops and livestock by protecting soil and water quality, both by managing nutrients and crop protection products, and by working with state and federal agencies to manage emerging contaminants. Michigan has been a leader in investigating, sampling, identifying sources, transport and fate of per- and polyfluoroalkyl substances (PFAS). The Michigan PFAS Action Response Team (MPART) has set a national example for establishing science-based tracking and regulation of PFAS substances.

We support EPA's work in addressing potential contamination, management, reduction, and environmental and public health protection from PFAS through its PFAS Strategic Roadmap. Reducing exposure and public health impacts from PFAS chemicals via drinking water is an important step, especially considering drinking water is a primary exposure pathway.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Michigan Farm Bureau (MFB) (Doc. #1562, SBC-043362)

These additional water quality protection regulations are necessary as EPA has identified in its strategic roadmap, [FN23: Environmental Protection Agency. 2021. PFAS Strategic Roadmap: EPA's Commitments to Action, 2021-2024. Retrieved from: https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf] which will be an important part of protecting public health. However, they also highlight the need to 1) ensure the best scientific and economic data is used to determine regulatory limits and financial assistance, and 2) provide clear direction for compliance including sufficient timelines to allow facilities to implement technologies and equipment that will meet those regulatory standards. Many programs beyond drinking water depend on these crucial steps being done correctly.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Aqua America, an Essential Utilities Company (Doc. #1623, SBC-043103)

This will also ensure that the various source water protection actions framed in the Strategic Roadmap for PFAS can be advanced, which is expected to help reduce PFAS contamination and exposures in impacted communities. This pragmatic timeframe will also ensure that polluters are forced to pay the bill for mitigating ongoing PFAS releases and contamination instead of relying on communities to pay for treatment of PFAS contamination for which they are not responsible.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044073)

ASDWA continues to recommend that EPA use all the Agency's regulatory and non-regulatory authorities to prevent PFAS from entering drinking water sources.

ASDWA continues to support EPA's work to holistically address PFAS under the Agency's PFAS Strategic Roadmap. The Agency's approaches to "get upstream of the problem" and "hold polluters accountable" are paramount to the long-term protection of both surface and ground water sources of drinking water.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

American Farm Bureau Federation et al. (Doc. #1642, SBC-043496)

In the PFAS Strategic Roadmap, EPA only committed to meeting its statutory deadline of December 2023. This proposed drinking water standard of 4 ppt will require drinking water

providers to treat drinking water sources for PFOA and PFOS and thus create more of a need for the management of treatment residues.

In the PFAS Strategic Roadmap, EPA did not identify plans to address PFOA and PFOS under the Resource Conservation and Recovery Act (RCRA), which, among other things, would have required EPA to conduct a rulemaking to establish management, treatment, and disposal standards that would apply to all RCRA-regulated PFOA and PFOS waste anywhere in the United States.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

New Jersey Department of Environmental Protection (NJDEP) (Doc. #1699, SBC-045010)

New Jersey commends EPA's action to propose primary drinking water standards and urges EPA to advance its PFAS Strategic Roadmap to improve public health protection by holistically addressing PFAS in other media areas and holding responsible parties accountable for the widespread contamination they have caused. We strongly urge EPA to continue supporting research and funding for technologies that can safely and permanently remove these contaminants from our environment.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

West Virginia Rivers Coalition (Doc. #3072-3, SBC-047357)

As outlined in the approaches included in the PFAS Strategic Roadmap, EPA must get upstream of the problem and prevent PFAS from entering source water in the first place. For context, the source water for almost half of the public water systems in West Virginia has levels of PFOA and PFOS that exceed the most recent health advisories. At the same time, the DuPont manufacturing plant that I mentioned earlier continues to discharge GenX chemicals magnitudes higher than the permit limits. Allowing polluters to continue discharging PFAS into source water while requiring utilities in indirectly affected communities to remove PFAS is an environmental injustice.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Alliance of Nurses for Healthy Environments (Doc. #1544, SBC-042674)

As nurses and healthcare providers quickly educate themselves on how to adequately assess patients and communities for PFAS exposure and provide resources on how to reduce exposure and take proactive steps to monitor for potential health outcomes, we are relying on the EPA to swiftly finalizing drinking water standards for PFAS, expedite efforts to prevent these forever

chemicals from polluting the environment in the first place by: controlling industrial discharges of PFAS into water, and addressing PFAS in state- and federal-issued permits consistent with EPA's 2022 guidance under the Clean Water Act; reduce unnecessary uses of PFAS, and prevent the entry of dangerous new PFAS chemicals into commerce under the Toxic Substances Control Act; minimize PFAS emissions under the Clean Air Act; clean up PFAS contaminated sites under the Comprehensive Environmental Response, Compensation, and Liability Act; and regulate PFAS disposal under the Resource Conservation and Recovery Act.

The ubiquitous nature of PFAS contamination underscores the need to curb all pathways of PFAS exposure and sources of pollution. EPA's 2021 Strategic PFAS Roadmap outlines a broad suite of actions to address the PFAS crisis, and following through on Roadmap commitments is of the utmost importance. Improved population health outcomes cannot wait therefore, we urge you to finalize the standards as quickly as possible with minimal concessions.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045553)

AWWA Comments on the Proposed "PFAS National Primary Drinking Water Regulation Rulemaking"

The American Water Works Association (AWWA) appreciates the opportunity to comment on the Environmental Protection Agency's (EPA or agency) "Proposed Per- and polyfluoroalkyl substances (PFAS) National Primary Drinking Water Regulation Rulemaking" (the proposal). AWWA has prepared the following comments to assist EPA in moving forward with a final rule to protect public health that is scientifically grounded, legally defensible, and crafted in a manner that embraces the objectives of the Safe Drinking Water Act (SDWA).

1. Overarching Comments

AWWA appreciates EPA's interest in addressing PFAS in drinking water to protect public health and maintain public trust in the nation's drinking water supply. AWWA has been engaged on PFAS issues since the early 2000s and has leveraged technical expertise from our members, which include more than 50,000 professional members and 4,500 utilities, to support the agency's broad efforts to address PFAS contamination. When the following guiding principles are followed, AWWA supports PFAS regulations:

1. Commitment to public health protection,

2. Fidelity to scientific process,

3. Seng regulatory requirements that are feasible to implement,

4. Ensuring affordability of safe drinking water, and 5. Effectively leveraging source water protection efforts.

In establishing drinking water regulations, embracing these guiding principles will ensure that communities and the public are effectively protected through a transparent rulemaking process and with a rule that prioritizes opportunities to reduce public health risks. The following comments and recommendations reflect these guiding principles.

Reinforcing the Polluter Pays Principle

EPA first published plans for a broad regulatory agenda to address PFAS as part of the EPA's PFAS Action Plan in 2019 (EPA, 2019a). In 2021, the agency published the more detailed PFAS Strategic Roadmap for regulatory actions (EPA, 2021a). The EPA's PFAS Action Plan and the PFAS Strategic Roadmap highlighted a variety of regulatory actions that the agency is pursuing, including setting effluent limitation guidelines and standards (ELGs) for industrial dischargers under the Clean Water Act (CWA). The implementation of these regulatory actions is critical in protecting the environment and the protection of drinking water sources. The actions, when completed, will reinforce the polluter pays principle for PFAS and help maintain the responsibility for the mitigation of PFAS contamination on the polluters instead of communities.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Connecticut Section of the AWWA (CTAWWA) and Connecticut Water Works Association (CWWA) (Doc. #1763, SBC-044231)

May 30, 2023

Mr. Michael S. Regan, Administrator

U.S. Environmental Protection Agency

EPA Docket Center, OLEM Docket, Mail Code 28221T

1200 Pennsylvania Avenue, NW

Washington, DC 20460

RE: Docket ID No. EPA-HQ-OW-2022-0114

Administrator Regan:

The Connecticut Section of the AWWA (CTAWWA) and Connecticut Water Works Association (CWWA) appreciate the opportunity to submit comments for consideration on the proposed PFAS Rule, which is the first-ever national drinking water standard to limit six per and polyfluoroalkyl substances (PFAS).

CTAWWA includes over 600 members and represents more than 60 utilities that supply water to approximately 2.5 million Connecticut residents. The organization is dedicated to the promotion of public health and welfare by assuring drinking water of unquestionable quality and sufficient quantity. CWWA membership is comprised of investor-owned, municipal, and regional utilities

with the mission of promoting and achieving effective state policies that assure reliable high-quality public water supplies to protect public health.

The Connecticut Interagency PFAS Task Force was established on July 8, 2019 to tackle the issue of PFAS. The plan that they developed was focused on minimizing the health risk to Connecticut's population by addressing PFAS in terms of historic releases and potential future exposure. As part of this response, the Connecticut Department of Public Health (CT DPH) issued drinking water Action Levels for four PFAS compounds on June 15, 2022. Prior to and following the issuance of these action levels, many utility members of CTAWWA and CWWA voluntarily sampled for PFAS and worked to communicate and educate customers and stakeholders. In addition, members have proactively begun to take action to minimize, treat, or otherwise address sources with PFAS. Consequently, exposure to PFAS via drinking water has been reduced and additional communities are anticipated to experience reduced PFAS levels through planned projects.

Similarly, at the federal level the PFAS Strategic Roadmap has been developed and a one-year progress update has already been released. It is the sincere hope of both CTAWWA and CWWA that the PFAS Strategic Roadmap and the Environmental Protection Agency (EPA) take aggressive action to minimize PFAS introduction into the environment and to pursue and hold accountable the originators of PFAS. Compliance with the PFAS Rule will certainly reduce customer exposure via a single pathway, but many other documented exposure pathways will persist. A comprehensive and balanced approach to addressing PFAS will yield the greatest reduction in PFAS exposure.

CTAWWA and CWWA respectfully submit the following comments:

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Center for Environmental Health et al. (Doc. #1764, SBC-044241)

In its 2021 PFAS Strategic Roadmap, EPA committed to addressing PFAS contamination through "…getting upstream of the problem, holding polluters accountable, ensuring science-based decision making, and ensuring disadvantaged communities have equitable access to solutions" [FN3: US EPA, "PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2025", (Oct 18, 2021), https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf].

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

National Ground Water Association (NGWA) (Doc. #1804, SBC-045474)

[The steps identified in that letter include:]

• leveraging available regulatory tools in other statutes to gather occurrence and health risk assessment data and organize them to support research and decision making, using regulatory tools that include the Toxics Release Inventory, Sections 4 and 8 of the Toxic Substances Control Act, the Unregulated Contaminant Monitoring Rule, the Resource Conservation and Recovery Act, and other existing authorities to protect drinking water supplies.

NGWA appreciates this significant step addressing this approach and the EPA PFAS Strategic Roadmap.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

WASHINGTON STATE BOARD OF HEALTH (Doc. #1837, SBC-044266)

We also encourage the U.S. Environmental Protection Agency to continue to apply a broad set of strategies to preventing and reducing PFAS contamination and exposure on all fronts in keeping with the agency's PFAS Strategic Roadmap.

Thank you for your consideration of our comments. If you have questions or need additional information from the Board, please contact Stuart Glasoe, Board Health Policy Advisor, at stuart.glasoe@sboh.wa.gov.

Sincerely,

Keith Grellner, Chair

Washington State Board of Health

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Student, University of Georgia (Doc. #3072-76, SBC-046386)

Good afternoon or evening, morning everybody. My name is Cheyenne Campbell. I am actually a graduate student at the University of Georgia who's getting her master's in public health degree in environmental health sciences. So pretty much my overall comment today is definitely mostly going to be surrounded on my research that I have found, and I was curious of within just PFAS, I definitely got into the world of PFAS, especially since my overall testing site was mainly on land application systems and how to control stormwater runoff. We need these land application systems and has been a noticeable problem that biosolids that are being used on these land application systems do contain PFAS. And then I did notice within the PFAS Strategic Roadmap, the finalized risk assessment for PFOA and PFOS in biosolids in particular is not to be expected until the winter of 2024. But within some of my conductive research that I was able to find, these high amounts of these different PFAS chemicals besides PFOA and PFOS in these biosolids. Yes, and even I agree from all these other public speakers that it is definitely being contributed to neurological and even all this physical or even psychological health issues. And I do believe that

there should be a little bit more of a push to maybe finalize these risk assessment of these biosolids, since these biosolids are being used a lot more by the public and even more raw use besides these land application systems and even a little bit more consideration as well as to trying to find different or maybe cost-effective cheap cleaning methods when trying to contain these PFAS contaminants from land application systems. Especially when you want to go to more rural counties or even some suburban counties, since it might be an issue that not all these different communities, especially the rural communities, would not be able to afford or access available to these better, different cleaning techniques when they're trying to actually ask us to entertain more of a monitoring system for PFAS analysis. Thank you.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Clean Water Action/Clean Water Fund (Doc. #1697, SBC-045007)

The proposed PFAS NPDWRs are a major step forward in limiting PFAS chemicals in drinking water. EPA needs to act equally aggressively to keep PFAS out of the environment and to curb use of these chemicals in order to avoid an ongoing downstream burden on communities and public health. Using the Clean Water Act's water pollution programs to keep PFAS chemicals out of water, including drinking water sources, is one example. EPA's December 2022 direction to states to include PFAS chemicals in water pollution permits is critical. [FN7: EPA Directs State to Use Water Pollution Permits to Control PFAS, Jennifer Peters blog post, December 7, 2022.] EPA needs to accelerate all activities, including but not limited to Effluent Limitation Guidelines (ELG) development, that will enable federal and state permit writers to include PFAS chemicals in National Pollution Elimination Discharge System (NPDES) permits. EPA has also made progress on other commitments in the PFAS Strategy Roadmap, and should accelerate and enhance these activities to reflect the seriousness of the health and environmental risks and of the concrete downstream burden demonstrated by the proposed NPDWRs.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Clean Water Action/Clean Water Fund (Doc. #1697, SBC-044999)

May 30, 2023

Via Regulations.gov

Assistant Administrator Radhika Fox Office of Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, N.W.

Washington, DC 20460

Re: PFAS National Primary Drinking Water Regulation Rulemaking,

Docket No. EPA–HQ–OW–2022–0114

Dear Assistant Administrator Fox,

Clean Water Action and Clean Water Fund respectively submit these comments on the proposed PFAS National Primary Drinking Water Regulation Rulemaking. They complement those we have joined with the Natural Resources Defense Council, Earthjustice, et al.

The Proposal is Consistent with the Safe Drinking Water Act and the PFAS Strategic Roadmap

The proposal is consistent with the Safe Drinking Water Act (SDWA), which requires the Environmental Protection Agency (EPA) to promulgate National Primary Drinking Water Regulations (NPDWRs) for contaminants that may have an adverse effect on people's health, that are known to occur or there is a substantial likelihood that they will occur in Public Water Systems with a frequency and at levels of public health concern, and where regulation presents a meaningful opportunity for health risk reduction. The proposal is also consistent with EPA's PFAS Strategic Roadmap, in which EPA committed to "Establish a national primary drinking water regulation for PFOA and PFOS that would set enforceable limits and require monitoring of public water supplies, while evaluating additional PFAS and groups of PFAS." [FN1: PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024, October 18, 2021, https://www.epa.gov/pfas/pfas‑strategic‑roadmap‑epas‑commitments‑action‑2021‑2024#ow.]

PFOA and PFOS first appeared on the Contaminant Candidate List in 2009. Out of the tens of thousands of possible chemicals, pathogens and other potential drinking water contaminants, there was enough information on health effects and occurrence for these chemicals to be included in a list of 116 contaminants (104 chemicals and 12 microbiological contaminants) that merited further research and consideration. Since that time, information on PFOA and PFOS and their health effects and occurrence in drinking water has confirmed the need for drinking water limits, and the pace of research on other PFAS chemicals has accelerated rapidly. As EPA summarizes in the proposal, PFAS chemicals present "significant and diverse" health risks. [FN2: PFAS National Primary Drinking Water Regulation Rulemaking, Federal Register / Vol. 88, No. 60 / Wednesday, March 29, p. 18643.] Some states have already adopted enforceable drinking water limits for some PFAS chemicals. The very existence of the PFAS Strategic Roadmap reflects the rapidly increasing concern about these chemicals among impacted communities, public health professionals, policymakers, researchers, water professionals, public health practitioners, and environmental and health advocates. EPA's proposal meets Safe Drinking Water Act criteria and communities nationwide need these limits to protect people's health and to address growing concern about their presence in drinking water. As noted elsewhere in these comments, aggressive action to rein in PFAS pollution and restrict use of these chemicals is desperately need to address their widespread use and the numerous ways that people are exposed to them.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Association of California Water Agencies et al. (Doc. #1701, SBC-043888)

Meaningfully Advancing a Holistic Approach to Address PFAS

The undersigned organizations support regulation based on scientific evidence that protects human health. We emphasize the shared goal of public water systems and EPA in ensuring access to safe drinking water to the public and we encourage EPA to meaningfully advance this objective through the implementation of its PFAS Strategic Roadmap. The responsibility for pollution remediation should not rest solely on public water systems and their ratepayers.

We recommend that EPA take more proactive measures to identify sources of PFAS and limit their discharges, as prevention is more cost-effective than attempting to clean up pollution later and maintains the polluter pays principle. Advancing regulatory actions that provide source water protection will also reduce the number of systems with PFAS contamination above the proposed drinking water standards. EPA should also work to collaborate with other agencies to address other pathways of public exposure to PFAS, such as food and household products.

As the Administrator, you are responsible for advancing these regulatory actions to protect communities from contamination and the financial burden of mitigating this contamination.

We welcome any opportunity to discuss this matter with EPA further. Please feel free to contact our respective organizations with any questions.

Sincerely,

Tom Dobbins

Chief Executive Officer

Association of Metropolitan Water Agencies

G. Tracy Mehan III

Executive Director of Government Affairs

American Water Works Association

Matthew Holmes

Chief Executive Officer

National Rural Water Association

Adam Krantz

Chief Executive Officer

National Association of Clean Water Agencies

Rob Powelson

President and CEO

National Association of Water Companies

Clarence E. Anthony

CEO and Executive Director

National League of Cities

Dave Eggerton

Executive Director

Association of California Water Agencies

Tom Cochran

CEO and Executive Director

The U.S. Conference of Mayors

Steve Dye

Legislative Director

Water Environment Federation

Patricia Sinicropi

Executive Director

WateReuse Association

Leslie Wollack

Executive Director

National Association of Regional Councils

Beth Eckert

President

North Carolina Water Quality Association

Susan Gilson

Executive Director

The National Association of Flood and Stormwater Management Agencies

Arthur Shapiro, P.E.

President

Maryland Association of Municipal Water Agencies

Chris Kahler

President

South Carolina Water Quality Association

Timothy A. Mitchell, P.E.

President

Virginia Municipal Drinking Water Association

Jeremiah Johnson

President

West Virginia Municipal Water Quality Association

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045142)

Wastewater and Stormwater

MassDEP supports EPA's work to address PFAS under the Agency's PFAS Strategic Roadmap. The Agency's approach to "get upstream of the problem" is paramount to the long-term protection of both surface water and ground water sources of drinking water.

EPA must expedite the Agency's work to address PFAS in wastewater and stormwater inflows and discharges, including the development of rulemakings for PFAS effluent limitation guidelines for the organic chemicals, plastics and synthetic fibers, and metal finishing and electroplating point source categories, as well as studying PFAS inputs and discharges from landfills, paper and textile mills, and electrical and electronic components. The Agency should work to finalize Draft Method 1633 in a timely manner for laboratories to analyze samples of surface water, groundwater, and other media. EPA should also finalize the national recommended ambient water quality criteria for PFAS. MassDEP awaits EPA's assistance and guidance in these areas in connection with the development of water quality standards and future regulation of the discharge of PFAS in wastewater effluent. Further Clean Water Act actions should continue to be taken simultaneously with the Agency's other efforts. PFAS will remain a

problem for drinking water systems so long as all sources of PFAS contamination are not addressed.

EPA Response: Please see section 15.1 of the EPA response in this *Response to Comments* document.

Section 15 References

No references were cited within the EPA response in this section.

16 Potential Final CFR Changes

16.1 §141.2 Amendments

Individual Public Comments

Environmental Monitoring Coalition (EMC) (Doc. #1625, SBC-043107)

As measurement experts, our additional comments below will pertain solely to method/measurement aspects of the regulation. Our comments for clarification are detailed below.

In addition, EMC wishes to point out a typographical error. In the proposed regulatory text at 141.2, the molecular formula for PFOA was shown as C8F15CO2–. The correct formula is C8F15O2–.

EPA Response: In response to this comment and others, the chemical formula has been corrected.

Association of Public Health Laboratories (APHL) (Doc. #1646, SBC-043308)

As measurement experts, our additional comments below will pertain solely to method/measurement aspects of the regulation. Our comments for clarification are detailed below.

In addition, EMC wishes to point out a typographical error. In the proposed regulatory text at 141.2, the molecular formula for PFOA was shown as C8F15CO2–. The correct formula is C8F15O2–.

EPA Response: Please see the EPA response to comment Doc. #1625, SBC-043107 in section 16.1 in this *Response to Comments* document.

16.2 §141.61 Amendments

Individual Public Comments

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045161)

Given the importance of the HBWCs, it would be appropriate to list them in a table in § 141.903 rather than referring to a footnote to the table in § 141.61 as is done in § 141.903(f)(2)(i).

EPA Response: The EPA agrees. The EPA has included a separate table (Table 4 to 141.61(c)) to list Health Based Water Concentrations (HBWCs) more prominently alongside Maximum Contaminant Levels (MCLs) for regulated PFAS.

16.3 §141.900-905 (Subpart Z) Additions

Individual Public Comments

Missouri Department of Natural Resources (Doc. #1563, SBC-042507)

General Comments

EPA should strive to make the language in the final rule more concise and easier to understand to aid small systems with the implementation of the rule. The hazard index, deviations from the synthetic organic contaminant (SOC) standard monitoring framework (SMF), and low quantifiable detections in the rule are very complex topics and they will make the rule more challenging for many public water systems to understand and implement. This is especially the case for small and medium-sized systems that already struggle to implement the existing framework of national primary drinking water regulations. The closer the rule can remain to the SOC standard monitoring framework, the easier it will be for systems to understand and for primacy agencies to implement.

EPA Response: The EPA has added language where appropriate to improve the understandability of the rule. Subpart Z has been revised to minimize redundancy and utilize more direct cross-referencing.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045174)

It is unclear why the same language is repeated, with small variations, in § 141.903 and § 141.905: § 141.903(b) matches § 141.905(b)(1); § 141.903(c) matches § 141.905(2)(ii); § 141.903(d) matches § 141.905(b)(2); § 141.903(e) matches § 141.905(b)(2)(i) and § 141.903(f)(1)(iii) and § 141.903(f)(2)(iii) match § 141.905(b)(2)(iii). Excessive language makes the rule more difficult to interpret, easier to miscite and more confusing to the regulated community.

EPA Response: The EPA has made changes to reduce redundancy, except where repetition of requirements was deemed necessary. Cross references between the sections have been added where appropriate.

16.3.1 §141.901 Analytical Requirements

Individual Public Comments

Oklahoma Department of Environmental Quality (DEQ) (Doc. #1616, SBC-043041)

Analytical Requirements

In proposed 141.901(b)(2)(i), it is indicated that data must be reported "for concentrations at least as low as the ones listed in the following table….” However, the referenced table appeared to be missing.

EPA Response: The EPA has corrected the subsection mentioned by the commenter, which is § 141.901(b)(2)(iii) in the final rule, to instead reference the correct table in § 141.902(a)(5).

Association of State Drinking Water Administrators (ASDWA) (Doc. #1628, SBC-044101)

Finally, a table appears to be missing from the proposed rule where it is referenced in 141.901(b)(2)(i) and says that “certified laboratories (that)must report “quantitative data for concentrations at least as low as the ones listed in the following table…”

EPA Response: Please see the EPA response to comment Doc. #1616, SBC-043041 in section 16.3.1 in this *Response to Comments* document.

North Carolina Division of Water Resources (NCDEQ) (Doc. #1652, SBC-044186)

Finally, there appears to be a table missing from the proposed rule where it is referenced in 141.901(b)(2)(i) and says that “certified laboratories (that)must report ‘quantitative data for concentrations at least as low as the ones listed in the following table…’

EPA Response: Please see the EPA response to comment Doc. #1616, SBC-043041 in section 16.3.1 in this *Response to Comments* document.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-052946)

• As previously noted, [sec] 141.901(b)(2)(i) states that laboratories should "report quantitative data for concentrations at least as low as the ones listed in the following table" for PFAS; however, that referenced table appears to be missing from the proposed regulatory language. As such, it is not clear what reporting levels are to be used for any of the six PFAS included in the proposed regulation. DEP is not able to comment on information missing from the proposed rulemaking. However, for the four PFAS components included in the HI calculation, their PQLs are listed in Table 1 to [sec] 141.903(f)(l)(iii) as:

[Table 1: See Docket ID: EPA-HQ-OW-2022-0114-1626]

It is not clear whether labs are to report only to these levels, or to levels that are one-third of the PQLs, for inclusion in the HI calculation. As noted previously, results reported below the PQL for any contaminant would be qualified data and would not be legally defensible results for use in determining compliance or monitoring frequencies.

EPA Response: The EPA agrees with the commenter that the referenced table was not appropriately cited within the Code of Federal Regulations (CFR) of the proposed regulatory

language. The EPA has clarified the requirements for laboratories to now read "For all samples analyzed for regulated PFAS in compliance with § 141.902 (Monitoring requirements), beginning [**INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER**], report data for concentrations as low as the trigger levels as defined in § 141.902(a)(5)." The EPA disagrees with the commenter's assertion that results reported below the practical quantitation level (PQL) would not be sufficient in determining required monitoring frequency. See section 8.8 and 8.1.2 of the EPA response in this *Response to Comments* document for a discussion of the use of data below PQLs for establishing monitoring frequencies, as well as section 8.2 of the EPA response in this *Response to Comments* document for compliance determinations.

16.3.2 §141.902 Monitoring Requirements

Individual Public Comments

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045155)

§ 141.902(b)(1)(i) should refer to Subpart H systems if that is what is meant by "surface water CWS and NTNCWS." This would make § 141.902(b)(1)(iii) unnecessary. Additionally, the language in § 141.902(b)(1)(iii), "based on system size" is irrelevant as all sizes of Subpart H systems must collect four consecutive quarterly samples.

EPA Response: The EPA acknowledges that Subpart H systems has been used to refer to public water systems using surface water or ground water under the direct influence of surface water (GWUDI) as a source that are subject to the requirements of Subpart H of 40 CFR Part 141. However, in order to be more explicit, the EPA has maintained § 141.902(b)(1)(iii) to directly refer to requirements for GWUDI systems. The EPA agrees that system size is irrelevant with respect to initial monitoring requirements for GWUDI and surface water systems and has therefore removed "based on system size" from the cited subsection.

Washington State Department of Health (DOH) (Doc. #1665, SBC-044438)

Page 18752, Table 2 to Paragraph (b)(2)(i)

• It is unclear what "except as otherwise provided by the State" means in the context of compliance monitoring and Table 2 to Paragraph (b)(2)(i). Does this mean States have the option to devise a different monitoring scheme? Please clarify.

• Using PFAS sample results below the PQL is not appropriate for calculating a running annual average. This approach seems to conflict with Table 1 to Paragraph (f)(1)(iii).

Page 18752, 141.XX Monitoring Requirements (iv)

• States may delete results of obvious sampling errors from this calculation. DOH requests the ability to delete sample results that have obvious laboratory errors.

EPA Response: Please see section 8.2 of the EPA response in this *Response to Comments* document regarding the ability of states to institute compliance monitoring requirements that are at least as stringent as those promulgated by the EPA, consistent with the requirements in § 142.16(r). In response to this commenter's concern, the EPA deleted "except as otherwise provided by the State" in the paragraph preceding the eligibility requirements for different sampling frequencies, which are identified in Table 3 to paragraph (b)(2) of section 141.902 in the final rule. Instead, the EPA has inserted language indicating that a state may increase the required monitoring frequencies in § 141.902 (b)(2)(vi) in the final rule.

Regarding the comments about samples containing concentrations below PQLs, please see section 8.2 of the EPA response in this *Response to Comments* document. Concentrations below the PQL are only treated as zero when calculating a running annual average (RAA) to determine rule compliance. See also sections 7.2 and 5.1.2 of the EPA response in this *Response to Comments* document for further discussion of PQLs. See sections 8.1.2 and 8.8 of the EPA response in this *Response to Comments* document for a discussion of the use of data below PQLs for establishing monitoring frequencies.

Regarding the allowance for states to delete the results of obvious sampling errors, please see the EPA response to comment Doc. #1679, SBC-044959 in section 8.2 in this *Response to Comments* document.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045157)

§ 141.902(b)(1)(vi) appears to require only that supplemental monitoring necessary to complete the requirements of Table 1 to Paragraph (b)(1)(iv) be completed by three years after final promulgation (the presumptive compliance date). There is a need to clarify whether all initial monitoring, using new samples, existing samples, or a combination of the two, must be completed by this same date. If the intent is to complete all initial monitoring by this date, MassDEP recommends that the final sentence of § 141.902(b)(1)(vi) be moved to a new subparagraph (vii).

EPA Response: A separate subparagraph (141.902(b)(1)(xi)) has been added to the final rule to clarify that all initial monitoring requirements must be completed by a date three years from final rule publication. See section 8.1.1 of the EPA response in this *Response to Comments* document for additional discussion of the initial monitoring timeline.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-052947)

• In [sec] 141.XX(a)(8) of the proposed rulemaking, it is not clear as written how this will apply to the HI MCL. The paragraph states: "Based on initial monitoring results, for each sampling point at which a contaminant listed in [sec] 141.61(c) is detected at a level greater than or equal to the trigger level, the system must monitor quarterly for all regulated PFAS beginning in the next quarter... " It is not clear whether this is referring to the HI calculated trigger level of 0.33,

or whether this is referring to some individual reporting level for the individual component PFAS in the HI calculation.

EPA Response: For the final rule, this section has been restructured. Table 1 in §141.902(a)(5) now provides trigger levels for individual contaminants as well as the Hazard Index. §141.902(b)(2)(i) now states that, based on initial monitoring, "systems may reduce monitoring at each sampling point at which all reported sample concentrations were below all rule trigger levels defined in § 141.902(a)(5)" and that "if a sampling point is not eligible for triennial monitoring, then the water system must monitor quarterly at the start of the compliance monitoring period." Thus, if a sampling point meets or exceeds the trigger level for the Hazard Index during initial monitoring, the system must begin quarterly monitoring for that sampling point. Note that for the final rule, the trigger level for the Hazard Index has been increased to 0.5; see section 8.8 of the EPA response in this *Response to Comments* document for further discussion about increasing the trigger level.

16.3.3 §141.903 Compliance Requirements

Individual Public Comments

Philadelphia Water Department (PWD) (Doc. #1709, SBC-045753)

EPA should revise Section 141.903(e) to read "If any quarterly sample result or quarterly average, if more than one sample is available for the quarter, will cause the running annual average to exceed the MCL at any sampling point, the system is out of compliance with the MCL immediately." Alternatively, if EPA does not wish to change the language of Section 141.903(e), EPA could add an additional subclause to Section 141.903(f) that states "For systems monitoring more frequently than quarterly, systems must average all the results in a quarter, then average the quarterly averages. Quarterly averages should not be computed until all samples within the quarter are collected."

EPA Response: Please see the EPA response to comment Doc. #1709, SBC-045752 in section 8.2 as well as section 8.2 of the EPA response in this *Response to Comments* document. The EPA has modified the language in 141.903(e) to reflect the possibility that multiple compliance samples may be available in a quarter due to the state requiring a confirmation sample.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-052949)

• [sec] 141.903(f)(2)(i) is not consistent on how the HI is to be calculated for systems on a quarterly monitoring frequency. The preamble to the proposed rulemaking, EPA webinars on the proposed rule, and guidance made available with the proposed rule all state that an RAA is to be used. However, the language in this paragraph is different and states (emphasis added): "For systems monitoring quarterly, divide observed sample analytical results by the corresponding HBWC listed in[sec] 141.61(c) to obtain a Hazard Quotient/or each sampling event at each

EPTDS. Sum the resulting Hazard Quotients together to determine the Hazard Index. If more than one compliance sample is available for an analyte in a quarter, systems must average all the results for that analyte in that quarter and then determine the Hazard Quotient(s) from those average values. If the Hazard Index exceeds the MCL, the system is not in compliance with the Hazard Index MCL requirements." Each sampling event is assumed to be each quarter, and there is no description of how to calculate an RAA; rather, the language seems to indicate that a single quarterly HI exceedance would result in a HI MCL violation. The language in paragraph (i) is very similar to the language in paragraph (ii).

EPA Response: §141.903(f)(2)(i) has been updated to accurately reflect that Hazard Index MCL exceedance is assessed based upon an RAA calculated from a year of quarterly monitoring and not based upon a single quarter (unless the conditions described in §141.903(e) apply).

16.3.4 §141.904 Reporting and Recordkeeping Requirements

Individual Public Comments

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045170)

Reporting and recordkeeping

MassDEP submits the following comments related to the reporting and recordkeeping requirements set forth in 40 CFR § 141.904 of the proposed rule (page 18753 of the Federal Register notice):

• In Table 1 to § 141.904 it appears that the reference to § 141.902 in item 3 for systems monitoring quarterly should point to § 141.903 as that is where the MCL compliance calculation is described.

EPA Response: The EPA agrees with the commenter that § 141.903 is the correct cross reference for the MCL compliance calculation. This has been updated in Table 2 of § 141.904 (after paragraph (b)). Note that an additional table (Table 1) has been added to the section to include reporting requirements from initial monitoring. Cross references regarding the trigger levels also now direct more specifically to § 141.902(a)(5).

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045163)

MassDEP suggests that EPA clarify why the language of § 141.903(f)(2)(ii) doesn't match the corresponding language in § 141.903(f)(1)(ii). In the first case the requirement is to "report the results of each sampling event" whereas the requirement to "report" is missing in the second case.

EPA Response: For the final rule, reporting requirements are discussed in § 141.904. References to "report" in the subsections cited by the commenter have been removed. Tables 1 and 2 in § 141.904 of the final rule indicate that systems must report all sample results.

16.3.5 §141.905 Violations

Individual Public Comments

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045172)

Violations

MassDEP submits the following comments and questions related to violations, as set forth in 40 CFR § 141.905 of the proposed rule (page 18753 of the Federal Register notice):

• § 141.905(a) is missing full citations ("§ 141.XX.d" and "§ 141.XX.c").

EPA Response: The incomplete citations mentioned by the commenter were intended to reference MCL compliance requirements and monitoring requirements, respectively. For the final rule, § 141.905 has been restructured. The language in the first sentence of paragraph (a) was updated to cite § 141.903 (where Compliance Requirements are identified) instead of 141.XX.d. The second sentence, regarding failure to monitor, was moved to a new paragraph (c), and the citation to § 141.XX.c was replaced with § 141.902.

16.4 §142.61-62 Amendments

Individual Public Comments

Robert Hollander (Doc. #1516, SBC-042716)

11. 88 FR 18754

The official Federal Register version shows a capital B instead of the correct lower case b in CFR 142.61 Table 2 - List of Small System Compliance Technologies for PFAS, under the column labeled "Limitations" for the "Unit Technology" GAC.

EPA Response: The EPA agrees that Table 2 of § 141.62, row 2, column 2 should have contained a single lowercase "b" instead of the upper case "B" in the proposed rule. For the final rule, this table has been restructured, and footnote b is no longer needed. The issue the commenter described is no longer present. The revised table is Table 3 in § 142.62 in the final rule.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045166)

Table 2 to Paragraph (a) in § 142.62(a) includes "B" in the Limitations for GAC. It is unclear if this refers to footnote "b." If so, it should be lower case. Footnote c to this same table should not refer to EPA's "proposed" MCLs as this language will not be accurate after the MCLs are final.

EPA Response: Please see the EPA response to comment Doc. #1516, SBC-042716 in section 16.4 in this *Response to Comments* document regarding footnote B. In addition, the title of the Table has been revised to remove the word "proposed."

16.5 Additional Comments

Individual Public Comments

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-044880)

• [sec] 141.900(a) states that "control of certain PFAS is required" for community water systems (CWS) and non-transient non-community water systems (NTNCWS), and that they must comply with the MCLs "for certain PFAS." DEP believes that the use of the phrase "certain PFAS" is unclear and misleading, since it implies that water systems must comply with some, but not all, of the MCLs for PFAS. DEP reiterates the need to define the terms "PFAS" and "regulated PFAS" and to use those phrases consistently throughout the proposed rulemaking.

• DEP believes that it is confusing to add PFAS to the best available technology (BAT) table in[sec] 141.61 because it only lists granular activated carbon (GAC) as BAT for the PFAS specified in[sec] 142.62. DEP also questions why PFAS BAT is specified in Part 142, but not in [sec] 141.61 or Subpart Z and questions the appropriateness of this.

• Neither [sec] 141.904 nor [sec] 141.31 provides the option that RAA values need not be reported if the state performs the calculation for the system. DEP notes that this should be explicitly stated if that is the intent of the proposed rulemaking.

• DEP notes that[sec] 141.903(d) states that a system "will not be considered in violation of an MCL until it has completed one year of quarterly sampling", but[sec] 141.903(e) states that "if any sample result will cause the running annual average to exceed the MCL... the system is out of compliance with the MCL immediately." These two statements appear to be contradictory. While DEP understands the intent of these paragraphs relative to implementation, it is contradictory to state that a system will not be considered in violation until they have a complete year of sampling when they could in fact be in violation after only one quarter if levels are high enough.

EPA Response: The commenter raises several points to which the EPA is responding below:

- The EPA has removed most instances of "certain PFAS" and instead generally references "regulated PFAS" in § 141.900 to 141.905. The one remaining use of "certain PFAS" in the definition of the Hazard Index for use in Consumer Confidence Reports (CCRs) is contextually appropriate as a plain language description of the Hazard Index because it is non-regulatory language that does not require further elaboration. The PFAS contaminants considered in the Hazard Index are included in one of the subsequent sentences of that definition.
- Regarding the best available technologies (BATs) tables for PFAS, the EPA has created separate tables for the PFAS MCLs and BATs for regulated PFAS in the final rule. The BATs provided in Table 5 and Table 6 in § 141.61 are now consistent with those shown in Table 1 and Table 3 in § 142.62.
- The EPA intends for the system to report the RAA to ensure the system is aware of the calculated RAA relative to the MCL. This requirement for systems monitoring quarterly to report the RAA is explicitly stated in Table 2 in § 141.904(b) in the final rule and was stated in Table 1 in § 141.904 of the proposed rule. Please also see section 11.2 of the EPA response in this *Response to Comments* document.
- Paragraphs 141.903(d) and 141.903(e) have been modified. Paragraph 141.903(e) now clarifies that, whenever a sample result in any quarter, or the average of multiple samples within a quarter if the state required a confirmation sample, causes the RAA to exceed the MCL at any sampling point regardless of the monitoring results of subsequent quarters required to complete a full year of quarterly monitoring, the system is out of compliance with the MCL immediately. This is consistent with the approach used for other SOCs. If a sample meets the exception criteria the system is immediately in violation of the MCL. Paragraph 141.903(d) is now limited to stating that systems monitoring annually or triennially that have a sample result equal to or exceeding an MCL or trigger level, respectively, must begin quarterly sampling. See also section 8.2 of the EPA response in this *Response to Comments* document for additional discussion of assessing violations based on an RAA, including scenarios that meet this exception.

Pennsylvania Department of Environmental Protection (Doc. #1626, SBC-044878)

DEP offers the following comments, questions, and recommendations to EPA to clarify and strengthen the proposed rulemaking. Comments are grouped by topic, as indicated by the heading of each section.

General Requirements

• Effective dates within the proposed rulemaking are inconsistent and are written as both the date of publication of the final rule in the Federal Register in some locations, and a date three years after the date of publication of the final rule in the Federal Register in other locations. Specifically:

o [sec] 141.6 lists an effective date three years after date of publication of the final rule for:

• [sec] 141.50 Maximum contaminant level goals (MCLG)for organic contaminants.

• [sec] 141.60 Effective dates. However,[sec] 141.60(a)(4) lists an effective date of the date of publication of the final rule in the Federal Register for MCLs and is inconsistent with and contradicts [sec] 141.6. Alternatively, this statement in[sec] 141.60(a)(4) is unimplementable because the statement itself is not effective until three years after the date of publication, as required by [sec] 141.6. Also, if MCLs are in fact effective upon publication, this is inconsistent with MCLGs, which are not effective until three years after publication.

• [sec] 141.61 Maximum contaminant levels for organic contaminants.

• [sec] 141.154 Required additional health information. DEP questions why this is separated out from the list that follows.

• [sec] 141.151 through 141.155 Consumer Confidence Report (CCR).

• [sec] 141.201 through 141.211 Public Notification (PN).

o [sec] 141.900(b) just reads "Compliance dates" but no compliance dates are identified. Compliance dates for initial monitoring are also not identified in [sec] 141.XX(b)(I) Initial compliance period. The timeframe specified in [sec] 141.XX(b)(vi) only applies to monitoring that is needed to supplement previously-acquired data to satisfy the initial monitoring requirements. DEP believes that compliance dates for the start of the initial compliance monitoring period must be identified in the rulemaking.

o [sec] 141.XX(a)(6) requires new systems, or systems using a new source after the date of publication of the final rule in the Federal Register to demonstrate compliance with the MCLs. However, the MCLs (and PN requirements for any MCL exceedances) are not effective until three years after publication, according to[sec] 141.6.

Consistent with Section 300g-l(b)(10) (relating to national drinking water regulations) of the federal Safe Drinking Water Act and in order to allow states sufficient time to review the final rule and promulgate associated state regulations, DEP strongly encourages EPA to set the effective date of the MCLs and any required monitoring and compliance provisions to take effect on the date that is three years after the date on which the final regulation is promulgated.

• DEP notes that there are missing cross references and cross references to citations or tables that do not exist in the proposed rulemaking. Specifically:

o [sec] 141.60(a)(4) is missing a cross reference to[sec] 141.61 and should read (emphasis added to suggested additional language): " The effective date for paragraphs (c)(34) through (c)(36) of[sec] 141.61 is ... "

o [sec] 141.lSl(d) specifies that the Consumer Confidence Reporti (CCR) must include PFAS results that are detected, and that "detected means: at or above the levels prescribed by ... [sec] 141.902(a)(9) for PFAS... ". However,[sec] 141.902 does not exist.

o DEP questions whether [sec] 141.XX Monitoring requirements is intended to be [sec] 141.902 since it comes between[sec] 141.01 and[sec] 141.903. If that is the case, [sec] 141.902(a)(9) (which is published as[sec] 141.XX(a)(9)) then refers to [sec] 141.903(f)(l)(i)(3) for a reportable detection. This is very confusing to have multiple cross references to multiple citations. The cross reference should be directly to the location containing the referred information.

o It is also important to note that the second cross reference noted above in [sec] 141.XX(a)(9)-which DEP believes is intended to be[sec] 141.902(a)(9)-to [sec] 141.903(f)(l)(i)(3) is also a citation that does not exist. DEP believes that this may have been intended to refer to the table listing the PQLs, located in [sec] 14l .903(f)(l)(iii). If that is the case, DEP has specific concerns relative to those reporting limits; those concerns are noted in separate comments below.

o Table 1 to[sec] 141.904 refers multiple times to[sec] 141.902. However, as noted above, [sec] 141.902 does not exist (unless 141.XX is intended to be[sec] 141.902).

o [sec] 141.01(b)(2)(i) states that labs should report "concentrations at least as low as the ones listed in the following table... ". However, the referenced table does not exist; there is no table listing minimum reporting concentrations in the proposed rulemaking.

o [sec] 141.01(b)(2)(i) also references compliance with[sec] 141.902 Monitoring requirements. Again, DEP notes that[sec] 141.902 does not exist, but assumes that [sec] 141.XX is intended to be[sec] 141.902.

o Appendix A to Subpart Q (relating to PN) references [sec] 141.XX as the citation for the PN violation tiers or PFAS. However, as already noted, DEP questions if this is in fact intended to refer to[sec] 141.902.

EPA Response: The commenter raises several points to which the EPA is responding below:

- The EPA has clarified the various applicable deadlines and effective dates throughout the CFR amendments, most broadly in § 141.6 and § 141.900. Some of these milestones fall 60 days after publication of the final rule in the Federal Register (analytical requirements), others fall 3 years after the date of promulgation (reporting of results from initial monitoring, meeting reporting and recordkeeping requirements, and the start of compliance monitoring requirements), and others fall five years after promulgation (meeting MCL compliance requirements). See section 12.1 of the EPA response in this *Response to Comments* document for discussion about the compliance deadline requirements for MCLs. The EPA has removed reference to any provisions being effective on the date of publication in the Federal Register.
- The EPA has clarified that the requirements in the cited language (§ 141.902(a)(4) in the final rule) only apply to systems that begin operation or use a new source of water after three years after the date of promulgation. After that time, these systems are required to document MCL compliance within a period of time specified by the state.

- The amendment to § 141.154 in the proposed rule mentioned by the commenter was removed from the final rule.
- The section labeled "§ 141.XX. Monitoring Requirements" in the proposed rule was corrected to § 141.902 for the final rule.
- Concerns regarding cross references mentioned by the commenter were also addressed.
    - A cross reference to § 141.61 was added to § 141.60(a)(4).
    - The cross reference included in § 141.151(d) for PFAS now leads directly to the location of the table that provides the trigger levels for the regulated PFAS: § 141.902(a)(5) in the final rule, which are used as the thresholds used for reporting detections of regulated PFAS in CCRs.
    - The contents of § 141.901(b)(2)(i) of the proposed rule are now located in § 141.901(b)(2)(iii) and now accurately also cross reference to § 141.902(a)(5).
- Regarding Appendix A to Subpart Q, the intended citation for Monitoring & Testing Procedure Violations was § 141.905(c), as this is the section that identifies violations.

Massachusetts Department of Environmental Protection (MassDEP) (Doc. #1726, SBC-045152)

6. Monitoring, Analyses, Recordkeeping and Violations

Compliance dates

40 CFR § 141.900(b) does not include any proposed Compliance dates (or a formula based on the date of final promulgation). EPA should include the usual placeholder that allows for three years after the date of the final rule promulgation.

Analytical requirements

MassDEP submits the following comments and questions related to the analytical requirements set forth in 40 CFR § 141.901 of the proposed rule (beginning on page 18750 of the Federal Register notice):

• There appears to be a table missing from the proposed rule as referenced in § 141.901(b)(2)(i) "Beginning…report quantitative data for concentrations at least as low as the ones listed in the following table [emphasis added] for all PFAS samples analyzed for compliance with § 141.902 (Monitoring Requirements)."

• It is unclear why a new Subpart would have a [Reserved] section at § 141.901(b)(2)(ii).

• MassDEP notes that EPA Method 537.1 v 2.0 (March 2020, EPA/600/R-20/006) is omitted from 40 CFR § 141.901(a)(2). Is it EPA's intent not to accept this updated version of Method 537.1? Similarly, was direct EPA certification of laboratories intentionally omitted in § 141.901(b)(2)? EPA certified laboratories are acceptable for other SOC analyses as per § 141.24(f)(17).

Monitoring and compliance requirements

MassDEP submits the following comments and questions related to the monitoring and compliance requirements set forth in 40 CFR § 141.902 and § 141.903 of the proposed rule (beginning on page 18751 of the Federal Register notice):

• The end of § 141.902(a)(7) should be reworded, "and 0.33 for the PFAS Hazard Index." Are these triggers evaluated using qualified ("J" estimated) sample results or are individual results below the PQL replaced with zeros as is proposed for MCL compliance calculations?

EPA Response: The commenter raises several points to which the EPA is responding below:

- Regarding compliance dates in § 141.900(b), the EPA has revised § 141.900(b) to include a list of compliance dates for specific aspects of the final rule.
- With respect to the missing table in § 141.901(b)(2)(i), please see the EPA response to comment Doc. #1616, SBC-043041 in section 16.3.1 in this *Response to Comments* document.
- There are no longer any sections marked [Reserved] in the CFR amendments.
- The EPA has corrected the citation and link included in the § 141.901(a)(2) to Method 537.1 Version 2.0 rather than Version 1.0.
- The EPA agrees that laboratories certified by either the EPA or the state are acceptable, consistent with certification requirements for laboratories analyzing for other chemicals, and has corrected § 141.901(b)(2) as well as § 141.28 to say "by EPA or the State."
- The EPA revised §141.902(a) so that the trigger levels are defined in Table 1 to 141.902(a)(5) for the final rule rather than in text.
- Per § 141.903(f)(1)(iv) and § 141.903(f)(2)(iv), zero is used in place of sample results less than the PQL when calculating RAAs to determine compliance with MCLs. However, per § 141.902(a)(6) and Table 3 in §141.902(b)(2)(iv), detections at or above the trigger level, even if below the PQL, impact the required monitoring frequency at a sampling point. Please see sections 8.1.2 and 8.2 of the EPA response in this *Response to Comments* document for further discussion of these issues.

<u>Environmental Protection Network (EPN) (Doc. #1773, SBC-043873)</u>

In the rule sections below, EPN recommends specific changes in order to clarify the monitoring requirements. We also recommend deleting redundant text in several sections because the language is inconsistent and can lead to confusion and poor implementation of the monitoring requirements. Para (l) – effective date should be the first day of a calendar quarter in order to simplify compliance monitoring. When the final rule is submitted to the Federal Register for publication, EPA should put a date certain rather than basing it on the vagaries of Federal Register publishing schedule. The Office of Ground Water and Drinking Water has done this in the past, including for the Stage 2 Disinfectants and Disinfection Byproducts Rule (DBPR) and the Long Term 2 Enhanced Surface Water Treatment Rule. This simplifies setting up quarterly monitoring.

§ 141.50

Para (b)(34) footnote 1 – there is inconsistent use of significant figures. For example, PFNA is 10 ppt, while PFHxS is 9.0 ppt, HFPO-DA is 10.0 ppt and PFBS is 2000.0 ppt. Also, the equation at the end of the footnote uses different significant figures. Finally, the use of i.e. instead of e.g. appears to be more appropriate.

§ 141.60

Para(a)(4) – refers to effective dates for paragraphs not included in the proposal. It appears that the reference should be to 141.61(c)(34)-(36).

§ 141.900

Para (b) – no language proposed.

Para (c) – appears to be at least partially redundant to the requirements in para (a).

§ 141.XX (assume this should be 141.902)

Para (a)(3) – monitoring violations should be for all quarters for which a missed sample would have been used for running annual average calculation, as was done for Stage 2 DBPR. See 141.625(b).

Para (a)(4) – Redundant to 141.903(c). Should be deleted.

Para (a)(6) – New systems and new sources should be required to be in compliance prior to going on line. The proposed language is ambiguous.

Para (b)(1)(i)-(iii) – use the already defined term "subpart H systems" (see 141.2) to refer to systems using either surface water or groundwater under the influence of surface water in paragraphs (i) and (ii). This will make paragraph (iii) redundant. Also, why is there a reference in paragraph (iii) to the State being allowed to require more frequent monitoring but no such reference in paragraphs (i) and (ii)? This could imply that the State couldn't require more frequent monitoring under those paragraphs, which doesn't appear to make sense.

Para (b)(1)(iv) – Table 1 is more specific and clear than paragraphs (b)(i)-(iii) except that systems using GWUDI are not included in the table. Use of "subpart H systems" in the table makes paragraphs (i)-(iii) redundant and reduces inconsistency and ambiguity. Also requiring samples at least 90 days apart for large groundwater systems and all subpart H systems is not practical. The requirement should be for samples to be collected every third month to ensure appropriate spacing while allowing systems and laboratories to collect and analyze samples in a cost-effective manner. EPA and States had implementation issues with the Stage 2 DBPR because of this issue. Finally, it is not clear why the term "taken" is used for one set of systems and "acquired" is used for another set of systems in the table and elsewhere in the rule.

Para (b)(1)(vi) – use "subpart H systems."

Para (b)(2)(i) – allows systems to be on reduced monitoring for some entry points and on routine monitoring for others. It could also be interpreted to allow reduced monitoring for some contaminants but not others at individual EPTDS. This is, at a minimum, a tracking nightmare and makes it difficult to develop and implement a monitoring plan. It also may be less protective of public health. However, Table 2 appears to require that all analytes meet the reduced monitoring requirement for any analyte to be on reduced monitoring. To reduce ambiguity and confusion, requirements should not be repeated if possible. Instead, they should be cross referenced as necessary. Also, tables are generally clearer than text.

Para (b)(2)(iii) – Use "locational running annual average" ("LRAA") in lieu of "running annual average" in this paragraph and elsewhere (e.g., 141.903(b)).

Para (b)(2)(vi) – Requires States to designate monitoring time. This imposes a tremendous and unnecessary implementation burden on the State. Should be "according to the monitoring plan for the system." The State retains its authority to review and require modifications.

§ 141.903

Para (c) – clarify that this is both a monitoring violation and that RAA/LRAA is calculated by dividing by the actual number of samples (which could also be an MCL violation if the RAA/LRAA exceeds the MCL).

Para (d) – seems partially redundant to 141.902(b)(2)(iii). System must begin quarterly monitoring when a result exceeds the trigger.

Para (e) – should be under paragraph (f) rather than as a separate paragraph.

Para (f)(1) – For clarity, add "determine MCL compliance at each EPTDS by calculating the LRAA for each subpart Z analyte" to the end of the sentence.

Para (f)(1)(ii)(A) – seems redundant and probably less stringent than 141.902(b)(2)(iii). Systems must begin quarterly monitoring when a result exceeds the trigger, not just the MCL.

Para (f)(1)(iii) – use of zero for monitoring results below the PQL for any analyte except PFBS is not protective of health. For example, assume EPTDS PFOA results for 4 consecutive quarters are 3.8, 3.8, 3.8, and 5.2 ppt. Using zero for the 3 quarters with results below the PQL of 4.0 results in an LRAA of 1.3 ppt ((0 + 0 + 0 + 5.2)/4). The system nearly meets criteria for reduced monitoring. If systems must use the detection limit, the LRAA is 4.1 ppt ((3.8 + 3.8 + 3.8 + 5.2)/4), which is an MCL violation. For HI calculations, there is a similar issue. Hazard quotients (HQ) for HFPO-DA <0.5 (<5/10), PFHxS <0.33 (<3/9), and PFNA < 0.4 (<4/10) would be zero for HI compliance calculations, which is not protective.

Para (f)(2)(i) – Last sentence should read "…, the system is in violation of the Hazard Index „„".

Para (f)(2)(ii) – See comments on paragraph (f)(1)(iii) of this section.

§ 141.904

Table 1 – references in 3 and 4 seem to be to 141.903, not to 141.902.

§ 141.905

Para (a) – correct reference to 141.XX.

Para (b)(2) and (b)(2)(i) – see 141.629(a)(1)(iii) for MCL RAA/LRAA violations based on fewer than four quarters of monitoring.

Para (b)(2)(iii) – redundant to 141.903. Also see other comments regarding use of zero for monitoring results < PQL.

EPA Response: The commenter raises several points to which the EPA is responding below:

- The EPA has revised the amendments to the CFR to reduce redundancy where possible. Please see section 8.1.1 of the EPA response in this *Response to Comments* document. As it notes, the EPA added specific dates under 40 CFR § 141.900(b)(2), including the date when compliance monitoring will begin, which is three years following rule promulgation pursuant to the requirements of the Safe Drinking Water Act (SDWA) Section 1412(b)(10) and will not necessarily be at the start of a calendar quarter.
- Regarding the commenter's remarks on the footnote to paragraph§ 141.50(b)(34), all numbers in the footnote regarding the Hazard Index calculation, as well as the MCLGs presented in paragraphs § 141.50(b)(34) through (37), have been updated to include a single significant figure and the footnote has been modified such that neither "e.g." nor "i.e." are included. Consistent use of significant figures has also been reflected in Table 4 of § 141.61 of the final rule as well as the associated footnote. The EPA notes that MCLs for PFOA and PFOS include two significant figures. See sections 4.3.4 and 5.1.7 of the EPA response in this *Response to Comments* document for further discussion of significant figures.
- With regard to the comment on § 141.60, paragraph (a)(4) has been updated to include the correct effective date (five years after publication) and further specify the location of the cited MCLs (Table 4 to § 141.61). See section 12.1 of the EPA response in this *Response to Comments* document for discussion about the compliance deadline requirements for MCLs.
- Within § 141.900, compliance dates have been added to paragraph (b). Further, paragraph (c) has been removed.
- The EPA confirms that the section header listed as "§ 141.XX. Monitoring requirements." in Subpart Z of the proposed rule was intended to be "§ 141.902 Monitoring requirements". This has been corrected for the final rule.
- Monitoring violations are described in § 141.903(c) and § 141.905(c), which state that each failure to monitor in accordance with § 141.902 is a monitoring violation. Please see also the EPA response to comment Doc. #1699, SBC-045033 in section 8.2 in this *Response to Comments* document.
- Per the commenter's suggestion, the content of § 141.902(a)(4) in the proposed rule was deleted due to redundancy.

- The EPA disagrees that new systems and new sources should be required to be in compliance prior to going online. The requirement for states to determine when new systems and new sources must meet the requirements gives the states, who have the most information about the systems they oversee, the authority to determine schedules for compliance; the language used for PFAS is consistent with what is required for other chemicals.
- Regarding the decision not to use the term "subpart H systems," please see the EPA response to comment Doc. #1726, SBC-045155 in section 16.3.2 in this *Response to Comments* document.
- The reference to the state being allowed to require more frequent monitoring, included in § 141.902(b)(1)(iii) of the proposed rule, has been moved to § 141.902(b)(1)(v) to clarify that it applies to systems of all source types. Additionally, GWUDI systems have been added to Table 2 to § 141.902(b)(1)(v). See also section 8.1.1 of the EPA response in this *Response to Comments* document for additional discussion of initial monitoring requirements.
- The required initial monitoring frequency for large groundwater systems as well as all surface water and GWUDI systems has been adjusted to 2 to 4 months apart for the final rule per § 141.902(b)(1)(i) and (iii). Please see section 8.1.1 of the EPA response in this *Response to Comments* document for more information.
- Table 2 to § 141.902(b)(1)(v) now uses the same verb ("taken") for both sets of systems.
- The EPA confirms that, per § 141.902(b)(2)(i), systems may have some sampling points on reduced monitoring and others on routine monitoring. However, per the footnote to Table 3 to § 141.902(b)(2)(iv) in the final rule, the monitoring frequency at a given sampling point must be the same for all regulated PFAS. See also the discussion in section VIII and section 8.1.2 of the EPA response in this *Response to Comments* document.
- The EPA disagrees with the suggestion to use "locational running annual average" (LRAA) in lieu of "running annual average." While LRAA has been used for NPDWRs concerning disinfection byproducts, the term has not been associated with volatile organic contaminants or synthetic organic contaminants.
- Regarding the commenter's concern for the requirement of states to designate monitoring time (now stated in § 141.902(b)(2)(vii) of the final rule), see sections 8.1.2 and 11.1 of the EPA response in this *Response to Comments* document. The EPA has removed the monitoring plan requirement for primacy applications. The state will need to establish a compliance monitoring schedule for each system based on the results of initial monitoring.
- The EPA has also updated § 141.903 for clarity. § 141.903(c) now specifies that, in the event of a monitoring violation, the RAA is still calculated using the total number of samples collected. The EPA disagrees with the commenter that § 141.903(e) should be merged with paragraph (f). This is because paragraph (e) describes an exception which supersedes the requirements listed in paragraph (f) for determining compliance and may result in a system being in violation of an MCL prior to having collected a full year of quarterly samples.

- Regarding the commenter's request for increased clarity in § 141.903(f)(1), the EPA has specified "at each sampling point" in paragraph (f) while (f)(1) specifies that this applies to each PFAS regulated by an individual MCL.
- The EPA has updated § 141.903(f)(1)(ii) and § 141.903(f)(1)(iii) of the final rule to clarify that, for systems on reduced monitoring, if a sample concentration (or average of samples if the state required a confirmation sample) equals or exceeds a trigger level (for triennial monitoring) or MCL (for annual monitoring), the systems must begin monitoring quarterly.
- Regarding the commenter's concern about the use of zero for monitoring results below the PQL when calculating MCL compliance, see section 8.2 of the EPA response in this *Response to Comments* document. For monitoring schedule frequency purposes, values below the PQL are not replaced with zeroes; see section 8.1.2 of the EPA response in this *Response to Comments* document.
- The sentence of concern near the end of § 141.903(f)(2)(i) has been revised to say "If the running annual average Hazard Index exceeds the MCL and two or more Hazard Index analytes had an observed sample analytical result above the PQL in any of the quarterly samples collected to determine the running annual average, the system is in violation of the Hazard Index MCL."
- References in Table 2 to § 141.904(b) in the final rule (Table 1 to § 141.904 in the proposed rule) have been updated to direct to § 141.903 when referring to an MCL violation and § 141.902(a)(5) when referring to the trigger level. Table 1 to § 141.904(a) for initial monitoring has also been added in the final rule.
- Per this comment and others, the EPA has also made revisions to § 141.905 (see also section 8.2 of the EPA response in this *Response to Comments* document).
    - Regarding references in § 141.905(a), please see EPA response to comment Doc. #1726, SBC-045172 in section 16.3.5 in this *Response to Comments* document.
    - § 141.905(a) states "that MCL violations are based on running annual average, as outlined under § 141.903…" This cross reference includes discussion of violations based on fewer than four quarters of monitoring.
    - The redundancy of § 141.905(b)(2)(iii) in the proposed rule has been removed from the final rule.

<u>City of Tulsa Water and Sewer Department (CoT WSD) (Doc. #1785, SBC-043790)</u>

May 30, 2023

Michael Regan, Administrator

U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, N.W. Mail Code: 1309

Washington, DC 20004

TRANSMITTED ELECTRONICALLY

RE: PFAS National Primary Drinking Water Regulation Rulemaking (88 FR 18638, EPA-HQ-OW-2022-0114)

Dear Administrator Regan,

The City of Tulsa Water and Sewer Department (CoT WSD) would like to present for Environmental Protection Agency's (EPA's) review the following editorial correction items for the preliminary regulatory determination and proposed rule for per- and polyfluoroalkyl substances (PFAS) National Primary Drinking Water Regulation (Federal Register document citation 88 FR 18638, document number 2023-05471; or Docket Document ID# EPA-HQ-OW-2022-0114-0027). These items are in the portion of the referenced Federal Register document that contains the proposed amended language for 40 CFR parts 141 and 142. This document submission is in addition to the City of Tulsa Water and Sewer Department's comments on the proposed rule, which are submitted in a separate document.

1. 88 FR 18748 item 7.a.: Appears that "at end of the table" should be "in alphabetical order", since the existing table in §141.61(b) is currently in alphabetical order.

2. 88 FR 18749 item 10, specifically footnote 2: "Subpart A of §141.2" looks like an incorrect listing of the citation, since §141.2 is actually a section of Subpart A. Suggest change this to "§141.2 of Subpart A" or simply "§141.2".

3. 88 FR 18749 item 11, 2 items:

a. In paragraph, insert "order" after "numerical"

b. In table, in the Monitoring & testing procedure violations Citation column, citation should be 141.902.

c. 88 FR 18750 item 12, specifically footnote 24: "Subpart A of §141.2" looks like an incorrect listing of the citation, since §141.2 is actually a section of Subpart A. Suggest change this to "§141.2 of Subpart A" or simply "§141.2".

4. 88 FR 18750 – 18754 All tables in added Subpart Z: Titles of all tables are confusing.

a. Table 2 is used in two different paragraphs, even though there is no Table 1 in those paragraphs.

b. For improved clarity, paragraph citation should include the m e.g. "Table 1 to §141.901(b)(i)". Or, change to descriptive title and remove citation (tables in other portions of NPDWR use descriptive titles).

5. 88 FR 18750 item 14, specifically §141.901(b)(2)(i):

a. Remove parentheses around "Monitoring Requirements"

b. The referenced table in this paragraph is missing.

6. 88 FR 18751 item 14, specifically §141.XX: This section should be §141.902.

7. 88 FR 18751 item 14, specifically §141.901(a)(9): Citation at end of paragraph does not exist. It appears that the reference citation should be §141.903(f)(1)(iii).

8. 88 FR 18752 item 14, specifically §141.903(f)(2)(i): It appears that description of calculation of Running Annual Average (RAA) using the quarterly Hazard Indexes (HI) was left out. The way it is written, it seems that the MCL is determined on each quarterly HI.

9. 88 FR 18753 item 14, specifically §141.903(f)(2)(iii): Citation in paragraph does not exist. It appears that the reference citation should be §141.903(f)(1)(iii).

10. 88 FR 18753 item 14, specifically §141.905(a): Two citation references to §141.XX, and incorrect notation for specific paragraphs.

a. It appears the first citation should be §141.903 Compliance Requirements

b. It appears the second citation should be §141.902 Monitoring Requirements

11. 88 FR 18753 item 14, specifically §141.905(b)(2)(iii): Citation in paragraph does not exist. It appears that the reference citation should be §141.903(f)(1)(iii).

12. 88 FR 18754 item 17, specifically §142.62(a) Table 2: "B" should be lower case "b" on 2nd line in "Limitations" column.

(This area is intentionally left blank)

The City of Tulsa Water and Sewer Department values the opportunity to comment on the preliminary regulatory determination and proposed rule for per- and polyfluoroalkyl substances (PFAS) National Primary Drinking Water Regulation, and appreciates EPA's consideration of the suggested editorial corrections in this letter. Please contact me if you have any questions.

Sincerely,

Eric Lee, Director

City of Tulsa Water and Sewer Department EL/cjg

Cc: Rick Hudson-TMUA

Shellie Chard - DEQ

Stefanie Hunter-CoT

WSD Jo Brown-CoT

WSD

EPA Response: The commenter raises several points to which the EPA is responding below:

- For the final rule, the regulated PFAS MCLs and BATs described in § 141.61 are now included in PFAS-specific tables rather than added to the previously existing tables.
- The commenter is correct that footnote 2 "Subpart A of § 141.2" was incorrectly stated. However, footnote 2 (as well as footnote 24 in Appendix B to Subpart Q) referencing §

141.2 in the proposed rule was removed in the final rule given that Hazard Index is defined within Subpart O § 141.153.

- Concerning the amendment to appendix A to Subpart Q the EPA has corrected the amendment description to say "numerical order" but disagrees that the citation for Monitoring & Testing Procedure Violations should be § 141.902. However, the citation has been updated to § 141.905(c), which concerns violations.
- For the final rule, the EPA has added or amended table titles for clarity.
- For the final rule, table numbers were amended to be more intuitive. Table numbering is reset at the beginning of a section. The description format of "Table X to paragraph Y" does not necessarily imply the specific paragraph has a certain number of tables, but rather clarifies where the specific table can be found (after the paragraph stated).
- Regarding the commenter's request for section numbers to be included in table paragraph locations, the EPA used the convention identified in the Office of the Federal Register (OFR) Handbook, the paragraphs should be clear because it is within the same section as the table listed; the EPA also has added descriptive titles to tables.
- In response to the commenter's concerns regarding § 141.901(b)(2)(i), which is § 141.901(b)(2)(iii) for the final rule:
    - For the final rule the name of the section (previously included as "Monitoring Requirements") has been removed and it is referred to here by the section number.
    - An accurate cross reference to the cited table has been added.
- § 141.XX has been corrected to § 141.902.
- There was no § 141.901(a)(9) in the proposed rule. However, the citation included at the end of § 141.902(a)(9) was intended to be § 141.903(f)(1)(iii) in the proposed rule. For the final rule, the section has been reorganized such that there is no longer need for a cross reference as the table for trigger levels is presented directly in § 141.902.
- The EPA has updated the language in §141.903(f)(2)(i) to clearly state that the RAA of the Hazard Index is used to assess compliance with the MCL.
- The citation in §141.903(f)(2)(iv), which was § 141.903(f)(2)(iii) in the proposed rule, has been corrected to direct to § 141.903(f)(1)(iv).
- The citations included in § 141.905(a) of the proposed rule have been corrected in the final rule. The citations are now seen in § 141.905(a) and (b).
- § 141.905 has been rearranged such that § 141.905(b)(2)(iii) no longer exists, however § 141.903 is accurately cross-referenced in § 141.905 (a) and (e), regarding how to calculate the RAA.
- Regarding the footnote in § 142.62(a) Table 2 of the proposed rule, please see the EPA response to comment Doc. #1516, SBC-042716 in section 16.4 in this *Response to Comments* document.

Section 16 References

No references were cited within the EPA responses in this section.

17 EPA's Next Steps and Timeline

17.1 Comment Period Extensions

Summary of Major Public Comments and EPA Responses

Many commenters requested an extension to the public comment period provided prior to finalizing the PFAS National Primary Drinking Water Regulation (NPDWR), with a few commenters requesting that the EPA provide additional time for comment via a supplemental comment period. Commenters asserted that, given the complexity and significance of this regulatory action, the public comment period was too short to provide detailed and constructive feedback. Commenters asserted that they perceived there was insufficient time to adequately review the proposed rule and key technical support documents, specifically noting that they sought extra time to review information on topics such as water treatment costs, feasibility to remove PFAS to levels at or below the proposed Maximum Contaminant Levels (MCLs), feasibility for water systems to implement the rule within the compliance timeline, and application of the Hazard Index for drinking water regulation, including considerations for risk communication, among other topics. Some commenters noted that this regulatory action has connections to actions taken on PFAS under other statutes and that there are other actions soliciting public comments simultaneously with the proposed PFAS NPDWR that will also impact drinking water utilities. These commenters asserted that a comment period extension would allow for a more robust review of the scientific and technical information provided by the agency.

Commenters noted that an additional comment period or extension to the comment period provided by the agency would allow for what they believed would be more informed public comments, as commenters would have additional time to consult with relevant stakeholders and workgroups. One commenter also noted that there is no statutory or regulatory deadline that compels the agency to provide such an abbreviated comment period. Commenters also cited challenges in reviewing the entirety of the regulatory package for this action in conjunction with other regulatory actions simultaneously and due to other competing responsibilities and limited resources. Additionally, one commenter cites the length of interagency review on the proposed rule as rationale for requesting an extension to the public comment period. Commenters also asserted that the EPA's prompt response on whether the comment period would be extended was necessary for "stakeholders to successfully balance available resources within the time the agency affords the public to draft comments."

First, neither the Safe Drinking Water Act (SDWA) nor the Administrative Procedure Act (APA) specify a length of comment period. Executive Order (EO) 12866, governing issuance of federal regulations, states that comment periods should in most cases be at least 60 days (EO 12866, Section 6). In this case, the EPA provided a comment period of 62 days. Second, because the agency provided public access to key documents immediately after signature, commenters had an additional 15 days for comment on the proposed rule.

Specifically, the EPA announced the issuance of the proposed PFAS NPDWR on March 14, 2023. To provide the public with additional time to review and prepare comments on the proposed rule and key supporting documents, the agency simultaneously made publicly available a pre-publication version of the proposed rule Federal Register Notice (FRN), as well as several of the significant underlying technical supporting documents, including the Economic Analysis (EA) and Appendices, *Toxicity Assessment and Proposed Maximum Contaminant Level Goal (MCLG) for PFOA* and Appendix, *Toxicity Assessment and Proposed MCLG for PFOS* and Appendix, *Framework for Estimating Noncancer Health Risks Associated with Mixtures of PFAS, MCLG Summary Document for a Mixture of Four PFAS*, and the *EPA's Response to Science Advisory Board Recommendations on Draft Documents for the Proposed PFAS NPDWR*. Additionally, the peer-reviewed paper which outlined the methodology for the EPA's national PFAS occurrence model (Cadwallader et al., 2022) was published in May 2022 in *American Water Works Association (AWWA) Water Science*. The publication included supplemental material, including model code and outputs. Both its contents and location were referenced in the pre-publication of the FRN for the action posted on March 14, 2023. As a result, stakeholders had access to the FRN preamble language, economic analysis, health information, and other key information on March 14, 2023, a full 15 days before the start of the official comment period. Hence, commenters had 77 days in total during which the rule was publicly available for stakeholder consideration prior to submitting comments by the close of the comment period.

Third, the EPA engaged in significant pre- and post-proposal actions to both inform and involve stakeholders in rule development. Specifically, during the proposed rule development, the EPA sought to actively involve stakeholders and members of the public in the rulemaking process, seek their input, and provide information through various consultations and engagements (see XV of the proposed rule preamble). The EPA received significant feedback and information from stakeholders during this time which meaningfully informed the proposed rule. Additionally, in November 2022, the EPA hosted a webinar entitled "Preparing for Engagement in EPA's Upcoming Proposed Per- and Polyfluoroalkyl Substances (PFAS) Drinking Water Regulatory Process". The purpose of this webinar was to provide members of the public, particularly those who do not typically engage in federal rulemaking activities, the information and tools they needed about the federal regulatory process so they would know how to submit their comments during the upcoming public comment period, thereby allowing prospective commenters to be fully prepared to review and develop comments on the proposal as soon as it was issued.

Following the rule proposal announcement, the EPA also offered opportunities for the public to learn more about the rule proposal including through two public webinars that the EPA hosted on March 16, 2023, and March 29, 2023, to provide an overview of the rule for both general public and technical stakeholders. These webinars, as well as other supporting materials, have been made available on EPA's PFAS NPDWR website as a resource (https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas). Additionally, the EPA held a public hearing for the proposed NPDWR on May 4, 2023, where members of the public had the opportunity to share their comments with the EPA on the proposed rule. For further discussion additional meetings and

consultations held on the PFAS NPDWR, see section 14 of this *Response to Comments* document.

Additionally, to ensure that commenters knew with adequate advanced notice that the agency would not be extending the comment period for this rulemaking, the EPA promptly responded to comment period extension requests from commenters. The agency responded to requests for a comment period extension on May 5, 2023 for all requests received prior to this date, a full 25 days before the close of the comment period.

Regarding commenter concerns that there were other PFAS regulatory actions under different statutes or other drinking water regulatory actions on which they might like to provide comment that may have overlapping comment periods with this regulatory action, the EPA notes that none of these other actions referenced by commenters impact the EPA's decision-making for this PFAS NPDWR. Potential PFAS-related actions have different underlying statutory drivers; for instance, the Advanced Notice of Proposed Rulemaking (ANPRM) on Potential Future Designations of PFAS as Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) Hazardous Substances was issued under CERCLA authorities and the information contained in that rule and comments received on that rule do not substantively impact the decision-making process for this regulation. Additionally, the EPA notes that the comment period for that action only partially overlapped with that for the PFAS NPDWR. Additionally, the EPA acknowledges that proposed revisions to the Consumer Confidence Report (CCR) Rule and call for nominations to the sixth Contaminant Candidate List (CCL 6) were also soliciting public comment during a portion of the comment period for this NPDWR. While SDWA is the statutory authority for the CCR Rule, CCL, and the PFAS NPDWR, the EPA notes any comments provided on the proposed revisions to the CCR Rule or nominations for CCL 6 and this action would not impact each other. The EPA also notes that these actions have different SDWA statutory drivers and decision-making processes than does the PFAS NPDWR. Finally, regarding a commenter's reference to the proposed Supplemental Effluent Limitations Guidelines and Standards for the Steam Electric Power Generating Point Source Category, the EPA notes that rule is proposed under the authority of the Clean Water Act (CWA), regulates entirely different pollutants than PFAS, and regulates entirely different entities than drinking water utilities. In short, these other regulatory activities in no way impacted the decision-making process or schedule under this regulatory action. Therefore, because commenters may choose to comment on those other actions (in cases when there were co-occurring comment periods), these other actions' schedules do not impact the EPA's obligations or schedule under this PFAS NPDWR.

Regarding a commenter's statement about the length of interagency review, the EPA notes that the length of the Office of Management and Budget (OMB)-led interagency review process, governed under EO 12866, is unrelated and immaterial to the length of the public comment period. The OMB-led interagency review and the EPA's consideration of public comments (including the public comment period itself) are driven by different authorities: neither impacts the other.

As the lead federal agency responsible for ensuring safe drinking water for Americans, the EPA anticipates that over many years this action will save thousands of lives and prevent tens of thousands of serious illnesses that would otherwise result from long-term exposure to PFAS. Therefore, due to the complexity and significance of the PFAS NPDWR, while the EPA felt it appropriate to allow public comments for 62 days, with an additional 15 days of rule availability, for a total of 77 days for commenters to review the proposed rule, further delays to protection of public health outweighed any benefits that might be realized by extending the public comment period. It is important to take final action on the proposal expeditiously to address PFAS exposure in communities across the country and ensure that the health benefits of the final rule could be realized as quickly as possible.

As described above, the agency believes the extended public comment period time, along with the extensive pre- and post-proposal activities to promote understanding of the rule and facilitate public comment, was sufficient for commenters to understand and meaningfully participate in the rulemaking process while also allowing the EPA to protect communities and the public from exposure to adverse PFAS health effects from drinking water as expeditiously as possible.

Individual Public Comments

American Water Works Association (AWWA) (Doc. #1465, SBC-042300)

March 30, 2023

Michael S. Regan

Administrator

Environmental Protection Agency

1200 Pennsylvania Avenue, N. W.

Mail Code: 4607M

Washington, DC 20460

RE: Request for Extension for Comment Period on EPA's Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation (Docket ID: EPA-HQ-OW-2022-0114)

Administrator Regan,

The comment period for EPA's proposed per- and polyfluoroalkyl substances (PFAS) drinking water regulation is only 62 days long. As of the writing of this letter, the docket contains nearly 1,300 supporting documents (26 of which total 5,000 pages) from the agency. These materials must be reviewed and considered in order for stakeholders to provide constructive feedback. There are multiple, key aspects of the proposed rule that will require extensive review, including but not limited to:

• The regulatory determinations for four additional PFAS

• An occurrence analysis, which relies on both a complex statistical approach and a novel national occurrence database that combines older data collected under the Unregulated Contaminant Monitoring Rule with a collection of state monitoring datasets

• Four Work Breakdown Structure-Based Cost models for PFAS treatment technologies which are newly published

• Updated support documents for maximum contaminant level goals (MCLGs) for perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS)

• Analysis to support an MCLG for a hazard index reflecting a mixture of four PFAS

• An updated approach for evaluating health risk reduction associated with cardiovascular disease and decreased birth weight

• An approach for evaluating reduced disinfection byproduct formation and associated health risk reduction benefits of the proposed rulemaking

• A novel drinking water regulatory approach utilizing a general hazard index

The American Water Works Association (AWWA) requests that EPA provide an extension of the comment deadline by 59 days to July 28, 2023. This extension would provide a total of 121 days for public comment. AWWA is requesting this extension to ensure that the proposed rule and supporting documents can be reviewed fully and considered in providing feedback to the agency. Your response by April 14, 2023, is necessary for stakeholders to successfully balance available resources within the time the agency affords the public to draft comments.

AWWA appreciates your attention to this matter. If you have any questions we encourage you to reach out to either myself at TMehan@awwa.org or Chris Moody at cmoody@awwa.og or (202) 326-6127.

FOR THE AMERICAN WATER WORKS ASSOCATION,

G. Tracy Mehan, III

Executive Director – Government Affairs

cc: Radhika Fox, EPA/OW

Jennifer McLain, EPA/OGWDW

Eric Burneson, EPA/OGWDW

Ryan Albert, EPA/OGWDW

Who is AWWA

The American Water Works Association is an international, nonprofit, scientific and educational society dedicated to providing total water solutions assuring the effective management of water. Founded in 1881, the Association is the largest organization of water supply professionals in the world. Our membership includes more than 4,500 utilities that supply roughly 80 percent of the nation's drinking water and treat almost half of the nation's wastewater. Our 50,000-plus total membership represents the full spectrum of the water community: public water and wastewater systems, environmental advocates, scientists, academicians, and others who hold a genuine interest in water, our most important resource. AWWA unites the diverse water community to advance public health, safety, the economy, and the environment.

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document. Additionally, the EPA notes that many of the materials listed by the commenter were made publicly available prior to the public comment period for this action.

For instance, the EPA's Science Advisory Board (SAB) PFAS Review Panel ("Review of EPA's Analysis to Support EPA's National Primary Drinking Water Rulemaking for PFAS") reviewed several of the agency's technical products that have been utilized or applied in this regulatory action, including its cardiovascular disease (CVD) risk reduction methodology, derivation of draft Maximum Contaminant Level Goals (MCLGs) for PFOA and PFOS, and framework for estimating noncancer health risk associated with mixtures of PFAS (which is applied through use of the Hazard Index in this regulatory action). The SAB's final report was published on August 22, 2022 and prior to this date, the SAB issued a draft report and convened multiple panel meetings to discuss their comments on the EPA's technical products. These meetings were open to the public, providing additional opportunities for public input. Additionally, the public had the opportunity to nominate experts to the panel and the SAB Staff Office also invited comments on Lists of Candidates. This provided an opportunity for the public to be informed about the candidate experts being considered and for the public to provide information, analysis, or documentation for the EPA to consider before finalizing membership on committee or panels. For more information on SAB review, please see: https://sab.epa.gov/ords/sab/f?p=100:18:10311539418988:::18:P18_ID:2601#charge.

In addition to the SAB-reviewed cardiovascular risk reduction methodology which was applied in the EPA's CVD benefits analysis, the EPA notes that the EPA's benefits analyses for both birth weight benefits and benefits resulting from disinfection byproduct (DBP) co-removal apply methodology from publicly available peer-reviewed papers (Almond et al., 2005; Ma and Finch, 2010; Regli et al., 2015). For more information on these analyses, see Sections 6.4 and 6.7 of the EA for discussion of the valuation of developmental effects and benefits from co-removal of DBPs, respectively (USEPA, 2024a).

In addition, with respect to the Work Breakdown Structure cost models, the EPA disagrees with the commenter's assertion that these are "newly published." Versions of the models incorporating annual updates have been available for external review and public use on the EPA's website since approximately 2016; see: https://www.epa.gov/sdwa/drinking-water-treatment-technology-unit-cost-models. The versions used to support this rulemaking were

available for review in the docket for the proposed regulation; likewise, the versions updated after considering public comments are available in the docket for this final action. All design parameters, including specific adjustments to estimate the cost of PFAS treatment, are also described in detail in the supporting documentation, also included in the docket. For more information, please see section 13.3.3 of the EPA response in this *Response to Comments* document.

With respect to the commenter's assertion that the EPA's occurrence analysis "relies on both a complex statistical approach and a novel national occurrence database," see section 6.5 of the EPA response in this *Response to Comments* document.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1466, SBC-042301)

March 30, 2023

Michael S. Regan

Administrator

US Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington, DC 20460

Via electronic submission

Re: Extension request of comment period for Docket ID #: EPA-HQ-OW-2022-0114; PFAS National Primary Drinking Water Regulation Rulemaking

Dear Administrator Regan,

The Association of Metropolitan Water Agencies (AMWA), an organization representing the largest publicly owned drinking water utilities in the United States, welcomes the opportunity to provide comments on the proposed National Primary Drinking Water Regulation of PFOA, PFOS, PFBS, GenX, PFNA, and PFHxS. AMWA was supportive of the determination to regulate certain PFAS and has repeatedly called for a regulation based on sound science and the most up-to-date data available. Due to the vast complexity of the rule and the effect it will have on AMWA members, the association respectfully requests at least a 30-day extension to the comment period to ensure useful and meaningful feedback.

A crucial step of the regulatory process is the public comment period. Feedback and recommendations from impacted stakeholders and the regulated community provide a unique perspective that often strengthens and improves a proposed rule. AMWA believes it is in the interest of EPA to provide an adequate comment period for such an important and consequential rule. AMWA will be able to provide much more insightful and helpful comments if given the time to review the many pages of documents and supporting materials provided by EPA.

At the time of the creation of this letter, there are 1,241 supporting or related material provided in the rulemaking docket to review. It is also unreasonable to expect a meaningful comment letter in 60 days when the Office of Management and Budget needed five months to conclude its own review. AMWA understands the agency cannot allow the same period for public comment but believes more time is a fair ask, given the rule's complexity.

While AMWA and its members will be diligently working to provide thoughtful comments on this proposed rule, it is important to remind EPA that this is not the only rulemaking being proposed with an open public comment period that will impact drinking water utilities. Contaminant Candidate List 6, Consumer Confidence Reports, ANPRM for additional PFAS CERCLA designations, and Steam Power ELGs are all in the process, or will be shortly, of soliciting public comments simultaneously with this proposed rule. A condensed period for public comment on this rule only diverts resources from providing robust comments to other notices currently open in the Federal Register.

While AMWA understands the importance of finalizing this rule in a timely manner, the association believes thoughtful public comments will only strengthen the final rule and ultimately provide more protections for public health. Therefore, AMWA respectfully requests EPA extend the comment period by at least 30 days. AMWA also asks EPA to respond to this request in a timely manner so comments can be developed with an accurate due date in mind.

AMWA appreciates EPA giving this request consideration. If you have any further questions, please contact Brian Redder (Redder@amwa.net), AMWA's Manager of Regulatory and Scientific Affairs.

Sincerely,

Tom Dobbins

Chief Executive Officer

cc: Radhika Fox, OW Bruno Pigott, OW

Jennifer McLain, OGWDW

Eric Burneson, OGWDW

Ryan Albert, OGWDW

Alexis Lan, OGWDW

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document.

Louisville Water Company (Doc. #1467, SBC-042302)

See attached file(s)

Please find attached a request to extend the public comment period for the proposed NPDWR for PFAS

April 3, 2023

Michael S. Regan

Administrator

Environmental Protection Agency

1200 Pennsylvania Avenue, N.W.

Mail Code: 4607M

Washington, DC 20460

RE: Request for Extension for Comment Period of EPA's Proposed Per-and Polyfluoralkyl Substances (PFAS) National Primary Drinking Water Regulation

(Docket ID: EPA-HQ-OW-2022-0114)

Administrator Regan,

The proposed National Primary Drinking Water Regulation for PFAS substances only provides a public review and comment period of 62 days. The corresponding docket contains more than 5,000 pages of supporting documentation. These materials must be reviewed and considered in order for stakeholders to provide constructive feedback.

Louisville Water is interested in reviewing the proposal and providing feedback to the EPA to present its perspective on the various aspects of the proposed rule, including:

• Water treatment costs associated with PFAS;

• Feasibility to remove PFAS to levels at or below the proposed standards;

• Feasibility for drinking water utilities to implement the proposed rule within the compliance timeline, and the factors influencing the implementation of treatment; and

• Application of the proposed Hazard Index for drinking water regulation, including considerations for risk communication.

Louisville Water respectfully requests an extension of the comment deadline by 59 days to July 28, 2023, to provide a total of 121 days for public comment. Your response by April 14, 2023, is requested as necessary for us to successfully balance available resources to best utilize the requested extension period.

Thank you for your consideration of this request.

Sincerely,

Spencer Bruce, President and CEO

Louisville Water Company

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

U.S. Chamber of Commerce et al. (Doc. #1468, SBC-042303)

The Honorable Radhika Fox

Assistant Administrator

Office of Water

Environmental Protection Agency

Washington, DC 20020

Re: Comment Period Extension Request for EPA's proposed regulatory determination for PFHxS, HPFO-DA, GenX chemicals, and PFNA; and EPA's proposed maximum contaminant levels (MCLs) and proposed maximum contaminant level goals (MCLGs)

Dear Assistant Administrator Fox:

We, the undersigned organizations representing a coalition of companies and trade associations from across the economy, urge you to provide a 30-day extension to the public comment period for 1) EPA's proposed regulatory determination for PFHxS, HPFO-DA, GenX chemicals, and PFNA; and 2) EPA's proposed maximum contaminant levels (MCLs) and proposed maximum contaminant level goals (MCLGs) for PFOA and PFOS and also the four PFAS chemistries for which EPA is proposing a regulatory determination.

We support national drinking water standards for select PFAS based on the best science and risk, rather than the current patchwork of state approaches. Our customers, employees, and the communities where we operate depend on clean, safe drinking water for a better quality of life and economic growth. EPA's proposal sets forth 59 specific questions for comment and provides more than 3,000 pages of very technical and complex information on the scientific basis, costs, and impacts for implementing these standards. This page count does not include even further additional technical supporting information that EPA made available in the docket on March 29, 2023. There are some 1,271 supporting documents included in the docket, which are not organized in a searchable or clear fashion.

More time is needed to practically offer constructive feedback on the challenges, unintended consequences especially on small entities, economic analysis, and the novel hazard index approach presented by the two proposed rules that are within the package EPA has asked the public to comment on. While the proposal focuses on setting standards for six PFAS, it also

includes within it a separate regulatory determination for four of the PFAS. Commenting on this regulatory determination will require an in-depth review of occurrence and hazard information for these PFAS. Accordingly, because the agency is asking for review of these regulatory determinations and the proposed MCL and MCLG for these new compounds (in addition to the proposed rule for PFOA and PFOS) and extension is warranted.

In the meantime, the U.S. Chamber of Commerce has submitted a report to the Office of Management and Budget (OMB) modelling the potential costs attributable to various drinking water treatment levels. The estimated annualized costs for a proposed MCL of 4 ppt are approximately $1.8 billion. Our cover letter to OMB and the report are here [Link: Broken] and here [Link: Broken]. The significant costs and impacts and their connection to other elements of the PFAS Strategic Roadmap, such as the proposed hazardous substance designation under CERCLA demand a full vetting by the stakeholder community requiring additional time.

Please feel free to contact us with any questions. We stand ready to work with you as this proposal moves forward.

Sincerely,

American Chemistry Council

American Farm Bureau Federation

American Forest & Paper Association

American Fuel and Petrochemical Manufacturers

American Petroleum Institute

American Waste and Recycling Association

Fluid Sealing Association

National Association of Chemical Distributors

National Association of Home Builders

National Association for Surface Finishing

National Council of Textile Organizations

National Oilseed Processors Association

National Mining Association

National Pork Producers Council PRINTING United Alliance

RCRA Corrective Action Project

Superfund Settlements Project

The Fertilizer Institute

U.S. Chamber of Commerce

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

Association of State Drinking Water Administrators (ASDWA) (Doc. #1469, SBC-042304)

Attached is a request for comment period extension from the Association of State Drinking Water Administrators.

March 29, 2023

Dr. Jennifer McLain

Director, Office of Ground Water and Drinking Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue NW

Washington, DC 20460

Via Regulations.gov

Re: Request for Comment Period Extension for Proposed PFAS National Primary Drinking Water Regulation (NPDWR) (EPA-HQ-OW-2022-0114)

Dear Dr. McLain,

The Association of State Drinking Water Administrators (ASDWA) appreciates the opportunity to provide input on the proposed National Primary Drinking Water Regulation (NPDWR) for per- and polyfluoroalkyl substances (PFAS). ASDWA is the professional association that serves the leaders (and their staff) of the 57 state and territorial drinking water programs. Formed in 1984 to address a growing need for state administrators to have national representation, ASDWA has become a respected voice for states with Congress, the Environmental Protection Agency (EPA), other Federal agencies, and professional organizations in the water sector. ASDWA would like to thank the Office of Ground Water and Drinking Water (OGWDW) for its continued efforts on such an important and precedent-setting rulemaking. This regulatory action by EPA is a step in the right direction to provide national leadership and consistency for assessing and addressing PFAS in drinking water nationwide.

As the representative of EPA's co-regulators in implementing NPDWRs, ASDWA appreciates EPA's early outreach to state drinking water programs as the Agency developed this proposal. ASDWA appreciates EPA's recognition of the importance of engaging state drinking water programs effectively and meaningfully to ensure that this NPDWR is implementable and

maximizes the public health benefit. ASDWA requests an extension of the comment deadline by 30 days, to a total of 90 days, to ensure ASDWA and state staff have sufficient time to review and analyze the proposal. ASDWA appreciates the Agency's interest in establishing this NPDWR in a timely manner, but an expeditious schedule should not come at the expense of obtaining meaningful engagement with stakeholders.

ASDWA requests that EPA decide whether to grant the extension within 30 days of the publication of the proposal in the Federal Register. In the past, the Agency has responded to public comment period extension requests very close to the deadline for submitting comments. Many stakeholders, ASDWA included, must draft their comments far in advance to allow for review by technical workgroups and review and approval by governing boards before submission to the docket. An early decision on the comment extension would benefit ASDWA's members and ensure a more robust review.

ASDWA thanks EPA for the opportunity to provide comment early in the process as the Agency works to address PFAS in drinking water. As co-regulators and the boots on the ground, it is vital that EPA collect state input throughout the process. We look forward to further engagement with the Agency on this critical rulemaking.

Sincerely Yours

J. Alan Roberson, P.E.

ASDWA Executive Director

Cc: Eric Burneson – EPA OGWDW

Ryan Albert – EPA OGWDW

Alex Lan - EPA OGWDW

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document.

City of St. Louis Water Division (Doc. #1477, SBC-042312)

City of Saint Louis

DEPARTMENT OF PUBLIC UTILITIES

TISHAURA O. JONES

MAYOR

OFFICE OF THE DIRECTOR

1640 So. Kingshighway Blvd.

Saint Louis, Missouri 631 10

(314) 633-9000

FAX (314) 664-6786

CURTIS B. SKOUBV, P.E.

DIRECTOR OF PUBLIC UTILITIES

April 5, 2023

Michael S. Regan

Administrator

Environmental Protection Agency

1200 Pennsylvania Avenue, N. W.

Mail Code: 4607M

Washington, D.C. 20460

RE: Request for Extension for Comment Period on EPA's Proposed Per- and Polyfluoroalkyl Substances (P FAS) National Primary Drinking Water Regulation (Docket ID: EPA-HQ-OW-2022-0114)

Administrator Regan,

The proposal only provides a public review and comment period of 62 days. At the time this letter is written, the docket contains more 5,000 pages of supporting documentation. These materials must be reviewed and considered in order for stakeholders to provide constructive feedback.

We are interested in reviewing the proposal and providing feedback to the EPA presenting our perspectives on the various aspects of the rule, including:

• Water treatment costs associated with per- and polyfluoroalkyl substances (PFAS);

• Feasibility to remove PFAS to levels at or below the proposed standards;

• Feasibility for drinking water utilities to implement the proposal within the compliance timeline and the factors influencing the implementation of treatment.

• Application of the hazard index for drinking water regulation, including considerations for risk communication.

We respectfully request that EPA provide an extension of the comment deadline by 59 days to July 28, 2023 to provide a total of 121 days for public comment. Your response by April, 14, 2023 is necessary for us to successfully balance available resources to best utilize the requested extension period. We appreciate your attention to this matter.

Curtis B. Skouby, P.E.

Director of Public Utilities City of St. Louis Water Division cskouby@stlwater.com

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

Pinellas County Utilities (Doc. #1478, SBC-042313)

April 7, 2023

Michael S. Regan

Administrator

Environmental Protection Agency

1200 Pennsylvania Avenue NW

Mail Code: 4607M

Washington, DC 20460

Re: Request for Extension for Comment Period on EPA's Proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation (Docket ID: EPA-HQ-OW-2022-0114) [Link: Broken]

Dear Administrator Regan:

The proposal only provides a public review and comment period of 62 days. At the time this letter is written, the docket contains more than 5,000 pages of supporting documentation. These material must be reviewed and considered in order for stakeholders to provide constructive feedback.

We are interested in reviewing the proposal and providing feedback to the EPA presenting our perspectives on the various aspects of the rule, including:

• Water treatment costs associated with PFAS;

• Feasibility to remove PFAS to levels at or below the proposed standards;

• Feasibility for drinking water utilities to implement the proposal within the compliance timeline and the factors influencing the implementation of treatment; and

• Application of the hazard index for drinkng water regulation, including considerations for risk communication.

We respectfully request that EPA provide an extension of the comment deadline by 59 days to July 28, 2023 to provide a total of 121 days for public comment. Your response by April 14,

2023 is necessary for us to successfully balance available resources to best utilize the requested extension period.

We appreciate your attention to this matter.

Sincerely,

Megan E. Ross, PE, ENV SP

Director of Utilities

Pinellas County Utilities

mross@pinellas.gov

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

Gainesville Regional Utilities (Doc. #1479, SBC-042314)

Request to extend public comment period for EPA's proposed PFAS Drinking Water Regulation

Apr 10, 2023

Michael S. Regan

Administrator

Environmental Protection Agency 1200 Pennsylvania Avenue, N. W.

Mail Code: 4607M

Washington, DC 20460

RE: Request for Extension for Comment Period on EPA's Proposed Per- and

Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation

(Docket ID: EPA-HQ-OW-2022-0114) [Link: https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0027]

Administrator Regan,

The proposal only provides a public review and comment period of 62 days. At the time this letter is written, the docket contains more 5,000 pages of supporting documentation. These materials must be reviewed and considered in order for stakeholders to provide constructive feedback.

We are interested in reviewing the proposal and providing feedback to the EPA presenting our perspectives on the various aspects of the rule, including:

• Water treatment costs associated with per- and polyfluoroalkyl substances (PFAS);

• Feasibility to remove PFAS to levels at or below the proposed standards;

• Feasibility for drinking water utilities to implement the proposal within the compliance timeline and the factors influencing the implementation of treatment.

• Application of the hazard index for drinking water regulation, including considerations for risk communication.

We respectfully request that EPA provide an extension of the comment deadline by 59 days to July 28, 2023 to provide a total of 121 days for public comment. Your response by April, 14, 2023 is necessary for us to successfully balance available resources to best utilize the requested extension period.

We appreciate your attention to this matter.

Jennifer McElroy

Jennifer McElroy (Apr 10, 2023 08:16 EDT)

Supervising Utility Engineer Gainesville Regional Utilities mcelroyja@gru.com

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

Southeast Florida Utility Council (SEFLUC) (Doc. #1480, SBC-042315)

Dear Mr. Regan,

I am writing to request that the Environmental Protection Agency (EPA) extend the comment deadline for the Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation by 59 days, to July 28, 2023. This extension would provide the public with a total of 121 days to review and comment on the proposed regulation/policy.

As you may be aware, this proposed regulation/policy has far-reaching implications and will significantly impact the environment, public health, and the economy. Therefore, the public must have adequate time to review the proposal, consult with stakeholders, and provide informed feedback.

Given the complexity of the proposed regulation/policy, an extension of 59 days is necessary to ensure that the public has sufficient time to provide thoughtful and substantive comments. This extension will also allow for more inclusive public participation, particularly among stakeholders who may require additional time to review and comment on the proposal.

Thank you for your attention to this matter.

Sincerely,

Marta Reczko

SEFLUC Chair

April 11, 2023

Michael S. Regan

Administrator

Environmental Protection Agency

1200 Pennsylvania Avenue, N. W.

Mail Code: 4607M

Washington, DC 20460

RE: Request for Extension for Comment Period on EPA's Proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation (Docket ID: EPA-HQ-OW-2022-0114)

Administrator Regan,

The proposal only provides a public review and comment period of 62 days. At the time this letter is written, the docket contains more 5,000 pages of supporting documentation. These materials must be reviewed and considered for stakeholders to provide constructive feedback.

The Southeast Florida Utility Council (SEFLUC) represents water utilities throughout South Florida that collectively provide potable water to over 6 million people. We are interested in reviewing the proposal and providing feedback to the EPA, presenting our perspectives on the various aspects of the rule, including:

• Water treatment costs associated with per- and polyfluoroalkyl substances (PFAS);

• Feasibility to remove PFAS to levels at or below the proposed standards;

• Feasibility for drinking water utilities to implement the proposal within the compliance timeline and the factors influencing the implementation of treatment.

• Application of the hazard index for drinking water regulation, including considerations for risk communication.

We respectfully request that EPA extend the comment deadline by 59 days to July 28, 2023, to provide 121 days for public comment. Your response by April 14, 2023, is necessary for us to successfully balance available resources to best utilize the requested extension period.

We appreciate your attention to this matter.

SEFLUC Chair

Marta Reczko

https://sefluc.org

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

Kentucky/Tennessee Section of American Water Works Association (KY/TN AWWA) (Doc. #1481, SBC-042316)

Please see attached request from the KY/TN Section of AWWA to extend the public comment period

April 10, 2023

Michael S. Regan

Administrator

Environmental Protection Agency 1200 Pennsylvania Avenue, N.W.

Mail Code: 4607M

Washington, DC 20460

RE: Request for Extension for Comment Period on EPA's Proposed Per- and Polyfluoroalkyl Substances

(PFAS) National Primary Drinking Water Regulation

(Docket ID: EPA-HQ-OW-2022-0114)

Administrator Regan,

The proposed National Primary Drinking Water Regulation for PFAS substances only provides a public review and comment period of 62 days. The corresponding docket contains more than 5,000 pages of supporting documentation. These materials must be reviewed and considered in order for stakeholders to provide constructive feedback.

Members of Kentucky/Tennessee Section of American Water Works Association (KY/TN AWWA) are interested in reviewing the proposal and providing feedback to EPA to present our perspectives on the various aspects of the proposed rule, including:

• Water treatment costs associated with PFAS;

• Feasibility to remove PFAS to levels at or below the proposed standards;

• Feasibility for drinking water utilities to implement the proposed rule within the compliance timeline, and the factors influencing the implementation of treatment; and

• Application of the proposed Hazard Index for drinking water regulation, including considerations for risk communication.

KY/TN AWWA respectfully requests an extension of the comment deadline by 59 days to July 28, 2023, to provide a total of 121 days for public comment. Your response by April 20, 2023, is requested as necessary for us to successfully balance available resources to best utilize the requested extension period.

Thank you for your consideration of this request.

Jacob J. Van Dyke, P.E.

KY/TN AWWA Chair

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

South Carolina American Water Works Association (Doc. #1482, SBC-042317)

Apr 12, 2023

Michael S. Regan

Administrator

Environmental Protection Agency 1200 Pennsylvania Avenue, N. W.

Mail Code: 4607M

Washington, DC 20460

RE: Request for Extension for Comment Period on EPA's Proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation (Docket ID: EPA-HQ-OW-2022-0114) [Link: https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0027]

Administrator Regan,

The proposal only provides a public review and comment period of 62 days. At the time this letter is written, the docket contains more 5,000 pages of supporting documentation. These materials must be reviewed and considered in order for stakeholders to provide constructive feedback.

We are interested in reviewing the proposal and providing feedback to the EPA presenting our perspectives on the various aspects of the rule, including:

• Water treatment costs associated with per- and polyfluoroalkyl substances (PFAS);

• Feasibility to remove PFAS to levels at or below the proposed standards;

• Feasibility for drinking water utilities to implement the proposal within the compliance timeline and the factors influencing the implementation of treatment.

• Application of the hazard index for drinking water regulation, including considerations for risk communication.

We respectfully request that EPA provide an extension of the comment deadline by 59 days to July 28, 2023 to provide a total of 121 days for public comment. Your response by April, 14, 2023 is necessary for us to successfully balance available resources to best utilize the requested extension period.

We appreciate your attention to this matter.

David G. Baize

David G. Baize (Apr 12, 2023 09:59 EDT)

Executive Director

South Carolina American Water Works Association

david@scwaters.org

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

The Southeast Morris County Municipal Utilities Authority (SMCMUA) (Doc. #1483, SBC-042318)

Attached please find comment period extension request letter.

April 10, 2023

VIA ELECTRONIC SUBMISSION

Michael S. Regan

Administrator

US Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington, DC 20460

Re: Extension request of comment period for Docket ID #: EPA-HQ-OW-2022-0114; PFAS National Primary Drinking Water Regulation Rulemaking

Dear Administrator Regan:

The Southeast Morris County Municipal Utilities Authority (SMCMUA) respectfully asks that, due to the vast complexity of the rule and the effect it will have on our organization, EPA grant at least a 30-day extension to the comment period to ensure useful and meaningful feedback.

A crucial step of the regulatory process is the public comment period. Feedback and recommendations from impacted stakeholders and the regulated community provide a unique perspective that often strengthens and improves a proposed rule. SMCMUA believes it is in the interest of EPA to provide an adequate comment period for such an important and consequential rule. We will be able to provide much more insightful and helpful comments if given the time to review the many pages of documents and supporting materials provided by EPA.

While SMCMUA will be diligently working to provide thoughtful comments on this proposed rule, it is important to remind EPA that this is not the only rulemaking being proposed with an open public comment period that will impact drinking water utilities. Contaminant Candidate List 6, Consumer Confidence Reports, ANPRM for additional PFAS CERCLA designations, and Steam Power ELGs are all in the process, or will be shortly, of soliciting public comments simultaneously with this proposed rule. At the time of the creation of this letter, there are 1,241 supporting or related material provided in the rulemaking docket to review. A condensed period for public comment on this rule only diverts resources from providing robust comments to other notices currently open in the Federal Register.

As part of the regulated community that will be significantly affected by this proposed rulemaking, we will be directly influenced by the significant cost and time this rule will impose on our operations. While SMCMUA understands the importance of finalizing this rule in a timely manner, we believe thoughtful public comments will only strengthen the final rule and ultimately provide more protections for public health. Therefore, we request EPA extend the comment period by at least 30 days. We also ask EPA to respond to this request in a timely manner so comments can be developed with an accurate due date in mind.

SMCMUA appreciates EPA giving this request consideration. If you have any further questions, please contact me at 973-261-4437 or lcummings@smcmua.org.

Sincerely,

Laura Cummings, PE

Executive Director

cc: Alexis Lan, OGWDW [lan.alexis@epa.gov]

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document.

JEA (Doc. #1484, SBC-042319)

April 11, 2023

Michael S. Regan

Administrator

Environmental Protection Agency

1200 Pennsylvania Avenue, N. W.

Mail Code: 4607M

Washington, DC 20460

RE: Request for Extension for Comment Period on EPA's Proposed Per- and Polyfluoralkyl Substances (PFAS) National Primary Drinking Water Regulation (Docket ID: EPA-HQ-OW-2022-0114) [Link: Broken]

Administrator Regan,

The proposal only provides a public review and comment period of 62 days. At the time this letter is written, the docket contains more than 5,000 pages of supporting documentation. These materials must be reviewed and considered in order for stakeholders to provide constructive feedback.

We are interested in reviewing the proposal and providing feedback to the EPA presenting our perspectives on the various aspects of the rule, including:

• Water treatment costs associated with PFAS;

• Feasibility to remove PFAS to levels at or below the proposed standards;

• Feasibility for drinking water utilities to implement the proposal within the compliance timeline and the factors influencing the implementation of treatment; and

• Application of the hazard index for drinking water regulation, including considerations for risk communication.

We respectfully request that EPA provide an extension of the comment deadline by 59 days to July 28, 2023 to provide a total of 121 days for public comment. Your response by April, 14, 2023 is necessary for us to successfully balance available resources to best utilize the requested extension period.

We appreciate your attention to this matter.

Wayne Young

O.W. Young

VP Environmental Services

JEA

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

Pinellas County Utilities (Doc. #1485, SBC-042320)

April 7, 2023

Michael S. Regan

Administrator

Environmental Protection Agency

1200 Pennsylvania Avenue NW

Mail Code: 4607M

Washington, DC 20460

Re: Request for Extension for Comment Period on EPA's Proposed Per- and Polyfluoralkyl Substances (PFAS) National Primary Drinking Water Regulation (Docket ID: EPA-HQ-OW-2022-0114)

Dear Administrator Regan:

The proposal only provides a public review and comment period of 62 days. At the time this letter is written, the docket contains more than 5,000 pages of supporting documentation. These material must be reviewed and considered in order for stakeholders to provide constructive feedback.

We are interested in reviewing the proposal and providing feedback to the EPA presenting our perspectives on the various aspects of the rule, including:

• Water treatment costs associated with PFAS;

• Feasibility to remove PFAS to levels at or below the proposed standards;

• Feasibility for drinking water utilities to implement the proposal within the compliance timeline and the factors influencing the implementation of treatment; and

• Application of the hazard index for drinkng water regulation, including considerations for risk communication.

We respectfully request that EPA provide an extension of the comment deadline by 59 days to July 28, 2023 to provide a total of 121 days for public comment. Your response by April 14, 2023 is necessary for us to successfully balance available resources to best utilize the requested extension period.

We appreciate your attention to this matter.

Sincerely,

Megan E. Ross, PE, ENV SP

Director of Utilities

Pinellas County Utilities

mross@pinellas.gov

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

Iowa Section AWWA (Doc. #1486, SBC-042321)

Apr 12, 2023

Michael S. Regan

Administrator

Environmental Protection Agency 1200 Pennsylvania Avenue, N. W.

Mail Code: 4607M

Washington, DC 20460

RE: Request for Extension for Comment Period on EPA's Proposed Per- and

Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation

(Docket ID: EPA-HQ-OW-2022-0114) [Link: https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0027]

Administrator Regan,

The proposal only provides a public review and comment period of 62 days. At the time this letter is written, the docket contains more 5,000 pages of supporting documentation. These materials must be reviewed and considered in order for stakeholders to provide constructive feedback.

We are interested in reviewing the proposal and providing feedback to the EPA presenting our perspectives on the various aspects of the rule, including:

• Water treatment costs associated with per- and polyfluoroalkyl substances (PFAS);

• Feasibility to remove PFAS to levels at or below the proposed standards;

• Feasibility for drinking water utilities to implement the proposal within the compliance timeline and the factors influencing the implementation of treatment.

• Application of the hazard index for drinking water regulation, including considerations for risk communication.

We respectfully request that EPA provide an extension of the comment deadline by 59 days to July 28, 2023 to provide a total of 121 days for public comment. Your response by April, 14, 2023 is necessary for us to successfully balance available resources to best utilize the requested extension period.

We appreciate your attention to this matter.

Jennifer Ruddy

Jennifer Ruddy (Apr 12, 2023 16:12 CDT)

IA AWWA Section Chair Iowa AWWA jenny.ruddy@strand.com

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

City of Fort Meade (Doc. #1488, SBC-042362)

Apr 13, 2023

Michael S. Regan

Administrator

Environmental Protection Agency 1200 Pennsylvania Avenue, N. W.

Mail Code: 4607M

Washington, DC 20460

RE: Request for Extension for Comment Period on EPA's Proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation (Docket ID: EPA-HQ-OW-2022-0114 [Link: https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0027])

Administrator Regan,

The proposal only provides a public review and comment period of 62 days. At the time this letter is written, the docket contains more 5,000 pages of supporting documentation. These materials must be reviewed and considered in order for stakeholders to provide constructive feedback.

We are interested in reviewing the proposal and providing feedback to the EPA presenting our perspectives on the various aspects of the rule, including:

• Water treatment costs associated with per- and polyfluoroalkyl substances (PFAS);

• Feasibility to remove PFAS to levels at or below the proposed standards;

• Feasibility for drinking water utilities to implement the proposal within the compliance timeline and the factors influencing the implementation of treatment.

• Application of the hazard index for drinking water regulation, including considerations for risk communication.

We respectfully request that EPA provide an extension of the comment deadline by 59 days to July 28, 2023 to provide a total of 121 days for public comment. Your response by April, 14, 2023 is necessary for us to successfully balance available resources to best utilize the requested extension period.

We appreciate your attention to this matter.

Thomas King

Thomas King (Apr 13, 2023 08:42 EDT)

Water and Wastewater Director City of Fort Meade tking@cityoffortmeade.com

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

Tampa Water Department (Doc. #1489, SBC-042365)

City of Tampa

Jane Castor, Mayor

Water Department

Office of the Director

711 E. Henderson Avenue

Tampa, FL 33602

Office: (813) 274-7105

Fax: (813) 231-1325

April 12, 2023

Michael S. Regan, Administrator

Environmental Protection Agency

1200 Pennsylvania Avenue, N.W.

MailCode: 4607M

Washington, DC 20460

RE: Request for Extension for Comment Period on EPA's Per-and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation (Docket ID: EPA-HQ-OW-2022-0114)

Administrator Regan,

The proposal only provides a public review and comment period of 62 days. At the time this letter is written, the docket contains more than 5,000 pages of supporting documentation. These materials must be reviewed and considered in order for stakeholders to provide constructive feedback.

We are interested in reviewing the proposal, providing feedback to the EPA and presenting our perspectives on the various aspects of the rule including:

- Water treatment costs associated with per- and polyfluoroalkyl substances (PFAS);
- Feasibility to remove PFAS to levels at or below the proposed standards;
- Feasibility for drinking water utilities to implement the proposal within the compliance timeline and the factors influencing the implementation of treatment.
- Application of the hazard index for drinking water regulation, including considerations for risk communication.

We respectfully request that EPA provide an extension of the comment deadline by 59 days to July 28, 2023 to provide a total of 121 days for public comment. Your response by April 14, 2023 is necessary for us to successfully balance available resources to best utilize the requested extension.

We appreciate your attention to this matter.

Charles J. Weber, P.E.

Director

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

Hidden Valley Lake Community Services District (Doc. #1490, SBC-042366)

Apr 10, 2023

Michael S. Regan

Administrator

Environmental Protection Agency 1200 Pennsylvania Avenue, N. W.

Mail Code: 4607M

Washington, DC 20460

RE: Request for Extension for Comment Period on EPA's Proposed Per- and

Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation

(Docket ID: EPA-HQ-OW-2022-0114 [Link: https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0027])

Administrator Regan,

The proposal only provides a public review and comment period of 62 days. At the time this letter is written, the docket contains more 5,000 pages of supporting documentation. These materials must be reviewed and considered in order for stakeholders to provide constructive feedback.

We are interested in reviewing the proposal and providing feedback to the EPA presenting our perspectives on the various aspects of the rule, including:

• Water treatment costs associated with per- and polyfluoroalkyl substances (PFAS);

• Feasibility to remove PFAS to levels at or below the proposed standards;

• Feasibility for drinking water utilities to implement the proposal within the compliance timeline and the factors influencing the implementation of treatment.

• Application of the hazard index for drinking water regulation, including considerations for risk communication.

We respectfully request that EPA provide an extension of the comment deadline by 59 days to July 28, 2023 to provide a total of 121 days for public comment. Your response by April, 14, 2023 is necessary for us to successfully balance available resources to best utilize the requested extension period.

We appreciate your attention to this matter.

Hannah Davidson

Water Resources Specialist

Hidden Valley Lake Community Services District

hdavidson@hvlcsd.org

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

Cobb County- Marieta Water Authority (Doc. #1491, SBC-042470)

Letter request for extension for comment period

Apr 13, 2023

Michael S. Regan

Administrator

Environmental Protection Agency 1200 Pennsylvania Avenue, N. W.

Mail Code: 4607M

Washington, DC 20460

RE: Request for Extension for Comment Period on EPA's Proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation (Docket ID: EPA-HQ-OW-2022-0114 [Link: https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0027])

Administrator Regan,

The proposal only provides a public review and comment period of 62 days. At the time this letter is written, the docket contains more 5,000 pages of supporting documentation. These materials must be reviewed and considered in order for stakeholders to provide constructive feedback.

We are interested in reviewing the proposal and providing feedback to the EPA presenting our perspectives on the various aspects of the rule, including:

• Water treatment costs associated with per- and polyfluoroalkyl substances (PFAS);

• Feasibility to remove PFAS to levels at or below the proposed standards;

• Feasibility for drinking water utilities to implement the proposal within the compliance timeline and the factors influencing the implementation of treatment.

• Application of the hazard index for drinking water regulation, including considerations for risk communication.

We respectfully request that EPA provide an extension of the comment deadline by 59 days to July 28, 2023 to provide a total of 121 days for public comment. Your response by April, 14, 2023 is necessary for us to successfully balance available resources to best utilize the requested extension period.

We appreciate your attention to this matter.

Karen Osborne

Laboratory Division Manager

Cobb County- Marieta Water Authority

kosborne@ccmwa.org

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

Tampa Bay Water (Doc. #1492, SBC-042478)

Apr 13, 2023

Michael S. Regan

Administrator

Environmental Protection Agency 1200 Pennsylvania Avenue, N. W.

Mail Code: 4607M

Washington, DC 20460

RE: Request for Extension for Comment Period on EPA's Proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation (Docket ID: EPA-HQ-OW-2022-0114 [Link: https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0027])

Administrator Regan,

The proposal only provides a public review and comment period of 62 days. At the time this letter is written, the docket contains more 5,000 pages of supporting documentation. These materials must be reviewed and considered in order for stakeholders to provide constructive feedback.

We are interested in reviewing the proposal and providing feedback to the EPA presenting our perspectives on the various aspects of the rule, including:

• Water treatment costs associated with per- and polyfluoroalkyl substances (PFAS);

• Feasibility to remove PFAS to levels at or below the proposed standards;

• Feasibility for drinking water utilities to implement the proposal within the compliance timeline and the factors influencing the implementation of treatment.

• Application of the hazard index for drinking water regulation, including considerations for risk communication.

We respectfully request that EPA provide an extension of the comment deadline by 59 days to July 28, 2023 to provide a total of 121 days for public comment. Your response by April, 14, 2023 is necessary for us to successfully balance available resources to best utilize the requested extension period.

We appreciate your attention to this matter.

Charles H. Carden

General Manager Tampa Bay Water ccarden@tampabaywater.org

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

City of St. Louis Water Division, Missouri (Doc. #1493, SBC-042486)

Apr 13, 2023

Michael S. Regan

Administrator

Environmental Protection Agency 1200 Pennsylvania Avenue, N. W.

Mail Code: 4607M

Washington, DC 20460

RE: Request for Extension for Comment Period on EPA's Proposed Per- and

Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation

(Docket ID: EPA-HQ-OW-2022-0114 [Link: https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0027])

Administrator Regan,

The proposal only provides a public review and comment period of 62 days. At the time this letter is written, the docket contains more 5,000 pages of supporting documentation. These materials must be reviewed and considered in order for stakeholders to provide constructive feedback.

We are interested in reviewing the proposal and providing feedback to the EPA presenting our perspectives on the various aspects of the rule, including:

• Water treatment costs associated with per- and polyfluoroalkyl substances (PFAS);

• Feasibility to remove PFAS to levels at or below the proposed standards;

• Feasibility for drinking water utilities to implement the proposal within the compliance timeline and the factors influencing the implementation of treatment.

• Application of the hazard index for drinking water regulation, including considerations for risk communication.

We respectfully request that EPA provide an extension of the comment deadline by 59 days to July 28, 2023 to provide a total of 121 days for public comment. Your response by April, 14, 2023 is necessary for us to successfully balance available resources to best utilize the requested extension period.

We appreciate your attention to this matter.

Michael J. Galluzzo, P.E.

Water Production Engineer

St. Louis City Water Division mjgalluzzo@stlwater.com

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

Hillsborough County Utilities (Doc. #1494, SBC-042563)

Apr 6, 2023

Michael S. Regan

Administrator

Environmental Protection Agency 1200 Pennsylvania Avenue, N. W.

Mail Code: 4607M

Washington, DC 20460

RE: Request for Extension for Comment Period on EPA's Proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation (Docket ID: EPA-HQ-OW-2022-0114 [Link: https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0027])

Administrator Regan,

The proposal only provides a public review and comment period of 62 days. At the time this letter is written, the docket contains more 5,000 pages of supporting documentation. These materials must be reviewed and considered in order for stakeholders to provide constructive feedback.

We are interested in reviewing the proposal and providing feedback to the EPA presenting our perspectives on the various aspects of the rule, including:

• Water treatment costs associated with per- and polyfluoroalkyl substances (PFAS);

• Feasibility to remove PFAS to levels at or below the proposed standards;

• Feasibility for drinking water utilities to implement the proposal within the compliance timeline and the factors influencing the implementation of treatment.

• Application of the hazard index for drinking water regulation, including considerations for risk communication.

We respectfully request that EPA provide an extension of the comment deadline by 59 days to July 28, 2023 to provide a total of 121 days for public comment. Your response by April, 14, 2023 is necessary for us to successfully balance available resources to best utilize the requested extension period.

We appreciate your attention to this matter.

Lisa R. Rhea, PE

Water Resources Director

Hillsborough County Public Utilities

RheaL@hillsboroughcounty.org

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

Orange County Water District (OCWD), California (Doc. #1495, SBC-042564)

ORANGE COUNTY WATER DISTRICT

April 13, 2023

Michael S. Regan

Administrator

US Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington, DC 20460

Via electronic submission

RE: Extension request of comment period for Docket ID #: EPA-HQ-OW-20220114; Proposed PFAS National Primary Drinking Water Regulation

Administrator Regan,

Orange County Water District (OCWD) respectfully asks that, due to the vast complexity of the above referenced proposed regulation and the effect it will have on our organization and service area, EPA grant a 59-day extension to July 28, 2023 to provide a total of 121 days for public comment. The docket contains more than 5,000 pages of supporting documentation and the current proposal only provides a public review and comment period of 61 days.

The public comment period is a crucial step in the regulatory process, especially for a regulation of this magnitude. As a part of the regulated community that will be significantly affected by the proposed rulemaking, we require additional time to review the proposal and provide meaningful feedback to EPA on various aspects of the regulation, including:

* Water treatment costs

* Feasibility for drinking water utilities to implement the proposal

* Application of the Hazard Index for drinking water regulation

OCWD appreciates EPA's consideration of this time extension request.

Michael R. Markus, P.E., D.WRE, BCEE, F.ASCE

General Manager

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

Utilities Division of Public Works, City of Fort Lauderdale, Florida (Doc. #1496, SBC-042565)

Please see attached file requesting a time extension. Thank you.

Apr 11, 2023

Michael S. Regan

Administrator

Environmental Protection Agency

1200 Pennsylvania Avenue, N. W.

Mail Code: 4607M

Washington, DC 20460

RE: Request for Extension for Comment Period on EPA's Proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation Docket ID: EPA-HQ-OW-2022-0114)

Administrator Regan,

The proposal only provides a public review and comment period of 62 days. At the time this letter is written, the docket contains more 5,000 pages of supporting documentation. These materials must be reviewed and considered in order for stakeholders to provide constructive feedback.

We are interested in reviewing the proposal and providing feedback to the EPA presenting our perspectives on the various aspects of the rule, including:

- Water treatment costs associated with per- and polyfluoroalkyl substances (PFAS);
- Feasibility to remove PFAS to levels at or below the proposed standards;
- Feasibility for drinking water utilities to implement the proposal within the compliance timeline and the factors influencing the implementation of treatment.
- Application of the hazard index for drinking water regulation, including considerations for risk communication.

We respectfully request that EPA provide an extension of the comment deadline by 59 days to July 28, 2023 to provide a total of 121 days for public comment. Your response by April, 14, 2023 is necessary for us to successfully balance available resources to best utilize the requested extension period.

We appreciate your attention to this matter.

Talal Abi-Karam

Assistant Public Works Director- Utilities

City of Fort Lauderdale

TAbi-Karam@fortlauderdale.gov

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

City of Sacramento Department of Utilities, California (Doc. #1497, SBC-042566)

The City of Sacramento Department of Utilities respectfully asks that, due to the vast complexity of the rule and the effect it will have on our organization, EPA grant at least a 30-day extension to the comment period to ensure useful and meaningful feedback.

April 12, 2023

Michael S. Regan

Administrator

US Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington, DC 20460

Via electronic submission

Re: Extension request of comment period for Docket ID #: EPA-HQ-OW-2022-0114; PFAS National Primary Drinking Water Regulation Rulemaking

Dear Administrator Regan,

The City of Sacramento Department of Utilities respectfully asks that, due to the vast complexity of the rule and the effect it will have on our organization, EPA grant at least a 30-day extension to the comment period to ensure useful and meaningful feedback.

A crucial step of the regulatory process is the public comment period. Feedback and recommendations from impacted stakeholders and the regulated community provide a unique perspective that often strengthens and improves a proposed rule. The City of Sacramento Department of Utilities believes it is in the interest of EPA to provide an adequate comment period for such an important and consequential rule. We will be able to provide much more insightful and helpful comments if given the time to review the many pages of documents and supporting materials provided by EPA.

While the City of Sacramento Department of Utilities will be diligently working to provide thoughtful comments on this proposed rule, it is important to remind EPA that this is not the only rulemaking being proposed with an open public comment period that will impact drinking water utilities. Contaminant Candidate List 6, Consumer Confidence Reports, ANPRM for additional PFAS CERCLA designations, and Steam Power ELGs are all in the process, or will be shortly, of soliciting public comments simultaneously with this proposed rule. At the time of the creation of this letter, there are 1,241 supporting or related materials provided in the rulemaking docket to review. A condensed period for public comment on this rule only diverts resources from providing robust comments to other notices currently open in the Federal Register.

As part of the regulated community that will be significantly affected by this proposed rulemaking, we will be directly influenced by the significant cost and time this rule will impose on our operations. While the City of Sacramento Department of Utilities understands the importance of finalizing this rule in a timely manner, we believe thoughtful public comments will only strengthen the final rule and ultimately provide more protections for public health. Therefore, we request EPA extend the comment period by at least 30 days. We also ask EPA to respond to this request in a timely manner so comments can be developed with an accurate due date in mind.

The City of Sacramento Department of Utilities appreciates EPA giving this request consideration. If you have any further questions, please contact Brian Sanders, Program Specialist, Governments Affairs, City of Sacramento Department of Utilities at bsanders@cityofsacramento.org.

Sincerely,

Sherill Huun

Engineering Division Manager

cc: Alexis Lan, OGWDW [lan.alexis@epa.gov]

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document.

South Walton Uility Company, Inc. (Doc. #1498, SBC-042567)

Mar 31, 2023

Michael S. Regan

Administrator

Environmental Protection Agency 1200 Pennsylvania Avenue, N. W.

Mail Code: 4607M

Washington, DC 20460

RE: Request for Extension for Comment Period on EPA's Proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation (Docket ID: EPA-HQ-OW-2022-0114 [Link: https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0027])

Administrator Regan,

The proposal only provides a public review and comment period of 62 days. At the time this letter is written, the docket contains more 5,000 pages of supporting documentation. These materials must be reviewed and considered in order for stakeholders to provide constructive feedback.

We are interested in reviewing the proposal and providing feedback to the EPA presenting our perspectives on the various aspects of the rule, including:

• Water treatment costs associated with per- and polyfluoroalkyl substances (PFAS);

• Feasibility to remove PFAS to levels at or below the proposed standards;

• Feasibility for drinking water utilities to implement the proposal within the compliance timeline and the factors influencing the implementation of treatment.

• Application of the hazard index for drinking water regulation, including considerations for risk communication.

We respectfully request that EPA provide an extension of the comment deadline by 59 days to July 28, 2023 to provide a total of 121 days for public comment. Your response by April, 14, 2023 is necessary for us to successfully balance available resources to best utilize the requested extension period.

We appreciate your attention to this matter.

Alicia Keeter (Mar 31, 2023 12:42 CDT)

General Manager

South Walton Utility Co., Inc.

aak@swuci.org

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

PFAS Regulatory Coalition (Doc. #1501, SBC-042570)

Attached on behalf of the PFAS Regulatory Coalition is a request for extension of the comment period on the EPA Proposed PFAS National Primary Drinking Water Regulation Rulemaking. Please feel free to call or e-mail if you have any questions. Thank you.

April 17, 2023

Ms. Alexis Lan

Office of Ground Water and Drinking Water

Standards and Risk Management Division (Mail Code 4607M) U.S. Environmental Protection Agency 1200 N. Pennsylvania Avenue, N.W.

Washington, D.C. 20460

Re: Request for Extension of Comment Period on EPA Proposed PFAS National Primary Drinking Water Regulation Rulemaking Docket ID No. EPA-HQ-OW-2022-0114

Dear Ms. Lan:

The PFAS Regulatory Coalition (the Coalition) requests that the U. S. Environmental Protection Agency (EPA) grant a 60-day extension on the comment period for its proposal, PFAS National Primary Drinking Water Regulation Rulemaking ("the EPA Proposal") (88 Fed. Reg. 18638, Mar. 29, 2023).

The Coalition is a group of industrial companies, municipal entities, agricultural parties, aviation representatives and trade associations, each of which has facilities or members that are directly affected by the development of policies and regulations related to per- and poly-fluoroalkyl substances (PFAS). Coalition membership includes entities in the automobile, airport, coke and coal chemicals, iron and steel, municipal, paper, petroleum, and other sectors. None of the Coalition members manufacture PFAS compounds. Coalition members, for purposes of these comments, include: Airports Council International – North America; American Coke and Coal Chemicals Institute; American Forest and Paper Association; American Fuel and Petrochemical Manufacturers; American Iron and Steel Institute; American Petroleum Institute; Barr Engineering; Brown & Caldwell; City of Pueblo, CO; Gary Sanitary District (IN); HDR; Illinois Association of Wastewater Agencies; National Oilseed Processors Association; Trihydro; and Western States Petroleum Association.

PFAS Regulatory Coalition member entities or their members own and operate facilities located throughout the country. Many of those facilities would incur substantial costs to comply with the new drinking water standards. In addition, these standards would affect other regulatory requirements that are regularly imposed on Coalition members and their operations, including remediation mandates. The Coalition, therefore, has a direct interest in the EPA Proposal.

A 60-day comment period on the EPA Proposal is simply not adequate to allow the PFAS Regulatory Coalition and other stakeholders to review the Agency materials, develop comments, and suggest positive solutions to address the concerns identified in the comments. The Proposal itself takes up 117 pages in the Federal Register, and raises some 59 separate questions on which stakeholders are invited to comment and submit information. Moreover, the supporting technical materials in the docket are voluminous. The docket includes over 1200 separate documents, totaling thousands of pages. It is unreasonable and contrary to the intent of the Administrative Procedure Act to expect impacted members of the public to conduct a careful review of this enormous set of documents in the allotted time, let alone prepare and submit helpful and carefully considered comments on the important issues raised by the EPA Proposal and the supporting materials. That is especially the case given that this Proposal is really two regulatory actions in one document - a regulatory determination as to four PFAS that have not been addressed previously, and proposed standards for PFOA, PFOS, and those four additional substances. The review time should be extended accordingly.

The PFAS Regulatory Coalition, and other regulated party groups that we work with, have commented on many EPA regulatory documents before. It is very unusual for an agency action as important as the EPA Proposal to be subject to a comment period as short as 60 days. There is no statutory or regulatory deadline that compels the Agency to provide such an abbreviated comment period in this situation. Hence, in order for stakeholders to participate in the Agency's process of considering whether the EPA Proposal is appropriate, an extension of the comment period by at least 60 days is needed. Therefore, we request that EPA extend the comment period to July 31, 2023.

The PFAS Regulatory Coalition looks forward to continuing to engage with EPA on the EPA Proposal, including through the filing of comments. Please feel free to call or e-mail if you have any questions, or if you would like any additional information concerning the issues raised in this letter.

Fredric Andes

fandes@btlaw.com

Tammy Helminski

thelminski@btlaw.com

Jeffrey Longsworth

jeffrey.longsworth@earthandwatergroup.com

Coordinators

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document.

Central Lake County Joint Action Water Agency (Doc. #1502, SBC-042571)

Apr 18, 2023

Michael S. Regan

Administrator

Environmental Protection Agency 1200 Pennsylvania Avenue, N. W.

Mail Code: 4607M

Washington, DC 20460

RE: Request for Extension for Comment Period on EPA's Proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation (Docket ID: EPA-HQ-OW-2022-0114 [Link: https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0027])

Administrator Regan,

The proposal only provides a public review and comment period of 62 days. At the time this letter is written, the docket contains more 5,000 pages of supporting documentation. These materials must be reviewed and considered in order for stakeholders to provide constructive feedback.

We are interested in reviewing the proposal and providing feedback to the EPA presenting our perspectives on the various aspects of the rule, including:

• Water treatment costs associated with per- and polyfluoroalkyl substances (PFAS);

• Feasibility to remove PFAS to levels at or below the proposed standards;

• Feasibility for drinking water utilities to implement the proposal within the compliance timeline and the factors influencing the implementation of treatment.

• Application of the hazard index for drinking water regulation, including considerations for risk communication.

We respectfully request that EPA provide an extension of the comment deadline by 59 days to July 28, 2023 to provide a total of 121 days for public comment. Your response by April, 14, 2023 is necessary for us to successfully balance available resources to best utilize the requested extension period.

We appreciate your attention to this matter.

William J. Soucie

William J. Soucie (Apr 18, 2023 11:11 CDT)

Executive Director

Central Lake County Joint Action Water Agency

soucie@clcjawa.comw

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

U.S. Small Business Administration's Office of Advocacy (Doc. #1505, SBC-042573)

U.S. Small Business Administration's Office of Advocacy's Recommendation to Extend the Comment Period for EPA's Proposed PFAS National Primary Drinking Water Regulation Rulemaking.

April 18, 2023

VIA ELECTRONIC SUBMISSION

The Honorable Michael S. Regan

Administrator

Environmental Protection Agency

Washington, DC 20460

Re: PFAS National Primary Drinking Water Regulation Rulemaking (Docket ID: EPAHQ-OW-2022-0114)

Dear Administrator Regan:

On March 29, 2023, the Environmental Protection Agency (EPA) published a proposed rule titled "PFAS National Primary Drinking Water Regulation Rulemaking."[FN1: 88 Fed. Reg. 18638 (March 29, 2023).] The Office of Advocacy (Advocacy) is concerned that given the complexity and scope of the rule, the current comment period will not be sufficient to allow small entity stakeholders to provide meaningful feedback. Therefore, Advocacy recommends EPA extend the public comment period for this proposed rule by at least 30 days.

I. Background

A. The Office of Advocacy

Congress established the Office of Advocacy under Pub. L. 94-305 to represent the views of small entities before Federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA). As such, the views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration. The Regulatory Flexibility Act (RFA), [FN2: 5 U.S.C. §601 et seq.] as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), [FN3: Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. §601 et seq.).] gives small entities a voice in the rulemaking process. For all rules that are expected to have a significant economic impact on a substantial number of small entities, the RFA requires federal agencies to assess the impact of the proposed rule on small entities and to consider less burdensome alternatives.

The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy. [FN4: Small Business Jobs Act of 2010 (PL. 111-240) §1601] The agency must include a response to these written comments in any explanation or discussion accompanying the final rule's publication in the Federal Register, unless the agency certifies that the public interest is not served by doing so. [FN5: Id.]

Advocacy's comments are consistent with Congressional intent underlying the RFA, that "[w]hen adopting regulations to protect the health, safety, and economic welfare of the nation, federal agencies should seek to achieve statutory goals as effectively and efficiently as possible without imposing unnecessary burdens on the public." [FN6: Id.]

B. The Proposed Rule

On March 29, 2023, EPA published its proposed National Primary Drinking Water Regulation (NPDWR) rulemaking, which includes the following per- and polyfluoroalkyl substances (PFAS):

• perfluorooctanoic acid (PFOA)

• perfluorooctane sulfonic acid (PFOS)

• perfluorohexane sulfonic acid (PFHxS)

• hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salt (also known as a GenX chemicals)

• perfluorononanoic acid (PFNA)

• perfluorobutane sulfonic acid (PFBS)

The proposed rule requires public water systems to monitor for these PFAS, notify the public of the levels of these PFAS, and reduce the levels of these PFAS in drinking water if they exceed the proposed standards. Reduction methods can include the installation of and disposal of PFAS residue from treatment technologies such as granular activated carbon, anion exchange, nanofiltration and reverse osmosis or switching to an alternative water source.

The proposal contains several agency actions:

1. Proposed legally enforceable levels, called Maximum Contaminant Levels (MCLs), for PFOA and PFOS at 4 parts per trillion (ppt).

2. Proposed preliminary determination to regulate PFHxS, GenX chemicals, PFNA and PFBS, and mixtures of these PFAS.

3. Proposed MCLs for the above four PFAS at a unitless MCL of 1.0, based on a novel approach called a hazard index, which is used to evaluate potential health risks from exposure to chemical mixtures.

4. Proposed health-based, non-enforceable Maximum Contaminant Level Goals (MCLGs) for these six PFAS. For PFOA and PFOS, the proposed MCLG is zero and for the PFAS mixture the agency proposes the same unitless 1.0 hazard index.

In advance of the proposed rule, EPA convened a SBREFA panel to consult with small entity representatives (SERs). EPA presented to the small entities some PFAS background (with only PFOA and PFOS specifically identified) and potential monitoring and reporting rule compliance considerations and treatment and feasibility considerations. EPA, however, did not provide the SERs with the identity of the other four PFAS, any MCL values, any MCLG values and the technical details and analyses supporting these additional elements.

II. Recommendation for Extension of the Public Comment Period

EPA's current comment deadline for May 30, 2023, provides stakeholders with only 62 days to review its proposed actions, and over 1,000 supporting materials replete with complex and technical analyses. The rule is expected to impose a costly regulatory burden on small entities such as small public water systems. Therefore, Advocacy urges EPA to extend this public comment period by at least 30 additional days to allow for a meaningful review of this important and consequential proposed rulemaking package.

Small entities and their representatives have expressed concerns about their ability to provide constructive feedback given the scope and complexity of the proposal. Small entities are usually constrained due to their limited resources. Adding the responsibility to review this proposal and its supporting materials within just two months may limit a small entity's ability to express their concerns and provide useful feedback. Based on our initial outreach, small entities are gravely concerned about the substantial compliance costs associated with the rule, especially in light of the low levels proposed for the MCLs.

EPA has received extension requests from trade associations representing the interests of large and small public water systems. Among this group is the Association of State Drinking Water Administrators (ASDWA), an organization that represents EPA's co-regulators in implementing the NPDWR. EPA also conducted outreach with this group in developing the proposal. In its request for additional time, ASDWA cautions EPA that "an expeditious schedule should not come at the expense of obtaining meaningful engagement with stakeholders."[FN7: Letter from the Association of State Drinking Water Administrators to the Environmental Protection Agency, (March 29, 2023), Request for Comment Period Extension for Proposed PFAS National Primary Drinking Water Regulation (NPDWR), Docket ID: EPA-HQ-OW-2022-0114-1469. [Link: https://www.regulations.gov/comment/EPA-HQ-OW-2022-0114-1469]] Advocacy agrees.

At least a 30-day extension of the public comment period will allow small entities the additional time needed to provide useful and important feedback to ensure that the finalized rule can be effectively implemented and lead to successful compliance.

III. Conclusion

Advocacy urges EPA to extend the public comment period by at least 30 days to allow for small entities to participate more meaningfully in this rulemaking process. Such an extension will help small entities provide more comprehensive and detailed comments on this important rulemaking.

If you have any questions or require additional information, please contact me or Assistant Chief Counsel Tayyaba Zeb at (202) 798-7405 or by email at tayyaba.zeb@sba.gov.

Sincerely,

Major L. Clark, III

Deputy Chief Counsel

Office of Advocacy

U.S. Small Business Administration

Tayyaba Zeb

Assistant Chief Counsel

Office of Advocacy

U.S. Small Business Administration

Copy to:Richard L. Revesz, Administrator

Office of Information and Regulatory Affairs

Office of Management and Budget

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document. For discussion of the EPA's actions taken as required under the Regulatory Flexibility Act (RFA) / Small Business Regulatory Enforcement Fairness Act (SBREFA), including the EPA's convening of a Small Business Advocacy Review (SBAR) Panel to obtain advice and recommendations from small entity representatives (SERs) that may be subject to the rule, please see section 14.3 of the EPA response in this *Response to Comments* document.

Lehigh County Authority (LCA) (Doc. #1507, SBC-042579)

April 19, 2023

Michael S. Regan, Administrator

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Mail Code: 4607M

Washington, DC 20460

Re: Request for Extension of the Comment Period on EPA's Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation (Docket ID: EPA-HW-OW-2022-0114)

Dear Administrator Regan,

Lehigh County Authority (LCA) requests that the U.S. Environmental Protection Agency (EPA) provide a 60-day extension of the comment deadline for the proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation (Docket ID: EPA-HW-OW-20220114). Further, we request that a decision on the comment deadline extension be announced as soon as possible, and at least by April 30, 2023, so that water utilities and other stakeholders have adequate notice and can properly allocate their resources toward reviewing this important proposed regulation.

An extension of the comment period is important to LCA and many other water utilities across the nation, as we consider the impact of this proposed regulation and review the approximately 5,000 pages of supporting documents that accompany it. The proposed rule includes many new components that have not been used in prior regulations, and they must be carefully considered

and understood before we can comment on them. For example, the "hazard index" approach is a novel idea that must be carefully examined.

LCA provides high-quality, reliable water service to more than 200,000 people in eastern Pennsylvania. Our community will be impacted by this regulation if it is finalized as proposed. We believe it is worth a little extra time to allow stakeholders like LCA to review the details of what is proposed and provide meaningful input.

LCA appreciates your attention to this matter. If you have any questions about this letter, please contact me at LieselGross@LehighCountyAuthority.org.

Sincerely,

Liesel M. Gross

Chief Executive Officer

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

National Ground Water Association (NGWA) (Doc. #1515, SBC-042607)

The National Ground Water Association requests that EPA consider extending the comment period to July 28, 2023, to allow adequate time for review of documents supporting the proposed rule, Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation, Docket ID No. EPA-HQ-OW-2022-0114. Please see attached file for the full explanation of the request. Thank you for your consideration.

April 19, 2023

SENT VIA ELECTRONIC MAIL to Federal eRulemaking portal: https://www.regulations.gov

Alexis Lan

Office of Ground Water and Drinking Water

Standards and Risk Management Division (Mail Code 4607M)

Environmental Protection Agency

1200 Pennsylvania Avenue NW

Washington, DC 20460

Re: Request for Time Extension of Public Comment Period on "PFAS National Primary Drinking Water Regulation Rulemaking"; Docket ID No. EPA-HQ-OW-2022-0114

Dear Ms. Lan:

The National Ground Water Association (NGWA) respectfully asks for a time extension in the review of and comment on the proposed rule to set maximum contaminant levels for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) as contaminants and regulate perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPODA) and its ammonium salt (also known as a GenX chemicals), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS), and mixtures of these PFAS as contaminants under Safe Drinking Water Act (SDWA) through use of a hazard index. We appreciate the Environmental Protection Agency's (EPA) focus on acting expeditiously to protect public health. The regulation of PFOA and PFOS with MCLs and the other PFAS using a hazard index has implications for the implementation of many other statutes, including but limited to the Resource, Conservation and Recovery Act; Comprehensive Environmental Response, Compensation and Liability Act; Clean Water Act; Federal Insecticide, Fungicide and Rodenticide Act; Toxic Substances Control Act; and other statutes that regulate chemicals in the environment that affect public health, we encourage you to consider an extension of review for this proposed rule by 59 days to July 28, 2023.

EPA has provided extensive amount of information that NGWA members desiring to comment will need this time to review and evaluate before providing comments. In particular, time to consider significant data and documentation in the following three areas would be important to their review:

• Analysis of the occurrence of these contaminants along with understanding the complex statistical approach utilized and applied to the national occurrence database that amalgamates previously collected data obtained through the Unregulated Contaminant Monitoring Rule process with state datasets.

• Development and application of a hazard index in place of a maximum contaminant level.

• The relation of the MCLs to other substantial work carried out by the groundwater industry in applying science and engineering to protect the public and remediate the environment.

NGWA, the largest trade association and professional society of groundwater professionals in the world, represents over 10,000 groundwater professionals within the United States and internationally. NGWA represents four key sectors: scientists and engineers; water-well contractors; the groundwater equipment manufacturers; and equipment suppliers. NGWA's mission is to advocate for and support the responsible development, management, and use of groundwater. Groundwater is an essential life-sustaining good that public policy should enable to be provided safely and adequately.

In providing additional time for review of this proposed rule, EPA would be enabling the affected public and industry stakeholders to assist the Agency with an improved outcome. The review time extension would allow fuller consideration of the substantial intertwined connections with and effects on other statutes and their regulatory implementation.

Thank you for considering our request. NGWA looks forward to working with EPA as a partner in providing safe water supply to residential, commercial and agricultural consumers. For further follow up to this letter, please contact Chuck Job, NGWA Regulatory Affairs Manager, at cjob@ngwa.org.

Sincerely,

Terry S. Morse, CAE, CIC

Chief Executive Officer

National Ground Water Association

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

Oregon Water Utilities Council (OWUC) (Doc. #1522, SBC-042610)

OREGON WATER UTILITIES COUNCIL

Pacific Northwest Section, American Water Works Association

PO Box 872467 Vancouver, WA 98687

Phone: 503.760.6460

April 17, 2023

Michael S. Regan

Administrator

Environmental Protection Agency

1200 Pennsylvania Ave, NW

Mail Code: 4670M

Washington, DC 20460

RE: Request for Extension for Comment Period on EPA's Proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation (Docket ID: EPA-HQ-OW-2022-0114)

Administrator Regan,

Oregon Water Utilities Council (OWUC) is a local affiliation of the American Water Works Association, and we represent nearly 75% of public drinking water providers across the state of Oregon, both small and large, rural, and urban.

The EPA's proposed regulation provides a public review and comment period of only 62 days. At the time this letter is written, the docket contains more than 5,000 pages of supporting documentation. These materials must be properly reviewed and considered in order for stakeholders to provide constructive feedback.

We are interested in reviewing the proposal and providing feedback to the EPA presenting our perspectives on the various aspects of the rule, including:

• Water treatment costs associated with per- and polyfluoroalkyl substances (PFAS).

• Feasibility to remove PFAS to levels at or below the proposed standards.

• Feasibility for drinking water utilities to implement the proposal within the compliance timeline and the factors influencing the implementation of treatment.

• Application of the hazard index for drinking water regulation, including considerations for risk communication.

We respectfully request that EPA provide an extension of the comment deadline by 59 days to July 28, 2023, to provide a total of 121 days of public comment. Your response by May 1, 2023, is necessary for us to successfully balance available resources to best utilize the requested extension period.

We appreciate your attention to this matter.

Sincerely,

Jessica Dorsey

Oregon Water Utilities Council, Chair

City of Hillsboro-Water Department

150 East Main Street

Hillsboro, OR 97123

503-615-6579

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

U.S. Chamber of Commerce (Doc. #1537, SBC-042643)

Statement on the Proposed Maximum Contaminant Limit (MCL) for PFOA and PFOS

EPA Public Hearing

May 4, 2023

My name is Chuck Chaitovitz, and I am Vice President of Environmental Affairs and Sustainability at the U.S. Chamber of Commerce ("Chamber"). The Chamber appreciates the opportunity to provide input today on the important role of the Safe Drinking Water Act (SDWA) in ensuring sustainable supplies of clean, safe drinking water in communities across our nation. Thank you to EPA for providing this very helpful briefing and public discussion.

We are pleased to be here on behalf of our member companies, trade associations, and state and local chambers, which span key U.S. supply chains using PFAS chemistries, and whose products and technologies are essential to America's economic growth, water infrastructure, and national security. The Chamber is leading a coalition of companies, trades, and other stakeholders who are committed to managing PFAS safely and protecting human health and the environment.

I would like to note that our coalition requested a modest extension of the comment period, which we believe EPA should grant given the length and complexity of the proposed MCL for PFOA and PFOS rule. This request stated that "EPA's proposal sets forth 59 specific questions for comment and provides more than 3,000 pages of very technical and complex information on the scientific basis, costs, and impacts for implementing these standards. This page count does not include even further additional technical supporting information that EPA made available in the docket on March 29, 2023. There are some 1,271 supporting documents included in the docket, which are not organized in a searchable or clear fashion." Without additional time, it will be impossible to conduct a thorough review of the scientific and technical information which underlies EPA's extensive proposal.

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document.

City of Vancouver, Washington (Doc. #1543, SBC-042664)

May 8, 2023

Michael S. Regan

Administrator Environmental Protection Agency

1200 Pennsylvania Avenue, N. W.

Mail Code: 4607M

Washington, DC 20460

RE: Request for Extension for Comment Period on EPA's Proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation (Docket ID: EPA-HQ-OW-2022-0114)

Administrator Regan,

The City of Vancouver is the third largest provider of drinking water in the State of Washington.

The EPA's proposed regulation only provides a public review and comment period of 62 days. At the time this letter is written, the docket contains more 5,000 pages of supporting documentation. These materials must be reviewed and considered in order for stakeholders to provide constructive feedback.

We are interested in reviewing the proposal and providing feedback to the EPA presenting our perspectives on the various aspects of the rule, including:

• Water treatment costs associated with PFAS;

• Feasibility to remove PFAS to levels at or below the proposed standards;

• Feasibility for drinking water utilities to implement the proposal within the compliance timeline and the factors influencing the implementation of treatment.

• Application of the hazard index for drinking water regulation, including considerations for risk communication.

While the City of Vancouver understands the importance of finalizing this rule in a timely manner, we believe thoughtful public comments will only strengthen the final rule and ultimately provide more protections for public health.

We respectfully request that EPA provide an extension of the comment deadline by 59 days to July 28, 2023 to provide a total of 121 days for public comment. Your immediate response is necessary for us to successfully balance available resources to best utilize the requested extension period.

Thank you for your consideration of these comments.

Sincerely,

Tyler Clary, P.E., WDM4

Water Engineering Program Manager

City of Vancouver

cc: Lon Pluckhahn

Brian Wilson

Tim Buck

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

North American Meat Institute (NAMI) (Doc. #1547, SBC-042680)

May 11, 2023

Alexis Lan

Office of Ground Water and Drinking Water

Standards and Risk Management Division

(Mail Code 4607M)

Environmental Protection Agency

1200 Pennsylvania Avenue NW

Washington, DC 20460

Re – Request for Extension of the Comment Period; PFAS National Primary Drinking Water Regulation Rulemaking; Preliminary Regulatory Determination and Proposed Rule; Request for Public Comment; Notice of Public Hearing; EPA–HQ–OW–2022–0114; FRL 8543–01–OW.

Dear Ms. Lan:

The North American Meat Institute (NAMI or the Meat Institute) submits this request for a 90-day extension of the comment period in the above-referenced proposed rule and request for public comments (proposal). The Meat Institute is the nation's oldest and largest trade association representing packers and processors of beef, pork, lamb, veal, turkey, and processed meat products and NAMI member companies account for more than 95 percent of United States output of these products. The Meat Institute provides regulatory, scientific, legislative, public relations, and educational services to the meat and poultry packing and processing industry.

The proposal is broad, raising numerous questions and seeking input on an array of complicated topics of interest to the meat industry and the food industry more generally. Indeed, the proposal specifically references food when discussing vectors for exposure to PFAS. [FN-1: 88 Fed. Reg. 18638 (March 29, 202).] Given the interrelationship and impact of the Environmental Protection Agency's regulations with those of other federal, state, and local agencies, to enable the Meat Institute and others to speak effectively and in a constructive manner requires additional time.

* * * * *

For the reason discussed above NAMI requests a 90-day extension of the comment period in the above-referenced docket. Thank you for your consideration.

Respectfully submitted,

Mark Dopp

Chief Operating Officer and General Counsel

North American Meat Institute

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document.

Arizona Corporation Commission (ACC) (Doc. #1552, SBC-042701)

Arizona Corporation Commission's request for an extension of time to file comments

BEFORE THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

PFAS National Primary)

Drinking Water) Docket No. EPA–HQ–OW–2022–0114

Regulation Rulemaking)

REQUEST FOR AN EXTENSION OF TIME TO FILE COMMENTS OF THE ARIZONA CORPORATION COMMISSION

The Arizona Corporation Commission ("ACC") respectfully requests an extension of the deadline to file comments by 59 days to July 28, 2023. This extension would provide a total of 121 days for public comment. Currently, the comment period for the Environmental Protection Agency's ("EPA") proposed per- and polyfluoroalkyl substances ("PFAS") drinking water regulation is only 62 days long.

The ACC is the state regulatory body responsible for the regulation of Arizona's public utilities. The ACC is constitutionally entrusted to set just and reasonable rates for public service corporations, including water utilities that will be impacted by the EPA's proposed PFAS drinking water regulation. In this respect, the ACC intends to review the proposed regulation and provide feedback on various aspects of the proposal, including but not limited to:

• Water treatment costs that will result from the proposed rule and impacts to ratepayers

• Cost and feasibility of implementing the proposal within the compliance timeline

• Availability of waivers or extensions of time to come into compliance for utilities unable to meet the compliance timeline

• Funding available to assist utilities in complying with the proposed rule

As the docket contains over 5,000 pages of supporting documentation, the requested 59-day extension of time to July 28, 2023, will enable the ACC to effectively review the documents and provide constructive comments. The ACC respectfully requests an expedited response to its request for an extension of time to file comments.

RESPECTFULLY submitted this 12th day of May, 2023.

/s/ Kathryn M. Ust

Kathryn M. Ust, Staff Attorney

Legal Division

Arizona Corporation Commission

1200 West Washington Street Phoenix, Arizona 85007 kust@azcc.gov (602) 542-3402

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

GFL Environmental (Doc. #1565, SBC-042502)

May 22, 2023

Michael S. Regan

Administrator

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue NW

Mail Code: 4607M

Washington, DC 20460

SUBMITTED ELECTRONICALLY

RE: DOCKET ID NO. EPA-HQ-OW-2022-0114, REQUEST FOR TIME EXTENSION OF PUBLIC COMMENT PERIOD ON THE "PER- AND POLYFLUOROALKYL SUBSTANCES (PFAS) NATIONAL PRIMARY DRINKING WATER REGULATION RULEMAKING"

Dear Administrator Regan,

GFL Environmental (GFL) submits this request for extension of the public comment period for the Proposed PFAS National Primary Drinking Water Regulation (EPA-HQ-OW-2022-0114). GFL requests that the US Environmental Protection Agency (EPA) grant a 60-day extension on the comment period for its proposal.

At the time of writing this letter, there are over 1440 documents including more than 5,000 pages of supporting documentation. GFL requests the extension to ensure all public comments can be formulated thoughtfully and thoroughly and are based on effective review of the proposal and supporting documentation. A 60-day public review period is inadequate.

We appreciate the efforts of EPA to address PFAS and protect human health and the environment and share the goal of holding entities accountable that are primary manufacturers

and users of PFAS. If you have further questions, please contact Selin Hoboy at 847-456-8889 or via email at shoboy@gflenv.com .

Sincerely,

GFL Environmental

Selin Hoboy

Vice President, Environmental Health, Safety and Compliance

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document.

National Association of Regulatory Utility Commissioners (NARUC) (Doc. #1566, SBC-042501)

National Association of Regulatory Utility Commissioners' Request for 60-Day Extension of Comment Period on EPA's proposed Per-and Polyfluoroalkyl Substances National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18638 (March 29, 2023) Docket ID No. EPA-HQ-OW-2022-0114, FRL 8543-01-OW. See attached file.

May 22, 2023

By Electronic Submission to http://www.regulations.gov/

Michael S. Regan, Administrator

U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, N.W.

Mail Code: 1101A

Washington, DC 20460

Re: Request for 60-Day Extension of Comment Period on EPA's proposed Per-and Polyfluoroalkyl Substances National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18638 (March 29, 2023) Docket ID No. EPA-HQ-OW-2022-0114, FRL 8543-01-OW.

Dear Administrator Regan:

The National Association of Regulatory Utility Commissioners (NARUC) is concerned by issues raised in the above referenced proposed rule – which proposes National Primary Drinking Water Regulation (NPDWR) and health-based Maximum Contaminant Level Goals (MCLG) for several PFAS compounds.

NARUC is a quasi-governmental nonprofit organization founded in 1889. For the last 130 years, NARUC has represented the interests of public utility commissioners from regulatory agencies in fifty States, the District of Columbia, Puerto Rico, and the Virgin Islands. NARUC's member commissions include the State agencies engaged in the economic, rate, safety and the reliability

regulation of public utilities that provide water electricity and natural gas services. These State officials have the obligation under State law to assure the establishment and maintenance of such water utility services as may be required by the public convenience and necessity, and to ensure that such services are provided at rates and conditions that are just, reasonable and nondiscriminatory.

NARUC is also a partner in EPA's Watersense program and as a member of EPA's "Water Infrastructure and Cyber Resilience Division Partners" Group and the Water sector Government Coordinating Council. Congress references NARUC as "the national organization of the State commissions" responsible for economic and safety regulation of the intrastate operation of carriers and utilities. [FN1: 1 Communications Act of 1934, as amended by the Telecommunications Act of 1996, 47 U.S.C. §151 et seq., Pub. L. No. 101-104, 110 Stat. 56 (1996). See 47 U.S.C. §410(c) (1971) (NARUC nominates members to Federal-State boards which consider universal service, separations, and other issues and provide recommendations the FCC must act upon.); Cf. 47 U.S.C. § 254 (1996) (describing the universal service board's functions). See also, NARUC, et al. v. ICC, 41 F.3d 721 (D.C. Cir 1994) ("[c]arriers, to get the cards, applied to [NARUC], an interstate umbrella organization that, as envisioned by Congress, played a role in drafting the regulations that the ICC issued.")] Both Congress and the courts [FN2: 2 See United States v. Southern Motor Carrier Rate Conference, Inc., 467 F. Supp. 471 (N.D. Ga. 1979), aff'd 672 F.2d 469 (5th Cir. 1982), aff'd en banc on reh'g, 702 F.2d 532 (5th Cir. 1983), rev'd on other grounds, 471 U.S. 48 (1985); (where the Supreme Court notes: "The District Court permitted (NARUC) to intervene as a defendant. Throughout this litigation, the NARUC has represented the interests of the Public Service Commissions of those States in which the defendant rate bureaus operate." 471 U.S. 52, n. 10. See also, Indianapolis Power and Light Co. v. ICC, 587 F.2d 1098 (7th Cir. 1982); Washington Utilities and Transportation Commission v. FCC, 513 F.2d 1142 (9th Cir. 1976); Compare, NARUC v. FERC, 475 F.3d 1277 (D.C. Cir. 2007); NARUC v. DOE, 851 F.2d 1424, 1425 (D.C. Cir. 1988); NARUC v. FCC, 737 F.2d 1095 (D.C. Cir. 1984), cert. denied, 469 U.S. 1227 (1985)] have consistently recognized NARUC as a proper entity to represent the generic interests of every State's utility commission.

The posted EPA proposal only provided about 6o days for comments. So far, the current docket appears to contain thousands of pages of supporting documentation. Those materials must be reviewed and considered for stakeholders to provide constructive feedback. That review would be challenging if each state commentor had several expert staff to look at them. But for almost all NARUC member commissions, that is not the case. State commissions have limited staff resources that have multiple responsibilities in addition to advising Commissions on how to respond to this rulemaking.

Several NARUC members are interested in reviewing the proposal and providing feedback to the EPA presenting our perspectives on the various aspects of the rule, including (i) Water treatment costs associated with per- and polyfluoroalkyl substances (PFAS) and their potential impact on rates; (ii) Practical ability of utilities to remove PFAS to levels at or below the proposed

standards; and (iii) Practical ability of drinking water utilities to implement the proposal within the compliance timeline.

We have been specifically requested by those members to seek additional time to formulate their comments. Given NARUC members crucial role in the oversight of drinking water and water treatment facilities, their input will be a valuable addition to the record in this proceeding. No other interested commenter is likely to be prejudiced by a two-month extension.

Accordingly, NARUC respectfully requests that EPA provide an extension of the comment deadline by 60 days to July 28, 2023, to provide a total of 121 days for public comment.

Respectfully submitted.

/s/ Brad Ramsay

James Bradford Ramsay

NARUC General Counsel

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

New Hampshire Water Works Association, Inc. (NHWWA) (Doc. #1576, SBC-042457)

The sixty (60) day comment period for a rulemaking of this magnitude and impact is insufficient and unreasonable. Given the complexity and potential costs to deal with PFAS at a national level, and the thousands of pages of supporting documents provided by EPA, additional response time is required to coordinate our shared resources to meet this national challenge.

Our Association and professional drinking water partners are committed to meeting health-based standards developed using sound science and proven technologies. We understand there is increasing public awareness and concern about PFAS chemicals and encourage EPA to follow its traditional thoughtful and thorough approach to promulgating national standards for PFAS in drinking water.

Thank you for considering our comments. Please do not hesitate to contact us if you should have any questions.

Sincerely,

Boyd Smith, President and CEO

Cc: Senators Shaheen and Hassan, Representatives Kuster and Pappas

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document.

Security Water District, Security Water and Sanitation Districts/Enterprises (Doc. #1587, SBC-042785)

Furthermore, we believe that an extended comment period will result in a better rule. Stakeholders have not had sufficient time to fully research and develop comments.

Once again, thank you for the opportunity to comment on the proposed PFAS rule. We sincerely appreciate the time and effort that has been devoted by all parties involved in this rulemaking.

Sincerely,

Security Water and Sanitation Districts

Roy E. Heald, General Manager

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document.

Texas Commission on Environmental Quality (TCEQ) (Doc. #1632, SBC-044121)

May 30, 2023

U.S. Environmental Protection Agency EPA Docket Center

Docket ID No. EPA-HQ-OW-2022-0114

Mail Code 28221T

1200 Pennsylvania Avenue, NW

Washington, DC 20460

Re: Docket ID No. EPA-HQ-OW-2022-0114, Comments on the Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

Dear Sir or Madam:

The Texas Commission on Environmental Quality (TCEQ) is providing the enclosed comments regarding the Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation, Docket ID No. EPA-HQ-OW-2022-0114, as requested by May 30, 2023.

It is our understanding the U.S. Environmental Protection Agency (EPA) will not be extending the comment period for this proposed rulemaking even after numerous requests from stakeholders to do so. The proposed rule will impact more than 5,500 public water systems in Texas and will necessitate significant resources for both primacy agencies and regulated entities to implement the rule after it becomes effective. Conducting a thorough and comprehensive review of this proposed rulemaking, which is complex and includes nearly 1,200 supporting documents in 62 days in addition to reviewing several other simultaneously open comment period EPA rulemakings, is not feasible.

It is vitally important that primacy agencies and other stakeholders are given adequate time to evaluate proposed rulemakings to be able to provide comprehensive comments and request clarification prior to the closing of public comment periods. We realize EPA is on an expedited schedule to establish a regulation, but it should not negate the importance of meaningful input from stakeholders which will only strengthen the final rule and ultimately provide more protections for public health.

If you have any questions concerning the enclosed comments, please contact Ms. Michele Risko, Water Supply Division Deputy Director, at (512) 239-1689 or michele.risko@tceq.texas.gov.

Sincerely,

Erin E. Chancellor, Interim Executive Director Texas Commission on Environmental Quality

Enclosure

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document.

Association of Environmental Authorities (AEA) (Doc. #1635, SBC-042966)

It is unfortunate that the EPA has denied requests to extend the comment period. The NPDWR has far-reaching implications. We agree with others who have commented that the May 30 deadline does not allow sufficient time for fully understanding them and bringing them to the attention of the EPA.

Very truly,

Peggy Gallos

Executive Director,

Association of Environmental Authorities

2333 Whitehorse-Mercerville Road, Suite 2,

Mercerville, NJ 08848

Cc: AEA Board and AEA Legislative Committee

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document.

Aidan Cecchetti (Doc. #1640, SBC-044357)

Michael S. Regan Administrator

Environmental Protection Agency

1200 Pennsylvania Avenue NW

Mail Code: 4607M

Washington, DC, 20460

Re: Comments on EPA's Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulations (Docket ID: EPA-HQ-OW2022-0114)

Dear Administrator Regan,

We are pleased to have the opportunity to provide comments on EPA's proposed per- and polyfluoroalkyl substances (PFAS) National Primary Drinking Water Regulations (NPDWR). As professional engineers working in the drinking water sector, regulation of PFAS in drinking water is a significant concern for us. Both commenters who compiled this letter, Aidan Cecchetti and Scott Miller, are regulatory engineers tasked with enforcement of the Safe Drinking Water Act (SDWA) for the primacy agency of the State of California, the California State Water Resources Control Board. Drs. Cecchetti and Miller both have conducted doctorate-level research on water quality engineering with experience related to contaminant removal processes and analytical chemistry. We provide this background information and a description of our professional affiliations as context for EPA's reviewers to understand how our comments are informed by our experience in the water sector and expertise on this specific topic. The comments contained within this letter are solely those of the named parties and do not represent official position statements for the California State Water Resources Control Board.

Before providing feedback on the requests for comments that EPA included in Docket ID: EPA-HQ-OW-2022-0114 for the proposed PFAS NPDWR, we want to provide support for and concurrence with AWWA's request for an extension of the comment period on this critical new regulation. As described in AWWA's letter, the docket for EPA's proposed PFAS NPDWR includes 5000+ pages of documentation, making it impossible for individuals and organizations alike to conduct the depth of review required to provide constructive feedback on the regulation within the 62-day comment period. For the time being, we have limited our review to topics with which we have relevant expertise. Should EPA choose to extend the public comment period, we will consider conducting review on additional topics and providing further comments in a separate follow-up letter.

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document.

National Chicken Council (NCC) (Doc. #1649, SBC-043216)

May 30, 2023

[Submitted electronically via Regulations.gov]

Administrator Regan

Agency Administrator

United States Environmental Protection Agency

EPA Docket Center

WJC West Building, Room 3334

1301 Constitution Avenue NW

Washington D.C. 20004

Re: Docket No. EPA-HQ-OW-2022-0114: PFAS National Primary Drinking Water Regulation Rulemaking

Dear Administrator Regan:

The National Chicken Council (NCC) appreciates the opportunity to comment on the Environmental Protection Agency's ("EPA" or "the Agency") preliminary regulatory determination and proposed rule, "PFAS National Primary Drinking Water Regulation Rulemaking," EPA-HGOW-2022-0114, RIN 2040-AG18, 88 Fed. Reg. 18638 (March 29, 2023) ("the proposed rule"). NCC is the national, non-profit trade association that represents vertically integrated companies that produce and process more than 95 percent of the chicken marketed in the United States and our members will be directly impacted by the proposed rule. As the most consumed protein source in the United States, the chicken industry has significant economic impact, especially in our country's rural communities, and chicken is a critical protein source in nearly every American's diet. The United States chicken industry drives the national and local economies by providing jobs and revenue to communities across the country while also supporting a broad network of chicken farms, ultimately providing opportunities for millions of Americans.

At the outset, NCC is concerned that the short 60-day comment period provides inadequate time for stakeholders to fully assess the proposal and the complicated scientific considerations. NCC therefore requests that the Agency extend the comment period an additional 90 days or reopen the comment period for an extra 90 days to allow stakeholders added time to evaluate and comment on the downstream effects of the proposed rule.

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document.

<u>New York State Department of Health (NYS DOH) (Doc. #1677, SBC-044966)</u>

28. The 60-day time frame for public review and comment does not permit sufficient time to fully analyze the cost estimates, benefits and economic analysis associated with the proposal. The Department is concerned considering the extent to which this proposal shifts the regulatory paradigm.

Again, the State of New York appreciates the leadership of the Administration and the EPA in the preparation of this proposal. We are happy to provide EPA with any data or supporting documentation necessary to finalize the rule and aid implementation.

Sincerely,

Gary Ginsberg, PhD

Director

Center for Environmental Health

New York State Department of Health

cc: J. McDonald

B. Seggos

M. Baldwin

S. Mahar

U. Bauer

D. Lang

C. Westerman

E. Lewis-Michi

T. Johnson

C. Vooris

K. Wheeler

N.S. Alderman

T. Hunt

References

ATSDR (Agency for Toxic Substances and Disease Registry). 2021. Toxicological Profile for Perfluoroalkyls. Atlanta, GA: Agency for Toxic Substances and Disease Registry, U.S. Department of Health and Human Services, Public Health Service. May 2021. https://www.atsdr.cdc.qov/toxprofiles/tp200.pdf.

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Science Advisory Board. "Transmittal of the Science Advisory Board Report titled, Review of EPA's Analyses to Support EPA's National Primary Drinking Water Rulemaking for PFAS.' August 22, 2022. EPA-SAB-22-008. https://sab.epa.qov/ords/sab/f?p=100:18:16490947993:::RP,18:P18ID:2601

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Manual (Part A). Office of Emergency and Remedial Response U.S. Environmental

Protection Agency Washington, D.C. EPA Document Number: EPA/540/1-89/002. Accessed at: https://www.epa.gov/sites/default/files/2015-09/documents/raqsa.pdf.

US EPA (2000) Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures. Risk Assessment Forum U.S. Environmental Protection Agency Washington, D.C. EPA Document Number: EPA/630/R-OO/002. Accessed at: https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=20533

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document.

New Hampshire Department of Environmental Services (NHDES) (Doc. #1690, SBC-044354)

5. Additional Comments from NHDES

a. Extension of the Public Comment Period. We believe that a longer public comment period will allow for a more thorough and meaningful review of the proposed MCLs and will facilitate a more robust public dialogue on this important issue. Additionally, we have heard concerns from stakeholders that the current 60-day comment period is not sufficient to provide thoughtful and comprehensive comments on the proposed rulemaking. Given the complexities of this issue and the potential impacts of the proposed MCLs, we believe that a 60-day extension of the comment period would be appropriate.

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document.

Alabama Water and Wastewater Institute (AWWI) (Doc. #1700, SBC-043507)

May 30, 2023

Michael S. Regan Administrator

Environmental Protection Agency 1200 Pennsylvania Avenue, NW Washington, DC 20460

RE: Comments on EPA's Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation (Docket ID: EPA-HQ-OW-2022-0114)

Administrator Regan,

The Alabama Water and Wastewater Institute (AWWI) appreciates the opportunity to review and comment on the proposed per- and polyfluoroalkyl substances (PFAS) national primary drinking water regulations by the United States Environmental Protection Agency (USEPA). AWWI is a statewide association of water and sewer systems and represents the majority of the population in Alabama that receive public water and sewer services. Our organization offers the following comments on behalf of our water and sewer system members in regard to the stringent proposed PFAS national primary drinking water regulation:

• AWWI strongly concurs with the comment submitted by the American Water Works Association (AWWA) requesting an extension of the comment deadline until July 28, 2023. As noted by AWWA, this would provide a total of 121 days for public comment, which is needed given the more than 1,200 supporting documents associated with the proposed PFAS regulation that require review by water and sewer systems.

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document.

Florida Section American Water Works Association - Water Utility Council (FSAWWA WUC) (Doc. #1737, SBC-044481)

May 30, 2023

Mr. Michael Regan, Administrator

Environmental Protection Agency

1200 Pennsylvania Avenue, N. W.

Mail Code: 4607M

Washington, DC 20460

TRANSMITTED ELECTRONICALLY

RE: Comments on EPA's Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation (88 FR 18638; EPA-HQ-OW-2022 -0114-0027)

Dear Administrator Regan ,

The Florida Section of the American Water Works Association Water Utility Council (FSAWWA WUC) is pleased to submit this letter addressing the Environmental Protection Agency's (EPA's) rulemaking titled "Proposed Designation of PFOA and PFOS as CERCLA Hazardous Substances" (herein referred to as the Proposal).

The FSAWWA's more than 2,800 members include 130 drinking water utilities who collectively supply the world's most precious and number one resource - water - to over 80 percent of the state's population and the millions of visitors to our great state. The FSAWWA WUC is actively engaged with EPA's continued efforts to address the challenges arising from per- and polyfluoroalkyl substances (PFAS) through the PFAS Strategic Roadmap including this Proposal.

We appreciate the opportunity to comment on the proposed rule that is over 250 pages long and the docket contains nearly 1,300 supporting documents (26 of which total 5,000). Due to the voluminous documents, EPA's 61-day restrictive review time made a thorough evaluation infeasible. We were disappointed EPA did not respond to numerous public comment letters (many from our members) to extend the comment period. Thus, the following reflect our initial, high-level comments on the proposed rule that we respectfully ask the U.S. EPA to consider when developing the final rule.

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document.

LSP Association (LSPA) (Doc. #1742, SBC-043595)

Submitted via the Federal eRulemaking Portal: https://www.regulations.gov/

May 30, 2023

Mr. Michael S. Regan, Administrator

U.S. Environmental Protection Agency, EPA Docket Center

Office of Ground Water and Drinking Water Docket, Mail Code 2822IT

1200 Pennsylvania Avenue NW

Washington, DC 20460

Subject:

PFAS National Primary Drinking Water Regulation Rulemaking Docket ID Number: EPA-HQ-OW-2022-0114

To Administrator Regan and the U.S. Environmental Protection Agency:

The LSP Association (LSPA) is the 800-member, non-profit association of Licensed Site Professionals (LSPs) and related practitioners in the Commonwealth of Massachusetts. LSPs are the scientists, engineers, and public health specialists licensed by the Commonwealth to work on behalf of property owners, operators, and other involved parties to oversee the assessment and cleanup of oil and hazardous materials released to the environment - including per- and polyfluoroalkyl substances (PFAS). With the Massachusetts Department of Environmental Protection (MassDEP) and the Board of Registration of Hazardous Waste Site Cleanup

Professionals (LSP Board of Registration), LSPs are the third "arm" of an innovative, privatized program created in 1993. The program has proven to be highly successful. LSPs have overseen the cleanup of over 45,000 sites in the past 30 years; they work with their government, non-profit, institutional, and private clients to remediate contaminated sites, so that these properties can be placed back into active and productive use.

The LSPA is keenly aware of the complex issues associated with PFAS; many of our members have been involved in the evaluation of PFAS in public and private water supplies, the investigation of potential sources of PFAS in the environment, and the remediation of PFAS sites. We are familiar with the challenges these persistent and widespread environmental contaminants present for both assessment and the identification of feasible cleanup options that are protective of human health and the environment.

MassDEP's hazardous waste site cleanup regulations, known as the Massachusetts Contingency Plan or MCP (310 CMR 40.0000, et seq.), were amended in December 2019 with newly promulgated stringent numeric cleanup standards for PFAS in soils and groundwater. One year later, MassDEP also established Maximum Contaminant Levels in drinking water for six PFAS contaminants. LSPA members interact closely with MassDEP as they work to identify the source and extent of PFAS contamination, to conduct cleanup actions, and to monitor exposure pathways that pose risks to public health and the environment. We all understand that the urgency and impacts from PFAS are real and significant and, as indicated by their informal "forever" nickname, persistent.

While this letter provides LSPA's comments in accordance with the May 30, 2023 deadline imposed on comments on the proposed National Primary Drinking Water Regulation (NPDWR) under Docket ID: EPA-HQ-OW-2022-0114, we note that, with more time, the LSPA could provide additional insight and suggestions to further refine the regulation. While it appears that USEPA is not planning to extend the comment deadline, we encourage USEPA to solicit public comment once again on a subsequent revised version of the NPDWR before the rules are finalized.

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document.

Las Cruces Utilities (LCU) (Doc. #1753, SBC-043903)

May 30, 2023

Michael S. Regan, Administrator Environmental Protection Agency 1200 Pennsylvania Avenue, N.W. Mail Code:4607M

Washington, DC, 20460

Subject: Comments for PFAS National Primary Drinking Water Regulation Rulemaking (Docket ID No. EPA-HQ-OW-2022-0114)

Dear Mr. Regan,

Due to the short duration (62 Days) of the proposed PFAS Drinking Water Regulation Comment Period and the volume of documentation associated with the Rulemaking, Las Cruces Utilities (LCU) respectfully requests that the EPA provide an extension of the comment period by at least an additional 59 Days to July 28, 2023. While LCU supports EPA rulemaking of water contaminants to protect public health, more time is needed for LCU to thoroughly review the proposed regulations and supporting documents to provide constructive comment. Please consider this request so that more thorough consideration can be made by both citizens and service providers before the rules are finalized.

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document.

American Water Works Association (AWWA) (Doc. #1759, SBC-045573)

Additionally, EPA only provided a 60-day public comment period for review and analysis of the entire proposal, including the occurrence analysis. Additionally, EPA only provided a 60-day public comment period for review and analysis of the entire proposal, including the occurrence analysis. AWWA and numerous additional stakeholders requested an extension of the comment period to support more in-depth of the occurrence analysis and the rule more broadly but the agency declined this request. The comment period is inadequate for reviewing this model and EPA neglects to provide informative sensitivity analyses and to clearly present model assumptions and outputs. In order to fulfill its obligations under the APA, AWWA therefore requests that EPA provide this information during a supplemental comment period prior to finalizing any rule.

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

California-Nevada Section American Water Works Association (CA-NV AWWA) (Doc. #1775, SBC-045281)

10. EPA should extend the comment period by sixty more days to allow more adequate time to sufficiently respond to the Agency's proposal.

We are grateful that the Agency provided extensive background information to inform the decisions and recommendations included in the proposed regulation. However, the amount of information is overwhelming, and a 60-day review period is inadequate. It is impossible to review and prepare adequate responses to EPA's almost 60 requests for stakeholder comments, more than 3,000 pages of highly technical information, and more than 1,440 technical supporting documents provided for public review. CA-NV AWWA recommends additional EPA

interactions with stakeholders and experts to strike a balance between needs to protect human health in a practical manner that is effectively deployable by public drinking water systems.

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document.

Neuse Regional Water and Sewer Authority (Doc. #1822, SBC-044566)

Initially, we note that the Proposed Rulemaking covers 117 Federal Register pages and is accompanied by a huge volume of EPA reference documents. As a public entity, NRWASA has limited resources it can expend on reviewing the Proposed Rulemaking during the relatively short public comment period. We have not been able to fully review and evaluate each of the 59 questions EPA seeks comment on in the Proposed Rulemaking. We encourage EPA to extend the comment period or divide the Proposed Rulemaking into a series of proposed rules that would be sequential and allow more complete review and comment. Nevertheless, NRWASA believes that the Proposed Rulemaking raises four serious concerns that we want to ensure receive comment before the published May 30 deadline.

"NRWASA Is an Equal Opportunity Provider and Employer"

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document.

Plymouth Village Water & Sewer District (Doc. #1827, SBC-044564)

• The sixty (60) day comment period for a rulemaking of this magnitude and impact is insufficient and unreasonable. Given the complexity and potential costs to deal with PFAS at a national level, and the thousands of pages of supporting documents provided by EPA, additional response time is required to coordinate our shared resources to meet this national challenge.

The PVWSD and fellow water system owners, managers, and operators throughout NH are committed to meeting health-based standards developed using sound science and proven technologies. We understand there is increasing public awareness and concern about PFAS chemicals and encourage EPA to follow its traditional thoughtful and thorough approach to promulgating national standards for PFAS in drinking water.

Thank you for considering our comments. Please do not hesitate to contact me if you should have any questions.

Sincerely,

Jason C. Randall

Water & Wastewater Superintendent

Cc: Senator Shaheen

Senator Hassan

Representative Kuster

Representative Pappas

Kim Haines, PVWSD Business Manager PVWSD

Board of Commissioners

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document.

Pennsylvania Municipal Authorities Association (Doc. #1832, SBC-045778)

20571-000

May 30, 2023

U.S. Environmental Protection Agency

EPA Docket Center

Office of Ground Water and Drinking Water Docket

Mail Code 2822IT

1200 Pennsylvania Avenue NW

Washington, DC 20460

Re: Docket ID No. EPA-HQ-OW-2022-0114

Proposed PFAS National Primary Drinking Water Regulation Rulemaking

Dear Sir/Madam:

The Pennsylvania Municipal Authorities Association ("PMAA") appreciates the opportunity to submit comments to the Proposed PFAS National Primary Drinking Water Regulation Rulemaking, Docket No. EPA-HQ-OW-2022-0114 ("Proposal"). The Proposal was published in the March 29, 2023 Federal Register, and, consistent with the May 30, 2023 deadline for comments, PMAA respectfully submits the following information and comments for consideration.

By way of background, PMAA is an association that represents the interests of over 700 municipal authorities in Pennsylvania, and these PMAA member municipal authorities collectively provide water, sewer, stormwater, waste management and other services to over five million Pennsylvania citizens (also referred to herein as "municipal entities" or "PMAA member authorities"). Founded in 1941, the mission of PMAA is to assist authorities in providing services that protect and enhance the environment, promote economic vitality, and further the

general welfare of the Commonwealth and its citizens. PMAA and its member municipal authorities, who are stewards of the environment, strive to provide the highest quality services to their customers and ratepayers. Many of PMAA member municipal authorities will be impacted by EPA's ultimate decision on the aforementioned Proposal.

PMAA's specific comments on the Proposal are as follows:

1. PMAA understands and appreciates EPA's desire to expeditiously finalize a regulation addressing PFAS chemicals, and agrees that the protection of human health and the environment is of paramount importance. However, PMAA agrees with a number of previously filed comments requesting an extension of time to file substantive comments to the Proposal. The Proposal is complex and presents many issues that the regulated community has never had to address (e.g. a Hazard Index for a Safe Drinking Water Act initiative). Moreover, there are over 5000 pages of supporting documentation that need to be reviewed in order to provide thoughtful and comprehensive comments on a number of issues related to the Proposal. Indeed, EPA had advised the public through its PFAS Strategic Roadmap that the Proposal would be published in the Fall of 2022. One can only surmise that the complexity of the Proposal was one reason for the nearly one-half year delay in EPA's issuance of the Proposal. Given its own experience in issuing the Proposal, EPA should not now deny the public a full and fair opportunity to review all of the necessary documentation to provide the aforementioned thoughtful and comprehensive comments to such a novel Proposal. Therefore, EPA should reopen the public comment period to allow for further comments to the Proposal.

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

City of Boynton Beach, Florida (Doc. #2309, SBC-046319)

Dear Mr. Regan, I am writing to request that the Environmental Protection Agency (EPA) extend the comment deadline for the Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation by 59 days, to July 28, 2023. This extension would provide the public with a total of 121 days to review and comment on the proposed regulation/policy. As you may be aware, this proposed regulation/policy has far-reaching implications and will significantly impact the environment, public health, and the economy. Therefore, the public must have adequate time to review the proposal, consult with stakeholders, and provide informed feedback. Given the complexity of the proposed regulation/policy, an extension of 59 days is necessary to ensure that the public has sufficient time to provide thoughtful and substantive comments. This extension will also allow for more inclusive public participation, particularly among stakeholders who may require additional time to review and comment on the proposal. Thank you for your attention to this matter. Sincerely, Poonam Kalkat, Utilities Director, City of Boynton Beach

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document.

Massachusetts Water Works Association (Doc. #2314, SBC-046320)

Massachusetts Water Works Association represents more than 1.400 public water supply professionals in Massachusetts. We are writing to EPA to request an extension on the deadline for comments on the proposed National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances noticed by EPA on March 29, 2023 under docket EPA-HQ-OW-2022-0114. This regulation is complex, and 60 days is not sufficient time for the drinking water profession to evaluate the impacts and provide thoughtful and thorough feedback to EPA. We respectfully request that EPA grant an additional 90 days beyond the original comment deadline of May 30, 2023. Massachusetts has a Maximum Contaminant Level for six PFAS compounds set at 20 parts per trillion; we know the significant costs that have, and are currently, being incurred by our utilities to comply with the Massachusetts standard which is higher than what EPA is proposing. Further complicating the review of this regulation is the fact that EPA is proposing a new way of evaluating compliance with 4 PFAS compounds through a Hazard Index approach; this has never before been utilized in drinking water standards and so we need more time to evaluate the impact this new approach will have on our utilities. For these reasons and given the enormous impact this rule will have on utilities in Massachusetts and across the nation, we ask you to grant our extension request.

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document and the EPA response to comment Doc. #1465, SBC-042300 in section 17.1 in this *Response to Comments* document.

Anonymous (Doc. #2569, SBC-047293)

It also seems that this is being rushed through since the public comment period is only 2 months. Nearly everyone I talk to is unaware of this and a longer comment period is needed for the word to get out.

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document.

NELAC Institute (Doc. #2960, SBC-046292)

The NELAC Institute Proficiency Testing Program Executive Committee (PTPEC) is currently developing Fields of Proficiency Testing for PFAS compounds in drinking water and requests the comment period for this proposed rulemaking be extended for 90 more days to allow for the committee to complete data evaluation for determination of Proficiency Testing acceptance limits for PFAS compounds. These acceptance limits will be based on data collected through

UCMR Proficiency Testing (Performance Evaluation) using TNI procedures for acceptance limit determination.

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document. With respect to the commenter's note about development of "Proficiency Testing acceptance limits for PFAS compounds," please see the EPA response to comment Doc. #1575, SBC-042458 in section 8.6 in this *Response to Comments* document. Please see 40 CFR § 141.901 for more information on the analytical requirements for the final rule; specifically, Table 2 to paragraph (b)(2)(ii) lists the acceptance limits for PFAS performance evaluation samples (70-130 percent). The EPA notes that the acceptance criteria set forth by the agency under this regulatory action must be followed by laboratories upon the compliance dates for the final rule, regardless of outside efforts to develop alternative criteria.

Massachusetts Water Resources Authority (Doc. #3072-49, SBC-047380)

EPA should extend the comment period for this rule as you've essentially crammed three separate processes into one request for comment. Setting health advisory levels for additional PFAS, regulatory determinations for four additional contaminants, and finally that actual proposed regulation. Typically, each of these would have its own public process and logical sequence and commenters would have sufficient time to comment on each step.

EPA Response: Please see section 17.1 of the EPA response in this *Response to Comments* document. Additionally, the commenter is incorrect that this action includes setting health advisory levels for additional PFAS. Through this action, the EPA is establishing MCLGs and enforceable standards for six PFAS. For more information, please see sections IV and V of the preamble for this action.

Association of Metropolitan Water Agencies (AMWA) (Doc. #1738, SBC-045963)

AMWA also understands that PFAS are a unique set of substances and that there are challenges in addressing dozens, hundreds, or even thousands of these substances, and as a result, these challenges may need creative solutions. The association has stated before (Attachment 5) that if EPA determines that regulatory action is needed beyond PFOA and PFOS, the agency should use the Negotiated Rulemaking Procedure ("Reg-Neg"). To implement a "Reg-Neg", the agency must decide there is a need for a rule, determine that there are a limited number of identifiable interests that will be significantly affected by the rule, and conclude that there is a reasonable likelihood that a committee could be convened which would consist of a balanced representation of the interests involved.

Due to the unique circumstances surrounding PFAS as a family, AMWA believes regulating additional PFAS would meet the criteria for a "Reg-Neg" and would save the agency time as all key stakeholder concerns would be discussed during a process that would bring those stakeholders into a risk-risk tradeoff discussion to help the agency come to a proposal with a higher likelihood of success. Throughout any regulatory process to address additional PFAS, the

agency must consider any future actions within the context that whatever path EPA chooses will set the stage for how the agency addresses other PFAS and other emerging contaminants going forward.

EPA Response: The EPA disagrees with the commenter's recommendation to pursue a negotiated rulemaking procedure to regulate additional PFAS. Although a negotiated rulemaking procedure is appropriate under specific circumstances, the EPA does not believe that the PFAS NPDWR is appropriate for a negotiated rulemaking procedure. Among other things, engaging in a negotiated rulemaking involves substantial additional processes that would substantially delay the finalization of this rulemaking effort and thus the public health protection it is anticipated to provide. The science is clear that long-term exposure to certain PFAS, including those proposed for regulation in this action, is linked to significant health risks. The EPA anticipates that over many years this action, if it is finalized, will save thousands of lives and prevent tens of thousands of serious illnesses that would otherwise result from long-term exposure to PFAS. Therefore, it is an EPA priority that the agency take final action on this regulation expeditiously to reduce PFAS exposure in communities across the country.

Furthermore, a successful negotiated rulemaking would be very challenging, if not impossible, within the timeframe that the EPA is statutorily compelled to complete this rulemaking. As required under SDWA 1412(b)(1)(E), the EPA was under a statutory obligation to have proposed the NPDWR for PFOA and PFOS at minimum by March 2023 and is obligated to finalize the regulation no later than September 2024. The EPA can, by notice in the Federal Register, extend the deadline up to nine additional months, giving the EPA until June 2025 to promulgate this regulation. However, even if exercising that extension, there would not be sufficient time to complete a negotiated rulemaking process. While the EPA has a successful history of negotiated rulemakings when there is adequate time and the subject matter lends itself to that forum, such as when the EPA is revising rules under SDWA section 1412(b)(9), those negotiated rulemakings are time-consuming. They have never been utilized under the SDWA rulemaking process as established in 1412(b)(1). From the time the EPA begins to form a committee until an agreement in principle is reached typically takes at least 18 months; see, for instance, the EPA's Revised Total Coliform Rule (RTCR), Long Term 2 Enhanced Surface Water Treatment Rule (LT2), and Stage II DBP rules (USEPA, 2013; USEPA, 2008; USEPA, 2006a; USEPA, 2006b; USEPA, 2000). It isn't until after reaching consensus in the negotiated rulemaking that the EPA would initiate the process for developing a rulemaking package that reflects the agreement, propose that rule for public comment, consider those comments, and then complete the same rulemaking process that the EPA engaged in for this rule. In short, establishing a federal advisory committee in this rulemaking would guarantee that the EPA would miss its statutory deadlines and delay necessary public health protection. Finally, the EPA notes that establishment of negotiated rulemakings is typically discretionary, and the agency is under no obligation to do so for this regulatory action.

17.2 Next Steps and Timeline

Summary of Major Public Comments and EPA Responses

Many commenters commended the EPA for taking action to address PFAS through an NPDWR and urged the agency to finish the rule as quickly as possible. The EPA has taken final action on the PFAS NPDWR rules as expeditiously as possible and ahead of its statutory deadline. Furthermore, through its PFAS Strategic Roadmap and associated actions, the agency is working expeditiously to address PFAS contamination in the environment and reduce environmental exposure to PFAS.

Several commenters recommended that the EPA postpone a final rulemaking addressing PFAS in drinking water. These commenters cited a need for more occurrence data (collected through the fifth Unregulated Contaminant Monitoring Rule (UCMR 5) or other sources), a greater understanding of economic costs and availability of treatment technologies, finalization of concurrent PFAS rulemakings including CERCLA hazardous waste designation, and/or the need to achieve accomplishments in source water reduction first. The EPA disagrees with delaying promulgation of this regulation. First, the EPA disagrees that he occurrence data used to inform this rule are not sufficient to provide the EPA the necessary information to develop an informed regulation reflective of best available science. As discussed in section VI of this preamble and section 6 of this *Response to Comments* document, sufficient and robust occurrence information including data from the third UCMR (UCMR 3), tens of thousands of samples from state datasets, and a nationally representative occurrence model are available and supportive of the agency's decision to regulate. The EPA is not required under the statute to wait for another round of UCMR data to be collected before proposing or finalizing a regulation. Please see the EPA response to comment Doc. #1684, SBC-044302 in section 6.1 in this *Response to Comments* document for discussion of what constitutes best *available* science (emphasis added). The completion of UCMR 5 data reporting is expected at the end of 2025, with the final dataset not being available until 2026. While the EPA is under no legal obligation to consider the preliminary, partial UCMR 5 dataset prior to rule promulgation, based on public comment and interest, the agency analyzed and considered UCMR 5 data released as of February 2024 (USEPA, 2024b).

Some commenters expressed concern about a potential designation of PFOA and PFOS as CERCLA hazardous substances. The EPA's rulemaking activities to designate PFOA and PFOS as CERCLA hazardous substances are beyond the scope of this PFAS NPDWR rulemaking; for discussion of topics outside the scope of this regulatory action, please see section 15 of this *Response to Comments* document. Additionally, the EPA disagrees with commenters that the agency should wait to promulgate the final NPDWR rulemaking as the CERCLA hazardous substance rulemaking is not anticipated to impact the factors the EPA considers when establishing an NPDWR, including treatment feasibility, cost, benefits, analytical methods, among other considerations. This NPDWR will protect the American people directly from everyday PFAS exposures that might otherwise occur from PFAS-contaminated drinking water,

complementing the many other actions in the PFAS Strategic Roadmap to protect public health and the environment from PFAS. For those reasons, the EPA is not delaying the final PFAS NPDWR to wait for finalization of the CERCLA PFOA and PFOS hazardous substance rulemaking. The EPA notes that it does not anticipate the CERCLA rulemaking substantially increasing disposal costs associated with this rulemaking. For the final rule, the EPA included a sensitivity analysis to determine the costs associated with the handling and disposal of PFAS treatment materials as hazardous waste; please see Appendix N of the EA for more information. Additional discussion of CERCLA issues, including costs, can be found in section 10.4.2 of the EPA response in this *Response to Comments* document.

The agency also disagrees that the economic costs and impacts have not been adequately described. The agency has prepared a final rule Health Risk Reduction and Cost Analysis (HRRCA) supporting document (USEPA, 2024a) for the PFAS NPDWR, in compliance with section 1412(b)(3)(C) of SDWA and under EO 12866. A detailed analysis of the costs and benefits of the final rule is included in section XII of the preamble for this rulemaking. Additionally, public comments related to costs, benefits, and the Administrator's determination that the costs are justified by the benefits are addressed in section 13 of the EPA response in this *Response to Comments* document. Likewise, the EPA disagrees that the agency does not have an adequate understanding of the availability of treatment technologies. Please see section X of the preamble for this rulemaking and section 10.6 of the EPA response in this *Response to Comments* document for additional discussion on treatment technology availability and capacity.

Individual Public Comments

Liliana Salcido (Doc. #1509, SBC-042587)

According to the Environmental Working Group, the estimates for industrial environmental polluters that release PFAS into the environment is at about 30,000 (Amarelo, 2023). The EPA must work fast in order to put these regulations in place. Not only are these chemicals found in all of our bodies, they have been found in food, soil, water, and other parts of the world. Companies have gone far too long putting their profits over the health and safety of every citizen in the United States, and it is the government's duty to stop this at once.

Sincerely,

Liliana

References

Amarelo, M. (2023, March 14). EPA proposes bold new limits for tackling "forever chemicals" in drinking water | Environmental Working Group. https://www.ewg.org/news-insights/news-release/2023/03/epa-proposes-bold-new-limit s-tackling-forever-chemicals-drinking

Isaacs-Thomas, B. (2023, March 17). 4 things to know about regulating "forever chemicals" in drinking water. PBS NewsHour. https://www.pbs.org/newshour/science/4-questions-about-the-epas-proposed-pfas-drinki ng-water-standard-answered

Nicole, W. (2013). PFOA and Cancer in a Highly Exposed Community: New Findings from the C8 Science Panel. Environmental Health Perspectives, 121(11–12), A340. https://doi.org/10.1289/ehp.121-A340

EPA Response: While the EPA is working through other activities to reduce PFAS discharges to the environment, those activities are beyond the scope of this rulemaking. Please see sections 15 and 17.2 of the EPA response in this *Response to Comments* document.

Liliana Salcido (Doc. #1509, SBC-042584)

It is extremely important for these chemicals in drinking water to be regulated as soon as possible because we have been aware of their consequences for decades (Amarelo, 2023) (Nicole, 2013). The EPA and companies like DuPont have known the dangers of these chemicals since the 1990s, and the more we delay the regulation of them, the higher the cancer rates will be in the U.S. If we know that PFAS are directly linked to cancer, reproductive harm, immune system damage and other serious health problems, then there should not be any more lax regulation oversight (Amarelo, 2023; Isaacs-Thomas, 2023; Nicole, 2013). This is not a problem of the future, people have been suffering and dying from cancer due to negligence from corporations and the government for decades. Now that we are all aware of the hazards of these chemicals, it is our responsibility as citizens, employees, and government officials to advocate for the regulation of these chemicals. Additionally, the general public should be made aware of the negative anticipated effects that these chemicals may have on their health and wellbeing.

EPA Response: The EPA has taken final action on the PFAS NPDWR for six PFAS as expeditiously as possible. Please see section 17.2 of the EPA response in this *Response to Comments* document.

Robert Adamski (Doc. #1530, SBC-043331)

I recommend delaying this rule and replacing it with more research and data collection

Robert E. Adamski

6160 Yorkshire Road

New Hope, PA 18938

(917) 836 2614

gatorbob85@gmail.com

April 28, 2023

U.S. Environmental Protection Agency

EPA Docket Center

Office of Ground Water and Drinking Water Docket

Mail Code 282IT

1200 Pennsylvania Avenue NW

Washington, DC 20460

Subject: Docket ID No. EPA-HQ-OW-2022-0114

Dear Sir,

I am writing to express my concern over EPA's proposed rules for PFAS/ PFOS. I believe they need to be delayed and replaced with additional monitoring of the presence and sources of the chemicals in industries, water supplies and water recovery facilities.

EPA Response: Please see section 17.2 of the EPA response in this *Response to Comments* document. The EPA disagrees that additional monitoring is needed before finalizing this rule. The agency has previously made a final determination that there is sufficient occurrence and health effects information to regulate PFOA and PFOS, and as discussed in section III of the final rule preamble and in section 3 of the EPA response in this *Response to Comments* document, the EPA has determined that PFHxS, PFNA, HFPO-DA, and mixtures of those PFAS with PFBS meet the statutory criteria for regulation.

Linda Shosie (Doc. #1533, SBC-043962)

I urge you to promptly finalize the proposed rule without any further delays, to continue to build on this rule and give it the teeth it needs to prevent another tragedy like this from happening again. We cannot afford to wait any longer to address these critical issues. Thank you for your attention to this matter.

Sincerely,

Linda Shosie

EPA Response: Please see section 17.2 of the EPA response in this *Response to Comments* document.

Linda Shosie (Doc. #1533, SBC-043967)

We urge the EPA to finalize the standards as quickly as possible, so our community can finally have access to the clean, safe, sustainable and affordable drinking water services that we deserve. Thank you for your attention to this matter.

Sincerely,

The Environmental Justice Task Force

EPA Response: Please see section 17.2 of the EPA response in this *Response to Comments* document.

Washington Suburban Sanitary Commission (WSSC Water) (Doc. #1585, SBC-042771)

Final rule promulgation:

WSSC Water also recommends that EPA postpone the promulgation of the final rule until it has collected sufficient or full occurrence data through UCMR5. This data will provide opportunities for the EPA to more appropriately assess nationwide occurrence and to identify possible issues with implementing compliance, such as laboratory proficiency, capacity, and monitoring costs. The statutory deadline for EPA to finalize the rule is September 2024, which provides additional time to ensure that this regulatory action aligns with the occurrence criterion.

EPA Response: Please see section 17.2 of the EPA response in this *Response to Comments* document. For more information related to UCMR 5 data, please see section 6.8 of the EPA response in this *Response to Comments* document.

Village of Woodbury (Doc. #1629, SBC-042947)

Submitted Electronically

MEMORANDUM

To: Michael S. Regan, Administrator

U.S. Environmental Protection Agency

From: On behalf of the Village of Woodbury

Natalie D. Barber, PE, Village Engineer

James J. Roberts, PE, Sr. Vice President

SUBJECT: Per- and Polyfluoroalkyl Substances (PFAS)

Proposed PFAS National Primary Drinking Water Regulation

Docket ID: EPA-HQ-OW-2022-0114

DATE: May 30, 2023

On behalf of the Village of Woodbury (Village), as part of the public comment period, please accept the following comments on the proposed National Primary Drinking Water Regulation

(NPDWR) for six PFAS announced by the Environmental Protection Agency (EPA) on March 14, 2023.

The Village owns and operates two water areas in Orange County, New York: Consolidated Water Area (Consolidated) and Amdur Park Water Area (Amdur). As an affected party, the Village appreciates the opportunity to provide comments on the proposed rule.

A) Technical Comments on Proposed Rule –

1. Based on industry data available to the Village at this time, we believe the economic costs and impacts of the rule are understated and there is a risk potential related to material availability and other concurrent rule making by the EPA on the management of contaminated filter media and implications on backwashing operations. We believe final promulgation of the rule should be deferred pending clear resolution of these issues.

EPA Response: Please see section 17.2 of the EPA response in this *Response to Comments* document. For responses to comments regarding costs associated with the rule, please see sections 13.2 and 13.3 of the EPA response in this *Response to Comments* document. The EPA notes that the commenter provided no specific information or data for the EPA to consider to adjust its cost estimates. For issues related to supply chain management (e.g., material availability) that may affect the compliance timeline, please see section 12.1 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Maine Organic Farmers and Gardeners Association (MOFGA) (Doc. #1660, SBC-043384)

Summary. EPA's proposed rule will save lives and protect health and should be adopted without delay

EPA Response: The EPA agrees with this commenter that there should not be a delay in taking final action on the PFAS NPDWR. Please see section 17.2 of the EPA response in this *Response to Comments* document.

Maine Organic Farmers and Gardeners Association (MOFGA) (Doc. #1660, SBC-043386)

In summary, MOFGA supports this rulemaking as an important first step, and opposes any delay in its adoption. We have waited long enough for federal action.

Respectfully submitted,

Heather Spalding, MOFGA Deputy Director

Sharon Anglin Treat

Attorney, on behalf of MOFGA

EPA Response: The EPA agrees that there should not be a delay in taking final action on this rulemaking. Please see section 17.2 of the EPA response in this *Response to Comments* document.

Rockbridge Area Conservation Council (RACC) (Doc. #1678, SBC-043737)

With that said, we respectfully request that: (1) a timeline be established identifying when the MCLG of "Zero" will be realized - at least for PFOA/PFOS;

EPA Response: The MCLG is set, as defined in Section 1412(b)(4)(A), at "the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." MCLGs are public health goals and are not enforceable. For more information, please see section 4.1.5 of the EPA response in this *Response to Comments* document and section IV of the FRN. With respect to the date by which the MCLs must be met, please see section 12.1 of the EPA response in this *Response to Comments* document.

Anonymous (Doc. #1685, SBC-044439)

These chemicals need to be monitored and "acceptable" limits be lowered. My kids grew up drinking the PFAS polluted water in Wilmington. Now one of my grand babies WAS BORN WITH LEUKEMIA and lost her life. Only lived a short 13 months. The other was born with a hole in her heart. These chemicals destroy lives. DO SOMETHING ABOUT THEM. YOU ARE SUPPOSE TO PROTECT THE PUBLIC AND NOT COMPANY'S PROFITS. Look at that precious face. She is no longer with us due to something ENVIRONMENTAL that caused her to have cancer prior to being born.

[Attachment: See docket ID EPA-HQ-OW-2022-0114-1685]

EPA Response: The EPA has taken final action on the PFAS NPDWR as expeditiously as possible. Once implemented, the EPA anticipates this regulation will prevent tens of thousands of PFAS-attributable serious illnesses. Regarding monitoring for PFAS, please see section 8 of the EPA response in this *Response to Comments* document. Additionally, please see section 17.2 of the EPA response in this *Response to Comments* document. While the EPA cannot speak to whether PFAS exposure is specifically what caused your granddaughter's Leukemia, we are sorry for your loss.

Wisconsin Department of Justice et al. (Doc. #1687, SBC-044449)

5. EPA should issue the final rule as quickly as possible because these contaminants are so toxic, while at the same time giving States the opportunity to revise their programs.

The toxicity of PFAS is well documented, and EPA references and discusses the human harms of PFAS throughout the proposed PFAS Rule, explaining that "[d]epending on the individual PFAS, health effects can include negative impacts on fetal growth after exposure during

pregnancy, on other aspects of development, reproduction, liver, thyroid, immune function, and/or the nervous system; and increased risk of cardiovascular and/or certain types of cancers, and other health impacts." [FN44:88 Fed. Reg. 18,638 (Mar. 29, 2023).] Because of these serious adverse health impacts, swift regulatory action is warranted.

The process of implementing drinking water regulations can be lengthy, with National Primary Drinking Water Regulations generally set to take effect as long as three years after a regulation is promulgated. [FN45: 42 U.S.C. § 300g-1(b)(10).] And states can allow individual water systems up to two additional years to comply if that time is reasonably needed to implement the necessary capital improvements to comply. [FN46:Id.] That means an MCL promulgated today might not take effect for five years for some residents of our States.

Given the toxicity of these PFAS and this anticipated long implementation period, it is crucial that EPA finalize the PFAS Rule as quickly as possible.

EPA Response: The EPA has taken final action on the PFAS NPDWR as expeditiously as possible and ahead of its statutory deadline. Please see section 17.2 of the EPA response in this *Response to Comments* document. Additionally, for additional discussion about the MCLs' compliance timeline, please see section 12.1 of the EPA response in this *Response to Comments* document on extensions and exemptions.

National Wildlife Federation et al. (Doc. #1702, SBC-043511)

May 30, 2023

Via Regulations.gov

The Honorable Michael Regan Administrator

U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, N.W. Washington, DC 20460

Re: Comments on Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation Docket ID No. EPA-HQ- OW-2022-0114

Dear Administrator Regan,

On behalf of the National Wildlife Federation, affiliates from Delaware, Georgia, Indiana, Iowa, Kentucky, Maine, Massachusetts, Missouri, New Hampshire, North Carolina, Oklahoma, Rhode Island, Texas, Vermont, Virginia, West Virginia, and our nearly 7 million members and supporters, we submit the following comments on the national primary drinking water regulations for PFAS proposed by the U.S. Environmental Protection Agency (EPA) under the authority of the Safe Drinking Water Act. This proposal is an important first step towards keeping our drinking water safe from six types of highly toxic PFAS. We greatly appreciate the Administration's commitment to addressing the nation's PFAS contamination crisis and we urge

the agencies to move swiftly to finalize protective standards to reduce PFAS in our drinking water.

EPA Response: The EPA has taken final action on the PFAS NPDWR as expeditiously as possible and ahead of its statutory deadline. Please see section 17.2 of the EPA response in this *Response to Comments* document.

National Wildlife Federation et al. (Doc. #1702, SBC-043516)

Our organizations urge the EPA to swiftly finalize the proposed drinking water standards for PFAS to improve the safety of our drinking water. We appreciate the Administration's efforts to curb PFAS exposure in our drinking water and look forward to working with you as you continue to implement the EPA's 2021 Strategic PFAS Roadmap to address all sources of PFAS pollution. Thank you for your consideration.

Sincerely,

Conservation Coalition of Oklahoma Conservation Federation of Missouri Delaware Nature Society Environmental Council of Rhode Island

Environmental League of Massachusetts Georgia Wildlife Federation

Indiana Wildlife Federation Iowa Wildlife Federation Kentucky Waterways Alliance National Wildlife Federation

Natural Resources Council of Maine New Hampshire Audubon

North Carolina Wildlife Federation Texas Conservation Alliance Vermont Natural Resources Council Virginia Natural Resources Council West Virginia Rivers Coalition

EPA Response: The EPA has taken final action on the PFAS NPDWR as expeditiously as possible and ahead of its statutory deadline. Please see section 17.2 of the EPA response in this *Response to Comments* document.

Susan Gorman-Chang (Doc. #1705, SBC-045084)

4. Since the Safe Drinking Water Act Section 1412(b)(10) mandates that "national primary drinking water regulation promulgated under the section (and any amendment thereto) shall take effect on the date that is 3 years after the date on which the regulation is promulgated unless the Administrator determines that an earlier date is practicable," please ensure that this 3 years is met or shortened as human beings will continue to suffer the effects of cancer, thyroid, kidney, cardiovascular, hepatic, endocrine, metabolic, musculoskeletal, reproductive and fetal issues all the while the EPA is taking its time. The section clearly states that "an earlier date" is possible! Please do not under any circumstances increase this 3 year date either.

5. Please finalize these regulations well before your December 31, 2023 deadline. You are free to work faster, and every day you do so will save lives.

EPA Response: The EPA has taken final action on the PFAS NPDWR as expeditiously as possible and ahead of its statutory deadline. Please see section 17.2 of the EPA response in this *Response to Comments* document. Additionally, for additional discussion about the MCLs' compliance timeline, please see section 12.1 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Citizens Campaign for the Environment (CCE) (Doc. #1710, SBC-045129)

CCE urges the EPA to move to adopt and implement the proposed regulations as quickly as possible in order to protect public health. People across the nation have already been exposed to these dangerous PFAS chemicals for too long, and we can't afford to wait any longer.

EPA Response: The EPA has taken final action on the PFAS NPDWR as expeditiously as possible and ahead of its statutory deadline. Please see section 17.2 of the EPA response in this *Response to Comments* document.

Protecting Our Water, Environment, and Ratepayers (POWER) (Doc. #1714, SBC-045927)

May 30, 2023

VIA Regulations.Gov

The Honorable Michael Regan

Administrator

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue NW

Washington, D.C. 20460

Ms. Jennifer McLain

Director Office of Groundwater and Drinking Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue NW

Washington, D.C. 20460

RE: EPA-HQ-OW-2022-0114: PFAS NATIONAL PRIMARY DRINKING WATER REGULATION RULEMAKING

Dear Administrator Regan and Director McLain,

Protecting Our Water, Environment, and Ratepayers Coalition ("POWER!") appreciates the opportunity to provide comments on the Environmental Protection Agency's ("EPA's") proposed rulemaking to establish a National Primary Drinking Water Regulation ("NPDWR") for six per- and polyfluoroalkyl substances ("PFAS"). POWER! is a coalition of water agencies, wastewater agencies, and municipalities who, together, are writing today to comment on several aspects of the proposed rule.

POWER! is encouraged that EPA is taking steps to address PFAS in our environment. POWER! supports drinking water standards that protect public health based on sound science and clear analysis of methods of attainment, costs, and benefits. However, POWER! believes that until EPA takes more aggressive steps to ensure adequate and reliable testing capability, halt the sources and upstream pathways, and provide disposal standards for all six PFAS substances covered, the current proposed rule is premature and will have unintended negative consequences for water agencies and the public we serve. This proposed rule may also harm the public's trust in the nation's water systems If the proposed rule is finalized, it will, at a minimum, subject public water agencies to the threat of yet-to-be developed standards and increased costs, and will result in higher water bills for households across the country. Therefore, in addition to the comments set forth below, POWER! requests that EPA delay finalizing the proposed rule until EPA has:

(1) Determined that laboratory capabilities provide sufficient and reliable testing capacity at the levels required to verify compliance with the standard and the lower proposed trigger levels for less frequent compliance monitoring;

(2) Used EPA's full powers under the Toxic Substances Control Act to stop the pipeline of all six PFAS substances into the nation's environment and water systems;

(3) Used EPA's powers under the Resource Conservation and Recovery Act ("RCRA") and Clean Water Act to limit the pathways of all six PFAS substances into the nation's water systems;

(4) Issued Health Advisories and determined a Reference Dose for perfluorohexane sulfonic acid ("PFHxS") and perfluorononanoic acid ("PFNA");

(5) Finalized standards for disposing of treatment residuals;

(6) Provided a robust analysis and opportunity to comment on the costs of complying with the proposed MCL and Hazard Index if (a) all six PFAS substances are designated as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA"), (b) the compressed timeframe for historic investments in treatment infrastructure increases costs, (c) reasonably foreseeable pathways continue to add PFAS to water sources, (d) reasonably foreseeable increases in PFAS treatment media requirements and costs occur;

(7) Received and considered data on the prevalence of hexafluoropropylene oxide dimer acid ("HFPO-DA" commonly known as "GenX"), and the prevalence of the remaining five PFAS at

the newer reporting levels, from the Fifth Unregulated Contaminant Monitoring Rule ("UCMR 5");

(8) Proposed what maximum containment levels ("MCL") would be appropriate if EPA adhered to its self-stated standards for reliable detections and set the Practical Quantitation Level for each PFAS at 5-10 times its Minimum Detection Level ("MDL").

EPA will be arbitrarily skipping critical steps in the established Safe Drinking Water Act ("SDWA") regulatory process if it now proceeds to a final MCL without adequately acting to control these substances' ongoing pathways, complete assessments of health risks and reference doses, establish appropriate disposal standards, ensure adequate technologies, provide a robust cost analysis, or adhere to its precedents for ensuring reliable detections.

EPA Response: The EPA disagrees with the commenter that the EPA skipped steps within the SDWA regulatory process. The SDWA does not require the EPA to be "adequately acting to control these substances' ongoing pathways" or "establish appropriate disposal standards" prior to rule finalization. In fact, many drinking water regulations have been established because of prior and ongoing contamination of source waters. Additionally, while not required for and beyond the scope of this rulemaking, the EPA continues to produce information related to the disposal and destruction of PFAS. See (5) below. In regard to whether the EPA has met its obligations for evaluating health risks, establishing or identifying reference doses, evaluating whether there are available treatment technologies to treat below MCL values, developing a robust cost analysis, and ensured there are available analytical methods, the EPA has completed all of these things. See section 4 of the EPA response in this *Response to Comments* document for discussion of health effects and reference doses, section 10 of the EPA response in this *Response to Comments* document for discussion of treatment technologies, sections 13.2 and 13.3 of the EPA response in this *Response to Comments* document for discussion of costs, and section 7 of the EPA response in this *Response to Comments* document for discussion of analytical methods.

The EPA refers the commenter to section I.I of the FRN as well as sections 1.1 and 3.3 of the EPA response in this *Response to Comments* document for further discussion related to the SDWA rulemaking process. Please see the following for a response to each of the commenter's numbered statements:

(1) For concerns related to laboratory capabilities, please see section 8.7 of the EPA response in this *Response to Comments* document.

(2) Regulatory actions under Toxic Substances Control Act (TSCA) are out of scope for this final NPDWR. As discussed in the PFAS Strategic Roadmap, the Office of Chemical Safety and Pollution Prevention (OCSPP) is engaging in several key actions related to PFAS, including ensuring a robust review process for new PFAS under TSCA to ensure these substances are safe before entering commerce, reviewing existing PFAS under TSCA (Inactive PFAS proposed rule published January 2023), and finalizing new PFAS reporting under TSCA Section 8 to better

characterize the sources and quantities of manufactured PFAS in the United States. Please see the Strategic Roadmap for more information.

(3) While regulatory actions under Resource Conservation and Recovery Act (RCRA) and the CWA are out of scope for this final NPDWR, other EPA offices are engaging in key actions related to PFAS in those contexts. Please see the Strategic Roadmap (USEPA, 2022) for more information.

(4) Health Advisories are beyond the scope of this regulatory action. Health Advisories are non-enforceable and non-regulatory in nature, are not a pre-requisite for an NPDWR under the SDWA, and there is nothing in the statute or EPA historical regulatory practice that suggests the agency should delay regulation of a contaminant in order to develop a Health Advisory first. The four HI PFAS, including PFHxS and PFNA, are well-studied PFAS for which the EPA or Agency for Toxic Substances and Disease Registry (ATSDR) have developed human health assessments and toxicity values (i.e., reference doses (RfDs), minimal risk levels). The EPA is finalizing the NPDWR using ATSDR minimal risk levels for the purpose of developing MCLGs for PFHxS and PFNA. Please see the EPA response to comment Doc. #1714, SBC-045940 in section 4.3.2 and section 4.3.3 of the EPA response in this *Response to Comments* document for more information.

(5) The National Defense Authorization Act for Fiscal Year 2020, Public Law No: 116-92 Section 7361 directs the EPA to revise the PFAS Destruction and Disposal Guidance triennially; the new destruction and disposal guidance is anticipated to be released approximately concurrently with this rule and further revisions may be expected before the effective dates for this rule. The EPA disagrees that the projected significant and direct public health protections for drinking water consumers in this rule should be delayed for the revision of guidance on management of PFAS waste streams. Please see section 10.4.1 of the EPA response in this *Response to Comments* document for more information.

(6) Please see the EA (USEPA, 2024a) and the EPA response to comment Doc. #1714, SBC-045931 in section 13.3.6 in this *Response to Comments* document for more information related to the costs and benefits of this rule. SDWA directs the EPA to analyze the costs and benefits of any proposed rule and directs the Administrator to make a determination as to whether the benefits of the proposed rule justify the costs. SDWA makes it clear that the EPA should consider, both quantified and unquantified, costs and benefits in making its determination. In addition to estimating the costs and benefits of the proposed PFAS NPDWR that the EPA was able to quantify, the EPA also discussed in some detail a number of health benefits, such as those associated with avoided adverse developmental, cardiovascular, liver, immune, endocrine, metabolic, reproductive, musculoskeletal, and carcinogenic effects, that the agency was unable to monetize or otherwise quantify. The Administrator's assessment that the benefits of the proposed PFAS NPDWR justified its costs was based on the totality of the evidence, specifically the quantified and unquantified benefits and costs.

(7) Please see section VI of the preamble for this rulemaking and the *Occurrence Technical Support Document* (USEPA, 2024c) for detailed information on occurrence of the 6 PFAS included this rule. Please also see section 6.8 of the EPA response in this *Response to Comments* document regarding UCMR 5 data. For HFPO-DA specifically, the robust amount of state occurrence data for HFPO-DA represent the current best available information, as required under SDWA, and demonstrate sufficient likelihood of occurrence of the PFAS being regulated. In the final regulation, based on public comment, the EPA updated the Occurrence Technical Support Document to include over 35,000 results of HFPO-DA from 25 states. For more information related to the occurrence statutory criterion for making regulatory determinations under SDWA, please see section 3.1.2 of the EPA response in this *Response to Comments* document.

(8) Please see the EPA response to comment Doc. #1714, SBC-045943 in section 7.2 in this *Response to Comments* document and the summary of major comments in section 5.1.2 (laboratory considerations and practical quantitation levels (PQLs)) in this *Response to Comments* document for more information. Alternative MCLs are discussed in section 5.1.3 in this *Response to Comments* document.

Private Citizen – General (Doc. #1722, SBC-043832)

From: Donna Reardon <info@sg.actionnetwork.org>

Sent: Tuesday, May 30, 2023 8:10 PM

To: OW-Docket

Cc: RemoteWorkAppeal

Subject: Please pass restrictive PFAS MCLs!

Follow Up Flag: Follow up

Flag Status: Flagged

Mr. Michael Regan,

Dear Administrator Regan,

We know that it is much cheaper to protect our drinking water, than to clean it up. We know that PFAS are dangerous to humans. Please do the right thing for your family and mine.

Please swiftly act to protect the public from exposure to dangerous PFAS chemicals in drinking water. While the March 2023 proposal is a step in the right direction we also need to do the following:

1. Please do not capitulate to the delay tactics by industry that wants you to extend the comment period.

EPA Response: Please see section 17.2 of the EPA response in this *Response to Comments* document. The EPA has taken final action on the PFAS NPDWR as expeditiously as possible and ahead of its statutory deadline. In regard to whether to extend the comment period, please see section 17.1 of the EPA response in this *Response to Comments* document.

Steven Alt (Doc. #1724, SBC-044473)

I strongly believe the EPA should accelerate the elimination of sources of PFAS which are polluting our waters but in the mean time I strongly agree the EPA should finalize the PFAS standards as quickly as possible. Note: Any Attachment highlights are not mine.

[Attachment 2: see docket ID EPA-HQ-OQ-2022-0114-1724].

[Attachment 3: see docket ID EPA-HQ-OQ-2022-0114-1724].

[Attachment 4: see docket ID EPA-HQ-OQ-2022-0114-1724].

[Attachment 5: see docket ID EPA-HQ-OQ-2022-0114-1724].

[Attachment 6: see docket ID EPA-HQ-OQ-2022-0114-1724].

EPA Response: The EPA has taken final action on the PFAS NPDWR as expeditiously as possible and ahead of its statutory deadline. Please see section 17.2 of the EPA response in this *Response to Comments* document.

Joe DiNardo (Doc. #1725, SBC-045758)

With that said, I respectfully request that: (1) a timeline be established identifying when the MCLG of "Zero" will be realized - at least for PFOA/PFOS;

EPA Response: Please see the EPA response to comment Doc. #1678, SBC-043737 in section 17.2 in this *Response to Comments* document.

San Gabriel Basin Water Quality Authority (WQA) (Doc. #1743, SBC-043612)

2. EPA is in the process of establishing regulations to designate PFOS and PFOA as hazardous substances under CERCLA. That designation may significantly increase the cost to dispose of filter media used to remove the contaminants from drinking water. Therefore, EPA should consider delaying the adoption of the proposed National Primary Drinking Water Regulation for the named PFAS contaminants until it finalizes its proposal to designate PFOS and PFOA as hazardous substances under CERCLA. This would allow for the full consideration of additional costs in connection with the disposal of media used to remove PFOS and PFOA from drinking water that could potentially be designated as a hazardous substance.

EPA Response: Please see section 17.2 of the EPA response in this *Response to Comments* document.

West Virginia Rivers Coalition et al. (Doc. #1746, SBC-045249)

It is imperative that as testing technologies advance, EPA review and reduce the maximum contaminant levels (MCLs) for PFOA and PFOS. As more laboratories upgrade their instrumentation and gain more experience analyzing drinking water samples for PFAS, more laboratories will become capable of quantitatively measuring PFAS at lower concentrations. The Safe Drinking Water Act (SDWA) requires EPA to review each existing National Primary Drinking Water Regulation (NPDWR) every six years. EPA should reassess laboratories' PFOA and PFOS detection capacity during each six-year review period and lower the MCL as close as feasible to the MCLG as technologies support a lower practical quantitation level (PQL).

EPA Response: Individual laboratories may be able to achieve quantitation limits below the proposed PQLs, but the proposed PQLs are based on results from a statistical evaluation of several drinking water laboratories (multi-laboratory minimum reporting level (MRL)). Please see section 7.2 of the EPA response in this *Response to Comments* document for more information. As required under SDWA 1412(b)(9), the agency intends to consider this PFAS NPDWR in future six year reviews as appropriate. The primary goal of the Six-Year Review process is to identify national primary drinking water regulations for possible regulatory revision. The EPA considers a possible revision to be "appropriate" if, at a minimum, it presents a meaningful opportunity to: improve the level of public health protection, or achieve cost savings while maintaining or improving the level of public health protection.

West Virginia Rivers Coalition et al. (Doc. #1746, SBC-045260)

Collectively, we urge EPA to move quickly to finalize this rule for the health and safety of our communities. Thank you for your consideration.

Sincerely,

Angie Rosser

West Virginia Rivers Coalition

Kay Schultz

Save Our Soil

Gary Zuckett

WV Citizen Action Group

Marilyn Shoenfeld

West Virginia Highlands Conservancy

Brad Riffee

WV Council of Trout Unlimited

Dave Bassage

New River Conservancy

Brent Walls

Potomac Riverkeeper Network

John Maxey

Blue Ridge Watershed Coalition

EPA Response: The EPA has taken final action on the PFAS NPDWR as expeditiously as possible and ahead of its statutory deadline. See section 17.2 of the EPA response in this *Response to Comments* document.

National Center for Health Research (NCHR) (Doc. #1749, SBC-044499)

Lastly, we recommend additional clarity and urgency to speed up the timeline for finalizing this national standard, and implementing it once finalized.

EPA Response: The EPA has taken final action on the PFAS NPDWR as expeditiously as possible and ahead of its statutory deadline. Please see section 17.2 of the EPA response in this *Response to Comments* document. For additional discussion about the compliance timeline, please see section 12.1 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Coralie Pryde (Doc. #1781, SBC-043816)

However, many of us know that our water is contaminated at levels several times the 17 ppt level. It seems clear that nothing will be done until the proposed enforceable limits of 4.0 ppt for both PFOA and PFOS are adopted.

For the sake of the health of all Delaware residents, I hope that these enforceable limits are written into law as soon as possible.

EPA Response: The EPA has taken final action on the PFAS NPDWR as expeditiously as possible and ahead of its statutory deadline. Please see section 17.2 of the EPA response in this *Response to Comments* document.

Silent Spring Institute (Doc. #1784, SBC-045796)

May 30, 2023

RE: Silent Spring Institute's Public Comments on the U.S. EPA PFAS National Primary Drinking Water Regulation Rulemaking, 40 CFR Parts 141 and 142 (Document ID: EPA- HQ-OW-2022-0114-0027)

Submitted via https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0027/comment

Silent Spring Institute is a non-profit research organization with a mission to understand links between environmental chemicals and disease, with a focus on breast cancer prevention. We are writing on behalf of the Silent Spring Institute to comment on the U.S. Environmental Protection Agency's proposed Per- and Polyfluoroalkyl (PFAS) National Primary Drinking Water Regulations. We appreciate this opportunity to share scientific information on PFAS exposures and health effects from our own research and other published studies. Given the extensive scientific evidence on harm from the PFAS class of chemicals, widespread contamination of drinking U.S. public drinking water supplies, and the need for monitoring and for addressing this significant public health issue by reducing exposures, it is critical that the EPA finalize these drinking water regulations without delay. EPA has been long aware of the harms associated with this class of chemicals, and urgent action is need to protect communities across the U.S. in keeping with EPA's mission and authority to protect human health and the environment.

EPA Response: The EPA has taken final action on the PFAS NPDWR as expeditiously as possible and ahead of its statutory deadline. Please see section17.2 of the EPA response in this *Response to Comments* document.

PFAS Project Lab (Doc. #1786, SBC-044713)

The longer that PFAS remain unregulated, the more people will be exposed and harmed, in violation of the Safe Drinking Water Act's mandate to protect against adverse health effects from drinking water contaminants.

EPA Response: The EPA has taken final action on the PFAS NPDWR as expeditiously as possible and ahead of its statutory deadline. Please see section 17.2 of the EPA response in this *Response to Comments* document.

PFAS Project Lab (Doc. #1786, SBC-044716)

In the absence of federal PFAS standards, 10 states have enforceable drinking water levels that require testing and remediation for PFAS in drinking water and two have regulations in development (Safer States 2023). Twelve other states have adopted non-enforceable guidance or notification levels for PFAS in drinking water (Safer States 2023). In a peer-reviewed paper published in 2019 in the Journal of Exposure Science and Environmental Epidemiology, our lab examined PFOA and PFOS water guideline levels adopted by the EPA and state agencies in order to understand how and why these levels differ (Cordner et al. 2019). While states who develop their own standards can serve as important models, not all states have the ability to do so: for example, some lack the funding, technical expertise, and occurrence data to set protective state standards. Our article on this has been cited 229 times. As a result, these differences in state standards regarding PFAS can lend themselves to public health disparities across the country. In addition, it takes much energy from affected residents, scientists, and environmental organizations to seek regulations in each state. By contrast, a "sufficiently protective,

scientifically sound, and enforceable federal standard would provide more consistent protection" for all communities (Cordner et al. 2019). It has been over four years since we published this peer-reviewed article, underscoring how these federal drinking standards are long overdue.

EPA Response: Please see section 17.2 of the EPA response in this *Response to Comments* document. For more information on state drinking water standards, please see section V.I.V of the FRN for this action.

Mindi Messmer (Doc. #1788, SBC-044706)

Agencies empowered to protect public health must employ the Precautionary Principle – that "enables decision-makers to adopt precautionary measures when scientific evidence about an environmental or human health hazard is uncertain and the stakes are high." While the proposed maximum contaminant levels (MCLs) are a welcome step in the right direction, based on the above I submit the following:

1. Please do not capitulate to the delay tactics of the industry that wants you to extend the comment period.

EPA Response: In regard to requests to extend the comment period, please see section 17.1 of the EPA response in this *Response to Comments* document. The EPA has used the best available science to establish the MCLGs and MCLs in this PFAS NPDWR. The final rule is based on the EPA's SDWA authorities, not a general precautionary principle.

Mark Gearreald (Doc. #1792, SBC-044295)

From: Mark Gearreald <info@sg.actionnetwork.org>

Sent: Tuesday, May 30, 2023 12:31 PM

To: OW-Docket

Cc: RemoteWorkAppeal

Subject: Please pass restrictive PFAS MCLs!

Follow Up Flag: Follow up

Flag Status: Flagged

Mr. Michael Regan,

Dear Administrator Regan,

In the closing years of my 19 years serving as the first in house Town Attorney for the Town of Hampton, NH, I became aware of the threat to the public posed by PFAS chemicals. These were detected in bedrock samples in the Coakley Landfill, an EPA superfund site, whose bedrock water flow to the south and east potentially imperils the wellhead protection area for Aquarion

Water Company, whose water serves the communities of Hampton, North Hampton, and two Rye Water Districts. Thankfully, your agency has become more insistent on the bedrock studies being extended in the face of the Coakley Landfill Group's downplaying of the PFAS results, which support the opinions on the direction of flow that I presented from an expert for the Towns of Hampton and North Hampton.

In 2021, I had our home well water tested from our home in Dover, NH and on a whim, included PFAS chemicals. To my shock, there were exceedences greater than 50 parts per trillion in two of the 4 PFAS chemicals for which NH has adopted maximum contaminant levels, and the presence of greater than 5 parts per trillion for two of the others. We have invested in a whole house GAC system recently, for which we have thankfully received a rebate from the State of NH DES PFAS rebate program, and our neighbors' are now having their wells tested, too.

I attended and spoke at the EPA sponsored regional forum at the Exeter, NH High School in 2021 and heard, as you probably have, the horror stories that exposure to PFAS can have on children and their families in the areas where St. Gobain has contaminated drinking water supplies in Vermont and New Hampshire, and where the Air Force's firefighting foam contaminated wells and properties in Newington, NH. The evidence is mounting that nothing good, and lots bad, results from PFAS exposure; now is the time for EPA to act, and not to balk, in the face of all this evidence, to protect human health and the environment from exposure to PFAS.

Please swiftly act to protect the public from exposure to dangerous PFAS chemicals in drinking water. While the March 2023 proposal is a step in the right direction we also need to do the following:

1. Please do not capitulate to the delay tactics by industry that wants you to extend the comment period.

EPA Response: Consistent with the concerns expressed by the commenter, the EPA has taken final action on the PFAS NPDWR as expeditiously as possible and ahead of its statutory deadline. Please see section 17.2 of the EPA response in this *Response to Comments* document. In regard to requests to extend the comment period, please see section 17.1 of the EPA response in this *Response to Comments* document.

While beyond the scope of this rulemaking activities, please see section 15.1 of the EPA response in this *Response to Comments* document for discussion of other activities in EPA's PFAS Strategic Roadmap.

James McConnell (Doc. #1793, SBC-044701)

From: James McConnell <info@sg.actionnetwork.org>

Sent: Monday, May 29, 2023 7:22 PM

To: OW-Docket

Cc: RemoteWorkAppeal

Subject: Please pass restrictive PFAS MCLs!

Follow Up Flag: Follow up

Flag Status: Flagged

Mr. Michael Regan,

Dear Administrator Regan,

I was a New Hampshire State Representative deeply involved in New Hampshire's early PFAS regulatory efforts. It is clear to me that any level of exposure to PFAS is extremely damaging.

Please swiftly act to protect the public from exposure to dangerous PFAS chemicals in drinking water. While the March 2023 proposal is a step in the right direction we also need to do the following:

1. Please do not capitulate to the delay tactics by industry that wants you to extend the comment period.

EPA Response: The EPA has taken final action on the PFAS NPDWR as expeditiously as possible and ahead of its statutory deadline. Please see section 17.2 of the EPA response in this *Response to Comments* document. Regarding requests to extend the comment period, please see section 17.1 of the EPA response in this *Response to Comments* document.

Ohio Environmental Council (Doc. #1794, SBC-045321)

EPA's proposal to set strong, scientifically supported drinking water standards for six PFAS is an important step toward fulfilling the Biden Administration's commitment to tackle these toxic forever chemicals. We commend EPA's recognition that both individual PFAS and chemical mixtures of PFAS can threaten human health. We urge you to finalize the standards as quickly as possible.

EPA Response: The EPA has taken final action on the PFAS NPDWR as expeditiously as possible and ahead of its statutory deadline. Please see section 17.2 of the EPA response in this *Response to Comments* document.

Peggy Kurtz (Doc. #1799, SBC-046047)

Please approve the draft PFAS regulations as quickly as possible – and move on to take further steps without delay.

Thank you,

Peggy Kurtz

EPA Response: The EPA has taken final action on the PFAS NPDWR as expeditiously as possible and ahead of its statutory deadline. Please see section 17.2 of the EPA response in this *Response to Comments* document.

Safe Drinking Water Branch, Hawaii Department of Hawaii (Doc. #1801, SBC-043758)

Since the PFAS necessary will definitely compete with other EPA mandates, including compliance with the Lead and Copper Rule Revisions (LCRR) and recently announced cybersecurity measures, the state agent, we suggest EPA considering postpose the finalization of the PFSA rule to give us and water purveyors more time to prepare.

EPA Response: Please see section 17.2 of the EPA response in this *Response to Comments* document. For additional discussion about the compliance timeline, please see section 12.1 of the EPA response in this *Response to Comments* document on extensions and exemptions.

Earthjustice et al. (Doc. #1808, SBC-046095)

With more than half of the nation drinking PFAS-contaminated water, [FN2: David Q. Andrews and Olga V. Naidenko, Population-Wide Exposure to Per- and Polyfluoroalkyl Substances from Drinking Water in the United States, Env't. Sci. & Tech. Letters 931 (2020), https://doi.org/10.1021/acs.estlett.0c00713.] the Proposed Rule is urgently needed and should be finalized expeditiously, with the revisions outlined below. But as EPA Administrator Michael Regan acknowledged, "[w]hile this proposal is a step forward, there's no doubt there's more work left to do." [FN3: Michael Regan, Admin., EPA, Remarks for the PFAS Drinking Water Standard Event, As Prepared for Delivery (Mar. 14, 2023), https://www.epa.gov/speeches/administrator-michael-regan-remarks-pfas-drinking-water-standard-event-prepared-delivery.]

EPA Response: The EPA has taken final action on the PFAS NPDWR as expeditiously as possible and ahead of its statutory deadline. Please see section 17.2 of the EPA response in this *Response to Comments* document.

Earthjustice et al. (Doc. #1808, SBC-046098)

EPA has known of the harms associated with PFAS since at least 1998, and it has known of the presence of PFAS in drinking water since at least 2001. [FN18: Scott Faber, For 20-plus Years, EPA Has Failed to Regulate 'Forever Chemicals', Env't Working Grp. (Jan. 9, 2020), https://www.ewg.org/research/20-plus-years-epa-has-failed-regulate-forever-chemicals.] More than two decades later, however, EPA has yet to establish any federal limits on PFAS levels in drinking water. The Proposed Rule, which would regulate six widespread and highly toxic PFAS, is necessary and long overdue. EPA should act swiftly to issue final drinking water standards for PFAS, with the changes recommended below.

EPA Response: The EPA has taken final action on the PFAS NPDWR as expeditiously as possible and ahead of its statutory deadline. Please see section 17.2 of the EPA response in this *Response to Comments* document.

Environmental Working Group et al. (Doc. #1810, SBC-044685)

Administrator Michael S. Regan

U.S. Environmental Protection Agency EPA Docket Center, OW Docket

Mail Code 28221T

1200 Pennsylvania Avenue NW Washington, DC 20460

May 30, 2023

Dear Administrator Regan,

Re: Per- and Polyfluoroalkyl Substances (PFAS): Proposed National Primary Drinking Water Regulations (Docket ID: EPA-HQ-OW-2022-0114)

The undersigned organizations strongly support the regulation of per- and polyfluoroalkyl substances (PFAS) in drinking water under the authority of the federal Safe Drinking Water Act, as proposed by the Environmental Protection Agency (EPA) and published in the Federal Register on March 29, 2023. EPA's proposal to set strong, scientifically supported drinking water standards for six PFAS is an important step toward fulfilling the Biden Administration's commitment to tackle these toxic forever chemicals. We commend EPA's recognition that both individual PFAS and chemical mixtures of PFAS can threaten human health. We urge you to finalize the standards as quickly as possible.

EPA Response: The EPA has taken final action on the PFAS NPDWR as expeditiously as possible and ahead of its statutory deadline. Please see section 17.2 of the EPA response in this *Response to Comments* document.

National Wildlife Federation Action Fund (Doc. #1811, SBC-045343)

We urge the Environmental Protection Agency to move swiftly to finalize health-protective standards to reduce PFAS in our drinking water. Thank you for your consideration and for your work to address our nation's PFAS crisis.

Sincerely,

Jim Murphy

Senior Advisor

National Wildlife Federation Action Fund

May 1, 2023

Re: Proposed PFAS National Primary Drinking Water Regulation Rulemaking Docket ID: EPA-HQ-OW-2022-0114

Dear Administrator Regan,

Thank you for taking this historic step to keep our drinking water safe from PFAS contamination. For decades, PFAS chemicals have contaminated both public and private drinking water supplies across the country. PFAS contamination exposes communities to serious health risks, including cancers, impacts to the immune and reproductive systems, and other harms. The EPA's proposed drinking water standards would provide long overdue federal protections against six types of highly toxic PFAS. I strongly support this proposed rule and urge EPA to move swiftly to finalize health-protective standards to reduce PFAS in our drinking water.

EPA Response: The EPA has taken final action on the PFAS NPDWR as expeditiously as possible and ahead of its statutory deadline. Please see section 17.2 of the EPA response in this *Response to Comments* document.

National Wildlife Federation Action Fund (Doc. #1811, SBC-045346)

I urge you to quickly finalize and implement the proposed PFAS drinking water standards rule to begin federally regulating PFAS in drinking water.

Thank you,

Jennifer Rier

9747 S Bass Ct

Pinckney, MI 48169-8229

[See Attachments:

Attachment “Mass Mail WA (2,000)”: see docket ID EPA-HQ-OQ-2022-0114-1811,

Attachment “Mass Mail WA (2,000) 3”: see docket ID EPA-HQ-OQ-2022-0114-1811,

Attachment “Mass Mail WA (2,000) 4”: see docket ID EPA-HQ-OQ-2022-0114-1811,

Attachment “Mass Mail WA (2,000) 5”: see docket ID EPA-HQ-OQ-2022-0114-1811,

Attachment “Mass Mail WA (2,000) 6”: see docket ID EPA-HQ-OQ-2022-0114-1811,

Attachment “Mass Mail WA (2,000) 7”: see docket ID EPA-HQ-OQ-2022-0114-1811,

Attachment “Mass Mail WA (2,000) 8”: see docket ID EPA-HQ-OQ-2022-0114-1811,

Attachment “Mass Mail WA (1,851)”: see docket ID EPA-HQ-OQ-2022-0114-1811]

EPA Response: The EPA has taken final action on the PFAS NPDWR as expeditiously as possible and ahead of its statutory deadline. Please see section 17.2 of the EPA response in this *Response to Comments* document.

Clean Water Action (Doc. #1813, SBC-045496)

Re: EPA-HQ-OW-2022-0114-0027

Included in this submission are [89 public comments from three attachments] signed in support of Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation and the following statement:

"Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals.

EPA Response: The EPA has taken final action on the PFAS NPDWR as expeditiously as possible and ahead of its statutory deadline. Please see section 17.2 of the EPA response in this *Response to Comments* document. For discussion of the Hazard Index, please see sections 4.3.2 and 5.2 of the EPA response in this *Response to Comments* document.

New England Water Works Association (Doc. #1836, SBC-047708)

Closing:

Thank you for the opportunity to provide these comments. As mentioned previously and throughout this letter, PWS understand the importance of ensuring that the drinking water that reaches their customers meets Safe Drinking Water Act requirements and supports continued public health protection. Water suppliers work hard each day to meet these goals and satisfy their customers' expectations. Addressing emerging contaminants is a huge challenge. Our members will be tasked with meeting regulatory requirements and standards. Therefore, EPA has an obligation to address our implementation concerns before finalizing the regulations. We look forward to working collaboratively with EPA and the state primacy agencies on reasonable and achievable standards.

Sincerely,

James DeCelles, PE President

CC: NEWWA Board of Directors

EPA Response: The EPA has considered all significant public comments submitted on this PFAS NPDWR rulemaking, including those from the commenter. Please see section 17.2 of

the EPA response in this *Response to Comments* document and section XI of the FRN for this action for concerns regarding implementation.

Midwest Environmental Advocates +more (Doc. #1846, SBC-045840)

IV. Conclusion

We appreciate the opportunity to comment on EPA's proposed NPDWRs. The proposed standards, which are science-based, protective, feasible, and cost-justified, are necessary to deliver meaningful risk reduction benefits to millions of Americans exposed to harmful PFAS. Thus, Commenters urge the Agency to finalize the rule expeditiously in protection of impacted communities in Wisconsin and nationwide.

Respectfully Submitted,

Jorge Roman-Romero, EJW Attorney

Dan Gustafson, Senior Staff Attorney

Midwest Environmental Advocates*

634 W Main Street, Suite 201

Madison, WI 53703

Evan Feinauer, Staff Attorney

Clean Wisconsin*

634 W Main Street, Suite 300

Madison, WI 53703

[FN*: Midwest Environmental Advocates and Clean Wisconsin are grateful to Jim Baumann, member of Wisconsin's Green Fire and former Water Quality Engineer at the WDNR, for his significant contributions to this Comment Letter.]

Wisconsin Conservation Voters

Peter Burress, Government Affairs Manager

River Alliance of Wisconsin

Allison Werner, Executive Director

League of Women Voters of Wisconsin, Inc.

Debra Cronmiller, Executive Director

Madison Environmental Justice Organization

Maria Powell, Executive Director

Milwaukee Riverkeeper

Cheryl Nenn, Riverkeeper

Milwaukee Water Commons

Brenda Coley, Co-Executive Director

Save Our Water – Marinette & Peshtigo

Cindy Boyle, Steering Committee Member

Citizens for a Clean Wausau

Terry Kilian, Co-Spokesperson

Citizens for Safe Water Around Badger

Laura Olah, Executive Director

EPA Response: The EPA has taken final action on the PFAS NPDWR as expeditiously as possible and ahead of its statutory deadline. Please see section 17.2 of the EPA response in this *Response to Comments* document.

Clean Water Action (Doc. #1852, SBC-045500)

Date:

Docket Number: #EPA-HQ-OW-2022-0114-0027

Dear Administrator Regan,

Thank you for proposing health-protective limits for PFAS chemicals in drinking water that reflect the latest scientific information on their health effects.

EPA should finalize these Safe Drinking Water Act regulations as quickly as possible, including the Hazard Index approach for four PFAS chemicals.

EPA Response: The EPA has taken final action on the PFAS NPDWR as expeditiously as possible and ahead of its statutory deadline. Please see section 17.2 of the EPA response in this *Response to Comments* document. For discussion of the Hazard Index, please see sections 4.3.2 and 5.2 of the EPA response in this *Response to Comments* document.

Douglas Whitbeck (Doc. #1853, SBC-045502)

Mr. Michael Regan,

Dear Administrator Regan,

Please swiftly act to protect the public from exposure to dangerous PFAS chemicals in drinking water. While the March 2023 proposal is a step in the right direction we also need to do the following:

1. Please do not capitulate to the delay tactics by industry that wants you to extend the comment period.

EPA Response: The EPA has taken final action on the PFAS NPDWR as expeditiously as possible and ahead of its statutory deadline. Please see section 17.2 of the EPA response in this *Response to Comments* document. Regarding requests to extend the comment period, please see section 17.1 of the EPA response in this *Response to Comments* document.

David McGraw (Doc. #1854, SBC-045521)

Mr. Michael Regan,

Dear Administrator Regan,

Please quickly act to protect the public from exposure to dangerous PFAS chemicals in drinking water. The March 2023 proposal is a step in the right direction BUT we also need to do the following:

1. Please do not capitulate to the delay tactics by industry that wants you to extend the comment period.

EPA Response: Please see the EPA response to comment Doc. #1853, SBC-045502 in section 17.2 in this *Response to Comments* document.

Barbara Glassman (Doc. #1855, SBC-045524)

Mr. Michael Regan,

Dear Administrator Regan,

Please swiftly act to protect the public from exposure to dangerous PFAS chemicals in drinking water. While the March 2023 proposal is a step in the right direction we also need to do the following:

1. Please do not capitulate to the delay tactics by industry that wants you to extend the comment period.

EPA Response: Please see the EPA response to comment Doc. #1853, SBC-045502 in section 17.2 in this *Response to Comments* document.

Elizabeth A. Trought (Doc. #1856, SBC-045527)

Mr. Michael Regan,

Dear Administrator Regan,

Please swiftly act to protect the public from exposure to dangerous PFAS chemicals in drinking water. While the March 2023 proposal is a step in the right direction we also need to do the following:

1. Please do not capitulate to the delay tactics by industry that wants you to extend the comment period.

EPA Response: Please see the EPA response to comment Doc. #1853, SBC-045502 in section 17.2 in this *Response to Comments* document.

Kris Pastoriza (Doc. #1857, SBC-045530)

Mr. Michael Regan,

Dear Administrator Regan,

protect the public from exposure to dangerous PFAS chemicals in drinking water.

1. Don't capitulate to the delay tactics by industry.

EPA Response: Please see the EPA response to comment Doc. #1853, SBC-045502 in section 17.2 in this *Response to Comments* document.

Andrea Thorn (Doc. #1858, SBC-045533)

Mr. Michael Regan,

Dear Administrator Regan,

Please swiftly act to protect the public from exposure to dangerous PFAS chemicals in drinking water. While the March 2023 proposal is a step in the right direction we also need to do the following:

1. Please do not capitulate to the delay tactics by industry that wants you to extend the comment period.

EPA Response: Please see the EPA response to comment Doc. #1853, SBC-045502 in section 17.2 in this *Response to Comments* document.

Jon Swan (Doc. #1859, SBC-045536)

Mr. Michael Regan,

Dear Administrator Regan,

Please swiftly act to protect the public from exposure to dangerous PFAS chemicals in drinking water. While the March 2023 proposal is a step in the right direction we also need to do the following:

1. Please do not capitulate to the delay tactics by industry that wants you to extend the comment period.

EPA Response: Please see the EPA response to comment Doc. #1853, SBC-045502 in section 17.2 in this *Response to Comments* document.

Steven Cea (Doc. #1860, SBC-045539)

Mr. Michael Regan,

Dear Administrator Regan,

Please swiftly act to protect the public from exposure to dangerous PFAS chemicals in drinking water. While the March 2023 proposal is a step in the right direction we also need to do the following:

1. Please do not capitulate to the delay tactics by industry that wants you to extend the comment period.

EPA Response: Please see the EPA response to comment Doc. #1853, SBC-045502 in section 17.2 in this *Response to Comments* document.

Kathy Malsbenden (Doc. #1861, SBC-045542)

Mr. Michael Regan,

Dear Administrator Regan,

Please do this. Present and future generations will thank you.

Please swiftly act to protect the public from exposure to dangerous PFAS chemicals in drinking water. While the March 2023 proposal is a step in the right direction we also need to do the following:

1. Please do not capitulate to the delay tactics by industry that wants you to extend the comment period.

EPA Response: Please see the EPA response to comment Doc. #1853, SBC-045502 in section 17.2 in this *Response to Comments* document.

Michael Letendre (Doc. #1862, SBC-045545)

Mr. Michael Regan,

Dear Administrator Regan,

Please swiftly act to protect the public from exposure to dangerous PFAS chemicals in drinking water. While the March 2023 proposal is a step in the right direction we also need to do the following:

1. Please do not capitulate to the delay tactics by industry that wants you to extend the comment period.

EPA Response: Please see the EPA response to comment Doc. #1853, SBC-045502 in section 17.2 in this *Response to Comments* document.

Sherry Masiulaniec (Doc. #3012, SBC-047512)

I urge you to quickly finalize the regulations of these six PFAS chemicals, implement a rule that is health protective, and then begin addressing all other types of PFAS...we have had some proems with our drinking water..they came to the conclusion it could affect babies & people with amunity problems & eldery also . I'm on kidney dialisis and 2 months before the city informed us with a short letter in our water bill of the problem. I had already started drinking bottled water because the tap water was making me feel I'll. It had a grayish tint & a foul taste! I feel there should be more strict rules to the testing of everyone's water. Then maybe it won't take 2 months to notify the public of a possible problem. I'm sure other people were getting sick & maybe just couldn't figure out it was their darn city water !!!

Thank you for listening & I hope something can be done to prevent this from happening again.

EPA Response: The EPA has taken final action on the PFAS NPDWR as expeditiously as possible and ahead of its statutory deadline. Please see section 17.2 of the EPA response in this *Response to Comments* document.

Section 17 References

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